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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 July 2022 (14.07.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/150320 A1

(51) International Patent Classification:
A61B 5/15 (2006.01) *A61M 5/32* (2006.01)
A61B 5/154 (2006.01) *A61M 5/34* (2006.01)

(21) International Application Number:
PCT/US2022/011209

(22) International Filing Date:
05 January 2022 (05.01.2022)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/134,054 05 January 2021 (05.01.2021) US

(71) Applicant: **BECTON, DICKINSON AND COMPANY** [US/US]; 1 Becton Drive, Franklin Lakes, New Jersey 07417 (US).

(72) Inventors: **BEGUIN, Steve**; Clarabeg North, Rathdrum, A67KW31 (IE). **LE GAL REDON, Patrick**; 23, allée des Balmes, 38172 Seyssinet-Pariset (FR). **COLEMAN, David, James**; Hillview Cottage, Lower Road, Shankill, D18X9Y0 (IE). **ABOUD, Danielle**; 46 Louvain Ardilea, Clonskeagh, Dublin 14, Dublin, D14 DD27 (IE). **MCGRATH, Sean**; 138 Hazelwood Park, Artane, Dublin 5, Artane, D05 V5W9 (IE). **PLEVNIK, Marko**; 112 Savernake Road, London NW3 2JR (GB). **LYELL, Nathan**; 81 Olympian Heights, Guildford Road, Woking, Surrey GU227RN (GB). **LESTER, Harry, Robert**; 19 Stormont Road, London SW11 5EQ (GB).

(74) Agent: **MILES, Kirk, M.** et al.; The Webb Law Firm, One Gateway Center, 420 Ft. Duquesne Blvd., Suite 1200, Pittsburgh, Pennsylvania 15222 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, 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, IT, JO, JP, KE, KG, KH, KN,

(54) Title: NEEDLE HUB WITH PRESSURE INTERLOCK FOR DRUG DELIVERY DEVICE

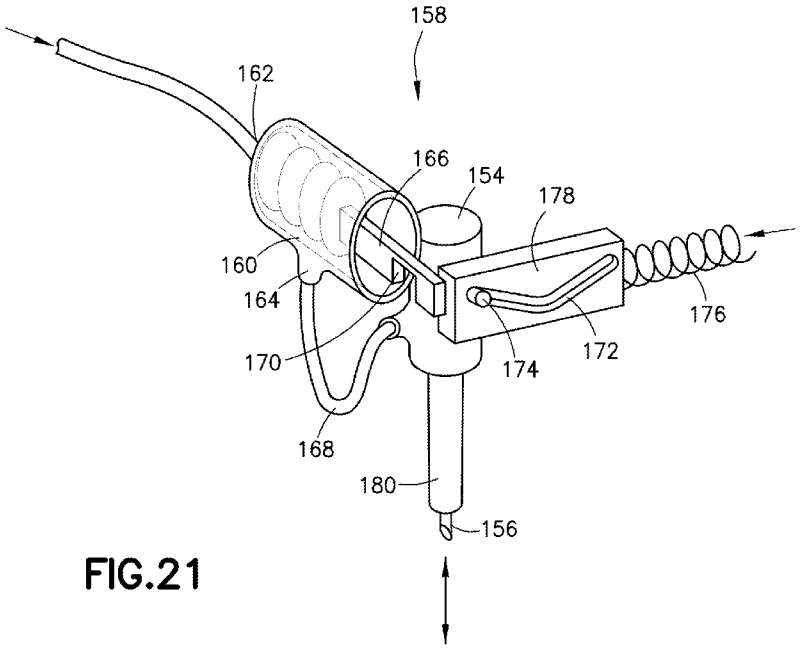

FIG.21

(57) Abstract: A needle hub for a drug delivery device includes a needle holder and a needle attached to the needle holder, a needle actuation assembly configured to move the needle holder from a retracted position, to an insertion position, and back to the retracted position, and a pressure interlock comprising an inlet configured to be in fluid communication with a fluid source, an outlet in fluid communication with the needle, and a lock member. The lock member having a first position where the lock member prevents actuation of the needle actuation assembly and a second position where the lock member allows actuation of the needle actuation assembly. The lock member is moved from the first position to the second position based on a pressure within the pressure interlock.

WO 2022/150320 A1

[Continued on next page]

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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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))*

NEEDLE HUB WITH PRESSURE INTERLOCK FOR DRUG DELIVERY DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to United States Provisional Application No. 63/134,054, filed January 5, 2021, which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present disclosure relates to a needle hub for a drug delivery device.

Description of Related Art

[0003] Wearable medical devices, such as automatic injectors, have the benefit of providing therapy to the patient at a location remote from a clinical facility and/or while being worn discretely under the patient's clothing. The wearable medical device can be applied to the patient's skin and configured to automatically deliver a dose of a pharmaceutical composition within a predetermined time period after applying the wearable medical device to the patient's skin. After the device delivers the pharmaceutical composition to the patient, the patient may subsequently remove and dispose of the device.

SUMMARY OF THE INVENTION

[0004] In one aspect or embodiment, a needle hub for a drug delivery device includes a needle holder and a needle attached to the needle holder, a needle actuation assembly configured to move the needle holder from a retracted position, to an insertion position, and back to the retracted position, and a pressure interlock including an inlet configured to be in fluid communication with a fluid source, an outlet in fluid communication with the needle, and a lock member. The lock member having a first position where the lock member prevents actuation of the needle actuation assembly and a second position where the lock member allows actuation of the needle actuation assembly. The lock member is moved from the first position to the second position based on a pressure within the pressure interlock.

[0005] The pressure interlock may include a cylinder and the lock member may include a piston, with the inlet and the outlet of the pressure interlock in fluid communication with the cylinder. The lock member may isolate the inlet from the outlet when the lock member is in the first position, with the lock member allowing fluid communication between the inlet and

the outlet when the lock member is in the second position. The pressure interlock may further include an exhaust vent configured to dispel air from the cylinder. The exhaust vent may include a hydrophobic membrane. The needle hub may further include tubing connected to the outlet and in fluid communication with the needle.

[0006] The lock member may include an opening, where a portion of the needle actuation assembly extends through the opening of the lock member when the lock member is in the second position. The needle actuation assembly may include a cam track, a cam member, and an actuation spring biasing the cam member relative to the cam track. A cam block may define the cam track, where the cam block extends through the opening of the lock member when the lock member is in the second position.

[0007] The needle hub may include a skin tenting reduction mechanism including an adhesive surface configured to be adhered to a skin surface of a person, with the skin tenting reduction mechanism configured to stretch the skin surface at a location where the needle penetrates the skin surface. The needle actuation assembly may further include a cannula, where the needle is received within the cannula when the needle holder is in the retracted position.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The above-mentioned and other features and advantages of this disclosure, and the manner of attaining them, will become more apparent and the disclosure itself will be better understood by reference to the following descriptions of embodiments of the disclosure taken in conjunction with the accompanying drawings.

[0009] **FIG. 1** is a schematic view of a drug delivery device according to one aspect or embodiment of the present application.

[0010] **FIG. 2** is a schematic view of the drug delivery device of FIG. 1.

[0011] **FIG. 3** is a perspective view of a needle hub according to one aspect or embodiment of the present application.

[0012] **FIG. 4A** is a top view of the needle hub of FIG. 3, showing an indicator prior to use of the needle hub.

[0013] **FIG. 4B** is a top view of the needle hub of FIG. 3, showing an indicator after insertion of a needle.

[0014] **FIG. 4C** is a top view of the needle hub of FIG. 3, showing an indicator after withdrawal of a cannula.

[0015] **FIG. 5** is a schematic view showing a method of using the needle hub of FIG. 3.

[0016] **FIG. 6A** is a schematic view of the needle hub of FIG. 3, showing actuation of an activation button.

[0017] **FIG. 6B** is a schematic view of the needle hub of FIG. 3, showing movement of a needle and cannula from a retracted position to an insertion position.

[0018] **FIG. 6C** is a schematic view of the needle hub of FIG. 3, showing a needle in a retracted position and a cannula in an insertion position.

[0019] **FIG. 6D** is a schematic view of the needle hub of FIG. 3, showing movement of a cannula to a retracted position.

[0020] **FIG. 7** is a perspective view of a needle hub according to a further aspect or embodiment of the present application.

[0021] **FIG. 8** is a front view of the needle hub of FIG. 7, showing an infusion mode.

[0022] **FIG. 9** is a front view of the needle hub of FIG. 7, showing a cannula withdrawal.

[0023] **FIG. 10** is a perspective view of a needle hub according to a further aspect or embodiment of the present application.

[0024] **FIG. 11** is a schematic view showing a method of using the needle hub of FIG. 7.

[0025] **FIG. 12A** is a schematic view of the needle hub of FIG. 7, showing a pre-use position of the needle hub.

[0026] **FIG. 12B** is a schematic view of the needle hub of FIG. 7, showing the needle hub being actuated.

[0027] **FIG. 12C** is a schematic view of the needle hub of FIG. 7, showing a needle being retracted.

[0028] **FIG. 12D** is a schematic view of the needle hub of FIG. 7, showing a needle in a retracted position.

[0029] **FIG. 12E** is a schematic view of the needle hub of FIG. 7, showing an applicator being detached from the needle hub.

[0030] **FIG. 12F** is a schematic view of the needle hub of FIG. 7, showing a cannula in a retracted position.

[0031] **FIG. 13** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application.

[0032] **FIG. 14** is a cross-sectional view of the needle hub of FIG. 13.

[0033] **FIG. 15** is a perspective view of a needle hub according to a further aspect or embodiment of the present application.

[0034] **FIG. 16** is a perspective view of a needle hub according to a further aspect or embodiment of the present application.

[0035] **FIG. 17** is a perspective view of a needle actuation assembly according to one aspect or embodiment of the present application.

[0036] **FIG. 18A** is a cross-sectional view of the needle hub of FIG. 15, showing a cannula insertion position.

[0037] **FIG. 18B** is a cross-sectional view of the needle hub of FIG. 15, showing a cannula retraction position.

[0038] **FIG. 19** is a perspective view of a needle hub according to a further aspect or embodiment of the present application.

[0039] **FIG. 20** is a schematic view showing a method of using the needle hub of FIG. 19.

[0040] **FIG. 21** is a perspective view of a needle actuation assembly according to a further aspect or embodiment of the present application.

[0041] **FIG. 22** is a perspective view of a drug delivery device and the needle hub according to a further aspect or embodiment of the present application.

[0042] **FIG. 23** is an exploded perspective view of the drug delivery device and the needle hub of FIG. 22.

[0043] **FIG. 24** is a perspective view of the drug delivery device and the needle hub of FIG. 22, showing the drug delivery device and the needle hub connected while delivering a medicament.

[0044] **FIG. 25** is a perspective view of the drug delivery device and the needle hub of FIG. 22, showing the needle hub separated from the drug delivery device while delivering a medicament.

[0045] **FIG. 26A** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application, showing an initial position of the needle hub.

[0046] **FIG. 26B** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application, showing engagement with a skin surface.

[0047] **FIG. 26C** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application, showing insertion of a needle.

[0048] **FIG. 27A** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application, showing an initial position of the needle hub.

[0049] **FIG. 27B** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application, showing engagement with a skin surface.

[0050] **FIG. 27C** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application, showing insertion of a needle.

[0051] **FIG. 28A** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application, showing an initial position of the needle hub.

[0052] **FIG. 28B** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application, showing engagement with a skin surface.

[0053] **FIG. 28C** is a cross-sectional view of a needle hub according to a further aspect or embodiment of the present application, showing insertion of a needle.

[0054] **FIG. 29** is a perspective view of a needle actuation assembly according to a further aspect or embodiment of the present application, showing an unactuated position.

[0055] **FIG. 30** is a perspective view of the needle actuation assembly of FIG. 29, showing an actuated position.

[0056] **FIG. 31** is a cross-sectional view of the needle actuation assembly of FIG. 29, showing an unactuated position.

[0057] **FIG. 32** is a cross-sectional view of the needle actuation assembly of FIG. 29, showing an actuated position.

[0058] **FIG. 33** is a cross-sectional view of the needle actuation assembly of FIG. 29, showing a retracted position.

[0059] **FIG. 34** is a perspective view of a needle hub according to a further aspect or embodiment of the present application.

[0060] **FIG. 35** is a schematic view of the needle hub of FIG. 34.

[0061] **FIG. 36** is a perspective view of a drug delivery device according to a further aspect or embodiment of the present application.

[0062] **FIG. 37** is a front view of the drug delivery device of FIG. 36.

[0063] **FIG. 38** is a front view of the drug delivery device of FIG. 36, showing a reservoir separated from the drug delivery device.

[0064] **FIG. 39** is a front view of the drug delivery device of FIG. 36, showing the drug delivery device attached to a patient.

[0065] **FIG. 40** is a partial cross-sectional view of a prior art valve assembly.

[0066] **FIG. 41** is a front view of a cam block of a needle actuation assembly according to one aspect or embodiment of the present application.

[0067] **FIG. 42** is a perspective view of a cam member of a needle actuation assembly according to one aspect or embodiment of the present application.

[0068] **FIG. 43** is a perspective view of a cannula holder of a needle actuation assembly according to one aspect or embodiment of the present application.

[0069] **FIG. 44** is a top perspective view of the cannula holder of FIG. 43, showing a cannula in an insertion position.

[0070] **FIG. 45** is a bottom perspective view of the cannula holder of FIG. 43, showing a cannula in an insertion position.

[0071] **FIG. 46** is a perspective view of a seal of a pressure interlock according to one aspect or embodiment of the present application.

[0072] **FIG. 47** is a front view of a lock member of a pressure interlock according to one aspect or embodiment of the present application.

[0073] **FIG. 48** is a perspective view of a pressure interlock for a needle actuation assembly according to one aspect or embodiment of the present application.

[0074] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate exemplary embodiments of the disclosure, and such exemplifications are not to be construed as limiting the scope of the disclosure in any manner.

DETAILED DESCRIPTION OF THE INVENTION

[0075] Spatial or directional terms, such as "left", "right", "inner", "outer", "above", "below", and the like, are not to be considered as limiting as the invention can assume various alternative orientations.

[0076] All numbers used in the specification and claims are to be understood as being modified in all instances by the term "about". By "about" is meant a range of plus or minus ten percent of the stated value. As used in the specification and the claims, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. The terms "first", "second", and the like are not intended to refer to any particular order or chronology, but instead refer to different conditions, properties, or elements. By "at least" is meant "greater than or equal to".

[0077] Referring to FIGS. 1-3, a drug delivery device 10 includes a reservoir 12, a power module 14, an insertion mechanism 16, control electronics 18, and a housing 20. In one aspect or embodiment, the drug delivery device 10 is a wearable automatic injector. The drug delivery device 10 may be mounted onto the skin of a patient and triggered to inject a pharmaceutical composition from the reservoir 12 into the patient. The drug delivery device 10 may be pre-filled with the pharmaceutical composition, or it may be filled with the pharmaceutical

composition by the patient or medical professional prior to use. The control electronics 18 may include a processor 22, such as a microcontroller, a motor driver 23, a sensing module 24, a visual driver 25, and/or audio driver 26. The drug delivery device 10 includes a drive mechanism 27 configured to dispense fluid from the reservoir 12. The drive mechanism 27 may be motor powered, spring powered, hydraulic powered, pneumatic powered, and/or other suitable drive mechanism.

[0078] The drug delivery device 10 is configured to deliver a dose of a pharmaceutical composition, e.g., any desired medicament, into the patient's body by a subcutaneous injection at a slow, controlled injection rate. Exemplary time durations for the delivery achieved by the drug delivery device 10 may range from about 5 minutes to about 60 minutes, but are not limited to this exemplary range. Exemplary volumes of the pharmaceutical composition delivered by the drug delivery device 10 may range from about 10 milliliters to about 50 milliliters, but are not limited to this exemplary range. The volume of the pharmaceutical composition delivered to the patient may be adjusted. The device 10 may communicate with another device, such as a mobile device or computer.

[0079] Referring to FIGS. 3-6D, according to one aspect or embodiment, the insertion mechanism 16 includes a needle hub 30 separate from the housing 20. The needle hub 30 includes a removal tab 32, an activation button 34, a status indicator 36, a finger grip, side grips, and an integrated cannula withdrawal tab 38. The needle hub 30 includes an in-dwelling cannula. The status indicator 36 may be white when unused (FIG. 4A), blue when the needle has been inserted and ready to infuse (FIG. 4B), and green when the cannula has been withdrawn (FIG. 4C). As shown in FIG. 5, the needle hub 30 is used by removing the packaging, removing an adhesive liner from the bottom of the needle hub 30, attaching the needle hub 30 to a skin surface, and squeezing the activation button 34, which causes the needle to automatically retract leaving an in-dwelling cannula in the patient. The medicament or fluid is then infused into the patient. Once the infusion is complete, the cannula withdrawal tab 38 is pulled, which retracts the cannula. The needle hub 30 can then be removed from the skin of the patient.

[0080] Referring to FIGS. 6A-6D, in one aspect or embodiment, the needle hub 30 includes a hub body 42, the activation button 34, a needle holder 44, a needle 46 attached to the needle holder 44, a needle spring 48, a cannula holder 50, a cannula 52 attached to the cannula holder 50, and a cannula spring 54. The activation button 34 is moveable relative to the hub body 42 and has a first actuation surface 56. The needle holder 44 is moveable relative to the hub body 42 and has a second actuation surface 58. The first actuation surface 56 of the activation button

34 is configured to engage the second actuation surface 58 of the needle holder 44. The needle spring 48 biases the needle holder 44 to a retracted position where the needle 46 is positioned within the hub body 42. The cannula holder 50 is moveable relative to the hub body 42 and the needle holder 44. The cannula 52 is configured to be in fluid communication with a fluid source, such as the fluid reservoir 12. The cannula spring 54 biases the cannula holder 50 to a retracted position where the cannula 52 is positioned within the hub body 42. Movement of the activation button 34 is configured to cause the first actuation surface 56 of the activation button 34 to engage the second actuation surface 58 of the needle holder 44 to move the needle holder 44 and the cannula holder 50 from the respective retracted positions to insertion positions where distal ends of the needle 46 and the cannula 52 are positioned outside of the hub body 42, with the needle holder 44 configured to return to the retracted position while the cannula holder 50 remains in the insertion position. Movement of a portion of the hub body 42 is configured to disengage a connection between the cannula holder 50 and the hub body 42 to allow the cannula holder 50 to return to the retracted position.

[0081] Referring again to FIGS. 6A-6D, the needle holder 44 includes a passageway 60 configured to be in fluid communication with the fluid reservoir 12, with the needle 46 in fluid communication with the passageway 60 of the needle holder 44. At least a portion of the needle 46 is received within the cannula 52. Fluid is configured to flow from the fluid reservoir 12 via tubing 62 to the passageway 60 of the needle holder 44, through the needle 46, and into the cannula 52. The cannula holder 50 includes a seal 64 engaged with the needle 46. The needle hub 30 includes a first projection 66 and the cannula holder 50 includes a second projection 68, with the first projection 66 of the needle hub 66 engaging the second projection 68 of the cannula holder 50 when the cannula 52 is in the insertion position to restrict movement of the cannula holder 50 to the retracted position.

[0082] Referring to FIGS. 3-6D, the needle hub 30 includes a removal tab 70, where movement of the removal tab 70 releases an engagement between the first projection 66 of the needle hub 30 and the second projection 68 of the cannula holder 50 to allow the cannula spring 54 to bias the cannula 52 to the retracted position. At least a portion of the removal tab 70 is configured to be engaged with a skin surface of a person after attaching the needle hub 30 to a person. The activation button 34 is moveable along a first axis 72, and the needle holder 44 and the cannula holder 50 are moveable along a second axis 74 perpendicular to the first axis 72. The first actuation surface 56 of the activation button 34 is configured to disengage from the second actuation surface 58 of the needle holder 44 after movement of the activation button 34 a predetermined distance along the first axis 72.

