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**Plumptre**

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(54) **DRUG DELIVERY DOSE SETTING MECHANISM WITH VARIABLE MAXIMUM DOSE**

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(51) **Int. Cl.**
***A61M 5/00*** (2006.01)
***A61M 5/315*** (2006.01)

(52) **U.S. Cl.**
CPC ... ***A61M 5/31536*** (2013.01); *A61M 2005/3154* (2013.01)

(58) **Field of Classification Search**
CPC .............. A61M 5/31; A61M 5/31536; A61M 2005/3154; A61M 5/31533; A61M 5/31535; A61M 5/3148; A61M 5/31528; A61M 5/31565; A61M 5/31593; A61M 5/31525
USPC .................................. 604/207–211, 187, 136
See application file for complete search history.

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*Assistant Examiner* — Bradley G Thomas, Jr.
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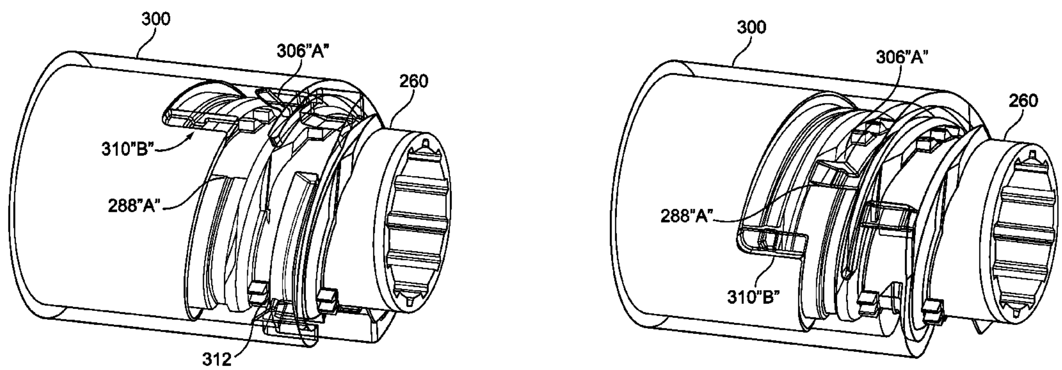
(57) **ABSTRACT**

A method and system for proving a drug delivery device having a variable dose. The drug delivery device comprising a first tubular member and a second tubular member rotatably coupled to the first tubular member. A maximum stop component is operatively coupled to the first and second tubular member such that the maximum stop component is movable from a first position to a second position. The first position defines a first maximum dose that may be set by a user of said drug delivery device and the second position defines a second maximum dose that may be set by the user of said drug delivery device.

**12 Claims, 19 Drawing Sheets**



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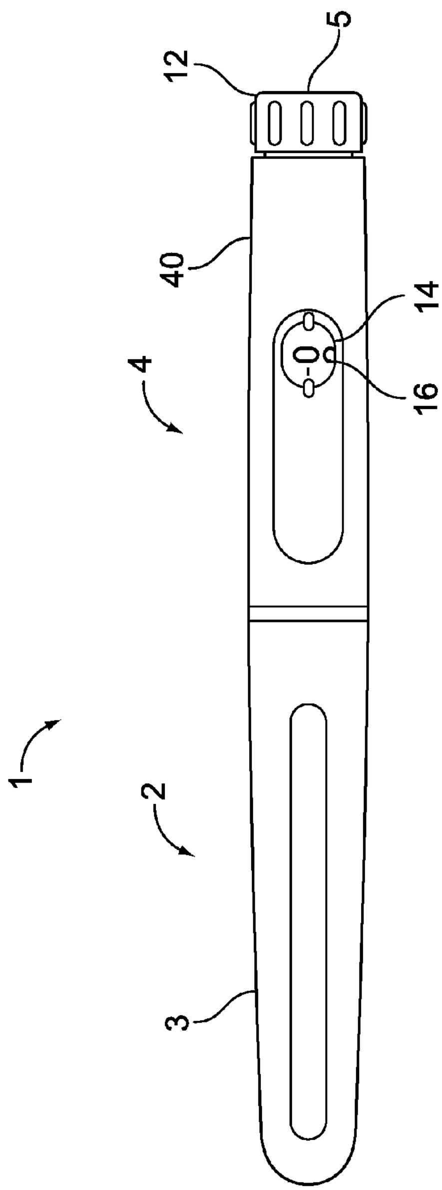
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FIG. 1

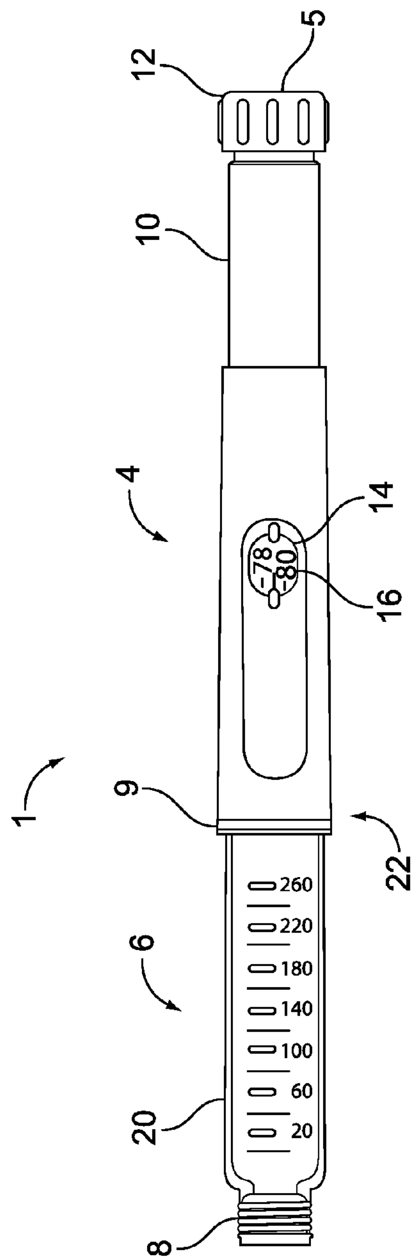
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FIG. 2

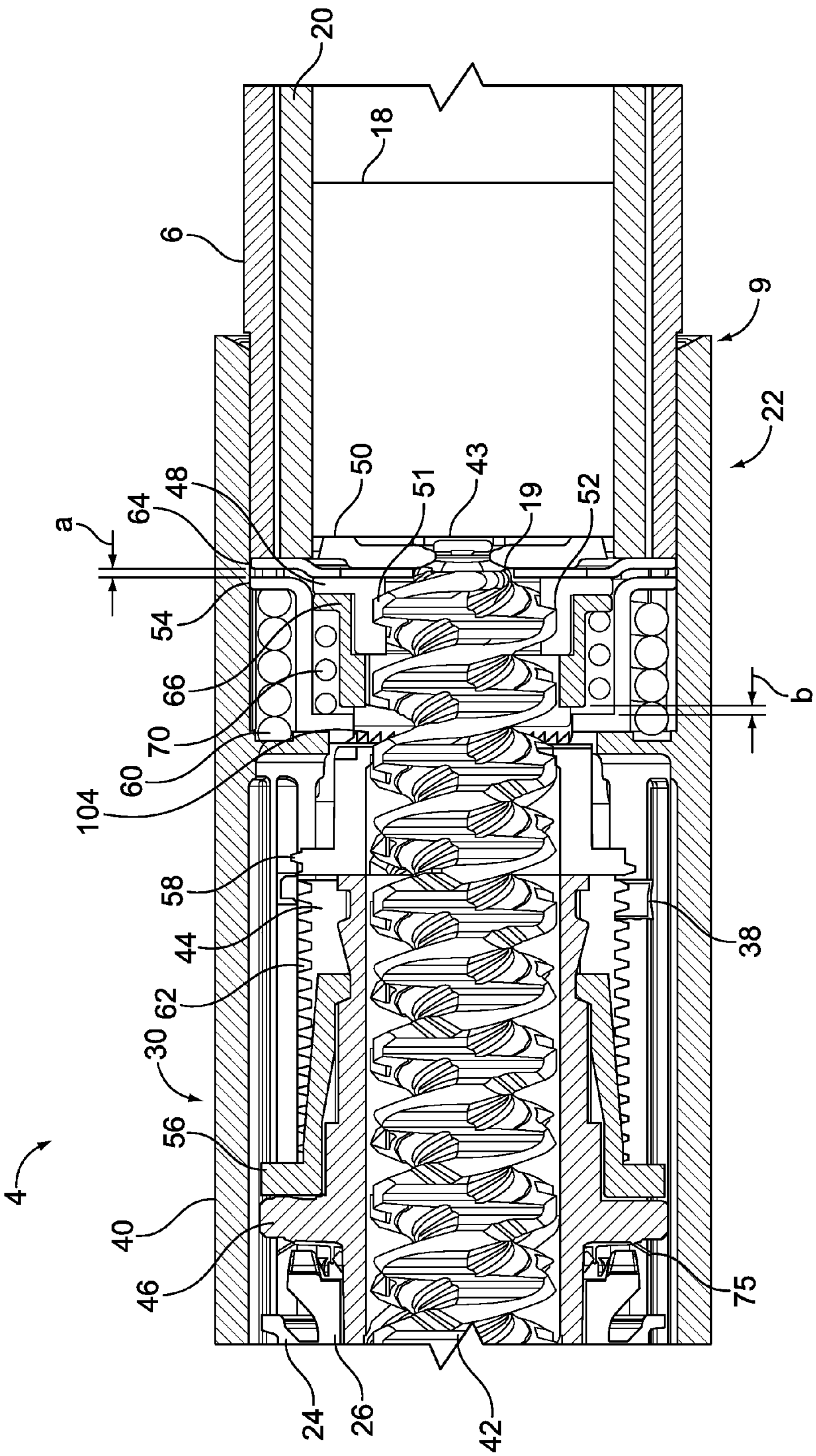
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FIG. 3

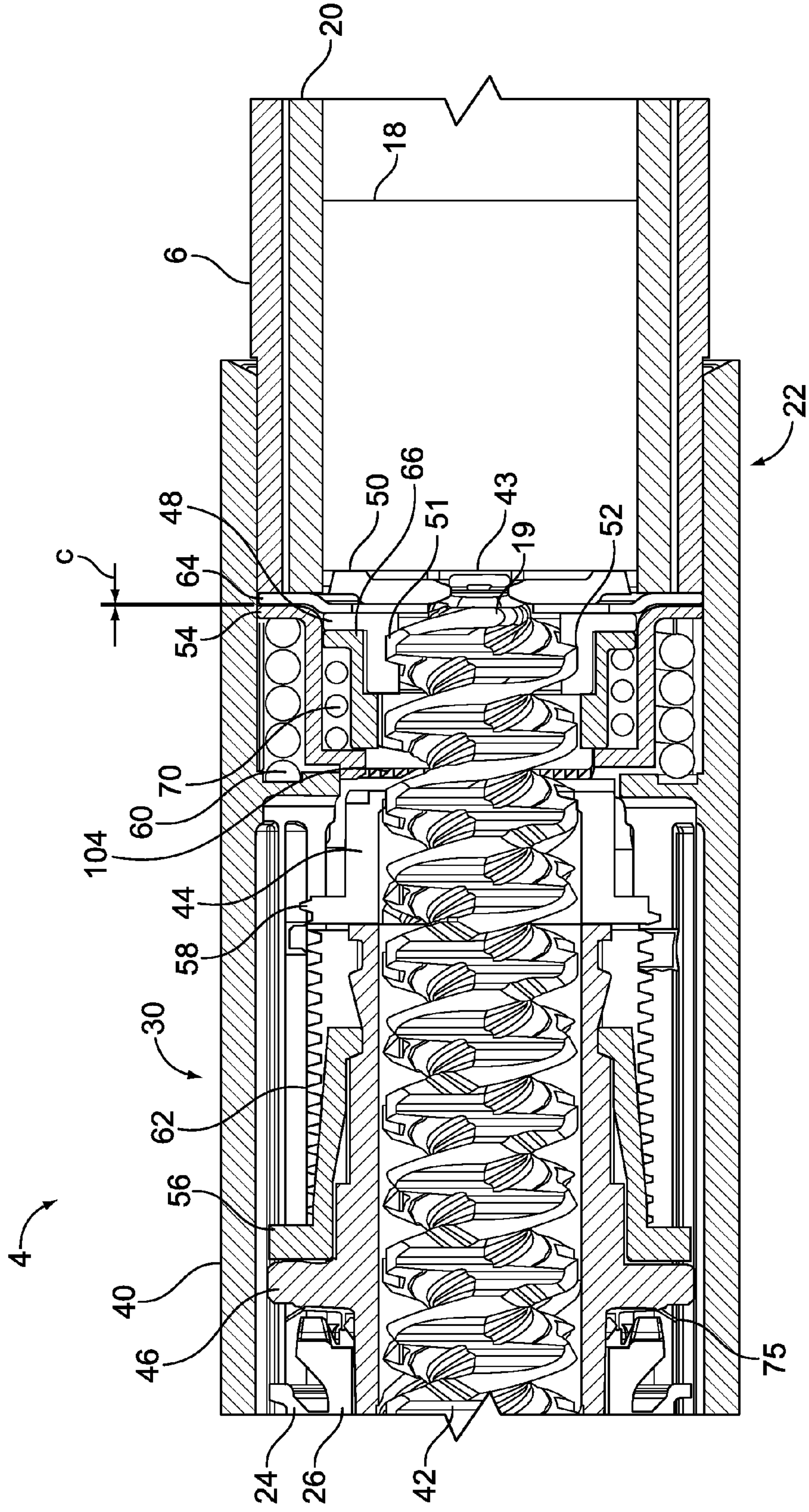
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FIG. 4

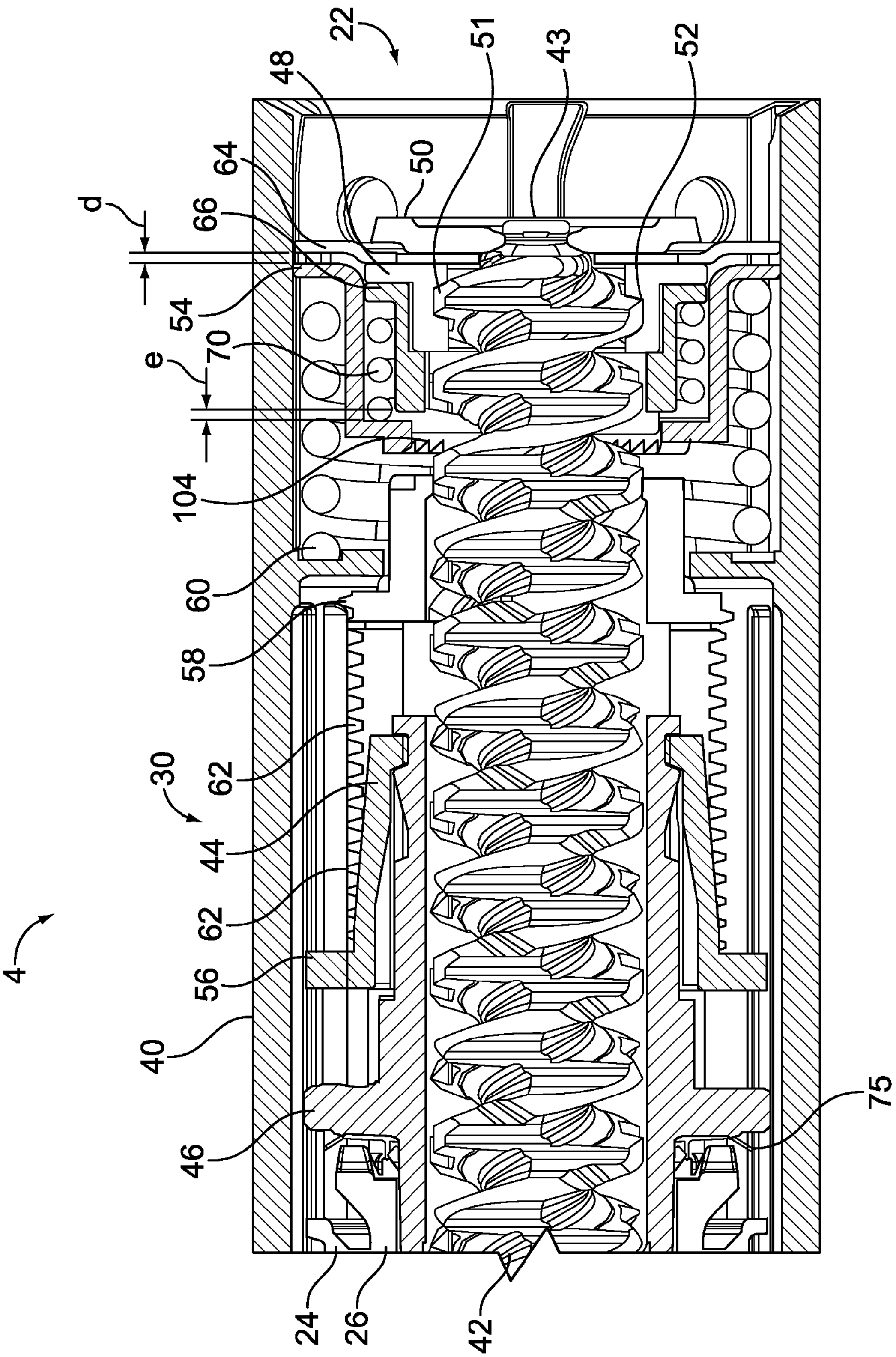
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FIG. 5

