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(54) Title: AUTO-INJECTOR WITH CAP

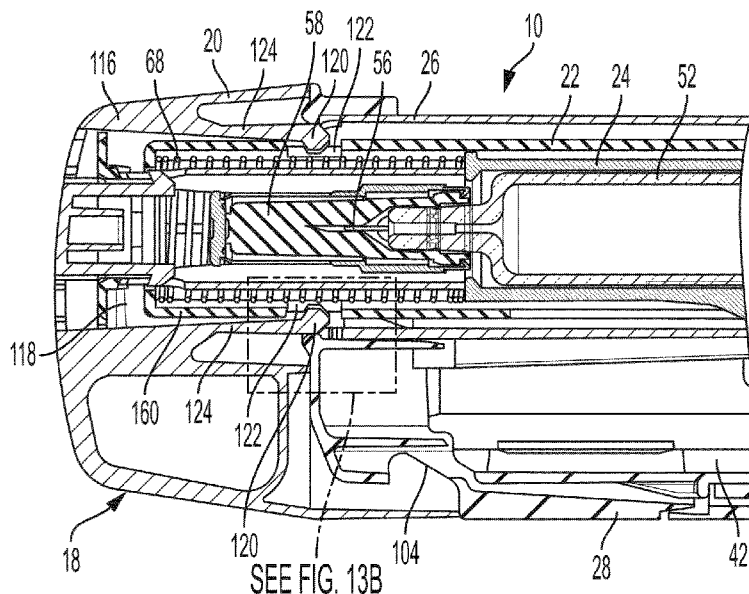


FIG. 13A

(57) Abstract: A drug delivery device (10) includes a housing (26), a syringe assembly (16) including a barrel (52), a stopper (54), a cannula (56), and a rigid needle shield (58) receiving at least a portion of the cannula, with at least a portion of the syringe assembly positioned within the housing, a drive assembly (40), with at least a portion of the drive assembly positioned within the housing, a cap (18) secured to the housing, with the cap including an outer portion (20) defining an interior space and a retainer (160) comprising a body with a removal projection (164) configured to remove the rigid needle shield upon axial movement of the outer portion of the cap away from the housing, and a needle cover (22) having a pre-use position, an actuation position, and a post-use position. The outer portion receives a portion of the needle cover, with the outer portion configured to prevent movement of the needle cover from the pre-use position to the actuation position.



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## **AUTO-INJECTOR WITH CAP**

### **BACKGROUND OF THE INVENTION**

#### Field of the Disclosure

[0001] The present disclosure relates generally to a drug delivery device and, more specifically, to an auto-injector.

#### Description of the Related Art

[0002] Various types of automatic injection devices have been developed to allow drug solutions and other liquid therapeutic preparations to be administered by untrained personnel or to be self-injected. Generally, these devices include a reservoir that is pre-filled with the liquid therapeutic preparation, and some type of automatic needle-injection mechanism that can be triggered by the user. Many of these devices, such as auto-injectors, are designed so that the reservoir, such as a pre-filled syringe, is assembled into the device during assembly of the device. In addition to automatically deploying the needle-injection mechanism, many drug delivery devices also automatically shield the needle after use of the device to prevent any unintended contact with the needle.

### **SUMMARY OF THE INVENTION**

[0003] In one aspect, a drug delivery device includes a housing, a syringe assembly including a barrel, a stopper, a cannula, and a rigid needle shield receiving at least a portion of the cannula, with at least a portion of the syringe assembly positioned within the housing, a drive assembly configured to move the stopper within the barrel upon actuation of the drive assembly, with at least a portion of the drive assembly positioned within the housing, a cap secured to the housing, with the cap including an outer portion defining an interior space and a retainer comprising a body with a removal projection configured to remove the rigid needle shield upon axial movement of the outer portion of the cap away from the housing, and a needle cover having a pre-use position where the cannula is positioned within the needle cover, an actuation position where the drive assembly is actuated, and a post-use position where the cannula is positioned within the needle cover. The outer portion receives a portion of the needle cover, with the outer portion configured to prevent movement of the needle cover from the pre-use position to the actuation position.

**[0004]** The outer portion includes a protrusion received by a cap opening defined by the needle cover, with the protrusion of the outer portion configured to engage the needle cover upon movement of the needle cover from the pre-use position to the actuation position.

**[0005]** A portion of the retainer may be received within the interior space of the outer portion, with the retainer secured to and axially moveable relative to the outer portion. The outer portion may include a retaining tab received by a retainer opening defined by the body of the retainer, with the retaining tab disengaged from the body of the retainer when the outer portion is secured to the housing, and the retaining tab of the outer portion configured to engage the retainer upon axial movement of the outer portion away from the housing and upon axial movement of the outer portion relative to the retainer. The retainer may include a pair of wings extending radially outward from the body of the retainer, with each wing configured to engage a rib extending radially inward from a body of the outer portion.

**[0006]** The retaining tab may extend radially outward through the retainer opening of the retainer. The retaining tab of the outer portion may be secured to the body of the cap via an extension arm, with the retaining tab moveable radially inward via the extension arm. The retainer may include a flange engaged with the outer portion when the outer portion is secured to the housing. The flange of the retainer may be spaced from the outer portion upon axial movement of the outer portion away from the housing. The surface of the removal projection may be planar and the corresponding surface of the rigid needle shield may be planar.

**[0007]** The body of the retainer may include a first end and a second end positioned opposite the first end, with the removal projection extending radially inward from body of the retainer via a removal arm, and the removal arm extending radially inward and in a direction extending from the second end of the body to the first end of the body. The removal projection may be moveable relative to the body of the retainer via the removal arm.

**[0008]** The device may further include a syringe holder positioned within the housing, with the syringe holder receiving the syringe assembly, and the syringe holder moveable relative to the housing. The syringe holder may be disengaged with the drive assembly when the outer portion is secured to the housing, with the syringe holder engaged with the drive assembly upon axial movement of the outer portion away from the housing.

**[0009]** A surface of the removal projection may be configured to engage a corresponding surface of the rigid needle shield to remove the rigid needle shield upon axial movement of the

outer portion of the cap away from the housing, with the surface of the removal projection is disengaged from the corresponding surface of the rigid needle shield when the outer portion is secured to the housing. The protrusion may be configured to be removed from the cap opening before the surface of the removal projection engages the corresponding surface of the rigid needle shield upon axial movement of the outer portion away from the housing.

**[0010]** The outer portion may include one of a lock protrusion and a lock recess and the housing may include the other of the lock protrusion and the lock recess, with the lock protrusion received by the lock recess to secure the outer portion to the housing, and where the lock protrusion is separated from the lock recess before the surface of the removal projection engages the corresponding surface of the rigid needle shield upon axial movement of the outer portion away from the housing.

**[0011]** The device may include one or several of the following features, taken individually or according to all technical possible combinations:

- the drug delivery device may comprise: a housing; a syringe assembly comprising a barrel, a stopper, a cannula, and a rigid needle shield receiving at least a portion of the cannula, at least a portion of the syringe assembly positioned within the housing; a drive assembly configured to move the stopper within the barrel upon actuation of the drive assembly, at least a portion of the drive assembly positioned within the housing; a cap secured to the housing, the cap comprises an outer portion defining an interior space and a retainer comprising a body with a removal projection, the removal projection configured to remove the rigid needle shield upon axial movement of the outer portion of the cap away from the housing, and a needle cover having a pre-use position where the cannula is positioned within the needle cover, an actuation position where the drive assembly is actuated, and a post-use position where the cannula is positioned within the needle cover, wherein the outer portion receives a portion of the needle cover, the outer portion configured to prevent movement of the needle cover from the pre-use position to the actuation position;
- the outer portion may include a protrusion received by a cap opening defined by the needle cover, the protrusion of the outer portion is configured to engage the

- needle cover upon movement of the needle cover from the pre-use position to the actuation position;
- a portion of the retainer may be received within the interior space of the outer portion of the cap, and wherein the retainer is secured to and axially moveable relative to the outer portion.
  - the outer portion may comprise a retaining tab received by a retainer opening defined by the body of the retainer, the retaining tab is disengaged from the body of the retainer when the outer portion is secured to the housing, the retaining tab of the outer portion is configured to engage the retainer upon axial movement of the outer portion away from the housing and upon axial movement of the outer portion relative to the retainer;
  - the retainer may comprise a pair of wings extending radially outward from the body of the retainer, each wing configured to engage a rib extending radially inward from a body of the outer portion;
  - the retaining tab may extend radially outward through the retainer opening of the retainer;
  - the retaining tab of the outer portion may be secured to the body of the outer portion via an extension arm, the retaining tab moveable radially inward via the extension arm;
  - the retainer may comprise a flange engaged with the outer portion when the outer portion is secured to the housing.
  - the flange of the retainer may be spaced from the outer portion upon axial movement of the outer portion away from the housing;
  - the surface of the removal projection may be planar, and wherein the corresponding surface of the rigid needle shield is planar.
  - the body of the retainer may comprise a first end and a second end positioned opposite the first end, the removal projection extending radially inward from the body of the retainer via a removal arm, the removal arm extending radially inward and in a direction extending from the second end of the body to the first end of the body;

- the removal projection is moveable relative to the body of the retainer via the removal arm;
- a syringe holder may be positioned within the housing, the syringe holder receiving the syringe assembly, the syringe holder moveable relative to the housing, wherein the syringe holder is disengaged with the drive assembly when the outer portion is secured to the housing, and wherein the syringe holder is engaged with the drive assembly upon axial movement of the outer portion away from the housing;
- a surface of the removal projection may be configured to engage a corresponding surface of the rigid needle shield to remove the rigid needle shield upon axial movement of the outer portion of the cap away from the housing, the surface of the removal projection is disengaged from the corresponding surface of the rigid needle shield when the outer portion is secured to the housing;
- the outer portion may comprise one of a lock protrusion and a lock recess and the housing comprises the other of the lock protrusion and the lock recess, the lock protrusion received by the lock recess to secure the outer portion to the housing, and wherein the lock protrusion is separated from the lock recess before the surface of the removal projection engages the corresponding surface of the rigid needle shield upon axial movement of the outer portion away from the housing.
- the drug delivery device may comprise: a housing; a syringe assembly comprising a barrel, a stopper, a cannula, and a rigid needle shield receiving at least a portion of the cannula, at least a portion of the syringe assembly positioned within the housing; a drive assembly configured to move the stopper within the barrel upon actuation of the drive assembly, at least a portion of the drive assembly positioned within the housing; and a cap secured to the housing, the cap comprises an outer portion defining an interior space and a retainer comprising a body with a removal projection, wherein a surface of the removal projection is configured to engage a corresponding surface of the rigid needle shield to remove the rigid needle shield upon axial movement of the outer portion of the cap away from the housing, the surface of the removal projection is disengaged from the corresponding surface of the rigid needle shield when the outer portion is secured to the housing;

- the drug delivery device may comprise: a housing; a syringe assembly comprising a barrel, a stopper, a cannula, and a rigid needle shield receiving at least a portion of the cannula, at least a portion of the syringe assembly positioned within the housing; a drive assembly configured to move the stopper within the barrel upon actuation of the drive assembly, at least a portion of the drive assembly positioned within the housing; and a cap secured to the housing, the cap comprises an outer portion defining an interior space and a retainer comprising a body with a removal projection, wherein a portion of the retainer is received within the interior space of the outer portion of the cap, and wherein the retainer is secured to and axially moveable relative to the outer portion, the outer portion comprising a retaining tab received by a retainer opening defined by the body of the retainer, the retaining tab is disengaged from the body of the retainer when the outer portion is secured to the housing, the retaining tab of the outer portion is configured to engage the retainer upon axial movement of the outer portion away from the housing and upon axial movement of the outer portion relative to the retainer;
- the drug delivery device may comprise: a housing; a syringe assembly comprising a barrel, a stopper, a cannula, and a rigid needle shield receiving at least a portion of the cannula, at least a portion of the syringe assembly positioned within the housing; a drive assembly configured to move the stopper within the barrel upon actuation of the drive assembly, at least a portion of the drive assembly positioned within the housing; a cap secured to the housing, the cap comprises an outer portion defining an interior space and a retainer comprising a body with a removal projection; and a syringe holder positioned within the housing, the syringe holder receiving the syringe assembly, the syringe holder moveable relative to the housing, wherein the syringe holder is disengaged with the drive assembly when the outer portion is secured to the housing, and wherein the syringe holder is engaged with the drive assembly upon axial movement of the outer portion away from the housing;



### BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The above-mentioned and other features and advantages of this disclosure, and the manner of attaining them, will become more apparent and the disclosure itself will be better understood by reference to the following descriptions of embodiments of the disclosure taken in conjunction with the accompanying drawings, wherein:

[0013] FIG. 1A is a perspective view of a drug delivery device according to one aspect of the present application, showing a storage position of the device.

[0014] FIG. 1B is a perspective view of the drug delivery device of FIG. 1, showing a pre-use position of the device.

[0015] FIG. 2A is a cross-sectional view of the drug delivery device of FIG. 1, showing a storage position of the device.

[0016] FIG. 2B is a cross-sectional view of the drug delivery device of FIG. 1, showing a pre-use position of the device.

[0017] FIG. 3 is a perspective view of the drug delivery device of FIG. 1, showing an actuation position of the device.

[0018] FIG. 4 is a cross-sectional view of the drug delivery device of FIG. 1, showing an actuation position of the device.

[0019] FIG. 5 is a perspective view of the drug delivery device of FIG. 1, showing an injection position of the device.

[0020] FIG. 6 is a cross-sectional view of the drug delivery device of FIG. 1, showing an injection position of the device.

[0021] FIG. 7 is a perspective view of the drug delivery device of FIG. 1, showing a post-use position of the device.

[0022] FIG. 8 is a cross-sectional view of the drug delivery device of FIG. 1, showing a post-use position of the device.

[0023] FIG. 9 is a perspective view of the drug delivery device of FIG. 1, showing a locking clip.

[0024] FIG. 10 is an exploded perspective view of the drug delivery device of FIG. 1, showing a locking clip.

- [0025] FIG. 11A is a partial cross-sectional view of the drug delivery device of FIG. 1, showing a lock arm of a cassette body.
- [0026] FIG. 11B is an enlarged cross-sectional view of the area indicated in FIG. 11A.
- [0027] FIG. 12 is a cross-sectional view of the drug delivery device of FIG. 1, showing a post-use position of the device prior to full delivery of medicament.
- [0028] FIG. 13A is a partial cross-sectional view of the drug delivery device of FIG. 1, showing a cap of the device.
- [0029] FIG. 13B is an enlarged cross-sectional view of the area indicated in FIG. 13A.
- [0030] FIG. 14 is a partial cross-sectional view of the drug delivery device of FIG. 1, showing a lever actuation member with the device in a storage position.
- [0031] FIG. 15A is a partial cross-sectional view of the drug delivery device of FIG. 1, showing a storage position of the device and movement of a needle cover.
- [0032] FIG. 15B is an enlarged cross-sectional view of the area indicated in FIG. 15A.
- [0033] FIG. 15C is an enlarged cross-sectional view of the area indicated in FIG. 15A.
- [0034] FIG. 16 is a perspective view of a lever actuation member according to one aspect of the present application.
- [0035] FIG. 17A is a cross-sectional view of the drug delivery device of FIG. 1, showing a storage position of the device.
- [0036] FIG. 17B is an enlarged cross-sectional view of the area indicated in FIG. 17A.
- [0037] FIG. 17C is an enlarged cross-sectional view of the area indicated in FIG. 17A.
- [0038] FIG. 17D is an enlarged cross-sectional view of the area indicated in FIG. 17A.
- [0039] FIG. 17E is an enlarged cross-sectional view of the area indicated in FIG. 17A.
- [0040] FIG. 17F is an enlarged cross-sectional view of the area indicated in FIG. 17A.
- [0041] FIG. 18A is a partial cross-sectional view of the drug delivery device of FIG. 1, showing an initial removal of a cap of the device.
- [0042] FIG. 18B is an enlarged cross-sectional view of the area indicated in FIG. 18A.
- [0043] FIG. 18C is an enlarged cross-sectional view of the area indicated in FIG. 18A.
- [0044] FIG. 18D is an enlarged cross-sectional view of the area indicated in FIG. 18A.
- [0045] FIG. 18E is an enlarged cross-sectional view of the area indicated in FIG. 18A.
- [0046] FIG. 18F is an enlarged cross-sectional view of the area indicated in FIG. 18A.

- [0047] FIG. 19A is a partial cross-sectional view of the drug delivery device of FIG. 1, showing removal of a cap of the device.
- [0048] FIG. 19B is an enlarged cross-sectional view of the area indicated in FIG. 19A.
- [0049] FIG. 19C is an enlarged cross-sectional view of the area indicated in FIG. 19A.
- [0050] FIG. 19D is an enlarged cross-sectional view of the area indicated in FIG. 19A.
- [0051] FIG. 19E is an enlarged cross-sectional view of the area indicated in FIG. 19A.
- [0052] FIG. 19F is an enlarged cross-sectional view of the area indicated in FIG. 19A.
- [0053] FIG. 20A is a partial cross-sectional view of the drug delivery device of FIG. 1, showing removal of a cap of the device.
- [0054] FIG. 20B is an enlarged cross-sectional view of the area indicated in FIG. 20A.
- [0055] FIG. 20C is an enlarged cross-sectional view of the area indicated in FIG. 20A.
- [0056] FIG. 20D is an enlarged cross-sectional view of the area indicated in FIG. 20A.
- [0057] FIG. 20E is an enlarged cross-sectional view of the area indicated in FIG. 20A.
- [0058] FIG. 20F is an enlarged cross-sectional view of the area indicated in FIG. 20A.
- [0059] FIG. 21A is a partial cross-sectional view of the drug delivery device of FIG. 1, showing removal of a cap of the device.
- [0060] FIG. 21B is an enlarged cross-sectional view of the area indicated in FIG. 21A.
- [0061] FIG. 21C is an enlarged cross-sectional view of the area indicated in FIG. 21A.
- [0062] FIG. 21D is an enlarged cross-sectional view of the area indicated in FIG. 21A.
- [0063] FIG. 21E is an enlarged cross-sectional view of the area indicated in FIG. 21A.
- [0064] FIG. 21F is an enlarged cross-sectional view of the area indicated in FIG. 21A.
- [0065] FIG. 22A is a partial cross-sectional view of the drug delivery device of FIG. 1, showing removal of a cap of the device.
- [0066] FIG. 22B is an enlarged cross-sectional view of the area indicated in FIG. 22A.
- [0067] FIG. 22C is an enlarged cross-sectional view of the area indicated in FIG. 22A.
- [0068] FIG. 22D is an enlarged cross-sectional view of the area indicated in FIG. 22A.
- [0069] FIG. 22E is an enlarged cross-sectional view of the area indicated in FIG. 22A.
- [0070] FIG. 22F is an enlarged cross-sectional view of the area indicated in FIG. 22A.
- [0071] FIG. 23 is a perspective view of a cap, retainer, and rigid needle shield according to one aspect of the present application.

[0072] FIG. 24 is a perspective view of a retainer according to one aspect of the present application.

[0073] FIG. 25 is a perspective view of a drug delivery device according to a further aspect of the present application, showing a storage position of the device.

[0074] FIG. 26 is a cross-sectional view taken along line 26-26 shown in FIG. 25.

[0075] FIG. 27 is a top perspective view of a motor body of the drug delivery device of FIG. 25.

[0076] FIG. 28 is a bottom perspective view of the motor body of FIG. 27.

[0077] FIG. 29 is a front perspective view of a plunger body of the drug delivery device of FIG. 25.

[0078] FIG. 30 is a rear perspective view of the plunger body of FIG. 29.

[0079] FIG. 31 is a front perspective view of a plunger rod portion of the drug delivery device of FIG. 25.

[0080] FIG. 32 is a rear perspective view of the plunger rod portion of FIG. 31.

[0081] FIG. 33 is a top perspective view of a lever actuation member of the drug delivery device of FIG. 25.

[0082] FIG. 34 is a bottom perspective view of the lever actuation member of the drug delivery device of FIG. 33.

[0083] FIG. 35 is a front perspective view of a syringe holder of the drug delivery device of FIG. 25.

[0084] FIG. 36 is a rear perspective view of the syringe holder of the drug delivery device of FIG. 35.

[0085] FIG. 37 is a front perspective view of a needle cover of the drug delivery device of FIG. 25.

[0086] FIG. 38 is a rear perspective view of the needle cover of the drug delivery device of FIG. 37.

[0087] FIG. 39 is a top perspective view of a cassette body of the drug delivery device of FIG. 25.

[0088] FIG. 40 is a bottom perspective of the cassette body of the drug delivery device of FIG. 39.

[0089] FIG. 41 is a top perspective view of a cap of the drug delivery device of FIG. 25.

- [0090] FIG. 42 is a cross-sectional view taken along line 42-42 in FIG. 41.
- [0091] FIG. 43 is a perspective view of a retainer of the drug delivery device of FIG. 25.
- [0092] FIG. 44 is a cross-sectional view of an upper housing shell of the drug delivery device of FIG. 25.
- [0093] FIG. 45 is perspective view of a lower housing shell of the drug delivery device of FIG. 25.
- [0094] FIG. 46 is a cross-sectional view taken along line 46-46 in FIG. 45.
- [0095] FIG. 47 is a cross-sectional view of the drug delivery device of FIG. 25, showing an injection position of the device.
- [0096] FIG. 48 is a partial cross-sectional view of the drug delivery system of FIG. 25.
- [0097] FIG. 49 is a cross-sectional view of the drug delivery system of FIG. 25.
- [0098] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate exemplary aspects of the disclosure, and such exemplifications are not to be construed as limiting the scope of the disclosure in any manner.

#### DETAILED DESCRIPTION

[0099] The following description is provided to enable those skilled in the art to make and use the described embodiments contemplated for carrying out the invention. Various modifications, equivalents, variations, and alternatives, however, will remain readily apparent to those skilled in the art. Any and all such modifications, variations, equivalents, and alternatives are intended to fall within the spirit and scope of the present invention.

[00100] For purposes of the description hereinafter, the terms “upper”, “lower”, “right”, “left”, “vertical”, “horizontal”, “top”, “bottom”, “lateral”, “longitudinal”, and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations, except where expressly specified to the contrary. It is also to be understood that the specific devices illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

**[00101]** Referring to FIGS. 1A-10 a drug delivery device 10 according to one aspect of the present invention includes a first subassembly 12, a second subassembly 14, and a syringe assembly 16. The first subassembly 12 includes a cap 18 having an outer portion 20, a needle cover 22, a syringe holder 24, a cassette body 26, and a lower housing shell 28. The second subassembly 14 includes a drive assembly 40, a motor body 42, a lever actuation member 44, and an upper housing shell 46. The syringe assembly 16 is received by the syringe holder 24 and includes a barrel 52, a stopper 54, a cannula 56, and a rigid needle shield (RNS) 58. Although an RNS is utilized, other suitable needle shield arrangements may be utilized. The lower housing shell 28, the cassette body 26, and the upper housing shell 46 generally form a housing for receiving the various components of the device 10, although other suitable housing arrangements may be utilized. As discussed in more detail below, the first subassembly 12 and the second subassembly 14 are secured to each other during assembly by a locking clip 64, although other suitable arrangements may be utilized. The drug delivery device 10 may be an auto-injector, although the features described herein may be incorporated into other suitable drug delivery devices.

**[00102]** The drug delivery device 10 is configured to automatically deliver a dose of medicament from the syringe assembly 16 to a patient upon actuation of the device 10. More specifically, upon actuation of the drug delivery device 10, the drive assembly 40 is configured to engage the stopper 54 of the syringe assembly 16, displace the syringe assembly 16 such that the cannula 56 pierces the skin of the patient, and displace the stopper 54 within the barrel 52 of the syringe assembly 16 to deliver the medicament within the barrel 52. The drug delivery device 10 includes a storage position (FIGS. 1A and 2A), a pre-use position (FIGS. 1B and 2B), an actuation position (FIGS. 3 and 4), an injection position (FIGS. 5 and 6), and a post-use position (FIGS. 7 and 8). As discussed in more detail below, the needle cover 22 is configured to shield the cannula 56 of the syringe assembly 16 from the patient when the device 10 is in the pre-use and the post-use positions. In particular, the needle cover 22 is moveable between a pre-use position, an actuation position, and a post-use position, with a spring 68 biasing the needle cover 22 towards the pre-use position and the post-use position. The spring 68 is positioned between the needle cover 22 and the syringe holder 24, although other suitable arrangements may be utilized. The lever actuation member 44 is moveable between a locked position where movement of the drive assembly 40 is prevented and a released position where movement of the drive assembly 40 is

allowed. More specifically, the lever actuation member 44 is rotatable about a rotation axis 70 between the locked position and the released position. When the lever actuation member 44 is in the locked position, the lever actuation member 44 is engaged with the motor body 42 and the drive assembly 40 to prevent movement of the drive assembly 40. When the lever actuation member 44 is in the released position, the lever actuation member 44 is disengaged from the motor body 42 thereby allowing movement of the drive assembly 40 toward the syringe assembly 16. The rotation axis 70 of the lever actuation member 44 extends perpendicular to a longitudinal axis of the device 10, although other suitable arrangements may be utilized.

**[00103]** Referring again to FIGS. 1-10, the drive assembly 40 includes a plunger body 80 having a plunger rod portion 82 and a drive member 84. The drive member 84 is a compression spring received within a drive opening 86 defined by the plunger body 80, although other suitable drive members may be utilized, including, but not limited to, compressed gas, an electric motor, hydraulic pressure, other types of springs, etc. The drive member 84 engages the plunger body 80 and the motor body 42 and biases the plunger body 80 in a direction extending from the second subassembly 14 toward the first subassembly 12. The plunger body 80 defines a lever opening 88 that receives the lever actuation member 44 and defines the rotation axis 70 of the lever actuation member 44. The lever actuation member 44 prevents movement of the plunger body 80 when the lever actuation member 44 is in the locked position through engagement of the lever actuation member 44 with the motor body 42. Upon rotation of the lever actuation member 44 from the locked position to the released position, the lever actuation member 44 is disengaged from the motor body 42 thereby allowing the drive member 84 to move the plunger body 80 and the plunger rod portion 82 toward the first subassembly 12. The plunger rod portion 82 and the drive member 84 are spaced from and parallel to each other and extend in a longitudinal direction of the device 10.

**[00104]** The drive assembly 40 further includes a spring guide member 90 secured to the upper housing shell 46 and received within the drive opening 86 of the plunger body 80. The drive member 84 is received by the spring guide member 90 such that the drive member 84 is positioned between the plunger body 80 and the spring guide member 90. The drive assembly 40 also includes a plunger rod cover 92 that receives the plunger rod portion 82 of the plunger body 80. The plunger rod cover 92 is configured to guide insertion of the plunger rod portion 82 into the barrel 52 of the syringe assembly 16 and engage the stopper 54 of the syringe assembly 16 to dispense the

medicament from the barrel 52 of the syringe assembly 16. The plunger rod cover 92 and the plunger rod portion 82 may be formed integrally or formed as separate components.

**[00105]** The plunger body 80 of the drive assembly 40 also includes an audio indicator member 94 configured to provide an audible indication to a user when the device 10 transitions to the post-use position. As discussed in more detail below, the audio indicator member 94 is configured to engage one or more ribs 96 of the cassette body 26 when the device 10 is in the injection position thereby deflecting the audio indicator member 94. When the drug delivery device 10 transitions from the injection position to the post-use position, the audio indicator member 94 disengages from the rib(s) 96 of the cassette body 26 and contacts the lower housing shell 28 to provide an audible click, although the audio indicator member 94 could also contact other suitable portions of the device 10 to provide the audible indicator.

