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Cronenberg et al.

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(54) **INJECTION PEN WITH DIAL BACK AND LAST DOSE CONTROL**

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This patent is subject to a terminal disclaimer.

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(62) Division of application No. 15/669,349, filed on Aug. 4, 2017, now Pat. No. 10,940,269, which is a division (Continued)

(51) **Int. Cl.**
A61M 5/315 (2006.01)
A61M 5/24 (2006.01)
(Continued)

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CPC **A61M 5/31548** (2013.01); **A61M 5/31535** (2013.01); **A61M 5/31541** (2013.01);
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(58) **Field of Classification Search**
CPC A61M 5/31548; A61M 5/31535; A61M 5/31541; A61M 5/31551; A61M 5/31556;
(Continued)

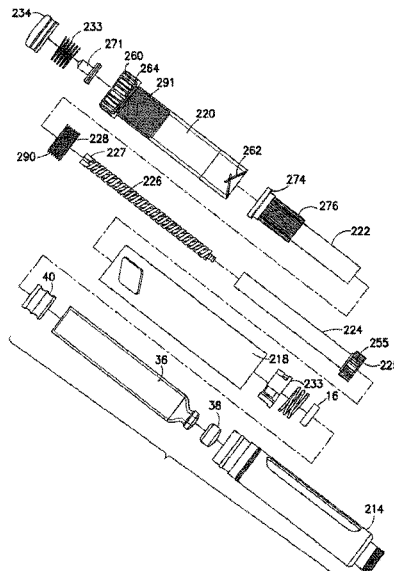
(56) **References Cited**
U.S. PATENT DOCUMENTS
5,725,508 A 3/1998 Chanoch
6,235,004 B1 5/2001 Steinfeldt-Jenen
(Continued)

FOREIGN PATENT DOCUMENTS
DE 102007054019 A1 5/2009
EP 1250167 B1 7/2005
(Continued)

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(57) **ABSTRACT**
A medication injection pen comprises a dose set knob rotatable with respect to a housing to set a desired injection dose. The dose set knob comprises at least one internal thread. A leadscrew includes a thread element for advancing in a first direction via a corresponding thread engagement. A driver is rotationally fixed to the leadscrew and is rotatable in a first direction to rotate and advance the leadscrew in the first direction. The setback member is rotationally fixed to the driver. The dose stop member is rotationally coupled to the setback member and is axially movable relative to the dose set knob when the dose set knob is rotated relative to the setback member. Axial movement of the dose stop member limits the user from setting a dose that is greater than an injectable volume of medication remaining in a cartridge.

10 Claims, 38 Drawing Sheets



Related U.S. Application Data

- of application No. 13/261,300, filed as application No. PCT/US2010/003059 on Nov. 30, 2010, now Pat. No. 9,757,525.
- (60) Provisional application No. 61/351,465, filed on Jun. 4, 2010, provisional application No. 61/265,562, filed on Dec. 1, 2009.
- (51) **Int. Cl.**
A61M 5/32 (2006.01)
A61M 5/34 (2006.01)
- (52) **U.S. Cl.**
 CPC *A61M 5/31551* (2013.01); *A61M 5/3156* (2013.01); *A61M 5/31563* (2013.01); *A61M 5/31585* (2013.01); *A61M 5/31595* (2013.01); *A61M 5/24* (2013.01); *A61M 2005/2407* (2013.01); *A61M 5/2466* (2013.01); *A61M 2005/2488* (2013.01); *A61M 2005/2492* (2013.01); *A61M 5/31543* (2013.01); *A61M 5/3157* (2013.01); *A61M 5/31573* (2013.01); *A61M 5/31575* (2013.01); *A61M 5/3202* (2013.01); *A61M 5/347* (2013.01); *A61M 2205/581* (2013.01)
- (58) **Field of Classification Search**
 CPC A61M 5/31563; A61M 5/31585; A61M 5/31595; A61M 5/24; A61M 5/2466; A61M 5/31543; A61M 5/3157; A61M 5/31573; A61M 5/31575; A61M 5/3202; A61M 5/347; A61M 2005/2407; A61M 2005/2488; A61M 2005/2492; A61M 2205/581; A61M 5/31556
- See application file for complete search history.

(56)

References Cited

U.S. PATENT DOCUMENTS

6,248,095	B1	6/2001	Giambattista	
6,936,032	B1	8/2005	Bush, Jr.	
7,195,616	B2	3/2007	Diller	
7,195,623	B2	3/2007	Burroughs	
7,241,278	B2	7/2007	Moller	
9,757,525	B2 *	9/2017	Cronenberg A61M 5/31595
2004/0097883	A1	5/2004	Roe	
2004/0127858	A1	7/2004	Bendek et al.	
2004/0199117	A1	10/2004	Giambattista	
2005/0165363	A1	7/2005	Judson et al.	
2005/0261634	A1	11/2005	Karlsson	
2006/0206057	A1 *	9/2006	DeRuntz A61M 5/31558 604/224
2007/0167921	A1	7/2007	Burren	
2009/0054851	A1	2/2009	Radmer et al.	
2021/0187202	A1 *	6/2021	Cronenberg A61M 5/3156

FOREIGN PATENT DOCUMENTS

JP	2002501790	A	1/2002
JP	2004510554	A	4/2004
JP	2006519075	A	8/2006
JP	2007502146	A	2/2007
JP	2008528144	A	7/2008
JP	2008529625	A	8/2008
JP	2008229346	A	10/2008
WO	2006084876	A1	8/2006
WO	2007017052	A1	2/2007
WO	2008003560	A1	1/2008

