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# DESCRIPTION

## FIELD

**[0001]** THIS INVENTION relates to drug delivery pumps. More particularly, this invention relates to drive mechanisms with integrated status indication and drug delivery pumps with status integrated drive mechanisms. Methods of operating such devices, and the methods of assembling such devices are also described.

## BACKGROUND

**[0002]** 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.

**[0003]** 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.

**[0004]** 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.

**[0005]** 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.

**[0006]** For example, in WO 2011/046950 there is described a fluid delivery device comprising a housing having a fluid reservoir. A needle is in fluid communication with the fluid reservoir in an engaged position and out of fluid communication with the fluid reservoir in armed and storage positions. A proximal end of a biasing member is coupled to the housing and a distal end of the biasing member is configured to deliver a force to the fluid reservoir. A piston member extends through the biasing member and is coupled to the distal end of the biasing member. The piston member is fixed with respect to the housing in a locked position such that the biasing member does not deliver the force to the fluid reservoir and moveable with respect to the housing in a released position such that the biasing member delivers the force to the fluid reservoir. Transitioning the needle from the storage position to the armed position transitions the piston from the locked position to the released position.

**[0007]** In WO 2010/112377 there is described a medicament delivery device comprising a housing for holding a medicament cartridge, a drive and a drive control means. The medicament cartridge has a medicament outlet and a bung able to be driven via a piston rod driven by the drive force of the drive and controlled by the drive control means. Additionally, the medicament delivery device comprises a restraining means for applying a restraining force to the piston rod, in a direction opposite to the drive force. By varying the restraining force by the drive control means the movement of the bung along the medicament cartridge can be controlled.

**[0008]** In WO 2013/033467, which comprises part of the state of the art by virtue of A.54(3) EPC, there is described a drive mechanism having integrated status indication. The drive mechanism includes a drive housing, a status switch interconnect, a drive biasing member, a piston, and a drug container having a cap, a pierceable seal, a barrel, and a plunger seal, wherein the drive biasing member is configured to bear upon an interface surface of the piston. The drive mechanism may include an incremental status stem having a stem interconnect, wherein the stem resides within the drive housing and the piston, and wherein the stem has an interconnect which engages one or more contacts on the piston to provide incremental feedback. A drug delivery pump with integrated status indication is also disclosed and includes a housing and an assembly platform, upon which an activation mechanism, an insertion mechanism, a fluid pathway connection, a power and control system, and the drive mechanism

having a drug container may be mounted.

**[0009]** 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.

**SUMMARY**

**[0010]** The present invention provides drive mechanisms with integrated status indication and drug delivery pumps which incorporate such drive mechanisms. Methods of operating such devices, and methods of assembling such devices are also described. The drive mechanisms of the present invention provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided with 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 pump 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 pump provide a true end-of-dose indication to the user. Additionally, embodiments of the present invention provide end-of-dose compliance to ensure that substantially the entire drug dose has been delivered to the user and that the status indication features have been properly contacted to provide accurate feedback 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 invention alleviate one or more of the problems associated with prior art devices, such as those referred to above.

**[0011]** According to the present invention there is provided a drug pump drive mechanism having the features of claim 1.

**[0012]** In a first embodiment, the present invention provides a drive mechanism having integrated status indication which includes: a drive housing, a status switch interconnect, a drive biasing member, a piston, and a drug container having a cap, a pierceable seal, a barrel, and a plunger seal. The drive biasing member may be configured to bear upon an interface surface of the piston. The drug container may preferably contain a drug fluid for delivery to the user. The drive mechanism may further include a connection mount attached to the pierceable seal. A cover sleeve may be utilized between the drive biasing member and the interface surface of the piston to, for example, provide more even distribution of force from the biasing member to the piston. A contact sleeve may be slidably mounted to the drive housing through

an axial aperture of the drive housing, such that sleeve hooks at a distal end of the contact sleeve are caused to contact the piston between the interface surface and a contact protrusion near
the proximal end of the piston. The piston may also include a locking groove, between the contact protrusion and the proximal end of the piston. The contact sleeve may have a radially extending ring at its proximal end, upon which reside one or more flex prongs.

**[0013]** The drive mechanism may further include one or more contact surfaces located on corresponding components. Such contact surfaces may be electrical contact surfaces, mechanical contact surfaces, or electro-mechanical contact surfaces. Such surfaces may initially be in contact and caused to disengage, or initially be disconnected and caused to engage, to permit a signal to be sent to and/or from the power control system. In at least one embodiment, the contact surfaces may be electrical contact surfaces which are initially disconnected and caused to come into engagement whereby, upon such engagement, the contact surfaces are capable of continuing an energy pathway or otherwise relaying a signal to the power and control system. In another embodiment of the present invention, the contact surfaces are mechanical contact surfaces which are initially in contact and caused to disengage whereby, upon such disengagement, such disengagement is communicated to the power and control system. Such signals may be transferred across one or more interconnects to the power and control system or by mechanical action to the power and control system. Such components may be utilized within the drive mechanism to measure and relay information related to the status of operation of the drive mechanism, which may be converted by the power and control system into tactile, auditory, and/or visual feedback to the user. Regardless of the electrical or mechanical nature of the contact surfaces, the motion of the components which permits transmission of a signal to the power control system is enabled by a biasing member axially translating a contact sleeve in the distal direction during operation of the device.

**[0014]** The drive mechanism may include a piston extension slidably mounted at a distal end and within an axial pass-through of piston; a piston extension biasing member, which is mounted within the axial pass-through of piston and initially compressed between the piston extension and piston; and, optionally, a piston biasing member support between the piston extension biasing member and piston extension. The piston extension is retained within the piston by interaction between one or more extension arms of the piston extension and one or more corresponding connection slots of the piston. The piston extension may be utilized to perform a compliance push of drug fluid from the drug container. Additionally or alternatively, the drive mechanism may utilize a
compressible plunger seal, wherein such compression capacity or distance permits a compliance push of drug fluid from the drug container. Other compliance features are described further herein.

**[0015]** In another embodiment of the present invention, a drive mechanism having integrated incremental status indication includes a drive housing, a drive biasing member, a piston, an incremental status stem having a stem interconnect mounted, affixed, printed, or otherwise

attached thereon, and a drug container having a cap, a pierceable seal, a barrel, and a plunger seal, wherein the incremental status stem resides within axial pass-throughs of the drive housing and the piston. The incremental status stem may have one or more interconnects which contact one or more contacts on the piston to provide incremental status feedback to the user. The incremental status embodiment may similarly utilize the electrical, mechanical, or electro-mechanical interconnects and contacts, and/or one or more of the compliance features, described above.

**[0016]** There is also described a drug delivery pump with integrated status indication. The drug pump includes a housing and an assembly platform, upon which an activation mechanism, an insertion mechanism, a fluid pathway connection, a power and control system, and a drive mechanism having a drug container may be mounted. The drive biasing member may be configured to bear upon an interface surface of the piston. The drug container may preferably contain a drug fluid for delivery to the user. The drive mechanism may further include a connection mount attached to the pierceable seal. A cover sleeve may be utilized between the drive biasing member and the interface surface of the piston to, for example, provide more even distribution of force from the biasing member to the piston. A contact sleeve may be slidably mounted to the drive housing through an axial aperture of the drive housing, such that sleeve hooks at a distal end of the contact sleeve are caused to contact the piston between interface surface and a contact protrusion near the proximal end of the piston. The piston may also include a locking groove, between contact protrusion and the proximal end of the piston. The contact sleeve may have a radially extending ring at its proximal end, upon which reside one or more flex prongs. The drive mechanism may further include one or more contact surfaces located on corresponding components. Such contact surfaces may be electrical contact surfaces, mechanical contact surfaces, or electro-mechanical contact surfaces. Such surfaces may initially be in contact and caused to disengage, or initially be disconnected and caused to engage, to permit a signal to be sent to and/or from the power control system. In one example the contact surfaces may be electrical contact surfaces which are initially disconnected and caused to come into engagement whereby, upon such engagement, the contact surfaces are capable of continuing an energy pathway or otherwise relaying a signal to the power and control system. In another example, the contact surfaces are mechanical contact surfaces which are initially in contact and caused to disengage whereby, upon such disengagement, such disengagement is communicated to the power and control system. Regardless of the electrical or mechanical nature of the contact surfaces, the motion of the components which permits transmission of a signal to the power control system is enabled by a biasing member axially translating a contact sleeve in the distal direction during operation of the device.

**[0017]** In another drug delivery pump with incremental status indication, the drug pump includes a housing and an assembly platform, upon which an activation mechanism, an insertion mechanism, a fluid pathway connection, a power and control system, and a drive mechanism having a drug container may be mounted. The drug pump further includes an incremental status stem having a stem interconnect mounted, affixed, printed, or otherwise attached thereon, wherein the incremental status stem resides within axial pass-throughs of

the drive housing and the piston, and wherein the incremental status stem has one or more interconnects which contact one or more contacts on the piston to complete a transmission to the power and control system to provide incremental feedback to the user. The drug delivery pump with incremental status indication may similarly utilize the electrical, mechanical, or electro-mechanical interconnects and contacts, and/or one or more of the compliance features, described above.

**[0018]** There is also described a method of assembly. The drug container may first be assembled and filled with a drug fluid. The drug container includes a cap, a pierceable seal, a barrel, and a plunger seal. The pierceable seal may be fixedly engaged between the cap and the barrel, at a distal end of the barrel. The barrel may be filled with a drug fluid through the open proximal end prior to insertion of the plunger seal from the proximal end of the barrel 58. An optional connection mount may be mounted to a distal end of the pierceable seal. The connection mount serves to guide the insertion of the piercing member of the fluid pathway connection into the barrel of the drug container. The drug container may then be mounted to a distal end of drive housing.

**[0019]** Prior to mounting the drug container to the housing, a switch status interconnect may be mounted to a proximal end of drive housing. A contact sleeve, having one or more sleeve hooks at a distal end and a ring at a proximal end having an electrical contact thereon, may be mounted to the drive housing through an axial pass-through from the proximal end of the drive housing. A drive biasing member may be inserted into a distal end of the drive housing. Optionally, a cover sleeve may be inserted into a distal end of the drive housing to substantially cover the biasing member. A piston may be inserted into the distal end of the drive housing and through an axial pass-through of the contact sleeve, such that a contact protrusion of the piston is proximal to the sleeve hooks of the contact sleeve. The piston and drive biasing member, and optional cover sleeve, may be compressed into the drive housing. Such assembly positions the drive biasing member in an initial compressed, energized state and preferably places a piston interface surface in contact with the proximal surface of the plunger seal within the proximal end of barrel. When a piston extension is employed, the piston extension and piston extension biasing member, and optional piston biasing member support, may be compressed into an axial pass-through of the piston prior to compression of the components. Prior to, or after, installing these components into the drive mechanism housing, the primary container may be attached.

**[0020]** When one or more interconnects or contacts are utilized for status indication, such components may be mounted, connected, printed, or otherwise attached to their corresponding components prior to assembly of such components into the drive mechanism. When a separate incremental status stem and a corresponding stem interconnect are utilized for such incremental status indication, the stem interconnect may be mounted, affixed, printed, or otherwise attached to the incremental status stem prior to assembly of the incremental status stem to the proximal end of the contact sleeve and/or the proximal end of the drive housing in a manner such that the incremental status stem resides within an axial pass-through of the contact sleeve and drive housing. The incremental status stem is further

mounted to reside within an axial pass-through of the piston.

**[0021]** The disclosure describes, in one aspect, a drug pump drive mechanism for use in cooperation with a drug container including a plunger seal. The drive mechanism has an axis and includes a drive housing, a piston adapted to impart movement to the plunger seal within the drug container, a plurality of biasing members disposed in parallel, and a retainer. The piston is disposed for movement from a retracted first position along the axis to an extended second position. The biasing members are adapted to move from an energized first position to a deenergized second position as a result of the release of energy. The biasing members are disposed to cause movement of the piston from the retracted first position to the extended second position as the biasing members move from the energized first position to the deenergized second position. The retainer is disposed to maintain the biasing members in the energized first position when the retainer is in a retaining first position, and to release the biasing members from the first energized position when the retainer moves to a releasing second position.

**[0022]** In at least one embodiment, the plurality of biasing members includes at least one of a tension spring or a compression spring. In at least one embodiment, the plurality of biasing members includes a pair of springs, in at least one embodiment of which the springs are compression springs. In at least one further embodiment, the compression springs are concentrically disposed, and disposed about at least a portion of the piston. In at least one embodiment, the retainer engages at least a portion of the piston to retain the piston in its retracted position when the retainer is in its retaining first position. At least one embodiment further includes a sleeve assembly disposed about at least one of the plurality of biasing members. In at least one embodiment, the sleeve assembly includes a plurality of telescoping sleeves, and the sleeve assembly is disposed to move to axially with the piston. At least one embodiment further includes at least one window and at least a portion of the sleeve assembly is visible through the window with at least a portion of the sleeve assembly being visible through said window until the piston is in the extended second position. At least one embodiment further includes an end-of-dose indicator disposed substantially adjacent the window, the end-of-dose indicator being adapted to identify at least one of when the sleeve assembly is disposed subjacent the window and when the sleeve assembly is not disposed subjacent the window, the relative motion of the sleeve assembly with reference to the window or another reference component, the stoppage of such motion, and the rate or change of rate of motion. In at least one embodiment, the end-of-dose indicator includes a sensor
disposed to sense at least one of when the sleeve assembly is disposed subjacent the window and when the sleeve assembly is not disposed subjacent the window. In at least one embodiment, the sensor is a mechanical sensor, an electrical sensor, an ultrasonic sensor, a capacitive sensor, a magnetic sensor, or an optical sensor. In at least one embodiment, the sensor is a mechanical sensor disposed to bear against the sleeve assembly when the sleeve assembly is disposed subjacent the window.

**[0023]** At least some embodiments of the present invention provide the necessary drive force to push a plunger seal and a drug fluid within a drug container, while reducing or minimizing

the drive mechanism and overall device footprint. Accordingly, the present invention may provide a drive mechanism which may be utilized within a more compact drug delivery pump device. Some embodiments of the present invention may similarly be utilized to provide additional force, as may be needed for highly viscous drug fluids or for larger volume drug containers.

**[0024]** The novel embodiments of the present invention provide drive mechanisms with integrated status indication, which are capable of providing incremental status of the drug delivery before, during, and after operation of the device, and provide means for ensuring drug dose compliance, i.e., ensuring substantially the entire drug dose has been delivered to the user. 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 invention may include one or more additional components which may be considered standard components in the industry of medical devices. The components, and the embodiments containing such components, are within the contemplation of the present invention and are to be understood as falling within the breadth and scope of the present invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0025]** The following non-limiting embodiments of the invention are described herein with reference to the following drawings, wherein:

FIG. 1A shows an isometric view of a drug delivery pump having safety integrated insertion mechanisms;

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

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

FIG. 2 shows an isometric view of a drive mechanism;

FIG. 3 shows an exploded view, along an axis "A," of the drive mechanism shown in FIG. 2,

FIG. 4A shows a cross-sectional view of the drive mechanism shown in FIG. 2 in an initial inactive state;

FIG. 4B shows a cross-sectional view of the drive mechanism shown in FIG. 2 in an actuated state;

FIG. 4C shows a cross-sectional view of the drive mechanism shown in FIG. 2 in a further actuated state as drug delivery from the mechanism continues;

FIG. 4D shows a cross-sectional view of the drive mechanism shown in FIG. 2 as the mechanism nears completion of drug delivery;

FIG. 4E shows a cross-sectional view of the drive mechanism shown in FIG. 2 as the mechanism performs a compliance push to ensure completion of drug delivery;

FIG. 5 shows an isometric view of a drive mechanism, according to a second arrangement;

FIG. 6 shows an exploded view, along an axis "A," of the drive mechanism shown in FIG. 5;

FIG. 7 shows a cross-sectional view of the drive mechanism shown in FIG. 5 in an actuated state;

FIG. 8 shows an isometric view of a drive mechanism according to a further arrangement;

FIG. 9A shows a cross-sectional view of the drive mechanism shown in FIG. 8 in an initial inactive state;

FIG. 9B shows a cross-sectional view of the drive mechanism shown in FIG. 8 in an actuated state and as the mechanism nears completion of drug delivery;

FIG. 9C shows a cross-sectional view of the drive mechanism shown in FIG. 8 as the mechanism completes drug delivery and triggers an end-of-dose signal.

FIG. 10A is an isometric view of another drug delivery pump having safety integrated insertion mechanisms;

FIG. 10B is an isometric view of the interior components of the drug delivery pump shown in FIG. 10A;

FIG. 10C is an isometric view of the bottom of the drug delivery pump shown in FIG. 10A;

FIG. 11 is an isometric view of a drive mechanism, according to an embodiment of the present invention;

FIG. 12 is an exploded view, along an axis "A," of the drive mechanism shown in FIG. 11,

FIG. 13A is a cross-sectional view of the drive mechanism shown in FIG. 11 in an initial inactive state;

FIG. 13B is a cross-sectional view of the drive mechanism shown in FIG. 11 in an actuated state;

FIG. 13C is a cross-sectional view of the drive mechanism shown in FIG. 11 at the completion of drug delivery;

FIG. 14A is a cross-sectional view of the drive mechanism taken along line 14-14 in FIG. 11; and

FIG. 14B is a cross-sectional view of the drive mechanism similar to FIG. 14A, but after the

activation of the sensor.

## DETAILED DESCRIPTION

**[0026]** As used herein to describe the drive mechanisms, drug delivery pumps, or any of the relative positions of the components of the present invention, 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 resoftened 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 syringes. 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 invention, the biasing member is a spring, preferably a compression spring.

**[0027]** The novel devices of the present invention 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 invention provide these desirable features without any of the problems associated with known prior art devices. Certain non-limiting examples of the drug delivery pumps, drive mechanisms, and their respective components are described further herein with reference to the accompanying figures.

