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(54) **Title:** DOSE SETTING MECHANISM AND MEDICAMENT DELIVERY DEVICE COMPRISING THE DOSE SETTING MECHANISM

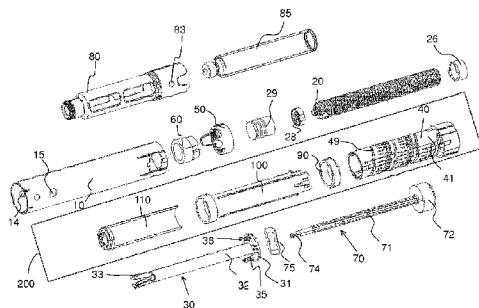


Fig. 5

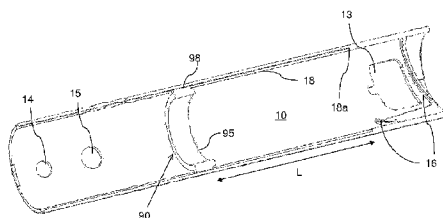


Fig. 7

(57) **Abstract:** A dose setting mechanism for a medicament delivery device, which dose setting mechanism comprises, a tubular member 10 having a longitudinal track 18 of a predetermined length; a dose drum 40, coaxial with the tubular member 10, and being axially and rotationally movable relative to the tubular member 10; a stop member 90, axially movable but rotationally locked relative to the tubular member 10, and further being in an axially slaved connection with the dose drum 40; wherein said stop member 90 comprises a track follower 98 in engagement with the longitudinal track 18, such that rotational movement of the dose drum 40 relative to the tubular member 10 may cause a maximum axial displacement of said dose drum 40 and said stop member 90, relative to the tubular member 10, corresponding to said predetermined length.



DOSE SETTING MECHANISM AND MEDICAMENT DELIVERY DEVICE
COMPRISING THE DOSE SETTING MECHANISM

TECHNICAL FIELD

5 The present invention relates to a dose setting mechanism for a medicament delivery device and in particular to a dose setting mechanism having a pre-determined maximum allowable dose. The invention also relates to a medicament delivery device comprising such a dose setting mechanism.

10 BACKGROUND

There are numerous devices for delivering medicament on the market where the medicament is arranged in a container, such as a syringe, a cartridge or the like, and wherein the medicament is ejected through a delivery member, such as a needle or a nozzle, by driving a movable stopper inside the container.

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The stopper is exposed to pressure, i.e. pushed into the compartment by a plunger rod. Actuation of the plunger rod could be done manually, as in the case of standard handheld syringes, or by pressure means such as springs. The latter is common in automatic or semi-automatic injectors. An example of a manual delivery device is the so called pen-injector.

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Different dose setting mechanisms have been developed for pen injectors to allow control of the dose to be delivered. Different factors determine the required amount of medicament, such as the severity of the ailment, the required effect, the body mass of the user, etc. One important aspect of dose setting is to prevent the user from over-dosing the drug. A solution to the problem is presented in US 8 545 456, wherein a pen injector is disclosed, having a dosage setting member that is rotated along a thread, relative to a casing. A rotational block is provided, which rotational block comprises a first and a second rotational stopper, such that when the dosage member has been rotated a certain distance, i.e. to an end position, the first and the second rotational stoppers abut against each other to prevent further rotation in that direction. The range of rotation allowed is set during design of the device and determines the maximum dose that may be set.

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However, there are alternative solutions for providing a maximum dose stop, as will be described herein.

5 SUMMARY

An object of the present invention is to provide a medicament delivery device wherein the drawbacks of the state of the art devices are remedied.

In the present application, when the term “distal” is used, this refers to the direction
10 pointing away from the dose delivery site. When the term “distal part/end” is used, this refers to the part/end of the delivery device, or the parts/ends of the members thereof, which under use of the medicament delivery device is/are located furthest away from the dose delivery site. Correspondingly, when the term “proximal” is used, this refers to the direction pointing to the dose delivery site. When the term “proximal
15 part/end” is used, this refers to the part/end of the delivery device, or the parts/ends of the members thereof, which under use of the medicament delivery device is/are located closest to the dose delivery site.

Further, the term “longitudinal”, with or without “axis”, refers to a direction or an axis
20 through the device or components thereof in the direction of the longest extension of the device or the component.

In a similar manner, the terms “radial” or “transversal”, with or without “axis”, refers to a direction or an axis through the device or components thereof in a direction
25 generally perpendicular to the longitudinal direction, e.g. “radially outward” would refer to a direction pointing away from the longitudinal axis.

Also, if nothing else is stated, in the following description wherein the mechanical structure of the device and the mechanical interconnection of its components is
30 described, the device is in an initial non-activated or non-operated state.

The invention relates to a dose setting mechanism for a medicament delivery device, which dose setting mechanism comprises, a tubular member having a longitudinal

track of a predetermined length; a dose drum coaxial with the tubular member, and being axially and rotationally movable relative to the tubular member; a stop member axially movable but rotationally locked relative to the tubular member, and further being in an axially slaved connection with the dose drum; wherein the stop member
5 comprises a track follower in engagement with the longitudinal track, such that rotational movement of the dose drum relative to the tubular member may cause a maximum axial displacement of said dose drum and said stop member, relative to the tubular member, corresponding to said predetermined length. Thus, it will not be possible to set a larger dose than the amount that corresponds to the predetermined
10 length of the longitudinal track.

In an embodiment of the invention the dose drum is in a first threaded connection with the tubular member. When the dose drum is rotated it is also axially displaced with respect to the tubular member.

15 In an embodiment of the invention said track follower is a radial protrusion in engagement with said longitudinal track such that rotational movement of the dose drum causes a rotationally locked, axial movement, of the stop member relative to the tubular member. Since the protrusion is locked in engagement with the
20 longitudinal track it follows that the stop member can only move axially with respect to the tubular member. Rotation is blocked.

In an embodiment of the invention said predetermined length is defined by a distance between an initial position of said track follower relative to the longitudinal track, and
25 a distal end wall of said longitudinal track. The track is created during manufacturing and the length is therefore predetermined and unchangeable.

In an embodiment of the invention the stop member is in said axially slaved connection between the initial position and the end wall, such that abutment of the

track follower against the distal end wall prevents the dose drum from further axial displacement. Thus when the track follower abuts the end wall, the slaved connection only allows movement away from the end wall.

- 5 In an embodiment the invention comprises a dose drum follower and a dose blocker sleeve, wherein the dose drum follower is axially and rotationally connected to the dose drum, and wherein the dose blocker sleeve is axially movable, but rotationally locked relative to the dose drum follower.
- 10 In an embodiment of the invention the dose drum follower comprises distal, radially resilient holding elements configured to interact with a slanting ledge of the dose drum, the dose drum follower further comprises a proximal support ring such that the stop member is distally biased against a proximal surface of the dose drum by the support ring of the dose drum follower through the interaction between the radially
- 15 flexible holding elements and the slanting ledge. Interaction with the slanting ledge means that the holding elements press against the slanting ledge, creating a longitudinally directed force that is counteracted by the support ring that presses in the opposite direction such that the stop member is held between the support ring and the proximal surface of the dose drum.
- 20 In an embodiment of the invention the proximal surface of the dose drum is a first undulating surface, and a distal circumferential surface of the stop member is a second undulating surface, such that rotation of the dose drum relative to the stop member causes a tactile and audible feedback signal. The signal is created by the
- 25 two undulating surfaces sliding against each other.

In an embodiment of the invention an applied proximally directed force to the dose drum follower causes the distal bias on the stop member by the support ring to be released. Since the dose drum is in a threaded connection with the tubular member,

a force applied to the dose drum follower will cause the holding members to flex slightly, creating a certain relative axial movement such the pressure on the stop member is released.

- 5 In an embodiment of the invention the stop member is positioned radially outside an elongated half-tubular sleeve of the dose drum follower, and wherein the half-tubular sleeve connects the proximal support ring with a distal forked sleeve of the dose drum follower.
- 10 In an embodiment of the invention the forked sleeve comprises distally extending arms, which distally extending arms comprise the holding elements, and wherein the distally extending arms are resilient in the radial direction.

In an embodiment of the invention the holding elements are arranged with slanting
15 proximal and distal surfaces.

An embodiment of the invention comprises a threaded plunger rod and a blocking ring, wherein said dose blocker sleeve is in a second threaded connection with the threaded plunger rod, and wherein the blocking ring is fixedly connected to the
20 threaded plunger rod. Thus when the dose drum is rotated along the first threaded connection with the tubular member, the dose drum follower and the dose blocker sleeve are also forced to rotate, but the dose blocker sleeve is in the second threaded connection with the plunger rod. Since the first and the second threaded connections have different pitches, axial displacement will also be different. The axial
25 displacement of the dose blocker sleeve will therefore be slower than the axial displacement of the dose drum and of the dose drum follower.

The invention also relates to a medicament delivery device comprising the herein-described dose setting mechanism.

Other aspects, features, and advantages will be apparent from the summary above, as well as from the description that follows, including the figures and the claims.

5 BRIEF DESCRIPTION OF THE DRAWINGS

The figures below disclose an embodiment of the invention for illustrational purposes only. In particular, the disclosure within the figures is not meant to limit the range of protection of the invention. The embodiment shown may be modified in different
10 ways within the scope of the claims.

- Fig. 1 shows a perspective view of a medicament delivery device according to a preferred embodiment of the invention, shown in the initial state;
- Fig. 2 shows a perspective view of a medicament delivery device according to
15 the preferred embodiment of Fig. 1, shown in the state when a dose is set;
- Fig. 3 shows a perspective view of a medicament delivery device according to the preferred embodiment of Fig. 1, shown after a set dose has been delivered;
- 20 Fig. 4 shows a perspective view of a medicament delivery device according to the preferred embodiment of Fig. 1, shown in a state having all medicament delivered;
- Fig. 5 shows an exploded view of the medicament delivery device according to the preferred embodiment of Fig. 1;
- 25 Fig. 6 shows an exploded view of a part of the medicament delivery device according to Fig. 1;
- Fig. 7 shows a detailed cross-sectional view of the tubular member of the medicament delivery device of Fig. 1;
- Fig. 8 shows an exploded view of a part of the medicament delivery device
30 according to Fig. 1;
- Fig. 9 shows a cross-sectional view of the medicament delivery device according to Fig. 1, shown in the initial state;

Fig. 10a-d show cross-sectional views of the medicament delivery device at different stages of dose setting and dose delivery;

DETAILED DESCRIPTION

5 Fig. 1 shows a perspective view of a medicament delivery device according to an embodiment of the invention. The medicament delivery device has a proximal end and a distal end and comprises a housing 10 having a proximal part or end 11 and a distal part or end 12. In the assembled state of the medicament delivery device, the housing 10 forms part of the outer surface or appearance of the medicament delivery
10 device, but since the herein-described technical features of the housing may be comprised in any sleeve-like or tubular member, the housing 10 will hereinafter be referred to as the tubular member 10.