* cited by examiner

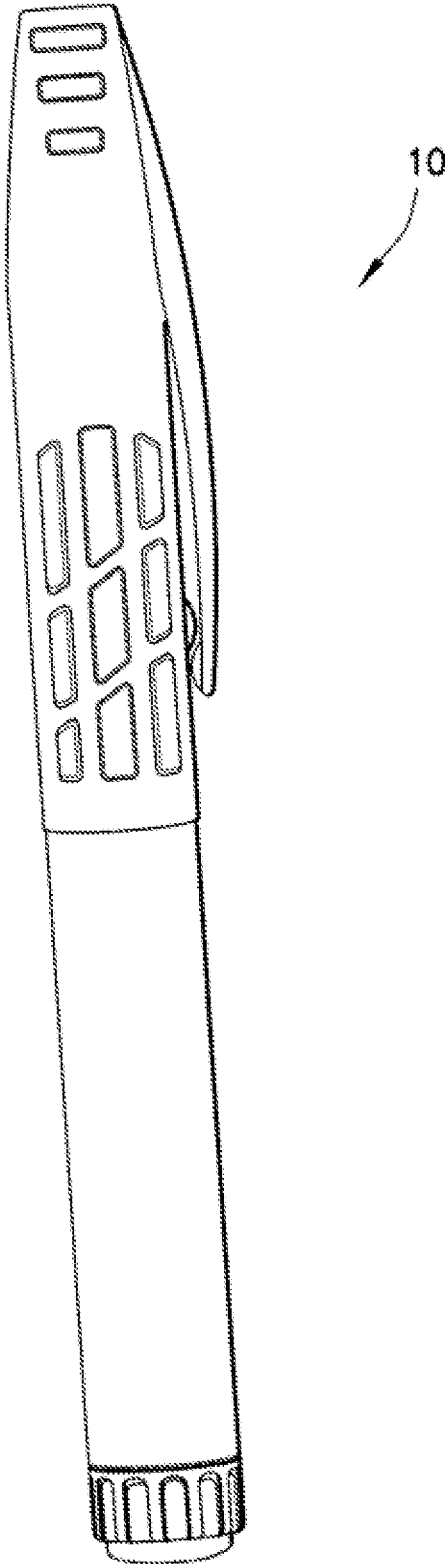


FIG. 1

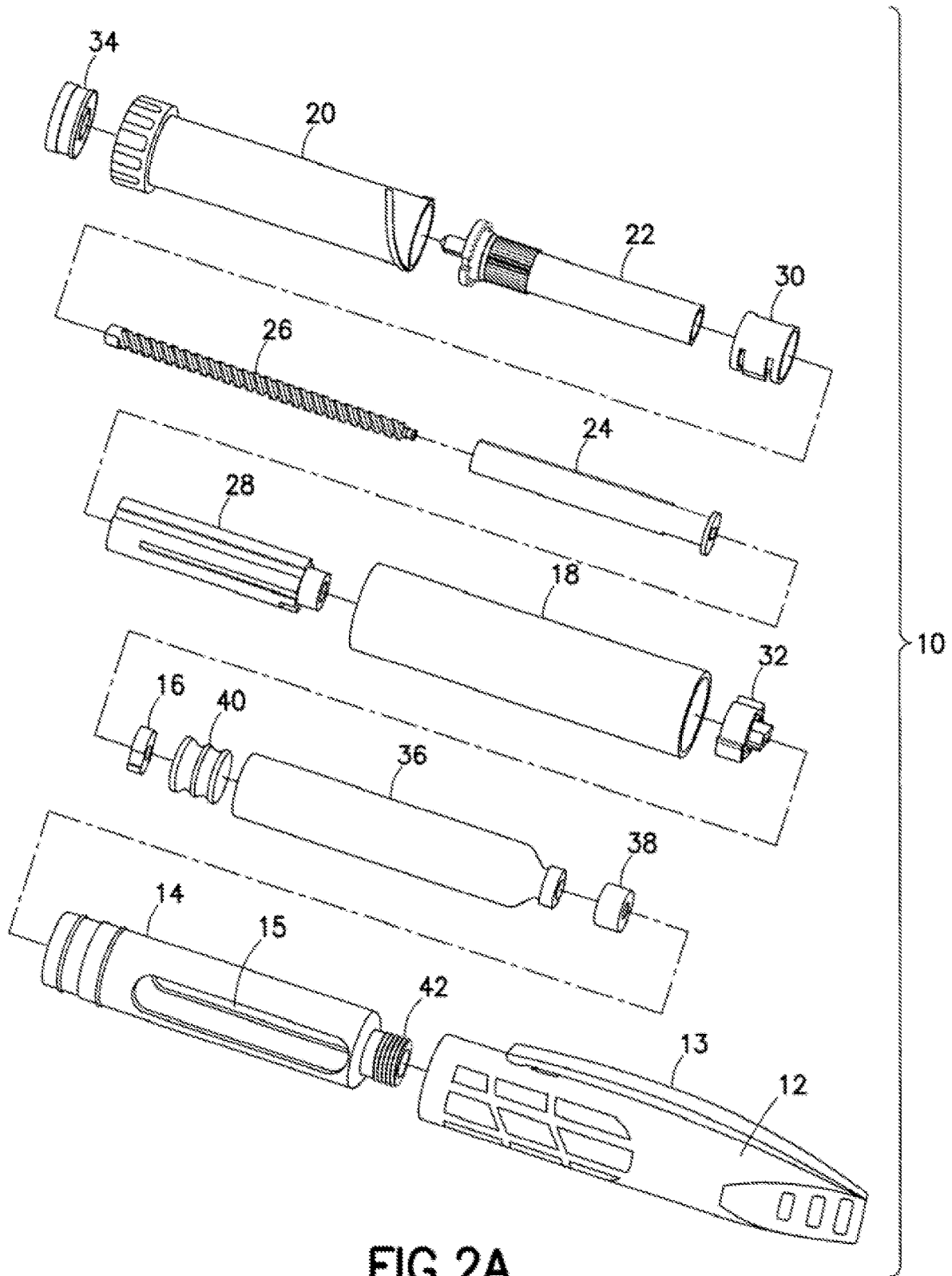


FIG. 2A

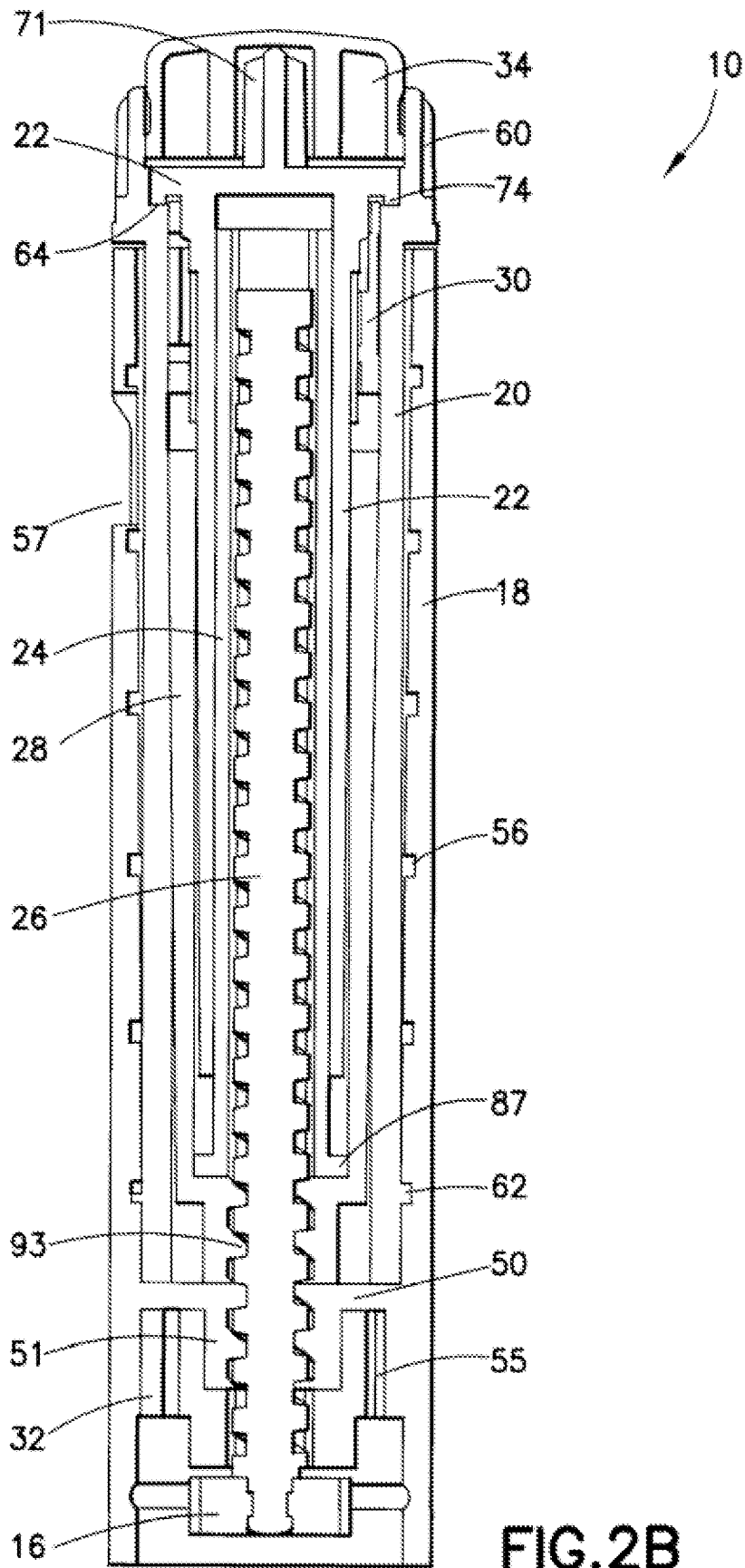


FIG. 2B

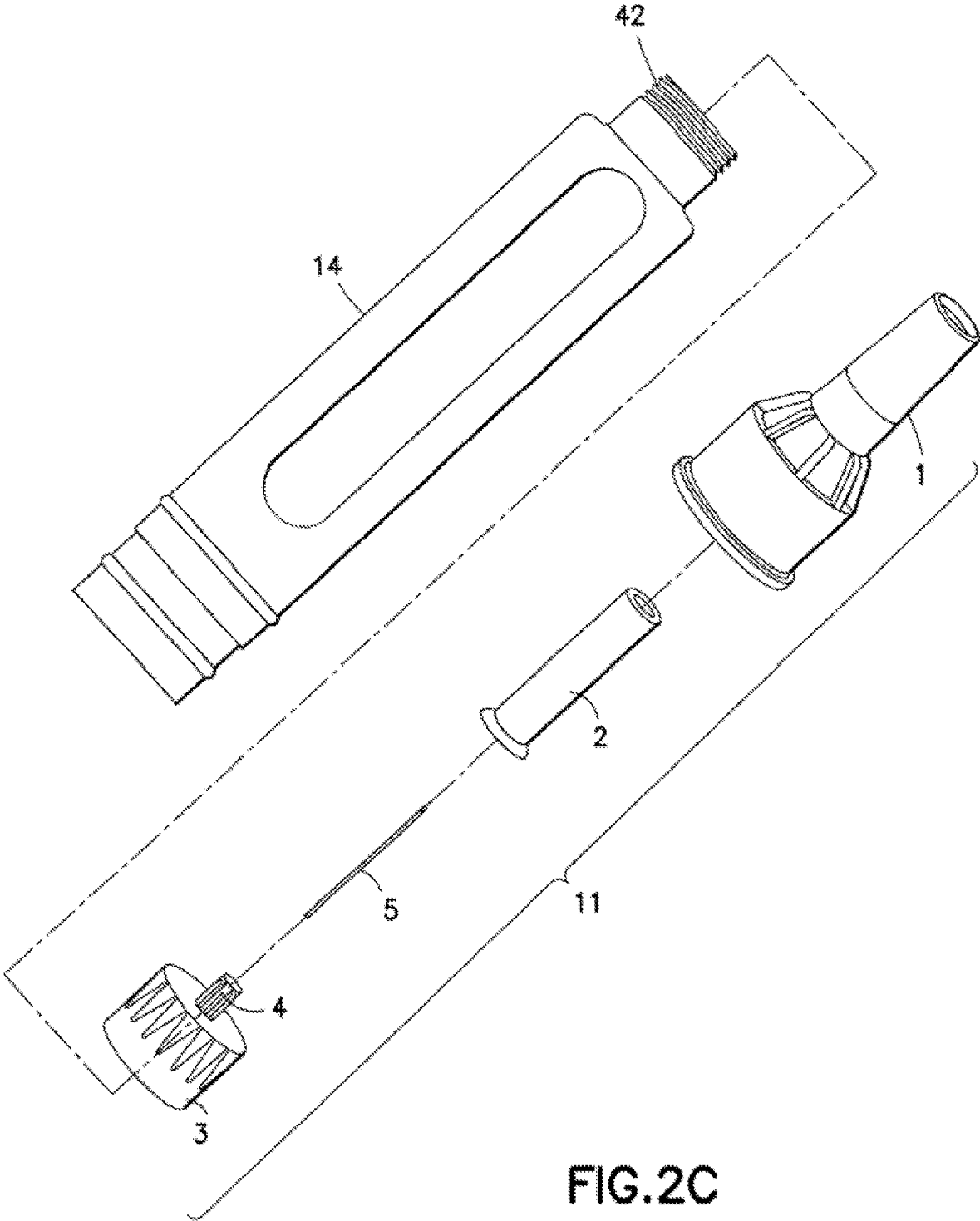


FIG.2C

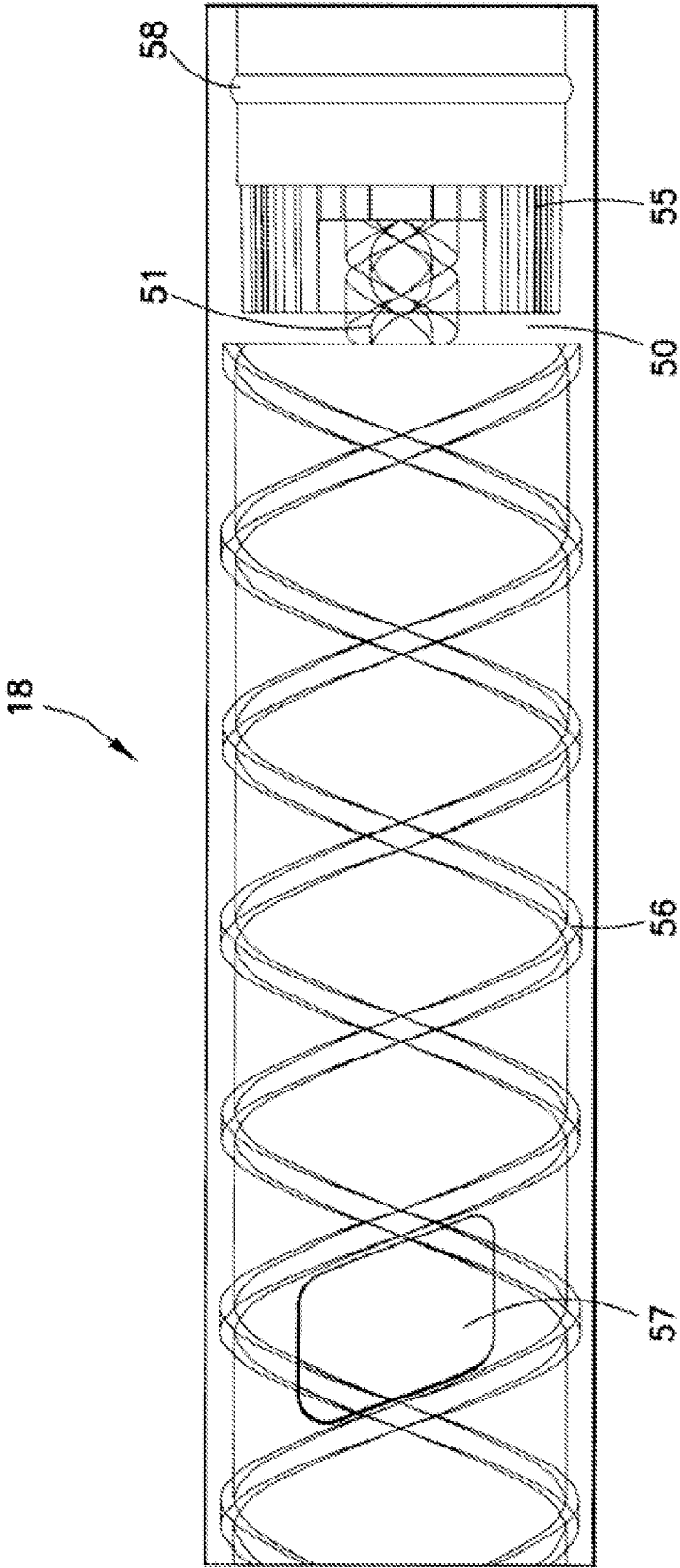


FIG.3A

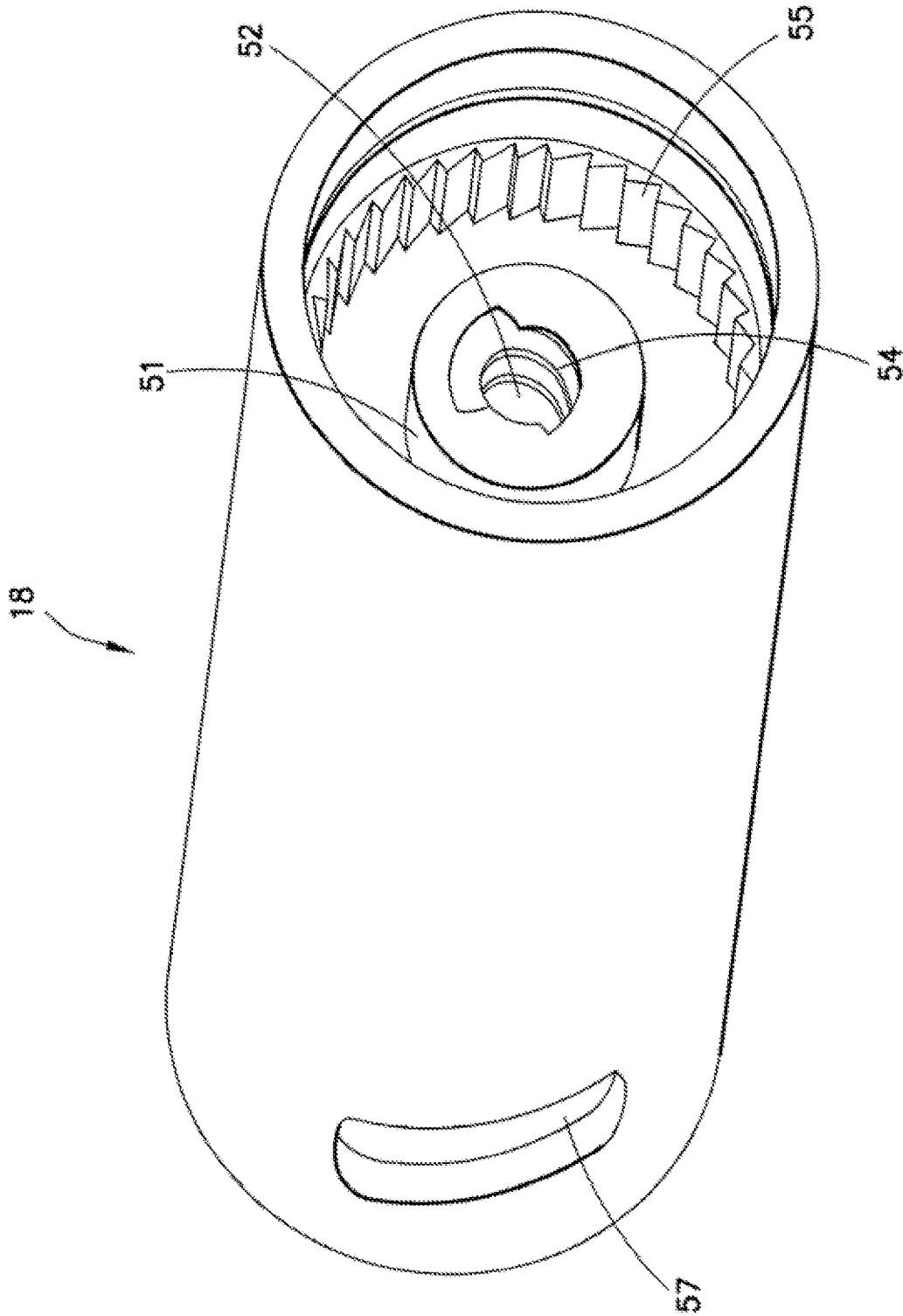


FIG.3B

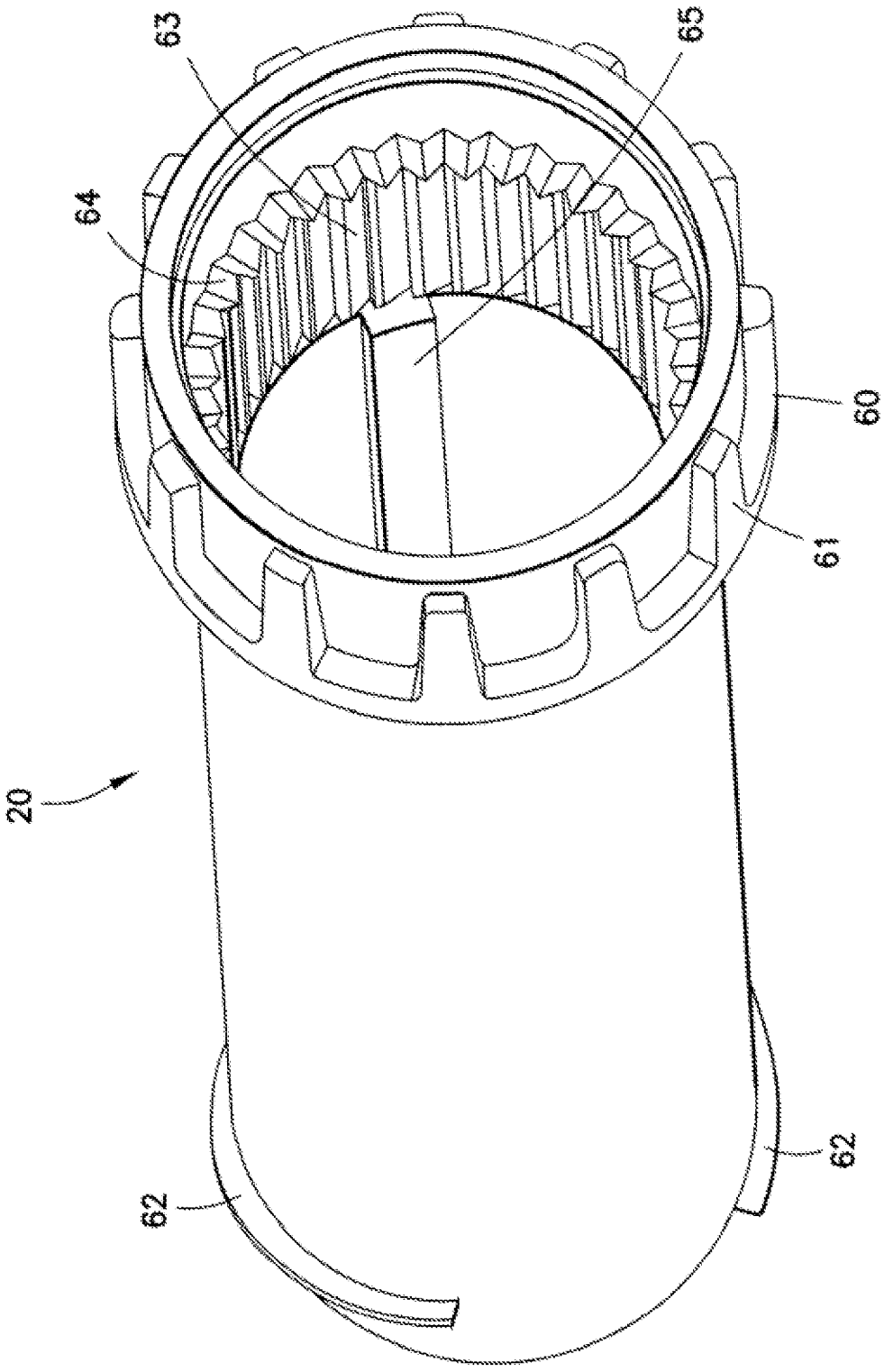


FIG. 4A

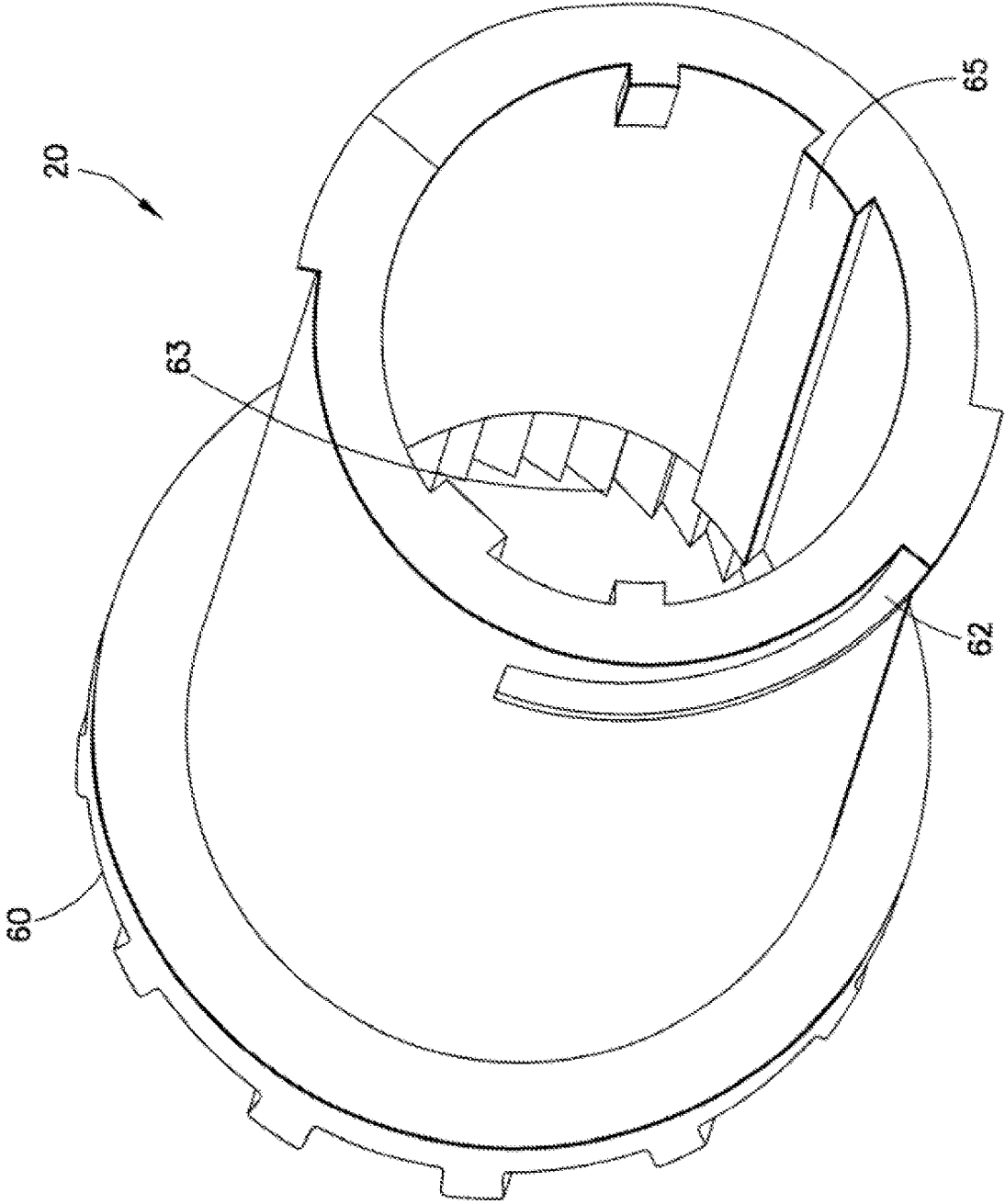


FIG. 4B

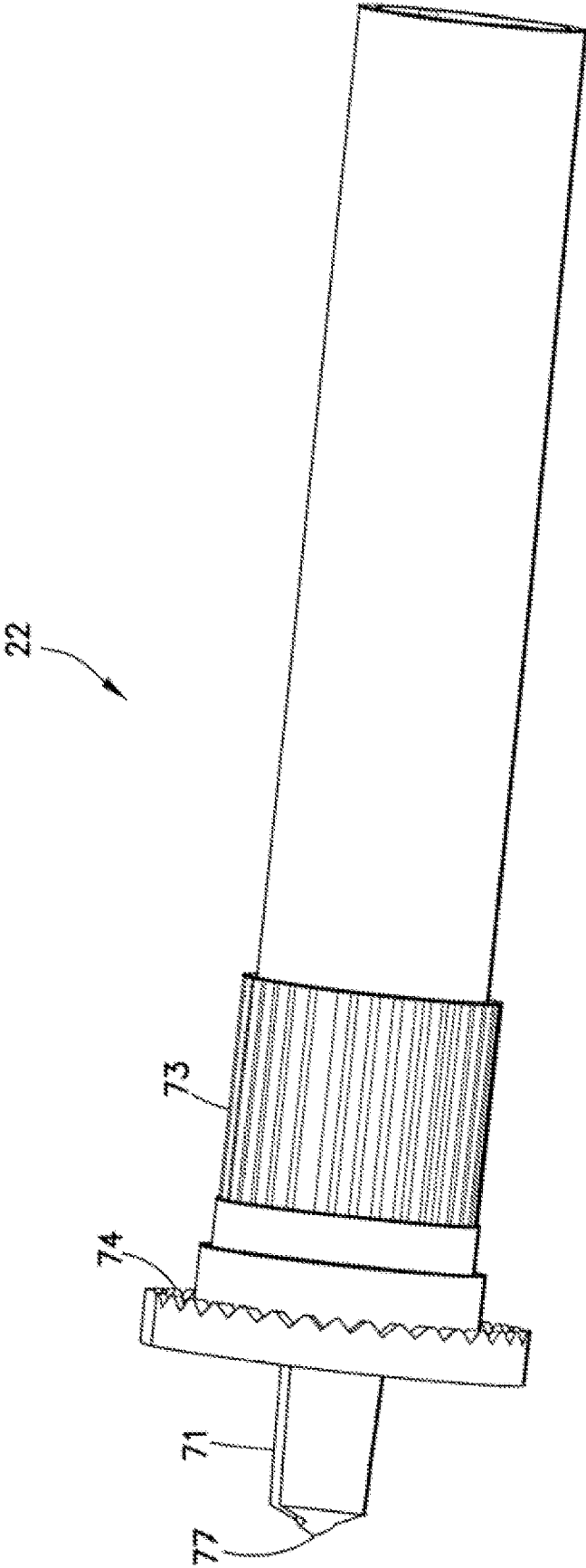


FIG. 5A

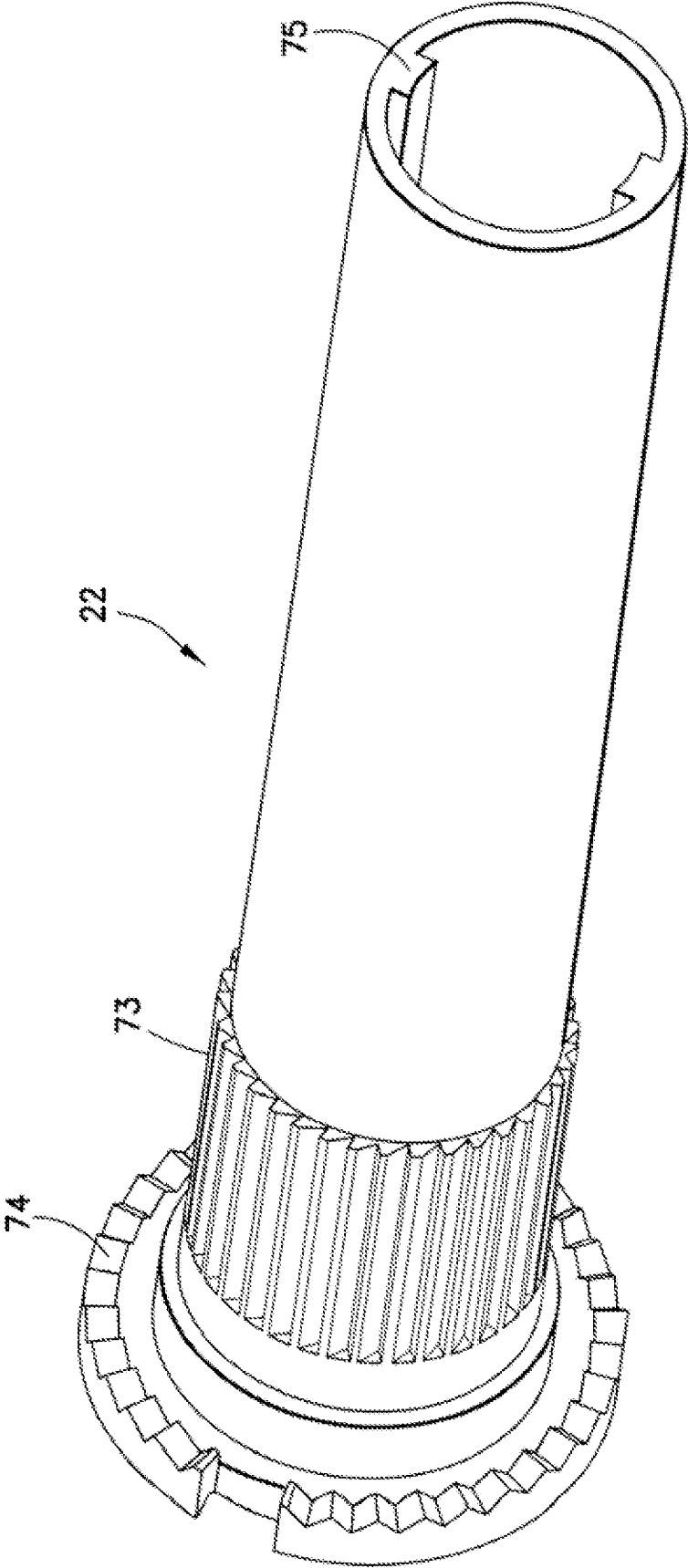


FIG. 5B

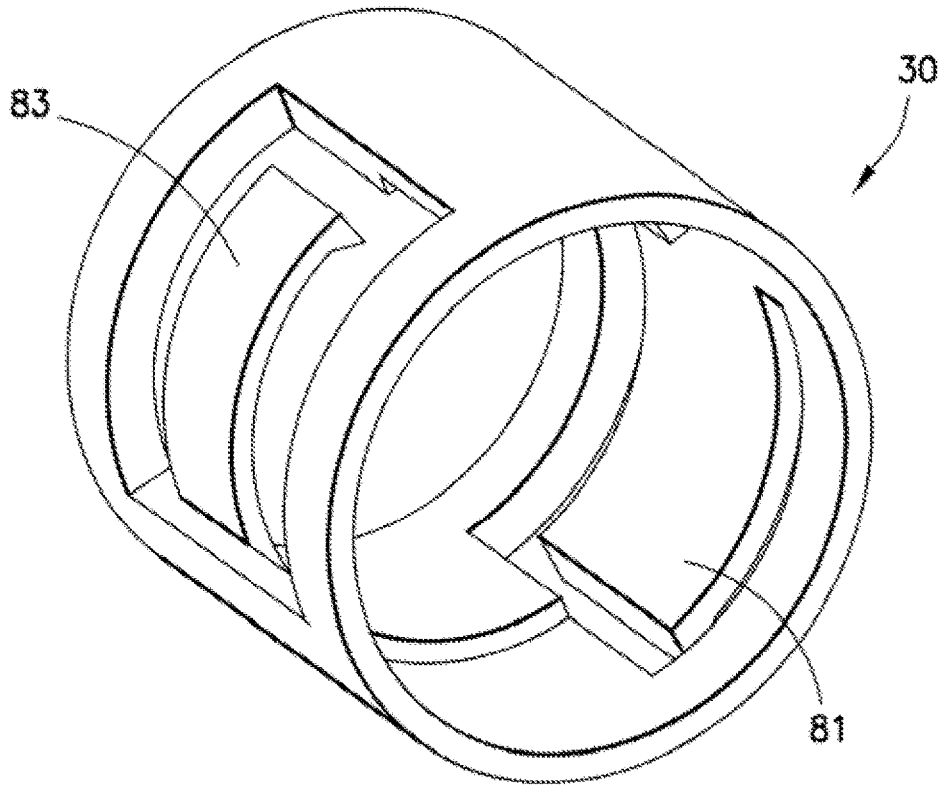


FIG. 6A

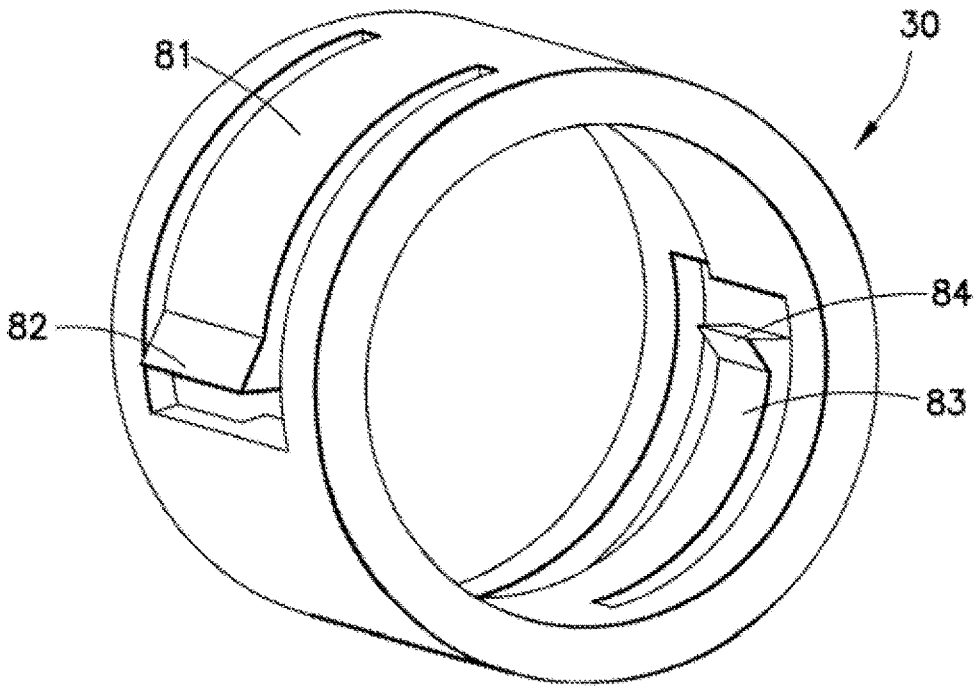


FIG. 6B

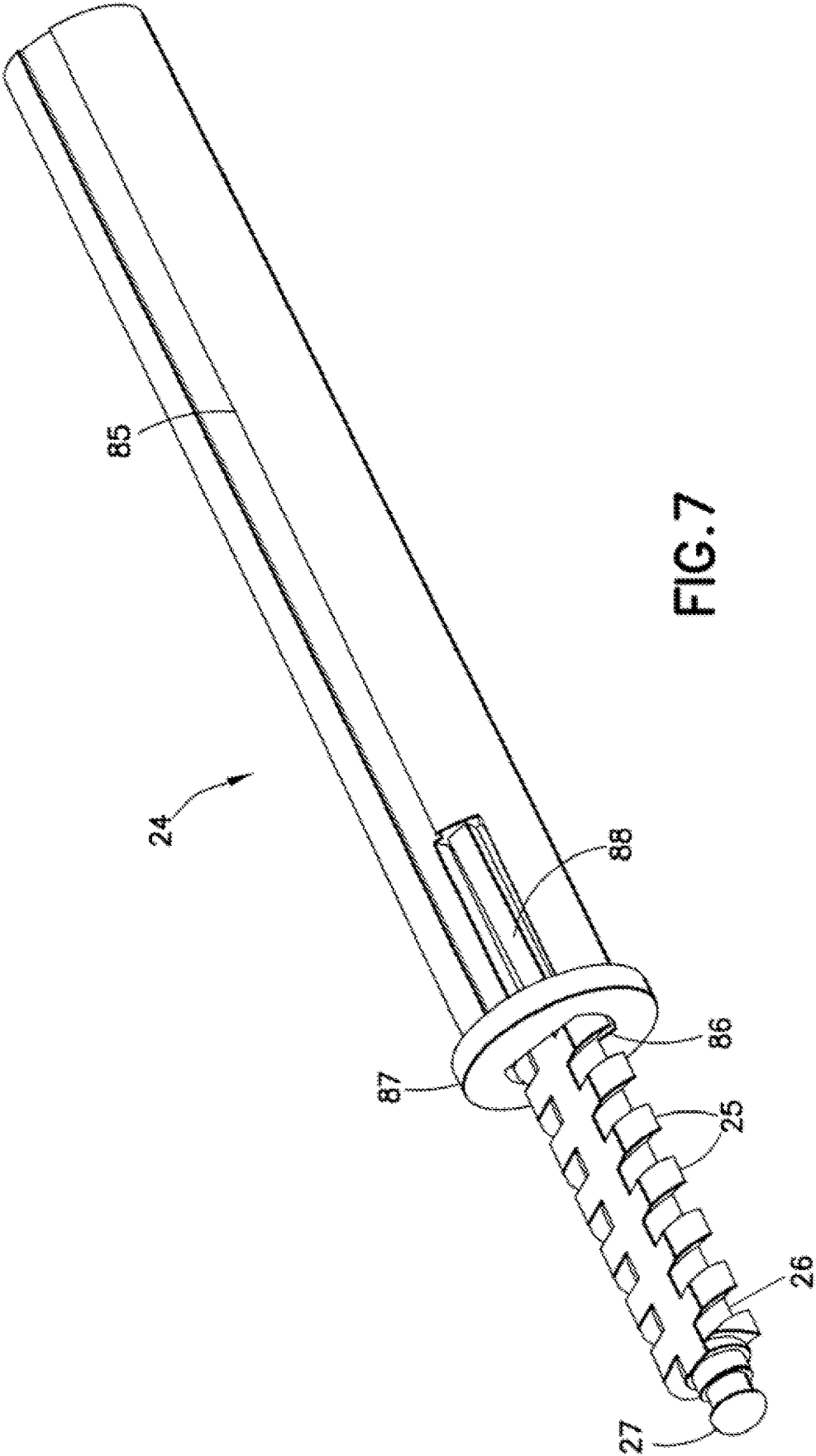


FIG. 7

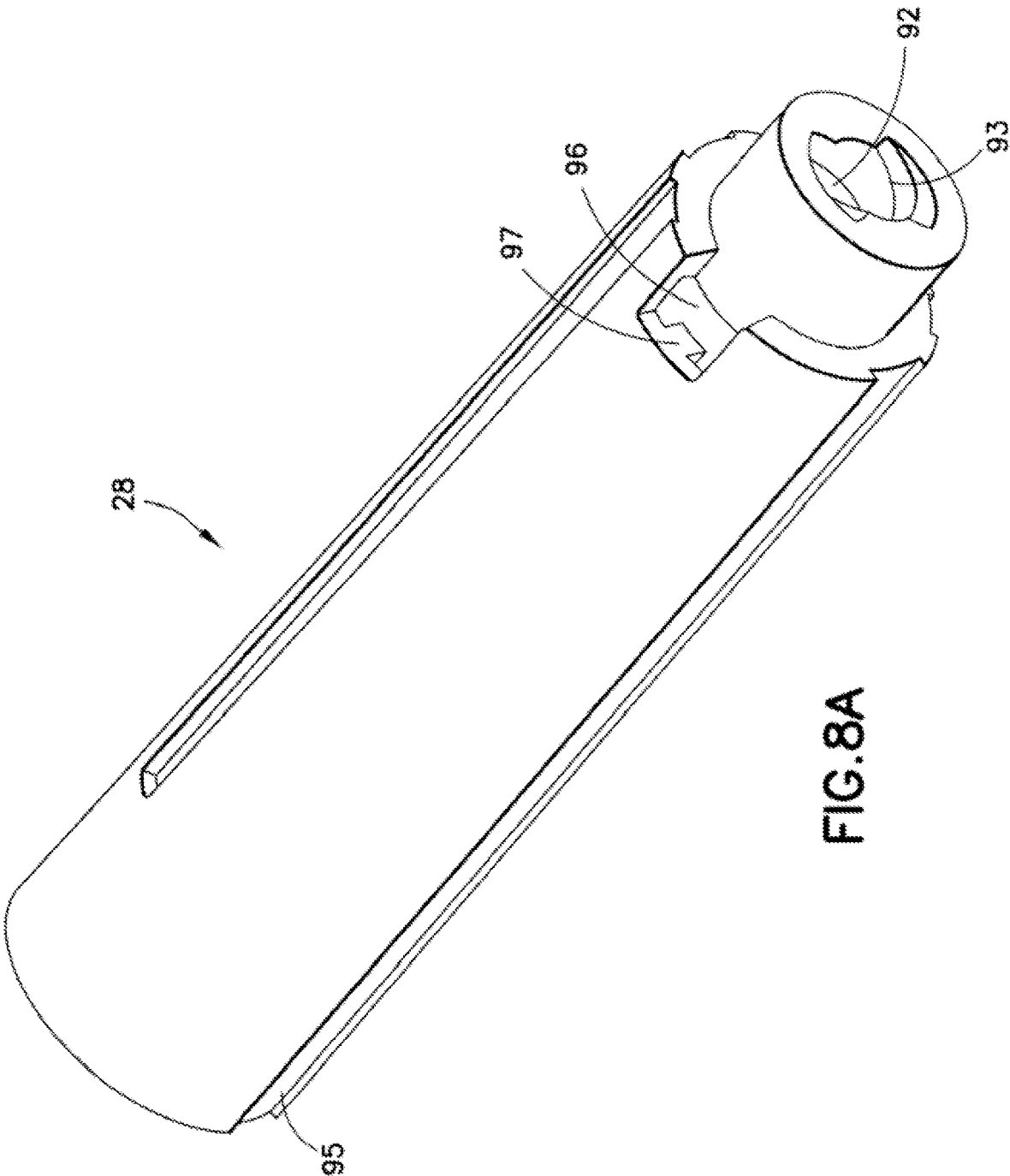


FIG.8A

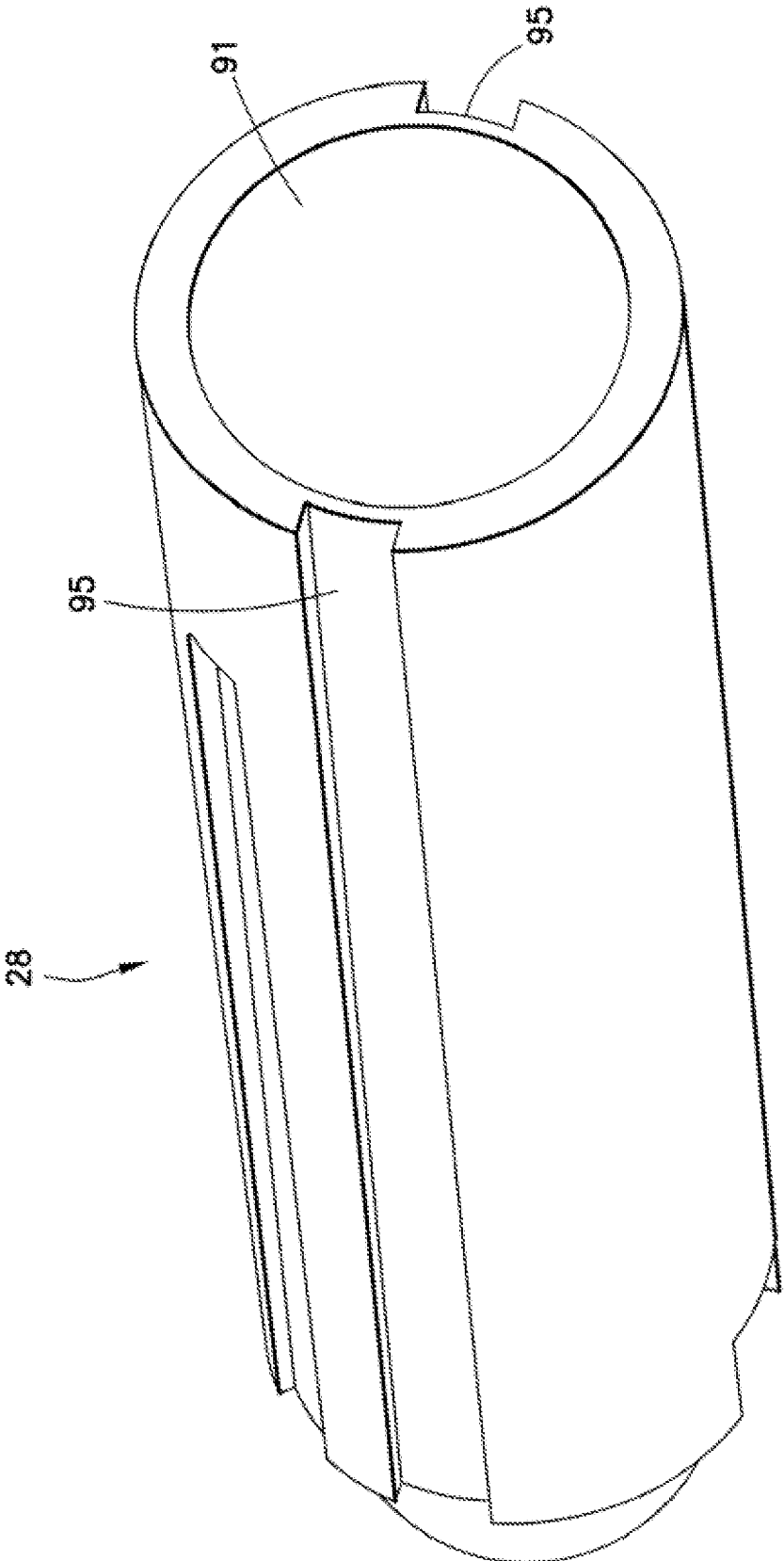


FIG.8B

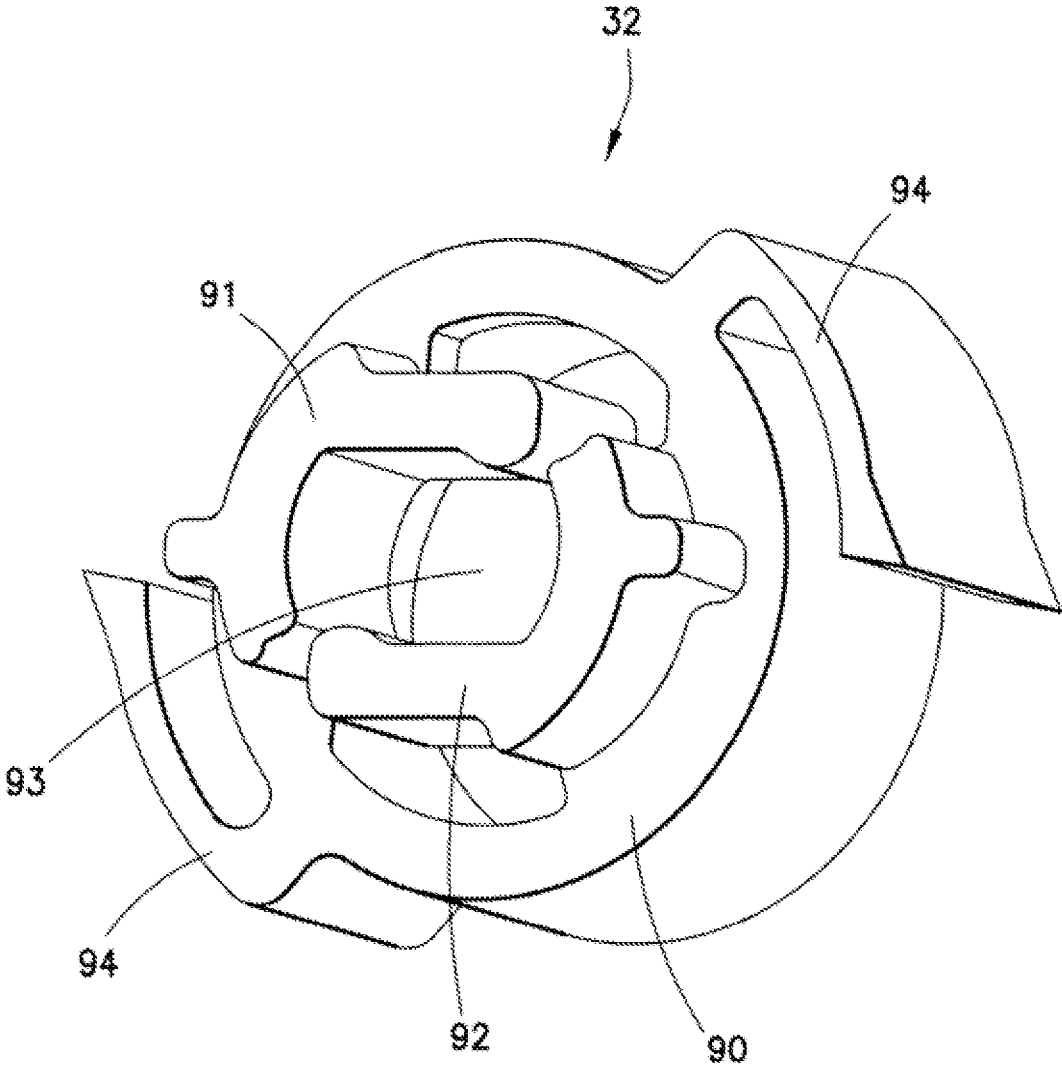


FIG.9A

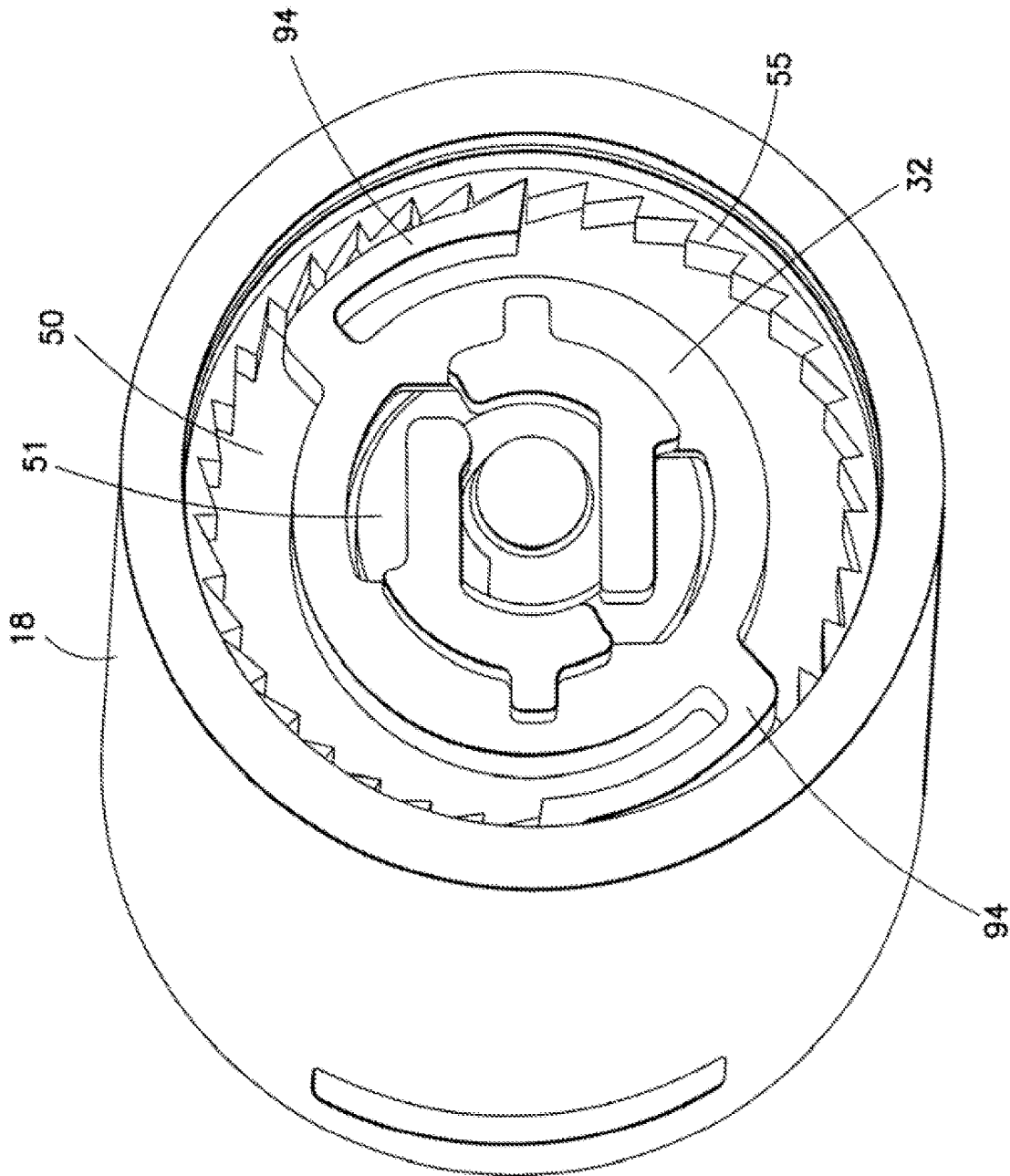


FIG.9B

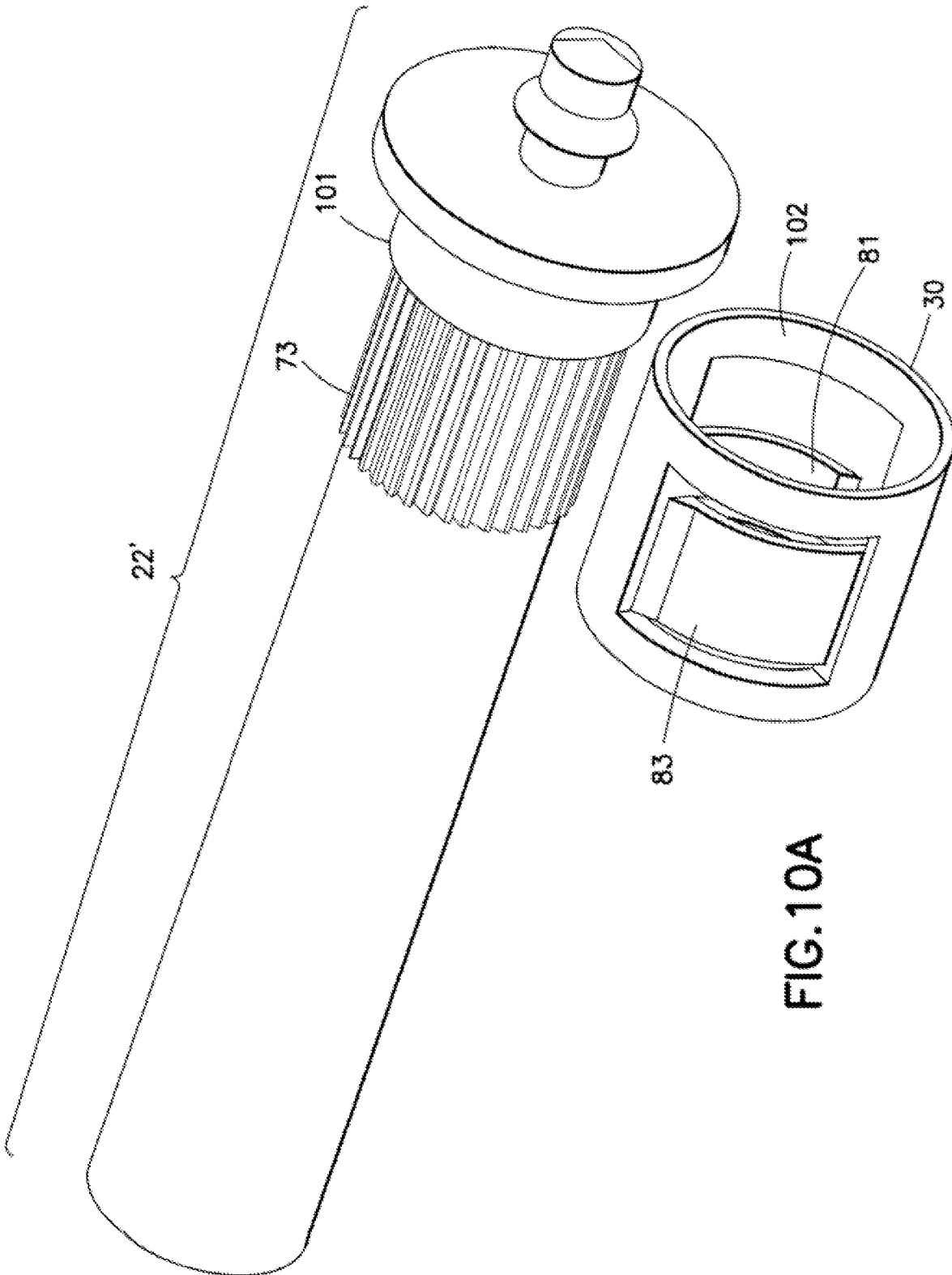


FIG.10A

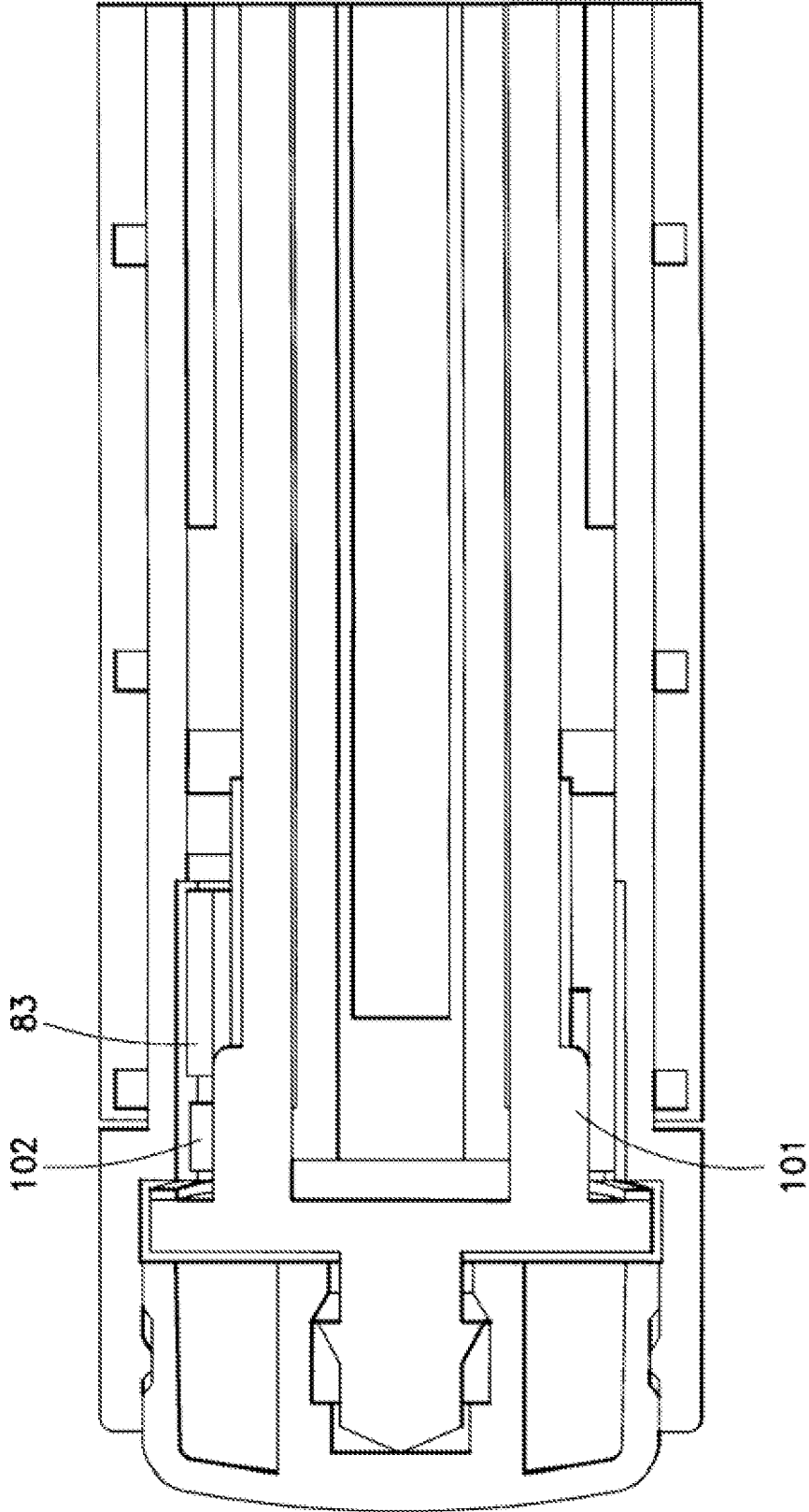


FIG. 10B

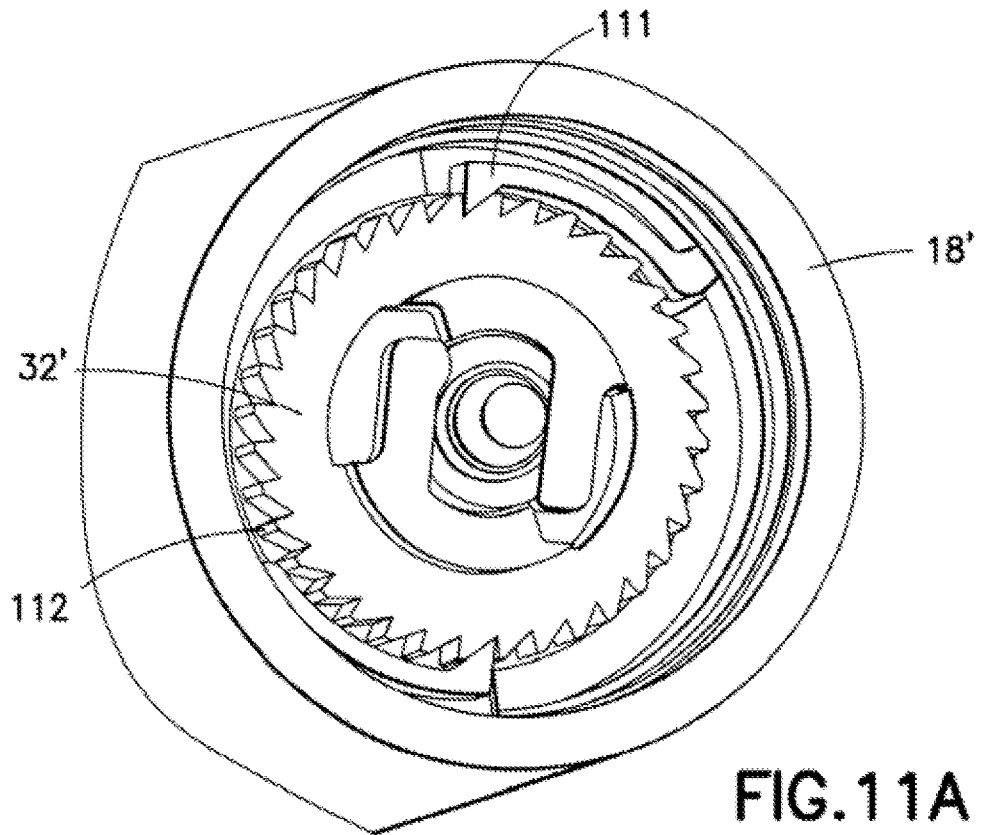


FIG. 11A

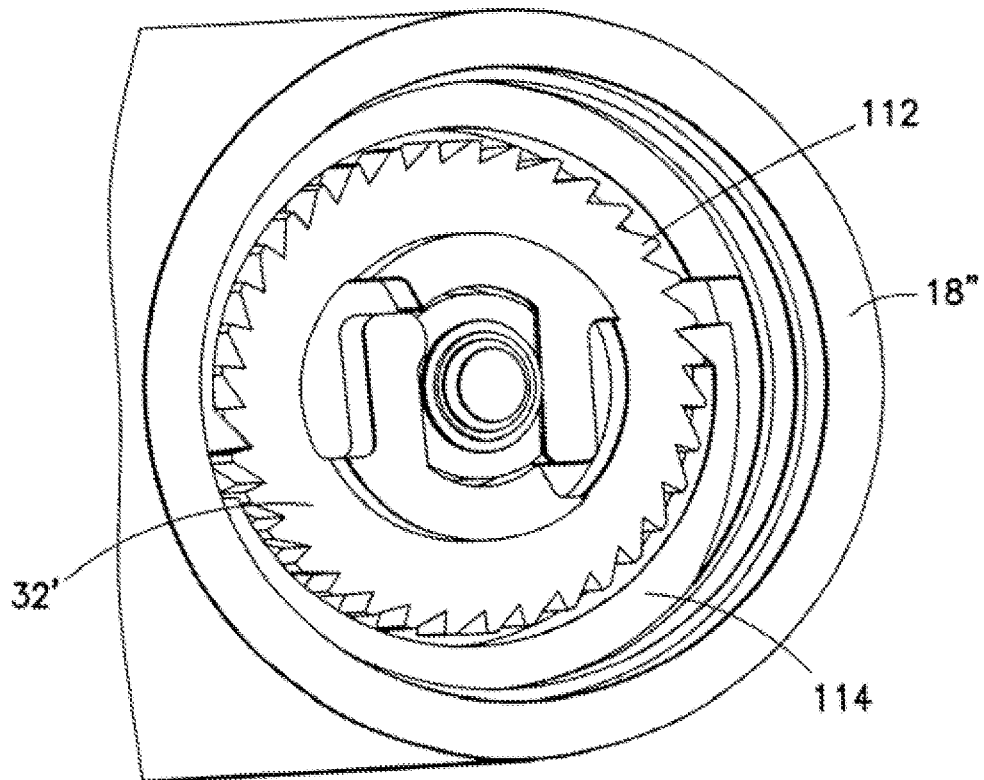


FIG. 11B

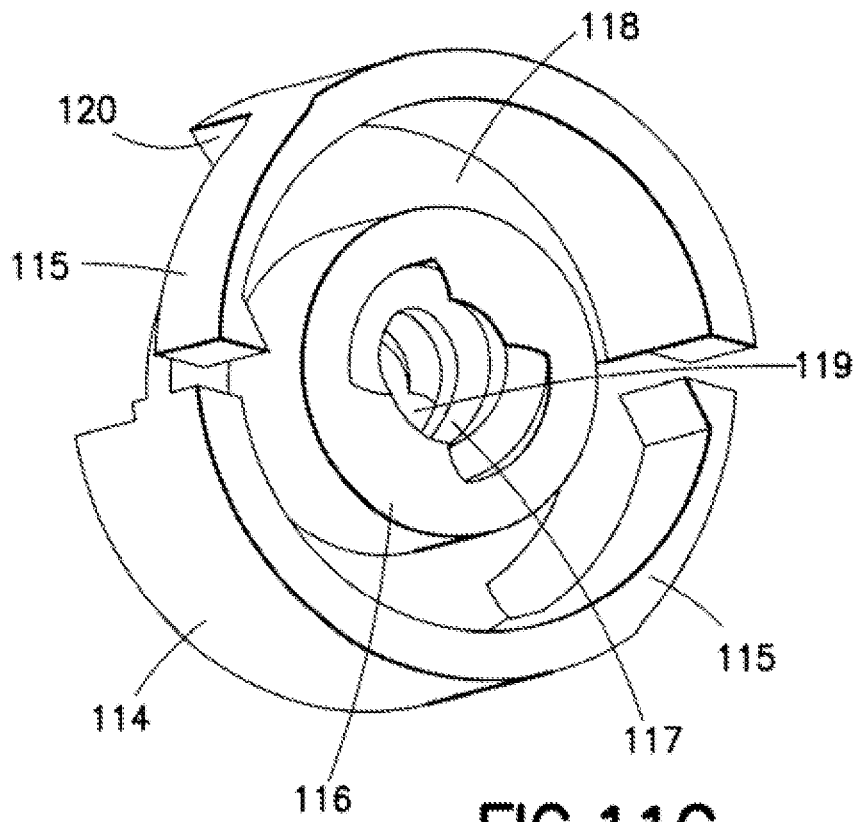


FIG. 11C

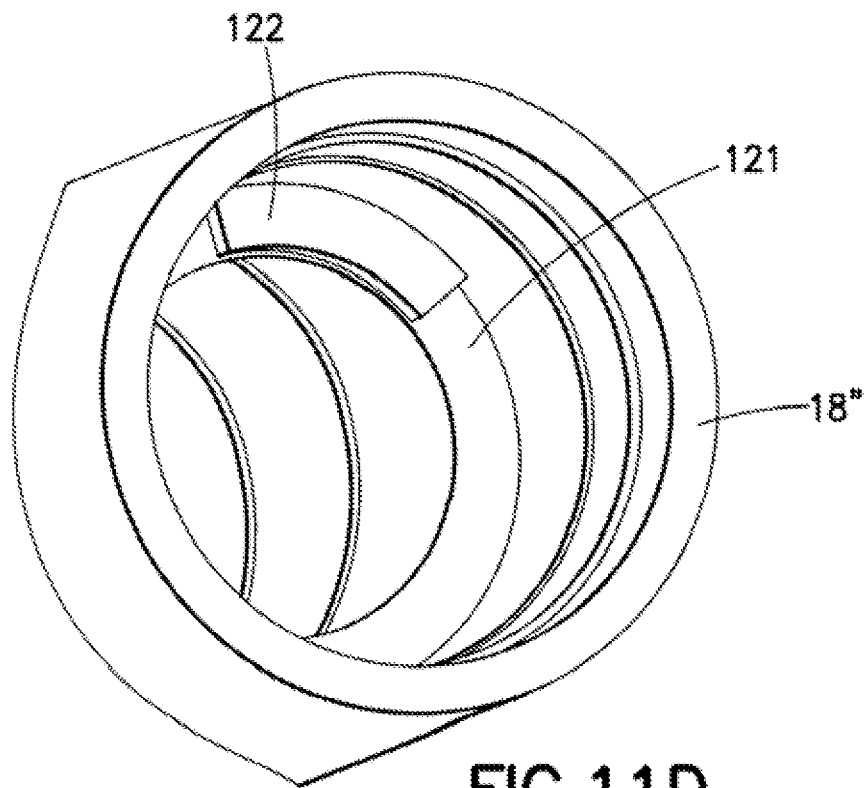


FIG. 11D

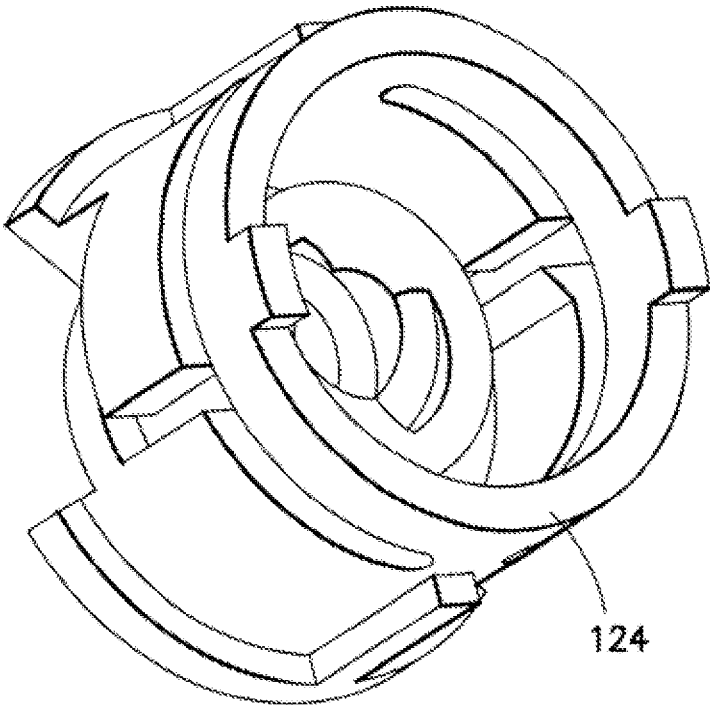


FIG. 11E

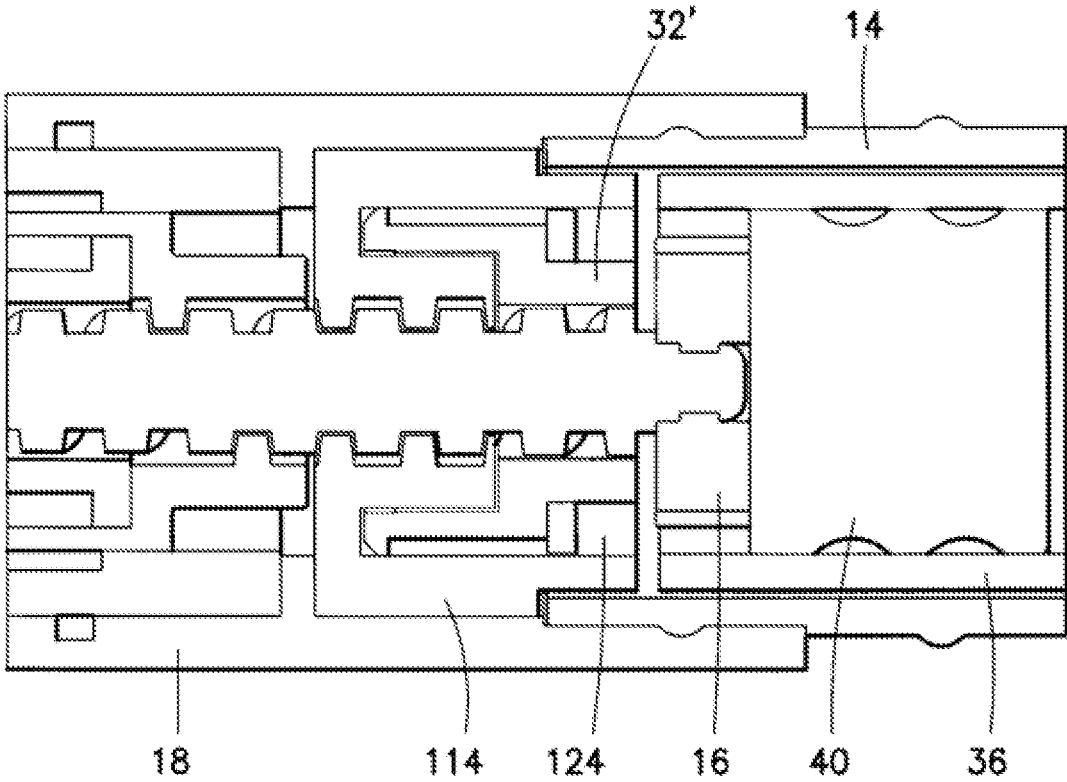


FIG. 11F

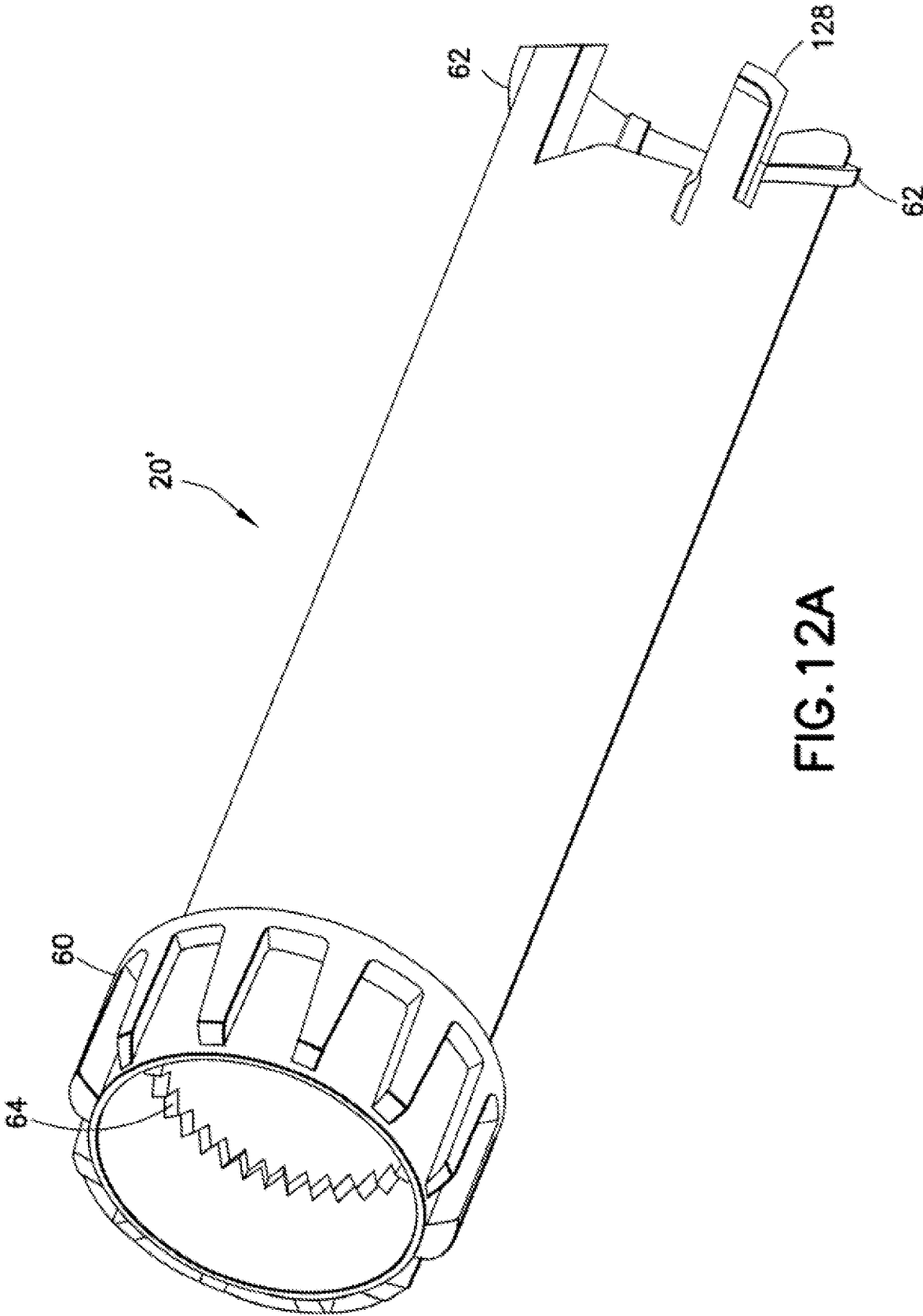


FIG. 12A

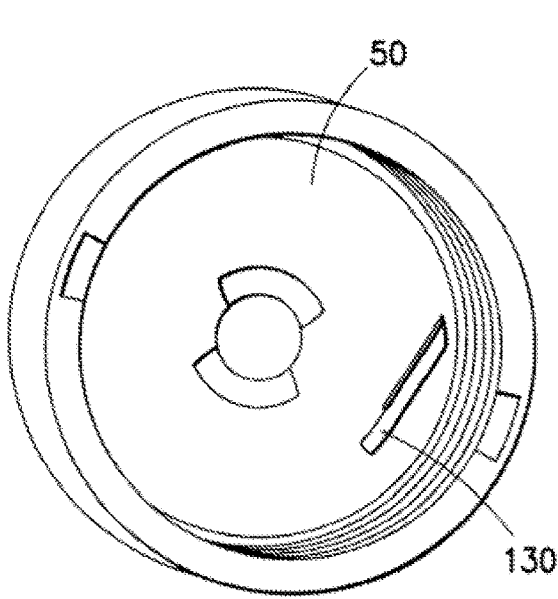


FIG. 12B

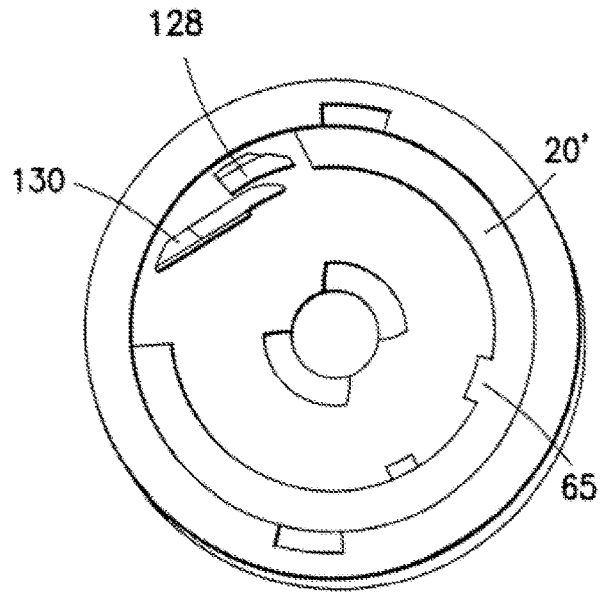


FIG. 12C

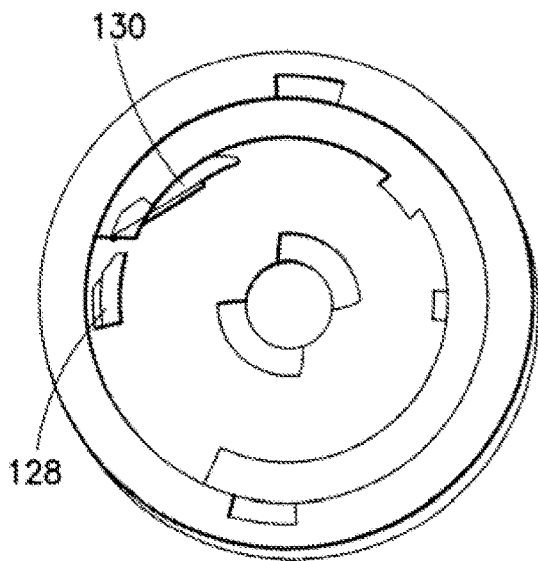


FIG. 12D

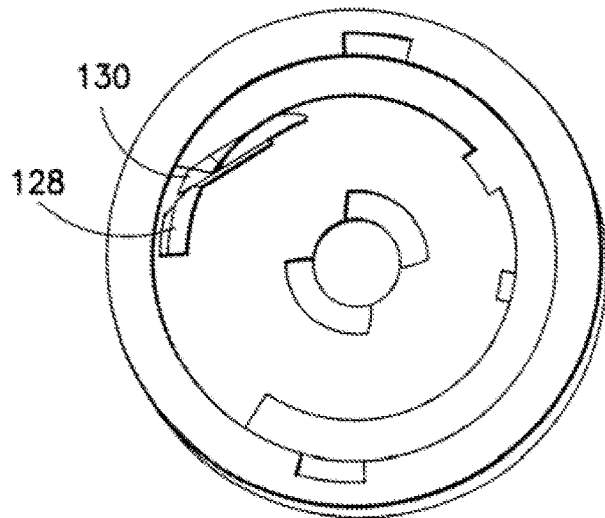


FIG. 12E

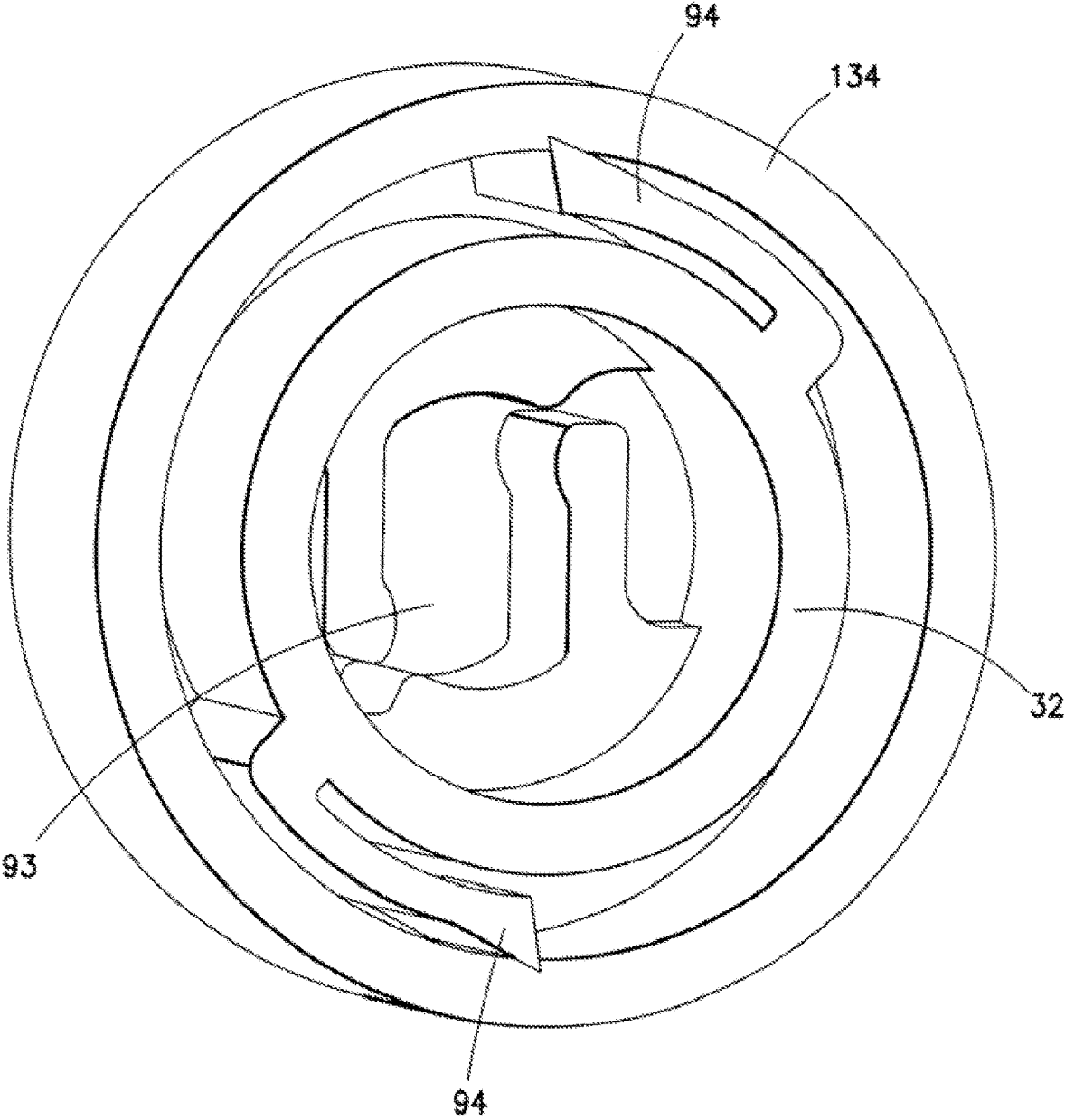


FIG. 13

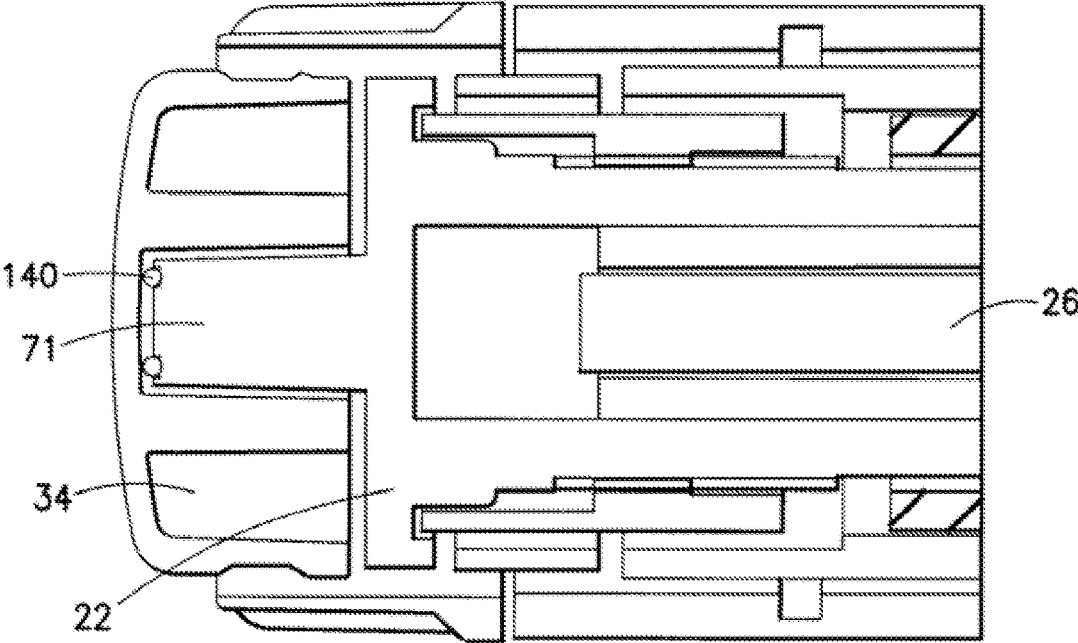


FIG.14A

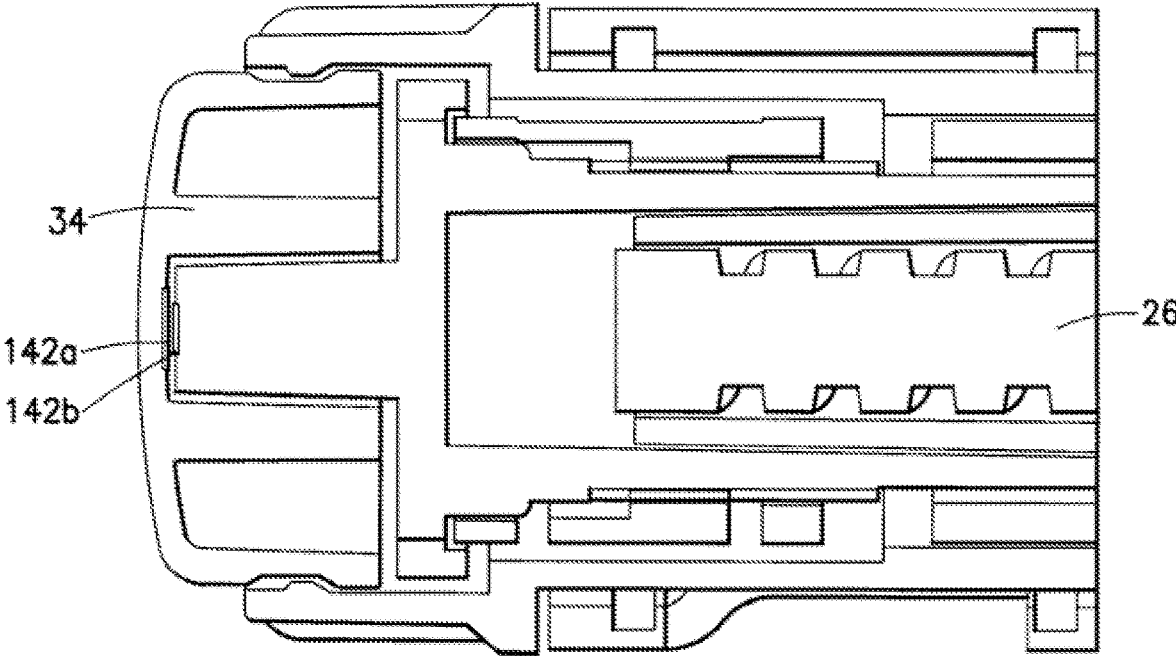


FIG.14B

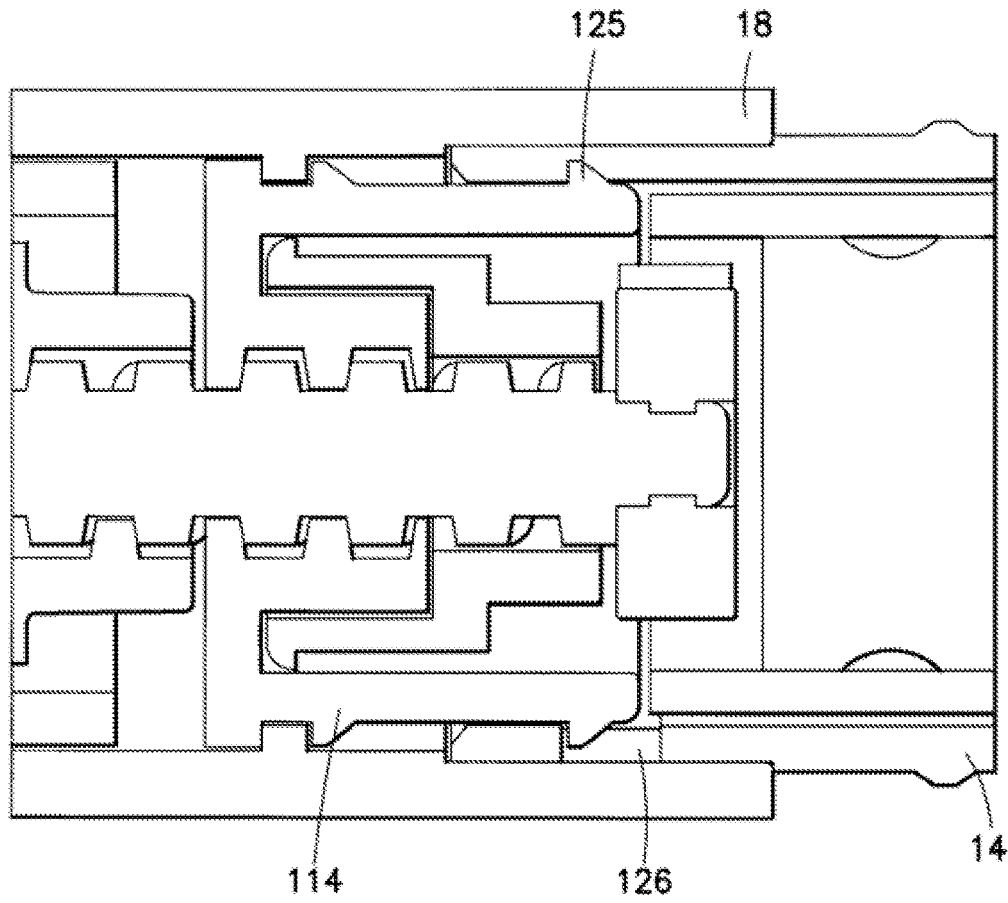


FIG.15A

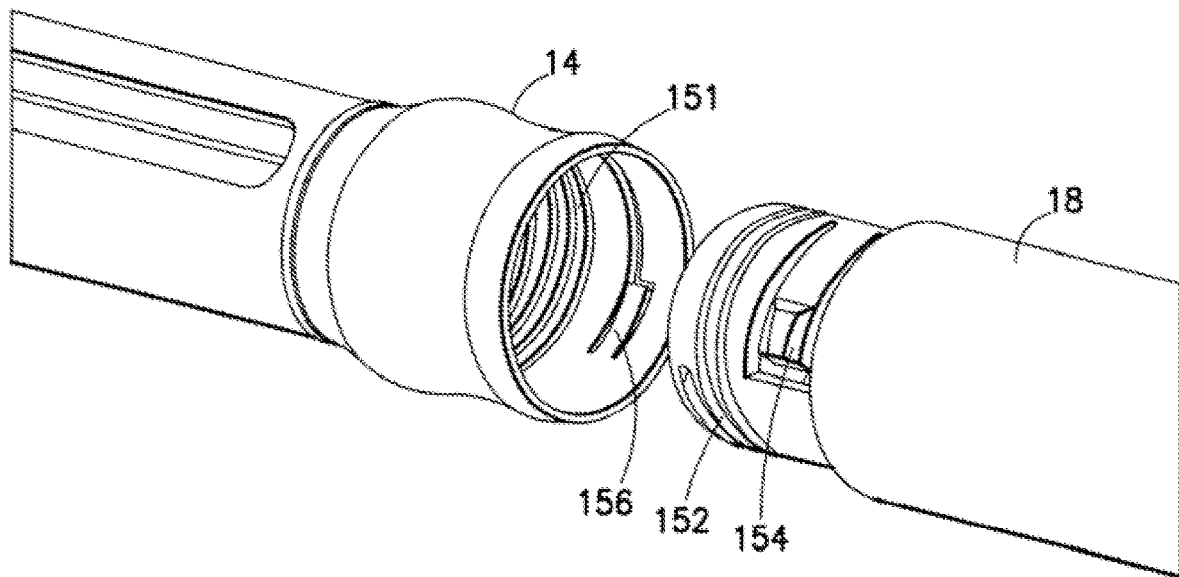


FIG.15B

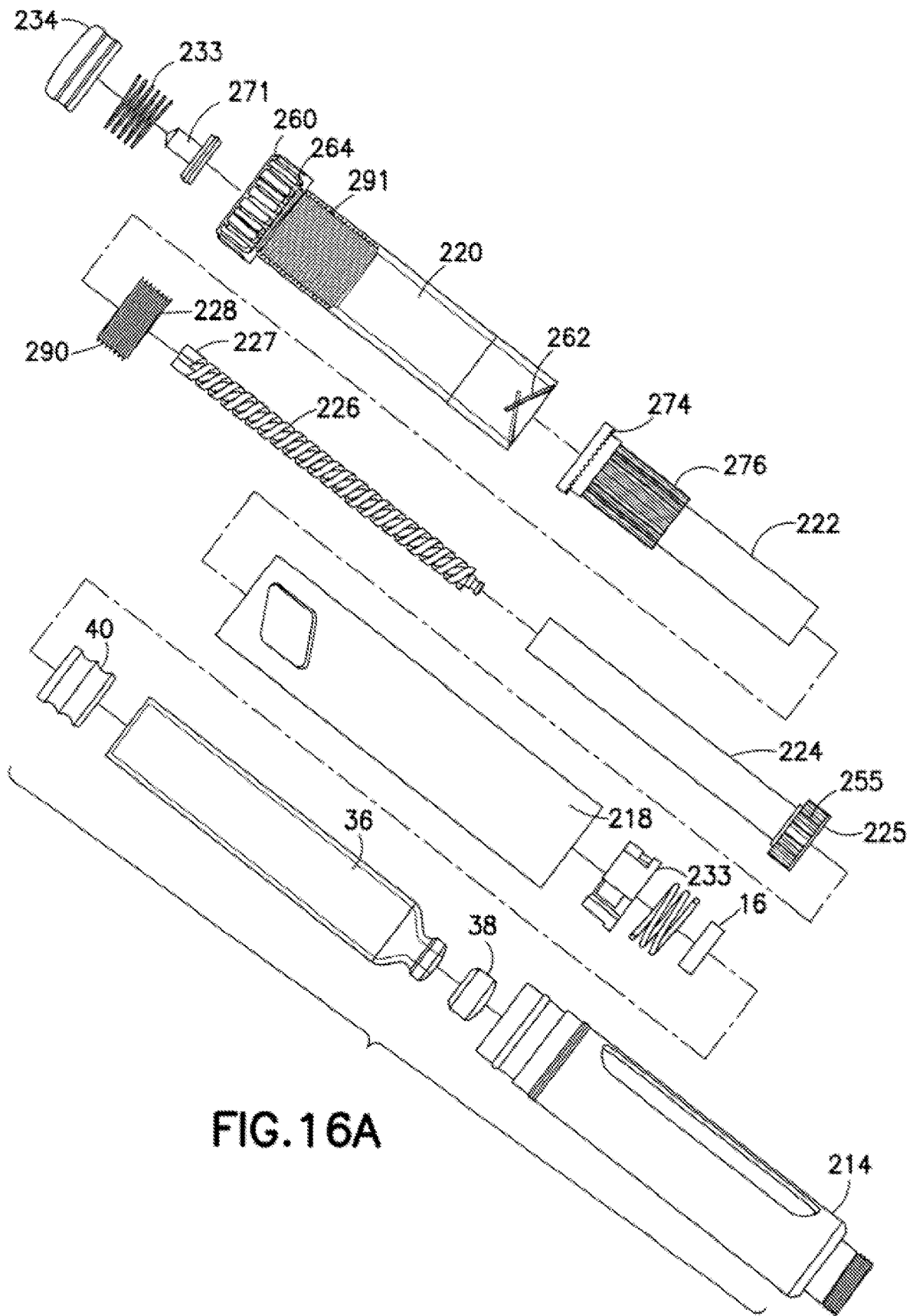


FIG. 16A

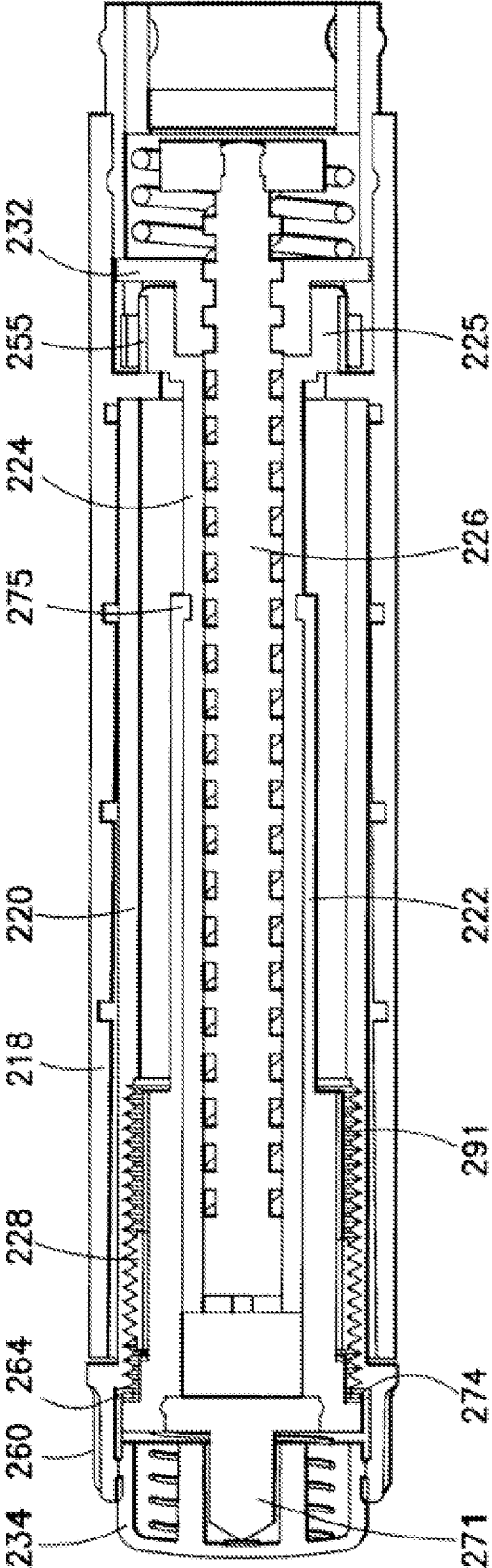


FIG. 16B

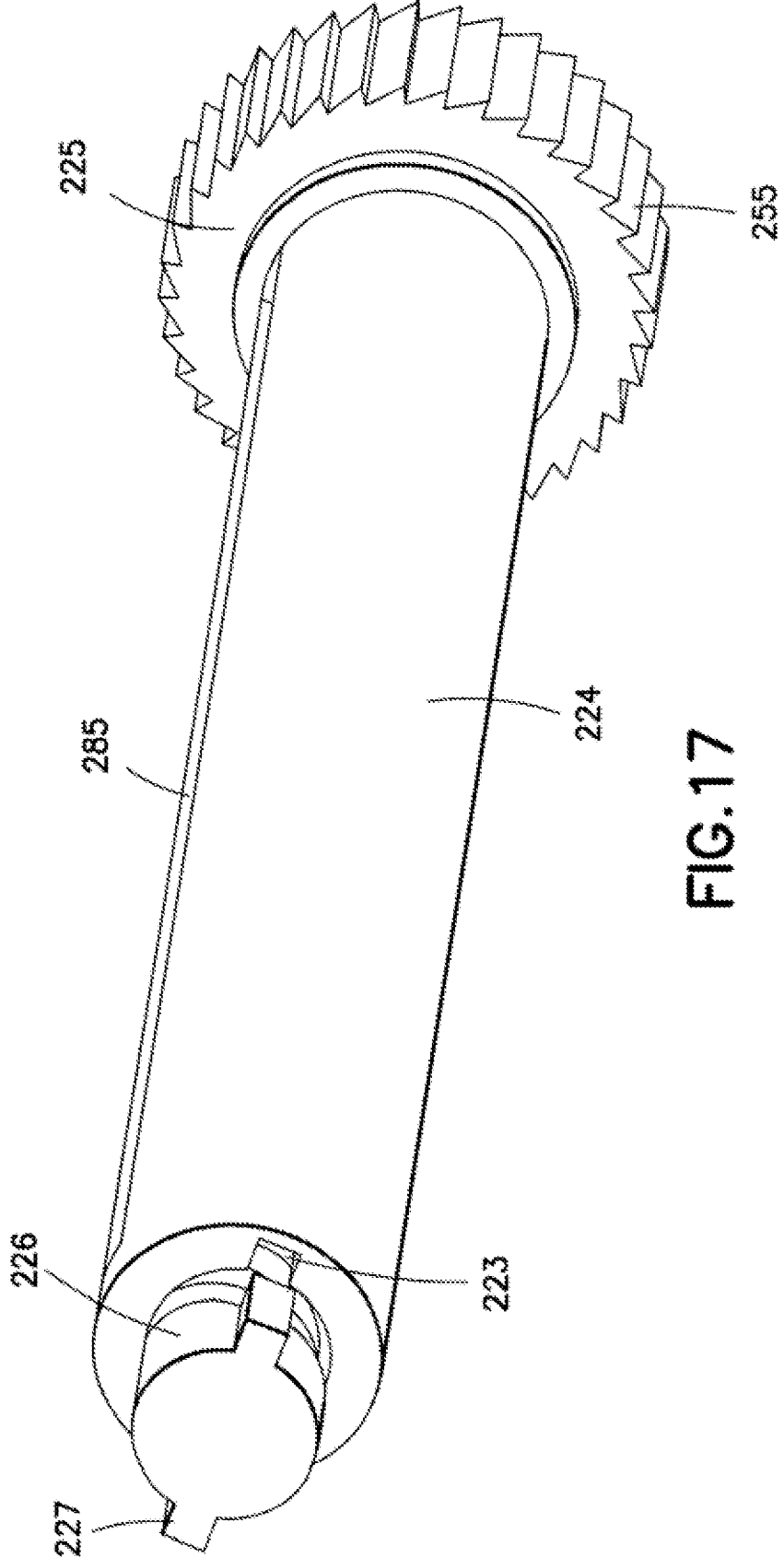


FIG.17

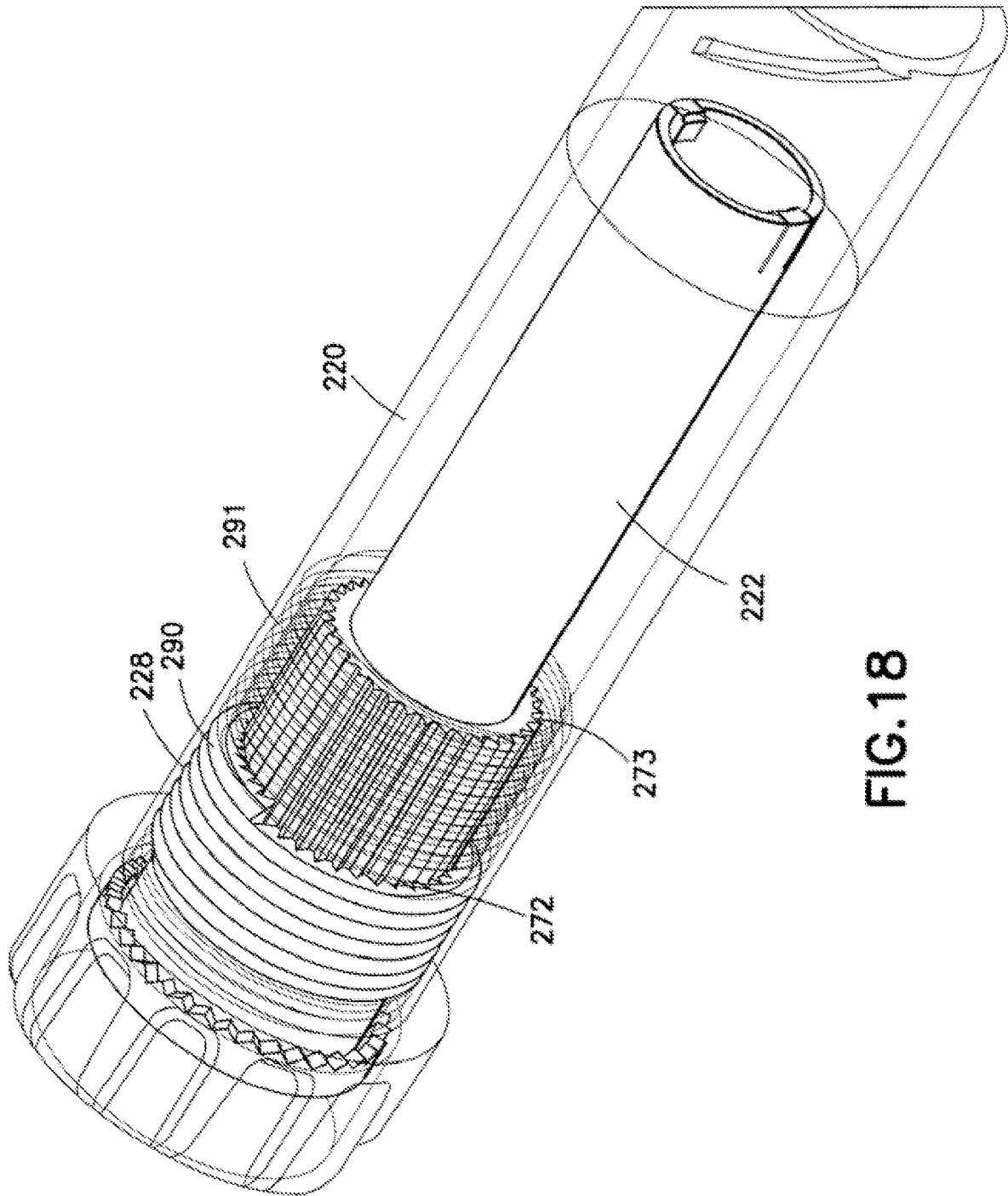


FIG. 18

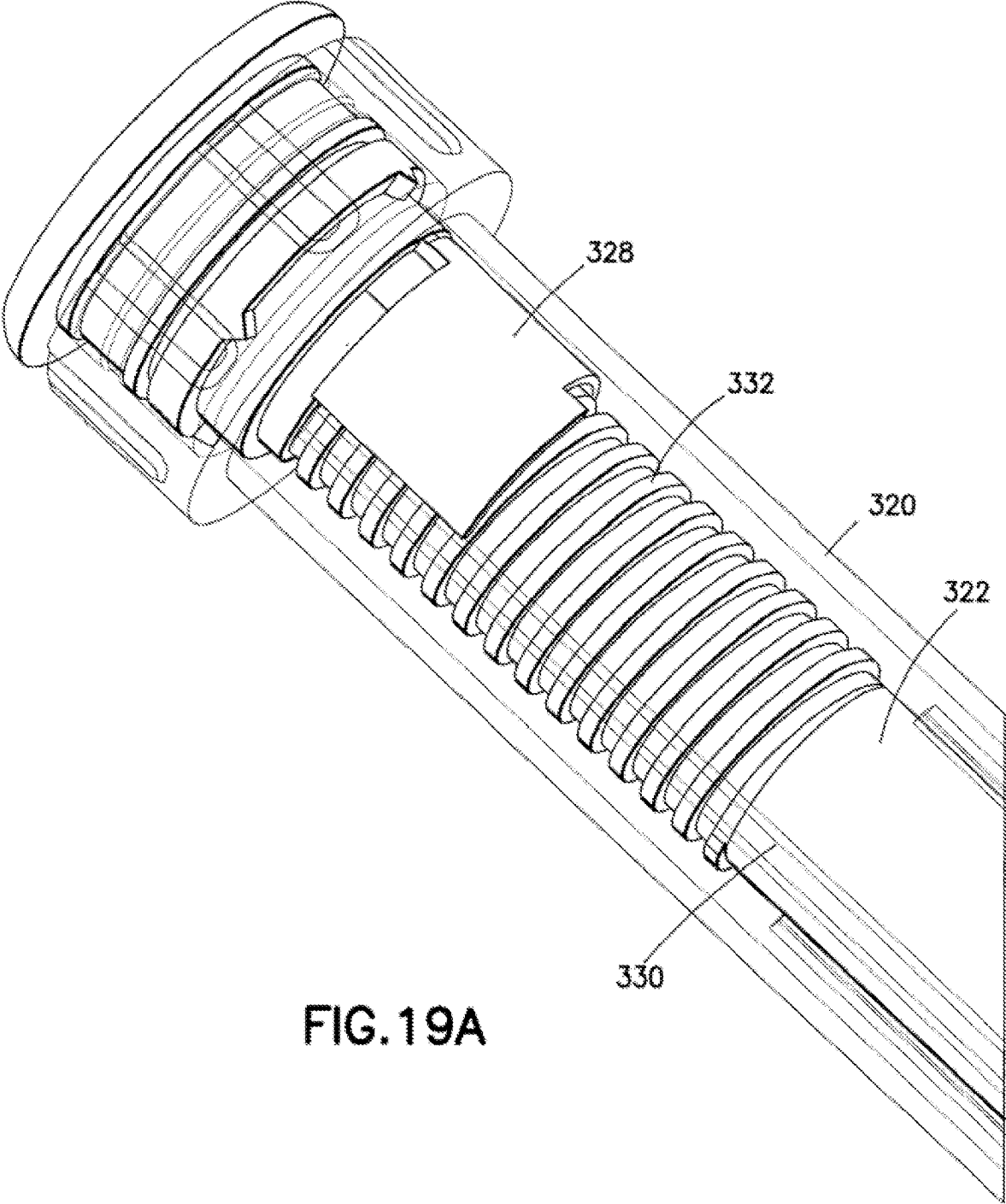


FIG. 19A

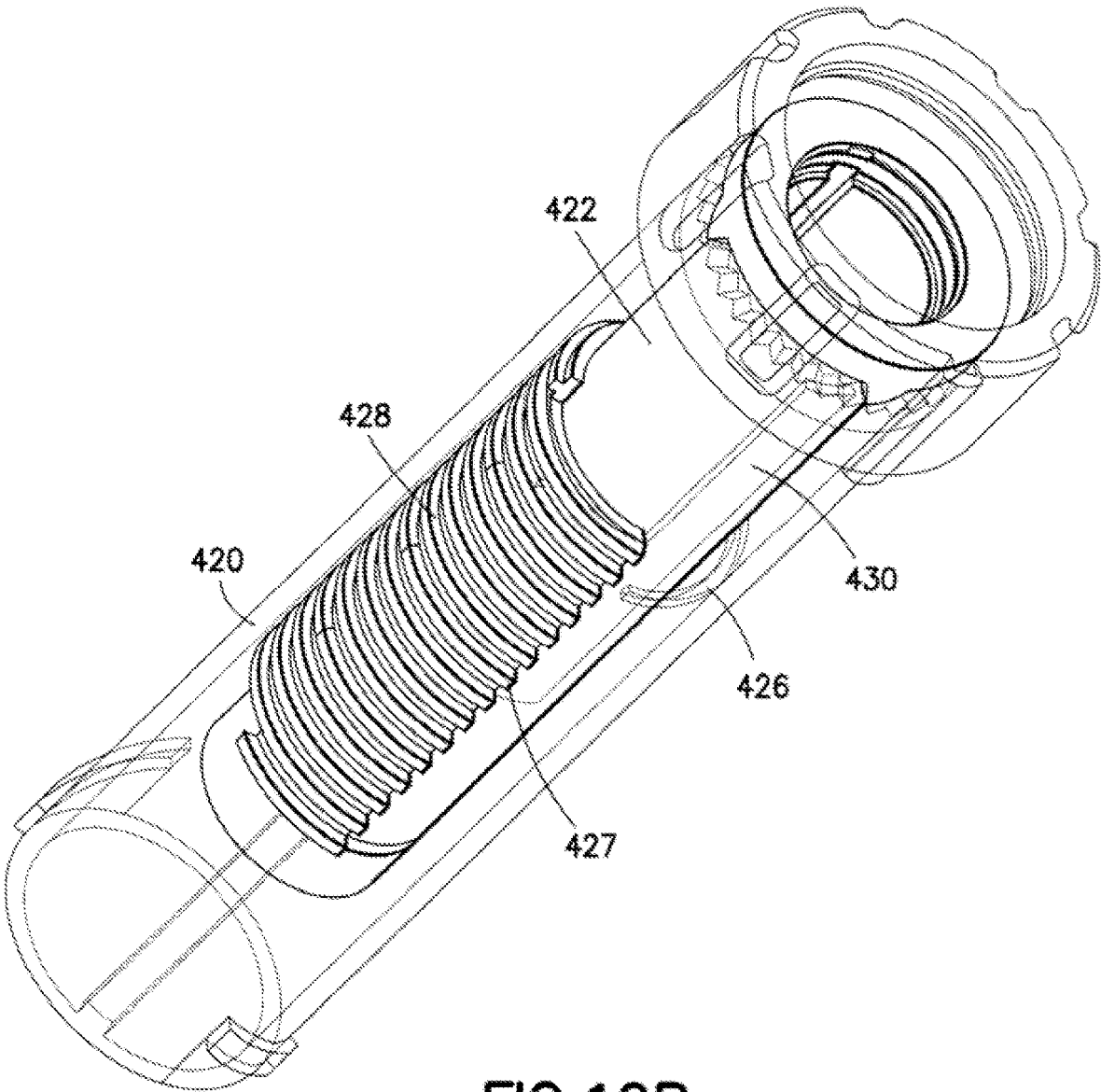


FIG. 19B

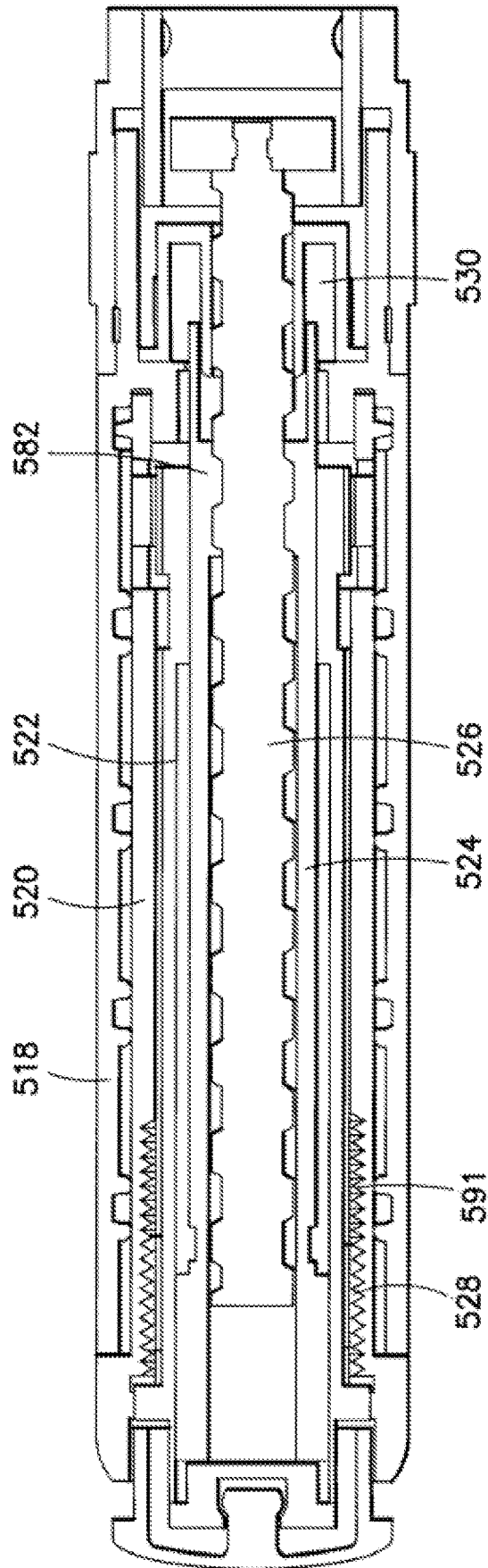