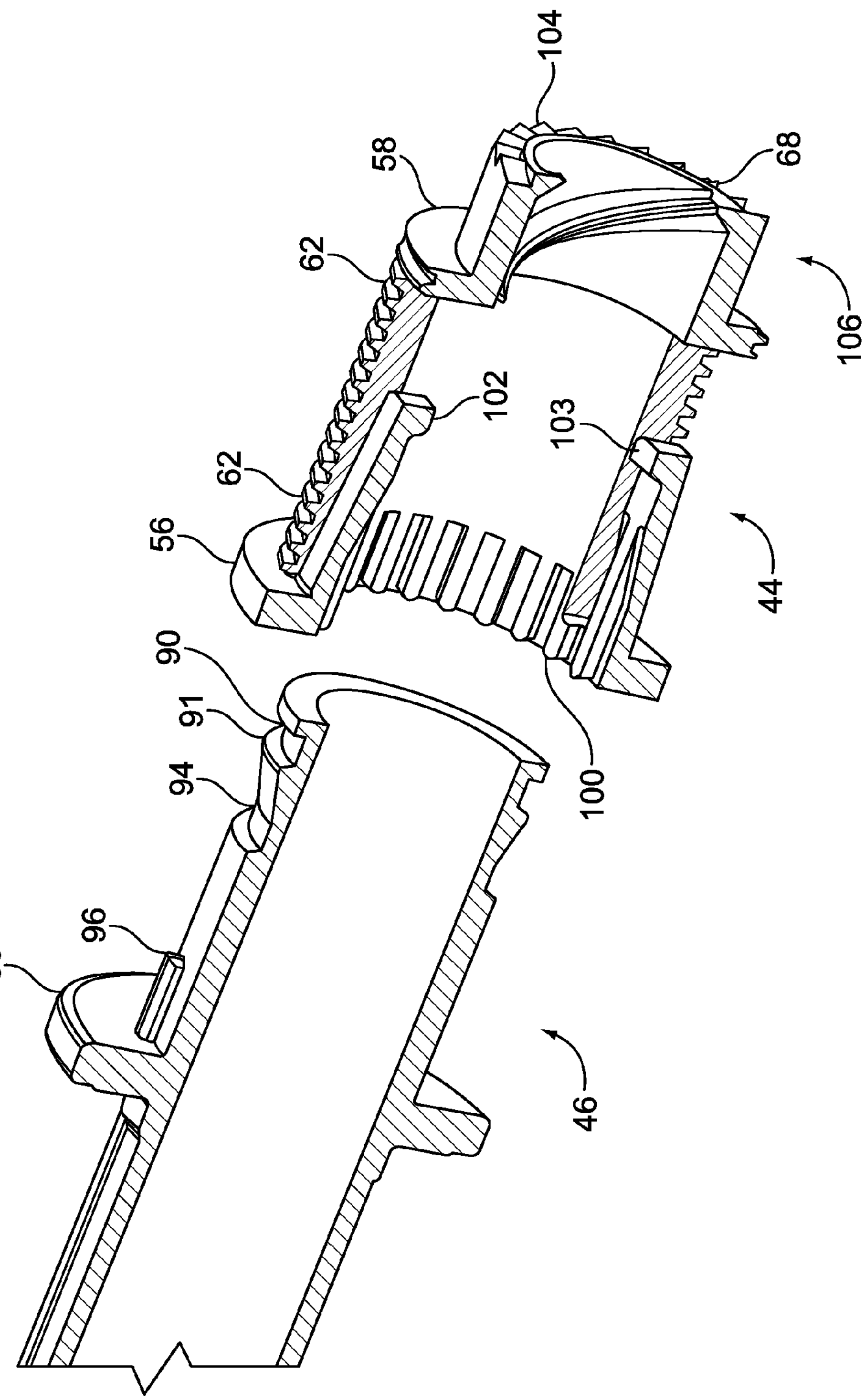



FIG. 6

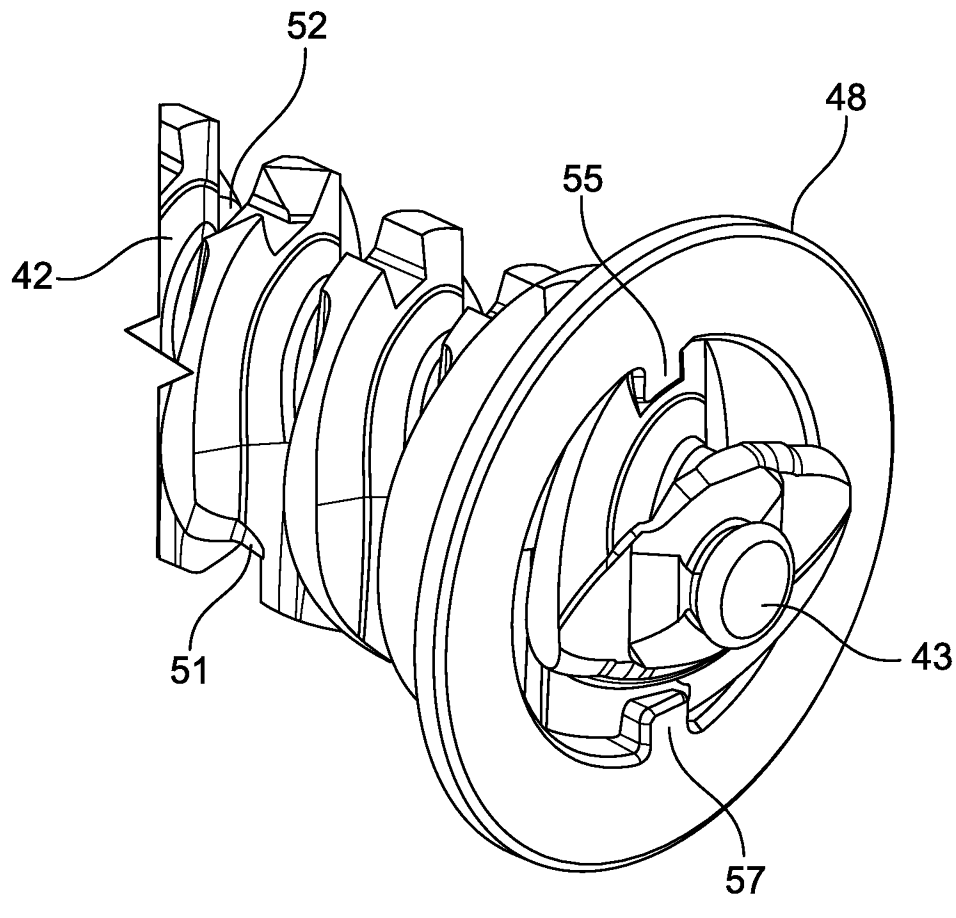



FIG. 7

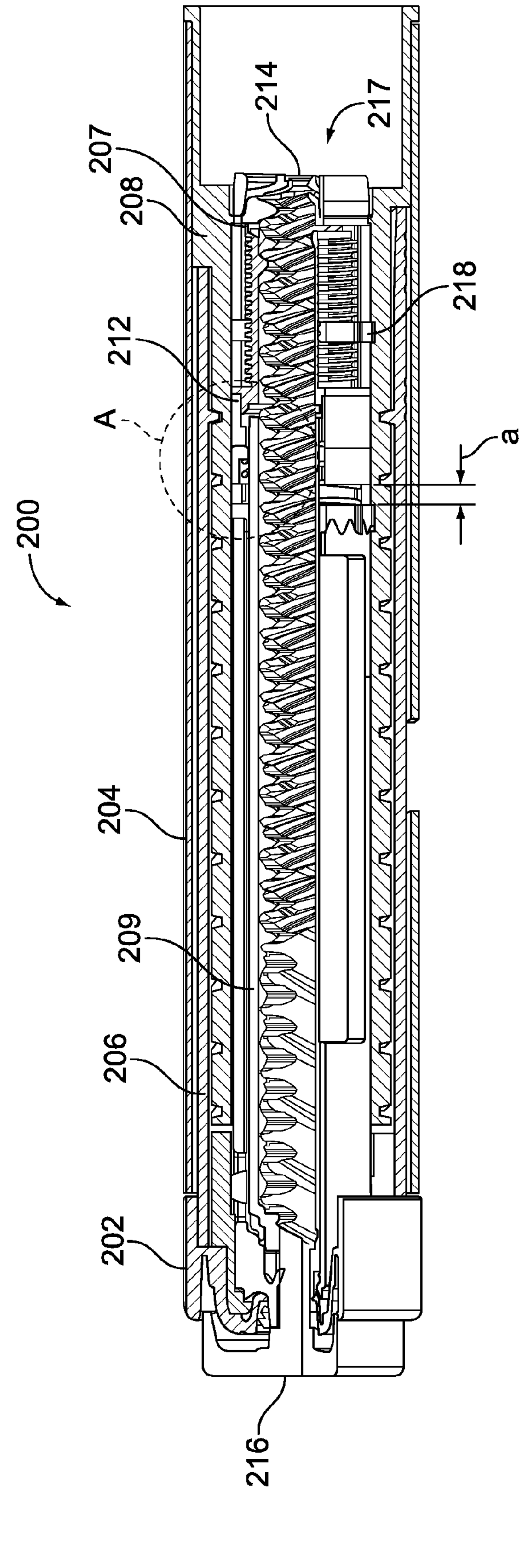



FIG. 8

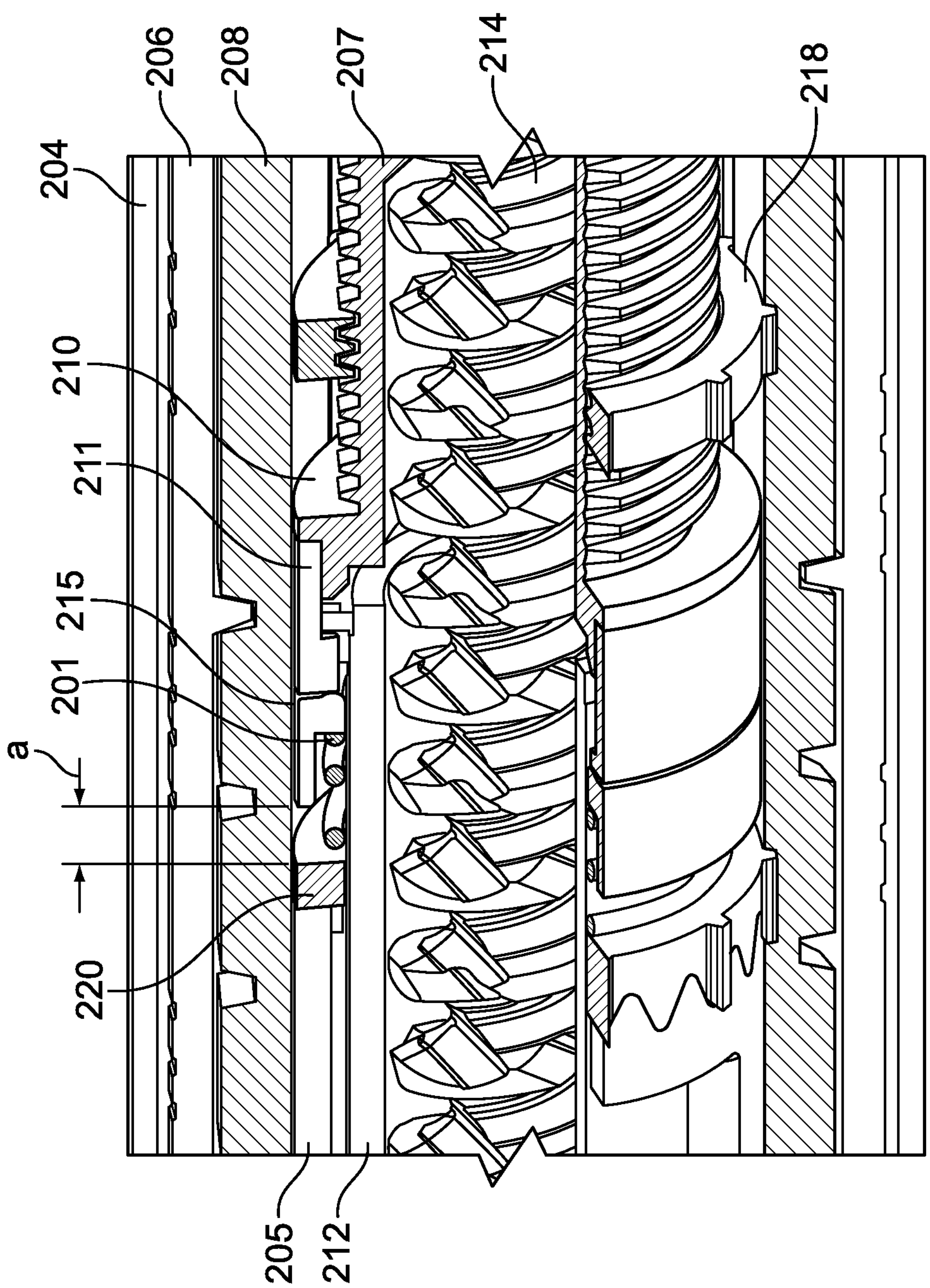
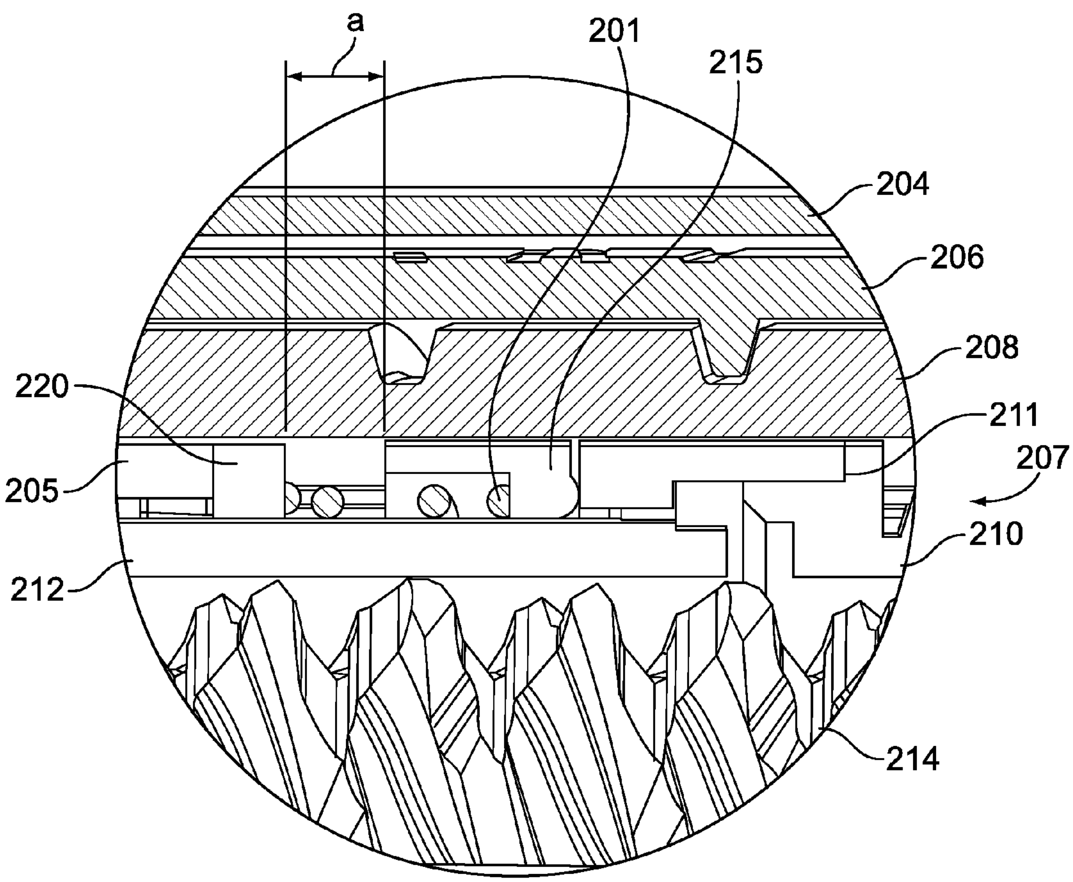



