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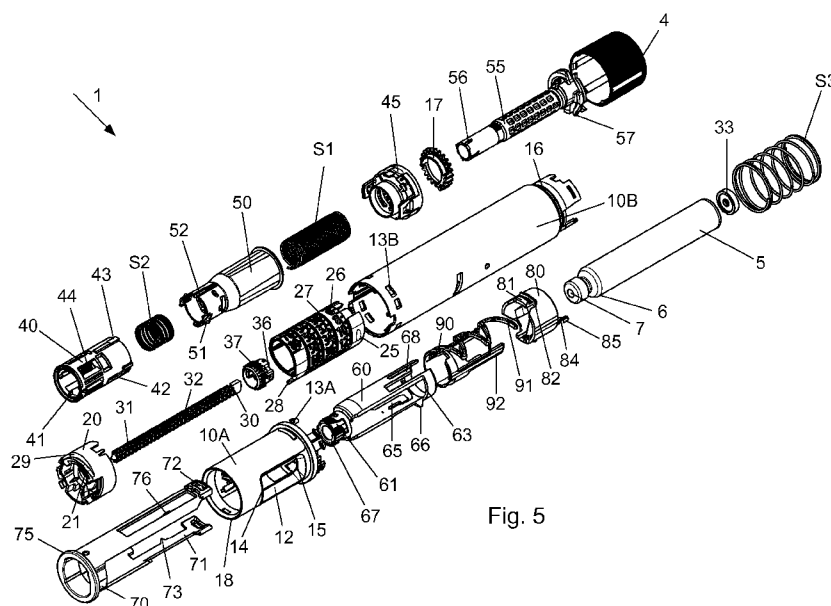


Fig. 5

(57) Abstract: The invention relates to a torsion spring driven injection device for injecting a plurality of set doses of a liquid drug. The injection needle used to perform an injection is carried by a needle holder (60) which is axially slidable in a housing (10). Between subsequent injections the distal part of the injection needle is covered by a retractable needle shield (70, 80). The needle shield also triggers the injection when moved into a proximal position. In the axial movement of the needle shield, the needle shield abuts and moves a separate activation part (90) which releases the torque applied to the torsion spring during dose setting.

A Torsion Spring Driven Injection Device

THE TECHNICAL FIELD OF THE INVENTION:

5 The invention relates to a spring injection device for injecting a plurality of set doses of a liquid drug. The injection device is of the kind in which a user sets the size of a dose to be injected by rotating a rotatable dose dial which at the same time strains a torsion spring such that a torque is built and stored in the torsion spring. During injection of the set dose, the torsion spring is released to automatically drive the set dose volume out from the cartridge. The
10 injection device is especially of the type in which a needle shield covers the injection part of the injection needle between injections and which needle shield when moved proximally activates the drive mechanism to release the torque stored in the torsion spring.

DESCRIPTION OF RELATED ART:

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US 9180250 discloses a manual injection device i.e. an injection device in which the user manually pushes an injection button back into the housing in order to perform an injection. This manual injection device has a sleeve which is rotated out from the proximal end of the housing during dose setting and manually pushed axially back into the housing during expelling of the set dose. During dose setting a compression spring maintains the cartridge in a
20 proximal position and during expelling of the set dose the force applied to the drive sleeve manually moves the cartridge in the distal direction against the force of the compression spring such that the proximal end of the attached needle cannula pierces the septum of the cartridge and establishes liquid communication. Once no force is applied to the drive sleeve,
25 the cartridge is urged, by the compression spring, in the proximal direction such that the cartridge is moved away from the proximal end of the needle cannula thus disconnecting the liquid communication.

A further injection device in which the set dose is automatically delivered by a torsion spring driven engine is disclosed in WO 2014/001318 and in WO 2014/0013199 which discloses
30 different embodiments and aspects of the same torsion spring driven injection device. This pre-filled injection device comprises a non-removable cartridge which is permanently embedded in the housing. The cartridge is further non-removably fixated in the housing such that the cartridge remains in the same physical position inside the housing at all times. The
35 needle assembly carrying the needle cannula is attached to a needle holder which is axially

movable in relation to housing and thus to the cartridge. When the needle holder is in its distal position, the proximal end of the needle cannula is outside the septum of the cartridge and when the needle holder is moved to its proximal position, the proximal end of the needle cannula has pierced through the septum of the cartridge thus establishing liquid communication. The needle holder is provided with a spring element which urges the needle holder in the distal direction. Further, the needle holder is proximally provided with one or more proximal extending trigger arms which arms activate the torque spring mechanism when the needle holder is moved to the proximal direction. The movement of the needle holder is done by a telescopically movable needle shield covering the tip of the needle cannula between injections. When a user pushes the needle shield against his (or hers) skin, this movement pushes both the needle shield and the needle holder proximally such that the proximal end of the needle cannula is pierced through the septum in the cartridge and the trigger arms activates the torque spring drive mechanism.

However, in such arrangement the proximal extending trigger arms which are an integral part of the needle holder are able to reach their final destination before the injection needle is properly engaged with the cartridge. If a user e.g. unintentional moves the needle holder in the proximal direction when a dose is set and the needle shield is in its extended position this could trigger the injection device to expel the set dose.

Such unintentional movement of the needle holder could e.g. happen if the user tries to mount a protective cap to the injection needle once a dose has been set.

DESCRIPTION OF THE INVENTION:

It is an object of the present invention to provide a release mechanism which overcomes the drawback of the prior art. It is especially an object to provide a release mechanism which cannot be accidentally released. This is preferably done by providing a separate activation member which is not physically connected to the needle holder and preferably axially separated from the needle holder such that the needle holder can move axially into proper connection with the cartridge independently of axial movement of the activation member.

According to the present invention, this is achieved by a torsion spring driven drug delivery device as defined in claim 1. This torsion spring driven drug delivery device comprises;

A housing which permanently and non-removably secures a cartridge in the housing thereby making up a pre-filled injection device. The cartridge is axially fixated in the housing and comprises a distal end sealed by a pierceable septum and a proximal end sealed by a movable plunger defining therebetween an interior containing the liquid drug.

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A rotatable dose setting arrangement by which a user is able to set the size of a variable dose to be delivered. The dose setting is preferably done by rotating a rotatable dose dial which thereby strains a torsion spring such that a torque is stored in the torsion spring.

10 A drive arrangement for automatically driving the plunger distally inside the cartridge by release of the torque stored in the torsion spring, the drive arrangement comprises a piston rod which is axially displaceable through engagement with a rotational piston rod guide rotatable by the torque stored in the torsion spring.

15 A telescopically movable needle shield axially movable between an extended position and a retracted position and which telescopically movable needle shield covers at least a distal end of an injection needle when in the extended position and which needle shield when axially moved to the retracted position exposes the distal end of the injection needle and simultaneously triggers the release of at least a portion of the torque stored in the torsion spring to
20 drive the piston rod and the plunger distally inside the cartridge.

A needle holder for carrying an injection needle which injection needle preferably is attachable via connection means provided on the needle holder. The needle holder is axially movable in relation to both the housing and to the telescopically movable needle shield.

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Further, according to the present invention, an activation member is provided which activation member is a separate part axially movable by the needle shield from a first position to a second position in which second position the activation member activates the dose setting arrangement to release the torque stored in the torsion spring to rotate the piston rod guide.

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The needle shield is preferably formed from a shield part connected to a base part. The shield part does the actual covering of the injection needle and the base part carries the shield part. The shield part and the base part can be moulded as one integral part or can be designed as an assembly made from any plurality of parts which are connected to form one

element. The needle shield henceforth operates as one unison part independently of the number of parts making up the needle shield.

The needle shield is releasable coupled to a needle holder such that axial movement of the needle shield can be transformed to an axial movement of the needle holder. Distally the needle holder is provided with connection means for carrying the injection needle.

Proximally to the needle holder and positioned between the needle shield and the dose setting arrangement a separate activation part is provided. By separate is here meant that the activation member is not an integral part of another element. It is especially stressed that the activation member is separate from the needle holder such that the needle holder is able to move axially without necessarily moving the activation part.

It is thus possible to move the needle holder axially without simultaneously moving the activation part and an erroneous movement of the needle holder is not transferred to the activation part. In fact the activation part is only moved into the activated position by axial movement of the needle shield preferably by having an engagement with the needle shield such that the activation part follows the axial movement of the needle shield independently of the needle holder.

In a further embodiment the torsion spring is encompassed between the housing and a drive tube. The torsion spring is preferably but not necessarily a helically wound metallic spring.

A clutch element couples the drive tube to the rotatable piston rod guide such that the drive tube, the clutch and the rotatable piston rod guide rotate in unison under the influence of the torque stored in the torsion spring during injection. During its rotation, the piston rod guide moves the piston rod axially.

The injection device herein described further comprises a rotatable dose setting arrangement and a drive arrangement. The dose setting arrangement comprises; the rotatable dose dial, the clutch, a drive tube and a ratchet element. The drive arrangement comprises; the piston rod, the piston rod guide and a nut member. The nut member is internally provided with a thread engaging an outer thread provided on the piston rod.

The clutch is axially movable from a locked position in which the clutch is rotational locked to a released position in which the clutch is rotational released. In the released position, the clutch is rotational coupled to the piston rod guide such that the torque stored in the torsion spring rotates the piston rod guide. The clutch is in both positions rotational coupled with the drive tube which henceforth rotates in unison with the clutch.

The needle shield which is axially movable from an extended position to a retracted position simultaneously moves the activation member axially from the first position to the second position. In order to move the needle shield from the retracted position to the extended position a shield spring is provided. Axial movement of the activation member from the first position to the second position moves the clutch axially from the locked position to the released position.

Further a compression spring is encompassed between the activation member and the housing urging the activation member into the first position. The activation member engages the needle shield to which the activation member is releasably coupled.

The needle holder is urged in the distal direction by the activation member when the activation member is released from the needle shield whereby the needle holder when moved in the distal direction into a distal position decouples the injection needle from the cartridge.

Further, the needle shield is guided axially and the activation member is rotational in relation to the needle shield.

The rotatable dose setting arrangement is adapted to rotate a scale drum which is threadably engaged with the housing and rotational coupled to the clutch to follow rotation of the clutch.

The scale drum thus performs a helical movement away from a zero position during dose setting and back to the initial zero position upon injection. When the scale drum is in its zero position the needle shield is locked and secured in its retracted position by the scale drum which preferably has a hook hooking the activation member.

DEFINITIONS:

An “**injection pen**” is typically an injection apparatus having an oblong or elongated shape somewhat like a pen for writing. Although such pens usually have a tubular cross-section, they could easily have a different cross-section such as triangular, rectangular or square or any variation around these geometries.