**[0028]** As used herein, the term "pump" is 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, for example, injection systems, infusion pumps, bolus injectors, and the like. FIGS. 1A-1C show an exemplary drug delivery device. The drug delivery device may be utilized to administer delivery of a drug treatment into a body of a user. As shown in FIGS. 1A-1C, the drug pump 10 includes a pump housing 12. Pump housing 12 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 pump 10 includes a pump housing 12 which includes an upper housing 12A and a lower housing 12B. The drug pump 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 pump may be viewed. As shown in FIG. 1B, the drug pump further includes assembly platform 20, sterile fluid conduit 30, drive mechanism 100 having drug container 50, insertion mechanism 200, fluid pathway connection 300, and power and control system 400. One or more of the components of such drug pumps 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 pump 10 during manufacturing.

**[0029]** The pump housing 12 contains all of the device components and provides a means of removably attaching the device 10 to the skin of the user. The pump housing 12 also provides protection to the interior components of the device 10 against environmental influences. The pump housing 12 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 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 user.

**[0030]** The drug pump 10 provides an activation mechanism 14 that is displaced by the user to trigger the start command to the power and control system 400. In a preferred example, the activation mechanism is a start button 14 that is located through the pump housing 12, such as through an aperture between upper housing 12A and lower housing 12B, and which contacts a control arm 40 of the power and control system 400. In at least one arrangement, the start button 14 may be a push button, and in other arrangements, may be an on/off switch, a toggle, or any similar activation feature known in the art. The pump housing 12 also provides a status indicator 16 and a window 18. In other arrangements, 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 user when the drug pump 10 is placed on the body of the user. Housing 12 is described in further detail hereinafter with reference to other components.

**[0031]** The drug pump is configured such that, upon activation by a user by depression of the activation mechanism, the drug pump 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 pump. For example, an optional on-body sensor 24 (shown in FIG. 1C) may be provided as a safety feature to ensure that the power and control system 400, or the activation mechanism, cannot be engaged unless the drug pump 10 is in contact with the body of the user. In one such arrangement, the on-body sensor 24 is located on the bottom of lower housing 12B where it may come in contact with the user's body. Upon displacement of the on-body sensor 24, depression of the activation mechanism is permitted. Accordingly, in one example the on-body sensor 24 is a mechanical safety mechanism, such as for example a mechanical lock out, that prevents triggering of the drug pump 10 by the activation mechanism 14. In another example, 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 examples, 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 400. These concepts are not mutually exclusive and one or more combinations may be utilized to prevent, for example, premature activation of the drug pump. In a preferred arrangement, the drug pump 10 utilizes one or more mechanical on-body sensors. Additional integrated safety mechanisms are described herein with reference to other components of the drug pumps.

**Power and Control System:**

**[0032]** The power and control system 400 includes a power source, which provides the energy for various electrical components within the drug pump, 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 user and interfaces with the drive mechanism 100. In one arrangement, the power and control system 400 interfaces with the control arm 40 to identify when the on-body sensor 24 and/or the activation mechanism 14 have been activated. The power and control system 400 may also interface with the status indicator 16 of the pump housing 12, which may be a

transmissive or translucent material which permits light transfer, to provide visual feedback to the user. 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 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 arrangement, the control interfaces between the power and control system and the other components of the drug pump are not engaged or connected until activation by the user. This is a desirable safety feature that prevents accidental operation of the drug pump and may additionally maintain the energy contained in the power source during storage, transportation, and the like.

**[0033]** The power and control system 400 may be configured to provide a number of different status indicators to the user. 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 arrangement 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 400 will power the drive mechanism 100 to begin delivery of the drug treatment through the fluid pathway connection 300 and sterile fluid conduit 30. In a preferred arrangement, the insertion mechanism 200 and the fluid pathway connection 300 may be caused to activate directly by user 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 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 400 may provide an okay-to-remove status signal via the status indicator 16. This may be independently verified by the user by viewing the drive mechanism and drug dose delivery through the window 18 of the pump 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.

**[0034]** Other power and control system configurations may be utilized with the drug pumps. 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 14 of the drug pump 10 prior to drug pump 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 pump. 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 pumps. An additional safety feature may be integrated into the activation mechanism to prevent partial depression and, therefore, partial activation of the drug pumps. 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 pumps.

**Fluid Pathway Connection:**

**[0035]** The fluid pathway connection 300 includes a sterile fluid conduit 30, a piercing member, a connection hub, and a sterile sleeve. The fluid pathway connection may further include one or more flow restrictors. Upon proper activation of the device 10, the fluid pathway connection 300 is enabled to connect the sterile fluid conduit 30 to the drug container of the drive mechanism 100. 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 100. 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.

**[0036]** In at least one example, the piercing member of the fluid pathway connection 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 connection such that displacement of the activation mechanism from its original position also causes displacement of the fluid pathway connection. In a preferred arrangement, 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 arrangement, a compressible sterile sleeve may be fixedly attached between the cap of the drug container and the connection hub of the fluid pathway connection. 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.

**[0037]** 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 arrangement, the drug delivery process is controlled by one or more flow restrictors within the fluid pathway connection and/or the sterile fluid conduit. In other arrangements, 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 connection 300 and the sterile fluid conduit 30 are provided hereinafter in later sections in reference to other arrangements.

**Insertion Mechanism:**

**[0038]** A number of insertion mechanisms may be utilized within the drug pumps. In at least one example, the insertion mechanism 200 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. 1B and FIG. 1C). The connection of the base to the assembly platform 20 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 pump 10. 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 30 to permit fluid flow through the manifold, cannula, and into the body of the user during drug delivery.

**[0039]** 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 a "trocars." In a preferred arrangement, the needle is a 27 gauge (0.4128mm outer diameter, 0.210 mm inner diameter) solid core trocar and in other arrangements, 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 one example, 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 254 (shown in FIG. 1C).

**[0040]** In one arrangement, 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. 1B, the lockout pin(s) 208 may be directly displaced by user depression of the activation mechanism 14. As the user disengages any safety mechanisms, such as an optional on-body sensor 24 (shown in FIG. 1C), the activation mechanism 14 may be depressed to initiate the drug pump. Depression of the activation mechanism 14 may directly cause translation or displacement of control arm 40 and directly or indirectly cause displacement of lockout pin(s) 208 from their initial position within locking windows 202A of insertion mechanism housing 202. Displacement of the lockout pin(s) 208 permits the 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.

**Drive Mechanism:**

**[0041]** With reference to the example shown in FIGS. 2 and 3, drive mechanism 100 includes a drive housing 130, a status switch interconnect 132, and a drug container 50 having a cap 52, a pierceable seal 56, a barrel 58, and a plunger seal 60. The drug container may contain a drug fluid, within the barrel between the pierceable seal and the plunger seal, for delivery through the insertion mechanism and drug pump into the body of the user. The seals described herein may be comprised of a number of materials but are preferably comprised of one or more elastomers or rubbers. The drive mechanism may further include a connection mount 54 to guide the insertion of the piercing member of the fluid pathway connection into the barrel 58 of the drug container 50. The drive mechanism 100 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 connection, for delivery through the fluid pathway connection, sterile fluid conduit, and insertion mechanism into the body of the user.

**[0042]** The drive mechanism may further include one or more contact surfaces located on corresponding components. Such contact surfaces may be electrical contact surfaces, mechanical contact surfaces, or electro-mechanical contact surfaces. Such surfaces may initially be in contact and caused to disengage, or initially be disconnected and caused to engage, to permit a signal to be sent to and/or from the power control system 400. In one example, as described further herein, the contact surfaces may be electrical contact surfaces which are initially disconnected and caused to come into engagement whereby, upon such engagement, the contact surfaces are capable of continuing an energy pathway or otherwise relaying a signal to the power and control system 400. In another example, the contact surfaces are mechanical contact surfaces which are initially in contact and caused to disengage whereby, upon such disengagement, such disengagement is communicated to the power and control system 400. Such signals may be transferred across one or more interconnects 132 to the power and control system 400 or by mechanical action to the power and control system 400. Such components may be utilized within the drive mechanism to measure and relay information related to the status of operation of the drive mechanism, which may be converted by the power and control system 400 into
tactile, auditory, and/or visual feedback to the user. Such arrangements are described further herein. Regardless of the electrical or mechanical nature of the contact surfaces, the motion of the components which permits transmission of a signal to the power control system 400 is enabled by a biasing member 122 axially translating a contact sleeve 140 in the distal direction

during operation of the device.

**[0043]** In one particular example, the drive mechanism 100 employs one or more compression springs as the biasing member(s). Upon activation of the drug pump 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 fluid pathway connection 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 connection, sterile fluid conduit, and insertion mechanism, and into the body of the user for drug delivery. In one arrangement, 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 hereinafter.

**[0044]** Referring now to the drive mechanism shown in FIG. 3, the drive mechanism 100 includes a drug container 50 having a cap 52, a pierceable seal 56, a barrel 58, and a plunger seal 60, and optionally a connection mount 54. The drug container 50 is mounted to a distal end of a drive housing 130. Compressed within the drive housing 130, between the drug container 50 and the proximal end of the housing 130, are a drive biasing member 122 and a piston 110, wherein the drive biasing member 122 is configured to bear upon an interface surface 110C of the piston 110, as described further herein. Optionally, a cover sleeve 120 may be utilized between the drive biasing member 122 and the interface surface 110C of the piston 110 to, for example, promote more even distribution of force from the drive biasing member 122 to the piston 110, prevent buckling of the drive biasing member 122, and/or hide biasing member from user view. Interface surface 110C of piston 110 is caused to rest substantially adjacent to, or in contact with, a proximal end of seal 60.

**[0045]** The drive mechanism 100 further includes, mounted at a distal end, a status switch interconnect 132. A contact sleeve 140 is slidably mounted to the drive housing 130 through an axial aperture of the housing 130, such that sleeve hooks 140B at a distal end of the contact sleeve 140 are caused to contact the piston 110 between interface surface 110C and a contact protrusion 110B near the proximal end of the piston 110. Piston 110 also includes a locking groove 110A, between contact protrusion 110B and the proximal end of the piston 110. Contact sleeve 140 has a radially extending ring 140C at its proximal end, upon which resides one or more flex prongs 140A. An electrical contact 134 may be connected, mounted, printed, or otherwise mounted to ring 140C which, during operation of the drive mechanism, may come in contact with corresponding status switch interconnect 132 to complete an electrical circuit or otherwise permit a transmission to the power and control system to provide feedback to the user.

**[0046]** The components of the drive mechanism 100, upon activation, may be used to drive axial translation in the distal direction of the plunger seal 60 of the drug container 50. Optionally, the drive mechanism 100 may include one or more compliance features which

enable additional axial translation of the plunger seal 60 to, for example, ensure that substantially the entire drug dose has been delivered to the user and make sure that the feedback contact mechanisms have connected. In one example, the sleeve hooks 140B are flex arms which may permit, upon sufficient application of force by the drive biasing member 122 on the piston 110, to allow interface surface 110C to translate axially beyond sleeve hooks 140B to drive further axial translation of the plunger seal 60 for a compliance push of drug fluid from the drug container. Additionally or alternatively, the plunger seal 60, itself, may have some compressibility permitting a compliance push of drug fluid from the drug container.

**[0047]** In at least one arrangement, a compliance push of drug fluid from the drug container is enabled by a piston extension 102. In such embodiments, the drive mechanism 100 further includes a piston extension 102 slidably mounted at a distal end and within an axial pass-through of piston 110. The piston extension 102 may be retained within piston 110 by interaction between extension arms 102B of the piston extension 102 and connection slots 110D of piston 110, as shown in FIGS. 4A-4E. Piston extension may be driven by a piston extension biasing member 106, which is mounted within the axial pass-through of piston 110 and initially compressed between piston extension 102 and piston 110. An optional piston biasing member support 104 may be utilized between piston extension biasing member 106 and piston extension 102 to, for example, promote more uniform distribution of force from piston extension biasing member 106 to piston extension 102. The function of the optional piston extension is described in further detail hereinafter.

**[0048]** The drive mechanisms described herein integrate status indication into the drug dose delivery. 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, and/or auditory, as described above, and may be redundant such that more than one signal or types of feedback are provided to the user during use of the device. For example, the user may be provided with 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 pump 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 pump provide a true end-of-dose indication to the user.

**[0049]** In one arrangement, as shown in FIG. 2 and FIG. 3, an end-of-dose status indication may be provided to the user once the status switch interconnect 132 is caused to contact electrical contact 134 at the end of axial travel of the piston 110 and plunger 60 within the barrel 58 of the drug container 50. In a further example, incremental status indications relaying various stages of drug delivery can be communicated to the user during operation. In one such example, sleeve hooks 140B may have one or more interconnects which come into contact with one or more electrical contacts on the outer surface of piston 110 during operation. As piston 110 translates axially in the distal direction to push plunger seal 60 distally, thereby pushing fluid out of the drug container through the pierceable seal end, the electrical contacts

of the piston 110 may sequentially contact the interconnect on the sleeve hooks 140B to relay the incremental status of operation. Depending on the number of electrical contacts located on the outer surface of the piston 110, the frequency of the incremental status indication may be varied as desired. 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.

**[0050]** In another drive mechanism 500, shown in FIGS. 5 and 6, incremental status indication may be measured and relayed by a separate incremental status stem 650 and a corresponding stem interconnect 652. The stem interconnect 652 may be mounted, affixed, printed, or otherwise attached to incremental status stem 650. Incremental status stem 650 may be a static component, i.e., it does not move or translate, that is mounted to the distal end of contact sleeve 640 and/or the distal end of drive housing 630 such that the incremental status stem 650 resides within an axial pass-through of contact sleeve 640 and drive housing 630. The incremental status stem 650 further resides within an axial pass-through of piston 610. In such an arrangement, one or more contacts may be located on an inner surface of the piston 610 such that they sequentially interface with one or more corresponding interconnects on the incremental status stem 650. As piston 610 translates axially in the distal direction to push plunger seal 560 distally, thereby pushing fluid out of the drug container through the pierceable seal end, the electrical contacts of the piston 610 may sequentially contact the interconnect on the incremental status stem 650 to relay the incremental status of operation. Depending on the number of electrical contacts, the frequency of the incremental status indication may be varied as desired. 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.

**[0051]** FIG. 7 shows a cross-sectional view of the drive mechanism shown in FIG. 5 during operation of the drive mechanism. As shown, incremental status stem 650 may be a static component that is mounted to the distal end of contact sleeve 640 and/or the distal end of drive housing 630 such that the incremental status stem 650 resides within an axial pass-through of contact sleeve 640 and drive housing 630. As piston 610 translates axially in the distal direction (i.e., in the direction of the solid arrow) to push plunger seal 560 distally, the electrical contacts of the piston 610 may sequentially contact the interconnect on the incremental status stem 650 to relay the incremental status of operation through stem interconnect 652.
Accordingly, incremental status of the drive mechanism, and therefore status of drug delivery, may be conveyed to the user during use of the device.

**[0052]** Returning now to the arrangement shown in FIGS. 2-3, further aspects of the drive mechanism will be described with reference to FIGS. 4A-4E. One or more of these aspects may similarly be utilized in the arrangement shown in FIG. 5, or any other variation described herein. FIG. 4A shows a cross-sectional view of the drive mechanism during its initial locked stage. A fluid, such as a drug fluid, may be contained within barrel 58, between plunger seal 60

and pierceable seal 56, for delivery to a user. Upon activation by the user, a fluid pathway connection may be connected to the drug container through the pierceable seal 56. As described above, this fluid connection may be facilitated by a piercing member of the fluid pathway connection which pierces the pierceable seal and completes the fluid pathway from the drug container, through the fluid pathway connection, the fluid conduit, the insertion mechanism, and the cannula for delivery of the drug fluid to the body of the user. Initially, one or more locking mechanisms (not shown) may reside within the locking grooves 110A of piston 110. Directly or indirectly upon activation of the device by the user, the locking mechanism may be removed from the locking grooves 110A of piston 110, to permit operation of the drive mechanism.

**[0053]** As shown in FIG. 4A, the piston extension biasing member 106 and drive biasing member 122 are both initially in a compressed, energized state. The drive biasing member 122 may be maintained in this state until activation of the device between internal features of drive housing 130 and interface surface 110C of piston 110. As the locking mechanism is removed from the locking groove 110A of piston 110, drive biasing member 122 is permitted to expand (i.e., decompress) axially in the distal direction (i.e., in the direction of the solid arrow). Such expansion causes the drive biasing member 122 to act upon and distally translate interface surface 110C and piston 110, thereby distally translating plunger 60 to push drug fluid out of the barrel 58. Distal translation of the piston 110 causes distal translation of the piston extension biasing member 106 and piston extension 102, when such optional features are incorporated into the device. As shown in FIG. 4B, such distal translation of the piston 110 and plunger seal 60 continues to force fluid flow out from barrel 58 through pierceable seal 56. Status switch interconnect 132 is prevented from prematurely contacting electrical contact 134 by one or more flex prongs 140A, as shown in FIG. 4C. Alternatively, low force springs or other resistance mechanisms may be utilized in addition to or alternatively from flex prongs 140A to achieve the same functions. During distal translation of the piston 110, sleeve hooks 140B may slidably contact the outer surface of piston 110. As described above, interconnects and electrical contacts may be located on these components to provide incremental status indication during operation of the drive mechanism.

**[0054]** As the drive mechanism 100 nears or reaches end-of-dose, flex prongs 140A may be caused to flex outwards (i.e., in the direction of the hollow arrows) by the decompression force of drive biasing member 122. Such flexion of the flex prongs 140A may permit status switch interconnect 132 to contact electrical contact 134, completing a circuit or otherwise permitting a transmission to the power and control system to provide feedback to the user. At this stage, one or more delivery compliance mechanisms may be utilized to ensure that the status switch interconnect 132 has contacted electrical contact 134 and/or that substantially the entire drug dose has been delivered. In one example the sleeve hooks 140B are flex arms which may permit, upon sufficient application of force by the drive biasing member 122 on the piston 110, to allow interface surface 110C to translate axially beyond sleeve hooks 140B to drive further axial translation of the plunger seal 60 for a compliance push of drug fluid from the drug container. Additionally or alternatively, the plunger seal 60, 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.

