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DESCRIPTION

Technical Field

[0001] The invention relates to an auto-injector for administering a dose of a liquid medicament.

Background of the Invention

[0002] Administering an injection is a process which presents a number of risks and challenges for users and healthcare professionals, both mental and physical.

[0003] Injection devices (i.e. devices capable of delivering medicaments from a medication container) typically fall into two categories - manual devices and auto-injectors.

[0004] In a manual device - the user must provide the mechanical energy to drive the fluid through the needle. This is typically done by some form of button / plunger that has to be continuously pressed by the user during the injection. There are numerous disadvantages to the user from this approach. If the user stops pressing the button / plunger then the injection will also stop. This means that the user can deliver an underdose if the device is not used properly (i.e. the plunger is not fully pressed to its end position). Injection forces may be too high for the user, in particular if the patient is elderly or has dexterity problems.

[0005] The extension of the button/plunger may be too great. Thus it can be inconvenient for the user to reach a fully extended button. The combination of injection force and button extension can cause trembling / shaking of the hand which in turn increases discomfort as the inserted needle moves.

[0006] Auto-injector devices aim to make self-administration of injected therapies easier for patients. Current therapies delivered by means of self-administered injections include drugs for diabetes (both insulin and newer GLP-1 class drugs), migraine, hormone therapies, anticoagulants etc.

[0007] Auto-injectors are devices which completely or partially replace activities involved in parenteral drug delivery from standard syringes. These activities may include removal of a protective syringe cap, insertion of a needle into a patient's skin, injection of the medicament, removal of the needle, shielding of the needle and preventing reuse of the device. This overcomes many of the disadvantages of manual devices. Injection forces / button extension, hand-shaking and the likelihood of delivering an incomplete dose are reduced. Triggering may be performed by numerous means, for example a trigger button or the action of the needle reaching its injection depth. In some devices the energy to deliver the fluid is provided by a

spring.

[0008] US 2002/0095120 A1 discloses an automatic injection device which automatically injects a pre-measured quantity of fluid medicine when a tension spring is released. The tension spring moves an ampoule and the injection needle from a storage position to a deployed position when it is released. The content of the ampoule is thereafter expelled by the tension spring forcing a piston forward inside the ampoule. After the fluid medicine has been injected, torsion stored in the tension spring is released and the injection needle is automatically retracted back to its original storage position.

[0009] WO 2009/062508 A1 discloses a disposable auto injector having a housing for accommodation of a syringe with a needle movably positioned in the housing between a first position in which the needle is inside the housing and a second position in which the needle protrudes outside the housing, a driver positioned laterally in relation to the syringe and configured for applying a force to the syringe thereby moving the syringe from the first position to the second position, a first injection lock configured in a locked state
for preventing syringe movement from the first position to the second position and an injection trigger member configured for releasing the first injection lock to an unlocked state wherein the first injection lock comprises a rotatable release shaft configured for rotation between a first angular position in which it prevents movement of the syringe from the first position to the second position and a second angular position in which position does not prevent movement of the syringe from the first position to the second position.

[0010] WO 2009/040602 A1 discloses an autoinjector comprising:

- a housing, a container movable within said housing between an initial position and an insertion position, said movement being prevented when the container is in its passive state, and permitted when the container is in its active state, and
- a safety shield movable with respect to said housing between a first position and a second position, said movement placing the container in its active state,
- first retaining means for maintaining said container in its passive state,
- first deactivating means, capable of rotating with respect to said first retaining means from a first position, in which said first retaining means maintain said container in its passive state, to a second position, in which said first retaining means allow the passage of said container in its active state, said rotation being caused by movement of said safety shield from its first position to its second position under distal pressure exerted on said housing.

[0011] GB 2 438 592 A discloses an injection device including a housing adapted to receive a syringe that is movable between a retracted position, in which its needle is contained within the housing, and an extended position, in which its needle extends from the housing through an exit aperture. The device includes a drive that acts upon the syringe to advance it from its retracted position to its extended position and to discharge its contents through its needle. A

syringe carrier is advanced with the syringe and a sleeve restrains the advancement of the syringe carrier as the syringe reaches its extended position. A damping element acts between the syringe carrier and the sleeve to cushion the impact as they come into contact, thereby reducing the transmission of energy from the impact to the components of the drive and preventing their fracture. The damping element also reduces the noise, which may be distressing to a user of the device, produced when the syringe carrier and the sleeve come into contact and reduces the pain suffered by a user upon operation of the device.