The term “**Needle Cannula**” is used to describe the actual conduit performing the penetration of the skin during injection. A needle cannula is usually made from a metallic material such as e.g. stainless steel and connected to a hub to form a complete injection needle also often referred to as a “**needle assembly**”. A needle cannula could however also be made from a polymeric material or a glass material. The hub also carries the connecting means for connecting the needle assembly to an injection apparatus and is usually moulded from a suitable thermoplastic material. The “**connection means**” could as examples be a luer coupling, a bayonet coupling, a threaded connection or any combination thereof e.g. a combination as described in EP 1,536,854.

As used herein, the term “**drug**” is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs includes pharmaceuticals such as peptides, proteins (e.g. insulin, insulin analogues and C-peptide), and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form.

“**Cartridge**” is the term used to describe the container actually containing the drug. Cartridges are usually made from glass but could also be moulded from any suitable polymer. A cartridge or ampoule is preferably sealed at one end by a pierceable membrane referred to as the “**septum**” which can be pierced e.g. by the non-patient end of a needle cannula. Such septum is usually self-sealing which means that the opening created during penetration seals automatically by the inherent resiliency once the needle cannula is removed from the septum. The opposite end is typically closed by a plunger or piston made from rubber or a suitable polymer. The plunger or piston can be slidably moved inside the cartridge. The space between the pierceable membrane and the movable plunger holds the drug which is pressed out as the plunger decreased the volume of the space holding the drug. However, any kind of container – rigid or flexible – can be used to contain the drug.

Since a cartridge usually has a narrower distal neck portion into which the plunger cannot be moved not all of the liquid drug contained inside the cartridge can actually be expelled. The term “**initial quantum**” or “**substantially used**” therefore refers to the injectable content contained in the cartridge and thus not necessarily to the entire content.

By the term “**Pre-filled**” injection device is meant an injection device in which the cartridge containing the liquid drug is permanently embedded in the injection device such that it cannot be removed without permanent destruction of the injection device. Once the pre-filled amount of liquid drug in the cartridge is used, the user normally discards the entire injection device.

- 5 This is in opposition to a “**Durable**” injection device in which the user can himself change the cartridge containing the liquid drug whenever it is empty. Pre-filled injection devices are usually sold in packages containing more than one injection device whereas durable injection devices are usually sold one at a time. When using pre-filled injection devices an average user might require as many as 50 to 100 injection devices per year whereas when using durable injection devices one single injection device could last for several years, however, the average user would require 50 to 100 new cartridges per year.

- “**Scale drum**” is meant to be a cylinder shaped element carrying indicia indicating the size of the selected dose to the user of the injection pen. The cylinder shaped element making up the scale drum can be either solid or hollow. “**Indicia**” is meant to incorporate any kind of printing or otherwise provided symbols e.g. engraved or adhered symbols. These symbols are preferably, but not exclusively, Arabian numbers from “0” to “9”. In a traditional injection pen configuration the indicia is viewable through a window provided in the housing.

- 20 Using the term “**Automatic**” in conjunction with injection device means that, the injection device is able to perform the injection without the user of the injection device delivering the force needed to expel the drug during dosing. The force is typically delivered – automatically - by an electric motor or by a spring drive. The spring for the spring drive is usually strained by the user during dose setting, however, such springs are usually prestrained in order to avoid problems of delivering very small doses. Alternatively, the spring can be fully preloaded by the manufacturer with a preload sufficient to empty the entire drug cartridge though a number of doses. Typically, the user activates a latch mechanism e.g. in the form of a element on, e.g. on the proximal end, of the injection device to release – fully or partially - the force accumulated in the spring when carrying out the injection.

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The term “**Permanently connected**” as used in this description is intended to mean that the parts, which in this application is embodied as a cartridge and a needle assembly, requires the use of tools in order to be separated and should the parts be separated it would permanently damage at least one of the parts.

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All references, including publications, patent applications, and patents, cited herein are incorporated by reference in their entirety and to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

- 5 All headings and sub-headings are used herein for convenience only and should not be construed as limiting the invention in any way.

The use of any and all examples, or exemplary language (e.g. such as) provided herein, is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention. The citation and incorporation of patent documents herein is done for convenience only and does not reflect any view of the validity, patentability, and/or enforceability of such patent documents.

- 10 This invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law.

BRIEF DESCRIPTION OF THE DRAWINGS:

- 20 The invention will be explained more fully below in connection with a preferred embodiment and with reference to the drawings in which:

Figure 1 show a perspective view of the injection device with the removable cap mounted.

- 25 Figure 2 show a perspective view of the injection device with the removable cap removed and an injection needle mounted.

Figure 3 show a perspective view of the injection device during dose setting.

- 30 Figure 4 show a perspective view of the injection device during injection.

Figure 5 show an exploded perspective view of the injection device.

Figure 6 show an exploded schematic view of the injection device .

Figure 7 show a side view of the distal part of the injection device during dose setting with the scale drum removed from its zero position.

Figure 7A Show an enlarged view of the area marked in figure 7.

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Figure 8 Show a side view of the distal part of the injection device during injection.

Figure 9 Show a side view of the distal part of the injection device during injection.

10 Figure 10 Show a side view of the distal part of the injection device during injection

Figure 11 Show an enlarged side view of a part of the injection device during injection.

15 Figure 12 Show a side view of the distal part of the injection device during triggering of the injection device.

Figure 13 Show a side view of the distal part of the injection device during injection as the needle shield is removed from the skin of the user.

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Figure 14 Show a side view of the distal part of the injection device during injection as the needle shield is further removed from the skin of the user.

Figure 15 Show a side view of the distal part of the injection device after performing an injection and with the scale drum in its zero position.

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The figures are schematic and simplified for clarity, and they just show details, which are essential to the understanding of the invention, while other details are left out. Throughout, the same reference numerals are used for identical or corresponding parts.

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DETAILED DESCRIPTION OF EMBODIMENT:

When in the following terms as “upper” and “lower”, “right” and “left”, “horizontal” and “vertical”, “clockwise” and “counter clockwise” or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are

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schematic representations for which reason the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

In that context it may be convenient to define that the term “distal end” in the appended figures is meant to refer to the end of the injection device which usually carries the injection needle whereas the term “proximal end” is meant to refer to the opposite end pointing away from the injection needle and usually carrying the dose dial element.

Distal and proximal is meant to be along an axial orientation extending along the longitudinal axis “X” of the injection device and is further indicated in the figures wherein the figures 1 to 4 disclose a perspective view of the injection device 1 according to the invention.

Initially the distal end of the injection device 1 is covered by a removable cap 2 which is removed to get access to the injection needle 3. In the figures 1 to 4 the housing 10 is depicted as one unitary housing 10, but it could easily be constructed from a number of individual parts. The dose to be ejected is set by rotating a rotatable dose dial 4 provided at the proximal end of the housing 10.

The housing 10 is usually provided with a scale window 11 through which the user can inspect indicia 26 printed on a rotatable scale drum 25. Distally the housing 10 is provided with a further longitudinal window 12 through which the user can inspect the liquid drug contained in the cartridge 5 of the injection device 1. This longitudinal extending window 12 has a front flange 14 and a back flange 15 extending radially inwardly, the use of which will be explained later.

When the user removes the removable cap 2 as disclosed in figure 2, the injection needle 3 can either be pre-mounted on the injection device 1 or the user mounts a new sterile injection needle 3 onto the fastening means 61 as will be explained later. As no dose has been set the number “0” will be visual in the scale window 11 thus indicating that no dose has been set and the scale drum 25 therefore is in its zero position.

As will be explained, the needle shield 70 is retracted or secured in its proximal position when no dose is set such that the user has full access to the fastening means 61 in order to mount the injection needle 3.

As will be explained later, the fastenings means 61 are carried on an axially movable needle holder 60 which however is prevented from axial movement by having an axial arm 68 which engages a releasable protrusion located on an inside surface of the housing 10. The needle holder 60 is thus not able to move axially when the needle holder 60 is extended into the position disclosed in figure 2. As best seen in figure 5, the needle shield 70 is provided with a knob 76 which is able to activate the releasable protrusion inside the housing 10 when the needle shield 70 is moved axially such that the needle holder 60 is released to move axially.

When a user rotates the dose dial 4 provided at the proximal end of the housing 10 as indicated with an "D" in figure 3, the needle shield 70 is released and moves distally to cover the injection needle 3 as also depicted in figure 3. At the same time the indicia 26 in the scale window 11 changes according to the size of the dose set. As can be seen in figure 3, the indicia 26 indicate that the user has here set a dose of 8 units.

In order to inject the set dose the user simply presses the needle shield 70 against the skin "S" as indicated by the arrow "I" in figure 4. This, fully or partly, releases the force accumulated in a torsion spring S1 which drives the injection. At the same time the scale drum 25 returns helically to its zero position. In the situation disclosed in figure 4, the indicia 26 indicates that an amount of 2 units (8 minus 6) has been ejected, however as the injection commences the indicia 26 will return to its zero position thus displaying a "0" in the scale window 11 when all the 8 set units has been expelled.

As the needle shield 70 moves in the proximal direction, the axial arm 68 on the needle holder 60 is released as explained above thus setting the needle holder 60 free to move axially.

Figure 5 and figure 6 further discloses exploded views of the injection device 1 according to the invention. The liquid drug to be injected is contained in a cartridge 5, which cartridge 5 is fixed inside the housing 10 and which housing 10 is formed from a distal part 10A and a proximal part 10B. The two parts 10A, 10B are provided with clicking means 13A, 13B for permanently connecting the two parts 10A, 10B together to form one housing 10.

The cartridge 5 is press fitted between a nut member 20 fixed in the housing 10 and an inwardly pointing front flange 14 provided internally in the distal housing part 10A. The distal forefront of the longitudinal window 12 provided in the distal housing part 10A has an inward-

ly pointing bend which makes up the front flange 14 which surrounds and grips the shoulder 6 of the cartridge 5 as also seen in figure 7A.

The housing 10 is thus clicked together around the cartridge 5 which thereby is fixated in the housing 10 and cannot move axially. The housing 10 with the embedded cartridge 5 henceforth makes up the reference frame to which the different movements relates as will be explained.

Most proximal, the proximal housing part 10B carries the rotatable dose dial 4 which is rotatable by a user to set a dose to be injected. The proximal housing part 10B has a circular recess 16 to which the dose dial 4 is connected such that the dose dial 4 can only rotate but not move axially relatively to the housing 10.

The nut member 20 is fitted to the housing 10 and preferably to the proximal housing part 10B. The nut member 20 is rotationally secured to housing 10, i.e. the nut member 20 is in-rotatable relatively to the housing 10. Alternatively, the nut member 20 could be moulded as an integral part of the housing 10 and preferably the proximal housing part 10B.