**[0055]** In one arrangement a compliance push of drug fluid from the drug container is enabled by a piston extension 102. In such an arrangement, the drive mechanism 100 further includes a piston extension 102 slidably mounted at a distal end and within an axial pass-through of piston 110. The piston extension 102 may be retained within piston 110 by interaction between extension arms 102B of the piston extension 102 and connection slots 110D of piston 110, as shown in FIG. 4D. Piston extension may be driven by a piston extension biasing member 106, which is mounted within the axial pass-through of piston 110 and initially compressed between piston extension 102 and piston 110. An optional piston biasing member support 104 may be utilized between piston extension biasing member 106 and piston extension 102 to, for example, promote more uniform distribution of force from piston extension biasing member 106 to piston extension 102.

**[0056]** As the piston 110 reaches its end of travel within barrel 58, piston extension 102 may be permitted to axially travel in the distal direction by the force exerted by piston extension biasing member 106. At this stage, the piston extension biasing member 106 is permitted to expand (i.e., decompress) axially in the distal direction such that extension arms 102B of the piston extension 102 may translate distally (i.e., in the direction of the solid arrow) within connection slots 110D of piston 110, as shown in FIG. 4D. As shown in FIG. 4E, such distal translation (i.e., in the direction of the hatched arrow) of the piston extension 102 enables a compliance push (shown by dimension "C" in FIG. 4E) of drug fluid from the drug container. Piston extension 102 may be configured such that extension arms 102B may contact and apply force upon a distal end of connections slots 110D to distally translate piston 110 further (i.e., in the direction of the hatched arrow). This further distal translation of the piston 110 may be utilized to ensure that status switch interconnect 132 has engaged contact 134.

**[0057]** As described above, the drive mechanisms integrate status indication into the drug dose delivery. Through integration of the end-of-dose status indication mechanisms to the axial translation of the piston, and thereby the plunger seal, true and accurate end-of-dose indication may be provided to the user. By use of one or more contact surfaces on corresponding components, 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 types of feedback are provided to the user during use of the device. FIGS. 4A-4E above show an arrangement which provides end-of-dose status indication to the user once the status switch interconnect 132 is caused to contact electrical contact 134 at the end of axial travel of the piston 110 and plunger 60 within the barrel 58 of the drug container 50. As described above, the novel devices described herein may additionally provide incremental status indications to relay various stages of drug delivery to the user during operation. In one such arrangement, sleeve hooks 140B may have one or more interconnects which come into contact with one or more electrical

contacts on the outer surface of piston 110 during operation. A redundant end-of-dose indication may be utilized upon contact between sleeve hooks 140B of contact sleeve 140 and contact protrusion 110B of piston 110. Electrical contacts or interconnects along piston 110 may sequentially contact the corresponding interconnects or contacts on the sleeve hooks 140B to relay the incremental status of operation. Depending on the number of electrical contacts located on the outer surface of the piston 110, the frequency of the incremental status indication may be varied as desired. 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.

**[0058]** In another drive mechanism 500, shown in FIGS. 5-7, incremental status indication may be measured and relayed by a separate incremental status stem 650 and a corresponding stem interconnect 652. As shown in FIG. 7, incremental status stem 650 may be a static component that is mounted to the distal end of contact sleeve 640 and/or the distal end of drive housing 630 such that the incremental status stem 650 resides within an axial pass-through of contact sleeve 640 and drive housing 630. As piston 610 translates axially in the distal direction (i.e., in the direction of the solid arrow) to push plunger seal 560 distally, the electrical contacts of the piston 610 may sequentially contact the interconnect on the incremental status stem 650 to relay the incremental status of operation through stem interconnect 652. Depending on the number of electrical contacts, the frequency of the incremental status indication may be varied as desired. 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. Accordingly, incremental status of the drive mechanism, and therefore status of drug delivery, may be conveyed to the user during use of the device.

**[0059]** In a further drive mechanism, shown in FIGS. 8 and 9A-9C, drive mechanism 1000 may be similar to mechanism 100 or mechanism 500, and incorporate the respective components and functions of such arrangements, but utilize mechanical contact surfaces instead of electrical contact surfaces, as described above. FIG. 8 shows an isometric view of a further drive mechanism 1000. FIGS. 9A-9C show cross-sectional views of the drive mechanism shown in FIG. 8 in an initial inactive state, an actuated state and as the mechanism nears completion of drug delivery, and as the mechanism completes drug delivery and triggers an end-of-dose signal. The status switch interconnect is a mechanical trigger 1150 and the contact surface is a pin 1140P. As shown in FIG. 9A, the optional piston extension biasing member 1106 and drive biasing member 1122 are both initially in a compressed, energized state. The drive biasing member 1122 may be maintained in this state until activation of the device between internal features of drive housing 1130 and interface surface 1110C of piston 1110. As the locking mechanism is removed from the locking groove 1110A of piston 1110, drive biasing member 1122 is permitted to expand (i.e., decompress) axially in the distal direction (i.e., in the direction of the solid arrow). Such expansion causes the drive biasing member 1122 to act upon and distally translate interface surface 1110C and piston 1110, thereby distally translating plunger 1060 to push drug fluid out of the barrel 1058. Distal translation of the piston 1110 causes distal translation of the piston extension biasing member

1106 and piston extension 1102, when such optional features are incorporated into the device.

**[0060]** As shown in FIG. 9B, such distal translation of the piston 1110 and plunger seal 1060 continues to force fluid flow out from barrel 1058 through pierceable seal 1056. As described above, interconnects and electrical contacts may be located on these components to provide incremental status indication during operation of the drive mechanism. As shown in FIG. 9C, as the drive mechanism 1000 reaches end-of-dose, pin 1140P disengages from mechanical trigger 1150 to permit a transmission to the power and control system 400 to provide feedback to the user. Disengagement of the pin 1140P from the mechanical trigger 1150 permits the trigger to rotate as it is biased by a biasing member, such as a constant-force spring 1170. Initially, the constant-force spring 1170 biases the mechanical trigger 1150 against the pin 1140P. Upon axial translation of the pin 1140P, as described above, pin 1140P disengages from mechanical trigger 1150 which then rotates or is otherwise displaced to permit transmission of feedback to the user. At this stage, one or more delivery compliance mechanisms, as described above, may be utilized to ensure that the pin 1140P has disengaged mechanical trigger 1150 and/or that substantially the entire drug dose has been delivered.

**[0061]** Assembly and/or manufacturing of drive mechanism 100, 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 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.

**[0062]** The drive mechanism may be assembled in a number of methodologies. In one method of assembly, the drug container 50 may first be assembled and filled with a fluid for delivery to the user. The drug container 50 includes a cap 52, a pierceable seal 56, a barrel 58, and a plunger seal 60. The pierceable seal 56 may be fixedly engaged between the cap 52 and the barrel 58, at a distal end of the barrel 58. The barrel 58 may be filled with a drug fluid through the open proximal end prior to insertion of the plunger seal 60 from the proximal end of the barrel 58. An optional connection mount 54 may be mounted to a distal end of the pierceable seal 56. The connection mount 54 serves to guide the insertion of the piercing member of the fluid pathway connection into the barrel 58 of the drug container 50. The drug container 50 may then be mounted to a distal end of drive housing 130.

**[0063]** One or more switch status interconnects 132 may be mounted to a proximal end of drive housing 130. A contact sleeve 140, having one or more sleeve hooks 140B at a distal end and a ring 140C at a proximal end having an electrical contact 134 thereon, may be mounted to the drive housing 130 through an axial pass-through from the proximal end of the drive housing 130. A drive biasing member 122 may be inserted into a distal end of the drive

housing 130. Optionally, a cover sleeve 120 may be inserted into a distal end of the drive housing 130 to substantially cover biasing member 122. A piston may be inserted into the distal end of the drive housing 130 and through an axial pass-through of contact sleeve 140, such that a contact protrusion 110B of piston 110 is proximal to the sleeve hooks 140B of contact sleeve 140. The piston 110 and drive biasing member 122, and optional cover sleeve 120, may be compressed into drive housing 130. Such assembly positions the drive biasing member 122 in an initial compressed, energized state and preferably places a piston interface surface 110C in contact with the proximal surface of the plunger seal 60 within the proximal end of barrel 58. When a piston extension 102 is employed, the piston extension 102 and piston extension biasing member 106, and optional piston biasing member support, may be compressed into an axial pass-through of piston 110. 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 130 prior to attachment or mounting of the drug container 50.

**[0064]** When one or more interconnects or contacts are utilized for status indication, such components may be mounted, connected, printed, or otherwise attached to their corresponding components prior to assembly of such components into the drive mechanism 100. When a separate incremental status stem 650 and a corresponding stem interconnect 652 are utilized for such incremental status indication, the stem interconnect 652 may be mounted, affixed, printed, or otherwise attached to incremental status stem 650. The incremental status stem 650 and stem interconnect 652 may be mounted to the proximal end of the contact sleeve 640 and/or the proximal end of the drive housing 630 in a manner such that the incremental status stem 650 resides within an axial pass-through of contact sleeve 640 and drive housing 630. The incremental status stem 650 is further mounted to reside within an axial pass-through of piston 610.

**[0065]** It will be appreciated that the end-of-dose indicator or interconnects/contact may include any appropriate arrangement, including, for example, mechanical, electrical, electromechanical, ultrasonic, capacitive or magnetic arrangements. Similarly, the drive mechanism may be of any appropriate design.

**[0066]** Alternate arrangements of both the drive mechanism and end-of-dose indicator or interconnects/contact are illustrated, for example, in FIGS. 10A-14B. For the sake of clarity, the reference numbers utilized in FIGS. 10A-14B are similar to those of the arrangements of FIGS. 1A-4C, only preceded by the number "2" or "20" as appropriate to provide a reference number having four digits, *i.e.,* 2XXX. For example, the drug pump and drive mechanism of FIGS. 10A-14B will be designated by the numbers 2010 and 2100, respectively, as opposed to the drug pump 10 and drive mechanism 100 of FIGS. 1A-4E. This correlation, however, should not be taken as an indication that the components of FIGS. 10A-14B with reference numbers similar to those of the embodiment of FIGS. 1A-4E are exactly the same as the respective components of FIGS. 1A-4E.

**[0067]** As shown in FIGS. 10A-10C, the drug pump 2010 includes a drive mechanism 2100 for

receiving a drug container 2050, an insertion mechanism 2200, a fluid pathway connection 2300 including a fluid conduit 2030, and a power and control system 2400, all residing within a housing 2012, and an activation mechanism 2014 actuable by a user from the outside of the housing 2012. The housing 2012 may take any number of configurations and be facilitated by any number of components, such as a single-body or multi-component housing 2012. Certain other components, such as electronics for power and signaling, activation buttons, and safety sensors are also omitted for clarity, but are understood to be standard components within such drug pump devices. While the housing 2012, insertion mechanism 2200, fluid pathway connection 2300, and power and control system 2400, as well as the activation mechanism 2014 are not discussed in detail, those of skill in the art will appreciate that they may be the same or similar to the components and systems discussed in detail with regard to the other arrangements disclosed herein.

**[0068]** The drive mechanism 2100, primary drug container 2050, and a portion of the fluid pathway connection 2300 are shown isometrically in FIG. 11 and exploded form in FIG. 12. FIGS. 13A-13C illustrate the drive mechanism 2100 in cross-section as it progresses through several stages of operation. FIGS. 14A-14B illustrate a lateral cross-section of the drive mechanism 2100 at several stages of operation.

**[0069]** The primary drug container 2050 retains the drug treatment that is to be injected or infused into the patient, and may be a vial or similar container from which a drug treatment can be dosed. To provide a sterile environment for the drug treatment, the drug container 2050 may include a cylindrical barrel 2058 with a pierceable seal 2056 disposed in a distal end and a plunger seal 2060 disposed within a proximal end. The pierceable seal 2056 and plunger seal 2060 may be formed of a number of materials, such as one or more elastomeric materials, and are sized and formulated to maintain a seal with the barrel 2058.

**[0070]** The portion of the fluid pathway connection 2300 illustrated in FIGS. 11-13C includes a connection mount 2054, a sterile boot 2310, and a piercing assembly 2320. The piercing assembly 2320 includes a piercing member 2322 extending from a hub 2324 which supports the piercing member 2322, and provides a fluid connection 2326 (see FIG. 11) to which the fluid conduit 2030 or other fluid connector may be fluidly coupled to fluidly couple the drug container 2050 to the insertion mechanism 2200. The connection mount 2054 is disposed adjacent the pierceable seal 2056 and includes an aperture adapted to guide the insertion of the piercing member 2322 of the fluid pathway connection into the pierceable seal 2056 of the drug container 2050. The sterile boot 2310 is disposed about the piercing assembly 2320 and provides a sterile environment for the completion of the fluid coupling of the fluid pathway connection 2300. A collar 2052 may be provided in order to secure a flange of the sterile boot 2310, the connection mount 2054, the pierceable seal, and the barrel 2058 in fixed relation to one another.

**[0071]** Referring to FIGS 10A and 10B, in operation, when a user activates the activation mechanism 2014, as by depressing the illustrated start button, an arm 2015 coupled to the activation mechanism 2014 exerts an axial force on the piercing assembly 2320 to move the

piercing member 2322 axially to pierce the pierceable seal 2056. The drive mechanism 2100 is adapted for use in cooperation with the proximal end of the drug container 2050 to axially advance the plunger seal 2060 within the barrel 2058 to dispense the drug treatment through the fluid pathway connection 2300 once the pierceable seal 2056 has been pierced by the piercing member 2322.

**[0072]** The drive mechanism 2100 includes a drive housing 2130 having an axis that is coincident with the axis A of the drive mechanism 2100 (see FIG. 11). The axis A may be disposed in coincident with axes in the container 2050 and the plunger seal 2060. A piston 2110 is at least partially disposed within the drive housing 2130 for longitudinal movement along the axis of the drive mechanism 2100. It will be appreciated that the term "axis" when used in connection with the drive housing 2130 is not intended to require the axis to be in a central location of the drive housing 2130 or that the drive housing 2130 be round.

**[0073]** The piston 2110 is mounted to move between a retracted first position (illustrated in FIG. 13A), wherein the piston 2110 is at least partially disposed within the drive housing 2130, and an extended second position (illustrated in FIGS. 13B and 13C), wherein the piston 2110 extends axially outward from drive housing 2130. The piston 2110 includes an interface surface 2110C that is disposed to either directly confront the plunger seal 2060 when assembled with a drug container 2050, or to otherwise transmit an actuating force to the plunger seal 2060. In other words, the piston 2110 of the drive mechanism 2100 of FIGS. 10A-14B is adapted to exert a dispensing force on the plunger seal 2060 of the drug container 2050 and to translate outward from a distal end of a housing 2012 to advance the plunger seal 2060 within the drug container 2050 to dispense the drug. While the initial position shown in FIG. 13A illustrates the interface surface 2110C of the piston 2110 as disposed substantially adjacent the distal end of the housing 2012, it will be appreciated that, in alternate embodiments, the piston may be initially disposed in a position extending outside of the drive housing 2130. In such an arrangement, in initial assembly of the drive mechanism 2100 with a drug container 2050, the piston 2110 may be initially at least partially disposed within proximal end of the drug container 2050.

**[0074]** In order to impart axial movement to the piston 2010, the drive mechanism 2100 further includes a plurality of piston biasing members 2106, 2122 disposed to move from an energized first position when the piston 2110 is in the retracted first position to a deenergized second position when the piston 2110 is in an extended second position. It will be appreciated that, for the purposes of this disclosure and the accompanying claims, the term "deenergized second position" is a relative term. That is, the piston biasing members 2106, 2122 in the "deenergized second position" have less energy than the piston biasing members 2106, 2122 in the "energized first position." That is not to say, however, that the piston biasing members 2106, 2122 in the "deenergized second position" are necessarily completely deenergized or storing no energy.

**[0075]** So long as the piston 2110 is maintained in the retracted first position, biasing members 2106, 2122 are maintained in their energized first position (see FIG. 13A). The

piston 2110 is maintained in the retracted first position by a retaining element or clip 2115. While any appropriate arrangement may be utilized to retain the piston 2110 in the retracted first position, the clip 2115 may bear against an outside surface of the drug pump housing 2012 and be received in a locking groove 2110A of the piston 2110. FIG. 13A illustrates the clip 2115 disposed in such a retaining first position. It will thus be appreciated by those of skill in the art that the engagement of the retaining element or clip 2115 to maintain the piston 2110 in its retracted first position with the biasing members 2106, 2122 in their energized first position, allows the drive mechanism 2100 to be handled as a self-contained unit such that it may be assembled into the drug pump 2010 or in cooperation with a drug container 2050. In operation, however, once the clip 2115 is removed or moved to a releasing second position (see FIGS. 13B and 13C), the piston biasing members 2106, 2122 exert an axial dispensing force on the piston 2110 as they move to a deenergized second position and the piston moves to its extended second position. In at least one embodiment, clip 2115 may be removed through an action caused, directly or indirectly, by movement of the activation mechanism 2014. The action of removing clip 2115 can be achieved in a number of ways. For example, with reference to FIG. 12, the action of removing clip 2115 is a linear, perpendicular movement relative to the axis "A" of the drug container 2050.

**[0076]** In accordance with an aspect of the invention as illustrated in the embodiment of FIGS. 10A-13C, the drive mechanism 2100 is small in size and/or device footprint, yet capable of providing the dispensing force needed to push a drug fluid from a drug container 2050 through a fluid conduit 2030 for drug delivery via an insertion mechanism 2200. In this embodiment of the drive mechanism 2100, the piston biasing members 2106, 2122 are disposed in parallel, in contrast to the series disposal of the arrangements of FIGS. 1A-9C. It will thus be appreciated by those of skill in the art that the drive mechanism 2100 of FIGS. 10A-14B yields a significantly smaller footprint than prior art devices or even the drive mechanisms 100, 500, 1000 of the other arrangements described herein.