FIG. 9

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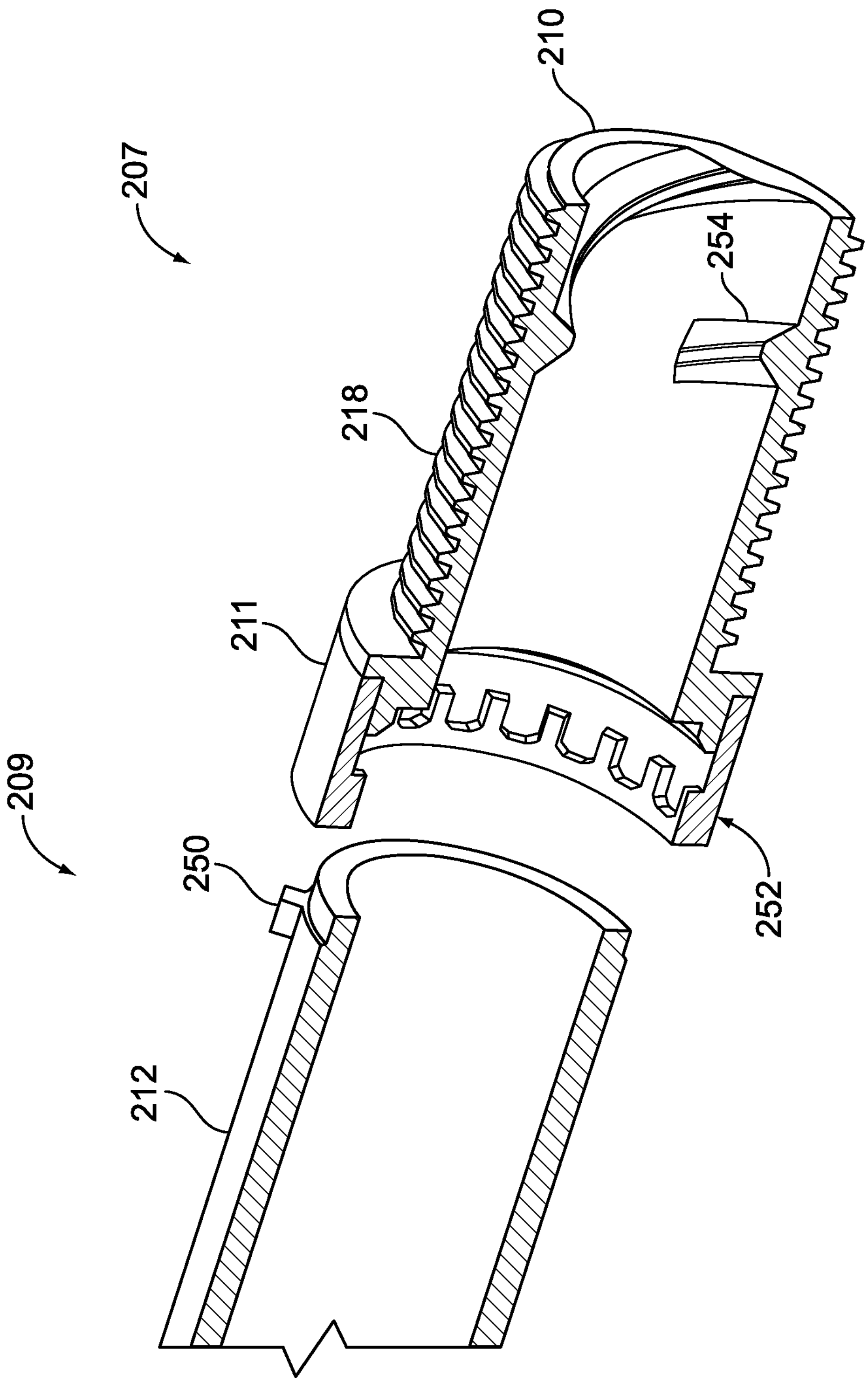
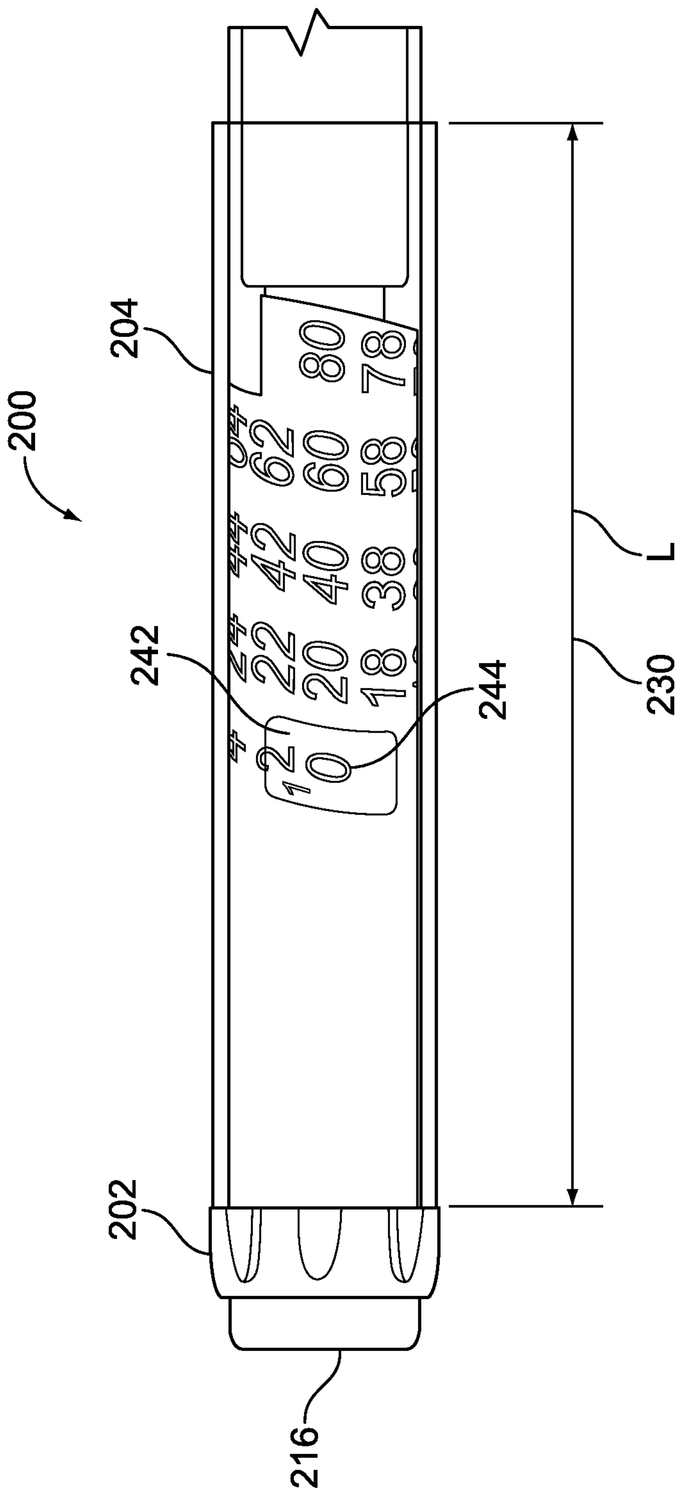



FIG. 11

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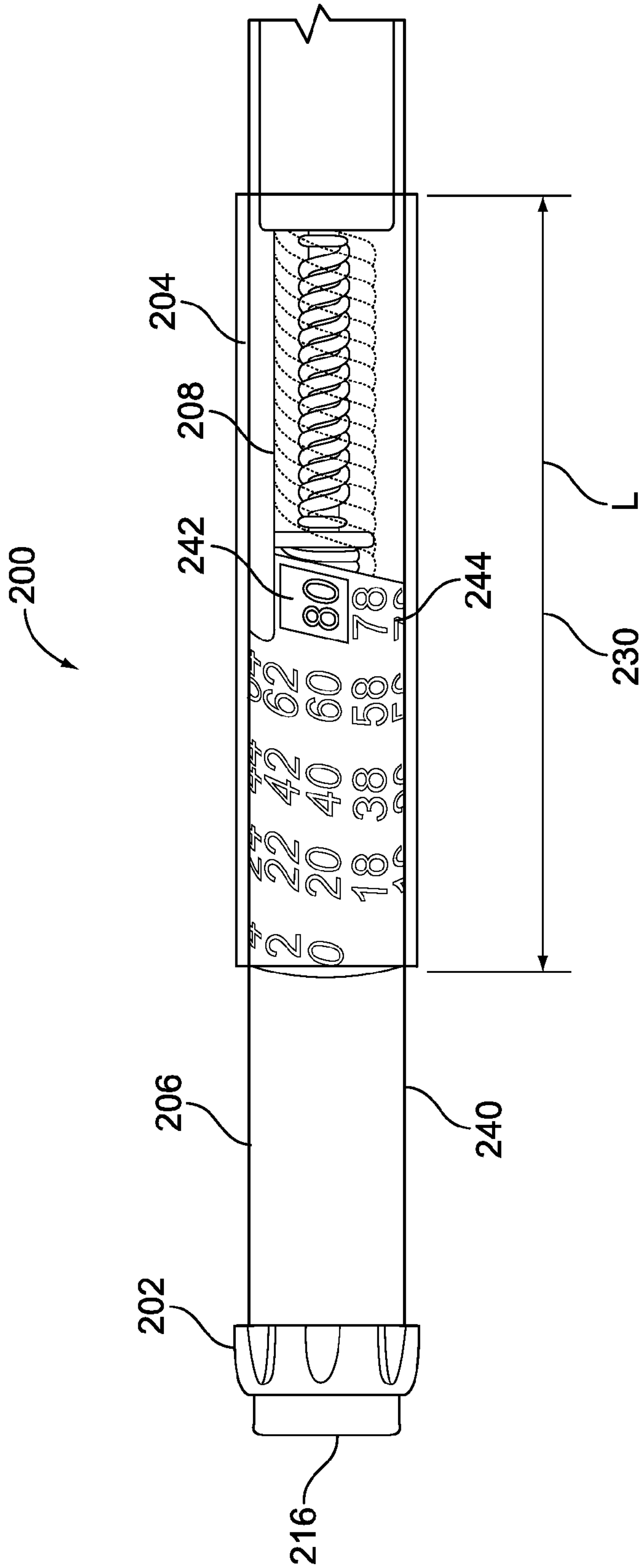
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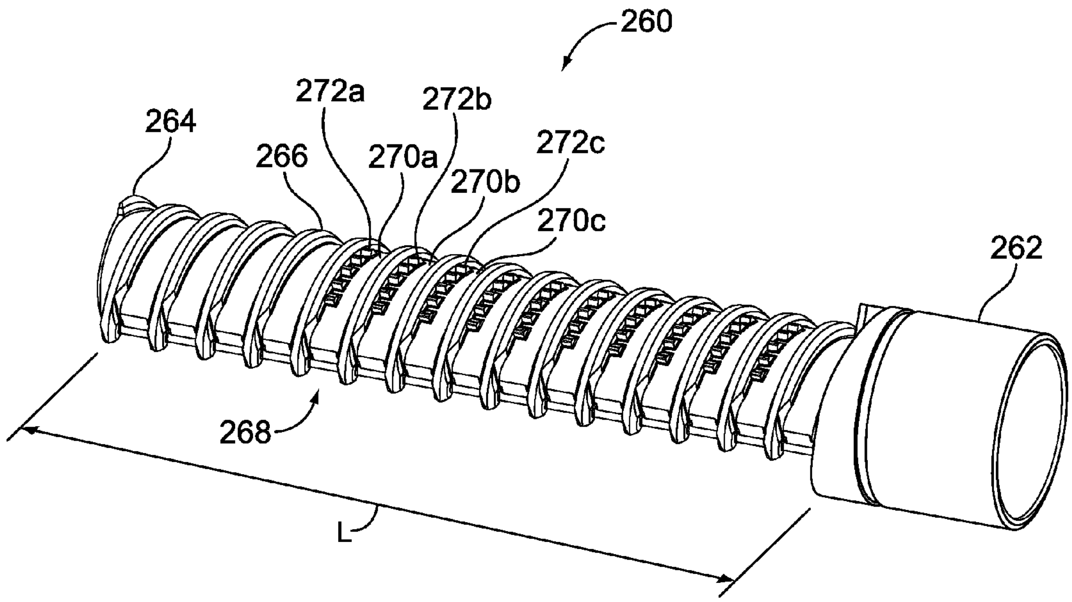
FIG. 13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270c
262
268
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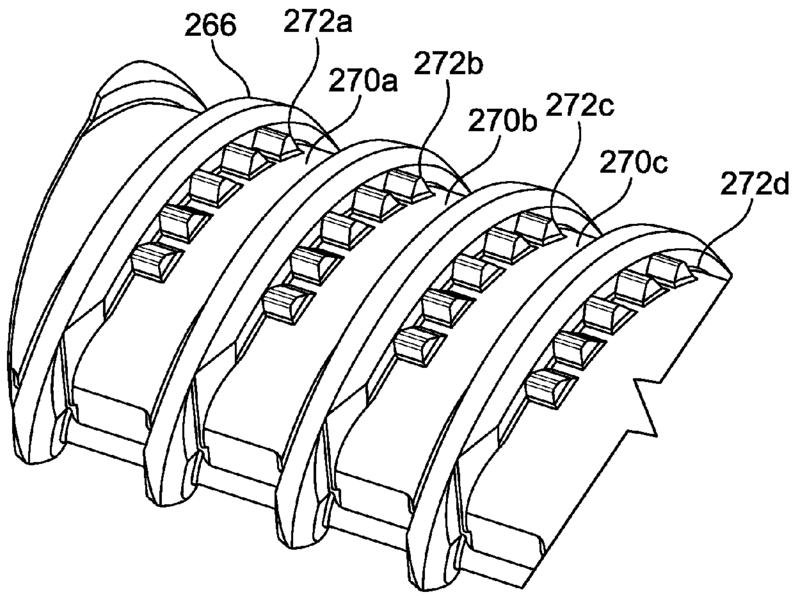
FIG. 14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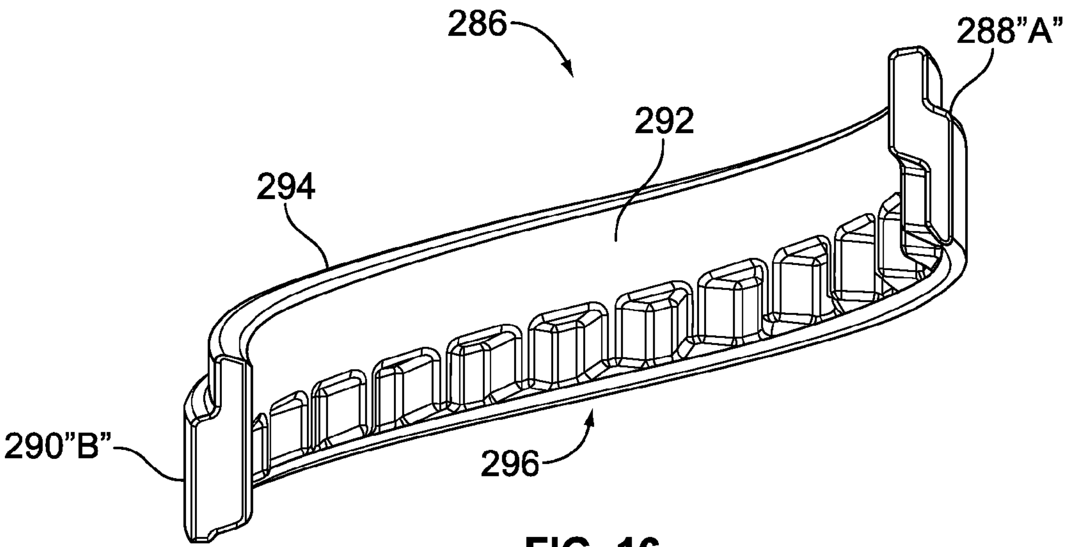
270b
272c
270c
272d