The cartridge 5 which is permanently fixed to the housing 10 when the two parts 10A, 10B (the proximal housing part 10B with the nut member 20 mounted therein) are clicked together to form one housing 10 is an ordinary glass cartridge 5 having a distal end sealed by a pierceable septum 7 and a proximal opening closed by a movable rubber plunger 8 (indicated by broken lines in figure 6) which can be moved in the distal direction by distal movement of the piston rod foot 33 which is moved distally by a piston rod 30. Distally the pierceable septum 7 is secured to the glass part by a metallic cap which defines a distal end surface 9

The nut member 20 is internally provided with an internal thread 21 which engage an outer thread 31 on the piston rod 30 such that the piston rod 30 is moved helically whenever the piston rod 30 is rotated relatively to the nut member 20 and the housing 10. At its distal end the piston rod 30 carries the piston rod foot 33.

To rotate the piston rod 30, a piston rod guide 35 is provided. This piston rod guide 35 is internally provided with a key-shape 36 which engages a similar key-shape 32 provided on the piston rod 30. In practise the key-shape 32 on the piston rod 30 is formed from one or more longitudinal flat surfaces.

A clutch 40 connects and disconnects the piston rod guide 35 with the torsion spring S1 driving the ejection of the liquid drug. The clutch 40 is internally provided with a number of inwardly pointing teeth 41 which engages outwardly pointing teeth 37 provided on the outer surface of the piston rod guide 35 such that the piston rod guide 35 rotates when the clutch 40 is rotated as will be explained.

Inside the proximal housing part 10B a rotatable scale drum 25 is fitted. The scale drum 25 carries the indicia 26 and has an outer thread 27 which engages a corresponding thread (or a thread segment) provided internally in the proximal housing part 10B such that the scale drum 25 moves helically relatively to the housing 10 whenever rotated. The scale drum 25 is rotated by engaging ribs 43 provided on the outer surface of the clutch 40 such that the scale drum 25 always rotates together with the clutch 40 but is able to slide axially relatively to the clutch 40.

The proximal end of the proximal housing part 10B is closed by a spring base 45 which is inrotatable clicked into the proximal housing part 10B. The torsion spring S1 is proximally coupled to the spring base 45 and distally coupled to a drive tube 50 such that a torque is built in the torsion spring S1 when the drive tube 50 is rotated relatively to the spring base 45 and the housing 10.

The drive tube 50 is distally provided with a number of outwardly pointing protrusions 51 which are sliding in longitudinal openings 42 provided in the clutch 40 such that the clutch 40 can move axially in relation to the drive tube 50 but the drive tube 50 and the clutch 40 are bound to rotate together. Other means for securing axial movement could also be provided. The drive tube 50 could e.g. be provided with ribs 52 could slide in not shown tracks inside the clutch 40

Further, a clutch spring S2 is encompassed between the clutch 40 and the drive tube 50 such that the clutch spring S2 urges the two parts 40, 50 away from each other.

In the position wherein the clutch 40 is pushed proximally against the force of the compression spring S2, the inwardly pointing teeth 41 engages the outwardly pointing teeth 37 on the piston rod guide 35 whereas when the clutch 40 is moved in distal direction by the compression spring S2 the clutch 40 decouples from the piston rod guide 35. The latter position being

during dose setting, meaning that the piston rod guide 35 is decoupled from the clutch 40 during dose setting and henceforth only coupled to the clutch 40 when the clutch 40 is moved proximally against the force of the clutch spring S2 to thereby expel the set dose.

- 5 The clutch 40 is further internally provided with inwardly pointing teeth 44 which engages with outwardly pointing distal teeth 56 provided distally on a ratchet element 55 such that a rotation of the ratchet element 55 is transformed to a rotation of the clutch 40. The ratchet element 55 is further coupled to the dose dial 4 and carries the End-of-Content counter 17.
- 10 Proximally the spring base 45 is provided with an internal toothing engaging at least one radial tooth 57 provided radially on the ratchet element 55. The ratchet element 55 is rotated by the dose dial 4 and rotates together with the dose dial 4 in one rotational direction during dose setting. When the dose dial 4 is rotated in an opposite direction to lower a set dose, the dose dial 4 engages the radial teeth 57 on the ratchet element 55 to release the radial tooth
- 15 57 from the internal toothing of the spring base 45 thus allowing the torsion spring S1 to counter rotate the ratchet element 55 and the clutch 40 which rotate together both during dose setting and during dose cancellation.

- When setting a dose to be injected, the user rotates the proximal located dose dial 4 which is
- 20 axially fixated in relation to the proximal housing part 10B. The rotation of the dose dial 4 is transformed to a rotation of the ratchet element 55. Further, since the outwardly pointing distal teeth 56 on the ratchet element 55 engage with the clutch 40, the clutch 40 rotate together with the ratchet element 55 during the setting and selection of the size of a dose to be injected. The clutch 40 also rotational engages the drive tube 50 which is thus also rotated. The
- 25 rotatable dose setting arrangement is thus made up from the dose dial, 4, the ratchet element 55, the drive tube 50 and the clutch 40 which all rotate in unison during dose setting.

- As the clutch 40 is rotational connected to the drive tube 50, the drive tube 50 rotates with the ratchet element 55 and the clutch 40 during dose setting. This rotation strains the torsion
- 30 spring S1 such that a torque is built in the torsion spring S1. Since the ratchet element 55 by the radial tooth 57 is in a releasable one-way coupling with the spring base 45 the torsion spring S1 is unable to counter-rotate during dose setting.

- Rotation of the dose dial 4, the ratchet element 55, the clutch 40 and the drive tube 50 are
- 35 thus transformed to a rotation of the distal end of the torsion spring S1. Since the proximal

end of the torsion spring S1 is secured to the spring base 45 this rotation causes a torque to be built in the torsion spring S1. The torque is maintained in the torsion spring S1 due to engagement of the radial tooth 57 with the internal toothing of the spring base 45.

5 In order to release the set dose, the clutch 40 is moved axially in the proximal direction such that the teeth 56 decouple the clutch 40 from the ratchet element 55. Since the clutch 40 and the drive tube 50 is rotational coupled, this allows the torque stored in the torsion spring S1 to rotate the drive tube 50 and the clutch 40 in unison. In this position wherein the clutch 40 is moved proximally, the clutch 40 engages the piston rod guide 35 which thus also rotate.

10 In order to perform an injection, the user needs to attach the injection needle 3 to the injection device 1 as depicted in figure 2. A needle holder 60 which is slidable arranged carries at its distal end a fastening means 61 for securing the injection needle 3 which preferably is a pen-needle having a distal part (indicated by "D" in figure 2) for penetrating the skin S of the user during injection and a not-shown proximal part for penetrating through the septum 7 of the cartridge 5 at least during injection.

20 The injection needle 3 when attached follows the axial movement of the needle holder 60. Since the needle holder 60 and thus the injection needle 3 slides relatively to the housing 10 and the cartridge 5 is embedded in the housing 10, the axial movement of the needle holder 60 brings the proximal end of the injection needle 3 in and out of its connection with the cartridge 5.

25 As can be seen in figure 5, the needle holder 60 is distally provided with an inwardly pointing rim 67. When the cartridge 5 is properly inserted into the needle holder 60 this inwardly pointing rim 67 abut the distal end surface 9 of the cartridge 5.

30 The needle holder 60 further has a longitudinal opening 62 (figure 6) which fits over the front flange 14 and the back flange 15 of the distal housing part 10A such that the needle holder 60 is able to slide relatively to the distal housing part 10A without rotating. This longitudinal opening 62 is proximally provided with an end surface 63 which abuts the back flange 15 when the needle holder 60 is in its most distal position (which is disclosed in figure 7).

35 The needle holder 60 is urged distally by an activation part 90 which is provided with a compression spring 91 urging both the activation part 90 and the needle holder 60 in the distal

direction away from the nut member 20. However, as mentioned, the needle holder 60 is stopped in its distal movement by the end surface 63 of the longitudinal opening 62 abutting the back flange 15 of the distal housing part 10A thus defining a maximum distal position of the needle holder 60 relatively to the housing 10.

5

Further, in order to cover at least the distal tip of the injection needle 3 between injections, a needle shield 70 is provided. Proximally this needle shield 70 comprises two arms 71 which secure a shield base 80 as can be seen in figure 7. Each arm 71 is provided with an opening 72 which is click-fitted to a similar protrusion 81 provided on the shield base 80 such that the needle shield 70 and the shield base 80 moves axially together and are rotational locked to each other i.e. prevented from relative rotation. The needle shield 70 and the shield base 80 could alternatively be moulded as one unitary part however in order to manufacture and properly assemble the injection device 1 it has proven most practical to manufacture the needle shield 70 and the shield base 80 as two separate parts and connect the two parts during assembly of the injection device to operate in unison.

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The two arms 71 of the needle shield 70 are further separated by a peripheral distance which is guided axially by the two flanges 14 , 15 of the housing 10 such that the needle shield 70 is maintained inrotatable.

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Distally the needle shield 70 is provided with a radial flange 75 which abuts the distal surface 18 of the distal housing part 10A when the needle shield 70 is pushed all the way back into the housing 10, see e.g. the figures 3 and 4.

25

Radially inwardly, in the neighbouring constructional layer, from the needle shield 70 and the shield base 80 and abutting the needle holder 60 lie the activation part 90 as will be explained. This activation part 90 is, as best seen in figure 5, provided with a moulded compression spring 91 which is moulded as an integral part of the activation part 90. The free end of this compression spring 91 abuts the nut member 20 and thus urges the activation part 90 in the distal direction.

30

The activation part 90 is separate from the needle holder 60 which can thus move axially independently of the activation part 90. This has the purpose that the needle holder 60 could e.g. be moved an axial distance without abutting the activation part 90 which again prevents

the activation part 90 from erroneously activating a set dose due to a faulty movement of the needle holder 60.

The activation part 90 further has two proximal trigger arms 92 for activating the drive mechanism during expelling of the set dose as will be explained. Between the two proximal trigger arms 92 a further arm 93 is provided. This further arm 93 is proximally provided with a radial release protrusion 94 as best seen in figure 7A. The body of the activation part 90 is also provided with a radial catching protrusion 95 which engages with the shield base 80.

The shield base 80 has, as can be seen in figure 5, a radial flange 82 for axially supporting a shield spring S3 which proximally lies against the nut member 20 thus urging the shield base 80 and the needle shield 70 in the distal direction.

Further, as best realized in figure 7 and 7A, the shield base 80 has an open track 83 for guiding the radial release protrusion 94 as will be explained. The shield base 80 is also provided with a proximal extending arm 84 which proximally is provided with a radial protrusion 85. This radial protrusion 85 can be engaged by a hook 28 provided on the scale drum 25 whenever the scale drum 25 is in its zero position i.e. when no dose has been set. The shield base 80 is further provided with a curved surface 87 allowing the catching protrusion 95 and thus the activation member 90 to rotate relatively to the shield base 80.

The figures 7 to 15 disclose different side views of the different modes occurring during an injection. For explanatory reasons the housing 10 is not disclosed in these figures, however the position of the front flange 14 and the back flange 15 which forms parts of the longitudinal window 12 of the distal housing part 10A is indicated when needed in the explanation of the working of the injection device.