FIG. 20

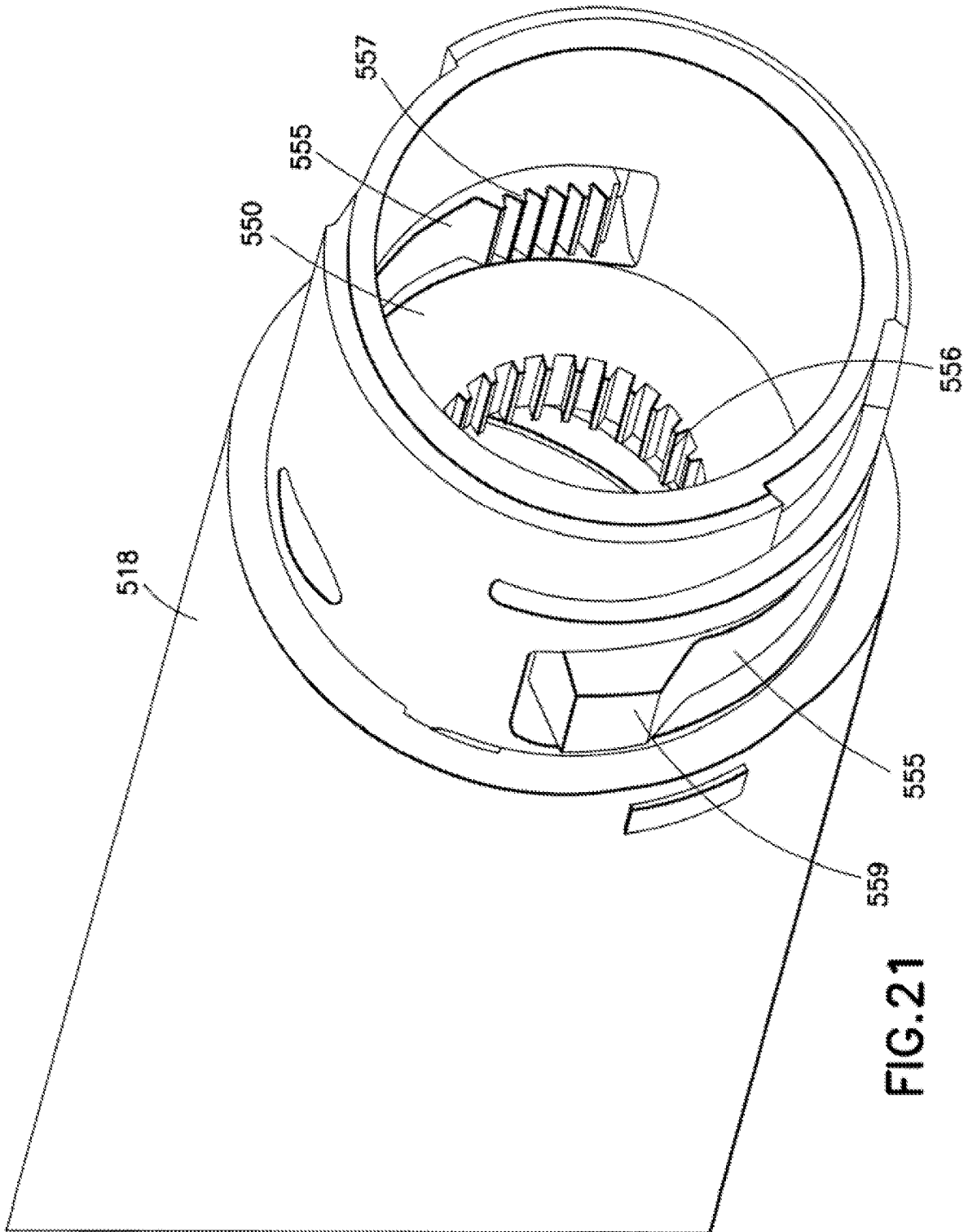


FIG. 21

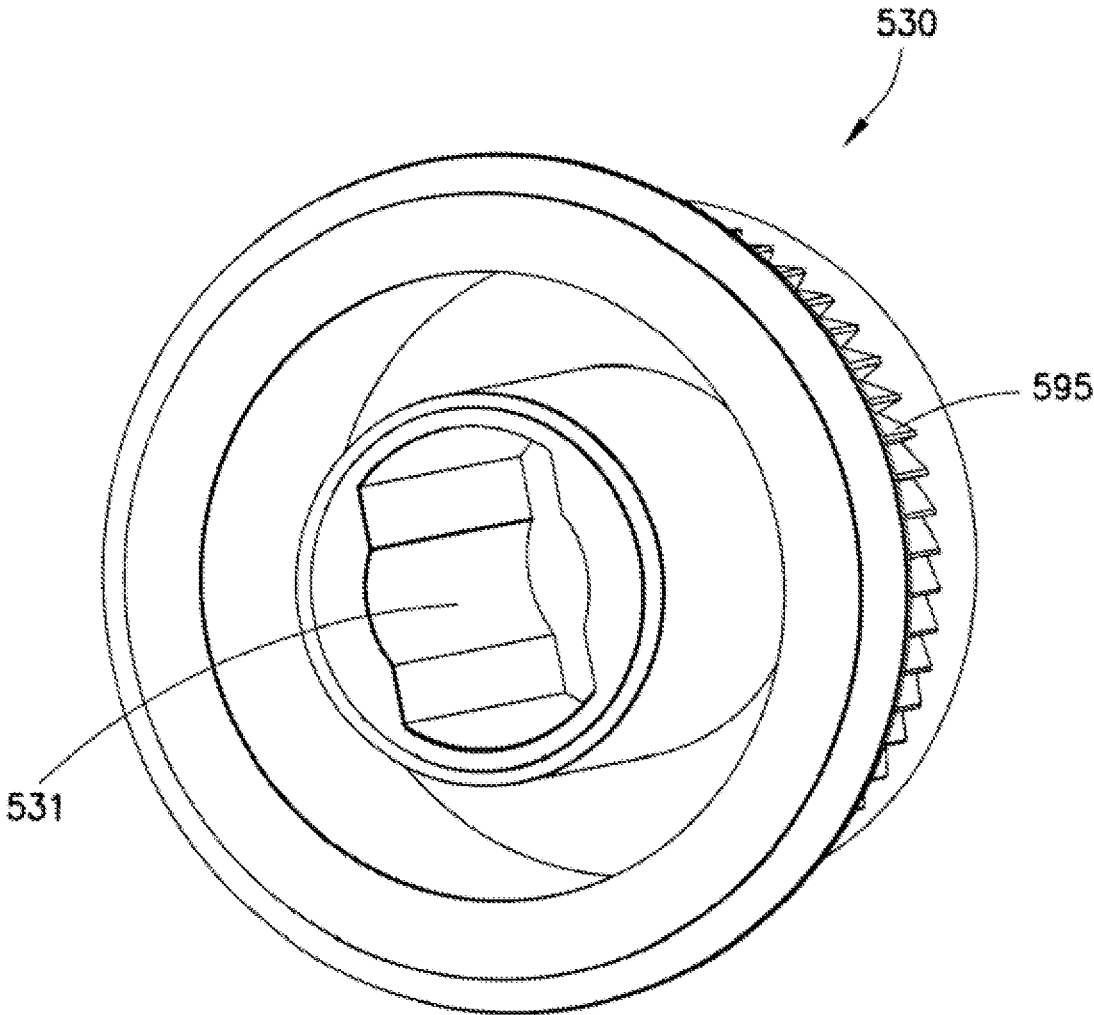


FIG. 22

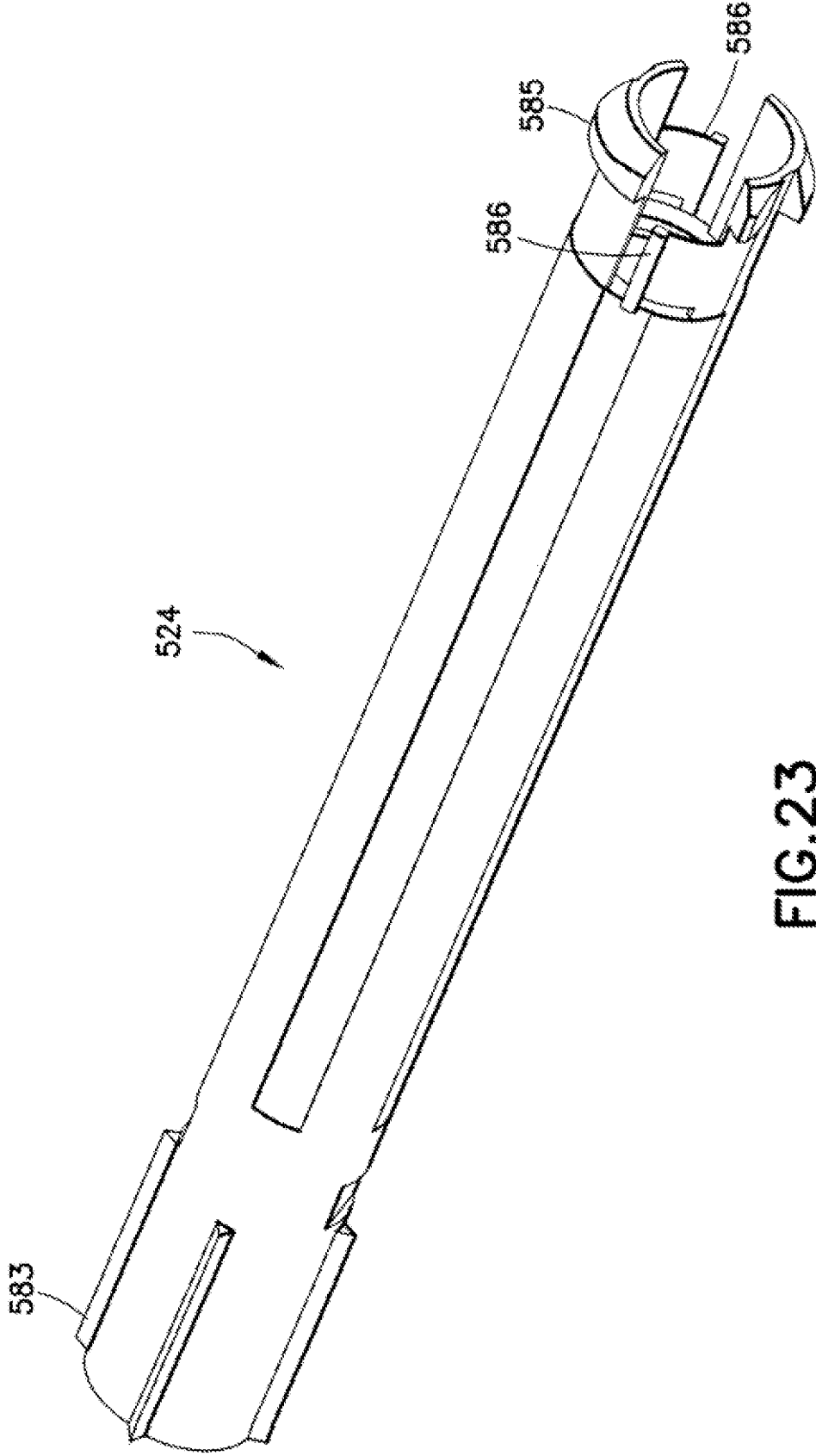


FIG. 23

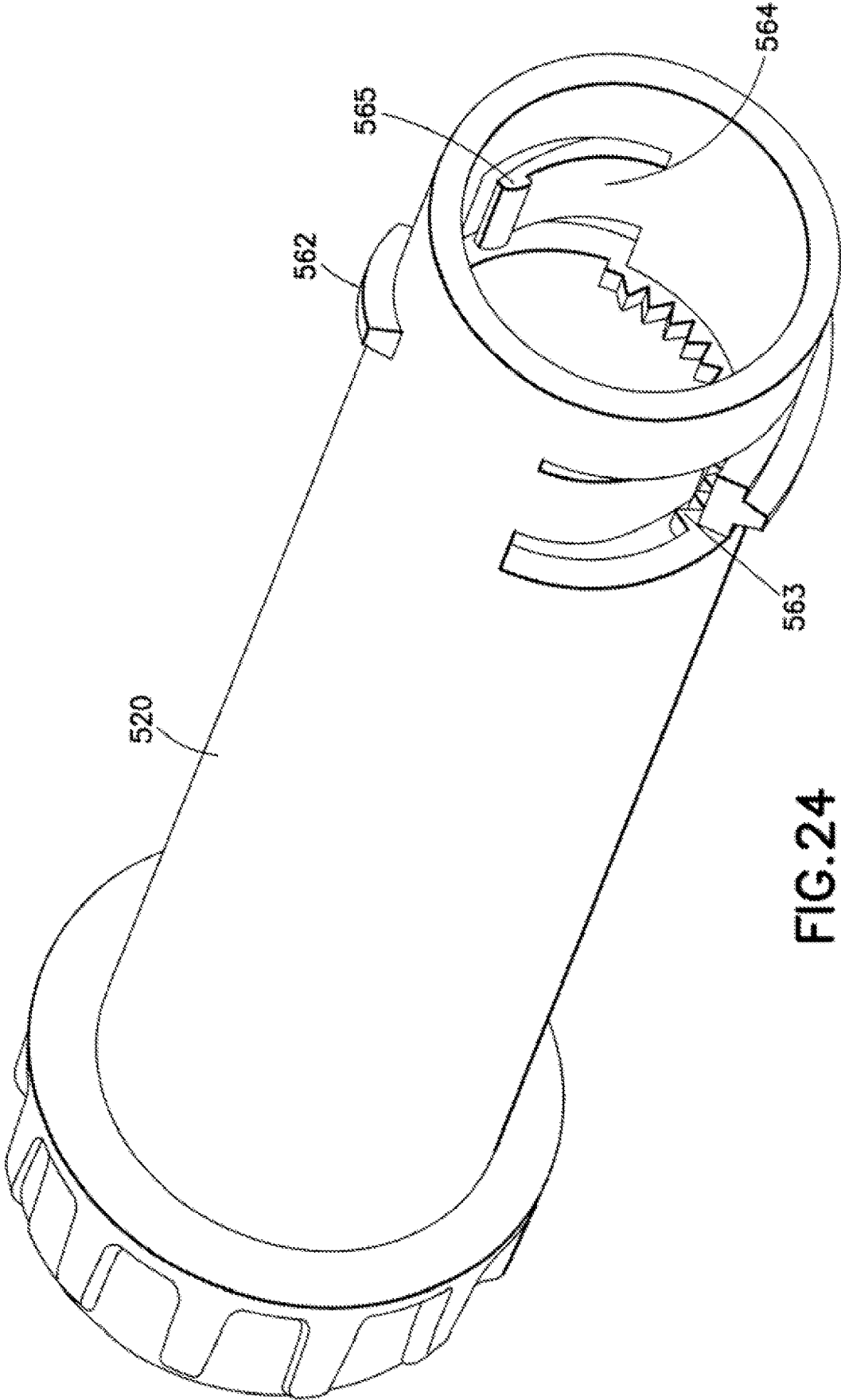


FIG.24

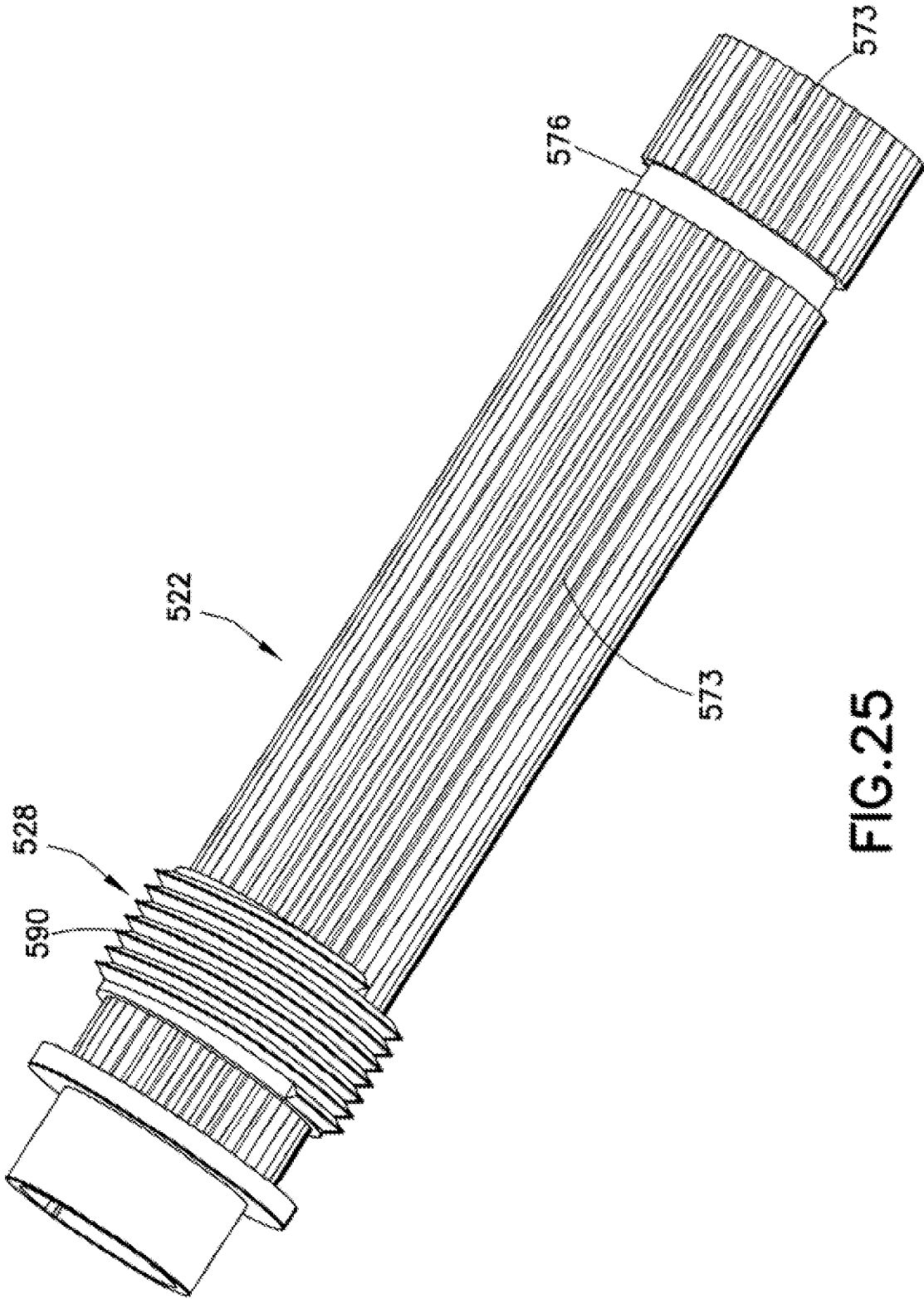


FIG.25

INJECTION PEN WITH DIAL BACK AND LAST DOSE CONTROL

RELATED APPLICATIONS

This application is a division of U.S. Nonprovisional application Ser. No. 15/669,349, filed on Aug. 4, 2017, now U.S. Pat. No. 10,940,269B2, issued Mar. 9, 2021, which is a division of U.S. Nonprovisional application Ser. No. 13/261,300, filed on Jul. 27, 2012, now U.S. Pat. No. 9,757,525B2, issued Sep. 12, 2017, which is a U.S. national stage application under 35 U.S.C. § 371 of International Application No. PCT/US10/003059, filed Nov. 30, 2010, which claims the benefit of U.S. Provisional Patent Applications Ser. No. 61/265,562, filed on Dec. 1, 2009, and Ser. No. 61/351,465, filed on Jun. 4, 2010, each of which is incorporated herein in its entirety.

FIELD OF THE INVENTION

The present application relates to multi-dose medication injection pen devices with improved functionality, including improved dial-back of a set dose, and improved last dose control.

BACKGROUND OF THE INVENTION

Various medication injection pen devices are known in the prior art. These prior art devices sometimes include features for enabling a user to correct a dose that has been set too large, which may be referred to as “dial back”. Another feature that may be provided by some of the prior art devices is the ability to control a last dose of a medication cartridge such that a user cannot set a dose greater than the remaining amount of medication in the cartridge. This feature is referred to as last dose control or last dose management. Both of these features are desired by users of such pen devices; however, the prior art devices do not satisfactorily meet these needs. Many prior art devices may provide one of these features, but not both. Further, many of the prior art devices require additional steps for performing dial back, which are cumbersome and not intuitive to the user. Thus, there is a need in the art to provide improved functionality of dial back and last dose control mechanisms together in a medication injection pen.

