Innovation, Sciences et Développement économique Canada
Office de la Propriété Intellectuelle du Canada

Innovation, Science and Economic Development Canada
Canadian Intellectual Property Office

CA 3020337 A1 2017/10/12

(21) 3 020 337

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 2017/04/07
(87) Date publication PCT/PCT Publication Date: 2017/10/12
(85) Entrée phase nationale/National Entry: 2018/10/05
(86) N° demande PCT/PCT Application No.: US 2017/026524
(87) N° publication PCT/PCT Publication No.: 2017/177094
(30) Priorités/Priorities: 2016/04/08 (US62/320,438);
2017/02/13 (US PCT/US2017/017627)

(51) Cl.Int./Int.Cl. *A61M 5/142* (2006.01),
A61M 5/145 (2006.01), *A61M 5/158* (2006.01),
A61M 5/315 (2006.01)

(71) Demandeur/Applicant:
AMGEN INC., US

(72) Inventeurs/Inventors:
GIBSON, SCOTT R., US;
MOBERG, SHELDON B., US;
TAHA, BASEL HASAN, US;
BOYAVAL, MARGAUX FRANCES, US;
DESTEFANO, MARK A., US;
LAURENCE, LAWTON, US;
...

(74) Agent: SMART & BIGGAR

(54) Titre : DISPOSITIF D'ADMINISTRATION DE MEDICAMENT, PROCEDE DE FABRICATION ET PROCEDE D'UTILISATION

(54) Title: DRUG DELIVERY DEVICE, METHOD OF MANUFACTURE, AND METHOD OF USE

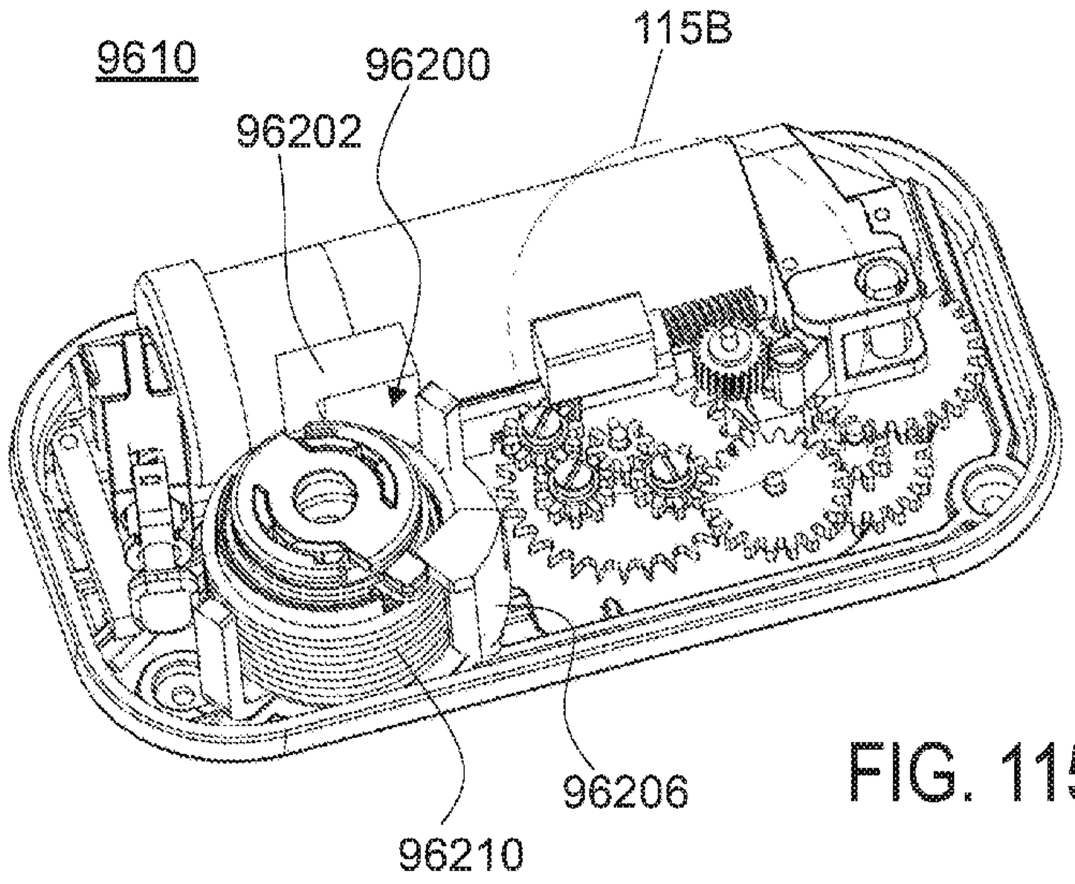


FIG. 115A

(57) Abrégé/Abstract:
Disclosed herein is a wearable drug delivery device including a container filled at least partially with a drug including at least one of a PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) specific antibody, a granulocyte colony-stimulating factor (G-CSF), a sclerostin antibody, or a calcitonin gene-related peptide (CGRP) antibody. The wearable drug delivery device includes a needle and an insertion mechanism configured to insert the needle into a patient. A fluid pathway connector defines a sterile fluid flowpath between the container and the insertion mechanism. A cannula initially disposed about the needle is included.

CA 3020337 A1 2017/10/12

(21) 3 020 337

(13) A1

(72) **Inventeurs(suite)/Inventors(continued)**: LOVE, JOHN C., US; HANSON, IAN B., US; BENTE, PAUL F., IV, US; CLEMENTE, MATTHEW J., US; UBACH, ANTONIO, US; RAMASWAMY, RAJAN, US; CODD, DANIEL S., US; BEAVER, SCOTT, US; BOKELMAN, KEVIN L., US; DARDANI, IAN P., US; O'CONNOR, SEAN M., US; FELDMAN, DANIELLE, US

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 October 2017 (12.10.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/177094 A3

(51) International Patent Classification:
A61M 5/142 (2006.01) *A61M 5/315* (2006.01)
A61M 5/145 (2006.01) *A61M 5/158* (2006.01)

(21) International Application Number:
PCT/US2017/026524

(22) International Filing Date:
07 April 2017 (07.04.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/320,438 08 April 2016 (08.04.2016) US
PCT/US2017/017627
13 February 2017 (13.02.2017) US

(71) Applicant: **AMGEN INC.** [US/US]; One Amgen Center Drive, Thousand Oaks, CA 91320-1799 (US).

(72) Inventors: **GIBSON, Scott, R.**; 12141 Bellando Court, Granada Hills, CA 91344 (US). **MOBERG, Sheldon, B.**; 1030 Chalet Circle, Thousand Oaks, CA 91362 (US). **TAHA, Basel, Hasan**; 1625 Berwick Place, Westlake Village, CA 91361 (US). **BOYAVAL, Margaux, Frances**; 684 Via Vista, Newbury Park, CA 91320 (US). **DESTEFANO, Mark, A.**; 255 Zvarick Road, Collegeville, PA 19426 (US). **LAURENCE, Lawton**; 619 Needle Street, Phoenixville, PA 19469 (US). **LOVE, John, C.**; 5173 Terraza Quintana, San Diego, CA 92124 (US). **HANSON, Ian, B.**; 690 Davis Lane, Wayne, PA 19087 (US). **BENTE, Paul, F.**; 87 Bunker Hill Court, Wayne, PA 19087 (US). **CLEMENTE, Matthew, J.**; 13939 Danube Drive, Carmel, IN 46032 (US). **UBACH, Antonio**; 119 South Irving Ave., Tucson, AZ 85711 (US). **RAMASWAMY, Rajan**; 18245 Moon Song Court, San Diego, CA 92127 (US). **CODD, Daniel, S.**; 330 Eldorado Drive, Escondido, CA 92025 (US). **BEAVER, Scott**; 969 Fortune Rd., San Marcos, CA 92078 (US). **BOKELMAN, Kevin, L.**; 16069 Bedford Hill, San Diego, CA 92127 (US). **DARDANI, Ian, P.**; 330 Upper Gulph Road, Radnor, PA 19087 (US). **O'CONNOR, Sean, M.**; 201 Ford Circle, West Chester, PA 19380 (US). **FELDMAN, Danielle**; 24 Bank St. #401, Philadelphia, PA 19128 (US).

(74) Agent: **CHAVKA, Daniel, T.**; MARSHALL, GERSTEIN & BORUN LLP, 233 S. Wacker Drive, 6300 Willis Tower, Chicago, IL 60606-6357 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM,

(54) Title: DRUG DELIVERY DEVICE

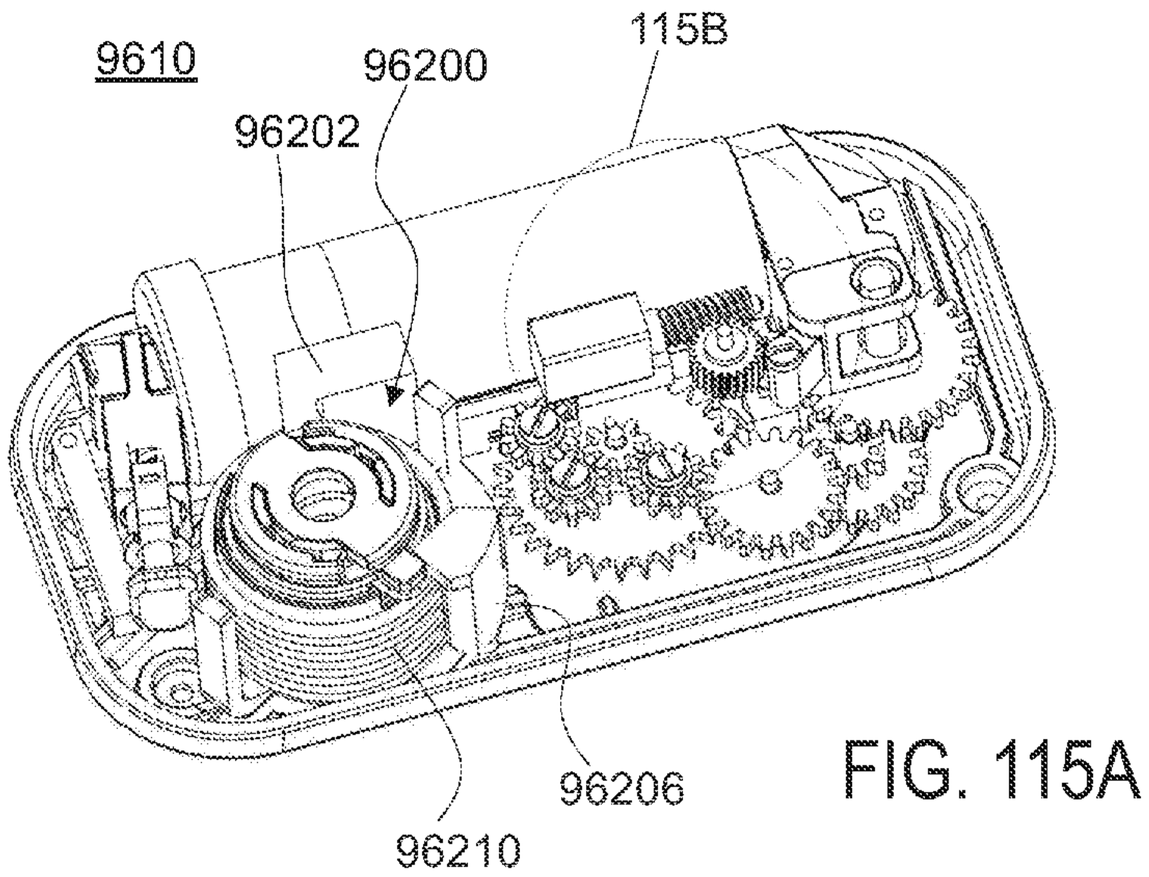


FIG. 115A

(57) Abstract: Disclosed herein is a wearable drug delivery device including a container filled at least partially with a drug including at least one of a PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) specific antibody, a granulocyte colony-stimulating factor (G-CSF), a sclerostin antibody, or a calcitonin gene-related peptide (CGRP) antibody. The wearable drug delivery device includes a needle and an insertion mechanism configured to insert the needle into a patient. A fluid pathway connector defines a sterile fluid flowpath between the container and the insertion mechanism. A cannula initially disposed about the needle is included.

[Continued on next page]

WO 2017/177094 A3

WO 2017/177094 A3

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
16 November 2017 (16.11.2017)

DEMANDE OU BREVET VOLUMINEUX

LA PRÉSENTE PARTIE DE CETTE DEMANDE OU CE BREVET COMPREND PLUS D'UN TOME.

CECI EST LE TOME	1	DE	3
CONTENANT LES PAGES	1	À	246

NOTE : Pour les tomes additionels, veuillez contacter le Bureau canadien des brevets

JUMBO APPLICATIONS/PATENTS

THIS SECTION OF THE APPLICATION/PATENT CONTAINS MORE THAN ONE VOLUME

THIS IS VOLUME	1	OF	3
CONTAINING PAGES	1	TO	246

NOTE: For additional volumes, please contact the Canadian Patent Office

NOM DU FICHIER / FILE NAME :

NOTE POUR LE TOME / VOLUME NOTE:

DRUG DELIVERY DEVICE, METHOD OF MANUFACTURE, AND METHOD OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the priority benefit of each of U.S. Provisional Patent Application No. 62/320,438, filed April 8, 2016, and International Patent Application No. PCT/US2017/017627, filed February 13, 2017. The entire contents of each of the foregoing are expressly incorporated by reference herein for all purposes.

FIELD OF THE DISCLOSURE

[0002] The present disclosure generally relates to drug delivery devices and, more particularly, a drug delivery device capable of being worn by a patient while the drug delivery device delivers a drug to the patient.

BACKGROUND

[0003] Parenteral delivery of various drugs, i.e., delivery by means other than through the digestive track, has become a desired method of drug delivery for a number of reasons. This form of drug delivery by injection may enhance the effect of the substance being delivered and ensure that the unaltered medicine reaches its intended site at a significant concentration. Similarly, undesired side effects associated with other routes of delivery, such as systemic toxicity, can potentially be avoided through parenteral delivery. By bypassing the digestive system of a mammalian patient, one can avoid degradation of the active ingredients caused by the catalytic enzymes in the digestive tract and liver and ensure that a necessary amount of drug, at a desired concentration, reaches the targeted site.

[0004] Traditionally, manually operated syringes and injection pens have been employed for delivering parenteral drugs to a patient. More recently, parenteral delivery of liquid medicines into the body has been accomplished by administering bolus injections using a needle and reservoir, continuously by gravity driven dispensers, or via transdermal patch technologies. Bolus injections often imperfectly match the clinical needs of the patient, and usually require larger individual doses than are desired at the specific time they are given. Continuous delivery of medicine through gravity-feed systems compromises the patient's mobility and lifestyle, and limits the therapy to simplistic flow rates and profiles. Another form of drug delivery, transdermal patches, similarly has its restrictions. Transdermal patches often require specific molecular drug structures for efficacy, and the control of the drug administration through a transdermal patch is severely limited.

[0005] Ambulatory infusion pumps have been developed for delivering liquid medicaments to a patient. These infusion devices have the ability to offer sophisticated fluid delivery profiles accomplishing bolus requirements, continuous infusion and variable flow rate delivery. These infusion capabilities usually result in better efficacy of the drug and therapy and less toxicity to the patient's system. Currently available ambulatory infusion devices are expensive, difficult to program and prepare for infusion, and tend to be bulky, heavy and very fragile. Filling these devices can be difficult and require the patient to carry both the intended medication as well as filling accessories. The devices often require specialized care, maintenance, and cleaning to assure proper functionality and safety for their intended long-term use, and are not cost-effective for patients or healthcare providers.

[0006] As compared to syringes and injection pens, pump type delivery devices can be significantly more convenient to a patient, in that doses of the drug may be calculated and delivered automatically to a patient at any time during the day or night. Furthermore, when used in conjunction with metabolic sensors or monitors, pumps may be automatically controlled to provide appropriate doses of a fluidic medium at appropriate times of need, based on sensed or monitored metabolic levels. As a result, pump type delivery devices have become an important aspect of modern medical treatments of various types of medical conditions, such as diabetes, and the like.

[0007] While pump type delivery systems have been utilized to solve a number of patient needs, manually operated syringes and injection pens often remain a preferred choice for drug delivery as they now provide integrated safety features and can easily be read to identify the status of drug delivery and the end of dose dispensing. However, manually operated syringes and injections pens are not universally applicable and are not preferred for delivery of all drugs. There remains a need for an adjustable (and/or programmable) infusion system that is precise and reliable and can offer clinicians and patients a small, low cost, light weight, simple to use alternative for parenteral delivery of liquid medicines.

[0008] There is a strong market demand for drug delivery devices which are easy-to-use, cost-efficient, and which include integrated safety features. However, manufacturing of such devices can be cost intensive, which results in higher costs to patients. Much of the manufacturing costs can be attributed to the need to maintain a sterile fluid pathway from the drug container to the needle, prior to introduction of the drug to the patient. Some commercial products seek to maintain the sterility of the device by manufacturing the components in a non-sterile environment and then sterilizing the

entire device. A recognized downside of such processes is the need to separately fill the drug container after device sterilization but prior to drug injection, as most pharmaceutical compounds are not capable of withstanding the device sterilization process. Alternatively, the drug delivery device may be manufactured as a pre-filled device, wherein the device is filled with the drug aseptically during assembly. Such manufacturing processes may be costly since the entire process must be kept sterile and because the fill and assembly lines need to be specially-tailored for the device. Accordingly, this adds substantial operating costs to pharmaceutical companies and contract drug-fillers.

[0009] Drug delivery devices are generally prepared by molding or shaping the various components and then assembling the components. The assembling steps and other processing operations typically produce a device that subsequently must be cleaned to remove particulates adhering to the surfaces to satisfy cleanliness standards for drug delivery devices. After cleaning, conventional drug delivery devices are packaged and sterilized. Such delivery devices have been classified into several general types. The first type is assembled and placed in sterile packaging which can be shipped with a vial or ampoule of a drug or other injectable solution. The delivery device is filled with the drug or other solution at the point of use and injected into the patient. These devices have the disadvantage of increasing the time and difficulty of filling the device at the point of use, increasing the risk of contamination of the delivery device and/or drug solution, and increasing the likelihood of accidental spills of the drug. There is a further risk of glass particles from the ampoules contaminating the drug solution when the ampoules are opened. Furthermore, the healthcare provider and/or patient may be require training to ensure that they fill the device properly

[0010] Several of these disadvantages are overcome by providing prefilled delivery devices which can be filled with a suitable drug solution prior to use. Prefilled delivery devices, as the term is known in the art, are devices that are filled by the drug manufacturer and shipped to the health care provider or self-administering patient in a condition that is ready for use. The vial or ampoule is generally made of glass or other clear material that does not interfere with the stability of the drug during prolonged storage. Prefilled delivery devices have the advantage of convenience and ease of application with reduced risk of contamination of the drug solution. Prefilled drug delivery devices are generally assembled and packaged in clean rooms to maintain proper cleanliness levels. The clean rooms are equipped with extensive filter assemblies and air control systems to remove particulates and pyrogens from the air in the room and to prevent particulates and pyrogens from

entering the room. The operators and other personnel in the clean room are required to wear appropriate protective garments to reduce contamination of the air and the drug delivery devices being manufactured or assembled. As people and equipment enter and leave the clean room, the risk of contamination and introduction of foreign particulates and pyrogens increases. Various operations are able to form clean and sterile drug delivery devices. However, subsequent handling, filling and printing of the drug delivery device can contaminate the device. It is then necessary to clean and sterilize such conventional drug delivery devices before use. Accordingly, there is a continuing need in the industry for an improved system for manufacturing and assembling clean and sterile medical devices and filling such devices.

SUMMARY

[0011] One aspect of the present disclosure provides a wearable drug delivery device including a main housing, a container, a drug, a window, a trocar or introducer needle, a cannula, a drive mechanism, an insertion mechanism, a fluid pathway connector, a button, and a trigger assembly. The container may be disposed in the main housing. The container may include a barrel, a plunger seal moveable through the barrel, and a first pierceable seal controlling access to an interior of the barrel. The drug may be disposed in the barrel. The drug may include at least one of a: Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) specific antibody, a granulocyte colony-stimulating factor (G-CSF), a sclerostin antibody, or a calcitonin gene-related peptide (CGRP) antibody. The trocar or introducer needle may have a proximal end and a distal end. The cannula may initially be disposed around the distal end of the trocar or introducer needle. The drive mechanism may be disposed in the main housing. The drive mechanism may include a drive housing, a piston moveable relative to the drive housing and configured to impart movement to the plunger seal, a gear assembly, an electrical actuator, a gear interface, a piston biasing member, and a tether. The gear interface may be rotatable by the electrical actuator. Rotation of the gear interface may cause the gear interface to selectively engage the gear assembly to prevent or allow rotation of the gear assembly. The piston biasing member may be disposed between the drive housing and the piston. The piston biasing member maybe initially retained in a piston biasing member energized state. The piston biasing member may be configured to move the piston as the piston biasing member de-energizes. The tether may be connected at opposite ends to the gear assembly and the piston. The tether may initially retain the piston biasing member in the piston biasing member energized state. Rotation of the gear assembly may create slack in the tether which allows the piston biasing member to de-energize. The fluid pathway connector may define a sterile fluid flowpath between

the container and the insertion mechanism. The fluid pathway connector may include a tubular conduit, a container access needle, and a connection hub. The tubular conduit may have a first end and a second end. The second end of the tubular conduit may be in fluid communication with a hollow interior of the cannula during drug delivery. The container access needle may be configured to pierce the first pierceable seal to establish fluid communication between the between the barrel and the tubular conduit during drug delivery. The connection hub may be connected to the container access needle and the first end of the tubular conduit. The connection hub may provide fluid communication between the container access needle and the tubular conduit during drug delivery. The insertion mechanism may be disposed in the main housing. The insertion biasing mechanism may include a base, an insertion mechanism housing rotatable relative to the base, a rotational biasing member connected to the insertion mechanism housing, a first retainer, a hub, a retraction biasing member, and a second retainer. The rotational biasing member may be initially retained in a rotational biasing member energized state. The rotational biasing member may be configured to rotate the insertion mechanism housing as the rotational biasing member de-energizes. The first retainer may be moveable between: (i) a first retainer retaining position, where the first retainer retains the rotational biasing member in the rotational biasing member energized state, and (ii) a first retainer releasing position, where the first retainer allows the rotational biasing member to de-energize. The hub may be connected to the proximal end of the trocar or introducer needle, and the hub may be configured to translate relative to the insertion mechanism housing. The retraction biasing member may be disposed between the hub and the base. The retraction biasing member may have a retraction biasing member energized state. The retraction biasing member may be configured to translate the hub in a proximal direction as the retraction biasing member de-energizes. The second retainer may be moveable between: (i) a second retainer retaining position, where the second retainer retains the retraction biasing member in the retraction biasing member energized state, and (ii) a second retainer releasing position, where the second retainer allows the retraction biasing member to de-energize. The button may protrude from the main housing and manually displaceable by a user. The trigger assembly may be configured to move the first retainer from the first retainer retaining position to the first retainer releasing position in response to displacement of the button by the user.

[0012] Another aspect of the present disclosure provides a wearable drug delivery device including a container, a drug disposed in the container, a trocar or introducer needle, an activation member manually operable by a patient, an insertion mechanism, a fluid pathway connector, a

locking assembly, and a selector. The drug may include at least one of a: Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) specific antibody, a granulocyte colony-stimulating factor (G-CSF), a sclerostin antibody, or a calcitonin gene-related peptide (CGRP) antibody. The insertion mechanism may be configured to move the trocar or introducer needle between a retracted position and an inserted position, the insertion mechanism including a rotatable housing and a rotational biasing member initially held in an energized state. The fluid pathway connector may define a sterile fluid flowpath between the container and the insertion mechanism. The locking assembly may have: (i) a lock configuration, where the locking assembly engages the rotatable housing to inhibit rotation of the rotatable housing, and (ii) an unlock configuration, where the locking assembly disengages the rotatable housing to permit rotation of the rotatable housing. The selector may have: (i) a first configuration, where the selector operatively decouples the activation member and the locking assembly, and (ii) a second configuration, where the selector operatively couples the activation member and the locking assembly to allow the activation member to change the locking assembly from the lock configuration to the unlock configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] It is believed that the disclosure will be more fully understood from the following description taken in conjunction with the accompanying drawings. Some of the figures may have been simplified by the omission of selected elements for the purpose of more clearly showing other elements. Such omissions of elements in some figures are not necessarily indicative of the presence or absence of particular elements in any of the exemplary embodiments, except as may be explicitly delineated in the corresponding written description. Also, none of the drawings is necessarily to scale.

[0014] FIG. 1A shows an isometric view of a drug delivery pump having safety integrated insertion mechanisms, according to one embodiment of the present invention;

[0015] FIG. 1B shows an isometric view of the interior components of the drug delivery pump shown in FIG. 1A;

[0016] FIG. 1C shows an isometric view of the bottom of the drug delivery pump shown in FIG. 1A;

[0017] FIG. 2A shows an isometric view of the interior components of a second embodiment of a drug delivery device;

[0018] FIG. 2B shows a second view of the interior components of the drug delivery device shown in FIG. 2A;

[0019] FIG. 3A is an isometric view of an embodiment of a fluid pathway connection assembly and drug container in an unmounted configuration;

[0020] FIG. 3B is an isometric view of the embodiment shown in FIG. 3A in a mounted, but unactuated, configuration;

[0021] FIG. 4A shows an exploded view of a fluid pathway connection assembly according to at least one embodiment of the present invention;

[0022] FIG. 4B shows a cross-sectional view of the exploded fluid pathway connection assembly of FIG. 4A;

[0023] FIG. 5A is a cross-sectional side view of an embodiment of a fluid pathway connection assembly and a drug container in a mounted, but unactuated, configuration;

[0024] FIG. 5B is an enlarged fragmentary cross-sectional side view of the embodiment shown in FIG. 5A;

[0025] FIG. 6A is a cross-sectional side view of the embodiment of the fluid pathway connection assembly and drug container of FIG. 4A in an actuated configuration;

[0026] FIG. 6B is an enlarged fragmentary cross-sectional side view of the embodiment shown in FIG. 6A;

[0027] FIG. 7A is a cross-sectional side view of the embodiment of the fluid pathway connection assembly and drug container of FIGS. 4A and 6A in a delivery configuration;

[0028] FIG. 7B is an enlarged fragmentary cross-sectional side view of the embodiment shown in FIG. 7A;

[0029] FIG. 8 shows an isometric view of a connection hub according to at least one embodiment of the present invention;

[0030] FIG. 9 shows an isometric view of a plate according to at least one embodiment of the present invention;

[0031] FIG. 10 shows an isometric view of an embodiment of a piercing member retainer according to at least one embodiment of the present invention;

[0032] FIG. 11 shows an isometric view of an embodiment of an introducer member retainer according to at least one embodiment of the present invention;

[0033] FIG. 12A is an isometric view of a second embodiment of a fluid pathway connection assembly and drug container in an unmounted configuration;

[0034] FIG. 12B is an isometric view of the embodiment shown in FIG. 12A in a mounted, but unactuated, configuration;

[0035] FIG. 13A is a cross-sectional side view of the embodiment of the fluid pathway connection assembly and drug container of FIGS. 11 A-1 IB in a mounted, but unactuated, configuration;

[0036] FIG. 13B is an enlarged fragmentary cross-sectional side view of the embodiment shown in FIG. 13A;

[0037] FIG. 14A is a cross-sectional side view of the embodiment of the fluid pathway connection assembly and drug container of FIG. 12A in an actuated configuration;

[0038] FIG. 14B is an enlarged fragmentary cross-sectional side view of the embodiment shown in FIG. 14A;

[0039] FIG. 15A is a cross-sectional side view of the embodiment of the fluid pathway connection assembly and a drug container of FIGS. 12A and 13A in a delivery configuration;

[0040] FIG. 15B is an enlarged fragmentary cross-sectional side view of the embodiment shown in FIG. 15A;

[0041] FIG.16A is a further isometric view of the fluid pathway connection assembly and container of FIGS. 12A-12B in a mounted, but unactuated, configuration;

[0042] FIG. 16B is an enlarged fragmentary isometric view of the fluid pathway connection assembly of FIG. 16 A;

[0043] FIG.17A is a further isometric view of the fluid pathway connection assembly and container of FIGS. 12A-12B in an actuated configuration;

[0044] FIG. 17B is an enlarged fragmentary isometric view of the fluid pathway connection assembly of FIG. 17A;

[0045] FIG.18A is a further isometric view of the fluid pathway connection assembly and container of FIGS. 12A-12B in a delivery configuration;

[0046] FIG. 18B is an enlarged fragmentary isometric view of the fluid pathway connection assembly of FIG. 18A;

[0047] FIG.19A is a bottom side view of the fluid pathway connection assembly and container of FIG. 18A;

[0048] FIG. 19B is an enlarged fragmentary isometric view of the fluid pathway connection assembly and drug container of FIG. 19A;

[0049] FIG. 20 shows an isometric view of a connection hub according to at least one embodiment of the present invention;

[0050] FIG. 21 shows an isometric view of an embodiment of an introducer member retainer according to at least one embodiment of the present invention;

[0051] FIG. 22 shows an isometric view of an embodiment of a piercing member retainer according to at least one embodiment of the present invention;

[0052] FIG. 23 shows an isometrically exploded view of a fluid pathway connection assembly according to at least one embodiment of the present invention;

[0053] FIG. 24A shows an isometric view of the fluid pathway connection assembly and drug container of FIG. 23 in an unmounted configuration;

[0054] FIG. 24B is an isometric view of the fluid pathway connection assembly and drug container of FIG. 24A in a mounted, but unactuated, configuration;

[0055] FIG. 24C is an isometric view of the fluid pathway connection assembly and drug container of FIG. 24B in an actuated configuration;

[0056] FIG. 24D is an isometric view of the fluid pathway connection assembly and drug container of FIGS. 24B-24C in a delivery configuration;

[0057] FIG. 25A is a cross-sectional side view of the fluid pathway connection assembly and drug container of FIG. 24B in the mounted, but unactuated, configuration;

[0058] FIG. 25B is an enlarged fragmentary cross-sectional side view of the embodiment shown in FIG. 25A;

[0059] FIG. 26A is a cross-sectional side view of the embodiment of the fluid pathway connection assembly and drug container of FIG. 24B in an actuated configuration;

[0060] FIG. 26B is an enlarged fragmentary cross-sectional side view of the embodiment shown in FIG. 26A;

[0061] FIG. 27A is a cross-sectional side view of the embodiment of the fluid pathway connection assembly and drug container of FIGS. 25A and 26A in a delivery configuration;

[0062] FIG. 27B is an enlarged fragmentary cross-sectional side view of the embodiment shown in FIG. 27A;

[0063] FIG. 28 shows an isometric view of a connection hub according to at least one embodiment of the present invention;

[0064] FIG. 29 shows a side elevational view of an embodiment of an introducer member retainer according to at least one embodiment of the present invention;

[0065] FIG. 30 shows an isometric view of an embodiment of a piercing member retainer according to at least one embodiment of the present invention;

[0066] FIG. 31 shows a fragmentary isometric view of the interior components of a drug delivery pump incorporating the fluid pathway connection assembly of FIGS. 23-27B;

[0067] FIG. 32A is a fragmentary isometric view of a fluid pathway connection assembly and a drug container of at least one embodiment of the present invention during fluid connection;

[0068] FIG. 32B is a fragmentary isometric view of the fluid pathway connection assembly and drug container of FIG. 32A upon disconnection;

[0069] FIG. 33A shows an isometric view of the interior components of a drug delivery device having a multi-function drive mechanism, according to one embodiment of the present disclosure (shown without the adhesive patch);

[0070] FIG. 33B shows an isometric view of the interior components of the drug delivery device shown in FIG. 33A (shown without the adhesive patch) from another viewpoint;

[0071] FIG. 33C shows an isometric view of the interior components of the drug delivery device shown in FIG. 33A (shown without the adhesive patch) from yet another viewpoint;

[0072] FIG. 34A is an isometric view of an embodiment of a fluid path connection assembly and drug container in an unmounted configuration;

[0073] FIG. 34B is an isometric view of the embodiment shown in FIG. 34A in a mounted configuration;

[0074] FIG. 34C is a cross-sectional isometric view of the embodiment shown in FIG. 34A in a mounted configuration;

[0075] FIG. 35A is an isometric view of an embodiment of a fluid path connection assembly and a drug container in an unmounted configuration;

[0076] FIG. 35B is an isometric view of the embodiment shown in FIG. 35A in a mounted configuration;

[0077] FIG. 35C is a cross-sectional isometric view of the embodiment shown in FIG. 35A in a mounted configuration;

[0078] FIG. 35D is a cross-sectional isometric view of the embodiment shown in FIG. 35A after connection of the fluid path;

[0079] FIG. 36A is a cross-sectional side view of an embodiment of a fluid path connection assembly and a drug container in an mounted configuration;

[0080] FIG. 36B is a cross-sectional side view of the embodiment shown in FIG. 36A after the first and second films have been pierced;

[0081] FIG. 36C is a cross-sectional side view of the embodiment shown in FIG. 36A after retraction of the outer piercing member;

[0082] FIG. 36D is a cross-sectional side view of the embodiment shown in FIG. 36A after connection of the fluid path;

[0083] FIG. 37A is a cross-sectional side view of an embodiment of a fluid path connection mechanism and a drug container in an unmounted configuration;

[0084] FIG. 37B is a cross-sectional side view of the embodiment shown in FIG. 37A after piercing of the first and second films by the outer piercing member;

[0085] FIG. 37C is a cross-sectional side view of the embodiment shown in FIG. 37A after connection of the fluid path;

[0086] FIG. 38A is a cross-sectional side view of an embodiment of a fluid path connection mechanism and a drug container in an unmounted configuration;

[0087] FIG. 38B is a cross-sectional side view of the embodiment shown in FIG. 38A in a mounted configuration;

[0088] FIG. 38C is a cross-sectional side view of the embodiment shown in FIG. 38A after piercing of the first and second films by the outer piercing member;

[0089] FIG. 38D is a cross-sectional side view of the embodiment shown in FIG. 38A after connection of the fluid path;

[0090] FIG. 39A is a cross-sectional side view of an embodiment of a fluid path connection mechanism and a drug container in a mounted configuration;

[0091] FIG. 39B is a cross-sectional side view of the embodiment of FIG. 39A after connection of the fluid path;

[0092] FIG. 40A is a cross-sectional side view of an embodiment of a fluid path connection mechanism and a drug container in an unmounted configuration;

[0093] FIG. 40B is a cross-sectional side view of the embodiment shown in FIG. 40A in a mounted configuration;

[0094] FIG. 40C is a cross-sectional side view of the embodiment shown in FIG. 40A after connection of the fluid path;

[0095] FIG. 41A is a cross-sectional side view of an embodiment of a fluid path connection mechanism and a drug container in an unmounted configuration;

[0096] FIG. 41B is a cross-sectional side view of the embodiment shown in FIG. 41A in a mounted configuration;

[0097] FIG. 41C is a cross-sectional side view of the embodiment shown in FIG. 41A during UV sterilization;

[0098] FIG. 41D is a cross-sectional side view of the embodiment shown in FIG. 41A after connection of the fluid path;

[0099] FIG. 42 shows a fluid path connection according to at least one embodiment of the present disclosure;

[00100] FIG. 43 shows an isometric view of a drug container according to at least one embodiment of the present disclosure;

[00101] FIG. 44 shows an isometric view of a drug container and a fluid pathway connection according to at least one embodiment of the present disclosure;

[00102] FIG. 45A shows an isometric view of the drug container and fluid pathway connection of FIG. 44 in an unmounted configuration;

[00103] FIG. 45B shows a cross-sectional isometric view of the drug container and fluid pathway connection of FIG. 44 in an initial mounting configuration;

[00104] FIG. 45C shows a cross-sectional isometric view of the drug container and fluid pathway connection of FIG. 44 in an intermediate mounting configuration;

[00105] FIG. 45D shows a cross-sectional isometric view of the drug container and fluid pathway connection of FIG. 44 in a mounted configuration;

[00106] FIG. 46A shows an isometric view of an embodiment of a drug container and fluid pathway connection in an unmounted configuration;

[00107] FIG. 46B shows a cross-sectional isometric view of the drug container and fluid pathway connection of FIG. 46A in a mounted configuration;

[00108] FIG. 47 shows a detail cross-sectional view of a fluid pathway connection according to at least one embodiment of the present disclosure;

[00109] FIG. 48 shows a cross-sectional isometric view of an embodiment of a drug container and fluid pathway connection in an unmounted configuration;

[00110] FIG. 49 shows an isometric view of an embodiment of a drug container and fluid pathway connection in an unmounted configuration;

[00111] FIG. 50 shows a cross-sectional view of an embodiment of a drug container and fluid pathway connection in an unmounted configuration;

[00112] FIG. 51 shows a cross-sectional isometric view of an embodiment of a drug container and fluid pathway connection in an unmounted configuration;

[00113] FIG. 52A shows an isometric view of an embodiment of a drug container and fluid pathway connection in an unmounted configuration;

[00114] FIG. 52B shows an end view of a drug container;

[00115] FIG. 52C shows a cross-sectional view of a drug container and fluid pathway connection in an unmounted configuration;

[00116] FIG. 52D shows a cross-sectional view of a drug container and fluid pathway connection in a connected configuration;

[00117] FIG. 53A is an isometric view of an integrated sterile fluid pathway connection and drug container, according to an embodiment;

[00118] FIG. 53B is a sectional isometric view of the integrated sterile fluid pathway connection and drug container shown in FIG. 53A;

[00119] FIG. 54A is an exploded, side view of the components of an embodiment of an integrated sterile fluid pathway connection and drug container, exploded along a longitudinal axis;

[00120] FIG. 54B is a sectional exploded view of the embodiment of FIG. 54A;

[00121] FIG. 55A is a sectional view of an integrated sterile fluid pathway connection and drug container, as shown in FIG. 53A, prior to user activation;

[00122] FIG. 55B is a sectional view of the embodiment with the fluid pathway connected; and FIG. 55C is a sectional view of the embodiment at the end of drug delivery;

[00123] FIG. 56A is an isometric perspective view, of the integrated sterile fluid pathway connection according to an embodiment of the present invention;

[00124] FIG. 56B is an exploded, perspective view of the components of the integrated sterile fluid pathway connection shown in FIG. 56A;

[00125] FIG. 57A is a sectional view of an embodiment of an integrated sterile fluid pathway connection, having a piercing member guide and drug container, prior to user activation;

[00126] FIG. 57B shows an isometric perspective view of the piercing member guide and piercing member of the embodiment shown in FIG. 57A; and FIG. 57C is an isometric view of the piercing member guide, piercing member, and connector hub of the embodiment of FIG. 57A;

[00127] FIG. 58 is a cross-sectional view of an integrated sterile fluid pathway connection and drug container according to an embodiment prior to user activation, in which the drug container

comprises more than one drug chamber, each drug chamber separated from the next by a pierceable membrane;

[00128] FIG. 59A to FIG. 59E are sectional views of an embodiment of a sterile fluid connector in which the pierceable seal is configured to maintain different positions within the connector in response to pneumatic and/or hydraulic pressure;

[00129] FIG. 60A to FIG. 60H are sectional and isometric sectional views of an embodiment of a sterile fluid connector in which the pierceable seal, in response to pneumatic and/or hydraulic pressure, engages or disengages a sensor mechanism that is capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector;

[00130] FIG. 61A to FIG. 61G are perspective and sectional views of another embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector;

[00131] FIG. 62A to FIG. 62D are sectional and isomeric sectional views of another embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector, showing more specific configurations of a sensor in the open and closed positions;

[00132] FIG. 63A to FIG. 63D are perspective and sectional views of an embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector, illustrating the unpressurized (FIG. 63B), pressurized (FIG. 63C), and end-of-delivery (FIG. 63D) positions of components of a sterile fluid connector;

[00133] FIG. 64A to FIG. 64C are perspective and sectional views of another embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector;

[00134] FIG. 65A is a sectional view and FIG. 65B is an isometric sectional view of another embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector;

[00135] FIG. 66A and FIG. 66B are sectional isometric views of another embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector, in which the pierceable seal comprises a conductive material or coating;

[00136] FIG. 67 is a sectional isometric view of another an embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector, in which signal is mediated using an conductive elastomeric film;

[00137] FIG. 68 is a sectional isometric view of another embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector, in which signal is mediated using a dome switch;

[00138] FIG. 69A shows an isometric view of the interior components of a drug delivery pump having a multi-function drive mechanism, according to one embodiment of the present invention (shown without the adhesive patch);

[00139] FIG. 69B shows an isometric view of the interior components of the drug delivery pump shown in FIG. 69A (shown without the adhesive patch) from another viewpoint;

[00140] FIG. 69C shows an isometric view of the interior components of the drug delivery pump shown in FIG. 69A (shown without the adhesive patch) from yet another viewpoint;

[00141] FIG. 69D shows a top view, along an axis "A," of the interior components of the drug delivery pump shown in FIG. 69A;

[00142] FIG. 70A shows an isometric view of a multi-function drive mechanism, according to at least one embodiment of the present invention prior to activation;

[00143] FIG. 70B shows an isometric view of a multi-function drive mechanism, according to at least one embodiment of the present invention during activation;

[00144] FIG. 70C shows an isometric view of a multi-function drive mechanism, according to at least one embodiment of the present invention at a later stage during activation;

[00145] FIG. 70D shows an isometric view of a multi-function drive mechanism, according to at least one embodiment of the present invention near or at completion of drug delivery;

[00146] FIGS. 71A-71D show top views which correspond with the stages of operation shown in FIGS. 70A-70D, respectively;

[00147] FIG. 72 shows the multi-function drive mechanism, according to at least one embodiment of the present invention, in isolation from the drug delivery device;

[00148] FIGS. 73A-73B show top and bottom views, respectively, of the multi-function drive mechanism shown in FIG. 72;

[00149] FIGS. 73C-73D show front and back perspective views, respectively, of the multi-function drive mechanism shown in FIG. 72;

[00150] FIG. 74A shows a cross-sectional view of a drug container and safety mechanism in an initial, unrestrained configuration;

[00151] FIG. 74B shows a cross-sectional view of the drug container and safety mechanism of FIG. 74A in an activated configuration;

[00152] FIG. 75A shows an isometric view of a drug delivery pump in which the insertion mechanism includes a rotational biasing member;

[00153] FIG. 75B shows an enlarged view of the drive mechanism shown in FIG. 75A.

[00154] FIG. 76A is an exemplary block diagram illustrating one embodiment of a power and control system of the drug delivery pump;

[00155] FIG. 76B is an exemplary block diagram depicting one embodiment of a drive control system of the drug delivery pump;

[00156] FIG. 76C is an exemplary block diagram of an embodiment illustrating various control mechanisms of the drug delivery pump;

[00157] FIG. 76D is an exemplary block diagram of another embodiment illustrating communication among an exemplary drug delivery pump device, an exemplary mobile device, an exemplary cloud server and one or more exemplary sensors;

[00158] FIGS. 77A-77C are flow-charts of embodiments describing methods of drug delivery by the drug delivery device based on one or more mechanisms;

[00159] FIG. 78A is an exemplary block diagram illustrating one embodiment of a power and control system of the drug delivery pump;

[00160] FIG. 78B is an exemplary block diagram depicting one embodiment of a drive control system of the drug delivery pump;

[00161] FIG. 78C is an exemplary block diagram of an embodiment illustrating various control mechanisms of the drug delivery pump;

[00162] FIGS. 79A-79B are flow-charts of embodiments describing methods of drug delivery by the drug delivery device based on one or more mechanisms;

[00163] FIG. 80A shows an isometric view of a drug delivery pump having a controlled delivery drive mechanism, according to one embodiment of the present invention;

[00164] FIG. 80B shows an isometric view of the interior components of the drug delivery pump shown in FIG. 80A (shown without the adhesive patch);

[00165] FIG. 80C shows an isometric view of the bottom of the drug delivery pump shown in FIG. 80A (shown without the adhesive patch);

[00166] FIG. 81A shows an exploded view, along an axis "A," of a drive mechanism and drug container, of one embodiment of the present invention;

[00167] FIG. 81B shows an exploded view, along an axis "B," of one embodiment of the present invention (biasing member, cover sleeve, plunger seal, barrel, and cap are not shown for clarity);

[00168] FIG. 82A shows an isometric view of a controlled delivery drive mechanism, according to at least one embodiment of the present invention;

[00169] FIG. 82B shows an isometric view of a controlled delivery drive mechanism, according to at least one embodiment of the present invention (the piston is shown exploded to illustrate attachment of tether);

[00170] FIGS. 83A-83C shows an enlarged view of an escapement regulating mechanism of a drive mechanism, according to at least one embodiment of the present invention;

[00171] FIGS. 83D-83H shows the progression of the escapement regulating mechanism, according to the embodiment shown in FIGS. 83A-83C, during operation;

[00172] FIG. 84A shows an isometric view of the drive mechanism and drug container shown in FIG. 81 in an initial inactive state;

[00173] FIG. 84B shows an isometric view of the drive mechanism shown in FIG. 81 as the mechanism completes drug delivery;

[00174] FIG. 85A shows a cross-sectional view of the drive mechanism shown in FIG. 81 in an initial inactive state;

[00175] FIG. 85B shows a cross-sectional view of the drive mechanism shown in FIG. 81 in an actuated state as the mechanism controls the rate or profile of drug delivery;

[00176] FIG. 85C shows a cross-sectional view of the drive mechanism shown in FIG. 81 as the mechanism completes drug delivery and, optionally, performs a compliance push to ensure completion of drug delivery;

[00177] FIG. 86A shows an isometric view of a drug delivery pump having a controlled delivery drive mechanism, according to one embodiment of the present invention;

[00178] FIG. 86B shows an isometric view of the interior components of the drug delivery pump shown in FIG. 86A (shown without the adhesive patch);

[00179] FIG. 86C shows an isometric view of the bottom of the drug delivery pump shown in FIG. 86A (shown without the adhesive patch);

[00180] FIG. 87 shows an isometric view of a controlled delivery drive mechanism, according to at least one embodiment of the present invention;

[00181] FIG. 88 shows an exploded view, along an axis "A," of the drive mechanism shown in FIG. 87 (but excluding the plunger seal, barrel, and cap for clarity);

[00182] FIG. 89A shows an isometric view of the drive mechanism shown in FIG. 87 in an initial inactive state;

[00183] FIG. 89B shows an isometric view of the drive mechanism shown in FIG. 87 in an actuated state as the mechanism controls the rate or profile of drug delivery;

[00184] FIG. 89C shows an isometric view of the drive mechanism shown in FIG. 87 as the mechanism completes drug delivery;

[00185] FIG. 90A shows a cross-sectional view of the drive mechanism shown in FIG. 89A in an initial inactive state;

[00186] FIG. 90B shows a cross-sectional view of the drive mechanism shown in FIG. 89B in an actuated state as the mechanism controls the rate or profile of drug delivery;

[00187] FIG. 90C shows a cross-sectional view of the drive mechanism shown in FIG. 89C as the mechanism completes drug delivery and, optionally, performs a compliance push to ensure completion of drug delivery;

[00188] FIG. 91 shows a perspective view of the drive mechanism which incorporates an incremental status indicator, according to a further embodiment of the present invention;

[00189] FIG. 92A shows an isometric view of a drug delivery pump having a variable rate controlled delivery drive mechanism, according to one embodiment of the present invention;

[00190] FIG. 92B shows an isometric view of the interior components of the drug delivery pump shown in FIG. 92A (shown without the adhesive patch);

[00191] FIG. 92C shows an isometric view of the bottom of the drug delivery pump shown in FIG. 92A (shown without the adhesive patch);

[00192] FIG. 93 shows an isometric view of a controlled delivery drive mechanism, according to at least one embodiment of the present invention;

[00193] FIG. 94A shows a partially exploded view, along an axis "A," of the drive mechanism shown in FIG. 93;

[00194] FIG. 94B shows a fully exploded view, along an axis "A" and along a perpendicular axis "B", of certain components of the drive mechanism shown in FIG. 93;

[00195] FIGS. 95A-95C shows an enlarged view of an escapement regulating mechanism of a drive mechanism, according to at least one embodiment of the present invention;

[00196] FIGS. 95D-95H shows the progression of the escapement regulating mechanism, according the embodiment shown in FIGS. 95A-95C, during operation;

[00197] FIG. 96A shows an isometric view of the drive mechanism shown in FIG. 93 in an initial inactive state;

[00198] FIG. 96B shows an isometric view of the drive mechanism shown in FIG. 93 in an actuated state as the mechanism controls the rate or profile of drug delivery;

[00199] FIG. 96C shows an isometric view of the drive mechanism shown in FIG. 93 as the mechanism completes drug delivery;

[00200] FIG. 97A shows a cross-sectional view of the drive mechanism shown in FIG. 96A in an initial inactive state;

[00201] FIG. 97B shows a cross-sectional view of the drive mechanism shown in FIG. 96B in an actuated state as the mechanism controls the rate or profile of drug delivery;

[00202] FIG. 97C shows a cross-sectional view of the drive mechanism shown in FIG. 96C as the mechanism completes drug delivery and, optionally, performs a compliance push to ensure completion of drug delivery;

[00203] FIG. 98 shows an isometric view of a controlled delivery drive mechanism which incorporates a status indicator, according to at least one embodiment of the present invention;

[00204] FIG. 99 shows an isometric view of a controlled delivery drive mechanism according to another embodiment of the present invention;

[00205] FIG. 100A shows an isometric view of a drug delivery pump having a variable rate controlled delivery drive mechanism, according to one embodiment of the present invention;

[00206] FIG. 100B shows an isometric view of the interior components of the drug delivery pump shown in FIG. 100A (shown without the adhesive patch);

[00207] FIG. 100C shows an isometric view of the bottom of the drug delivery pump shown in FIG. 100A (shown without the adhesive patch);

[00208] FIG. 101 shows an isometric view of a variable rate controlled delivery drive mechanism, according to at least one embodiment of the present invention;

[00209] FIG. 102 shows an exploded view, along an axis "A," of the drive mechanism shown in FIG. 101;

[00210] FIG. 103A shows an isometric cross-sectional view of the drive mechanism shown in FIG. 101 in an initial inactive state;

[00211] FIG. 103B shows an isometric cross-sectional view of the drive mechanism shown in FIG. 101 in an actuated state as the mechanism controls the rate or profile of drug delivery;

[00212] FIG. 103C shows an isometric cross-section view of the drive mechanism shown in FIG. 101 as the mechanism completes drug delivery;

[00213] FIG. 104A shows a cross-sectional view of the drive mechanism shown in FIG. 103A in an initial inactive state;

[00214] FIG. 104B shows a cross-sectional view of the drive mechanism shown in FIG. 103B in an actuated state as the mechanism controls the rate or profile of drug delivery;

[00215] FIG. 104C shows a cross-sectional view of the drive mechanism shown in FIG. 103C as the mechanism completes drug delivery and, optionally, performs a compliance push to ensure completion of drug delivery;

[00216] FIG. 105 shows an isometric view of a variable rate controlled delivery drive mechanism, according to another embodiment of the present invention;

[00217] FIG. 106 shows an exploded view, along an axis "A," of the drive mechanism shown in FIG. 105;

[00218] FIG. 107A shows an isometric cross-sectional view of the drive mechanism shown in FIG. 105 in an initial inactive state;

[00219] FIG. 107B shows an isometric cross-sectional view of the drive mechanism shown in FIG. 105 in an actuated state as the mechanism controls the rate or profile of drug delivery;

[00220] FIG. 107C shows an isometric cross-sectional view of the drive mechanism shown in FIG. 105 as the mechanism completes drug delivery;

[00221] FIG. 108A shows a cross-sectional view of the drive mechanism shown in FIG. 107A in an initial inactive state;

[00222] FIG. 108B shows a cross-sectional view of the drive mechanism shown in FIG. 107B in an actuated state as the mechanism controls the rate or profile of drug delivery;

[00223] FIG. 108C shows a cross-sectional view of the drive mechanism shown in FIG. 107C as the mechanism completes drug delivery and, optionally, performs a compliance push to ensure completion of drug delivery;

[00224] FIG. 109A shows an isometric view of a variable rate controlled delivery drive mechanism which incorporates a mechanical status indicator, according to a further embodiment of the present invention;

[00225] FIG. 109B shows an isometric view of a variable rate controlled delivery drive mechanism which incorporates an optical status indicator, according to yet another embodiment of the present invention;

[00226] FIG. 110A is an isometric view of a drug delivery pump having a drive mechanism, according to one embodiment of the present invention (shown without the adhesive patch);

[00227] FIG. 110B is an isometric view of the interior components of the drug delivery pump shown in FIG. 110A (shown without the adhesive patch);

[00228] FIG. 110C is an isometric view of the drug delivery pump shown in FIG. 110A (shown without the adhesive patch) from yet another viewpoint;

[00229] FIG. 111A is a top view, along an axis "A," of the interior components of an exemplary drug delivery pump;

[00230] FIG. 111B is an isometric view of a drive mechanism, according to at least one embodiment of the present invention prior to activation;

[00231] FIG. 111C is an isometric view of a drive mechanism, according to at least one embodiment of the present invention during activation;

[00232] FIG. 111D is an isometric view of a drive mechanism, according to at least one embodiment of the present invention at a later stage during activation;

[00233] FIG. 111E is an isometric view of a drive mechanism, according to at least one embodiment of the present invention near or at completion of drug delivery;

[00234] FIGS. 112A-112D are top views which correspond with the stages of operation shown in FIGS. 111A-111E, respectively;

[00235] FIG. 113 is an isometric view of the drive mechanism, according to at least one embodiment of the present invention, in isolation from the drug delivery device;

[00236] FIGS. 114A-114B are top and bottom views, respectively, of the drive mechanism shown in FIG. 113;

[00237] FIGS. 114C-114D are front and back perspective views, respectively, of the drive mechanism shown in FIG. 113;

[00238] FIG. 115A is an isometric view of a drug delivery pump in which the insertion mechanism includes a rotational biasing member;

[00239] FIG. 115B is an enlarged view of the drive mechanism shown in FIG. 115A

[00240] FIG. 116A is an isometric view of an insertion mechanism in an initial configuration;

[00241] FIG. 116B is an enlarged, fragmentary isometric view of the insertion mechanism of FIG. 116A;

[00242] FIG. 117A is a side elevation view of the insertion mechanism of FIG. 116A in an initial configuration;

[00243] FIG. 117B is an enlarged, fragmentary, side elevation view of the insertion mechanism of FIG. 117A;

[00244] FIG. 118A is an isometric view of the insertion mechanism of FIG. 116A in an intermediate configuration;

[00245] FIG. 118B is an enlarged, fragmentary isometric view of the insertion mechanism of FIG. 118A;

[00246] FIG. 119A is a side elevation view of the insertion mechanism of FIG. 118A in an intermediate configuration;

[00247] FIG. 119B is an enlarged, fragmentary, side elevation view of the insertion mechanism of FIG. 119A;

[00248] FIG. 120A is an isometric view of the insertion mechanism of FIG. 116A in an released configuration;

[00249] FIG. 120B is an enlarged, fragmentary isometric view of the insertion mechanism of FIG. 120A;

[00250] FIG. 121A is a side elevation view of the insertion mechanism of FIG. 120A in an released configuration;

[00251] FIG. 121B is an enlarged, fragmentary, side elevation view of the insertion mechanism of FIG. 121A;

[00252] FIG. 122A is a side elevation view of an enabling mechanism according to at least one embodiment of the present invention;

[00253] FIG. 122B is an enlarged, fragmentary side elevation view of the enabling mechanism of FIG. 122A;

[00254] FIG. 123 is an isometric view of a regulating mechanism according to at least one embodiment of the present invention;

[00255] FIGS. 124A-124B are isometric views of a key according to at least one embodiment of the present invention;

[00256] FIG. 124C is an isometric views of a key according to another embodiment of the present invention;

[00257] FIG. 125 is a plan view of a main gear according to at least one embodiment of the present invention;

[00258] FIG. 126A is an isometric view of a drive mechanism according to one embodiment of the invention in a first configuration;

[00259] FIG. 126B is an enlarged, fragmentary, isometric view of the drive mechanism of FIG. 126A in the first configuration;

[00260] FIG. 127A is an isometric view of the drive mechanism of FIG. 126A in a second configuration;

[00261] FIG. 127B is an enlarged, fragmentary, isometric view of the drive mechanism of FIG. 127A in the second configuration;

[00262] FIG. 128A is an isometric view of the drive mechanism of FIG. 126A in a third configuration;

[00263] FIG. 128B is an enlarged, fragmentary, isometric view of the drive mechanism of FIG. 128A in the third configuration;

[00264] FIG. 129A is an isometric view of the drive mechanism of FIG. 126A in a fourth configuration;

[00265] FIG. 129B is an enlarged, fragmentary, isometric view of the drive mechanism of FIG. 129A in the fourth configuration;

[00266] FIG. 130A is an isometric view of one embodiment of a winch drum and winch gear in a first configuration;

[00267] FIG. 130B is an isometric view of the winch drum and winch gear of FIG. 130A in a second configuration;

[00268] FIG. 131 is an isometric view of a winch gear of the embodiment of FIGS. 130A-131B;

[00269] FIG. 132 is an isometric view of a coupler of a winch drum of the embodiment of FIGS. 131A-131B;

[00270] FIG. 133 is an isometric view of a capstan of a winch drum of the embodiment of FIGS. 130A-130B;

[00271] FIG. 134A is a cross-sectional view of a safety mechanism according to one embodiment of the invention in an initial configuration;

[00272] FIG. 134B is an enlarged, fragmentary, cross-sectional view of the safety mechanism of FIG. 134A in an initial configuration;

[00273] FIG. 135A is a cross-sectional view of a safety mechanism of FIG. 134A in an actuated configuration;

[00274] FIG. 135B is an enlarged, fragmentary, cross-sectional view of the safety mechanism of FIG. 135A in the actuated configuration;

[00275] FIG. 136A is a cross-sectional view of a safety mechanism of FIG. 134A in a retracted configuration;

[00276] FIG. 136B is an enlarged, fragmentary, cross-sectional view of the safety mechanism of FIG. 136A in the retracted configuration;

[00277] FIGS. 137A-137B are cross-sectional views of a safety mechanism according to another embodiment of the present invention;

[00278] FIG. 138 is an isometric view according to one embodiment of a spring retainer for the safety mechanism of FIGS. 137A-137B;

[00279] FIG. 139 is an isometric view according to another embodiment of a spring retainer for the safety mechanism of FIGS. 137A-137B;

[00280] FIG. 140 is an isometric view of a sleeve for the safety mechanism of FIGS. 137A-137B;

[00281] FIG. 141A is a fragmentary cross-sectional view of a drug container and safety mechanism in an initial, unrestrained configuration; and

[00282] FIG. 141B is a fragmentary cross-sectional view of the drug container and safety mechanism of FIG. 141A in an activated configuration;

[00283] FIG. 142A shows an exploded view, exploded along an axis "A," of an insertion mechanism according to at least one embodiment of the present disclosure;

[00284] FIG. 142B shows a cross-sectional exploded view, exploded along an axis "A," of an insertion mechanism according to at least one embodiment of the present disclosure;

[00285] FIG. 143A shows an isometric view of an insertion mechanism housing according to at least one embodiment of the present disclosure;

[00286] FIG. 143B shows a cross-section view of the insertion mechanism housing shown in FIG. 143A;

[00287] FIG. 144 shows an isometric view of a hub according to at least one embodiment of the present disclosure;

[00288] FIG. 145 shows an isometric view of a sleeve according to at least one embodiment of the present disclosure;

[00289] FIG. 146 shows an embodiment of a base of an insertion mechanism according to at least one embodiment of the present disclosure;

[00290] FIG. 147A shows an isometric view of an insertion mechanism according to at least one embodiment of the present disclosure in an initial configuration;

[00291] FIG. 147B shows a cross-sectional view of an insertion mechanism according to at least one embodiment of the present disclosure in an initial configuration;

[00292] FIG. 148A shows an isometric view of an insertion mechanism according to at least one embodiment of the present disclosure in a needle inserted configuration;

[00293] FIG. 148B shows a cross-sectional view of an insertion mechanism according to at least one embodiment of the present disclosure in a needle inserted configuration;

[00294] FIG. 149A shows an isometric view of an insertion mechanism according to at least one embodiment of the present disclosure in a needle retracted configuration;

[00295] FIG. 149B shows a cross-sectional view of an insertion mechanism according to at least one embodiment of the present disclosure in a needle retracted configuration;

[00296] FIG. 150 shows an isometric view of an insertion mechanism according to at least one embodiment of the present disclosure;

[00297] FIG. 151 shows a cross-sectional side view of the embodiment of FIG. 150;

[00298] FIG. 152 shows a cross-sectional front view of the embodiment of FIG. 150;

[00299] FIG. 153A shows a cross-sectional view of an insertion mechanism according to at least one embodiment of the present invention in an initial configuration;

[00300] FIG. 153B shows a cross-sectional view of the insertion mechanism of FIG. 153A in an inserted configuration;

[00301] FIG. 153C shows a cross-sectional view of the insertion mechanism of FIG. 153A in a delivery configuration;

[00302] FIG. 154A shows a cross-sectional side elevational view of an insertion mechanism housing according to at least one embodiment of the present invention;

[00303] FIG. 154B shows a cross-sectional isometric view of the insertion mechanism housing of FIG. 154A;

[00304] FIG. 155A is an enlarged, fragmentary cross-sectional view of the insertion mechanism of FIGS. 153A-153C, while in a delivery configuration;

[00305] FIG. 155B is an enlarged, fragmentary cross-sectional view of the insertion mechanism of FIGS. 153A-153C, while in a retracted position

[00306] FIG. 156A shows a cross-sectional view of an insertion mechanism according to at least one embodiment of the present invention in an initial configuration;

[00307] FIG. 156B shows a cross-sectional view of the insertion mechanism of FIG. 156A in an inserted configuration;

[00308] FIG. 156C shows a cross-sectional view of the insertion mechanism of FIG. 156A having the needle hub in a partially-retracted configuration;

[00309] FIG. 156D shows a cross-sectional view of the insertion mechanism of FIG. 156A having the needle hub in a fully-retracted configuration;

[00310] FIG. 157A shows a cross-sectional view of the insertion mechanism of FIG. 156A in an initial configuration taken at 45^{O} rotation to the view of FIG. 156A;

[00311] FIG. 157B shows a cross-sectional view of the insertion mechanism of FIG. 157A in an inserted configuration;

[00312] FIG. 157C shows a cross-sectional view of the insertion mechanism of FIG. 157A having the needle hub in a retracted configuration;

[00313] FIG. 158A shows a cross-sectional view of the insertion mechanism of FIGS. 156A and 157A in an initial configuration taken at 270^{O} rotation to the view of FIG. 157A;

[00314] FIG. 158B shows a cross-sectional view of the insertion mechanism of FIG. 158A in an inserted configuration;

[00315] FIG. 158C shows a cross-sectional view of the insertion mechanism of FIG. 158A having the needle hub in a retracted configuration;

[00316] FIG. 159 is an isometric view of a clip illustrated in FIGS. 156A-158C;

[00317] FIG. 160 is an isometric view of a cannula retainer illustrated in FIGS. 156A-158C;

[00318] FIG. 161 is an isometric view of a needle hub illustrated in FIGS.156A-158C;

[00319] FIG. 162 is cross-sectional isometric view of a housing illustrated in FIGS. 156A-158C;

[00320] FIG. 163A is an isometric view of a NIM activation mechanism according to at least one embodiment of the present invention in an initial configuration;

[00321] FIG. 163B is an isometric view of the NIM activation mechanism of FIG. 163A in an activated configuration;

[00322] FIG. 164A is a top view of a NIM retraction mechanism according to at least one embodiment of the present invention in a delivery configuration;

[00323] FIG. 164B is a top view of the NIM retraction mechanism of FIG. 164A in a retracted configuration;

[00324] FIG. 165 is an isometric view of a drug delivery device incorporating an embodiment of a fill-finish cartridge according to aspects of the disclosure;

[00325] FIG. 166A is a schematic representation of an exemplary fill-finish cartridge of the present disclosure;

[00326] FIG. 166B is a chart of exemplary combinations of components of a fill-finish cartridge according to aspects of the disclosure;

[00327] FIG. 167 is an exploded isometric view of a fill-finish cartridge, according to an embodiment of the disclosure;

[00328] FIG. 168 is an enlarged fragmentary isometric cross-sectional view of the fluid pathway connector of the fill-finish cartridge shown in FIG. 167, cross-hatching being eliminated for the purposes of clarity;

[00329] FIG. 169 is an isometric view of the fill-finish cartridge of FIG. 167 before insertion of a plunger seal, elements of FIG. 169 being shown in partial transparency;

[00330] FIG. 170 is an isometric view of the fill-finish cartridge of FIG. 167 after insertion of a plunger seal, elements of FIG. 30 being shown in partial transparency;

[00331] FIG. 171 is an exploded isometric view of a tray which may be utilized to retain a plurality of fill-finish cartridges for use in a fill-finish process, elements of FIG. 170 being shown in partial transparency;

[00332] FIG. 172 is an isometric view of the a tray of FIG. 171 in an assembled form and holding a plurality of fill-finish cartridges for use in a fill-finish process;

[00333] FIG. 173 is a side elevational view of another embodiment of a fill-finish cartridge, wherein the cartridge includes a fully disposable carrier;

[00334] FIG. 174 is an exploded view of the fill-finish cartridge of FIG. 173;

[00335] FIG. 175 is a cross-sectional view of the fill-finish cartridge of FIGS. 173 and 174, cross-hatching being eliminated for the purposes of clarity;

[00336] FIG. 176 is a side elevational view of the fill-finish cartridge of FIGS. 173-175 with the carrier removed;

[00337] FIG. 177 is an isometric view of a drug delivery device incorporating another embodiment of a fill-finish cartridge according to the disclosure, a portion of a housing of the drug delivery device being removed;

[00338] FIG. 178 is a side elevational view of the fill-finish cartridge of FIG. 177 prior to placement in the housing, and including partially disposable carrier;

[00339] FIG. 179 is a cross-sectional view of the fill-finish cartridge of FIG. 177, cross-hatching being eliminated for the purposes of clarity;

[00340] FIG. 180 is a side elevational view of another embodiment of a fill-finish cartridge in an assembled configuration;

[00341] FIG. 181 is a cross-sectional view of the fill-finish cartridge of FIG. 180, cross-hatching being eliminated for the purposes of clarity;

[00342] FIG. 182 is a partially exploded view of the fill-finish cartridge of FIGS. 180 and 181, showing a fluid conduit in the final configuration;

[00343] FIG. 183 is an exploded view of the fluid pathway connector of the fill-finish cartridge of FIGS. 180-182;

[00344] FIG. 184 is a cross-sectional view of the fill-finish cartridge of FIG. 180 similar to the view of FIG. 181, but prior to the coupling of the fluid pathway connector to the needle insertion mechanism, cross-hatching being eliminated for the purposes of clarity;

[00345] FIG. 185 is a side elevational view of another embodiment of a fill-finish cartridge in an assembled configuration;

[00346] FIG. 186 is a cross-sectional view of the fill-finish cartridge of FIG. 181, cross-hatching being eliminated for the purposes of clarity;

[00347] FIG. 187 is a cross-sectional view of the fill-finish cartridge of FIG. 181 similar to the view of FIG. 182, but prior to the coupling of the fluid pathway connector to the needle insertion mechanism, cross-hatching being eliminated for the purposes of clarity;

[00348] FIG. 188 is a schematic illustration of a drug delivery device including a temperature control system, according to one embodiment of the present disclosure;

[00349] FIG. 189A illustrates an embodiment of an adhesive patch for a drug delivery device constructed in accordance with principles of the present disclosure;

[00350] FIG. 189B illustrates an embodiment of an adhesive patch for a drug delivery device constructed in accordance with principles of the present disclosure;

[00351] FIG. 190 depicts an embodiment of a non-adhesive patch liner in combination with a drug delivery device constructed in accordance with principles of the present disclosure;

[00352] FIG. 191A illustrates an exploded assembly view of an embodiment of an adhesive patch for a drug delivery device constructed in accordance with principles of the present disclosure;

[00353] FIG. 191B depicts the adhesive patch of FIG. 191A in an assembled form;

[00354] FIG. 192 illustrates an isometric view of a drug delivery device including an adhesive patch with stiffening members, according to one embodiment of the present disclosure;

[00355] FIG. 193 illustrates a bottom view an embodiment of a non-adhesive patch liner;

[00356] FIG. 194A-194C illustrate a process of attaching the drug delivery device of FIG. 192 to a patient's skin;

[00357] FIG. 195 is a schematic diagram of a drug delivery device in communication with a data processing network according to one embodiment of the present disclosure;

[00358] FIGS. 196A-196C are schematic diagrams illustrating the operation of an energy management system according to one embodiment of the present disclosure;

[00359] FIGS. 197A-197C are schematic diagrams illustrating the operation of an energy management system according to another embodiment of the present disclosure;

[00360] FIGS. 198A-198C are schematic diagrams illustrating the operation of an energy management system according to another embodiment of the present disclosure;

[00361] FIG. 199 is an isometric view of an energy management system according to another embodiment of the present disclosure;

[00362] FIG. 200 is an isometric view of an energy management system according to another embodiment of the present disclosure;

[00363] FIG. 201A shows an exploded view of a medical device with an integrated stimulant source according to at least one embodiment of the present invention;

[00364] FIG. 201B shows the medical device of the embodiment of FIG. 201A applied to a patient's skin and the stimulant source activated;

[00365] FIG. 201C shows the medical device of the embodiment of FIG. 201A after removal from the patient's skin;

[00366] FIG. 202A shows an exploded view of a medical device with an external stimulant source according to at least one embodiment of the present invention;

[00367] FIG. 202B shows the medical device of the embodiment of FIG. 202A applied to a patient's skin;

[00368] FIG. 202C shows the medical device of the embodiment of FIG. 202A after removal of the body of the medical device and the stimulant source activated;

[00369] FIG. 202D illustrates removal of the adhesive from the patient's skin;

[00370] FIG. 203A is a cross-sectional view of an embodiment of a fluid pathway connector and drug container prior to drug delivery;

[00371] FIG. 203B is a cross-sectional view of the embodiment of a fluid pathway connector and drug container of FIG. 203A during drug delivery; and

[00372] FIG. 203C is a cross-sectional view of the embodiment of a fluid pathway connector and drug container of FIG. 203A following completion of drug delivery.

DETAILED DESCRIPTION

[00373] The present disclosure provides drug delivery devices having advantageous insertion mechanisms, drive mechanisms, sterile fluid pathway assemblies, status indicators, safety features, and other advantageous components. Such drug delivery devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The drug delivery devices described herein incorporate features which make activation, operation, and lock-out of the drug delivery device simple for even untrained patients. The drug delivery devices of the present disclosure provide these desirable features without various problems associated with known prior art devices. Furthermore, the sterile fluid pathway assemblies of the present disclosure may filled with pharmaceutical treatments using standard filling equipment and systems. This advantage is enabled by the fill-finish cartridges of the present disclosure which function to maintain the sterility of the fluid pathway assemblies and allow them to nest, mount, or otherwise be removably inserted into trays for standard fill-finish processes, as discussed is more detail below.

[00374] As discussed in more detail below, the drug delivery devices of the present disclosure may contain a drug, which may also be also be referred to as a medication or a medicament. The drug may be, but is not limited to, various biologicals (e.g., peptides, peptibodies, or antibodies), biosimilars, large-molecule drugs (e.g., a drug with a molecular weight of greater than or equal to approximately 900 Daltons), small-molecule drugs (e.g., a drug with a molecular weight of less than or equal to approximately 900 Daltons), high viscosity drugs, low viscosity drugs, drugs exhibiting non-Newtonian fluid characteristics such as shear thinning, and/or drugs exhibiting Newtonian fluid characteristics. The drug may be in a fluid or liquid form, although the disclosure is not limited to a

particular state (e.g., no differentiation is intended between a solution, a gel, or a lyophilized product for example).

[00375] One perceived disadvantage of certain known drug delivery devices is their inability to deliver highly viscous drugs such as certain biologics in a timely manner and/or with little patient discomfort. High viscosity drugs typically require more time for injection than low viscosity drugs. Patients may find it difficult and/or undesirable to hold an autoinjector or a syringe against their skin for the amount of time necessary to inject a high viscosity drug. While the injection time can be decreased by increasing the force of the drive mechanism, a more powerful drive mechanism increases the risk of breakage of the drug container and other internal components of the device. Also, a more powerful drive mechanism increases the possibility that the patient will experience an impulse or mechanical shockwave that may disturb or surprise the patient. As a result, the patient may attempt to pull the drug delivery device away from skin, which can compromise complete dosing.

[00376] Long injection times are more likely to be tolerated by patients if the drug is administered via a wearable drug delivery device. Unlike a syringe or an autoinjector, a wearable drug delivery device does not have to be held in place by the patient during drug delivery. Therefore, the patient can resume physical activities after the wearable drug delivery device has been placed on the skin and initiated or otherwise not burdened by holding the drug delivery device in place.

[00377] Certain aspects of wearable drug delivery devices, however, have discouraged their adoption in the field of high viscosity drugs. In order to achieve a compact design with a low profile that does not significantly protrude from the patient's body, wearable drug delivery devices oftentimes include a drug container that is offset and orthogonal to an insertion mechanism. This arrangement usually requires a tubular conduit with one of more turns to fluidly couple the drug container and the insertion mechanism. Therefore, as compared to syringes and autoinjectors, the internal fluid flowpath of wearable drug delivery devices tend to be relatively long and tortuous.

[00378] For drugs that behave as Newtonian fluids (i.e., fluids for which shear rate is directly proportional to flow rate), a longer flow path can result in a slower flow rate. Thus, wearable drug delivery devices, due to their long internal flowpaths, have the potential to exacerbate the injection problems associated with high viscosity drugs. The force of the drive mechanism can be increased to compensate for the reduction in flow rate, but a more powerful drive mechanism increases the

risk of drug container breakage and therefore is typically considered undesirable. For at least these reasons, wearable drug delivery devices were viewed by some as not being particularly well suited for the delivery of high viscosity drugs.

[00379] The inventors of the present disclosure found that various high viscosity drugs (e.g., PCSK9 specific antibodies, G-CSFs, sclerostin antibodies, and CGRP antibodies) exhibit non-Newtonian fluid characteristics when injected via a wearable drug delivery device. One such characteristic is shear thinning, which is the ability of a non-Newtonian fluids to exhibit decreased viscosity when subjected to shear strain. Shear thinning reduces the viscosity of a fluid as it is pushed through a conduit. Accordingly, the force needed to push the fluid through a conduit is less than it would be if the fluid was Newtonian. In the context of wearable drug delivery devices, shear shinning mitigates the clogging effect of the device's long internal flowpath. Therefore, an unexpected benefit of wearable drug delivery devices found by the inventors of the present disclosure is that they are well suited for delivering high viscosity drugs having non-Newtonian characteristics such as shear thinning. The inventors of the present disclosure found that shear thinning oftentimes occurs in drugs such as biologics which have relatively large protein molecules with a molecular weight greater than or equal to approximately (e.g., ±10%) 900 daltons. Any of the wearable drug delivery devices described herein may have a drug container filled with a high viscosity drug having shear thinning capabilities, and therefore realize the unexpected benefits of shear thinning on the operation and use of the device.

[00380] Certain non-limiting embodiments of the drug delivery device and its respective components will now be described with reference to the accompanying figures.

[00381] As used herein to describe the drive mechanisms, the insertion mechanisms, fluid pathway connectors, drug delivery devices, or any of the relative positions of the components of the present disclosure, the terms "axial" or "axially" refer generally to a longitudinal axis "A" around which a component is preferably positioned, although not necessarily symmetrically there-around. The term "radial" refers generally to a direction normal to axis A. The terms "proximal," "rear," "rearward," "back," or "backward" refer generally to an axial direction in the direction "P". The terms "distal," "front," "frontward," "depressed," or "forward" refer generally to an axial direction in the direction "D". As used herein, the term "glass" should be understood to include other similarly non-reactive materials suitable for use in a pharmaceutical grade application that would normally require glass, including but not limited to certain non-reactive polymers such as cyclic olefin

copolymers (COC) and cyclic olefin polymers (COP). The term "plastic" may include both thermoplastic and thermosetting polymers. Thermoplastic polymers can be re-softened to their original condition by heat; thermosetting polymers cannot. As used herein, the term "plastic" refers primarily to moldable thermoplastic polymers such as, for example, polyethylene and polypropylene, or an acrylic resin, that also typically contain other ingredients such as curatives, fillers, reinforcing agents, colorants, and/or plasticizers, etc., and that can be formed or molded under heat and pressure. As used herein, the term "plastic" is not meant to include glass, non-reactive polymers, or elastomers that are approved for use in applications where they are in direct contact with therapeutic liquids that can interact with plastic or that can be degraded by substituents that could otherwise enter the liquid from plastic. The term "elastomer," "elastomeric" or "elastomeric material" refers primarily to cross-linked thermosetting rubbery polymers that are more easily deformable than plastics but that are approved for use with pharmaceutical grade fluids and are not readily susceptible to leaching or gas migration under ambient temperature and pressure. As used herein, "fluid" refers primarily to liquids, but can also include suspensions of solids dispersed in liquids, and gasses dissolved in or otherwise present together within liquids inside the fluid-containing portions of drug delivery devices. According to various aspects and embodiments described herein, reference is made to a "biasing member", such as in the context of one or more biasing members for insertion or retraction of the needle, trocar, and/or cannula. It will be appreciated that the biasing member may be any member that is capable of storing and releasing energy. Non-limiting examples include a spring, such as for example a coiled spring, a compression or extension spring, a torsional spring, and a leaf spring, a resiliently compressible or elastic band, or any other member with similar functions. In at least one embodiment of the present disclosure, the biasing member is a spring, preferably a compression spring. Also, as used herein, the term "drug delivery device" is intended to include any number of devices which are capable of dispensing a fluid to a patient upon activation. Such drug delivery devices include, for example, wearable drug delivery devices, on-body injectors, off-body injectors, autoinjectors, infusion pumps, bolus injectors, and the like. Furthermore, as used herein, the term “wearable drug delivery device” is intended to include any number of devices which are capable dispensing a fluid to a patient upon activation and capable of being attached to the patient’s skin or clothing. Such wearable drug delivery devices include, for example, on-body injectors and off-body injectors.

[00382] I. Drug Delivery Device

[00383] FIGS. 1A-1C show an exemplary drug delivery device 10 according to at least one embodiment of the present disclosure. The drug delivery device 10 may be utilized to administer delivery of a drug treatment into a body of a patient. As shown in FIGS. 1A-1C, the drug delivery device 10 includes a housing 12. The housing 12 may include one or more housing subcomponents which are fixedly engageable to facilitate easier manufacturing, assembly, and operation of the drug delivery device 10. For example, drug delivery device 10 includes the housing 12 which includes an upper housing 12A and a lower housing 12B. The drug delivery device 10 may further include an activation mechanism 14, a status indicator 16, and a window 18. Window 18 may be any translucent or transmissive surface through which the operation of the drug delivery device 10 may be viewed. In at least one embodiment, the window 18 may be configured to connect and hold together the upper housing 12A and the lower housing 12B. As shown in FIG. 1B, drug delivery device 10 further includes assembly platform 20, sterile fluid conduit 30, drive mechanism 100 having drug container 50, insertion mechanism 200, fluid pathway connector 300 configured to establish a sterile fluid flow path between the drug container 50 and the needle or cannula of the insertion mechanism 200, and power and control system 400. One or more of the components of the drug delivery device 10 may be modular in that they may be, for example, pre-assembled as separate components and configured into position onto the assembly platform 20 of the drug delivery device 10 during manufacturing. In some embodiments, the assembly platform 20 may be a portion of the housing 12, such as a portion of the lower housing 12, or alternatively, may be a separate component.

[00384] The housing 12 may contain some or all of the device components. In some embodiments, the housing 12 may provide a means of removably attaching the drug delivery device 10 to the skin or clothing of the patient, thereby rending the drug delivery device 10 a wearable drug delivery device. In some embodiments, a layer of adhesive may be applied to an exterior surface of the housing 12, such as the surface through which a cannula protrudes during operation, for releseably attaching the drug delivery device 10 to a patient's skin.

[00385] The housing 12 also provides protection to the interior components of the drug delivery device 10 against environmental influences. In some embodiments, the housing may be configured to at least partially prevent contaminants and other harmful matter from entering the drug delivery device 10. For example, the housing 12 may be configured to restrict the passage of fluids into the drug delivery device 10. As such, this may allow the drug delivery device 10 to be worn in the shower, while swimming, and/or other water-related activities. The housing 12 is ergonomically

and aesthetically designed in size, shape, and related features to facilitate easy packaging, storage, handling, and use by patients who may be untrained and/or physically impaired. Furthermore, the external surface of the housing 12 may be utilized to provide product labeling, safety instructions, and the like. Additionally, as described above, housing 12 may include certain components, such as status indicator 16 and window 18, which may provide operation feedback to the patient.

[00386] The container 50, or any other container described herein, may be configured to contain variety of different drug dose volumes, including drug dose volumes in a range of approximately (e.g., ±10%) 0.5 – 20 mL, or 1 – 10 mL, or 2 – 10 mL, or 2 – 8 mL, or 2 – 6 mL, or 2 – 4 mL, or 0.5 – 2 mL, or 0.5 – 1 mL, or 3.5 mL, or less than or equal to approximately (e.g., ±10%) 3.0 mL, or less than or equal to approximately (e.g., ±10%) 2.5 mL, or less than or equal to approximately (e.g., ±10%) 2.0 mL, or less than or equal to approximately (e.g., ±10%) 1.5 mL, or less than or equal to approximately (e.g., ±10%) 1.0 mL. The container 50 may be completely or partially filled with the drug. The drug may be one or more of the drugs described below, such as, for example, a granulocyte colony-stimulating factor (G-CSF), a PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) specific antibody, a sclerostin antibody, or a calcitonin gene-related peptide (CGRP) antibody.

[00387] In at least one embodiment, the drug delivery device 10 provides an activation mechanism that is displaced by the patient to trigger a start command to a power and control system 400. In a preferred embodiment, the activation mechanism is a start button 14 that is located through the housing 12, such as through an aperture between the upper housing 12A and the lower housing 12B, and which contacts a control arm 40 of the power and control system 400. In at least one embodiment, the start button 14 may be a push button, and in other embodiments, may be an on/off switch, a toggle, or any similar activation feature known in the art. The housing 12 also provides a status indicator 16 and a window 18. In other embodiments, one or more of the activation mechanism 14, the status indicator 16, the window 18, and combinations thereof may be provided on the upper housing 12A or the lower housing 12B such as, for example, on a side visible to the patient when the drug delivery device 10 is placed on the body of the patient. Housing 12 is described in further detail hereinafter with reference to other components and embodiments of the present disclosure.

[00388] The drug delivery device 10 may be configured such that, upon activation by a patient by depression of the activation mechanism, the drug delivery device 10 is initiated to: insert a fluid

pathway into the patient; enable, connect, or open necessary connections between a drug container, a fluid pathway, and a sterile fluid conduit; and force drug fluid stored in the drug container through the fluid pathway and fluid conduit for delivery into a patient. One or more optional safety mechanisms may be utilized, for example, to prevent premature activation of the drug delivery device 10. For example, an optional on-body sensor 24 (shown in FIG. 1C) may be provided in one embodiment as a safety feature to ensure that the power and control system 400, or the activation mechanism, cannot be engaged unless the drug delivery device 10 is in contact with the body of the patient. In one such embodiment, the on-body sensor 24 is located on the bottom of lower housing 12B where it may come in contact with the patient's body. Upon displacement of the on-body sensor 24, depression of the activation mechanism is permitted. Accordingly, in at least one embodiment the on-body sensor 24 is a mechanical safety mechanism, such as for example a mechanical lock out, that prevents triggering of the drug delivery device 10 by the activation mechanism 14. In another embodiment, the on-body sensor may be an electro-mechanical sensor such as a mechanical lock out that sends a signal to the power and control system 400 to permit activation. In still other embodiments, the on-body sensor can be electrically based such as, for example, a conductive-, capacitive- or impedance-based sensor which must detect tissue before permitting activation of the power and control system 400. In at least one embodiment, such an electrically based on-body sensor may incorporate a resistor with an impedance of approximately (e.g., ±10%) 1 MΩ. These concepts are not mutually exclusive and one or more combinations may be utilized within the breadth of the present disclosure to prevent, for example, premature activation of the drug delivery device 10. In a preferred embodiment, the drug delivery device 10 utilizes one or more mechanical on-body sensors. Additional integrated safety mechanisms are described herein with reference to other components of the drug delivery device 10.

[00389] The fluid pathway connector 300 includes a sterile fluid conduit 30, a piercing member, a connection hub, and a sterile sleeve. The fluid pathway connector 300 may further include one or more flow restrictors. Upon proper activation of the drug delivery device 10, the fluid pathway connector 300 is enabled to connect the sterile fluid conduit 30 to the drug container 50. Such connection may be facilitated by a piercing member, such as a needle, penetrating a pierceable seal of the drug container 50. The sterility of this connection may be maintained by performing the connection within a flexible sterile sleeve. Upon substantially simultaneous activation of the insertion mechanism, the fluid pathway between drug container and insertion mechanism is complete to permit drug delivery into the target tissue.

[00390] In at least one embodiment of the present disclosure, the piercing member of the fluid pathway connector is caused to penetrate the pierceable seal of the drug container of the drive mechanism by direct action of the user, such as by depression of the activation mechanism by the user. For example, the activation mechanism itself may bear on the fluid pathway connector such that displacement of the activation mechanism from its original position also causes displacement of the fluid pathway connector. In a preferred embodiment, this connection is enabled by the user depressing the activation mechanism and, thereby, driving the piercing member through the pierceable seal, because this prevents fluid flow from the drug container until desired by the user. In such an embodiment, a compressible sterile sleeve may be fixedly attached between the cap of the drug container and the connection hub of the fluid pathway connector. The piercing member may reside within the sterile sleeve until a connection between the fluid pathway connector and the drug container is desired. The sterile sleeve may be sterilized to ensure the sterility of the piercing member and the fluid pathway prior to activation.

[00391] Alternatively, or additionally, the sterility of the flow path may be preserved by one or more membranes or foils defining one or more sterile chambers of the fluid pathway connector. The membranes or foils may be pierced at the time of use of the drug pump by the piercing member or, alternatively, by an introducer member. In such an embodiment, the piercing member may be at least partially disposed within a lumen of the introducer member to prevent the piercing member from coming in contact with foreign substances.

[00392] The drug pump is capable of delivering a range of drugs with different viscosities and volumes. The drug pump is capable of delivering a drug at a controlled flow rate (speed) and/or of a specified volume. In one embodiment, the drug delivery process is controlled by one or more flow restrictors within the fluid pathway connector and/or the sterile fluid conduit. In other embodiments, other flow rates may be provided by varying the geometry of the fluid flow path or delivery conduit, varying the speed at which a component of the drive mechanism advances into the drug container to dispense the drug therein, or combinations thereof. Still further details about the fluid pathway connector 300 and the sterile fluid conduit 30 are provided hereinafter in later sections in reference to multiple embodiments.

[00393] Another embodiment of a drug delivery device 6010 is shown in Figs. 2A-2B. The drug delivery device 6010 includes many of the same elements as the drug delivery device 10. Elements of the drug delivery device 6010 which are similar to, or the same as, the drug delivery device 10

are designated by the same reference numeral, incremented by 6010. A description of many of these elements is abbreviated or even eliminated in the interest of brevity. The drug delivery device 6010 may include a container 6050 filled with a volume of a fluid(s) for delivery to a patient. The fluid(s) may include one or more of the drugs described below, such as, for example, a granulocyte colony-stimulating factor (G-CSF), a PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) specific antibody, a sclerostin antibody, or a calcitonin gene-related peptide (CGRP) antibody. In drug delivery device 6010, one or more of an insertion mechanism 6200, fluid pathway connector 6300, and a drive mechanism 6100 are controlled by motion of a motor 6207, solenoid or other electrical actuator, as well as the rotation of one or more gears 6209. Additionally, or alternatively, an escapement mechanism may be used to control the rate of rotation of the one or more gears 6209. One of the gears 6209 may be engaged with teeth 6208 of an insertion mechanism housing 6202. As such, the rotation of the one or more gears 209 of the gear train may control the rotation of the insertion mechanism housing 6202 and, thereby, the insertion of the needle or trocar into the skin of the patient. The operation of various embodiments of the insertion mechanism 6200 are described in more detail below.

[00394] II. Power and Control System

[00395] The power and control system 400 includes a power source, which provides the energy for various electrical components within the drug delivery device 10, one or more feedback mechanisms, a microcontroller, a circuit board, one or more conductive pads, and one or more interconnects. Other components commonly used in such electrical systems may also be included, as would be appreciated by one having ordinary skill in the art. The one or more feedback mechanisms may include, for example, audible alarms such as piezo alarms and/or light indicators such as light emitting diodes (LEDs). The microcontroller may be, for example, a microprocessor. The power and control system 400 controls several device interactions with the patient and interfaces with the drive mechanism 100. In one embodiment, the power and control system 400 interfaces either directly or indirectly with the on-body sensor 24 to identify when the device is in contact with patient and/or the activation mechanism 14 to identify when the drug delivery device 10 has been activated. The power and control system 400 may also interface with the status indicator 16 of the housing 12, which may be a transmissive or translucent material which permits light transfer, to provide visual feedback to the patient. The power and control system 400 interfaces with the drive mechanism 100 through one or more interconnects to relay status indication, such as activation, drug delivery, and end-of-dose, to the patient. Such status indication may be presented to

the patient via auditory tones, such as through the audible alarms, and/or via visual indicators, such as through the LEDs. In a preferred embodiment, the control interfaces between the power and control system and the other components of the drug delivery device 10 are not engaged or connected until activation by the patient. This is a desirable safety feature that prevents accidental operation of the drug delivery device 10 and may additionally maintain the energy contained in the power source during storage, transportation, and the like.

[00396] The power and control system 400 may be configured to provide a number of different status indicators to the patient. For example, the power and control system 400 may be configured such that after the on-body sensor and/or trigger mechanism have been pressed, the power and control system 400 provides a ready-to-start status signal via the status indicator 16 if device start-up checks provide no errors. After providing the ready-to-start status signal and, in an embodiment with the optional on-body sensor, if the on-body sensor remains in contact with the body of the patient, the power and control system 400 will power the drive mechanism 100 to begin delivery of the drug treatment through the fluid pathway connector 300 and sterile fluid conduit 30 to the needle or cannula of the insertion mechanism 200. In a preferred embodiment of the present disclosure, the insertion mechanism 200 and the fluid pathway connector 300 may be caused to activate directly by patient operation of the activation mechanism 14. During the drug delivery process, the power and control system 400 is configured to provide a dispensing status signal via the status indicator 16. After the drug has been administered into the body of the patient and after the end of any additional dwell time, to ensure that substantially the entire dose has been delivered to the patient, the power and control system 400 may provide an okay-to-remove status signal via the status indicator 16. This may be independently verified by the patient by viewing the drive mechanism 100 and drug dose delivery through the window 18 of the housing 12. Additionally, the power and control system 400 may be configured to provide one or more alert signals via the status indicator 16, such as for example alerts indicative of fault or operation failure situations.

[00397] Additionally, the power and control system 400 may be configured to identify removal of the drug delivery device from its packaging. The power and control system 400 may be mechanically, electronically, or electro-mechanically connected to the packaging such that removal of the drug delivery device from the packaging may activate or power-on the power and control system for use, or simply enable the power and control system to be powered-on by the patient. In such an embodiment, without removal of the drug delivery device from the packaging the drug delivery device cannot be activated. This provides an additional safety mechanism of the drug

delivery device 10 and for the patient. In at least one embodiment, the drug delivery device 10 or the power and control system may be electronically or electro-mechanically connected to the packaging, for example, such as by one or more interacting sensors from a range of: Hall effect sensors; giant magneto resistance (GMR) or magnetic field sensors; optical sensors; capacitive or capacitance change sensors; ultrasonic sensors; and linear travel, LVDT, linear resistive, or radiometric linear resistive sensors; and combinations thereof, which are capable of coordinating to transmit a signal between components to identify the location there-between. Additionally or alternatively, the drug delivery device or the power and control system may be mechanically connected to the packaging, such as by a pin and slot relationship which activates the system when the pin is removed (i.e., once the drug delivery device is removed from the packaging).

[00398] In a preferred embodiment of the present disclosure, once the power and control system 400 has been activated, a multi-function drive mechanism (e.g., drive mechanism 100) is initiated to actuate the insertion mechanism 200 and the fluid pathway connector 300, while also permitting the drug fluid to be forced from the drug container 50. During the drug delivery process, the power and control system 400 is configured to provide a dispensing status signal via a status indicator (e.g., status indicator 16). After the drug has been administered into the body of the patient and after the end of any additional dwell time, to ensure that substantially the entire dose has been delivered to the patient, the power and control system 400 may provide an okay-to-remove status signal via the status indicator. This may be independently verified by the patient by viewing the drive mechanism and drug dose delivery through the window 18 formed in the housing 12. Additionally, the power and control system 400 may be configured to provide one or more alert signals via the status indicator, such as for example alerts indicative of fault or operation failure situations.

[00399] The power and control system 400 may additionally be configured to accept various inputs from the patient to dynamically control the drive mechanisms 100 to meet a desired drug delivery rate or profile. For example, the power and control system 400 may receive inputs, such as from partial or full activation, depression, and/or release of the activation mechanism, to set, initiate, stop, or otherwise adjust the control of the drive mechanism 100 via the power and control system 400 to meet the desired drug delivery rate or profile. Similarly, the power and control system 400 may be configured to receive such inputs to adjust the drug dose volume; to prime the drive mechanism, fluid pathway connector, and fluid conduit; and/or to start, stop, or pause operation of the drive mechanism 100. Such inputs may be received by the patient directly acting on the drug delivery device 10, such as by use of the activation mechanism 14 or a different control

interface, or the power and control system 400 may be configured to receive such inputs from a remote control device. Additionally or alternatively, such inputs may be pre-programmed.

[00400] Other power and control system configurations may be utilized with the drug delivery device of the present disclosure. For example, certain activation delays may be utilized during drug delivery. As mentioned above, one such delay optionally included within the system configuration is a dwell time which ensures that substantially the entire drug dose has been delivered before signaling completion to the patient. Similarly, activation of the drug delivery device 10 may require a delayed depression (i.e., pushing) of the activation mechanism 14 of the drug delivery device 10. Additionally, the system may include a feature which permits the patient to respond to the end-of-dose signals and to deactivate or power-down the drug delivery device 10. Such a feature may similarly require a delayed depression of the activation mechanism, to prevent accidental deactivation of the device. Such features provide desirable safety integration and ease-of-use parameters to the drug delivery device 10. An additional safety feature may be integrated into the activation mechanism to prevent partial depression and, therefore, partial activation of the drug delivery device. For example, the activation mechanism and/or power and control system may be configured such that the device is either completely off or completely on, to prevent partial activation. Such features are described in further detail hereinafter with regard to other aspects of the drug delivery device 10.

[00401] The foregoing description of the power and control system 400 applies to the power and control system 6400 of the drug delivery device 6010, where appropriate.

[00402] III. Fluid Pathway Connector

[00403] At least some of the drug delivery devices described in this application, including at least those described in connection with Figs. 1A-2B, may be configured to incorporate the embodiments of the fluid pathway connector described below in connection with Figs. 3A-32B. The embodiments of the fluid pathway connector described below in connection with Figs. 3A-32B may be used to replace, in its entirety or partially, the above-described fluid pathway connector 300 or 6300, or any other fluid pathway connector described herein, where appropriate.

[00404] The present disclosure provides container connections which maintain the sterility and/or aseptic condition of the fluid pathway, and drug delivery pumps which incorporate such sterile fluid pathway connector assemblies to drug containers. Such devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The fluid pathway

connector may be initiated directly by the user, or may be activated by another mechanism of the device (as described herein) after some initial user step. The devices described herein incorporate features which make activation, operation, and lock-out of the device simple for even untrained users. The novel devices of the present disclosure provide these desirable features without problems associated with known prior art devices. Certain non-limiting embodiments of the novel drug delivery pumps, fluid pathway connector assemblies, and their respective components are described further herein with reference to the accompanying figures.

[00405] Conventional drug delivery devices often require filling at time-of-use because the terminal sterilization of the device cannot be completed with the pharmaceutical drug within the drug container. Various pharmaceutical drugs cannot withstand the temperatures, pressures, and other conditions necessary for sterilization of the device after assembly. In other words, because existing manufacturing processes require sterilization of the entire device, the drug cannot be "pre-filled" into the device prior to sterilization. This adds a complex step after final assembly of the device, which often requires costly additional equipment, handling of separate drug containers, and/or training of the patient to perform the filling step themselves prior to injection. Instead, the embodiments of the present disclosure enable the manufacture, assembly, and use of pre-filled drug delivery devices which maintain the sterility and/or aseptic condition of the fluid pathway assembly through the various manufacturing steps.

[00406] Additionally, because the drug delivery devices according to the present disclosure do not need to be terminally sterilized, the components of the devices may be constructed of other, often less expensive, materials which would not normally withstand the sterilization environment. For example, less expensive plastics may be utilized for certain device components because they do not need to be sterilized after assembly. Furthermore, the embodiments of the present disclosure permit device architecture and/or component integration in ways which are not suitable for devices that require terminal sterilization. For example, when sterilization of the entire device is necessary, the device architecture often requires adequate spacing of components to permit the sterilization gas or material to effectively reach the target surfaces. Removing the need for terminal sterilization permits reduction or elimination of those spaces and allows for device architectures that offer smaller overall dimensions, human factors benefits, and/or industrial design options that are not available for devices that require terminal sterilization.

[00407] In other words, the embodiments of the present disclosure may allow the manufacturer to sterilize only the components which will be in contact with the drug fluid and/or which are necessary to maintain sterile and/or aseptic fluid pathways. These embodiments may also allow the pharmaceutical filler to maintain the sterility and/or aseptic condition of these components during the filling and finishing steps associated with the assembly of the drug delivery devices. Similarly, drug delivery devices which incorporate the fluid pathway connector assemblies of the present disclosure may have smaller or more efficient geometries as the device does not have to be configured for sterilization after assembly.

[00408] Additionally, the embodiments of the present disclosure allow for the utilization of standard fill-finish processes to fill the drug container. This greatly simplifies the manufacturing processes used to build drug delivery devices. Standard fill-finish processes utilize trays which hold multiple drug containers, such as syringes. The embodiments of the present disclosure enable a drug delivery device manufacturer, pharmaceutical company, or contract drug filler to fill the drug containers for infusion or injection pumps using the same standard fill-finish processes. These drug containers can be filled aseptically, as is common industry practice, in a cost-efficient manner. After mounting of the fluid pathway connector assembly the combined assembly can then be mated into a drug delivery device without requiring the remainder of the device components to be sterilized. Accordingly, embodiments of the present disclosure may provide novel components which enable the fluid pathway assemblies to be sterilized, assembled, filled, and incorporated into drug delivery devices in a cost-efficient and streamlined process.

[00409] In the processes of filling drug containers and other drug delivery devices, it is sometimes necessary to connect two or more sterile components or subassemblies. For example, wearable injectors or drug delivery devices may include a drug container which may be filled with a fluid drug using standard pharmaceutical fill-finish processes. After filling of the drug container, it may be necessary to connect the drug container to one or more additional components or subassemblies such that a fluid communication may be established between the drug container and these components. Maintaining the fluid path in an aseptic condition is critical, preventing the introduction of harmful microbes or particulates to the drug and/or fluid pathway. The connection of two or more aseptic components or subassemblies is typically performed in an aseptic environment, such as a clean room, thereby ensuring that no harmful microbes or particulates are introduced to the assembly. This, however, may lead to increased cost to manufacture the drug delivery devices.

[00410] The present disclosure provides fluid pathway connector assemblies with integrated safety features and drug delivery pumps which incorporate such fluid pathway connector assemblies. Such devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The devices described herein incorporate features which make activation, operation, and lock-out of the device simple for even untrained users. The novel devices of the present disclosure provide these desirable features without any of the problems associated with known prior art devices. Certain non-limiting embodiments of the novel drug delivery device, fluid pathway connector assemblies, and their respective components are described further herein with reference to the accompanying figures. The devices described herein may be configured for delivery of controlled substances and may further include features that prevent so-called "run-away" delivery of medicament. When delivering controlled substances, this may be an important safety feature to protect the patient. For example, some medicaments can be dangerous, and potentially even deadly, when administered in too large a quantity and/or at too rapid of a rate. By providing such automatic safety stop mechanisms, the safety of the patient may be ensured.

[00411] The present disclosure provides devices and methods for establishing aseptic connections between two or more components or subassemblies. The devices may be used in medical devices such as drug delivery pumps. In some embodiments, a connection is made between a drug container and a fluid pathway connector assembly. The fluid pathway connector assembly may include a connection hub, a piercing member, and a piercing member retainer. The mechanism may further include a first film or seal covering an aperture, thereby maintaining the aseptic condition of a cavity adjacent the aperture. The drug container may hold a fluid drug and include a pierceable seal. A second film may cover an aperture of one or more components of the drug container and the seal, and thereby maintain the aseptic condition of the pierceable seal. The piercing member may be caused to pierce the first and second film and the pierceable seal to open a fluid pathway for delivery of the fluid drug to a patient.

[00412] In a first embodiment, the present disclosure provides a fluid pathway connector. The fluid pathway connector assembly includes: a connection hub, a piercing member, a piercing member retainer, and a drug container having a cap, a pierceable seal, and a barrel, wherein the piercing member is at least partially disposed in a sterile cavity defined by the connection hub. The drug container may contain a drug fluid for delivery through the fluid pathway connector assembly to the target. The pierceable seal includes a seal barrier that may be penetrated by the piercing member. The fluid pathway connector assembly may further include a first film which is fixedly

attached over an aperture over an aperture of the connection hub and prevents foreign substances such as microbes from entering the sterile cavity formed by the connection hub. The drug container may further include a second film fixedly connected over a cavity formed by the pierceable seal and the second film to prevent foreign substances such as microbes from entering the cavity. The first and second films may be pierced by the piercing member. The fluid pathway connector may be initiated directly by the user, or may be activated by another mechanism of the device (as described herein) after some initial user step.

[00413] In another embodiment, the present disclosure provides a drug delivery pump with integrated sterility maintenance features having a housing and an assembly platform, upon which an activation mechanism, a fluid pathway connector assembly, a power and control system, and a drive mechanism having a drug container may be mounted, said fluid pathway connector assembly including a connection hub, a piercing member, a piercing member retainer, and a drug container having a cap, a pierceable seal, and a barrel, wherein the piercing member is at least partially disposed in a sterile cavity defined by the connection hub. The drug container may contain a drug fluid for delivery through the fluid pathway connector assembly to the target. The pierceable seal includes a seal barrier that may be penetrated by the piercing member. The fluid pathway connector assembly may further include a first film which is fixedly attached over an aperture over an aperture of the connection hub and prevents foreign substances such as microbes from entering the sterile cavity formed by the connection hub. The fluid pathway connector assembly may further include a second film fixedly connected over a cavity formed by the pierceable seal and prevents foreign substances such as microbes from entering the cavity. The first and second films may be pierced by the piercing member.

[00414] The devices described herein may further include features which prevent the delivery of an excess volume of medicament or delivery at too rapid of a rate, e.g., to prevent a run-away condition of uncontrolled or undesired delivery of the medicament. By providing such automatic safety mechanisms, the safety of the patient may be ensured. Some medicaments, such as insulin or other treatments for diabetes, can be dangerous, and potentially even deadly, if they are not delivered according to prescribed parameters. The safety features described below may ensure that delivery of the medicament is terminated if delivery deviates from the specified parameters.

[00415] In a further embodiment of the present disclosure, the fluid pathway connector assembly may include one or more biasing members. In one such embodiment, a biasing member may be

included to bias the fluid pathway connector assembly to connect, i.e., to open the fluid pathway between the drug container and the fluid conduit which enables drug flow to the needle insertion mechanism and into the target. In such a configuration, the fluid pathway connector assembly is biased to facilitate the connection upon, for example, movement of a pin or blocking aspect. In at least one embodiment, the biasing member(s) may be internal to the fluid pathway connector assembly and/or external to the fluid pathway connector assembly to facilitate the connection once triggered. Additionally or alternatively, one or more biasing members may be included to disconnect the fluid pathway connector assembly. This may provide a desirable safety feature, to disconnect the fluid pathway upon signaling of an error condition either automatically by the drug delivery pump or upon action by the user. Once the fluid pathway connector assembly is disconnected, flow of drug fluid is restricted or blocked between the drug container and the fluid conduit to limit or prevent fluid flow to the needle insertion mechanism and into the target.

[00416] According to an aspect of the disclosure, there is provided a fluid pathway connector assembly for use with a drug container in a drug delivery pump. The drug container includes a barrel, a cap and a pierceable seal. The fluid pathway connector assembly includes an unactuated configuration, an actuated configuration, and a delivery configuration. The fluid pathway connector assembly includes a connection hub including an aperture, a first film, an introducer member, a piercing member, and a piercing member retainer. The first film is sealed along the aperture. The connection hub includes a sterile cavity sealed by the first film. The introducer member is at least partially disposed within the sterile cavity in the unactuated configuration. The piercing member is configured to telescope from the introducer member. The piercing member includes a piercing tip at least partially disposed within the introducer member in the unactuated configuration. The piercing member retainer is connected to the piercing member. The introducer member is configured to move relative to the connection hub from the unactuated configuration to the actuated configuration in which the introducer member pierces the first film. The piercing member is configured to telescope from the introducer member to move from the unactuated configuration to the delivery configuration in which the piercing tip is not disposed within the introducer member. The piercing member is adapted to pierce the pierceable seal in the delivery configuration, the piercing member providing a fluid pathway through the piercing member connection hub in the delivery configuration. In at least one embodiment, there is provided a combination of the fluid pathway connector assembly and the drug container. In at least one embodiment, there is provided

a drug delivery pump including a housing, an activation mechanism, the fluid pathway connector assembly, and a drug container.

[00417] In at least one embodiment, the fluid pathway connector assembly is configured to move the piercing member from the delivery configuration to a retracted configuration wherein the piercing member is disengaged from the pierceable seal in response to a termination mechanism.

[00418] Described below are embodiments of fluid pathway connector assemblies to allow connections to be made between two or more components or subassemblies of the drug delivery devices disclosed herein in a septic environment while maintaining the aspect condition of the fluid flow path. As will be seen, the fluid pathway connector assemblies may be arranged in any orientation. For example, as illustrated in FIGS. 3A-11, the piercing member may be axially aligned with the drug container. In other embodiments, as shown in FIGS. 23-30, the fluid pathway connector assembly may be arranged such that the piercing member of the fluid pathway connector assembly is oriented at an angle with respect to the drug container. In an alternative embodiment, the piercing member may be arranged in an arcuate manner. An exemplary embodiment of such an arrangement is shown in FIGS. 12A-22. The orientation of the fluid pathway connector assembly may be chosen based on the desired overall size and shape of drug delivery device 10 and the available space within the drug delivery device 10.

[00419] FIGS. 3A-11 show one embodiment of such a fluid pathway connector. As seen in FIGS. 3A-3B, the fluid pathway connector 300 may be connected to the drug container 50. FIG. 3A shows these components prior to connection and FIG. 3B shows the components after connection. As will be described herein, fluid pathway connector 300 may be mounted to drug container 50 without compromising the aseptic condition of the fluid flow path. Fluid pathway connector 300 includes introducer member 320, piercing member 316, introducer member retainer 330, piercing member retainer 314, connection hub 312, plate 334, biasing member 336, sterile boot 340, and first film 318. FIGS. 4A-4B show exploded views of the fluid pathway connector 300. As used herein, "piercing member" may refer to any container access needle having at least one pointed end and a hollow interior configured to establish fluid communication with the drug container 50.

[00420] According to one aspect of the disclosure (see FIGS. 5A and 5B), the connection hub 312 includes a cavity 312A. Sterile boot 340 may further define the cavity 312A as aseptic. In one embodiment, sterile boot 340 is fixedly connected at a first end to connection hub 312 and at a second end to introducer member retainer 330. Sterile boot 340 may be constructed from a flexible

material, such as an elastomer, thereby allowing the sterile boot to deform to maintain engagement with both connection hub 312 and introducer member retainer 330 during operation. A first film 318 is disposed covering an aperture 312B of connection hub 312 to prevent microbes and other contaminants from entering cavity 312A through aperture 312B. In this way, the area contained or bounded by the sterile boot 340, the connection hub 312, and the first film 318 defines cavity 312A and maintains the aseptic condition of the cavity 312A.

[00421] In an unmounted configuration, such as illustrated in FIG. 3B, and in an initial, unactuated configuration, as shown in FIGS. 5A-5B, at least a portion of introducer member 320 is disposed within aseptic cavity 312A. At least a piercing tip of the piercing member 316 is partially retained within lumen 320A of introducer member 320, the piercing member 316 being disposed to telescope within the introducer member 320. The piercing member 316 is also at least partially disposed in piercing member retainer 314. In this way, introducer member 320 and piercing member 316 are likewise maintained in an aseptic condition within cavity 312A.

[00422] Piercing member 316 is engaged with piercing member retainer 314 such that translation of piercing member retainer 314 is transferred to piercing member 316 such that they maintain a substantially fixed spatial relationship throughout operation. Piercing member 316 may be engaged with piercing member retainer 314 using any method known to one skilled in the art, such as bonding, press-fit, staking, etc. The piercing member 316 may be, for example, a hollow needle.

[00423] Introducer member 320 is at least partially retained by introducer member retainer 330 and is engaged with the introducer member retainer 330 such that translation of introducer member retainer 330 is transferred to introducer member 320 such that they maintain a substantially fixed spatial relationship throughout operation. Introducer member 320 may be engaged with introducer member retainer 330 using any method known to one skilled in the art, such as bonding, press-fit, staking, or any other appropriate method.

[00424] Piercing member retainer 314 and introducer member retainer 330 are engaged with connection hub 312 and may be configured for translation with respect to the connection hub in a direction parallel to the long axis of piercing member 316 (axis "A" shown in FIG. 5B). Connection hub 312, piercing member retainer 314, and introducer member retainer 330 may include one or more features to maintain orientation and position with respect to one another as will be described in more detail below.

[00425] The fluid pathway connector 300 may further be provided with an insertion driver disposed to advance one or both of the piercing member 316 and the introducer member 320 toward the drug container 50. In this embodiment, at least one biasing member 336 is provided to advance one or both of the piercing member 316 and the introducer member 320 toward the drug container 50. Biasing member 336 is initially in a compressed or energized condition and is restrained from decompressing or de-energizing. A first end of biasing member 336 is in contact with plate 334, which is axially stationary, and a second end of biasing member 336 is in contact with piercing member retainer 314. In one embodiment, biasing member 336 is in contact with shoulder 314D of piercing member retainer 314. Motion of plate 334 is restrained by engagement with snaps 312C of connection hub 312 (see FIG. 9) which are inserted through passages 334A of plate 334 (see FIG. 9) during assembly. In an initial configuration, shaft 314A of piercing member retainer 314 (see FIG. 10) passes through central bore 334B of plate 334 and is engaged by interlock 338 (see FIGS. 3A, 3B, 5A, 5B). Interlock 338 is located on the distal side of plate 334 and engages one or more lobes 314B on shaft 314A to prevent translation of piercing member retainer 314 with respect to plate 334. In this way, decompression or de-energizing of biasing member 336 is restrained. As will be described further herein, transformation of interlock 338, to a configuration in which it does not restrain translation of piercing member retainer 314, allows decompression of biasing member 336 and connection of the fluid pathway to drug container 50.

[00426] The drug container 50 may include a crimp cap 324 that maintains a connection between a pierceable seal 326 and a barrel 58. The pierceable seal maintains the fluid drug within the barrel and prevents microbes and other substances from entering the drug chamber. A recess 328 (best seen in FIG. 5B) is formed by the geometry of the pierceable seal 326. A second film 322 is affixed to the drug container such that it encloses recess 328, thereby maintaining recess 328 in an aseptic condition.

[00427] The first and second films may be constructed of any material capable of providing the barrier properties required to maintain the aseptic condition of the associated surfaces. In a preferred embodiment, the films are constructed from a foil material. Alternatively, the films may be any type of sterilizable membrane, film, or foil. Additionally, the film may be removable and/or pierceable as well as breathable and/or permeable.

[00428] A surface treatment may be applied to the exterior surfaces of both first film 318 and second film 322 prior to joining the fluid pathway connector and the drug container. The surface

treatment may contain antimicrobial, antibacterial, or antiviral compounds to limit or reduce the number of such substances on the surface of the seals.

[00429] Connection hub 312 may include a barrel-engaging aspect 312D. Barrel-engaging aspect 312D may include one or more flex arms 312E configured to engage crimp cap 324 and/or neck 58A of barrel 58. During connection, flex arms 312E may engage crimp cap 324 or another portion of the drug container, thereby limiting axial translation of the fluid pathway connector with respect to the drug container. In this position, first film 318 and second film 322 are in contact with, or in close proximity to, one another. In one embodiment, first film 318 and second film 322 include an adhesive such that the films are bonded to one another during assembly.

[00430] FIGS. 5A-5B show a cross-sectional side view of the connection hub 312 and drug container 50 in a mounted, unactuated configuration, that is, after they have been joined. In this configuration, introducer member 320 is at least partially disposed within cavity 312A and engagement of interlock 338 with piercing member retainer 314 retains biasing member 336 in a compressed or energized state. First film 318 and second film 322 are intact, thereby maintaining the aseptic condition of cavity 312A and pierceable seal 326, respectively.

[00431] An actuated configuration is illustrated in FIGS. 6A-6B. In one embodiment, activation may displace or transform interlock 338 such that it no longer restricts translation of piercing member retainer 314. Upon activation, the piercing member retainer 314 and introducer member retainer 330 may be translated axially with respect to the connection hub and drug container 50. The translation may be caused by decompression or de-energizing of biasing member 336. In one embodiment, biasing member 336 is a compression spring. Because piercing member retainer 314 is in contact with introducer member retainer 330, as piercing member retainer 314 translates, introducer member retainer 330 translates together with piercing member retainer 314. For example, proximal face 314C of piercing member retainer 314 (see FIG. 10) may contact projections 330A of introducer member retainer 330 (see FIG. 11). Proximal face 314C may include a chamfered or radiused portion which contacts projections 330A. The contacting faces of piercing member retainer 314 and introducer member retainer 330 may be configured such that piercing member retainer 314 applies a radially inwardly directed force to projections 330A and, thereby, extensions 330D, in addition to an axial force. However, initially, fingers 330C of extensions 330D are prevented from inward displacement by contact with ribs 312G of connection hub 312 (see FIGS. 4A, 4B, 6B). Hence, introducer member retainer 330 translates along with piercing member retainer 314.

Translation of the piercing member retainer 314 causes piercing member 316 to translate and translation of the introducer member retainer 330 causes translation of the introducer member 320. This translation causes the introducer member 320 to pierce first film 318 and second film 322, as shown in FIGS. 6A-6B. It will be appreciated that, because the piercing member 316 is disposed within introducer member 320, it does not contact the first 318 and second 322 films; hence, any contaminants present on the surface of the films do not come in contact with the piercing member 316.

[00432] After the introducer member 320 pierces first film 318 and second film 322, translation of introducer member retainer 330 is restricted such that its translation is terminated with the tip of the introducer member disposed in recess 328 (i.e., the introducer member does not pass through pierceable seal 326). Translation of introducer member retainer 330 may, for example, be restricted by contact of a portion of the proximal face 330B with flange 312F of connection hub 312. It is not necessary that the entire proximal face 330B of introducer member retainer 330 contact flange 312F. For example, fingers 330C may contact flange 312F. In this position, fingers 330C are no longer in contact with ribs 312G of connection hub 312. Because of this, extensions 330D are able to flex radially inward. As a result, continued decompression of biasing member 336 and translation of piercing member retainer 314 causes the extensions 330D to move inward and piercing member retainer 314 is able to pass over introducer member retainer 330.

[00433] Turning now to FIGS. 7A-7B, there is illustrated a delivery configuration of the fluid pathway connector 300. Continued decompression of biasing member 336 may cause the piercing member retainer 314 to be further displaced, leading to the piercing of pierceable seal 326 by piercing member 316. Hence, with further translation of introducer member retainer 330 prevented by contact with connection hub 312, continued decompression of biasing member 336 causes piercing member retainer 314 to translate in a proximal direction relative to introducer member retainer 330. After piercing of the pierceable seal, a fluid path is established from the drug container and through the piercing member 316. Those of skill in the art will appreciate that the piercing member 316 may also be in fluid communication with a conduit 30 (as in FIG. 31), the conduit being configured to carry the fluid contents to a delivery mechanism, such as an insertion mechanism, for delivery to a patient.

[00434] In an alternative embodiment, piercing of the first and second films occurs at the time of assembly. In such an embodiment, piercing of the pierceable seal at or near the time-of-use may be initiated by interaction with an activation mechanism.

[00435] In at least one embodiment, the first and second films are pierced by the introducer member at a first time, for example time of assembly, and the piercing member pierces the pierceable seal at a later time, for example upon activation. In such an embodiment, the end of the piercing member may remain disposed within recess 328 until time-of-use. The pierceable seal may be configured such that, in response to hydraulic and/or pneumatic pressure within the drug chamber, pierceable seal 326 deforms or is displaced and is caused to come into contact with the piercing member. This deformation of the pierceable seal 326 leads to the piercing of the seal by the piercing member 316. In such an embodiment, introducer member 320 may be retracted after piercing the first and second films.

[00436] Although the embodiment shown in FIGS. 3A-11 is configured such that piercing member 316 is substantially axially aligned with drug container 50, one skilled in the art would recognize that this orientation can be configured in any orientation. For example, the axis of piercing member 316 may be oriented orthogonal to the central axis of the drug container 50. Alternatively, the axes may be oriented at any angle between parallel and orthogonal. Selection of this angle or orientation may be chosen based on the space requirements of drug delivery device 10.

[00437] In another embodiment, shown in FIGS. 12A-22, the introducer member and piercing member are arranged in an arcuate manner. The arcuate configuration of the fluid pathway connector may allow the footprint of the fluid pathway connector to be reduced, allowing for a smaller overall size of drug delivery device 10. Fluid pathway connector 1300 includes introducer member 1320, piercing member 1316, introducer member retainer 1330, piercing member retainer 1314, connection hub 1312, shaft 1342, and first film 1318. As described above, connection hub 1312 may be configured to engage drug container 1050, for example, by engaging crimp cap 1324 and/or neck 1058A of drug container 1050.

[00438] Introducer member 1320 may be either directly or indirectly coupled to introducer member retainer 1330. For example, in the embodiment shown, introducer member 1320 is fixedly connected to first sleeve 1344. In turn, first sleeve 1344 is engaged with second sleeve 1346. Finally, second sleeve 1346 is engaged with introducer member retainer 1330, for example by the

keyed engagement shown. First sleeve 1344 and second sleeve 1346 may further retain septum 1348, through which piercing member 1316 may pass.

[00439] Similarly, piercing member 1316 may be directly or indirectly coupled to piercing member retainer 1314. In the embodiment shown, piercing member 1316 is engaged with keeper 1350. Keeper 1350 is engaged with piercing member retainer 1314 by, for example, the keyed arrangement shown.

[00440] In an initial, unactuated configuration, shown in FIGS. 13A-13B, introducer member 1320 is initially at least partially disposed in cavity 1312A. Piercing member 1316 is at least partially disposed within the lumen 1320A of introducer member 1320. Cavity 1312A is maintained in an aseptic condition by first film 1318. The aseptic condition of cavity 1312A may be further maintained by cap 1354 and ring seal 1352. Ring seal 1352 is held in sealing engagement with connection hub 1312 and/or introducer member 1320 by cap 1354. Although ring seal 1352 is shown here with a circular cross-section, the ring seal may take on any shape known to one skilled in the art. Alternatively, for example, the aseptic condition may be maintained by a septum.

[00441] Upon activation, introducer member retainer 1330 and piercing member retainer 1314 are caused to rotate about shaft 1342. It will be appreciated that shaft 1342 may be integrally formed with connection hub 1312, as shown in FIG. 20, may be a feature of housing 12, or may be a pin or other component engaged with connection hub 1312 or housing 12. While the latter two of these embodiments are not specifically illustrated, they will be readily understood by those of skill in the art. An insertion driver may be provided to advance one or both of the piercing member 1316 and the introducer member 1320 toward the drug container 1050. For example, the rotation about the axis of the shaft may be caused by de-energizing of a biasing member, such as a torsion spring. Alternatively, the rotation may be caused by a driving member of drug delivery device 10. For example, needle insertion mechanism 200 may include a driving member that, upon activation, contacts an aspect of piercing member retainer 1314 and causes rotation of piercing member retainer 1314 and introducer member retainer 1330. In another embodiment, the biasing member of the needle insertion mechanism bears against the piercing member retainer 1314 and causes rotation thereof.

[00442] Piercing member retainer 1314 and introducer member retainer 1330 may initially rotate as a unit. Referring to FIGS. 16B and 22, introducer member retainer 1330 may initially be disposed between projection 1314E and tooth 1314F, both features of piercing member retainer 1314. The

retainers move in conjunction to the actuated configuration shown in FIGS. 14A-14B. In this position, the introducer member 1320 has pierced the first film 1318 and second film 1322, but has not pierced pierceable seal 1326. At or near to this position, flex arm 1314G of piercing member retainer 1314 contacts connection hub 1312 and/or cap 1354. Hence, continued rotation of piercing member retainer 1314 causes flex arm 1314G to be displaced downward. As a result, contact of projection 1314E with introducer member retainer 1330 no longer causes rotation of introducer member retainer 1330. Thus, further rotation of piercing member retainer 1314 does not cause additional rotation of introducer member retainer 1330.

[00443] As shown in the delivery configuration illustrated in FIGS. 15A-15B, continued rotation of piercing member retainer 1314 causes piercing member 1316 to pierce pierceable seal 1326, thus opening a flow path from the drug container 1050, through piercing member 1316. Piercing member 1316 may be in fluid communication with insertion mechanism 200, for example by a fluid conduit, to allow for delivery of the fluid drug to the patient. As shown in FIGS. 19A-19B, in this configuration, tooth 1314F may engage cap 1354 and/or connection hub 1312 to prevent retraction of piercing member 1316.

[00444] FIG. 23 shows an exploded view of another embodiment of a fluid pathway connector 2300. The fluid pathway connector 2300 includes connection hub 2312, introducer member 2320, introducer member retainer 2330, piercing member 2316, piercing member retainer 2314, and, optionally, blocking aspect 2356. Additionally, first film 2318 may be provided such that it maintains the aseptic condition of at least a portion of the fluid pathway connector. The fluid pathway connector may also include ring seal 2352 and septum 2348 configured to maintain the aseptic condition of at least a portion of the fluid pathway connector as described above. Blocking aspect 2356 may be configured with an interlock 2338 engaging connection hub 2312 at coupling aspect 2312H. Additionally, or alternatively, blocking aspect 2356 may be configured to engage an aspect of housing 12. Blocking aspect 2356 may be configured for rotation about these engagement points.

[00445] FIG. 24A shows the drug container 50 and fluid pathway connector 2300 in an unactuated configuration, prior to assembly. As will be understood from the above discussion, this assembly step may take place in an uncontrolled or less controlled environment than that required for prior art designs. In order to mount the fluid pathway connector 2300 to the crimp cap 2324 coupling the pierceable seal 2326 to the barrel 2058, a barrel-engaging aspect may include one or

more flex arms 2312E of the connection hub 2312, which engage the pierceable seal 2326 or crimp cap 2324. FIG. 23B-23D show isometric views of the stages of operation of the fluid pathway connector 2300 once mounted to the drug container 2050.

[00446] Initially, in the unactuated configuration illustrated in FIG. 24B, blocking aspect 2356 is initially engaged with piercing member retainer 2314 such that blocking aspect 2356 prevents translation of piercing member retainer 2314 toward drug container 2050. Additionally, or alternatively, one or more arms 2330E of introducer member retainer 2330 (see FIG. 29) are initially disposed in one or more primary windows 2312J of connection hub 2312 (see FIG. 28). This engagement may further prevent inadvertent activation of the fluid pathway connector. For example, in at least one embodiment, arms 2330E are configured to provide sufficient flexural stiffness to resist disengagement from primary windows 2312J and prevent inadvertent activation. Application of sufficient force for activation will cause arms 2330E to disengage from primary windows 2312J, allowing translation of introducer member retainer 2330.

[00447] Upon activation, blocking aspect 2356 is displaced, for example by rotating about axis C. After displacement of blocking aspect 2356, piercing member retainer 2314 is able to translate toward drug container 2050 in response to application of a driving force from an insertion driver, such as the rotational biasing member 2210 shown in FIG. 31. FIG. 31 is a detail view showing one method of actuating the fluid pathway connector 2300. As shown, rotational biasing member 2210 is initially held in a compressed or energized state. A first end of rotational biasing member 2210 is engaged with an aspect of fluid pathway connector 2300, here piercing member retainer 2314. Further, a blocking aspect 2356, such as a rotatable latch, prevents de-energizing of rotational biasing member 2210 and, hence, activation of fluid pathway connector 2300. To activate the fluid pathway connector 2300, the blocking aspect 2356 may be displaced such that it no longer restricts de-energizing of rotational biasing member 2210. As such, upon displacement of the locking aspect 2356, rotational biasing member 2210 at least partially de-energizes and causes the fluid pathway connector 2300 to open a fluid path to the drug container 2050, fluidly coupling the drug container 2050 to the needle insertion mechanism 200 via the fluid pathway connector 2300 and a sterile fluid conduit 30 coupled to the piercing member 2316 and the needle insertion mechanism 200. Displacement of the blocking aspect 2356 may occur in response to depression, by the user, of activation mechanism 14 or, alternatively, may be controlled by interaction with a separate mechanism.

[00448] Returning now to FIGS. 24B-27B, initially, as is described further hereinafter, piercing member retainer 2314 and introducer member retainer 2330 move together toward drug container 2050. FIG. 24C shows the fluid pathway connector in the actuated configuration, that is, after introducer member 2320 pierces first film 2318 and second film 2322. After piercing of first film 2318 and second film 2322, introducer member 2320 is restricted from further movement. In one embodiment, arms 2330E of introducer member retainer 2330 are positioned within one or more secondary windows 2312K, in this configuration. This engagement may lock the introducer member retainer in place, preventing inadvertent translation toward or away from the drug container. Continued translation of piercing member retainer 2314 causes piercing member 2316 to pierce pierceable seal 2326 to open a fluid flow path from drug container 2050. This delivery configuration is shown in FIG. 24D.

[00449] FIGS. 25A and 25B show cross-sectional views of the fluid pathway connector in the initial, unactuated configuration. As can be seen in these figures, blocking aspect 2356 is engaged with piercing member retainer 2314 to prevent translation of piercing member retainer 2314 toward the drug container. Piercing member 2316 is disposed at least partially within introducer member 2320. As shown, in this or any embodiment, introducer member 2320 may be an integral portion of introducer member retainer 2330. Introducer member 2320 and piercing member 2316 are both at least partially disposed in sterile cavity 2312A, which is defined by connection hub 2312, first film 2318, ring seal 2352, and septum 2348. Shoulder 2314H of piercing member retainer 2314 is in contact with extensions 2330D of introducer member retainer 2330. Extensions 2330D are configured to be relatively flexible aspects of introducer member retainer 2330. However, in the initial configuration, extensions 2330D are prevented from flexing by contact with connection hub 2312. Hence, initially, translation of piercing member retainer 2314, toward drug container 2050, causes commensurate translation of piercing member retainer 2314.

[00450] FIGS. 26A-26B show the fluid pathway connector 2300 in an intermediate, actuated configuration. In this configuration, blocking aspect 2356 has been displaced such that it does not restrict translation of piercing member retainer 2314. Introducer member 2320 has pierced first film 2318 and second film 2322 and piercing member 2316 is positioned adjacent to pierceable seal 2326. Also, in this configuration, extensions 2330D are positioned adjacent to recesses 2312L of connection hub 2312. Hence, extensions 2330D are no longer restricted from flexing outward (i.e., in the direction of the hatched arrows in FIG. 26B). Because extensions 2330D are able to flex outward, into recesses 2312L, additional translation of piercing member retainer 2314 causes

shoulders 2314H to disengage from extensions 2330D. This allows piercing member retainer 2314 to translate toward drug container 2050 without causing translation of introducer member retainer 2330. As shown in the delivery configuration of FIGS. 27A-26B, this allows piercing member 2316 to pierce pierceable seal 2326 and open the fluid flow path from the drug container 2050.

[00451] In some embodiments, an additional film or seal may be present at the tip of introducer member 320, 1320, 2320 sealing the lumen of the introducer member and, thereby, further isolating the lumen of the introducer member and, hence, the piercing member in order to maintain the aseptic condition of the piercing member. This film may remain intact as the introducer member pierces first film 318, 1318, 2318 and second film 322, 1322, 2322. This may further prevent any microbes or other contaminants that are present on the surfaces of the seals from coming in contact with the piercing member.

[00452] In at least one other embodiment, the first and second films are removed from the fluid pathway connector and drug container just prior to mounting of the fluid pathway connector 300 to the drug container 50. Prior to removal of the films, their placement maintains the sterility of the pierceable seal of the drug container and cavity 312A. Connection hub 312 and drug container 50 may be configured such that connection of the connection hub to the barrel provides a sealing engagement to maintain the aseptic condition of the pierceable seal and piercing member. In such an embodiment, connection hub 312 and/or drug container 50 may include an elastomeric aspect which is configured to provide sealing engagement.

[00453] In another embodiment, after mounting of connection hub 312 to drug container 50, the cavity 312A and pierceable seal 326 may be sterilized using UV sterilization. The connection hub 312 may be in sealing engagement with the drug container such that after sterilization microbes and other foreign elements are unable to contact the aseptic surfaces. In such embodiments, at least a portion of the connection hub may be constructed from a substantially translucent material, such as glass.

[00454] In each of the embodiments described herein, the connection hub, piercing member retainer, and/or the introducer member retainer may include one or more features to prevent the inadvertent activation of the fluid pathway connector during assembly, storage, transportation, and handling. These features may prevent activation unless a force above a threshold value is applied. These features may, for example, include flexible aspects or frangible aspects which are displaced or severed upon application of a force above the threshold.

[00455] In addition to the advantages described above, the insertion mechanisms described herein may also be capable of terminating flow of medicament to the target tissue by disconnecting the fluid path. This may be an important safety feature to protect the patient. For example, some medicaments, such as insulin, can be dangerous, and potentially even deadly, when administered in too large a quantity and/or at too rapid of a rate. By providing such automatic safety stop mechanisms, so-called "run-away" delivery of medicament may be prevented, thereby ensuring the safety of the patient. While the methods and associated structures for terminating flow may be discussed with regard to one or more specific insertion mechanisms disclosed herein, it will be appreciated that the method and associated structures may be utilized or adapted for any of the fluid pathway connector assemblies disclosed herein or within the spirit and scope of this disclosure.

[00456] An interruption in delivery of medicament through the fluid pathway connector may be triggered, for example, by an error in delivery of the medicament or by an input from the user. For example, the user may realize that they have already taken their drug dose and wish to pause or terminate drug delivery from the device. Upon such user input to the device, the delivery of the drug can be stopped and/or the fluid passageway through the piercing member may be terminated by retraction of the piercing member to a retracted position, as described below.

[00457] Additionally or alternatively, the device may pause or terminate drug delivery if it receives an error alert during operation. For example, if the drive mechanism is not functioning correctly, the fluid pathway connector may be triggered to retract the piercing member from the pierceable seal to terminate drug delivery through the fluid pathway connector to prevent over-delivery of a medication. This capability of the fluid pathway connector provides a valuable safety feature for drug delivery to a target.

[00458] In some embodiments, retraction is activated upon removal of the drug delivery device from the target tissue. In other embodiments, retraction is activated if it is determined that an error has occurred in the delivery of the substances to the target tissue. For example, an occlusion of the drug delivery pathway which prevents the flow of medicament may be detected by a sensing function of the drug delivery pump. Upon the sensing of the occlusion an electrical or mechanical input may be used to initiate retraction of the needle.

[00459] Additionally or alternatively, one or more biasing members may be included to disconnect the fluid pathway connector. This may provide a desirable safety feature, to disconnect the fluid pathway upon signaling of an error condition either automatically by the drug delivery

pump or upon action by the user. For example, a locking aspect may initially restrain a secondary biasing member from expanding from its original energized state. Upon activation of the locking aspect, the secondary biasing member is caused to de-energize from its original position and, thereby, act upon and axially translate the piercing member retainer to disconnect the piercing member from the pierceable seal. Once the fluid pathway connector is disconnected, flow of drug fluid is restricted or blocked between the drug container and the fluid conduit to limit or prevent fluid flow to the needle insertion mechanism and into the target. As described herein, the disconnection may be triggered by a number of operations, automatically by the system and/or upon direct or indirect user initiation, as an added safety precaution to prevent over-delivery of the drug fluid to the target.

[00460] One such embodiment is shown in FIGS. 32A and 32B. As shown in FIG. 32A, secondary biasing member 362 is initially restrained between connection hub 312 and one or more release arms 360A of locking aspect 360. Locking aspect 360 is disposed against the proximal face of connection hub 312 with one or more release arms extending in the distal direction. In the event of a fault in the operation of the drug delivery device, or upon activation by the user, locking aspect 360 is caused to rotate about axis A from the position shown in FIG. 32A to the position shown in FIG. 32B. The rotation may be caused by contact of a throw arm with activation arm 360B, for example. As locking aspect 360 is rotated, each of the one or more release arms 360A contact a ramped surface 312M of connection hub 312. The contact with ramped surface 312M causes displacement of the one or more release arms 360A in an outwardly radial direction or, alternatively, fracture of the one or more release arms 360A. As a result, secondary biasing member 362 is able to decompress or deenergize. Secondary biasing member 362 comes into contact with piercing member retainer 314 and causes piercing member retainer 314 to translate in the distal direction. This translation causes the piercing member to be withdrawn from the pierceable seal. Hence, no additional medicament will be delivered through the piercing member, thereby terminating delivery to the patient. As shown in FIG. 32B, after rotation, each of the one or more release arms 360A may flex radially outward to permit the secondary biasing member 362 to deenergize, and then return radially inward to be disposed in a notch 312N of the connection hub. Locking aspect 360 may thereby be prevented from any further rotation.

[00461] Any of the illustrated embodiments may be equipped with such a safety feature. Alternatively, a component of the drug delivery device may directly engage a portion of the fluid pathway connector to withdraw the piercing member from the pierceable seal. For example, a slide

or throw arm may contact piercing member retainer 2314, displacement of the slide or throw arm causing displacement of piercing member retainer 2314 to withdraw the piercing member from the pierceable seal.

[00462] Withdrawal of the piercing member from the pierceable seal may be activated in the event of, for example, failure or loss of tension in the tether, failure of the drive mechanism, removal of the drug delivery device from the target tissue, or activation by the user. The safety mechanism may be purely mechanical or, alternatively, may include the power and control system. For example, an electrical signal from the power and control system may initiate withdrawal of the piercing member from the pierceable seal.

[00463] It will be appreciated from the above description that the fluid pathway connector assemblies and drug delivery devices disclosed herein provide an efficient and easily-operated system for automated drug delivery from a drug container. The novel devices of the present disclosure provide container connections maintain the aseptic condition of the fluid pathway, and drug delivery pumps which incorporate such fluid pathway connector assemblies to drug containers. Such devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The devices described herein incorporate features which make activation, operation, and lock-out of the device simple for even untrained users. Because the fluid path is disconnected until drug delivery is desired by the user, the aseptic condition of the fluid pathway connector, the drug container, the drug fluid, and the device as a whole is maintained. These aspects provide highly desirable storage, transportation, and safety advantages to the user. Furthermore, the novel configurations of the fluid pathway connector assemblies and drug delivery devices of the present disclosure maintain the aseptic condition of the fluid path throughout operation of the device. Because the path that the drug fluid travels within the device is entirely maintained in an aseptic condition, only these components need be sterilized during the manufacturing process. Such components include the drug container of the drive mechanism, the fluid pathway connector, the sterile fluid conduit, and the insertion mechanism. In at least one embodiment, the power and control system, the assembly platform, the activation mechanism, the housing, and other components of the drug delivery device do not need to be sterilized. This greatly improves the manufacturability of the device and reduces associated assembly costs. Accordingly, the devices of the present disclosure do not require terminal sterilization upon completion of assembly. A further benefit is that the components described herein are designed to be modular such that, for example, housing and other components of the pump drug may readily be configured to accept and operate

connection hub 312, 1312, 2312, or a number of other variations of the components described herein.

[00464] Assembly and/or manufacturing of fluid pathway connector 300, 1300, 2300, drug delivery pump 10, or any of the individual components may utilize a number of known materials and methodologies in the art. For example, a number of known cleaning fluids such as isopropyl alcohol and hexane may be used to clean the components and/or the devices. A number of known adhesives or glues may similarly be employed in the manufacturing process. Additionally, known siliconization and/or lubrication fluids and processes may be employed during the manufacture of the novel components and devices. Furthermore, known sterilization processes may be employed at one or more of the manufacturing or assembly stages to ensure the sterility of the final product.

[00465] The fluid pathway connector and drug container may be assembled in a number of methodologies. In one method of assembly, the drug container 50 may be assembled and filled with a fluid for delivery to the target. The drug container 50 includes a cap 324, a pierceable seal 326, a barrel 58, and a plunger seal 60. The plunger seal 60 may be inserted into barrel 58. The barrel 58 may be filled with a drug fluid through the open distal end prior to insertion of the pierceable seal at the open distal end of the barrel 58. The pierceable seal 326 may then be fixedly engaged between the cap 324 and the barrel 58, at a distal end of the barrel 58. In this way, the drug container can be filled and sealed using standard fill-finish processes and equipment. For example, drug container 50 may be filled and sealed using processes and equipment commonly employed in the filling and sealing of standard vials. Additionally, cap 324 may be a crimp cap similar to those commonly used in such processes. Before or after applying cap 324, second seal or film 322 may be applied to the distal face of drug container 50.

[00466] Piercing member 316 may be fixedly engaged with piercing member retainer 314. Shaft 314A of piercing member retainer 314 may be inserted through central bore 334B of plate 334 and interlock 338 may engage piercing member retainer 314 such that biasing member 336 is prevented from decompressing. Introducer member 320 may be fixedly connected to introducer member retainer 330. Additionally, sterile boot 340 may be connected to introducer member retainer 330. Introducer member retainer 330 may be positioned within piercing member retainer 314 such that piercing member 316 is at least partially disposed within lumen 320A of introducer member 320. Connection hub 312 may then be connected to plate 334 by inserting snaps 312C through passages 334A. In this position, a portion of introducer member 320 is disposed within cavity 312A and

sterile boot 340 is engaged with connection hub 312. Second film 322 may be placed over aperture 312B of connection hub 312 to define cavity 312A. Additionally, during assembly, the fluid conduit may be fluidly connected to piercing member 316. The insertion mechanism 200 may be assembled and attached to the other end of the fluid conduit. The fluid pathway connector may then be assembled to drug container 50. The connection of the fluid pathway connector to the drug container may or may not occur in a clean room or sterile environment. Because first film 318 and second film 322 maintain the aseptic condition of pierceable seal 326 and cavity 312A, respectively, the flow path is not exposed to contaminants.

[00467] The steps of assembly may, optionally, also include the step of disposing a locking aspect against the proximal face of the connection hub. The steps of assembly may also include disposing a secondary biasing member concentrically around a portion of the connection hub such that the secondary biasing member is retained in a compressed or energized state by the locking aspect.

[00468] In the embodiment shown in FIGS. 12A-22, assembly may include the steps outlined above and may also include additional or different steps. The additional or different steps may include connection of cap 1354 to connection hub 1312 such that ring seal 1352 is positioned between connection hub 1312 and cap 1354. The additional or different steps may also include placing piercing member retainer 1314 and introducer member retainer 1330 on shaft 1342 such that they are able to rotate about shaft 1342. Additionally, the steps may include fixedly engaging introducer member 1320 to first sleeve 1344 and engaging first sleeve 1344 to second sleeve 1346 such that septum 1348 is positioned between the sleeves. The steps may also include fixedly engaging piercing member 1316 to keeper 1350.

[00469] The embodiment shown in FIGS. 23-30 may also be assembled using any of the steps outlined above and may also include additional or different steps. The additional or different steps may include, for example, coupling a blocking aspect with the connection hub at a coupling aspect of the connection hub.

[00470] The drive mechanism 100 may be attached to the proximal end of the drug container 50. Certain components of this sub-assembly may be mounted to the assembly platform 20 or directly to the interior of the housing 12, while other components are mounted to the guide 390 for activation by the user.

[00471] Manufacturing of a drug delivery device includes the step of attaching both the fluid pathway connector and drug container, either separately or as a combined component, to an assembly platform or housing of the drug delivery device. The method of manufacturing further includes attachment of the drive mechanism, drug container, and insertion mechanism to the assembly platform or housing. The additional components of the drug delivery device, as described above, including the power and control system, the activation mechanism, and the control arm may be attached, preformed, or pre-assembled to the assembly platform or housing. An adhesive patch and patch liner may be attached to the housing surface of the drug delivery device that contacts the target during operation of the device.

[00472] A method of operating the drug delivery device includes the steps of: activating, by a user, the activation mechanism; displacing a control arm to actuate an insertion mechanism; actuating a fluid pathway connector; and actuating a power and control system to activate a drive control mechanism to drive fluid drug flow through the drug delivery device, wherein actuating the fluid pathway connector causes a piercing member to penetrate a pierceable seal thereby opening a fluid path from a drug container to the fluid pathway connector. The method may further include the step of: engaging an optional on-body sensor prior to activating the activation mechanism. Furthermore, the method of operation may include translating a plunger seal within the drive control mechanism and drug container to force fluid drug flow through the drug container, the fluid pathway connector, a sterile fluid conduit, and the insertion mechanism for delivery of the fluid drug to the target.

[00473] IV. Additional Embodiments of Fluid Pathway Connector

[00474] At least some of the drug delivery devices described in this application, including at least those described in connection with Figs. 1A-2B, may be configured to incorporate the embodiments of the fluid pathway connector described below in connection with Figs. 33A-33C. The embodiments of the fluid pathway connector described below in connection with Figs. 33A-33C may be used to replace, in its entirety or partially, the above-described fluid pathway connector 300 or 6300, or any other fluid pathway connector described herein, where appropriate.

[00475] A number of fluid pathway connectors may be utilized within the embodiments of the present disclosure. Generally, a suitable fluid pathway connector includes a sterile fluid conduit, a piercing member, and a sterile sleeve attached to a drug container or a sliding pierceable seal integrated within a drug container. The fluid pathway connector may further include one or more

flow restrictors. Upon proper activation of the device 8000, the fluid pathway connector 8300 is enabled to connect the sterile fluid conduit 8030 to the drug container of the drive mechanism 8100. Such connection may be facilitated by a piercing member, such as a needle, penetrating a pierceable seal of the drug container of the drive mechanism 8100. The sterility of this connection may be maintained by performing the connection within a flexible sterile sleeve. Upon substantially simultaneous activation of the insertion mechanism, the fluid pathway between drug container and insertion mechanism is complete to permit drug delivery into the body of the patient. In one such embodiment, the fluid pathway connector may be substantially similar to that described in International Patent Application No. PCT/US2012/054861, which is included by reference herein in its entirety for all purposes. In such an embodiment, a compressible sterile sleeve may be fixedly attached between the cap of the drug container and the connection hub of the fluid pathway connector. The piercing member may reside within the sterile sleeve until a connection between the fluid connection pathway and the drug container is desired. The sterile sleeve may be sterilized to ensure the sterility of the piercing member and the fluid pathway prior to activation.

[00476] Alternatively, the fluid pathway connector may be integrated into a drug container as described in International Patent Applications No. PCT/US2013/030478 or No. PCT/US2014/052329, for example, which are included by reference herein in their entirety for all purposes. According to such an embodiment, a drug container may have a drug chamber within a barrel between a pierceable seal and a plunger seal. A drug fluid is contained in the drug chamber. Upon activation of the device by the patient, a drive mechanism asserts a force on a plunger seal contained in the drug container. As the plunger seal asserts a force on the drug fluid and any air/gas gap or bubble, a combination of pneumatic and hydraulic pressure builds by compression of the air/gas and drug fluid and the force is relayed to the sliding pierceable seal. The pierceable seal is caused to slide towards the cap, causing it to be pierced by the piercing member retained within the integrated sterile fluid pathway connector. Accordingly, the integrated sterile fluid pathway connector is connected (i.e., the fluid pathway is opened) by the combination pneumatic/hydraulic force of the air/gas and drug fluid within the drug chamber created by activation of a drive mechanism. Once the integrated sterile fluid pathway connector is connected or opened, drug fluid is permitted to flow from the drug container, through the integrated sterile fluid pathway connector, sterile fluid conduit, and insertion mechanism, and into the body of the patient for drug delivery. In at least one embodiment, the fluid flows through only a manifold and a cannula and/or needle of the

insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during drug delivery.

[00477] In a preferred embodiment, the sterile fluid pathway connector is initiated by movement of the needle insertion mechanism, which itself is initiated by the multi-function drive mechanism. Additionally or alternatively, the sterile fluid pathway connector is initiated by movement directly of the multi-function drive mechanism. For example, the multi-function drive mechanism may include a rotational gear, such as the star gear described in detail herein, that acts concurrently or sequentially to control the rate of drug delivery, to actuate the needle insertion mechanism, and/or initiate the sterile fluid pathway connector. In one particular embodiment, shown in Figs. 33A-33C, the multi-function drive mechanism performs all of these steps substantially concurrently. The multi-function drive mechanism rotates a gear that acts upon several other components. The gear acts on a gear assembly to control the rate of drug delivery, while also contacting a needle insertion mechanism to introduce a fluid pathway into the patient. As the needle insertion mechanism is initiated, the sterile fluid connection is made to permit drug fluid flow from the drug container, through the fluid conduit, into the needle insertion mechanism, for delivery into the patient as the gear and gear assembly of the multi-function drive mechanism control the rate of drug delivery.

[00478] Regardless of the fluid pathway connector utilized by the drug delivery device, the drug delivery device is capable of delivering a range of drugs with different viscosities and volumes. The drug delivery device is capable of delivering a drug at a controlled flow rate (speed) and/or of a specified volume. In one embodiment, the drug delivery process is controlled by one or more flow restrictors within the fluid pathway connector and/or the sterile fluid conduit. In other embodiments, other flow rates may be provided by varying the geometry of the fluid flow path or delivery conduit, varying the speed at which a component of the drive mechanism advances into the drug container to dispense the drug therein, or combinations thereof. Still further details about the fluid pathway connector 8300 and the sterile fluid conduit 8030 are provided hereinafter in later sections in reference to other embodiments.

[00479] V. Other Embodiments of Fluid Pathway Connector

[00480] At least some of the drug delivery devices described in this application, including at least those described in connection with Figs. 1A-2B and 33A-33C, may be configured to incorporate the embodiments of the fluid pathway connector described below in connection with Figs. 34A-42. The embodiments of the fluid pathway connector described below in connection with Figs. 34A-42 may

be used to replace, in its entirety or partially, the above-described fluid pathway connector 300, 6300, or 8300, or any other fluid pathway connector described herein, where appropriate.

[00481] In the processes of filling drug containers and other drug delivery devices, it is sometimes necessary to connect two or more sterile components or subassemblies. For example, wearable injectors or drug pumps may include a drug container which may be filled with a fluid drug using standard pharmaceutical fill-finish processes. After filling of the drug container, it may be necessary to connect the drug container to one or more additional components or subassemblies such that a fluid communication may be established between the drug container and these components. Maintaining the fluid path in an aseptic condition is critical, preventing the introduction of harmful microbes to the drug and/or fluid pathway. The connection of two or more aseptic components or subassemblies is typically performed in an aseptic environment, such as a clean room, thereby ensuring that no harmful microbes are introduced to the assembly. This, however, may lead to increased cost to manufacture the drug delivery devices

[00482] Embodiments of the present disclosure allow aseptic connections to be made between two or components or subassemblies in a septic environment. As seen in Figs. 34A-34C, the connection hub 310 of a fluid pathway connector (e.g., fluid pathway connectors 300, 6300, and/or 8300) may be connected to a drug container 350. Fig. 34A shows these components prior to connection. A first film 318 is in place on connection hub 312. First film 318 covers aperture 312B of connection hub 312 and prevents microbes from entering cavity 312A through aperture 312B, thereby maintaining cavity 312B and piercing member 316 in an aseptic condition. Piercing member 316 is partially disposed in cavity 312A and at least partially disposed in retainer 314. The piercing member may be a hollow needle. Retainer 314 is engaged with connection hub 312 and may be configured for translation with respect to the connection hub in a direction parallel to the long axis of piercing member 316. The retainer may include one or more locking arms 314A which may engage one or more first recesses 312C in connection hub 312. The locking arms may include protrusions at their lower end, which in the locked position are at least partially disposed in the upper recesses. The engagement of the flex arms maintains the spatial relationship of the retainer and the connection hub.

[00483] The drug container 350 may include a crimp cap 324 that maintains a connection between a pierceable seal 326 and a barrel (not shown). The pierceable seal maintains the fluid drug within the barrel and prevents microbes and other substances from entering the drug chamber. A

recess 328 is formed by the geometry of the pierceable seal. A second film 322 is affixed to the drug container such that it encloses recess 328, thereby maintaining recess 328 in an aseptic condition. The first and second films may be constructed of any material capable of providing the barrier properties required to maintain the aseptic condition of the associated surfaces. In a preferred embodiment, the films are constructed from a foil material. Alternatively, the films may be any type of sterilizable membrane, film, or foil. Additionally, the film may be removable and/or pierceable as well as breathable and/or permeable.

[00484] An adhesive may be applied to the exterior surfaces of both first film 318 and second film 322 prior to joining the fluid pathway connector and the drug container 350. The adhesive may contain antimicrobial, antibacterial, and antiviral compounds to limit or reduce the number of such substances on the surface of the seals. During connection, flex arms 312E may engage crimp cap 324 or another portion of the drug container 350, thereby limiting axial translation of the fluid pathway connector with respect to the drug container 350. In this position, first film 318 and second film 322 are in contact with, or in close proximity to, one another. If an adhesive is present on the faces of one or more of the films the films may be bonded together.

[00485] After the fluid pathway connector and drug container 350 are joined, the retainer 314 may be translated axially with respect to the connection hub. Translation of the retainer causes locking arms 314A to flex and become disengaged from first recess 312C. Translation of the retainer causes needle 316 to also translate. This translation causes the needle to pierce first film 318 and second film 322. After translation of the retainer, the piercing member is at least partially disposed in recess 328 of pierceable seal 326. The retainer may be further translated, leading to the piercing of pierceable seal 326 by piercing member 316. After piercing of the pierceable seal a fluid path is established from the drug container and through the needle. The needle may also be in fluid communication with a conduit, the conduit being configured to carry the fluid contents to a delivery mechanism such as an insertion mechanism for delivery to a patient. Piercing of the first and second films may occur at the time of assembly. Alternatively, the piercing of the films may occur at or near the time-of-use of the drug delivery device. Piercing of the pierceable seal at or near the time-of-use may be initiated, by the patient, by interaction with an activation mechanism.

[00486] In some embodiments, the end of the piercing member may remain disposed within cavity 328 until time-of-use. The pierceable seal may be configured such that, in response to hydraulic and/or pneumatic pressure within the drug chamber, it deforms and is caused to come into

contact with the piercing member. This deformation of the pierceable seal leads to the piercing of the seal by the piercing member.

[00487] FIGS. 35A-35D show an embodiment in which a connection hub 1312 of a fluid pathway connector is connected to a drug container such that the long axis of the piercing member 1316 is orthogonal to the long axis of the drug barrel 1330 of the drug container. As seen in Fig. 35B, flex arms 1312E engage a portion of cap 1324 to securely attach the fluid pathway connector to the drug container. The fluid pathway connector may further include insert 1332 disposed within connection hub 1312. Extension 1314D of retainer 1314 may be sealingly engaged with insert 1332 and be configured for axial translation with respect to the insert. Protrusions 1314B of retainer 1314 are initially disposed in first recesses 1312C of connection hub 1312. In this position, the piercing end of piercing member 1316 is disposed within insert 1332. Fig. 35C shows a cross-sectional view of the drug container and fluid pathway connector after assembly and before connection of the fluid path. As seen in the cross-section, cap 1324 may contain side port 1324A which allows the piercing member to access the pierceable seal. Also shown in Fig. 35C is conduit port 1314C which may be configured to allow a conduit to be connected to the retainer. This conduit may provide a fluid path that connects the drug container to a delivery mechanism for delivery of the fluid drug to the patient. Fig. 35D is a cross-section showing the assembly in an open fluid path configuration. As shown, retainer 1314 has been displaced toward the center axis of the drug container. Protrusions 1314B of flex arms 1314 have disengaged from first recesses 1312C and have engaged second recesses 1312D. Piercing member 1316 has pierced first film 1318, second film 1322, and pierceable seal 1326. The piercing of each of these may occur at time of use upon patient initiation. Alternatively, the first and second film may be pierced at time of assembly. This creates a fluid path from the drug container, through the piercing member, conduit, and insertion mechanism for delivery to the patient. The connection of the fluid pathway connector such that the long axis of the piercing member is orthogonal to the long axis of the drug container may allow for more compact packaging in a drug delivery device.

[00488] In other embodiments, shown in Figs. 36A-36D, the piercing member includes an inner piercing member 2316A and an outer piercing member 2316B. The inner piercing member 2316A is disposed within the hollow outer piercing member 2316B. After connection of the connection hub 2312 to the drug container 2330, the outer piercing member 2316B pierces the first film 2318 covering terminal end of the connection hub 2312 and the second film 2318 covering the terminal end of the drug container 2330, while maintaining the inner piercing member 2316A within its

hollow inner cavity. The piercing may be caused by joint motion of the piercing members 2316A and 2316B toward the drug container or, alternatively, may be caused by the drug container displacing the connection hub, thereby exposing the outer piercing member 2316B. Because the inner piercing member 2316A does not contact the first and second films 2318 and 2322, any contaminants present on the surface of the films 2318 and 2322 are not in contact with the inner piercing member 2316A. After piercing the films 2318 and 2322 the outer piercing member is retracted, thereby exposing the inner piercing member 2316A. In this position, shown in Fig. 36C, the end of the inner piercing member 2316A is disposed in the cavity 2328 created by the pierceable seal 2326. In response to increased hydraulic and/or pneumatic pressure within the drug container the pierceable seal 2326 may deform, as shown in Fig. 36D. The deformation of the pierceable seal 2326 causes the inner piercing member 2316A to pierce the pierceable seal 2326, thereby creating a fluid path from the drug container 2330 through the inner piercing member 2316A for delivery to the patient.

[00489] As shown in the alternative embodiment of Figs. 37-38, the fluid pathway connector may include an elastomeric component 3334. At least a portion of the outer piercing member 2316B may be embedded in the elastomeric component 3334. The outer piercing member 2316B may be embedded in the elastomeric component 334 while in an aseptic environment. The aseptic condition of the embedded portion of the outer piercing member 2316B is maintained when the fluid path connection mechanism is transferred to a septic environment due to the sealing engagement of the outer piercing member 2316B with the elastomeric component 3334. Hence, after mounting the fluid pathway connector to the drug container, the fluid pathway connector may be transformed to the open configuration by initially piercing of the first and second films 2318 and 2322 with the outer piercing member 2316B, and then piercing the pierceable seal 3324 with the inner piercing member 2316A by moving the inner piercing member 2316A relative to the outer piercing member 2316B while keeping the outer piercing member 2316B stationary. In this way, the inner piercing member 2316A is not contaminated by touching the non-sterile exterior surfaces of the first and second foils 2318 and 2322. In alternative embodiments, the outer piercing member 2316B may be the sole piercing member and/or may pierce the pierceable seal 3324 in addition to the first and second films 2318 and 2322. As seen in the further alternative embodiment of Figs. 38A-D, the first film 2318 and/or the second film2322 may further include an adhesive containing antimicrobial agents as described above. Initially, the antimicrobial adhesive of the first film 2318 may be covered by a removable liner 2319 and the antimicrobial adhesive of the second film 2322 may be

covered by a removable liner 2323. Prior to assembling the first film 2318 in engagement with the second film 2322, the removable liners 2319 and 2323 may be removed. This presence of the antimicrobial adhesive on the exterior surfaces of the first and second films 2318 and 2322 inhibits or prevents contamination of those surfaces if this step of the assembly is performed in a non-sterile environment.

[00490] In some embodiments, as shown in Figs. 39A-B, an additional film or seal 4336 may be present on the outer piercing member 4316B which further isolates the inner cavity of the outer piercing member 4316B and hence the inner piercing member 4316A. This seal 4336 may remain intact as the outer piercing member pierces first film 4318 and second film 4322. This may prevent any microbes that are present on the surfaces of the seals from coming in contact with the inner piercing member. After piercing the first and second films 4318 and 4322 the translation of the outer piercing member 4318B may be restricted prior to the outer piercing member piercing the piercable seal 4326. The inner piercing member 4316A continues to translate toward the drug container 2330 and pierces the first and second films 4318 and 4322 and the pierceable seal 4326, thereby opening the fluid path. Furthermore, in the embodiment shown in Figs. 39A-B, an antimicrobial adhesive 4325 may initially cover the exterior surface(s) of the first film 4318 and/or the second film 4322.

[00491] In other embodiments, shown in Figs. 40A-C, the first and second films are removed from the fluid pathway connector and drug container just prior to mounting of the fluid pathway connector. Prior to removal of the films, their placement maintains the sterility of the pierceable seal of the drug container and the face of the elastomeric component of the fluid pathway connector. Except for the removal of the first and second films prior to connection of the fluid pathway connector and the drug container and the omission of the outer piercing member 2316B, the embodiment shown in Figs. 40A-C includes same or similar elements as the embodiment shown in Figs. 37A-C. Thus, same reference numerals are used to indicate same or similar elements in both sets of figures. It is noted that the outer piercing member 2316B of the embodiment shown in Figs. 37A-C can be implemented in an alternative version of the embodiment shown n Figs. 40A-C. Also, it is noted that the elastomeric component 3334 of the Figs. 40A-C embodiment, unlike the elastomeric component 3334 of the Figs. 37A-C embodiment, includes a recess or cavity 2327 configured to receive and form a tight fit (e.g., an airtight interference or press fit) with a distal end 2329 of the drug container 2330. This tight fit may prevent the ingress of contaminants and thereby maintain sterility of the interface between the drug container and the fluid pathway connector. In

some embodiments, the distal end 2329 of the drug container 2330 may be inserted into the recess 2327 and the elastomeric component 3334 under non-sterile or aseptic conditions so that contaminants are not trapped between distal end 2329 of the drug container 2330 and the elastomeric component 3334 as the result of assembly.

[00492] As shown in the alternative embodiment of Figs. 41A-D, the fluid pathway connector may also be mounted to the drug container 2330 using a glass tube 2335. After mounting, the glass tube 2335 and the surfaces of the elastomeric piercing member retainer or component 3334 and pierceable seal 3324 may be sterilized using UV sterilization (see Fig. 41C). The glass tube may be in sealing engagement (e.g., an airtight seal) with both the drug container 2330 and the elastomeric component 3334 of the fluid pathway connector such that after sterilization microbes and other foreign elements are unable to enter the glass tube, thereby maintaining the aseptic condition of the interior of the glass tube 2335. Except for the omission of the first and second foils 2318 and 2322 and the inclusion of the glass tube 2335, the embodiment shown in Figs. 41A-D may include the same or similar elements as the embodiment shown in Figs. 40A-C. Therefore, same reference numerals are used to indicate same or similar elements in both sets of figures.

[00493] The embodiment shown in Fig. 42 shows a connection which is made orthogonal to the long axis of the drug container. In this embodiment, a first film 5318 is initially in place over and maintaining the sterility of a cavity 5312A of the connection hub 5312. During connection, the first film 5318 is pierced by an insert 5340 of the drug container. The pierced portion is retained within the concave portion 5342 of the insert after piercing. By retaining this pierced portion within the concave portion the non-aseptic surface of the first film is isolated and any substances present thereon are prevented from contaminating the drug fluid or fluid path. A second film 5322 is initially in place over an aperture 5340A in the insert 5340, maintaining the aseptic condition of the aperture. The second film 5322 may be a rigid or elastomeric component which is in tight conformity to the insert such that it prevents microbes and other contaminants from entering the aperture. Upon mounting of the connection hub to the drug container the second film may be displaced from its initial position, thereby allowing a fluid path to be established from the drug container through the fluid pathway connector. After mounting of the connection hub to the drug container the aperture 5340A in the insert 5340 is aligned with an aperture 5312B in the connection hub 5312. A pierceable seal may be in place over one or more of the apertures which may be pierced by a piercing member to establish a fluid path. One or more snap arms may retain the insert

in position in relation to the drug barrel. The snap arms may connect to the drug barrel itself or another component of the drug container.

[00494] VI. Additional Embodiments of Fluid Pathway Connector

[00495] At least some of the drug delivery devices described in this application, including at least those described in connection with Figs. 1A-2B and 33A-33C, may be configured to incorporate the embodiments of the fluid pathway connector described below in connection with Figs. 43-52D. The embodiments of the fluid pathway connector described below in connection with Figs. 43-52D may be used to replace, in its entirety or partially, the above-described fluid pathway connectors 300, 6300, or 8300, or any other fluid pathway connector described herein, where appropriate.

[00496] As shown in the embodiment of Figs. 43-45, the drug container 1850 may consist of barrel 1858, cap 1852, and pierceable seal 1856. Base 1856A of pierceable seal 1856 may be in sealing engagement with the inside of barrel 1858. Cap 1852 may be fixedly engaged to the outside of barrel 1858 and may retain pierceable seal 1856 in position and restrict movement of pierceable seal 1856 with respect to barrel 1858. Cap 1852 may include one or more locking arms 1852A which extend from ring 1852B of cap 1852 substantially parallel to axis A-A and in a distal direction. The locking arms 1852A may include a radially extending protrusion 1852C at or near their distal ends. The drug container may further include toroidal seal 1857. In an initial configuration, shown in Fig. 43, the toroidal seal is retained between protrusions 1852B and proximal circumferential rib 1856B of pierceable seal 1856. Pierceable seal 1856 may further include distal circumferential rib 1856C which further retains toroidal seal 1857. By placing the toroidal seal in this position when the drug container is in an aseptic environment the portion of pierceable seal 1856 in contact with the inner face of toroidal seal 1857 (i.e., the area between the proximal circumferential rib and the distal circumferential rib) is maintained in an aseptic condition even if the drug container is moved to a septic environment.

[00497] The fluid pathway connector 18300 includes connection hub 18310, retainer 18320, piercing member 18330, and plug seal 18330. As shown in Fig. 45A, plug seal 18330 is initially disposed within bore 18310A of connection hub 18310. When the fluid pathway connector is assembled, the plug seal maintains the aseptic condition of at least a portion of the fluid pathway connector by maintaining a sealing engagement with bore 18310A. The retainer is disposed for sliding translation with respect to connection hub 18310 in a direction parallel to axis B-B (shown in Fig. 45D). Initially, translation of retainer 18320 may be restricted. The restriction may be by

engagement of flex arms 18320B with recesses in connection hub 18310. Piercing member 18330 may be fixedly engaged with retainer 18320 such that translation of retainer 18320 is transferred to the piercing member. The piercing member may be bonded, press-fit, or engaged to the retainer using other appropriate means. The piercing member may initially be at least partially disposed within cavity 18310D and/or aperture 18310C of connection hub 18310. Both cavities 18310D and 18310C are maintained in an aseptic condition by plug seal 18340. Retainer 18320 may further include conduit connection 18320A to which the sterile fluid conduit 30 (see Fig. 1B) may be attached. This provides a sterile fluid path from the sterile fluid pathway connector to the insertion mechanism. Piercing member 18330 may be a hollow needle such that fluids may pass through the hollow interior of the piercing member and into the sterile fluid conduit.

[00498] FIGS. 45A-D show the steps of connecting the fluid pathway connector to the drug container. This connection may be performed in a non-aseptic environment. In Fig. 45A, the plug seal of the fluid pathway connector is substantially aligned with axis A-A (i.e., the plug seal 18340 is aligned with the distal end of the pierceable seal 56). Fig. 45B shows a cross-section view of the fluid pathway connector 18300 in contact with the drug container. Recesses 18310B of connection hub 18310 are aligned with locking arms 1852A, this alignment guides the installation of the fluid pathway connector and prevents rotation of the fluid pathway connector with respect to the drug container. As shown in Fig. 45C, as the connection hub is translated in the proximal direction along axis A-A the plug seal 18340 is prevented from translating with the connection hub due to contact with pierceable seal 1856. This causes the plug seal to be displaced from its position within bore 18310A. Additionally, contact of shoulder 18310E of connection hub 18310 with toroidal seal 1857 causes the toroidal seal to translate in the proximal direction along axis A-A. As the connection hub is translated along axis A-A only bore 18310A comes in contact with the portion of the pierceable seal which was previously covered by toroidal seal 1857. Further, as the connection hub comes into contact with the toroidal seal these components sealingly engage such that microbes and other foreign substances may not come in contact with the sterile portions of the pierceable seal and fluid pathway connector. In this way the aseptic condition of the pierceable seal 1856, aperture 18310C, cavity 18310D, and piercing member 18330 are maintained during installation of the fluid pathway connector.

[00499] As seen in Fig. 45D, further proximal translation of the connection hub brings the connection hub into contact with a portion of drug container 1850, thus preventing further distal translation of the connection hub. In the embodiment shown, the connection hub contacts a portion

of cap 1852. When the connection hub reaches this position, the plug seal may be removed from the assembly and discarded. Snap arms 1852A may engage one or more aspects of the connection hub and thereby prevent the connection hub from being removed from the drug container.

[00500] After installation, the piercing member is aligned with the sterile portion of the pierceable seal which was originally engaged with the toroidal seal. The components may be assembled into the drug delivery device 10 (see Figs. 1A-1C) and remain in this configuration until activation of the drug pump by the user. Upon activation, the retainer 18320 is translated in a direction parallel to axis B-B with respect to the connection hub, causing translation of piercing member 18330. Due to this translation, the piercing member comes in contact with and, subsequently, pierces the pierceable seal 1856. This opens a fluid pathway from the drug container and through the piercing member. The fluid pathway may further include sterile fluid conduit 30 (see Fig. 1B) which is engaged with conduit connection 18320A of retainer 18320. In this way a sterile fluid path is provided from the drug container to the insertion mechanism for delivery to the patient.

[00501] FIGS. 46A-46B show another embodiment of the present disclosure in which connection hub 181310 includes snap arms 181310F which may engage cap 181052 of drug container 181050. Toroidal seal 181057 is initially retained between proximal circumferential rib 181056B and distal circumferential rib 181056C of pierceable seal 181056 and is caused to translate in the proximal direction by contact with the connection hub. After mounting of the fluid pathway connector to the drug container, opening of the fluid pathway is substantially similar as that described above.

[00502] FIG. 47 shows a detail view of the plug seal disposed within the bore of the connection hub. This shows a possible method of retaining the plug seal in position using tabs 181310G. These tabs control the location of the plug seal in the inner bore.

[00503] FIGS. 48-50 show additional embodiments of the disclosure illustrating alternative configurations of the cap and pierceable seal.

[00504] In the embodiment shown in Fig. 51, bore 182310A is enclosed on its distal face by distal film 182350 and on its proximal face by proximal film 182352. The proximal and distal films may be constructed from any material with barrier properties sufficient to prevent the passage of foreign matter. For example, the films may be constructed from a foil material. The films may be bonded or otherwise securely affixed to the connection hub. In this way, bore 182310A is maintained in an aseptic condition.

[00505] As the fluid pathway connector is brought into contact with the drug container, a portion of the drug container pierces, tears, or otherwise removes a portion of proximal film 182352 from the connection hub. For example, as shown in Fig. 51, a portion of the cap 182052 contacts the proximal film during installation and disengages a portion thereof from the connection hub. The disengaged portion of proximal seal 182352 may be retained within void 182055 formed by cap 182052 and pierceable seal 182056, thereby preventing the septic portion of proximal film 182352 from contacting the aseptic portion of pierceable seal 182056.

[00506] Also shown in Fig. 51, seal 182057 may be configured to maintain the aseptic condition of only a portion of the circumference of pierceable seal 182056. This portion may be configured to be aligned with aperture 182310C and piercing member 182330 after installation of fluid pathway connector 182300. During installation, seal 182057 is displaced by the connection hub as described in reference to other embodiments. Seal 182057 may be retained in position with respect to the pierceable seal by engagement of the seal with slot 182052D of cap 182052, proximal circumferential rib 182056B, and distal circumferential rib 182056C. During displacement, the seal may translate within slot 182052D in the proximal direction.

[00507] FIGS. 52A-52D show another embodiment of a fluid pathway connector in which the fluid pathway connector includes first rotating disk 183360 and drug container 183050 includes second rotating disk 183051. First rotating disk 183360 may be configured for rotation with respect to connection hub 183310 about a central axis and further include first opening 183360A. As shown in Fig. 52A, the first rotating disk may also include post 183360B and receptacle 183360C. Second rotating disk 183051 may include complementary features to allow for alignment of the first opening 183360A with the second opening 183051A. Second rotating disk 183051 may be configured for rotation with respect to the drug container and have second opening 183051A. One or both of the openings may initially be covered by a film such that the film prevents foreign materials from entering the openings.

[00508] As seen in Fig. 52C, during installation the first and second rotating disks are brought into contact such that the first and second openings are aligned. The rotating disks may be joined through the use of an adhesive or, alternatively, may be held in contact by features such as the snap arms described previously in relation to other embodiments. Once connected, the disks may be rotated such that they align with chimney 183053 and third opening 183310F in connection hub 183310. Chimney 183053 may be biased for axial movement in the distal direction, such as by a

spring or other biasing member capable of storing energy. As shown in Fig. 52D, upon alignment with the first and second opening, the chimney translates in the distal direction, passing through both the first and second opening. The chimney may have a pass-through which allows contents to flow from the drug container. In this way, a sterile fluid path is created between the drug container and the fluid pathway connector. The fluid pathway connector may further include a piercing member which is configured to, upon activation by a user, pass through the chimney and pierce a pierceable seal of the drug container. After the pierceable seal is pierced, drug fluid may pass through the piercing member and be delivered to the patient. The piercing member may be engaged with retainer 183320. The retainer may also be configured for connection of sterile fluid conduit 30 (see Fig. 1B) at conduit connection 183320A. The translation of the piercing member may be caused by translation of the retainer.

[00509] In at least one embodiment, the present disclosure provides a user-initiated fluid pathway connector. The fluid pathway connector includes: a connection hub, a piercing member, a piercing member retainer, and a drug container having a cap, a pierceable seal, and a barrel, wherein the piercing member is at least partially disposed in a sterile chamber defined by the connection hub. The fluid pathway connector is configured such that it may be connected to the drug container while maintaining the aseptic condition of a fluid pathway. The drug container may contain a drug fluid for delivery. The fluid pathway connector may further be in fluid communication with a conduit that provides a fluid pathway for delivery of the fluid drug to the patient. Upon initiation by the user, the fluid drug is delivered through the fluid pathway to the body of the user. The pierceable seal includes a seal barrier that may be penetrated, upon user initiation, by the piercing member.

[00510] In another embodiment, the present disclosure provides a drug delivery pump with integrated sterility maintenance features having a housing and an assembly platform, upon which an activation mechanism, a fluid pathway connector, a power and control system, and a drive mechanism having a drug container may be mounted, said fluid pathway connector including a connection hub, a piercing member, a piercing member retainer, and a drug container having a cap, a pierceable seal, and a barrel, wherein the piercing member is at least partially disposed in a sterile chamber defined by the connection hub. The fluid pathway connector is configured such that it may be connected to the drug container while maintaining the aseptic condition of a fluid pathway. The drug container may contain a drug fluid for delivery. The fluid pathway connector may further be in fluid communication with a conduit that provides a fluid pathway for delivery of the fluid drug to the patient. Upon initiation by the user, the fluid drug is delivered through the fluid pathway

connector to the body of the user. The pierceable seal includes a seal barrier that may be penetrated, upon user initiation, by the piercing member.

[00511] VII. Additional Embodiments of Fluid Pathway Connector

[00512] At least some of the drug delivery devices described in this application, including at least those described in connection with Figs. 1A-2B and 33A-33C, may be configured to incorporate the embodiments of the fluid pathway connector described below in connection with Figs. 53A-68. The embodiments of the fluid pathway connector described below in connection with Figs. 53A-68 may be used to replace, in its entirety or partially, the above-described fluid pathway connector 300, 6300, or 8300, or any other fluid pathway connector described herein, where appropriate.

[00513] In general, the present embodiments provide for container connections that maintain the sterility of a fluid pathway and are integrated into a fluid container; drug delivery devices that incorporate such sterile fluid pathway connectors to fluid containers; methods of operating such devices; and methods of assembling such devices. The fluid pathway connectors of the present embodiments provide integrated safety features that ensure the sterility of the fluid pathway before, during, and after fluid delivery. In one aspect, the fluid pathway remains disconnected from the fluid container until the device has been initiated by the operator. In another aspect, the fluid pathway maintains the sterility of a piercing member prior to connection with the fluid container within a sterile cavity prior to activation by the operator. Upon activation by the operator, at least a portion of a pierceable seal is translated, such as by pneumatic and/or hydraulic pressure or force within the fluid, towards a substantially fixed piercing member such that the pierceable seal is pierced and the fluid pathway is connected or opened to enable fluid flow through the fluid pathway for fluid delivery from the device.

[00514] A drug delivery device, such as an infusion pump or a bolus injector, may be needed to deliver a particular amount of fluid within a period of time. For example, when delivering a drug fluid subcutaneously it is important to control the flow of fluid that is delivered into the patient and to maintain the sterility of the fluid container and fluid pathway prior to activation or operation of the fluid delivery device. It may be desired that the fluid pathway connector remains disconnected, for container integrity, sterility, and other purposes, until the user has activated the device and initiated fluid flow from a container. Some drug delivery devices may utilize one or more active fluid pathway control mechanisms to prevent premature fluid pathway connector or drug delivery. Other drug delivery devices are configured such that fluid pathway connector is made upon

manufacture, and fluid delivery is blocked until desired by the user. Such designs do not provide the beneficial advantages associated with maintaining container integrity and sterility of the internal components of the drug delivery device. The present embodiments provide an integrated fluid pathway connector mechanism for sterile drug delivery devices. These novel embodiments provide both a connection mechanism to open or connect a sterile fluid pathway between a fluid container and a fluid conduit, without adding unnecessary steps for the user. This is enabled by activation of the drive mechanism and translation of the plunger seal, resulting in pneumatic and/or hydraulic pressure within the fluid that forces translation of at least a portion of a pierceable seal, causing it to impact upon a substantially stationary piercing member, thus opening a sterile fluid pathway between the fluid container and the fluid conduit.

[00515] Accordingly, the embodiments of the present disclosure provide a sterile fluid pathway connector that is integrated into a fluid container and opened, connected, activated, or otherwise enabled by the operation of the device and drive mechanism. The activation of the drive mechanism and the force transferred from the drive mechanism to the plunger seal is, itself, used to open a sterile fluid pathway between the fluid container and the fluid conduit. Accordingly, container integrity and sterility of the fluid container may be maintained prior to and during operation of the device. This novel configuration also automates the sterile fluid pathway connector step, greatly reducing the complexity of the device and operational steps needed to be performed by the device or the user. The novel embodiments of the present disclosure also permit flexibility in device component configurations, and reduce the layout or overall footprint of the device because no separate sterile fluid pathway connector mechanism is needed on the cap-side of the fluid container. The present embodiment may also be implemented fully or utilized in standard production of sterile fluids, including drug fill-finish processes, including applications that require the pulling of a vacuum. Additionally, the present embodiments may also integrate a number of different status indication mechanisms into the device, including utilizing the piercing member or the plunger seal as parts of an indication mechanism that relates status of fluid transfer from the sterile fluid container to the connector. For example, when the fluid container is a drug container, such components and devices provide an end-of-dose indication coupled to the actual travel and drug delivery status of the plunger seal.

[00516] At least one embodiment provides for a sterile fluid pathway connector that includes a piercing member, a connector hub, and a pierceable seal. More specifically, at least one embodiment provides for sterile fluid connector comprising a first portion configured to connect a

sterile fluid pathway and a second portion comprising a housing configured to mount a sterile fluid container; a connector hub; a pierceable seal disposed at least partially between the connector hub and the sterile fluid container and forming a sterile fluid chamber between the connector hub and the pierceable seal; and a piercing member disposed within the connector hub capable of providing a sterile fluid communication between the sterile fluid chamber and the sterile fluid pathway; wherein at least a portion of the pierceable seal is configured to transform from a non-activated state in which the pierceable seal is intact, to an activated state in which the pierceable seal is disrupted by the piercing member to create a sterile fluid communication between the sterile fluid container and the sterile fluid pathway. The housing may be further configured to recess a portion of the connector within the sterile fluid container. The connector hub may further comprise at least one port or vent. The sterile fluid pathway may also include at least one sensor configured to indicate the status of fluid transfer from the sterile fluid container to the connector. Additionally, the sterile fluid pathway connector may include one or more flow restrictors. In at least one embodiment, the connector hub may at least partially function as a fluid conduit or flow restrictor. In at least one embodiment, the fluid pathway connector further includes a filter. A number of known filters may be utilized within the embodiments of the present disclosure, which would readily be appreciated by an ordinarily skilled artisan. For example, the filter may comprise a permeable membrane, semi-permeable membrane or porous membrane, which encloses the sterile cavity from the outside environment.

[00517] The piercing member is initially retained in a substantially fixed position within a sterile cavity between the connector hub and the pierceable seal. Upon activation by the operator (e.g., a patient), at least a portion of the pierceable seal is caused to move to a second position in which the pierceable seal is penetrated by the piercing member. Force, such as pneumatic and/or hydraulic force, applied on the pierceable seal on the side opposing the sterile cavity, causes translation of at least a portion of the pierceable seal towards the piercing member. The translation of the pierceable seal causes it to impact upon the substantially stationary or fixed piercing member to open a fluid pathway through the pierceable seal. Accordingly, at least a portion of the pierceable seal is configured to move from the first position to the second position by force applied by a fluid on the pierceable seal. Penetration by the piercing member of the pierceable seal upon movement of a portion of the pierceable seal from the first position to the second position opens a fluid pathway through the pierceable seal and the piercing member to a fluid conduit.

[00518] In at least one embodiment, the pierceable seal comprises a seal barrier that can be penetrated by the piercing member. The piercing member may initially be in contact with, or adjacent to, the seal barrier.

[00519] The fluid pathway connector may further include a piercing member guide, wherein the piercing member guide is capable of engaging with or translating upon the connector hub. The piercing member guide may function to ensure that the pierceable seal, or at least a portion thereof such as a seal barrier, properly contacts the piercing member and translates thereupon to become pierced and open the fluid pathway through the pierceable seal and piercing member to a fluid conduit.

[00520] The piercing member may be configured to pass into the connector hub and connect to a fluid conduit. In another embodiment, the connector hub may connect the piercing member to the fluid conduit, and the fluid conduit may be at least partially a part of the connector hub. In at least one embodiment, the fluid conduit passes into the connector hub at a port in the connector hub.

[00521] In at least one embodiment, the sterile fluid connector includes at least one sensor configured to indicate the status of fluid transfer from the sterile fluid container to the connector. For example, the sterile fluid pathway connector may further include one or more interconnects and, optionally, one or more corresponding contacts, to transmit a signal to the user. For example, the interconnect(s) may be within or at least partially proximal to a plunger seal translatable within a fluid container such that the piercing member is capable of penetrating the plunger seal and acting as a contact(s) for the interconnect(s) to transmit a signal to the user. Additionally or alternatively, the interconnect(s) or the contact(s) is within or at least partially proximal to a plunger seal translatable within a drug container and the other is within or at least partially distal to the pierceable seal to transmit a signal to the user when the plunger seal and the pierceable seal are substantially in contact. Additionally or alternatively, the interconnect(s) and contact(s) are within the sterile cavity between the connector hub and pierceable seal such that release of pneumatic and/or hydraulic pressure at the end of fluid transfer releases interconnection to transmit or cease transmission of a signal to the user. A number of known interconnects and contacts may be utilized within the embodiments of the present disclosure, which would readily be appreciated by an ordinarily skilled artisan. For example, a range of: Hall effect sensors; giant magneto resistance (GMR) or magnetic field sensors; optical sensors; capacitive or capacitance change sensors; ultrasonic sensors; and linear travel, LVDT, linear resistive, or radiometric linear resistive sensors;

and combinations thereof, which are capable of coordinating to transmit a signal to the user may be utilized for such purposes.

[00522] Another embodiment provides for an integrated fluid pathway connector and drug container having a piercing member, a connector hub, and a pierceable seal integrated at least partially within a drug container having a barrel and a plunger seal. The pierceable seal is translatable upon a substantially stationary piercing member, and the pierceable seal is configured to move from a first position, where the piercing member is positioned within a sterile cavity between the connector hub and the pierceable seal, to a second position, where the pierceable seal has been penetrated by the piercing member. The fluid container contains a fluid chamber between the pierceable seal and the plunger seal to initially retain a fluid, and the pierceable seal is configured to move from the first position to the second position by a force applied by the fluid on the pierceable seal. In at least one embodiment, the pierceable seal has a seal barrier that can be penetrated by the piercing member, and the piercing member is initially in contact with, or adjacent to, the seal barrier.

[00523] The integrated fluid pathway connector may further include a piercing member guide piece attached to the connector hub or piercing member, wherein the piercing member guide slidably engages the connector hub or piercing member to permit translation of the pierceable seal, or a portion thereof, in the direction of fluid exit from the connector. Translation of the pierceable seal in the direction of the fluid container may be prevented by retention of a portion of the pierceable seal by, for example, a housing, such as a crimped cap, mounted to the fluid container barrel that retains the connector hub, piercing member, and pierceable seal in position during operation. Such a configuration may be used to permit the fluid chamber of the fluid container to be evacuated, such as by vacuum, prior to filling with a fluid without compromising the function of the sterile fluid pathway connector.

[00524] In at least one embodiment, the connector hub has a header with a conduit port, a chamber, and a vacuum port with a channel that leads into the chamber such that the sterile cavity may be evacuated through the channel. The conduit port may have a membrane or seal that permits fluid flow out of the chamber, and may be capable of being plugged. Similarly, the vacuum port may be capable of being plugged, such as by a polymeric plug. Such configurations allow, for example, the sterile cavity to be evacuated to maintain both sterility and pressure equilibrium between the sterile cavity and the opposing side of the pierceable seal, or otherwise assist in

maintaining the relative positions of the components prior to or during operation of the device by the user.

[00525] In at least one embodiment, the pierceable seal, or at least a portion thereof, is translatable upon the piercing member and the pierceable seal is further configured to move from the second position, where the pierceable seal has been penetrated by the piercing member, to a third position wherein at least one sensor indicates the status of fluid transfer from the sterile fluid container to the connector. For example, in a third position, one or more interconnects and one or more corresponding contacts are permitted to transmit a signal to the user. In one such embodiment, the interconnect(s) or the contact(s) is upon an aspect of a drive mechanism and the other is within or at least partially proximal to the plunger seal to transmit a signal to the user when the plunger seal and the pierceable seal are substantially in contact. Alternatively, the interconnect(s) or the contact(s) is within or at least partially distal to the pierceable seal and the other is proximal to the connector hub to transmit a signal to the user when the plunger seal and the pierceable seal are substantially in contact. Additionally or alternatively, the interconnect(s) and contact(s) are within the sterile cavity between the connector hub and pierceable seal such that release of pneumatic and/or hydraulic pressure at end of dose releases interconnection to transmit or cease transmission of a signal to the user. A number of known interconnects and contacts may be used with the present embodiments, which would readily be appreciated by a skilled artisan. For example, a range of: Hall effect sensors; giant magneto resistance (GMR) or magnetic field sensors; optical sensors; capacitive or capacitance change sensors; ultrasonic sensors; and linear travel, LVDT, linear resistive, or radiometric linear resistive sensors; and combinations thereof, which are capable of coordinating to transmit a signal to the user may be utilized for such purposes.

[00526] Yet another embodiment provides a drug delivery device with integrated sterility maintenance features comprising a housing within which an activation mechanism, an insertion mechanism, and a fluid container having a plunger seal may be mounted. The fluid container is connected at one end to a drive mechanism and at another end to a fluid pathway connector. The fluid pathway connector includes a piercing member, a connector hub, and a pierceable seal, wherein the piercing member is retained within a sterile cavity between the connector hub and the pierceable seal, and wherein the pierceable seal is configured to move from a first position to a second position in which the pierceable seal has been penetrated by the piercing member. The fluid container contains a fluid chamber between the pierceable seal and the plunger seal to initially retain a fluid, and wherein the pierceable fluid seal is configured to move from the first position to

the second position by a force applied by the fluid on the pierceable seal. In at least one embodiment, the pierceable seal has a seal barrier that can be penetrated by the piercing member, and the piercing member is initially in contact with, or adjacent to, the seal barrier.

[00527] The drug delivery device may further include a piercing member guide engaged with the connector hub or piercing member, wherein the piercing member guide slidably engages the connector hub or piercing member to permit translation of the pierceable seal, or a portion thereof, in the distal direction (i.e., towards the fluid conduit from where fluid exits the connector). Translation of the pierceable seal in the proximal direction may be prevented by retention of the pierceable seal, or a portion thereof, by, for example, a housing such as a crimped cap mounted to the barrel, which housing retains the connector hub, piercing member, and pierceable seal in position during operation. Such a configuration may be used to permit the drug chamber of the drug container to be evacuated, such as by vacuum, prior to filling with a fluid without compromising the function of the sterile fluid pathway connector. In at least one embodiment, the connector hub has a header with a conduit port, a chamber, and a vacuum port with a channel that leads into the chamber such that the sterile cavity may be evacuated through the channel. The conduit port may have a filter, membrane or seal to permit or restrict fluid flow out of the chamber. Similarly, the vacuum port may be capable of being plugged, such as by a polymeric plug. Such configurations may allow, for example, the sterile cavity to be evacuated to maintain sterility, the maintenance of pressure equilibrium between the sterile cavity and the opposing side of the pierceable seal, or assist in maintaining the relative positions of the components prior to or during operation of the device by a user.

[00528] In at least one embodiment, the pierceable seal is translatable upon the piercing member or an aspect of the connector hub and is further configured to move from the second position, where the pierceable seal has been penetrated by the piercing member, to a third position where one or more interconnects and one or more corresponding contacts are permitted to transmit a signal to the user. The interconnect(s) and the corresponding contact(s) are configured such that, for example: (a) the interconnect(s) or the contact(s) is positioned upon an aspect of the drive mechanism and the other is positioned within or at least partially proximal to the plunger seal, to transmit a signal to the user when the plunger seal and the pierceable seal are substantially in contact; (b) the interconnect(s) or the contact(s) is positioned within or at least partially distal to the pierceable seal and the other is positioned proximal to the connector hub, to transmit a signal to the user when the plunger seal and the pierceable seal are substantially in contact; (c) the interconnect(s) and the

contact(s) are situated within the sterile cavity between the connector hub and the pierceable seal, such after the seal is pierced, continued pressure within the drug chamber causes interconnection which transmits a signal to the user, which signal is terminated once pressure inside the drug chamber drops and interconnection is lost, i.e., at end of dose. A number of known interconnects and contacts may be utilized within the embodiments of the present disclosure, which would readily be appreciated by an ordinarily skilled artisan. For example, a range of: Hall effect sensors; giant magneto resistance (GMR) or magnetic field sensors; optical sensors; capacitive or capacitance change sensors; ultrasonic sensors; and linear travel, LVDT, linear resistive, or radiometric linear resistive sensors; and combinations thereof, which are capable of coordinating to transmit a signal to the user may be utilized for such purposes.

[00529] Additionally, the fluid pathway connectors may include one or more flow restrictors. In at least one embodiment, the connector hub may at least partially function as a fluid conduit or flow restrictor. In at least one embodiment, the fluid pathway connector further includes a filter. A number of known filters can be utilized within the embodiments of the present disclosure, which would readily be appreciated by an ordinarily skilled artisan. For example the filter may be a permeable membrane, semi-permeable membrane, or porous membrane, which encloses the sterile cavity from the outside environment.

[00530] The novel devices of the present embodiments provide container fluid pathway connectors that maintain the sterility of the fluid pathway and that are integrated into the fluid container, and drug delivery devices that incorporate such integrated sterile fluid pathway connectors to fluid containers. Because the fluid path is disconnected until fluid delivery is desired by the operator, the sterility of the fluid pathway connector, the fluid container, the fluid, and the interior of the device as a whole is maintained. Furthermore, the novel configurations of the fluid pathway connectors and drug delivery devices of the present disclosure maintain the sterility of the fluid path through operation of the device. Because the path that the fluid travels within the device is entirely maintained in a sterile condition, only these components need be sterilized during the manufacturing process. Such components include the fluid container of the drive mechanism, the fluid pathway connector, the sterile fluid conduit, and the insertion mechanism. In at least one embodiment of the present disclosure, the power and control system, the assembly platform, the control arm, the activation mechanism, the housing, and other components of the drug delivery device do not need to be sterilized. This greatly improves the manufacturability of the device and reduces associated assembly costs. Accordingly, the devices of the present embodiments do not

require terminal sterilization upon completion of assembly. A further benefit of the present embodiments is that the components described herein are designed to be modular such that, for example, the fluid pathway connector and other components of the device may be integrated into a housing and readily interface to function as a drug delivery device.

[00531] A further embodiment provides a method of assembly of an integrated sterile fluid pathway connector and fluid container. The sterile fluid pathway connector may first be assembled and then attached, mounted, connected, or otherwise integrated into fluid container such that at least a portion of the pierceable seal is contained within the drug container. The fluid container can then be filled with a fluid for delivery to the user and plugged with a plunger seal at an end opposite the pierceable seal. The barrel can be filled with a fluid through the open proximal end prior to insertion of the plunger seal from the proximal end of the barrel. A drive mechanism can then be attached to the proximal end of the fluid container such that a component of the drive mechanism is capable of contacting the plunger seal. An insertion mechanism can be assembled and attached to the other end of the fluid conduit. This entire sub-assembly, including drive mechanism, drug container, fluid pathway connector, fluid conduit, and insertion mechanism can be sterilized, as described above, before assembly into a drug delivery device. Certain components of this sub-assembly may be mounted to an assembly platform within the housing or directly to the interior of the housing, and other components may be mounted to a guide, channel, or other component or aspect for activation by the user. A method of manufacturing a drug delivery device includes the step of attaching both the fluid pathway connector and fluid container, either separately or as a combined component, to an assembly platform or housing of the drug delivery device. The method of manufacturing further includes attachment of the drive mechanism, fluid container, and insertion mechanism to the assembly platform or housing. The additional components of the drug delivery device, as described herein, including the power and control system, the activation mechanism, and the control arm may be attached, preformed, or pre-assembled to the assembly platform or housing. In the instance in which the fluid is a drug, and the drug delivery device is an ambulatory infusion device, an adhesive patch and patch liner may be attached to the housing surface of the drug delivery device that contacts the user during operation of the device.

[00532] A method of operating the drug delivery device includes one or more of the following steps: activating, by a user, the activation mechanism; displacing a control arm to actuate an insertion mechanism; activating a drive control mechanism to push the plunger seal, connect the sterile fluid pathway connector, and drive fluid flow through the drug delivery device; wherein the

pushing of the plunger seal translates the fluid and thus causes a pierceable seal to deform in the direction of the fluid conduit and be pierced by a piercing member, to thereby open a fluid path from the fluid container to the fluid conduit. The drive control mechanism may be activated by actuating a power and control system. The method may further include the step of: engaging an optional on-body sensor prior to activating the activation mechanism. Furthermore, the method of operation may include translating a plunger seal within the drive control mechanism and fluid container to force fluid flow through the fluid container, the fluid pathway connector, the fluid conduit, and the insertion mechanism for delivery of the fluid to the desired target, e.g., to the body of a patient.

[00533] The novel devices of the present embodiments provide container connections which maintain the sterility of the fluid pathway and which are integrated into the fluid container, and drug delivery devices which incorporate such integrated sterile fluid pathway connectors to fluid containers. For example, such devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients.

[00534] In at least one embodiment, the presently disclosed sterile fluid pathway connector includes a piercing member, a connector hub, and a pierceable seal; wherein at least a portion of the pierceable seal is configured to move from a first position in which the piercing member is retained within a sterile cavity between the pierceable seal and the connector hub, to a second position in which the pierceable seal has been penetrated by the piercing member. A filter may be utilized to enclose the sterile cavity from the outside environment. Such fluid pathway connectors may be integrated into a fluid container having a barrel and a plunger seal. The components of the fluid pathway connector may further be capable of transmitting a signal to the user upon completion of fluid delivery, for example, upon contact between the plunger seal and the pierceable seal. A fluid delivery pump includes such integrated fluid pathway connectors and fluid containers.

[00535] The novel embodiments presented herein provide integrated sterile fluid pathway connectors and fluid containers, and drug delivery devices that utilize such connections, configured to maintain the sterility of the fluid pathway before, during, and after operation of the device, and that enable active safety controls for the device. Integration of the fluid pathway connector into a portion of the fluid container helps ensure container integrity and sterility of the fluid pathway. Additionally, by integrating the sterile fluid pathway connector into a portion of the fluid container, the connection for fluid transfer can be controlled by the user (i.e., is user-activated) and enabled by

the function of the drive mechanism. Accordingly, user-activation steps and the internal operation of the drug delivery device can be greatly simplified by the novel integrated sterile fluid pathway connectors of the present embodiments.

[00536] The novel embodiments provide container connections that maintain the sterility of the fluid pathway and are integrated into the fluid container, and drug delivery devices that incorporate such integrated sterile fluid pathway connectors to fluid containers. The present embodiments also further integrate the sterile pathway connector into the fluid container, to reduce the necessary components or to provide easier and more efficient operation of the connection and drug delivery devices. The connector, the sterile fluid pathway assembly, and the infusion pump disclosed here are not limited to medical applications, but may include any application, including industrial uses, where sterile or uncontaminated fluid delivery may be desired. When the fluid is a drug, the present embodiments provide for devices that are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The embodiment described herein incorporate features which make activation, operation, and lock-out of the device simple for even untrained users. One or more of the components of the present embodiments may be modular in that they can be, for example, pre-assembled as separate components and configured into position within the housing of the drug delivery device during manufacturing.

[00537] FIG. 53A and FIG. 53B show an initial configuration of an embodiment of a sterile fluid pathway connector 23030 integrated with fluid container 23050 having fluid chamber 23021 and plunger seal 23060. In some embodiments, the fluid pathway connector 23030 and the fluid container 23050 may be substituted, partially or entirely, for the fluid pathway connector 30 and the fluid container 50 illustrated in FIG. 1B of the present application. Fluid pathway connector 23030 may be mounted, connected or otherwise attached, permanently or removably, to fluid container 23050 at an end opposite plunger seal 23060. As shown in the embodiment of FIG. 53A and FIG. 53B, fluid container 23050 has mutable fluid chamber 23021 within barrel 23058, defined by the position of pierceable seal 23056 and plunger seal 23060. The seals described herein can be made of a number of materials, but are typically made of one or more elastomers or rubbers. Fluid chamber 23021 may contain a fluid for delivery through the integrated sterile fluid pathway connector 23030. In the embodiment of FIG. 53A and FIG. 53B, the fluid pathway connector 23030 includes sterile fluid conduit 23035, piercing member 23033, connector hub 23031, and pierceable seal 23056. Fluid pathway connector 23030 includes piercing member guide 37 engaged with connector hub 23031, upon which pierceable seal 23056 may interface with piercing member 23033 of connector

hub 23031 during operation. A permeable, semi-permeable, or porous membrane, such as filter 23039, may be used to allow venting of air from within the fluid pathway connector 23030 during operation of the device, such as through port or vent 23031B in connector hub 23031. Filter 23039 may be attached, mounted, bonded, over-molded, co-molded, pre-formed, or otherwise connected to enclose sterile cavity 23032 between the exterior of connector hub 23031 and pierceable seal 23056. The term "enclose" or "enclosure" is used herein to define at least a semi-permeable or porous confined area that is capable of being sterilized, evacuated by vacuum, and vented, but is not penetrable by microorganisms, contaminants, or other undesirable environmental factors. For example, filter 23039 can be over-molded at least partially within connector hub 23031 to separate the sterile cavity 23032 from the outside environment. In some embodiments, the filter is a membrane, e.g., a semi-permeable membrane, which allows the venting of air during the actuation of pierceable seal 23056, fluid pathway connector 23030, and the pump device. Filter 23039 may be sterilized by methods well-known to one having skill in the art, thus the filter can maintain a sterile barrier to prevent exposure of the piercing member 23033 to microorganisms, contaminants, or other undesirable environmental factors.

[00538] As shown in FIG. 53B, piercing member 23033 is retained within the integrated sterile fluid pathway connector 23030, at or near seal barrier 23056C of pierceable seal 23056. Piercing member 23033 may be an aspect of fluid conduit 23035 or may be a separate component from fluid conduit 23035, as would readily be appreciated by one having skill in the art. Additionally, fluid pathway connector 23030 may optionally include one or more gaskets, O-rings, or other sealing members, compressed to seal between barrel 23058, particularly at lip 23058A, connector hub 23031, and housing 23052. In at least one embodiment, sealing aspect 23056A of the pierceable seal 23056 may be configured as a seal between barrel lip 23058A, connector hub 23031, and housing 23052. Housing 23052 may be a separate component, such as a crimp cap, or may be an aspect of connector hub 23031 capable of mounting to barrel 23058. The housing or cap could also have screw threads configured to complement screw threads in a fluid container, or use other impermanent means for connecting the fluid container to the sterile fluid pathway connector. As shown in FIG. 53A and FIG. 53B, the sterile fluid pathway connector 23030 may be attached to (i.e., integrated with) fluid container 23050; which in turn can be mounted, by a number of known methods, either fixedly or removably to an assembly platform or housing of a fluid pump, such as the drug delivery device 10 as shown in FIGS. 1A-1C. The assembly platform may be a separate component from the housing, or may be a unified component of the housing such as a pre-formed

mounting aspect on the interior surfaces of the housing. In such configurations, the sterility of the fluid pathway is maintained, the pathway for fluid flow is not connected until desired by the user, and user-initiated activation causes the connection of the fluid chamber and the fluid pathway connector. The fluid pathway connector may, optionally, further include one or more separate flow restrictors or one or more of piercing member 23033 and fluid conduit 23035 may additionally function as flow restrictors.

[00539] The integrated fluid connection of the present embodiments is further illustrated with reference to a drive mechanism, as shown in FIG. 54A and FIG. 54B. The embodiment comprises fluid conduit 23035, engaged with piercing member 23033 at engagement 23038, connector hub 23031 that includes vent 23031B, filter 23039 which is housed against connector hub 23031, and pierceable seal 23056, which sealing portion 23056A abuts connector hub 23031 and the end of barrel 23058, all of which are housed in cap 23052. Barrel 23058 comprises mutable fluid chamber 23021, and houses plunger seal 23060 which is slidably disposed therein and in contact with a drive mechanism (e.g., the drive mechanism 100 illustrated in FIG. 1B), which includes biasing member 23099. FIG. 54A is an exploded side view of components of an integrated sterile fluid pathway connector and fluid container according to at least one embodiment. FIG. 54B shows a sectional exploded view of the same embodiment. Sterile fluid pathway connector 23030 may be integrated at least partially within fluid container 23050 at an end opposite of plunger seal 23060. An exemplary drive mechanism 23090 is shown in these figures to clarify the orientation of these components. The components of the novel sterile fluid pathway connector 23030 may be pre-assembled (see, e.g., FIG. 56A) and subsequently attached, mounted, connected or otherwise mated, permanently or removably, with a fluid container such as fluid container 23050.

[00540] A number of drive mechanisms may be utilized to force fluid from a fluid container for delivery. In one such embodiment, the drive mechanism 23090 may be substantially similar to that described in WO 2013/023033467 (PCT/US2012/023052303241). The components of the drive mechanism upon activation, may be used to drive axial translation in the distal direction (i.e., toward housing 23052 of FIG. 53) of the plunger seal of the fluid container. Optionally, the drive mechanism may include one or more compliance features that enable additional axial translation of the plunger seal to ensure, for example, that substantially the entire drug dose has been delivered to the user and that the feedback contact mechanisms have connected or interconnected. Furthermore, the drive mechanism may include one or more safety mechanisms, such as premature activation prevention mechanisms, to enhance the safety and usability of the mechanism and the device.

[00541] In a particular embodiment, drive mechanism 23090 employs one or more compression springs 23099 as biasing member(s), as shown in FIG. 54B. Upon activation of the fluid pump by the user, the power and control system is actuated to directly or indirectly release the compression spring(s) from an energized state. Upon release, the compression spring(s) may bear against and act upon the plunger seal 23060 to force the fluid out of the mutable fluid chamber 23021 of drug container 23050 as further described with reference to FIG. 55A-55C.

[00542] FIG. 55A to FIG. 55C illustrate the features of an embodiment before use, upon piercing of the pierceable seal, and upon completion of fluid delivery. More specifically, in the configuration shown in FIG. 55A, piercing member 23033 is maintained within sterile cavity 23032 with a first end (a proximal end) adjacent to, or contacting, pierceable seal 23056 of fluid pathway connector 23030. The sterility of cavity 23032 and piercing member 23033 is maintained, for example, by filter 23039 disposed between sterile cavity 23032 and the outside environment. In at least one embodiment, as shown in FIG. 55, filter 23039 is connected to, engaged with, or part of connector hub 23031, and encloses sterile cavity 23032 from the outside environment. Sterile cavity 23032 can be vented via vent or port 23031B within hub connection 23031. Accordingly, fluid pathway connector 23030, in at least one embodiment, is mounted to and integrated with fluid container 23050, for example by housing (cap) 23052 engaged with lip 23058A of barrel 23058. The piercing member may be a number of cannulas or conduits, such as rigid needles, and may be comprised of a number of materials, such as steel. In at least one embodiment, piercing member 23033 is a rigid steel needle. Pierceable seal 23056 may have sealing aspect 23056A that permits pierceable seal 23056 to be mounted directly to or otherwise be held in position between barrel 23058, connector hub 23031, and cap 23052. Connector hub 23031 includes an internal seal mount 23034 that further stabilizes the position of more stationary aspects of pierceable membrane 23056. At least a portion of pierceable seal 23056, such as seal barrier 23056C, is translatable upon connector hub 23031, as described herein, to rupture against piercing member 23033 and enable the fluid pathway connector to sterile fluid conduit 23035. Advantageously, such an arrangement permits pierceable seal 23056 to translate towards cap 23052 but not towards the plunger seal 23060. This is a desirable feature that permits the mutable fluid chamber 23021 of the fluid container 23050 to be evacuated, such as by vacuum, prior to filling with a fluid without compromising the function of sterile fluid pathway connector 23030.

[00543] In an initial position the proximal end of piercing member 23033 may reside adjacent to, or in contact with, seal barrier 23056C of pierceable seal 23056 to, for example, minimize the

distance of translation of the seal barrier 23056C to become pierced and open fluid container 23050 to fluid pathway connector 23030. In a particular embodiment, proximal end of the piercing member 23033 may reside at least partially within seal barrier 23056C of pierceable seal 23056, yet not fully passing there-through, until activation of the device by a user.

[00544] As shown in FIG. 55B, once the pump device is activated and the drive mechanism pushes plunger seal 23060, plunger seal 23060 asserts a force on fluid chamber 23021, and pneumatic and/or hydraulic pressure builds by compression of the fluid in chamber 23021. As pneumatic and/or hydraulic pressure builds within fluid chamber 23021, the force is relayed to pierceable seal 23056, causing barrier seal 23056C to transform. This transformation may include a shift, inversion, translation, flexion, deformation, pop, snap, or any other functionally equivalent change, such that a portion of pierceable seal 23056, such as seal barrier 23056C, impinges against the substantially fixed position of piercing member 23033 and causes piercing member 23033 to pierce pierceable seal 23056 at seal barrier 23056C, as shown in FIG. 55B, thereby opening or otherwise connecting the fluid pathway between mutable fluid chamber 23021, piercing member 23033, and fluid conduit 23035.

[00545] Accordingly, integrated sterile fluid pathway connector 23030 is connected (i.e., the fluid pathway is opened) by the pneumatic and/or hydraulic force of the fluid within the fluid chamber 23021 created by activation of the drive mechanism. Once integrated sterile fluid pathway connector 23030 is connected or opened, fluid is permitted to flow from the fluid container 23050, through integrated sterile fluid pathway connector 23030 and sterile fluid conduit 23035. In aspects in which the fluid pump is an ambulatory drug infusion pump, fluid drug then flows through the insertion mechanism and into the body of the user for drug delivery. In at least one embodiment, a number of flow restrictors may be optionally utilized to modify the flow of fluid within the fluid pathway connector. In at least one embodiment, the fluid flows through only a manifold and a cannula or needle of the insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during fluid delivery.

[00546] Additionally or alternatively, plunger seal 23060 or the pierceable seal 23056 may have some compressibility permitting a compliance push of fluid from drug container 23050. Additionally, the drive mechanism, plunger seal 23060, connector hub 23031, pierceable seal 23056, or a combination thereof, may include one or more sensors or status indication mechanisms,

such as interconnects and contacts, to measure and communicate the status of drug delivery drive before, during, and after operation of the device to deliver fluid.

[00547] FIG. 55C shows the components of fluid container 23050 and sterile fluid pathway connector 23030 after substantially all of the fluid has been pushed out of the fluid container 23050. In particular, plunger seal 23060 is in the most-distal position in barrel 23058. In the embodiment of FIG. 55C, the connector hub-side (e.g., distal end) of plunger seal 23060 is configured with an optional protrusion and cavity aspect 23069, which structure minimizes residual volume left in fluid chamber 23021, now collapsed. Alternatively, plunger seal may be a flat-faced plunger seal (e.g., plunger seal 23160 in FIG. 57A and FIG. 58), or may have any number of other configurations as would be readily appreciated by one having skill in the art. In the embodiment shown in FIG. 55, plunger seal 23060 further comprises interconnect/contact 23061; and connector hub 23031 further comprises interconnect/contact 62. At end-of-delivery, interconnect/contact 61 of plunger seal 23060 and interconnect/contact 62 of connector hub 23031 interconnect and transduce a signal that may be perceived by a user. As described herein, numerous sensors and signal transducing means can be incorporated or adapted for use in the present embodiments.

[00548] Because of the novel design of the fluid pathway connector of the present embodiments and their integration at least partially within fluid containers, sterility of the fluid pathway is maintained throughout transport, storage, and operation of the device; user-activation of the device is simplified; and the fluid pathway is only connected when desired by the user. The sterility of the fluid pathway connector is initially maintained by performing the connection within a sterile cavity 23032 between connector hub 23031, pierceable seal 23056, and piercing member guide 23037. In at least one embodiment, the sterility of cavity 23032 is maintained by filter 23039 that abuts, is engaged with or part of, connector hub 23031. Filter 23039 may be, for example, a semi-permeable membrane that allows the venting of air through vent 23031B of connector hub 23031 during the actuation and translation of pierceable seal 23056. Filter 23039 may be sterilized by typical sterilization methods, which would readily be appreciated by one having skill in the art, and may be used to maintain a sterile barrier that prevents exposing piercing member 23033 to microorganisms, contaminants, or other undesirable environmental factors. For example, upon substantially simultaneous activation of the insertion mechanism, the fluid pathway between mutable fluid chamber 23021 and insertion mechanism is complete to permit drug delivery into the body of the user. Because fluid pathway connector 23030 is not in fluid connection or communication with fluid chamber 23021 until activation of the fluid pump and drive mechanism, fluid flow from the fluid

container 23050 is prevented until desired by the user. This provides an important safety feature to the user and also maintains the container integrity of the fluid container and sterility of the fluid pathway.

[00549] The drive mechanism that translates the plunger seal 23060 may contain one or more drive biasing members (e.g., as shown in FIG. 54B). The components of the drive mechanism function to force a fluid from the mutable fluid chamber 23021 through pierceable seal 23056 and through the piercing member 23033 or sterile fluid conduit 23035, for delivery through fluid pathway connector 23030. Further regarding the drive mechanism, a number of drive mechanisms may be utilized to force fluid from a drug container for delivery into the body of a user. In one such embodiment, the drive mechanism 23090 may be substantially similar to that described in WO 2013/023033467 (PCT/US2012/023052303241), which is hereby incorporated by reference in its entirety. The components of the drive mechanism, upon activation, drive axial translation in the distal direction of the plunger seal of the drug container. Optionally, drive mechanism may include one or more compliance features which enable additional axial translation of the plunger seal to, for example, ensure that substantially the entire fluid dose has been delivered to the user and make sure that the feedback contact mechanisms have connected. Furthermore, the drive mechanism may include one or more safety mechanisms, such as premature activation prevention mechanisms, to enhance the safety and usability of the mechanism and the device.

[00550] At least one embodiment provides for a modular fluid pathway connector. FIG. 56A and FIG. 56B detail an embodiment of a modular fluid pathway connector that comprises connector hub 23031, which abuts filter 23039 and pierceable seal 23056 at sealing member 23056A. Connector hub 23031, filter 23039 and pierceable seal 23056 are housed within cap 23052, as shown in FIG. 56A. Connector hub 23031 further comprises header 23031C, which forms a junction for fluid conduit 23035 and piercing member 23033. As shown in FIG. 56A and FIG. 56B, fluid conduit 23035 may be connected directly to piercing member 23033. Alternatively, as shown in FIG. 57A fluid conduit 223035 may be connected via conduit port 223038. Nevertheless, a modular fluid pathway connector can be adapted for use with a number of alternative barrel and drive configurations, and used within a variety of ambulatory infusion devices. The components of the novel sterile fluid pathway connector 23030 may be pre-assembled, to appear as exemplified in FIG. 56A, and subsequently attached, mounted, connected, or otherwise mated with a fluid container such as fluid container 23050. Alternatively, the components of sterile fluid pathway connector 23030 may be assembled directly into drug container 23050. As would be readily

appreciated by one skilled in the art, a number of glues or adhesives, or other connection methods such as snap-fit, interference fit, screw fit, fusion joining, welding, ultrasonic welding, laser welding, and mechanical fastening, and the like, can be used to engage one or more of the components described herein in permanent or impermanent connection as desired for a particular use. For example, glue can be used between distal end of barrel 23058, sealing member 23056A, or connector hub 23031A. Additionally or alternatively, the components of the sterile fluid pathway connector 23030 may be mounted to barrel 23058 and held in place crimping cap 23052 to distal aspect of barrel 23058, such as to a flanged aspect or lip of barrel 23058A.

[00551] In at least one embodiment, as shown in FIG. 57A to FIG. 57C, piercing member guide 230237 may be utilized to guide pierceable seal 23056 and to slidably engage the connector hub 230231. Additionally or alternatively, piercing member guide 230237 may be utilized to ensure that piercing member 230233 remains substantially centered on the axis so as to pierce pierceable seal 23056 at the desired portion of seal barrier 23056C. The embodiment of FIG. 57A shows fluid container comprising barrel 23058 and forming mutable fluid chamber 23021 between plunger seal 230260 and pierceable seal 56. As shown in FIG. 57A, plunger seal 230260 is a flat plunger seal, but a variety of plunger seal shapes can be adapted for use with the fluid connection and infusion pumps of the present embodiments. The embodiment of FIG. 57A further comprises filter 23039, which abuts connector hub 230231 and is used to maintain sterility of sterile chamber 23032 between connector hub 230231 and pierceable seal 23056. Connector hub 230231 also includes seal mount 230234 that abuts pierceable seal 23056; and flange 230231A that abuts seal member 23056A of seal 23056, and that, in turn, abuts the distal lip 23058A of barrel 23058. The meeting surfaces of connector hub 230231A, sealing member 23056A and barrel lip 23058A are positioned in place and secured within the rims of cap 23052. Connector hub 230231 also houses piercing member 230233, which connects to fluid conduit 230235. Connector hub 230231 also has vacuum port 230231B, a filtered channel that leads into sterile chamber 23032. Connector hub 230231 is also configured with conduit port 230231D, which provides exit from sterile fluid connector 230230 to the rest of the infusion device (e.g., injection means), such as via sterile fluid conduit 23035 (not shown). Conduit port 230231D and vacuum port 230231B may contain a membrane or seals, such as one-way seals, which permit fluid flow out of chamber 23032 through the respective ports but do not permit fluid flow into the chamber 23032 through these ports. Additionally, or alternatively, conduit port 230231D and vacuum port 230231B may be plugged at certain points of assembly or operation. For example, vacuum port 230231B may be used to evacuate sterile cavity 23032 during

manufacturing, assembly, or at any point prior to operation of the device; and then vacuum port 230231B can be plugged after the evacuation has been completed.

[00552] Further regarding piercing member guide 230237, this component may be slidably attached to connector hub 230231. A number of means known in the art may be used to facilitate this slidable attachment such as, for example, engagement between a connector prong 230237D and leg 230237A of piercing member guide 230237 with complementary cavity 230236 in connector hub 230231. These components are more clearly visible in FIG. 57A and FIG. 144B. FIG. 57B shows the orientation of piercing member 230233 within piercing member guide 230237, which emerges from piercing member guide 230237 at header 230237C; and FIG. 57C shows the orientation of piercing member 23033 and piercing member guide 230237 within connector hub 230231. Such an arrangement permits the pierceable seal 23056 and piercing member guide 230237 to translate towards housing 23052 together, at least for a portion of the translation of seal barrier 23056C. Additionally, pierceable seal 23056 may be removably attached to piercing member guide 230237 by a number of means known in the art such as, for example, removable snap-fit engagement or it may be configured to enable contact between the components to guide the translation of the seal barrier 23056C upon the piercing member 230233. When a piercing member guide is used, such as piercing member guide 230237 in FIG. 57A, the piercing member guide may translate with pierceable seal 23056, for at least a portion of the translation, to ensure that the seal barrier 23056C contacts and is pierced by the piercing member 230233. Once the fluid pathway is opened or connected, translation of plunger seal 230160 in the distal direction by the drive mechanism causes fluid within drug chamber 23021 to be forced through the sterile fluid connector. In some embodiments, a needle insertion mechanism, as described herein, may be connected at the other end of the fluid conduit 23035 to insert a needle into the body of the user to facilitate fluid transfer to the user.

[00553] The embodiment shown in FIG. 57A also comprises plunger seal 260, which may be used as a part of the status indication mechanism along with piercing member guide 237. More specifically, in this embodiment plunger seal 260 includes interconnect/contact 261 and the corresponding interconnect/contact 262 is located on piercing member guide 237. When plunger seal 260 and piercing member guide 237 reach proximity at end-of-delivery (e.g., as in FIG. 57C), interconnect/contact 261 and interconnect/contact 261 interconnect and transduce a perceptible signal to the user.

[00554] The novel embodiments presented herein provide integrated sterile fluid pathway connectors and fluid containers, and fluid pumps that utilize such connections, that are configured to maintain the sterility of the fluid pathway before, during, and after operation of the device, and that enable active safety controls for the device. Integration of the fluid pathway connector into a portion of the fluid container helps ensure container integrity and sterility of the fluid pathway. Additionally, by integrating the sterile fluid pathway connector into a portion of the fluid container, the connection for fluid transfer can be controlled by the user (i.e., user-activated) and enabled by the function of the drive mechanism. Accordingly, user-activation steps and the internal operation of the fluid pump can be greatly simplified by the novel integrated sterile fluid pathway connectors of the present embodiments.

[00555] In another embodiment, the fluid container comprises at least two mutable internal compartments, wherein each compartment-compartment interface comprises a distinct pierceable seal capable of being disrupted by the piercing member of the sterile fluid pathway connector to create a sterile fluid communication between the sterile fluid pathway and that compartment of the sterile fluid container. As shown in FIG. 58, container 23050 may utilize one or more seals in addition to plunger seal 230160 and pierceable seal 230156. This may be applicable, for example, when multiple fluid substances are desired to be delivered by the container and the infusion pump device. FIG. 58 shows one such embodiment that utilizes two additional seals, 230163 and 230165, to create compartments or chambers 230121A, 230121B and 230121C, within which one or more fluid substances may be stored for delivery. The embodiment of FIG. 58, pierceable seal 230156 includes seal barrier 230156C and base 230156A, which base 230156A abuts barrel lip 23058A on its distal side and connector hub 230131A on its proximal side, which abutments are held within housing 23052. Connector hub 230151 further includes vacuum port 230131B, with a channel that leads into sterile chamber 23032. Connector hub 230131 is also configured with conduit port 230131D, which provides exit from sterile fluid connector 230130 to the rest of the infusion device (e.g., an injection mechanism). Conduit port 230131D and vacuum port 230131B may each contain a membrane, filter or seals, such as one-way seals, which permit fluid flow out of chamber 23032 through the respective ports but do not permit fluid flow into the chamber 23032 through said ports. Additionally, or alternatively, conduit port 230131D and vacuum port 230131B may be plugged at certain points of assembly or operation. For example, vacuum port 230131B may be used to evacuate sterile cavity 32 during manufacturing, assembly, or at any point prior to operation of the device; and then vacuum port 230131B can be plugged after the evacuation has been completed.

[00556] Upon activation of the fluid pump, pressure at interface 230168 of plunger seal 230160 causes distal translation of plunger seal 230160 towards housing 23052. The pneumatic and/or hydraulic pressure within the fluid substance(s) held in drug chambers 230121A, 230121B and 230121C relays the force to, and causes distal translation of, chamber seal 230163, chamber seal 230165, and pierceable seal 230156, causing seal barrier 230156C to translate towards housing 23052 and become pierced by piercing member 230133. This causes the sterile fluid pathway connector to be made or opened, as described herein. Upon further translation of plunger seal 160, the fluid substance held in mutable drug chamber 230121A is dispensed through conduit 230135. Upon further translation of the fluids and seals, seal 230165 may be then be pierced by piercing member 230133, thereby permitting the fluid substance in mutable fluid chamber 230121B to be dispensed from the fluid pathway connector. If further compartments or chambers are desired, more seals and chambers (such as seal 230163 and mutable chamber 230121C) may be configured, and subsequently engaged in the same manner until plunger seal 230160 has been fully translated towards housing 23052. This configuration may offer advantages over single-compartment fluid containers. For example, a diluent may be stored in mutable fluid chamber 230121A and a therapeutic drug may be stored in mutable fluid chamber 230121B, such that the sterile fluid pathway is first purged by the diluent prior to delivery of the drug therapy to the patient. When drug combinations are desired for delivery, multiple therapeutic agents may be stored and delivered using the configuration provided by this embodiment. Any number of seals and drug chambers may be utilized in such a configuration provided that the piercing member 230133, the drive mechanism, and other components of the embodiments are configured appropriately for such delivery.

[00557] The novel integrated sterile fluid pathway connectors of the present disclosure may additionally incorporate status indication into the fluid delivery mechanisms. Such status indication features may be incorporated into the drive mechanism 23090, as described in WO 2013033467. Additionally or alternatively, status indication features may be incorporated into the components of the sterile fluid pathway connectors. In one embodiment, one or more interconnects are contained within, or proximal of, the plunger seal. At the end of fluid delivery, the piercing member may be utilized to contact the, or as a contact for, interconnect to open, close, or otherwise create a signal to the power and control system to provide feedback to the user. In another embodiment, one of either interconnects/contacts are contained within, or proximal of the plunger seal, while the other is contained within or distal of the pierceable seal, such as in or on a seal mount or guide piece. At the

end of fluid delivery, interconnects and corresponding contacts are close enough to permit a signal to be sent to the power and control system to provide feedback to the user.

[00558] In another embodiment, the surface of the connector hub sequestered in sterile chamber 23032 may incorporate, or itself be utilized as, a contact or interconnect for the status indication mechanism. For example, an end-of-delivery signal can be provided using a leaf/flex arm or spring style switch mechanism contained within sterile compartment 23032, engaged with the surface of the connector hub and connected through the hub to the appropriate electronics. In this arrangement, in the unpressurized state (before device activation), the switch rests in the open position, and there is no contact/interconnect or signal transduced. When the device is activated, i.e., when the drive engages the plunger seal within the drug container, pneumatic and/or hydraulic pressure causes the pierceable seal to translate into the piecing member, thus disrupting the pierceable seal and allowing fluid to flow through the sterile fluid connector. Pneumatic and/or hydraulic pressure further causes the septum of the pierceable seal to press against the switch mechanism until it interconnects with its complementary contacts, which closes the circuit and allows a signal to transduce to the user, indicating that drug delivery has started. At end-of-delivery, the pneumatic and/or hydraulic pressure within the sterile chamber is released and the switch re-opens, breaking the circuit and providing an end-of-delivery signal to the user.

[00559] Such a configuration, in which the surface of the connector hub sequestered in the sterile chamber of the sterile fluid pathway connector may incorporate, or itself be utilized as, a contact or interconnect for the status indication mechanism, may be facilitated by a configuration of the pierceable seal. For example, as shown in FIG. 59A to FIG. 59E, fluid chamber 23058 comprises plunger seal 230160, configured to engage a drive mechanism that forces plunger seal 230160 towards sterile fluid connector 230130. In the initial position (i.e., before the drive is engaged), pierceable seal 230356 maintains sterile chamber 23032 within the space defined by pierceable seal 230356 and connector hub 230131, particularly as partially maintained by seal mount 230134, as shown in FIG. 59A. Connector hub 230131 further includes piercing member 23033, and vacuum port or vent 131B in which sterility of chamber 23032 is maintained by filter 23039. Connector hub base 230131A, sealing member 230356A of pierceable member 230356, and barrel lip 23058A are all secured in housing 23052, which housing can be a cap such as a crimp cap. Connector hub 230131 also includes exit port 230131D, which provides an exit passage for fluid conduit 23035 from the sterile fluid pathway connector. Once a pump drive is activated and plunger seal 230160 is forced toward piercing member 23033, pneumatic and/or hydraulic pressure within mutable fluid

chamber 23021 forces seal barrier 230356C of pierceable seal 230356 into piercing member 23033, which pierces seal barrier 230356C and opens the sterile fluid pathway. Continued pneumatic and/or hydraulic pressure within mutable chamber 23021 forces at least a portion of pierceable seal 230356 to contact at least a portion of connector hub 230131 within sterile chamber 23032, as shown in FIG. 59B. This continued pneumatic and/or hydraulic pressure, as long as the drive is activated and fluid remains in mutable chamber 23021, maintains the contact between seal 230356 and connector hub 230131, as shown in FIGS. 59C and 59D. When fluid has been pumped out of mutable fluid chamber 23021, such that this chamber essentially no longer exists, pneumatic and/or hydraulic pressure against seal 230356 is released, and seal 230356 returns to a non-pressurized state within chamber 23032, in which there is no longer contact between seal 230356 and hub 230131, as shown in FIG. 59E.

[00560] This aspect of the embodiments is advantageous for a number of devices and configurations useful to provide the sterile fluid pathway connector with at least one sensor configured to indicate the status of fluid transfer from the sterile fluid container to the connector. An example of such a sensor is a "switch" mechanism contained within the sterile chamber in the sterile fluid connector. For example, in the embodiment shown in FIG. 60A to FIG. 60H, fluid container 230350 includes barrel 230358, which houses fluid chamber 230321 and plunger seal 230360, configured to engage a drive mechanism that forces plunger seal 230360 and fluid in mutable fluid chamber 230321 toward sterile fluid connector 230330. Pierceable seal 230356 maintains sterile chamber 230332 within the space defined by pierceable seal 230356 and connector hub 230331, as shown in FIG. 60A and FIG. 60B, in which the fluid pathway is "closed." Connector 230330 further includes connector hub 230331, which further vacuum port 230331B, in which sterility of chamber 230332 is maintained by filter 230339; exit port 230331D, which provides an exit passage for fluid conduit 230335 from sterile fluid pathway connector 230330; and engages piercing member 333. Connector hub base 230331A, pierceable seal 230356 sealing member 230356A, and barrel lip 230358A are secured in housing 230352. Connector hub 230331 further houses, in sterile chamber 230332, stamped ring 230391 fitted on seal mount 230334 of connector hub 230331; contact 230392; spring 230393; and interconnects 230362 which are in communication with flexible power strip 230394 (flex). As shown in FIG. 60A and FIG. 60B, in the initial state before activation of the drive, spring 230393 rests in a non-compressed state, and contact 230392 is held between spring 230393 and stamped ring 230391 in a position in which there is no contact between interconnects 230362 and contact 230392. Contact 230392 is further stabilized within sterile chamber 230332 by

the position of piercing member 230333 that passes through contact 230392 through passage 230392C.

[00561] As shown in FIG. 60C and FIG. 60D, once the drive mechanism is activated and plunger seal 230360 is forced toward piercing member 230333, as indicated by the arrow, pneumatic and/or hydraulic pressure within mutable fluid chamber 230321 forces seal barrier 230356C of pierceable seal 230356 into piercing member 230333, thereby piercing seal barrier 230356C and opening the sterile fluid pathway such that fluid can pass to sterile fluid conduit 230335. This pneumatic and/or hydraulic pressure within mutable chamber 230321 also forces at least a portion of barrier seal 230356C against at least a portion of contact 230392, such that spring 230393 is compressed until contact 230392 meets with interconnects 230362 within sterile chamber 230332, forming an interconnection. A signal can then be transduced via contact 230392, interconnect 230362, and flex 230394. Continued pneumatic and/or hydraulic pressure (see arrow), as long as the drive is activated and fluid remains in mutable chamber 230321, compresses spring 230393 and maintains the contact between seal 230356, contact 230392 and interconnect 230362, such that interconnection continues, as shown in FIG. 60E to FIG. 60F. When fluid has been pumped out of mutable fluid chamber 230321, such that this chamber essentially no longer exists and flow through the sterile fluid connector 230330 has ceased, as shown in FIG. 60G and FIG. 60H (the latter is a different sectional view of the sterile fluid pathway connector showing the position of interconnects 230362 within connector hub 230331), pneumatic and/or hydraulic pressure against seal 230356 is released, and spring 230393 returns to the non-compressed state, pushing contact 230362 back toward stamped ring 230391 and breaking interconnection between contact 230392 and interconnect 230362. Once this interconnection is broken, signal can no longer be transduced via flex 230394.

[00562] Other switch mechanisms can be designed that use the position of the membrane in pressured and unpressurized states to facilitate transduction of a signal to indicate the status of fluid transfer from the sterile fluid container to the connector. For example, as shown in FIG. 61A to FIG. 61G, connector hub 230331 can house components of a switch comprising a leaf/flex arm contacts 395. FIG. 61B, FIG. 61D and FIG. 61E show the sterile fluid pathway connector in the pre-use position, in which pierceable seal 230356 is unpierced and intact. In this position, contacts 230395 are not touching (or in close enough proximity with) interconnects 230362, and no signal can be transduced. FIG. 61C, FIG. 61F and FIG. 61G show the sterile fluid pathway connector in the activated, pressurized position, in which pneumatic and/or hydraulic pressure from the fluid

chamber has deformed barrier seal 230356C against piercing member 230333, piercing pierceable seal 230356 and opening the fluid pathway. In this position, barrier seal 230356C has further been forced against contacts 230395, such that contacts 230395 meet (or become in close enough proximity) with interconnects 230362, such that interconnection forms a signal that can be transduced via flex 230394. FIGS. 148D and 10F are perspectives (in which the barrel and housing are not shown), that illustrate the positions of pierceable seal 230356, connector hub 230331, and piercing member 230333 in pre-use and pressurized positions, respectively. FIGS. 61E and 61G are perspectives in which the barrel, housing and pierceable seal are not shown, to illustrate the positions of contacts 230395 and interconnects 230362 in pre-use (no interconnection) and pressurized (interconnected) positions, respectively.

[00563] FIG. 62A to FIG. 62D further illustrate an embodiment in which leaf/arm contacts 230395 do not form interconnection with interconnects 362 until and unless, as shown in FIG. 62B and FIG. 62D, pneumatic and/or hydraulic pressure force seal barrier 230356C onto connects 230395, which force then transferred to place contacts 230395 in contact with interconnects 230362, which then allows signal flow via flex 230394. Additionally, as shown in the embodiment of FIG. 62A to FIG. 62D, connector hub 230331 further includes internal post 230334A, a structure that limits position of contacts 230395 and membrane 230356 to avoid an over-center position that might interfere with fluid passage through the sterile fluid pathway connector.

[00564] FIG. 63A to FIG. 63D further illustrate an embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector. FIG. 63B illustrates the position of components of a sterile fluid connector 230330 in an unpressurized state, while FIG. 63C illustrates the pressurized state and FIG. 63D illustrates an end-of-delivery state. Interconnect(s) 230362 and contact(s) 230395 are situated within sterile chamber 230332 between connector hub 230331 and pierceable seal 230356, such that after pierceable seal 230356 is pierced, continued pressure within drug chamber 230321 causes interconnection between one or more interconnect(s) 230362 and one or more contact(s) 230395, which transmits a signal to the user, and which signal is terminated once pressure inside the drug chamber 321 drops and interconnection is lost, i.e., at end-of-delivery. A number of known interconnects and contacts may be used with the present embodiments, which would readily be appreciated by a skilled artisan. For example, a range of: Hall effect sensors; giant magneto resistance (GMR) or magnetic field sensors; optical sensors; capacitive or capacitance change sensors; ultrasonic sensors; and linear travel, LVDT, linear resistive, or radiometric linear resistive

sensors; and combinations thereof, which are capable of coordinating to transmit a signal to the user may be utilized for such purposes. FIG. 64A to FIG. 64C illustrate another embodiment of a sterile fluid connector capable of transmitting a signal indicating the status of fluid transfer from the sterile fluid container to the connector.

[00565] Yet another switch mechanism is shown in FIG. 65A and FIG. 65B, which show sectional and sectional isometric views of a sterile fluid pathway connector (barrel not shown). In this embodiment, sterile chamber 230332, defined in part by the position of pierceable seal 230356 seal mount 230334 and hub connection 230331. Connector hub also holds piercing member 230333 and interconnects 230362 within the sterile chamber 230332. The switch mechanism includes interconnects 230362, first compression spring 230393, contact 230392, and second compression spring 230396. In this embodiment, shown in the un-activated, depressurized state, both compression springs 230393 and 396 compress in order for contact 230392 to form an interconnection with interconnects 230362. Before and upon release of pneumatic and/or hydraulic pressure against seal barrier 230356, compression springs 230393 and 230396 decompress and interconnection is broken.

[00566] Another embodiment of a switch mechanism is shown in FIG. 66A and FIG. 66B. In this embodiment, pierceable seal 230456 comprises a conductive material or coating. Connector hub 230431 includes rib 434A, a structure that ensures that continuity between conductive pierceable seal 230456 and contacts 230462 is broken when system pressure drops at the end of fluid delivery. More specifically, as shown in FIG. 66B, in the pressurized system in which pneumatic and/or hydraulic pressure has caused conductive pierceable membrane 230456 to have been ruptured by piercing member 230433, conductive pierceable membrane 230456 must deform further proximal to rib 230434 in order to meet interconnects 230462. Once pneumatic and/or hydraulic pressure ceases, i.e., at the end of fluid delivery, conductive pierceable membrane 230456 is naturally released from interconnection by proximal to rib 230434

[00567] Yet another embodiment of a switch mechanism is shown in FIG. 67. In this embodiment, connector hub 230531 comprises conductive elastomer 230597 held in sterile chamber 230532 between connector hub 230531 and pierceable membrane 230556. In this embodiment, at least a portion of conductive elastomer 230597 is affixed to or otherwise engaged with seal mount 230534, and is configured with a centrally located aperture to allow barrier seal 230556C to be forced into contact with piercing member 230533 upon activation of the pump and creation of

pneumatic and/or hydraulic pressure against pierceable membrane 230556. Conductive elastomer 230597 is "springy" in nature and can deform (i.e., stretch) in response to distal force from pierceable seal 230556, thereby deformed into meeting interconnects 230362 under pressure from pierceable seal 230356. The elastomeric nature of conductive elastomer 230597 allows it to return to the pre-deformed state, in which there is no interconnection, in an unpressurized environment. Therefore, once pneumatic and/or hydraulic pressure ceases, i.e., at end-of-delivery, conductive elastomer film 230597 is passively released from contact with interconnections 230562, and signal is interrupted.

[00568] In another embodiment, shown in FIG. 68, the sterile fluid pathway connector includes a sensor mechanism comprising dome switch 230666, which dome is made or of includes conductive material such that dome switch 230666 can act as a contact to create a signal when dome switch 230666 meets with, or moves sufficiently close to, interconnects 230662 to complete the circuit. Dome switch 230666 is configured with at least one outer portion 230666A that resists deformation and engages with or bears against the inner wall of connector hub seal mount 230634. Alternatively, the outer deformation-resistant portion of the dome switch can be a radial ring, or any structure that will stabilize the position of the dome within the sterile fluid pathway connector. The conductive portion of the dome switch may comprise shape-memory alloy that "remembers" its dome shape, but can be deformed into a more flattened shape under pressure, then return to the dome shape once pressure is relieved. In the embodiment of FIG. 68, dome switch 230666 further comprises aperture 230666C through which piercing member 230633 can pass as dome switch 230666 is pressed in the direction of interconnects 230662. More specifically, when the pump device is actuated and pneumatic and/or hydraulic pressure builds against the pierceable membrane (not shown), the pierceable membrane is forced onto piercing member 230633 and ruptured to open the fluid pathway. Dome switch 230666 is similarly deformed by the pneumatic and/or hydraulic pressure or by the distal pressure of the deformed portion of the pierceable seal bearing against it, and dome switch 666 flattens towards interconnects 230662 to allow a signal to be transduced. Once the pneumatic and/or hydraulic pressure stops, i.e., at end-of-delivery, the dome switch returns to its pre-deformed dome shape and interconnection ceases. As shown in FIG. 68, dome switch 230666 is configured for placement under the pierceable seal (not shown), within the sterile cavity of the fluid pathway connector. The dome switch could, however, be configured to "ride" on top of the pierceable seal, and upon pressurization would be pushed in close enough proximity with interconnects 230662 to generate a signal. Alternatively, the dome switch could be made of evenly

deformable/resistant shape-memory material with the conductive portion of the dome switch configured in the outer portions or rim of the dome, and be placed "upside down" (as a bowl shape) in the sterile chamber of the fluid pathway connector. In this configuration, the pneumatic and/or hydraulic pressure against the pierced pierceable membrane would sufficiently flatten the dome until the outer conductive part of the dome made sufficient contact with interconnects positioned in the connector hub to allow a signal. Upon cessation of pressure, i.e., at end-of-delivery, the dome would pop back to its remembered dome shape, and thereby remove the connective contacts from interconnection.

[00569] As should be clear from the preceding discussions, a number of known interconnects and contacts, or similar components, are known in the art and may be utilized within the novel embodiments disclosed herein. As would readily be appreciated by one having skill in the art, a vast range of magnets, sensors, coils, and the like may be utilized to connect, transmit, or relay a signal for user feedback. Generally, any RLC circuit systems having a resistor, an inductor, and a capacitor, connected in series or in parallel, may be utilized for this purpose. For example, Hall effect sensors; giant magneto resistance (GMR) or magnetic field sensors; optical sensors; capacitive or capacitance change sensors; ultrasonic sensors; or linear travel, LVDT, linear resistive, or radiometric linear resistive sensors may be utilized as interconnects and corresponding contacts used to permit a signal to be sent to the power and control system to provide feedback to the user. The location of the contacts and interconnects may be interchanged or in a number of other configurations which permit completion of an electrical circuit or otherwise permit a transmission between the components. By use of one or more status switch interconnects and one or more corresponding electrical contacts, the status of the drive mechanism before, during, and after operation can be relayed to the power and control system to provide feedback to the user. Such feedback may be tactile, visual or auditory, and may be redundant such that more than one signals or types of feedback are provided to the user during use of the device.

[00570] Additionally, the embodiments of the present disclosure provide end-of-delivery compliance to ensure that substantially the entire fluid volume has been delivered and that the status indication features have been properly contacted to provide accurate feedback to the user. Through these mechanisms, confirmation of fluid delivery can accurately be provided to the user or administrator. Accordingly, the novel devices of the present disclosure alleviate one or more of the problems associated with prior art devices. Optionally, the drive mechanism may include one or more compliance features that enable additional axial translation of the plunger seal to, for example,

ensure that substantially the entire fluid volume has been delivered and make sure that the feedback contact mechanisms have connected. For example, in one embodiment of the present disclosure, the drive mechanism may be configured to drive further axial translation of at least a portion of the plunger seal for a compliance push of the plunger seal, or of fluid, from the fluid container. Additionally or alternatively, the plunger seal, itself, may have some compressibility permitting a compliance push. For example, when a pop-out plunger seal is employed, i.e., a plunger seal that is deformable from an initial state, the plunger seal may be caused to deform or "pop-out" to provide a compliance push. Similarly, the plunger seal may be porous, compressible, deformable, or the like to itself be capable of providing a compliance push.

[00571] As described above, the location of the contacts and interconnects may be interchanged or in a number of other configurations that permit completion of an electrical circuit or otherwise permit a transmission between the components. In one embodiment, the plunger seal may incorporate, or itself be utilized as, a contact or interconnect for the status indication mechanism (e.g., 23061 in FIG. 55C). In one embodiment, the seal mount may incorporate, or itself be utilized as, a contact or interconnect for the status indication mechanism (e.g., 23062 in FIG. 55C). In one embodiment, a guide piece may incorporate, or itself be utilized as, a contact or interconnect for the status indication mechanism (e.g., 230232 in FIG. 57A). In another embodiment, the proximal surface of the connector hub sequestered in sterile chamber 32 may incorporate, or itself be utilized as, a contact or interconnect for the status indication mechanism (e.g., FIG. 60 to FIG. 68).

[00572] Other components of the sterile fluid pathway connector may similarly be utilized for multiple functions. Alternatively, other optional components may be utilized within the novel embodiments of the present disclosure. For example, one or more optional flow restrictors may be utilized within the configurations of the fluid pathway connector described herein. In at least one embodiment, a flow restrictor may be utilized at the connection between the piercing member and the fluid conduit. The fluid pump is capable of delivering a range of fluid with different viscosities and volumes. The fluid pump is capable of delivering a fluid at a controlled flow rate (speed) or of a specified volume. In one embodiment, the fluid delivery process is controlled by one or more flow restrictors within the fluid pathway connector and/or the sterile fluid conduit. In other embodiments, other flow rates may be provided by varying the geometry of the fluid flow path or delivery conduit, varying the speed at which a component of the drive mechanism advances into the fluid container to dispense the fluid therein, or combinations thereof. In at least one embodiment of the present

disclosure, the connector hub itself may be utilized as part of the fluid path and may, optionally, function as a flow restrictor.

[00573] It will be appreciated from the above description that the fluid pathway connectors and fluid pumps disclosed herein provide an efficient and easily-operated system for automated fluid delivery from a fluid container. The novel devices of the present disclosure provide container connections which maintain the sterility of the fluid pathway and which are integrated into the fluid container, and fluid delivery pumps that incorporate such integrated sterile fluid pathway connectors to fluid containers. Such devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The devices described herein incorporate features which make activation, operation, and lock-out of the device simple for even untrained users. Because the fluid path is disconnected until fluid delivery is desired by the operator, the sterility of the fluid pathway connector, the fluid container, the fluid, and the device as a whole is maintained. These aspects of the present embodiments provide highly desirable storage, transportation, and safety advantages to the operator. Furthermore, the novel configurations of the fluid pathway connectors and drug pumps of the present disclosure maintain the sterility of the fluid path through operation of the device. Because the path that the fluid travels within the device is entirely maintained in a sterile condition, only these components need be sterilized during the manufacturing process. Such components include the fluid container of the drive mechanism, the fluid pathway connector, the sterile fluid conduit, and, when the fluid is a drug, the insertion mechanism. In at least one embodiment of the present disclosure, the power and control system, the assembly platform, the control arm, the activation mechanism, the housing, and other components of the fluid pump do not need to be sterilized. This greatly improves the manufacturability of the device and reduces associated assembly costs. Accordingly, the devices of the present disclosure do not require terminal sterilization upon completion of assembly. A further benefit of the present embodiments is that the components described herein are designed to be modular such that, for example, the fluid pathway connector and other components of the device may be integrated into a housing and readily interface to function as a fluid pump.

[00574] Assembly or manufacturing of fluid pathway connector 23030 or any of the individual components may utilize a number of known materials and methodologies in the art. For example, a number of known cleaning fluids such as isopropyl alcohol and hexane may be used to clean the components or the devices. A number of known adhesives may similarly be employed in the manufacturing process. Additionally, known siliconization or lubrication fluids and processes may

be employed during the manufacture of the novel components and devices. Furthermore, known sterilization processes may be employed at one or more of the manufacturing or assembly stages to ensure the sterility of the final product.

[00575] The fluid pathway connector may be assembled in a number of methodologies. In one method of assembly, the sterile fluid pathway connector may be assembled, e.g., as shown in FIG. 56A and FIG. 56B, and then attached, mounted, connected, or otherwise integrated into fluid container 23050 such that at least a portion of the pierceable seal 23056 is contained within the fluid container 23050. The fluid container 23050 may then be filled with a fluid and plugged with a plunger seal 23060 at an end opposite the pierceable seal 23056. The barrel 23058 may be filled with a fluid through the open proximal end prior to insertion of the plunger seal 23060 from the proximal end of the barrel 23058. The drive mechanism 23090 may then be attached to the proximal end of the fluid container 23050 such that a component of the drive mechanism 23090 is capable of contacting the plunger seal 23060. The insertion mechanism 23070 may be assembled and attached to the other end of the fluid conduit 23035. This entire sub-assembly, including drive mechanism 23090, fluid container 23050, fluid pathway connector 23030, fluid conduit 23035, and insertion mechanism 23070, may be sterilized by known techniques before assembly into the drug delivery device. Certain components of this sub-assembly may be mounted to an assembly platform within the housing 12A, 12B or directly to the interior of the housing 12A, 12B, while other components may be mounted to a guide, channel, or other component or aspect for activation by the user.

[00576] Manufacturing of a fluid pump includes the step of attaching both the fluid pathway connector and fluid container, either separately or as a combined component, to an assembly platform or housing of the drug pump. The method of manufacturing further includes attachment of the drive mechanism, fluid container, and insertion mechanism to the assembly platform or housing. The additional components of the fluid pump, as described above, including the power and control system, the activation mechanism, and the control arm may be attached, preformed, or pre-assembled to the assembly platform or housing. An adhesive patch and patch liner may be attached to the housing surface of the drug pump that contacts the user during operation of the device.

[00577] A method of operating the fluid pump includes one or more of the following steps: activating, by a user, the activation mechanism; displacing a control arm to actuate an insertion mechanism; activating a drive control mechanism to push the plunger seal, connect the sterile fluid pathway connector, and drive fluid flow through the fluid pump, wherein translating the fluid

pathway connector causes a pierceable seal to be pierced by a piercing member thereby opening a fluid path from the fluid container to the fluid pathway connector. The drive control mechanism may be activated by actuating a power and control system. The method may further include the step of: engaging an optional on-body sensor prior to activating the activation mechanism. Furthermore, the method of operation may include translating a plunger seal within the drive control mechanism and fluid container to force fluid drug flow through the fluid container, the fluid pathway connector, a sterile fluid conduit, and, optionally the insertion mechanism for delivery of the fluid to the body of a user.

[00578] VIII. Multi-Function Drive Mechanism

[00579] At least some of the drug delivery devices described in this application, including at least those described in connection with Figs. 1A-2B and 33A-33C, may be configured to incorporate the embodiments of the drive mechanism described below in connection with Figs. 69A-77C. The embodiments of the drive mechanism described below in connection with Figs. 69A-77C may be used to replace, in its entirety or partially, the above-described drive mechanisms 100, 6100, or 8100, or any other drive mechanism described herein, where appropriate.

[00580] The present disclosure provides multi-function drive mechanisms for the controlled delivery of drug substances, controlled drug delivery pumps with such drive mechanisms, the methods of operating such devices, and the methods of assembling such devices. Notably, the multi-function drive mechanisms of the present disclosure enable or initiate several functions, including: (i) controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container; (ii) triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a user; and (iii) connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. The embodiments of the present disclosure thus are capable of delivering drug substances at variable rates. The drive mechanisms of the present disclosure may be pre-configurable or dynamically configurable, such as by control by the power and control system, to meet desired delivery rates or profiles, as explained in detail below. Additionally, the drive mechanisms of the present disclosure provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug

delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication. Because the end-of-dose indication is related to the physical end of axial translation and/or travel of one or more components of the drive mechanism, the drive mechanism and drug delivery device provide a true end-of-dose indication to the user. Through these mechanisms, confirmation of drug dose delivery can accurately be provided to the user or administrator. Accordingly, the devices of the present disclosure alleviate one or more of the problems associated with prior art devices, such as those referred to above.

[00581] In a first embodiment, the present disclosure provides a multi-function drive mechanism which includes an actuator, a gear assembly including a main gear, a drive housing, and a drug container having a cap, a pierceable seal (not visible), a barrel, and a plunger seal. The main gear may be, for example, a star gear disposed to contact multiple secondary gears or gear surfaces. A drug chamber, located within the barrel between the pierceable seal and the plunger seal, may contain a drug fluid for delivery through the insertion mechanism and drug delivery device into the body of the user. A piston, and one or more biasing members, wherein the one or more biasing members are initially retained in an energized state and is configured to bear upon an interface surface of the piston, may also be incorporated in the multi-function drive mechanism. The piston is configured to translate substantially axially within a drug container having a plunger seal and a barrel. A tether is connected at one end to the piston and at another end to a winch drum/gear of a regulating mechanism, wherein the tether restrains the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The drug container may contain a drug fluid within a drug chamber for delivery to a user. Optionally, a cover sleeve may be utilized between the biasing member and the interface surface of the piston to hide the interior components of the barrel (namely, the piston and the biasing member) from view during operation of the drive mechanism. The tether is configured to be released from a winch drum/gear of a regulating mechanism of the multi-function drive mechanism to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon.