**[00106]** Referring to FIGS. 1A-2B, in the storage position, the cap 18 is secured to the lower housing shell 28 and engaged with the needle cover 22. Movement of the needle cover 22 from the pre-use position to the actuation position causes engagement between the needle cover 22 and the lever actuation member 44 thereby actuating the drive assembly 40. After removal of the cap 18 by grasping the outer portion 20, the needle cover 22 may be moved from the pre-use position to the actuation position by pressing the needle cover 22 against a skin surface of a patient and axially pressing the device 10 against the skin surface. As detailed below, the engagement between the cap 18 and the needle cover 22 prevents the needle cover 22 from moving into engagement with the lever actuation member 44. Accordingly, removal of the cap 18 from the device 10 allows for the actuation of the device 10. As discussed in more detail below, removal of the cap 18 from the device 10, as shown in FIGS. 1B and 2B, also removes the RNS 58 from the syringe barrel 52 thereby exposing the cannula 56, which is still received within the needle cover 22 in the pre-use position of the device 10.

**[00107]** Referring to FIGS. 3 and 4, in the actuation position, the cap 18 is removed and the needle cover 22 is positioned in the actuation position by engaging a skin surface of a patient, which moves the needle cover 22 further within the device 10 toward the second subassembly 14. When the needle cover 22 has moved a sufficient distance within the device 10, a portion of the needle cover 22 engages the lever actuation member 44, which rotates the lever actuation member 44 about the rotation axis 70 from the locked position to the released position.



**[00108]** Referring to FIGS. 5 and 6, in the injection position, the lever actuation member 44 is in the released position, which allows the plunger body 80 of the drive assembly 40 to move toward the first subassembly 12 such that the plunger body 80 or the plunger rod cover 92 engages the stopper of the syringe assembly 16. Initial engagement of the drive assembly 40 with the syringe assembly 16 moves the syringe assembly 16 and the syringe holder 24 within the device 10 and relative to the cassette body 26 until the syringe holder 24 abuts a stop 102 defined by the cassette body 26. During this initial movement of the syringe assembly 16 and syringe holder 24 with the needle cover 22 pressed against a skin surface of a patient, the cannula 56 of the syringe assembly 16 extends beyond the needle cover 22 and pierces the skin surface of the patient. Further movement of the plunger body 80, which is driven by the drive member 84, moves the stopper 54 relative to the barrel 52 of the syringe assembly 16 to dispense medicament from the barrel 52 of the syringe assembly 16, through the cannula 56, and into the patient. The plunger body 80 will continue moving until the stopper 54 bottoms out on the barrel 52 of the syringe assembly 16. When the stopper 54 bottoms out or just before the stopper 54 bottoms out, the audio indicator member 94 will disengage from the rib(s) 96 of the cassette body 26 and contact the lower housing shell 28 at approximately the same time to provide the audible indication to the patient that the dose of medicament has been delivered. In addition to the audible indication, the drug delivery device 10 provides one or more visual indicators to notify a patient of the status of the device 10. In particular, the cassette body 26 may be formed from transparent material to allow visual confirmation of movement of the stopper 54 and/or another visual indicator provided by the drive assembly 40, syringe holder 24, and/or syringe assembly 16. The lower housing shell 28 also defines an indicator opening 104, which provides visual indication that the plunger body 80 is in a final position and the dose of medicament has been delivered. The visual indicators may utilize contrasting colors, symbols, patterns, or any other suitable visual indicia to indicate the various statuses of the device.

**[00109]** Referring to FIGS. 7, 8, 11A, 11B, and 12, in the post-use position, the needle cover 22 extends to the post-use position to shield the cannula 56 when the needle cover 22 is removed from a skin surface of a patient. As shown more clearly in FIG. 11B, the cassette body 26 includes at least one lock arm 106 and the needle cover 22 includes at least one lock protrusion 108, although other suitable configurations may be utilized. The lock arm 106 of the cassette body 26 engages the lock protrusion 108 of the needle cover 22 to prevent any further use of the device 10

and exposing of the cannula 56 of the syringe assembly 16. During the transition of the device 10 from the injection position to the post-use position, the lock arm 106 of the cassette body 26 deflects to allow the lock protrusion 108 of the needle cover 22 to pass by the cassette body 26 with the lock arm 106 returning to its original position to prevent movement of the needle cover 22 back toward the pre-use and actuation positions. In the pre-use position of the needle cover 22, a portion of the needle cover 22 engages a cover stop 110 of the syringe holder 24 to limit axial movement of the needle cover 22 in a direction extending from the second subassembly 14 toward the first subassembly 12. After use of the device 10, the syringe holder 24 is displaced within the cassette body 26 relative to the needle cover 22, which allows the needle cover 22 to extend to the post-use position when a patient removes the needle cover 22 from a skin surface. As shown in FIG. 12, the needle cover 22 will move to the post-use position when the needle cover 22 is removed from a skin surface of a patient regardless of a position of the stopper 54 within the barrel 52 of the syringe assembly 16. Accordingly, if a patient removes the needle cover 22 from a skin surface after only a portion of the dose of medicament has been delivered, the needle cover 22 will still move to the post-use position and will prevent further use of the device 10.

**[00110]** Referring to FIGS. 1A, 1B, and 13A-15C, as discussed above, engagement between the cap 18 and the needle cover 22 prevents the needle cover 22 from moving into engagement with the lever actuation member 44. The cannula 56 is positioned within the needle cover 22 when the needle cover 22 is in the pre-use position and the post-use position. The needle cover 22 is configured to actuate the drive assembly 40 when the needle cover 22 is in the actuation position. Removal of the cap 18 from the device 10 allows for the actuation of the device 10. More precisely, in one aspect of the present application, the outer portion 20 of the cap 18 includes a body 116 defining an interior space 118 that receives a portion of the needle cover 22 when the device 10 is in the storage position with the outer portion 20 secured to the lower housing shell 28. The outer portion 20 of the cap 18 is secured to the lower housing shell 28 via a lock protrusion 112 that is received by a lock recess 114 defined by the body 116 of the outer portion 20 of the cap 18. The outer portion 20 also includes a grip surface 130 to facilitate the grasping and removal of the outer portion 20 of the cap 18 from the lower housing shell 28.

**[00111]** The outer portion 20 includes a pair of protrusions 120 received by cap openings 122 defined by the needle cover 22, although one or more protrusions 120 and one or more cap openings 122 may be utilized. The protrusions 120 of the outer portion 20 are configured to engage

the needle cover 22 upon movement of the needle cover 22 from the pre-use position to the actuation position. For instance, with the device 10 in the storage position with the outer portion 20 secured to the lower housing shell 28, if the device 10 is dropped or impacted to apply a force to the needle cover 22, the lever actuation member 44, and/or other component, the protrusions 120 of the outer portion 20 restrict movement of the needle cover 22, which prevents any unintended actuation of the device 10. The protrusions 120 of the outer portion 20 are moveable in a radial direction via extension arms 124 of the outer portion 20. As shown in FIG. 13B, for example, engagement between the extension arms 124 and the lower housing shell 28 prevents radially outward movement of the protrusions 120. More precisely, the lower housing shell 28 includes a skirt configured to surround the extension arms 124 of the outer portion 20 when the outer portion 20 is mounted on the lower housing shell 28, which prevents radially outward movement of the protrusions 120 as long as the outer portion 20 is mounted on the lower housing shell 28. The protrusions 120 are configured to be removed from the cap opening 122 of the needle cover 122 upon axial movement of the outer portion 20. In particular, the protrusions 120 are configured to engage the needle cover 22 and deflect radially outward upon axial movement of the outer portion 20 of the cap 18.

**[00112]** Referring to FIG. 13B, the protrusions 120 each define a first cam surface 126 and the needle cover 22 defines a second cam surface 128, with the first cam surface 126 configured to engage the second cam surface 128 to deflect each protrusion 120 radially outward, which allows separation of the outer portion 20 from the needle cover 22. The first and second cam surfaces 126, 128 are complementary, inclined surfaces, although other suitable arrangements may be utilized.

**[00113]** Referring to FIGS. 14-16, the needle cover 22 prevents movement or rotation of the lever actuation member 44 from the locked position to the released position when the needle cover 22 is in the pre-use position. The lever actuation member 44 includes a body 132 having a restriction surface 134 configured to engage the needle cover 22 and restrict rotation of the lever actuation member 44 when the needle cover 22 is in the pre-use position. When the device 10 is in the storage position, if the device 10 is dropped or impacted to apply a force to the lever actuation member 44, the lever actuation member 44 is prevented from fully rotating to allow actuation of the drive assembly 40 due to the engagement between the restriction surface 134 of the lever actuation member 44 and the needle cover 22. The restriction surface 134 is spaced from the

needle cover 22 to form a gap 136 when the device 10 is in the storage and pre-use positions to prevent any increase in friction in the movement of the needle cover 22 while still preventing unintended actuation of the device 10.

**[00114]** The body 132 of the lever actuation member also includes an assembly surface 138 configured to engage a locking pin (not shown) received by a pin opening 140 defined by the motor body 42. Prior to assembly, the second subassembly 14 may include a locking pin that extends through the pin opening 140, which prevents rotation of the lever actuation member 44 and unintentional actuation of the drive assembly 40 during assembly of the device 10. The body 132 of the lever actuation member also includes a needle cover contact surface 142, a motor body contact surface 144, and defines a recessed area 146. The needle cover contact surface 142 of the lever actuation member 44 engages a lever contact portion 148 of the needle cover 22 when the needle cover 22 is moved to the actuation position thereby rotating the lever actuation member 44 from the locked position to the released position. The motor body contact surface 144 of the lever actuation member 44 engages a stop surface 150 of the motor body 42 when the lever actuation member 44 is in the locked position, which prevents movement of the plunger body 80. When the lever actuation member 44 rotates from the locked position to the released position, the motor body contact surface 144 disengages from the stop surface 150 of the motor body 42, which allows the drive member 84 to move the plunger body 80.

**[00115]** The recessed area 146 of the lever actuation member 44 provides clearance for the lever contact portion 148 of the needle cover 22 to allow for rotation of the lever actuation member 44 from the locked position to the released position. The position of the restriction surface 134 of the lever actuation member 44 overlaps in an axial direction of the device 10 with the position of the lever contact portion 148 of the needle cover 22 when the needle cover 22 is in the pre-use position and until the needle cover 22 has fully moved to the actuation position, which prevents unintentional actuation of the device 10 as discussed above. When the needle cover 22 is fully moved to the actuation position, the lever contact portion 148 of the needle cover 22 no longer overlaps with the position of the restriction surface 134 of the lever actuation member and, instead, overlaps with the position of the recessed area 146 in a direction extending in an axial direction of the device 10 and engages the needle cover contact surface 142 to rotate the lever actuation member 44 as described above. The restriction surface 134 of the lever actuation member 44 is planar and is configured to engage a corresponding planar surface on the bottom of the needle

cover contact surface 142 when the needle cover 22 is in the pre-use position, although other suitable configurations may be utilized.

**[00116]** Referring to FIGS. 17A-24, according to one aspect of the present application, the device further includes a retainer 160 having a body 162 with a removal projection 164 configured to remove the RNS 58 upon axial movement of the outer portion 20 of the cap 18 away from the lower housing shell 28. A portion of the retainer 160 is received within the interior space 118 of the outer portion 20. The outer portion 20 includes a retaining tab 166 received by a retainer opening 168 defined by the body 162 of the retainer 160 to secure the retainer 160 to the outer portion 20. As detailed below, the retaining tab 166 is configured to engage the retainer 160 upon axial movement of the outer portion 20 away from the lower housing shell 28. As shown more clearly in FIGS. 23 and 24, the retainer 160 further includes a pair of wings 170 extending radially outward from the body 162 of the retainer 160, with each wing 170 configured to engage a rib 172 extending radially inward from the body 162 of the outer portion 20. The wings 170 prevent wobbling between the outer portion 20 and the retainer 160 once the outer portion 20, the retainer 160, and the RNS 58 has been removed.

**[00117]** As shown in FIG. 17C, the retaining tab 166 of the outer portion 20 is disengaged from the retainer 160 when the outer portion 20 is secured to the lower housing shell 28 with the device 10 in the storage position. As shown in FIGS. 20C, 21C, and 22C, the retaining tab 166 of the outer portion 20 is disengaged from the retainer 160 when the outer portion 20 is secured to the lower housing shell 28. The retaining tab 166 of the outer portion 20 is secured to the body 116 of the outer portion 20 via an extension arm 174. The retaining tab 166 is moveable radially inward via the extension arm 174. The flexibility of the extension arm 174 facilitates the assembly of the retainer 160 to the outer portion 20 by allowing the retaining tab 166 to deflect radially inward as the retaining tab 166 engages the retainer 160 until the retaining tab 166 is received within the retainer opening 168. The retainer 160 includes a flange 176, which is engaged with the outer portion 20 when the outer portion 20 is secured to the lower housing shell 28. The flange 176 of the retainer 160 is spaced from the outer portion 20 upon axial movement of the outer portion 20 away from the lower housing shell 28.

**[00118]** As shown in FIG. 17E, the body 162 of the retainer 160 is cylindrical and includes a first end 178 and a second end 180 positioned opposite the first end 178. The removal projection 164 extends radially inward from body 162 of the retainer 160 via a removal arm 182. The removal

arm 182 extends radially inward and in a direction extending from the second end 180 of the body 162 to the first end 178 of the body 162, which allows the retainer 160 to be positioned over the RNS 58 and syringe assembly 16 during assembly of the outer portion 20 and the retainer 160 onto the device 10. The removal projection 164 is moveable relative to the body 162 of the retainer 160 via the removal arm 182. More specifically, the removal projection 164 is moveable radially outward during assembly of the retainer 160 to the RNS 58 and moveable radially inward during removal of the outer portion 20 and the retainer 160. The removal projection 164 includes a surface 184 that is configured to engage a complementary surface 186 of the RNS 58. The surface 184 of the removal projection 164 of the retainer 160 is disengaged from the corresponding surface 186 of the RNS 58 when the outer portion 20 is secured to the lower housing shell 28. The surface 184 of the removal projection 164 is planar, although other suitable shapes and configurations may be utilized. The corresponding surface 186 of the RNS 58 is planar, although other suitable shapes and configurations may be utilized. The corresponding surface 186 of the RNS 58 is defined by a flange portion of the RNS 58.

**[00119]** Referring to FIG. 17F, the syringe holder 24 is disengaged with the plunger body 80 of the drive assembly 40 when the outer portion 20 is secured to the lower housing shell 28. Referring to FIG. 19F, for example, the syringe holder 24 is engaged with the plunger body 80 of the drive assembly 40 upon axial movement of the outer portion 20 of the cap 18 away from the lower housing shell 28. More specifically, a pair of arms extend from the syringe holder 24 and engage the audio indicator member 94 of the plunger body 80, although other suitable configurations may be utilized. The engagement between syringe holder 24 and the plunger body 80 of the drive assembly 40 prevents the removal of the outer portion 20 and the RNS 58 from moving the syringe holder 24 relative to the cassette body 26 due to the friction between the syringe assembly 16 and the syringe holder 24. The engagement between the syringe holder 24 and the plunger body 80 also restricts the axial movement of the syringe holder 24 within the device 10 caused by movement of the device 10 or by gravity when the device is in the pre-use position.

**[00120]** Referring to FIGS. 17A-17F, when the device 10 is in the storage position with the outer portion 20 secured to the lower shell assembly 28, the flange 176 of the retainer 160 abuts the outer portion 20 (FIG. 17B), the retaining tab 166 of the outer portion 20 is positioned within the retainer opening 168 and spaced from the proximal portion of the body 162 of the retainer 160 (FIG. 17C), the protrusion 120 of the cap is received within the cap opening 122 of the needle

cover 22 and spaced from the needle cover 22 (FIG. 17D), the surface 184 of the removal projection 164 is spaced from the corresponding surface 186 of the RNS 58 (FIG. 17E), and the syringe holder 24 is spaced from the plunger body 80 of the drive assembly 40 (FIG. 17F). In the storage position of the device 10, the retainer 160 is engaged with the syringe holder 24. When the flange 176 of the retainer 160 abuts the outer portion 20, the planar surface 184 of the removal projection 164 of the retainer 160 is properly positioned relative to the complementary surface 186 of the RNS 58. In other words, abutment of the flange 176 with the outer portion 20 ensures the retainer 160 is sufficiently positioned axially towards the lower housing shell 28 to allow removal of the RNS 58 as described below.

**[00121]** Referring to FIGS. 18A-18F, as the outer portion 20 is initial axially moved away from the lower housing shell 28 (FIG. 18B) with the lock protrusion 112 only partially received within the lock recess 114, the flange 176 of the retainer 160 is spaced from the outer portion 20 and the retaining tab 166 is still spaced from the body 162 of the retainer 160 (FIG. 18C), the protrusion 120 of the outer portion 20 is engaged with the needle cover 22 (FIG. 18D), the surface 184 of the removal projection 164 is spaced from the corresponding surface 186 of the RNS 58 (FIG. 18E), and the syringe holder 24 is spaced from the plunger body 80 of the drive assembly 40 (FIG. 18F).

**[00122]** Referring to FIGS. 19A-19F, as the outer portion 20 continues to be axially moved away from the lower housing shell 28 (FIG. 19B) with the lock protrusion 112 only partially received within the lock recess 114, the flange 176 of the retainer 160 is spaced from the outer portion 20 and the retaining tab 166 is still spaced from the body 162 of the retainer 160 (FIG. 19C), the protrusion 120 of the outer portion 20 is engaged with the needle cover 22 (FIG. 19D), the surface 184 of the removal projection 164 is spaced from the corresponding surface 186 of the RNS 58 (FIG. 19E), and the syringe holder 24 is engaged with the plunger body 80 of the drive assembly 40 (FIG. 19F).

**[00123]** Referring to FIGS. 20A-20F, as the outer portion 20 continues to be axially moved away from the lower housing shell 28 (FIG. 20B) with the lock protrusion 112 separated from the lock recess 114, the flange 176 of the retainer 160 is further spaced from the outer portion 20 and the retaining tab 166 is engaged with the body 162 of the retainer 160 (FIG. 20C) such that the outer portion 20 and the retainer 160 move together axially away from the lower housing shell 28, the protrusion 120 of the outer portion 20 disengages with the needle cover 22 (FIG. 20D) and is removed from the cap opening 122, the surface 184 of the removal projection 164 is spaced from

the corresponding surface 186 of the RNS 58 (FIG. 20E), and the syringe holder 24 is engaged with the plunger body 80 of the drive assembly 40 (FIG. 20F).

**[00124]** Referring to FIGS. 21A-21F, as the outer portion 20 continues to be axially moved away from the lower housing shell 28 (FIG. 21B), the flange 176 of the retainer 160 is spaced from the outer portion 20 and the retaining tab 166 is engaged with the body 162 of the retainer 160 (FIG. 21C) such that the outer portion 20 and the retainer 160 move together axially away from the lower housing shell 28, the protrusion 120 of the outer portion 20 continues to be disengaged from the needle cover 22 (FIG. 21D), the surface 184 of the removal projection 164 engages the corresponding surface 186 of the RNS 58 (FIG. 21E), and the syringe holder 24 is engaged with the plunger body 80 of the drive assembly 40 (FIG. 21F).

**[00125]** Referring to FIGS. 22A-22F, as the outer portion 20 continues to be axially moved away from and separated from the lower housing shell 28 (FIG. 22B), the flange 176 of the retainer 160 is spaced from the outer portion 20 and the retaining tab 166 is engaged with the body 162 of the retainer 160 (FIG. 22C) such that the outer portion 20 and the retainer 160 move together axially away from the lower housing shell 28, the protrusion 120 of the outer portion 20 continues to be disengaged from the needle cover 22 (FIG. 22D), the surface 184 of the removal projection 164 continues to be engaged with the corresponding surface 186 of the RNS 58 and axially displaces the RNS 58 relative to the barrel 52 of the syringe assembly 16 (FIG. 22E), and the syringe holder 24 is engaged with the plunger body 80 of the drive assembly 40 (FIG. 22F).

**[00126]** Referring to FIG. 23, upon complete removal of the outer portion 20 from the lower housing shell 28, the RNS 58 continues to remain engaged with the retainer 160 with the RNS 58 entirely separated from the barrel 52 of the syringe assembly 16.

**[00127]** Referring again to FIGS. 17A-24, as discussed above, the outer portion 20 and the retainer 160 are configured to minimize the amount of force required to remove the outer portion 20 and retainer 160 from the device 10 by separating the various components from each other sequentially, rather than at the same time. By sequencing the removal of the outer portion 20 from the lower housing shell 28, the separation of the protrusion 120 of the outer portion 20 from the needle cover 22, and the removal of the RNS 58 from the syringe assembly 16, a patient is only required to apply sufficient force for each step in the sequence rather than a larger force that would be required to remove such components at the same time. As discussed above, such sequencing is provided via the relative movement between the outer portion 20 and the retainer 160, relative



movement between the outer portion 20 and the needle cover 22, and the relative movement between the retainer 160 and the RNS 58.

**[00128]** Referring to FIGS. 25-49, a drug delivery device 300 according to a further aspect of the present invention is shown. The drug delivery device 300 is similar to the drug delivery device 10 shown in FIGS. 1A-24, with certain differences discussed below in detail. The drug delivery device 300 includes, among other components, a motor body 302, a plunger body 304, a plunger rod portion 306, a lever actuation member 308, a syringe holder 310, a needle cover 312, a cassette body 314, a cap 316, a retainer 318, an upper housing shell 320, and a lower housing shell 322.

**[00129]** Referring to FIGS. 24-28, the motor body 302 is similar and functions similarly to the motor body 42 of Figs. 1A-24, but further includes a longitudinal groove 324, reinforcing rib(s) 326, and cassette clip(s) 328. The longitudinal groove 324 is configured to receive a molding split line of the plunger body 304 to ensure smooth sliding between the motor body 302 and the plunger body 304. The reinforcing rib(s) 326 provide additional support for the pair of arms 260 of the motor body 302. The cassette clip(s) 328 is received by an opening(s) 330 defined by the cassette body 314 to secure the motor body 302 to the cassette body 314, which is discussed in more detail below. The cassette clip(s) 328 include an angled face 332 and a planar face 334, which is configured to allow insertion of the cassette clip(s) 328 into the opening(s) 330 of the cassette body 314, but prevent the easy removal of the cassette clip(s) 328 once inserted into the opening(s) 330 of the cassette body 314. A bottom surface 336 of the motor body 302 includes chamfered portions 338 to aid assembly of the device 300.

**[00130]** Referring to FIGS. 26 and 29-32, the plunger body 304 is formed separately from the plunger rod portion 306 rather than being formed integrally. Further, the device 300 does not include the plunger rod cover 92. The plunger body 304 defines an opening 340 that receives a plunger rod clip 342 of the plunger rod portion 306. The plunger rod clip 342 is barb-shaped and configured to be inserted into the opening 340 of the plunger body 304, but not easily removed from the opening 340, although other suitable shapes and configurations may be utilized. The plunger rod clip 342 defines a central opening 344, which allows the plunger rod clip 342 to compress as the plunger rod clip 342 is inserted into the opening 340 of the plunger body 304 and expand to its original shape once received within the plunger body 304. The plunger rod portion 306 includes a plunger body stop(s) 346 and a biasing member 348. The plunger body stop(s) 346, which may be one or more projections, contact the plunger body 304 when the plunger rod clip

342 is inserted into the opening 340 of the plunger body 304. The biasing member 348 engages the plunger body 304 during insertion of the plunger rod clip 342 into the opening 340 of the plunger body 304 and biases the plunger rod portion 306 toward the plunger body 304. The biasing member 348 provides additional leeway for insertion of the plunger rod clip 342 into the opening 340 of the plunger body 304 while ensuring there is no gap between the plunger body 304 and the plunger rod portion 306 after assembly. The biasing member 348 of the plunger rod portion 306 is annular, although other suitable shapes and configurations may be utilized.

**[00131]** The plunger rod portion 306 further includes a stopper interface 350 that is received by the stopper 54. The stopper interface 350 is a cruciform projection, although other suitable shapes and configurations may be utilized. The plunger rod portion 306 has a conical external shape configured to reduce stress on the syringe assembly 16, although other suitable shapes may be utilized. The plunger body 304 includes a lever rib 352 extending into the lever opening 88 of the plunger body 304. The lever rib 352 is configured to be received by the lever actuation member 308, as discussed in more detail below.

**[00132]** Referring to FIGS. 33 and 34, the lever actuation member 308 is similar to and functions similarly to the lever actuation member 44 described above and shown in FIGS. 1A-24. The lever actuation member 308, however, defines a groove 354 at the rotation axis 70 that receives the lever rib 352 of the plunger body 304. The engagement between the groove 354 and the lever rib 352 prevents relative lateral movement between the plunger body 304 and the lever actuation member 308. The needle cover contact surface 142 of the lever actuation member 308 includes a larger surface compared to the needle cover contact surface 142 of the lever actuation member 44 of FIGS. 1A-24.

**[00133]** Referring to FIGS. 35 and 36, the syringe holder 310 is similar to and functions similarly to the syringe holder 24 of FIGS. 1A-24. The syringe holder 310, however, further includes a plurality of ribs 356 extending circumferentially around the syringe holder 310. The plurality of ribs engage the spring 68. The securing ring 220 of the syringe holder 310 further includes a plurality of projections 358 that extend radially inward. The plurality of projections 358 engage the syringe assembly 16 to remove any gap between the outer surface of the syringe assembly 16 and the syringe holder 310. The plurality of projections 358 are elastomeric and may compress when the syringe assembly 16 is received within the syringe holder 310.

**[00134]** Referring to FIGS. 37 and 38, the needle cover 312 is similar to and functions similarly to the needle cover 22 of FIGS. 1A-24. The needle cover 312 includes a spring rib 360 which engages the spring 68 to hold the spring 68 between the needle cover 312 and the syringe holder 310. The needle cover 312 also includes a cassette rib(s) 362 to guide movement of the needle cover 312 relative to the cassette body 314.

**[00135]** Referring to FIGS. 39, 40, 48, and 49, the cassette body 314 is similar to and functions similarly to the cassette body 26 of FIGS. 1A-24. As discussed above, the cassette body 314 includes the opening(s) 330 that receive the cassette clip(s) 328 of the motor body 302. The cassette body 314 includes a needle cover clip(s) 364 that engage clip surface(s) 366 of the needle cover 312. The clip surface(s) 366 of the needle cover 312 are planar, although other suitable shapes and configurations may be utilized. The needle cover clip(s) 364 are configured to restrict the axial movement of the needle cover 312 relative to the cassette body 314. The cassette body 314 further includes motor body rib(s) 368 and upper housing shell rib(s) 370, which are configured to engage corresponding portions of the motor body 302 and the upper housing shell 320 to aid in the assembly of the device 300. The cassette body 314 also includes syringe holder stop(s) 372, which are configured to engage portions of the syringe holder 310 to limit the axial movement of the syringe holder 310 relative to the cassette body 314. Although not shown in FIG. 48, the locking clip 64 may also be utilized with the drug delivery device 300.