Summary of the Invention

[0012] It is an object of the present invention to provide an improved auto-injector.

[0013] The object is achieved by an auto-injector according to claim 1.

[0014] Preferred embodiments of the invention are given in the dependent claims.

[0015] In the context of this specification, the terms distal and proximal are defined from the point of view of a person receiving an injection. Consequently, a proximal direction refers to a direction pointing towards the body of a patient receiving the injection and a proximal end defines an end of an element that is directed towards the body of the patient. Respectively, the distal end of an element or the distal direction is directed away from the body of the patient receiving the injection and opposite to the proximal end or proximal direction.

[0016] According to the invention, an auto-injector for administering a dose of a liquid medicament comprises all the features of appended claim 1.

[0017] A stopper may be arranged in the syringe barrel arranged to seal its distal end and to expel the dose of medicament. A coupling shroud may be slidably arranged within the housing and releasably coupled to a plunger that is connected to the stopper. The drive means may be arranged between a distal end of the housing and the coupling shroud to bias the coupling shroud in a proximal direction towards the skin of a patient receiving an injection.

[0018] The rotating collar creates friction to slow down a proximal movement of the needle shroud that rests on the skin of the patient during the injection. The rotating collar acts as a dampening element that alleviates the pressure exerted upon the skin of the patient by the needle shroud that is driven by the drive means. Thus, the risk of injuries is reduced and, in particular, bruises may be avoided. Furthermore, the modulus of resilience of the single drive means may be chosen to be sufficiently large without having to worry about potential injury risks. Thus, the modulus of resilience of the drive means is adapted to reliably provide an energy supply for executing a plurality of actions comprising, among others, the advancing and releasing of the needle shroud, the displacement of the stopper to expel the medicament and the decoupling of the plunger and the coupling shroud.

[0019] Preferably, the rotating collar comprises a pin that engages a helical recess formed into the needle shroud. The engagement of the helical recess and the pin forces the rotating collar to rotate around the needle shroud when the needle shroud is translated. This dampens the proximal movement of the needle shroud and thus reduces the pressure exerted upon the skin of the patient by generating friction.

[0020] According to a possible embodiment of the invention, the needle shroud is slidable in a distal direction from an advanced position to a retracted position. In particular, the needle shroud may be slid to the retracted position by placing the auto-injector onto the skin of the patient receiving the injection and pressing the needle shroud against the skin of the patient. The needle shroud in the retracted position indicates the correct placement of the auto-injector. An activation of a mechanism of the auto-injector delivering the medicament to the patient requires the needle shroud to be positioned in the retracted position to ensure that the auto-injector is properly used. The needle shroud is slidable in the proximal direction from the retracted position to the safe position, wherein the needle shroud surrounds an injection needle of the pre-filled syringe to prevent accidental needle stick injuries after the injection has been carried out.

[0021] According to another possible embodiment of the invention, the drive means is arranged to be released by manual actuation of a release element that is hinged to a lateral side of the housing. Conventional auto-injectors are commonly activated by actuating a push button or the like arranged at a distal end of the auto-injector. An inexperienced user of such a conventional auto-injector may easily mistake the distal end for a proximal end of the auto-injector and thus may pierce his finger while trying to actuate the auto-injector. The lateral arrangement of the release element is a simple means to prevent such accidental needle stick injuries resulting from a misuse of the auto-injector.

[0022] Alternatively, the release element is in slidable arrangement with the housing and may be translated with respect to the housing in the proximal direction to release the drive means. The auto-injector according to this embodiment of the invention is particularly intuitive to operate.

[0023] According to another possible embodiment of the invention, the auto-injector comprises safety means that cooperate with the needle shroud that is arranged to prevent a release of the drive means when the needle shroud is in the advanced position and hence is not pushed against the skin of the patient. This mechanism avoids an early release of the drive means and thus a premature expelling of the medicament. Furthermore, injuries resulting from an activation of the drive means when the autoinjector is not placed, or not properly placed onto the skin of the patient are reduced.

[0024] The safety means may comprise a blocking element slidably arranged relative to the housing. The blocking element is arranged to limit a pivoting movement of the release element hinged to the lateral side of the housing when the needle shroud is in the advanced position. A release of the drive means is thus prevented. The release element is allowed to pivot about the

hinge when the needle shroud is moved to the retracted position by pressing the needle shroud against the skin surface of the patient receiving the injection.