The medicament delivery device further comprises a medicament container holder 80
15 which accommodates a medicament container. The medicament container holder 80 also forms part of the outer surface or appearance of the medicament delivery device. The proximal part of the container holder 80 is further arranged with a neck 82 at its proximal end, for attaching a per se known and conventional delivery member, e.g. an injection needle (not shown). It is to be understood that other types of connection
20 members, such as bayonet fitting, luer-lock fittings, and the like may be arranged. Also, the medicament container may have an injection needle integrated in its body, in which case the coupling for the delivery member may be omitted.

A removable cap (not shown) may be provided to cover the proximal end of the
25 device, and the proximal end of the medicament container holder 80, when the medicament delivery device is not in use.

Through window 81, a user can see a medicament container accommodated in the medicament container holder 80, allowing the user to view the remaining amount of a
30 drug in the medicament container. A distal part of the medicament container may reach into the proximal part of the tubular member 10 when the medicament container holder is connected to the tubular member 10.

Furthermore, at the distal end 12 of the tubular member 10, a dose window 13 is provided that shows a set dose to the user, as described in more detail below. At the distal end 12 of the tubular member 10, a dose setting knob 41a is also arranged.

5 Fig. 1 shows the medicament delivery device in an initial state. When the user grasps the dose setting knob 41a and rotates it in a first direction to set a dose, the dose setting knob 41a and other components move distally, as will be explained in detail below.

10 Fig. 2 shows a perspective view of the medicament delivery device in such state, i.e. when a dose is set.

Fig. 3 shows a perspective view of the medicament delivery device after the set dose has been delivered. As can be seen, the dose setting knob 41a and the components
15 linked therewith have been moved proximally and the dose setting knob 41a is again in its initial position. However, a threaded plunger rod 20 of the medicament delivery device has also been displaced in the proximal direction, pushing a stopper 29 into view within the medicament container.

20 Fig. 4 shows a perspective view of the medicament delivery device in a final state having expelled the entire content of the medicament container, which means that several individual doses have been delivered. The stopper 29 can be seen located at the proximal end of the medicament container, and part of the plunger rod 20, with its outer thread 21, can be seen through windows 81.

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The medicament container holder 80 is arranged with attachment means for connecting or attaching it to the proximal part 11 of the tubular member 10. In the embodiment shown the attachment means comprises a protrusion 83 (see Fig. 5) fitting into a corresponding recess 14. Alternatively, the connection could be
30 designed as a protrusion on the inside of the tubular member 10 that connects with a corresponding recess on the medicament container holder 80. It is also to be understood that other attachment members may be utilized, such as bayonet fittings,

threads, or the like for attaching the medicament container holder 80 to the tubular member 10.

Fig. 5 serves as an overview of the constituent parts of the complete medicament
5 delivery device, except for a medicament delivery member.

Figs. 6 and 7 show the elongated plunger rod 20, which is arranged inside the tubular member 10 and has a longitudinal axis generally corresponding to the longitudinal axis of the medicament delivery device. The plunger rod 20 is arranged with the outer
10 thread 21 on at least part of its outer surface. The plunger rod 20 is further arranged with at least one longitudinal groove 25. In the present embodiment, two such grooves 25 are provided on opposite sides of the plunger rod. The proximal end of the plunger rod 20 is arranged with a spinner 28, (Fig. 5) configured as an interface between the stopper 29 and the plunger rod 20 for reducing frictional resistance
15 arising when the plunger rod 20 rotates in relation to the stopper 29. The stopper 29 is movably received inside the medicament container 85. A blocking ring 26, having longitudinal splines on an inner circumferential surface, is mounted on a distal part of the plunger rod 20 at a predetermined distance from a dose blocker sleeve 110, wherein the longitudinal splines engage the longitudinal groove 25 of the plunger rod
20 20. The blocking ring 26 is thus rotationally locked to the plunger rod 20.

Fig. 6 further shows a tubular dose drum 40, an annular stop member 90, a dose drum follower 100, and the dose blocker sleeve 110, which together form a dose setting assembly 200 (Fig. 5). The dose drum 40 is in a first threaded connection with
25 the tubular member 10, whereby a proximal part of the dose drum 40 is arranged with a spirally extending groove 49 adapted to interact with a protrusion, or spirally extending ledge 16 (Fig. 7), on the inside surface of the tubular member 10, such that rotation of the dose drum 40 relative to the tubular member 10 also causes the dose drum to move axially, relative to the tubular member.

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The dose drum 40 is further provided with indicia on the outer circumferential surface. As the dose drum 40 moves relative to the tubular member 10, the indicia are shown through the dose window 13, informing the user about the set dose. When the dose

drum is assembled with the tubular member 10, the dose knob 41a, at the distal part of the dose drum, is accessible to the user, allowing him/her to rotate the dose drum to set a dose. The outer circumferential surface of the dose knob 41a is preferably flush with the outer surface of the tubular member 10. A circumferential slanting ledge 42 is arranged on the inside surface of the distal part of the dose drum 40. The slanting ledge 42 is configured to interact with radially flexible holding elements 102 on distally extending arms 101 of the dose drum follower 100, as will be explained below in detail. The annular proximal end surface of the tubular dose drum 40 is arranged with a first undulating surface comprising peaks and valleys, which mate with peaks and valleys of a second undulating surface 95 of a distal annular end surface of the stop member 90.

Cut-outs are arranged in the circumferential surface, adjacent the dose knob 41a. The cut-outs 43 are configured to accommodate radially protruding ledges 103 of the dose drum follower 100. A certain axial play between the cut-outs of the dose drum 40 and the ledges of the dose drum follower 100 creates a gap between a proximally facing surface of the ledges 103 and a distally facing edge of the cut-outs 43. This axial play allows the dose drum follower 100 to be slightly proximally displaced with respect to the dose drum 40 during medicament delivery, which will be further explained below. The proximally facing edges of the cut-outs interact with the ledges to prevent the dose drum follower from exiting the dose drum in the distal direction. Longitudinally extending ribs 44 on the inner surface of the dose drum 40 interact with longitudinally extending grooves 104, 114 on the outer surface of the dose drum follower 100 and of the dose blocker sleeve 110 such that the dose drum follower and the dose blocker sleeve are longitudinally movable, but rotationally fixed, relative to the dose drum.

The dose drum follower 100 is arranged coaxially with, and radially inside, the dose drum 40. The dose drum follower 100 comprises a proximal support ring 105 and a distal forked sleeve 107, which support ring and forked sleeve are connected by a longitudinally elongated half-tubular sleeve 106. The outer surface of the elongated half-tubular sleeve is arranged with the longitudinally extending grooves 104. The inner radius of the support ring 105 is generally equal to the outer radius of the half-

tubular sleeve, and the outer radius of the support ring 105 is generally equal to the outer radius of the proximal part of the dose drum 40, such that an annular, distally-facing support shelf 108 is formed by the support ring 105. The forked sleeve 107 comprises distally extending resilient arms 101 arranged with holding elements 102, which holding elements protrude radially outwards from the forked sleeve. The holding elements 102 are arranged with slanting proximal and distal surfaces and are configured to interact with the slanting ledge 42 of the dose drum 40. The arms 101 are resilient in the generally radial direction, and consequently the holding elements 102 are also radially resilient. Further to the description above, the ledges 103 are arranged on the outer circumferential surface of the forked sleeve 107 and protrude radially outwards, into the windows 43 of the dose drum 40.

The stop member 90 is preferably annular, or sleeve- or ring-shaped, and arranged coaxially with, and radially outside, the half-tubular sleeve 106. The stop member 90 is held between the dose drum follower 100 and the dose drum 40 such that it is supported by its proximal annular surface by the support shelf 108 of the support ring 105, and in abutment by its distal surface, i.e. the second undulating surface 95, with the first undulating surface 45 of the dose drum 40. The stop member is rotationally movable relative to the dose drum 40 and to the dose drum follower 100.

The longitudinal distance between the support shelf 108 and the holding elements 102 is chosen such that the stop member 90 is pressed between the support shelf 108 of the dose drum follower 100, and the first undulating surface 45 of the dose drum 40. The slanting proximal surfaces of the resilient holding members 102 presses radially outwards against the slanting ledge 42 of the cut-outs 43, resulting in a component force in the longitudinal direction, such that the dose drum follower 100 and the dose drum 40 are resiliently biased towards each other. The stop member is in an axially slaved connection with the dose drum 40, meaning that an axial displacement of the dose drum 40, and of the dose drum follower 100, causes an axial displacement of the stop member 90.

Fig. 7 shows a cross-sectional view of the tubular member and the stop member 90. The stop member is arranged with a track follower 98, e.g. a radial protrusion,

configured to engage a longitudinal track 18 of the tubular member 10, such that the stop member is rotationally fixed relative to the tubular member 10. Fig. 7 shows an initial state of the medicament delivery device, defined as the relative positions of the various components, except for the plunger rod 20 and the blocking ring 26, before a dose is set. Rotation of the dose drum 40 causes it to climb the protrusion 16, via the first threaded connection, bringing the dose drum follower 100 along axially. Since the stop member 90 is in an axially slaved connection with the dose drum, and with the dose drum follower, stop member is also displaced axially in relation to the tubular member 10. However, the stop member 90 moves rotationally locked relative to the tubular member. The maximum distance L that the stop member 90 may be displaced axially is predetermined and set during manufacturing and assembly of the medicament delivery device. The maximum distance L is defined as the distance between an initial position (before a dose is set) of the track follower 98 relative to the longitudinal track 18 and a distal end wall 18a of the longitudinal track 18. When the stop member 90 abuts the distal end wall 18a, the dose member 40 and the dose follower 100 may not move further, distally, via the first threaded connection with the tubular member 10. Thus, the maximum distance L corresponds to the maximum dose that may be set by the dose setting mechanism of the medicament delivery device.

