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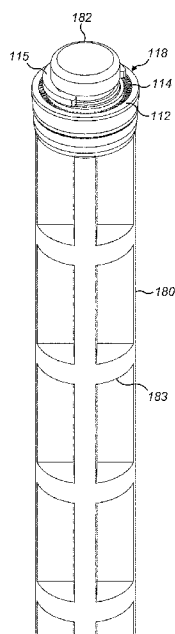


FIG. 6

(57) Abstract: Provided is a trainer device (101) for an auto-injector comprising a housing (120,122,124); within said housing (120,122,124), a barrel (110); within said barrel (110), a plunger (118); in communication with said plunger (118), a plunger rod (180); and a source of drive (148) capable of providing drive force to said plunger rod (180) to move said plunger (118) within said barrel (110), wherein said plunger (118) comprises a frictional component (112,114) for frictionally damping movement of the plunger (118) within the barrel (110). In embodiments, the frictional component (112,114) comprises a circular jacket (112) that encloses a radial spring (114). Also provided is a recharger device (190) for the trainer device (101) and an assembly for use in a trainer device (101).



Trainer device for an auto-injector

5 Background

The present invention relates to a trainer device that is suitable for training a user in how to use an auto-injector device that is arranged for receipt of a syringe for use in the injected delivery of a drug formulation to a patient.

- 10 It is well-known to use syringes for the delivery of injectable liquid drug formulation to a patient. Syringes rely on puncturing of the patient's skin by a hollow needle through which the injectable liquid drug (e.g. in solution or suspension form) is delivered to the muscle or tissue of the patient. Typically, syringes comprise a barrel for containing a volume of the liquid drug; a hollow needle defining a needle tip for dispensing of the liquid; and a plunger
15 that is axially movable within the barrel.

It is also well-known to provide auto-injectors for use with syringes. Such auto-injectors typically comprise a housing comprising one or more housing parts for housing the syringe and an actuating mechanism, which is triggered in use, to allow for automatic delivery of the
20 liquid drug formulation from the syringe. Actuating mechanisms typically comprise a source of drive (e.g. a strong spring) for drivable movement of a drive transfer element (e.g. a plunger rod) that transfers drive to the plunger for axial movement thereof within the syringe barrel. Such movement of the plunger results in the plunger driving of the liquid drug from the syringe barrel to the hollow needle for dispensing to the patient via the needle tip thereof.
25

The majority of auto-injectors are configured as a single device that incorporates both syringe and actuating mechanism in the same device housing. It is common for such devices to be arranged to be disposable such that following injected delivery of the liquid drug formulation, and typically also following retraction of the syringe back into the housing, the
30 whole device may be safely disposed of.

One problem associated with the use of such auto-injectors is to safely and conveniently allow for patient training in the use thereof. For such training purposes it is undesirable to employ a device that comprises a loaded syringe. It may be appreciated to be wasteful to fire typically expensive, drug formulation from a syringe during training operations. In addition, 5 for safety reasons, it is undesirable for a syringe needle to be presented at all during such training operations. In part-solution of this problem, Applicant has appreciated the need for a trainer device for an auto-injector that has for all practical purposes, a similar outward form to that of the auto-injector, but which comprises no syringe component.

10 For such training purposes it is also desirable to employ a trainer device that effectively mimics the operation of an auto-injector device, particularly in terms of the feel and timing of the device firing operation. Where the auto-injector is arranged for delivery of a viscous drug formulation, the delivery of drug from the syringe may take several seconds, perhaps as much as 5 to 15 seconds where a highly viscous drug formulation is employed. It is thus, 15 desirable that the trainer device has a similar timing profile for its (mimicked 'drug delivery') firing operation. In part-solution of this problem, Applicant has appreciated that the trainer device can be provided with a plunger having a frictional component (acting in some ways as a pseudo or mock 'syringe plunger') component that interacts with the inner wall of a hollow barrel (acting in some ways as a pseudo or mock 'syringe barrel') component to provide the 20 required mimicking action.

It is desirable that such a trainer device is re-useable and thus, may be employed in plural training operations, thereby giving the user sufficient opportunity to learn how to use the auto-injector set up. This requirement for re-use of the trainer device is different from that of 25 the prescription auto-injector itself, which is generally arranged for single use and then disposal. Thus, Applicant has recognized the need for the trainer device to be provided with a reset mechanism to allow it to 'mimic' both pre-use and post-use states of the auto-injector and for re-setting thereof from a post-use to a pre-use state. The reset mechanism desirably needs to be of simple operation since many of the intended users of auto-injector devices 30 have compromised manual dexterity (e.g. arthritic hands).

Applicant's PCT publication no. WO2016/046131 A1 describes a prior art auto-injector. The trainer device herein is particularly, suitable for training a user in how to use an auto-injector of this type. US patent publications nos. US2014/0264205 A1 and US2014/0276568 A1 describe a trainer device for use in training a user in how to use an auto-injector device and a
5 recharger device therefor.

According to one aspect of the present invention there is provided a trainer device for an auto-injector comprising a housing; within said housing, a barrel; within said barrel, a plunger; in communication with said plunger, a plunger rod; and a source of drive capable of
10 providing drive force to said plunger rod to move said plunger within said barrel, wherein said plunger comprises a frictional component for frictionally damping movement of the plunger within the barrel.

These and other embodiments of the present invention are set forth in the later description,
15 which describes for illustrative purposes only various embodiments thereof.

In relation to aspects of the trainer device for an auto-injector described herein the term 'forward' is used to mean that end of the device, which locates closest to the injection site in use and the term 'rear' or 'rearward' is used to mean that end of the device, which locates
20 furthest from the injection site in use. The term axial herein is used by reference to an axis, which runs from the forward end of the device to the rearward end of the device, and which typically corresponds to the axis of the barrel in the trainer device.

There is provided a trainer device for use in training a user in how to use an auto-injector
25 device. Such an auto-injector device is typically arranged for use with a syringe that contains a liquid drug formulation. The syringe is arranged to be suitable for use in the injected delivery of the liquid drug formulation to a patient. The trainer device comprises no syringe component.

The trainer device comprises a housing, which defines a housing cavity. The housing cavity is arranged for receipt of a barrel and is therefore typically sized and shaped for this purpose. The housing may be arranged as a single part or a multi-part (e.g. two part) housing assembly. In embodiments, the housing has at least one window (i.e. window opening or
5 aperture) defined therein.

The trainer device comprises a barrel, which locates within the housing. In embodiments, the barrel locates within the housing such as to be in fixed axial relationship to it. In embodiments, one or more positioning and/or retaining features are provided to the housing
10 for positioning and/or retaining the barrel in the housing cavity. In embodiments, the one or more positioning and/or retaining features comprise one or more snap features provided interiorly to the housing.

The trainer device comprises a plunger, which locates within the barrel. The plunger is
15 axially movable within the barrel. The barrel is typically comprised of a relatively hard plastic polymer such as hardened polyethylene, polycarbonate or cyclic olefin polymers.

The trainer device comprises a plunger rod, which is in communication with said plunger for providing plunging force to the plunger.
20

The housing and any inner housing sub assembly thereof is shaped to define a housing cavity within which the barrel is receivable. The housing cavity is typically cylindrical in form, thereby matching the typically cylindrical outer profile of the barrel. The housing cavity may be further shaped with any manner of grooves, indentations or other shaping or surface
25 details to define a 'lock and key' relationship between the housing and any inner housing sub assembly thereof and the barrel. Colour guides, arrows and any other surface markings may also be employed.

Typically, the housing and /or any inner housing sub assembly thereof is provided with a barrel receiving part for receiving the barrel; and a plunger rod receiving part for receiving the plunger rod.

- 5 In embodiments, the housing is provided with a removable cap that fits over and thereby, acts such as to close off, a forward projection aperture thereof. It may therefore, be appreciated that when in the capped position, the removable cap acts such as to prevent ingress of contaminants into the housing.
- 10 In terms of function, the trainer device arranged to mimic the actuation (i.e. firing) of an auto-injector device. The trainer device thus, comprises a source of drive capable of providing drive force to the plunger rod to move the plunger within said barrel, subject to the frictional damping of the frictional component.
- 15 In embodiments, the trainer device comprises a drive transfer element for transferring axial drive to the plunger rod. In embodiments, that drive transfer element takes the form of a drive shuttle, but other suitable forms are also envisaged.

In embodiments, the trainer device additionally comprises a puller arranged for receipt of the
20 plunger rod. In embodiments, the puller is provided with one or more protrusions arranged for receipt within one or more cavities of the drive transfer element.

- In embodiments, the trainer device includes an energy store for storing energy that can then be released to the source of drive to provide the axial drive to the plunger rod. In
25 embodiments, the energy store comprises a mechanical energy store such as a spring (e.g. a compression or torsion spring). In other aspects, the energy store may be provided by a container of compressed liquid or gas propellant that on release provides a source of jet energy propulsion.

In embodiments, the energy store is able to exert an axial drive force of up to 60N on the plunger rod. Where the energy store is a compression spring the force exerted typically varies over the actuation profile such as from a range of 60 to 40N at the start of actuation to from 40 to 20N at the end of the actuation profile. Where the energy store is a compressed liquid or gas propellant a more constant force is typically exerted over the actuation profile.

In embodiments, the trainer device comprises an actuating mechanism, which is triggered in use, to allow for release of axial drive force to the plunger rod. In embodiments, release of axial drive force (e.g. actuation of the actuating mechanism) is responsive to a trigger (e.g. a user-actuable trigger). In embodiments, the trigger comprises a button, switch or lever arrangement. In other embodiments, a press actuation mechanism that is actuable in response to pressing of the housing of the device against the skin is envisaged.

The plunger comprises a frictional component for frictionally damping movement of the plunger within the barrel (e.g. by providing frictional contact with the inner wall of the barrel). Thus, the plunger is axially movable within the barrel, but subject to the frictional damping of the frictional component (e.g. with the inner wall of the barrel). Such frictional damping acts such as to slow down (i.e. delay) axial movement of the plunger within the barrel, and therefore may act such as to mimic the action of a plunger within a syringe barrel, wherein that syringe barrel comprises a drug formulation (e.g. viscous formulation) which provides frictional resistance to plunging movement of the plunger within the syringe barrel. In embodiments, the frictional damping is such that plunging movement of the plunger within the barrel takes from 5 to 15 seconds during use of the trainer device.

In embodiments, the frictional component is comprised of a natural or synthetic polymer friction material, which frictionally interacts with the side wall of the syringe barrel. Suitable frictional materials include natural or synthetic rubbers or elastomeric materials.

In embodiments, the frictional component comprises a circular jacket that encloses a radial spring. The jacket defines a circular outer wall that is received by the inner wall of the barrel.

The circular outer wall can make contact with the inner wall of the barrel with different contact profiles. In embodiments, the profile comprises a circular ridge, which may be arranged to provide a point load to the inner wall of the barrel. In other embodiments, the profile comprises a flat ring of predetermined width. The profile is selected dependent upon a
5 number of factors such as the level of contact friction resistance that is required for the application. Both the jacket and the spring work together to provide the frictional capability. Such a component is sometimes referred to as an ‘energized seal’. Components of this type are known in the aerospace and mining industries to provide high performance sealing between a piston rod and a tubular component.

10

In embodiments, the circular jacket comprises a polymer material, which can be made out of a range of polymers to suit individual applications. Suitable polymer materials have self-lubricating characteristics. One suitable polymer material is polytetrafluoroethylene (PTFE). Other suitable polymer materials for use in the circular jacket include thermoplastic elastomer
15 (TPE) and polypropylene (PP).

In embodiments, the plunger rod is provided with a circular head part that is sized and shaped for receipt of the circular jacket. In embodiments, a slip ring is provided to secure the circular jacket in position.

20

In embodiments, the radial spring can be made in a number of configurations to provide a range of spring forces and force curve profiles. One example of a suitable radial spring for use herein is the NPI 500 series V-Spring as sold by Nelson Products, Inc. of 13551 West. 43rd Drive, Unit G, Golden, CO 80403, United States of America, which is a cantilever beam
25 geometry made from stainless steel or other alloys that functions as a radial or axial compression energizer.