FIG. 15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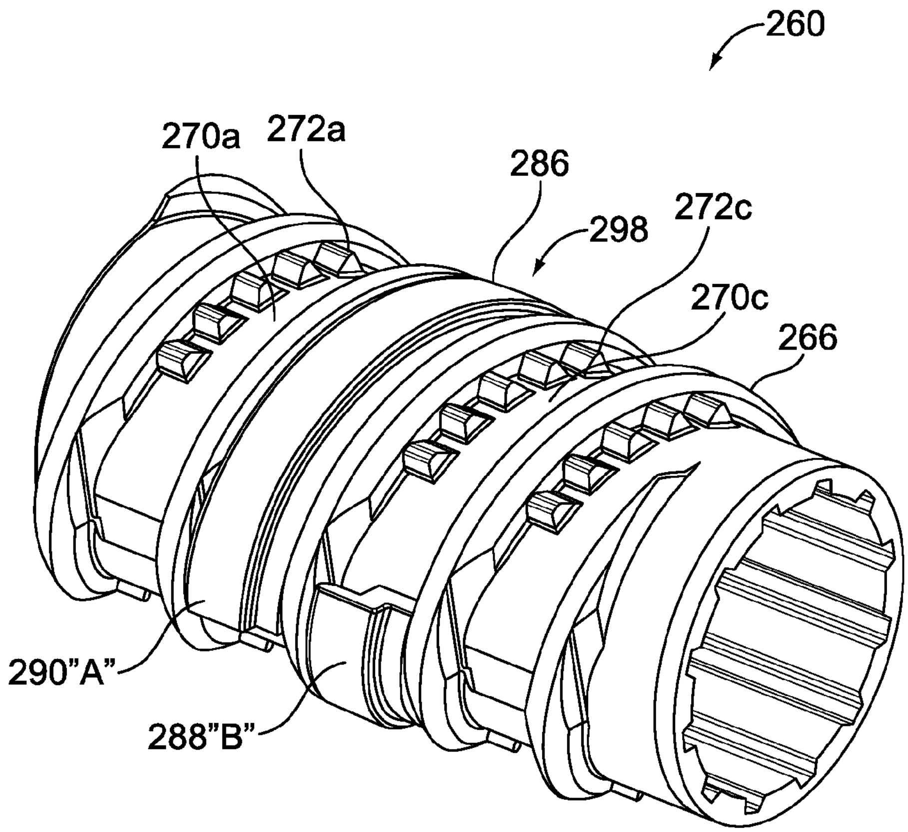
296

FIG. 16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298
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288"B"

FIG. 17

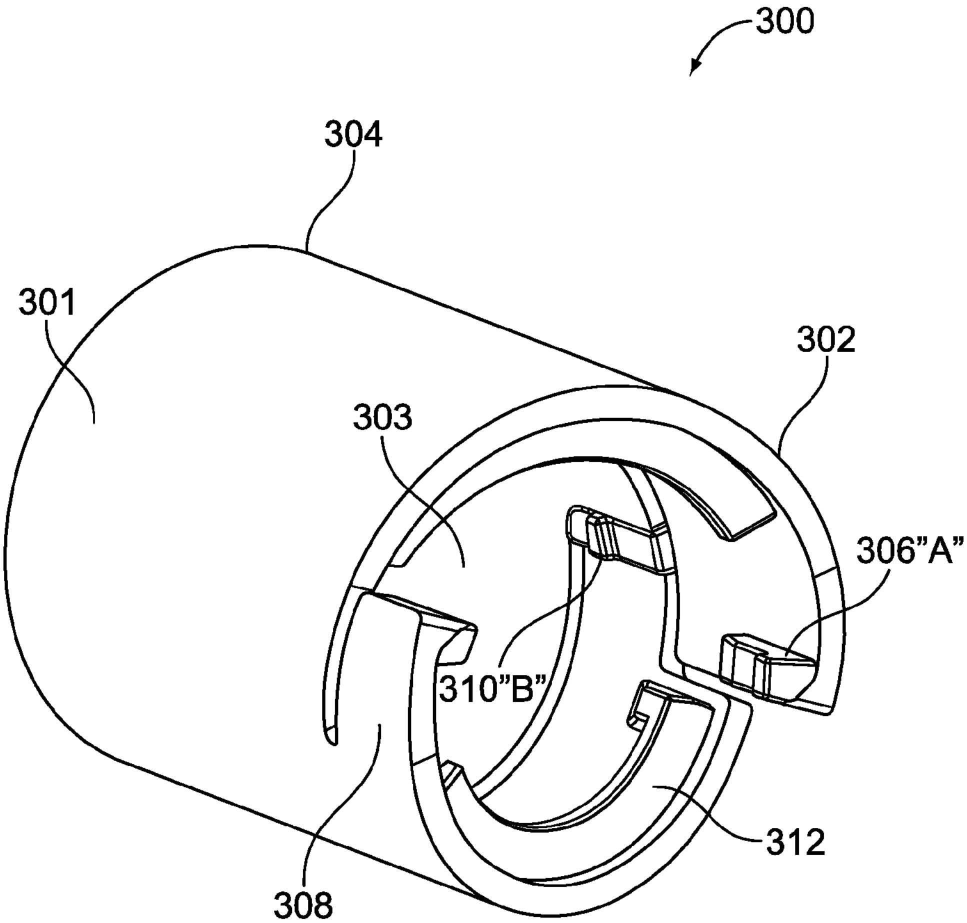
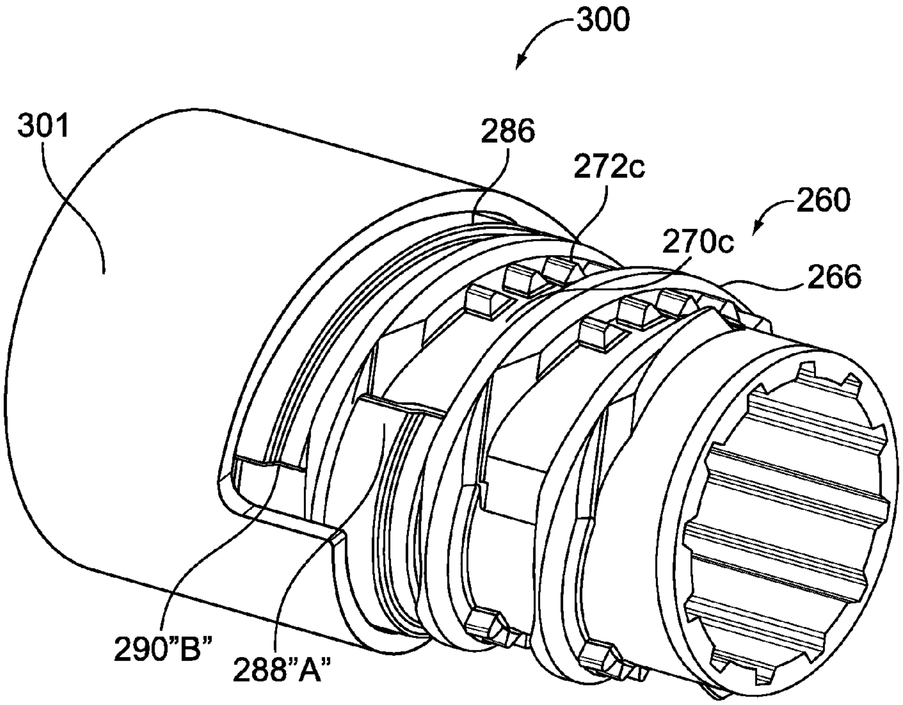



FIG. 18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301
286
272c
260
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FIG. 19

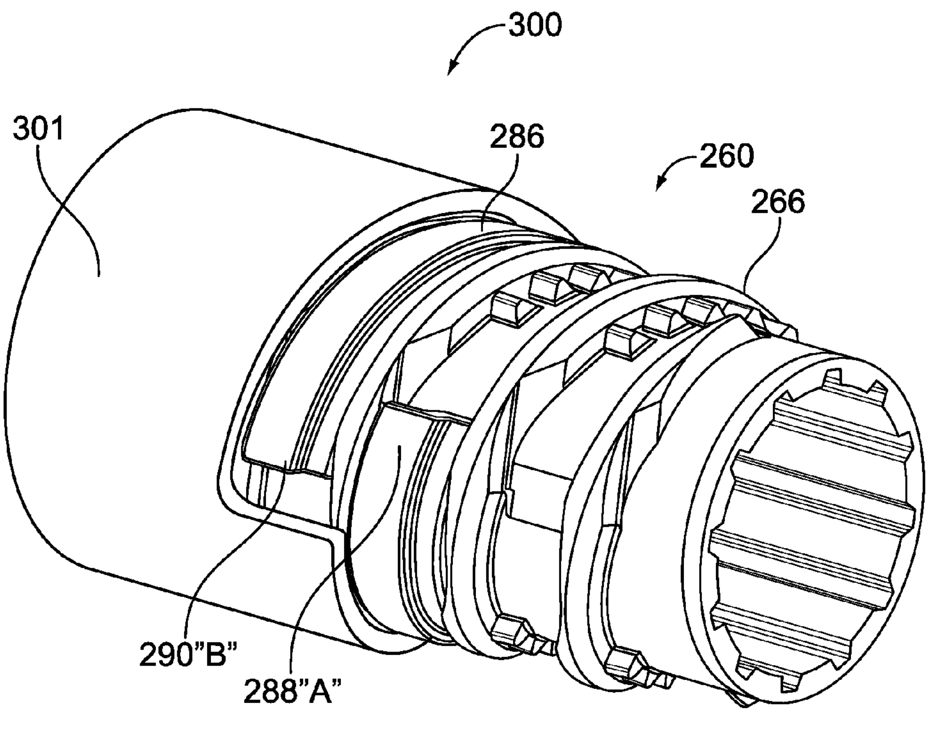
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FIG. 20