[00582] In at least one embodiment of the present disclosure, the regulating mechanism is gear assembly driven by an actuator of the multi-function drive mechanism. The regulating mechanism retards or restrains the distribution of tether, only allowing it to advance at a regulated or desired rate. This restricts movement of piston within barrel, which is pushed by one or more biasing members, hence controlling the movement of plunger seal and delivery of the drug contained in

chamber. As the plunger seal advances in the drug container, the drug substance is dispensed through the sterile pathway connection, conduit, insertion mechanism, and into the body of the user for drug delivery. The actuator may be a number of power/motion sources including, for example, a motor (e.g., a DC motor, AC motor, or stepper motor) or a solenoid (e.g., linear solenoid, rotary solenoid). In a particular embodiment, the actuator is a rotational stepper motor with a notch that corresponds with the gear teeth of the main/star gear.

[00583] The regulating mechanism may further include one or more gears of a gear assembly. One or more of the gears may be, for example, compound gears having a small diameter gear attached at a shared center point to a large diameter gear. The gear assembly may include a winch gear coupled to a winch drum/gear upon which the tether may be releasably wound. Accordingly, rotation of the gear assembly initiated by the actuator may be coupled to winch drum/gear (i.e., through the gear assembly), thereby controlling the distribution of tether, the rate of expansion of the biasing members and the axial translation of the piston, and the rate of movement of plunger seal within barrel to force a fluid from drug chamber. The rotational movement of the winch drum/gear, and thus the axial translation of the piston and plunger seal, are metered, restrained, or otherwise prevented from free axial translation by other components of the regulating element, as described herein. Notably, the regulating mechanisms of the present disclosure do not drive the delivery of fluid substances from the drug chamber. The delivery of fluid substances from the drug chamber is caused by the expansion of the biasing member from its initial energized state acting upon the piston and plunger seal. The regulating mechanisms instead function to provide resistance to the free motion of the piston and plunger seal as they are pushed by the expansion of the biasing member from its initial energized state. The regulating mechanism does not drive the delivery but only controls the delivery motion. The tether limits or otherwise restrains the motion of the piston and plunger seal, but does not apply the force for the delivery.

[00584] In addition to controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container (thereby delivering drug substances at variable rates and/or delivery profiles); the multi-function drive mechanisms of the present disclosure may concurrently or sequentially perform the steps of: triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a user; and connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. In at least one embodiment, initial motion by the actuator of the multi-function drive mechanism

causes rotation of main/star gear. In one manner, main/star gear conveys motion to the regulating mechanism through gear assembly. In another manner, main/star gear conveys motion to the needle insertion mechanism through gear. As gear is rotated by main/star gear, gear engages the needle insertion mechanism to initiate the fluid pathway connector into the user, as described in detail above. In one particular embodiment, needle insertion mechanism is a rotational needle insertion mechanism. Accordingly, gear is configured to engage a corresponding gear surface of the needle insertion mechanism. Rotation of gear causes rotation of needle insertion mechanism through the gear interaction between gear of the drive mechanism and corresponding gear surface of the needle insertion mechanism. Once suitable rotation of the needle insertion mechanism occurs, the needle insertion mechanism may be initiated to create the fluid pathway connector into the user, as described in detail herein.

[00585] In at least one embodiment, rotation of the needle insertion mechanism in this manner may also cause a connection of a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. Ramp aspect of needle insertion mechanism is caused to bear upon a movable connection hub of the sterile fluid pathway connector. As the needle insertion mechanism is rotated by the multi-function drive mechanism, ramp aspect of needle insertion mechanism bears upon and translates movable connection hub of the sterile fluid pathway connector to facilitate a fluid connection therein. In at least one embodiment, the needle insertion mechanism may be configured such that a particular degree of rotation enables the needle/trocar to retract as detailed above. Additionally or alternatively, such needle/trocar retraction may be configured to occur upon a user-activity or upon movement or function of another component of the drug delivery device. In at least one embodiment, needle/trocar retraction may be configured to occur upon end-of-drug-delivery, as triggered by, for example, the regulating mechanism and/or one or more of the status readers as described herein.

[00586] In yet another embodiment, the drive mechanism may include a status reader configured to read or recognize one or more corresponding status triggers. The status triggers may be incrementally spaced on the tether, wherein, during operation of the drive mechanism, interaction between the status reader and the status triggers transmit a signal to a power and control system to provide feedback to a user. The status reader may be an optical status reader and the corresponding status triggers are optical status triggers, an electromechanical status reader and the

corresponding status triggers are electromechanical status triggers, or a mechanical status reader and the corresponding status triggers are mechanical status triggers.

[00587] In a further embodiment, the present disclosure provides a drug delivery pump with controlled drug delivery. The drug delivery pump having a housing and an assembly platform, upon which an activation mechanism, an insertion mechanism, a fluid pathway connector, a power and control system, and a controlled delivery drive mechanism may be mounted, said drive mechanism having a drive housing, a piston, and a biasing member, wherein the biasing member is initially retained in an energized state and is configured to bear upon an interface surface of the piston. The piston is configured to translate substantially axially within a drug container having a plunger seal and a barrel. A tether is connected at one end to the piston and at another end to a winch drum/gear of a delivery regulating mechanism, wherein the tether restrains the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The drug container may contain a drug fluid within a drug chamber for delivery to a user. Optionally, a cover sleeve may be utilized between the biasing member and the interface surface of the piston to hide the interior components of the barrel (namely, the piston and the biasing member) from view during operation of the drive mechanism. The tether is configured to be released from a winch drum/gear of the delivery regulating mechanism to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon.

[00588] In another embodiment, the drug delivery device further includes a gear assembly. The gear assembly may include a winch gear connected to a winch drum/gear upon which the tether may be releasably wound, rotation of the winch drum/gear releases the tether from the winch drum/gear to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The metering of the tether controls the rate or profile of drug delivery to a user. The piston may be one or more parts and connects to a distal end of the tether. The winch drum/gear is coupled to a regulating mechanism which controls rotation of the winch drum/gear and hence metering of the translation of the piston.

[00589] In yet another embodiment, the drug delivery device may include a status reader configured to read or recognize one or more corresponding status triggers. The status triggers may be incrementally spaced on the tether, wherein, during operation of the drive mechanism, interaction between the status reader and the status triggers transmit a signal to a power and control

system to provide feedback to a user. The status reader may be an optical status reader and the corresponding status triggers are optical status triggers, an electromechanical status reader and the corresponding status triggers are electromechanical status triggers, or a mechanical status reader and the corresponding status triggers are mechanical status triggers.

[00590] In another embodiment, the power and control system of the drug delivery device is configured to receive one or more inputs to meter the release of the tether by the winch drum/gear and thereby permit axial translation of the piston by the biasing member to translate a plunger seal within a barrel. The one or more inputs may be provided by the actuation of the activation mechanism, a control interface, and/or a remote control mechanism. The power and control system may be configured to receive one or more inputs to adjust the restraint provided by the tether and winch drum/gear on the free axial translation of the piston upon which the biasing member bears upon to meet a desired drug delivery rate or profile, to change the dose volume for delivery to the user, and/or to otherwise start, stop, or pause operation of the drive mechanism.

[00591] In at least one embodiment of the present disclosure, the delivery profile of the medicament is adjustable. For example, it may be desirable to deliver a bolus injection of medicament before, during, or subsequent to certain activities such as eating, exercising, sleeping, etc. A "bolus injection" is any measured drug volume that is delivered often irrespective of the delivery time or duration. Conversely, a "basal injection" is often a controlled rate of delivery and/or a drug delivery profile having various rates of delivery at different time intervals. Similarly, the user may desire to increase or decrease the basal delivery rate of the medicament at these or other times. In at least one embodiment, the delivery profile may be adjustable by the user to achieve this desired drug delivery. The user may adjust the delivery profile by interacting with the drug delivery device itself or, alternatively, may use an external device, such as a smart-phone, to do so. For example, the user may adjust the delivery profile by displacing the activation mechanism or may engage a separate device-integrated or external delivery control mechanism.

[00592] In another embodiment of the present disclosure, the delivery profile may be adjusted automatically based on one or more inputs. For example, the delivery profile may be adjusted based on the patient's activity level, heart rate, blood sugar level, blood pressure, etc. As above, these measurements may be used to determine the need for a bolus injection or for the increase or decrease of the basal injection delivery rate or adjustment to the basal injection delivery profile. In at least one embodiment, these input measurements may be monitored by the device itself.

Additionally, or alternatively, they may be monitored by a secondary device such as a smart-phone, smart watch, heart rate monitor, glucose monitor, blood pressure monitor, or the like. In some embodiments, the delivery profile may be adjusted based on these measurements with no required user intervention. In the case of monitoring and/or control by a secondary device, the secondary device and drug delivery device may be in wireless or wired communication with one another. This communication may be through Bluetooth, near field communication, Wi-Fi, or any other method known to one having ordinary skill in the relevant art of device interconnectivity.

[00593] In a preferred embodiment, however, the monitoring/adjustment mechanism may alert and make recommendations to the user and the user may have active control to initiate/authorize or disregard the recommendation made by the monitoring/adjustment mechanism. For example, if one or more of the measurements is above or below a specified threshold value the device may emit an audible, visual, or tactile alert to the user. In one example, the alert is provided by a vibration of the device, thereby providing a discrete alert to the user. Additionally or alternatively, the alert may be provided by the user's smart-phone or other secondary device. The user may be able to view the current status of the measurements in a computer program or web interface on the device itself, a computer, smart-phone, or other device. The computer program or web interface may provide a recommended adjustment to the delivery profile. Based on this information, the user may adjust the delivery rate of the drug delivery device. As above, the user may adjust the delivery profile by displacing the activation mechanism or engaging a separate device-integrated or external delivery control mechanism.

[00594] In one embodiment, in response to a signal to adjust the delivery profile, either based on user input or based on the measurements described above, the power and control system may cause a change in the rate of movement of the actuator. The change in the rate of movement of the actuator causes a change in the rotation rate of the regulating mechanism which, in turn, controls the rate of drug delivery to the user. Alternatively, the delivery profile may be altered by a change in the characteristics of the flow path of medicament through the conduit connecting the drug container and insertion mechanism. The change may be caused by the introduction, removal, or modification of a flow restrictor which restricts flow of medicament from the drug container to the insertion mechanism. For example, a flow restrictor may have multiple flow paths which may be selectively placed in fluid communication with an input and an output of the flow restrictor. By providing flow paths which are of different length or cross-section the rate of delivery may be controlled. In other embodiments, the delivery profile may be altered by the introduction or removal

of an impingement of the conduit. An impingement of the flow path may interrupt or slow flow of medicament through the conduit, thereby controlling the rate of delivery to the user. Accordingly, one or more embodiments of the present disclosure are capable of producing a change to the rate of medicament delivery from the drug container thereby providing a dynamic control capability to the multi-function drive mechanism and/or the drug delivery device.

[00595] The embodiments of the present disclosure provide drive mechanisms which are capable of metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thereby, controlling the rate of delivery of drug substances. The control delivery drive mechanisms are additionally capable of providing the incremental status of the drug delivery before, during, and after operation of the device. Throughout this specification, unless otherwise indicated, "comprise," "comprises," and "comprising," or related terms such as “includes” or “consists of,” are used inclusively rather than exclusively, so that a stated integer or group of integers may include one or more other non-stated integers or groups of integers. As will be described further below, the embodiments of the present disclosure may include one or more additional components which may be considered standard components in the industry of medical devices. For example, the embodiments may include one or more batteries utilized to power the motor, drive mechanisms, and drug delivery devices of the present disclosure. The components, and the embodiments containing such components, are within the contemplation of the present disclosure and are to be understood as falling within the breadth and scope of the present disclosure.

[00596] The present disclosure provides systems and methods that are related to delivery of drug substances at a predetermined time and at an adjusted delivery rate. Particularly, the present disclosure relates to drug delivery device delivery devices that include control systems and sub-systems that are configured to control and drive multi-function drive mechanisms. Additionally, the control systems and sub-systems may be configured to deliver drug substances at appropriate delivery rates after a certain wait time period has elapsed.

[00597] In one example, a user may be provided with a pre-filled drug delivery pump device to inject the drug substance via the parenteral method. In such an example, activation of the pump device may establish short range communication with a mobile device (e.g., a smart phone). In one embodiment, the drug delivery device delivery device may be activated by press of an activation button or a power button. The mobile device may include one or more mobile applications that may

be configured to process, receive and transmit data related to the drug delivery process. The mobile application may communicate with external sensors (e.g., a heart rate sensor and a glucose rate sensor) and receive information (e.g., heart rate of the user, glucose/ insulin information, etc.) related to the health and/or state of the patient during a monitoring period. The mobile application may further calculate an adjusted delivery rate for the drug based on the data received from the sensors.

[00598] Moreover, the drug delivery device may request user-activation for the needle insertion, after the device has been activated. The drug delivery device may provide visual or audio cues for the needle activation or, alternatively, cause the mobile device to provide the request notification for needle activation. When the needle insertion has been actuated by the user, the drug delivery device may then initiate a timer to track a wait time period, prior to the delivery of the drug. Alternatively, the timer may be initiated upon activation of the device. The drug delivery device may optionally monitor the temperature to determine whether the drug has reached an optimal temperature for delivery. Additionally, the power and control system may be configured to determine whether the predetermined wait time period has elapsed, and based on the determination may notify the user about the initiation of the drug delivery process. Optionally, the user may have the option of initiating drug delivery after the predetermined wait time has elapsed.

[00599] It is noted that, based on the type of the drug and the dose, the drug delivery device may regulate the delivery rate of the drug. The regulation and/or adjustment of the delivery rate may also be based on information received from sensors (e.g., temperature sensor, heart rate sensor, glucose monitor sensor).

[00600] The drug delivery device may further determine whether the drug delivery has ended, and based on the determination, may transmit the end of drug delivery information to the mobile device.

[00601] The mobile device may further provide the received end of delivery information to a remote server (e.g., a cloud computer server). The end of delivery information may include, but not limited to, end of delivery indication, delivery rate, delivery start and end times, total delivery time, drug temperature, and data gathered by the sensors. The information may also include information related to the drug and/or pump device such as drug volume, manufacturing date, filling date, serial/lot number, etc.

[00602] Moreover, the drug delivery device may switch between an active power mode and a non-active power mode. During the active power mode, the power and control system may interact with one or more motors of a drive control system to actuate one or more drive mechanisms, and as such, both the power and control system and the motors may receive power from an energy source (e.g., batteries). On the other hand, in some instances, the power and control system may not need to interact with the drive control system to execute one or more operations of the drug delivery pump device. For example, the drug delivery device may establish and communicate with the mobile device, or monitor temperature of the drug without interacting with the drive control system of the drug delivery device. In such instances, the power and control system may only be powered, and the drive control system may not receive power from the batteries. Additionally, one or more components or functions of the pump device may be powered intermittently in one or more modes.

[00603] The switching between the active power mode and the non-active power mode may substantially save power resources of the drug delivery device. For example, upon switching to the non-active power mode, the drug delivery device does not need to provide power to the motors, which may, otherwise, significantly drain the batteries.

[00604] Particularly, during the active power mode, the power and control system of the drug delivery pump device controls the multi-function drive mechanisms to initiate several sub-systems or functions, including: (i) controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container; (ii) triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a user; and (iii) connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user.

[00605] The drive mechanisms of the present disclosure control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thus, are capable of delivering drug substances at variable rates and/or delivery profiles. Additionally, the drive mechanisms of the present disclosure may include integrated status indication features, such as sensors, which may provide feedback to the power and control system, and in turn, to the user before, during, and after drug delivery. For example, the user may be prompted by one or more sensors to identify that the devices are operational and ready for drug delivery. Upon activation of one or more devices, the

sensors may provide one or more drug delivery status indications to the user such as an end-of-dose indication at completion of drug delivery.

[00606] As used herein to describe the drive mechanisms, drug delivery pumps, or any of the relative positions of the components of the present disclosure, the terms "axial" or "axially" refer generally to a longitudinal axis "A" around which the drive mechanisms are preferably positioned, although not necessarily symmetrically there-around. The term "radial" refers generally to a direction normal to axis A. The terms "proximal," "rear," "rearward," "back," or "backward" refer generally to an axial direction in the direction "P". The terms "distal," "front," "frontward," "depressed," or "forward" refer generally to an axial direction in the direction "D". As used herein, the term "glass" should be understood to include other similarly non-reactive materials suitable for use in a pharmaceutical grade application that would normally require glass, including but not limited to certain non-reactive polymers such as cyclic olefin copolymers (COC) and cyclic olefin polymers (COP). The term "plastic" may include both thermoplastic and thermosetting polymers. Thermoplastic polymers can be re-softened to their original condition by heat; thermosetting polymers cannot. As used herein, the term "plastic" refers primarily to moldable thermoplastic polymers such as, for example, polyethylene and polypropylene, or an acrylic resin, that also typically contain other ingredients such as curatives, fillers, reinforcing agents, colorants, and/or plasticizers, etc., and that can be formed or molded under heat and pressure. As used herein, the term "plastic" is not meant to include glass, non-reactive polymers, or elastomers that are approved for use in applications where they are in direct contact with therapeutic liquids that can interact with plastic or that can be degraded by substituents that could otherwise enter the liquid from plastic. The term "elastomer," "elastomeric" or "elastomeric material" refers primarily to cross-linked thermosetting rubbery polymers that are more easily deformable than plastics but that are approved for use with pharmaceutical grade fluids and are not readily susceptible to leaching or gas migration under ambient temperature and pressure. "Fluid" refers primarily to liquids, but can also include suspensions of solids dispersed in liquids, and gasses dissolved in or otherwise present together within liquids inside the fluid-containing portions of the drug pumps. According to various aspects and embodiments described herein, reference is made to a "biasing member", such as in the context of one or more biasing members for asserting force on a plunger seal. It will be appreciated that the biasing member may be any member that is capable of storing and releasing energy. Non-limiting examples include a spring, such as for example a coiled spring, a compression or extension spring, a torsional spring, or a leaf spring, a resiliently compressible or elastic band, or any other member

with similar functions. In at least one embodiment of the present disclosure, the biasing member is a spring, preferably a compression spring.

[00607] The devices of the present disclosure provide drive mechanisms with integrated status indication and drug delivery pumps which incorporate such drive mechanisms. Such devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The devices described herein incorporate features which make activation, operation, and lock-out of the device simple for even untrained users. The devices of the present disclosure provide these desirable features without any of the problems associated with known prior art devices. Certain non-limiting embodiments of the drug delivery pumps, drive mechanisms, and their respective components are described further herein with reference to the accompanying figures.

[00608] As used herein, the terms "pump" and "delivery device" are intended to include any number of drug delivery systems which are capable of dispensing a fluid to a user upon activation. Such drug delivery systems include, but are not limited to, for example, injection systems, infusion pumps, bolus injectors, on-body injectors, and the like. FIGS. 69A-69C show an exemplary drug delivery device according to at least one embodiment of the present disclosure with the top housing removed so that the internal components are visible. The drug delivery device may be utilized to administer delivery of a drug treatment into a body of a user. As shown in FIGS. 69A-69C, the drug delivery device 9010 includes a pump housing 9012. Pump housing 9012 may include one or more housing subcomponents which are fixedly engageable to facilitate easier manufacturing, assembly, and operation of the drug pump. For example, drug delivery device 9010 includes a pump housing 9012 which may include an upper housing and a lower housing (not shown for ease of viewing internal components). The pump housing 9012 may include one or more tamper evidence features to identify if the drug delivery device has been opened or tampered with. For example, the pump housing 9012 may include one or more tamper evidence labels or stickers, such as labels that bridge across the upper housing and the lower housing. Additionally or alternatively, the housing 9012 may include one or more snap arms or prongs connecting between the upper housing and the lower housing. A broken or altered tamper evidence feature would signal to the user, the physician, the supplier, the manufacturer, or the like, that the drug delivery device has potentially been tampered, e.g., by accessing the internal aspects of the device, so that the device is evaluated and possibly discarded without use by or risk to the user. The drug delivery device may further include an activation mechanism, a status indicator, and a window. Window may be any translucent or transmissive surface through which the operation of the drug delivery device may be viewed. As

shown in FIG. 69B, drug delivery device 9010 further includes assembly platform 9020, sterile fluid conduit 9030, drive mechanism 90100 having drug container 9050, insertion mechanism 90200, fluid pathway connector 90300, and a power and control system (not shown). One or more of the components of such drug delivery devices may be modular in that they may be, for example, pre-assembled as separate components and configured into position onto the assembly platform 9020 of the drug delivery device 9010 during manufacturing.

[00609] The pump housing 9012 contains all of the device components and provides a means of removably attaching the device 9010 to the skin of the user. The pump housing 9012 also provides protection to the interior components of the device 9010 against environmental influences. The pump housing 9012 is ergonomically and aesthetically designed in size, shape, and related features to facilitate easy packaging, storage, handling, and use by users who may be untrained and/or physically impaired. Furthermore, the external surface of the pump housing 9012 may be utilized to provide product labeling, safety instructions, and the like. Additionally, as described above, housing 9012 may include certain components, such as one or more status indicators (e.g., LED lights, audio tones via speakerphones) and windows, which may provide operation feedback to the user.

[00610] In one example, the power and control system may be configured to provide a number of different status indications to the user. For example, the power and control system may be configured such that after the on-body sensor (e.g., skin sensor) is triggered, the power and control system provides a ready-to-start status signal via the status indicator (e.g., audio tones and/or blinking lights) if device start-up checks provide no errors. After providing the ready-to-start status signal and, in an embodiment with the optional on-body sensor, if the on-body sensor remains in contact with the body of the user, the power and control system will power the drive mechanism 90100 to begin delivery of the drug treatment through the fluid pathway connector 90300 and sterile fluid conduit 9030.

[00611] Additionally, the power and control system may be configured to identify removal of the drug delivery device from its packaging. The power and control system may be mechanically, electronically, or electro-mechanically connected to the packaging such that removal of the drug delivery device from the packaging may activate or power-on the power and control system for use, or simply enable the power and control system to be powered-on by the user. In such an embodiment, without removal of the drug delivery device from the packaging the drug delivery

device cannot be activated. This provides an additional safety mechanism of the drug delivery device and for the user. In at least one embodiment, the drug delivery device or the power and control system may be electronically or electro-mechanically connected to the packaging, for example, such as by one or more interacting sensors from a range of: Hall effect sensors; giant magneto resistance (GMR) or magnetic field sensors; optical sensors; capacitive or capacitance change sensors; ultrasonic sensors; and linear travel, LVDT, linear resistive, or radiometric linear resistive sensors; and combinations thereof, which are capable of coordinating to transmit a signal between components to identify the location there-between.

[00612] Additionally or alternatively, the drug delivery device or the power and control system may be mechanically connected to the packaging, such as by a pin and slot relationship which activates the system when the pin is removed (i.e., once the drug delivery device is removed from the packaging).

[00613] In a preferred embodiment of the present disclosure, once the power and control system has been activated, and after a predetermined wait time period, the multi-function drive mechanism is initiated to actuate the drug fluid to be forced from the drug container.

[00614] During the drug delivery process, the power and control system may be further configured to provide a dispensing status signal via the status indicator. After the drug has been administered into the body of the user and after the end of any additional dwell time, to ensure that substantially the entire dose has been delivered to the user, the power and control system may provide an okay-to-remove status signal via the status indicator. This may be independently verified by the user by viewing the drive mechanism and drug dose delivery through the window of the pump housing 9012. Additionally, the power and control system may be configured to provide one or more alert signals via the status indicator, such as for example alerts indicative of fault or operation failure situations.

[00615] The power and control system may additionally be configured to accept various inputs (e.g., via an activation button) from the user to dynamically control the drive mechanisms 90100 to meet a desired drug delivery rate or profile. For example, the power and control system may receive inputs, such as from partial or full activation, depression, and/or release of the activation mechanism, to set, initiate, stop, or otherwise adjust the control of the drive mechanism 90100 via the power and control system to meet the desired drug delivery rate or profile. Similarly, the power and control system may be configured to receive such inputs to initiate communication

with the mobile device, adjust the drug dose volume, to prime the drive mechanism, fluid pathway connector, and fluid conduit; and/or to start, stop, or pause operation of the drive mechanism 90100. Such inputs may be received by the user directly acting on the drug delivery device 9010, such as by use of the activation mechanism 9014 or a different control interface, or the power and control system may be configured to receive such inputs from a remote device (e.g., a mobile device). Additionally or alternatively, such inputs may be pre-programmed.

[00616] Other power and control system configurations may be utilized with the drug delivery devices of the present disclosure. For example, certain activation delays may be utilized prior to, or during drug delivery. For example, a wait-time period may be a pre-determined time that may be set in the power and control system, and which may delay the delivery of the drug by the pre-determined amount of time. As mentioned above, one such delay optionally included within the system configuration is a dwell time which ensures that substantially the entire drug dose has been delivered before signaling completion to the user. Similarly, activation of the device may require a delayed depression (i.e., pushing) of the activation mechanism of the drug delivery device 9010 prior to drug delivery device activation. Additionally, the system may include a feature which permits the user to respond to the end-of-dose signals and to deactivate or power-down the drug delivery device. Such a feature may similarly require a delayed depression of the activation mechanism, to prevent accidental deactivation of the device. Such features provide desirable safety integration and ease-of-use parameters to the drug delivery devices. An additional safety feature may be integrated into the activation mechanism to prevent partial depression and, therefore, partial activation of the drug delivery devices. For example, the activation mechanism and/or power and control system may be configured such that the device is either completely off or completely on, to prevent partial activation. Such features are described in further detail hereinafter with regard to other aspects of the drug delivery devices.

[00617] In one embodiment, the drug delivery pump device 9010 may include one or more control systems such as, but not limited to, power and control system 90800 and drive control system 90820. As disclosed above, the drug delivery pump 9010 may further include various mechanisms or sub-systems such as, but not limited to, drive mechanism or sub-system 90100, needle insertion mechanism (NIM) or sub-system 90200, sterile fluid pathway connector (SFPC) or sub-system 90300, and regulating mechanism or sub-system 90500. In some examples, the control systems may include printed circuit board (PCB), motherboards and/or daughter boards.

[00618] In some embodiments, the sub-systems may be included in the control systems. For example, the drive control system 90820 may include the drive sub-system 90100, NIM sub-system 90200, and/or the regulating sub-system 90500. In such examples, the power and control system 90800 may control the sub-systems by sending command signals to the drive control system 90820.

[00619] In other examples, the drive control system 90820 may not include the sub-systems. As such, in those examples, the power and control system 90800 may control the sub-systems via the drive control system 90820. For example, the power and control system 90800 may send command signals to the drive control system 90820. The drive control system 90820, for example, may then selectively control one or more of the sub-systems based on the received command signals from the power and control system 90810.

[00620] Yet in another embodiment, the power and control system 90800 may directly control the sub-systems. In that embodiment, the sub-systems may include respective control units or controller and storage units (not shown) that may be configured to directly communicate with the power and control system 90800.

[00621] Alternatively, in some implementations, the power and control system 90800 may include the drive control system 90820 and the sub-systems, and one or more other control systems and sub-systems.

[00622] As shown in FIG. 76A, in one exemplary embodiment, the power and control system 90800 may be included in the drug delivery pump 9010. The power and control system 90800 may include one or more control units that are connected to one or more sensors, timers and storage units of the drug delivery pump 9010.

[00623] In some implementations, the power and control system 90800 may be configured to control a delay time period related to drug delivery. In such implementations, the power and control system 90800 may monitor and control time parameters for initiating and delivering the drug after the activation of the drug delivery pump 9010. For example, upon the activation of the device 9010, the power and control system 90800 may monitor a wait period time (e.g., a predetermined delay time) prior to the initiation of the drug delivery. In one example, during the wait period, the power and control system 90800 may optionally prime the device.

[00624] In one example, the power and control system 90800 may provide request notification to activate the NIM mechanism after the device has been activated. The request notification may be provided directly by the drug delivery device delivery device 9010, or via the mobile device 9011.

Upon notifying the user to initiate the NIM mechanism 90200, the power and control system may further determine whether an activation/initiation signal (e.g., from the user) is received via the activation button.

[00625] When the power and control system 90800 determines that the activation signal is received (e.g., within an NIM activation predetermined time), the power and control system may cause the NIM sub-system to activate. Alternatively, the NIM may be directly activated by the user. The power and control system 90800 may further notify the user that the delivery of the drug has been initiated. It is noted that, the power and control system 800 may activate the NIM mechanism upon receiving the activation signal related for the NIM activation and, upon further receiving signal from on-body sensor that indicates that the drug delivery device 9010 is sensing the skin of the user. Optionally, when the power and control system determines that the activation signal is not received, and/or the on-body sensor is not sensing a skin portion of the user, the power and control system 90800 may notify the user (e.g., via an audible tone), and optionally terminate drug delivery process.

[00626] Moreover, in some implementations, when the power and control system 90800 determines that the wait period time has elapsed, the power and control system may notify the user about the initiation of the delivery of the drug. The power and control system may further notify the user that the delivery of the drug has been initiated.

[00627] Optionally, the power and control system 90800 may further notify the user of a time period of the drug delivery (e.g., the total time that will be taken for delivering the drug). The power and control system 90800 may communicate the notification to an external device via the communication unit 90830.

[00628] Upon the initiation of the drug delivery, the power and control system may further control timing and/or rate parameters for the drug delivery. For example, the power and control system may control the regulating sub-system or mechanism to deliver the drug in a given period of time. Moreover, the power and control system may process various data captured by the internal and external sensors to determine the timing and/or rate parameters for the drug delivery. Based on the determination, the power and control system may deliver the drug to the user within the appropriate time period.

[00629] The power and control system may or may not include all the elements of the power and control system 90800, and/or may include additional elements. Additionally, in some examples, the

drug delivery device 9010 may include one or more control systems, including, but not limited to, the power and control system, and may include additional elements for the operations of the drug delivery device.

[00630] In some implementations, control system 90800 may include a main control unit or control unit 90810. The main control unit 90810 may include one or more controllers, microcontrollers, microprocessors, or application specific integrated circuits (ASICs). Main control unit 90810 may be implemented as hardware or a combination of hardware and software that may be programmed with instructions. The main control unit 90810 may be configured to execute such instructions to effect various operations of the drug delivery device 9010. Moreover, the power and control system or the main control unit 90810 may communicate, for example, by receiving and/or sending signal or data to and from the communication unit 90830, timer unit 90812, storage unit 90813, on-body sensor 90840, temperature sensor 90880, and I/O unit 90850. The main control unit 90810 may process and interpret the data collected or monitored by the various elements in the one or more control systems in order to determine and execute various functions and operations of the drug delivery device 9010.

[00631] It is noted that, the drug delivery device 9010 may operate in two power modes, namely, an active power mode and a non-active power mode. During the active power mode, the power and control system 90800 and the motor 90101 may receive power from the power source (e.g., batteries), and the power and control system 90800 may command the drive control system 90820 to drive various operations, such as the NIM mechanism 90200, and/or regulating mechanism 90500. Whereas, during the non-active power mode, the power and control system 90800 may be powered, and the motor 90101 may not be powered. During the non-active power mode, the power and control system 90800 may execute various operations of the drug delivery device 9010 that may not require operations related to the motor 90101. For example, the power and control system 90800 may establish communication link with the mobile device 9011, and further communicate intermittently or continuously with the mobile device 9011 during the non-active power mode. Additionally, during the non-drive mode, the power and control system 90800 may provide notifications, and alert to the user, and may further communicate with the various sensors (e.g., the temperature sensor and on-body sensor), and/or determine timings of various operations. Optionally, the drug delivery device 9010 may be primed during the non-active power mode.

[00632] Moreover, the drug delivery device 9010 may switch between the active power mode and the non-active power mode.

[00633] The different power modes may be initiated, based on: (a) type of activation (e.g., device activation, activation of the drug delivery, control of the drug delivery, initiation of the timer, etc.), (b) predetermined time set (e.g., after, or, during the wait time period), and/or (c) operations (e.g., communication with the mobile device and/or sensors, control of the various operations by the power and control system 90800) of the drug delivery device 9010. Alternatively, the activation and/or switching between the modes may be performed manually by the user of the drug delivery device 9010.

[00634] It will be appreciated that, by appropriately powering up the motor 90101 and the power and control system 90800, the overall power requirement of the drug delivery device 9010 may be reduced. For example, powering the motor 90101 while the motor 90101 is idle may prematurely drain the power source or battery of the drug delivery device 9010. As such, by managing the power cycle, for example, by providing power to the motor 90101 only when activities related to the motor 90101 are initiated, the life of the battery to operate the drug delivery device 9010 may be suitably increased or the demand for power to operate the drug delivery device 9010 over the life of the drug delivery period may be significantly reduced.

[00635] Timer unit 90812 may be a digital clock that may be programmed, for example, to set up time periods for various operations of the drug delivery device 9010. For example, the timer unit 90812 may be configured to indicate, to the main control unit 90810, a wait time or a delay period time for a drug (i.e., a time period before the drug can be forced to be delivered).

[00636] Additionally, timer unit 90812 may indicate a time-out period for receiving an activation signal (i.e., a time period within which a user may provide an activation signal to initiate drug delivery or NIM 90200). In some embodiments, timer unit 90812 may directly communicate with the control units of various sensors. In some implementations, the timer unit 90812 may be included in the main control unit 90810.

[00637] Control system 90800 may include storage unit 90813. Storage unit 90813 may include one more storage units, such as a random access memory (RAM) or other dynamic storage device, and/or a read only memory (ROM), and/or an electrically erasable programmable read only memory (EEPROM) for storing temporary parameters, information and instructions for the main control unit 90810. In some implementations, the storage unit may be implemented as a non-transitory computer

readable medium which stores instructions that may be processed and executed by the control unit to control operations of the control system of the drug delivery device. Additionally, storage unit 90813 may store error codes or error notification for various operations associated with the sensors and control unit of the drug delivery device 9010. The error codes may be pre-programmed into the storage unit 90813.

[00638] Storage unit 90813, may additionally, store various predetermined delay or wait time periods related to the drug delivery.

[00639] In some examples, power and control system 90800 may include communication unit 90830. Communication unit 90830 may include one or more 90802.11 Wi-Fi transceivers, a cellular transceiver, IEEE 90802.14 ZigBee transceiver, a Bluetooth transceiver, and/or a Bluetooth Low Energy (BLE) transceiver, and for other wireless communication protocols, such as near-field communication (NFC), infrared or ultrasonic. The drug delivery device 9010 may include appropriate antenna (not shown), for communication with an external computer device, and may receive/transmit data via the communication unit 90830.

[00640] As shown in FIG. 76D, the drug delivery device 9010 may communicate with an external computing device (via the communication unit 90830). The external computing device may be mobile computing device 9011 such as a smart phone which may include various mobile applications and may be configured with the appropriate communication protocols.

[00641] In one example, the mobile device 9011 may include a pump device mobile application (app) 9010a that communicates with the drug delivery device 9010. In such an example, the mobile app 9010a may be provided (from the manufacturer of the drug or drug delivery device 9010) to the user upon purchasing the drug or the drug delivery device 9010. For example, the container or the box of the drug delivery device 9010 may include a unique download identifier that the user may use to download the drug delivery device mobile app 10a. For example, the user may use the download identifier to download the app 9010a from Apple Store or Google Play store.

[00642] Upon downloading the drug delivery device app 9010a to the mobile device 9010a, the user may communicate with the drug delivery device 9010 using the drug delivery device application 9010a (e.g., upon establishing a wireless communication link with the drug delivery device 9010). The mobile app 9010a may be configured to cause the mobile device 9011 to process various information received from the drug delivery device 9010, external entities, such as sensors 9011a and 9011b, and/or optionally data received from a cloud server. Based on the processing of

such data, the mobile app 9010a may cause the mobile device 9011 to transfer appropriate data to the external cloud server 9011c. Mobile app 10a may further cause the mobile device 9011 to display appropriate notification to the user based on the processing of such data.

[00643] In one example, the user may optionally select the activation button 9010b to establish a short range wireless connection with the drug delivery device 9010. In one example, the activation button 9010b may initiate a Bluetooth discovery and pairing process for the mobile device 9011.

[00644] Moreover, when the drug delivery device 9010 is activated and in communication with the mobile device 9011, mobile app 9010a may receive a notification from the drug delivery device 9010 (via the communication unit 90830) that indicates activation of the drug delivery device 9010. In some examples, activation button 9010b may additionally be configured to initiate, modify and/or terminate various mechanisms of the drug delivery process.

[00645] In some examples, drug delivery device app 9010a may gather and provide various time period information of the drug delivery process to the user. Particularly, in one example, selection of the timer button 9010c may provide information related to various timing periods related to the drug delivery process. The timer button 9010c may be triggered, in one example, upon the selection of the activation button 10b. In one example, the selection of the timer button 9010c may evoke a clock or stop watch application of the mobile device 9011.

[00646] In one example, upon the activation of the drug delivery device 9010 and the initiation of the timer unit 90812, the user may gather information related to the predetermined wait time period prior to the initiation of the drug delivery.

[00647] Optionally, drug delivery device app 9010a may provide alarm notification. For example, the timer button 9010c may be configured to provide alarm notification prior to the initiation of the drug delivery process. In one example, the user may optionally indicate how often to receive alarm notification prior to the drug delivery process. Timer button 9010c may be further configured to indicate the delivery time period when the drug is being delivered to the user.

[00648] Moreover, drug delivery device app 9010a may be configured to receive information, for example, from the drug delivery device 9010. For example, a user may select the Tx/Rx notification and data button 9010d to receive notification related to the drug delivery process (e.g., from the drug delivery pump device 9010), and transmit information related to the drug delivery process (e.g., to the cloud server 9011c).

[00649] In one example, upon the selection of the Tx/Rx button 9010d, the user may view notification related to the drug delivery process, such as the activation of the drug delivery device 9010, and/or end of dose notification.

[00650] Additionally, the user may view data via the Tx/Rx button 9010d related to the drug delivery process, such as the rate at which the drug was delivered, the total time period of the delivery process. In one example, the user may further transfer the data and/or notification to a cloud server 9011c of relevant entities (e.g., physician, health insurance company, etc.) In such a scenario, the drug delivery device application 9010a may evoke the communication interface (e.g., a cellular communication interface) of the mobile device 9011 to communicate such information that is received from drug delivery device 9010 to the external cloud server 9011c.

[00651] In one example, the mobile app 9010a may collect information from other sensors that are local or external to the mobile device. For example, the mobile app 9010a may collect information from a wireless heart rate sensor 9011a, a wireless glucose rate monitor 9011b and cause the mobile device 9011 to process such information. Based on the processed information, the mobile app 9010a may determine delivery rate for the drug, and provide instruction to the user about the delivery rate information and activation inputs for the drug delivery device 9010.

[00652] It is contemplated that, the drug delivery device 9010 may wirelessly communicate with the heart rate sensor 9011a and/or the glucose rate monitor 9011b and process the received information to determine the drug delivery rate for the drug.

[00653] Referring back to FIG. 76A the power and control system 90800 may include on-body sensors 90840, such as mechanical, electro-mechanical skin sensors, and/or electrical skin sensors, for example, capacitive skin sensor. In one example, the on-body sensor 90840 may be configured to detect whether the pump device 9010 is in contact with the skin of the patient. Based on the determination, the on-body sensor may provide appropriate indication (e.g., signals) to the control unit 90810. The control unit 90810 may then control various functions of the drug delivery device 9010. For example, the control unit 90810 may notify the user to initiate a delivery of the drug only when the pump device 9010 is in contact with the skin of the user. This may be a safety feature of the drug delivery device 9010, as the drive control system 90820 may not be activated until the power and control system receives a signal from the on-body sensor 90840.

[00654] In one example, on-body sensor 90840 may be a mechanical switch, and the depression of the mechanical on-body sensor 90840 may trigger the activation of the power and control system

90810, and/or the drive control system 90820. In another embodiment, the on-body sensor may be a capacitive- or impedance-based skin sensor, and the power and control system and/or the drive control system 90820 may be functional upon receiving signal from the on-body sensor. These concepts are not mutually exclusive and one or more combinations may be utilized within the breadth of the present disclosure to prevent, for example, premature activation of the drug delivery device 9010. In a preferred embodiment, the drug delivery device 9010 utilizes one or more mechanical on-body sensors. Additional integrated safety mechanisms are described herein with reference to other components of the drug delivery devices.

[00655] Power and control system 90800 may optionally include one or more temperature sensors 90880. The temperature sensor 90880 may be suitably positioned near the drug or the drug container 9050, and configured to detect the temperature of the drug. The temperature sensor may be thermocouples or thermistors (i.e., resistors whose resistances vary significantly with temperature), and electrically coupled to the control unit 90810. The control unit 90810 may process the detected temperature information that is received from the temperature sensor 90880 to control various operations of the drug delivery device 9010. In one example, based on the detected temperature of the drug, the control unit 90810 may notify the user to initiate the delivery of the drug prior to, or after a predetermined time has elapsed. In such a scenario, the control unit 90810 may be configured to override the pre-defined wait period time related to the drug delivery.

[00656] The power and control system 90800 may include a power source, such as batteries (not shown), that provides power to various electrical components of the drug delivery device 9010.

[00657] Moreover, the input/output electro-mechanical unit 90850 may include an activation button, one or more feedback mechanisms, for example, audible alarms such as piezo alarms and/or light indicators such as light emitting diodes (LEDs).

[00658] In one embodiment, the control unit 90810 of the power and control system 90800 interfaces with the mechanical on-body sensor 9024 or the electrical and/or electro mechanical on-body sensor 90840 to identify when the device is in contact with the user and/or the activation mechanism to identify when the device has been activated.

[00659] The power and control system 90800 interfaces and controls the drive control system 90820 through one or more interconnects to relay status indication, such as activation, drug delivery, and end-of-dose, and receives status feedback from the drive control system. The status

indication or the status feedback may be presented to the user via the I/O unit 90850, such auditory tones or alarms, and/or via visual indicators, such as through the LEDs.

[00660] In one embodiment, the control interfaces between the power and control system 90800 and the other components of the drive control system 90820 are not engaged or connected until activation by the user (e.g., via the activation button). This is a desirable safety feature that prevents accidental operation of the drug delivery device, and may additionally maintain and save the battery power during storage, transportation, and the like.

[00661] In one implementation, upon activation of the drug delivery device 9010 (e.g., via the activation button of the I/O unit 90850), the multi-function drive mechanism 90100 of the drive control system 90820 is activated to: insert a fluid pathway into the user; enable, connect, or open necessary connections between a drug container, a fluid pathway, and a sterile fluid conduit; and force drug fluid stored in the drug container through the fluid pathway and fluid conduit for delivery into a user. In at least one embodiment, such delivery of drug fluid into a user is performed by the drive control system multi-function drive mechanism in a controlled manner (e.g., via the flow rate control sub-system 90825).

[00662] FIG. 76B illustrates an exemplary drive control system 90820 that may be configured to drive and control various mechanical and electro-mechanical components of the drug delivery device 9010. One or more components of the power and control system 90800 (e.g., the control unit 90810) may interface with the drive control system 90820, and instruct the actuator/motor 90101 to drive various elements of the drug delivery device 9010.

[00663] In some embodiments, control unit 90810 is electrically coupled and configured to communicate with motor 90101, and any other elements of the drive control system 90820.

[00664] In some examples, the drive control system 90820 may optionally include various sensors such as, but not limited to, pressure sensor 90870 (not shown) that may be configured to provide information of the pressure in the container 9050, tether sensor 90875 (not shown) that may be configured to provide a status information of the tether 90525 and a valve senor 90877 (not shown) that may be configured to provide a status information of the valve (not shown) that may be provided on the container. The sensors 90870, 90875 and 90877 may be electrical and/or electro-mechanical components and may communicate with the control unit 90810 by providing status signals corresponding to the respective sensors. The control unit 90810 may process such signals to execute and/or delay execution of the control of various sub-systems via the motor 90101.

[00665] In one example, the drive control system 90820 may optionally include timer unit 90860. Timer unit 90860 may be a digital clock that is coupled to the control unit 90810. In one example, the timer unit 90860 may be included in the control unit 90810. In some examples, the timer unit 90860 may be the same as timer unit 90812.

[00666] The drive control system may include an actuator or motor 90101. The actuator 90101 may be a number of power/motion sources including, for example, a solenoid, a stepper motor, or a rotational drive motor. In one embodiment, the actuator 90101 is a rotational stepper motor with a notch that corresponds with the gear teeth of the main/star gear 90102. Commonly, such a rotational stepper motor may be referred to as a 'Pac-Man' motor.

[00667] In some embodiments (see FIGS. 69A-73D), the actuator 90101 is in vertical alignment and in direct engagement with the main/star gear 90102. As would be readily appreciated by one having ordinary skill in the mechanical arts, the actuator 90101 could be modified to be in horizontal alignment. Additionally or alternatively, the actuator 90101 may be modified to be in indirect engagement with the main/star gear 90102, as discussed below with reference to FIG. 75.

[00668] With reference to FIG. 76C, the drive control system 90820 may control the multiple drive mechanisms of the drug delivery device 9010. In one example, the drive control system may control the drive mechanism or sub-system 90100 to control the NIM or sub-system 90200, establish the SFPC 90300 and further control the regulating mechanism 90200 of the drug delivery device 9010.

[00669] In one example, the initiation time of the needle insertion mechanism 90200, time to establish the fluid pathway connector 90300, and a drug delivery rate of the drug may be determined by the power and control system 90800 based on the various inputs received by the power and control system from external sensors (e.g., the glucose rate, heart rate, etc.) The power and control system 90800 may then transmit the appropriate command signals and information (e.g., the delivery rate information) to the drive control system 90820.

[00670] Furthermore, the storage unit 90865 of the drive control system 90820, and/or the storage unit 90813 may store, in a lookup table and/or database, pre-programmed configurations and setting information such as ratio of gear assembly information (e.g., ratio of gear assembly 90516), rate of rotation of gear information (e.g., rate of rotation of the main star gear 90102), and diameter information of gears and drums. As such, upon receiving the delivery rate information, the control unit 90810 may consult the storage unit 90865 or storage unit 90813 to identify and select

the appropriate configuration of the gear assembly and the motor from the lookup table or the database. Based on the selection, the control unit 90810 may drive the motor 90101 to control the drive mechanism 90100, NIM mechanism 90200 and the regulating mechanism 90500 to deliver the drug at the desired rate.

[00671] Moreover, the drive control system 90820 may interact with the power and control system 90810 and receive command signals after a predetermined time to control the various drive mechanisms of the drug delivery device 9010.

[00672] For example, the drive control system 90820 may receive the command signal and timing information to control or initiate the driving mechanism after a predetermined time. In this example, the control unit 90810 may consult the timer unit 90860 or timer unit 90812 to determine the initiation time of the activation of the drive mechanism. Upon determination, control unit 90810 may command the actuator/motor 90101 after the predetermined time to initiate a drug delivery process by controlling the drive mechanisms as discussed below.

[00673] After the initiation of the drug delivery, the control unit 90810 may further consult the timer unit 90860 or timer unit 90812 to complete the drug delivery in a predetermined time. The power and control system 90800 may determine the timing periods, and may send command signals to the drive control system 90820 prior to, during, and after the drug delivery process to control the drug delivery process.

[00674] It is noted that, the drive mechanism 90100, insertion mechanism 90200, fluid pathway connector 90300 and the regulating mechanism 90500 may be controlled by the drive control system 90820, concurrently, sequentially and/or non-sequentially, based on a timing period set by the power and control system 90810.

[00675] In some examples, the drive control system 90820 may drive or control the insertion mechanism or sub-system 90200 via the drive mechanism 90100. The controlling of the insertion mechanism 90200 may be performed based on the predetermined wait time period or delay time period, either directly by the power and control system 90810, or by the drive control system 90820.

[00676] In one example, the drive control system 90820 may additionally control the insertion mechanism 90200 to concurrently provide a fluid pathway connector for drug delivery to a user.

[00677] Alternatively, the drive control system 90820 may separately (and prior to or after the insertion mechanism 90200) establish the sterile fluid pathway connector 90300 by connecting a

sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. Details of the control of the insertion mechanism 90200 are discussed below.

[00678] VIII.A. Insertion Mechanism:

[00679] A number of insertion mechanisms may be utilized within the drug delivery devices to activate the needle insertion into the body of the patient. The pump-type delivery devices of the present disclosure may be connected in fluid flow communication to a patient or user, for example, through any suitable hollow tubing. A solid bore needle may be used to pierce the skin of the patient and place a hollow cannula at the appropriate delivery position, with the solid bore needle being removed or retracted prior to drug delivery to the patient. The fluid may be introduced into the body through any number of means, including but not limited to: an automatically inserted needle, cannula, micro-needle array, or infusion set tubing.

[00680] In one example, the control unit 90810 of the power and control system 90800 may receive activation inputs to initiate the drug delivery device 9010. After a predetermined time or after the determination that the on-body sensor 90840 is sensing a skin portion of the user, the power and control system 90800 may instruct the drive control system 90820 to initiate the NIM 90200. After the wait time period, the control unit 90810 may actuate one or more biasing members to initiate the needle insertion mechanism or sub-system 90200. For example, a biasing member such as a spring may be actuated by the motor 90101 to provide sufficient force to cause the needle and cannula to pierce the skin of the patient. The same spring, an additional spring, or another similar mechanism may be utilized to retract the needle from the patient.

[00681] In one embodiment, the power and control system 90800 and/ or the drive control system 90820 may actuate the insertion mechanism 90200 as described in International Patent Application No. PCT/US2012/53174, which is included by reference herein in its entirety for all purposes. Such a configuration may be utilized for insertion of the drug delivery pathway into, or below, the skin (or muscle) of the patient in a manner that minimizes pain to the patient. Other known methods for insertion of a fluid pathway may be utilized and are contemplated within the bounds of the present disclosure, including a rigid needle insertion mechanism and/or a rotational needle insertion mechanism as developed by the assignee of the present disclosure.

[00682] In at least one embodiment, the insertion mechanism 90200 includes an insertion mechanism housing having one or more lockout windows, and a base for connection to the

assembly platform and/or pump housing (as shown in FIG. 69B and FIG. 69C). The connection of the base to the assembly platform 9020 may be, for example, such that the bottom of the base is permitted to pass-through a hole in the assembly platform to permit direct contact of the base to the body of the user. In such configurations, the bottom of the base may include a sealing membrane that is removable prior to use of the drug delivery device 9010. The insertion mechanism may further include one or more insertion biasing members, a needle, a retraction biasing member, a cannula, and a manifold. The manifold may connect to sterile fluid conduit 9030 to permit fluid flow through the manifold, cannula, and into the body of the user during drug delivery.

[00683] As used herein, "needle" is intended to refer to a variety of needles including but not limited to conventional hollow needles, such as a rigid hollow steel needles, and solid core needles more commonly referred to as "trocars." In a preferred embodiment, the needle is a 9027 gauge solid core trocar and in other embodiments, the needle may be any size needle suitable to insert the cannula for the type of drug and drug administration (e.g., subcutaneous, intramuscular, intradermal, etc.) intended. A sterile boot may be utilized within the needle insertion mechanism. The sterile boot is a collapsible sterile membrane that is in fixed engagement at a proximal end with the manifold and at a distal end with the base. In at least on embodiment, the sterile boot is maintained in fixed engagement at a distal end between base and insertion mechanism housing. Base includes a base opening through which the needle and cannula may pass-through during operation of the insertion mechanism, as will be described further below. Sterility of the cannula and needle are maintained by their initial positioning within the sterile portions of the insertion mechanism. Specifically, as described above, needle and cannula are maintained in the sterile environment of the manifold and sterile boot. The base opening of base may be closed from non-sterile environments as well, such as by for example a sealing membrane (not visible).

[00684] According to at least one embodiment of the present disclosure, the insertion mechanism is initially locked into a ready-to-use stage by lockout pin(s) which are initially positioned within lockout windows of the insertion mechanism housing. In this initial configuration, insertion biasing member and retraction biasing member are each retained in their compressed, energized states. In one example, the power and control system 90800 may send command signals to the drive control system 90820 to initiate the needle insertion mechanism 90200 after the wait time period. Upon receiving the command signal, the actuator 90101 may cause displacement of the lockout pin(s), such as pulling, pushing, sliding, and/or rotation. This may cause the insertion biasing member to decompress from its initial compressed, energized state. Particularly, the decompression of the

insertion biasing member drives the needle and, optionally, the cannula into the body of the user. At the end of the insertion stage or at the end of drug delivery (as triggered by the multi-function drive mechanism 90100 and/or the regulating mechanism 90500), the retraction biasing member is permitted to expand in the proximal direction from its initial energized state. This axial expansion in the proximal direction of the retraction biasing member retracts the needle. If an inserter needle/trocar and cannula configuration are utilized, retraction of the needle may occur while maintaining the cannula in fluid communication with the body of the user. Accordingly, the insertion mechanism may be used to insert a needle and cannula into the user and, subsequently, retract the needle while retaining the cannula in position for drug delivery to the body of the user.

[00685] As further discussed below, in some examples, the power and control system 90800 and/or the drive control system 90820 may control the needle insertion mechanism 90200 via the multi-function drive mechanism 90100. Additionally, the power and control system 90800 and/or the drive control system 90820 may control the rate of drug delivery via the drive mechanism 90100 and regulating mechanism 90500 such as by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container (thereby delivering drug substances at variable rates and/or delivery profiles).

[00686] Referring back to FIGS. 70A-70D and 71A-71D, the multi-function drive mechanisms 90100 may concurrently or sequentially perform the steps of: triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a user; and connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user.

[00687] In at least one embodiment, as shown in FIGS. 70A-70D and 71A-71D, the control unit 90810 may initiate motion of the actuator 90101 of the drive control system 90820, which may cause rotation of the main/star gear 90102 of the multi-function drive mechanism 90100. Main/star gear 90102 is shown as a compound gear with aspects 90102A and 90102B (see FIG. 72). In one example, main/star gear 90102 conveys motion to the regulating mechanism 90500 through gear assembly 90516.

[00688] In another example, main/star gear 90102 conveys motion to the needle insertion mechanism 90200 through gear 90112. As gear 90112 is rotated by main/star gear 90102, gear 90112 engages the needle insertion mechanism 90200 to initiate the fluid pathway connector into the user, as described in detail above. In one particular embodiment, needle insertion mechanism

90200 is a rotational needle insertion mechanism. Accordingly, gear 90112 is configured to engage a corresponding gear surface 90208 of the needle insertion mechanism 90200 (see FIGS. 70A and 71B). Rotation of gear 90112 causes rotation of needle insertion mechanism 90200 through the gear interaction between gear 90112 of the drive mechanism 90100 and corresponding gear surface 90208 of the needle insertion mechanism 90200. Once suitable rotation of the needle insertion mechanism 90200 occurs, for example rotation along axis 'R' shown in FIG. 70B-70C, the needle insertion mechanism may be initiated to create the fluid pathway connector into the user.

[00689] In an alternative embodiment, as shown in FIG. 75A, the insertion mechanism 90200 includes a rotationally biased member 90210 which is initially held in an energized state. In one example, the rotationally biased member is a torsional spring. The drive control system 90820 may actuate one or more components of the multi-function drive mechanism 90100, insertion mechanism 90200 and/or the regulating mechanism 90500 to prevent and/or control the rotation of the rotational biasing member 90210.

[00690] The gear 90112 may be configured to engage a corresponding gear surface of a control arm 90202 (visible in FIG. 75B) that contacts or blocks the needle insertion mechanism 90200. Rotation of gear 90112 causes movement of the control arm 90202, which may initiate or permit rotation of needle insertion mechanism 90200.

[00691] Moreover, the rotational biasing member may be prevented from de-energizing by contact of a component of the insertion mechanism with a rotation prevention feature, such as a blocking aspect of the control arm, of the drug delivery device. In one example, the rotational biasing member 90210 may be prevented from de-energizing by interaction of gear surface 90208 with gear 90112.

[00692] It is contemplated that, in one example, at least the prevention of the rotation of the rotational biasing member 90210 may be implemented prior to the on-body sensing. As such, when the on-body sensor 90840 senses skin portion of the user, and/or the power and control system 90800 receives input for initiation of the drug delivery (e.g., via the activation button) and/or input for needle insertion, the power and control system 90800 may command the drive control system 90820 to permit the rotationally biased member 90210 to, at least partially, de-energize. This may cause one or more components of the insertion mechanism 90200, drive control mechanism 90100 and/or regulating mechanism 90500 to rotate and, in turn, cause, or allow, the insertion of the needle into the patient. Furthermore, a cannula may be inserted into the patient as described above.

[00693] As detailed below, during the delivery of the drug, based on the interactions among the drive control system 90820, the drive mechanism 100 and the regulating mechanism 90500, the insertion mechanism may be further controlled. For example, when the control arm or another component of the drive control system 90820 recognizes a slack in the tether, the rotationally biased member may be allowed to further de-energize, causing additional rotation of one or more components of the insertion mechanism 90200.

[00694] This rotation may cause, or allow, the drive control system 90820 to retract the needle from the patient. The needle may be fully retracted in a single step or there may be multiple steps of retraction.

[00695] In at least one embodiment, the needle insertion mechanism 90200 may be configured such that a particular degree of rotation upon rotational axis 'R' (shown in FIGS. 70B-70C) enables the needle/trocar to retract as detailed above. Additionally or alternatively, such needle/trocar retraction may be configured to occur upon a user-activity or upon movement or function of another component of the drug delivery device. In at least one embodiment, needle/trocar retraction may be configured to occur upon end-of-drug-delivery, as triggered by, for example, the regulating mechanism 90500 and/or one or more of the sensors (e.g., the tether sensor, pressure sensor, etc.) During these stages of operation, delivery of fluid substances from the drug chamber 9021 may be initiated, on-going, and/or completed by the expansion of the biasing member 90122 from its initial energized state acting upon the piston 90110A, 90110B and plunger seal 9060.

[00696] Additionally or alternatively, the drive control system 90820 may indirectly engage the needle insertion mechanism 90200 in order to establish the sterile fluid connection sub-system 90300, as described below.

[00697] VIII.B. Fluid pathway connector:

[00698] The power and control system 90800 and/or drive control system 90820 may additionally establish the fluid pathway connector or sub-system 90300 by connecting the sterile fluid conduit to the drug container, to enable the fluid pathway connector.

[00699] The establishment of the fluid pathway connector 90300 may be performed prior to, during, or after the wait time period. Additionally, the pathway connection 90300 may be established prior to, or during the actuation of the insertion mechanism 90200. In some embodiments, the power and control system 90800 may cause the establishment of the fluid pathway connector 90300 via the multi-function drive mechanism 90100, and/or one of the other

sub-systems such as the needle insertion mechanism or sub-system 90200. Generally, a suitable fluid pathway connector includes a sterile fluid conduit, a piercing member, and a sterile sleeve attached to a drug container or a sliding pierceable seal integrated within a drug container. The fluid pathway connector may further include one or more flow restrictors. Upon activation of the device 9010, the fluid pathway connector 90300 is established to connect the sterile fluid conduit 9030 to the drug container of the drive mechanism 90100. Such connection may be facilitated by a piercing member, such as a needle, penetrating a pierceable seal of the drug container of the drive mechanism 90100. The sterility of this connection may be maintained by performing the connection within a flexible sterile sleeve. Upon substantially simultaneous activation of the insertion mechanism 90200, the fluid pathway between drug container and insertion mechanism is complete to permit drug delivery into the body of the user. In one such embodiment, the fluid pathway connector may be substantially similar to that described in International Patent Application No. PCT/US2012/054861, which is included by reference herein in its entirety for all purposes. In such an embodiment, a compressible sterile sleeve may be fixedly attached between the cap of the drug container and the connection hub of the fluid pathway connector. The piercing member may reside within the sterile sleeve until a connection between the fluid connection pathway and the drug container is desired. The sterile sleeve may be sterilized to ensure the sterility of the piercing member and the fluid pathway prior to activation.

[00700] Alternatively, the fluid pathway connector may be integrated into a drug container as described in International Patent Applications No. PCT/US2013/030478 or No. PCT/US2014/052329, for example, which are included by reference herein in their entirety for all purposes.

[00701] According to such an embodiment, a drug container 9050 may have a drug chamber 9021 within a barrel between a pierceable seal (not shown) and a plunger seal 9060. A drug fluid is contained in the drug chamber 9021. Upon activation of the device by the user, a drive mechanism (e.g., multi-function drive mechanism 90100) asserts a force on a plunger seal 9060 contained in the drug container. As the plunger seal 9060 asserts a force on the drug fluid and any air/gas gap or bubble, a combination of pneumatic and hydraulic pressure builds by compression of the air/gas and drug fluid and the force is relayed to the sliding pierceable seal. The pierceable seal is caused to slide towards the cap 9052, causing it to be pierced by the piercing member retained within the integrated sterile fluid pathway connector. Accordingly, the integrated sterile fluid pathway connector is connected (i.e., the fluid pathway is opened) by the combination pneumatic/hydraulic

force of the air/gas and drug fluid within the drug chamber created by activation of a drive mechanism 90100. Once the integrated sterile fluid pathway connector is connected or opened, drug fluid is permitted to flow from the drug container 9050, through the integrated sterile fluid pathway connector 90300, sterile fluid conduit 9030, and insertion mechanism 90200, and into the body of the user for drug delivery. In at least one embodiment, the fluid flows through only a manifold and a cannula and/or needle of the insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during drug delivery.

[00702] In one embodiment, the power and control system 90800 may command the drive control system 90820 to establish or activate the sterile fluid pathway subsystem or connection 90300. For example, the connection 90300 may be established via the needle insertion mechanism 90200 which may be activated or controlled by the multi-function drive mechanism 90100.

[00703] Additionally or alternatively, the sterile fluid pathway connector 90300 may be directly initiated directly by the multi-function drive mechanism 90100. For example, the control unit 90810 may command the motor 90101 to actuate a rotational gear, such as the star gear 90102 described in detail herein, that may operate concurrently or sequentially to: (a) control the rate of drug delivery, (b) to actuate the needle insertion mechanism 90200, and/or (c) initiate the sterile fluid pathway connector 90300, based on various predetermined times (e.g., the wait time period, the drug delivery period) as provided by the power and control system 90800.

[00704] In one embodiment, shown in FIGS. 69A-69C, the multi-function drive mechanism 90100 performs all of these steps substantially concurrently. In that embodiment, the drive control system 90820 causes the multi-function drive mechanism 90100 to rotate a gear (e.g., star gear 90102) that acts upon several other components (e.g., other gear assemblies). For example, the gear acts on a gear assembly to control the rate of drug delivery, while also contacting a needle insertion mechanism 90200 to introduce a fluid pathway connector 90200 into the user. As the needle insertion mechanism 90200 is initiated, the sterile fluid connection is made to permit drug fluid flow from the drug container 9050, through the fluid conduit 9030, into the needle insertion mechanism 90200, for delivery into the patient as the gear and gear assembly of the multi-function drive mechanism control the rate of drug delivery.

[00705] It will be appreciated that, the drug delivery device 9010 is configured to deliver a range of drugs with different viscosities and volumes via the established sterile fluid pathway subsystem or connection 90300. In addition, the drug delivery device 9010 delivers a drug at a controlled flow

rate (speed) and/or of a specified volume. In one embodiment, the drug delivery process is controlled by one or more flow restrictors (not shown) within the fluid pathway connector and/or the sterile fluid conduit. In other embodiments, other flow rates may be provided by varying the geometry of the fluid flow path or delivery conduit

[00706] As shown in FIGS. 70A-70D and 71A-71D, rotation of the needle insertion mechanism 90200 in this manner may also cause a connection of a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. In such an example, the control unit 90810 may command and control: (a) drive mechanism 90100, (b) the needle insertion mechanism 200, and (c) the sterile fluid pathway connector 90300. For example, ramp aspect 90222 of needle insertion mechanism 90200 is caused to bear upon a movable connection hub 90322 of the sterile fluid pathway connector 90300. As the needle insertion mechanism 90200 is rotated by the multi-function drive mechanism 90100 (based on the control unit 90810 command), ramp aspect 90222 of needle insertion mechanism 90200 bears upon and translates movable connection hub 90322 of the sterile fluid pathway connector 90300 to facilitate a fluid connection therein. Such translation may occur, for example, in the direction of the hollow arrow along axis 'C' shown in FIGS. 70B and 71B.

[00707] Moreover, the drug delivery device 9010 may control the flow rate of the drug. In one example, the flow rate may be controlled by the drive control system 90820 (e.g., the motor of the drive control system) by varying the speed at which one or more components of the drive mechanism 90100 advances into the drug container 9050 to dispense the drug. It is noted that, a combination of the different flow rate control methods may be implemented to control the flow of the drug via the sterile fluid pathway connector 90300.

[00708] The power and control system 90800 (e.g., the control unit 90810) may send command signal to the drive control system 90820 to control the flow rate control sub-system or regulating mechanism 90500 via the multifunction drive mechanism 90100 as discussed below. The rate of drug delivery as controlled by the drive control system 90820 may be determined by: selection of the gear ratio of gear assembly 90516; selection of the main/star gear 90102; selection of the diameter of winding drum/gear 90520 and further driving such elements by commanding the actuator 90101 to control the rate of rotation of the main/star gear 90102; or any other method known to one skilled in the art. By using electromechanical actuator 90101 to control and adjust the

rate of rotation of the main/star gear 90102, it may be possible to configure the drug delivery device 9010 to provide a variable dose rate (i.e., the rate of drug delivery is varied during a treatment).

[00709] Additionally, the drive control system 90820 may control the regulating mechanism or sub-system 90500 which may include controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container.

[00710] With references to the embodiments shown in FIGS. 70A-70D and 71A-71D, the power and control system 90820 may control the drive mechanism 90100 via the motor 90101. The drive mechanism 90100 may include a gear assembly 90110 including a main gear 90102, a drive housing 130, and a drug container 9050 having a cap 9052, a pierceable seal (not visible), a barrel 9058, and a plunger seal 9060. The main gear 90102 may be, for example, a star gear disposed to contact multiple secondary gears or gear surfaces. A drug chamber 9021, located within the barrel 9058 between the pierceable seal and the plunger seal 9060, may contain a drug fluid for delivery through the insertion mechanism and drug delivery device into the body of the user. The seals described herein may be comprised of a number of materials but are, in a preferred embodiment, comprised of one or more elastomers or rubbers. The drive mechanism 90100 may further contain one or more drive biasing members, one or more release mechanisms, and one or more guides, as are described further herein. The components of the drive mechanism 90100 function to force a fluid from the drug container out through the pierceable seal, or preferably through the piercing member of the fluid pathway connector 90300, for delivery through the fluid pathway connector, sterile fluid conduit, and insertion mechanism into the body of the user.

[00711] In one particular embodiment, the drive mechanism 90100 employs one or more compression springs as the drive biasing member(s) 90122. In such embodiment, upon the activation of the drug delivery device by the user (e.g., via the activation button) the power and control system 90800 may be configured to directly or indirectly (and electromechanically) release the drive biasing members 90122 from an energized state. Upon release, the drive biasing members 90122 may bear against and act upon the plunger seal 9060 to force the fluid drug out of the drug container. The compression spring may bear against and act upon a piston which, in turn, acts upon the plunger seal 9060 to force the fluid drug out of the drug container. In one example, one or more drive biasing members 90122 may be compressed between the drive housing 90130 and piston

90110, wherein the drive biasing members 90122 may bear upon an interface surface 90110C of the piston.

[00712] Optionally, a cover sleeve (not shown) may be utilized between the drive biasing members 90122 and the interface surface 90110C of the piston 90110 for example, to promote even distribution of force from the drive biasing member 90122 to the piston 90110, prevent buckling of the drive biasing members 90122, and/or hide biasing members 90122 from user view. Interface surface 90110C of piston 90110 is caused to rest substantially adjacent to, or in contact with, a proximal end of seal 9060. Although the embodiments shown in FIGS. 70A-70D and 71A-71D show a singular biasing member it is also contemplated that one or more biasing members disposed to act in parallel may be used.

[00713] As discussed below, in some embodiments, the drive control system 90820 and/or the power and control system 90800 may control the delivery rate of the drug via the drive mechanism 90100, insertion mechanism 90200 and the regulating mechanism 90500.

[00714] As best shown in FIG. 70D and FIG. 71D, the piston 90110 may be comprised of two components 90110A and 90110B and have an interface surface 90110C to contact the plunger seal 9060.

[00715] Moreover, a tether, ribbon, string, or other retention strap (referred to herein as the "tether" 90525) may be connected at one end to the piston 90110A, 90110B. For example, the tether 90525 may be connected to the piston 90110A, 90110B by retention between the two components of the piston 90110A, 90110B when assembled. The tether 90525 is connected at another end to a winch drum/gear 90520 of regulating control mechanism 90500. Through the use of the winch drum/gear 90520 connected to one end of the tether 90525, and the tether 90525 connected at another end to the piston 90110A, 90110B, the regulating mechanism 90500 functions to control, meter, provide resistance, or otherwise prevent free axial translation of the piston 90110A, 90110B and plunger seal 9060 utilized to force a drug substance out of a drug container 9050.

[00716] Accordingly, the power and control system 90800 may control the regulating sub-system or mechanism 90500 which may be a portion of the gear assembly 90116 aspect of the multi-function drive mechanism, and which together may function to control the rate or profile of drug delivery to the user.

[00717] With reference to FIG. 76C, the power and control system, via the drive control system 90820, may control the regulating mechanism 500 (e.g., via the drive control mechanism 90100).

For example, the control unit 90810 may drive the actuator or Pac-Man motor 90101 to drive various gear assembly (e.g., gear assembly 90516) of the regulating mechanism 90500, by selecting appropriate configurations for the motor 90101 and gear assembly. Moreover, the driving of the regulating mechanism may be time-controlled, as discussed herein.

[00718] As shown in FIGS. 70A-70D and 71A-71D, and in isolation in FIGS. 72 and 73A-73B, in the embodiments of the present disclosure, the regulating mechanism 90500 is gear assembly driven by an actuator 90101. Moreover, upon receiving command signals from the control unit 90810, the motor 90101 may control the regulating mechanism 90500 to retard or restrain the distribution of tether 90525, thus allowing the tether 90525 to advance at a regulated or desired rate. This restricts movement of piston 90110 within barrel 9058, which is pushed by one or more biasing members 90122, hence controlling the movement of plunger seal 9060 and delivery of the drug contained in chamber 9021. As the plunger seal 9060 advances in the drug container 9050, the drug substance is dispensed through the sterile pathway connection 90300, conduit 9030, insertion mechanism 90200, and into the body of the user for drug delivery. In one example, the regulated motion of the tether 90525 may be monitored by an optional tether sensor 90875 which may provide status feedback to the control unit 90810 of the power and control system 90800. The control unit 90810 may process the feedback status information of the regulated motion of the tether 90525 to further control the regulating mechanism 90500.

[00719] As discussed above, in at least one embodiment, the motor 90101 may be a Pac-Man motor that has a gear interface within which one or more teeth of the main gear may partially reside during operation of the drug delivery pump device 9010. The operation of the Pac-Man motor may be controlled by the control unit 90810.(see FIGS. 73A-73B).

[00720] In one example, when the gear interface 90101A of the Pac-Man motor 90101 is in alignment with a tooth 90102A of the main gear 90102, rotational motion of the Pac-Man motor 90101 causes gear interface rotation of the main gear 90102. When the Pac-Man motor 90101 is between gear teeth of the main gear, it may act as a resistance for, for example, back-spinning or unwinding of the gear assembly 90116. In one particular embodiment, the Pac-Man motor 90101 utilizes an alternating direction type motor to rotate the Pac-Man motor 90101 backwards and forwards. This configuration aids in the prevention of a runaway condition, where the motor and the gears are freely permitted to rotate, by using the multi-direction of the motor to prevent continuous spin in one direction (as would be needed for a runaway condition). This bi-directional movement

of the motor, coupled with the use of the gear interface cut within the Pac-Man motor, may provide suitable safety features to prevent a runaway condition that could potentially lead to over-delivery of drug to the user. Further detail about the gear assembly 90116, regulating mechanism 90500, and multi-function drive mechanism 90100 are provided herein. In a particular embodiment shown in FIGS. 73A-73B, the regulating mechanism 90500 further includes one or more gears 90511, 90512, 90513, 90514, of a gear assembly 90516. One or more of the gears 90511, 90512, 90513, 90514 may be, for example, compound gears having a small diameter gear attached at a shared center point to a large diameter gear. Gear 90513 may be rotationally coupled to winch drum/gear 90520, for example by a keyed shaft, thereby coupling rotation of gear assembly 90516 to winch drum/gear 90520. Compound gear 90512 engages the small diameter gear 90513 such that rotational movement of the compound gear aspect 90512B is conveyed by engagement of the gears (such as by engagement of corresponding gear teeth) to gear 90513. Compound gear aspect 90512A, the rotation of which is coupled to gear aspect 90512B, is caused to rotate by action of compound gear aspect 102B of the main/star gear 90102. Compound gear aspect 90102B, the rotation of which is coupled to main/star gear 90102, is caused to rotate by interaction between main/star gear 90102A and interface 90101A of the actuator 90101. Thus, rotation of main/star gear 90102 is conveyed to winch drum/gear 90520. Accordingly, rotation of the gear assembly 90516 initiated by the actuator 90101 (of the drive control system 90820) may be coupled to winch drum/gear 90520 (i.e., through the gear assembly 90516), thereby controlling the distribution of tether 90525, and the rate of movement of plunger seal 9060 within barrel 9058 to force a fluid from drug chamber 9021. The rotational movement of the winch drum/gear 90520, and thus the axial translation of the piston 90110 and plunger seal 9060, are metered, restrained, or otherwise prevented from free axial translation by other components of the regulating element 90500, as described herein. As described above, the actuator 90101 may be a number of known power/motion sources including, for example, a motor (e.g., a DC motor, AC motor, or stepper motor) or a solenoid (e.g., linear solenoid, rotary solenoid).

[00721] As discussed above, the embodiments shown in FIGS. 75A-75B show an actuator 90101 that is driven by the control unit 90810, and is in horizontal alignment and indirect engagement with the main/star gear 90102. Such an embodiment may utilize a rack and pinion engagement, a drive screw, or a worm gear 90101W, as shown in FIGS. 75A-75B, to change the direction of motion from horizontal to vertical (i.e., perpendicular interaction). Actuator 90101 (based on command signals received from the control unit 90810) rotates worm gear 90101W, which engages gear

90101G and conveys the motion to the Pac-Man gear 90101A. The Pac-Man gear 90101A engages main/star gear 90102 to enable operation of the drive mechanism and the drug delivery device, as described herein.

[00722] The control unit 90810 controls main star gear 90102 via the motor 90101. The main star gear 90102 may then drive other gear assembly. For example, main/star gear 90102 may drive operation of gear 90112 to enable operation of the needle insertion mechanism 90200, as described herein.

[00723] In one embodiment, the control unit 90810 provides command signals such that the actuator 90101 rotate the worm gear 90101W, gear 90101G, and Pac-Man gear 90101A backwards and forwards. This configuration aids in the prevention of a runaway condition, where the motor and the gears are freely permitted to rotate, by using the multi-direction of the motor to prevent continuous spin in one direction (as would be needed for a runaway condition). This bi-directional movement of the actuator 90101, coupled with the use of the gear interface of the worm gear 90101W, gear 90101G, and Pac-Man gear 90101A with the main/star gear 90102, provide suitable safety features to prevent a runaway condition that could potentially lead to over-delivery of drug to the user.

[00724] Additionally, the motor 90101 may include a stop member 90101B that stops the rotation of the Pac-Man gear 90101A against a stop block 90150. Stop block 90150 further prevents over-rotation of the Pac-Man gear 90101A and, accordingly, the main/star gear 90102 to prevent a runaway condition that could potentially lead to over-delivery of drug to the user. For the device to function in this configuration, the Pac-Man gear 90101A must be rotated backwards the other direction before rotating forwards again to progress the main/star gear 90102 because the stop member 90101B prevents over rotation in one direction by interaction with the stop block 90150.

[00725] Additionally, the geometry of worm gear 90101W may be configured such that it is self-locking and/or cannot be back-driven by gear 90101G. This may be done by configuration of parameters such as: pitch, lead angle, pressure angle, and number of threads. In so doing, runaway conditions of the drive mechanism will be prevented by the worm gear's resistance to rotations that are not caused by actuator 90101. Alternatively or additionally, the control unit 90810 may be configured to determine whether there is any feedback from the worm gear 90101W that is caused by the rotations of other gears (e.g., gear 90101G) and not by the motor 90101. If the control unit

90810 determines or receives such feedback, the control unit 90810 may terminate further operations.

[00726] It is noted that, the power and control system 90800 does not control the regulating mechanisms 90500 of the present disclosure to drive the delivery of fluid substances from the drug chamber 9021. The delivery of fluid substances from the drug chamber 9021 is caused by the expansion of the biasing member 90122 from its initial energized state acting upon the piston 90110A, 90110B and plunger seal 9060 (which may be actuated by the control unit 90810 via the motor 101). The regulating mechanisms 90500 instead function to provide resistance to the free motion of the piston 90110A, 90110B and plunger seal 9060 as they are pushed by the expansion of the biasing member 90122 from its initial energized state. The regulating mechanism 90500 does not drive the delivery but only controls the delivery motion. The tether limits or otherwise restrains the motion of the piston 90110 and plunger seal 9060, but does not apply the force for the delivery. According to a preferred embodiment, the controlled delivery drive mechanisms and drug delivery devices of the present disclosure include a regulating mechanism indirectly or directly connected to a tether metering the axial translation of the piston 90110A, 90110B and plunger seal 9060, which are being driven to axially translate by the biasing member 90122.

[00727] In one example, the power and control system 90800 of the drug delivery device 9010 may be configured to receive one or more regulating parameters for controlling the regulating mechanism 90500. Alternatively, or additionally the power and control system 90800 may receive sensor inputs (e.g., heart rate sensor, glucose monitor sensor information) and may then translate the sensor inputs into regulating parameters. The control unit 90810 may then control the regulating mechanism 90500 after a predetermined time (e.g., after the wait time period). Based on the inputs, the control unit 90810 may meter the release of the tether 90525 by the winch drum/gear 90520 and thereby permit axial translation of the piston 90110 by the biasing member 90122 to translate a plunger seal 9060 within a barrel 9058.

[00728] Based on the regulating parameters, the control unit 90810 and motor 90101 may additionally control the restraint provided by the tether 90525 and winch drum/gear 90520 on the free axial translation of the piston 90110 upon which the biasing member 90122 bears upon via the motor 90101. The control unit 90810 may control such operations to provide a desired drug delivery rate or profile, to change the dose volume for delivery to the user, and/or to otherwise start, stop, or pause operation of the drive mechanism. In one example, the control unit 90810 may control the

drug delivery rate in order to complete a drug delivery dose within a desired or a predetermined time.

[00729] During the drug delivery process, and after a predetermined wait time period, the power and control system may provide delivery instructions to the drive control system 90820. Based on the instructions, the drive control system may control the components of the drive mechanism 90100, to axially translate the plunger seal 9060 of the drug container 9050 in the distal direction. Optionally, the drive mechanism 90100 and/or the regulating mechanism 90500 may include one or more compliance features which enable additional axial translation of the plunger seal 9060 to, for example, ensure that substantially the entire drug dose has been delivered to the user. For example, the plunger seal 9060, itself, may have some compressibility permitting a compliance push of drug fluid from the drug container.

[00730] For example, the controlled delivery drive mechanisms and/or drug delivery devices of the present disclosure may additionally enable a compliance push to ensure that substantially all of the drug substance has been pushed out of the drug chamber 9021. The plunger seal 9060, itself, may have some compressibility permitting a compliance push of drug fluid from the drug container. For example, when a pop-out plunger seal is employed, i.e., a plunger seal that is deformable from an initial state, the plunger seal may be caused to deform or "pop-out" to provide a compliance push of drug fluid from the drug container. Additionally or alternatively, an electromechanical status switch may be utilized to contact, connect, or otherwise enable a transmission to the control unit 90810 of the power and control system 90800 to signal end-of-dose to the user. This configuration may further enable true end-of-dose indication to the user.

[00731] As discussed with reference to FIG. 76B, the drive control system 90820 may include various sensors (e.g., the tether sensor 90875, valve sensor 90877, pressure sensor 90870) that may be coupled to the control unit 90810 and/or to the motor 90101. The sensors may be configured to provide signal or status information for various elements of the systems and sub-systems of the drug delivery device 9010. In one example, the control unit 90810 may process the feedback signals or the status information received from the sensors to control the sub-systems, such as the regulating sub-system or mechanism 90500.

[00732] Additionally, the power and control system 90800 may provide notification to the user based on the feedback provided by the sensors to the control unit. The notification may be tactile, visual, and/or auditory, as described above, and may be redundant such that more than one signal or

type of notification is provided to the user during use of the device. For example, the user may be provided an initial notification to indicate that the drug delivery device 9010 is operational and ready for drug delivery and may further may provide an end-of-dose notification, based on the feedback signal provided, for example, by one or more sensors. In one example, pressure sensor 90870 and/or a valve sensor 90877, positioned at appropriate location in the drug delivery device 9010, may sense the end-of-dose when the piston reaches the end of its axial translation. Accordingly, the control unit 90810 may then provide an end-of-dose notification based on the sensor signals received from the sensors.

[00733] Additionally or alternatively, tether 90525 may have one or more sensor triggers such as electrical contacts, optical markings, and/or electromechanical pins or recesses that are configured to provide status feedback to the tether sensors 90875, and in turn, to the control unit 90820. In at least one embodiment, an end-of-dose status notification may be provided to the user once the tether sensor 90875 detects that the final status trigger positioned on the tether 90525 has reached a final position upon the end of axial travel of the piston 90110A, 90110B and plunger 9060 within the barrel 9058 of the drug container 9050. The tether sensor 90875 may be, for example, an electrical switch reader to contact the corresponding electrical contacts, an optical reader to recognize the corresponding optical markings, or a mechanical or electromechanical reader configured to contact corresponding pins, holes, or similar aspects on the tether 90525.

[00734] In one example, the status triggers (not shown) may be positioned along the tether 90525 to be read or detected at positions which correspond with the beginning and end of drug delivery, as well as at desired increments during drug delivery.

[00735] In some examples, the drive control system 90820 initiates the drug delivery (upon actuation of the drive mechanism 90100) by release of the biasing member 90122 and the resulting force applied to the piston 90110A, 90110B and plunger seal 9060. The power and control system 90800 further instructs the drive control system 90820 to control the rate or profile of drug delivery to the user by controlling the regulating mechanism 90500, gear assembly 90516, winch drum/gear 90520, releasing the tether 90525 and permitting expansion of the biasing member 90122 and axial translation of the piston 90110A, 90110B and plunger seal 9060. As this occurs, the status triggers of the tether 90525 are contacted or recognized by the tether sensor and the status of the drive mechanism before, during, and after operation can then be relayed to the control unit 90810 of the power and control system 90800 to provide feedback to the user. Depending on the number of status

triggers located on the tether 90525, the frequency of the incremental status indication may be varied as desired. As described above, a range of tether sensors may be utilized depending on the status triggers utilized.

[00736] In some embodiments, the tether sensor may include one or more sensors of similar type, and/or a combination of different types of sensors. In one example, a tension force may be applied to the tether 90525 (e.g., according to one or more command signals from the control unit 90810). When the drug delivery device 9010 reaches the end-of-dose, the tether 90525 goes slack which may be detected by a tether sensor 90875 such as an electrical or electromechanical switch. The tether sensor 90875 may signal a slack in the tether 90525 to the control unit 90810 of the power and control system 90800.

[00737] Additionally, gear 90511A and/or gear 90511B of gear assembly 90516 may be configured as an encoder along with a sensor. For example, the sensor/encoder combination may be configured to provide feedback of gear assembly rotation. In one example, the encoder/sensor may be calibrated to an initial position of the piston (e.g., the position of piston 90110 when there is no slack in the tether 90525). Moreover, this positional information may be recorded or stored in the control unit 90810. As such, the control unit 90810 or the power and control system 800 may receive positional feedback, end-of-dose signal, and error indication, such as an occlusion, for example, due to a slack in the tether 90525 prior to reaching the expected number of motor rotations as counted by the sensor/encoder. Alternatively or additionally, the drive control system 90820 may control the rate of flow of drug via the tether 90525 in combination with the regulating mechanism 90500.

[00738] It will be appreciated that, additional and/or alternative means may be implemented for terminating or restraining the flow of the medicament in the case of slack in, or failure of, the tether 90525 (e.g., during a breakage of the tether).

[00739] FIGS. 74A-74B shows one such embodiment for a safety-stop during a failure of the tether 90525. Disposed within barrel 9058 are brake 9064, sleeve 9062, and plug 9068, and optionally retainer 9066. Biasing member 90122 bears against sleeve 9062. Initially, the tether 90525 is engaged with plug 9068, thereby allowing tether 90525 to restrain the motion of sleeve 9062. This restraint controls the rate of expansion or de-energizing of biasing member 90122. When tether 90525 is under tension, plug 9068 bears against distal face 9064A of brake 9064, causing proximal face 9064B of brake 9064 to bear against sleeve 9062. Due to this contact, and the profile

of the distal end 9062A of sleeve 9062, brake 9064 is maintained in a substantially conical configuration as shown in FIG. 74A. In this configuration, expansion or de-energizing of biasing member 90122 is restrained. Also, in this conical configuration, the outer diameter of brake 9064 is less than the inner diameter of barrel 9058, thus translation of the brake is not restrained by contact with the inner wall of the drug container. Also, a portion of brake 64 is in contact with retainer 9066. Because brake 9064 is maintained in this configuration by plug 9068 and sleeve 9062, translation of sleeve 9062, caused by decompression of biasing member 90122, is transferred to retainer 9066. Likewise, contact of retainer 9066 with plunger seal 9060 causes translation of plunger seal 9060.

[00740] As shown in FIG. 74B, in the event of slack in, or failure of, tether 90525, plug 9068 is no longer held in position by tether 90525 and, therefore, no longer restrains motion of sleeve 9062. As biasing member 90122 decompresses or de-energizes, brake 9064 transforms to a relatively less conical or flatter configuration. This may be caused by a natural bias of brake 9064 to transform to this configuration or, alternatively, may be caused by contact of brake 9064 with both retainer 9066 and sleeve 9062. As the brake is transformed, it comes into contact with the inner wall of barrel 9058. The brake thus acts as a wedge to restrict translation of sleeve 9062. This may prevent further translation or may act to restrict the rate of translation. Optionally, restoring tension in the tether may cause the plug to contact the brake and to transform the brake back to its conical configuration and thus restore normal operation of the drug delivery device.

[00741] FIGS. 74A-74B shows the plug as having a spherical shape and the brake as having a conical shape. Such shapes are used herein merely for exemplary purposes and other shapes or configurations could readily be utilized to achieve the same or similar functionality. For example, the plug may itself be conical in shape and, in one embodiment, be shaped to interface the brake when the brake is in a conical shape. In such a configuration, the conical shape of the plug assists in maintaining the conical shape of the brake, thereby preventing contact between the outer diameter of the brake with the inner diameter of the barrel in order to restrict the axial translation of the sleeve 9062 (i.e., applying a braking force). In another embodiment, the brake 9064 could employ a star-shaped or other configuration when in a substantially flattened position so as to make contact with the inner diameter of the barrel 9058 to prevent or restrict further axial translation of sleeve 9062. Without further translation of sleeve 9062, biasing member 90122 cannot expand or de-energize further which, in turn, prevents or restricts further drug delivery to the user. This provides

a necessary and useful safety measure for drug delivery, to prevent over-delivery or accelerated delivery of drug to the user.

[00742] Moreover, as discussed above, the control of the tether 90525 may be provided by the control unit 90810. Additionally, any feedback related to slack or failure of the tether 90525 may be provided to the drive control system 90820 and/or to the power and control system 90800.

[00743] As described above, the regulating mechanisms 90500 provide resistance to the free motion of the piston 90110A, 90110B and plunger seal 9060 as they are pushed by the expansion of the biasing member 90122 from its initial energized state. The regulating mechanism 90500 may not drive the delivery but may only control the delivery motion.

[00744] It is noted that, the tether may limit or restrain the motion of the piston 90110 and plunger seal 9060, but may not apply the force for the delivery (see FIGS. 70A-70D and 71A-71D). The motion of the piston 90110A, 90110B and plunger seal 9060 as they are pushed by the expansion of the biasing member 90122 from its initial energized state are shown in the direction of the solid arrow along axis 'A' from proximal or first position 'P' to the distal or second position 'D', as shown in the transition of FIGS. 70A-70D and 71A-71D.

[00745] Control of the tether 90525 is further described with reference to FIG. 72 and FIGS. 73A-73B.

[00746] FIG. 72 shows a perspective view of the multi-function drive mechanism, according to at least a first embodiment, during its initial locked stage. Initially, the tether 90525 may retain the biasing member 90122 in an initial energized position within piston 90110A, 90110B. When the power and control system 90800 receives inputs for activation, it commands the drive control system to initiate the multi-function drive mechanism 90100. In one example, the drive mechanism 90100 may cause the biasing member to impart a force to piston 90110 and therefore to tether 90525. This force on tether 90525 imparts a torque on winding drum 90520 which causes the gear assembly 90516 and regulating mechanism 90500 to begin motion.

[00747] Moreover, as shown in FIG. 71C, the piston 90110 and biasing member 90122 are both initially in a compressed, energized state behind the plunger seal 9060. The biasing member 90122 may be maintained in this state until activation of the device between internal features of drive housing 90130 and interface surface 90110C of piston 90110A, 90110B. As the drug delivery device 9010 is activated and the drive mechanism 90100 is triggered to operate, biasing member 90122 is permitted to expand (i.e., decompress) axially in the distal direction (i.e., in the direction of

the solid arrow shown in FIGS. 70A-70D and FIGS. 71A-71D). Such expansion causes the biasing member 90122 to act upon and distally translate interface surface 90110C and piston 90110, thereby distally translating plunger seal 9060 to push drug fluid out of the drug chamber 9021 of barrel 9058.

[00748] As discussed above, an end-of-dose status indication may also be provided to the user once one or more sensors contacts or detects the end of axial travel of the piston 90110A, 90110B and plunger seal 9060 within the barrel 9058 of the drug container 9050 (e.g., based on a status trigger positioned on the tether 90525). The status triggers may be positioned along the tether 90525 at various increments, such as increments which correspond to certain volume measurement, to provide incremental status indication to the user. In at least one embodiment, the sensor is an optical status reader configured to recognize the corresponding optical status triggers on the tether. As would be understood by an ordinarily skilled artisan, such optical status triggers may be markings which are recognizable by the optical status reader. In another embodiment, the status reader is a mechanical or electromechanical reader configured to physically contact corresponding pins, holes, or similar aspects on the tether. Electrical contacts could similarly be utilized on the tether as status triggers which contact or are otherwise recognized by the corresponding electrical sensors. The status triggers may be positioned along the tether 90525 to be read or recognized at positions which correspond with the beginning and end of drug delivery, as well as at desired increments during drug delivery. As shown, tether 90525 passes substantially axially through the drive mechanism housing 90130, the biasing member 90122, and connects to the piston 90110 A, 90110B to restrict the axial translation of the piston 90110A, 90110B and the plunger seal 9060 that resides adjacent thereto. The sensors may communicate the detected information (e.g., the end of dose information, incremental motion, restricted motion, etc.) to the drive control system 90820 and/or to the power and control system 90800 to notify or provide feedback of the controlled motion of the various components.

[00749] As mentioned above various sensors may be coupled directly to the power and control system 800 or via the drive control system 90820, and may be configured to provide the incremental status indication. A user may then be notified of such indication based on, for example, the detection of the rotational movement of one or more gears of gear assembly 90516. For example, as the gear assembly 90516 rotates, a sensor may read or detect one or more corresponding status triggers on one of the gears in the gear assembly to provide incremental status indication before,

during, and after operation of the variable rate controlled delivery drive mechanism. A number of sensors may be utilized within the embodiments of the present disclosure.

[00750] In one example, the drive mechanism 90100 may utilize an electro-mechanical sensor which may be physically in contact with the gear teeth of one of the gears of the gear assembly. As the sensor is contacted by the status or sensor trigger(s), which in this exemplary embodiment may be the gear teeth of one of the gears (or holes, pins, ridges, markings, electrical contacts, or the like, upon the gear), the sensor measures or detects the rotational position of the gear and transmits a signal to the power and control system 90800 for status indication or notification to the user.

[00751] Additionally or alternatively, the drive mechanism 90100 may utilize an electro-optical sensor. The optical sensor may include a light beam that may be configured detect a motion and transmit a status signal to the power and control system. For example, the optical sensor may be configured to detect motion of the gear teeth of one of the gears in the gear assembly (or holes, pins, ridges, markings, electrical contacts, or the like, upon the gear). In another embodiment, the sensor may be an electrical switch configured to recognize electrical contacts on the gear. In any of these embodiments, the sensor may be utilized to then transmit a signal to the power and control system to provide notification feedback to the user about the controlled motion and/or the delivery of the drug.

[00752] As would be appreciated by one having ordinary skill in the art, electro-optical sensors and corresponding triggers, electromechanical sensors and corresponding triggers, and/or electrical or mechanical sensor and corresponding triggers may all be implemented by the embodiments of the present disclosure to provide incremental status indication to the user power and control system 90800. While the drive mechanisms of the present disclosure are described with reference to the gear assembly and regulating mechanism, a range of configurations may be acceptable and capable of being employed within the embodiments of the present disclosure, as would readily be appreciated by an ordinarily skilled artisan. Accordingly, the embodiments of the present disclosure are not limited to the specific gear assembly and regulating mechanism described herein, which is provided as an exemplary embodiment of such mechanisms for employment within the controlled delivery drive mechanisms and drug delivery pumps.

[00753] Moreover, in at least one embodiment of the present disclosure, the delivery profile of the medicament is adjustable. For example, it may be desirable to deliver a bolus injection of medicament before, during, or subsequent to certain activities such as eating, exercising, sleeping,

etc. A "bolus injection" is any measured drug volume that is delivered often irrespective of the delivery time or duration. Conversely, a "basal injection" is often a controlled rate of delivery and/or a drug delivery profile having various rates of delivery at different time intervals. Similarly, the user may desire to increase or decrease the basal delivery rate of the medicament at these or other times. In at least one embodiment, the delivery profile may be adjustable by the user to achieve this desired drug delivery. The user may adjust the delivery profile by interacting with the drug delivery device itself or, alternatively, may use an external device, such as a smart-phone, to do so. For example, the user may adjust the delivery profile by displacing the activation mechanism or may engage a separate device-integrated or external delivery control mechanism.

[00754] In another embodiment of the present disclosure, the delivery profile may be adjusted automatically based on one or more inputs. For example, the delivery profile may be adjusted based on the patient's activity level, heart rate, blood sugar level, blood pressure, etc. As above, these measurements may be used to determine the need for a bolus injection or for the increase or decrease of the basal injection delivery rate or adjustment to the basal injection delivery profile. In at least one embodiment, these input measurements may be monitored by the device itself. Additionally, or alternatively, they may be monitored by a secondary device such as a smart-phone, smart watch, heart rate monitor, glucose monitor, blood pressure monitor, or the like. In some embodiments, the delivery profile may be adjusted based on these measurements with no required user intervention. In the case of monitoring and/or control by a secondary device, the secondary device and drug delivery device may be in wireless or wired communication with one another. This communication may be through Bluetooth, near field communication, Wi-Fi, or any other method known to one having ordinary skill in the relevant art of device interconnectivity.

[00755] In a preferred embodiment, however, the monitoring/adjustment mechanism may alert and make recommendations to the user and the user may have active control to initiate/authorize or disregard the recommendation made by the monitoring/adjustment mechanism. For example, if one or more of the measurements is above or below a specified threshold value the device may emit an audible, visual, or tactile alert to the user. In one example, the alert is provided by a vibration of the device, thereby providing a discrete alert to the user. Additionally or alternatively, the alert may be provided by the user's smart-phone or other secondary device. The user may be able to view the current status of the measurements in a computer program or web interface on the device itself, a computer, smart-phone, or other device. The computer program or web interface may provide a recommended adjustment to the delivery profile. Based on this information, the user may adjust the

delivery rate of the drug delivery device. As above, the user may adjust the delivery profile by displacing the activation mechanism or engaging a separate device-integrated or external delivery control mechanism.

[00756] In one embodiment, in response to a signal to adjust the delivery profile, either based on user input or based on the measurements described above, the power and control system may cause a change in the rate of movement of actuator 90101. The change in the rate of movement of actuator 90101 causes a change in the rotation rate of regulating mechanism 500 which, in turn, controls the rate of drug delivery to the user. Alternatively, the delivery profile may be altered by a change in the characteristics of the flow path of medicament through the conduit connecting the drug container and insertion mechanism. The change may be caused by the introduction, removal, or modification of a flow restrictor which restricts flow of medicament from the drug container to the insertion mechanism. For example, a flow restrictor may have multiple flow paths which may be selectively placed in fluid communication with an input and an output of the flow restrictor. By providing flow paths which are of different length or cross-section the rate of delivery may be controlled. In other embodiments, the delivery profile may be altered by the introduction or removal of an impingement of the conduit. An impingement of the flow path may interrupt or slow flow of medicament through the conduit, thereby controlling the rate of delivery to the user. Accordingly, one or more embodiments of the present disclosure are capable of producing a change to the rate of medicament delivery from the drug container thereby providing a dynamic control capability to the multi-function drive mechanism and/or the drug delivery device.

[00757] Details of an exemplary method associated with drug delivery in a predetermined time are now provided with references to FIG. 9A. One or more steps of the method 90900 may be executed during active power mode or non-active power mode of the power and control system 90800.The method 90900, for example, includes steps related to initiating and delivering drug at an adjusted rate to a user by a drug delivery device 9010 after a predetermined wait time period. The method includes steps of communication between the drug delivery device 9010 and a mobile device 9011. The method may optionally monitor and receive information (e.g., heart rate of the user, glucose/ insulin information, etc.) related to the health of the patient during the monitoring period. Particularly, the method requests a user of the drug delivery device 9010 to activate the needle insertion (i.e., initiate NIM 90200), after the device has been activated. When the needle insertion has been actuated, the drug delivery device 9010 may then initiate a timer to track delay time period. Alternatively, a timer may be initiated by the activation of the device.

[00758] Furthermore, the method determines whether the predetermined wait time period has elapsed, and based on the determination notifies the user accordingly about the initiation of the drug delivery process. The method regulates the delivery rate of the drug based on information received from sensors (e.g., temperature sensor, heart rate sensor, glucose monitor sensor). Regulation of the delivery rate may be based on optimization of the effectiveness of the drug. Alternatively, or additionally, the delivery rate may be regulated to reduce and/or minimize the user's discomfort. For example, delivery of a relatively cold drug may cause pain to the user. Hence, if the temperature sensor provides a signal to the control unit that the drug and/or drug container is low, the delivery rate may be reduced.

[00759] The method may further determine whether the drug delivery has ended, and based on the determination, in one example may further transmit the end of drug delivery information to the mobile device. The mobile device may further provide the received information to a remote server (e.g., a cloud server). Other parameters may be regulated based on the inputs from the sensors. For example, the delay between activation of an end-of-dose sensor and notification, to the user, that drug delivery has completed. The viscosity of the drug may be dependent on the temperature of the drug and a more viscous drug may require additional time to be fully delivered to the user. Hence, the control unit may use the input from the temperature sensor to determine how long to delay notification to the user of completion of delivery. The control unit may, for example, compare the input from the temperature sensor to a look-up table which is either stored locally or is accessed remotely. Alternatively, the control unit may use the input from the temperature sensor as an input in an equation used to calculate the delay.

[00760] Referring now to FIGS. 77A, the process flows depicted are merely embodiments of the disclosure and are not intended to limit the scope of the disclosure. For example, the steps recited in any of the method or process descriptions may be executed in any order and are not limited to the order presented. Furthermore, it will be appreciated that the following description makes appropriate references not only to the steps depicted in FIGS. 77A, but also to the various system components as described with reference to the present disclosure.

[00761] Referring now to FIG. 77A, at step 90901, the pump device 9010 is activated. The drug delivery device 9010 may be configured with an activation mechanism that may include receiving a trigger signal from the user to power the power and control system 90800. In one example, a user may activate the drug delivery device 9010 by pressing a start button that may be an on/off switch,

and/or a toggle switch. The activation button or the switch may be located through the pump housing 9012, such as through an aperture between upper housing and lower housing, and which contacts either directly or indirectly the power and control system 90800 (e.g., a via electrical contacts). The user may press the activation button or the switch a predetermined number of times (e.g., one single press) to initially activate the drug delivery device 9010. Alternatively, the pump device 9010 may be configured such that it is activated upon removal from a portion of its packaging. The pump device 9010 may include one or more packaging status sensors that are configured to detect the removal of the pump device from a portion of the packaging. The packaging status sensor may take any form capable of detecting a removal of the pump device from a portion of the packaging. For example, the packaging status sensor may be in the form of a pin interconnect on the power and control system 800 that is either connected or disconnected when packaged. Removal from the packaging may cause the pin interconnect to change state from connected to disconnected or vice versa. This change of state may cause initiation of the timer. Alternatively, the packaging status sensor may consist of an optical sensor which is configured to detect a change in lighting conditions caused by a removal of the pump device 9010 from a portion of the packaging.

[00762] In one example, upon receiving the activation input, a short-range wireless communication link may be initiated between the drug delivery device 9010 and the mobile device 9011. In one example, the wireless communication link may be established based on a Bluetooth pairing between the mobile device 9011 and the drug delivery device 9010.

[00763] In one example, during and/or upon the activation, the drug delivery device 9010 may be in a discovery mode, during which the mobile device 9011 may discover the drug delivery device 9010, and establish the wireless communication with the drug delivery device 9010. Alternatively, the drug delivery device 9010 may initiate and establish the wireless communication with the mobile device 9011 by sending short-burst signals or pings to the mobile device 9011.

[00764] Upon receiving the activation signal, the pump device 9010 may provide notification or feedback to the user to indicate that the device 9010 has been activated. For example, notification signals, such as audible tones, and/or visual notification such as LED lights, may be provided by the power and control system 90800.

[00765] It is contemplated that, in one example, a user may use the mobile device 9011 to activate the drug delivery device 9010. In such an example, prior to activation, the drug delivery

device 9010 may be in communication only mode during which the drug delivery device 9010 may be configured to establish a communication link with the mobile device 9011 (e.g., Bluetooth pairing). Upon establishing the communication link between the two devices, the user may select or press activation/start button 9010b to activate the drug delivery device 9010.

[00766] In one example, the housing 9012 may include one or more status indicators (e.g., light emitting diodes (LEDs) and/or speakers) and windows that may provide indication of the activation of the drug delivery device 9010. The activation mechanism, the status indicator, the window, and combinations thereof may be provided on the upper housing or the lower housing such as, for example, on a side visible to the user when the drug delivery device 9010 is placed on the body of the user. Housing 9012 is described in further detail hereinafter with reference to other components and embodiments of the present disclosure.

[00767] Additionally or alternatively, the drug delivery device 9010 may push the activation notification to the mobile device 9011. In this example, the mobile app 9010a may cause the mobile device 9011 to provide the notification via speakers or LED lights (not shown) of the mobile device 9011. Alternatively, the user may select the notification/data button 9010d to receive the notification of the activation.

[00768] When the drug delivery device 9010 and the mobile device 9011 are linked via the short range wireless communication based on the device activation, the mobile device 9011 may provide notification and guidance related to the operation of the drug delivery device 9010. In one example, the mobile device 9011 may provide instruction to place the drug delivery device 9010 on the body of the user.

[00769] It is noted that, during the device activation step, the drug delivery device 9010 may be in the non-active power mode (i.e., the power and control system 90800 may be receiving power from the power source and the drive control system 90820 (i.e., motor 90101) may not be receiving power from the power source).

[00770] At step 90903, after the drug delivery device 9010 has been activated, the control unit 90810 may determine the status of the on-body skin sensor 90840. For example, the control unit 90810 may monitor signals from the on-body skin sensor 90840 and/or the electro-mechanical skin sensor to determine whether the drug delivery device 9010 is in contact with the user's skin or body. When the control unit 90810 determines that the on-body skin sensor 90840 is in contact with

the skin of the user for a predetermined amount of time (e.g., 2 minutes), the control unit 90810 may set a flag to "on".

[00771] It will be appreciated that, the status check of the on-body sensor provides safety measure for the drug delivery device 9010. Specifically, because the control unit 90810 monitors the on-body sensor indication signal for substantial amount of time prior to setting the flag to "on", any quick contact (for a few seconds) or touch (e.g., by mistake) between the drug delivery device 9010 and the skin of the user may be disregarded by the control unit 90810. Moreover, any subsequent activation button press by the user for various operations of the drug delivery device 9010 may only be recognized by the control unit, upon determining that the on-body sensor 90840 is on.

[00772] At step 90904, the drug delivery device 9010 may provide notification to terminate the drug delivery process if the control unit 90810 determines that the drug delivery device 9010 is not in contact with the body of the user for the predetermined amount of time. Additionally or alternatively, the drug delivery device 9010 may notify the user of the termination of the drug delivery process or to properly position the drug delivery device 9010 via the mobile app 9010a.

[00773] At step 905, the drug delivery device 9010 provides a request notification to the user to activate the needle insertion. For example, as described above the request notification may be provided via audible tones (continuous or variable tones) and/or via LED lights of the drug delivery device 9010 to press the activation button a predetermined number of times (e.g., two times) to activate the needle insertion.

[00774] In another example, the request notification may be provided via the mobile device 9011 after control unit 90810 determines that the "on" status of the on-body skin sensor 90840. In that example, the drug delivery device mobile app 9010a may cause the mobile device 9011 to provide the request notification for activation of the needle insertion. In one example, the mobile device may provide the user with a request notification to press the activation button (e.g., two times) to activate the needle insertion. For example, the request and/or notification may be provided via a text message. In another example, the user may receive an indication of the notification of the request message via the notification button 9010d. Upon selecting the button 9010d, the user may be provided with the request notification message.

[00775] At step 90907, the control unit 90810 may determine whether the user has provided the appropriate input for the activation of the needle insertion (e.g., double press of the activation button).

[00776] At step 90908, when the control unit 90810 determines that the needle activation has not been activated within a predetermined amount of time, the method may notify the user to terminate the drug delivery process. In such an example, the control unit 90810 may wait for the predetermined amount of time, prior to providing the termination notification.

[00777] At step 90907, the control unit may determine that the user has responded to the request notification by executing the needle insertion activation (e.g., by pressing the activation button according to the request message). The method then proceeds to step 90909. Alternatively, the user may directly activate the NIM. (i.e., the pump device may be configured such that the NIM is mechanically activated by input by the user).

[00778] It is noted that, the user initiated needle insertion activation is beneficial, as this makes the user aware of the activation of the needle insertion into the body of the user and/or initiation of the drug delivery process.

[00779] At step 90909, the power and control system 90800, may prepare or prime the drug delivery device 9010. In one example, the power and control system 90800 may activate the needle insertion mechanism 90200, upon receiving user activation at step 90907.

[00780] Additionally, the power and control system may prime or initiate the SFPC sub-system 90300. It is contemplated that, in some embodiments, the SFPC may be initiated when the drug is being delivered (e.g., at step 90921), or concurrently with the needle insertion activation. In one example, during the priming of the device, the piston may be controlled to fill the fluid conduit with fluid drug, thereby displacing any air originally present therein.

[00781] It is noted that, during the steps 90901, 90903, 90904, 90907 and 90908 the power and control system may be in non-active power mode (i.e., the drive control system 90820 or motor 90101 may not be receiving any power from the power source). Whereas, during the needle insertion activation and/or SFPC, for example, the drug delivery device 9010 may be in active power mode.

[00782] At step 90911, timer unit 90812 may be initiated automatically. For example, the control unit 90810 may initialize the timer unit 90812 which may start the wait time period. Optionally, the

wait time period may be monitored by the mobile device 9011. For example, upon the initiation of the timer unit 90812, the control unit 90810 may communicate the timing information (e.g., when the timer was initiated, the amount of time left before the drug delivery, etc.) to the mobile device 9011. The user may receive such timing information via app 9011a (e.g., by pressing timer button 9010c).

[00783] It is noted that, the control unit 90810 may access or consult the timer unit 90812 to monitor a wait time period or a delay period. The wait time period may correspond to a time period that needs to be elapsed prior to the initiation of the drug delivery. In one example, the wait time period may be pre-programmed in the power and control system 90800. In one example, the wait time period may be 27 hours. Alternatively, the wait time period may be any other suitable time period for the drug delivery process.

[00784] Moreover, during the wait time period, the drug delivery device 9010 may be in the non-active power mode. In one example, the drug delivery device 9010 may communicate with the mobile device 9011 intermittently during the wait time period. For example, the control unit 90810 via the communication unit 90830 of the drug delivery device 9010 may send a status signal (e.g., a ping signal) to the mobile device 9011 to indicate that the drug delivery device 9010 is operational. Additionally, the drug delivery device 9010 may send information related to timing information (as discussed above) to the mobile device 9011.

[00785] At step 90913, the power and control system 90800 may monitor sensor signals from the various internal and/or external sensors. For example, the control unit 90810 may monitor signals from the temperature sensor 90880 to determine the temperature of the drug. In one example, the control unit 90810 may process the detected temperature values to determine that the drug has reached predetermined optimal temperature for drug delivery. The drug delivery device 9010 may send the temperature information of the drug to the mobile device 9011, during the wait time period. The mobile device 9011 may process such received data to provide further notification to the user during the wait time period. Step 90913 may also include the continuous monitoring of the on-body sensor by the control unit. In the event that the on-body sensor indicates to the control system 90800 that the pump device 9010 is not in contact with the patient's skin, the control system may provide a notification to the user.

[00786] Optionally, the control unit 90810 may request the mobile device 9011 to monitor signals or data from external sensors such as the glucose rate monitor 9011b and the heart rate monitor 9011a, and further process the captured data.

[00787] In one example, based on the request signal from the drug delivery device 9010, the mobile app 9010a may process the data received from the external sensors to determine various operations of the drug delivery process. For example, based on the data received from the external sensors, the mobile app 9010a may determine an adjusted drug delivery rate of the drug that may be delivered to the patient.

[00788] In one example, a user may work-out during the wait time period, during which, the mobile app 9010a may monitor the heart rate of the user by communicating with the heart rate monitor 9011a. The mobile app 9010a may execute an algorithm to determine and adjust the drug delivery rate based on the change in the heart rate of the user. Additionally, or alternatively, the mobile app 9010a may communicate with the glucose rate monitor 9011b to determine and adjust the drug delivery rate based on the change in the glucose rate of the user. Accordingly, the mobile app 9011a may provide notification and instruction that provides information as to how to deliver the drug at the adjusted rate. In one example, the user may access such information via the notification button 9010d. For example, the notification may include the number of times the user needs to press the activation button on the drug delivery device 9010 to deliver the drug at the adjusted rate. During the drug delivery period, the control unit 90810 of drug delivery device 9010, upon receiving such specified activation signal (e.g., the number of the press of activation button), may consult the storage unit 90813 to translate the adjusted delivery rate information into the drive mechanism information (e.g., gear ratio of various gear assemblies, rate of rotation of the motor 90101, etc.) in order to deliver the drug at the adjusted delivery rate. For example, the control unit 90810 may control the regulating mechanism 90500 or the flow-rate control sub-system 90825 via the drive control system 90820.

[00789] Optionally, in another example, the mobile device 9011 may wirelessly communicate the adjusted drug delivery rate to the drug delivery device 9010, and the drug delivery device 9010 may automatically deliver the drug at the adjusted rate when the predetermined wait time period expires. In that example, the user may not need to press the activation button to adjust the delivery rate of the drug.

[00790] Yet in another example, for a bolus delivery of the drug, the drug delivery device 9010 may not adjust the delivery rate. In that example, the control unit 90810 may monitor the temperature of the drug during the wait time period, and deliver the drug to the user after the wait time period elapses. Optionally, after the wait time period has elapsed, drug delivery may be further delayed if the temperature of the drug and/or drug container is below a predefined value. Additionally, the mobile app 9011a may provide notification to the user prior to the delivery of the drug.

[00791] At step 90915, the drug delivery device 9010 may determine whether the wait time period has elapsed and/or nearing the end of the wait time period. For example, the control unit 810, upon consulting the timer unit 90812, may perform the determination.

[00792] In one example, the control unit 90810 may determine that the wait time period has elapsed and/or nearing the end of the wait time period. The method may then proceed to step 90917.

[00793] However, if it is determined that the wait time period has not elapsed and/or not near the wait time period (e.g., if the control unit 90810 performs the check 4 hours prior to the end of the wait time period), the method goes back to step 90913.

[00794] In one example, for a bolus delivery process, at step 90917, the drug delivery device 9010 provides notification to the user to indicate that the wait time period has elapsed and/or the end of the wait time period is approaching. The notification may further indicate that the drug delivery will be initiated. For example, as described above, the notification may be provided via audible tones (continuous or variable tones) and/or via LED lights of the drug delivery device 9010. In another example, the notification may be provided via the mobile device 9011. As described above, the mobile device 9010 may receive indication signal from the drug delivery device 9010, or alternatively, may determine that the drug is to be delivered. Accordingly, the mobile device 9011 may then provide the appropriate notification to the user.

[00795] In another example, the drug device may be configured such that the user has the option of initiating drug delivery near to the completion of the wait time, or soon thereafter. In such a scenario, the notification may be provided just before the predetermined time has elapsed (e.g., about 5 minutes before the 27 hour wait period). This may provide the user with sufficient time to prepare and initiate the drug delivery process. For example, the user may be in an office meeting when the predetermined wait time period is about to elapse, and may not be aware of the wait time period. As such, if the user receives the alarm or notification alert prior to end of the wait time

period, the user may have sufficient time to step out of the office meeting to initiate the drug delivery, or simply initiate the drug delivery while at the meeting.

[00796] In another example, the notification may be provided via the pump device 9010 or mobile device 9011 after or near the wait time period expiration. In that example, the drug delivery device mobile app 9010a may cause the mobile device 9011 to provide notification, as described above. In one example, the mobile app 9010a may further provide the user with a request message to prepare to initiate the drug delivery (based on the monitored external sensor data). For example, the request and/or notification may be provided via a text message. In another example, the user may receive an indication of the notification of the request message via the notification button 9010d. Upon selecting the button 9010d, the user may be provided with the request and/or the notification message. Alternatively, or in addition, the pump device may provide notification to the user of the expiration of the wait time period through audible tones, visual indications, or other means.

[00797] It is contemplated that, the mobile drug delivery device app 9010a may track the wait time period. For example, the user may select the timer button 9010c to gather information such as how much time is left or how much time has elapsed in the wait time period prior to the drug delivery. In some examples, based on the information, the user may terminate the drug delivery process, or send information to the drug delivery device 9010.

[00798] As described above, the notification may further provide instruction related to the delivery of adjusted drug delivery rate to the user. The power and control system 800 may determine if the user has activated the initiation of the drug delivery within a predetermined time. For example, the control unit 90810 may determine whether the activation button has been pressed (e.g., within about 2 minutes), after the notification.

[00799] If the drug delivery device 9010 determines that the user has not provided any input to initiate the drug delivery process within the predetermined time at the adjusted rate, the control unit 90810 may terminate the drug delivery process. However, if the user provides the input for activation within the predetermined time upon receiving the notification, the method then proceeds to step 90919.

[00800] Optionally, as shown in FIG. 9B, the pump device 9010 may be configured such that, the user has the option to initiate drug delivery within some predetermined time after completion of the

wait time period. If the user does not initiate drug delivery within this predetermined time, the pump device may automatically initiate drug delivery at the expiration of the predetermined time.

[00801] At step 90919, the power and control system 90800 may provide instructions to the drive control system 90820 to control the various drive mechanisms of the drug delivery device 9010 to deliver the drug after the predetermined wait time period.

[00802] For example, the control unit of the power and control system 90800 may translate the delivery rate information to the settings and configurations for the various components of the drive control system to enable the delivery of the drug according to the determined delivery rate. As described above, the translation may include consulting lookup tables and/or databases stored in the storage units. Alternatively, the power and control system 90810 may send the delivery rate information to the drive control system 90820, and another controller (not shown) of the drive control system may perform the translation to enable the delivery of the drug according to the determined delivery rate, as described above.

[00803] Optionally, at step 90919, the power and control system 90800 may appropriately change (e.g., increase or decrease) the drug delivery rate, based on the processed data received from the external sensors (e.g., based on the heart rate and/or the glucose rate information of the user, as described at step 90913).

[00804] Accordingly, the control unit 90810 may instruct the drive control system 90820 to initiate the drug delivery process (irrespective of the user activation). The drive control system may then deliver the drug by controlling via the drive mechanism 90100.

[00805] It is contemplated that, in some examples, the power and control system 90800 may instruct the drive control system to initiate the insertion mechanism 90200 and create the connection between the drug container and the sterile pathway during the drug delivery, after the predetermined wait time period has elapsed. In such a scenario, the user may provide the input for the NIM activation after the predetermined time has elapsed. In another embodiment, the NIM is activated by the power and control system 90800 prior to initiation of drug delivery.

[00806] At step 90921, the power and control system 90810 may determine whether the delivery of the drug has ended. For example, motor 90101 may receive signal from the tether sensor 90875, a valve sensor 90877 and/or pressure sensor 90870 that indicates an end-of-dose of the drug. Accordingly, the drive control system 90820 may then communicate the end-of-dose information to the control unit 90810. The method then proceeds to step 90923.

[00807] When the drug delivery device 9010 determines that the drug has been delivered, the power and control system 90800 may provide notification via audible tones and/or LED lights as described above. Additionally and/or alternatively, notification of the end-of-dose information may be provided by the drug delivery device 9010 via the drug delivery device mobile app 9010a.

[00808] In one example, the drug delivery device 9010 may determine that the drug has not been delivered or the end-of-dose did not occur in a predetermined amount of time. In such a case, the drug delivery device 9010 may provide error notification (e.g., via the LED lights and/or via the drug delivery device mobile app 9010a), and the method may then go back to step 90919. Alternatively, the power and control system 90800 may terminate drug delivery and/or activate retraction of the NIM if an end-of-dose signal is not received within the expected delivery time.

[00809] At step 90923, upon the determination that the end-of-dose of the drug has occurred (i.e., the drug has been delivered in a predetermined time and/or according to a desired rate of delivery), the drug delivery device 9010 may communicate various end-of delivery information to the drug delivery device mobile app 9010a. The mobile app 9010a may then cause the mobile device 9011 to transmit such information to one or more remote servers or storage 9011c of various entities (e.g., healthcare provider, health insurance provider, drug manufacturer, etc.). In one example, data stored in the drug delivery device app 9010a related to the end of delivery information may be transmitted to the cloud server 9011c via cellular network interface. Moreover, the end of delivery information may include, but is not limited to, validation of the end-of-dose, total time period of the drug delivery, delivery rate information, etc. In one example, a user may select the button 9010d of the mobile app 9010a to transfer such information. In one example, the mobile app 9010a may be configured to selectively transfer the end of delivery information to the various entities. It is contemplated that, the end of delivery information, and/or any other information related to the drug delivery may not be stored permanently upon transfer of such information to the cloud server 9011c.

[00810] FIGS. 77B and 77C show alternative methods of operation of the pump device 9010 and/or mobile device 9011. In the methods illustrated in FIGS. 77B and 9C, activation of the device initiates the timer to mark the beginning of the predetermined wait time. Additionally, device activation also initiates the first step in the NIM activation process. As shown in the figures, the first step in the NIM activation process may be to determine if the on-body sensor detects the presence of a target. If the target is detected for the required time period, the device may be prepared for NIM

activation. The preparation of the device for NIM activation may include configuring one or more of the drive mechanism, regulating mechanism, and actuation mechanism such that the user may activate the NIM. After the device is prepared for NIM activation, the user may be notified to activate the NIM. The notification may be in the form of audible, visual, or tactile feedback from the pump device. Alternatively, or additionally, the notification may be provided by the mobile device.

[00811] After notification, the user may activate the NIM to insert the fluid path into the target. For example, the user may activate the NIM by depressing or actuating the actuation mechanism or another mechanism of the pump device.

[00812] As shown in FIG. 77B, after the predetermined wait time has elapsed, the user may be notified that the pump device may be activated to begin drug delivery. The user may be able to initiate drug delivery within a predetermined "user initiation time." After the user initiation time has elapsed, the pump device may automatically initiate drug delivery. The user may, optionally, be notified upon initiation of drug delivery. The notification may in the form of visual, audible, or tactile indication by the pump device or, alternatively, by notification by the mobile device.

[00813] In the method shown in FIG. 77C, the pump device 9010 is configured such that drug delivery is automatically initiated after the wait time elapses. The user may be notified that drug delivery will be, or has been, initiated. The user may be notified by an audible, visual, or tactile notification from the pump device. Alternatively, the user may be notified by the mobile device.

[00814] Assembly and/or manufacturing of controlled delivery drive mechanism 90100, drug delivery pump 9010, or any of the individual components may utilize a number of known materials and methodologies in the art. For example, a number of known cleaning fluids such as isopropyl alcohol and hexane may be used to clean the components and/or the devices. A number of known adhesives or glues may similarly be employed in the manufacturing process. Additionally, known siliconization and/or lubrication fluids and processes may be employed during the manufacture of the components and devices. Furthermore, known sterilization processes may be employed at one or more of the manufacturing or assembly stages to ensure the sterility of the final product.

[00815] The drive mechanism may be assembled in a number of methodologies. In one method of assembly, the drug container 9050 may first be assembled and filled with a fluid for delivery to the user. The drug container 9050 includes a cap 9052, a pierceable seal 9056, a barrel 9058, and a plunger seal 9060. The pierceable seal 9056 may be fixedly engaged between the cap 9052 and the

barrel 9058, at a distal end of the barrel 9058. The barrel 9058 may be filled with a drug fluid through the open proximal end prior to insertion of the plunger seal 9060 from the proximal end of the barrel 9058. An optional connection mount 9054 may be mounted to a distal end of the pierceable seal 9056. The connection mount 9054 may guide the insertion of the piercing member of the fluid pathway connector into the barrel 9058 of the drug container 9050. The drug container 9050 may then be mounted to a distal end of drive housing 90130.

[00816] One or more drive biasing members 90122 may be inserted into a distal end of the drive housing 90130. Optionally, a cover sleeve 90140 may be inserted into a distal end of the drive housing 90130 to substantially cover biasing member 90122. A piston may be inserted into the distal end of the drive housing 90130 such that it resides at least partially within an axial pass-through of the biasing member 90122 and the biasing member 90122 is permitted to contact a piston interface surface 90110C of piston 90110A, 90110B at the distal end of the biasing member 90122. An optional cover sleeve 90140 may be utilized to enclose the biasing member 90122 and contact the piston interface surface 90110C of piston 90110A, 90110B. The piston 90110A, 90110B and drive biasing member 90122, and optional cover sleeve 90140, may be compressed into drive housing 90130. Such assembly positions the drive biasing member 90122 in an initial compressed, energized state and preferably places a piston interface surface 90110C in contact with the proximal surface of the plunger seal 9060 within the proximal end of barrel 9058. The piston, piston biasing member, contact sleeve, and optional components, may be compressed and locked into the ready-to-actuate state within the drive housing 90130 prior to attachment or mounting of the drug container 9050. The tether 90525 is pre-connected to the proximal end of the piston 90110A, 90110B and passed through the axial aperture of the biasing member 90122 and drive mechanism 90130, and then wound through the interior of the drug delivery device with the other end of the tether 90525 wrapped around the winch drum/gear 90520 of the regulating mechanism 90500.

[00817] A fluid pathway connector, and specifically a sterile sleeve of the fluid pathway connector, may be connected to the cap and/or pierceable seal of the drug container. A fluid conduit may be connected to the other end of the fluid pathway connector which itself is connected to the insertion mechanism such that the fluid pathway, when opened, connected, or otherwise enabled travels directly from the drug container, fluid pathway connector, fluid conduit, insertion mechanism, and through the cannula for drug delivery into the body of a user. The components which constitute the pathway for fluid flow are now assembled. These components may be

sterilized, by a number of known methods, and then mounted either fixedly or removably to an assembly platform or housing of the drug delivery device, as shown in FIG. 69B.

[00818] Certain optional standard components or variations of drive mechanism 90100 or drug delivery device 9010 are contemplated while remaining within the breadth and scope of the present disclosure. For example, the embodiments may include one or more batteries utilized to power a motor or solenoid, drive mechanisms, and drug delivery devices of the present disclosure. A range of batteries known in the art may be utilized for this purpose. Additionally, upper or lower housings may optionally contain one or more transparent or translucent windows 9018 to enable the user to view the operation of the drug delivery device 9010 or verify that drug dose has completed. Similarly, the drug delivery device 9010 may contain an adhesive patch 9026 and a patch liner 9028 on the bottom surface of the housing 9012. The adhesive patch 9026 may be utilized to adhere the drug delivery device 9010 to the body of the user for delivery of the drug dose. As would be readily understood by one having ordinary skill in the art, the adhesive patch 9026 may have an adhesive surface for adhesion of the drug delivery device to the body of the user. The adhesive surface of the adhesive patch 9026 may initially be covered by a non-adhesive patch liner 9028, which is removed from the adhesive patch 9026 prior to placement of the drug delivery device 9010 in contact with the body of the user. Removal of the patch liner 9028 may further remove the sealing membrane 254 of the insertion mechanism 90200, opening the insertion mechanism to the body of the user for drug delivery (as shown in FIG. 69C).

[00819] Similarly, one or more of the components of controlled delivery drive mechanism 90100 and drug delivery device 9010 may be modified while remaining functionally within the breadth and scope of the present disclosure. For example, as described above, while the housing of drug delivery device 9010 is shown as two separate components upper housing 9012A and lower housing 9012B, these components may be a single unified component. As discussed above, a glue, adhesive, or other known materials or methods may be utilized to affix one or more components of the controlled delivery drive mechanism and/or drug delivery device to each other. Alternatively, one or more components of the controlled delivery drive mechanism and/or drug delivery device may be a unified component. For example, the upper housing and lower housing may be separate components affixed together by a glue or adhesive, a screw fit connection, an interference fit, fusion joining, welding, ultrasonic welding, and the like; or the upper housing and lower housing may be a single unified component. Such standard components and functional variations would be appreciated by

one having ordinary skill in the art and are, accordingly, within the breadth and scope of the present disclosure.

[00820] It will be appreciated from the above description that the controlled delivery drive mechanisms and drug delivery devices disclosed herein provide an efficient and easily-operated system for automated drug delivery from a drug container. The embodiments described herein provide drive mechanisms for the controlled delivery of drug substances and drug delivery pumps which incorporate such controlled delivery drive mechanisms. The drive mechanisms of the present disclosure control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thus, are capable of delivering drug substances at variable rates and/or delivery profiles. Additionally, the drive mechanisms of the present disclosure may provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication. The controlled delivery drive mechanisms of the present disclosure may be directly or indirectly activated by the user. Furthermore, the configurations of the controlled delivery drive mechanism and drug delivery devices of the present disclosure maintain the sterility of the fluid pathway during storage, transportation, and through operation of the device. Because the path that the drug fluid travels within the device is entirely maintained in a sterile condition, only these components need be sterilized during the manufacturing process. Such components include the drug container of the drive mechanism, the fluid pathway connector, the sterile fluid conduit, and the insertion mechanism. In at least one embodiment of the present disclosure, the power and control system, the assembly platform, the control arm, the activation mechanism, the housing, and other components of the drug delivery device do not need to be sterilized. This greatly improves the manufacturability of the device and reduces associated assembly costs. Accordingly, the devices of the present disclosure do not require terminal sterilization upon completion of assembly.

[00821] Manufacturing of a drug delivery device includes the step of attaching both the controlled delivery drive mechanism and drug container, either separately or as a combined component, to an assembly platform or housing of the drug delivery device. The method of manufacturing further includes attachment of the fluid pathway connector, drug container, and

insertion mechanism to the assembly platform or housing. The additional components of the drug delivery device, as described above, including the power and control system, the activation mechanism, and the control arm may be attached, preformed, or pre-assembled to the assembly platform or housing. An adhesive patch and patch liner may be attached to the housing surface of the drug delivery device that contacts the user during operation of the device.

[00822] A method of operating the drug delivery device includes the steps of: activating, by a user, the activation mechanism; displacing a control arm to actuate an insertion mechanism; and actuating a power and control system to activate a controlled delivery drive mechanism to drive fluid drug flow through the drug delivery device according to a controlled rate or drug delivery profile. The method may further include the step of: engaging an optional on-body sensor prior to activating the activation mechanism. The method similarly may include the step of: establishing a connection between a fluid pathway connector to a drug container. Furthermore, the method of operation may include translating a plunger seal within the controlled delivery drive mechanism by the expansion of the biasing member acting upon a piston within a drug container to force fluid drug flow through the drug container, the fluid pathway connector, a sterile fluid conduit, and the insertion mechanism for delivery of the fluid drug to the body of a user, wherein a regulating mechanism acting to restrain the distribution of a tether is utilized to meter the free axial translation of the piston. The method of operation of the drive mechanism and the drug delivery device may be better appreciated with reference to FIGS. 70A-70D and FIGS. 71A-71D, as described above.

[00823] IX. Additional Embodiments of Multi-Function Drive Mechanism

[00824] At least some of the drug delivery devices described in this application, including at least those described in connection with Figs. 1A-2B and 33A-33C, may be configured to incorporate the embodiments of the drive mechanism described below in connection with Figs. 69A-75B and 78A-79B. The embodiments of the drive mechanism described below in connection with Figs. 69A-75B and 78A-79B may be used to replace, in its entirety or partially, the above-described drive mechanism 100, 6100, or 8100, or any other drive mechanism described herein, where appropriate.

[00825] The present disclosure provides multi-function drive mechanisms for the controlled delivery of drug substances, controlled drug delivery pumps with such drive mechanisms, the methods of operating such devices, and the methods of assembling such devices. Notably, the multi-function drive mechanisms of the present disclosure enable or initiate several functions, including: (i) controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing

free axial translation of the plunger seal utilized to force a drug substance out of a drug container; (ii) triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a user; and (iii) connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. The novel embodiments of the present disclosure thus are capable of delivering drug substances at variable rates. The drive mechanisms of the present disclosure may be pre-configurable or dynamically configurable, such as by control by the power and control system, to meet desired delivery rates or profiles, as explained in detail below. Additionally, the drive mechanisms of the present disclosure provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication. Because the end-of-dose indication is related to the physical end of axial translation and/or travel of one or more components of the drive mechanism, the drive mechanism and drug delivery device provide a true end-of-dose indication to the user. Through these mechanisms, confirmation of drug dose delivery can accurately be provided to the user or administrator. Accordingly, the novel devices of the present disclosure alleviate one or more of the problems associated with prior art devices, such as those referred to above.

[00826] In a first embodiment, the present disclosure provides a multi-function drive mechanism which includes an actuator, a gear assembly including a main gear, a drive housing, and a drug container having a cap, a pierceable seal (not visible), a barrel, and a plunger seal. The main gear may be, for example, a star gear disposed to contact multiple secondary gears or gear surfaces. A drug chamber, located within the barrel between the pierceable seal and the plunger seal, may contain a drug fluid for delivery through the insertion mechanism and drug delivery device into the body of the user. A piston, and one or more biasing members, wherein the one or more biasing members are initially retained in an energized state and is configured to bear upon an interface surface of the piston, may also be incorporated in the multi-function drive mechanism. The piston is configured to translate substantially axially within a drug container having a plunger seal and a barrel. A tether is connected at one end to the piston and at another end to a winch drum/gear of a regulating mechanism, wherein the tether restrains the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The drug container may contain a drug fluid within a drug chamber for delivery to a

user. Optionally, a cover sleeve may be utilized between the biasing member and the interface surface of the piston to hide the interior components of the barrel (namely, the piston and the biasing member) from view during operation of the drive mechanism. The tether is configured to be released from a winch drum/gear of a regulating mechanism of the multi-function drive mechanism to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon.

[00827] In at least one embodiment of the present disclosure, the regulating mechanism is gear assembly driven by an actuator of the multi-function drive mechanism. The regulating mechanism retards or restrains the distribution of tether, only allowing it to advance at a regulated or desired rate. This restricts movement of piston within barrel, which is pushed by one or more biasing members, hence controlling the movement of plunger seal and delivery of the drug contained in chamber. As the plunger seal advances in the drug container, the drug substance is dispensed through the sterile pathway connection, conduit, insertion mechanism, and into the body of the user for drug delivery. The actuator may be a number of power/motion sources including, for example, a motor (e.g., a DC motor, AC motor, or stepper motor) or a solenoid (e.g., linear solenoid, rotary solenoid). In a particular embodiment, the actuator is a rotational stepper motor with a notch that corresponds with the gear teeth of the main/star gear.

[00828] The regulating mechanism may further include one or more gears of a gear assembly. One or more of the gears may be, for example, compound gears having a small diameter gear attached at a shared center point to a large diameter gear. The gear assembly may include a winch gear coupled to a winch drum/gear upon which the tether may be releasably wound. Accordingly, rotation of the gear assembly initiated by the actuator may be coupled to winch drum/gear (i.e., through the gear assembly), thereby controlling the distribution of tether, the rate of expansion of the biasing members and the axial translation of the piston, and the rate of movement of plunger seal within barrel to force a fluid from drug chamber. The rotational movement of the winch drum/gear, and thus the axial translation of the piston and plunger seal, are metered, restrained, or otherwise prevented from free axial translation by other components of the regulating element, as described herein. Notably, the regulating mechanisms of the present disclosure do not drive the delivery of fluid substances from the drug chamber. The delivery of fluid substances from the drug chamber is caused by the expansion of the biasing member from its initial energized state acting upon the piston and plunger seal. The regulating mechanisms instead function to provide resistance to the free motion of the piston and plunger seal as they are pushed by the expansion of the biasing

member from its initial energized state. The regulating mechanism does not drive the delivery but only controls the delivery motion. The tether limits or otherwise restrains the motion of the piston and plunger seal, but does not apply the force for the delivery.

[00829] In addition to controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container (thereby delivering drug substances at variable rates and/or delivery profiles); the multi-function drive mechanisms of the present disclosure may concurrently or sequentially perform the steps of: triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a user; and connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. In at least one embodiment, initial motion by the actuator of the multi-function drive mechanism causes rotation of main/star gear. In one manner, main/star gear conveys motion to the regulating mechanism through gear assembly. In another manner, main/star gear conveys motion to the needle insertion mechanism through gear. As gear is rotated by main/star gear, gear engages the needle insertion mechanism to initiate the fluid pathway connector into the user, as described in detail above. In one particular embodiment, needle insertion mechanism is a rotational needle insertion mechanism. Accordingly, gear is configured to engage a corresponding gear surface of the needle insertion mechanism. Rotation of gear causes rotation of needle insertion mechanism through the gear interaction between gear of the drive mechanism and corresponding gear surface of the needle insertion mechanism. Once suitable rotation of the needle insertion mechanism occurs, the needle insertion mechanism may be initiated to create the fluid pathway connector into the user, as described in detail herein.

[00830] In at least one embodiment, rotation of the needle insertion mechanism in this manner may also cause a connection of a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. Ramp aspect of needle insertion mechanism is caused to bear upon a movable connection hub of the sterile fluid pathway connector. As the needle insertion mechanism is rotated by the multi-function drive mechanism, ramp aspect of needle insertion mechanism bears upon and translates movable connection hub of the sterile fluid pathway connector to facilitate a fluid connection therein. In at least one embodiment, the needle insertion mechanism may be configured such that a particular degree of rotation enables the needle/trocar to retract as detailed above. Additionally or alternatively, such needle/trocar retraction may be configured to occur upon a user-activity or upon movement or

function of another component of the drug delivery device. In at least one embodiment, needle/trocar retraction may be configured to occur upon end-of-drug-delivery, as triggered by, for example, the regulating mechanism and/or one or more of the status readers as described herein.

[00831] In yet another embodiment, the drive mechanism may include a status reader configured to read or recognize one or more corresponding status triggers. The status triggers may be incrementally spaced on the tether, wherein, during operation of the drive mechanism, interaction between the status reader and the status triggers transmit a signal to a power and control system to provide feedback to a user. The status reader may be an optical status reader and the corresponding status triggers are optical status triggers, an electromechanical status reader and the corresponding status triggers are electromechanical status triggers, or a mechanical status reader and the corresponding status triggers are mechanical status triggers.

[00832] In a further embodiment, the present disclosure provides a drug delivery pump with controlled drug delivery. The drug delivery pump having a housing and an assembly platform, upon which an activation mechanism, an insertion mechanism, a fluid pathway connector, a power and control system, and a controlled delivery drive mechanism may be mounted, said drive mechanism having a drive housing, a piston, and a biasing member, wherein the biasing member is initially retained in an energized state and is configured to bear upon an interface surface of the piston. The piston is configured to translate substantially axially within a drug container having a plunger seal and a barrel. A tether is connected at one end to the piston and at another end to a winch drum/gear of a delivery regulating mechanism, wherein the tether restrains the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The drug container may contain a drug fluid within a drug chamber for delivery to a user. Optionally, a cover sleeve may be utilized between the biasing member and the interface surface of the piston to hide the interior components of the barrel (namely, the piston and the biasing member) from view during operation of the drive mechanism. The tether is configured to be released from a winch drum/gear of the delivery regulating mechanism to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon.

[00833] In another embodiment, the drug delivery device further includes a gear assembly. The gear assembly may include a winch gear connected to a winch drum/gear upon which the tether may be releasably wound, rotation of the winch drum/gear releases the tether from the winch

drum/gear to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The metering of the tether controls the rate or profile of drug delivery to a user. The piston may be one or more parts and connects to a distal end of the tether. The winch drum/gear is coupled to a regulating mechanism which controls rotation of the winch drum/gear and hence metering of the translation of the piston.

[00834] In yet another embodiment, the drug delivery device may include a status reader configured to read or recognize one or more corresponding status triggers. The status triggers may be incrementally spaced on the tether, wherein, during operation of the drive mechanism, interaction between the status reader and the status triggers transmit a signal to a power and control system to provide feedback to a user. The status reader may be an optical status reader and the corresponding status triggers are optical status triggers, an electromechanical status reader and the corresponding status triggers are electromechanical status triggers, or a mechanical status reader and the corresponding status triggers are mechanical status triggers.

[00835] In another embodiment, the power and control system of the drug delivery device is configured to receive one or more inputs to meter the release of the tether by the winch drum/gear and thereby permit axial translation of the piston by the biasing member to translate a plunger seal within a barrel. The one or more inputs may be provided by the actuation of the activation mechanism, a control interface, and/or a remote control mechanism. The power and control system may be configured to receive one or more inputs to adjust the restraint provided by the tether and winch drum/gear on the free axial translation of the piston upon which the biasing member bears upon to meet a desired drug delivery rate or profile, to change the dose volume for delivery to the user, and/or to otherwise start, stop, or pause operation of the drive mechanism.

[00836] In at least one embodiment of the present disclosure, the delivery profile of the medicament is adjustable. For example, it may be desirable to deliver a bolus injection of medicament before, during, or subsequent to certain activities such as eating, exercising, sleeping, etc. A “bolus injection” is any measured drug volume that is delivered often irrespective of the delivery time or duration. Conversely, a “basal injection” is often a controlled rate of delivery and/or a drug delivery profile having various rates of delivery at different time intervals. Similarly, the user may desire to increase or decrease the basal delivery rate of the medicament at these or other times. In at least one embodiment, the delivery profile may be adjustable by the user to achieve this desired drug delivery. The user may adjust the delivery profile by interacting with the

drug delivery device itself or, alternatively, may use an external device, such as a smart-phone, to do so. For example, the user may adjust the delivery profile by displacing the activation mechanism or may engage a separate device-integrated or external delivery control mechanism.

[00837] In another embodiment of the present disclosure, the delivery profile may be adjusted automatically based on one or more inputs. For example, the delivery profile may be adjusted based on the patient's activity level, heart rate, blood sugar level, blood pressure, etc. As above, these measurements may be used to determine the need for a bolus injection or for the increase or decrease of the basal injection delivery rate or adjustment to the basal injection delivery profile. In at least one embodiment, these input measurements may be monitored by the device itself. Additionally, or alternatively, they may be monitored by a secondary device such as a smart-phone, smart watch, heart rate monitor, glucose monitor, blood pressure monitor, or the like. In some embodiments, the delivery profile may be adjusted based on these measurements with no required user intervention. In the case of monitoring and/or control by a secondary device, the secondary device and drug delivery device may be in wireless or wired communication with one another. This communication may be through Bluetooth, near field communication, Wi-Fi, or any other method known to one having ordinary skill in the relevant art of device interconnectivity.

[00838] In a preferred embodiment, however, the monitoring/adjustment mechanism may alert and make recommendations to the user and the user may have active control to initiate/authorize or disregard the recommendation made by the monitoring/adjustment mechanism. For example, if one or more of the measurements is above or below a specified threshold value the device may emit an audible, visual, or tactile alert to the user. In one example, the alert is provided by a vibration of the device, thereby providing a discrete alert to the user. Additionally or alternatively, the alert may be provided by the user's smart-phone or other secondary device. The user may be able to view the current status of the measurements in a computer program or web interface on the device itself, a computer, smart-phone, or other device. The computer program or web interface may provide a recommended adjustment to the delivery profile. Based on this information, the user may adjust the delivery rate of the drug delivery device. As above, the user may adjust the delivery profile by displacing the activation mechanism or engaging a separate device-integrated or external delivery control mechanism.

[00839] In one embodiment, in response to a signal to adjust the delivery profile, either based on user input or based on the measurements described above, the power and control system may cause

a change in the rate of movement of the actuator. The change in the rate of movement of the actuator causes a change in the rotation rate of the regulating mechanism which, in turn, controls the rate of drug delivery to the user. Alternatively, the delivery profile may be altered by a change in the characteristics of the flow path of medicament through the conduit connecting the drug container and insertion mechanism. The change may be caused by the introduction, removal, or modification of a flow restrictor which restricts flow of medicament from the drug container to the insertion mechanism. For example, a flow restrictor may have multiple flow paths which may be selectively placed in fluid communication with an input and an output of the flow restrictor. By providing flow paths which are of different length or cross-section the rate of delivery may be controlled. In other embodiments, the delivery profile may be altered by the introduction or removal of an impingement of the conduit. An impingement of the flow path may interrupt or slow flow of medicament through the conduit, thereby controlling the rate of delivery to the user. Accordingly, one or more embodiments of the present disclosure are capable of producing a change to the rate of medicament delivery from the drug container thereby providing a dynamic control capability to the multi-function drive mechanism and/or the drug delivery device.

[00840] The novel embodiments of the present disclosure provide drive mechanisms which are capable of metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thereby, controlling the rate of delivery of drug substances. The novel control delivery drive mechanisms are additionally capable of providing the incremental status of the drug delivery before, during, and after operation of the device. Throughout this specification, unless otherwise indicated, "comprise," "comprises," and "comprising," or related terms such as “includes” or “consists of,” are used inclusively rather than exclusively, so that a stated integer or group of integers may include one or more other non-stated integers or groups of integers. As will be described further below, the embodiments of the present disclosure may include one or more additional components which may be considered standard components in the industry of medical devices. For example, the embodiments may include one or more batteries utilized to power the motor, drive mechanisms, and drug delivery devices of the present disclosure. The components, and the embodiments containing such components, are within the contemplation of the present disclosure and are to be understood as falling within the breadth and scope of the present disclosure.

[00841] The present disclosure provides multi-function drive mechanisms for the controlled delivery of drug substances and drug delivery pumps which incorporate such multi-function drive

mechanisms. The multi-function drive mechanisms of the present disclosure enable or initiate several functions, including: (i) controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container; (ii) triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a user; and (iii) connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. The drive mechanisms of the present disclosure control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thus, are capable of delivering drug substances at variable rates and/or delivery profiles. Additionally, the drive mechanisms of the present disclosure provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication.

[00842] As used herein to describe the drive mechanisms, drug delivery pumps, or any of the relative positions of the components of the present disclosure, the terms “axial” or “axially” refer generally to a longitudinal axis “A” around which the drive mechanisms are preferably positioned, although not necessarily symmetrically there-around. The term “radial” refers generally to a direction normal to axis A. The terms “proximal,” “rear,” “rearward,” “back,” or “backward” refer generally to an axial direction in the direction “P”. The terms “distal,” “front,” “frontward,” “depressed,” or “forward” refer generally to an axial direction in the direction “D”. As used herein, the term “glass” should be understood to include other similarly non-reactive materials suitable for use in a pharmaceutical grade application that would normally require glass, including but not limited to certain non-reactive polymers such as cyclic olefin copolymers (COC) and cyclic olefin polymers (COP). The term “plastic” may include both thermoplastic and thermosetting polymers. Thermoplastic polymers can be re-softened to their original condition by heat; thermosetting polymers cannot. As used herein, the term “plastic” refers primarily to moldable thermoplastic polymers such as, for example, polyethylene and polypropylene, or an acrylic resin, that also typically contain other ingredients such as curatives, fillers, reinforcing agents, colorants, and/or plasticizers, etc., and that can be formed or molded under heat and pressure. As used herein, the term “plastic” is not meant to include glass, non-reactive polymers, or elastomers that are approved

for use in applications where they are in direct contact with therapeutic liquids that can interact with plastic or that can be degraded by substituents that could otherwise enter the liquid from plastic. The term “elastomer,” “elastomeric” or “elastomeric material” refers primarily to cross-linked thermosetting rubbery polymers that are more easily deformable than plastics but that are approved for use with pharmaceutical grade fluids and are not readily susceptible to leaching or gas migration under ambient temperature and pressure. “Fluid” refers primarily to liquids, but can also include suspensions of solids dispersed in liquids, and gasses dissolved in or otherwise present together within liquids inside the fluid-containing portions of the drug delivery devices. According to various aspects and embodiments described herein, reference is made to a “biasing member”, such as in the context of one or more biasing members for asserting force on a plunger seal. It will be appreciated that the biasing member may be any member that is capable of storing and releasing energy. Non-limiting examples include a spring, such as for example a coiled spring, a compression or extension spring, a torsional spring, or a leaf spring, a resiliently compressible or elastic band, or any other member with similar functions. In at least one embodiment of the present disclosure, the biasing member is a spring, preferably a compression spring.

[00843] The novel devices of the present disclosure provide drive mechanisms with integrated status indication and drug delivery pumps which incorporate such drive mechanisms. Such devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The devices described herein incorporate features which make activation, operation, and lock-out of the device simple for even untrained users. The novel devices of the present disclosure provide these desirable features without any of the problems associated with known prior art devices. Certain non-limiting embodiments of the novel drug delivery pumps, drive mechanisms, and their respective components are described further herein with reference to the accompanying figures.

[00844] As used herein, the terms “pump” and “delivery device” are intended to include any number of drug delivery systems which are capable of dispensing a fluid to a user upon activation. Such drug delivery systems include, but are not limited to, for example, injection systems, infusion pumps, bolus injectors, on-body injectors, and the like. FIGS. 69A-69C show an exemplary drug delivery device according to at least one embodiment of the present disclosure with the top housing removed so that the internal components are visible. The drug delivery device may be utilized to administer delivery of a drug treatment into a body of a user. As shown in FIGS. 69A-69C, the drug delivery device 9010 includes a pump housing 9012. Pump housing 9012 may include one or more

housing subcomponents which are fixedly engageable to facilitate easier manufacturing, assembly, and operation of the drug delivery device. For example, drug delivery device 9010 includes a pump housing 9012 which may include an upper housing and a lower housing (not shown for ease of viewing internal components). The pump housing 9012 may include one or more tamper evidence features to identify if the drug delivery device has been opened or tampered with. For example, the pump housing 9012 may include one or more tamper evidence labels or stickers, such as labels that bridge across the upper housing and the lower housing. Additionally or alternatively, the housing 9012 may include one or more snap arms or prongs connecting between the upper housing and the lower housing. A broken or altered tamper evidence feature would signal to the user, the physician, the supplier, the manufacturer, or the like, that the drug delivery device has potentially been tampered, e.g., by accessing the internal aspects of the device, so that the device is evaluated and possibly discarded without use by or risk to the user. The drug delivery device may further include an activation mechanism, a status indicator, and a window. Window may be any translucent or transmissive surface through which the operation of the drug delivery device may be viewed. As shown in FIG. 69B, drug delivery device 9010 further includes assembly platform 9020, sterile fluid conduit 30, drive mechanism 90100 having drug container 9050, insertion mechanism 90200, fluid pathway connector 90300, and a power and control system (not shown). One or more of the components of such drug delivery devices may be modular in that they may be, for example, pre-assembled as separate components and configured into position onto the assembly platform 9020 of the drug delivery device 9010 during manufacturing.

[00845] The pump housing 9012 contains all of the device components and provides a means of removably attaching the device 9010 to the skin of the user. The pump housing 9012 also provides protection to the interior components of the device 9010 against environmental influences. The pump housing 9012 is ergonomically and aesthetically designed in size, shape, and related features to facilitate easy packaging, storage, handling, and use by users who may be untrained and/or physically impaired. Furthermore, the external surface of the pump housing 9012 may be utilized to provide product labeling, safety instructions, and the like. Additionally, as described above, housing 9012 may include certain components, such as one or more status indicators and windows, which may provide operation feedback to the user.

[00846] In at least one embodiment, the drug delivery device 9010 provides an activation mechanism that is displaced by the user to trigger the start command to the power and control system. In a preferred embodiment, the activation mechanism is a start button that is located

through the pump housing 9012, such as through an aperture between upper housing and lower housing, and which contacts either directly or indirectly the power and control system. In at least one embodiment, the start button may be a push button, and in other embodiments, may be an on/off switch, a toggle, or any similar activation feature known in the art. The pump housing 9012 also provides one or more status indicators and windows. In other embodiments, one or more of the activation mechanism, the status indicator, the window, and combinations thereof may be provided on the upper housing or the lower housing such as, for example, on a side visible to the user when the drug delivery device 9010 is placed on the body of the user. Housing 9012 is described in further detail hereinafter with reference to other components and embodiments of the present disclosure.

[00847] Drug delivery device 9010 is configured such that, upon activation by a user by depression of the activation mechanism, the multi-function drive mechanism is activated to: insert a fluid pathway into the user; enable, connect, or open necessary connections between a drug container, a fluid pathway, and a sterile fluid conduit; and force drug fluid stored in the drug container through the fluid pathway and fluid conduit for delivery into a user. In at least one embodiment, such delivery of drug fluid into a user is performed by the multi-function drive mechanism in a controlled manner. One or more optional safety mechanisms may be utilized, for example, to prevent premature activation of the drug delivery device. For example, an optional on-body sensor (not visible) may be provided in one embodiment as a safety feature to ensure that the power and control system, or the activation mechanism, cannot be engaged unless the drug delivery device 9010 is in contact with the body of the user. In one such embodiment, the on-body sensor is located on the bottom of lower housing where it may come in contact with the user's body. Upon displacement of the on-body sensor, depression of the activation mechanism is permitted. Accordingly, in at least one embodiment the on-body sensor is a mechanical safety mechanism, such as for example a mechanical lock out, that prevents triggering of the drug delivery device 9010 by the activation mechanism. In another embodiment, the on-body sensor may be an electro-mechanical sensor such as a mechanical lock out that sends a signal to the power and control system to permit activation. In still other embodiments, the on-body sensor can be electrically based such as, for example, a capacitive- or impedance-based sensor which must detect tissue before permitting activation of the power and control system. These concepts are not mutually exclusive and one or more combinations may be utilized within the breadth of the present disclosure to prevent, for example, premature activation of the drug delivery device. In a preferred embodiment, the drug

delivery device 9010 utilizes one or more mechanical on-body sensors. Additional integrated safety mechanisms are described herein with reference to other components of the novel drug delivery devices.

[00848] IX.A. Power and Control System

[00849] The power and control system may include a power source, which provides the energy for various electrical components within the drug delivery device, one or more feedback mechanisms, a microcontroller, a circuit board, one or more conductive pads, and one or more interconnects. Other components commonly used in such electrical systems may also be included, as would be appreciated by one having ordinary skill in the art. The one or more feedback mechanisms may include, for example, audible alarms such as piezo alarms and/or light indicators such as light emitting diodes (LEDs). The microcontroller may be, for example, a microprocessor. The power and control system controls several device interactions with the user and interfaces with the drive mechanism 90100. In one embodiment, the power and control system interfaces either directly or indirectly with the on-body sensor 9024 to identify when the device is in contact with the user and/or the activation mechanism to identify when the device has been activated. The power and control system may also interface with the status indicator of the pump housing 9012, which may be a transmissive or translucent material which permits light transfer, to provide visual feedback to the user. The power and control system interfaces with the drive mechanism 90100 through one or more interconnects to relay status indication, such as activation, drug delivery, and end-of-dose, to the user. Such status indication may be presented to the user via auditory tones, such as through the audible alarms, and/or via visual indicators, such as through the LEDs. In a preferred embodiment, the control interfaces between the power and control system and the other components of the drug delivery device are not engaged or connected until activation by the user. This is a desirable safety feature that prevents accidental operation of the drug delivery device and may additionally maintain the energy contained in the power source during storage, transportation, and the like.

[00850] The power and control system may be configured to provide a number of different status indicators to the user. For example, the power and control system may be configured such that after the on-body sensor and/or trigger mechanism have been pressed, the power and control system provides a ready-to-start status signal via the status indicator if device start-up checks provide no errors. After providing the ready-to-start status signal and, in an embodiment with the optional on-body sensor, if the on-body sensor remains in contact with the body of the user, the power and

control system will power the drive mechanism 90100 to begin delivery of the drug treatment through the fluid pathway connector 90300 and sterile fluid conduit 9030 (not shown).

[00851] Additionally, the power and control system may be configured to identify removal of the drug delivery device from its packaging. The power and control system may be mechanically, electronically, or electro-mechanically connected to the packaging such that removal of the drug delivery device from the packaging may activate or power-on the power and control system for use, or simply enable the power and control system to be powered-on by the user. In such an embodiment, without removal of the drug delivery device from the packaging the drug delivery device cannot be activated. This provides an additional safety mechanism of the drug delivery device and for the user. In at least one embodiment, the drug delivery device or the power and control system may be electronically or electro-mechanically connected to the packaging, for example, such as by one or more interacting sensors from a range of: Hall effect sensors; giant magneto resistance (GMR) or magnetic field sensors; optical sensors; capacitive or capacitance change sensors; ultrasonic sensors; and linear travel, LVDT, linear resistive, or radiometric linear resistive sensors; and combinations thereof, which are capable of coordinating to transmit a signal between components to identify the location there-between. Additionally or alternatively, the drug delivery device or the power and control system may be mechanically connected to the packaging, such as by a pin and slot relationship which activates the system when the pin is removed (i.e., once the drug delivery device is removed from the packaging).

[00852] In a preferred embodiment of the present disclosure, once the power and control system has been activated, the multi-function drive mechanism is initiated to actuate the insertion mechanism 90200 and the fluid pathway connector 90300, while also permitting the drug fluid to be forced from the drug container. During the drug delivery process, the power and control system is configured to provide a dispensing status signal via the status indicator. After the drug has been administered into the body of the user and after the end of any additional dwell time, to ensure that substantially the entire dose has been delivered to the user, the power and control system may provide an okay-to-remove status signal via the status indicator. This may be independently verified by the user by viewing the drive mechanism and drug dose delivery through the window of the pump housing 9012. Additionally, the power and control system may be configured to provide one or more alert signals via the status indicator, such as for example alerts indicative of fault or operation failure situations.

[00853] The power and control system may additionally be configured to accept various inputs from the user to dynamically control the drive mechanisms 90100 to meet a desired drug delivery rate or profile. For example, the power and control system may receive inputs, such as from partial or full activation, depression, and/or release of the activation mechanism, to set, initiate, stop, or otherwise adjust the control of the drive mechanism 90100 via the power and control system to meet the desired drug delivery rate or profile. Similarly, the power and control system may be configured to receive such inputs to adjust the drug dose volume; to prime the drive mechanism, fluid pathway connector, and fluid conduit; and/or to start, stop, or pause operation of the drive mechanism 90100. Such inputs may be received by the user directly acting on the drug delivery device 9010, such as by use of the activation mechanism 9014 or a different control interface, or the power and control system may be configured to receive such inputs from a remote control device. Additionally or alternatively, such inputs may be pre-programmed.

[00854] Other power and control system configurations may be utilized with the novel drug delivery devices of the present disclosure. For example, certain activation delays may be utilized during drug delivery. As mentioned above, one such delay optionally included within the system configuration is a dwell time which ensures that substantially the entire drug dose has been delivered before signaling completion to the user. Similarly, activation of the device may require a delayed depression (i.e., pushing) of the activation mechanism of the drug delivery device 9010 prior to drug delivery device activation. Additionally, the system may include a feature which permits the user to respond to the end-of-dose signals and to deactivate or power-down the drug delivery device. Such a feature may similarly require a delayed depression of the activation mechanism, to prevent accidental deactivation of the device. Such features provide desirable safety integration and ease-of-use parameters to the drug delivery devices. An additional safety feature may be integrated into the activation mechanism to prevent partial depression and, therefore, partial activation of the drug delivery devices. For example, the activation mechanism and/or power and control system may be configured such that the device is either completely off or completely on, to prevent partial activation. Such features are described in further detail hereinafter with regard to other aspects of the novel drug delivery devices.

[00855] IX.B. Insertion Mechanism

[00856] A number of insertion mechanisms may be utilized within the drug delivery devices of the present disclosure. The pump-type delivery devices of the present disclosure may be connected

in fluid flow communication to a patient or user, for example, through any suitable hollow tubing. A solid bore needle may be used to pierce the skin of the patient and place a hollow cannula at the appropriate delivery position, with the solid bore needle being removed or retracted prior to drug delivery to the patient. As stated above, the fluid can be introduced into the body through any number of means, including but not limited to: an automatically inserted needle, cannula, micro-needle array, or infusion set tubing. A number of mechanisms may also be employed to activate the needle insertion into the patient. For example, a biasing member such as a spring may be employed to provide sufficient force to cause the needle and cannula to pierce the skin of the patient. The same spring, an additional spring, or another similar mechanism may be utilized to retract the needle from the patient. In a preferred embodiment, the insertion mechanism may generally be as described in International Patent Application No. PCT/US2012/53174, which is included by reference herein in its entirety for all purposes. Such a configuration may be utilized for insertion of the drug delivery pathway into, or below, the skin (or muscle) of the patient in a manner that minimizes pain to the patient. Other known methods for insertion of a fluid pathway may be utilized and are contemplated within the bounds of the present disclosure, including a rigid needle insertion mechanism and/or a rotational needle insertion mechanism as developed by the assignee of the present disclosure.

[00857] In at least one embodiment, the insertion mechanism 90200 includes an insertion mechanism housing having one or more lockout windows, and a base for connection to the assembly platform and/or pump housing (as shown in FIG. 69B and FIG. 69C). The connection of the base to the assembly platform 9020 may be, for example, such that the bottom of the base is permitted to pass-through a hole in the assembly platform to permit direct contact of the base to the body of the user. In such configurations, the bottom of the base may include a sealing membrane that is removable prior to use of the drug delivery device 9010. The insertion mechanism may further include one or more insertion biasing members, a needle, a retraction biasing member, a cannula, and a manifold. The manifold may connect to sterile fluid conduit 9030 to permit fluid flow through the manifold, cannula, and into the body of the user during drug delivery.

[00858] As used herein, "needle" is intended to refer to a variety of needles including but not limited to conventional hollow needles, such as a rigid hollow steel needles, and solid core needles more commonly referred to as "trocars." In a preferred embodiment, the needle is a 9027 gauge solid core trocar and in other embodiments, the needle may be any size needle suitable to insert the cannula for the type of drug and drug administration (e.g., subcutaneous, intramuscular,

intradermal, etc.) intended. A sterile boot may be utilized within the needle insertion mechanism. The sterile boot is a collapsible sterile membrane that is in fixed engagement at a proximal end with the manifold and at a distal end with the base. In at least on embodiment, the sterile boot is maintained in fixed engagement at a distal end between base and insertion mechanism housing. Base includes a base opening through which the needle and cannula may pass-through during operation of the insertion mechanism, as will be described further below. Sterility of the cannula and needle are maintained by their initial positioning within the sterile portions of the insertion mechanism. Specifically, as described above, needle and cannula are maintained in the sterile environment of the manifold and sterile boot. The base opening of base may be closed from non-sterile environments as well, such as by for example a sealing membrane (not visible).

[00859] According to at least one embodiment of the present disclosure, the insertion mechanism is initially locked into a ready-to-use stage by lockout pin(s) which are initially positioned within lockout windows of the insertion mechanism housing. In this initial configuration, insertion biasing member and retraction biasing member are each retained in their compressed, energized states. Displacement of the lockout pin(s), by one or more methods such as pulling, pushing, sliding, and/or rotation, permits insertion biasing member to decompress from its initial compressed, energized state. This decompression of the insertion biasing member drives the needle and, optionally, the cannula into the body of the user. At the end of the insertion stage or at the end of drug delivery (as triggered by the multi-function drive mechanism), the retraction biasing member is permitted to expand in the proximal direction from its initial energized state. This axial expansion in the proximal direction of the retraction biasing member retracts the needle. If an inserter needle/trocar and cannula configuration are utilized, retraction of the needle may occur while maintaining the cannula in fluid communication with the body of the user. Accordingly, the insertion mechanism may be used to insert a needle and cannula into the user and, subsequently, retract the needle while retaining the cannula in position for drug delivery to the body of the user.

[00860] In at least one embodiment, as shown in FIG. 75, the insertion mechanism includes a rotationally biased member 90210 which is initially held in an energized state. In a preferred embodiment, the rotationally biased member is a torsional spring. The rotational biasing member may be prevented from de-energizing by interaction of gear surface 90208 with gear 90112 or, alternatively, by contact of a component of the insertion mechanism with a rotation prevention feature of the drug delivery device. Upon activation of the device, or another input, the rotationally biased member 90210 is permitted to, at least partially, de-energize. This causes one or more

components of the insertion mechanism to rotate and, in turn, cause, or allow, the insertion of the needle into the patient. Further, a cannula may be inserted into the patient as described above. At a later time, such as when the control arm or another component of the device recognizes a slack in the tether, the rotationally biased member may be allowed to further de-energize, causing additional rotation of one or more components of the insertion mechanism. This rotation may cause, or allow, the needle to be retracted from the patient. The needle may be fully retracted in a single step or there may be multiple steps of retraction.

[00861] IX.C. Fluid pathway connector

[00862] A number of fluid pathway connectors may be utilized within the embodiments of the present disclosure. Generally, a suitable fluid pathway connector includes a sterile fluid conduit, a piercing member, and a sterile sleeve attached to a drug container or a sliding pierceable seal integrated within a drug container. The fluid pathway connector may further include one or more flow restrictors. Upon proper activation of the device 9010, the fluid pathway connector 90300 is enabled to connect the sterile fluid conduit 9030 to the drug container of the drive mechanism 90100. Such connection may be facilitated by a piercing member, such as a needle, penetrating a pierceable seal of the drug container of the drive mechanism 90100. The sterility of this connection may be maintained by performing the connection within a flexible sterile sleeve. Upon substantially simultaneous activation of the insertion mechanism, the fluid pathway between drug container and insertion mechanism is complete to permit drug delivery into the body of the user. In one such embodiment, the fluid pathway connector may be substantially similar to that described in International Patent Application No. PCT/US2012/054861, which is included by reference herein in its entirety for all purposes. In such an embodiment, a compressible sterile sleeve may be fixedly attached between the cap of the drug container and the connection hub of the fluid pathway connector. The piercing member may reside within the sterile sleeve until a connection between the fluid connection pathway and the drug container is desired. The sterile sleeve may be sterilized to ensure the sterility of the piercing member and the fluid pathway prior to activation.

[00863] Alternatively, the fluid pathway connector may be integrated into a drug container as described in International Patent Applications No. PCT/US2013/030478 or No. PCT/US2014/052329, for example, which are included by reference herein in their entirety for all purposes. According to such an embodiment, a drug container may have a drug chamber within a barrel between a pierceable seal and a plunger seal. A drug fluid is contained in the drug chamber.

Upon activation of the device by the user, a drive mechanism asserts a force on a plunger seal contained in the drug container. As the plunger seal asserts a force on the drug fluid and any air/gas gap or bubble, a combination of pneumatic and hydraulic pressure builds by compression of the air/gas and drug fluid and the force is relayed to the sliding pierceable seal. The pierceable seal is caused to slide towards the cap, causing it to be pierced by the piercing member retained within the integrated sterile fluid pathway connector. Accordingly, the integrated sterile fluid pathway connector is connected (i.e., the fluid pathway is opened) by the combination pneumatic/hydraulic force of the air/gas and drug fluid within the drug chamber created by activation of a drive mechanism. Once the integrated sterile fluid pathway connector is connected or opened, drug fluid is permitted to flow from the drug container, through the integrated sterile fluid pathway connector, sterile fluid conduit, and insertion mechanism, and into the body of the user for drug delivery. In at least one embodiment, the fluid flows through only a manifold and a cannula and/or needle of the insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during drug delivery.

[00864] In a preferred embodiment, the sterile fluid pathway connector is initiated by movement of the needle insertion mechanism, which itself is initiated by the multi-function drive mechanism. Additionally or alternatively, the sterile fluid pathway connector is initiated by movement directly of the multi-function drive mechanism. For example, the multi-function drive mechanism may include a rotational gear, such as the star gear described in detail herein, that acts concurrently or sequentially to control the rate of drug delivery, to actuate the needle insertion mechanism, and/or initiate the sterile fluid pathway connector. In one particular embodiment, shown in FIGS. 69A-69C, the multi-function drive mechanism performs all of these steps substantially concurrently. The multi-function drive mechanism rotates a gear that acts upon several other components. The gear acts on a gear assembly to control the rate of drug delivery, while also contacting a needle insertion mechanism to introduce a fluid pathway into the user. As the needle insertion mechanism is initiated, the sterile fluid connection is made to permit drug fluid flow from the drug container, through the fluid conduit, into the needle insertion mechanism, for delivery into the patient as the gear and gear assembly of the multi-function drive mechanism control the rate of drug delivery.

[00865] Regardless of the fluid pathway connector utilized by the drug delivery device, the drug delivery device is capable of delivering a range of drugs with different viscosities and volumes. The drug delivery device is capable of delivering a drug at a controlled flow rate (speed) and/or of a specified volume. In one embodiment, the drug delivery process is controlled by one or

more flow restrictors within the fluid pathway connector and/or the sterile fluid conduit. In other embodiments, other flow rates may be provided by varying the geometry of the fluid flow path or delivery conduit, varying the speed at which a component of the drive mechanism advances into the drug container to dispense the drug therein, or combinations thereof. Still further details about the fluid pathway connector 90300 and the sterile fluid conduit 9030 are provided hereinafter in later sections in reference to other embodiments.

[00866] IX.D. Multi-Function Drive Mechanism:

[00867] The multi-function drive mechanisms of the present disclosure enable or initiate several functions, including: (i) controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container; (ii) triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a user; and (iii) connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. With reference to the embodiments shown in FIGS. 70A-70D and 3A-3D, multi-function drive mechanism 90100 includes an actuator 90101, a gear assembly 90110 including a main gear 90102, a drive housing 90130, and a drug container 9050 having a cap 9052, a pierceable seal (not visible), a barrel 9058, and a plunger seal 9060. The main gear 90102 may be, for example, a star gear disposed to contact multiple secondary gears or gear surfaces. A drug chamber 9021, located within the barrel 9058 between the pierceable seal and the plunger seal 9060, may contain a drug fluid for delivery through the insertion mechanism and drug delivery device into the body of the user. The seals described herein may be comprised of a number of materials but are, in a preferred embodiment, comprised of one or more elastomers or rubbers. The drive mechanism 90100 may further contain one or more drive biasing members, one or more release mechanisms, and one or more guides, as are described further herein. The components of the drive mechanism function to force a fluid from the drug container out through the pierceable seal, or preferably through the piercing member of the fluid pathway connector, for delivery through the fluid pathway connector, sterile fluid conduit, and insertion mechanism into the body of the user.

[00868] In one particular embodiment, the drive mechanism 90100 employs one or more compression springs as the biasing member(s). Upon activation of the drug delivery device by the user, the power and control system may be actuated to directly or indirectly release the compression spring(s) from an energized state. Upon release, the compression spring(s) may bear against and act

upon the plunger seal to force the fluid drug out of the drug container. The compression spring may bear against and act upon a piston which, in turn, acts upon the plunger seal to force the fluid drug out of the drug container. The fluid pathway connector may be connected through the pierceable seal prior to, concurrently with, or after activation of the drive mechanism to permit fluid flow from the drug container, through the fluid pathway connector, sterile fluid conduit, and insertion mechanism, and into the body of the user for drug delivery. In at least one embodiment, the fluid flows through only a manifold and a cannula of the insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during drug delivery. Such components and their functions are described in further detail herein.

[00869] Referring now to the embodiment of the multi-function drive mechanism shown in FIGS. 70A-70D and 71A-71D, multi-function drive mechanism 100 includes an actuator 90101, a gear assembly 90110 including a main gear 90102, a drive housing 90130, and a drug container 9050 having a cap 9052, a pierceable seal (not visible), a barrel 9058, and a plunger seal 9060. The main gear 90102 may be, for example, a star gear disposed to contact multiple secondary gears or gear surfaces. A drug chamber 9021, located within the barrel 9058 between the pierceable seal and the plunger seal 9060, may contain a drug fluid for delivery through the insertion mechanism and drug delivery device into the body of the user. Compressed within the drive housing 90130, between the drug container 9050 and the proximal end of the housing 90130, are one or more drive biasing members 90122 and a piston90 110, wherein the drive biasing members 90122 are configured to bear upon an interface surface 90110C of the piston 90110, as described further herein. Optionally, a cover sleeve (not shown) may be utilized between the drive biasing members 90122 and the interface surface 90110C of the piston 90110 to, for example, promote more even distribution of force from the drive biasing member 90122 to the piston 90110, prevent buckling of the drive biasing members 90122, and/or hide biasing members 90122 from user view. Interface surface 90110C of piston 90110 is caused to rest substantially adjacent to, or in contact with, a proximal end of seal 9060. Although the embodiments shown in FIGS. 70A-70D and 71A-71D show a singular biasing member it is also contemplated that one or more biasing members disposed to act in parallel may be used.

[00870] As best shown in FIG. 70D and FIG. 71D, the piston 90110 may be comprised of two components 90110A and 90110B and have an interface surface 90110C to contact the plunger seal. A tether, ribbon, string, or other retention strap (referred to herein as the "tether" 90525) may be connected at one end to the piston 90110A, 90110B. For example, the tether 90525 may be

connected to the piston 90110A, 90110B by retention between the two components of the piston 90110A, 90110B when assembled. The tether 90525 is connected at another end to a winch drum/gear 90520 of a delivery control mechanism 90500. Through the use of the winch drum/gear 90520 connected to one end of the tether 90525, and the tether 90525 connected at another end to the piston 90110A, 90110B, the regulating mechanism 90500 functions to control, meter, provide resistance, or otherwise prevent free axial translation of the piston 90110A, 90110B and plunger seal 9060 utilized to force a drug substance out of a drug container 9050. Accordingly, the regulating mechanism 90500 is a portion of the gear assembly 90116 aspect of the multi-function drive mechanism, which together function to control the rate or profile of drug delivery to the user.

[00871] As shown in FIGS. 70A-70D and 71A-71D, and in isolation in FIGS. 72 and 73A-73B, in the embodiments of the present disclosure, the regulating mechanism 90500 is gear assembly driven by an actuator 90101 of the multi-function drive mechanism 90100. The regulating mechanism retards or restrains the distribution of tether 90525, only allowing it to advance at a regulated or desired rate. This restricts movement of piston 90110 within barrel 9058, which is pushed by one or more biasing members 90122, hence controlling the movement of plunger seal 9060 and delivery of the drug contained in chamber 9021. As the plunger seal 9060 advances in the drug container 9050, the drug substance is dispensed through the sterile fluid pathway connector 90300, conduit 9030, insertion mechanism 90200, and into the body of the user for drug delivery. The actuator 90101 may be a number of power/motion sources including, for example, a solenoid, a stepper motor, or a rotational drive motor. In a particular embodiment, the actuator 90101 is a rotational stepper motor with a notch that corresponds with the gear teeth of the main/star gear 90102. Commonly, such a rotational stepper motor may be referred to as a 'Pac-Man' motor. In at least one embodiment, the Pac-Man motor has a gear interface within which one or more teeth of the main gear may partially reside during operation of the system. This is more clearly visible in FIGS. 73A-73B. When the gear interface 90101A of the Pac-Man motor 90101 is in alignment with a tooth 90102A of the main gear 90102, rotational motion of the Pac-Man motor 90101 causes gear interface rotation of the main gear 90102. When the Pac-Man motor 90101 is between gear teeth of the main gear, it may act as a resistance for, for example, back-spinning or unwinding of the gear assembly 90116. In one particular embodiment, the Pac-Man motor 90101 utilizes an alternating direction type motor to rotate the Pac-Man motor 90101 backwards and forwards. This configuration aids in the prevention of a runaway condition, where the motor and the gears are freely permitted to rotate, by using the multi-direction of the motor to prevent continuous spin in

one direction (as would be needed for a runaway condition). This bi-directional movement of the motor, coupled with the use of the gear interface cut within the Pac-Man motor, provide suitable safety features to prevent a runaway condition that could potentially lead to over-delivery of drug to the user. Further detail about the gear assembly 90116, regulating mechanism 90500, and multi-function drive mechanism 90100 are provided herein.

[00872] In a particular embodiment shown in FIGS. 73A-73B, the regulating element 90500 further includes one or more gears 90511, 90512, 90513, 90514, of a gear assembly 90516. One or more of the gears 90511, 90512, 90513, 90514 may be, for example, compound gears having a small diameter gear attached at a shared center point to a large diameter gear. Gear 90513 may be rotationally coupled to winch drum/gear 90520, for example by a keyed shaft, thereby coupling rotation of gear assembly 90516 to winch drum/gear 90520. Compound gear 90512 engages the small diameter gear 90513 such that rotational movement of the compound gear aspect 90512B is conveyed by engagement of the gears (such as by engagement of corresponding gear teeth) to gear 90513. Compound gear aspect 90512A, the rotation of which is coupled to gear aspect 90512B, is caused to rotate by action of compound gear aspect 90102B of the main/star gear 90102. Compound gear aspect 90102B, the rotation of which is coupled to main/star gear 90102, is caused to rotate by interaction between main/star gear 90102A and interface 90101A of the actuator 90101. Thus, rotation of main/star gear 90102 is conveyed to winch drum/gear 90520. Accordingly, rotation of the gear assembly 90516 initiated by the actuator 90101 may be coupled to winch drum/gear 90520 (i.e., through the gear assembly 90516), thereby controlling the distribution of tether 90525, and the rate of movement of plunger seal 9060 within barrel 9058 to force a fluid from drug chamber 9021. The rotational movement of the winch drum/gear 90520, and thus the axial translation of the piston 90110 and plunger seal 9060, are metered, restrained, or otherwise prevented from free axial translation by other components of the regulating element 90500, as described herein. As described above, the actuator 90101 may be a number of known power/motion sources including, for example, a motor (e.g., a DC motor, AC motor, or stepper motor) or a solenoid (e.g., linear solenoid, rotary solenoid).

[00873] The embodiment described above and shown in FIGS. 69A-73D show an actuator 90101that is in vertical alignment and in direct engagement with the main/star gear 90102. As would readily be appreciated by one having ordinary skill in the mechanical arts, the actuator 90101 could be modified to be in horizontal alignment. Additionally or alternatively, the actuator 90101 could be modified to be in indirect engagement with the main/star gear 90102. The embodiments

shown in FIGS. 75A-75B show an actuator 90101 that is in horizontal alignment and indirect engagement with the main/star gear 90102. Such an embodiment may utilize a rack and pinion engagement, a drive screw, or a worm gear 90101W, as shown in FIGS. 75A-75B, to change the direction of motion from horizontal to vertical (i.e., perpendicular interaction). Actuator 90101 rotates worm gear 90101W, which engages gear 90101G and conveys the motion to the Pac-Man gear 90101A. The Pac-Man gear 90101A engages main/star gear 90102 to enable operation of the drive mechanism and the drug delivery device, as described herein. Main/star gear 90102 also drives operation of gear 90112 to enable operation of the needle insertion mechanism 90200, as described herein. In one particular embodiment, the actuator 90101 utilizes an alternating direction type motor to rotate the worm gear 90101W, gear 90101G, and Pac-Man gear 90101A backwards and forwards. This configuration aids in the prevention of a runaway condition, where the motor and the gears are freely permitted to rotate, by using the multi-direction of the motor to prevent continuous spin in one direction (as would be needed for a runaway condition). This bi-directional movement of the actuator 90101, coupled with the use of the gear interface of the worm gear 90101W, gear 90101G, and Pac-Man gear 90101A with the main/star gear 90102, provide suitable safety features to prevent a runaway condition that could potentially lead to over-delivery of drug to the user. Additionally, the actuator 90101 may include a stop member 90101B that stops the rotation of the Pac-Man gear 90101A against a stop block 90150. Stop block 90150 further prevents over-rotation of the Pac-Man gear 90101A and, accordingly, the main/star gear 90102 to prevent a runaway condition that could potentially lead to over-delivery of drug to the user. For the device to function in this configuration, the Pac-Man gear 90101A must be rotated backwards the other direction before rotating forwards again to progress the main/star gear 90102 because the stop member 90101B prevents over rotation in one direction by interaction with the stop block 90150. Additionally, the geometry of worm gear 90101W may be configured such that it is self-locking and/or cannot be back-driven by gear 90101G. This may be done by configuration of parameters such as: pitch, lead angle, pressure angle, and number of threads. In so doing, runaway conditions of the drive mechanism will be prevented by the worm gear's resistance to rotations that are not caused by actuator 90101.

[00874] Notably, the regulating mechanisms 90500 of the present disclosure do not drive the delivery of fluid substances from the drug chamber 9021. The delivery of fluid substances from the drug chamber 9021 is caused by the expansion of the biasing member 90122 from its initial energized state acting upon the piston 90110A, 90110B and plunger seal 9060. The regulating

mechanisms 90500 instead function to provide resistance to the free motion of the piston 90110A, 90110B and plunger seal 9060 as they are pushed by the expansion of the biasing member 90122 from its initial energized state. The regulating mechanism 90500 does not drive the delivery but only controls the delivery motion. The tether limits or otherwise restrains the motion of the piston 90110 and plunger seal 9060, but does not apply the force for the delivery. According to a preferred embodiment, the controlled delivery drive mechanisms and drug delivery devices of the present disclosure include a regulating mechanism indirectly or directly connected to a tether metering the axial translation of the piston 90110A, 90110B and plunger seal 9060, which are being driven to axially translate by the biasing member 90122. The rate of drug delivery as controlled by the regulating mechanism may be determined by: selection of the gear ratio of gear assembly 90516; selection of the main/star gear 90102; selection of the diameter of winding drum/gear 90520; using electromechanical actuator 90101 to control the rate of rotation of the main/star gear 90102; or any other method known to one skilled in the art. By using electromechanical actuator 90101 the rate of rotation of the main/star gear 90102 it may be possible to configure a drug delivery device to provide a variable dose rate (i.e., the rate of drug delivery is varied during a treatment).

[00875] In another embodiment, the power and control system of the drug delivery device is configured to receive one or more inputs to meter the release of the tether 90525 by the winch drum/gear 90520 and thereby permit axial translation of the piston 90110 by the biasing member 90122 to translate a plunger seal 9060 within a barrel 9058. The one or more inputs may be provided by the actuation of the activation mechanism, a control interface, and/or a remote control mechanism. The power and control system may be configured to receive one or more inputs to adjust the restraint provided by the tether 90525 and winch drum/gear 90520 on the free axial translation of the piston 90110 upon which the biasing member 90122 bears upon to meet a desired drug delivery rate or profile, to change the dose volume for delivery to the user, and/or to otherwise start, stop, or pause operation of the drive mechanism.

[00876] The components of the drive mechanism 90100, upon activation, may be used to drive axial translation in the distal direction of the plunger seal 9060 of the drug container 9050. Optionally, the drive mechanism 90100 may include one or more compliance features which enable additional axial translation of the plunger seal 9060 to, for example, ensure that substantially the entire drug dose has been delivered to the user. For example, the plunger seal 9060, itself, may have some compressibility permitting a compliance push of drug fluid from the drug container.

[00877] The novel controlled delivery drive mechanisms of the present disclosure may optionally integrate status indication into the drug dose delivery. By use of one or more status triggers and a corresponding status reader, the status of the drive mechanism before, during, and after operation can be relayed to the power and control system to provide feedback to the user. Such feedback may be tactile, visual, and/or auditory, as described above, and may be redundant such that more than one signal or type of feedback is provided to the user during use of the device. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication. As the end-of-dose indication is tied to the piston reaching the end of its axial translation, the drive mechanism and drug delivery device provide a true end-of-dose indication to the user.

[00878] The tether 90525 may have one or more status triggers, such as electrical contacts, optical markings, or electromechanical pins or recesses, which are capable of contacting or being recognized by a status reader. In at least one embodiment, an end-of-dose status indication may be provided to the user once the status reader contacts or recognizes the final status trigger positioned on the tether 90525 that would contact the status reader at the end of axial travel of the piston 90110A, 90110B and plunger 9060 within the barrel 9058 of the drug container 9050. The status reader may be, for example, an electrical switch reader to contact the corresponding electrical contacts, an optical reader to recognize the corresponding optical markings, or a mechanical or electromechanical reader configured to contact corresponding pins, holes, or similar aspects on the tether. The status triggers may be positioned along the tether 90525 to be read or recognized at positions which correspond with the beginning and end of drug delivery, as well as at desired increments during drug delivery. As the drug delivery device is activated and drug delivery is begun by release of the biasing member 90122 and the resulting force applied to the piston 90110A, 90110B and plunger seal 6900, the rate or profile of drug delivery to the user is controlled by the regulating mechanism 90500, gear assembly 90516, and winch drum/gear 90520 releasing the tether 90525 and permitting expansion of the biasing member 90122 and axial translation of the piston 90110A, 90110B and plunger seal 9060. As this occurs, the status triggers of the tether 90525 are contacted or recognized by the status reader and the status of the drive mechanism before, during, and after operation can be relayed to the power and control system to provide feedback to the user. Depending on the number of status triggers located on the tether 90525, the frequency of the

incremental status indication may be varied as desired. As described above, a range of status readers may be utilized depending on the status triggers utilized by the system.

[00879] In a preferred embodiment, the status reader may apply a tensioning force to the tether 90525. When the system reaches end-of-dose, the tether 90525 goes slack and the status reader 90544 is permitted to rotate about a fulcrum. This rotation may operate an electrical or electromechanical switch, for example a switch, signaling slack in the tether 90525 to the power and control system. Additionally, a gear 90511 of gear assembly 90516 may act as an encoder along with a sensor. The sensor/encoder combination is used to provide feedback of gear assembly rotation, which in turn can be calibrated to the position of piston 90110 when there is no slack in the tether 90525. Together, the status reader and sensor/encoder may provide positional feedback, end-of-dose signal, and error indication, such as an occlusion, by observing slack in the tether 90525 prior to reaching the expected number of motor rotations as counted by the sensor/encoder.

[00880] Additional means may exist for terminating or restraining the flow of the medicament in the case of slack in, or failure of, the tether. FIGS. 74A-74B show one such embodiment. Disposed within barrel 9058 are brake 9064, sleeve 9062, and plug 9068, and optionally retainer 9066. Biasing member 90122 bears against sleeve 9062. Tether 90525 is engaged with plug 9068, thereby allowing tether 90525 to restrain the motion of sleeve 9062. This restraint controls the rate of expansion or de-energizing of biasing member 90122. When tether 90525 is under tension, plug 9068 bears against distal face 9064A of brake 9064, causing proximal face 9064B of brake 9064 to bear against sleeve 9062. Due to this contact, and the profile of the distal end 9062A of sleeve 9062, brake 9064 is maintained in a substantially conical configuration as shown in FIG. 74A. In this configuration, expansion or de-energizing of biasing member 90122 is restrained. Also, in this conical configuration, the outer diameter of brake 9064 is less than the inner diameter of barrel 9058, thus translation of the brake is not restrained by contact with the inner wall of the drug container. Also, a portion of brake 9064 is in contact with retainer 9066. Because brake 9064 is maintained in this configuration by plug 9068 and sleeve 9062, translation of sleeve 9062, caused by decompression of biasing member 90122, is transferred to retainer 9066. Likewise, contact of retainer 9066 with plunger seal 9060 causes translation of plunger seal 9060.

[00881] As shown in FIG. 74B, in the event of slack in, or failure of, tether 90525, plug 9068 is no longer held in position by tether 90525 and, therefore, no longer restrains motion of sleeve 9062. As biasing member 90122 decompresses or de-energizes, brake 9064 transforms to a relatively less

conical or flatter configuration. This may be caused by a natural bias of brake 9064 to transform to this configuration or, alternatively, may be caused by contact of brake 9064 with both retainer 9066 and sleeve 9062. As the brake is transformed, it comes into contact with the inner wall of barrel 9058. The brake thus acts as a wedge to restrict translation of sleeve 9062. This may prevent further translation or may act to restrict the rate of translation. Optionally, restoring tension in the tether may cause the plug to contact the brake and to transform the brake back to its conical configuration and thus restore normal operation of the drug delivery device.

[00882] FIGS. 74A-74B show the plug as having a spherical shape and the brake as having a conical shape. Such shapes are used herein merely for exemplary purposes and other shapes or configurations could readily be utilized to achieve the same or similar functionality. For example, the plug may itself be conical in shape and, in one embodiment, be shaped to interface the brake when the brake is in a conical shape. In such a configuration, the conical shape of the plug assists in maintaining the conical shape of the brake, thereby preventing contact between the outer diameter of the brake with the inner diameter of the barrel in order to restrict the axial translation of the sleeve 9062 (i.e., applying a braking force). In another embodiment, the brake 9064 could employ a star-shaped or other configuration when in a substantially flattened position so as to make contact with the inner diameter of the barrel 9058 to prevent or restrict further axial translation of sleeve 9062. Without further translation of sleeve 9062, biasing member 90122 cannot expand or de-energize further which, in turn, prevents or restricts further drug delivery to the user. This provides a necessary and useful safety measure for drug delivery, to prevent over-delivery or accelerated delivery of drug to the user.

[00883] Referring back to FIGS. 70A-70D and 71A-71D, in addition to controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container (thereby delivering drug substances at variable rates and/or delivery profiles); the multi-function drive mechanisms of the present disclosure may concurrently or sequentially perform the steps of: triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a user; and connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. In at least one embodiment, as shown in FIGS. 70A-70D and 71A-71D, initial motion by the actuator 90101 of the multi-function drive mechanism 90100 causes rotation of main/star gear 90102. Main/star gear 90102 is shown as a compound gear with aspects 90102A and 90102B (see FIG. 72). In one manner, main/star gear 90102 conveys

motion to the regulating mechanism 90500 through gear assembly 90516. In another manner, main/star gear 90102 conveys motion to the needle insertion mechanism 90200 through gear 90112. As gear 90112 is rotated by main/star gear 90102, gear 90112 engages the needle insertion mechanism 90200 to initiate the fluid pathway connector into the user, as described in detail above. In one particular embodiment, needle insertion mechanism 90200 is a rotational needle insertion mechanism. Accordingly, gear 90112 is configured to engage a corresponding gear surface 90208 of the needle insertion mechanism 90200. Rotation of gear 90112 causes rotation of needle insertion mechanism 90200 through the gear interaction between gear 90112 of the drive mechanism 90100 and corresponding gear surface 90208 of the needle insertion mechanism 90200. Once suitable rotation of the needle insertion mechanism 90200 occurs, for example rotation along axis 'R' shown in FIG. 70B-70C, the needle insertion mechanism may be initiated to create the fluid pathway connector into the user, as described in detail above. In an alternative embodiment, as shown in FIGS. 75A-75B, gear 90112 may indirectly engage the needle insertion mechanism 90200 to initiate the fluid pathway connector into the user. For example, gear 90112 may be configured to engage a corresponding gear surface of a control arm 90202 (visible in FIG. 75) that contacts or blocks the needle insertion mechanism 90200. Rotation of gear 90112 causes movement of the control arm 90202, which may initiate or permit rotation of needle insertion mechanism 90200. Such a needle insertion mechanism, as shown in FIGS. 75A-75B, includes a rotationally biased member 90210 which is initially held in an energized state. The rotational biasing member may be prevented from de-energizing by contact of a component of the insertion mechanism with a rotation prevention feature, such as a blocking aspect of the control arm, of the drug delivery device. Upon activation of the device, or another input, the rotationally biased member 90210 is permitted to, at least partially, de-energize. This causes one or more components of the insertion mechanism to rotate and, in turn, cause, or allow, the insertion of the needle into the patient. Further, a cannula may be inserted into the patient as described above. At a later time, such as when the control arm or another component of the device recognizes a slack in the tether 90525, the rotationally biased member may be allowed to further de-energize, such as by further interaction with the control arm, causing additional rotation of one or more components of the insertion mechanism. This rotation may cause, or allow, the needle to be retracted from the patient. The needle may be fully retracted in a single step or there may be multiple steps of retraction.

[00884] As shown in FIGS. 70A-70D and 71A-71D, rotation of the needle insertion mechanism 90200 in this manner may also cause a connection of a sterile fluid pathway to a drug container to

permit fluid flow from the drug container to the needle insertion mechanism for delivery to the user. Ramp aspect 90222 of needle insertion mechanism 90200 is caused to bear upon a movable connection hub 90322 of the sterile fluid pathway connector 90300. As the needle insertion mechanism 90200 is rotated by the multi-function drive mechanism 90100, ramp aspect 90222 of needle insertion mechanism 90200 bears upon and translates movable connection hub 90322 of the sterile fluid pathway connector 90300 to facilitate a fluid connection therein. Such translation may occur, for example, in the direction of the hollow arrow along axis 'C' shown in FIGS. 70B and 71B. In at least one embodiment, the needle insertion mechanism 90200 may be configured such that a particular degree of rotation upon rotational axis 'R' (shown in FIGS. 70B-70C) enables the needle/trocar to retract as detailed above. Additionally or alternatively, such needle/trocar retraction may be configured to occur upon a user-activity or upon movement or function of another component of the drug delivery device. In at least one embodiment, needle/trocar retraction may be configured to occur upon end-of-drug-delivery, as triggered by, for example, the regulating mechanism 90500 and/or one or more of the status readers as described above. During these stages of operation, delivery of fluid substances from the drug chamber 9021 may be initiated, on-going, and/or completed by the expansion of the biasing member 90122 from its initial energized state acting upon the piston 90110A, 90110B and plunger seal 60. As described above, the regulating mechanisms 90500 function to provide resistance to the free motion of the piston 90110A, 90110B and plunger seal 9060 as they are pushed by the expansion of the biasing member 90122 from its initial energized state. The regulating mechanism 90500 does not drive the delivery but only controls the delivery motion. The tether limits or otherwise restrains the motion of the piston 90110 and plunger seal 9060, but does not apply the force for the delivery. This is visible through the progression of the components shown in FIGS. 70A-70D and 71A-71D. The motion of the piston 90110A, 90110B and plunger seal 9060 as they are pushed by the expansion of the biasing member 90122 from its initial energized state are shown in the direction of the solid arrow along axis 'A' from proximal or first position 'P' to the distal or second position 'D', as shown in the transition of FIGS. 70A-70D and 71A-71D.

[00885] Further aspects of the novel drive mechanism will be described with reference to FIG. 72 and FIGS. 73A-73B. FIG. 72 shows a perspective view of the multi-function drive mechanism, according to at least a first embodiment, during its initial locked stage. Initially, the tether 90525 may retain the biasing member 90122 in an initial energized position within piston 90110A, 90110B. Directly or indirectly upon activation of the device by the user, the multi-function drive

mechanism 90100 may be activated to permit the biasing member to impart a force to piston 90110 and therefore to tether 90525. This force on tether 90525 imparts a torque on winding drum 90520 which causes the gear assembly 90516 and regulating mechanism 90500 to begin motion. As shown in FIG. 73A, the piston 90110 and biasing member 90122 are both initially in a compressed, energized state behind the plunger seal 60. The biasing member 90122 may be maintained in this state until activation of the device between internal features of drive housing 90130 and interface surface 90110C of piston 90110A, 90110B. As the drug delivery device 9010 is activated and the drive mechanism 90100 is triggered to operate, biasing member 90122 is permitted to expand (i.e., decompress) axially in the distal direction (i.e., in the direction of the solid arrow shown in FIGS. 70A-70D and FIGS. 71A-71D). Such expansion causes the biasing member 90122 to act upon and distally translate interface surface 90110C and piston 90110, thereby distally translating plunger seal 9060 to push drug fluid out of the drug chamber 9021 of barrel 9058. In at least one embodiment, an end-of-dose status indication may be provided to the user once the status reader contacts or recognizes a status trigger positioned on the tether 90525 to substantially correspond with the end of axial travel of the piston 90110A, 90110B and plunger seal 9060 within the barrel 9058 of the drug container 9050. The status triggers may be positioned along the tether 90525 at various increments, such as increments which correspond to certain volume measurement, to provide incremental status indication to the user. In at least one embodiment, the status reader is an optical status reader configured to recognize the corresponding optical status triggers on the tether. As would be understood by an ordinarily skilled artisan, such optical status triggers may be markings which are recognizable by the optical status reader. In another embodiment, the status reader is a mechanical or electromechanical reader configured to physically contact corresponding pins, holes, or similar aspects on the tether. Electrical contacts could similarly be utilized on the tether as status indicators which contact or are otherwise recognized by the corresponding electrical status reader. The status triggers may be positioned along the tether 90525 to be read or recognized at positions which correspond with the beginning and end of drug delivery, as well as at desired increments during drug delivery. As shown, tether 90525 passes substantially axially through the drive mechanism housing 90130, the biasing member 90122, and connects to the piston 90110 A, 90110B to restrict the axial translation of the piston 90110A, 90110B and the plunger seal 9060 that resides adjacent thereto.

[00886] The novel embodiments of the present disclosure may be utilized to meter, restrain, or otherwise prevent free rotational movement of winding drum 90520 and, thus, axial translation of

the components of the controlled delivery drive mechanism 90100. Accordingly, the regulating mechanism 90500 only controls the motion of the drive mechanism, but does not apply the force for the drug delivery. One or more additional biasing members 90122, such as compression springs, may be utilized to drive or assist the driving of the piston 90110. For example, a compression spring may be utilized within the drive housing 90130 for this purpose. The regulating mechanism 90500 only controls, meters, or regulates such action. The controlled delivery drive mechanisms and/or drug delivery devices of the present disclosure may additionally enable a compliance push to ensure that substantially all of the drug substance has been pushed out of the drug chamber 9021. The plunger seal 9060, itself, may have some compressibility permitting a compliance push of drug fluid from the drug container. For example, when a pop-out plunger seal is employed, i.e., a plunger seal that is deformable from an initial state, the plunger seal may be caused to deform or "pop-out" to provide a compliance push of drug fluid from the drug container. Additionally or alternatively, an electromechanical status switch and interconnect assembly may be utilized to contact, connect, or otherwise enable a transmission to the power and control system to signal end-of-dose to the user. This configuration further enables true end-of-dose indication to the user.

[00887] In at least one embodiment, incremental status indication may be provided to the user by reading or recognizing the rotational movement of one or more gears of gear assembly 90516. As the gear assembly 90516 rotates, a status reader may read or recognize one or more corresponding status triggers on one of the gears in the gear assembly to provide incremental status indication before, during, and after operation of the variable rate controlled delivery drive mechanism. A number of status readers may be utilized within the embodiments of the present disclosure. For example, the drive mechanism may utilize a mechanical status reader which is physically contacted by gear teeth of one of the gears of the gear assembly. As the status reader is contacted by the status trigger(s), which in this exemplary embodiment may be the gear teeth of one of the gears (or holes, pins, ridges, markings, electrical contacts, or the like, upon the gear), the status reader measures the rotational position of the gear and transmits a signal to the power and control system for status indication to the user. Additionally or alternatively, the drive mechanism may utilize an optical status reader. The optical status reader may be, for example, a light beam that is capable of recognizing a motion and transmitting a signal to the power and control system. For example, the drive mechanism may utilize an optical status reader that is configured to recognize motion of the gear teeth of one of the gears in the gear assembly (or holes, pins, ridges, markings, electrical contacts, or the like, upon the gear). Similarly, the status reader may be an electrical switch

configured to recognize electrical contacts on the gear. In any of these embodiments, the sensor may be utilized to then relay a signal to the power and control system to provide feedback to the user.

[00888] As would be appreciated by one having ordinary skill in the art, optical status readers and corresponding triggers, electromechanical status readers and corresponding triggers, and/or mechanical status readers and corresponding triggers may all be utilized by the embodiments of the present disclosure to provide incremental status indication to the user. While the drive mechanisms of the present disclosure are described with reference to the gear assembly and regulating mechanism shown in the figures, a range of configurations may be acceptable and capable of being employed within the embodiments of the present disclosure, as would readily be appreciated by an ordinarily skilled artisan. Accordingly, the embodiments of the present disclosure are not limited to the specific gear assembly and regulating mechanism described herein, which is provided as an exemplary embodiment of such mechanisms for employment within the controlled delivery drive mechanisms and drug delivery pumps.

[00889] In at least one embodiment of the present disclosure, the delivery profile of the medicament is adjustable. For example, it may be desirable to deliver a bolus injection of medicament before, during, or subsequent to certain activities such as eating, exercising, sleeping, etc. A "bolus injection" is any measured drug volume that is delivered often irrespective of the delivery time or duration. Conversely, a "basal injection" is often a controlled rate of delivery and/or a drug delivery profile having various rates of delivery at different time intervals. Similarly, the user may desire to increase or decrease the basal delivery rate of the medicament at these or other times. In at least one embodiment, the delivery profile may be adjustable by the user to achieve this desired drug delivery. The user may adjust the delivery profile by interacting with the drug delivery device itself or, alternatively, may use an external device, such as a smart-phone, to do so. For example, the user may adjust the delivery profile by displacing the activation mechanism or may engage a separate device-integrated or external delivery control mechanism.

[00890] In another embodiment of the present disclosure, the delivery profile may be adjusted automatically based on one or more inputs. For example, the delivery profile may be adjusted based on the patient's activity level, heart rate, blood sugar level, blood pressure, etc. As above, these measurements may be used to determine the need for a bolus injection or for the increase or decrease of the basal injection delivery rate or adjustment to the basal injection delivery profile. In at least one embodiment, these input measurements may be monitored by the device itself.

Additionally, or alternatively, they may be monitored by a secondary device such as a smart-phone, smart watch, heart rate monitor, glucose monitor, blood pressure monitor, or the like. In some embodiments, the delivery profile may be adjusted based on these measurements with no required user intervention. In the case of monitoring and/or control by a secondary device, the secondary device and drug delivery device may be in wireless or wired communication with one another. This communication may be through Bluetooth, near field communication, Wi-Fi, or any other method known to one having ordinary skill in the relevant art of device interconnectivity.

[00891] In a preferred embodiment, however, the monitoring/adjustment mechanism may alert and make recommendations to the user and the user may have active control to initiate/authorize or disregard the recommendation made by the monitoring/adjustment mechanism. For example, if one or more of the measurements is above or below a specified threshold value the device may emit an audible, visual, or tactile alert to the user. In one example, the alert is provided by a vibration of the device, thereby providing a discrete alert to the user. Additionally or alternatively, the alert may be provided by the user's smart-phone or other secondary device. The user may be able to view the current status of the measurements in a computer program or web interface on the device itself, a computer, smart-phone, or other device. The computer program or web interface may provide a recommended adjustment to the delivery profile. Based on this information, the user may adjust the delivery rate of the drug delivery device. As above, the user may adjust the delivery profile by displacing the activation mechanism or engaging a separate device-integrated or external delivery control mechanism.

[00892] In one embodiment, in response to a signal to adjust the delivery profile, either based on user input or based on the measurements described above, the power and control system may cause a change in the rate of movement of actuator 90101. The change in the rate of movement of actuator 90101 causes a change in the rotation rate of regulating mechanism 90500 which, in turn, controls the rate of drug delivery to the user. Alternatively, the delivery profile may be altered by a change in the characteristics of the flow path of medicament through the conduit connecting the drug container and insertion mechanism. The change may be caused by the introduction, removal, or modification of a flow restrictor which restricts flow of medicament from the drug container to the insertion mechanism. For example, a flow restrictor may have multiple flow paths which may be selectively placed in fluid communication with an input and an output of the flow restrictor. By providing flow paths which are of different length or cross-section the rate of delivery may be controlled. In other embodiments, the delivery profile may be altered by the introduction or removal

of an impingement of the conduit. An impingement of the flow path may interrupt or slow flow of medicament through the conduit, thereby controlling the rate of delivery to the user. Accordingly, one or more embodiments of the present disclosure are capable of producing a change to the rate of medicament delivery from the drug container thereby providing a dynamic control capability to the multi-function drive mechanism and/or the drug delivery device.

[00893] Assembly and/or manufacturing of controlled delivery drive mechanism 90100, drug delivery pump 9010, or any of the individual components may utilize a number of known materials and methodologies in the art. For example, a number of known cleaning fluids such as isopropyl alcohol and hexane may be used to clean the components and/or the devices. A number of known adhesives or glues may similarly be employed in the manufacturing process. Additionally, known siliconization and/or lubrication fluids and processes may be employed during the manufacture of the novel components and devices. Furthermore, known sterilization processes may be employed at one or more of the manufacturing or assembly stages to ensure the sterility of the final product.

[00894] The drive mechanism may be assembled in a number of methodologies. In one method of assembly, the drug container 9050 may first be assembled and filled with a fluid for delivery to the user. The drug container 9050 includes a cap 9052, a pierceable seal 9056, a barrel 9058, and a plunger seal 9060. The pierceable seal 9056 may be fixedly engaged between the cap 9052 and the barrel 9058, at a distal end of the barrel 9058. The barrel 9058 may be filled with a drug fluid through the open proximal end prior to insertion of the plunger seal 9060 from the proximal end of the barrel 9058. An optional connection mount 9054 may be mounted to a distal end of the pierceable seal 9056. The connection mount 9054 may guide the insertion of the piercing member of the fluid pathway connector into the barrel 58 of the drug container 9050. The drug container 9050 may then be mounted to a distal end of drive housing 90130.

[00895] One or more drive biasing members 90122 may be inserted into a distal end of the drive housing 90130. Optionally, a cover sleeve 90140 may be inserted into a distal end of the drive housing 90130 to substantially cover biasing member 90122. A piston may be inserted into the distal end of the drive housing 90130 such that it resides at least partially within an axial pass-through of the biasing member 90122 and the biasing member 90122 is permitted to contact a piston interface surface 90110C of piston 90110A, 90110B at the distal end of the biasing member 90122. An optional cover sleeve 90140 may be utilized to enclose the biasing member 90122 and contact the piston interface surface 90110C of piston 90110A, 90110B. The piston 90110A, 90110B

and drive biasing member 90122, and optional cover sleeve 90140, may be compressed into drive housing 90130. Such assembly positions the drive biasing member 90122 in an initial compressed, energized state and preferably places a piston interface surface 90110C in contact with the proximal surface of the plunger seal 9060 within the proximal end of barrel 9058. The piston, piston biasing member, contact sleeve, and optional components, may be compressed and locked into the ready-to-actuate state within the drive housing 90130 prior to attachment or mounting of the drug container 9050. The tether 90525 is pre-connected to the proximal end of the piston 90110A, 90110B and passed through the axial aperture of the biasing member 90122 and drive mechanism 90130, and then wound through the interior of the drug delivery device with the other end of the tether 90525 wrapped around the winch drum/gear 90520 of the regulating mechanism 90500.

[00896] A fluid pathway connector, and specifically a sterile sleeve of the fluid pathway connector, may be connected to the cap and/or pierceable seal of the drug container. A fluid conduit may be connected to the other end of the fluid pathway connector which itself is connected to the insertion mechanism such that the fluid pathway, when opened, connected, or otherwise enabled travels directly from the drug container, fluid pathway connector, fluid conduit, insertion mechanism, and through the cannula for drug delivery into the body of a user. The components which constitute the pathway for fluid flow are now assembled. These components may be sterilized, by a number of known methods, and then mounted either fixedly or removably to an assembly platform or housing of the drug delivery device, as shown in FIG. 69B.

[00897] Certain optional standard components or variations of drive mechanism 90100 or drug delivery device 9010 are contemplated while remaining within the breadth and scope of the present disclosure. For example, the embodiments may include one or more batteries utilized to power a motor or solenoid, drive mechanisms, and drug delivery devices of the present disclosure. A range of batteries known in the art may be utilized for this purpose. Additionally, upper or lower housings may optionally contain one or more transparent or translucent windows 9018 to enable the user to view the operation of the drug delivery device 9010 or verify that drug dose has completed. Similarly, the drug delivery device 9010 may contain an adhesive patch 9026 and a patch liner 9028 on the bottom surface of the housing 9012. The adhesive patch 9026 may be utilized to adhere the drug delivery device 9010 to the body of the user for delivery of the drug dose. As would be readily understood by one having ordinary skill in the art, the adhesive patch 9026 may have an adhesive surface for adhesion of the drug delivery device to the body of the user. The adhesive surface of the adhesive patch 9026 may initially be covered by a non-adhesive patch liner 9028, which is removed

from the adhesive patch 9026 prior to placement of the drug delivery device 9010 in contact with the body of the user. Removal of the patch liner 9028 may further remove the sealing membrane 90254 of the insertion mechanism 90200, opening the insertion mechanism to the body of the user for drug delivery (as shown in FIG. 69C).

[00898] Similarly, one or more of the components of controlled delivery drive mechanism 90100 and drug delivery device 9010 may be modified while remaining functionally within the breadth and scope of the present disclosure. For example, as described above, while the housing of drug delivery device 9010 is shown as two separate components upper housing 9012A and lower housing 9012B, these components may be a single unified component. As discussed above, a glue, adhesive, or other known materials or methods may be utilized to affix one or more components of the controlled delivery drive mechanism and/or drug delivery device to each other. Alternatively, one or more components of the controlled delivery drive mechanism and/or drug delivery device may be a unified component. For example, the upper housing and lower housing may be separate components affixed together by a glue or adhesive, a screw fit connection, an interference fit, fusion joining, welding, ultrasonic welding, and the like; or the upper housing and lower housing may be a single unified component. Such standard components and functional variations would be appreciated by one having ordinary skill in the art and are, accordingly, within the breadth and scope of the present disclosure.

[00899] It will be appreciated from the above description that the controlled delivery drive mechanisms and drug delivery devices disclosed herein provide an efficient and easily-operated system for automated drug delivery from a drug container. The novel embodiments described herein provide drive mechanisms for the controlled delivery of drug substances and drug delivery pumps which incorporate such controlled delivery drive mechanisms. The drive mechanisms of the present disclosure control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thus, are capable of delivering drug substances at variable rates and/or delivery profiles. Additionally, the drive mechanisms of the present disclosure may provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication. The novel controlled delivery drive

mechanisms of the present disclosure may be directly or indirectly activated by the user. Furthermore, the novel configurations of the controlled delivery drive mechanism and drug delivery devices of the present disclosure maintain the sterility of the fluid pathway during storage, transportation, and through operation of the device. Because the path that the drug fluid travels within the device is entirely maintained in a sterile condition, only these components need be sterilized during the manufacturing process. Such components include the drug container of the drive mechanism, the fluid pathway connector, the sterile fluid conduit, and the insertion mechanism. In at least one embodiment of the present disclosure, the power and control system, the assembly platform, the control arm, the activation mechanism, the housing, and other components of the drug delivery device do not need to be sterilized. This greatly improves the manufacturability of the device and reduces associated assembly costs. Accordingly, the devices of the present disclosure do not require terminal sterilization upon completion of assembly.

[00900] Manufacturing of a drug delivery device includes the step of attaching both the controlled delivery drive mechanism and drug container, either separately or as a combined component, to an assembly platform or housing of the drug delivery device. The method of manufacturing further includes attachment of the fluid pathway connector, drug container, and insertion mechanism to the assembly platform or housing. The additional components of the drug delivery device, as described above, including the power and control system, the activation mechanism, and the control arm may be attached, preformed, or pre-assembled to the assembly platform or housing. An adhesive patch and patch liner may be attached to the housing surface of the drug delivery device that contacts the user during operation of the device.

[00901] A method of operating the drug delivery device includes the steps of: activating, by a user, the activation mechanism; displacing a control arm to actuate an insertion mechanism; and actuating a power and control system to activate a controlled delivery drive mechanism to drive fluid drug flow through the drug delivery device according to a controlled rate or drug delivery profile. The method may further include the step of: engaging an optional on-body sensor prior to activating the activation mechanism. The method similarly may include the step of: establishing a connection between a fluid pathway connector to a drug container. Furthermore, the method of operation may include translating a plunger seal within the controlled delivery drive mechanism by the expansion of the biasing member acting upon a piston within a drug container to force fluid drug flow through the drug container, the fluid pathway connector, a sterile fluid conduit, and the insertion mechanism for delivery of the fluid drug to the body of a user, wherein a regulating

mechanism acting to restrain the distribution of a tether is utilized to meter the free axial translation of the piston. The method of operation of the drive mechanism and the drug delivery device may be better appreciated with reference to FIGS. 70A-70D and FIGS. 71A-71D, as described above.

[00902] In some embodiments, the power and control system 91810: (a) determines optimal temperature of the drug, appropriate time for delivery, etc. based on signals from an on-body sensor 91840, temperature sensor 91880, and/or other sensors; (b) sends command signals to the drive control system 91820 for initiating drug delivery; (c) provides a "delivery rate" information to the drive control system 91820; and (d) receives 'drug delivery information' and transmits 'end of delivery information' to a remote computing device via a communication unit 91830.

[00903] In some embodiments, the drive control system 91820: (a) drives the multi-function drive mechanism, such as the drive mechanism 90100, regulating mechanism 90500, needle insertion mechanism, connecting fluid pathway (see FIG. 78C); and (b) controls the regulating element 90500 or gear assembly.

[00904] In some embodiments, the controller may be included in the drive control system 91820. The controller 91822 may drive the actuator/motor 90101 based on the command signals received from the power and control system 91810. The controller 91822 may translate the delivery rate information into: selection of gears, selection of diameters, rate of rotation, selection, etc. The controller 91822 may then drive the various components of the drive control system 91820 to deliver the drug according to the required "delivery rate (see FIG. 78B).

[00905] X. Other Embodiments of Multi-Function Drive Mechanism

[00906] At least some of the drug delivery devices described in this application, including at least those described in connection with Figs. 1A-2B and 33A-33C, may be configured to incorporate the embodiments of the drive mechanism described below in connection with Figs. 69A-73D. The embodiments of the drive mechanism described below in connection with Figs. 69A-73D may be used to replace, in its entirety or partially, the above-described drive mechanism 100, 6100, or 8100, or any other drive mechanism described herein, where appropriate.

[00907] The multi-function drive mechanisms of the present disclosure enable or initiate several functions, including: (i) controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container; (ii) triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a patient; and (iii) connecting a sterile fluid pathway to a drug container to permit fluid

flow from the drug container to the needle insertion mechanism for delivery to the patient. With reference to the embodiments shown in Figs. 70A-70D and 71A-71D, multi-function drive mechanism 90100 includes an actuator 90101, a gear assembly 90110 including a main gear 90102, a drive housing 90130, and a drug container 9050 having a cap 9052, a pierceable seal (not visible), a barrel 9058, and a plunger seal 9060. The main gear 90102 may be, for example, a star gear disposed to contact multiple secondary gears or gear surfaces. A drug chamber 9021, located within the barrel 9058 between the pierceable seal and the plunger seal 9060, may contain a drug fluid for delivery through the insertion mechanism and drug delivery device into the body of the patient. The seals described herein may be comprised of a number of materials but are, in a preferred embodiment, comprised of one or more elastomers or rubbers. The drive mechanism 90100 may further contain one or more drive biasing members, one or more release mechanisms, and one or more guides, as are described further herein. The components of the drive mechanism function to force a fluid from the drug container out through the pierceable seal, or preferably through the piercing member of the fluid pathway connector, for delivery through the fluid pathway connector, sterile fluid conduit, and insertion mechanism into the body of the patient.

[00908] In one particular embodiment, the drive mechanism 90100 employs one or more compression springs as the biasing member(s). Upon activation of the drug delivery device by the patient, the power and control system may be actuated to directly or indirectly release the compression spring(s) from an energized state. Upon release, the compression spring(s) may bear against and act upon the plunger seal to force the fluid drug out of the drug container. The compression spring may bear against and act upon a piston which, in turn, acts upon the plunger seal to force the fluid drug out of the drug container. The fluid pathway connector may be connected through the pierceable seal prior to, concurrently with, or after activation of the drive mechanism to permit fluid flow from the drug container, through the fluid pathway connector, sterile fluid conduit, and insertion mechanism, and into the body of the patient for drug delivery. In at least one embodiment, the fluid flows through only a manifold and a cannula of the insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during drug delivery. Such components and their functions are described in further detail herein.

[00909] Referring now to the embodiment of the multi-function drive mechanism shown in Figs. 70A-70D and 70A-70D, multi-function drive mechanism 90100 includes an actuator 90101, a gear assembly 90110 including a main gear 90102, a drive housing 90130, and a drug container 9050 having a cap 9052, a pierceable seal (not visible), a barrel 9058, and a plunger seal 9060. The main

gear 90102 may be, for example, a star gear disposed to contact multiple secondary gears or gear surfaces. A drug chamber 9021, located within the barrel 9058 between the pierceable seal and the plunger seal 9060, may contain a drug fluid for delivery through the insertion mechanism and drug delivery device into the body of the patient. Compressed within the drive housing 90130, between the drug container 9050 and the proximal end of the housing 90130, are one or more drive biasing members 90122 and a piston 90110, wherein the drive biasing members 90122 are configured to bear upon an interface surface 90110C of the piston 90110, as described further herein. Optionally, a cover sleeve (not shown) may be utilized between the drive biasing members 90122 and the interface surface 90110C of the piston 90110 to, for example, promote more even distribution of force from the drive biasing member 90122 to the piston 90110, prevent buckling of the drive biasing members 90122, and/or hide biasing members 90122 from patient view. Interface surface 90110C of piston 90110 is caused to rest substantially adjacent to, or in contact with, a proximal end of seal 9060. Although the embodiments shown in Figs. 70A-70D and 71A-71D show a singular biasing member it is also contemplated that one or more biasing members disposed to act in parallel may be used.

[00910] As best shown in Fig. 70D and Fig. 71D, the piston 90110 may be comprised of two components 90110A and 90110B and have an interface surface 90110C to contact the plunger seal. A tether, ribbon, string, or other retention strap (referred to herein as the "tether" 90525) may be connected at one end to the piston 90110A, 90110B. For example, the tether 90525 may be connected to the piston 90110A, 90110B by retention between the two components of the piston 8110A, 8110B when assembled. The tether 8525 is connected at another end to a winch drum/gear 90520 of a delivery control mechanism 90500. Through the use of the winch drum/gear 90520 connected to one end of the tether 90525, and the tether 90525 connected at another end to the piston 90110A, 90110B, the regulating mechanism 90500 functions to control, meter, provide resistance, or otherwise prevent free axial translation of the piston 90110A, 90110B and plunger seal 9060 utilized to force a drug substance out of a drug container 9050. Accordingly, the regulating mechanism 90500 is a portion of the gear assembly 90116 aspect of the multi-function drive mechanism, which together function to control the rate or profile of drug delivery to the patient.

[00911] As shown in Figs. 70A-70D and 71A-71D, and in isolation in Figs. 72 and 73A-73B, in the embodiments of the present disclosure, the regulating mechanism 90500 is gear assembly driven by an actuator 90101 of the multi-function drive mechanism 90100. The regulating mechanism

retards or restrains the distribution of tether 90525, only allowing it to advance at a regulated or desired rate. This restricts movement of piston 90110 within barrel 9058, which is pushed by one or more biasing members 90122, hence controlling the movement of plunger seal 9060 and delivery of the drug contained in chamber 9021. As the plunger seal 9060 advances in the drug container 9050, the drug substance is dispensed through the sterile pathway connection 90300 , conduit 9030, insertion mechanism 90200, and into the body of the patient for drug delivery. The actuator 90101 may be a number of power/motion sources including, for example, a solenoid, a stepper motor, or a rotational drive motor. In a particular embodiment, the actuator 90101 is a rotational stepper motor with a notch that corresponds with the gear teeth of the main/star gear 90102. Commonly, such a rotational stepper motor may be referred to as a 'Pac-Man' motor. In at least one embodiment, the Pac-Man motor has a gear interface within which one or more teeth of the main gear may partially reside during operation of the system. This is more clearly visible in Figs. 73A-73B. When the gear interface 90101A of the Pac-Man motor 90101 is in alignment with a tooth 90102A of the main gear 90102, rotational motion of the Pac-Man motor 90101 causes gear interface rotation of the main gear 90102. When the Pac-Man motor 90101 is between gear teeth of the main gear, it may act as a resistance for, for example, back-spinning or unwinding of the gear assembly 90116. Further detail about the gear assembly 90116, regulating mechanism 90500, and multi-function drive mechanism 90100 are provided herein.

[00912] In a particular embodiment shown in Figs. 73A-73B, the regulating element 90500 further includes one or more gears 90511, 90512, 90513, 90514, of a gear assembly 90516. One or more of the gears 90511, 90512, 90513, 90514 may be, for example, compound gears having a small diameter gear attached at a shared center point to a large diameter gear. Gear 90513 may be rotationally coupled to winch drum/gear 90520, for example by a keyed shaft, thereby coupling rotation of gear assembly 90516 to winch drum/gear 90520. Compound gear 90512 engages the small diameter gear 90513 such that rotational movement of the compound gear aspect 90512B is conveyed by engagement of the gears (such as by engagement of corresponding gear teeth) to gear 90513. Compound gear aspect 90512A, the rotation of which is coupled to gear aspect 90512B, is caused to rotate by action of compound gear aspect 90102B of the main/star gear 90102. Compound gear aspect 90102B, the rotation of which is coupled to main/star gear 90102, is caused to rotate by interaction between main/star gear 90102A and interface 90101A of the actuator 90101. Thus, rotation of main/star gear 90102 is conveyed to winch drum/gear 90520. Accordingly, rotation of the gear assembly 90516 initiated by the actuator 90101 may be coupled to winch drum/gear 90520

(i.e., through the gear assembly 90516), thereby controlling the distribution of tether 90525, and the rate of movement of plunger seal 9060 within barrel 9058 to force a fluid from drug chamber 9021. The rotational movement of the winch drum/gear 90520, and thus the axial translation of the piston 90110 and plunger seal 9060, are metered, restrained, or otherwise prevented from free axial translation by other components of the regulating element 90500, as described herein. As described above, the actuator 90101 may be a number of known power/motion sources including, for example, a motor (e.g., a DC motor, AC motor, or stepper motor) or a solenoid (e.g., linear solenoid, rotary solenoid).

[00913] Notably, the regulating mechanisms 90500 of the present disclosure do not drive the delivery of fluid substances from the drug chamber 9021. The delivery of fluid substances from the drug chamber 9021 is caused by the expansion of the biasing member 90122 from its initial energized state acting upon the piston 90110A, 90110B and plunger seal 9060. The regulating mechanisms 90500 instead function to provide resistance to the free motion of the piston 90110A, 90110B and plunger seal 9060 as they are pushed by the expansion of the biasing member 90122 from its initial energized state. The regulating mechanism 90500 does not drive the delivery but only controls the delivery motion. The tether limits or otherwise restrains the motion of the piston 90110 and plunger seal 9060, but does not apply the force for the delivery. According to a preferred embodiment, the controlled delivery drive mechanisms and drug delivery devices of the present disclosure include a regulating mechanism indirectly or directly connected to a tether metering the axial translation of the piston 90110A, 90110B and plunger seal 9060, which are being driven to axially translate by the biasing member 90122. The rate of drug delivery as controlled by the regulating mechanism may be determined by: selection of the gear ratio of gear assembly 90516; selection of the main/star gear 90102; selection of the diameter of winding drum/gear 90520; using electromechanical actuator 90101 to control the rate of rotation of the main/star gear 90102; or any other method known to one skilled in the art. By using electromechanical actuator 90101 the rate of rotation of the main/star gear 90102 it may be possible to configure a drug delivery device to provide a variable dose rate (i.e., the rate of drug delivery is varied during a treatment).

[00914] In another embodiment, the power and control system of the drug delivery device is configured to receive one or more inputs to meter the release of the tether 90525 by the winch drum/gear 90520 and thereby permit axial translation of the piston 90110 by the biasing member 90122 to translate a plunger seal 9060 within a barrel 9058. The one or more inputs may be

provided by the actuation of the activation mechanism, a control interface, and/or a remote control mechanism. The power and control system may be configured to receive one or more inputs to adjust the restraint provided by the tether 90525 and winch drum/gear 90520 on the free axial translation of the piston 90110 upon which the biasing member 90122 bears upon to meet a desired drug delivery rate or profile, to change the dose volume for delivery to the patient, and/or to otherwise start, stop, or pause operation of the drive mechanism.

[00915] The components of the drive mechanism 90100, upon activation, may be used to drive axial translation in the distal direction of the plunger seal 9060 of the drug container 9050. Optionally, the drive mechanism 8100 may include one or more compliance features which enable additional axial translation of the plunger seal 9060 to, for example, ensure that substantially the entire drug dose has been delivered to the patient. For example, the plunger seal 9060, itself, may have some compressibility permitting a compliance push of drug fluid from the drug container.

[00916] The novel controlled delivery drive mechanisms of the present disclosure may optionally integrate status indication into the drug dose delivery. By use of one or more status triggers and a corresponding status reader, the status of the drive mechanism before, during, and after operation can be relayed to the power and control system to provide feedback to the patient. Such feedback may be tactile, visual, and/or auditory, as described above, and may be redundant such that more than one signal or type of feedback is provided to the patient during use of the device. For example, the patient may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the patient. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication. As the end-of-dose indication is tied to the piston reaching the end of its axial translation, the drive mechanism and drug delivery device provide a true end-of-dose indication to the patient.

[00917] The tether 90525 may have one or more status triggers, such as electrical contacts, optical markings, or electromechanical pins or recesses, which are capable of contacting or being recognized by a status reader. In at least one embodiment, an end-of-dose status indication may be provided to the patient once the status reader contacts or recognizes the final status trigger positioned on the tether 90525 that would contact the status reader at the end of axial travel of the piston 90110A, 90110B and plunger 9060 within the barrel 8058 of the drug container 9050. The status reader may be, for example, an electrical switch reader to contact the corresponding electrical

contacts, an optical reader to recognize the corresponding optical markings, or a mechanical or electromechanical reader configured to contact corresponding pins, holes, or similar aspects on the tether. The status triggers may be positioned along the tether 90525 to be read or recognized at positions which correspond with the beginning and end of drug delivery, as well as at desired increments during drug delivery. As the drug delivery device is activated and drug delivery is begun by release of the biasing member 90122 and the resulting force applied to the piston 90110A, 90110B and plunger seal 9060, the rate or profile of drug delivery to the patient is controlled by the regulating mechanism 90500, gear assembly 90516, and winch drum/gear 90520 releasing the tether 90525 and permitting expansion of the biasing member 90122 and axial translation of the piston 90110A, 90110B and plunger seal 9060. As this occurs, the status triggers of the tether 8525 are contacted or recognized by the status reader and the status of the drive mechanism before, during, and after operation can be relayed to the power and control system to provide feedback to the patient. Depending on the number of status triggers located on the tether 90525, the frequency of the incremental status indication may be varied as desired. As described above, a range of status readers may be utilized depending on the status triggers utilized by the system.

[00918] In a preferred embodiment, the status reader may apply a tensioning force to the tether 90525. When the system reaches end-of-dose, the tether 90525 goes slack and the status reader 90544 is permitted to rotate about a fulcrum. This rotation may operate an electrical or electromechanical switch, for example a switch, signaling slack in the tether 90525 to the power and control system. Additionally, a gear 90511 of gear assembly 90516 may act as an encoder along with a sensor. The sensor/encoder combination is used to provide feedback of gear assembly rotation, which in turn can be calibrated to the position of piston 90110 when there is no slack in the tether 90525. Together, the status reader and sensor/encoder may provide positional feedback, end-of-dose signal, and error indication, such as an occlusion, by observing slack in the tether 90525 prior to reaching the expected number of motor rotations as counted by the sensor/encoder.

[00919] Referring back to Figs. 70A-70D and 71A-71D, in addition to controlling the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container (thereby delivering drug substances at variable rates and/or delivery profiles); the multi-function drive mechanisms of the present disclosure may concurrently or sequentially perform the steps of: triggering a needle insertion mechanism to provide a fluid pathway for drug delivery to a patient; and connecting a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle

insertion mechanism for delivery to the patient. In at least one embodiment, as shown in Figs. 70A-70D and 71A-71D, initial motion by the actuator 90101 of the multi-function drive mechanism 90100 causes rotation of main/star gear 90102. Main/star gear 90102 is shown as a compound gear with aspects 90102A and 90102B (see Fig. 72). In one manner, main/star gear 90102 conveys motion to the regulating mechanism 90500 through gear assembly 90516. In another manner, main/star gear 90102 conveys motion to the needle insertion mechanism 90200 through gear 90112. As gear 90112 is rotated by main/star gear 90102, gear 90112 engages the needle insertion mechanism 90200 to initiate the fluid pathway connector into the patient, as described in detail above. In one particular embodiment, needle insertion mechanism 90200 is a rotational needle insertion mechanism. Accordingly, gear 90112 is configured to engage a corresponding gear surface 90208 of the needle insertion mechanism 90200. Rotation of gear 90112 causes rotation of needle insertion mechanism 90200 through the gear interaction between gear 90112 of the drive mechanism 90100 and corresponding gear surface 90208 of the needle insertion mechanism 90200. Once suitable rotation of the needle insertion mechanism 90200 occurs, for example rotation along axis 'R' shown in Fig. 70B-70C, the needle insertion mechanism may be initiated to create the fluid pathway connector into the patient, as described in detail above.

[00920] As shown in Figs. 70A-70D and 71A-71D, rotation of the needle insertion mechanism 90200 in this manner may also cause a connection of a sterile fluid pathway to a drug container to permit fluid flow from the drug container to the needle insertion mechanism for delivery to the patient. Ramp aspect 90222 of needle insertion mechanism 90200 is caused to bear upon a movable connection hub 322 of the sterile fluid pathway connector 90300 . As the needle insertion mechanism 90200 is rotated by the multi-function drive mechanism 90100, ramp aspect 90222 of needle insertion mechanism 90200 bears upon and translates movable connection hub 322 of the sterile fluid pathway connector 90300 to facilitate a fluid connection therein. Such translation may occur, for example, in the direction of the hollow arrow along axis 'C' shown in Figs. 70B and 71B. In at least one embodiment, the needle insertion mechanism 90200 may be configured such that a particular degree of rotation upon rotational axis 'R' (shown in Figs. 70B-70C) enables the needle/trocar to retract as detailed above. Additionally or alternatively, such needle/trocar retraction may be configured to occur upon a patient-activity or upon movement or function of another component of the drug delivery device. In at least one embodiment, needle/trocar retraction may be configured to occur upon end-of-drug-delivery, as triggered by, for example, the regulating mechanism 90500 and/or one or more of the status readers as described above. During these stages

of operation, delivery of fluid substances from the drug chamber 9021 may be initiated, on-going, and/or completed by the expansion of the biasing member 90122 from its initial energized state acting upon the piston 90110A, 90110B and plunger seal 9060. As described above, the regulating mechanisms 90500 function to provide resistance to the free motion of the piston 90110A, 90110B and plunger seal 9060 as they are pushed by the expansion of the biasing member 90122 from its initial energized state. The regulating mechanism 90500 does not drive the delivery but only controls the delivery motion. The tether limits or otherwise restrains the motion of the piston 90110 and plunger seal 9060, but does not apply the force for the delivery. This is visible through the progression of the components shown in Figs. 70A-70D and 71A-71D. The motion of the piston 90110A, 90110B and plunger seal 9060 as they are pushed by the expansion of the biasing member 90122 from its initial energized state are shown in the direction of the solid arrow along axis 'A' from proximal or first position 'P' to the distal or second position 'D', as shown in the transition of Figs. 70A-70D and 71A-71D.

[00921] Further aspects of the novel drive mechanism will be described with reference to Fig. 72 and Figs. 73A-73B. Fig. 4 shows a perspective view of the multi-function drive mechanism, according to at least a first embodiment, during its initial locked stage. Initially, the tether 90525 may retain the biasing member 90122 in an initial energized position within piston 90110A, 90110B. Directly or indirectly upon activation of the device by the patient, the multi-function drive mechanism 90100 may be activated to permit the biasing member to impart a force to piston 90110 and therefore to tether 90525. This force on tether 90525 imparts a torque on winding drum 90520 which causes the gear assembly 90516 and regulating mechanism 90500 to begin motion. As shown in Fig. 73A, the piston 90110 and biasing member 90122 are both initially in a compressed, energized state behind the plunger seal 9060. The biasing member 90122 may be maintained in this state until activation of the device between internal features of drive housing 90130 and interface surface 90110C of piston 90110A, 90110B. As the drug delivery device 9010 is activated and the drive mechanism 90100 is triggered to operate, biasing member 90122 is permitted to expand (i.e., decompress) axially in the distal direction (i.e., in the direction of the solid arrow shown in Figs. 70A-70D and Figs. 71A-71D). Such expansion causes the biasing member 90122 to act upon and distally translate interface surface 90110C and piston 90110, thereby distally translating plunger seal 9060 to push drug fluid out of the drug chamber 9021 of barrel 9058. In at least one embodiment, an end-of-dose status indication may be provided to the patient once the status reader contacts or recognizes a status trigger positioned on the tether 90525 to substantially correspond

with the end of axial travel of the piston 90110A, 90110B and plunger seal 9060 within the barrel 9058 of the drug container 9050. The status triggers may be positioned along the tether 90525 at various increments, such as increments which correspond to certain volume measurement, to provide incremental status indication to the patient. In at least one embodiment, the status reader is an optical status reader configured to recognize the corresponding optical status triggers on the tether. As would be understood by an ordinarily skilled artisan, such optical status triggers may be markings which are recognizable by the optical status reader. In another embodiment, the status reader is a mechanical or electromechanical reader configured to physically contact corresponding pins, holes, or similar aspects on the tether. Electrical contacts could similarly be utilized on the tether as status indicators which contact or are otherwise recognized by the corresponding electrical status reader. The status triggers may be positioned along the tether 90525 to be read or recognized at positions which correspond with the beginning and end of drug delivery, as well as at desired increments during drug delivery. As shown, tether 90525 passes substantially axially through the drive mechanism housing 90130, the biasing member 90122, and connects to the piston 90110A, 90110B to restrict the axial translation of the piston 90110A, 90110B and the plunger seal 9060 that resides adjacent thereto.

[00922] The novel embodiments of the present disclosure may be utilized to meter, restrain, or otherwise prevent free rotational movement of winding drum 90520 and, thus, axial translation of the components of the controlled delivery drive mechanism 90100. Accordingly, the regulating mechanism 90500 only controls the motion of the drive mechanism, but does not apply the force for the drug delivery. One or more additional biasing members 90122, such as compression springs, may be utilized to drive or assist the driving of the piston 90110. For example, a compression spring may be utilized within the drive housing 90130 for this purpose. The regulating mechanism 90500 only controls, meters, or regulates such action. The controlled delivery drive mechanisms and/or drug delivery devices of the present disclosure may additionally enable a compliance push to ensure that substantially all of the drug substance has been pushed out of the drug chamber 9021. The plunger seal 9060, itself, may have some compressibility permitting a compliance push of drug fluid from the drug container. For example, when a pop-out plunger seal is employed, i.e., a plunger seal that is deformable from an initial state, the plunger seal may be caused to deform or “pop-out” to provide a compliance push of drug fluid from the drug container. Additionally or alternatively, an electromechanical status switch and interconnect assembly may be utilized to contact, connect, or

otherwise enable a transmission to the power and control system to signal end-of-dose to the patient. This configuration further enables true end-of-dose indication to the patient.

[00923] In at least one embodiment, incremental status indication may be provided to the patient by reading or recognizing the rotational movement of one or more gears of gear assembly 90516. As the gear assembly 90516 rotates, a status reader may read or recognize one or more corresponding status triggers on one of the gears in the gear assembly to provide incremental status indication before, during, and after operation of the variable rate controlled delivery drive mechanism. A number of status readers may be utilized within the embodiments of the present disclosure. For example, the drive mechanism may utilize a mechanical status reader which is physically contacted by gear teeth of one of the gears of the gear assembly. As the status reader is contacted by the status trigger(s), which in this exemplary embodiment may be the gear teeth of one of the gears (or holes, pins, ridges, markings, electrical contacts, or the like, upon the gear), the status reader measures the rotational position of the gear and transmits a signal to the power and control system for status indication to the patient. Additionally or alternatively, the drive mechanism may utilize an optical status reader. The optical status reader may be, for example, a light beam that is capable of recognizing a motion and transmitting a signal to the power and control system. For example, the drive mechanism may utilize an optical status reader that is configured to recognize motion of the gear teeth of one of the gears in the gear assembly (or holes, pins, ridges, markings, electrical contacts, or the like, upon the gear). Similarly, the status reader may be an electrical switch configured to recognize electrical contacts on the gear. In any of these embodiments, the sensor may be utilized to then relay a signal to the power and control system to provide feedback to the patient.

[00924] As would be appreciated by one having ordinary skill in the art, optical status readers and corresponding triggers, electromechanical status readers and corresponding triggers, and/or mechanical status readers and corresponding triggers may all be utilized by the embodiments of the present disclosure to provide incremental status indication to the patient. While the drive mechanisms of the present disclosure are described with reference to the gear assembly and regulating mechanism shown in the Figures, a range of configurations may be acceptable and capable of being employed within the embodiments of the present disclosure, as would readily be appreciated by an ordinarily skilled artisan. Accordingly, the embodiments of the present disclosure are not limited to the specific gear assembly and regulating mechanism described herein, which is

provided as an exemplary embodiment of such mechanisms for employment within the controlled delivery drive mechanisms and drug delivery pumps.

[00925] Assembly and/or manufacturing of controlled delivery drive mechanism 90100, drug delivery drug delivery device 9010, or any of the individual components may utilize a number of known materials and methodologies in the art. For example, a number of known cleaning fluids such as isopropyl alcohol and hexane may be used to clean the components and/or the devices. A number of known adhesives or glues may similarly be employed in the manufacturing process. Additionally, known siliconization and/or lubrication fluids and processes may be employed during the manufacture of the novel components and devices. Furthermore, known sterilization processes may be employed at one or more of the manufacturing or assembly stages to ensure the sterility of the final product.

[00926] The drive mechanism may be assembled in a number of methodologies. In one method of assembly, the drug container 9050 may first be assembled and filled with a fluid for delivery to the patient. The drug container 9050 includes a cap 9052, a pierceable seal 9056, a barrel 9058, and a plunger seal 9060. The pierceable seal 9056 may be fixedly engaged between the cap 9052 and the barrel 9058, at a distal end of the barrel 9058. The barrel 9058 may be filled with a drug fluid through the open proximal end prior to insertion of the plunger seal 9060 from the proximal end of the barrel 9058. An optional connection mount 9054 may be mounted to a distal end of the pierceable seal 9056. The connection mount 9054 may guide the insertion of the piercing member of the fluid pathway connector into the barrel 9058 of the drug container 9050. The drug container 9050 may then be mounted to a distal end of drive housing 90130.

[00927] One or more drive biasing members 90122 may be inserted into a distal end of the drive housing 90130. Optionally, a cover sleeve 90140 may be inserted into a distal end of the drive housing 90130 to substantially cover biasing member 90122. A piston may be inserted into the distal end of the drive housing 90130 such that it resides at least partially within an axial pass-through of the biasing member 90122 and the biasing member 90122 is permitted to contact a piston interface surface 90110C of piston 90110A, 90110B at the distal end of the biasing member 90122. An optional cover sleeve 90140 may be utilized to enclose the biasing member 90122 and contact the piston interface surface 90110C of piston 90110A, 90110B. The piston 90110A, 90110B and drive biasing member 90122, and optional cover sleeve 90140, may be compressed into drive housing 90130. Such assembly positions the drive biasing member 90122 in an initial compressed,

energized state and preferably places a piston interface surface 90110C in contact with the proximal surface of the plunger seal 9060 within the proximal end of barrel 9058. The piston, piston biasing member, contact sleeve, and optional components, may be compressed and locked into the ready-to-actuate state within the drive housing 90130 prior to attachment or mounting of the drug container 9050. The tether 90525 is pre-connected to the proximal end of the piston 90110A, 90110B and passed through the axial aperture of the biasing member 90122 and drive mechanism 90130, and then wound through the interior of the drug delivery device with the other end of the tether 90525 wrapped around the winch drum/gear 90520 of the regulating mechanism 90500.

[00928] A fluid pathway connector, and specifically a sterile sleeve of the fluid pathway connector, may be connected to the cap and/or pierceable seal of the drug container. A fluid conduit may be connected to the other end of the fluid pathway connector which itself is connected to the insertion mechanism such that the fluid pathway, when opened, connected, or otherwise enabled travels directly from the drug container, fluid pathway connector, fluid conduit, insertion mechanism, and through the cannula for drug delivery into the body of a patient. The components which constitute the pathway for fluid flow are now assembled. These components may be sterilized, by a number of known methods, and then mounted either fixedly or removably to an assembly platform or housing of the drug delivery device, as shown in Fig. 69B.

[00929] Certain optional standard components or variations of drive mechanism 90100 or drug delivery device 9010 are contemplated while remaining within the breadth and scope of the present disclosure. For example, the embodiments may include one or more batteries utilized to power a motor or solenoid, drive mechanisms, and drug delivery devices of the present disclosure. A range of batteries known in the art may be utilized for this purpose. Additionally, upper or lower housings may optionally contain one or more transparent or translucent windows 18 to enable the patient to view the operation of the drug delivery device 9010 or verify that drug dose has completed. Similarly, the drug delivery device 9010 may contain an adhesive patch 9026 and a patch liner 9028 on the bottom surface of the housing 9012. The adhesive patch 9026 may be utilized to adhere the drug delivery device 9010 to the body of the patient for delivery of the drug dose. As would be readily understood by one having ordinary skill in the art, the adhesive patch 9026 may have an adhesive surface for adhesion of the drug delivery device to the body of the patient. The adhesive surface of the adhesive patch 9026 may initially be covered by a non-adhesive patch liner 9028, which is removed from the adhesive patch 9026 prior to placement of the drug delivery device 9010 in contact with the body of the patient. Removal of the patch liner 9028 may further remove the

sealing membrane 254 of the insertion mechanism 90200, opening the insertion mechanism to the body of the patient for drug delivery (as shown in Fig. 69C). In some embodiments, removal of the patch liner 9028 may also wake-up onboard electronics (e.g., the power and control system 2400) by supplying them with electricity from an onboard battery.

[00930] Similarly, one or more of the components of controlled delivery drive mechanism 90100 and drug delivery device 9010 may be modified while remaining functionally within the breadth and scope of the present disclosure. For example, as described above, while the housing of drug delivery device 9010 is shown as two separate components upper housing 9012A and lower housing 9012B, these components may be a single unified component. As discussed above, a glue, adhesive, or other known materials or methods may be utilized to affix one or more components of the controlled delivery drive mechanism and/or drug delivery device to each other. Alternatively, one or more components of the controlled delivery drive mechanism and/or drug delivery device may be a unified component. For example, the upper housing and lower housing may be separate components affixed together by a glue or adhesive, a screw fit connection, an interference fit, fusion joining, welding, ultrasonic welding, and the like; or the upper housing and lower housing may be a single unified component. Such standard components and functional variations would be appreciated by one having ordinary skill in the art and are, accordingly, within the breadth and scope of the present disclosure.

[00931] It will be appreciated from the above description that the controlled delivery drive mechanisms and drug delivery devices disclosed herein provide an efficient and easily-operated system for automated drug delivery from a drug container. The novel embodiments described herein provide drive mechanisms for the controlled delivery of drug substances and drug delivery pumps which incorporate such controlled delivery drive mechanisms. The drive mechanisms of the present disclosure control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thus, are capable of delivering drug substances at variable rates and/or delivery profiles. Additionally, the drive mechanisms of the present disclosure may provide integrated status indication features which provide feedback to the patient before, during, and after drug delivery. For example, the patient may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the patient. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication. The novel controlled delivery drive

mechanisms of the present disclosure may be directly or indirectly activated by the patient. Furthermore, the novel configurations of the controlled delivery drive mechanism and drug delivery devices of the present disclosure maintain the sterility of the fluid pathway during storage, transportation, and through operation of the device. Because the path that the drug fluid travels within the device is entirely maintained in a sterile condition, only these components need be sterilized during the manufacturing process. Such components include the drug container of the drive mechanism, the fluid pathway connector, the sterile fluid conduit, and the insertion mechanism. In at least one embodiment of the present disclosure, the power and control system, the assembly platform, the control arm, the activation mechanism, the housing, and other components of the drug delivery device do not need to be sterilized. This greatly improves the manufacturability of the device and reduces associated assembly costs. Accordingly, the devices of the present disclosure do not require terminal sterilization upon completion of assembly.

[00932] Manufacturing of a drug delivery device includes the step of attaching both the controlled delivery drive mechanism and drug container, either separately or as a combined component, to an assembly platform or housing of the drug delivery device. The method of manufacturing further includes attachment of the fluid pathway connector, drug container, and insertion mechanism to the assembly platform or housing. The additional components of the drug delivery device, as described above, including the power and control system, the activation mechanism, and the control arm may be attached, preformed, or pre-assembled to the assembly platform or housing. An adhesive patch and patch liner may be attached to the housing surface of the drug delivery device that contacts the patient during operation of the device.

[00933] A method of operating the drug delivery device includes the steps of: activating, by a patient, the activation mechanism; displacing a control arm to actuate an insertion mechanism; and actuating a power and control system to activate a controlled delivery drive mechanism to drive fluid drug flow through the drug delivery device according to a controlled rate or drug delivery profile. The method may further include the step of: engaging an optional on-body sensor prior to activating the activation mechanism. The method similarly may include the step of: establishing a connection between a fluid pathway connector to a drug container. Furthermore, the method of operation may include translating a plunger seal within the controlled delivery drive mechanism by the expansion of the biasing member acting upon a piston within a drug container to force fluid drug flow through the drug container, the fluid pathway connector, a sterile fluid conduit, and the insertion mechanism for delivery of the fluid drug to the body of a patient, wherein a regulating

mechanism acting to restrain the distribution of a tether is utilized to meter the free axial translation of the piston. The method of operation of the drive mechanism and the drug delivery device may be better appreciated with reference to Figs. 70A-70D and Figs. 71A-71D, as described above.

[00934] XI. Other Embodiments of Multi-Function Drive Mechanism

[00935] At least some of the drug delivery devices described in this application, including at least those described in connection with Figs. 1A-2B, 33A-33C, and 69A-73D may be configured to incorporate the embodiments of the drive mechanism described below in connection with Figs. 80A-85C. The embodiments of the drive mechanism described below in connection with Figs. 80A-85C may be used to replace, in its entirety or partially, the above-described drive mechanism 100, 6100, 8100, or 9010, or any other drive mechanism described herein, where appropriate.

[00936] The present disclosure provides drive mechanisms for the controlled delivery of drug substances, drug delivery pumps with controlled delivery drive mechanisms, the methods of operating such devices, and the methods of assembling such devices. Notably, the drive mechanisms of the present disclosure control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container. The novel embodiments of the present disclosure thus are capable of delivering drug substances at variable rates. The controlled delivery drive mechanisms of the present disclosure may be pre-configurable or dynamically configurable, such as by control by the power and control system, to meet desired delivery rates or profiles, as explained in detail below. Additionally, the drive mechanisms of the present disclosure provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication. Because the end-of-dose indication is related to the physical end of axial translation of one or more components of the drive mechanism, the drive mechanism and drug delivery device provide a true end-of-dose indication to the user. Through these mechanisms, confirmation of drug dose delivery can accurately be provided to the user or administrator. Accordingly, the novel devices of the present disclosure alleviate one or more of the problems associated with prior art devices, such as those referred to above.

[00937] In a first embodiment, the present disclosure provides a controlled delivery drive mechanism which includes a drive housing, a piston, and one or more biasing members, wherein the one or more biasing members are initially retained in an energized state and is configured to bear upon an interface surface of the piston. The piston is configured to translate substantially axially within a drug container having a plunger seal and a barrel. A tether is connected at one end to the piston and at another end to a winch drum of a regulating mechanism, wherein the tether restrains the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The drug container may contain a drug fluid within a drug chamber for delivery to a user. Optionally, a cover sleeve may be utilized between the biasing member and the interface surface of the piston to hide the interior components of the barrel (namely, the piston and the biasing member) from view during operation of the drive mechanism. The tether is configured to be released from a winch drum of the regulating mechanism to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon.

[00938] In at least one embodiment, the regulating mechanism is an escapement regulating mechanism coupled to, or acting with, the winch drum. The escapement regulating mechanism may further include a gear train having one or more gears, wherein the rotation of at least one gear of the gear train is coupled to the rotation of the winch drum. In a particular embodiment, the escapement regulating mechanism further includes a lever and an escape wheel configured to engage and meter the rotational movement of the gear train. The lever has pins and a prong, wherein the prong movably engages a post and is configured to removably engage an impulse pin of a balance wheel, and wherein the balance wheel engages and is capable of oscillating around a post in combination with a hair spring. An electromechanical actuator such as a motor or solenoid may additionally be used to control the oscillation and/or rotation of the balance wheel. For example, a DC or stepper motor may be used, or a linear or rotary solenoid may be used. The escape wheel is a compound gear having escape teeth around the circumference of a large diameter escape gear and a small diameter gear configured to engage and meter the gear train. The metering of the gear train and/or winch drum by an escapement regulating mechanism controls the rate or profile of drug delivery to a user.

[00939] The gear train may include a winch gear coupled to a winch drum upon which the tether may be releasably wound. The winch gear may be configured to engage a first compound gear, such that rotation of the winch gear and the small gear of the first compound gear are linked. The gear

assembly may additionally include a second compound gear, wherein the large gear of the first compound gear is engaged with the small gear of the second compound gear. The large gear of the second compound gear may be engaged with a gear of the escape wheel such that rotation of the second compound gear and escape wheel are coupled. In this way rotation of the escape wheel is coupled to rotation of the winch drum and can thereby control the release of the tether from the winch drum to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The metering of the tether by the regulating mechanism controls the rate or profile of drug delivery to a user. The piston may be one or more parts and connects to a distal end of the tether.