In embodiments, the radial spring held within the circular jacket is arranged such that it provides a relatively flat load deflection force, such that it can deflect increments of

30 millimetres, holding a relatively small change in outward force. This has the effect of being

able to absorb a range of manufacturing tolerances, e.g. in barrel and friction rod diameters, thereby narrowing the range of timings capable of being provided by the trainer device.

In embodiments, the frictional component comprises a rubber or polyurethane O-ring. In
5 embodiments, wherein an O-ring is employed, a lubricant is also employed to modulate the
frictional action of the O-ring with the inner wall of the barrel. However, such a lubricant
may be sensitive to temperature and this can affect its frictional capability, and hence also
affect the amount of delay of timing of movement of the plunger within the barrel. By
contrast, a positive factor of the 'energized seal' is that it is made of self-lubricating material
10 and therefore does not require the barrel to be lubricated. Where a polyurethane O-ring is
employed, this is stiffer and harder at cold temperatures and consequently the trainer device
actuation timing will be slower in cold temperatures.

According to a further aspect of the present invention there is provided a kit of parts
15 comprising trainer device as described above and a recharger device therefor.

In embodiments, the recharger device comprises a recharger housing defining a recharger
housing cavity therein, and within said recharger housing cavity, an upstanding column
defining a column head. In embodiments, the column head is arranged for abutting
20 interaction with a plunger head of the plunger rod.

According to a further aspect of the present invention there is provided an assembly for use
in a trainer device for an auto-injector comprising a barrel; within said barrel, a plunger; in
communication with said plunger, a plunger rod, wherein said plunger comprises a frictional
25 component for frictionally damping movement of the plunger within the barrel. The assembly
is employed to 'mimic' the action of a filled syringe within a trainer device herein, and
typically comprises no needle and also is typically not arranged to contain any liquid (e.g.
drug formulation). The assembly may in embodiments, be considered to be a mock or
'pseudo' syringe assembly.

Brief Description of the Drawings

The disclosure is further described with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a prior art auto-injector herein in the 'pre-use' position with
5 removable cap thereof in docked receipt by the outer housing thereof;

Figure 2 is a perspective view of the prior art auto-injector of Figure 1 in the 'pre-use'
position with removable cap thereof removed from the outer housing thereof;

10 Figure 3a is an exploded view of the forward assembly parts of the prior art auto-injector of
Figure 1;

Figure 3b is an exploded view of the rearward assembly parts of the prior art auto-injector of
Figure 1;

15 Figure 4 is a perspective view of a trainer device for an auto-injector herein in the 'pre-use'
position with removable cap thereof removed from the outer housing thereof;

Figure 5a is an exploded view of the forward assembly parts of the trainer device of Figure 4;
20

Figure 5b is an exploded view of the rearward assembly parts of the trainer device of Figure
4;

Figure 6 is a perspective view of the plunger rod and plunger with energized seal parts of the
25 rearward part of the trainer device of Figure 4;

Figures 7a to 7c respectively show perspective, top and side views of the energized seal parts
of the rearward part of the trainer device of Figure 4;

Figures 8a shows a side view and Figure 8b shows a sectional view taken along line A-A of Figure 8a of the trainer device of Figure 4 in the 'pre-use' position;

Figures 9a shows a side view and Figure 9b shows a sectional view taken along line B-B of Figure 9a of the trainer device of Figure 4 in the 'end of use' (i.e. uncharged) position;

Figure 10a shows a side view and Figure 10b shows a sectional view taken along line A-A of Figure 10a of the trainer device of Figure 4 absent its removable cap in conjunction with a recharger device therefor, wherein the trainer device in the 'end of use' (i.e. uncharged) position;

Figure 11a shows a side view and Figure 11b shows a sectional view taken along line B-B of Figure 11a of the trainer device of Figure 4 absent its removable cap in conjunction with a recharger device therefor, wherein the trainer device in the 'part-charged' position; and

Figure 12a shows a side view and Figure 12b shows a sectional view taken along line C-C of Figure 12a of the trainer device of Figure 4 absent its removable cap in conjunction with a recharger device therefor, wherein the trainer device in the 'fully charged' (i.e. 'pre-use') position.

Detailed Description

To provide an overall understanding of the systems, devices and methods described herein, certain illustrative embodiments will now be described. For the purpose of clarity and illustration these systems and methods will be described with respect to auto-injectors that are arranged to receive a syringe and trainer devices therefor. It will be understood by one of ordinary skill in the art that the systems, devices and methods described herein may be adapted and modified as is appropriate, and that these systems, devices and methods may be employed in other suitable applications, and that other such additions and modifications will not depart from the scope hereof.

The trainer device herein is suitable for training a user in how to use an auto-injector of the general type, as shown at Figures 1 to 3b. A more complete description of an auto-injector of this type is provided by Applicant's PCT publication no. WO2016/046131 A1, the contents of which are herein incorporated by reference.

5

Referring now to the drawings, Figures 1 and 2 show a prior art auto-injector device 1, wherein Figure 1 shows the device 1 in a capped configuration and Figure 2 shows the auto-injector device 1 with its removable cap 60 removed. Figures 3A and 3B, in combination, show an exploded view of the auto-injector device 1, which is arranged for use with a syringe
10 10 that contains a liquid drug formulation 5. The auto-injector device 1 comprises a generally cylindrical form rear outer housing that is formed of two clam shell parts 20, 22; and a forward housing part 24, also of generally cylindrical form. The housing 20, 22, 24 is arranged for receipt of the syringe 10 and is sized and shaped for this purpose. The forward outer housing 24 is provided with a viewing port 2 that allows for viewing of the contents of
15 the syringe 10 to check for dispensing of drug 5 there from.

The syringe 10 comprises a barrel 12 for holding the liquid drug formulation 5; a hollow needle 14 (not visible at Figures 3A and 3B, but see for example, Figures 8C and 9C) at a forward end of the barrel 12; a syringe flange 16 at the rear end of the barrel; and a syringe
20 plunger 18 in the form of a rubber stopper that is arranged for axial movement within the barrel 12 in response to driven movement of plunger rod 80 such as to enable the liquid drug formulation 5 to be expelled through the hollow needle 14. The hollow needle 14 defines a needle bore, which is of circular cross-section (e.g. 23G, 25G or 27G bore diameter) and a needle tip 15. The syringe 10 is further provided with a needle cover (not visible at Figures
25 3A and 3B and rigid needle shield 19.

The syringe 10 is received within syringe carrier 35, which has a forward lip 36 defining a forward opening; forward flange 37; and at the rear thereof is provided with pair of diametrically oppositely located trailing latch arms 38 arranged for receipt of syringe flange
30 guard 39. In injected use, the tip 15 of the needle 14 of the syringe 10 protrudes from the

opening defined by the forward lip 36 of the syringe carrier 35. The syringe 10 has limited axial movement within the syringe carrier 35, wherein interaction of the syringe flange guard 39 with the syringe flange 16 limits the extent of rearward axial movement thereof. As will be explained in more detail later, during injected use, drive force to move the syringe carrier 5 35 and syringe 10 carried thereby from a rest to an injection position is received by the syringe flange guard 39. Further details of a suitable syringe flange guard 39 for use herein are provided at Applicant's PCT publication no. WO2015/015,230.

Return spring 27 fits around the forward part of the syringe carrier 35 such that its rearward 10 end abuts the forward flange 37 thereof. The forward end of the return spring 27 is received within forward head part 26 of the device 1, which forward head part 26 defines a needle delivery aperture 29.

Needle cover gripper 56 in the form of a cage-like (or 'flower') structure and defining plural 15 gripping elements 58 arranged about a central hub 59 is further provided to the removable cap 60. Such gripping elements 58 are arranged for gripping of the rigid needle sheath shield 19 on removal of the removable cap 60 such that removal of the cap 60 also results in removal of the rigid needle sheath shield 19 and needle sheath 17 enclosed thereby, and hence, unsheathing of the needle tip 15.

20

As shown at Figure 3B, the housing 20, 22, 24 of the auto-injector device 1 is arranged to receive an inner housing sleeve 40 that fixes by means of visual plug 42 to the rear housing part 20, 22 and that defines a threaded forward end 43 for threaded engagement with forward head part 26. The inner housing sleeve 40 defines an inner housing cavity within which the 25 syringe 10 and its syringe carrier 35 are received. The inner housing sleeve 40 also defines a housing for drive spring 48; drive spring cap 49; and drive shuttle 50 having forward 52 and rearward legs 54, the action of all of which will be describe in more detail hereinafter. Rear cylinder 45 fits around the rear end of the inner housing sleeve 40.

As shown at Figure 3A, the device 1 is provided with an anti-fire latch mechanism comprising a pair of buttons 62, each with inner head pip 63, that are received by apertures within forward housing part 24. Each button 62 co-operates with a latch spring 64. The head pip 63 of each button 62 protrudes through pip-receiving aperture of the latch spring 64.

5 Arms 65 with serrated edges 66 of each latch spring 64 seat within a latch spring 64 receiving cavity defined within the inner wall of the forward housing part 24. In the capped configuration of Figure 1, the inner wall of the removable cap 60 acts to push in each button 62 against the bias of the latch spring 64 such that the radially innermost aspect of latch spring 64 interferes with the inner housing sleeve 40 such as to lock any relative movement
10 of the inner housing sleeve 40 relative to the front housing part, thereby preventing any inadvertent actuation of the device 1. In the uncapped configuration of Figure 2, the removable cap 60 has been removed, and thus can no longer act on the buttons 62. Under the biasing action of its latch spring 64, each button 62 is now pushed radially outwards such that the radially innermost aspect of latch spring 64 no longer interferes with the inner housing
15 sleeve 40, thereby no longer locking any relative movement of the inner housing sleeve 40 relative to the front housing part. The uncapped device 1 may therefore now be actuated by user action.

A full description of a typical use operation of a prior auto-injector 1 of this type is provided
20 by Applicant's PCT publication no. WO2016/046131 A1, the contents of which are herein incorporated by reference.

In a first stage of a typical use operation of the prior art auto-injector 1, as shown at Figure 1, the device 1 is 'pre-use' and the removable cap 60 is in place. In this position, the needle 14
25 and dispensing tip 15 of the syringe 10 are sheathed by the needle cover and its rigid needle shield 19. The anti-fire latch mechanism 62, 64 acts to prevent any inadvertent actuation of the device 1, wherein the inner wall of the removable cap 60 acts to push in each button 62 against the bias of the latch spring 64 such that the radially innermost aspect of latch spring 64 interferes with the inner housing sleeve 40 to lock any unintended relative movement of
30 the inner housing sleeve 40 relative to the front housing part 24.

In a second stage of a typical use operation, as shown at Figure 2, the cap 60 has been removed to uncover the forward head part 26 of the device 1 and its needle delivery aperture 29. Removal of the cap 60 also results in removal of the rigid needle sheath shield 19 and needle sheath 17, which attach to the cap 60 by means of the needle cover gripper 56, and hence, in unsheathing of the tip 15 of the syringe needle 14.

The device 1 is now in its 'ready to use' state, in which it is noted that the tip 15 of the needle 14 remains surrounded by the forward head part 26. In this uncapped configuration, the removable cap 60 can no longer act on the buttons 62. Under the biasing action of its latch spring 64, each button 62 is now pushed radially outwards such that the radially innermost aspect of latch spring 64 no longer interferes with the inner housing sleeve 40, thereby no longer locking any relative movement of the inner housing sleeve 40 relative to the front housing part. The uncapped device 1 may therefore now be actuated in response to user action.

15

The user now grips the device 1 at the rear housing 20, 22 and places the needle delivery aperture 29 against the skin at the desired injection point. Pressure is now applied to the forward head part 26 by pushing this against the injection surface of the skin, which pressure results in rearward motion of the forward head part 26 and inner housing sleeve 40 relative to the housing 20, 22, 24. As a result of this motion, firing of the device 1 is actuated.