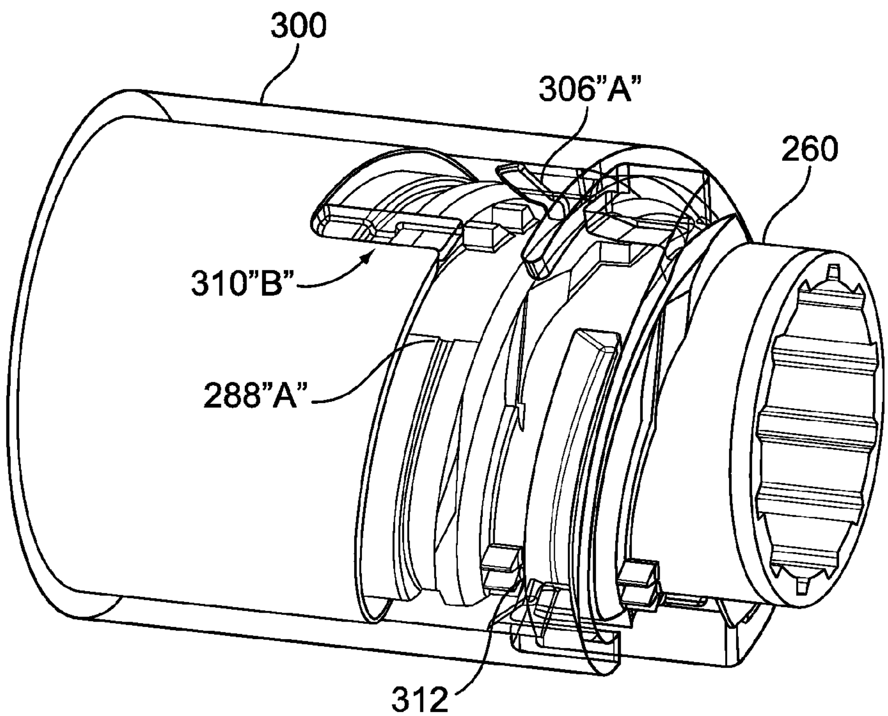


FIG. 21

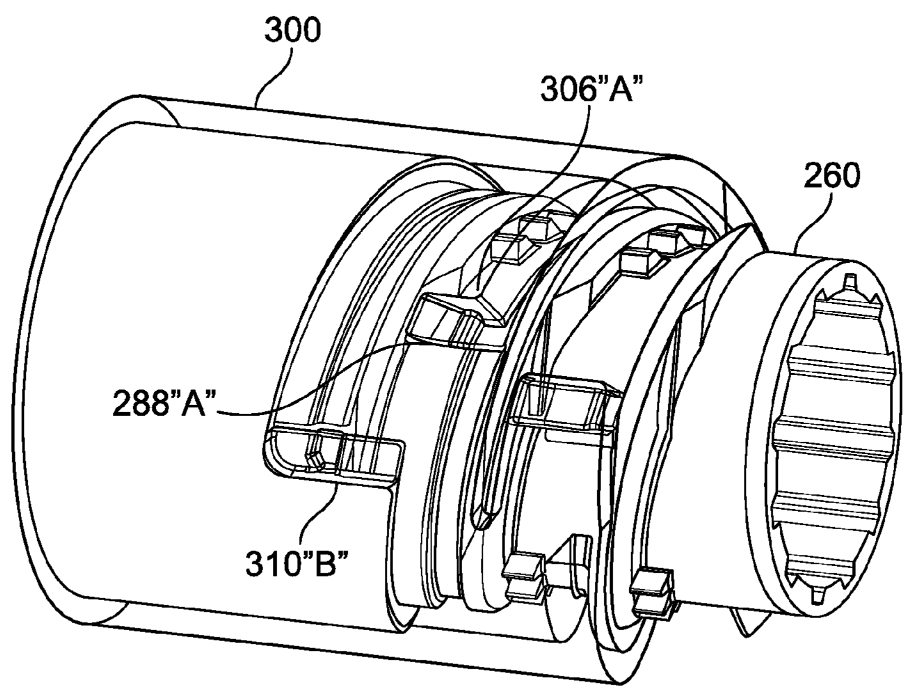


FIG. 22

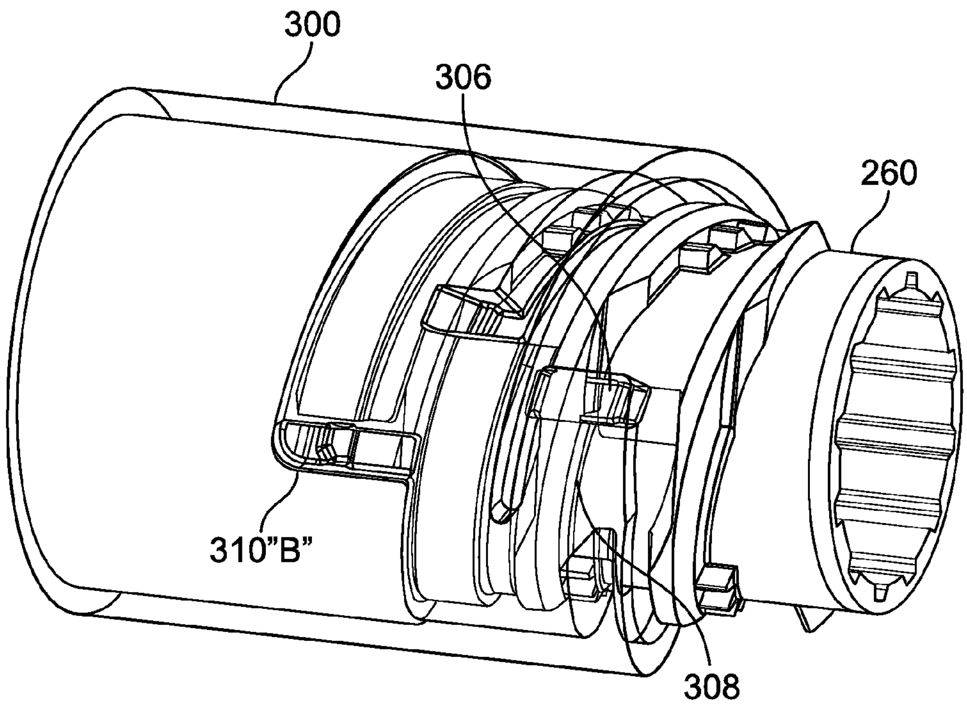


FIG. 23

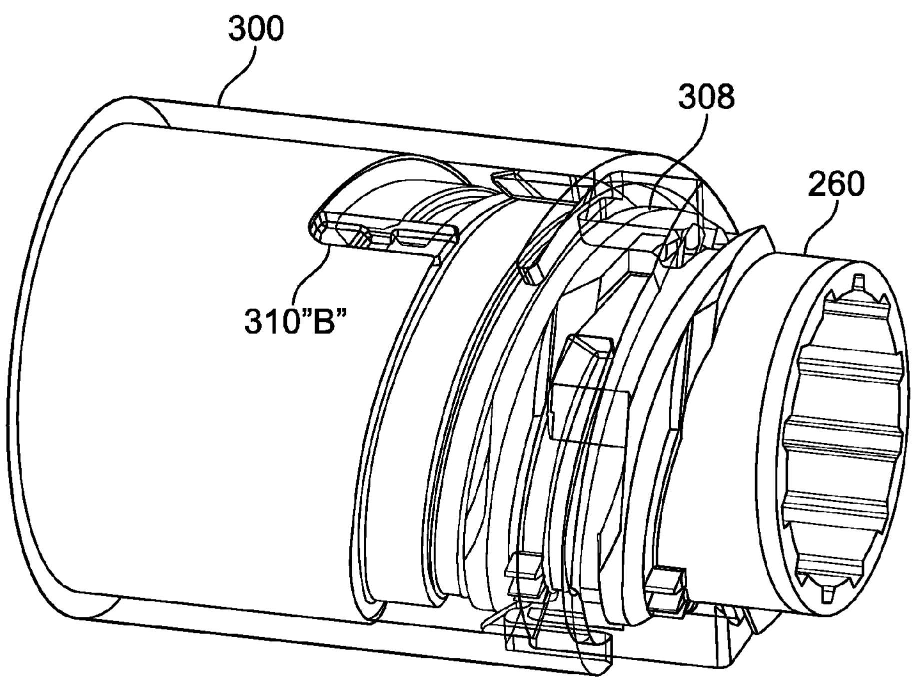


FIG. 24

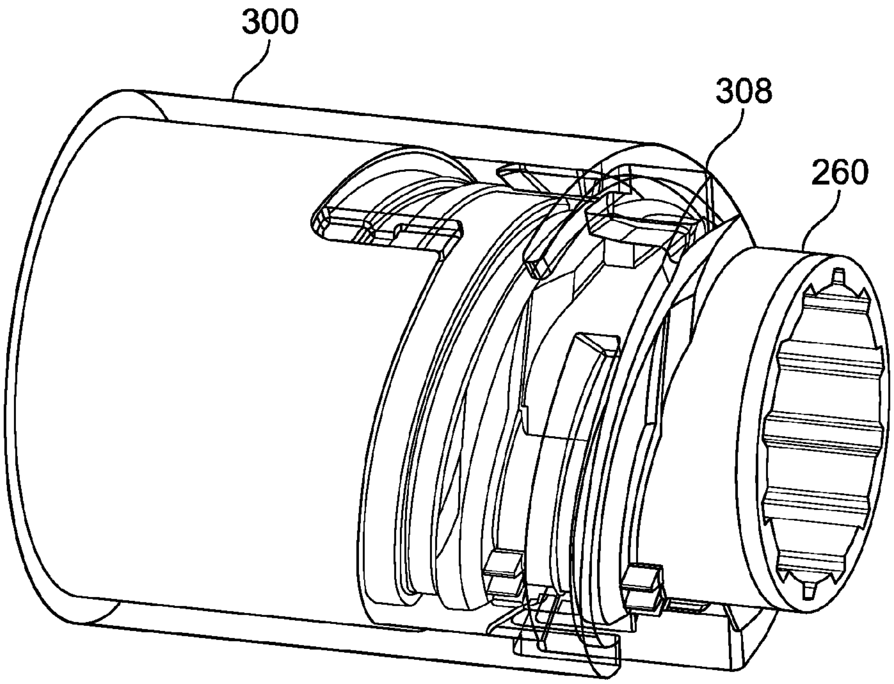


FIG. 25

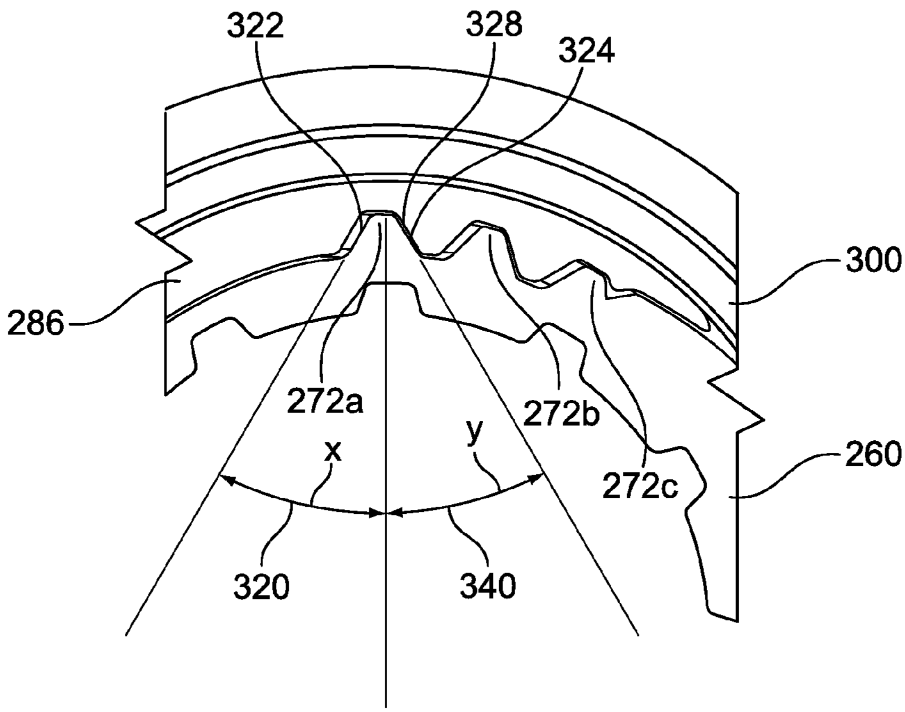


FIG. 26

# DRUG DELIVERY DOSE SETTING MECHANISM WITH VARIABLE MAXIMUM DOSE

## FIELD OF THE PRESENT PATENT APPLICATION

The present application is generally directed to dose setting mechanisms for drug delivery devices. More particularly, the present application is generally directed to dose setting mechanisms comprising a variable maximum dose. Aspects of the invention may be equally applicable in other scenarios as well.

## BACKGROUND

Pen type drug delivery devices have application where regular injection by persons without formal medical training occurs. This may be increasingly common among patients having diabetes where self-treatment enables such patients to conduct effective management of their disease.

There are basically two types of pen type delivery devices that allow a user set to a variable dose of medication: resettable devices (i.e., reusable) and non-resettable (i.e., disposable). These types of pen delivery devices (so named because they often resemble an enlarged fountain pen) are generally comprised of three primary elements: (i) a cartridge section that includes a cartridge often contained within a housing or holder; (ii) a needle assembly connected to one end of the cartridge section; and (iii) a dosing section connected to the other end of the cartridge section. A cartridge (often referred to as an ampoule) typically includes a reservoir that is filled with a medication (e.g., insulin), a movable rubber type bung or stopper located at one end of the cartridge reservoir, and a top having a pierceable rubber seal located at the other, often necked-down, end. A crimped annular metal band is typically used to hold the rubber seal in place. While the cartridge housing may be typically made of plastic, cartridge reservoirs have historically been made of glass.

The needle assembly is typically a replaceable double-ended needle assembly. Before an injection, a replaceable double-ended needle assembly is attached to one end of the cartridge assembly, a dose is set, and then a dose is administered. Such removable needle assemblies may be threaded onto, or pushed (i.e., snapped) onto the pierceable seal end of the cartridge assembly.

The dosing section or dose setting mechanism is typically the portion of the pen device that is used to set a dose. During an injection, a spindle contained within the dose setting mechanism presses against the bung or stopper of the cartridge. This force causes the medication contained within the cartridge to be injected through an attached needle assembly. After an injection, as generally recommended by most drug delivery device and/or needle assembly manufacturers and suppliers, the needle assembly is removed and discarded.

Different types of pen delivery devices, including disposable (i.e., non-resettable) and reusable (i.e., resettable) varieties, have evolved over the years. For example, disposable pen delivery devices are supplied as self-contained devices. Such self-contained devices do not have removable pre-filled cartridges. Rather, the pre-filled cartridges may not be removed and replaced from these devices without destroying the device itself. Consequently, such disposable devices need not have a resettable dose setting mechanism.

In contrast to typical disposable pen type devices, typical reusable pen delivery devices feature essentially two main reusable components: a cartridge holder and a dose setting mechanism. After a cartridge is inserted into the cartridge holder, this cartridge holder is attached to the dose setting mechanism. The user uses the dose setting mechanism to select a dose. Before the user injects the set dose, a replaceable double-ended needle assembly is attached to the cartridge housing. This needle assembly may be threaded onto or pushed onto (i.e., snapped onto) a distal end of the cartridge housing. In this manner, a double ended needle mounted on the needle assembly penetrated through a pierceable seal at a distal end of the cartridge. After an injection, the needle assembly is removed and discarded. After the insulin in the cartridge has been exhausted, the user detaches the cartridge housing from the dose setting mechanism. The user can then remove the empty cartridge from the cartridge retainer and replace the empty cartridge with a new (filled) cartridge.

In certain typical a variable dose drug delivery devices such as those described above, a dial sleeve is engaged with the housing of the device via a helical groove. Typically, this dial sleeve is rotated out away from the housing on a helical path to allow the user to set a variable dose of medication. This dial sleeve spins back or rotates back towards the housing when the set dose is delivered.

This helical thread may have one or more radial stop faces that engage when the dial sleeve has been dialed up to a certain non-variable maximum dose. For example, in certain typical drug delivery devices used for the administration of insulin, such a non-variable maximum dose may be on the order of 50-80 International Units (IU). In this manner, a user is prevented from dialing up a dose greater than this non-variable maximum dose. In certain known devices, these stop faces can be molded into the plastic components as fixed stop faces. These stop faces may or may not be part of the helical thread form.

Known dose setting mechanisms that do not allow for varying such a maximum dose setting have certain perceived disadvantages. For example, a drug delivery device having a non-variable maximum dose stop does not enable a user or healthcare professional to limit the maximum dose that can be dialed on a variable dose pen. Therefore, one disadvantage of this arrangement is that it tends to increase the risk of a potential dose error. In addition, such an arrangement makes the device more difficult to set in low light conditions or for users having poor vision.

Another disadvantage of drug delivery devices having a fixed maximum dose is that a parent or a care giver cannot limit the maximum dose that can be delivered from a device. Consequently, such a device may pose certain safety issues when used by a child or elderly patient without supervision.

There is, therefore, a general need for an adjustable maximum dose stop that enables a user or healthcare professional to limit the maximum dose that can be dialed on a variable dose pen. A drug delivery device that utilizes an adjustable maximum dose stop offers a number of advantages. As one example, a user can pre-set the maximum dose of the drug delivery device to be a certain regular daily dose and thereby reduce the risk of a potential dose error. In addition, an adjustable maximum dose stop makes the drug delivery device easier to set in low light conditions or for users having poor vision. For example, with such an arrangement, the user simply dials the dose dial grip until the maximum dose stop engages and then delivers the dose. In addition, such an adjustable maximum dose stop allows a healthcare professional to limit or set the dose for the patient who has poor dexterity, poor vision or limited understanding of variable dose pen types.

There is, therefore, a general need to take these disadvantages associated with issues into consideration in the design and development of drug delivery devices having a non-variable maximum dose stop. Such desired drug delivery devices would allow parents or care givers to set a specific maximum dose that may be set by the drug delivery device and therefore potentially avert an overdose. Such desired devices would also allow patient care givers the opportunity to provide a maximum dose region over which the user can re-adjust the maximum dose.

## SUMMARY

According to an exemplary arrangement, a drug delivery device having a variable maximum dose comprises a first tubular member and a second tubular member rotatably coupled to the first tubular member. A maximum stop component is operatively coupled to the first tubular member and the second tubular member. The maximum stop component is movable from a first position to a second position. The first position defines a first maximum dose that may be set by a user of said drug delivery device, and the second position defines a second maximum dose that may be set by the user of the drug delivery device.

According an alternative arrangement; a drug delivery device having a variable maximum dose comprises a housing comprising a helical groove, and a plurality of ratchet teeth. A dial sleeve is coupled to the helical groove and a first stop component engages a first set of the plurality of ratchet teeth. The first stop component is located at a first stop position and defines a first maximum dose of the drug delivery device. The dial sleeve moves the first stop component to a second set of the plurality of the ratchet teeth so that the first stop component moves to a second stop location. The second stop location defines a second maximum dose of the drug delivery device.

In yet another alternative arrangement, a method for providing a drug delivery device having a first and a second maximum dose. The method comprises the steps of:

a. positioning a plurality of ratchet teeth on an inner housing;

b. engaging a first stop component having a plurality of internal features along a set of said plurality of ratchet teeth of said inner housing;

c. positioning a number sleeve in a first position so that said plurality of ratchet teeth of said inner housing engage a first set of said plurality of said internal features of said first stop component defining said first maximum dose, and said number sleeve preventing said inner housing plurality of ratchet teeth from disengaging said plurality of internal feature of said first stop component;

d. displacing said number setting sleeve in a second position so that said number sleeve no longer prevents said disengagement;

e. manipulating said number sleeve so as to select a second maximum dose.