[00940] In yet another embodiment, the drive mechanism may include a status reader configured to read or recognize one or more corresponding status triggers. The status triggers may be incrementally spaced on the tether, wherein, during operation of the drive mechanism, interaction between the status reader and the status triggers transmit a signal to a power and control system to provide feedback to a user. The status reader may be an optical status reader and the corresponding status triggers are optical status triggers, an electromechanical status reader and the corresponding status triggers are electromechanical status triggers, or a mechanical status reader and the corresponding status triggers are mechanical status triggers.

[00941] In a further embodiment, the present disclosure provides a drug delivery pump with controlled drug delivery. The drug delivery pump having a housing and an assembly platform, upon which an activation mechanism, an insertion mechanism, a fluid pathway connector, a power and control system, and a controlled delivery drive mechanism may be mounted, said drive mechanism having a drive housing, a piston, and a biasing member, wherein the biasing member is initially retained in an energized state and is configured to bear upon an interface surface of the piston. The piston is configured to translate substantially axially within a drug container having a plunger seal and a barrel. A tether is connected at one end to the piston and at another end to a winch drum of a delivery regulating mechanism, wherein the tether restrains the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The drug container may contain a drug fluid within a drug chamber for delivery to a user. Optionally, a cover sleeve may be utilized between the biasing member and the interface surface of the piston to hide the interior components of the barrel (namely, the piston and the biasing member) from view during operation of the drive mechanism. The tether is configured to be released from a winch drum of the delivery regulating mechanism to meter the free expansion

of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon.

[00942] In another embodiment, the drug delivery device further includes a gear assembly. The gear assembly may include a winch gear connected to a winch drum upon which the tether may be releasably wound, rotation of the winch drum releases the tether from the winch drum to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The metering of the tether controls the rate or profile of drug delivery to a user. The piston may be one or more parts and connects to a distal end of the tether. The winch drum is coupled to a regulating mechanism which controls rotation of the winch drum and hence metering of the translation of the piston.

[00943] The drug delivery device may utilize the regulating mechanism described above in the first embodiment, which configuration utilizes an escapement regulating mechanism to control the metering of the tether. The escapement regulating mechanism may further include a gear train having one or more gears. In a particular embodiment, the escapement regulating mechanism further includes a lever and an escape wheel configured to engage and meter the rotational movement of the gear train. The lever has pins and a prong, wherein the prong movably engages a post and is configured to removably engage an impulse pin of a balance wheel, and wherein the balance wheel engages and is capable of oscillating around a post in combination with a hair spring. A motor, such as a DC motor or stepper motor, or a linear or rotary solenoid may additionally be used to control the oscillation and/or rotation of the balance wheel. The escape wheel is a compound gear having escape teeth around the circumference of a large diameter escape gear and a small diameter gear configured to engage and meter the gear train. The metering of the gear train by an escapement regulating mechanism controls the rate or profile of drug delivery to a user. The piston is configured to contact and axially translate the plunger seal within the barrel.

[00944] In yet another embodiment, the drug delivery device may include a status reader configured to read or recognize one or more corresponding status triggers. The status triggers may be incrementally spaced on the tether, wherein, during operation of the drive mechanism, interaction between the status reader and the status triggers transmit a signal to a power and control system to provide feedback to a user. The status reader may be an optical status reader and the corresponding status triggers are optical status triggers, an electromechanical status reader and the

corresponding status triggers are electromechanical status triggers, or a mechanical status reader and the corresponding status triggers are mechanical status triggers.

[00945] In another embodiment, the power and control system of the drug delivery device is configured to receive one or more inputs to meter the release of the tether by the winch drum and thereby permit axial translation of the piston by the biasing member to translate a plunger seal within a barrel. The one or more inputs may be provided by the actuation of the activation mechanism, a control interface, and/or a remote control mechanism. The power and control system may be configured to receive one or more inputs to adjust the restraint provided by the tether and winch drum on the free axial translation of the piston upon which the biasing member bears upon to meet a desired drug delivery rate or profile, to change the dose volume for delivery to the user, and/or to otherwise start, stop, or pause operation of the drive mechanism.

[00946] The novel embodiments of the present disclosure provide drive mechanisms which are capable of metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thereby, controlling the rate of delivery of drug substances. The novel control delivery drive mechanisms are additionally capable of providing the incremental status of the drug delivery before, during, and after operation of the device. As will be described further below, the embodiments of the present disclosure may include one or more additional components which may be considered standard components in the industry of medical devices. For example, the embodiments may include one or more batteries utilized to power the motor, drive mechanisms, and drug delivery devices of the present disclosure. The components, and the embodiments containing such components, are within the contemplation of the present disclosure and are to be understood as falling within the breadth and scope of the present disclosure.

[00947] The present disclosure provides drive mechanisms for the controlled delivery of drug substances and drug delivery pumps which incorporate such controlled delivery drive mechanisms. The drive mechanisms of the present disclosure control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thus, are capable of delivering drug substances at variable rates and/or delivery profiles. Additionally, the drive mechanisms of the present disclosure provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the

system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug delivery device may provide an end-of-dose indication.

[00948] The novel devices of the present disclosure provide drive mechanisms with integrated status indication and drug delivery pumps which incorporate such drive mechanisms. Such devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The devices described herein incorporate features which make activation, operation, and lock-out of the device simple for even untrained users. The novel devices of the present disclosure provide these desirable features without any of the problems associated with known prior art devices. Certain non-limiting embodiments of the novel drug delivery pumps, drive mechanisms, and their respective components are described further herein with reference to the accompanying figures.

[00949] As used herein, the terms "pump" and "delivery device" are intended to include any number of drug delivery systems which are capable of dispensing a fluid to a user upon activation. Such drug delivery systems include, but are not limited to, for example, injection systems, infusion pumps, bolus injectors, on-body injectors, and the like. FIGS. 80A-80C show an exemplary drug delivery device according to at least one embodiment of the present disclosure. The drug delivery device may be utilized to administer delivery of a drug treatment into a body of a user. As shown in FIGS. 80A-80C, the drug delivery device 9210 includes a pump housing 9212. Pump housing 9212 may include one or more housing subcomponents which are fixedly engageable to facilitate easier manufacturing, assembly, and operation of the drug delivery device. For example, drug delivery device 9210 includes a pump housing 9212 which includes an upper housing 9212A and a lower housing 9212B. The drug delivery device may further include an activation mechanism 9214, a status indicator 9216, and a window 9218. Window 9218 may be any translucent or transmissive surface through which the operation of the drug delivery device may be viewed. As shown in FIG. 80B, drug delivery device 9210 further includes assembly platform 9220, sterile fluid conduit 9230, drive mechanism 92100 having drug container 9250, insertion mechanism 92200, fluid pathway connector 92300, and a power and control system (not shown). One or more of the components of such drug delivery devices may be modular in that they may be, for example, pre-assembled as separate components and configured into position onto the assembly platform 9220 of the drug delivery device 9210 during manufacturing.

[00950] The pump housing 9212 contains all of the device components and provides a means of removably attaching the device 9210 to the skin of the user. The pump housing 9212 also provides protection to the interior components of the device 9210 against environmental influences. The pump housing 9212 is ergonomically and aesthetically designed in size, shape, and related features to facilitate easy packaging, storage, handling, and use by users who may be untrained and/or physically impaired. Furthermore, the external surface of the pump housing 9212 may be utilized to provide product labeling, safety instructions, and the like. Additionally, as described above, housing 9212 may include certain components, such as status indicator 9216 and window 9218, which may provide operation feedback to the user.

[00951] In at least one embodiment, the drug delivery device 9210 provides an activation mechanism 9214 that is displaced by the user to trigger the start command to the power and control system. In a preferred embodiment, the activation mechanism is a start button 9214 that is located through the pump housing 9212, such as through an aperture between upper housing 9212A and lower housing 9212B, and which contacts a control arm 40 of the power and control system. In at least one embodiment, the start button 14 may be a push button, and in other embodiments, may be an on/off switch, a toggle, or any similar activation feature known in the art. The pump housing 9212 also provides a status indicator 16 and a window 9218. In other embodiments, one or more of the activation mechanism 9214, the status indicator 9216, the window 9218, and combinations thereof may be provided on the upper housing 9212A or the lower housing 9212B such as, for example, on a side visible to the user when the drug delivery device 9210 is placed on the body of the user. Housing 9212 is described in further detail hereinafter with reference to other components and embodiments of the present disclosure.

[00952] Drug delivery device 9210 is configured such that, upon activation by a user by depression of the activation mechanism, the drug delivery device is initiated to: insert a fluid pathway into the user; enable, connect, or open necessary connections between a drug container, a fluid pathway, and a sterile fluid conduit; and force drug fluid stored in the drug container through the fluid pathway and fluid conduit for delivery into a user. One or more optional safety mechanisms may be utilized, for example, to prevent premature activation of the drug delivery device. For example, an optional on-body sensor 9224 (shown in FIG. 80C) may be provided in one embodiment as a safety feature to ensure that the power and control system, or the activation mechanism 9214, cannot be engaged unless the drug delivery device 9210 is in contact with the body of the user. In one such embodiment, the on-body sensor 9224 is located on the bottom of

lower housing 9212B where it may come in contact with the user's body. Upon displacement of the on-body sensor 9224, depression of the activation mechanism is permitted. Accordingly, in at least one embodiment the on-body sensor 9224 is a mechanical safety mechanism, such as for example a mechanical lock out, that prevents triggering of the drug delivery device 9210 by the activation mechanism 9214. In another embodiment, the on-body sensor may be an electro-mechanical sensor such as a mechanical lock out that sends a signal to the power and control system to permit activation. In still other embodiments, the on-body sensor can be electrically based such as, for example, a capacitive- or impedance-based sensor which must detect tissue before permitting activation of the power and control system. These concepts are not mutually exclusive and one or more combinations may be utilized within the breadth of the present disclosure to prevent, for example, premature activation of the drug delivery device. In a preferred embodiment, the drug delivery device 10 utilizes one or more mechanical on-body sensors. Additional integrated safety mechanisms are described herein with reference to other components of the novel drug delivery devices.

[00953] XI.A. Power and Control System

[00954] The power and control system includes a power source, which provides the energy for various electrical components within the drug delivery device, one or more feedback mechanisms, a microcontroller, a circuit board, one or more conductive pads, and one or more interconnects. Other components commonly used in such electrical systems may also be included, as would be appreciated by one having ordinary skill in the art. The one or more feedback mechanisms may include, for example, audible alarms such as piezo alarms and/or light indicators such as light emitting diodes (LEDs). The microcontroller may be, for example, a microprocessor. The power and control system controls several device interactions with the user and interfaces with the drive mechanism 92100. In one embodiment, the power and control system interfaces with the control arm 9240 to identify when the on-body sensor 9224 and/or the activation mechanism 9214 have been activated. The power and control system may also interface with the status indicator 9216 of the pump housing 9212, which may be a transmissive or translucent material which permits light transfer, to provide visual feedback to the user. The power and control system interfaces with the drive mechanism 92100 through one or more interconnects to relay status indication, such as activation, drug delivery, and end-of-dose, to the user. Such status indication may be presented to the user via auditory tones, such as through the audible alarms, and/or via visual indicators, such as through the LEDs. In a preferred embodiment, the control interfaces between the power and control

system and the other components of the drug delivery device are not engaged or connected until activation by the user. This is a desirable safety feature that prevents accidental operation of the drug delivery device and may additionally maintain the energy contained in the power source during storage, transportation, and the like.

[00955] The power and control system may be configured to provide a number of different status indicators to the user. For example, the power and control system may be configured such that after the on-body sensor and/or trigger mechanism have been pressed, the power and control system provides a ready-to-start status signal via the status indicator 9216 if device start-up checks provide no errors. After providing the ready-to-start status signal and, in an embodiment with the optional on-body sensor, if the on-body sensor remains in contact with the body of the user, the power and control system will power the drive mechanism 92100 to begin delivery of the drug treatment through the fluid pathway connector 92300 and sterile fluid conduit 9230 (not shown). In a preferred embodiment of the present disclosure, the insertion mechanism 92200 and the fluid pathway connector 92300 may be caused to activate directly by user operation of the activation mechanism 9214. During the drug delivery process, the power and control system is configured to provide a dispensing status signal via the status indicator 9216. After the drug has been administered into the body of the user and after the end of any additional dwell time, to ensure that substantially the entire dose has been delivered to the user, the power and control system may provide an okay-to-remove status signal via the status indicator 9216. This may be independently verified by the user by viewing the drive mechanism and drug dose delivery through the window 9218 of the pump housing 9212. Additionally, the power and control system may be configured to provide one or more alert signals via the status indicator 9216, such as for example alerts indicative of fault or operation failure situations.

[00956] The power and control system may additionally be configured to accept various inputs from the user to dynamically control the drive mechanisms 92100 to meet a desired drug delivery rate or profile. For example, the power and control system may receive inputs, such as from partial or full activation, depression, and/or release of the activation mechanism 9214, to set, initiate, stop, or otherwise adjust the control of the drive mechanism 92100 via the power and control system to meet the desired drug delivery rate or profile. Similarly, the power and control system may be configured to receive such inputs to adjust the drug dose volume; to prime the drive mechanism, fluid pathway connector, and fluid conduit; and/or to start, stop, or pause operation of the drive mechanism 92100. Such inputs may be received by the user directly acting on the drug delivery

device 9210, such as by use of the activation mechanism 9214 or a different control interface, or the system 92400 may be configured to receive such inputs from a remote control device. Additionally or alternatively, such inputs may be pre-programmed.

[00957] Other power and control system configurations may be utilized with the novel drug delivery devices of the present disclosure. For example, certain activation delays may be utilized during drug delivery. As mentioned above, one such delay optionally included within the system configuration is a dwell time which ensures that substantially the entire drug dose has been delivered before signaling completion to the user. Similarly, activation of the device may require a delayed depression (i.e., pushing) of the activation mechanism 9214 of the drug delivery device 9210 prior to drug delivery device activation. Additionally, the system may include a feature which permits the user to respond to the end-of-dose signals and to deactivate or power-down the drug delivery device. Such a feature may similarly require a delayed depression of the activation mechanism, to prevent accidental deactivation of the device. Such features provide desirable safety integration and ease-of-use parameters to the drug delivery devices. An additional safety feature may be integrated into the activation mechanism to prevent partial depression and, therefore, partial activation of the drug delivery devices. For example, the activation mechanism and/or power and control system may be configured such that the device is either completely off or completely on, to prevent partial activation. Such features are described in further detail hereinafter with regard to other aspects of the novel drug delivery devices.

[00958] XI.B. Fluid Pathway Connector

[00959] A number of fluid pathway connectors may be utilized within the embodiments of the present disclosure. Generally, a suitable fluid pathway connector includes a sterile fluid conduit, a piercing member, and a sterile sleeve attached to a drug container or a sliding pierceable seal integrated within a drug container. The fluid pathway connector may further include one or more flow restrictors. Upon proper activation of the device 9210, the fluid pathway connector 92300 is enabled to connect the sterile fluid conduit 30 to the drug container of the drive mechanism 92100. Such connection may be facilitated by a piercing member, such as a needle, penetrating a pierceable seal of the drug container of the drive mechanism 92100. The sterility of this connection may be maintained by performing the connection within a flexible sterile sleeve. Upon substantially simultaneous activation of the insertion mechanism, the fluid pathway between drug container and insertion mechanism is complete to permit drug delivery into the body of the user.

[00960] In at least one embodiment of the present disclosure, the piercing member of the fluid pathway connector is caused to penetrate the pierceable seal of the drug container of the drive mechanism by direct action of the user, such as by depression of the activation mechanism by the user. For example, the activation mechanism itself may bear on the fluid pathway connector such that displacement of the activation mechanism from its original position also causes displacement of the fluid pathway connector. In one such embodiment, the fluid pathway connector may be substantially similar to that described in International Patent Application No. PCT/US2012/054861, which is included by reference herein in its entirety for all purposes. According to such an embodiment, the connection is enabled by the user depressing the activation mechanism and, thereby, driving the piercing member through the pierceable seal, because this prevents fluid flow from the drug container until desired by the user. In such an embodiment, a compressible sterile sleeve may be fixedly attached between the cap of the drug container and the connection hub of the fluid pathway connector. The piercing member may reside within the sterile sleeve until a connection between the fluid connection pathway and the drug container is desired. The sterile sleeve may be sterilized to ensure the sterility of the piercing member and the fluid pathway prior to activation.

[00961] Alternatively, the fluid pathway connector may be integrated into a drug container as described in International Patent Application No. PCT/US2013/030478, for example, which is included by reference herein in its entirety for all purposes. According to such an embodiment, a drug container may have a drug chamber within a barrel between a pierceable seal and a plunger seal. A drug fluid is contained in the drug chamber. Upon activation of the device by the user, a drive mechanism asserts a force on a plunger seal contained in the drug container. As the plunger seal asserts a force on the drug fluid and any air/gas gap or bubble, a combination of pneumatic and hydraulic pressure builds by compression of the air/gas and drug fluid and the force is relayed to the sliding pierceable seal. The sliding pierceable seal is caused to slide towards the cap, causing it to be pierced by the piercing member retained within the integrated sterile fluid pathway connector. Accordingly, the integrated sterile fluid pathway connector is connected (i.e., the fluid pathway is opened) by the combination pneumatic/hydraulic force of the air/gas and drug fluid within the drug chamber created by activation of a drive mechanism. Once the integrated sterile fluid pathway connector is connected or opened, drug fluid is permitted to flow from the drug container, through the integrated sterile fluid pathway connector, sterile fluid conduit, and insertion mechanism, and into the body of the user for drug delivery. In at least one embodiment, the fluid flows through only

a manifold and a cannula and/or needle of the insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during drug delivery.

[00962] Regardless of the fluid pathway connector utilized by the drug delivery device, the drug delivery device is capable of delivering a range of drugs with different viscosities and volumes. The drug delivery device is capable of delivering a drug at a controlled flow rate (speed) and/or of a specified volume. In one embodiment, the drug delivery process is controlled by one or more flow restrictors within the fluid pathway connector and/or the sterile fluid conduit. In other embodiments, other flow rates may be provided by varying the geometry of the fluid flow path or delivery conduit, varying the speed at which a component of the drive mechanism advances into the drug container to dispense the drug therein, or combinations thereof. Still further details about the fluid pathway connector 92300 and the sterile fluid conduit 30 are provided hereinafter in later sections in reference to other embodiments.

[00963] XI.C. Insertion Mechanism

[00964] A number of insertion mechanisms may be utilized within the drug delivery devices of the present disclosure. The pump-type delivery devices of the present disclosure may be connected in fluid flow communication to a patient or user, for example, through any suitable hollow tubing. A solid bore needle may be used to pierce the skin of the patient and place a hollow cannula at the appropriate delivery position, with the solid bore needle being removed or retracted prior to drug delivery to the patient. As stated above, the fluid can be introduced into the body through any number of means, including but not limited to: an automatically inserted needle, cannula, micro-needle array, or infusion set tubing. A number of mechanisms may also be employed to activate the needle insertion into the patient. For example, a biasing member such as a spring may be employed to provide sufficient force to cause the needle and cannula to pierce the skin of the patient. The same spring, an additional spring, or another similar mechanism may be utilized to retract the needle from the patient. In a preferred embodiment, the insertion mechanism may generally be as described in International Patent Application No. PCT/US2012/53174, which is included by reference herein in its entirety for all purposes. Such a configuration may be utilized for insertion of the drug delivery pathway into, or below, the skin (or muscle) of the patient in a manner that minimizes pain to the patient. Other known methods for insertion of a fluid pathway may be utilized and are contemplated within the bounds of the present disclosure.

[00965] In at least one embodiment, the insertion mechanism 92200 includes an insertion mechanism housing having one or more lockout windows, and a base for connection to the assembly platform and/or pump housing (as shown in FIG. 80B and FIG. 80C). The connection of the base to the assembly platform 9220 may be, for example, such that the bottom of the base is permitted to pass-through a hole in the assembly platform to permit direct contact of the base to the body of the user. In such configurations, the bottom of the base may include a sealing membrane that is removable prior to use of the drug delivery device 9210. The insertion mechanism may further include one or more insertion biasing members, a needle, a retraction biasing member, a cannula, and a manifold. The manifold may connect to sterile fluid conduit 9230 to permit fluid flow through the manifold, cannula, and into the body of the user during drug delivery.

[00966] As used herein, "needle" is intended to refer to a variety of needles including but not limited to conventional hollow needles, such as a rigid hollow steel needles, and solid core needles more commonly referred to as "trocars." In a preferred embodiment, the needle is a 9227 gauge solid core trocar and in other embodiments, the needle may be any size needle suitable to insert the cannula for the type of drug and drug administration (e.g., subcutaneous, intramuscular, intradermal, etc.) intended. A sterile boot may be utilized within the needle insertion mechanism. The sterile boot is a collapsible sterile membrane that is in fixed engagement at a proximal end with the manifold and at a distal end with the base. In at least on embodiment, the sterile boot is maintained in fixed engagement at a distal end between base and insertion mechanism housing. Base includes a base opening through which the needle and cannula may pass-through during operation of the insertion mechanism, as will be described further below. Sterility of the cannula and needle are maintained by their initial positioning within the sterile portions of the insertion mechanism. Specifically, as described above, needle and cannula are maintained in the sterile environment of the manifold and sterile boot. The base opening of base may be closed from non-sterile environments as well, such as by for example a sealing membrane 92254 (shown in FIG. 80C).

[00967] According to at least one embodiment of the present disclosure, the insertion mechanism is initially locked into a ready-to-use stage by lockout pin(s) which are initially positioned within lockout windows of the insertion mechanism housing. In this initial configuration, insertion biasing member and retraction biasing member are each retained in their compressed, energized states. As shown in FIG. 80B, the lockout pin(s) 92208 may be directly displaced by user depression of the activation mechanism 9214. As the user disengages any safety mechanisms, such as an optional on-

body sensor 9224 (shown in FIG. 80C), the activation mechanism 9214 may be depressed to initiate the drug delivery device. Depression of the activation mechanism 9214 may directly cause translation or displacement of control arm 40 and directly or indirectly cause displacement of lockout pin(s) 92208 from their initial position within locking windows 92202A of insertion mechanism housing 92202. Displacement of the lockout pin(s) 92208 permits insertion biasing member to decompress from its initial compressed, energized state. This decompression of the insertion biasing member drives the needle and the cannula into the body of the user. At the end of the insertion stage, the retraction biasing member is permitted to expand in the proximal direction from its initial energized state. This axial expansion in the proximal direction of the retraction biasing member retracts the needle, while maintaining the cannula in fluid communication with the body of the user. Accordingly, the insertion mechanism may be used to insert a needle and cannula into the user and, subsequently, retract the needle while retaining the cannula in position for drug delivery to the body of the user.

[00968] XI.D. Drive Mechanism

[00969] With reference to the embodiments shown in FIG. 81 and 82, drive mechanism 92100 includes a drive housing 92130, and a drug container 9250 having a cap 9252, a pierceable seal (not visible), a barrel 9258, and a plunger seal 9260. A drug chamber 9221, located within the barrel 9258 between the pierceable seal and the plunger seal 9260, may contain a drug fluid for delivery through the insertion mechanism and drug delivery device into the body of the user. The seals described herein may be comprised of a number of materials but are, in a preferred embodiment, comprised of one or more elastomers or rubbers. The drive mechanism may further include a connection mount 9254 to guide the insertion of the piercing member of the fluid pathway connector into the barrel 9258 of the drug container 9250. The drive mechanism 92100 may further contain one or more drive biasing members, one or more release mechanisms, and one or more guides, as are described further herein. The components of the drive mechanism function to force a fluid from the drug container out through the pierceable seal, or preferably through the piercing member of the fluid pathway connector, for delivery through the fluid pathway connector, sterile fluid conduit, and insertion mechanism into the body of the user.

[00970] In one particular embodiment, the drive mechanism 92100 employs one or more compression springs as the biasing member(s). Upon activation of the drug delivery device by the user, the power and control system may be actuated to directly or indirectly release the compression

spring(s) from an energized state. Upon release, the compression spring(s) may bear against and act upon the plunger seal to force the fluid drug out of the drug container. The compression spring may bear against and act upon a piston which, in turn, acts upon the plunger seal to force the fluid drug out of the drug container. The fluid pathway connector may be connected through the pierceable seal prior to, concurrently with, or after activation of the drive mechanism to permit fluid flow from the drug container, through the fluid pathway connector, sterile fluid conduit, and insertion mechanism, and into the body of the user for drug delivery. In at least one embodiment, the fluid flows through only a manifold and a cannula of the insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during drug delivery. Such components and their functions are described in further detail herein.

[00971] Referring now to the embodiment of the drive mechanism shown in FIG. 81 and FIG. 9282, the drive mechanism 92100 includes a drug container 9250 having a cap 9252, a pierceable seal (not visible), a barrel 9258, and a plunger seal 9260, and optionally a connection mount 9254. The drug container 9250 is mounted to a distal end of a drive housing 92130. Compressed within the drive housing 92130, between the drug container 9250 and the proximal end of the housing 92130, are drive biasing members 92122a and 92122b and a piston 92110, wherein the drive biasing members 92122a, 92122b are configured to bear upon an interface surface 92110C of the piston 92110, as described further herein. Optionally, a cover sleeve 92140 may be utilized between the drive biasing members 92122 and the interface surface 92110C of the piston 92110 to, for example, promote more even distribution of force from the drive biasing member 92122 to the piston 92110, prevent buckling of the drive biasing member 92122, and/or hide biasing members 92122 from user view. Interface surface 92110C of piston 92110 is caused to rest substantially adjacent to, or in contact with, a proximal end of seal 9260. Although the embodiments shown in FIGS. 81 and 82 show a plurality of biasing members it is also contemplated that a single biasing member may be used.

[00972] As best shown in FIG. 82B, the piston 92110 may be comprised of two components 92110A and 92110B and have an interface surface 92110C to contact the plunger seal. A tether, ribbon, string, or other retention strap (referred to herein as the "tether" 92512) may be connected at one end to the piston 9210A, 92110B. For example, the tether 92512 may be connected to the piston 92110A, 92110B by retention between the two components of the piston 92110A, 92110B when assembled. The tether 92512 is connected at another end to a winch drum 92520 of a delivery control mechanism 92500. Through the use of the winch drum 92520 connected to one end of the

tether 92512, and the tether 92512 connected at another end to the piston 92110A, 92110B, the regulating mechanism 92500 functions to control, meter, provide resistance, or otherwise prevent free axial translation of the piston 92110A, 92110B and plunger seal 9260 utilized to force a drug substance out of a drug container 9250. Accordingly, the regulating mechanism 92500 and the drive mechanism 92100 (collectively referred to herein as the "controlled delivery drive mechanism") together function to control the rate or profile of drug delivery to the user.

[00973] As shown in FIGS. 81 and 82, in the embodiments of the present disclosure, the regulating mechanism 92500 is an escapement regulating mechanism. The escapement regulating mechanism retards or restrains the distribution of tether 92512, only allowing it to advance at a regulated or desired rate. This restricts movement of piston 92110 within barrel 9258, hence controlling the movement of plunger seal 9260 and delivery of the drug contained in chamber 9221. As the plunger seal 9260 advances in the drug container 9250, the drug substance is dispensed through the sterile pathway connection 92300, conduit 9230, insertion mechanism 92200, and into the body of the user for drug delivery. In turn, tension on tether 92512, caused by the force of biasing member 92122 on piston 92110, imparts a torque on winch drum 92520 which is transferred through gear train 92510 to the escapement regulating mechanism. Optionally, a power spring may be included, coupled to the escapement regulating mechanism. This may be done in order to impart additional torque to the winding drum and/or gear train.

[00974] In at least one embodiment of the present disclosure, the drive mechanism 92100 utilizes an escapement regulating element 92500. The regulating element 92500 further includes one or more gears 92512, 92514, 92516 of a gear train 92510. One or more of the gears 92512, 92514, 92516 may be, for example, compound gears having a small diameter gear attached at a shared center point to a large diameter gear. First gear 92512 may be rotationally coupled to winch drum 92520, for example by a keyed shaft, thereby coupling rotation of gear train 92510 to winch drum 92520. First compound gear 92512 engages the small diameter gear 92514B of compound gear 92514 such that rotational movement of the first gear 92512 is conveyed by engagement of the gears (such as by engagement of corresponding gear teeth) to the second compound gear 92514. Large gear 92514A of compound gear 92514 engages the small gear 92516B of second compound gear 92516, conveying rotation thereto. Large gear 92516A of second compound gear 92516 engages small gear 92562B of escape wheel 92562, thereby coupling rotation of escape wheel 92562 to winch drum 92520. Rotation of the gear train 92510 may be coupled to winch drum 92520 thereby controlling the distribution of tether 92512, and the rate of movement of plunger seal 9260

within barrel 9258 to force a fluid from drug chamber 9221. The rotational movement of the winch drum 92520, and thus the axial translation of the piston 92110 and plunger seal 9260, are metered, restrained, or otherwise prevented from free axial translation by other components of the escapement regulating element 92500, as described herein.

[00975] The escape wheel 92562 is a compound gear having escape teeth around the circumference of a large diameter escape gear 92562A and a small diameter gear 92562B (not visible) configured to engage the gear train 92510 and meter, restrain, or otherwise prevent free rotational movement thereof. The escapement regulating element 500 further includes a lever 92564. The lever 92564 has pins 92564A,B and prong 92564C. Prong 92564C movably engages a post 92566A and is configured to removably engage an impulse pin 92566B of a balance wheel 92566. The balance wheel 92566 engages and functions as an oscillator around a pivot point 92564D in combination with a hair spring 92568. The gear train 92510, escape wheel 92562, balance wheel 92566, hair spring 92568, and lever 92564 may be mounted on and able to freely rotate or move on a first plate 92504 and/or a second plate 92506. The first plate 92504 and second plate 92506 may utilize one or more spacer columns to maintain the desired spacing between components and one or more pivot pins upon which the components may be mounted and freely rotated. An electromechanical actuator 92570 may be provided in addition to or in lieu of the hair spring 92568. Electromechanical actuator 92570 may be configured to control and/or adjust the rotation and/or oscillation of balance wheel 92566 as will be discussed further hereinafter.

[00976] The function of the escape wheel 92562, balance wheel 92566, hair spring 92568, and lever 92564 components of the escapement regulating element 92500 are explained with reference to FIG. 81B and FIGS. 83A-83H. The escape wheel 92562 and lever 92564 may initially be in an activation position, as shown in FIG. 83A. The escape wheel 562 and lever 92564 generally function to perform two steps, termed the locking action and the impulse action. These two actions are illustrated in FIG. 83B and FIG. 83C, respectively, and in which the gear train 510 is applying a clockwise torque on the escape wheel 92562. The clockwise torque may come as a result of biasing members 92122 applying a force to piston 92110 which in turn applies a tension to tether 92512. The tension of tether 92512 imparts a torque on winding drum 92520 which is transmitted through gear train 92510 to escape wheel 92562. Optionally, a power spring may additionally be used to impart torque to gear train 92510. In the locking action, one of two lever pins 92564A,B blocks escape wheel 92562 rotation on the radial face of a tooth on the escape gear 92562A. This locks the gear train 92510 between impulse actions. In the impulse action, a lever pin 92564A,B slides up to

this tooth face due to action of the balance wheel 92566 on the lever 92564. The escape wheel becomes unlocked and does mechanical work on the lever pin 92564A, B via a sliding action, which in turn imparts kinetic energy to the balance wheel 92566. The lever 92564 pivots upon a pivot point 92564D until the opposite pin 92564A,B engages with an escape wheel tooth on the escape gear 92562A, and the locked state is re-entered after a half tooth advance of the escape wheel 92562. The transition from locking action to impulse action is triggered by the balance wheel 92566, which functions as an oscillator in combination with the hair spring 92568 and/or electromechanical actuator 92570. It cycles at a natural frequency that serves as the rate control. Alternatively, the rate can be controlled and/or varied by the electromechanical actuator 92570. The balance wheel 92566 contains an impulse pin 92566B which interacts with the lever 92564 at prong 92564C. For the impulse phase depicted in FIG. 83C, a clockwise moment on the lever 92564 exerts a counterclockwise moment on the balance wheel 92566, adding to its kinetic energy. The balance wheel 92566 rotates until its kinetic energy is absorbed by the hair spring 92568 or until it is caused to stop by electromechanical actuator 92570. It stops, reverses, and reengages the impulse pin 92566B with the lever 92564. A complete cycle is shown in the transition between FIGS. 83D-83H. For example, a motor (e.g., a DC motor, AC motor, or stepper motor) or a solenoid (e.g., linear solenoid, rotary solenoid) may be used to rotate the balance wheel. This electromechanical actuator may be used in addition to the hair spring or in place of the hair spring. The electromechanical actuator may be controlled by the power and control system. By providing an electromechanical actuator the rate of drug delivery may be adjusted and/or controlled. In one embodiment, electromechanical actuator 92570 is a rotary solenoid. Upon receipt of an input signal from the power and control system the core of the rotary solenoid may rotate. This rotation may be imparted to balancing wheel 92566 by, for example, a keyed shaft. The rotary solenoid may later, upon either removal of the input signal or the receipt of a second input signal, rotate the balancing wheel back in the opposite direction or, alternatively, a hair spring may be used to return the balancing wheel in the opposite direction. This action could similarly be performed by a linear solenoid using an appropriate linkage to convert the linear motion of the solenoid core to rotational motion of the balancing wheel. A motor may also be configured to perform similarly.

[00977] To unlock the escapement regulating mechanism 92500, the balance wheel 92566 must have enough kinetic energy to drag the lever pin 92564A,B up the face of the tooth of the escape gear 92562A of the escape wheel 92562. If the impulse action adds less energy than is lost to friction, the balance wheel 92566 will rotate less and less and finally stall, locking the escapement

regulating mechanism 92500. If the escapement stops in this way under load, it will not restart easily. To be self-starting, the hair spring 92568 must align the lever 92564 along the axis connecting the pivot of the escape wheel 92562 and the pivot of the balance wheel 92566, as shown in FIG. 83A. The lever pins 92564A,B will be positioned so that a bevel tooth face can immediately start an impulse action upon application of a drive torque. This alignment can occur only with the escapement regulating mechanism 92500 in an unloaded state. The tension on the tether provided by the force of the biasing member 92122 on the piston 92110 must be isolated from the escapement regulating mechanism 500 until the start of delivery. This may be done by, for example, providing a lock-out feature which, in a first configuration, prevents motion of piston 92110. After transformation to a second configuration, the lock-out feature does not prevent motion of piston 92110 and thereafter the tension on tether 92512 acts to create a torque on winding drum 92520. Alternatively, escapement regulating mechanism 92500 may be initiated by a user imparting a force on an activation mechanism and, directly or indirectly through a power and control system, applying a drive torque to start the initial impulse action. Once the escapement regulating mechanism 92500 is initiated, it can be effectively utilized to meter, restrain, or otherwise prevent free rotational movement of the gear train 92510, winding drum 92520 and piston 92110, and, thus, plunger seal 9260. In a particular embodiment, the escape wheel 92562 is a compound gear having escape teeth around the circumference of a large diameter escape gear 92562A and a small diameter gear 92562B (not visible). The small diameter gear 92562B of the escape wheel 92562 engages the drive train 92510, which engages with winding drum 92520 through rotation shaft 92518. This novel configuration directly permits the escape wheel 92562 to regulate the rotation of the drive train 92510 and winding drum 92520, which then efficiently regulates the tether 92512 and the piston 92110.

[00978] Notably, the regulating mechanisms 92500 of the present disclosure do not drive the delivery of fluid substances from the drug chamber 9221. The delivery of fluid substances from the drug chamber 9221 is caused by the expansion of the biasing member 92122 from its initial energized state acting upon the piston 92110A, 92110B and plunger seal 9260. The regulating mechanisms 92500 instead function to provide resistance to the free motion of the piston 92110A, 92 110B and plunger seal 9260 as they are pushed by the expansion of the biasing member 92122 from its initial energized state. The regulating mechanism 92500 does not drive the delivery but only controls the delivery motion. The tether limits or otherwise restrains the motion of the piston 92110 and plunger seal 9260, but does not apply the force for the delivery. According to a preferred

DEMANDE OU BREVET VOLUMINEUX

LA PRÉSENTE PARTIE DE CETTE DEMANDE OU CE BREVET COMPREND PLUS D'UN TOME.

CECI EST LE TOME	1	DE	3
CONTENANT LES PAGES	1	À	246

NOTE : Pour les tomes additionels, veuillez contacter le Bureau canadien des brevets

JUMBO APPLICATIONS/PATENTS

THIS SECTION OF THE APPLICATION/PATENT CONTAINS MORE THAN ONE VOLUME

THIS IS VOLUME	1	OF	3
CONTAINING PAGES	1	TO	246

NOTE: For additional volumes, please contact the Canadian Patent Office

NOM DU FICHIER / FILE NAME :

NOTE POUR LE TOME / VOLUME NOTE:

What is claimed is:

1. A wearable drug delivery device comprising:

a main housing;

a container disposed in the main housing, the container including a barrel, a plunger seal moveable through the barrel, and a first pierceable seal controlling access to an interior of the barrel;

a drug disposed in the barrel, the drug comprising at least one of a Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) specific antibody, a granulocyte colony-stimulating factor (G-CSF), a sclerostin antibody, or a calcitonin gene-related peptide (CGRP) antibody;

a trocar or introducer needle having a proximal end and a distal end;

a cannula initially disposed around the distal end of the trocar or introducer needle;

a drive mechanism disposed in the main housing, the drive mechanism including:

a drive housing,

a piston moveable relative to the drive housing and configured to impart movement to the plunger seal,

a gear assembly,

an electrical actuator,

a gear interface rotatable by the electrical actuator, rotation of the gear interface causing the gear interface to selectively engage the gear assembly to prevent or allow rotation of the gear assembly,

a piston biasing member disposed between the drive housing and the piston, the piston biasing member being initially retained in a piston biasing member energized state, the piston biasing member being configured to move the piston as the piston biasing member de-energizes,

a tether connected at opposite ends to the gear assembly and the piston, the tether initially retaining the piston biasing member in the piston biasing member energized state, wherein rotation of the gear assembly creates slack in the tether which allows the piston biasing member to de-energize;

an insertion mechanism disposed in the main housing;

a fluid pathway connector defining a sterile fluid flowpath between the container and the insertion mechanism, the fluid pathway connector including:

a tubular conduit having a first end and a second end, the second end of the tubular conduit being in fluid communication with a hollow interior of the cannula during drug delivery,

a container access needle configured to pierce the first pierceable seal to establish fluid communication between the between the barrel and the tubular conduit during drug delivery, and

a connection hub connected to the container access needle and the first end of the tubular conduit, the connection hub providing fluid communication between the container access needle and the tubular conduit during drug delivery;

the insertion mechanism including:

a base,

an insertion mechanism housing rotatable relative to the base,

a rotational biasing member connected to the insertion mechanism housing, the rotational biasing member being initially retained in a rotational biasing member energized state, the rotational biasing member being configured to rotate the insertion mechanism housing as the rotational biasing member de-energizes,

a first retainer moveable between: (i) a first retainer retaining position, where the first retainer retains the rotational biasing member in the rotational biasing member energized state, and (ii) a first retainer releasing position, where the first retainer allows the rotational biasing member to de-energize,

a hub connected to the proximal end of the trocar or introducer needle, the hub being configured to translate relative to the insertion mechanism housing,

a retraction biasing member disposed between the hub and the base, the retraction biasing member having a retraction biasing member energized state, the retraction biasing member being configured to translate the hub in a proximal direction as the retraction biasing member de-energizes, and

a second retainer moveable between: (i) a second retainer retaining position, where the second retainer retains the retraction biasing member in the retraction biasing member energized state, and (ii) a second retainer releasing position, where the second retainer allows the retraction biasing member to de-energize;

a button protruding from the main housing and manually displaceable by a user; and

a trigger assembly configured to move the first retainer from the first retainer retaining position to the first retainer releasing position in response to displacement of the button by the user.

2. The wearable drug delivery device of claim 1, the container access needle being fixed relative to the main housing, and the barrel being slidably connected to the main housing such that de-energizing the piston biasing member initially causes the barrel to move toward the container access needle.

3. The wearable drug delivery device of claim 2, the container access needle accessing the interior of the barrel through the first pierceable seal as a result of movement of the barrel toward the container access needle during de-energization of the piston biasing member.

4. The wearable drug delivery device of claim 3, the connection hub including a barrel connector connected to the barrel and a container access needle manifold connected to the container access needle, the barrel connector being moveable relative to the container access needle manifold.

5. The wearable drug delivery device of claim 4, the connection hub including a flexible sealing member connecting the barrel connector and the container access needle manifold and defining a sterile chamber therebetween.

6. The wearable drug delivery device of claim 5, the container access needle including a pointed end initially disposed in the sterile chamber, wherein the pointed end of the container access needle accesses the interior of the barrel through the first pierceable seal as a result of movement of the barrel toward the container access needle during de-energization of the piston biasing member.

7. The wearable drug delivery device of any one of claims 1 to 6, wherein at least one of the first retainer or the second retainer is formed by the insertion mechanism housing.

8. The wearable drug delivery device of any one of claims 1 to 7, the gear interface including a selector member, the selector member being rotatable between: (i) a selector member first position, where the selector member operatively decouples the trigger assembly and the first retainer so that the trigger assembly cannot move the first retainer, and (ii) a selector member second position, where the selector member operatively couples the trigger assembly and the first retainer so that the trigger assembly can move the first retainer.

9. The wearable drug delivery device of claim 8, the first retainer including a lock member rotatable relative to the main housing, the lock member engaging the insertion mechanism housing to inhibit rotation of the insertion mechanism housing when the first retainer has the first retainer retaining position, the rotatable lock member disengaging the insertion mechanism housing to allow rotation of the insertion mechanism housing when the first retainer has the first retainer releasing position.

10. The wearable drug delivery device of claim 9, the first retainer including an interlock member configured to be translated relative to the main housing by the trigger assembly, the interlock member inhibiting rotation of the lock member when the first retainer has the first retainer retaining position, the interlock member allowing rotation of the lock member when the first retainer has the first retainer releasing position.

11. The wearable drug delivery device of any one of claims 8 to 10, comprising a body contact sensor configured to detect contact between the patient and an exterior surface of the main housing, wherein the selector member is rotated from the selector member first position to the selector member second position in response to the body contact sensor detecting contact between the patient and an exterior surface of the wearable drug delivery device.

12. The wearable drug delivery device of any one of claims 1 to 11, comprising:

a battery configured to supply the electrical actuator with electricity;

an adhesive applied to an exterior surface of the main housing; and

an adhesive liner covering the adhesive, wherein removal of the adhesive liner from the adhesive causes the battery to supply the electrical actuator with electricity.

13. The wearable drug delivery device of any one of claims 1 to 12, the gear assembly comprising at least one of a winch drum or a winch gear, wherein one of the ends of the tether is connected to the at least one of a winch drum or the winch gear.

14. The wearable drug delivery device of any one of claims 1 to 12 or 13, comprising:

an electrically-powered element;

a battery configured to supply the electrically-powered element with electricity;

an adhesive applied to an exterior surface of the main housing; and

an adhesive liner covering the adhesive, wherein removal of the adhesive liner from the adhesive causes the battery to supply the electrically-powered element with electricity.

15. The wearable drug delivery device of any one of claims 1 to 14, comprising a heating element disposed adjacent to the tubular conduit and configured to warm the drug as the drug flows through the tubular conduit during delivery.

16. The wearable drug delivery device of claim 15, the heating element including an electrically-conductive coil wrapped around an exterior of the tubular conduit.

17. The wearable drug delivery device of any one of claims 1 to 16, comprising a wireless communication unit configured to wirelessly communicate via at least one of Bluetooth, Bluetooth low energy, radio-frequency identification (RFID), Zigbee, Wi-Fi, or near field communication (NFC).

18. The wearable drug delivery device according to any one of claims 1 to 17, comprising:

a lock having a locked state wherein delivery of the drug from the container is limited and an unlocked state wherein delivery of the drug from the container is not limited;

a temperature sensor;

an output device; and

a controller coupled to the lock, the temperature sensor, and the output device, the controller being programmed:

(a) to determine if the temperature of a drug disposed in the reservoir exceeds an upper limit, and if the temperature exceeds the upper limit, to activate the output device at least once and to place the lock in the locked state;

(b) to determine if the temperature of a drug disposed in the reservoir is below a lower limit, and if the temperature is below the lower limit, to activate the output device at least once and to place the lock in the locked state; and

(c) to determine if the temperature of the drug is between the upper limit and the lower limit subsequent to (b), and if the temperature is between the upper limit and the lower limit, to place the lock in the unlocked state.

19. The wearable drug delivery device according to claim 18, comprising:

a heater coupled to the controller and proximate to at least one of the reservoir and the drug delivery device; and

the controller programmed to activate the heater if the temperature of the drug is below the lower limit, and to deactivate the heater if the temperature of the drug is between the upper and lower limits.

20. A support system for a patient, the system comprising:

the wearable drug delivery device according to any one of claims 1 to 19;

the wearable drug delivery device including a first communication module configured to transmit a report representative of at least one of a condition or an operational state of the wearable drug delivery device; and

an external computing device comprising:

a second communication module configured to receive the report;

a processor; and

a memory coupled to the processor and configured to store non-transitory, computer-executable instructions that, when executed by the processor, cause the processor to:

associate the patient with the at least one support group;

store, in the memory, a predefined criteria for determining compliance with a treatment regimen;

compare the report with the predefined criteria to determine if the patient is compliant with the treatment regimen; and

in response to a determination that the patient is not compliant with the treatment regimen, control the second communication module to transmit a communication to the at least one support group requesting the at least one support group to at least counsel the patient about the treatment regimen.

21. A wearable drug delivery device comprising:

a container;

a drug disposed in the container, the drug comprising at least one of a Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) specific antibody, a granulocyte colony-stimulating factor (G-CSF), a sclerostin antibody, or a calcitonin gene-related peptide (CGRP) antibody;

a trocar or introducer needle;

an activation member manually operable by a patient;

an insertion mechanism configured to move the trocar or introducer needle between a retracted position and an inserted position, the insertion mechanism including a rotatable housing and a rotational biasing member initially held in an energized state;

a fluid pathway connector defining a sterile fluid flowpath between the container and the insertion mechanism; and

a locking assembly having: (i) a lock configuration, where the locking assembly engages the rotatable housing to inhibit rotation of the rotatable housing, and (ii) an unlock configuration, where the locking assembly disengages the rotatable housing to permit rotation of the rotatable housing; and

a selector having: (i) a first configuration, where the selector operatively decouples the activation member and the locking assembly, and (ii) a second configuration, where the selector operatively couples the activation member and the locking assembly to allow the activation member to change the locking assembly from the lock configuration to the unlock configuration.

22. The wearable drug delivery device of claim 21, the locking assembly comprising a retainer rotatable relative to the rotatable housing of the insertion mechanism, the retainer being configured to engage the rotatable housing to inhibit rotation of the rotatable housing when the locking assembly has the lock configuration, and the retainer being configured to disengage the rotatable housing to permit rotation of the rotatable housing when the locking assembly has the unlock configuration.

23. The wearable drug delivery device of claim 22, the locking assembly comprising an interlock member linearly translatable between a first position and a second position, the interlock member inhibiting rotation of the retainer when the interlock member occupies the first position,

and the interlock member permitting rotation of the retainer when the interlock member occupies the second position.

24. The wearable drug delivery device of any one of claims 21 to 23, the insertion mechanism comprising:

a shell disposed in an internal chamber of the rotational housing;

a hub connected to a proximal end of the trocar or introducer needle; and

a retraction biasing member initially held in an energized state between the hub and the shell.

25. The wearable drug delivery device of any one of claims 21 to 24, comprising a drive mechanism including:

a gear assembly;

a piston connected configured to move axially within the container;

a biasing member initially retained in an energized state, the biasing member being configured to expand to impart axial movement to the piston when released from the energized state; and

a tether having a first end and a second end connected to, respectively, the piston and the gear assembly, the tether being configured to restrain expansion of the biasing member when the biasing member is released from the energized state, such that the tether restrains axial movement of the piston within the container.

26. The wearable drug delivery device of claim 25, the gear assembly comprising at least one of a winch drum or a winch gear, wherein the second end of the tether is connected to the at least one of a winch drum or the winch gear.

27. The wearable drug delivery device of any one of claims 21 to 26, comprising:

a body contact sensor configured to detect contact between the patient and an exterior surface of the wearable drug delivery device; and

wherein the selector changes from the first configuration to the second configuration in response to the body contact sensor detecting contact between the patient and an exterior surface of the wearable drug delivery device.

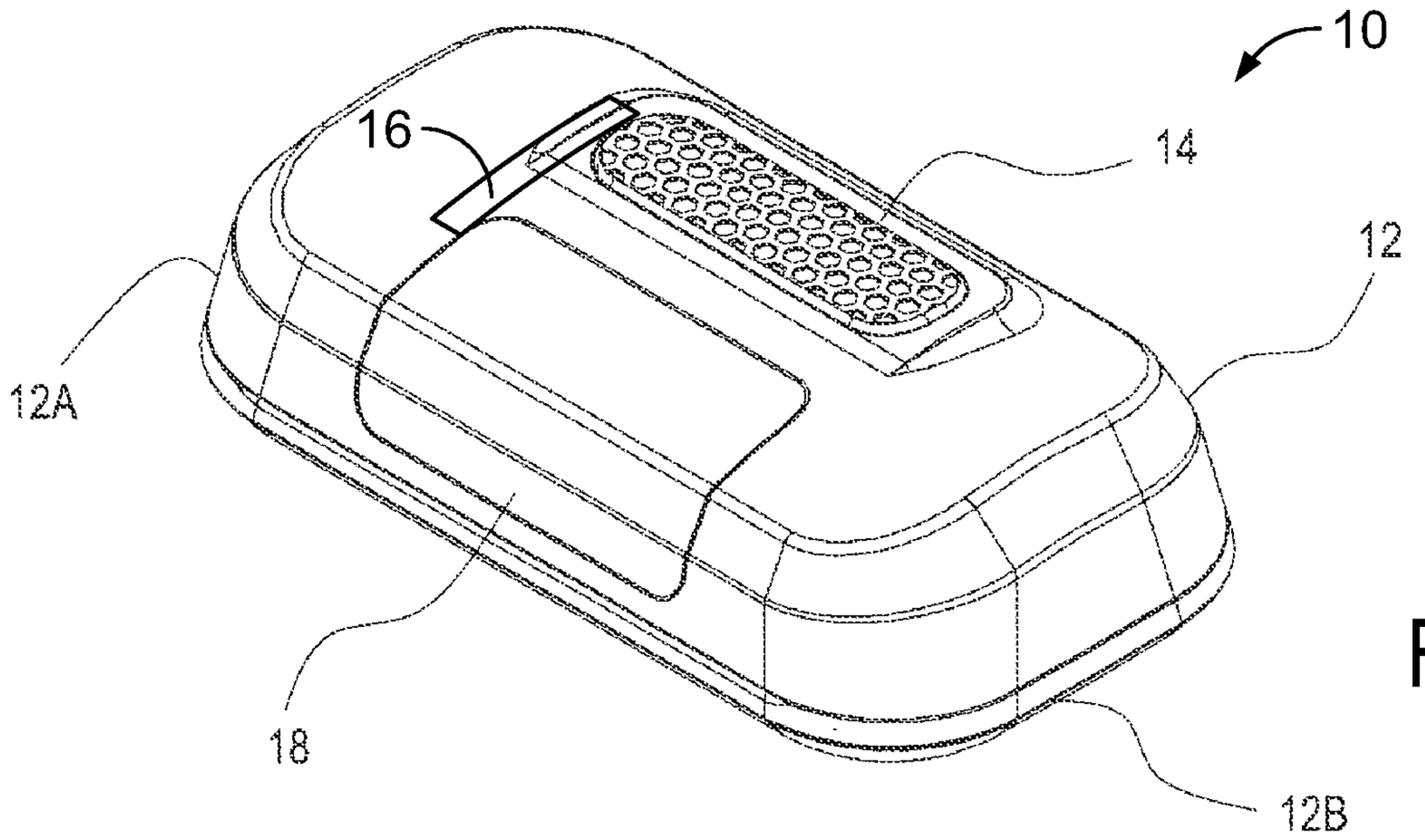


FIG. 1A

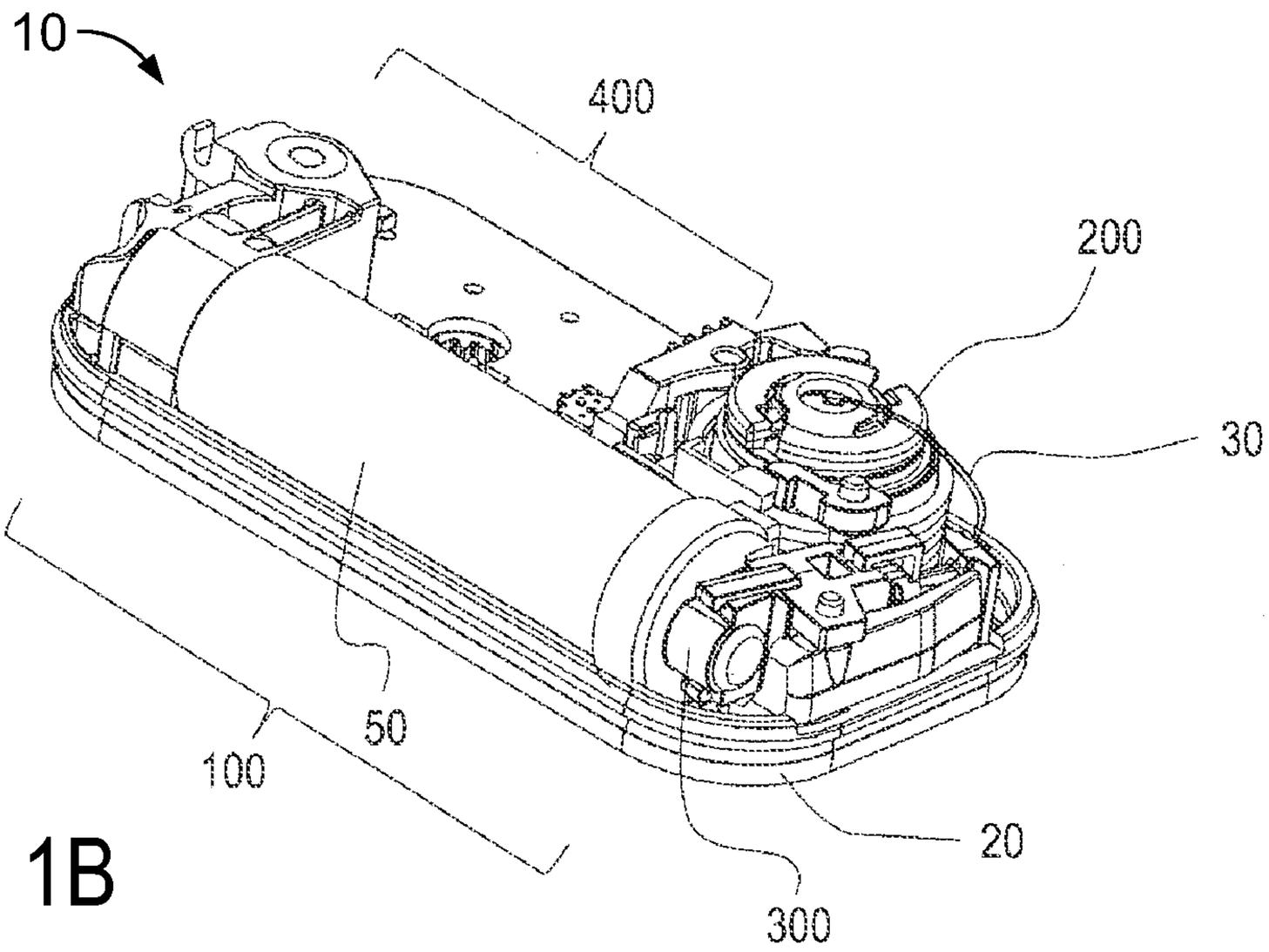


FIG. 1B

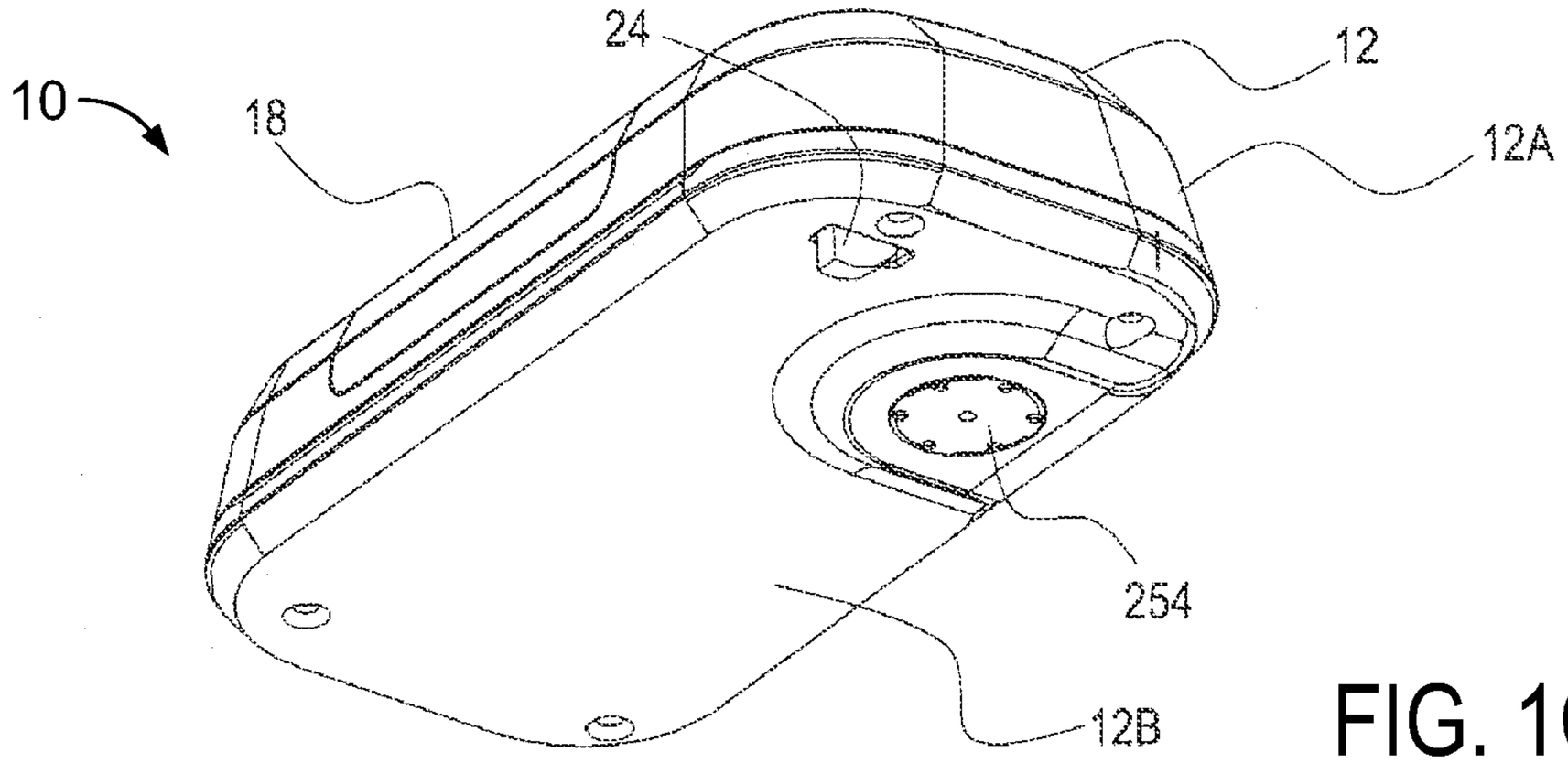


FIG. 1C

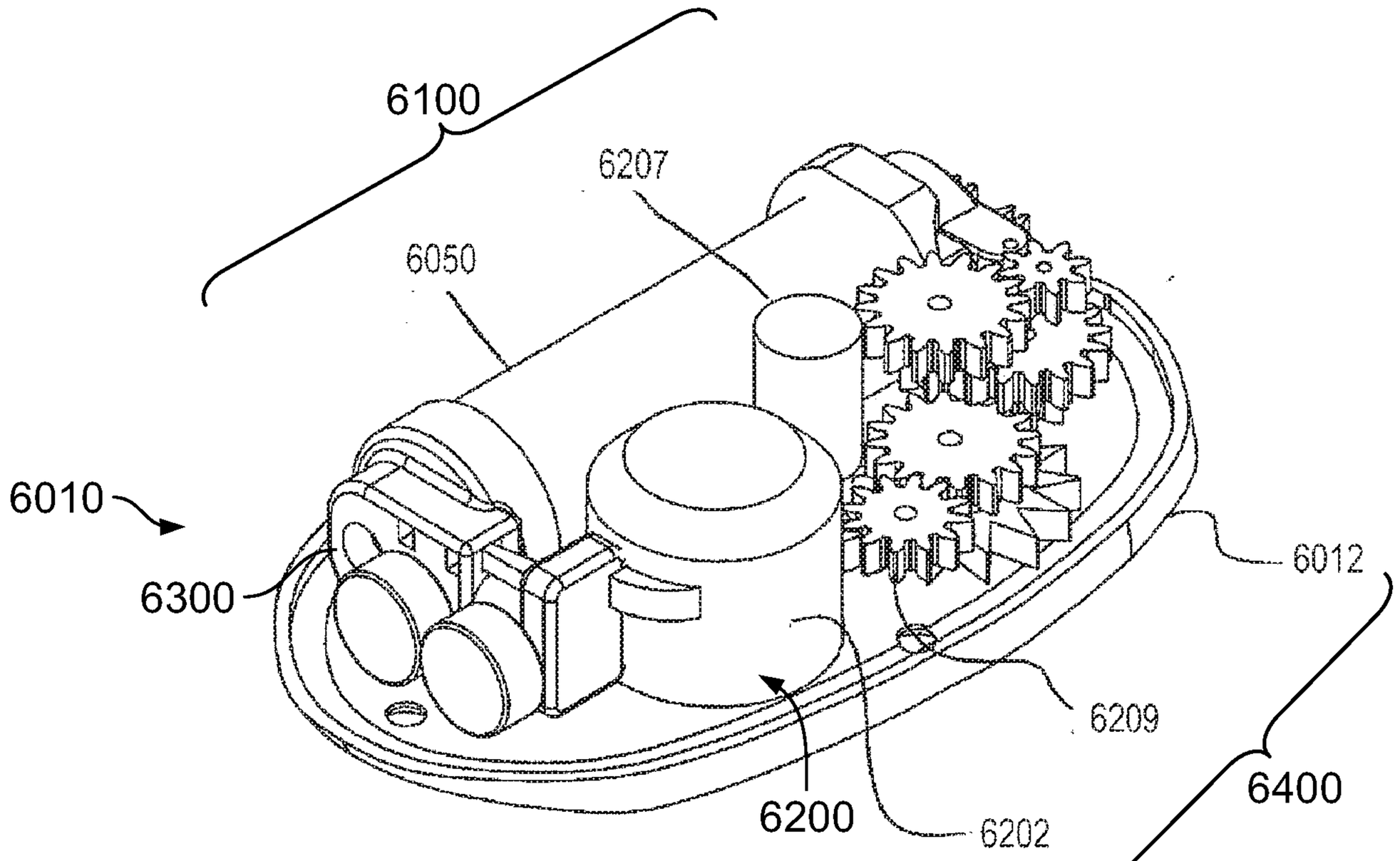

6100
6207
6050
6010
6300
6012
6209
6400
6200
6202

FIG. 2A

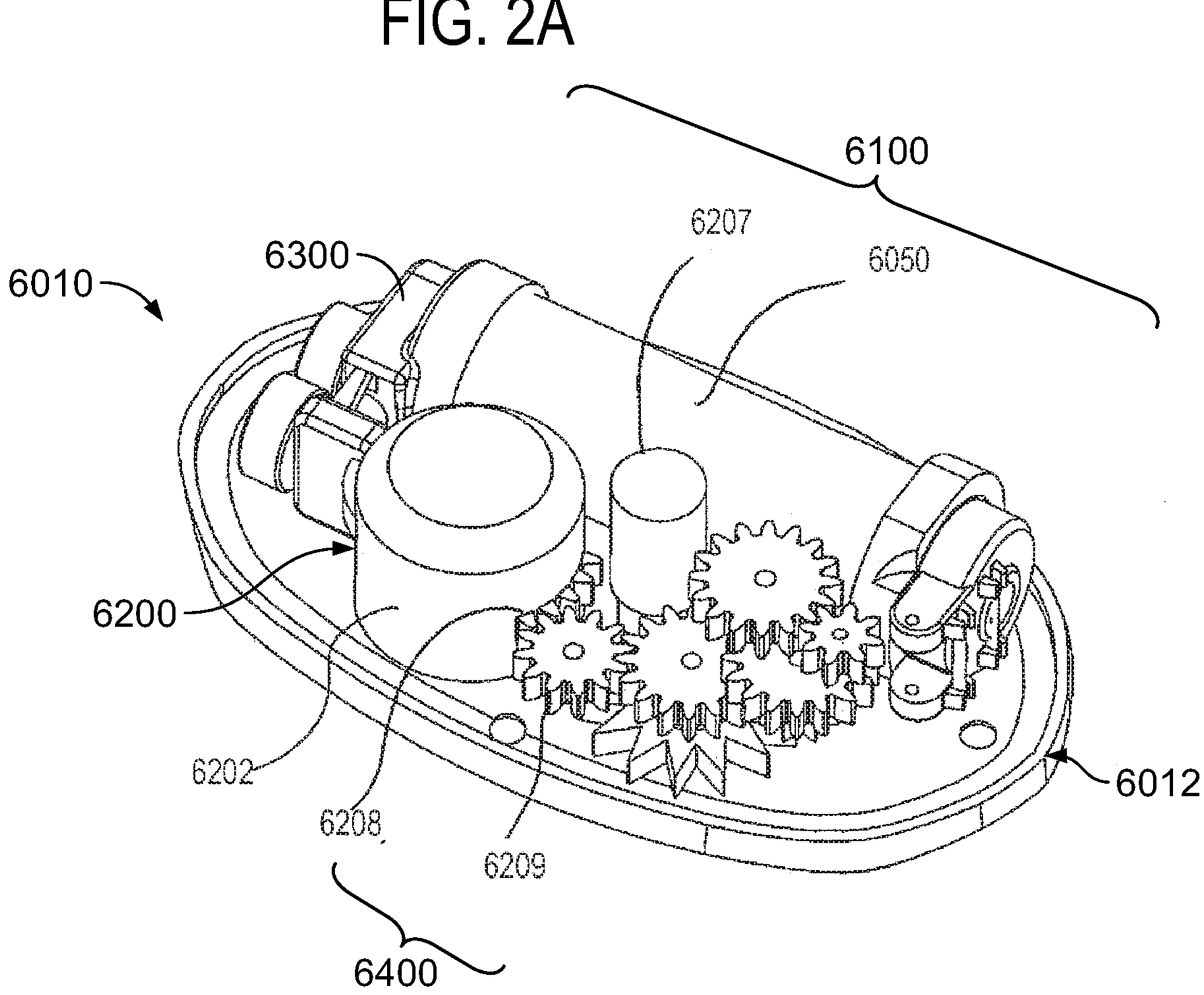

6100
6207
6050
6010
6300
6200
6202
6208
6209
6400
6012

FIG. 2B

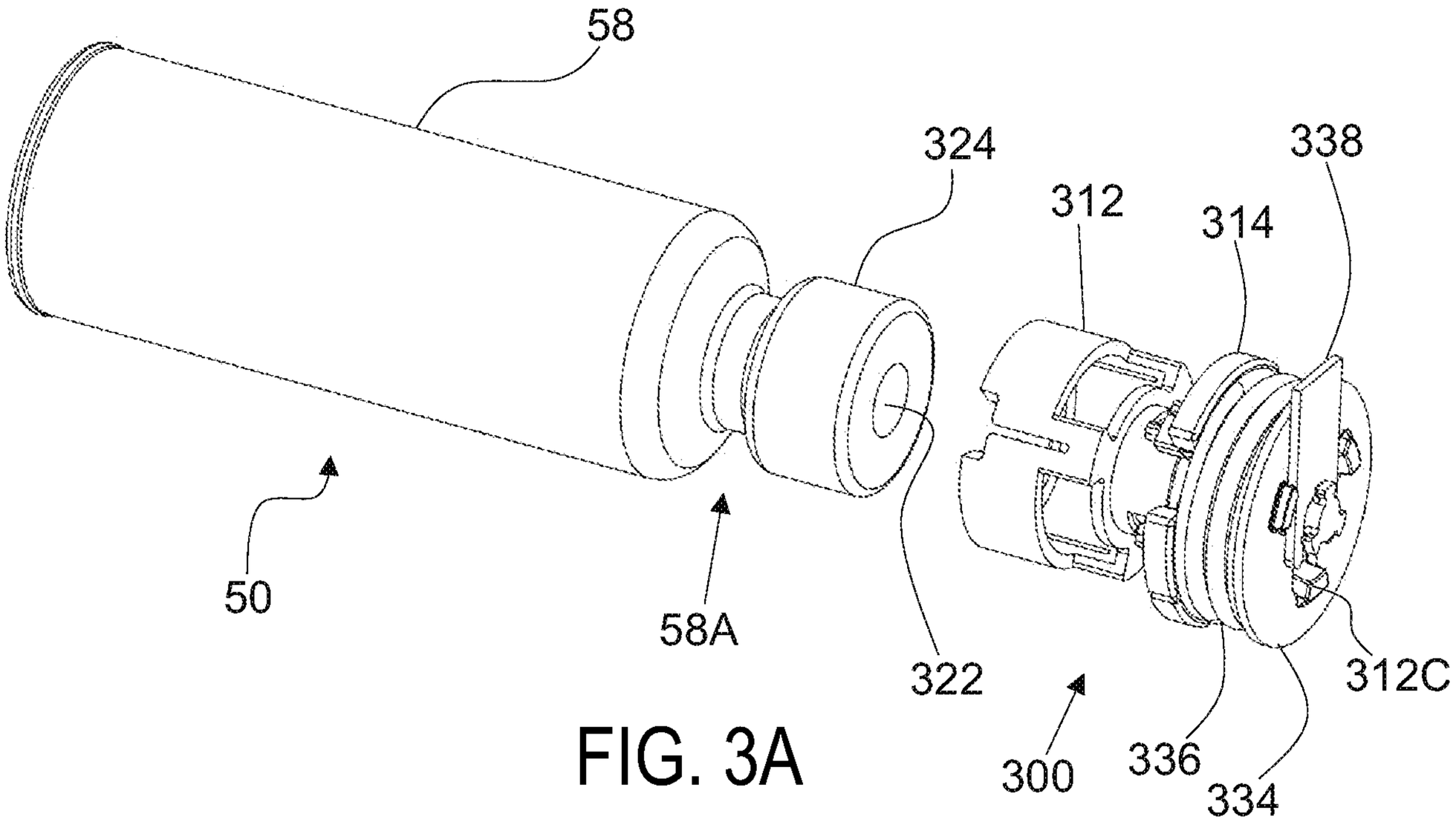

58
324
338
312
314
50
58A
322
312C
300
336
334

FIG. 3A

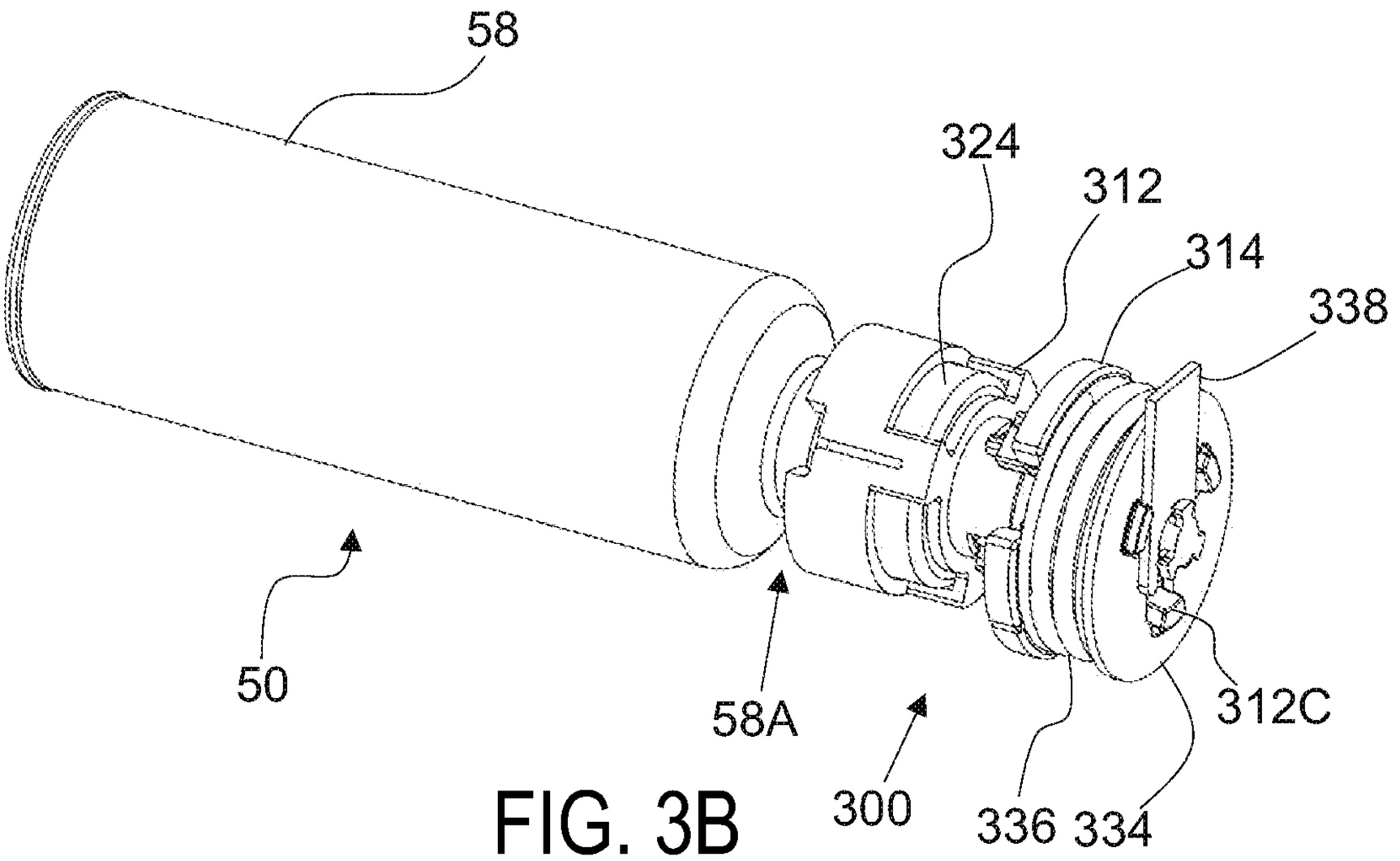

58
324
312
314
338
50
58A
300
312C
336
334

FIG. 3B

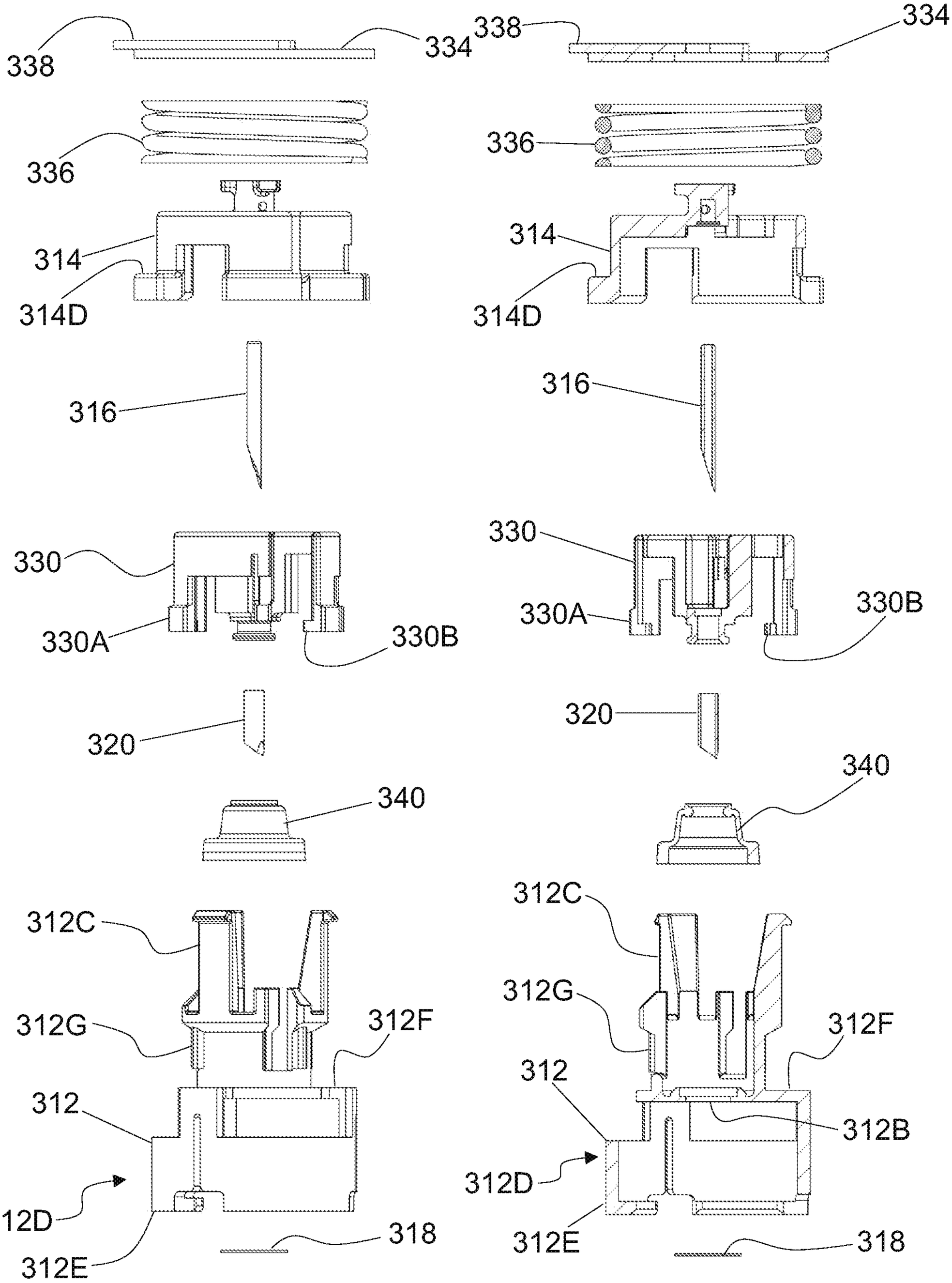

338
334
336
314
314D
316
330
330A
330B
320
340
312C
312G
312F
312
312D
312E
318
338
334
336
314
314D
316
330
330A
330B
320
340
312C
312G
312F
312
312B
312D
312E
318