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Returning to Fig. 6, the dose blocker sleeve 110 is arranged coaxially with the dose drum follower 100 and comprises a longitudinally elongated half-tubular body 116 having threaded ring 111 at a proximal part thereof. The threaded ring 111 is in a second threaded connection with the outer thread 21 of the plunger rod 20. The half-tubular body 116 of the dose blocker sleeve 110 has a complementary shape to the half-tubular sleeve 106 of the dose drum follower 100, and also has radius generally equal to the radius of the half-tubular sleeve 106. Therefore, the dose blocker sleeve 110 is rotationally locked, but axially movable in relation to the dose drum follower 100 and to the dose drum 40 because the longitudinal edges of the half-tubular body 110 abut the longitudinal edges of the half-tubular sleeve. Consequently, rotation of the dose drum 40 causes rotation of the dose drum follower 100 and of the dose blocker sleeve 110. However, because a pitch of the first threaded connection is greater than a pitch of the second threaded connection, the dose drum 40 and the dose drum

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follower 100 are displaced faster in the axial direction than the dose blocker sleeve 110, causing a telescopic movement of the telescopic dose setting assembly 200. In an initial state there is a slight play between a distal annular surface of the threaded ring 111 and a proximal half-annular surface of the half-tubular sleeve 106. In a dose-
5 set state the distal annular surface of the threaded ring 111 is separated from the proximal half-annular surface of the half-tubular sleeve 106 by a distance that corresponds to the set dose and to the difference in pitch between the first and the second threaded connections. Delivery of a set dose of medicament returns the dose
10 blocker sleeve 110 and the dose drum follower 100 to their relative positions of the initial state, but the axial position of the telescopic dose setting assembly 200 relative to/along the plunger rod 20 will change with each successive delivered dose, as will be explained in detail below.

The distal annular surface of the threaded ring 111 is further provided with a
15 sawtooth structure configured to engage a corresponding sawtooth structure of a proximal surface of the blocking ring 26 (Fig. 5).

In an unused medicament delivery device, the threaded ring 111 is arranged at a
20 predetermined distance from the blocking ring 26, which distance corresponds to the total amount of medicament in the medicament container. Each time a dose is set the dose blocker sleeve 110 climbs the threads 21 of the plunger rod 20, reducing the distance between the threaded ring 111 and the blocking ring 26. Thus if a user attempts to set a dose that exceeds the remaining amount of medicament in the
25 medicament container, the sawtooth structure of the threaded ring 111 will engage the sawtooth structure of the blocking ring 26. Since the blocking ring 26 is rotationally locked to the plunger rod 20, further rotation of the dose blocker sleeve 110 is blocked, and consequently further dose setting via the dose setting assembly 200 is also blocked.

30 The plunger rod 20 fits into a coaxial insert 50, arranged with a central passage 51, (Fig. 8) the center of which coincides with the longitudinal axis of the medicament delivery device. The central passage 51 of the thread insert is arranged with an inner thread 52 corresponding to the outer thread 21 of the plunger rod 20. The outer

surface of the insert 50 comprises at least one protrusion 53, fitting into corresponding recesses 15 (Fig. 5) on the inner surface of the tubular member 10. The protrusion 53 locks the insert 50 to the tubular member 10. As shown in Fig. 5, the recess 15 in the tubular member may be formed as a through-hole.

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The insert 50 further comprises a central bore 54 on the proximal side of the thread insert 50. The diameter of the central bore 54 is larger than the diameter of the central passage 51 so that a stepped configuration between the central passage and the central bore is provided. The inner circumferential surface of the central bore 54 is arranged with a circumferentially extending ratchet 55 having sawtooth-shaped teeth.

The ratchet 55 cooperates with a ring-shaped back rotation blocker 60 (Fig. 8) which is arranged with two oppositely positioned arms 62, extending along the outer circumferential surface 61 of the back rotation blocker 60. Although two such arms 62 are shown in Fig. 8, a single arm may also suffice. Two or more arms could also be provided, depending on the size of the blocking member 60. The arms 62 are flexible in the radial direction. On the outwardly directed surfaces of the arms 62, a ledge 63 is arranged. Each ledge 63 has a shape complementary to the ratchet 55 of the thread insert 50. The back rotation blocker 60 is further arranged with a central passage 65 (Fig. 8) through which the plunger rod 20 extends. The central passage 65 is arranged with radially inwardly directed ribs 66, which ribs 66 fit into the elongated grooves 25 on the outer surface of the plunger rod 20. Since the thread insert 50 is fixed to the tubular member 10, this structure provides a rotational lock of the plunger rod 20 in one direction because the ledges 63 of the arms 62 engage the ratchet 55, but allows rotational motion in the other direction, as well as axial movement of the plunger rod 20 in the longitudinal direction. The plunger rod 20 may therefore propagate proximally if it rotates relative to the thread insert 50, through the threaded central passage 51, but it cannot move distally due to the rotational lock of the back rotation blocker 60.

The plunger rod 20 is further arranged with a plurality of longitudinal splines or ribs 23 provided on the inner circumferential surface of the hollow plunger rod 20 (Fig. 6).

A drive drum sleeve 30 (Figs. 5, 9b, 9c) of generally tubular shape is arranged coaxially with, and radially inside, the plunger rod 20. The drive drum sleeve 30 is provided with a distal end wall 31 transversal to the longitudinal axis of the drive drum sleeve 30. The distal end wall 31 has central opening and the drive drum sleeve is hollow in order to receive an actuator rod 70 (Fig. 9a) therein, as will be described below. The proximal end of the drive drum sleeve 30 comprises one or more, preferably two, flexible arms 33 extending in the proximal direction. The arms 33 are flexible in that their proximal ends are radially deflectable upon application of a radial force thereon, as will be describe below. The outer surface of each flexible arm 33 comprises a radially projecting, longitudinally aligned, plunger rod engagement surface 34 for selectively engaging the longitudinal splines 23 on the inner surface of the plunger rod 20. The shape of the surface 34 may generally correspond to the shape of the circumferentially arranged ribs 23 on the plunger rod 20. The inner surface of each flexible arm 33 comprises a step 37 for engagement with a shoulder 77 of the actuator rod 70 located radially inside the hollow drive drum sleeve 30.

The distal end wall 31 forms a coupling element by means of two proximally extending locking arms 35. The locking arms 35 comprise, at their respective outer surface, a locking structure 36, such as a hook, for rotationally locking the drive drum sleeve 30 to the cut-outs 43 of the dose drum 40, although a slight longitudinal play still exists between the dose drum 40 and the drive drum sleeve 30.

The actuator rod 70 comprises a longitudinal rod 71 and a distal push button 72. The push button is intended to act as a contact surface for a finger of a user during drug delivery, for applying a driving force to expel medicament. In line with the description above, the longitudinal rod 71 of the actuator rod 70 is accommodated coaxially with, and radially inside, the hollow drive drum sleeve 30. The actuator rod is always rotationally movable relative to the drive drum sleeve. At its proximal end, the longitudinal rod 71 comprises an engagement structure comprising a circumferential groove 73 (Fig. 9a). Adjacent the groove and in the proximal direction is a knob 74 and in the distal direction a shoulder 77. Fig. 9b shows that the size of the groove 73 and its position on the longitudinal rod 71 in relation to the drive drum sleeve 30 is such that the step 37 of the flexible arms 33 of the drive drum sleeve 30 is received

in the groove 73 when no axial force is exerted on the push button 72. In such a state, the flexible arms 33 are not deflected radially outwards, but are in a relaxed state. In the relaxed state, the drive drum sleeve 30 is rotationally movable in relation to the plunger rod 20. The knob prevents the actuator rod 70 from falling out of the drive drum sleeve 30 when no pressure is applied to the push button 72.

The axial length of the actuator rod 70 in comparison to the drive drum sleeve 30 is such that, in the relaxed state of the medicament delivery device, i.e. with the step 37 being received in the groove 73, the proximal surface of the push button 72 is spaced from the distal surface of the distal end wall 31 by a certain gap (Fig. 9b). This gap is maintained when a dose is set by a user and the first part 41 of the dose drum 40, the drive drum sleeve 30 and the resilient spinning means 70 are moved distally. However, as soon as the push button 72 is pushed in the proximal direction, the push button 72 first bridges the gap thereby moving the longitudinal rod 71 in the proximal direction relative to the drive drum sleeve 30. Due to such relative displacement, the shoulder 77 is moved in contact with, and is pressed against, the step 37 of the flexible arms 33, thus deflecting the arms 33 outwardly, moving the engagement surfaces 34 into engagement with the longitudinal splines 23 on the inner surface of the plunger rod 20, thereby rotationally locking the drive drum sleeve 30 to the plunger rod 20.

A spring washer 75 is arranged between the distal end wall 31 of the drive drum sleeve 30 and the push button 72 of the actuator rod 70 is compressed when the push button is pressurized. When pressure on the push button is released, the actuator rod will be forced back in the distal direction by the spring washer 75, re-establishing the gap of the relaxed state. Consequently, since the shoulder 77 is moved distally, the arms 33 relax and the engagement surfaces 34 are moved out of engagement with the splines 23 of the plunger rod 20, such that the plunger rod 20 is again rotationally movable in relation to the drive drum sleeve 30.

The function of the medicament delivery device will now be described. Fig. 10a shows the medicament delivery device in the initial state, before a dose has been set. The container holder 80, the container 85 and the stopper 29 are not shown.

In order for a dose to be delivered, the device must be operated to set a dose. In order to set a dose to be delivered the user grips the tubular member 10 and the distally arranged dose setting knob 41a and turns them in relation to each other, where the dose setting knob 41a is turned in the clockwise direction, for example. The turning of the dose setting knob 41a will cause the dose drum 40 to be rotated. Due to the first threaded connection between the helical groove 49 of the dose drum 40 and the spiral ledge segment 16 of the tubular member 10, the rotation will cause the dose drum 40 to move in the distal direction in relation to the tubular member 10. Inside the dose setting drum 40 the dose drum follower 100 will also rotate and "follow" the dose drum 40 distally due to the engagement between the longitudinally extending ribs 44 of the dose drum 40 and the longitudinally extending grooves 104 of the dose drum follower 100. In addition, the dose blocker sleeve 110 rotates since it is rotationally locked to the dose drum follower. However, it moves distally at a lower speed than the dose drum 40 and the dose drum follower 100 since it is connected to the outer thread 21 of the plunger rod 20 via the second threaded connection, whose pitch is lower than the pitch of the first threaded connection. The plunger rod does not rotate since it is rotationally locked in the dose setting direction by the back rotation blocker 60 interacting with the ratchet 55 of the insert 50.

During dose setting, since the dose drum 40 and the dose drum follower 100 are biased towards each other by the resilient holding members 102 interacting with the slanting ledge 42, a tactile and audible feedback signal is perceived by the user as the first undulating surface 45 of the dose drum slides over the second undulating surface 95 of the stop member 90, as described above.

Further during dose setting, indicia on the dose drum 40 are shown through the window or opening 13 at the distal end 12 of the tubular member 10. The user thus rotates the dose setting knob 41a until the prescribed dose quantity is displayed. If the user sets a too large dose, he/she may simply turn the dose setting knob 41a in the opposite direction, whereby both the dose drum 40 and the drive drum sleeve 30 are turned in the opposite direction until the correct dose has been reached.

The drive drum sleeve 30 rotates with the dose drum 40 because of the engagement of the locking structure 36 with the cut-outs 43 of the dose drum 40.