[0025] In one possible embodiment of the invention, the safety means comprises an elastic bushing that engages a plunger of the pre-filled syringe and/or a coupling shroud that is biased by the drive means and coupled to the plunger of the pre-filled syringe. The elastic bushing is firmly attached to a proximal end of the housing and may engage the coupling shroud and/or the plunger to prevent an inadvertent release of the drive means.

[0026] In another preferred embodiment of the invention, the drive means is capable of, upon release, driving the coupling shroud releasably coupled to the plunger from a first position in the proximal direction. The coupling shroud is driven by the drive means to interact with different components of the auto-injector, so that the resilient force provided by the drive means may be used to power a variety of functions of the auto-injector. The proximal translatory movement of the coupling shroud with respect to the housing

- translates a syringe retainer receiving the pre-filled syringe in the proximal direction to expose the injection needle of the pre-filled syringe,
- depresses the plunger connected to a stopper into the syringe barrel to expel the dose of medicament and
- translates the needle shroud in the proximal direction. The coupling shroud mediates the resilient force provided by the drive means to this variety of different components of the auto-injector and thus allows for a compact design of the auto-injector. In particular, the auto-injector may be powered by just a single drive means to accomplish a plurality of tasks necessary for safely carrying out the injection.

[0027] According to yet another possible embodiment of the invention, the syringe retainer is releasably mounted to the housing. The needle shroud in the retracted position releases the syringe retainer to allow for the proximal translation of the syringe retainer with respect to the housing. Thus, a proximal movement of the syringe retainer that in particular inserts the injection needle into the skin of the patient is prevented until the auto-injector is correctly placed upon the skin of the patient and the needle shroud is pushed against the skin surface towards the retracted position. This prevents an inadvertent early release of the drive means.

[0028] The coupling shroud is initially in a first position, and coupled to the plunger to translate the syringe retainer proximally, whereby the injection needle is inserted into the skin of the patient, and to depress the stopper into the syringe barrel to expel the medicament. The plunger and the coupling shroud are decoupled from each other at the proper pre-determined second position after the medicament has been completely or partially delivered. The pre-determined second position is defined by a longitudinal aperture in the housing.

[0029] According to another possible embodiment of the invention, a coupling catch is arranged to abut against a shoulder formed to the plunger as a particularly simple and reliable

means to releasably couple the plunger to the coupling shroud. The coupling shroud is moved by the action of the relaxing drive means in the proximal direction and is coupled to the plunger connected to the stopper to insert the injection needle before the injection and to expel the medication during the injection.

[0030] The aperture formed into the lateral side of the housing at the second position allows the coupling catch to deflect radially outwards at the second position, so that the coupling shroud is decoupled from the plunger after the medicament is partially or completely delivered.

[0031] Preferably, the drive means is arranged as a single compression spring. The mechanism of the auto-injector is arranged in a manner that a plurality of functions is executed by the single drive means. The injection needle is inserted into the skin of the patient, the plunger is translated to expel the medicament and the needle shroud is moved proximally to provide needle safety after the injection is completed by the action of the spring means. Conventional auto-injectors usually comprise a plurality of spring means to accomplish these tasks. The auto-injector according to the invention comprises only few parts and is particularly inexpensive to mass-produce. Consequently, the auto-injector is particularly suited as a single-use device that may be disposed after an injection has been carried out.

[0032] The auto-injector may preferably be used for subcutaneous or intra-muscular injection, particularly for delivering one of an analgetic, an anticoagulant, insulin, an insulin derivate, heparin, Lovenox, a vaccine, a growth hormone, a peptide hormone, a proteine, antibodies and complex carbohydrates.

[0033] Further scope of applicability of the present invention will become apparent from the detailed description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the scope of the appended claims will become apparent to those skilled in the art from this detailed description.

Brief Description of the Drawings

[0034] The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only, and thus, are not limitive of the present invention, and wherein:

Figures 1A und 1B
: show two different sectional views of an auto-injector according to a first embodiment of the invention with a hinged release element before an injection,

Figure 2
: an expanded sectional view of the auto-injector according to the first embodiment, wherein the release element is blocked to prevent an inadvertent release of a drive

means,

Figure 3

an expanded sectional view of the hinged release element that is actuated to release the drive means,

Figures 4A and 4B

two different sectional views of the auto-injector according to the first embodiment after a drug has been delivered,

Figure 5

an isometric view of a needle shroud,

Figures 6A and 6B

two different sectional views of the auto-injector according to the first embodiment after an injection has been performed,

Figures 7A and 7B

two different sectional views of an auto-injector according to a second embodiment of the invention,

Figure 8

a sectional view of a distal end section of the auto-injector according to the second embodiment of the invention,

Figure 9A and 9B

two different sectional views of an auto-injector according to a third embodiment of the invention,

Figure 10

a sectional view of a distal end section of the auto-injector according to the third embodiment of the invention.