These as well as other advantages of various aspects of the present invention will become apparent to those of ordinary skill in the art by reading the following detailed description, with appropriate reference to the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Exemplary embodiments are described herein with reference to the drawings, in which:

FIG. **1** illustrates a first embodiment of a resettable drug delivery device;

FIG. **2** illustrates a sectional view of the first embodiment of the drug delivery device illustrated in FIG. **1**;

FIG. **3** illustrates a sectional view of the first embodiment of the drug delivery device of FIG. **2** in a first position;

FIG. **4** illustrates a sectional view of the first embodiment of the drug delivery device of FIG. **2** in a second position;

FIG. **5** illustrates a sectional view of the first embodiment of the drug delivery device of FIG. **2** in a third position;

FIG. **6** illustrates a first arrangement of the driver illustrated in FIGS. **2-5** comprising a first driver portion and a second driver portion;

FIG. **7** illustrates a distal end of the spindle of the dose setting mechanism illustrated in FIGS. **2-5**;

FIG. **8** illustrates a sectional view of a second embodiment of a dose setting mechanism of the drug delivery device illustrated in FIG. **1**;

FIG. **9** illustrates a partial sectional view of the second embodiment of the dose setting mechanism illustrated in FIG. **8**;

FIG. **10** illustrates a close up view of Gap A illustrated in FIG. **8**;

FIG. **11** illustrates a second arrangement of the driver illustrated in FIGS. **8-10** comprising a first driver portion and a second driver portion;

FIG. **12** illustrates the dose setting mechanism illustrated in either FIGS. **2-5** or FIGS. **8-10**, and

FIG. **13** illustrates the dose setting mechanism illustrated in FIG. **12** in which a user has set a dose.

FIG. **14** illustrates one arrangement of an inner housing that may be used with a dose setting mechanism having a variable maximum dose setting feature;

FIG. **15** illustrates one close up view of the inner housing illustrated in FIG. **14**;

FIG. **16** illustrates one arrangement of a stop component that can be used with the inner housing illustrated in FIG. **14**;

FIG. **17** illustrates the stop component of FIG. **16** releasably engaged to the inner housing illustrated in FIG. **14**;

FIG. **18** illustrates a portion of the number or dial sleeve that may be used to releasably engage the inner housing illustrated in FIG. **14**;

FIG. **19** illustrates the dial sleeve of FIG. **18** engaged to the inner housing of FIG. **14** in a dose setting position;

FIG. **20** illustrates the dial sleeve of FIG. **19** in a second position;

FIG. **21** illustrates the dial sleeve of FIG. **20** in a position prior to engagement of the first maximum stop face of the dial sleeve;

FIG. **22** illustrates the dial sleeve of FIG. **21** once the maximum dose has been dialed;

FIG. **23** illustrates a first step of setting a variable maximum dose with the dial sleeve illustrated in FIG. **22**;

FIG. **24** illustrates the dial sleeve of FIG. **23** after the dial sleeve has been rotated;

FIG. **25** illustrates a position of the dial sleeve of FIG. **24** after a new maximum dose stop has been set; and

FIG. **26** illustrates a cross-sectional view of the dial sleeve illustrated in FIG. **25**.

## DETAILED DESCRIPTION

Referring to FIG. **1**, there is shown a drug delivery device **1** in accordance with a first arrangement of the present invention. The drug delivery device **1** comprises a housing having a first cartridge retaining part **2**, and dose setting mechanism **4**. A first end of the cartridge retaining means **2** and a second end of the dose setting mechanism **4** are secured together by retaining features. In this illustrated arrangement, the cartridge retaining means **2** is secured within the second end of the dose setting mechanism **4**. A removable cap **3** is releasably retained over a second end or distal end of a cartridge retaining part. As will be described in greater detail, the dose setting mechanism **4** comprises a dose dial grip **12** and a window or lens **14**. To set a dose of medication contained within the drug delivery device **1**, a user rotates the dose dial grip **12** and the window allows a user to view the dialed dose by way of a dose scale arrangement **16**.

FIG. **2** illustrates the medical delivery device **1** of FIG. **1** with the cover **3** removed from the distal end of the medical delivery device. As illustrated, a cartridge **20** from which a number of doses of a medicinal product may be dispensed is provided in the cartridge housing **6**. Preferably, the cartridge **20** contains a type of medicament that must be administered often, such as once or more times a day. Once such medicament is insulin. A bung or stopper (not illustrated in FIG. **2**) is retained in a first end or a proximal end of the cartridge **20**.

The dose setting mechanism **4** of the drug delivery device illustrated in FIG. **2** may be utilized as a reusable (and hence resettable) or a non-reusable (and hence non-resettable) drug delivery device. Where the drug delivery device **1** comprises a reusable drug delivery device, the cartridge is removable from the cartridge housing **6**. The cartridge **20** may be removed from the device without destroying the device but merely by the user disconnecting the dose setting mechanism **4** from the cartridge holder **20**.

In use, once the removable cap **3** is removed, a user can attach a suitable needle assembly to the distal end of the cartridge holder. Such needle unit may be screwed onto a distal end of the housing or alternatively may be snapped onto this distal end. A replaceable cap **3** is used to cover the cartridge holder **6** extending from the dose setting mechanism **4**. Preferably, the outer dimensions of the replaceable cap **3** are similar or identical to the outer dimensions of the dose setting mechanism **4** so as to provide an impression of a unitary whole when the replaceable cap **3** is in position covering the cartridge holder **2**.

FIG. **3** illustrates a sectional view of the dose setting mechanism **4** removably connected to the cartridge holder **29**. The dose setting mechanism **4** comprises an outer housing **40** containing a spindle **42**, a number sleeve **24**, a clutch **26**, and a driver **30**. A first helical groove **19** extends from a first end of a spindle **42**. In one arrangement, the spindle **42** is of generally circular in cross section however other arrangements may also be used. The first end of the spindle **42** (a distal end **43** of the spindle **42**) extends through a pressure plate **64**. A spindle bearing **50** is located at the distal end **43** of the spindle **42**. The spindle bearing **50** is disposed to abut a second end of the cartridge piston **18**. The driver **30** extends about the spindle **42**. The clutch **26** is disposed about the driver **30**, between the driver **30** and a number sleeve **24**. The clutch **26** is located adjacent the second end of the driver **30**. A number sleeve **24** is provided outside of the clutch **26** and radially inward of the housing **40**. The main housing **4** is provided with a window **14** through which a part of an outer surface **11** of the number sleeve **10** may be viewed.

Returning to FIGS. **1-2**, a dose dial grip **12** is disposed about an outer surface of the second end of the number sleeve **10**. An outer diameter of the dose dial grip **12** preferably corresponds to the outer diameter of the housing **40**. The dose dial grip **12** is secured to the number sleeve **10** to prevent relative movement between these two components. In one preferred arrangement, the dose dial grip and number sleeve **10** comprise a one piece component that is rotationally coupled to a clutch and drive sleeve and axially coupled to the number sleeve **10**. However, alternative coupling arrangements may also be used.

Returning to FIGS. **3-5**, in this arrangement, driver **30** comprises a first driver portion **44** and a second driver portion **46** and these portions extend about the spindle **42**. Both the first and the second driver portions **44**, **46** are generally cylindrical. As can be seen from FIG. **6**, the first drive portion **44** is provided at a first end with a first radially extending flange **56**. A second radially extending flange **58** is provided spaced a distance along the first driver portion **44** from the first flange **56**. An intermediate helical groove **62** is provided on an outer part of the first driver portion **44** extending between the first flange **56** and the second flange **58**. A portion or a part helical groove **68** extends along an internal surface of the first driver portion **44**. The spindle **42** is adapted to work within this part helical groove **68**.

A dose limiter **38** (Illustrated in FIG. **3**) is located between the driver **30** and the housing **4**, disposed between the first flange **56** and the second flange **58**. In the illustrated arrangement, the dose limiter **38** comprises a half-nut. The dose limiter **38** has an internal helical groove matching the helical groove **66** of the driver **30**. In one preferred arrangement, the outer surface of the dose limiter **38** and an internal surface of the housing **40** are keyed together by way of splines. This prevents relative rotation between the dose limiter **38** and the housing **40** while allowing relative longitudinal movement between these two components.

Referring back to FIGS. **2-5**, essentially, in normal use, the operation of the dose setting mechanism **4** occurs as follows. To dial a dose in the arrangement illustrated in FIGS. **1-5**, a user rotates the dose dial grip **12**. The driver **30**, the clutch **26** and the number sleeve **10** rotate along with the dose dial grip **12**.

The number sleeve **10** extends in a proximal direction away from the housing **40**. In this manner, the driver **30** climbs the spindle **42**. At the limit of travel, a radial stop on the number sleeve **10** engages either a first stop or a second stop provided on the housing **40** to prevent further movement. Rotation of the spindle **42** is prevented due to the opposing directions of the overhauled and driven threads on the spindle **42**. The dose limiter **38**, keyed to the housing **40**, is advanced along the thread **66** by the rotation of the driver **30**.

FIG. **2** illustrates the medical delivery device after a desired dose of 79 International Units (IU) has been dialed. When this desired dose has been dialed, the user may then dispenses the desired dose of 79 IU by depressing the dial grip **12**. As the user depresses the dial grip **12**, this displaces the clutch **26** axially with respect to the number sleeve **10**, causing the clutch **26** to disengage. However the clutch **26** remains keyed in rotation to the driver **30**. The number sleeve **10** and associated dose dial grip **12** is now free to rotate.

The driver **30** is prevented from rotating with respect to the main housing **4** but it is free to move axially with respect thereto. The longitudinal axial movement of the driver **30** causes the spindle **42** to rotate and thereby to advance the piston **18** in the cartridge **20**.

In normal use, the first and second portions **44**, **46** of the driver **30** are coupled together when the dose dial sleeve **10** is rotated. That is, in normal use, the first and second portions **44**, **46** of the driver **30** are coupled together with the dose dial sleeve **10** when a user sets a dose by turning the dose dial grip **12**. After each dispensed dose, the spindle **42** is pushed in a distal direction, acting on the bung **18** of the cartridge **20** to continue to expel a dialed dose of medication out of an attached needle assembly releasably connected to the distal end **8** of the cartridge holder **6**. After a user uses the drug delivery device **1** to dispense all of the medication contained in the cartridge **20**, the user may wish to replace the empty cartridge in the cartridge holder **6** with a new cartridge. The user must then also reset the dose setting mechanism **4**: for example, the user must then retract or push the spindle **42** back into the dose setting mechanism **4**.

If the user decides to replace an empty cartridge and reset the device **1**, the first and second driver portions **44**, **46** must be de-coupled from one another. After decoupling the first driver portion **44** from the second driver portion **46**, the first driver portion **44** will be free to rotate while the second driver portion **46** will not be free to rotate.

During a device resetting step, rotating the first driver portion **44** achieves at least two results. First, rotation of the first driver portion **44** will reset the axial position of the spindle **42** with respect to the dose setting mechanism **4** since rotation of the first driver portion **44** causes the spindle **42** to rotate. Rotation of the spindle **42** (because the spindle is splined with the spindle guide **48**) moves the spindle in a proximal direction back into the dose setting mechanism. For example, FIG. **7** illustrates one arrangement for connecting the spindle **42** to the spindle guide **48**. In FIG. **7**, the spindle **42** comprises a first **51** spline and a second spline **52**. The spindle guide **48** comprises an essentially circular member having an aperture. The aperture includes two inner protruding members **55**, **57** that engage the first and second splines **51**, **52** respectively, so that the spindle guide **48** locks onto the spindle and rotates along with the spindle during spindle rotation.

Second, rotation of the first driver portion **44** will also axial move or reset a dose limiter **38** to an initial or start position. That is, as the first driver portion **44** is rotated back to an initial start position, because the dose limiter **38** is threadedly engaged to the outer groove and splined to an inner surface of a housing portion, such as the outer housing **40**. In this configuration, the dose limiter **38** is prevented from rotating but will move along the outer groove **62** of the first driver portion **44** as this portion is rotated during a resetting step.

Referring to a first driver arrangement illustrated in FIG. **3**, the two portions of the driver **30** are decoupled when the first driver portion **44** is pulled axially away from the second driver portion **46**. This may be achieved by the use of a biasing means (such as at least one spring) that interacts together when the cartridge holder **6** is removed from the front or distal end of the device to first lock the relative rotation between the spindle **42** and a spindle guide **48** through which the spindle passes, and then to push this spindle guide **48** and also nut **66** axially a fixed distance. Because the spindle **42** is rotationally locked to the spindle guide **48** and is threadedly engaged with this spindle nut **66**, the spindle **42** will move axially.

The spindle **42** is coupled via a groove engaged to the first driver portion **44**. The first driver portion **44** is prevented from rotation by a clutched connection to the second driver portion **46**. In one preferred arrangement, the second driver portion **46** is prevented from rotation by a clicker detent **75**. The clicker detent **75** resides between the clutch and the flange **80** on the drive sleeve **46**. Therefore, axial movement of the spindle **42** decouples the two driver portions **44**, **46** so that the clutched connection becomes de-coupled.

This sequence of operation as the cartridge holder **6** is removed or disconnected from the dose setting mechanism **4** is illustrated in FIGS. **3**-**5**. In FIG. **3**, the various component parts of the drug delivery device include: a dose setting housing **40**, a cartridge **20**, a spindle **42**, first driver portion **44**; second driver portion **46**, spindle bearing **50**, spindle guide **48**; spring plate **54**; a main spring **60**, a pressure plate **64**, a cartridge holder **20**; a spindle nut **66**; and a second spring **70**. In this preferred arrangement, the spindle guide **54** is rotationally fixed relative to the spindle **20**. In addition, the spring plate **54**, pressure plate **64** and spindle nut **66** are all rotationally fixed relative to the outer housing.

In FIG. **3**, the cartridge holder **6** is fitted via apertures in the pressure plate **64** and applies a load to the spring plate **54**. This compresses the first biasing means or main spring **60**. These apertures in the pressure plate **64** (not shown) allow the pressure plate **64** to move away from the spring plate **54** (in a distal direction towards the cartridge holder **6**) under the action of the second biasing means or second spring **70**. This will open up a Gap "A" as shown in FIG. **3**. Gap "A" is a gap created between the pressure plate **64** and the spring plate **54**. This will also open Gap "B", a gap between the spindle nut **66** and the spring plate **54**. This Gap B is illustrated in FIG. **3**. The Gap B in conjunction with the light force from the second spring or biasing means **70** moves the spindle nut **66** towards the distal end of the drug delivery device **1**. This applies light pressure to the spindle guide **48**. The spindle guide **48** is compressed under the action of the second spring **70** between the spindle nut **66** and pressure plate **64**. This light force coupled with the friction coefficient on either side of a flange of the spindle guide **48** through which this force acts, provides a resistance to rotation of the spindle guide **48** and therefore a resistance to rotation of spindle **42** as well. One advantage of this configuration is that at the end of a dose, it is advantageous to prevent the spindle **42** from back-winding into the dose setting mechanism **4** under light residual loads that may remain from the cartridge bung **18**. By preventing the spindle **42** from back-winding in a proximal direction, a distal end **43** of the spindle **42** (and hence the spindle bearing **50**) remains on the bung **18**. Maintaining the distal end **43** of the spindle **42** on the bung **18** helps to prevent a user from administrating a potential under-dose.

When the user delivers a dose, as the dispense force increases, the rearward load on the spindle nut **66** increases to a point at which the spindle nut **66** travels back in a proximal direction and compresses the second spring **70**. This releases the axial force acting on the spindle guide **48**. This removes the resistance to rotation of the spindle guide **48** and hence spindle **42**. This configuration therefore prevents back-winding of the spindle **42** under low loads caused by the cartridge bung **18** but does not add to the dispense force once this dispense force has increased above a certain threshold level.

FIG. **4** illustrates the dose setting mechanism **4** of FIG. **3** with the cartridge holder **6** rotated to release a connection type between the housing **40** of dose setting mechanism **4** and the cartridge holder **6**. In one arrangement, this connection type **22** is a bayonet connection. However, those of ordinary skill in the art will recognize that other connection types **22** may be used as well such as threads, snap locks, snap fits, luer locks and other similar connection types. In the arrangement illustrated in FIGS. **3**-**5**, by rotating the cartridge holder **6** with respect to housing **40**, features that were initially acting on the spring plate **54** to compress the main biasing means **60** through apertures in the pressure plate **64**, rotate so that they now release this force created by the main biasing means **60**. This allows the spring plate **54** to move in a distal direction until the spring plate **54** contacts the spindle nut **66** on an inside face of the spindle nut **66**.