[0083] Referring to FIGS. 7-14, a needle hub 80, according to a further aspect or embodiment, includes an applicator 82 having a needle holder 84, a needle 86 attached to the needle holder 84, a needle retraction spring 88, and an activation button 90, and a hub body 92 having a cannula holder 94, a cannula 96 attached to the cannula holder 94, a cannula withdrawal button 98, and a cannula retraction spring 100. At least a portion of the hub body 92 is configured to be received within the applicator 82 and the applicator 82 is configured to be separated from the hub body 92. Movement of the activation button 90 is configured to move the needle holder 84 and the cannula holder 94 from a retracted position, where the needle 86 and the cannula 96 are positioned within the applicator 82 or hub body 92, to an insertion position, where distal ends of the needle 86 and the cannula 96 are positioned outside of the applicator 82 and the hub body 92. The cannula withdrawal button 98 locks the cannula holder 94 in the insertion position against a biasing force of the cannula retraction spring 100 when the cannula holder 94 is moved from the retracted position to the insertion position. As shown in FIG. 10, in one aspect or embodiment, the cannula withdrawal button 98 may be omitted.

[0084] Referring to FIGS. 12A-12F, the needle holder 84 is configured to move to the retracted position after movement of the cannula holder 94 to the insertion position. The activation button 90 includes an extension 102 having a drive protrusion 103 and the applicator 82 includes a drive surface 104 configured to engage the drive protrusion 103. Upon movement of the activation button 90, the drive protrusion 103 engages the needle holder 84 to move the needle holder 84 and the cannula holder 94 to the insertion position, with the drive protrusion 103 engaging the drive surface 104 of the applicator 82 to move the extension 102 radially outward thereby releasing the needle holder 84 from the drive protrusion 103 to allow the needle retraction spring 100 to return the needle holder 84 to the retracted position. Actuation of the cannula withdrawal button 98 is configured to move the cannula holder 94 from the insertion position to the retracted position. The hub body 92 further includes an adhesive pad 105 configured to secure the hub body 92 to a skin surface of a person. The adhesive pad 105 includes a removal tab 106 extending radially outward from the hub body 92. The activation button 90 is received within an opening 107 defined by a body 108 of the applicator 82. The cannula holder 94 includes a port 109 configured to be in fluid communication with the fluid reservoir 12, with the cannula 96 in fluid communication with the port 109. Tubing 110 is connected to the port of the cannula holder 94.

[0085] Referring to FIG. 11, in one aspect or embodiment, the needle hub 80 is used by removing the packaging, removing an adhesive liner, attaching the needle hub 80 to a skin surface of a patient and removing a safety cap, and pressing the activation button 90 of the

applicator 82, which automatically actuates and retracts the needle 86 to leave the in-dwelling cannula 96. The applicator 82 can then be removed from the hub body 92 and the infusion can commence. Once the infusion is complete, the cannula withdrawal button 98 may be pressed to remove the cannula 96 from the patient, with the hub body 92 being removed from the skin of the patient using the removal tab 106.

[0086] Referring to FIGS. 13 and 14, in one aspect or embodiment, the cannula holder 94 includes a portion of the adhesive pad 105, which removes a portion of the adhesive pad 105 from the skin of the patient when the cannula holder 94 is removed from the hub body 92 to facilitate easier removal of the remainder of the adhesive pad 105 from the skin of the patient.

[0087] Referring to FIGS. 15-18B, a needle hub 112, according to a further aspect or embodiment, includes a hub body 114, an activation button 116, a needle holder 118 and a needle 120 attached to the needle holder 118, a cannula holder 122 and a cannula 124 attached to the cannula holder 122, a needle actuation mechanism 126, and a cannula spring 128. The needle actuation mechanism 126 is configured to move the needle holder 118 and the cannula holder 122 from a retracted position to an insertion position and is configured to move the needle holder 118 back to the retracted position. The needle actuation mechanism 126 includes a cam track 130, a cam member 132 received within the cam track 130, and a torsion spring 134. The torsion spring 134 biases the cam member 132 relative to the cam track 130. The cannula spring 128 biases the cannula holder 122 to a retracted position. Movement of the activation button 116 is configured to cause the needle holder 118 and the cannula holder 122 to move from the retracted position to the insertion position, with the needle holder 118 configured to return to the retracted position while the cannula holder 122 remains in the insertion position. As shown in FIG. 16, in one aspect or embodiment, the needle hub 112 includes two lateral activation squeeze buttons 116. The needle hub 112 is used in the same manner as described above in connection with the needle hub 30 shown in FIG. 5.

[0088] Referring to FIGS. 17-18B, the hub body 114 includes a cannula lock 136 configured to lock the cannula holder 122 in the insertion portion. The needle hub 112 includes an adhesive pad 138 configured to secure the hub body 114 to a skin surface of a person, with the adhesive pad 138 including a removal tab 140. Movement of the removal tab 140 is configured to disengage the cannula lock 136 and the hub body 114 to allow the cannula holder 122 to return to the retracted position. The cannula lock 136 is biased away from the cannula holder 122 via a lock spring 142, where the hub body 112 includes a hinged portion 144, with the hinged portion 144 configured to rotate upon movement of the removal tab 140 and disengage from the cannula lock 136. The cannula holder 122 includes a port 146 configured to be in

fluid communication with the fluid reservoir 12, with the cannula 124 in fluid communication with the port 146. The needle hub 112 includes tubing 148 connected to the port 146 of the cannula holder 122. The cannula holder 122 includes a seal 150 engaged with the needle 120, with at least a portion of the needle 120 received within the cannula 124.

[0089] Referring to FIGS. 19-21, a needle hub 152, according to a further aspect or embodiment, includes a needle holder 154 and a needle 156 attached to the needle holder 154, a needle actuation assembly 158 configured to move the needle holder 154 from a retracted position, to an insertion position, and back to the retracted position, and a pressure interlock 160 including an inlet 162 configured to be in fluid communication with the fluid reservoir 12, an outlet 164 in fluid communication with the needle 156, and a lock member 166. The lock member 166 has a first position where the lock member 166 prevents actuation of the needle actuation assembly 158 and a second position where the lock member 166 allows actuation of the needle actuation assembly 158. The lock member 166 is moved from the first position to the second position based on a pressure within the pressure interlock 160.

[0090] Referring to FIG. 21, the lock member 166 isolates the inlet 162 from the outlet 164 when the lock member 166 is in the first position, and the lock member 166 allows fluid communication between the inlet 162 and the outlet 164 when the lock member 166 is in the second position. The needle hub 152 further includes tubing 168 connected to the outlet 164 and in fluid communication with the needle 156. The lock member 166 includes an opening 170, with a portion of the needle actuation assembly 158 extending through the opening 170 of the lock member 166 when the lock member 166 is in the second position. The needle actuation assembly 158 includes a cam track 172, a cam member 174, and an actuation spring 176 biasing the cam member 174 relative to the cam track 172. A cam block 178 defines the cam track 172, with the cam block 178 extending through the opening 170 of the lock member 166 when the lock member 166 is in the second position. The needle actuation assembly 158 further includes a cannula 180, where the needle 156 is received within the cannula 180 when the needle holder 156 is in the retracted position.

[0091] Referring again to FIGS. 19-21, the needle hub 152 includes a housing 182 and a removal tab 184. A top surface 186 of the housing 182 is smooth and free of activation buttons. As shown in FIG. 20, the needle hub 152 is used by removing packaging, removing an adhesive liner, attaching the needle hub 152 to a skin surface of a patient, and activating the drive mechanism 27 to insert the needle 156, with the needle 156 automatically retracting leaving the in-dwelling cannula 180. After infusion is complete, the needle hub 152 is removed by grasping the removal tab 184 and lifting upwards, with the cannula 180 automatically

retracting. In one aspect or embodiment, pulling the removal tab 184 causes a drop in pressure of the pressure interlock 160 to cause the cannula holder and/or the cannula 180 to automatically retract.

[0092] Referring to FIGS. 22-25, a drug delivery device 190 and a needle hub 192, according to a further aspect or embodiment, is shown. The drug delivery device 190 may be similar to the drug delivery device 10 shown in FIGS. 1 and 2. The drug delivery device 190 and the needle hub 192 of FIGS. 22-25, however, is modular, with the needle hub 192 optionally integrated within the drug delivery device 190 (FIG. 24) or with the needle hub 192 separated from the drug delivery device 190 and separately attached to a skin surface of a patient (FIG. 25). In one aspect or embodiment, the drug delivery device 190 and the needle hub 192 may remain connected or integral for lower drug volume and separated with a fluid connection therebetween for larger drug volumes.

[0093] Referring to FIGS. 26A-26C, a needle hub 200 with a skin tenting reduction feature according to one aspect or embodiment is shown. The needle hub 200 includes a rotating engagement mechanism 202, with a portion of the rotating engagement mechanism 202 first contacting a skin surface of the patient and adhering to the skin surface and further rotating as the needle hub 200 is fully pressed onto the skin surface. The initial adherence and further rotation of the rotating engagement mechanism stretches the skin to reduce skin tenting.

[0094] Referring to FIGS. 27A-27C, a needle hub 204 with a skin tenting reduction feature according to one aspect or embodiment is shown. The needle hub 204 includes an adhesive ring 206 that is pressed onto the skin prior to insertion of a needle when an activation button is depressed or actuated. The adhesive ring 206 stretches the skin to reduce skin tenting.

[0095] Referring to FIGS. 28A-28C, a needle hub 208 with a skin tenting reduction feature according to one aspect or embodiment is shown. The needle hub 208 includes skin stretching member 210 that is moved radially outward after being initially adhered to a skin surface of a patient. An activation button 212 engages the skin stretching member 210 to move the skin stretching member 210 radially outward, which stretches the skin locally to reduce skin tenting.

[0096] The skin tenting reduction features and associated mechanisms of FIGS. 26A-28C may be incorporated into any of the aspect or embodiments of the needle hub or needle insertion arrangements disclosed herein.

[0097] Referring to FIGS. 29-33, a needle actuation assembly 220, according to one aspect or embodiment, includes a clip 222 that holds a needle actuator body 224 and cannula body 226 in the retracted position, which are biased by a spring 228. Pushing the clip 222 inwards releases the needle actuator body 224 and cannula body 226 to cause insertion of a needle 230

and a cannula 232. When the cannula body 226 reaches the bottom of a housing 233, the cannula body 226 contacts angled features causing the cannula body 226 to rotate and/or twist. The cannula body 226 is held down by clips 236 in the walls of the housing 233. After the cannula body 226 rotates and/or twists, the needle actuator body 224 is released and a return spring 238 retracts the needle 230.

[0098] Referring to FIGS. 34 and 35, a needle hub 240 according to a further aspect or embodiment is configured to be decoupled from remaining components of a drug delivery device. The needle hub 240 includes a protective cap 242, a needle insertion mechanism 244, connection arrangement 246 configured to place the needle hub 240 in fluid communication with the reservoir 12 and the drive mechanism 27, a fluid path 248, and an adhesive pad and/or layer 250. The connection arrangement 246 may provide for aseptic connection between the needle hub 240 and the reservoir 12. The needle retraction may be manually activated or automatically activated via a triggering mechanism connected to an end of dose event and/or a wireless connection between the driving unit and the needle hub 240. The triggering mechanism may include a flexible rigid connection to plunger rod movement (totally or partially at the end of translation). The fluid path 248 and connection arrangement 246 is maintained sterile until the connection is established, with sterilization of the sub-system and reservoir.

[0099] Referring to FIGS. 36-39, a drug delivery device 252, according to a further aspect or embodiment, includes a flexible reservoir 254, with at least a portion of the flexible reservoir 254 positioned externally from a remaining portion of the drug delivery device 252. The drug delivery device 252 may be similar to the drug delivery device 10 shown in FIGS. 1 and 2. As shown in FIG. 39, for smaller volumes, such as 10 mL-30 mL, the flexible reservoir 254 may be directly attached to the drug delivery device 252 and worn on a skin surface of the patient. As shown in FIG. 38, for larger volumes, such as 50 mL, the flexible reservoir 254 may be separated from the drug delivery device 252 and fluidly connected to the drug delivery device 252 via a fluid path 256, such as a tube. The flexible reservoir 254 may be separately attached to the patient via a belt clip, harness, strap, or other suitable arrangement.

[00100] Referring to FIG. 40, the drug delivery devices in any of the aspects or embodiments discussed above may utilize a valve assembly 260 that engages a reservoir and/or container to facilitate the fluid connection between the reservoir and/or container and the fluid path to the needle and/or cannula. The valve assembly 260 may be similar to and operate in the same manner as the valve assembly shown and described in U.S. Patent Application Publication No. 2017/0354788.

[00101] Referring to FIGS. 41-48, a pressure interlock 270, according to a further aspect or embodiment, of the present application is shown. The pressure interlock 270 is similar to and functions similarly to the pressure interlock 160 discussed above in connection with FIGS. 19-21. Like reference numbers are used for like elements. As shown in FIG. 48, the pressure interlock 270 includes a cylinder 272 and the lock member 166 includes a piston 274, with the inlet 162 and the outlet 164 of the pressure interlock 270 in fluid communication with the cylinder 272. The pressure interlock 270 includes an exhaust vent 276 configured to dispel air from the cylinder 272. The exhaust vent 276 includes a hydrophobic membrane 278. In one aspect or embodiment, the hydrophobic membrane 278 has a breakthrough pressure of 41 psi. In one aspect or embodiment, the exhaust vent 276 includes a one-way valve. The pressure interlock 270 includes tubing 280 connected to the outlet 164 and in fluid communication with the needle 156. As shown in FIG. 41, in one aspect or embodiment, the cam track 172 of the cam block 178 is V-shaped to correspond to the downward movement of the needle 156 and subsequent retraction of the needle 156.

[00102] Referring to FIGS. 42 and 43, in one aspect or embodiment, the cam member 174 includes a base 282 having a pair of extensions 284 and a cylindrical protrusion 286 that is received within the cam track 172. In one aspect or embodiment, the cannula 180 is attached to a cannula holder 288.

[00103] Referring to FIGS. 44 and 45, in one aspect or embodiment, after actuation of the needle 156 and the cannula 180, the cannula holder 288 is locked in an insertion position via one or more clips 290 provided on a baseplate or housing 292 of a drug delivery device.

[00104] Referring to FIGS. 46 and 47, in one aspect or embodiment, the lock member 166 includes a seal 294 that engages and forms a seal with the cylinder 272. The seal 294 may be a rubber stopper or O-ring, although other suitable seal arrangements may be utilized. The seal 294 is received by a seal engagement portion 296 of the lock member 166.

[00105] Referring to FIG. 48, the pressure interlock 270 operates in the same manner as the pressure interlock 160 of FIG. 21. Prior to actuation, the lock member 166 is positioned adjacent to the inlet 162 such that the inlet 162 is isolated from the outlet 164. The needle actuation assembly 158 is prevented from actuating due to the lock member 166 blocking or engaging the cam block 178. When fluid is delivered to the inlet 162 via a drug delivery device, such as the drug delivery device 10 shown in FIGS. 1 and 2, the increase in pressure within the cylinder 272 causes the lock member 166 and the seal 294 to move to the position shown in FIG. 48 such that the opening 170 of the lock member 166 is aligned with the cam block 178 to allow for the actuation of the needle 156 and the cannula 180 and also placing the inlet 162

in fluid communication with the outlet 164. As fluid is introduced into the cylinder 272, air is dispelled through the exhaust vent 276. Although a cylindrical cylinder 272 is shown, other suitable shaped cylinders may be utilized, such as a rounded rectangular cylinder or barrel.

[00106] Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

THE INVENTION CLAIMED IS

1. A needle hub for a drug delivery device comprising:

a needle holder and a needle attached to the needle holder;

a needle actuation assembly configured to move the needle holder from a retracted position, to an insertion position, and back to the retracted position; and

a pressure interlock comprising an inlet configured to be in fluid communication with a fluid source, an outlet in fluid communication with the needle, and a lock member, the lock member having a first position where the lock member prevents actuation of the needle actuation assembly and a second position where the lock member allows actuation of the needle actuation assembly, wherein the lock member is moved from the first position to the second position based on a pressure within the pressure interlock.

2. The needle hub of claim 1, wherein the pressure interlock comprises a cylinder and the lock member comprises a piston, the inlet and the outlet of the pressure interlock are in fluid communication with the cylinder.

3. The needle hub of claim 1, wherein the lock member isolates the inlet from the outlet when the lock member is in the first position, and wherein the lock member allows fluid communication between the inlet and the outlet when the lock member is in the second position.

4. The needle hub of claim 2, wherein the pressure interlock further comprises an exhaust vent configured to dispel air from the cylinder.

5. The needle hub of claim 4, wherein the exhaust vent comprises a hydrophobic membrane.

6. The needle hub of claim 2, further comprising tubing connected to the outlet and in fluid communication with the needle.

7. The needle hub of claim 1, wherein the lock member comprises an opening, and wherein a portion of the needle actuation assembly extends through the opening of the lock member when the lock member is in the second position.

8. The needle hub of claim 7, wherein the needle actuation assembly comprises cam track, a cam member, and an actuation spring biasing the cam member relative to the cam track.

9. The needle hub of claim 8, wherein a cam block defines the cam track, and wherein the cam block extends through the opening of the lock member when the lock member is in the second position.

10. The needle hub of claim 1, further comprising a skin tenting reduction mechanism comprising an adhesive surface configured to be adhered to a skin surface of a person, the skin tenting reduction mechanism configured to stretch the skin surface at a location where the needle penetrates the skin surface.

11. The needle hub of claim 1, wherein the needle actuation assembly further comprises a cannula, and wherein the needle is received within the cannula when the needle holder is in the retracted position.