In figure 7, the scale drum 25 has been rotated away from its zero position (and is therefore not visible in figure 7) thus indicating that a dose has been set. The shield base 80 and thus the needle shield 70 has been released from the scale drum 25 and the shield spring S3 has moved the shield base 80 and the needle shield 70 in the distal direction as also shown in figure 3. The activation part 90 is also positioned in its distal position and the catching protrusion 95 abut the shield base 80 (the shield spring S3 is in figure 7 drawn as an arrow representing the force applied by this shield spring S3).

In the position depicted in figure 7, the end surface 63 of the longitudinal opening 62 of the needle holder 60 abuts the back flange 15 on the distal housing part 10A and is thus prevented from moving further in the distal direction. The activation part 90 is therefore not able to move further in the distal direction. Figure 7 thus depicts the most distal position of the activation part 90 and the needle holder 60. In perspective this position is the one depicted in figure 3 wherein a dose is set (or being set) and the injection device is ready to perform an injection.

As can be seen from figure 7A, the shoulder 6 of the cartridge 5 abuts the front flange 14 of the distal housing part 10A and the needle holder 60 abuts the back flange 15. Since the needle holder 60 carrying the injection needle 3 is moved in the distal direction, the injection needle 3 is in the position of figure 7 de-coupled from the cartridge 5 thus the proximal end of the injection needle 3 is positioned outside the septum 7 of the cartridge 5.

As mentioned earlier, the cartridge 5 is at all times held in a fixed position between the nut member 20 and the front flange 14 of the housing 10.

The needle holder 60 is, as mentioned, provided with an inwardly pointing rim 67 (best seen in figure 5) and the cartridge 5 is provided with a distal end surface 9. The position of the inwardly pointing rim 67 and the distal end surface 9 is indicated by broken lines in figure 7. The distance between these two broken lines indicates that the injection needle 3 is not yet inserted into the cartridge 5.

One of the two arms 71 of the needle shield 70 is provided with a peripheral protrusion 73 extending in the peripheral direction. In figure 7A this peripheral protrusion 73 points downward and the arm 71 is opposite the peripheral protrusion 73 provided with a longitudinal surface 74. The peripheral protrusion 73 catches a similar protrusion 64 provided on a proximal pointing and flexible arm 65 on the needle holder 60

Further, the needle holder 60 is provided with a radial protrusion 66 which is guided on the longitudinal surface 74 of the needle shield 70 such that the needle holder 60 is held inrotatable in relation to the needle shield 70.

Figure 7 thus depicts a situation in which a dose has been set, or is in the progress of being set and the compression spring S3 has moved the needle shield 70 and the shield base 80 in

the distal direction as also depicted in figure 3. The shield base 80 has via the catching protrusion 95 also moved the activation part 90 in the distal direction and the activation member 90 has moved the needle holder 60 in the distal direction such that the end surface 63 (of the needle holder 60) abuts the back flange 15 (of the distal housing part 10A). In this situation, the injection needle 3 is decoupled from the cartridge 5 i.e. the proximal part of the injection needle 3 is positioned outside the cartridge 5 and distal to the septum 7 of the cartridge 5.

Figure 8 and figure 9 discloses the situation in which the users presses the needle shield 70 against the skin as indicated by the arrow "I". This movement of the needle shield 70 in the proximal direction is also transferred to the shield base 80 which also moves proximally against the bias of the compression spring S3. The needle holder 60 and the activation part 90 however remains in their initial position, which brings the release protrusion 94 on the activation part 90 into contact with a radial surface 86 on the shield base 80. Since the needle shield 70 slides proximally in relation to the needle holder 60 the inwardly pointing rim 67 is in figure 9 located nearer the distal end of the needle shield 70 and the distal part D of the injection needle 3 is now positioned outside the needle shield 70 as an injection is in progress. At this point the distal part D of the injection needle 3 is actually penetrated into the skin S of the user.

In figure 8 and 9 the position of the distal end surface 9 of the cartridge 5 is the same as in figure 7 as the cartridge 5 is axially fixated in the housing 10.

In figure 10 the protrusion 64 on the flexible arm 65 engages the peripheral protrusion 73 on the arm 71 of the needle shield 70 and the release protrusion 94 engages the radial surface 86. In this situation a small gap "Y" is established between the needle holder 60 and the activation part 90. Further, the distal part of the injection needle "D" is exposed in front of the needle shield 70 as indicated in figure 10. However, the needle holder 60 and the proximal part of the injection needle 3 have not been moved into contact with the cartridge 5 and no flow has been established.

As the user keeps applying pressure "I" to the needle shield 70 both the needle shield 70, the shield base 80 and the activation part 90 moves proximally into the position disclosed in figure 11. In this position, the trigger arms 92 has moved through axial openings in the nut element 20 and stands right at the distal end of the clutch 40. Further, in this position the inwardly pointing rim 67 of the needle holder 60 has been brought into contact with the distal

end surface 9 of the cartridge and the proximal part of the injection needle 3 has penetrated through the septum 7 and into the cartridge 5 such that liquid flow has been established. The injection device is thus ready to inject in this situation.

- 5 As the needle shield 70 moves proximally it is followed by the needle holder 60 due to the engagement between the peripheral protrusion 73 on the needle shield 70 and the protrusion 64 on the flexible arm 65 of the needle holder 60.

10 In figure 11 a part of the outer surface indicated with an "A" has been visually cut away to allow a view to the inner side of the nut element 20. On the inside of the nut element 20 a sloped surface 22 and a stop surface 23 are provided. The sloped surface 22 and the stop surface 23 further define a longitudinal track 24.

15 As can be seen from figure 11, the axial movement of the activation member 90 has started to rotate the release protrusion 94 (and thus the activation member 90) up the sloped surface 22. The geometry of the release protrusion 94 is preferably such that this rotation is enhanced. However, the release protrusion 94 is still prevented from moving in the distal direction due to its engagement with the radial surface 86 of the shield base 80.

20 In the position in figure 11 (and also in figure 12) the inwardly pointing rim 67 of the needle holder 60 abut with the distal end surface 9 of the cartridge 5 which is indicated in figure 12 by the punctured line ("67" = "9"). This means that the injection needle 3 is now fully inserted into the cartridge 5.

25 In figure 12, the needle shield 70, the shield base 80 and the activation part 90 has moved a small distance further into the final proximal position. In this position the trigger arms 92 have moved the clutch 40 proximal and the torque spring S1 is released to drive an ejection. Further, in this position the distal flange 75 on the needle shield 70 abut the distal end surface 18 of the distal housing part 10A and the needle shield 70 cannot be moved further into the housing 10.

30 The needle holder 60 cannot move further in the proximal direction due to the abutment between the inwardly pointing rim 67 of the needle holder 60 and the distal end surface 9 of the cartridge 5 and the protrusion 64 is therefore forced over the peripheral protrusion 73. At the same time the release protrusion 94 has moved further into the track 24 which means that

the activation member 90 has moved a few millimetres proximally and thus released the torque saved in the torsion spring S1.

The activation member 90 has now rotated a small angle and the release protrusion 94 is position on a sloped part 86a of the radial surface 86 of the shield base 80. However, the radial protrusion 94 cannot pass by the stop surface 23 on the nut member 20.

As the liquid drug is being injected the scale drum 25 returns to the zero position. When viewing figure 12 is noted that the nut member 20 is provided with a helical track part 29 into which the hook 28 provided distally on the scale drum 25 can rotate as the scale drum 25 rotatably returns to its zero position at the end of an injection.

In figure 13 the liquid drug has been injected and the scale drum 25 has reached its zero position. The hook 28 of the scale drum 25 has entered the helical track part 29 provided on the outer surface of the nut element 20 and the user starts to remove the needle shield 70 from the skin.

As the user removes the needle shield 70 from the skin S, the compression spring S3 starts to move the shield base 80 and the needle shield 70 in the distal direction. However, the radial protrusion 85 on the shield base 80 is caught by the hook 28 on the scale drum 25 which prevents the shield base 80 (and the needle shield 70) from moving further in the distal direction. However, the axial movement made is long enough to allow the radial protrusion 94 to slide off the sloped surface 86a as shown in figure 13 and figure 14.

The needle shield 70 is thus prevented from axial movement in the distal direction but the compression spring 91 on the activation member 90 forces the activation member 90 which is now free of the shield base 80 to move distally. As disclosed in figure 14 and figure 15, the distal movement of the activation member 90 is transferred to the needle holder 60 which therefore also move in the distal direction.

At the same time, the protrusion 64 flexes over the peripheral protrusion 73 and the needle holder 70 is forced in the distal direction until the fastening means 61 provided distally on the needle holder 60 is positioned distal to the needle shield 70.

As the activation part 90 moves distally due to the compression spring 91 both the trigger arms 92 and the clutch 40 moves distally. The clutch 40 moves under the influence of the clutch spring S2 and releases from the piston rod guide 35 and re-engages the ratchet element 55.

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Further, when the needle holder 60 slides distally, the inwardly pointing rim 67 of the needle holder 60 is removed from the distal end surface 9 of the cartridge 5 and the proximal part of the injection needle 3 is automatically removed from the septum 7 of the cartridge 5 thereby preventing any further dripping from the injection needle 3. This is seen in figure 15 wherein the end surface 63 of the longitudinal opening 62 abuts the back flange 15 of the distal housing part 10A.

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When the user want to perform a new injection, a fresh and sterile injection needle is mounted onto the fastening means 61 and a new dose is set by rotating the rotatable dose dial.

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Once the user rotates the rotatable dose dial 4 to set a new dose to be injected, the scale drum 25 rotates away from its zero position and the hook 28 thus release the radial protrusion 85 on the shield base 80 such that the needle base 80 and the needle shield 70 is moved distal by the compression spring S3 and into the position depicted in figure 3 and figure 7.

20

Some preferred embodiments have been shown in the foregoing, but it should be stressed that the invention is not limited to these, but may be embodied in other ways within the subject matter defined in the following claims.