SUMMARY OF EMBODIMENTS OF THE INVENTION

Exemplary embodiments of the present invention address at least the above problems and/or disadvantages and provide at least the advantages described below.

Accordingly, first exemplary embodiment of the present invention provides a medication injection pen comprising a housing, for housing a dose set knob, a leadscrew, a driver, a setback member, and a dose stop member. The dose set knob is rotatable with respect to said housing to set a desired injection dose, and comprises at least one internal thread. The leadscrew includes a thread element by which it is advanceable in a first direction via a corresponding thread engagement, said first direction being that which expels medication from a cartridge. The driver is rotationally fixed to said leadscrew for preventing relative rotation therebetween, said driver being rotatable in a first direction to rotate and advance said leadscrew in said first direction. The setback member is rotationally fixed to said driver for preventing relative rotation therebetween. The dose stop

member is rotationally fixed to said setback member and comprises an external thread in threaded engagement with said internal thread of said dose set knob, said dose stop member being axially movable relative to said dose set knob when said dose set knob is rotated relative to said setback member, and wherein axial movement of said dose stop member limits the user from setting a dose that is greater than an injectable volume of medication remaining in the cartridge.

According to another exemplary embodiment of the present invention a medication injection pen is provided comprising a housing, for housing a dose set knob, a leadscrew, a driver, a setback member, and a dose stop member. The dose set knob is rotatable with respect to said housing to set a desired injection dose. The leadscrew includes a thread element by which it is advanceable in a first direction via a corresponding thread engagement, said first direction being that which expels medication from a cartridge. The driver is rotationally fixed to said leadscrew