**[00136]** Referring to FIGS. 41-46, the cap 316 is similar to and functions similarly to the cap 18 described above and shown in FIGS. 1A-24. The cap 316 includes a protrusion(s) 374 that is received by a cap opening(s) 376 defined by the needle cover 312, which is positioned 90 degrees relative to the position of those elements of the cap 18 of FIGS. 1A-24. The protrusion(s) 374 of the cap 316 is configured to engage the needle cover 312 upon movement of the needle cover 312 from the pre-use position to the actuation position. For instance, with the device 300 in the storage position with the cap 316 secured to the lower housing shell 322, if the device is dropped or impacted to apply a force to the needle cover 312, the lever actuation member 308, and/or other component, the protrusion(s) 374 restricts movement of the needle cover 312, which prevents any unintended actuation of the device 300. The cap 316 further includes a retainer clip(s) 378 and a rib(s) 380 for engaging a wing(s) 382 of the retainer 318. The retainer clip(s) 378 and the rib(s) 380 secure the retainer 318 to the cap 316 and prevent any movement or wobbling of the retainer 318 relative to the cap 316. The retainer 318 is configured to remove the RNS 58 when the cap

316 is removed from the lower housing shell 322. The cap 316 includes a lower housing shell clip(s) 384 for engaging the lower housing shell 322 to secure the cap 316 to the lower housing shell 322. The upper housing shell 320 and the lower housing shell 322 are similar and function similarly to the upper housing shell 46 and the lower housing shell 28 discussed above and shown in FIGS. 1A-24. The lower housing shell 322, however, has a cap interface 386 to receive the lower housing shell clip(s) 384 of the cap 316.

**[00137]** Referring to FIG. 47, the drug delivery device 300 is shown in an injection position. The injection depth of the cannula 56 is determined by contact between the syringe holder 310 and the cassette body 314 at point X and contact between the needle cover 312 and the syringe holder 310 at point Y.

**[00138]** Referring to FIG. 47, the drug delivery device 300 includes an audio indicator member 388, which is similar to and functions similarly to the audio indicator member 94 described above and shown in FIGS. 1A-24. In the same manner as the audio indicator member 94, which is described above, the audio indicator member 388 of the drug delivery device 300 is configured to provide an audible indication to a user when the device 300 transition to the post-use position. The audio indicator member 388 is configured to engage rib(s) 390 of the cassette body 314 when the device 300 is in the injection position thereby deflecting the audio indicator member 388. The audio indicator member 388 disengages from the rib(s) 390 of the cassette body 314 and contacts the lower housing shell 322 to provide an audible click when the drug delivery device 300 transition from the injection position to the post-use position. However, a distal end 392 of the rib(s) 390 of the cassette body 314 is angled rearward toward the upper housing shell 320, which beneficially provides a louder audible click compared to the arranged of the rib(s) 96 of the cassette body 26 discussed above in connection with FIGS. 1A-24.

**[00139]** In one aspect or embodiment, an angle Z of the distal end 392 of the rib(s) 390 of the cassette body 314 relative to a plane extending perpendicularly to a longitudinal axis of the device 300 is greater than 5 degrees. In one aspect or embodiment, the angle Z of the distal end 392 of the rib(s) 390 is greater than 10 degrees. In one aspect or embodiment, the angle Z of the distal end 392 is 25 degrees.

**[00140]** Elements of one disclosed aspect can be combined with elements of one or more other disclosed aspects to form different combinations, all of which are considered to be within the scope of the present invention.

**[00141]** While this disclosure has been described as having exemplary designs, the present disclosure can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the disclosure using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this disclosure pertains and which fall within the limits of the appended claims.

**WHAT IS CLAIMED IS:**

1. A drug delivery device (10) comprising:
  - a housing (26, 28, 46);
  - a syringe assembly (16) comprising a barrel (52), a stopper (54), a cannula (56), and a rigid needle shield (58) receiving at least a portion of the cannula (56), at least a portion of the syringe assembly (16) positioned within the housing (26, 28, 46);
  - a drive assembly (40) configured to move the stopper (54) within the barrel (52) upon actuation of the drive assembly (40), at least a portion of the drive assembly (40) positioned within the housing (26, 28, 46);
  - a cap (18) secured to the housing (26, 28, 46), the cap (18) comprises an outer portion (20) defining an interior space (118) and a retainer (160) comprising a body (162) with a removal projection (164), the removal projection (164) configured to remove the rigid needle shield (58) upon axial movement of the outer portion (20) of the cap (18) away from the housing (26, 28, 46); and
  - a needle cover (22) having a pre-use position where the cannula (56) is positioned within the needle cover (22), an actuation position where the drive assembly (40) is actuated, and a post-use position where the cannula (56) is positioned within the needle cover (22), wherein the outer portion (20) receives a portion of the needle cover (22), the outer portion (20) configured to prevent movement of the needle cover (22) from the pre-use position to the actuation position.
2. The drug delivery device (10) of claim 1, wherein the outer portion (20) includes a protrusion (120) received by a cap opening (122) defined by the needle cover (22), the protrusion (120) of the outer portion (20) is configured to engage the needle cover (22) upon movement of the needle cover (22) from the pre-use position to the actuation position.
3. The drug delivery device (10) of claims 1 or 2, wherein a portion of the retainer (160) is received within the interior space (118) of the outer portion (20) of the cap (18), and wherein the retainer (160) is secured to and axially moveable relative to the outer portion (20).

4. The drug delivery device (10) of claim 3, wherein the outer portion (20) comprises a retaining tab (166) received by a retainer opening (168) defined by the body (162) of the retainer (160), the retaining tab (166) is disengaged from the body (162) of the retainer (160) when the outer portion (20) is secured to the housing (26, 28, 46), the retaining tab (166) of the outer portion (20) is configured to engage the retainer (160) upon axial movement of the outer portion (20) away from the housing (26, 28, 46) and upon axial movement of the outer portion (20) relative to the retainer (160).

5. The drug delivery device (10) of any of claims 1-4, wherein the retainer (160) comprises a pair of wings (170) extending radially outward from the body (162) of the retainer (160), each wing (170) configured to engage a rib (172) extending radially inward from a body (116) of the outer portion (20).

6. The drug delivery device (10) of claim 4, wherein the retaining tab (166) extends radially outward through the retainer opening (168) of the retainer (160).

7. The drug delivery device (10) of claim 4, wherein the retaining tab (166) of the outer portion (20) is secured to the body (116) of the outer portion (20) via an extension arm (174), the retaining tab (166) moveable radially inward via the extension arm (174).

8. The drug delivery device (10) of any of claims 1-7, wherein the retainer (160) comprises a flange (176) engaged with the outer portion (20) when the outer portion (20) is secured to the housing (26, 28, 46).

9. The drug delivery device (10) of claim 8, wherein the flange (176) of the retainer (160) is spaced from the outer portion (20) upon axial movement of the outer portion (20) away from the housing (26, 28, 46).

10. The drug delivery device (10) of any of claims 1-9, wherein the surface (184) of the removal projection (164) is planar, and wherein the corresponding surface (186) of the rigid needle shield (58) is planar.

11. The drug delivery device (10) of any of claims 1-10, wherein the body (162) of the retainer (160) comprises a first end (178) and a second end (180) positioned opposite the first end, the removal projection (164) extending radially inward from the body (162) of the retainer (160) via a removal arm (182), the removal arm (182) extending radially inward and in a direction extending from the second end (180) of the body (162) to the first end (178) of the body (162).

12. The drug delivery device (10) of claim 11, wherein the removal projection (164) is moveable relative to the body (162) of the retainer (160) via the removal arm (182).

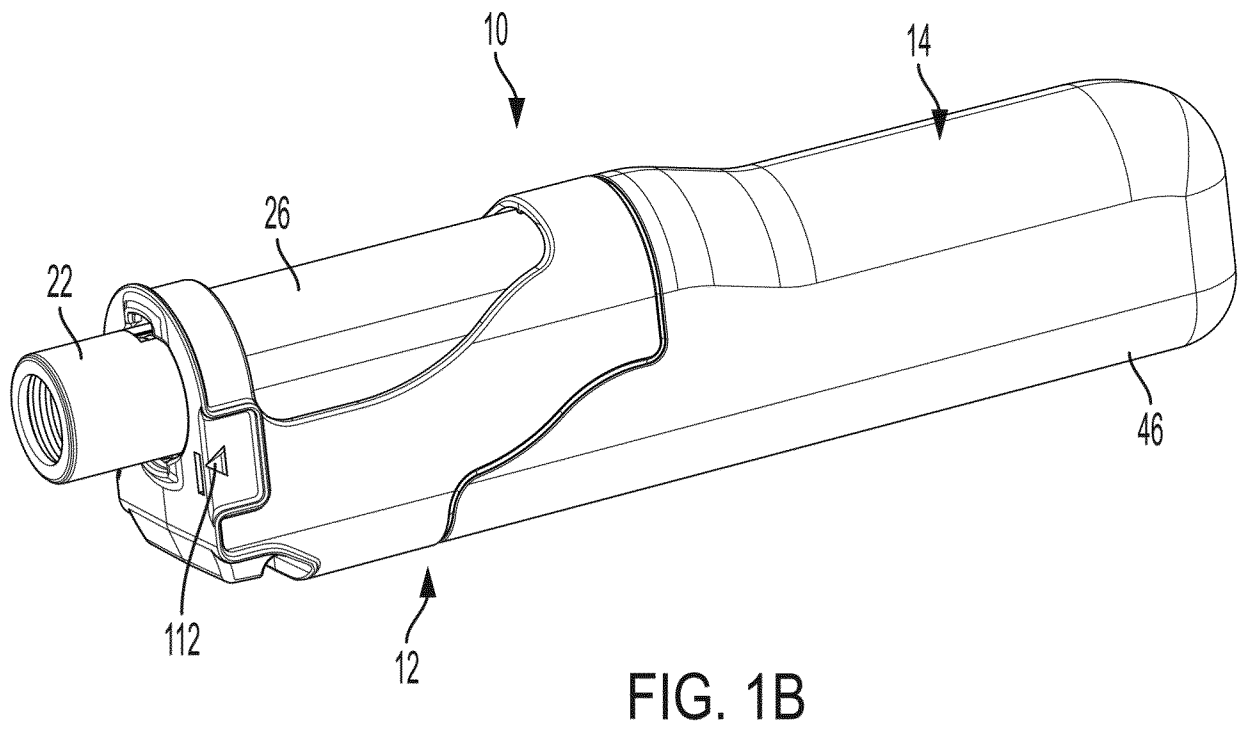
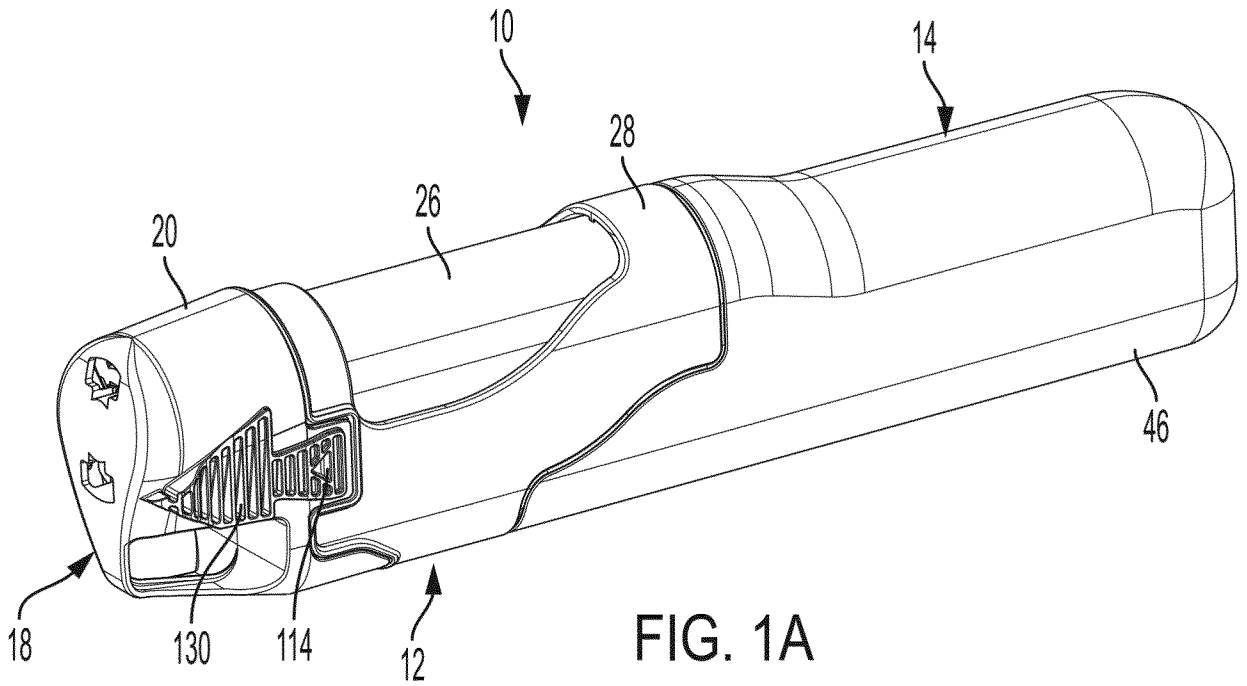
13. The drug delivery device (10) of any of claims 1-12, further comprising a syringe holder (24) positioned within the housing (26, 28, 46), the syringe holder (24) receiving the syringe assembly (16), the syringe holder (24) moveable relative to the housing (26, 28, 46), wherein the syringe holder (24) is disengaged with the drive assembly (40) when the outer portion (20) is secured to the housing (26, 28, 46), and wherein the syringe holder (24) is engaged with the drive assembly (40) upon axial movement of the outer portion (20) away from the housing (26, 28, 46).

14. The drug delivery device (10) of any of claims 1-13, wherein a surface (184) of the removal projection (164) is configured to engage a corresponding surface (186) of the rigid needle shield (58) to remove the rigid needle shield (58) upon axial movement of the outer portion (20) of the cap (18) away from the housing (26, 28, 46), the surface (184) of the removal projection (164) is disengaged from the corresponding surface (186) of the rigid needle shield (58) when the outer portion (20) is secured to the housing (26, 28, 46).

15. The drug delivery device (10) of claim 14, wherein the protrusion (120) is configured to be removed from the cap opening (122) before the surface (184) of the removal projection (164) engages the corresponding surface (186) of the rigid needle shield (58) upon axial movement of the outer portion (20) away from the housing (26, 28, 46).



16. The drug delivery device (10) of any of claims 1-15, wherein the outer portion (20) comprises one of a lock protrusion (112) and a lock recess (114) and the housing (26, 28, 46) comprises the other of the lock protrusion (112) and the lock recess (114), the lock protrusion (112) received by the lock recess (114) to secure the outer portion (20) to the housing (26, 28, 46), and wherein the lock protrusion (112) is separated from the lock recess (114) before the surface (184) of the removal projection (164) engages the corresponding surface (186) of the rigid needle shield (58) upon axial movement of the outer portion (20) away from the housing (26, 28, 46).