Claims:

1. A torsion spring driven injection device for injecting a plurality of set doses of a liquid drug comprising:

5

A housing (10) securing a cartridge (5) permanently embedded in the housing (10) and containing the liquid drug to be injected, the cartridge (5) being axially fixated in the housing (10) and further comprises a distal end sealed by a pierceable septum (7) and a proximal end sealed by a movable plunger (8) defining there between an interior containing the liquid drug,

10

A rotatable dose setting arrangement (4, 40, 50, 55) for setting the size of a dose to be delivered by rotating a rotatable dose dial (4) thereby straining a torsion spring (S1) such that a torque is stored in the torsion spring (S1),

15

A drive arrangement (20, 30, 35) for automatically driving the plunger (8) distally inside the cartridge (5) by release of the torque stored in the torsion spring (S1), the drive arrangement comprising a piston rod (30) which is axially displaceable through engagement with a rotational piston rod guide (35) rotatable by the torque stored in the torsion spring (S1),

20

A telescopically movable needle shield (70, 80) axially movable between an extended position and a retracted position and which telescopically movable needle shield (70, 80) covers at least a distal end of an injection needle (3) when in the extended position and which needle shield (70, 80) when axially moved to the retracted position exposes a distal end (D) of the injection needle (3) and triggers the release of at least a portion of the torque stored in

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the torsion spring (S1) to drive the piston rod (30) and the plunger (8) distally inside the cartridge (5),

30

A needle holder (60) for carrying the injection needle (3) and which needle holder (60) is axially movable in relation to both the housing (10) and to the telescopically movable needle shield (70, 80), and wherein

35

A separate activation member (90) is axially movable by the needle shield (70, 80) from a first position to a second position in which second position the activation member (90) activates the dose setting arrangement (4, 40, 50, 55) to release the torque stored in the torsion spring (S1) to rotate the piston rod guide (35).

2. A torsion spring driven injection device according to claim 1, wherein the torsion spring (S1) is encompassed between the housing (10) and a drive tube (50).

3. A torsion spring driven injection device according to claim 2, wherein a clutch (40) couples the drive tube (50) to the rotatable piston rod guide (35) during injection such that the drive tube (50), the clutch (40) and the rotatable piston rod guide (35) rotate in unison under the influence of the torque stored in the torsion spring (S1).

4. A spring driven drug device according to claim 3 wherein the rotatable dose setting arrangement (4, 40, 50, 55) comprises, the rotatable dose dial (4), the clutch (40), a drive tube (50) and a ratchet element (55), and the drive arrangement (20, 30, 35) comprises, the piston rod (30), the piston rod guide (35) and a nut member (20) provided with an internal thread (21) engaging an outer thread (31) provided on the piston rod (30),

5. A spring driven drug device according to claim 3 or 4, wherein the clutch (40) is axially movable from a locked position in which the clutch (40) is rotational locked to a released position in which the clutch (40) is rotational released and coupled to the piston rod guide (35) such that the torque stored in the torsion spring (S1) in the released position rotates the piston rod guide (35)

6. A spring driven drug delivery device according to any of the previous claims, wherein the needle shield (70, 80) when moved from the extended position to the retracted position simultaneously moves the activation member (90) axially from the first position to the second position.

7. A spring driven drug delivery device according to any of the previous claims, wherein a shield spring (S3) urges the needle shield (70, 80) from the retracted position to the extended position.

8. A spring driven drug delivery device according to any of the claims 3 to 7, wherein movement of the activation member (90) from the first position to the second position moves the clutch (40) axially from the locked position to the released position.

9. A spring driven drug delivery device according to any of the previous claims, wherein a compression spring (91) is encompassed between the activation member (90) and the housing (10) urging the activation member (90) into the first position.

5 10. A spring driven drug delivery device according to any of the previous claims, wherein the activation member (90) is releasably coupled to the needle shield (70, 80).

11. A spring driven drug delivery device according to claim 10, wherein the activation member (90) engages the needle shield (70, 80).

10

12. A spring driven drug delivery device according to any of the previous claims, wherein the needle holder (60) is urged in the distal direction by the activation member (90) when the activation member (90) is released from the needle shield (70, 80).

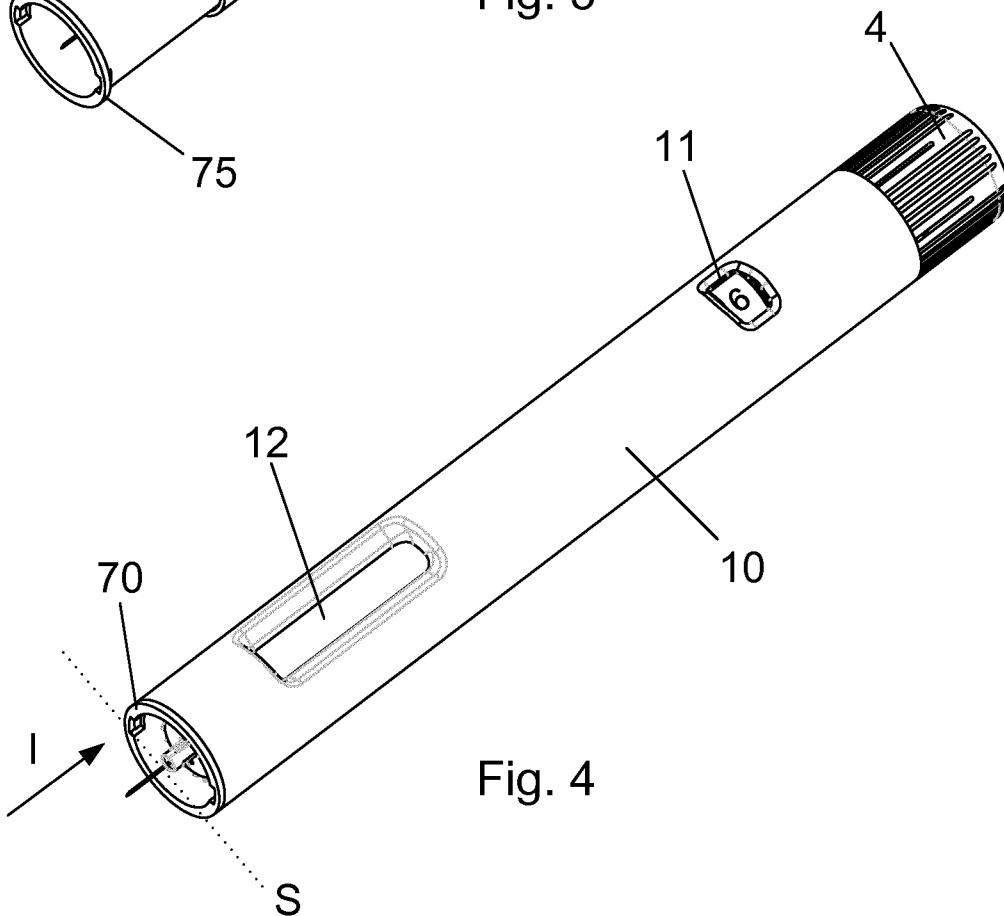
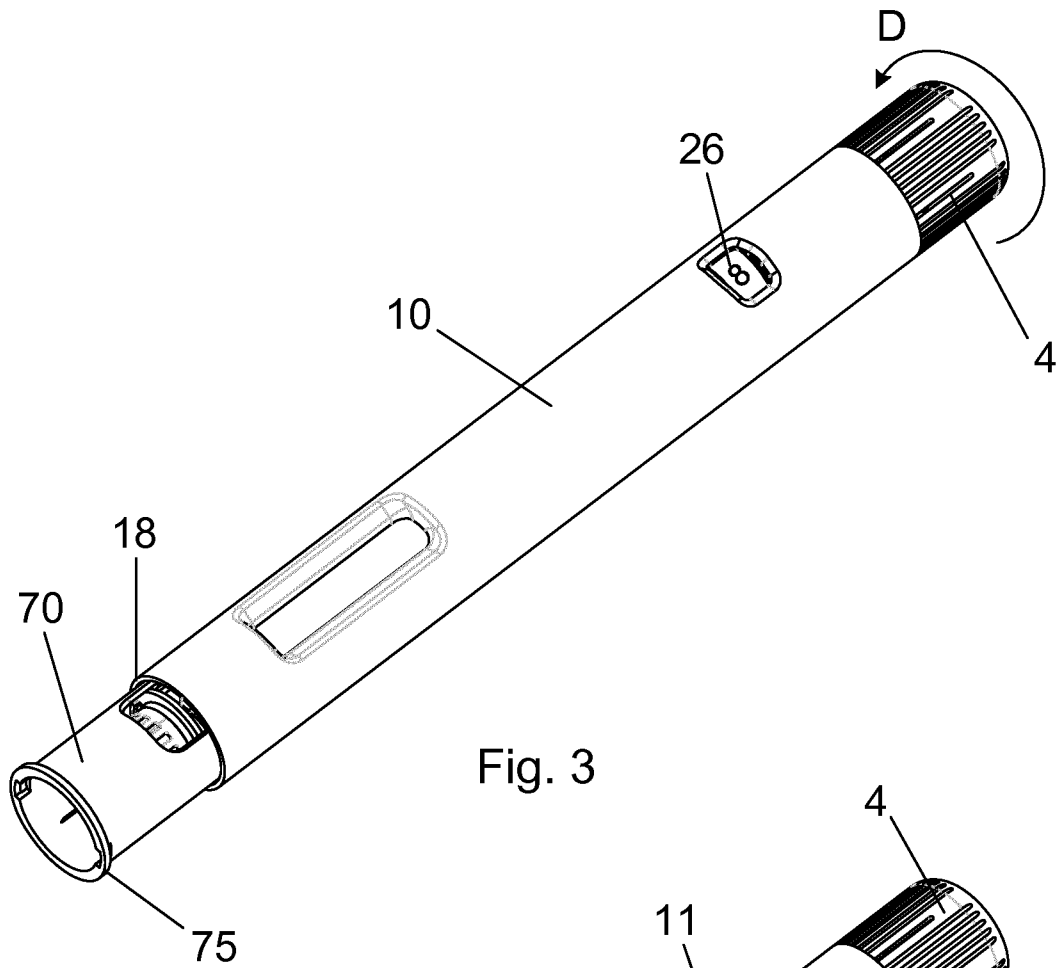
15 13. A spring driven drug delivery device according to any of the previous claims, wherein the needle holder (60) when moved in the distal direction into a distal position decouples the injection needle (3) from the cartridge (5).

20 14. A spring driven drug delivery device according to any of the previous claims, wherein the needle shield (70, 80) is guided axially and the activation member (90) is rotational in relation to the needle shield (70, 80).