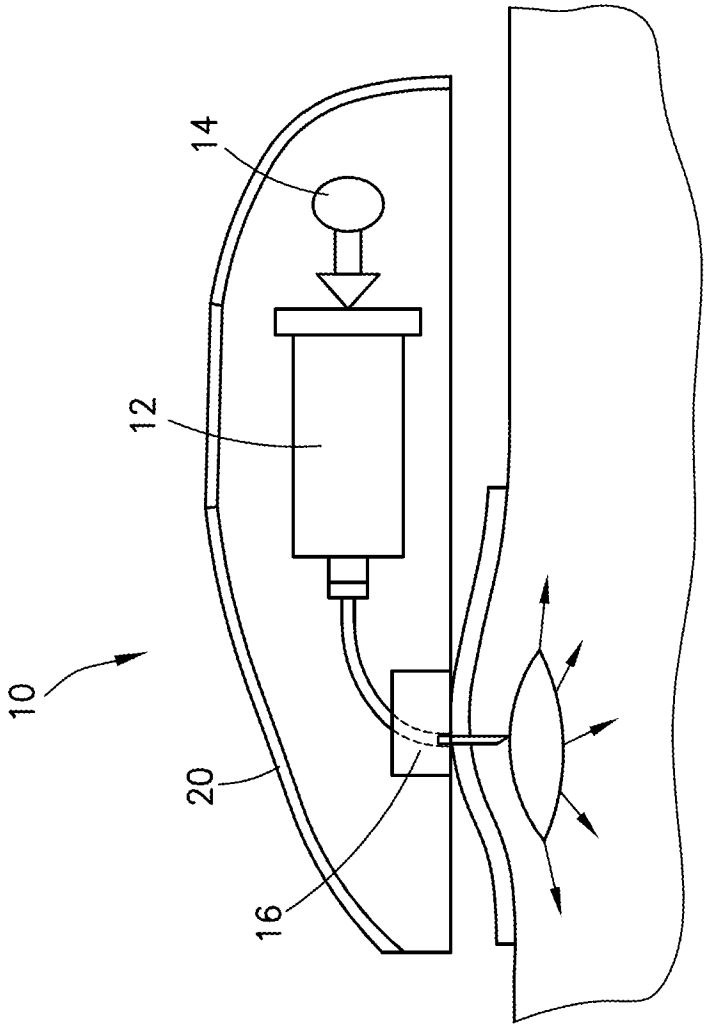

FIG.1

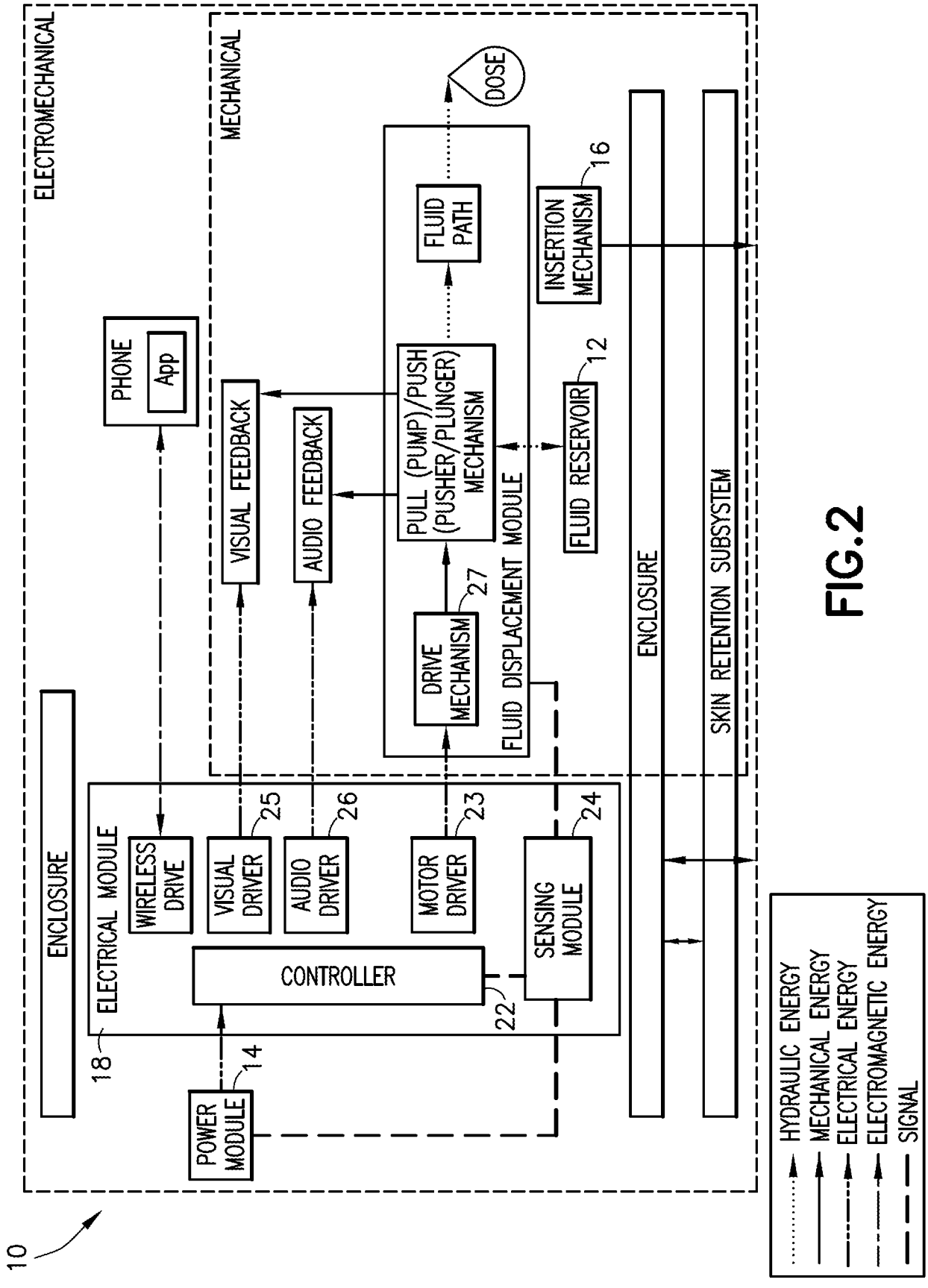
ELECTROMECHANICAL
MECHANICAL
DOSE
FLUID PATH
INSERTION MECHANISM
16
PHONE
App
VISUAL FEEDBACK
AUDIO FEEDBACK
PULL (PUMP)/PUSH (PUSHER/PLUNGER) MECHANISM
FLUID RESERVOIR
12
DRIVE MECHANISM
27
FLUID DISPLACEMENT MODULE
ENCLOSURE
SKIN RETENTION SUBSYSTEM
ENCLOSURE
ELECTRICAL MODULE
WIRELESS DRIVE
VISUAL DRIVER
25
AUDIO DRIVER
26
MOTOR DRIVER
23
SENSING MODULE
24
CONTROLLER
22
18
POWER MODULE
14
10
HYDRAULIC ENERGY
MECHANICAL ENERGY
ELECTRICAL ENERGY
ELECTROMAGNETIC ENERGY
SIGNAL

FIG.2

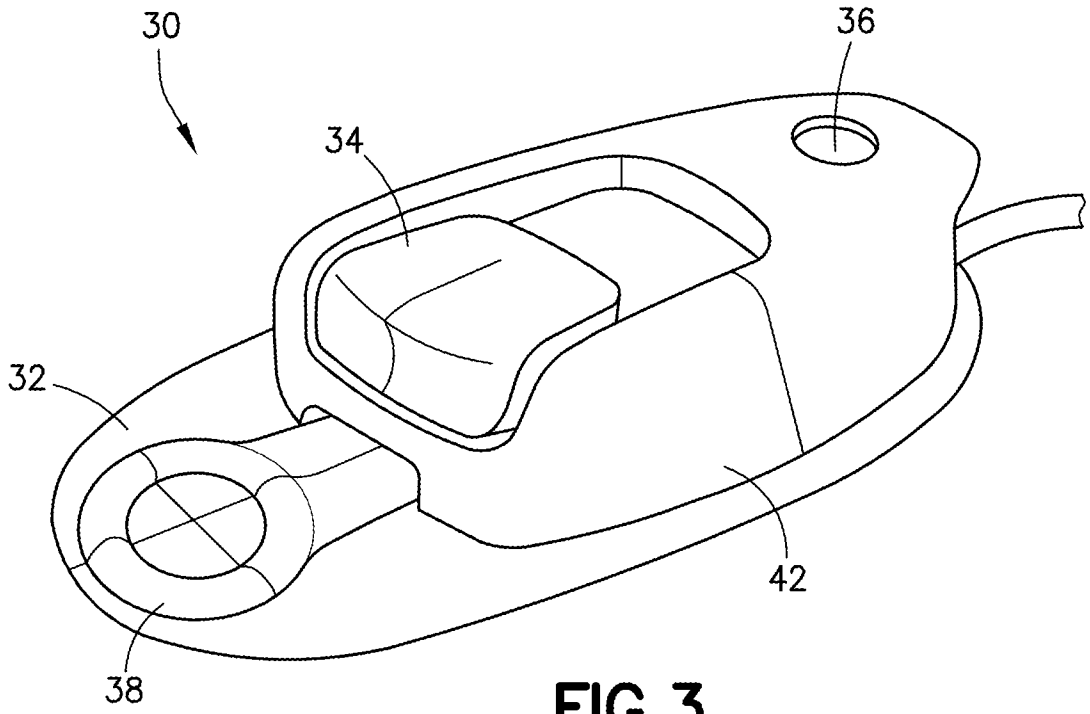

FIG.3

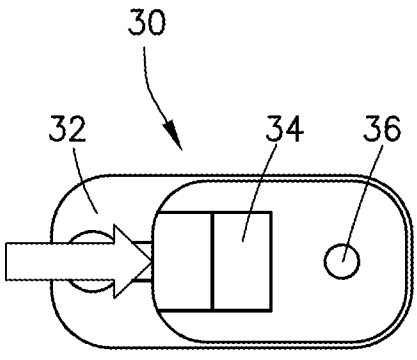

FIG.4A

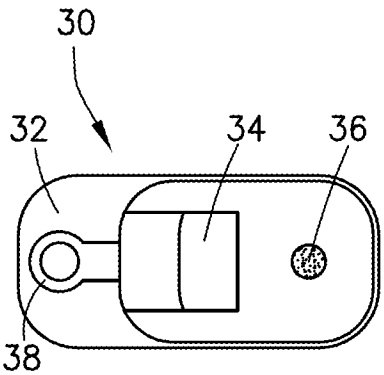

FIG.4B

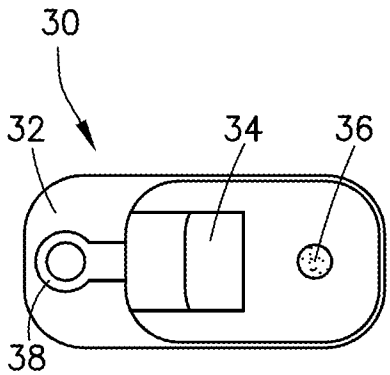

FIG.4C

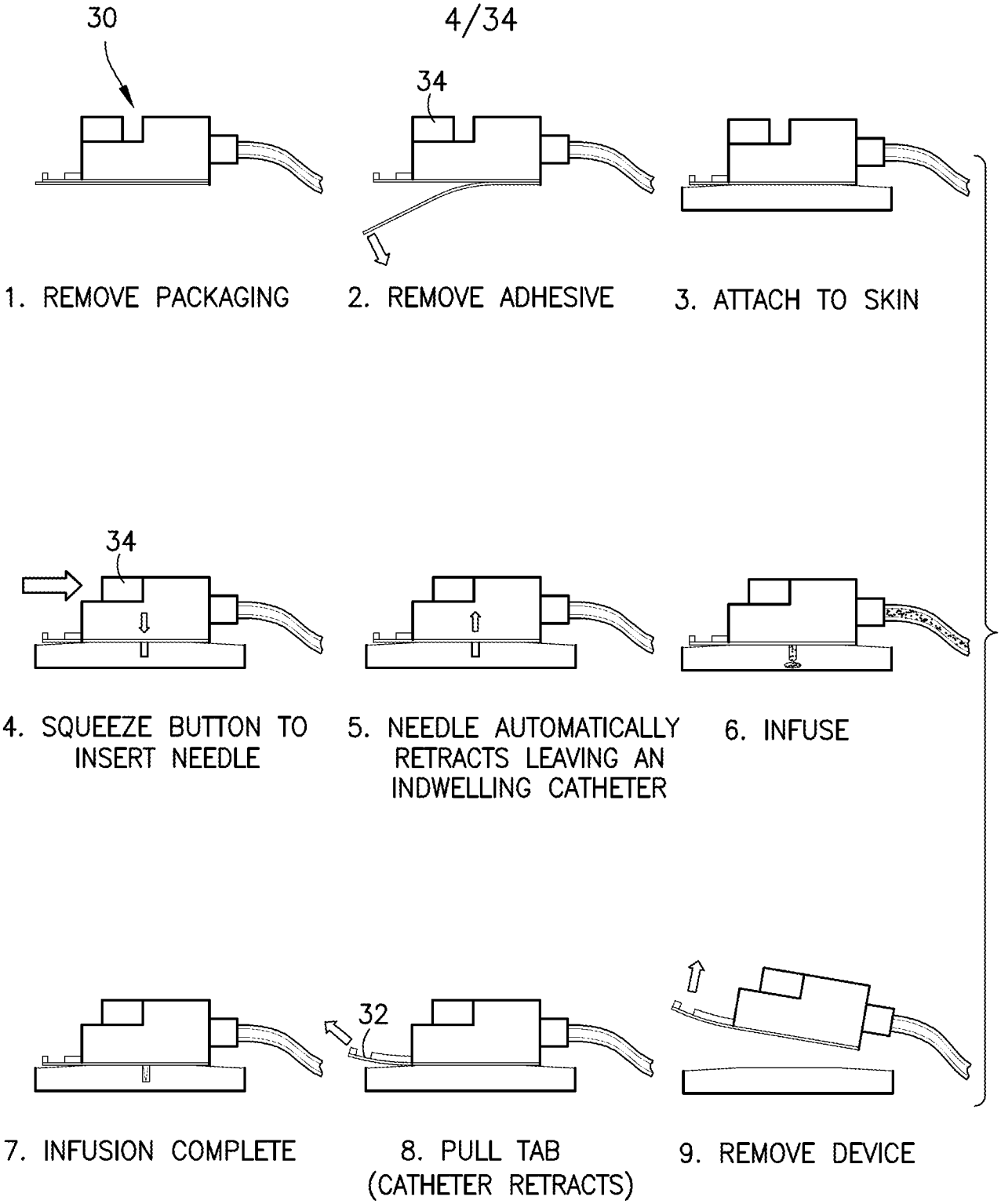
30
34
1. REMOVE PACKAGING
2. REMOVE ADHESIVE
3. ATTACH TO SKIN
34
4. SQUEEZE BUTTON TO INSERT NEEDLE
5. NEEDLE AUTOMATICALLY RETRACTS LEAVING AN INDWELLING CATHETER
6. INFUSE
32
7. INFUSION COMPLETE
8. PULL TAB (CATHETER RETRACTS)
9. REMOVE DEVICE

FIG.5

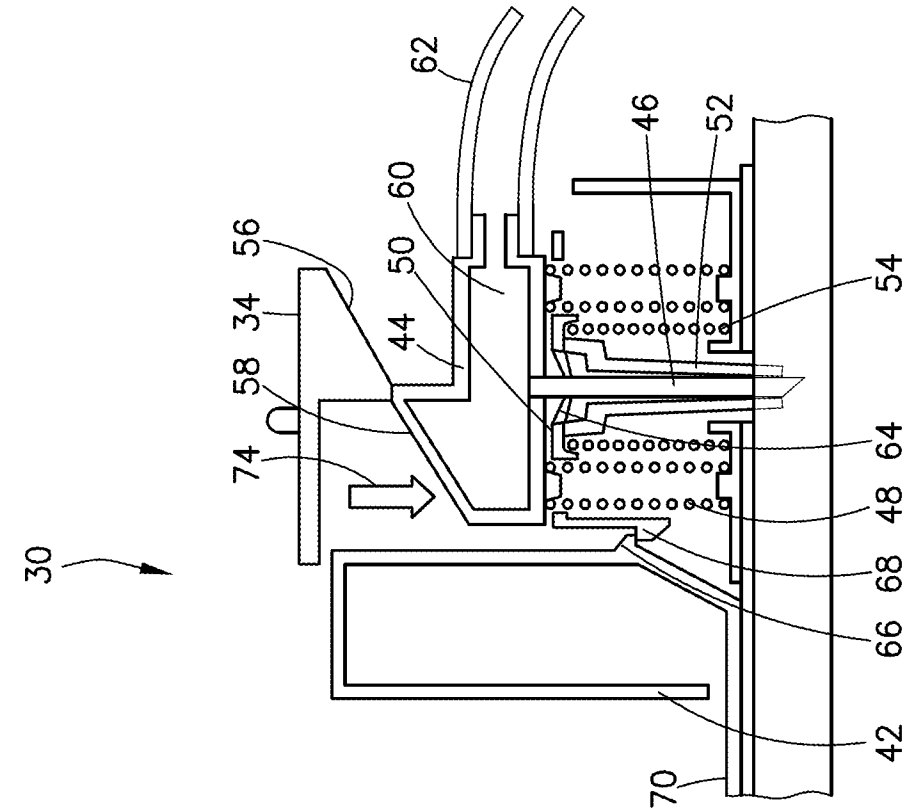
30
62
46
52
60
50
56
54
34
44
58
64
74
48
68
66
42
70

FIG.6B

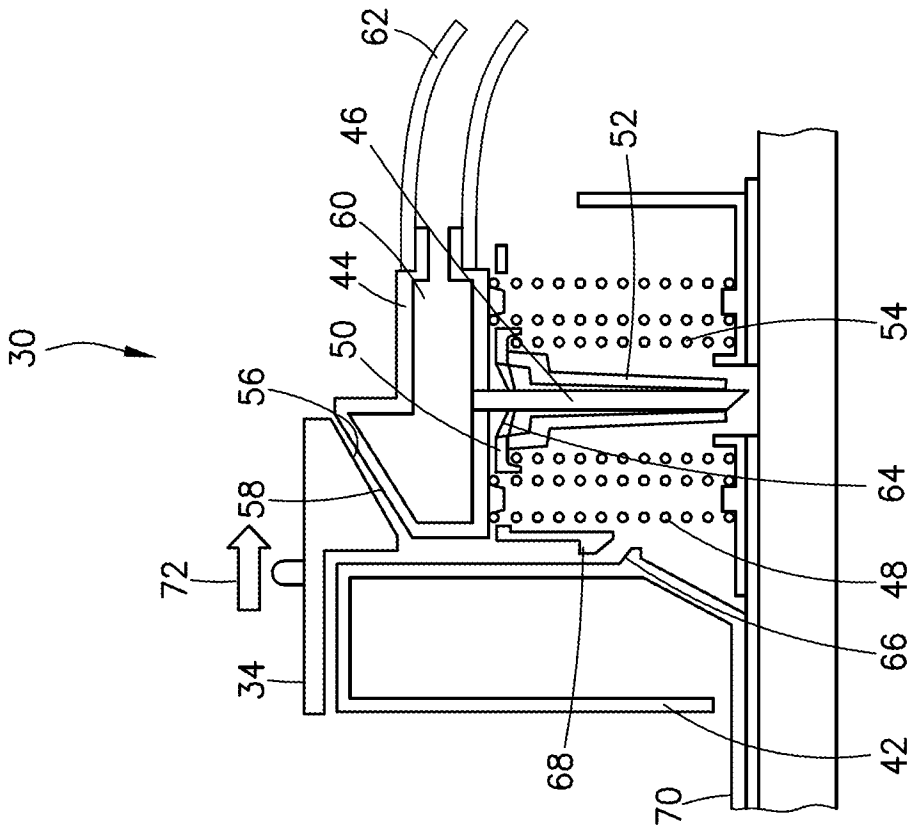
30
62
46
52
60
44
54
50
56
64
58
48
72
66
34
68
42
70