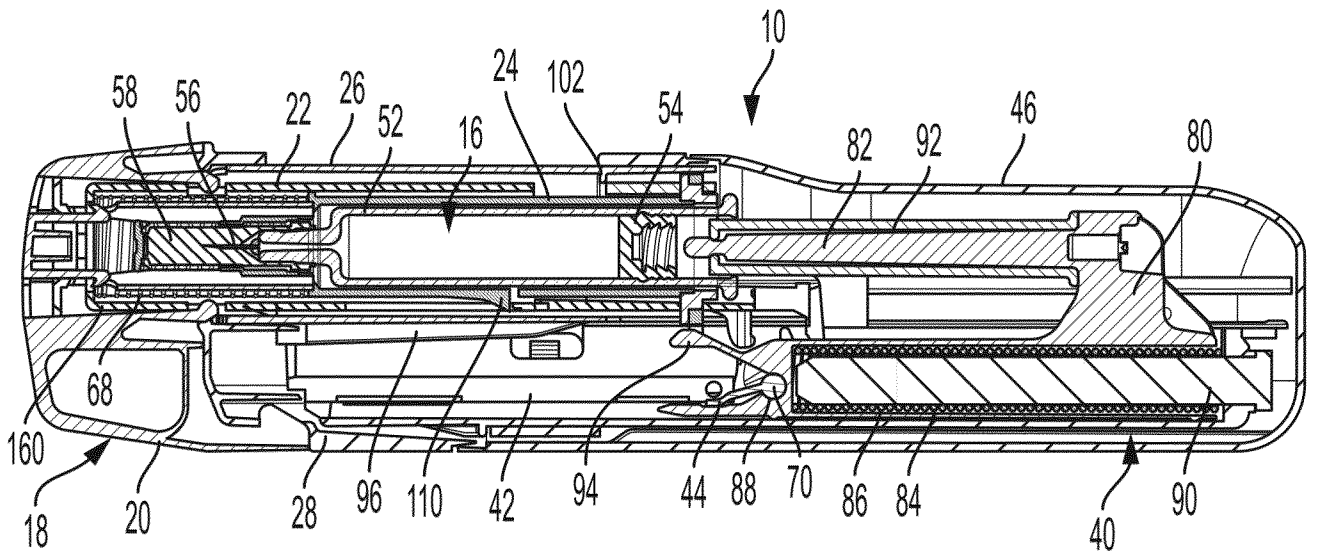


FIG. 2A

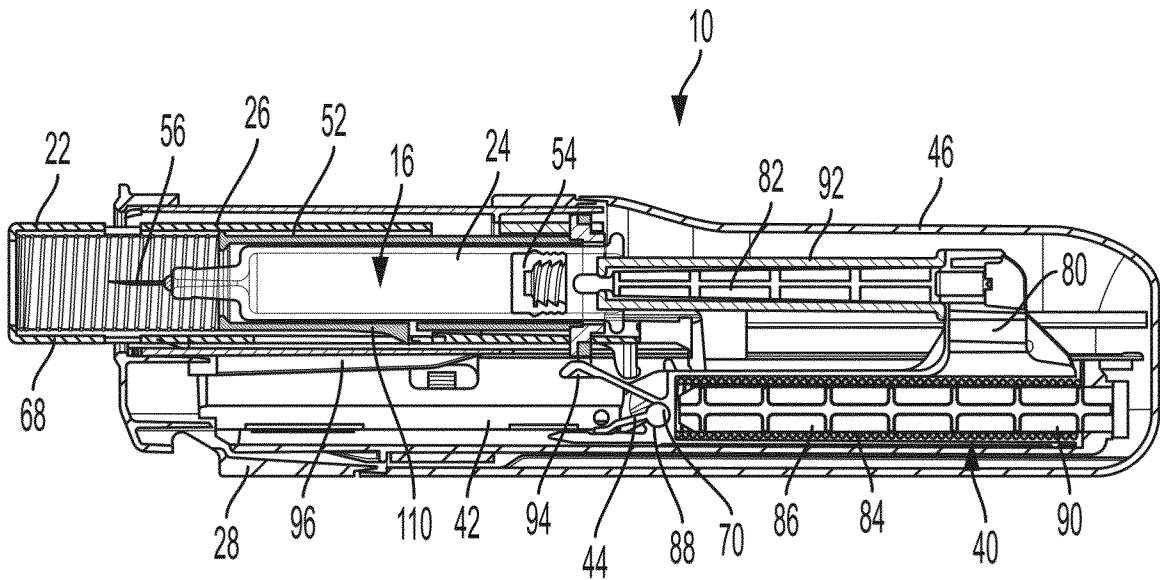


FIG. 2B

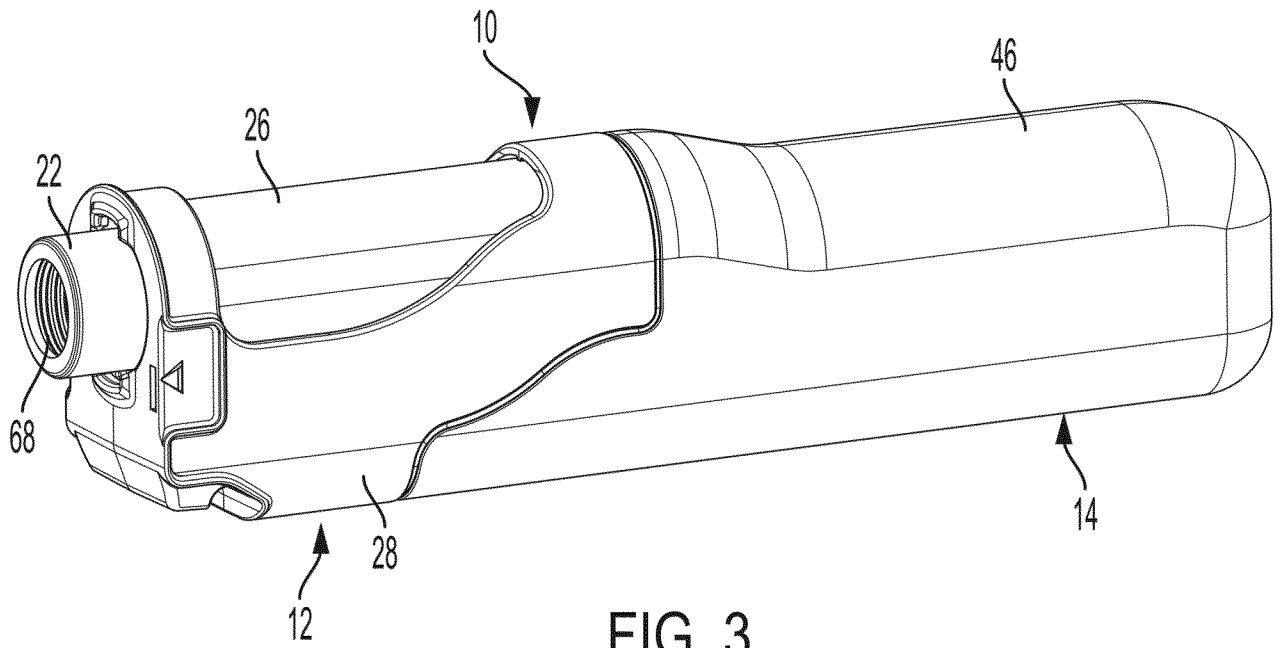


FIG. 3

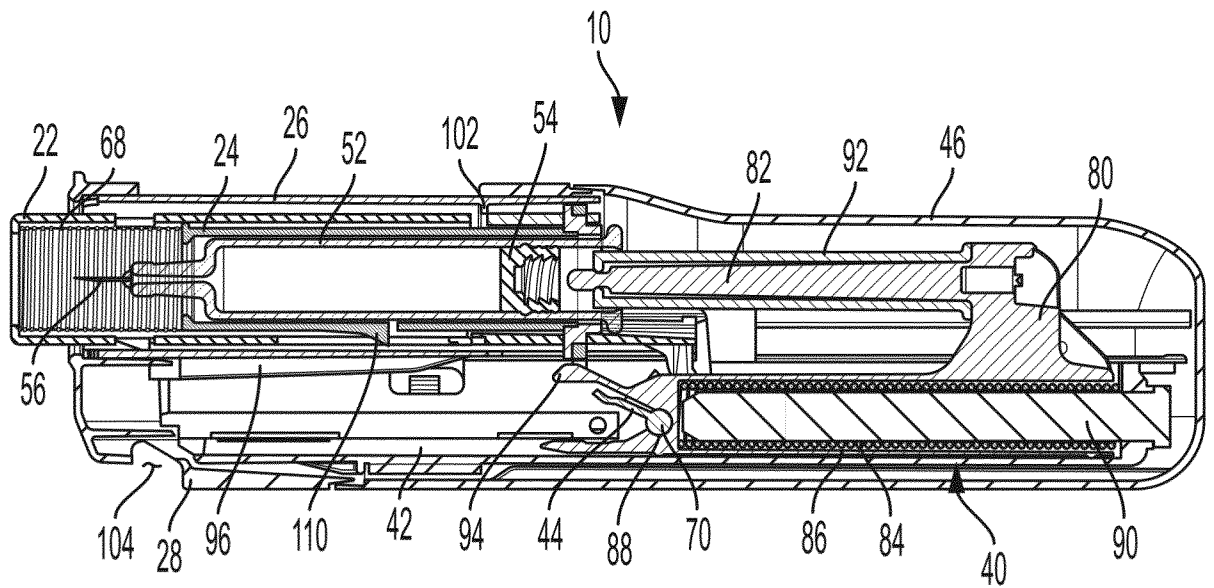


FIG. 4

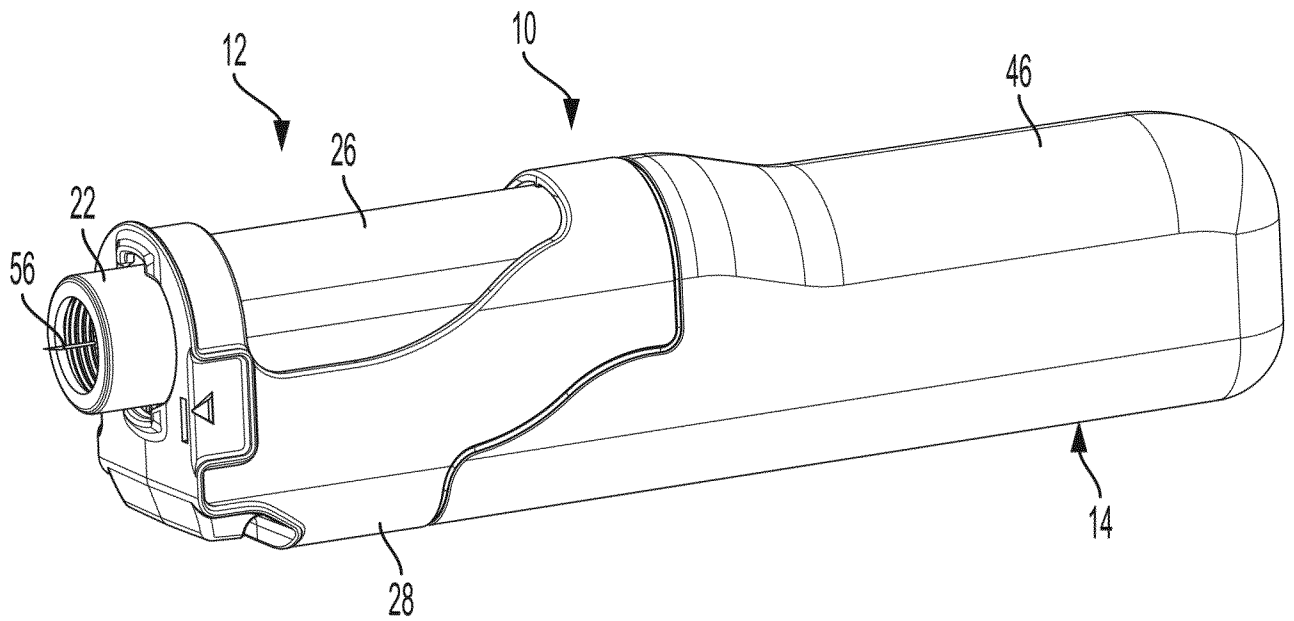


FIG. 5

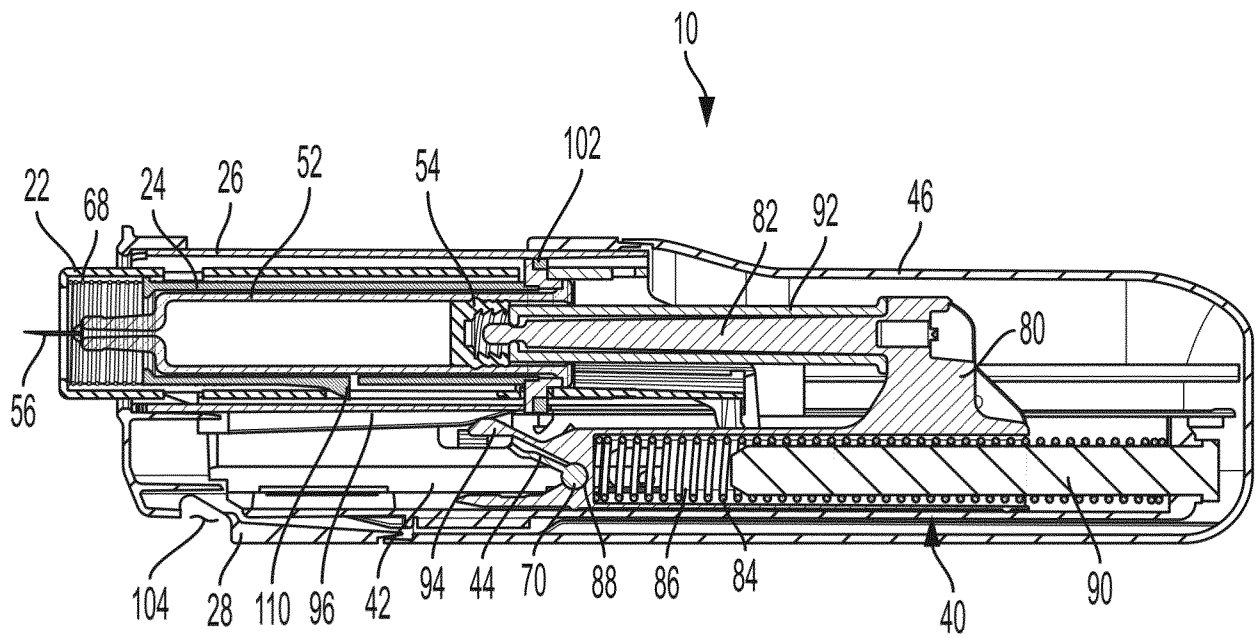


FIG. 6

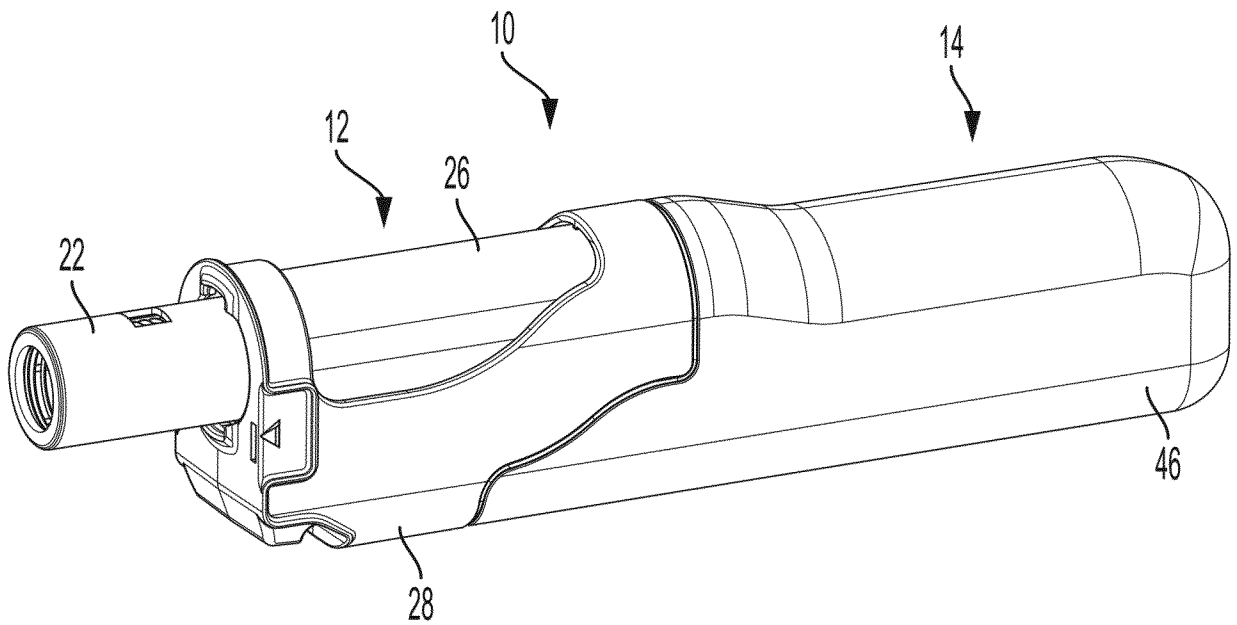


FIG. 7

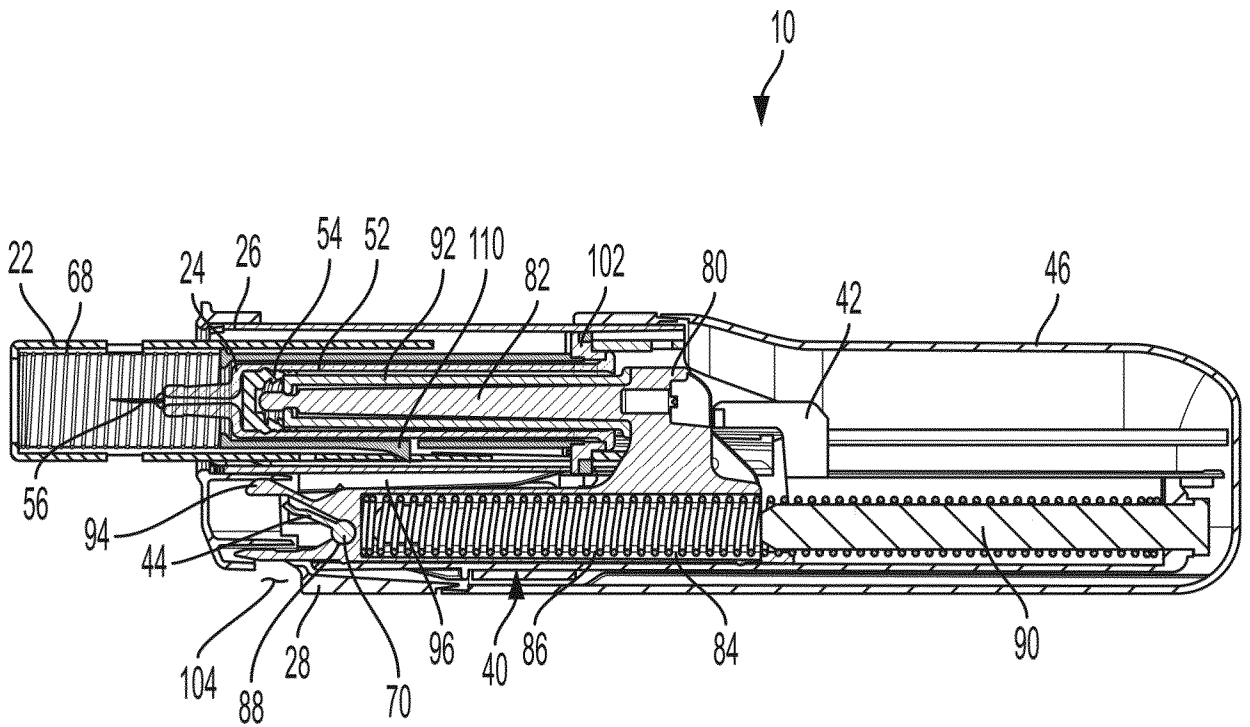


FIG. 8

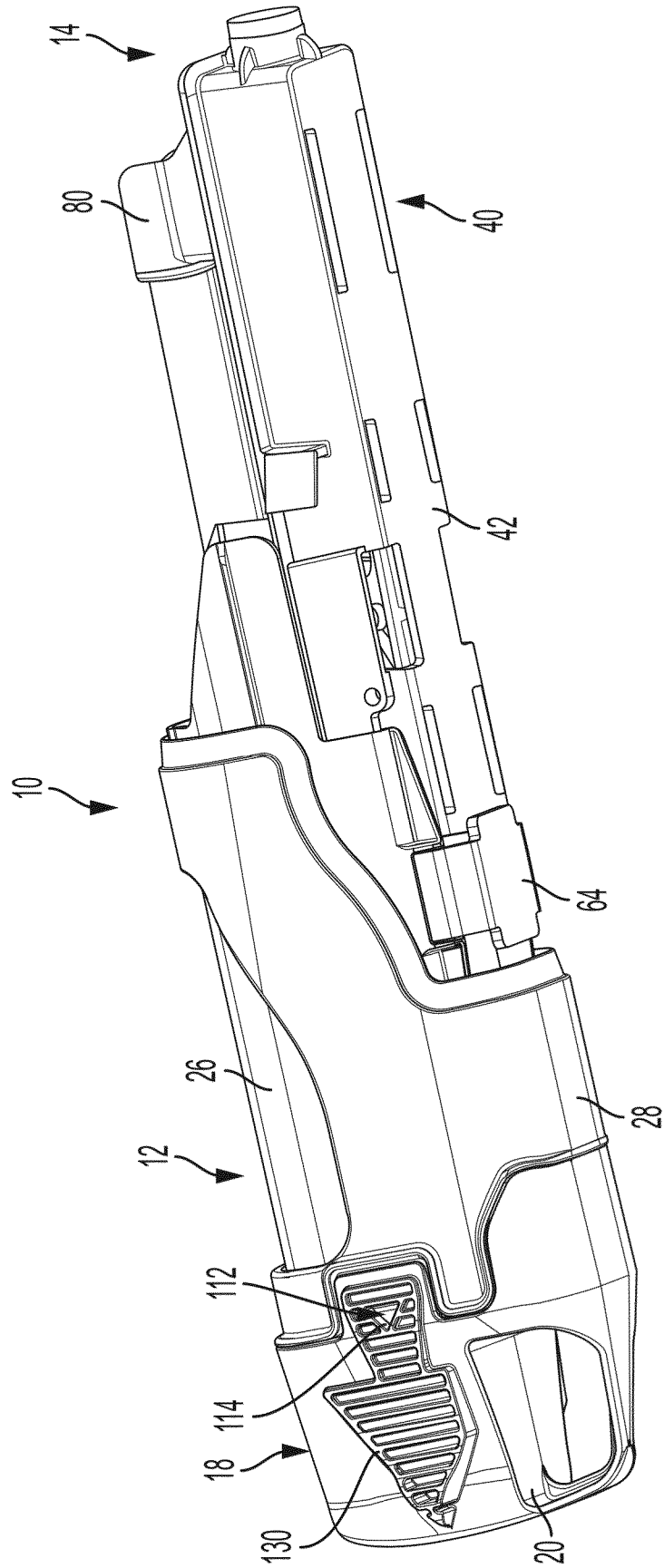


FIG. 9

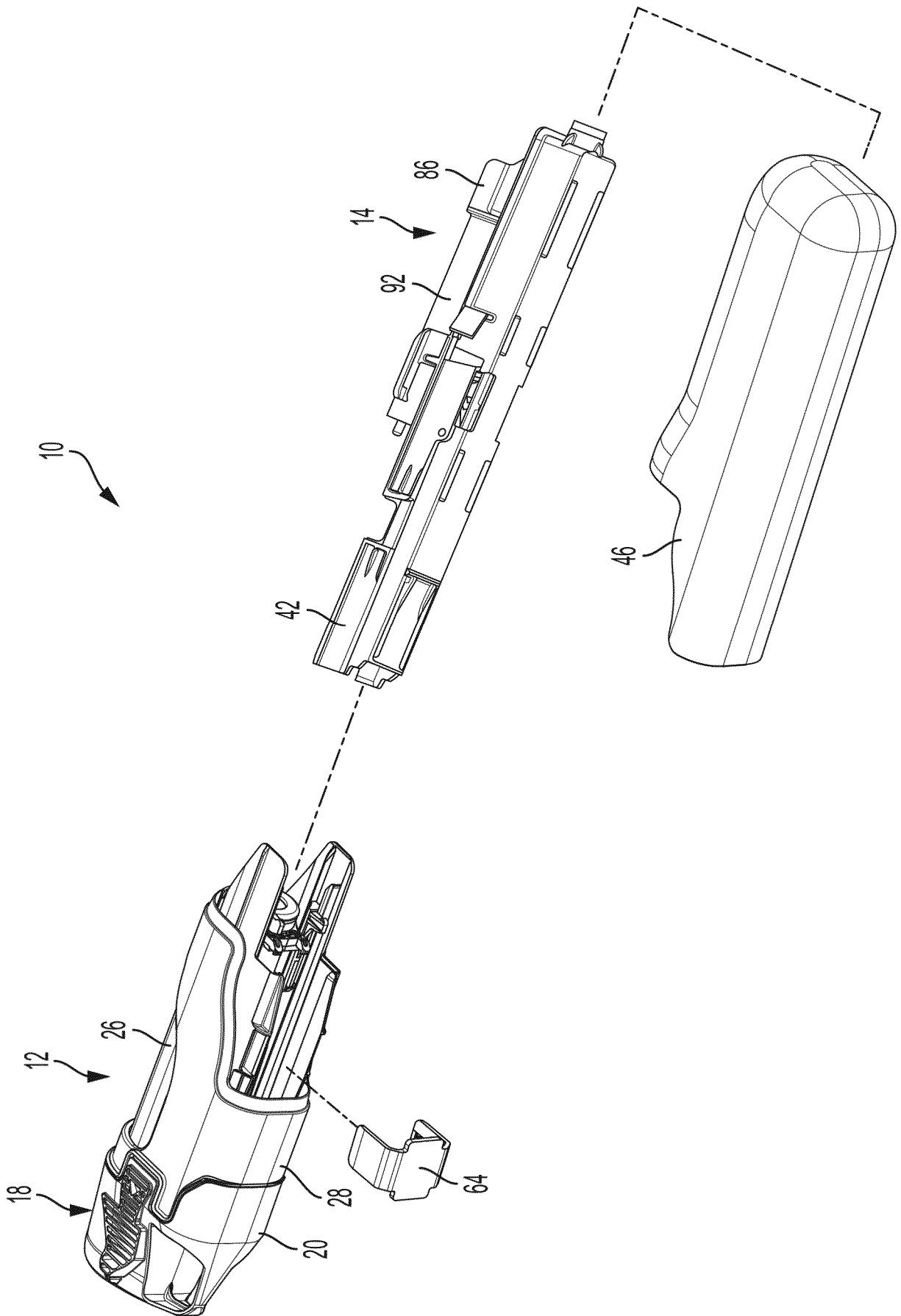


FIG. 10



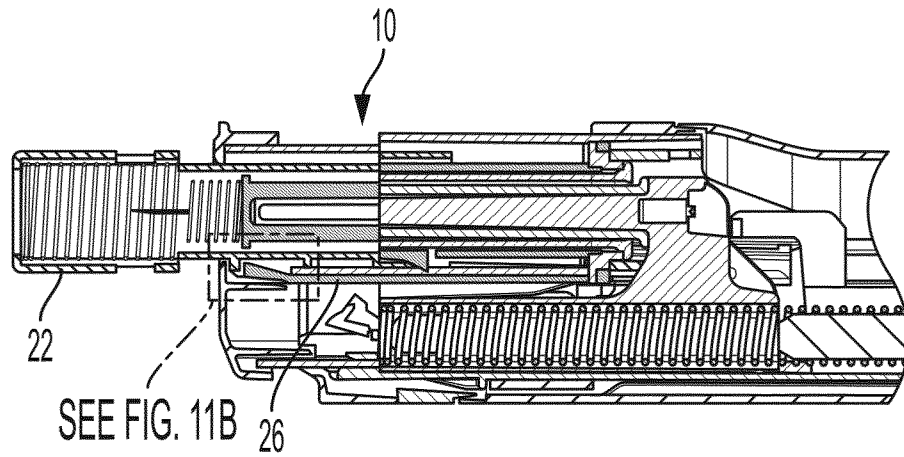


FIG. 11A

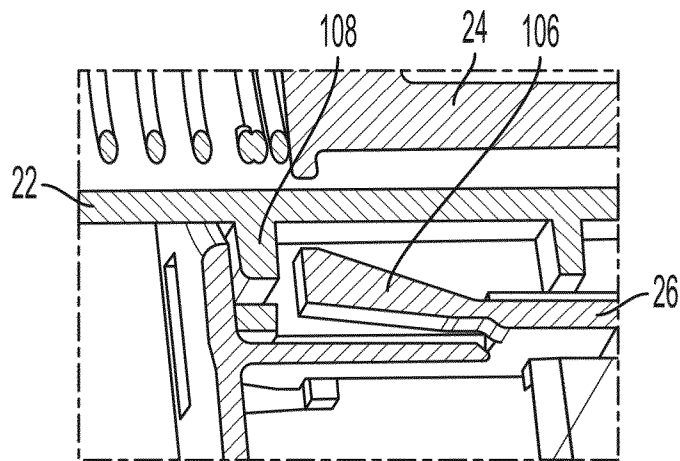


FIG. 11B

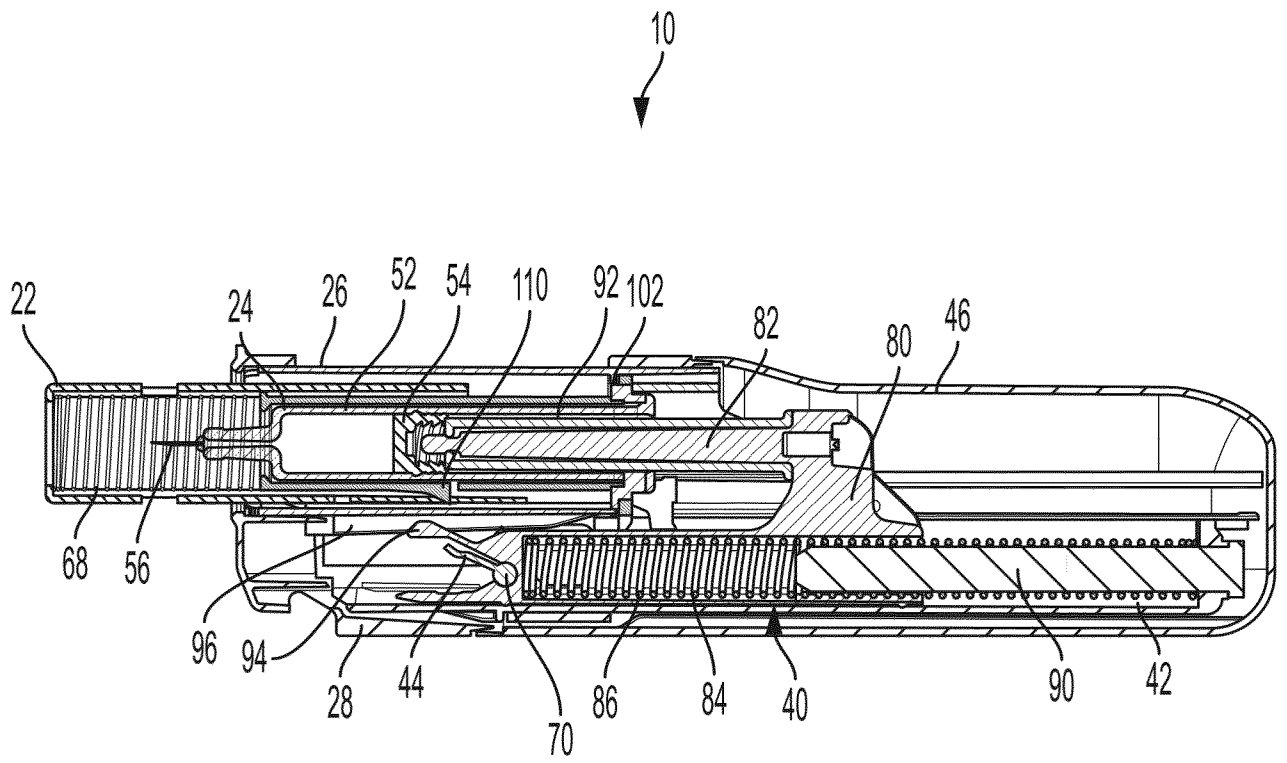


FIG. 12

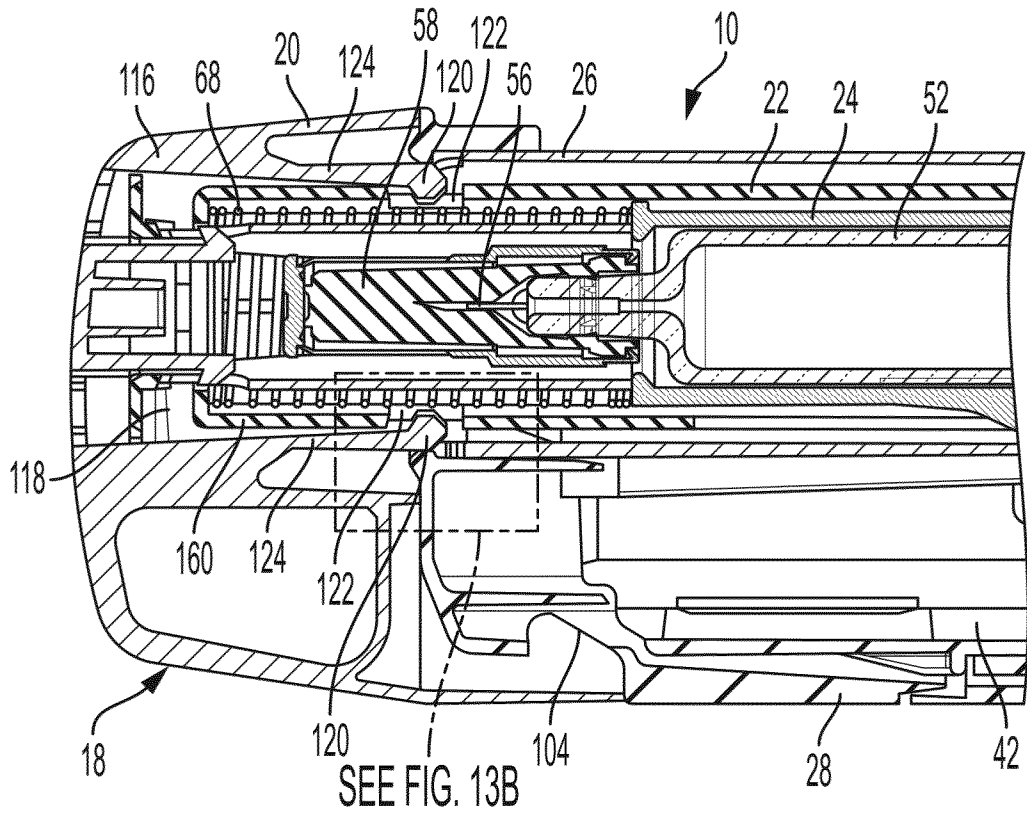


FIG. 13A

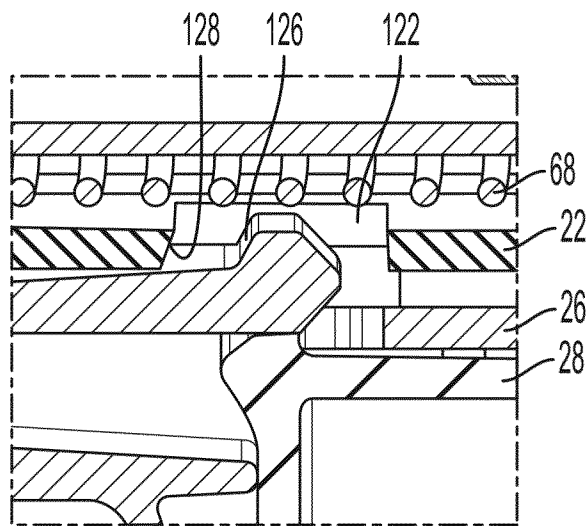


FIG. 13B

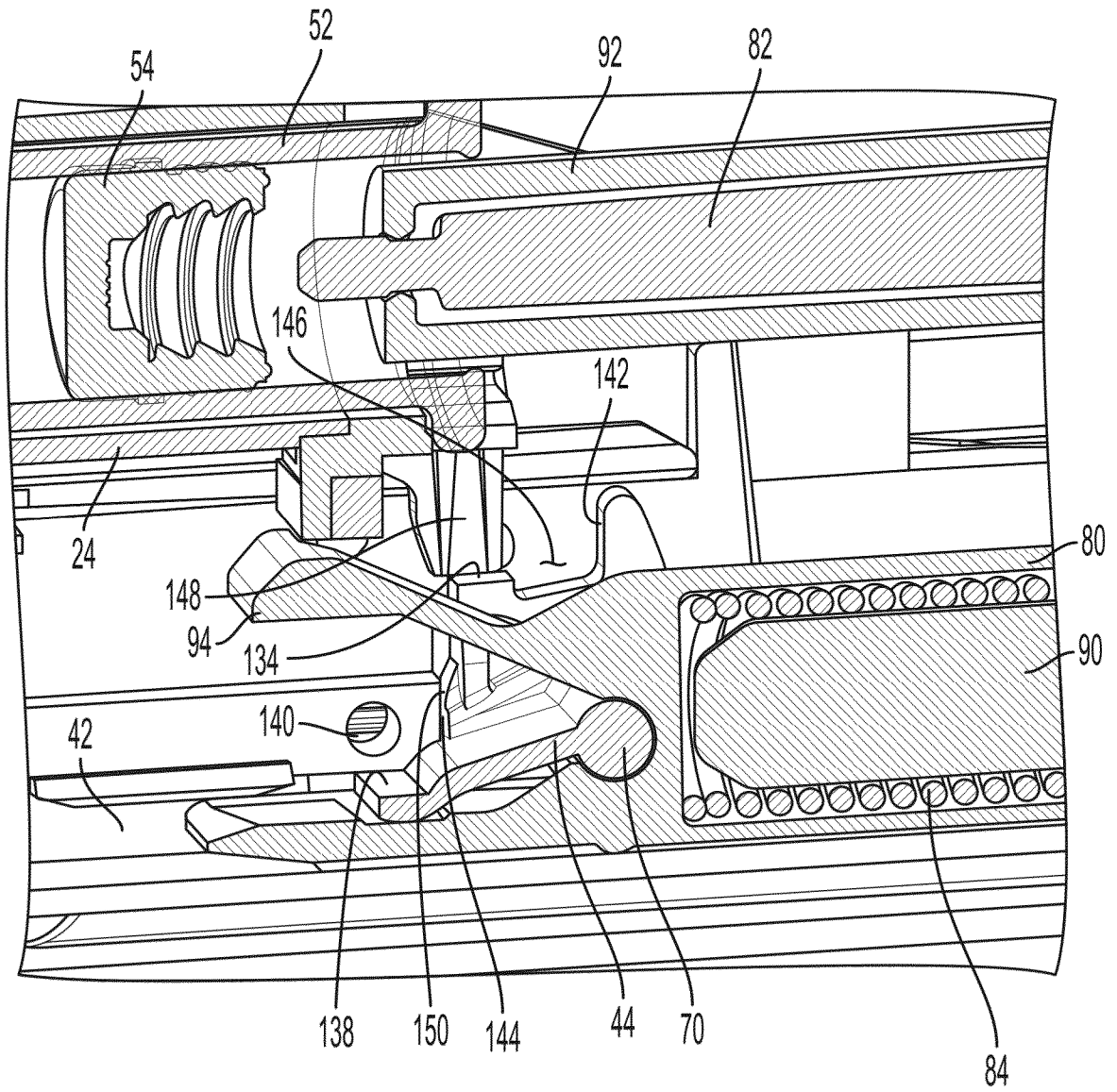


FIG. 14

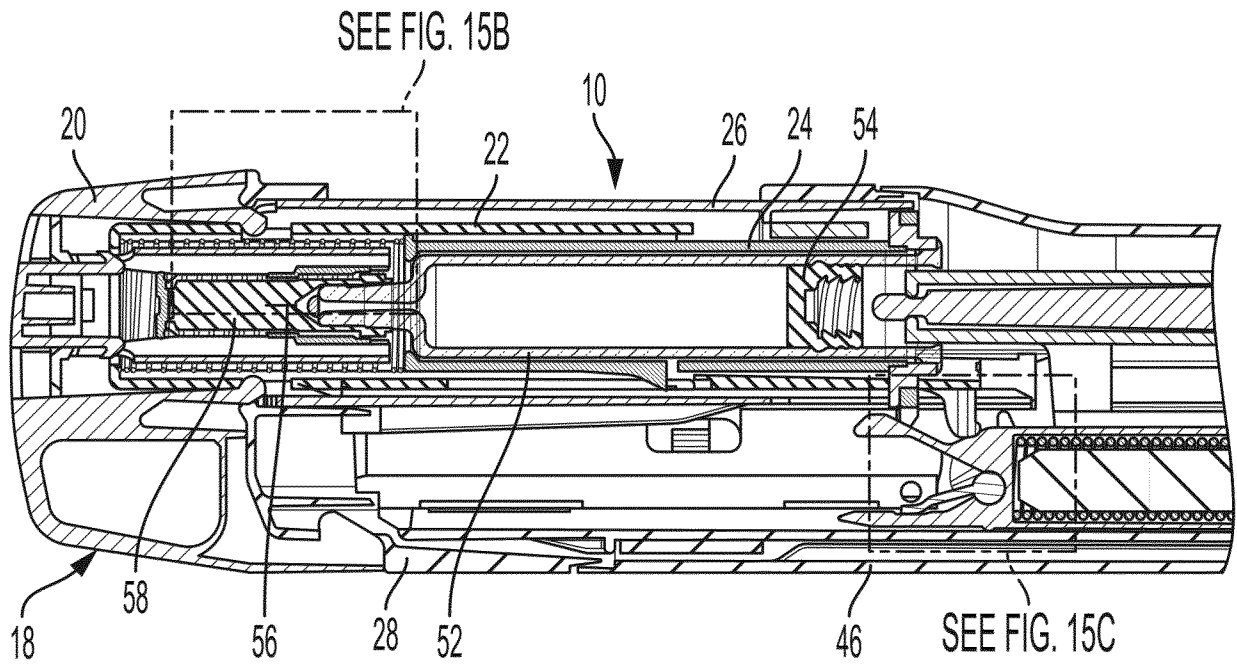


FIG. 15A

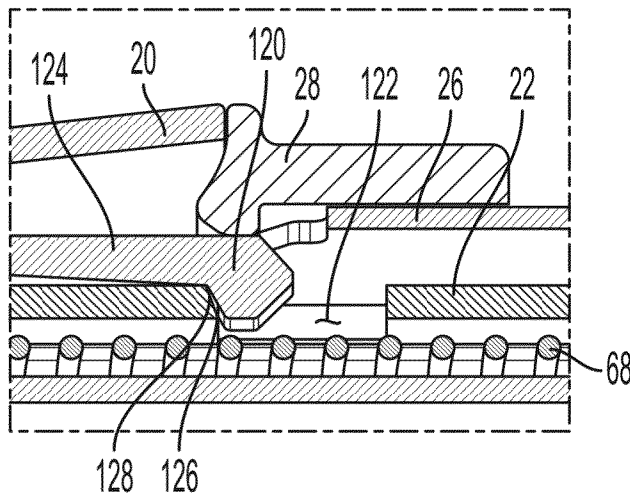


FIG. 15B

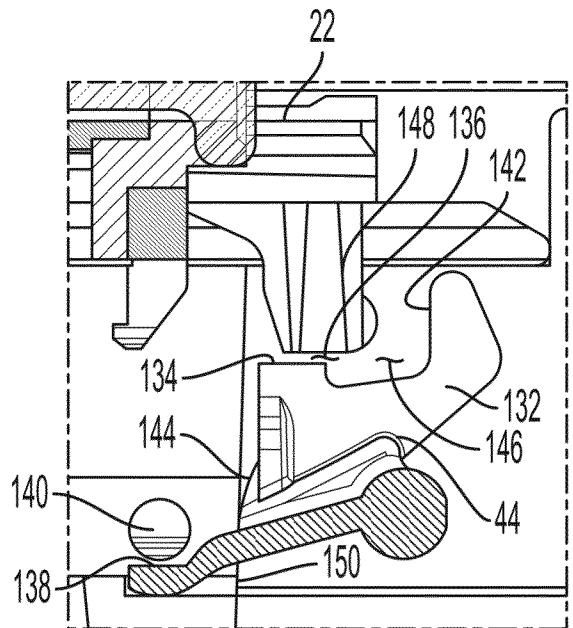


FIG. 15C

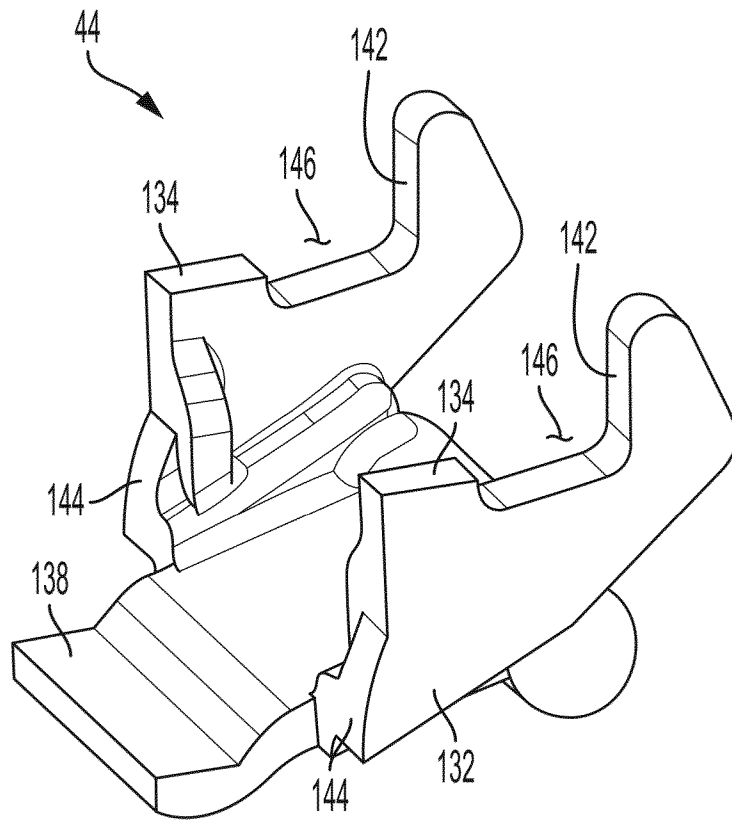


FIG. 16

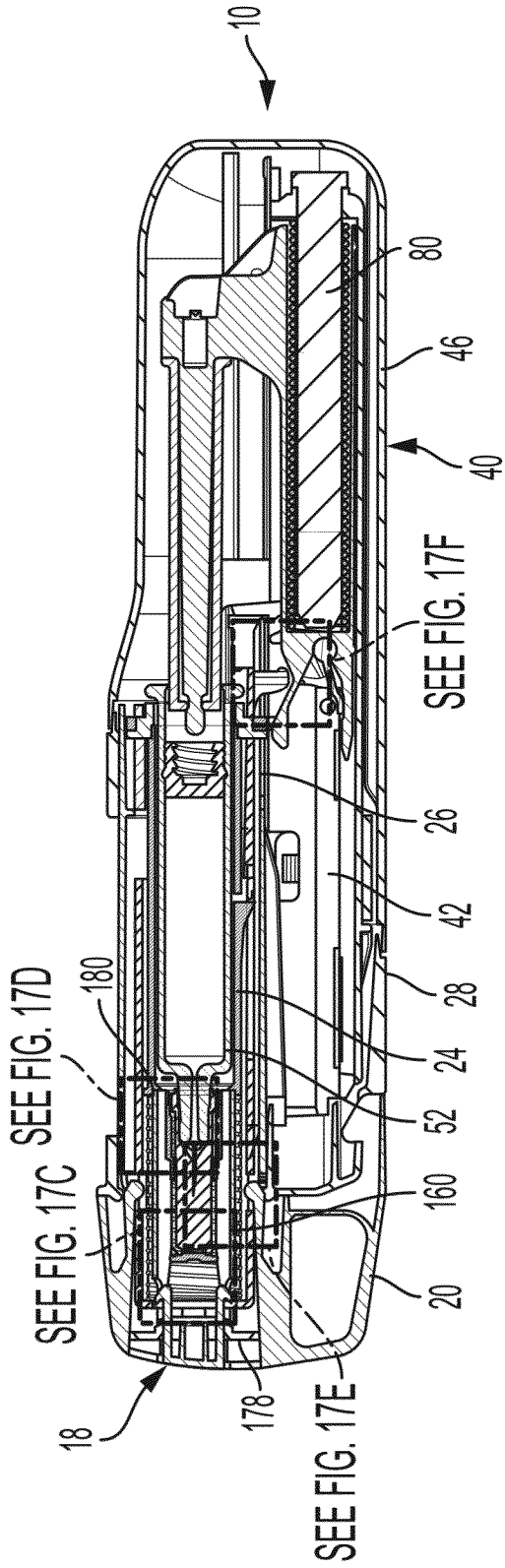