**[0077]** For the purposes of this disclosure and its claims, when used in connection with biasing members, be it a specific embodiment of biasing members, such as springs, or the general use of the term "biasing members," the terms "series" and "parallel" are to be interpreted as they would by those of skill in the art. That is, the terms "series," "in series," or "disposed in series" are to be interpreted as springs disposed and operating as they would when connected end to end, and the terms "parallel," "in parallel," or "disposed in parallel" are to be interpreted as springs disposed and operating as they would in a side-by-side relationship.

**[0078]** Those of skill in the art will appreciate that for biasing members disposed in series, the inverse of equivalent spring constant will equal the sum of the respective inverses of the spring constants of the individual biasing members. In contrast, the equivalent spring constant of biasing members 2106, 2122 in a parallel relationship will be the sum of the spring constants of the individual biasing members. Similarly, the dispensing force exerted by the biasing members 2106, 2122 in a parallel relationship will be the sum of the forces exerted by the biasing members 2106, 2122 individually. As a result, the use of biasing members 2106, 2122

disposed in parallel provides the desired dispensing force in a substantially more compact package, allowing the drive mechanism 2100 to be more compact than the arrangements of FIGS. 1A-9C. By extension, the use of biasing members 2106, 2122 disposed in parallel may allow the entire drug pump 2010 to be substantially more compact than an arrangement wherein the biasing members are disposed in series.

**[0079]** In this embodiment, the biasing members 2106, 2122 are in the form of a pair of concentrically disposed compression springs. Alternate arrangements are envisioned, however. For example, one or more of the biasing members could alternately, for example, be tension springs, depending upon the structure of the components of the drive mechanism. Moreover, in the illustrated drive mechanism 2100, the biasing members 2106, 2122 are disposed concentrically with respect to each other and the piston 2100. In an alternate embodiment, however, the biasing members may be alternately disposed, as, by way of example only, in a side by side arrangement, or on opposite sides of the piston. In still further embodiments, three or more biasing members could be provided and disposed in parallel in any appropriate configuration. It will further be appreciated, that an additional biasing member may be provided and disposed in series with one or more of the parallelly disposed biasing members. For example, in an embodiment where the piston includes an extension, similar to the piston extension 102 of the arrangement of FIGS. 1A-4E, for example, an additional biasing member may be provided to engage the piston extension.

**[0080]** Returning now to the embodiment of FIGS. 10A-14B, the drive mechanism 2100 includes an end-of-dose indicator 2133. The end-of-dose indicator 2133 includes a switch interconnect 2132 and a contact sleeve assembly 2120 adapted for movement with the piston 2110. Piston 2110 has an interface surface 2112 that is capable of contacting or otherwise bearing upon plunger seal 2060 to force drug fluid out of barrel 2058 through the fluid pathway connection 2300 for delivery to a patient. In order to provide access to the end-of-dose indicator 2133 the interior of the drive housing 2130 includes an access window 2131, the significance of which will be described further below.

**[0081]** The contact sleeve assembly 2120 of the embodiment illustrated in FIGS. 11-13C includes a pair of telescoping sleeves 2124, 2126. The first sleeve 2124 is adapted for movement with the piston 2110 as the piston biasing members 2106, 2122 are deenergized. A distal, generally radially extending flange 2124A of the first sleeve 2124 is disposed subjacent the head 2111 of the piston 2110. In this way, one or both of the biasing members 2106, 2122 bear against the flange 2124A, which bears against the piston head 2111 to impart axial movement to the piston 2110. The second sleeve 2126 is slidably coupled to the first sleeve 2124, the first sleeve 2124 sliding distally outward from the second sleeve 2126. In order to permit the second sleeve 2126 to travel with the first sleeve 2124 when the first sleeve 2124 is fully extended from the second sleeve 2126, a coupling structure is provided. In the illustrated embodiment the sleeves 2124, 2126 include respective flanges 2124B, 2126A that engage as the proximal end of the first sleeve 2124 approaches the distal end of the second sleeve 2126 (see FIG. 13A) to cause the second sleeve 2126 to likewise move in an axial direction with the piston 2110 (see FIG. 13C).

**[0082]** It will be appreciated, however, that alternate arrangements are envisioned. By way of example only, the first sleeve 2124 could alternatively be integrally formed with the piston 2110. In this way, the first sleeve 2124 formed with the piston 2110 would telescope outward from a second sleeve 2126 in a manner similar to that described above. Moreover, while the sleeve assembly 2120 has been described as including a pair of telescoping sleeves, alternate numbers of sleeves may be used, such as three or more telescoping sleeves. The number of sleeves may be dependent upon the cooperative structures, however, such as the relative dimensions of the drive housing 2130, and the travel of the piston 2110. For example, in an embodiment utilizing a smaller drive housing, but having a similar piston travel, three or more telescoping sleeves may be desirable. In some embodiments where multiple sleeves are provided about the biasing members 2106, 2122, and the biasing members 2106, 2122 are in the form of compression springs, such as shown in the illustrated embodiment, the springs in a compressed, energized state may have a length equal to the untelescoped sleeves 2124, 2126, yet have an uncompressed, deenergized length that is equal to the length of the telescoped sleeves. Further, while the end-of-dose indicator 2133 is described in connection with a drive mechanism 2100 including a plurality of biasing members disposed in parallel, those of skill in the art will appreciate that the end-of-dose indicator 2133 could also be utilized in connection with a drive mechanism including a single biasing device or a plurality of biasing members disposed in series and/or parallel.

**[0083]** As the sleeve assembly 2120 moves axially outward, the proximal end 2126B of the sleeve assembly 2120 passes the window 2131 of the drive housing 2130. In the illustrated embodiment in particular, as the second sleeve 2126 moves axially outward, the proximal end 2126B of the second sleeve 2126 passes the window 2131 of the drive housing 2130.

**[0084]** The switch interconnect 2132 includes a sensor 2134 and an electronic coupling 2136 to the power and control system 2400. At least a portion of the sensor 2134 is disposed adjacent the window 2131, and is adapted to identify a change in the presence of the contact sleeve assembly 2120 proximal to the window 2131 within the drive housing 2130. For example, in the illustrated embodiment, the sensor 2134 may read that the sleeve assembly 2120 is no longer present proximal to the window 2131.

**[0085]** In order to better illustrate the relationship of the sensor 2134 and the sleeve assembly 2120 during movement of the sleeve assembly 2120, portions of the sleeve assembly 2120 are broken away in FIGS. 13A-13B; in FIGS. 14A-14B, the housing 2130, sleeve 2126, biasing members 2106, 2122, and end-of-dose indicator 2133 are shown in cross-section taken along line 14-14 in FIG. 11. In the illustrated embodiment, the sleeve assembly 2120 is disposed adjacent the window 2131 when the piston 2110 is in the retracted first position (see FIG. 13A), and as the sleeve assembly 2120 begins to telescope outward with the piston 2110 (see FIGS. 13B and 14A). Conversely, the sleeve assembly 2120 is not disposed adjacent the window 2131 when the piston 2110 is in a fully extended second position (see FIGS. 13C and 14B). As the proximal end 2126B of the second sleeve 2126 passes the window, the switch interconnect 2132 identifies that the sleeve assembly has passed the window 2131 , and that the end of

dose has occurred, and provides that information to the power and control system 2400. The electronic coupling 2136 may be of any appropriate design. In the illustrated embodiment, for example, the sensor 2134 connects directly to a PCB board 2138.

**[0086]** The switch interconnect 2132 illustrated includes a mechanical sensor 2134 in the form of a pivotably mounted trigger 2135, in essence, an on/off mechanical switch. The trigger 2135 is disposed in a first position in contact with the sleeve
assembly 2120 when the piston 2110 is in a retracted first position. As the piston 2110 moves outward from the drive housing 2130, the trigger 2135 slides along the telescoping sleeve assembly 2120 until such time as the proximal end 2126B of the second sleeve 2126 passes the window 2131, that is, the trigger 2135. As the second sleeve 2126 passes the trigger 2135, the trigger 2135 moves to a second position. The movement of the trigger 2135 to the second position results in the electronic coupling 2135 providing a signal indicating the end of dose to the power and control system 2400.

**[0087]** The switch interconnect 2132 may be of any appropriate design, however. For example, the switch interconnect 2132 may include a sensor of an electromechanical nature, such as the one illustrated in FIGS. 10A-14B, or a sensor of an electrical nature, such as, for example, an optical reader or sensor. Additionally or alternatively, the switch interconnect 2132 may utilize an ultrasonic sensor, a capacitive sensor, a magnetic sensor, or a number of other types of sensors. Accordingly, the sensor may not require physical contact with the corresponding reference component. In an embodiment including an optical sensor, the sensor may read the presence or absence of the sleeve assembly 2120, for example, reading the interior of the drive housing 2130 opposite the window 2131. The sensor may be configured to additionally or alternatively identify at least one of when the sleeve assembly is disposed subjacent the window and when the sleeve assembly is not disposed subjacent the window, the relative motion of the sleeve assembly with reference to the window or another reference component, the stoppage of such motion, and the rate or change of rate of motion.

**[0088]** Although illustrated as an electromechanical arrangement that reads the position of a telescoping sleeve, any appropriate arrangement may be provided to read the relative position of any appropriate component, the end-of-dose indicator providing a signal to the power and control system to indicate that all of the drug has been administered. Additionally, the switch interconnects and corresponding contacts and/or reference component may be utilized to provide incremental status indication in addition to an end-of-dose indication. For example, in the switch interconnect arrangement described above with reference to FIGS. 10A-13C, the switch interconnect 2132 may be an electromechanical sensor configured to recognize a number of bumps, ridges, or grooves, in the corresponding sleeve 2126 or any other reference component,
the contact with which permits the switch interconnect to signal an incremental status indication (e.g., delivery initiation, amount of volume delivered, duration of plunger travel, etc.) and a final end-of-dose indication. As described herein, similar incremental status indication may be provided in this configuration by utilizing a different type of sensor arrangement. For example, the switch interconnect 2132 may be an optical sensor configured to recognize a number of

markings on the corresponding sleeve 2126 or any other reference component. As the optical sensor recognizes the number of markings, it permits the switch interconnect to signal an incremental status indication (e.g., delivery initiation, amount of volume delivered, duration of plunger travel, etc.) and a final end-of-dose indication. Any appropriate arrangement may be provided to read the relative position of a number of markings, ridges, grooves, or respective indicators on any appropriate reference component, and recognition of such indicators by the switch interconnect permits it to provide a signal to the power and control system to indicate the incremental status of drug delivery, including the final status that all of the drug has been administered. As would be appreciated by an ordinarily skilled artisan in the relevant arts, the indicators may not necessarily be defined aspects on a reference component, and the switch interconnects may be configured to recognize the actual travel of the reference component itself. The switch interconnects may thus be configured to recognize the rate of change, the distance of travel, or other related measurements in the actual travel of the reference components and enable a signal to the power and control system to provide the user with such information or feedback.

**[0089]** It will be appreciated by those of skill in the art that the embodiments of the present invention provide the necessary drive force to push a plunger seal and a drug fluid within a drug container, while reducing or minimizing the drive mechanism and overall device footprint. Accordingly, the present invention provides a drive mechanism which may be utilized within a more compact drug delivery pump device. The embodiments of the present invention may similarly be utilized to provide additional force, as may be needed for highly viscous drug fluids or for larger volume drug containers.

**[0090]** The embodiments shown and detailed herein disclose only a few possible variations of the present invention; other similar variations are contemplated and incorporated within the breadth of this disclosure.

**[0091]** The drive mechanism may further include one or more contact surfaces located on corresponding components. Such contact surfaces may be electrical contact surfaces, mechanical contact surfaces, or electro-mechanical contact surfaces. Such surfaces may initially be in contact and caused to disengage, or initially be disconnected and caused to engage, to permit a signal to be sent to and/or from the power control system 2400.

**[0092]** A fluid pathway connection, and specifically a sterile sleeve of the fluid pathway connection, 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 connection 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 connection, 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 pump, as shown in FIG. 1B.

**[0093]** Certain optional standard components or variations of drive mechanism 100 or drug pump 10 are contemplated. For example, upper or lower housings may optionally contain one or more transparent or translucent windows 18, as shown in FIG. 1A, to enable the user to view the operation of the drug pump 10 or verify that the drug dose has been completed. Additionally, the drug pump 10 may contain an adhesive patch 26 and a patch liner 28 on the bottom surface of the housing 12. The adhesive patch 26 may be utilized to adhere the drug pump 10 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 26 may have an adhesive surface for adhesion of the drug pump to the body of the user. The adhesive surface of the adhesive patch 26 may initially be covered by a non-adhesive patch liner 28, which is removed from the adhesive patch 26 prior to placement of the drug pump 10 in contact with the body of the user. Removal of the patch liner 28 may further remove the sealing membrane 254 of the insertion mechanism 200, opening the insertion mechanism to the body of the user for drug delivery (as shown in FIG. 1C).

**[0094]** Similarly, one or more of the components of drive mechanism 100 and drug pump 10 may be modified. For example, as described above, while the housing of drug pump 10 is shown as two separate components upper housing 12A and lower housing 12B, these components may be a single unified component. Similarly, while electrical contact 134 is shown as a separate component from contact sleeve 140, it may be a unified component printed onto the ring surface of the contact sleeve 140. As discussed above, a glue, adhesive, or other known materials or methods may be utilized to affix one or more components of the drive mechanism and/or drug pump to each other. Alternatively, one or more components of the drive mechanism and/or drug pump 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.

**[0095]** It will be appreciated from the above description that the drive mechanisms and drug pumps disclosed herein provide an efficient and easily-operated system for automated drug delivery from a drug container. The novel embodiments described herein provide integrated status indication to provide feedback to the user. The novel drive mechanisms of the present invention may be directly or indirectly activated by the user. For example, in at least one embodiment the lockout pin(s) which maintain the drive mechanism in its locked, energized state are directly displaced from the corresponding lockout grooves of the piston by user depression of the activation mechanism. Furthermore, the configurations of the drive mechanism and drug pumps 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 connection, the sterile fluid conduit, and

the insertion mechanism. In at least one arrangement the power and control system, the assembly platform, the control arm, the activation mechanism, the housing, and other components
of the drug pump do not need to be sterilized. This greatly improves the manufacturability of the device and reduces associated assembly costs. Accordingly, the devices 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 drive mechanism 100, drive mechanism 500, or a number of other variations of the drive mechanism described herein.

**[0096]** Manufacturing of a drug pump includes the step of attaching both the drive mechanism and drug 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 fluid pathway connection, drug container, and insertion mechanism to the assembly platform or housing. The additional components of the drug 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.

**[0097]** A method of operating the drug pump 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 drive control mechanism to drive fluid drug flow through the drug pump. 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 connection to a drug container. 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 connection, a sterile fluid conduit, and the insertion mechanism for delivery of the fluid drug to the body of a user. The method of operation of the insertion mechanism and the drug pump may be better appreciated with reference to FIGS. 4A-4E, as described above.

**[0098]** Throughout the specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Various changes and modifications may be made to the embodiments described and illustrated without departing from the present invention.

# REFERENCES CITED IN THE DESCRIPTION

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**Patent documents cited in the description**


- WO2011046950A **[0006]**
- WO2010112377A **[0007]**
- WO2013033467A **[0008]**

Patentkrav

1. Drivmekanisme til lægemiddelpumpe (2100) til anvendelse ved samvirkning med en lægemiddelbeholder (2050), der indbefatter en stempelforsegling (2060), hvilken drivmekanisme (2100) omfatter:
et drivhus (2130), der indbefatter en akse;
et stempel (2110), der er disponeret til bevægelse fra mindst en tilbagetrukket første position til en fremskudt anden position langs aksen, hvor stemplet (2110) er indrettet til at overføre bevægelse til stempelforseglingen (2060) i lægemiddelbeholderen (2050);
en flerhed af påvirkningsdele (2106, 2122), der er disponeret til at fungere parallelt og indrettet til at bevæge sig fra en spændt første position til en afspændt anden position som følge af frigivelsen af energi; og
et fikseringsmiddel (2115), hvilket fikseringsmiddel (2115) er bevægeligt mellem en fikserende første position og en frigørende anden position, og hvilket fikseringsmiddel (2115) er disponeret til opretholdelse af påvirkningsdelene (2106, 2122) i den spændte første position, når fikseringsmidlet (2115) er i den fikserende første position, og til frigørelse af påvirkningsdelene (2106, 2122) fra den første spændte position, når fikseringsmidlet (2115) bevæges til den frigørende anden position,
hvor påvirkningsdelene (2106, 2122) er disponeret, så de forårsager bevægelse af stemplet (2110) fra den tilbagetrukne første position til den fremskudte anden position, når påvirkningsdelene (2106, 2122) bevæges fra den spændte første position til den afspændte anden position.

2. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 1, hvor flerheden af påvirkningsdele (2106, 2122) indbefatter mindst én af en trækfjeder eller en kompressionsfjeder.

3. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 1, hvor flerheden af påvirkningsdele (2106, 2122) indbefatter en par koncentrisk disponerede kompressionsfjedre.

4. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 3, hvor kompressionsfjedrene er koncentrisk disponeret omkring mindst en del af stemplet (2110).

5. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 1, hvor fikseringsmidlet (2115) går i indgreb med mindst en del af stemplet (2110) til fiksering af stemplet (2110) i dets tilbagetrukne position, når fikseringsmidlet (2115) er i dets fikserende første position.

6. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 5, hvor stemplet (2110) indbefatter en låserille, og fikseringsmidlet (2115) er mindst delvist modtaget i låserillen til fiksering af stemplet (2110) i dets tilbagetrukne første position, når fikseringsmidlet (2115) er i dets fikserende første position.

7. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 6, hvor fikseringsmidlet (2115) hviler mod en ydre overflade af drivhuset (2130), når fikseringsmidlet (2115) er i dets fikserende første position.

8. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 1, der yderligere indbefatter en muffesamling (2120), der er disponeret omkring mindst én af flerheden af påvirkningsdele (2106, 2122).

9. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 8, hvor muffesamlingen (2120) indbefatter en flerhed af teleskopiske muffer (2124, 2126).

10. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 8, hvor muffesamlingen (2120) er disponeret omkring flerheden af påvirkningsdele (2106, 2122).

11. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 8, hvor muffesamlingen (2120) er disponeret, så de bevæges

aksialt med stemplet (2110).

12. Drivmekanisme til lægemiddelpumpe (2100) ifølge et hvilket som helst af kravene 1 til 11, der yderligere indbefatter en slut-på-dosis-indikator (2133).

13. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 12, hvor drivhuset (2130) indbefatter mindst ét vindue (2131), idet mindst en del af muffesamlingen (2120) er synlig gennem vinduet (2131), idet muffesamlingen (2120) er indrettet til at bevæge sig langs aksen med stemplet (2110), og mindst delen af muffesamlingen (2120) er synlig gennem vinduet (2131), indtil stemplet (2110) er i den fremskudte anden position.

14. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 13, der yderligere indbefatter en slut-på-dosis-indikator (2133), der er disponeret i det væsentlige tilstødende vinduet (2131), idet slut-på-dosis-indikatoren (2133) er indrettet til at identificere mindst den ene af, når muffesamlingen (2120) er disponeret underliggende vinduet (2131), og når muffesamlingen ikke er disponeret underliggende vinduet (2131), den relative bevægelse af muffesamlingen (2120) i forhold til vinduet (2131) eller en anden referencekomponent, standsningen af en sådan bevægelse og hastigheden eller hastighedsændringen af bevægelse.

15. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 14, hvor slut-på-dosis-indikatoren (2133) indbefatter en sensor (2134), der er disponeret til at føle mindst én af, når muffesamlingen (2120) er disponeret underliggende vinduet (2131), og når muffesamlingen (2120) ikke er disponeret underliggende vinduet (2131).

16. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 15, hvor sensoren (2134) er mindst én af en mekanisk sensor, en elektrisk sensor, en ultralydssensor, en kapacitiv sensor, en magnetisk sensor eller en optisk sensor.

17. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 16, hvor sensoren (2134) er en mekanisk sensor (2134), der er disponeret til at hvile mod muffesamlingen (2120), når muffesamlingen (2120) er disponeret underliggende vinduet (2131).

18. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 17, hvor muffesamlingen (2120) har en sporkant (2126B), og den mekaniske sensor (2134) er disponeret i en første position, der hviler mod muffesamlingen (2120), når stemplet (2110) er i den tilbagetrukne første position, og en udløst anden position, når sporkanten af muffesamlingen (2120) bevæges aksialt forbi vinduet (2131).

19. Drivmekanisme til lægemiddelpumpe (2100) ifølge krav 15, hvor sensoren (2134) er indrettet, så den kan elektrisk tilkobles et strømforsynings- og styresystem (2400), der er forbundet med lægemiddelpumpen (2010).

# DRAWINGS

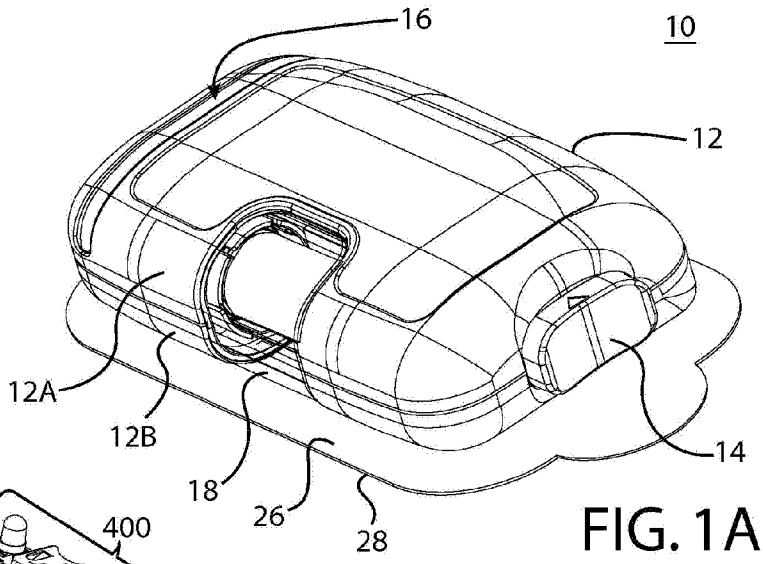



FIG. 1A

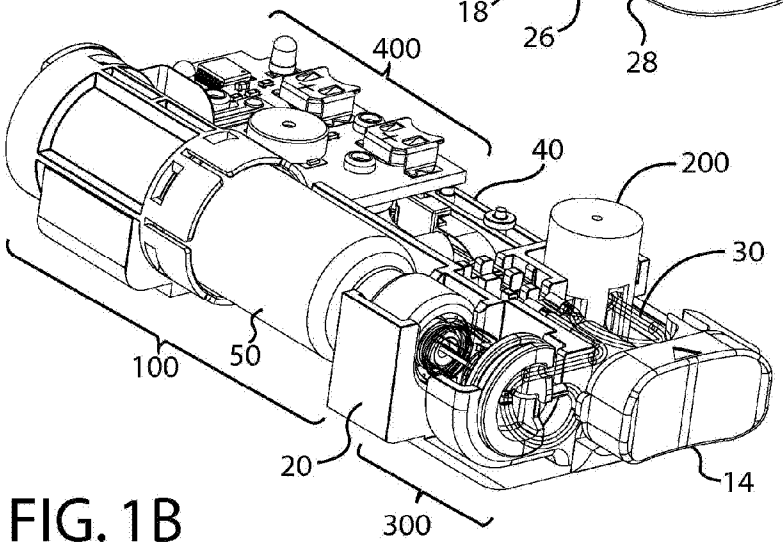



FIG. 1B

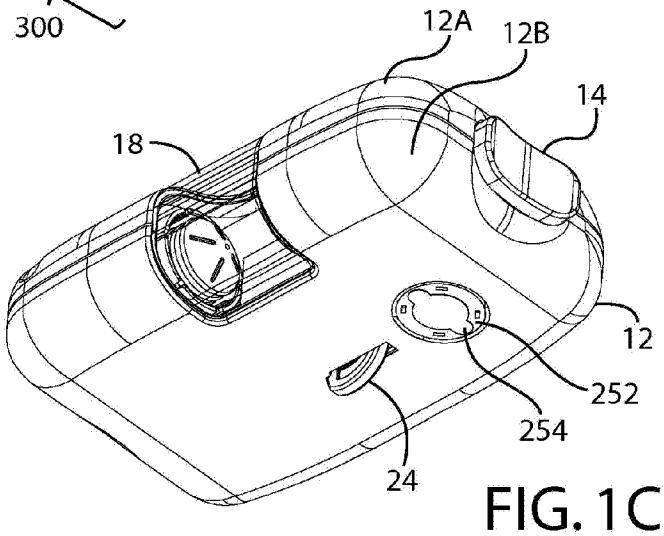



FIG. 1C

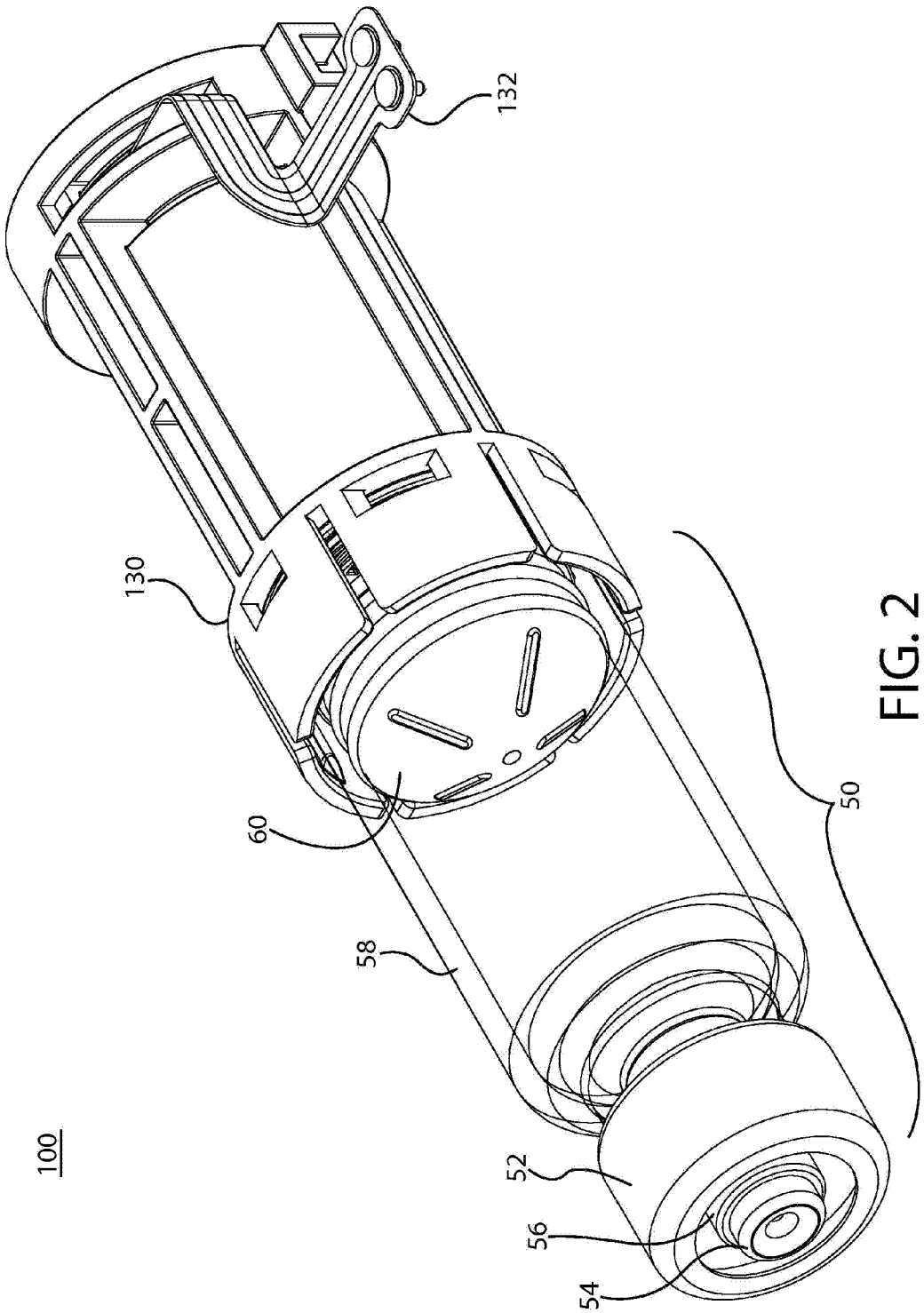
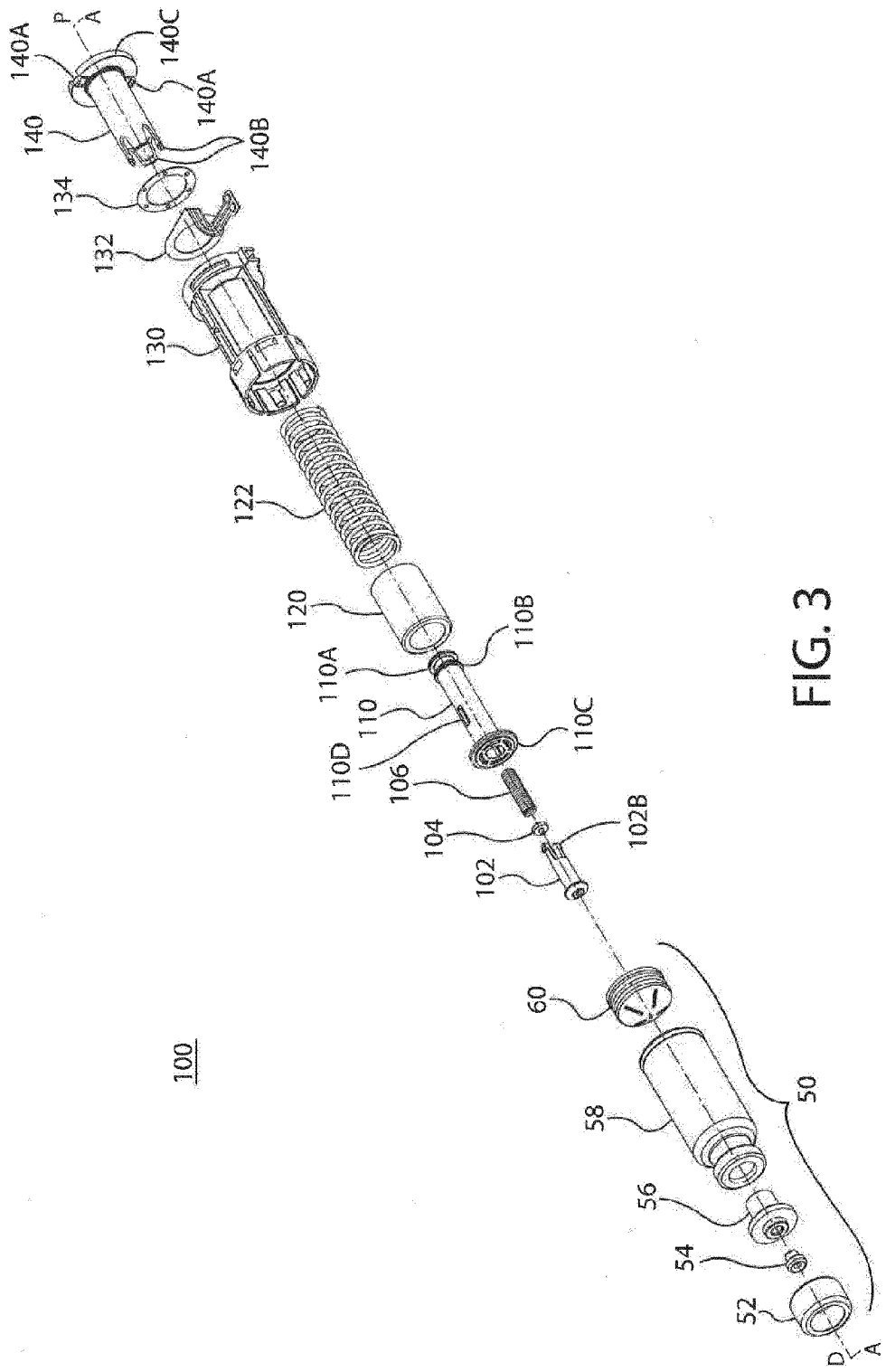



FIG. 2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P
A
140C
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134
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130
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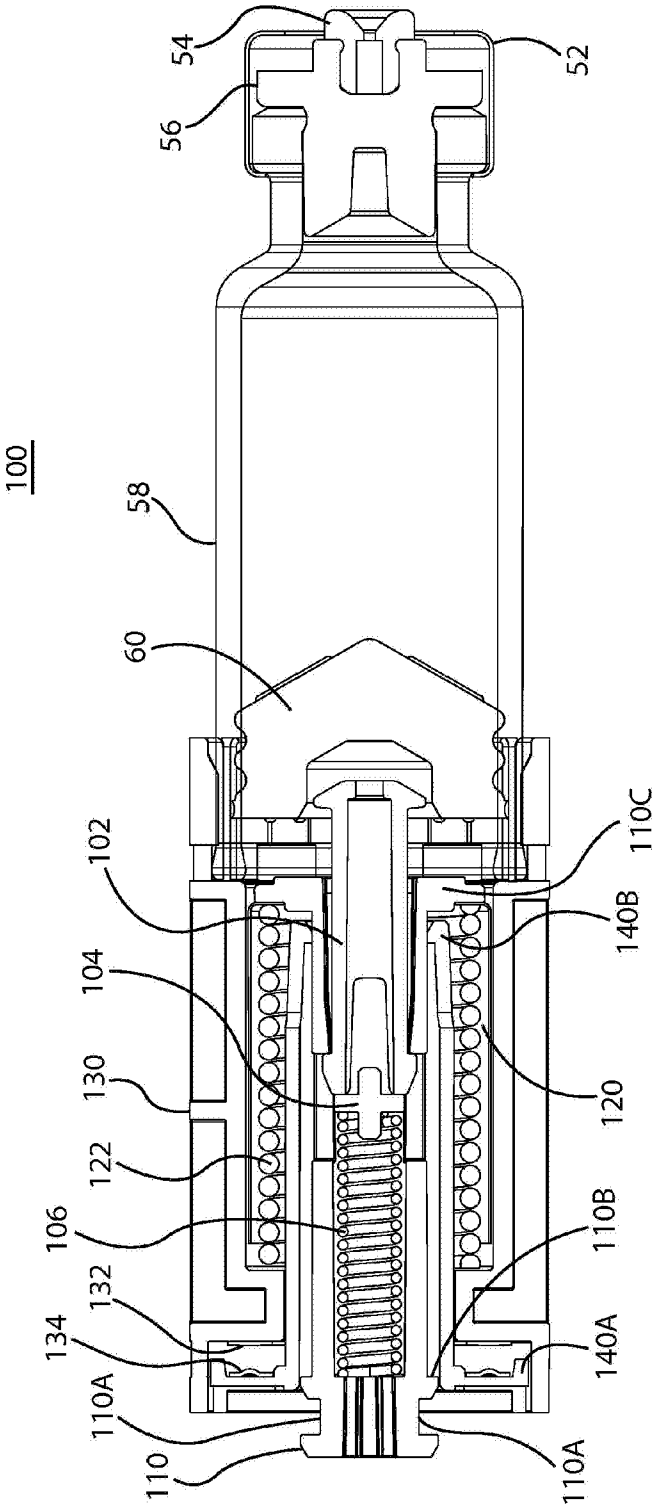
110D
106
104
102B
102
60
58
50
56
54
52
D
A