for preventing relative rotation therebetween, said driver being rotatable in a first direction to rotate and advance said leadscrew in said first direction. The setback member is rotationally fixed to said driver for preventing relative rotation therebetween, and is provided with an external thread thereon. The dose stop member is rotationally fixed to said dose set knob and comprises an internal thread in threaded engagement with said external thread of said setback member, said dose stop member being axially movable relative to said dose set knob when said dose set knob is rotated relative to said setback member, and wherein axial movement of said dose stop member limits a user from setting a dose that is greater than an injectable volume of medication remaining in the cartridge.

According to yet another exemplary embodiment of the present invention a medication injection pen is provided comprising a housing, for housing a dose set knob, a leadscrew, a driver, a setback member, and a dose stop member. The dose set knob is rotatable with respect to said housing to set a desired injection dose. The leadscrew includes a thread element by which it is advanceable in a first direction via a corresponding thread engagement, said first direction being that which expels medication from a cartridge. The driver is rotationally fixed to said leadscrew for preventing relative rotation therebetween, said driver being rotatable in a first direction to rotate and advance said leadscrew in said first direction. The setback member is rotationally fixed to said driver for preventing relative rotation therebetween. The dose stop member is rotationally fixed to said dose set knob and comprises an internal thread in threaded engagement with said thread of said leadscrew, said dose stop member being axially movable relative to said dose set knob when said dose set knob is rotated relative to said setback member, and wherein axial movement of said dose stop member limits a user from setting a dose that is greater than an injectable volume of medication remaining in the cartridge.