[0035] Corresponding parts are marked with the same reference symbols in all figures.

Detailed Description of Preferred Embodiments

[0036] Figures 1A and 1B show two sectional views of an essentially cylindrical auto-injector 1 according to a first embodiment of the invention, wherein the sectional plane shown in figure 1A is oriented perpendicularly to the one shown in figure 1B. The auto-injector 1 comprises a housing 2, a proximal needle shroud 3, a syringe retainer 4 adapted to mount and move translatably with a pre-filled syringe 5 within the housing 2, a coupling shroud 6 slidably arranged within the housing 2 and a release element 7 hinged to a lateral side of the substantially cylindrical housing 2 of the auto-injector 1.

[0037] A single drive means 8 is arranged between the distal end of the housing 2 and the coupling shroud 6 to bias the coupling shroud 6 in a proximal direction P towards the skin of a patient receiving an injection.

[0038] According to one possible embodiment of the invention, the drive means 8 is arranged as a single, conventional compression spring.

[0039] The coupling shroud 6 is releasably coupled to a plunger 9 that is connected to a stopper 10 fluid-tightly sealing a distal end of a syringe barrel 11 containing a dose of a medicament M. An inner cavity of the syringe barrel 11 is in fluid communication with an injection needle 12, so that the dose of the medicament M may be expelled through the injection needle 12 by displacing the stopper 10 in the proximal direction P.

[0040] Before the injection, the coupling shroud 6 abuts against a distal end of the release element 7 to releasably retain the coupling shroud 6 in a first position I, wherein the coupling shroud 7 is located at a distal end of the housing 2. The drive means 8 is compressed, so that the coupling shroud 6 is strongly biased in the proximal direction P.

[0041] The plunger 9 extends from the syringe barrel 11 in a distal direction D and comprises a shoulder 9.1 of increased diameter. The coupling shroud 6 comprises an inwardly protruding coupling catch 6.1 that bears against the shoulder 9.1 so that the plunger 9 and the coupling shroud 6 may be jointly moved in the proximal direction P by the action of the relaxing drive means 8.

[0042] The proximal end of the needle shroud 3 is designed to be pushed against the skin surface of the patient during the injection. Edges of the needle shroud 3 may thus be smoothed to avoid injuries. The needle shroud 3 is slidably arranged within the housing 2 of the auto-injector 1, so that the needle shroud 3 may be pushed from an advanced position PA shown in figures 1A and 1B in the distal direction D. A biasing means 13 bears against the needle shroud 3 and the housing 2 to bias the needle shroud 3 towards the advanced position PA.

[0043] An annular rotating collar 14 engages an outer surface of the needle shroud 3. The rotating collar 14 rotates around an axis of the substantially cylindrical auto-injector 1 when the needle shroud 3 is longitudinally displaced in the proximal and/or the distal direction P, D. The rotating collar 14 acts as a damping means that creates friction to slow down the movement of the needle shroud 3 and to reduce the pressure exerted onto the skin of the patient receiving the injection.

[0044] The release element 7 hinged to the housing 2 works like a see-saw: a proximal section may be pushed radially inwards, whereby the release element 7 pivots about a hinge 15, so that the distal section of the release element 7 moves radially outwards and the coupling shroud 6 is disengaged to release the drive means 8.

[0045] The auto-injector 1 comprises safety means S that prevent an early release of the drive means 8. The safety means S ensure that the needle shroud 3 is pushed against the skin of the person receiving the injection before the drive means 8 may be released.

[0046] According to the first embodiment of the invention, the safety means S comprise a blocking element 16 slidably arranged with the housing 2. When the needle shroud 3 is positioned in the advanced position PA, the blocking element 16 is positioned to prevent a pivoting movement of the release element 7 and thus a release of the coupling shroud 6. A radially outwards protruding blocking projection 16.1 of the blocking element 16 is located opposite to an inward protrusion 7.1 formed to the release element 7. If the proximal section of the release element 7 is pushed inwards, the inward protrusion 7.1 abuts against the blocking projection 16.1 to limit the pivoting movement of the release element 7, so that a release of the coupling shroud 6 and the drive means 8 is prevented.