Fig. 10b shows a cross-sectional view of the medicament delivery device in the state
5 where a dose has been set, but before the push button 72 has been pressed.

Notably, the track follower 98 of the stop member 90 has moved some distance towards the end wall 18a of the longitudinal track of the tubular member 10. The threaded ring 111 of the dose blocker 110 has also been longitudinally separated from the dose drum follower 100 and the dose drum 40.

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If the user should attempt to set a larger dose than prescribed, i.e. a larger than allowed by the device design, the track follower 98 of the stop member 90 will abut the end wall 18a of the longitudinal track 18 of the tubular member 10. Consequently due to the slaved connection between the stop member 90 and the dose drum 40,
15 the dose drum follower 100 will be prevented from further distal movement via its support ring 105, which in turns prevents the dose drum from further distal or rotational movement. Thus the dose setting drum 40, dose drum follower 100 and the stop member 90 are limited to move distally the maximum distance L, as shown in Fig. 7.

20

In order to deliver a dose of medicament, the user presses the proximal end of the device against a dose delivery site, performing a skin penetration in case the delivery member is a needle. The next step is to press on the push button 72 at the distal end of the device. This causes the gap to close due to the force applied by the user at the
25 push button 72. Fig. 10c shows the device when the push button 72 has been pressed but before the device starts expelling medicament.

The force applied to the push button 72 and the actuator rod 70 brings the drive drum sleeve 30 into engagement with the inner surface of the plunger rod 20, as described
30 above. Secondly, once the gap push button 72 and the distal end wall 31 has been reduced, the force on the push button 72 is transmitted to the dose drum follower as a proximal surface of the distal end wall 31 makes contact with a distal end of the distally extending arms 101, thereby urging the dose follower in the proximal direction.

This proximal force will be transferred to the dose drum 40 due to the holding members 102 of the dose drum follower 100 being pushed proximally against the slanting ledge 42, thereby causing rotation of the dose drum 40 via the first threaded connection, which also leads to a proximal movement of the dose drum 40 relative to the tubular member 10.

The proximal force applied to the dose drum follower 100 releases the pressure on the stop member 90 against the proximal circumferential surface of the dose drum 40. Therefore, when the dose is expelled, the undulating surfaces of the stop member 90 and of the dose drum 40 will not slide against each other. Thus no tactile or audible signal will be generated by the undulating surfaces during medicament delivery.

Because of the rotational lock between the dose drum 40 and the drive drum sleeve 30, the latter will also rotate. Due to the radial flexing of the arms 33 of the drive drum sleeve 30, the engagement surfaces 34 of the drive drum sleeve 30 firmly engage the splines 23 of the plunger rod 20.

Thus when the dose drum 40 and the drive drum sleeve 30 rotate, the latter will drive the plunger rod 20 to rotate as well. This direction of rotation will be allowed by the back rotating blocking element 60 due to the design of its arms 62 in contact with the ratchet 55 of the thread insert 50. The plunger rod 20 will thus rotate together with the back rotating blocking element 60, and the ledges 63 of the arms 62 of the back rotating blocking element 60 will slide over the ratchet 55 of the thread insert 50, generating an audible and tactile feedback signal that the dose of medicament is being administered. Further the rotation of the plunger rod 20 will cause it to be moved in the proximal direction due to its threaded connection with the thread insert 50, whereby the movement of the plunger rod 20 will urge the stopper 29 in the proximal direction, thereby expelling a dose of medicament through the dose delivery member. During rotation of the plunger rod 20, the dose blocker sleeve 110 also rotates as it is urged to rotate by the dose drum follower 100. The dose blocker sleeve 110 therefore maintains its axial position with respect to the plunger rod, i.e. the dose blocker sleeve 110 rotates together with the plunger rod 20 and propagates proximally as the plunger rod 20 rotates through the threaded insert 50. In a manner

similar to the dose setting procedure, the dose drum 40 and the dose drum follower 100 move proximally at a higher speed since the dose drum 40 is in the first threaded connection with the tubular member 10 and since the pitch of the first threaded connection is greater than the pitch of the threaded insert 50. The dose has been
5 delivered when the dose drum 40 has moved back to its initial position relative to the dose drum follower 100 and the dose blocker sleeve 110.

Fig. 10d shows the device after a dose of medicament has been delivered, but before the pressure on the push button 72 has been released. Compare to Fig. 10a, it can
10 be seen that the plunger rod has moved proximally relative to thread insert 50 and to the tubular member 10, and also relative to the dose setting assembly 200. Thus, the stop member 90 is in the initial position relative to the end wall 18a, and the dose blocker sleeve 110, comprising the threaded ring 111, is closer to the blocking ring 26 than before the previous dose was set.

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After dose administration the device is removed from the dose delivery site, and the medicament delivery member is discarded. If the medicament container 85 still contains a large enough dose to be delivered, the above steps may be repeated.

20 If the medicament container however contains a dose that is smaller than the prescribed dose, the present invention prevents setting a dose that is larger than the remaining dose, as previously described.

25 Since the device is arranged with indicia that indicates the quantity of the last, non-sufficient, dose the user may complement the last dose with a new device comprising a new container. In this manner, the whole content of a container may be used so that no medicament will go to waste.

30 While the invention has been illustrated and described in detail in the drawings and in the foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive. It will be understood that changes and modifications may be made, by those of ordinary skill in the art without departing from the spirit of the invention.

Furthermore, in the claims the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. A single unit may fulfill the functions of several features recited in the claims. The terms

5 "essentially", "about", "approximately" and the like in connection with an attribute or a value particularly also define exactly the attribute or exactly the value, respectively. Any reference signs in the claims should not be construed as limiting the scope.

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CLAIMS

1. A dose setting mechanism for a medicament delivery device, which dose setting mechanism comprises,
- 5 - a tubular member 10 having a longitudinal track 18 of a predetermined length;
- a dose drum 40, coaxial with the tubular member 10, and being axially and rotationally movable relative to the tubular member 10;
- a stop member 90, axially movable but rotationally locked relative to the tubular member 10, and further being in an axially slaved connection with the
- 10 dose drum 40;
- characterised in that** said stop member 90 comprises a track follower 98 in engagement with the longitudinal track 18, such that rotational movement of the dose drum 40 relative to the tubular member 10 may cause a maximum axial displacement of said dose drum 40 and said stop member 90, relative to the
- 15 tubular member 10, corresponding to said predetermined length.
2. A dose setting mechanism for a medicament delivery device according to claim 1, wherein the dose drum 40 is in a first threaded connection with the tubular member 10.
- 20
3. A dose setting mechanism for a medicament delivery device according to claim 2, wherein said track follower 98 is a radial protrusion in engagement with said longitudinal track 18 such that rotational movement of the dose drum 40 causes a rotationally locked, axial movement, of the stop member 90 relative to the tubular
- 25 member 10.
4. A dose setting mechanism for a medicament delivery device according to claim 1, wherein said predetermined length is defined by a distance between an initial position of said track follower relative to the longitudinal track, and a distal end
- 30 wall 18a of said longitudinal track 18.

5. A dose setting mechanism for a medicament delivery device according to claim 4, wherein the stop member 90 is in said axially slaved connection between the initial position and the end wall 18a, such that abutment of the track follower 98 against the distal end wall 18a prevents the dose drum 40 from further axial displacement
6. A dose setting mechanism for a medicament delivery device according to claim 1, further comprising a dose drum follower 100 and a dose blocker sleeve 110, wherein the dose drum follower 100 is axially and rotationally connected to the dose drum 40, and wherein the dose blocker sleeve 110 is axially movable, but rotationally locked relative to the dose drum follower 100.
7. A dose setting mechanism for a medicament delivery device according to claim 6, wherein the dose drum follower 100 comprises distal, radially resilient holding elements 102 configured to interact with a slanting ledge 42 of the dose drum 40, the dose drum follower 100 further comprising a proximal support ring 105 such that the stop member 90 is distally biased against a proximal surface of the dose drum by the support ring 105 of the dose drum follower 100 through the interaction between the radially flexible holding elements 102 and the slanting ledge 42.
8. A dose setting mechanism for a medicament delivery device according to claim 7, wherein the proximal surface of the dose drum is a first undulating surface 45, and wherein a distal circumferential surface of the stop member 90 is a second undulating surface 95, such that rotation of the dose drum 40 relative to the stop member 90 causes a tactile and audible feedback signal.

9. A dose setting mechanism for a medicament delivery device according to claim 8, wherein an applied proximally directed force to the dose drum follower 100 causes the distal bias on the stop member 90 by the support ring 105 to be released.
- 5
10. A dose setting mechanism for a medicament delivery device according to claim 7, wherein the stop member 90 is positioned radially outside an elongated half-tubular sleeve 106 of the dose drum follower 100, and wherein the half-tubular sleeve 106 connects the proximal support ring 105 with a distal forked sleeve 107
- 10 of the dose drum follower 100.
11. A dose setting mechanism for a medicament delivery device according to claim 10, wherein the forked sleeve 107 comprises distally extending arms 101, which distally extending arms comprise the holding elements 102, and wherein the
- 15 distally extending arms are resilient in the radial direction.
12. A dose setting mechanism for a medicament delivery device according to claim 7 or 11, wherein the holding elements 102 are arranged with slanting proximal and distal surfaces.
- 20
13. A dose setting mechanism for a medicament delivery device according to claim 6, further comprising a threaded plunger rod 20 and a blocking ring 26, wherein said dose blocker sleeve 110 is in a second threaded connection with the threaded plunger rod 20, and wherein the blocking ring 26 is fixedly connected to the
- 25 threaded plunger rod 20.
14. A medicament delivery device comprising a dose setting mechanism according to any of the claims 1-13.
- 30