According to yet another exemplary embodiment of the present invention a medication injection pen is provided comprising a housing, for housing a dose set knob, a leadscrew, a driver, a setback member, and a click element. The dose set knob is rotatable with respect to said housing to set a desired injection dose. The leadscrew includes a thread element by which it is advanceable in a first direction via a corresponding thread engagement, said first direction being that which expels medication from a cartridge. The driver is rotationally fixed to said leadscrew for preventing relative rotation therebetween, said driver being rotatable in

a first direction to rotate and advance said leadscrew in said first direction. The setback member is rotationally fixed to said driver for preventing relative rotation therebetween. The click element is positioned between said dose set knob and said setback member, said click element comprising a first arm member engaging an internal surface of said dose set knob, and a second arm member engaging an external surface of said setback member, wherein one of the said first and second arms produces an audible signal when said dose set knob is rotated with respect to said housing.

According to yet another exemplary embodiment of the present invention a medication injection pen is provided comprising a housing, for housing a dose set knob, a leadscrew, a driver, and a setback member. The dose set knob is rotatable with respect to said housing to set a desired injection dose. The leadscrew includes a thread element by which it is advanceable in a first direction via a corresponding thread engagement, said first direction being that which expels medication from a cartridge. The driver is rotationally fixed to said leadscrew for preventing relative rotation therebetween, said driver being rotatable in a first direction to rotate and advance said leadscrew in said first direction. The setback member is rotationally fixed to said driver for preventing relative rotation therebetween. The housing further comprises a flexible protrusion provided on a surface within said housing, and the dose set knob further comprises a flexible tab element which engages said protrusion to produce an audible signal upon completion of injection of a set dose.