FIG.6A

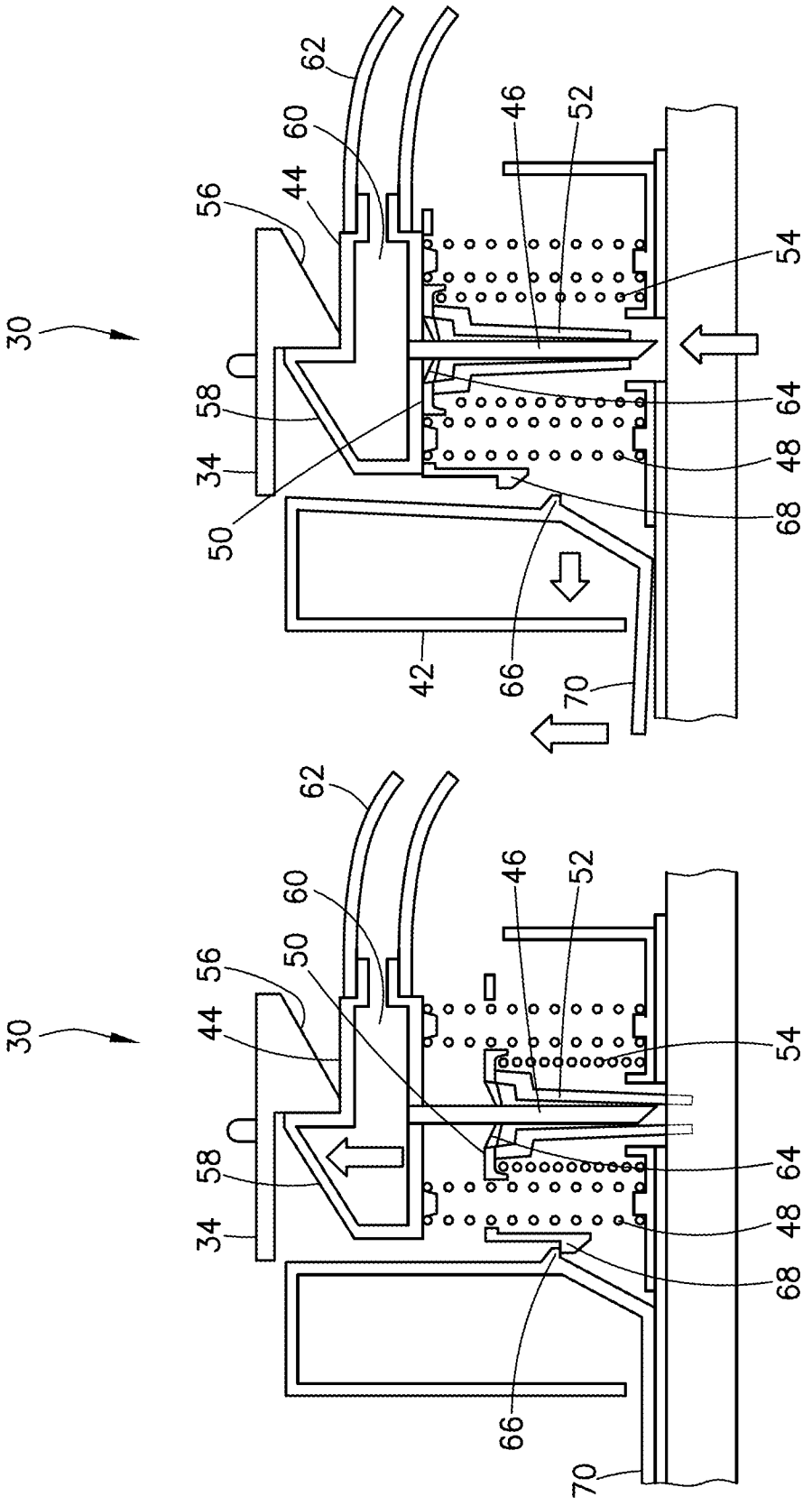

FIG.6C

FIG.6D

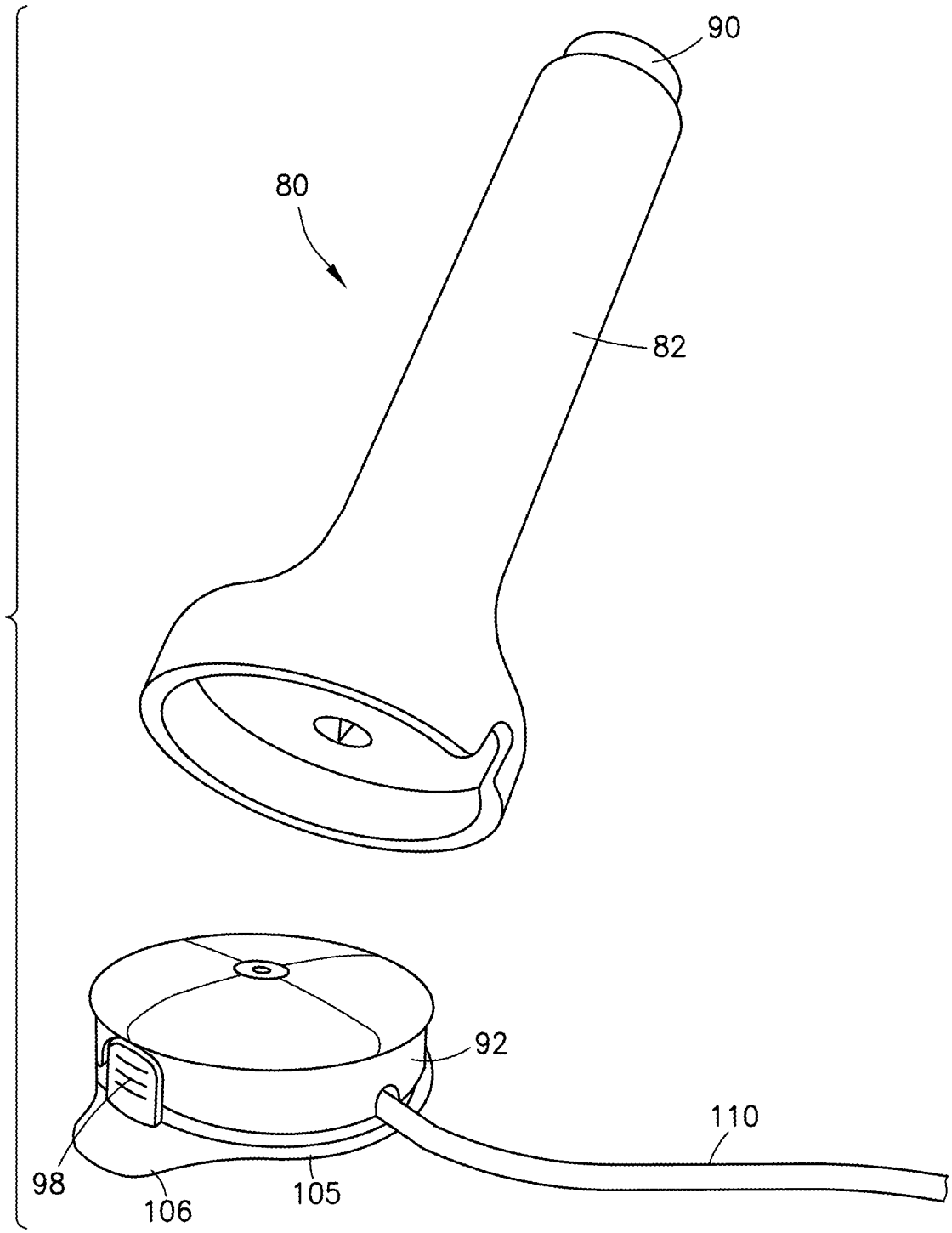

FIG.7

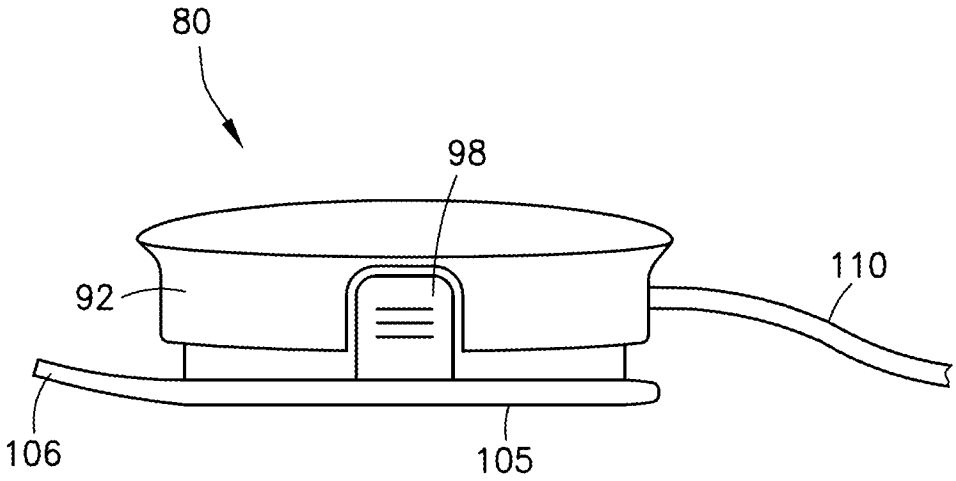

FIG.8

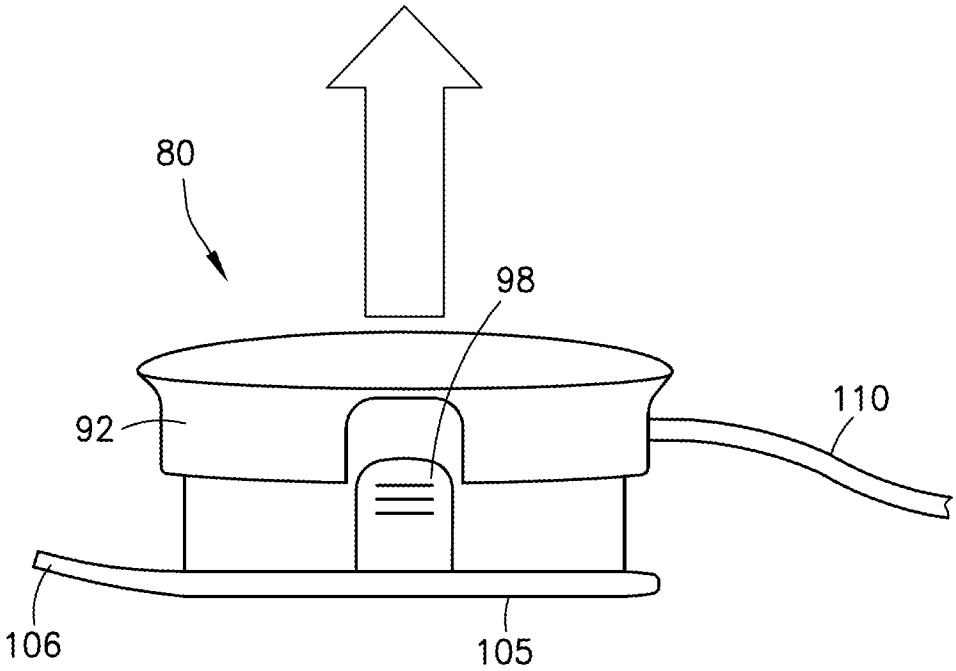

FIG.9

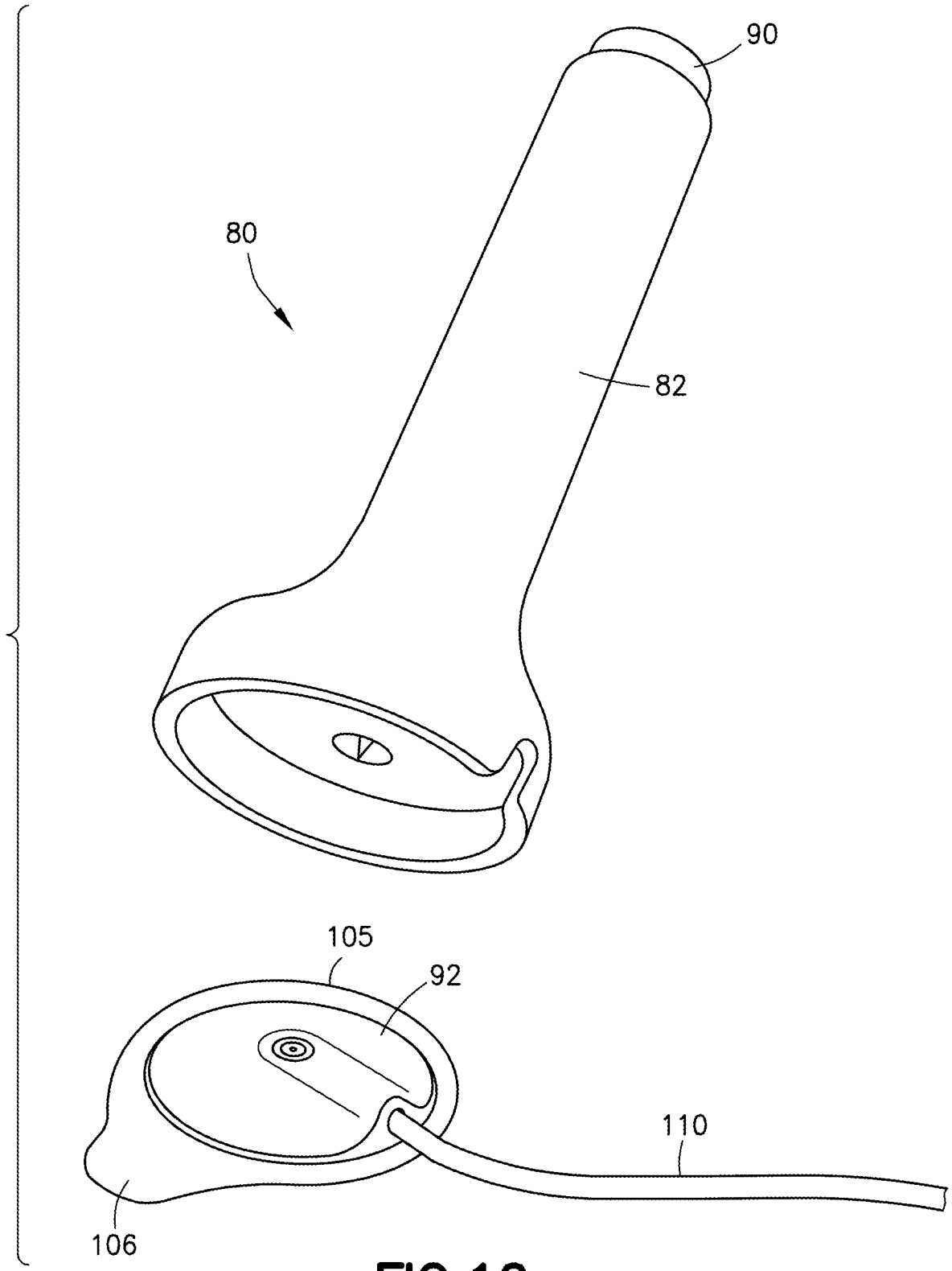

FIG.10

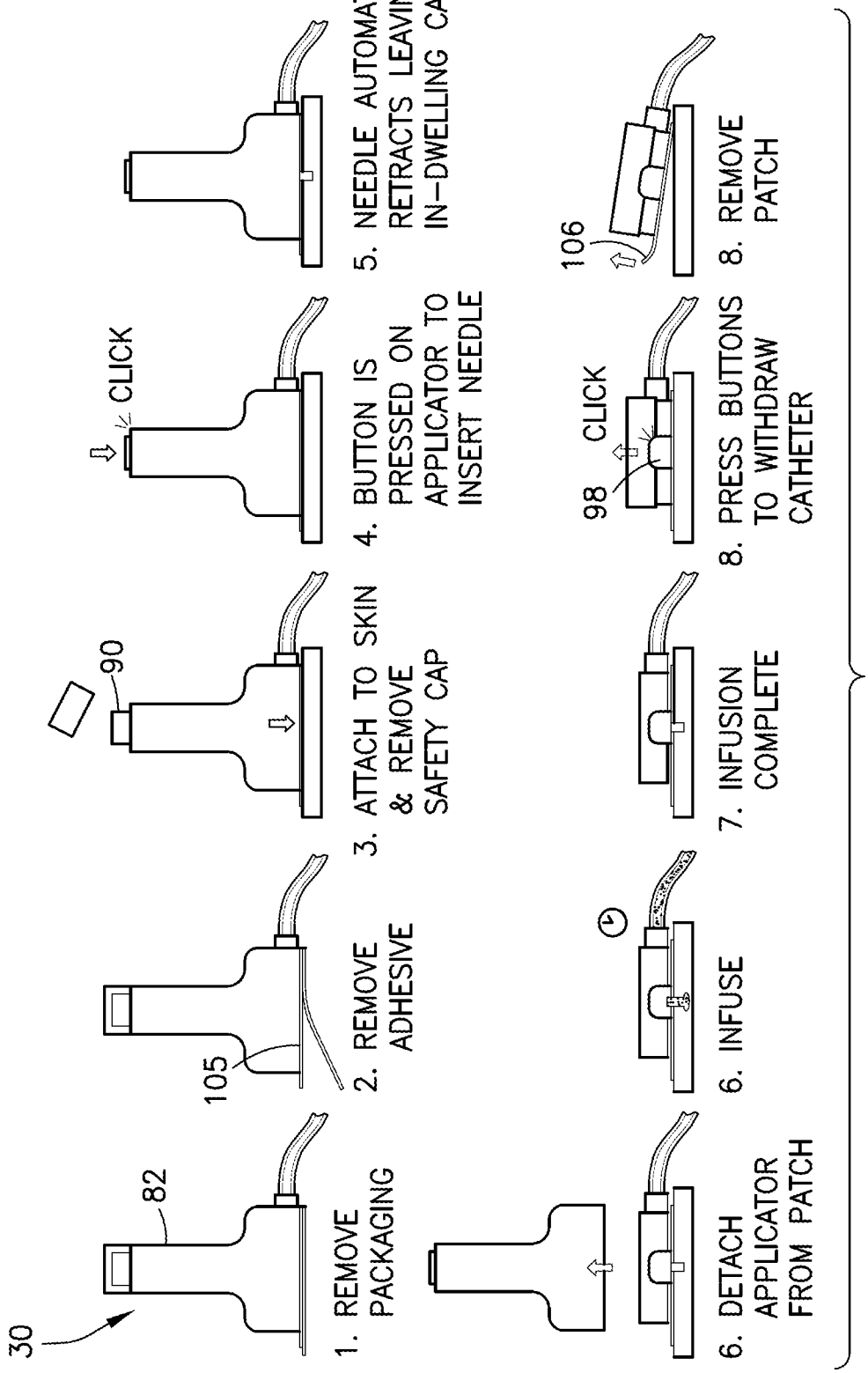
30
82
1. REMOVE PACKAGING
105
2. REMOVE ADHESIVE
90
3. ATTACH TO SKIN & REMOVE SAFETY CAP
CLICK
4. BUTTON IS PRESSED ON APPLICATOR TO INSERT NEEDLE
5. NEEDLE AUTOMATICALLY RETRACTS LEAVING AN IN-DWELLING CATHETER
6. DETACH APPLICATOR FROM PATCH
6. INFUSE
7. INFUSION COMPLETE
98 CLICK
8. PRESS BUTTONS TO WITHDRAW CATHETER
106
8. REMOVE PATCH