On actuation, the drive shuttle 50 is also initially moved slightly rearwards as a result of the engagement of the forward legs 52 thereof with a first ledge 41 of the inner housing sleeve 40. As the drive shuttle 50 moves rearward, the rear legs 54 thereof are flexed inwards as a result of interaction with ribs (not visible) on the rear cylinder 45 to decouple from the inner housing sleeve 40. As a result of this inwards flexing, the rear legs 54 thereby form a 'hammer head', which can interact in driving fashion with the tapered drive head 82 of the plunger rod 80 to thereby couple the drive shuttle 50 and plunger rod 80.

The forward legs 52 define a ramped surface, which interacts with a second ledge 44 of the rear cylinder 45, the effect being to push the forward legs 52 inwards, thereby allowing for forward movement of the drive shuttle 50 relative to the inner housing sleeve 40 under the driving force of the drive spring 48 transferred via the drive spring cap 49. A further result of this inwards-flexing of the forward legs 52 is to bring the leading faces of the forward legs 52 into engagement with the rear face of the syringe flange guard 39 of the syringe carrier 35 assembly such that forward movement of the drive shuttle 50 also results in forward movement of the syringe carrier 35 and syringe 10 carried thereby.

10 The drive shuttle 50 now moves forward under the drive force of the drive spring 48, thereby advancing the syringe carrier 35 and syringe 10 carried thereby to the 'syringe advanced' position, in which the syringe needle tip 15 protrudes from the needle delivery aperture 29. Since the syringe stopper 18 does not move forward within the syringe barrel 12, no fluid 5 is expelled during this syringe advancement step. The advancement of the syringe 10 is only
15 lightly resisted by the return spring 27, which interacts with the forward end flange 37 of the syringe carrier 35. At the 'syringe advanced' position the forward flange 37 of syringe carrier 35 abuts a projecting circular inner end wall 28 of the front housing part 26 and further forward movement of the syringe 10 is prevented.

20 At or about this point, the forward legs 52 of the drive shuttle flex outwardly into the front slot 44 (see Figure 3B) of the inner housing sleeve 40 such as to enable disengagement of those legs 52 from the syringe flange guard 39 of the syringe carrier 35, thereby decoupling the drive shuttle 50 from the syringe carrier 35 and syringe 10 carried thereby.

25 As a result of the decoupling of the drive shuttle 50 from the syringe carrier 35, all further forward drive experienced by the drive shuttle 50 is transferred to the plunger rod 80 by way of the 'hammer head' interaction of the inwardly flexed rear legs 54 thereof with the tapered head 82 of the plunger rod 80. The plunger rod 80 is therefore pushed down the syringe barrel 12 to exert axial force to the syringe stopper 18, the plunging movement of which
30 results in expelling of the fluid contents 5 of the syringe 10.

As the end of the injection stroke is reached, the rear legs 54 of the drive shuttle 50 flex outwards and are received within mid-slot 46 (see Figure 3B) of the inner housing sleeve 40. The effect of this outwards-flexing is to bring the heads of the rear legs 54 out of engagement with the tapered drive head 82 of the plunger rod 80, thereby removing the ‘hammer head’
5 and decoupling the drive shuttle 50 from the plunger rod 80. The plunger rod 80 is then able to move axially within the inner housing sleeve 40 free from any influence of the drive spring 48.

The syringe carrier 35 and syringe 10 carried thereby, now experience the return force of the
10 earlier-compressed return spring 27, which acts such as to move the syringe carrier 35 backwards to retract the syringe 10 to the ‘end of use’ position, in which the tip 15 of the syringe needle 14 is again shrouded by the front housing part 26. The plunger rod head 82 passes through the rearward legs 54 of the drive shuttle 50 in this phase, the rear outward tags 54 having been deflected outwards into mid-slot 46 of the inner housing sleeve 40 to permit
15 this. The syringe 10 is thus, effectively returned to its initial shrouded position, thereby removing any danger of possible inadvertent contact of the used needle 14, 15 with a user. Also in this ‘end of injection’ position, forward tags 52 of drive shuttle 50 seat up against a front ledge end of front slot 44 of the inner housing sleeve 40, thereby preventing any further forward movement of the drive shuttle 50. Typically, the device 1 is disposed of after use.

20

The prior art auto-injector 1 provides the user with two visual indicators as to its use state. As shown at Figure 2, in the ‘pre-use’ state, the inner housing sleeve 40 is clearly visible as a ‘band’ between the forward head part 26 and the forward outer housing 24. In aspects, the inner housing sleeve 40 is brightly-coloured (e.g. orange) and therefore an ‘orange band’ is
25 clearly visible in this ‘pre-use’ state. Also, as shown at Figure 2, in the ‘pre-use’ state the viewing window 2 is ‘open’, allowing the user to see the drug 5 within the syringe 10. In the ‘post use’ (i.e. ‘fired’) state, the ‘orange band’ is no longer visible and the viewing window is “closed” by part of the inner housing sleeve 40. Once fired, in the prior art auto-injector 1, the state of these indicators cannot be changed. In the trainer device 101, as described

hereinafter, these indicators need to be both present and resettable to the 'pre-use' state to allow for repeated use.

The prior art auto-injector 1 also makes two distinct 'clicks' during use; once when it is fired,
5 and again once the injection has finished and the needle 14 is retracted back into the device 1. The timing between these clicks is wholly decided by the drug being injected and can range from 5 seconds to 15, dependent on the temperature of the drug. To accurately, mimic the action of the auto-injector device 1 both the clicks and the delayed time between them need are desirably also present in the trainer device 101.

10

Figures 4 to 9b provide details of a trainer device 101 herein, which is arranged for use in training a user how to use an auto-injector 1 of the general type as described in relation to Figures 1 to 3b. The outward form of the trainer device 101 may be seen to correspond exactly to that of the outward form of the auto-injector 1. Operation of the trainer device 101
15 is arranged to mimic that of the auto-injector 1, but without allowing for any delivery of drug from a syringe 10 via a needle 14 provided thereto. The trainer device 101 thus, replaces the syringe 10; needle 14 and syringe plunger 18 components of the auto-injector device 1 with other components that act to mimic the feel of an injected delivery operation.

20 The trainer device 101 comprises a generally cylindrical form rear outer housing that is formed of two clam shell parts 120, 122; and a forward housing part 124, also of generally cylindrical form. The housing 120, 122, 124 is arranged for receipt of barrel 110 and is sized and shaped for this purpose. The forward outer housing 124 is provided with a viewing port 102 that allows for viewing of the barrel 110 and plunger 118 there within. Forward head
25 part 126 provided to the forward outward housing 124 defines a forward aperture 129. Removable cap 160 is also provided to the forward outer housing 124.

Barrel 110 locates within the housing 120, 122, 124 and is arranged for receipt of a plunger 118 that is arranged for axial movement within the barrel 110 in response to driven

movement of plunger rod 180. The barrel 110 has a forward lip 136 defining a forward opening; and a forward flange 137.

Further details of the plunger 118 and plunger rod 180 may be seen by reference to Figures 6 to 7c. The plunger comprises a circular jacket 112 defining an open circular cavity for receipt of radial spring 114. The circular jacket 112 is received by the radial head 182 of the plunger rod 180. As shown at Figure 6, the circular jacket 112 is held in place by slip ring 115. As shown, the shaft 181 of the plunger rod 180 defines various radial cross-pieces 183, although other structural forms of the shaft are also possible. In combination, the circular jacket 112 and radial spring 114 elements comprise a frictional component for frictionally damping of the movement of the plunger 118 within the barrel 110.

As shown at Figure 5B, as shown at Figure 5B, the rear housing part 120, 122 of the trainer device 101 is arranged to receive a visual plug 142. The housing 120, 122, 124 of the trainer device 101 is further arranged to receive an inner housing sleeve 140 that defines a threaded forward end 143 for threaded engagement with forward head part 126. The inner housing sleeve 140 defines an inner housing cavity within which the barrel 110 is received. The inner housing sleeve 140 also defines a housing for drive spring 148; and drive shuttle 150 having forward legs 152, the action of all of which will be describe in more detail hereinafter. The force profile of drive spring 148 is typically less than that of the drive spring 48 of the prior art auto-injector device 1. Rear cylinder 145 fits around the rear end of the inner housing sleeve 140. Rear cylinder 145 is held firmly by the rear housing part 120, 122.

As shown at Figure 5A, the forward housing 124 is also provided with puller 170, which is sized and shaped for receipt of plunger rod 180. The puller 170 is provided with an arrangement of four inwardly facing protrusions 172, which allow for fixing to retaining cavities 153 of the drive shuttle 150. Some relative axial movement of the puller 170 relative to the drive shuttle 150 is permitted governed by the degree of movement permitted by the protrusions 172 within the retaining cavities 153. The forward housing is further provided with slip ring 174, which provides a housing for the barrel 110.

As shown at Figure 5A, the device 1 is provided with an anti-fire latch mechanism of a type similar to that described in relation to the prior art auto-injector device 1. Thus, the anti-fire latch mechanism comprises a pair of buttons 162, each with inner head pip, that are received by apertures within forward housing part 124. Each button 162 co-operates with a latch
5 spring 164. The head pip of each button 162 protrudes through pip-receiving aperture of the latch spring. Arms with serrated edges of each latch spring 164 seat within a latch spring receiving cavity defined within the inner wall of the forward housing part 124. In the capped configuration of Figures 9a and 9b, the inner wall of the removable cap 160 acts to push in each button 162 against the bias of the latch spring 164 such that the radially innermost
10 aspect of latch spring interferes with the inner housing sleeve 140 such as to lock any relative movement of the inner housing sleeve 140 relative to the front housing part, thereby preventing any inadvertent actuation of the trainer device 101. In the uncapped configuration of Figure 4, the removable cap 160 has been removed, and thus can no longer act on the buttons 162. Under the biasing action of its latch spring 164, each button 162 is now pushed
15 radially outwards such that the radially innermost aspect of latch spring 164 no longer interferes with the inner housing sleeve 140, thereby no longer locking any relative movement of the inner housing sleeve 140 relative to the front housing part. The uncapped trainer device 101 may therefore now be actuated by user action.

20 In a first stage of a typical use operation of the trainer device 101, as shown at Figures 8a and 8b, the trainer device 101 is 'pre-use' position and the removable cap 160 is in place. The anti-fire latch mechanism 162 acts to prevent any inadvertent actuation of the trainer device 101, wherein the inner wall of the removable cap 160 acts to push in each button 162 against the bias of the latch spring 164 such that the radially innermost aspect of latch spring 164
25 interferes with the inner housing sleeve 140 to lock any unintended relative movement of the inner housing sleeve 140 relative to the front housing part 124.

In a second stage of a typical use operation, as shown at Figure 4, the cap 160 has been removed to uncover the forward head part 126 of the trainer device 101 and its forward
30 aperture 129. The trainer device 101 is now in its 'ready to use' state. In this uncapped

configuration, the removable cap 160 can no longer act on the buttons 162. Under the biasing action of its latch spring 164, each button 162 is now pushed radially outwards such that the radially innermost aspect of latch spring 164 no longer interferes with the inner housing sleeve 140, thereby no longer locking any relative movement of the inner housing sleeve 140 relative to the front housing part 124. The uncapped trainer device 101 may therefore now be actuated in response to user action.

The user now grips the trainer device 101 at the rear housing 120, 122 and places the needle forward aperture 129 against the skin. Pressure is now applied to the forward head part 126 by pushing this against the skin, which pressure results in rearward motion of the forward head part 126 and inner housing sleeve 140 relative to the housing 120, 122, 124. As a result of this motion, firing of the trainer device 101 is actuated. On firing actuation, the forward head part 126 makes sharp contact with the forward outer housing part 124, producing a first audible 'click'.

On actuation, the drive shuttle 150 is also initially moved slightly rearwards as a result of the engagement of the forward legs 152 thereof with a first ledge 141 (see Figure 8b) of the inner housing sleeve 140. The forward legs 152 define a ramped surface, which interacts with a second ledge 144 (again, see Figure 8b) of the rear cylinder 145, the effect of initial rearwards movement of the drive shuttle is also to push the forward legs 152 inwards, thereby allowing for forward and releasing movement of the drive shuttle 150 relative to the inner housing sleeve 140 under the driving force of the drive spring 148. The drive shuttle 150 now moves forward under the drive force of the drive spring 148, thereby advancing the puller 170, plunger rod 180 and plunger 118 carried thereby to the 'post use' (or 'fired') position, as shown at Figure 9b.