In this second condition, the previous discussed Gap "A" (from FIG. **3**) has now been reduced to a Gap "C" (as seen in FIG. **4**). In this manner, the relative high axial force from the main biasing means **60** acts through the spring plate **54** to the spindle nut **66** and from the spindle nut **66** through the spindle guide **48** to the pressure plate **64**. This relative high axial force from the main biasing means **60** is sufficient to prevent the spindle guide **48**, and hence spindle **42**, from rotating. After sufficient rotation of the cartridge holder **6**, the cartridge holder **6** disengages from the connection type **22** with the housing **40**. The cartridge holder **6** is then driven in an axial direction away from the housing **40** by the main biasing means **60** (i.e., in a distal direction). However, during this movement, the main spring **60** continues to load the cartridge holder **6** through the spindle guide **48** and therefore the spindle **42** is prevented from rotation. As the spindle **42** is also threaded to the first driver portion **44**, the first driver portion **44** is also pulled axially in a distal direction and in this manner becomes disengaged from the second driver portion **46**. The second driver portion **46** is axially fixed and is prevented from rotation. In one arrangement, the second driver portion **46** is prevented from rotation by clicker elements and prevented from axial movement by its axial coupling to the number sleeve.

FIG. **5** illustrates the dose setting mechanism illustrated in FIG. **3** in a third position, that is, with the cartridge holder **6** removed. As the cartridge holder **6** is removed from the housing **40**, the bayonet features shown in FIG. **5** (illustrated as round pegs extending radially inwards on inside of inner housing), limit travel of the pressure plate **64** but allows Gap "C" (as shown in FIG. **4**) to increase to a wider Gap "D" (as shown in FIG. **5**). As a result, Gap "E" develops. Gap "E" removes the high spring force created by the main biasing means **60** from the spindle guide **48**. The dose setting mechanism **4** in FIG. **4** is now ready to be rest.

To reset this dose setting mechanism **4**, a user retracts the spindle **42** in a proximal direction back into the housing **40** by pushing on the distal end **43** of the spindle **42**. Therefore, during this re-setting step of the dose setting mechanism **4**, as the spindle **42** is pushed back into the dose setting mechanism **4**, the movement of the spindle **42** causes the spindle nut **66** to move back against a light spring force created by the second biasing means **70**. This movement releases the axial load and hence resistance to rotation from the spindle guide **48**. Therefore, as the dose setting mechanism **4** is reset by the spindle **42** rotating back into the dose setting mechanism **4**, the spindle guide **48** also rotates.

As the spindle **42** is pushed back further into the dose setting mechanism **4**, the spindle **42** rotates through the spindle nut **66**. As the first driver portion **44** is de-coupled from the second driver portion **46**, the first driver portion **44** rotates (with the flexible elements **102**, **103** running on a conical surface groove **90** formed by the first annular ring **91** on the second half of the dial sleeve **46**, FIGS. **5** and **6**). This accommodates the axial and rotational movement of the spindle **42**.

As the first driver portion **44** rotates during reset, first driver portion **44** also re-sets the dose nut. More specifically, as the first driver portion **44** rotates, the dose nut which is not rotatable since it is splined to an inner surface of the housing **40**, traverses along the helical groove **62** provided along an outer surface of the first driver portion **44** and traverses back to an initial or starting position. In one preferred arrangement, this starting position of the dose nut resides along the first radial **56** flange of the first driver portion **44**.

After the dose setting mechanism **4** has been reset, the dose setting mechanism **4** must be re-connected to the cartridge holder **6**. When re-connecting these two components, the process generally works in reverse. However, this time the axial compression of the main spring **60** causes the first driver portion **44** to re-engage with the second driver portion **46**. In this manner, the flexible elements re-engage with the second annular ring **94** on the second driver portion **46**.

FIG. **6** illustrates a first arrangement of the second driver portion **46** and the first driver portion **44** illustrated in FIG. **3**. As shown in FIG. **6**, second driver portion **46** is generally tubular in shape and comprises a first annular groove **90** at a distal end of the second driver portion **46**. The first annular groove **90** comprises a conical face **91**. The second driver portion further comprises a second annular groove **94** and at least one spline **96** positioned along a surface of the second driver portion. The first driver portion **44** is also generally tubular in shape and comprises a first and a second flexible element **102**, **103** and a plurality of spline recesses **100**. The plurality of recesses **100** releasably connect the longitudinal spline **96** of the first driver portion **44** to second driver portion **46** when both first and second driver portions **44**, **46** are pushed axially together so that they releasably engage one another. When pushed together, the flexible elements **102**, **103** of the first driver portion **44** are pushed over the first annular groove **90** of the second driver portion **46** and then stop when the flange **80** of the second driver portion abuts the first axial flange **56** of the first driver portion **44**.

The first driver portion **44** also includes a plurality of ratchet features **104**. These ratchet features **104** are provided at a distal end **106** of the first driver portion **44**. These ratchet features **104** engage similar ratchet features on the spring plate **25** which are splined to the housing **2**. (See e.g., FIGS. **3-5**) At the end of the resetting step, these ratchet features engage one another so as to prevent the first driver portion **44** from rotating thereby ensuring that as the spindle **42** is reset further, the first driver portion moves axially to re-engage the second driver portion **46** rather than rotate on the conical face **90**. These features also orientate the spring plate **25** relative to the second driver portion **44** so that the two driver portions **44**, **46** engage easily during assembly or after reset. Therefore, these ratchet features also prevent the coupling features **96**, **100** from clashing with one another.

A second arrangement of resettable dose setting mechanism is illustrated in FIGS. **8-10**. FIG. **8** illustrates a section view of a second arrangement of a dose setting mechanism **200**. Those of skill in the art will recognize that dose setting mechanism **200** may include a connection mechanism for releasably connecting to a cartridge holder, like the cartridge holder **6** illustrated in FIG. **2**. However, as those of ordinary skill in the art will recognize, the dose setting mechanism may also include a permanent connection mechanism for permanently connecting to a cartridge holder. FIG. **9** illustrates a portion of the dose setting mechanism illustrating the driver operation. FIG. **10** illustrates a close up view of the coupling between the first driver portion and the second driver portion illustrated in FIG. **9**. The second arrangement of the dose setting mechanism **200** operates in generally a similar fashion to the first arrangement of the dose setting mechanism **4** illustrated in FIGS. **1-5**.

With reference to FIGS. **8-10**, the dose setting mechanism **200** comprises a dose dial grip **202**, a spring **201**, an outer housing **204**, a clutch **205**, a driver **209**, a number sleeve **206**, and an inner housing **208**. Similar to the driver **30** illustrated in FIGS. **2-5**, driver **209** of dose setting mechanism comprises a first driver portion **207** and a second driver portion **212**. In one arrangement, the first driver portion **207** comprises a first component part **210** and a second component part **211**. Alternatively, the first driver portion **207** is an integral component part.

Where the dose setting mechanism **200** illustrated in FIGS. **8** and **9** comprises a resettable dose setting mechanism, the driver **209** is de-coupled from the dose setting mechanism **200** when the first driver portion **207** is pushed axially towards the second driver portion **212** (i.e., pushed in a proximal direction). In one arrangement, this may be achieved by pushing axially on a distal end of the spindle **214**. This does not require any mechanism associated with removal of a cartridge holder. The mechanism is also designed such that the first and second driver portions **207**, **212** and the spindle

214 remain locked together rotationally during dose setting as well as during dose administration.

An axial force on the spindle 214 causes the spindle 214 to rotate due to its threaded connection to the inner housing 204. This rotation and axial movement of the spindle 214 in turn causes the first driver portion 207 to move axially towards the second driver portion 212. This will eventually de-couple the coupling elements 250 between the first driver portion 207 and second driver portion 212. This can be seen from FIG. 11.

This axial movement of the first driver portion 207 towards the second driver portion 212 results in certain advantages. For example, one advantage is that the metal spring 201 will compress and will therefore close the Gap A illustrated in FIGS. 8-10. This in turn prevents the clutch 205 from disengaging from the clicker 220 or from the number sleeve 206. The second driver portion 212 is prevented from rotating since it is splined to the clutch 205. The clicker 220 is splined to the housing 204. Therefore, when the Gap A is reduced or closed up, the second driver portion 212 cannot rotate relative to either the housing 204 or the number sleeve 206. As a consequence, the number sleeve 206 cannot rotate relative to the housing 204. If the number sleeve 206 is prevented from rotating then, as the spindle 214 is retracted back into the dose setting mechanism 200 and thereby re-set, there will be no risk of the number sleeve 206 being pushed out of the proximal side of the dose setting mechanism 200 as a result of a force being applied on the spindle 214.

Similarly, when the drug delivery device is being dispensed, the user applies an axial load to a dose button 216. The dose button 216 is axially coupled to the clutch 205 and this prevents relative axial movement. Therefore, the clutch 205 moves axially towards the cartridge end or the distal end of the dose setting mechanism 200. This movement disengages the clutch 205 from the number sleeve 206, allowing for relative rotation while closing up the Gap A.

As described above, this prevents the clutch 205 from rotating relative to the clicker 220 and hence relative to the housing 204. However, in this scenario, it also prevents the coupling between the first driver portion 210 and the second driver portion 212 from becoming disengaged. Therefore, any axial load on the spindle 214 only disengages the first and second driver portions 210, 212 when the dose button 216 is not axially loaded. This, therefore, does not happen during dispense.

With the dose setting mechanism 200, as a user dials a dose with the dose dial grip 202, the metal spring 201 is selected to be strong enough to maintain engagement of both clutched couplings: the clutched coupling between the clutch 205 and the number sleeve 206 and clutched coupling between the first driver portion 207 and second driver portion 212.

FIG. 11 shows in detail of a first arrangement of the first driver portion 207 and the second driver portion 212 illustrated in FIG. 8. As illustrated in FIG. 11, the second driver portion 212 is generally tubular in shape and comprises at least one drive dog 250 located at a distal end of the second driver portion 212. The first driver portion 207 also has a generally tubular shape and comprises a plurality of recesses 252 sized to engage with the drive dog 250 on the second driver portion 212. The construction of the drive dog and recesses allow disengagement with the drive dog 250 when the first and second driver portions are axially pushed together. This construction also creates a rotational coupling when these components are sprung apart. A dose limiter could be provided on first driver portion 207 and operate similarly to the dose limiter 38 illustrated in FIG. 3.

In this arrangement, the first driver portion 207 comprises a first portion 211 that is permanently clipped to a second portion 210. In this arrangement, the first portion 211 comprises the drive dogs 252 and the second component 210 includes the outer groove for the last dose nut as well as an internal groove 254. This internal groove 254 is used to connect to the spindle 214 and drives the spindle 214 during dose administration.

In the illustrated arrangement, the internal groove 254 comprises a part helical groove rather than a complete helical groove. One advantage of this arrangement is that it is generally easier to manufacture.

As may be seen from the arrangement illustrated in FIGS. 8-10 there is, in addition, certain feature enhancements over the dose setting mechanism 4 illustrated in FIGS. 3-5. These can be added independently of the ability to re-set the device to replace an empty cartridge with a new cartridge. These enhancements, therefore, are relevant to both a re-settable and non-re-settable dose setting mechanism.

One of the advantages of both arrangements illustrated but perhaps in particular in the arrangement illustrated in FIGS. 8-11 is that the dose setting mechanism 200 has a reduced number of components over other known dose setting mechanisms. In addition, apart from the metal coil spring 201 (see FIGS. 9 and 10), all of these components making up the dose setting mechanism 200 may be injection molded using inexpensive and unsophisticated tooling. As just one example, these components making up the dose setting mechanism 200 may be injection molded without the expense and sophistication of a rotating core.

Another advantage of a dose setting mechanism 200 comprising an inner housing 208 such as that illustrated in FIGS. 8-11 is that the dose setting mechanism 200 can be designed, with a slight modification, as a drug delivery device platform that is now capable of supporting both re-settable and non-resettable drug delivery devices. As just one example, to modify the re-settable dose setting mechanism 200 variant illustrated in FIGS. 8-11 into a non-resettable drug delivery device, the first driver portion 211 and 210 and the second driver portion 212 can be molded as one unitary part. This reduces the total number of drug delivery device components by two. Otherwise, the drug delivery device illustrated in FIGS. 8-11 could remain unchanged.

The illustration in FIGS. 8-11 shows an inner housing 208 having a length "L" 230 generally similar in overall length to the dose setting mechanism 200. As will be described, providing the inner housing 208 with a length of "L" has a number of advantages over other known dose setting mechanisms that do not utilize an inner body or an inner body having a length generally equal to that of the length of a dose setting mechanism.

The inner housing 208 comprises a groove 232 provided along an external surface 234 of the inner housing. A groove guide 236 provided on an inner surface 238 of the number sleeve 206 is rotatably engaged with this groove 232.

One advantage of this dose setting mechanism 200 utilizing the inner housing 208 is that the inner housing 208 can be made from an engineering plastic that minimizes friction relative to the number sleeve 206 groove guide 236 and the groove 232. For example, one such an engineering plastic could comprise Acetal. However, those of ordinary skill in the art will recognize that other comparable engineering plastics having a low coefficient of friction could also be used. Using such an engineering plastic enables the material for the outer housing 204 to be chosen for aesthetic or tactile reasons with no friction related requirements since the outer housing 204 does not engage any moving components during normal use.

The inner housing 208 also enables the number sleeve 206 to be provided with a helical groove on an inner surface 238 of the number sleeve **206**, rather than providing such a helical groove on an external surface **240** of the number sleeve **206**. Providing such an internal groove results in a number of advantages. For example, this results in the advantage of providing more surface area along the outer surface **240** of number sleeve **206** so as to provide the scale arrangement **242**. More number sleeve surface area may be used for drug or device identification purposes. Another advantage of providing the helical groove **236** on the inner surface **238** of the dial sleeve **206** is that this inner groove **236** is now protected from dirt ingress. In other words, it is more difficult for dirt to become logged in this inner groove interface than if the groove were provided along the outer surface **240** of the number sleeve **206**. This feature is particularly important for a re-settable drug delivery device which will have to function over a much longer period of time compared to a non-resettable device.

The effective driving diameter (represented by 'D') of the grooved interface between the number sleeve **206** and the inner housing **208** is reduced compared to certain known drug delivery devices for the same outer body diameter. This improves efficiency and enables the drug delivery device to function with a lower pitch (represented by 'P') for this groove and groove guide connection. In other words, as the helix angle of the thread determines whether when pushed axially, the number sleeve will rotate or lock to the inner body wherein this helix angle is proportional to the ratio of P/D.

The number sleeve **206** can be made the length of the mechanism "L" **230** rather than having to split this length into the space required for the number sleeve **206** and a space required for a clicker and a dose limiter. One advantage of this configuration is that it ensures a good axial engagement between the number sleeve **206** and the outer housing **204**. This improves the functionality (and perceived quality) of the dose setting mechanism when a user uses the drug delivery device to dial out a maximum settable dose. FIG. **13** illustrates the dose setting mechanism **200** dialed out to a maximum settable dose of 80 International Units ("IU").

Another advantage is that it enables the scale arrangement **242** to be hidden within the outer housing **204** even when the number sleeve **206** is fully dialed out as may be seen from FIG. **13**. However, the design does not limit the position of the window **14** to that shown in FIG. **8** but allows this window **14** to be positioned at near the dose dial grip **202** of the device. However, in arrangements illustrated in FIGS. **12** and **13**, the scale arrangement **242** will only be visible by way of the window **14**. Also the driver **209** (whether made in two portions or just one unitary component) can be made with a plain internal through hole plus a thread form that can be molded with axially moving core pins. This avoids the disadvantage of a driver having an internal thread with more than one turn and therefore requires a core pin to be rotated out several turns during a de-molding process.