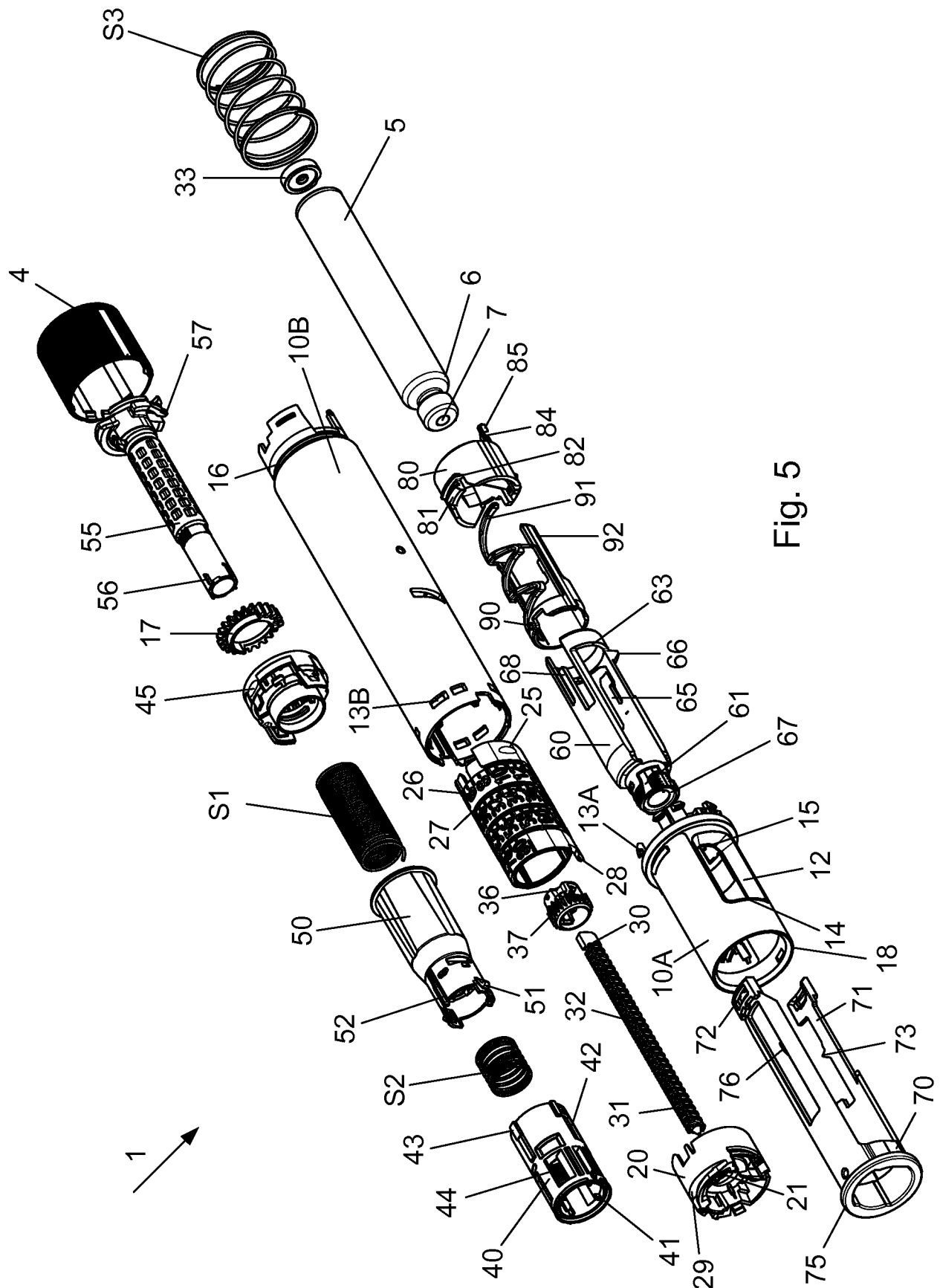
25 15. A spring driven drug delivery device according to any of the previous claims, wherein the rotatable dose setting arrangement (4, 40, 50, 55) upon rotation of the rotatable dose dial (4) is adapted to rotate a scale drum (25) which is threadably engaged with the housing (10) and rotationally coupled to the clutch (40) to follow rotation of the clutch (40) to thereby perform a helical movement away from a zero position during dose setting and back to the initial zero position upon injection.

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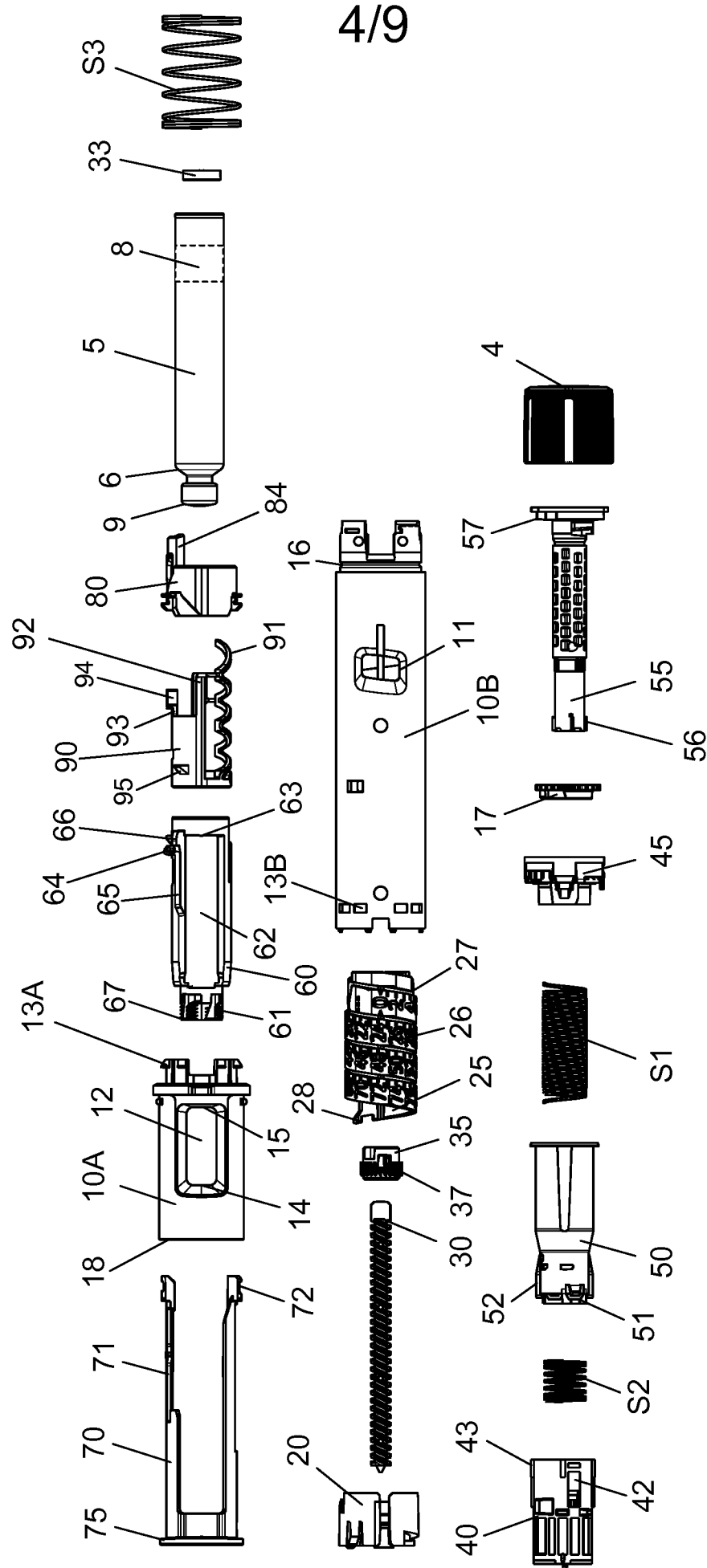