FIG.11

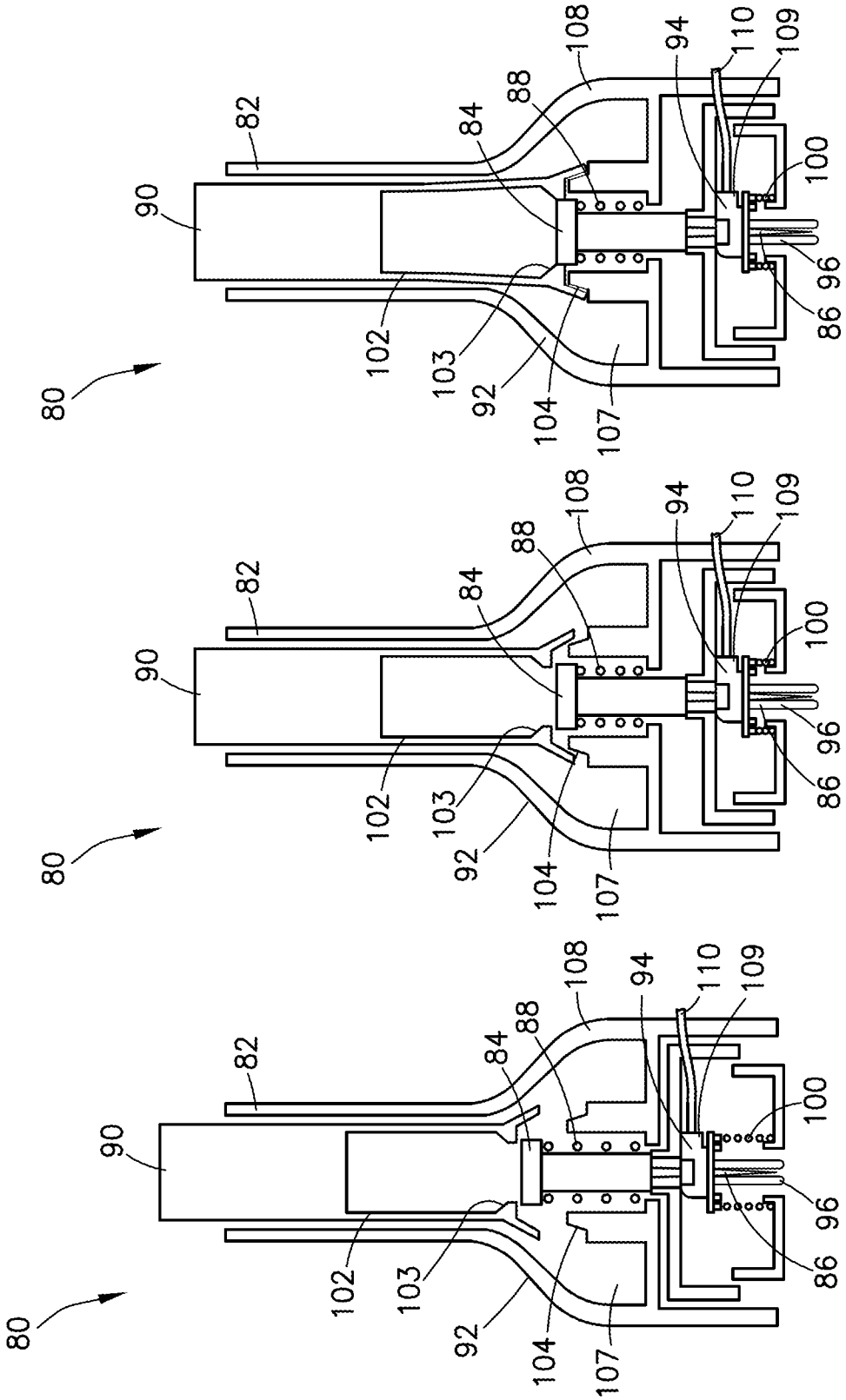

FIG.12A

FIG.12B

FIG.12C

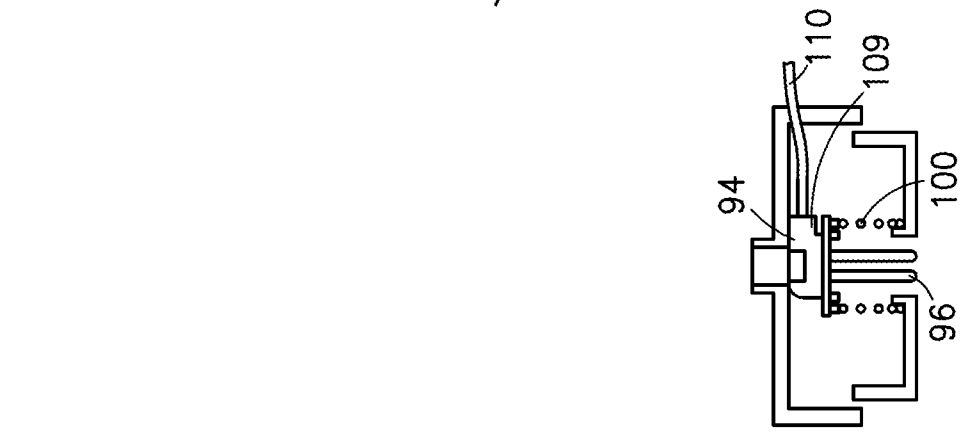

FIG.12F

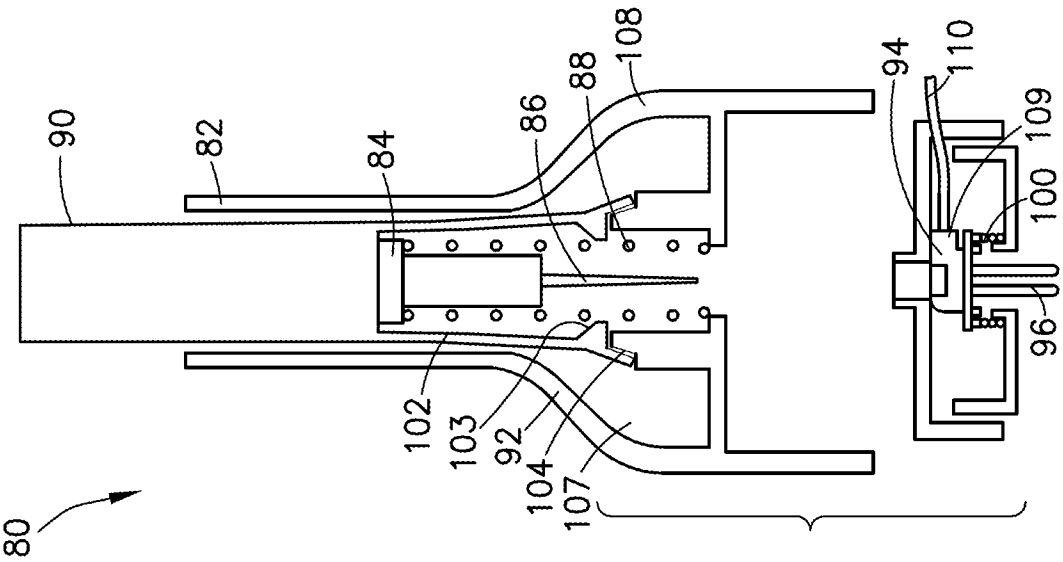

FIG.12E

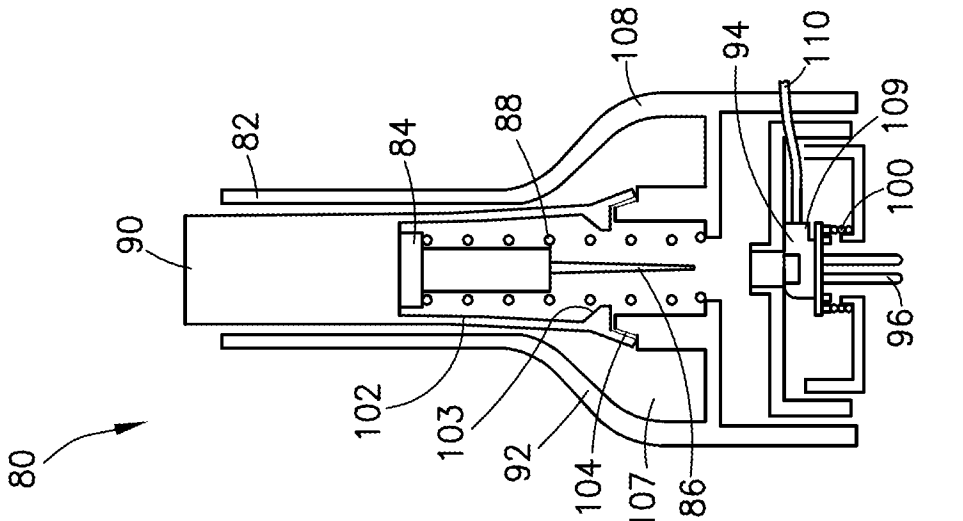

FIG.12D

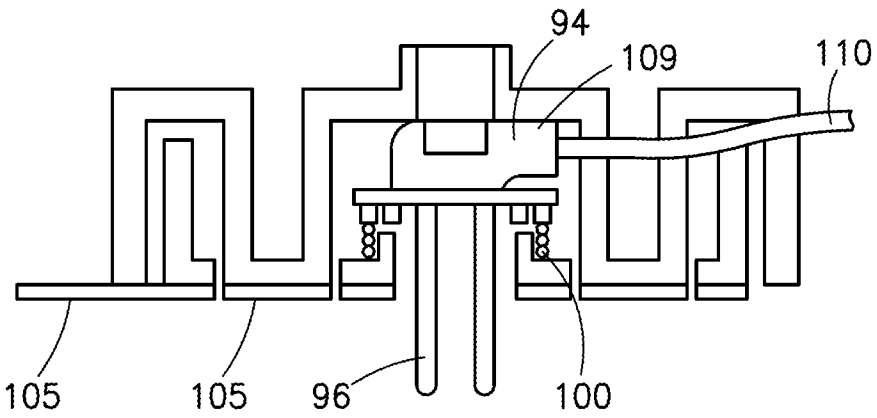

FIG.13

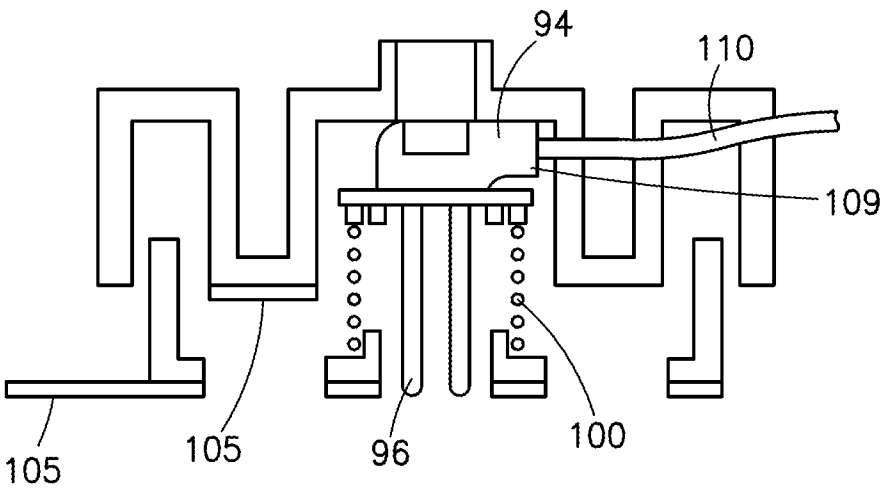

FIG.14

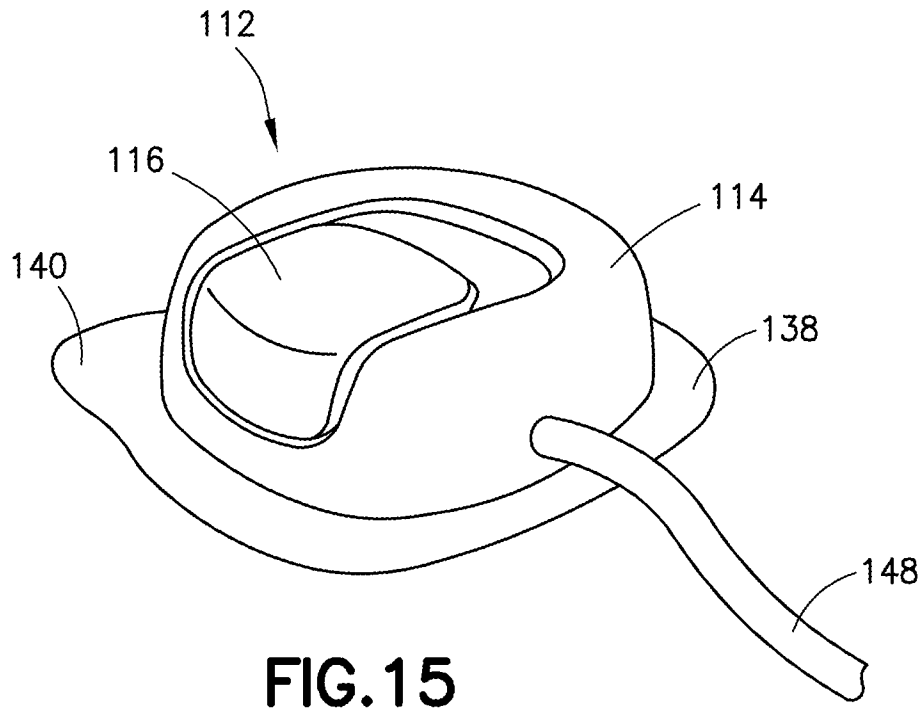

FIG.15

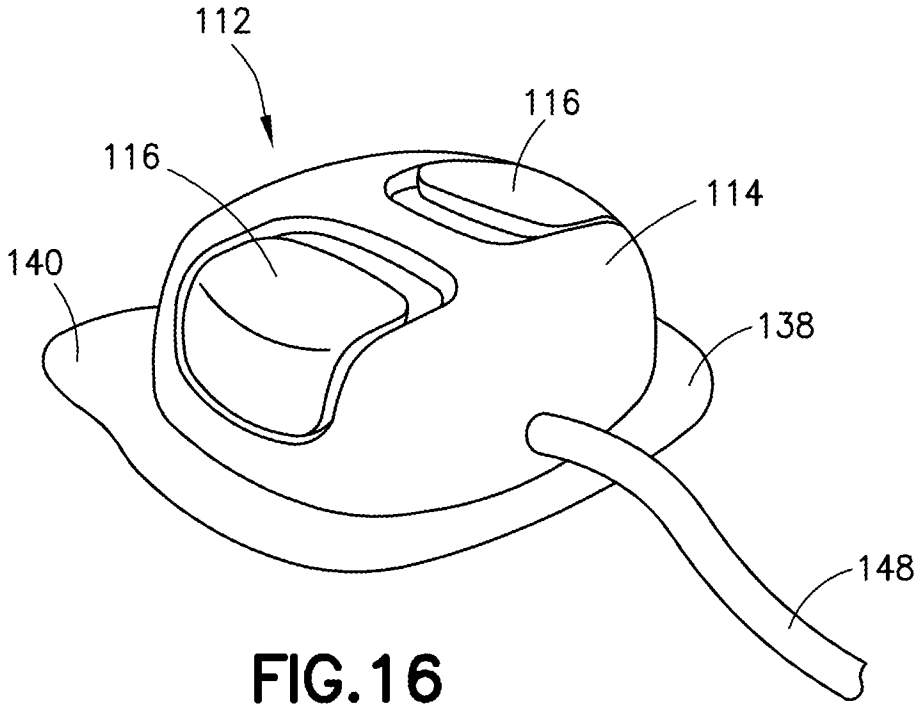

FIG.16

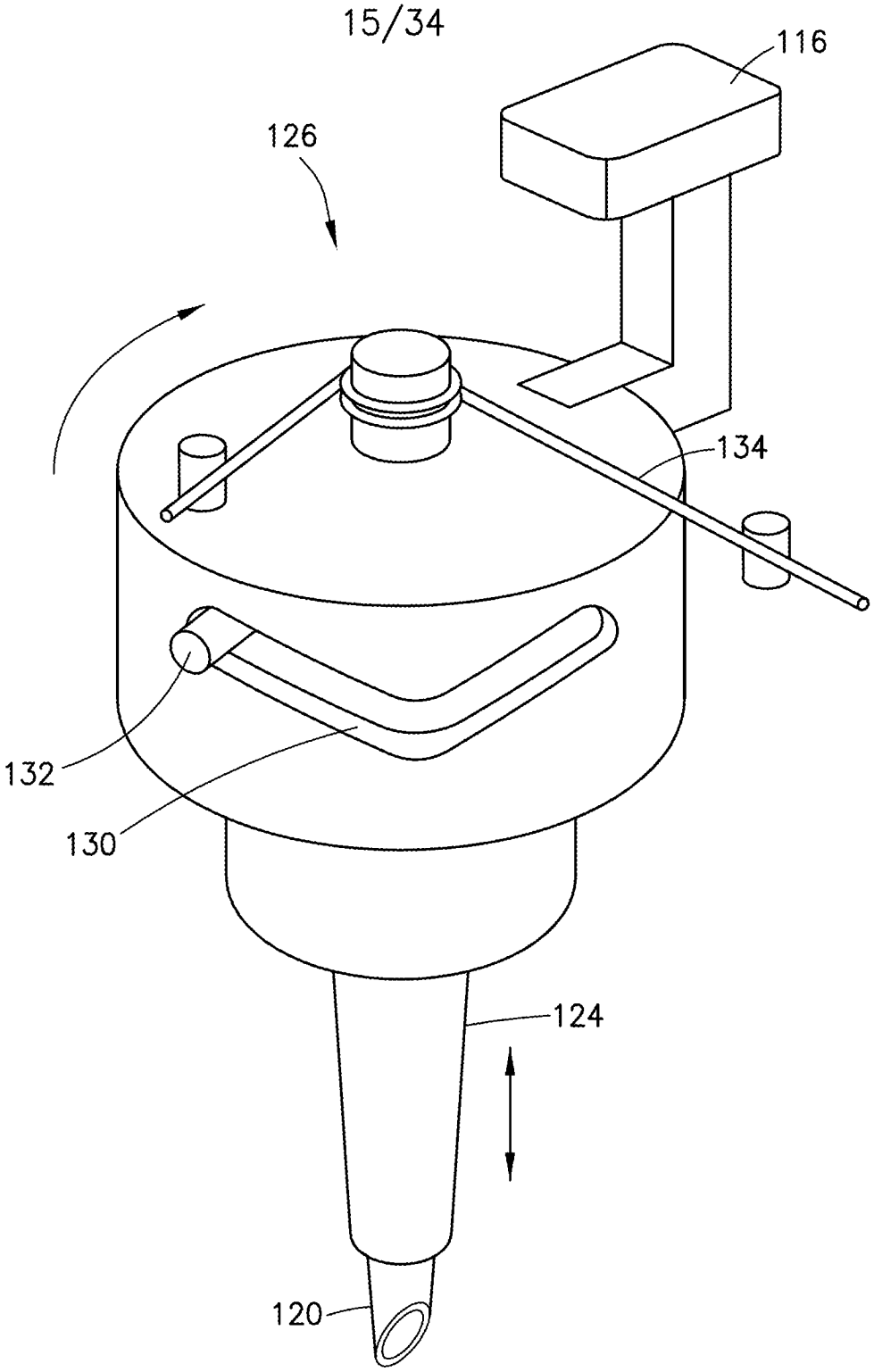