Additional objects, advantages and salient features of exemplary embodiments of the invention will become apparent to those skilled in the art from the following detailed description, which, taken in conjunction with annexed drawings, discloses exemplary embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other exemplary features and advantages of certain exemplary embodiments of the present invention will become more apparent from the following description of certain exemplary embodiments thereof when taken in conjunction with the accompanying drawings, in which:

FIG. 1 depicts a medication injection pen according to an exemplary embodiment of the present invention;

FIGS. 2A and 2B depict unassembled and assembled cross-sectional views, respectively, of exemplary components provided in a medication injection pen according to a first exemplary embodiment of the present invention;

FIG. 2C depicts an unassembled view of a pen needle usable in exemplary embodiments of the present invention;

FIGS. 3A and 3B depict views of a body provided in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 4A and 4B depict views of a dose set knob provided in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 5A and 5B depict views of a setback member provided in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 6A and 6B depict views of a click element provided in a medication injection pen according to the first exemplary embodiment of the present invention;

FIG. 7 depicts a view of a driver and leadscrew arrangement provided in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 8A and 8B depict views of a dose stop member provided in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 9A and 9B depict views of a leadscrew brake provided in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 10A and 10B depict views of an alternative injection coupling mechanism provided in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 11A-11F depict views of alternative leadscrew brake and threaded insert embodiments provided in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 12A-12E depict views of an end-of-injection click mechanism in a medication injection pen according to the first exemplary embodiment of the present invention;

FIG. 13 depicts a view of a muted injection click mechanism in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 14A and 14B depict views of an additional mechanism for reducing friction between components in a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 15A and 15B depict exemplary mechanisms for connecting a cartridge to a medication injection pen according to the first exemplary embodiment of the present invention;

FIGS. 16A and 16B depict unassembled and assembled cross-sectional views, respectively, of exemplary components provided in a medication injection pen according to a second exemplary embodiment of the present invention;

FIG. 17 depicts a view of a driver and leadscrew arrangement provided in a medication injection pen according to the second exemplary embodiment of the present invention;

FIG. 18 depicts a view of a last dose control mechanism provided in a medication injection pen according to the second exemplary embodiment of the present invention;

FIGS. 19A and 19B depict views of alternative last dose control mechanisms provided in a medication injection pen according to the second exemplary embodiment of the present invention;

FIG. 20 depicts an assembled cross-sectional view of exemplary components provided in a medication injection pen according to a third exemplary embodiment of the present invention;

FIG. 21 depicts a view of a body provided in a medication injection pen according to the third exemplary embodiment of the present invention;

FIG. 22 depicts a view of an insert provided in a medication injection pen according to the third exemplary embodiment of the present invention;

FIG. 23 depicts a view of a driver provided in a medication injection pen according to the third exemplary embodiment of the present invention;

FIG. 24 depicts a view of a dose set knob provided in a medication injection pen according to the third exemplary embodiment of the present invention; and

FIG. 25 depicts a view of a setback member provided in a medication injection pen according to the third exemplary embodiment of the present invention.

Throughout the drawings, like reference numerals will be understood to refer to like elements, features and structures.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

The matters exemplified in this description are provided to assist in a comprehensive understanding of exemplary

embodiments of the present disclosure with reference to the accompanying drawing figures. Accordingly, those of ordinary skill in the art will recognize that various changes to and modifications of the exemplary embodiments described herein can be made without departing from the scope and spirit of the claimed invention. Also, descriptions of well-known functions and constructions are omitted for clarity and conciseness.

With reference to the drawing figures, particularly FIG. 1, a medication injection pen is shown and generally designated with the reference numeral 10. The medication injection pen 10 may be used for the administration of various medications, preferably liquid in nature, including but not limited to insulin and human growth hormone. The term “medication” is used in an illustrative and non-limiting manner to refer to any substance that may be injected into a patient for any purpose. The medication injection pen 10 is provided for administering multiple injections, the dose or volume of which may be set by the user and may vary for each injection. Exemplary embodiments of medication injection pen 10 of the present disclosure may be either disposable or reusable when the supply of medication therein has been exhausted.

With reference to FIGS. 2A and 2B, in an exemplary embodiment, the medication injection pen 10 generally includes a cap 12, a cartridge holder 14, a spinner 16, a body 18, a dose knob 20, a setback member 22, a driver member 24, a leadscrew 26, a dose stop member 28, a bi-directional click element 30, a leadscrew brake 32, and a push button 34.

The cartridge holder 14 is formed to accommodate a medication cartridge 36, which may be of any conventional design. By way of non-limiting example, the cartridge 36 may include an elastomeric septum 38 at a distal end thereof, and an open proximal end 37 which exposes a slidably engageable plunger 40. A medication is contained within the cartridge 36 between the septum 38 and the plunger 40. As will be described in more detail below, the spinner 16 is configured to engage the plunger 40 and force a distal movement thereof to expel the medication from the cartridge 36. The spinner 16 includes an aperture formed to snap fit or otherwise engage a distal end bead portion 27 (FIG. 7) of leadscrew 26 in mounting the spinner 16 onto the leadscrew 26. A standard pen needle 11 (FIG. 2C) is used to administer medication from the medication injection pen 10. The needle is a double-ended cannula 5 which is threadedly mounted onto threads 42 of the cartridge holder 14, as is well known in the art. One end of the cannula 5 is exposed for insertion into a patient, while the second end of the cannula is disposed to pierce the septum 38 of the cartridge 36. After administration of a set dose, the needle 11 may be removed, in which case, the septum 38 may be self-sealing. The cap 12 is formed to releasably mount onto the cartridge holder 14, such as with a snap in or other releasable engagement, to limit contamination of the septum 38 and the surrounding portions of the cartridge holder 14. A resilient holding arm 13 may extend from the cap 12 to provide a holding force for retaining the injection pen 10 in the user’s pocket, purse, or carrying case. One or more windows 15 may also be provided in the cartridge holder 14 to give a visual indication of the medication volume remaining in the cartridge 36.

An exploded perspective view of a pen needle 11 of an exemplary injection pen is shown in FIG. 2C. The pen needle 11 includes the cover (outer shield) 1, an inner shield 2, a needle cannula 5, and a hub 3. During manufacture, a proximal end of the needle cannula 5 is inserted into a center opening in the distal (patient) end 4 of the hub 3 until a

predetermined length of the distal (patient) end of the needle cannula 5 remains extended. The needle cannula 5 is secured by epoxy or adhesive in the distal end 4 of the hub 3. To protect users from injury and the needle cannula 5 from being damaged, the inner shield 2 covers the exposed portion of the needle cannula 5. The open proximal end of the inner shield 2 is placed over the exposed portion of the needle cannula 5. The open proximal end of the cover 1 envelops the inner shield 2, needle cannula 5, and hub 3. The distal end of the cover 1 is closed to prevent contamination and damage to the inner components of the pen needle 11, and to prevent injury to anyone who may handle it prior to use. When the user is ready to use the pen needle, the hub 3 is screwed onto threads 42 of cartridge holder 14 of the injection pen it) (FIGS. 1, 2A and 2B), and the cover 1 and shield 2 are separately removed from the hub 3/cannula 5 subassembly by a pulling action. The distal end of the inner shield 2 is closed to protect the user from an accidental needle stick by the needle cannula 5 after the cover 1 is removed. The inner shield 2 is then removed to access the needle cannula 5.

With reference to FIGS. 3A and 3B, the body 18 is generally cylindrical, and includes a cylindrical partition or wall 50 extending across the interior of the body 18 through which a channel 51 is formed comprising an aperture 52. Cylindrical wall 50 effectively divides body 18 into two compartments, a first compartment proximal to wall 50 for housing the plurality of dose setting and injecting components, as shown in FIGS. 2A and 2B, and a second compartment distal of wall 50 for housing the leadscrew brake 32 and connecting to the cartridge holder 14. The channel 51 comprises internal threads 54 threadedly engaging corresponding threads of the leadscrew 26. In an exemplary embodiment, the leadscrew 26 is provided with a non-circular cross-section, in which case, the aperture 52 is defined to allow rotational and thereby axial movement of the leadscrew 26 therethrough. A plurality of second threads 56 are provided on the interior of the body 18 in the first compartment and threadedly engaged with corresponding threads 62 provided on the dose set knob 20, as discussed further below. Body 18 preferably includes a window 57 enabling the user to view a set dose indicated on the outer surface of the dose set knob 20. As described further below, a series of angled steps or teeth 55 are provided on the interior of the second compartment of body 18, circumferentially surrounding the distal end of channel 51. Teeth 55 are provided as part of a unidirectional coupling with the leadscrew brake 32 to allow the leadscrew 26 to rotate through the channel 51 in only one direction, that which causes the leadscrew to expel medication from cartridge 36. In an exemplary embodiment, body 18 also includes a circumferential rib or groove 58 onto which the cartridge holder 14 may be mounted with a snap fit.

With reference to FIGS. 4A and 4B, a generally cylindrical dose set knob 20 with open proximal and distal ends is provided with an enlarged proximal portion or handle 60 defining a knob-like feature. Handle 60 may include a plurality of grooves 61 enabling a user to securely grip handle 60 to set a dose of medication for an injection. Dose set knob 20 includes at least one thread element 62 provided on its external surface, preferably near the distal end and threadedly engaging corresponding threads 56 on the interior of body 18. An injection dose is set by the user by rotating dose set knob 20 in a predetermined direction. Due to the threaded engagement with the body 18, rotation of the dose set knob 20 translates into axial movement of the dose set knob in the proximal direction extending away from and

out of the body **18**. Provided on the outer surface of body **18**, are a plurality of dosing indicia (not shown) indicating a set dose to be viewed through window **57** provided on body **18**.

A plurality of radially directed ridges **63** are provided circumferentially along the interior surface of dose set knob **20** adjacent to handle **60**. Ridges **63** provide part of a clicking means in conjunction with an externally directed ratchet element **82** provided on click arms **81** (FIG. 6A, 6B) of click element **30**. Ridges **63** each comprise a sloped edge and a flat face for allowing relative rotational movement between the dose set knob **20** and click element **30** in only one direction in which the click arm **81** is enabled to slide over ridges **63**, thus providing an audible and tactile signal. Additionally, the proximal edges of ridges **63** define a proximally facing surface having a plurality of teeth **64** disposed thereon. In an exemplary embodiment, teeth **64** are included as part of a clutch mechanism when engaged with corresponding teeth **74** (FIGS. 5A and 5B) disposed on setback member **22**. When pressed together during injection, teeth **64** and **74** lock together, thus preventing relative rotation between setback member **22** and dose set knob **20**, as further described below. Additionally, during dose setting, teeth **64** provided on the dose set knob **20** function as a shelf, causing axial movement of the setback member **74** together with the dose set knob **20**, as the dose set knob is rotated and moved axially out of the body **18**. Dose set knob **20** also includes a plurality of longitudinally extending keys or splines **65** provided substantially along the interior surface preferably extending from the open distal end to the enlarged proximal portion **60**. Longitudinal splines **65** engage with corresponding grooves **95** provided on the exterior of dose stop member **28** to prevent relative rotation between the dose set knob **20** and the dose stop member **28**, but to allow relative axial movement therebetween.

Setback member **22** comprises a generally cylindrical elongated member as shown in FIGS. 5A and 5B. Provided near the proximal end of setback member **22** are a plurality of ridges **73** spaced along the external surface thereof. When the exemplary injection pen **10** is assembled, ridges **73** of setback member **22** face ridges **63** provided on the internal surface of dose set knob **20**. Ridges **73** include sloped edges and flat faces for engaging an internally directed ratchet element **84** provided on flexible arm **83** of click element **30**. As similarly described above, ridges **73** enable relative rotational movement between the setback member **22** and click element **30** in only one direction in which the internally directed ratchet element **84** is enabled to slide over ridges **73** providing an audible and tactile signal. The allowed direction of relative rotation between the setback member **22** and click element **30** is in the direction opposite that enabled by similar engagement between the dose set knob **20** and the click element **30**, so that the relative rotation between dose set knob **20** and setback member **22** is bi-directional.

Click element **30** is described with reference to FIGS. 6A and 6B. As shown, click element **30** is a cylindrical tube like element comprising a plurality of radially flexible arms **81** and **83** oppositely disposed from each other. The click element **30** is preferably constructed with a longitudinal dimension similar to the length of the ridge portions **63**, **73** provided on the dose set knob **20** and setback member **22**, respectively. Flexible arm **81** includes an externally directed ratchet element **82** provided at the free end thereof facing ridges **63** provided on the interior of dose set knob **20**. Flexible arm **83**, on the other hand, includes an internally directed ratchet element **84** provided at the free end thereof facing ridges **73** provided on the exterior of setback member **22**. During dose setting, click element **30** is permitted to

rotate relative to both the setback member **22** and dose set knob **20**, but in only one direction with respect to each. In other words, during dose setting, click element **30** is rotationally locked to one of the setback member **22** or the dose set knob **20** via flexible arms **83** and **81**, respectively, depending on the direction of relative rotation for either normal setting of a dose or dialing back of the set dose. When the dose set knob **20** is rotated in the direction in which ridges **63** are enabled to slide over the externally directed ratchet element **82** and produce an audible signal, the click element **30** does not move rotationally relative to the setback member **22** since such a movement is prevented by an engagement between click arm **83** and ridges **73**. Conversely, when the dose set knob **20** is rotated in the opposite direction, the externally directed ratchet element **82** engages with one of the ridges **63** causing the click element to rotate together with the dose set knob **20**. In this case, the internally directed ratchet element **84** is now permitted to slide past ridges **73** on the setback member, thereby producing an audible signal.

The exemplary construction of click element **30** described above allows relative rotation in both directions between the setback member **22** and the dose set knob **20**. Such a click element is not restricted to the design depicted in FIGS. 6A and 6B. Any similar element(s) enabling bi-rotational movement between setback member **22** and dose set knob **20**, as described above, may be implemented in this embodiment, as would be evident to one of ordinary skill in the art.

As shown in FIG. 5A, setback member **22** includes an adapter element **71** for snap-fitting with an internal cavity of push button **34**. Push button **34** is of any conventional design, but it is preferred that the snap engagement enables the push button to freely rotate on the adapter element **71**. Alternatively, push button **34** may be unitarily formed with the adapter element **71**. Additionally, as shown in FIG. 5B, a plurality of longitudinally extending keys or splines **75** are provided along the internal cylindrical surface of setback member **22**. Splines **75** are formed to engage corresponding longitudinal grooves **85** provided on the external surface of driver member **24**, shown in FIG. 7, thus preventing relative rotation between the setback member **22** and driver **24**, while allowing relative axial movement therebetween. With reference to FIG. 7, the driver **24** includes open proximal and distal ends which provide a passage **86** for leadscrew **26**. In an exemplary embodiment, passage **86** comprises a non-circular cross-section corresponding to the non-circular cross-section of leadscrew **26**, thus preventing relative rotation therebetween. Driver **24** includes a disk **87** formed at the proximal end for snap-engaging with at least one flexible tab **97** provided on the interior surface of dose stop element **28** (FIG. 8A). With the snap engagement, the driver **24** is fixed axially relative to the dose stop element **28**, yet is able to rotate relative thereto. Driver **24** may also include one or more flexible legs **88** inwardly biased to engage leadscrew **26**. Flexible leg **88** may be provided to reduce any play between the mating cross sections of leadscrew **26** and aperture **86** to improve dose accuracy of the exemplary injection pen **10**.

With reference to FIGS. 8A and 8B, a generally cylindrical dose stop element **28** is provided for enabling last dose control so that a dose cannot be set or dialed up that is greater than the amount of medication remaining in the cartridge **36**, as further discussed below. Dose stop element **28** includes a plurality of longitudinal grooves **95** on the external surface thereof. Grooves **95** engage with corresponding splines **65** provided on the interior of dose set knob **20**, thereby preventing relative rotation therebetween, but

allowing relative axial movement. Dose stop element **28** has an open proximal end **91** and open distal end **92**, the distal end **92** preferably comprising a section of reduced diameter. Open distal end **92** defines a threaded opening with threads **93** disposed thereon for threadedly engaging corresponding threads **25** of the leadscrew **26** when assembled. Proximal end **91** defines a cavity housing setback member **22**, driver **24**, and leadscrew **26**. Flexible tabs **97** are provided adjacent to the open distal end **92**, extending into the interior of the dose stop element **28**. A recess **96** or cutout is provided in the external cylindrical wall of the dose stop element defining an area into which flexible tabs **97** are allowed to flex. During assembly, driver **24** is inserted into the open proximal end **91**, upon which disk **87** disposed near the distal end of driver **24** engages flexible tabs **97**, and causes them to flex outwardly into recess **96** until the disk **87** moves past the flexible tabs, at which time the flexible tabs **97** return to their initial positions to provide a blocking surface for the driver **24**, preventing relative axial movement therebetween.

While the above components are described as comprising specific features for engaging and interconnecting other components of an exemplary injection pen, the above components are not limited to these specific features. For instance, instead of the described mating non-circular cross-sections to prevent relative rotation between leadscrew **26** and driver **24**, one of ordinary skill in the art will appreciate that similar functionality may be provided using a spline/groove engagement for preventing relative rotation therebetween while also allowing relative axial movement. Conversely, the above described spline/groove features may be replaced with non-circular mating arrangements or other known features for preventing relative rotation while allowing relative axial movement therebetween.

With reference to FIGS. **9A** and **9B**, leadscrew brake **32** comprises a generally cylindrical housing portion **90** provided with a first diameter large enough to surround channel **51**, as shown in FIG. **9B**. Extending in the distal direction, a pair of wall portions **92** is provided defining an aperture **93** with a non-circular cross-section to mate with the non-circular cross section of leadscrew **26**. Due to the mating non-circular aperture **93**, the leadscrew **26** is prevented from rotating with respect to the leadscrew brake. Further, the leadscrew brake **32** comprises a pair of flexible ratchet arms **94** configured to engage the cylindrical ring of ratchet teeth **55** provided on the interior of the body **18** to define a unidirectional coupling therebetween. Ratchet arms **94** are configured to allow rotation of the leadscrew brake **32**, and therefore the leadscrew **26**, in only one direction with respect to the body **18**. The allowed direction is that which causes the leadscrew **26** to rotate through the threaded channel **51** in the distal direction to expel medication. During injection, the leadscrew brake **32** rotates relative to body **18**, and ratchet arms **94** ride over the slanted or ramped portion of teeth **55** to produce an audible clicking signal indicating the injection is being performed. Rotation of the leadscrew brake in the opposite direction causes the free ends of ratchet arms **94** to engage the flat faces of teeth **55**, which resist ratcheting of the ratchet arms **94** and thereby prevent relative rotation in this direction. Due to the unidirectional coupling between leadscrew brake **32** and teeth **55**, an undesired rearward movement of the leadscrew **26** is prevented.

Having described exemplary structures, features and interrelationships between particular elements of the exemplary embodiment of medication injection pen **10** herein, the intended functionality of such an exemplary medical pen device will now be described.

Following assembly of the exemplary elements as shown in FIGS. **2A**, **2B**, and as described above, to set a desired dose, the patient or user first grips and rotates the enlarged proximal end **60** of the dose set knob **20**. The dose set knob **20** is rotated a number of rotations relative to the body **18** until a desired dose is shown through the window **57** on the body **18**. Due to the threaded engagement of thread **62** on the dose set knob **20** with the internal thread **56** of the body, the dose set knob is caused to screw out of the proximal end of the body, carrying the setback member **22** along with it by substantially the same distance. The dose stop member **28** is also caused to rotate together with the dose set knob **20** due to the spline/groove engagement between spline **65** provided on the interior of the dose set knob **20** and groove **95** provided on the exterior of dose stop **28**. Rotation of the dose stop member **28** causes axial movement of the dose stop member with respect to the body **18** in the proximal direction due to the threaded engagement between threads **93** on the dose stop member and threads **25** of the leadscrew **26**. The dose stop element **28**, however, moves a shorter distance axially than the dose set knob **20** due to a difference in the pitch of the thread **25** of the leadscrew **26** and the inner thread **56** of the body **18**.

During normal dose setting for increasing a set dose, the leadscrew **26** is prevented from rotating with respect to the body **18** in the dose setting direction due to the unidirectional coupling between the leadscrew brake **32** and the teeth **55** disposed on the body **18**. Setback member **22** and driver **24**, which are rotationally fixed to each other due to spline/groove connection **75/85**, are therefore also prevented from rotating with respect to body **18** during dose setting, since the driver is rotationally fixed to the leadscrew via the mating of the non-circular cross-section of leadscrew **26** and the non-circular aperture **86** of the driver **24**. Due to the snap fit between disk **87** of the driver **24**, and flexible tabs **97** provided on the dose stop member **28**, as the dose stop member screws out of the body in the proximal direction, the driver **24** moves axially by the same distance, but does not rotate.

The setback member **22** is interconnected to the dose set knob **20** through the bi-directional click element **30**. During normal dose setting, the dose set knob **20** rotates relative to the click element **30**, and thus an audible signal is provided due to the inner grooves (**3**) of the dose set knob **20** sliding past the externally directed ratchet element **82** on flexible arm **81**. The externally directed ratchet element **82** tends to slide past ridges **63** in the dose setting direction because the internally directed ratchet element **84** of flexible arm **83** is locked with the ridges **73** provided on the setback member **22**, which is prevented from rotating in this direction due to its engagement with the driver **24** and leadscrew **26**.

If the user initially sets a dose larger than desired, the set dose can be “dialed back” or reduced by simply turning the dose set knob **20** in the opposite direction. Rotation of the dose set knob **20** in this reverse direction, which is the direction of injection, would normally cause rotation of the leadscrew **26** and thus axial movement of the leadscrew into the cartridge **36**. During injection, rotation of the leadscrew **26** is effected due to the coupling between teeth **64** on the dose set knob and teeth **74** on the setback member **22**, which is indirectly rotationally fixed to the leadscrew **26**. During dial back, however, the dose set knob **20** and setback member **22** are not coupled via teeth **64/74** and the dose set knob **20** rotates in this reverse direction relative to the setback member **22** through the click element **30**. Reverse rotation of the dose set knob **20**, during dial back now causes the internal ridges **63** on the dose set knob **20** to engage and

lock with the externally directed ratchet element **82**, forcing the click element **30** to rotate in this same direction. The internally directed ratchet element **84** is now caused to slide over ridges **63** provided on the setback member **22**, thereby producing an audible signal indicating the dose is being reduced. Ratchet element **84** tends to slide over ridges **73** in this direction since there is less friction provided between ratchet element **84** and ridges **73** than there is between the unidirectional coupling between the leadscrew brake **32** and the body **18**. In other words, the force required to dial back a set dose is not great enough to overcome the friction between the ratchet arms **94** of leadscrew brake **32** and the teeth **55** of body **18**.

Once a desired dose is set, and the user desires to inject the set dose of medication, the medical injection pen **10** is applied to the skin of the patient to insert the needle cannula **5**. The pen needle **11** is attached to the threaded portion **42** of the cartridge holder **14** prior to or after setting the desired dosage, as a matter of user preference. Once the pen needle **11** has been attached to the cartridge holder **14** and inserted into the patient, the push button **34** is depressed. The axial force applied to the push button **34** by the user causes the teeth **74** on the setback member **22** to engage with the teeth **64** on the dose set knob **20** to mesh and rotationally lock the setback member **22** with the dose set knob **20**, forming an injection coupling. The applied force causes the dose set knob **20** (due to a non self-locking threaded engagement with the body **18** via threads **56** and **62**) to rotate in the direction opposite that which occurs during normal dose setting. This rotation is now imparted to the setback member **22** and therefore the driver **24** (due to the spline/groove connection **75**, **85**). Since the driver **24** mates with the non-circular cross-section of the leadscrew **26**, the leadscrew is also caused to rotate relative to body **19**, which translates into axial movement of the leadscrew into the cartridge **36** to expel a dose (due to the threaded engagement between threads **25** on the leadscrew and threads **54** disposed on channel **51** of the body **18**). Axial movement of the leadscrew in the distal direction urges the spinner **16** against the plunger **40** to expel medication from the cartridge **32**. The injection force is greater than the frictional force in the leadscrew brake **32**, and hence the leadscrew brake allows rotation of the leadscrew **26** in this direction during injection. As the leadscrew brake **32** rotates with the leadscrew **26**, oppositely disposed ratchet arms **94** slide over the teeth **55** disposed on the interior of body **18** to produce a clicking sound as the injection is carried out.

The dose administration process described above may be repeated until the medication in the cartridge **36** is spent. Prior to expelling the last dose from the cartridge **36**, it is desired to ensure that the last dose expelled is consistent with the dose set by the user. In other words, the user should not be able to set a dose for an amount greater than the remaining volume of medication in the cartridge **36**. This last dose control is realized when threads **93** disposed on the dose stop element **2K** abut against a non-threaded portion of the leadscrew **26** at its proximal end, preventing further rotation of the dose stop member **28** on leadscrew **26**. When this occurs, the indicia on the dose set knob **20**, read through window **57**, indicate the last remaining injectable volume of medication in the cartridge **36**. Once the dose stop member **28** is prevented from rotating further, the dose set knob **20** is also prevented from further rotating in this direction for setting a larger dose, due to the spline/groove engagement **65/95** between dose set knob **20** and dose stop member **28**.

During dose setting, the dose stop member **28** changes its relative position on the leadscrew **26** based on the number of

rotations of the dose set knob **20**. Axial movement of the dose stop member **28** during dose setting is by substantially the same distance as the leadscrew **26** moves into cartridge **36** during injection. The length of axial movement of leadscrew **26**, and therefore the volume of medication to be expelled, is determined in part by the thread pitch of the leadscrew threads **25** and threads **54** of the body, which is substantially the same as the pitch of the threads **93** of the dose stop member **28**. Thus, the relative position of the dose stop member **28** on the leadscrew **26** throughout administration is indicative of the remaining dosage amount in the cartridge **36**. The dose stop member maintains its relative position on the leadscrew **26** during injection due to its spline/groove engagement **65/95** with the dose set knob **20**. During injection, the dose set knob **20**, dose stop member **28**, setback member **22**, driver **24** and leadscrew **26**, are all rotationally locked together. Since the threads **93** of the dose stop member **28** and the threads **54** of the body **18** are of substantially the same pitch, simultaneous rotation of the dose stop member **28** and leadscrew **26** results in the same axial movement. Thus, during injection, the dose stop member **28** does not move axially relative to leadscrew **26**, and therefore maintains its relative position with respect to the leadscrew as determined during the dose setting procedure. After administration of the last dose, if the injection pen **10** is reusable, the cartridge can be replaced, whereas, if the pen is disposable, the entire pen **10** may be disposed of.