FIG. 4A

FIG. 4B

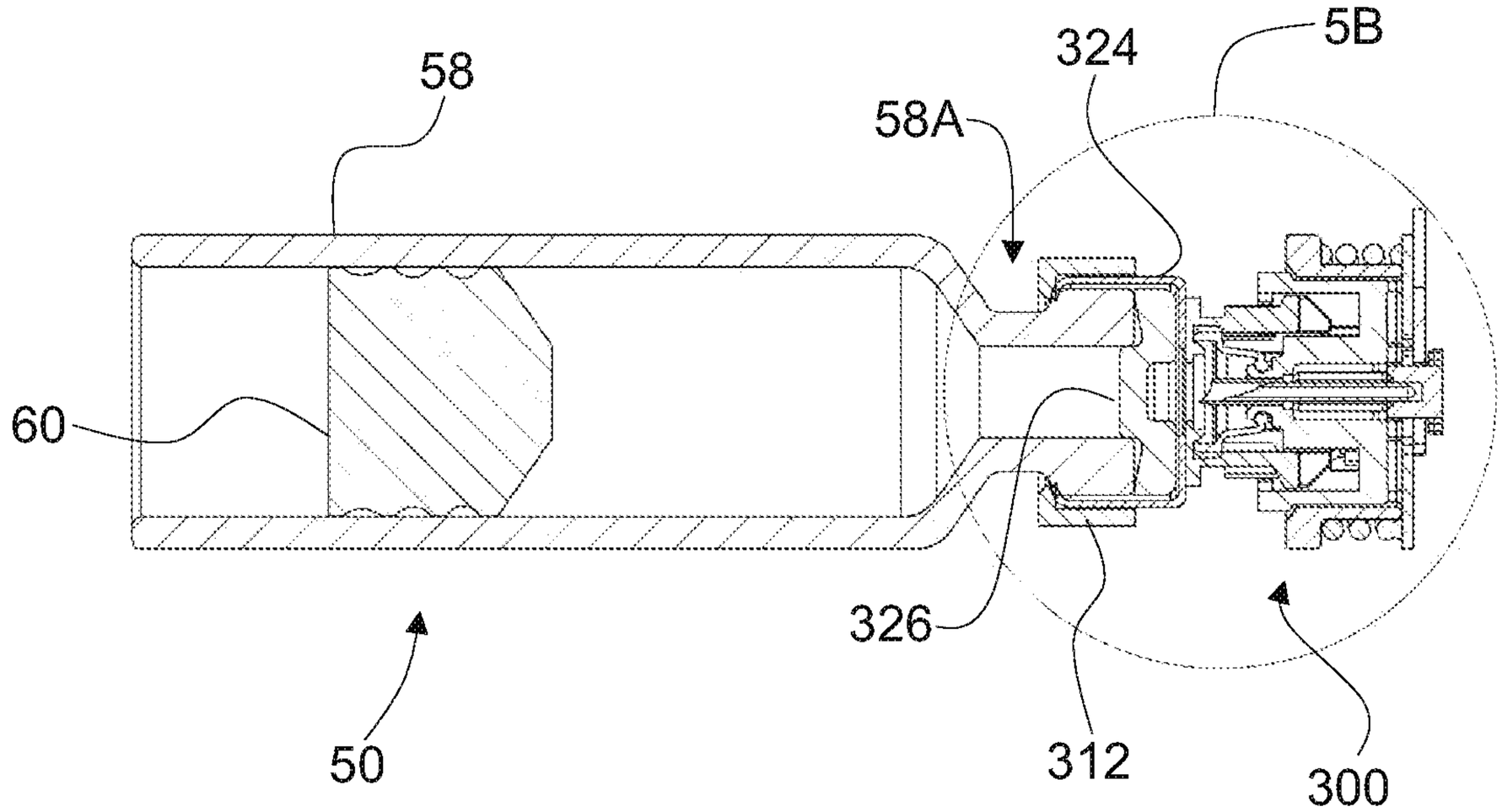

58
324
5B
58A
60
326
50
312
300

FIG. 5A

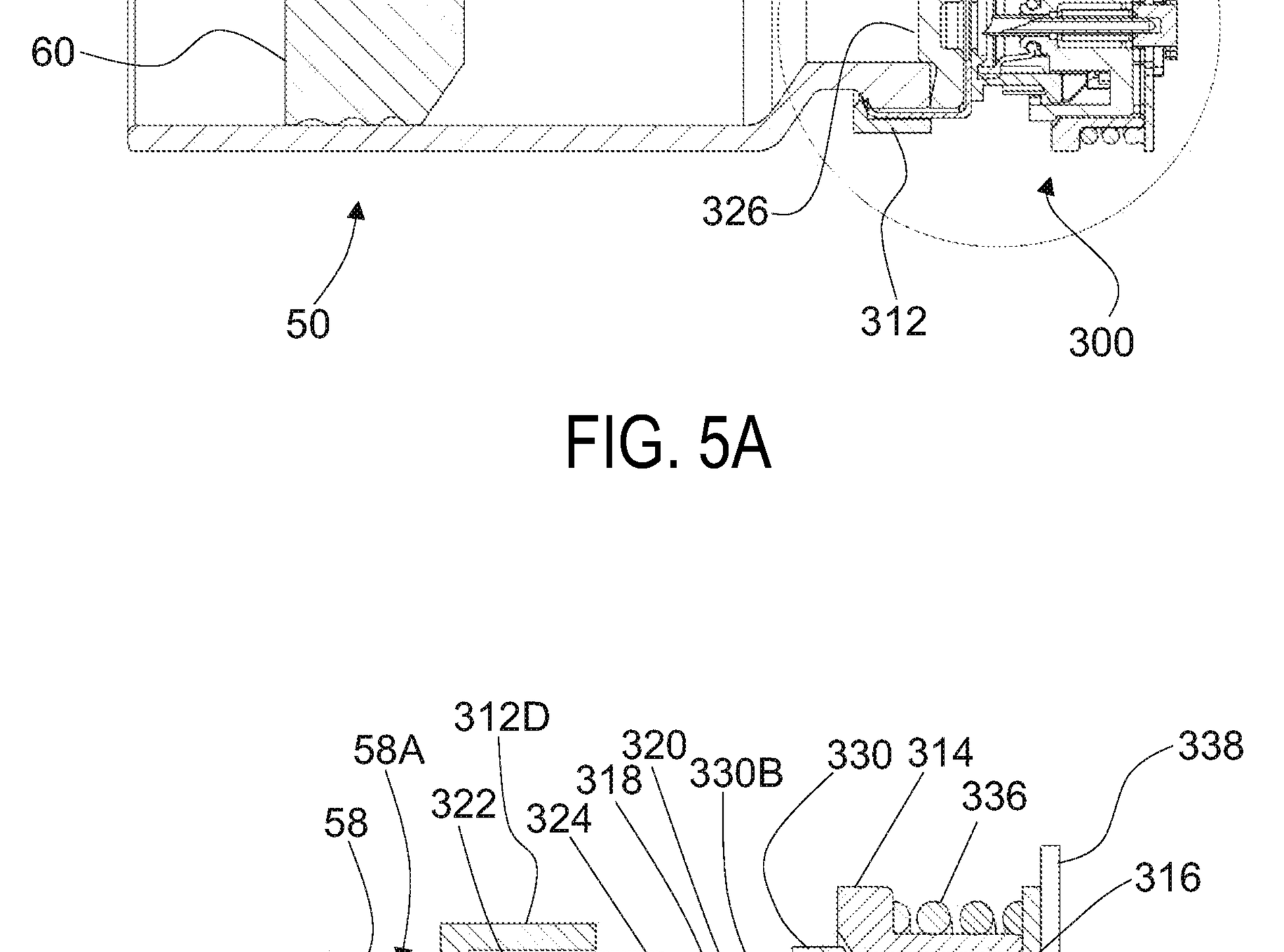

312D
58A
320
330
314
338
318
330B
336
322
324
58
316
314B
A
328
P
D
326
312E
312B
312
312A
312G
340
330B
314D
334

FIG. 5B

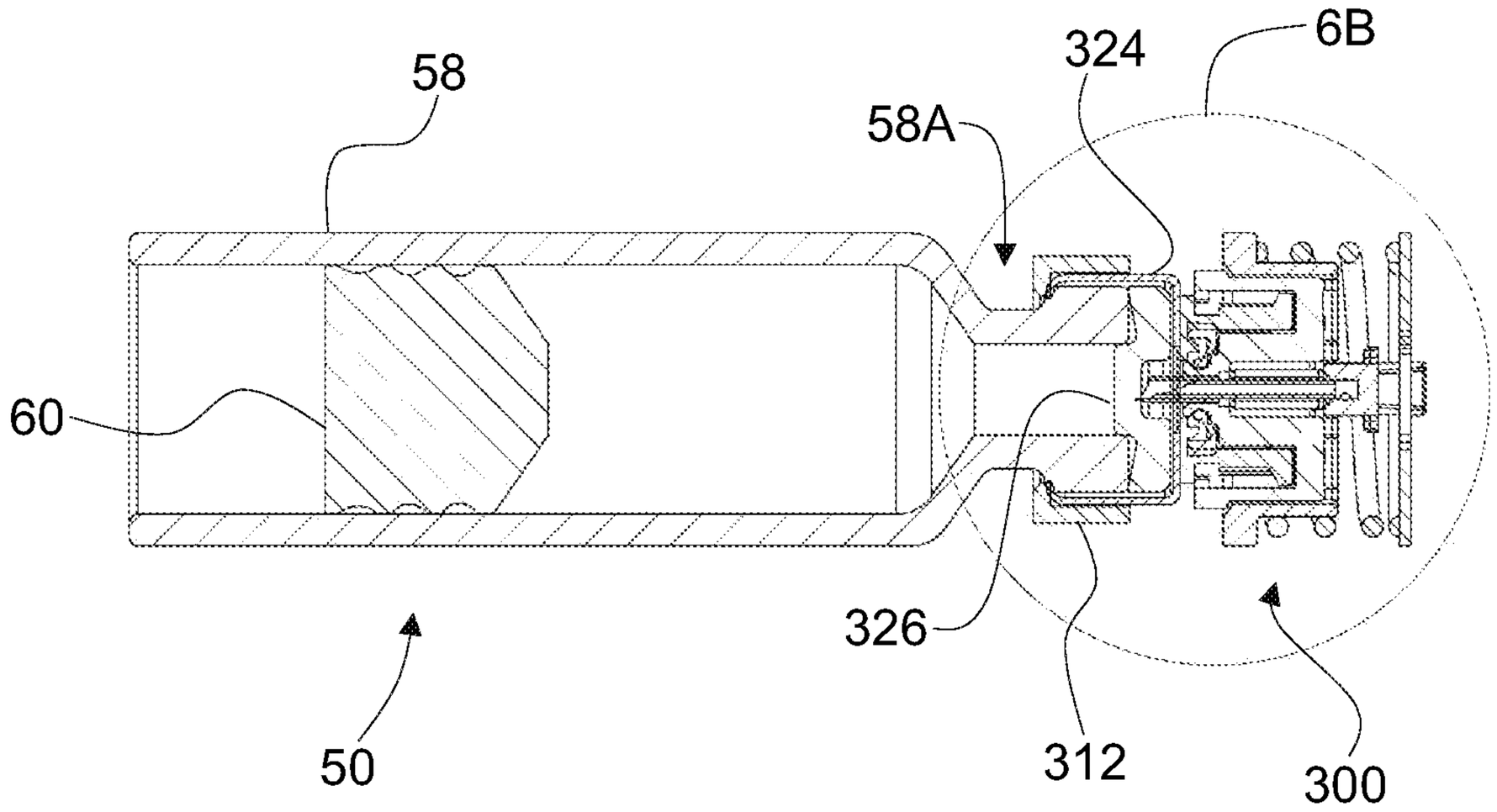

58
58A
324
6B
60
326
50
312
300

FIG. 6A

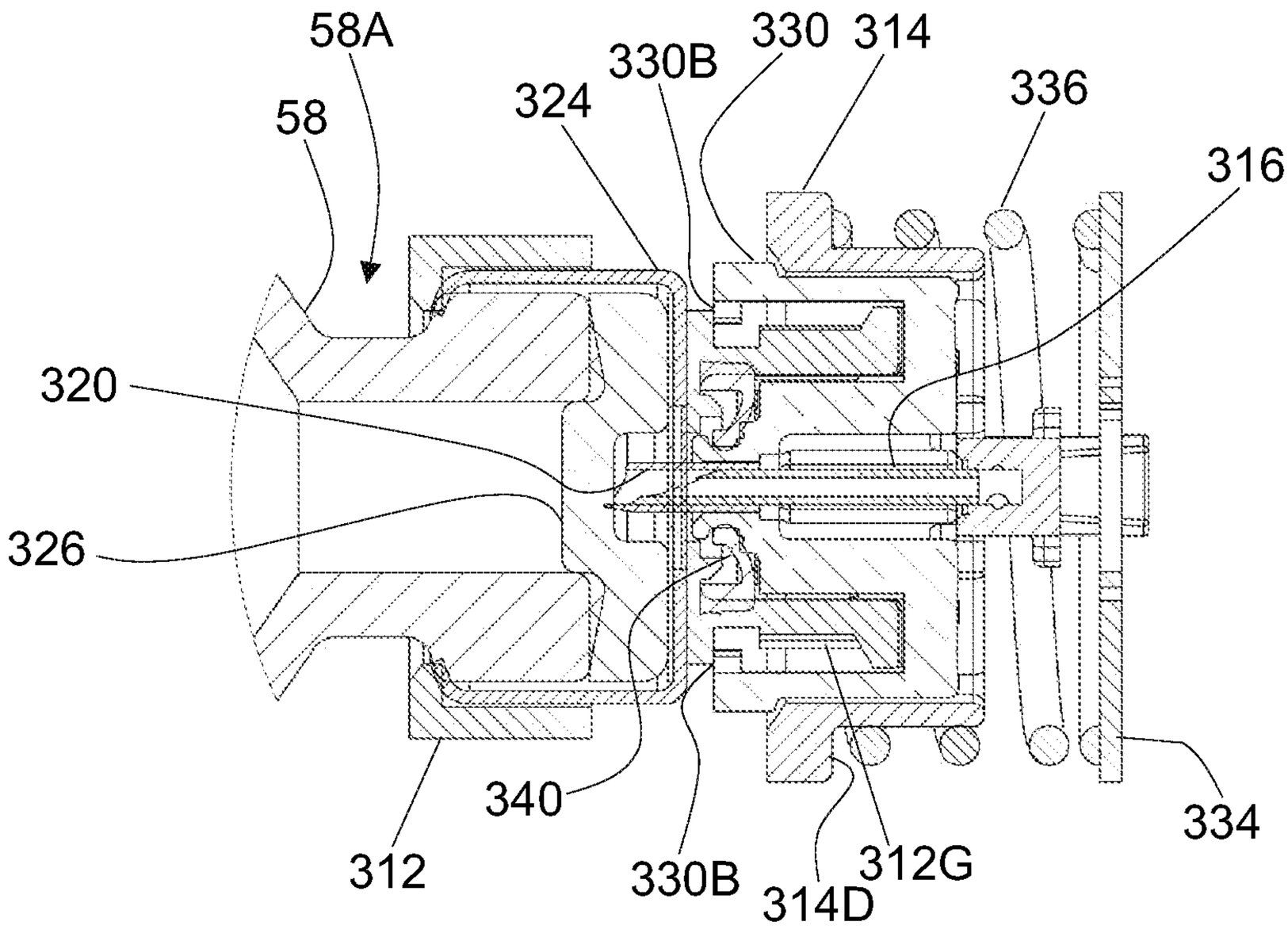

58A
330
314
330B
324
58
336
316
320
326
340
312
330B
314D
312G
334

FIG. 6B

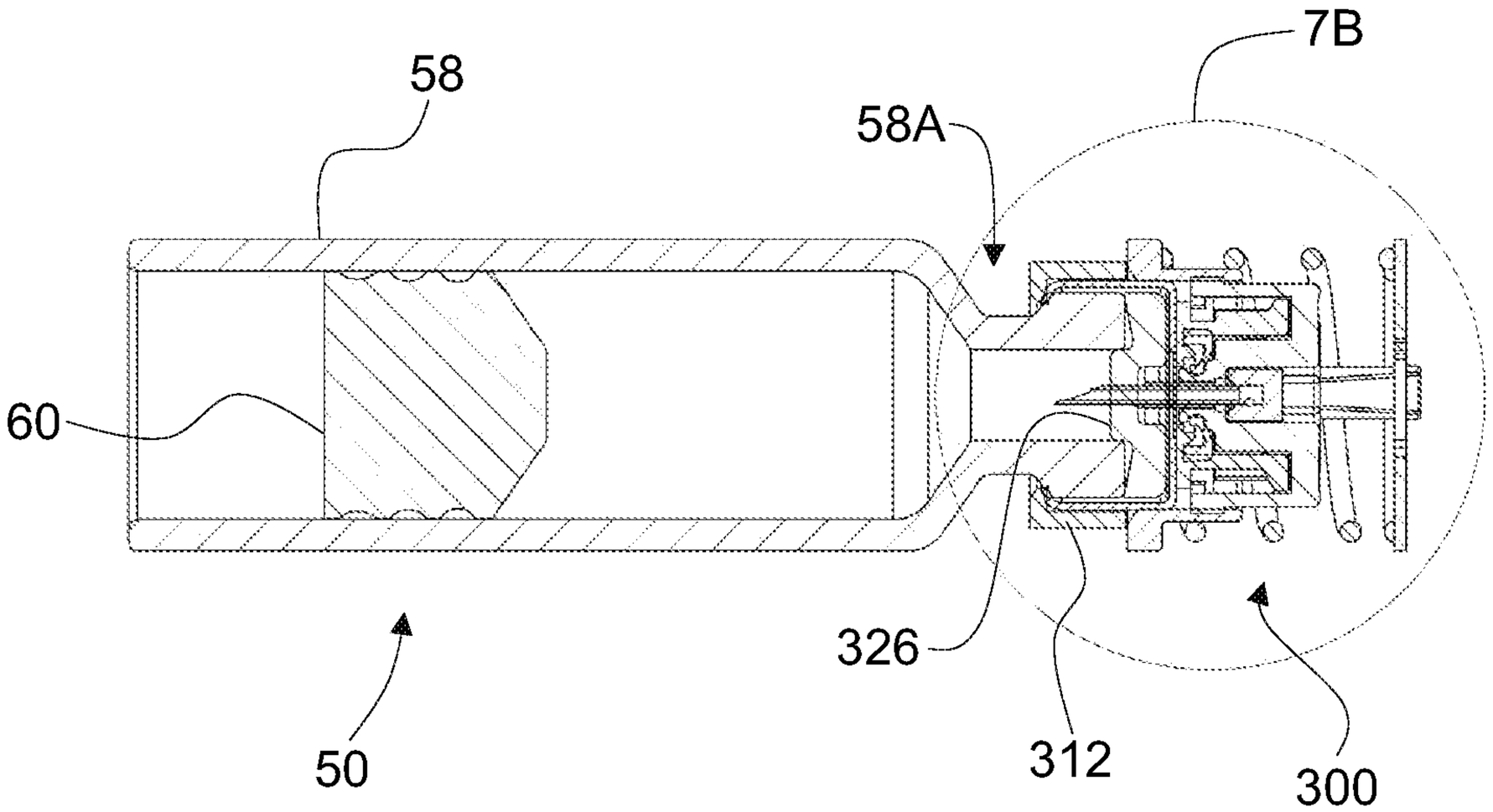

58
58A
7B
60
326
50
312
300

FIG. 7A

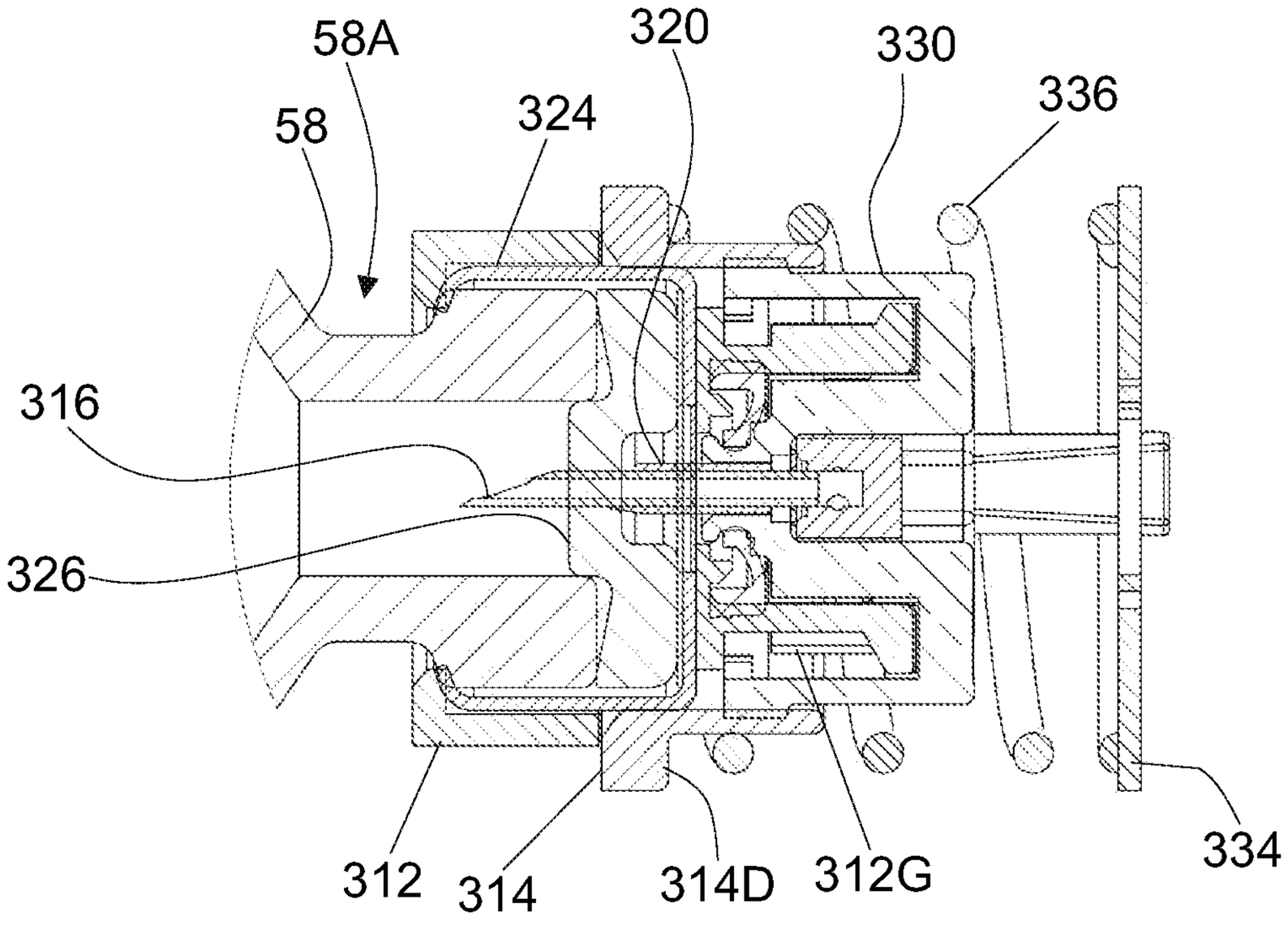

58A
320
330
336
58
324
316
326
312
314
314D
312G
334

FIG. 7B

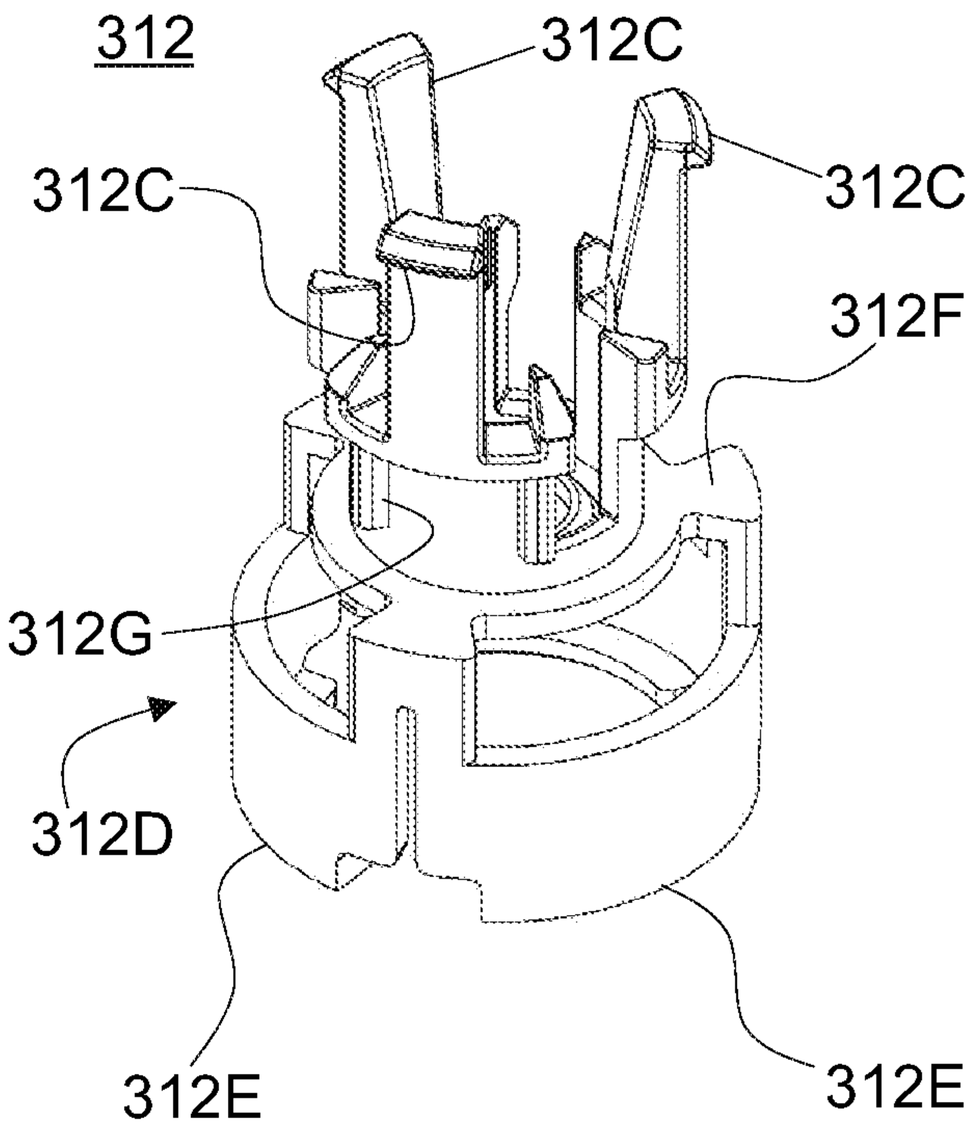


FIG. 8

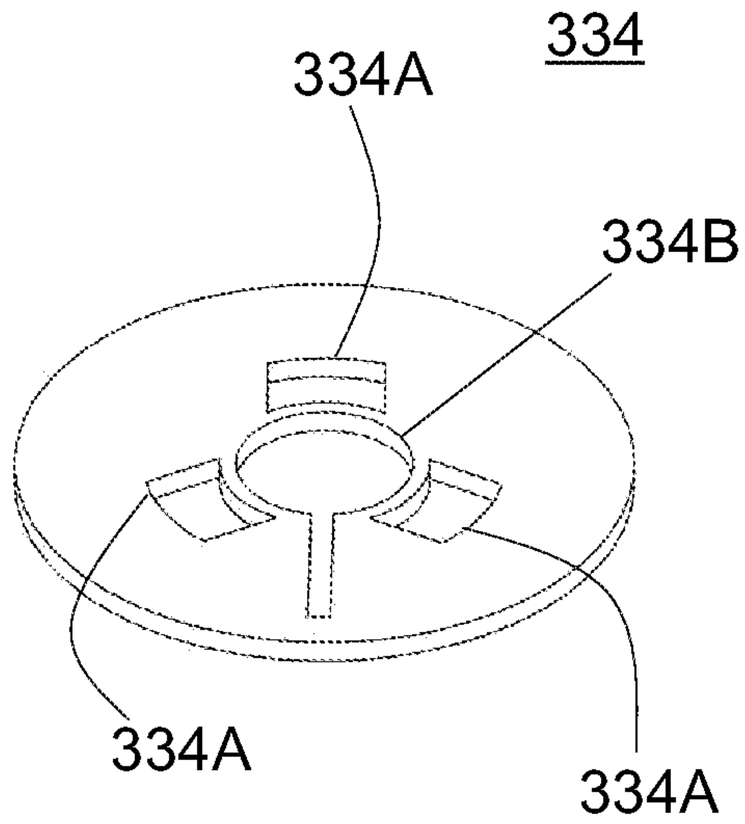


FIG. 9

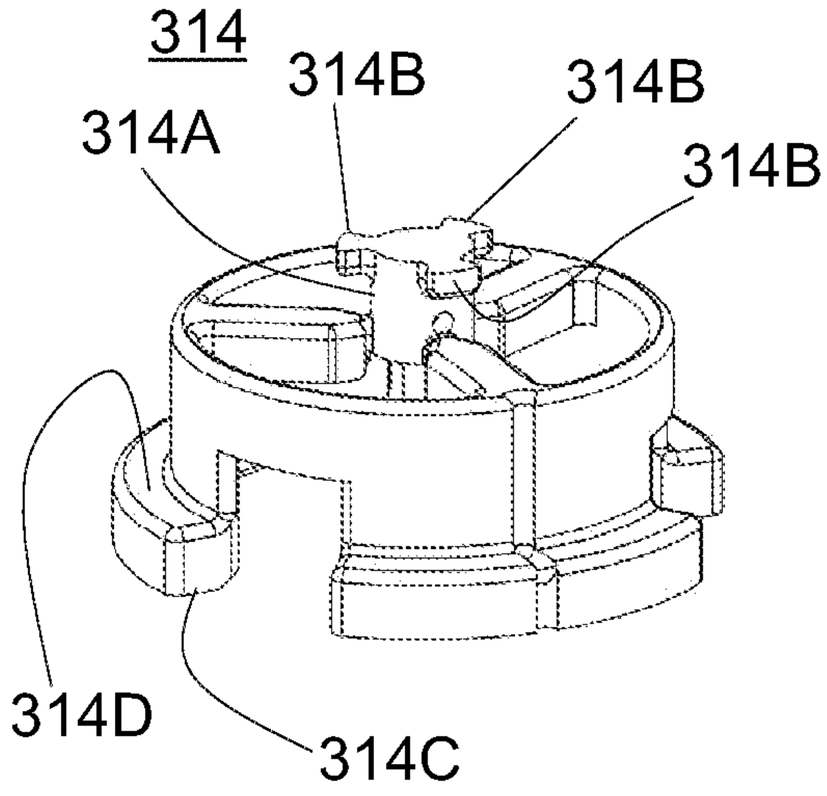


FIG. 10

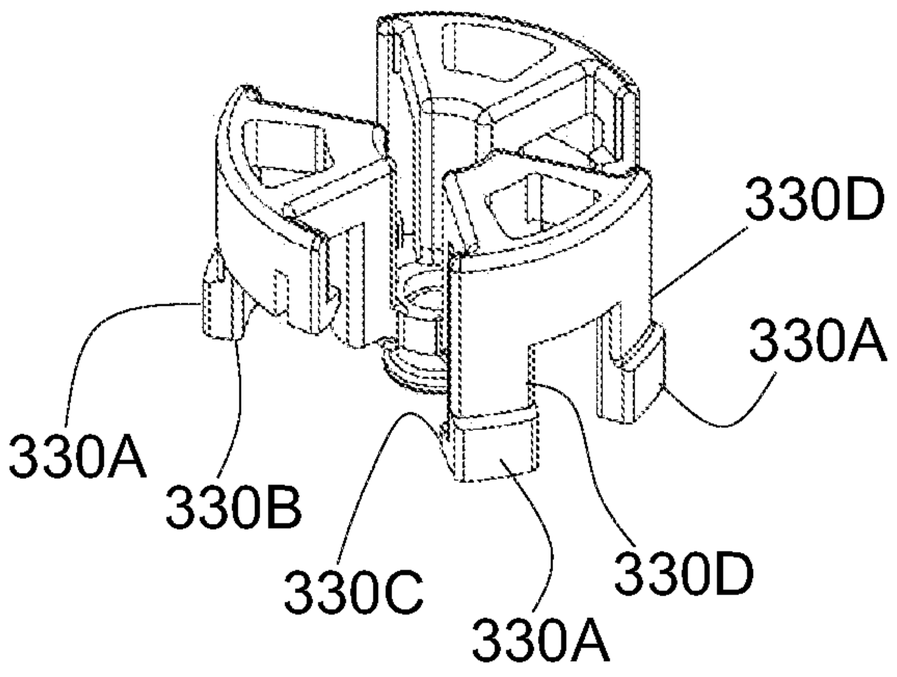


FIG. 11

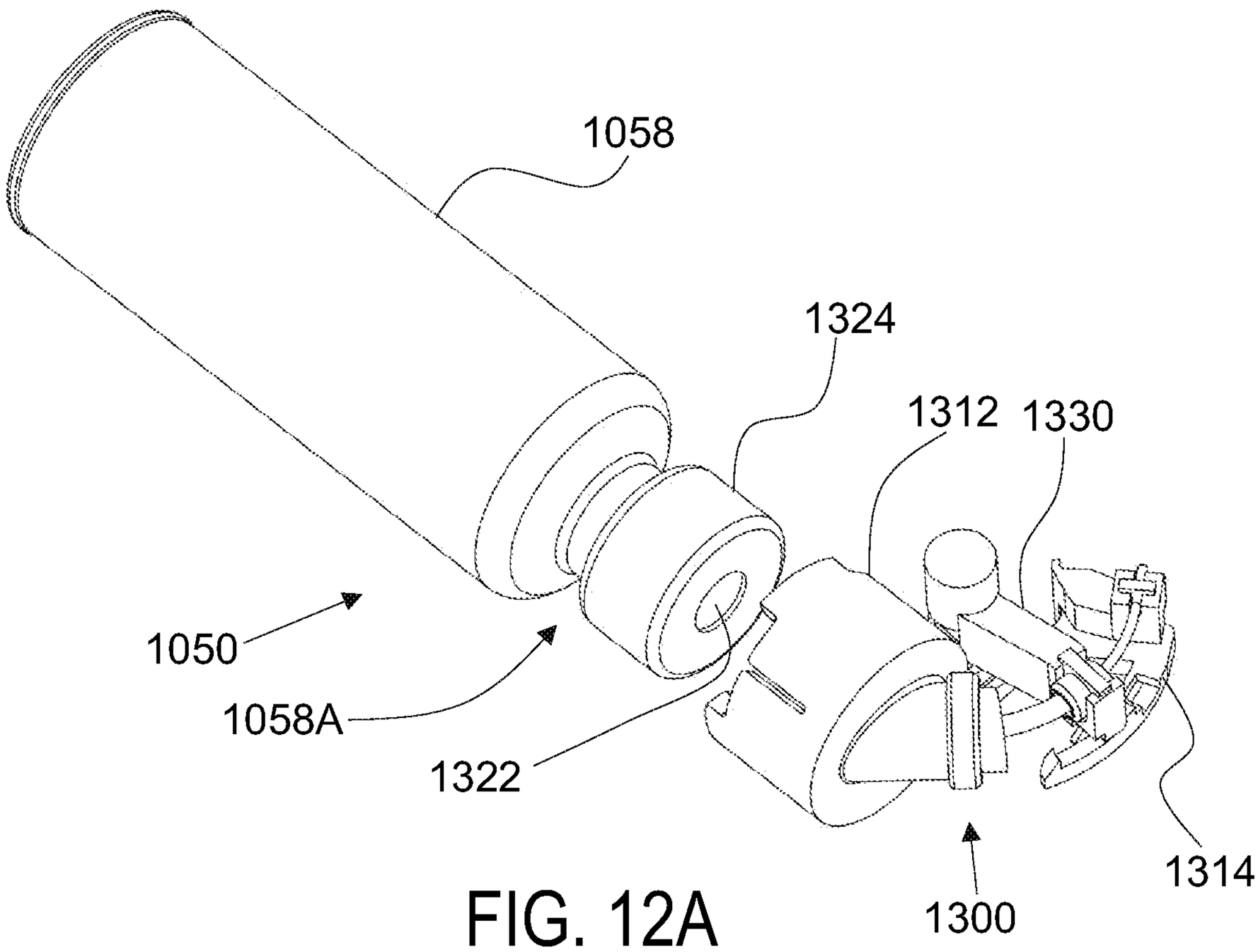


FIG. 12A

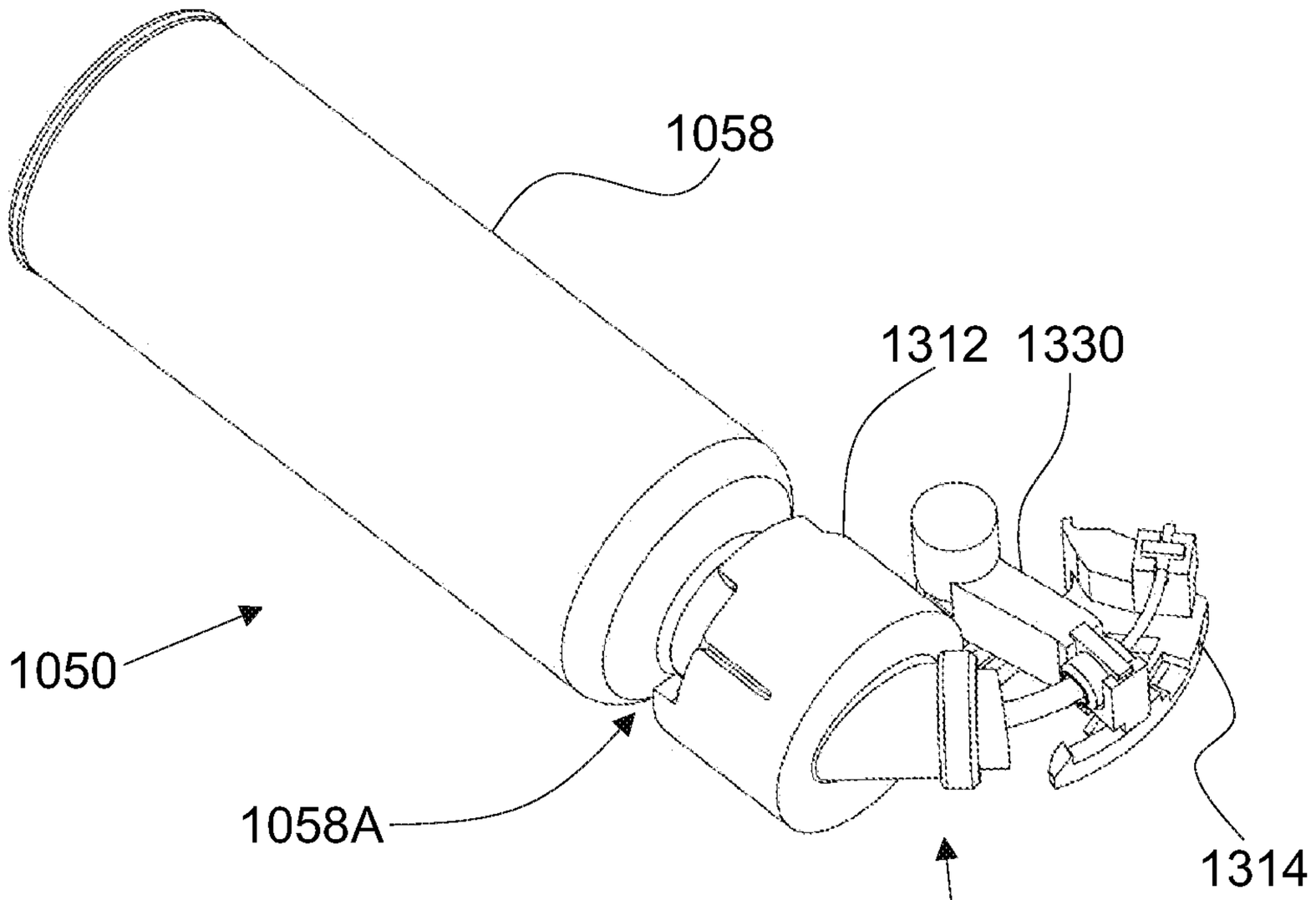


FIG. 12B

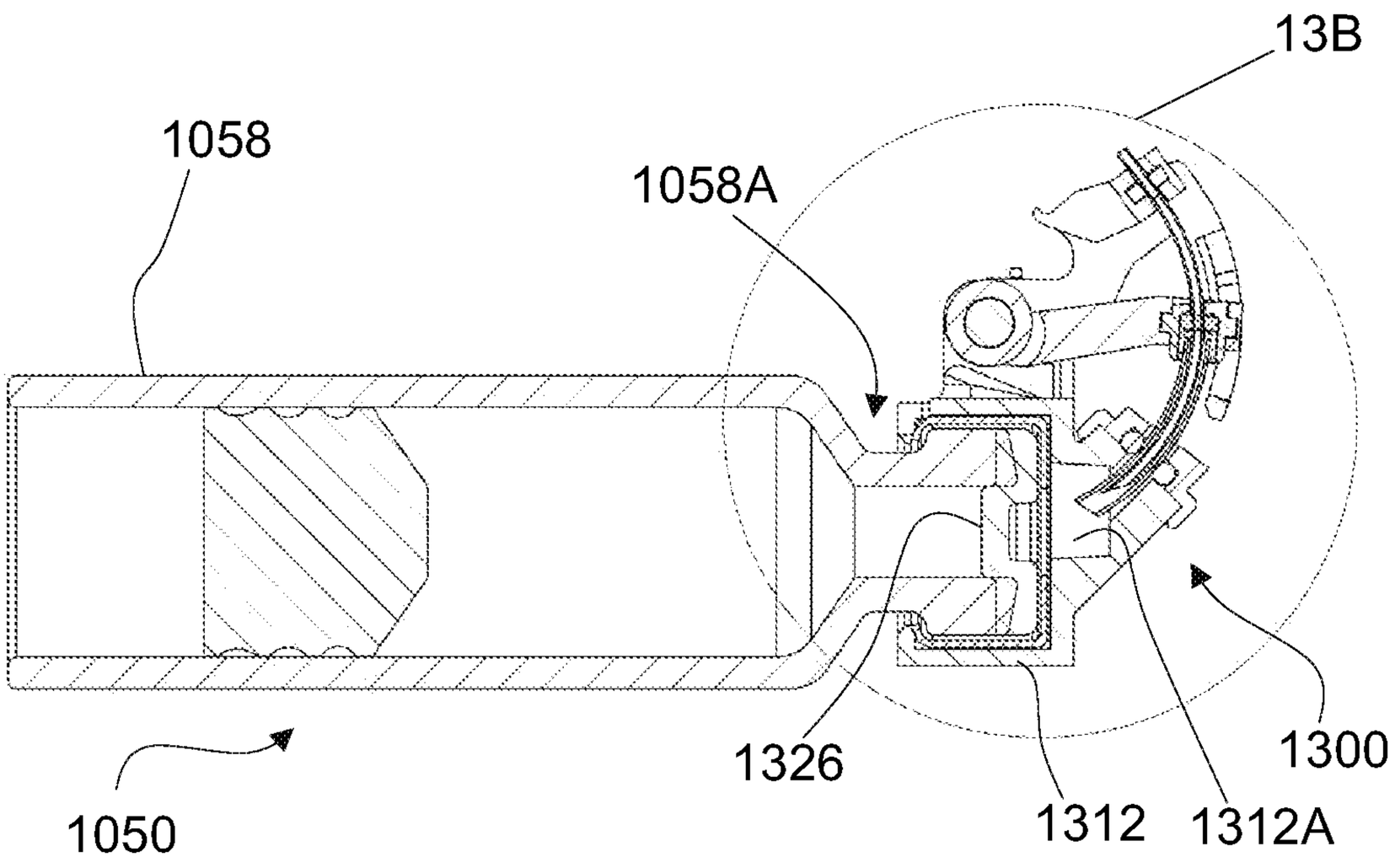


FIG. 13A

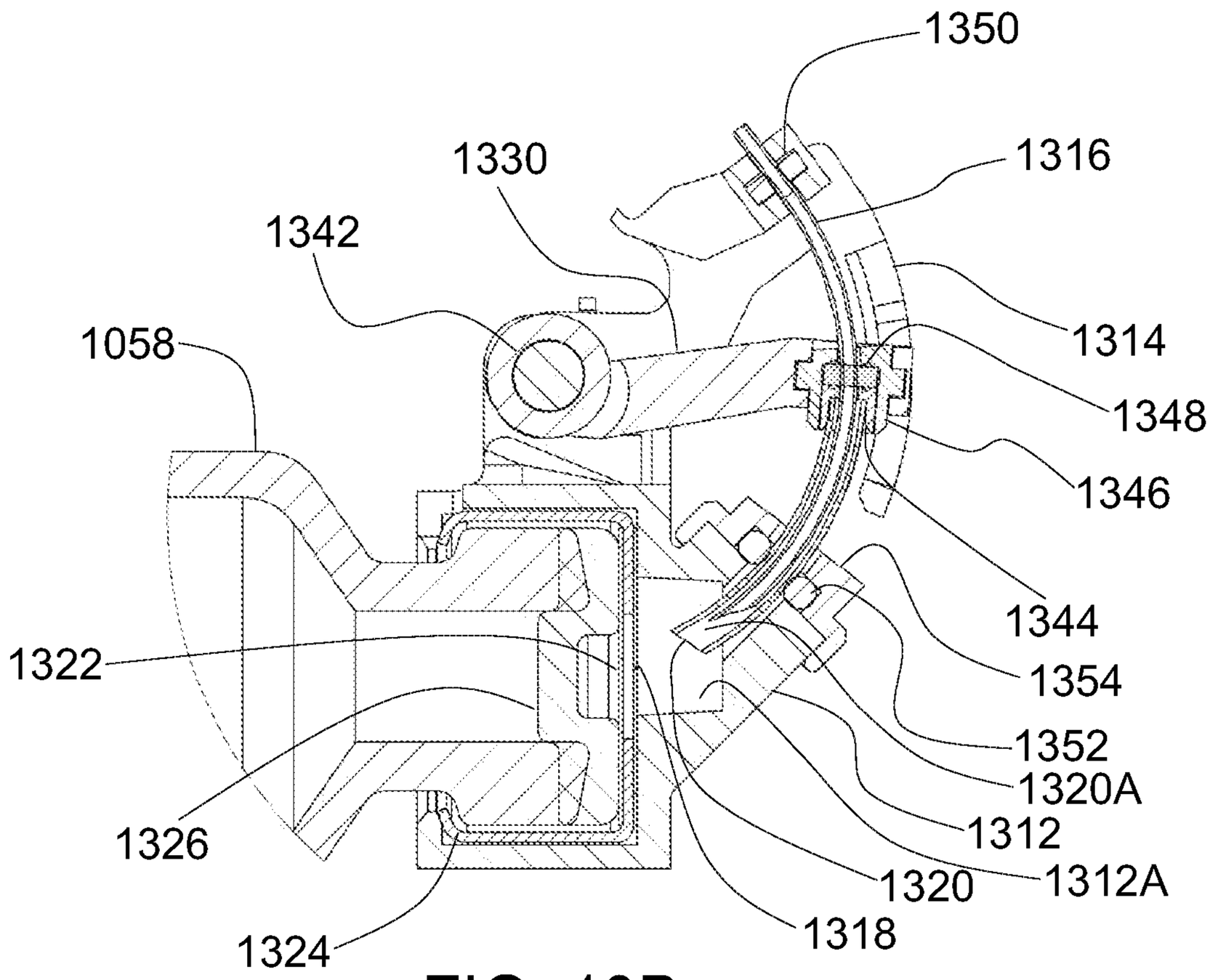


FIG. 13B

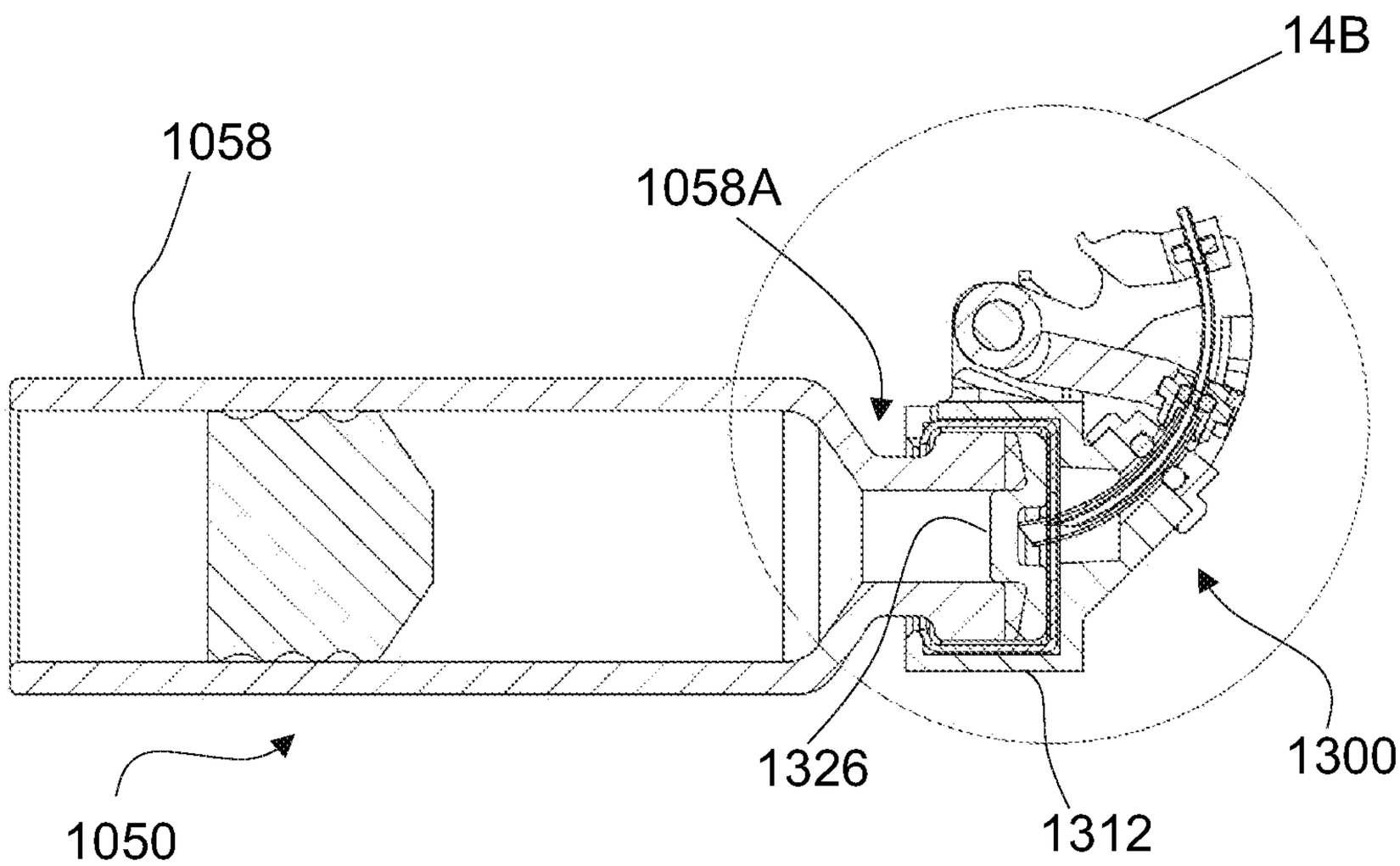


FIG. 14A

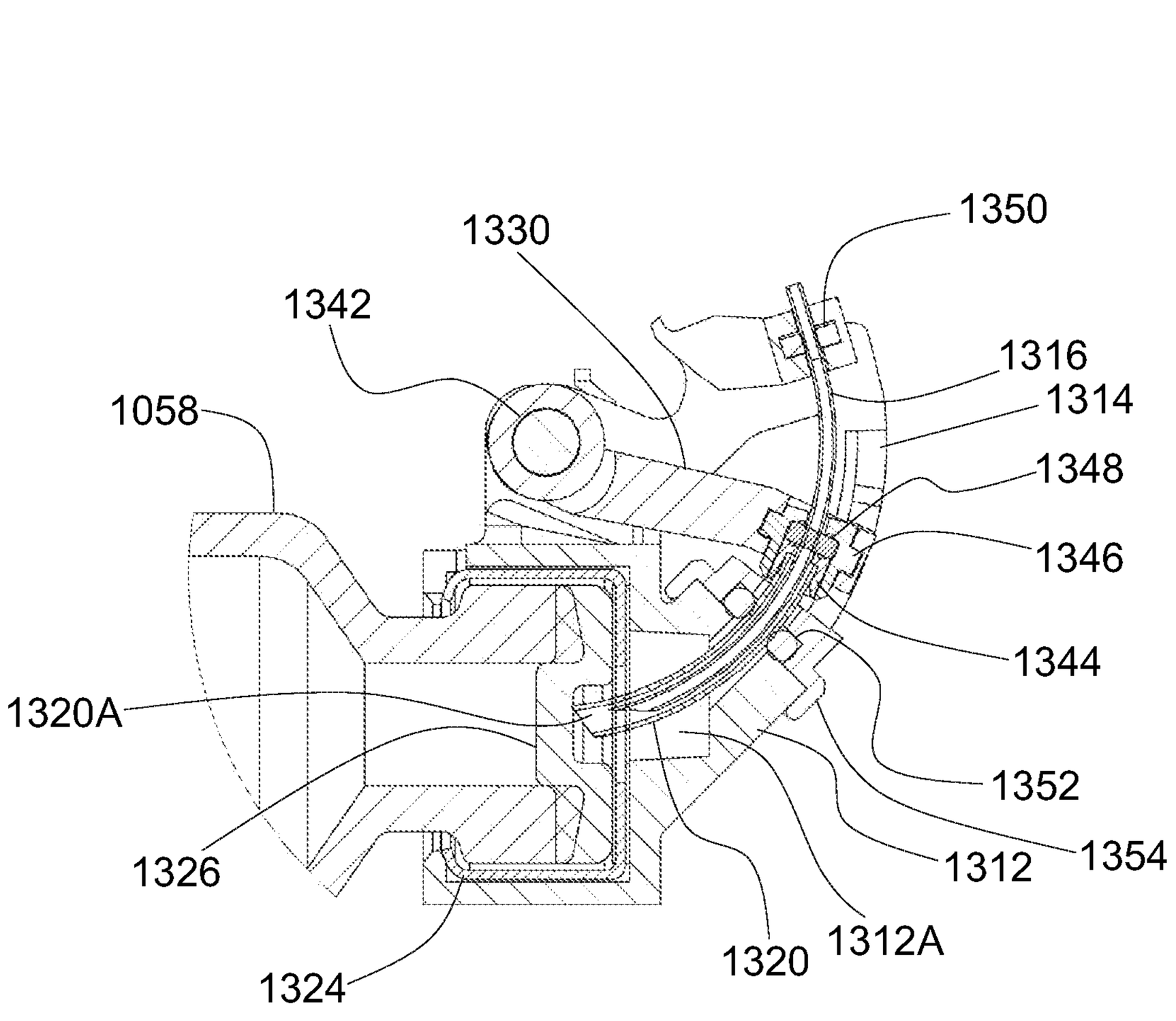


FIG. 14B

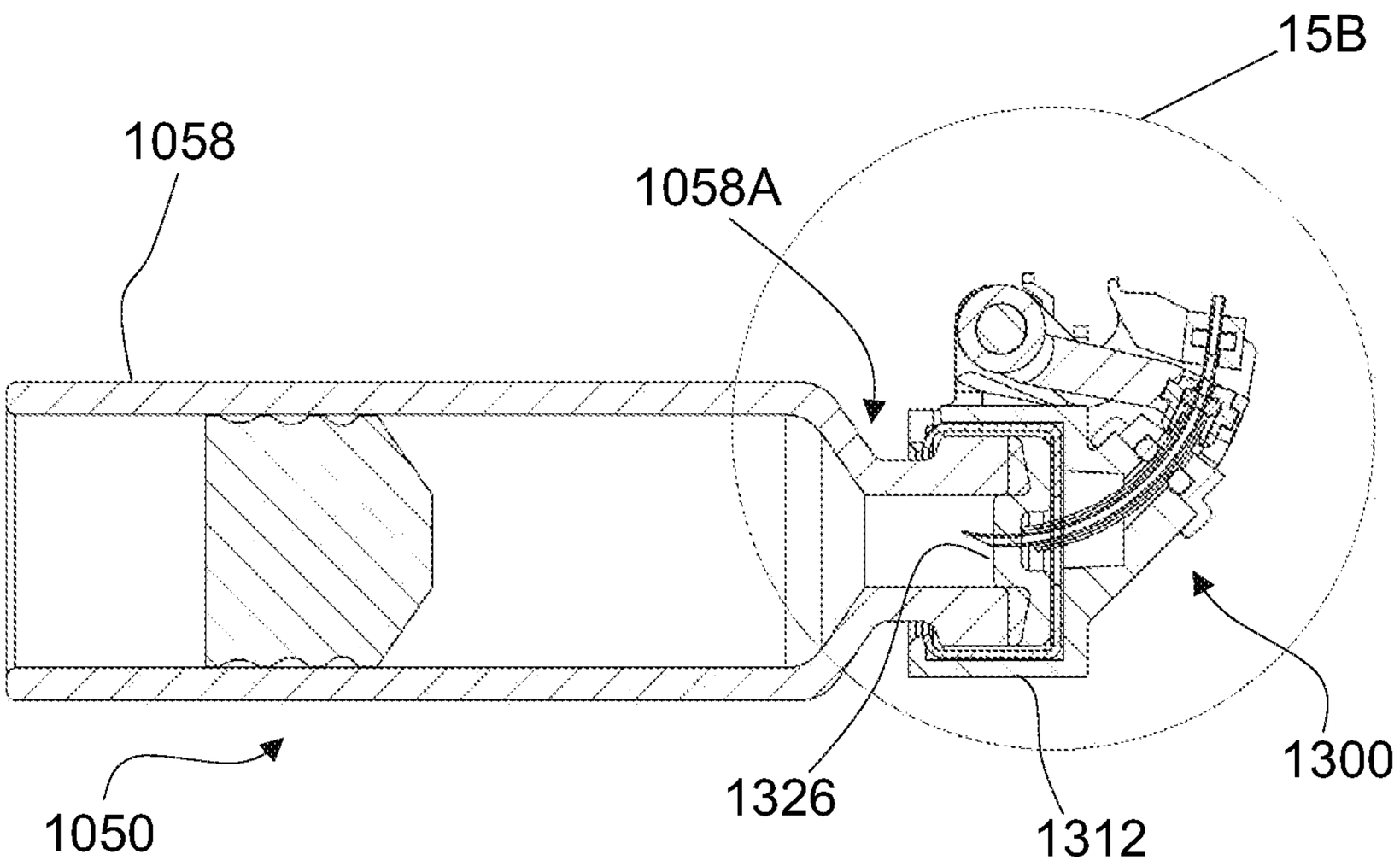


FIG. 15A

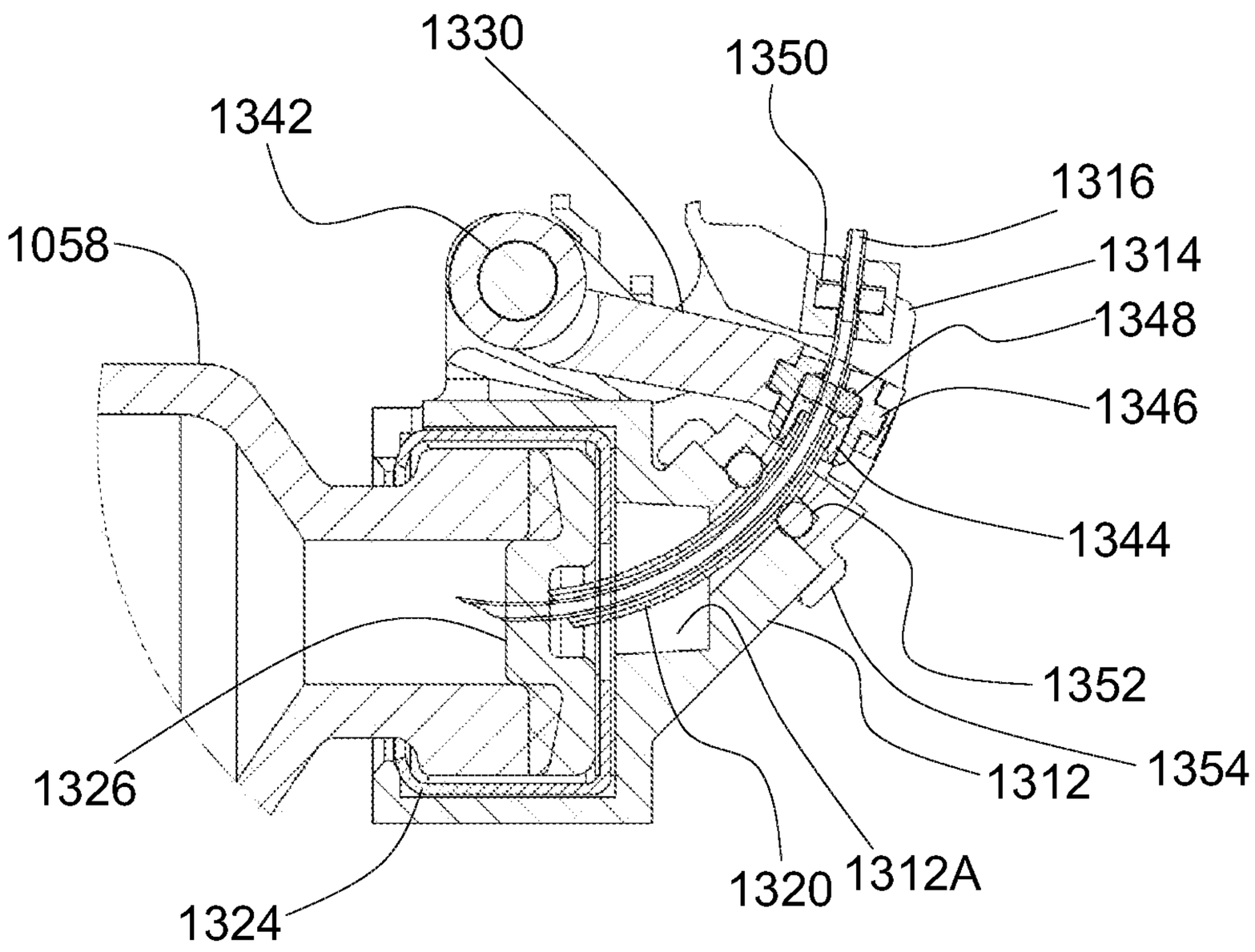


FIG. 15B

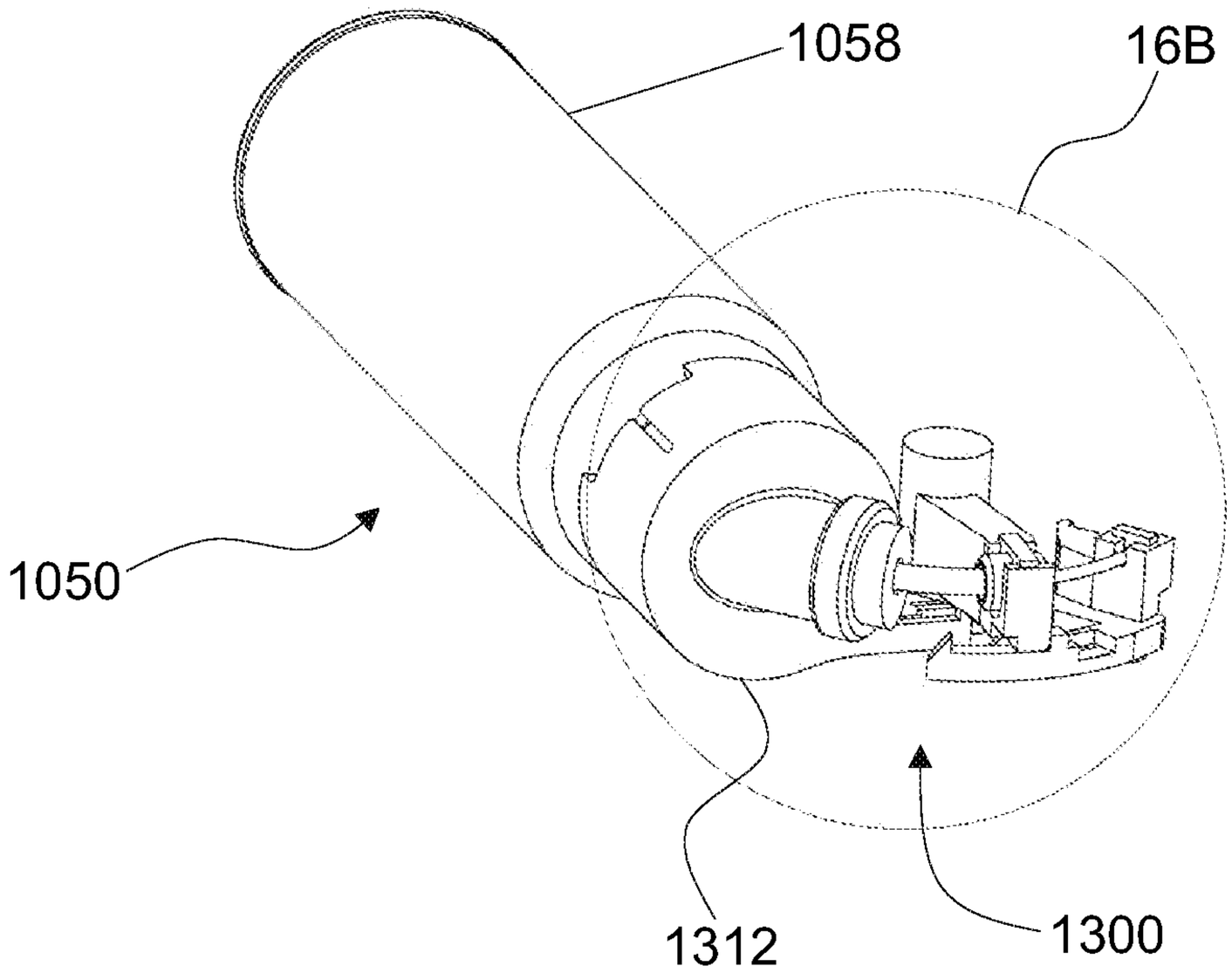


FIG. 16A

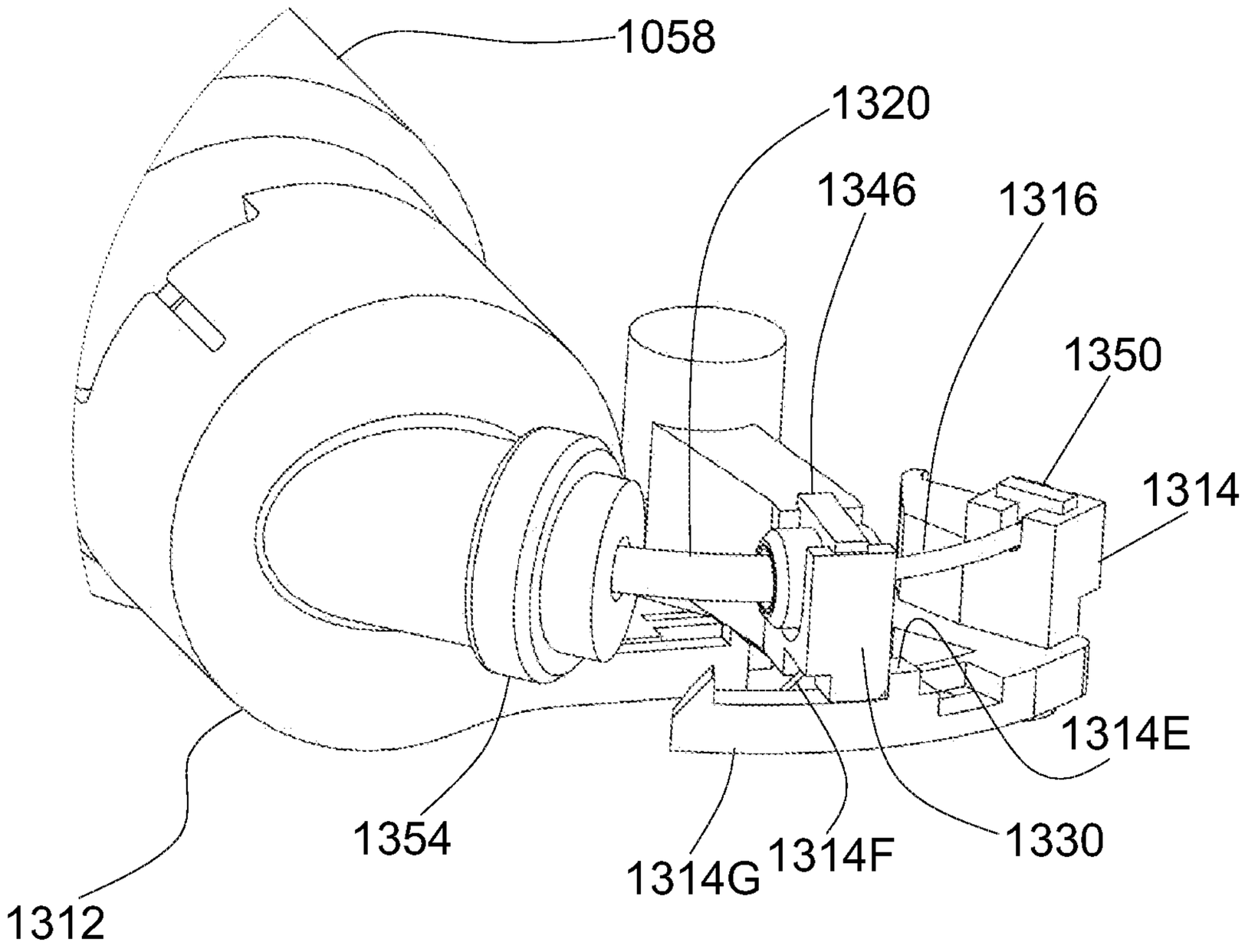


FIG. 16B

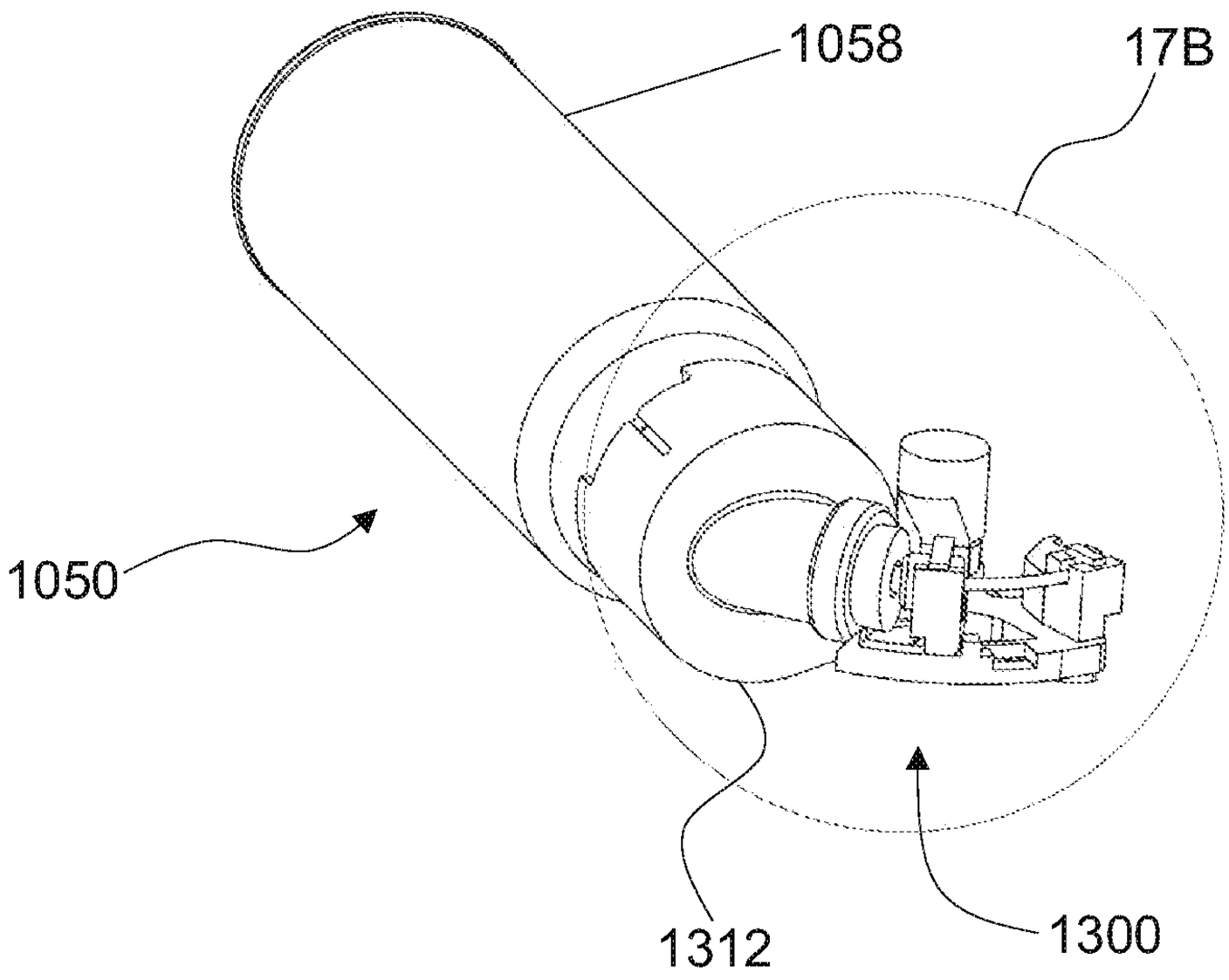


FIG. 17A

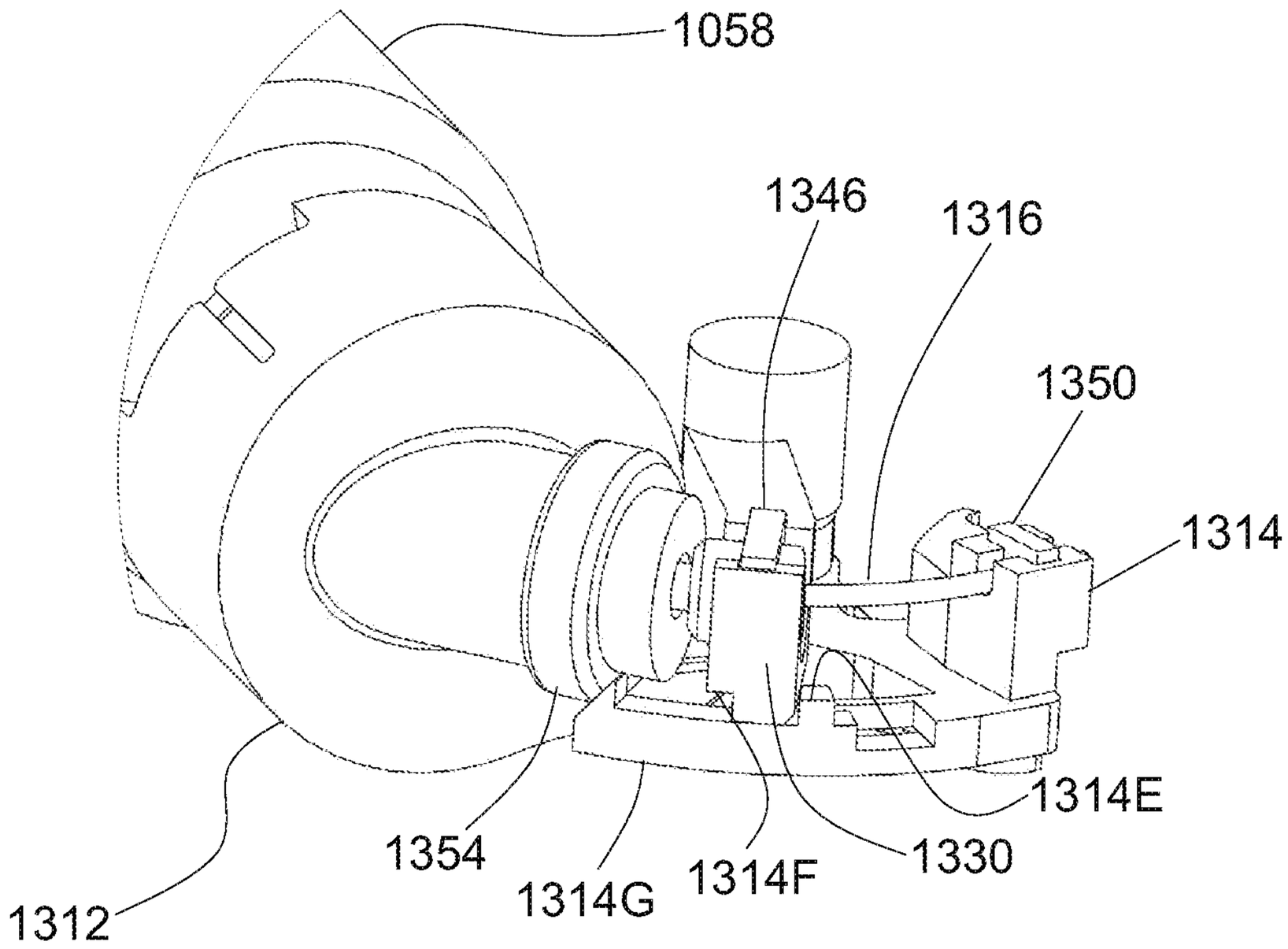


FIG. 17B

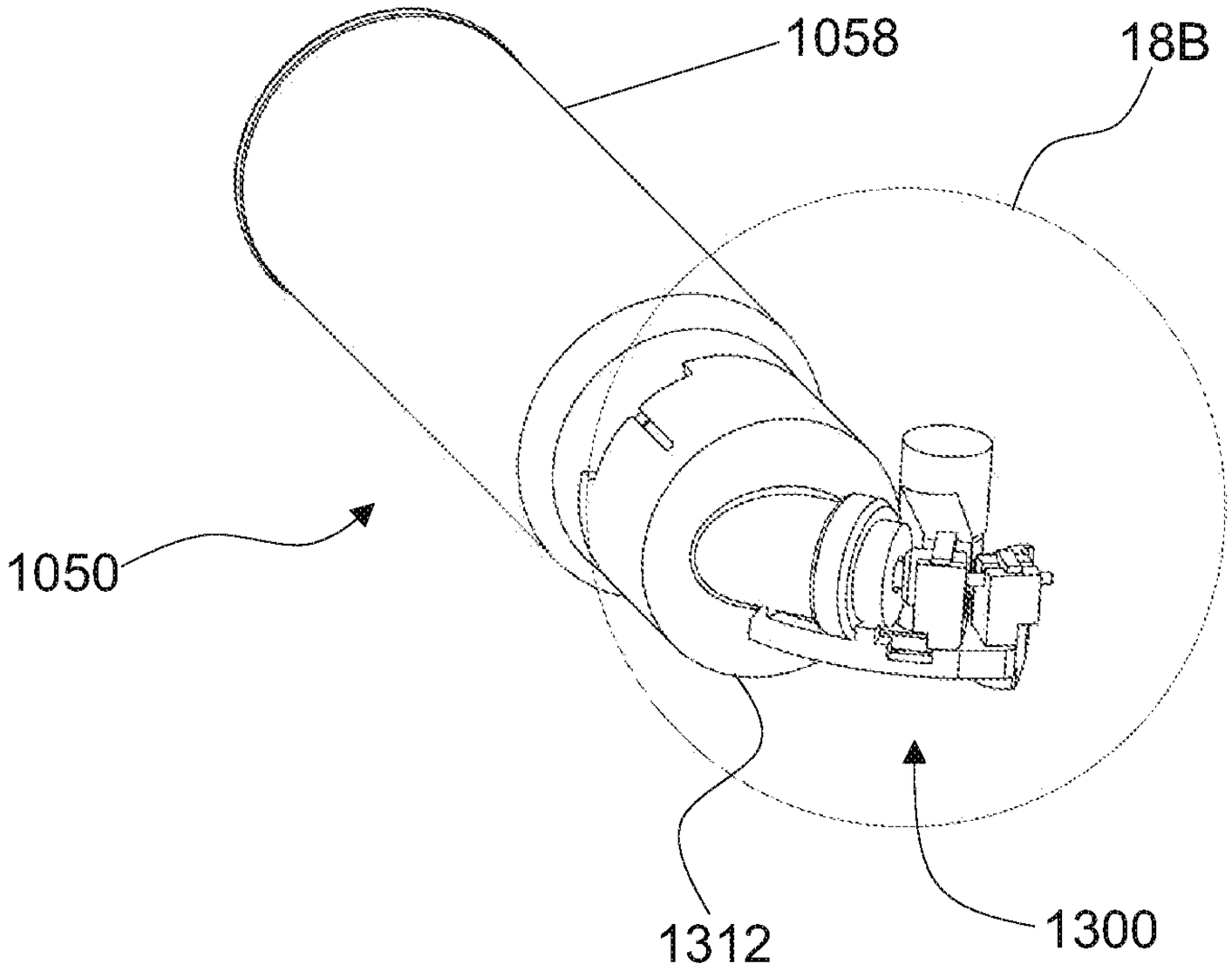


FIG. 18A

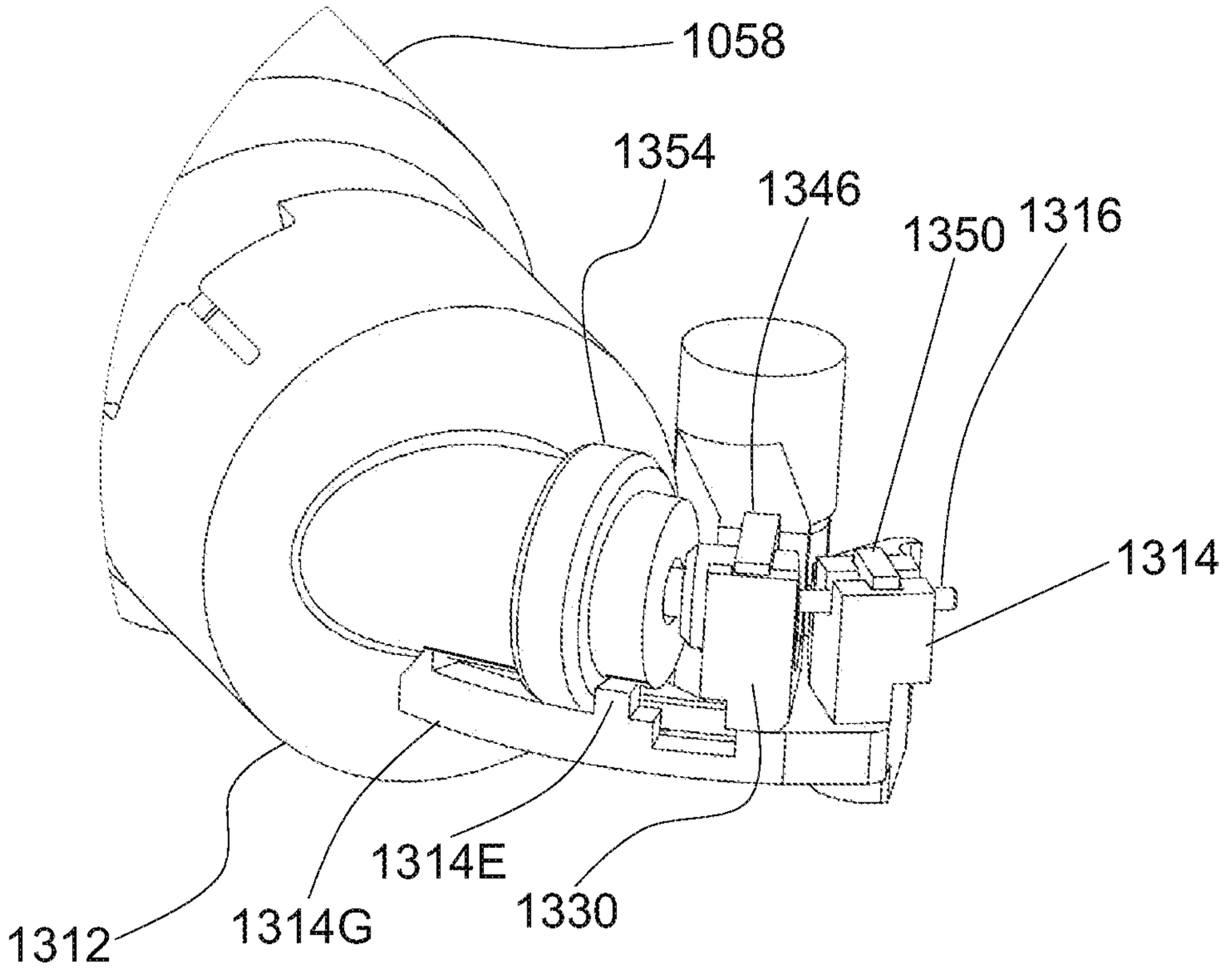


FIG. 18B

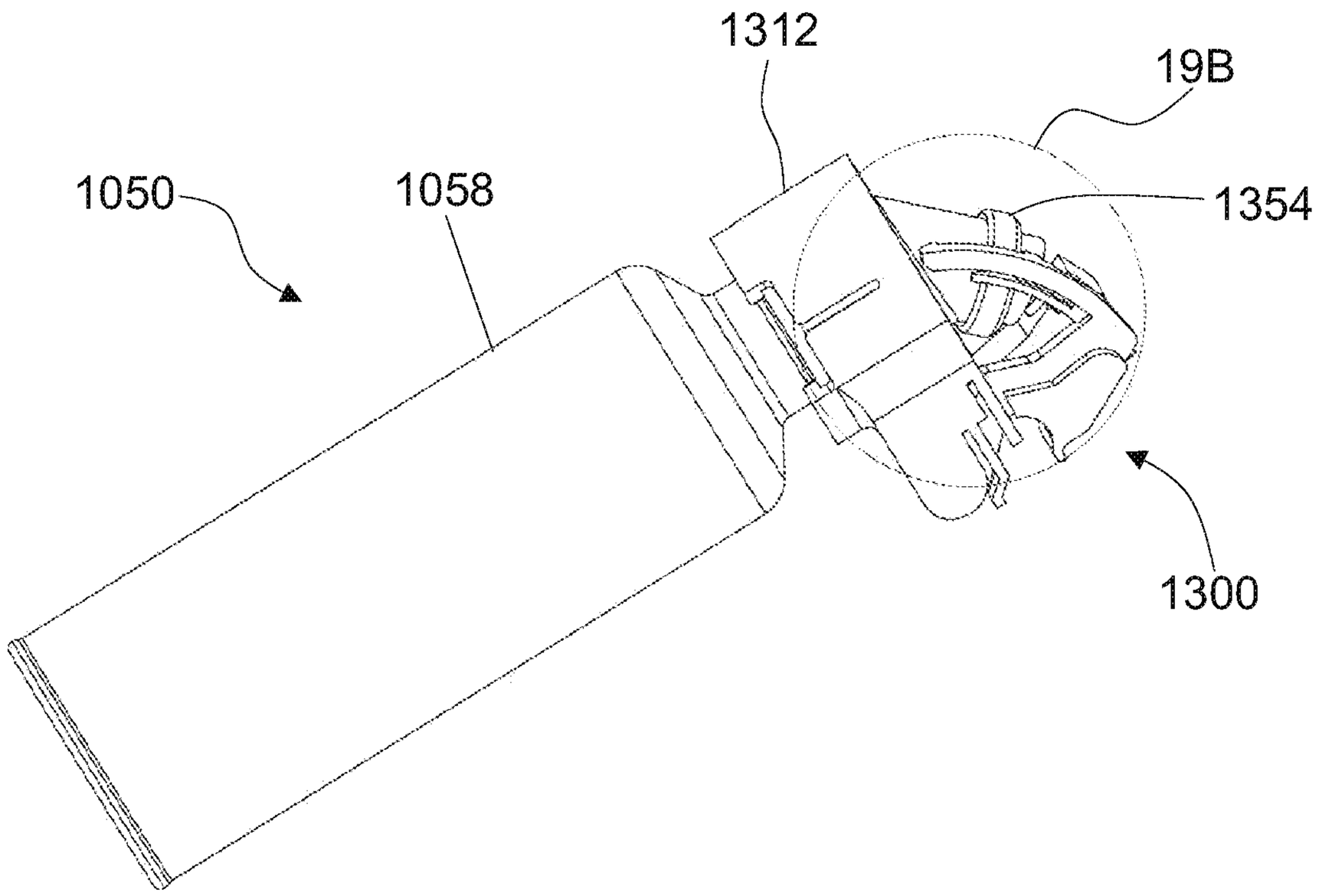


FIG. 19A

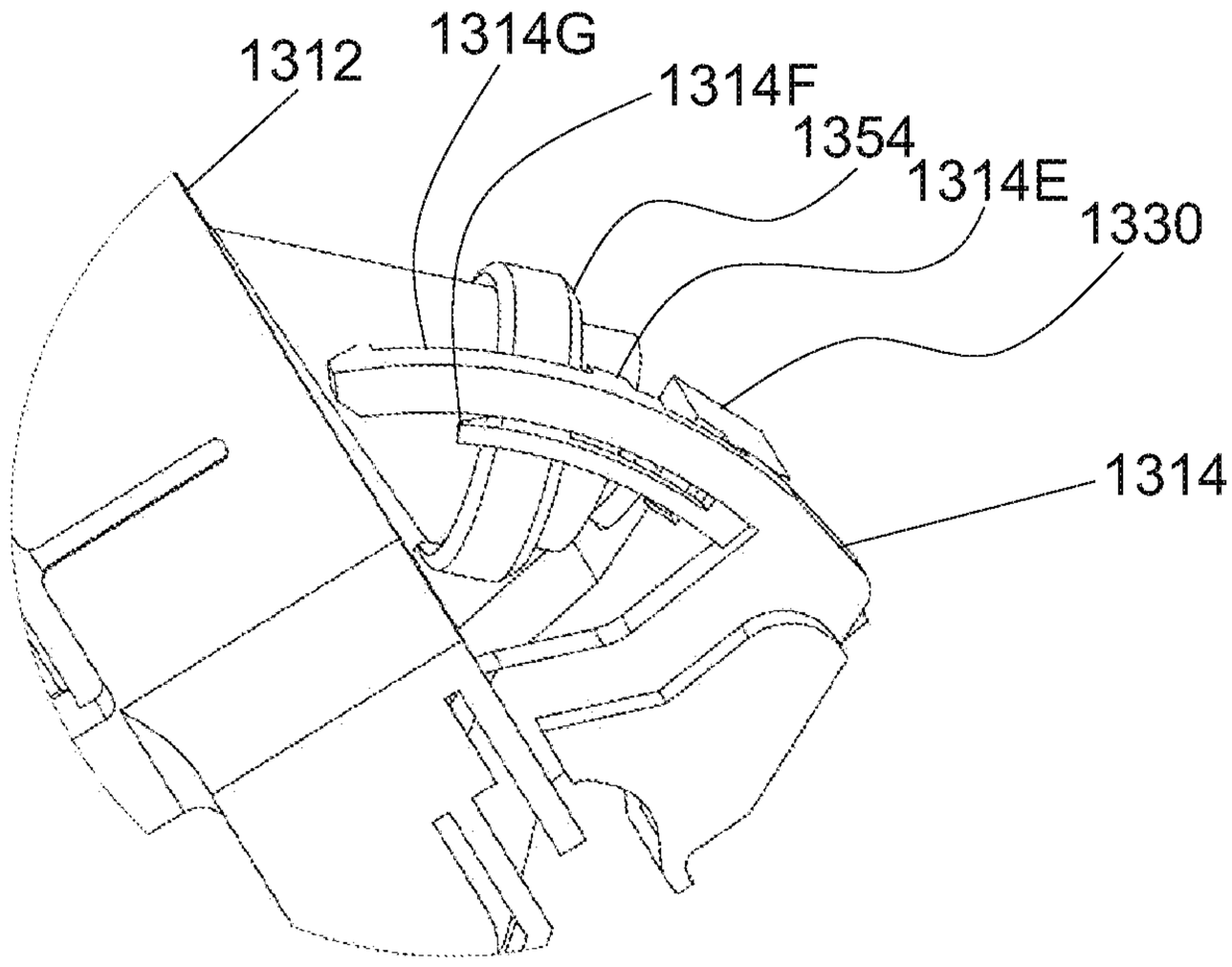


FIG. 19B

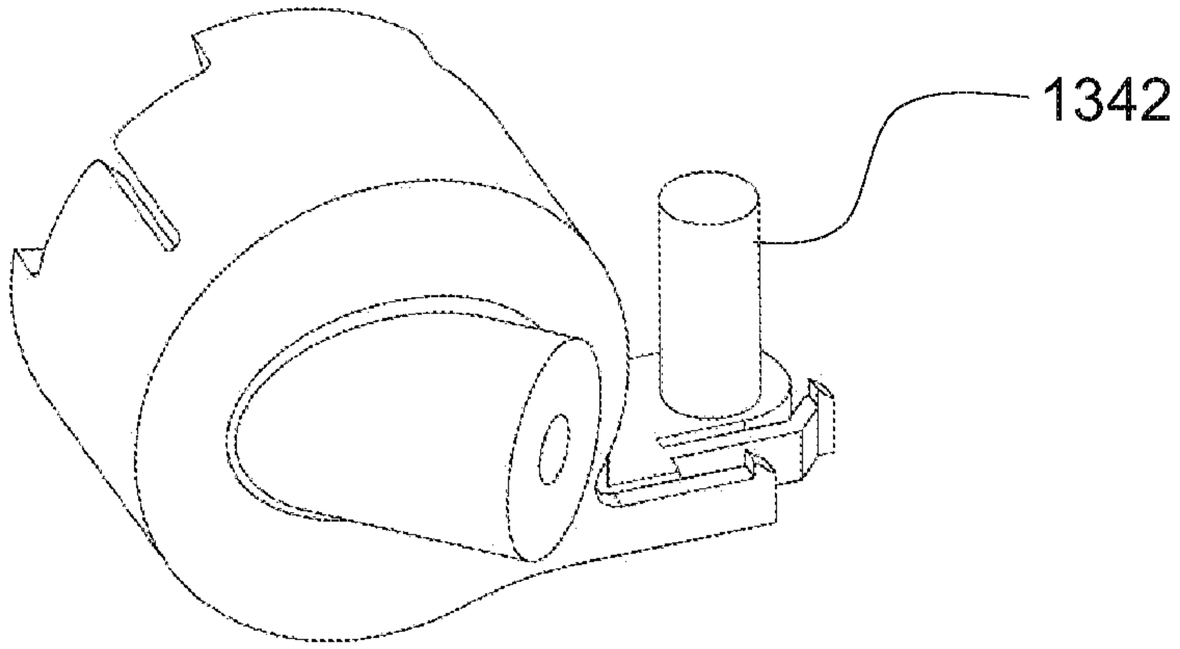


FIG. 20

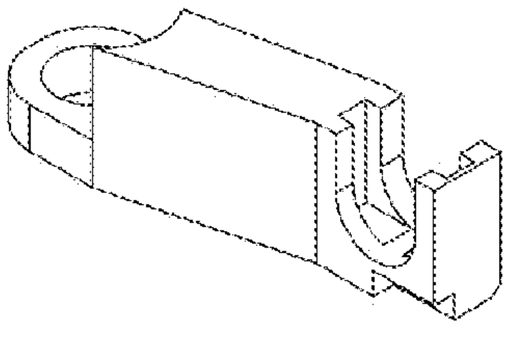


FIG. 21

FIG. 22

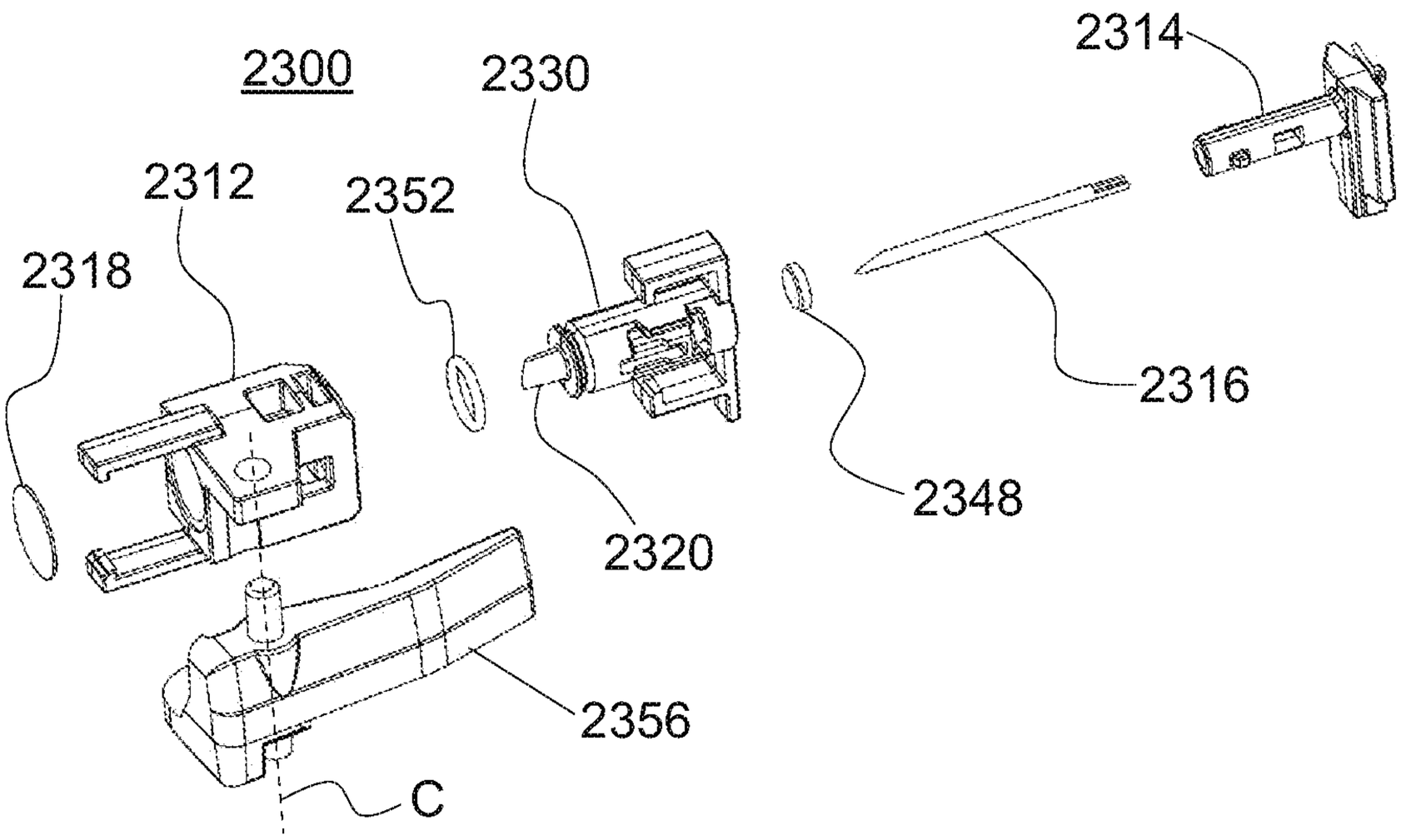


FIG. 23

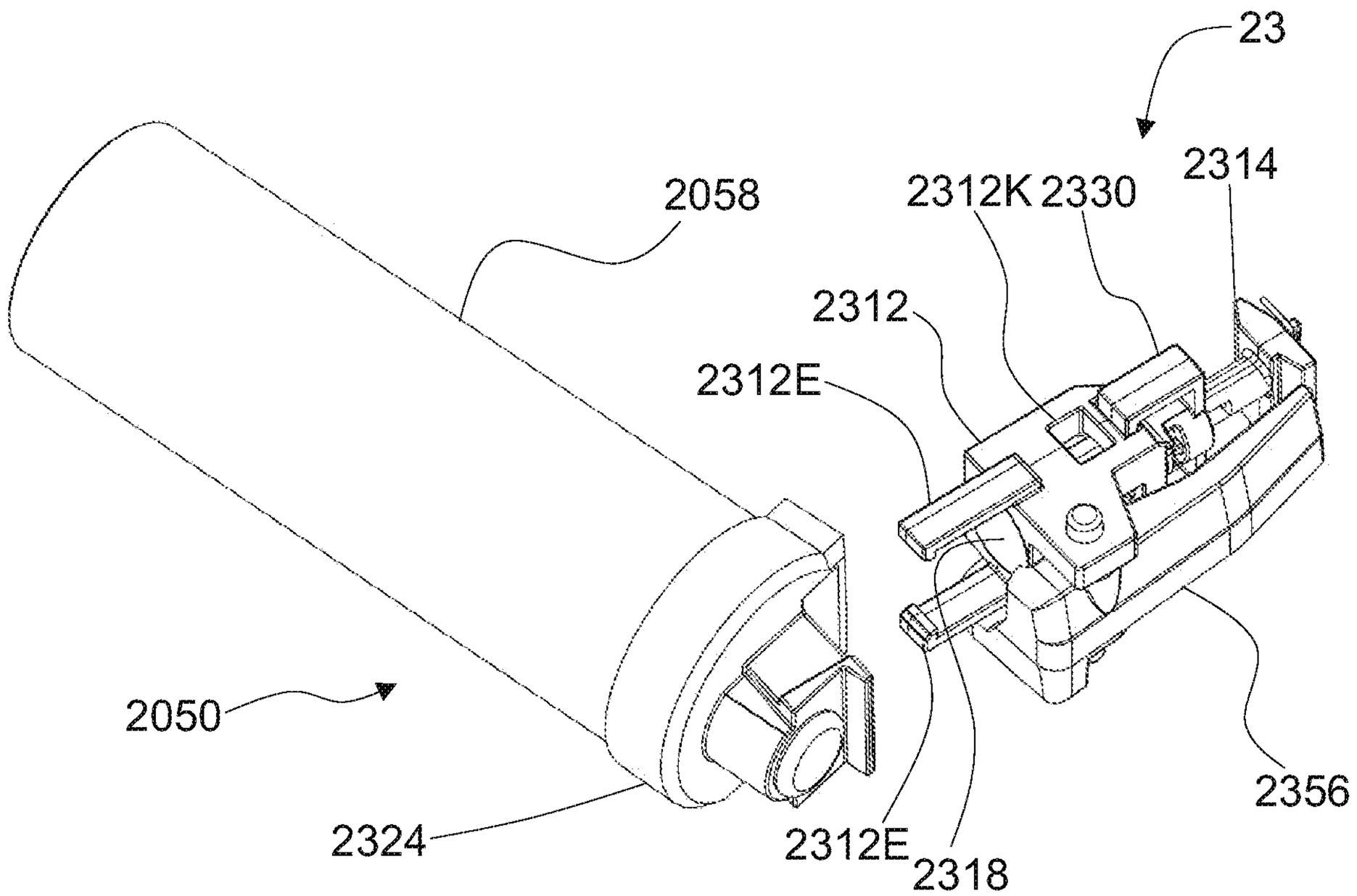


FIG. 24A

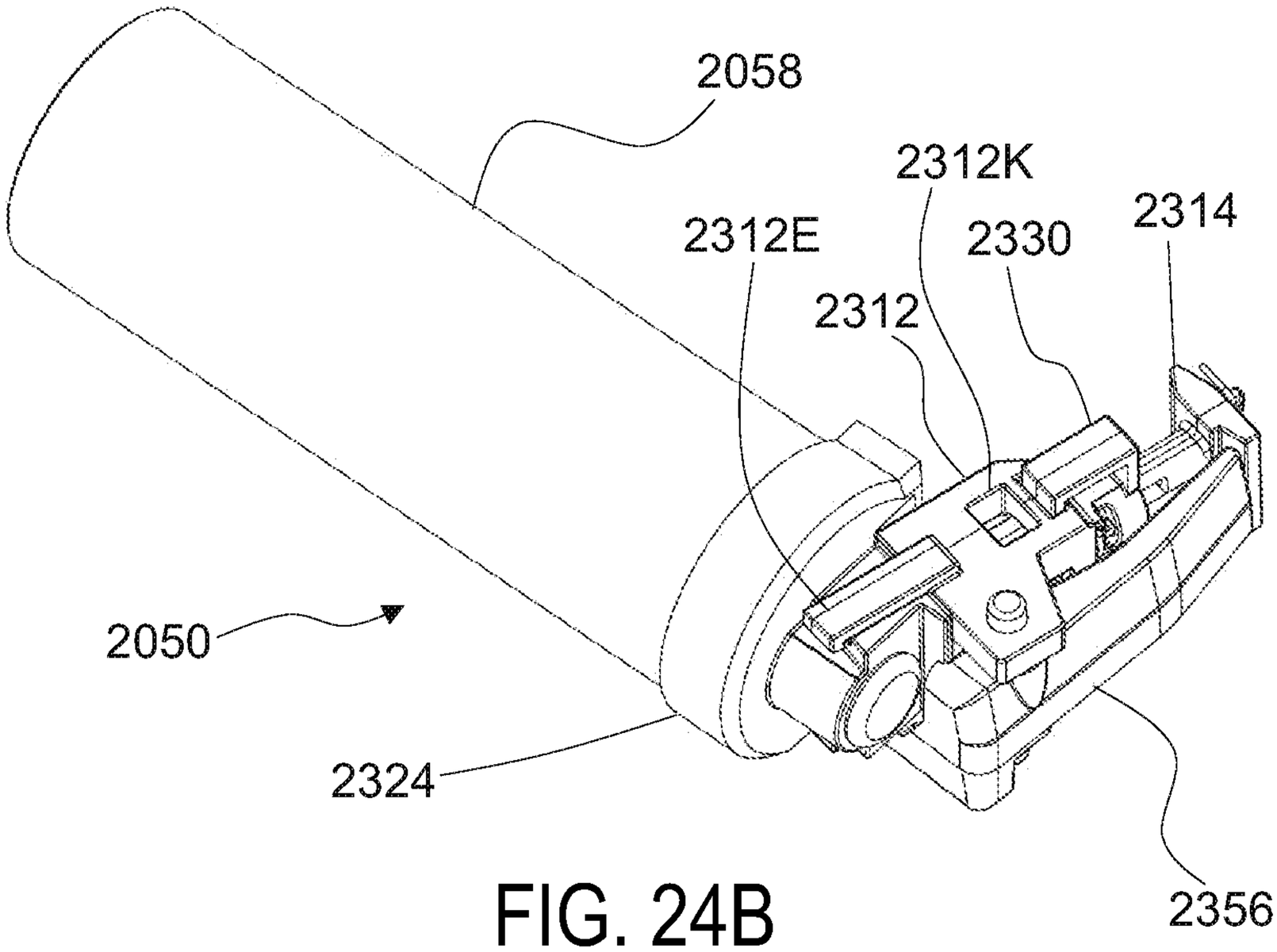


FIG. 24B

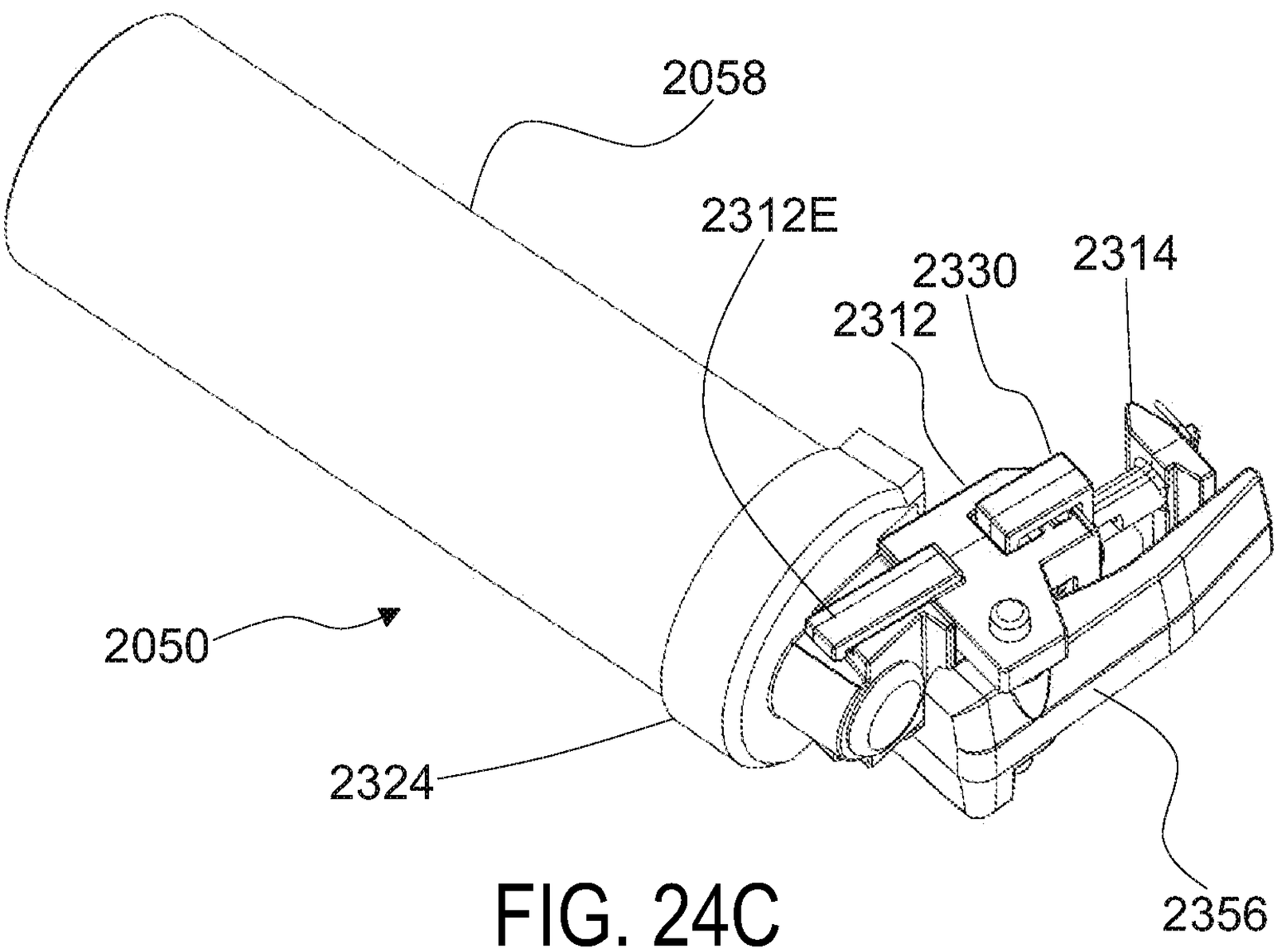


FIG. 24C

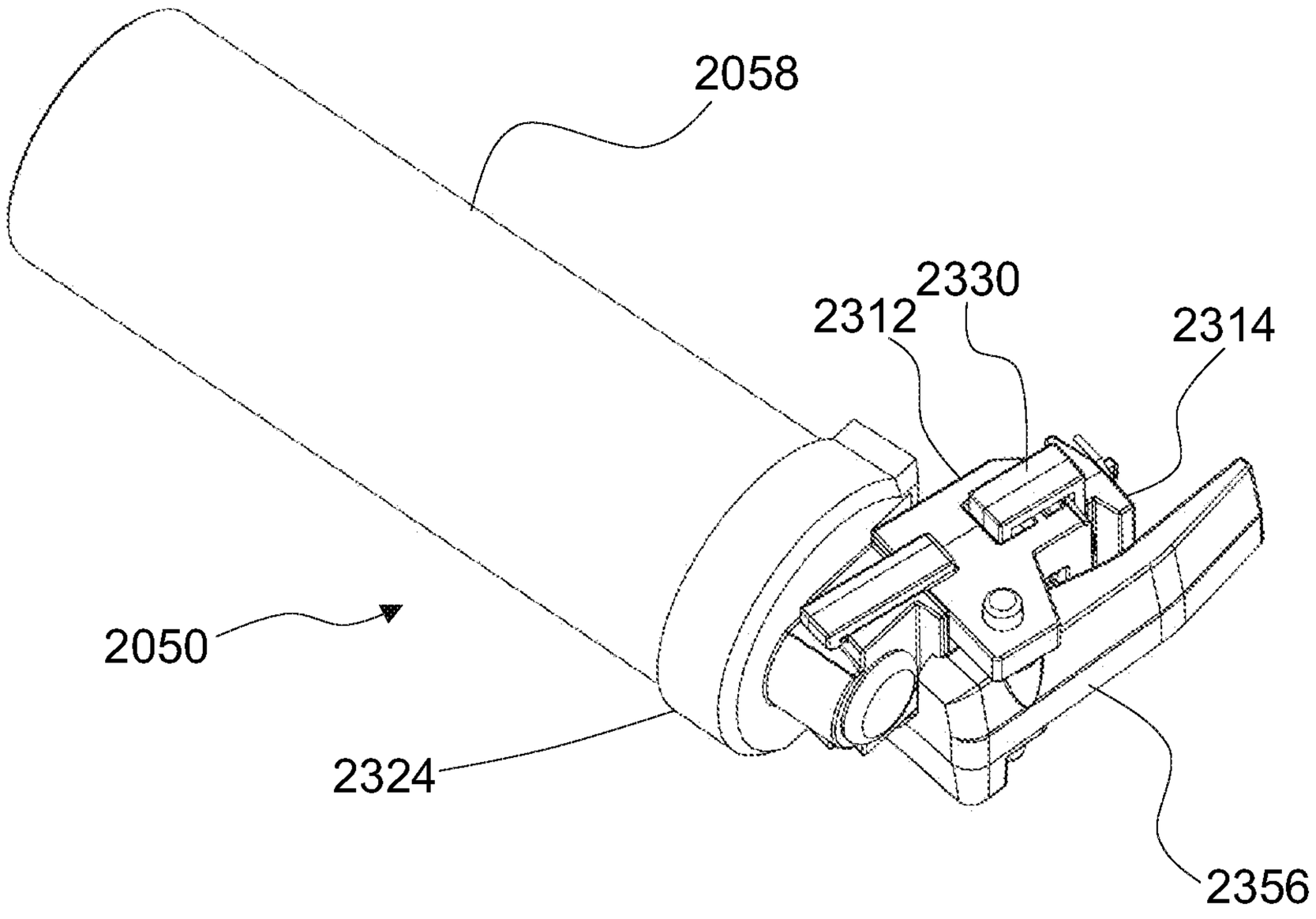


FIG. 24D

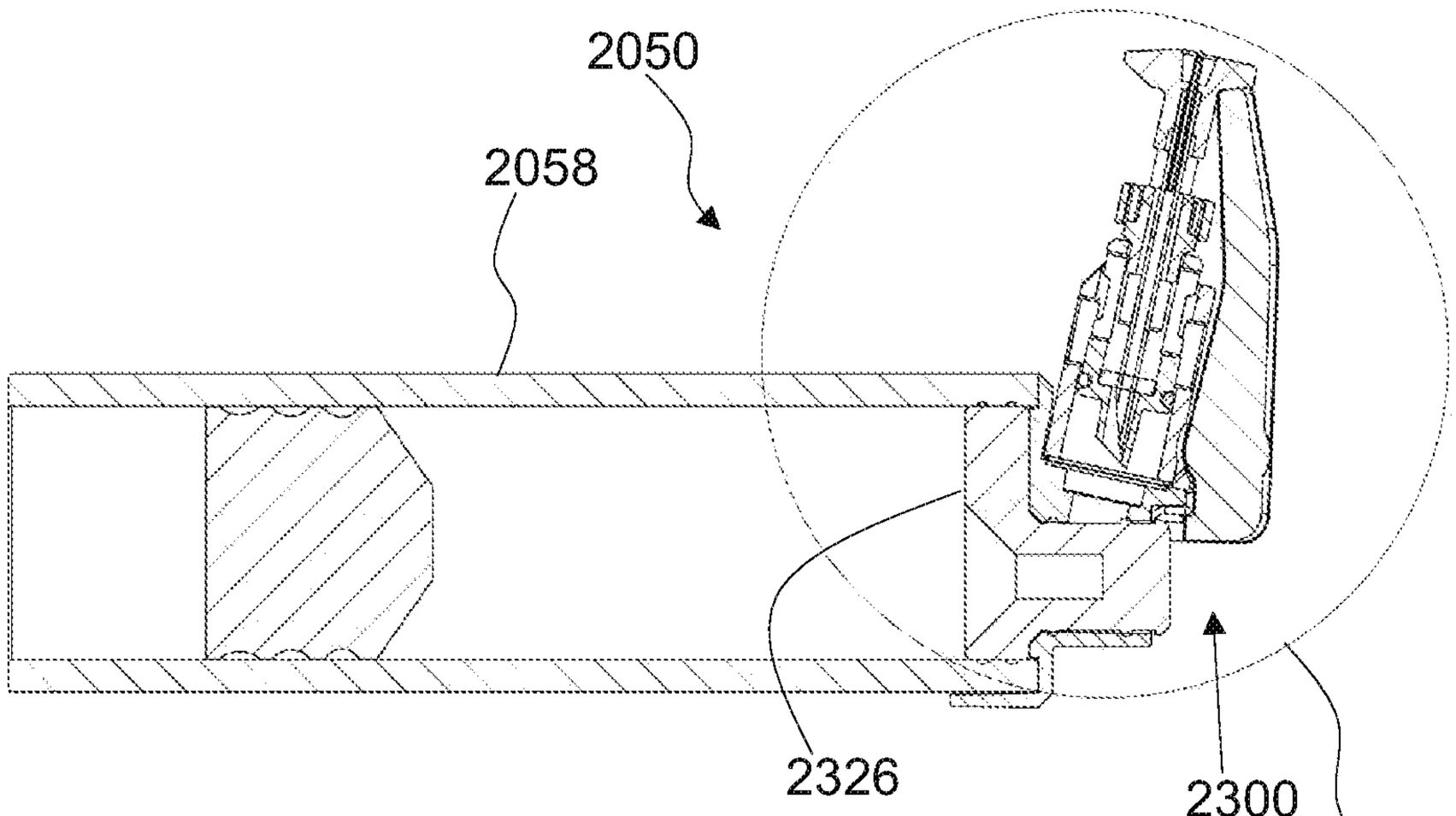


FIG. 25A

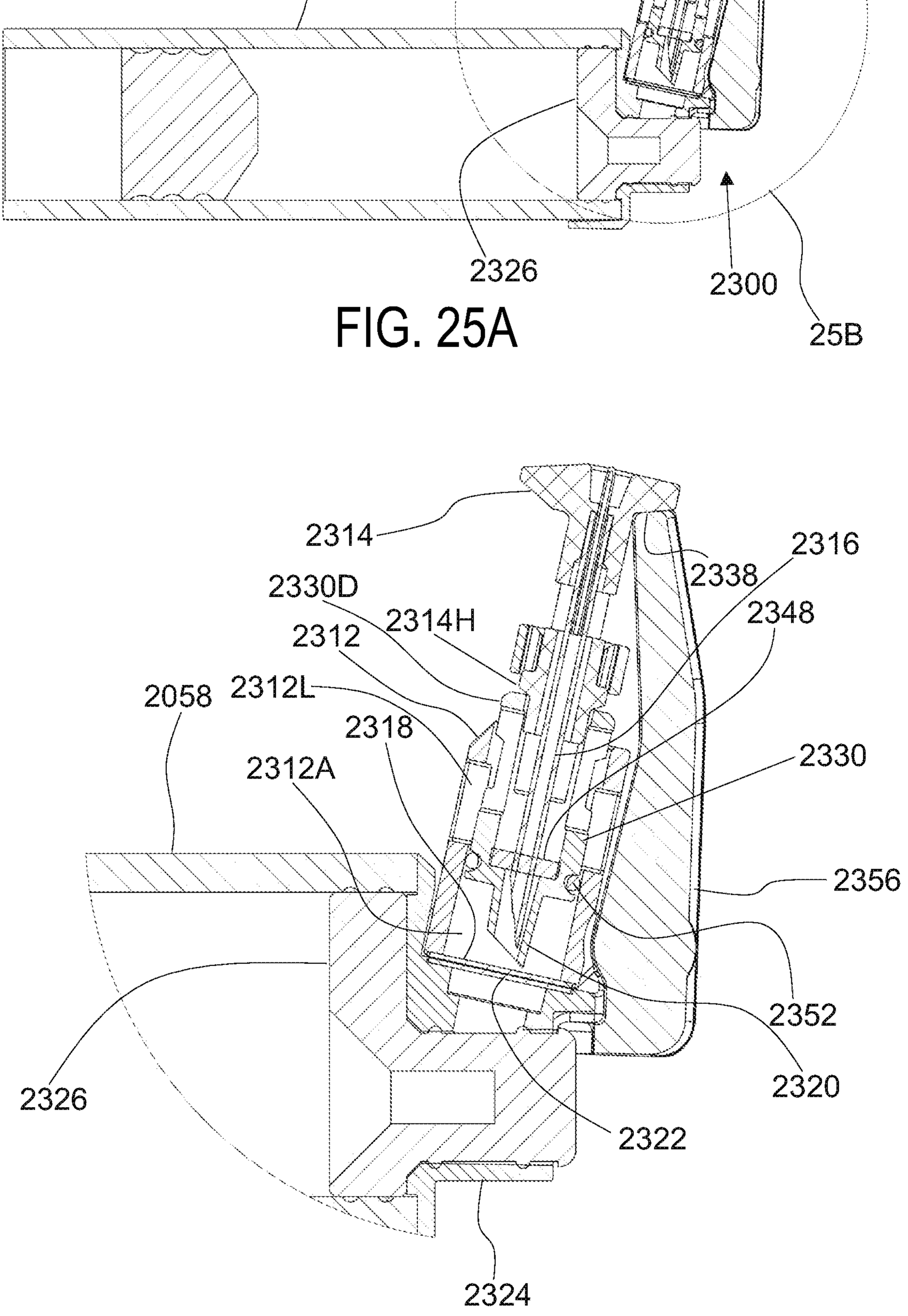


FIG. 25B

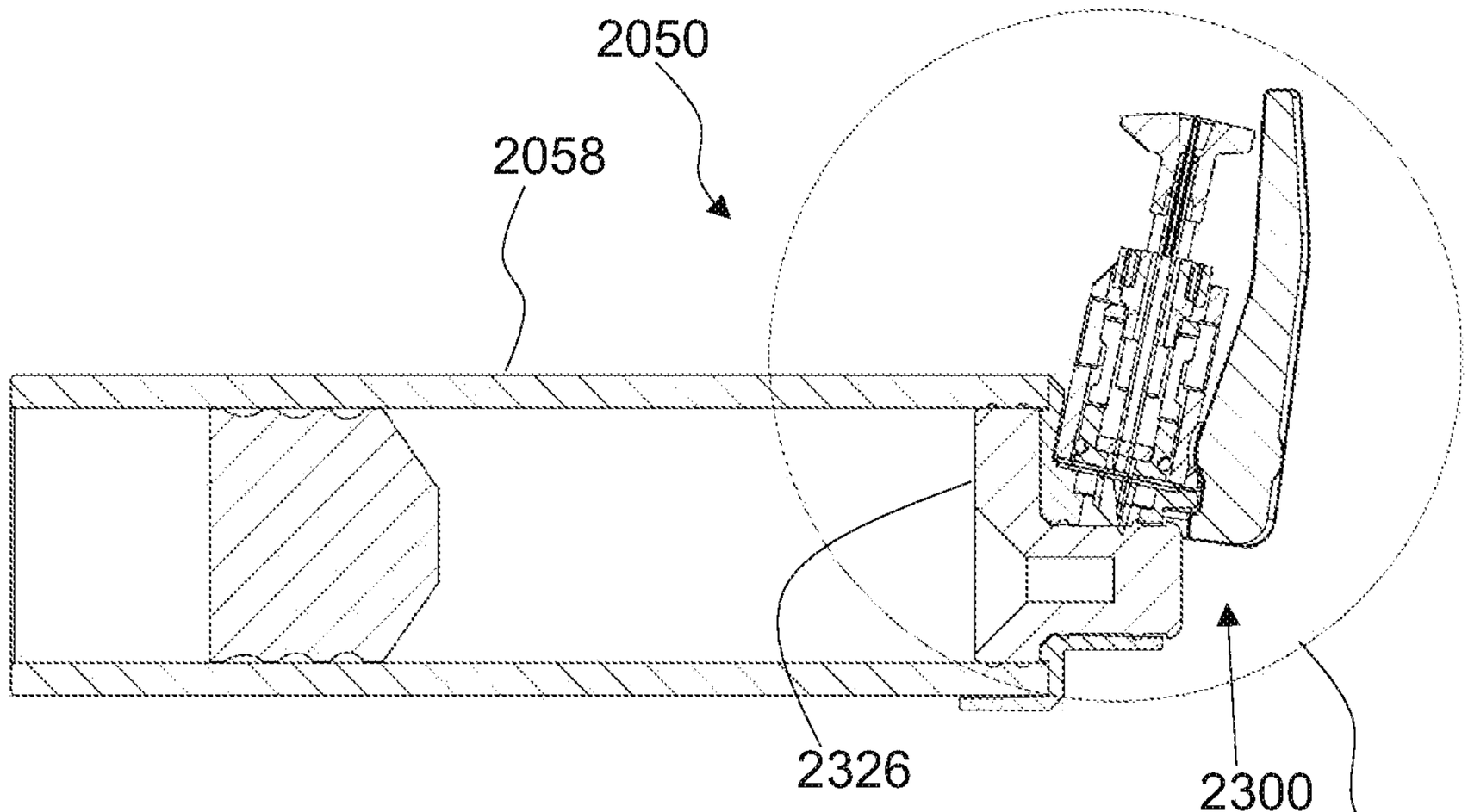


FIG. 26A

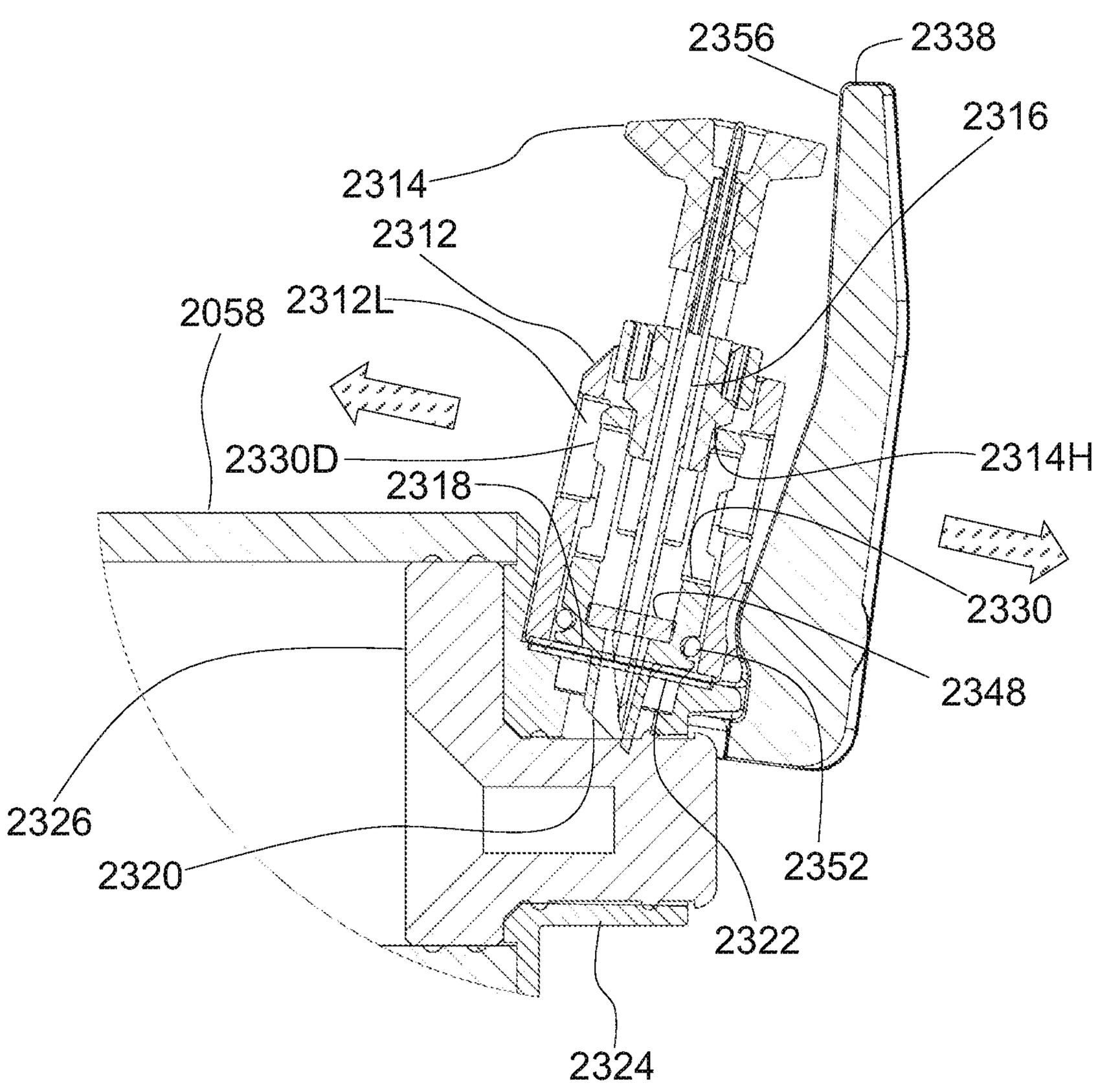


FIG. 26B

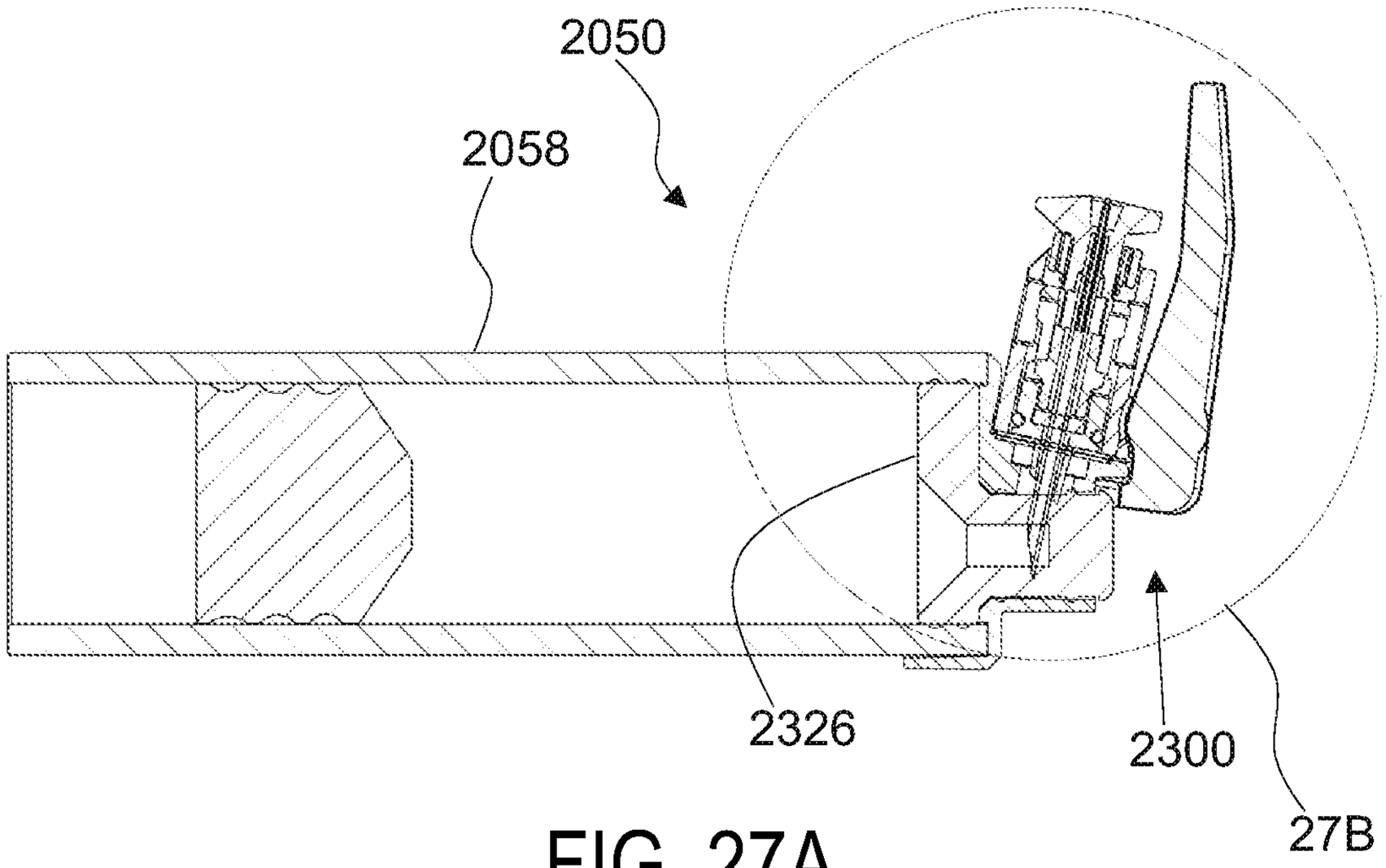


FIG. 27A

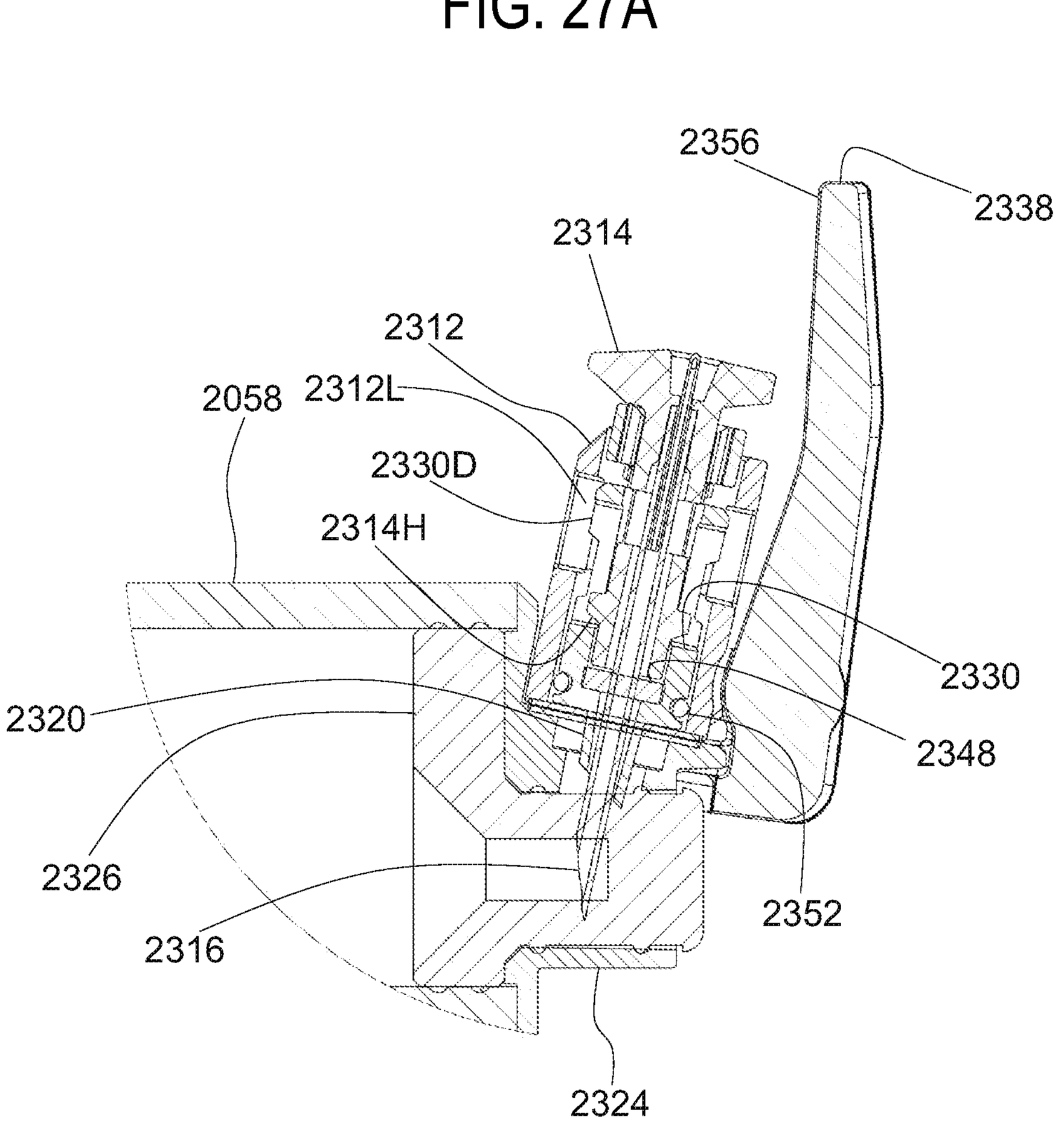


FIG. 27B

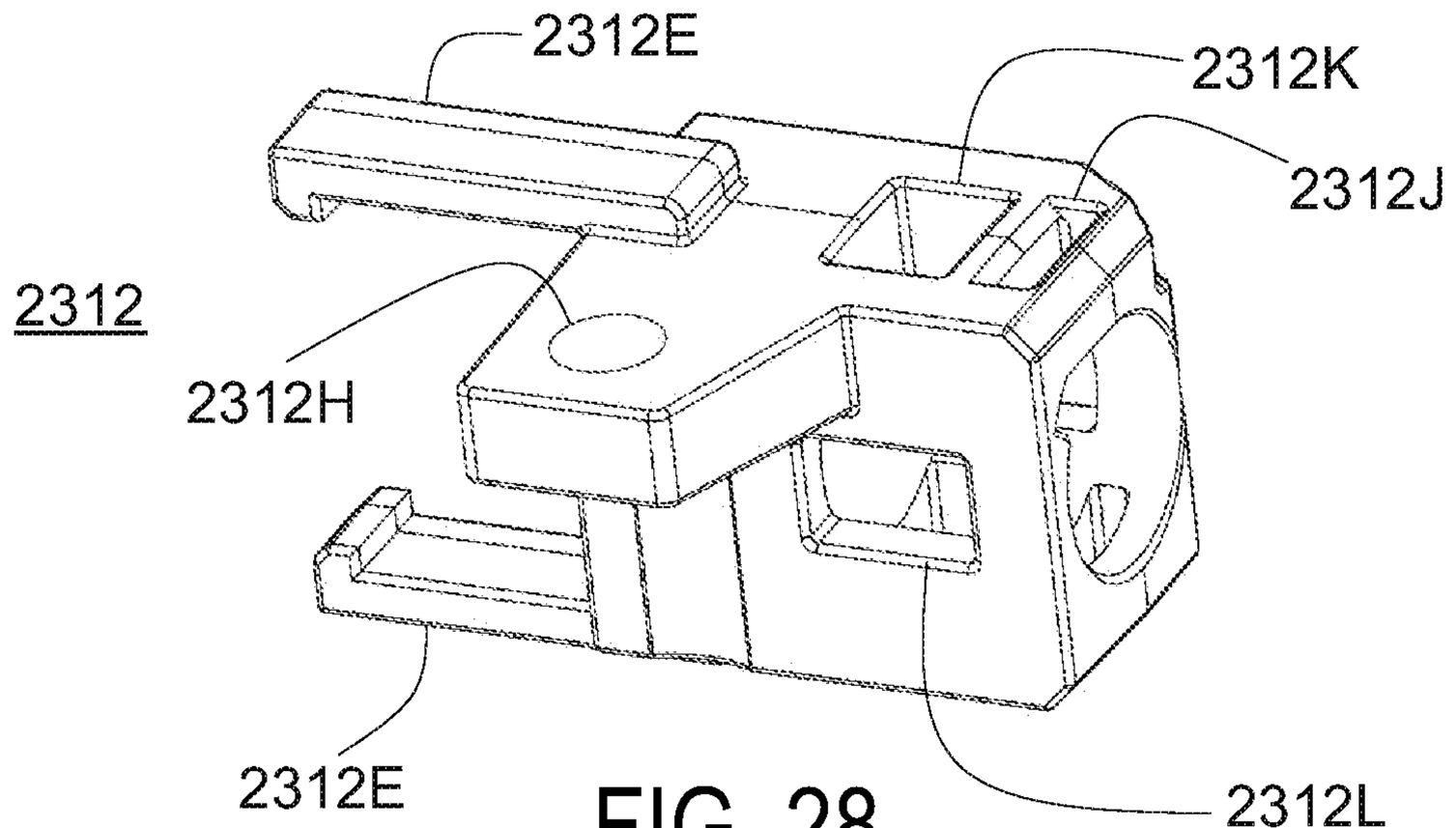


FIG. 28

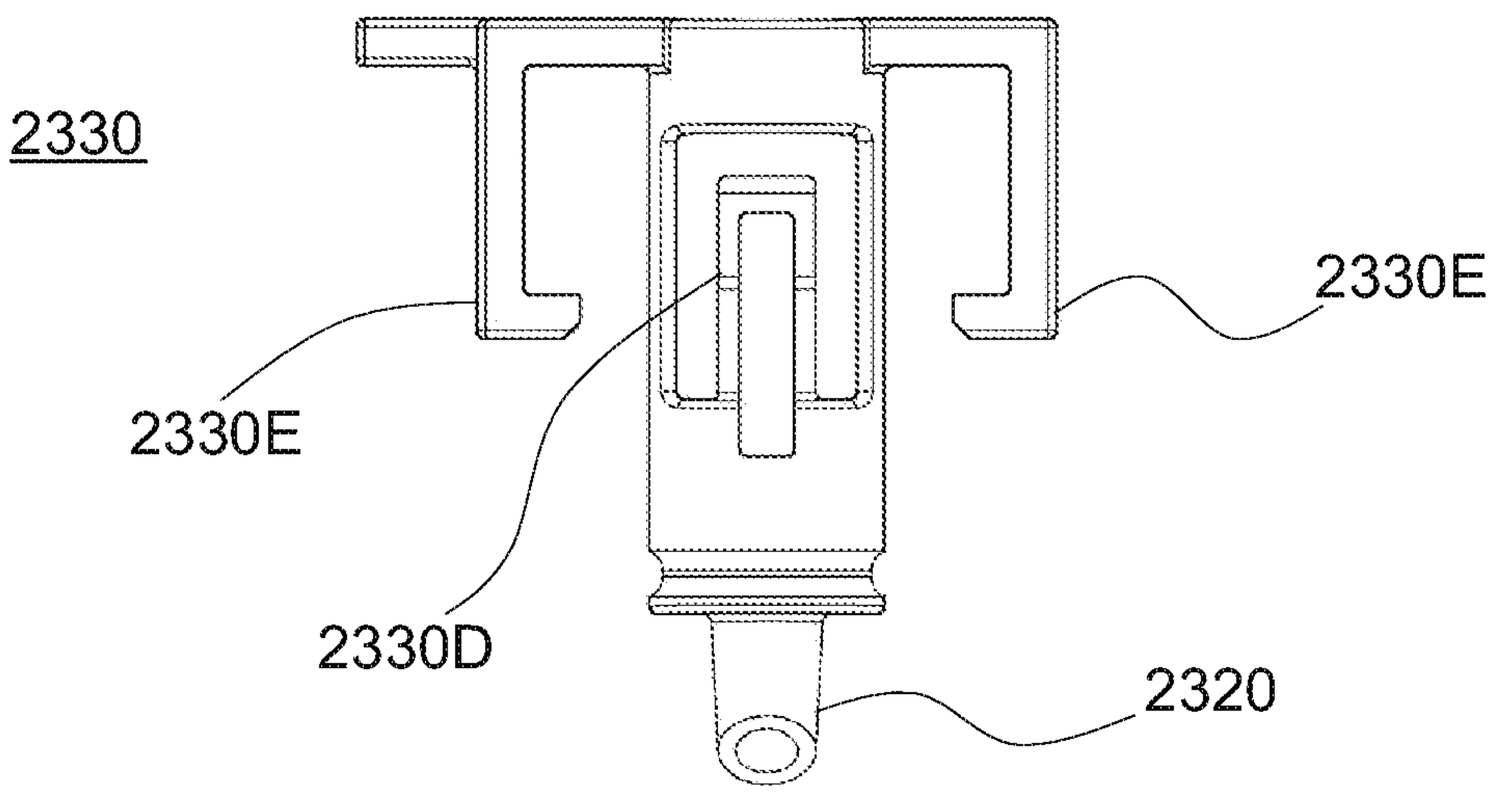


FIG. 29

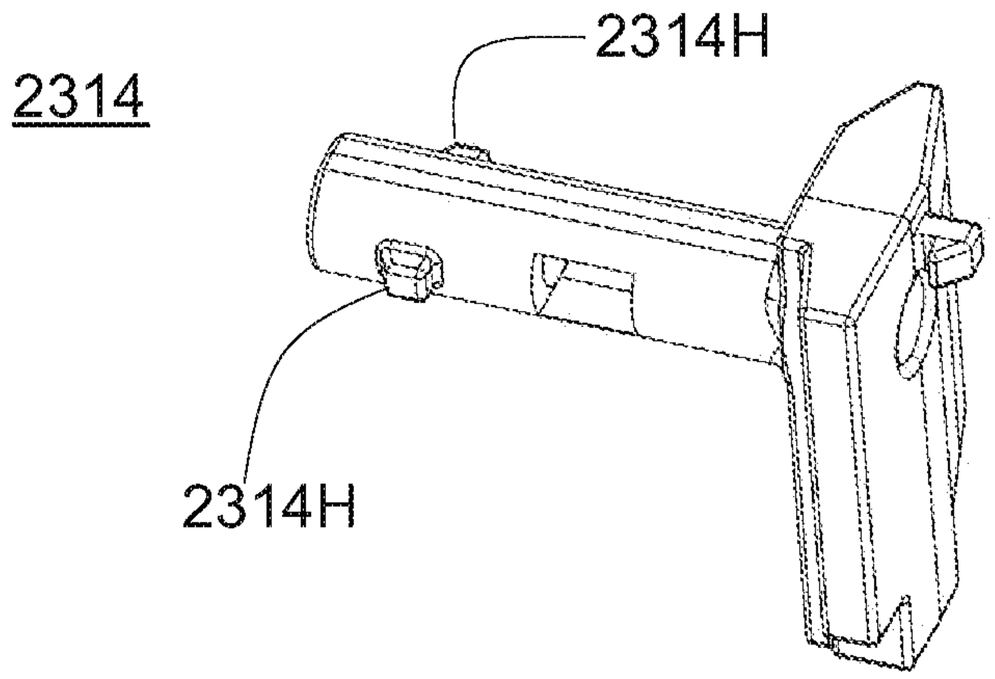


FIG. 30

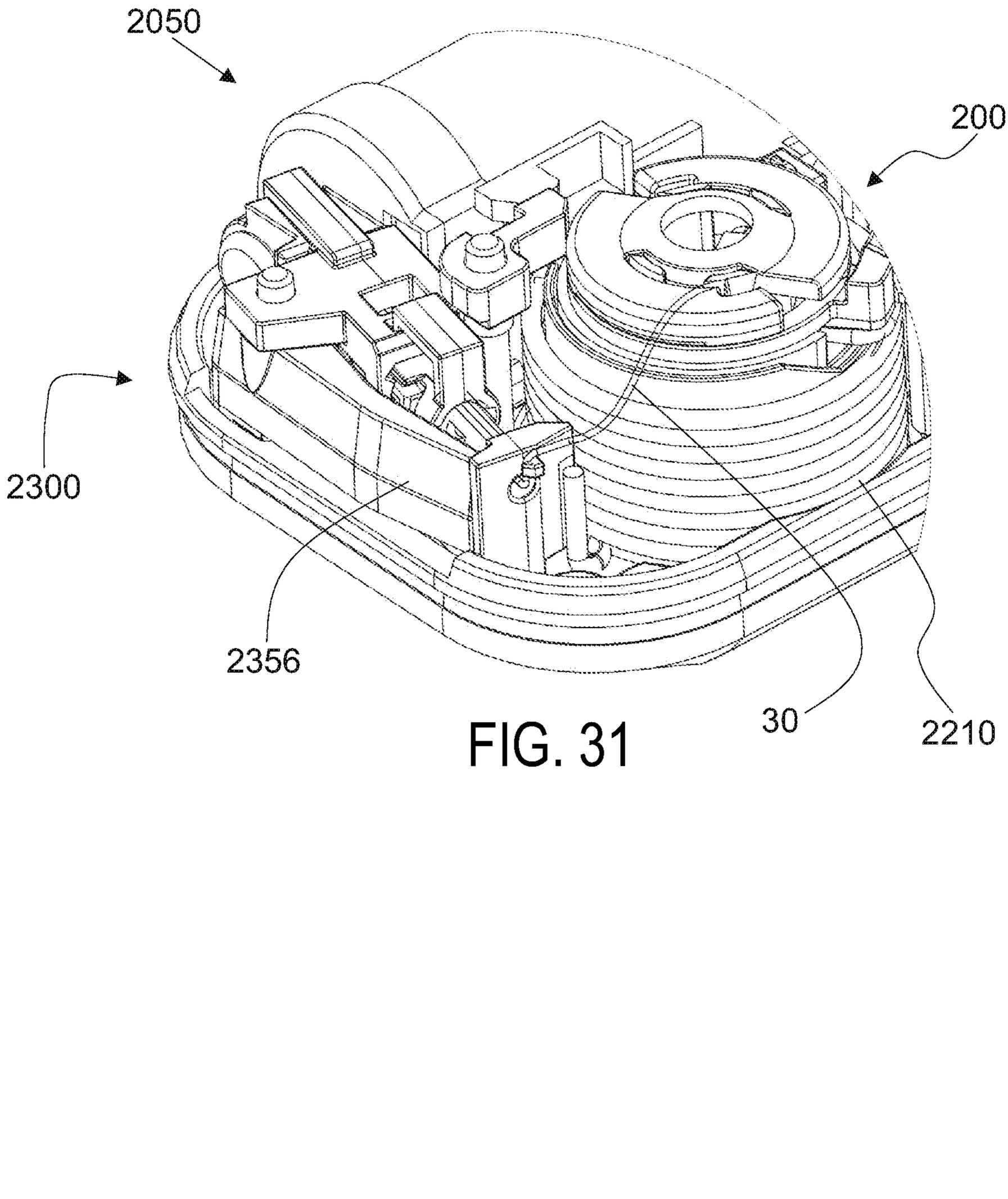


FIG. 31

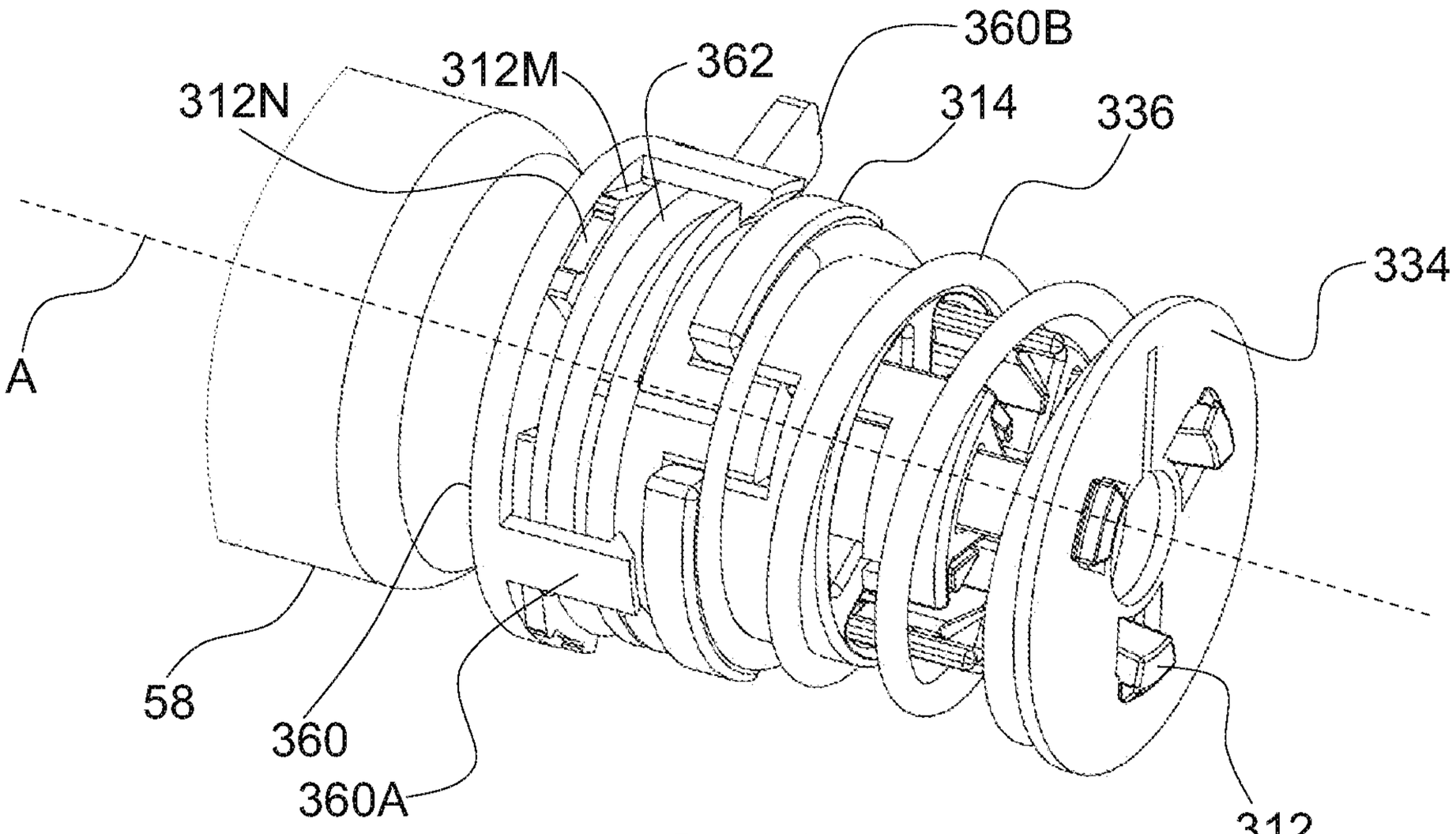


FIG. 32A

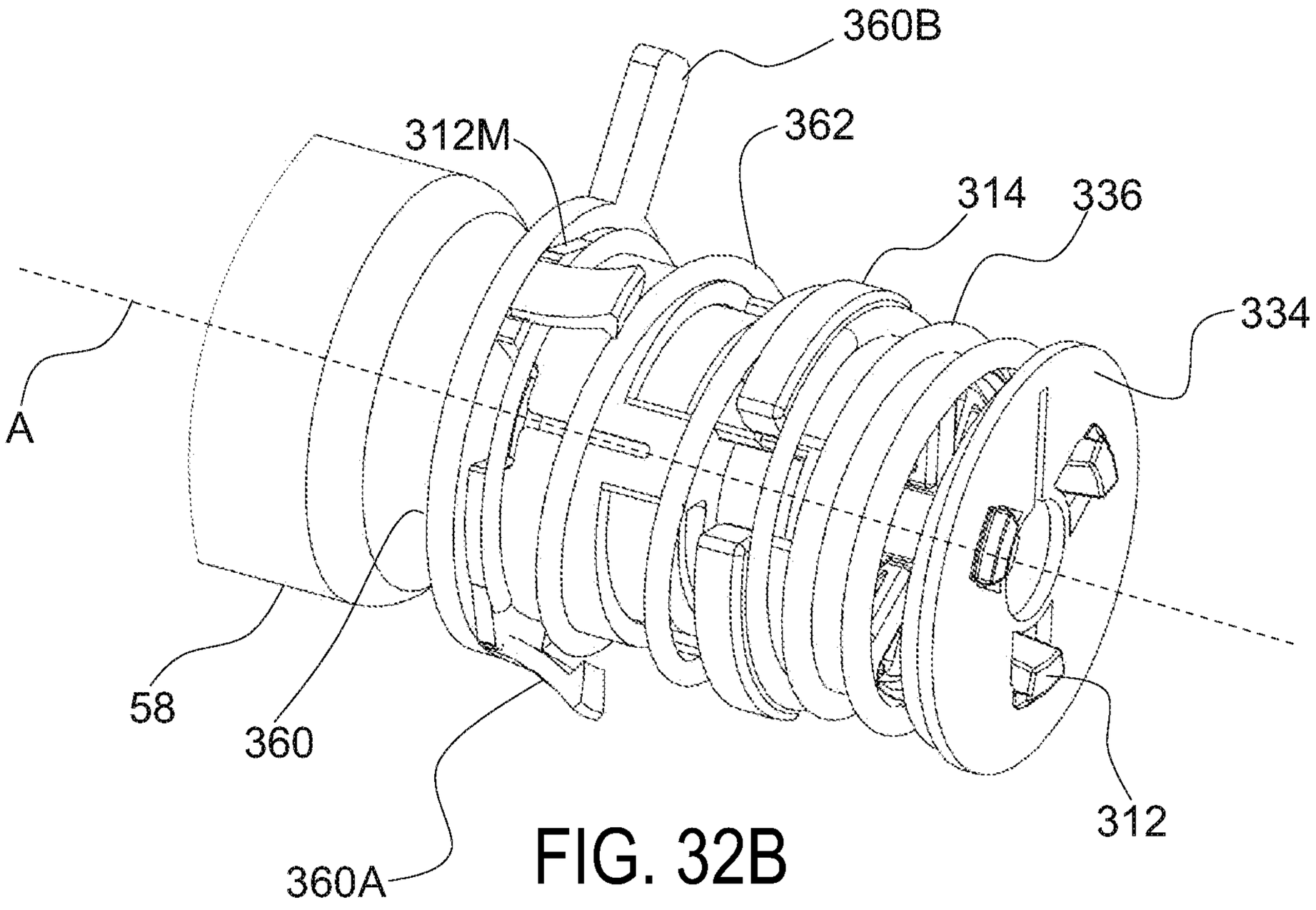


FIG. 32B

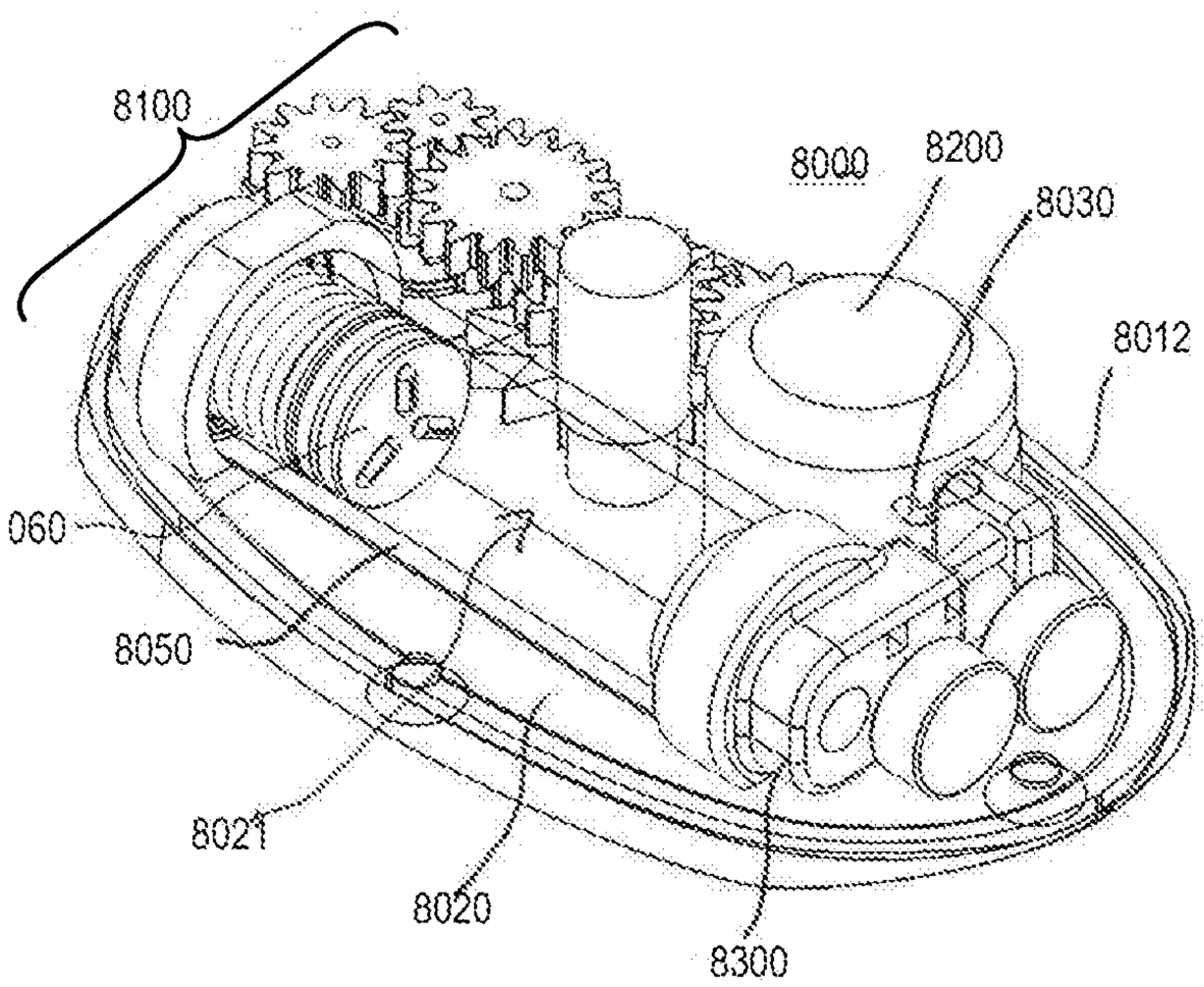


FIG. 33A

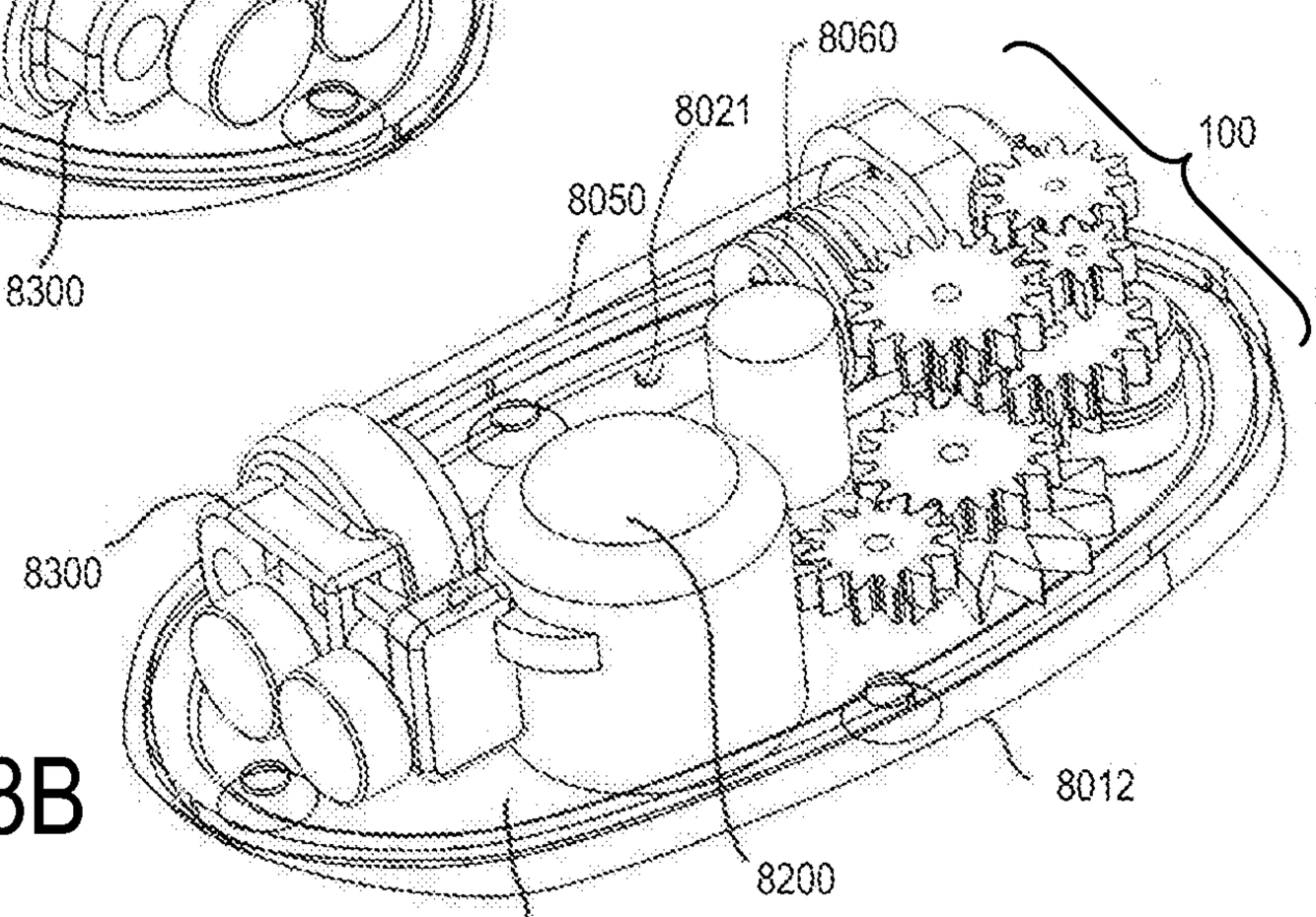


FIG. 33B

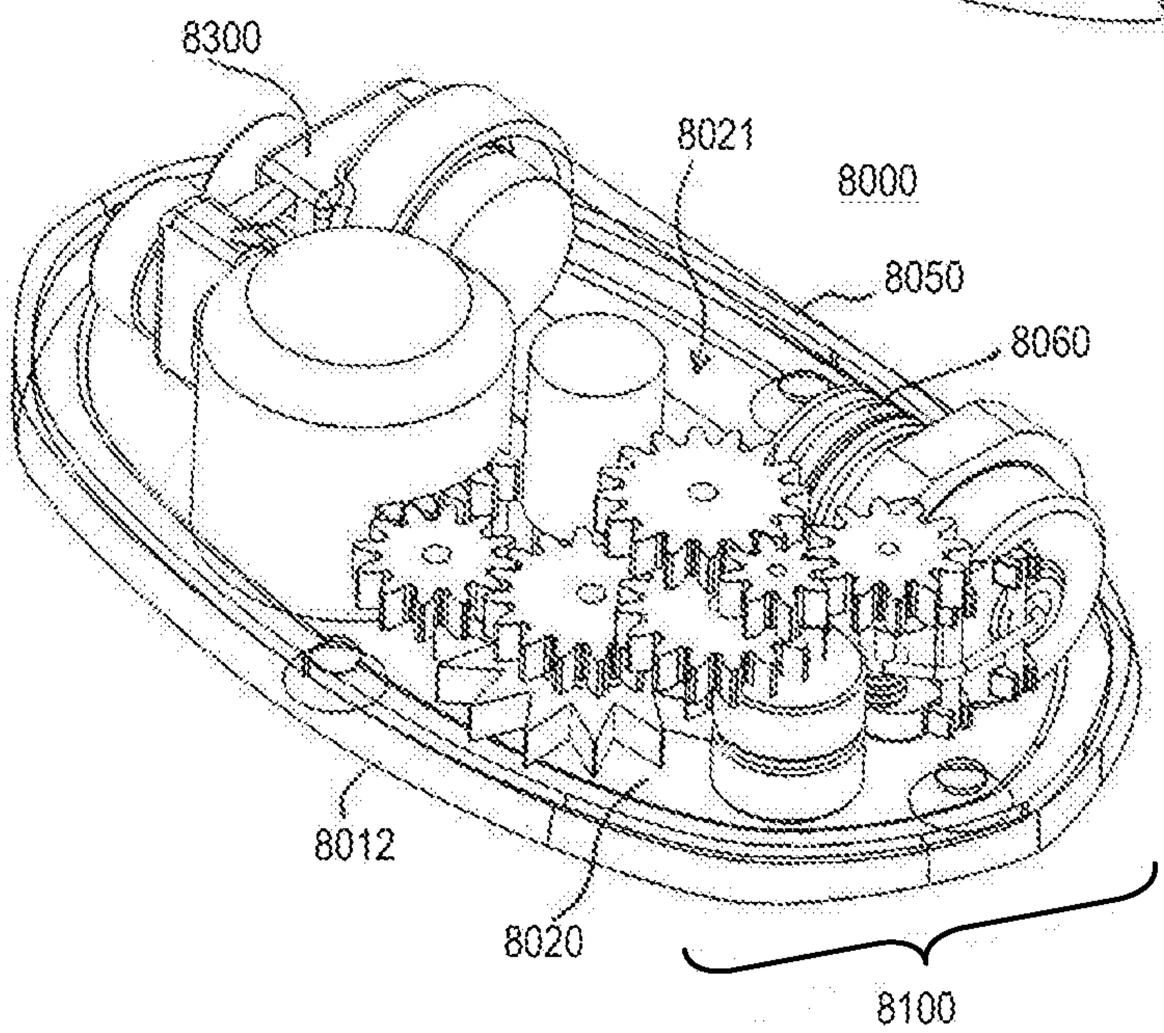


FIG. 33C

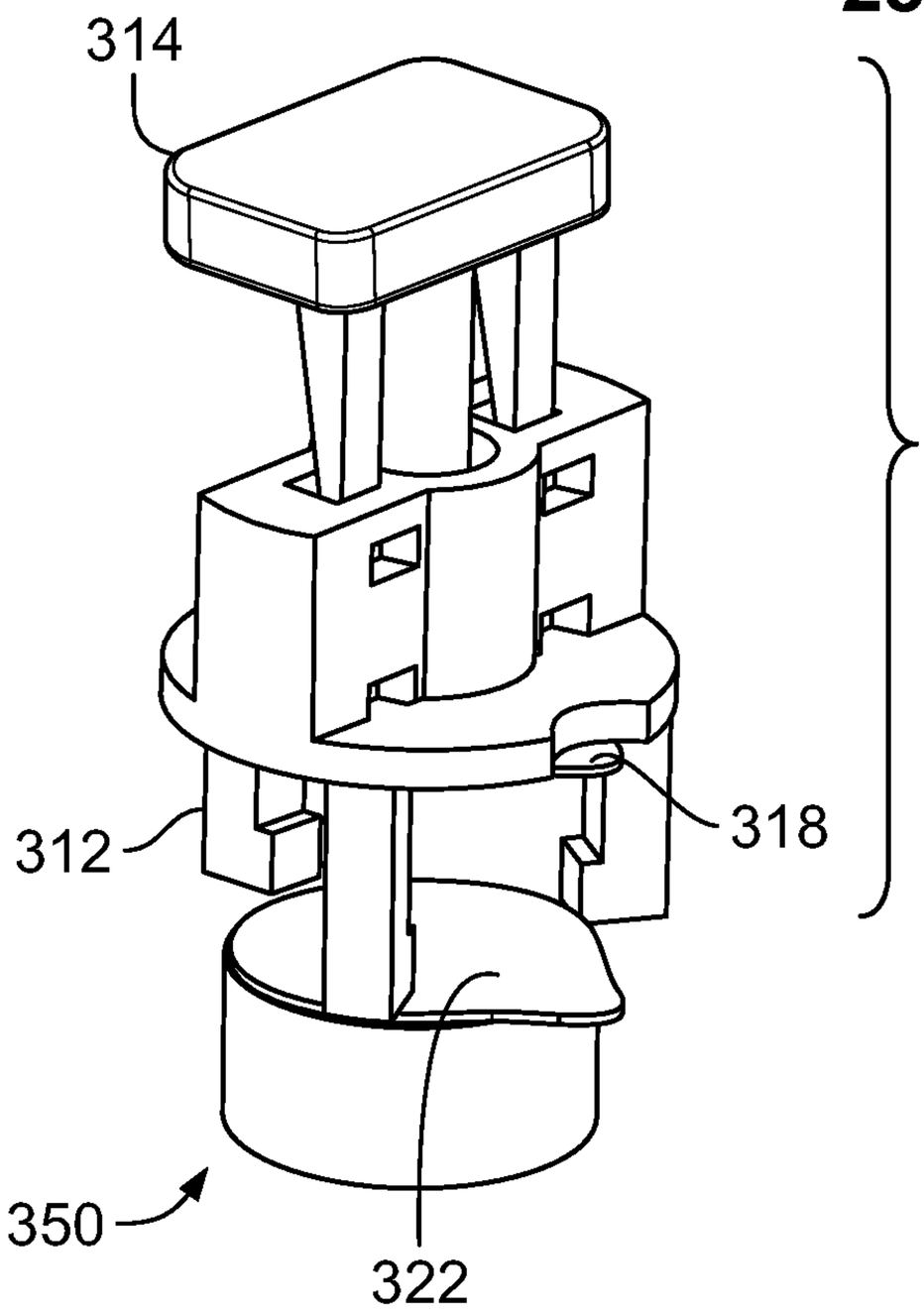


FIG. 34A

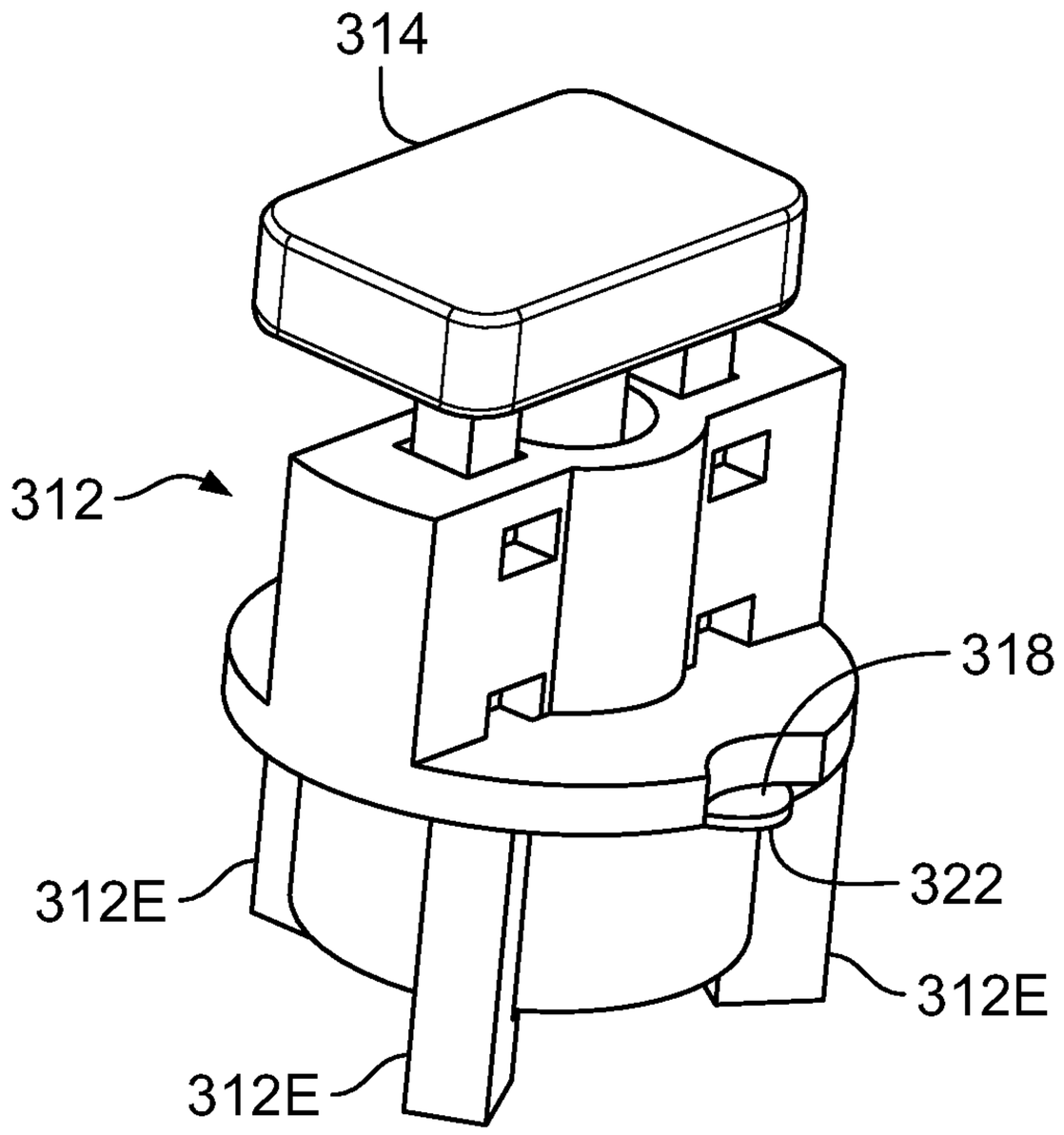


FIG. 34B

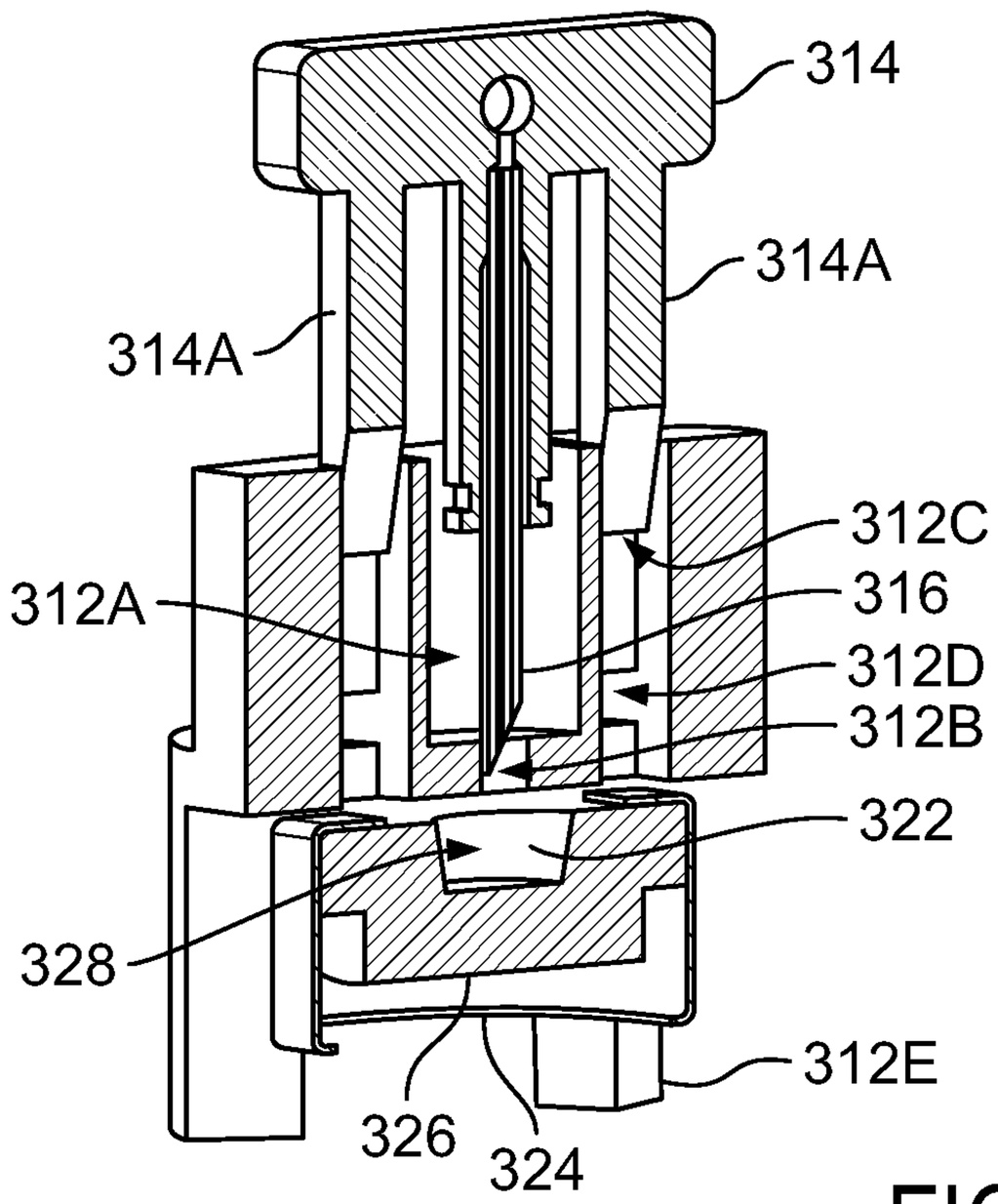


FIG. 34C

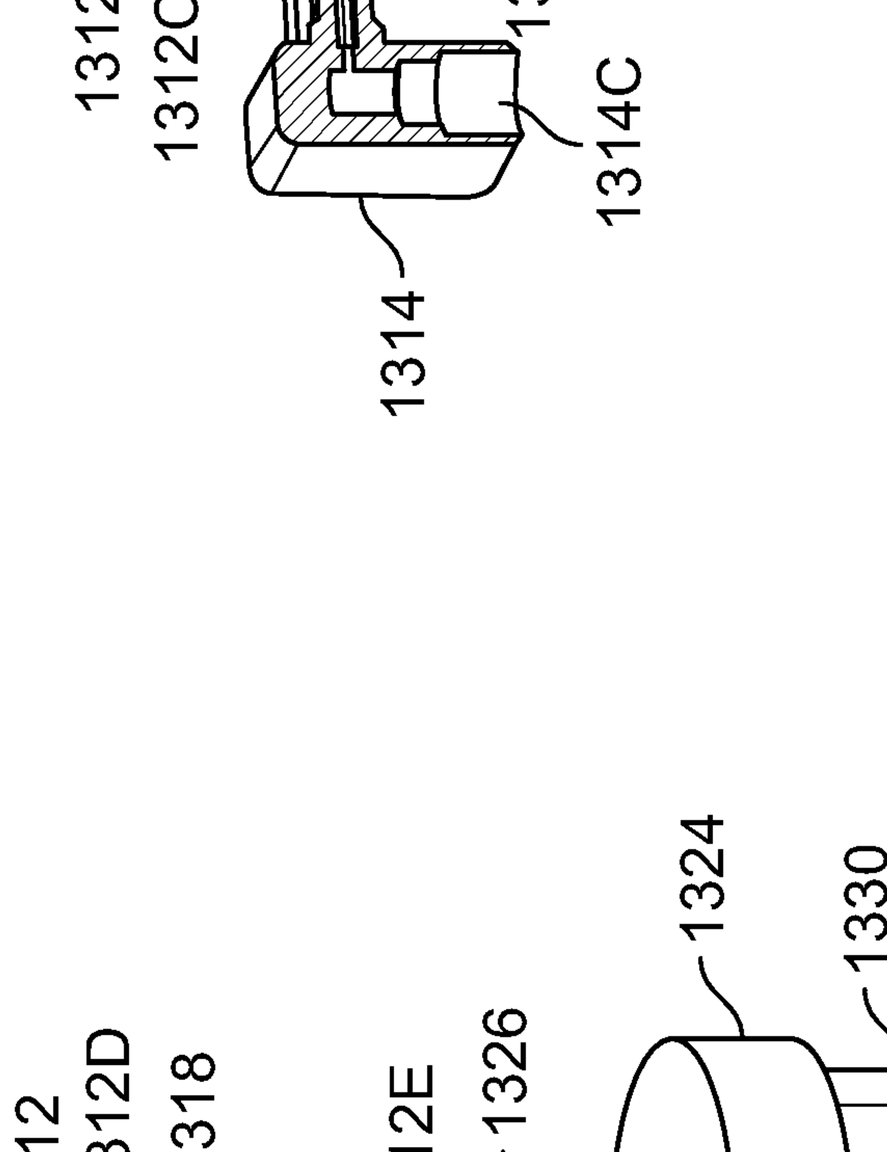


FIG. 35C

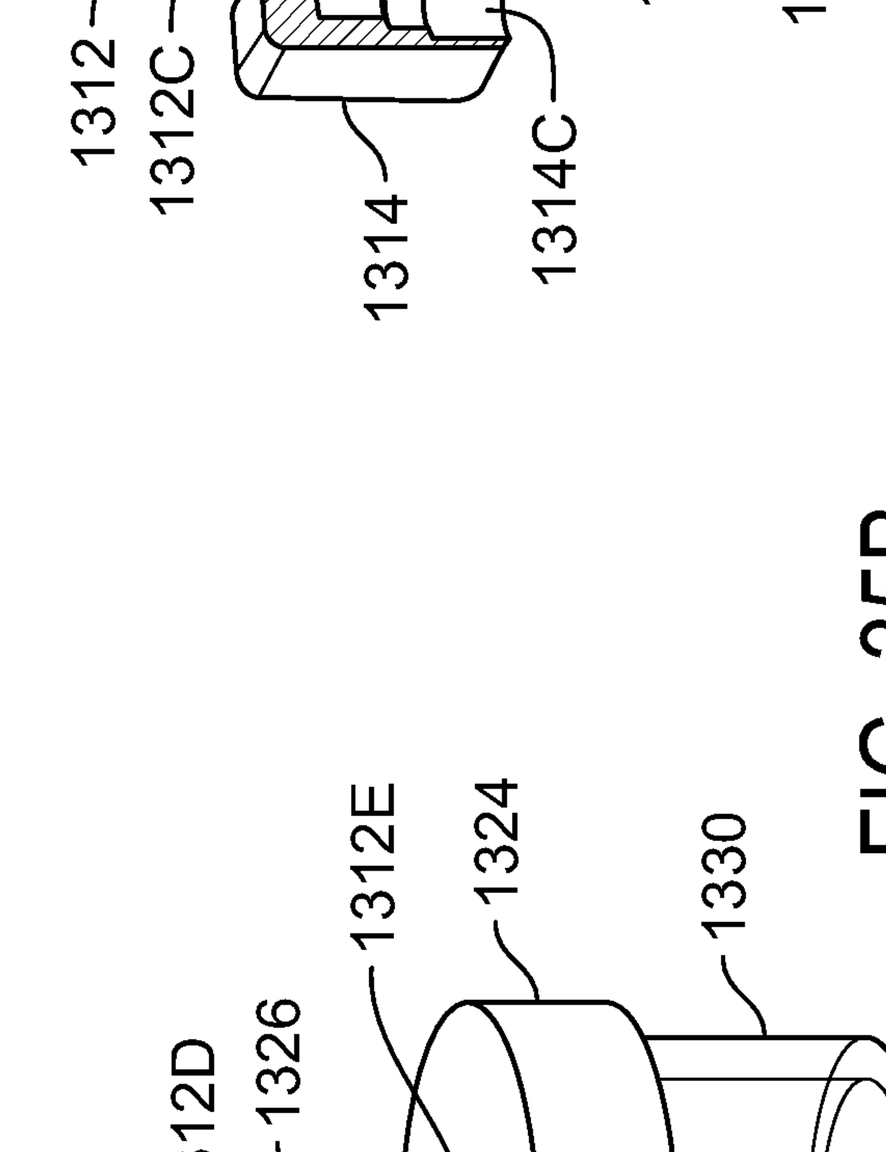


FIG. 35D

FIG. 35A

FIG. 35B

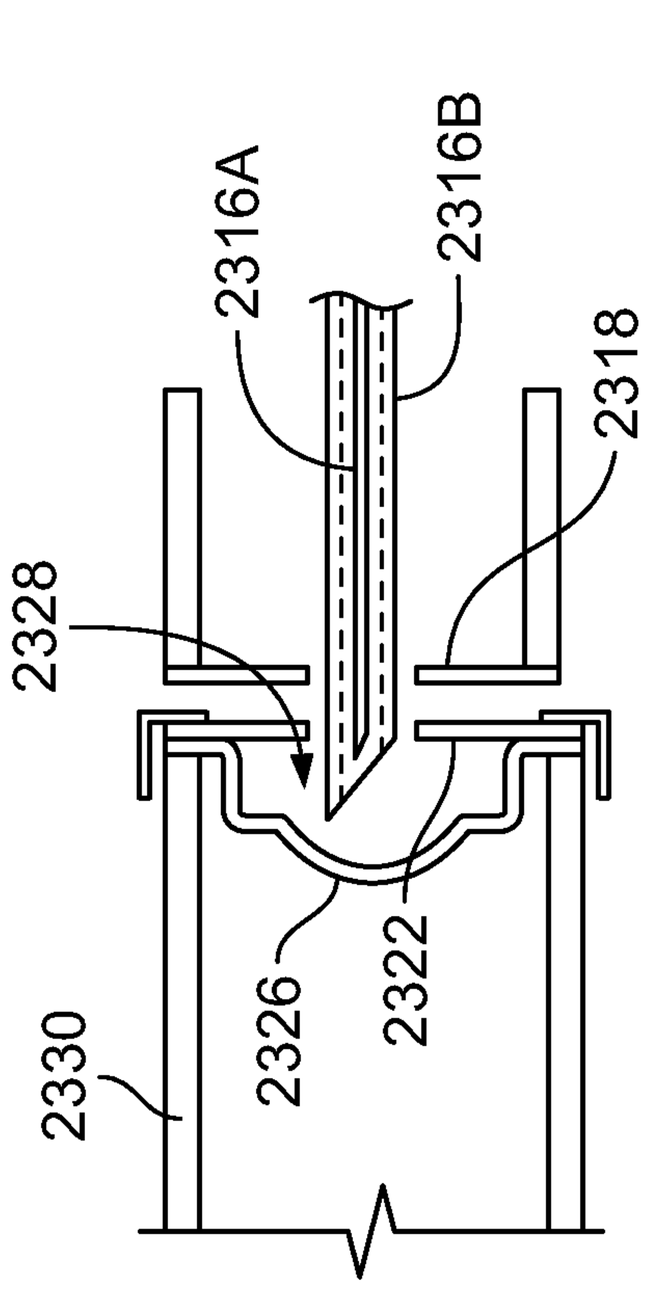


FIG. 36B

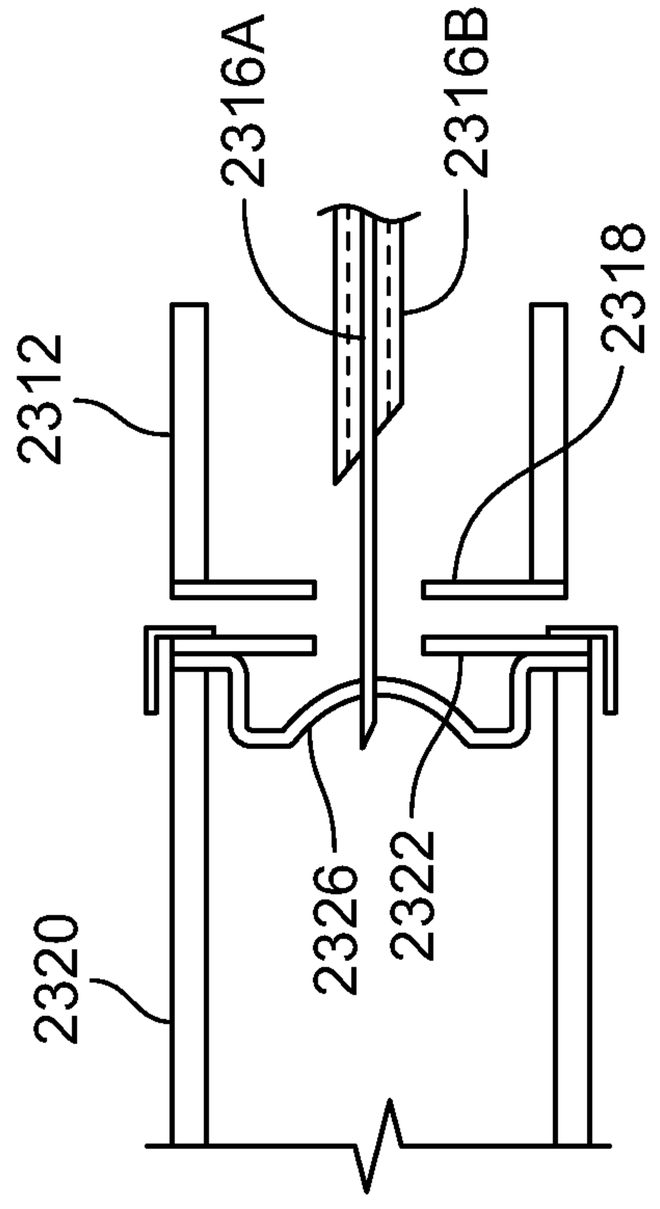


FIG. 36D

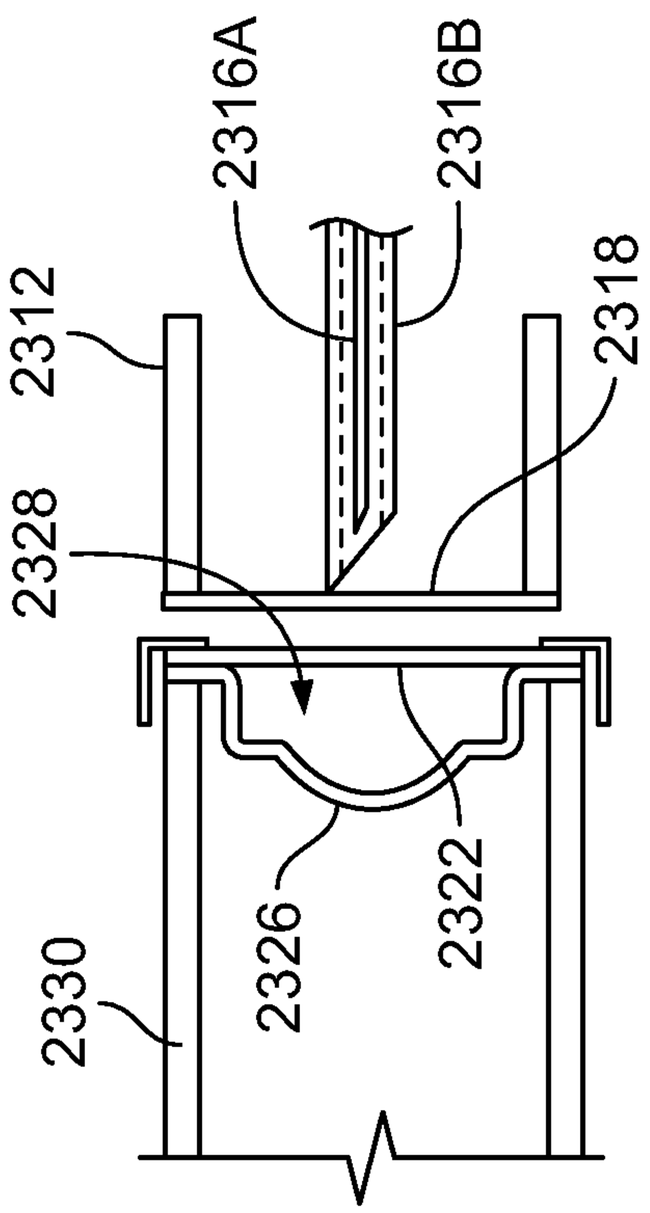


FIG. 36A

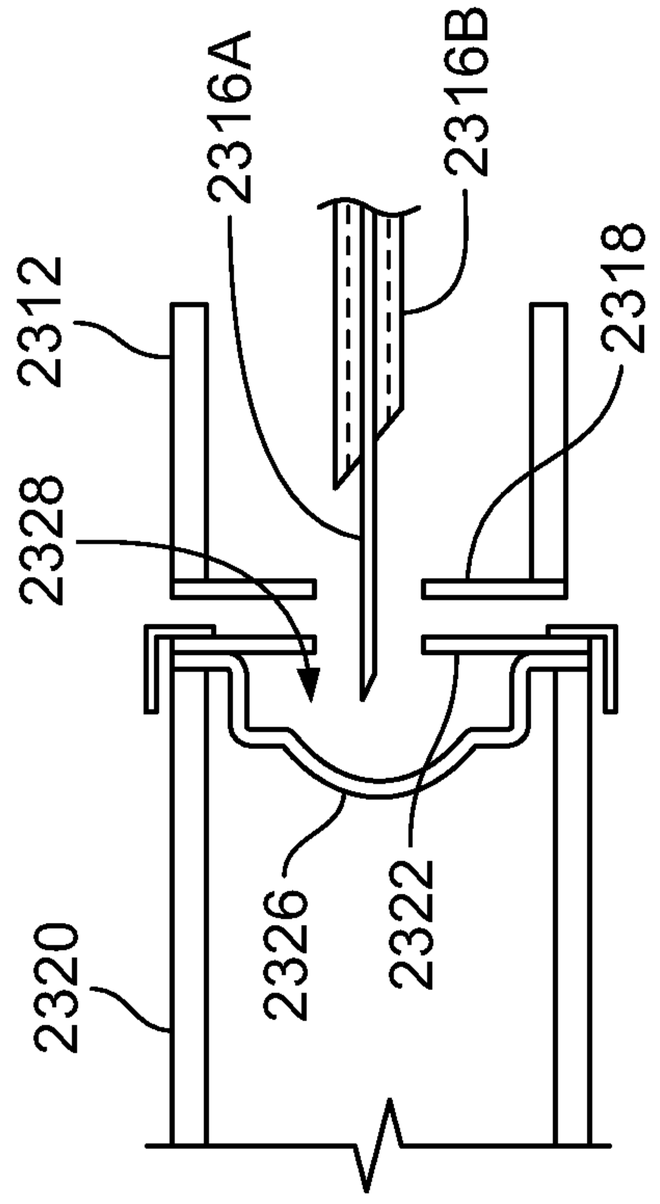


FIG. 36C

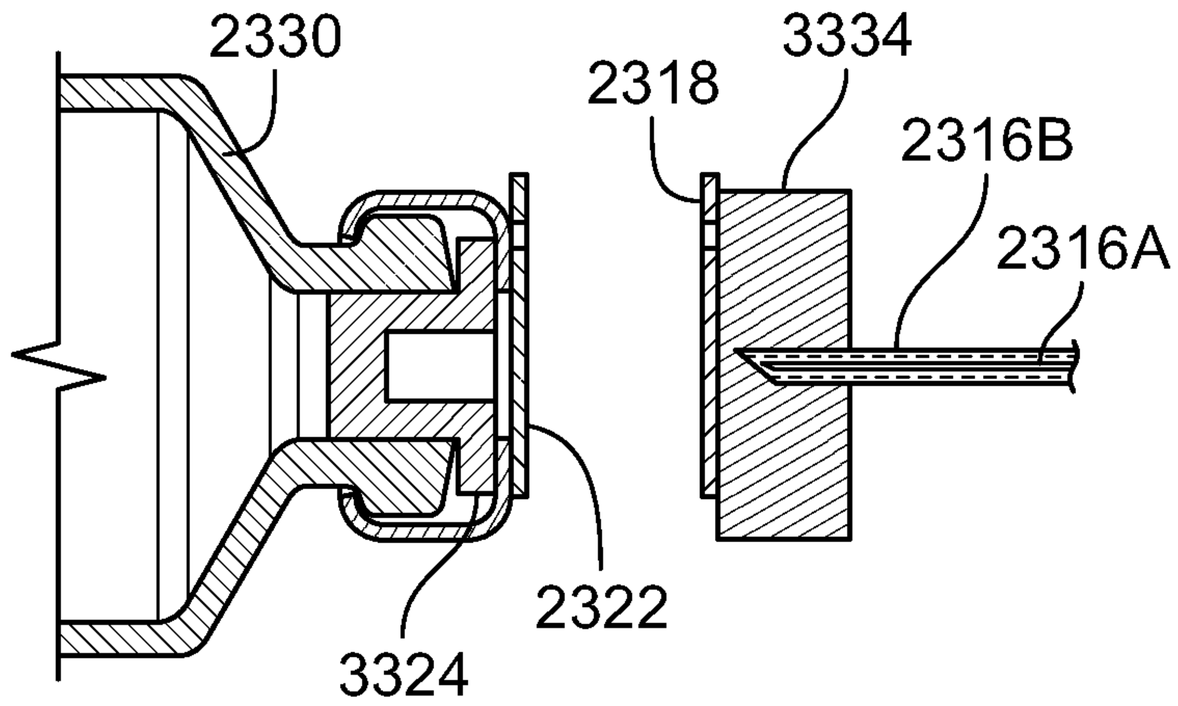


FIG. 37A

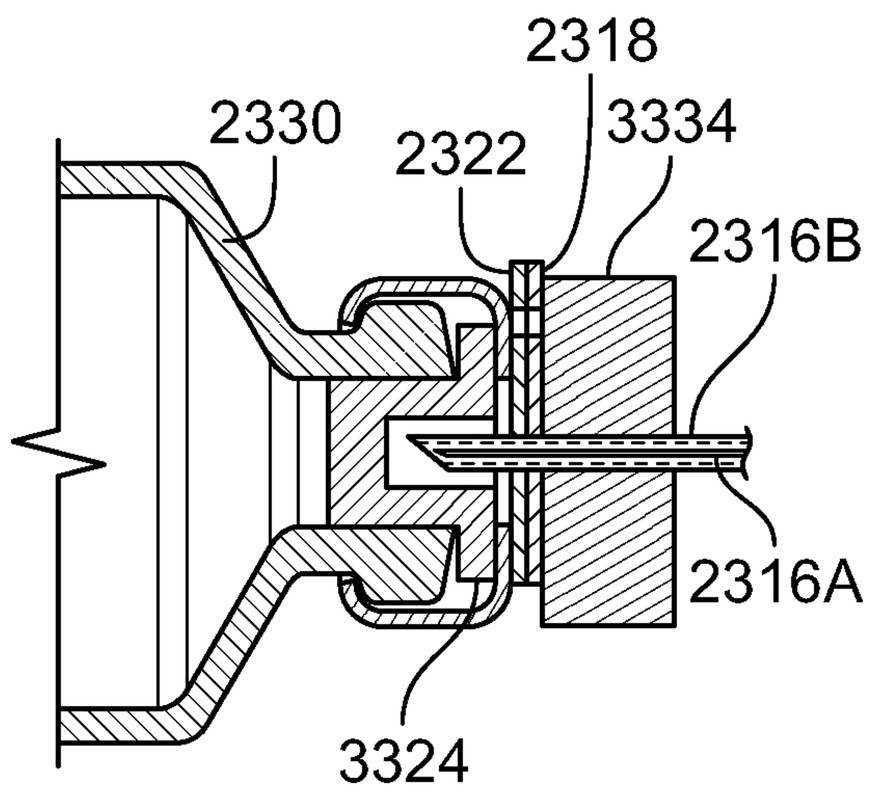


FIG. 37B

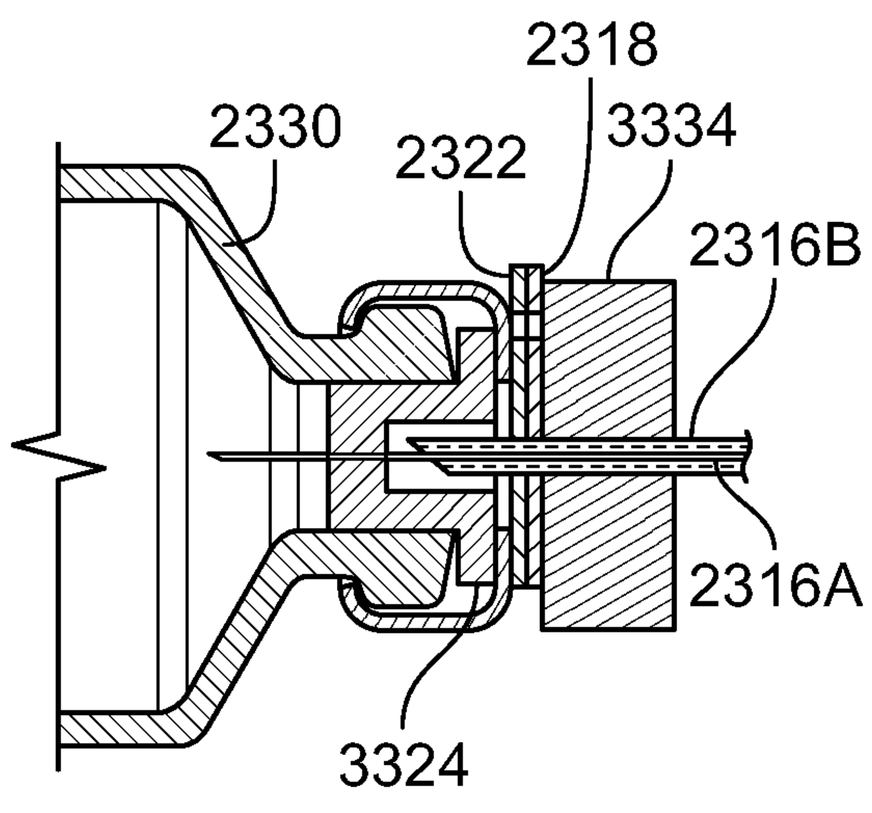


FIG. 37C

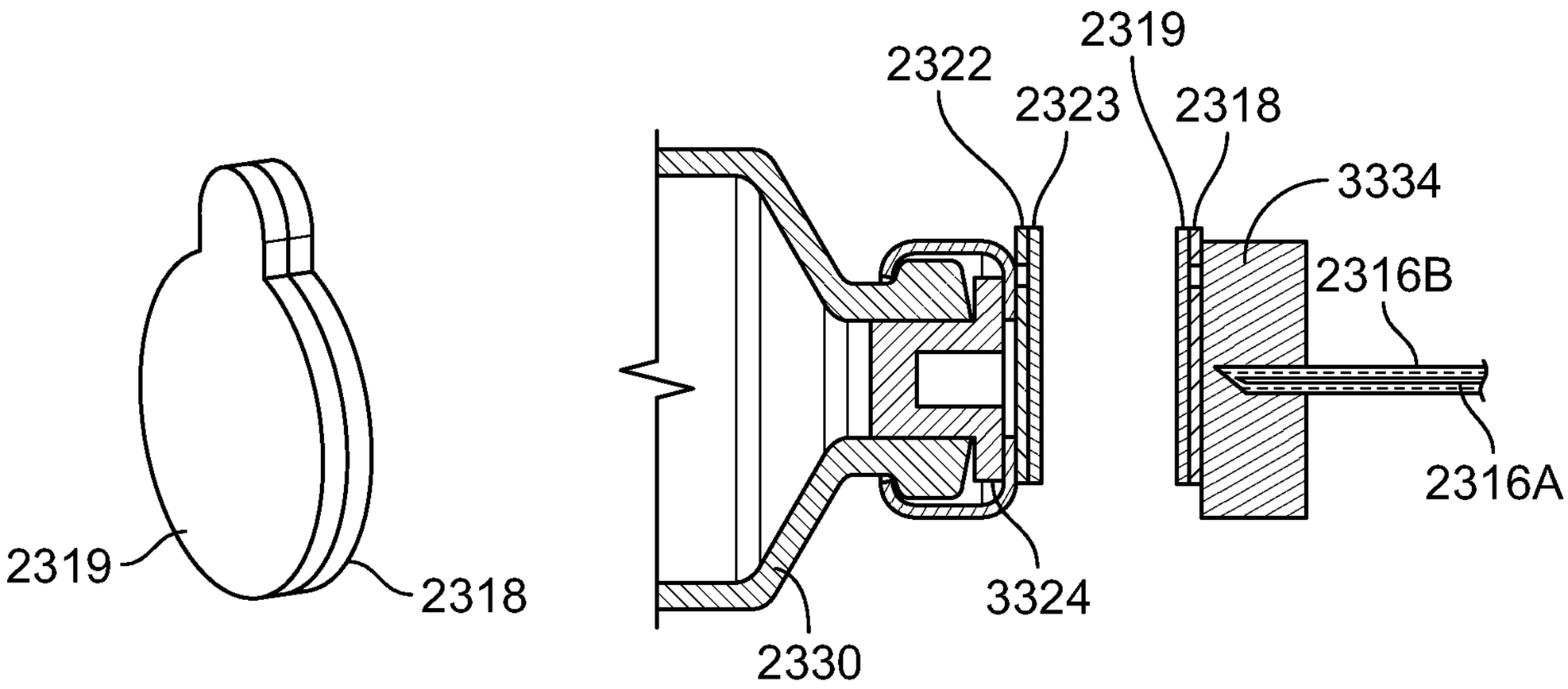


FIG. 38A

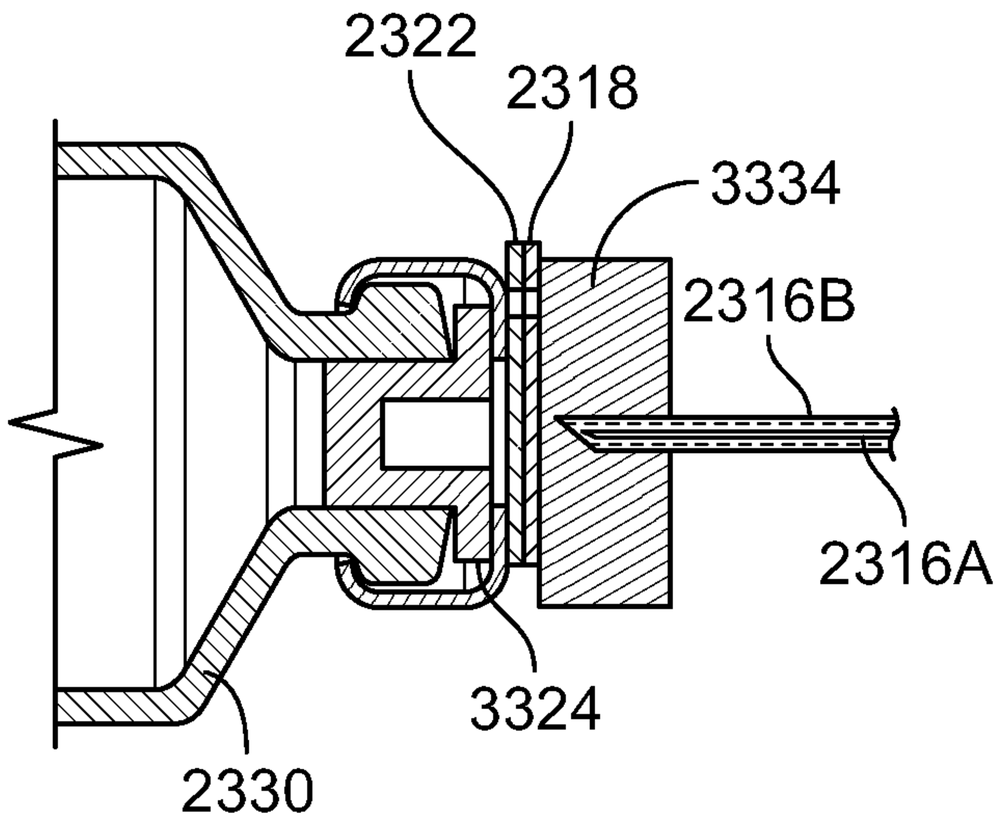


FIG. 38B

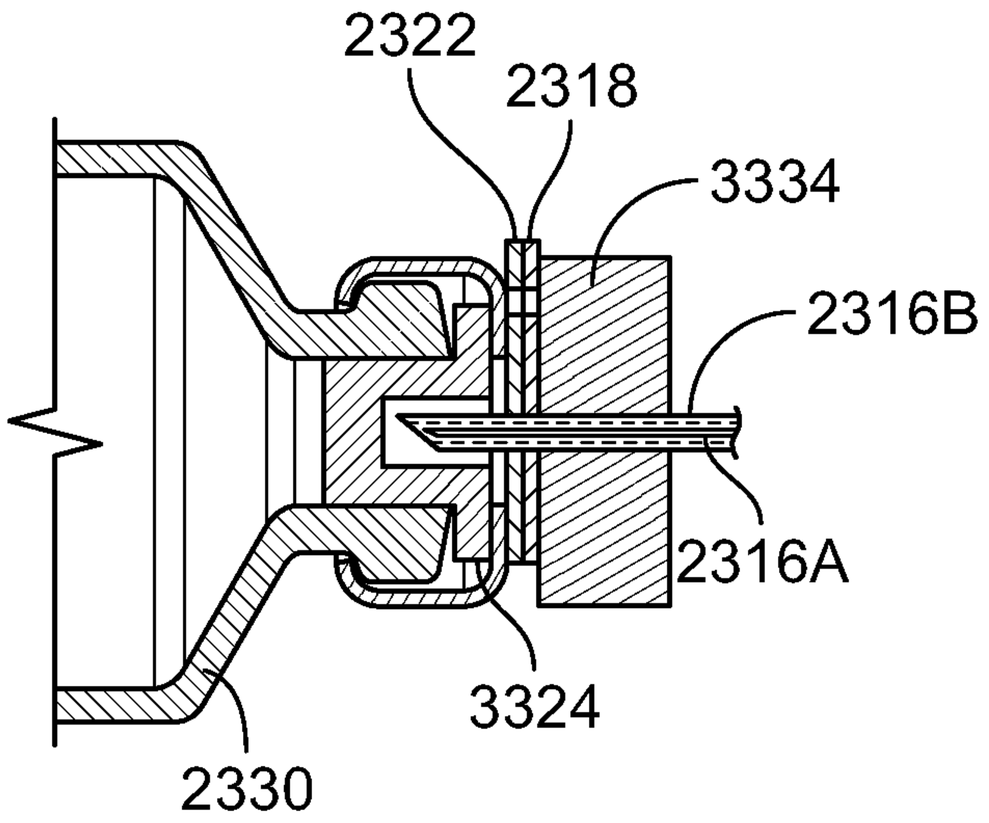


FIG. 38C

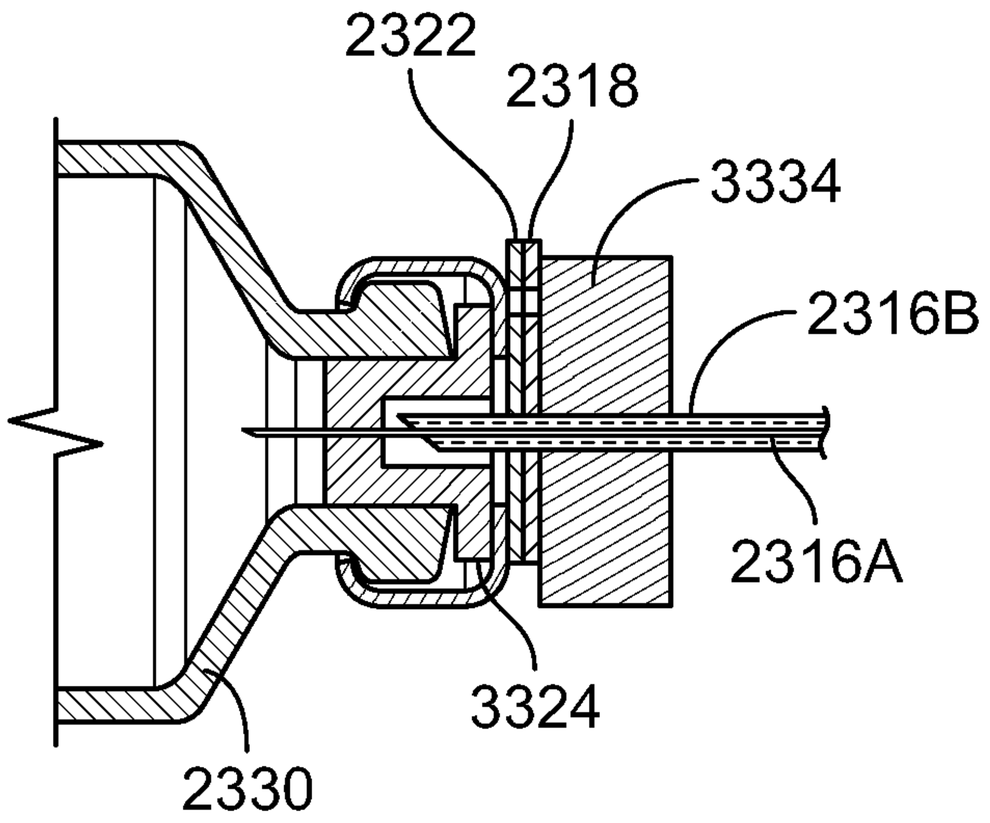


FIG. 38D

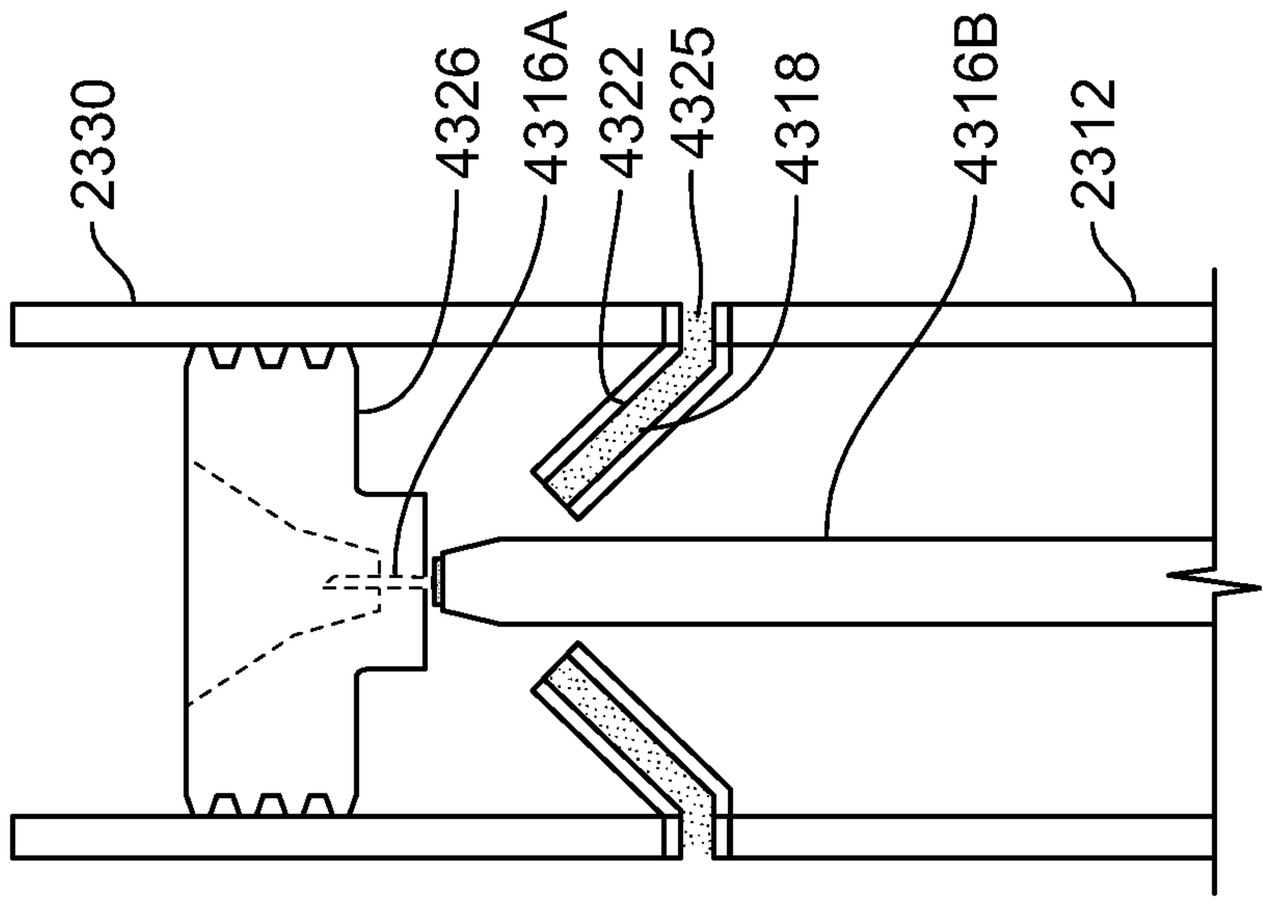


FIG. 39B

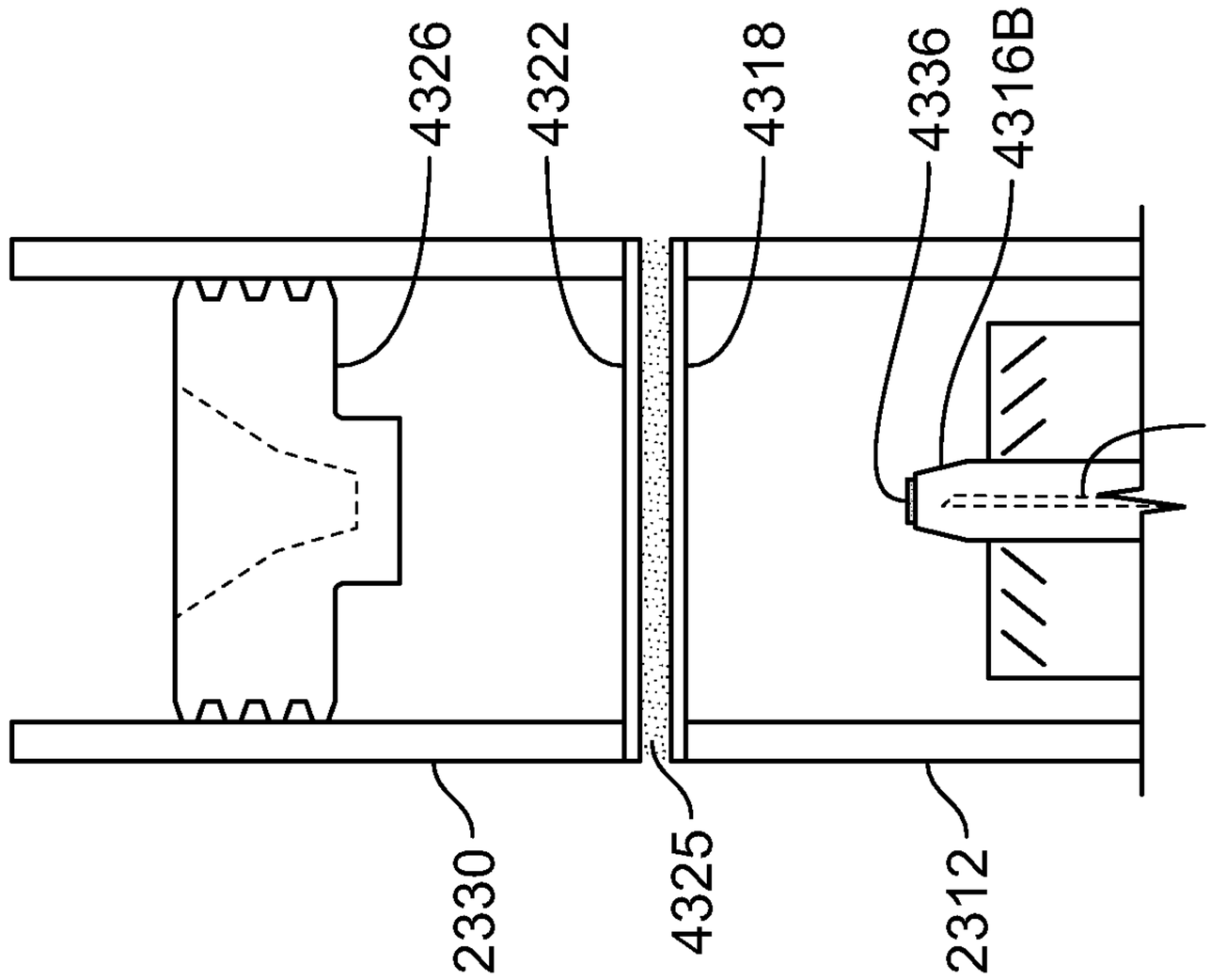


FIG. 39A

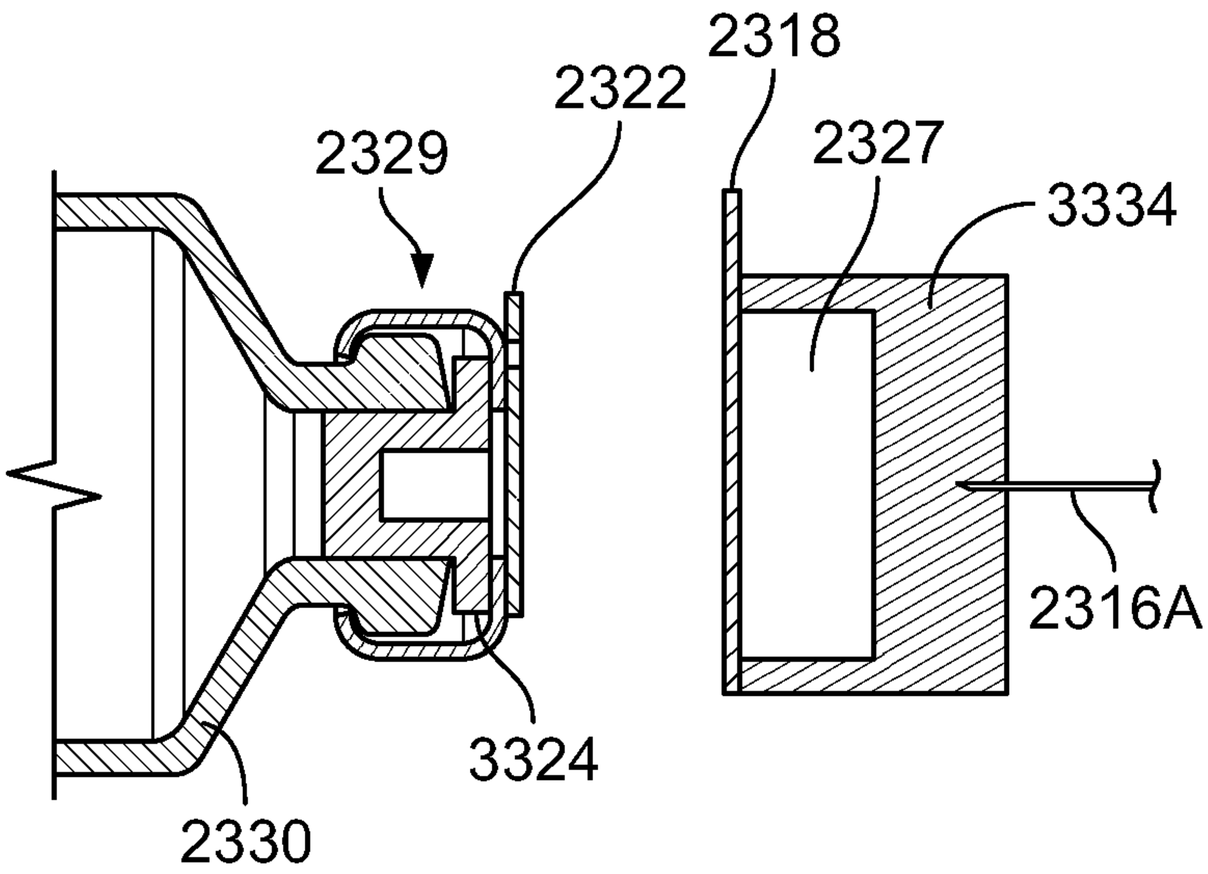


FIG. 40A

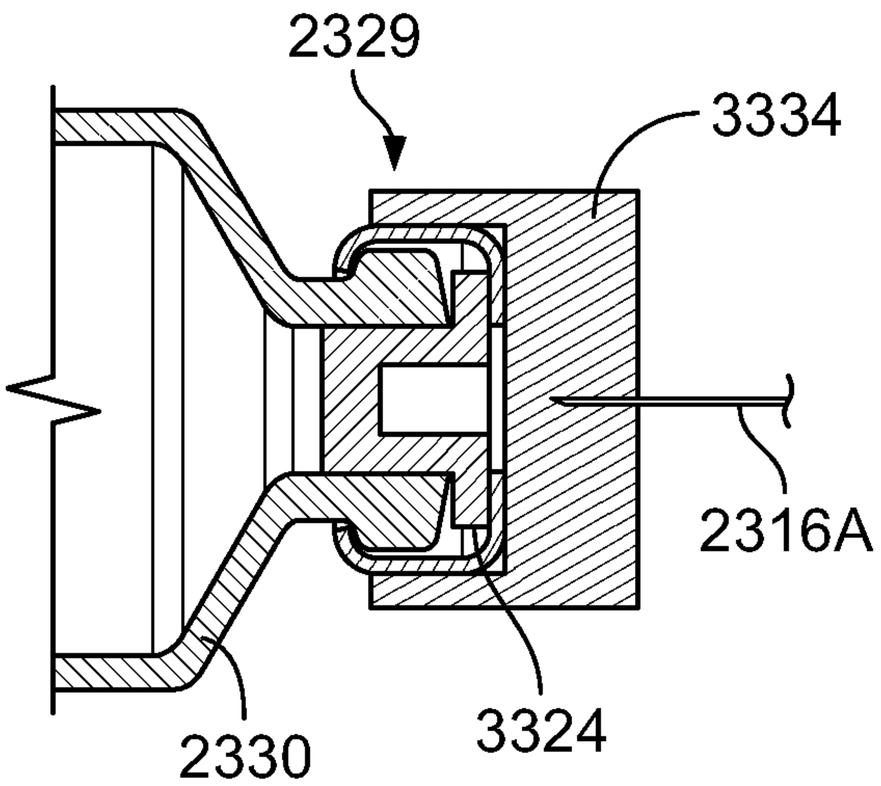


FIG. 40B

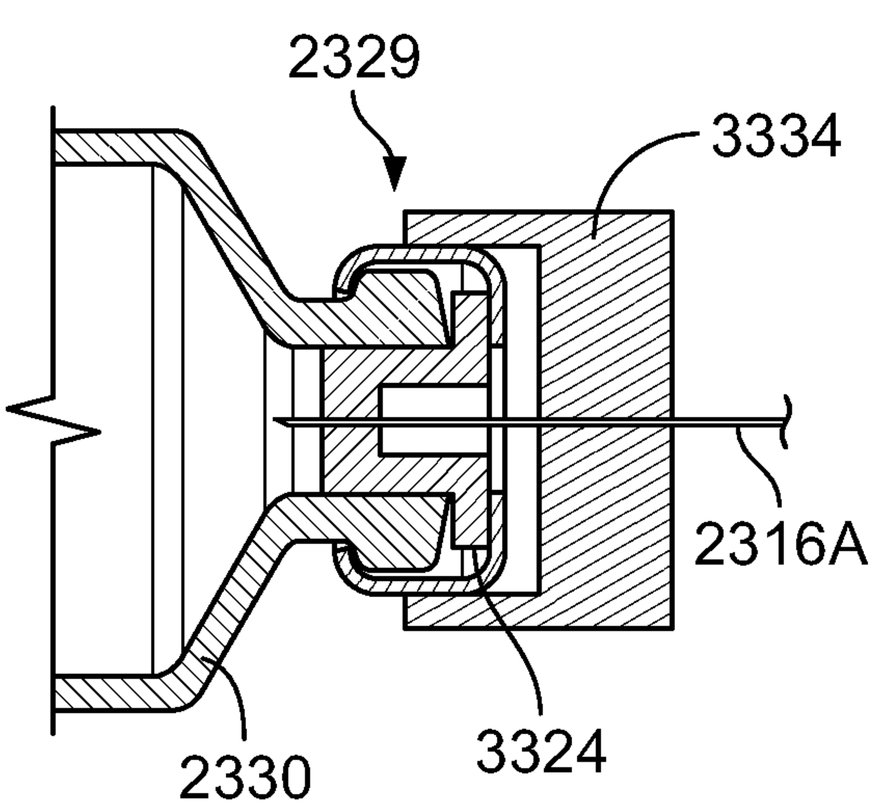


FIG. 40C

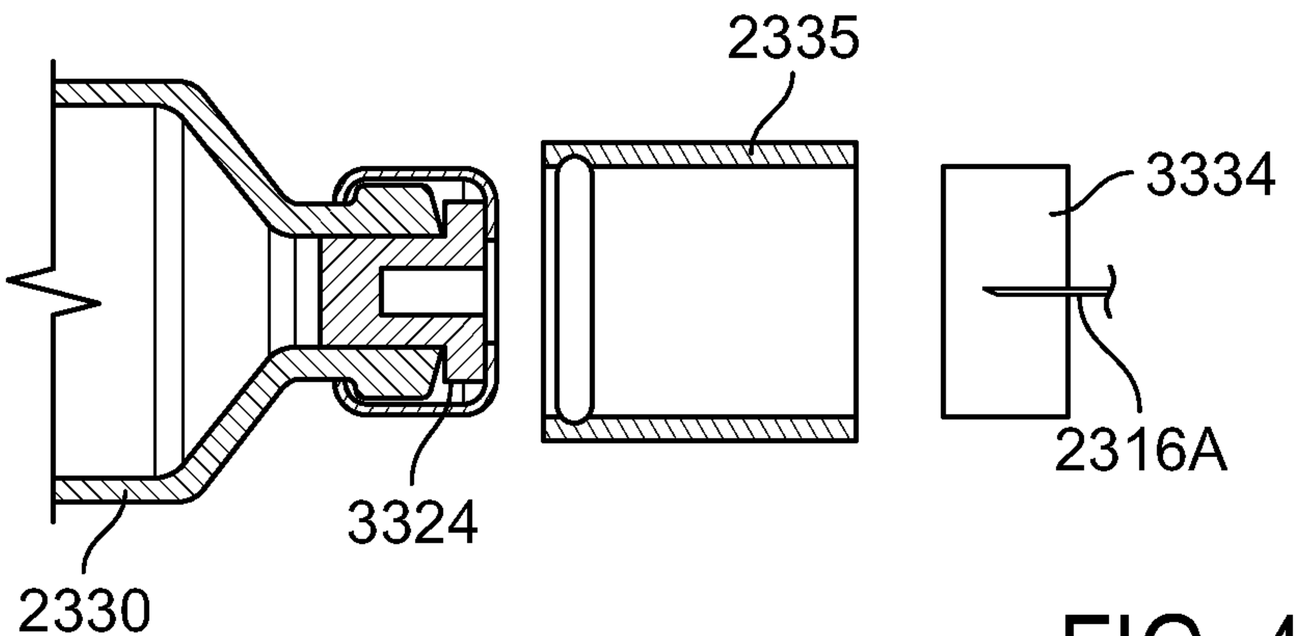


FIG. 41A

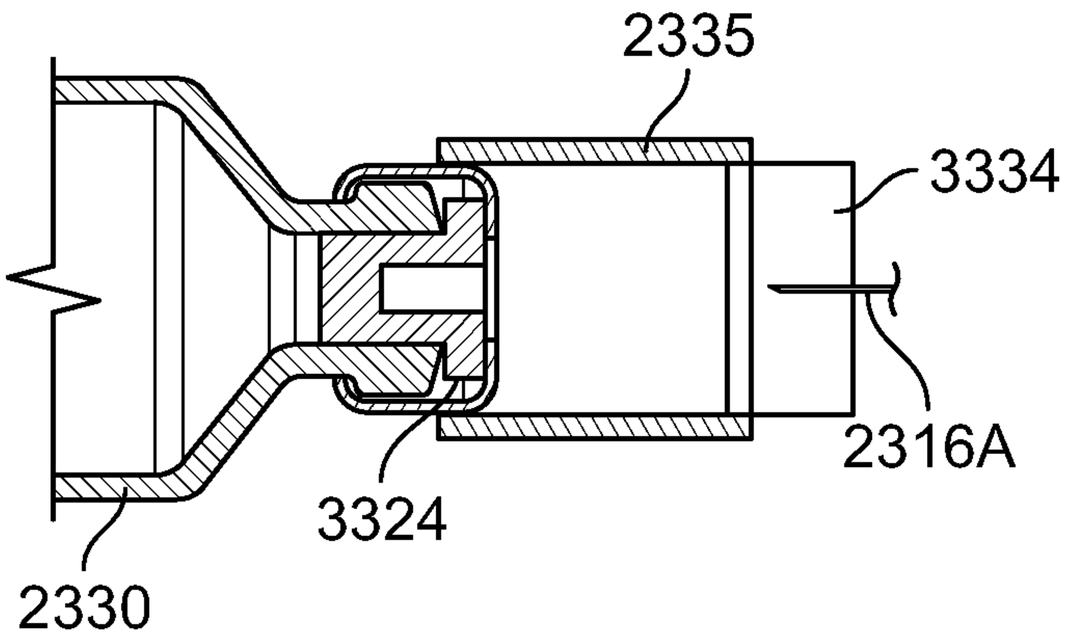


FIG. 41B

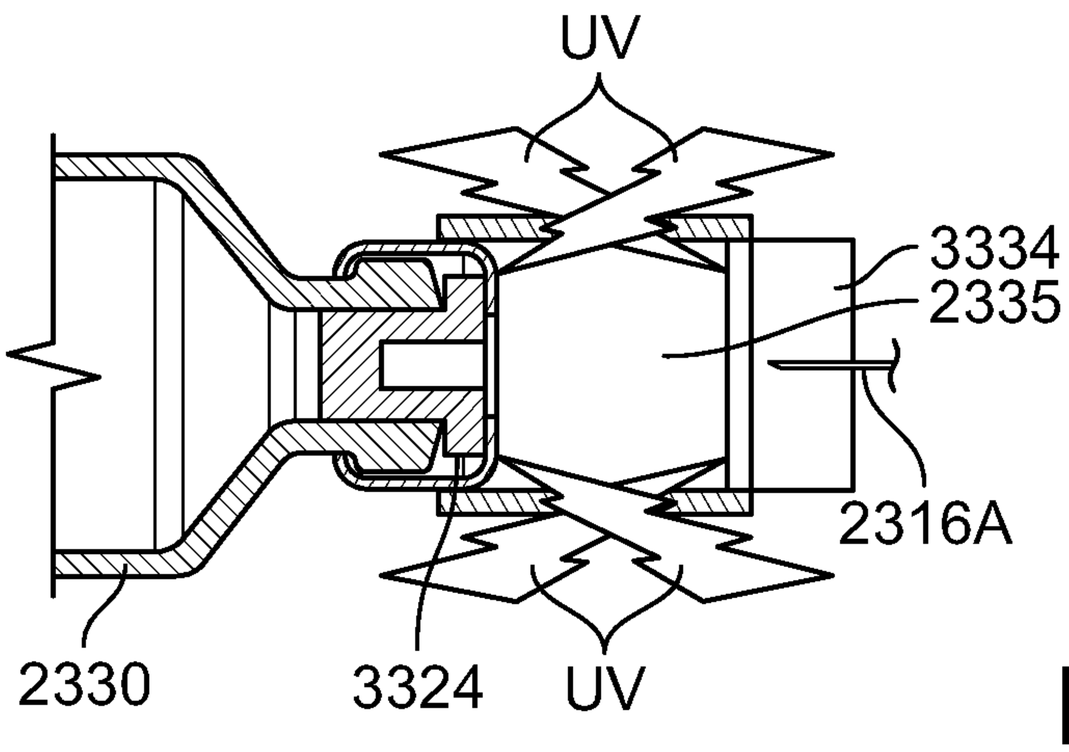


FIG. 41C

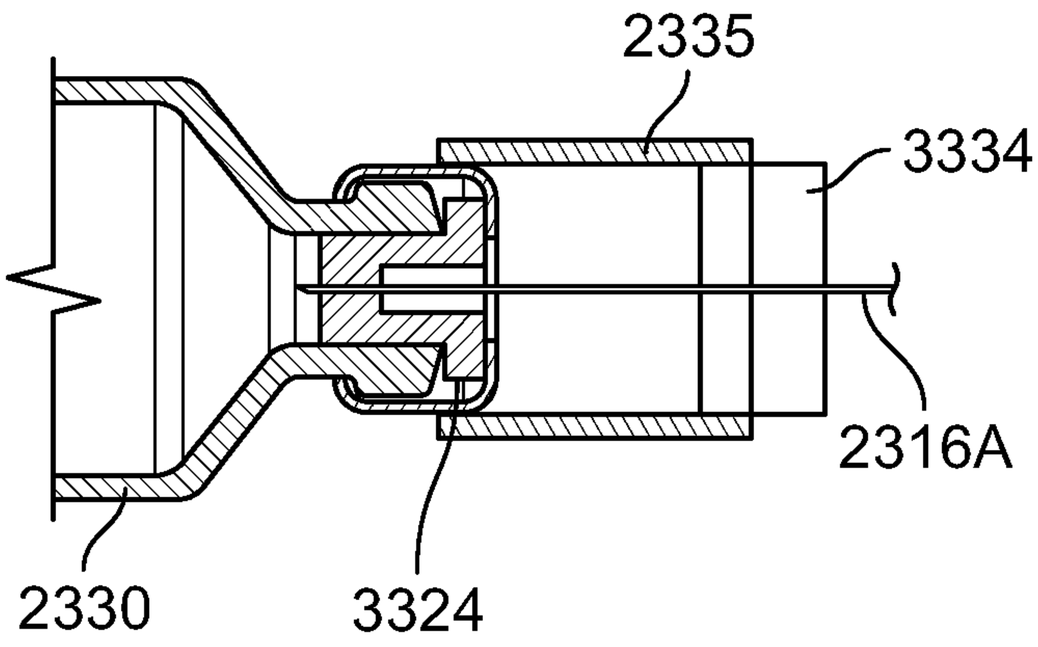
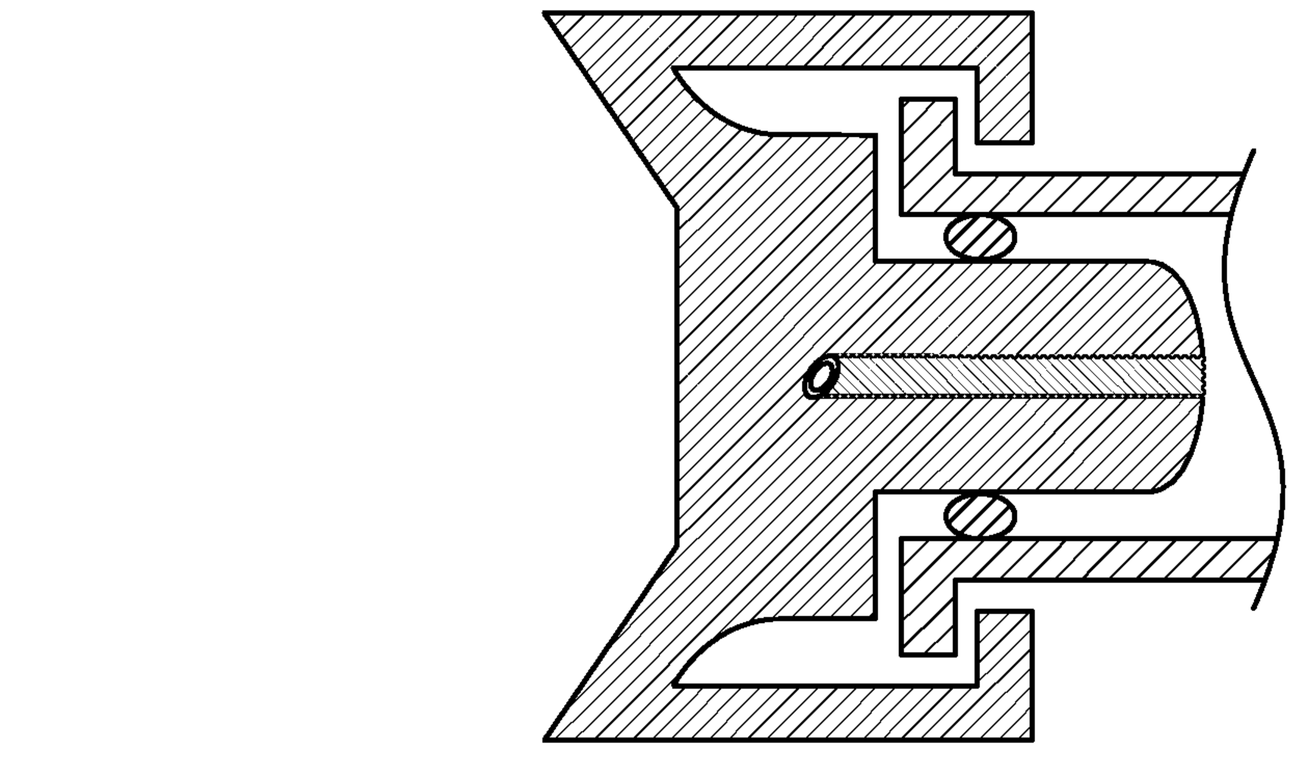


FIG. 41D



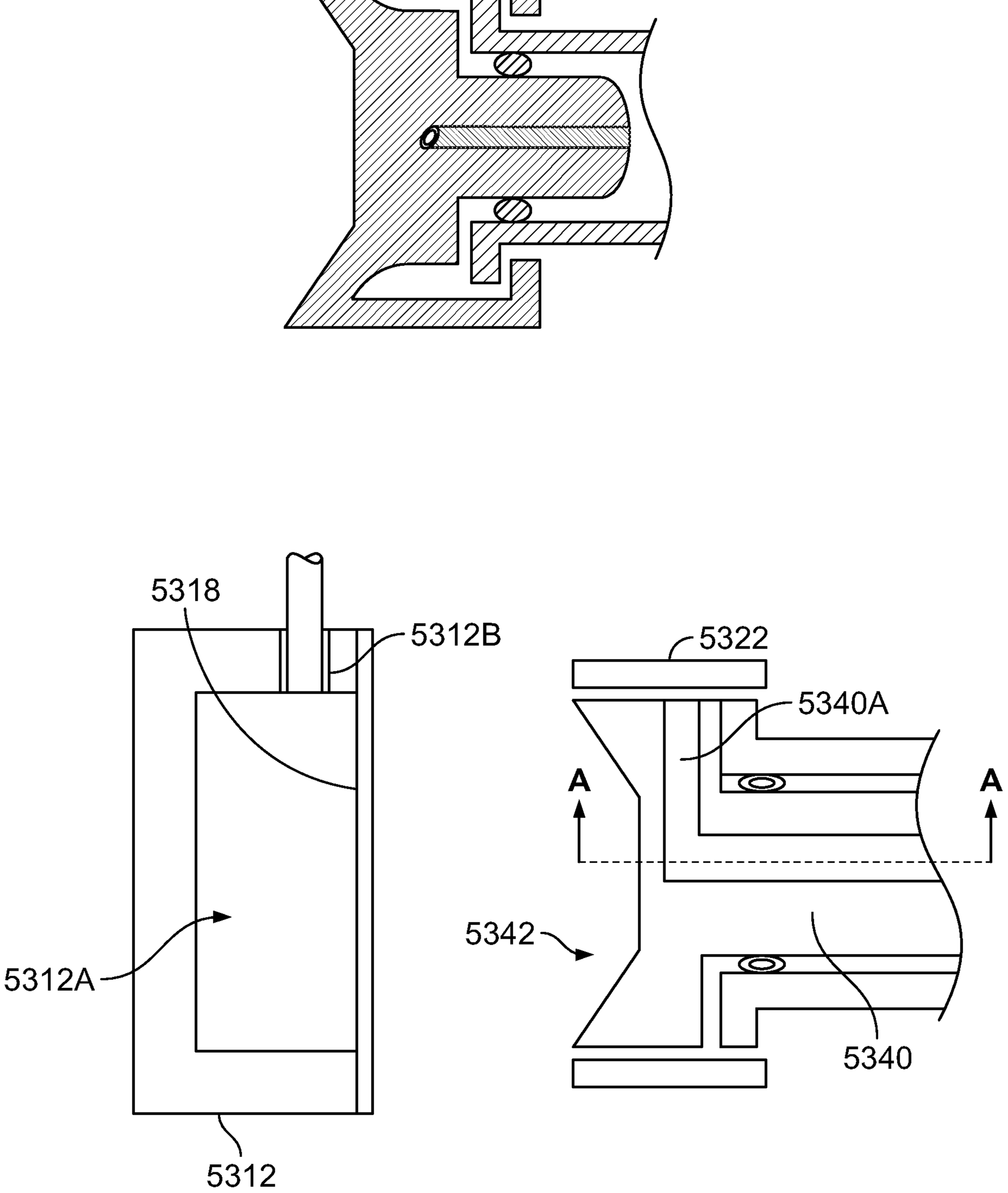


FIG. 42

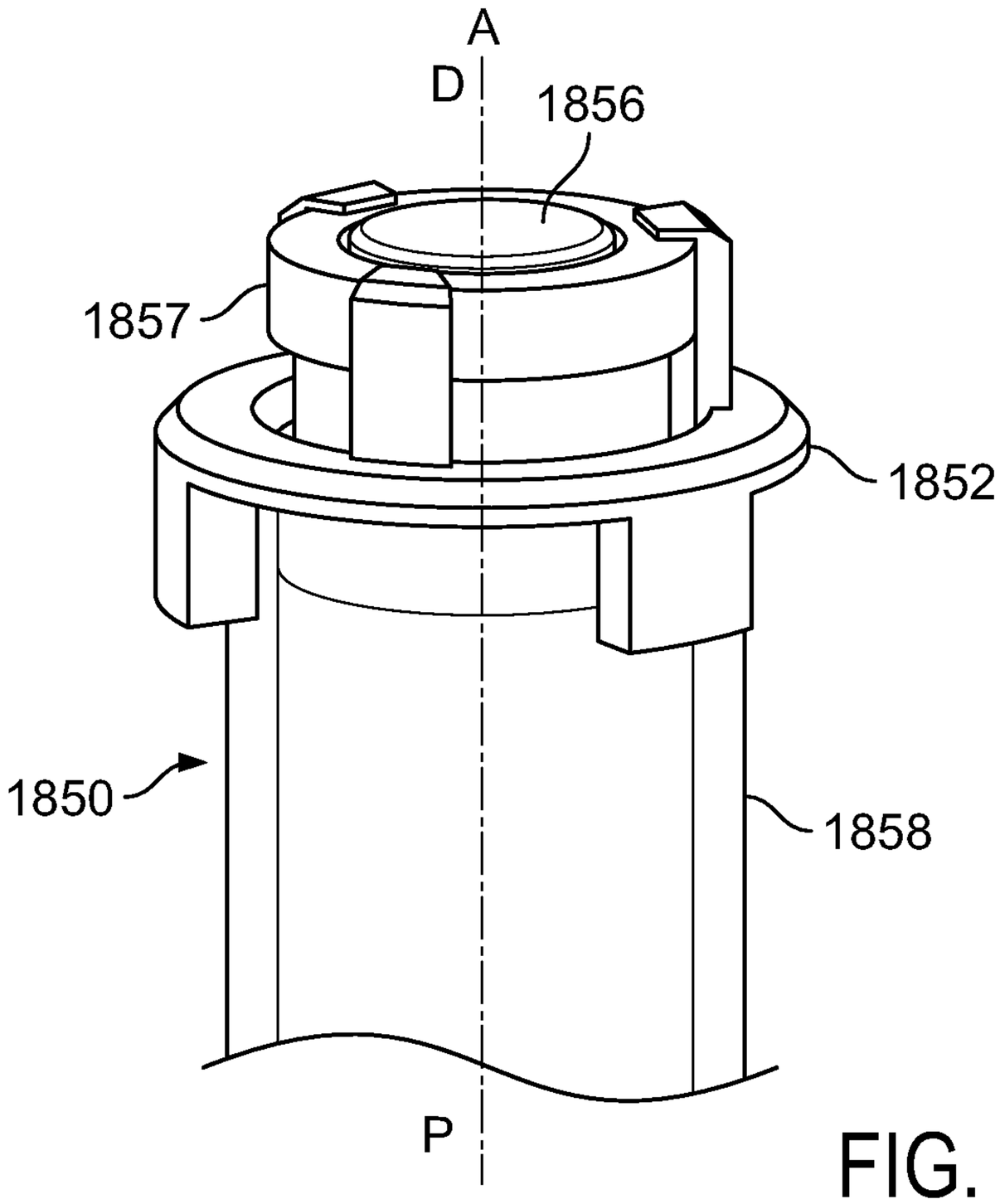

A
D
1856
1857
1852
1850
1858
P

FIG. 43

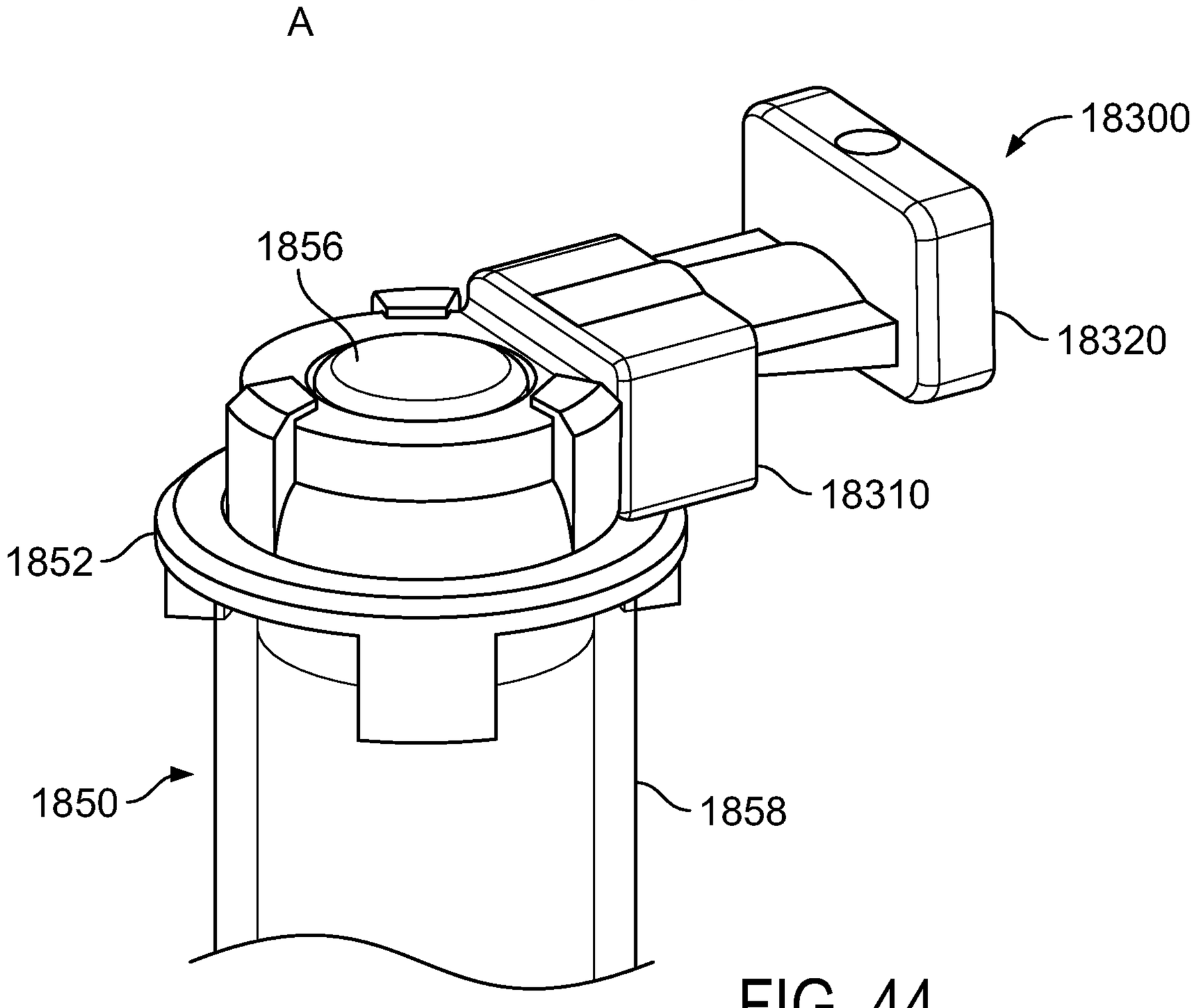

A
18300
1856
18320
18310
1852
1850
1858

FIG. 44

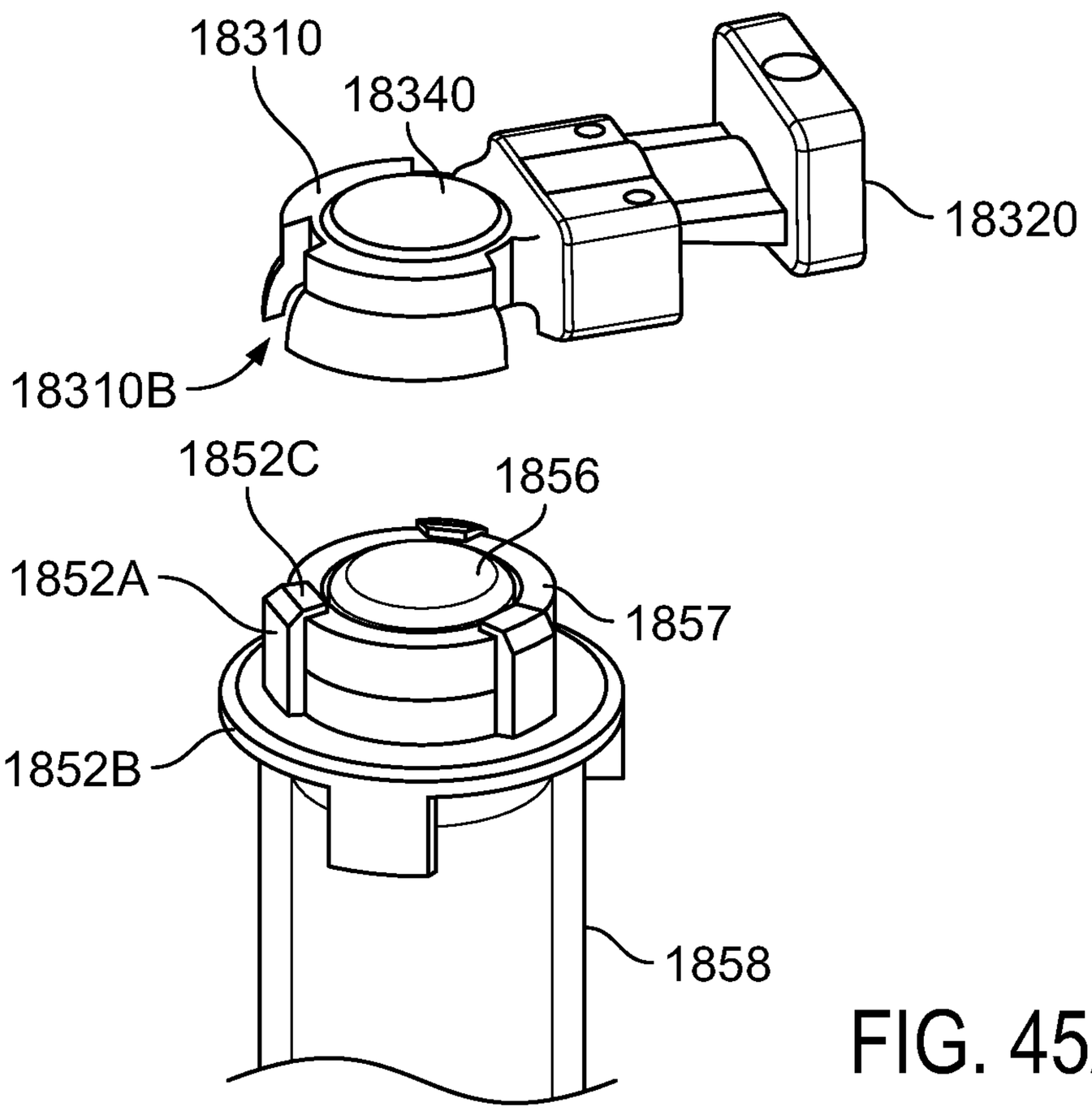


FIG. 45A

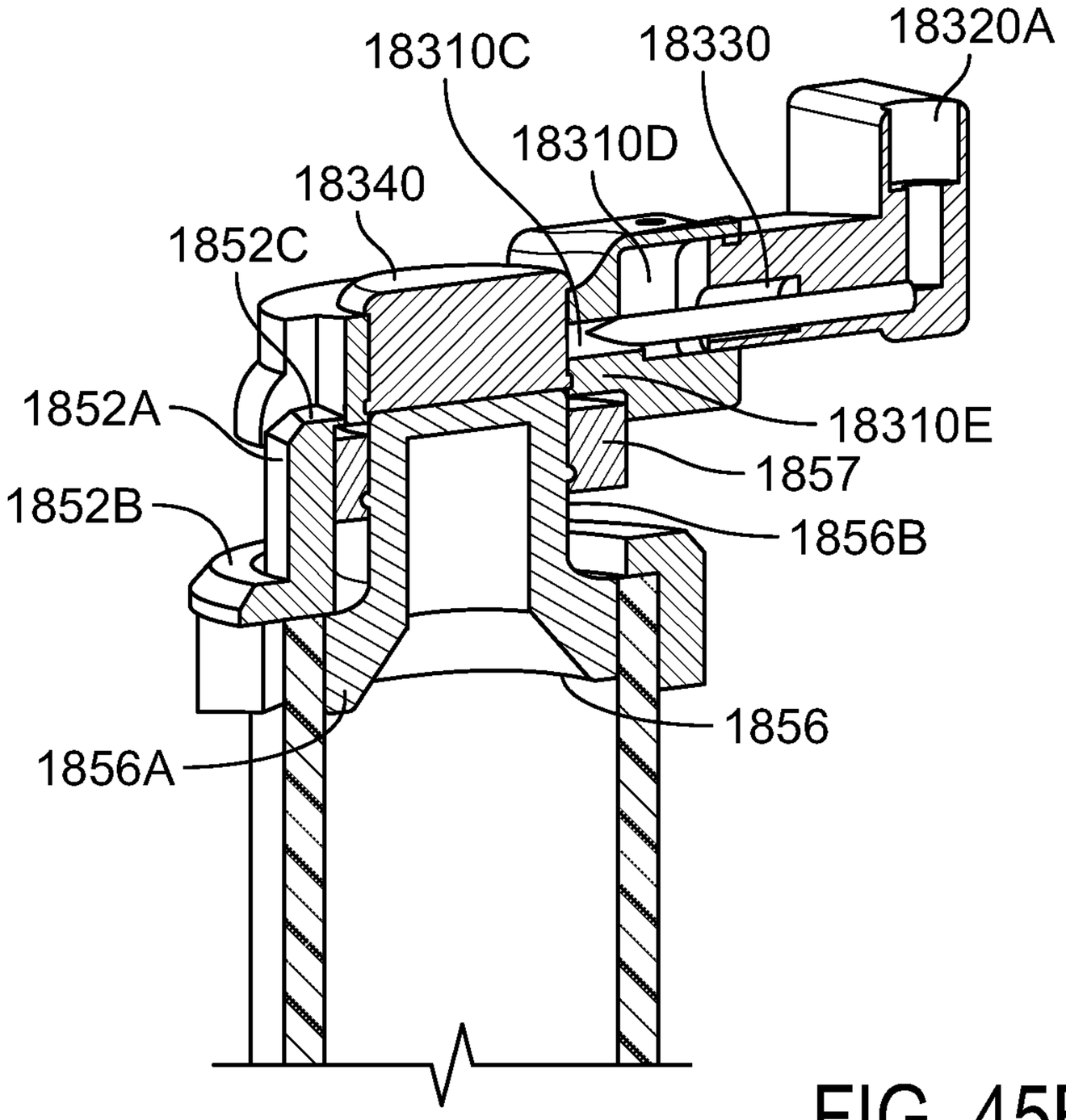


FIG. 45B

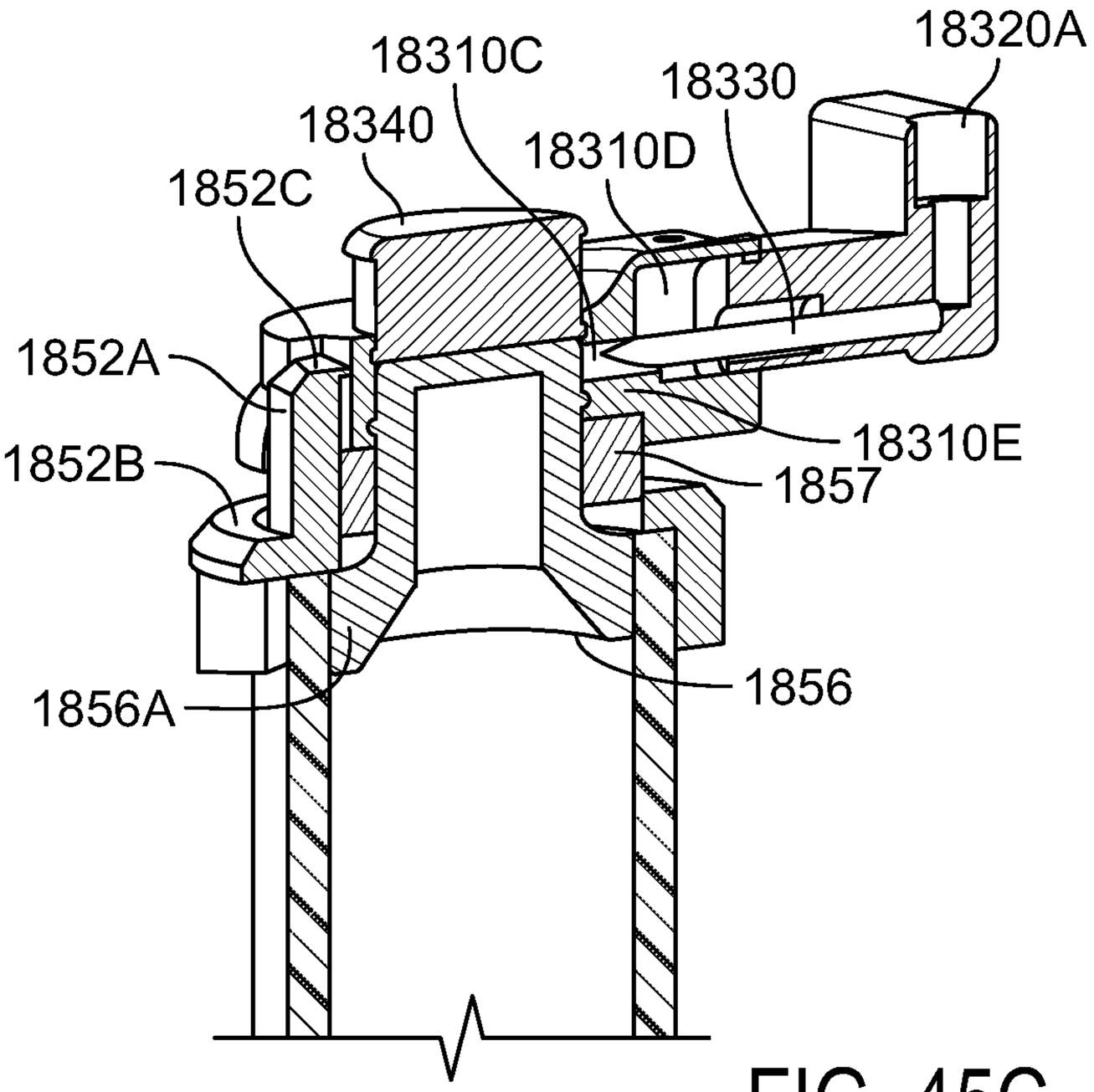


FIG. 45C

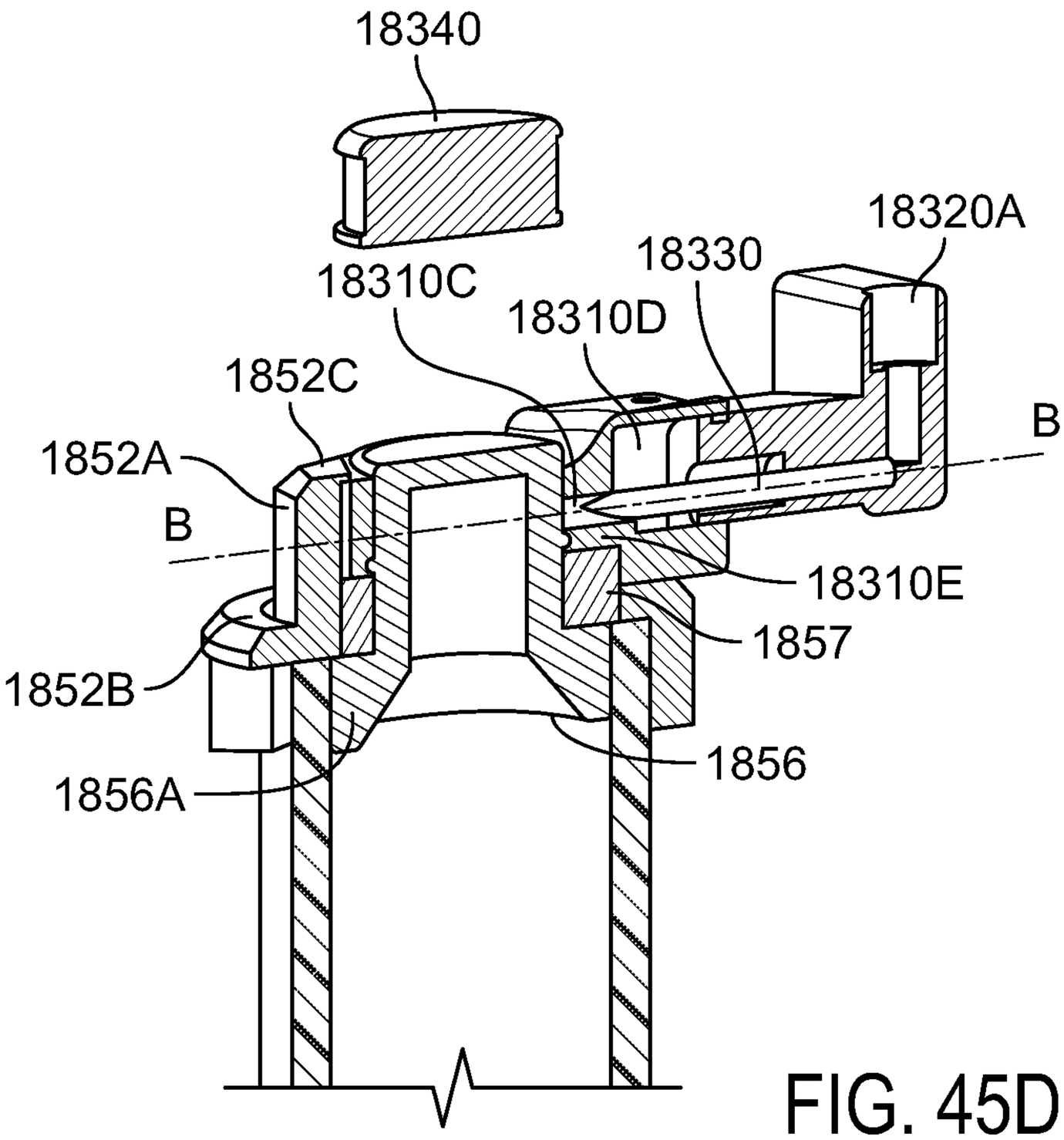


FIG. 45D

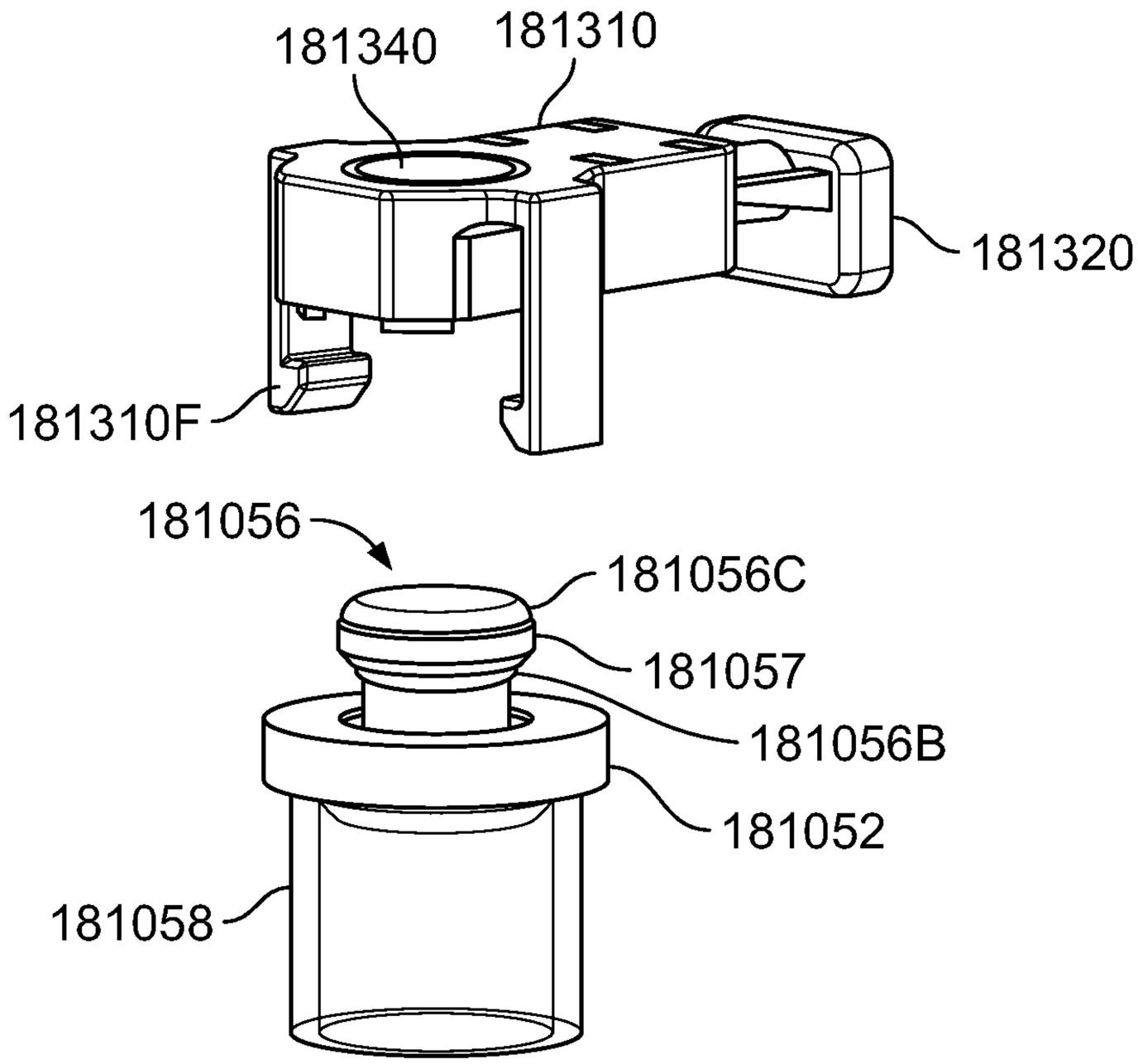


FIG. 46A

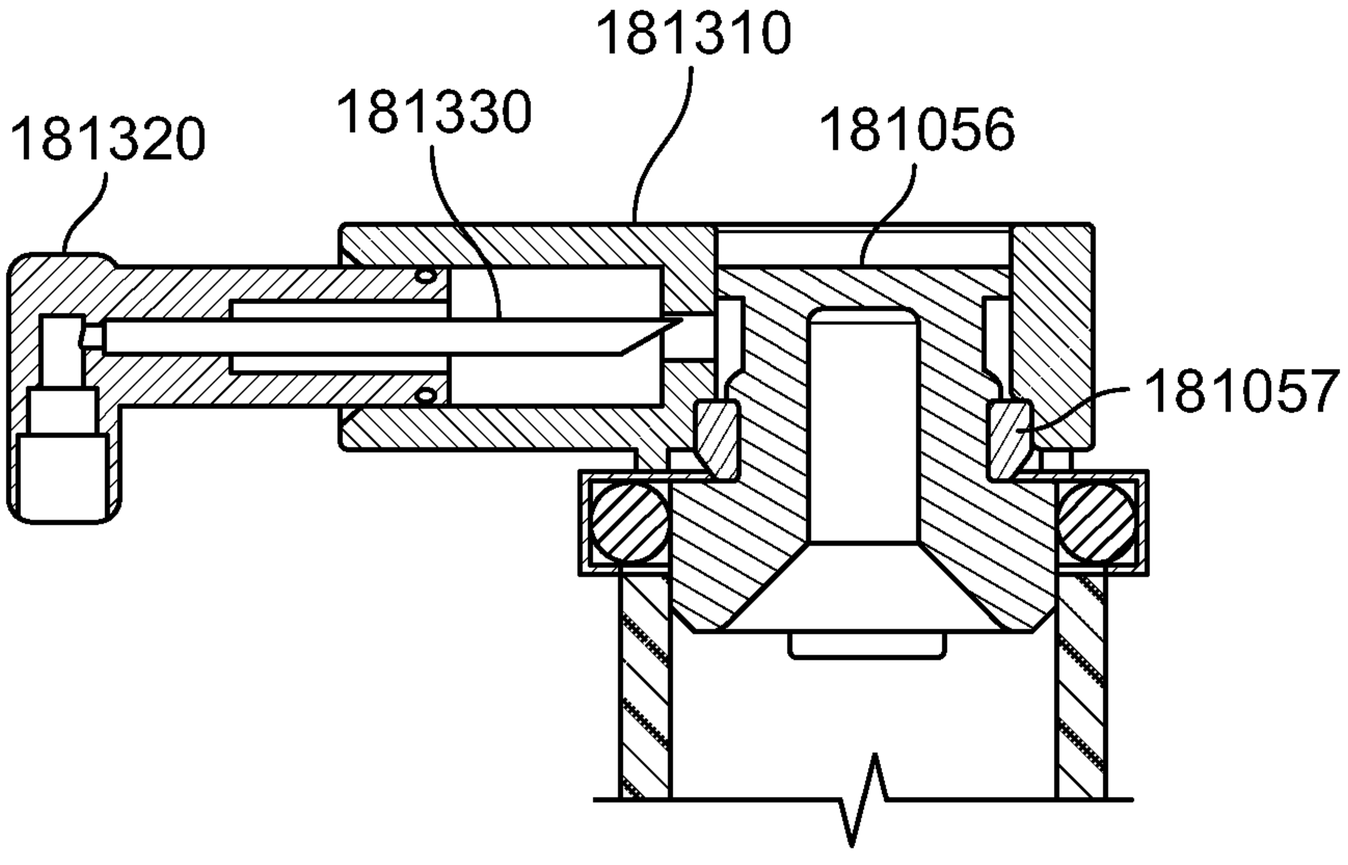


FIG. 46B

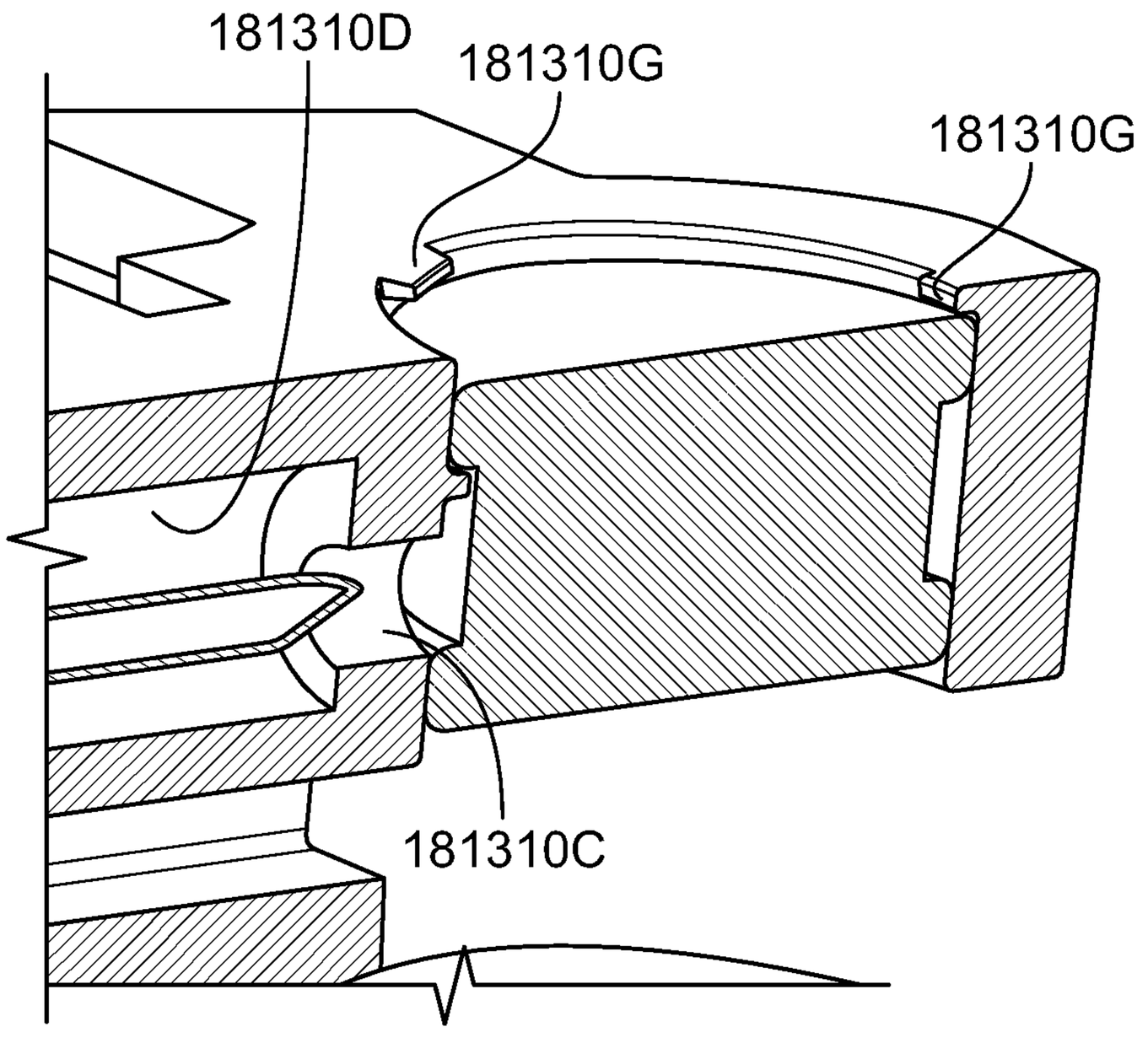


FIG. 47

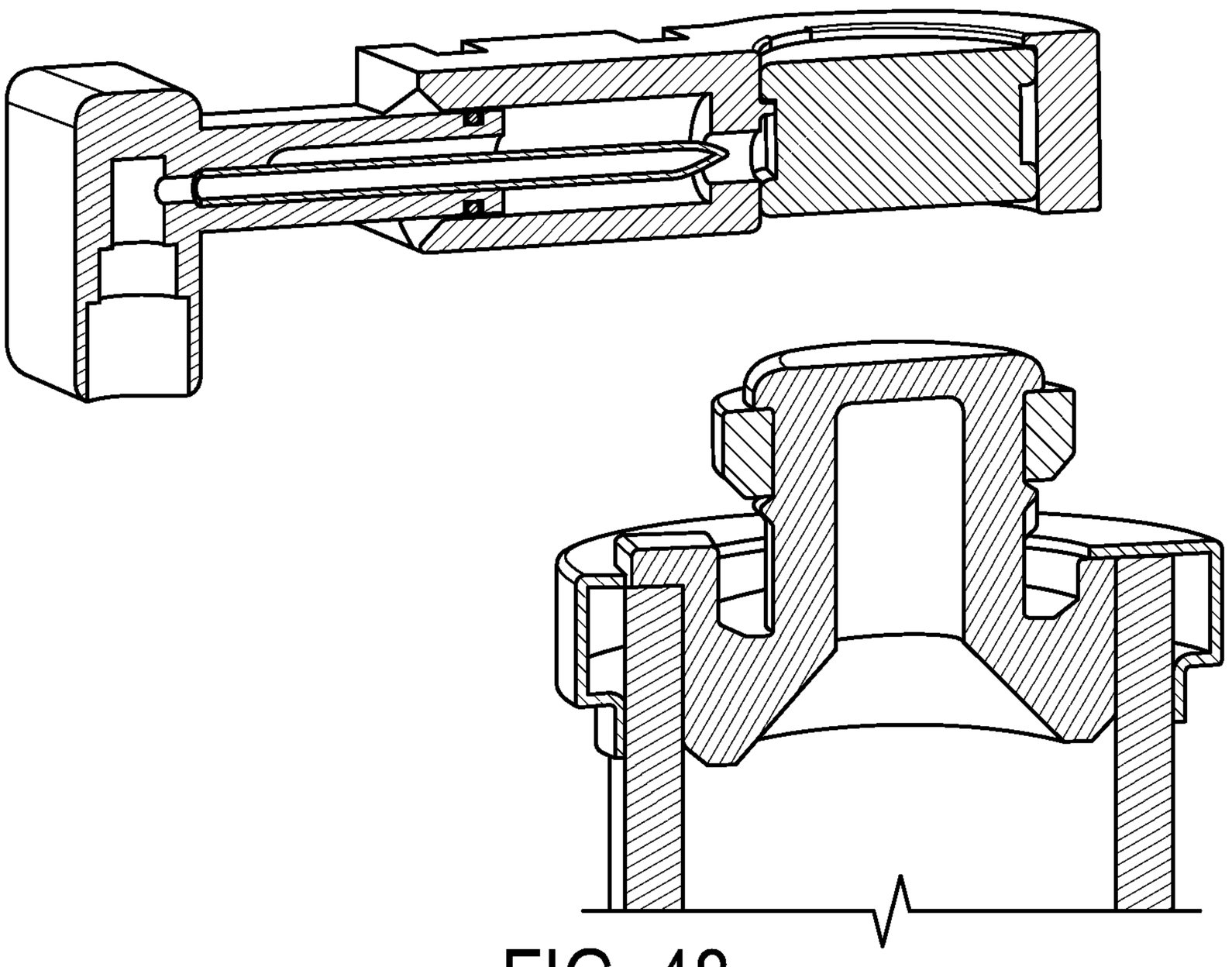


FIG. 48

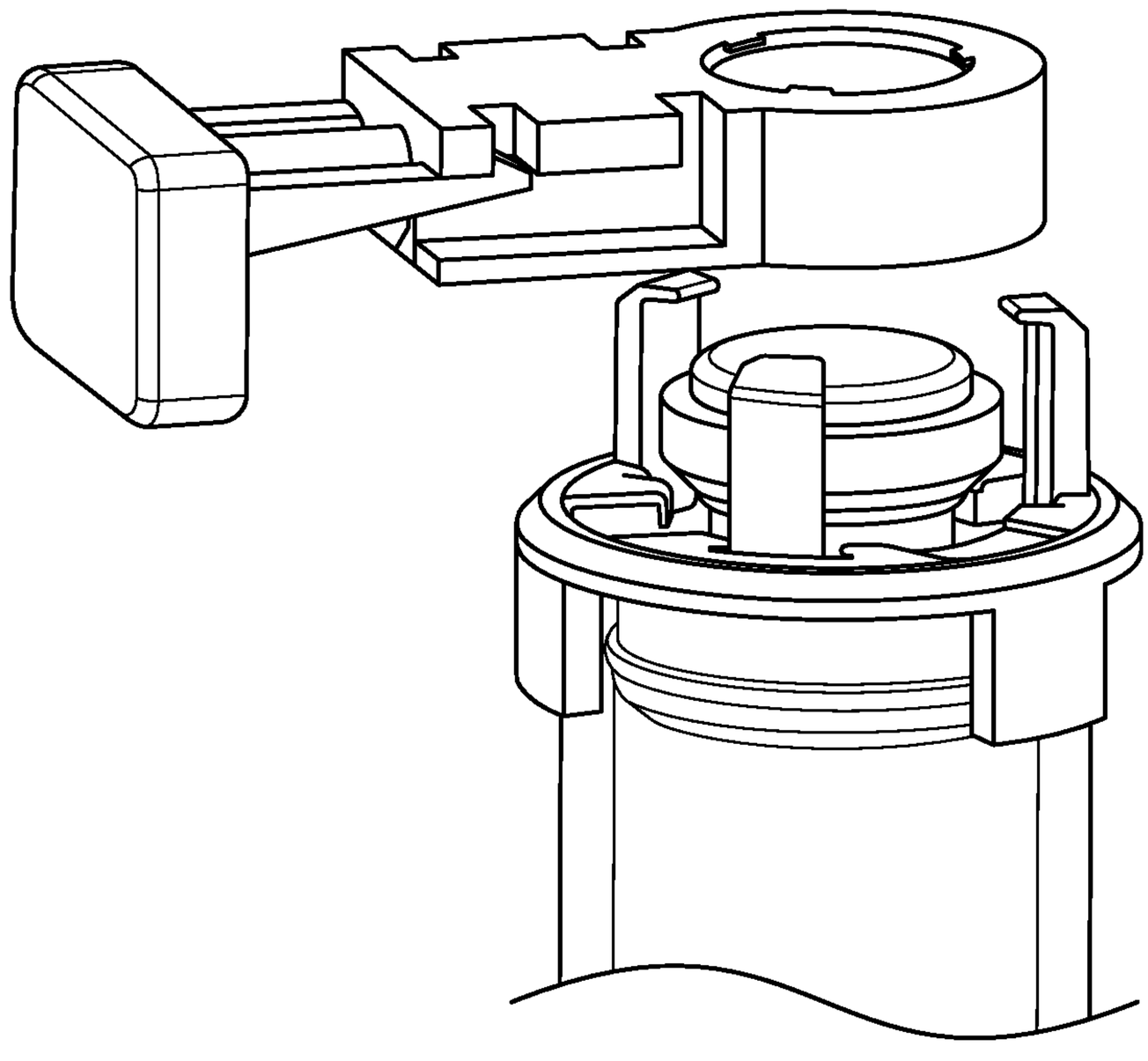
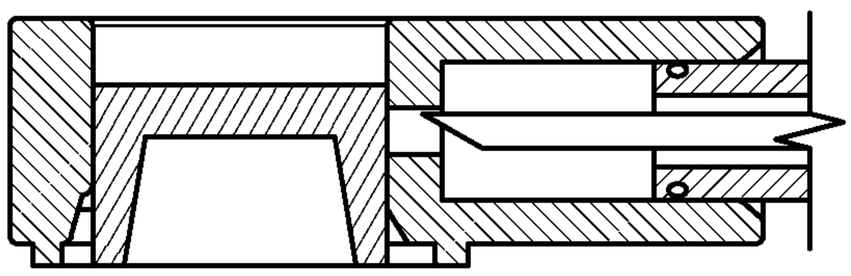


FIG. 49



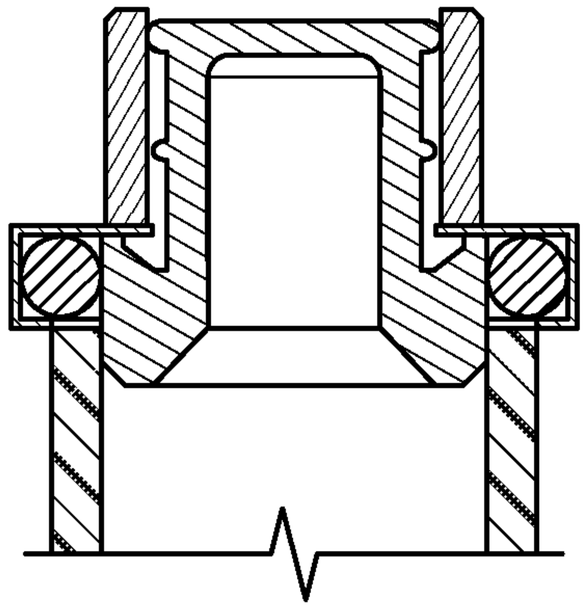


FIG. 50

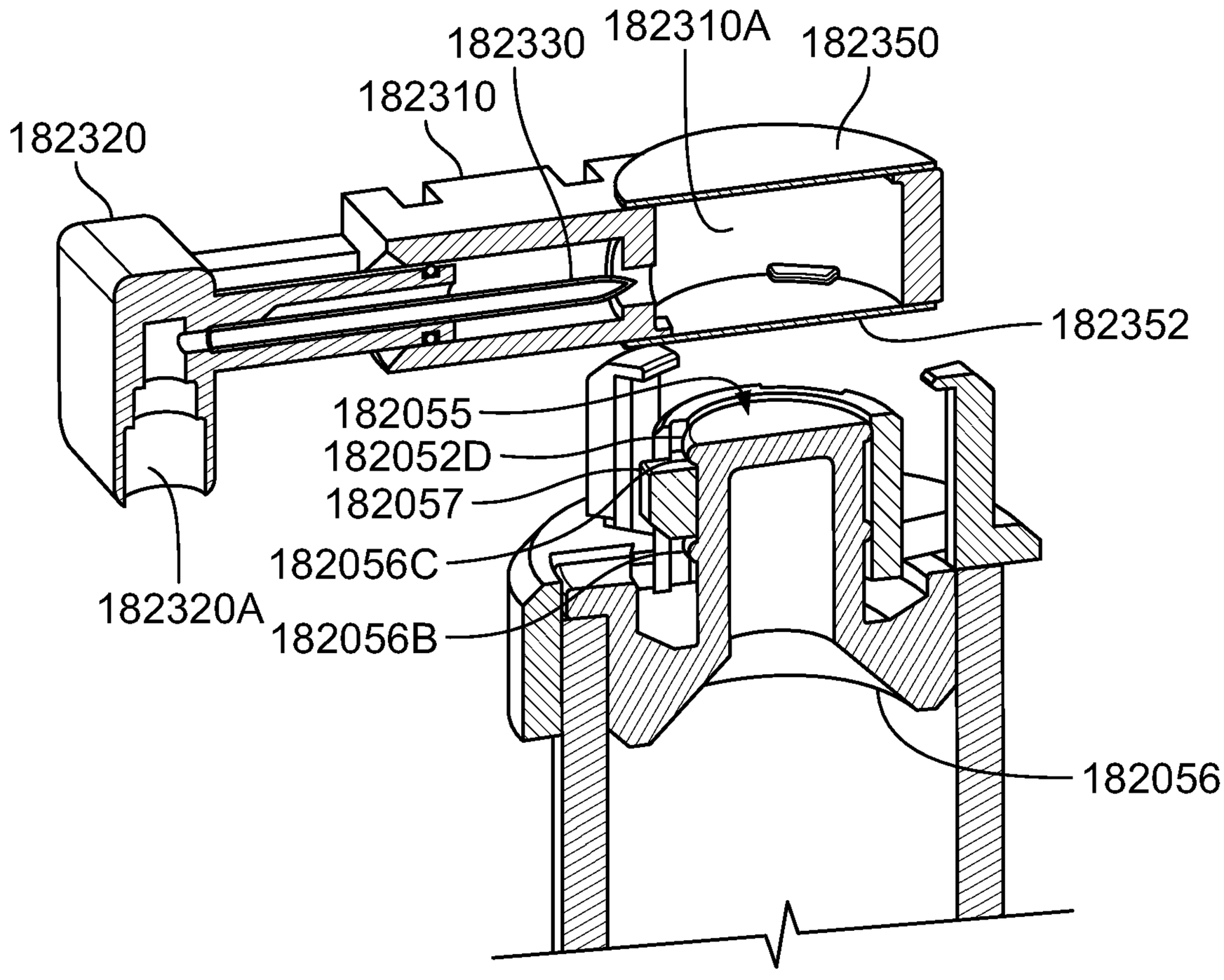

182330
182310A
182350
182310
182320
182352
182055
182052D
182057
182056C
182320A
182056B
182056

FIG. 51

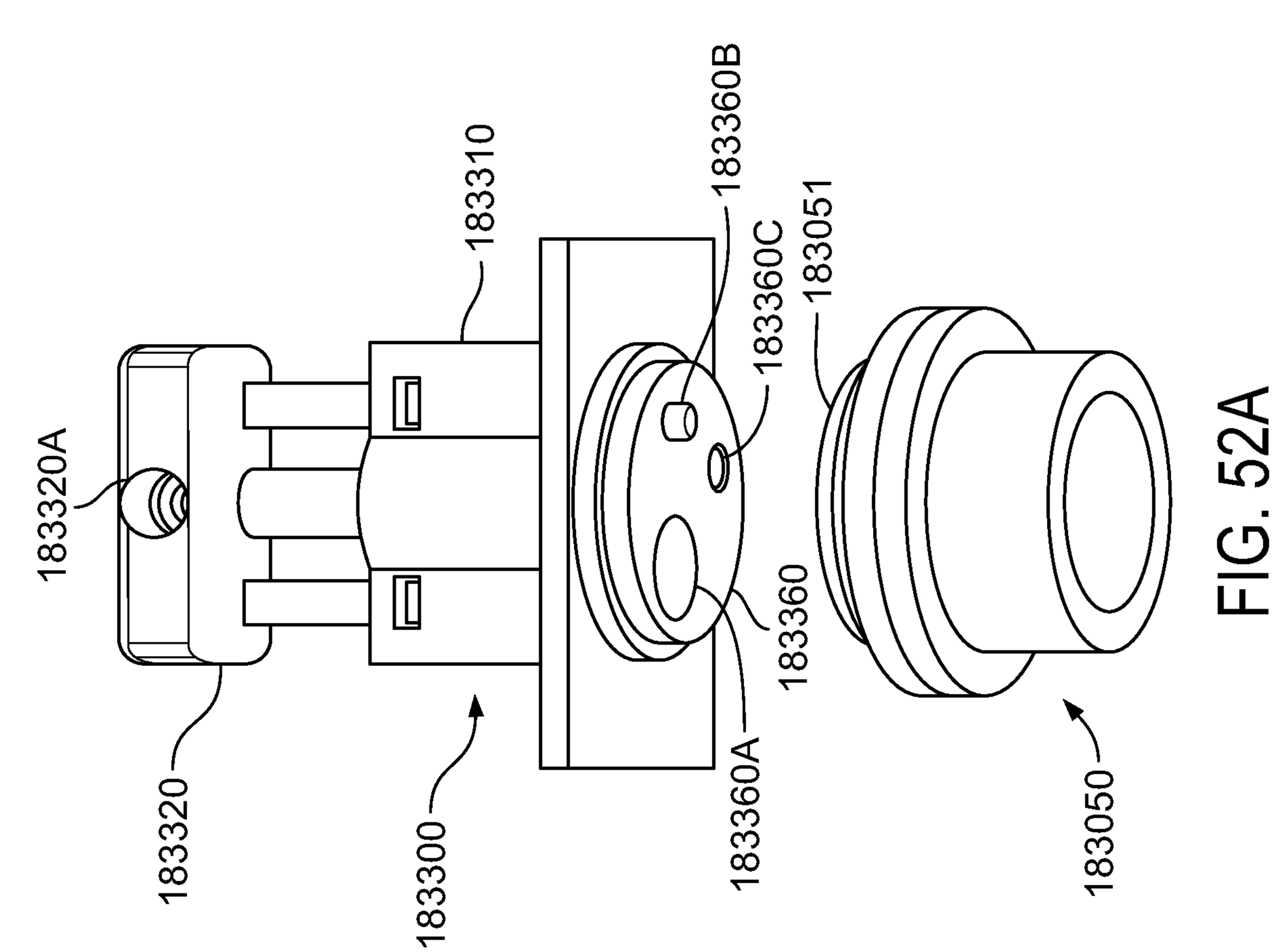


FIG. 52A

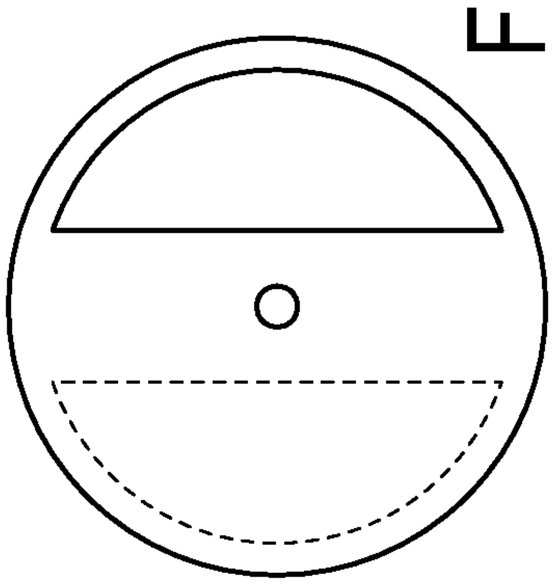


FIG. 52B

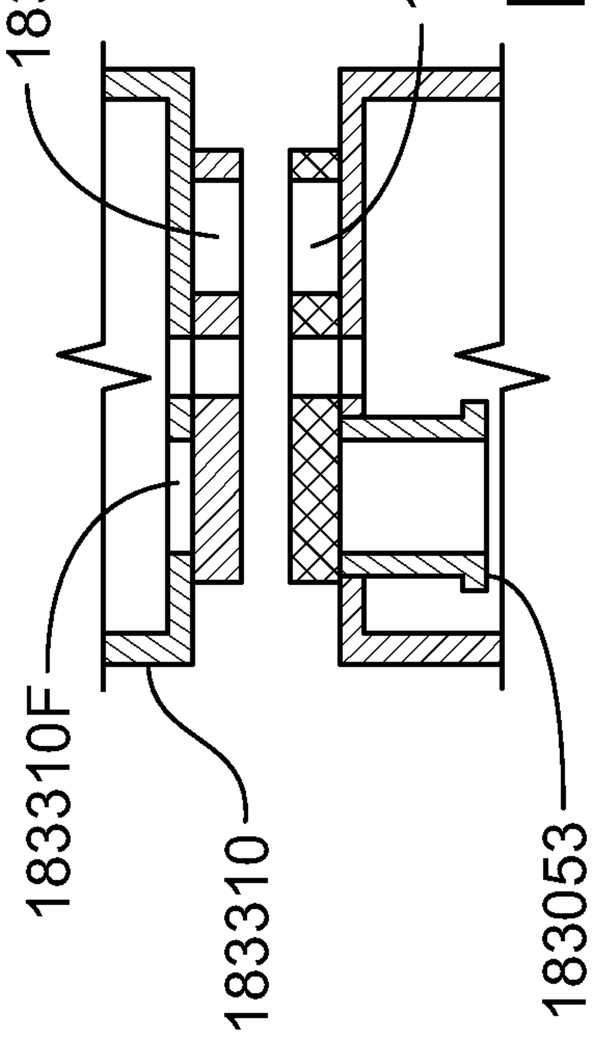


FIG. 52C

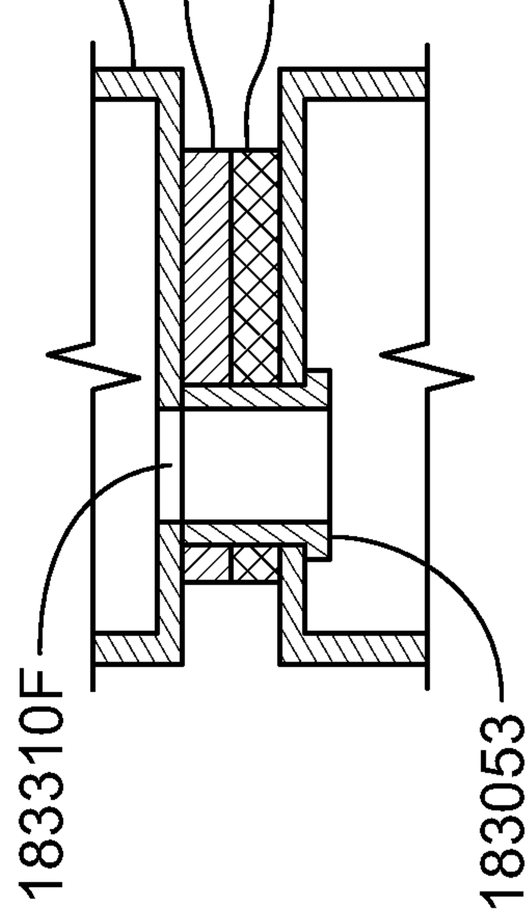


FIG. 52D

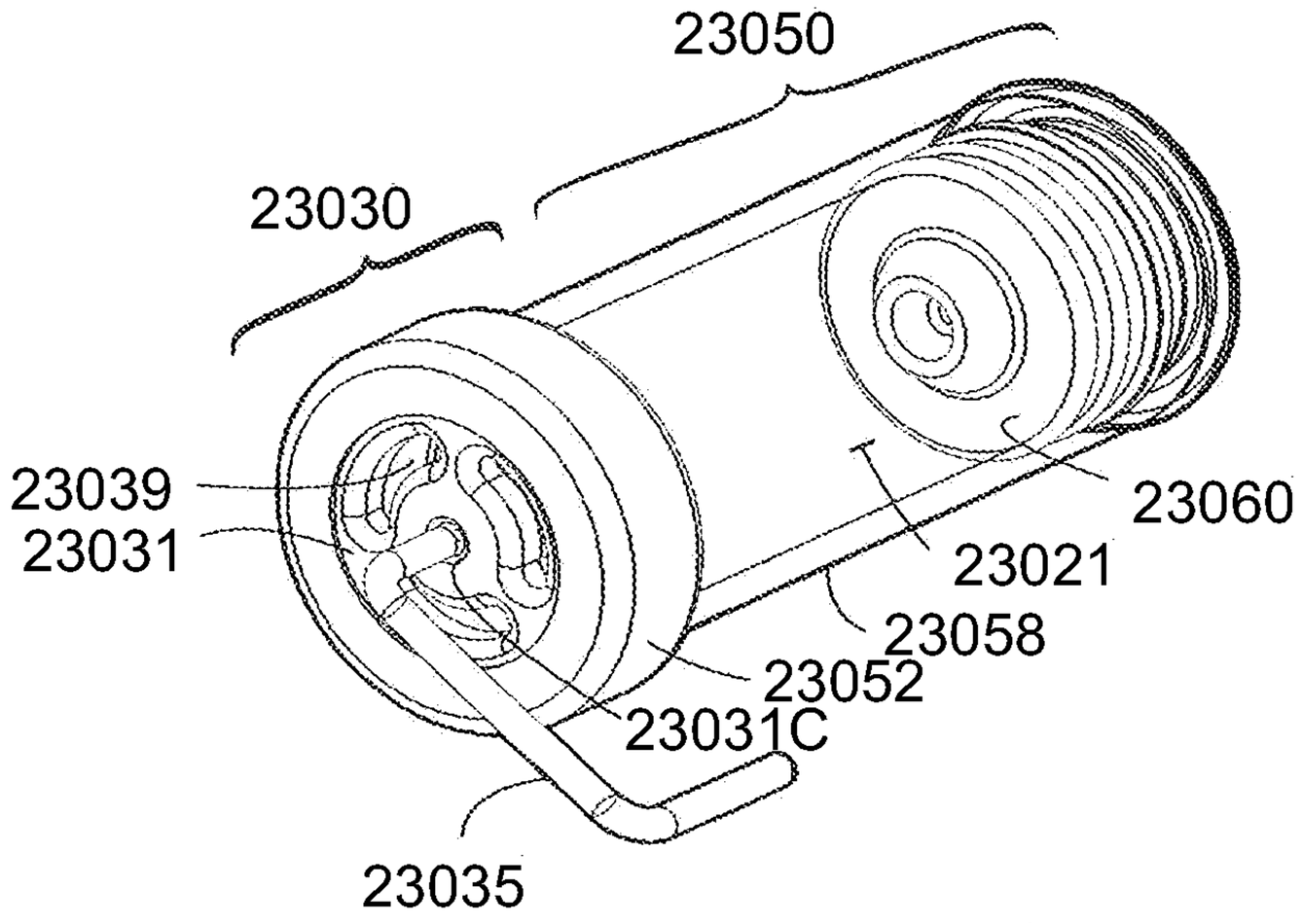


FIG. 53A

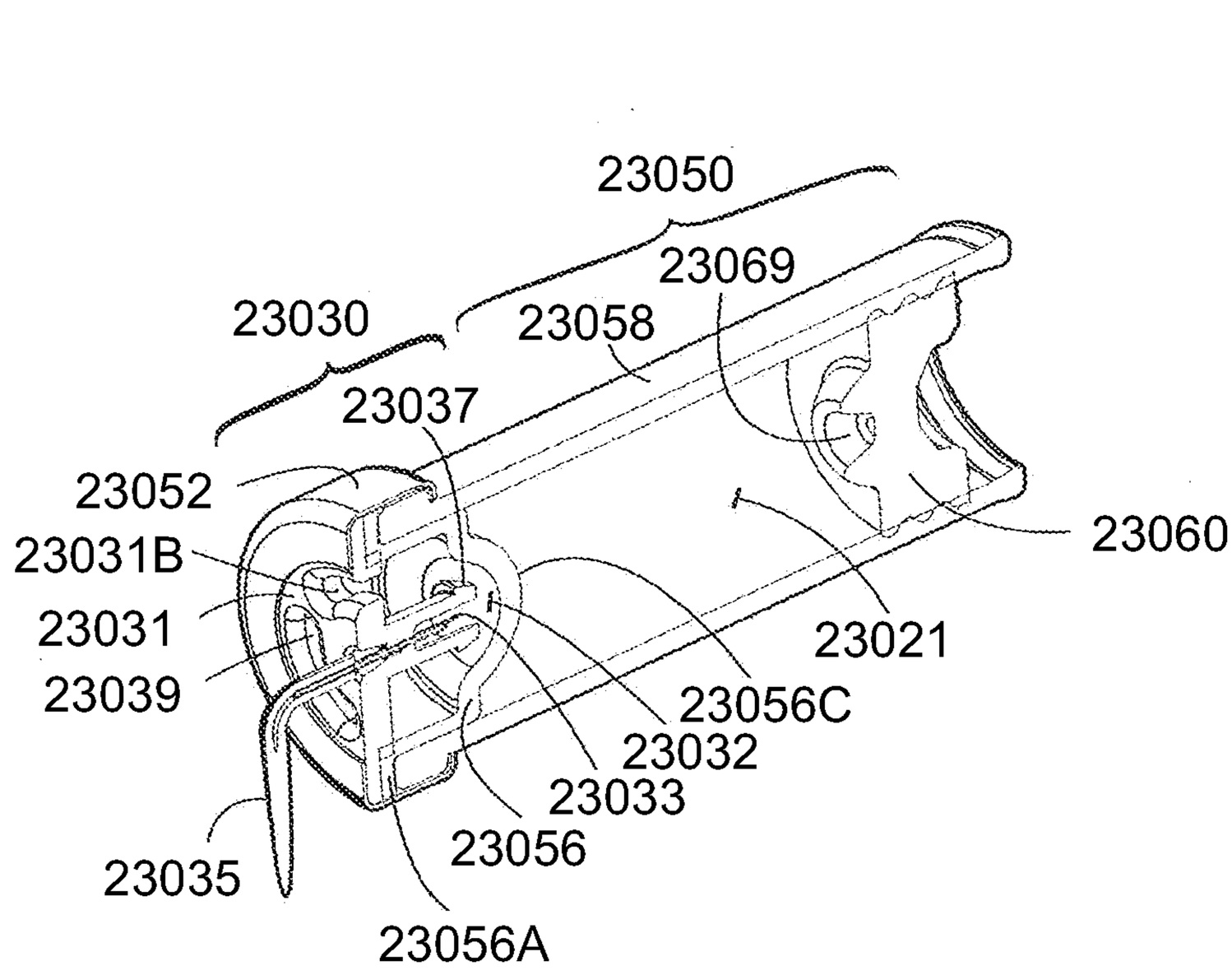
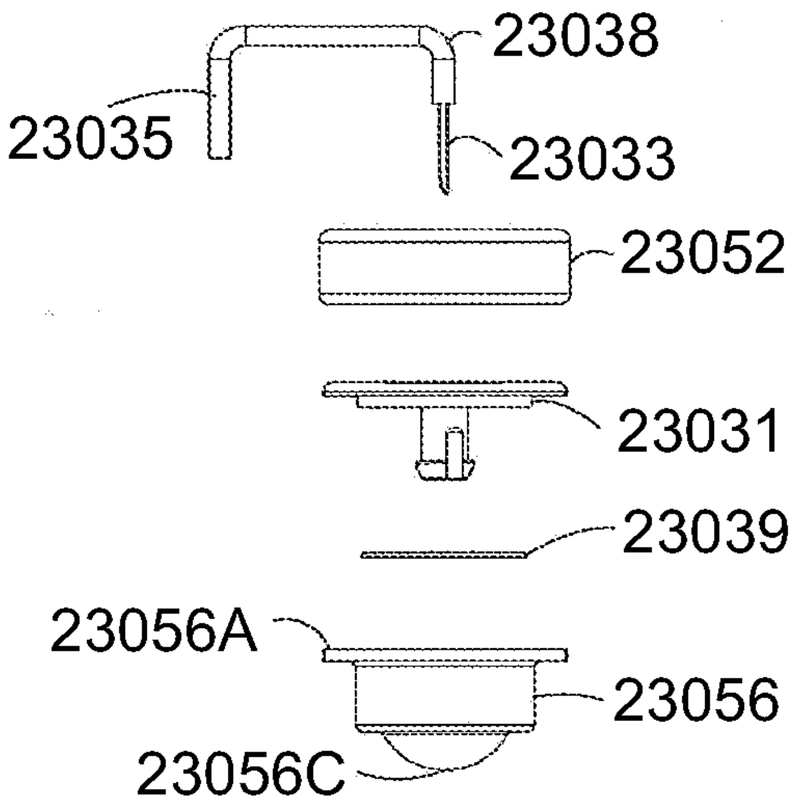
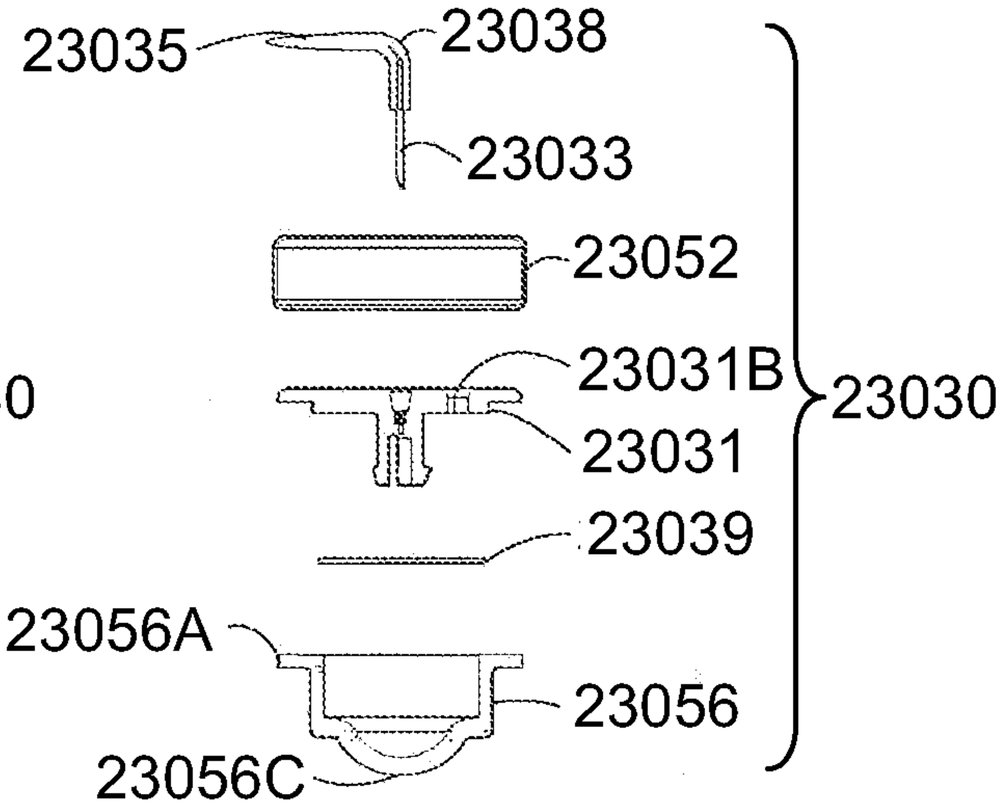
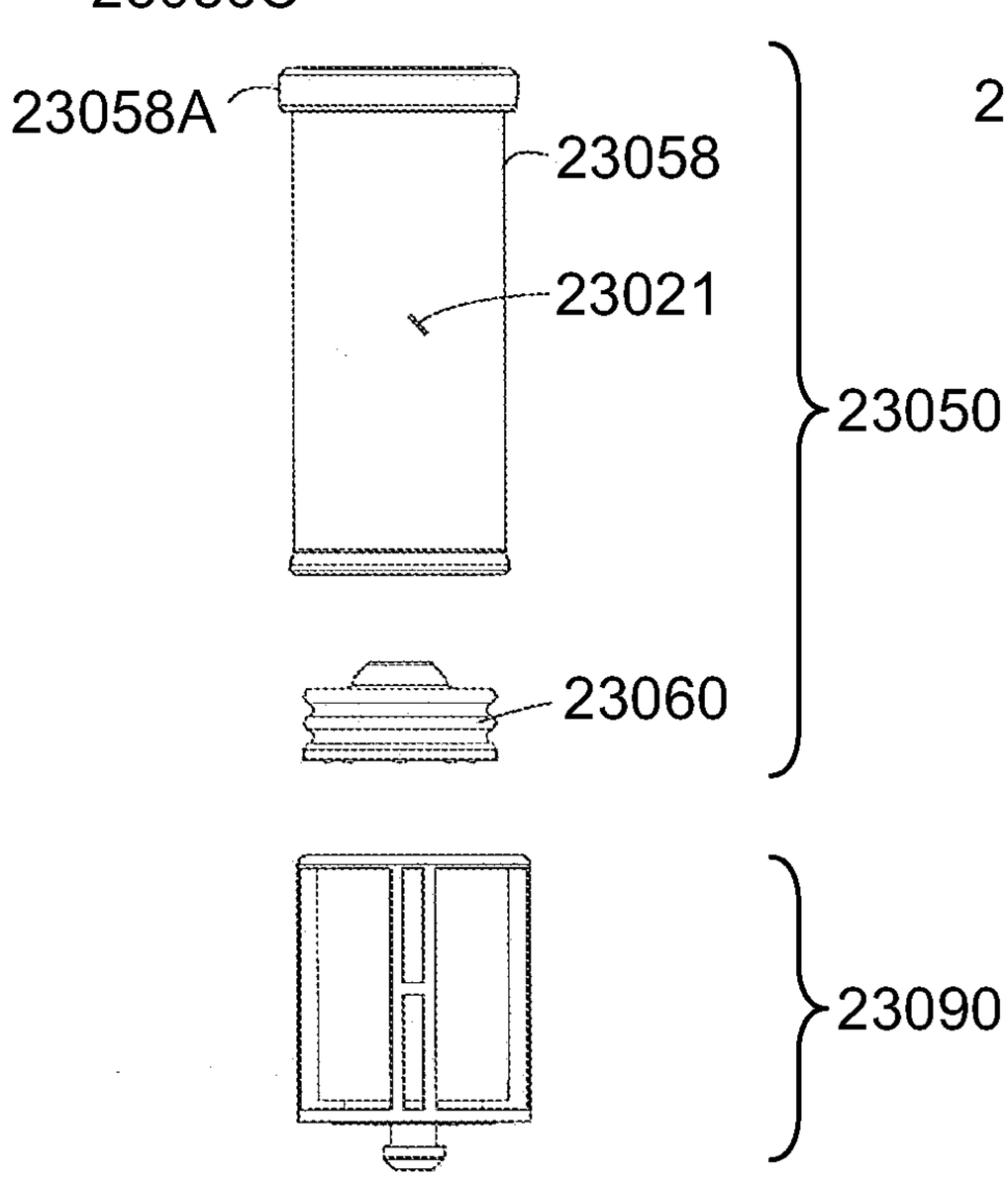


FIG. 53B







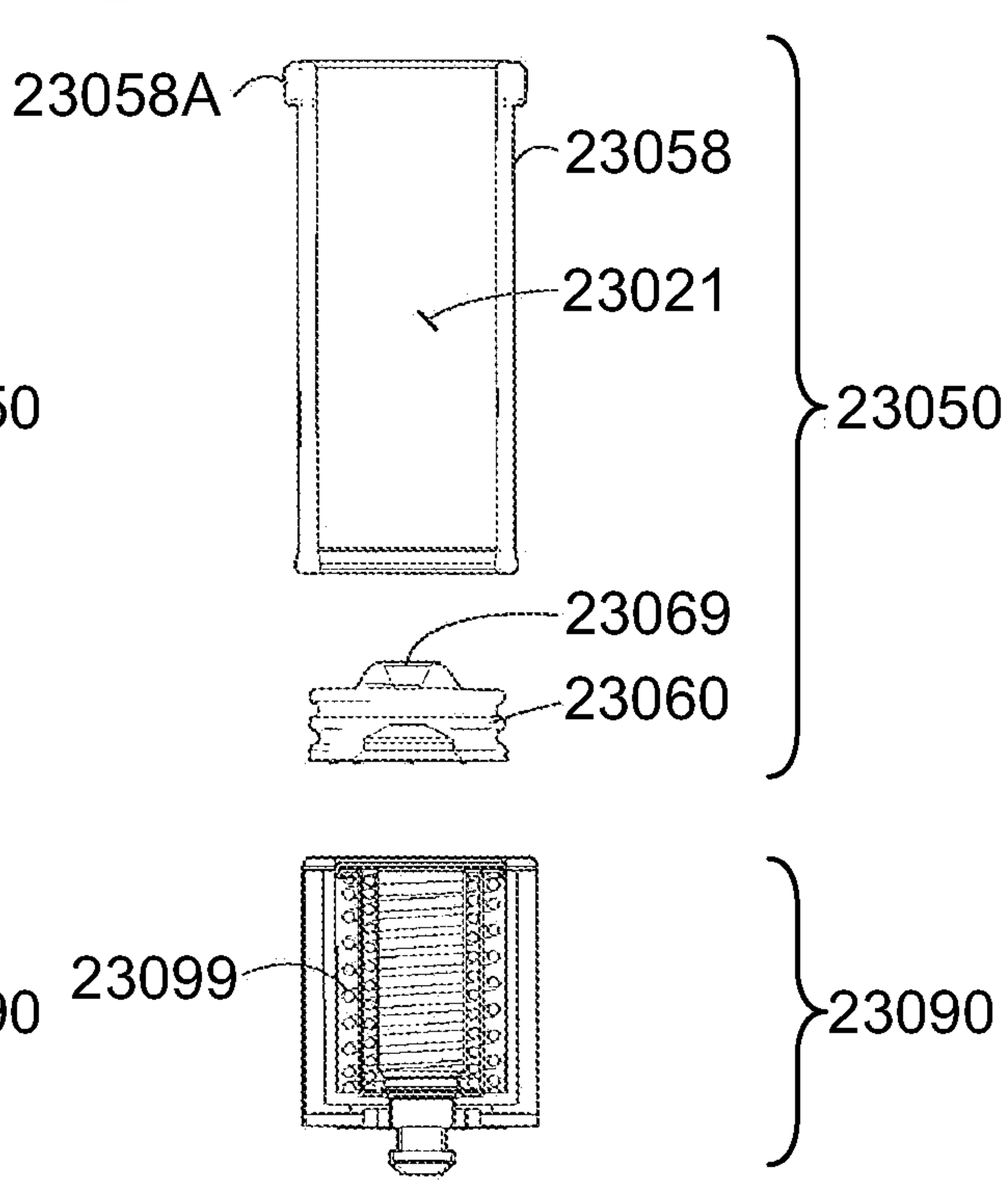


FIG. 54A

FIG. 54B

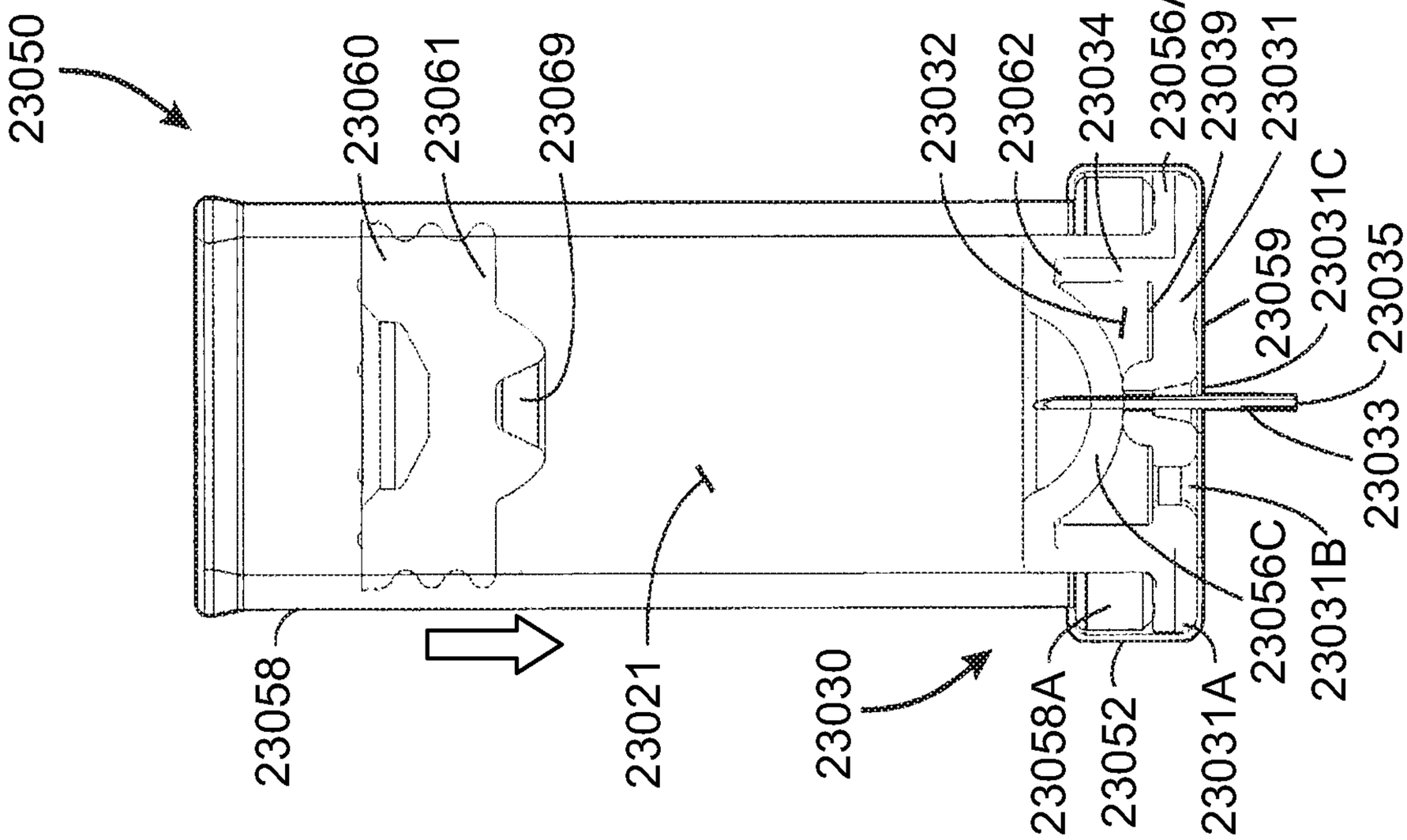


FIG. 55B

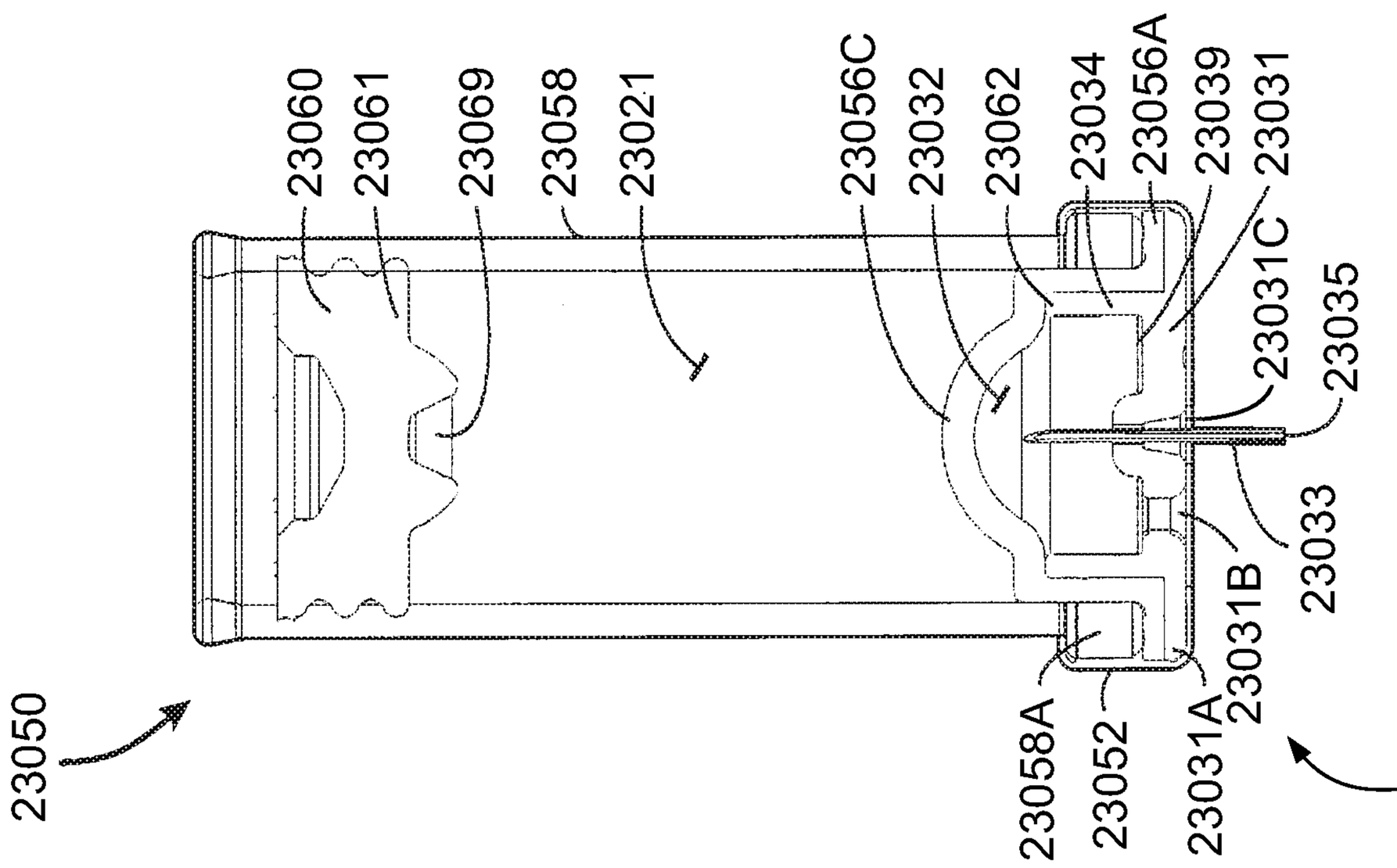


FIG. 55A

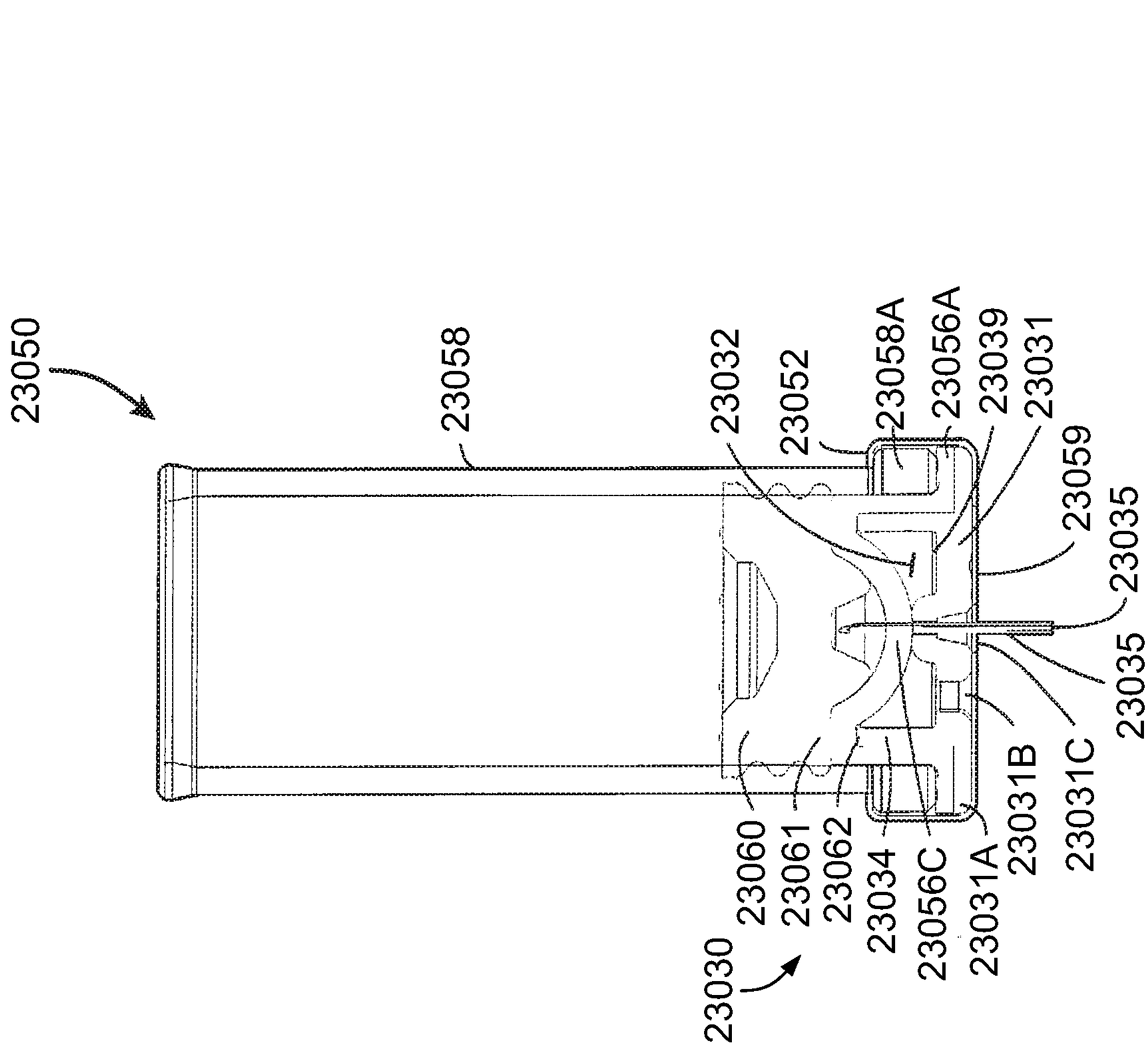

23050
23058
23032
23052
23058A
23056A
23039
23031
23059
23035
23031C
23031B
23031A
23056C
23034
23062
23061
23060
23030

FIG. 55C

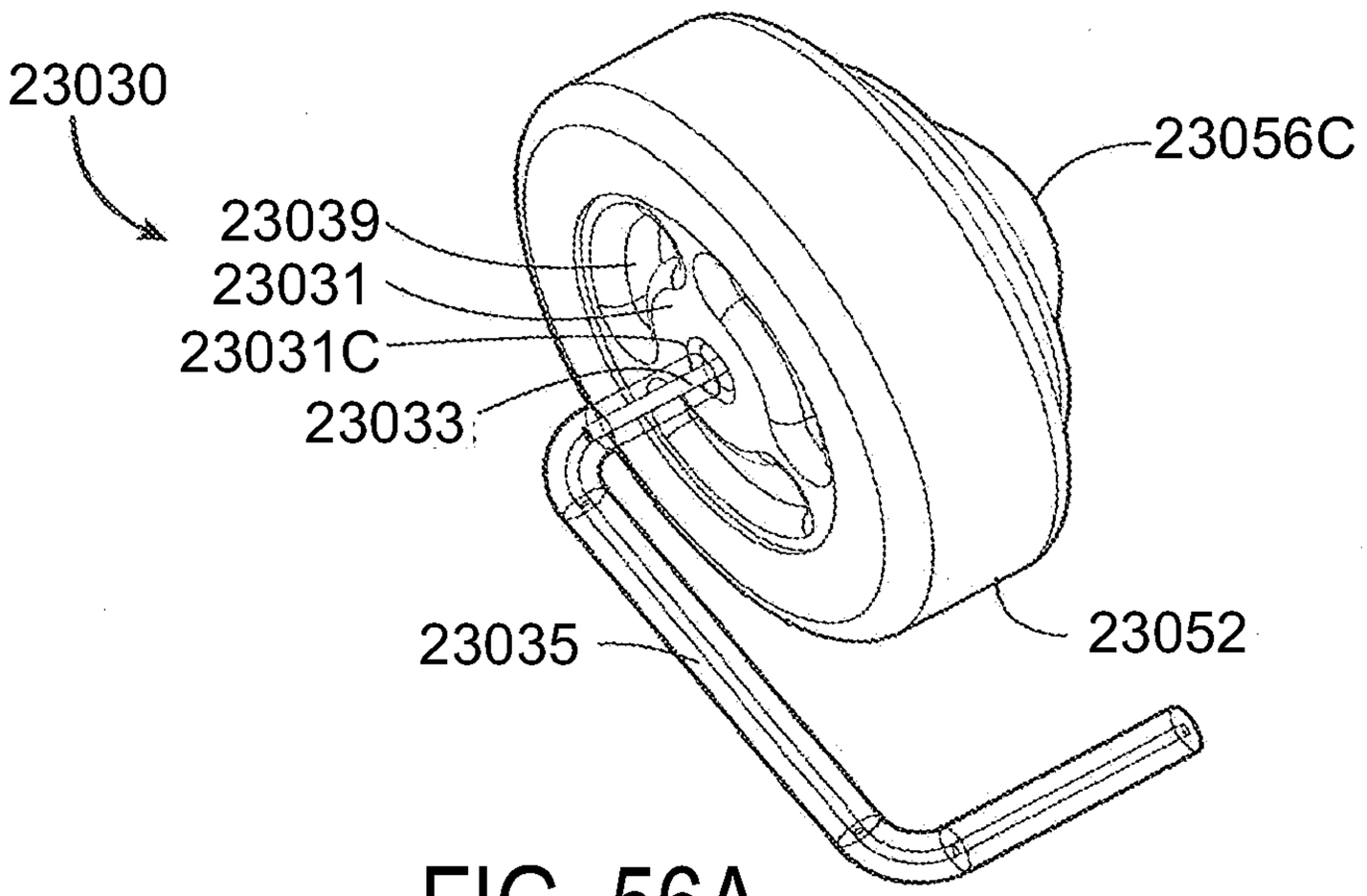


FIG. 56A

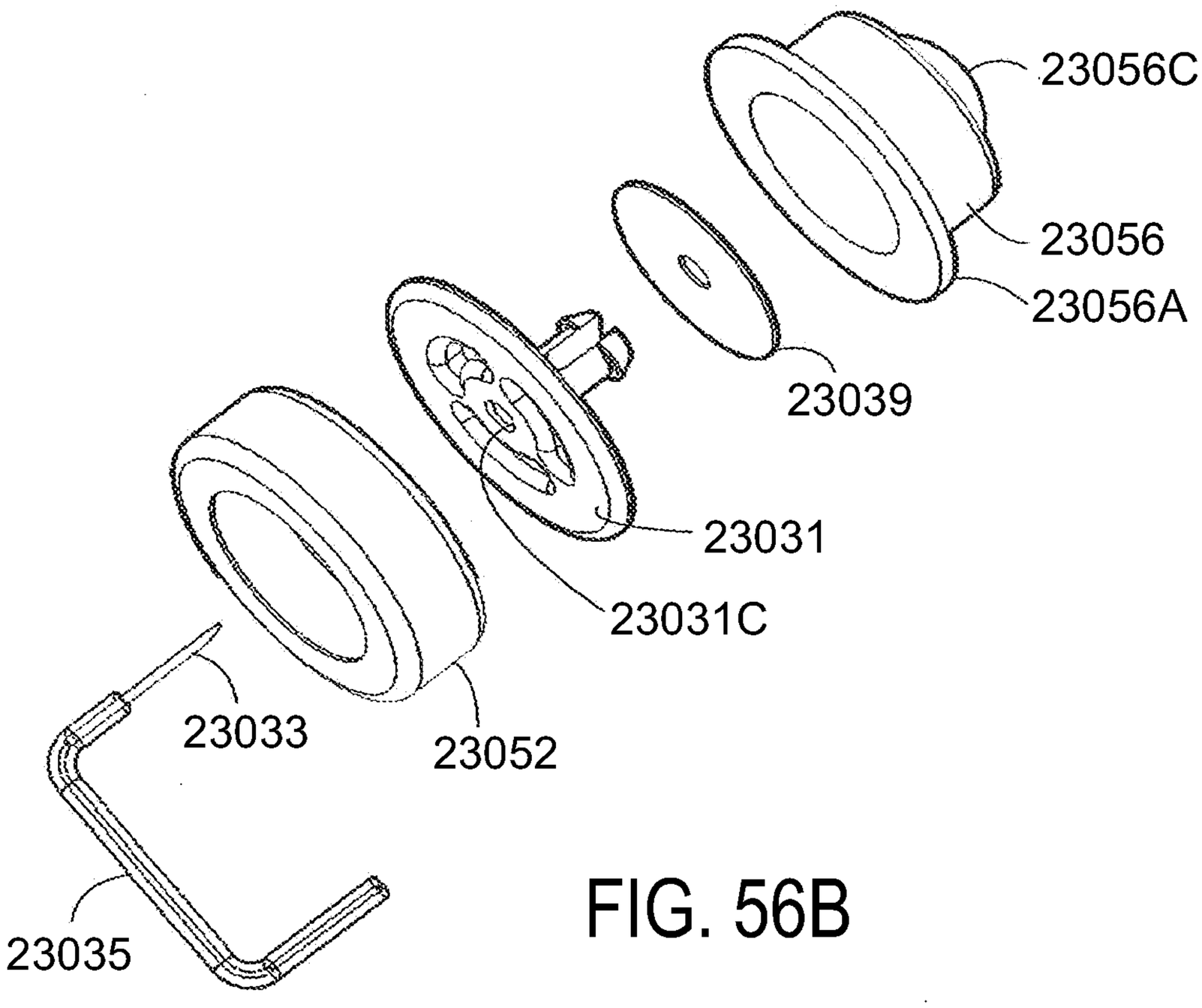


FIG. 56B

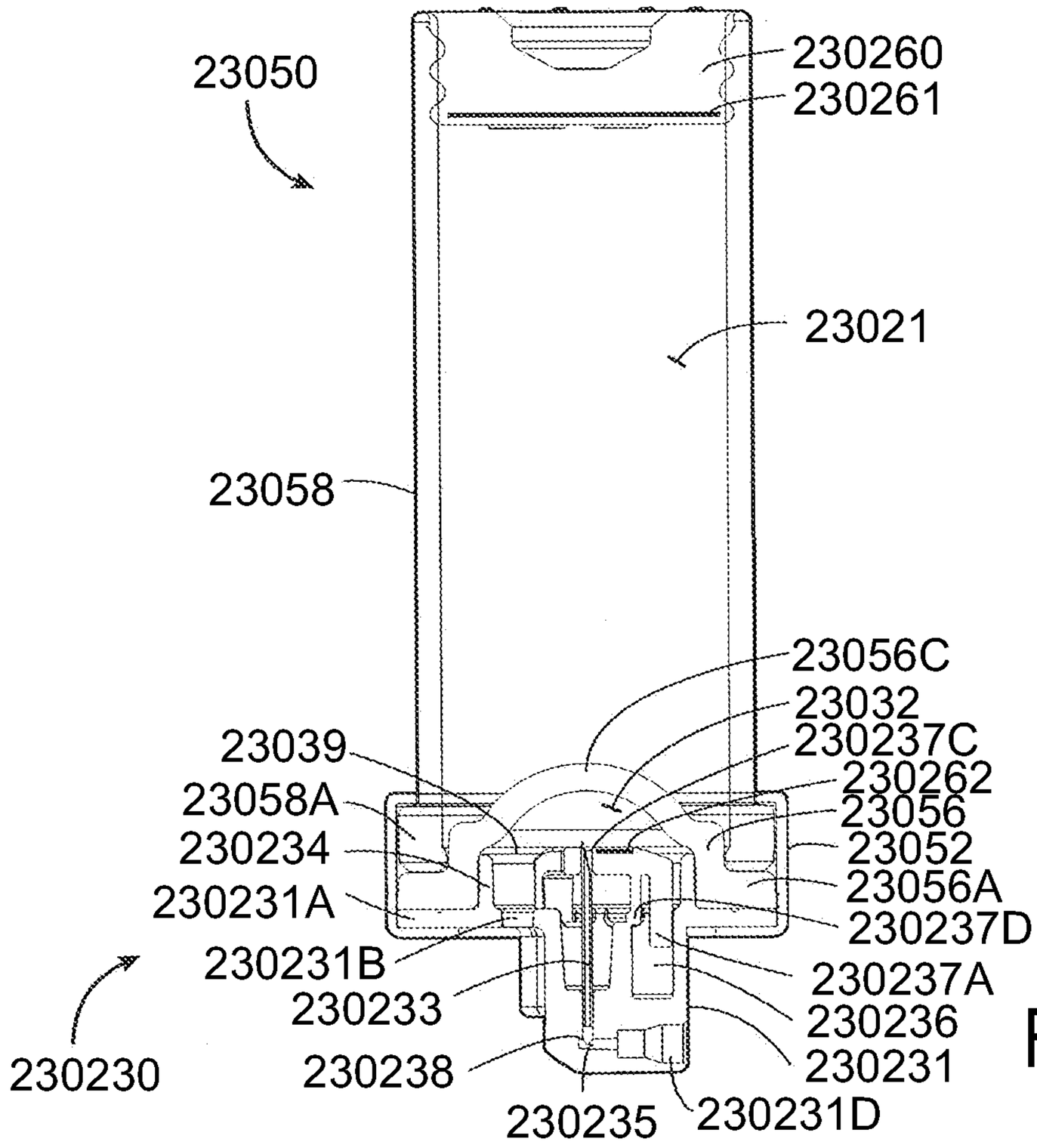


FIG. 57A

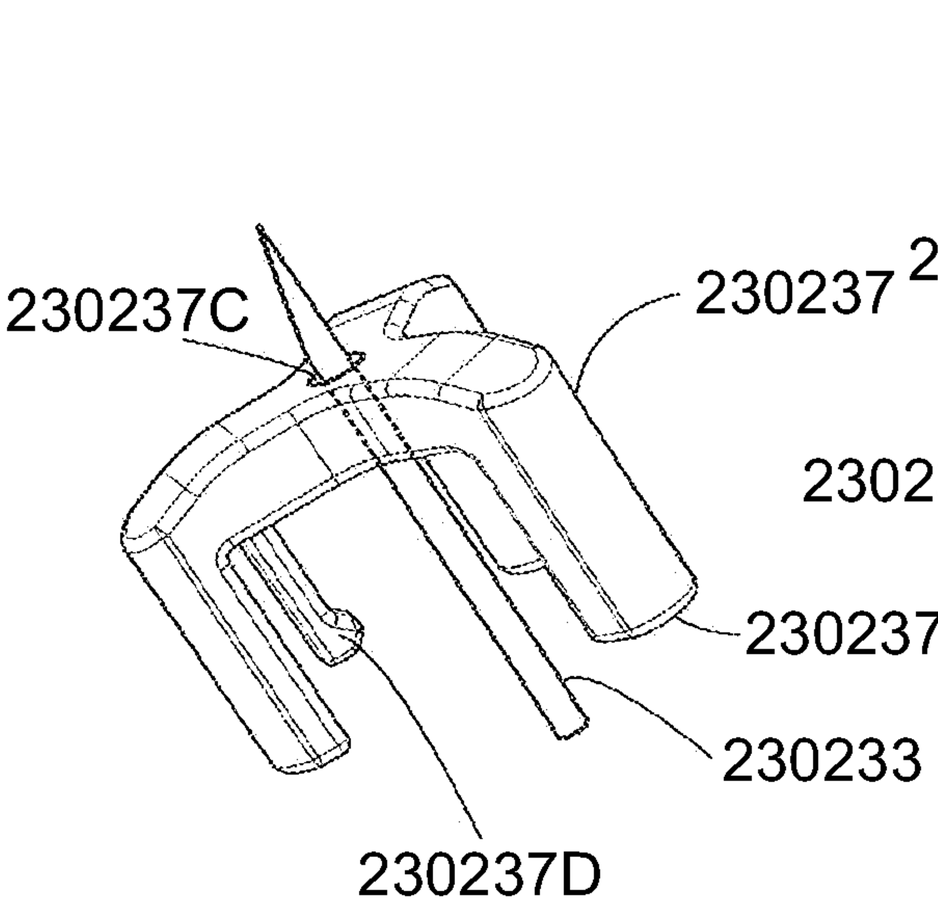


FIG. 57B

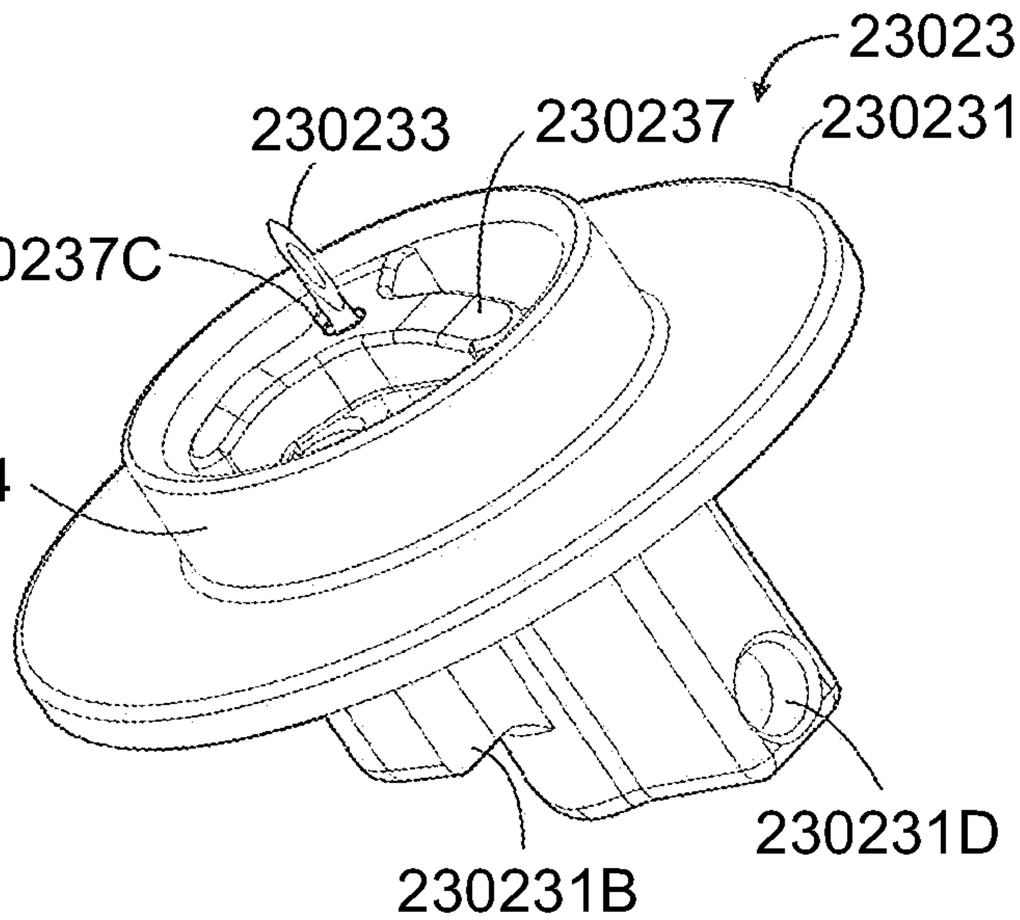


FIG. 57C

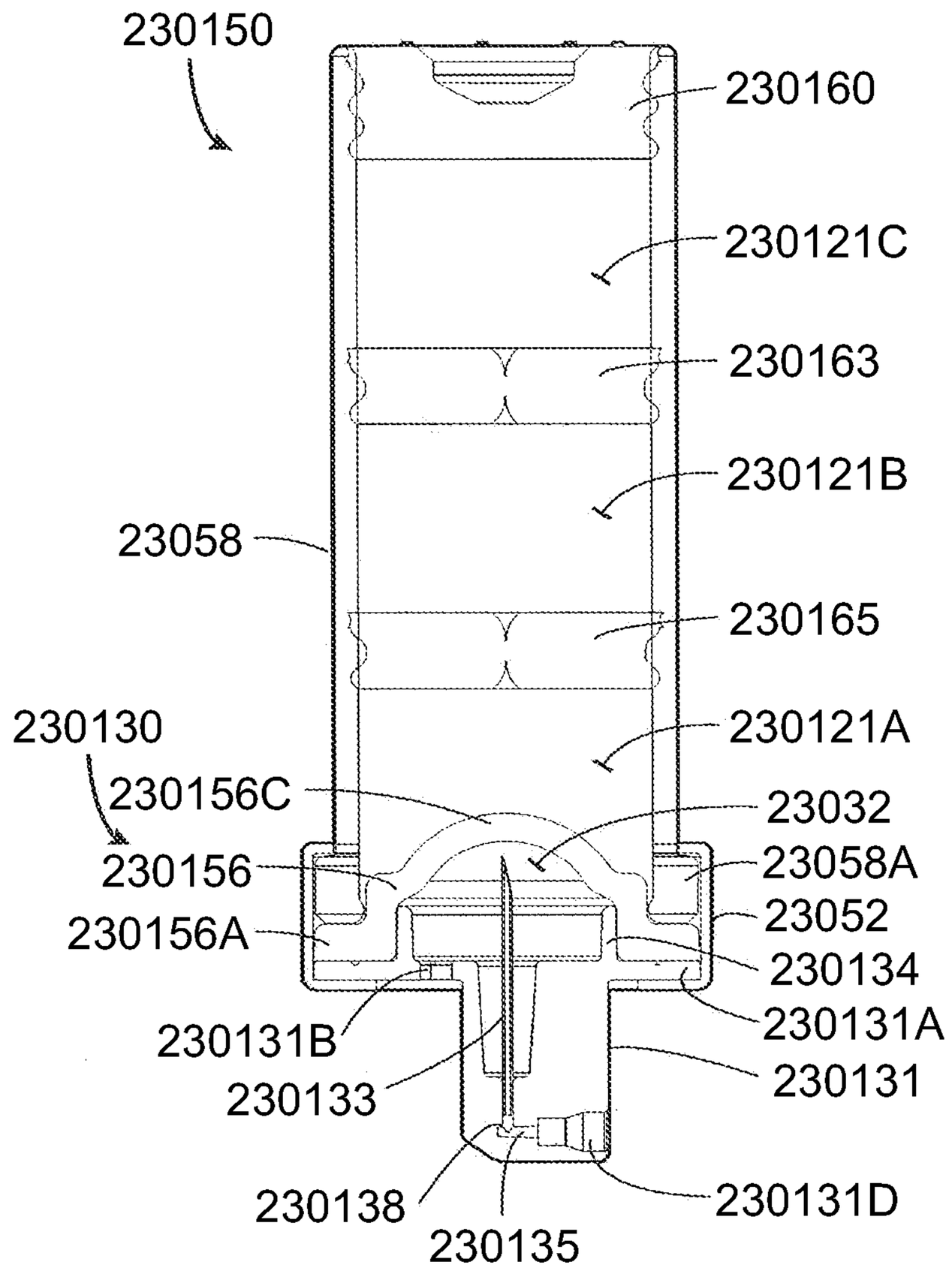

230150
230160
230121C
230163
230121B
23058
230165
230130
230121A
230156C
23032
230156
23058A
230156A
23052
230134
230131B
230131A
230133
230131
230138
230131D
230135