FIG.17

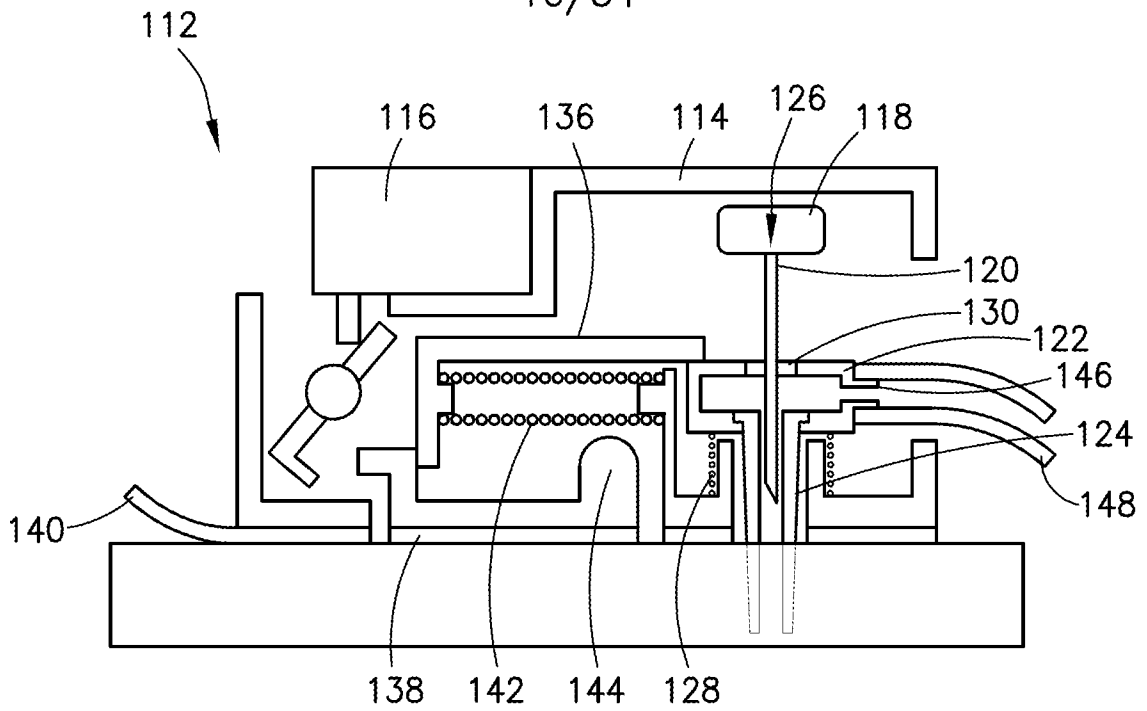

FIG.18A

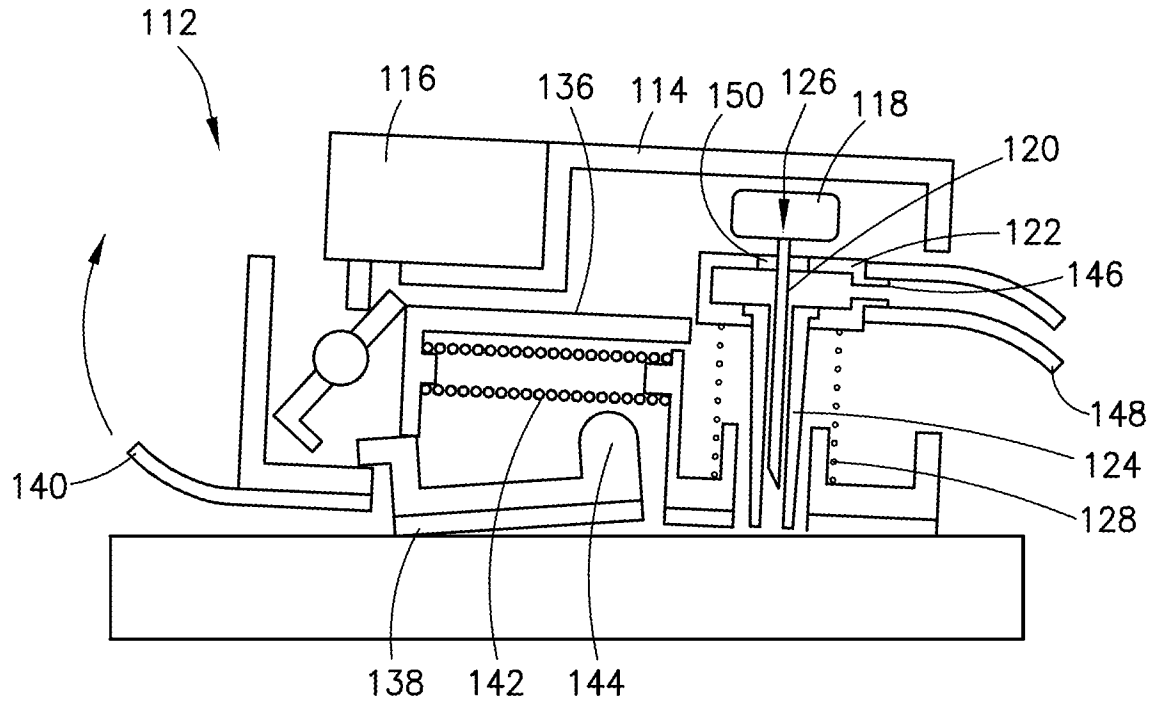

FIG.18B

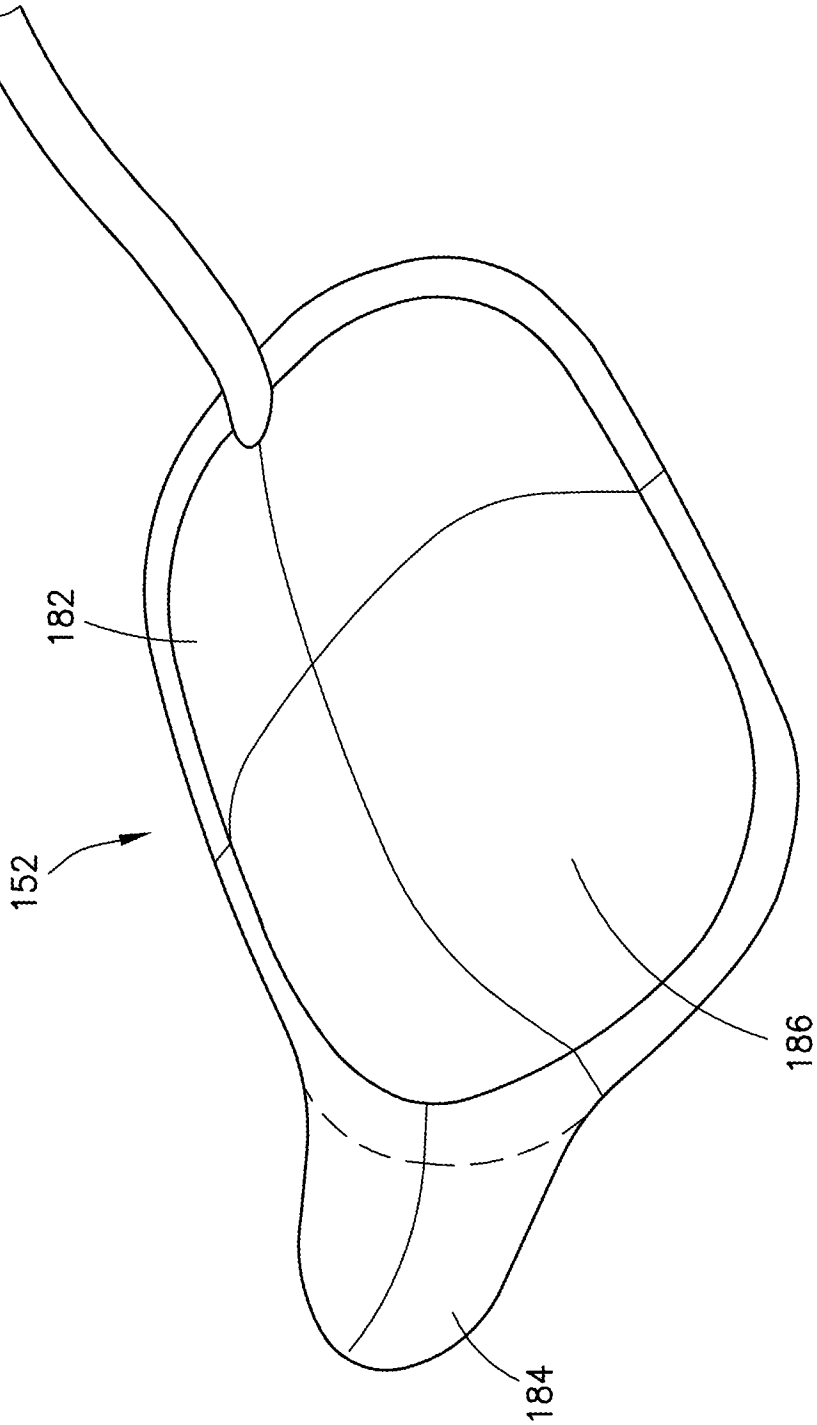

FIG.19

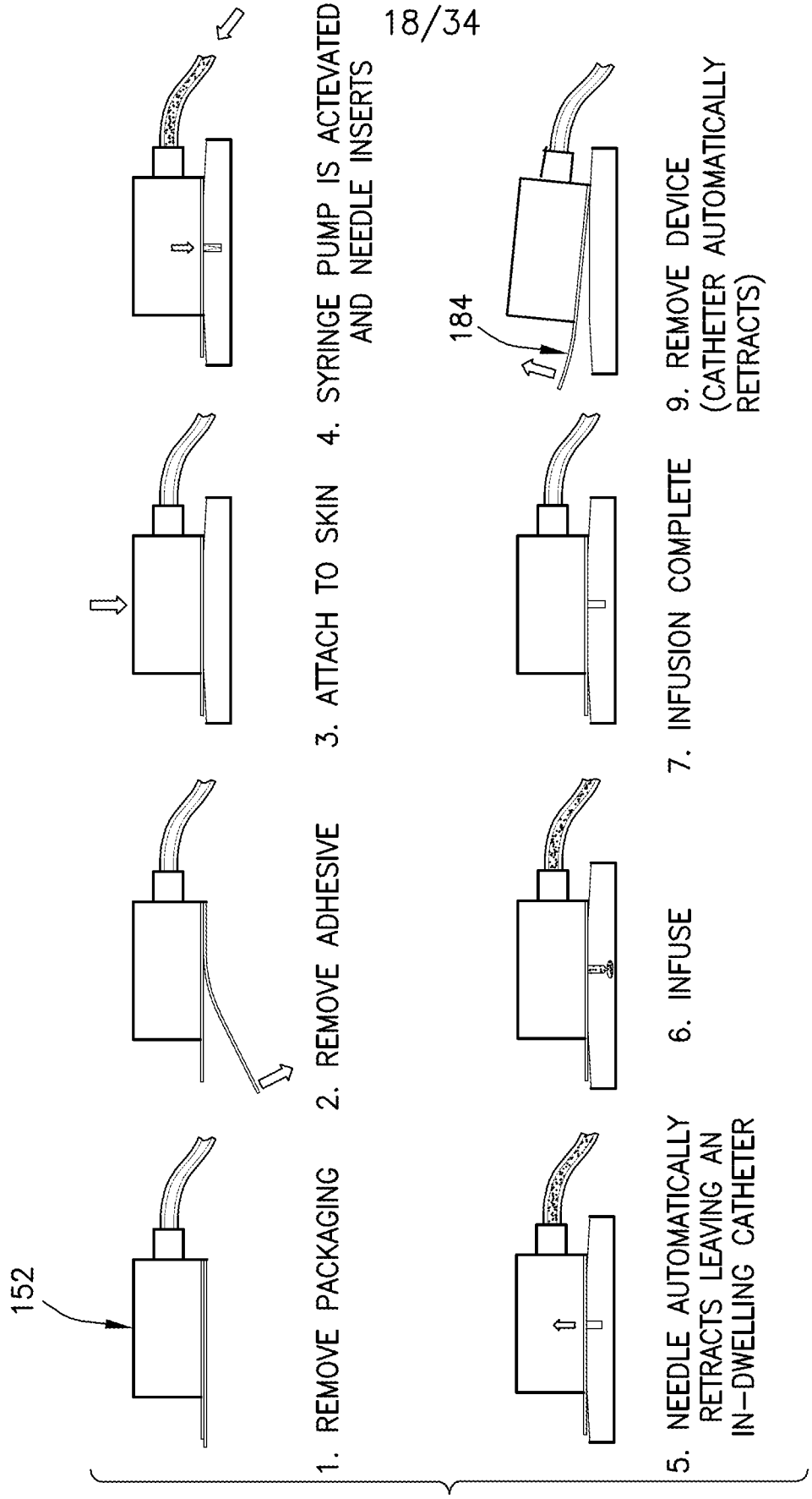
152
184
1. REMOVE PACKAGING
2. REMOVE ADHESIVE
3. ATTACH TO SKIN
4. SYRINGE PUMP IS ACTEVATED AND NEEDLE INSERTS
5. NEEDLE AUTOMATICALLY RETRACTS LEAVING AN IN-DWELLING CATHETER
6. INFUSE
7. INFUSION COMPLETE
9. REMOVE DEVICE (CATHETER AUTOMATICALLY RETRACTS)