FIG. 3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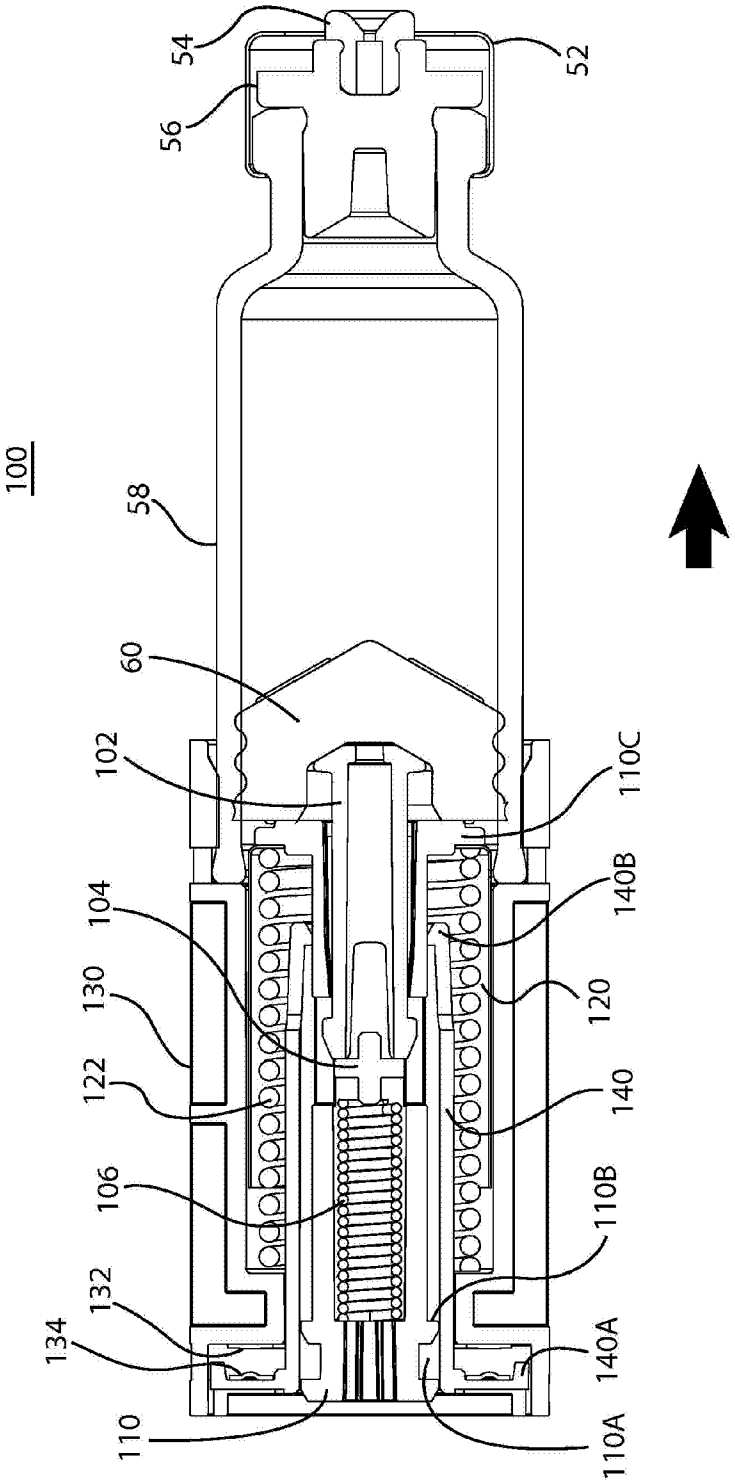
110A

FIG. 4A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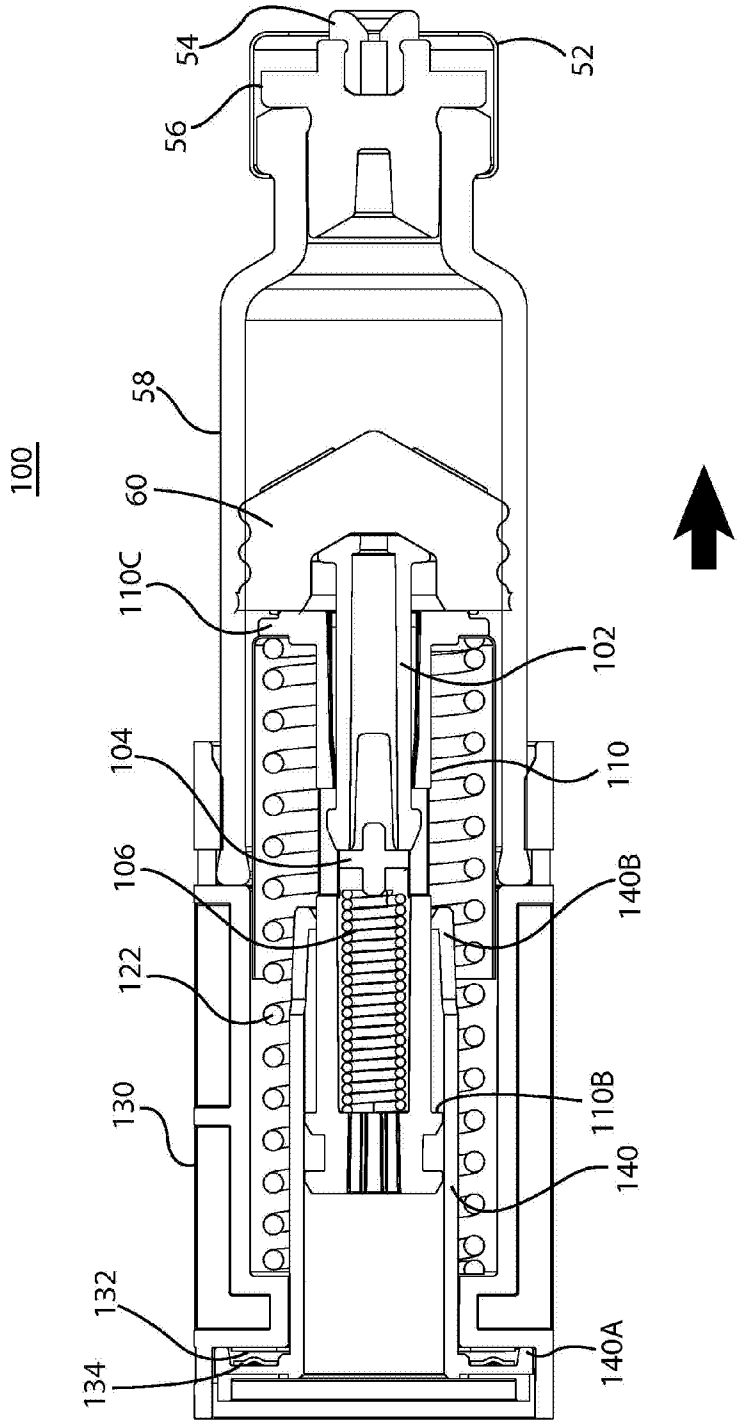
110
110A

FIG. 4B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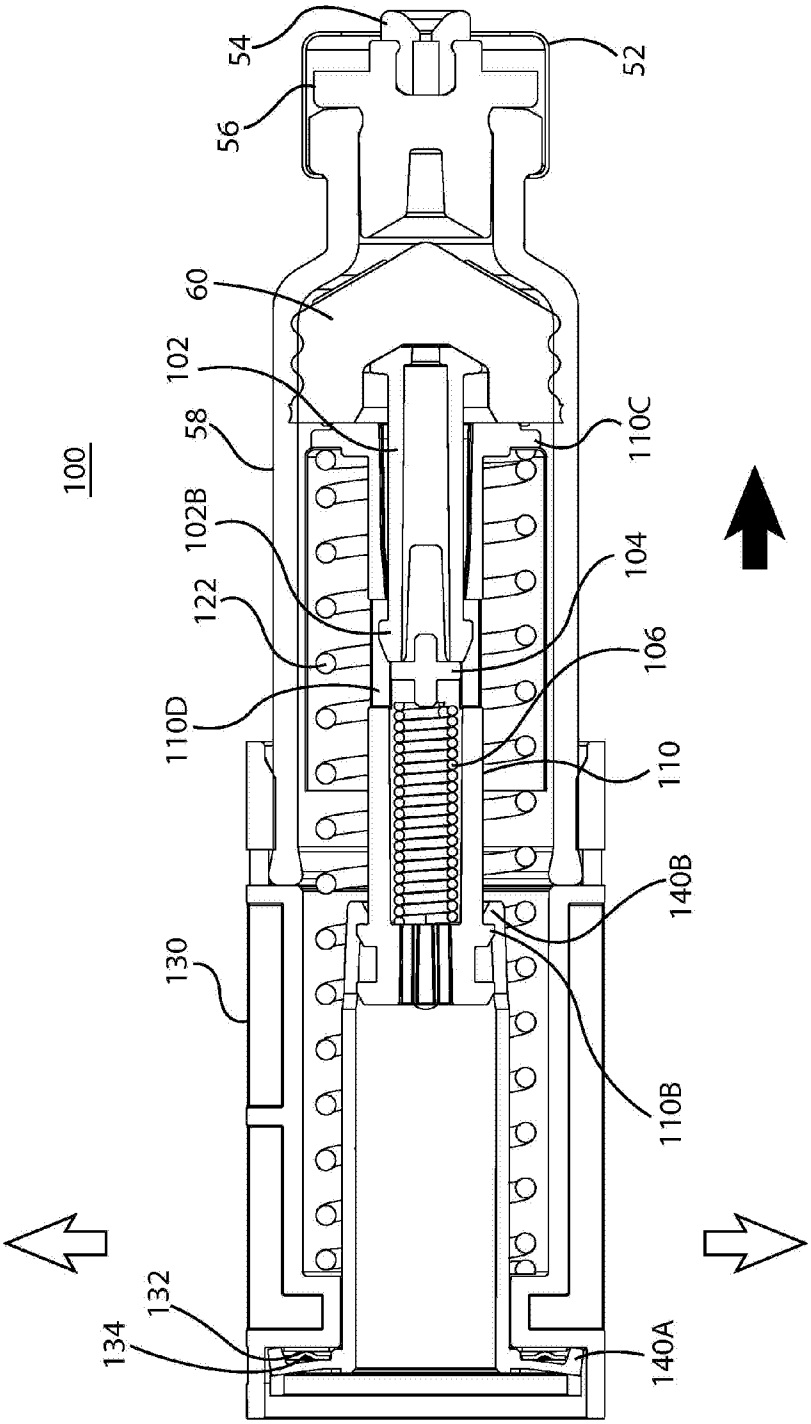
134
140A

FIG. 4C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140A

FIG. 4D

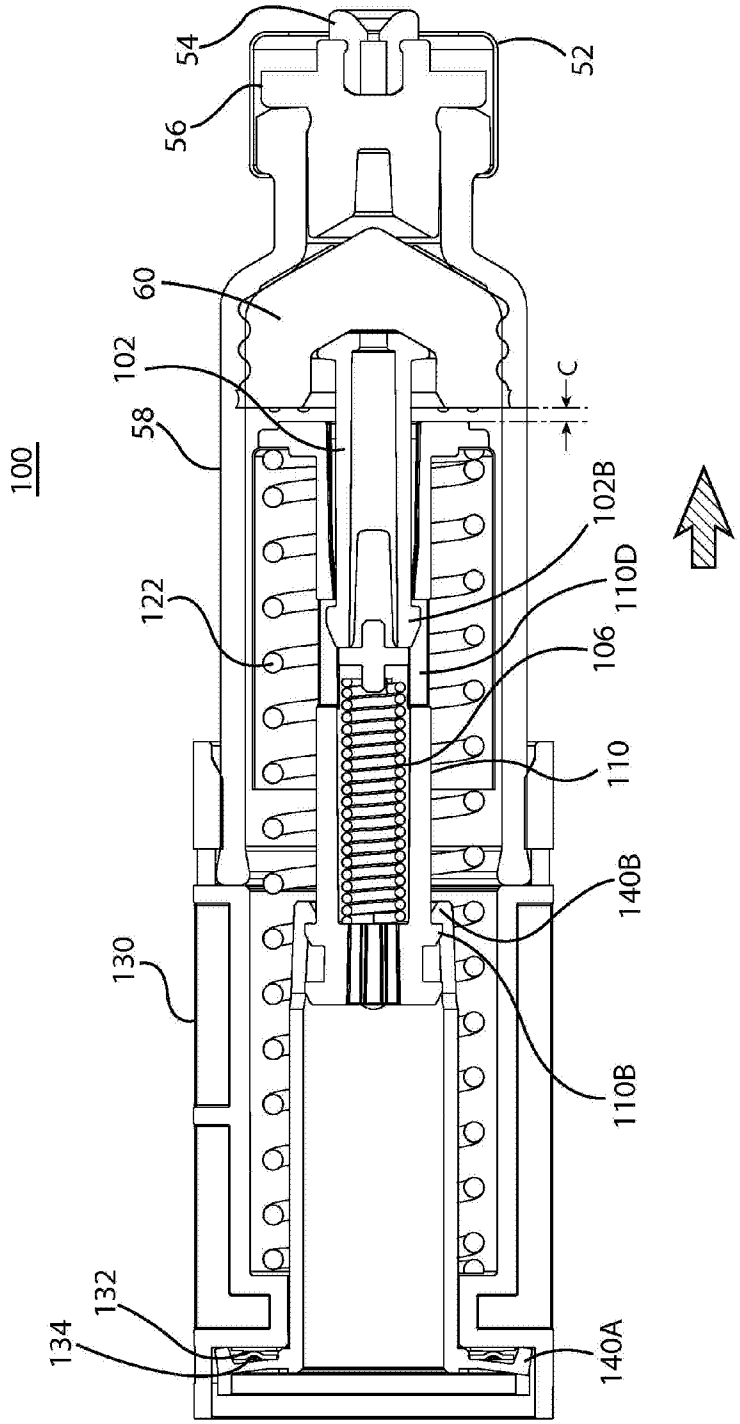
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FIG. 4E