The forward travel of the plunger 118 through the barrel 110 is delayed by the frictional interaction of the damping frictional components 112, 114 thereof with the inner wall of the barrel 110. Typically, a time period of from 5 to 15 seconds is required for the plunger to travel from its 'ready to use' (Figure 8b) to 'post use' position (Figure 9b).

As shown at Figure 9b, since the plunger rod 180 is slightly longer than the barrel 110, in the 'post use' position, it emerges from the forward end of the barrel 110. This means that for the last few millimetres of the journey, the plunger 118 with its frictional components 112, 114 makes no contact with the barrel 10. As a result of this the components accelerate into the forward position, the puller 170 makes hard contact with the slip ring 115, thereby producing a second audible 'click'.

As described previously, the prior art auto-injector device 1 provides the use with both visual (orange 'band' and window) and auditory indicators as to the state of use. Since many corresponding components are used in the trainer device 101, no change is required in order to provide the corresponding visual indicators. However the auditory indicators ('clicks') need to be generated from different components hitting each other. Thus, on firing the trainer device 101, the forward head part 126 makes sharp contact with the forward outer housing part 124, producing the first click. The second click is produced by internal components propelled by the spring 148 hitting each other at the end of the "injection," stroke.

It is desirable that the trainer device 101 herein, is re-chargeable and thus, may be used in plural training operations. Figures 10a to 12b therefore show details of how a trainer device 101, herein may be re-charged, partly by use of a recharger device 190 herein.

20

From a user standpoint, a recharging operation starts by the user pulling the forward head part 126 away from the forward outer housing part 124 to reveal the inner housing sleeve 140 there between, and to thereby restore the 'orange band' visual indicator. Recharger device 190 is then used to reset the drive spring 148 of the drive mechanism, as shown at Figures 10a to 12b. In essence, it acts to push back the plunger rod 180 and attached components to the 'recharged' position where it is then ready to be fired once more. Doing this also 'opens' the viewing window 102. The movements required by the user are simple, pulling out the forward head part 126, inserting the trainer device 101 into the recharger 190, and then pushing down the trainer device 101 until it is clicked into a reset position.

30

Details of the interaction of the trainer device 101 with the recharger 190 may further appreciated by reference to Figures 10b, 11b and 12b.

In a first stage as shown at Figure 10b, the trainer device 101 is inserted into a retainer clip
5 192 of movable carriage 191 of the recharger 190, which holds the trainer device between the forward head part 126 away from the forward outer housing part 124 (i.e. at the 'orange band'). The carriage 191 is movable axially within a cavity 193 of the recharger 190 subject to a return force provided by a light return spring 195.

10 In a second stage as shown at Figure 11b, the trainer device 101 is pushed downwards into the recharger 190, thereby moving the carriage 191 into the cavity 193 of the recharger against the force of the light return spring 195. Head 196 of upstanding column 194 is brought into abutting relationship with the head 182 of the plunger rod 180. As the trainer device 101 and carriage 191 are pushed further downwards, this abutting relationship results
15 in the plunger rod 180 being pushed back into the trainer device 101, and hence, also the plunger 118 and pusher 170 being similarly pushed backwards into the trainer device 101. Pusher 170 further acts on the drive spring 148 of the trainer device 101 to compress it.

In a third stage as shown at Figure 12b, the 'reset' (i.e. 'pre-use' position) has been reached.
20 In this position, the forward legs 152 of the drive shuttle 150 have locked with a first ledge 141 of the inner housing sleeve 140. At this position, the drive spring 148 of the trainer device 101 is loaded and the device 101 is recharged. Also, in this position, the viewing window again 'opens up' so that the barrel 110, plunger rod 180 and plunger 118 become visible there through.

25

In a fourths stage, the now 'recharged' trainer device 101 is removed from the recharger 190 and the carriage 191 returns to its initial position (as shown as Figure 10b) under the action of the return spring 195.

It is to be understood that the foregoing description is merely illustrative and is not to be limited to the details given herein. While several embodiments have been provided in the present disclosure, it should be understood that the disclosed systems, devices, and methods, and their components, may be embodied in many other specific forms without departing from
5 the scope of the disclosure.

Variations and modifications will occur to those of skill in the art after reviewing this disclosure. The disclosed features may be implemented, in any combination and subcombinations (including multiple dependent combinations and subcombinations), with
10 one or more other features described herein. The various features described or illustrated above, including any components thereof, may be combined or integrated in other systems. Moreover, certain features may be omitted or not implemented. Examples of changes, substitutions, and alterations are ascertainable by one skilled in the art and could be made without departing from the scope of the information disclosed herein. All references cited
15 herein are incorporated by reference in their entirety and made part of this application.

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described herein. They may take
20 the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims.

Claims

1. A trainer device for an auto-injector comprising
 - 5 a housing;

within said housing, a barrel;

within said barrel, a plunger;
10 in communication with said plunger, a plunger rod; and

a source of drive capable of providing drive force to said plunger rod to move said plunger within said barrel,
15 wherein said plunger comprises a frictional component for frictionally damping movement of the plunger within the barrel.
2. A trainer device according to claim 1, wherein the frictional component comprises a
20 circular jacket that encloses a radial spring.
3. A trainer device according to claim 2, wherein the jacket defines a circular outer wall that is received by an inner wall of the barrel.
- 25 4. A trainer device according to either of claims 2 or 3, wherein the circular jacket comprises a polymer material.
5. A trainer device according to claim 4, wherein said polymer material is PTFE.

6. A trainer device according to any of claims 2 to 5, wherein the radial spring is held within the circular jacket such as to provide a consistent outwardly radial force.
7. A trainer device according to any of claims 1 to 6, additionally comprising a drive
5 transfer element for transferring said drive force to the plunger rod.
8. A trainer device according to any of claim 1 to 7, additionally comprising a puller arranged for receipt of the plunger rod.
- 10 9. A trainer device according to claim 8 as dependent on claim 7, wherein said puller is provided with one or more protrusions arranged for receipt within one or more cavities of the drive transfer element.
10. A kit of parts comprising a trainer device according to any of claims 1 to 9, and a
15 recharger device therefor.
11. A kit of parts according to claim 10, wherein the recharger device comprises a recharger housing defining a recharger housing cavity therein, and within said recharger housing cavity, an upstanding column defining a column head.
20
12. A kit of parts according to claim 11, wherein said column head is arranged for abutting interaction with a plunger head of the plunger rod.
13. An assembly for use in a trainer device for an auto-injector comprising
25 a barrel;
- within said barrel, a plunger;
- 30 in communication with said plunger, a plunger rod,

wherein said plunger comprises a frictional component for frictionally damping movement of the plunger within the barrel.

14. An assembly according to claim 13, wherein the frictional component comprises a
5 circular jacket that encloses a radial spring.

15. An assembly according to claim 14, wherein the jacket defines a circular outer wall that is received by an inner wall of the barrel.

10 16. An assembly according to either of claims 14 or 15, wherein the circular jacket comprises a polymer material.

17. An assembly according to claim 16, wherein said polymer material is PTFE.

15 18. An assembly according to any of claims 14 to 17, wherein the radial spring is held within the circular jacket such as to provide a consistent outwardly radial force.

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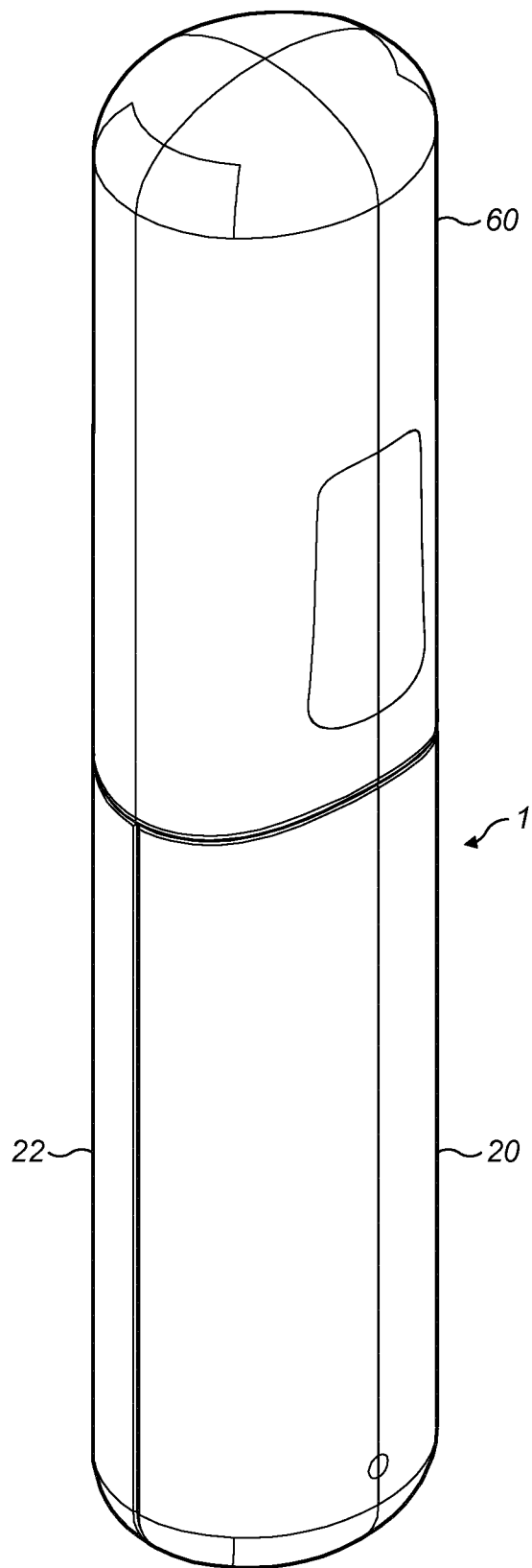


FIG. 1

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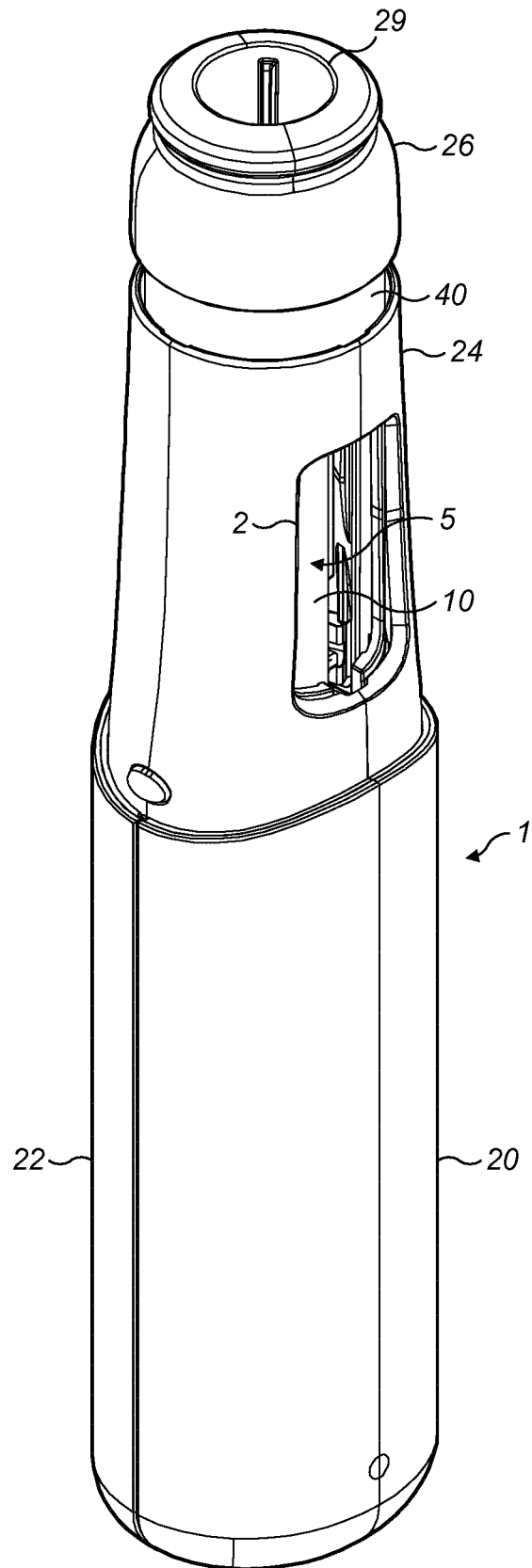