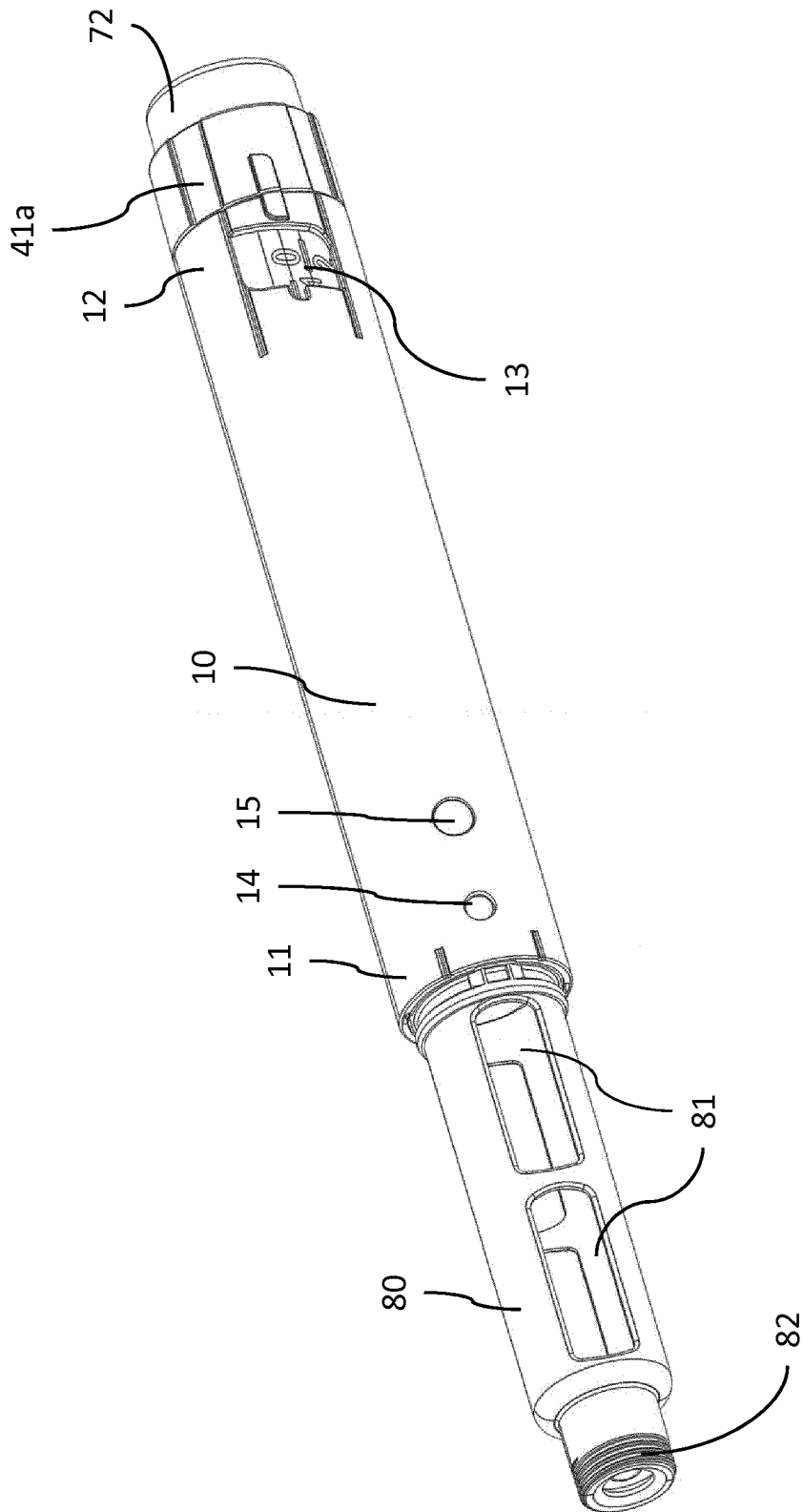


Fig. 1

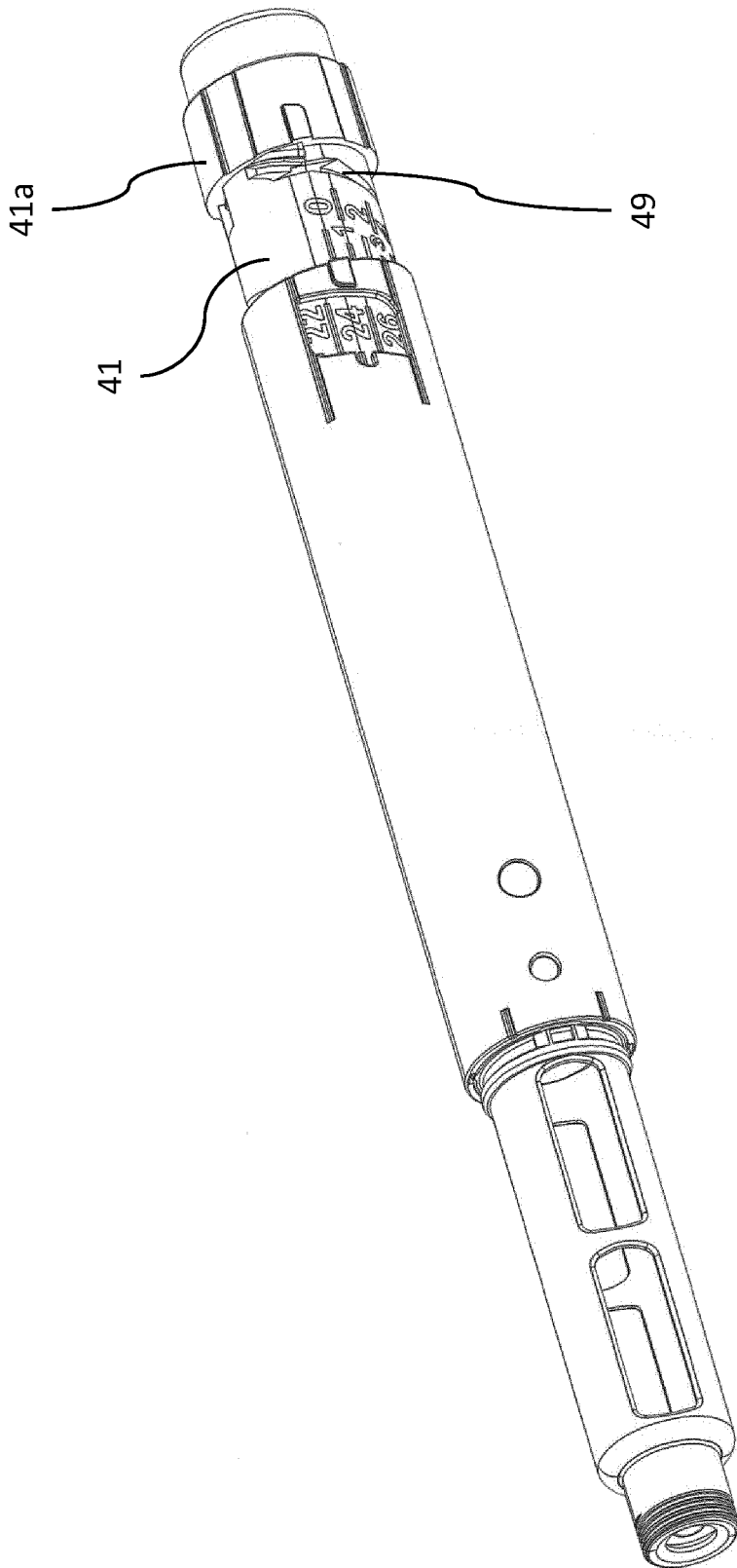


Fig. 2

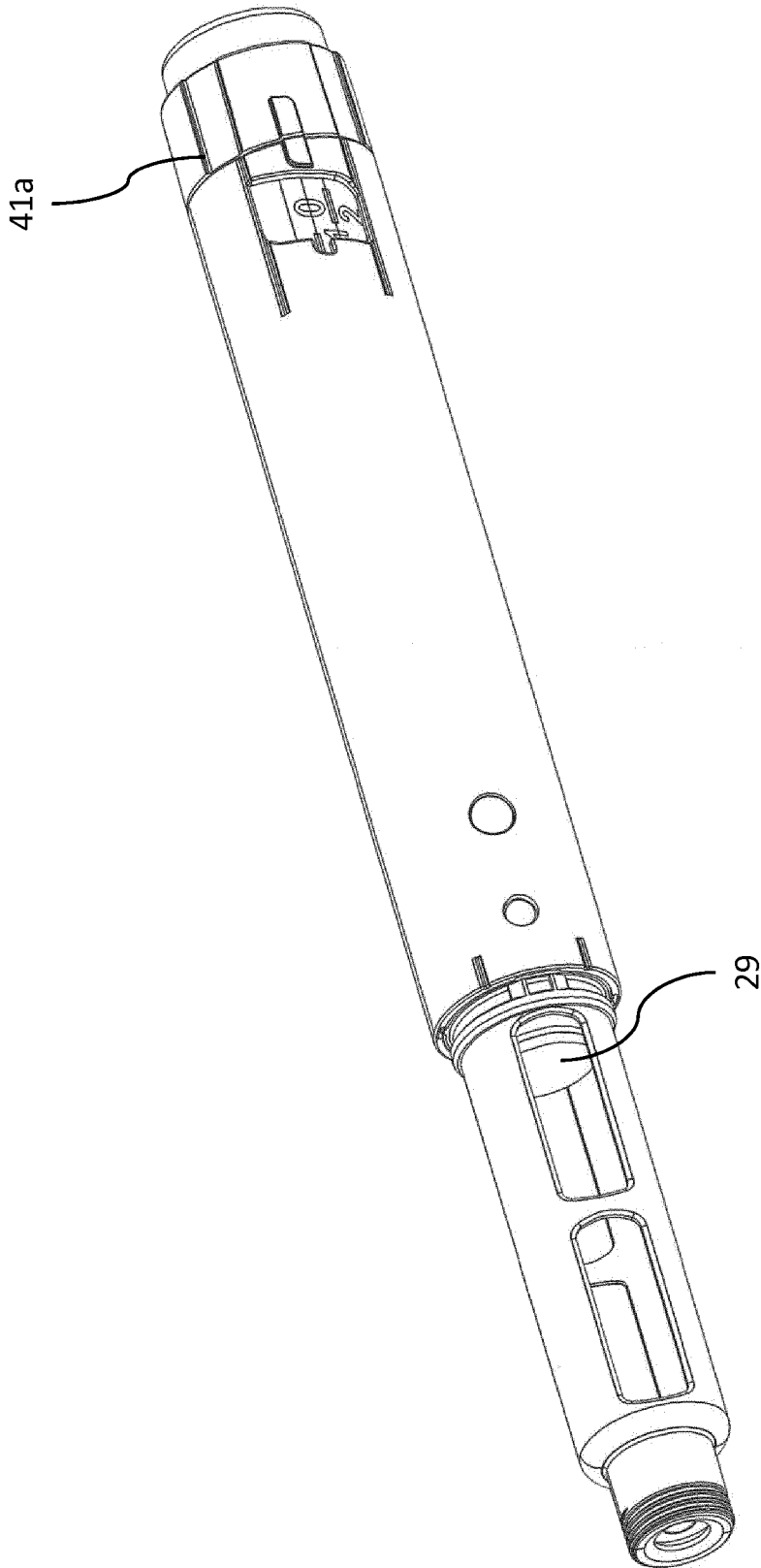


Fig. 3

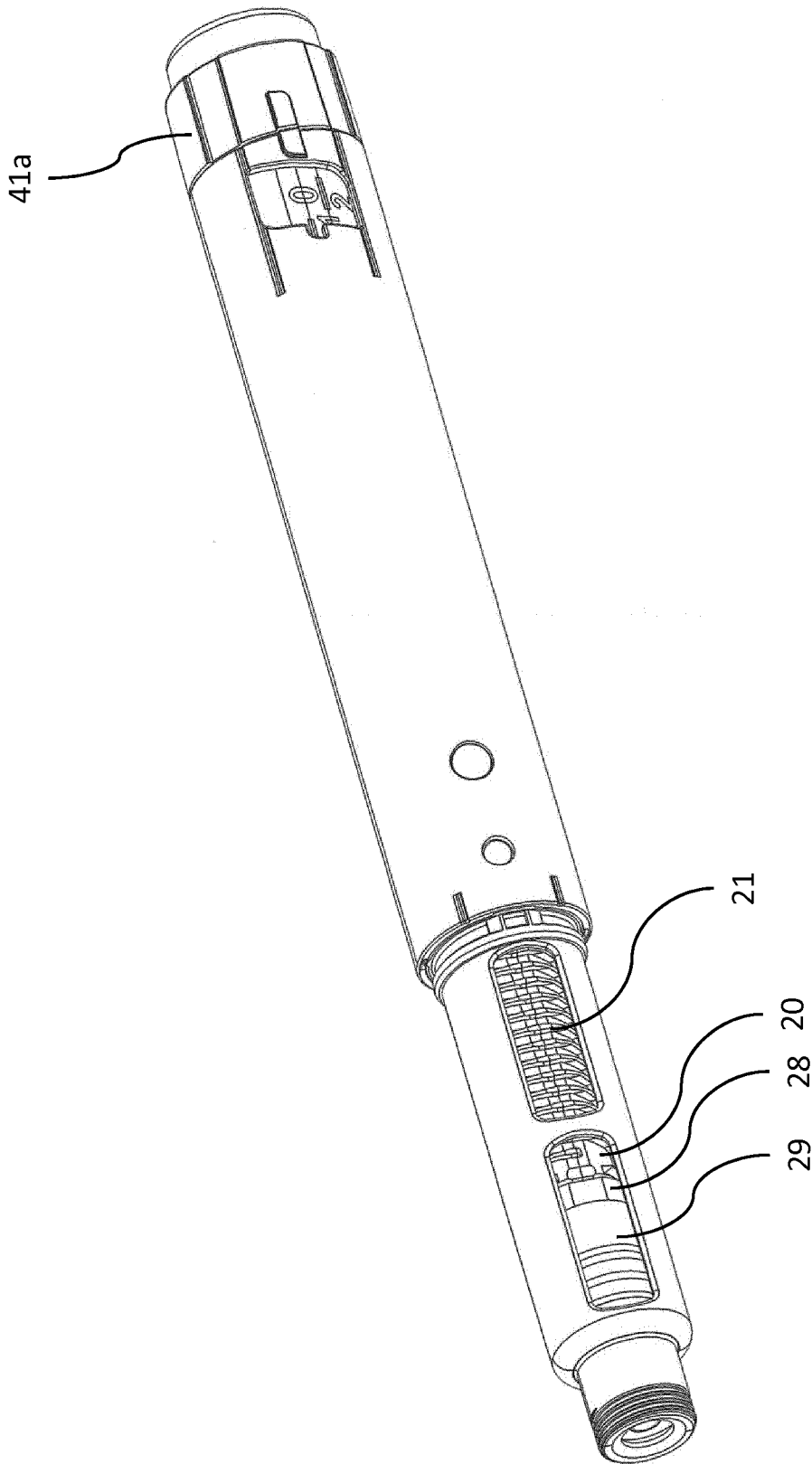


Fig. 4

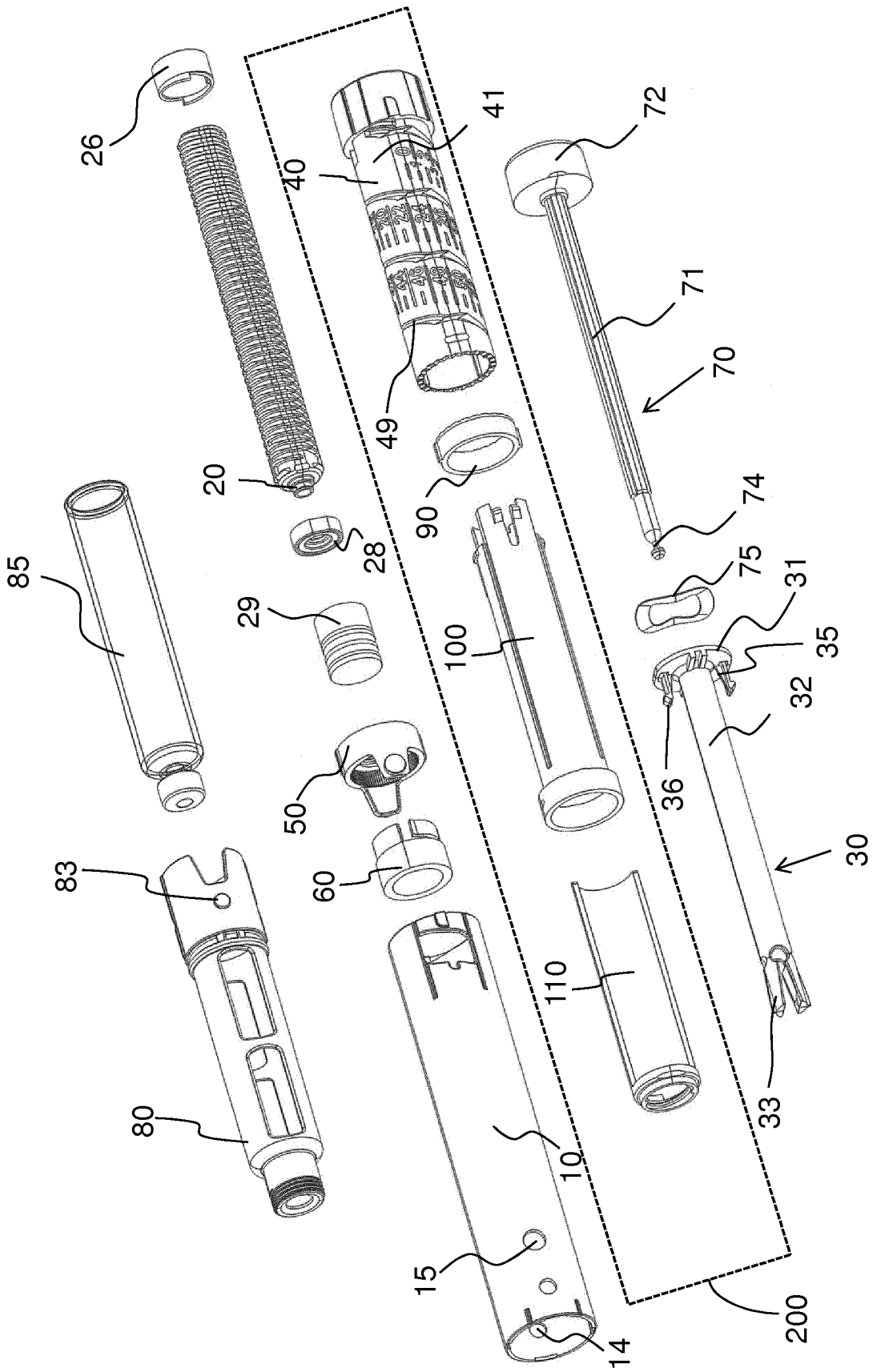


Fig. 5

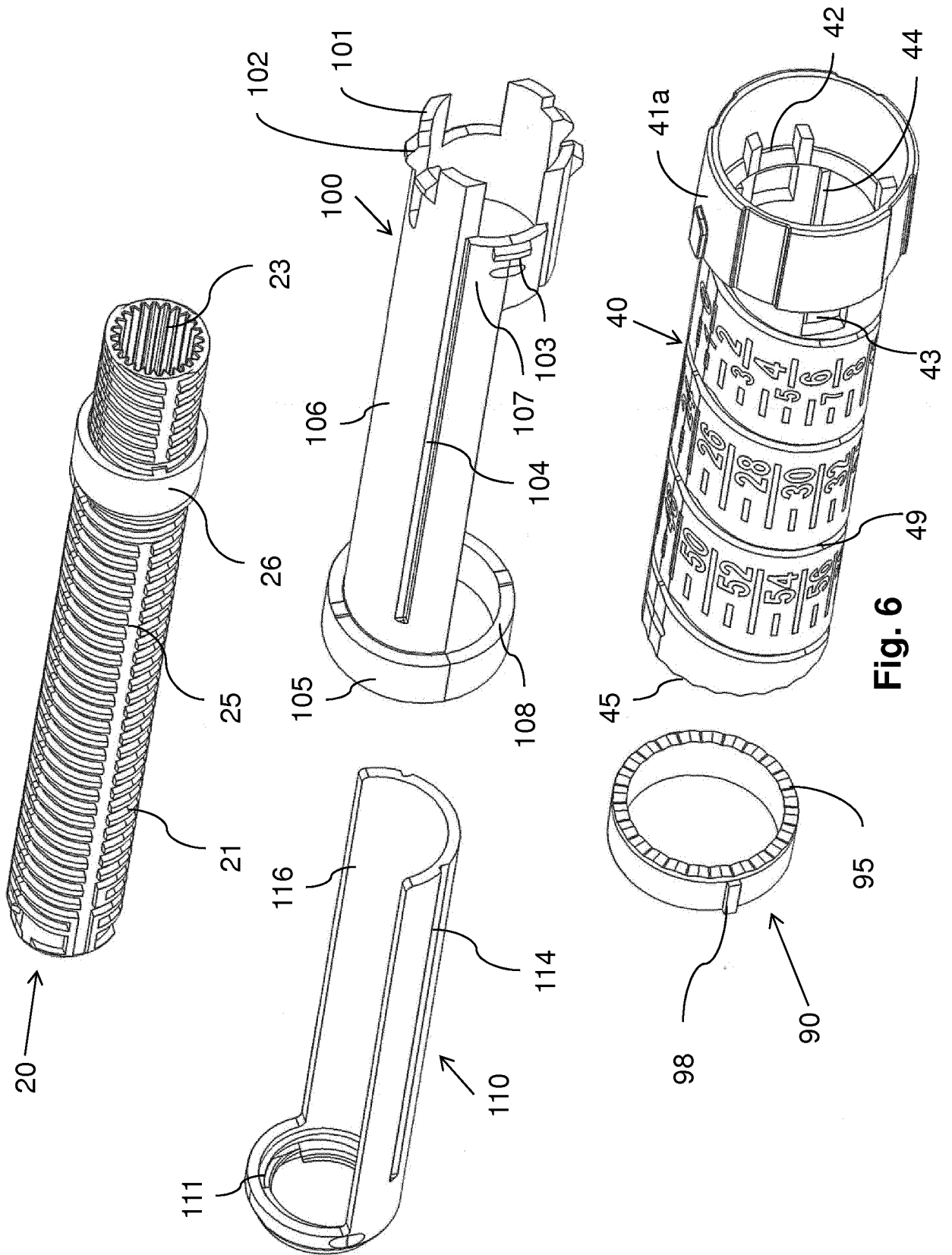


Fig. 6

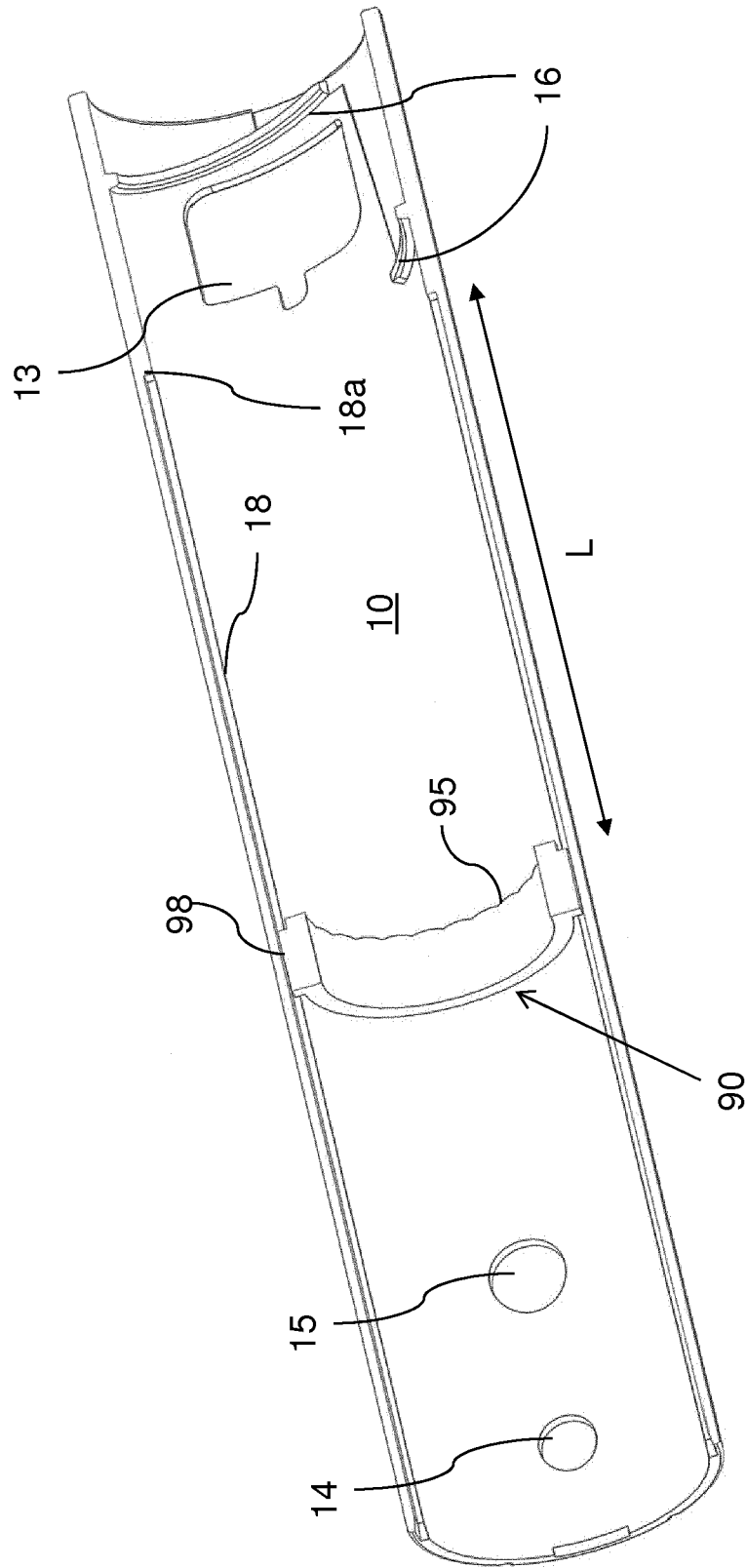


Fig. 7

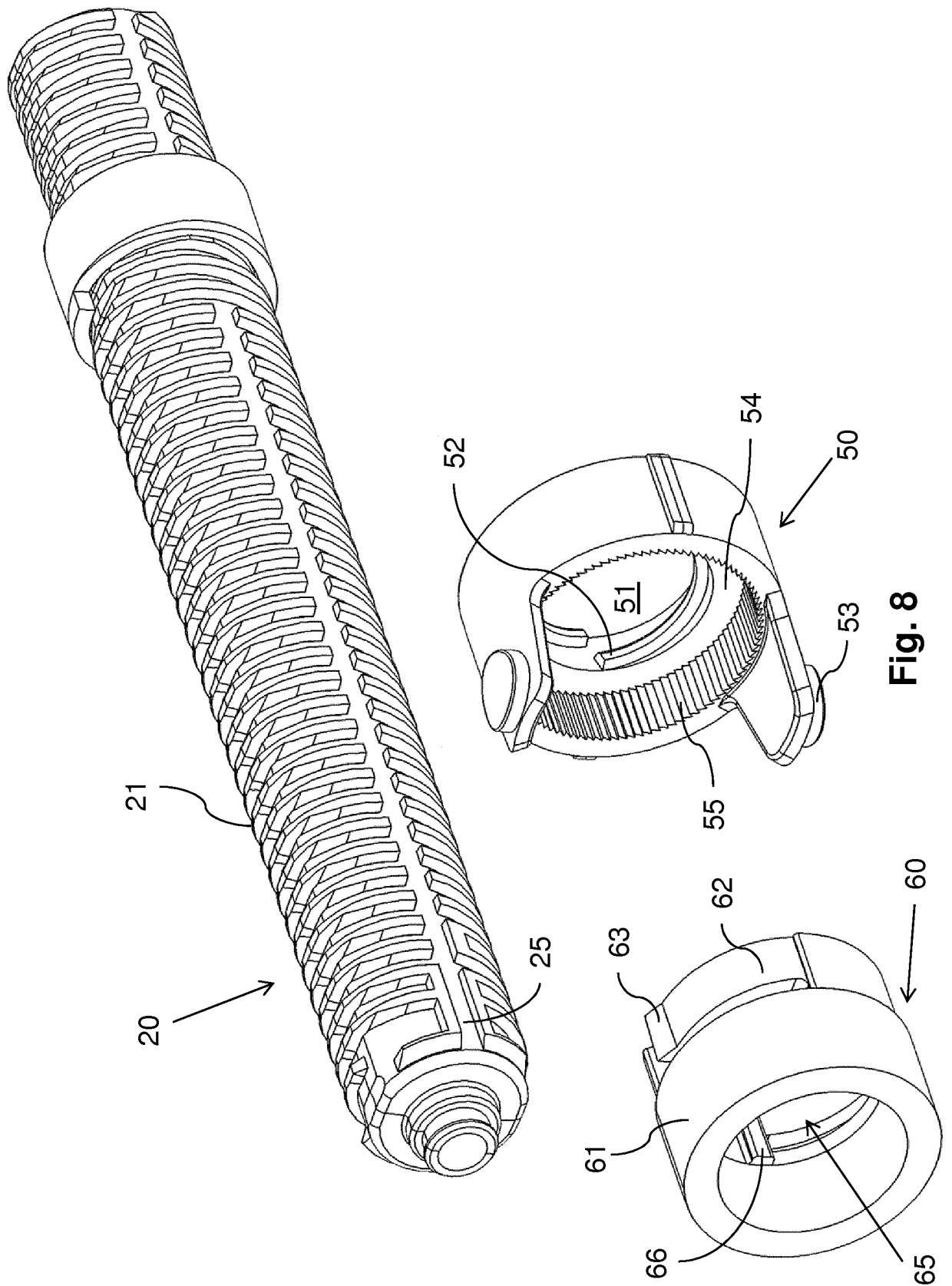


Fig. 8