FIG. 58

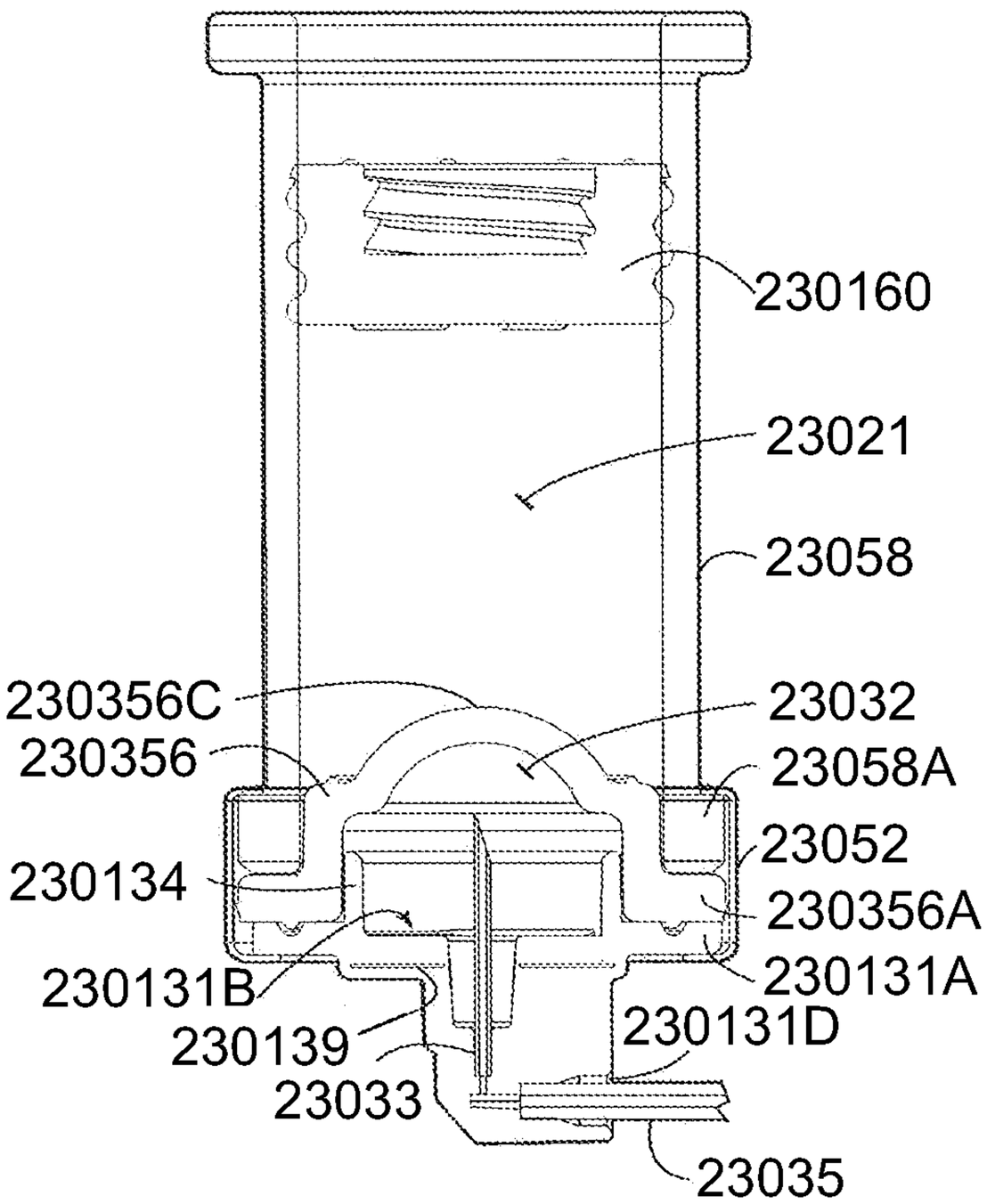


FIG. 59A

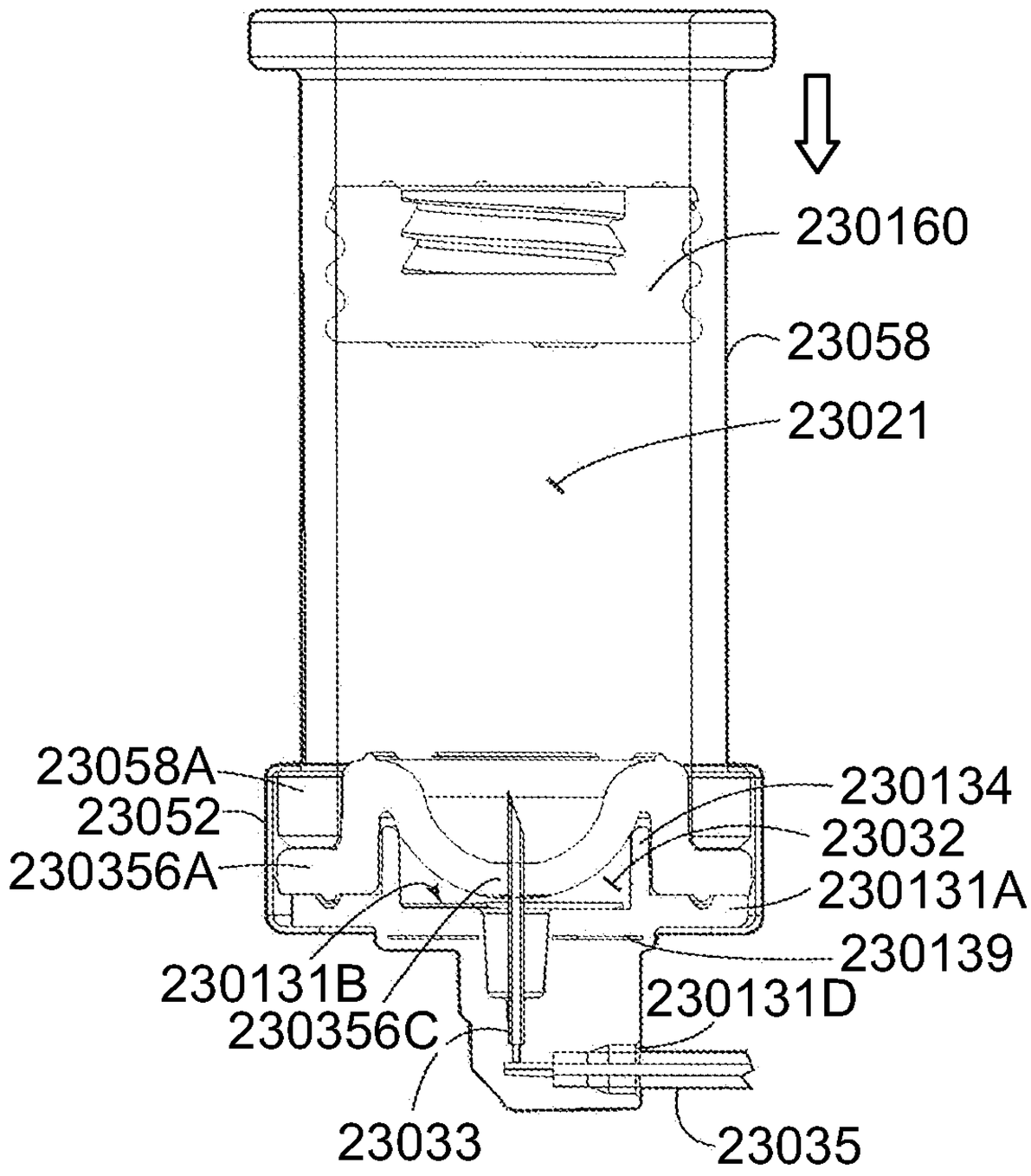


FIG. 59B

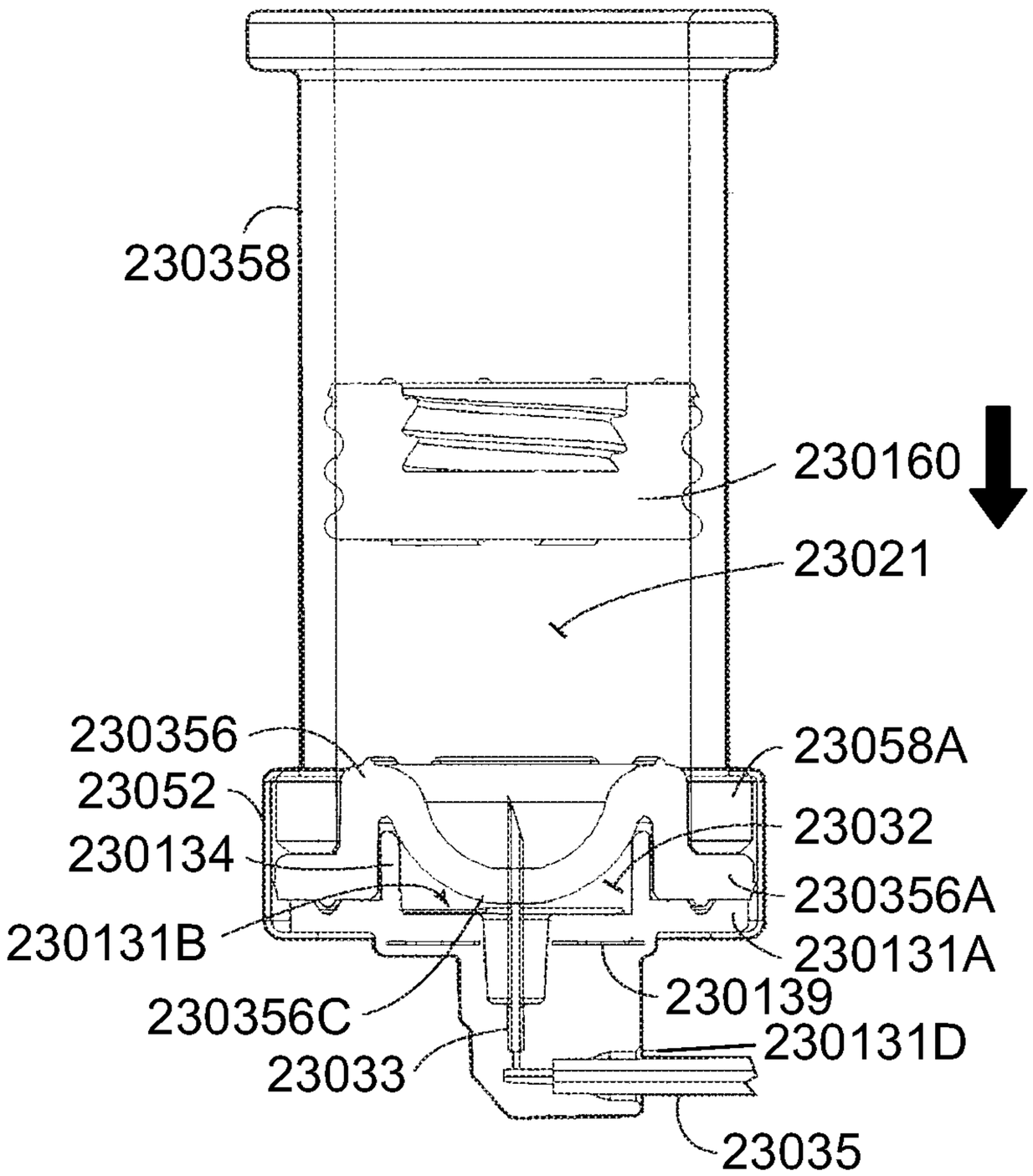


FIG. 59C

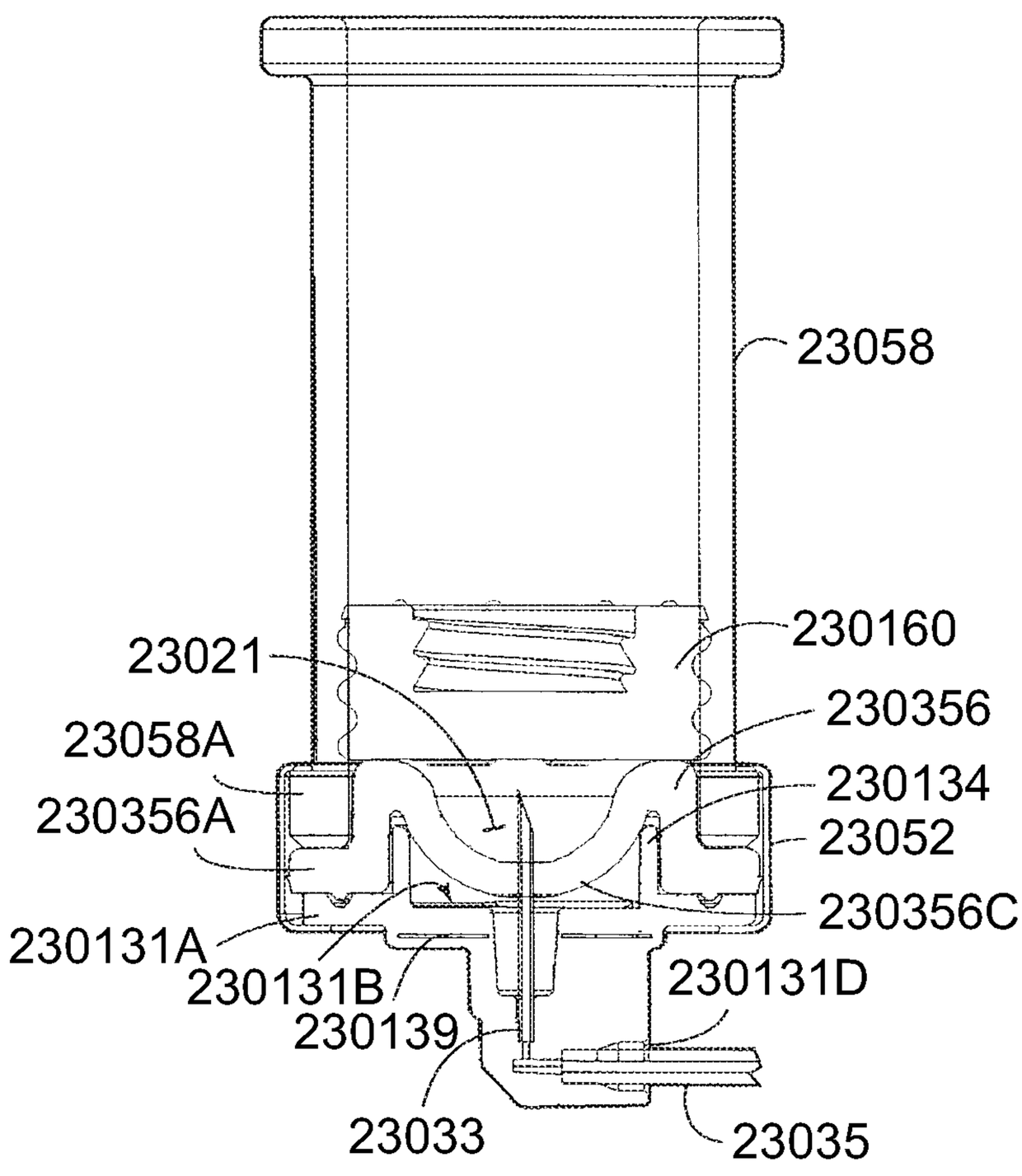


FIG. 59D

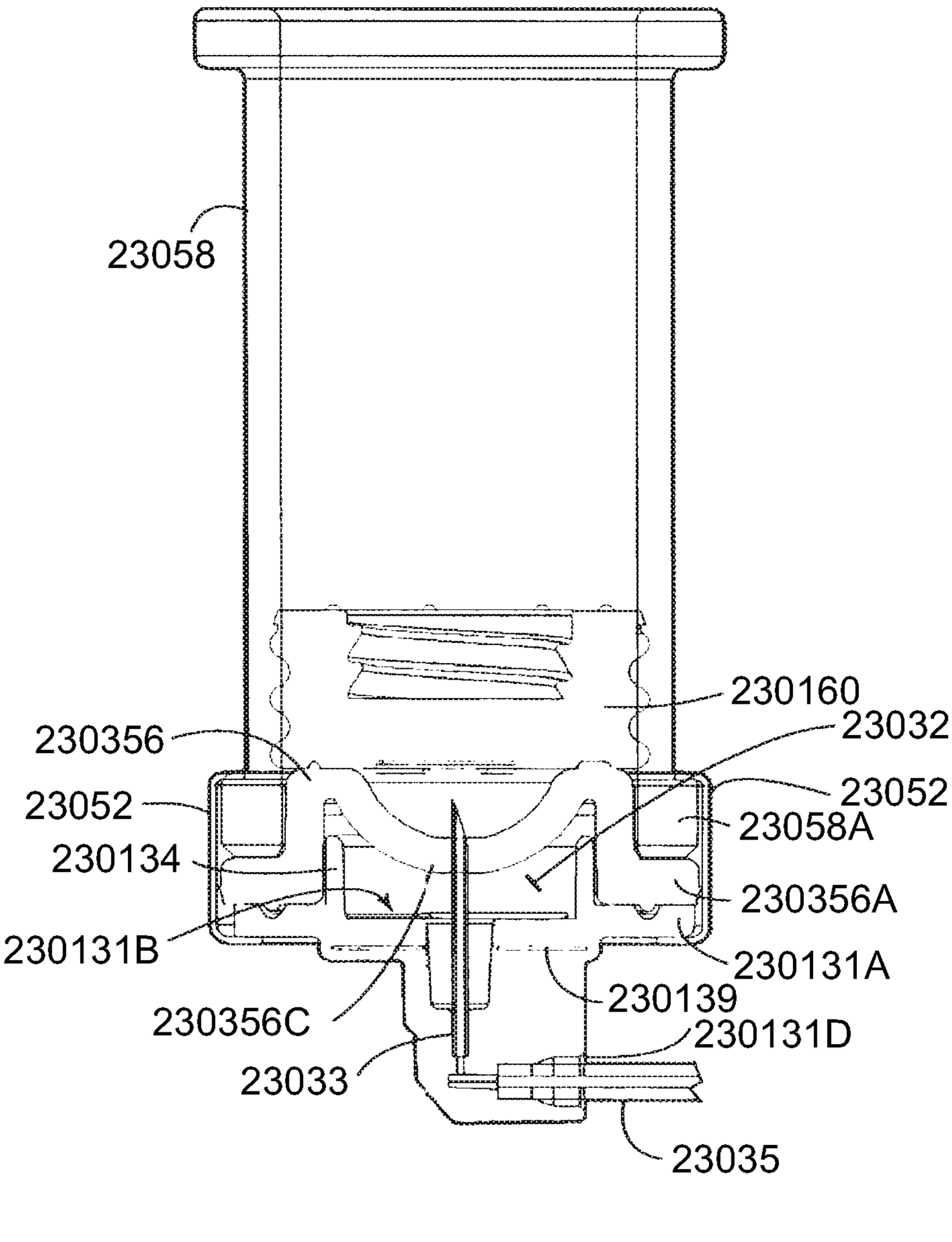

23058
230160
230356
23032
23052
23052
230134
23058A
230356A
230131B
230131A
230139
230356C
230131D
23033
23035

FIG. 59E

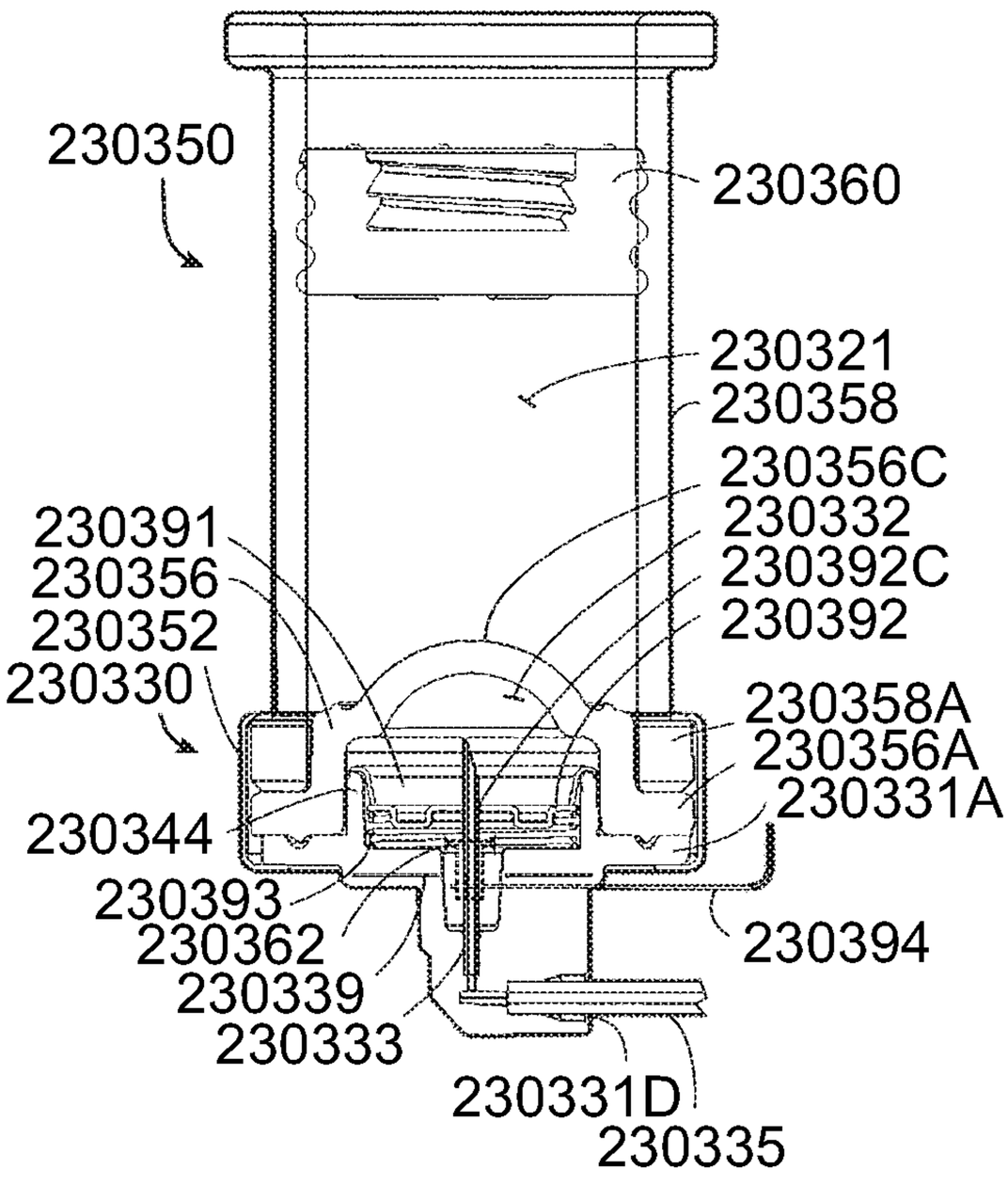


FIG. 60A

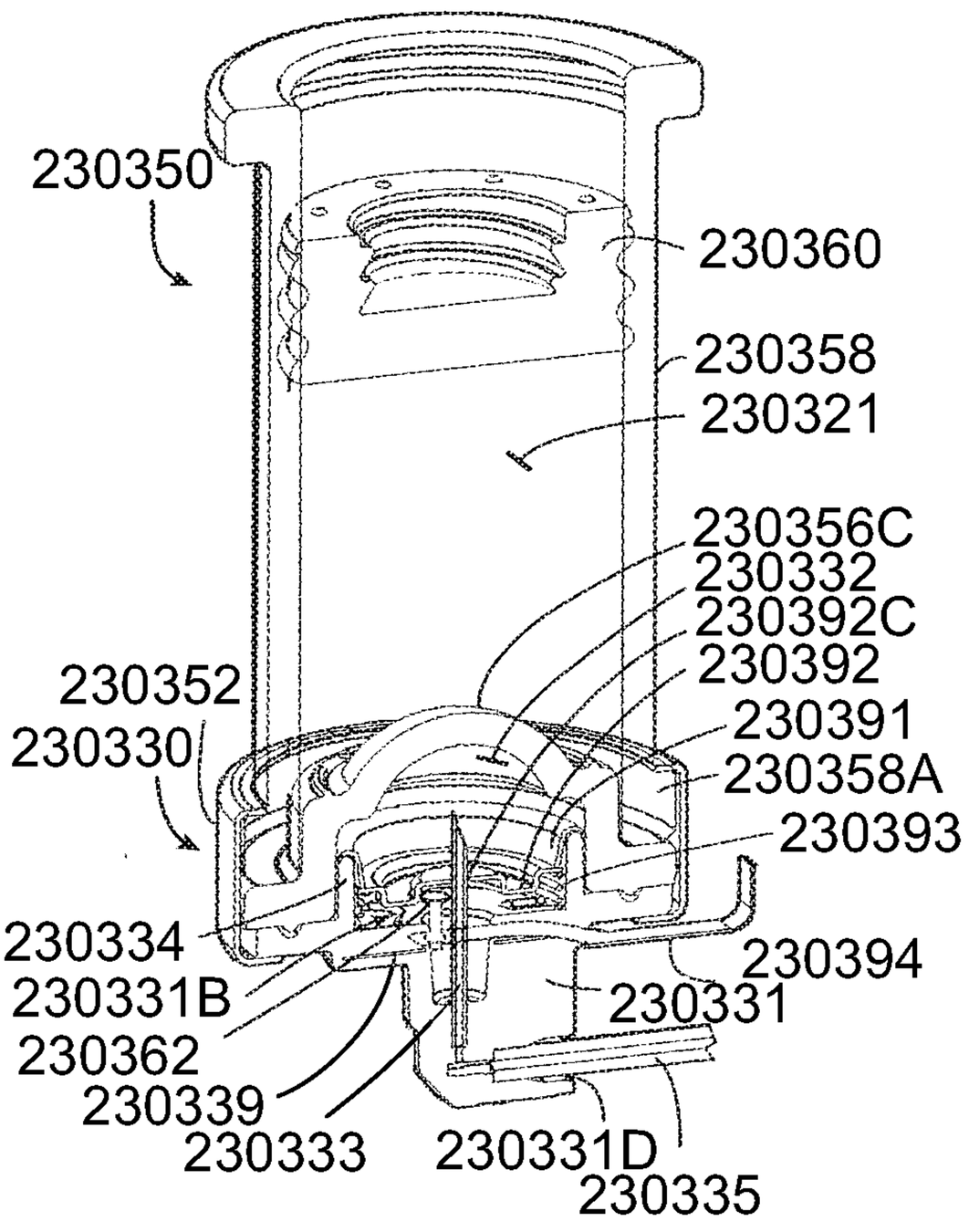


FIG. 60B

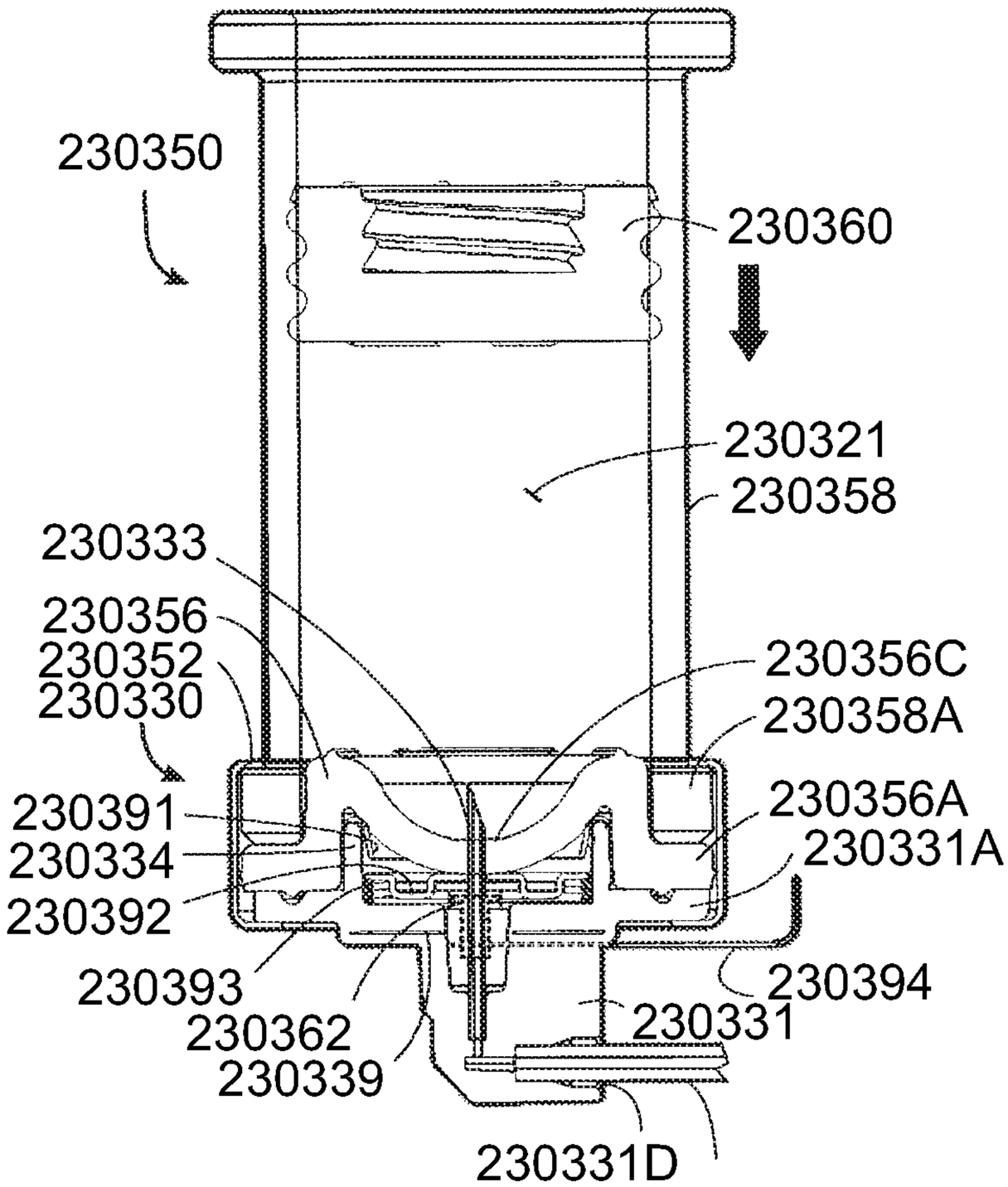


FIG. 60C

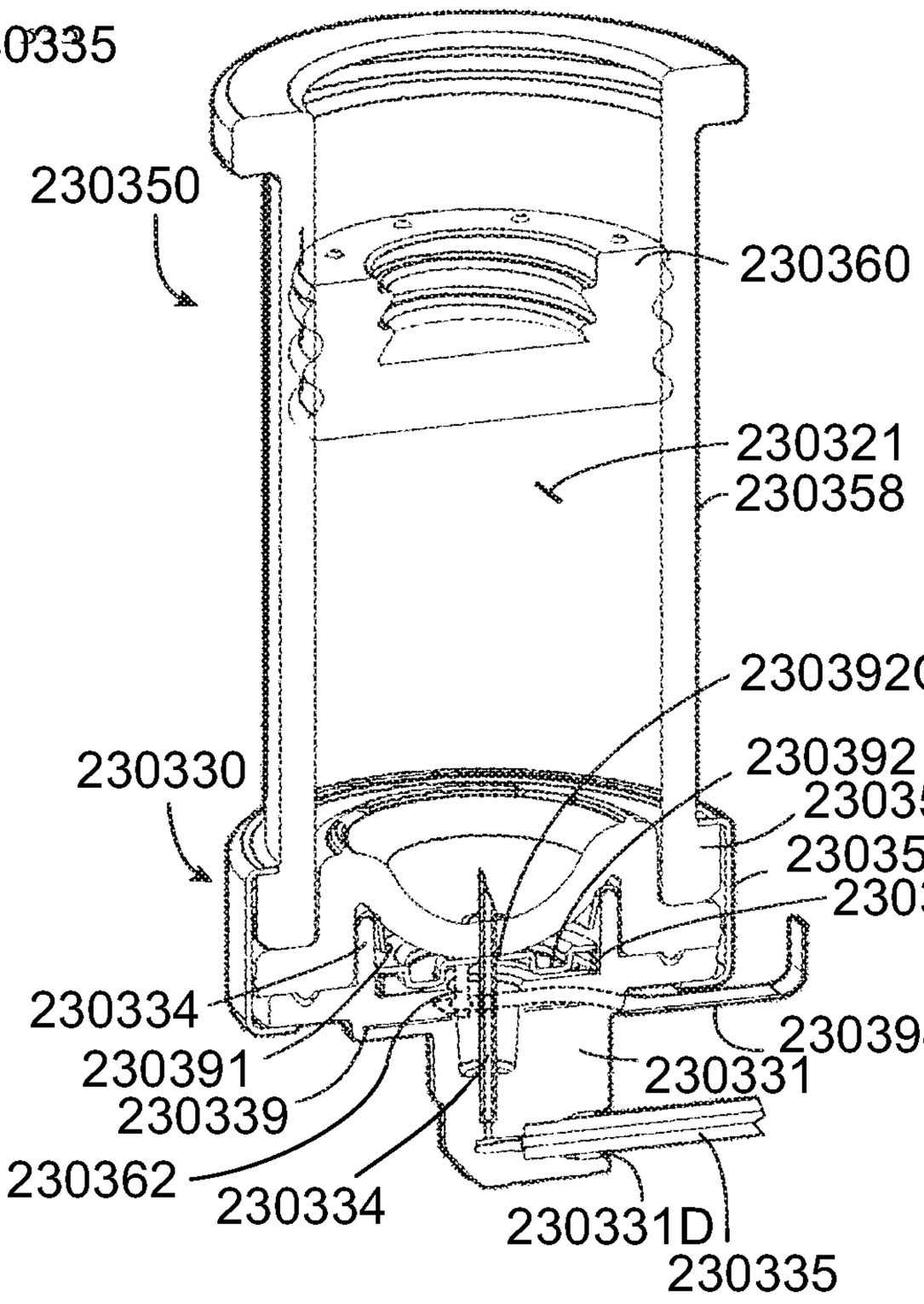


FIG. 60D

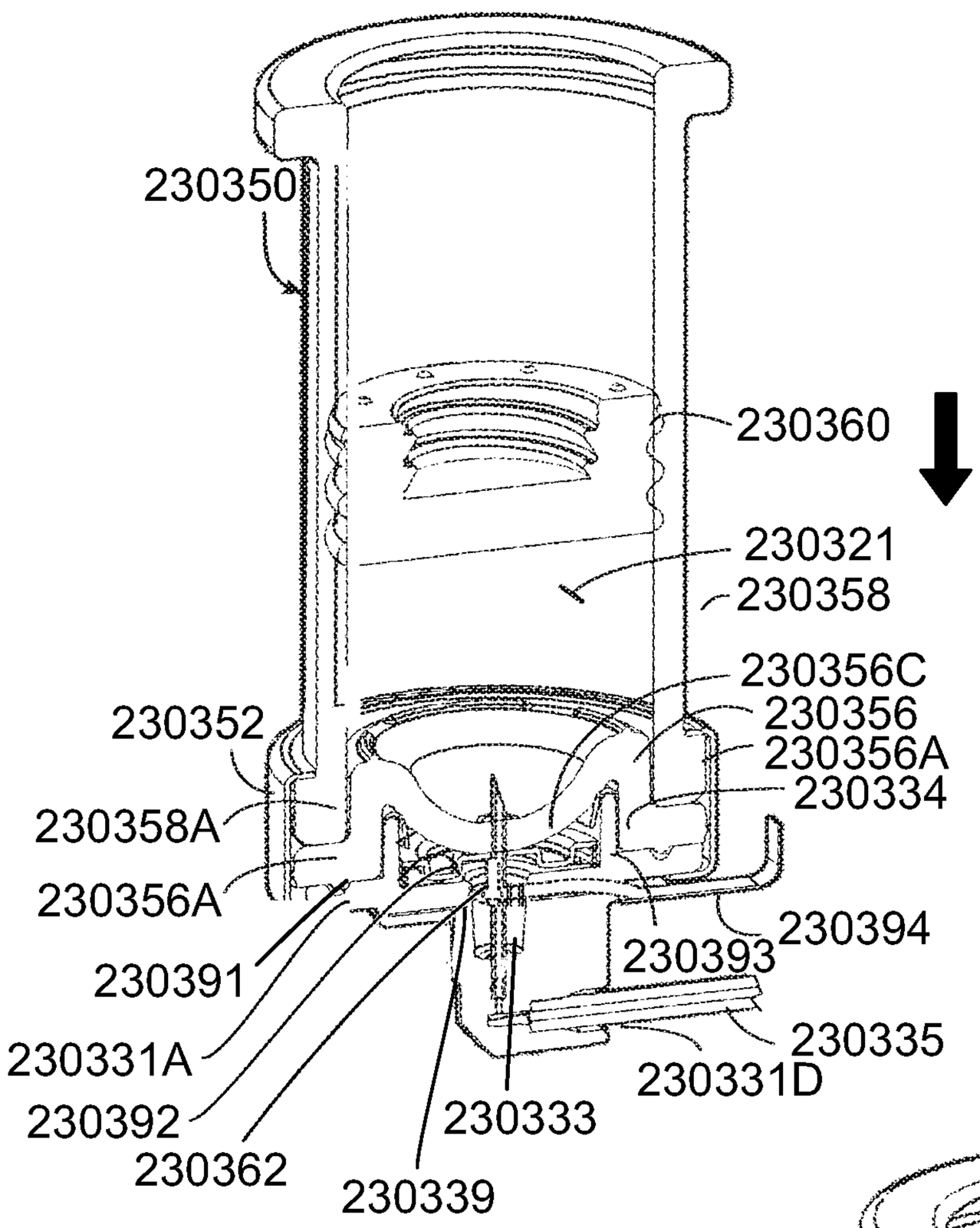


FIG. 60E

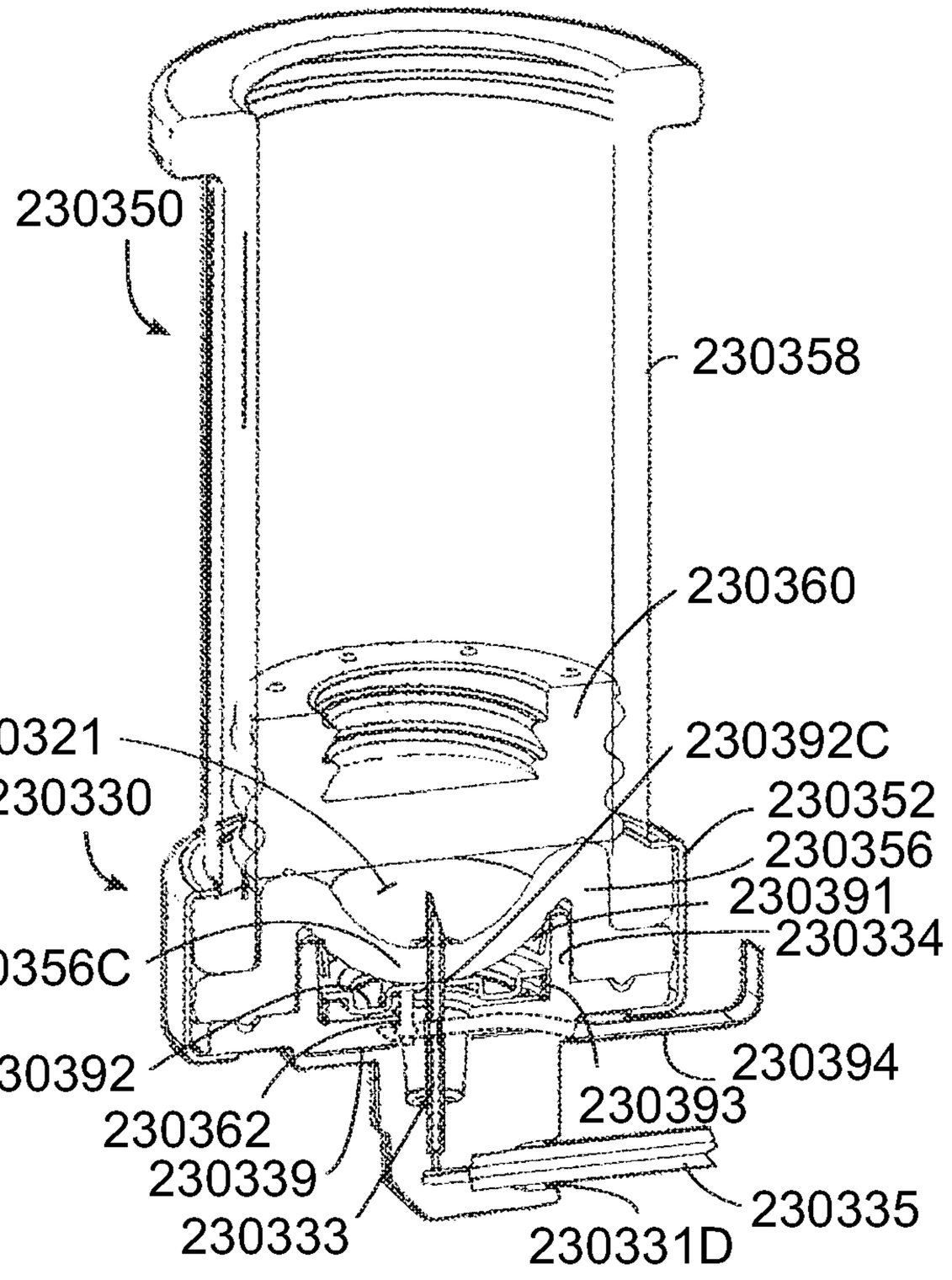


FIG. 60F

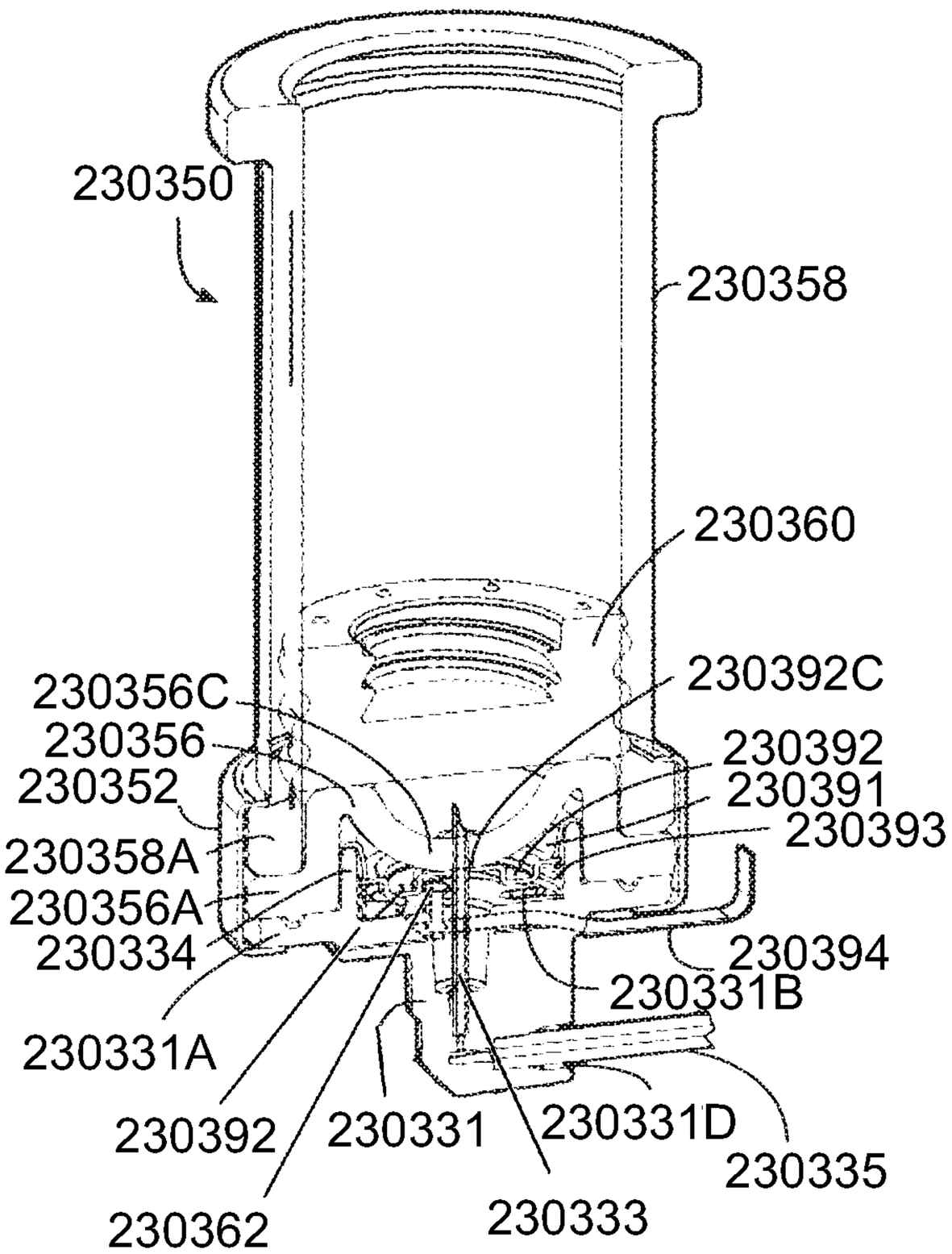


FIG. 60G

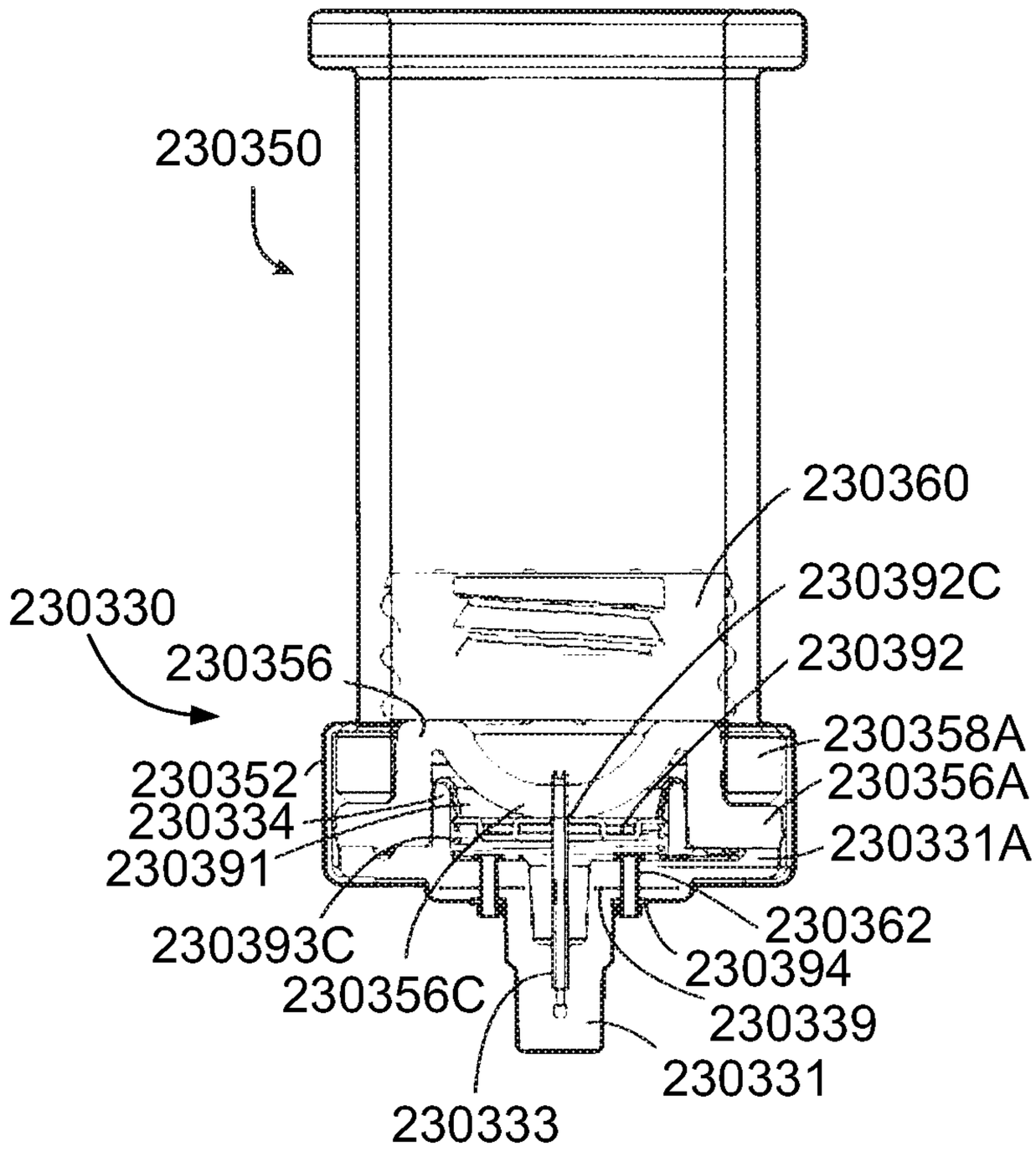


FIG. 60H

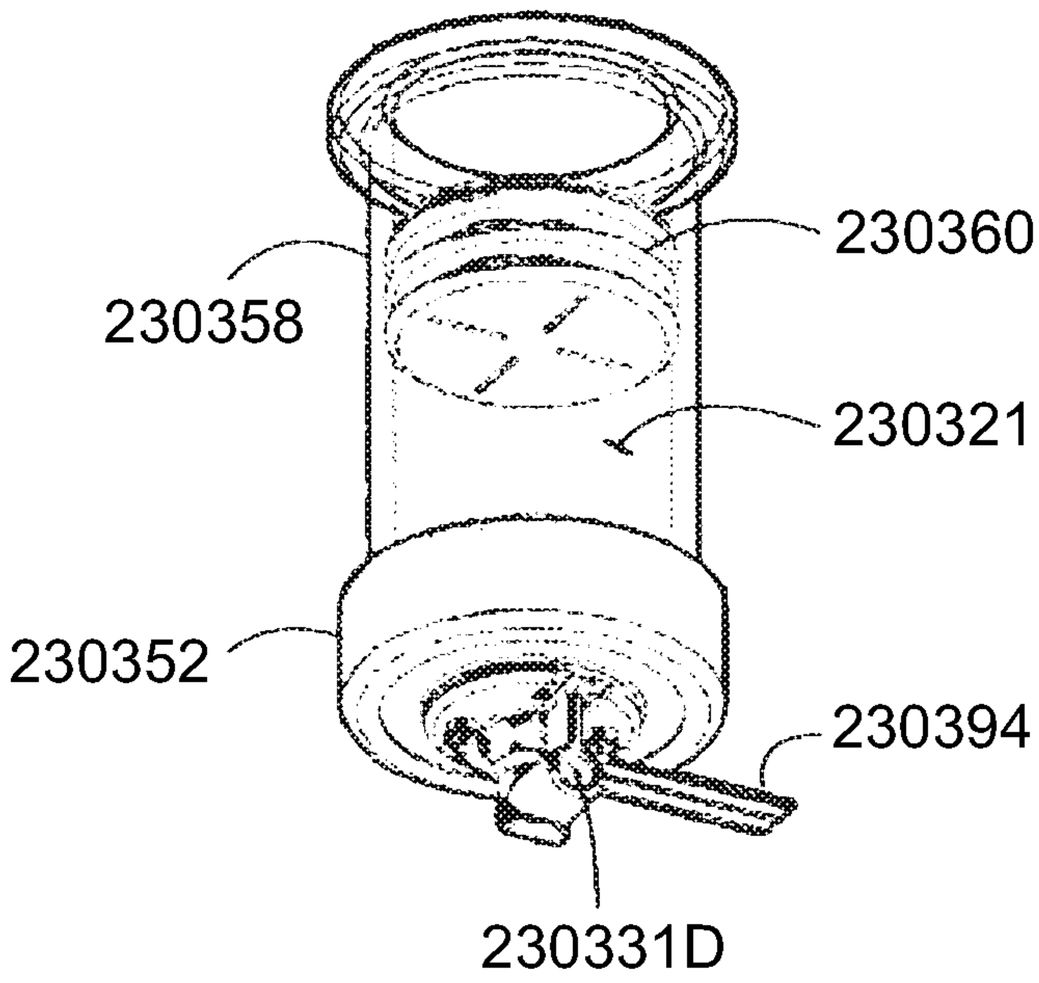


FIG. 61A

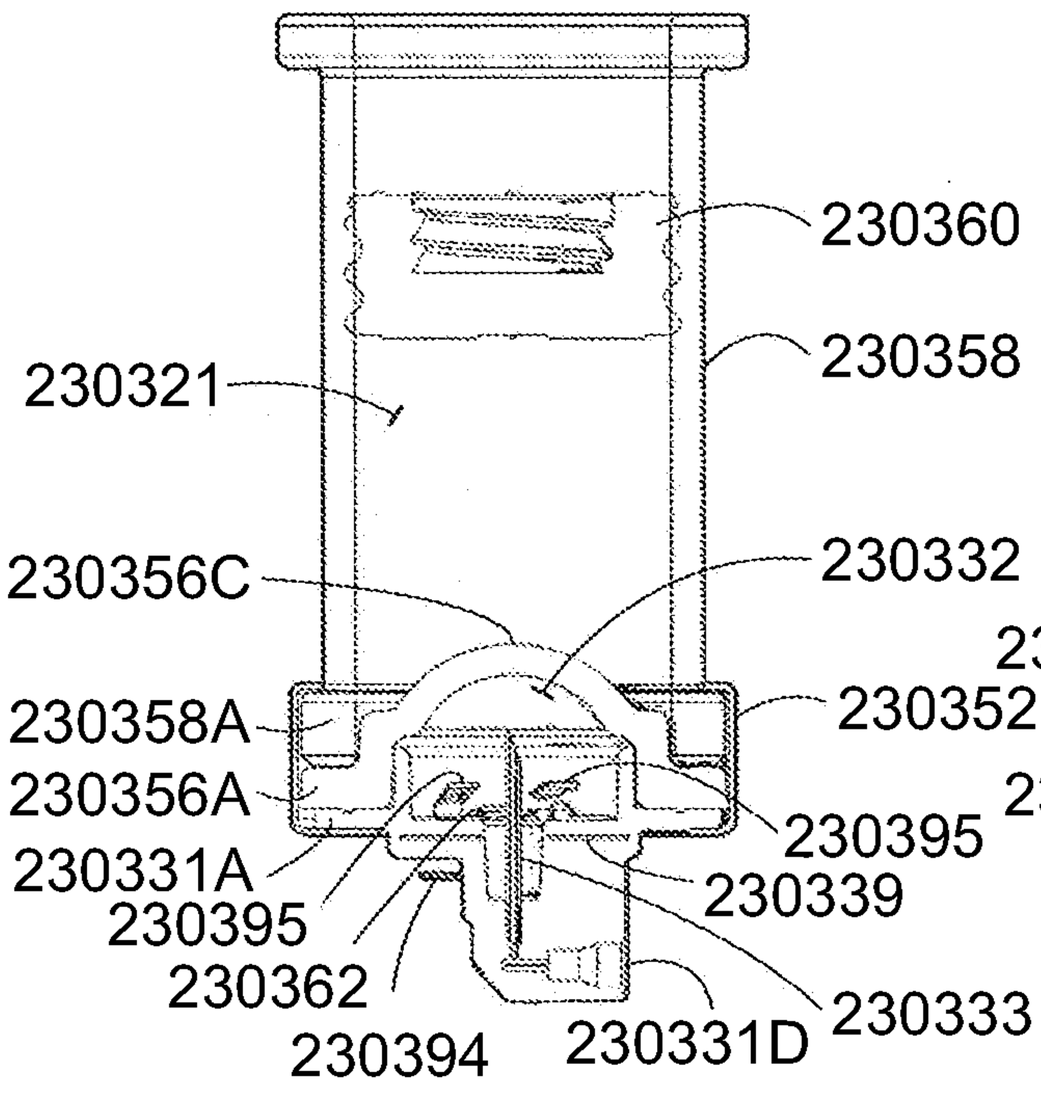


FIG. 61B

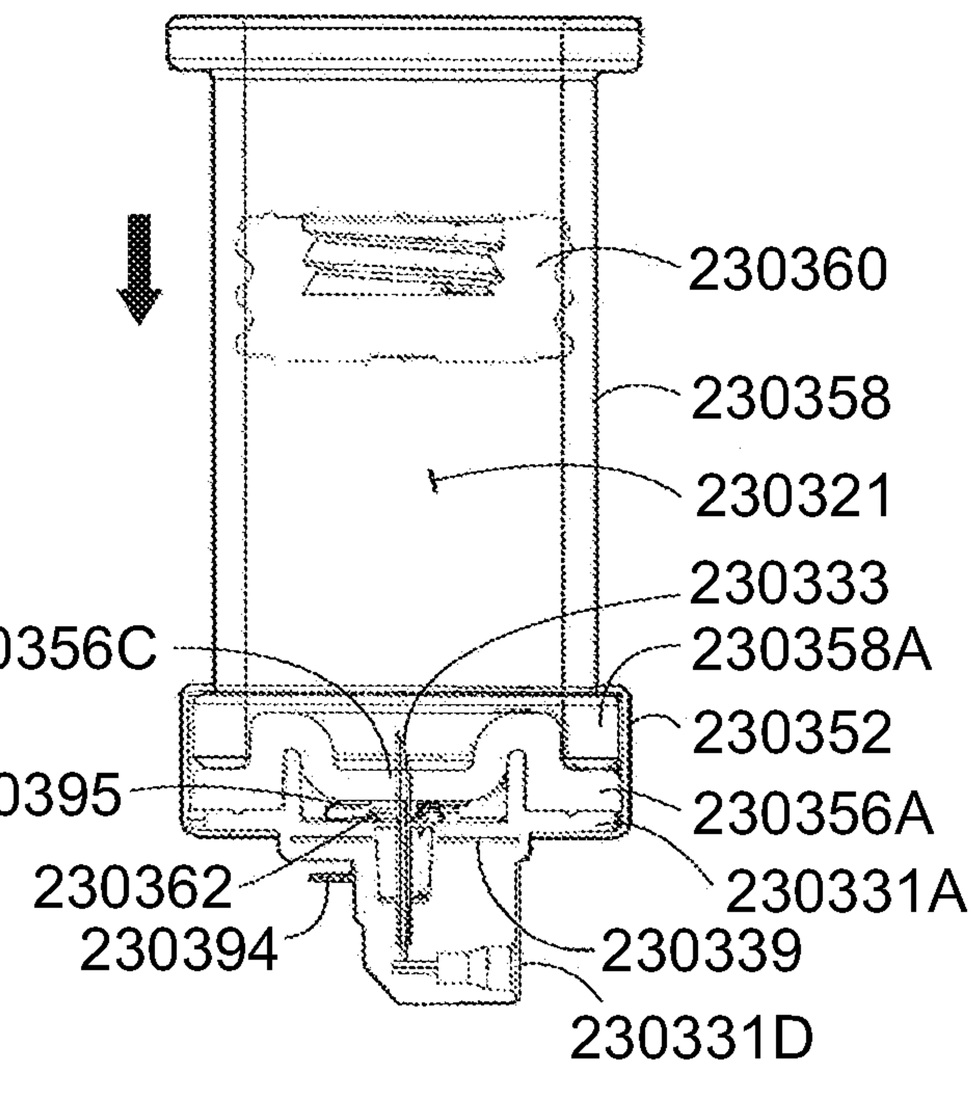


FIG. 61C

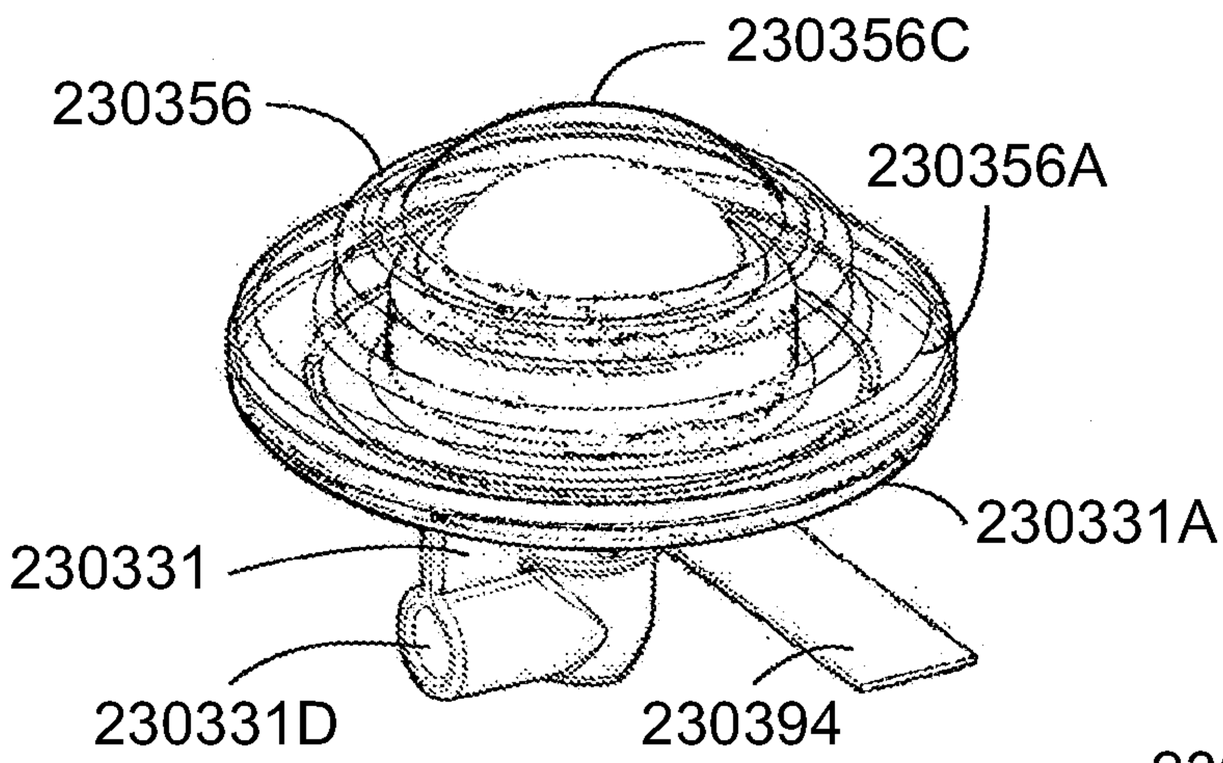


FIG. 61D

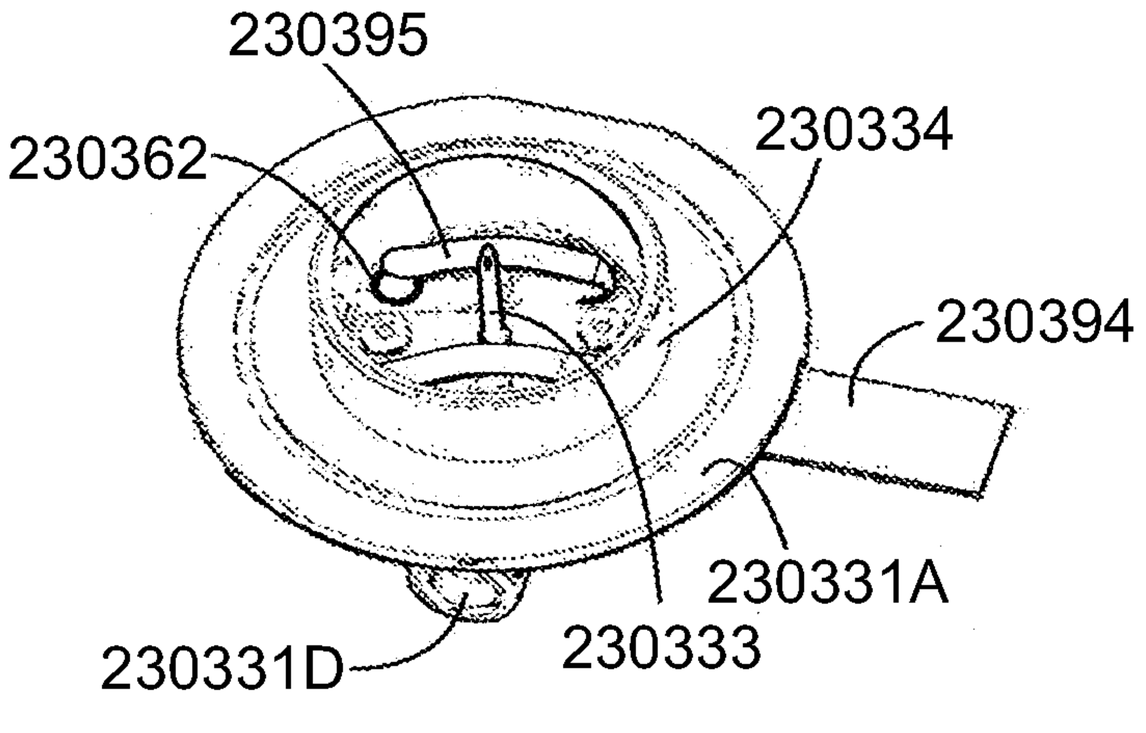


FIG. 61E

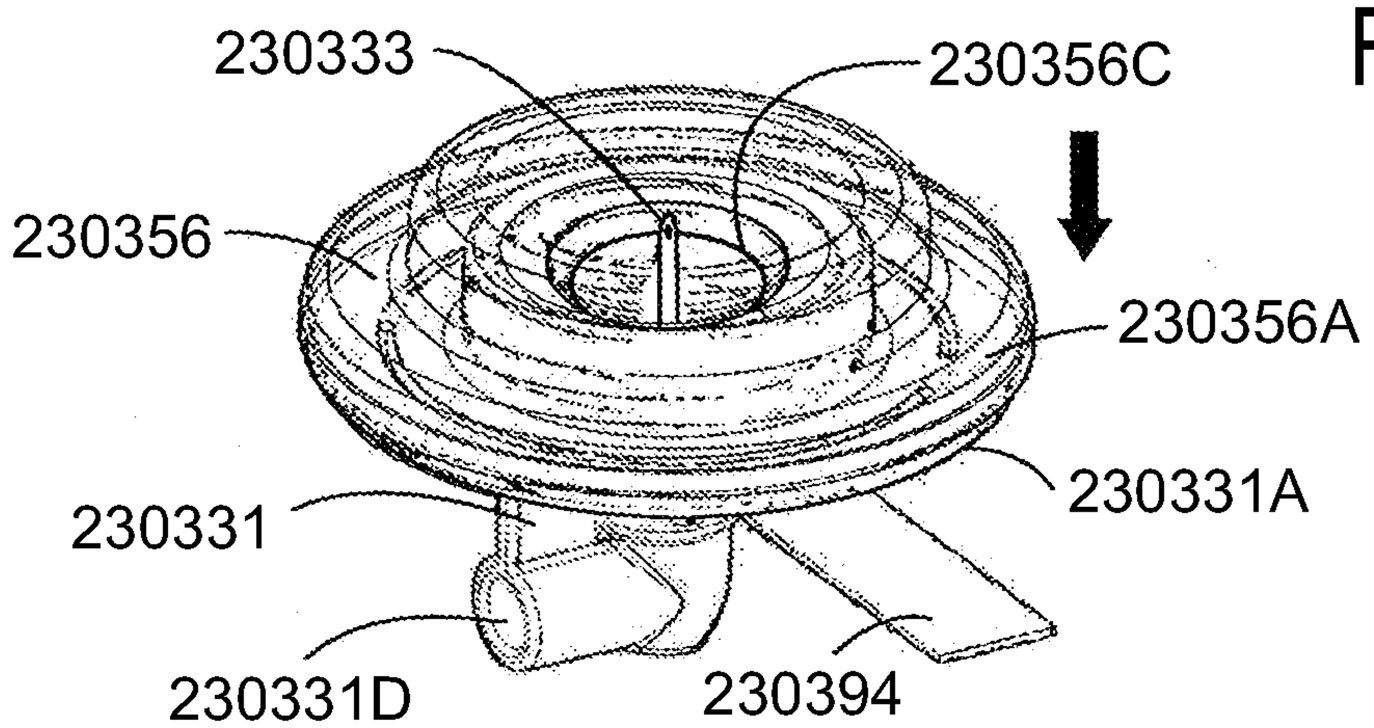


FIG. 61F

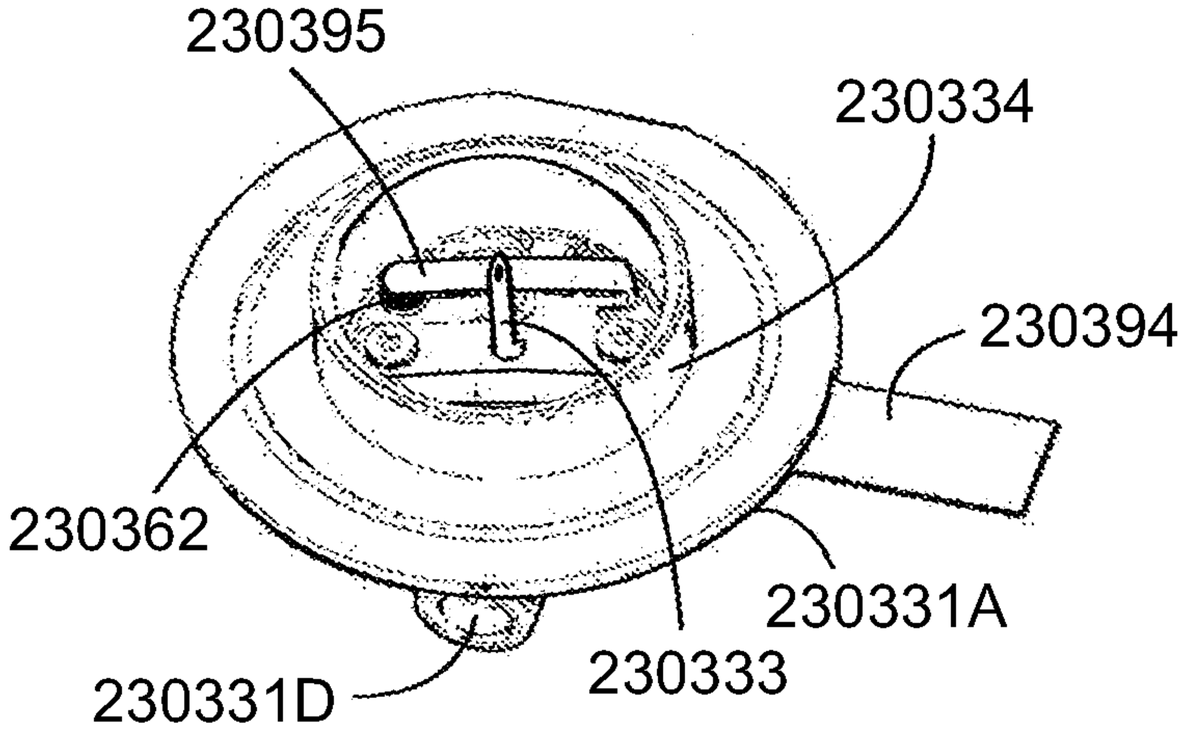


FIG. 61G

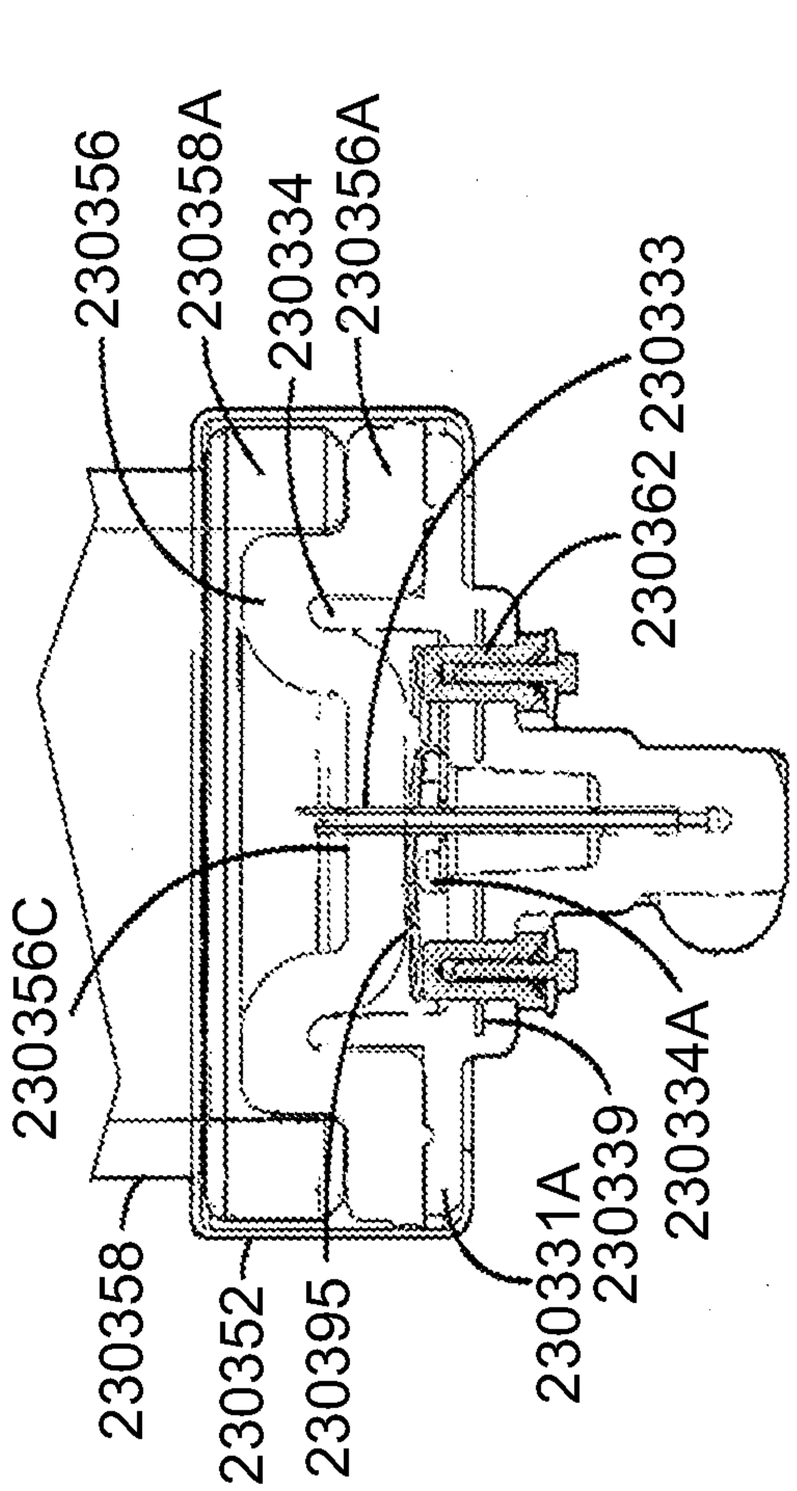


FIG. 62B

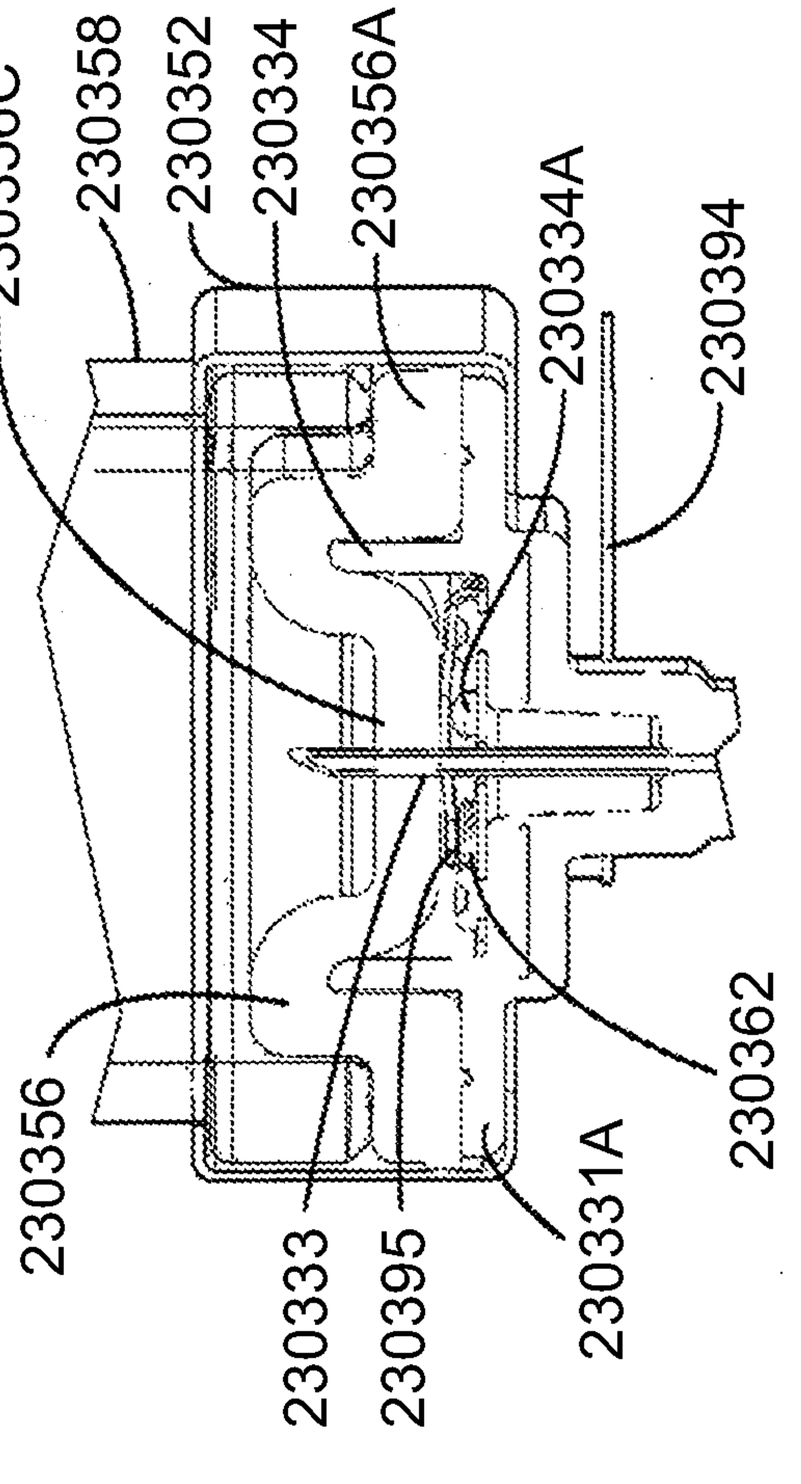


FIG. 62D

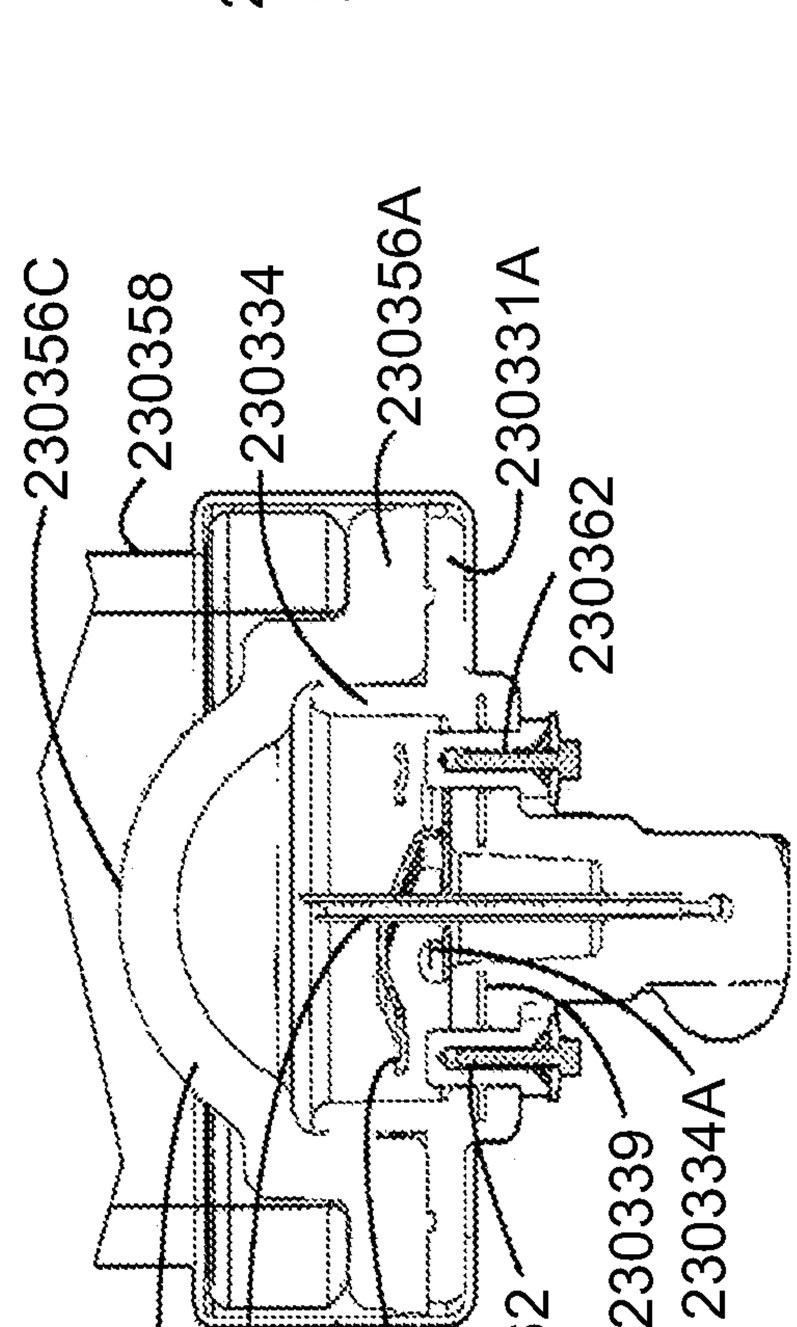


FIG. 62A

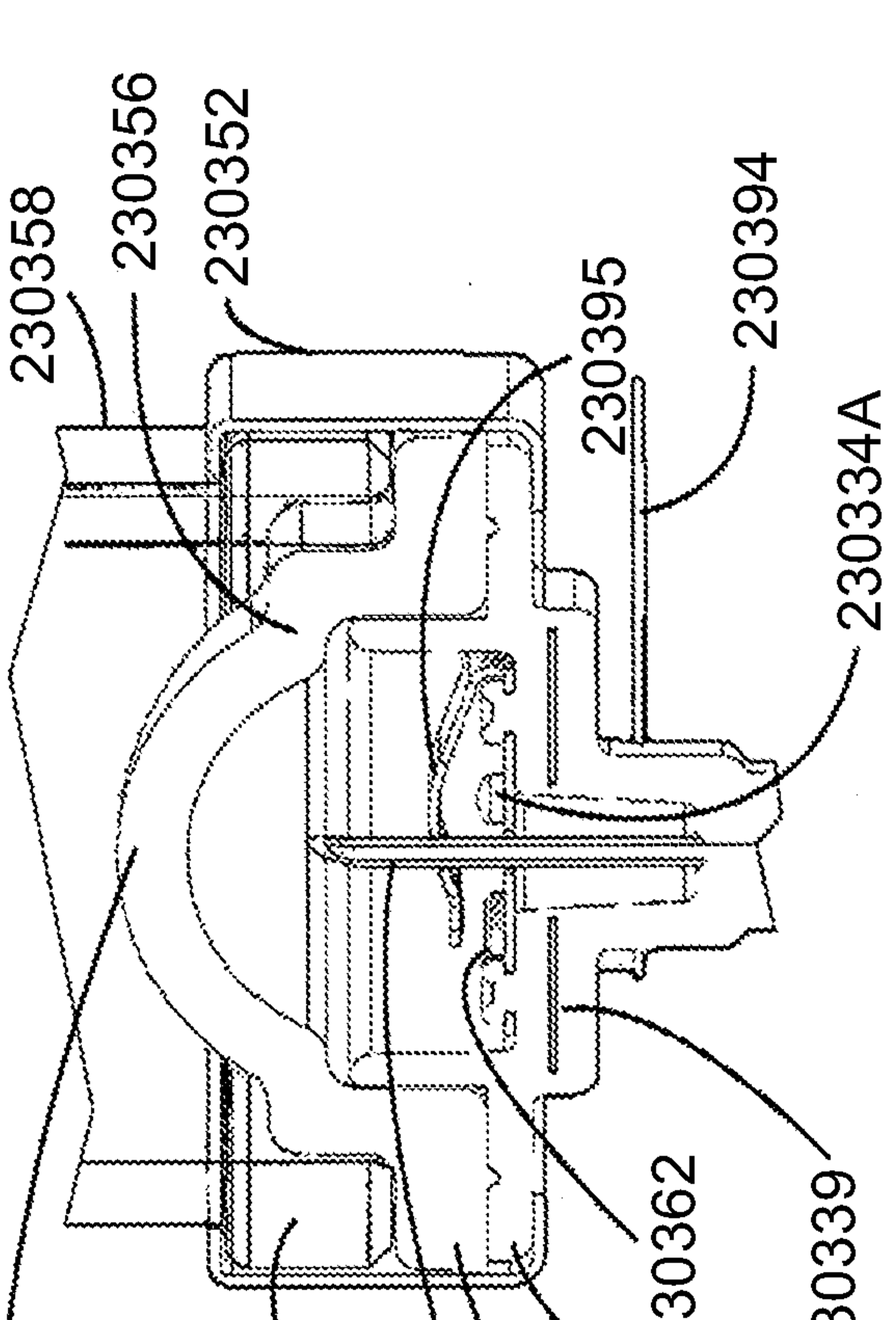


FIG. 62C

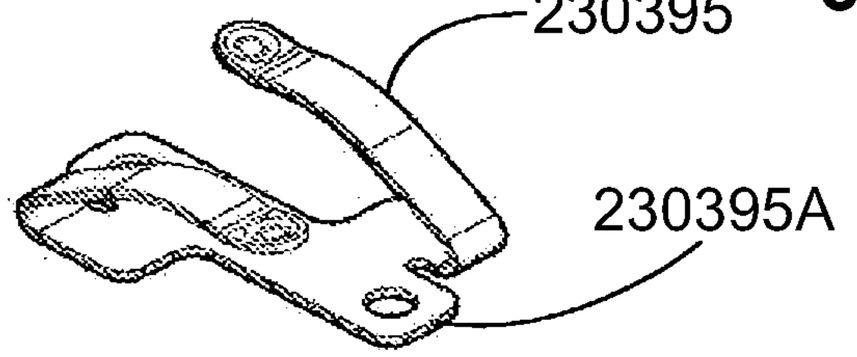


FIG. 63A

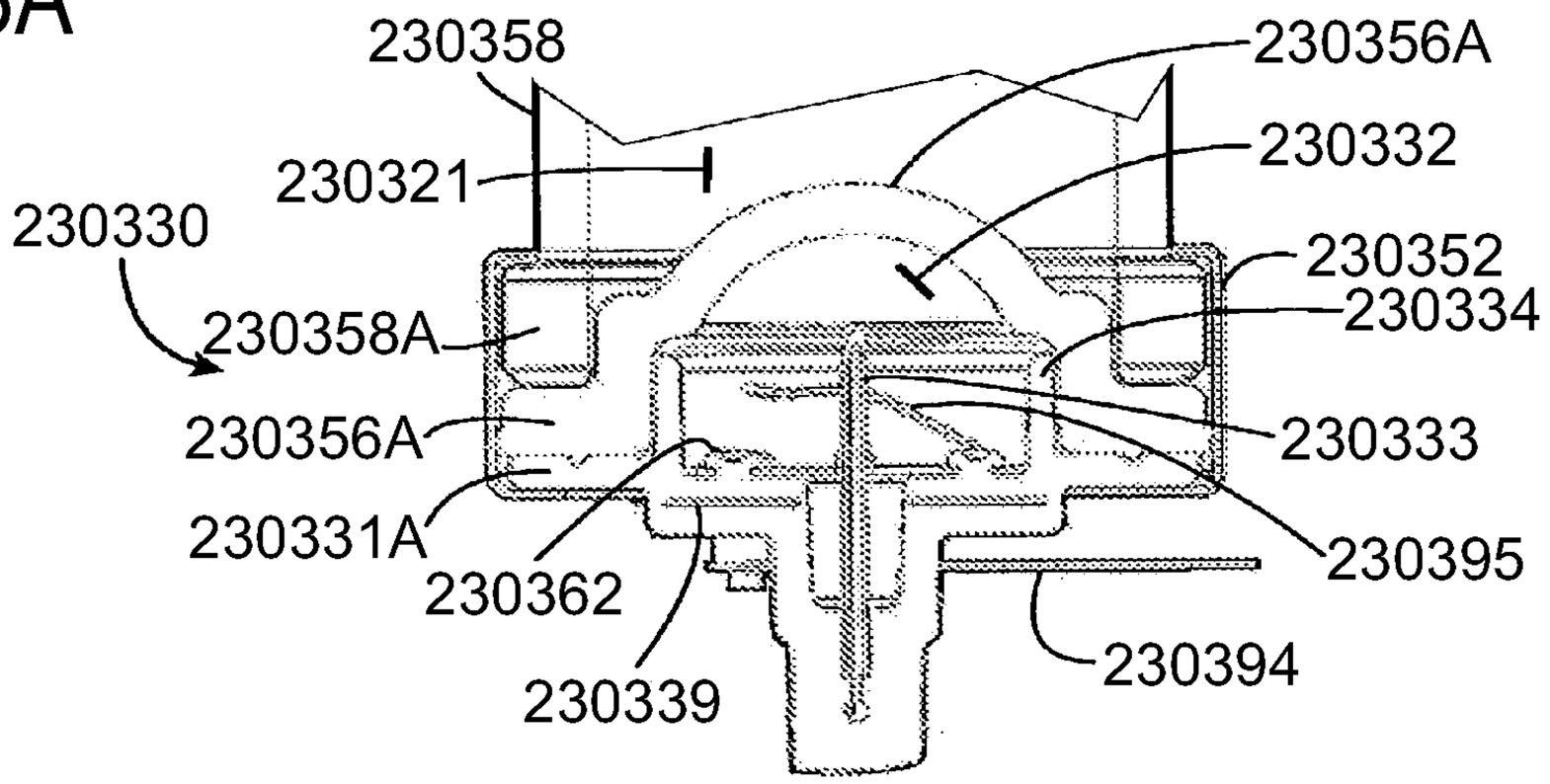


FIG. 63B

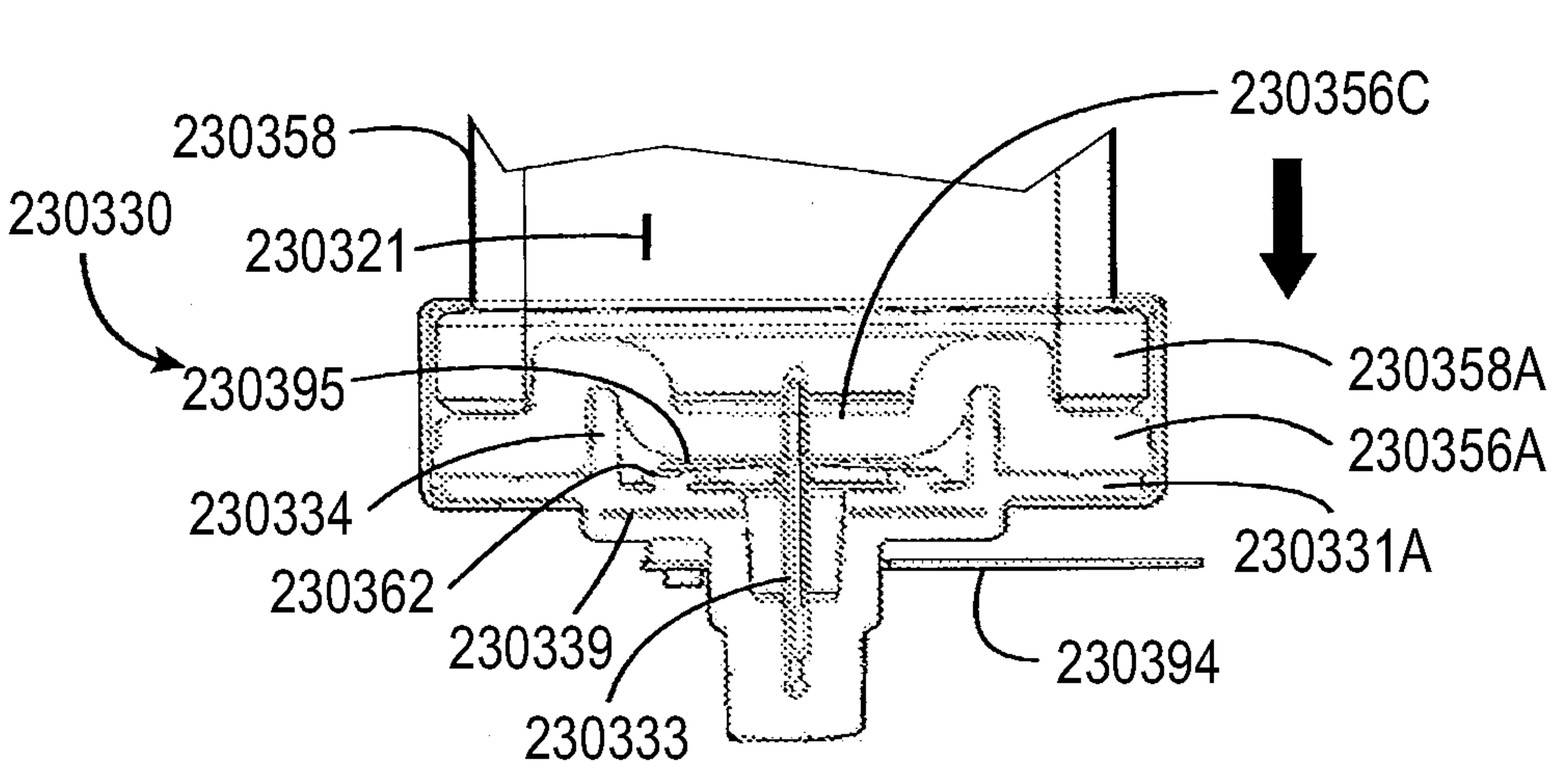


FIG. 63C

FIG. 63D

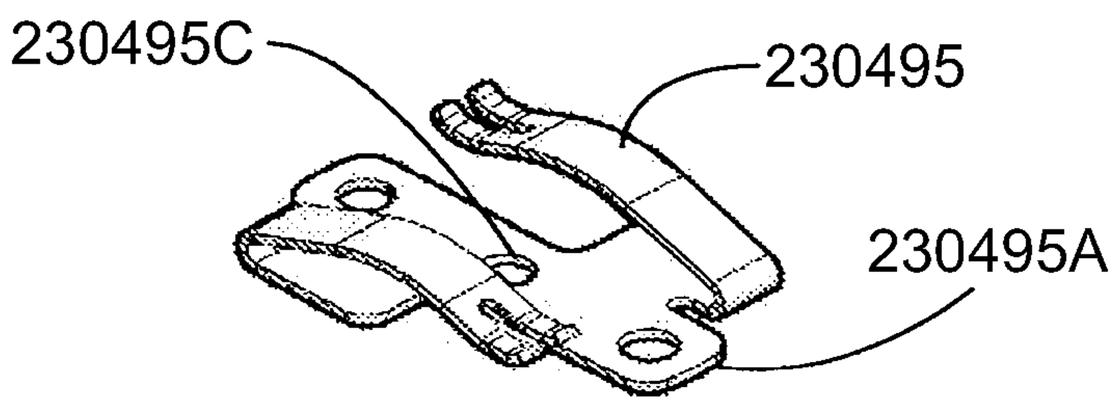


FIG. 64A

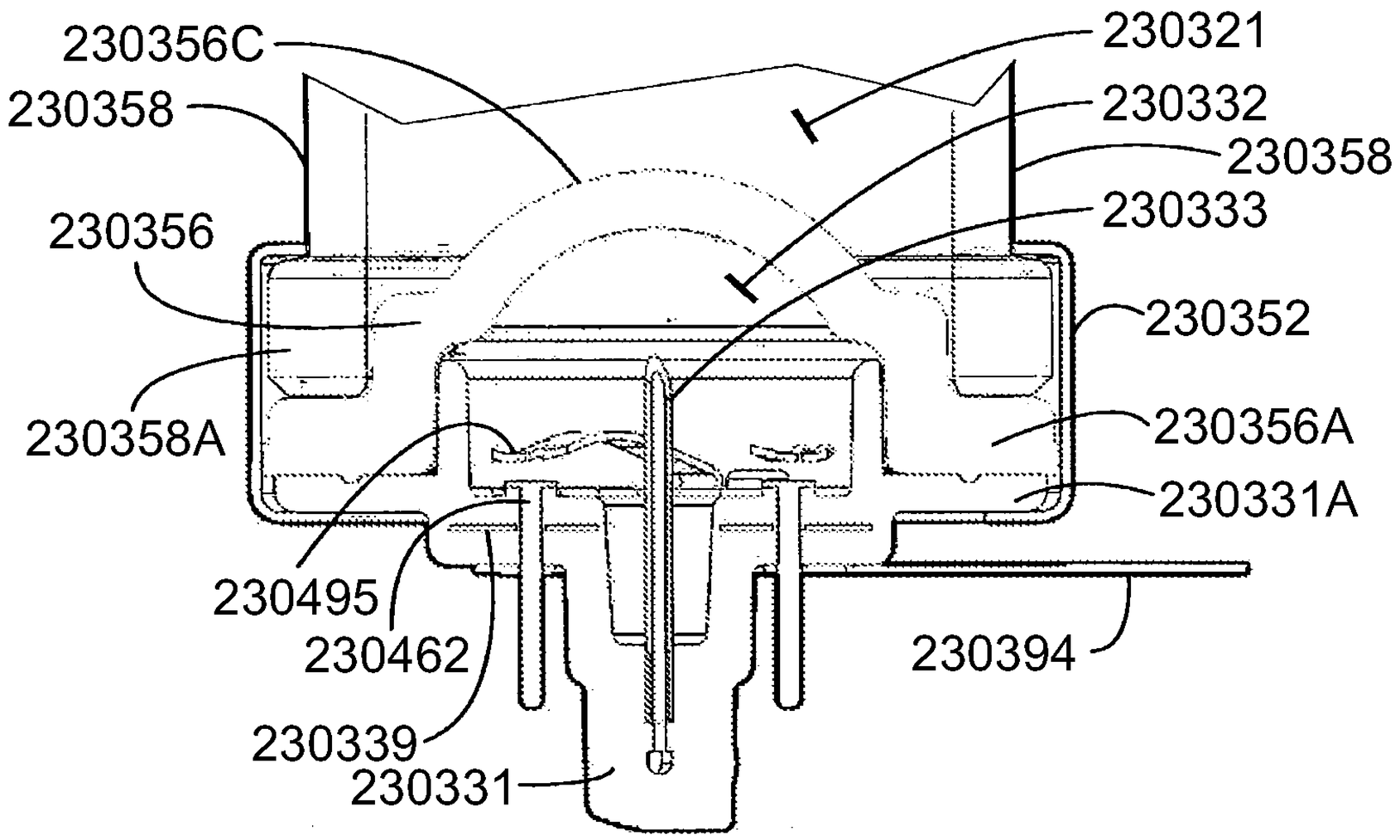


FIG. 64B

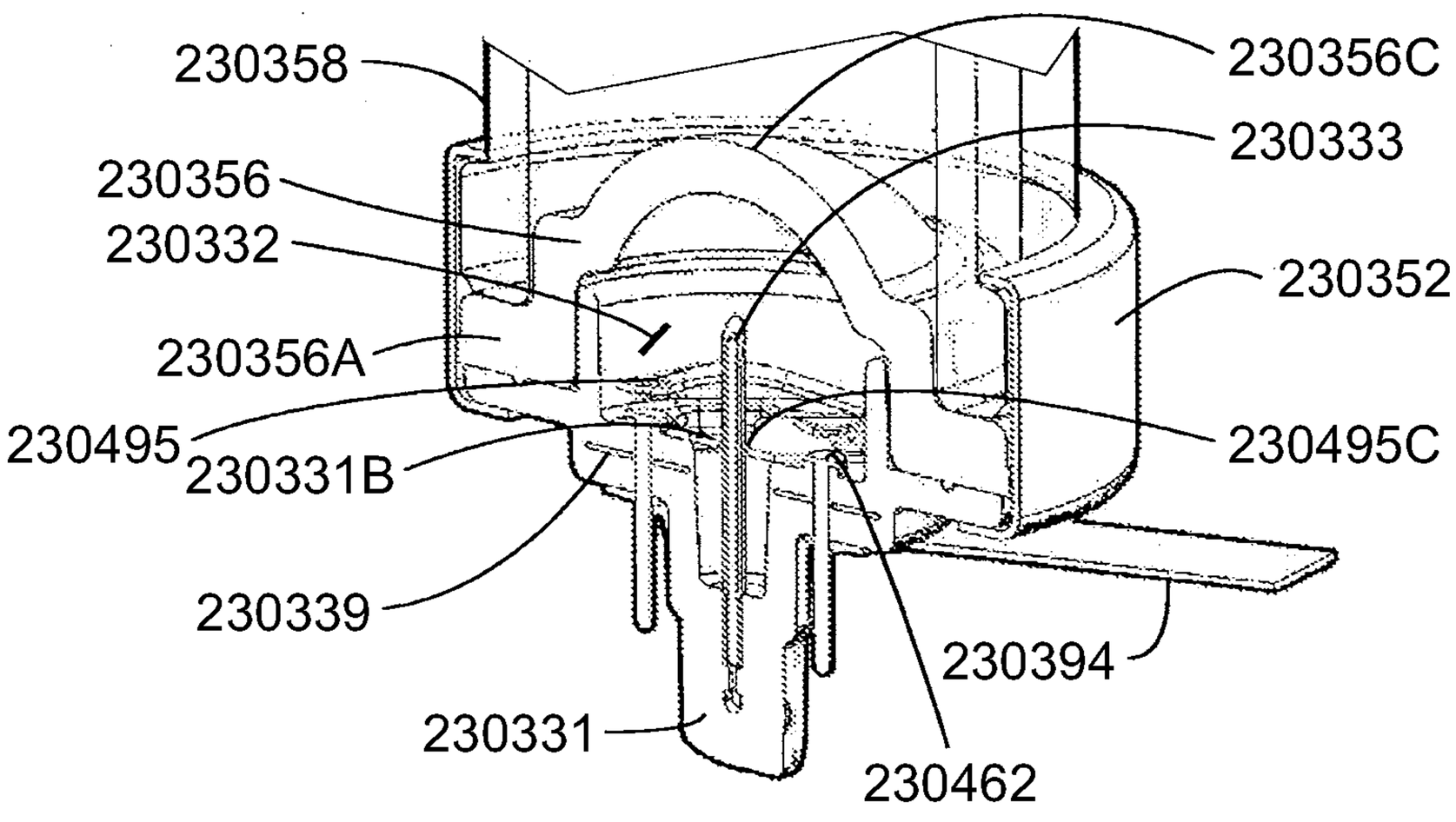


FIG. 64C

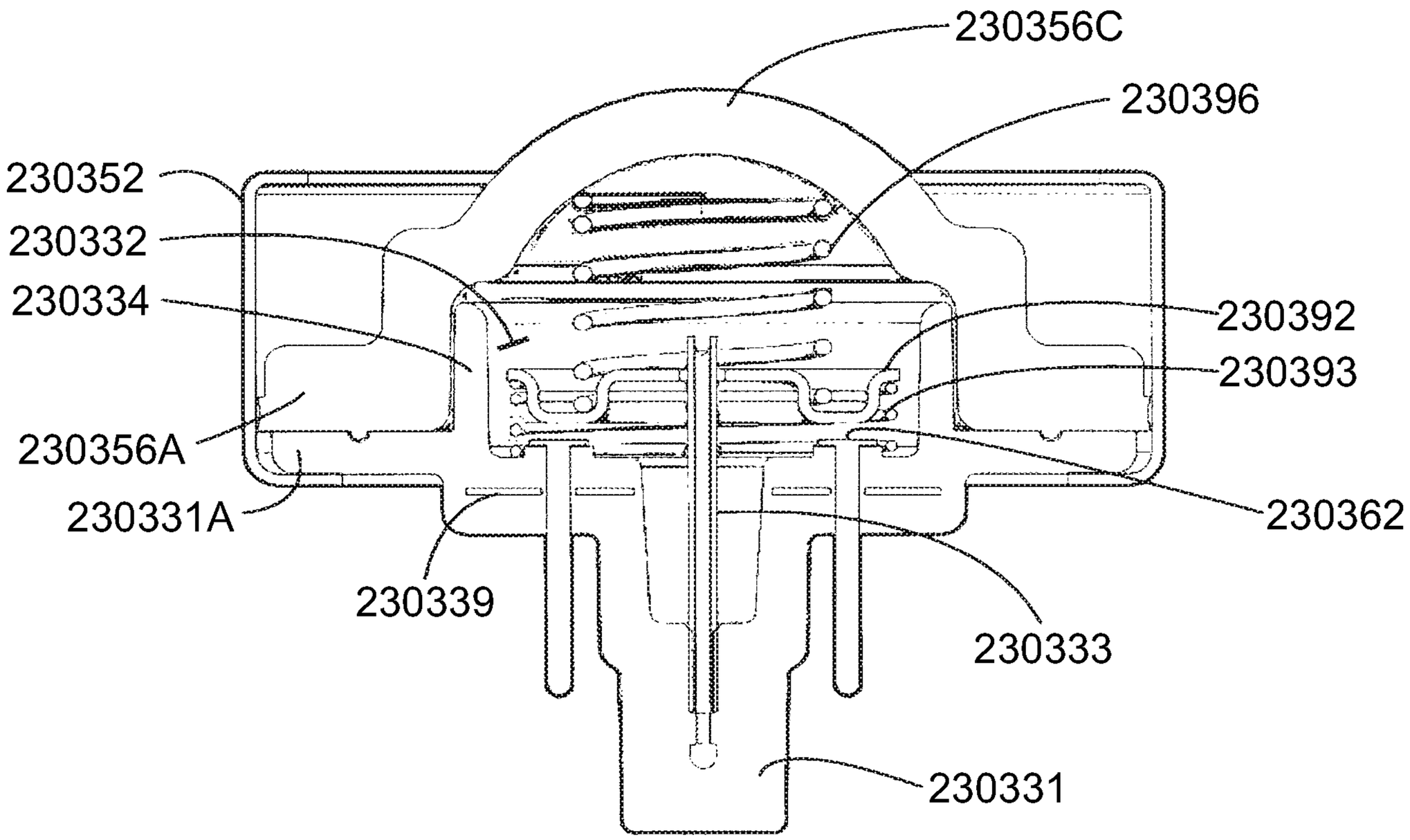


FIG. 65A

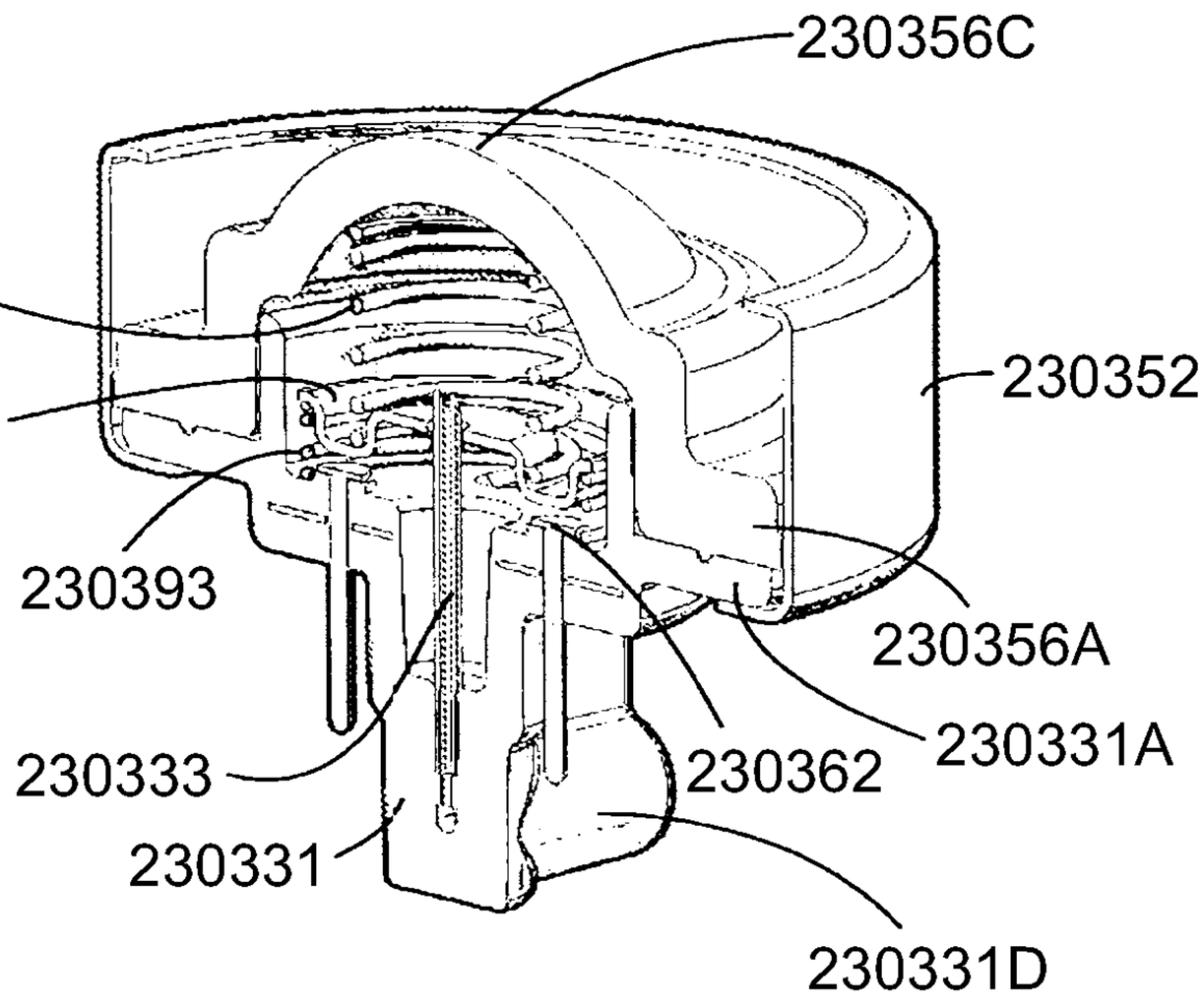


FIG. 65B

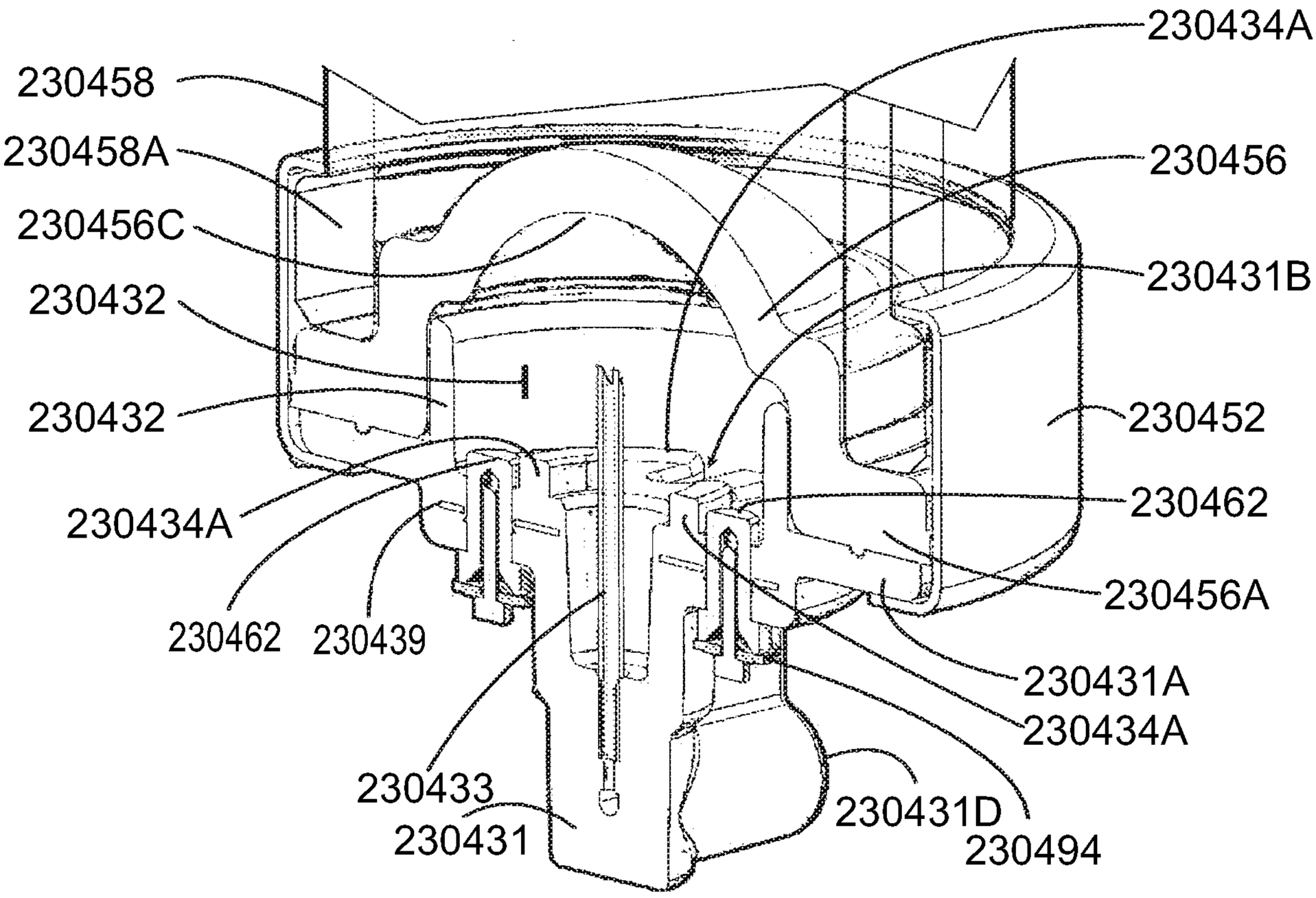


FIG. 66A

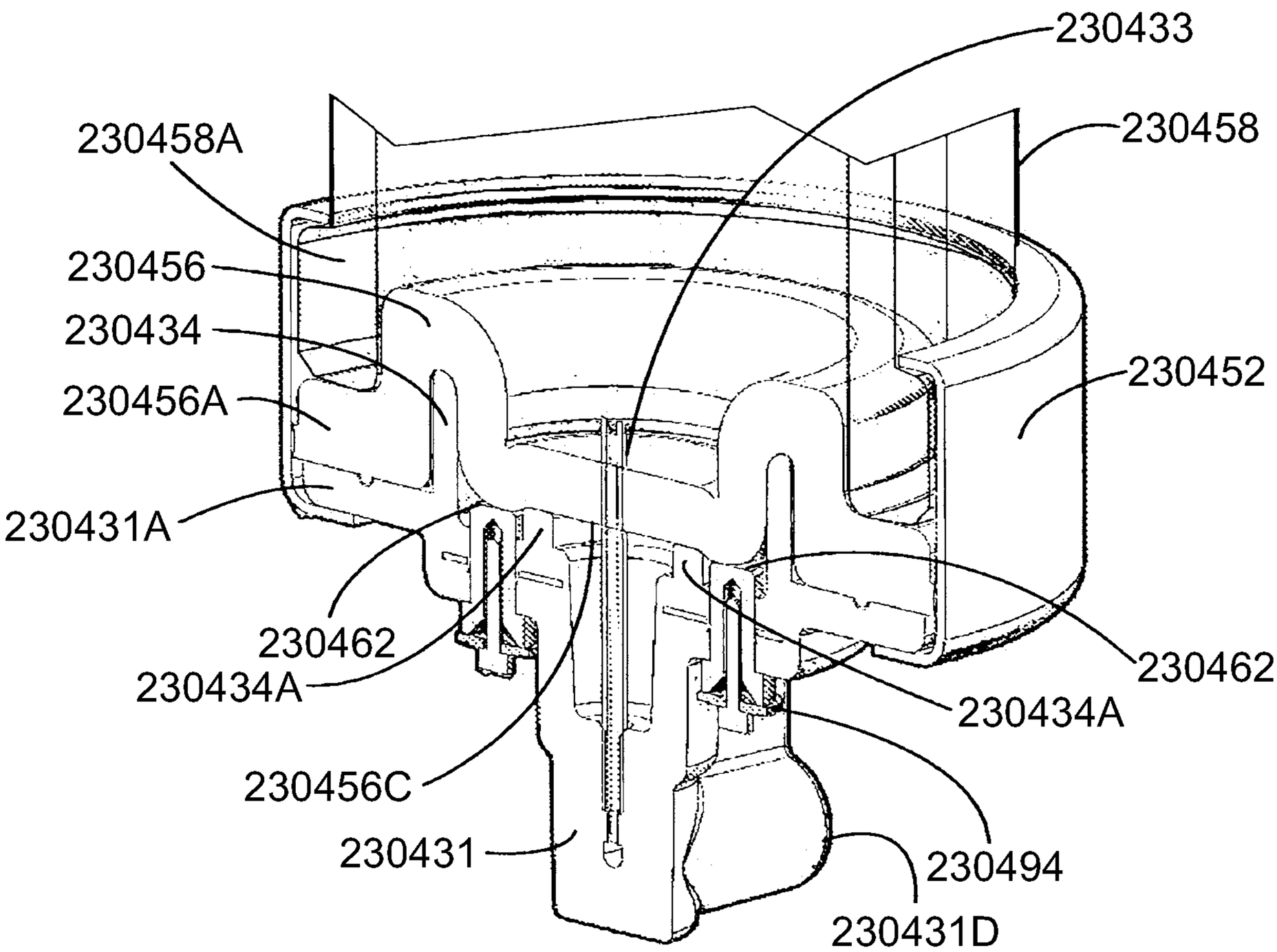


FIG. 66B

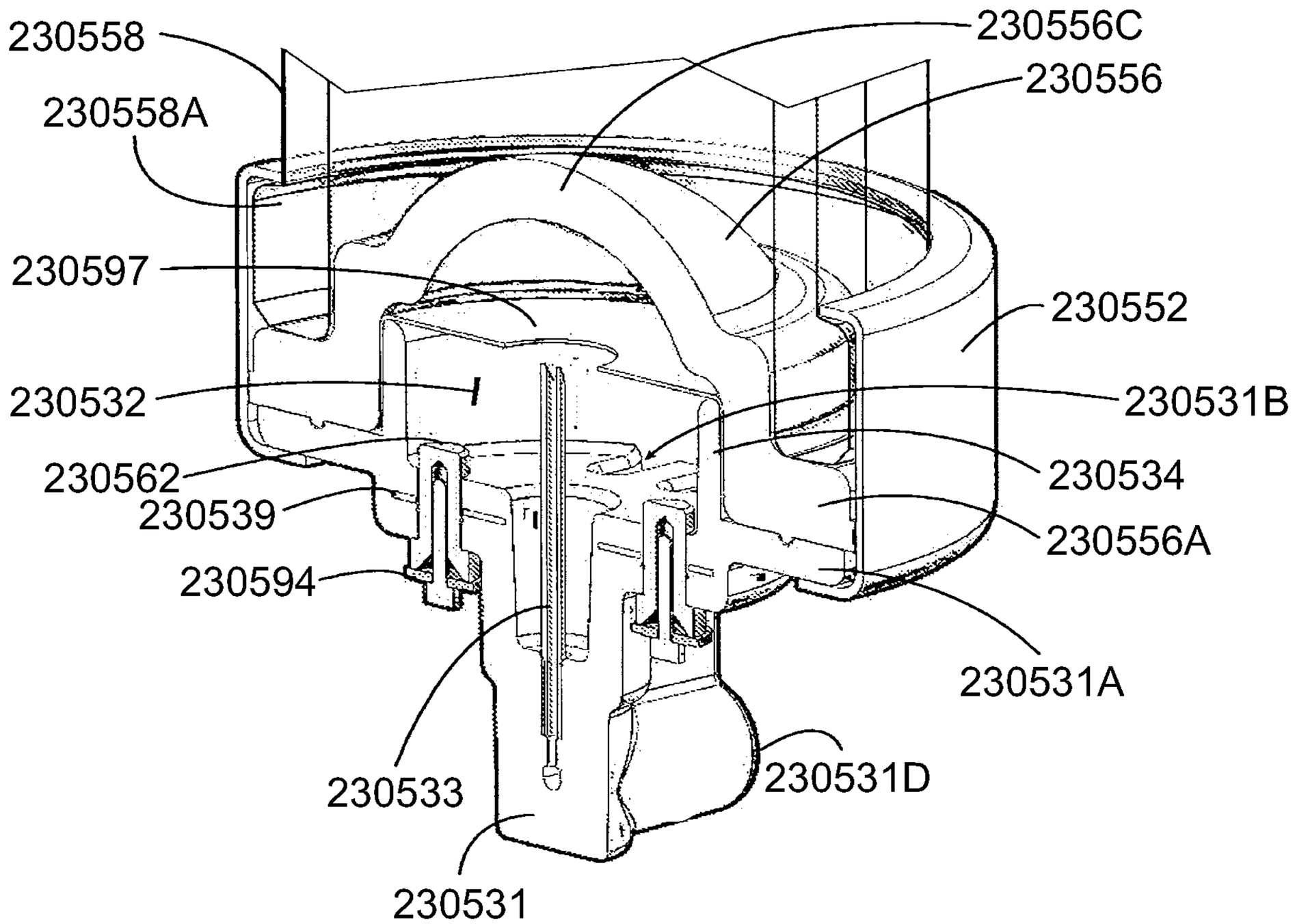

230558
230558A
230597
230532
230562
230539
230594
230533
230531
230556C
230556
230552
230531B
230534
230556A
230531A
230531D

FIG. 67

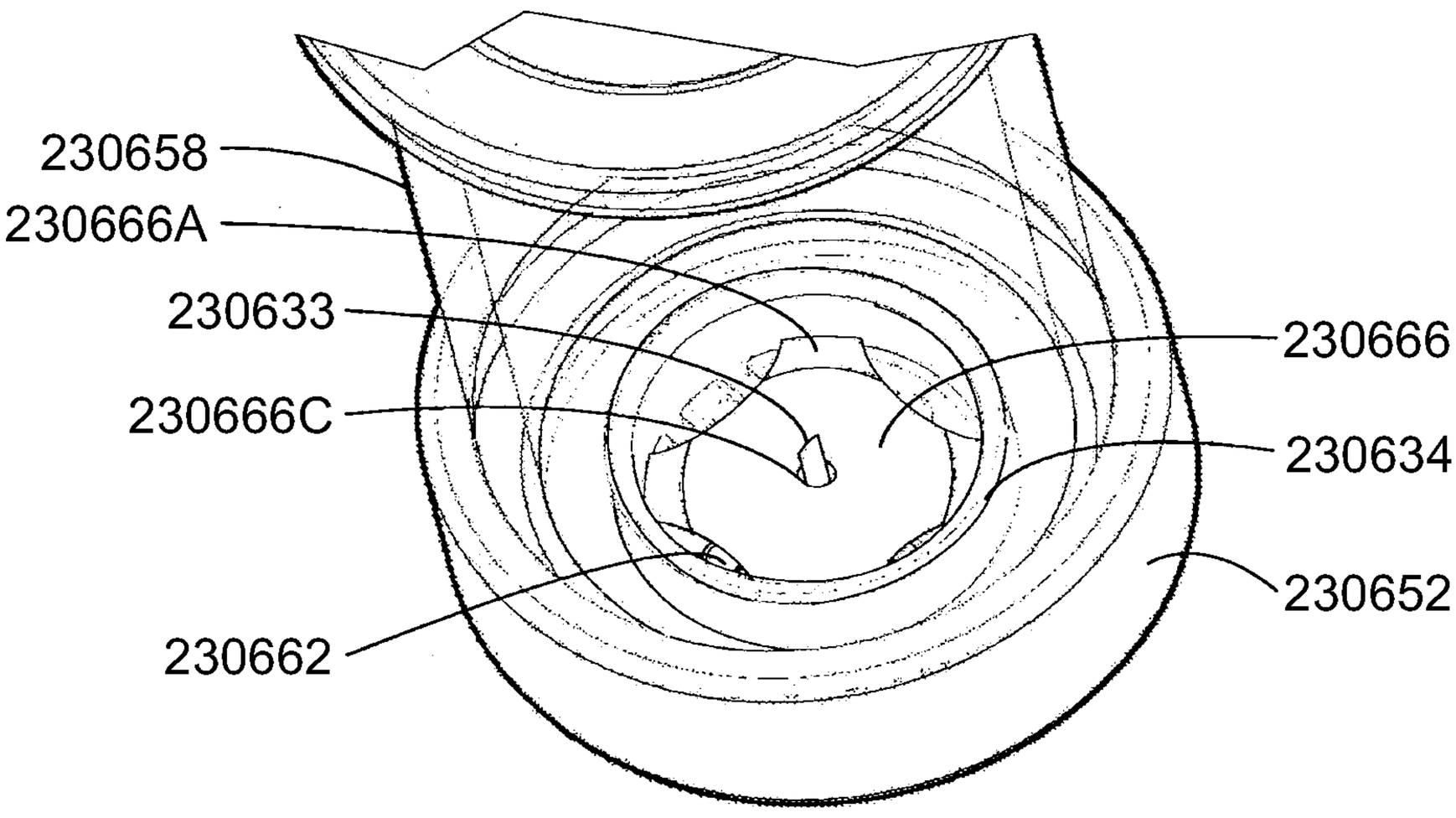

230658
230666A
230633
230666C
230662
230666
230634
230652

FIG. 68

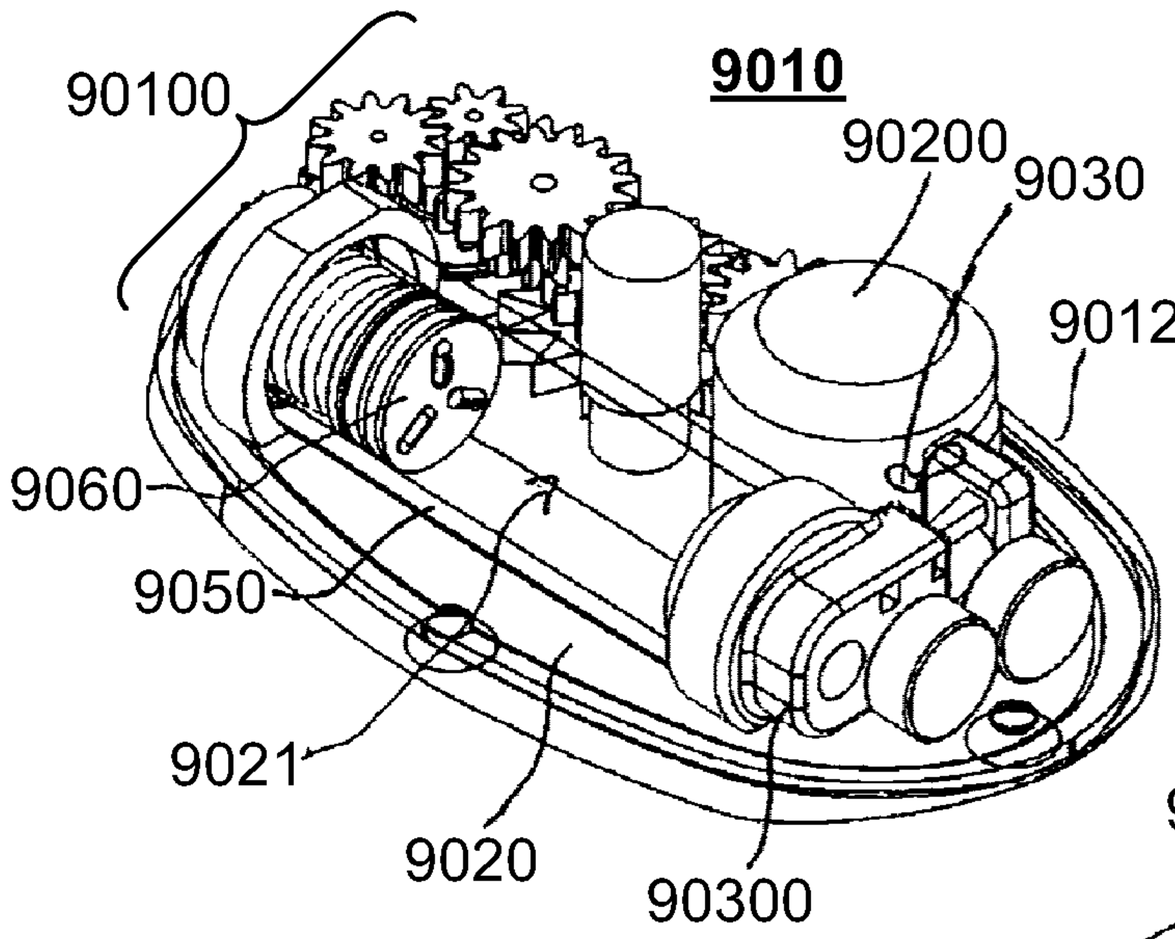


FIG. 69A

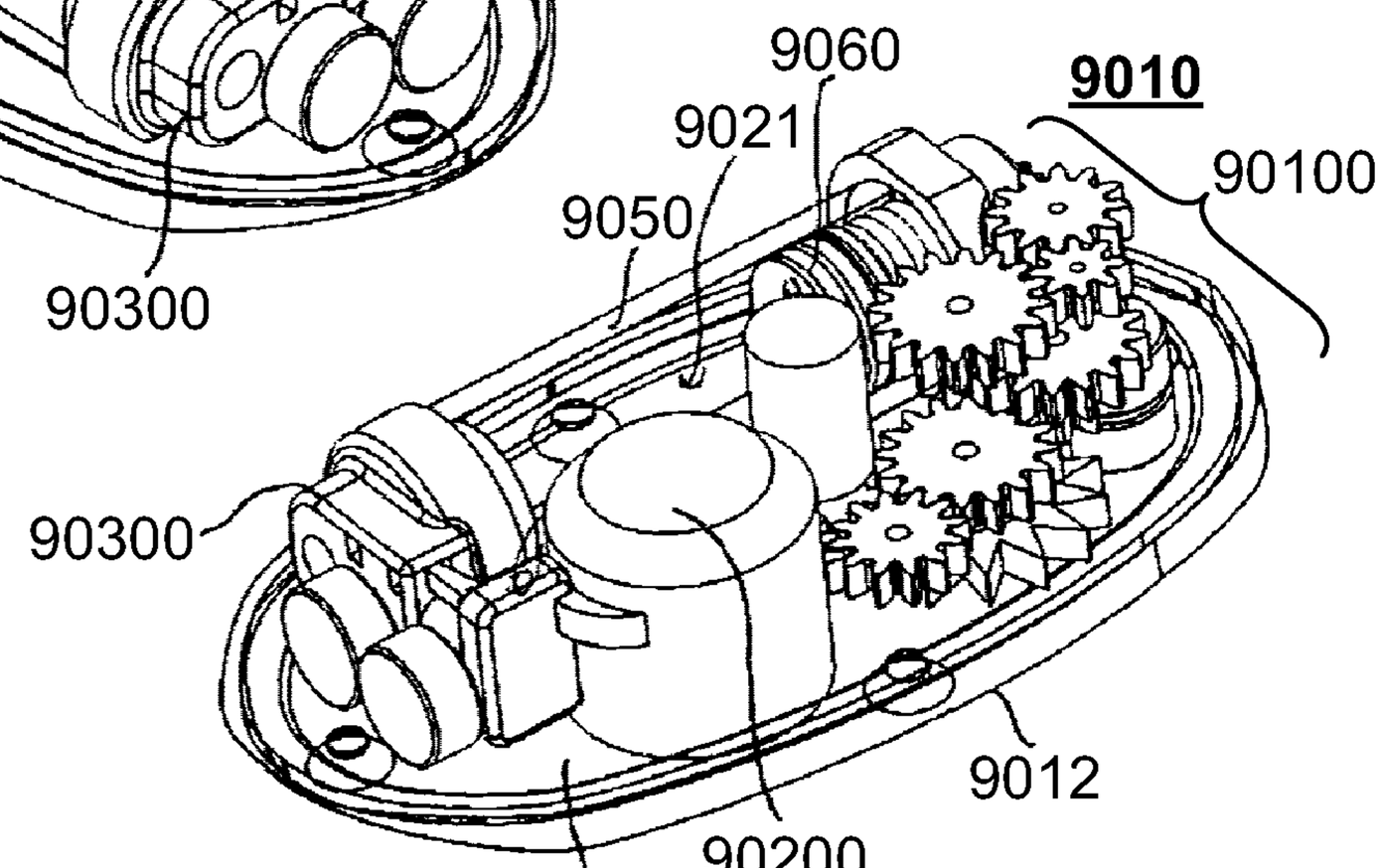


FIG. 69B

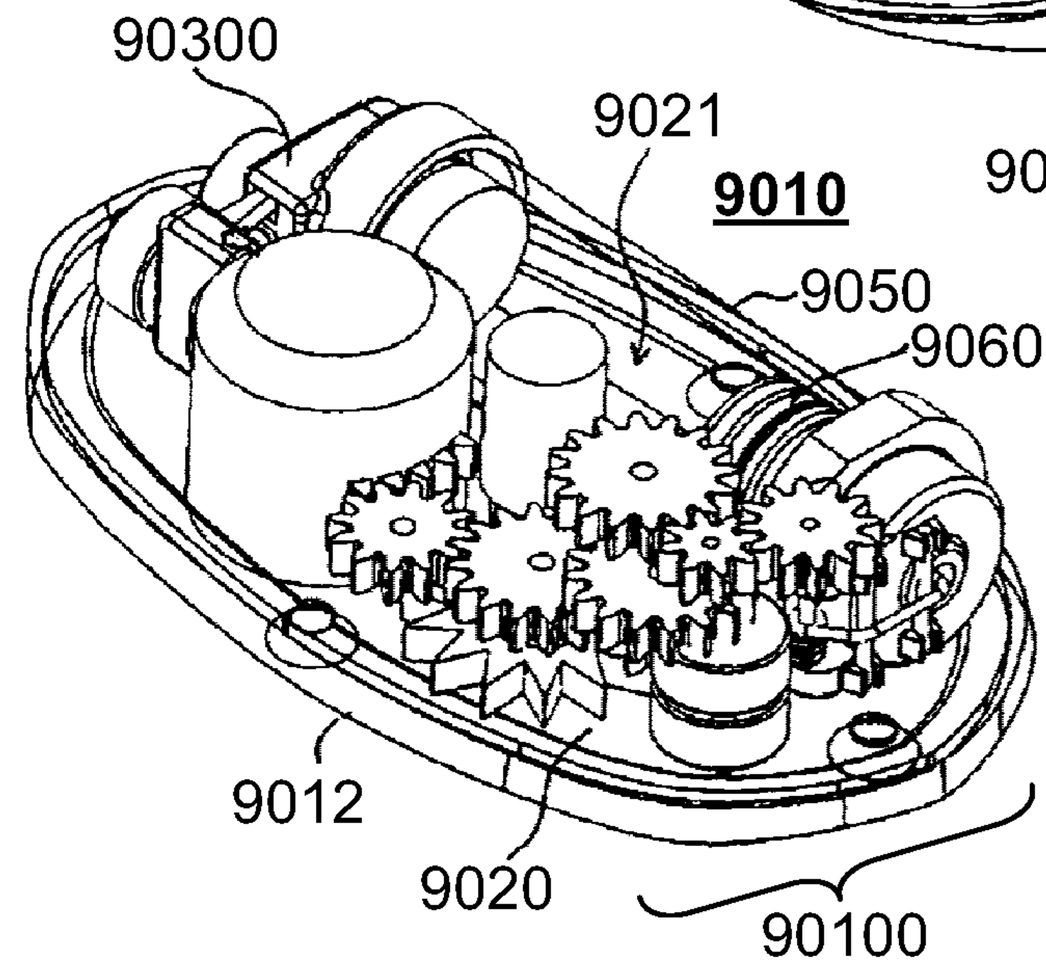


FIG. 69C

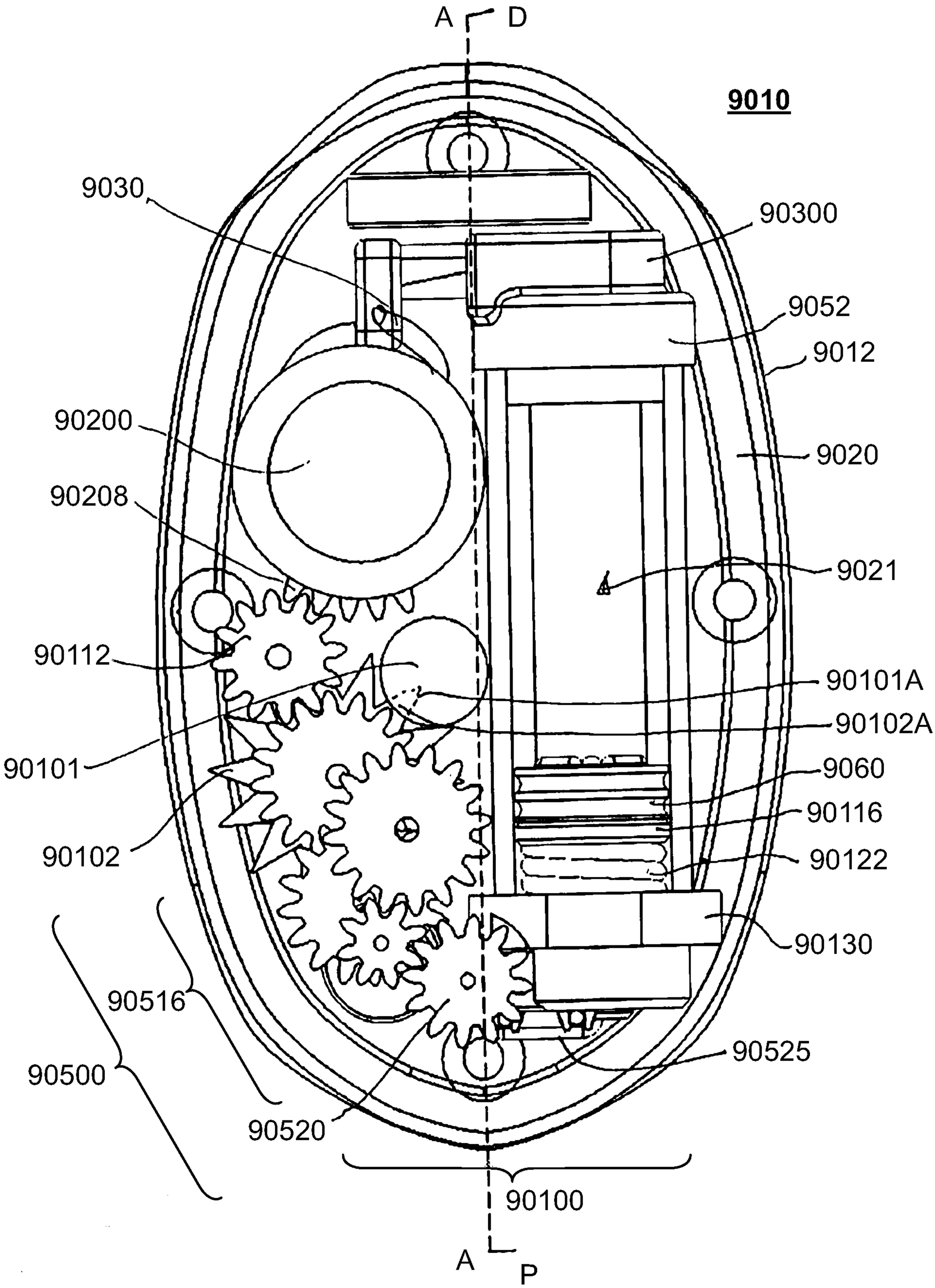

A
D
9010
9030
90300
9052
9012
90200
9020
90208
9021
90112
90101A
90102A
90101
9060
90116
90102
90122
90130
90516
90525
90500
90520
90100
A
P

FIG. 69D

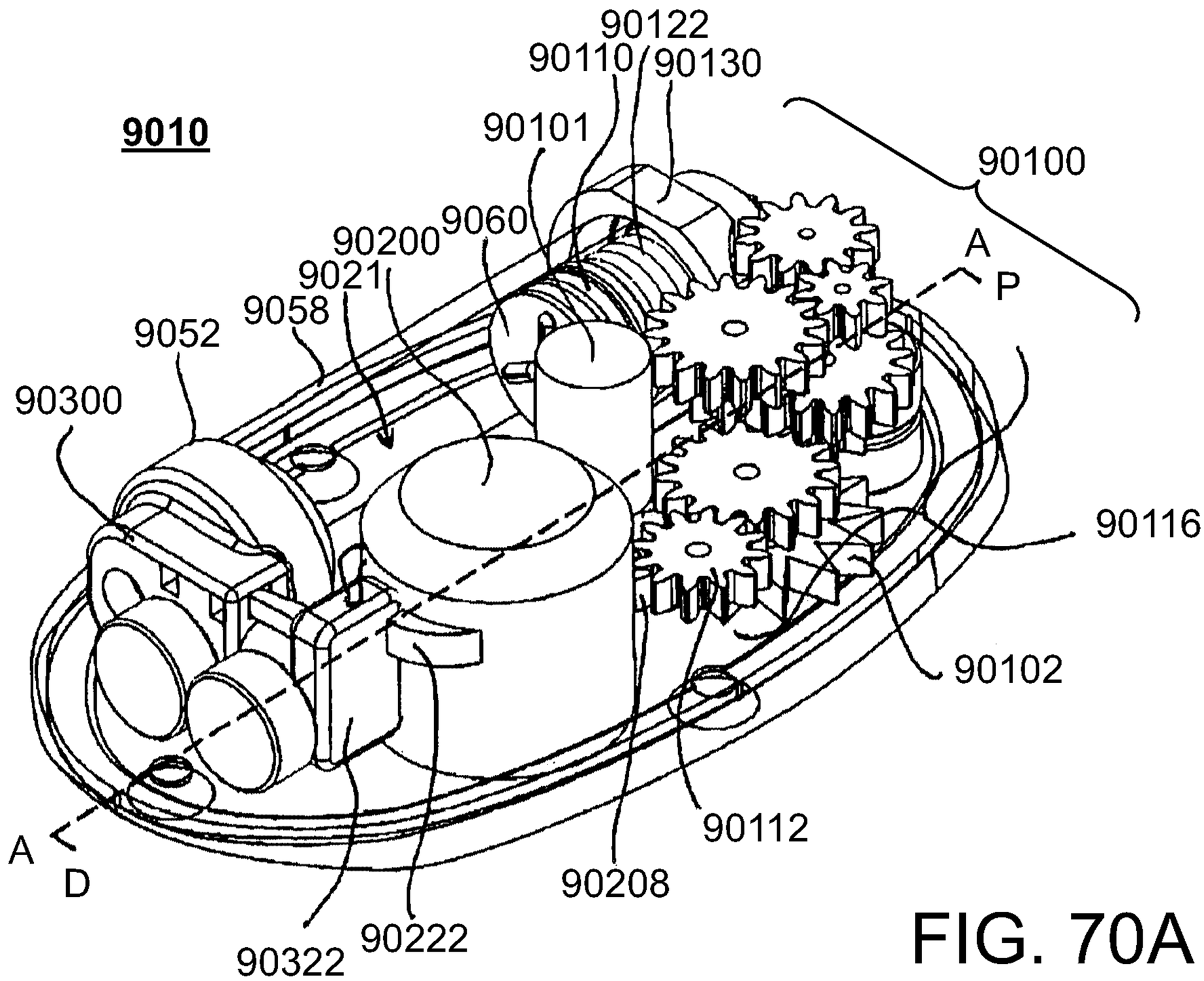


FIG. 70A

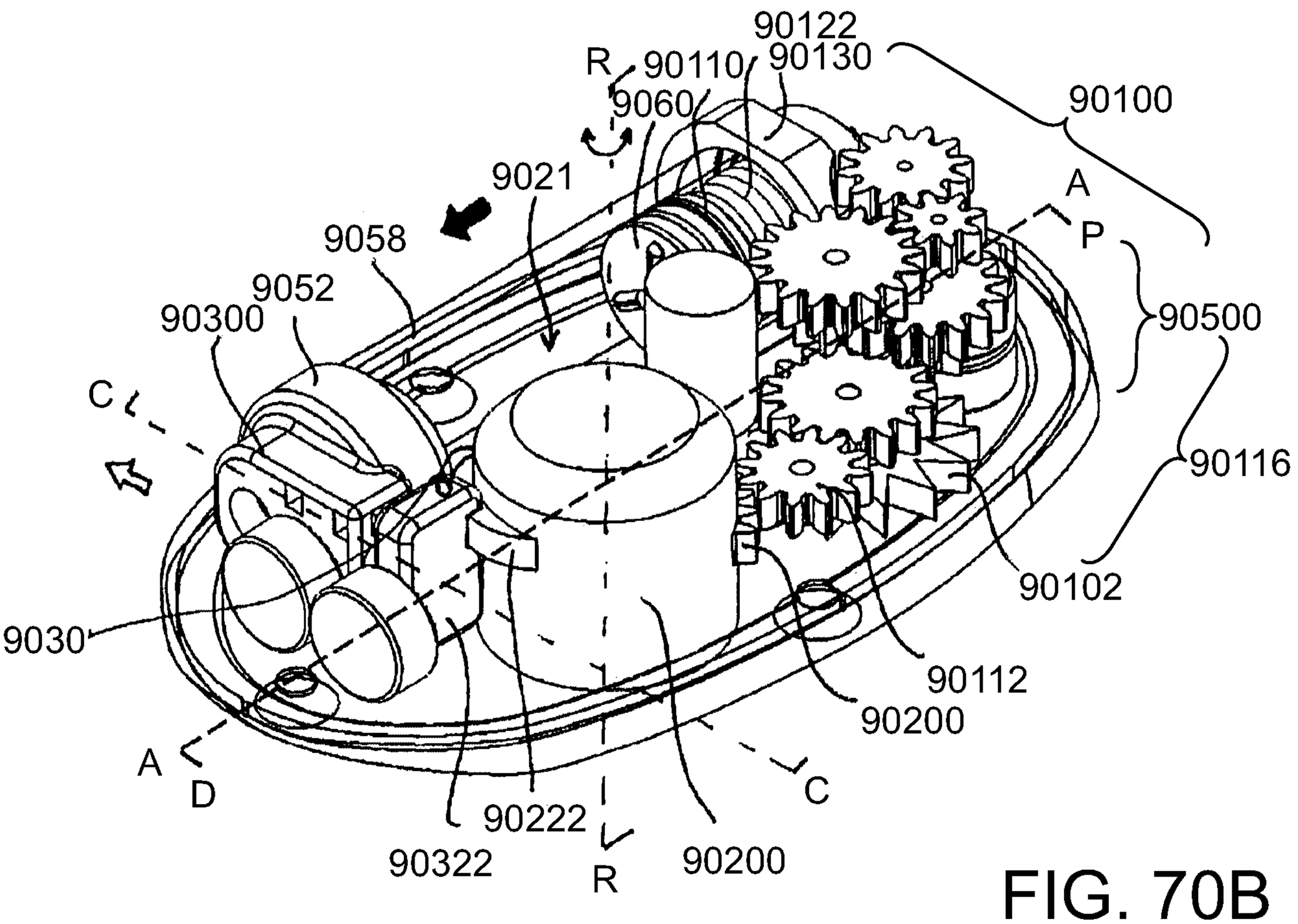


FIG. 70B

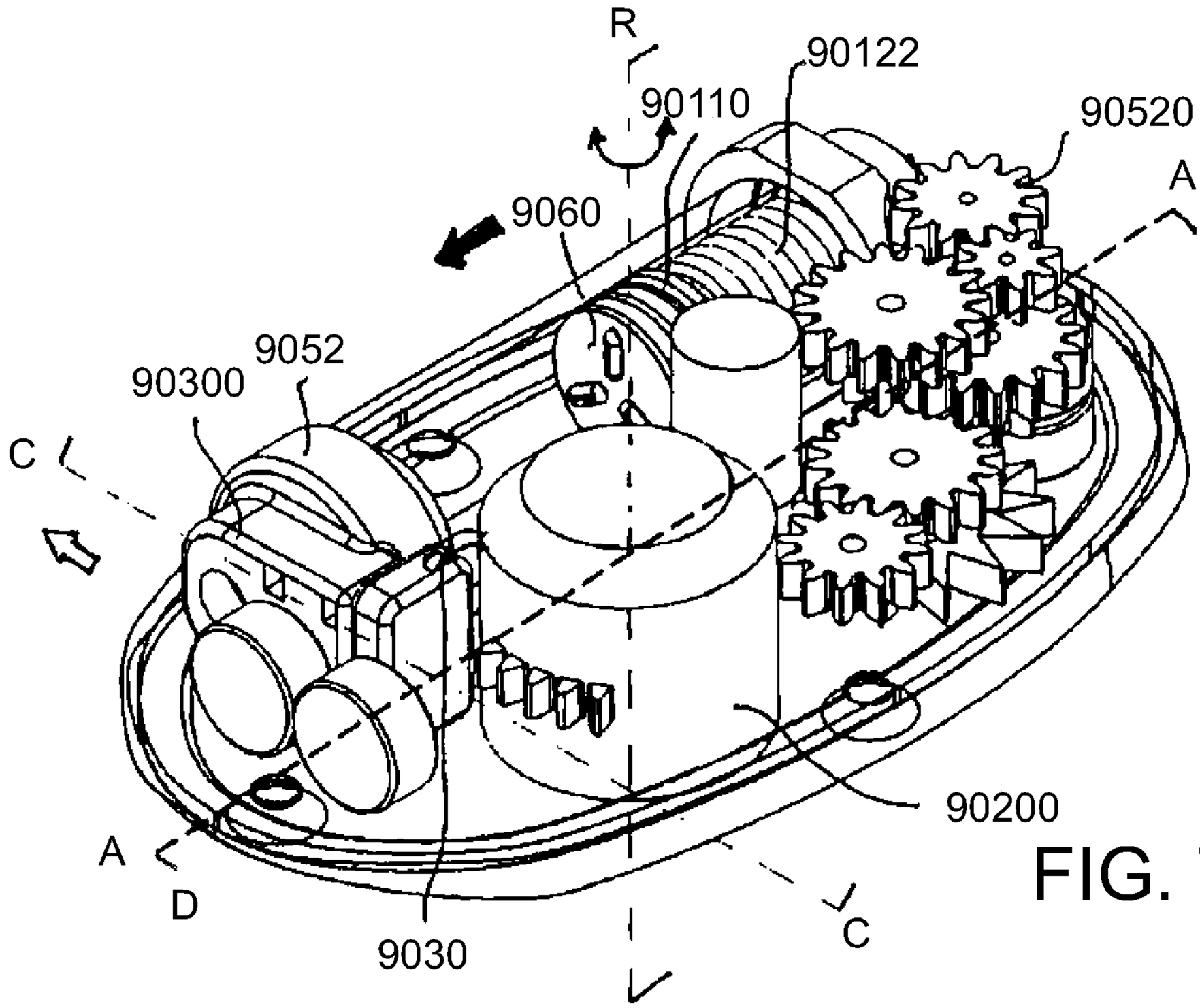


FIG. 70C

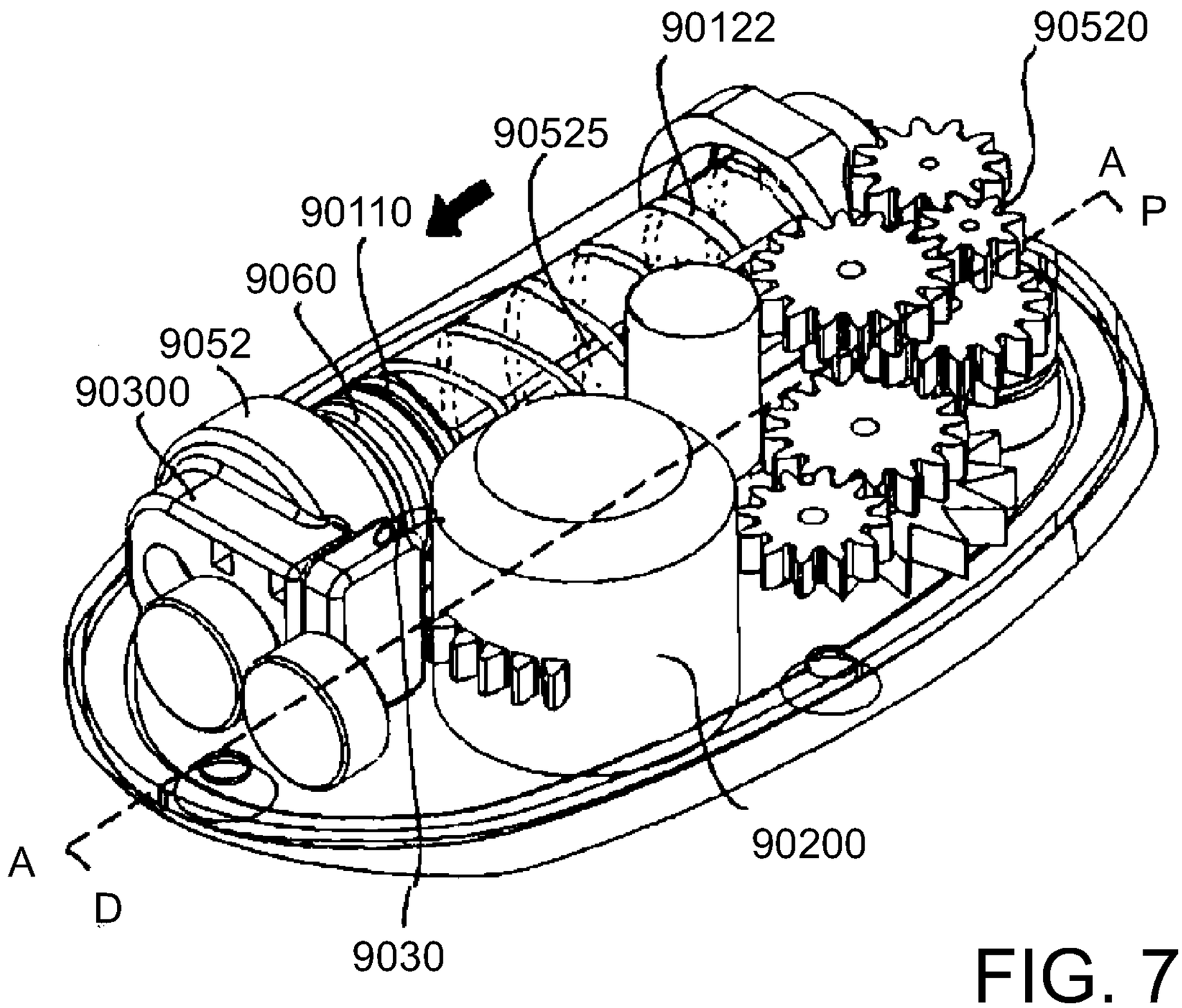


FIG. 70D

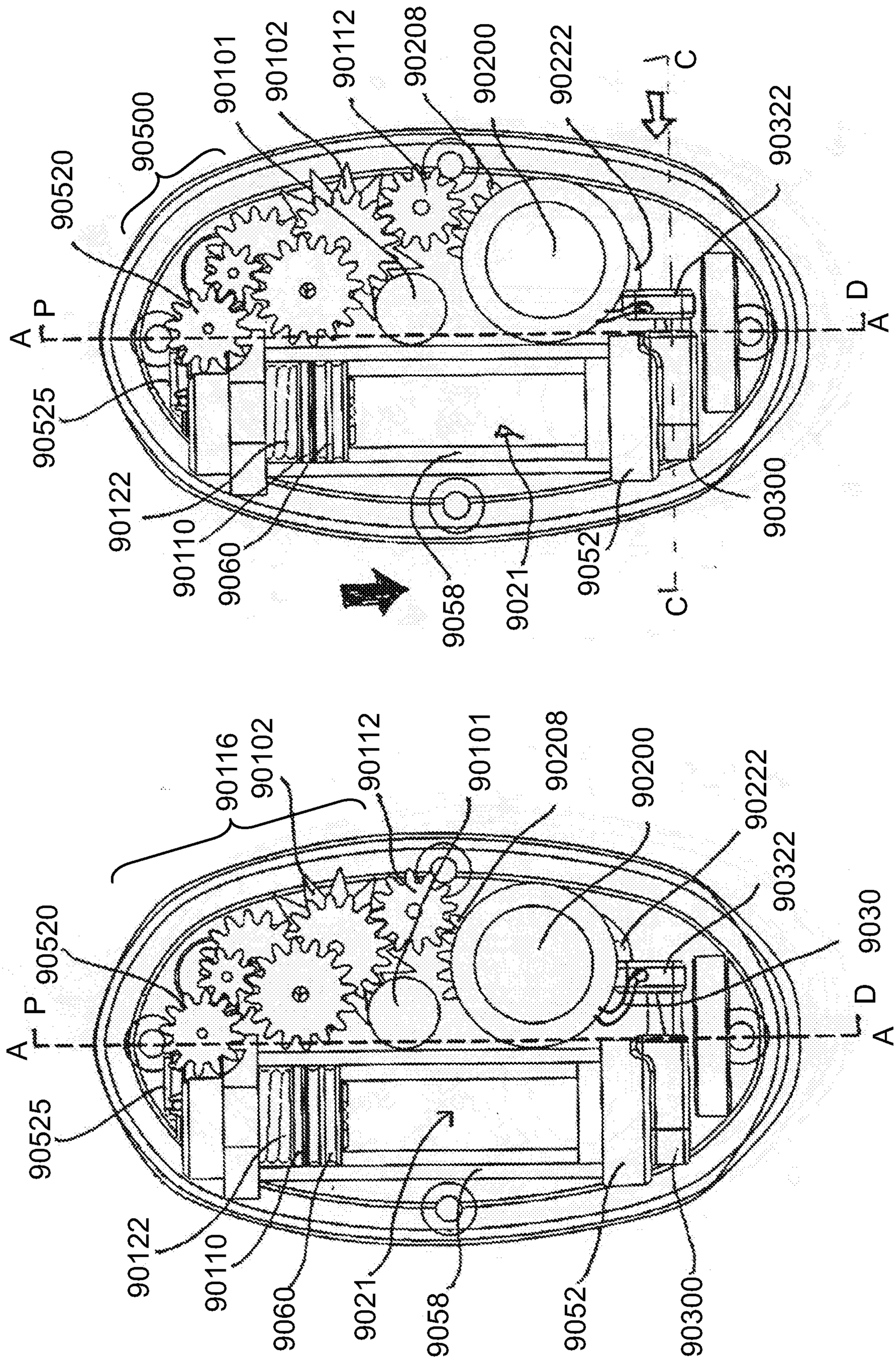


FIG. 71B

FIG. 71A

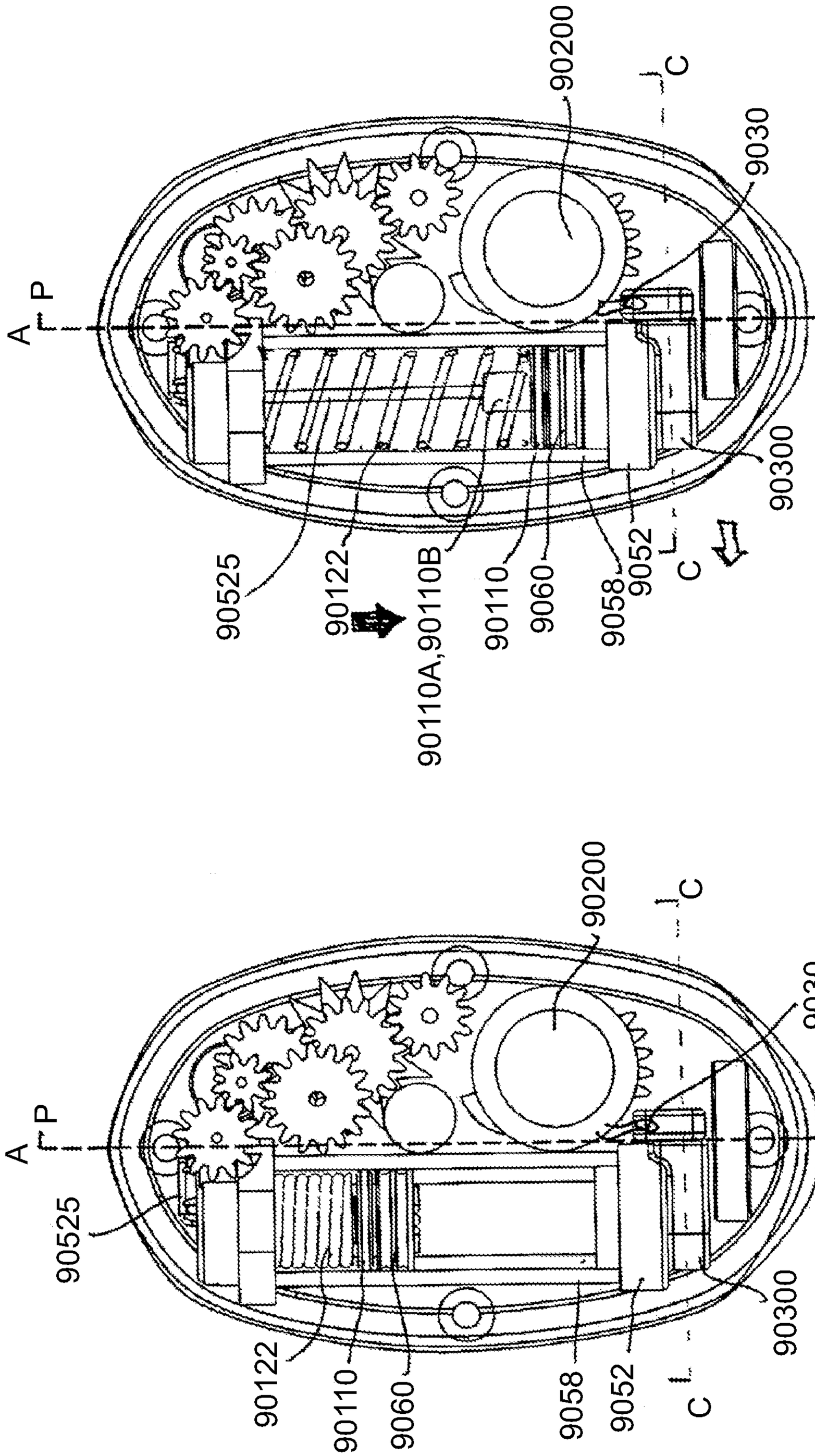


FIG. 71D

FIG. 71C

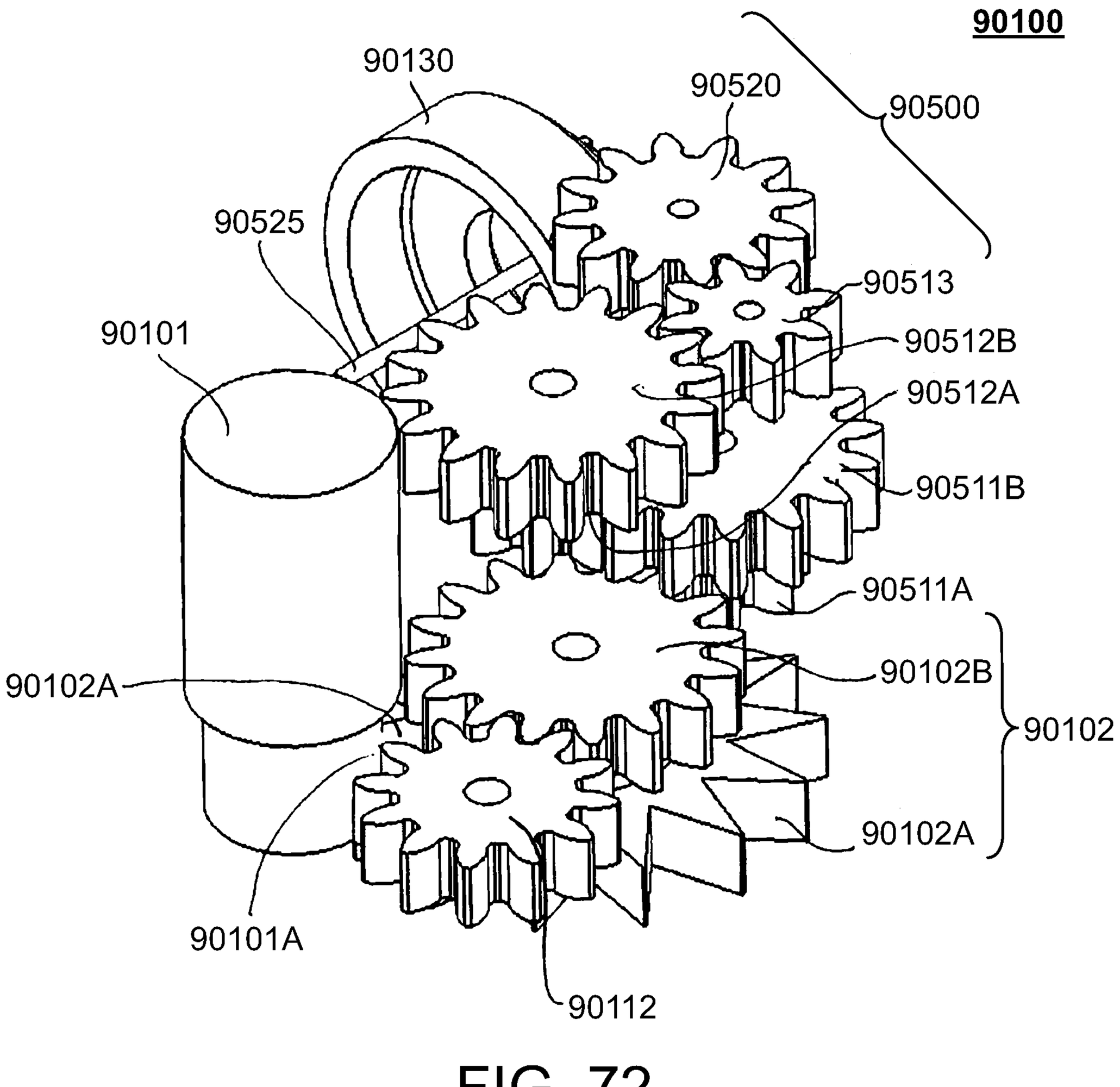

90100
90130
90520
90500
90525
90513
90101
90512B
90512A
90511B
90511A
90102B
90102A
90102
90102A
90101A
90112

FIG. 72

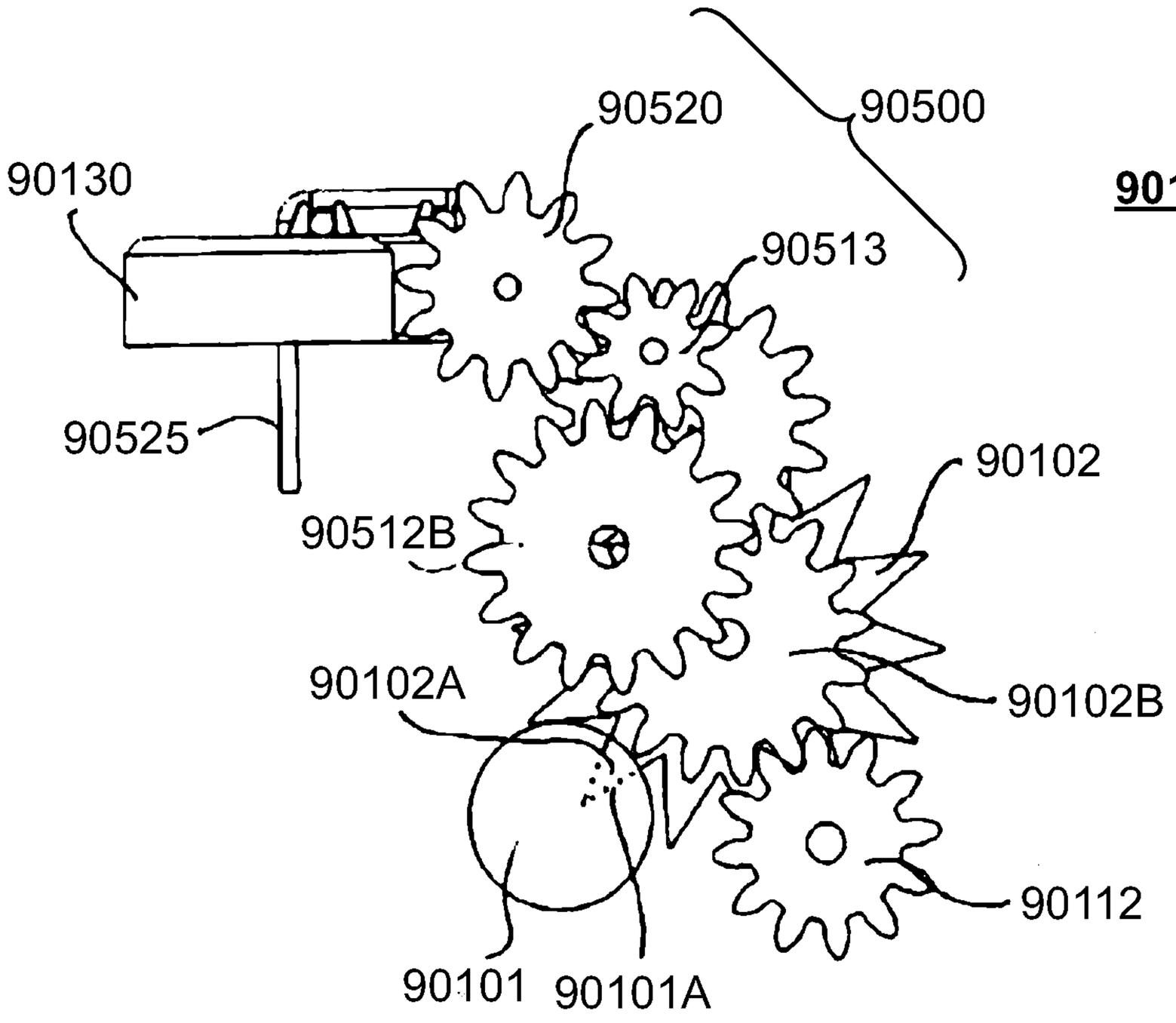


FIG. 73A

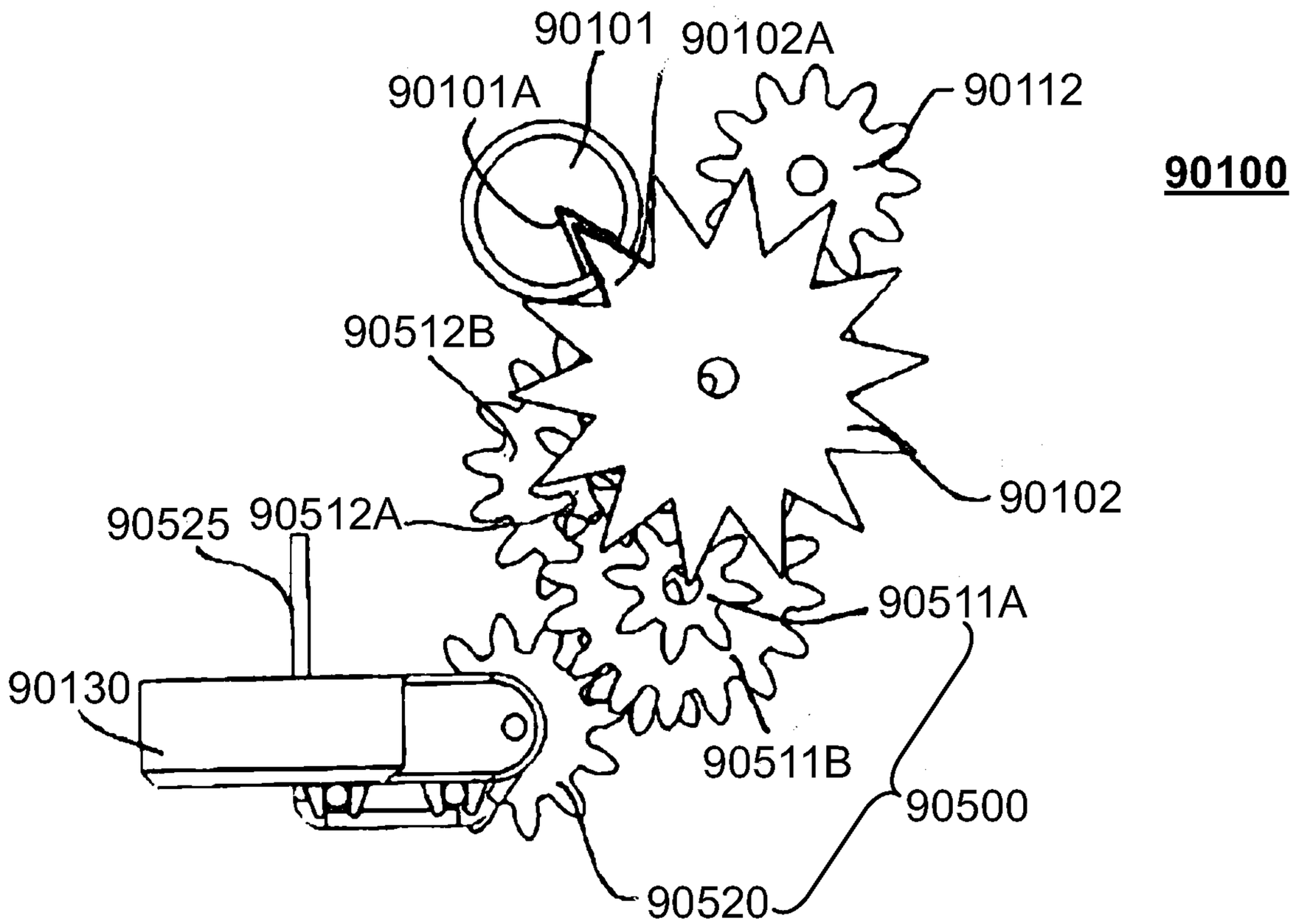


FIG. 73B

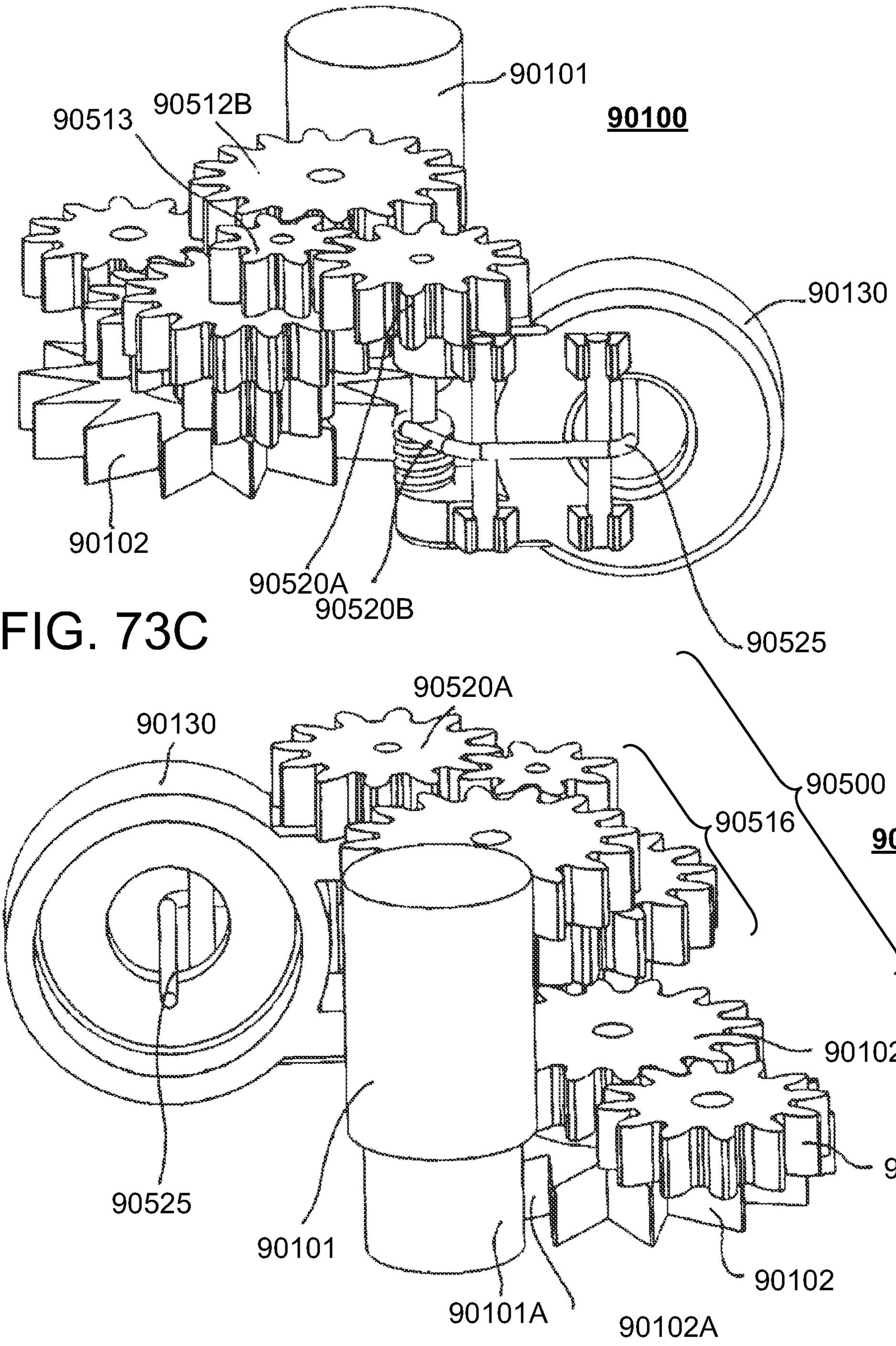


FIG. 73C

FIG. 73D

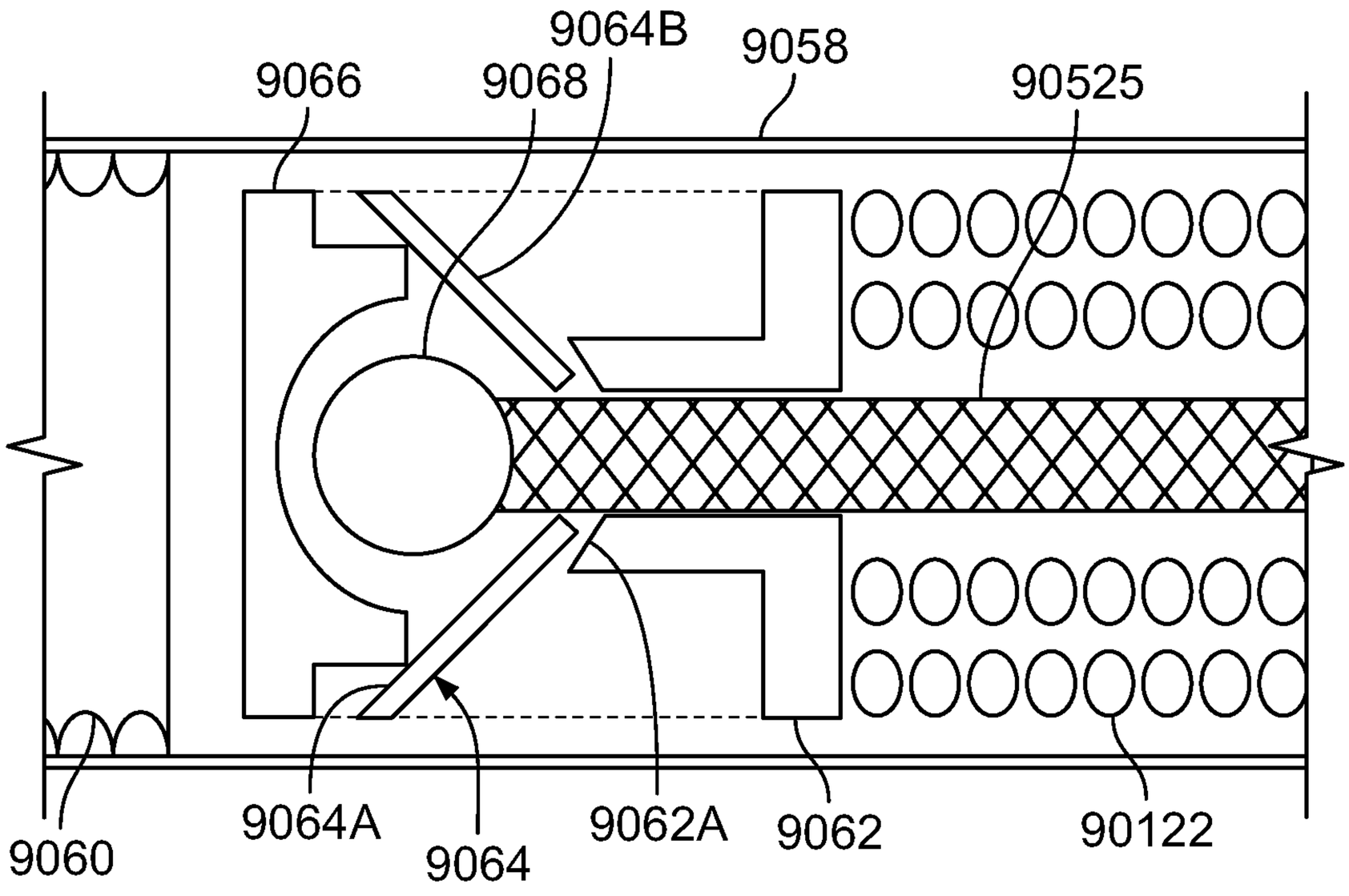


FIG. 74A

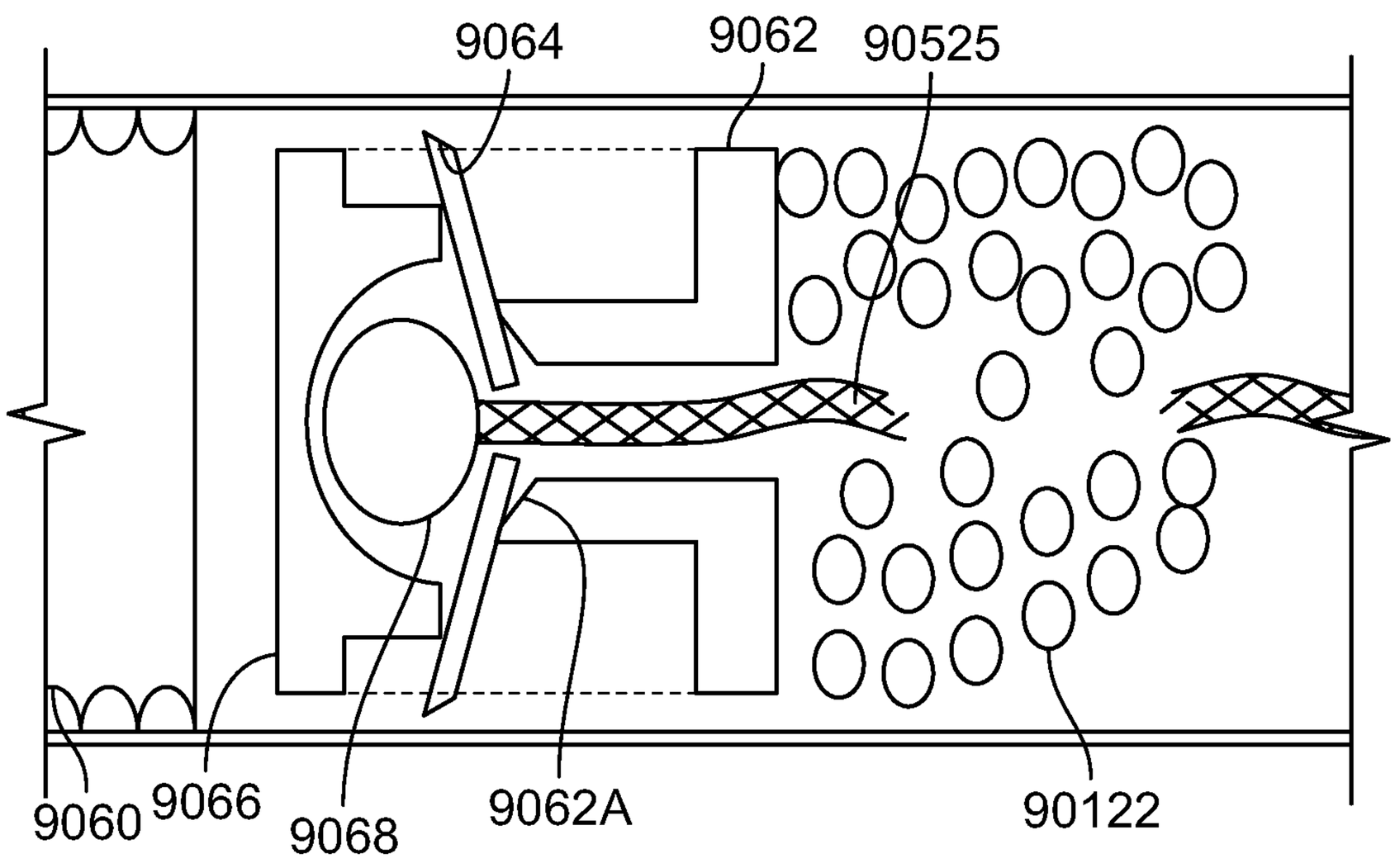


FIG. 74B

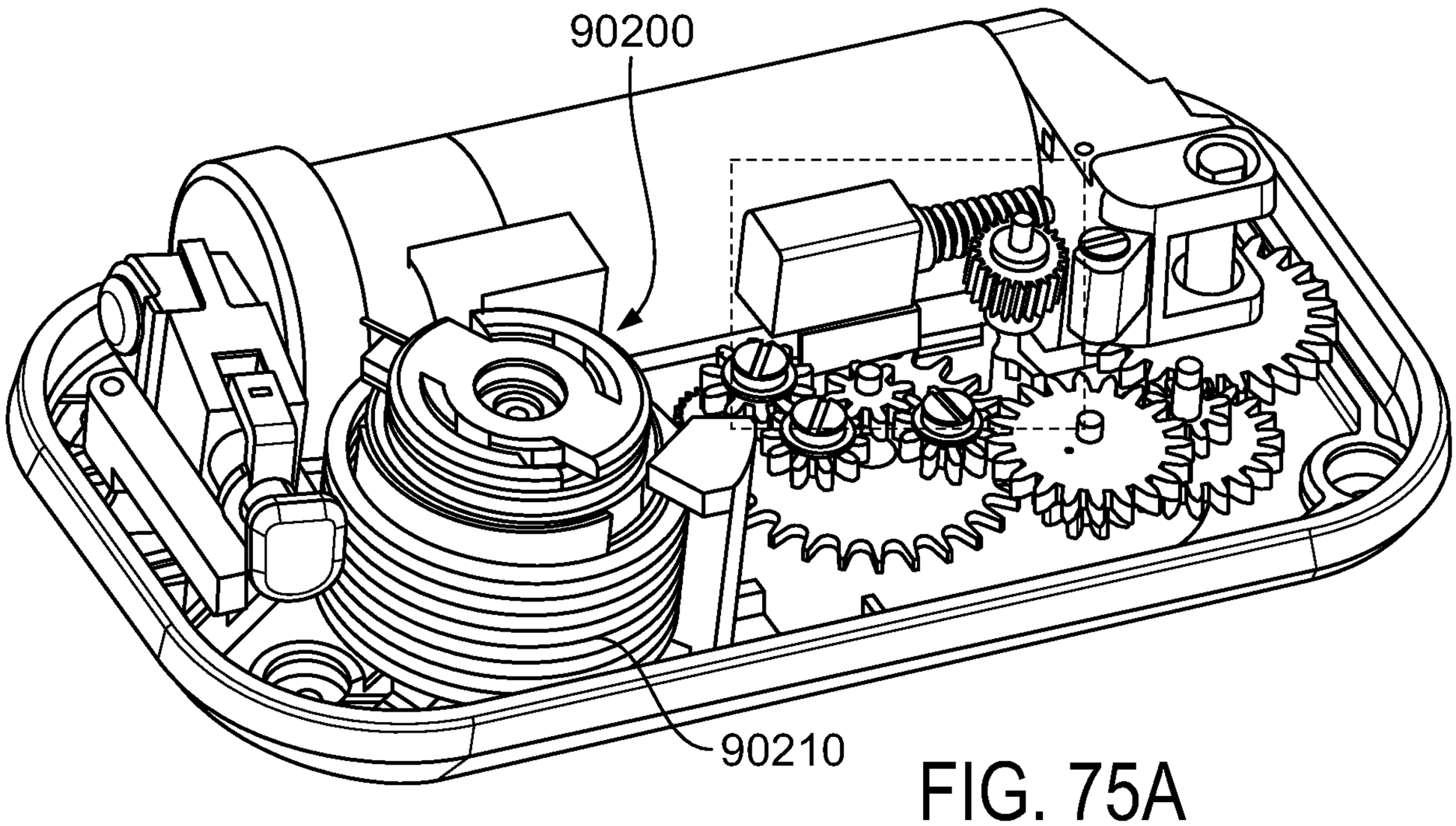


FIG. 75A

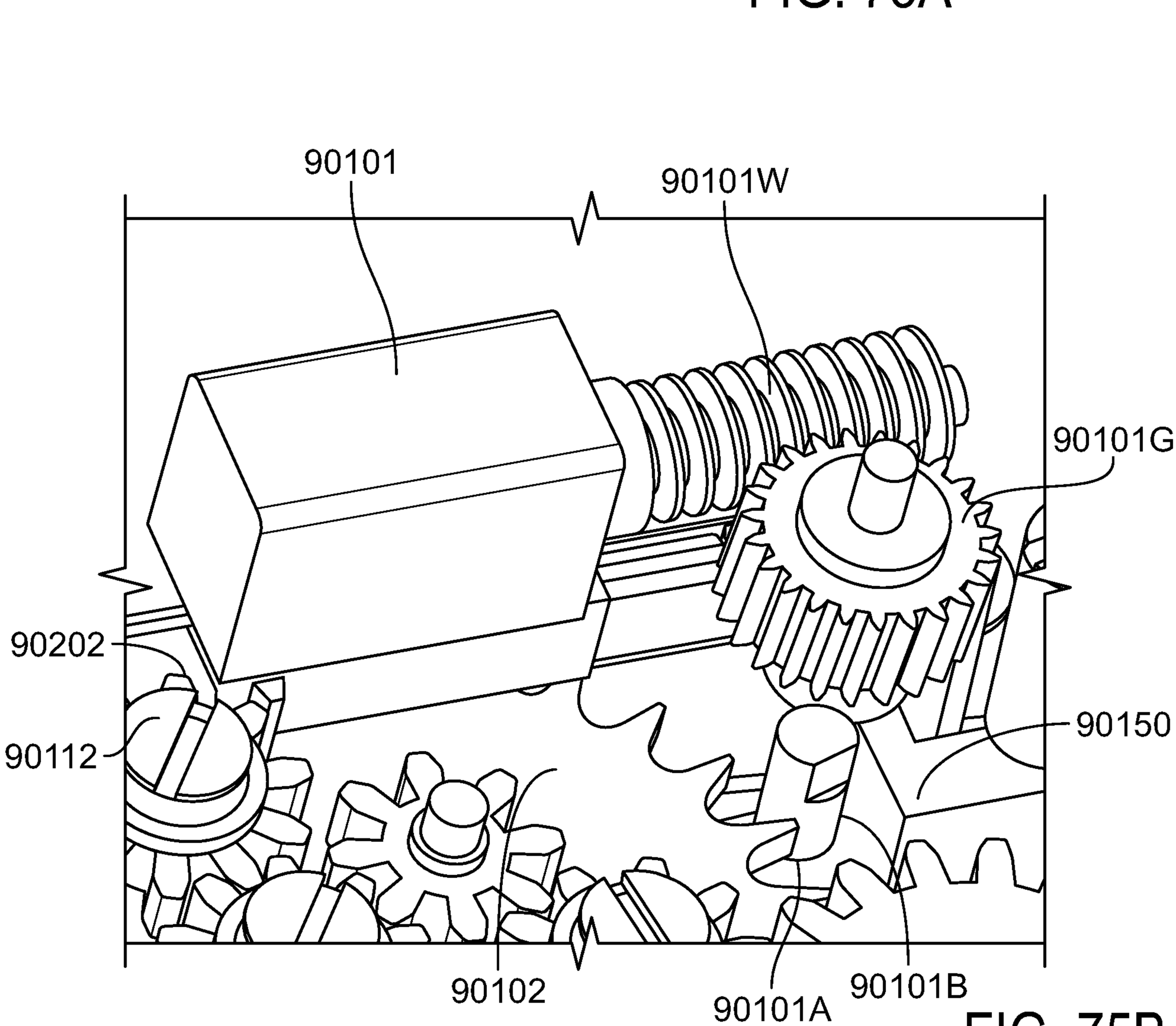


FIG. 75B

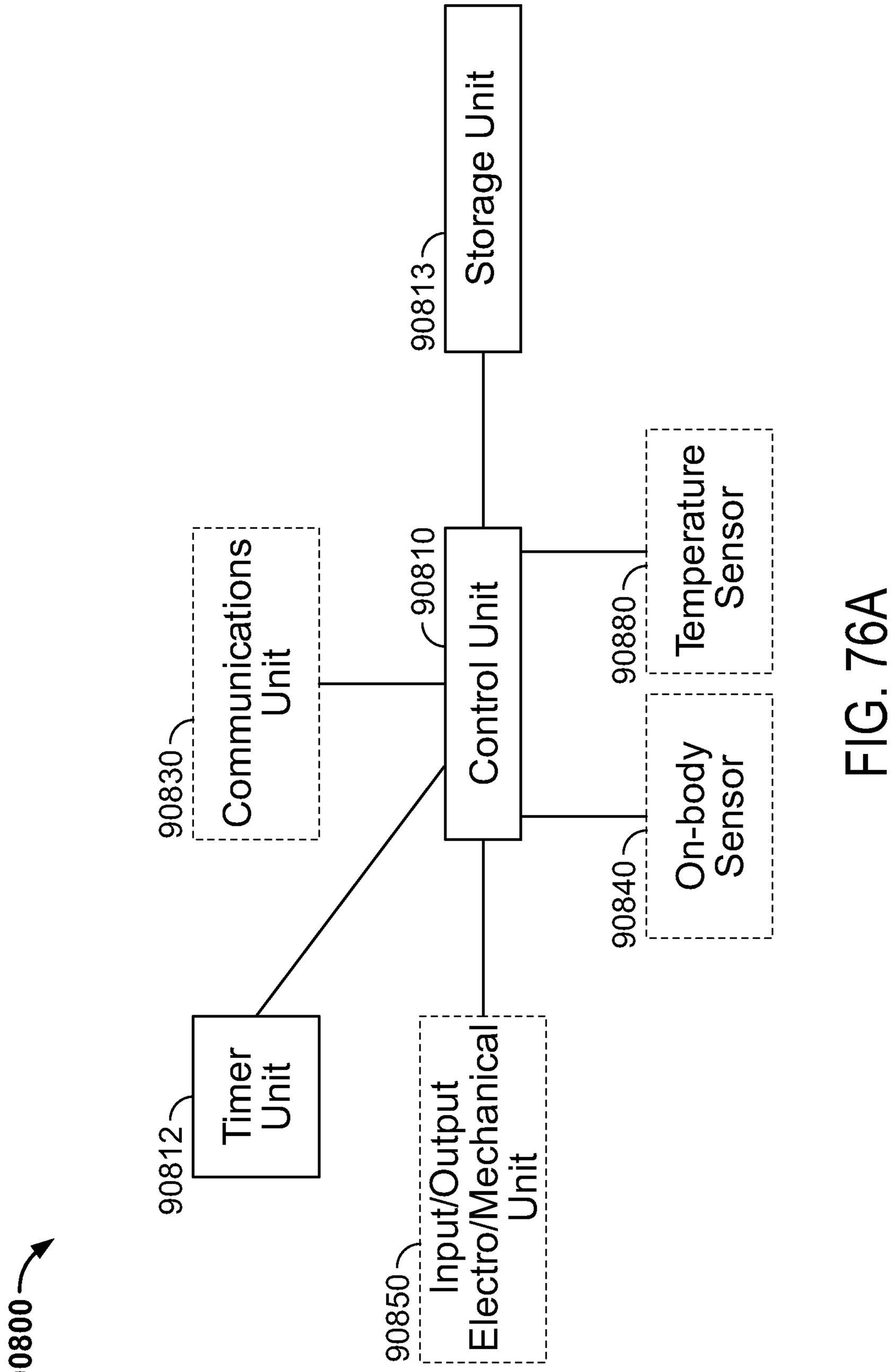

90800
90810
Control Unit
90813
Storage Unit
90830
Communications Unit
90812
Timer Unit
90880
Temperature Sensor
90840
On-body Sensor
90850
Input/Output Electro/Mechanical Unit

FIG. 76A

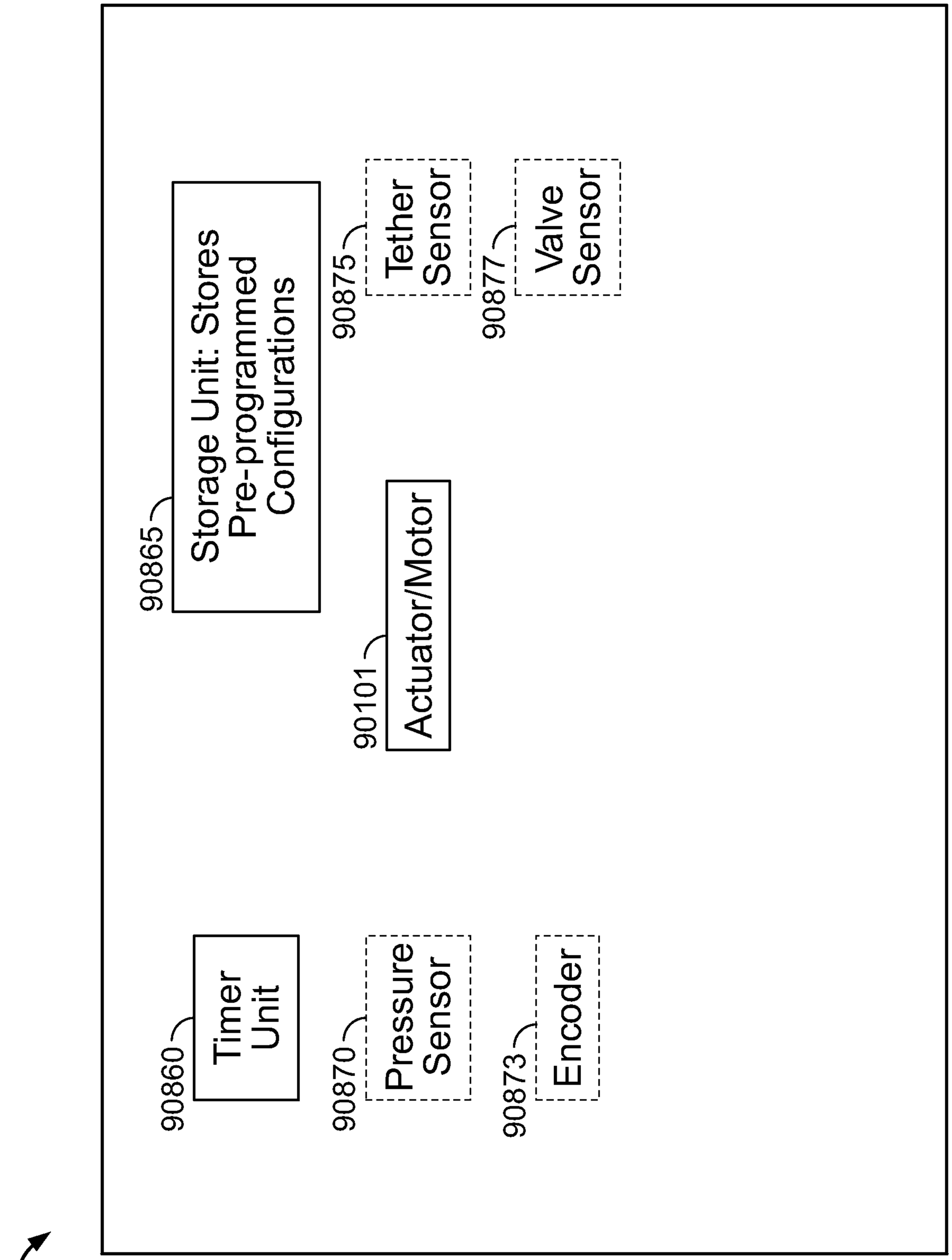

90820
90865
Storage Unit: Stores Pre-programmed Configurations
90875
Tether Sensor
90877
Valve Sensor
90101
Actuator/Motor
90860
Timer Unit
90870
Pressure Sensor
90873
Encoder

FIG. 76B

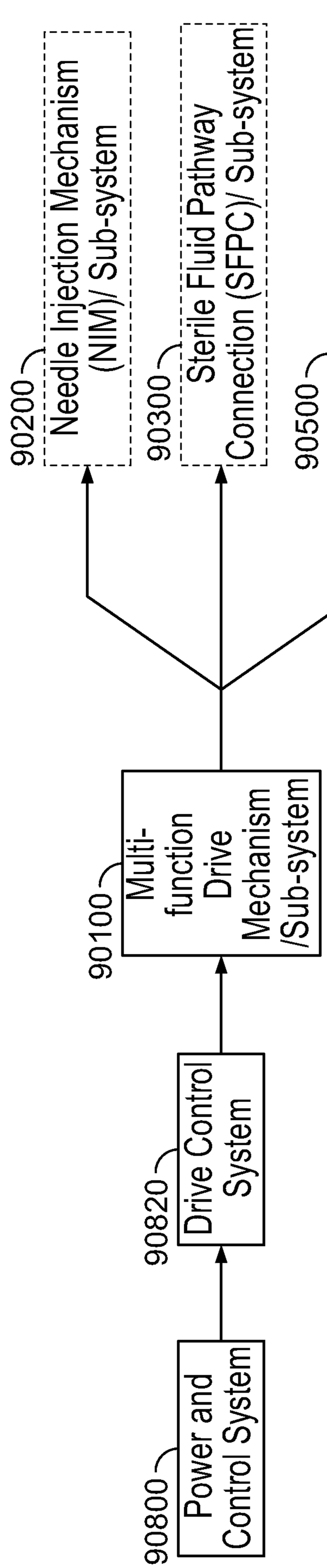
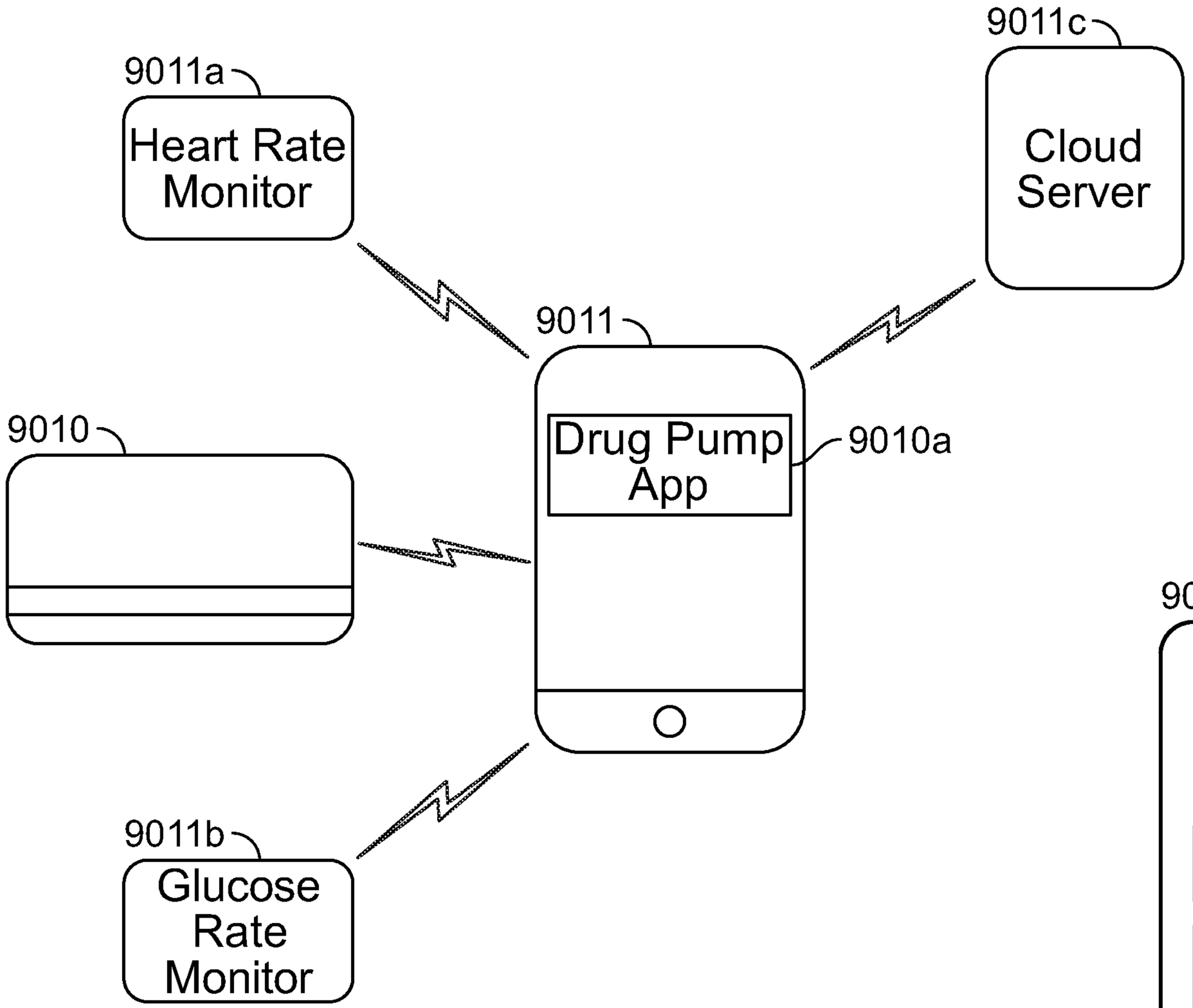

90800
Power and Control System
90820
Drive Control System
90100
Multi-function Drive Mechanism /Sub-system
90200
Needle Injection Mechanism (NIM)/ Sub-system
90300
Sterile Fluid Pathway Connection (SFPC)/ Sub-system
90500
Regulating Mechanism/System

FIG. 76C


9011a
Heart Rate Monitor
9011c
Cloud Server
9011
Drug Pump App
9010a
9010
9011b
Glucose Rate Monitor

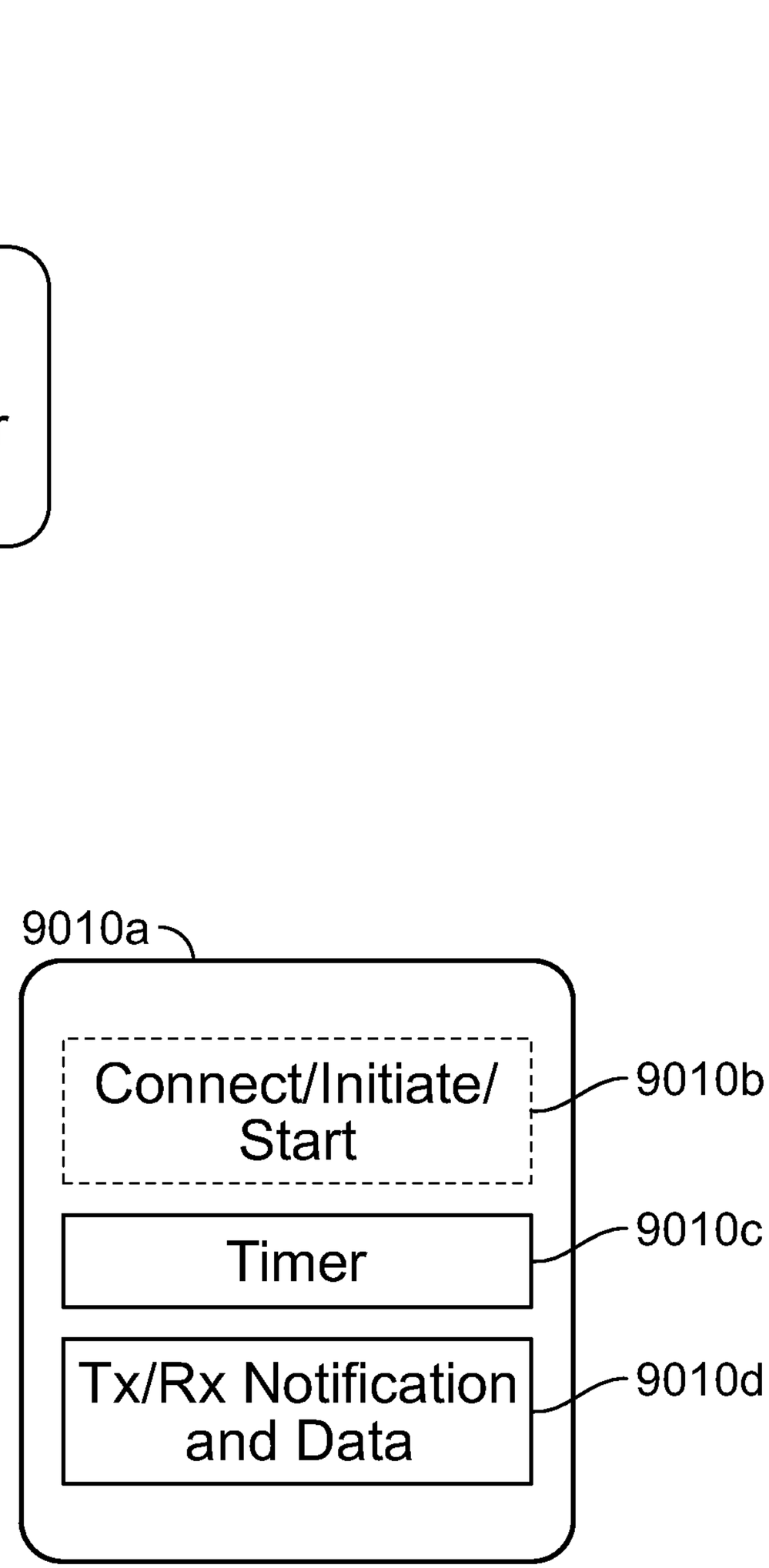

9010a
Connect/Initiate/ Start
9010b
Timer
9010c
Tx/Rx Notification and Data
9010d

FIG. 76D

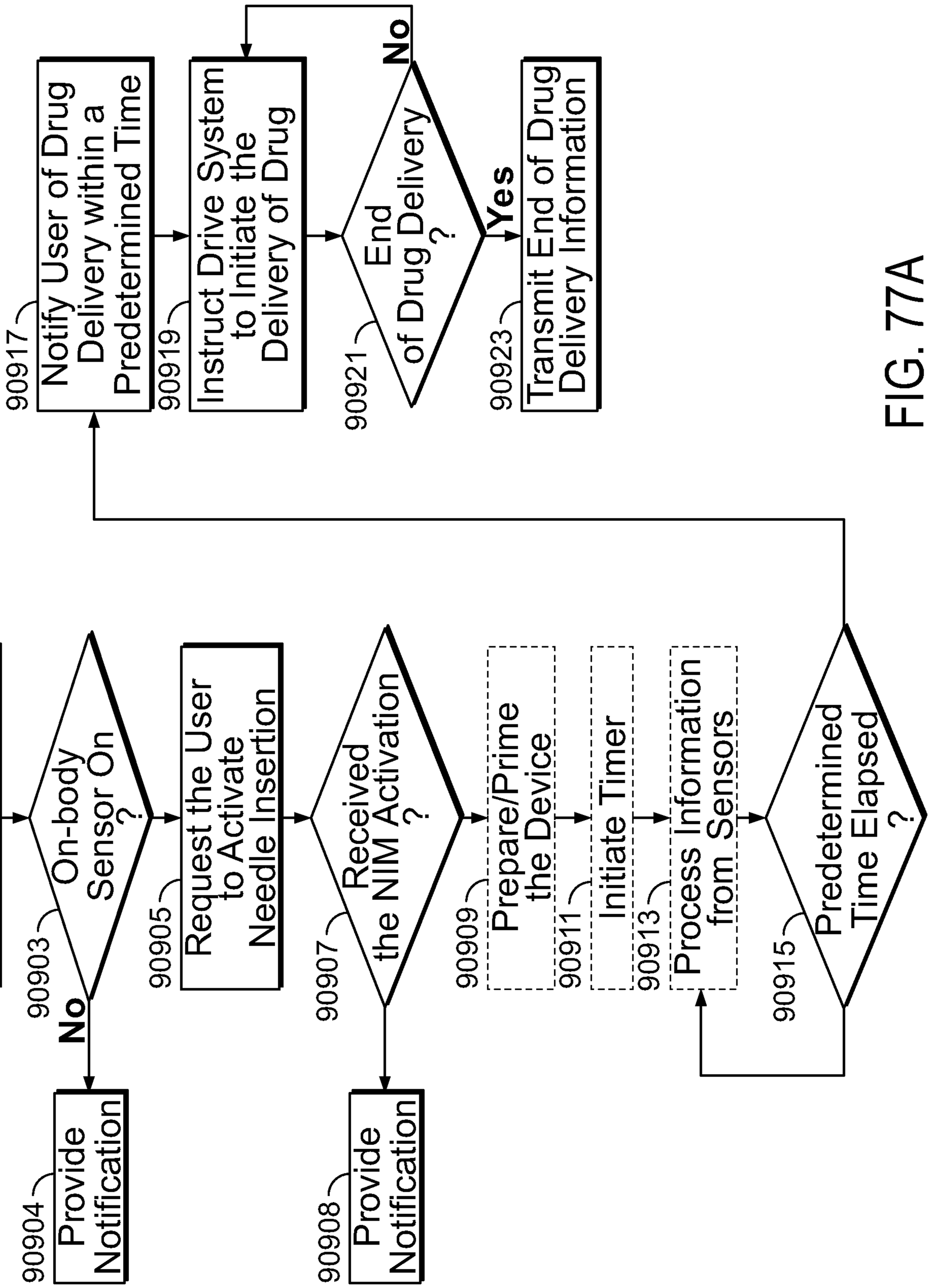

90901
Device Activation
90903
On-body Sensor On ?
No
90904
Provide Notification
Yes
90905
Request the User to Activate Needle Insertion
90907
Received the NIM Activation ?
No
90908
Provide Notification
Yes
90909
Prepare/Prime the Device
90911
Initiate Timer
90913
Process Information from Sensors
90915
Predetermined Time Elapsed ?
No
90917
Notify User of Drug Delivery within a Predetermined Time
90919
Instruct Drive System to Initiate the Delivery of Drug
90921
End of Drug Delivery ?
Yes
90923
Transmit End of Drug Delivery Information

FIG. 77A

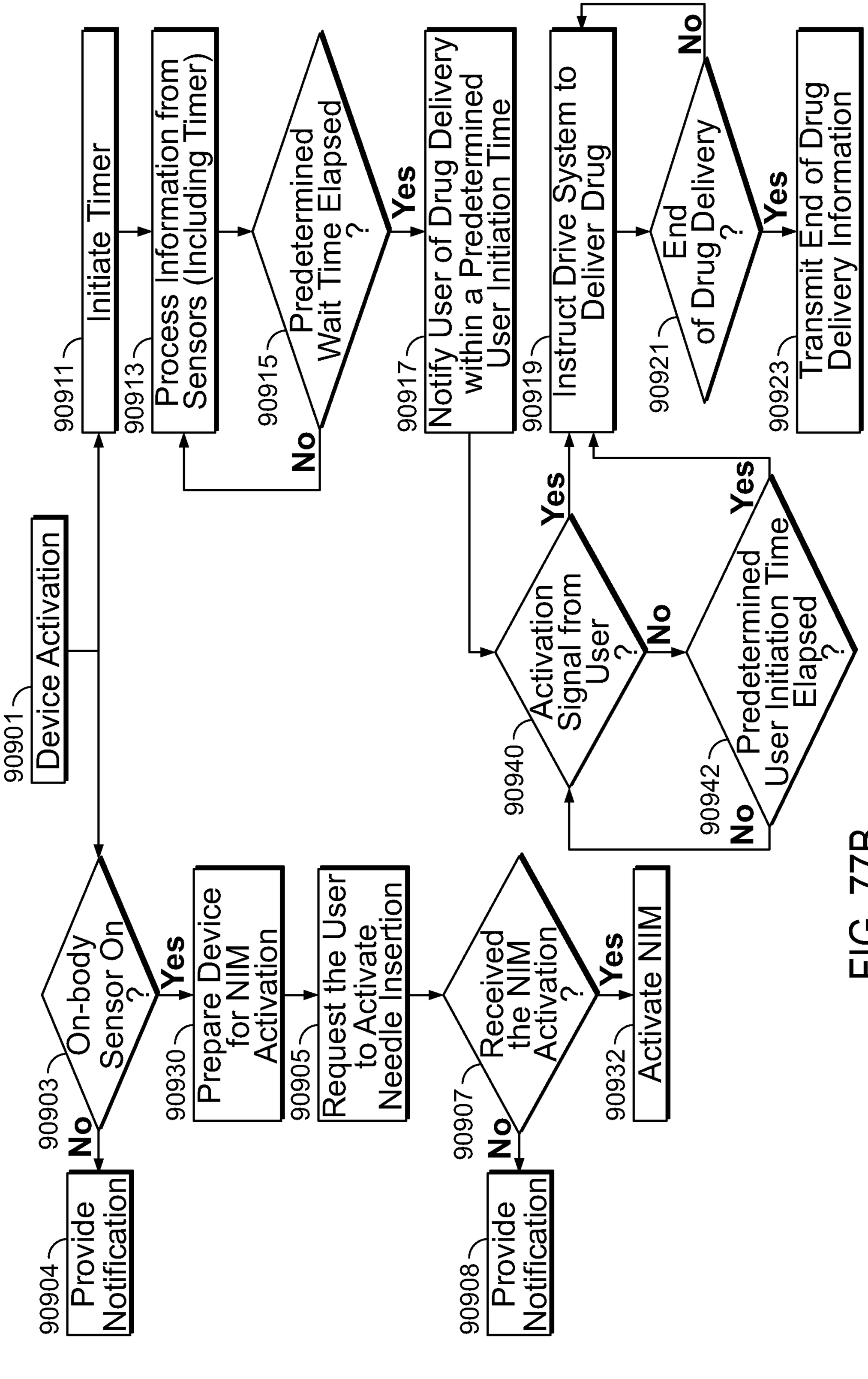

90901
Device Activation
90903
On-body Sensor On ?
Yes
No
90904
Provide Notification
90930
Prepare Device for NIM Activation
90905
Request the User to Activate Needle Insertion
90907
Received the NIM Activation ?
Yes
No
90908
Provide Notification
90932
Activate NIM
90940
Activation Signal from User ?
Yes
No
90942
Predetermined User Initiation Time Elapsed ?
Yes
No
90911
Initiate Timer
90913
Process Information from Sensors (Including Timer)
90915
Predetermined Wait Time Elapsed ?
Yes
No
90917
Notify User of Drug Delivery within a Predetermined User Initiation Time
90919
Instruct Drive System to Deliver Drug
90921
End of Drug Delivery ?
Yes
No
90923
Transmit End of Drug Delivery Information

FIG. 77B

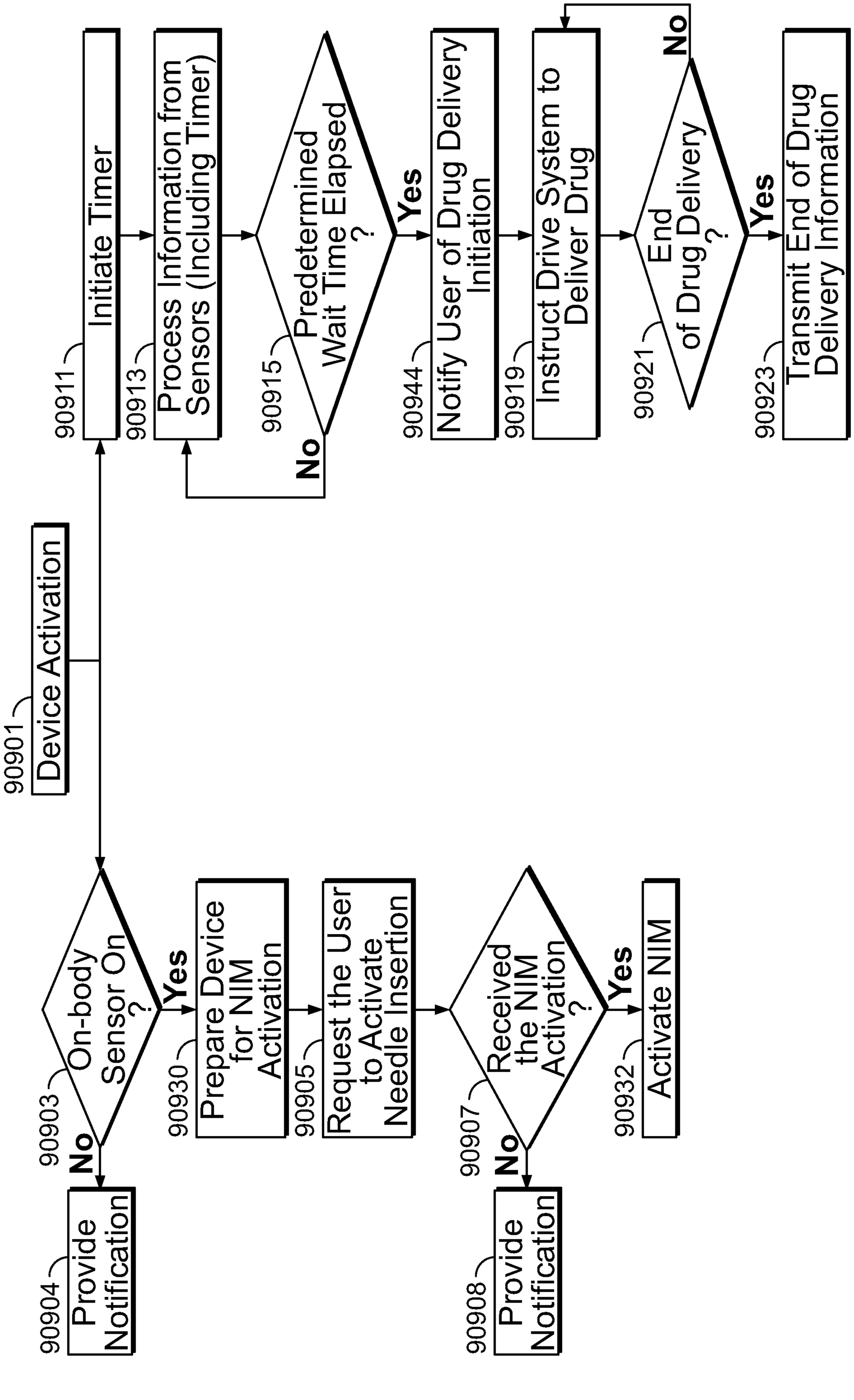

90901
Device Activation
90903
On-body Sensor On ?
No
90904
Provide Notification
Yes
90930
Prepare Device for NIM Activation
90905
Request the User to Activate Needle Insertion
90907
Received the NIM Activation ?
No
90908
Provide Notification
Yes
90932
Activate NIM
90911
Initiate Timer
90913
Process Information from Sensors (Including Timer)
90915
Predetermined Wait Time Elapsed ?
No
Yes
90944
Notify User of Drug Delivery Initiation
90919
Instruct Drive System to Deliver Drug
90921
End of Drug Delivery ?
No
Yes
90923
Transmit End of Drug Delivery Information

FIG. 77C

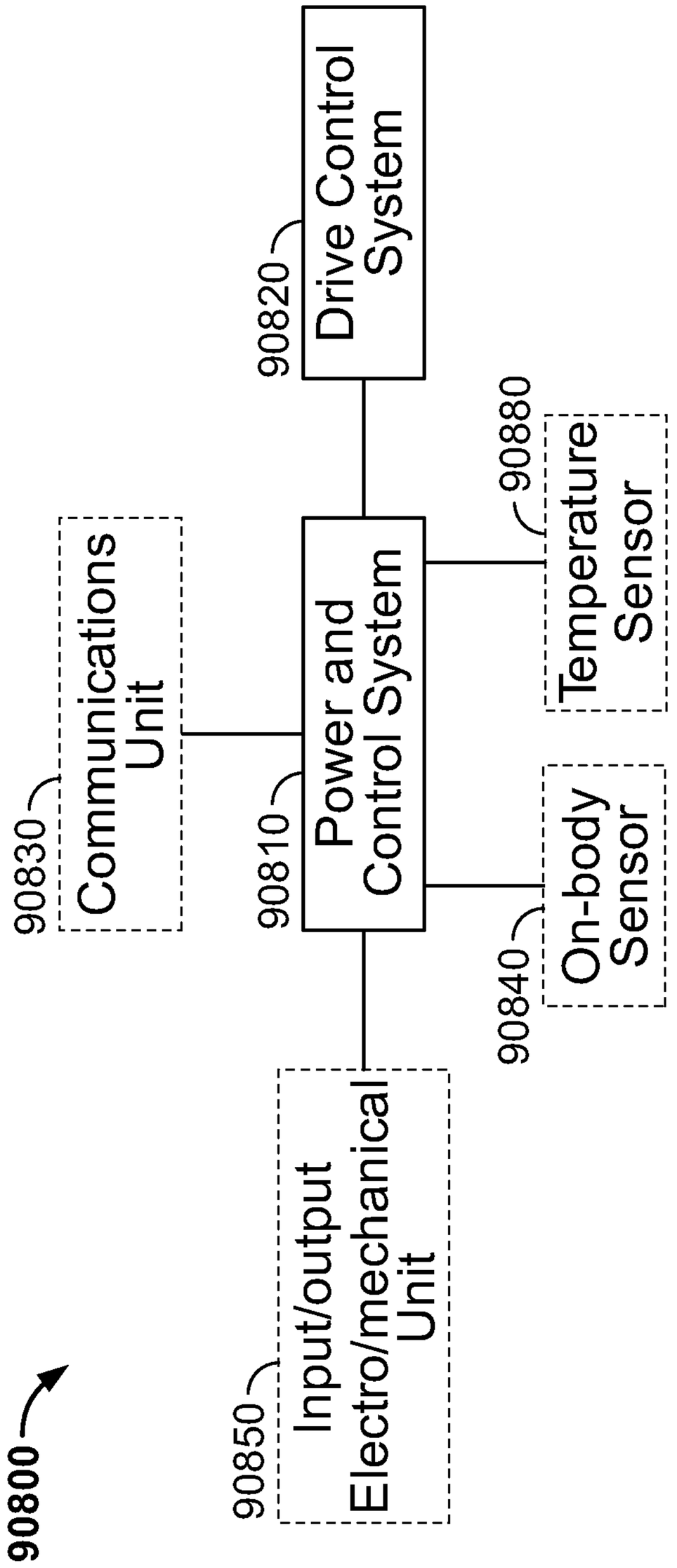

90800
90850
Input/output
Electro/mechanical
Unit
90830
Communications
Unit
90810
Power and
Control System
90820
Drive Control
System
90840
On-body
Sensor
90880
Temperature
Sensor

FIG. 78A

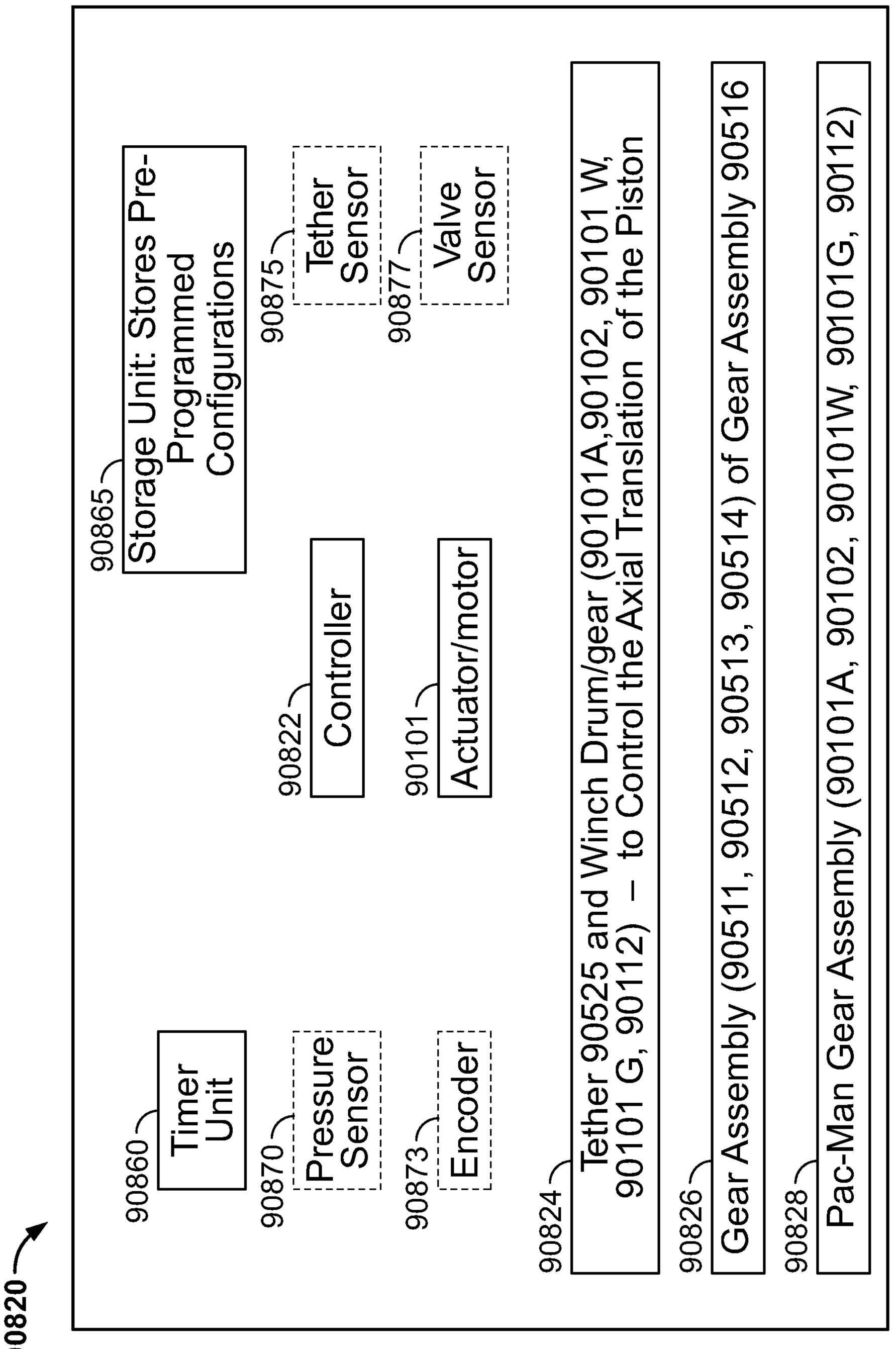

90820
90865
Storage Unit: Stores Pre-Programmed Configurations
90875
Tether Sensor
90877
Valve Sensor
90822
Controller
90101
Actuator/motor
90860
Timer Unit
90870
Pressure Sensor
90873
Encoder
90824
Tether 90525 and Winch Drum/gear (90101A,90102, 90101 W, 90101 G, 90112) – to Control the Axial Translation of the Piston
90826
Gear Assembly (90511, 90512, 90513, 90514) of Gear Assembly 90516
90828
Pac-Man Gear Assembly (90101A, 90102, 90101W, 90101G, 90112)

FIG. 78B

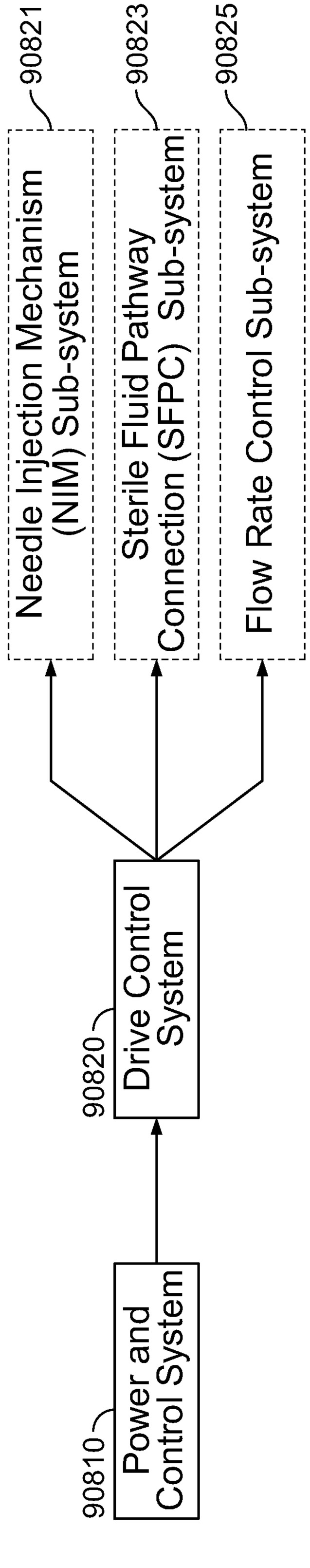

90821
Needle Injection Mechanism (NIM) Sub-system
90823
Sterile Fluid Pathway Connection (SFPC) Sub-system
90825
Flow Rate Control Sub-system
Drive Control System
90820
Power and Control System
90810

FIG. 78C

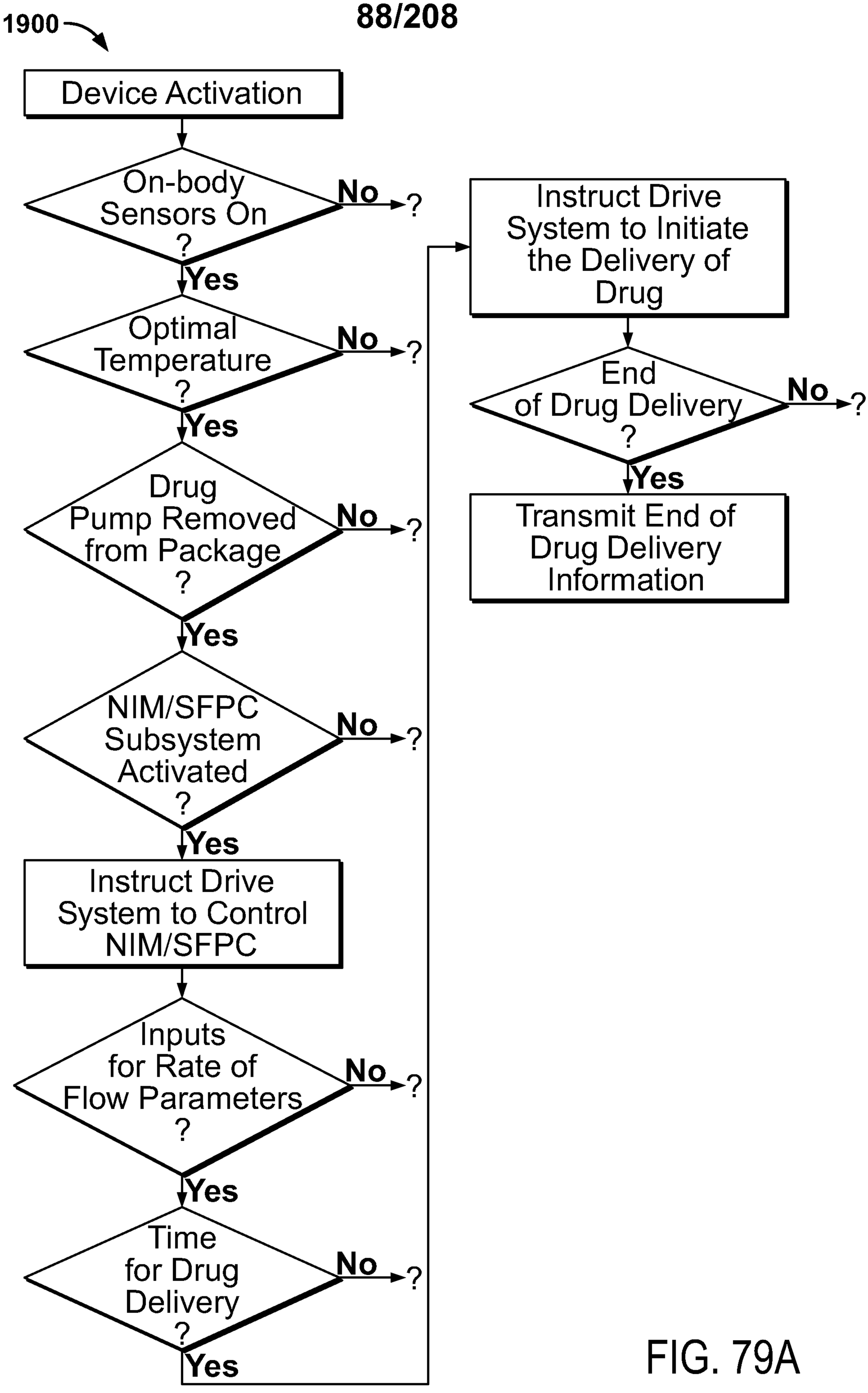

1900
Device Activation
On-body Sensors On ?
No
?
Yes
Optimal Temperature ?
No
?
Yes
Drug Pump Removed from Package ?
No
?
Yes
NIM/SFPC Subsystem Activated ?
No
?
Yes
Instruct Drive System to Control NIM/SFPC
Inputs for Rate of Flow Parameters ?
No
?
Yes
Time for Drug Delivery ?
No
?
Yes
Instruct Drive System to Initiate the Delivery of Drug
End of Drug Delivery ?
No
?
Yes
Transmit End of Drug Delivery Information

FIG. 79A

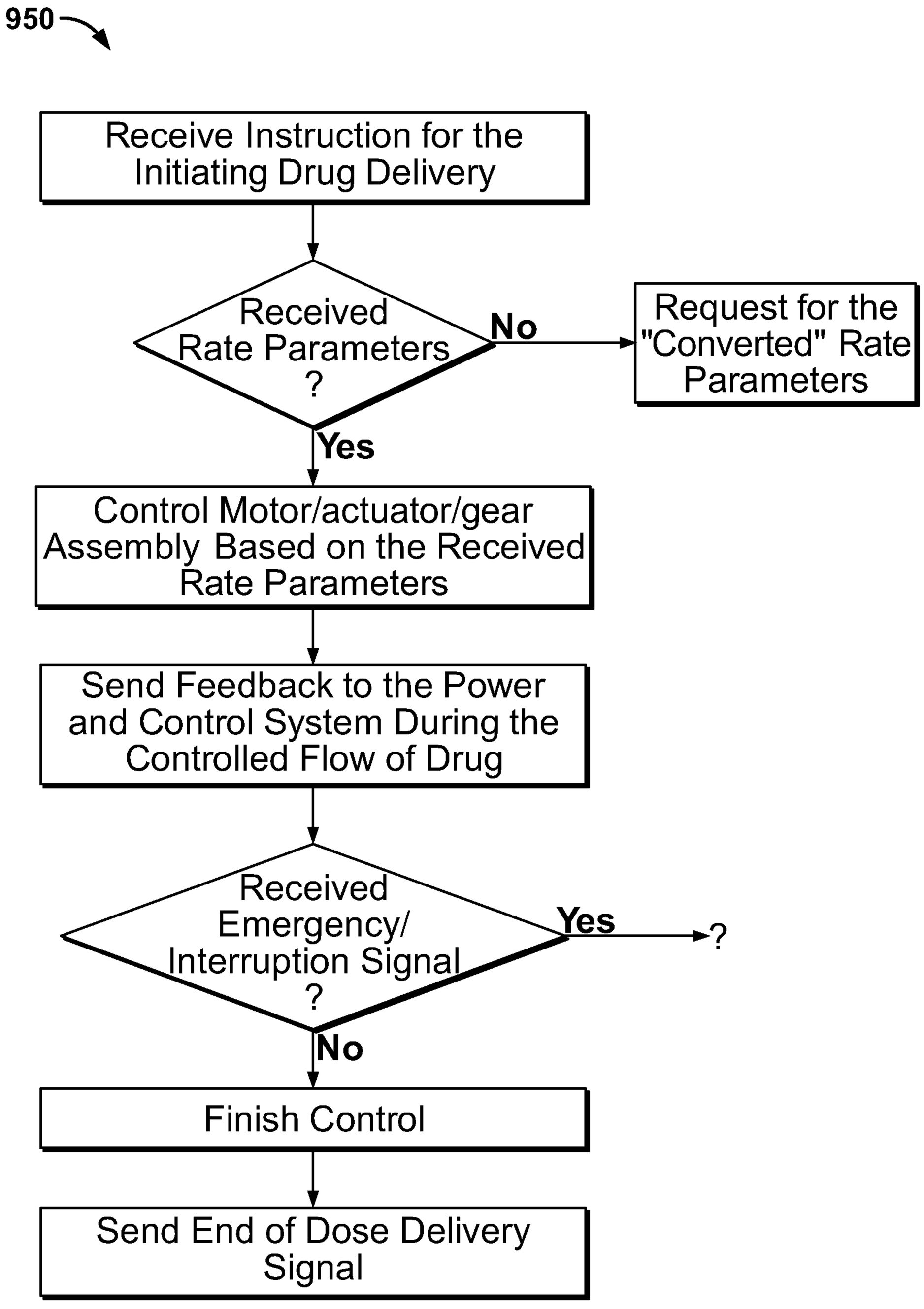

950
Receive Instruction for the Initiating Drug Delivery
Received Rate Parameters ?
No
Request for the "Converted" Rate Parameters
Yes
Control Motor/actuator/gear Assembly Based on the Received Rate Parameters
Send Feedback to the Power and Control System During the Controlled Flow of Drug
Received Emergency/ Interruption Signal ?
Yes
?
No
Finish Control
Send End of Dose Delivery Signal

FIG. 79B

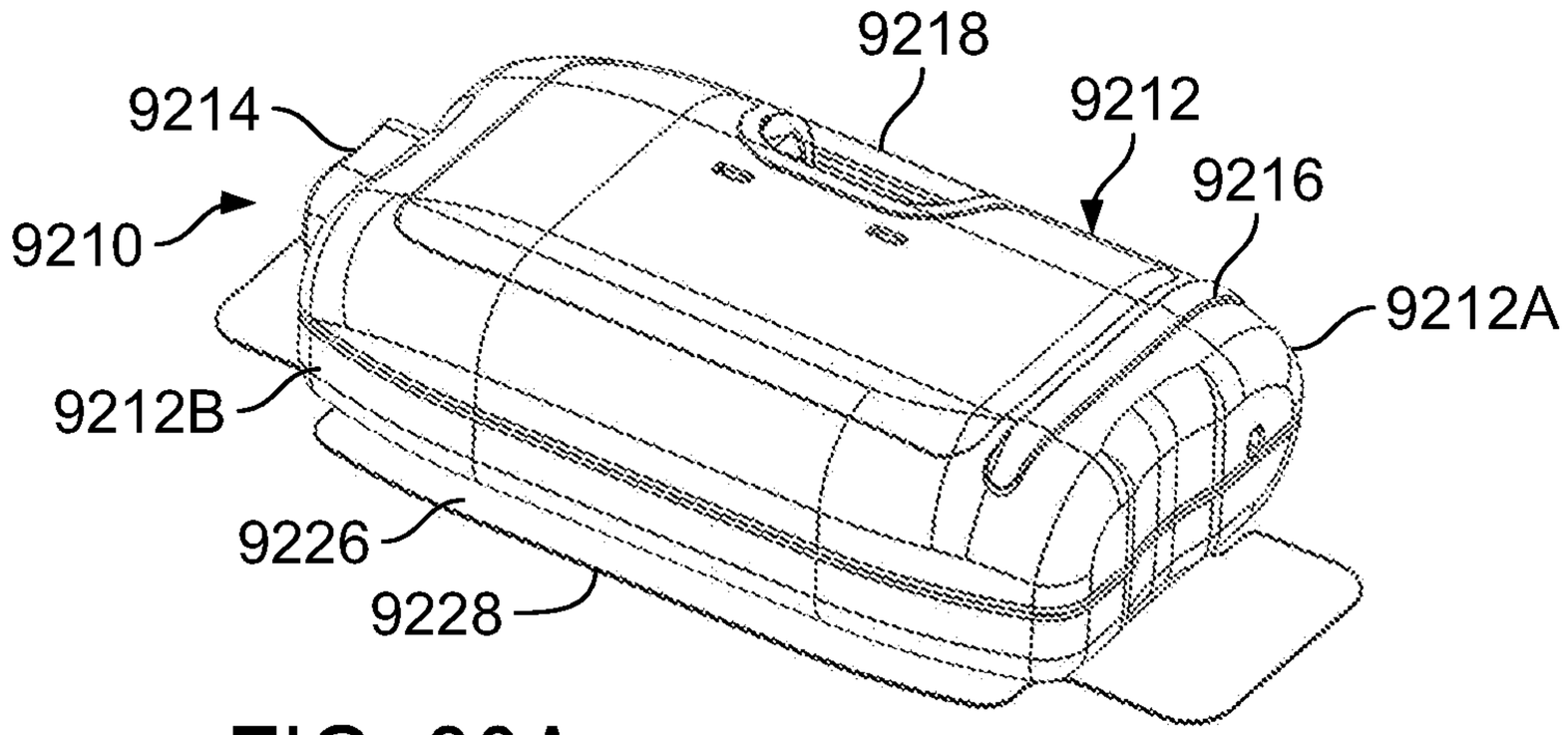


FIG. 80A

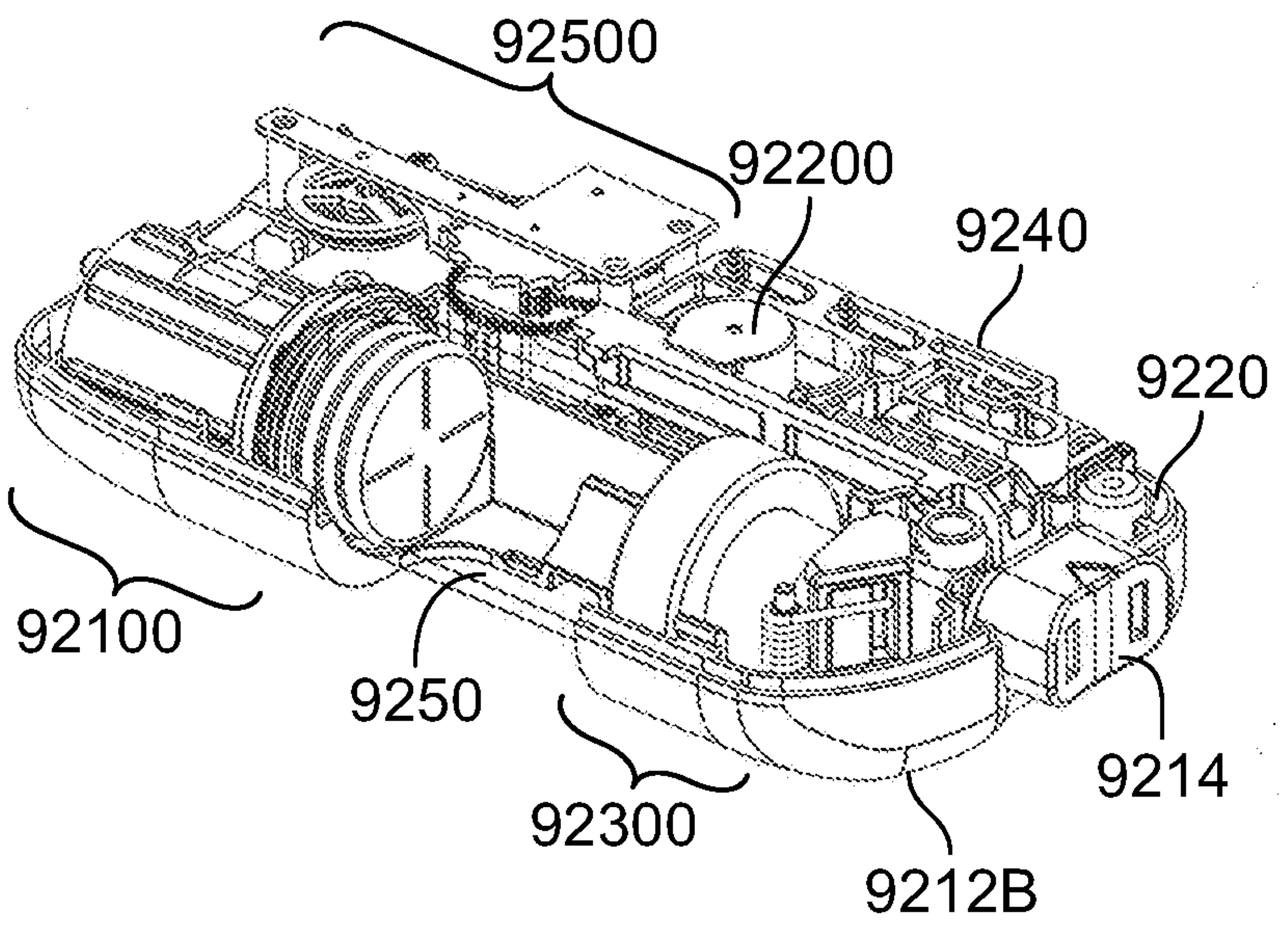


FIG. 80B

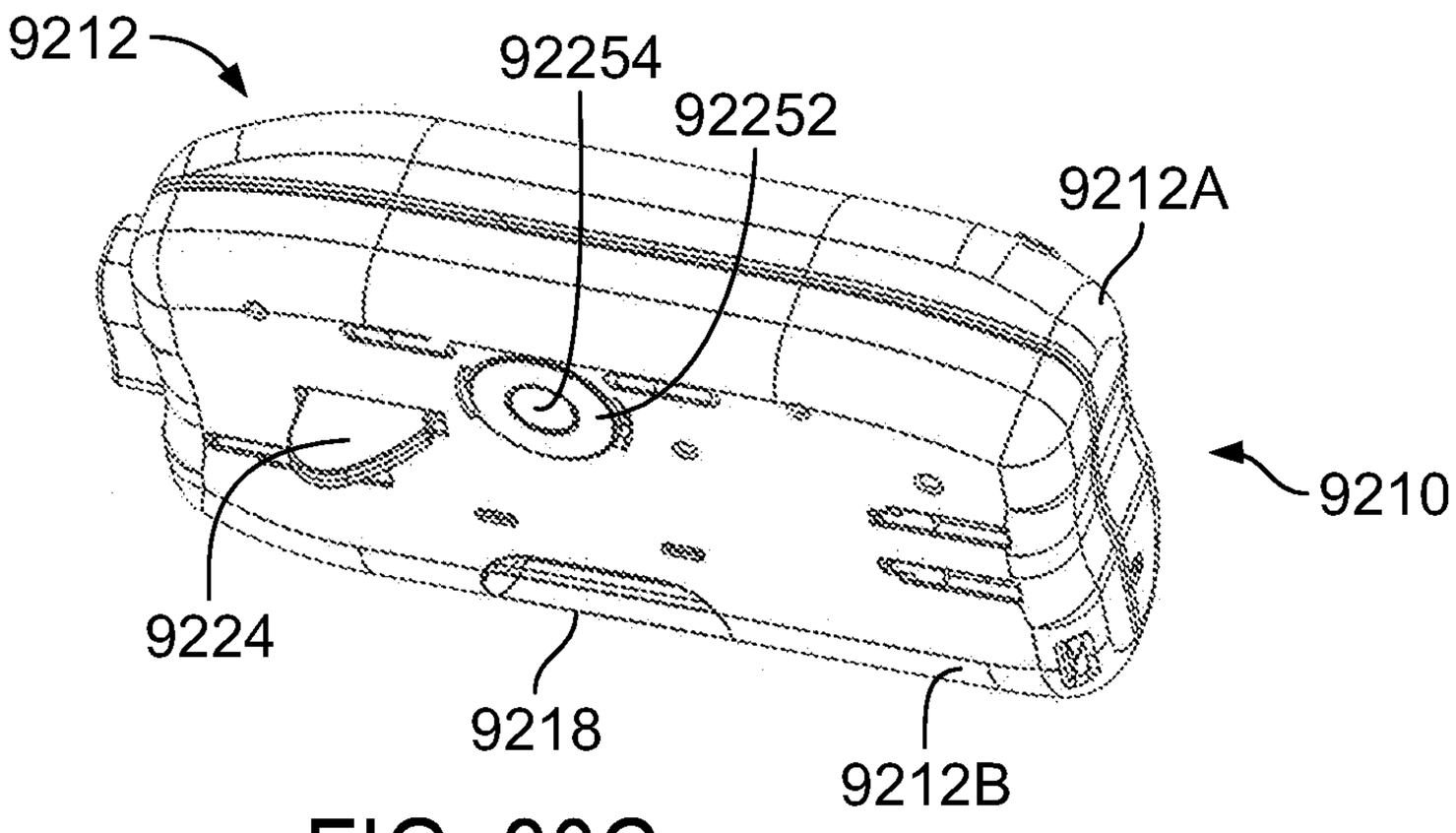


FIG. 80C

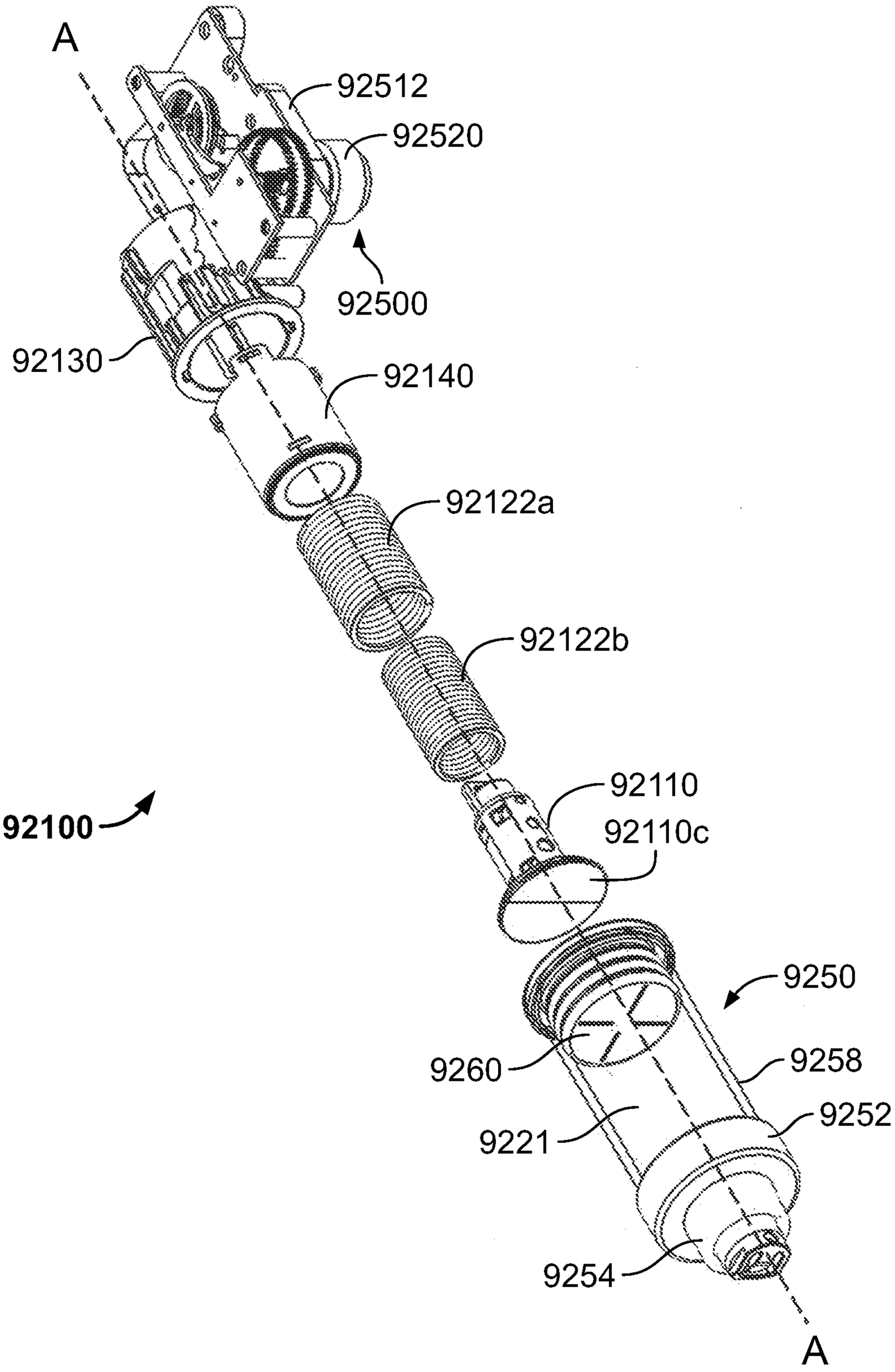

A
92512
92520
92500
92130
92140
92122a
92122b
92100
92110
92110c
9250
9260
9258
9221
9252
9254
A

FIG. 81A

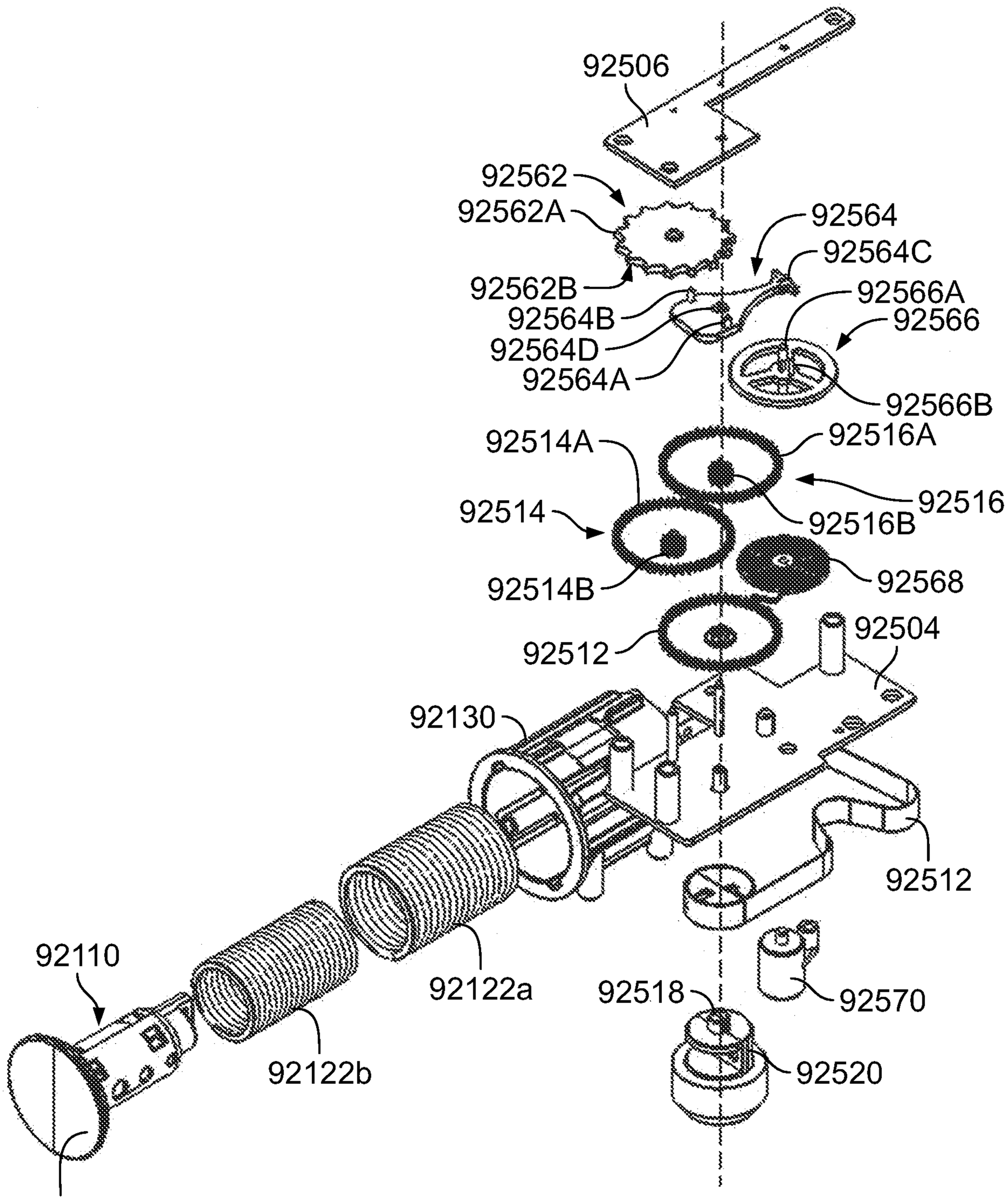

92506
92562
92562A
92562B
92564
92564C
92564B
92564D
92564A
92566A
92566
92566B
92514A
92516A
92514
92516
92516B
92514B
92568
92512
92504
92130
92512
92110
92122a
92122b
92518
92570
92520
92110C

FIG. 81B

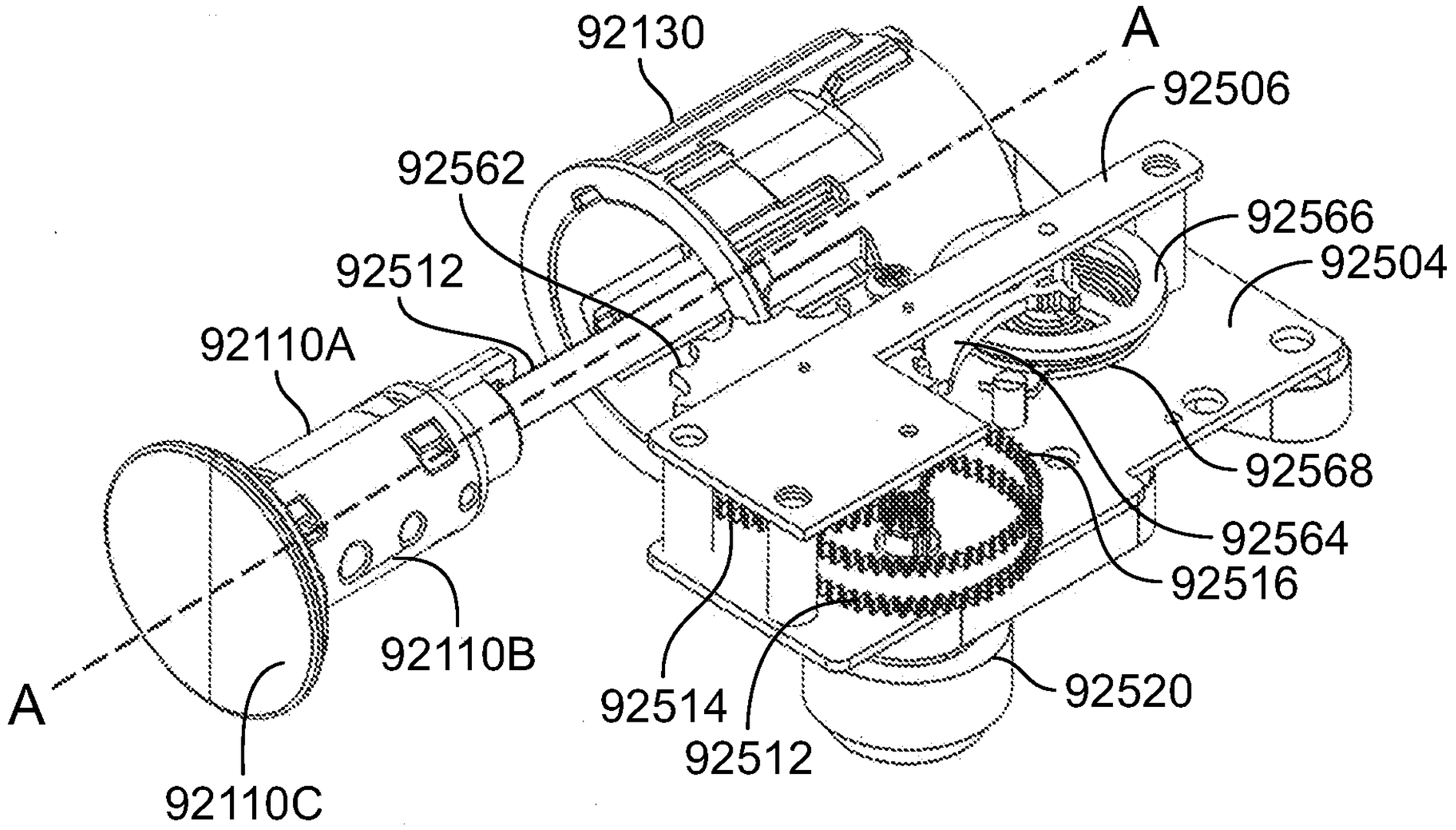


FIG. 82A

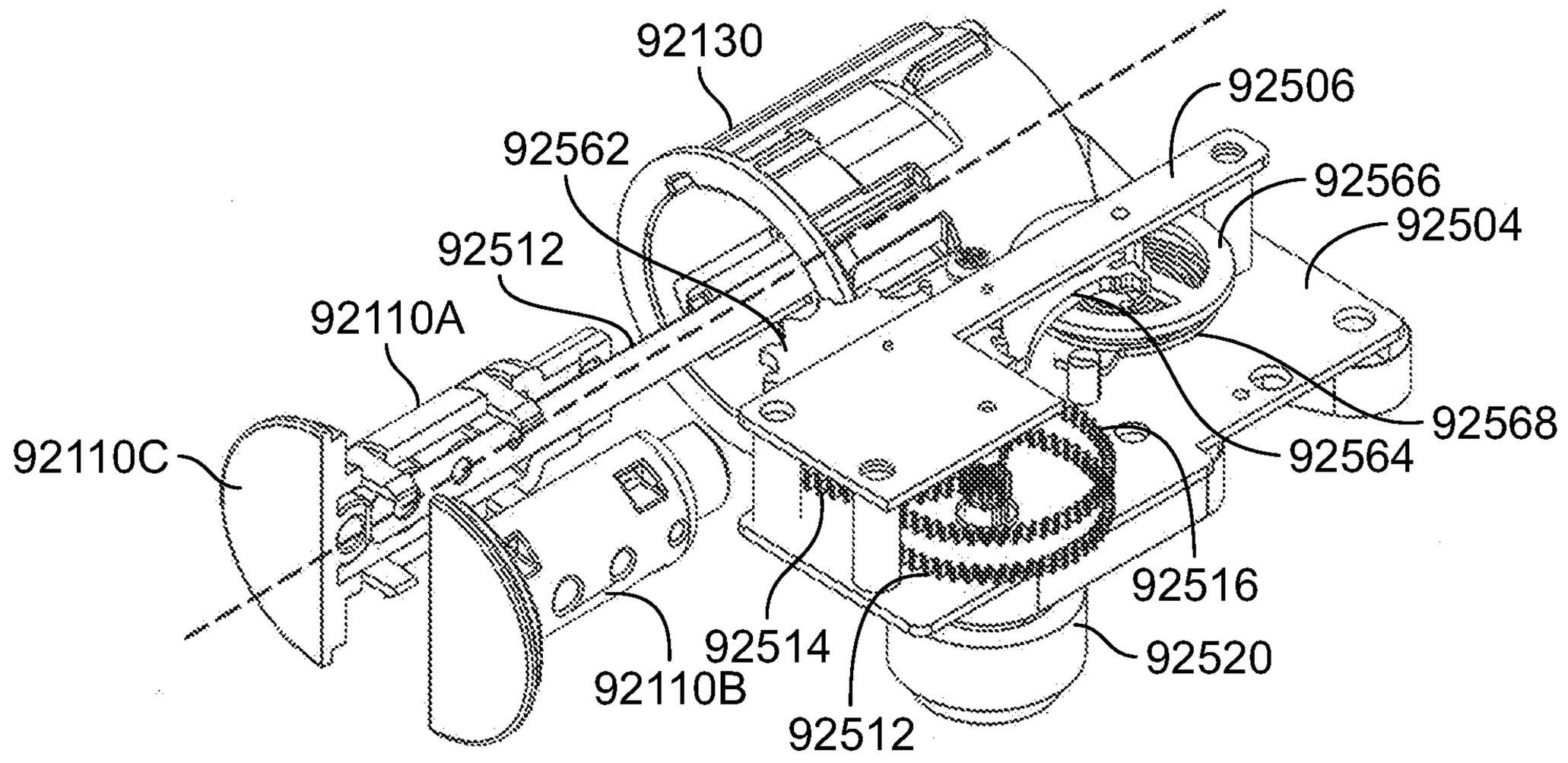


FIG. 82B

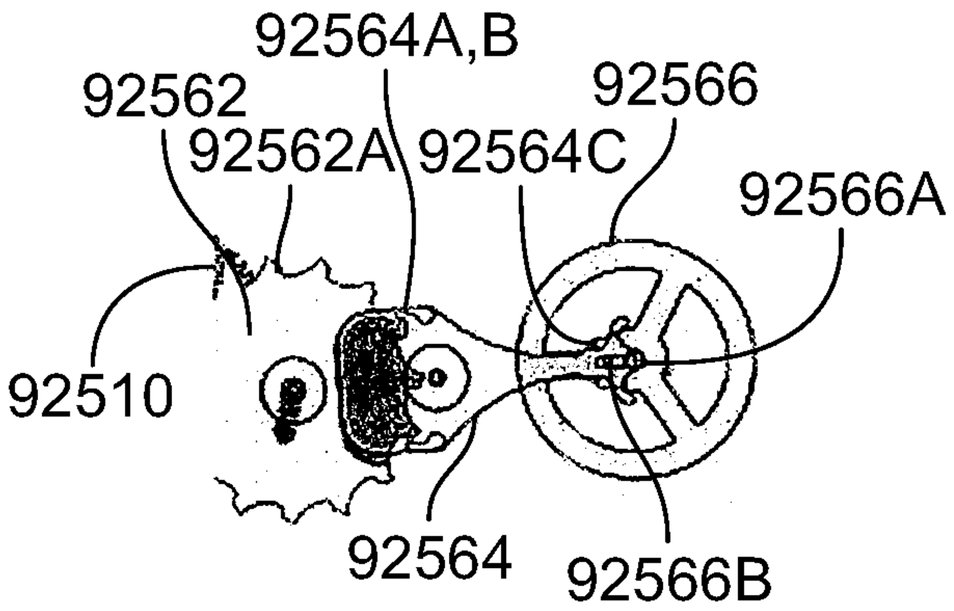


FIG. 83A

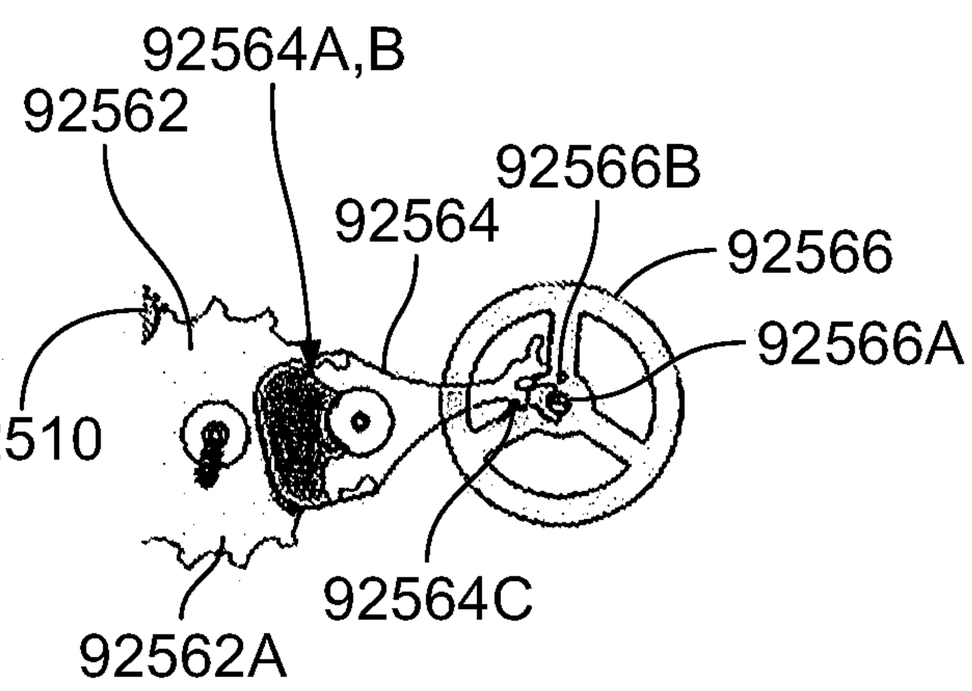


FIG. 83B

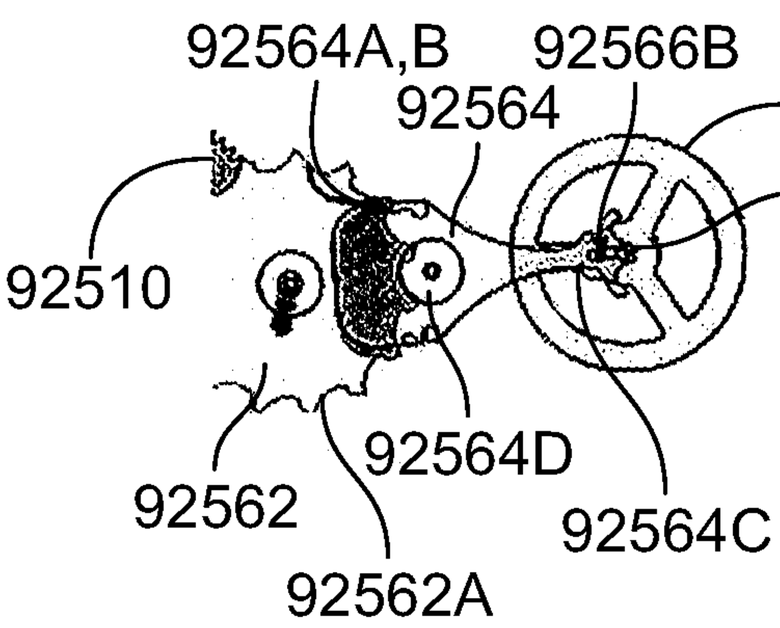


FIG. 83C

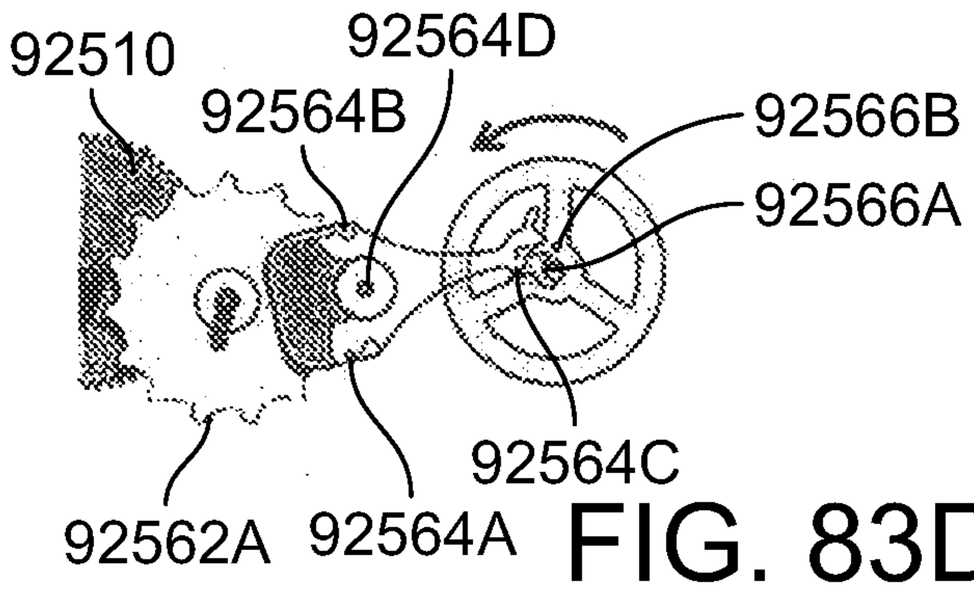


FIG. 83D

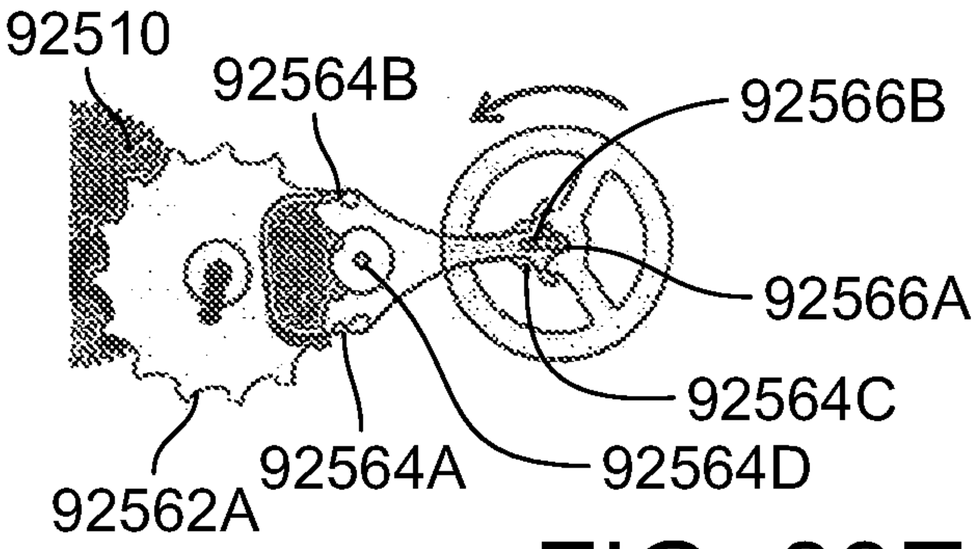


FIG. 83E

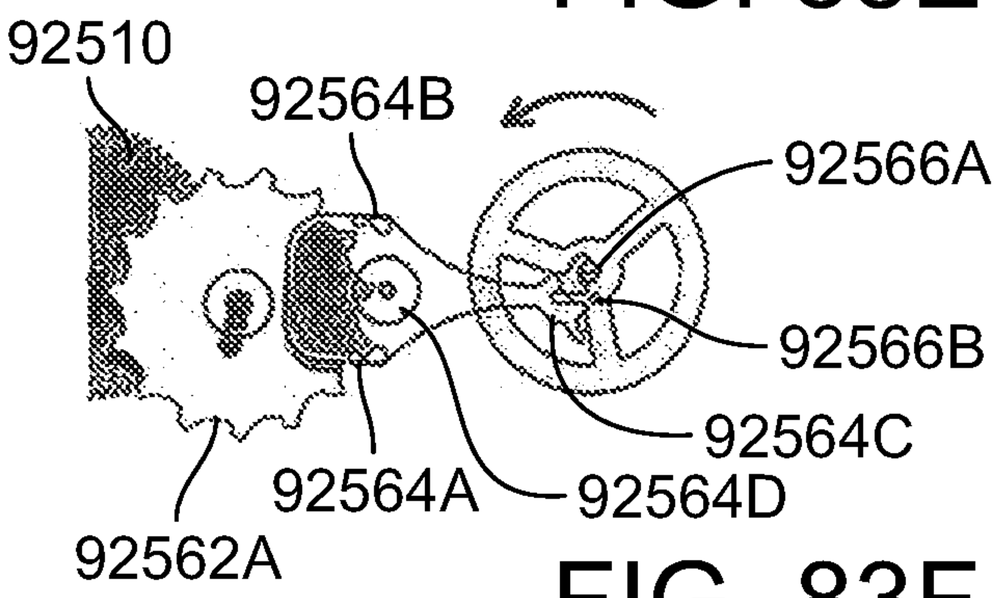


FIG. 83F

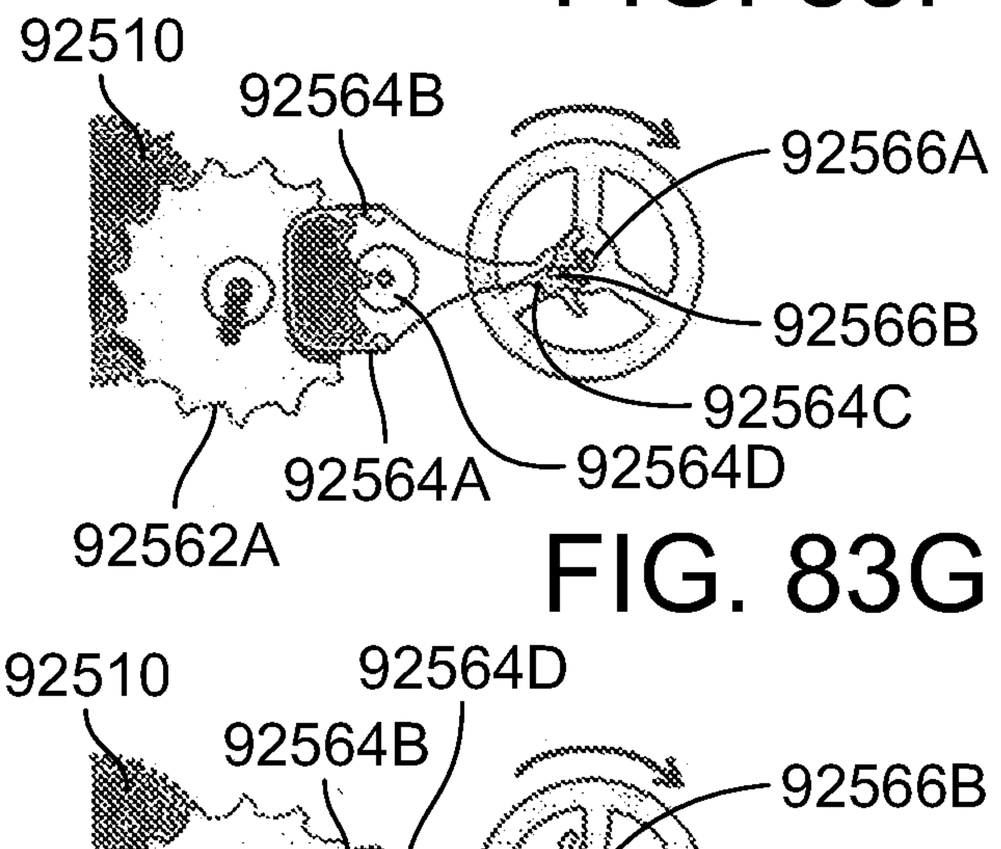


FIG. 83G

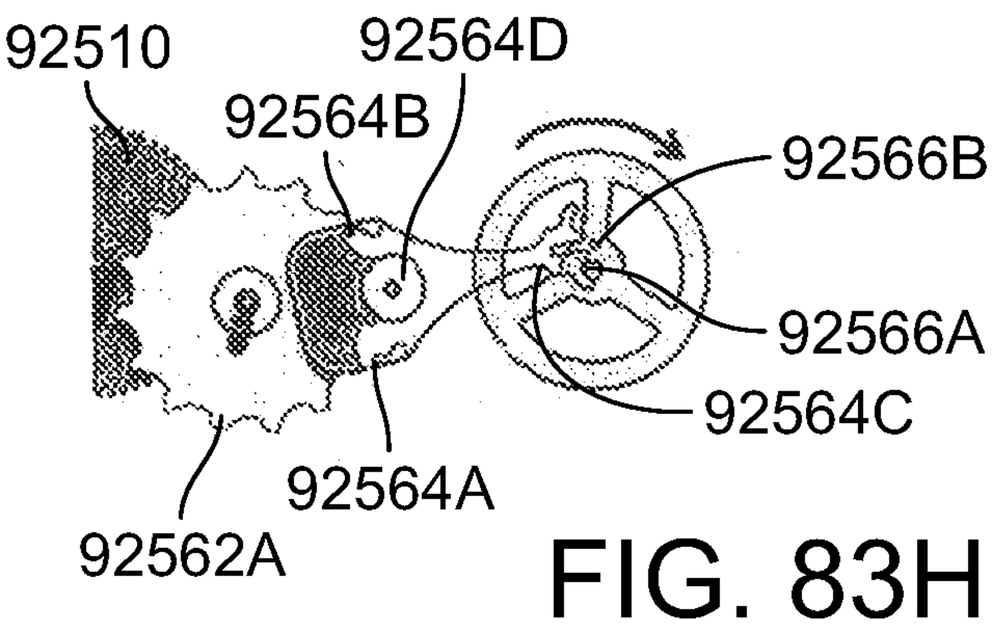


FIG. 83H

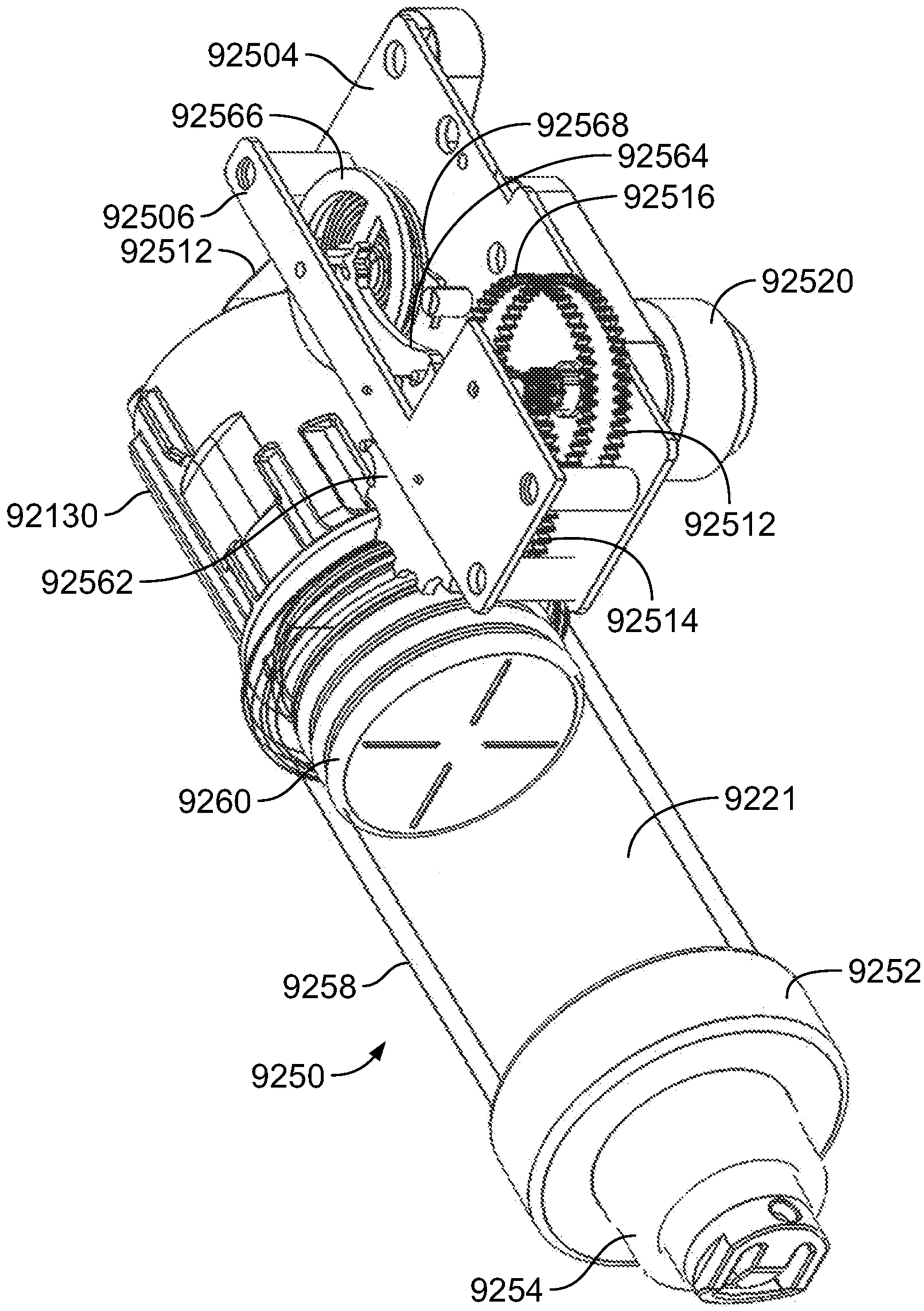

92504
92566
92568
92564
92516
92506
92512
92520
92130
92562
92512
92514
9260
9221
9258
9252
9250
9254

FIG. 84A

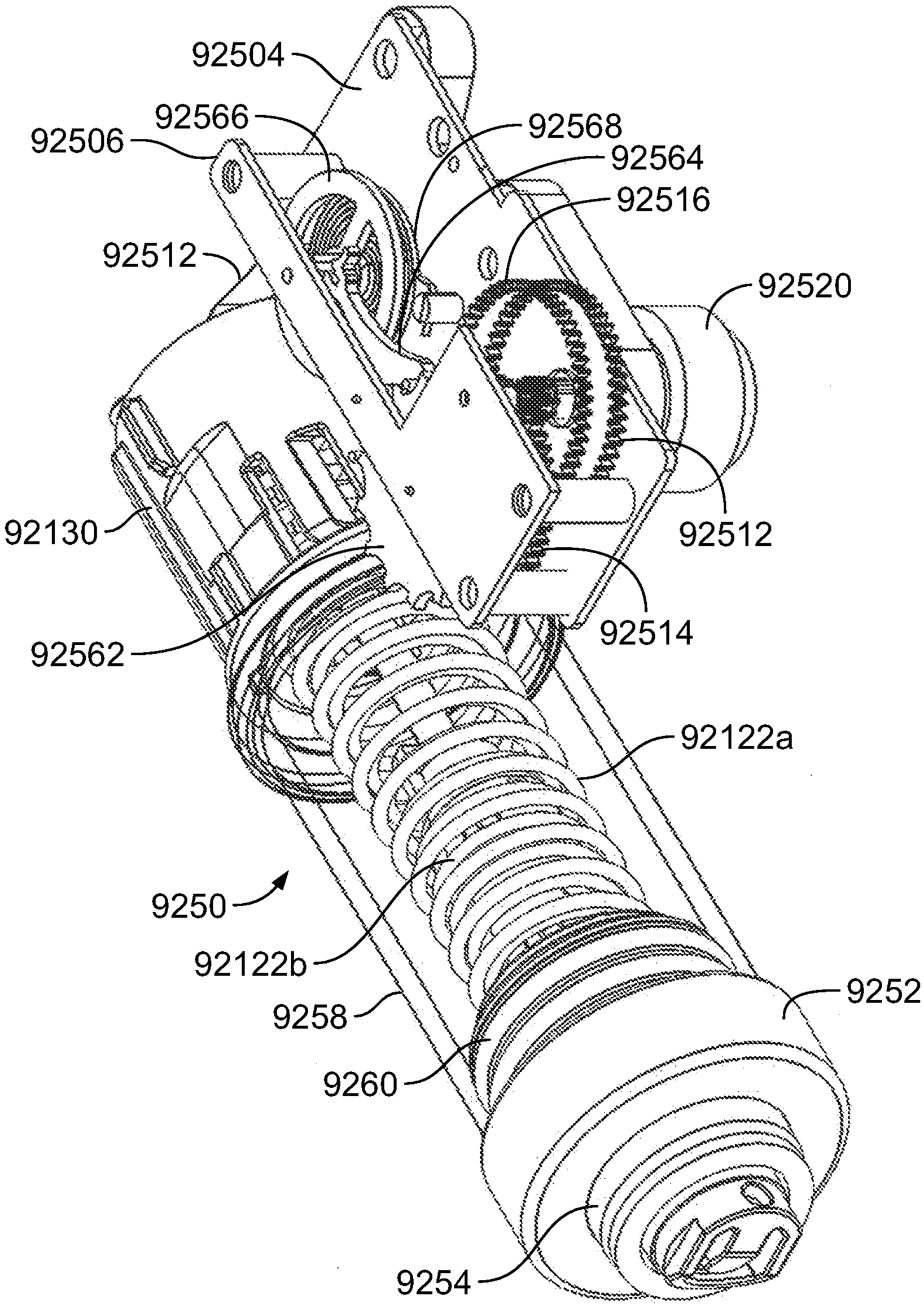

92504
92566
92506
92568
92564
92516
92512
92520
92130
92512
92514
92562
92122a
9250
92122b
9252
9258
9260
9254