FIG. 2

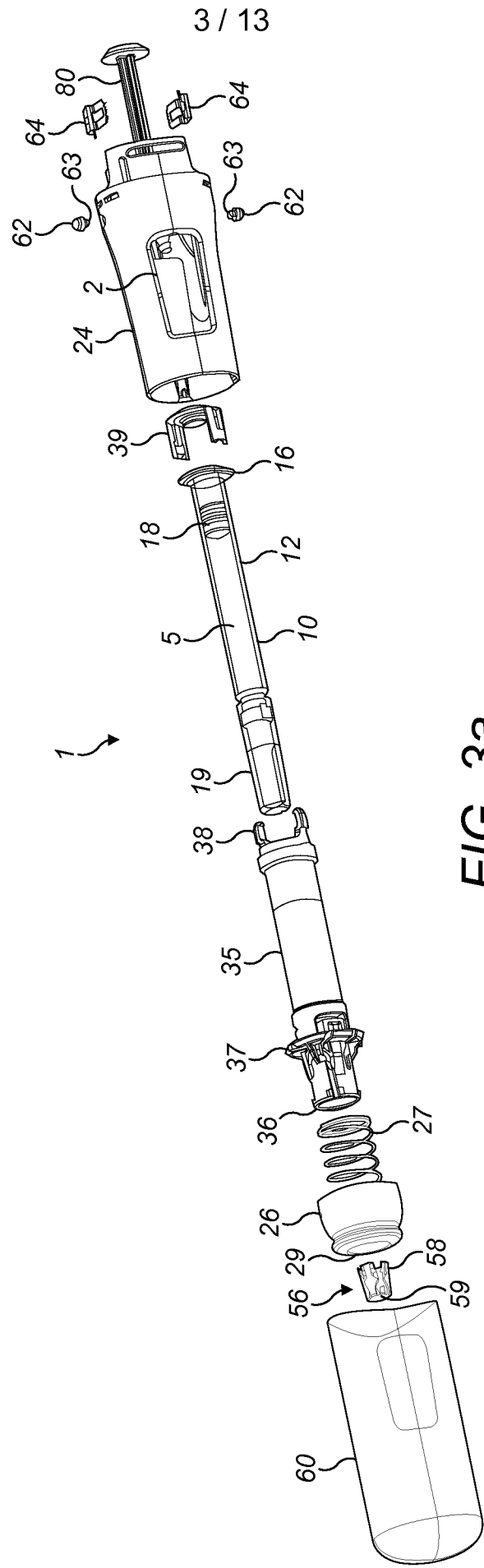


FIG. 3a

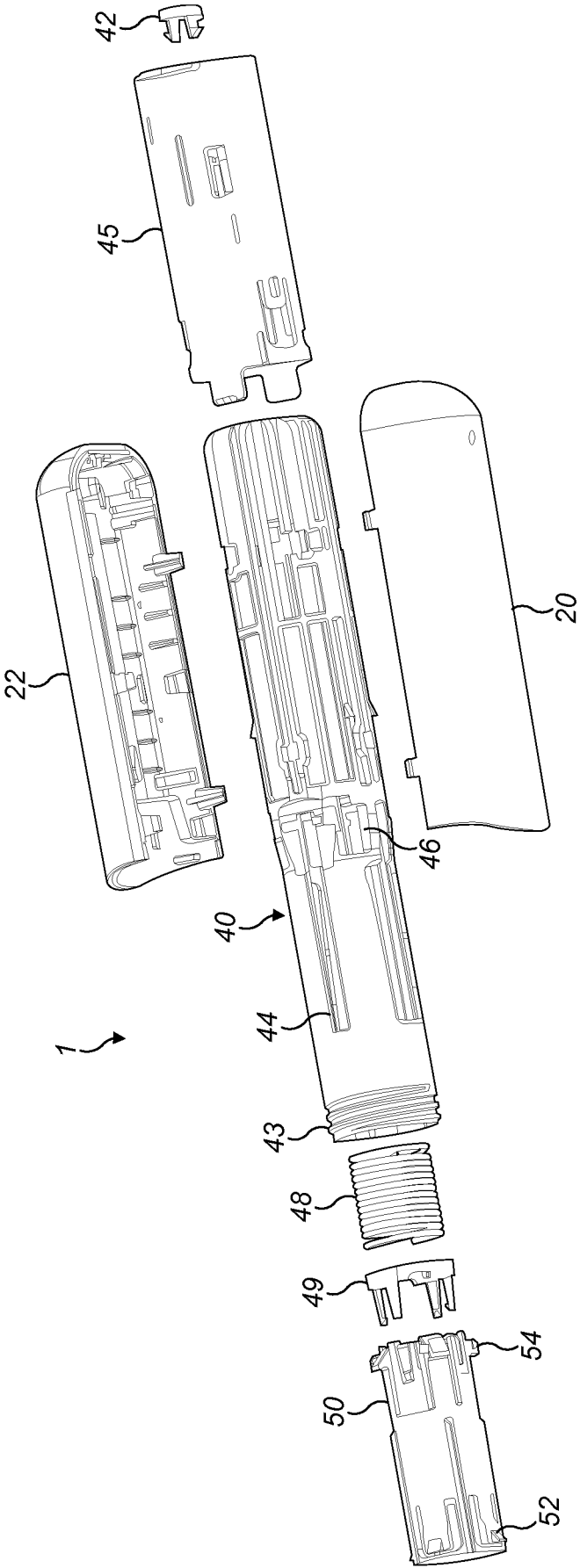


FIG. 3b

5 / 13

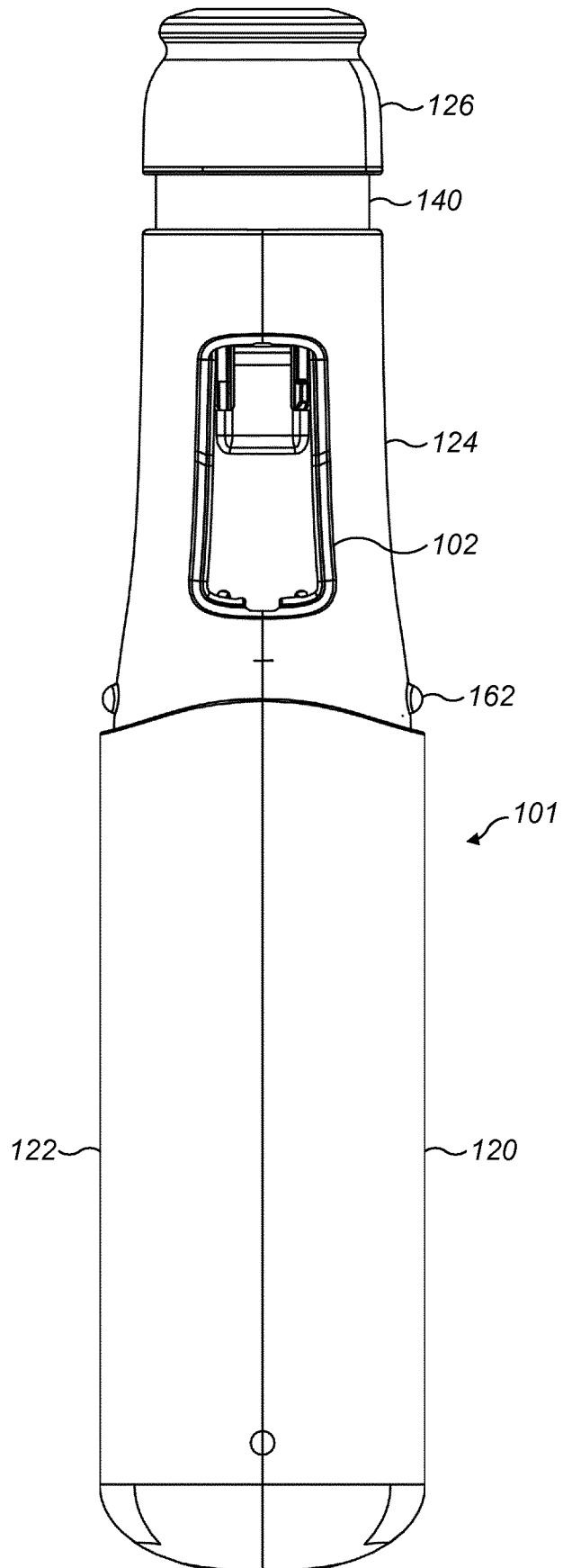
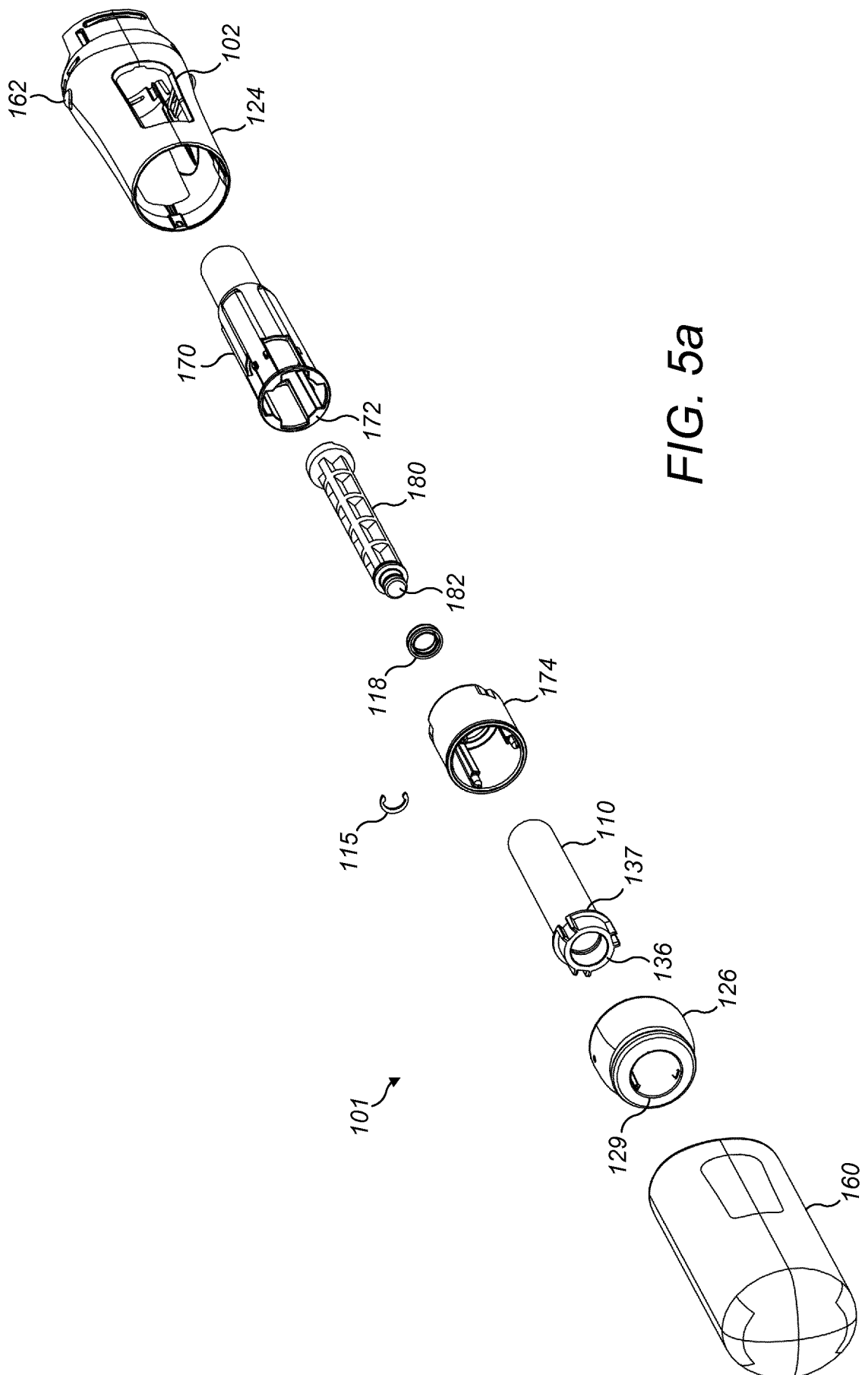
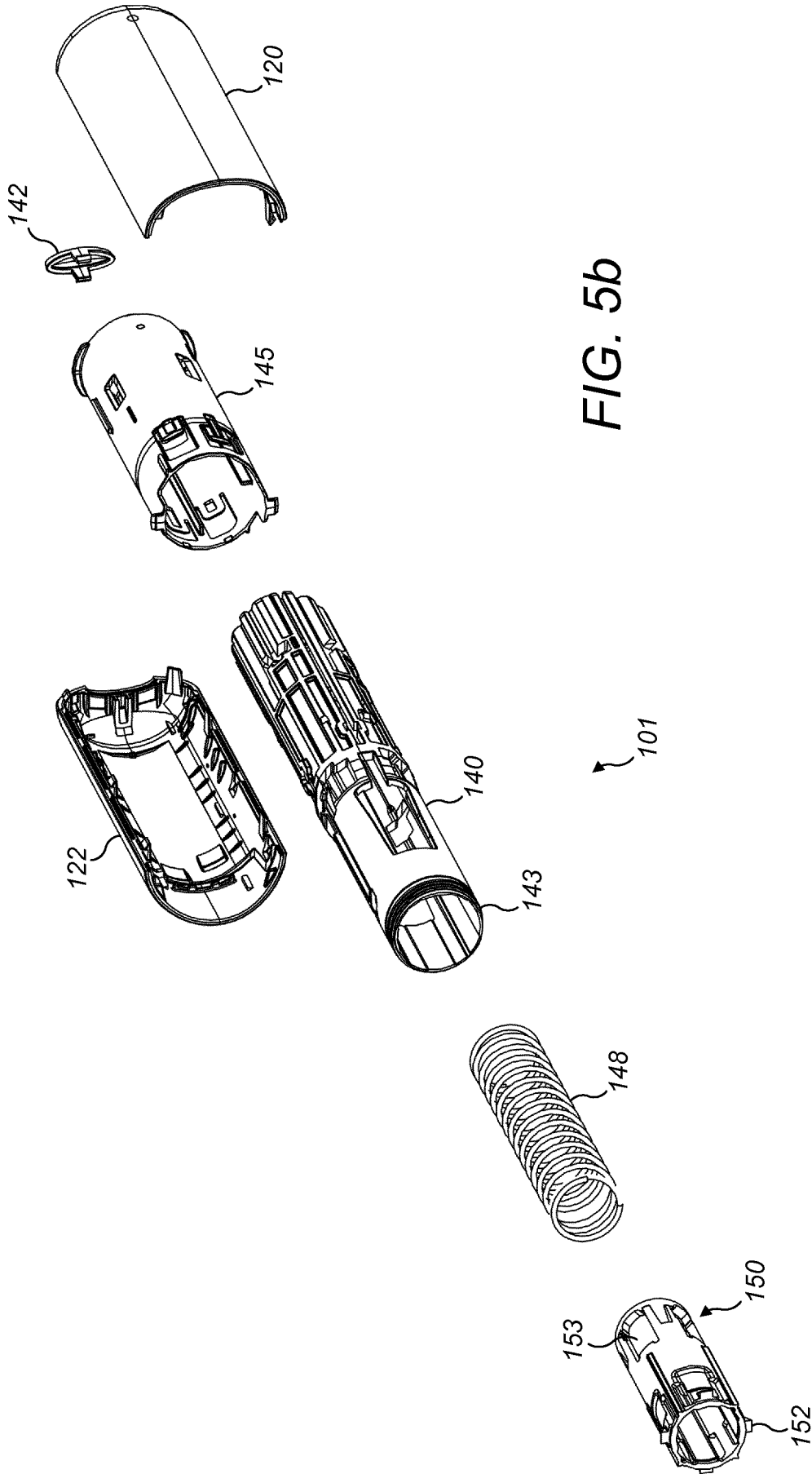