FIG.20

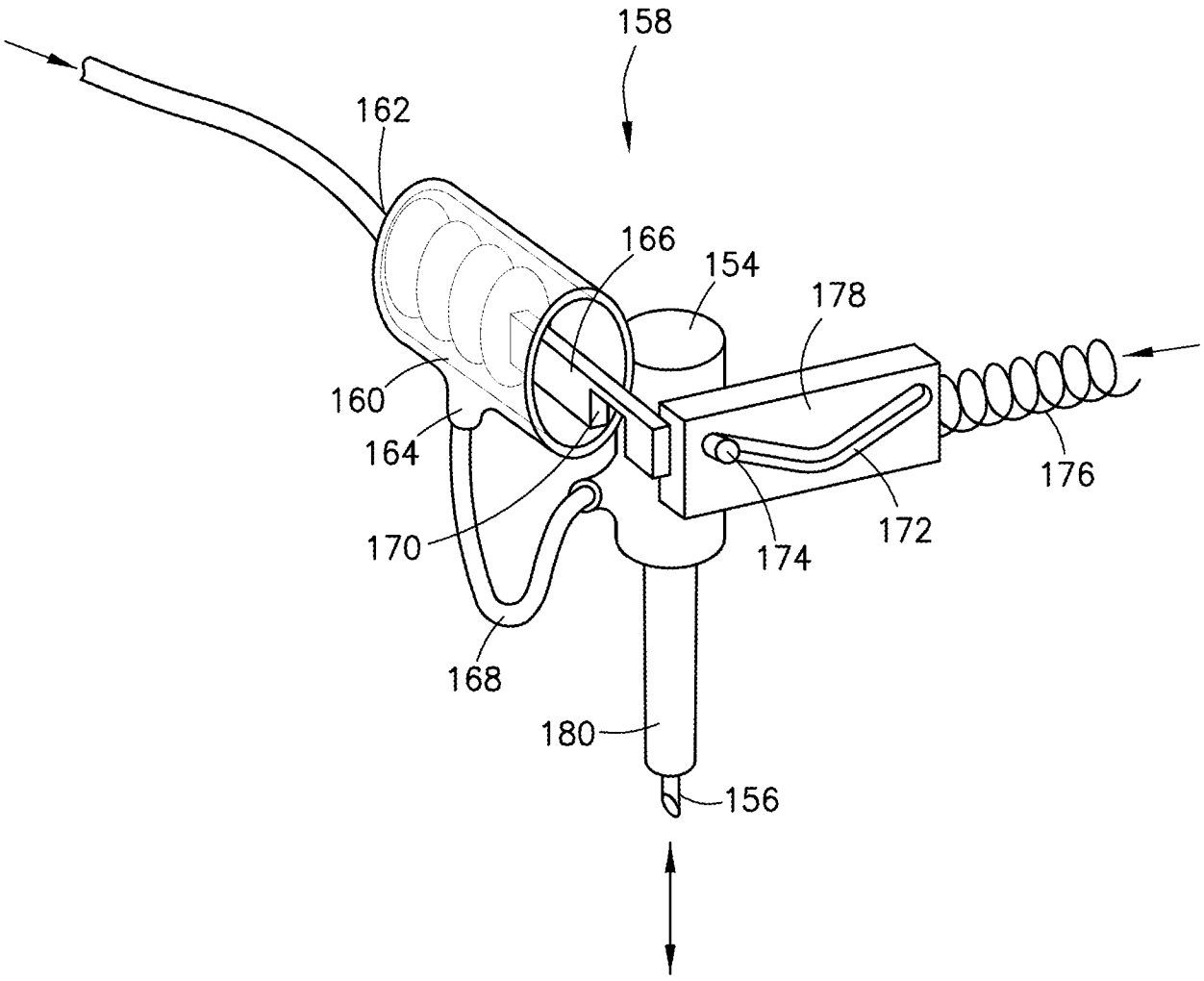

FIG.21

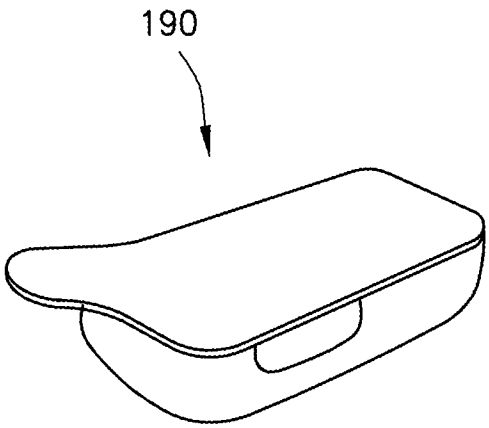

FIG.22

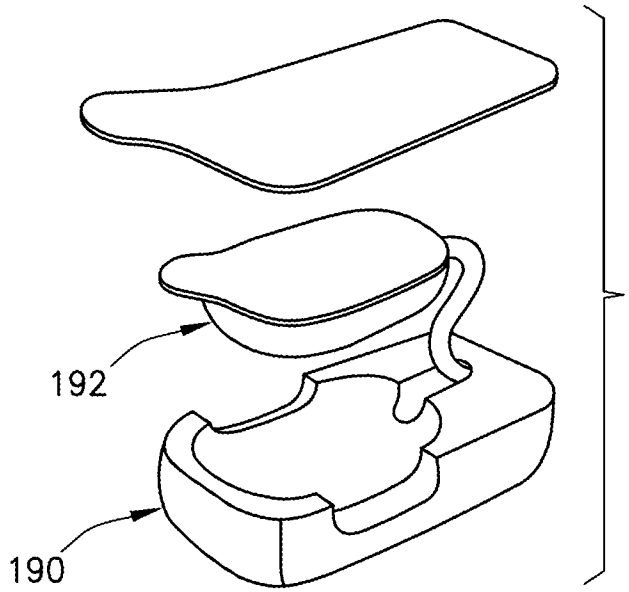

FIG.23

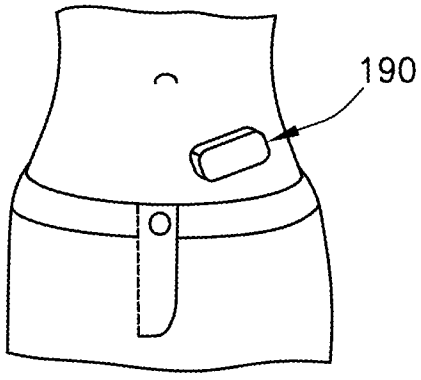

FIG.24

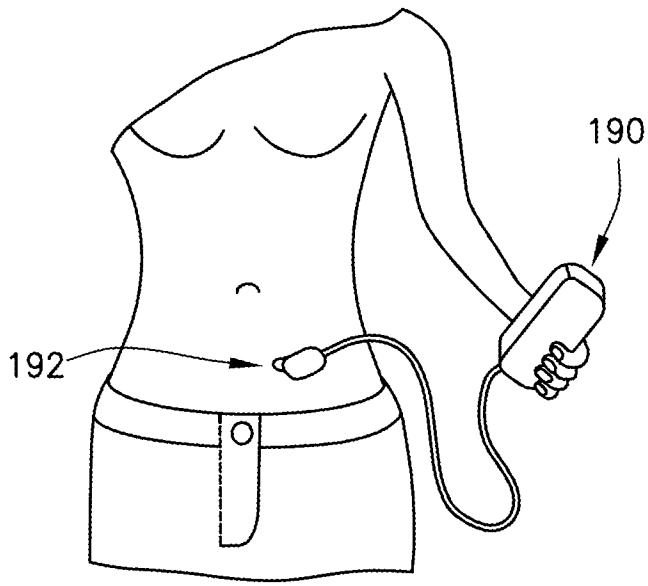

FIG.25

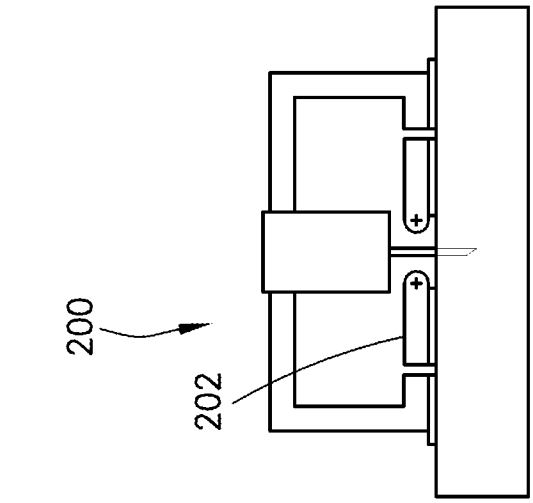

FIG.26C

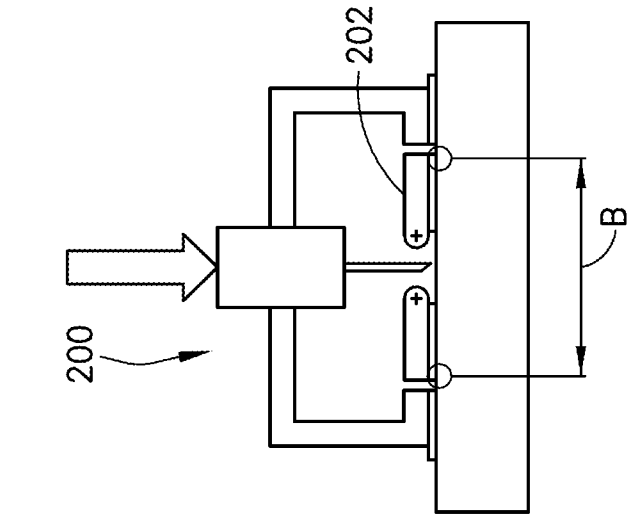

FIG.26B

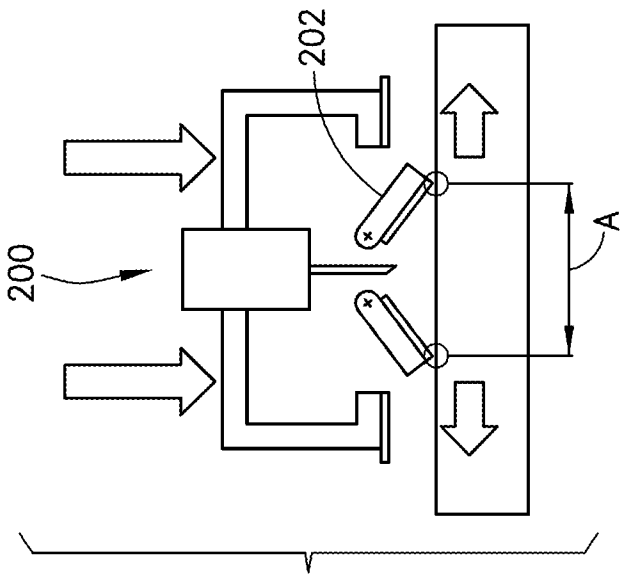

FIG.26A

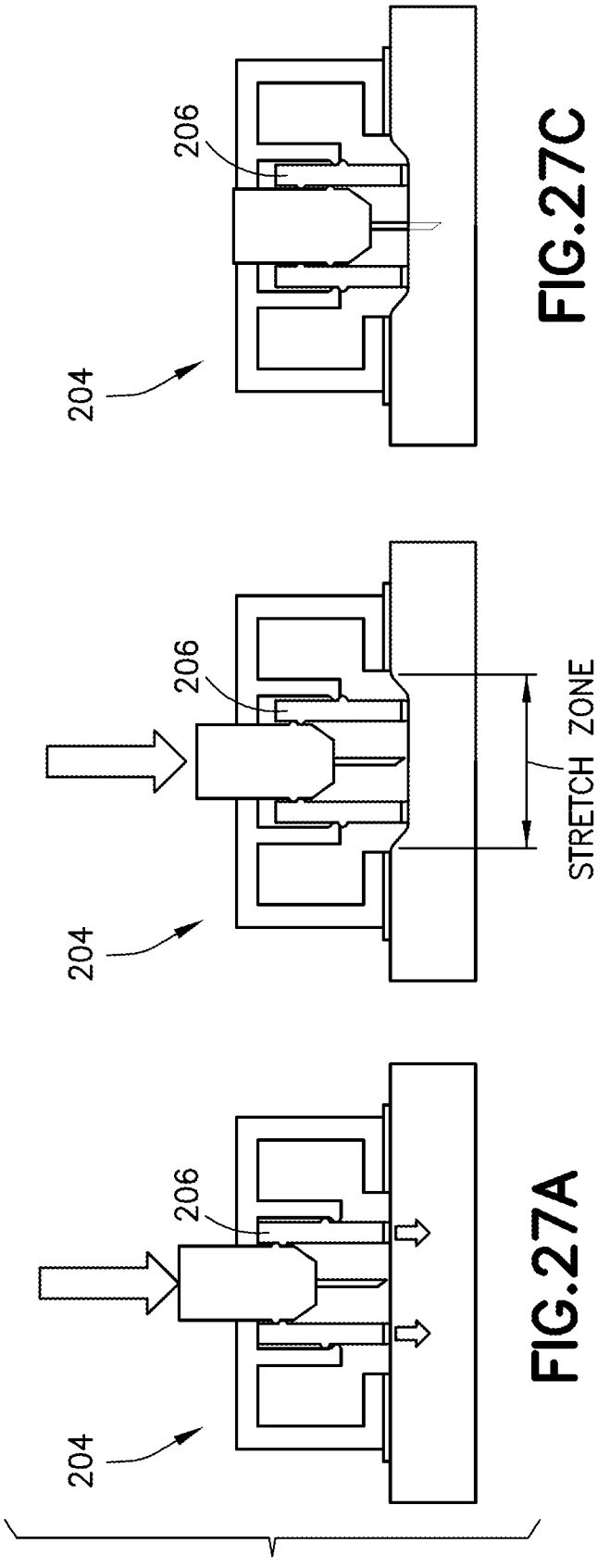

FIG.27C

FIG.27B

FIG.27A

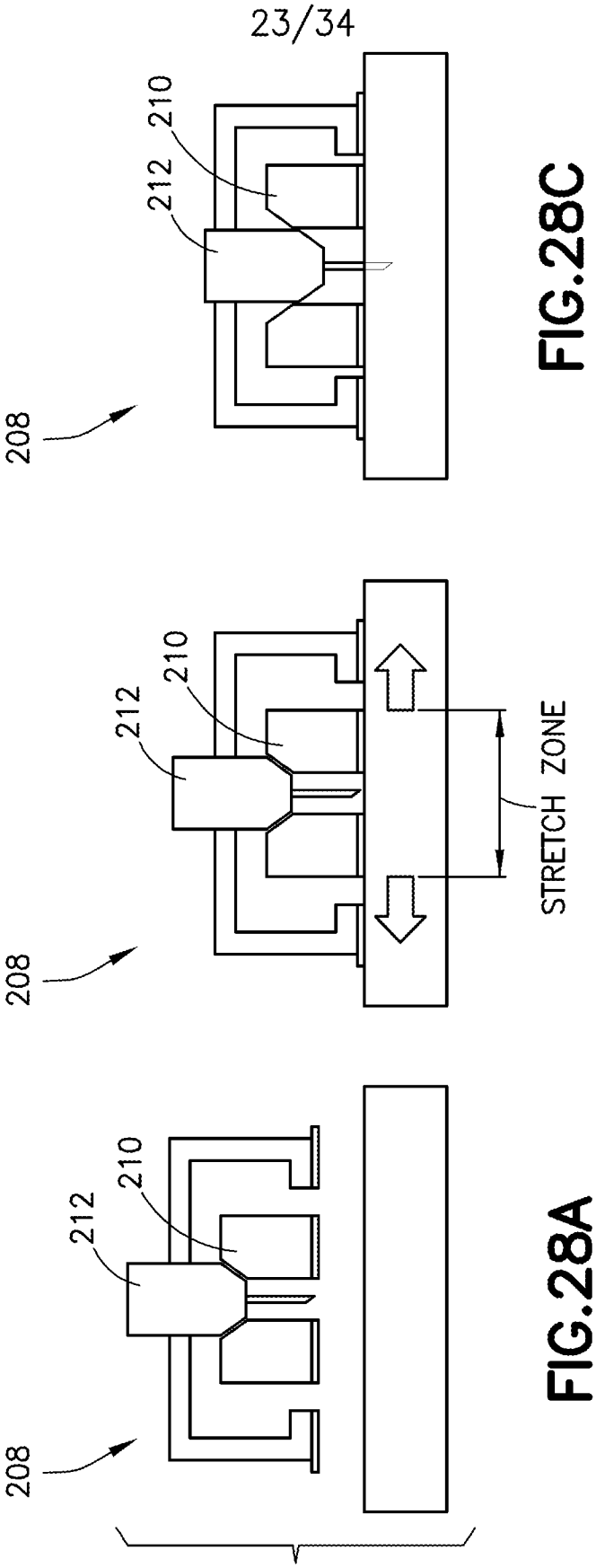

FIG.28C

FIG.28B

FIG.28A

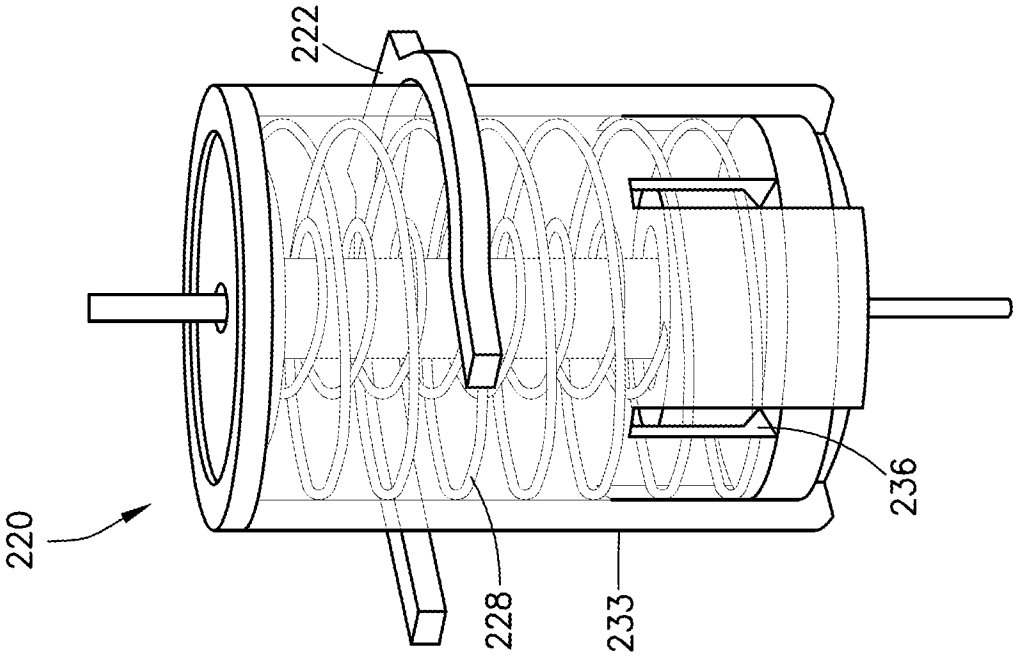

FIG.30

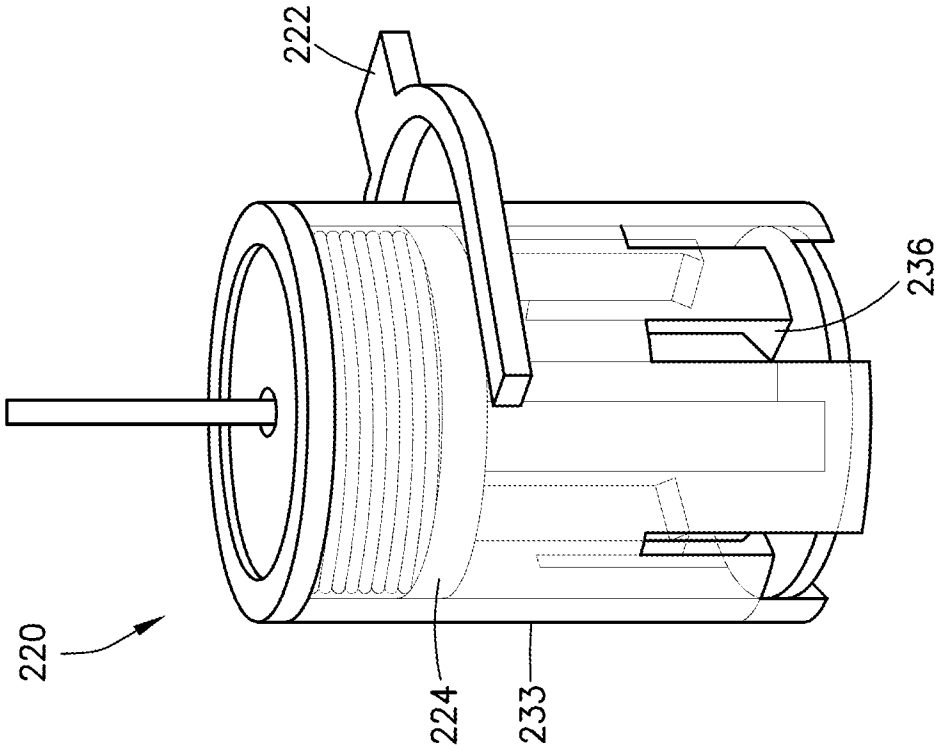

FIG.29

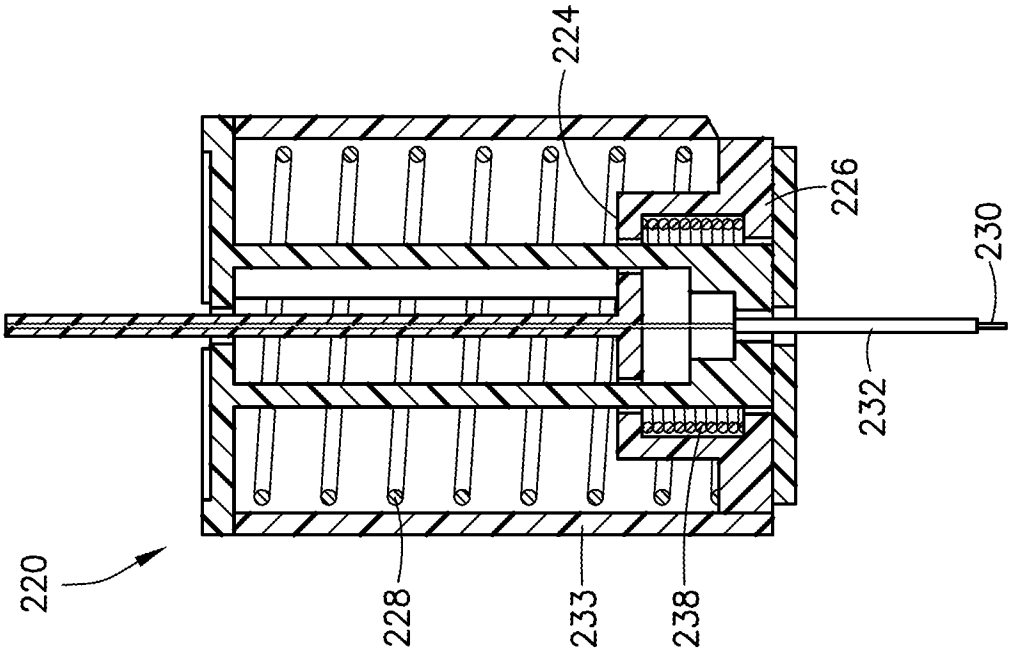
224
226
230
232
220
228
233
238

FIG.32

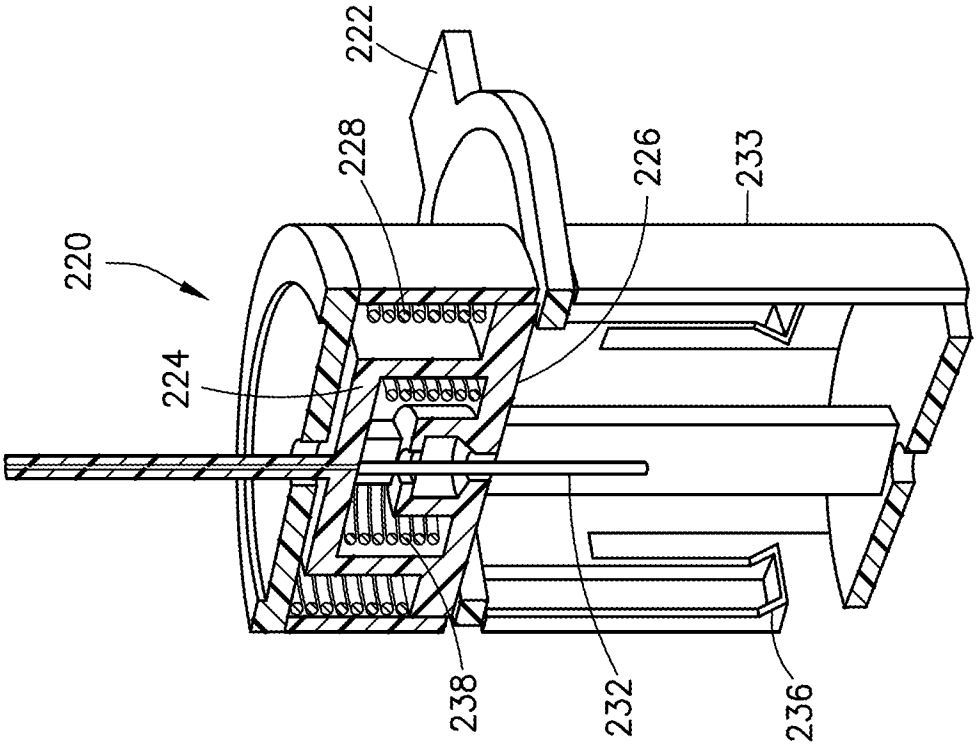
222
228
226
233
220
224
238
232
236

FIG.31

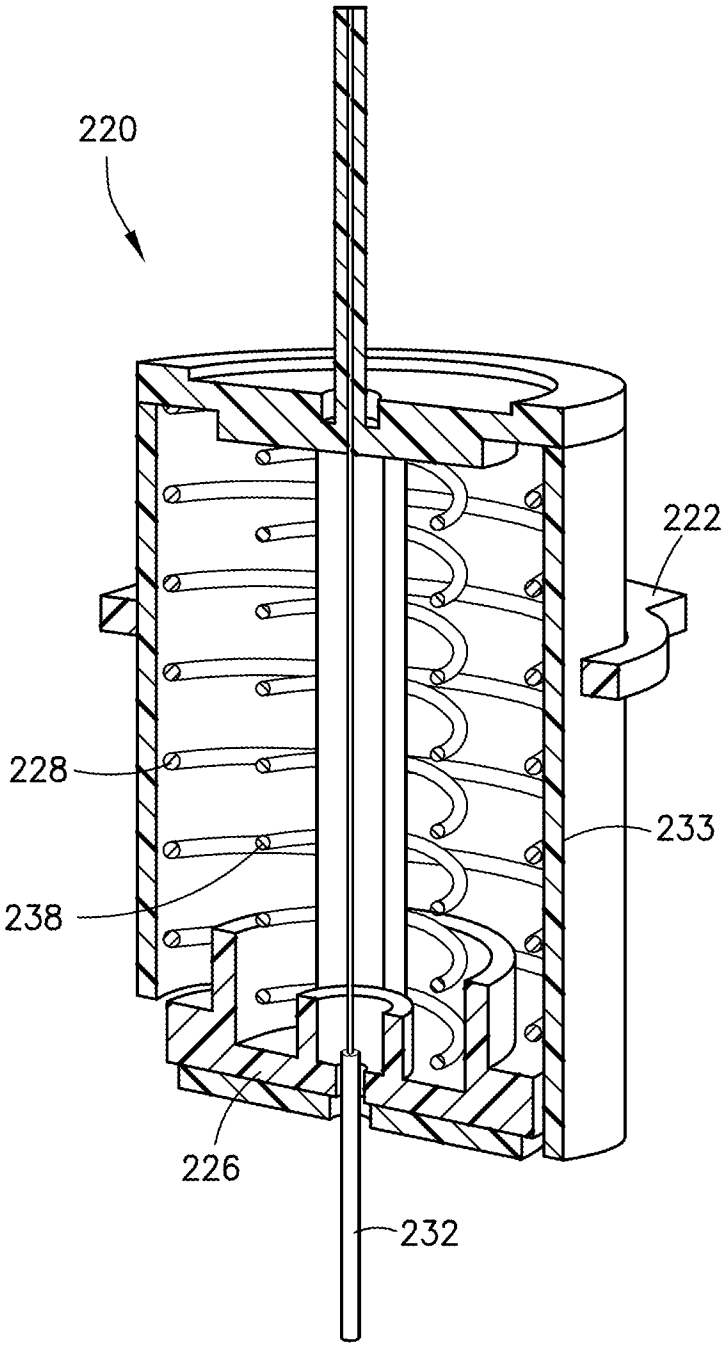

FIG.33

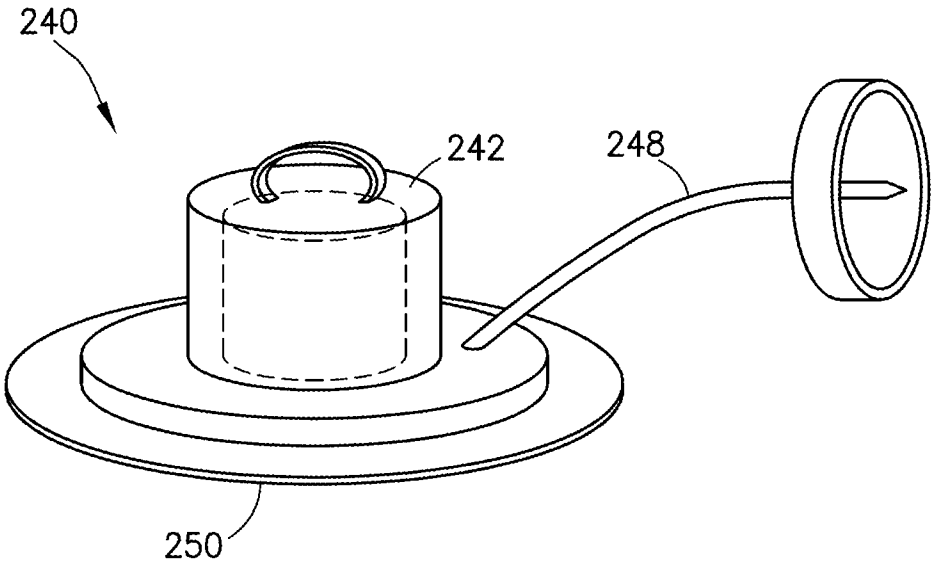

FIG.34

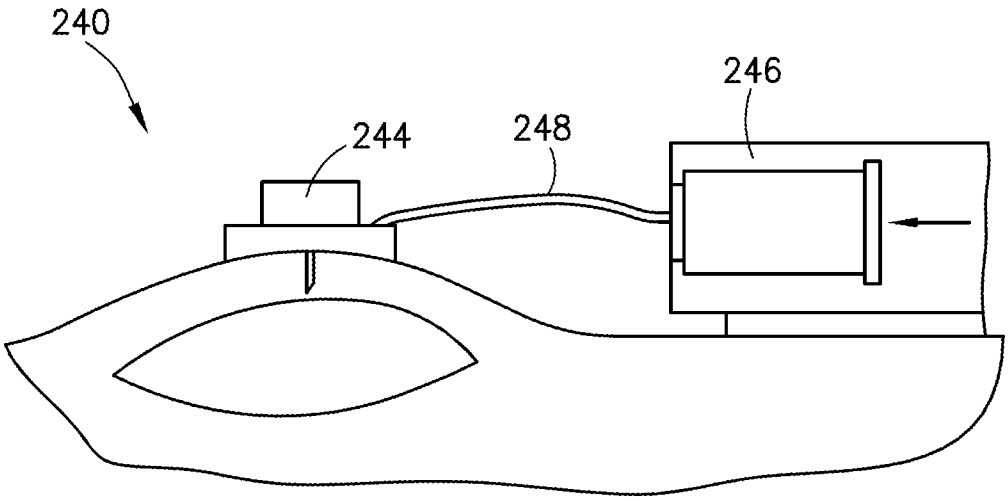

FIG.35

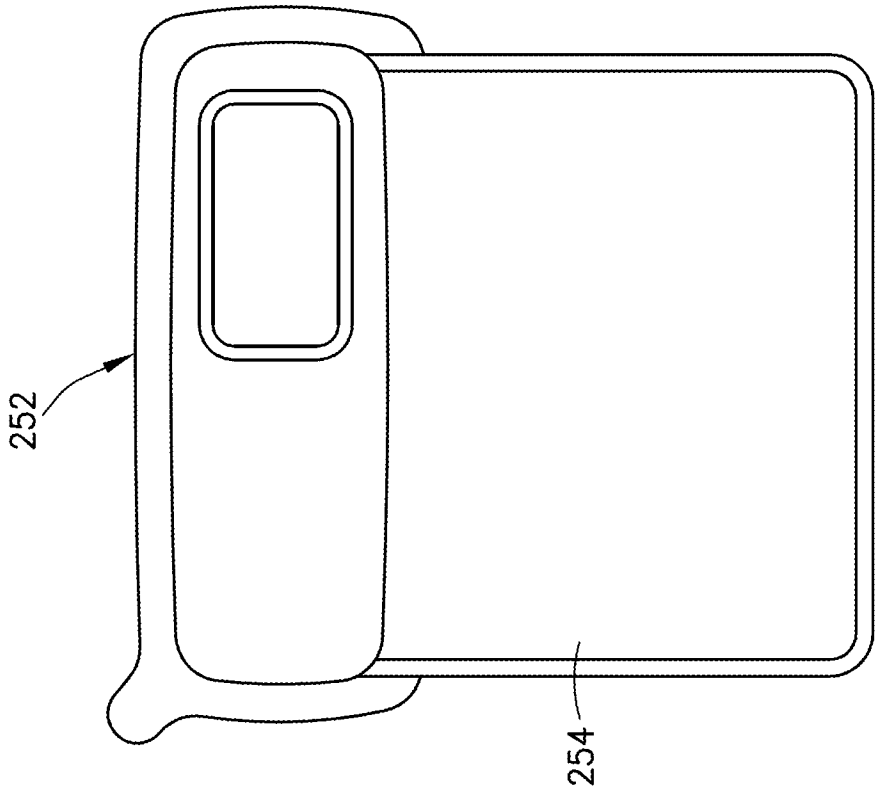

FIG.37

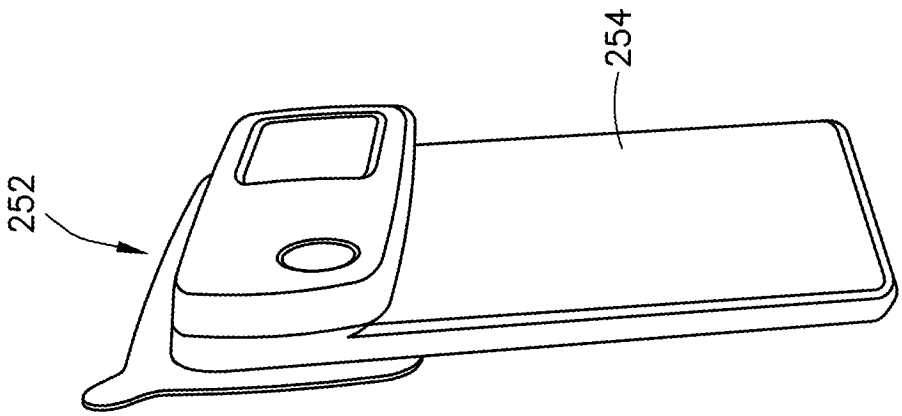

FIG.36

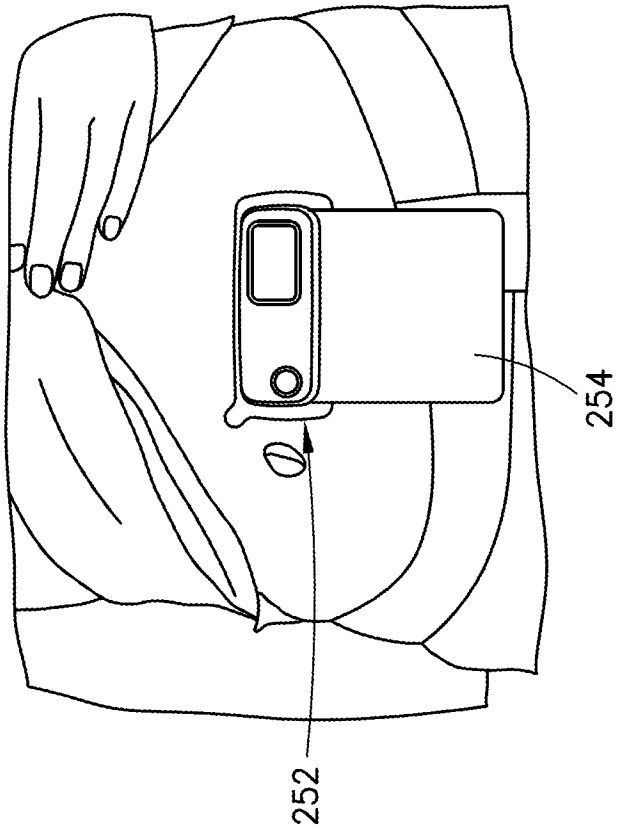

FIG.39

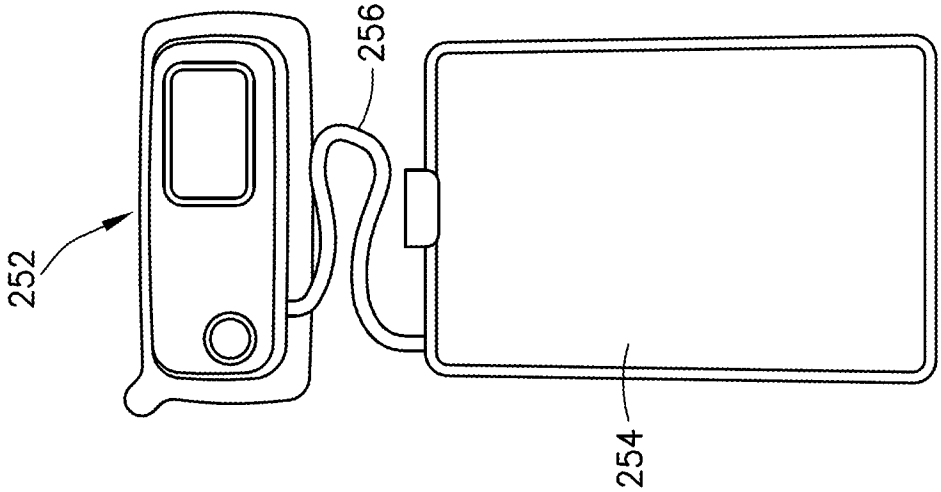

FIG.38

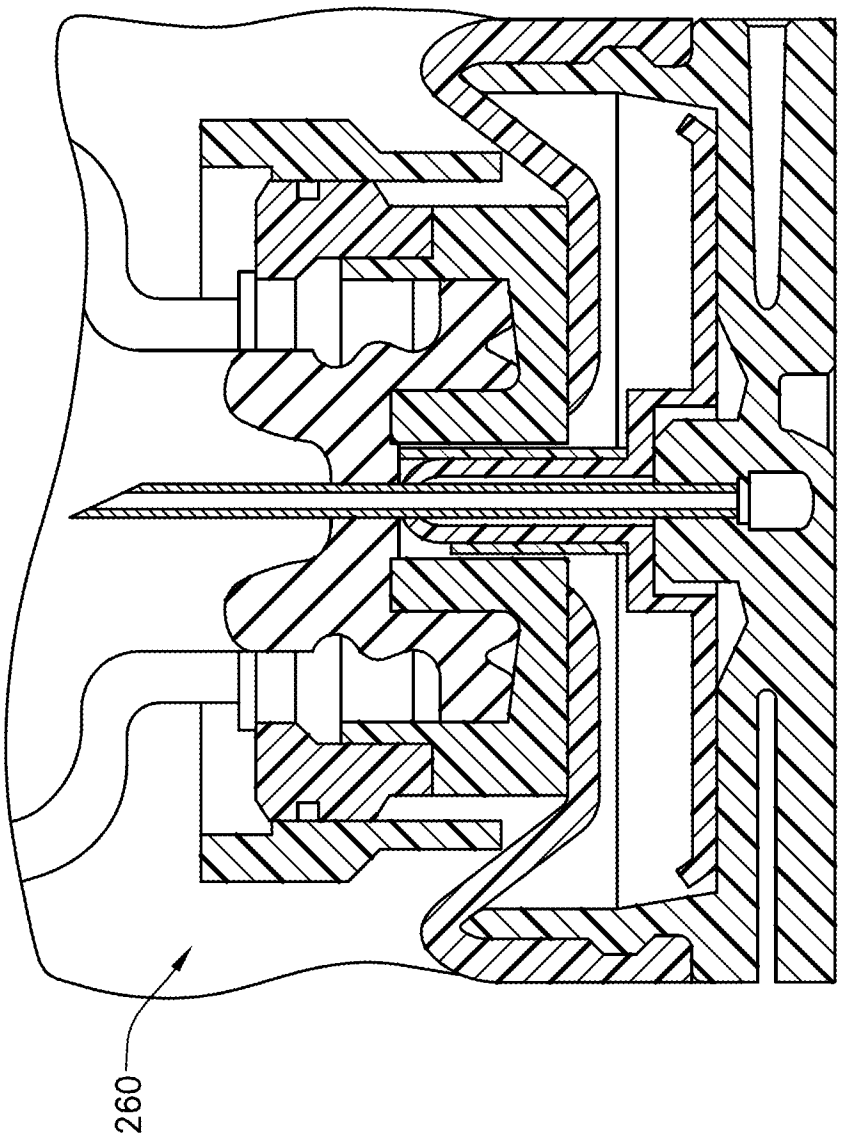

FIG.40

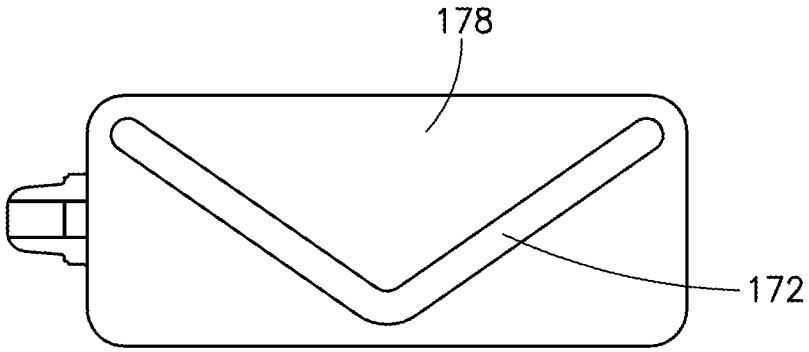

FIG.41