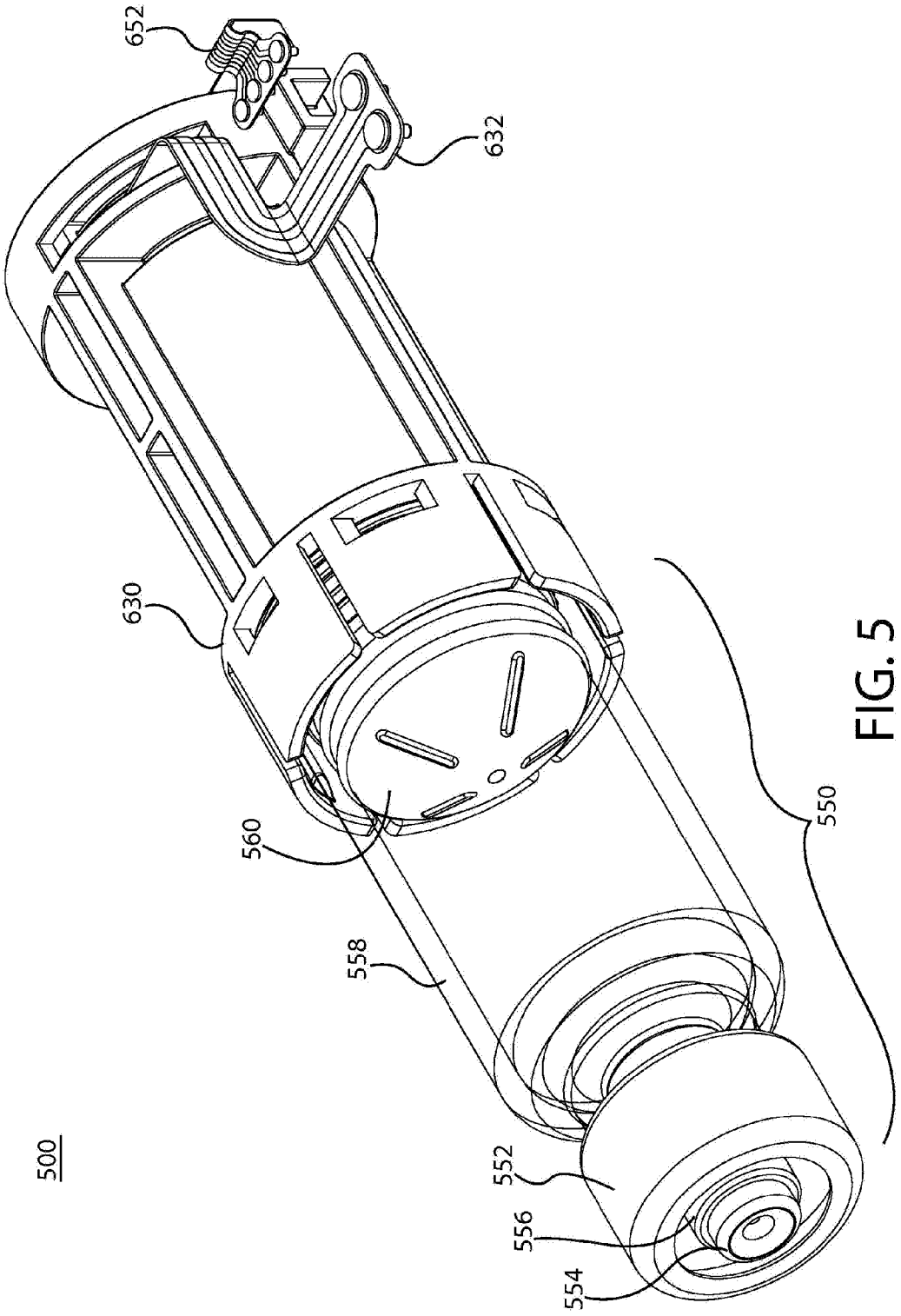
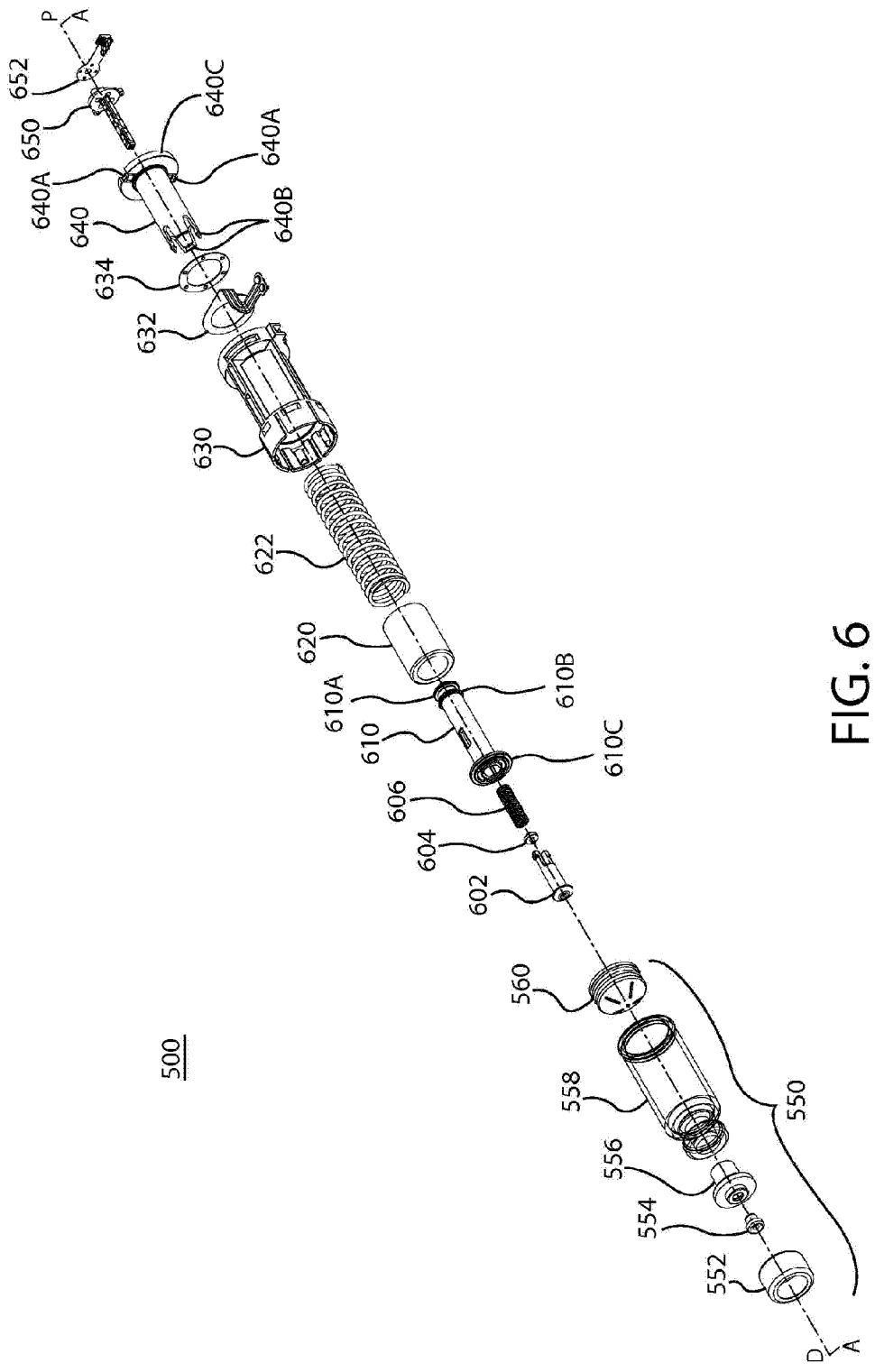



FIG. 5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610C
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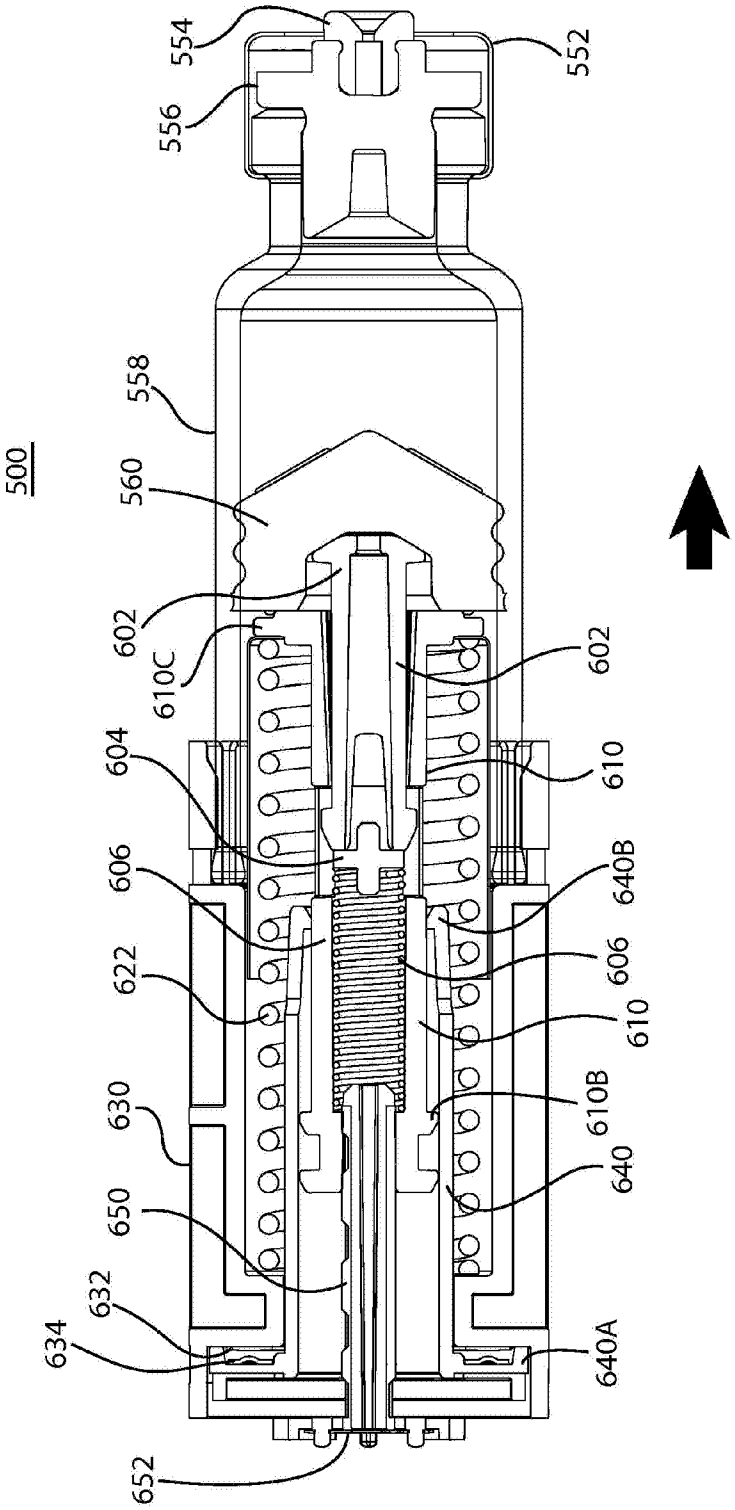
P
A
D
A