One potential disadvantage of utilizing a dose setting mechanism comprising the inner housing **208** is that the use of the inner housing **208** adds a component part to the overall dose setting mechanism **200**. Consequently, this inner housing **208** will tend to increase the overall wall thickness that must be designed to fit between the clutch **205** and number sleeve **206**. One way to work around this design issue, as illustrated in FIG. **8**, is to reduce the diameter of the clutch **205** and number sleeve **206**. This in turn can be achieved because the thread form between the driver **209** and the spindle **214** comprises a male internal feature on the driver **209** and a female external groove form on the spindle **214** that is overlapping with (on a similar diameter with) the spindle groove form that interfaces with the groove along the outer surface **234** of the inner housing **208**.

The overlapping of groove forms on the spindle **214** reduces the effective diameter of the thread interface with the driver **209**. This also reduces the potential outer diameter of the driver **209** enabling the addition of the inner housing **208** without increasing the overall outer diameter of the dose setting mechanism **200**. Another added benefit of the reduced effective diameter of the thread interface with the driver **209** is that it improves efficiency of the drug delivery device during dispense, as explained above.

The window **244** through which the scale arrangement **242** may be viewed can either be just an aperture in the outer housing **204** or can include a clear lens or window designed to magnify the scale arrangement (i.e., printed or laser marked dose numbers) along a portion of the outer surface **240** on the number sleeve **206**. The connection of a cartridge holder into the outer housing **204** can be achieved using either a screw or bayonet type connection. Alternatively, any similarly robust design used in drug delivery devices requiring a largely cylindrical part to be removed and then reattached could also be used.

The dose setting mechanism discussed in the previous figures may be utilized either for a drug delivery device comprising a fixed maximum dose setting feature or an adjustable or variable maximum dose setting feature. In order to design a drug delivery device having a dose setting mechanism that allows for an adjustable or variable maximum dose stop, at least one movable member is required. Preferably, this movable member may be moved from a first position defining a first maximum dose to a second position defining a second maximum dose. In this manner, the value of the maximum dose may be varied or adjusted by changing the position of the movable member relative to the housing.

As described below, a device and device components are described that illustrate a drug delivery device where, if the user pulls axially on the number sleeve and displaces this number sleeve axially when a maximum dose stop component is engaged, then the user is able to adjust the position of the additional part(s) relative to an inner housing. This may be accomplished by rotating the number sleeve in this displaced position to thereby alter the maximum dose stop position. Based on a construction of the ratchet teeth of the device (and as will be described in greater detail below), this may be accomplished by rotating the number sleeve either in the clock-wise or the counter clock-wise.

For example, FIG. **14** illustrates one arrangement of an inner housing **260** that may be used with a drug delivery device having a variable maximum dose setting feature. Such an inner housing **260** may have a generally tubular shape and be used with a dose setting mechanism, such as the dose setting mechanism illustrated in FIG. **8**. In the arrangement illustrated in FIG. **14**, the inner housing **260** comprises a distal end **262** and a proximal end **264**. In one preferred arrangement, the inner housing **260** has a length "L" generally similar to the length of the dose setting mechanism, such as the dose setting mechanism illustrated in FIG. **8**.

Referring back to FIG. **14**, a male guide **266** is provided along an outer surface **268** of the inner housing **260**. In a preferred arrangement, this male guide **266** extends along the length "L" of the external surface **268** of the inner housing **260**, although other arrangements may also be utilized. In one preferred arrangement, this male guide **266** defines a plurality of grooves (such as grooves **270***a*, **270***b*, and **270***c*) along the outer surface **268** of the inner housing **260**. It is the plurality of grooves **270** (*a-c*) that engage a male guide of the number sleeve, such as the number sleeve **206** illustrated in FIG. **8**.

Those of ordinary skill in the art will recognize, however, that these male and female guides can be inter-changed.

Preferably, along the outer surface **268** of the inner housing **260** and along a set of the plurality of grooves **270** (*a-c*), a plurality of ratchet teeth **272** (*a-c*) are provided. As just one example, FIG. **15** illustrates one close up view of the inner housing **260** illustrated in FIG. **14** where these ratchet teeth are illustrated in greater detail. In the arrangement illustrated in FIG. **15**, four sets of a plurality of ratchet teeth **272** (*a-d*) are provided along a first portion of the inner housing **260**. However, those of ordinary skill in the art will recognize, alternative ratchet teeth arrangements could also be used. As just one example, one alternative ratchet teeth arrangement could be provided only near the proximal end **264** of the inner housing **260**. As another example, yet another alternative ratchet teeth arrangement could be provided along the entire outer surface of the inner housing **260**.

FIG. **16** illustrates a stop component **286** that may be used with the inner housing **260** illustrated in FIGS. **14** and **15**. The stop component **286** comprises a first maximum dose stop face "A" **288** and a second face "B" **290**. As will be described below, the second face "B" **290** may be used for decreasing a maximum stop position of the stop component **286**. The stop component **286** further comprises a first or an inner surface **292** and a second or outer surface **294**. Preferably, the first or inner surface **292** includes a plurality of internal features **296**. In one arrangement, these internal features **296** are shaped to releasably engage a first set **298** of the plurality of the ratchet teeth **272** (*a-c*) provided along the outer surface **268** of the inner housing **260**.

For example, FIG. **17** illustrates the stop component **286** of FIG. **16** releasably engaged in a first maximum stop position **299** along the outer surface **268** of the inner housing **260** illustrated in FIG. **15**. Although only one stop component **286** is illustrated in FIG. **17**, a second or a third stop component could also be included. One advantage of including two or more stop components along the outer surface **294** of the inner housing **260** is that the overall stop strength of the dose setting mechanism may be increased. As just one example, if the outer surface of the inner housing has a twin start grooves spaced by 180° rotation, then one stop component can be used within each groove.

In one preferred arrangement, the stop component **286** wraps around the outer circumference of the inner housing **260** by more than 180 degrees. This enables the stop component **286** to clip or snap onto the inner housing **260**.

FIG. **18** illustrates a portion of a number or dial sleeve **300** that may be used to releasably engage the inner housing **260** illustrated in FIG. **14**. The number sleeve **300** is generally of a tubular shape and is similar in operation to the number sleeve **206** illustrated in FIG. **8**. The dial sleeve **300** comprises a generally smooth outer surface **301** and an inner surface **303**. As discussed previously, a scale arrangement may be provided along this generally smooth other surface **301**.

The dial sleeve **300** further comprises a proximal end **304** and a distal end **302**. Near the distall end **304**, the dial sleeve **300** comprises a maximum dose stop face "A" **306**. In addition, dial sleeve **300** further comprises a face "B" **310**. As will be described below, during a maximum dose setting step, the face "B" **310** engages the second face "B" **290** of the stop component **286** so as to decrease the maximum dose stop position of the stop component **286**.

The dial sleeve **300** further comprises a main drive thread **312**. This main drive thread **312** engages the groove **274** of the inner housing **260** during a dose setting step and a dose dispense step. A flexible element **308** is also provided near the distal end **304** of the dial sleeve **300**.

FIG. **19** illustrates the dial sleeve of FIG. **18** engaged to the inner housing **260** of FIG. **14** in a dose setting position. In this dial sleeve position, the distall end **304** of the dial sleeve **300** is illustrated. The stop component **286** is shown as being prevented from disengaging from the inner housing **260** by the distall end **304** of the dial sleeve **300** because this distal end **304** is overlapping with the stop component **286**. In this position, the dose setting mechanism of the drug delivery device may be used to set a dose having a first maximum dose that is defined by the position of the stop component **286** along the groove **270** of the inner housing **260**.

In order for this stop component **286** to be moved to a second maximum dose position, the stop component **286** must be allowed to disengage from the inner hosing **260**. This may occur by moving or pulling the dial sleeve **260** in a proximal direction so that the distal end **301** of the dial sleeve **300** moves proximally relative to the inner housing **260** and the dial sleeve resides in a second position to define a second maximum dose stop.

This second position of the dial sleeve **300** is illustrated in FIG. **20**. As can be seen from FIG. **20**, the dial sleeve **260** has been moved in a proximal direction. By moving the dial sleeve **300** proximally relative to the inner housing **260**, this allows access to the stop component **286** so that it can be rotated to a second position. FIG. **21** illustrates the dial sleeve **300** in a position prior to engagement of the first maximum stop face **288** "A" of the stop component **286** with the "A" maximum dose stop face **306** of the dial sleeve **300**. FIG. **22** illustrates the dial sleeve illustrated in FIG. **21** once the maximum dose has been dialed. In this position, the first maximum stop face **288** "A" of the stop component **286** engages the "A" maximum dose stop face **306** of the dial sleeve **300**. In other words, FIG. **22** illustrates the position of the dial sleeve **300** with respect to the inner housing **260** when the maximum variable dose has been dialed. If the dial sleeve **300** is pulled in a proximal direction, the second maximum stop face "B" **290** of the stop component **286** engages the face "B" **310** of the dial sleeve **300**. The dose setting mechanism is now in a state where the first set maximum dose (i.e., as defined by a first position of the stop component **286** along the inner housing **260**) may be changed to a new or second set maximum dose (i.e., as defined by a second position of the stop component **286** along the inner housing **260**).

FIG. **23** illustrates a first step of setting a variable maximum dose with the dial sleeve illustrated in FIG. **22**. In FIG. **23**, the dial sleeve **300** is pulled back in a proximal direction so as to engage the stop faces "B." Engagement of these stop faces allows rotation of the dial sleeve **300**. Depending upon the orientation of the respective ratchet teeth, rotation of the dial sleeve in either the clock-wise or the counter clock-wise direction may increase the variable maximum dose. In this position, rotation of the dial sleeve will also rotate the stop component **286** relative to the inner housing **260**. In this proximal position of the dial sleeve **300**, the flexible element **308** on the distal end **302** of the dial sleeve **300** interferes with the inner housing **260**. This provides a spring like force to counteract the user pulling proximally back on the dial sleeve **300**.

FIG. **24** illustrates dial sleeve **300** of FIG. **23** after the dial sleeve has been rotated. As the user rotates the dial sleeve **300** in this pulled back or proximal position, because the inner face **303** of the dial sleeve does not overlap the outer face **294** of the stop component, the dial sleeve **300** may now be rotated to adjust (i.e., rotate) the stop component **286** to a new maximum dose position: a position that either increases or decreases the previously set maximum dose.

During rotation of the dial sleeve **300** and concurrently rotation of the engaged stop component **286**, the stop component **286** flexes out radially while bumping over the ratchet teeth **272** (*a-c*) provided along the outer surface **268** of the inner body **260**. Interference of flexible element **308** of the dial sleeve **300** with inner housing **260** is more clearly shown in FIG. **24**. Preferably in use, the flexible element **308** flexes radially outwards to relieve interference.

FIG. **25** illustrates a third position of the dial sleeve **300** illustrated in FIG. **18**. In this position, when the user releases the axial force pulling back on the dial sleeve as illustrated in FIG. **24**, the flexible elements **308** return the dial sleeve **300** in the distal direction. In this position, the stop component **286** is prevented from rotating since the proximal end of the dial sleeve **300** now overlaps the stop component **286**. FIG. **26** illustrates one preferred arrangement of a cross-sectional view of the dial sleeve **300**, the stop component **286**, and the inner housing **260** illustrated in FIG. **25**. As can be seen from FIG. **26**, the ratchet teeth **272** (*a-c*) of the inner housing **260** engage the internal features **296** of the stop component **286**. In particular, the ratchet tooth **272**(*a*) comprises a leading edge **322** and a following edge **324**. These edges **322**, **324** define two angles: angles "X" **320** and angle "Y" **340**. In one arrangement, the angles "X" **320** and "Y" **340** can be chosen so that the stop component **286** can be rotated in both directions so as to either increase or decrease the previously set maximum dose as shown.

In one alternative arrangement, angle "Y" **340** can be reduced by modifying the following edge **324** of ratchet tooth **272** (*a*). This would prevent the stop component **286** from rotating in a certain direction. In this manner, the maximum dose can only be reduced and could not be increased. One advantage of such an arrangement is that the maximum settable dose may not be overridden by a child or other patient. Alternatively, angle "Y" **340** could be reduced by modifying the first leading edge **328** of the stop component **286**. Similarly, the follower edge **324** of the ratchet tooth **272** (*a*) could also be modified. One advantage of this configuration is that if, for example, a maximum dose range of 0-25 UI has been established, the maximum dose would be adjustable up or down within this specific range. However, the stop component **286** could not be rotated so as to set a maximum dose greater than this specified range (i.e., greater than 25 UI), but rather could only be rotated so as to decrease the maximum dose.

One advantage of this arrangement of providing a maximum dose range is that the dose stop also has the option to pre-define a region over which the user can re-adjust the maximum dose. Such an arrangement may be important in reducing risk of an overdose for a child or an elderly patient having limited visibility or limited knowledge of drug delivery device operation.

Alternatively, the ratchet teeth may be configured such that when the dial sleeve w is pulled back, the user can either rotate the dial clockwise or counter-clockwise. Therefore, if the ratchet teeth between the inner housing and the stop component are configured to be symmetric, or rather if the angles X **320** and Y **340** of FIG. **26** are both significantly greater than 0°, then the dial sleeve will increase the maximum dose when it is rotated clockwise and will decrease the maximum dose when rotated anticlockwise. Alternatively, if the angle Y approaches 0° then this will essentially block the adjustment of the stop component in one direction but will allow rotation in the other direction, thereby allowing the user to just to decrease the maximum dose. Exemplary embodiments of the present invention have been described. Those skilled in the art will understand, however, that changes and modifications may be made to these embodiments without departing from the true scope and spirit of the present invention, which is defined by the claims.

The invention claimed is:

**1**. A drug delivery device having a variable maximum dose, said device comprising:

a housing, said housing comprising
  a helical groove, and
  a plurality of ratchet teeth;

a dial sleeve rotatably coupled to said helical groove of said housing, and

a first stop component engaging a first set of said plurality of ratchet teeth of said housing, said first stop component located at a first stop location along an outer surface of said housing defining a first maximum dose of said drug delivery device;

wherein said dial sleeve moves said first stop component to a second set of said plurality of said ratchet teeth so that said first stop component moves along said outer surface of said housing to a second stop location, said second stop location defining a second maximum dose of said drug delivery device, and

wherein said first stop component is user-adjustable (i) from said first stop location to said second stop location and (ii) from said second stop location to said first stop location, such that the variable maximum dose for the drug delivery device can be increased and decreased.

**2**. The invention of claim **1** wherein rotational movement of said dial sleeve moves said first stop component to said second stop position location.

**3**. The invention of claim **2** wherein when said dial sleeve is moved to said first position stop location, a first stop face of said dial sleeve engages said maximum dose stop face of said first stop component and thus defines a first maximum dose.

**4**. The invention of claim **3** further comprising:

a second stop face of said dial sleeve, said second stop face engages said maximum dose stop position face and moves said first stop component along said inner housing such that said internal features of said first stop component engage a second set of said plurality of ratchet teeth of said inner housing to define a second maximum dose.

**5**. The invention of claim **1** wherein clockwise rotational movement of said dial sleeve moves said first stop component to said second stop position location.

**6**. The invention of claim **1** wherein counter clockwise rotational movement of said dial sleeve moves said first stop component to said second stop position location.

**7**. The invention of claim **1** wherein dial sleeve may be rotated in either a clockwise or a counter-clockwise direction.

**8**. The invention of claim **1** wherein said stop component comprises a plurality of internal features that releasably engage said first set of said plurality of external ratchet teeth,

a maximum dose stop face; and

a maximum dose stop position face.

**9**. The invention of claim **1** wherein said first maximum dose is greater than said second maximum dose.

**10**. The invention of claim **1** further comprising a second stop component.

**11**. The invention of claim **1** wherein said dial sleeve includes a numeric scale, said scale viewable by a user of the drug delivery device and representative of a dose that may be set by said pen type drug delivery device.

**12**. The invention of claim **1** wherein said first position stop location defines a maximum dose range, said maximum dose range being a pre-defined region over which said user can re-adjust a maximum dose.

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