FIG. 4





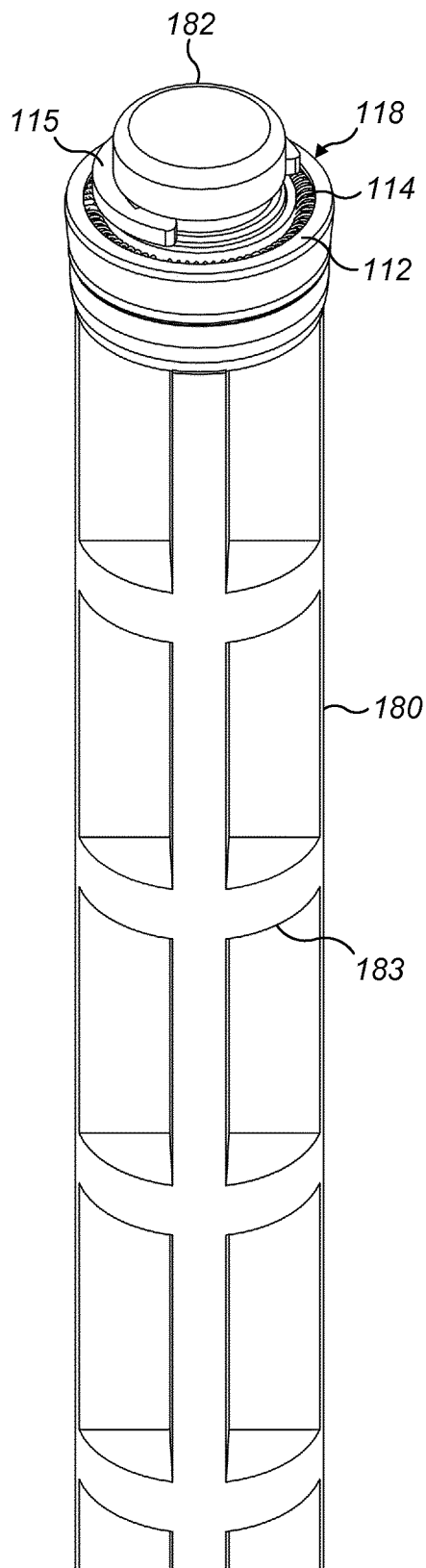


FIG. 6

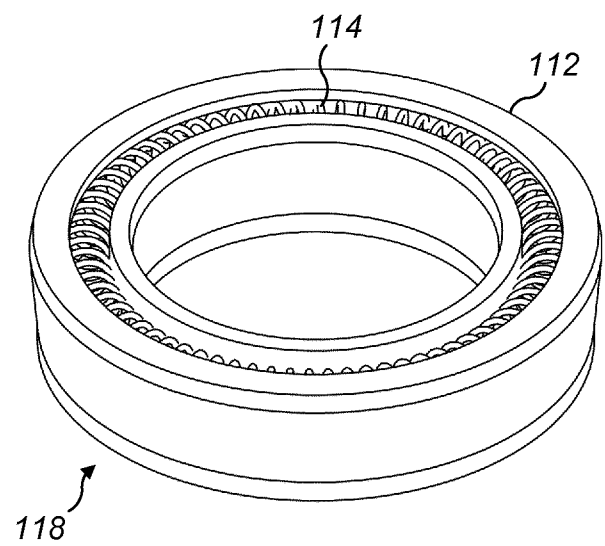


FIG. 7a

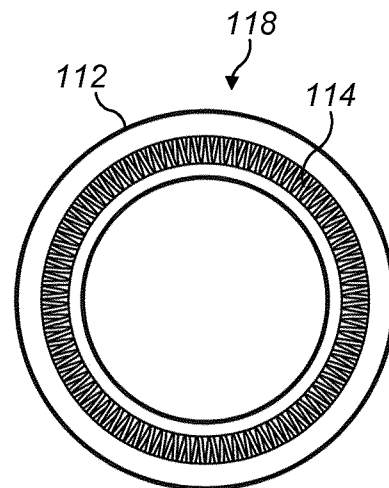


FIG. 7b

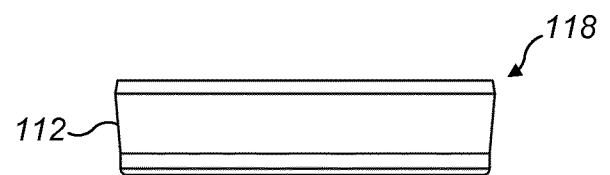


FIG. 7c

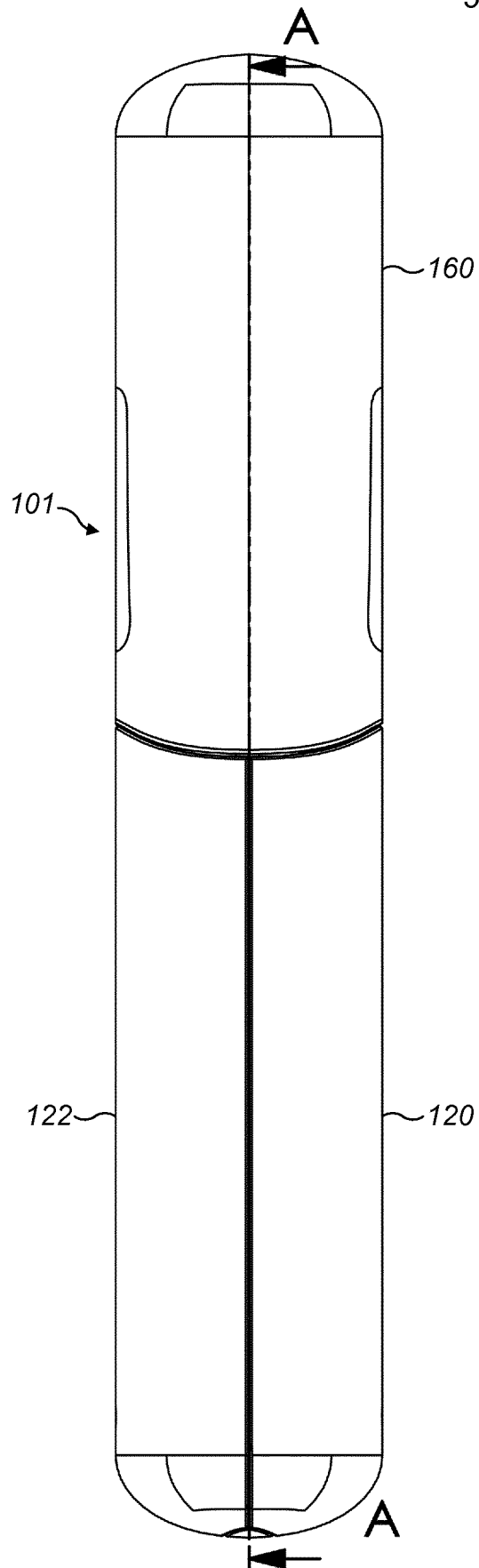


FIG. 8a

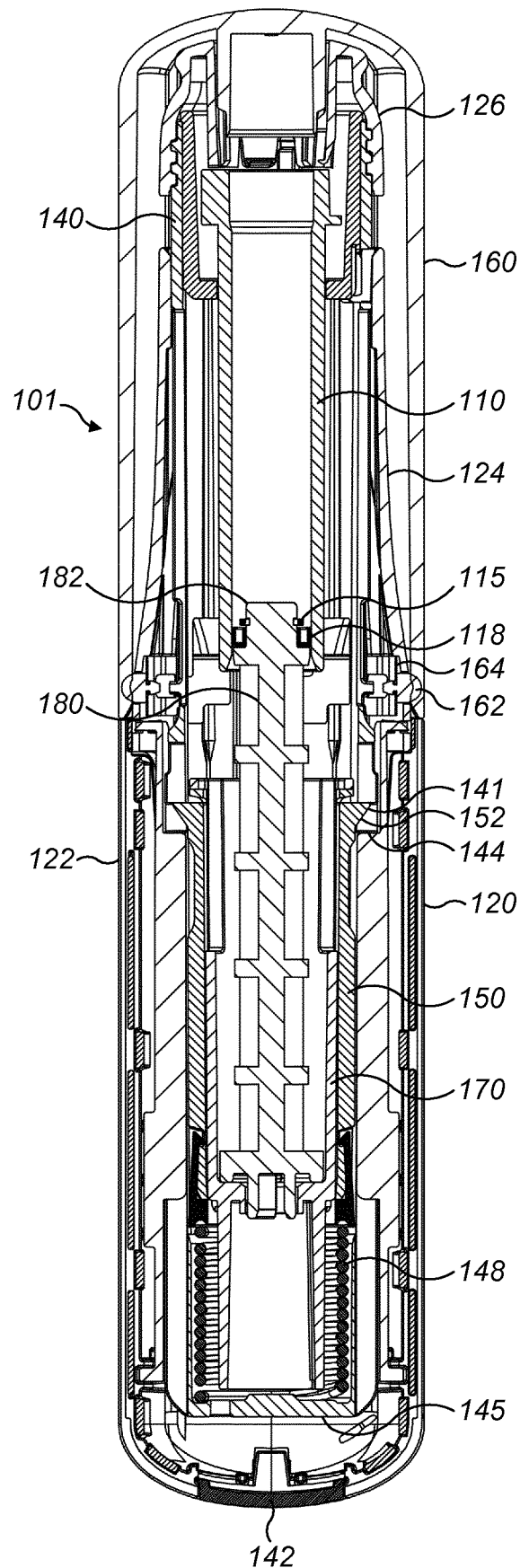


FIG. 8b

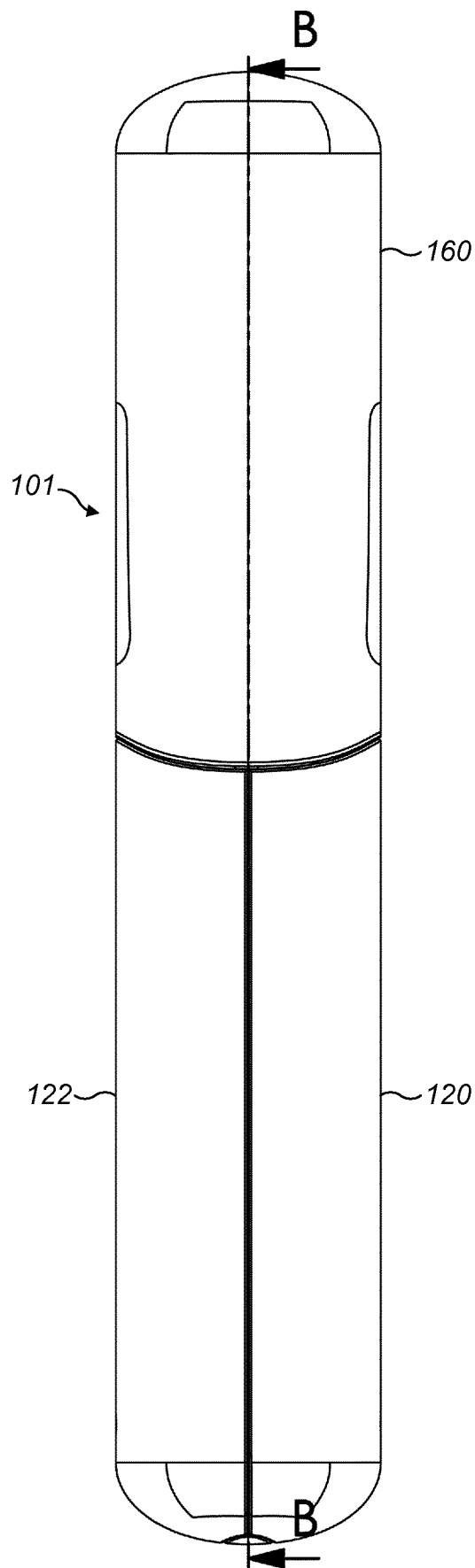


FIG. 9a

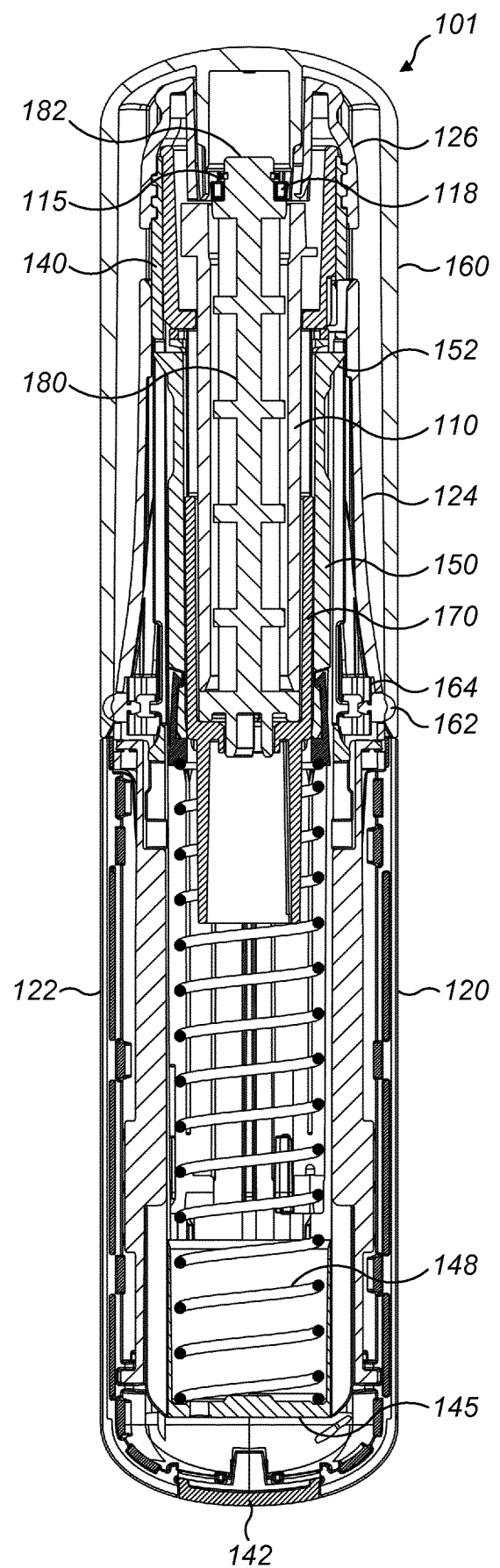


FIG. 9b

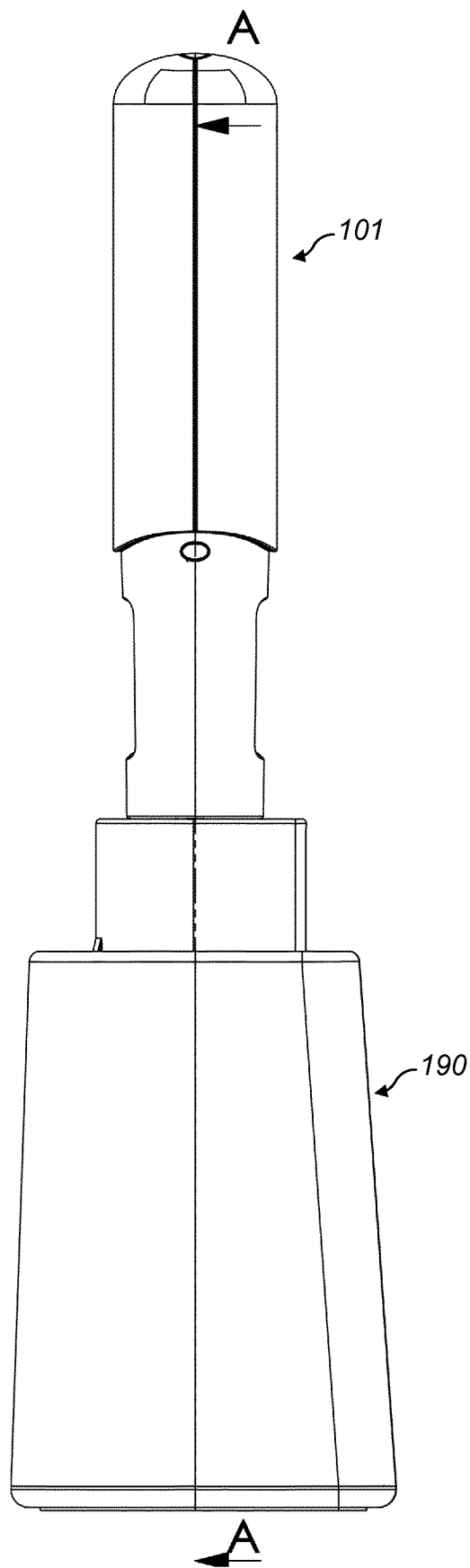


FIG. 10a

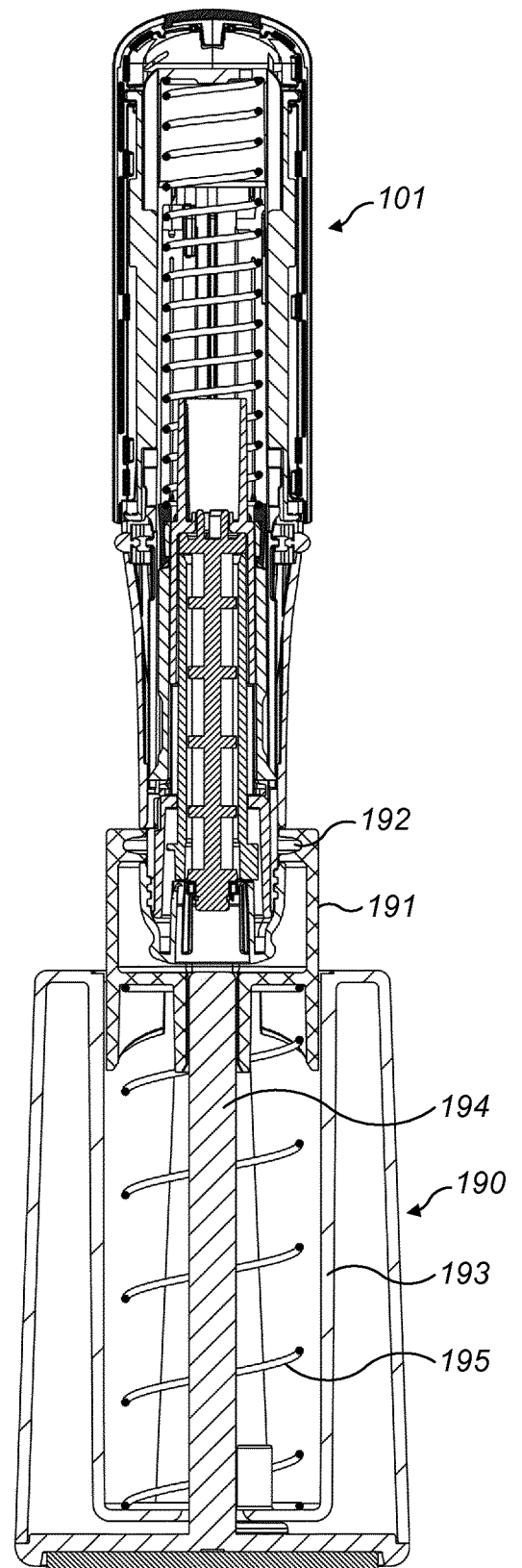


FIG. 10b

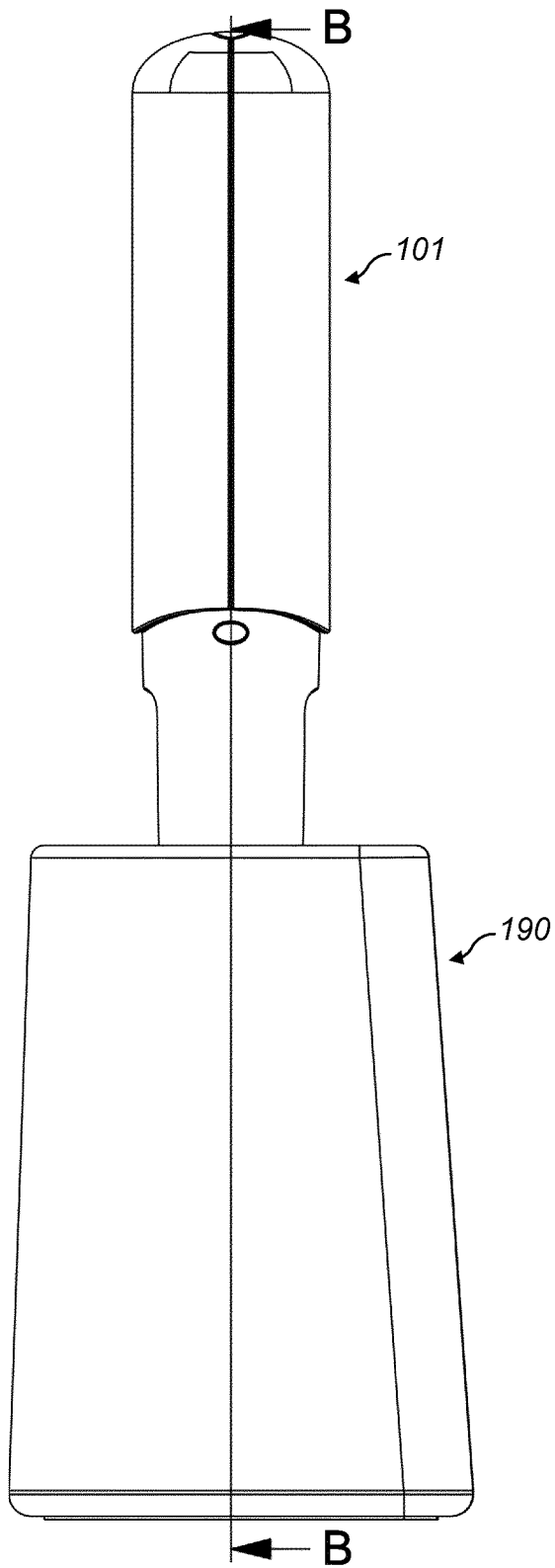


FIG. 11a

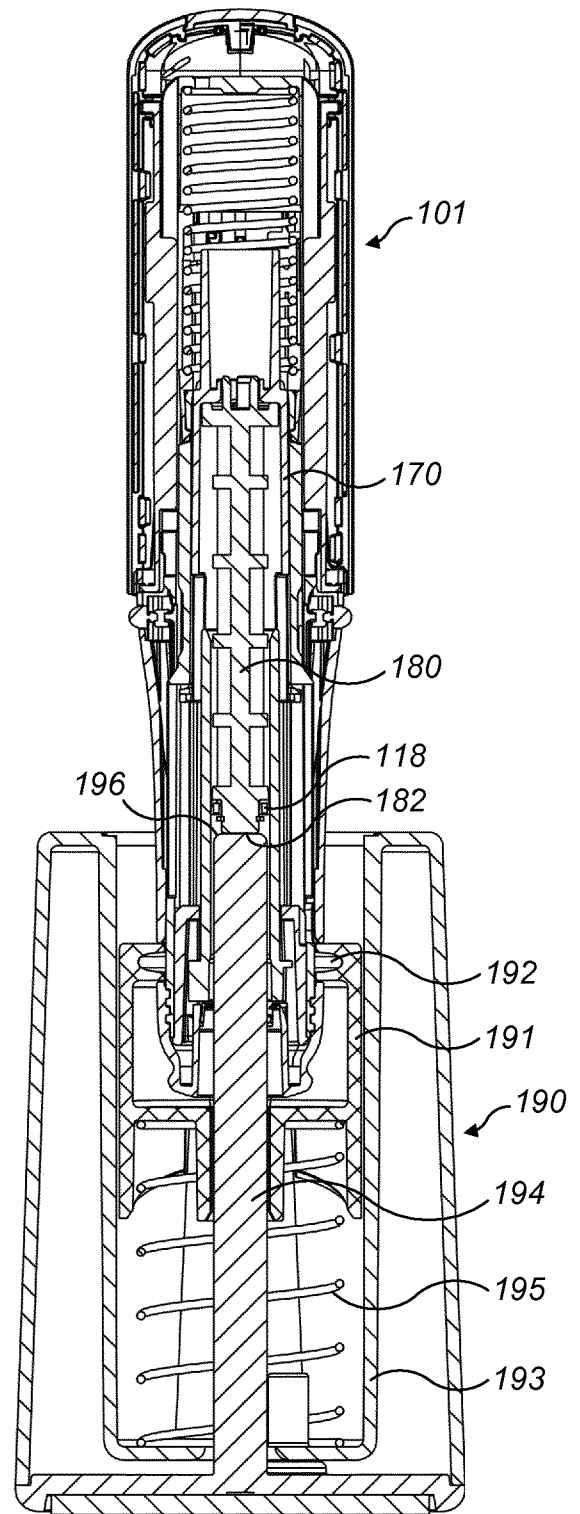


FIG. 11b

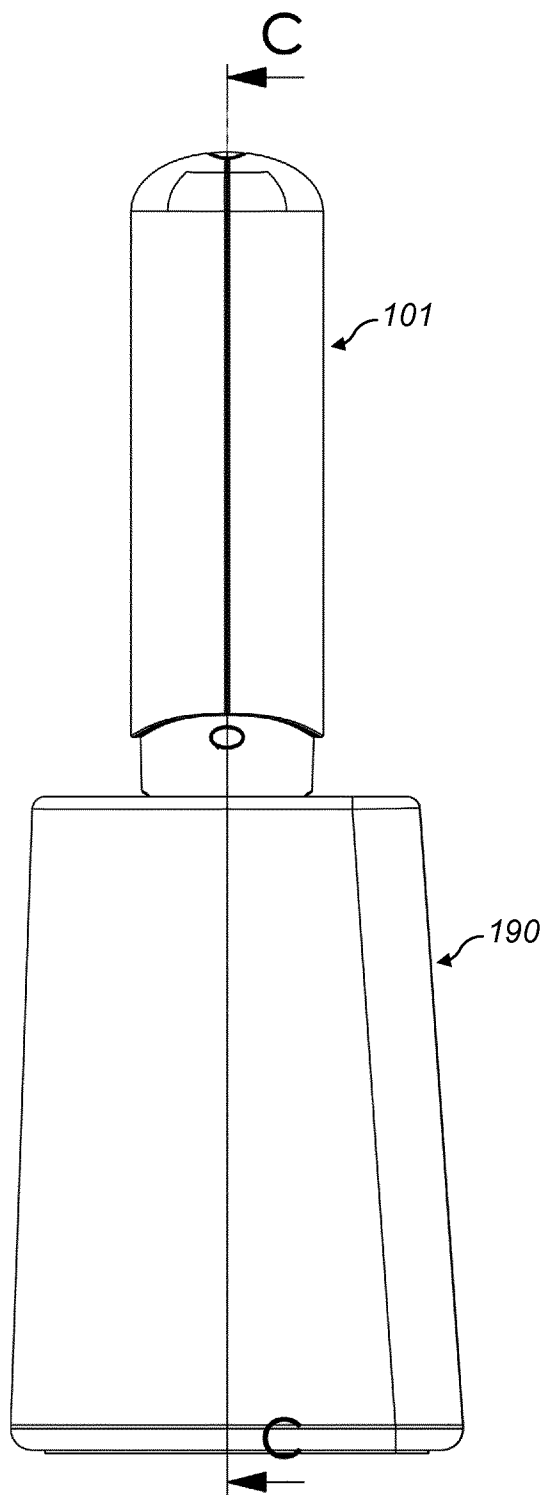


FIG. 12a

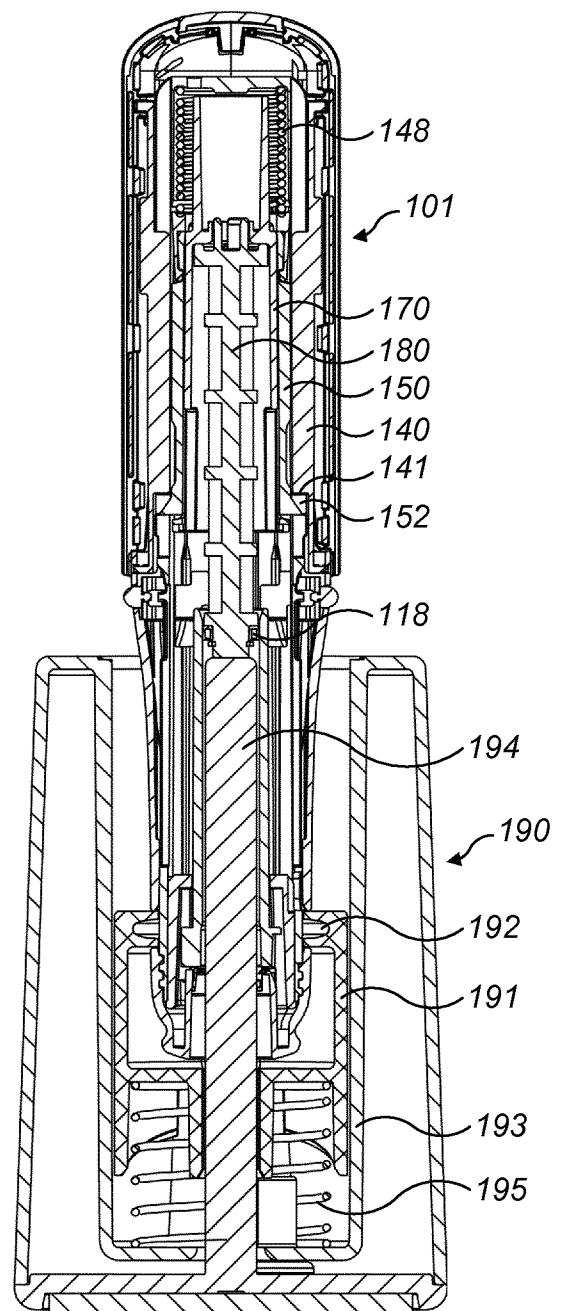


FIG. 12b