As will be appreciated by those skilled in the art, various modifications can be made to the above exemplary embodiments without substantially altering the functionality of the injection pen **10**. For example, such modifications may be made to ease the assembly of the various components, reduce the complexity of manufacturing, reduce the number of elements, or provide some additional improved functionality. Some such exemplary modifications are described below.

In one alternative embodiment, teeth **64** on the dose set knob **20**, described above as part of an injection coupling with corresponding teeth **74** (FIGS. **5A** and **5B**) disposed on setback member **22**, can generate dose setting click signals in the absence of click element **30**. A spring element or wave washer with similar functionality may be provided to bias the teeth **74** of setback member **22** toward the corresponding teeth **64** provided on the dose set knob **20**, so that they are in constant meshed engagement. The spring force, however, is easily overcome by relative rotation between the dose set knob **20** and setback member **22**, which causes the corresponding teeth **64/74** to slip over each other producing an audible and tactile signal.

In another exemplary embodiment, an alternate injection coupling is provided between a modified dose set knob **20** (teeth **64** removed) and a modified setback member **22'**, shown in FIG. **10**. In this embodiment, the injection coupling described above with respect to teeth **64** on the dose set knob **20** and corresponding teeth **74** on the setback member **22**, is replaced by an extended surface **101** provided near the proximal end of the setback member **22'**, the extended surface **101** being defined by a larger diameter with respect to ridges **73**. Click element **30** includes a first surface **102** positioned co-axially on and surrounding the extended surface **101**. During the dose setting operation, click element **30** is positioned on setback member **22'**, such that click arms **81** and **83** are free to flex and slide past ridges **73** and **63**, respectively. In this embodiment, the dose setting and dial back mechanism is unchanged. During injection, however, upon the user applying an injection force to push button **34**, the setback member **22'** is pushed into the dose set knob **20**

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and into click element 30. As the setback member 22' moves axially toward click element 30, the extended surface 101 is moved into engagement with click arm 83, as shown in FIG. 10B. In this position, click arm 83 is prevented from flexing radially inward to slide past grooves 63 in the dose set knob, thus locking click element 30 to dose set knob 20. Relative rotation of the dose set knob 20 with respect to the setback member 22' in this direction during dose setting would have enabled the ratchet arm 83 to ride over ridges 63 to reduce a set dose. During injection, however, ratchet arm 83 is now prevented from flexing away from ridges 63, and thus prevented from sliding over ridges 63, by the blocking engagement of extended surface 101. Accordingly, the setback member 22' is now rotationally locked to dose set knob 20 via non-sliding engagement with ratchet arm 83, thus enabling injection of a set dose, as described above.

In another embodiment, the exemplary injection pen 10 is modified to facilitate the manufacture of injection pens providing different dosing needs. For example, an injection pen for administering a first medication may desire finer dosing intervals for more precise dosage control than that of another medication. To utilize the same dose setting and injection functionality of the exemplary injection pen described above, it is desired to be able to provide a plurality of pens meeting the various dosing needs with greater compatibility, so as to reduce the complexity of manufacturing multiple such pens.

One such modification is made to the embodiment illustrated in FIG. 9B to switch the ratchet arms 94 provided on the leadscrew brake 32 with the ratchet teeth 55 provided on body 18, as shown in FIG. 11A. As shown, the body 18' now includes ratchet arms 111 and the leadscrew brake 32' now includes teeth 112. Engagement between ratchet arms 111 and teeth 112 serves to provide similar unidirectional functionality as described in the previous embodiment. Leadscrew brake 32' in this alternative embodiment facilitates a change in a desired injection click interval necessitated by a desired change in a dosing interval. For example, the injection clicks realized by relative rotation of the leadscrew brake 32' preferably correspond to a dose increment, and are related to the spacing of the teeth 112. If the dose increment is changed to have a greater or smaller interval, a leadscrew brake with a corresponding spacing of teeth 112 is assembled in the injection pen as shown, as opposed to providing a new body 18 with the desired spacing or teeth 55, as in the earlier embodiment. The smaller leadscrew brake 32 is easier and less costly to manufacture than the body 18, and hence it is advantageous to replace leadscrew brake 32 in the modified injection pen as opposed to replacing the body 18.

A further modification, shown in FIGS. 11B-11F, enables an easier change of the thread pitch of the leadscrew if desired to increase or decrease a dose rate. For example, the threads 25 of the leadscrew 26 may be modified to include a larger pitch, so that the same number of rotations of the leadscrew results in greater axial movement of the leadscrew into cartridge 36 and therefore a larger dose volume. In the previous embodiment, if the threads 25 of the leadscrew 26 are modified, the threads 54 of the body are also modified accordingly. The additional modification shown in FIG. 11B provides an insert 114 which replaces the features of the partitioning wall 50 and channel 51 with threads 54 disposed thereon of the exemplary embodiment (see FIG. 3A). Insert 114 is a nut-like element with ratchet arms 115 disposed thereon. Insert 114 comprises a wall 118 with an aperture 119 therethrough. Aperture 119 is defined by a cylindrical channel 116 with threads 117 disposed on the interior

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thereof. Body 18" now includes a shelf or ledge 121 forming a contact surface engaging with a proximal surface of insert 114 to determine axial placement of the insert 114 into body 18". Shelf 121 comprises at least one protrusion member 122 configured to engage a corresponding recess 120 on the proximal face of insert 114. Engagement between protrusion 122 and recess 120 prohibits relative rotational movement between insert 114 and body 18". Alternatively, any similar key/groove type structure may be provided to limit relative rotational movement between insert 114 and body 18".

Insert 114 may also be provided with an additional molded spring feature 124 to maintain the positioning of insert 114 against shelf 121 in body 18". Molded spring feature 124 also presses against cartridge 36, as shown in FIG. 11F, to prevent the cartridge from moving when the needle 5 is inserted into the cartridge septum 38 prior to injection. This feature provides greater accuracy in dose injection and prevents undesired wasting of medication. In prior art injection pens, the cartridge may be allowed to move a slight distance in the proximal direction during this operation, resulting a small waste or "drool" of the medication.

In another exemplary embodiment, an end of injection click or signal is provided by a modified dose set knob 20' including a radially flexible leg 128 near the distal end of dose set knob 20' extending in the distal direction. Flexible leg 128 interacts with an angled protrusion 130, shown in FIG. 12B, disposed on a proximal surface of partitioning wall 50 of the body 18. Angled protrusion 130 is preferably fixed to partitioning wall 50 at only one end, which is the end spaced farther away from the internal surface of body 18. At a zero dose position, when the dose set knob 20' abuts partitioning wall 50, flexible leg 128 is positioned near protrusion 130, but not in touching engagement. Upon setting of a desired dose, as the dose set knob 20' is rotated, flexible leg 128 moves between the angled protrusion 130 and an internal surface of body 18, as shown in FIG. 12C. Since the angled protrusion 130 is not fixed to the partitioning wall 50 at the end closest to the internal surface of the body 18, the angled protrusion flexes radially to allow passage of the flexible leg therebetween and reduce the friction for initially overcoming the protrusion during dose setting. Once flexible leg 128 passes behind protrusion 130, continued rotation of the dose set knob 20' will result in axial movement of the dose set knob away from partitioning wall 50 so that the flexible leg 128 no longer interacts with protrusion 130. Normal setting of the dose is now performed.

As the set dose is injected, dose set knob 20' screws back into body 18 and moves toward partitioning wall 50. As the injection is nearing its end, flexible leg 128 once again engages protrusion 130 as shown in FIG. 12E. This time, as flexible leg 128 abuts against protrusion 130, it is not allowed to pass between the protrusion 130 and the internal surface of body 18. Now, the flexible leg 128 is caused to flex radially inward to slide past protrusion 130 until it moves past the end of protrusion 130, at which time flexible leg 128 snaps against the internal surface of body 18 providing an audible and tactile signal. At this point, the set dose is completely delivered and the injection pen is at a zero dose position.

In one embodiment, an end of dose click may be provided as a distinct signal distinguishable from the injection clicks provided by the leadscrew brake 32 as discussed above with respect to FIG. 9. In another embodiment, however, the injection clicks are muted, and a user senses only the end of

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injection click provided between the flexible leg **128** and protrusion **130**. One way to mute the injection clicks is to replace ratchet teeth **55** provided on the body **18** with a rubber like ring or brake **134**, as shown in FIG. **13**. During injection, the leadscrew brake **32** still rotates with respect to body **18**, but in this embodiment, ratchet arms **94** slide along the surface of the rubber brake **134** without providing an audible or tactile signal. Rubber brake **134** is fixed to the body **18** using an adhesive or other structure, so that it does not rotate relative to the body **18**, and therefore is still capable of functioning as a unidirectional coupling with leadscrew brake **32**. Ratchet arms **94** of the leadscrew brake **32** are preferably beveled or otherwise configured to grip the rubber brake **134** to prevent relative rotation therebetween, similar to the embodiment discussed in FIG. **9B**. Additionally, one of ordinary skill in the art will appreciate that rubber brake **134** may be modified as similarly discussed in FIGS. **11A** and **11B**.

In another exemplary embodiment, an element or elements are added to improve the mechanical efficiency of an exemplary injection pen **10**, by eliminating or reducing the friction between elements rotating relative to each other or those moving axially with respect to each other. One particular engagement with undesirable friction is between the push button **34** and the adapter element **71** provided on the setback member. During dose setting and injection, push button **34** preferably rotates freely on adapter element **71**. In an exemplary embodiment, as partly shown in FIG. **5A**, adapter element **71** includes a point **77** provided at the center of the axis of rotation of the setback element **22**. This point **77** contacts push button **34** near its center of rotation. Providing such a contact surface between these elements at or near the center of rotation reduces frictional torque between these elements during relative rotation, and thereby increases efficiency. To further reduce the friction between setback member **22** and push button **34**, one embodiment includes at least one rolling ball (i.e. ball bearing) **140** situated between an internal surface of the push button **34** and a surface of the adapter element **71**, as shown in FIG. **14A**. Rolling balls **140** function to translate sliding friction between engaging elements into a reduced rolling friction. In another embodiment, shown in FIG. **14B**, a pair of magnets **142a** and **142b** with the same polarity are provided on adjacent contact surfaces facing each other. For instance, a first magnet **142a** is provided on the interior of push button **34**, whereas the second magnet **142b** is provided on a contact surface of adapter element **71** facing the first magnet. Due to the same polarity between magnets **142a** and **142b**, the resulting repulsion force reduces the contact force between these two surfaces, thus reducing friction therebetween without affecting the push force required for injecting medication. One of ordinary skill in the art will appreciate that the above methods may also be implemented in combination. Further, such methods may be implemented between any two components with a linear or rotational contact surface, to further improve mechanical efficiency.

The exemplary embodiments described above may be provided as a reusable or disposable pen. In a disposable implementation, cartridge holder **14** and body **18** are preferably irreversibly assembled. In one embodiment, as described with respect to FIG. **3A**, a circumferential rib provided on the cartridge holder **14** snaps into engagement with a groove **58** on body **18**. In another embodiment, shown in FIG. **15A**, threaded insert **114** may include at least one tab **125** for snap-fitting with a recess **126** provided on cartridge holder **114**. Since threaded insert **114**, as discussed with respect to FIGS. **11B** and **11C**, is fixed both axially and

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rotationally to body **18**, snap-engagement of the cartridge holder **14** to threaded insert **114** prevents relative rotation between the cartridge holder and the body.

In a preferred embodiment shown in FIG. **15B**, cartridge holder **14** and body **18** comprise a set of threads **151** and **152** which provide a secure threaded coupling between the cartridge holder **14** and body **18**. Additionally, one of the cartridge holder and the body comprises a snap **154** and the other comprise a recess **156** for engaging snap **154**. The snap/recess engagement is preferably a one-way radial snap. Thus, once the body **18** and the cartridge holder **14** are screwed together, the snap **154** moves into engagement with recess **156** until they snap together providing a secure, irreversible connection, with minimal or no play between the cartridge holder **14** and body **18** thereby increasing accuracy of the dose injection and reducing/eliminating unnecessary waste of medication.

In view of the above description, another exemplary embodiment comprising similar components and functionality is shown in FIGS. **16A** and **16B**. The components shown in FIGS. **16A** and **16B** have similar functionality to those described above, unless noted otherwise, and therefore their detailed description is omitted herein. In this embodiment, body **218** is similar to the body **18** shown in FIGS. **11B** and **11D**. A first compartment defined by the interior of body **218**, proximal to wall **250**, houses a dose set knob **220**, a setback member **222**, a dose stop member **228**, a driver **224**, and a leadscrew **226**. The second compartment defined by the interior of body **218**, distal to wall **250**, houses a threaded drive insert **233** and a distal end **225** of driver **224**. Wall **250** is provided with an aperture sized to fit the main cylindrical body of driver **224**, but not the enlarged distal end **225**, as shown in FIG. **16B**, thus axially fixing the driver **224** to the body **218**.

In this embodiment, the leadscrew **226** has a circular cross-section, and is rotatably fixed to driver **224** via a key/groove engagement as shown in FIG. **17**. A proximal end of leadscrew **226** includes keys **217** engaging in longitudinal grooves **223** provided on the interior of driver **224**. Via this key/groove engagement, the leadscrew **226** is rotationally fixed to the driver **224** but is allowed to move axially relative thereto. Driver **224** comprises longitudinal grooves **285** engaging internal keys or splines **275** provided on the interior of setback member **222** to rotationally lock the driver **224** thereto. Driver **224** now includes an enlarged distal end **225** provided with a ring of teeth **255** circumferentially disposed thereon and functioning similarly to the toothed leadscrew brake **32'** in FIGS. **11A** and **11B**. Distal end **225** comprises part of a unidirectional coupling along with the threaded insert **233**, as similarly discussed above with respect to FIGS. **9B** and **11B**. Threaded insert **233** comprises an aperture with threads disposed thereon, which are threadedly coupled to corresponding threads on leadscrew **226**, similar to insert **114** of FIG. **11C**.

In this embodiment, last dose control is provided by a modified dose stop member **228**, as shown in FIG. **18**. Dose stop member **228** comprises a ring link structure provided with a series of threads **290** disposed on the exterior surface thereof and threadedly engaged to threads **291** disposed on the dose set knob **220**. Dose stop member **228** is rotationally fixed to setback member **222** via corresponding ridges **272** provided on the interior surface of dose stop member **228**, which mesh with similar ridges **273** disposed on the setback member, as shown. In this embodiment, as the dose set knob **220** is rotated to set a desired dose or decrease a too-large dose, dose stop member **228** screws into threads **291** disposed on the dose set knob by an amount related to the set

dose. During injection, the dose stop member **228** maintains its relative position with respect to threads **291**, since the setback member **228** is rotationally fixed to the dose set knob **220**. Therefore, dose stop member **228** and dose set knob **220** rotate together and there is no relative movement therebetween. Once the dose stop member **228** screws into the end thread of the threads **291**, it is prevented from rotating further, and thus further rotation of the dose set knob to set a larger dose is also prevented. Such an occurrence indicates a Final dose of medication remaining in the cartridge.

To set a desired dose for injection the user rotates the dose set knob **220**. Audible clicking of the set dose is provided by slipping of teeth **264** on dose set knob **220** with teeth **274** on setback member **222**, as similarly described in the previous embodiment above. Teeth **264** and **274** are held in meshed engagement by a spring element **233** provided within push button **234**. Similar to the previous embodiment, when the user presses push button **234** to inject a dose, the setback member **222** is rotationally locked to the dose set knob **220** via engagement between the teeth **264** and **274**. Setback member **222** now rotates with dose set knob **220**, as the dose set knob screws back into body **218**. Rotation of the setback member **222** translates to driver **224** which rotates the leadscrew **226**. The leadscrew **224** rotates through the fixed threaded drive insert **233** and into the cartridge to expel a dose. As the driver **225** rotates in this direction, the distal ring of teeth **255** provides the injection clicking as teeth **255** slip past ratchet arms disposed on threaded drive insert **233**.

In another embodiment, last dose control is similarly provided with a modified dose stop element **328**, as shown in FIG. **19A**. Dose stop element **328** is a half-nut like member with a series of threads disposed on the internal surface thereof, threadedly engaging threads **332** provided on threaded setback member **322**. Dose set knob **320** comprises two longitudinally extending ribs or splines **330**, circumferentially spaced from each other by a distance substantially the same as the length of the dose stop element **328**. Splines **330** engage corresponding edges of dose stop element **328** to rotationally lock the dose stop element to the dose set knob **320**. During setting of a dose, dose stop member **328** screws onto threads **332** of setback member **322**, its relative position indicated the remaining volume of medication in the cartridge. When the dose stop member **328** reaches an end of thread **332** or a fixed stop on either the dose set knob **320** or setback member **322**, dose stop element **328** is prevented from rotating further and thus limiting the dose to that remaining in the cartridge.

Yet another embodiment, using a similar principle of operation, is shown in FIG. **19B**. In this embodiment, dose stop element **428** is threaded along its outer surface with threads **427**. The inner surface of the dose set knob **420** is provided with at least one thread disposed thereon with a length sufficient to maintain constant engagement with threads **427** of dose stop member **428**. Setback member **422** comprises two longitudinally extending ribs or splines **430**, circumferentially spaced from each other by a distance substantially the same as the length of the dose stop element **428**. Splines **430** engage corresponding edges of dose stop element **428** to rotationally lock the dose stop element to the setback member **422**. The outer surface of the setback member **422** in this embodiment is provided with a substantially smooth surface to enable axial movement of dose stop element **428** thereon. In this embodiment, the last dose volume is that indicated when dose stop element **428** is prevented from moving any farther axially with respect to setback member **422**. Axial movement of dose stop element

428 is prevented when a first edge of element **428** abuts a fixed stop in the dose set knob **420** or on the setback member **422**.

In view of the above description, yet another exemplary embodiment of an injection pen comprising similar functionality is shown in FIG. **20**. As shown in the cross-sectional view, an exemplary injection pen in this embodiment comprises a main body **518**, a dose set knob **520**, a setback member **522**, a driver **524**, a leadscrew **526**, a dose stop member **528**, and an insert **530**. The body **518** is modified as shown in FIG. **21**. As shown, at least one ratchet arm **555**, attached at one end of a sidewall of the body **18** distal to the partition wall **550**, is internally directed and preferably provided with series of ridges or teeth **557** at the free end thereof. Teeth **557** engage with teeth **595** disposed on the outer surface of insert **530**, as shown in FIG. **22**. Teeth **557** are forced into engagement with teeth **595** on the insert **530** when a cartridge holder is attached to body **18**, due to the cartridge holder engaging protrusion **559** provided on the outer surface of ratchet arm **555**. When the cartridge holder is attached to the body **518**, the insert **530** is prevented from rotating in either direction due to the forced toothed engagement. When the cartridge holder is removed, such as to re-use the injection pen, the ratchet arms **555** are free to ratchet and enable relative rotation between the insert **530** and the body **518**, to reload the leadscrew for subsequent use of the injection pen. The insert **530** comprises an aperture **531** with a non-circular cross-section for mating a similar non-circular cross-section of the leadscrew, to prevent relative rotation therebetween. A plurality of teeth **556** are provided circumferentially along an internal surface of the body **518** proximal to the partitioning wall **550**. Teeth **556** serve to engage a ratchet element **586** provided near a distal end of driver **524**, as shown in FIG. **23**, described further below.

As shown in FIG. **23**, driver **524** comprises an elongated cylindrical member with open distal and proximal ends for allowing passage of the leadscrew **526** therethrough. Driver **524** includes a plurality of splines **583** provided near the proximal end for engaging corresponding grooves on the interior of setback member **522** for rotationally coupling the driver **524** and setback member **522** together. A pair of protrusions **585** is provided near the distal end of driver **524** for snap-engaging with the body **518** behind partitioning wall **550**. This snap-engagement prohibits relative axial movement between the driver **524** and the body **518** while allowing relative rotational movement therebetween. Driver **524** includes at least one thread element **582** provided on the interior surface for threadedly engaging with a corresponding thread of the leadscrew **526**. As discussed further below, it is this thread engagement that forces the leadscrew **526** to move axially in the distal direction to inject a set dose.

As shown in FIG. **24**, the dose set knob **520** is an elongated cylindrical member provided with an outer thread **562** threadedly engaging an internal thread of the dose set knob, similar to the above embodiments. In this embodiment, the dose set knob **520** comprises at least one ratchet arm **564** provided near the distal end thereof, for engaging a plurality of ridges **573** provided on the outer surface of the setback member **522**, as shown in FIG. **25**. The ratchet arm **564** includes a rounded protrusion **565** for enabling slipping of the ratchet element in both directions over ridges **573** provided on setback member **522**, to provide audible click signals during both normal dose setting and dial-back. Dose set knob **520** also includes a plurality of teeth **563** provided circumferentially along an internal surface of the dose set knob, as shown. During dose setting, teeth **563** are situated

in the recess 576 on the outer surface of the setback member, as shown in FIG. 25. The teeth 563, in this embodiment, serve as an injection coupling to rotationally lock the dose set knob 520 to the setback member 522. In another embodiment, the injection coupling may be between a set of engaging teeth provided on the setback member 522 and the dose set knob 520, as similarly discussed with respect to the first embodiment shown in FIGS. 4A and 5A (teeth 64 and 74). Dose set knob 520 comprises a plurality of threads 591 provided along the internal surface thereof for threadedly engaging with threads 590 of the dose stop member 528.

Having described exemplary structures, features and interrelationships between the particular elements of FIGS. 20-25, the intended functionality of such an exemplary injection pen will now be described. Discussion of particular elements and features similar to the above embodiments, have been omitted herein.

To set a desired dose for injection, a user rotates the dose set knob 520 in a first direction. Relative rotation between the dose set knob 520 and the setback member 522 produces a series of dose-setting clicks due to the engagement between ridges 573 and ratchet elements 564, 565. If a too-large dose is set by the user, the user can rotate the dose set knob 520 in a second, opposite direction to dial back the set dose. During dose setting, the dose set knob is free to rotate in both the first and second direction with respect to the setback member 522. To inject a set dose, the user presses a push button 34, which pushes the setback member 522 in the distal direction and causes ridges 573 on the setback member to engage teeth 563 provided on the dose set knob. The dose set knob 520 and the setback member 522 are now rotationally fixed with respect to each other. Now, as the dose set knob rotates back into the body 518, the setback member 522 is also caused to rotate which forces driver 524 to rotate therewith. The leadscrew is prevented from rotating with respect to body 518 due to its mating engagement with the insert 530, which is rotationally fixed to the body 518 when the cartridge holder is attached to the body 518, as described above. Since the leadscrew 526 is rotationally fixed, relative rotation between the driver 524 and the leadscrew 526 causes the leadscrew 526 to move axially into the cartridge to inject a set dose, due to its threaded engagement with threads 582 provided on the driver 524. During injection, as the driver 524 rotates relative to body 518, ratchet arms 586 provide an injection click signal as they ride over teeth 556 provided on the interior of body 518. In this embodiment, last dose control is performed similarly to that described above with respect to FIG. 18, to prevent a user from setting a dose larger than a remaining volume of medication remaining in the cartridge.

While the present invention has been shown and described with reference to particular illustrative embodiments, it is not to be restricted by the exemplary embodiments but only by the appended claims and their equivalents. It is to be appreciated that those skilled in the art can change or modify the exemplary embodiments without departing from the scope and spirit of the present invention.

What is claimed is:

1. A medication injection pen comprising:
 - a housing;
 - a dose set knob comprising at least one internal thread and being rotatable with respect to said housing to set a desired injection dose;
 - a leadscrew provided with a thread element and advanceable in a first axial direction, said first axial direction being that which expels a medication from a cartridge;
 - a driver rotatable in a first rotation direction to rotate said leadscrew and advance said leadscrew in said first axial direction;
 - a setback member rotationally fixed to said driver for preventing relative rotation therebetween; and
 - a dose stop member rotationally fixed to said setback member and comprising an external thread in threaded engagement with said at least one internal thread of said dose set knob, said dose stop member being a unitary member axially movable relative to said dose set knob when said dose set knob is rotated relative to said setback member,
 - wherein axial movement of said dose stop member limits setting of the desired injection dose that is greater than an injectable volume of medication remaining in the cartridge.
2. The medication injection pen according to claim 1, wherein said dose stop member is rotationally coupled to the setback member between a pair of longitudinally extending ribs provided on said setback member.
3. The medication injection pen according to claim 2, wherein said dose stop member comprises a partial nut situated on said setback member between said longitudinally extending ribs.
4. The medication injection pen according to claim 3, wherein the axial movement of said dose stop member is limited when a first edge of the dose stop member abuts a fixed stop on said dose set knob or on said setback member.
5. The medication injection pen according to claim 2, wherein the axial movement of said dose stop member is limited when a first edge of the dose stop member abuts a fixed stop on said dose set knob or on said setback member.
6. The medication injection pen according to claim 1, wherein said dose stop member is rotationally coupled to the setback member via engagement between corresponding ridges provided on an internal surface of said dose stop member and an external surface of said setback member.
7. The medication injection pen according to claim 6, wherein said dose stop member comprises a ring link structure situated on said setback member.
8. The medication injection pen according to claim 7, wherein the axial movement of said dose stop member is limited when a first edge of the dose stop member abuts a fixed stop on said dose set knob or on said setback member.
9. The medication injection pen according to claim 6, wherein the axial movement of said dose stop member is limited when a first edge of the dose stop member abuts a fixed stop on said dose set knob or on said setback member.
10. The medication injection pen according to claim 1, wherein the axial movement of said dose stop member is limited when a first edge of the dose stop member abuts a fixed stop on said dose set knob or on said setback member.

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