FIG. 6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640A
652

FIG. 7

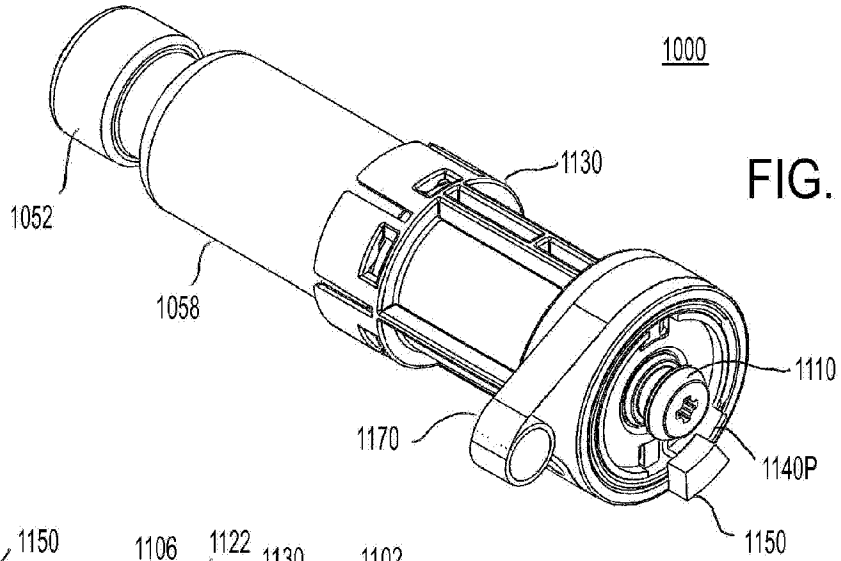



FIG. 8

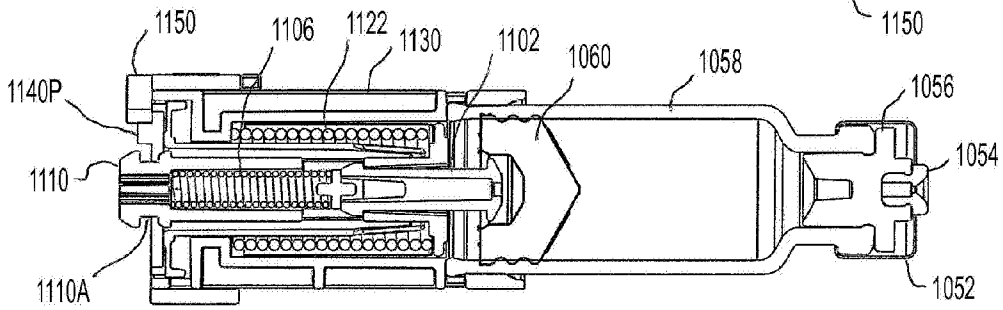



FIG. 9A

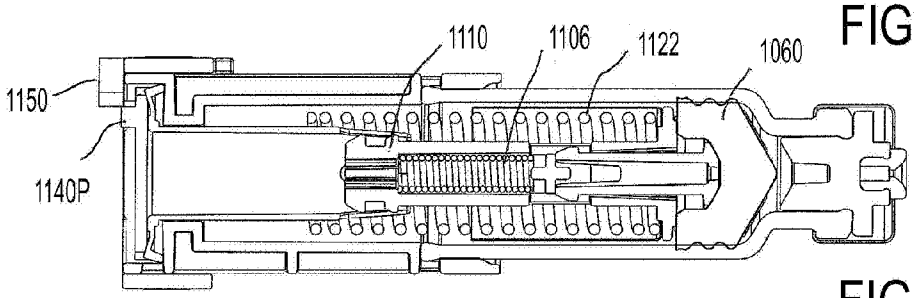



FIG. 9B

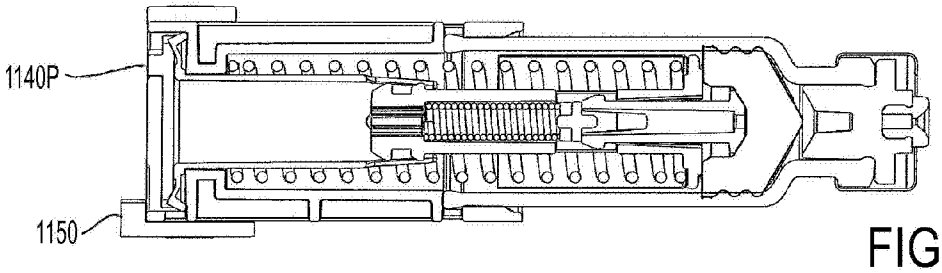



FIG. 9C

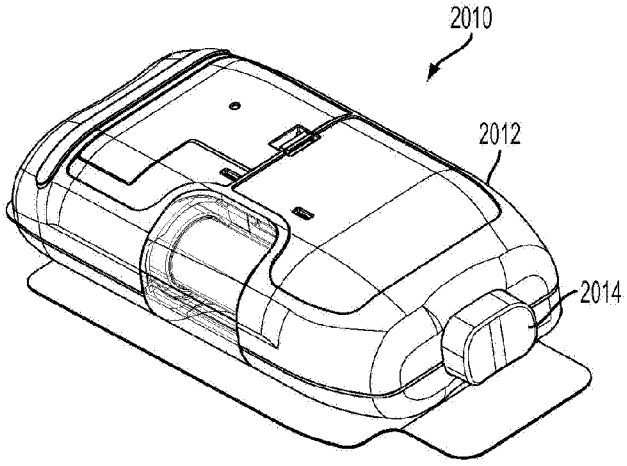



FIG. 10A

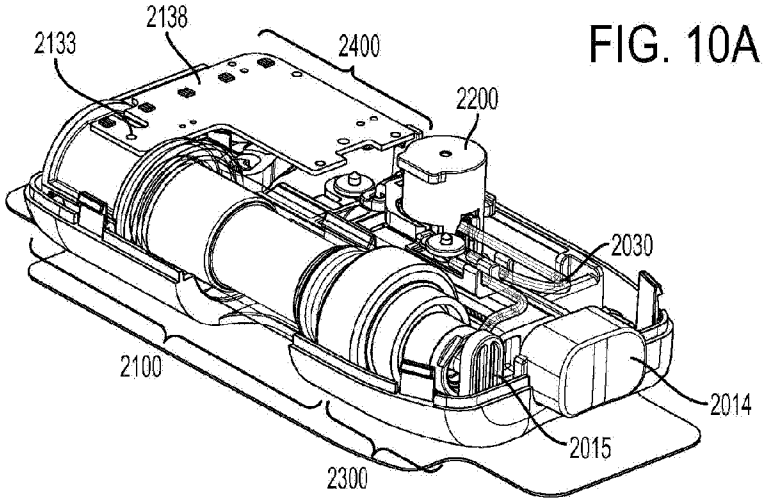



FIG. 10B

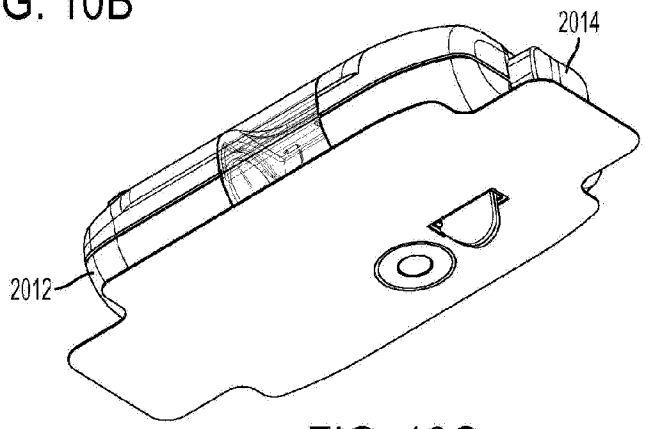



FIG. 10C

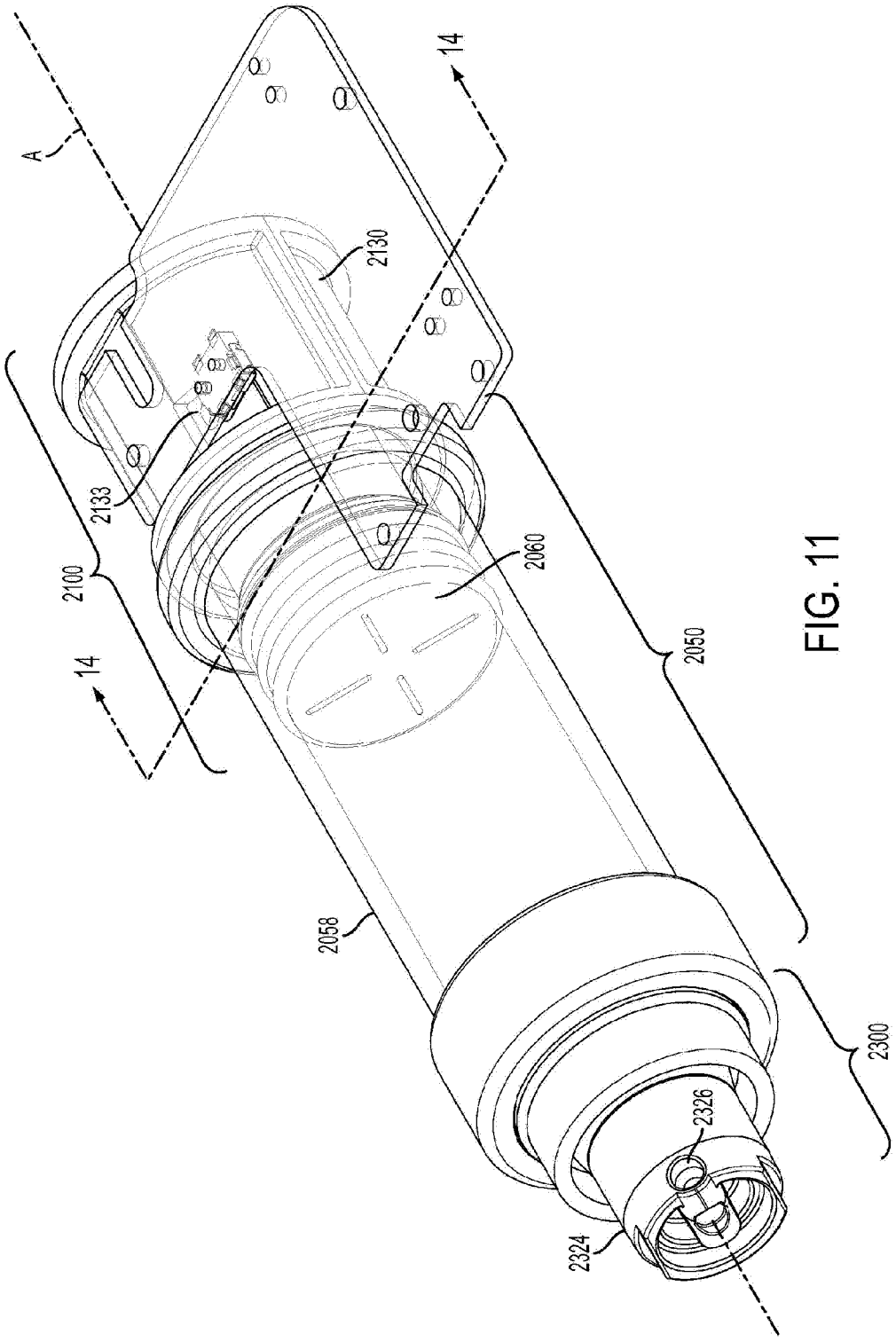
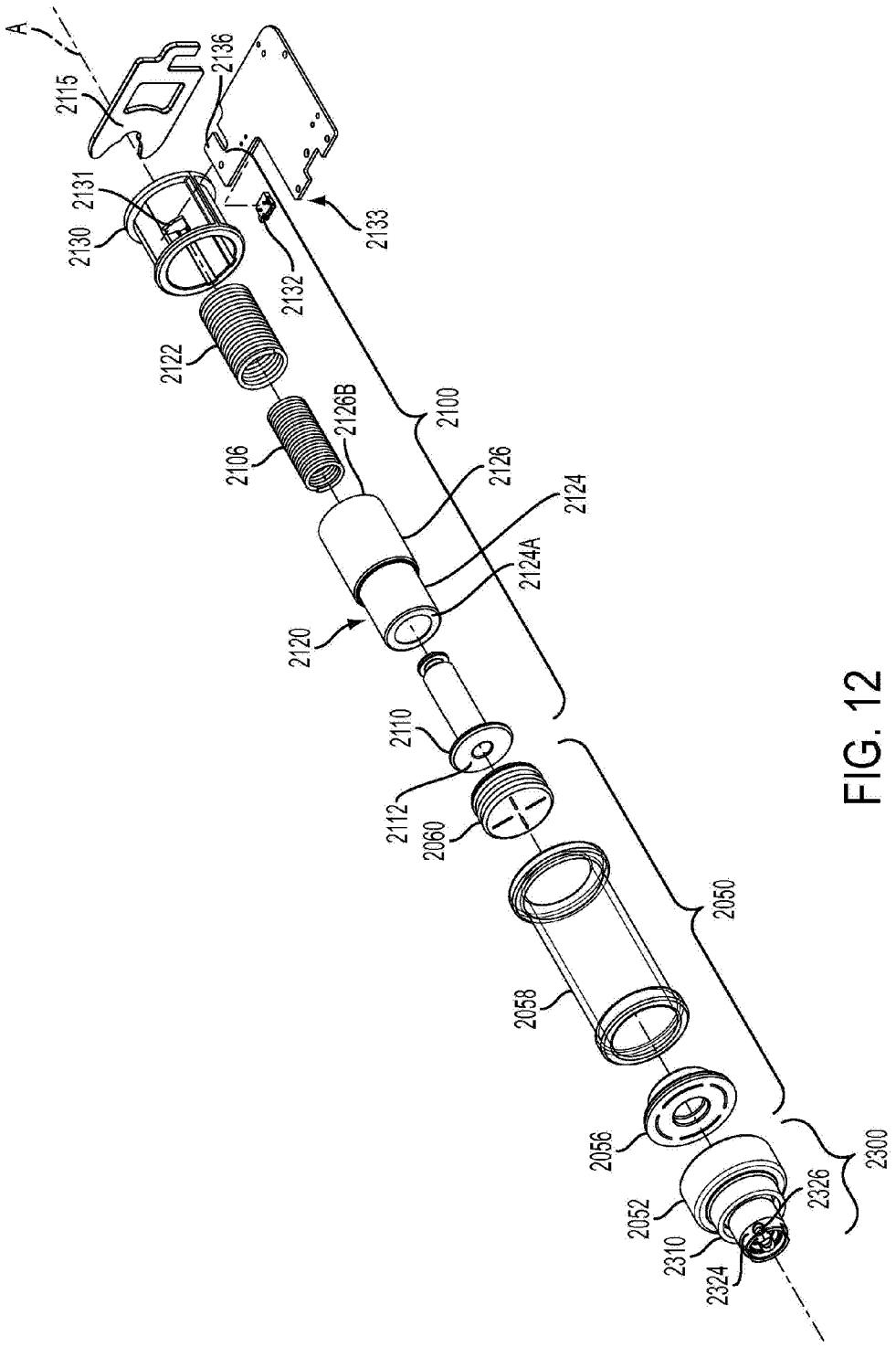



FIG. 11


A
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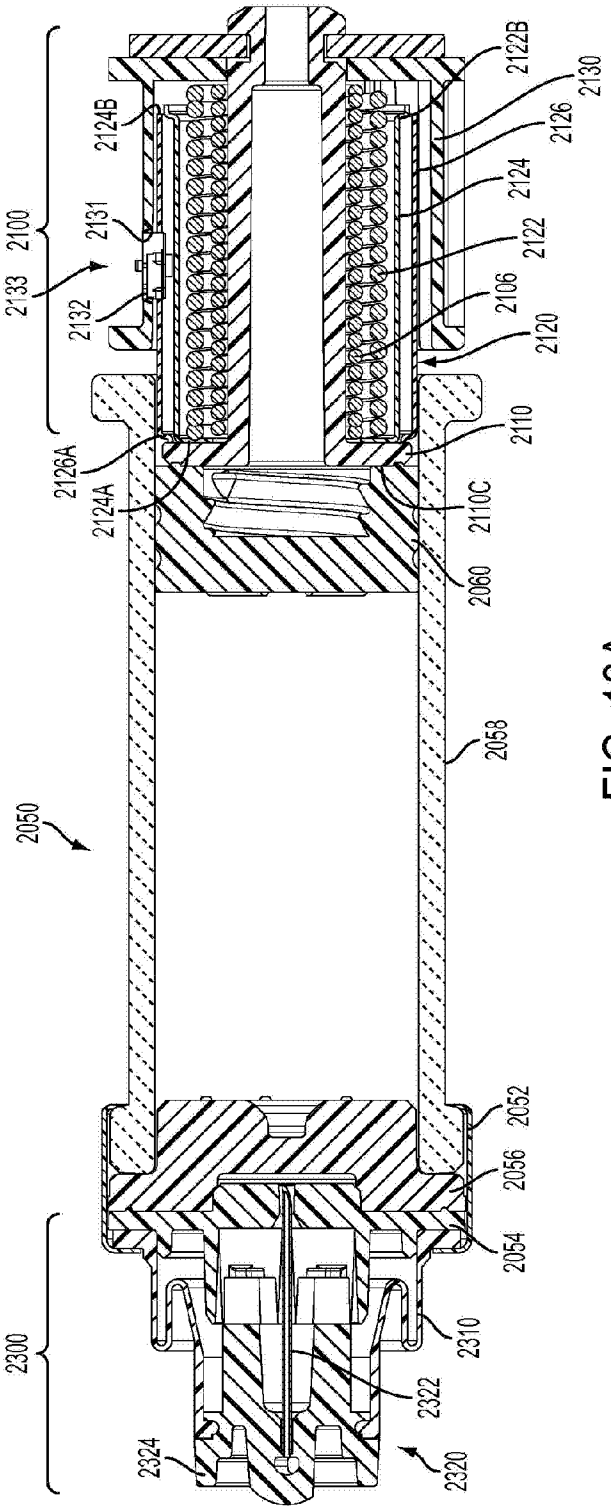
2326
2300

FIG. 12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2320

FIG. 13A

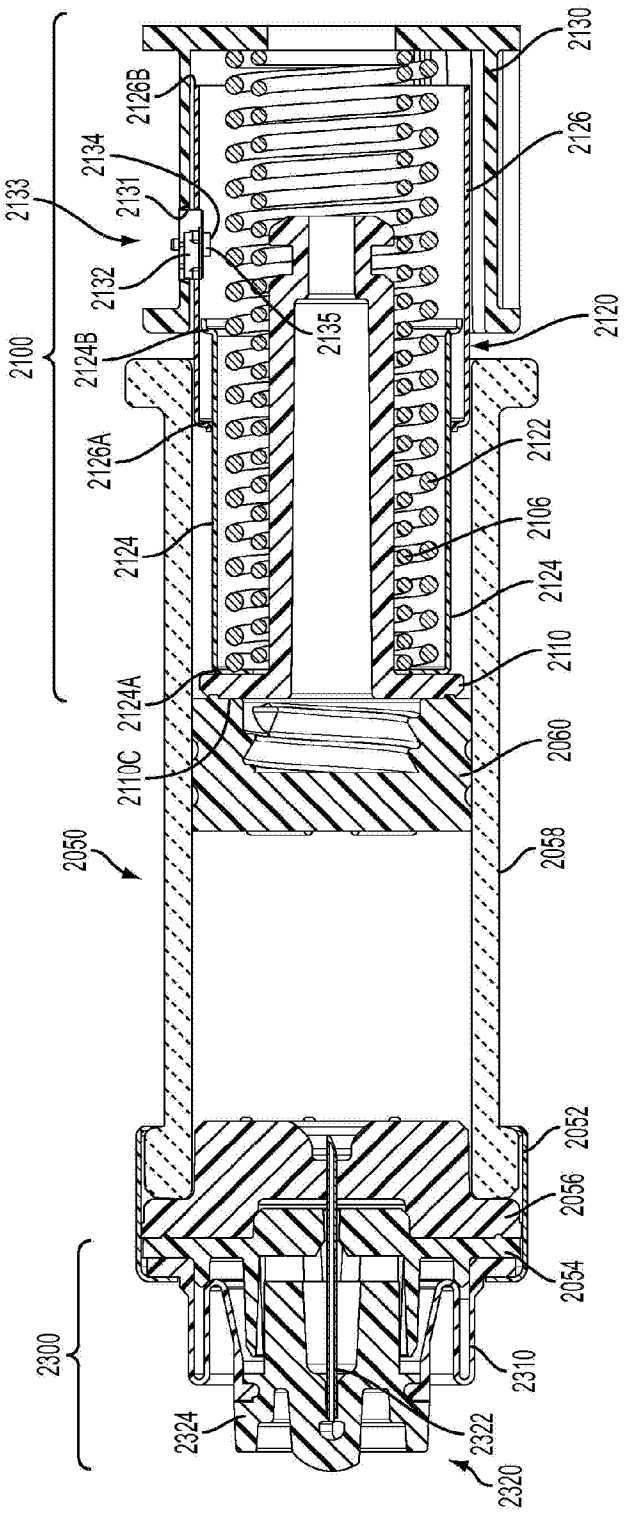
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FIG. 13B

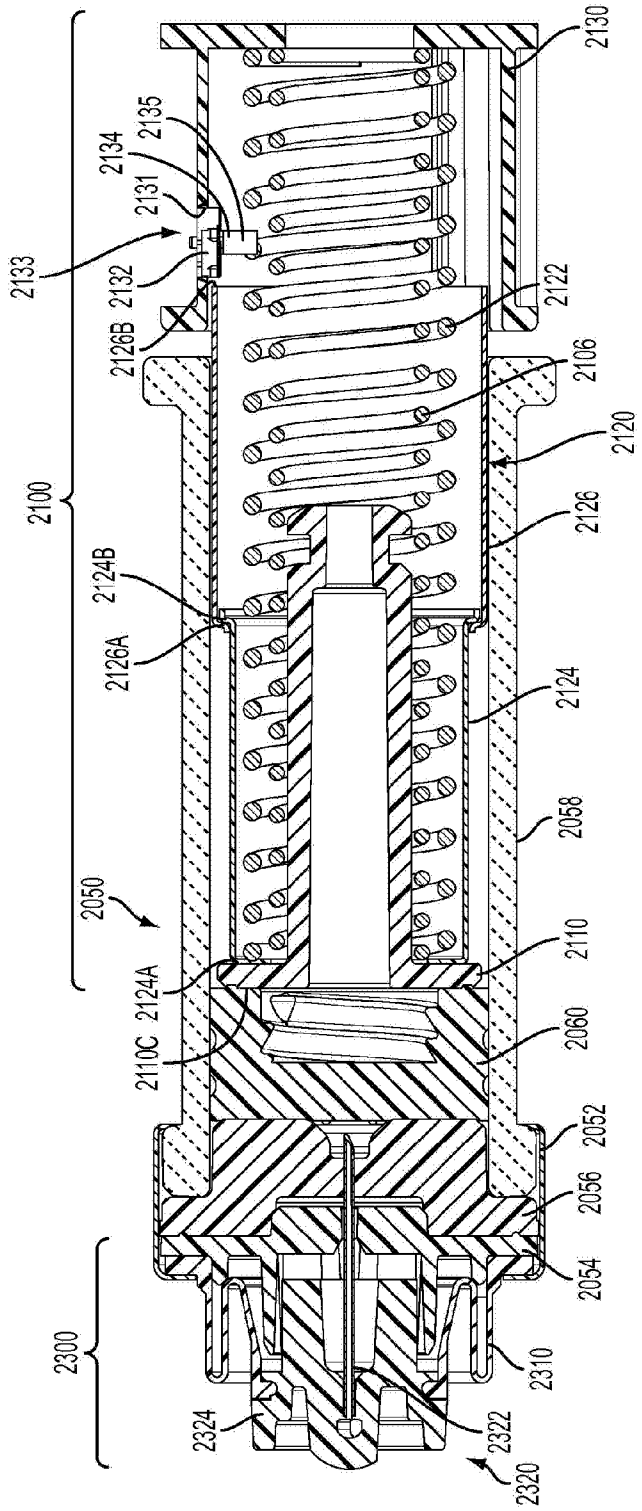
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FIG. 13C

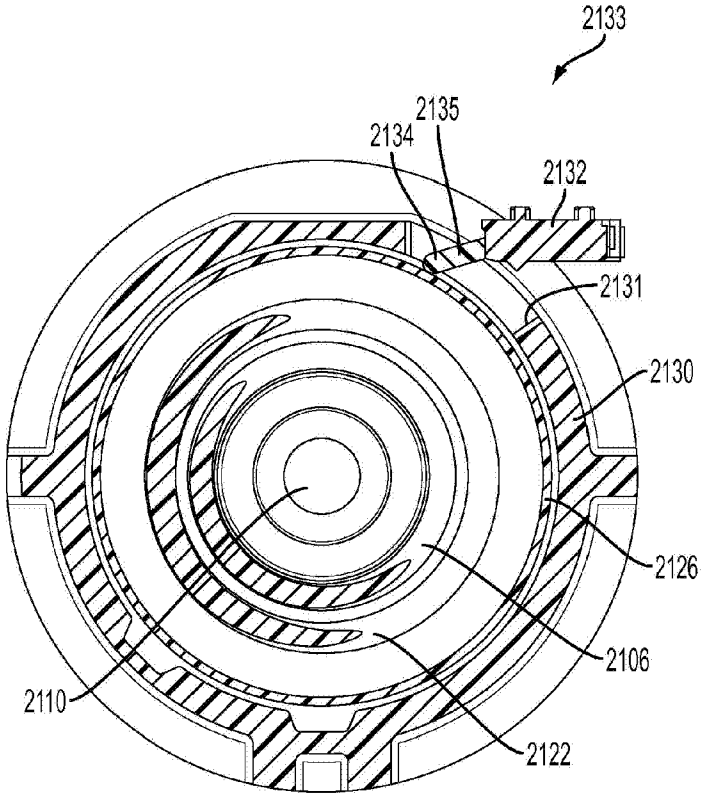


FIG. 14A

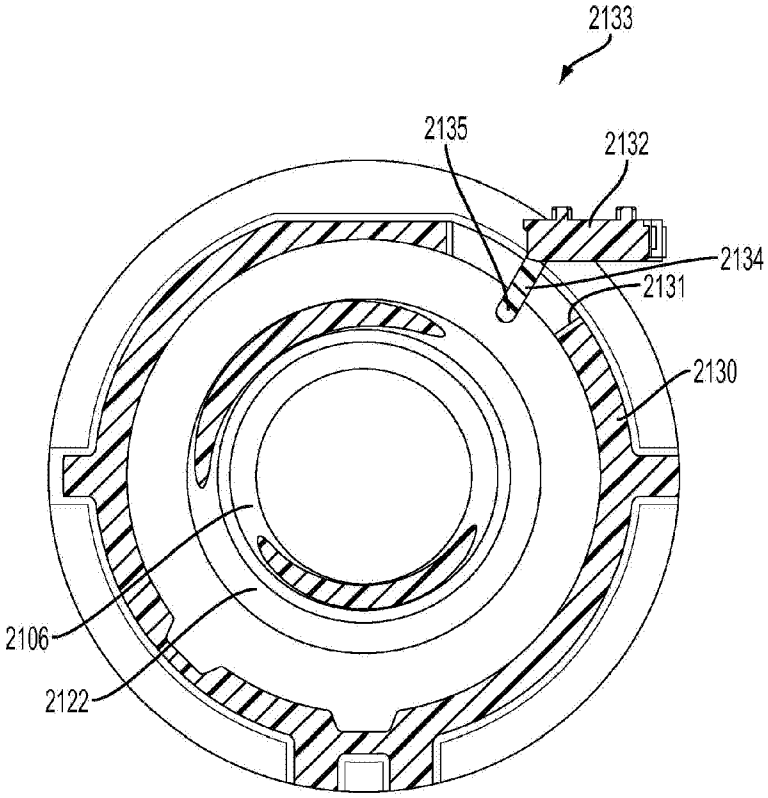


FIG. 14B