FIG. 17A

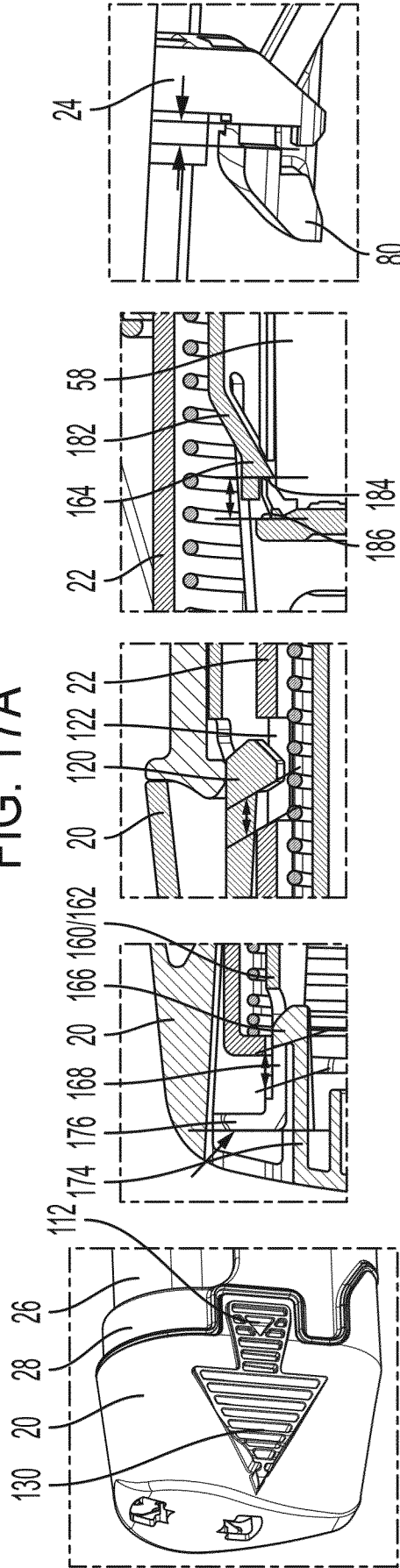


FIG. 17B

FIG. 17C

FIG. 17D

FIG. 17E

FIG. 17F

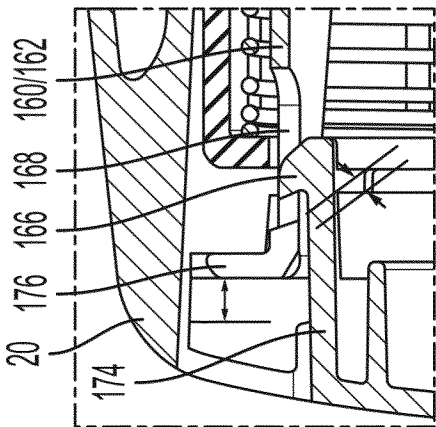


FIG. 18C

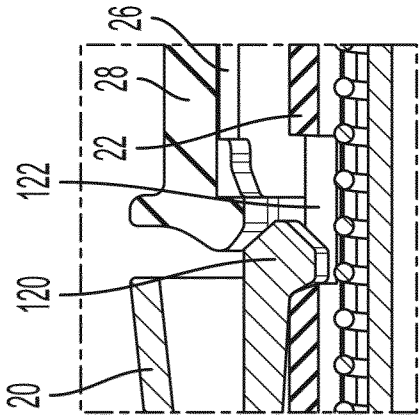


FIG. 18D

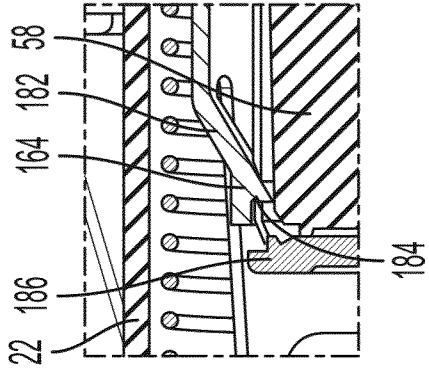


FIG. 18E

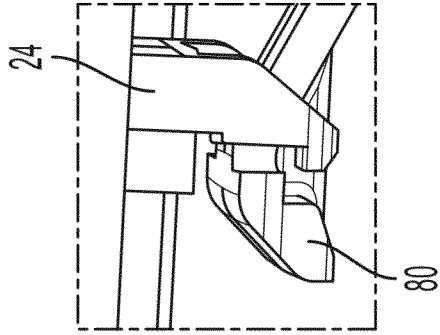


FIG. 18F

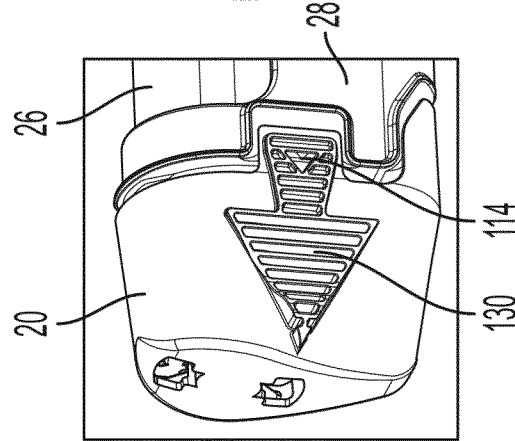


FIG. 18B

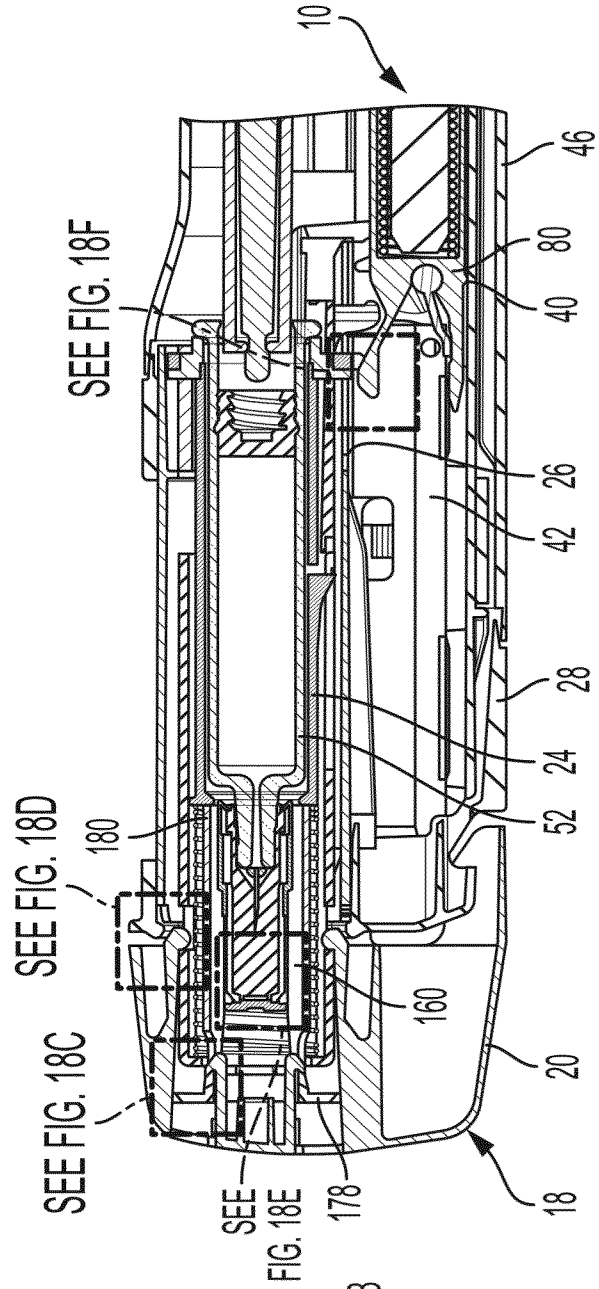


FIG. 18A



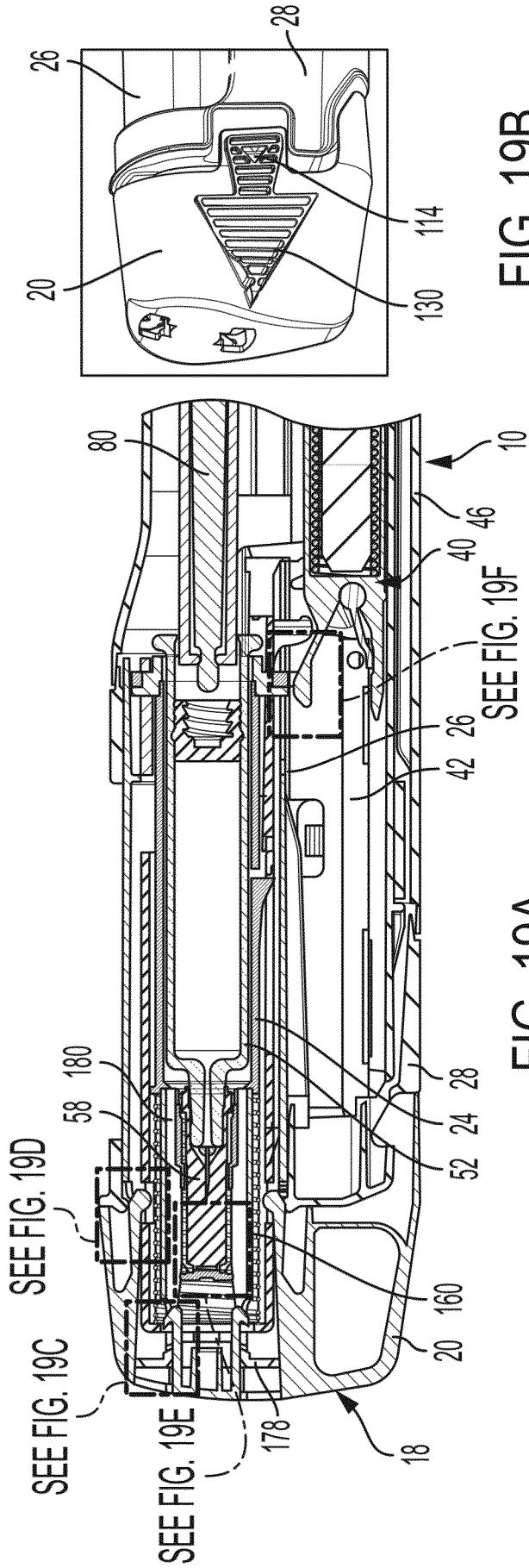


FIG. 19A

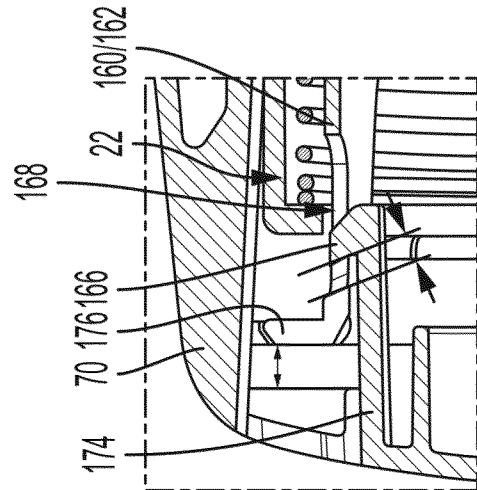


FIG. 19C

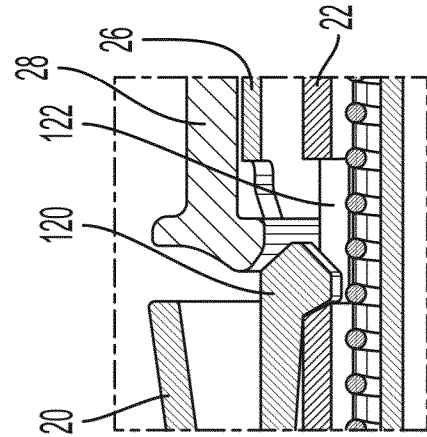


FIG. 19D

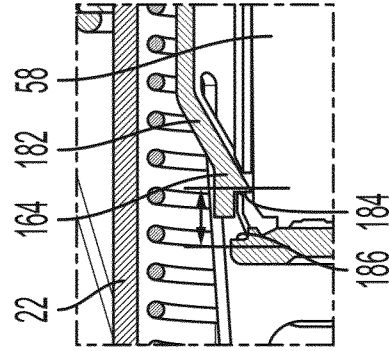


FIG. 19E

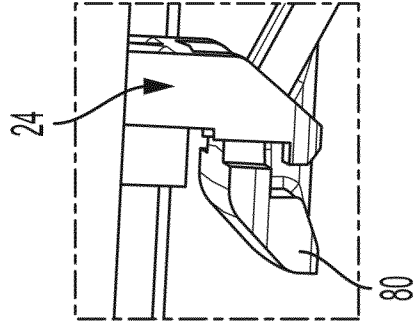


FIG. 19F

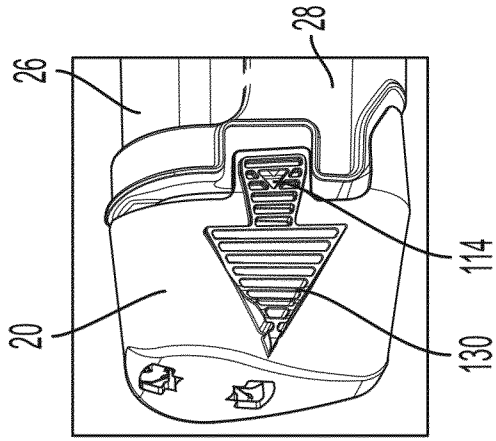


FIG. 19B

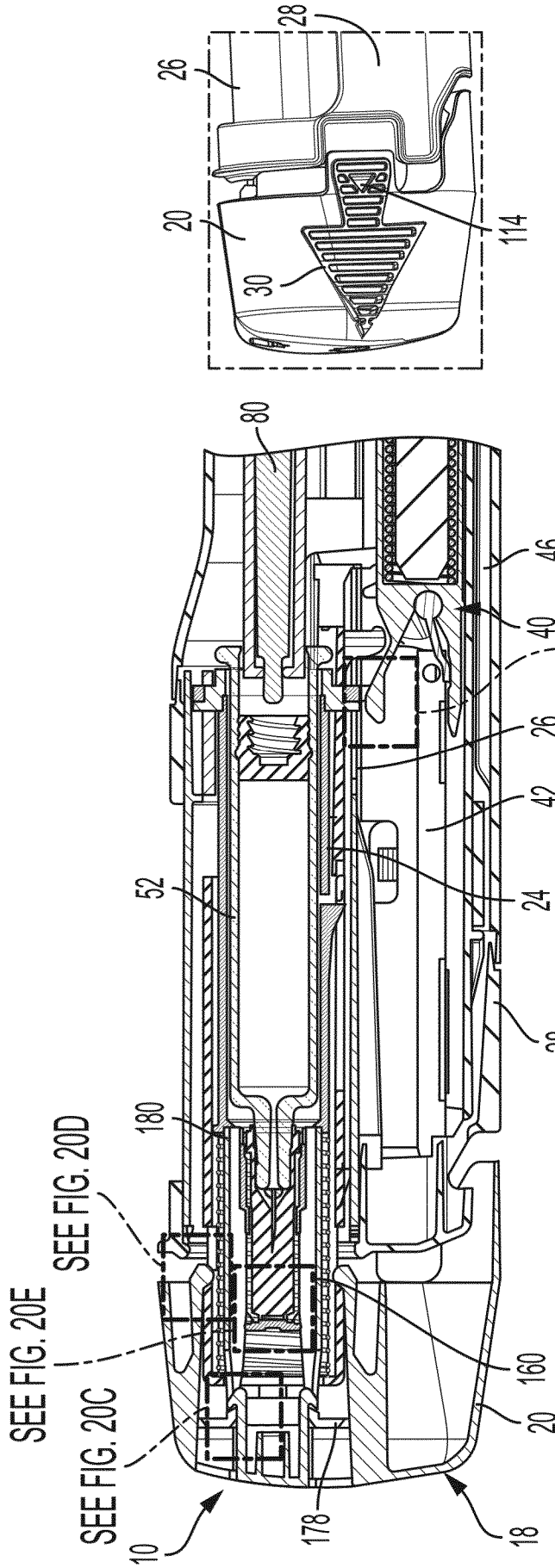


FIG. 20A

SEE FIG. 20F

FIG. 20B

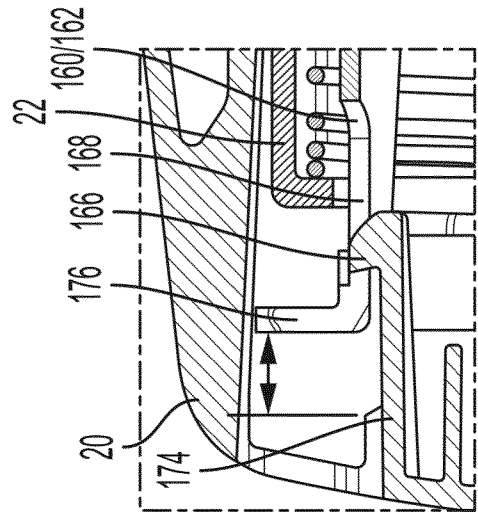


FIG. 20C

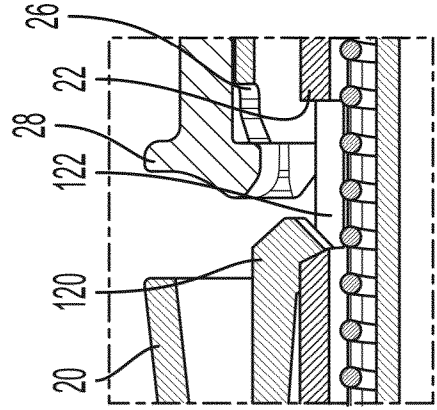


FIG. 20D

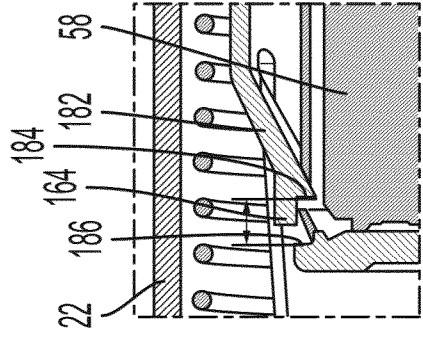


FIG. 20E

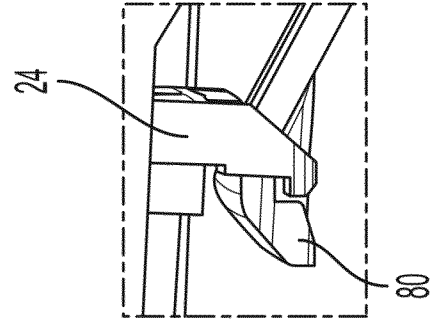
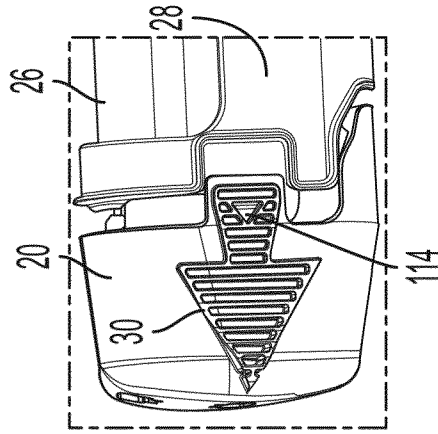