Fig. 6

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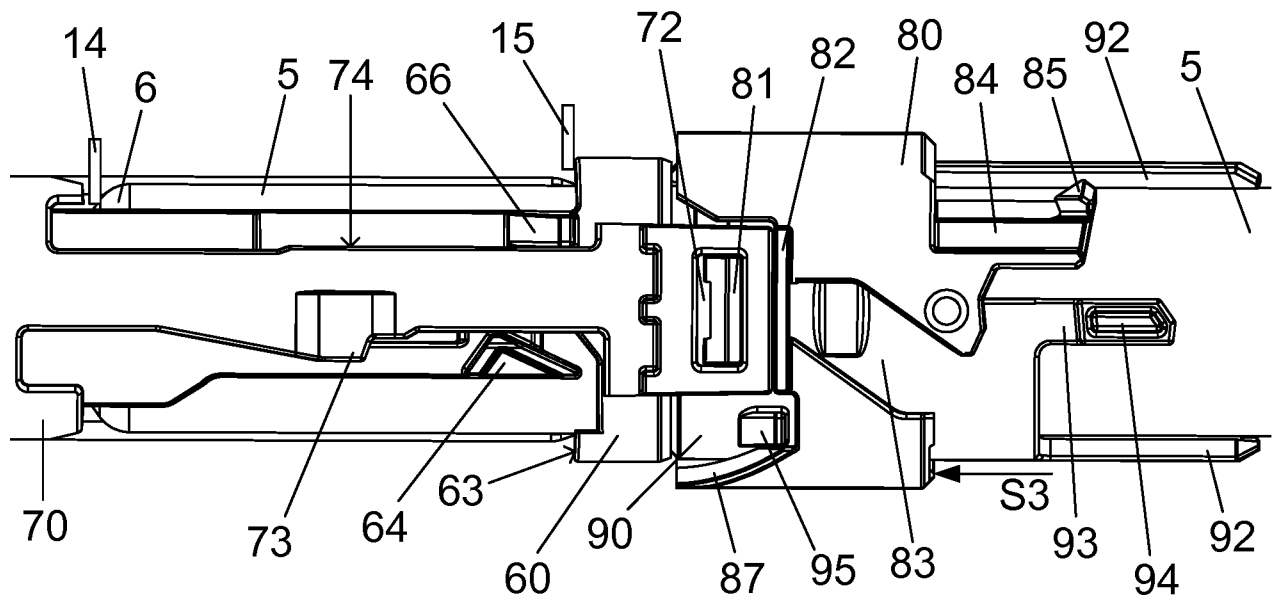
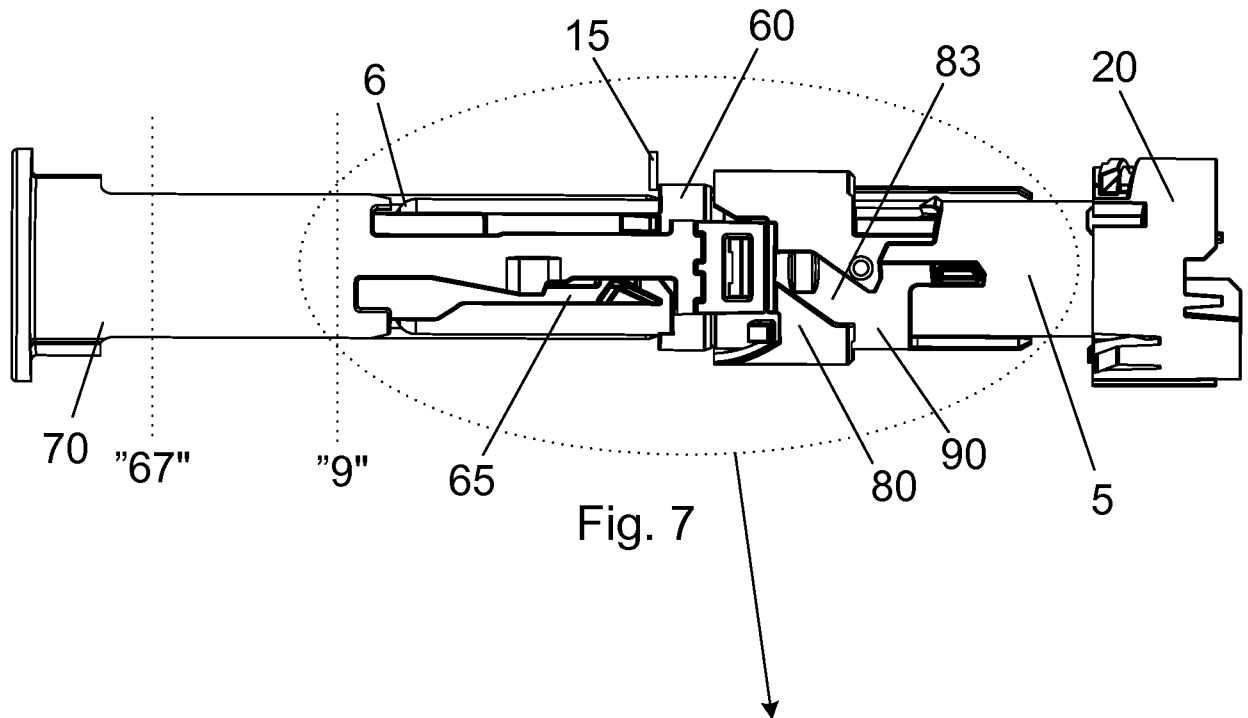
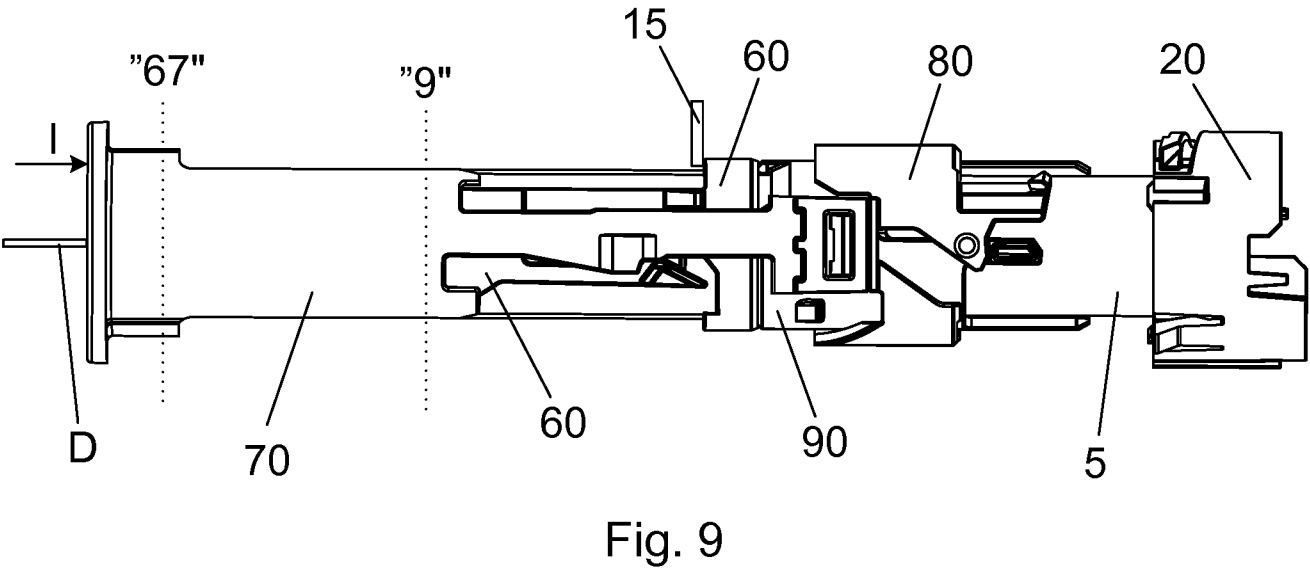
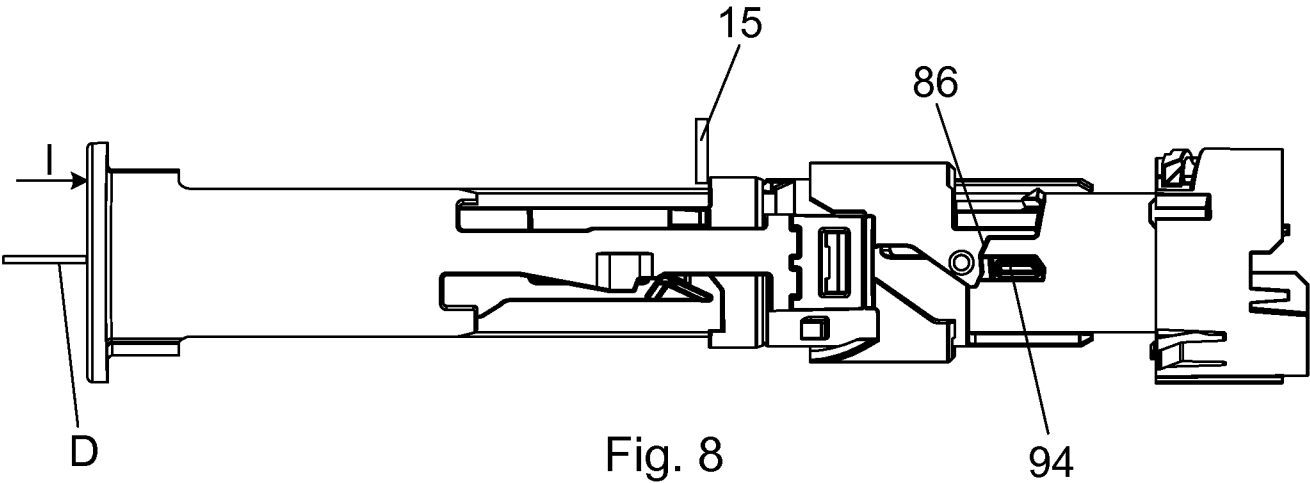


Fig. 7A



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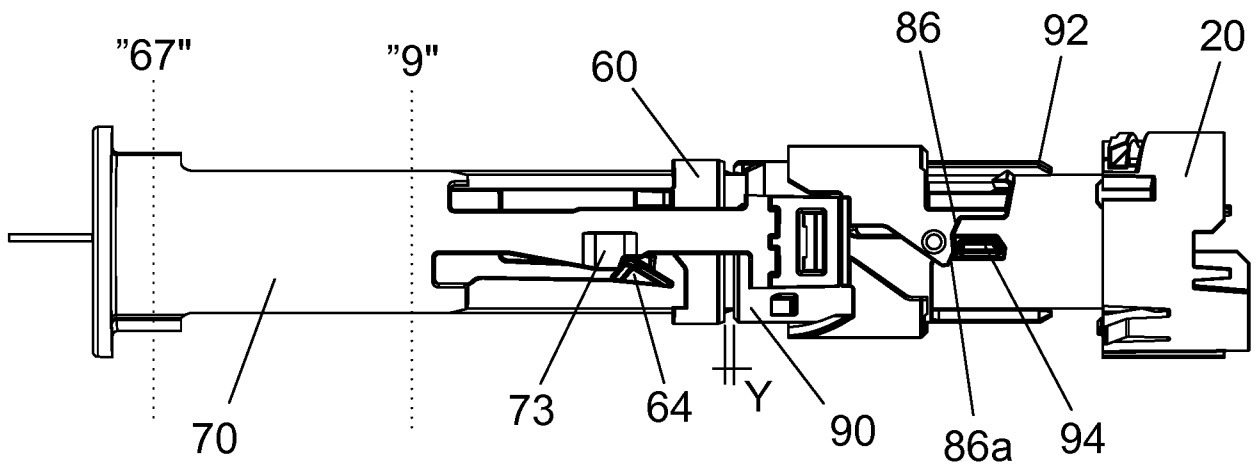