[0047] Figure 2 shows a proximal section of the auto-injector 1 in a sectional view with the blocking element 16 positioned to prevent an inadvertent actuation of the hinged release element 7 to release the drive means 8.

[0048] A distal end of the needle shroud 3 is clipped to the housing 2 and retained between two inwardly protruding retaining protrusions 2.1 formed into an inner surface of the housing 2. The two retaining protrusions 2.1 are longitudinally displaced from each other to limit the range of axial displacement of the needle shroud 3 with respect to the housing 2. A boss 3.1 formed into an outer surface of the needle shroud 3 bears against an inner surface of the blocking element 16, so that the blocking element 16 may move with the needle shroud 3 in the proximal direction P to deblock the release element 7.

[0049] The blocking projection 16.1 comprises a central indention that forces a user of the auto-injector 1 to perform a sequence of actions necessary to inject the dose of the medicament M in the proper order. If the release element 7 is pushed inwards before the needle shroud 3 is moved proximally from the advanced position PA towards a retracted position PR (see Figure 3) by pushing the needle shroud 3 towards the skin of the patient, the inward projection 7.1 is retained in the central indentation of the blocking projection 16.1, so that both the longitudinal displacement of the needle shroud 3 and the pivoting movement of the release element 7 is blocked.

[0050] A proper sequence of actions for injecting the dose of the medicament M is described in the following. First, the user pushes the needle shroud 3 against the skin to move the needle shroud 3 distally to the retracted position PR illustrated in figure 3. The blocking element 16 jointly moves with the needle shroud 3 in the distal direction D, so that the release element 7 may be manually actuated to pivot about the hinge 15, whereby the drive means 8 are released.

[0051] Upon release of the drive means 8, the coupling shroud 6 is urged in the proximal direction P. The single and fully compressed drive means 8 drives the coupling shroud 6 and the plunger 9 coupled thereto in the proximal direction P. The coupling shroud 6 first pushes the syringe retainer 4 by means of plunger 9, stopper 10 and the friction between stopper 10 and syringe 11 proximally to insert the injection needle 12 into the skin of the patient and a first clip connection 2.2 formed into a lateral side of the housing 2 latches to an outward protrusion

4.1 of the syringe retainer 4, as illustrated in more detail in figure 4B.

[0052] The syringe retainer 4 and the pre-filled syringe 5 mounted thereto is now locked to the housing 2. The coupling shroud 6 is moved further in the proximal direction P by the action of the relaxing drive means 8, whereby the plunger 9 is depressed into the syringe barrel 11 to expel the dose of the medicament M contained therein through the injection needle 12.

[0053] Figure 4A and 4B show two sectional views of the auto-injector 1 according to the first embodiment of the invention with the plunger 9 fully depressed within the syringe barrel 11. The dose of the medicament M has been delivered beneath the skin of the patient. The coupling shroud 6 is located in an intermediate second position II. The drive means 8 is not yet completely discharged and biases the coupling shroud 6 in the proximal direction P. The shoulder 9.1 engages a ramp of the coupling catch 6.1 to deflect the coupling catch 6.1 in a radial outward direction. An aperture 2.3 is formed into the housing 2 to allow for a radial outward deflection of the coupling catch 6.1, so that the coupling catch 6.1 overcomes the shoulder 9.1 decoupling the coupling shroud 6 from the plunger 9.

[0054] In a possible embodiment of the invention, the aperture 2.3 defining the second position II is located at a longitudinal position along the housing 2 that allows for a full depression of the plunger 9 completely emptying the syringe barrel 11 before the plunger 9 is decoupled from the coupling shroud 6.

[0055] Alternatively, the aperture 2.3 defining the second position II may be located at a longitudinal position along the housing 2 that allows for an adjustment space accounting for manufacturing tolerances. The adjustment space is dimensioned as to allow for a reliable decoupling of the plunger 9 from the coupling shroud 6 even if the parts constituting the auto-injector 1 comprise mismatch in mould or are slightly misaligned. In this alternative embodiment, the dose of the medicament M may or may not be completely expelled before the plunger 9 is decoupled from the coupling shroud 6.

[0056] The retaining protrusions 2.1 are elastically supported and may be deflected radially outwards to release the needle shroud 3. The coupling shroud 6 engages a ramp of the retaining protrusions 2.1 and splays the retaining protrusions 2.1 outwards, whereby the needle shroud 3 is released and allowed to move proximally from the retracted position PR towards an extended safe position PS.