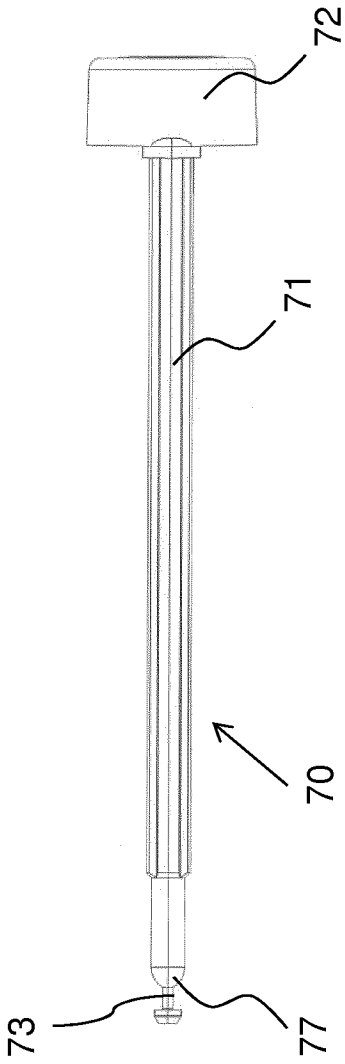


Fig. 9a

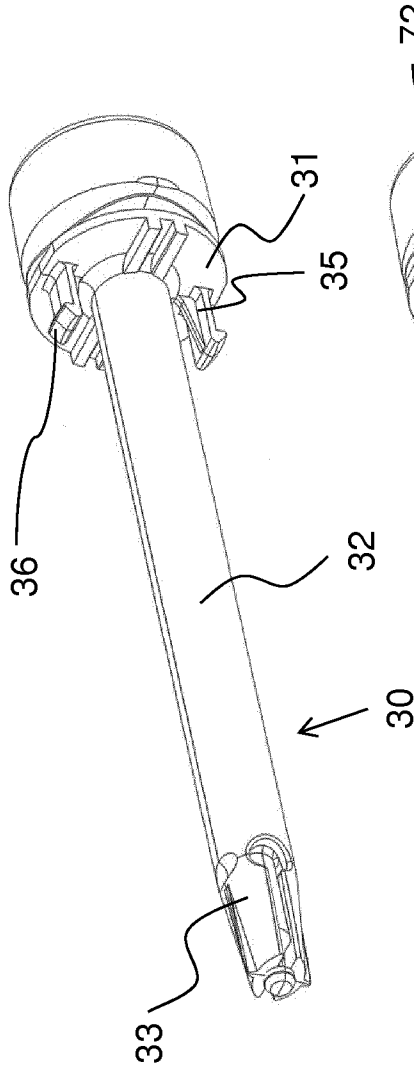


Fig. 9b

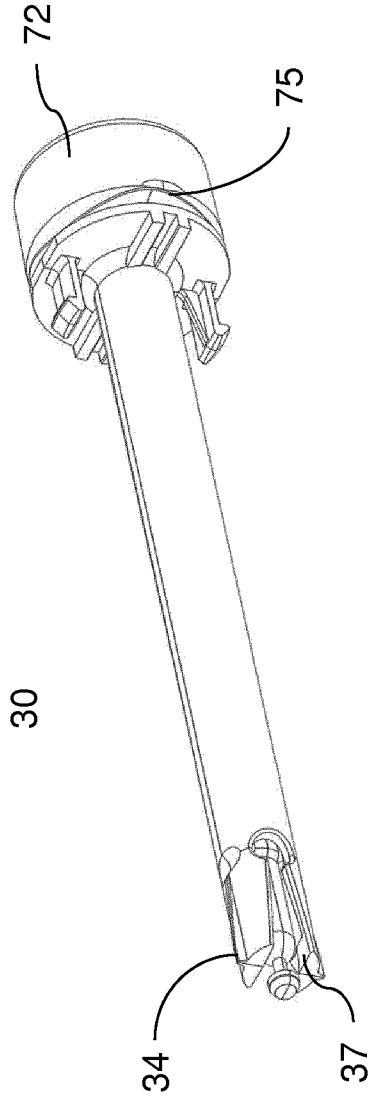


Fig. 9c

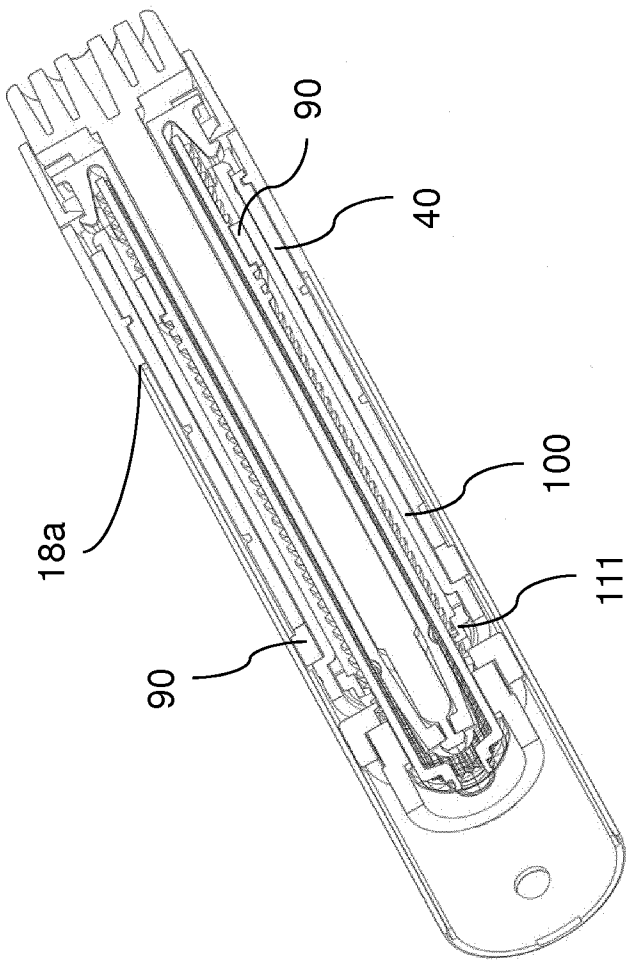


Fig. 10a

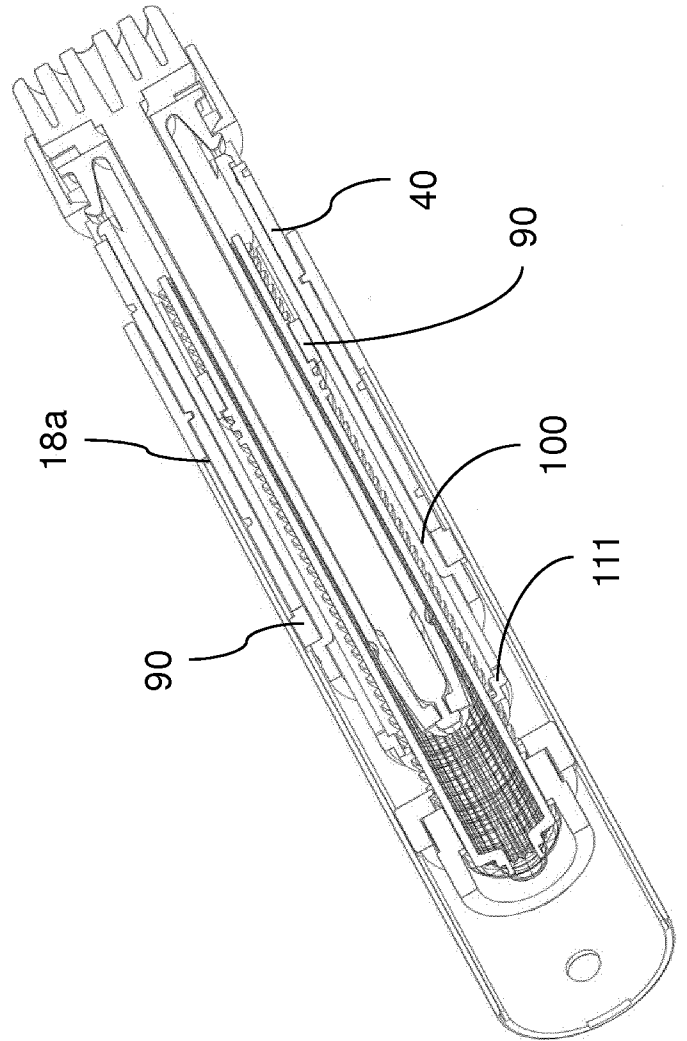


Fig. 10b

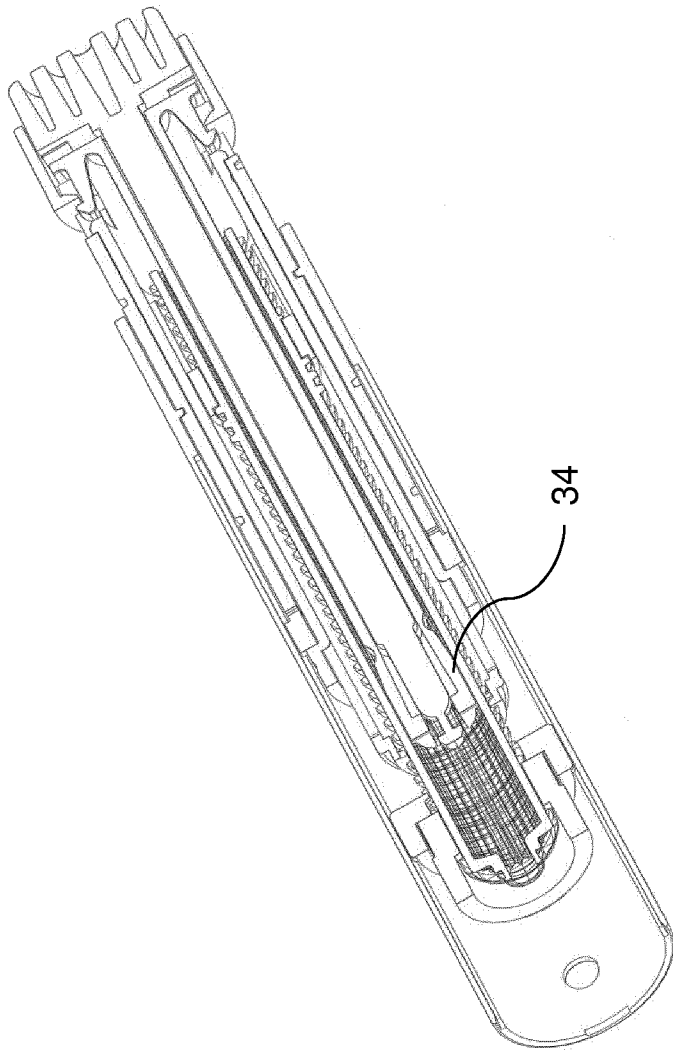


Fig. 10c

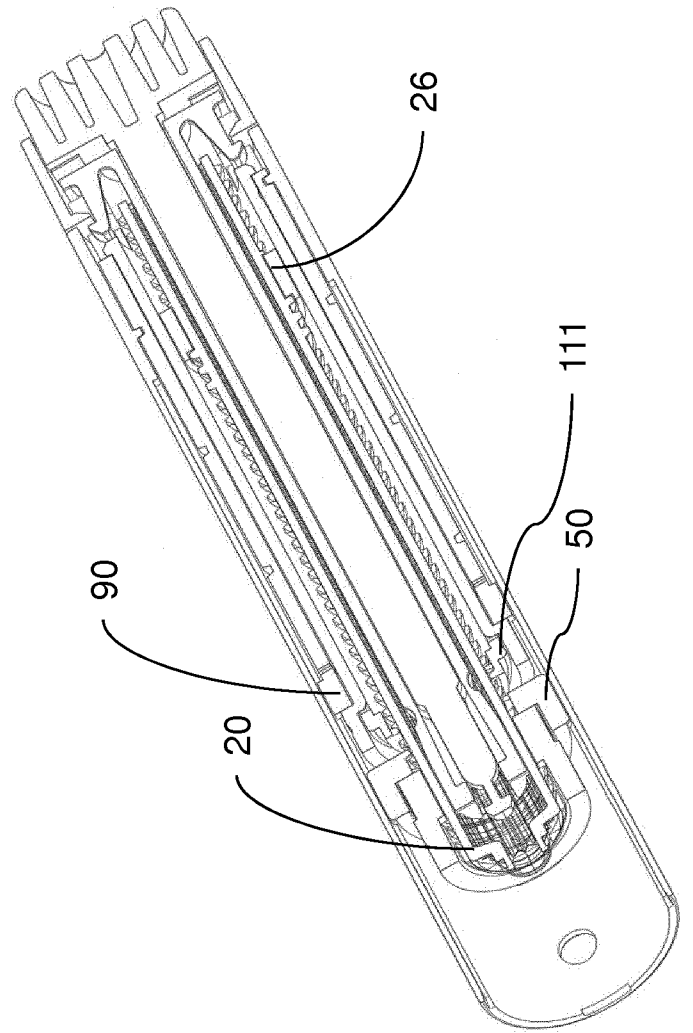


Fig. 10d

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/077139

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61M5/315
 ADD. A61M5/24

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2013/156345 A2 (CAREBAY EUROPE LTD [MT]) 24 October 2013 (2013-10-24) page 16, line 9 - line 20 figures 6, 11 -----	1-14

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "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
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- "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 9 February 2016	Date of mailing of the international search report 18/02/2016
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Sedy, Radim
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2015/077139

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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