Fig. 10

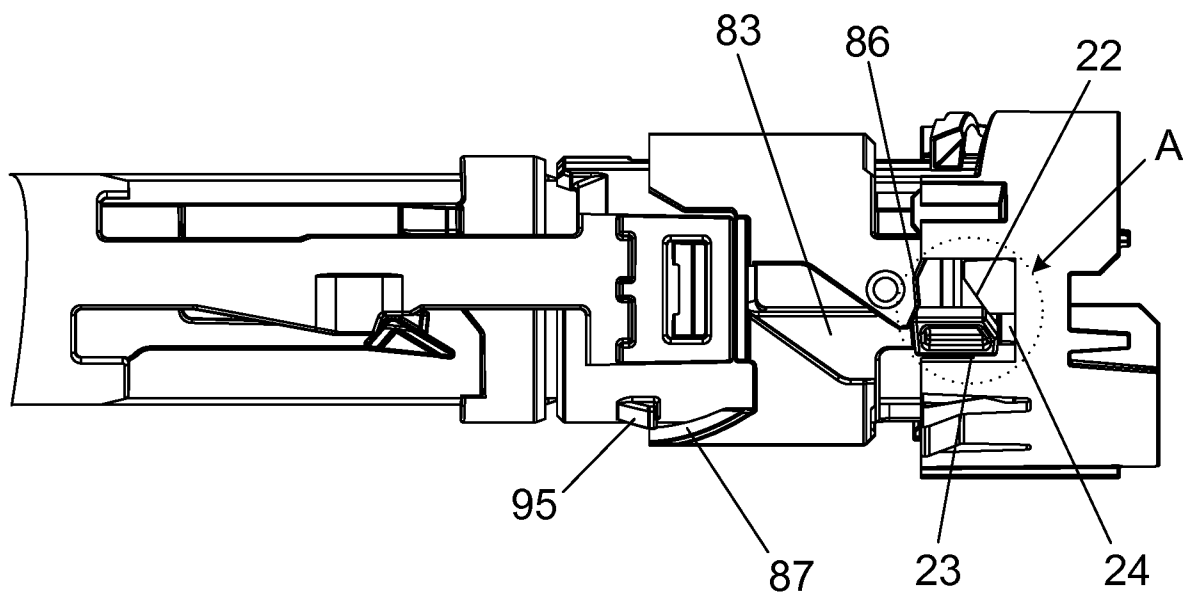
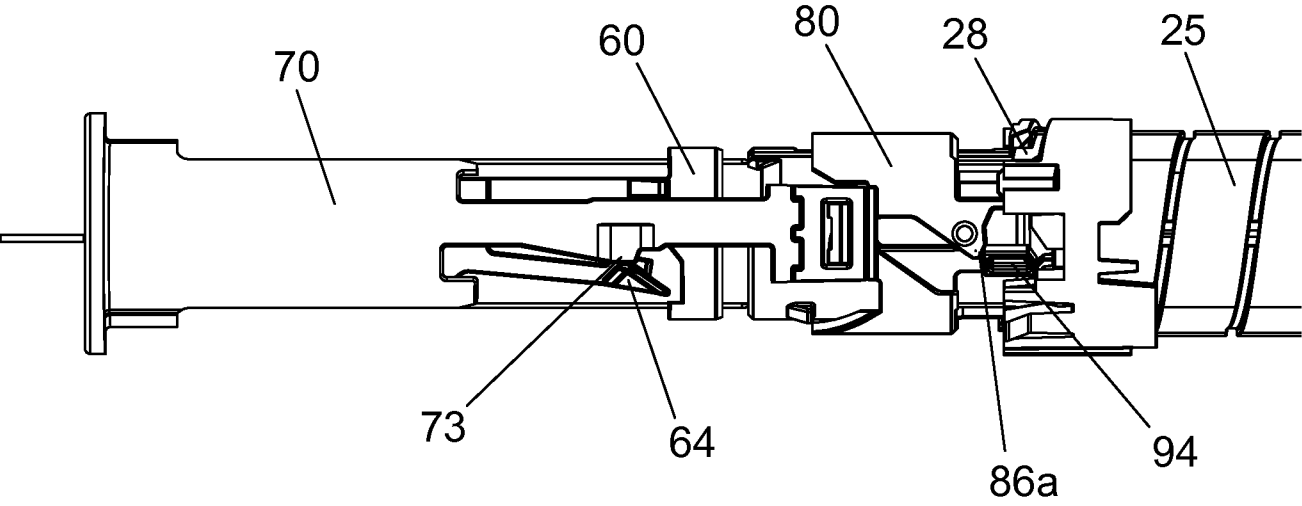
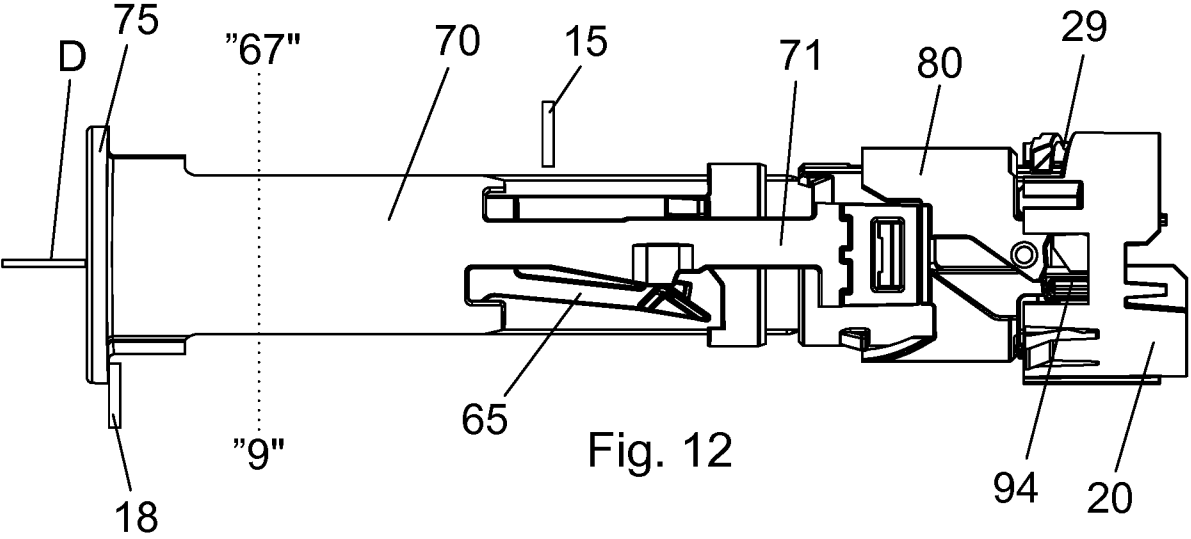


Fig. 11



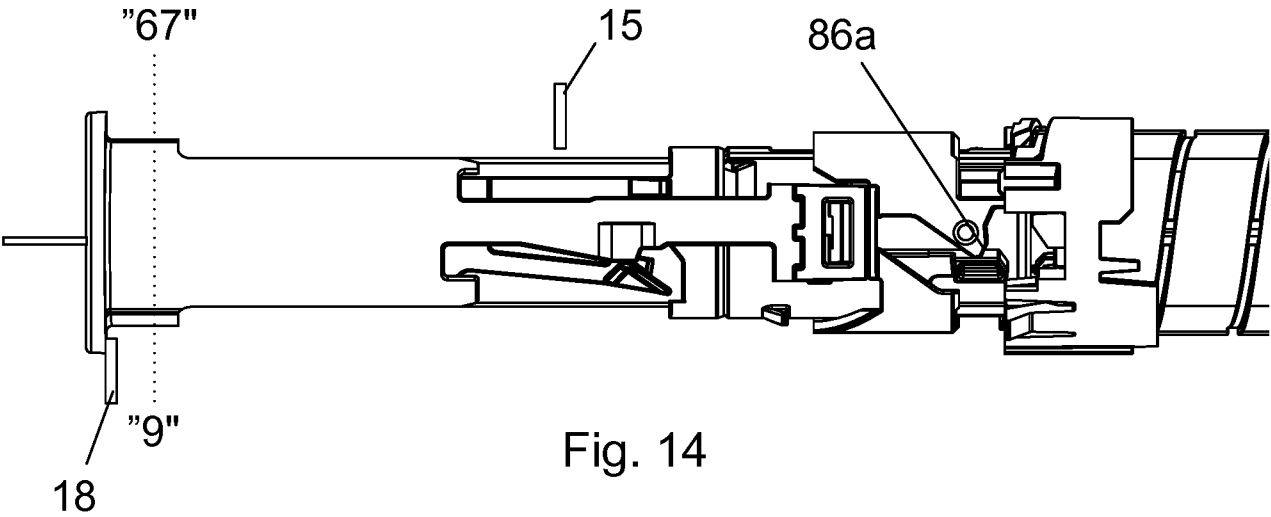


Fig. 14

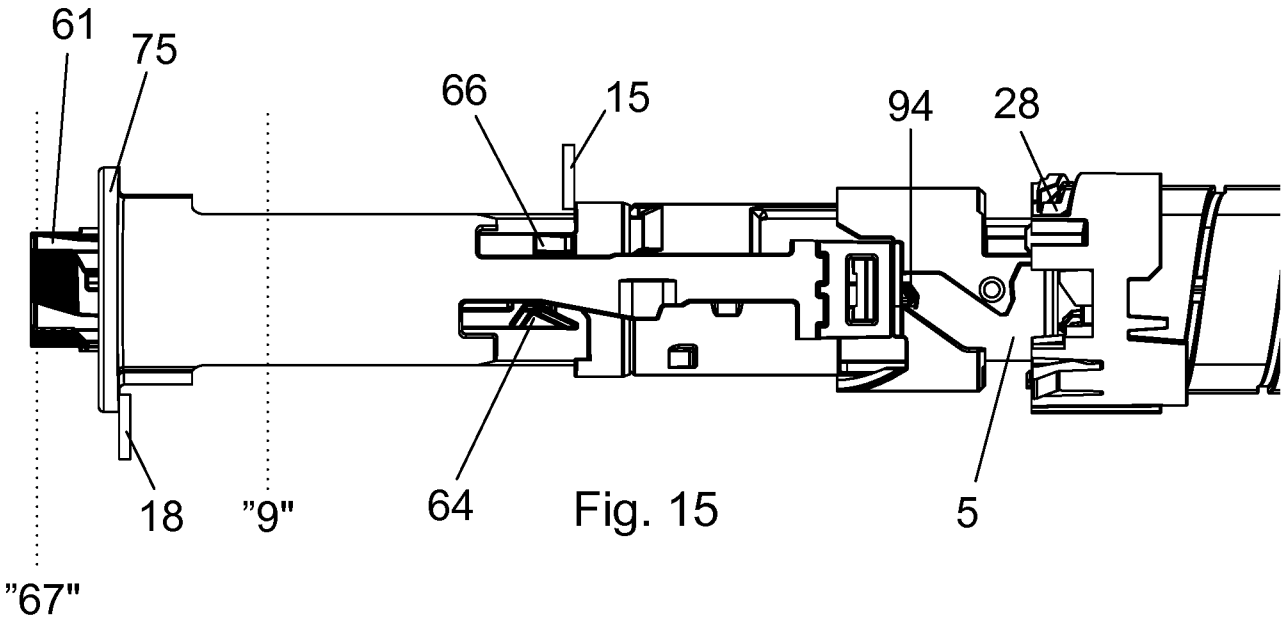


Fig. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/057544

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/20 A61M5/315 A61M5/32
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2014/001319 A1 (NOVO NORDISK AS [DK]) 3 January 2014 (2014-01-03) pages 16-22; figures 1-18 pages 25-28; figures 19-26 -----	1-15
X	WO 2013/048310 A1 (SHL GROUP AB [SE]; KARLSSON SEBASTIAN [SE]; DANIEL MATTIAS [SE]) 4 April 2013 (2013-04-04) pages 12-149; figures -----	1-15
X	WO 2015/052221 A1 (CAREBAY EUROPE LTD [MT]) 16 April 2015 (2015-04-16) pages 8-5; figures -----	1-15
A	WO 2014/060369 A1 (NOVO NORDISK AS [DK]) 24 April 2014 (2014-04-24) pages 13-22; figures -----	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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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

13 June 2017

Date of mailing of the international search report

26/06/2017

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2017/057544

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2014001319	A1	03-01-2014	CN 104379196 A 25-02-2015
			CN 104428020 A 18-03-2015
			EP 2866857 A2 06-05-2015
			EP 2866861 A1 06-05-2015
			JP 2015521511 A 30-07-2015
			JP 2015525583 A 07-09-2015
			US 2015174335 A1 25-06-2015
			US 2015202365 A1 23-07-2015
			WO 2014001318 A2 03-01-2014
			WO 2014001319 A1 03-01-2014
WO 2013048310	A1	04-04-2013	AU 2012316786 A1 10-04-2014
			CA 2850105 A1 04-04-2013
			CN 103945881 A 23-07-2014
			EP 2750739 A1 09-07-2014
			JP 5847316 B2 20-01-2016
			JP 2014527894 A 23-10-2014
			KR 20140082728 A 02-07-2014
			TW 201325647 A 01-07-2013
			US 2014228769 A1 14-08-2014
			US 2015250951 A1 10-09-2015
			WO 2013048310 A1 04-04-2013
WO 2015052221	A1	16-04-2015	EP 3055004 A1 17-08-2016
			TW 201526939 A 16-07-2015
			US 2016250417 A1 01-09-2016
			WO 2015052221 A1 16-04-2015
WO 2014060369	A1	24-04-2014	CN 104736188 A 24-06-2015
			EP 2906271 A1 19-08-2015
			JP 2015534837 A 07-12-2015
			US 2015265776 A1 24-09-2015
			WO 2014060369 A1 24-04-2014