[0057] The drive means 8 is still partially loaded when the coupling shroud 6 is located in the second position II. In a possible embodiment of the invention the biasing force of the drive means 8 exerted on the coupling shroud 6 in the second position II is about 10 N.

[0058] The coupling shroud 6 bears against a distal end of the needle shroud 3, so that the needle shroud 3 may be moved to the safe position PS by the action of the further relaxing drive means 8. As the biasing force exerted onto the needle shroud 3 by the drive means 8 may be relatively large and could even bruise the patient, the rotating collar 14 is arranged

within the housing 2 to partially absorb the excess energy of the drive means 8 and slow down the proximal movement of the needle shroud 3 by generating friction.

[0059] Figure 5 shows an isometric view of the needle shroud 3. A helical recess 3.2 is formed into a tubular proximal section 3.3 of the needle shroud 3. The proximal section 3.3 of the needle shroud 3 is inserted into the annular rotating collar 14, wherein a pin 14.1 formed to an inner surface of the rotating collar 14 protrudes into the helical recess 3.2 as shown in figure 6A. The linear translatory movement of needle shroud 3 towards the safe position PS thus causes the rotating collar 14 to rotate within the housing 2 around the axis of the auto-injector 1.

[0060] Figures 6A and 6B show two different sectional views of the auto-injector 1 according to the first embodiment of the invention after the injection has been performed. The needle shroud 3 is permanently locked to the safe position PS by a second clip connection 2.4 formed into the housing 2. The needle shroud 3 surrounds the injection needle 12 and extends a suitable distance proximally beyond the needle tip to avoid accidental needle stick injuries after the auto-injector 1 has been used.

[0061] Figures 7A and 7B show two different sectional views of an auto-injector 1 according to a second embodiment of the invention before the injection. The sectional plane shown in figure 7A is oriented perpendicularly to the sectional plane shown in figure 7B.

[0062] The needle shroud 3 of the auto-injector 1 according to the second embodiment substantially extends over the axial length of the housing 2. Before the injection, the needle shroud 3 is mounted to the housing 2 by the retaining protrusions 2.1 that protrude into orifices formed into a lateral side of the needle shroud 3. The orifices comprise a longitudinal length that allows the needle shroud 3 to be slid from the advanced position PA to the retracted position PR.

[0063] A retaining catch 2.5 is formed to an inner surface of the housing 2 and protrudes through an opening formed into the needle shroud 3 to releasably mount the syringe retainer 4 retaining the pre-filled syringe 5. The retaining catch 2.5 comprises a bevelled ramp and is deflectable in a radial outward direction. The retaining catch 2.5 latches to the outward protrusion 4.1 formed to the outer surface of the syringe retainer 4 when the needle shroud 3 is in the advanced position PA.

[0064] The needle shroud 3 abuts against the bevelled ramp of the retaining catch 2.5 when the needle shroud 3 is moved from the advanced position PA in the distal direction D, whereby the retaining catch 2.5 is deflected in a radial outward direction and disengages the outward protrusion 4.1, so that the syringe retainer 4 may be moved in the proximal direction P.

[0065] The release element 7, shown in more detail in figure 8, is arranged as a push button and mounted to a distal end of the housing 2. The release element 7 may be pushed in the proximal direction P to release the drive means 8 when the needle shroud 3 is in the retracted

position PR, whereas the release element 7 and thus the release of the drive means 8 is blocked when the needle shroud 7 is in the advanced position PA.

[0066] According to the second embodiment of the invention, the safety means S that prevent the early release of the drive means 8 comprises clips 2.6 that may deflect in a radial outward direction and a bushing 17 locking the plunger 9 before use of the autoinjector 1.

[0067] Before the auto-injector 1 is used, the clips 2.6 formed to the housing 8 latch to the release element 7. (See Figure 7B) The clips 2.6 block the movement of the release element 7 in the proximal direction P, so that a manual actuation of the release element 7 is prevented as long as the needle shroud 3 is in the advanced position PA. A distal movement of the release element 7 is blocked by a first detent 2.7 engaging an inner surface of the release element 7.

[0068] The clip 2.6 comprises a ramp that the needle shroud 3 engages when pushed distally from the advanced position PA to the retracted position PR, whereby the clip 2.6 is deflected radially outwards to disengage the needle shroud 3. The release element 7 may be pushed in the proximal direction P when the needle shroud 3 is in the retracted position PR.