FIG. 84B

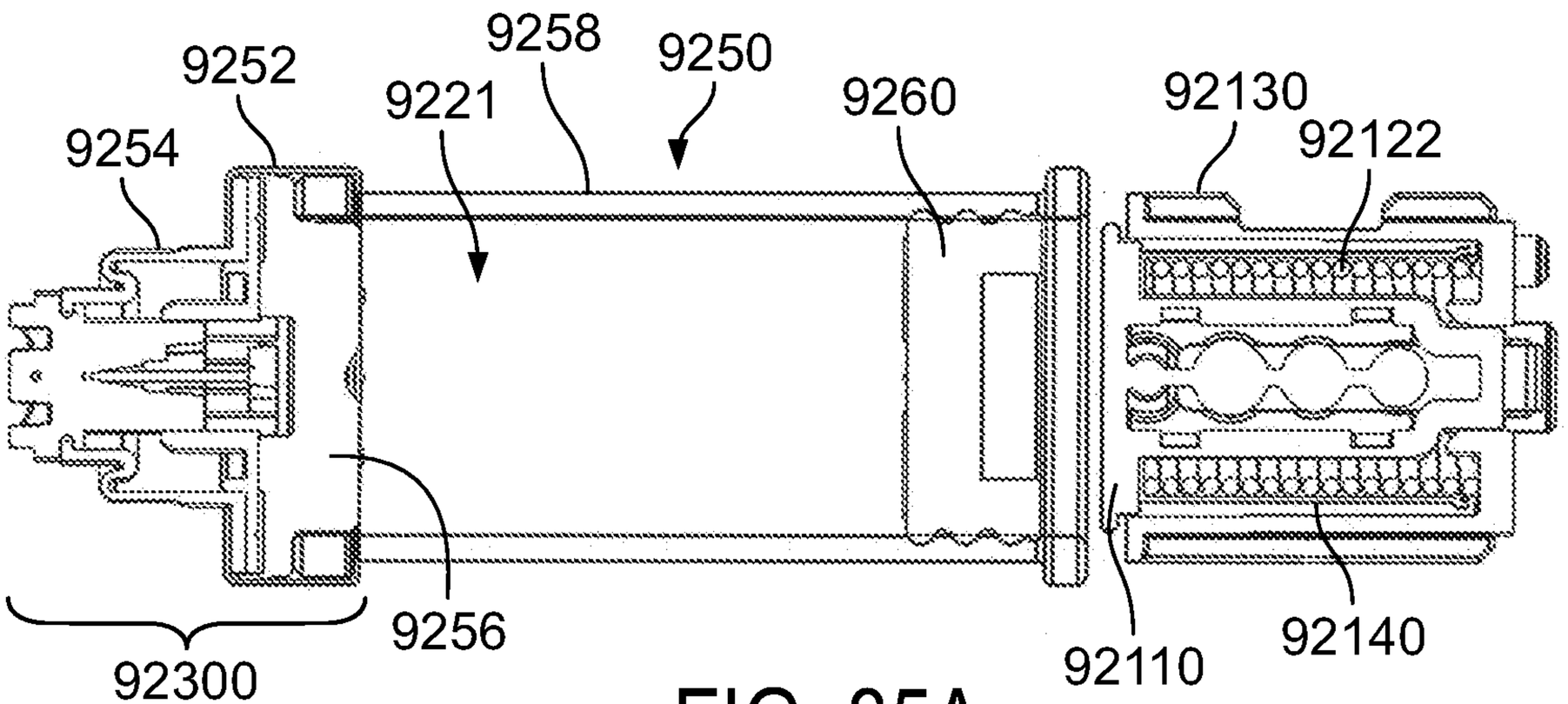


FIG. 85A

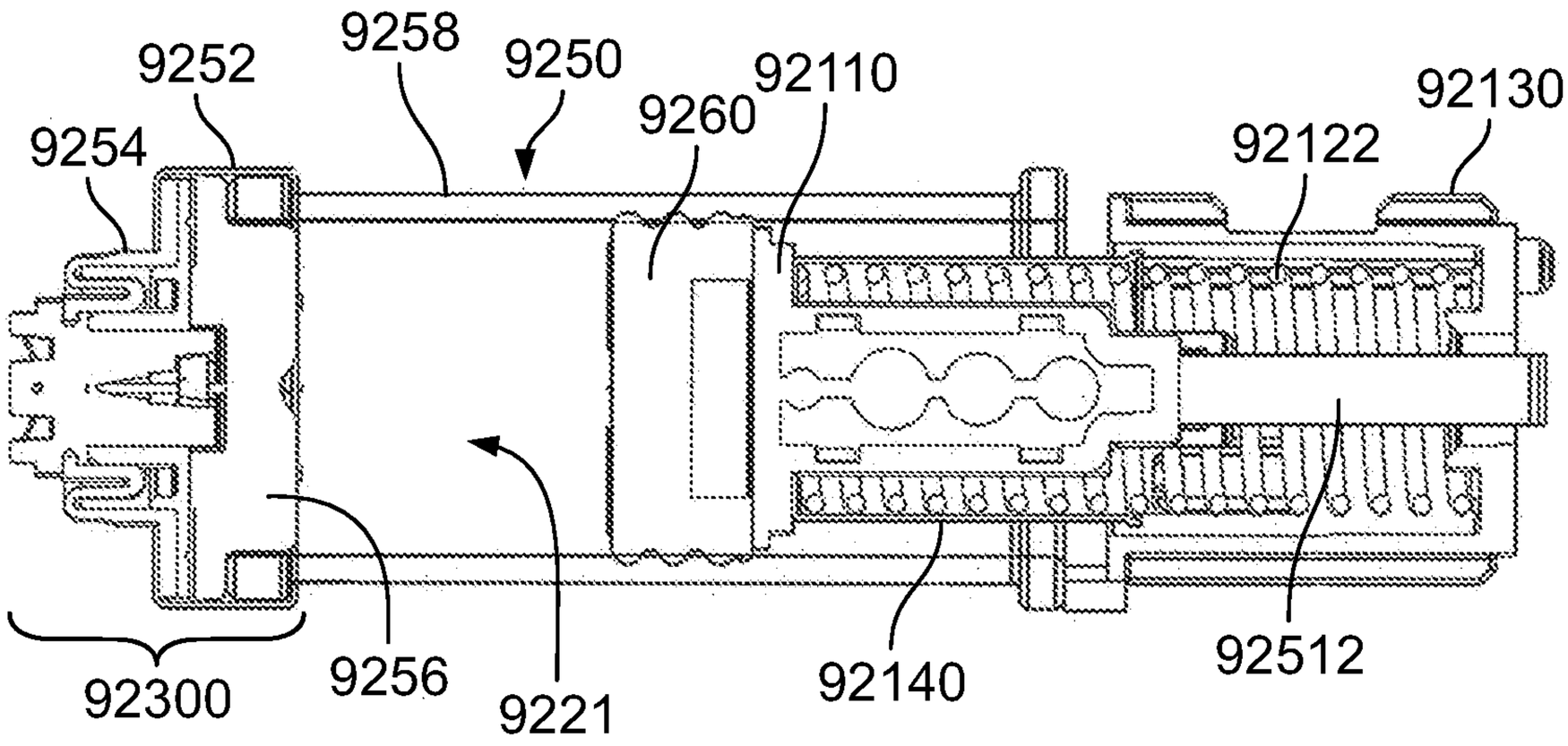


FIG. 85B

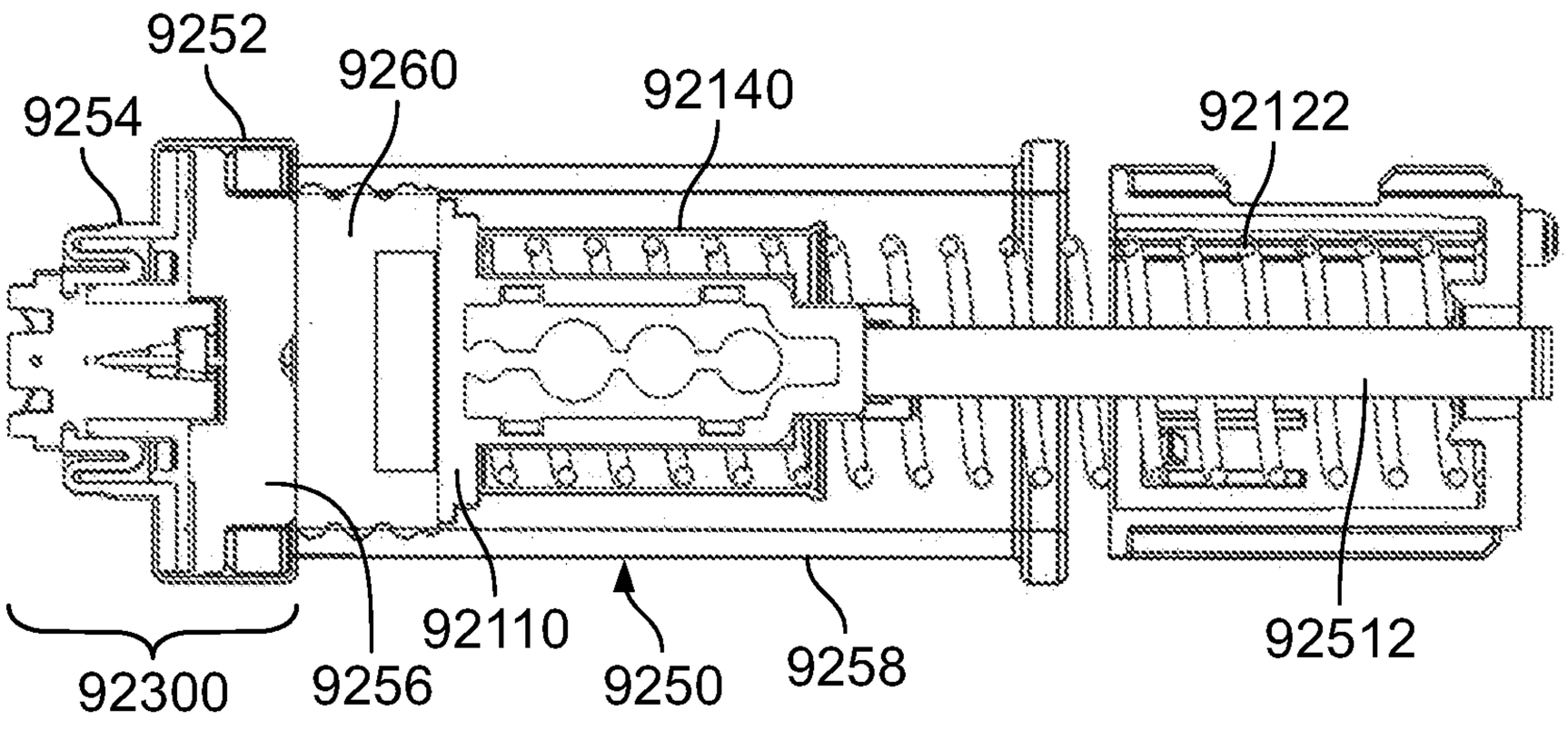


FIG. 85C

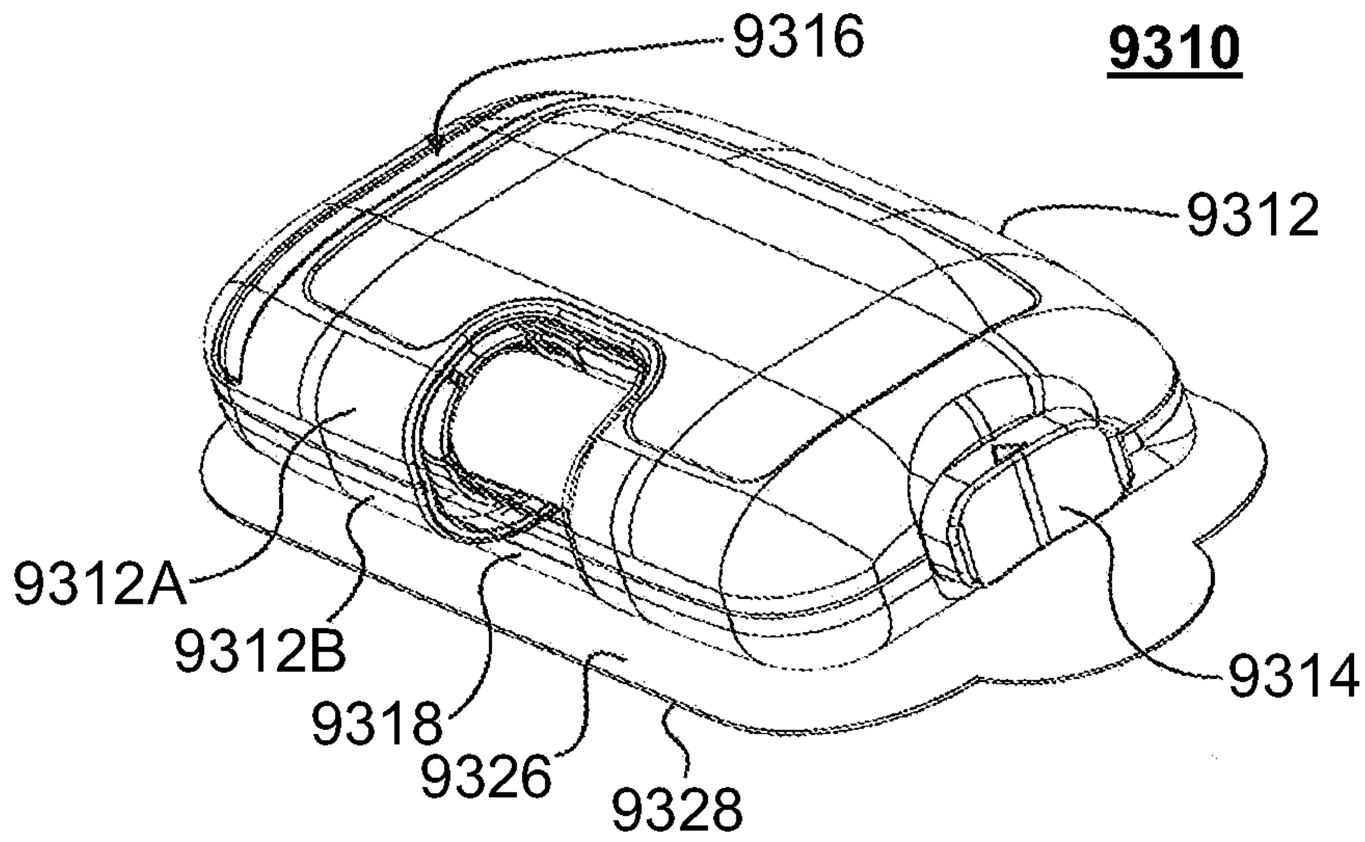


FIG. 86A

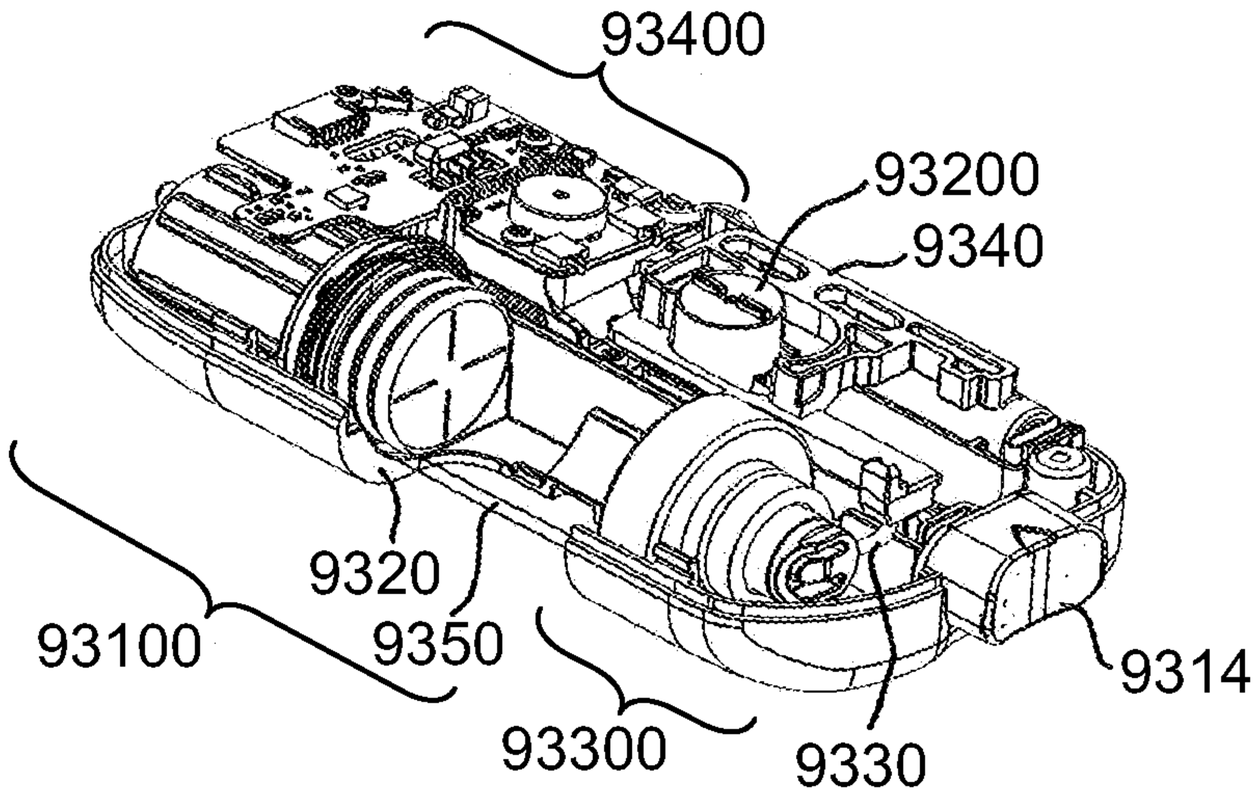


FIG. 86B

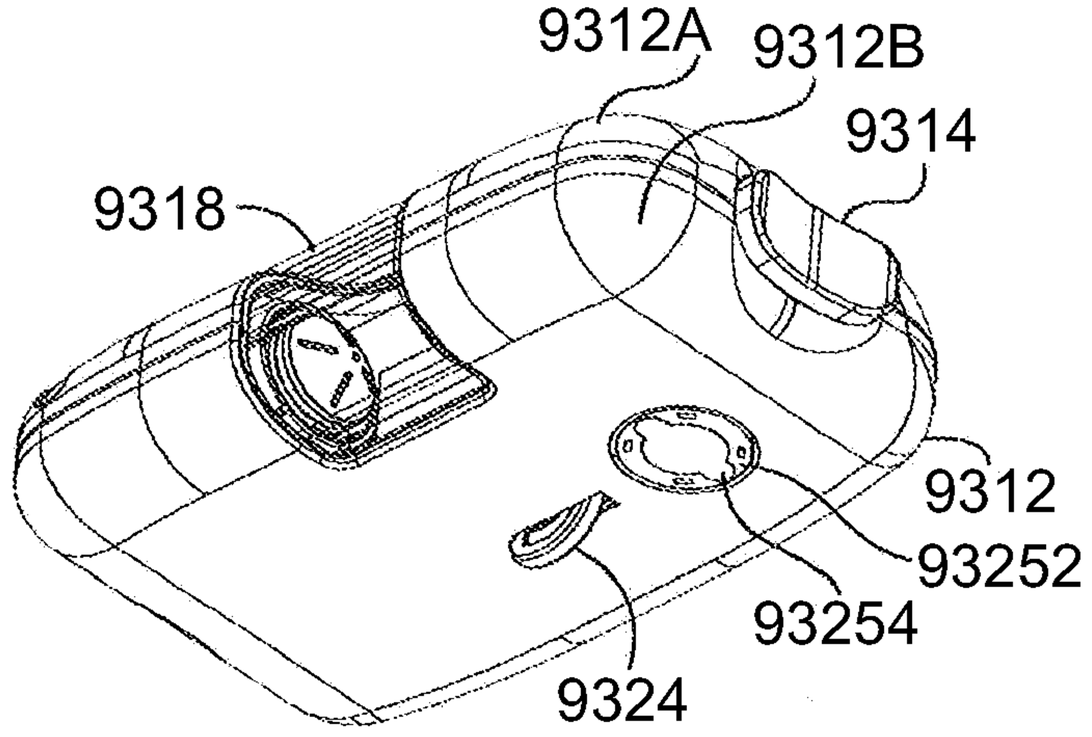


FIG. 86C

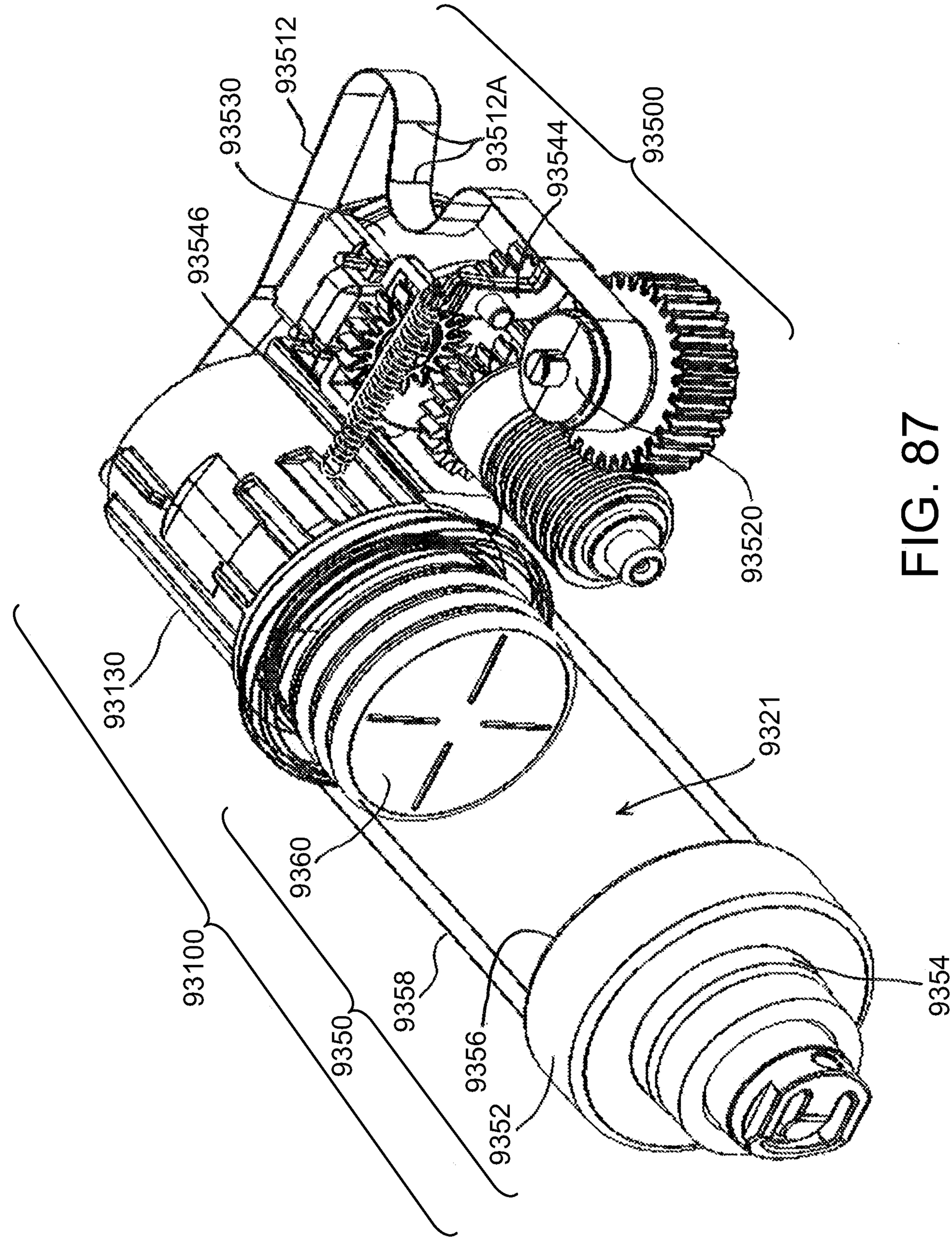

93100
93130
93530
93
93546
93512A
93544
93500
93520
9321
9360
9358
9350
9356
9352
9354

FIG. 87

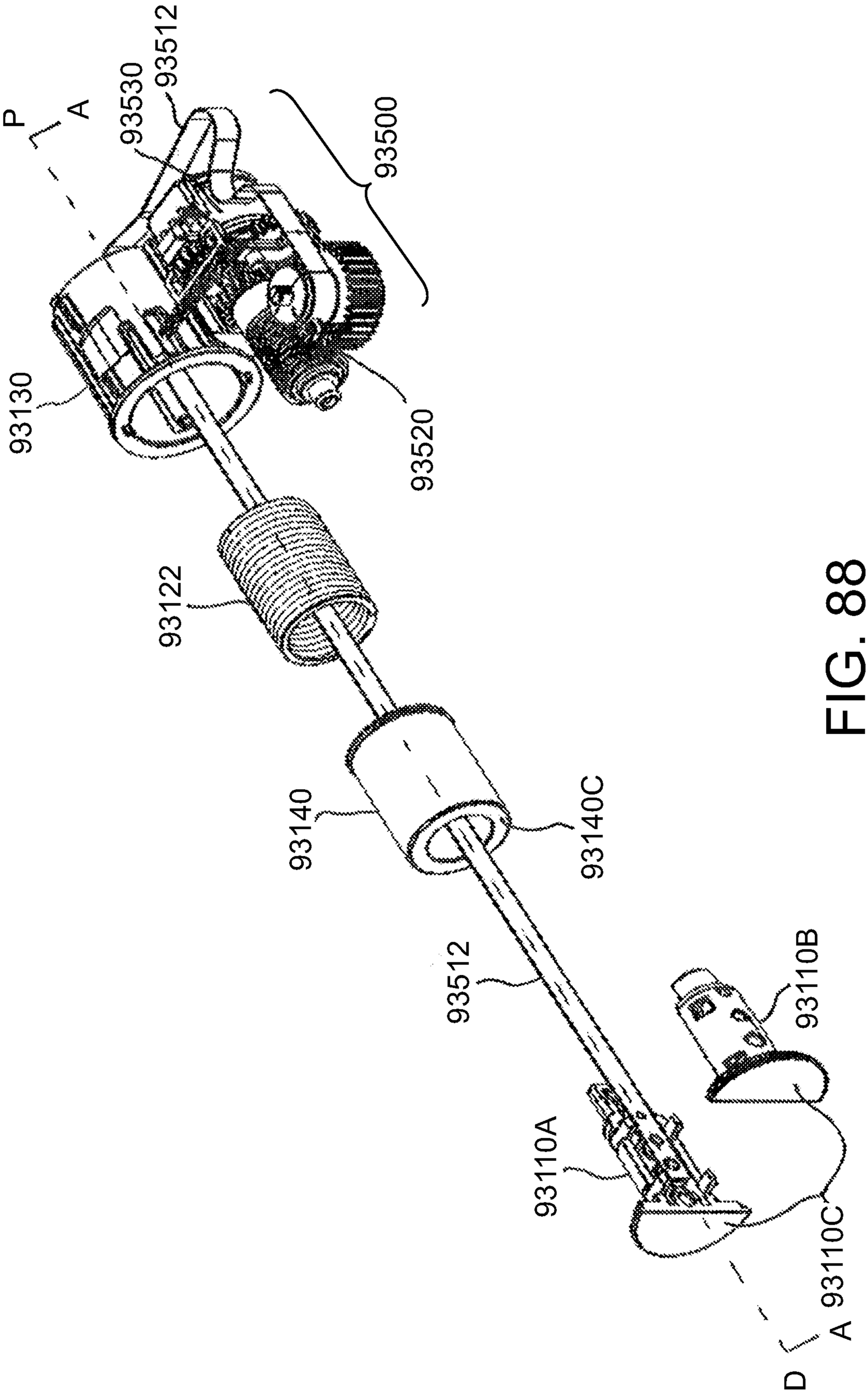

P
A
93530
93512
93500
93130
93520
93122
93140
93140C
93512
93110B
93110A
93110C
D
A

FIG. 88

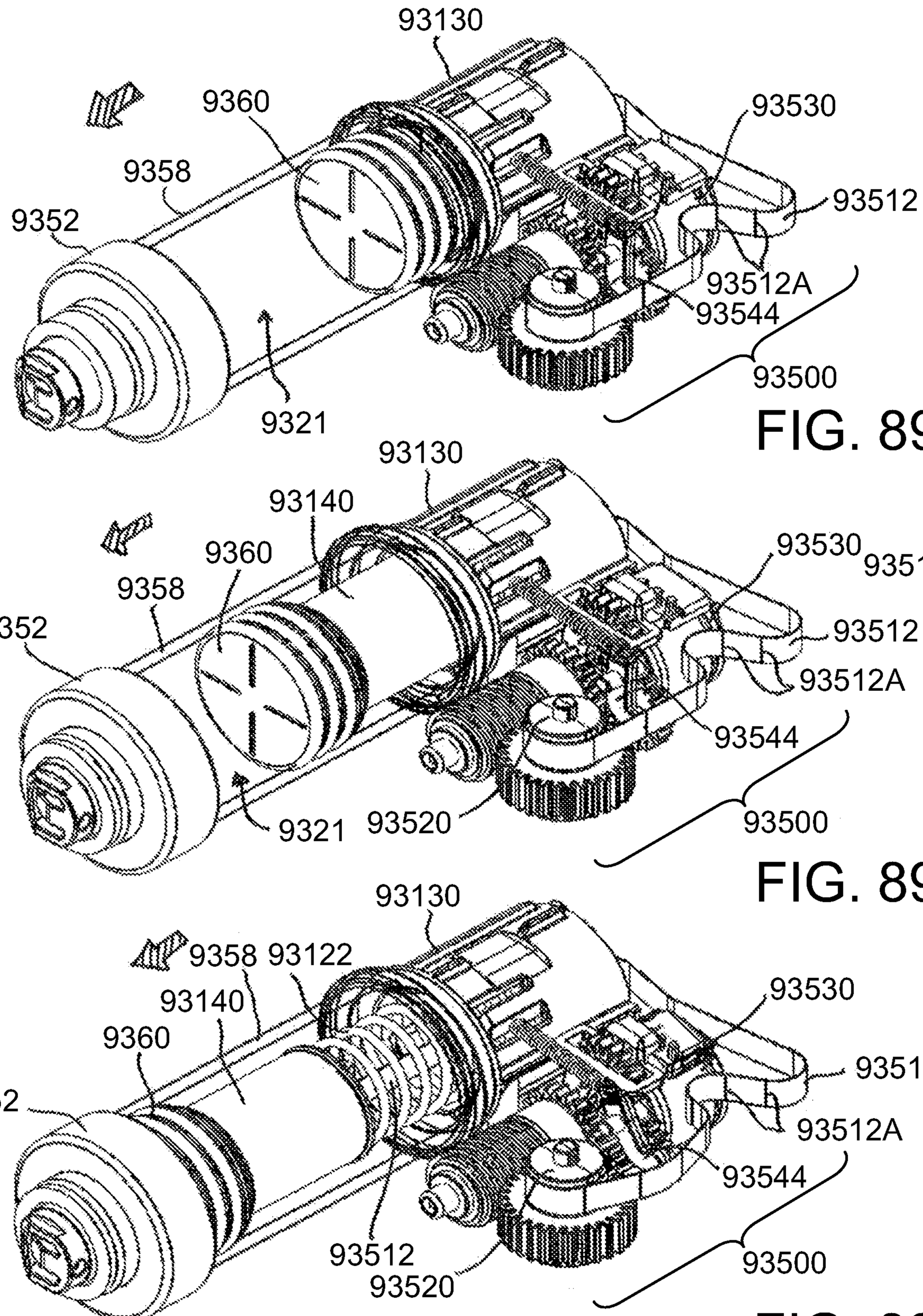


FIG. 89A

FIG. 89B

FIG. 89C

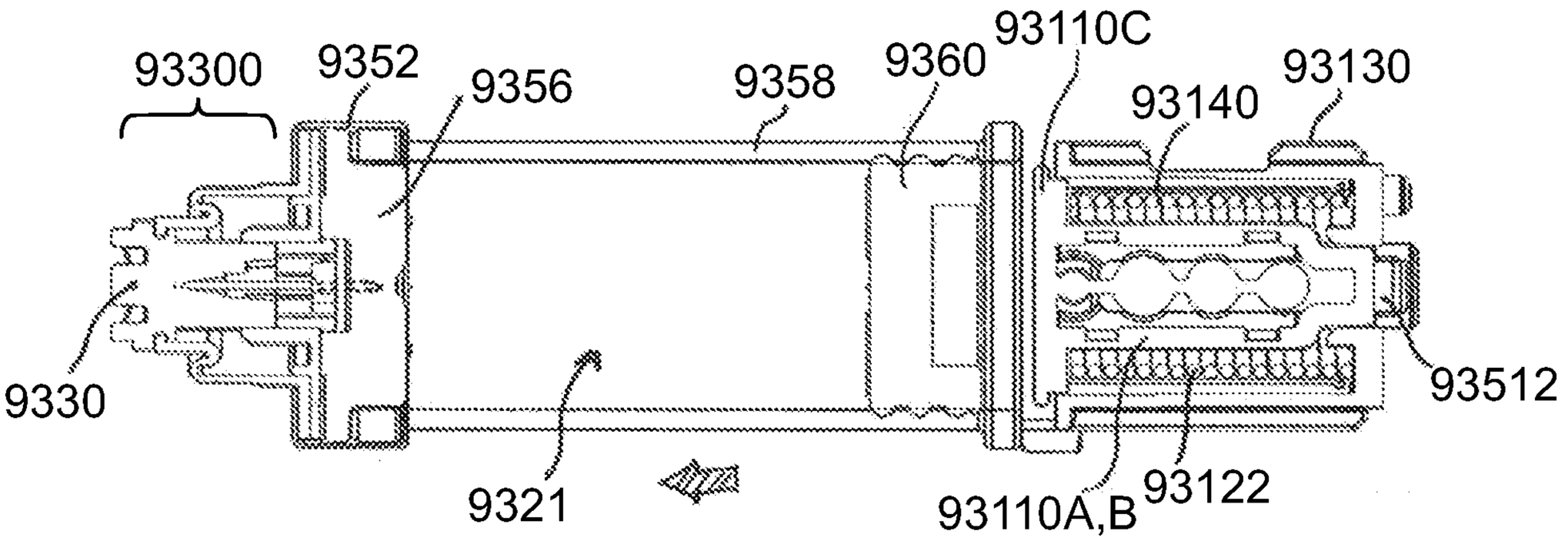


FIG. 90A

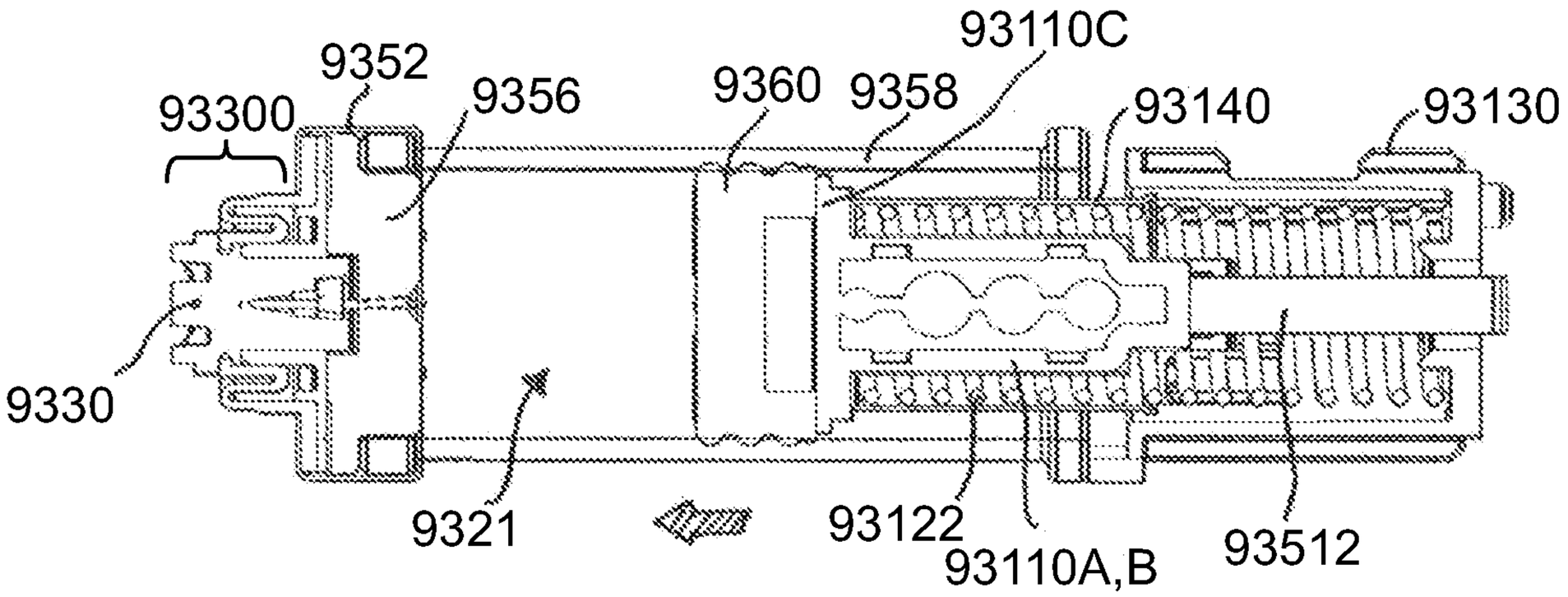


FIG. 90B

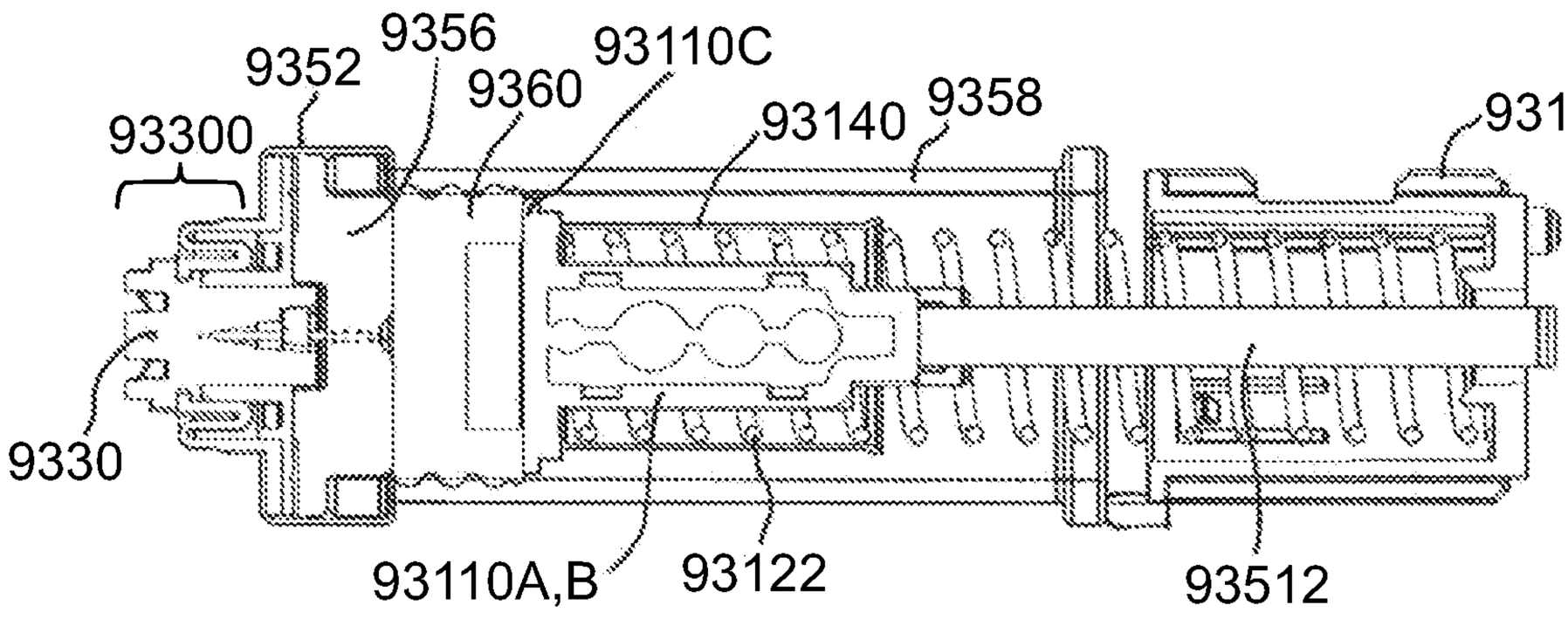


FIG. 90C

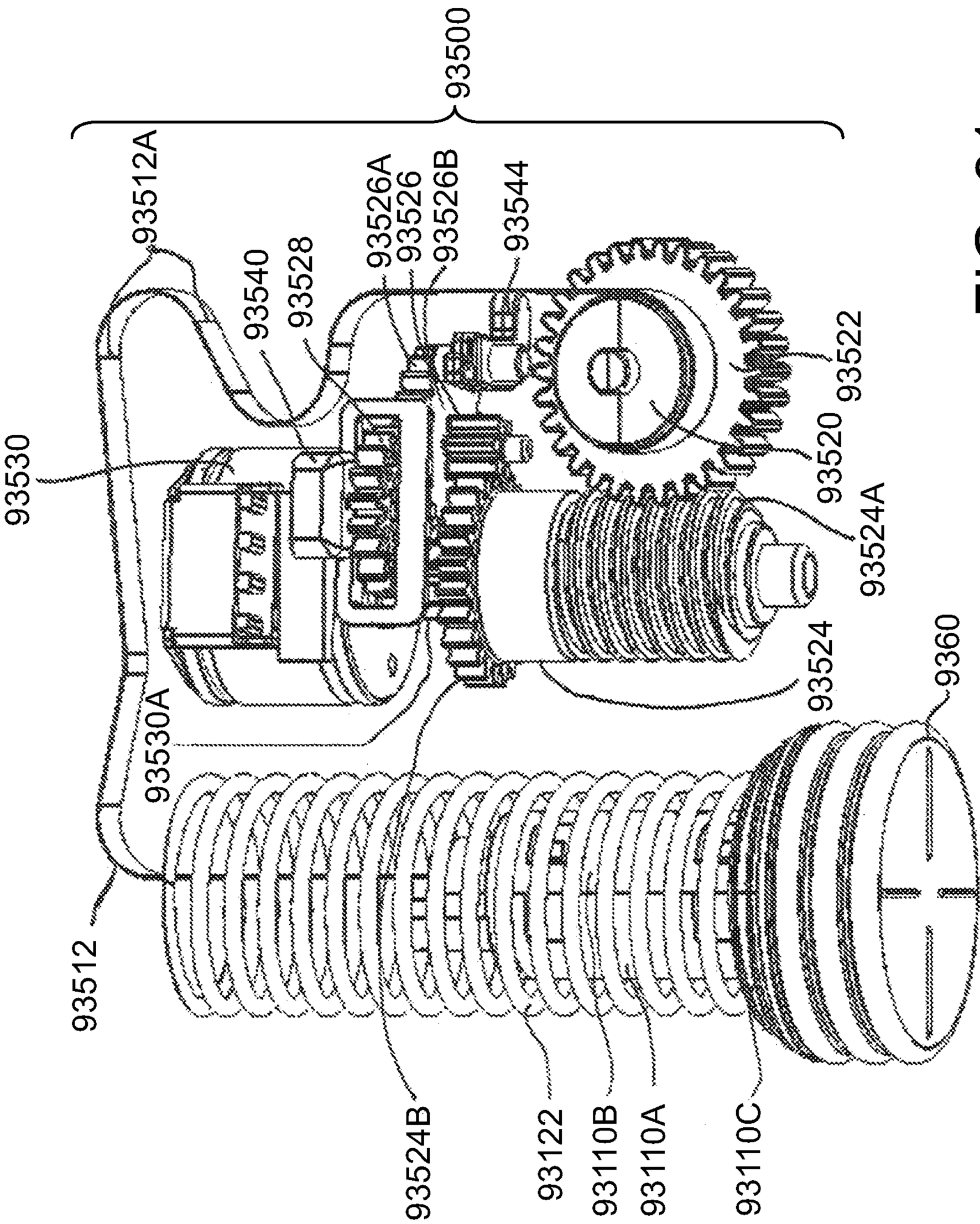

93500
93512A
93540
93528
93526A
93526
93526B
93544
93530
93522
93520
93524A
93530A
93524
9360
93512
93524B
93122
93110B
93110A
93110C

FIG. 91

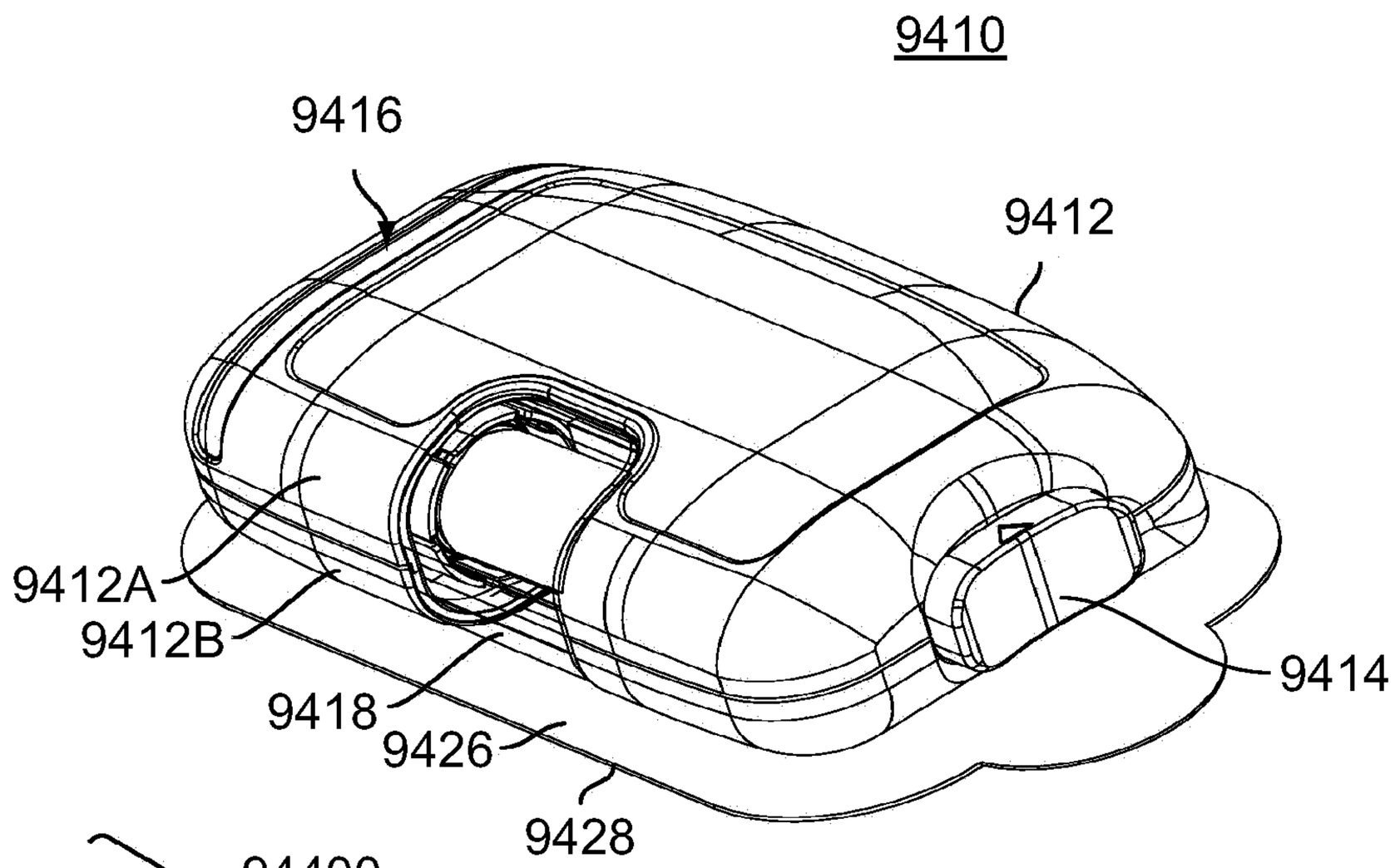


FIG. 92A

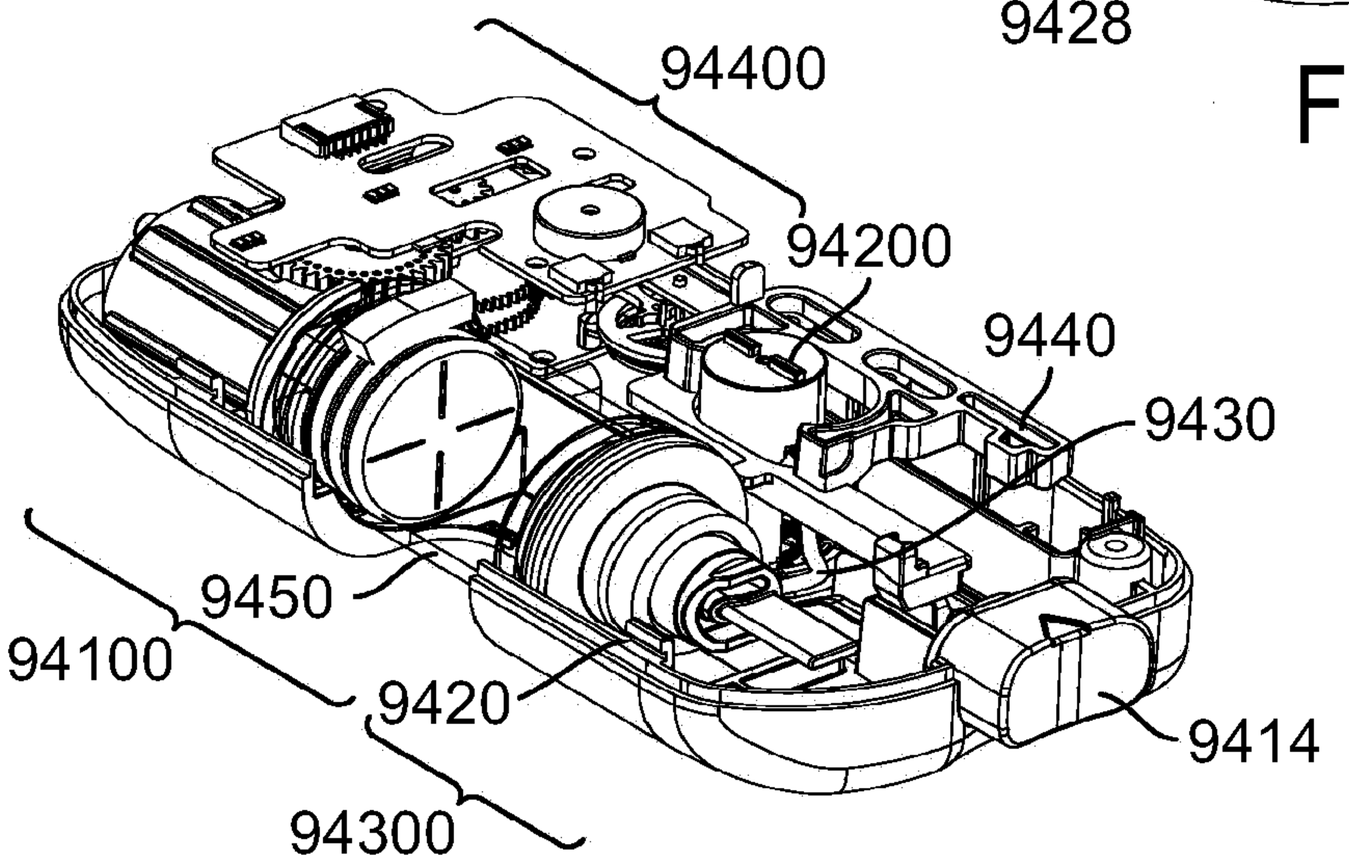


FIG. 92B

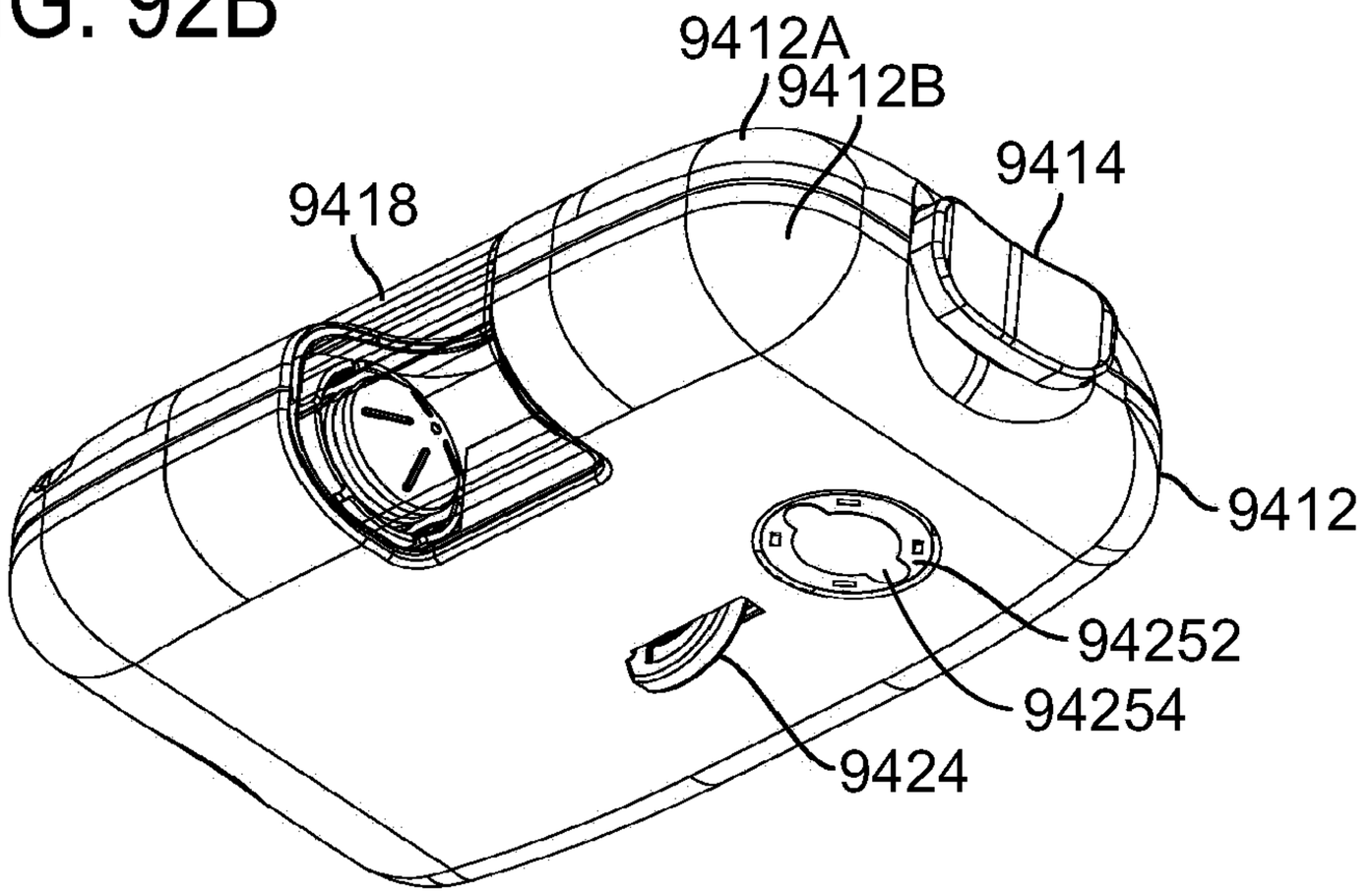


FIG. 92C

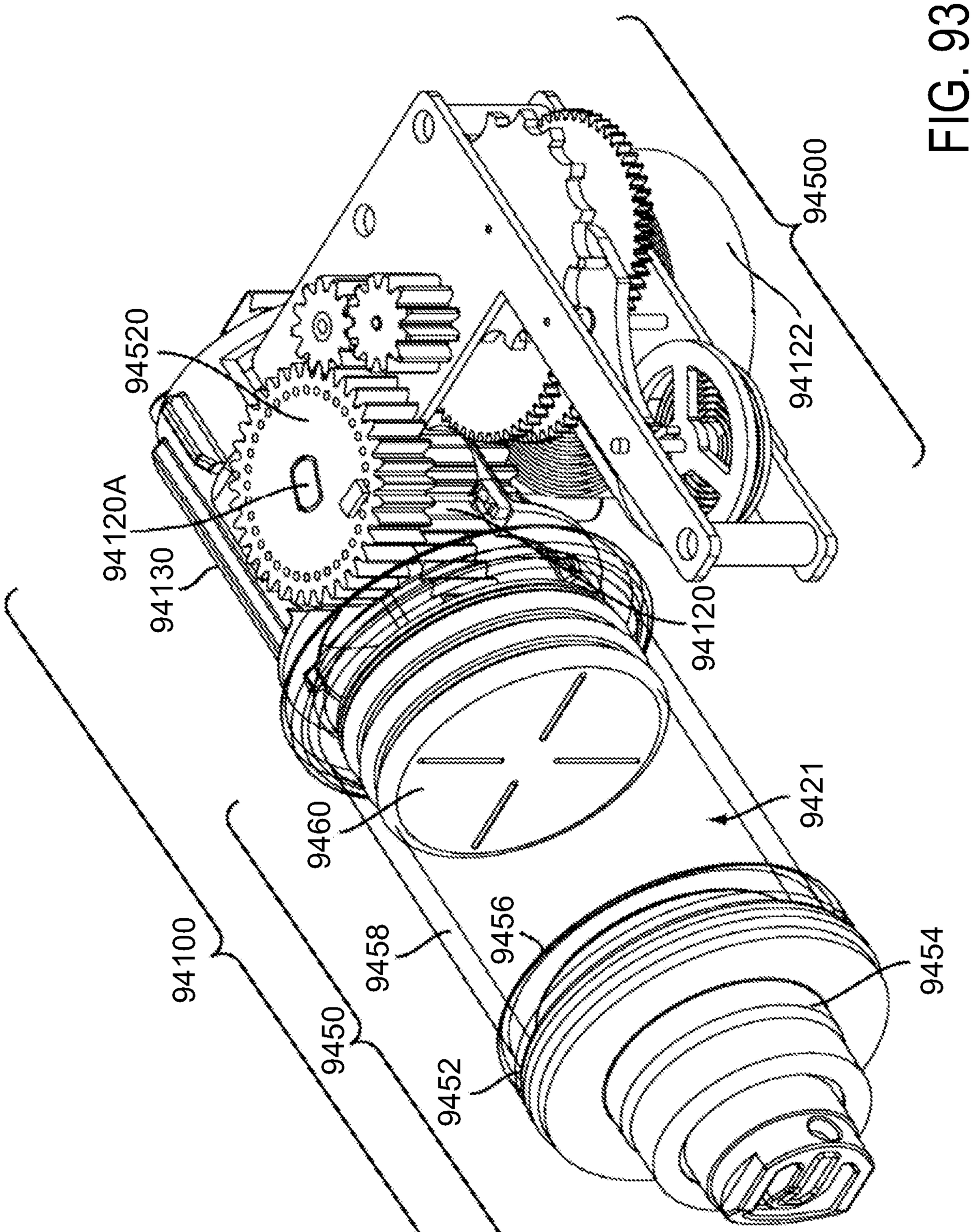

94520
94120A
94122
94130
94500
94120
94100
9460
9421
9458
9456
9450
9454
9452

FIG. 93

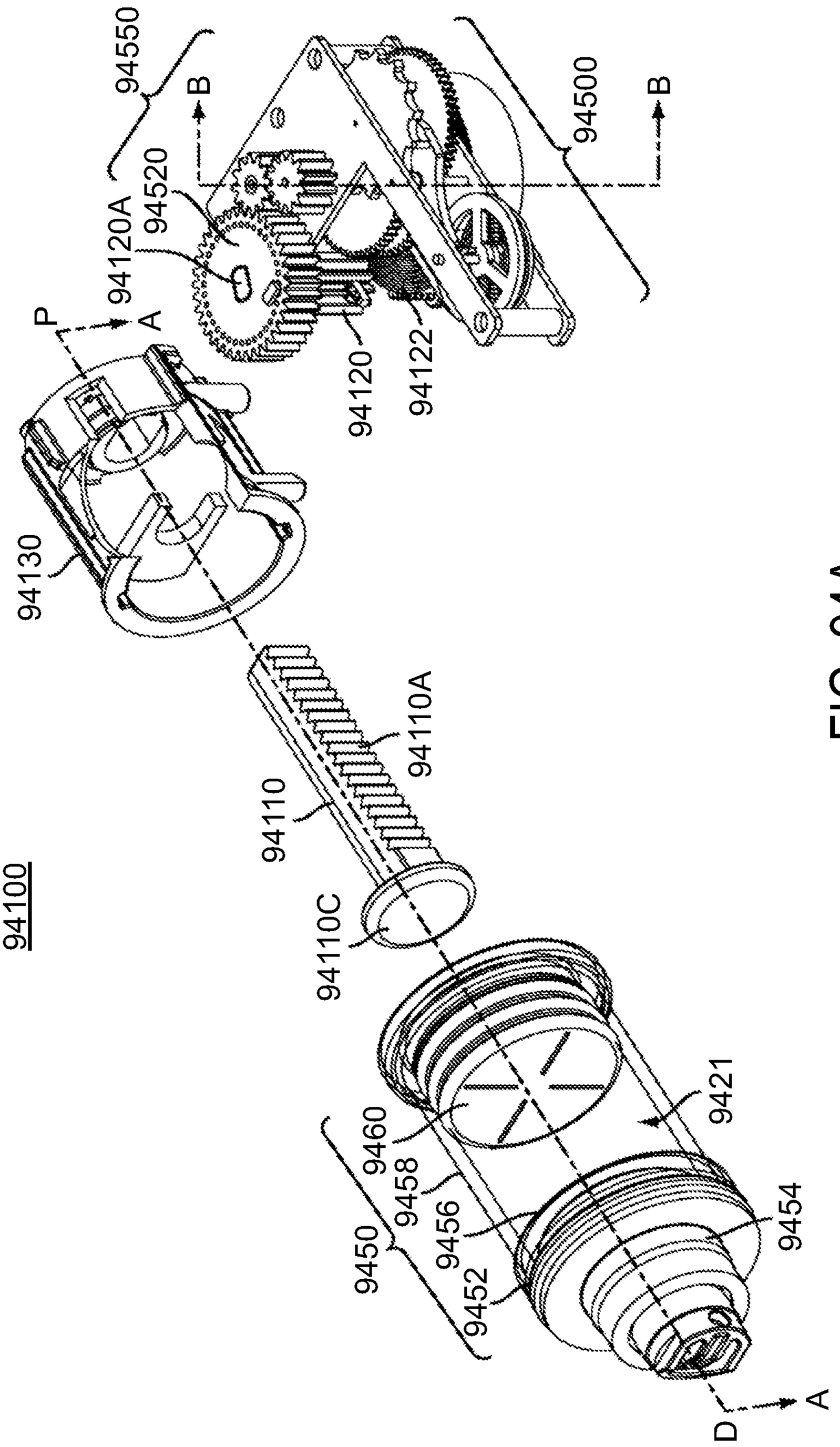

94100
94110
94110A
94110C
9421
9450
9452
9454
9456
9458
9460
94120
94120A
94122
94130
94500
94520
A
B
B
D
P

FIG. 94A

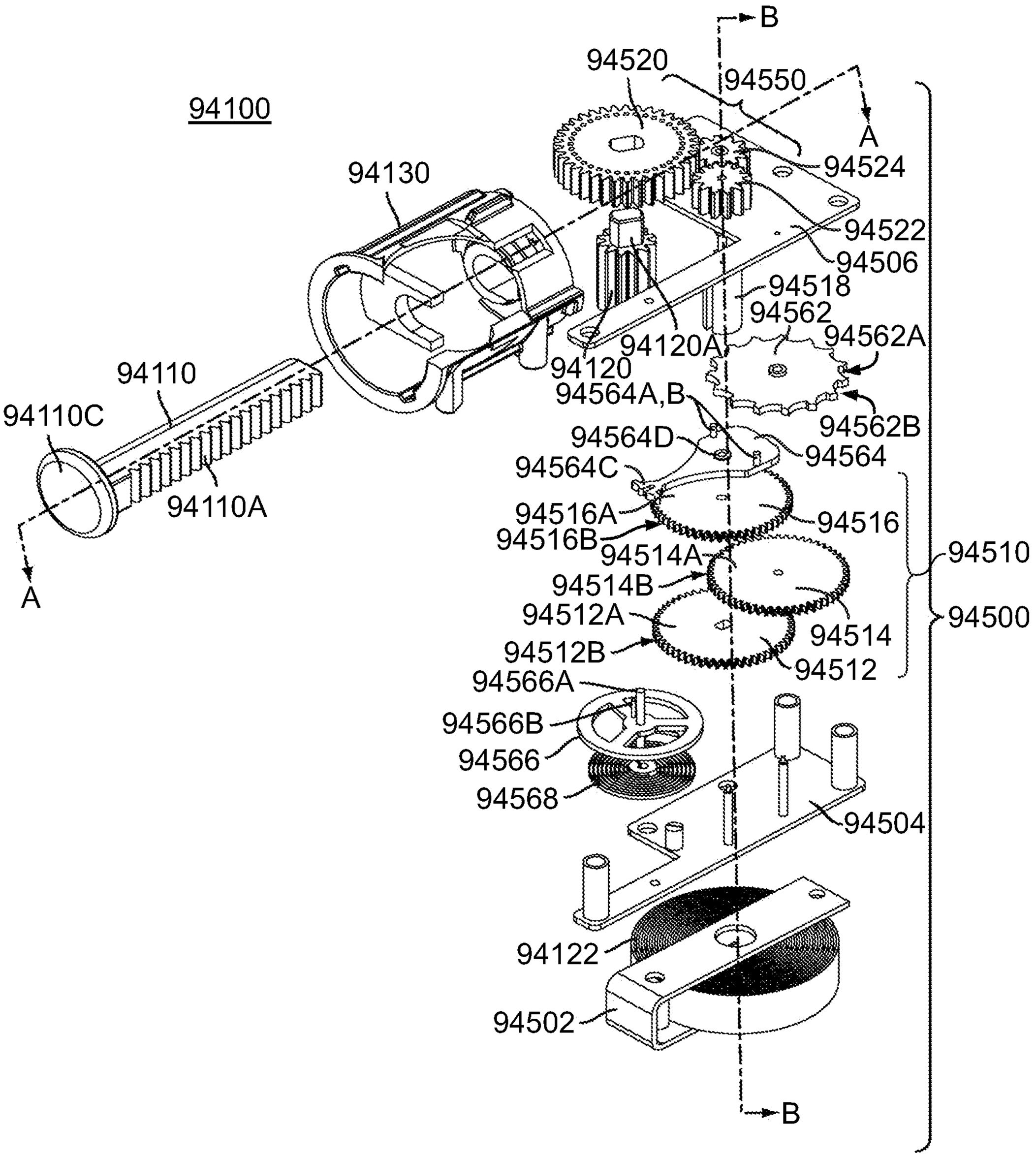

94100
B
94520
94550
A
94524
94130
94522
94506
94518
94562
94562A
94120A
94120
94110
94564A,B
94110C
94564D
94562B
94564
94564C
94110A
94516A
94516
94516B
94514A
94510
94514B
94512A
94500
94514
94512B
94512
94566A
94566B
94566
94568
94504
94122
94502
A
B

FIG. 94B

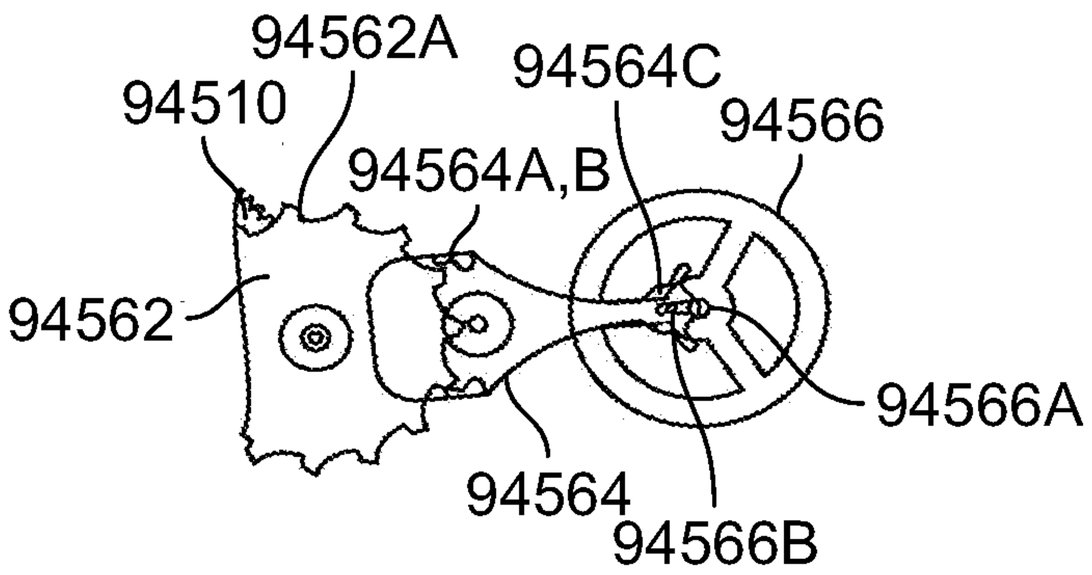


FIG. 95A

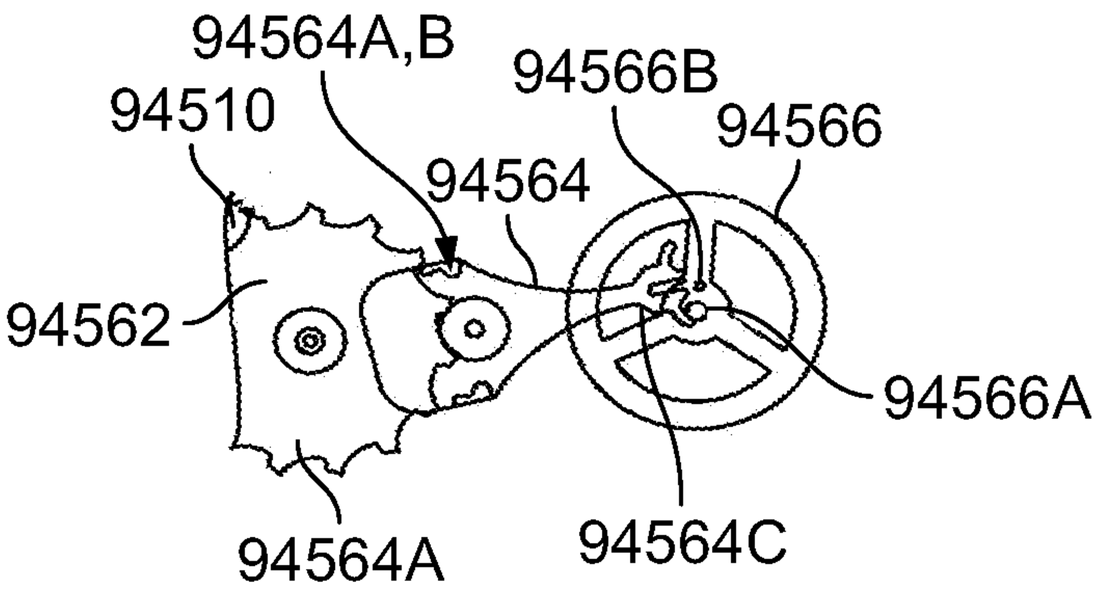


FIG. 95B

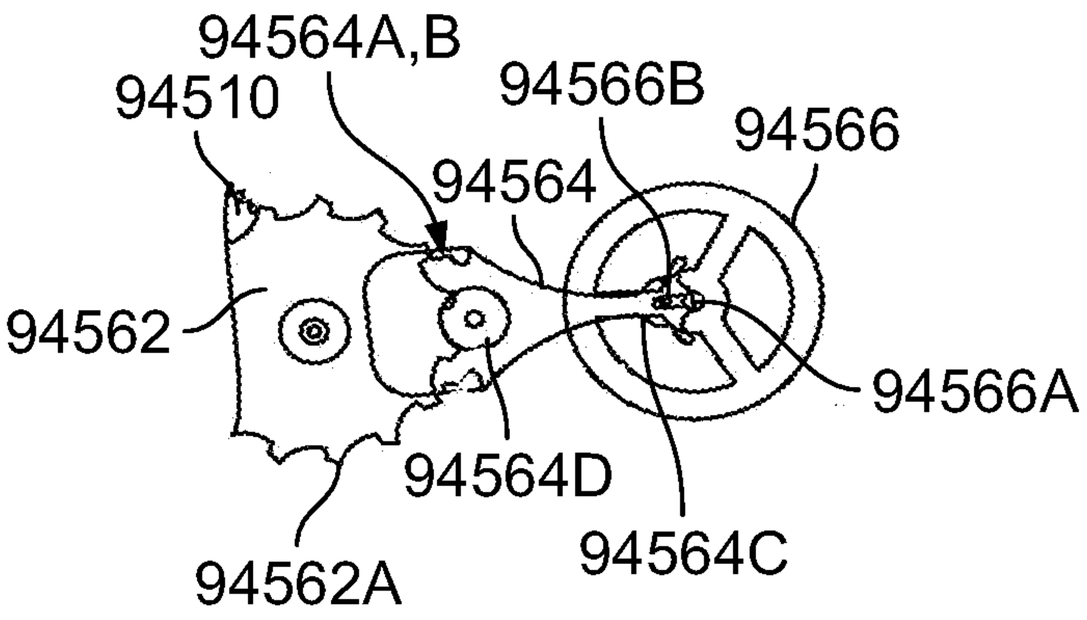


FIG. 95C

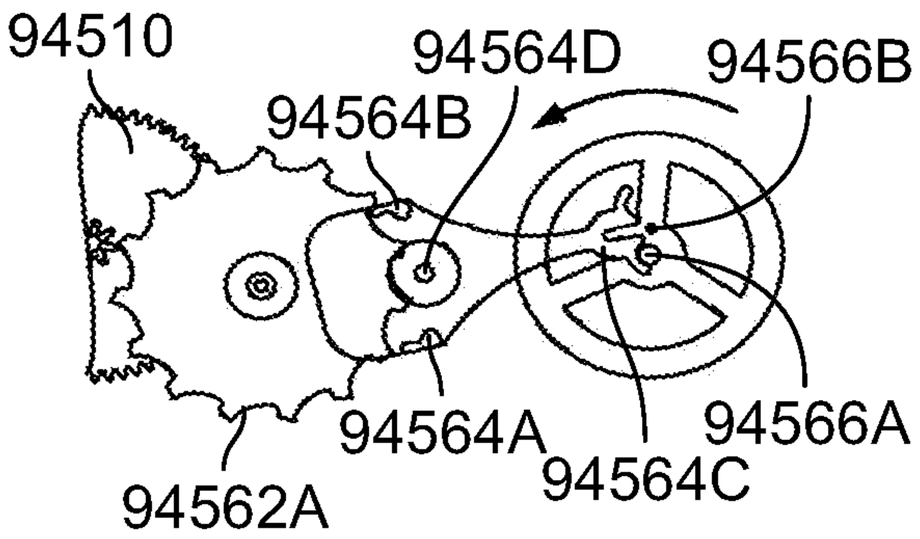


FIG. 95D

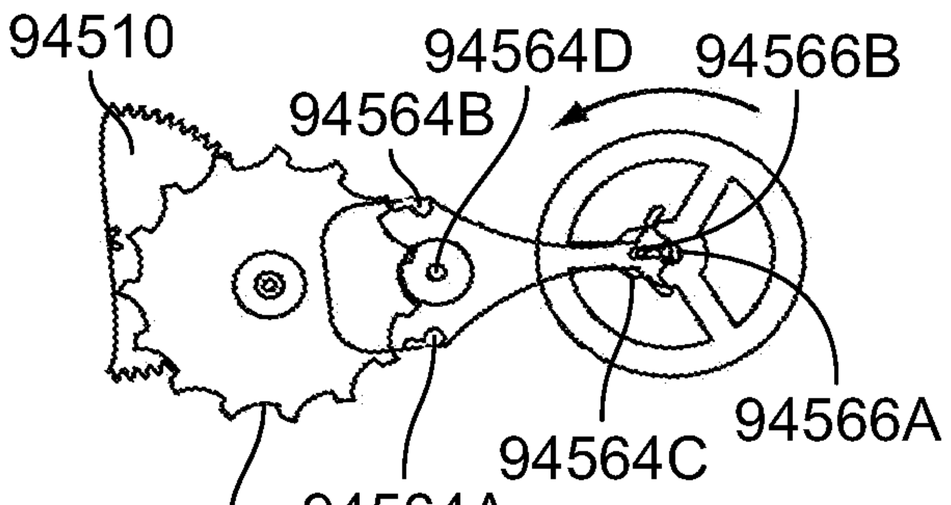


FIG. 95E

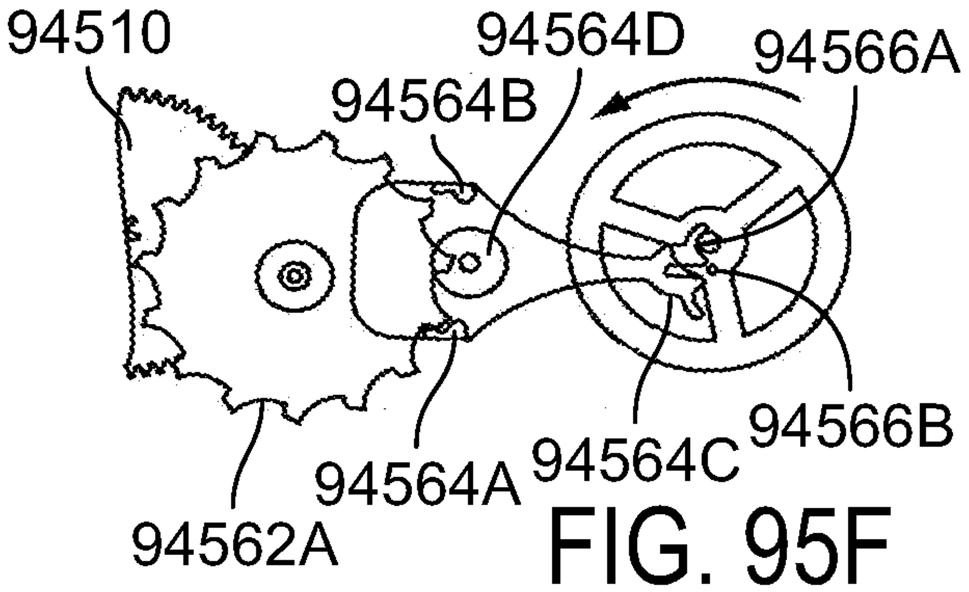


FIG. 95F

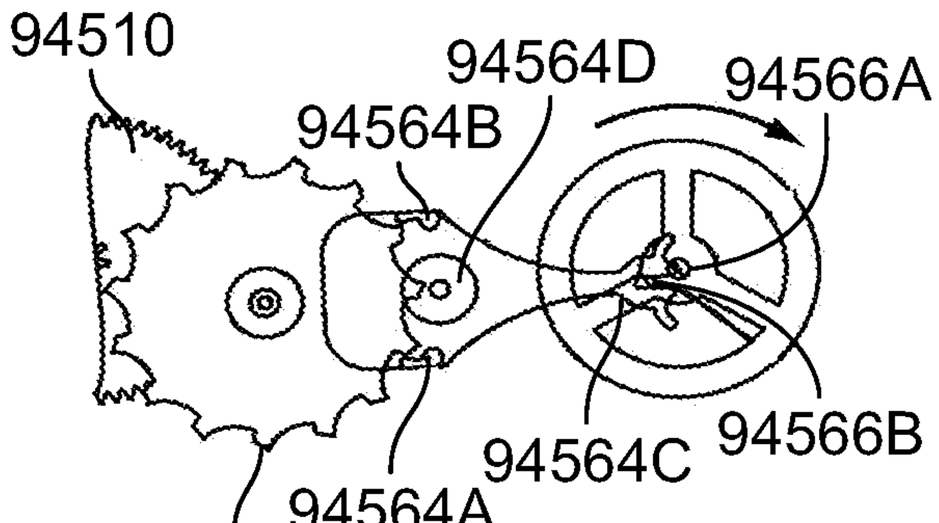


FIG. 95G

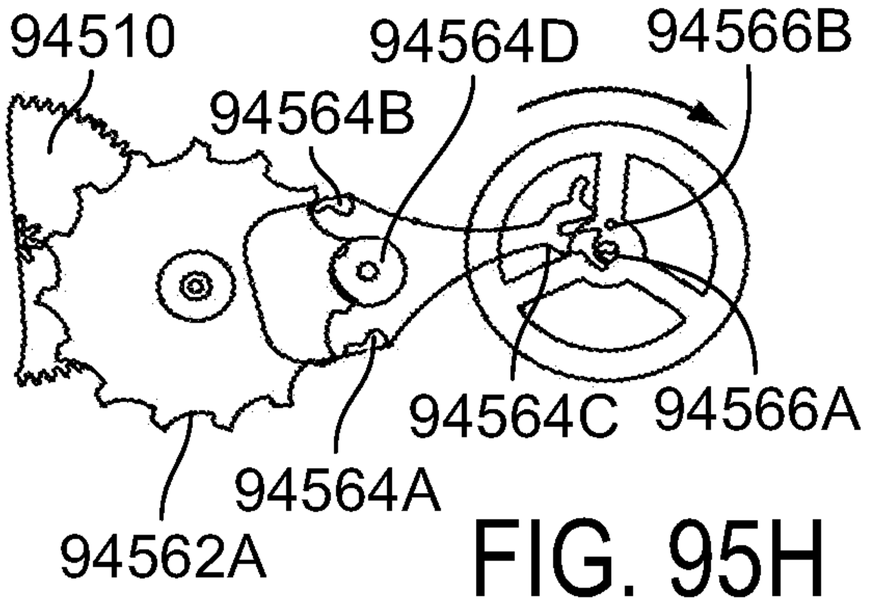


FIG. 95H

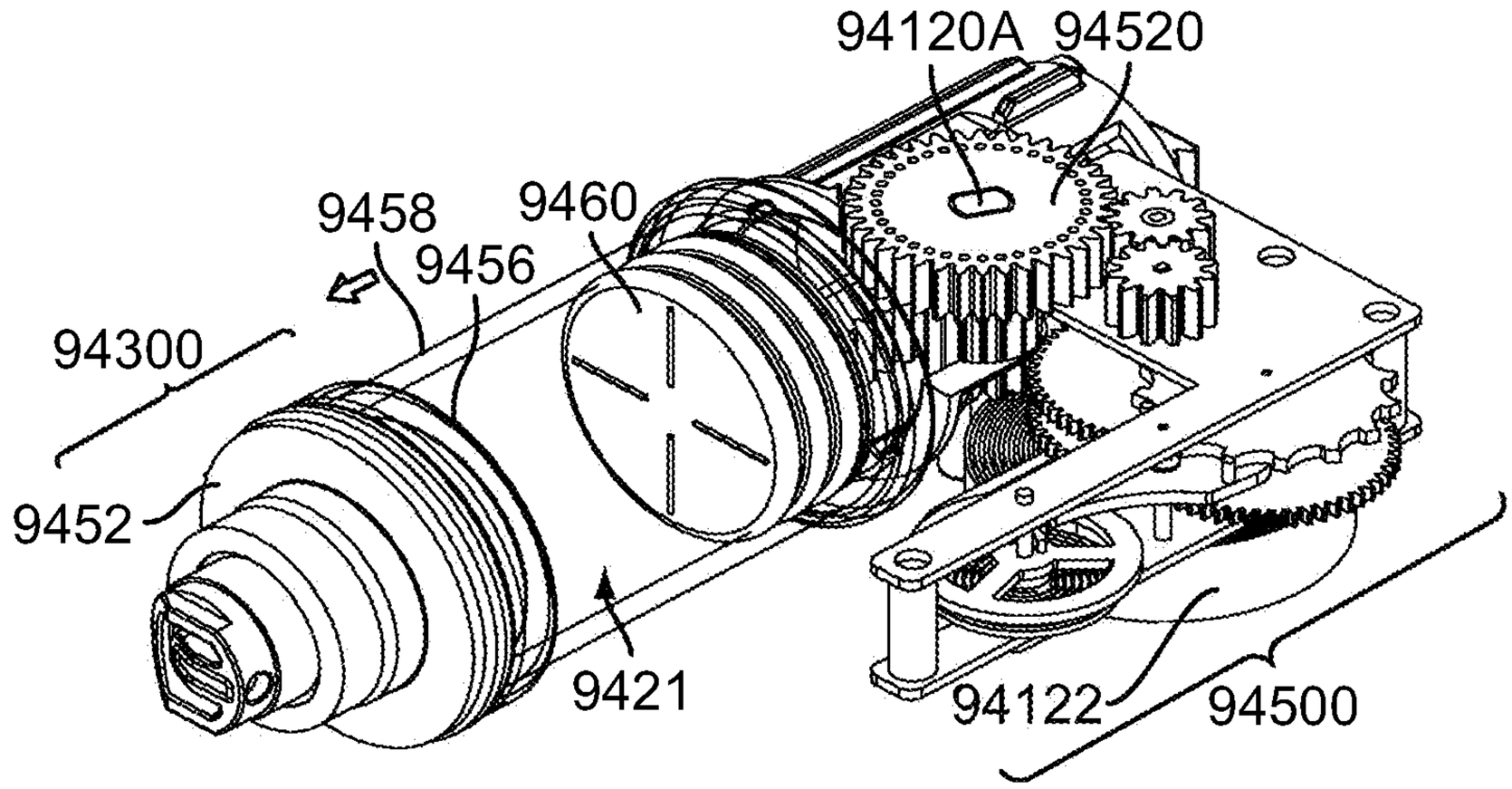


FIG. 96A

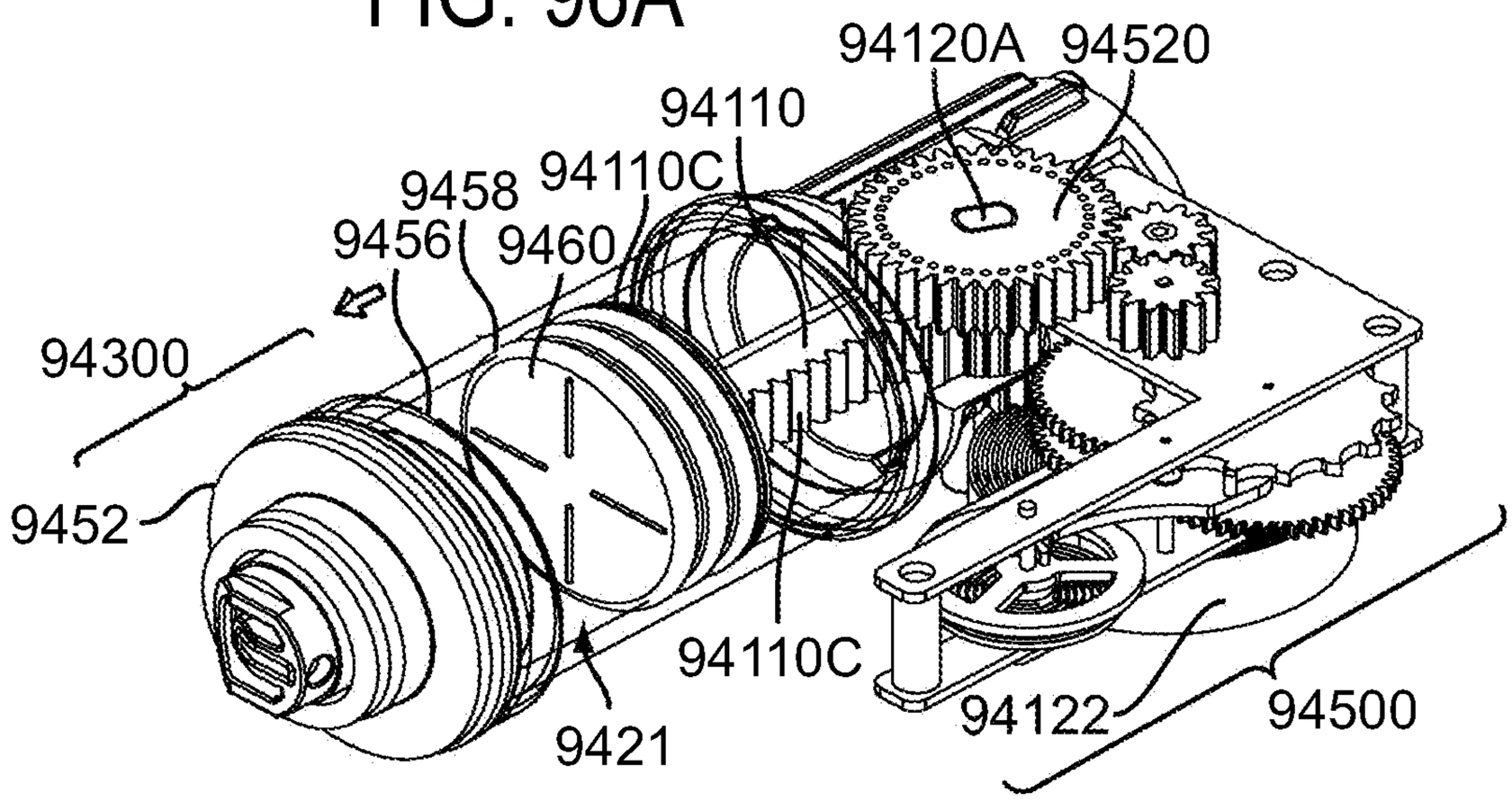


FIG. 96B

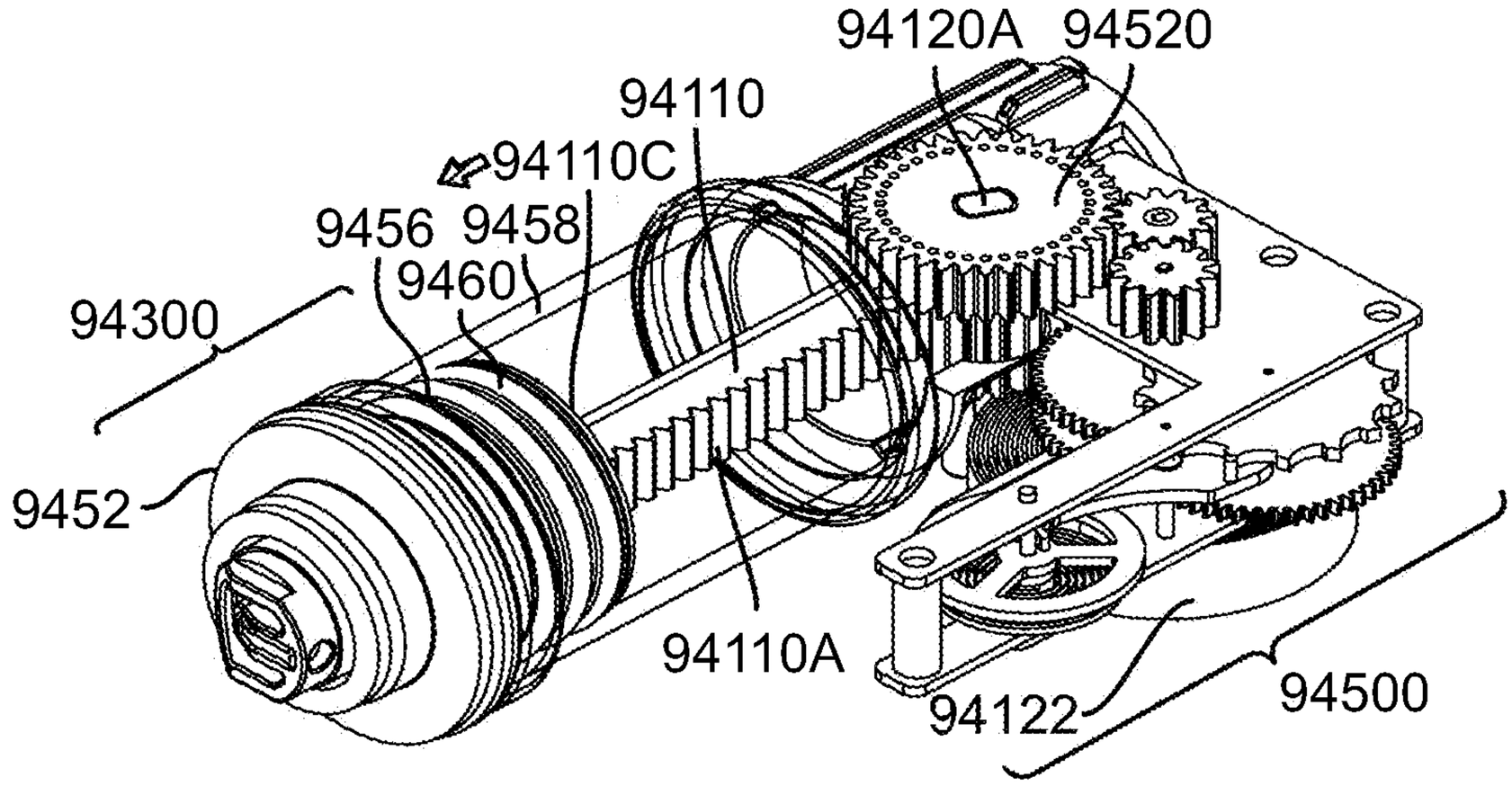


FIG. 96C

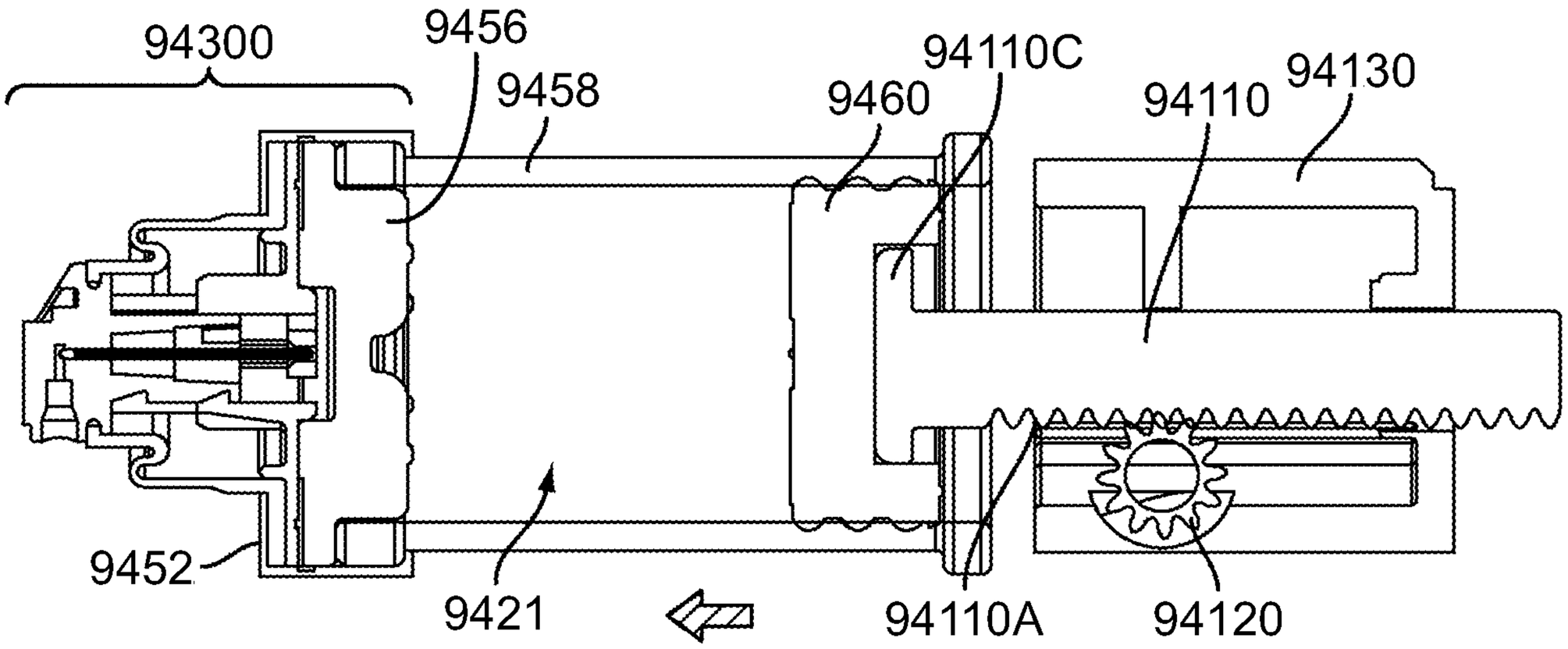


FIG. 97A

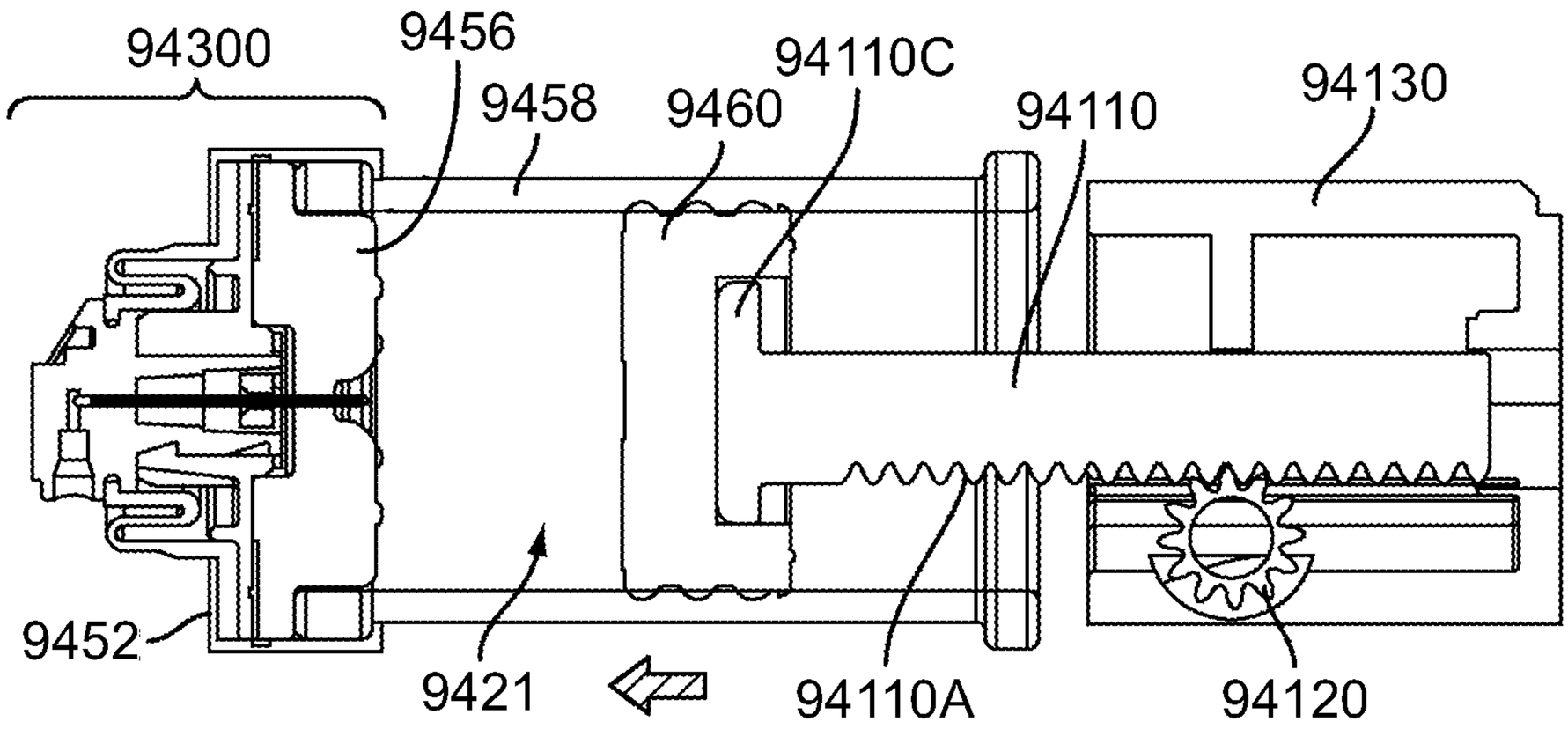


FIG. 97B

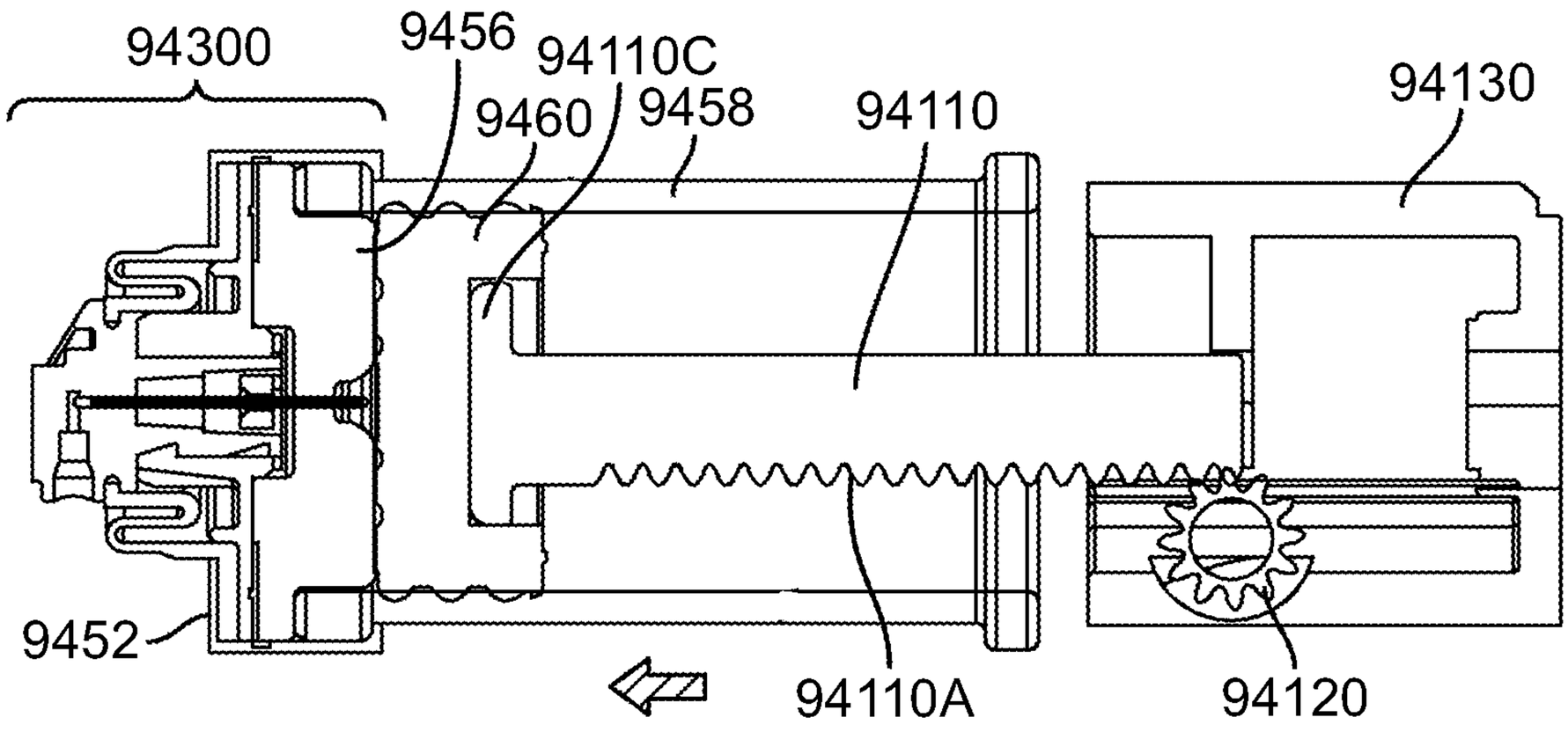


FIG. 97C

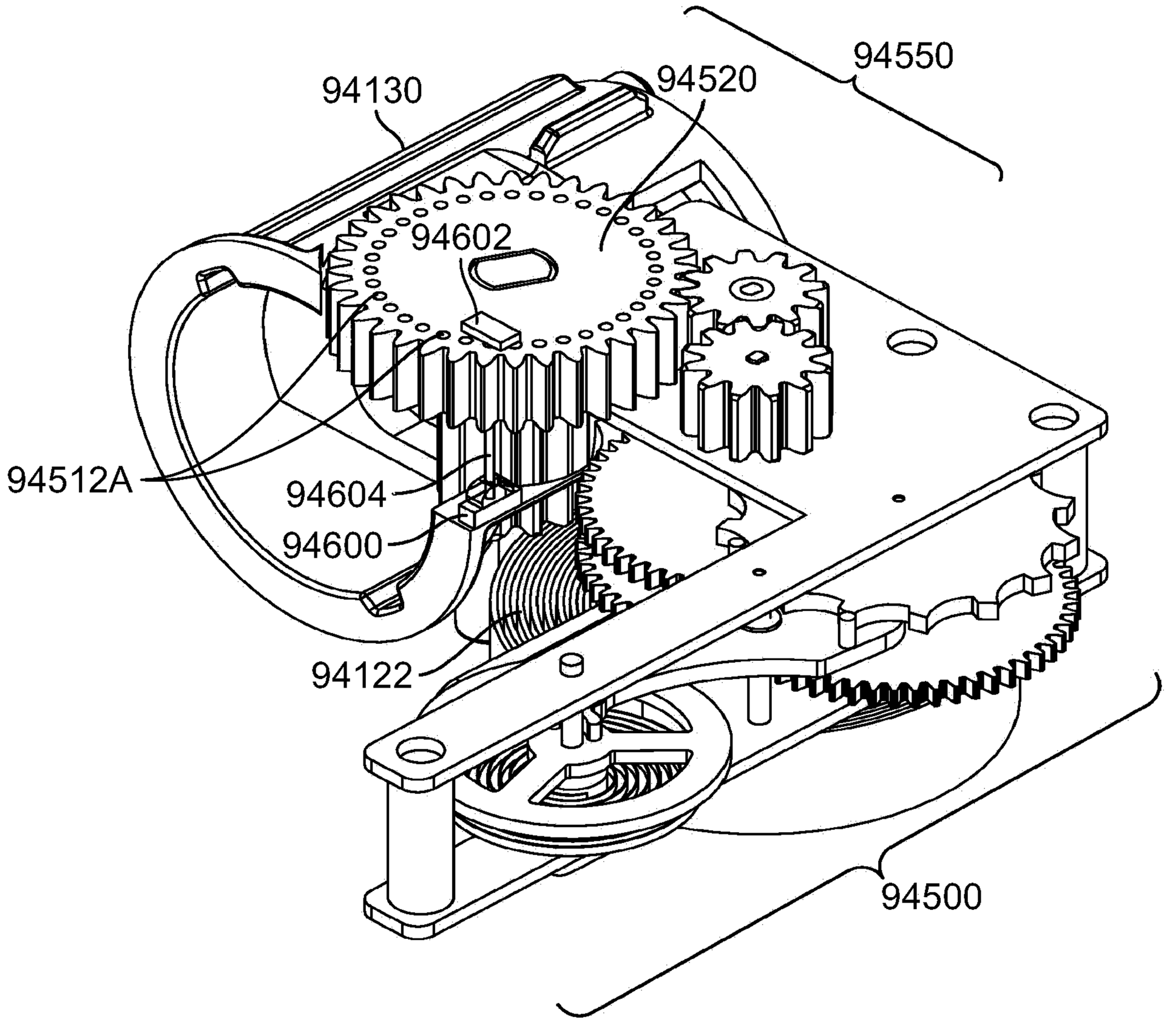


FIG. 98

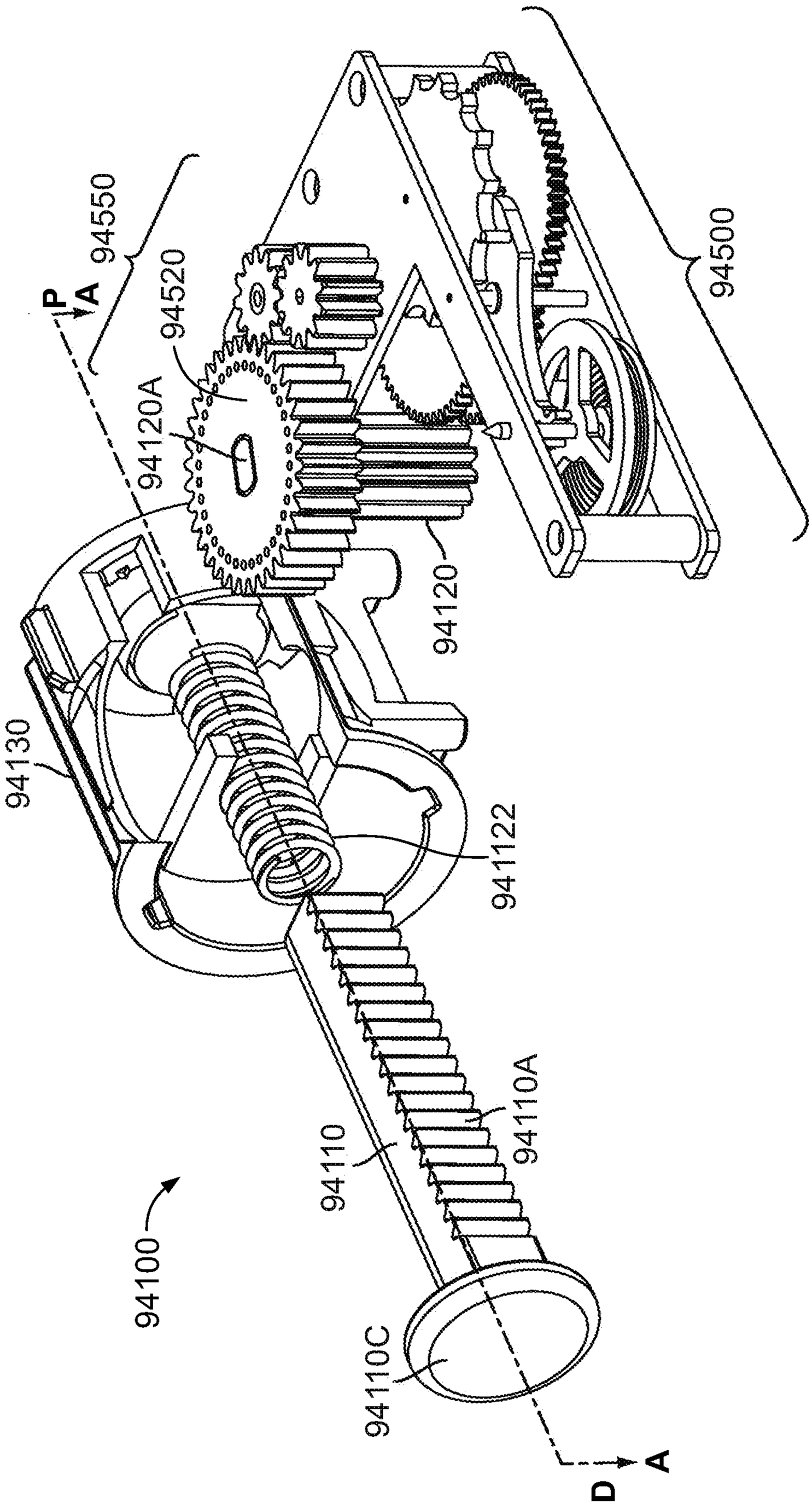

94550
P
A
94520
94120A
94130
94122
94110
94110A
94100
94110C
D
A
94500

FIG. 99

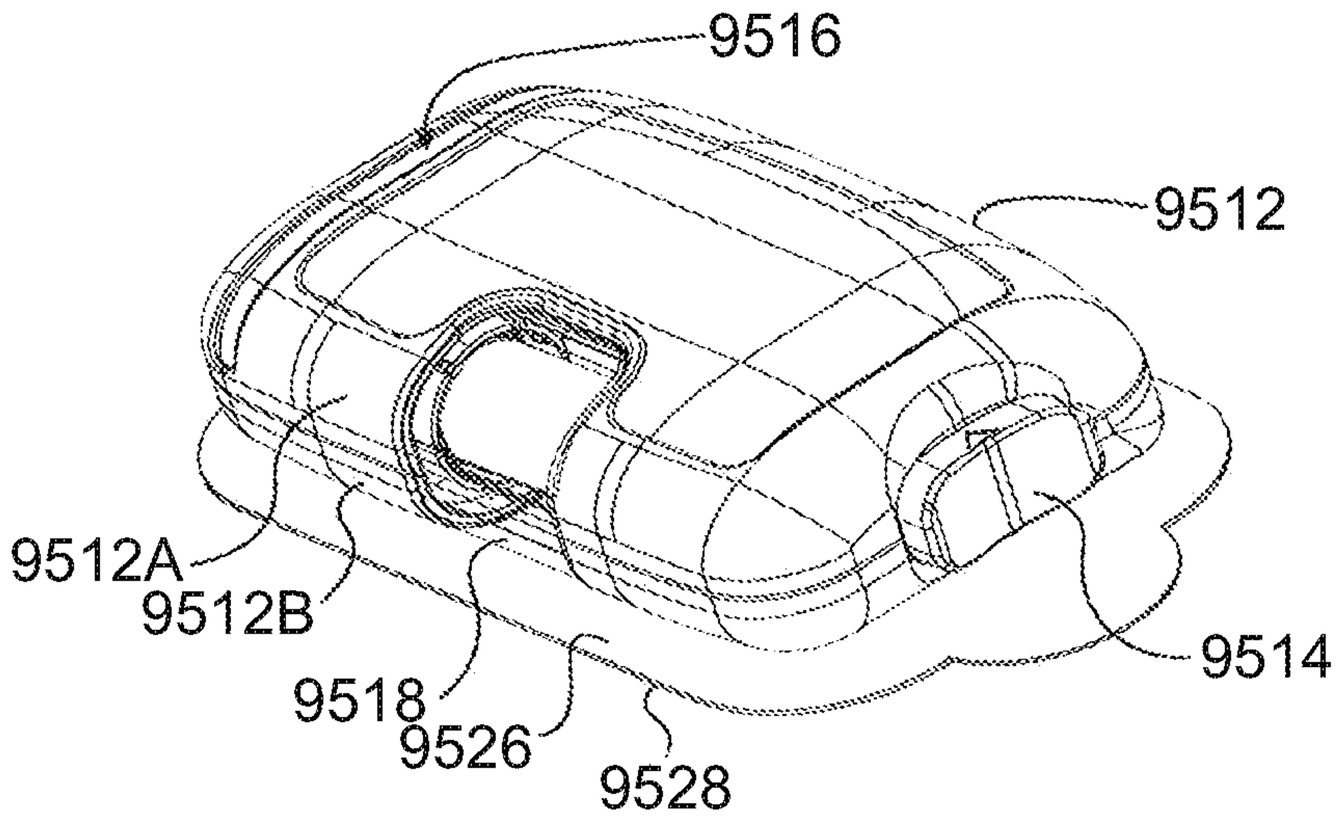


FIG. 100A

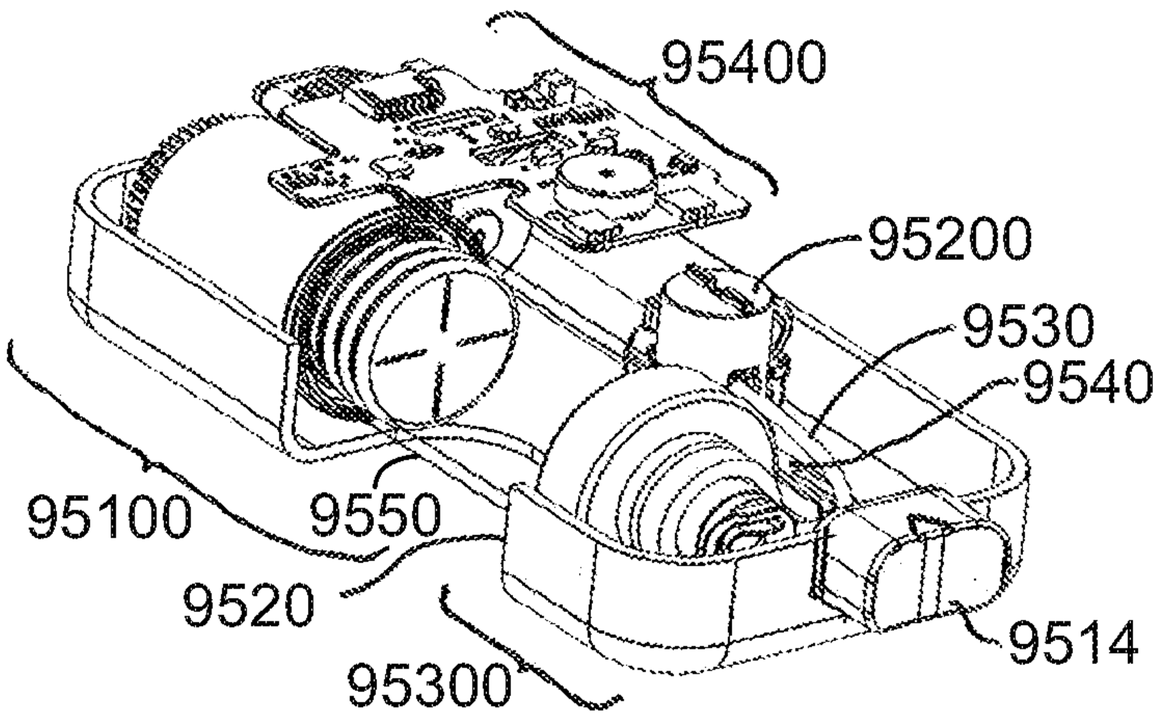


FIG. 100B

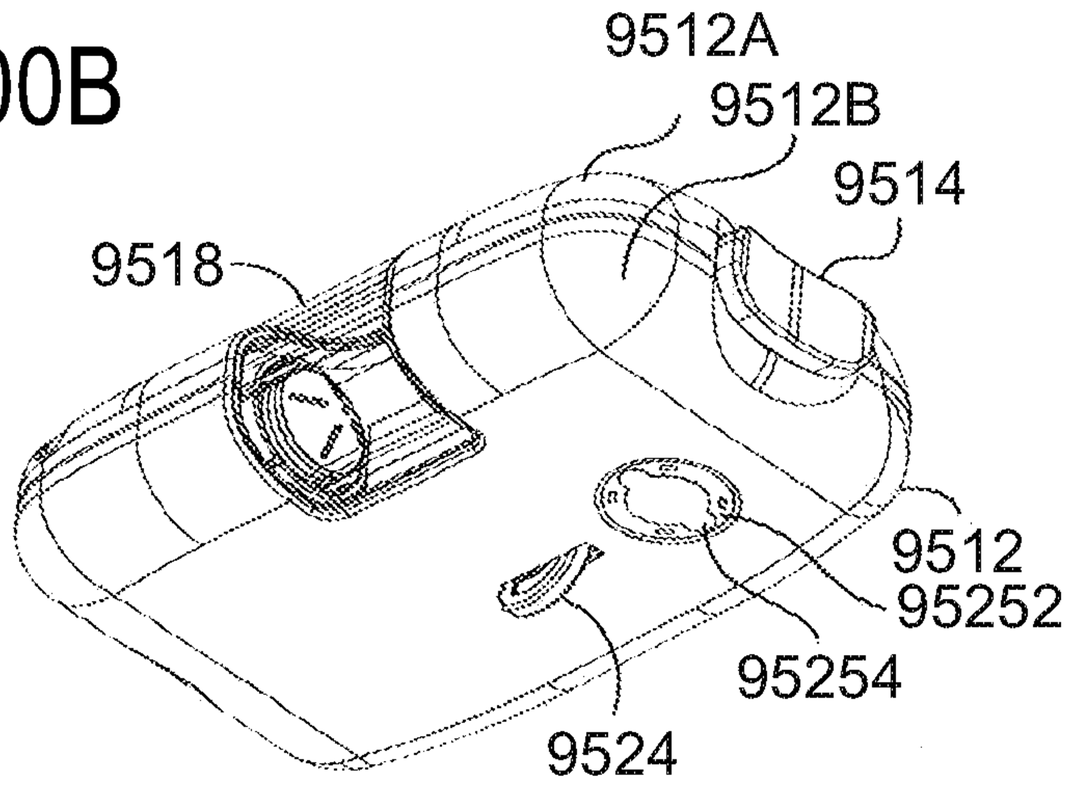


FIG. 100C

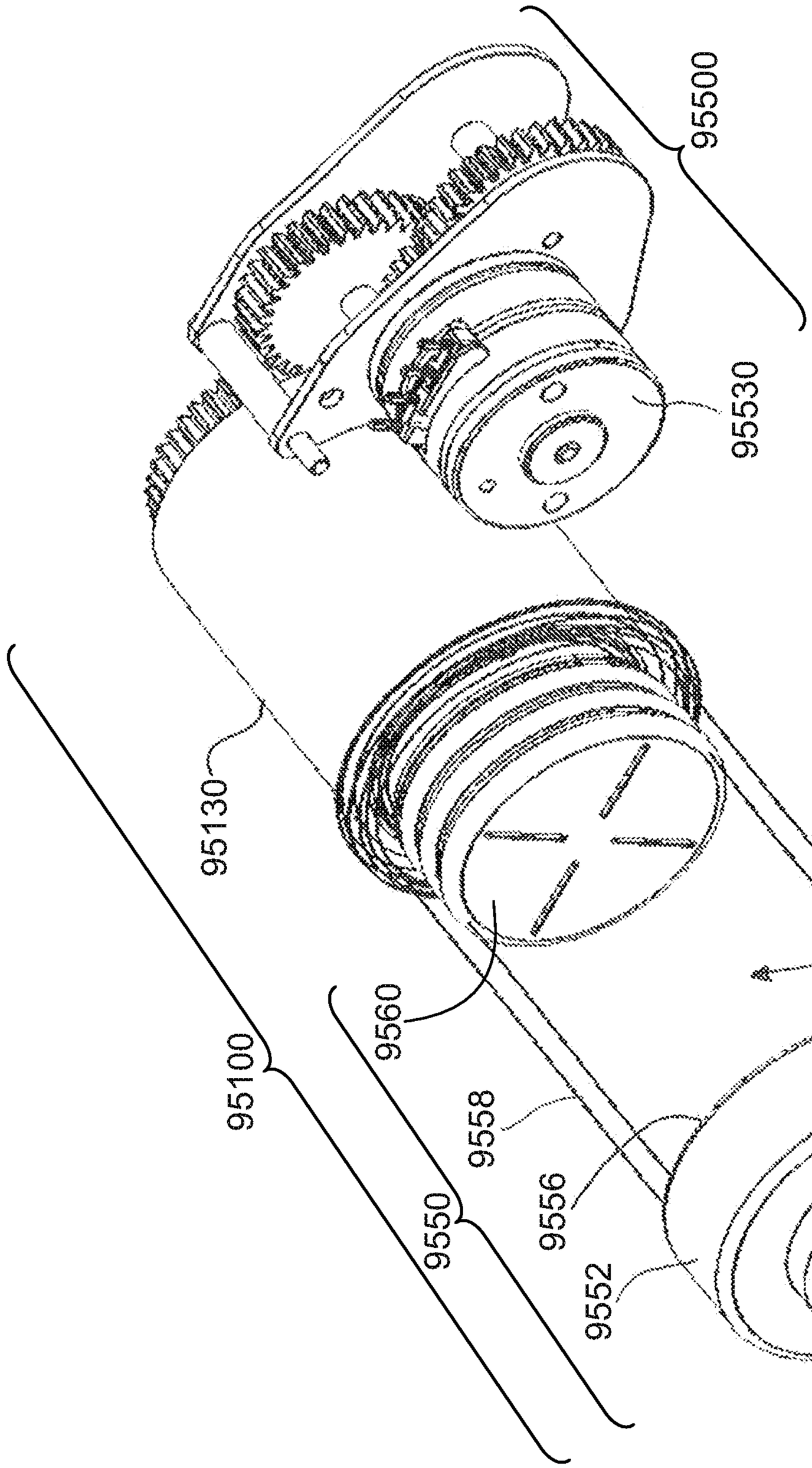


FIG. 101

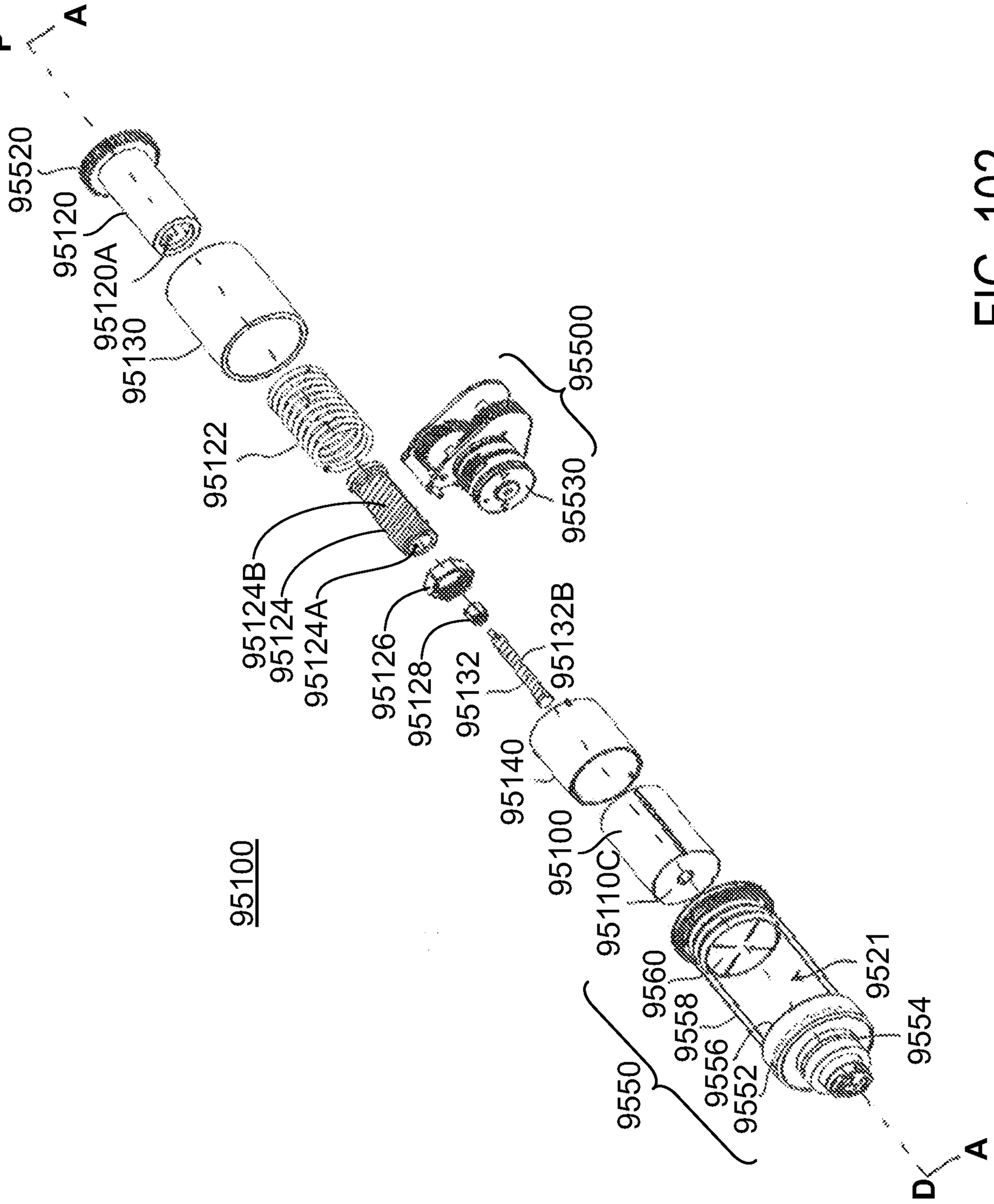

A
95520
95120
95120A
95130
95122
95124B
95124
95124A
95126
95128
95132
95132B
95140
95100
95110C
95560
9558
9556
9552
9550
95530
95500
9554
9521
D
A
95100

FIG. 102

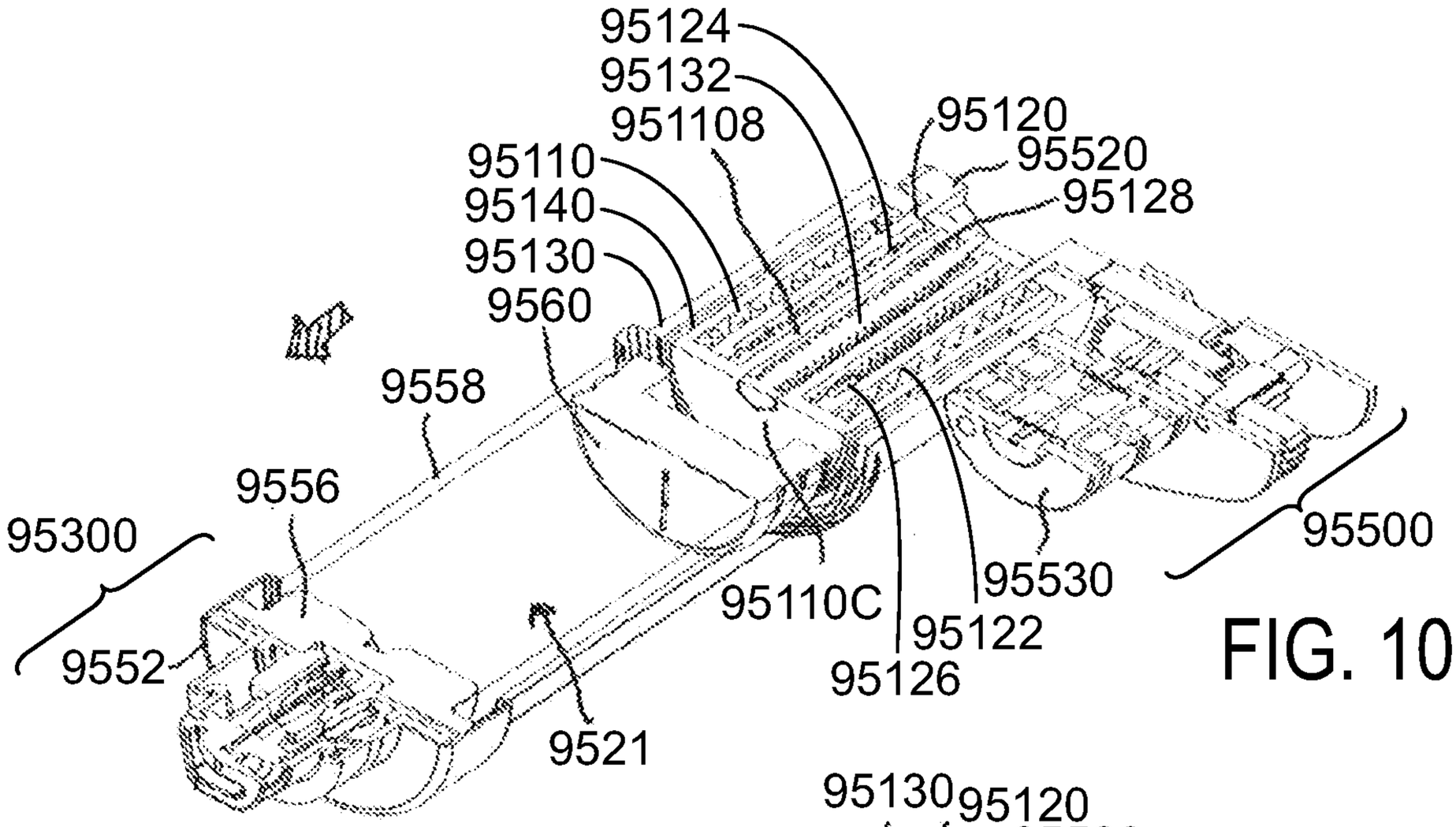


FIG. 103A

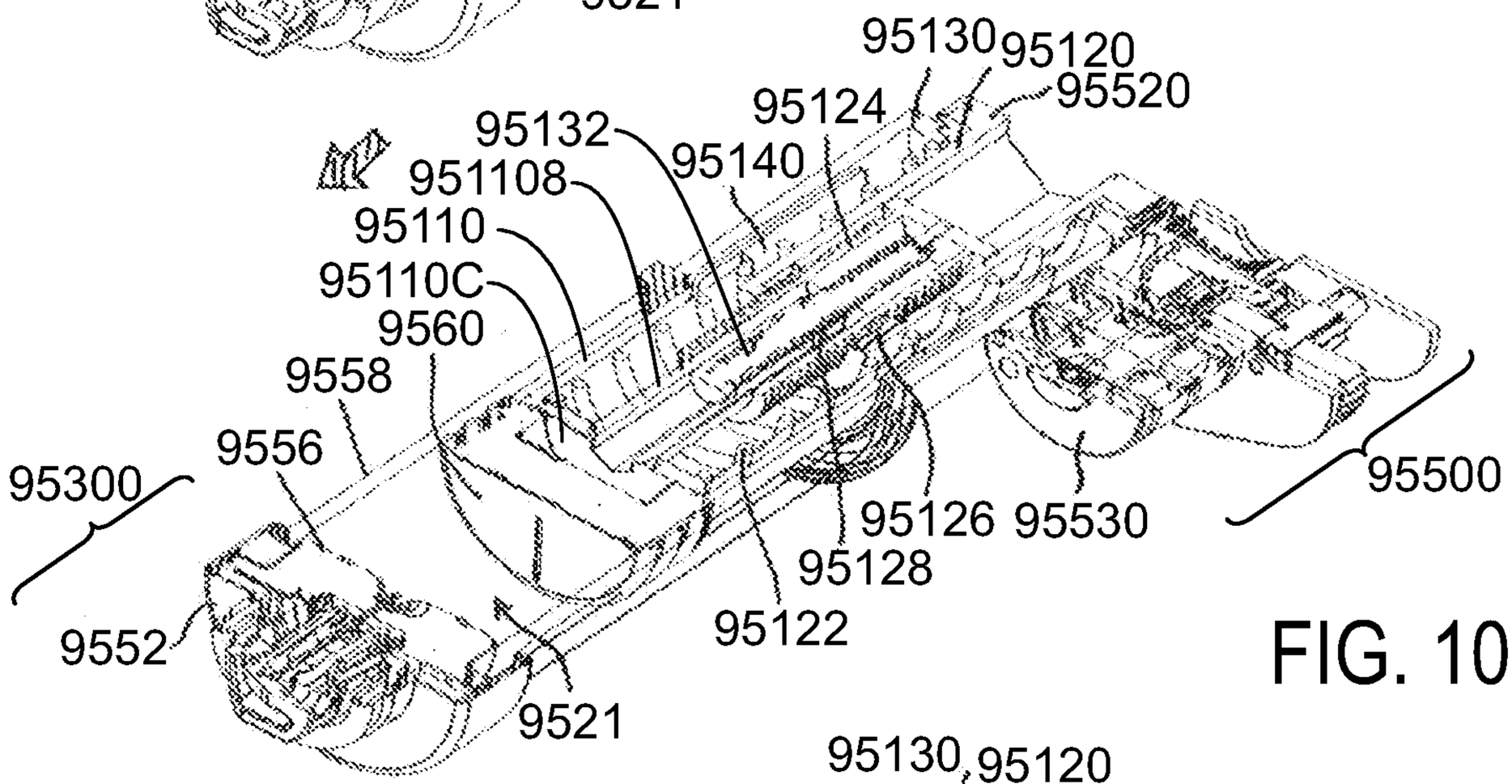


FIG. 103B

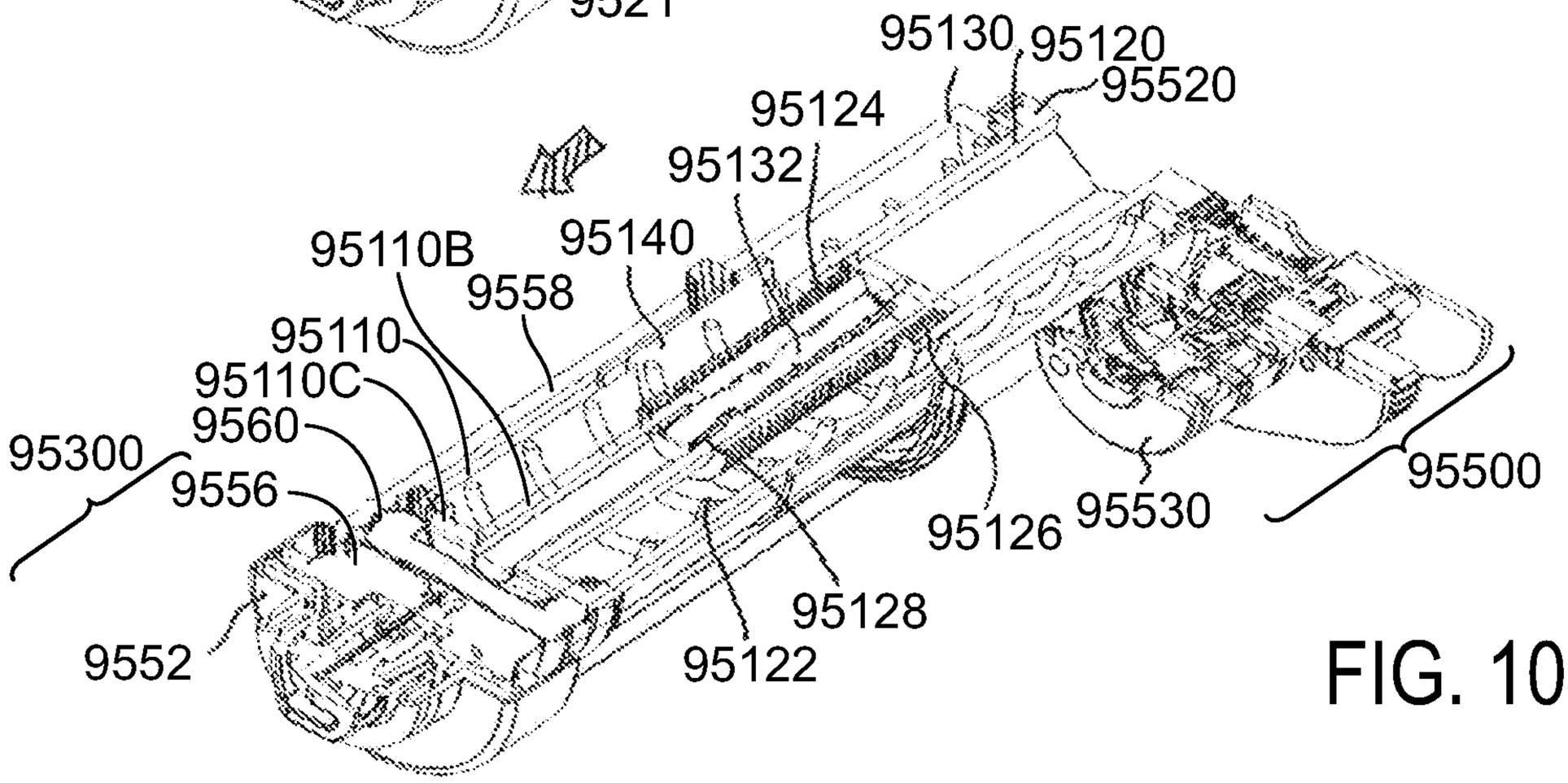


FIG. 103C

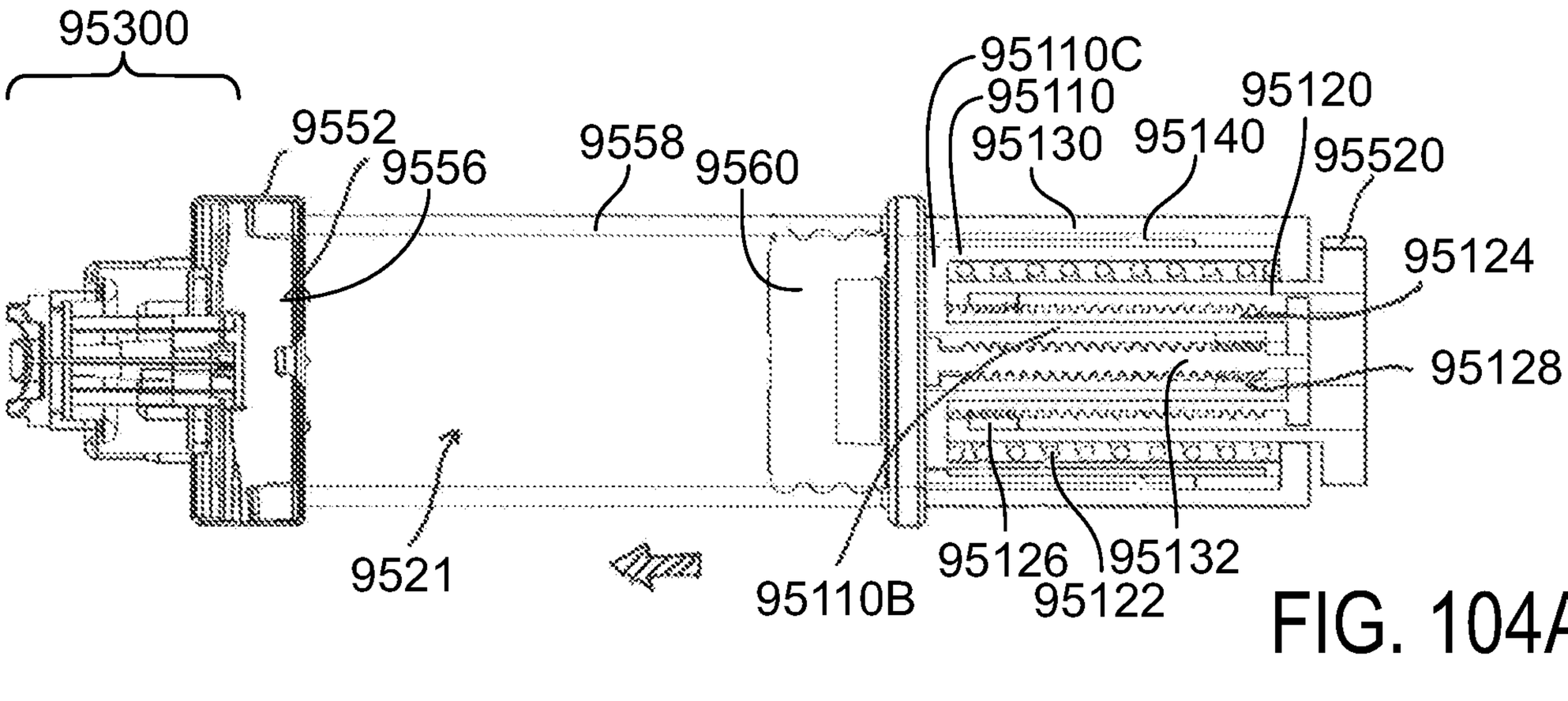


FIG. 104A

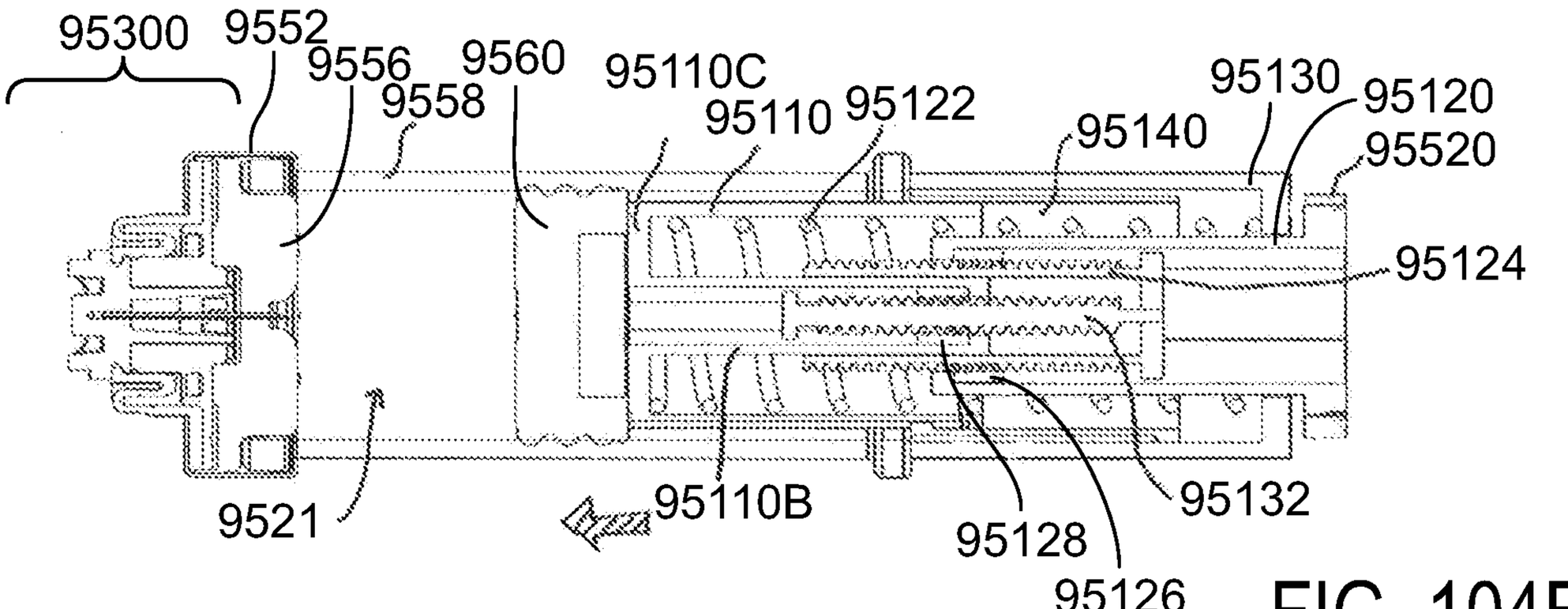


FIG. 104B

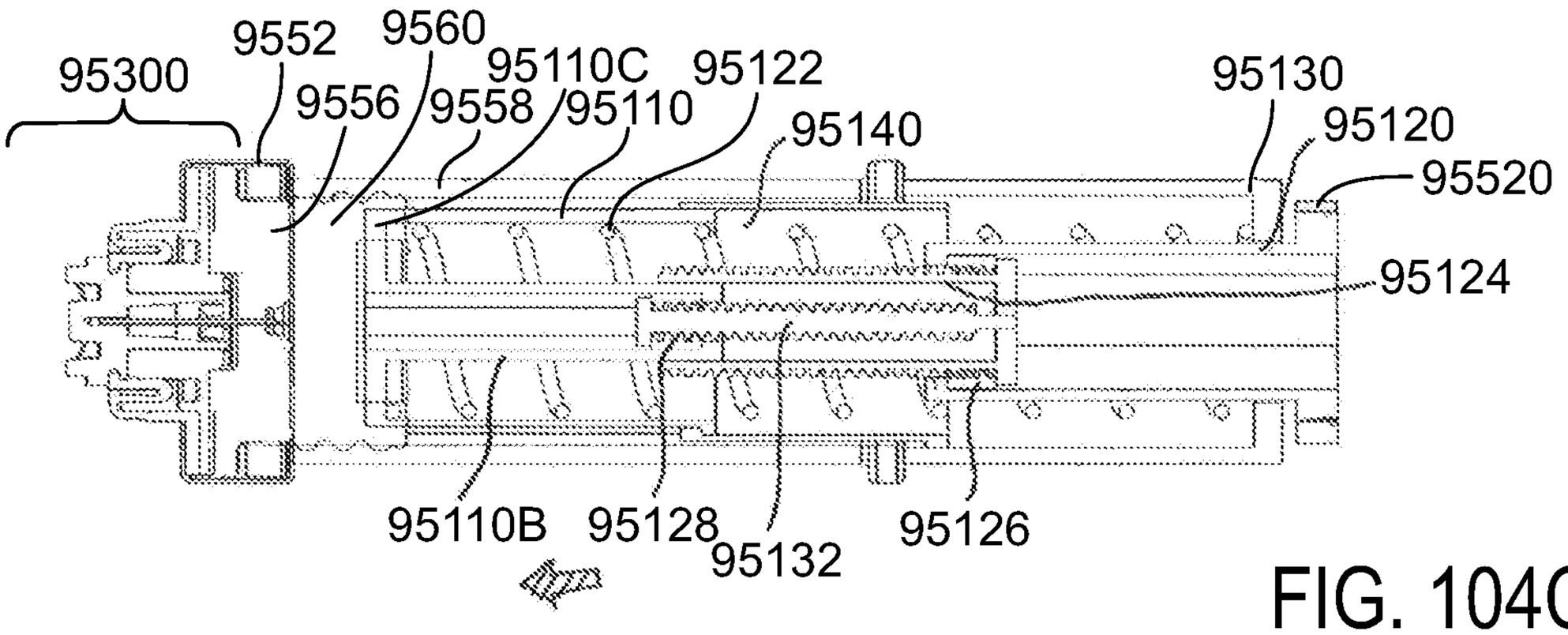


FIG. 104C

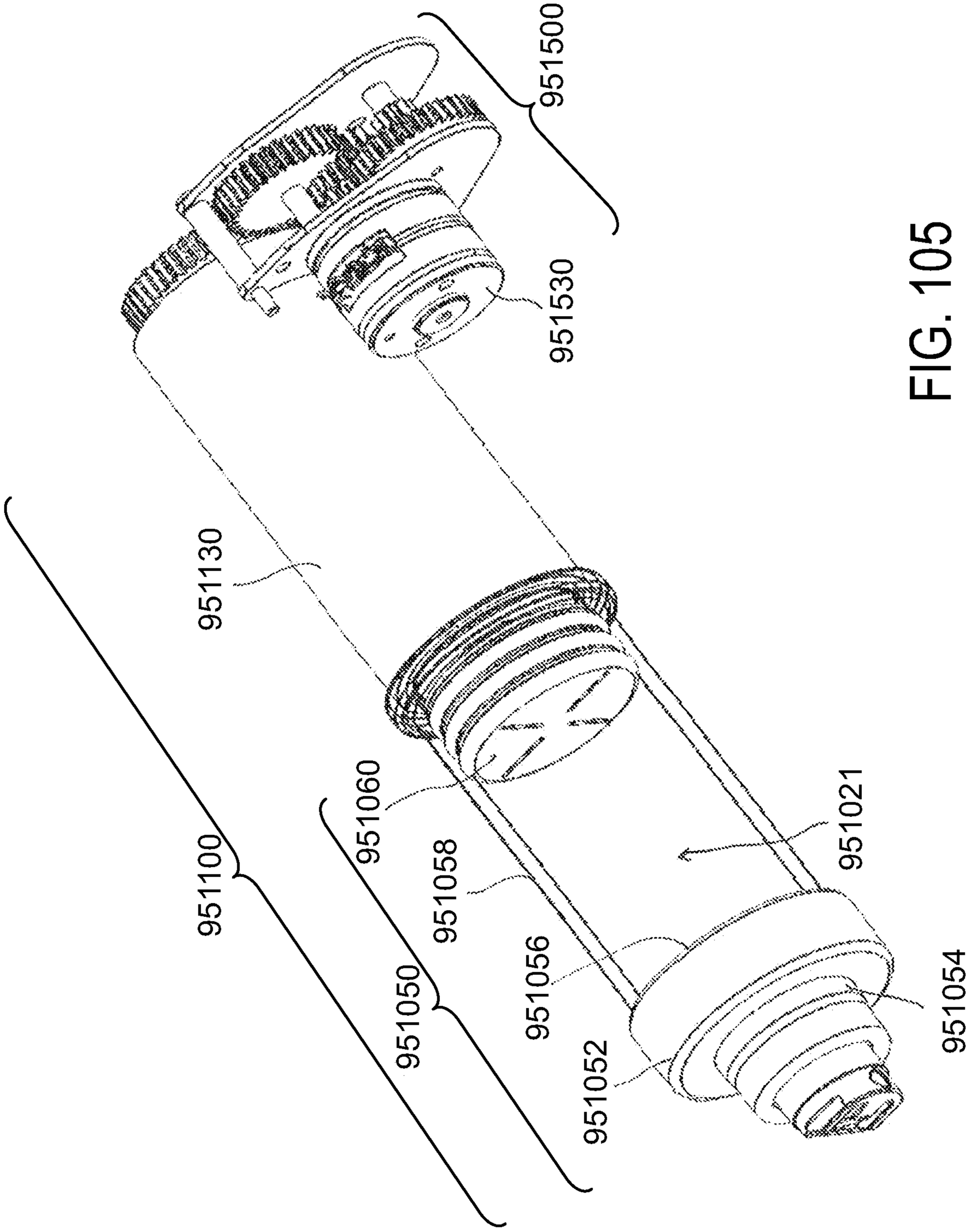

951500
951530
951130
951100
951060
951058
951050
951056
951021
951052
951054

FIG. 105

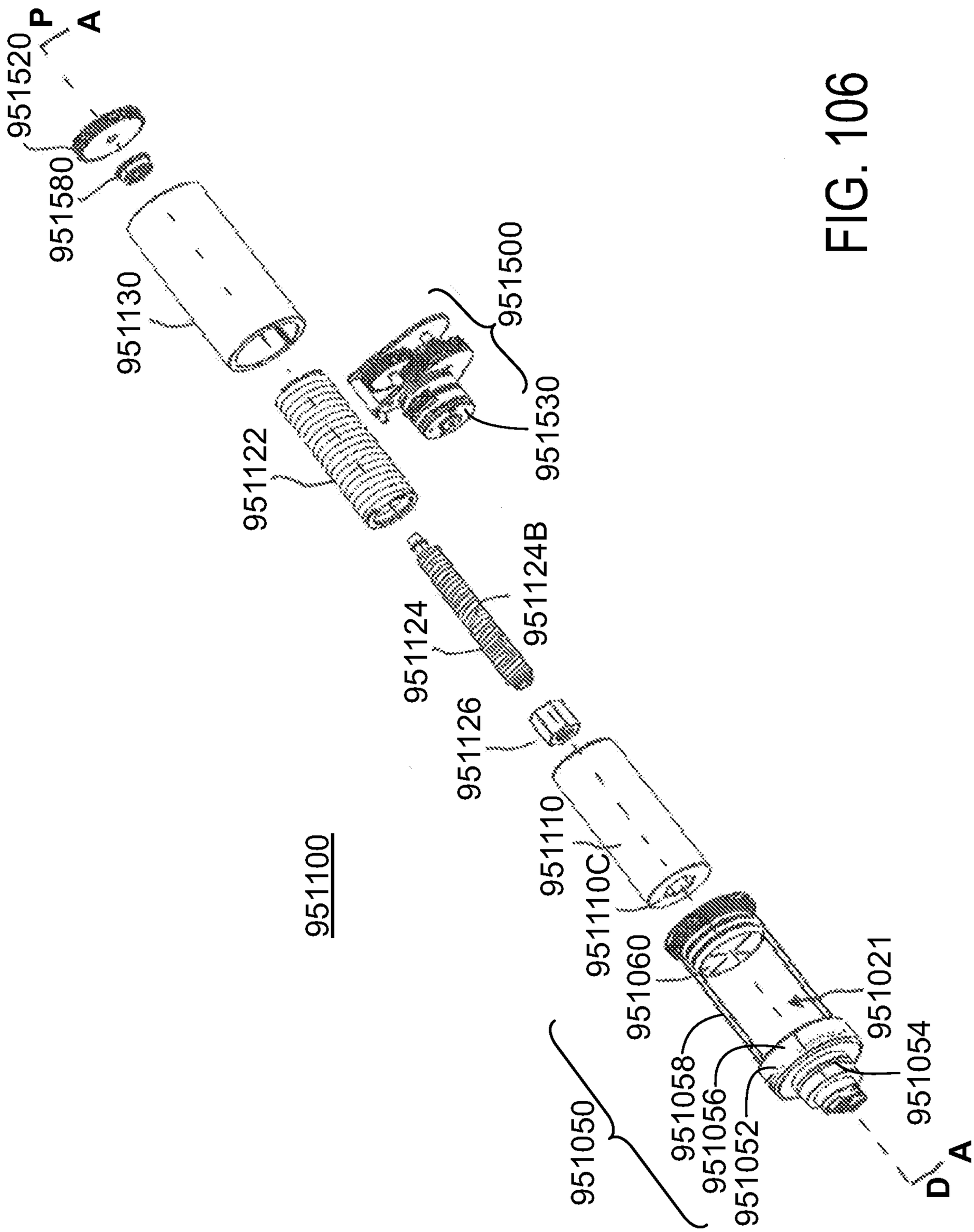

9515
951580
951130
951122
951500
951530
951124
951124B
951126
951110
951110C
951100
1060
1021
951050
951058
951056
951052
951054
A
D