FIG. 20F



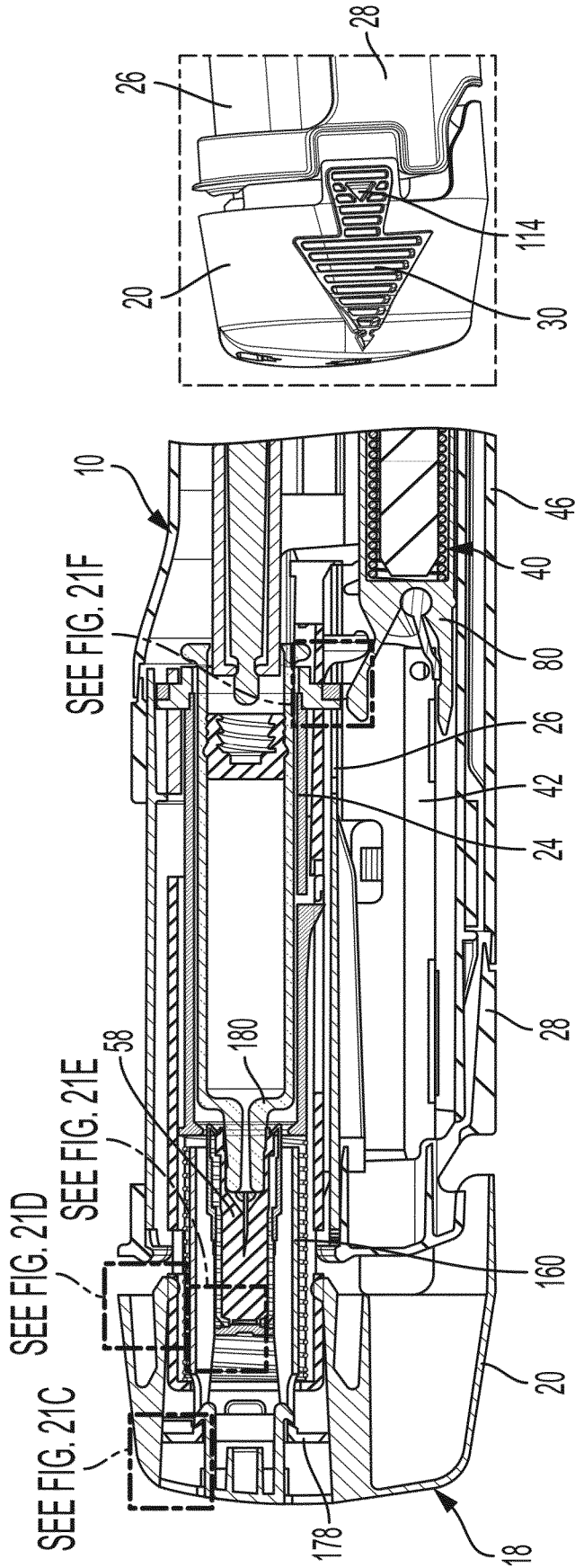


FIG. 21A

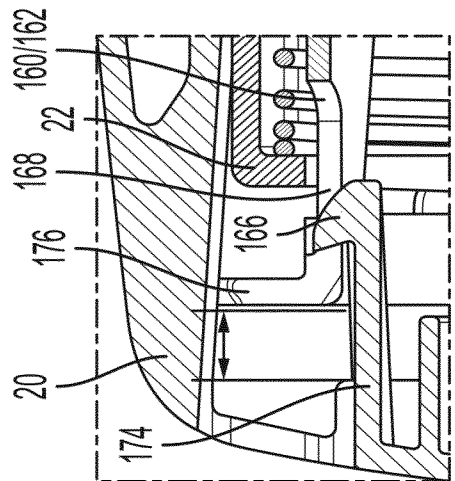


FIG. 21C

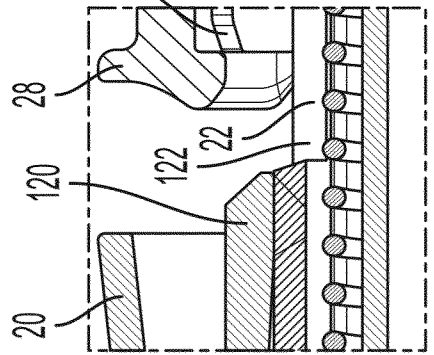


FIG. 21D

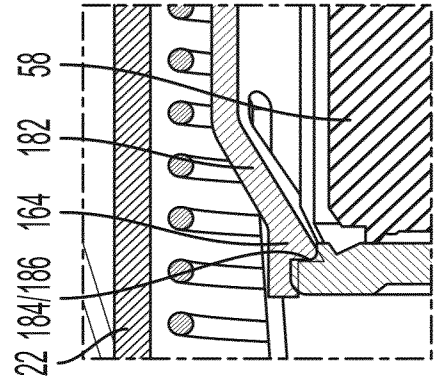


FIG. 21E

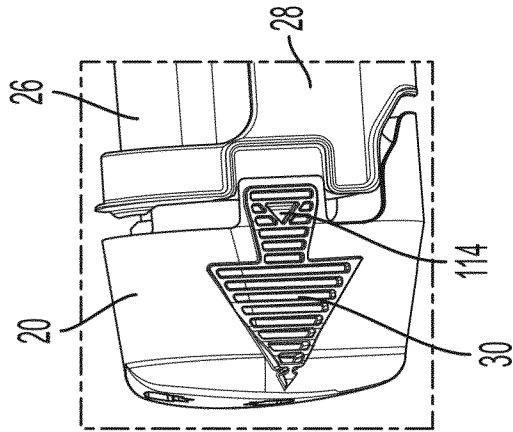


FIG. 21B

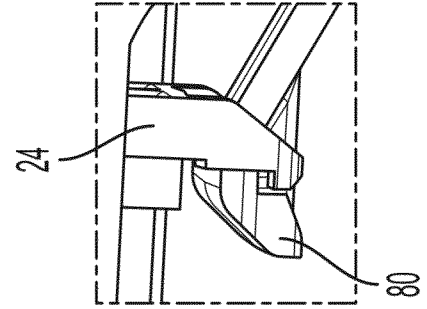


FIG. 21F

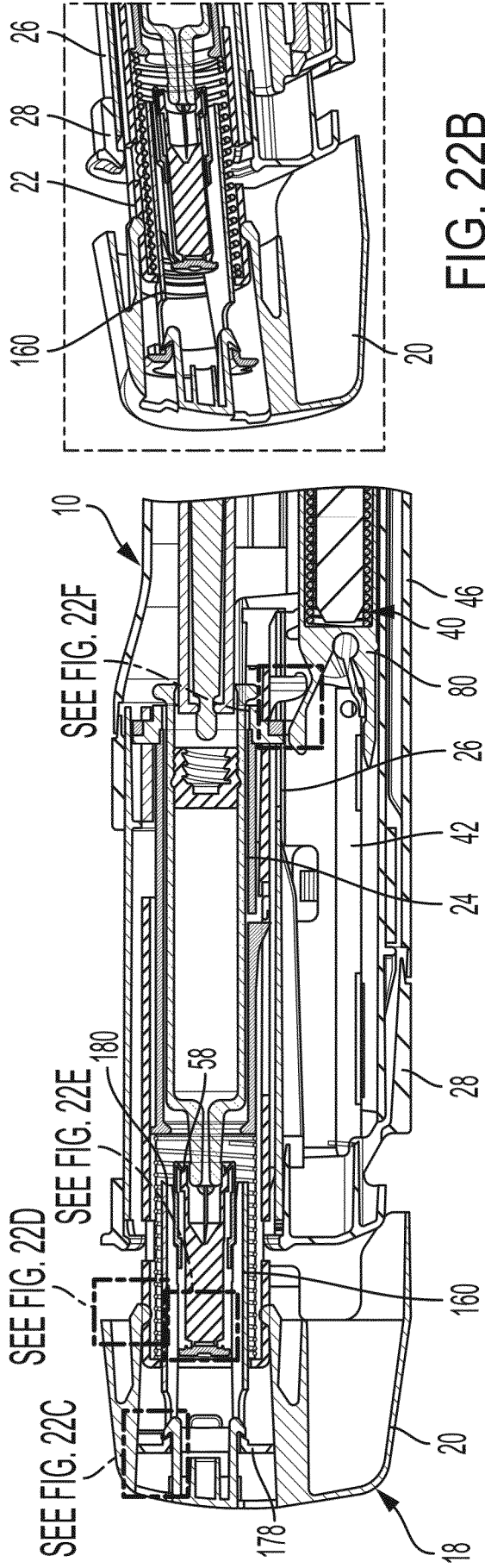


FIG. 22A

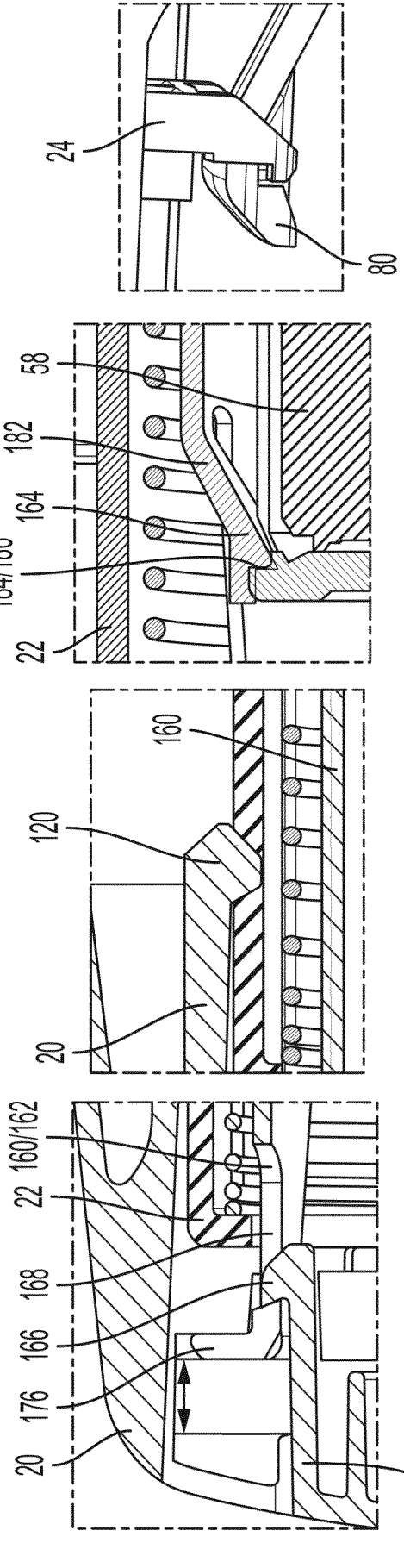


FIG. 22B

FIG. 22F

FIG. 22E

FIG. 22D

FIG. 22C

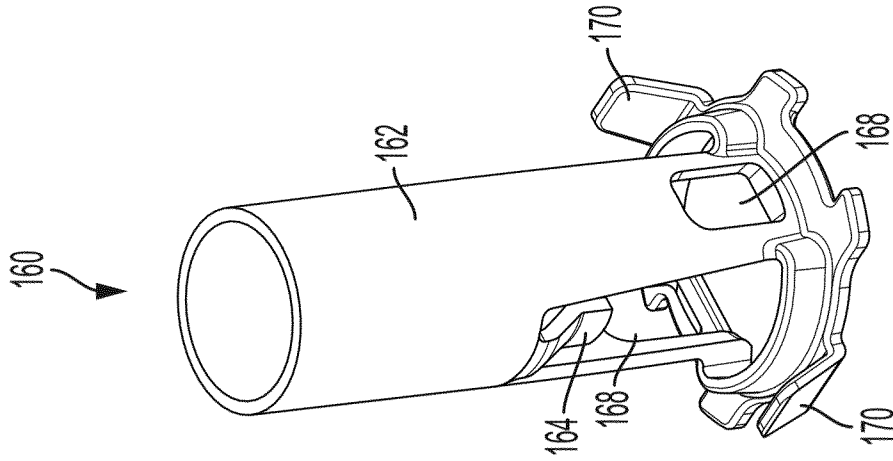


FIG. 24

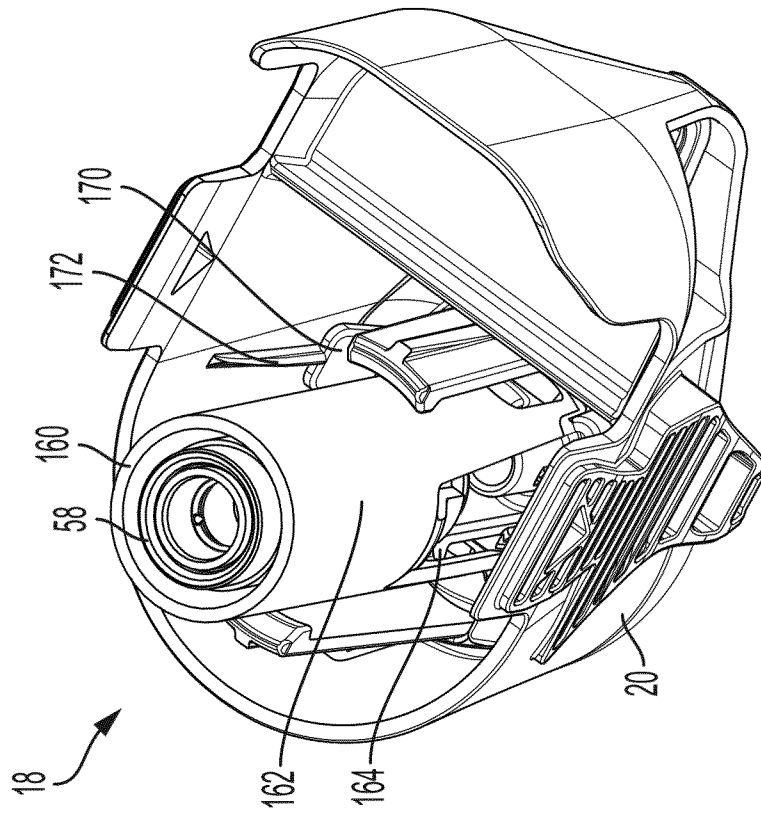


FIG. 23

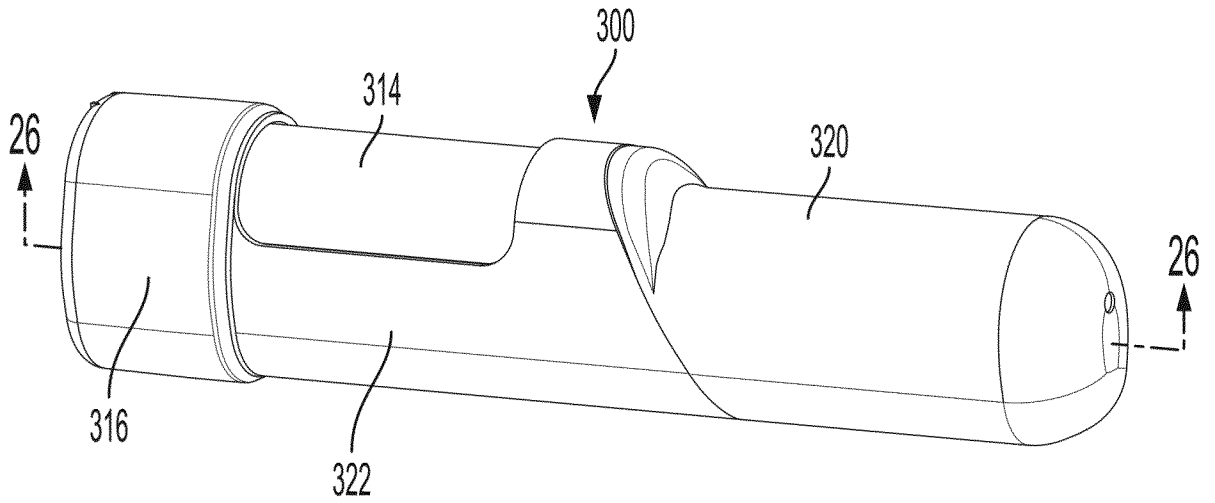


FIG. 25

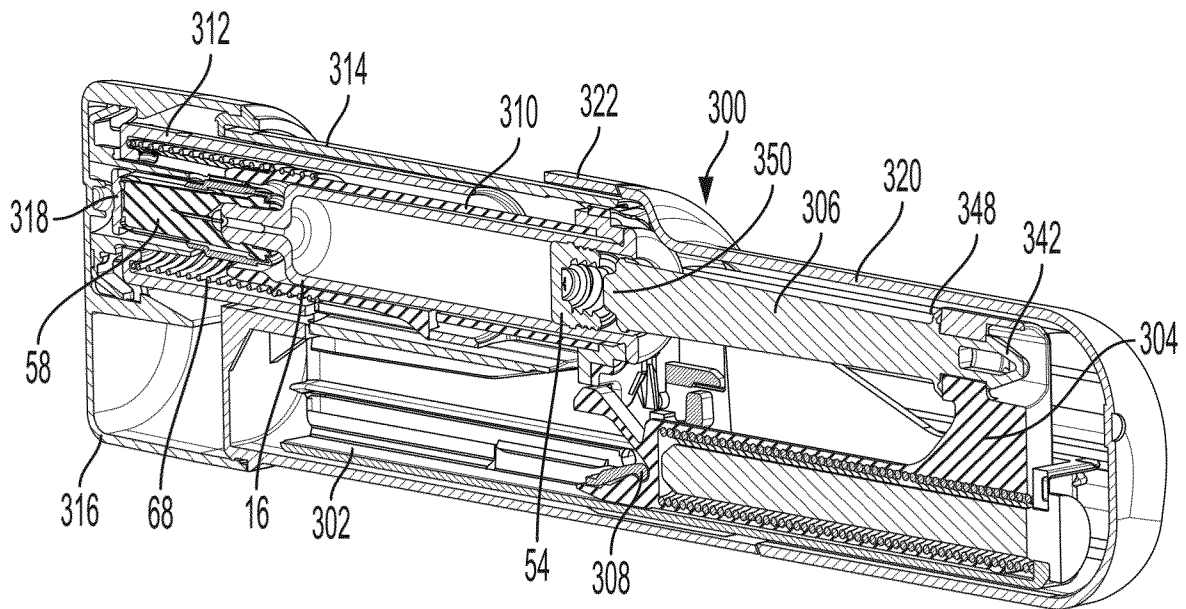


FIG. 26

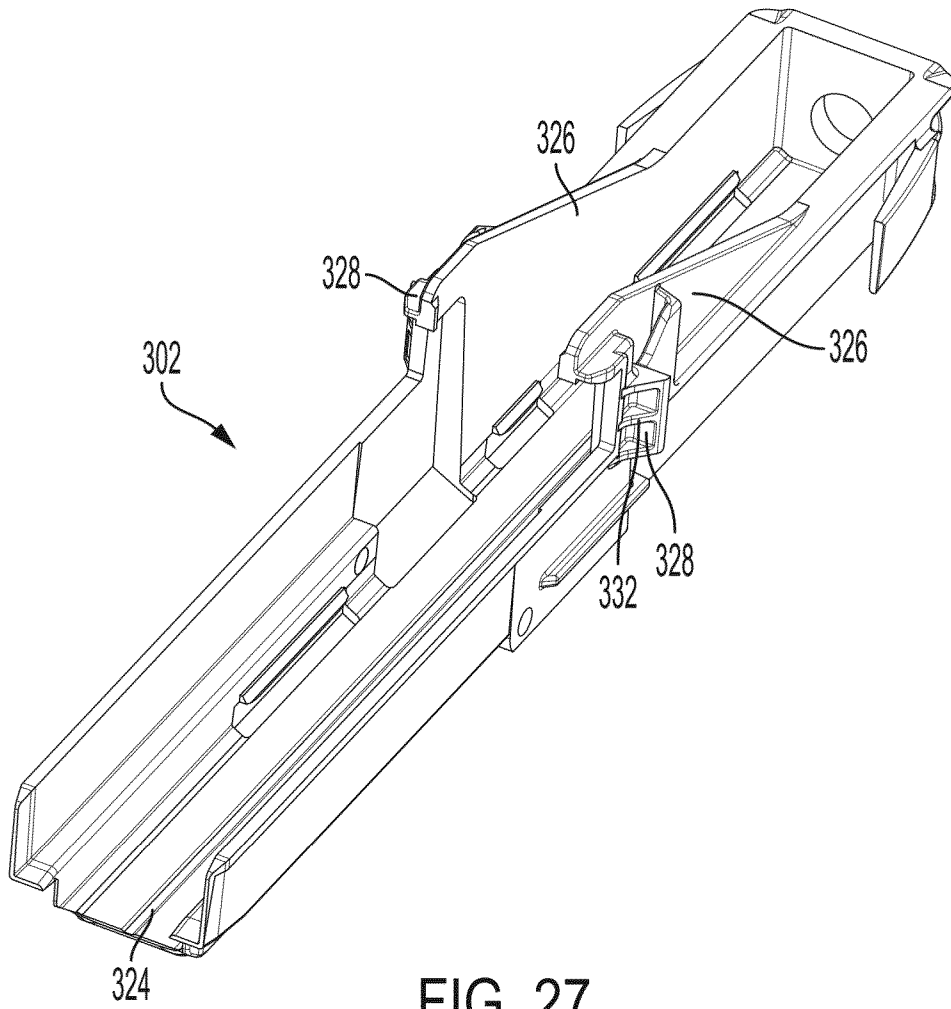


FIG. 27

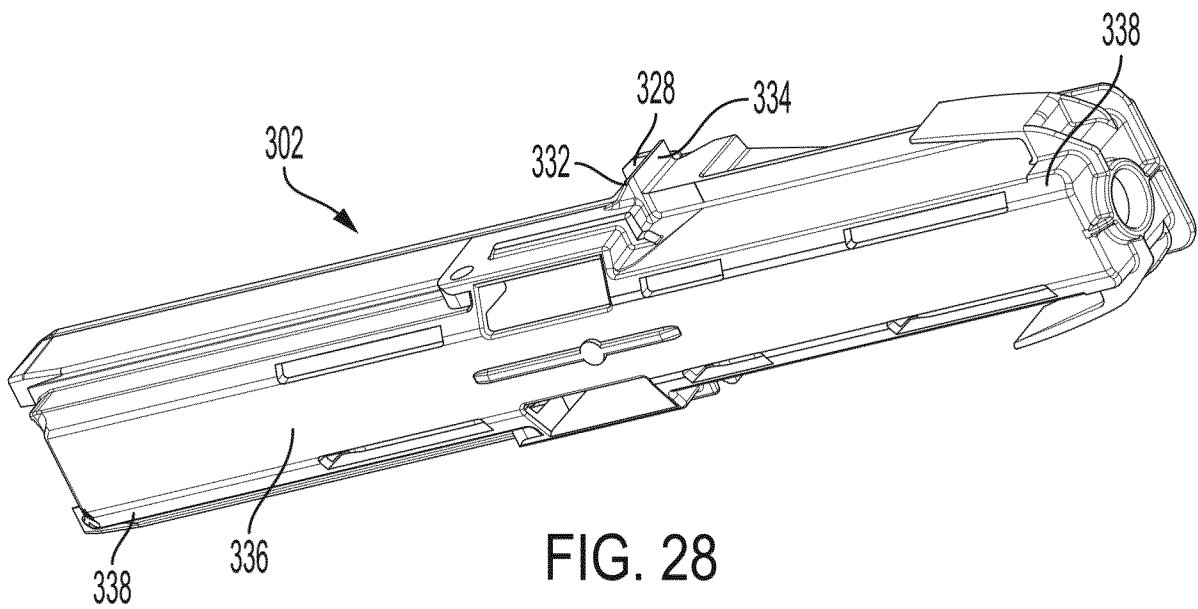


FIG. 28

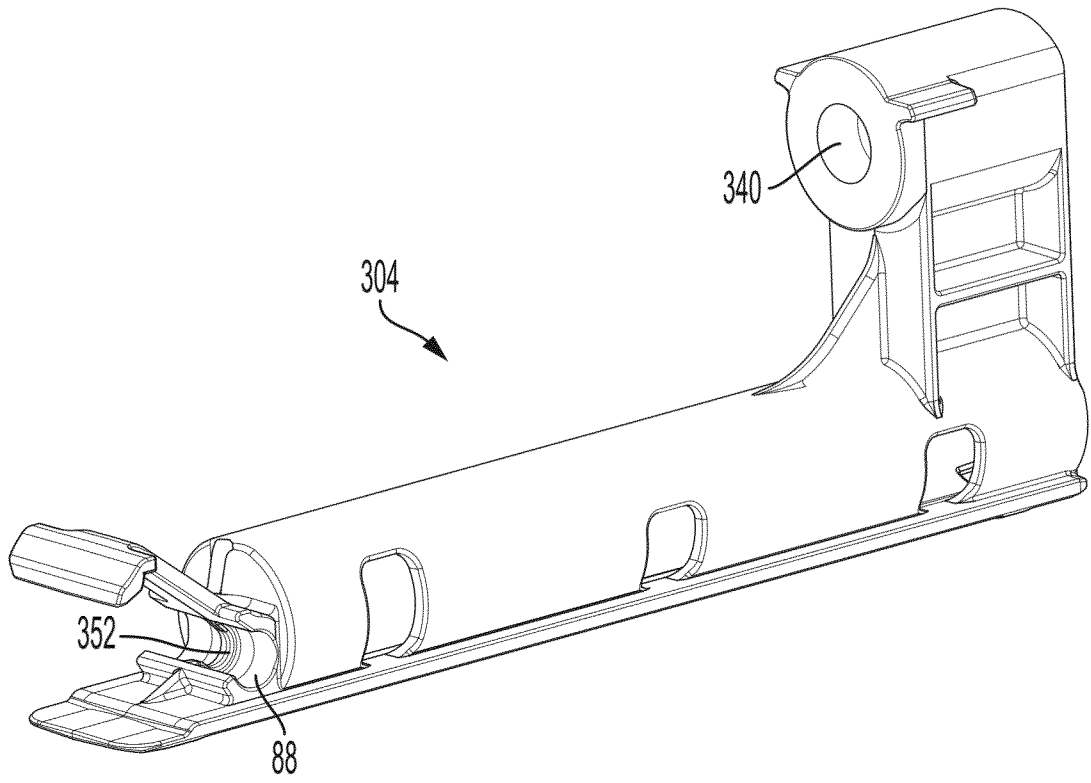


FIG. 29

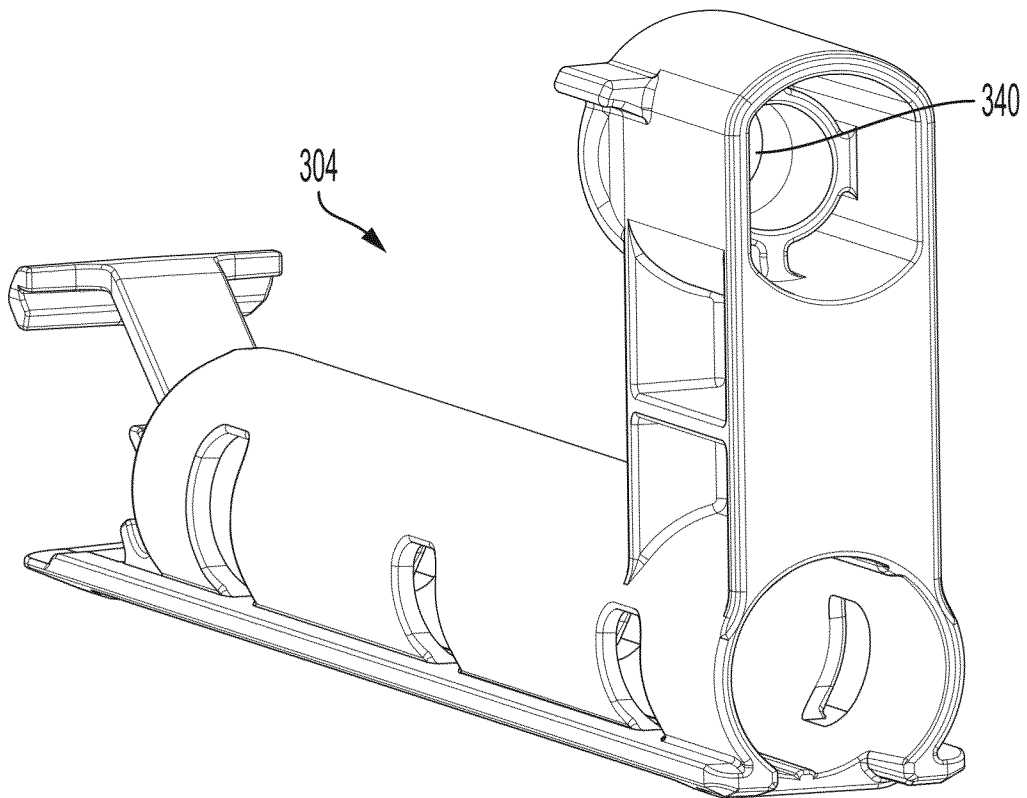


FIG. 30



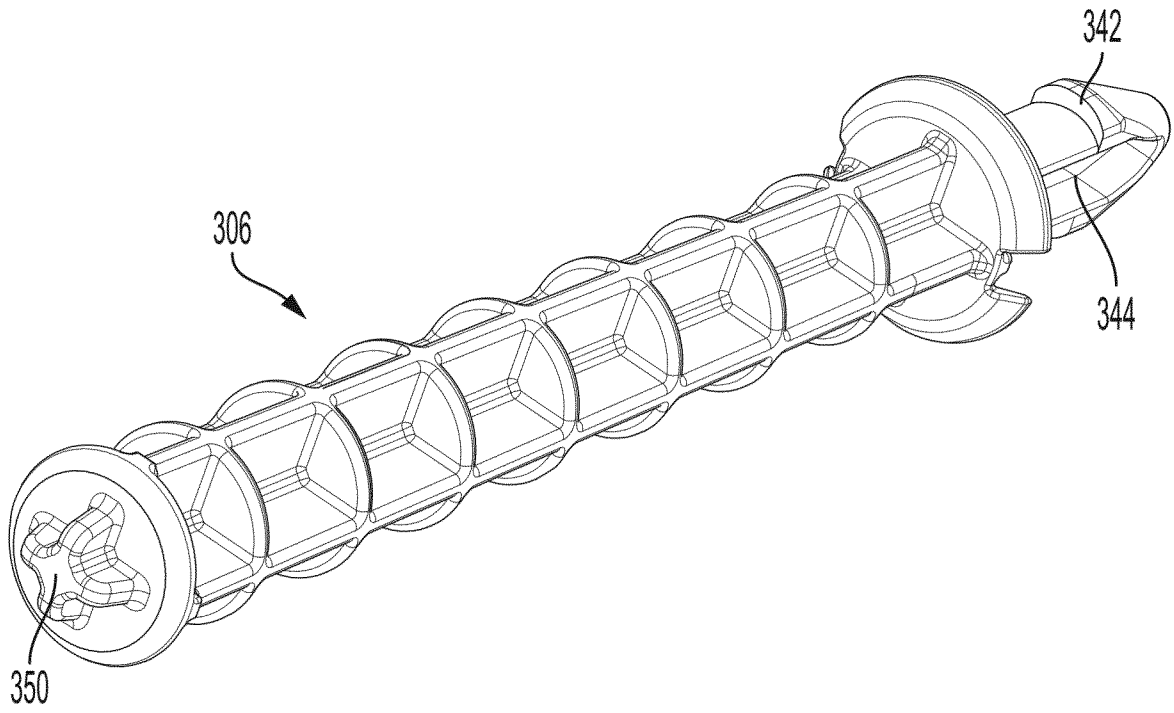


FIG. 31

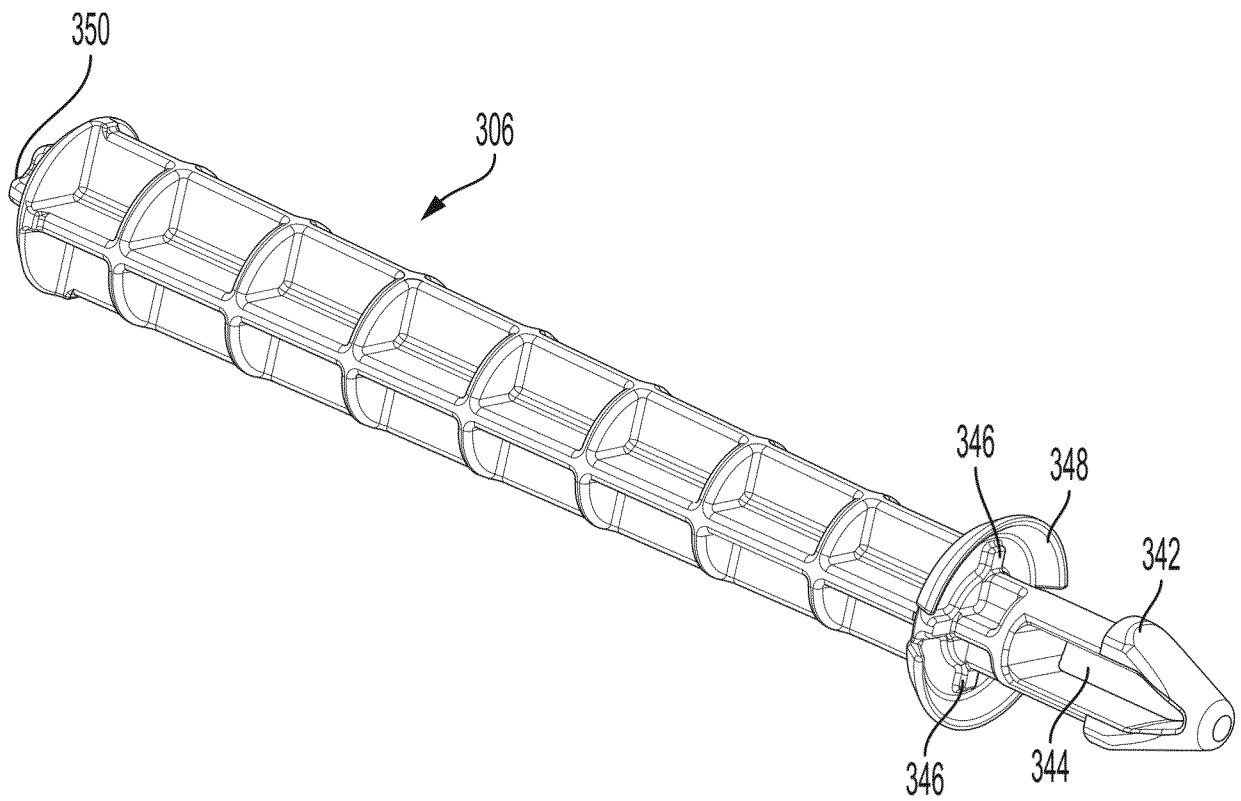


FIG. 32

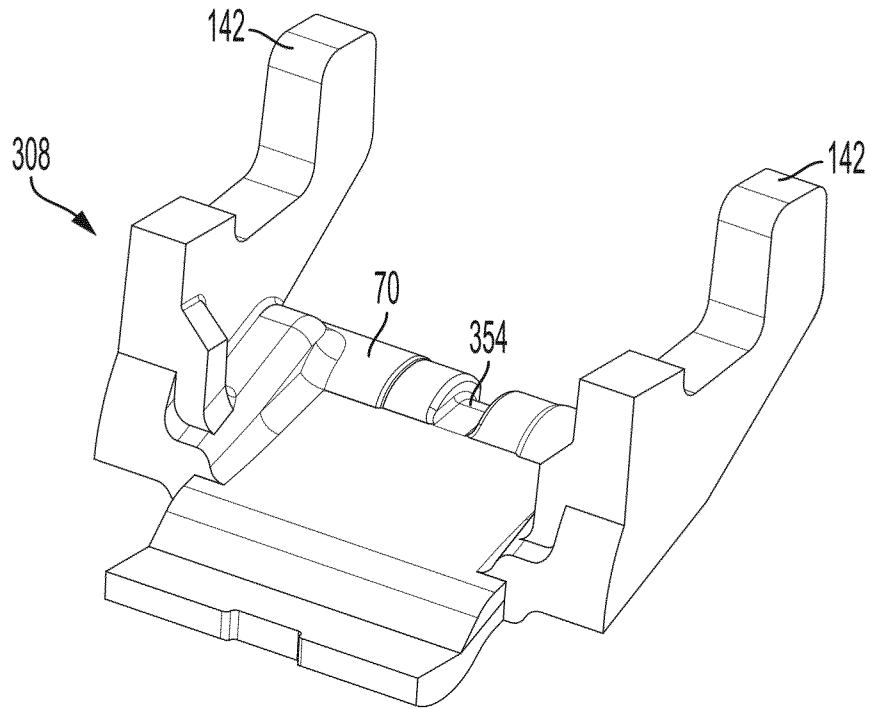


FIG. 33

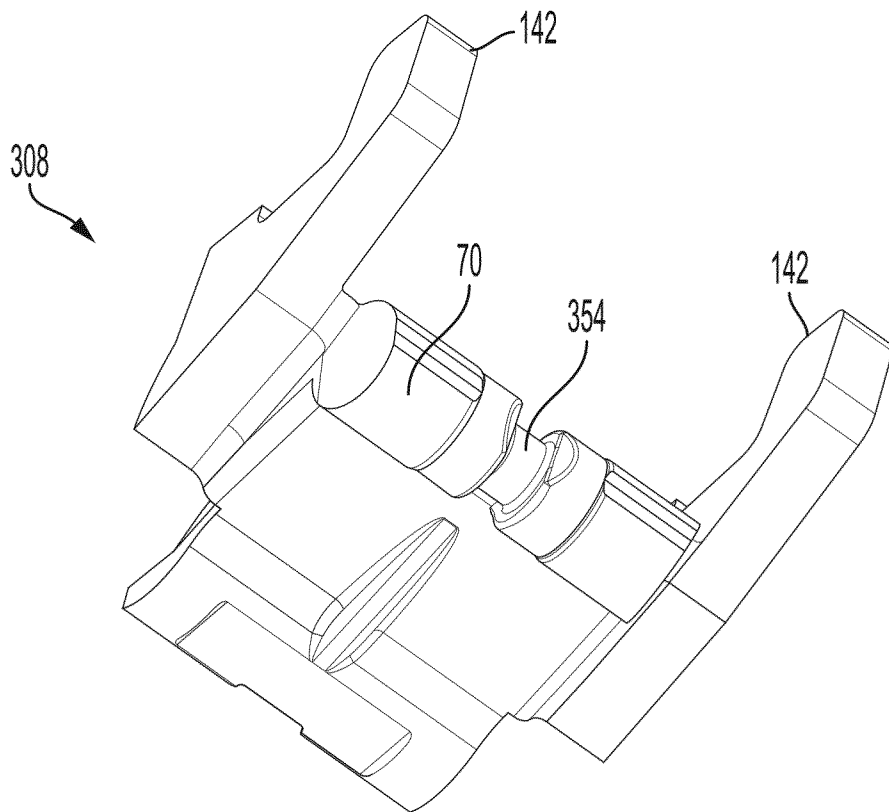


FIG. 34

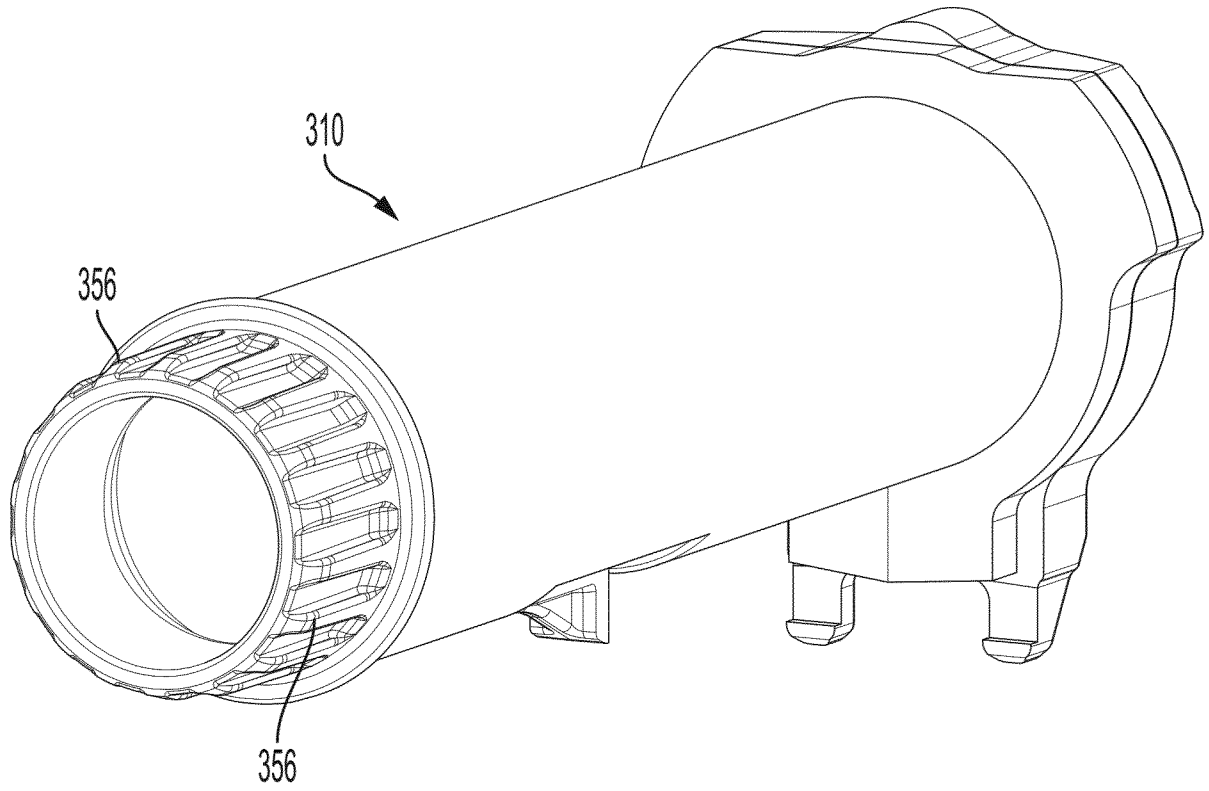


FIG. 35

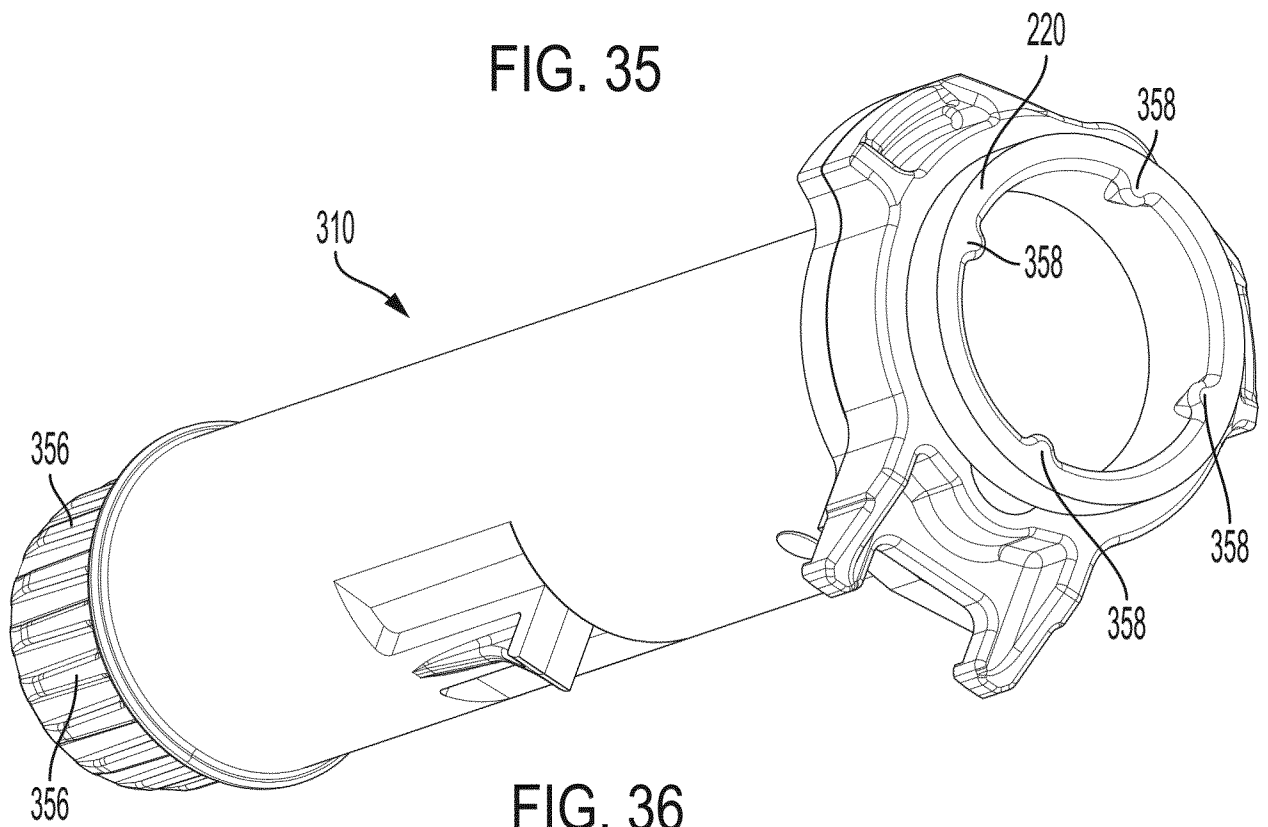