[0069] The plunger 9 comprises a distal end 9.2 of increased diameter that is retained in the bushing 17 firmly attached to a distal end of the housing 2. The bushing 17 comprises an inner surface corresponding to the distal end 9.2 of the plunger 9 that engages the distal end 9.2 in a locked position L to lock the plunger 9 and the coupling shroud 6 coupled thereto to the housing 2 before use of the auto-injector 1. The bushing 17 abuts radially against an annular inner collar 7.2 of the release element 7 in the locked position L shown in figures 7A and 7B. A radial outward deflection of the bushing 17 releasing the plunger 9 is thus prevented.

[0070] Figure 8 shows a sectional view of a distal end section of the auto-injector 1 according to the second embodiment of the invention. The needle shroud 3 is located in the retracted position PR and the release element 7 is pushed in the proximal direction P, so that the bushing 17 disengages the annular inner collar 7.2 of the release element 7. The bushing 17 is positioned in an unlocked position U and may deflect outwardly to release the plunger 9.

[0071] Furthermore, the bushing 17 acts as a counter bearing for the drive means 8 bearing against the bushing 17 in the distal direction D.

[0072] Figure 9A and 9B show two different sectional views of an auto-injector 1 according to a third embodiment of the invention, wherein the release element 7 is arranged as an outer sleeve extending over a substantial length of the auto-injector 1.

[0073] According to the third embodiment of the invention, the safety means S that prevent the early release of the drive means 8 comprise clips 2.6, second and third detents 2.8, 7.3, a locking catch 6.2 formed to the coupling shroud 6 and the bushing 17 that comprises an inner sleeve 17.1 receiving a lug 7.4, wherein the locking catch 6.2 latches to a collar 17.2 of the inner sleeve 17.1.

[0074] The release element 7 of the third embodiment is gripped by a user to perform the injection. When the needle shroud 3 is in the advanced position PA, the proximal displacement of the release element 7 is blocked by the clips 2.6 in a similar manner as in the second embodiment described herein above.

[0075] Additionally, the release element is releasably retained in position before the injection by the second and the third detents 2.8, 7.3 respectively formed to an outer surface of the housing 2 and to an inner surface of the release element 7, wherein the second and third detents 2.8, 7.3 comprise correspondingly shaped ramps facing each other.

[0076] The bushing 17 of the third embodiment comprises the inner sleeve 17.1 that receives the lug 7.4 formed to an inner surface of the release element 7. A proximal end of the lug 7.4 snugly fits in the central aperture of the inner sleeve 17.1, so that an inward deflection of the inner sleeve 17.1 is prevented.

[0077] The inner sleeve 17.1 comprises a collar 17.2. An inwardly protruding locking catch 6.2 of the coupling shroud 6 latches to the collar 17.2 before use of the auto-injector 1 to releasably retain the coupling shroud 6 in the first position I.

[0078] Figure 10 shows a sectional view of a distal end section of the auto-injector 1 according to the third embodiment of the invention. The release element 7 is actuated and moved in the proximal direction P. The proximal end of the lug 7.4 disengages the inner sleeve 17.1 of the bushing 17, so that the inner sleeve 17.1 may bend radially inwards, whereby the locking catch 6.2 disengages the collar 17.2 and releases the coupling shroud 8 and the drive means 8.

List of References

[0079]

1 auto-injector

2 housing

2.1 retaining protrusion

2.2 first clip connection

2.3 aperture

2.4 second clip connection

2.5

retaining catch
2.6
clip
2.7
first detent
2.8
second detent
3
needle shroud
3.1
boss
3.2
helical recess
3.3
proximal section
4
syringe retainer
4.1
outward protrusion
5
pre-filled syringe
6
coupling shroud
6.1
coupling catch
6.2
locking catch
7
release element
7.1
inward protrusion
7.2
inner collar
7.3
second detent
7.4
lug
8
drive means
9
plunger
9.1
shoulder
9.2

distal end

10
stopper

11
syringe barrel

12
injection needle

13
biasing means

14
rotating collar

14.1
pin

15
hinge

16
blocking element

16.1
blocking projection

17
bushing

17.1
inner sleeve

17.2
collar

M
medicament

S
safety means

I
first position

II
second position

PA
advanced position

PR
retracted Position

PS
safe position

L
locked position

U
unlocked position

P

proximal direction

D

distal direction

REFERENCES CITED IN THE DESCRIPTION

Cited references

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Patent documents cited in the description