FIG. 106

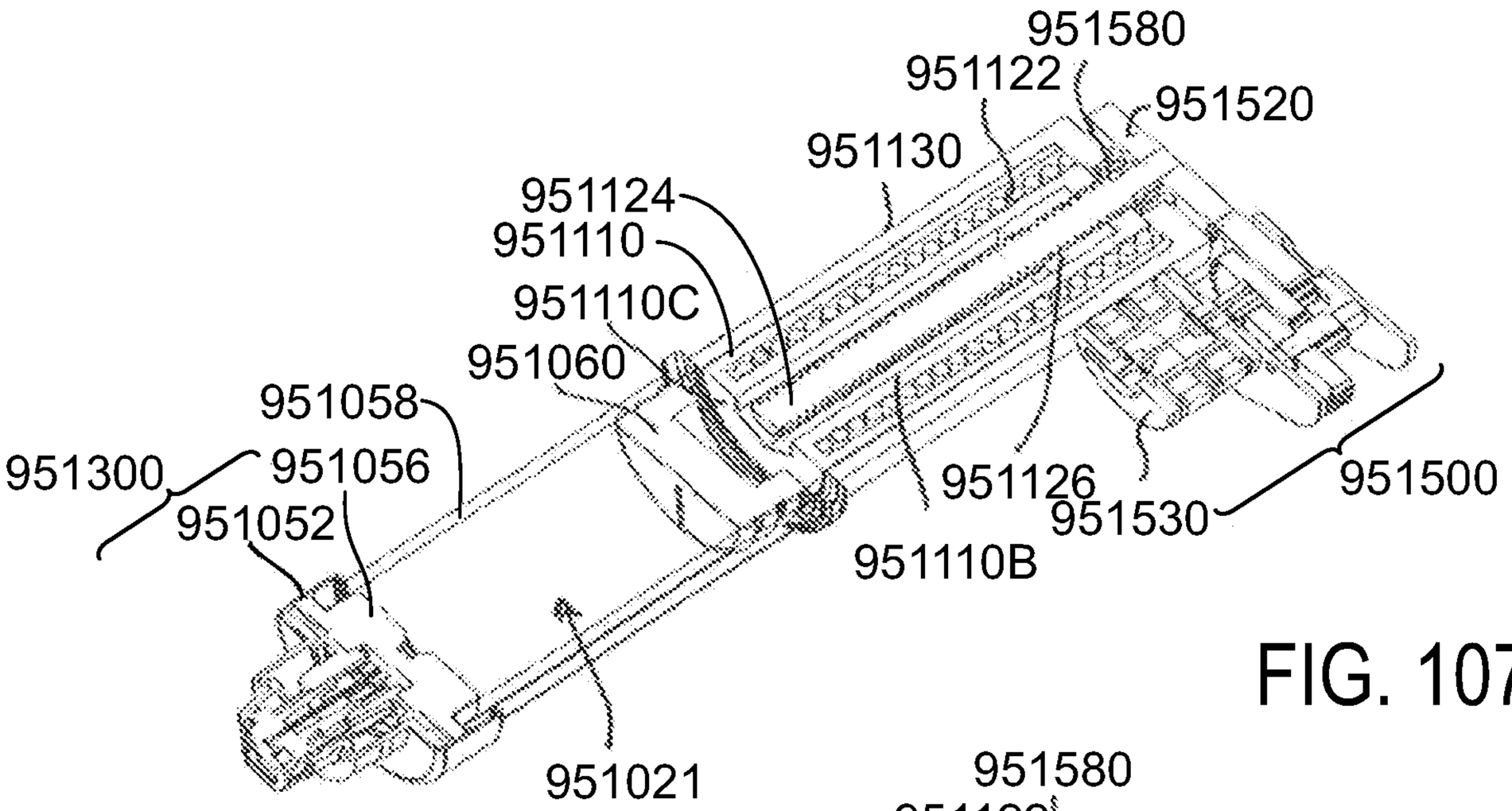


FIG. 107A

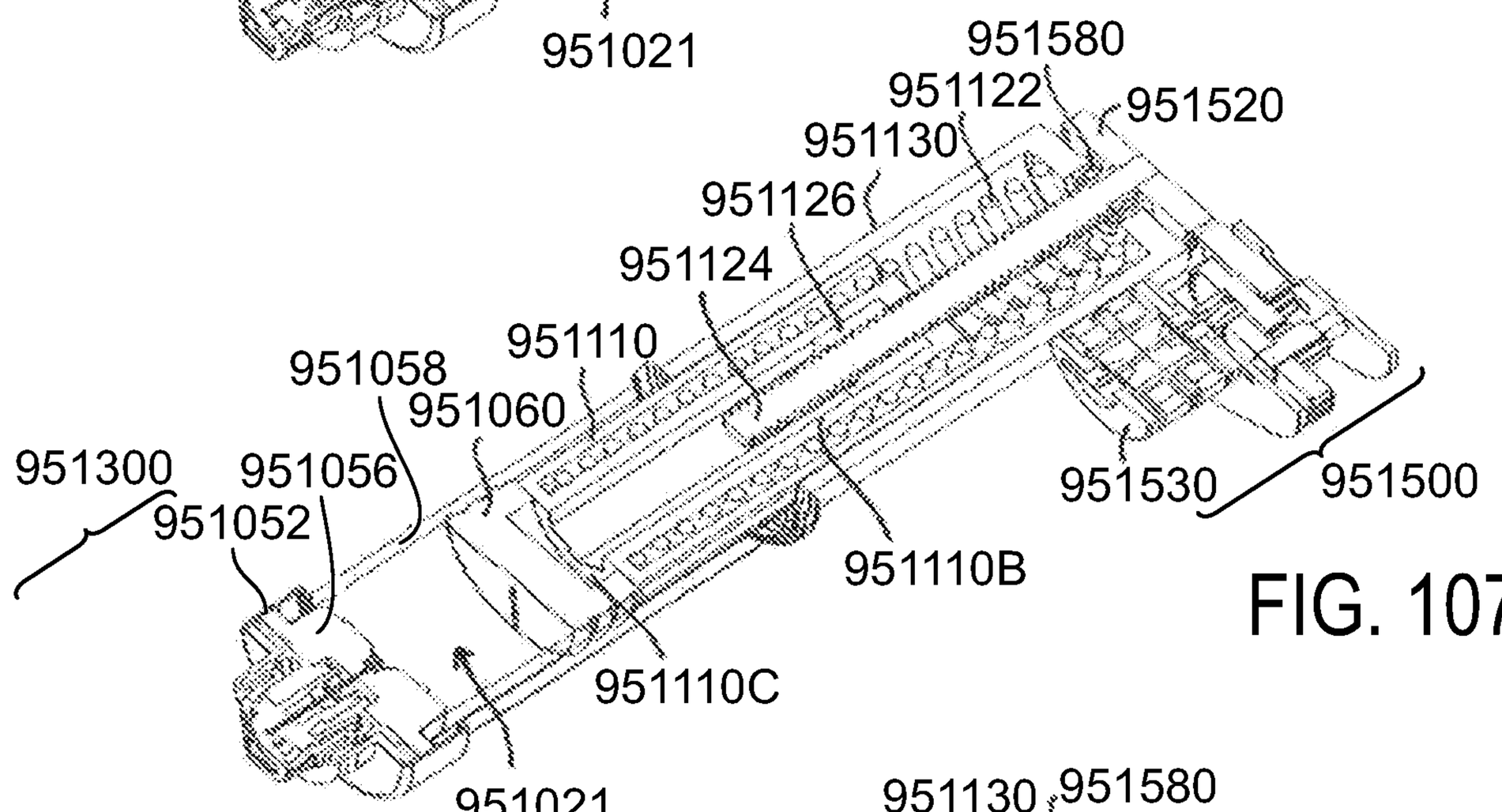


FIG. 107B

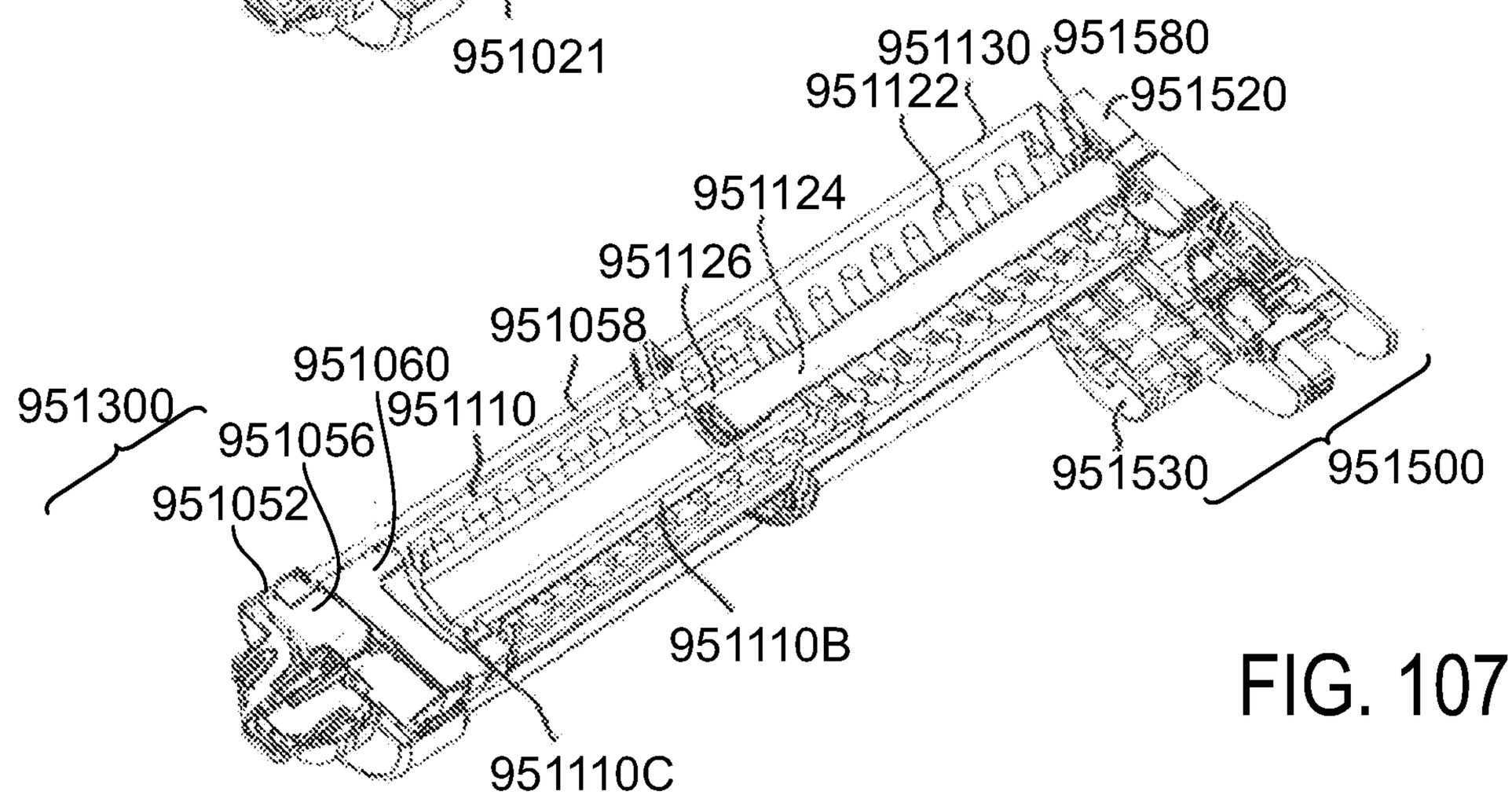


FIG. 107C

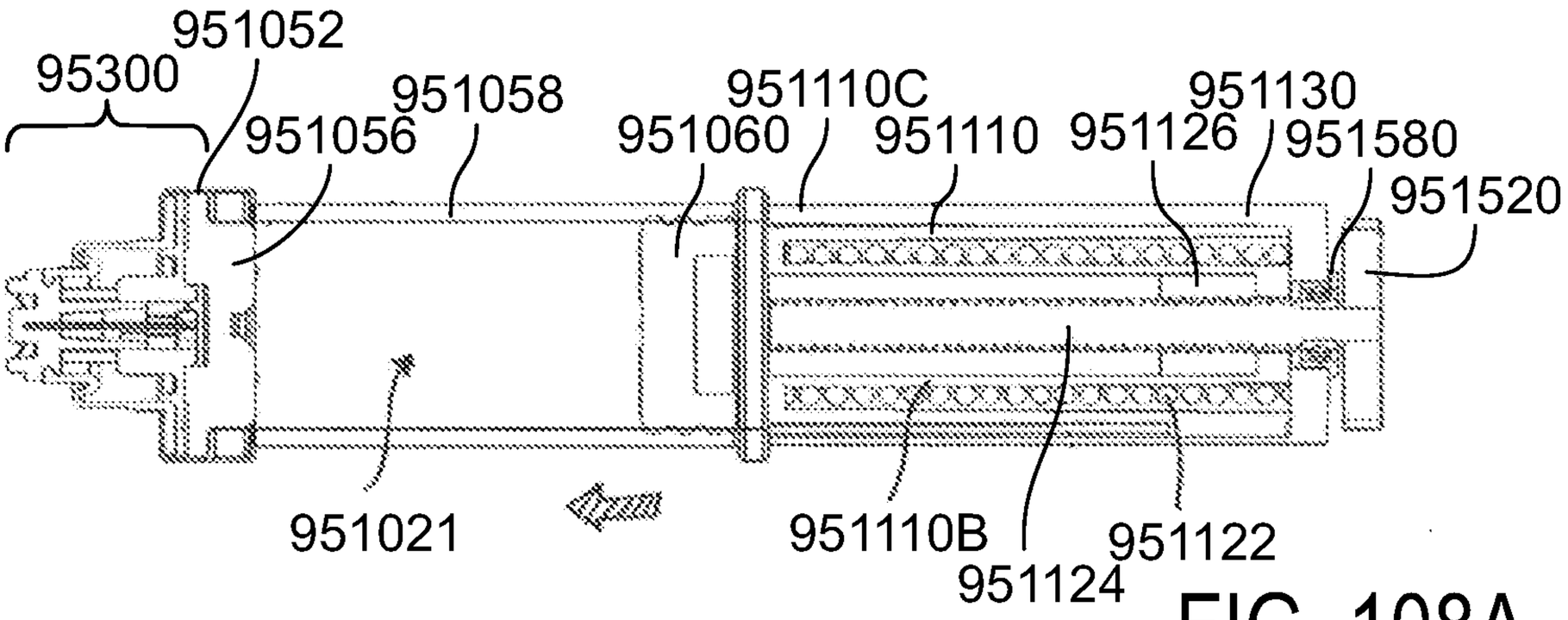


FIG. 108A

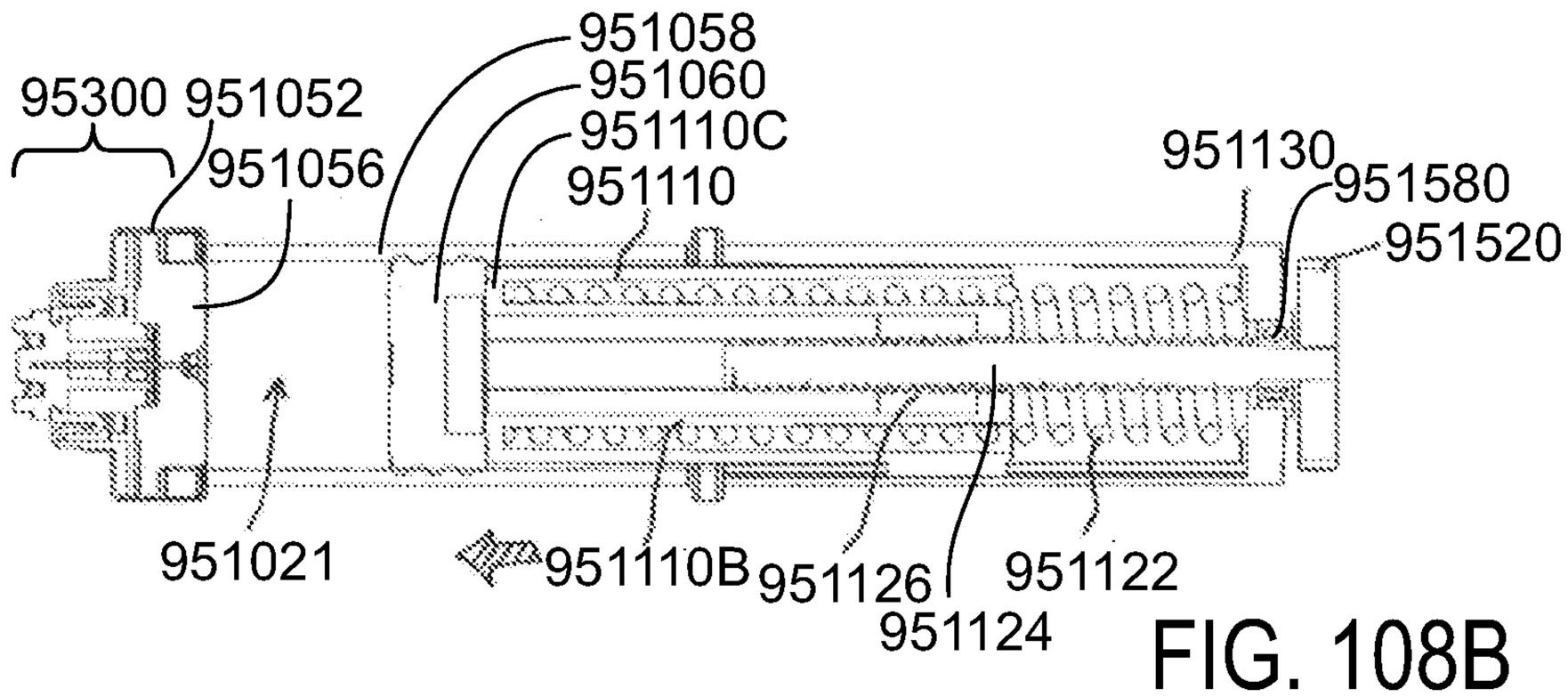


FIG. 108B

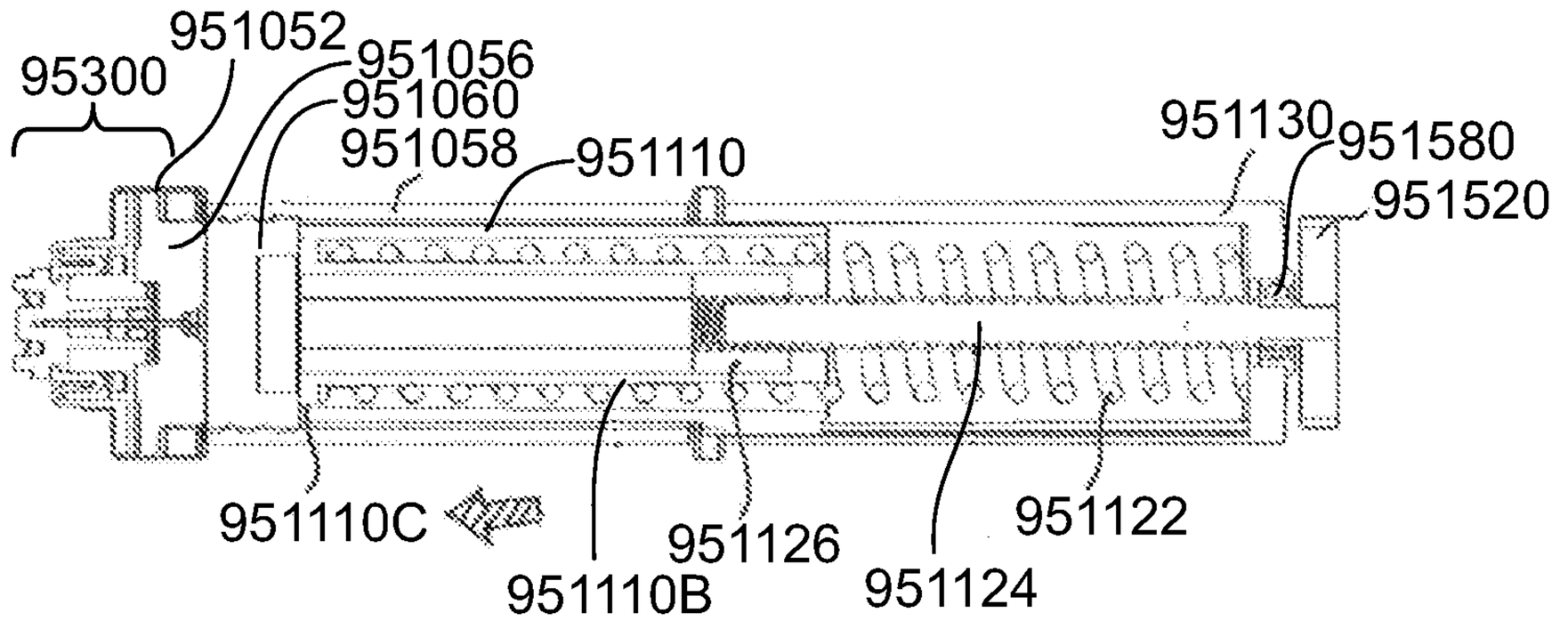


FIG. 108C

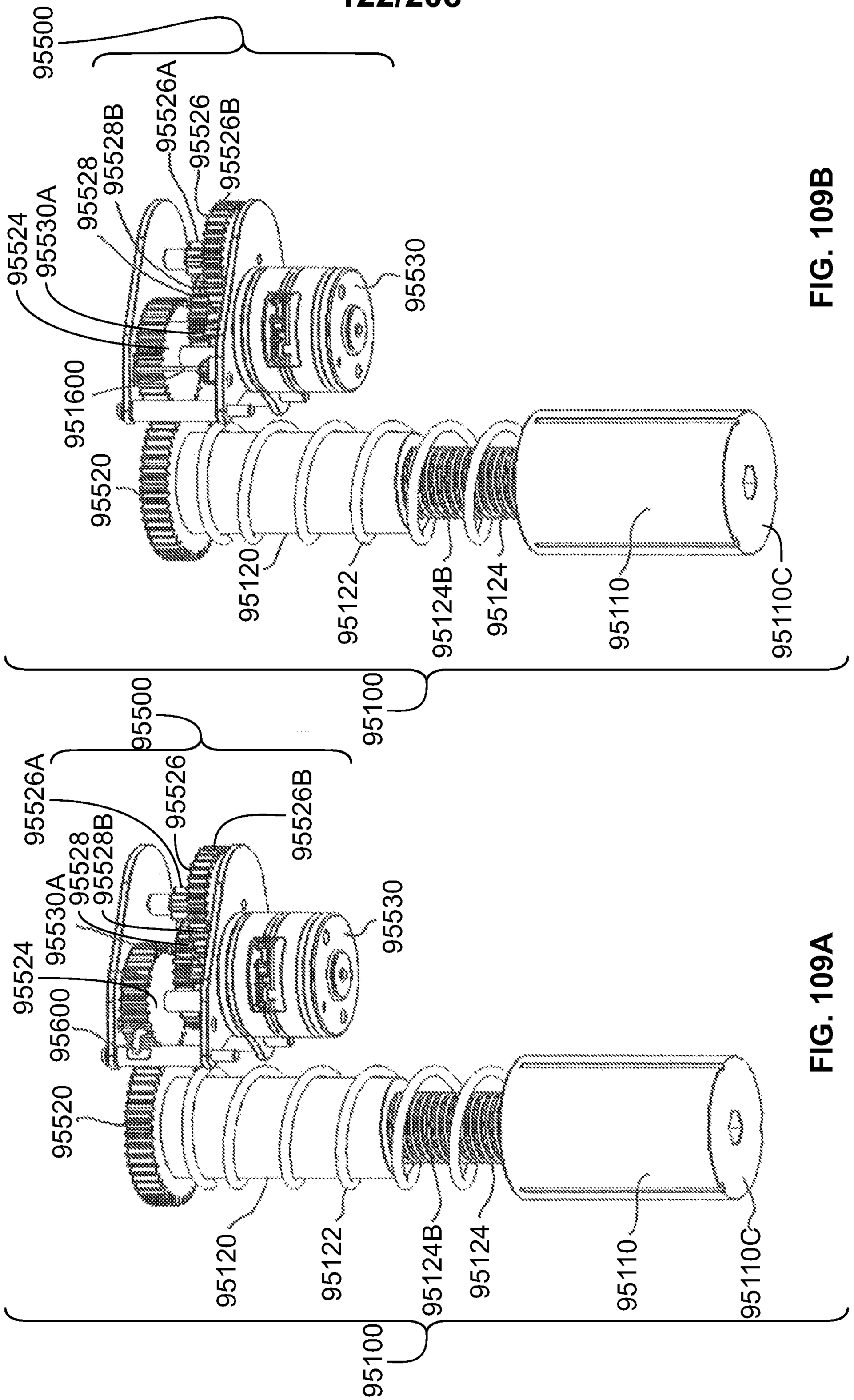


FIG. 109B

FIG. 109A

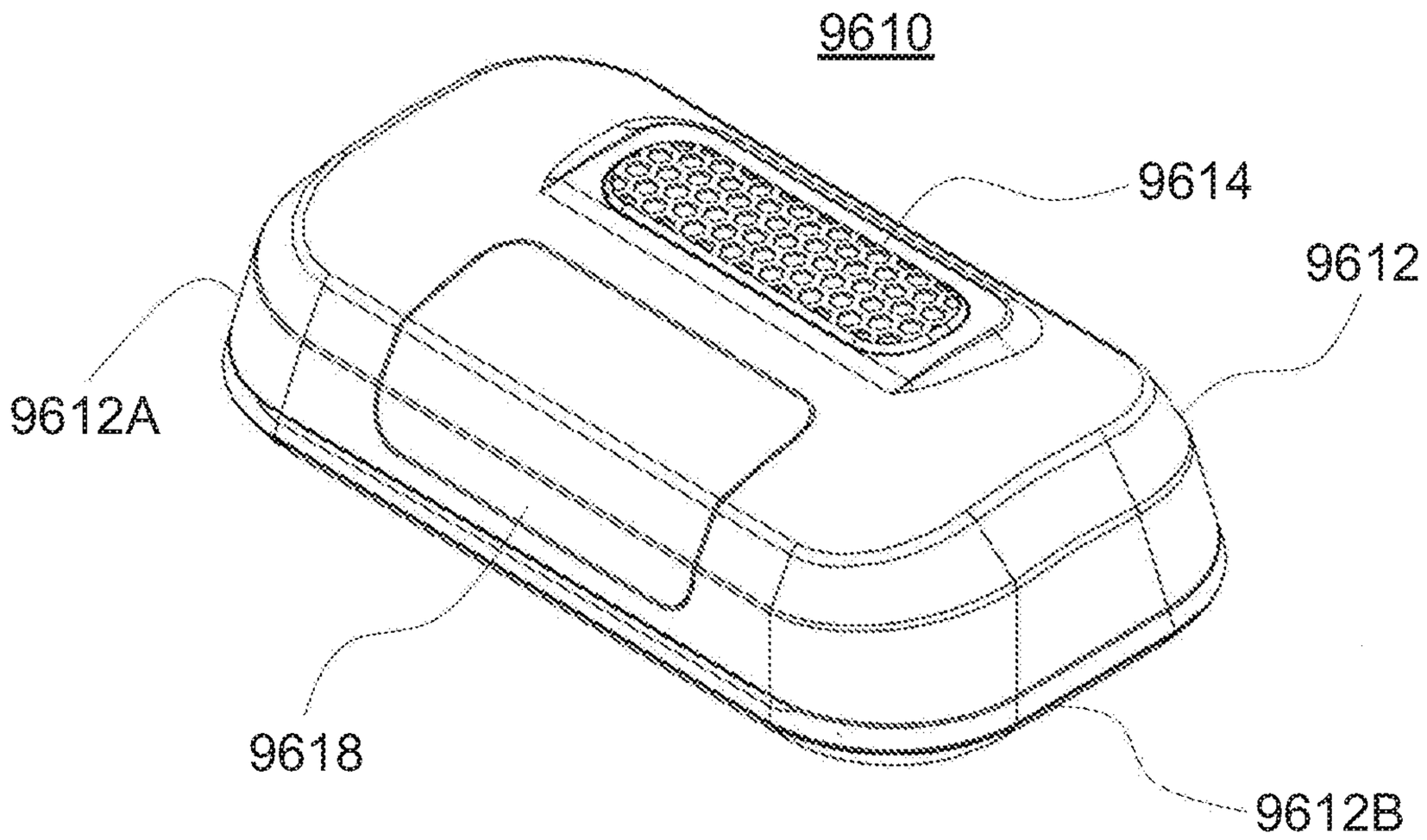


FIG. 110A

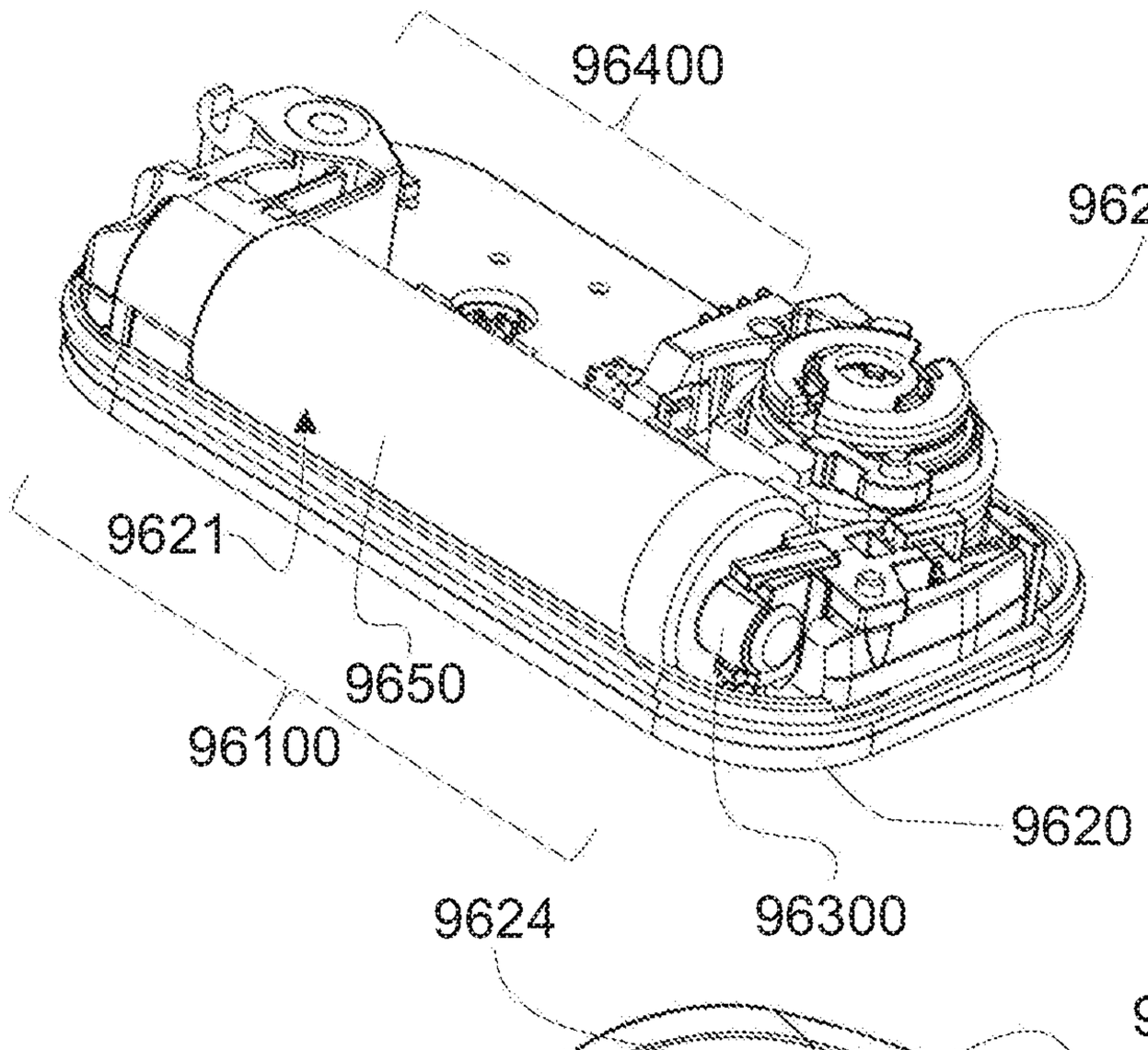


FIG. 110B

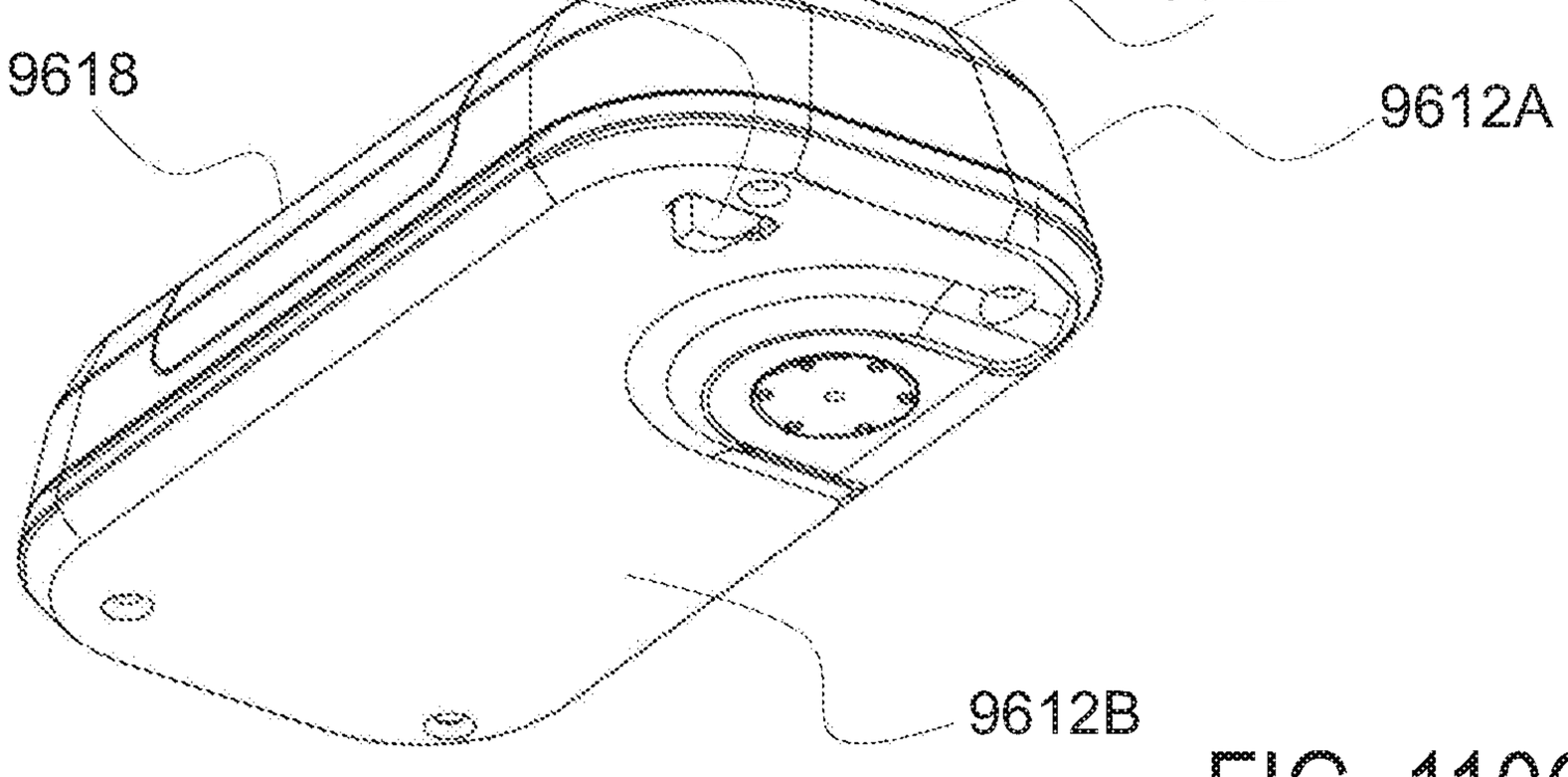


FIG. 110C

9610

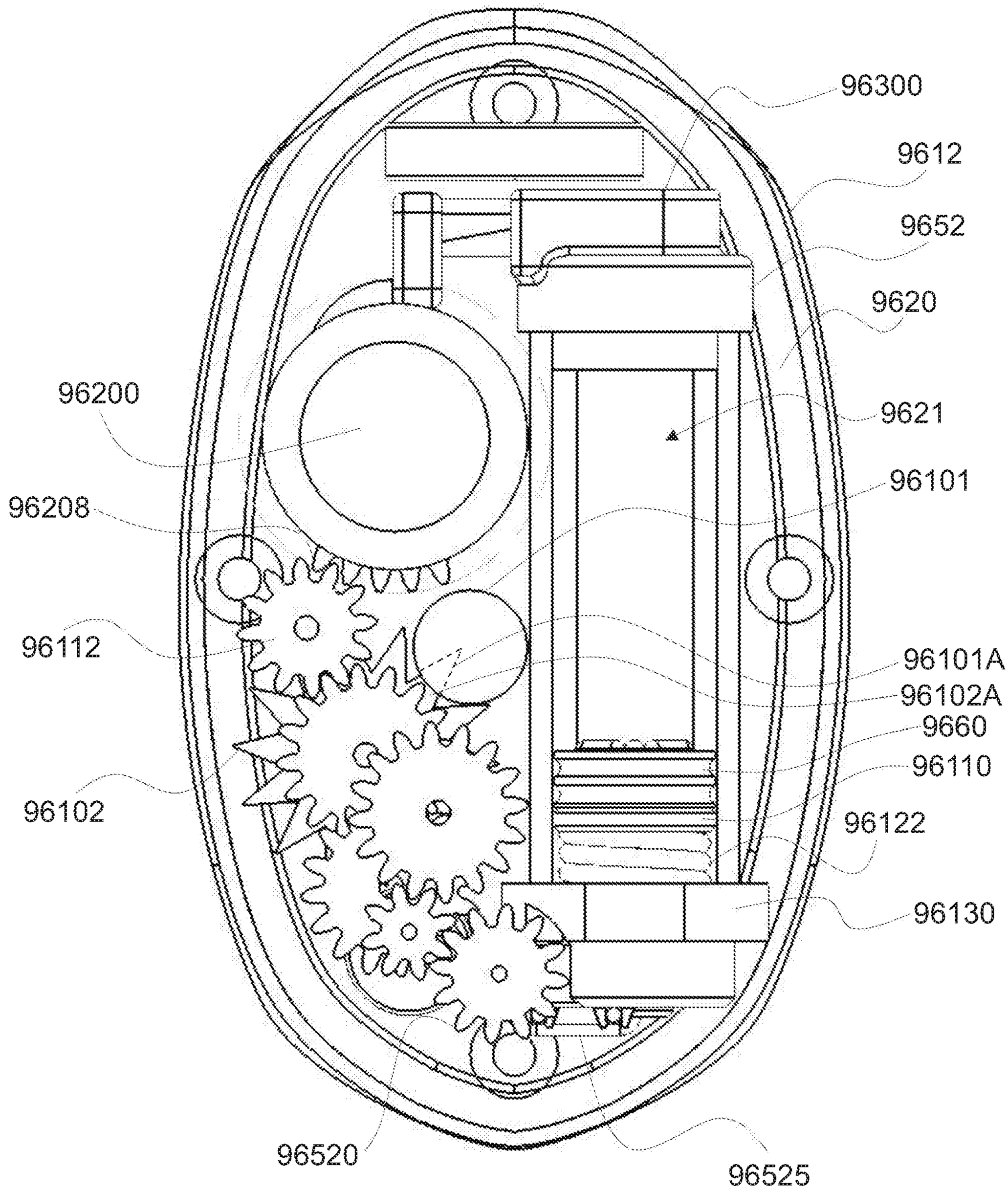


FIG. 111A

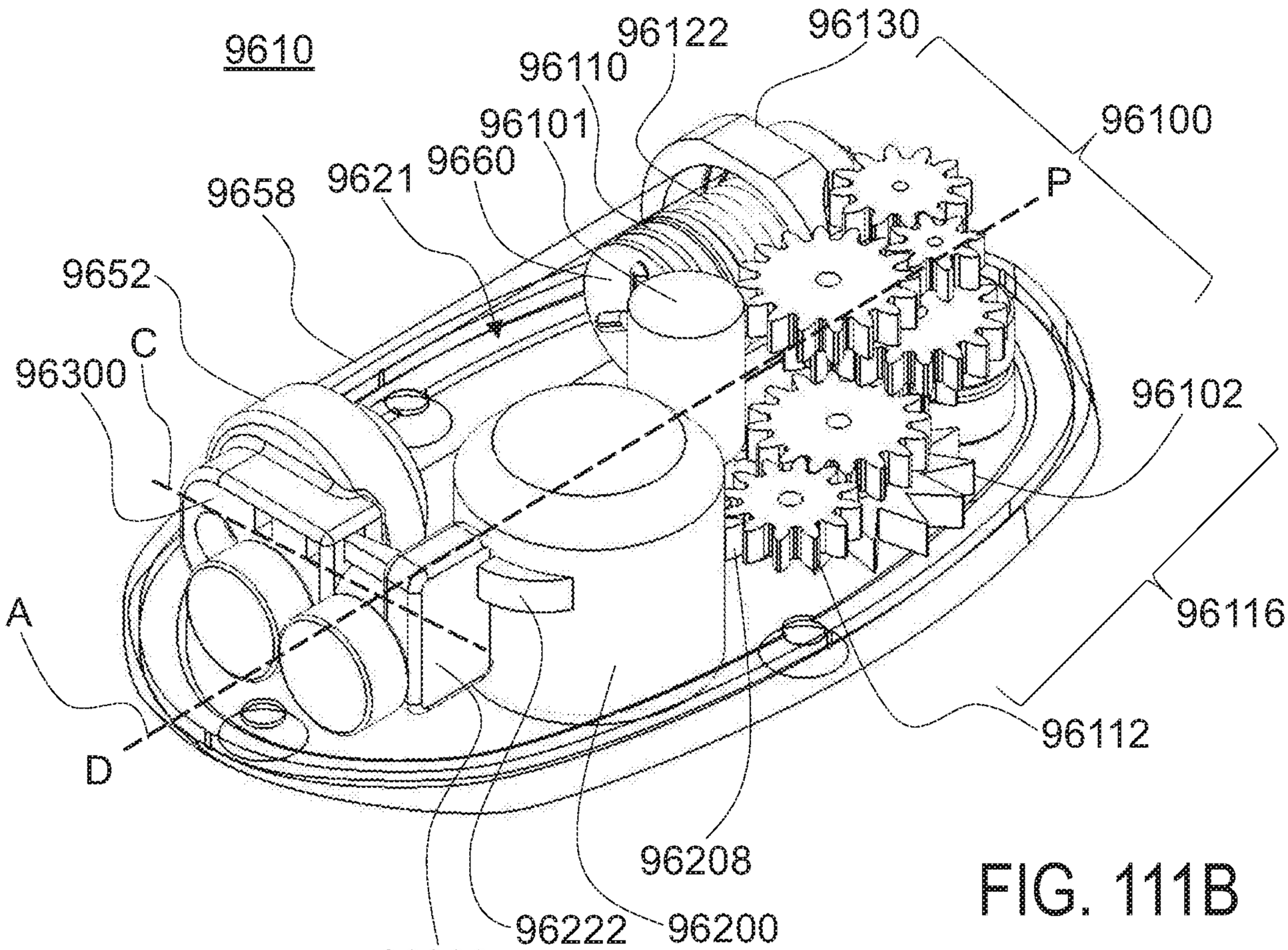


FIG. 111B

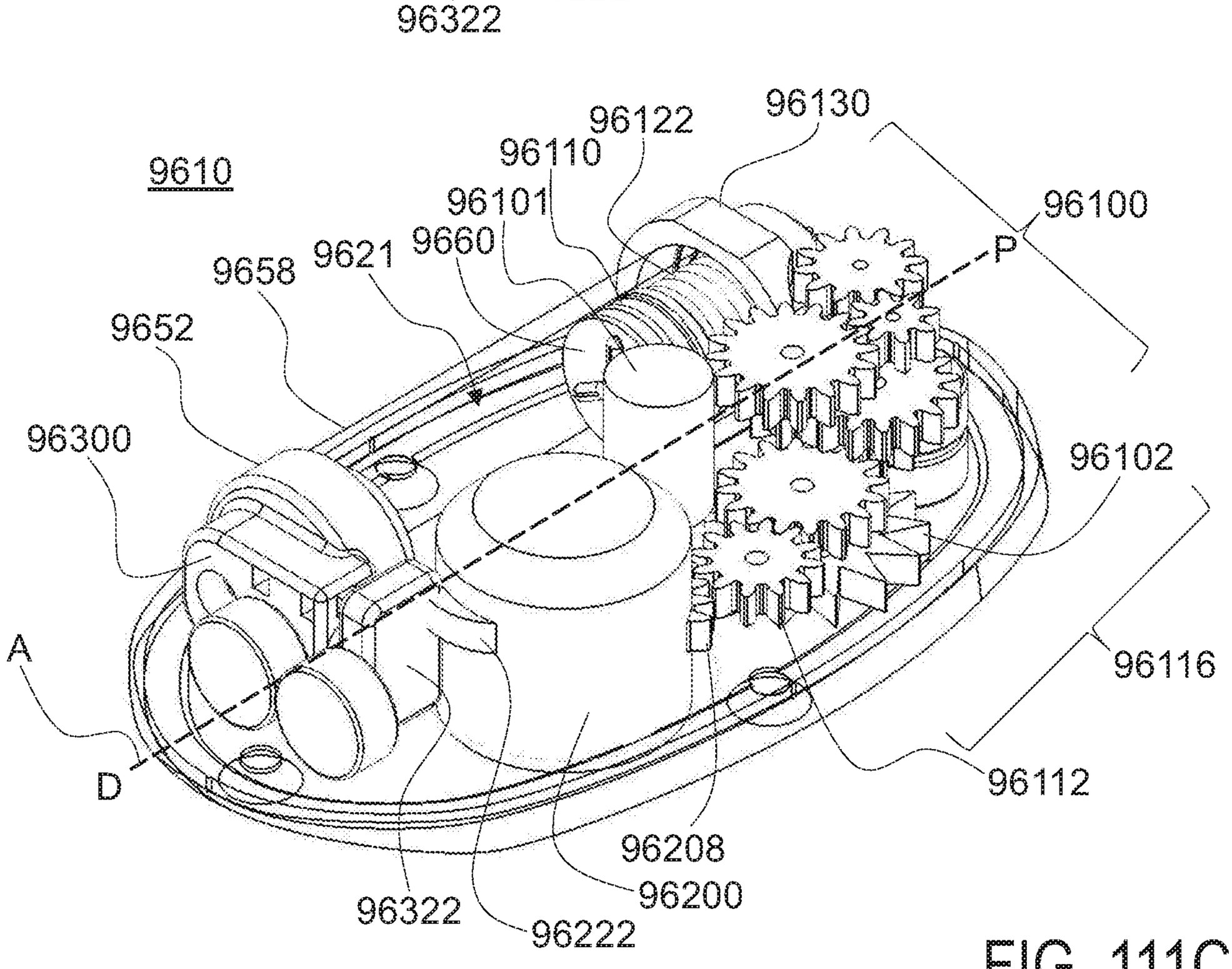


FIG. 111C

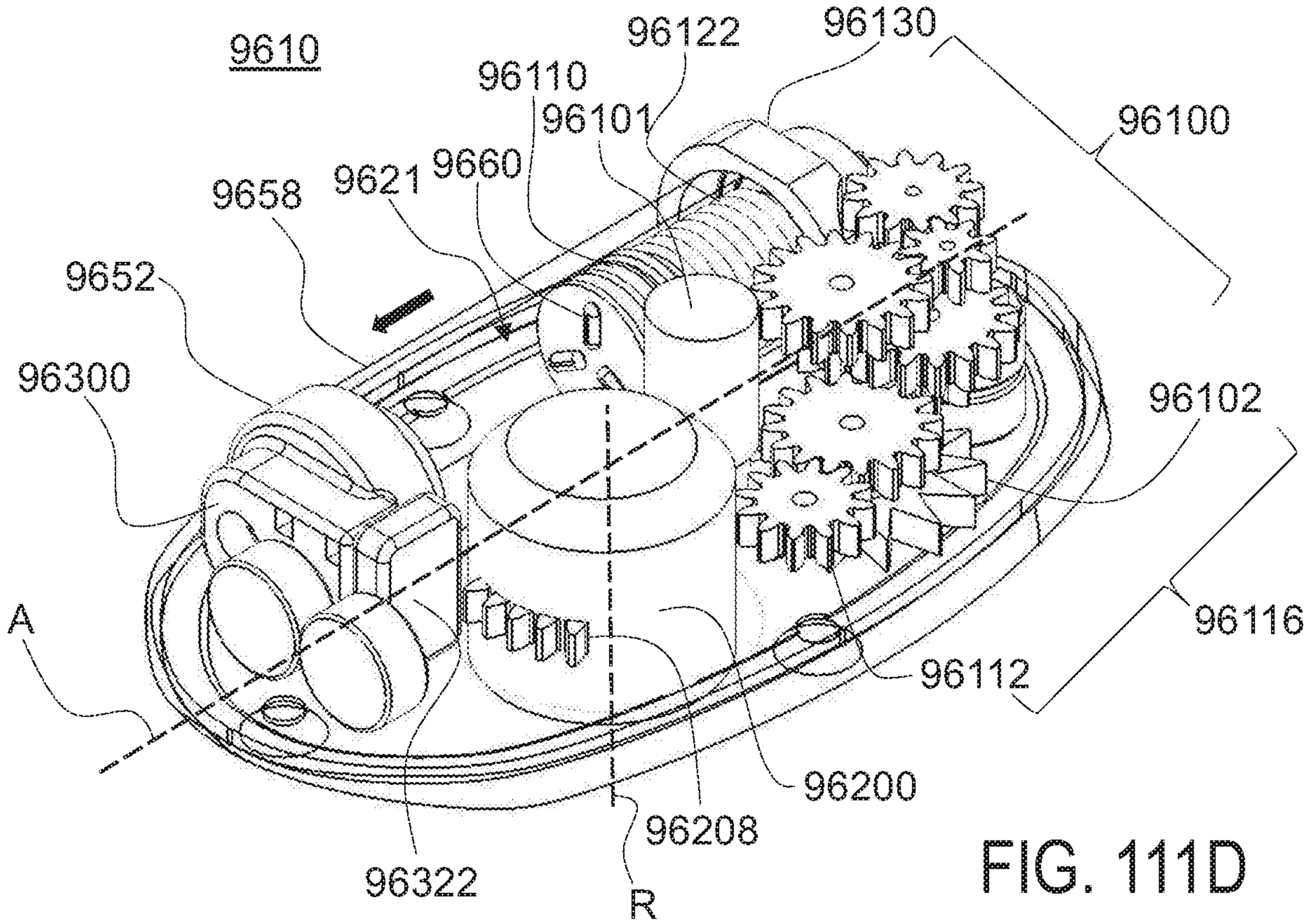


FIG. 111D

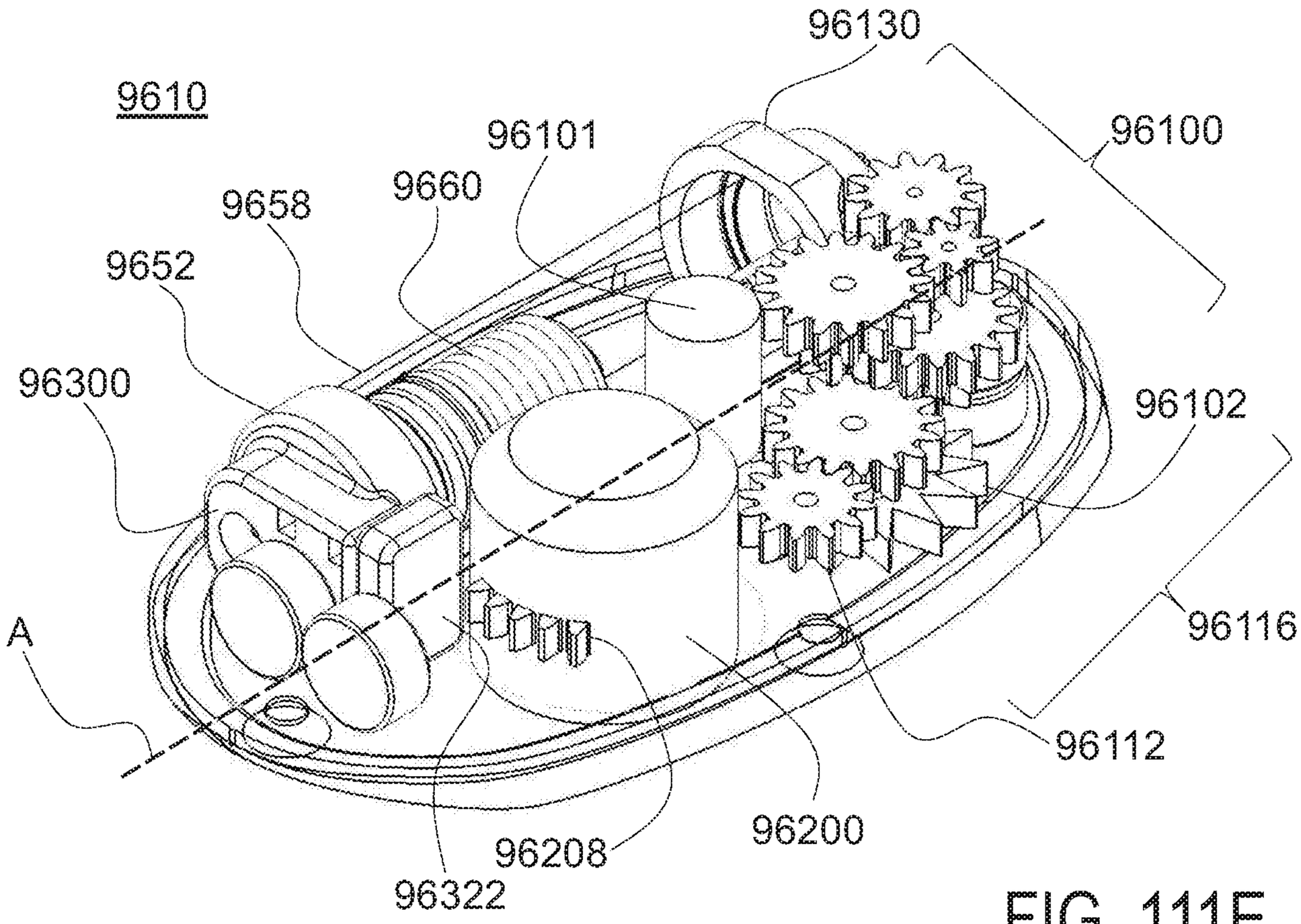


FIG. 111E

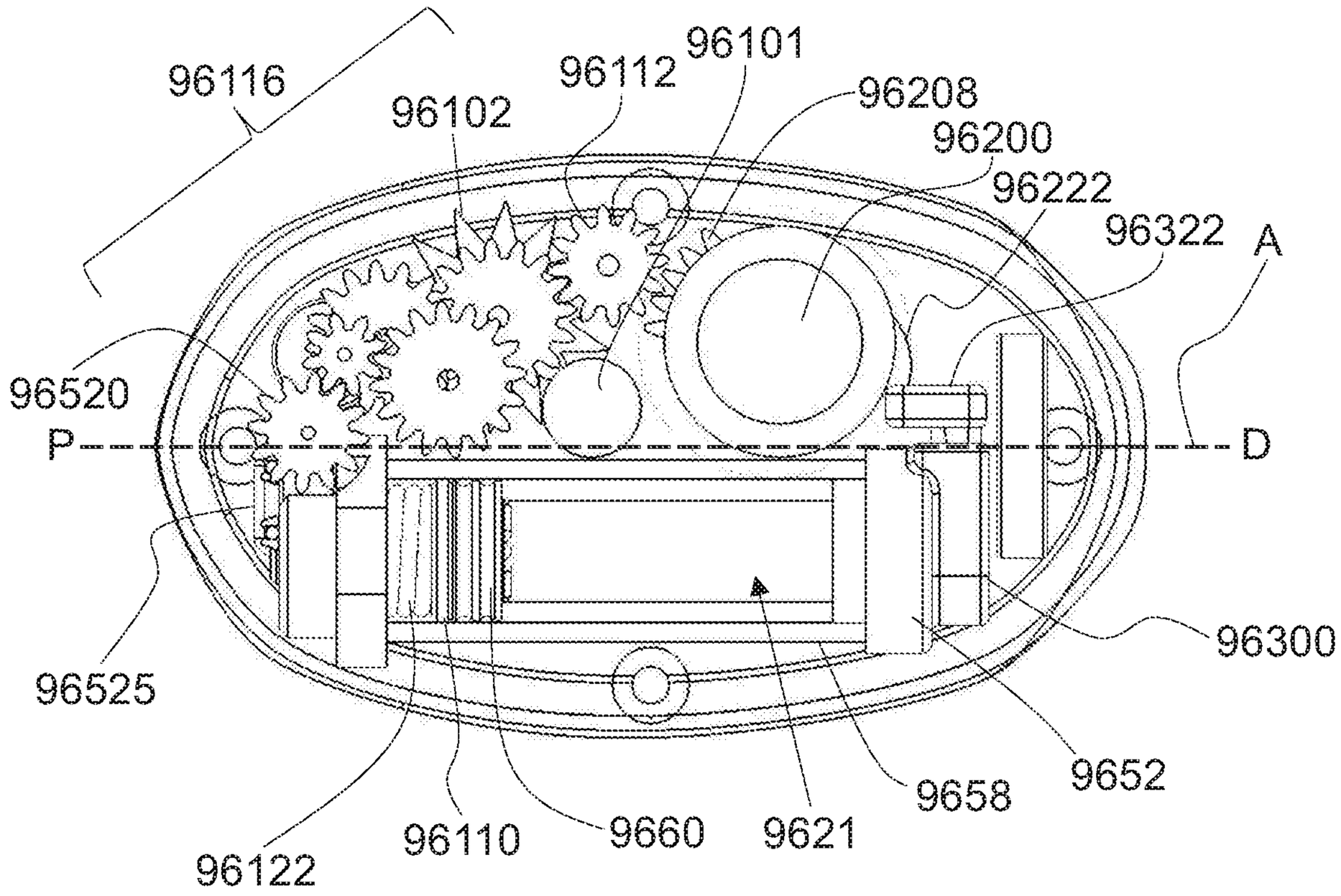


FIG. 112A

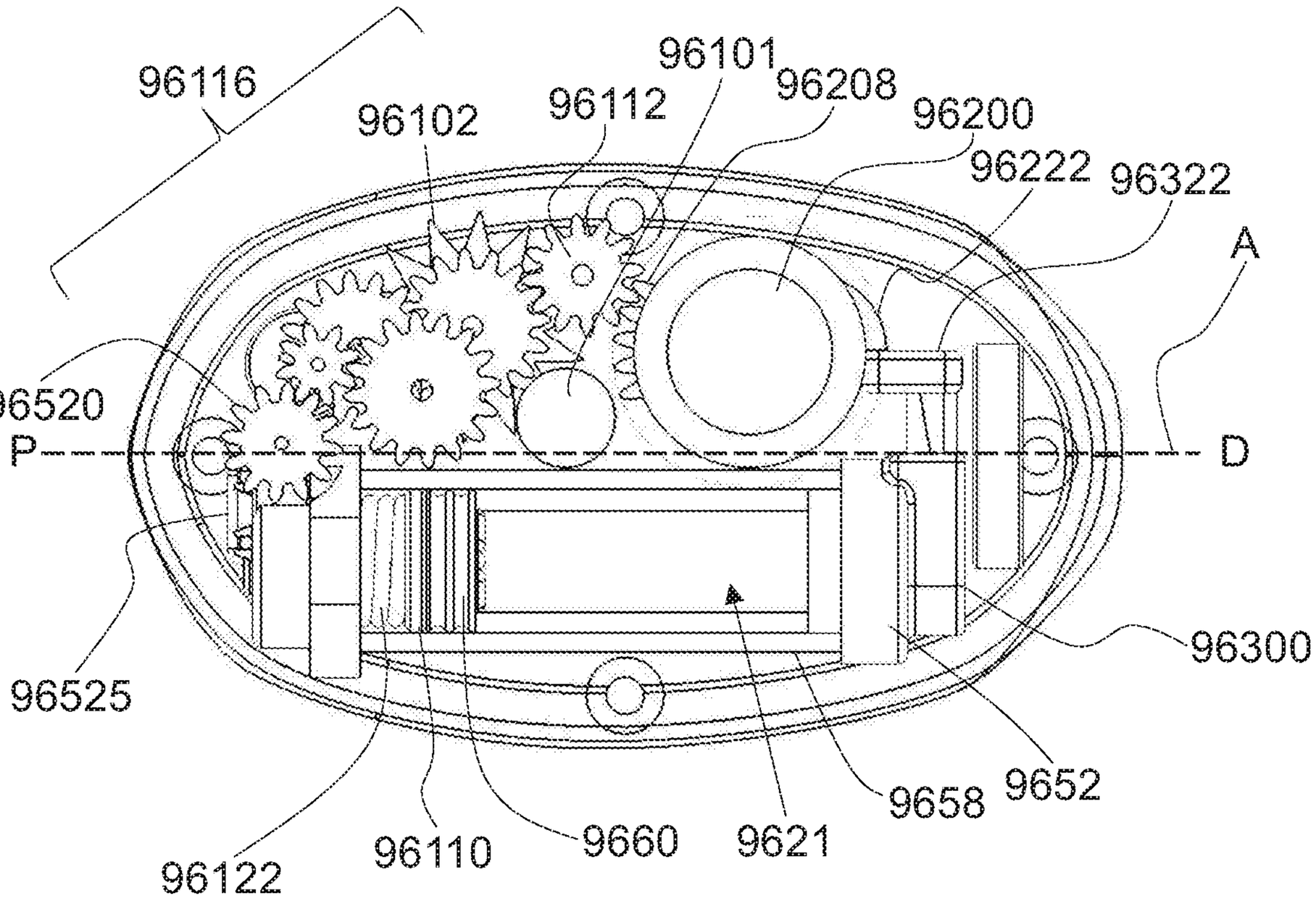


FIG. 112B

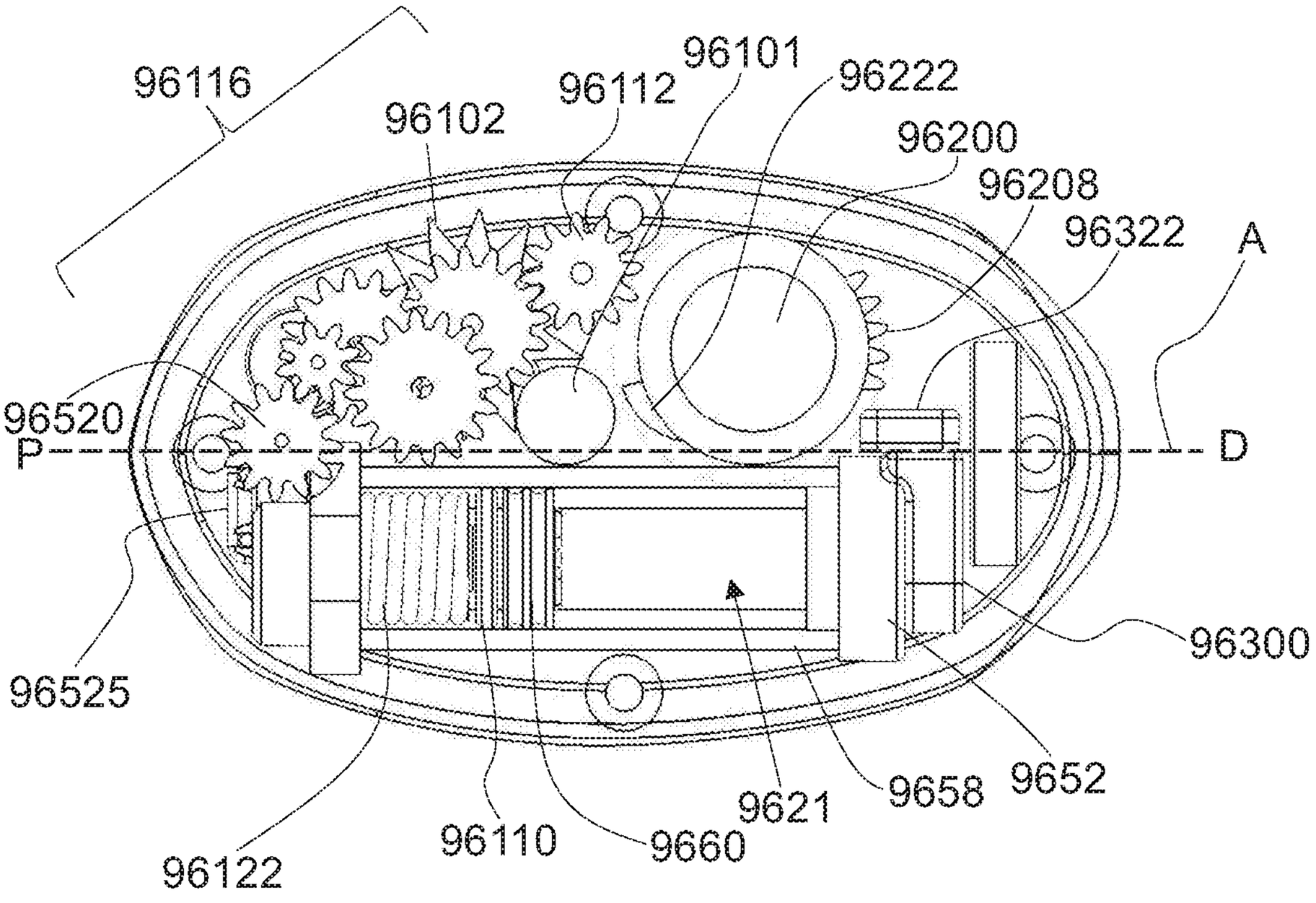


FIG. 112C

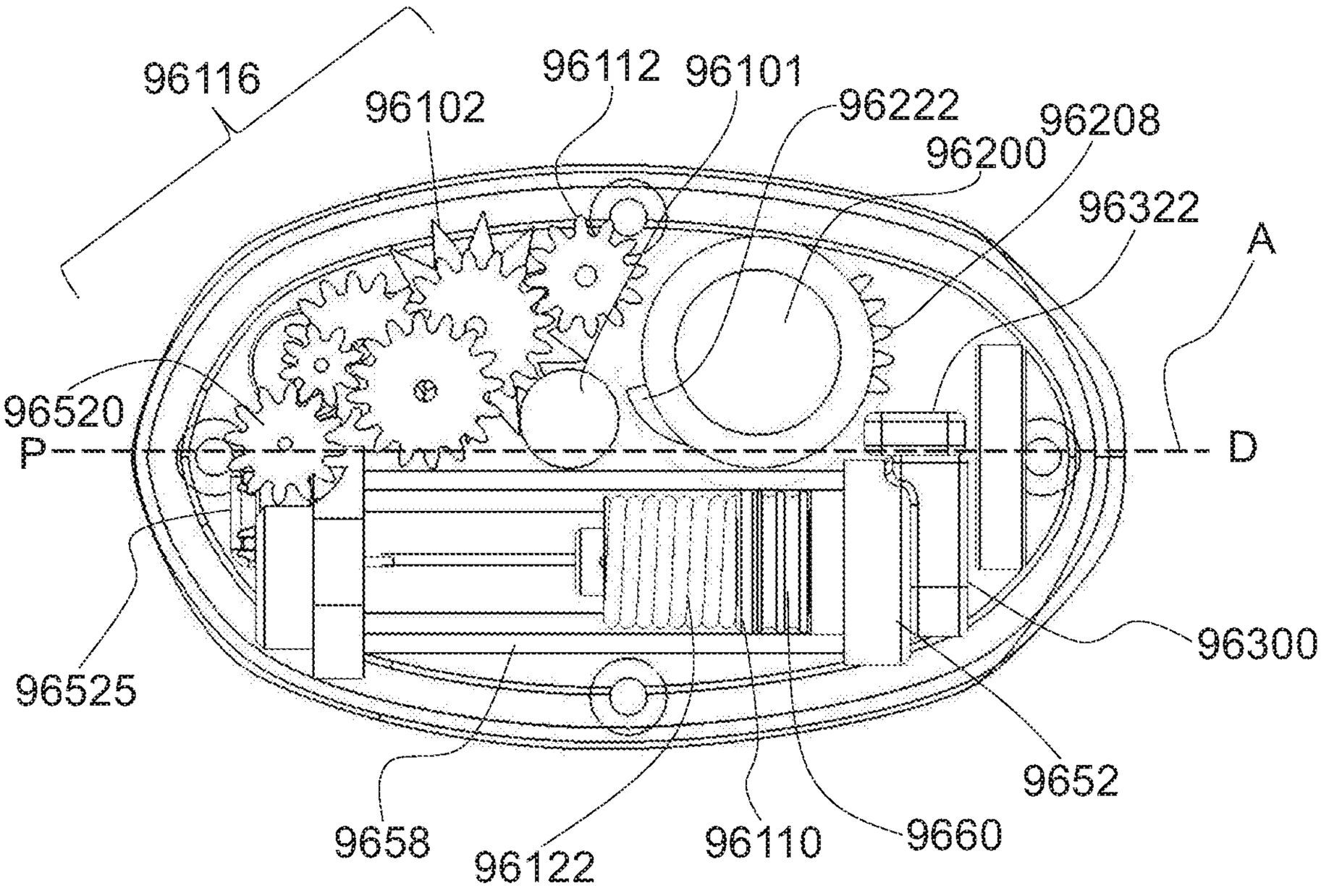


FIG. 112D

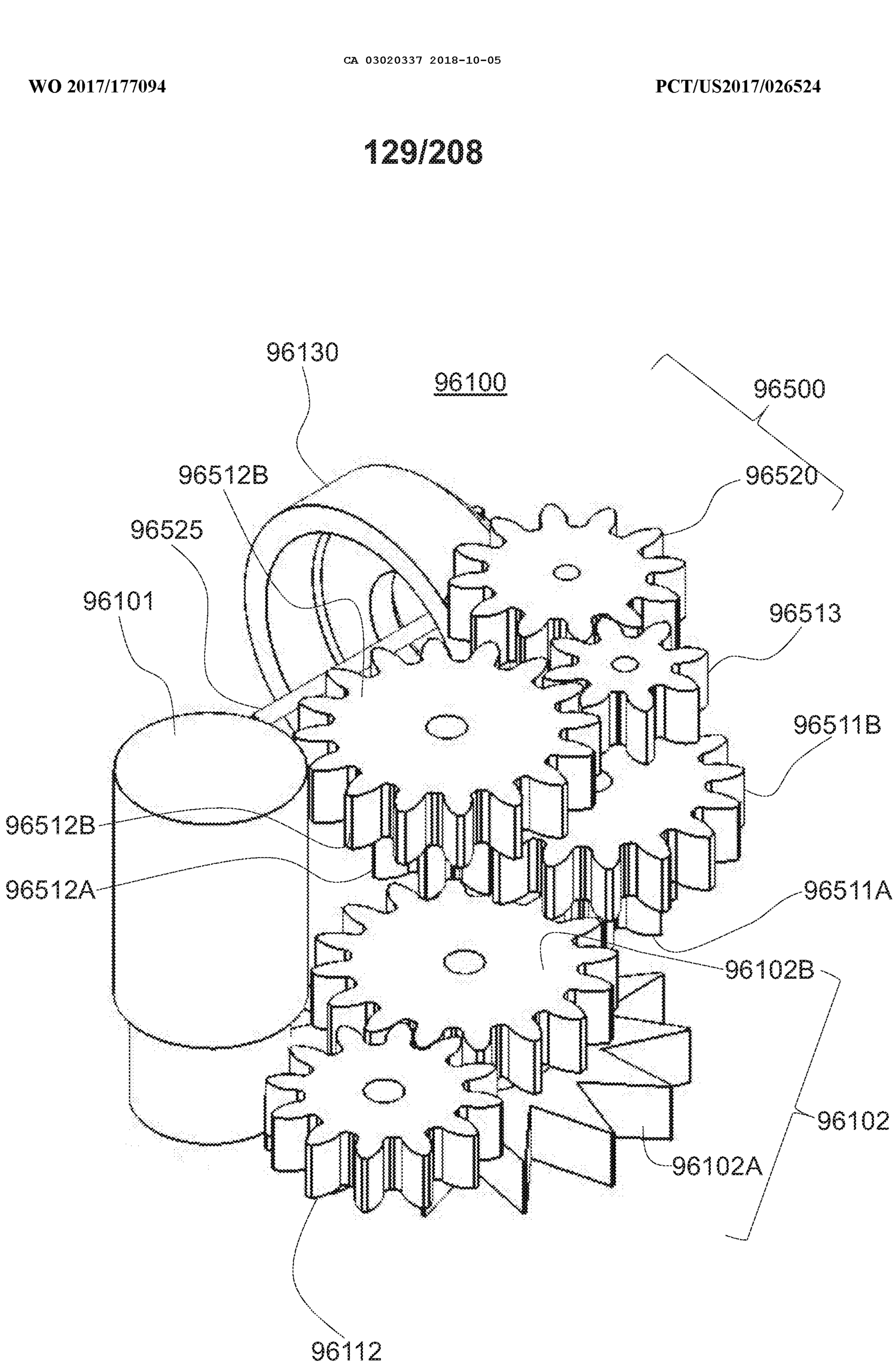

96130
96100
96500
96512B
96520
96525
96101
96513
96511B
96512B
96512A
96511A
96102B
96102
96102A
96112

FIG. 113

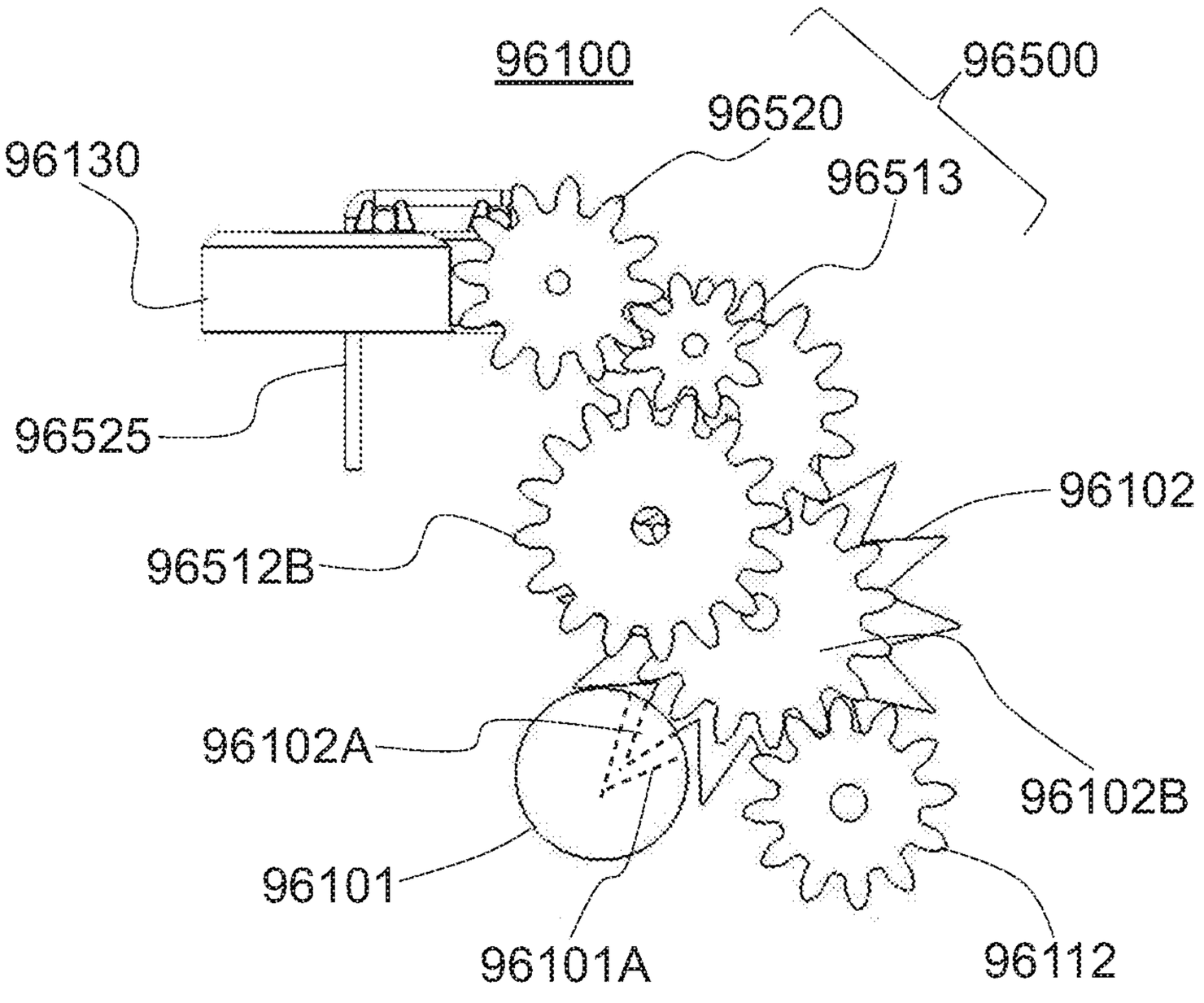


FIG. 114A

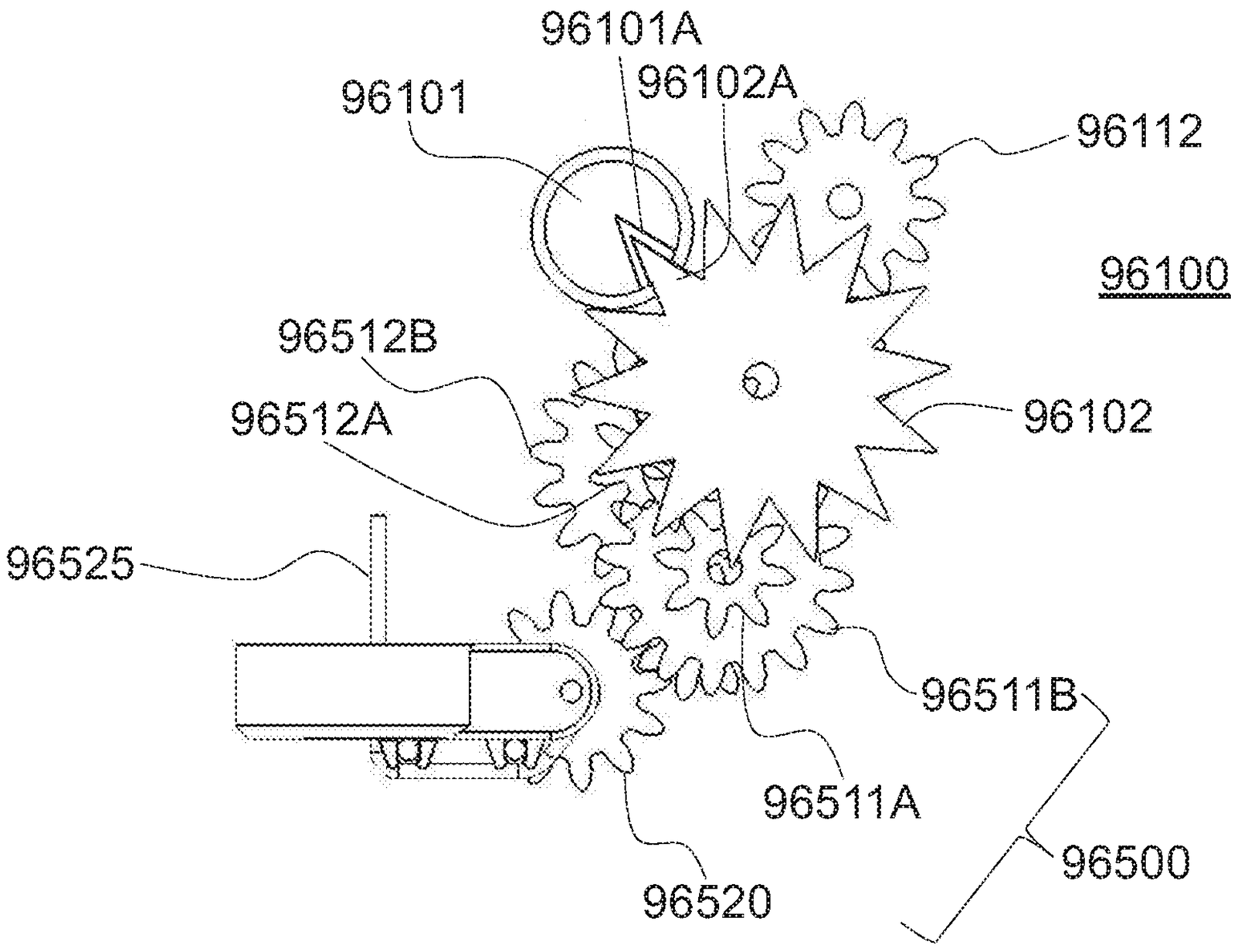


FIG. 114B

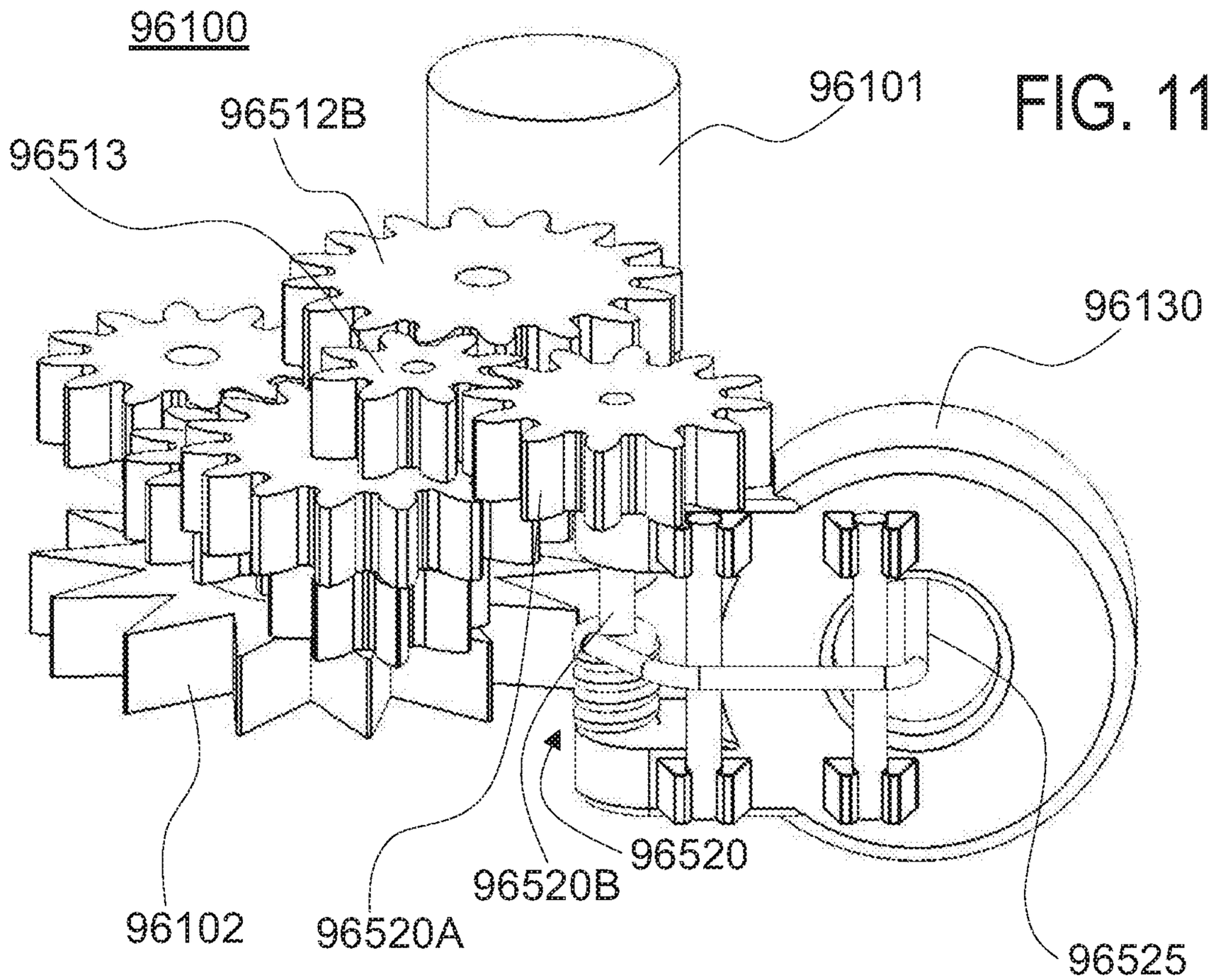


FIG. 114C

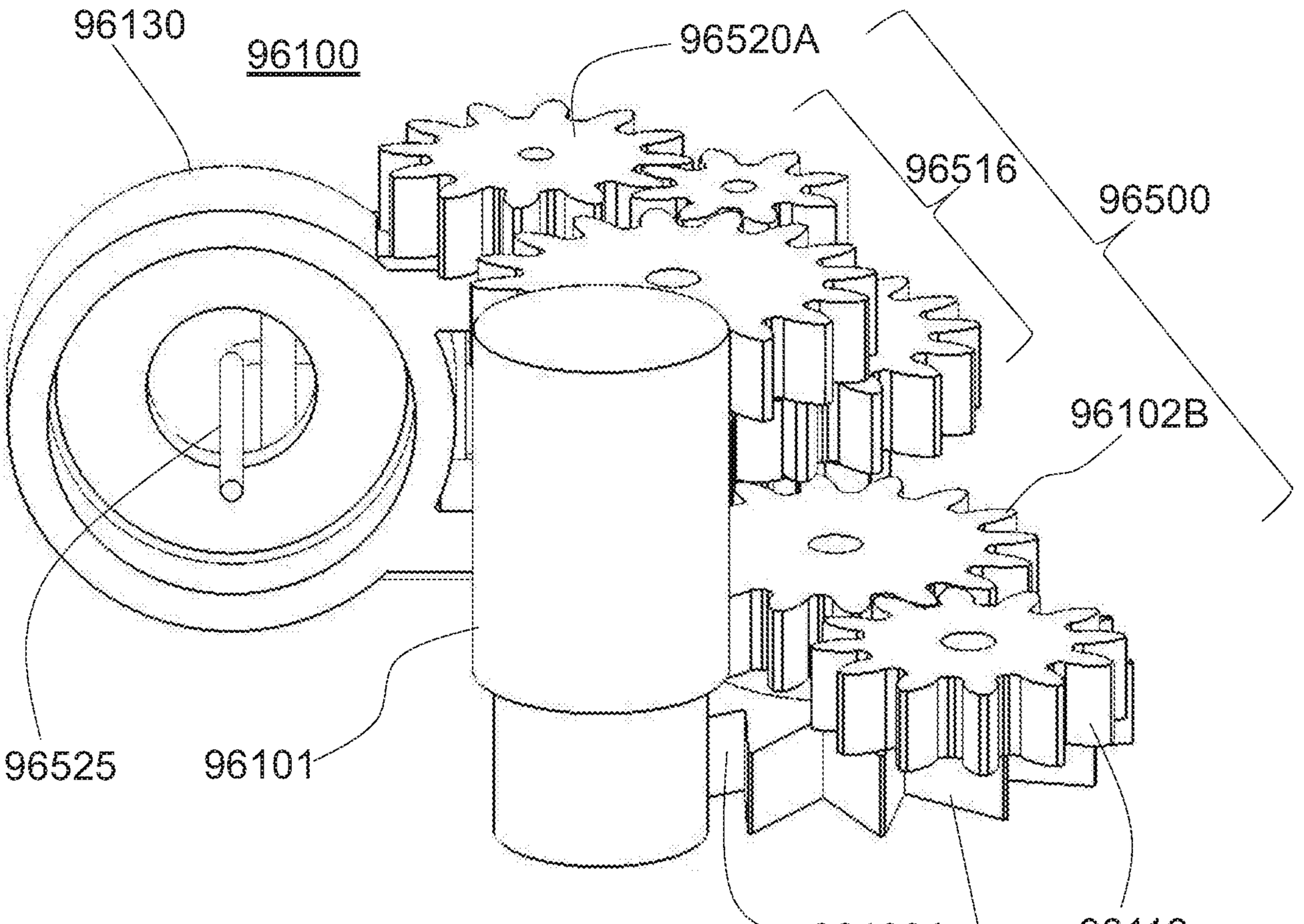


FIG. 114D

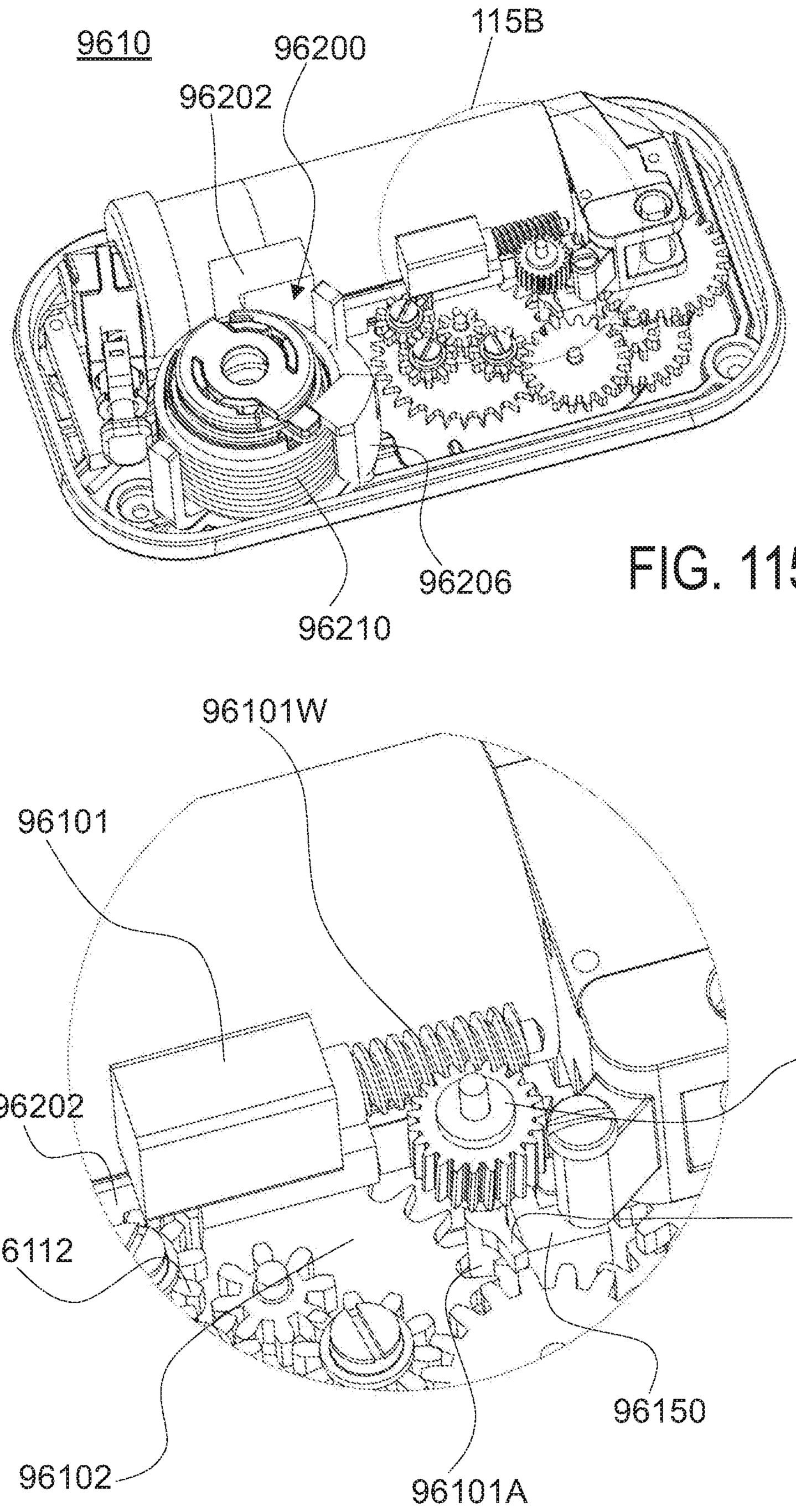


FIG. 115A

FIG. 115B

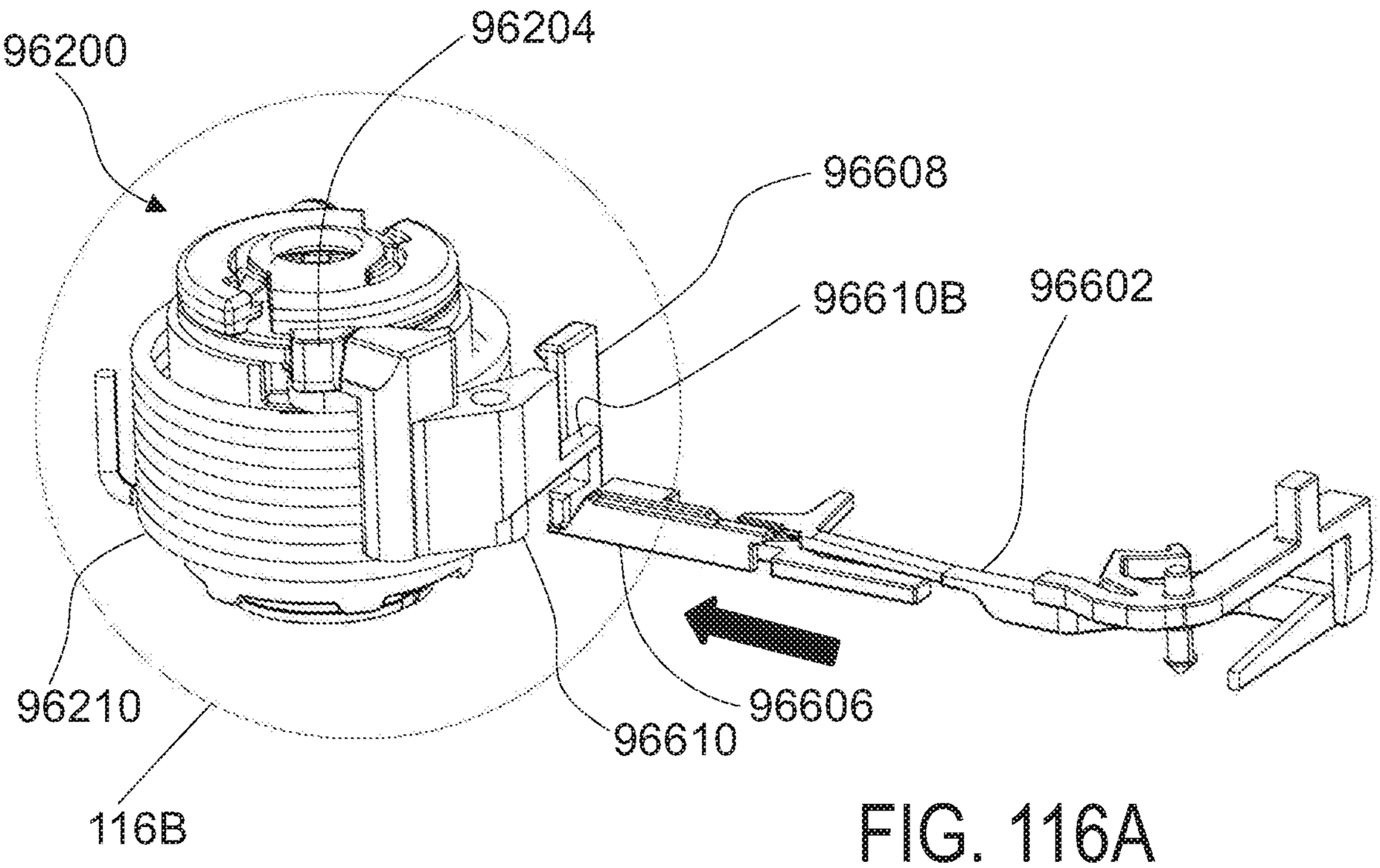


FIG. 116A

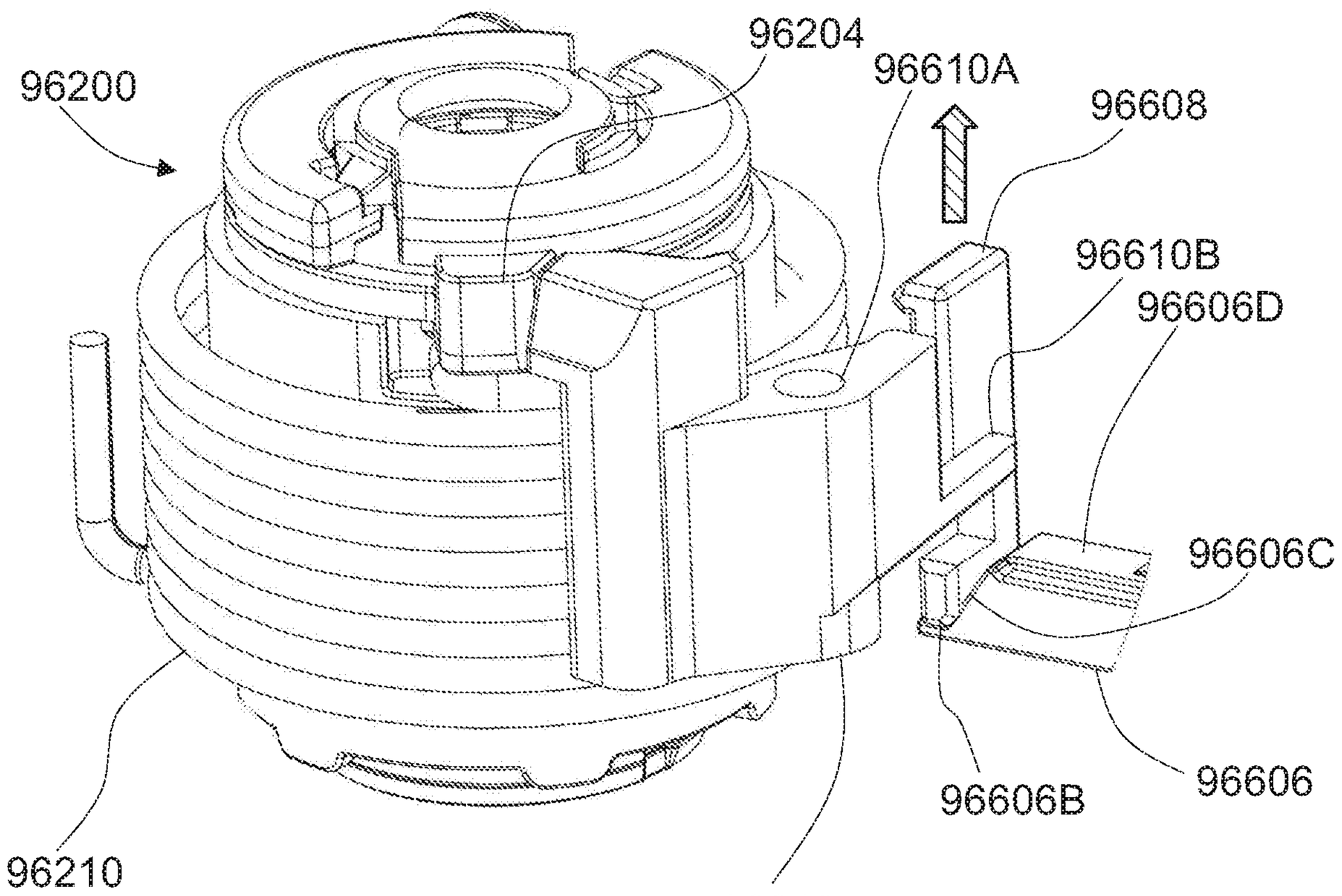


FIG. 116B

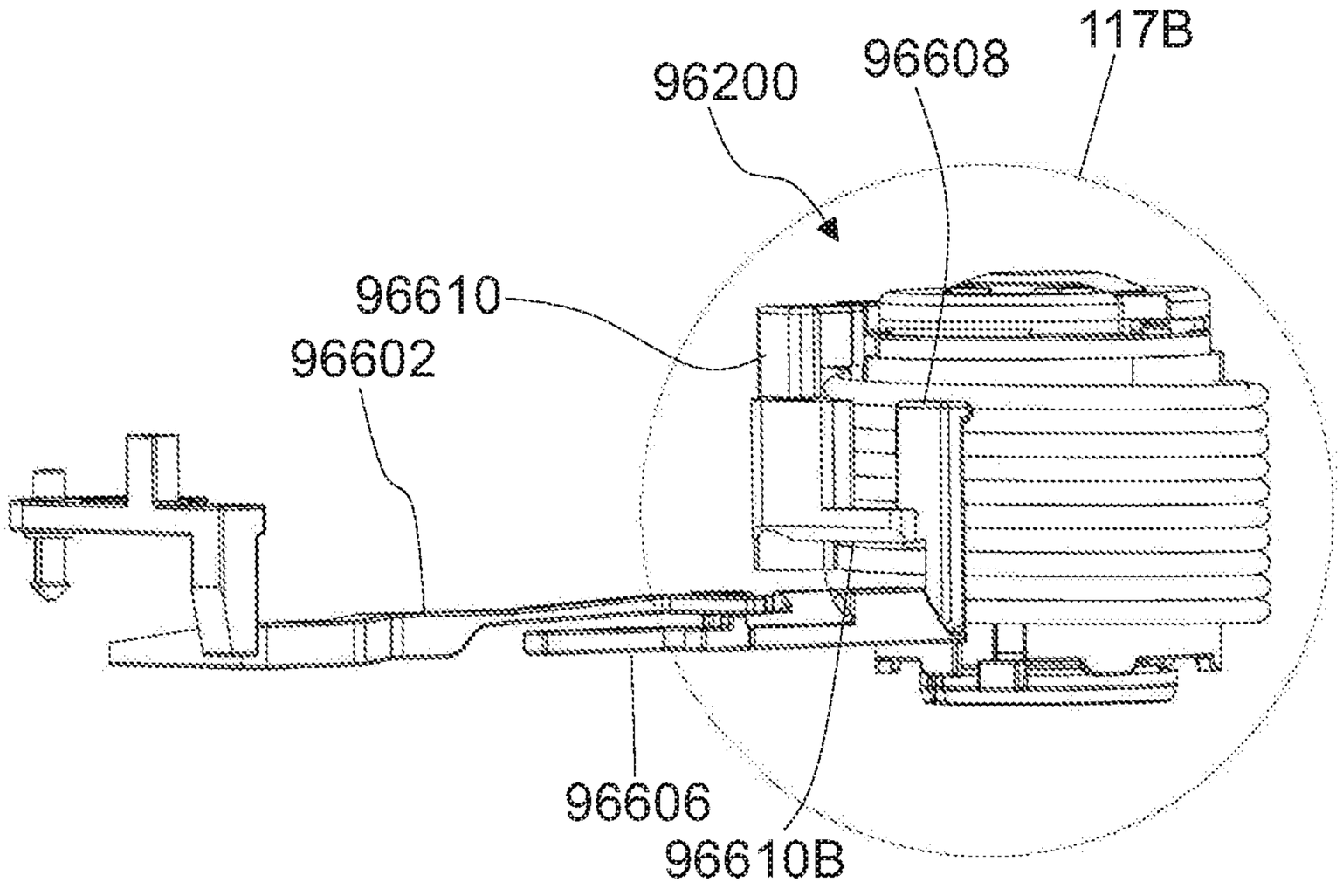


FIG. 117A

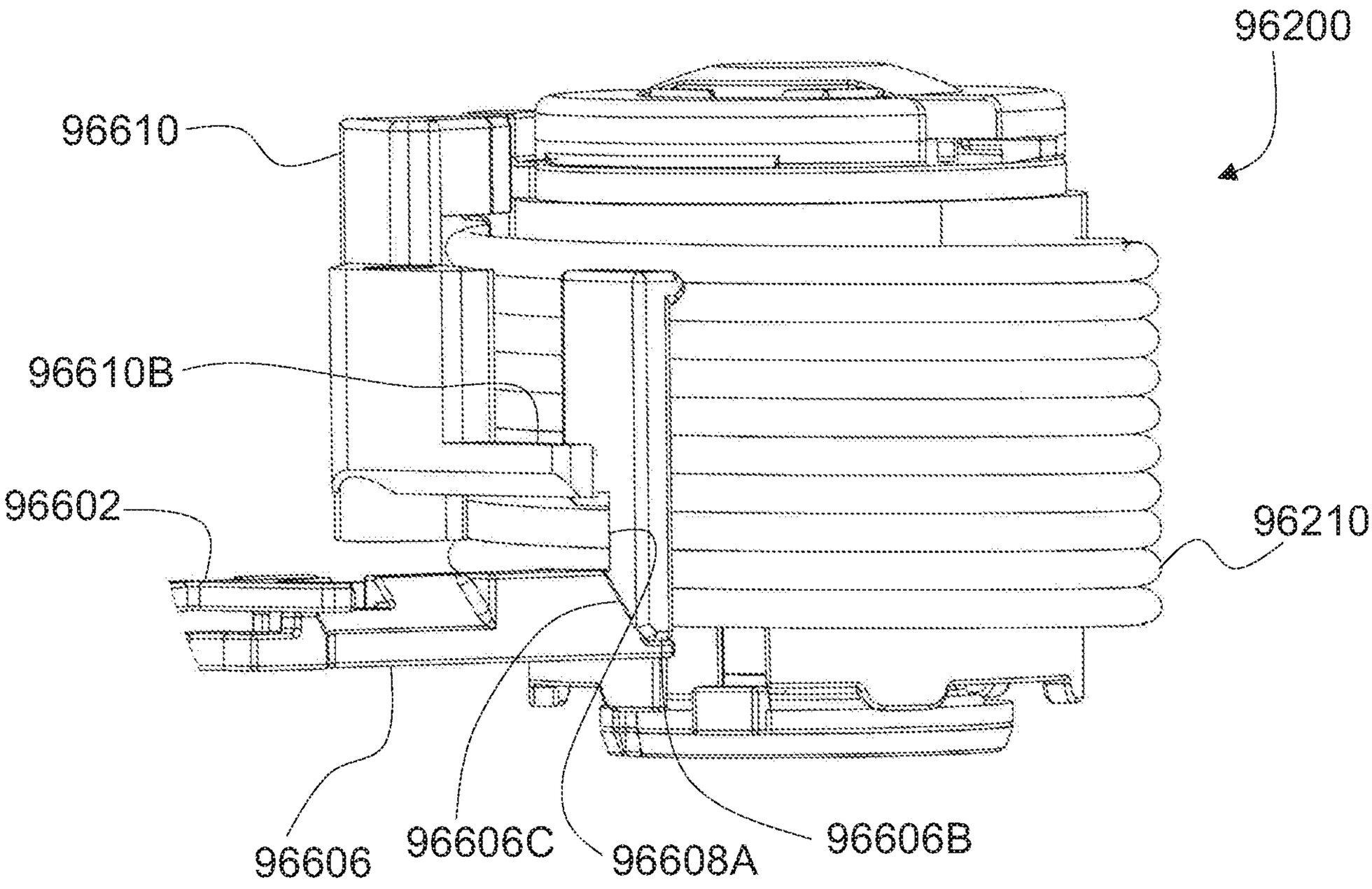


FIG. 117B

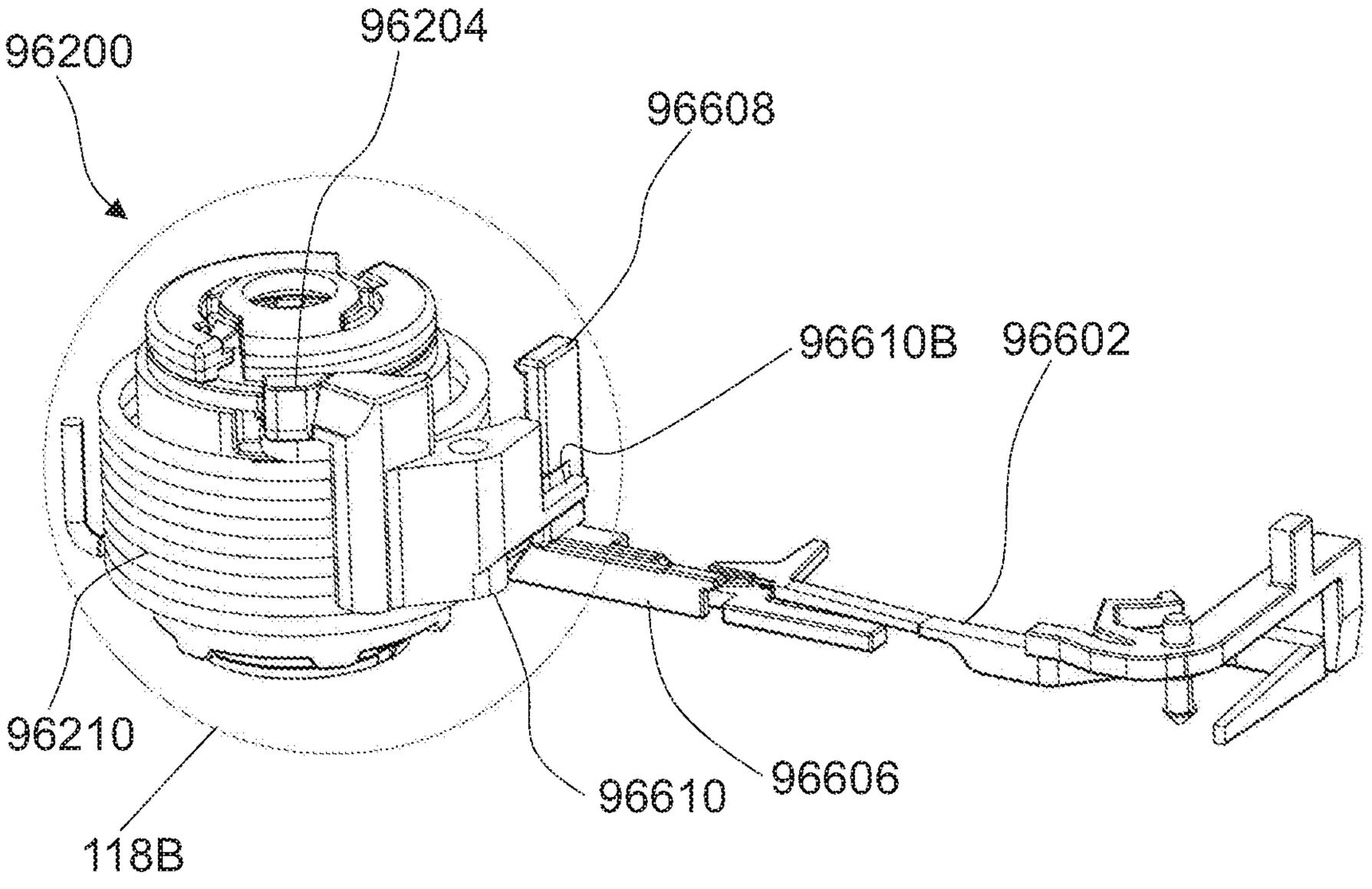


FIG. 118A

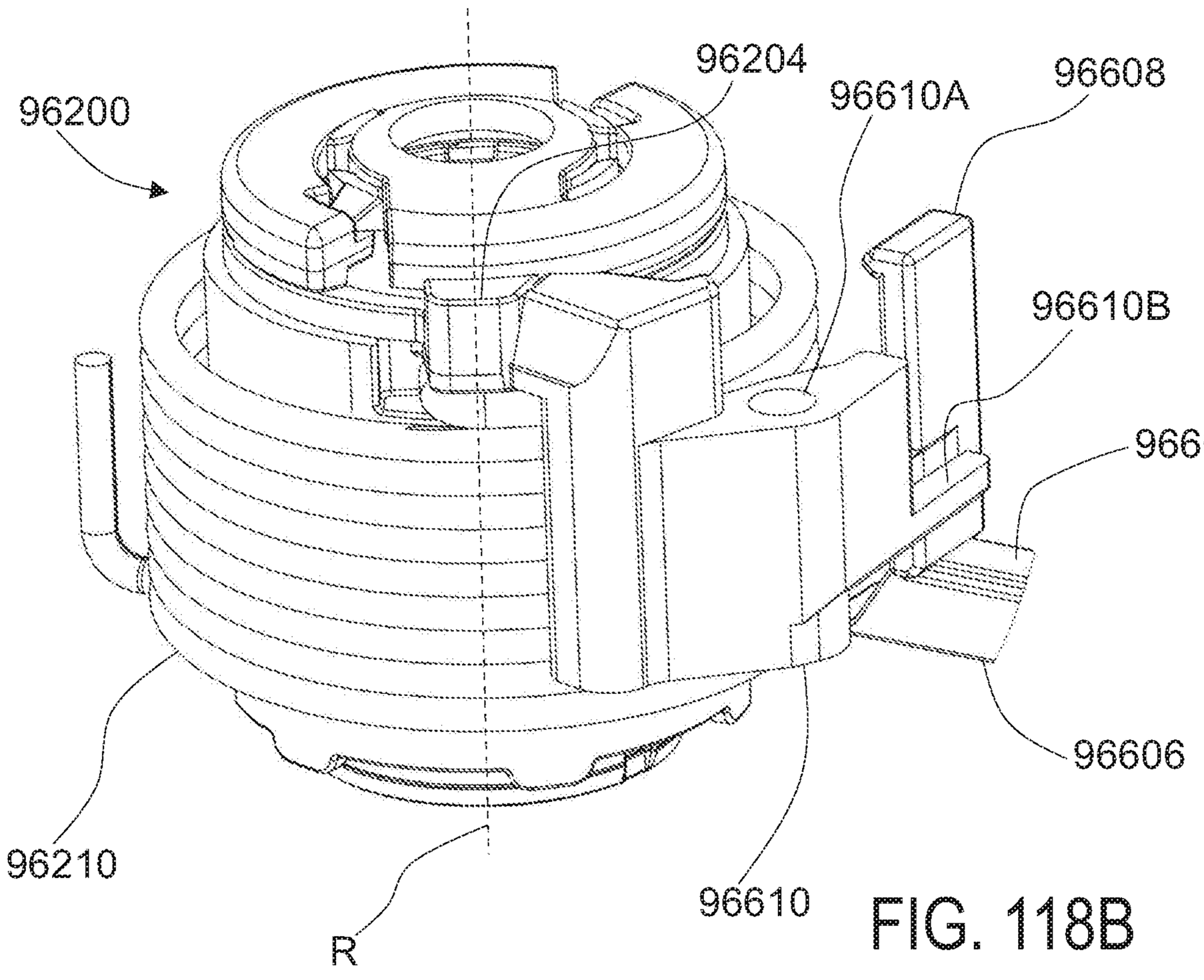


FIG. 118B

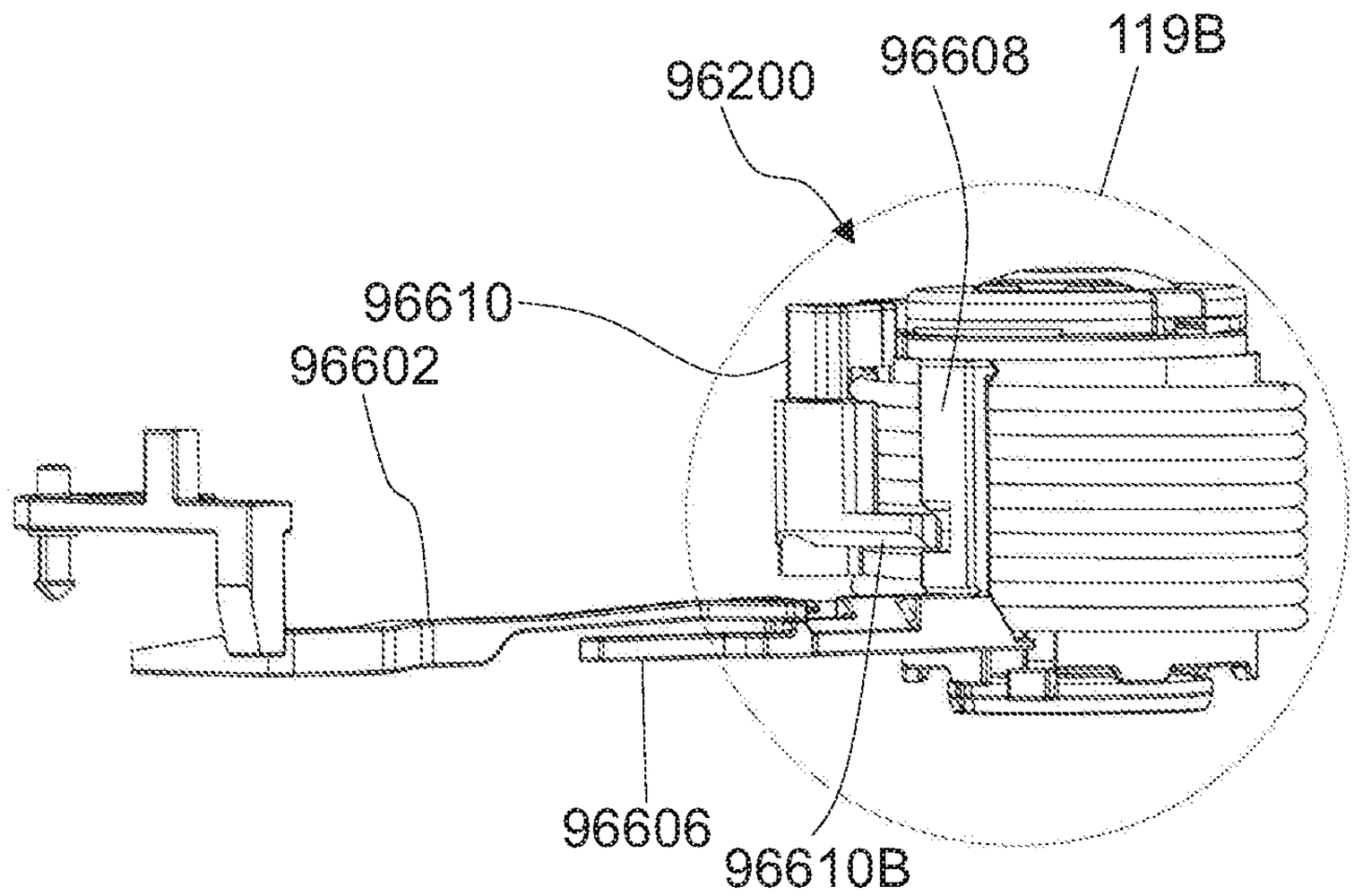


FIG. 119A

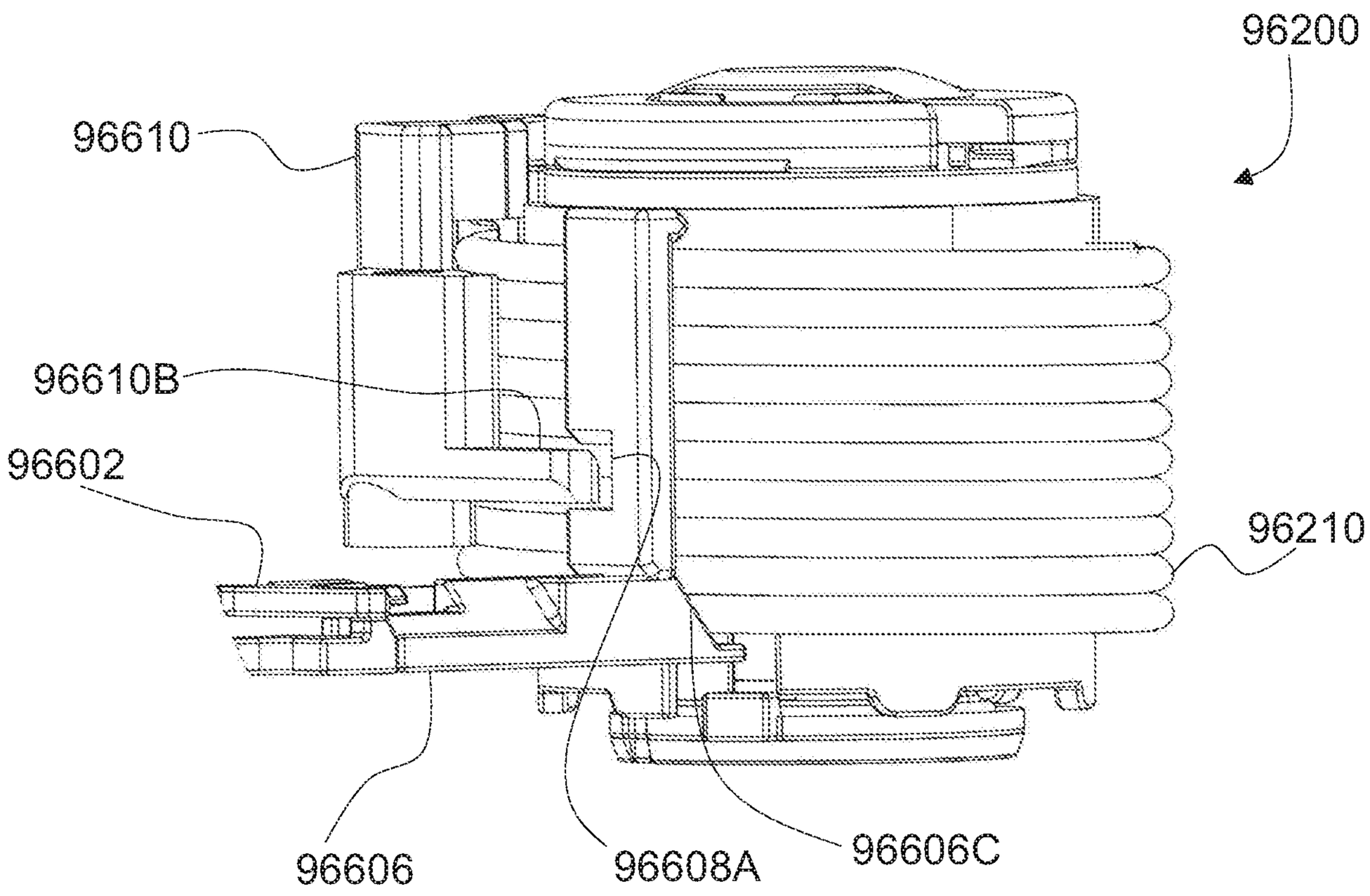


FIG. 119B

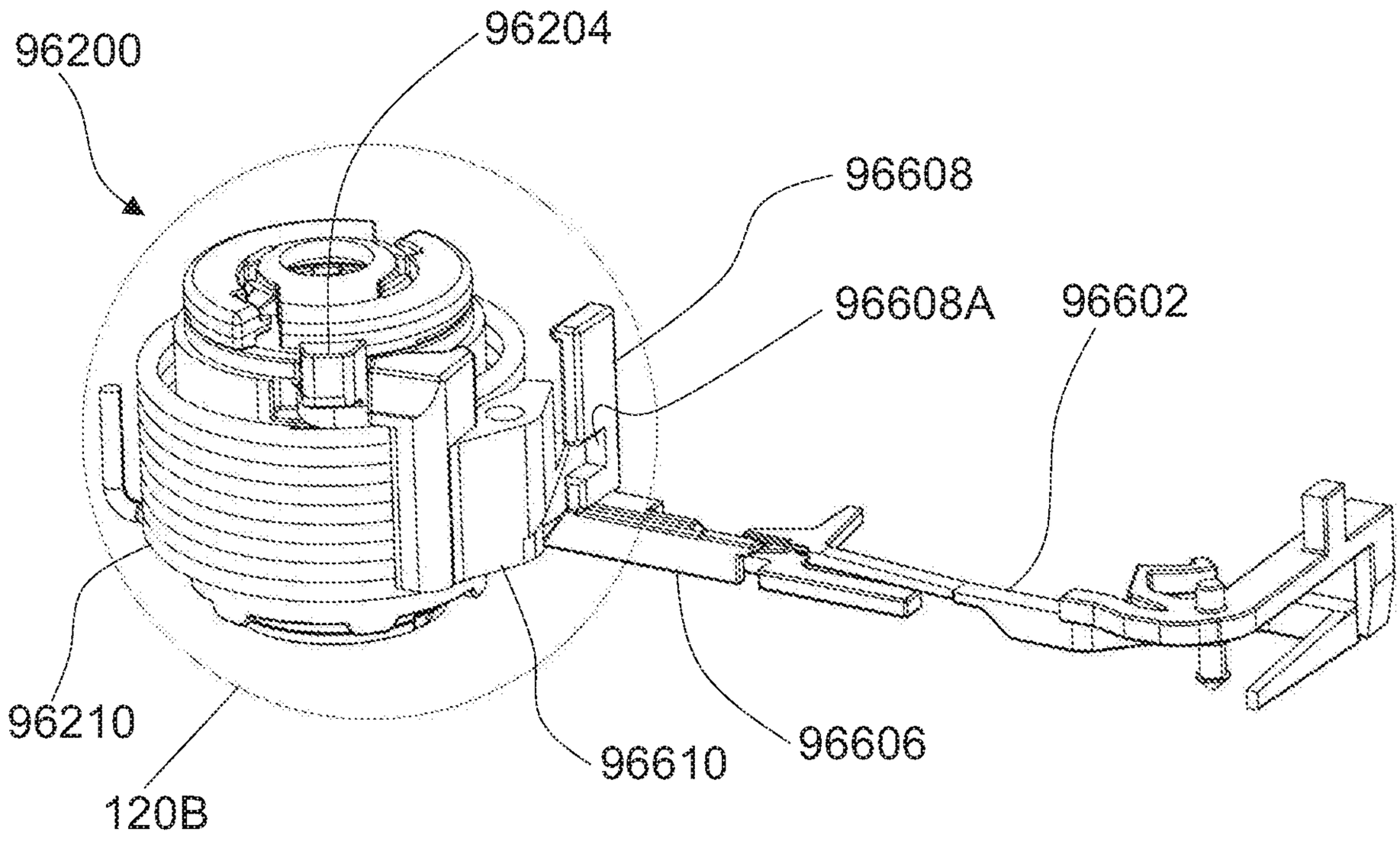


FIG. 120A

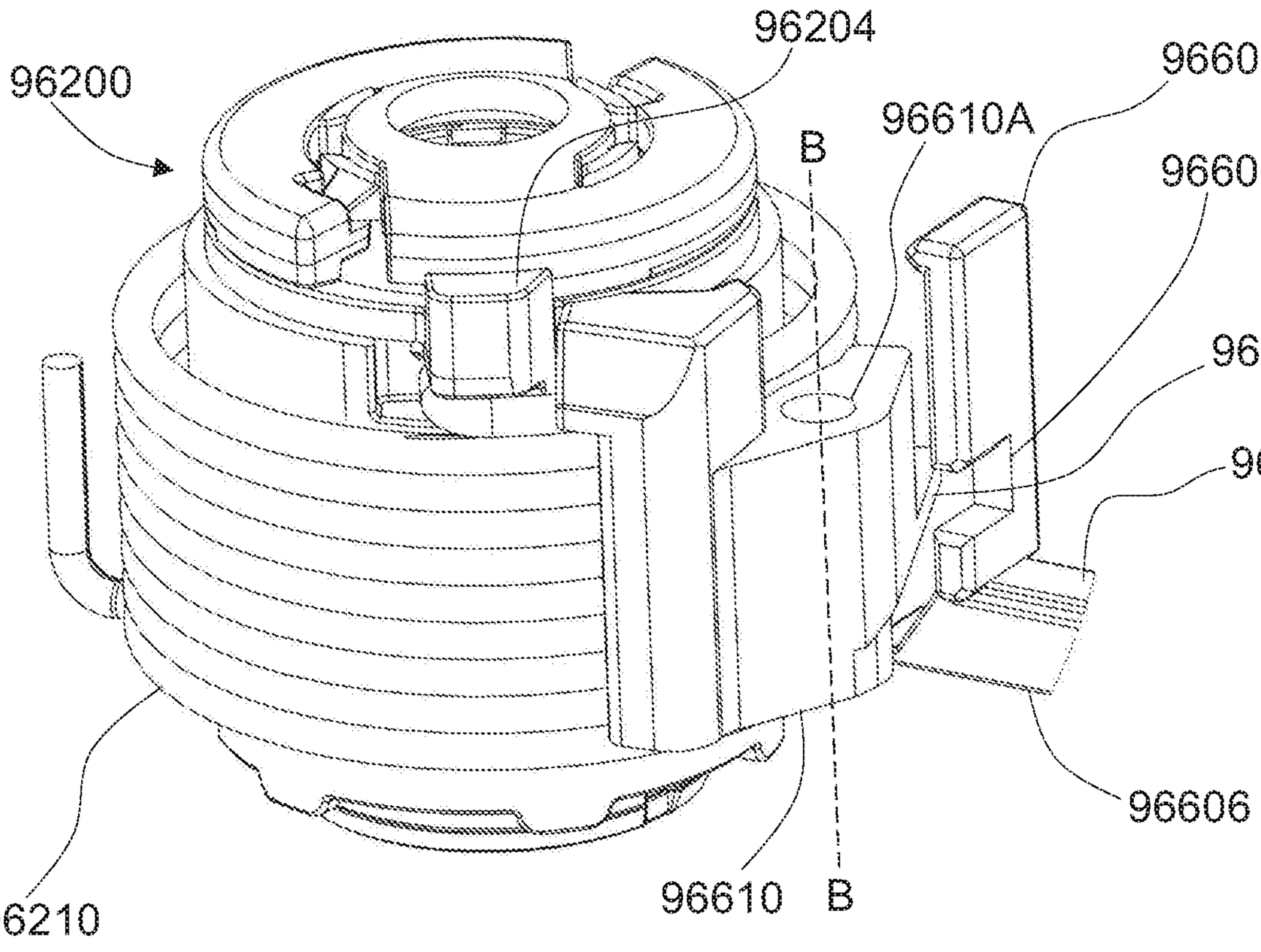


FIG. 120B

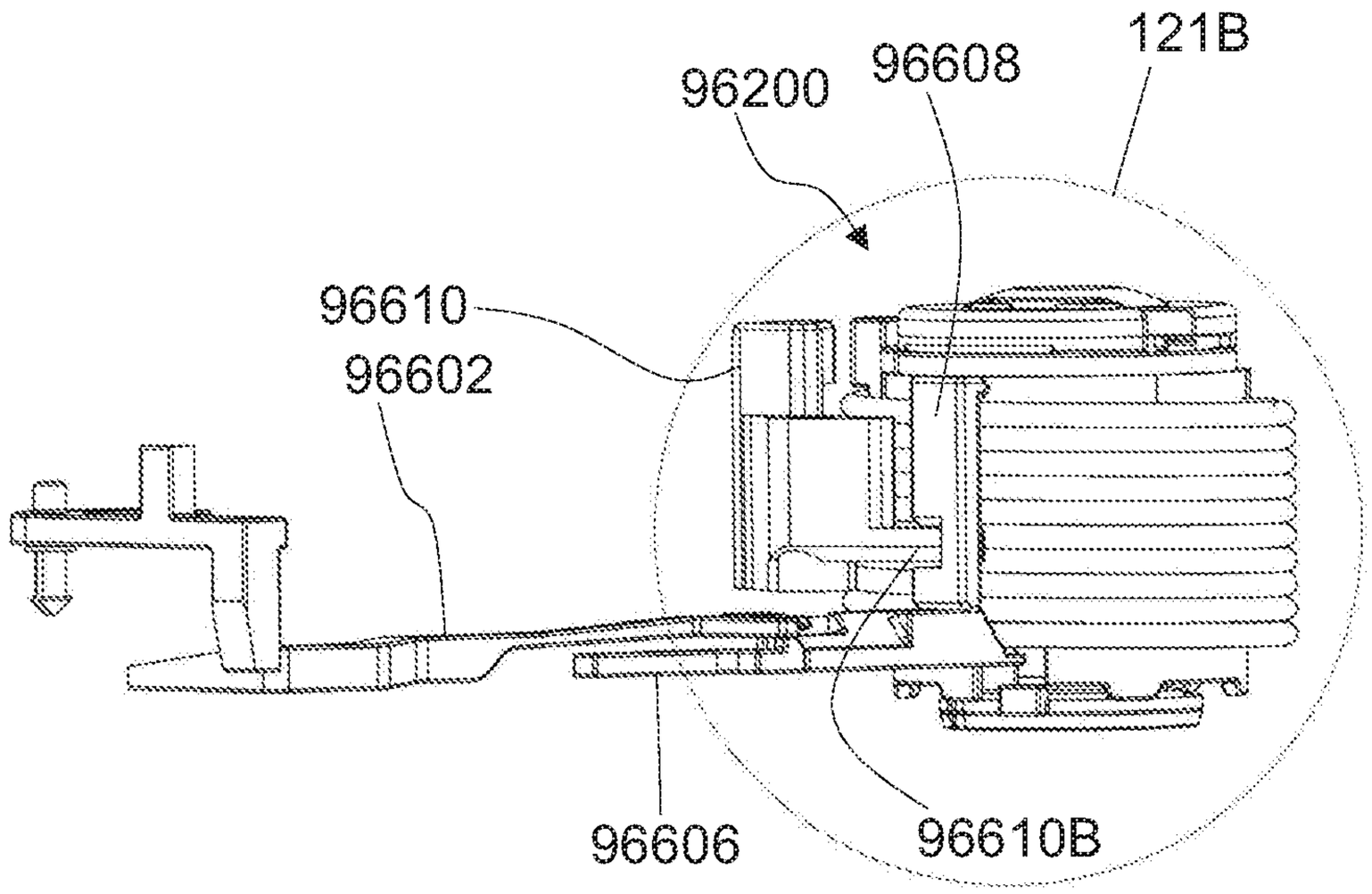


FIG. 121A

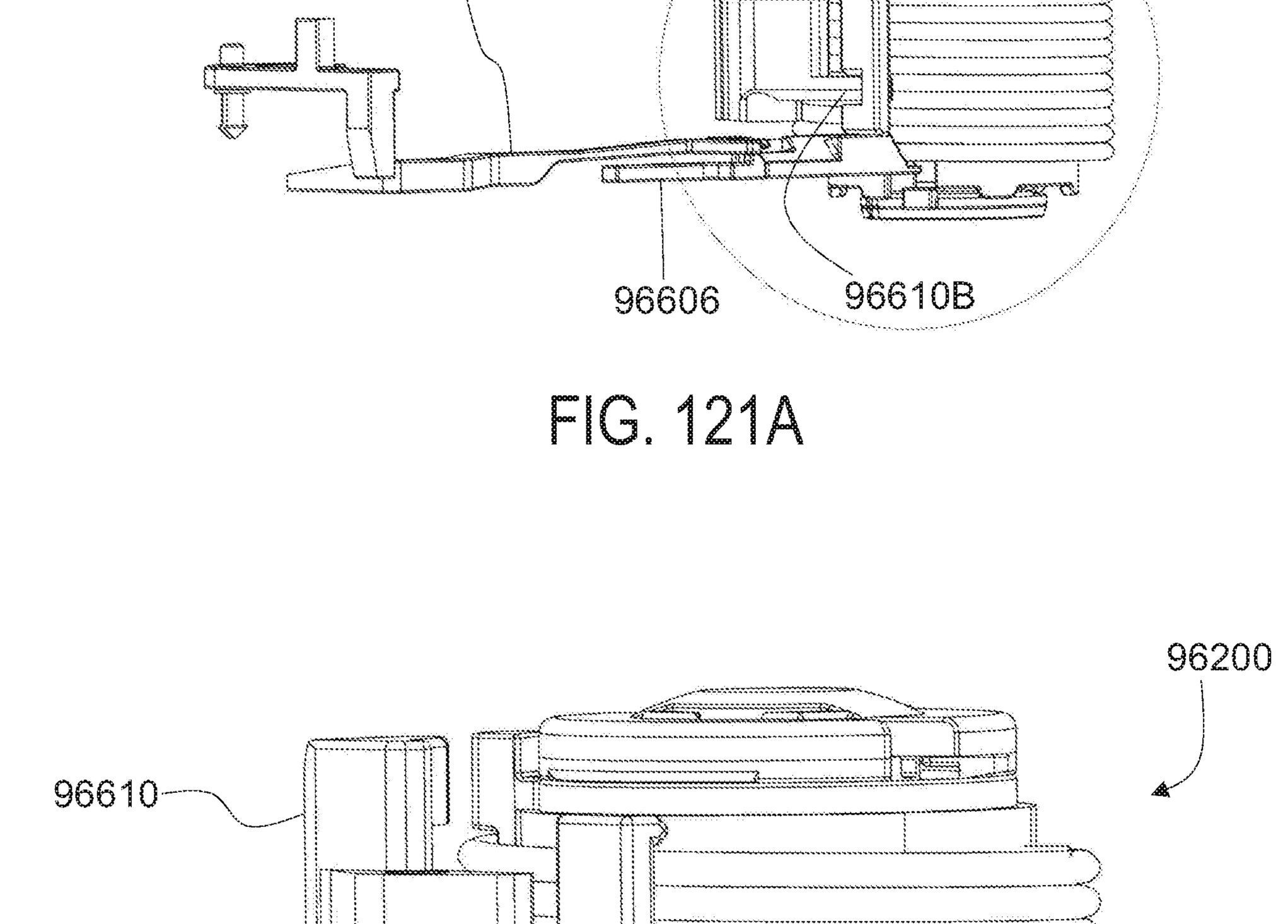


FIG. 121B

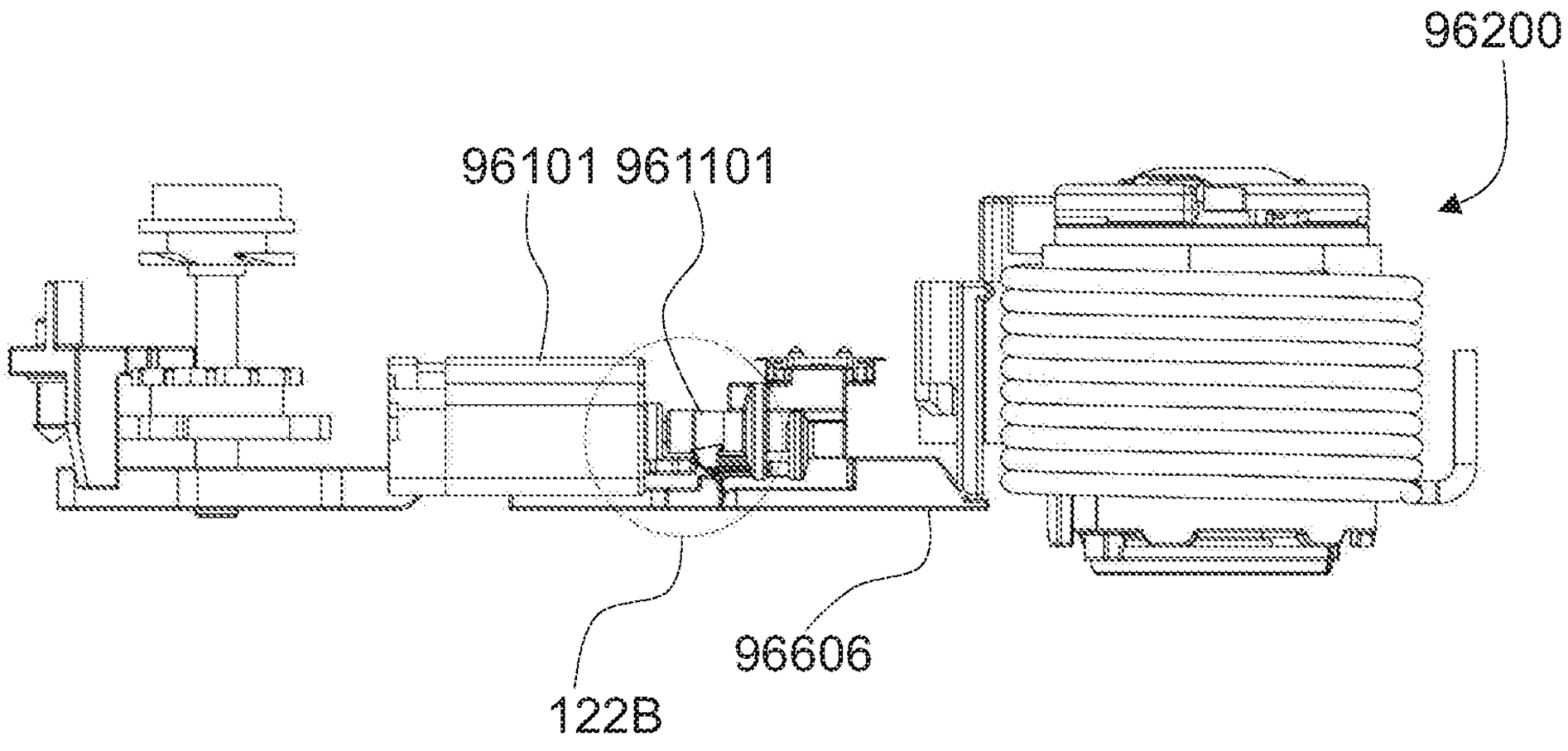


FIG. 122A

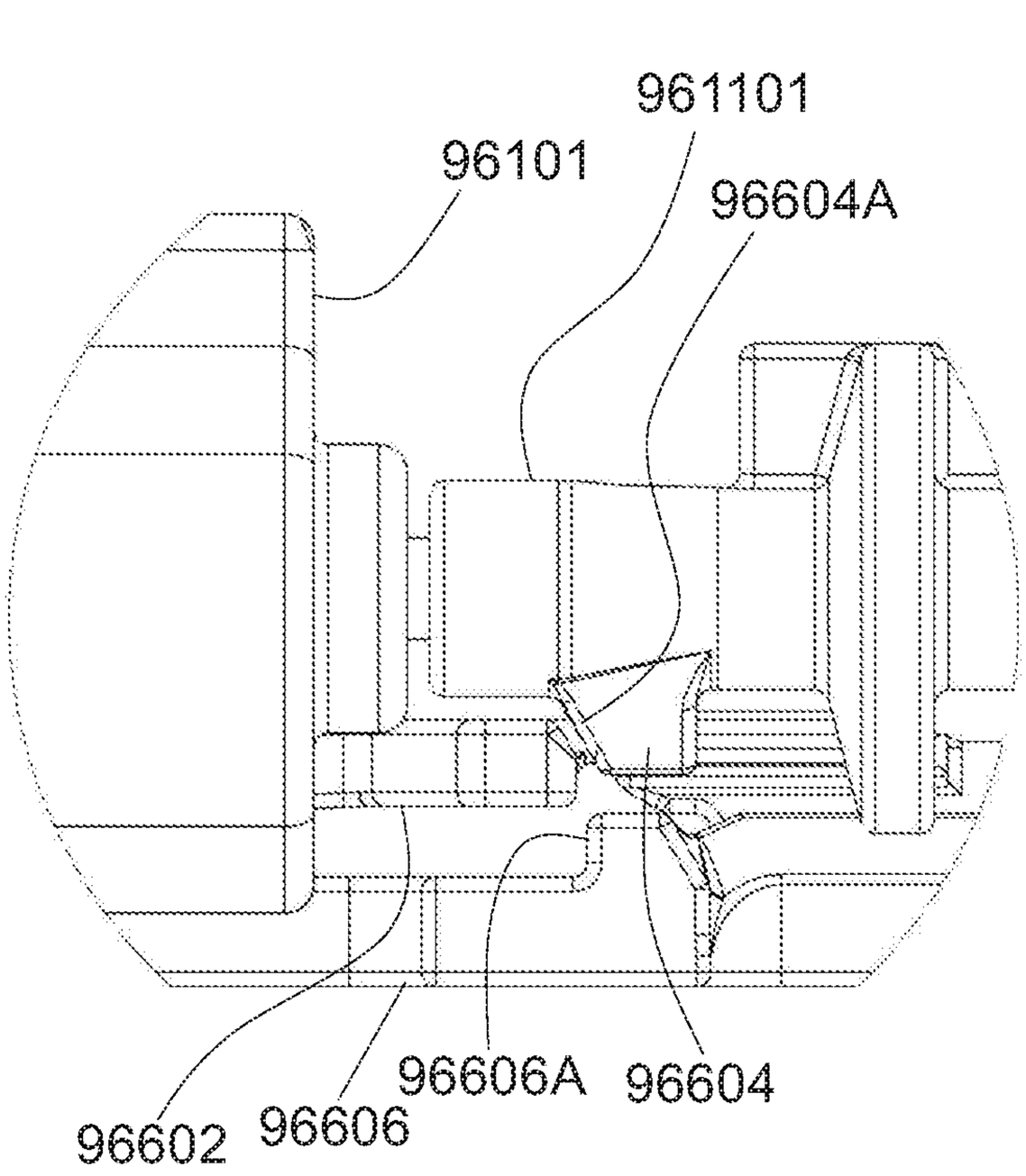


FIG. 122B

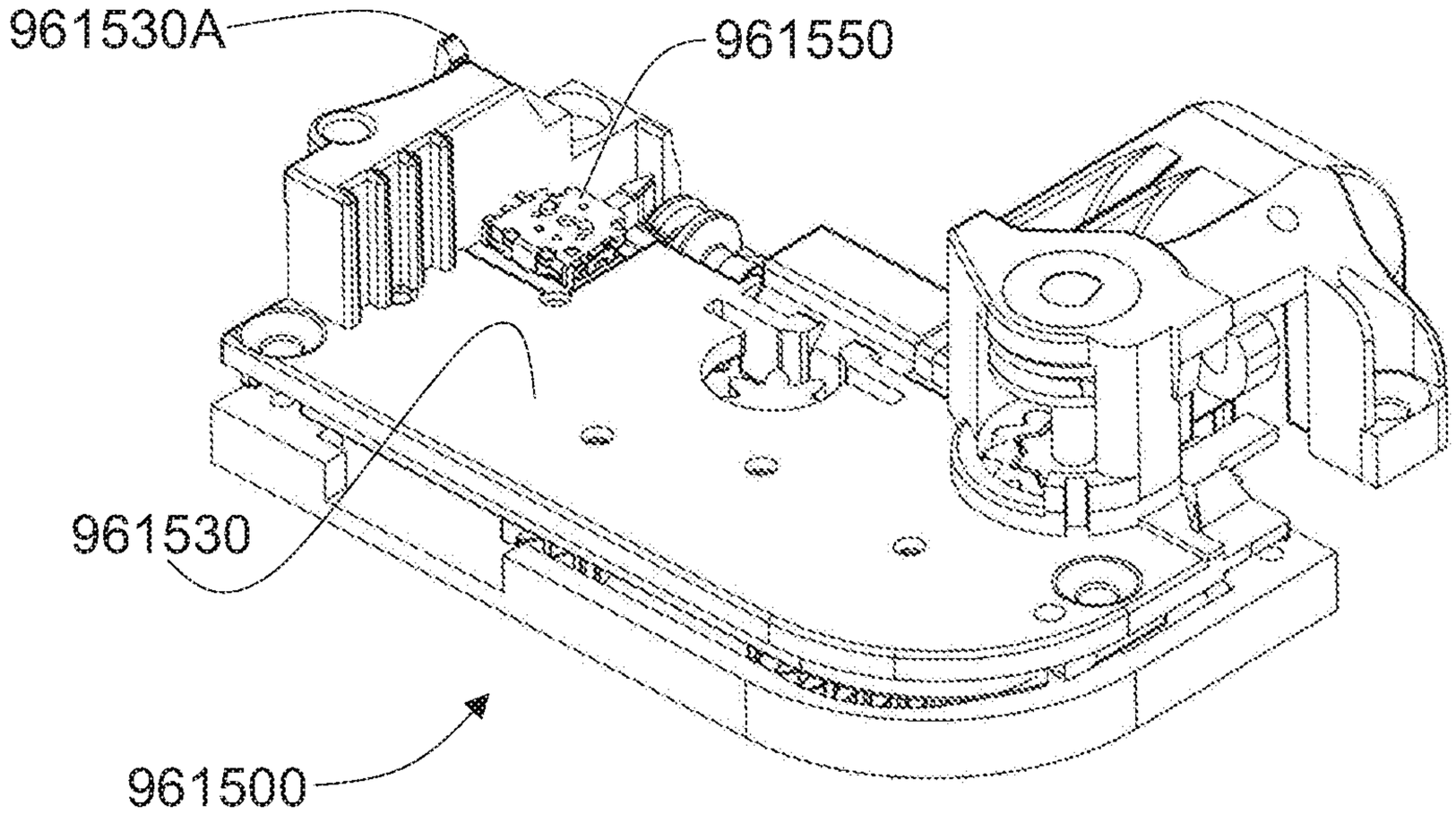


FIG. 123

FIG. 124A

FIG. 124B

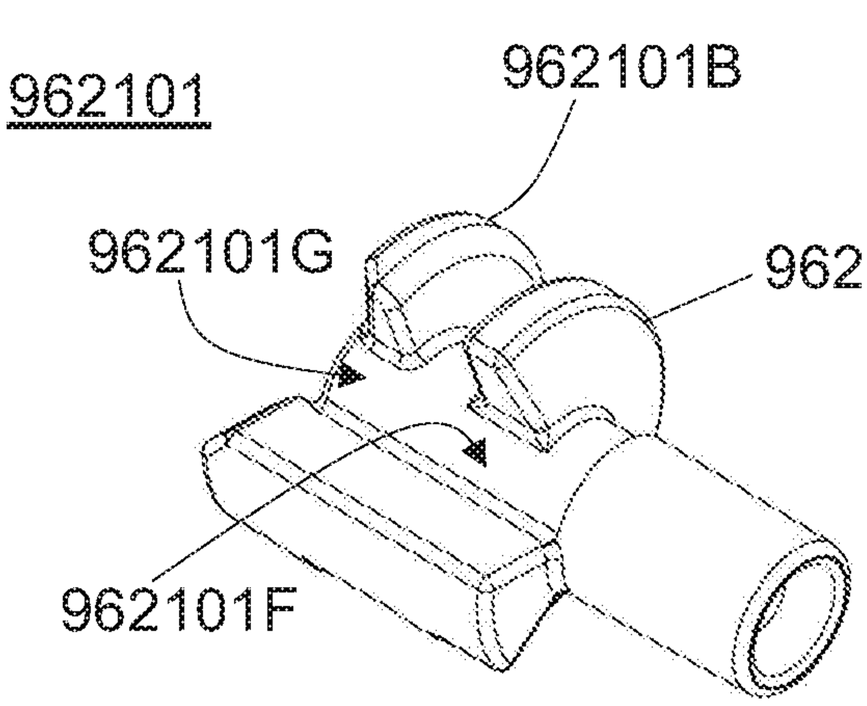


FIG. 124C

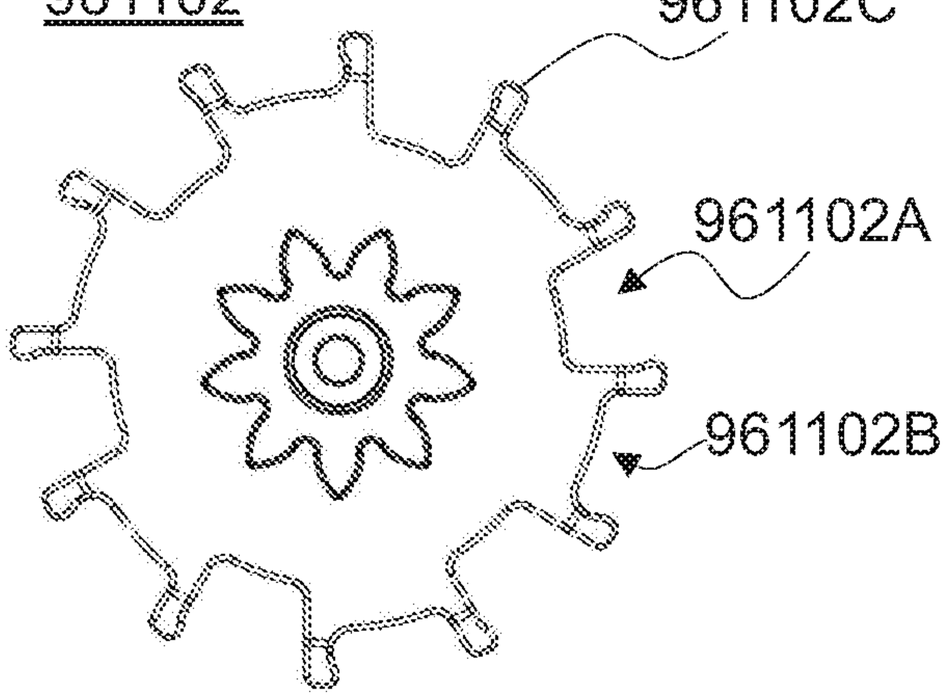


FIG. 125

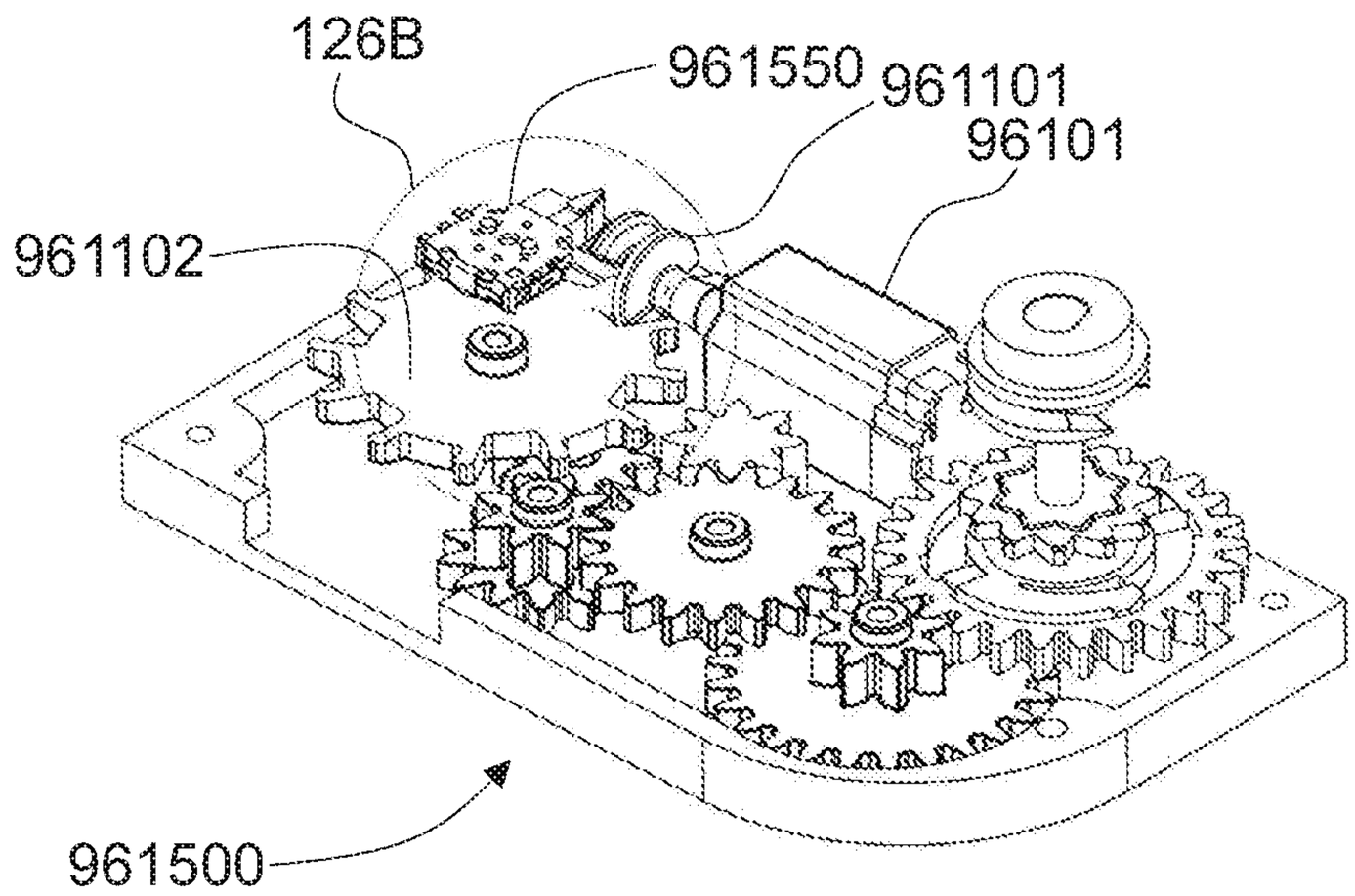


FIG. 126A

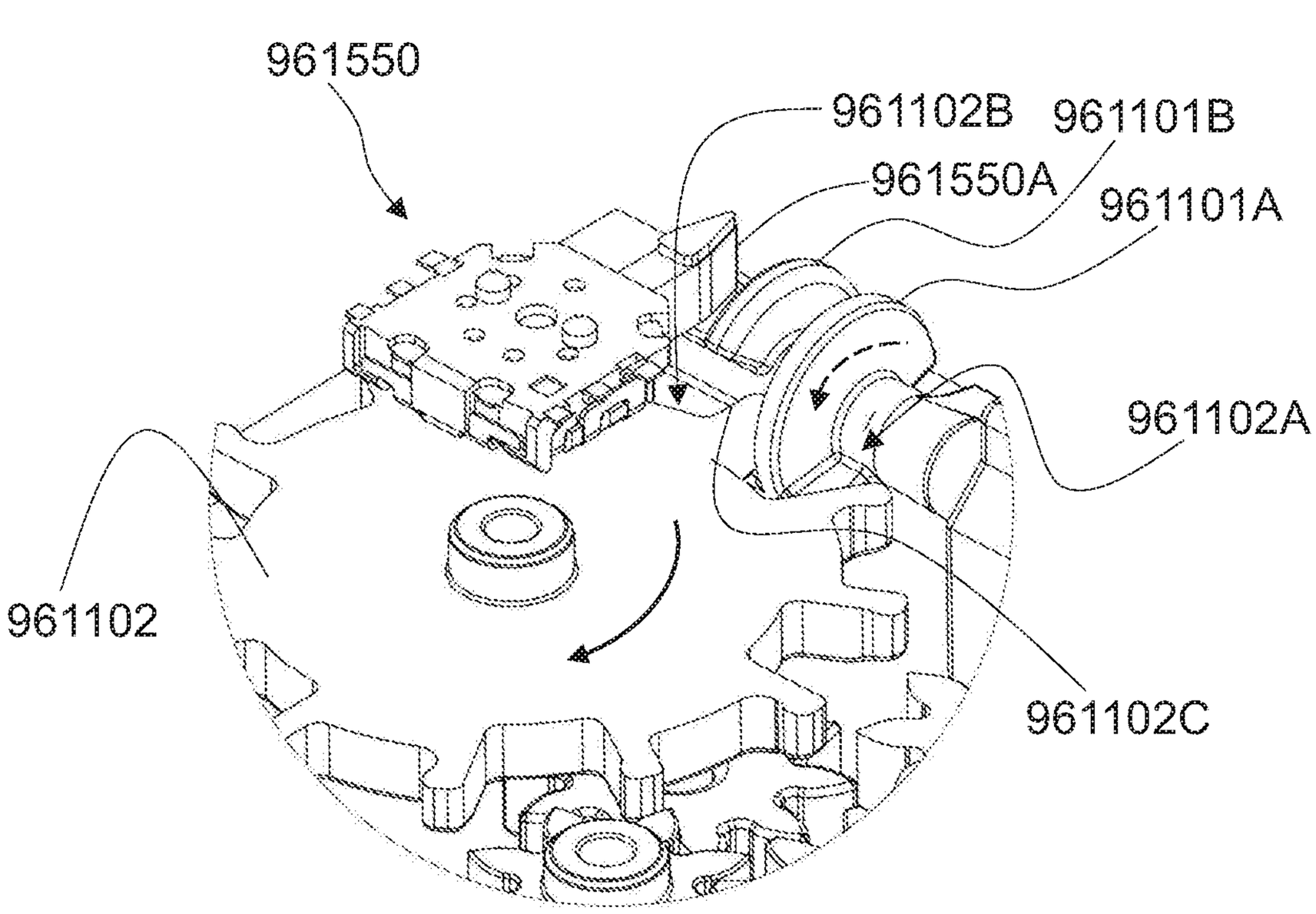


FIG. 126B

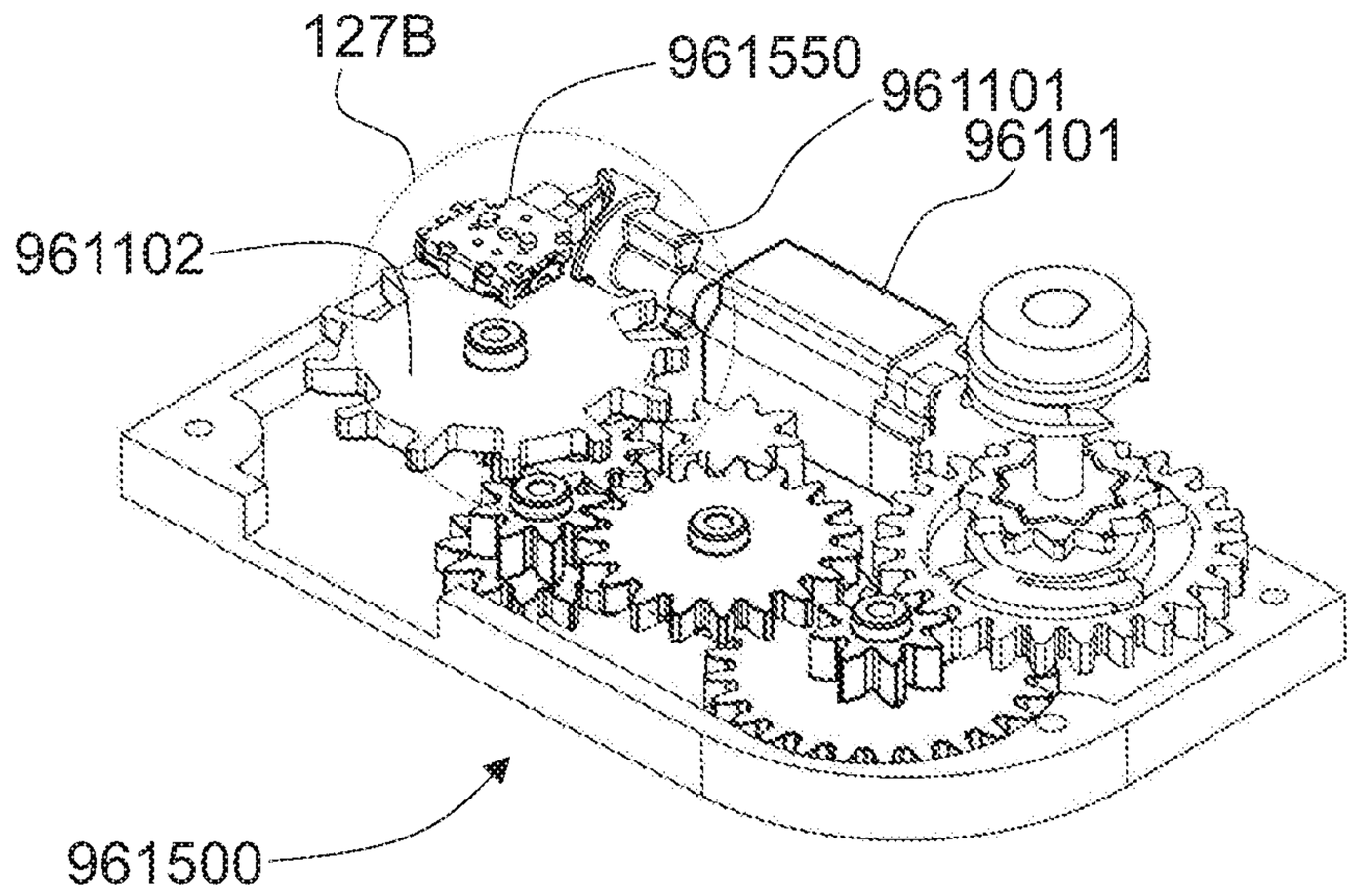


FIG. 127A

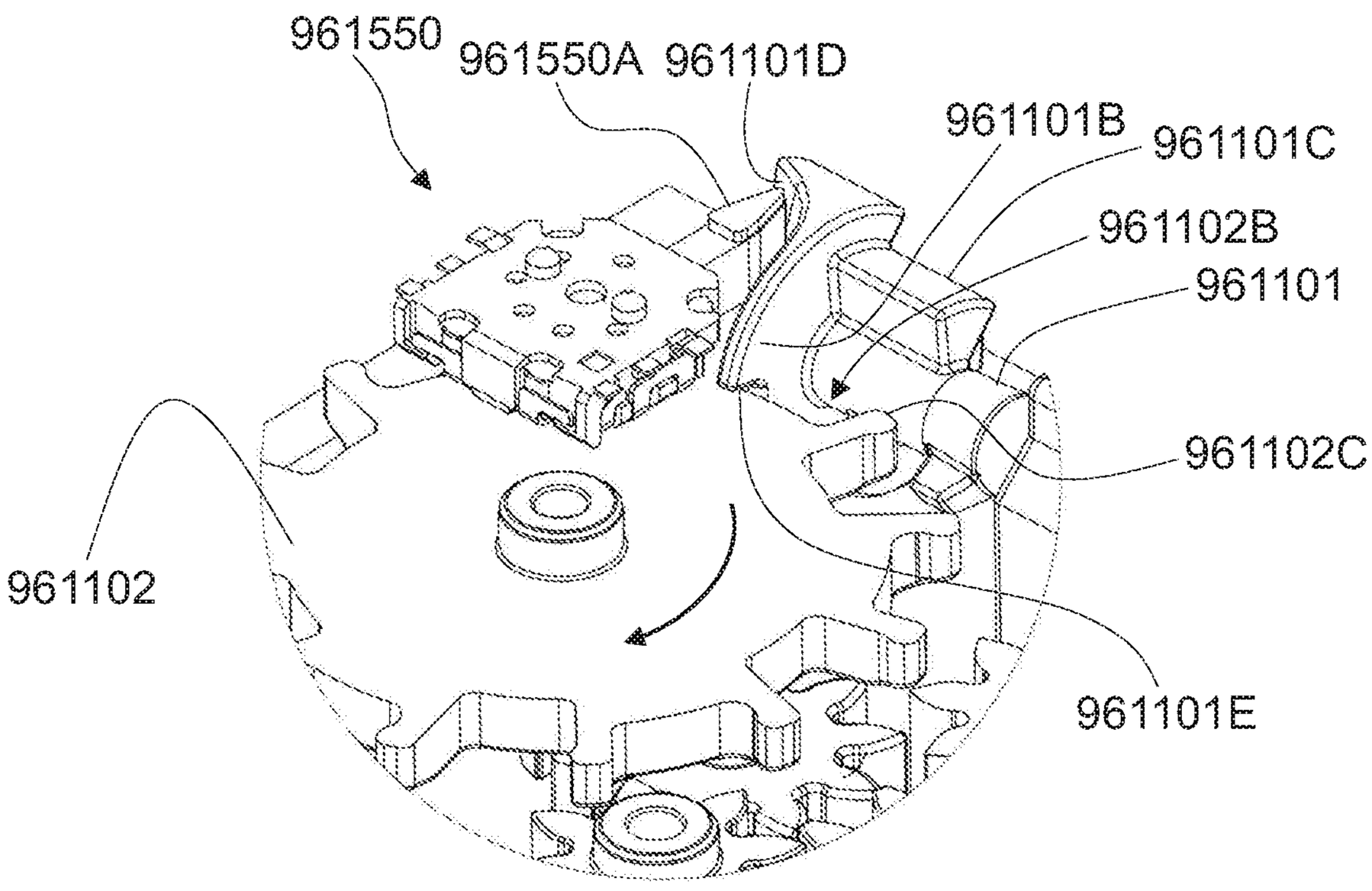


FIG. 127B

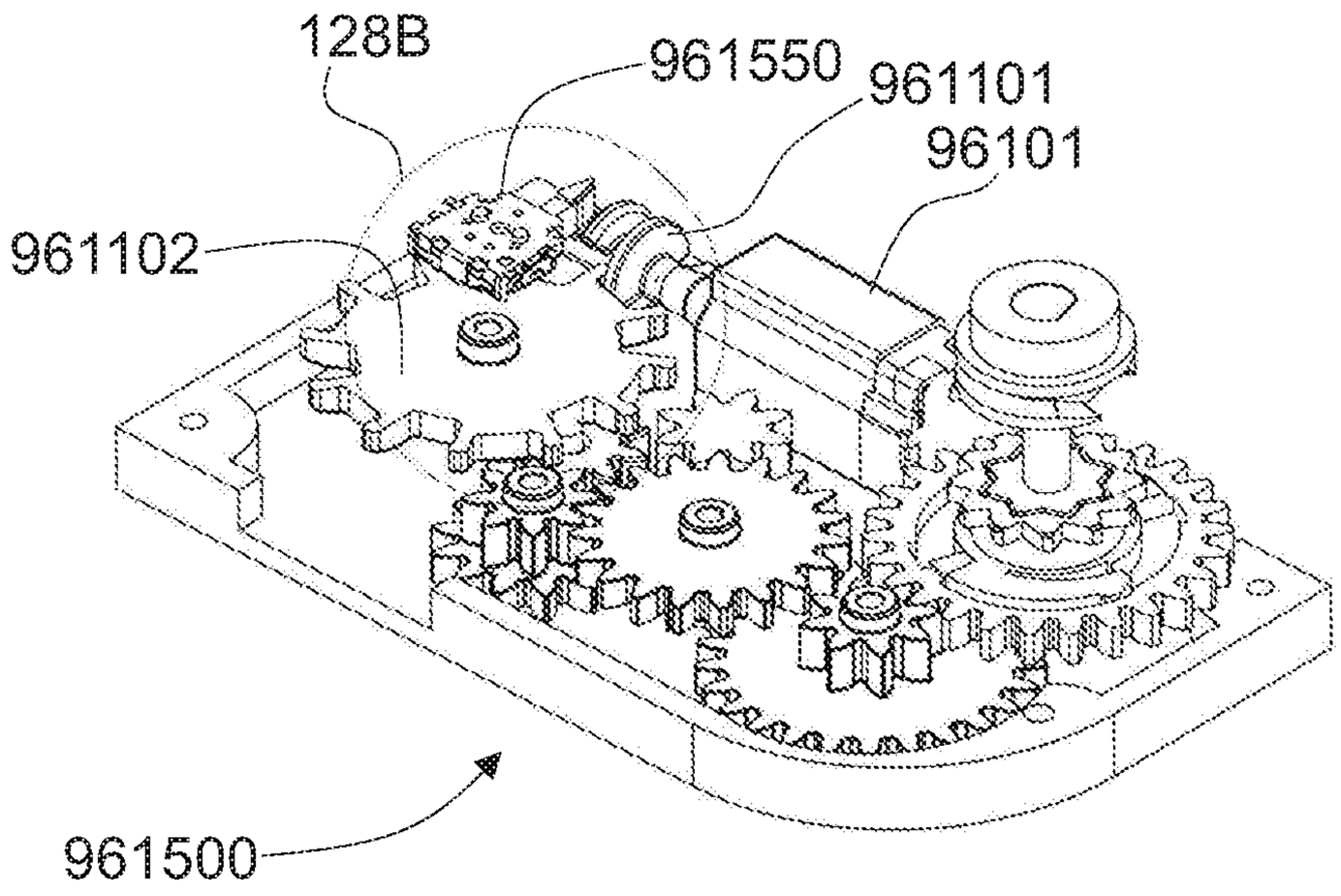


FIG. 128A

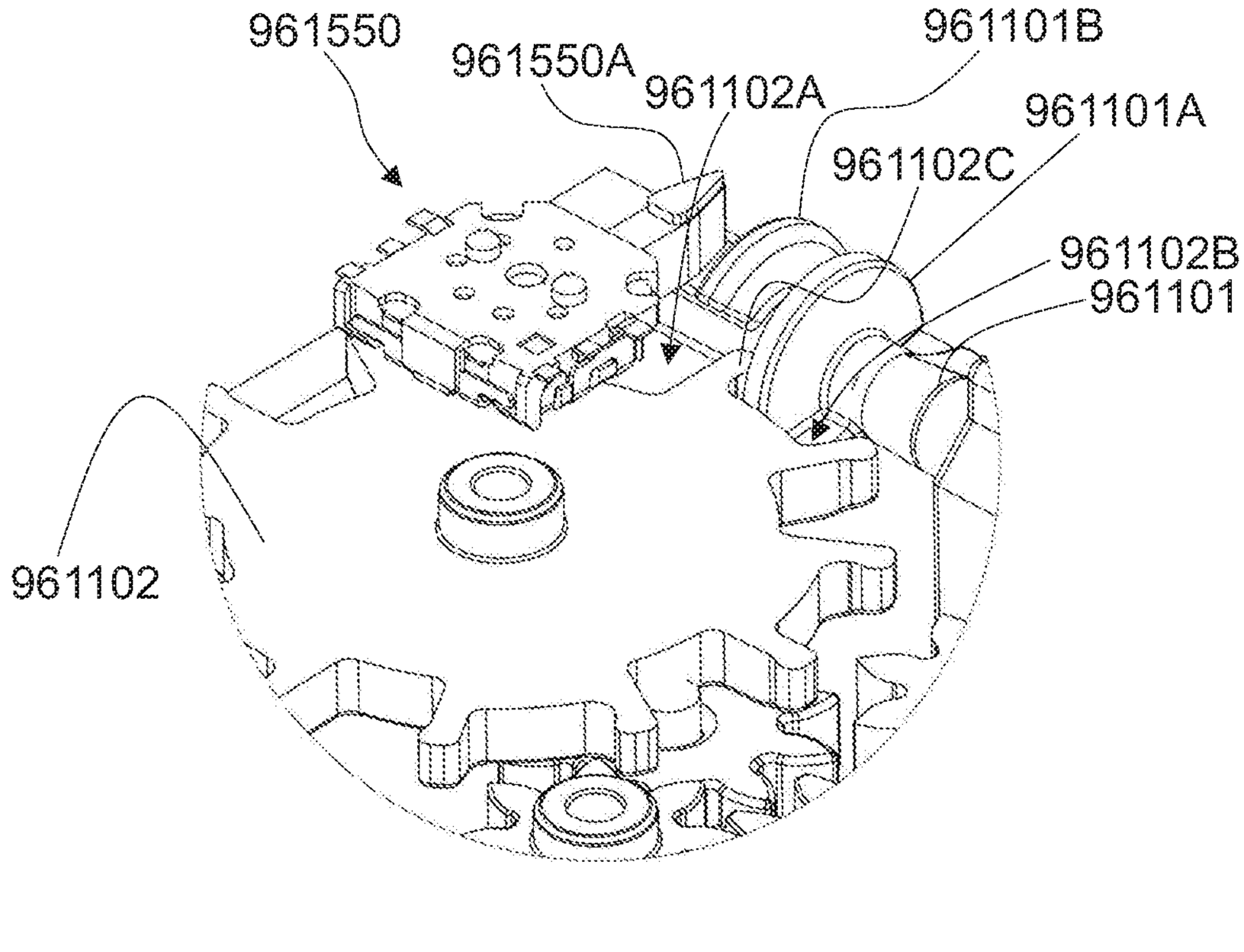


FIG. 128B

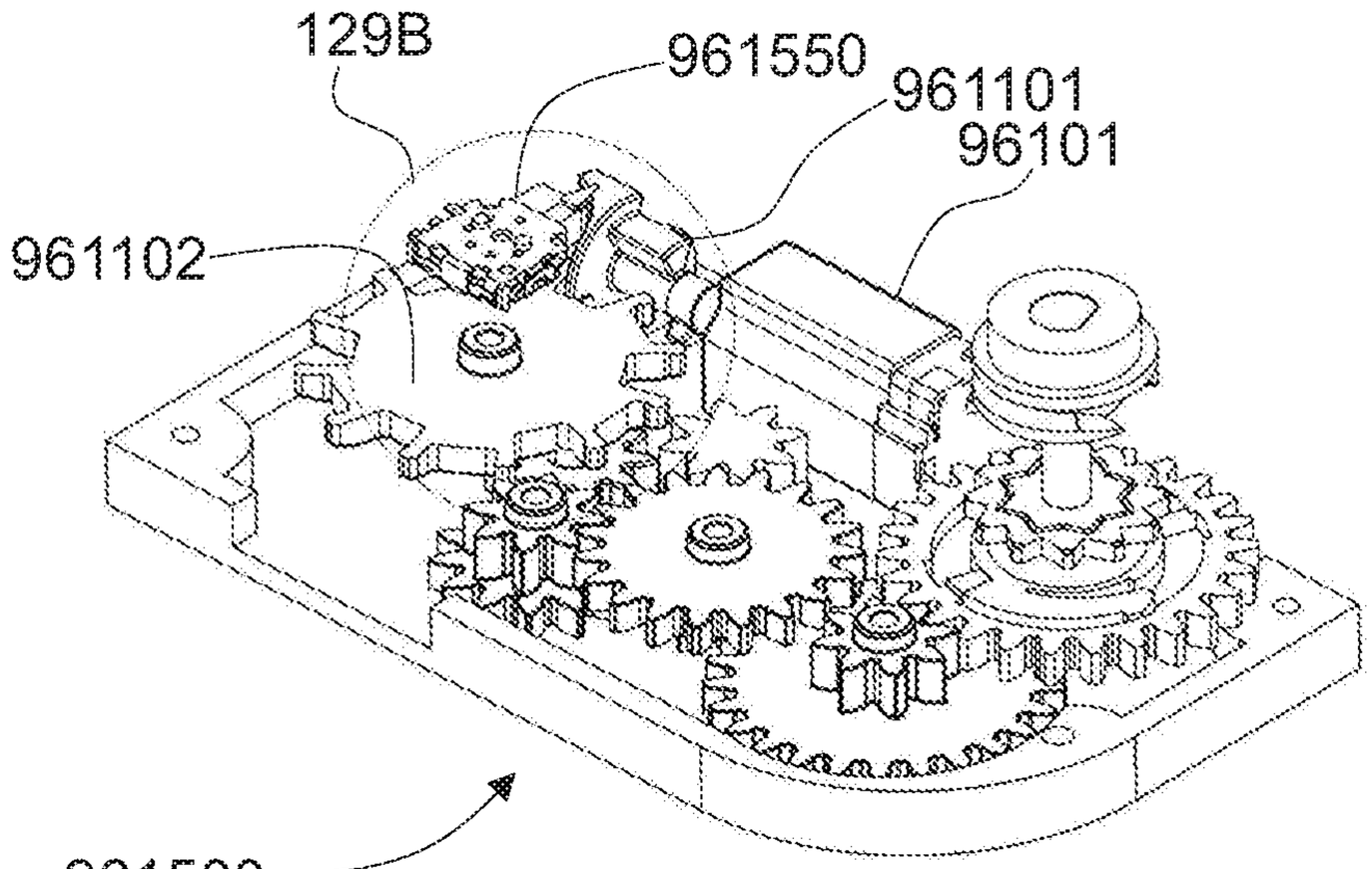


FIG. 129A

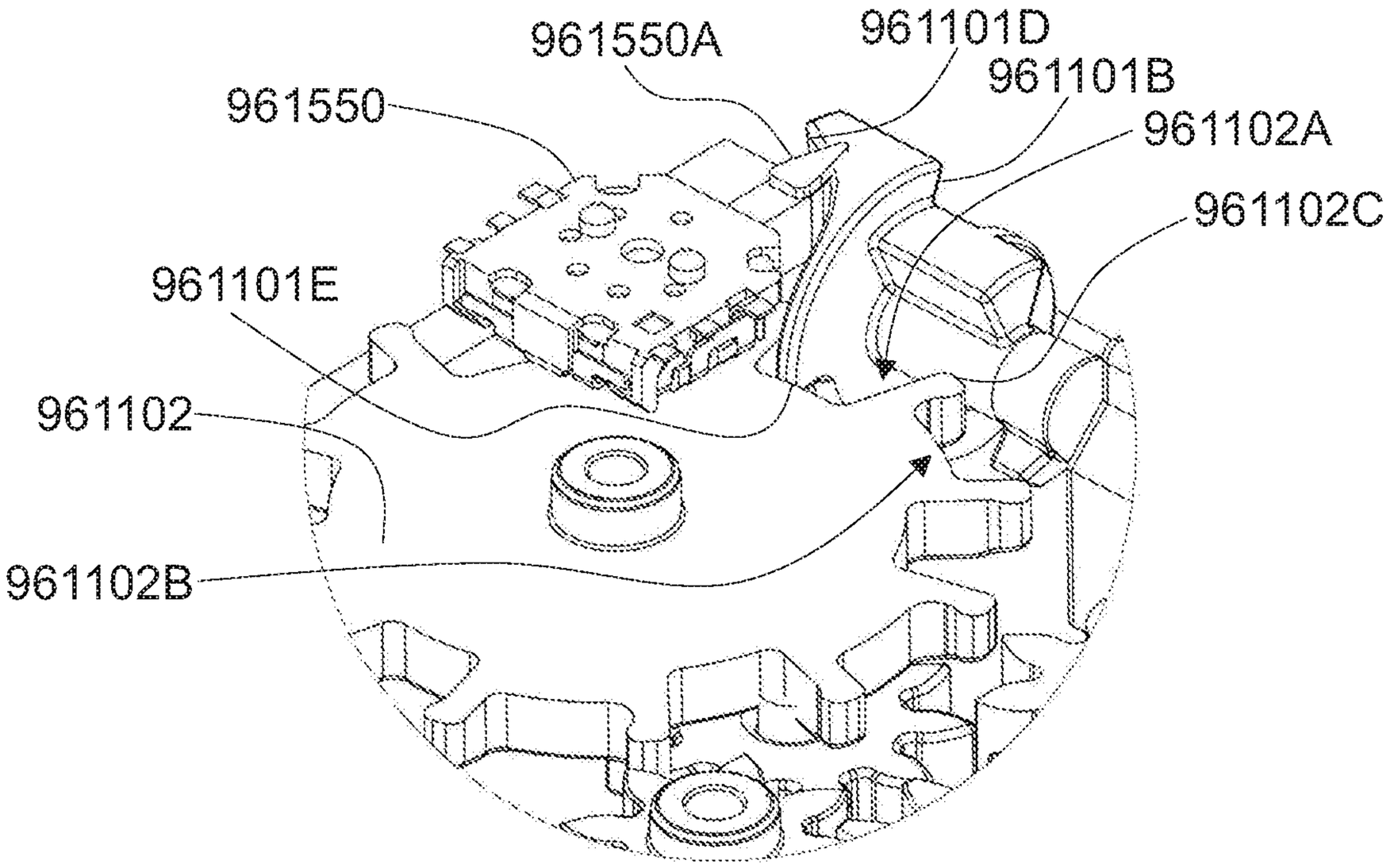


FIG. 129B

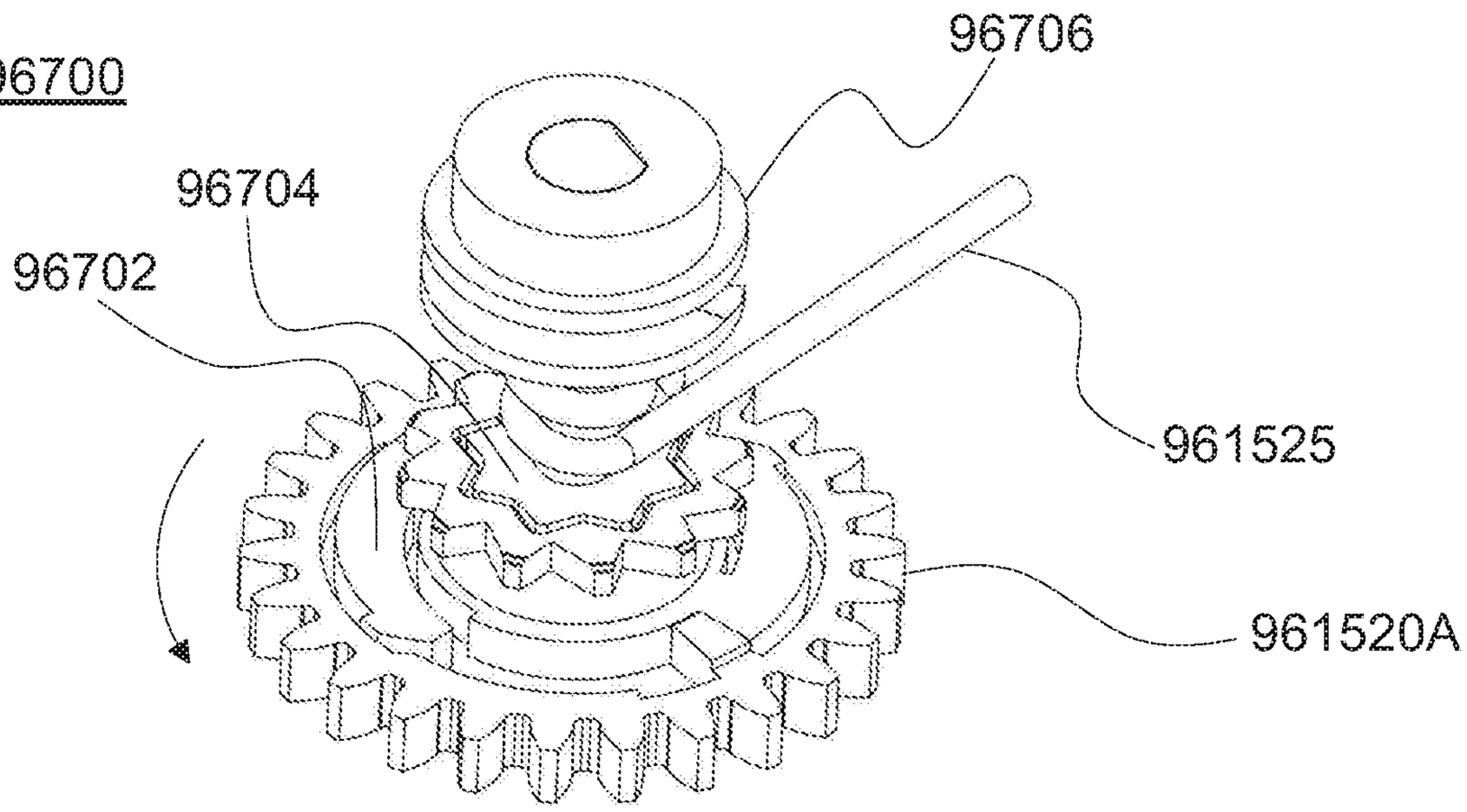


FIG. 130A

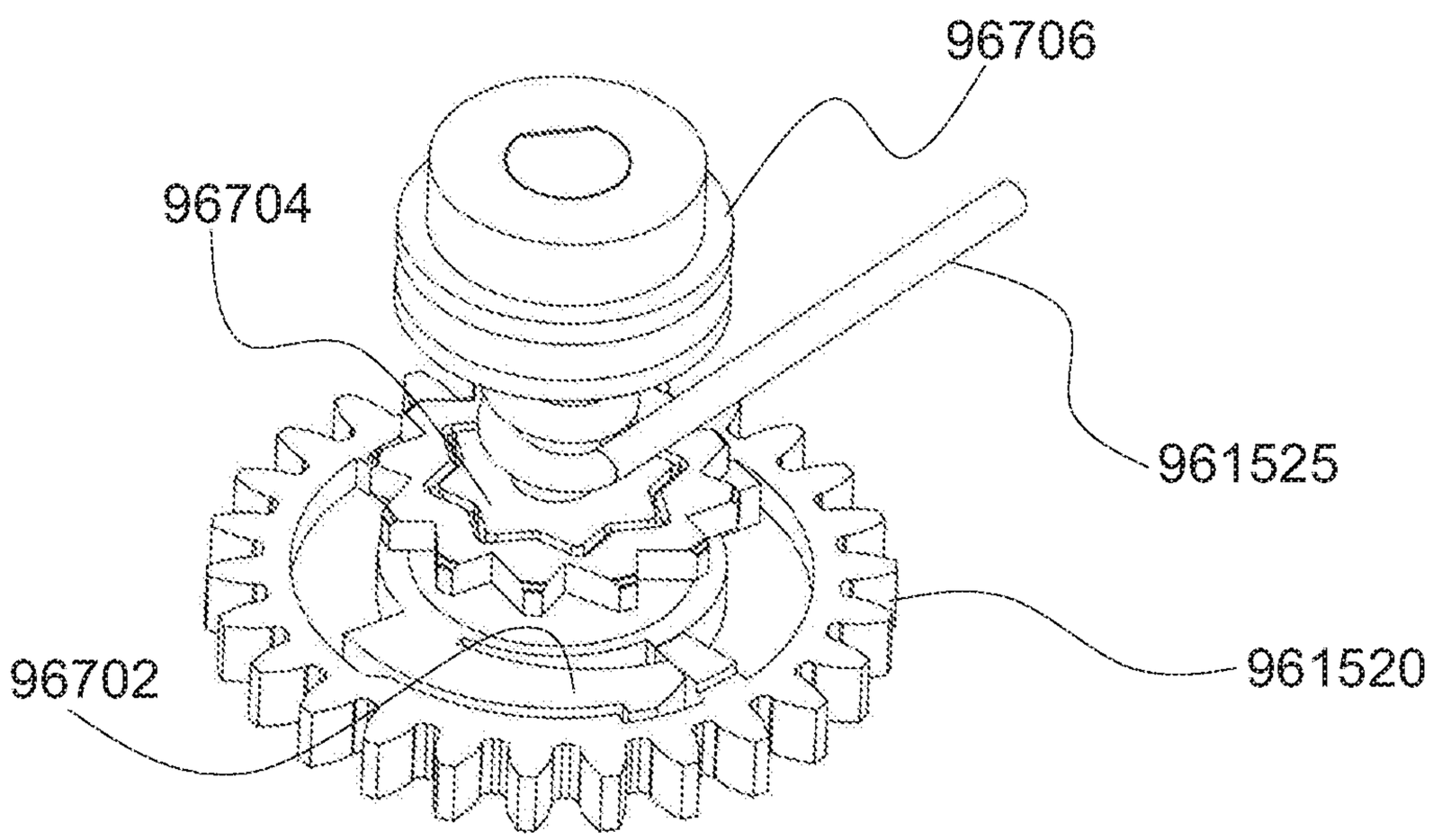


FIG. 130B

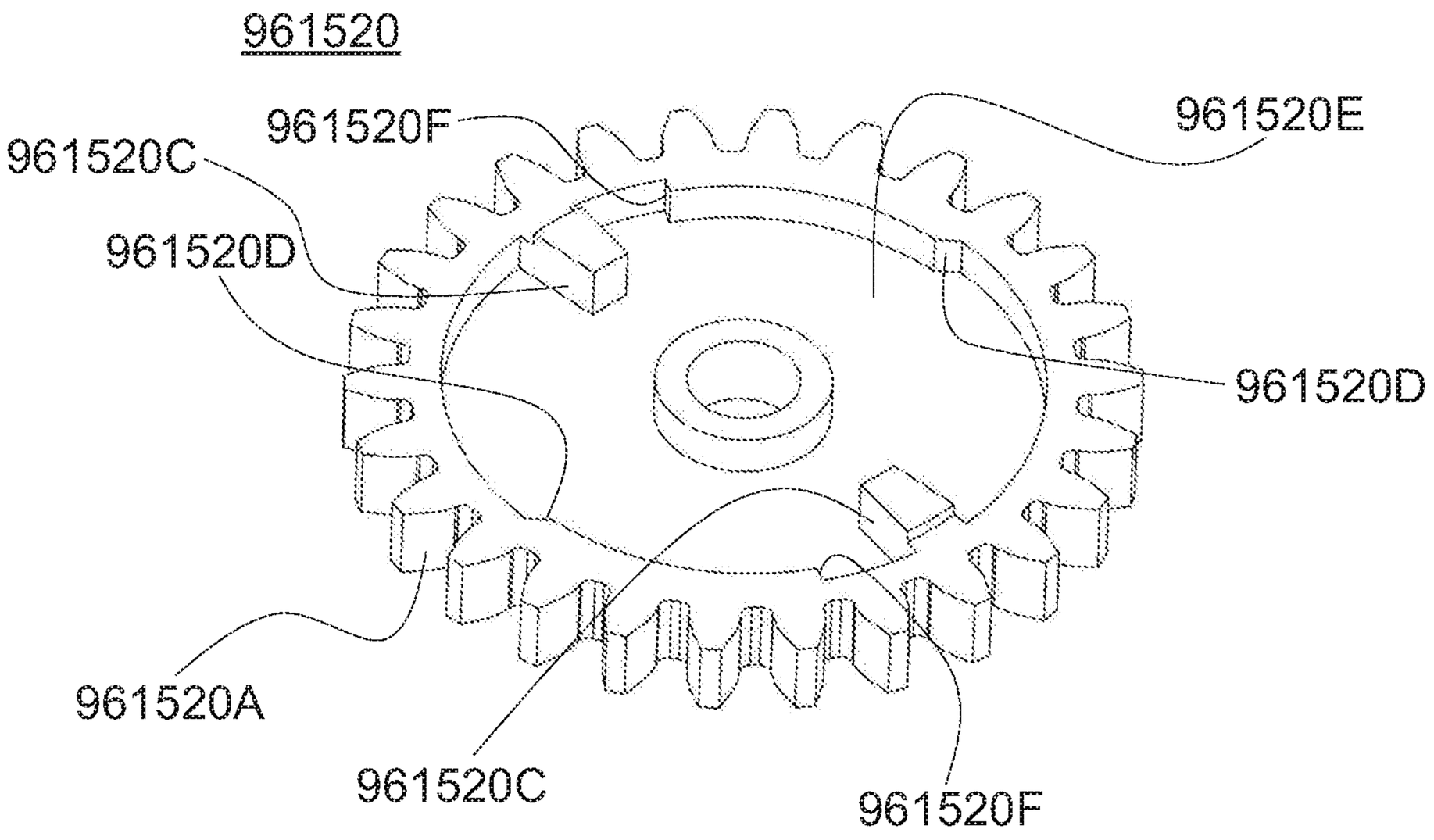


FIG. 131

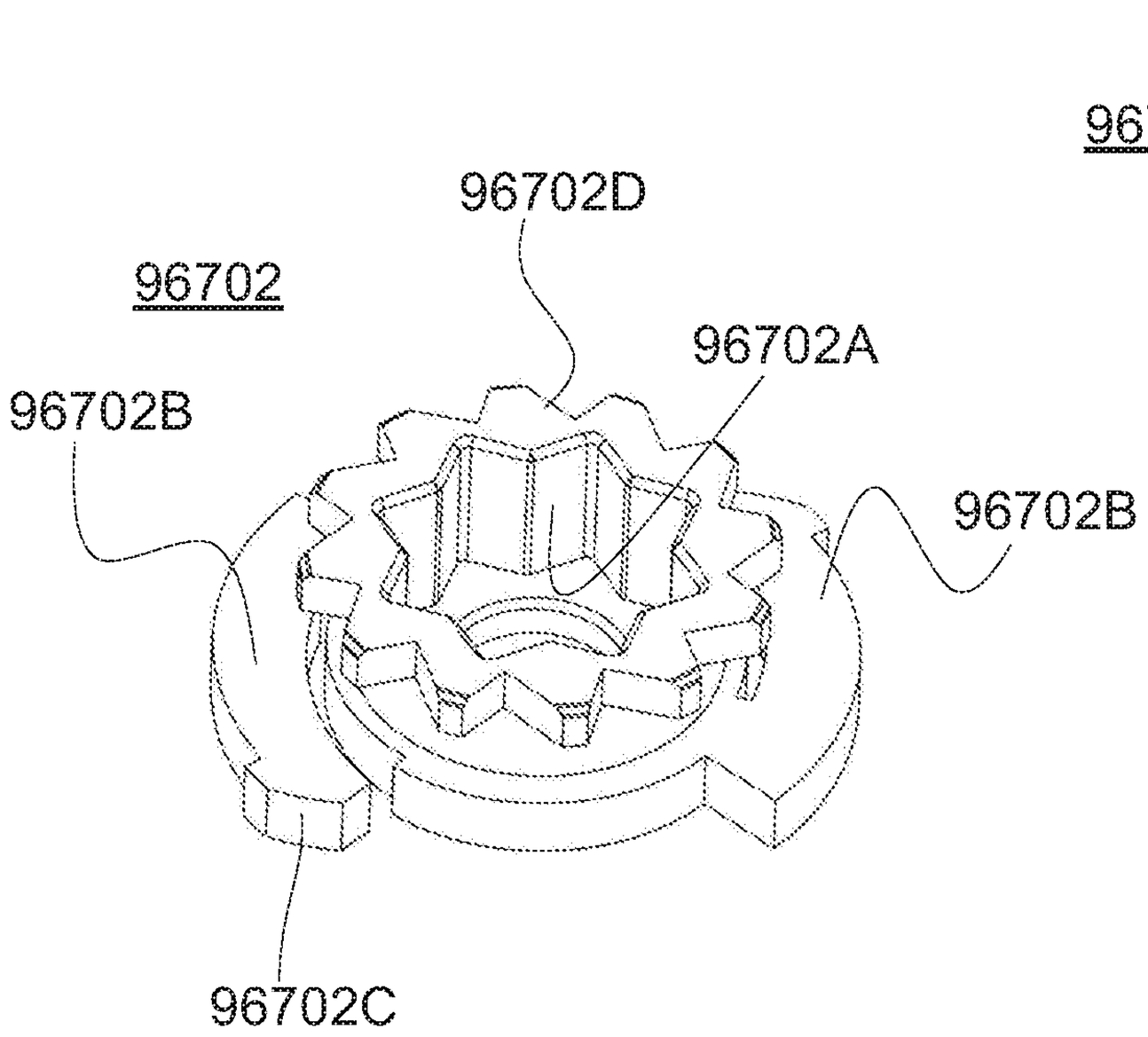


FIG. 132

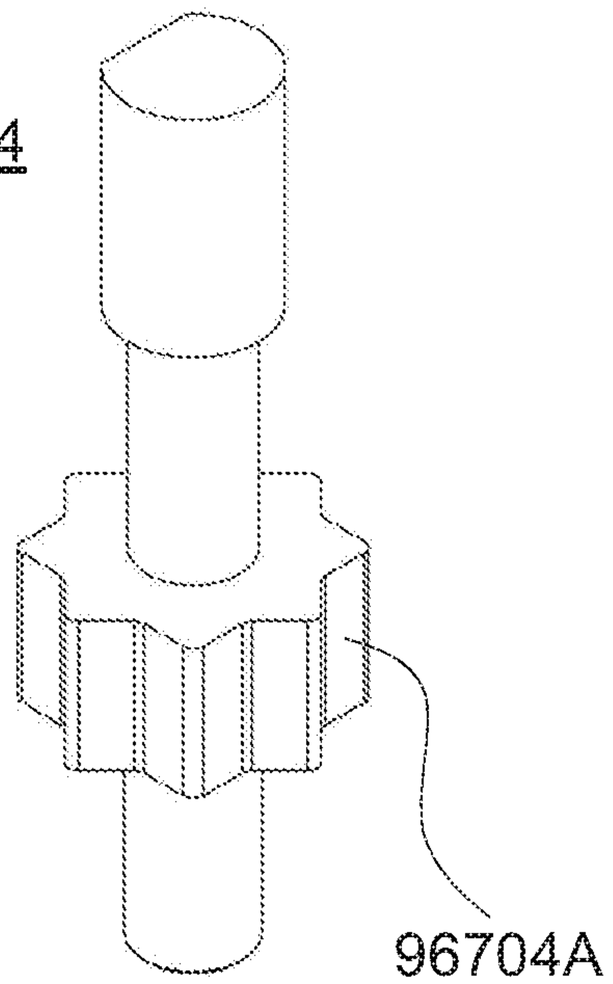


FIG. 133

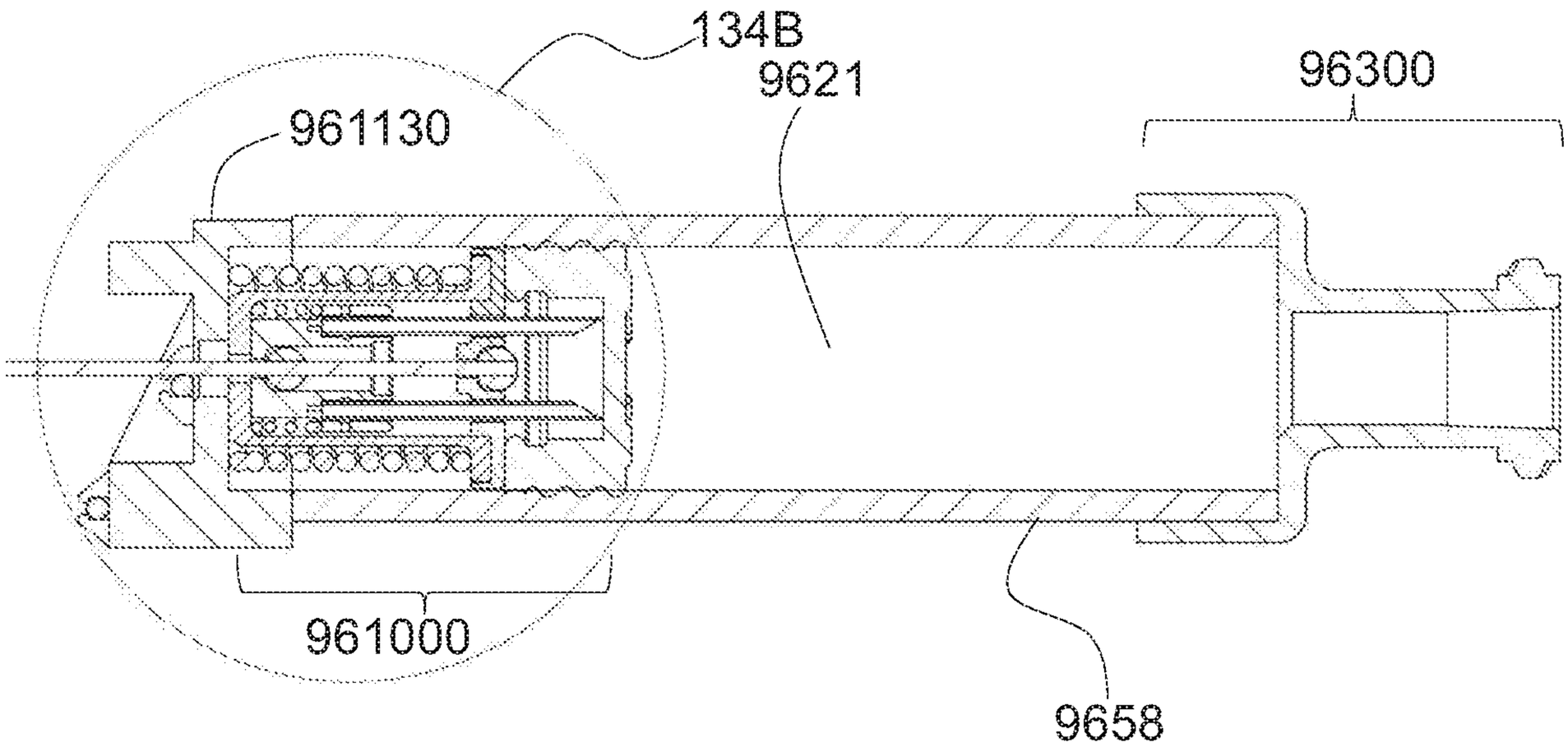


FIG. 134A

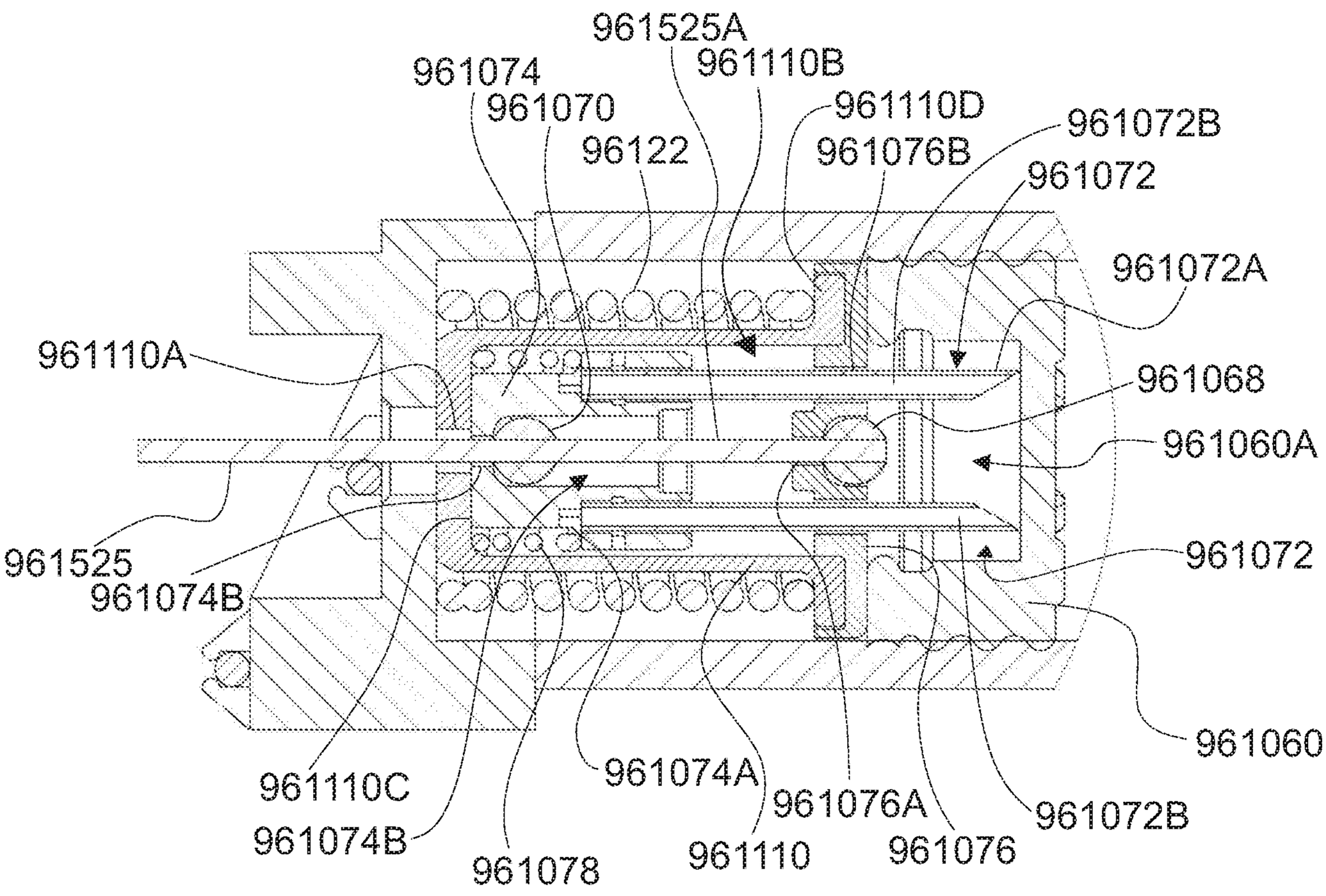


FIG. 134B

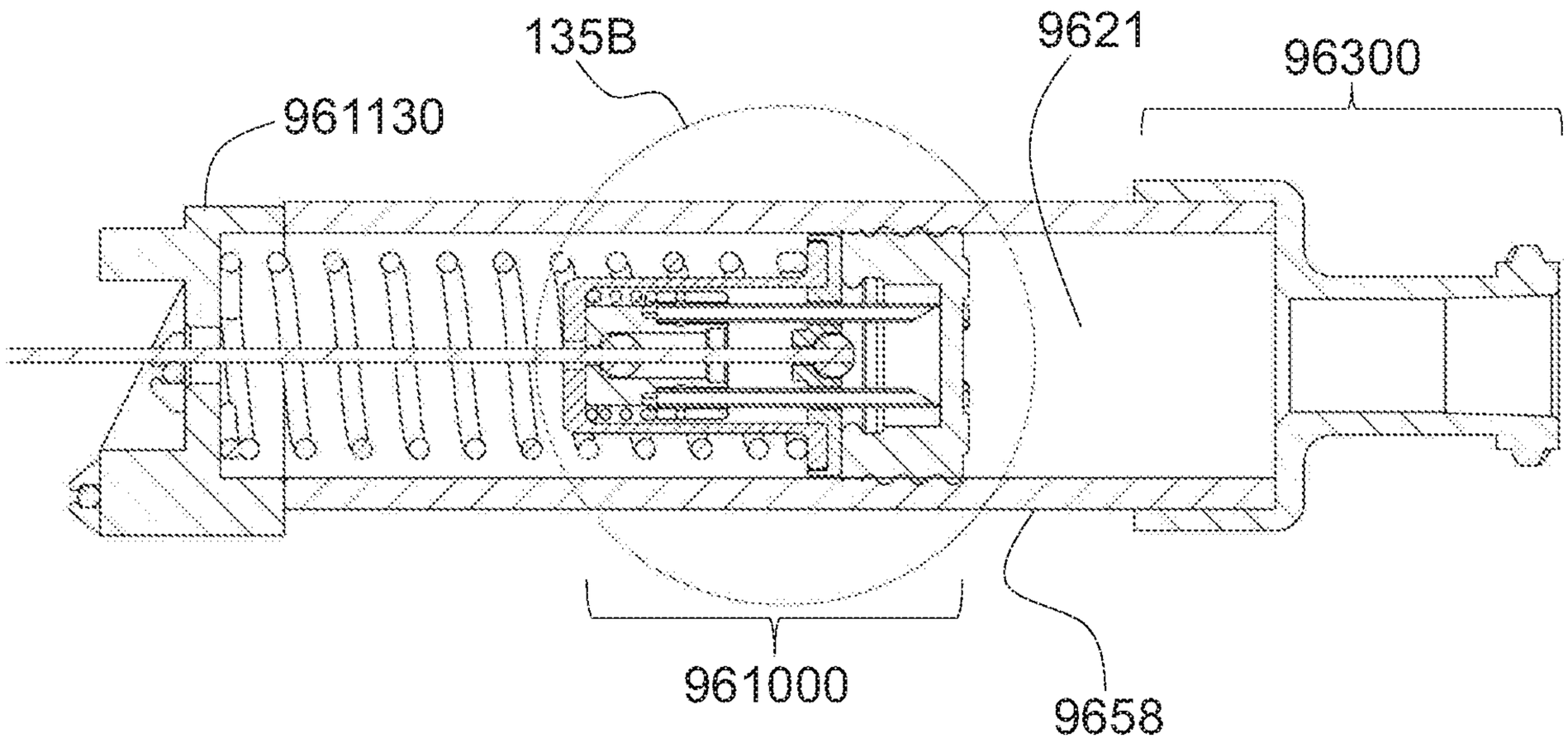


FIG. 135A

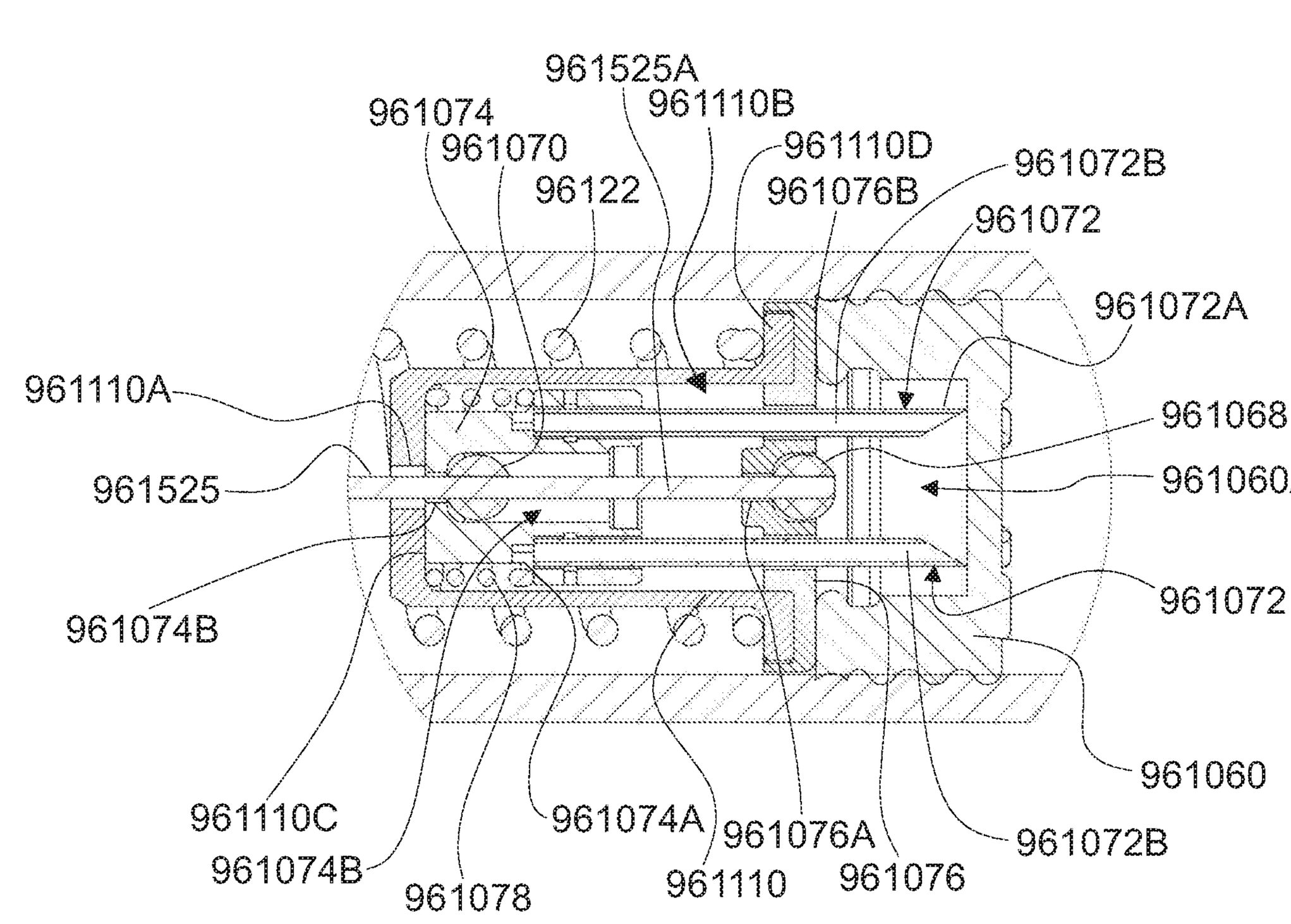


FIG. 135B

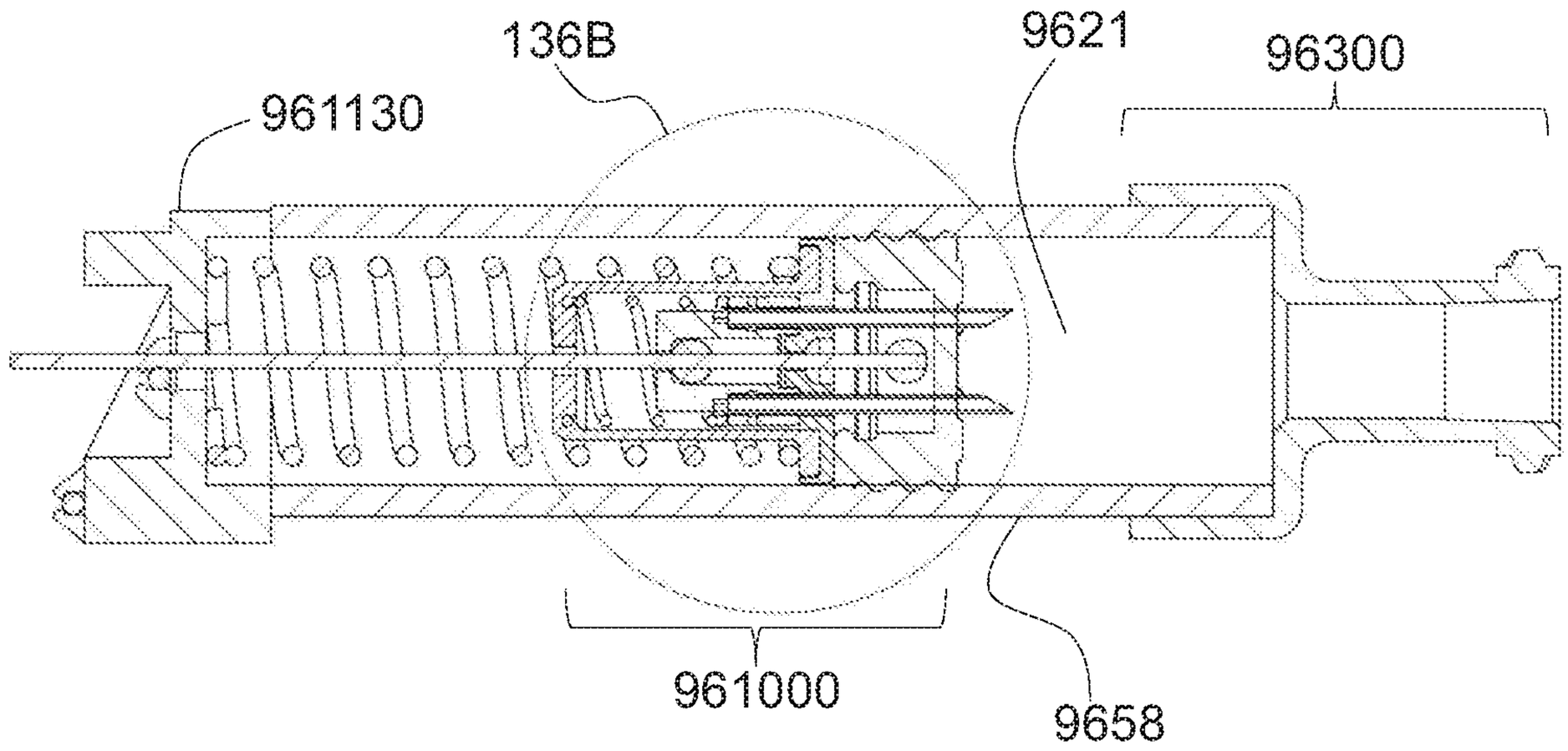


FIG. 136A

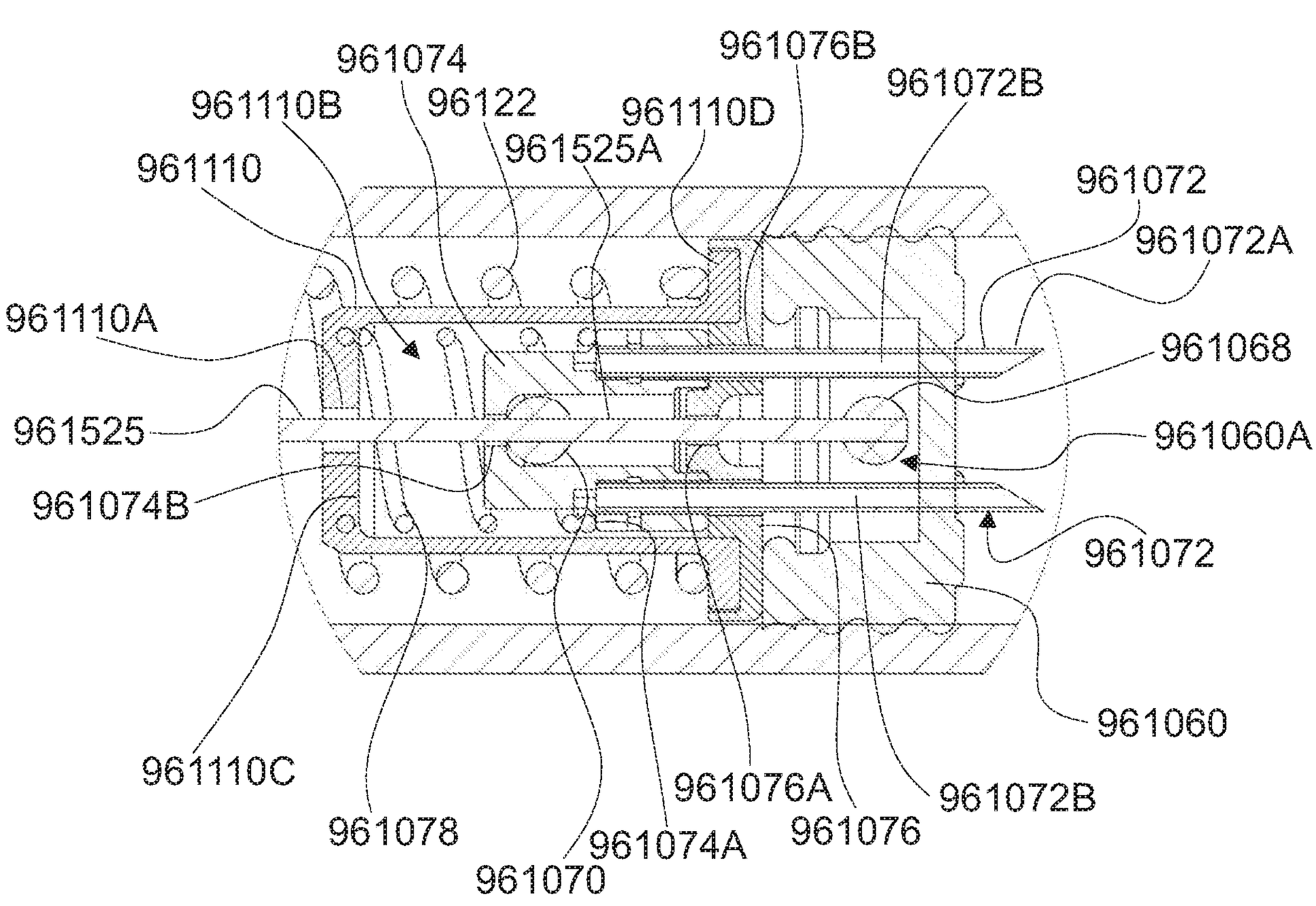


FIG. 136B

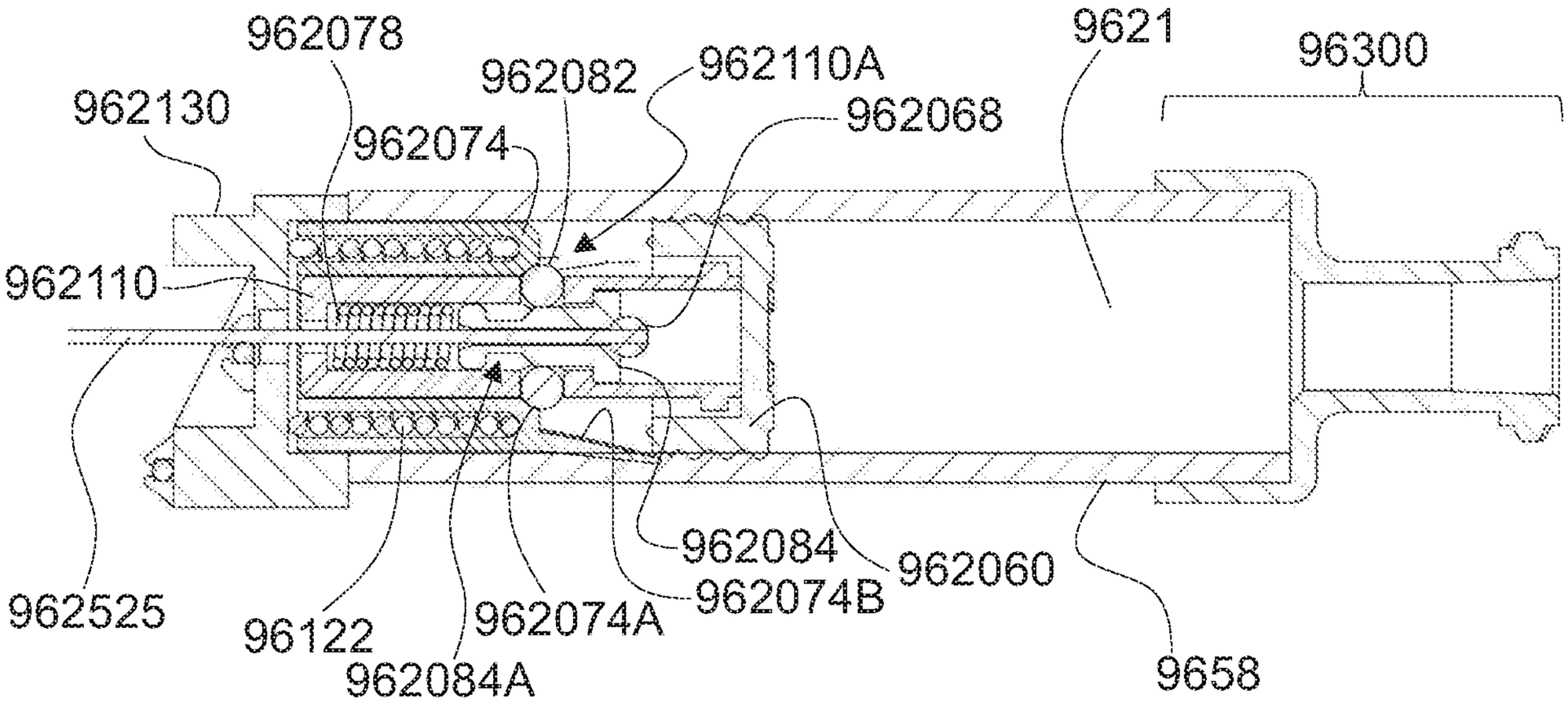


FIG. 137A

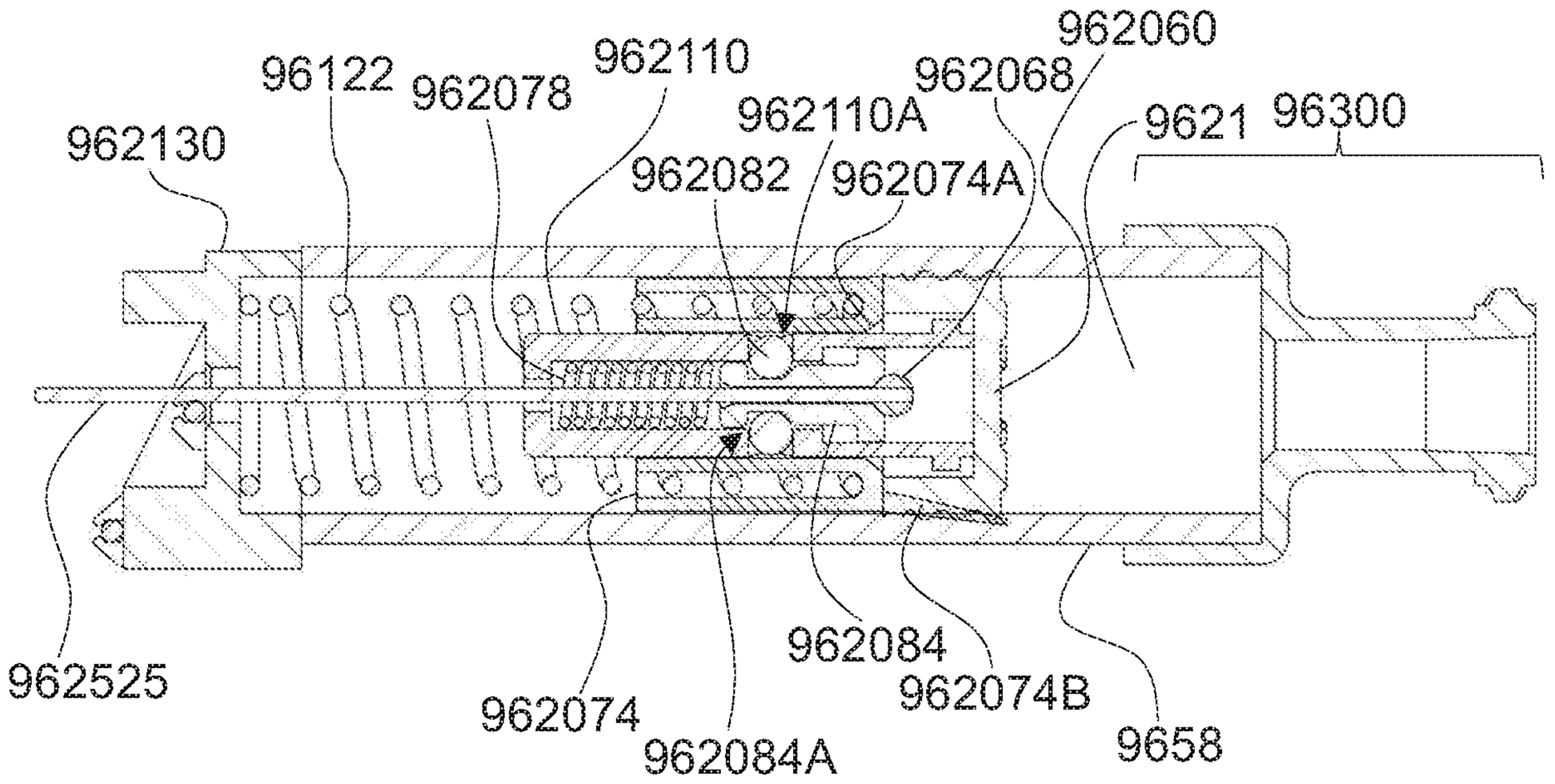


FIG. 137B

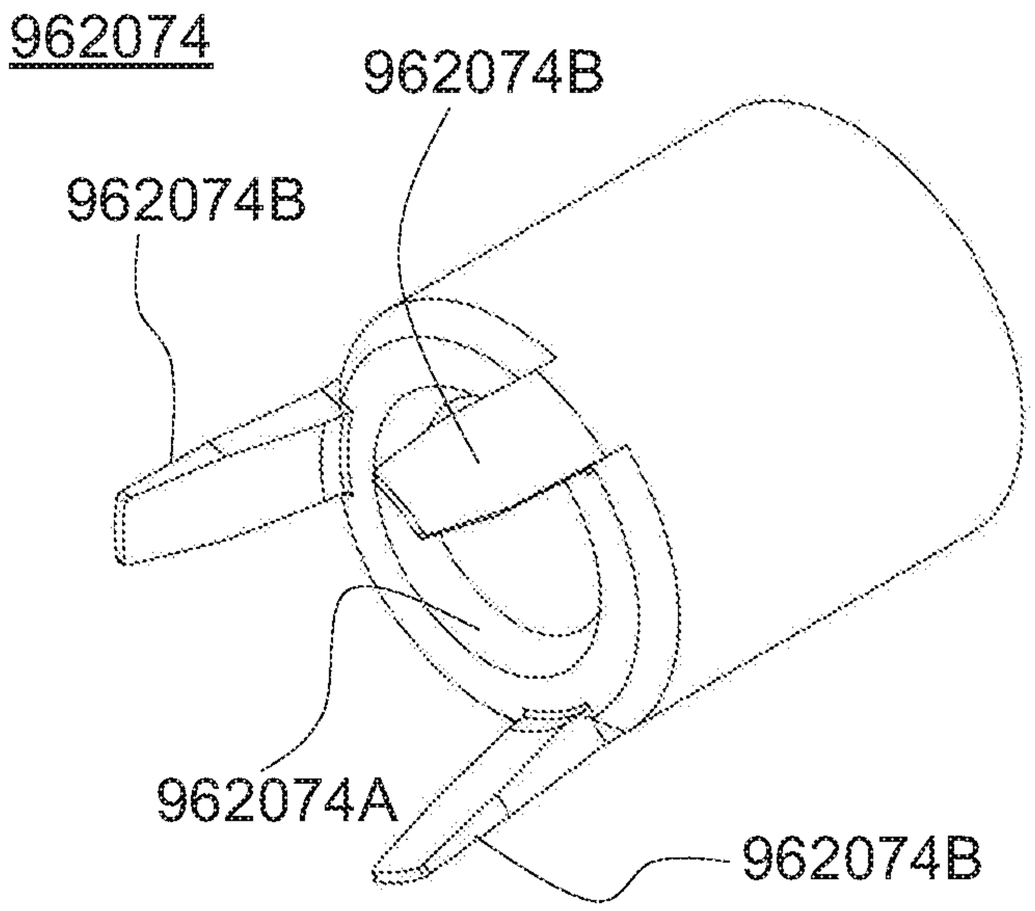


FIG. 138

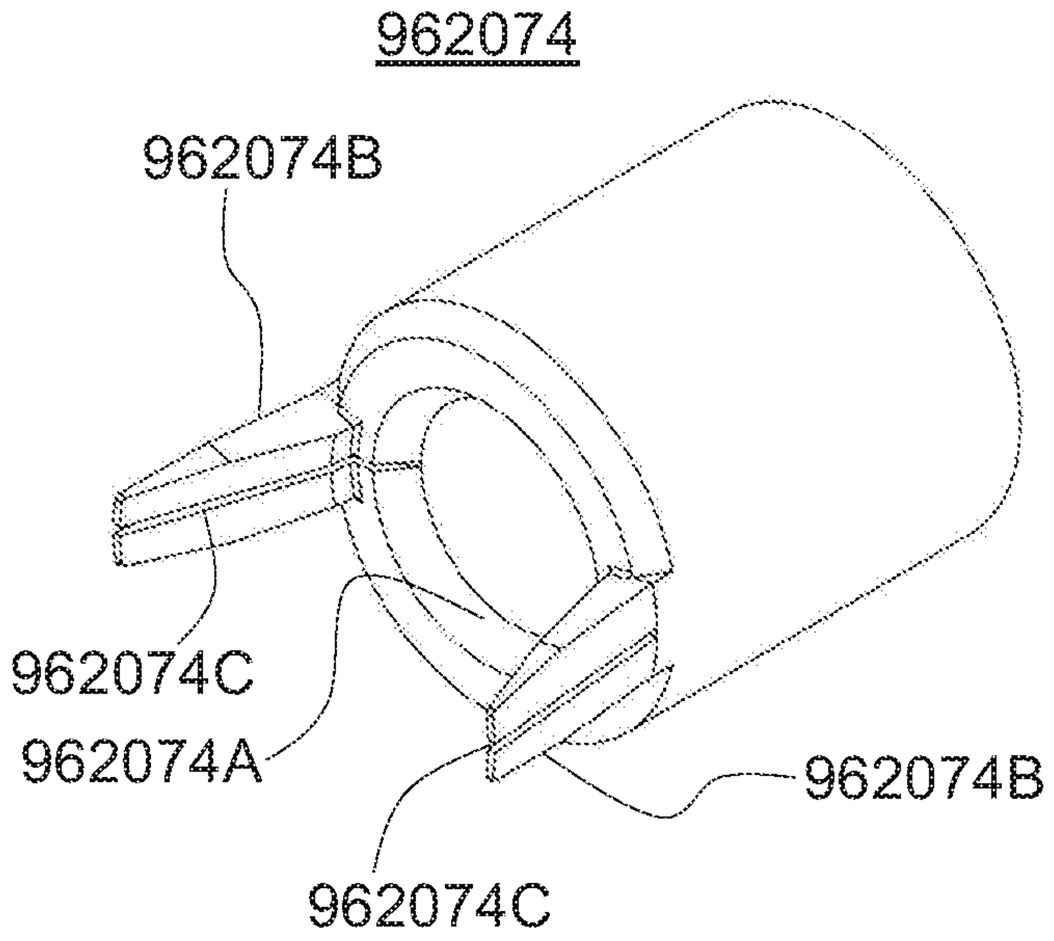


FIG. 139

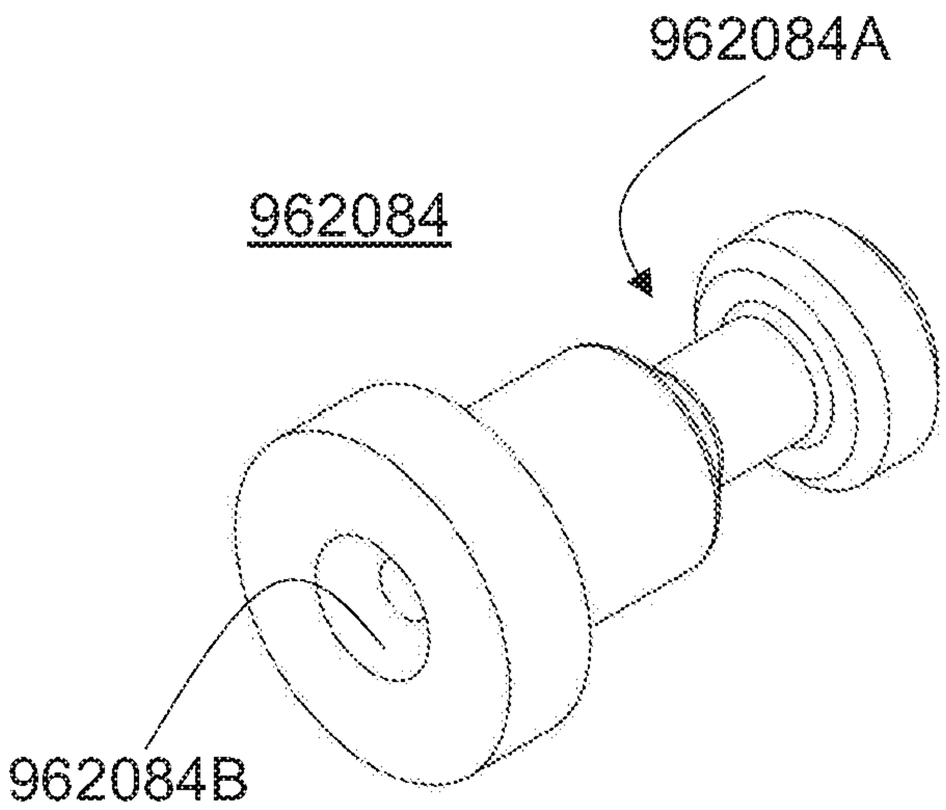


FIG. 140

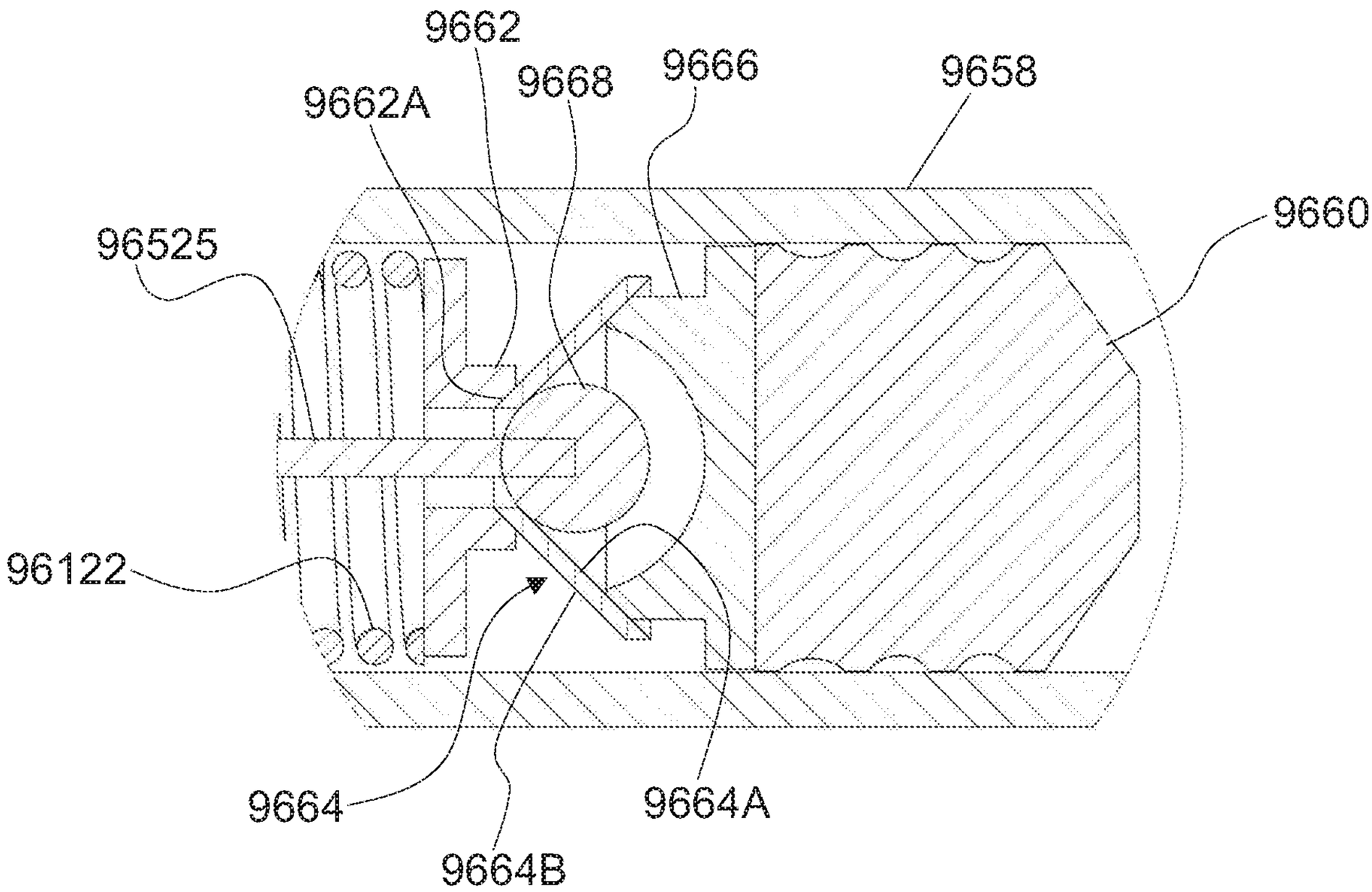


FIG. 141A

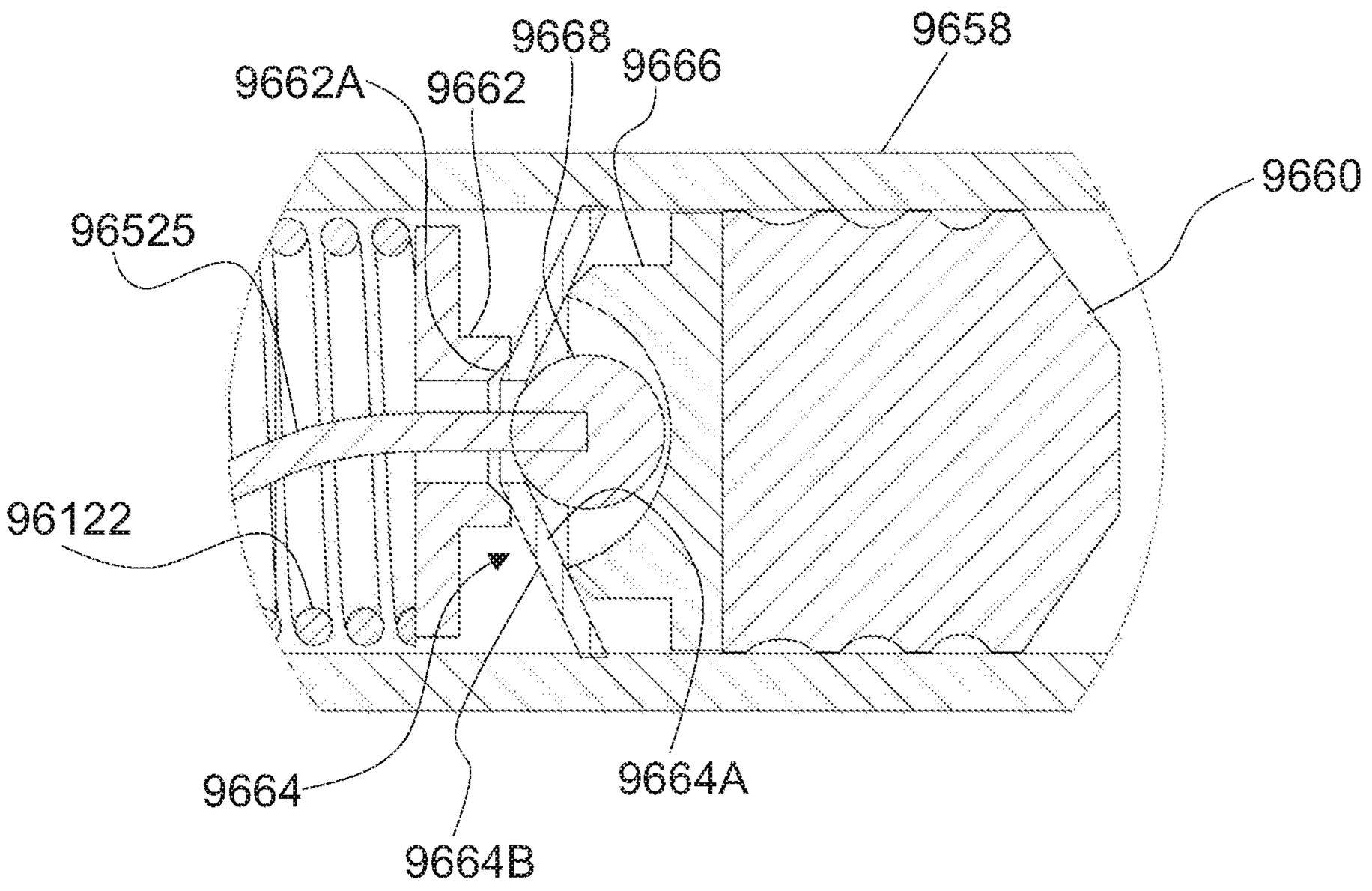


FIG. 141B

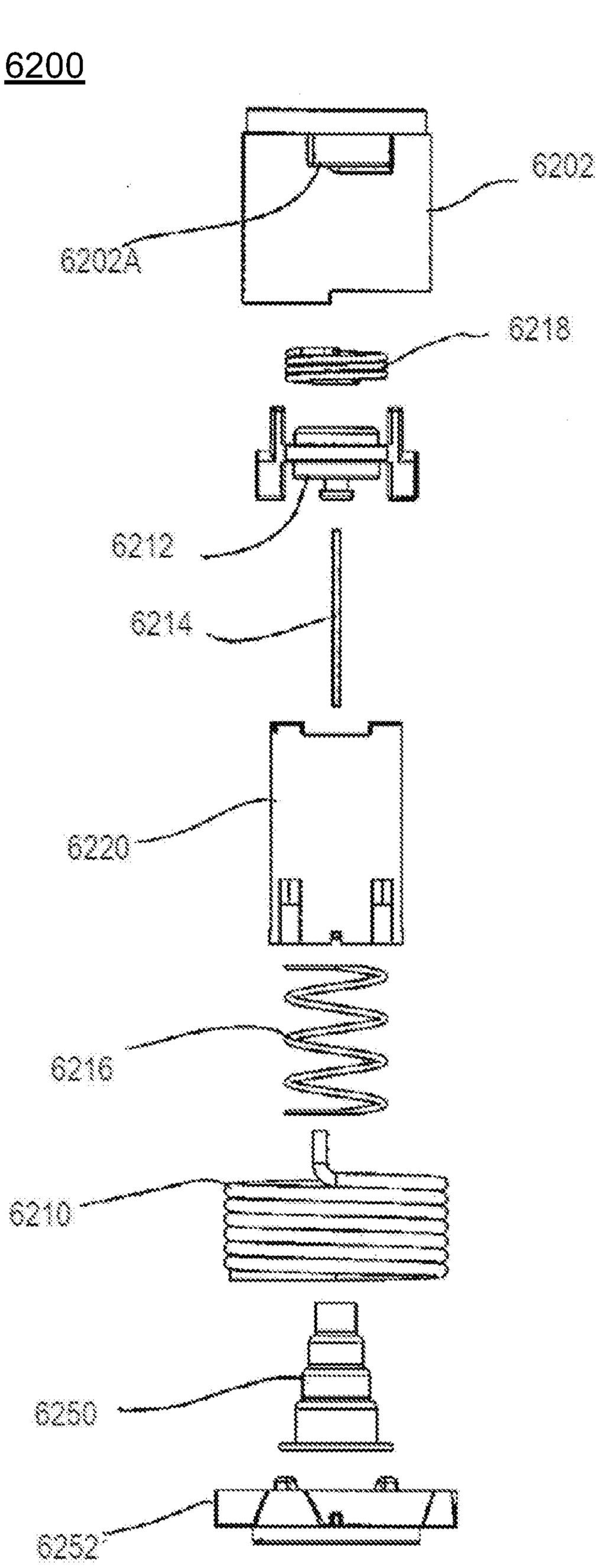


FIG. 142A

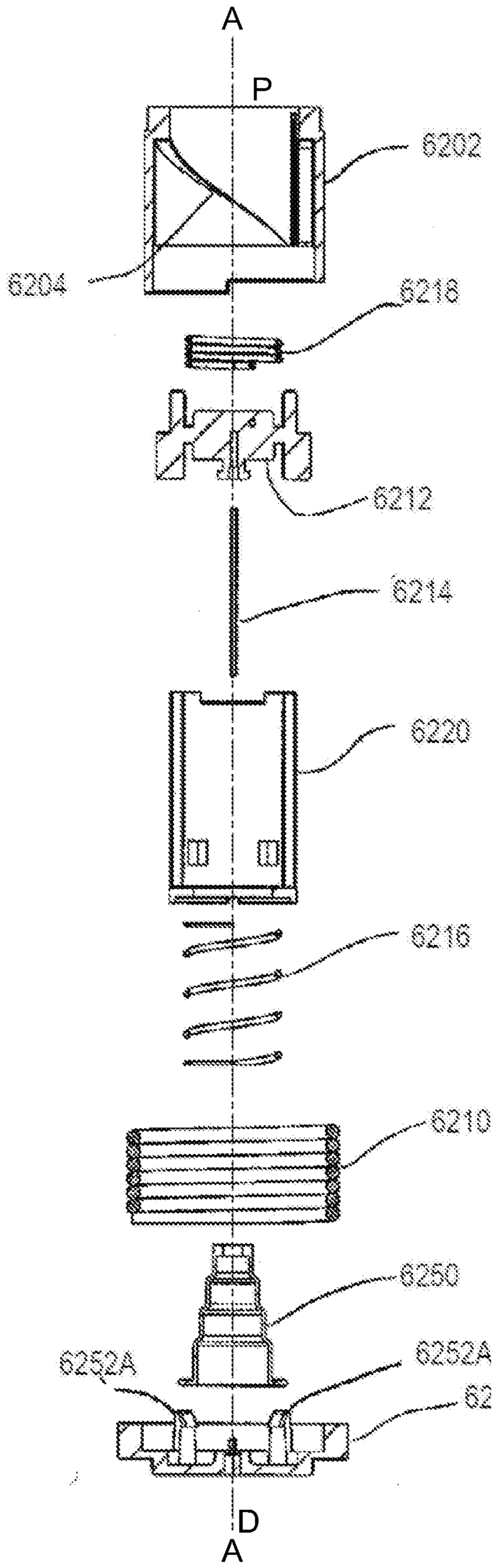


FIG. 142B

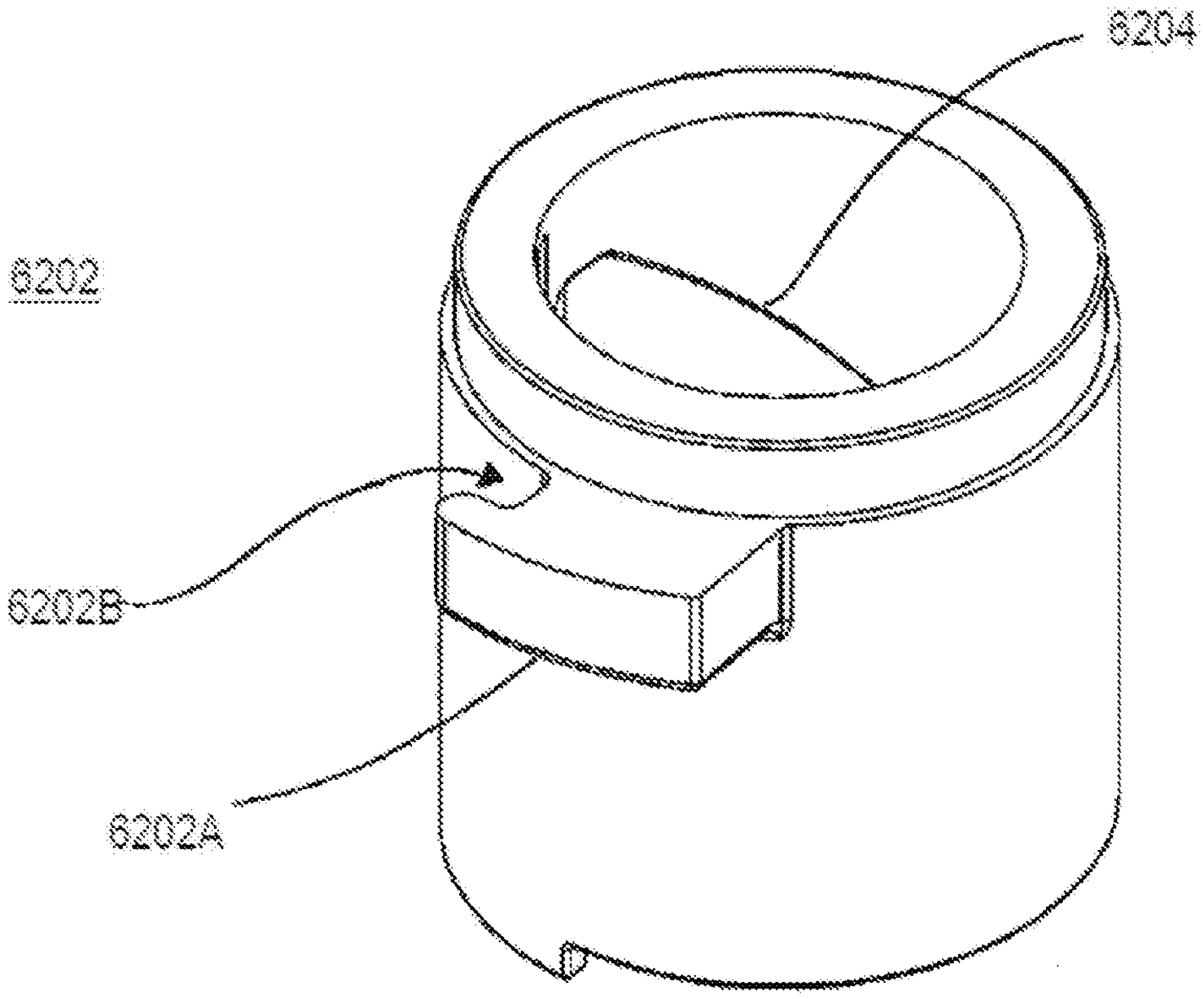


FIG. 143A

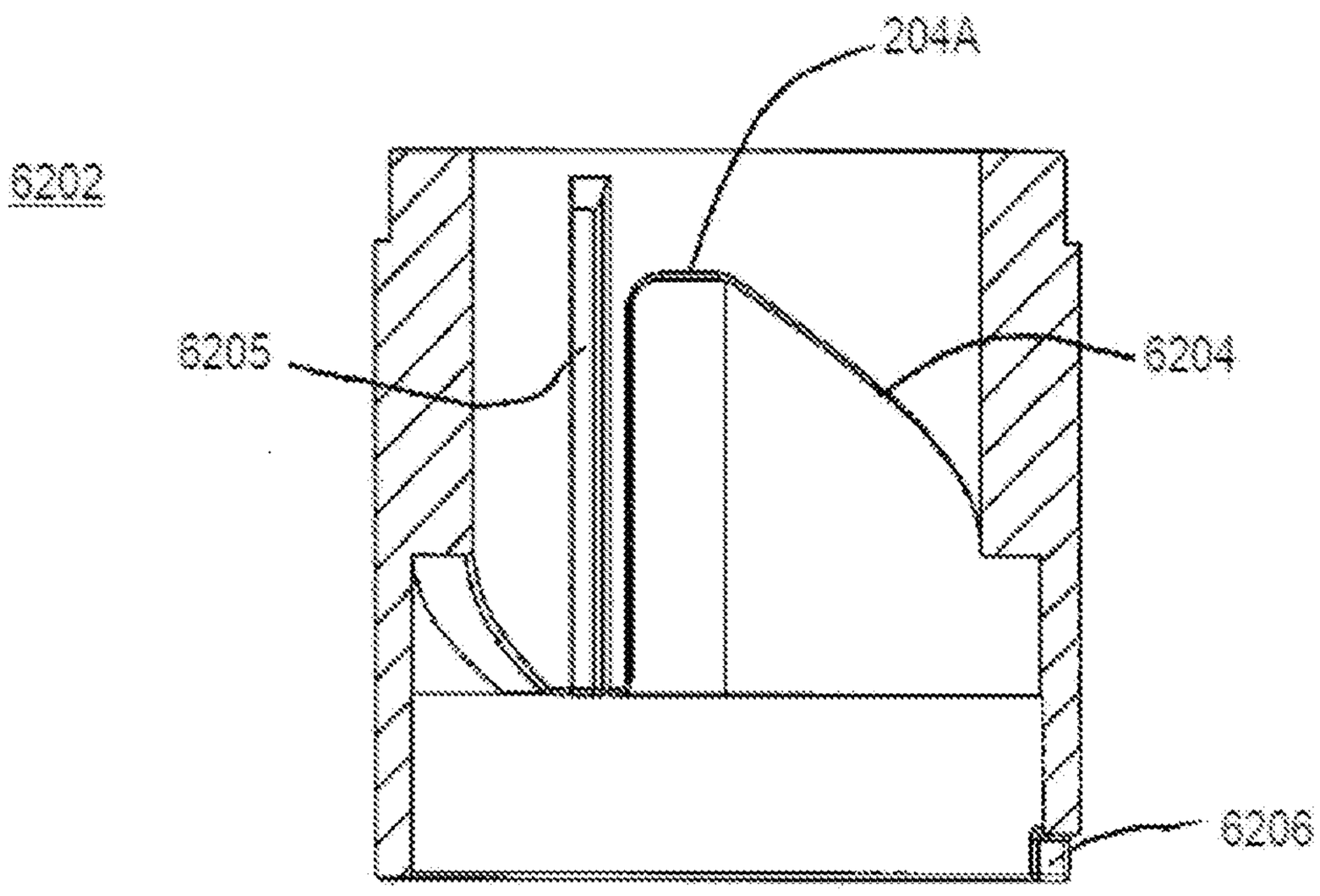


FIG. 143B

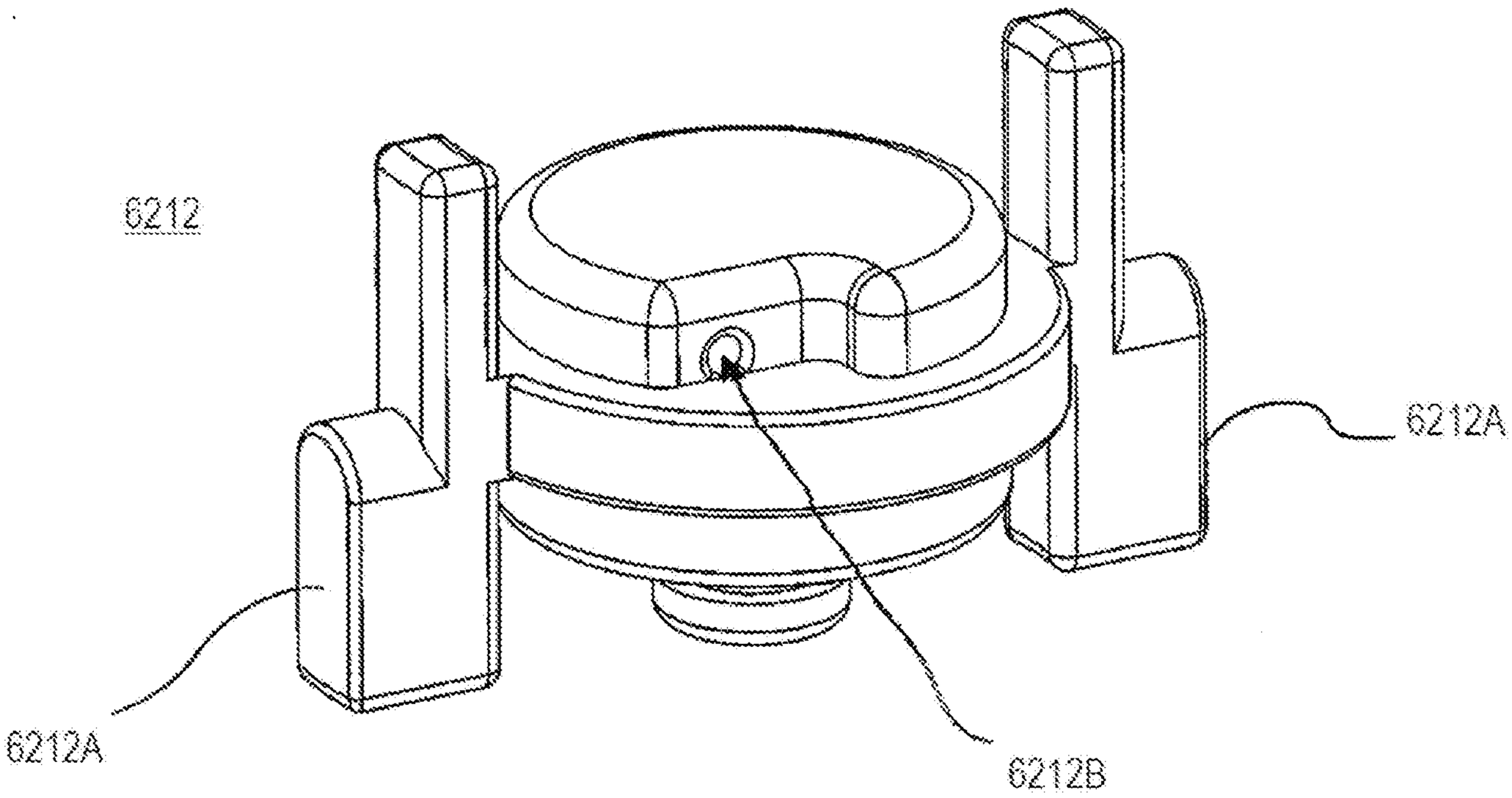


FIG. 144

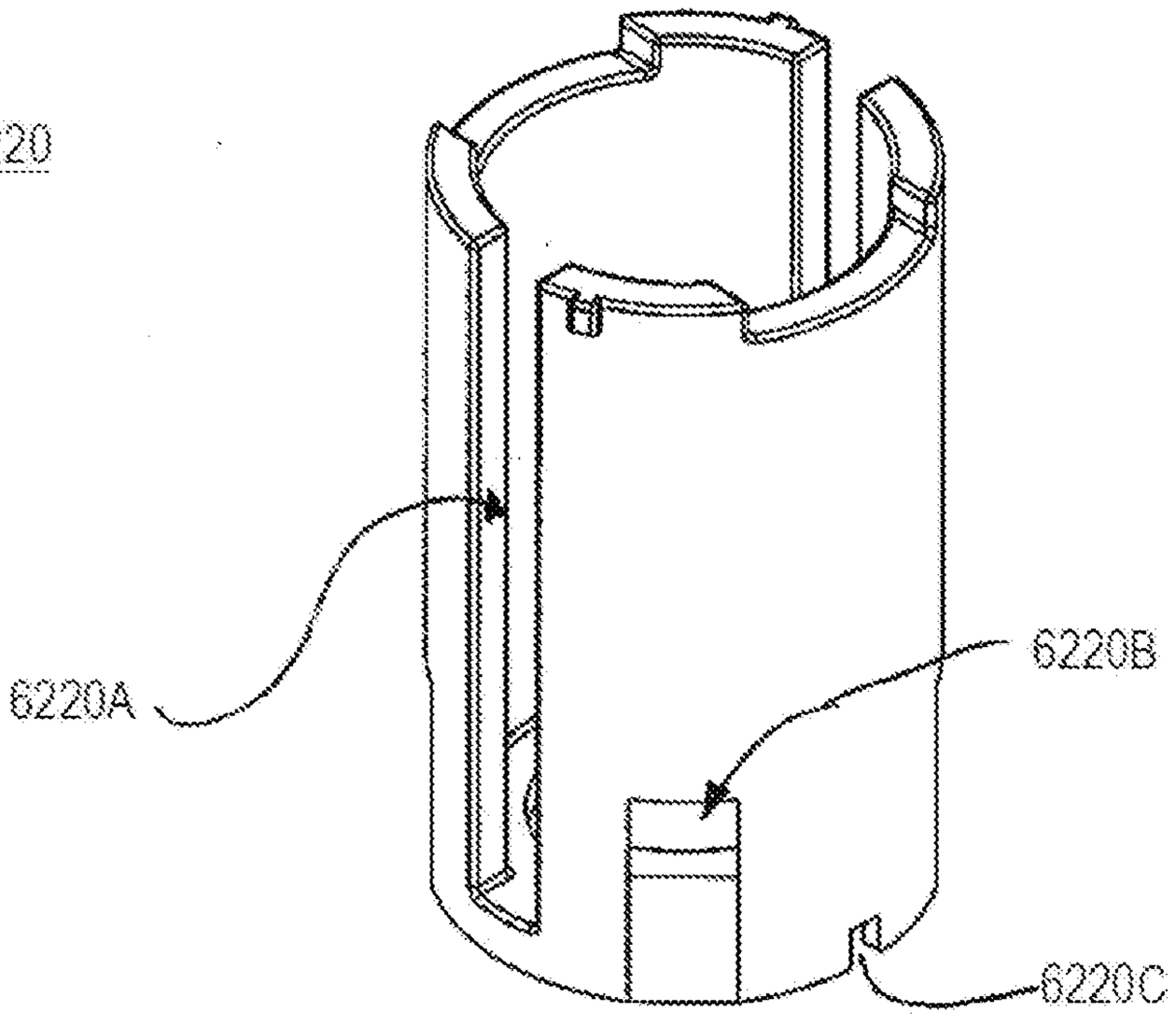


FIG. 145

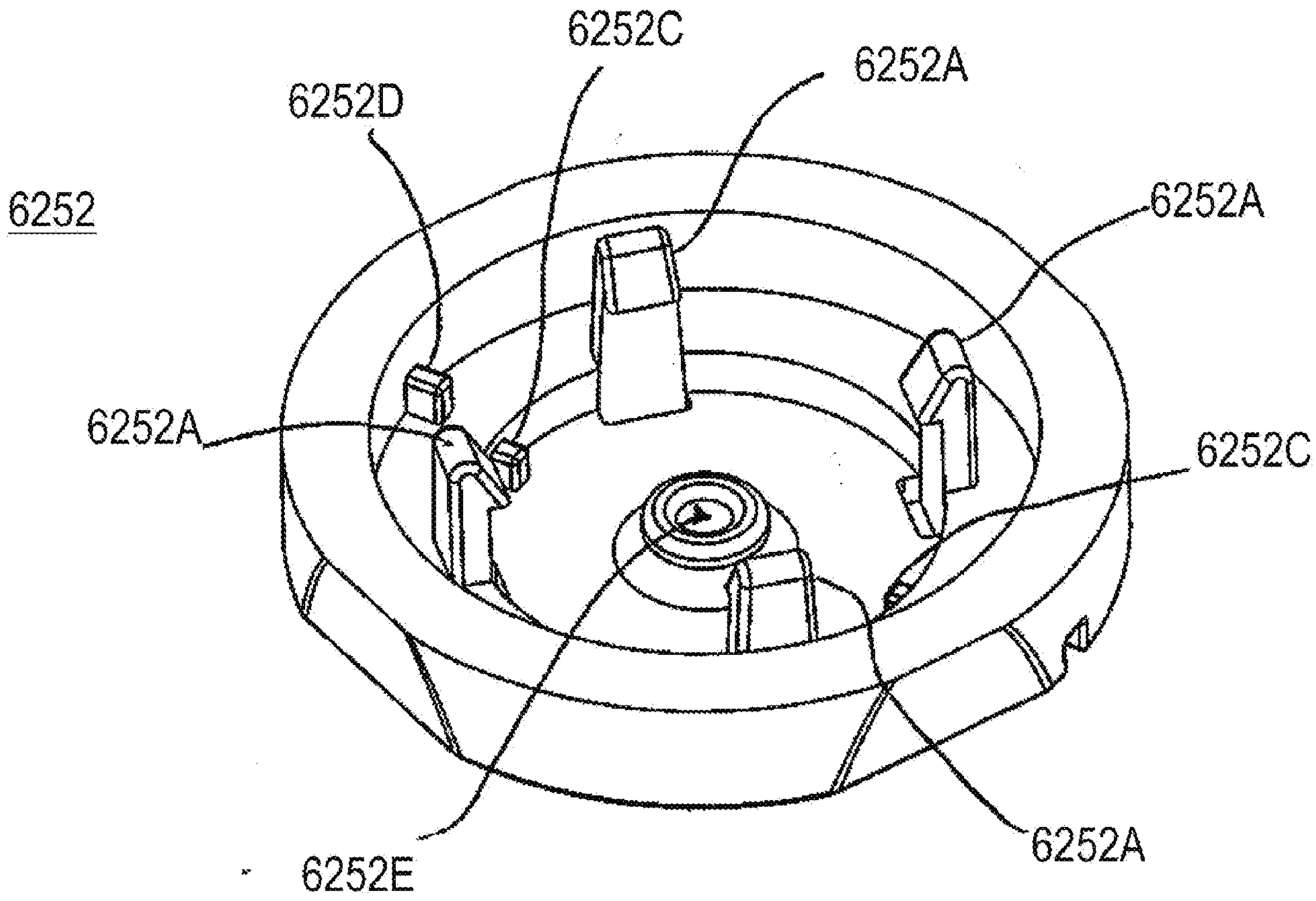


FIG. 146

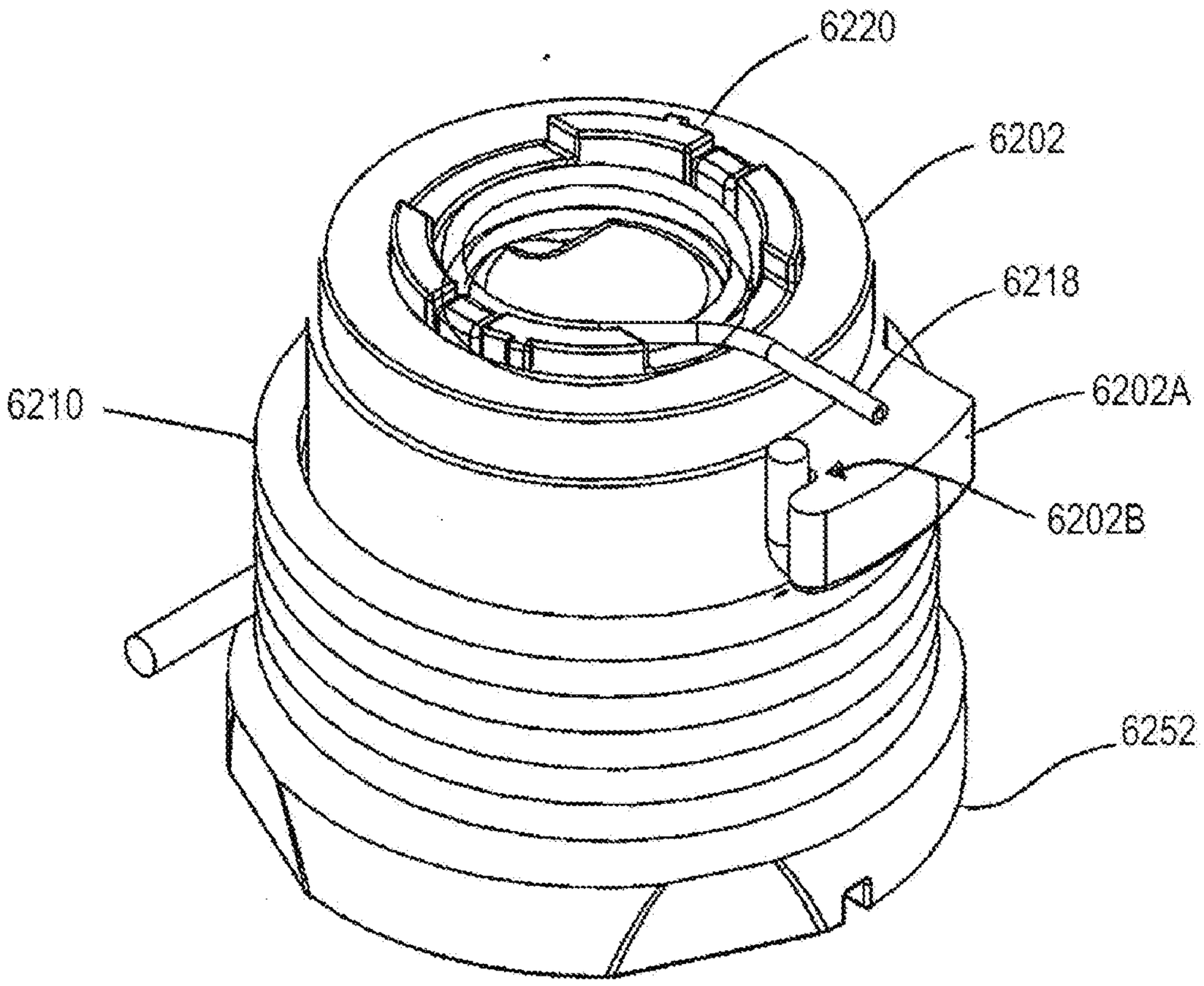


FIG. 147A

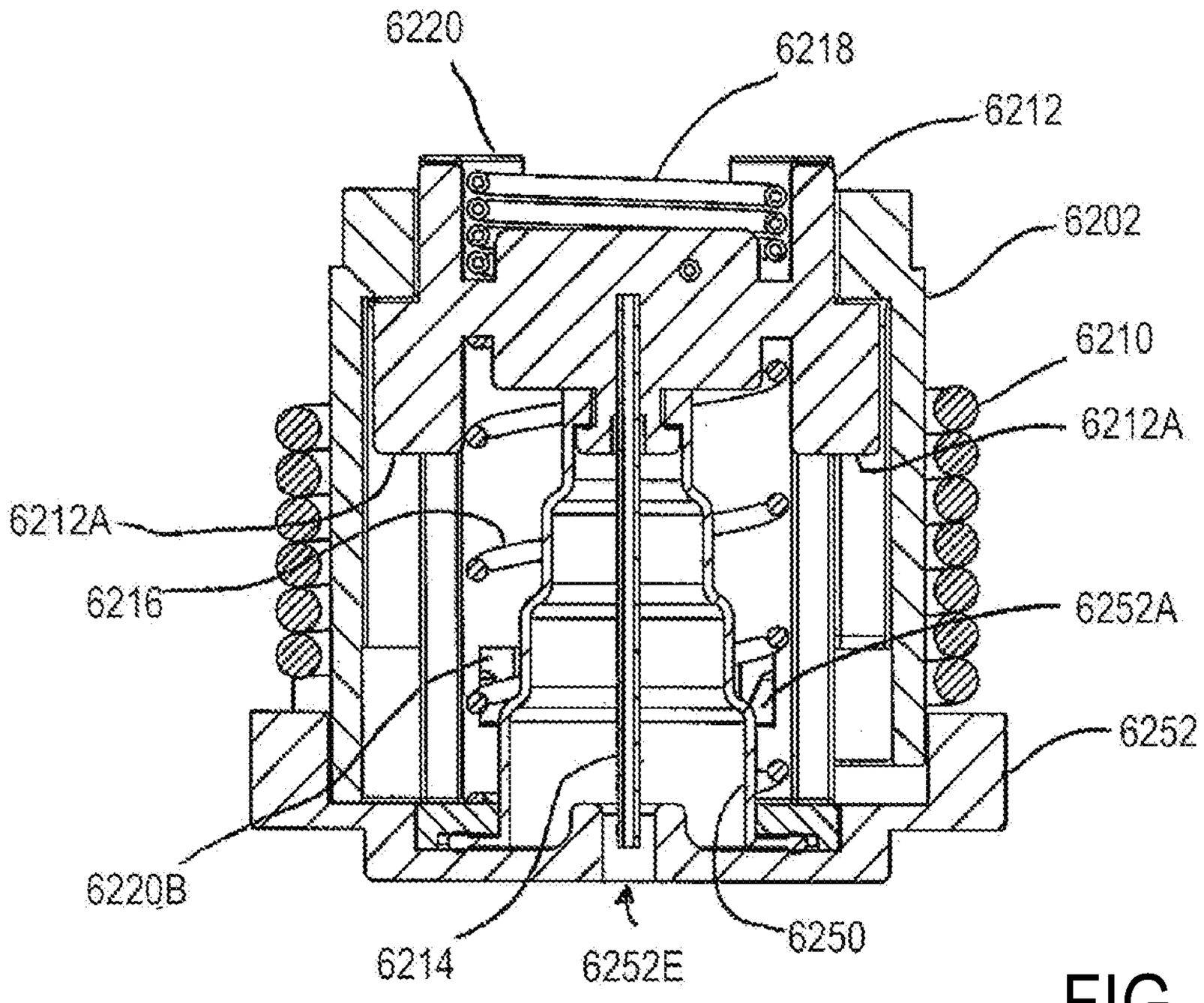


FIG. 147B

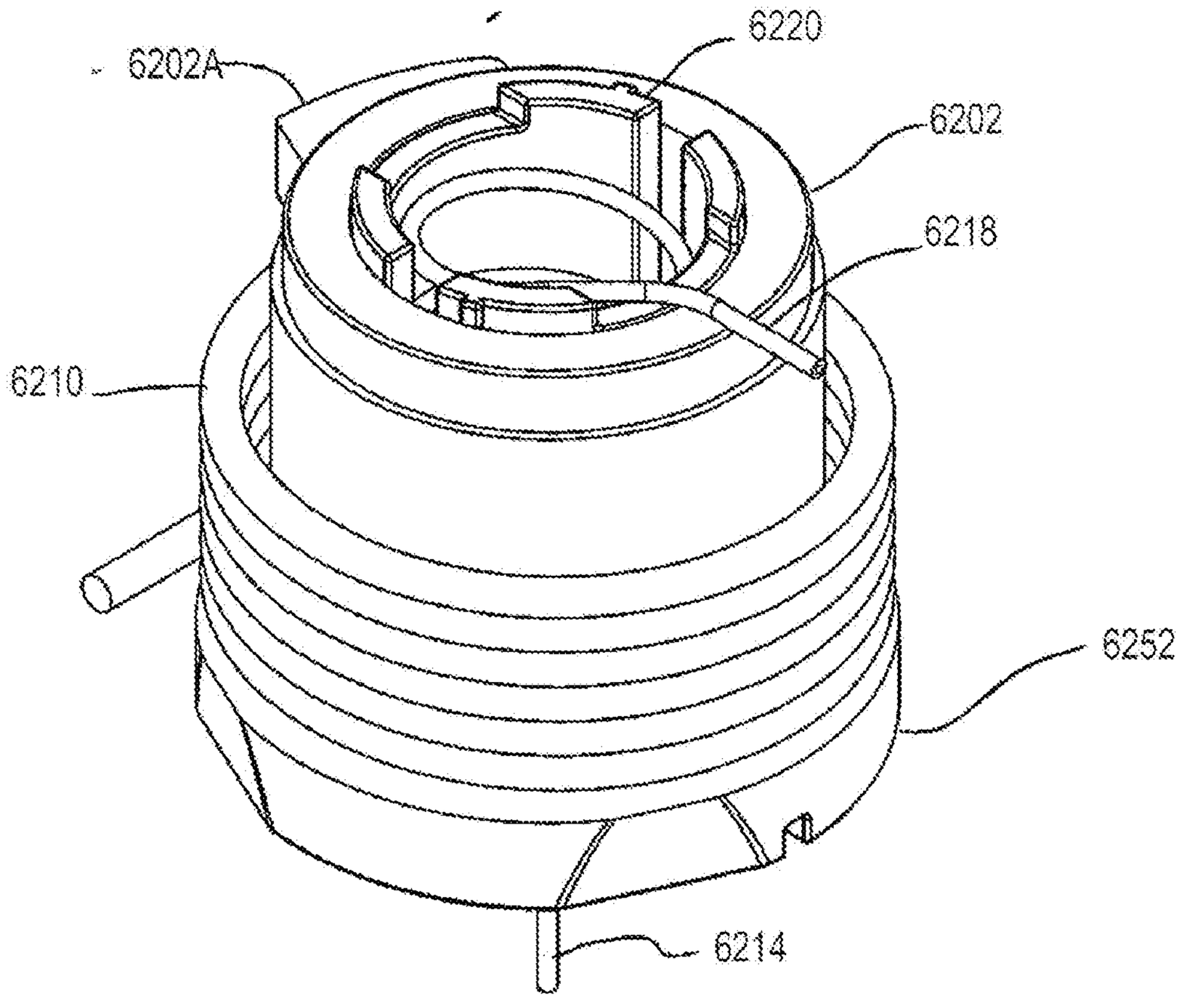


FIG. 148A

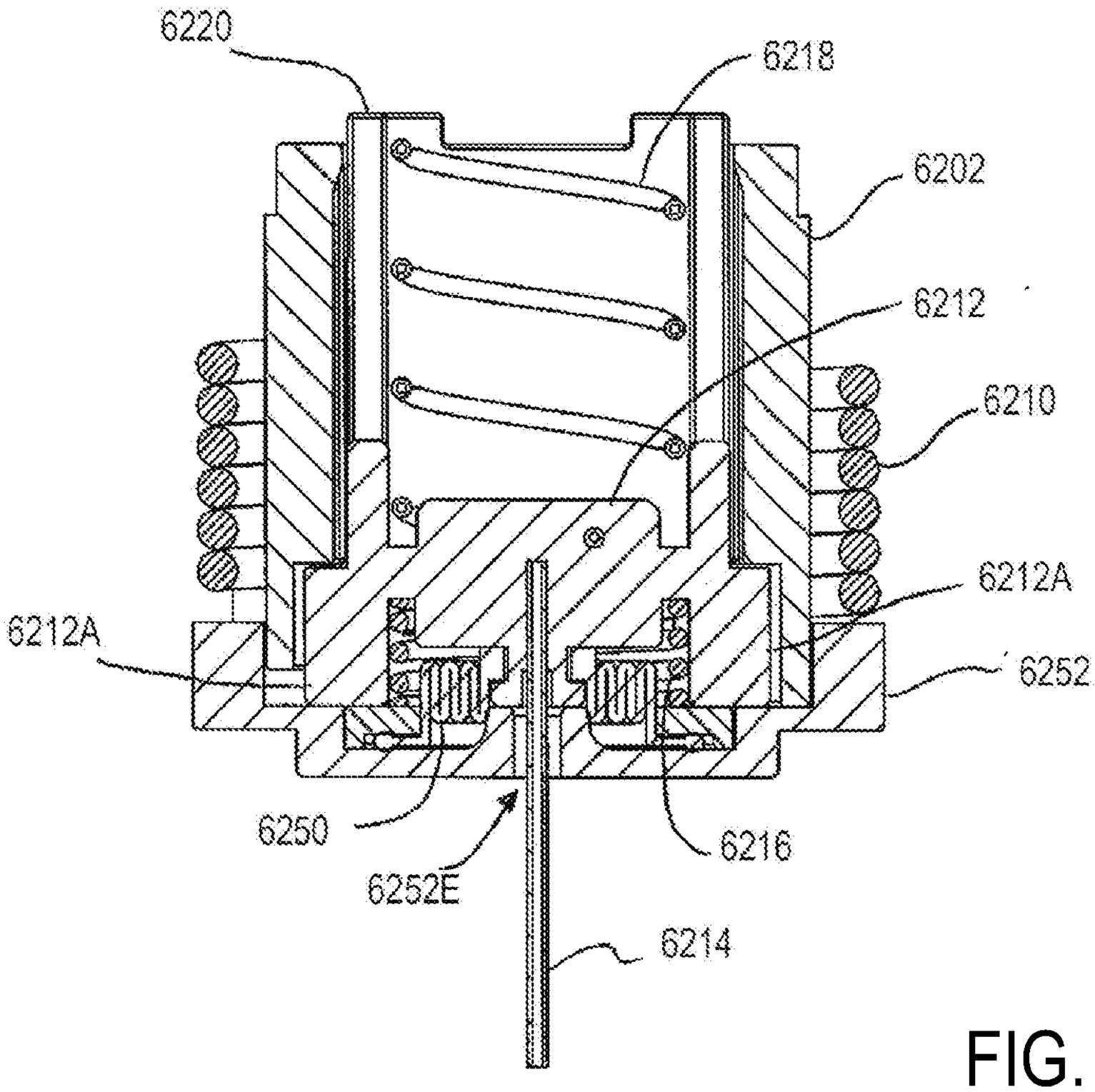


FIG. 148B

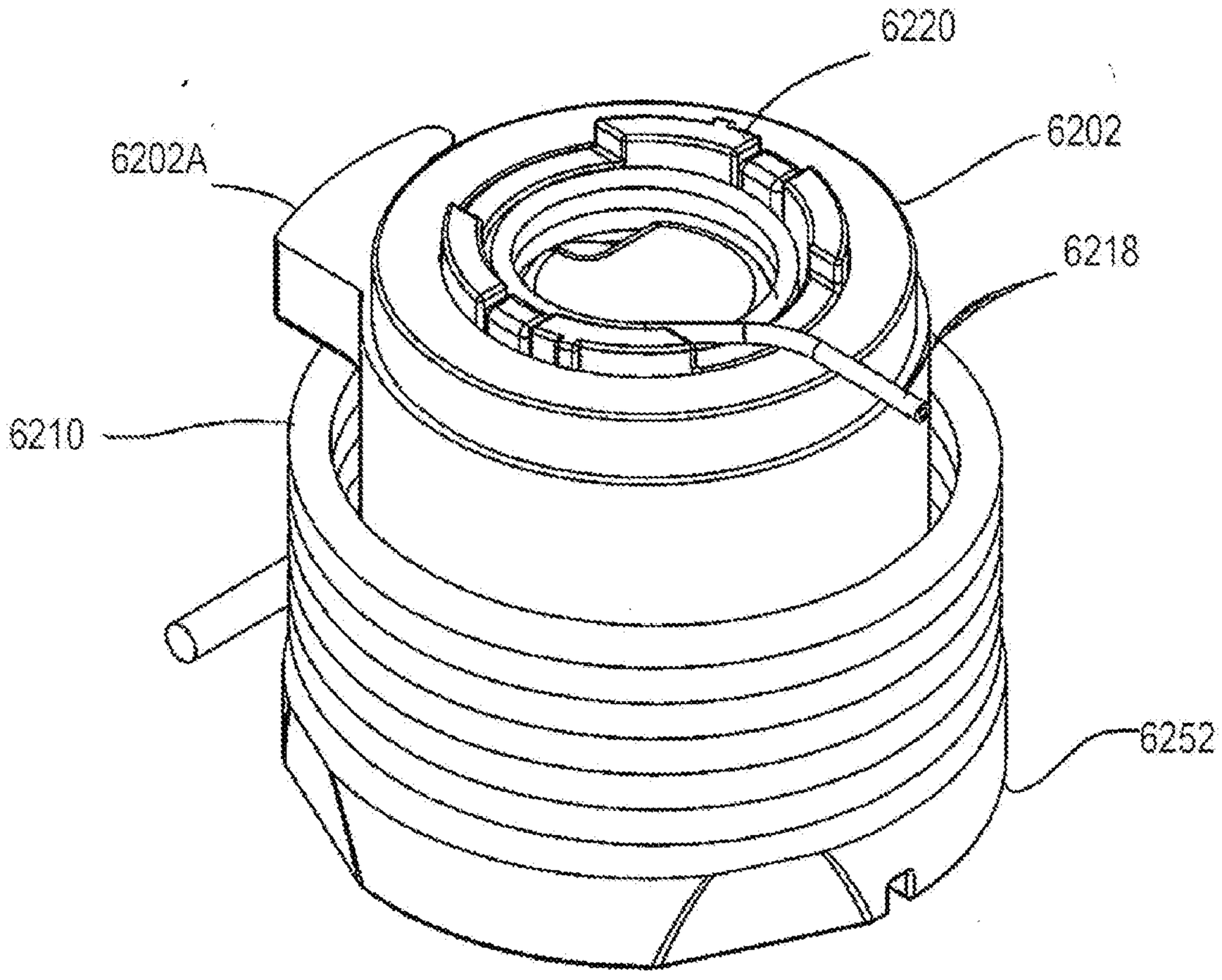


FIG. 149A

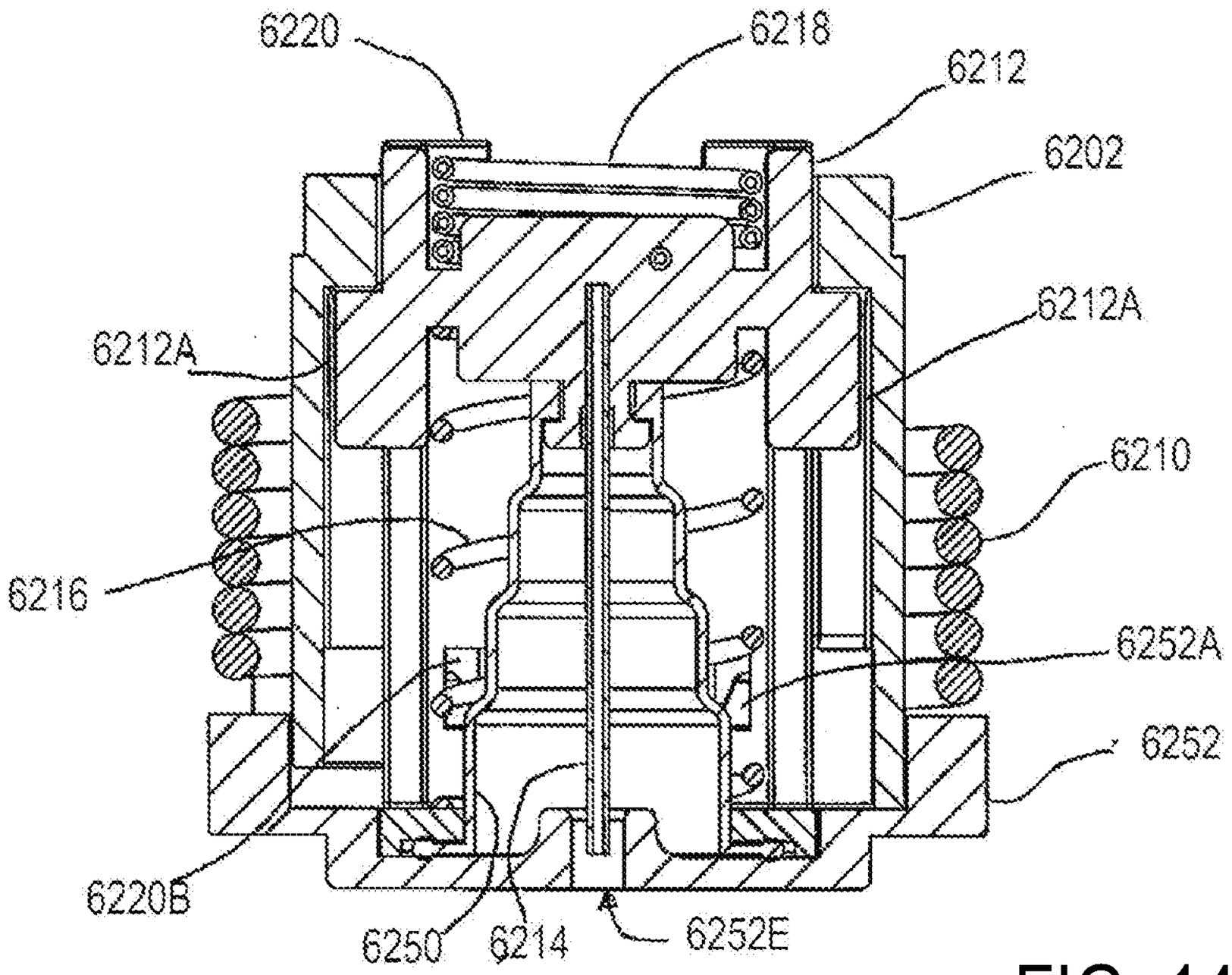


FIG. 149B

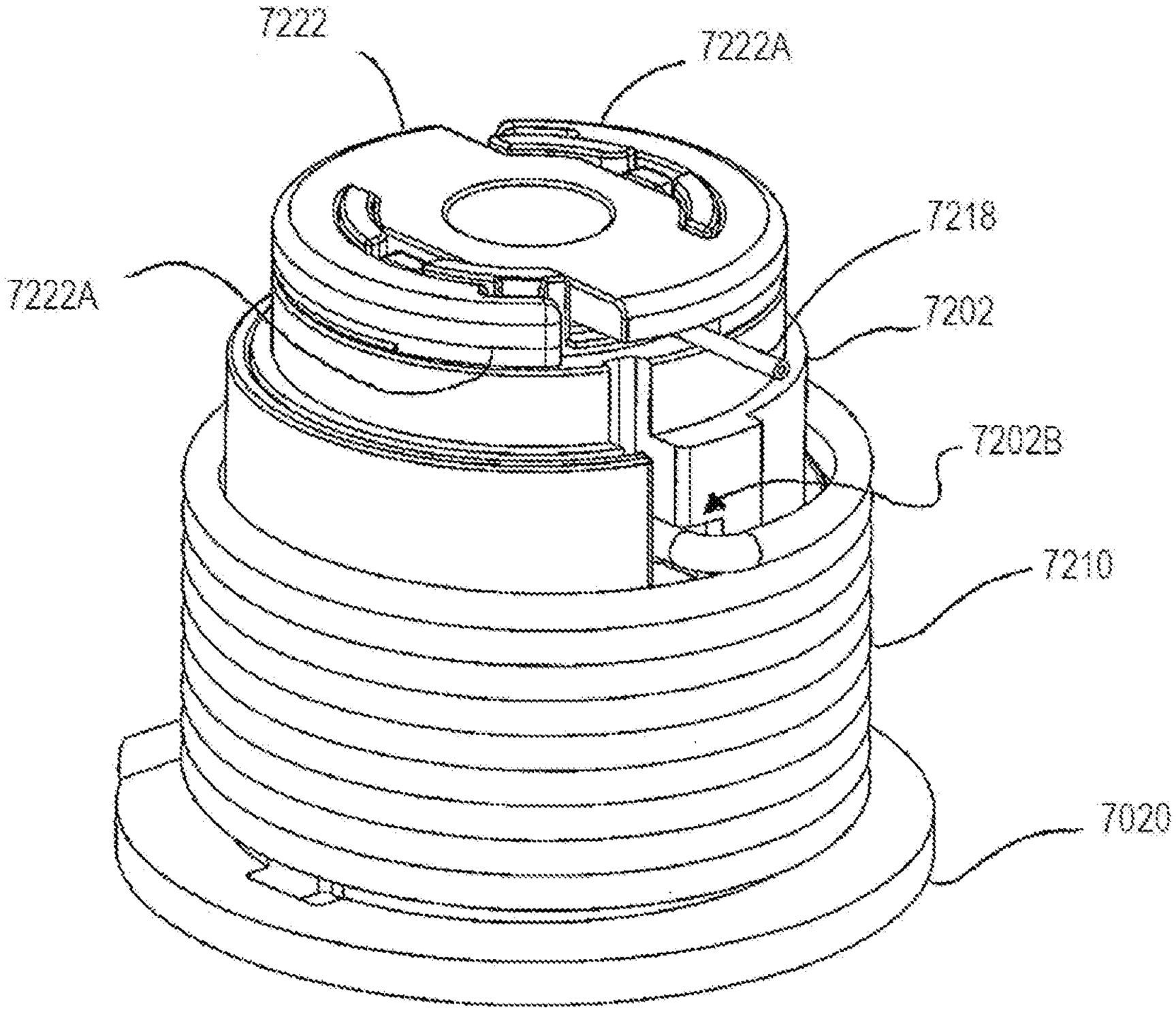


FIG. 150

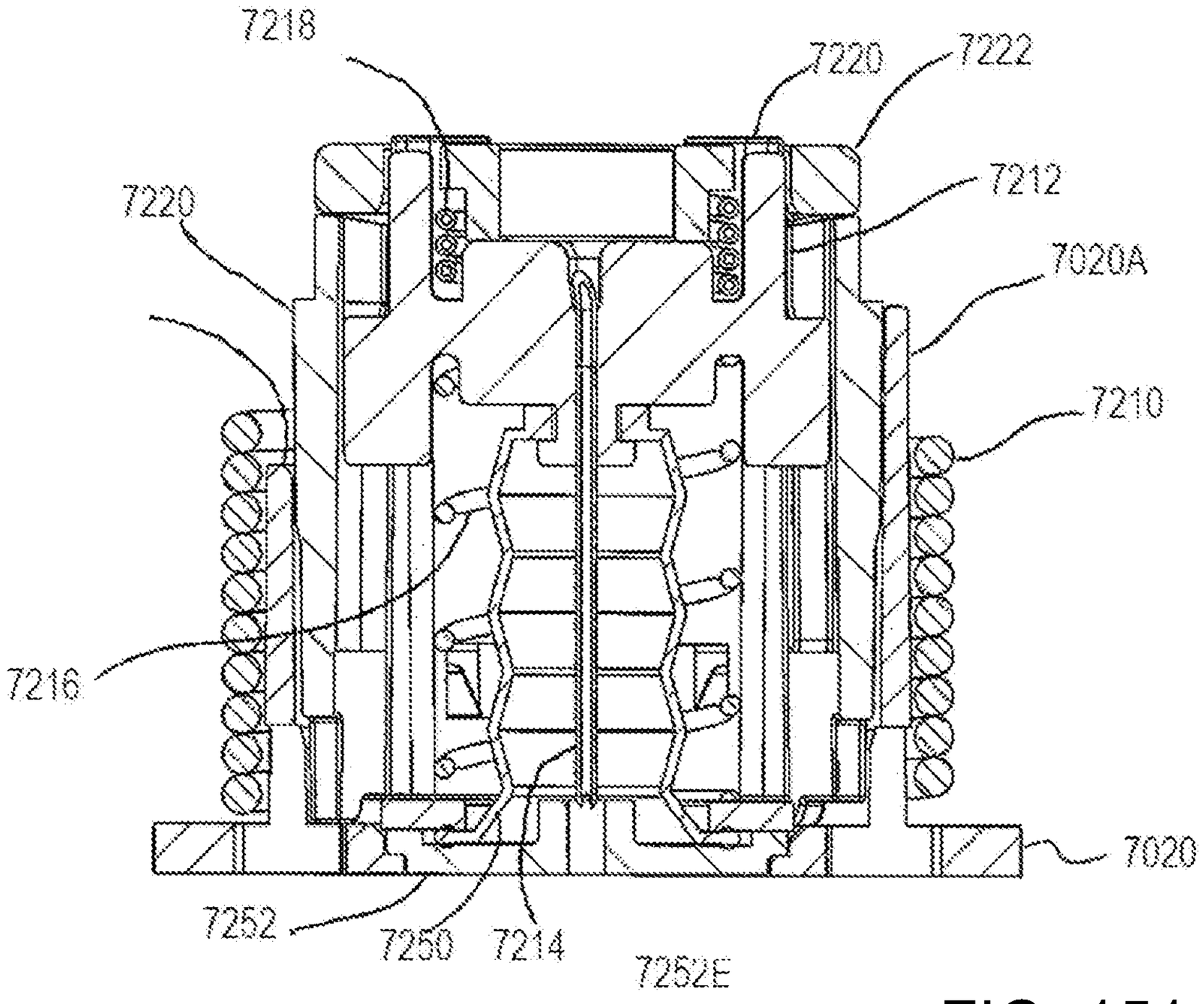


FIG. 151

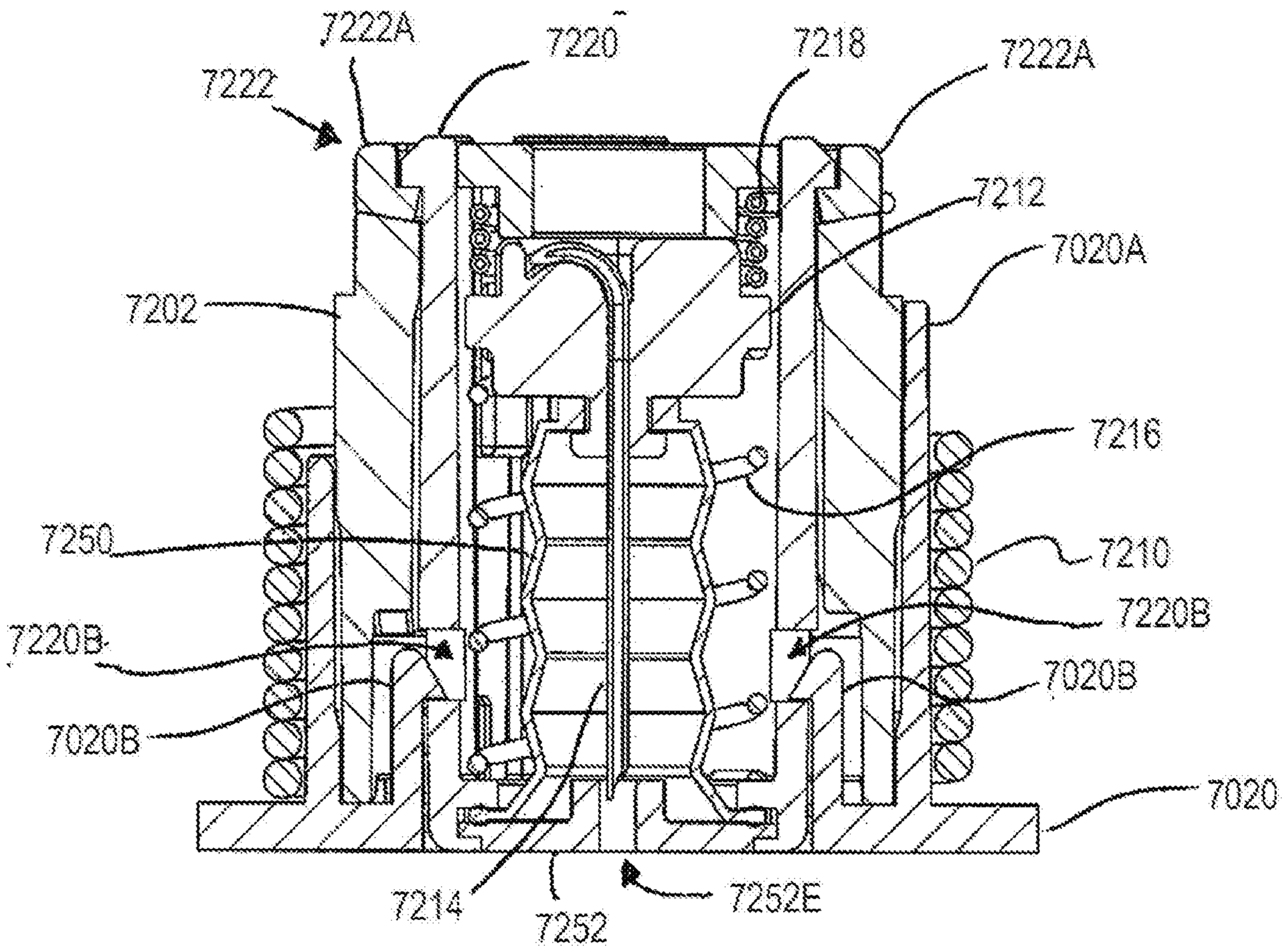

7222A
7220
7218
7222A
7222
7212
7020A
7202
7216
7250
7210
7220B
7220B
7020B
7020B
7020
7214
7252
7252E

FIG. 152

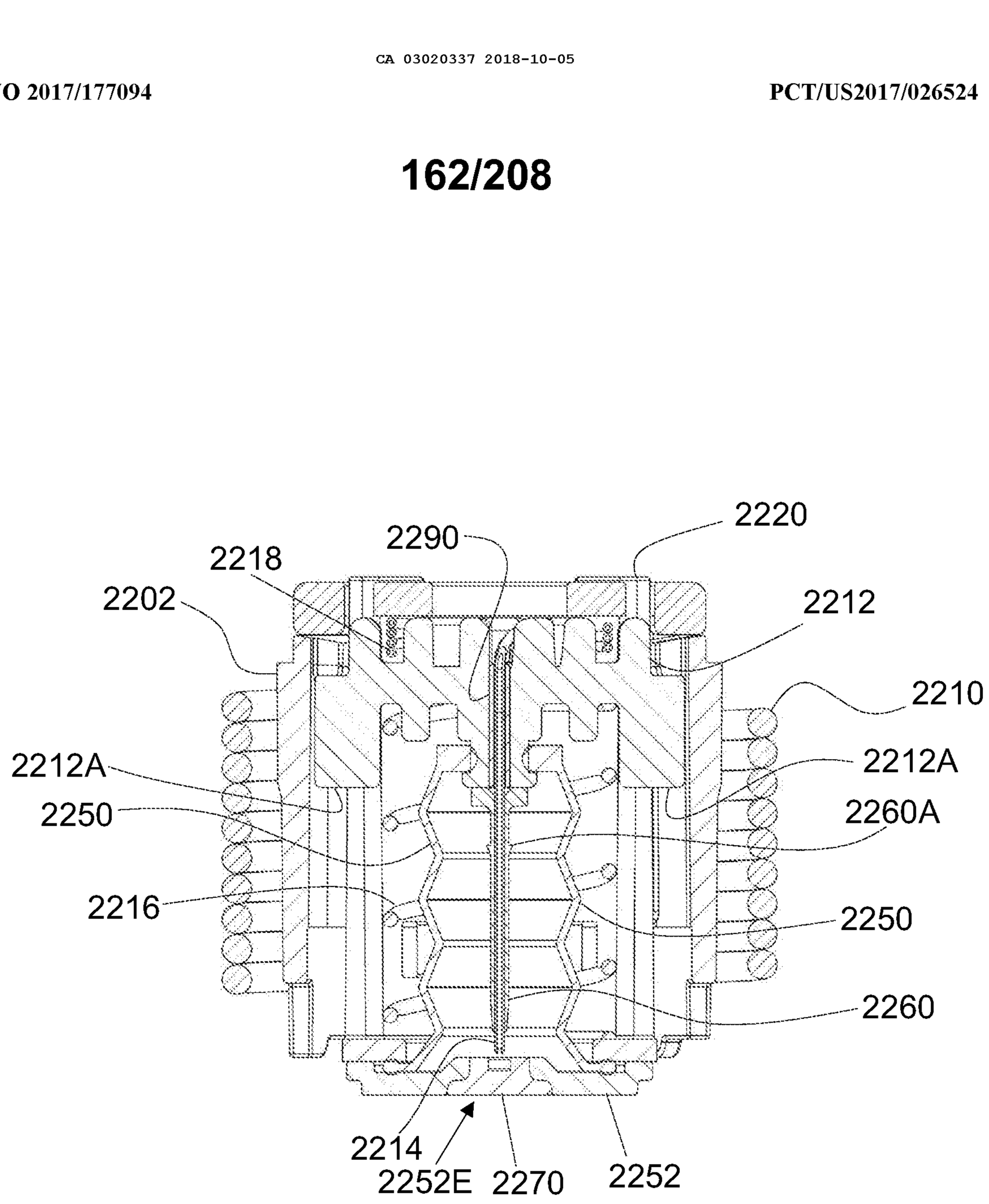

2220
2290
2218
2202
2212
2210
2212A
2212A
2250
2260A
2216
2250
2260
2214
2252E
2270
2252

FIG. 153A

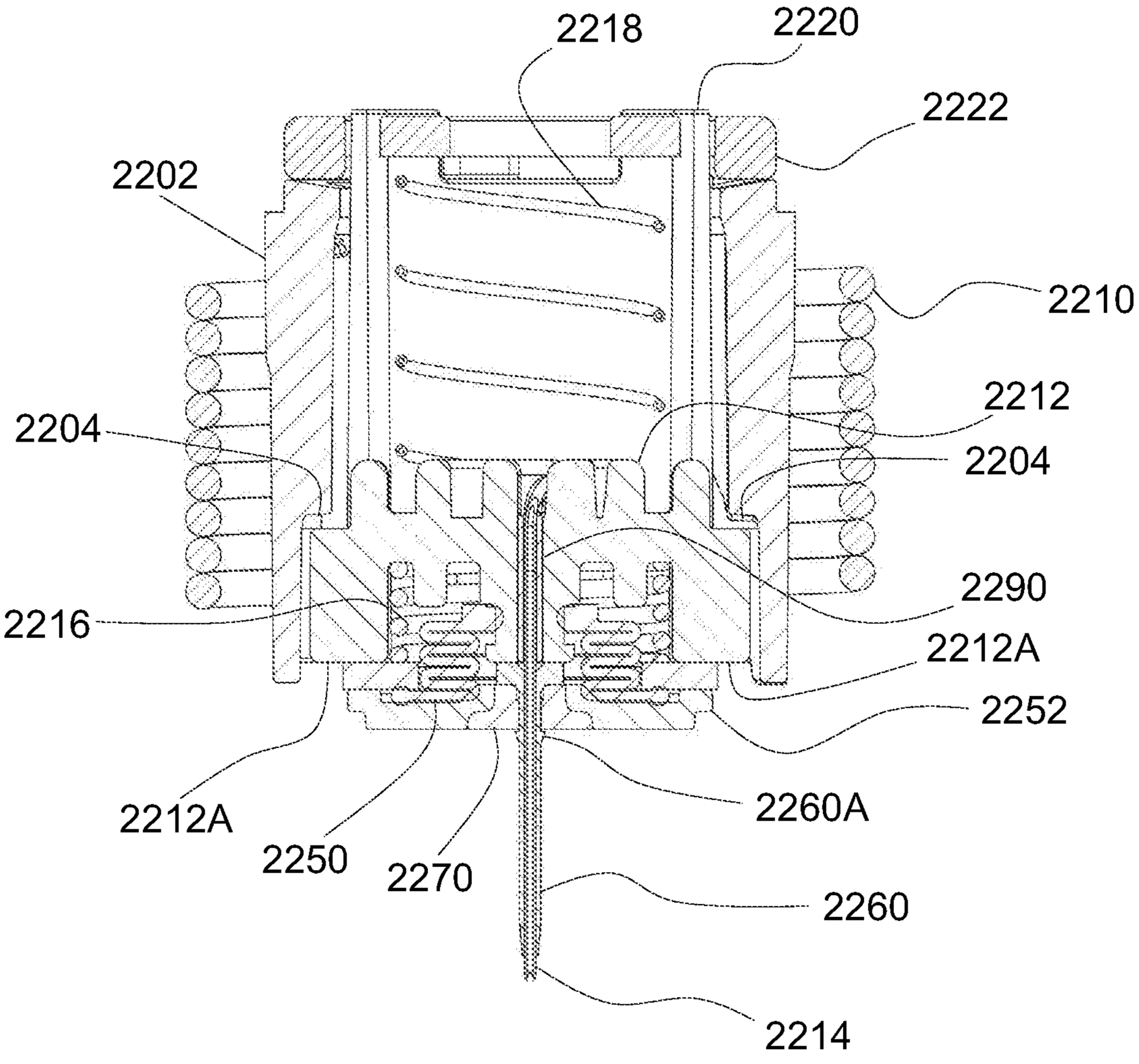

2218
2220
2222
2202
2210
2212
2204
2204
2290
2216
2212A
2252
2212A
2250
2270
2260A
2260
2214

FIG. 153B

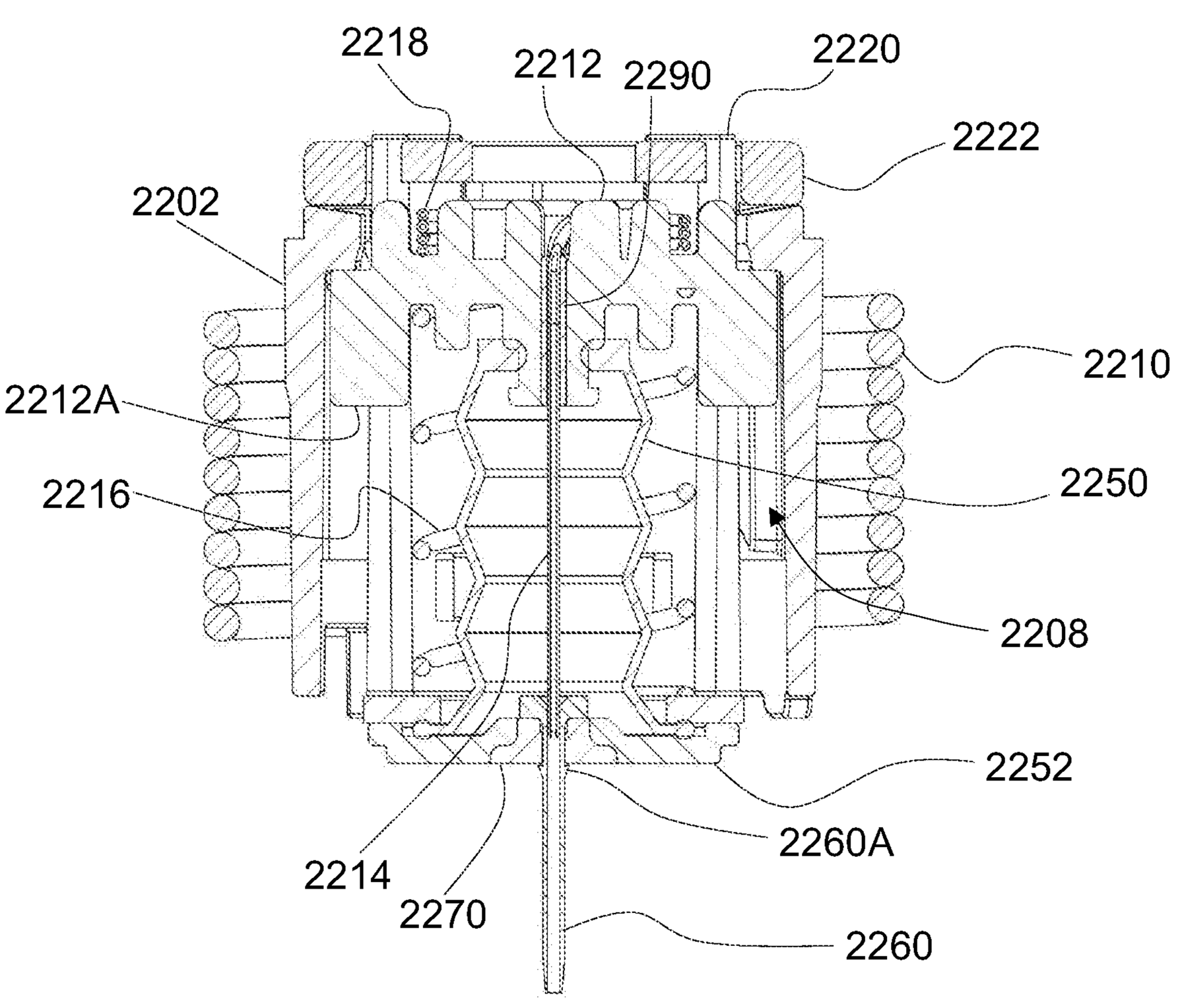

2218
2212
2290
2220
2222
2202
2210
2212A
2250
2216
2208
2252
2260A
2214
2270
2260

FIG. 153C

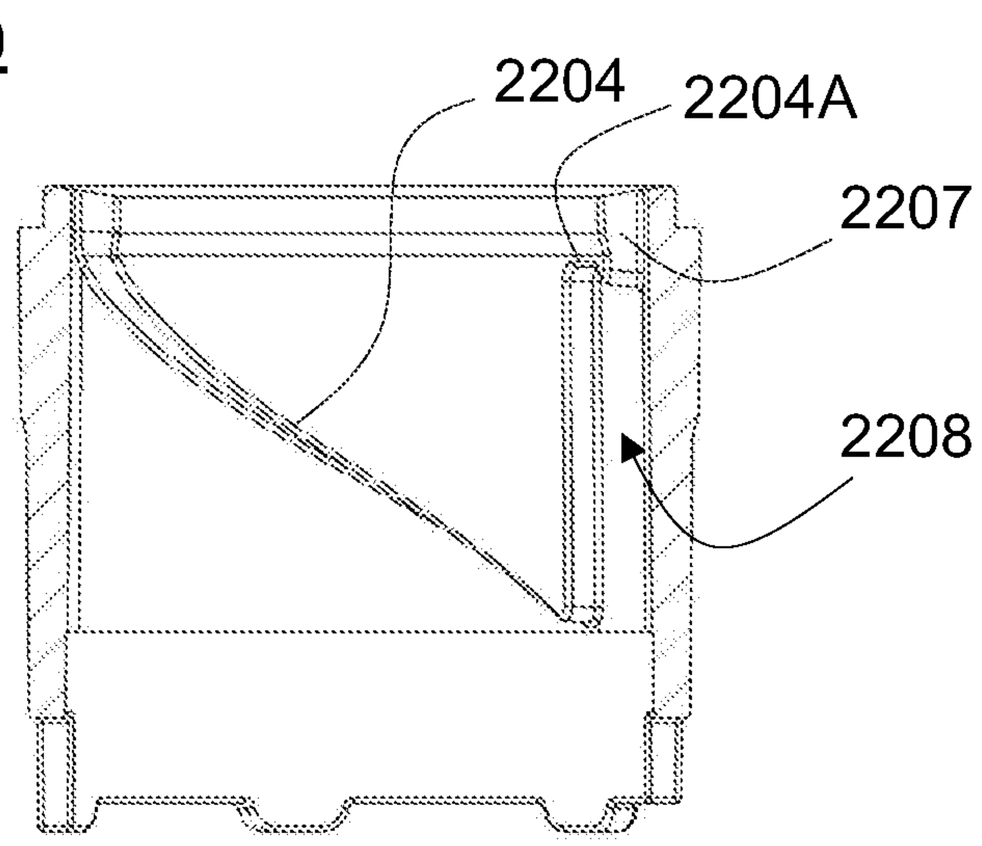


FIG. 154A

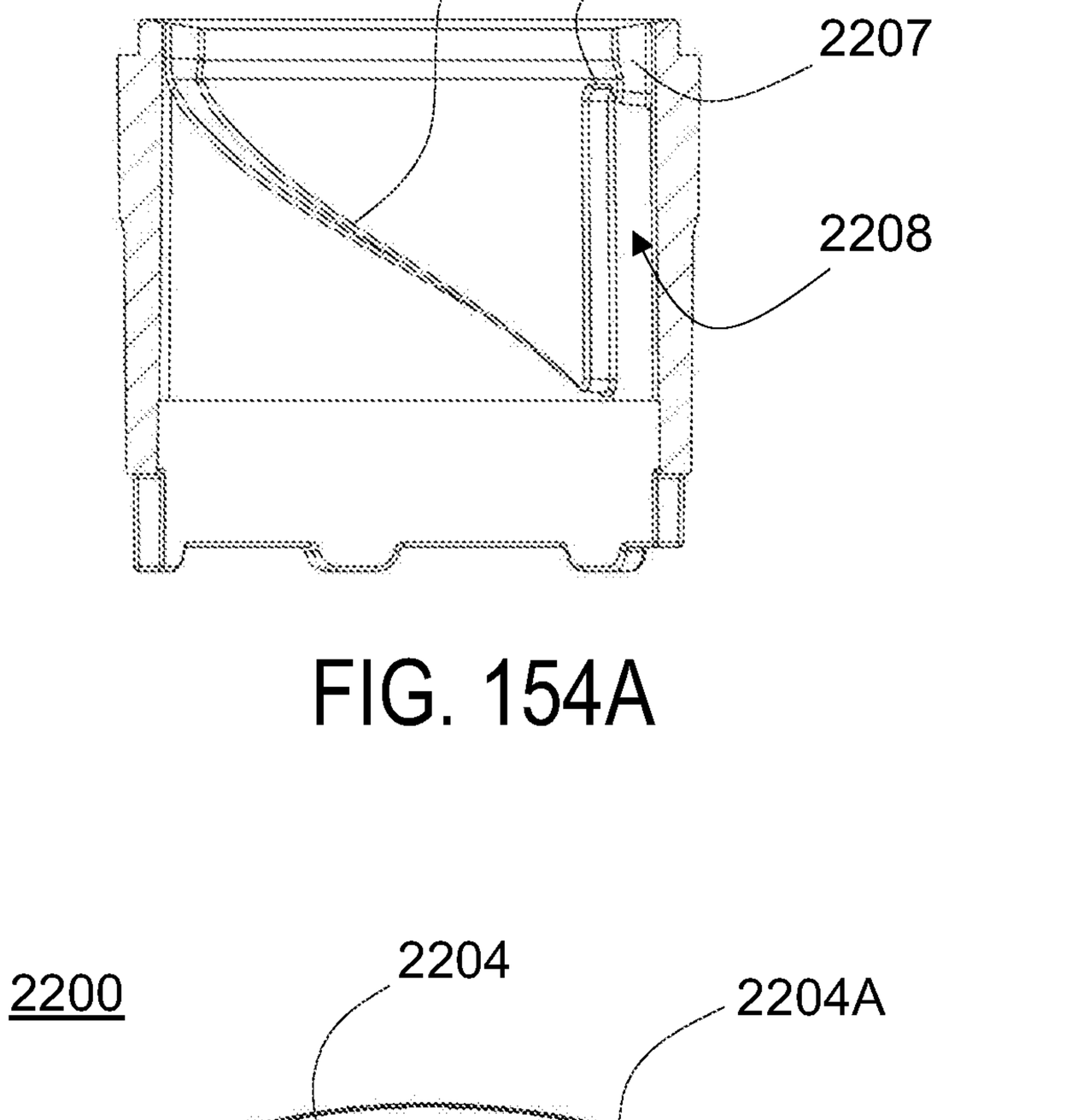


FIG. 154B

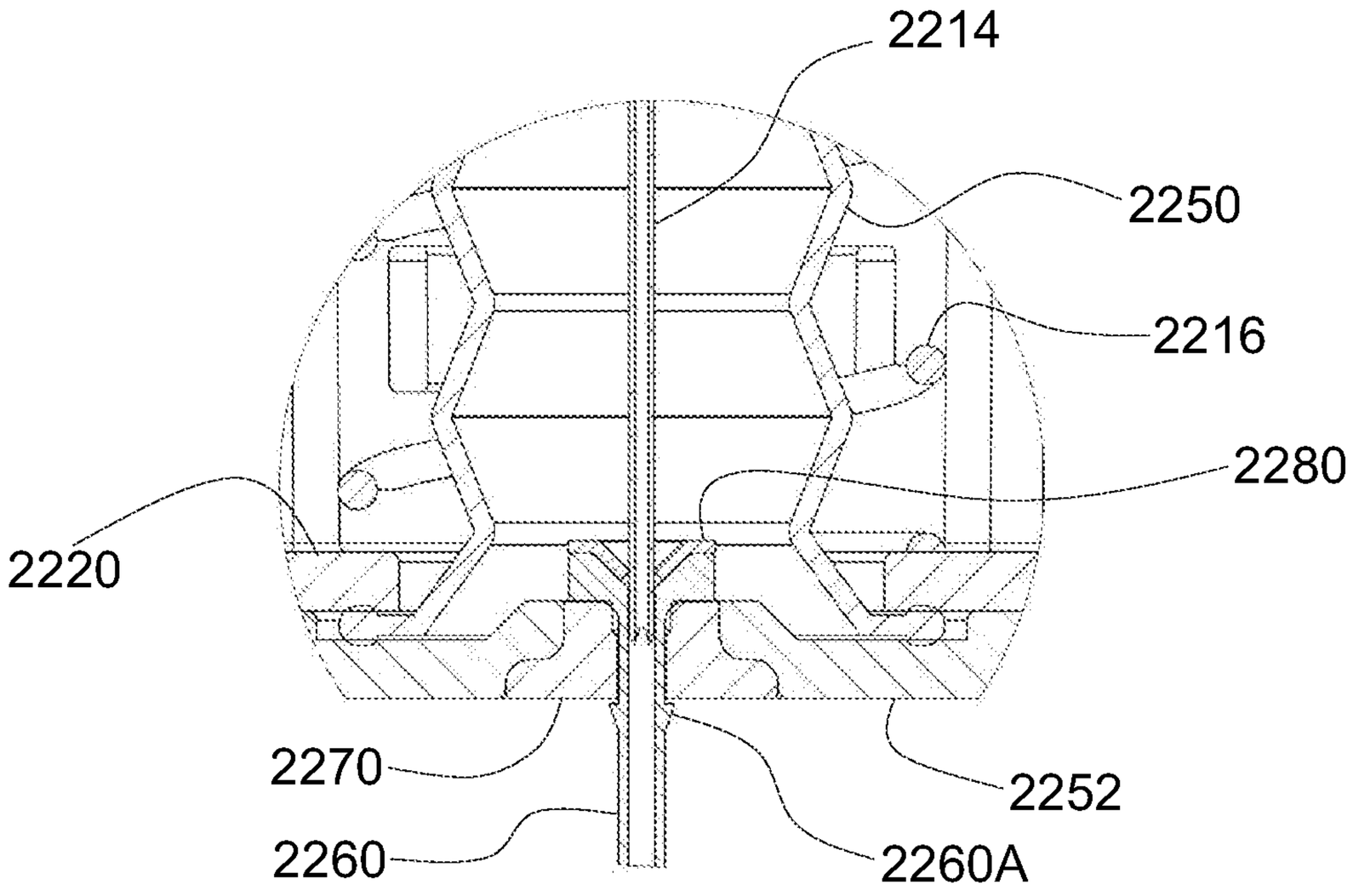


FIG. 155A

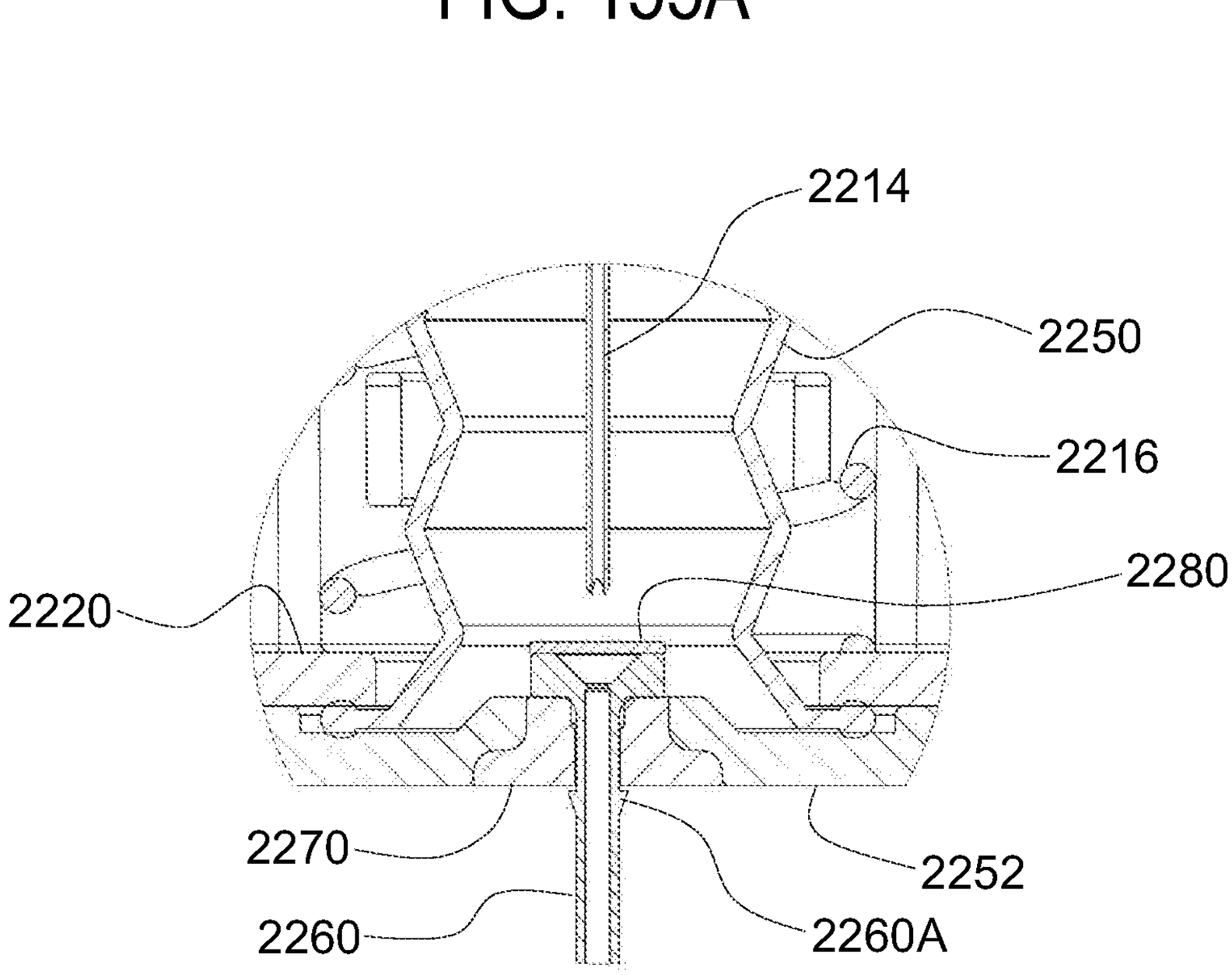


FIG. 155B

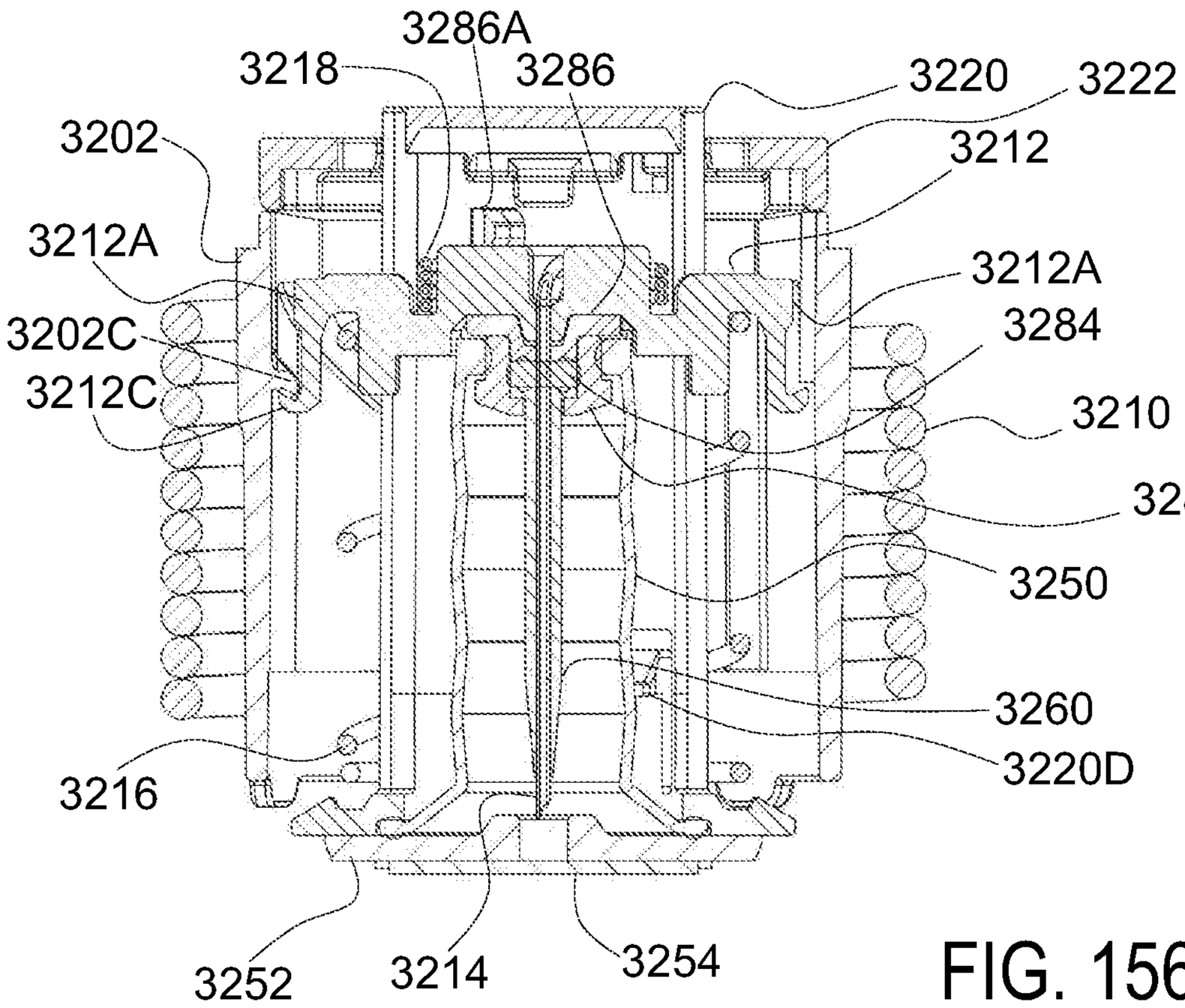


FIG. 156A

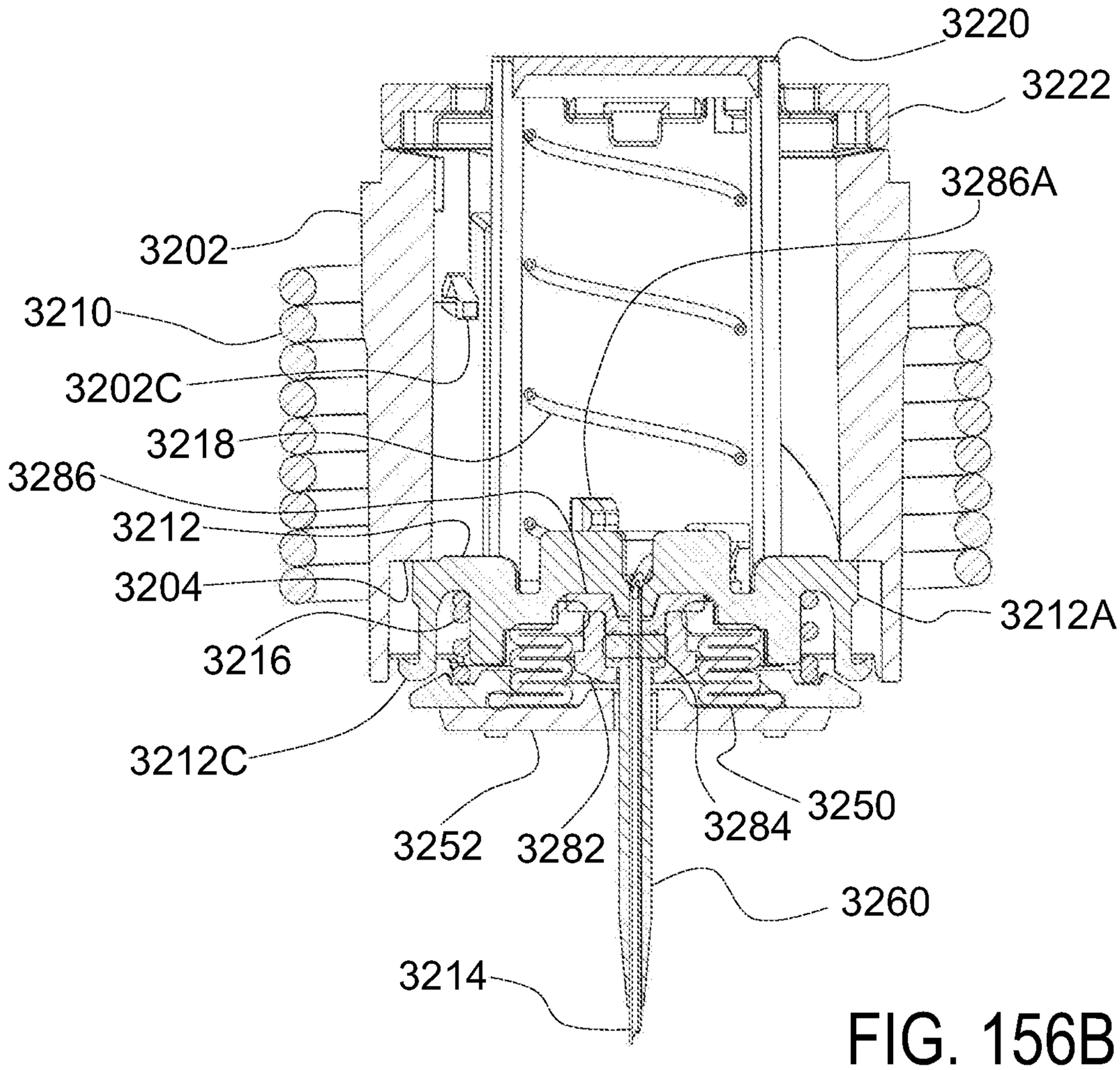


FIG. 156B

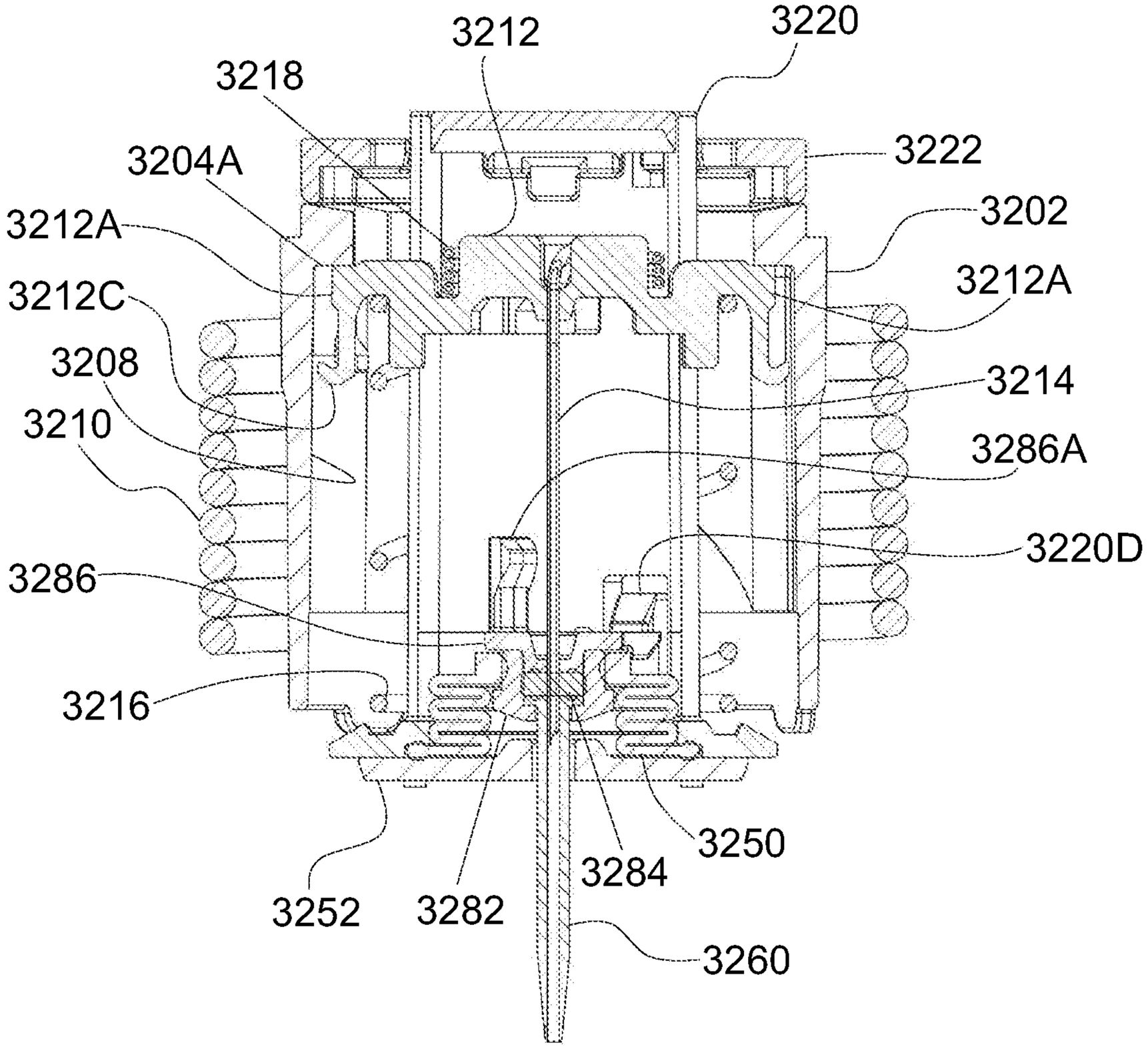

3212
3220
3218
3222
3204A
3202
3212A
3212A
3212C
3214
3208
3286A
3210
3220D
3286
3216
3250
3284
3252
3282
3260

FIG. 156C

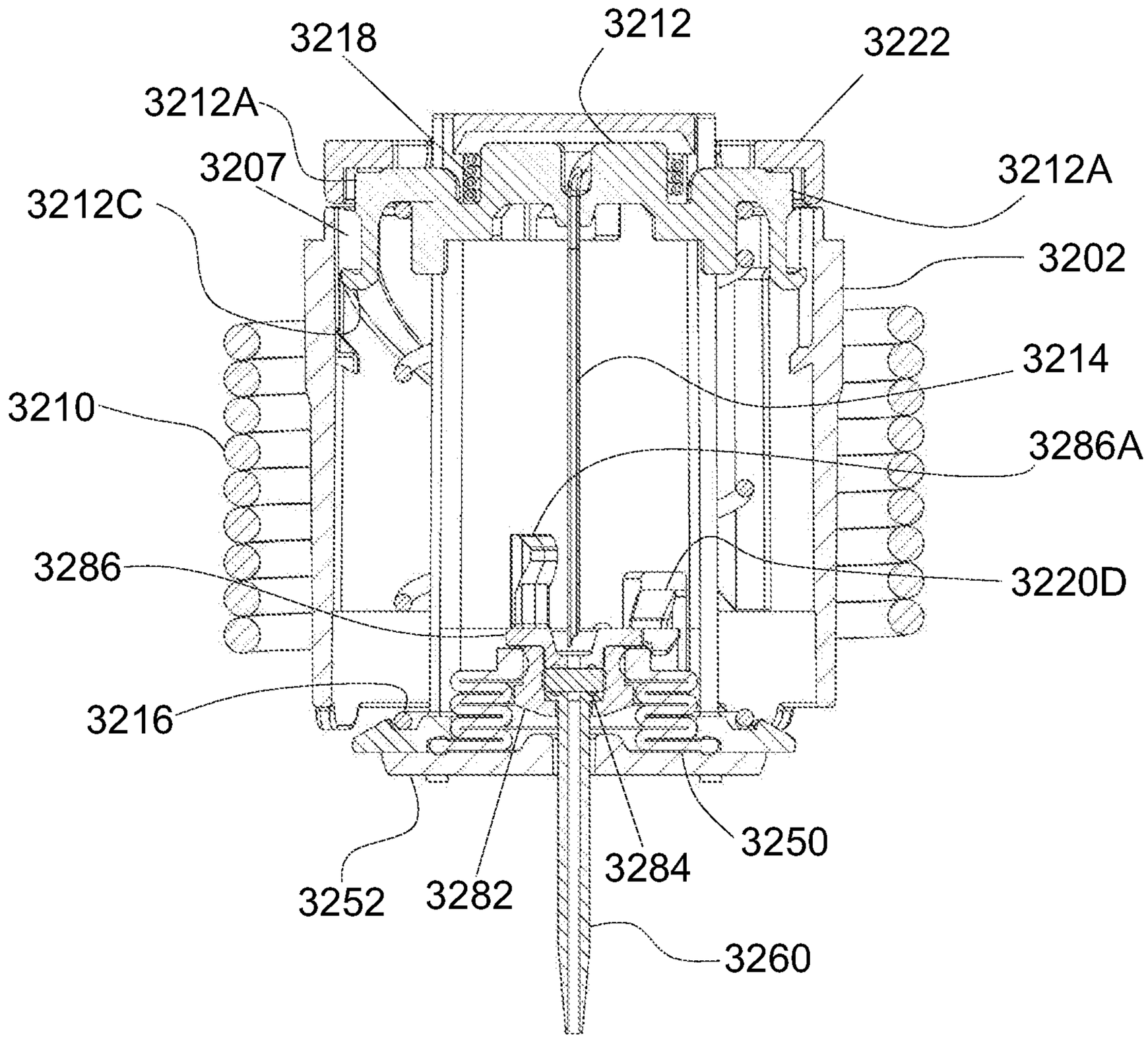