FIG. 36

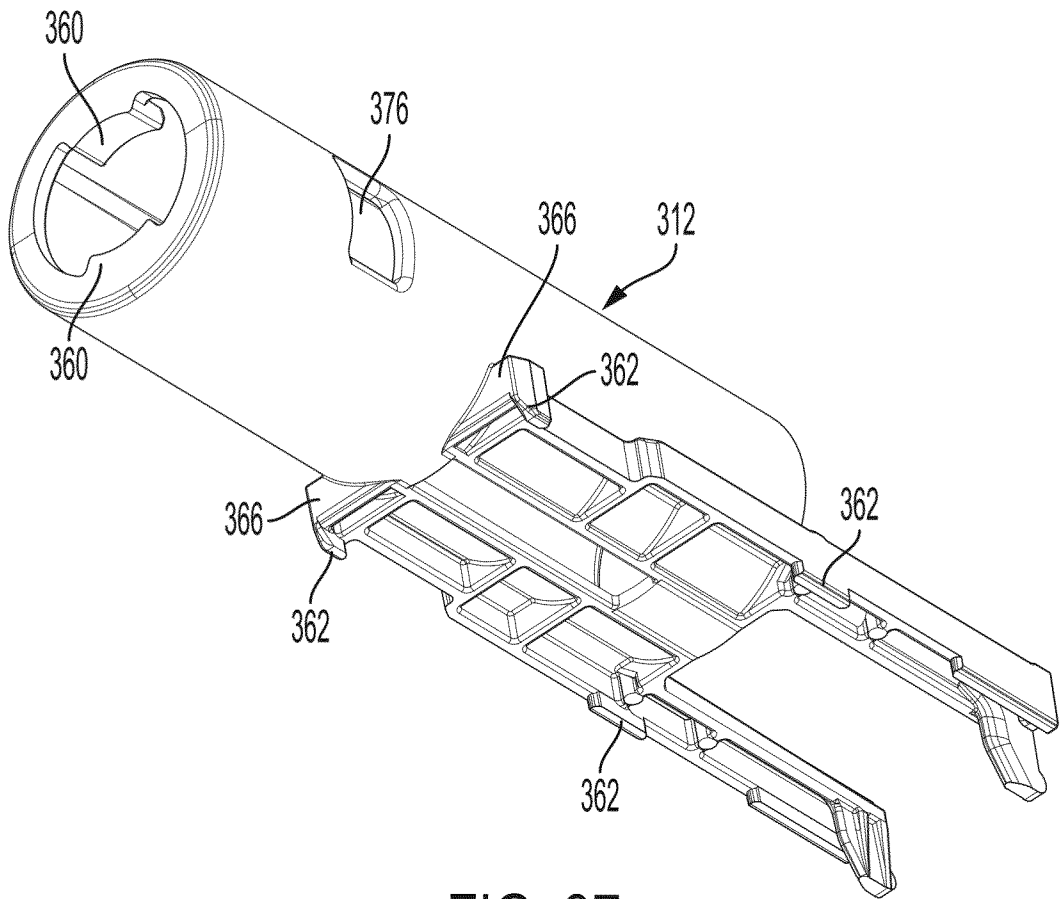


FIG. 37

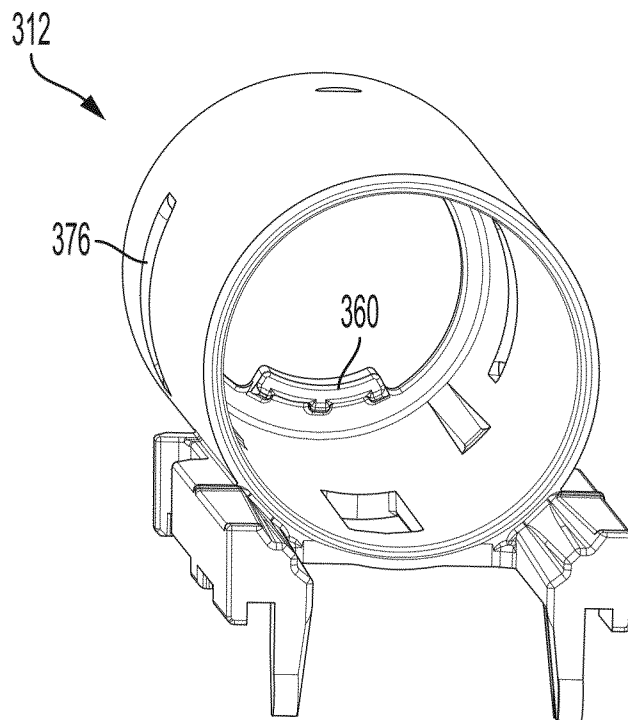


FIG. 38

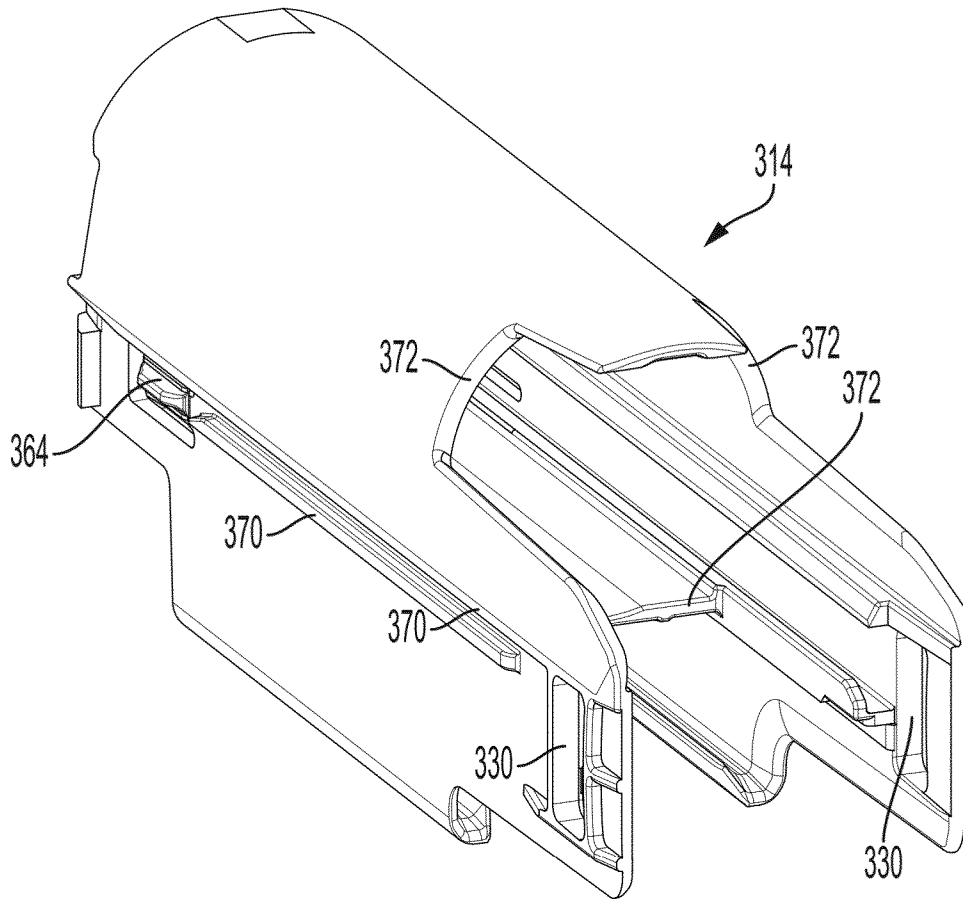


FIG. 39

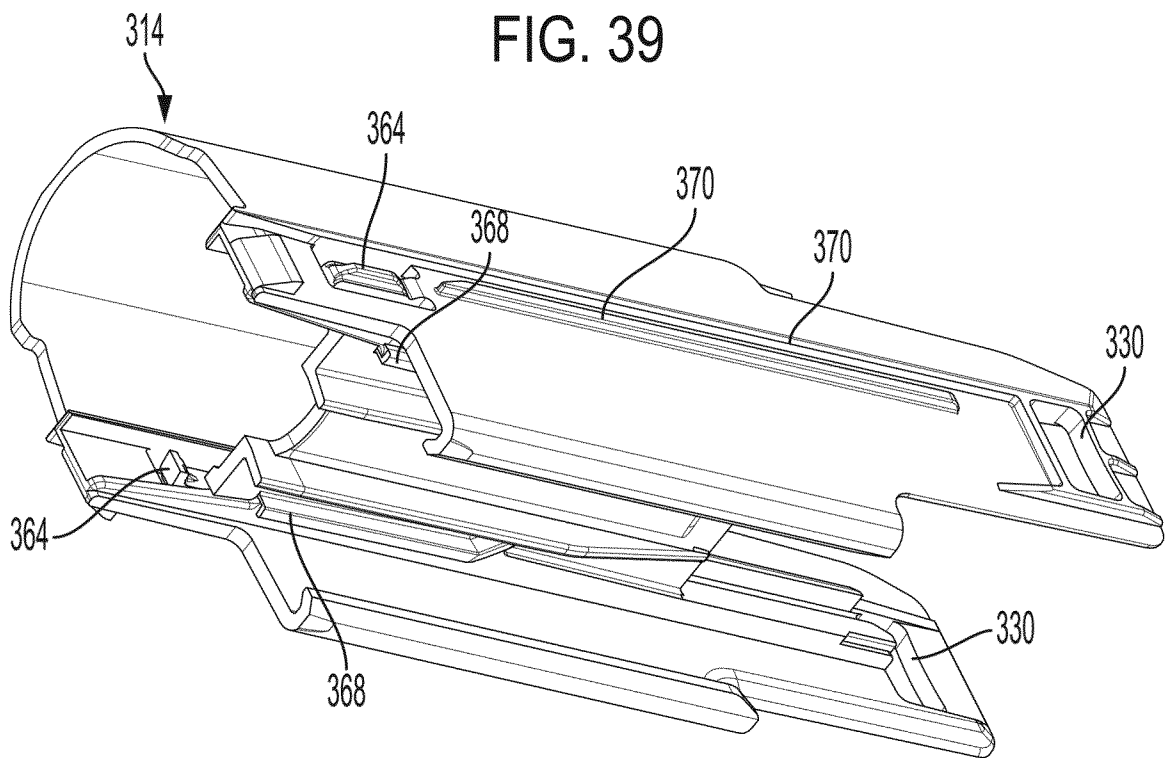


FIG. 40

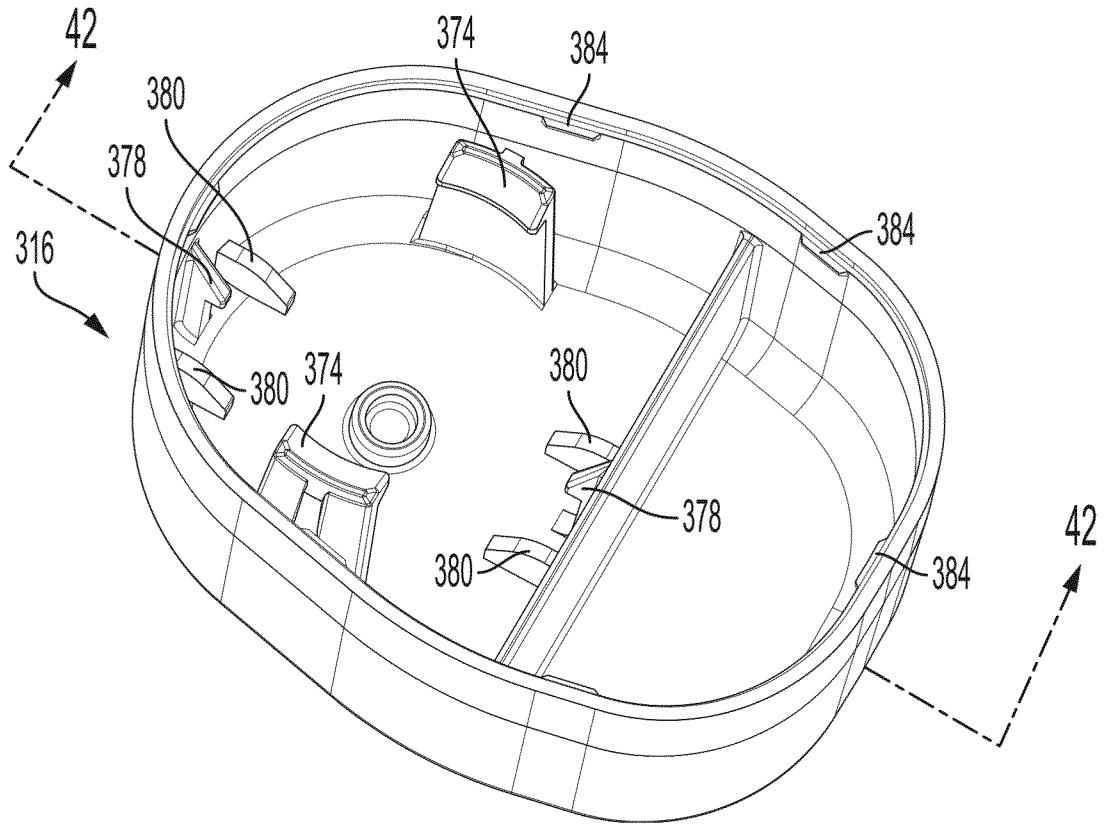


FIG. 41

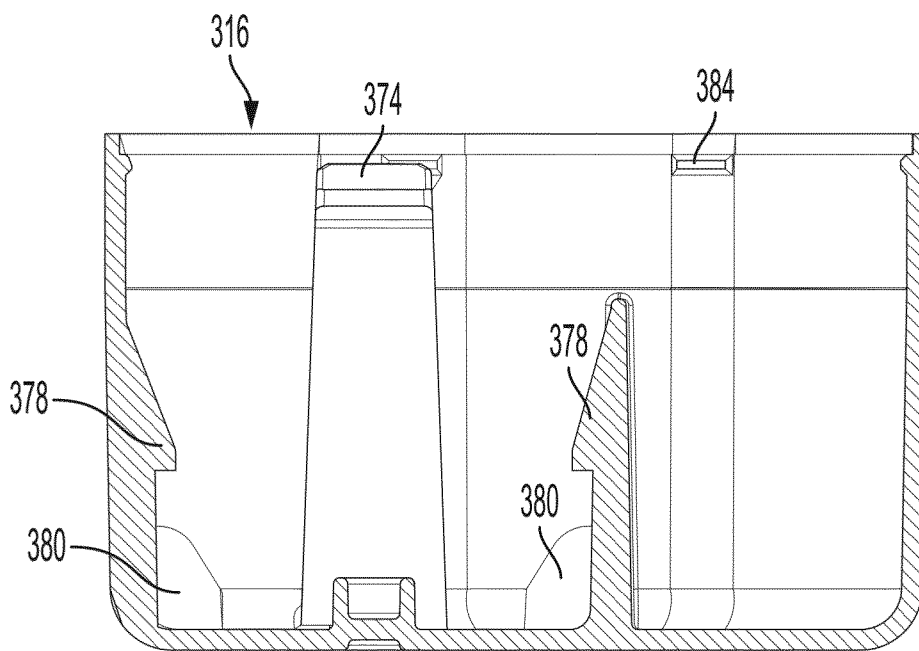


FIG. 42

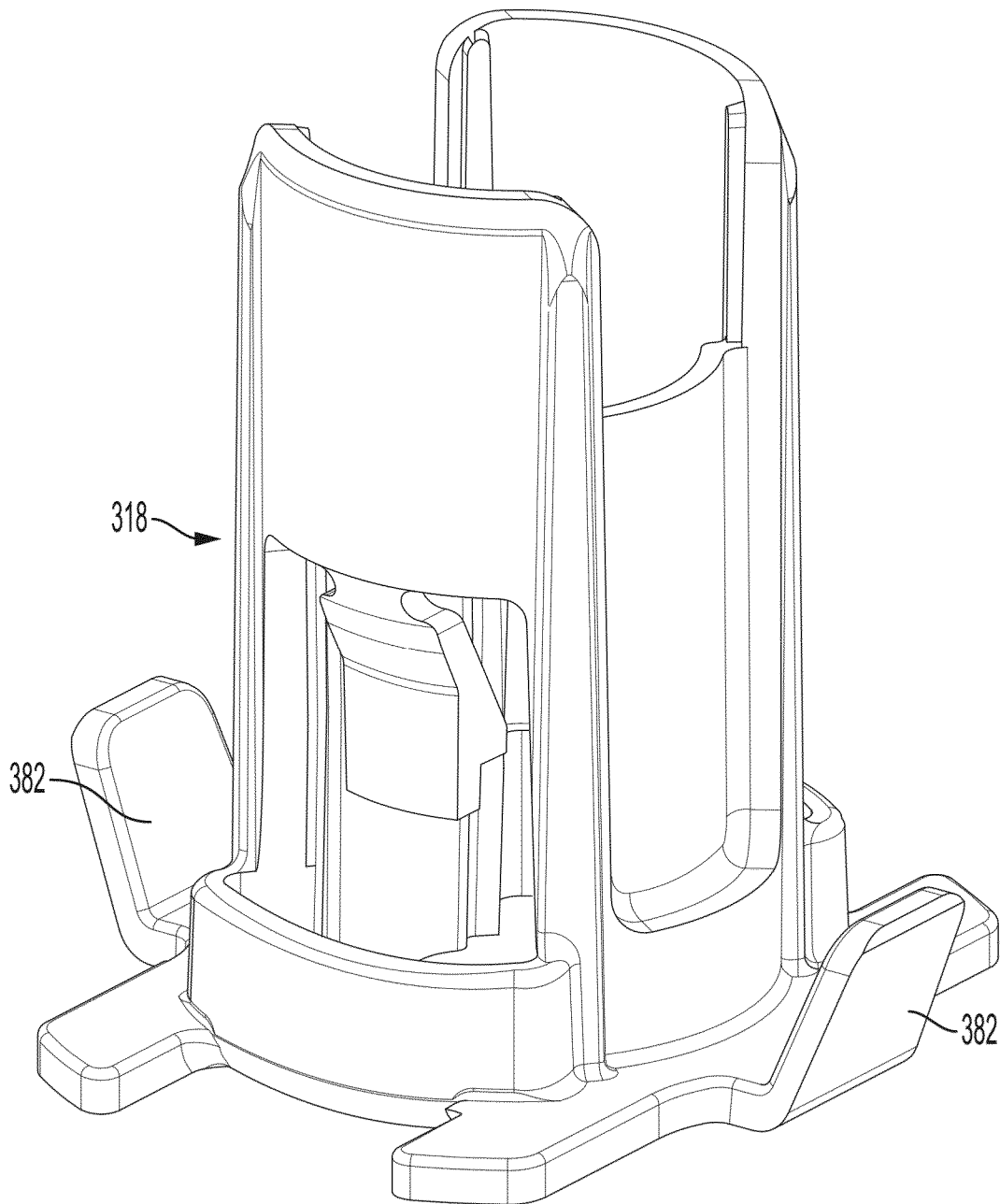


FIG. 43

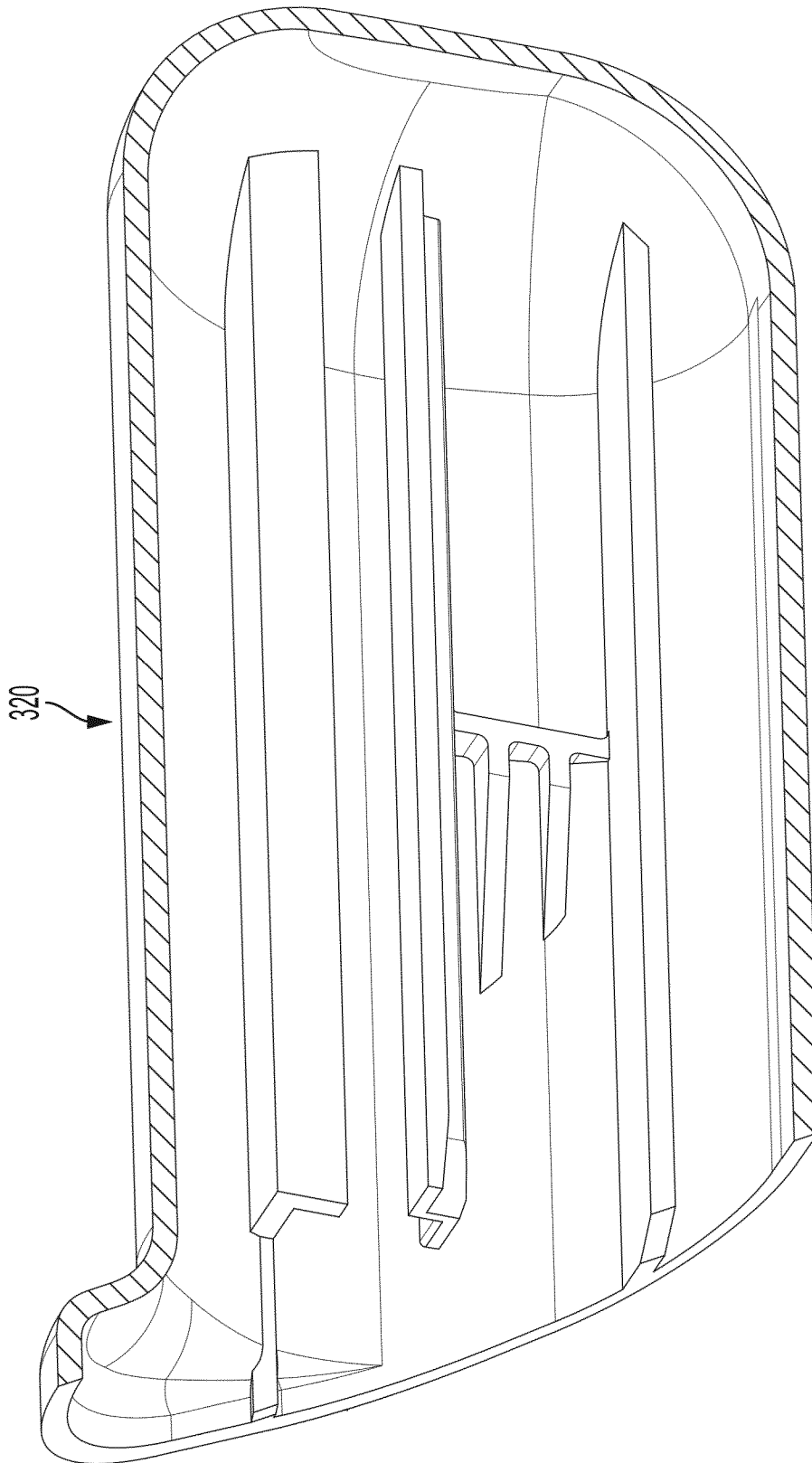


FIG. 44



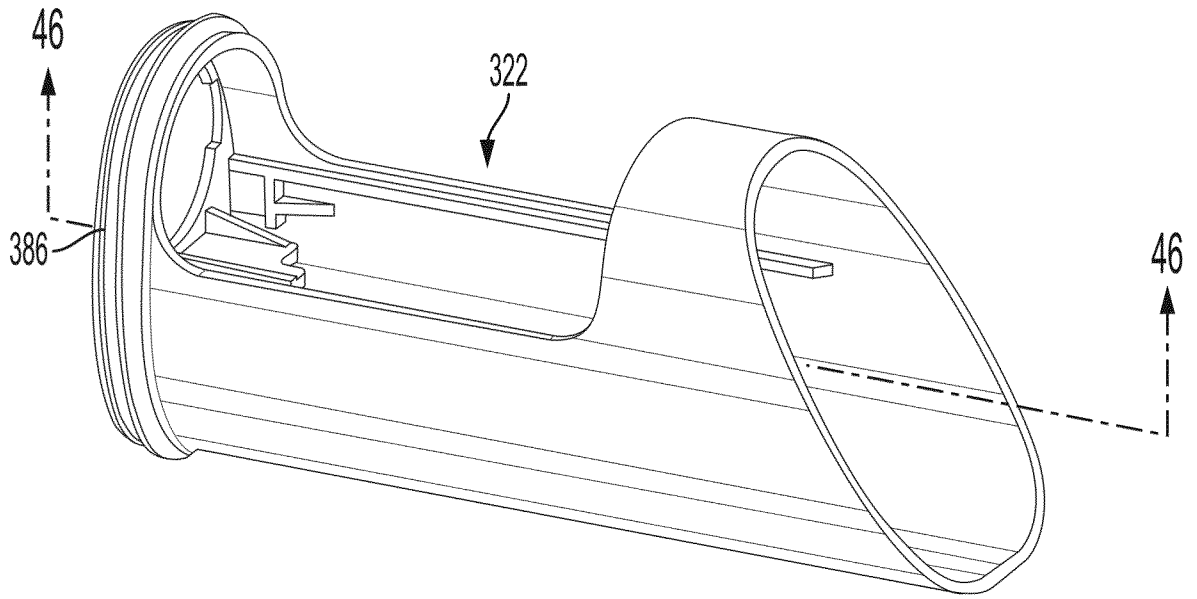


FIG. 45

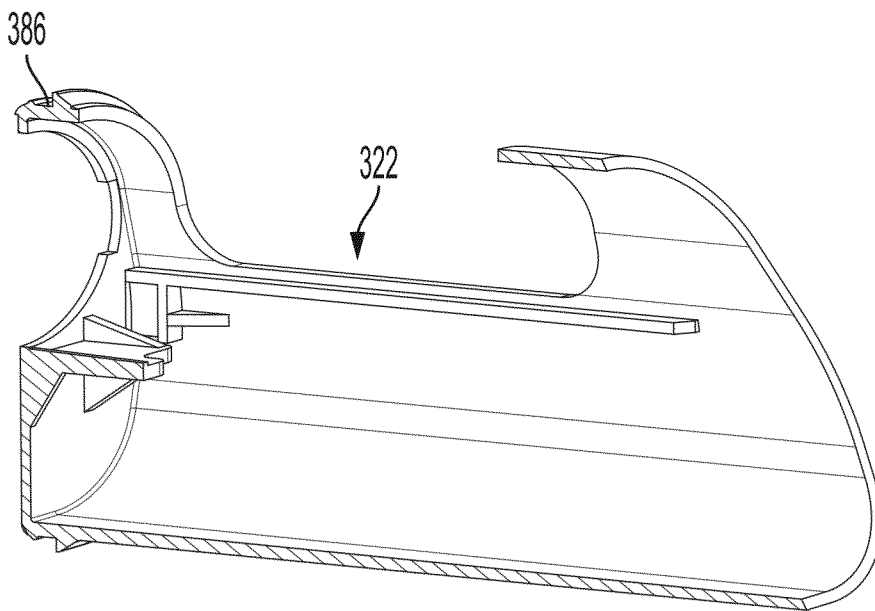


FIG. 46

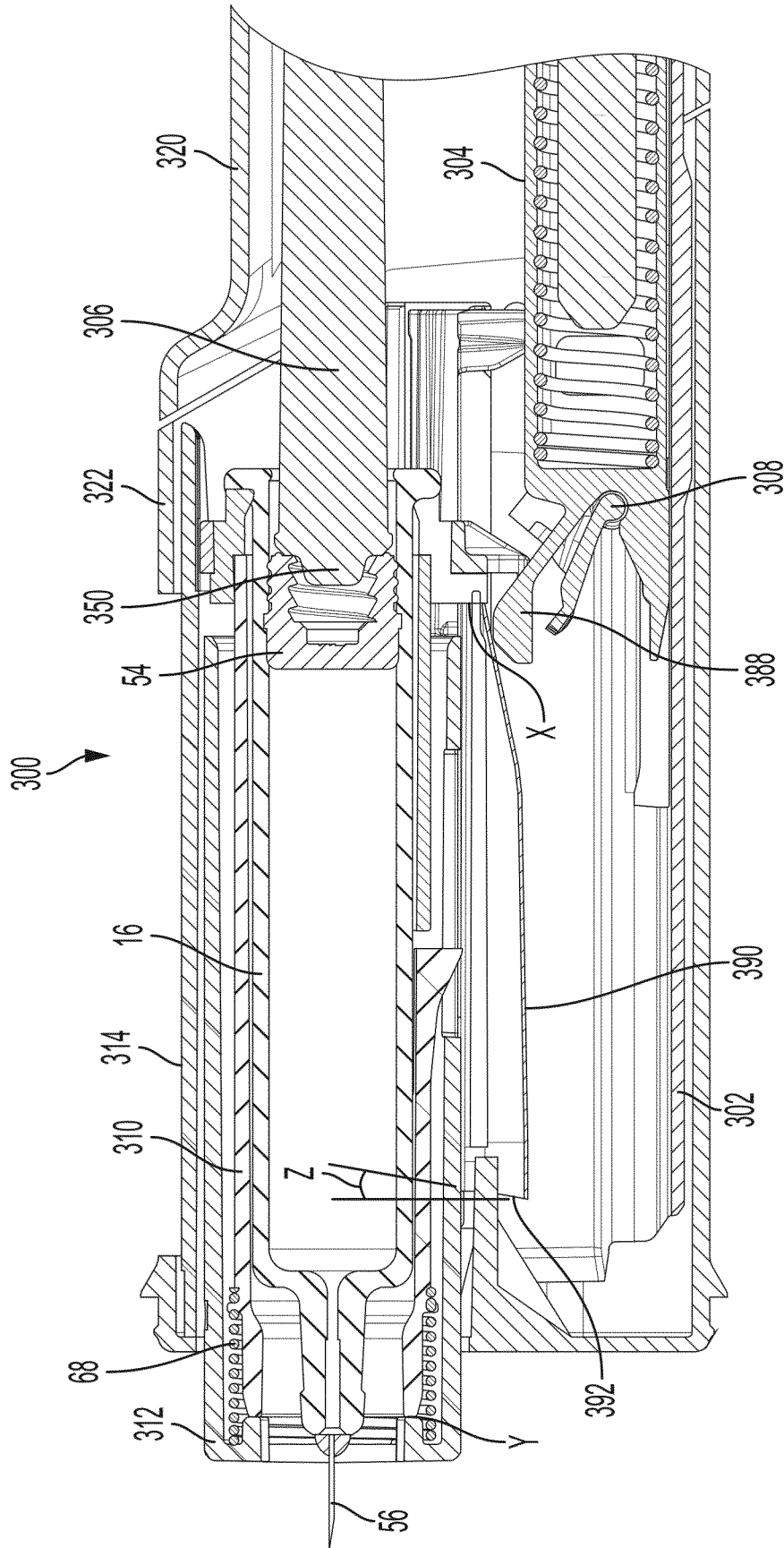


FIG. 47

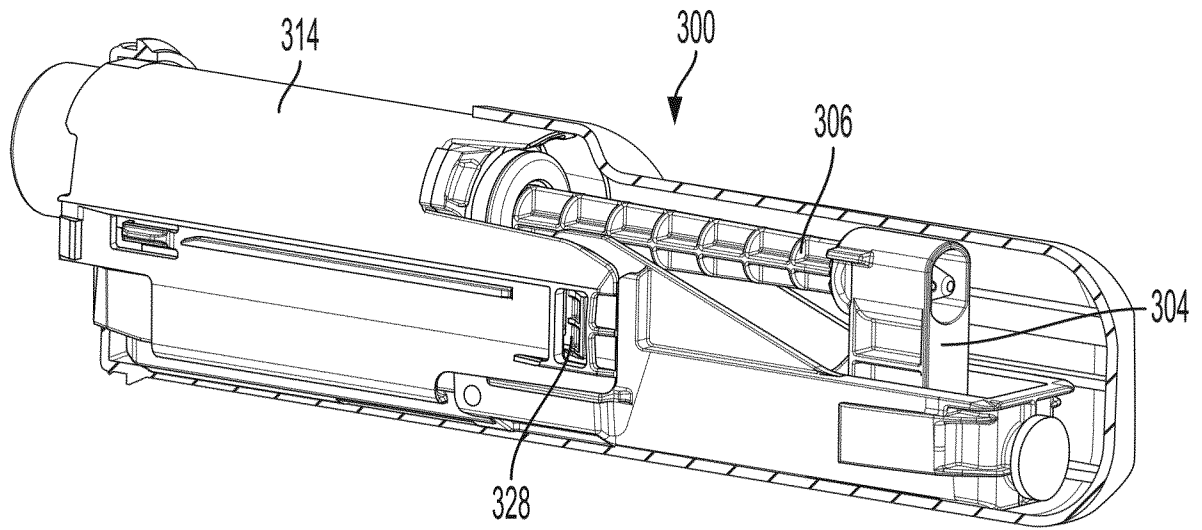


FIG. 48

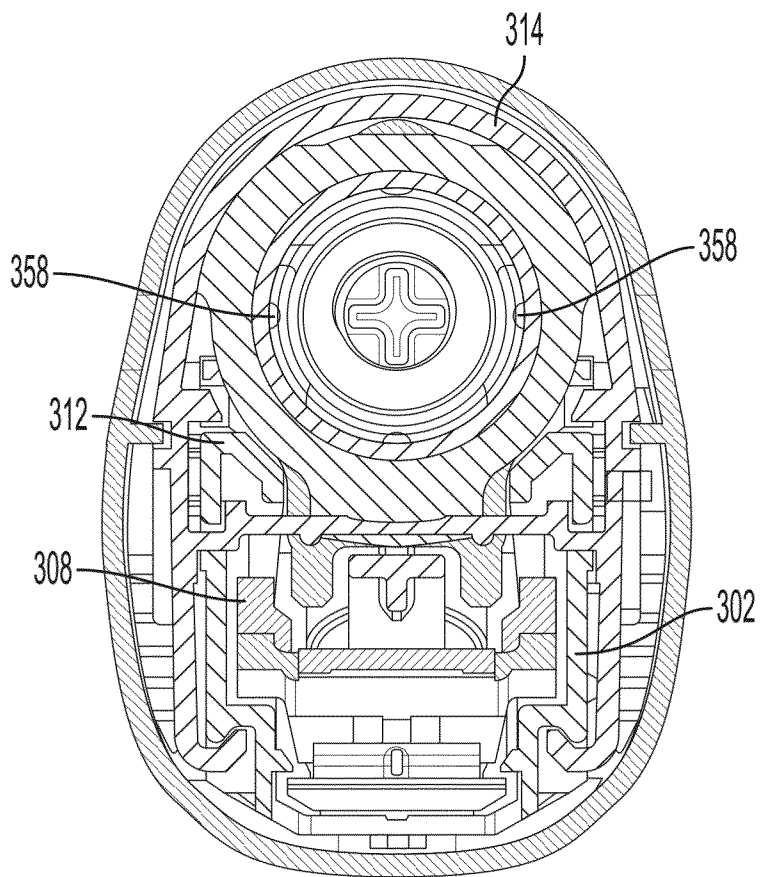


FIG. 49

**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/EP2020/055008

**A. CLASSIFICATION OF SUBJECT MATTER**  
 INV. A61M5/20 A61M5/32  
 ADD.  
 According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**  
 Minimum documentation searched (classification system followed by classification symbols)  
 A61M  
 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
 EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/089269 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]) 1 June 2017 (2017-06-01) page 5, line 29 - page 12, line 6; figure 3 -----	1-16
X	US 2018/110936 A1 (HATCH STEVEN [GB] ET AL) 26 April 2018 (2018-04-26) paragraph [0044] - paragraph [0053]; figure 1 -----	1
X	US 2018/110926 A1 (SCHRUL CHRISTIAN [CH] ET AL) 26 April 2018 (2018-04-26) paragraph [0074] - paragraph [0077]; figures 2a,2b -----	1

Further documents are listed in the continuation of Box C.

See patent family annex.

- \* Special categories of cited documents :
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  - "O" document referring to an oral disclosure, use, exhibition or other means
  - "P" document published prior to the international filing date but later than the priority date claimed
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Date of the actual completion of the international search <b>31 March 2020</b>	Date of mailing of the international search report <b>09/04/2020</b>
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer <b>Feber, Laurent</b>
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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/EP2020/055008
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