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2017/066780

A. CLASSIFICATION OF SUBJECT MATTER

INV. G09B23/28

ADD. A61M5/20

A61M5/315

A61M5/32

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

G09B A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/276568 A1 (WORDEN MORRIS ELIJAH [US] ET AL) 18 September 2014 (2014-09-18)	1,7-9,13
Y	paragraphs [0031], [0033], [0042], [0043] figures 3a,3b,3c	2-6, 10-12, 14-18
Y	----- EP 2 784 766 A1 (HOFFMANN LA ROCHE [CH]) 1 October 2014 (2014-10-01) paragraphs [0004], [0013]	2-6, 10-12, 14-18
A	----- US 2016/047473 A1 (FOSTER MIKE [US] ET AL) 18 February 2016 (2016-02-18) paragraph [0002] paragraph [0002]; figure 8b figure 8b ----- -/-	1-18



Further documents are listed in the continuation of Box C.



See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

29 August 2017

Date of mailing of the international search report

21/09/2017

Name and mailing address of the ISA/

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Fax: (+31-70) 340-3016

Authorized officer

Walther, Manuel

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2017/066780

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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Y	US 2014/264205 A1 (WORDEN MORRIS ELIJAH [US] ET AL) 18 September 2014 (2014-09-18) figures 1a,1c,3a paragraph [0041] -----	10-12

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Information on patent family members

International application No

PCT/EP2017/066780

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