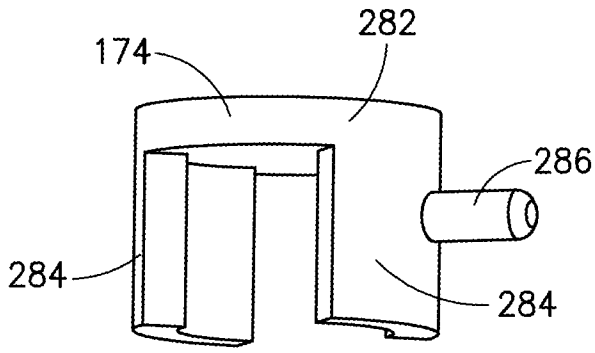

FIG.42

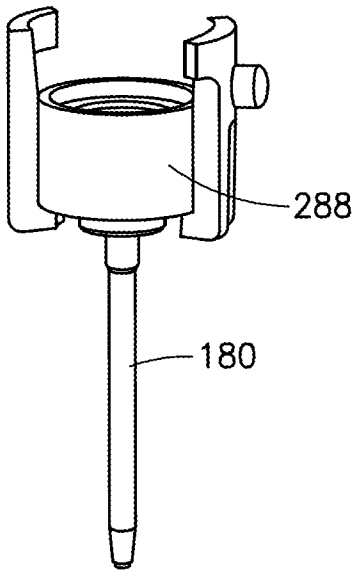

FIG.43

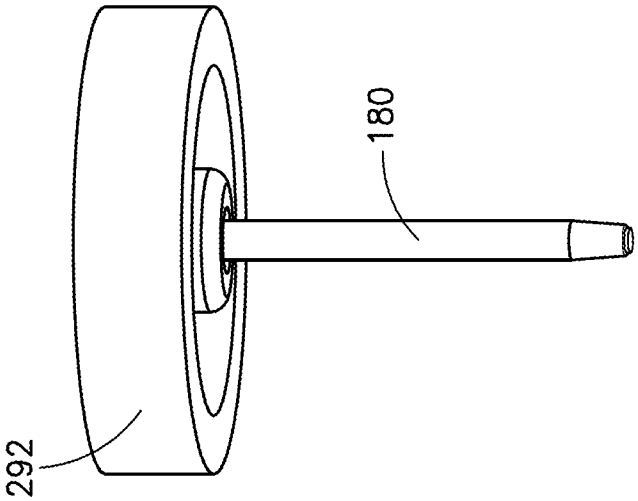

FIG.45

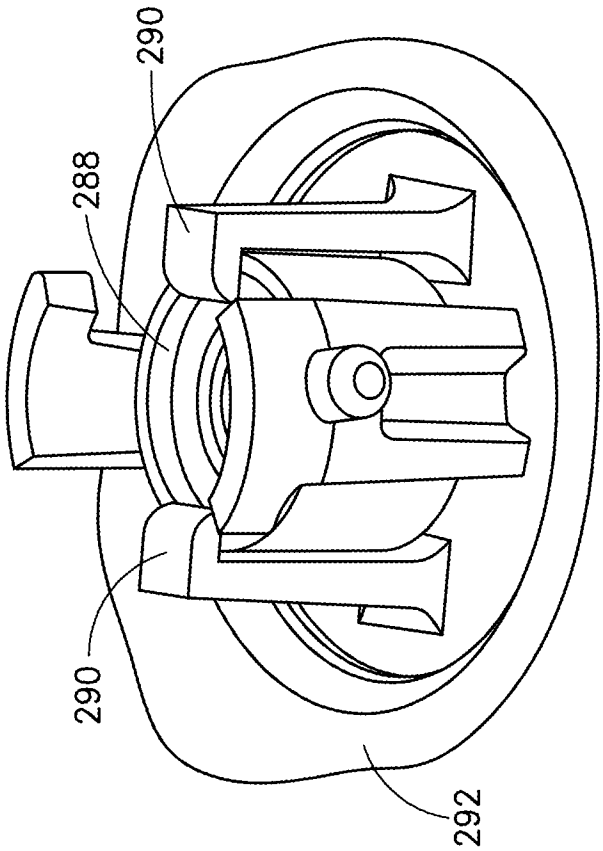

FIG.44

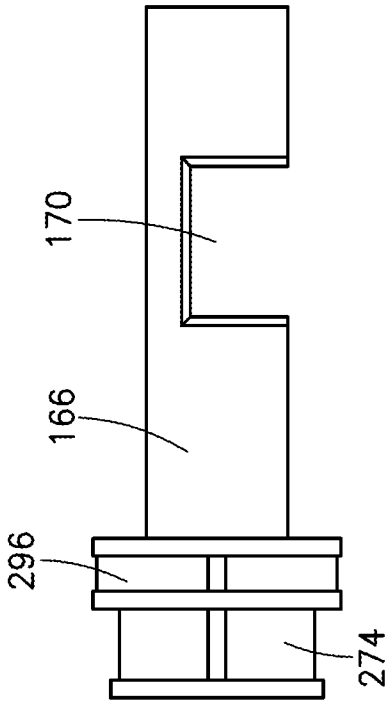

FIG.47

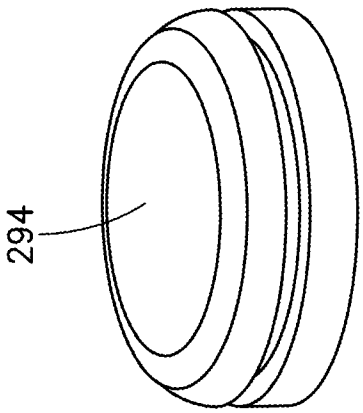

FIG.46

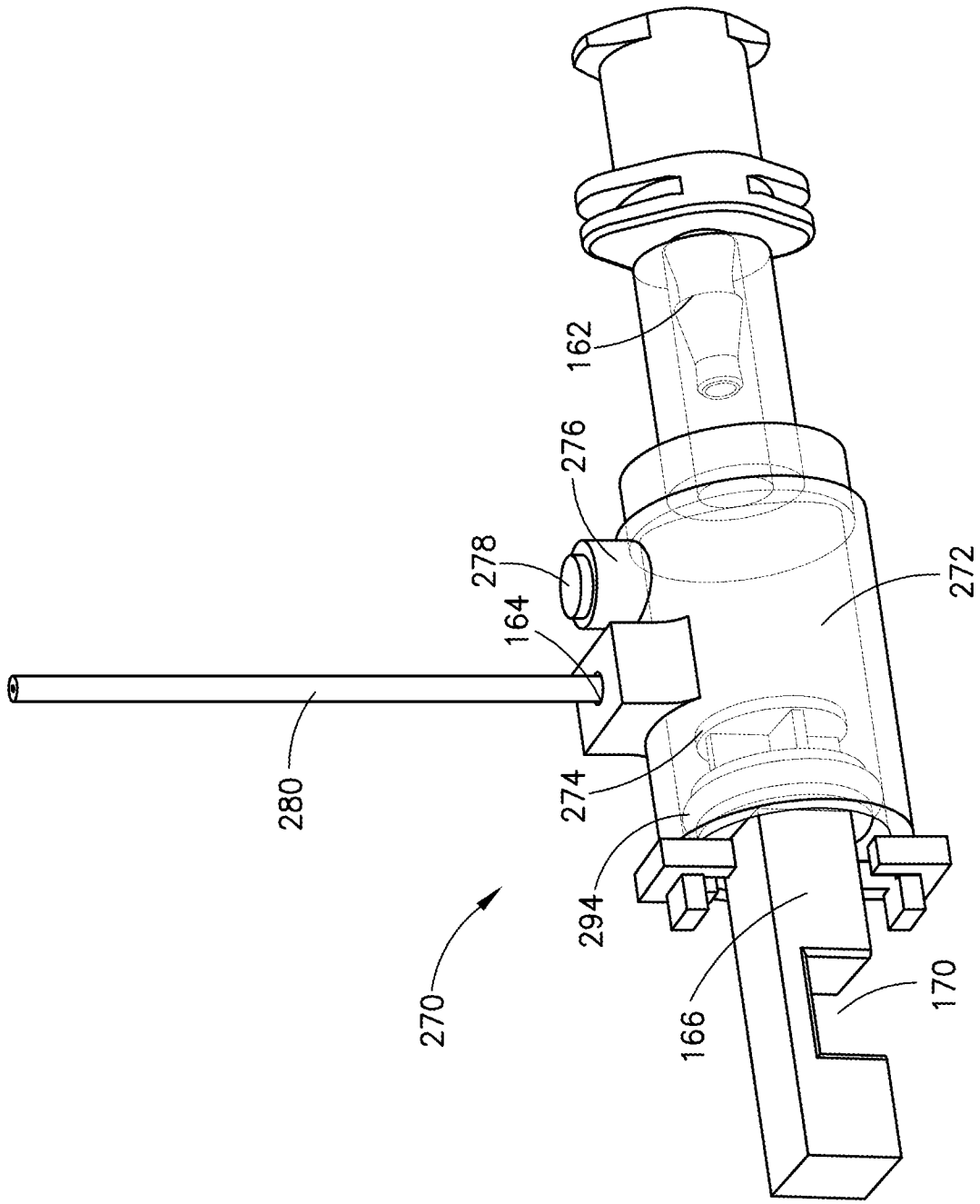

FIG.48

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2022/011209

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/15; A61B 5/154; A61M 5/32; A61M 5/34 (2022.01)
CPC - A61B 5/150519; A61B 5/1433; A61B 5/15; A61B 5/150007; A61B 5/150496; A61B 5/150732 (2022.02)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
see Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
see Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0058719 A1 (EDWARDS et al) 06 March 2008 (06.03.2008) entire document	1-4, 6, 7, 11
---		---
Y		5
Y	US 2005/0273019 A1 (CONWAY et al) 08 December 2005 (08.12.2005) entire document	5
A	US 2011/0270220 A1 (GENOSAR) 03 November 2011 (03.11.2011) entire document	1-11
A	US 4,284,077 A (WAGNER) 18 August 1981 (18.08.1981) entire document	1-11

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 March 2022	MAR 24 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Harry Kim Telephone No. PCT Helpdesk: 571-272-4300