3218
3212
3222
3212A
3207
3212A
3212C
3202
3214
3210
3286A
3286
3220D
3216
3250
3284
3252
3282
3260

FIG. 156D

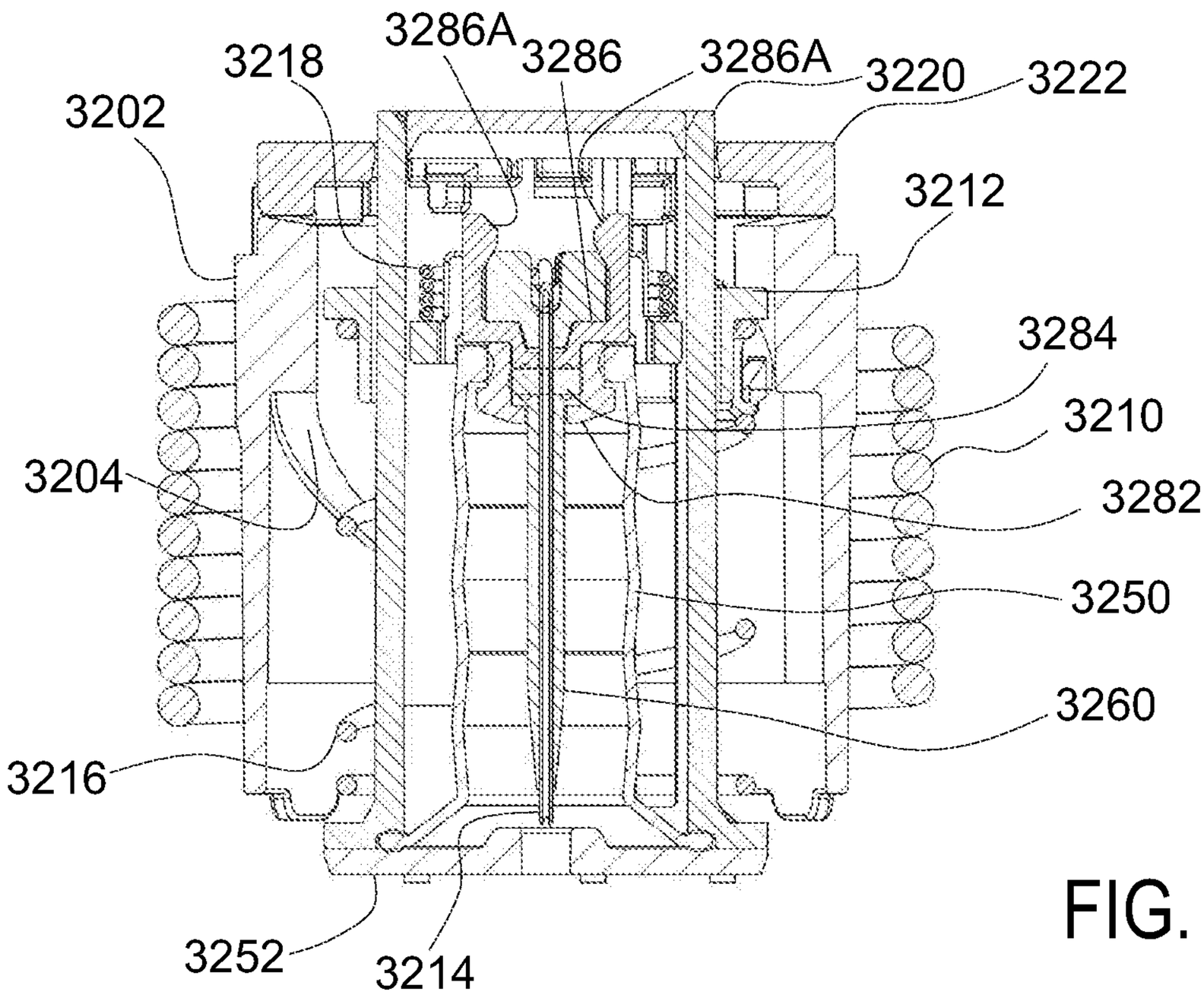


FIG. 157A

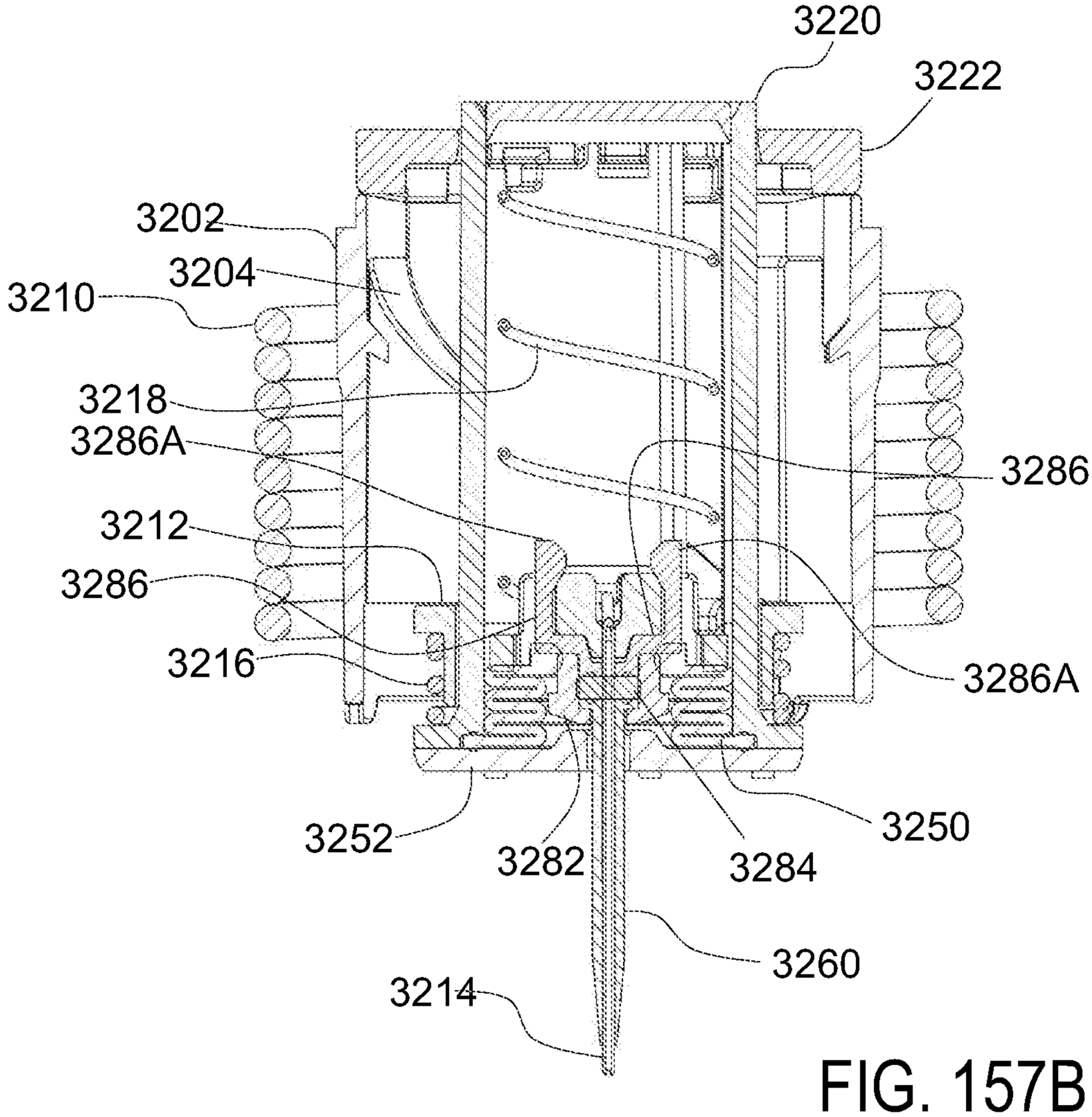


FIG. 157B

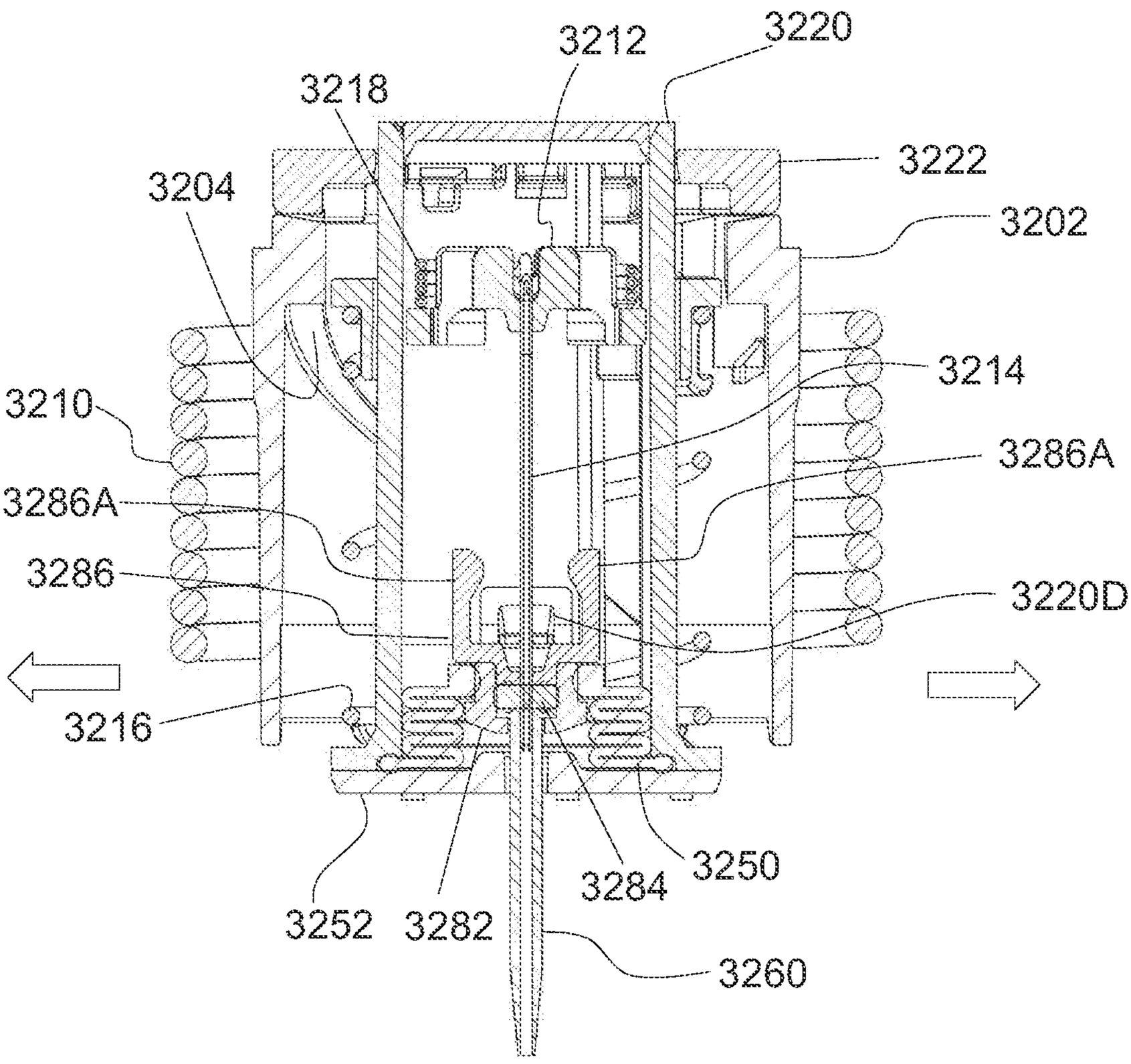

3212
3220
3218
3222
3204
3202
3214
3210
3286A
3286A
3286
3220D
3216
3250
3284
3252
3282
3260

FIG. 157C

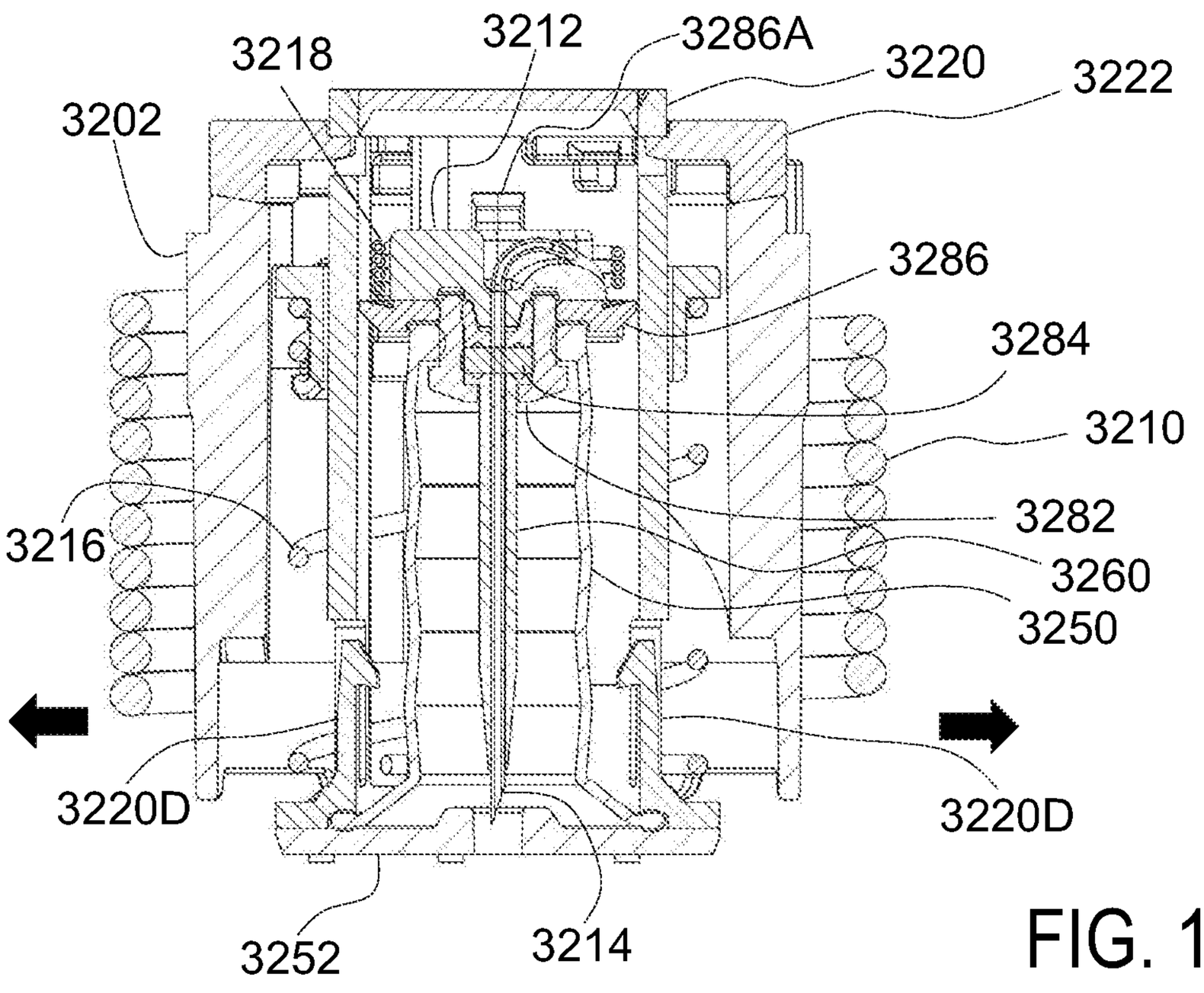


FIG. 158A

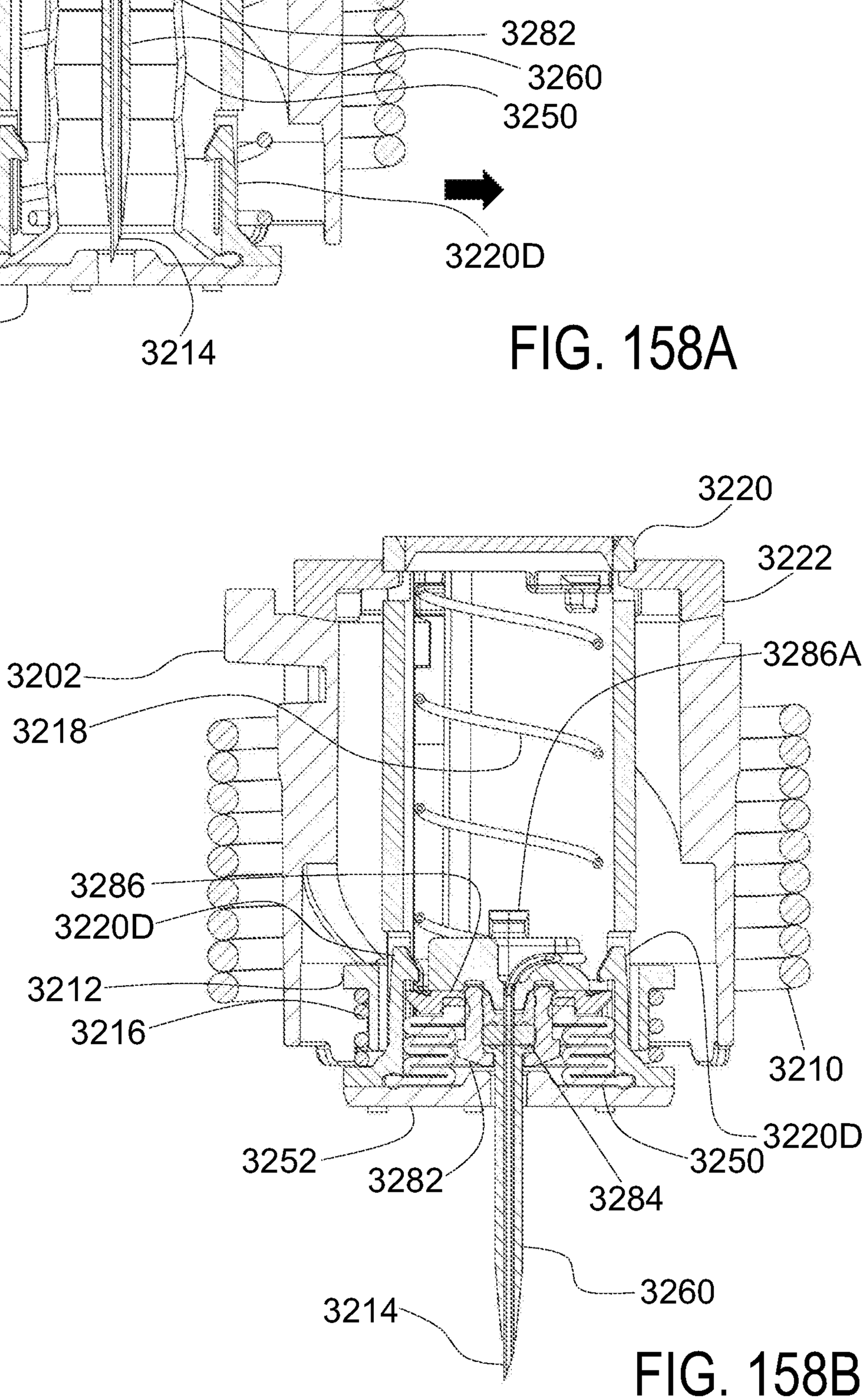


FIG. 158B

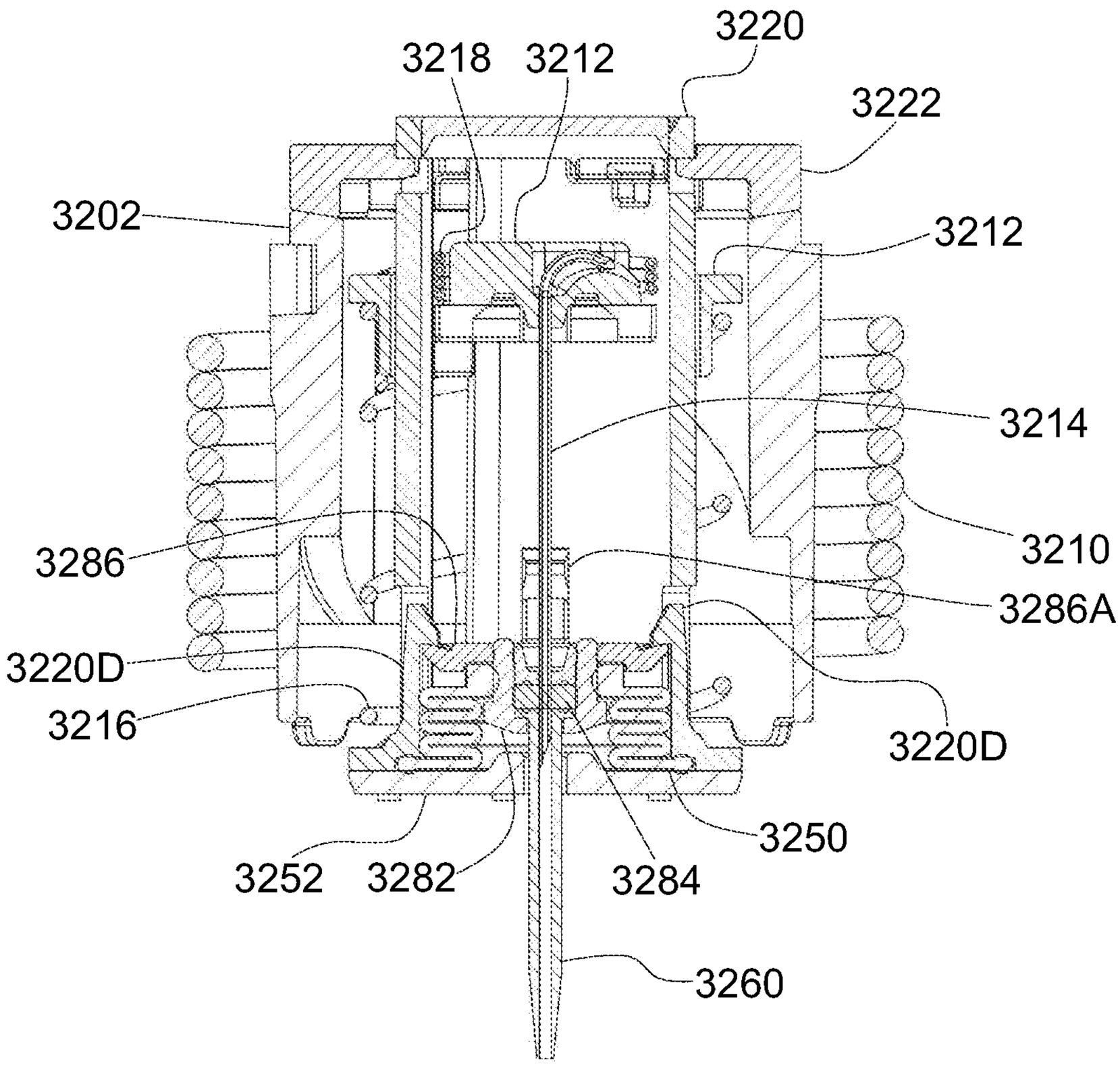

3220
3218
3212
3222
3202
3212
3214
3286
3210
3286A
3220D
3216
3220D
3250
3252
3282
3284
3260

FIG. 158C

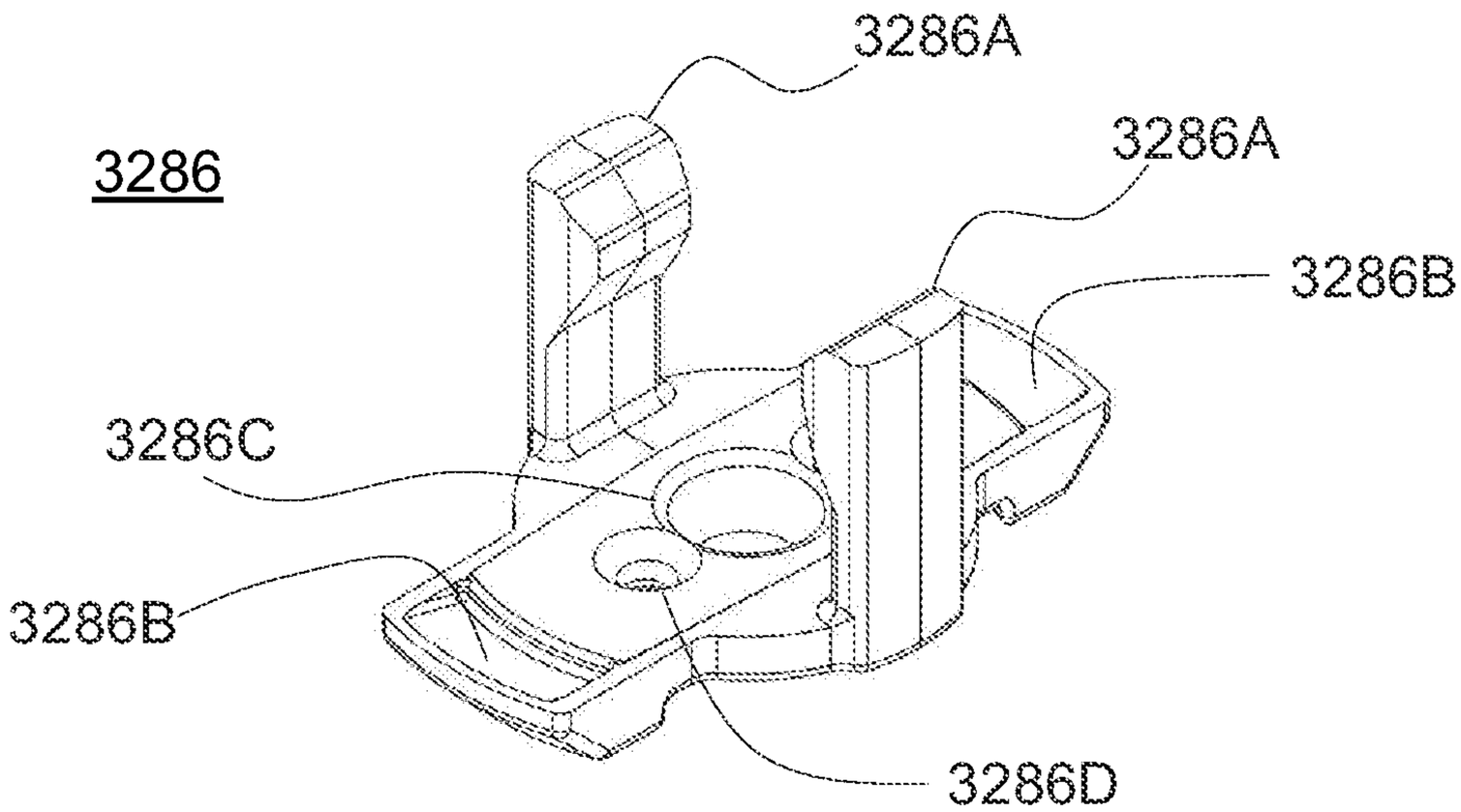


FIG. 159

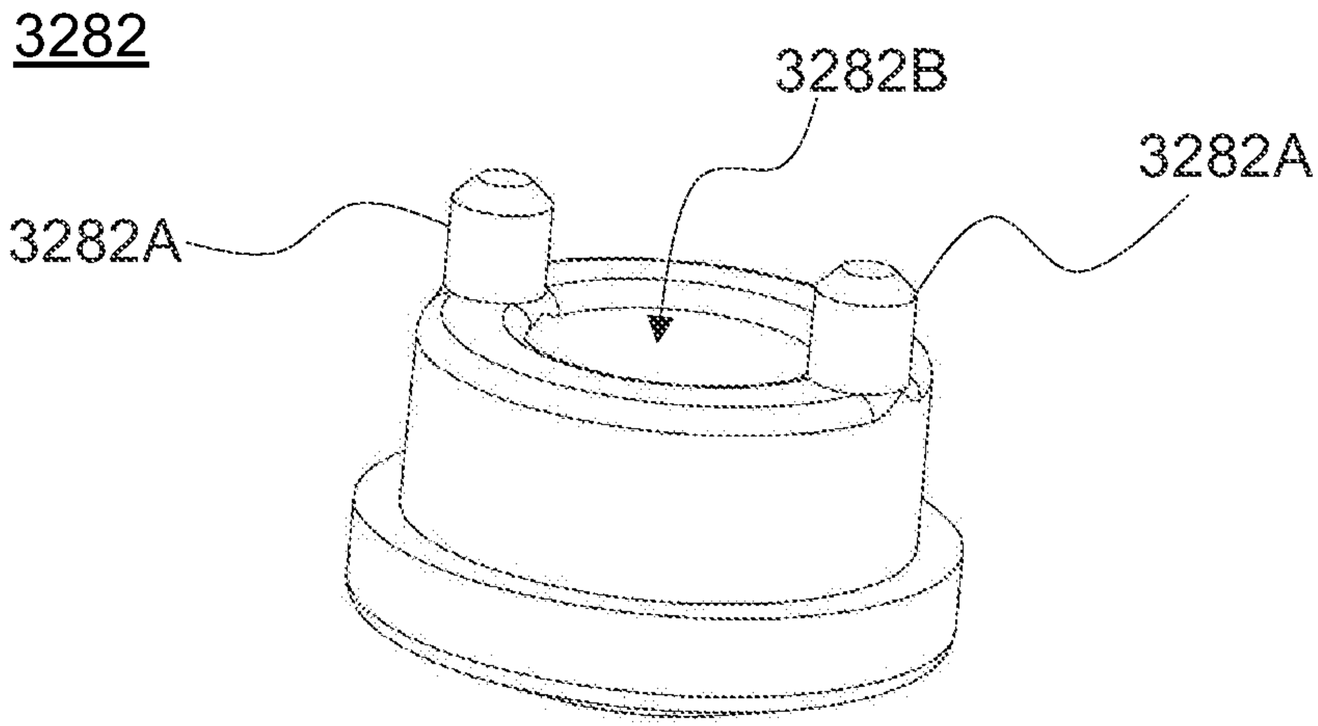


FIG. 160

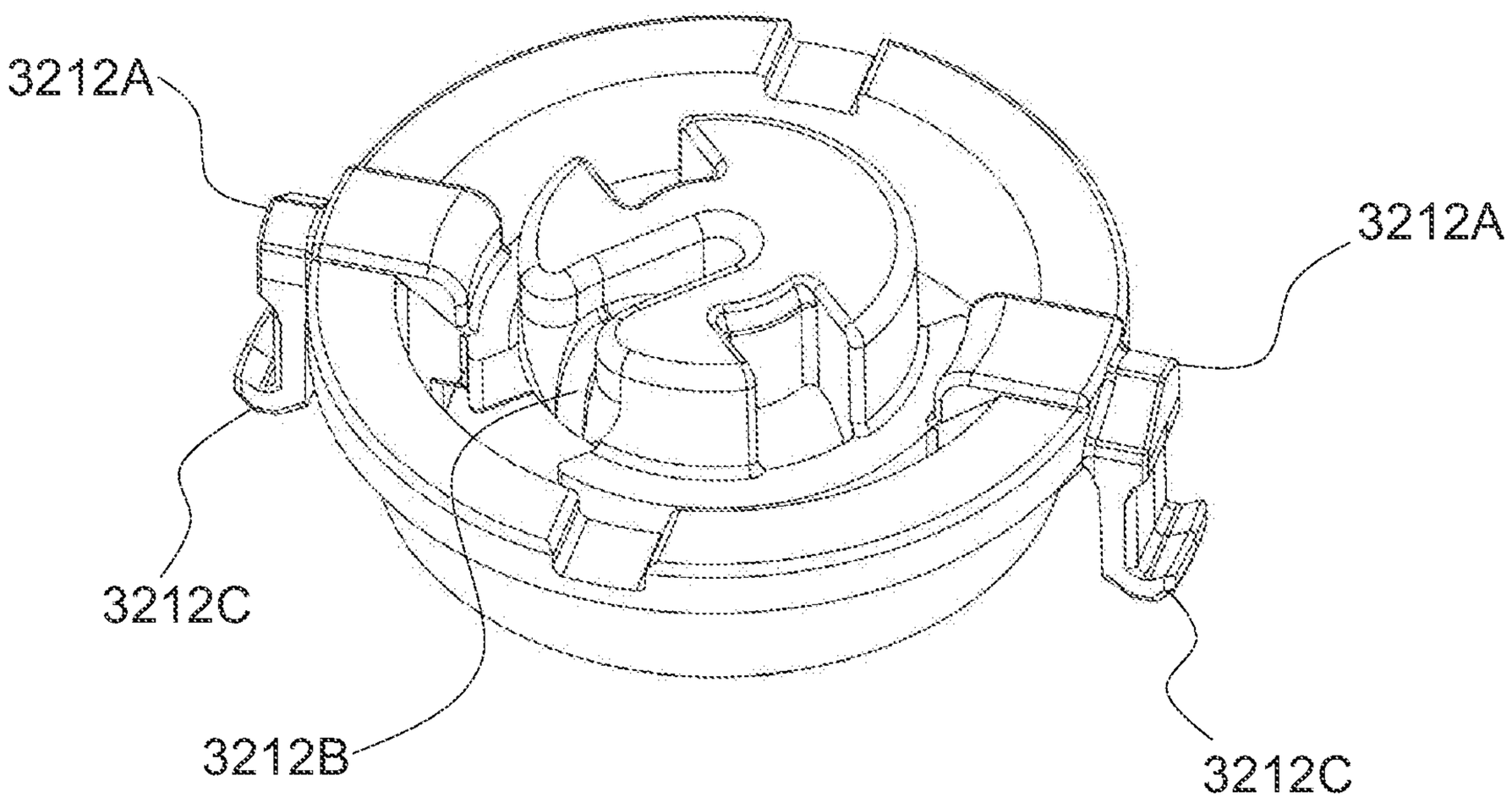


FIG. 161

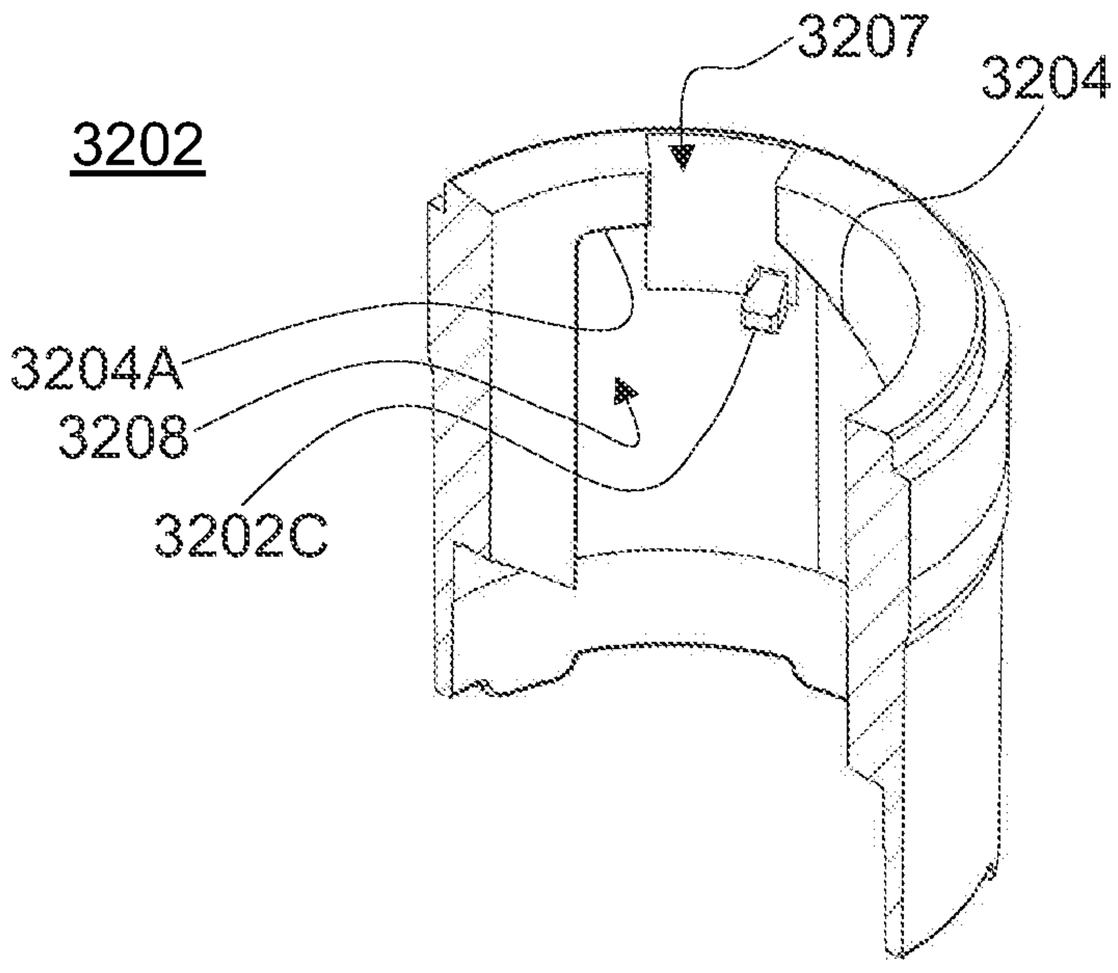


FIG. 162

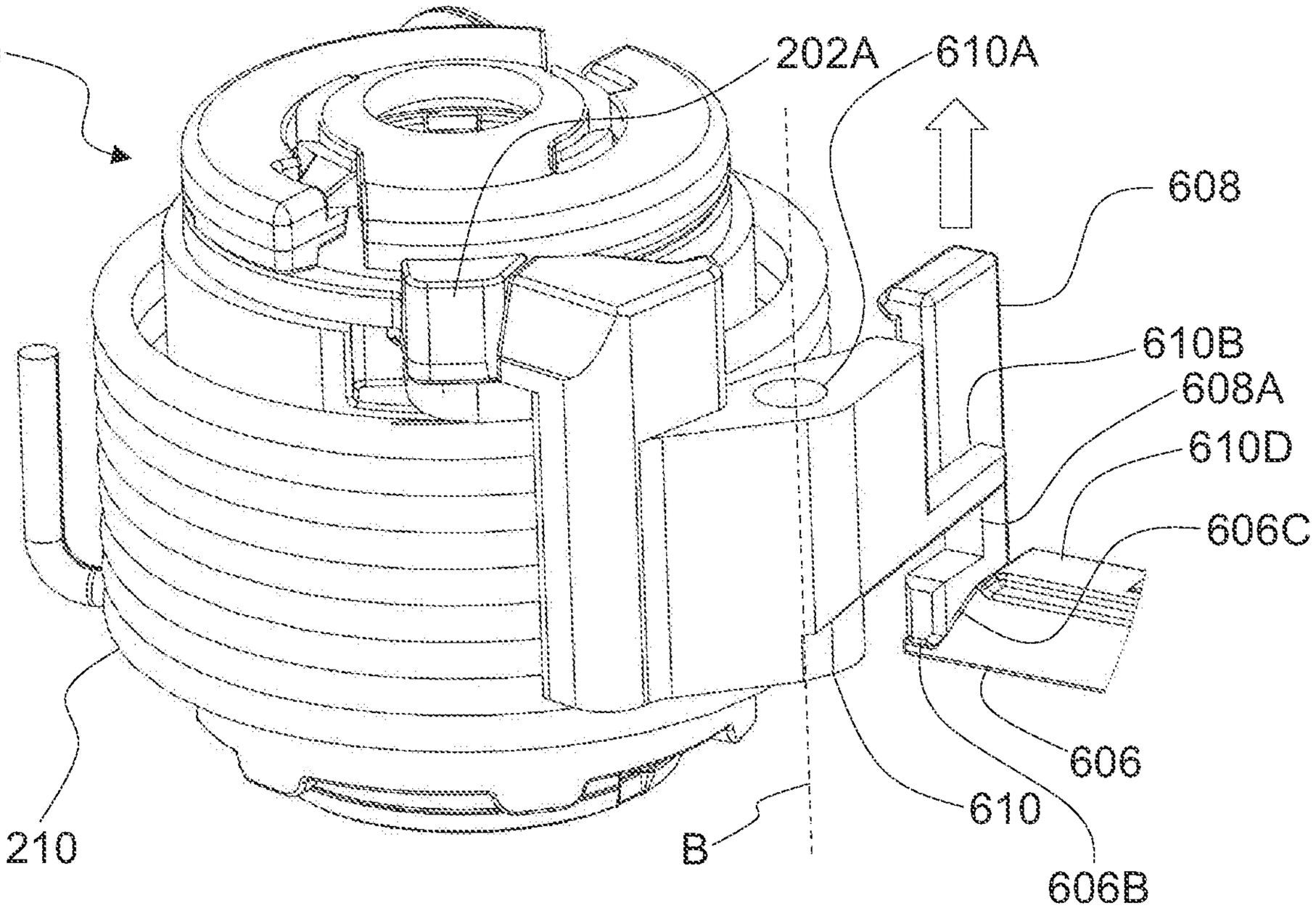


FIG. 163A

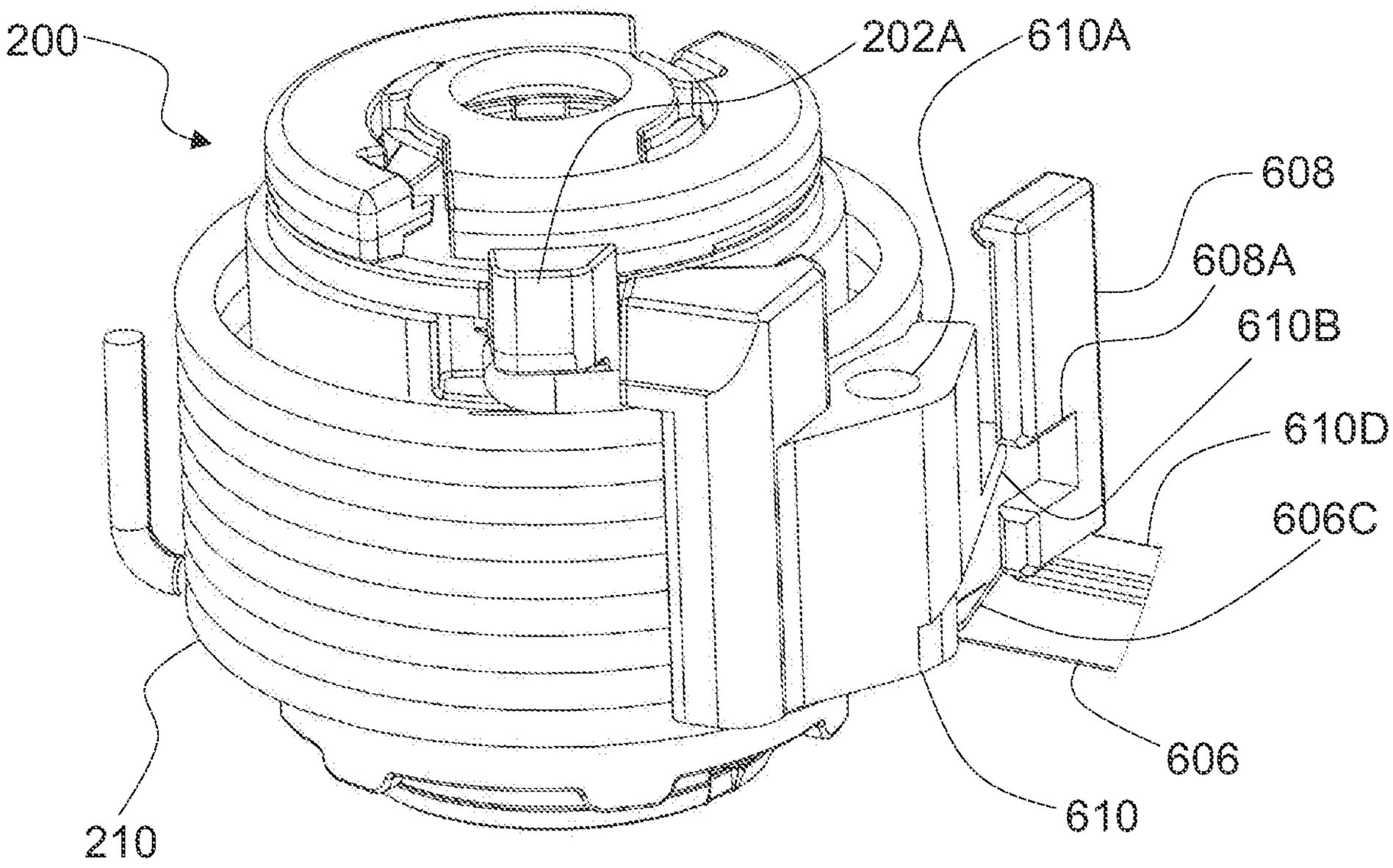


FIG. 163B

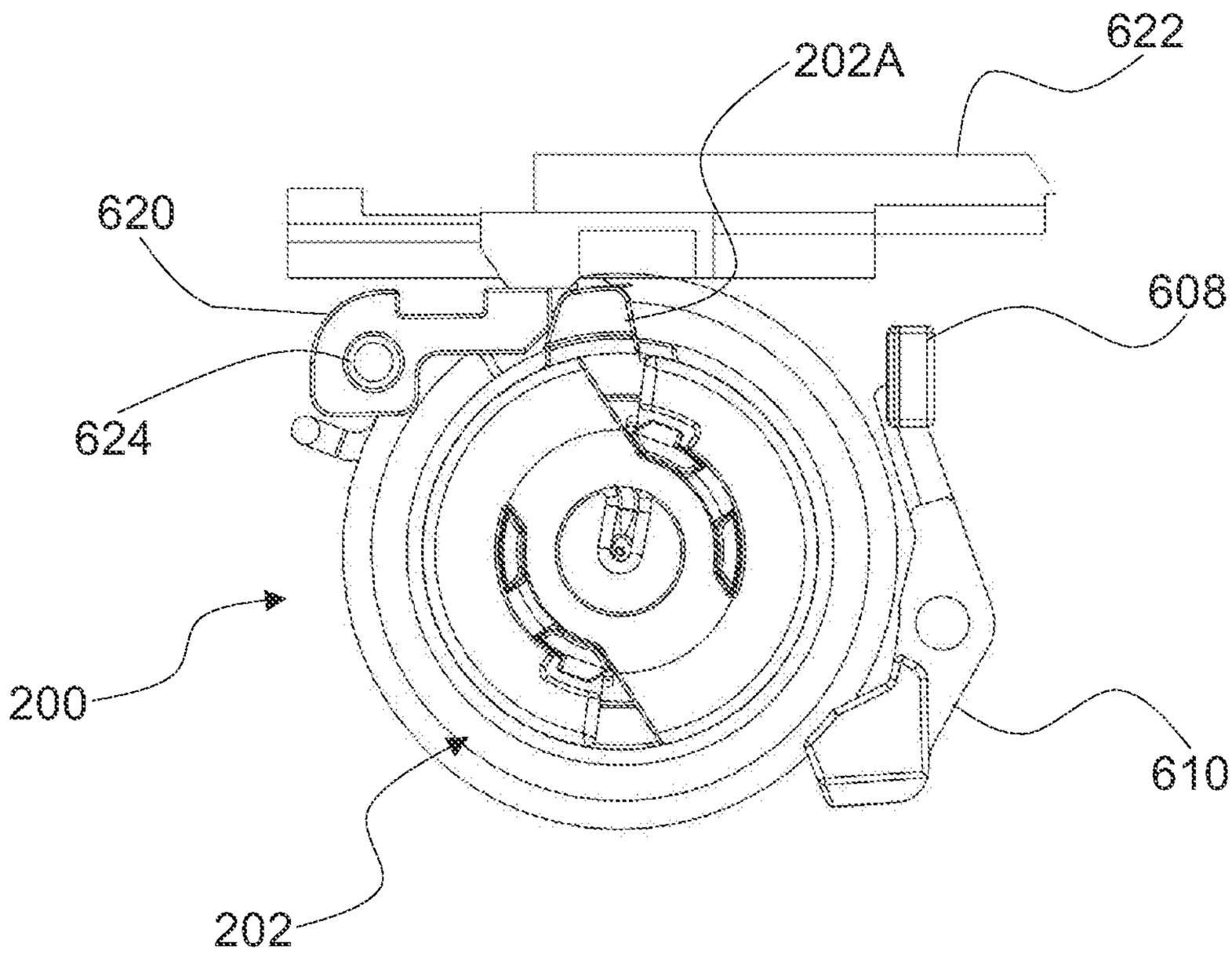


FIG. 164A

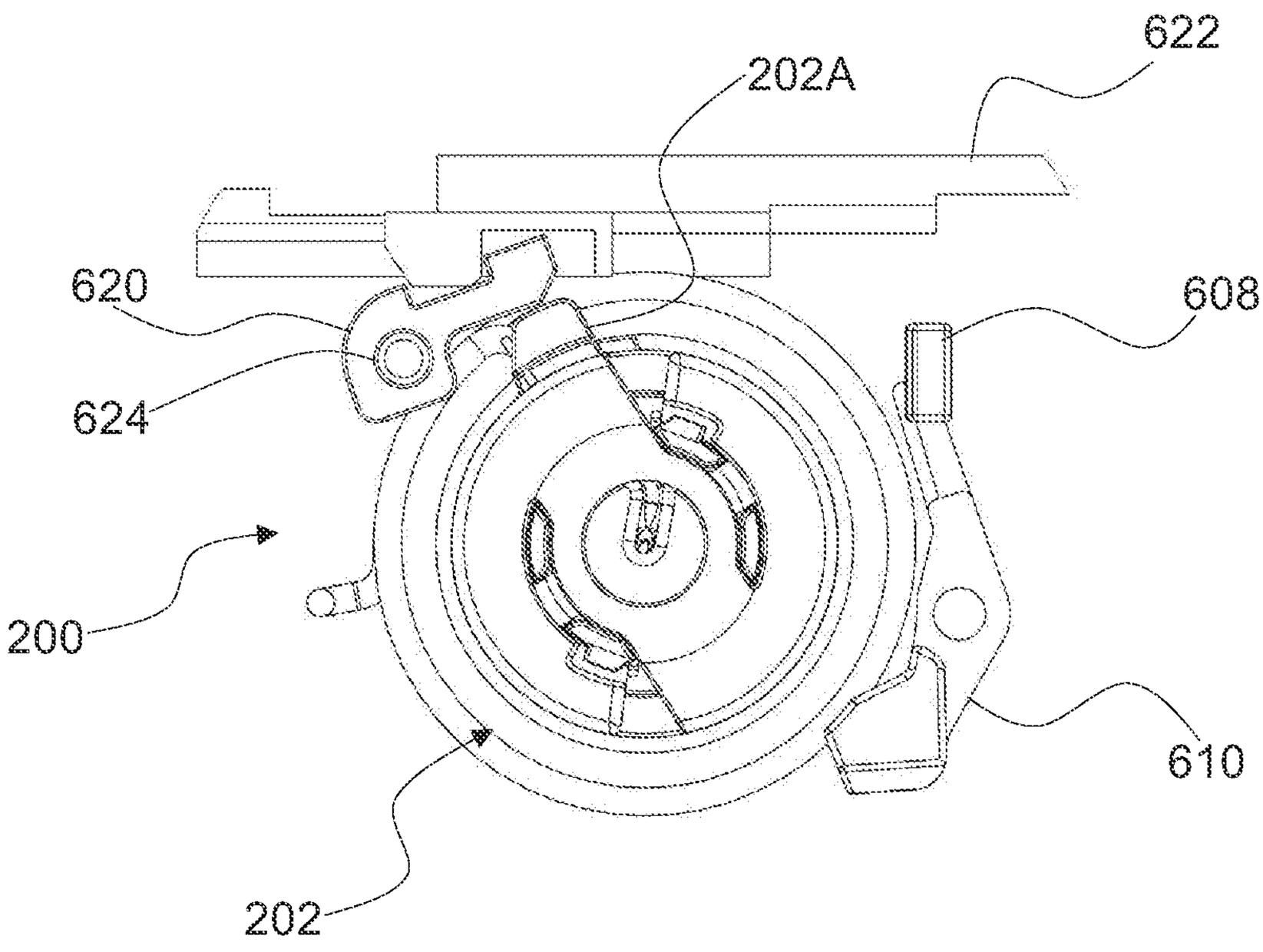


FIG. 164B

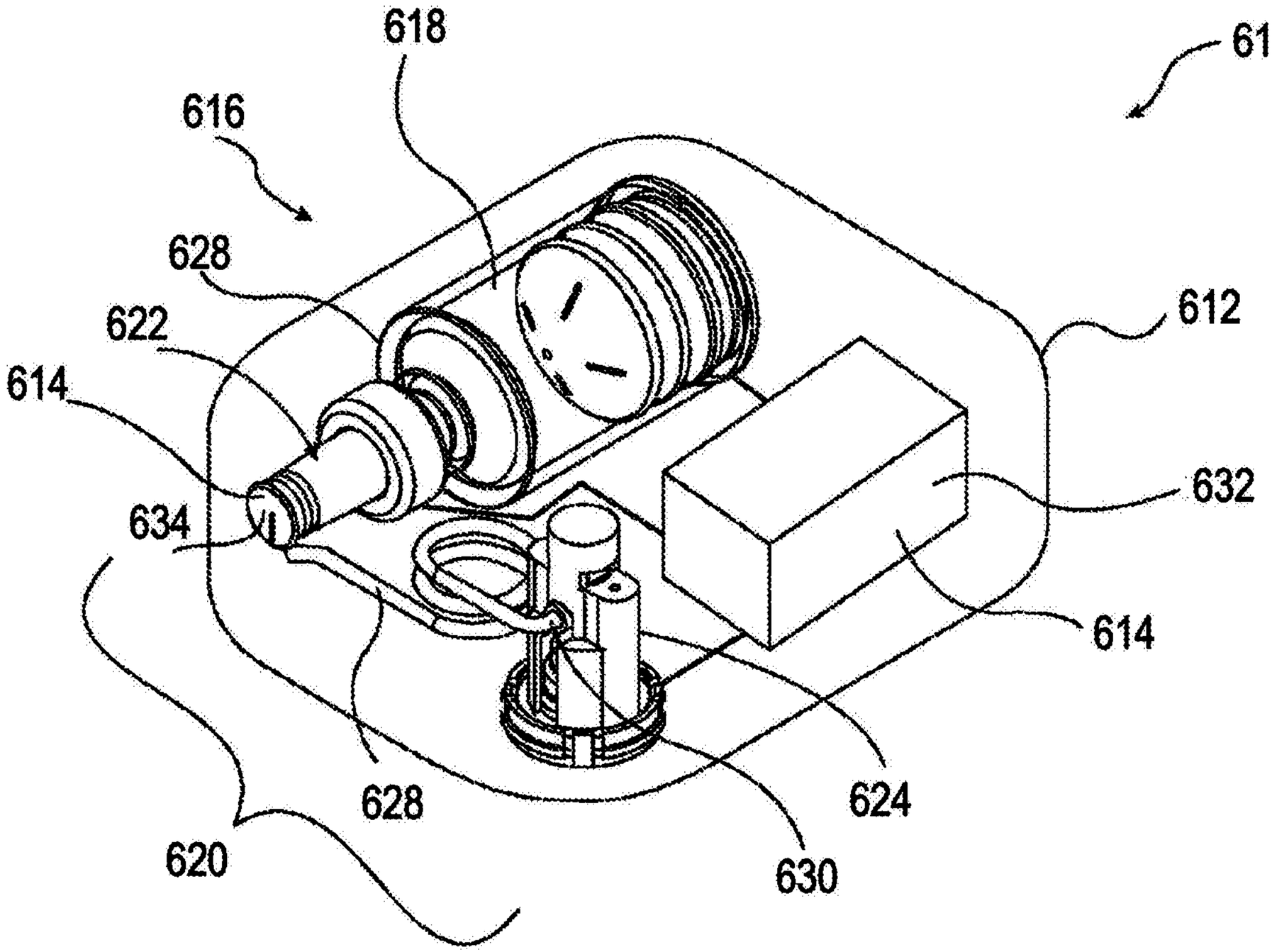


FIG. 165

Fluid Pathway Connection with Drug Container	Fluid Pathway Connection Attachment to Needle Insertion Mechanism	Fill-Finish Cartridge Alignment	Carrier
Mounted	Snap	Axial fill and use	None
Integrated	Threaded	Axial fill and non-axial use	Integrated
Other	Interference	Non-axial fill and axial use	Fully Disposable
	Tongue and groove	Non-axial fill and use	Partially Disposable
	External support		
	Other		

FIG. 166B

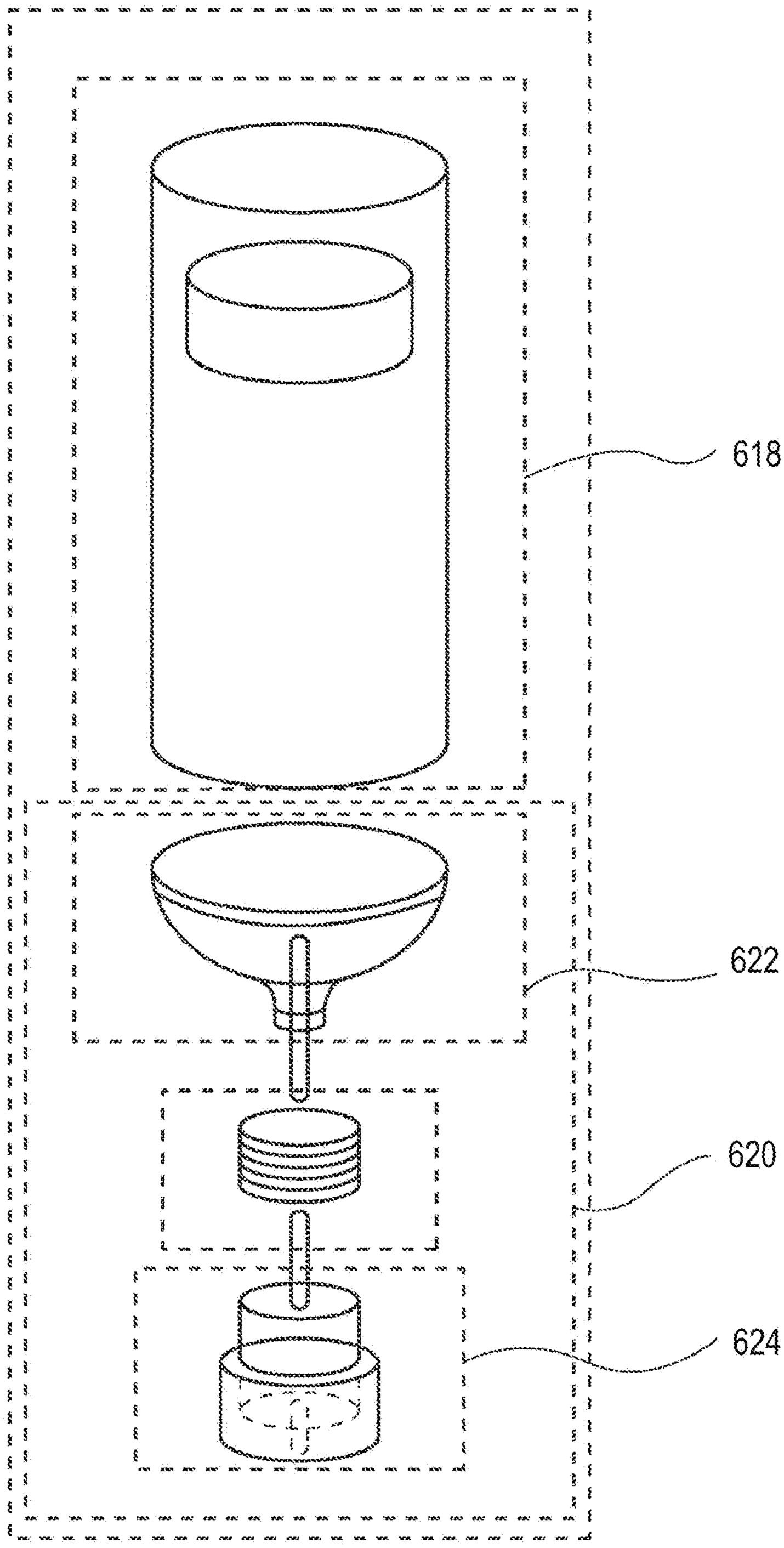


FIG. 166A

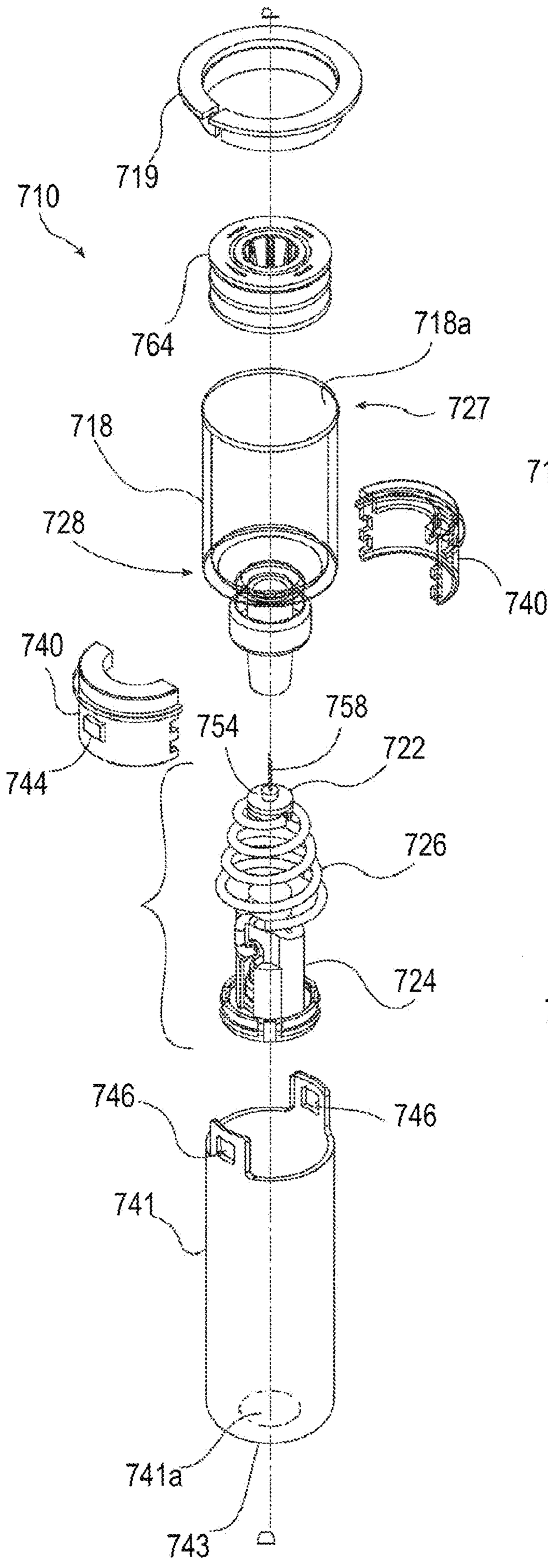


FIG. 167

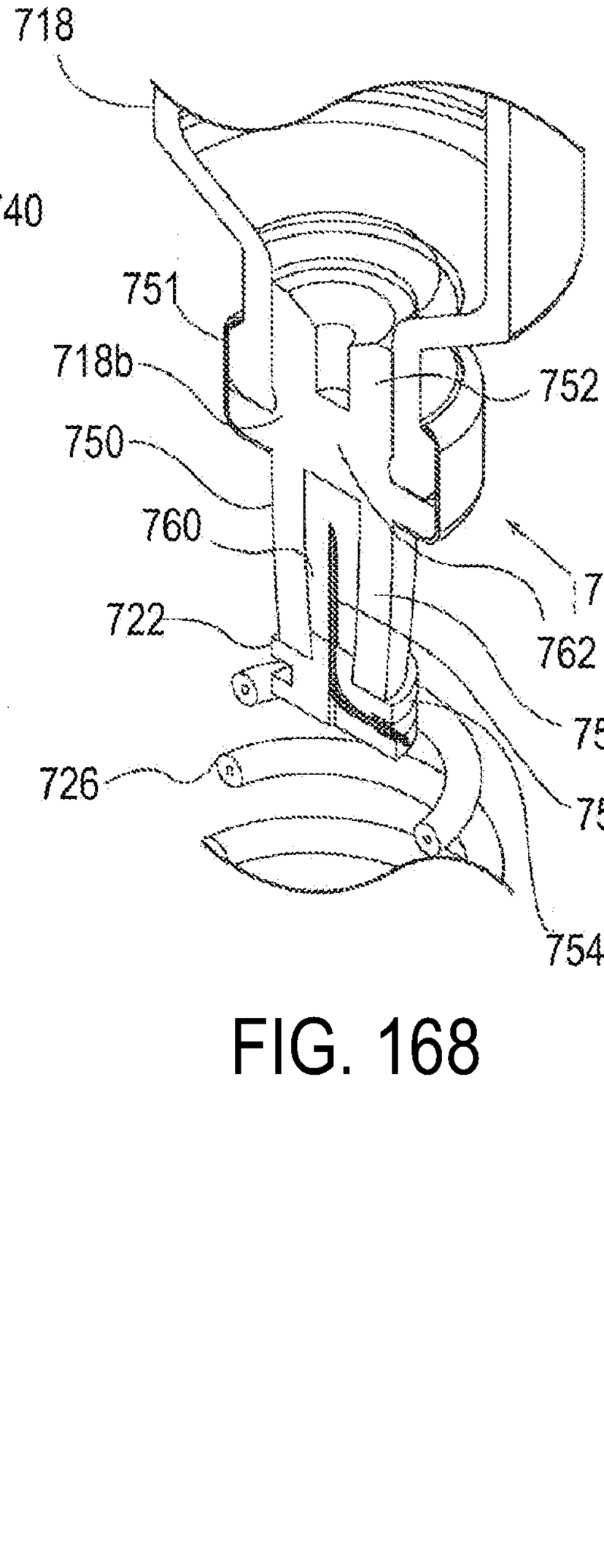


FIG. 168

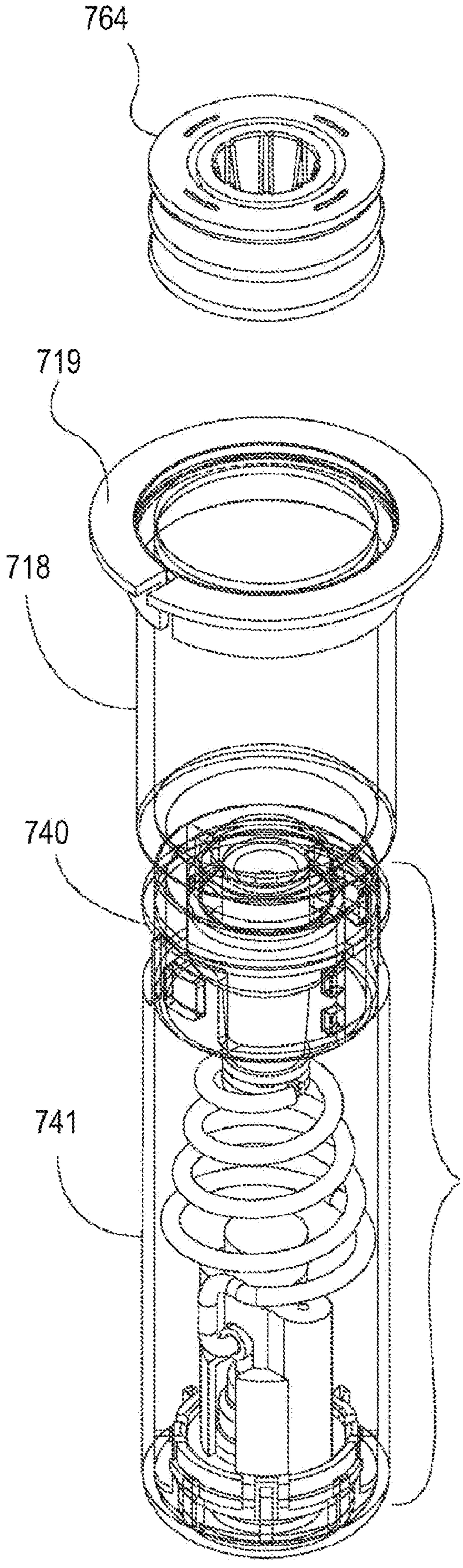


FIG. 169

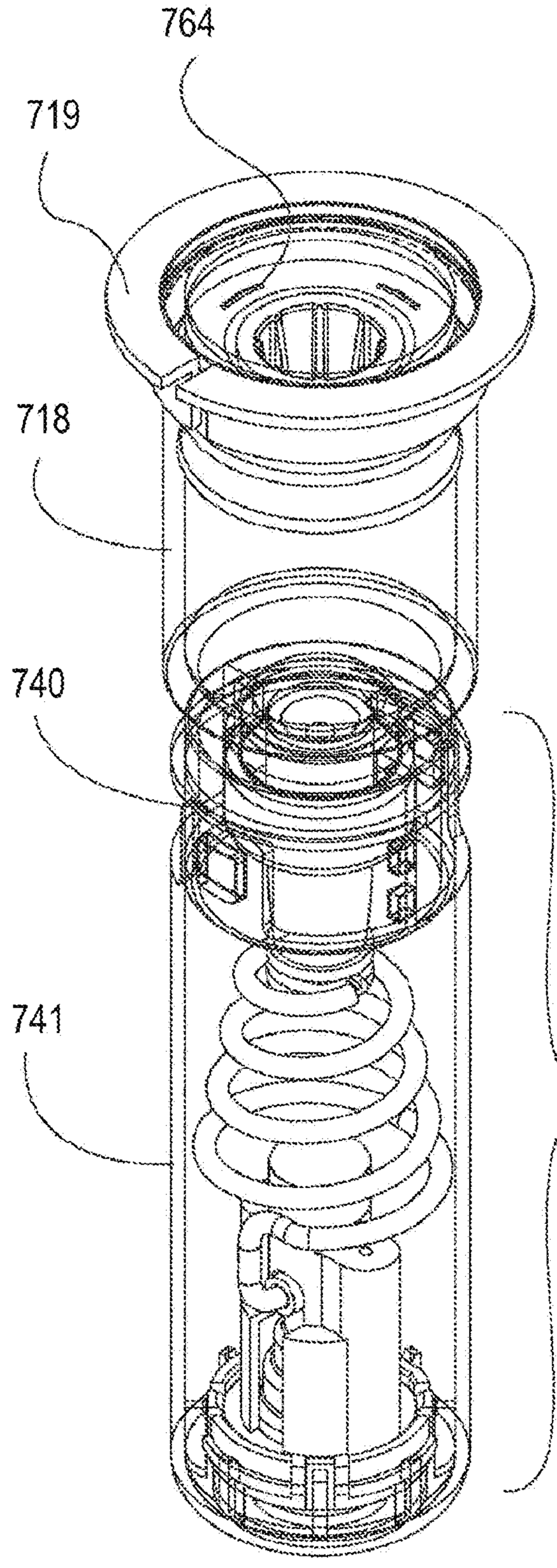


FIG. 170

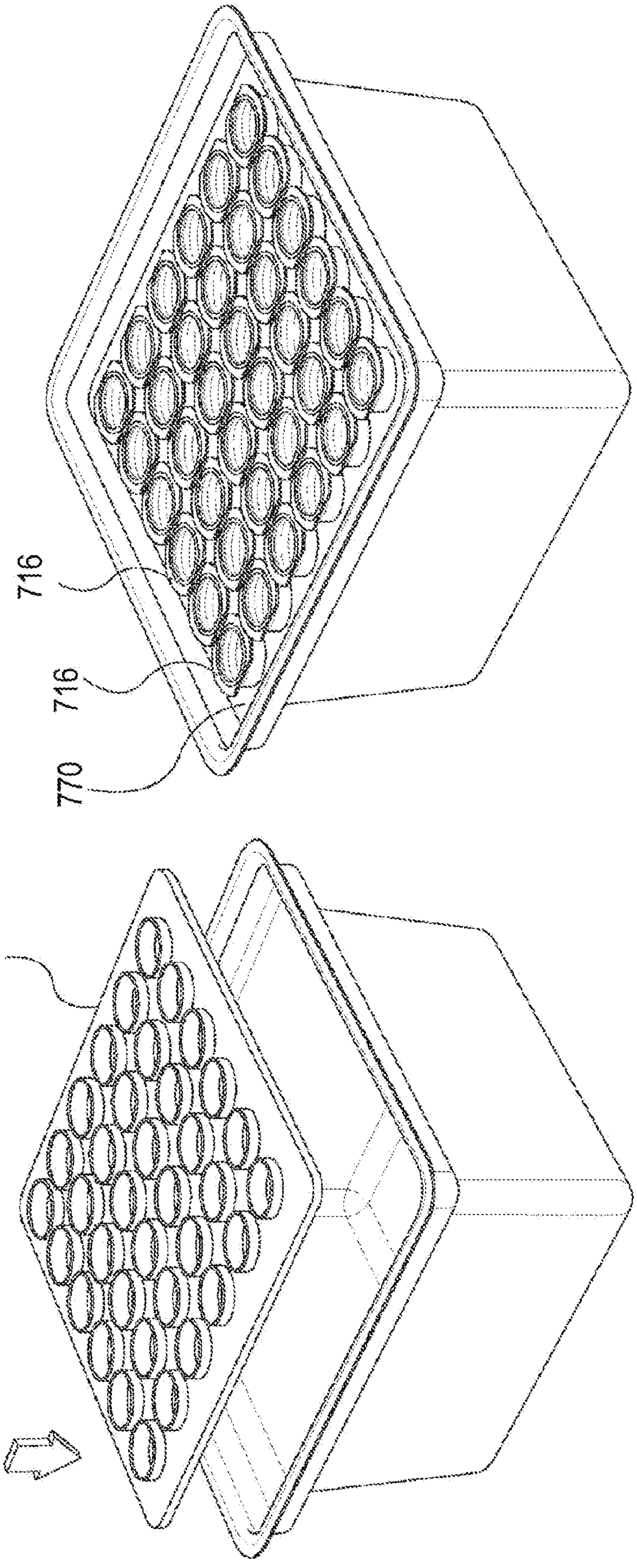


FIG. 172

FIG. 171

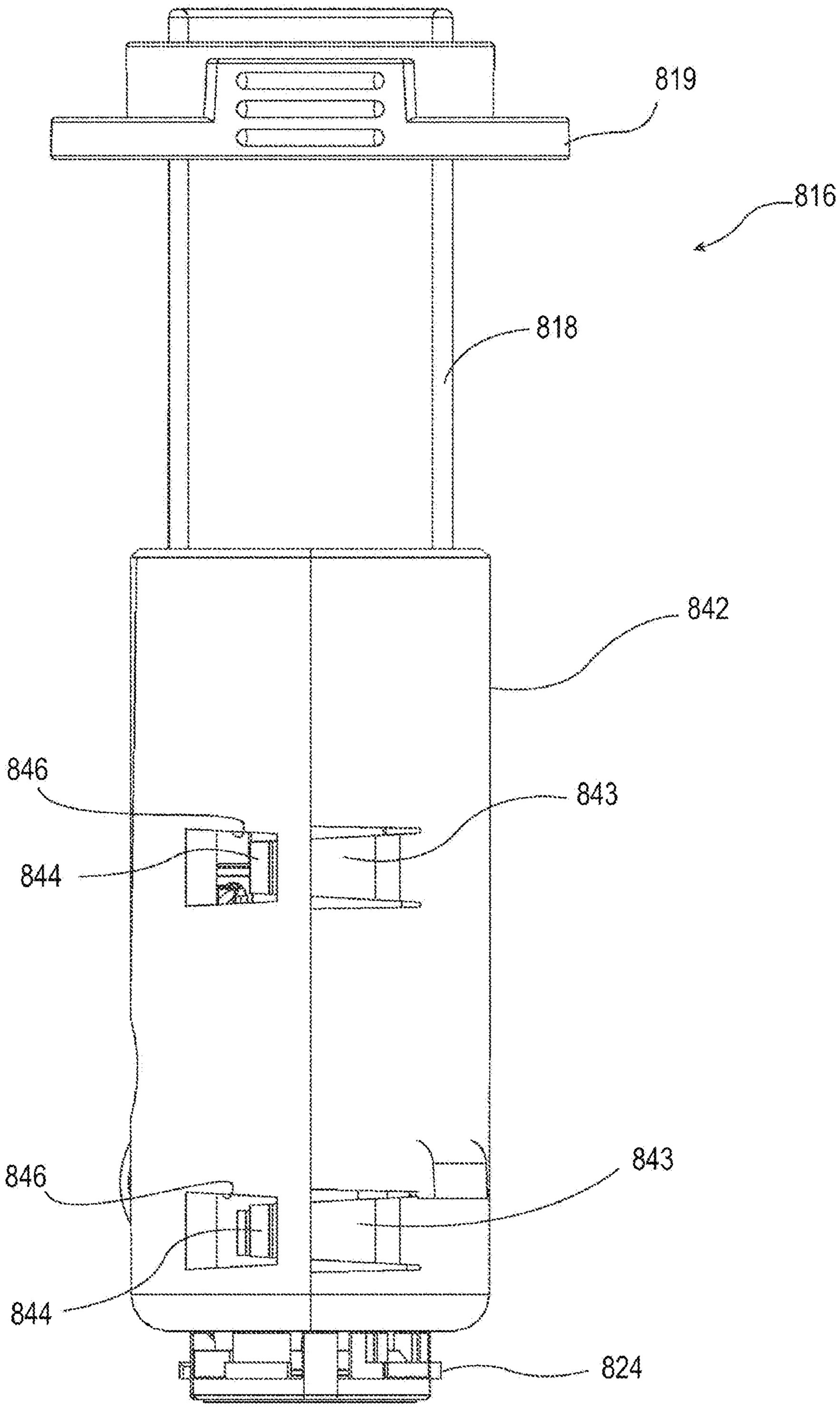


FIG. 173

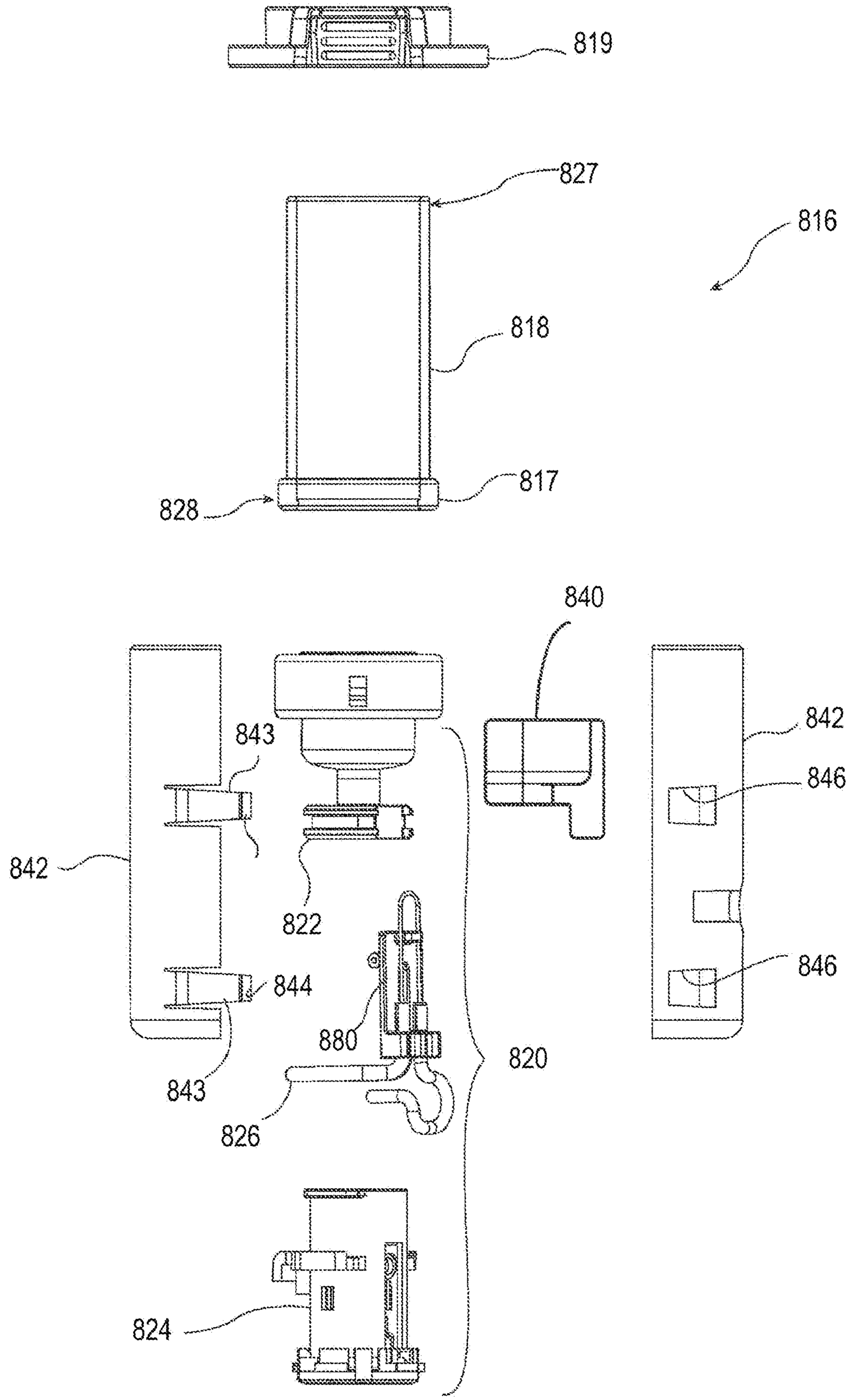


FIG. 174

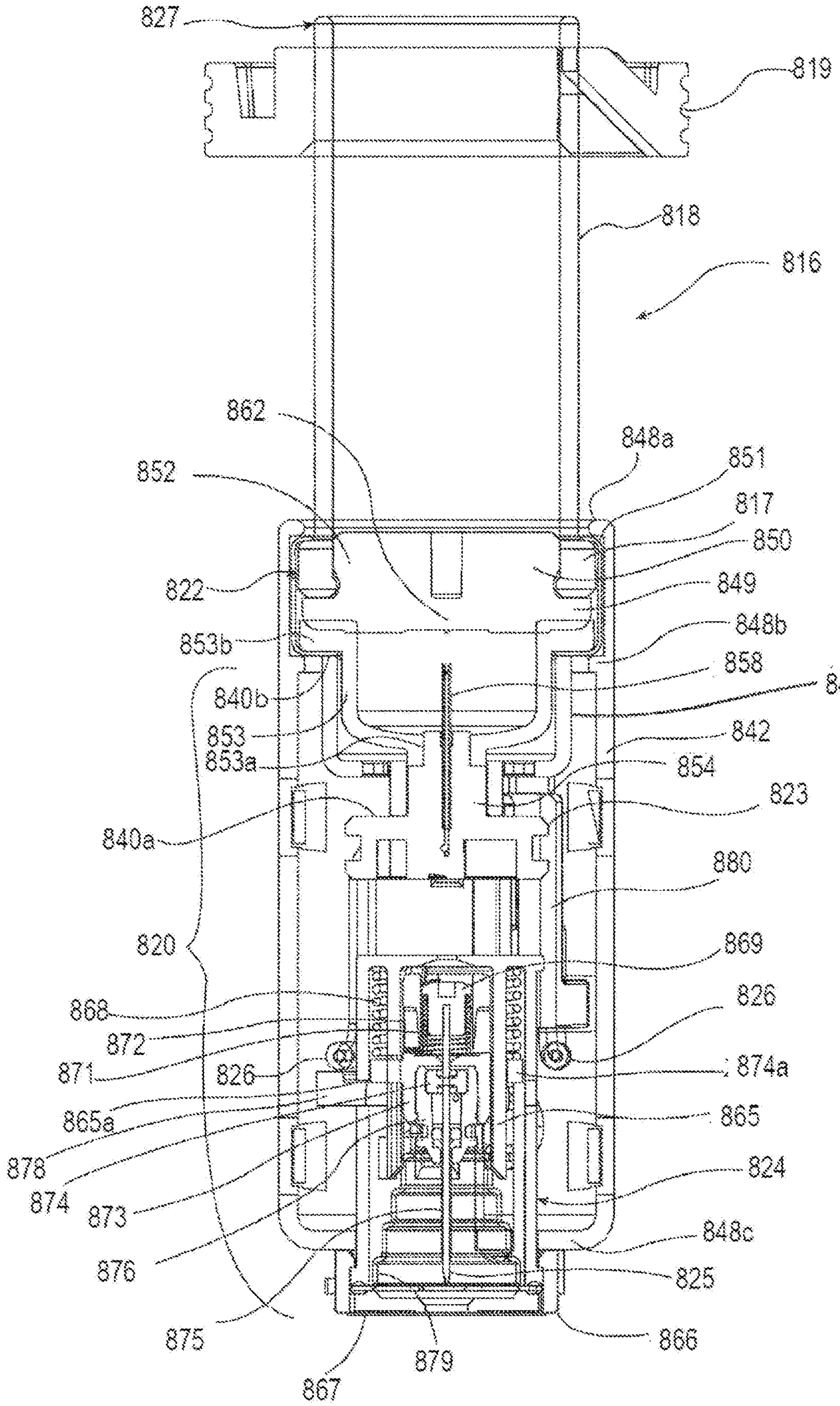

827
819
818
816
862
848a
851
852
817
850
822
849
848b
853b
858
840
840b
842
853
853a
854
823
840a
880
820
869
868
826
872
871
826
874a
865
865a
824
878
874
873
848c
876
825
875
879
866
867

FIG. 175

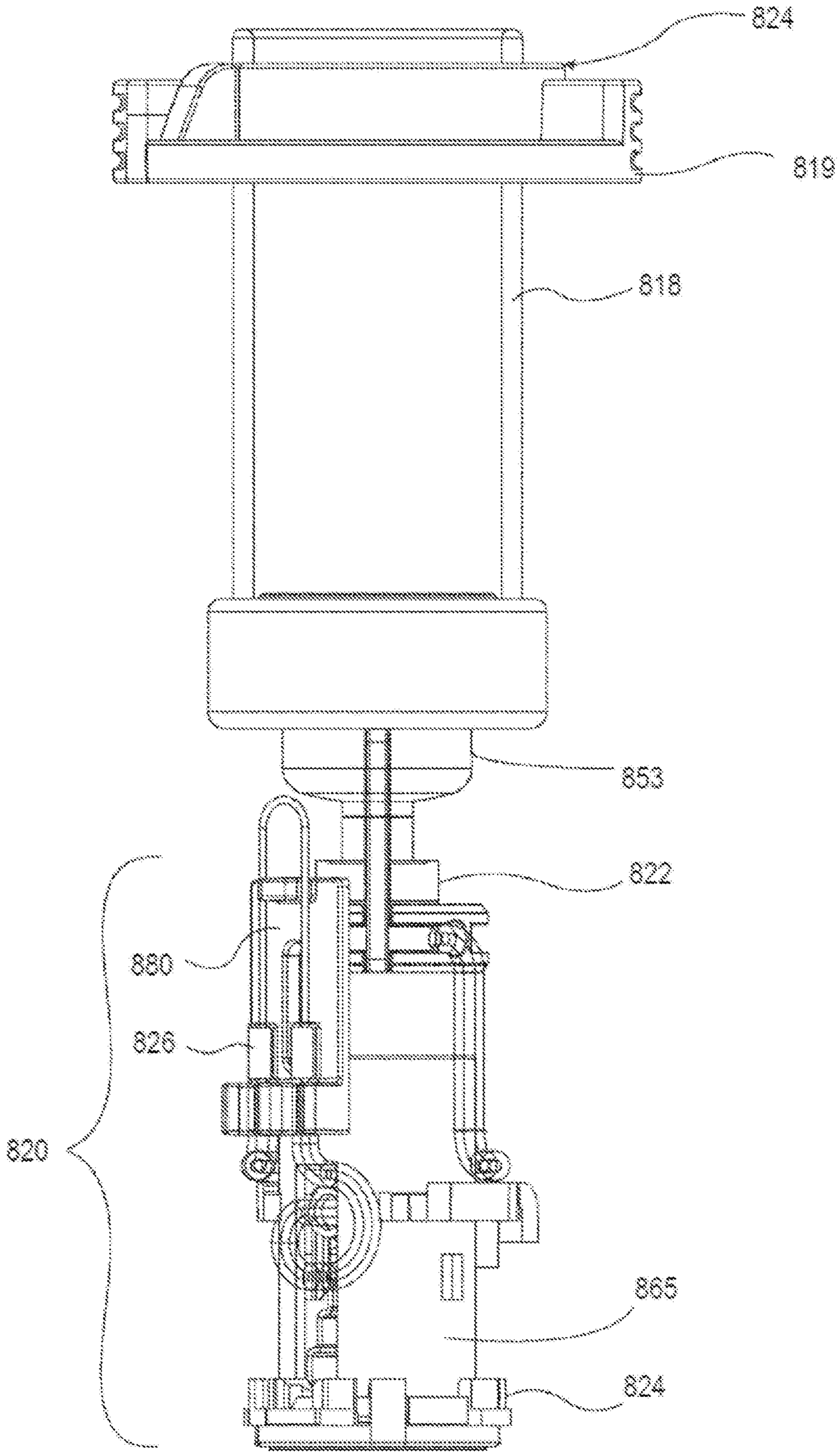


FIG. 176

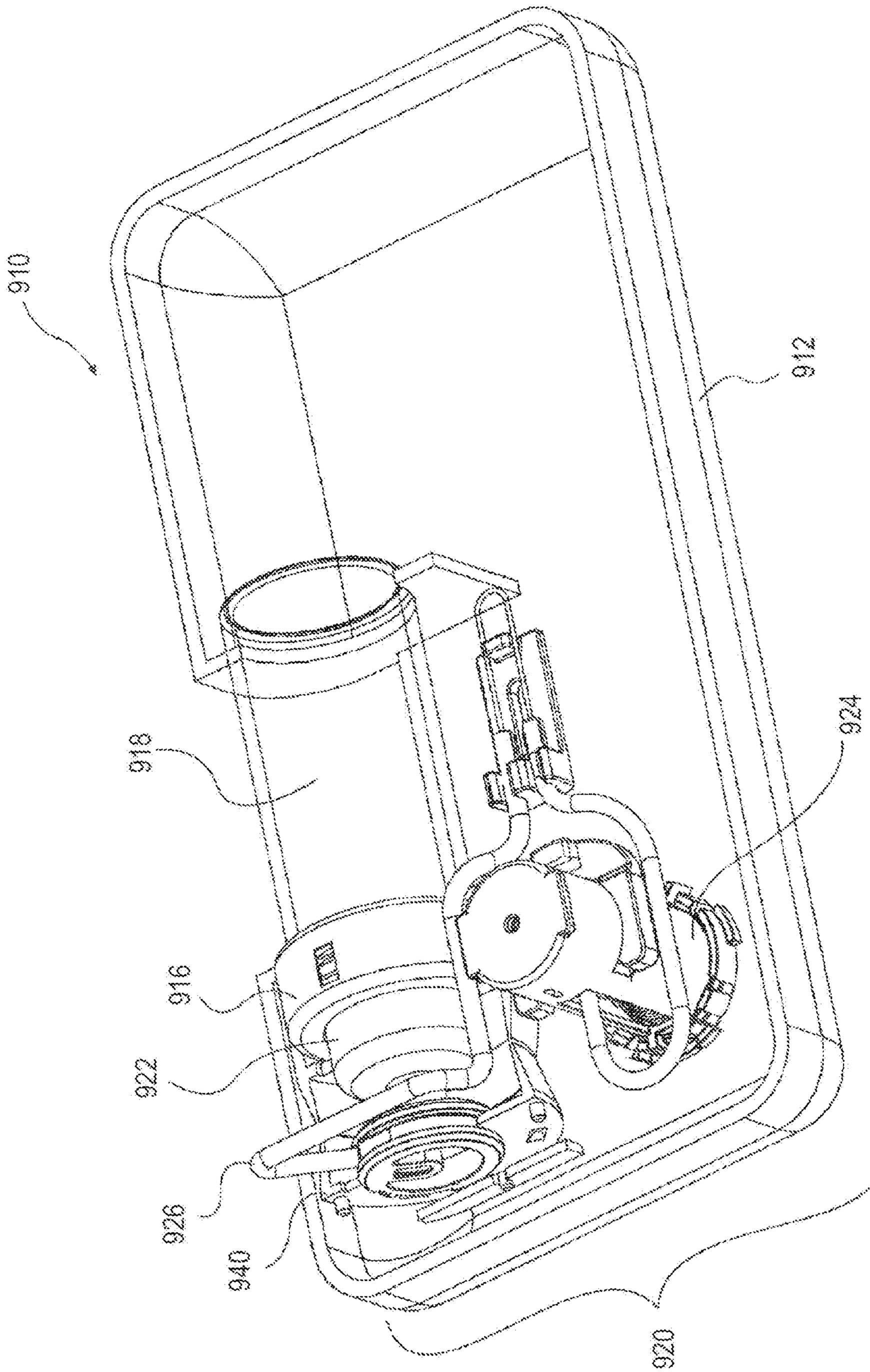


FIG. 177

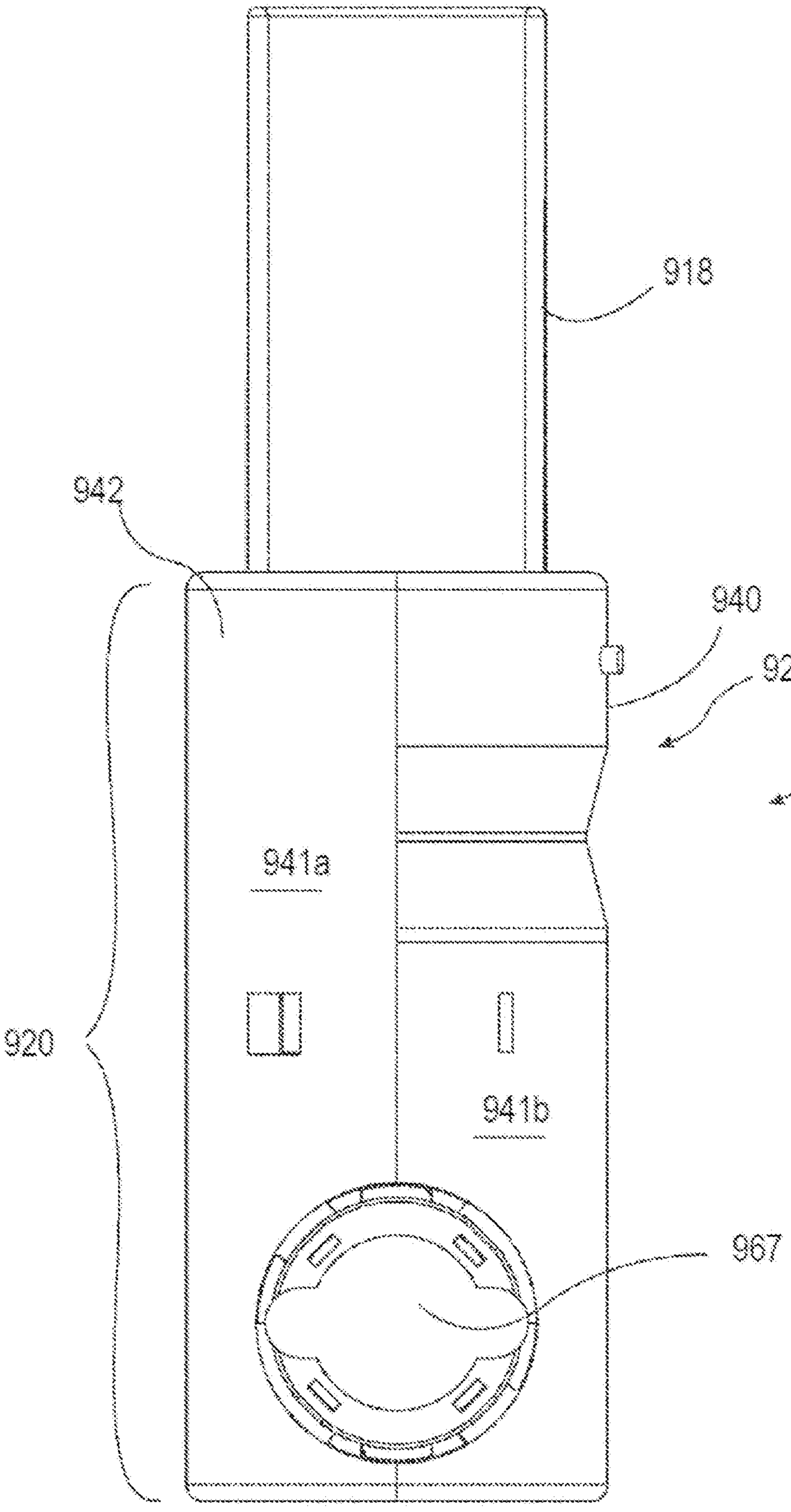


FIG. 178

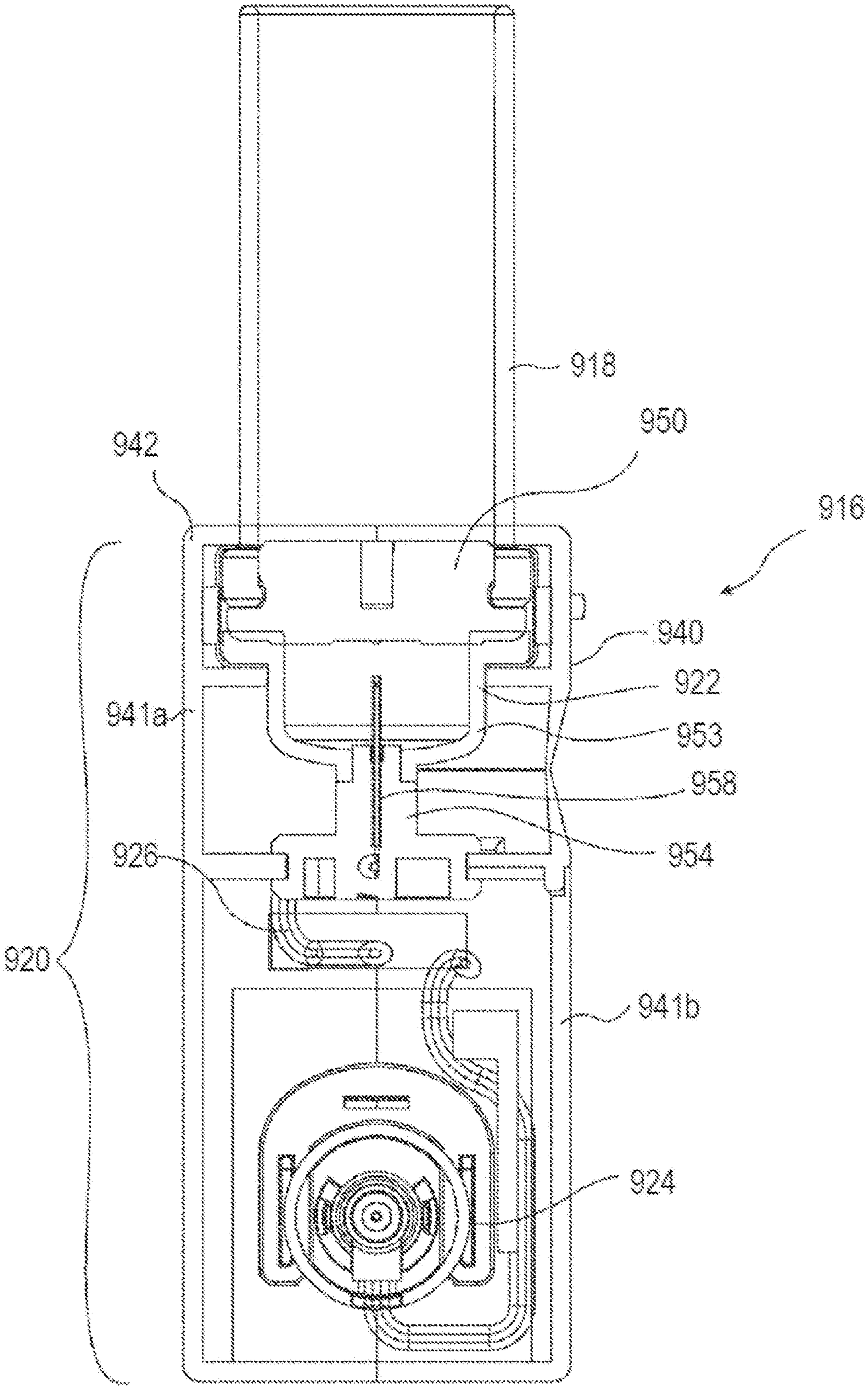


FIG. 179

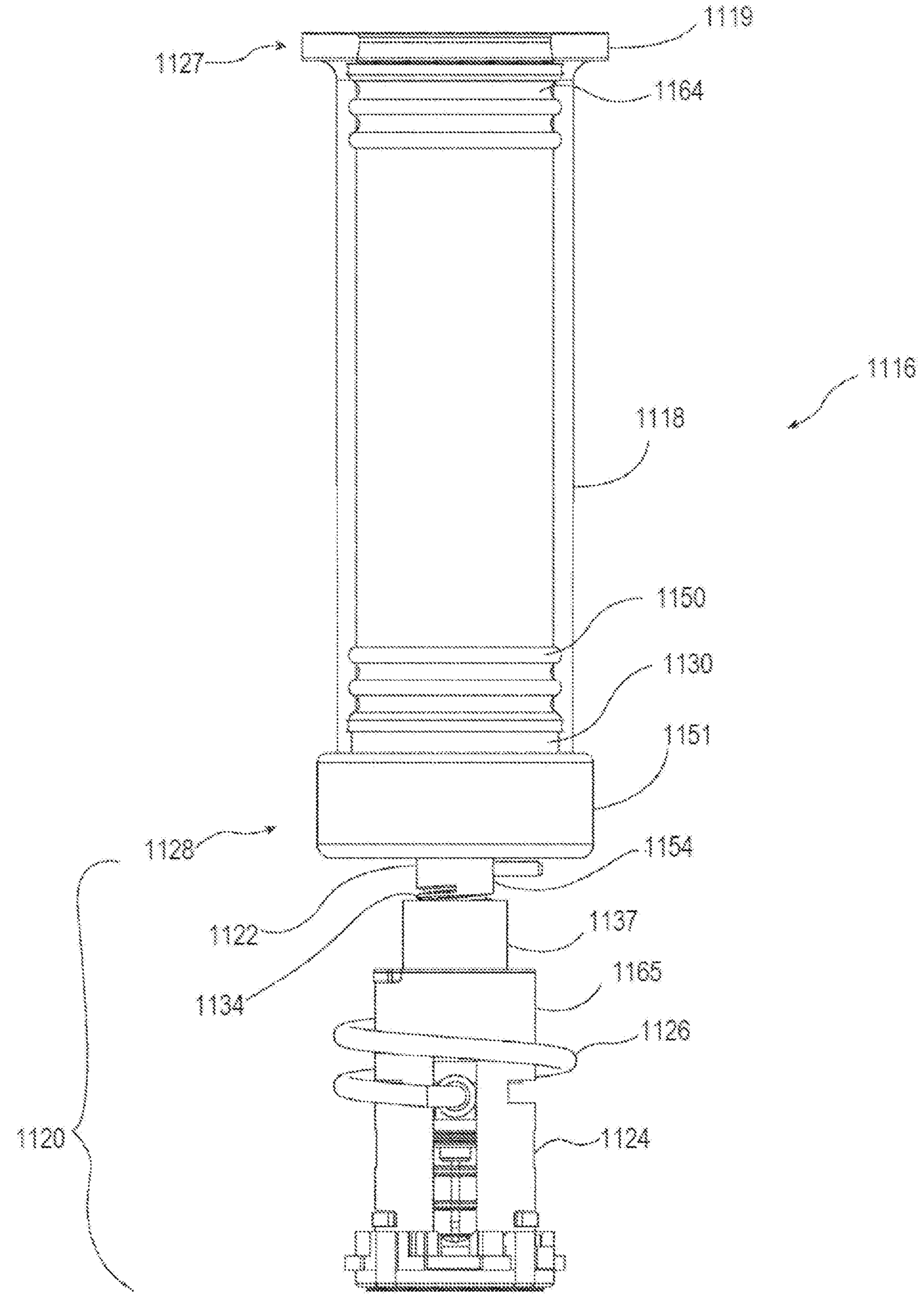

1119
1127
1164
1116
1118
1150
1130
1151
1128
1154
1122
1137
1134
1165
1126
1120
1124

FIG. 180

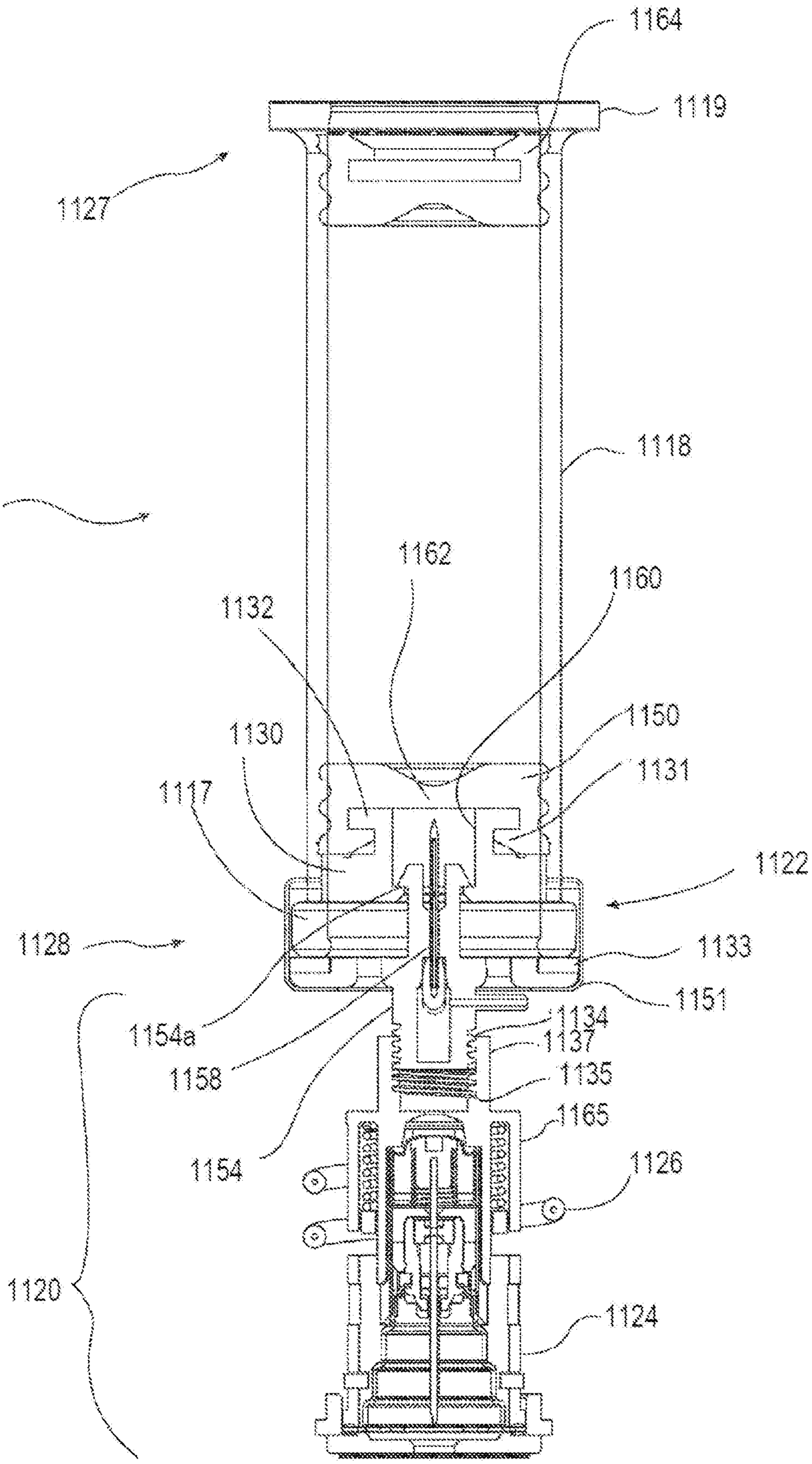

1164
1119
1127
1118
1116
1162
1132
1160
1150
1130
1131
1117
1122
1128
1133
1151
1134
1154a
1137
1158
1135
1165
1154
1126
1120
1124

FIG. 181

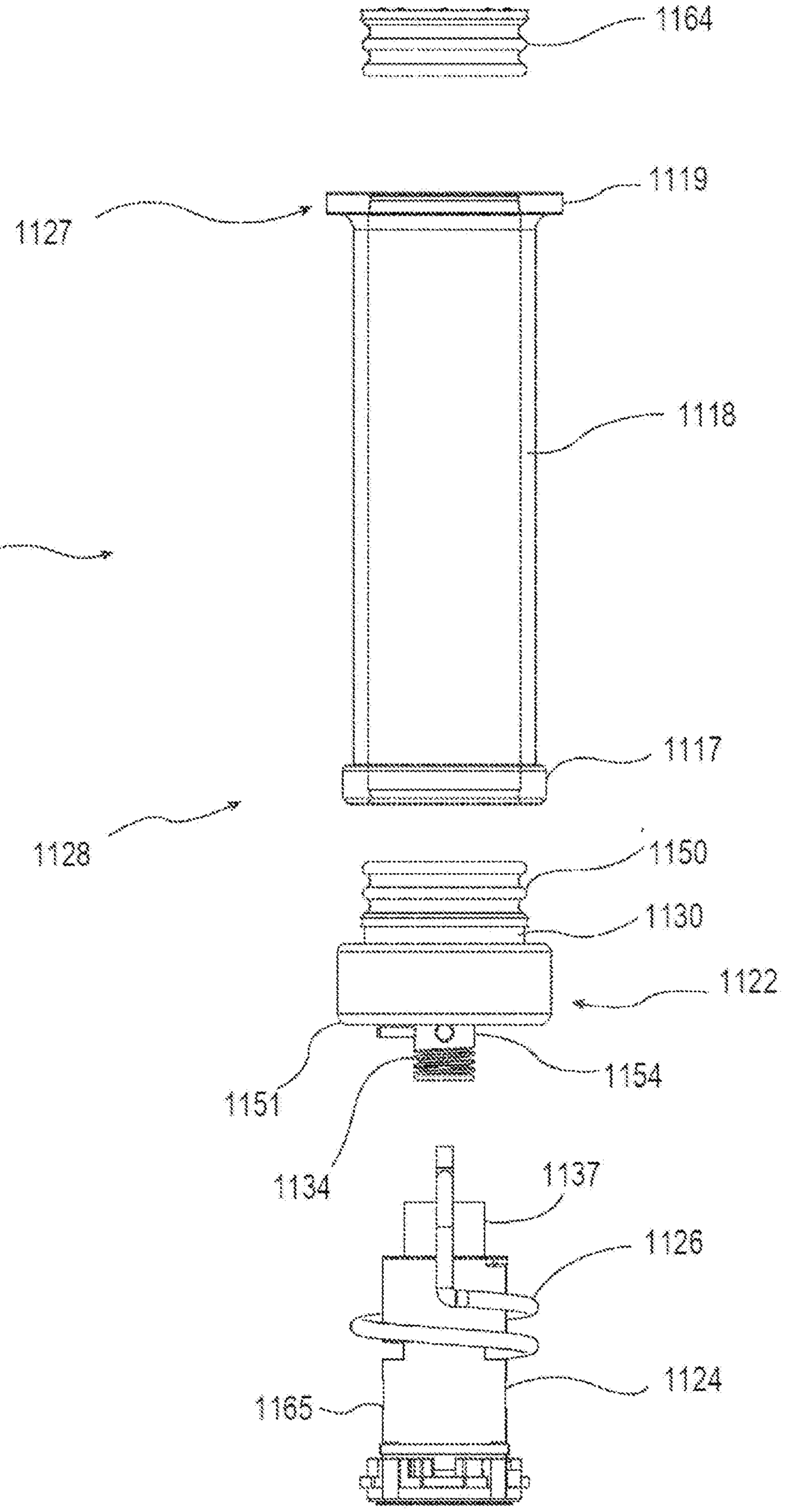

1164
1119
1127
1116
1118
1117
1128
1150
1130
1122
1151
1154
1134
1137
1126
1124
1165

FIG. 182

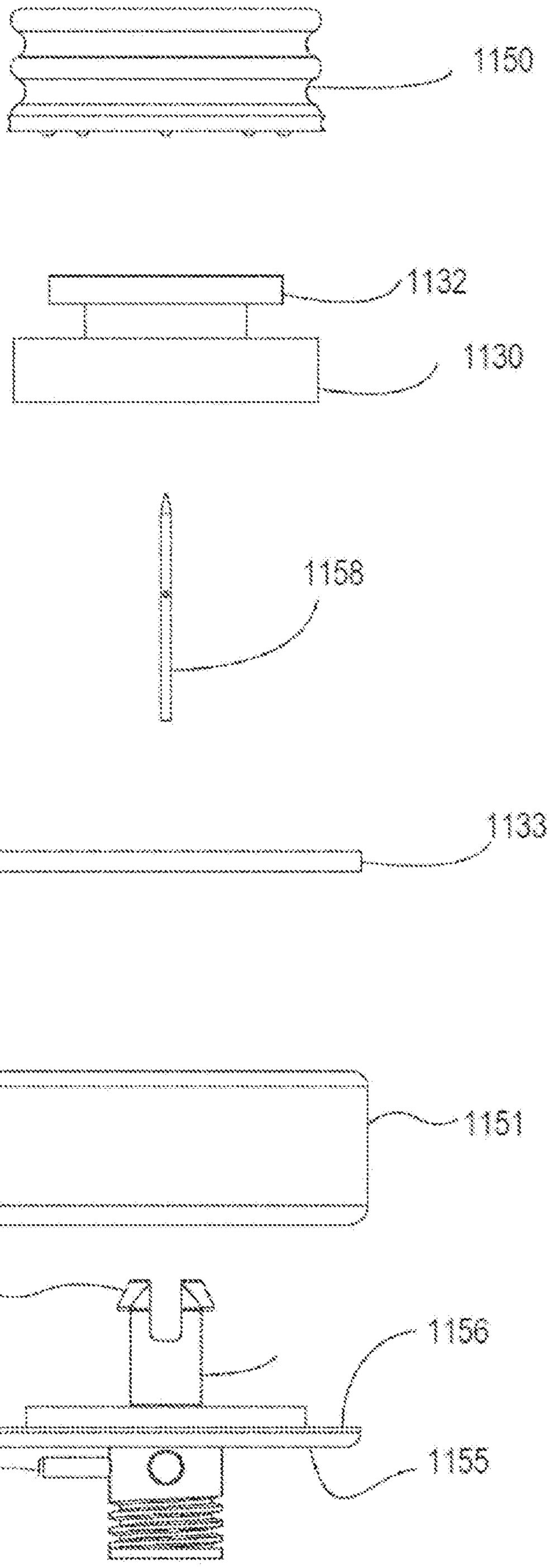


FIG. 183

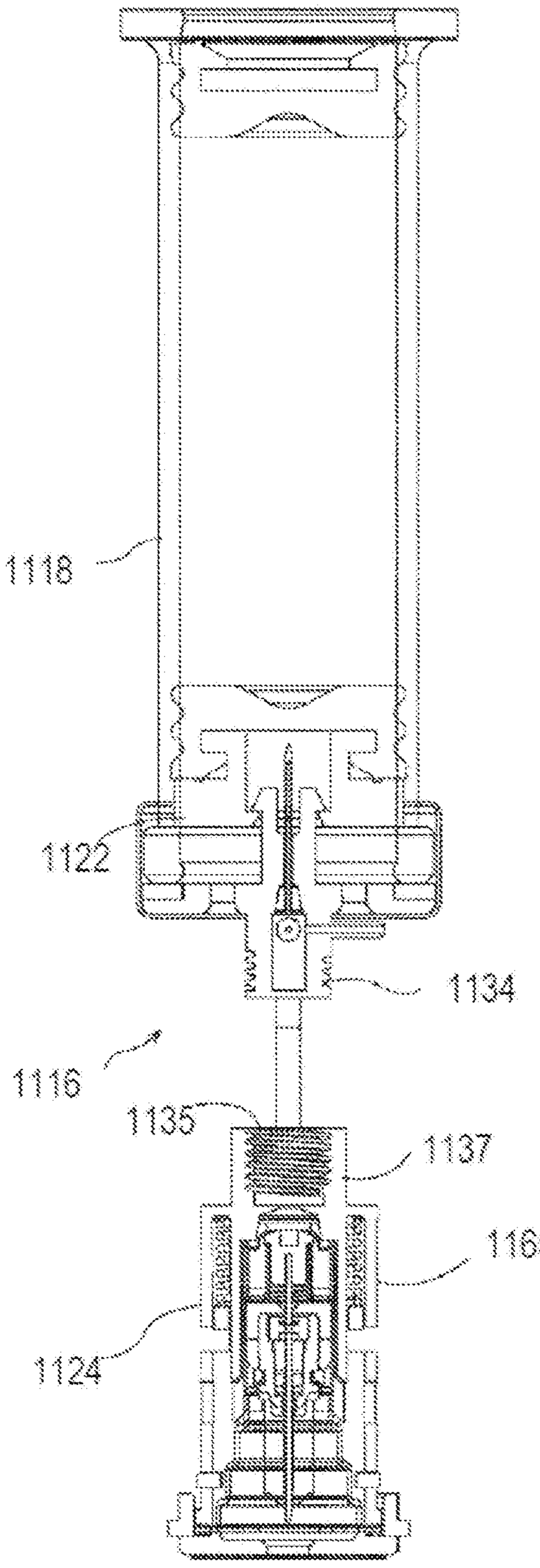


FIG. 184

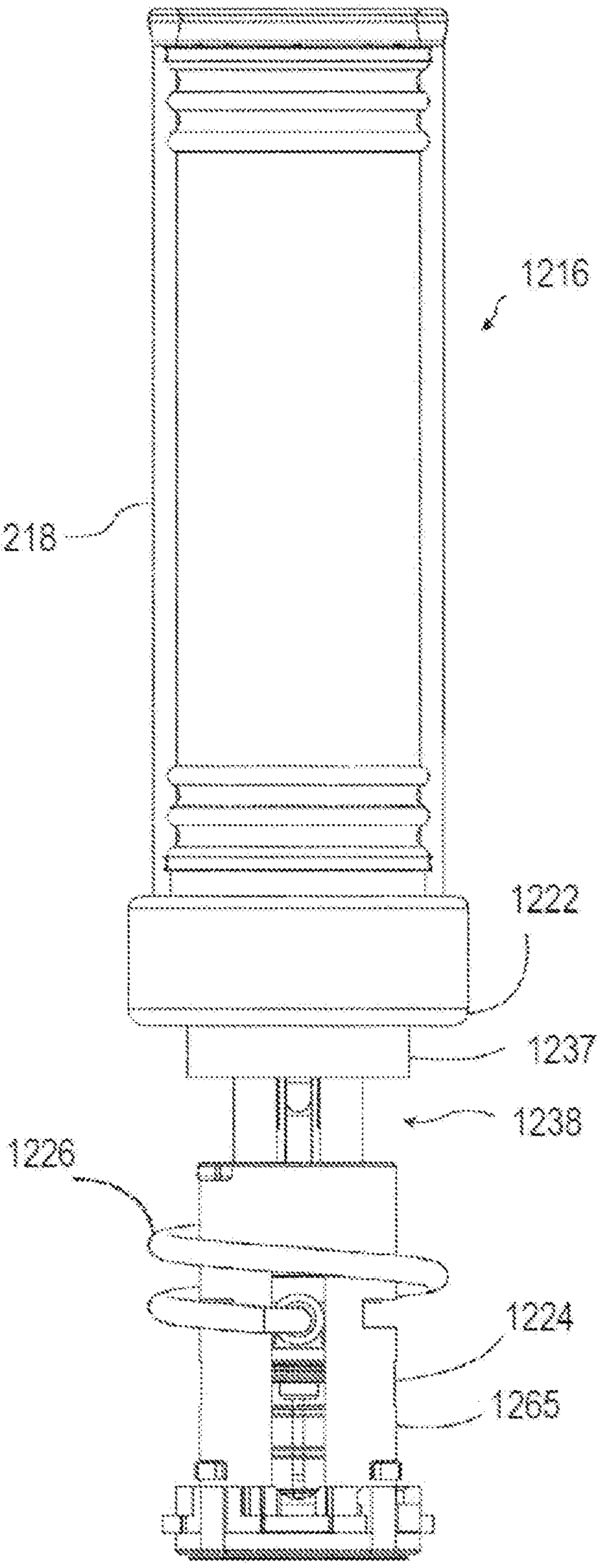


FIG. 185

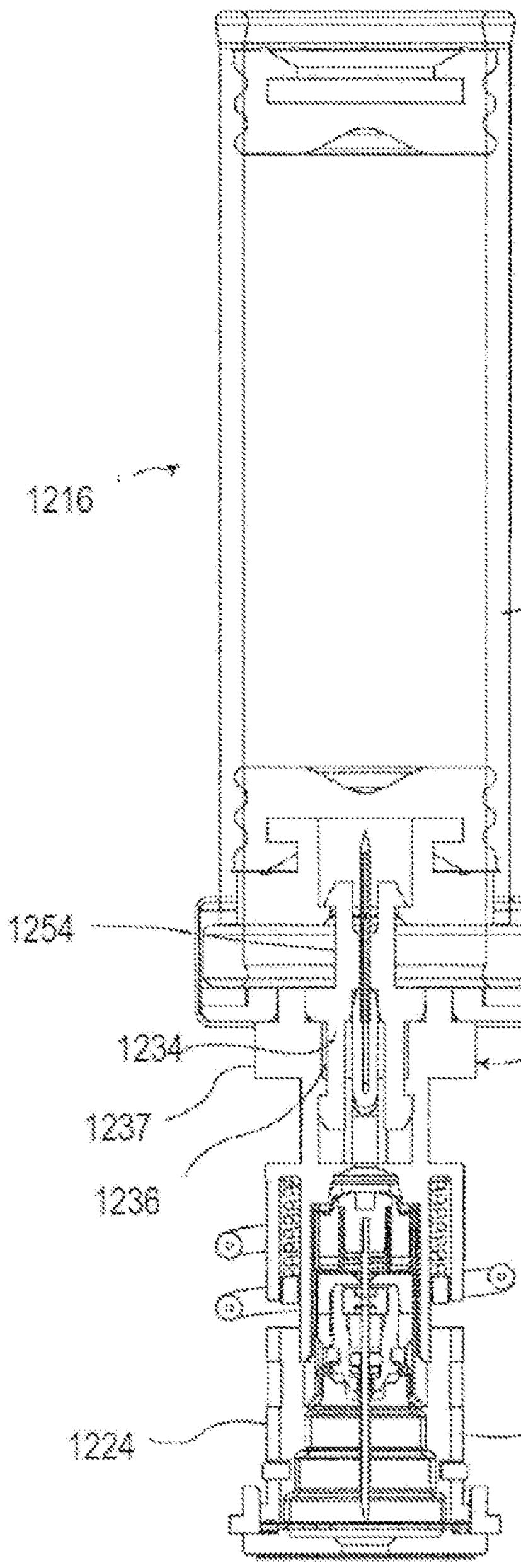


FIG. 186

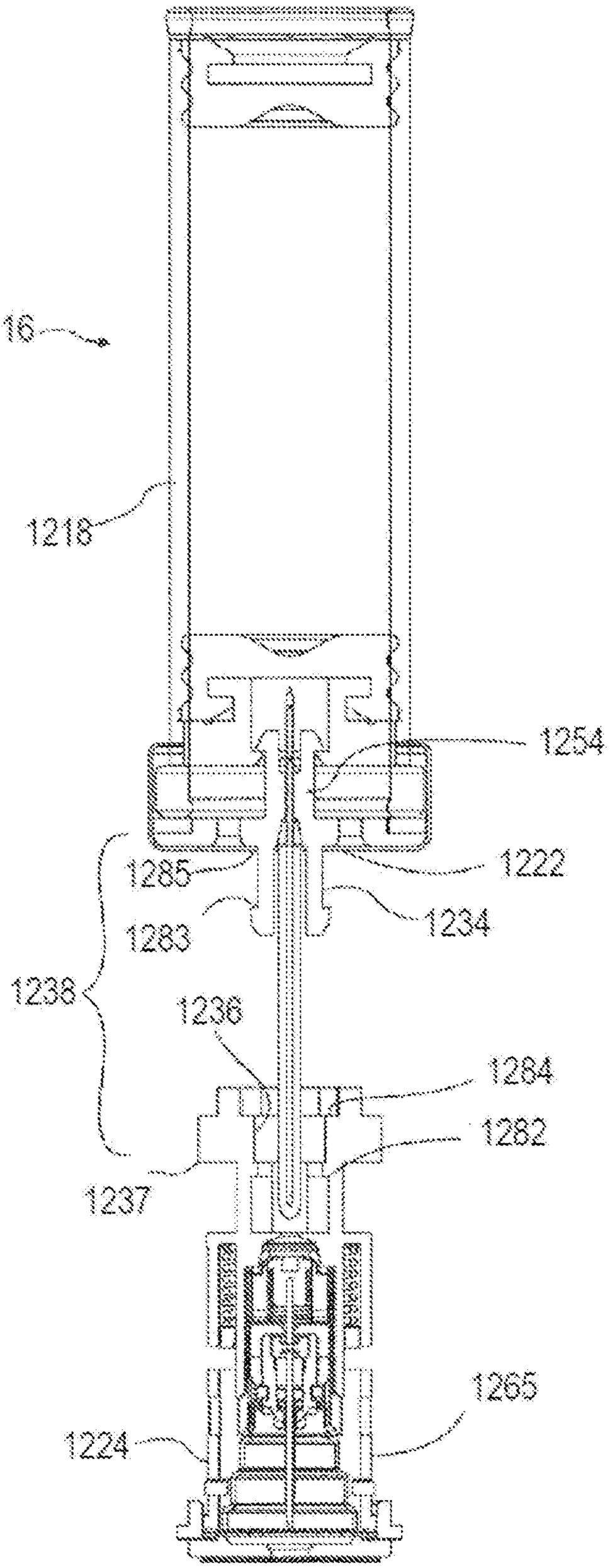


FIG. 187

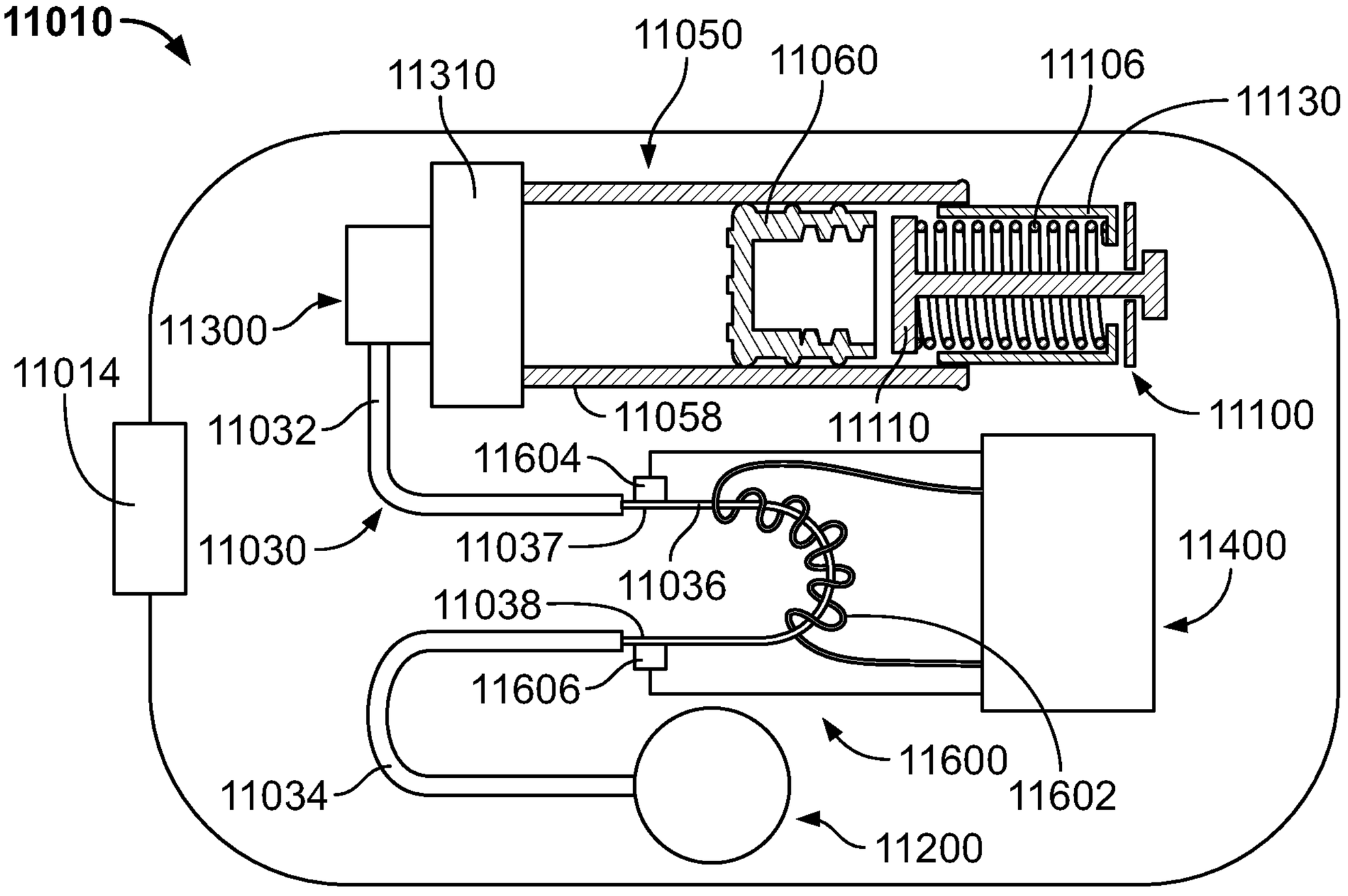

11010
11050
11310
11060
11106
11130
11300
11014
11032
11058
11110
11100
11604
11030
11037
11036
11400
11038
11606
11600
11602
11034
11200

FIG. 188

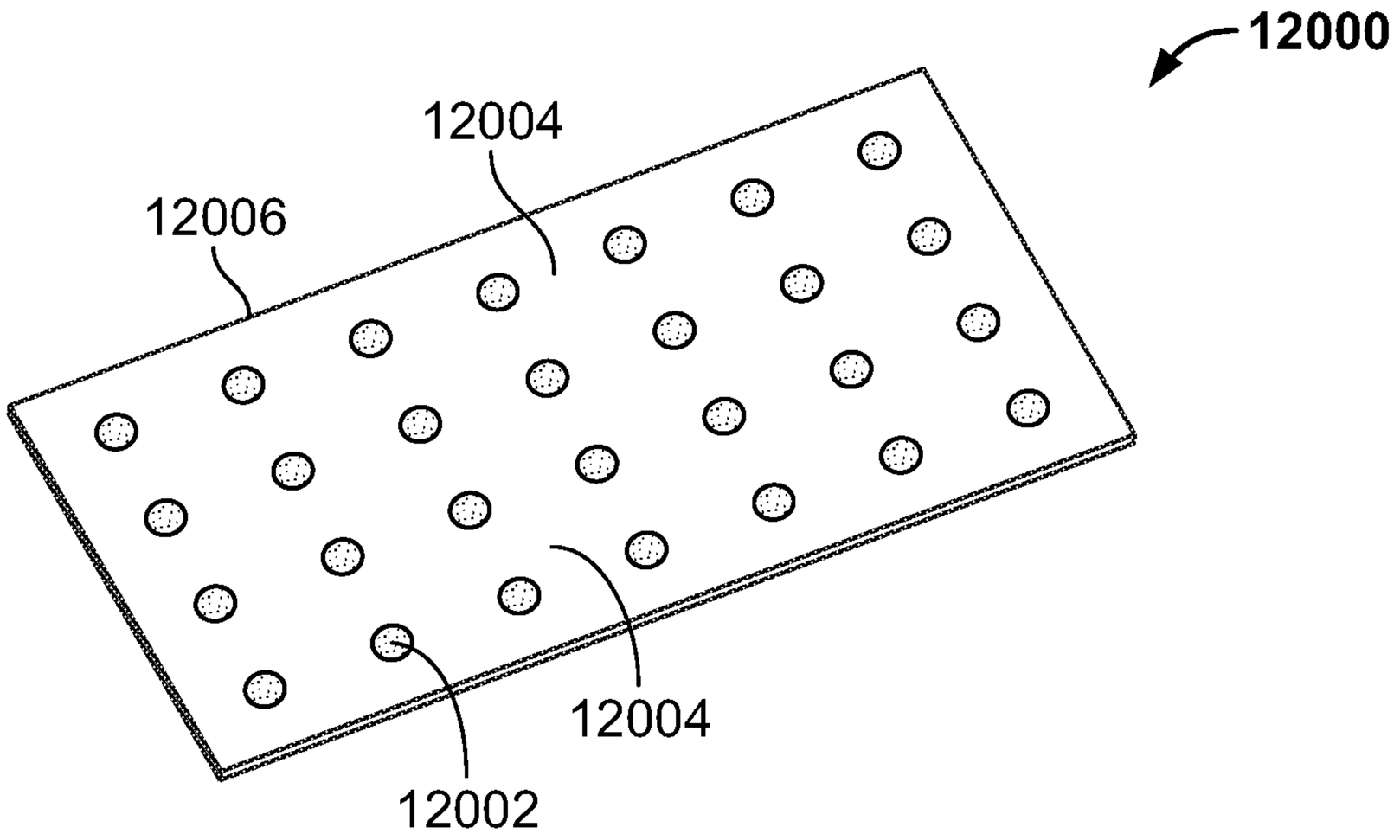


FIG. 189A

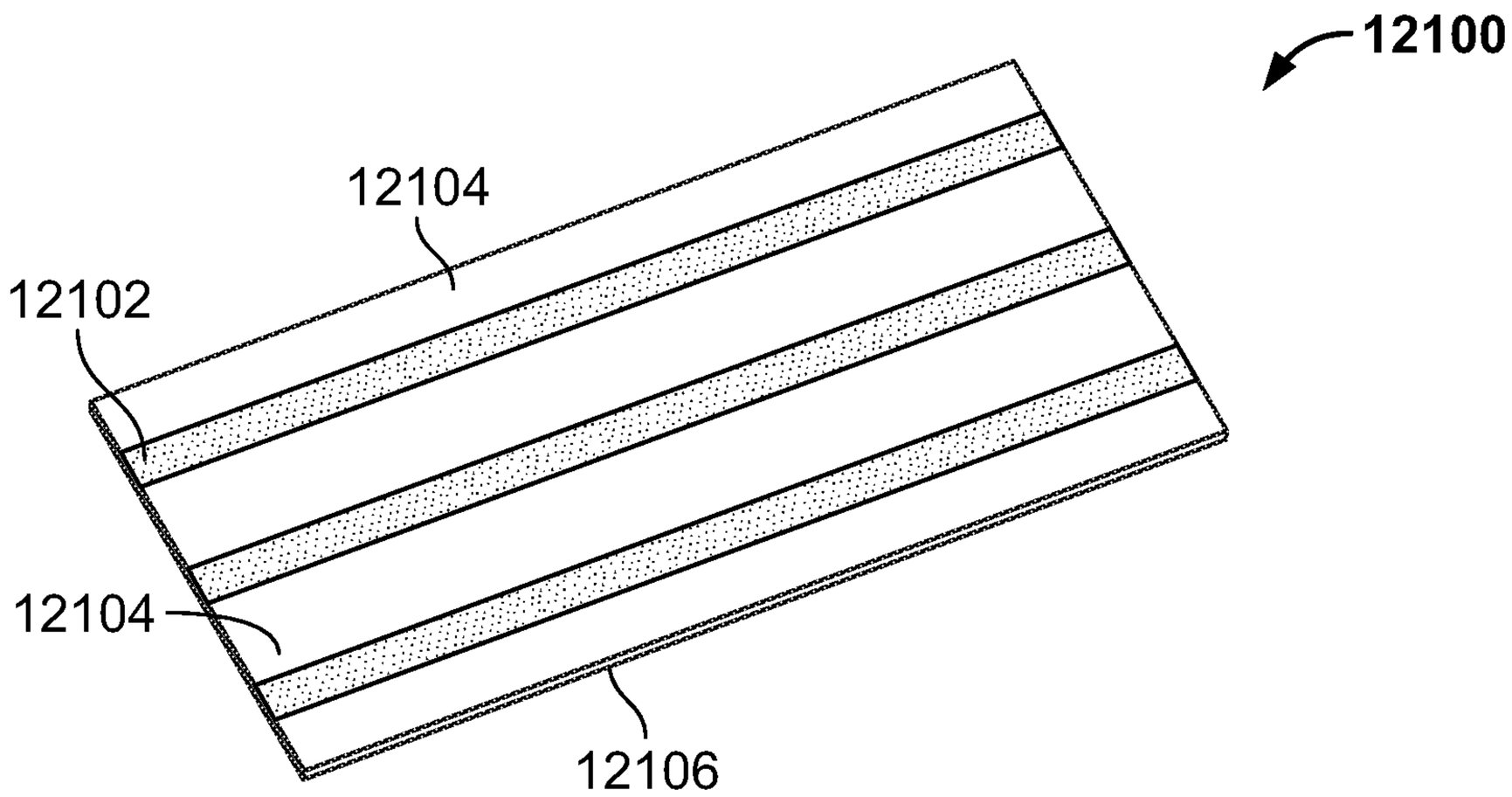


FIG. 189B

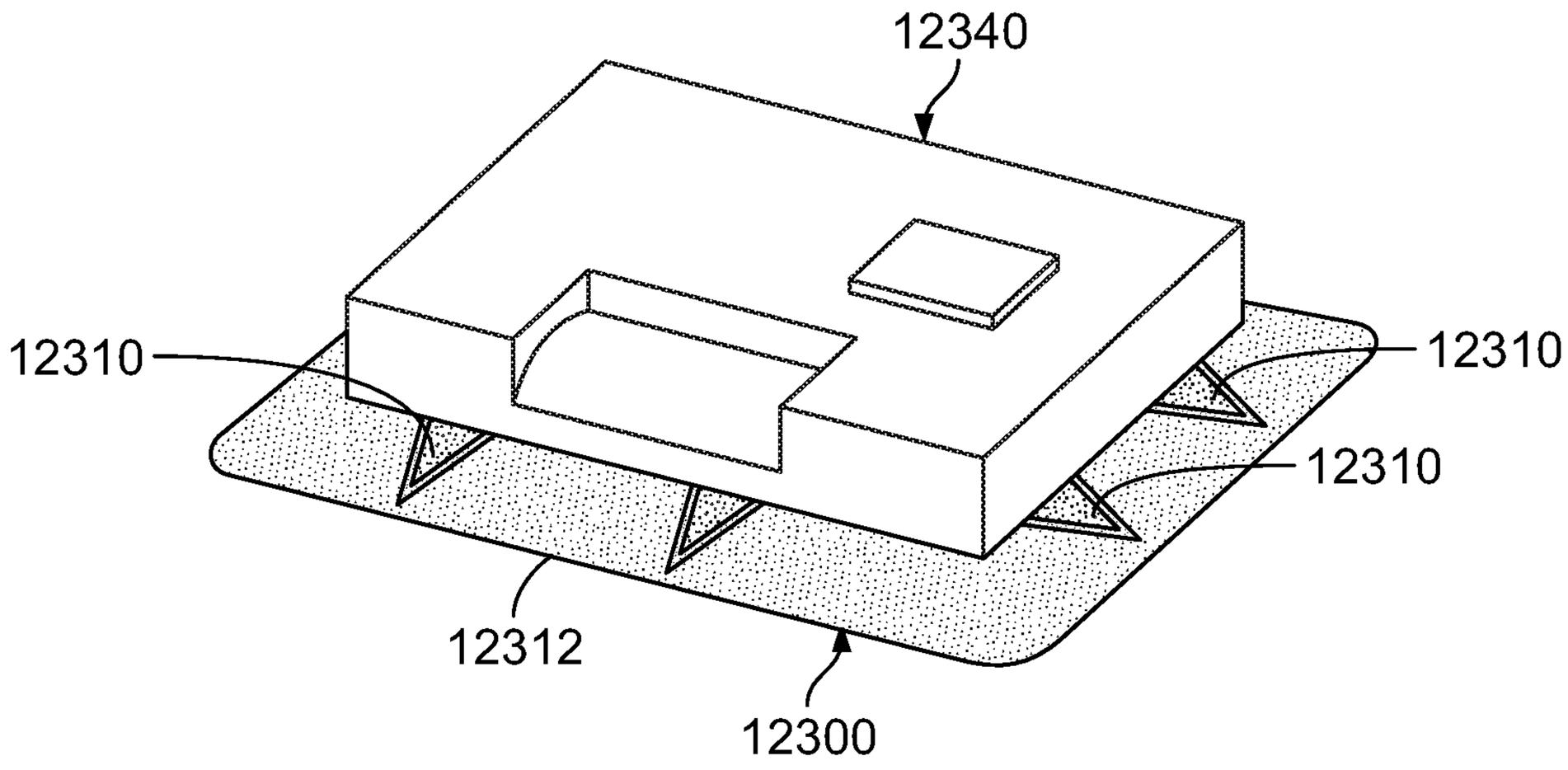


FIG. 190

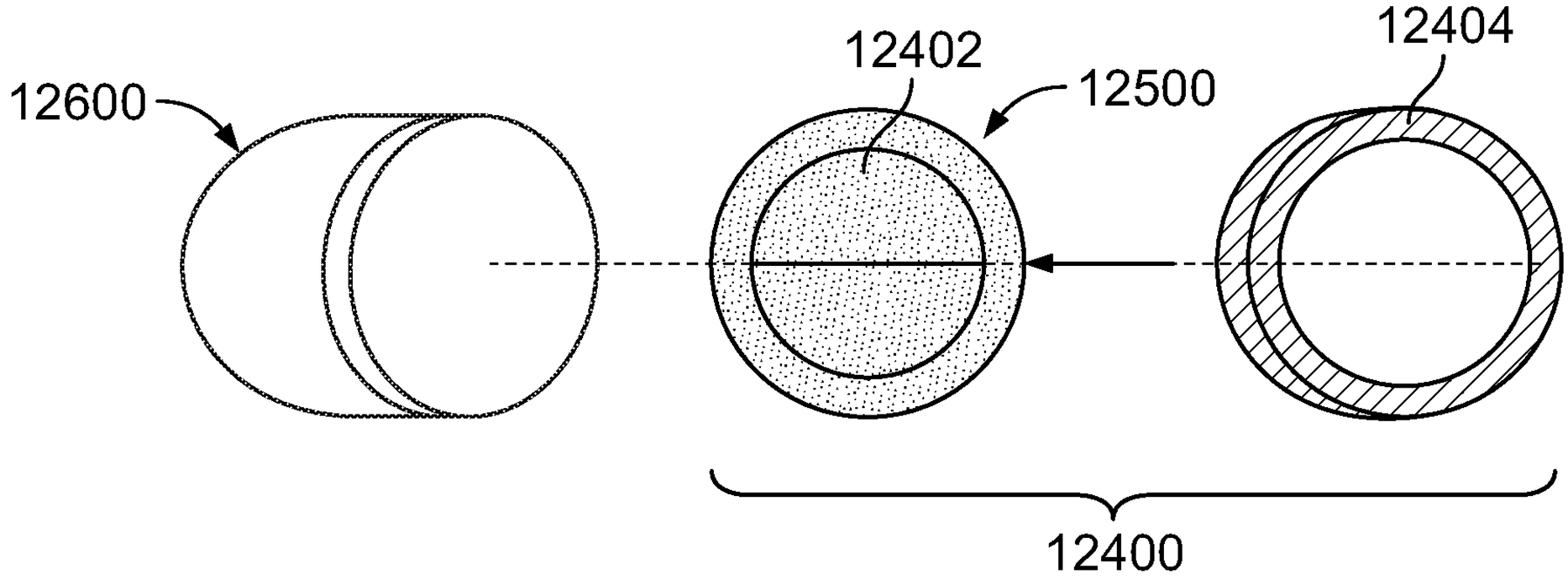


FIG. 191A

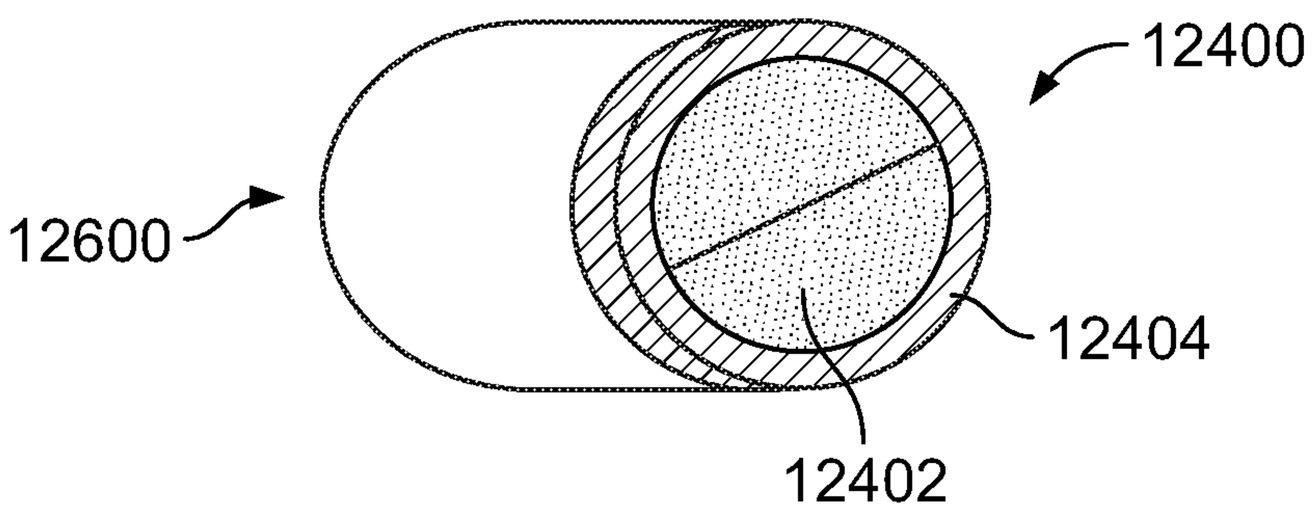


FIG. 191B

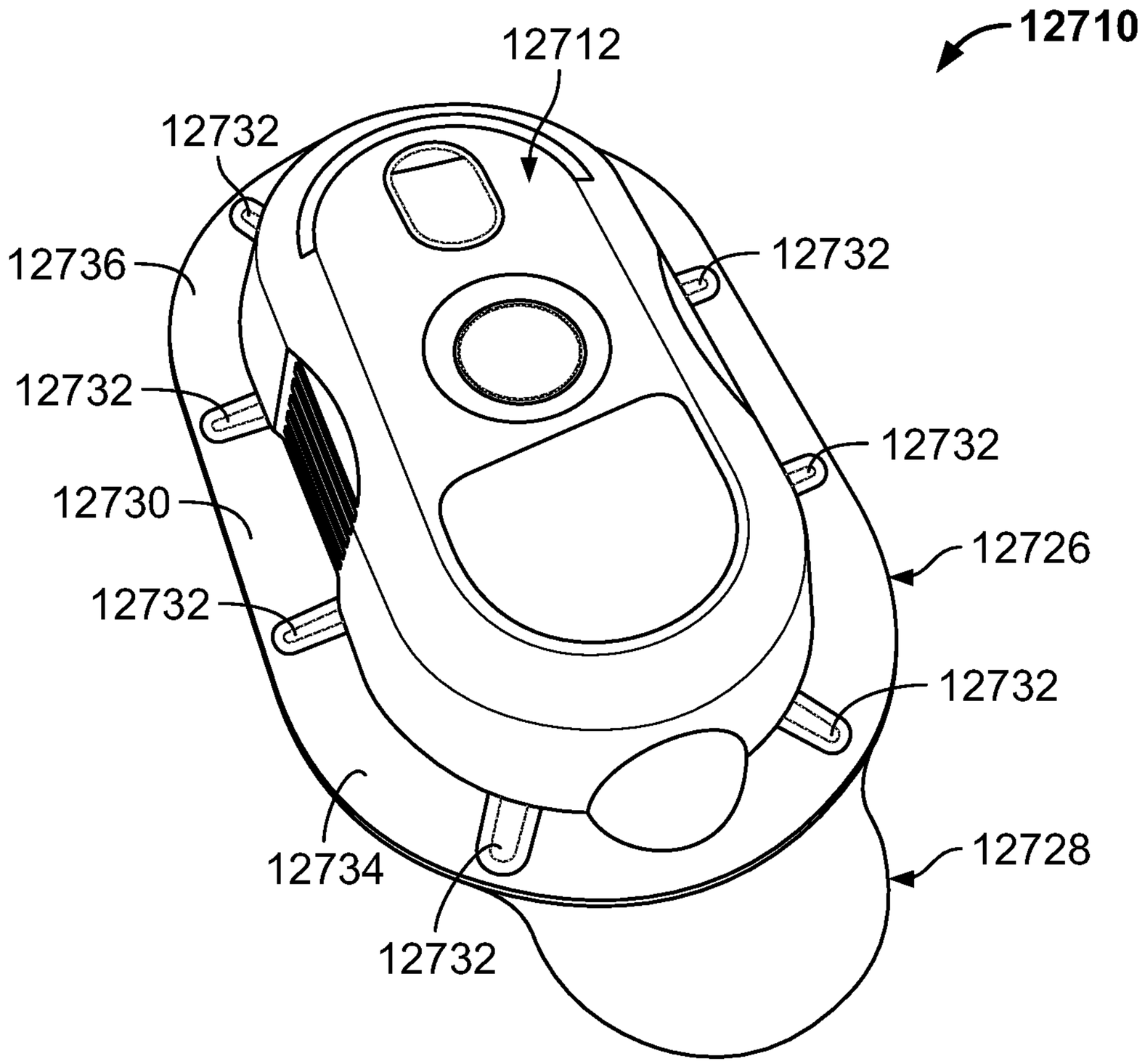


FIG. 192

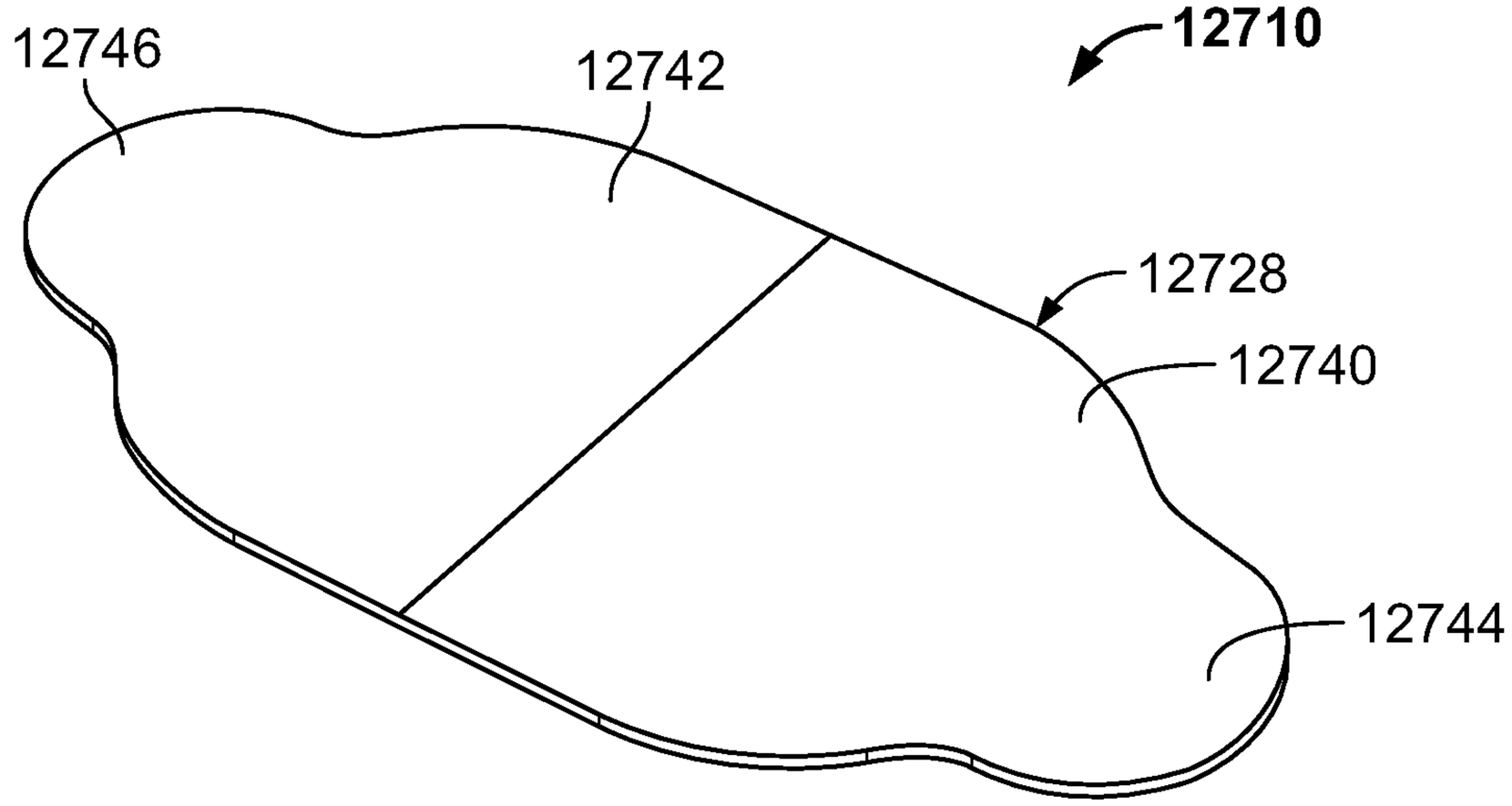


FIG. 193

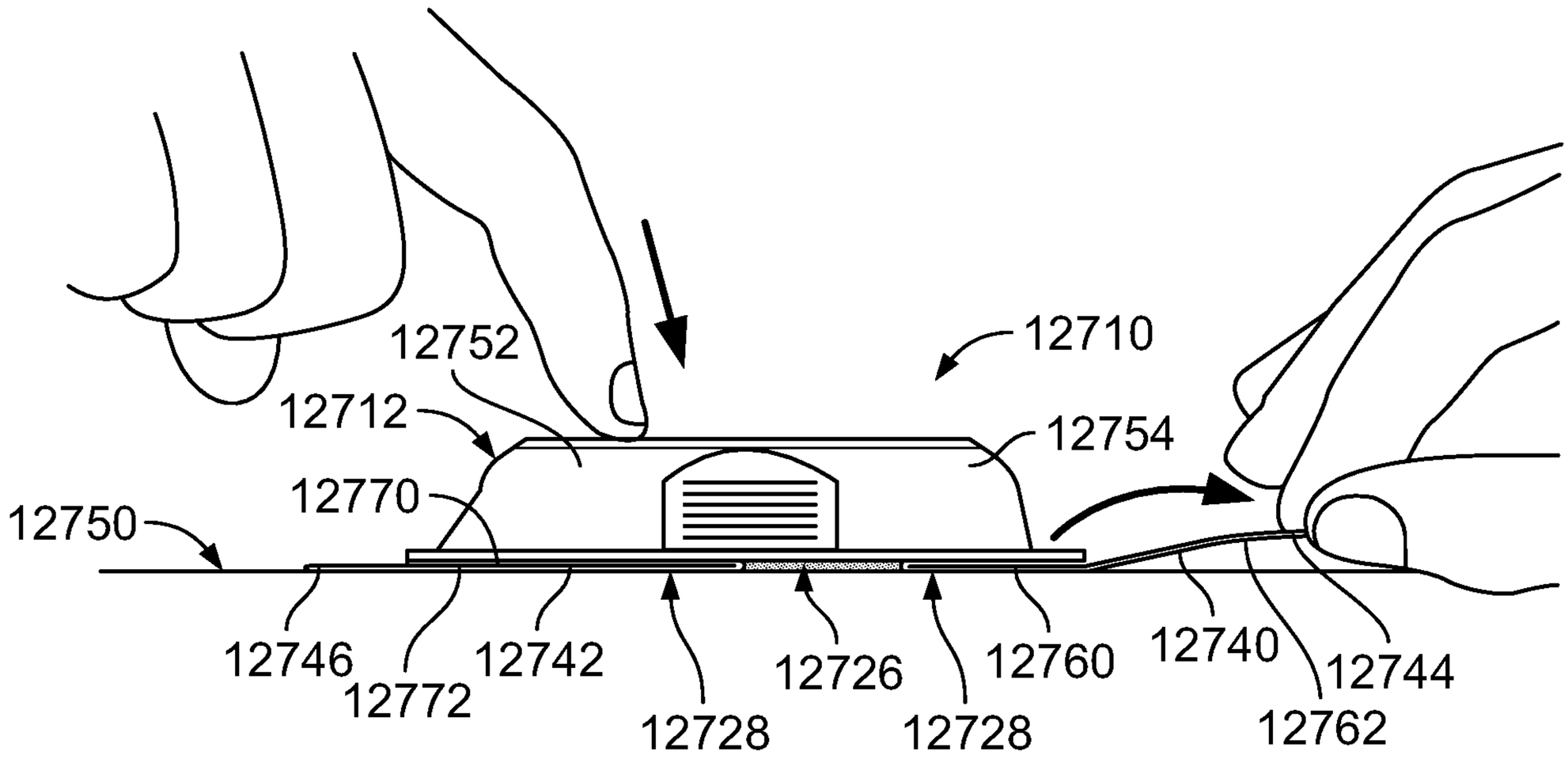


FIG. 194A

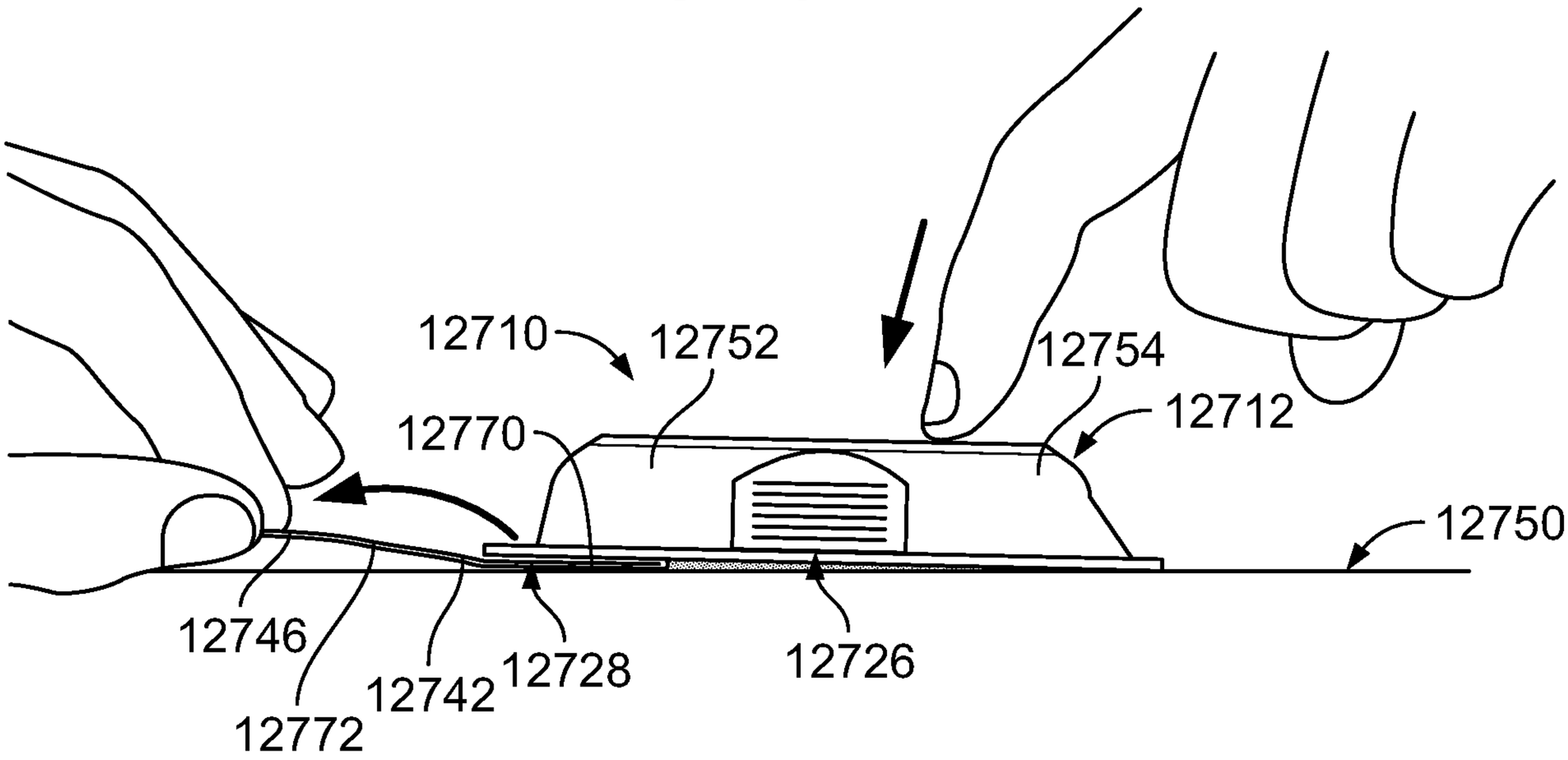


FIG. 194B

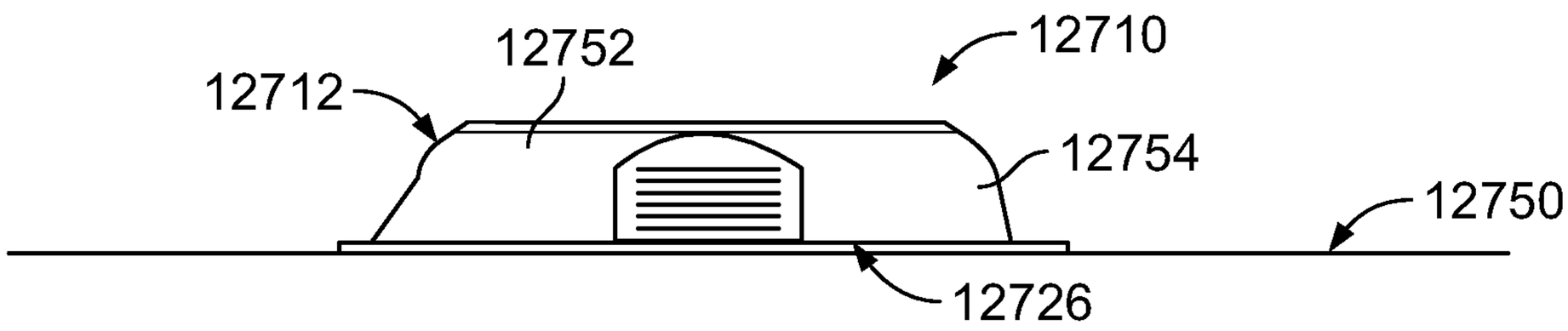


FIG. 194C

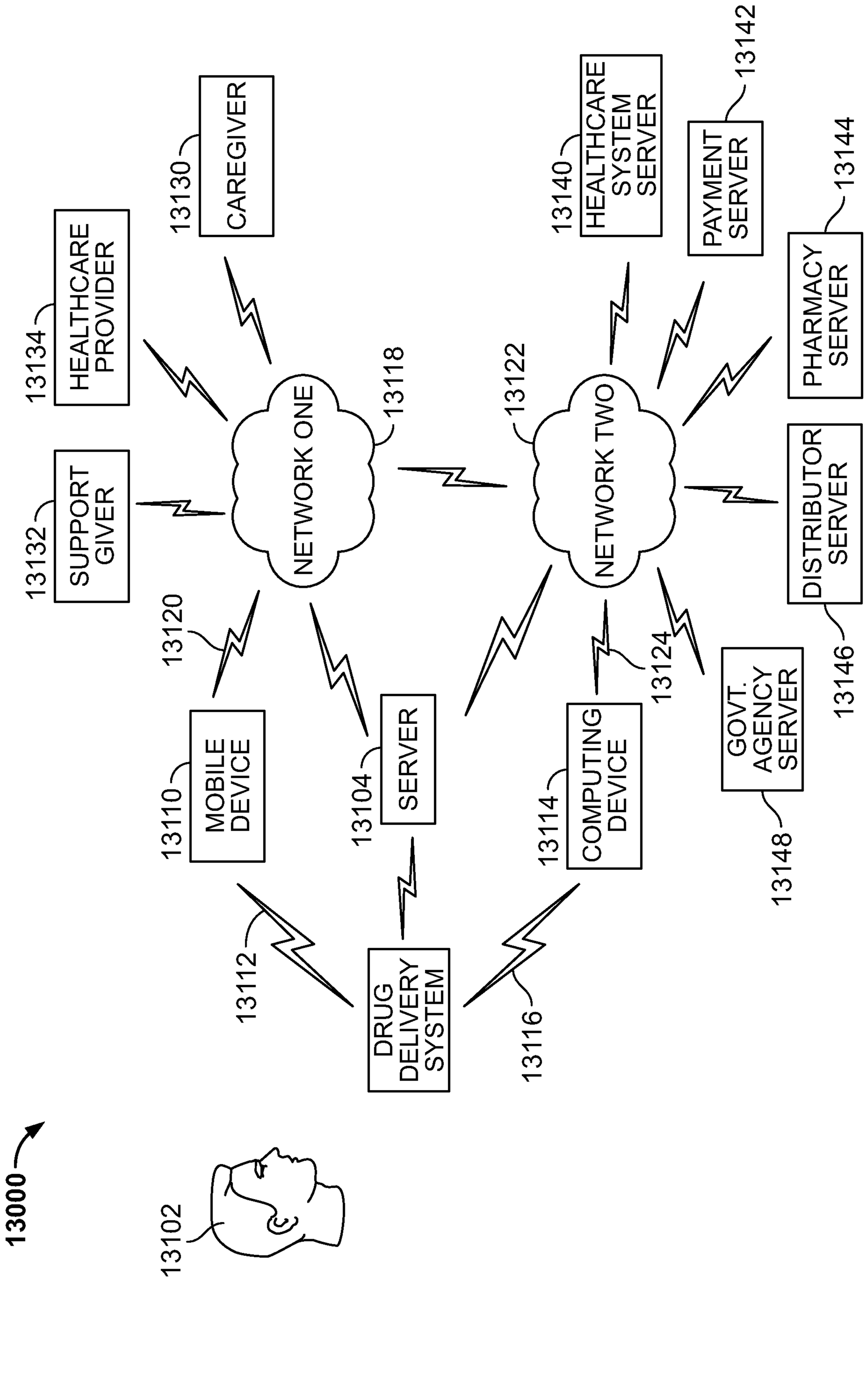

13000
13102
13110
MOBILE DEVICE
13112
13116
DRUG DELIVERY SYSTEM
13120
13130
CAREGIVER
13132
SUPPORT GIVER
13134
HEALTHCARE PROVIDER
13104
SERVER
13118
NETWORK ONE
13122
NETWORK TWO
13124
13140
HEALTHCARE SYSTEM SERVER
13142
PAYMENT SERVER
13144
PHARMACY SERVER
13146
DISTRIBUTOR SERVER
13148
GOVT. AGENCY SERVER
13114
COMPUTING DEVICE

FIG. 195

202/208

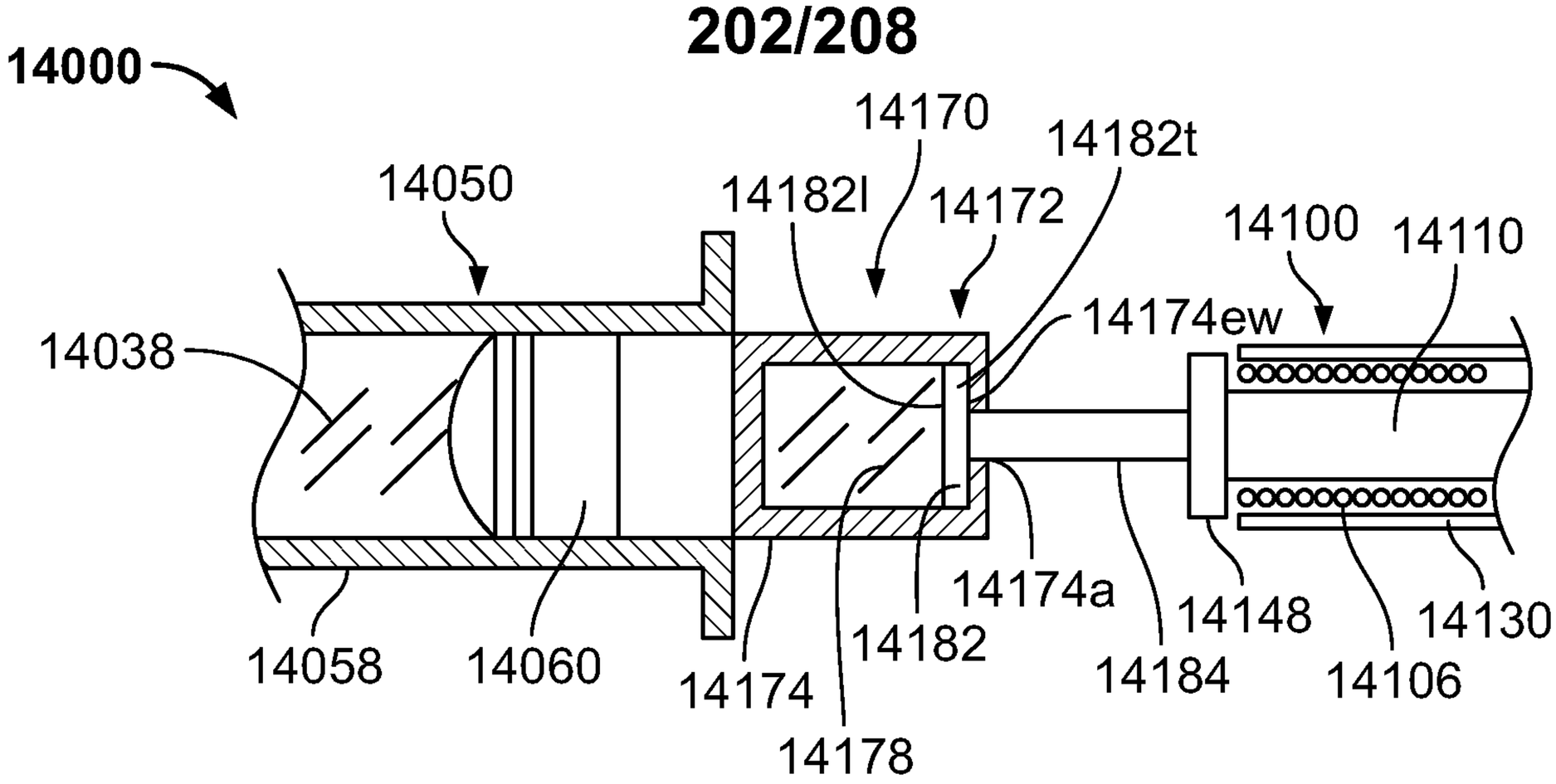


FIG. 196A

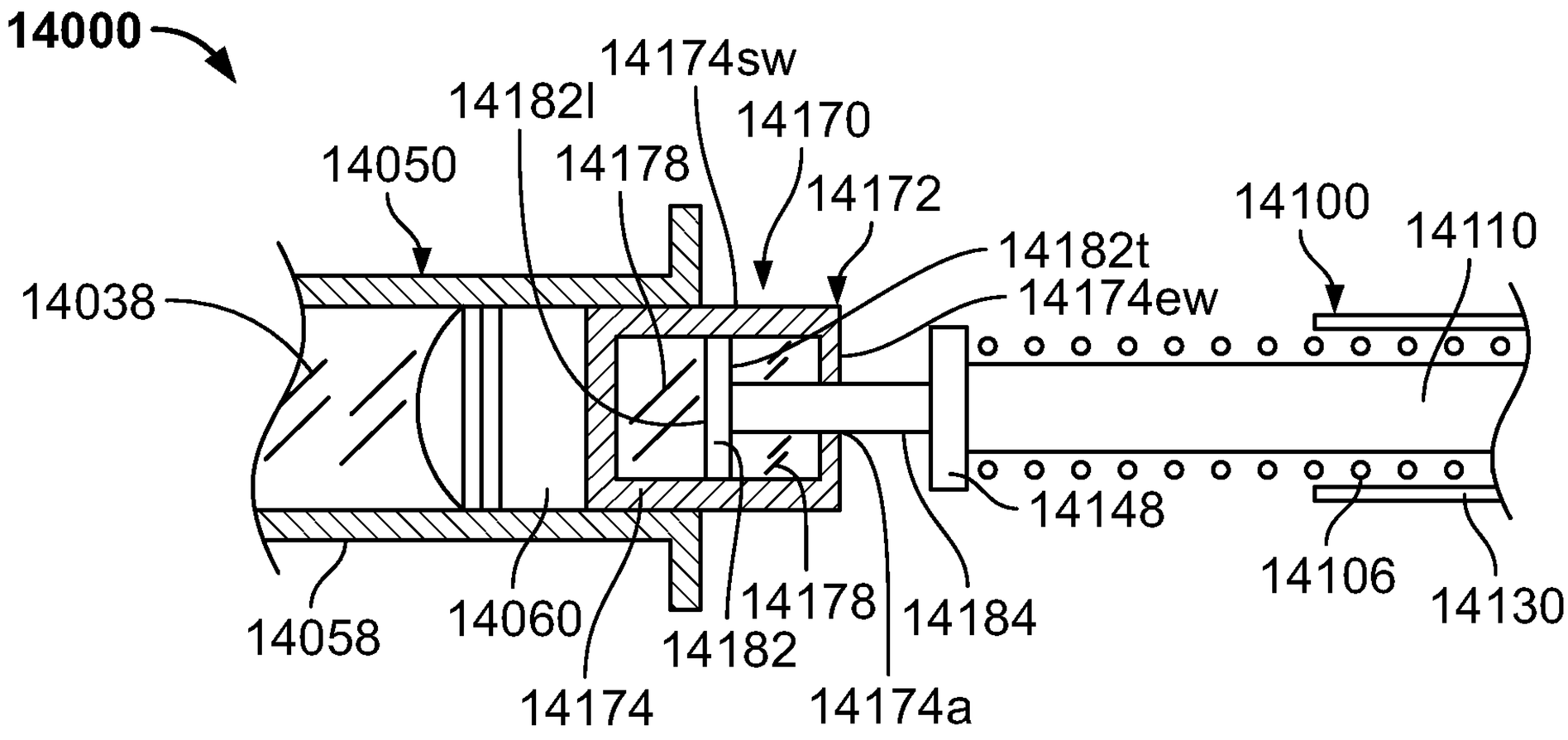


FIG. 196B

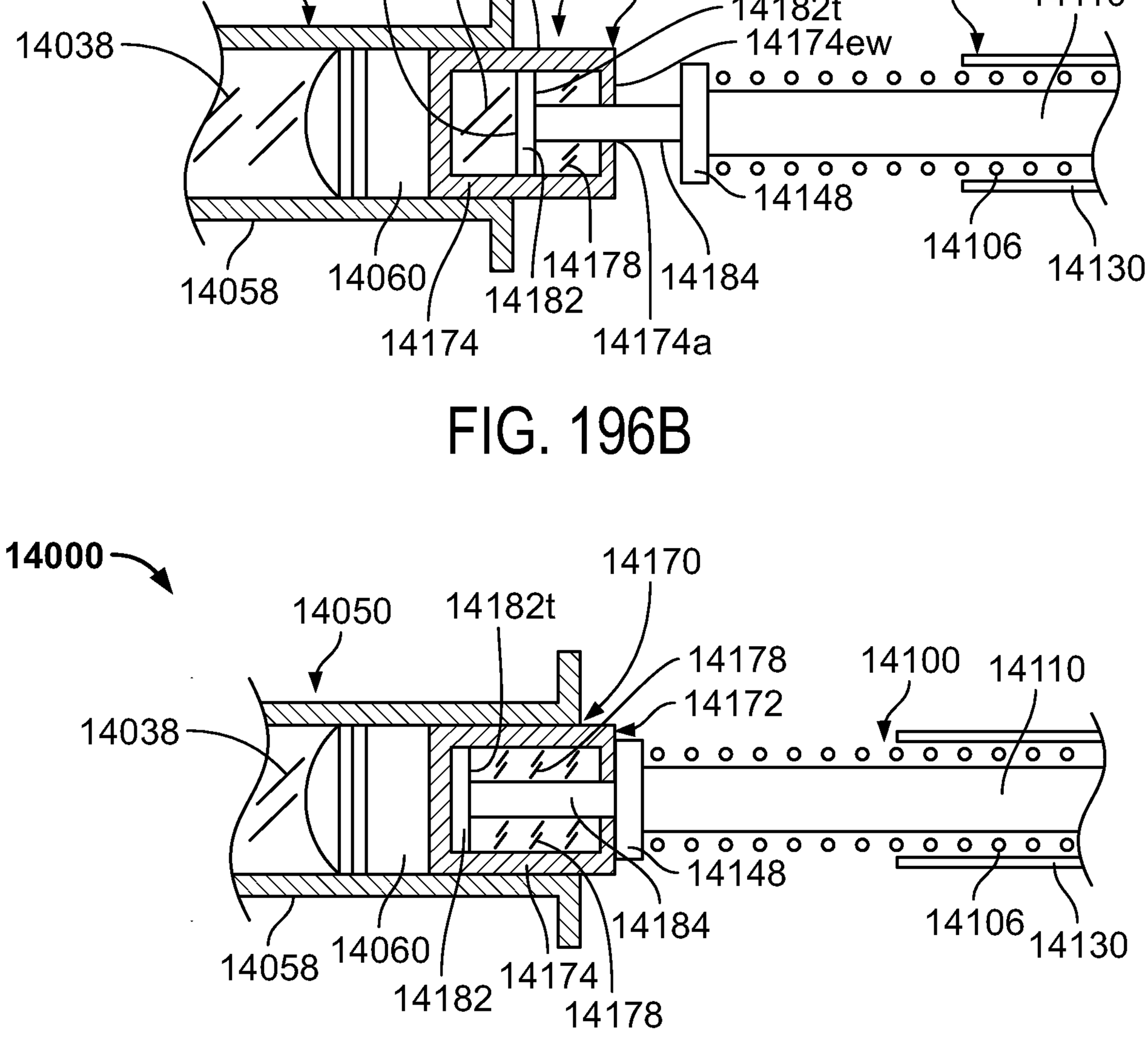
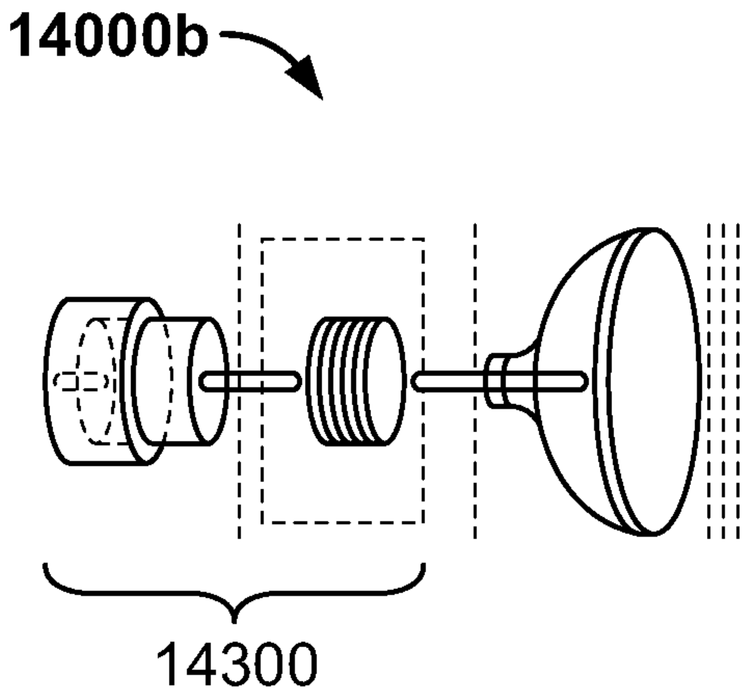


FIG. 196C



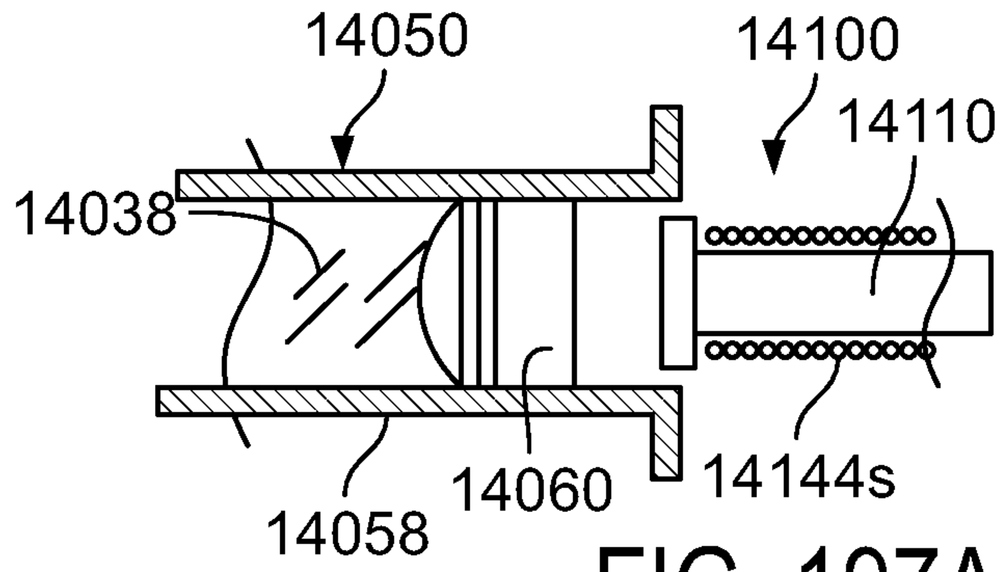
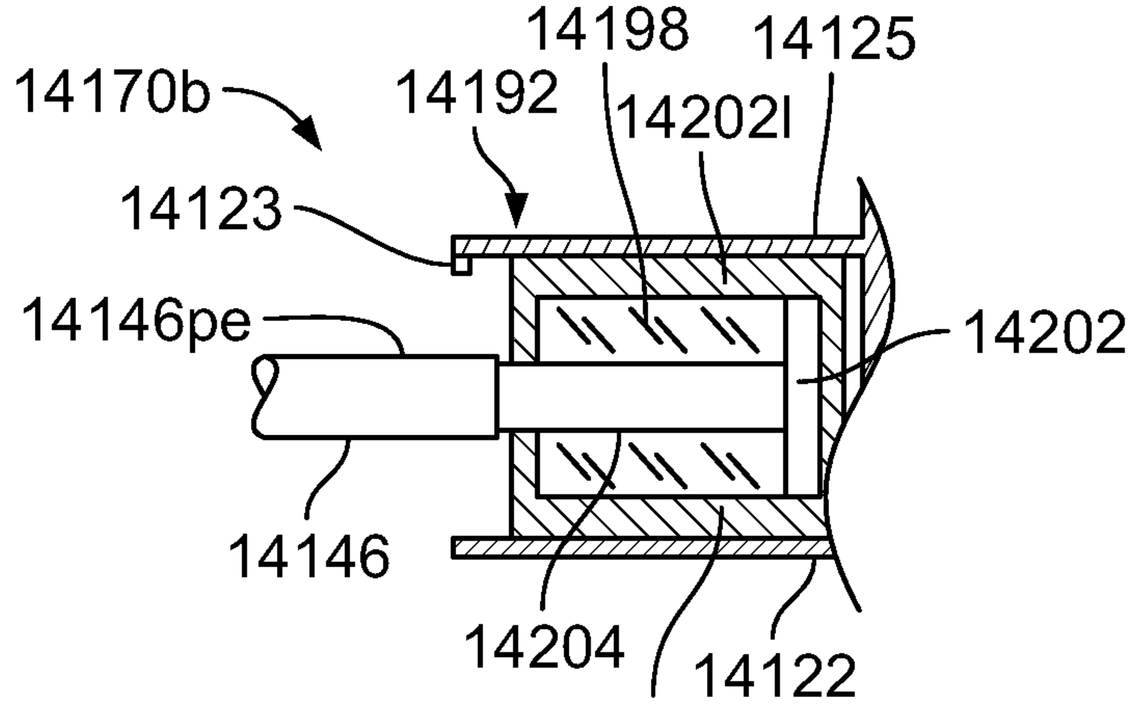
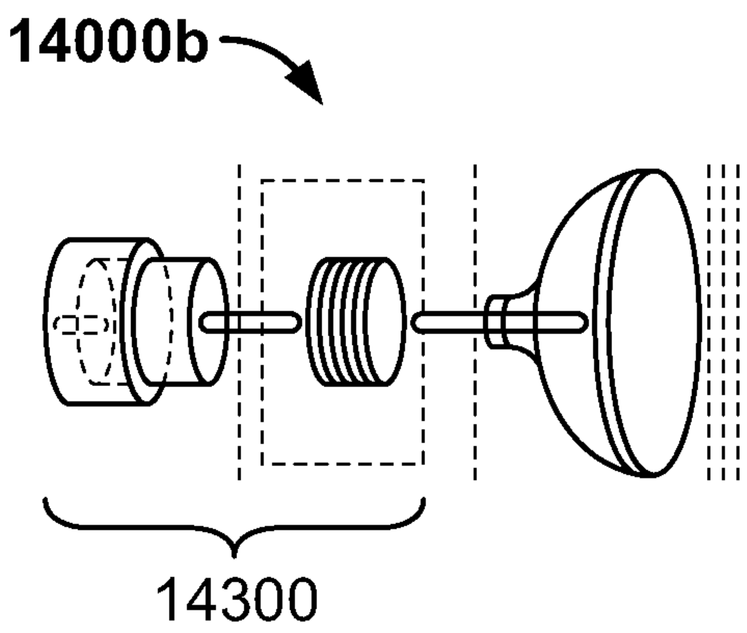


FIG. 197A





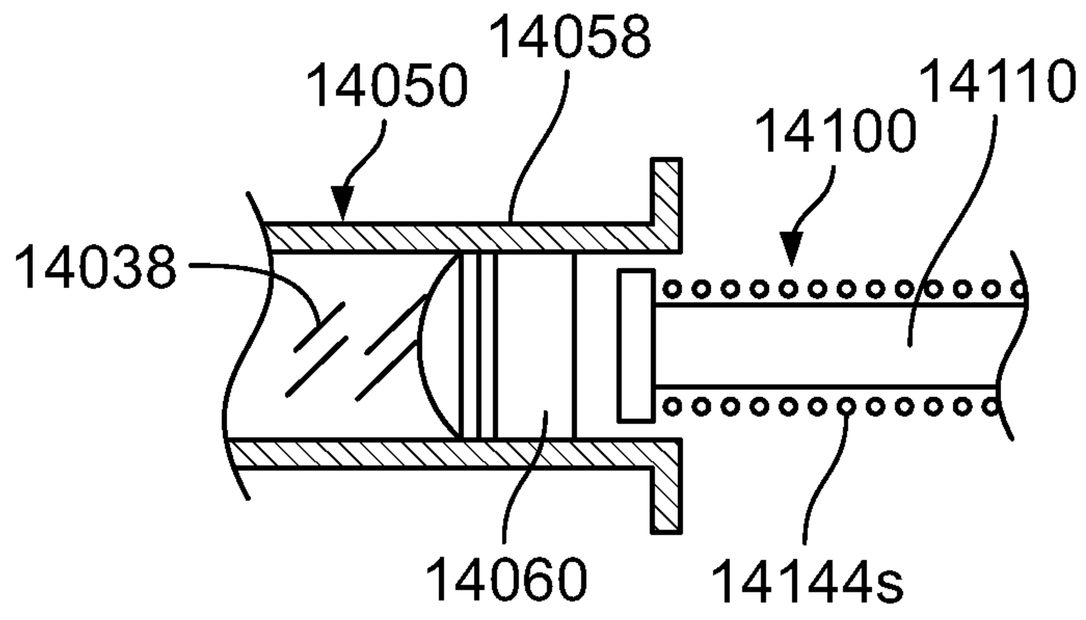
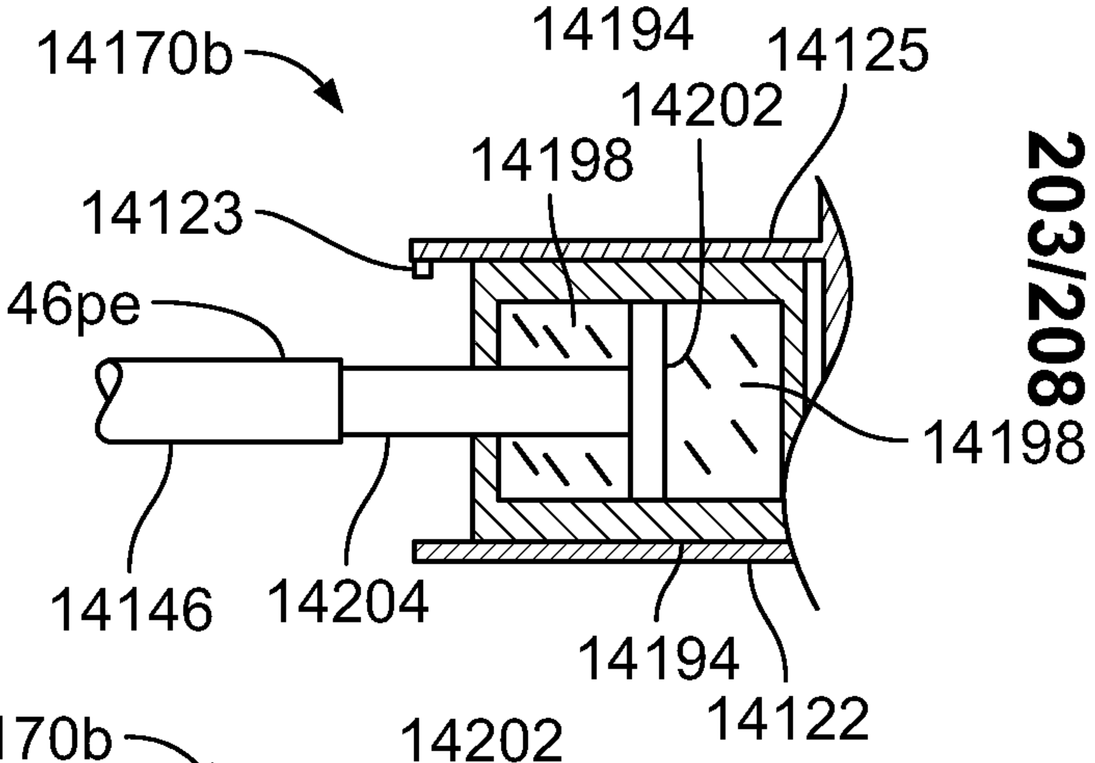
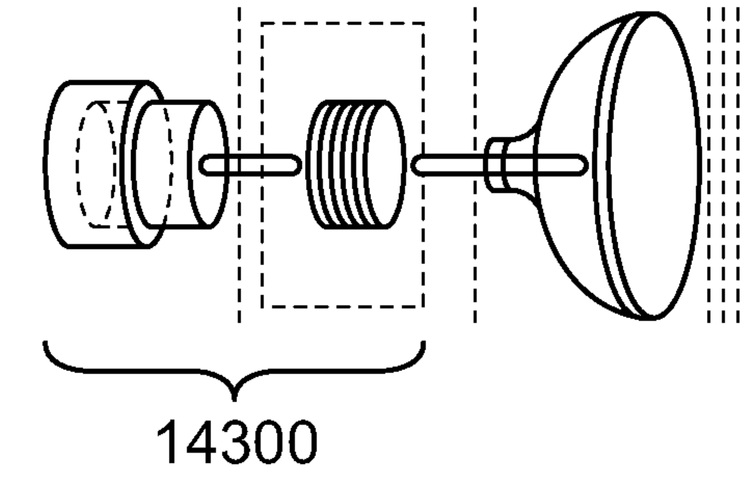
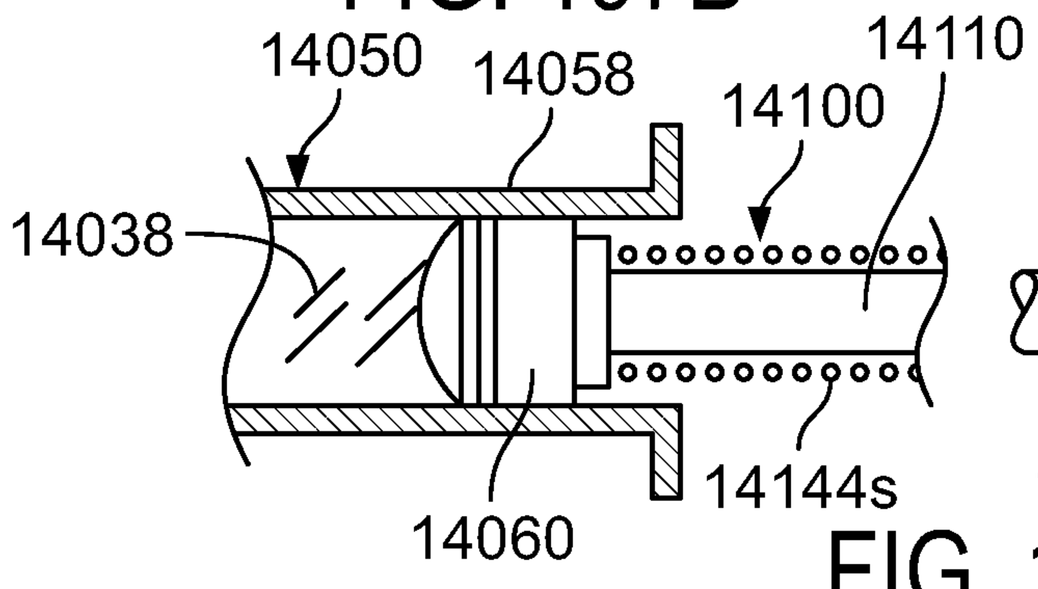


FIG. 197B







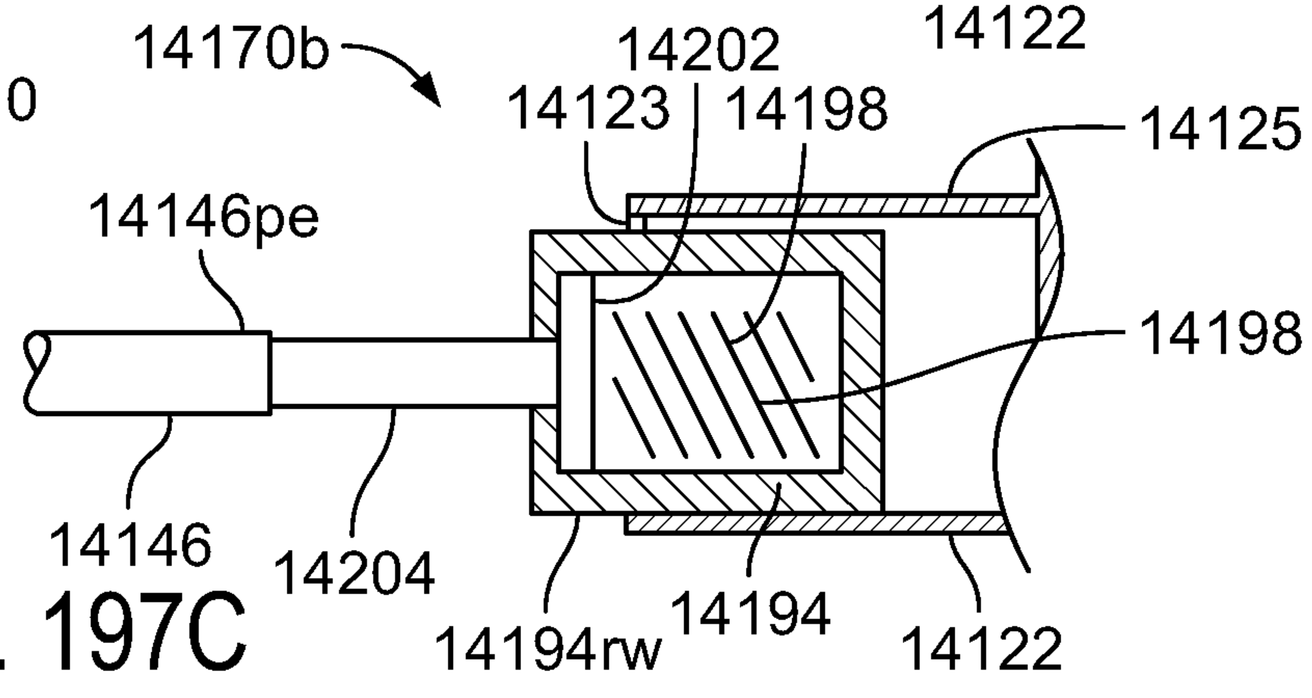


FIG. 197C

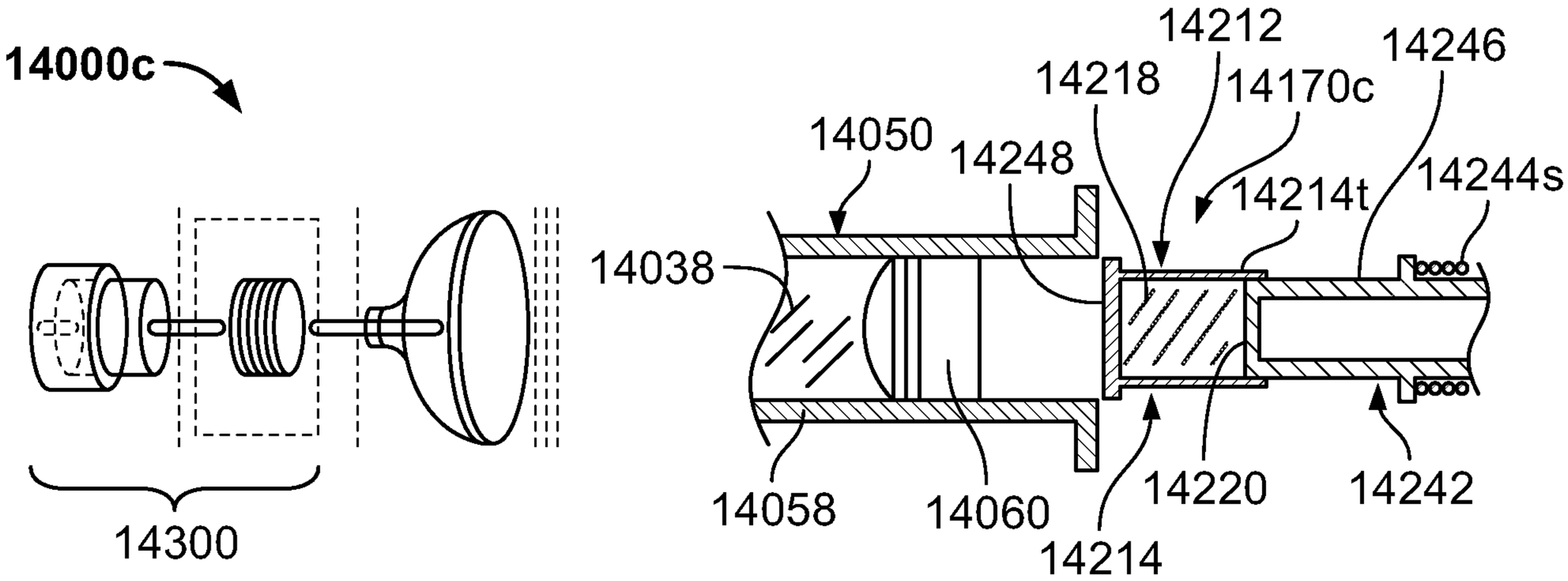


FIG. 198A

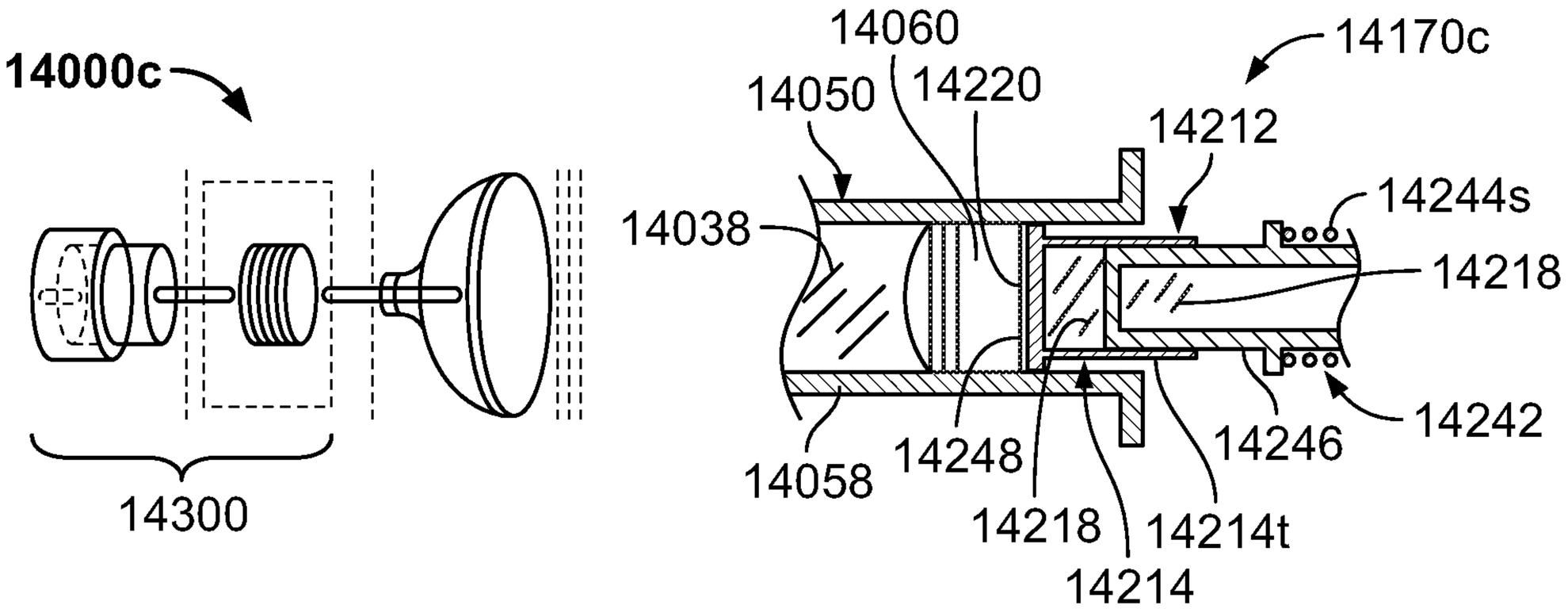


FIG. 198B

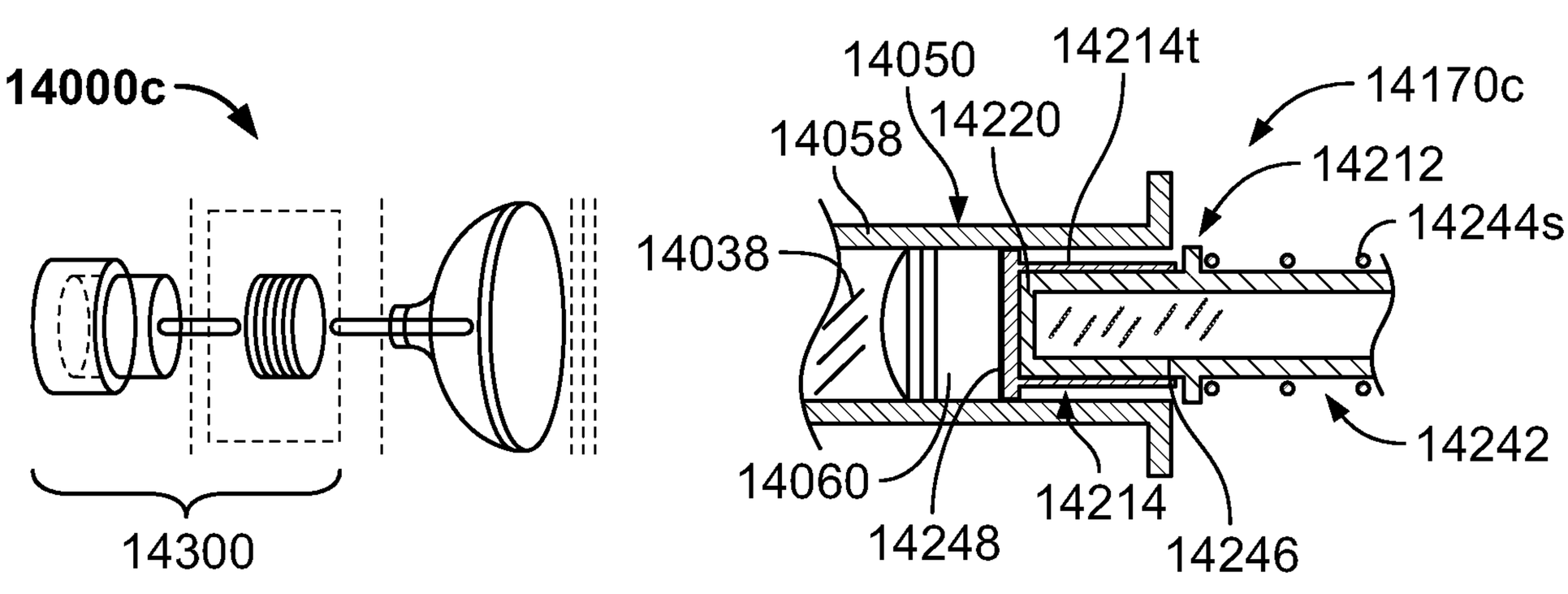


FIG. 198C

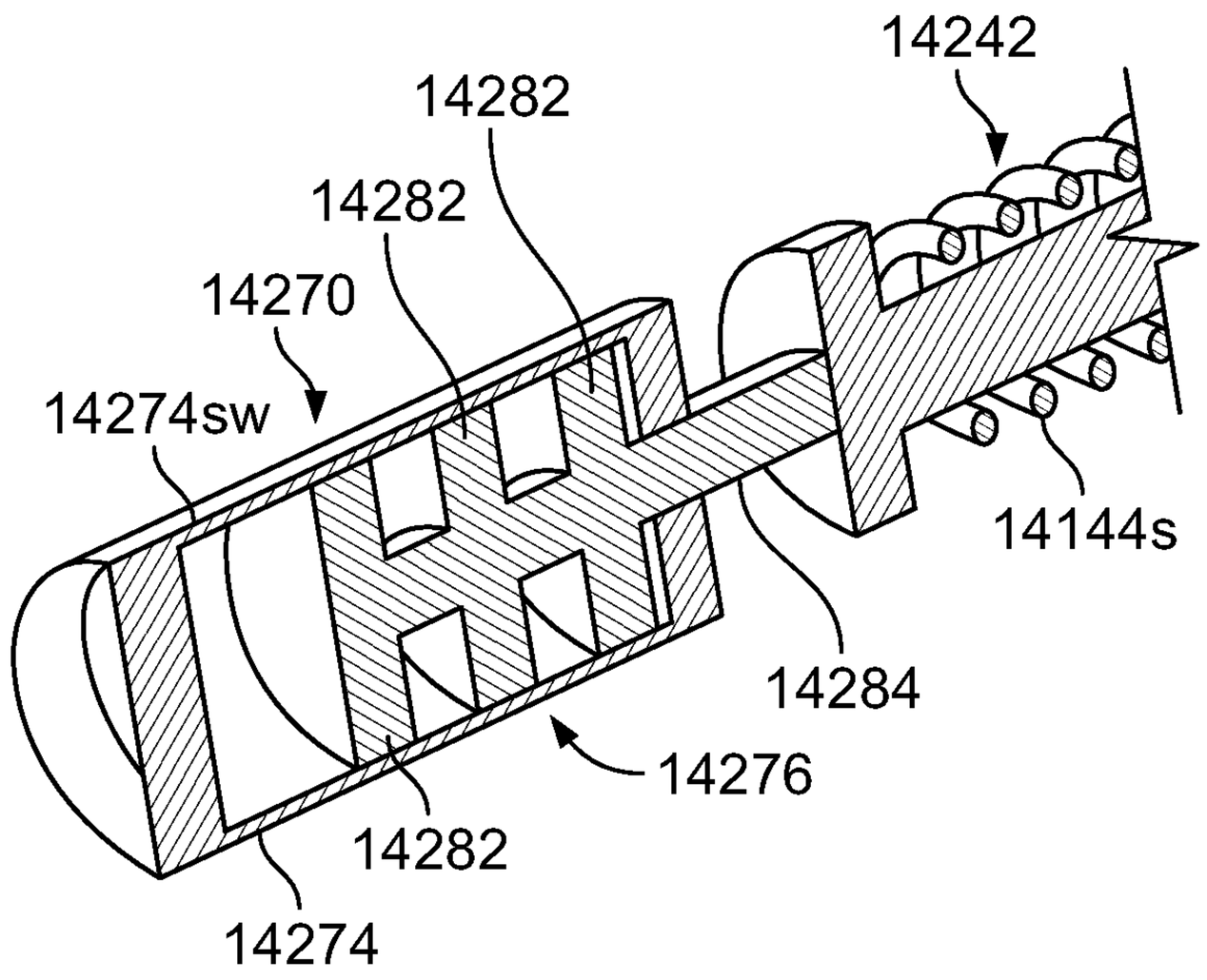


FIG. 199

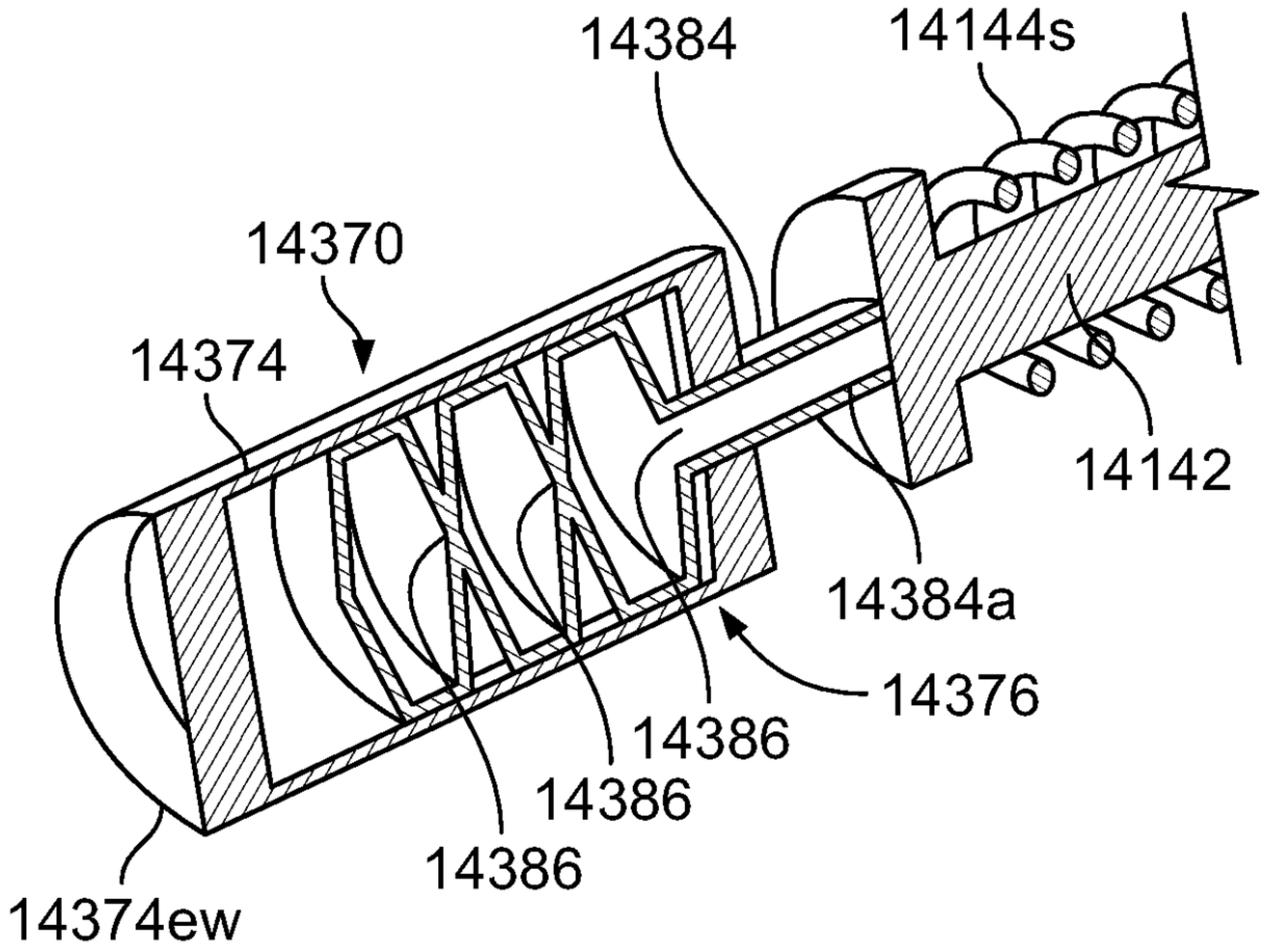


FIG. 200

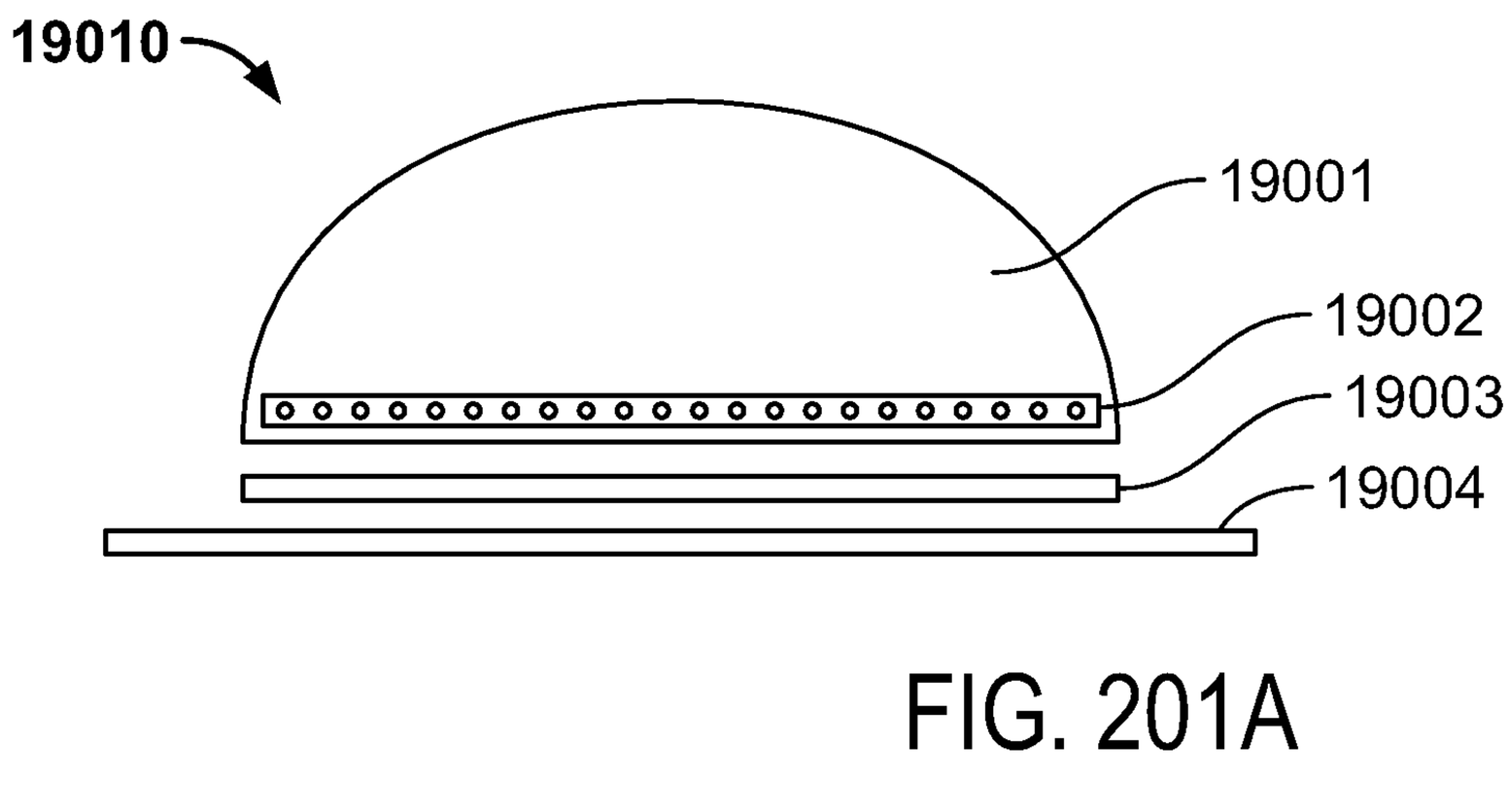


FIG. 201A

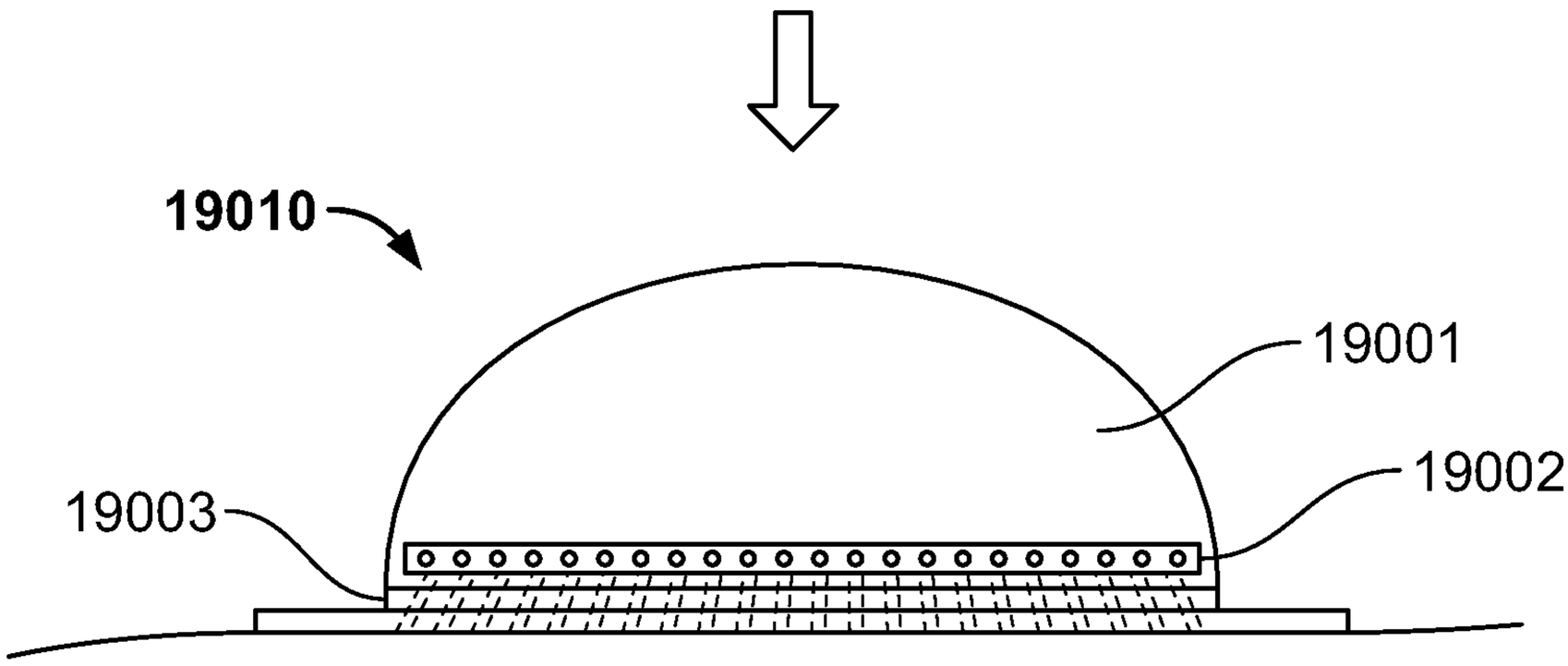


FIG. 201B

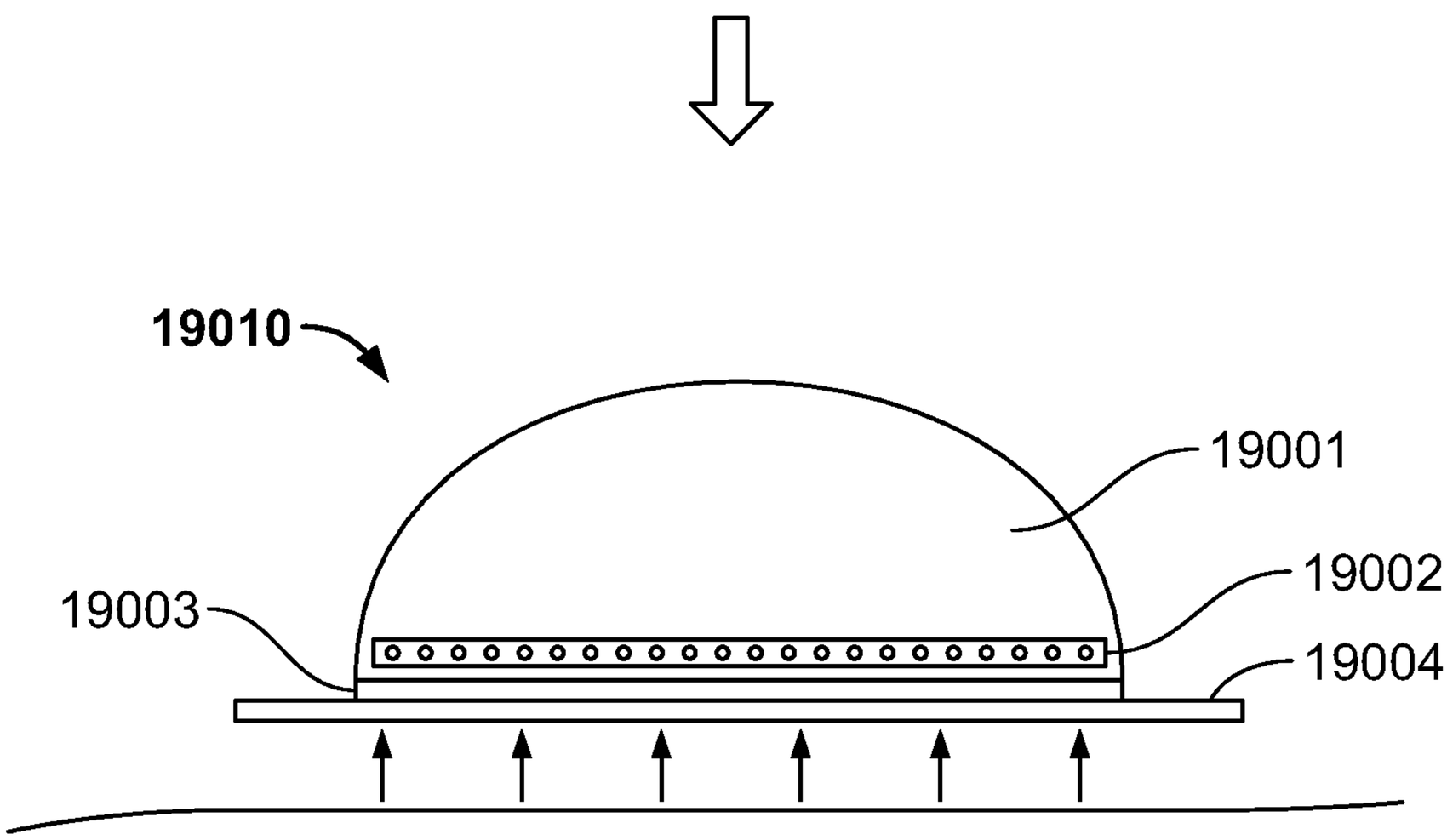


FIG. 201C

207/208

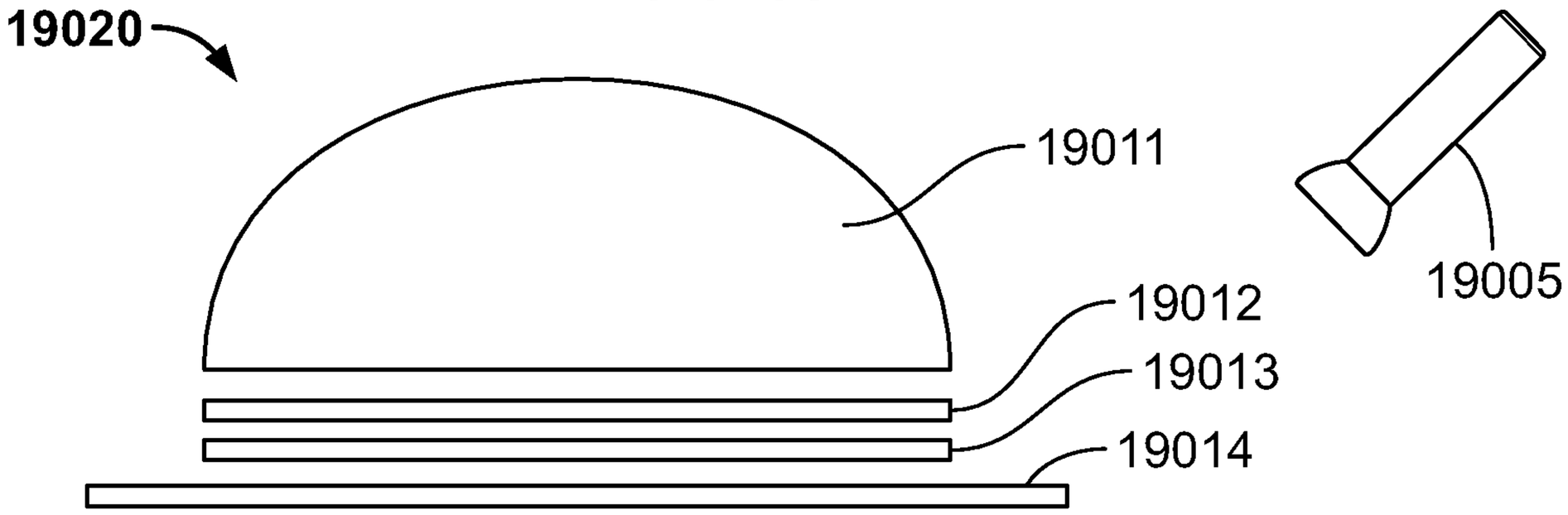


FIG. 202A

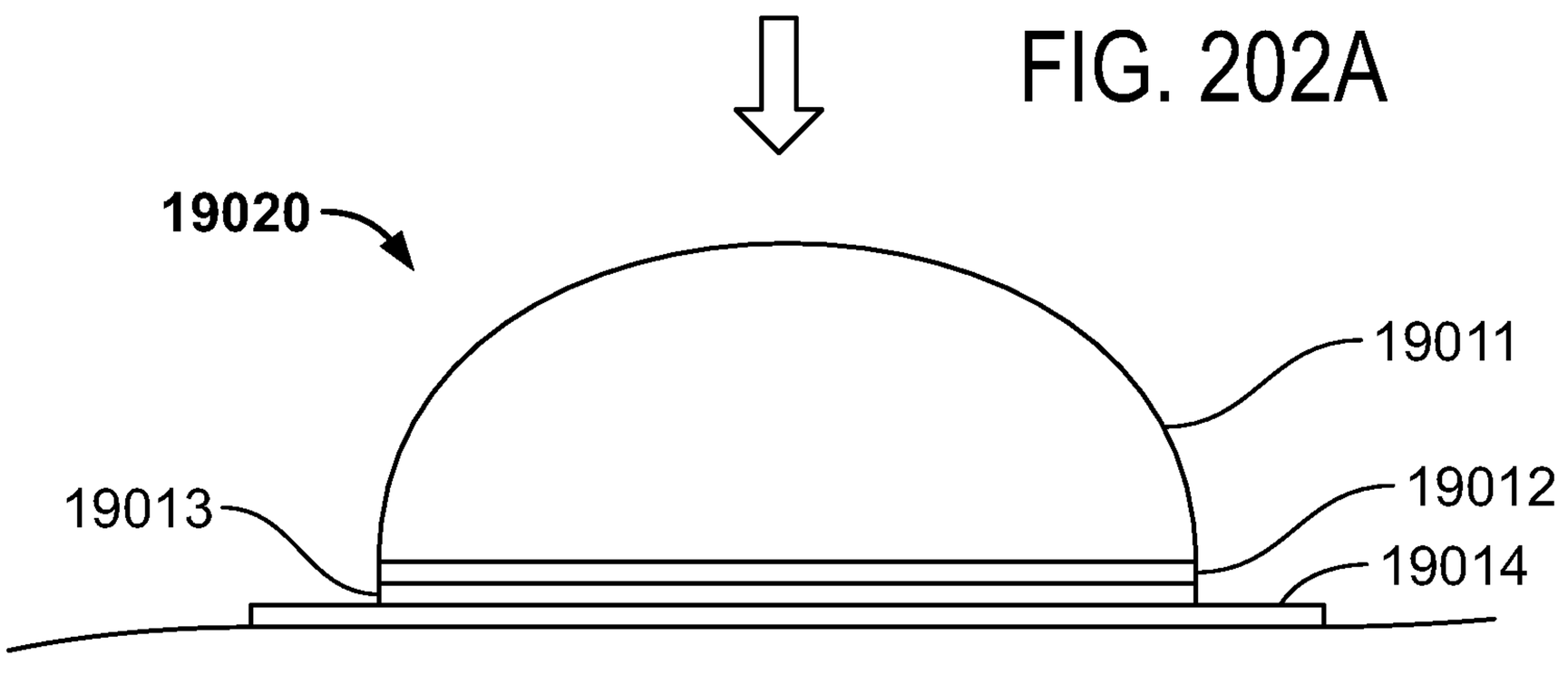


FIG. 202B

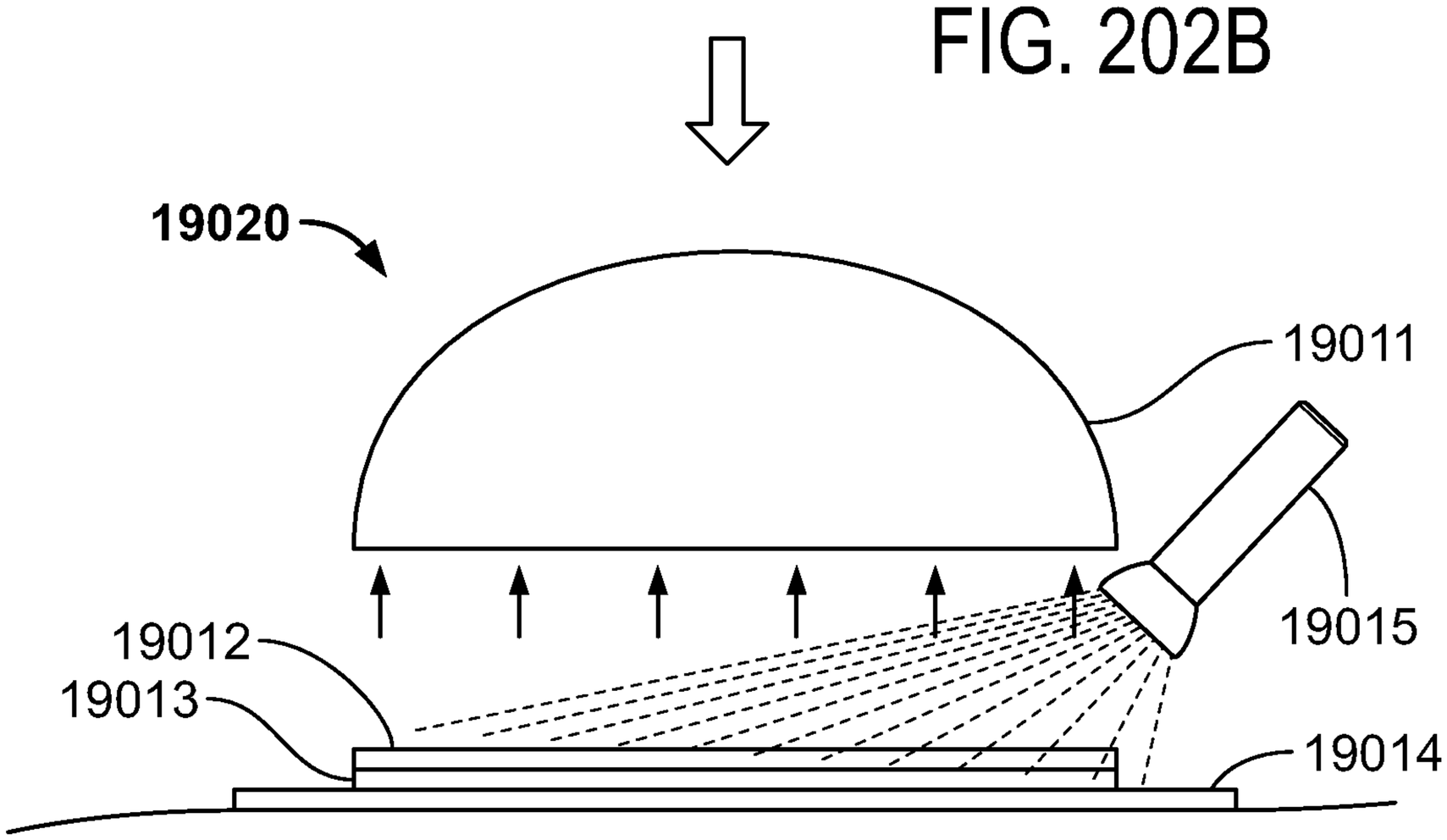


FIG. 202C

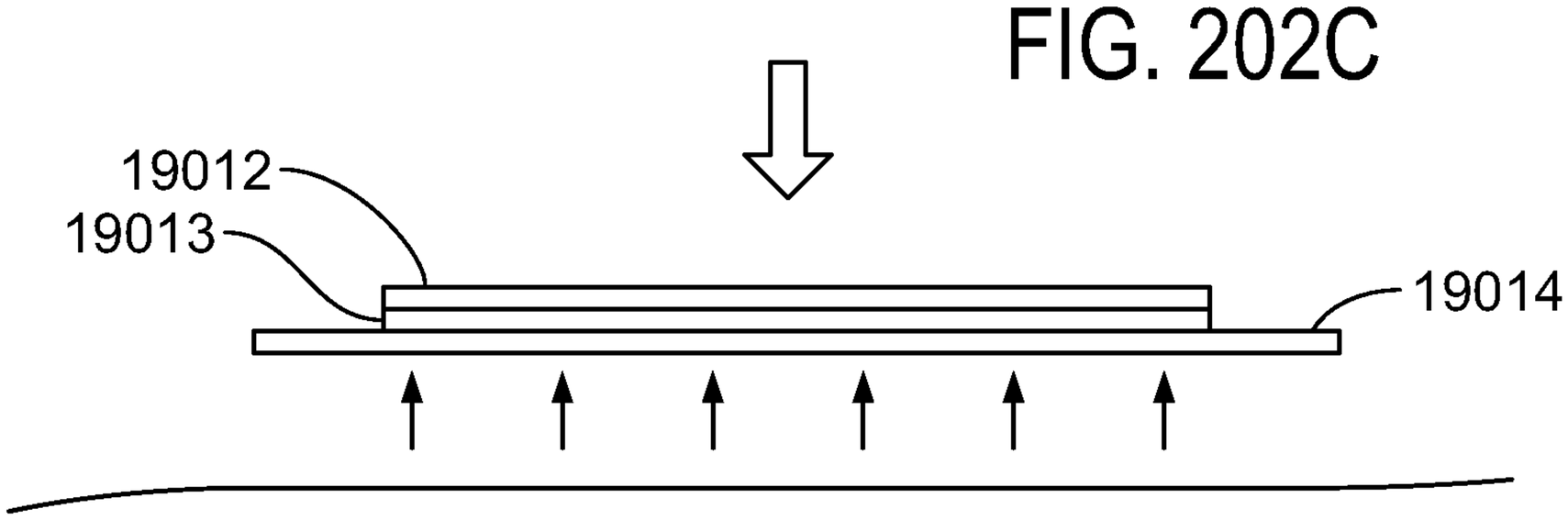


FIG. 202D

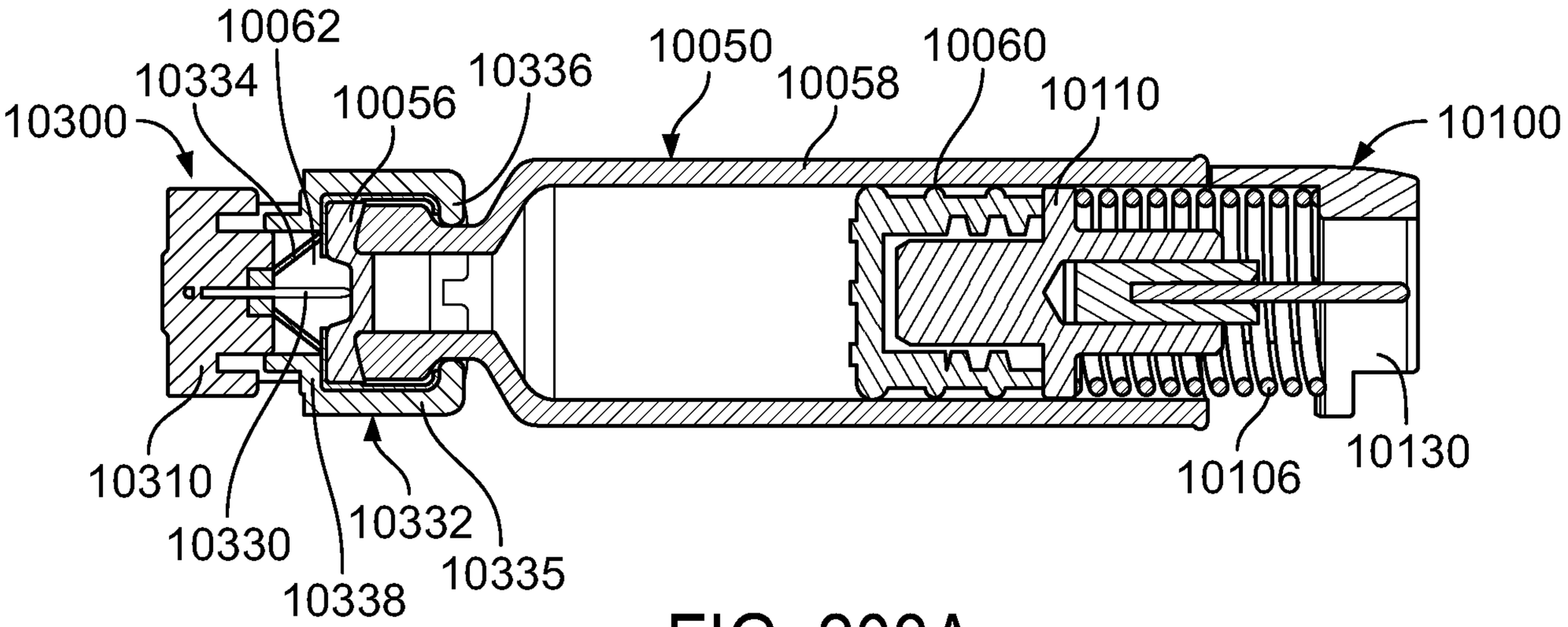


FIG. 203A

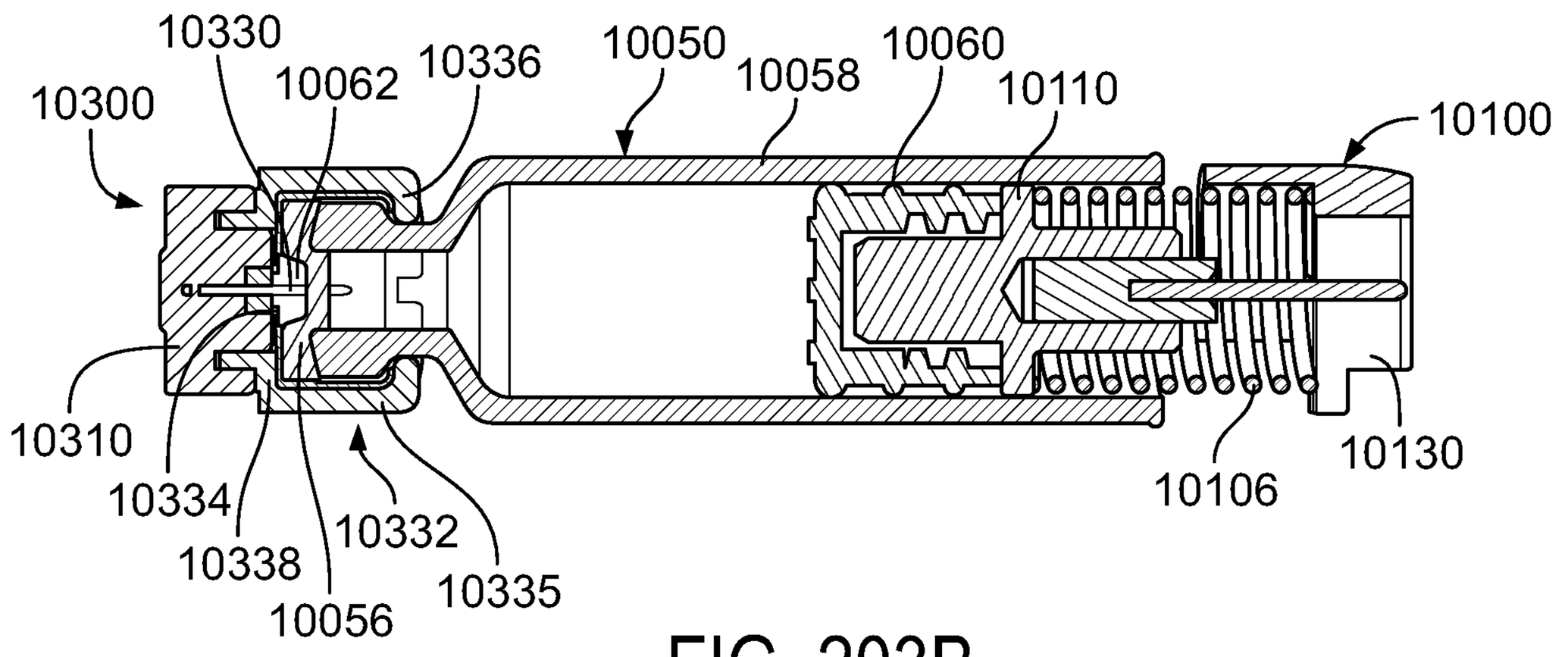


FIG. 203B

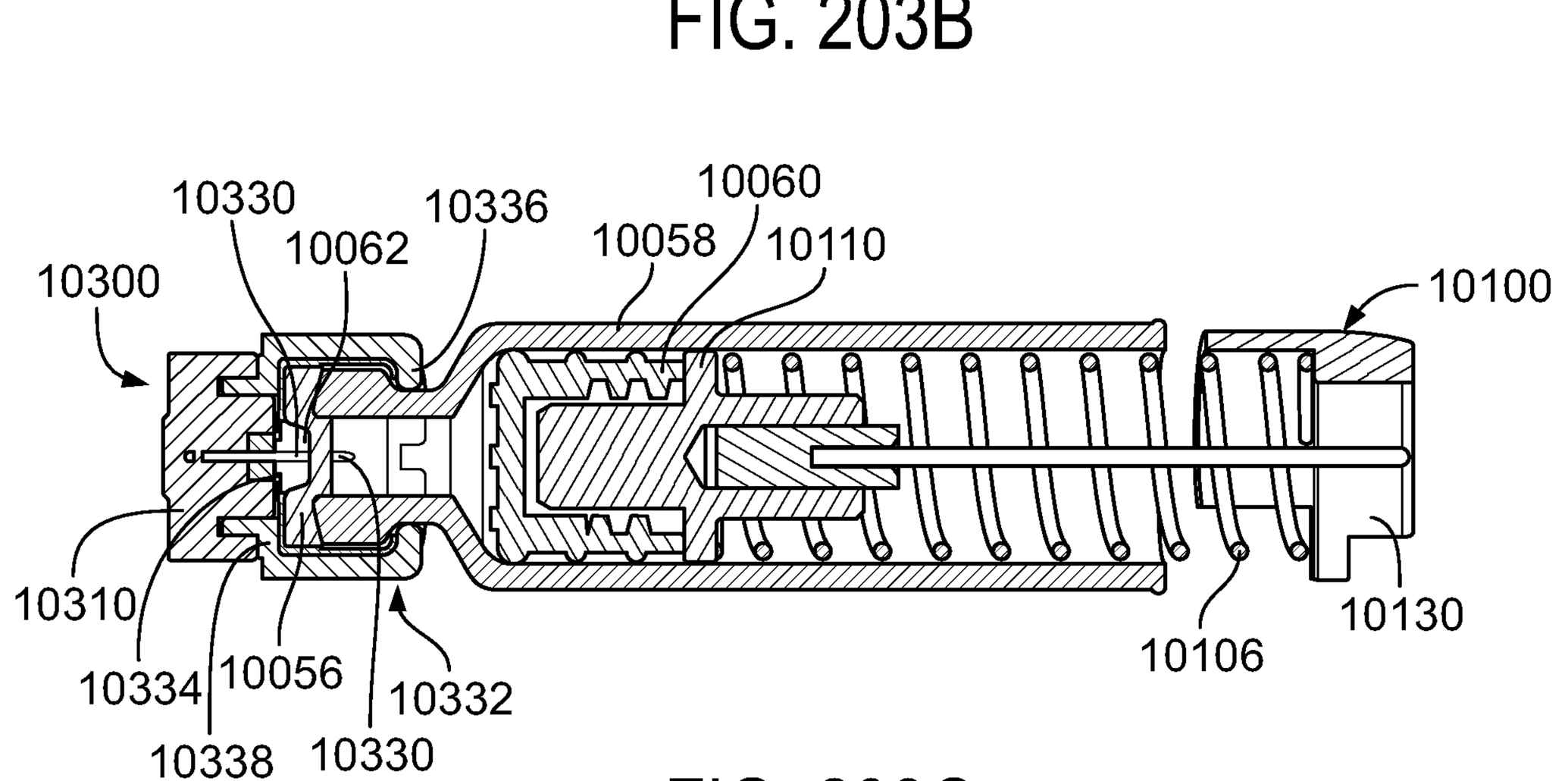


FIG. 203C

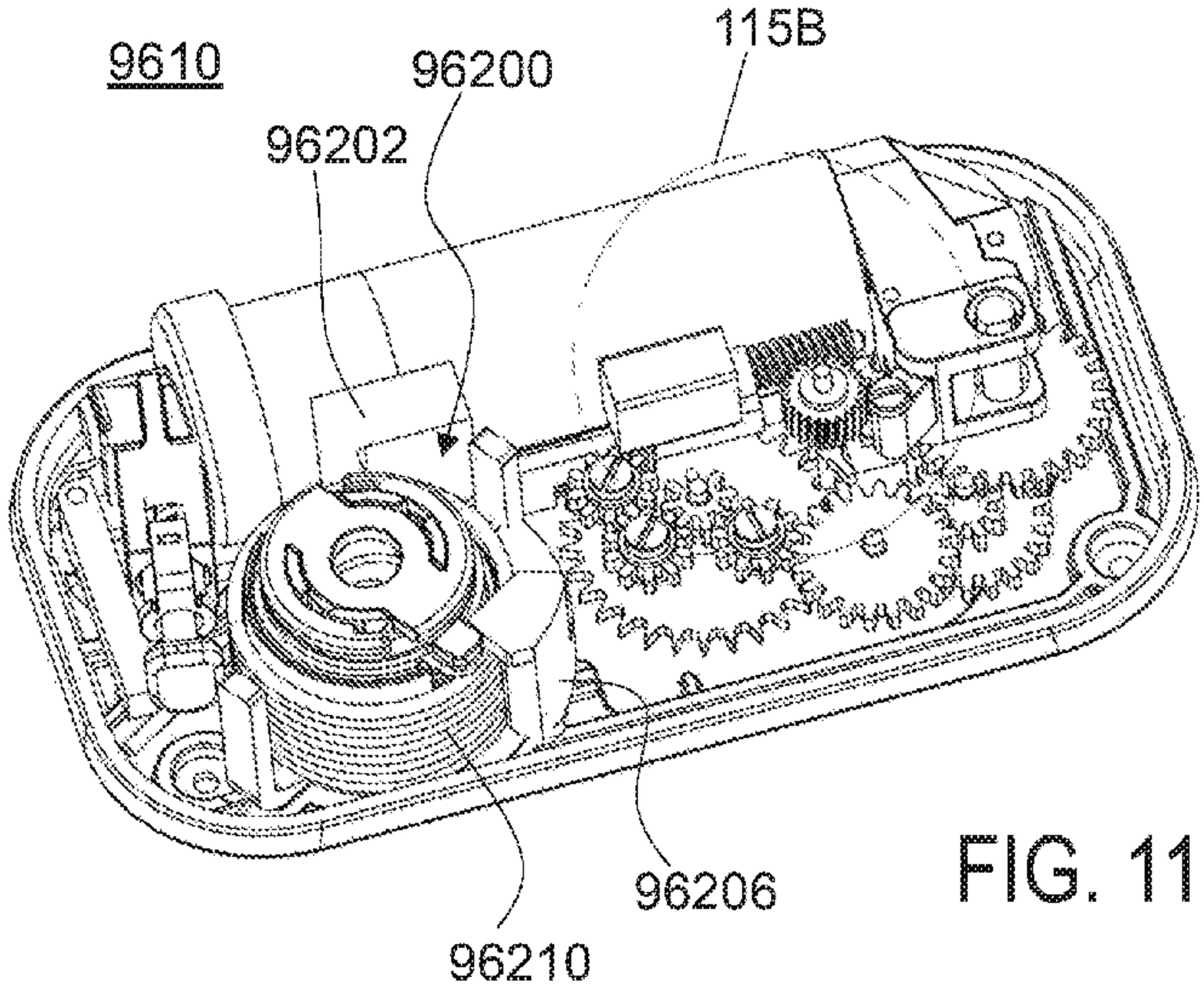


FIG. 115A