- US20020095120A1 **[0008]**
- WO2009062508A1 **[0009]**
- WO2009040602A1 **[0010]**
- GB2438592A **[0011]**

Patentkrav

1. Autoinjektor (1) til administrering af en dosis af et væskeformigt medikament (M), som omfatter
- et i det væsentlige cylindrisk hus (2), der er indrettet til at indeholde en fyldt sprøjte (5) fyldt med medikamentet (M),
- en kanylebeskytter (3), der er anbragt glidbart i forhold til huset (2) og indrettet til at hvile på huden hos en patient, der får en injektion,
- et udløseligt drivmiddel (8), der er anbragt i huset (2) og i stand til ved udløsning at translatere kanylebeskytteren (3) i en proksimal retning (P) mod en sikker position (PS),
- en roterende krave (14), der er anbragt roterbart i huset (2),
hvor kanylebeskytteren (3) i den sikre position (PS) omgiver injektionskanylen (12), og hvor kanylebeskytteren (3) kan glide i den proksimale retning fra en tilbagetrukket position til den sikre position, og hvor kanylebeskytteren (3) i den sikre position omgiver en injektionskanyle på den fyldte sprøjte til forhindring af utilsigtede kanylestikskader, efter injektionen er udført,
og hvor den roterende krave (14) går i indgreb med kanylebeskytteren (3) på en måde, der tvinger den roterende krave (14) til at rotere inde i huset (2), når kanylebeskytteren (3) translateres i den proksimale retning (P) mod den sikre position (PS), hvorved den roterende krave (14) frembringer friktion til sænkning af hastigheden af den proksimale bevægelse af kanylebeskytteren (3).

2. Autoinjektor (1) ifølge krav 1,
der er kendetegnet ved, at den roterende krave (14) omfatter en tap (14.1), der går i indgreb med en spiralformet fordybning (3.2), der er dannet i kanylebeskytteren (3).

3. Autoinjektor (1) ifølge krav 1 eller 2,
der er kendetegnet ved, at kanylebeskytteren (3) kan glide fra en fremskudt position (PA) i en distal retning (D) til en tilbagetrukket position (PR) og fra den tilbagetrukne position (PR) i den proksimale retning (P) til den sikre position (PS).

4. Autoinjektor (1) ifølge ét af ovennævnte krav, der er kendetegnet ved, at drivmidlet (8) er indrettet til at blive udløst ved manuel aktivering af et udløserelement (7), der er hængslet til huset (2) eller anbragt glidbart i forhold til huset (2).

5. Autoinjektor (1) ifølge krav 3 eller 4, der er kendetegnet ved, at et sikkerhedsmiddel (S) er indrettet til at samvirke med kanylebeskytteren (3) til forhindring af udløsning af drivmidlet (8), når kanylebeskytteren (3) er i den fremskudte position (PA).

6. Autoinjektor (1) ifølge krav 5, der er kendetegnet ved, at sikkerhedsmidlet (S) omfatter et blokeringselement (16), der er anbragt glidbart i forhold til huset (2), hvor blokeringselementet (16) er indrettet til at begrænse en drejende bevægelse af udløserelementet (7), der er hængslet til en lateral side af huset (2), når kanylebeskytteren (3) er i den fremskudte position (PA), og hvor blokeringselementet (16) er indrettet til at muliggøre, at udløserelementet (7) kan dreje omkring et hængsel (15), når kanylebeskytteren (3) er i den tilbagetrukne position (PR).

7. Autoinjektor (1) ifølge krav 5, der er kendetegnet ved, at sikkerhedsmidlet (S) omfatter en bøsning (17), der går i indgreb med et stempel (9) i den fyldte sprøjte (5) og/eller en koblingskappe (6), der er anbragt glidbart i huset (2), til forhindring af udløsning af drivmidlet (8).

8. Autoinjektor (1) ifølge krav 7, der er kendetegnet ved, at drivmidlet (8) er i stand til ved udløsning at drive koblingskappen (6), der er frigørligt koblet til stemplet (9), fra en første position (I) i den proksimale retning (P), hvor den proksimale translationsbevægelse af koblingskappen (6) i forhold til huset (2)

- translaterer en sprøjteholder (4), der modtager den fyldte sprøjte (5), i den proksimale retning (P) til eksponering af injektionskanylen (12) på den fyldte sprøjte (5),
- trykker stemplet (9), der er forbundet til en prop (10), ind i sprøjtecylinderen (11) til udstødning af dosen af medikament (M) og
- translaterer kanylebeskytteren (3) i den proksimale retning (P).

9. Autoinjektor (1) ifølge krav 8,
der er kendetegnet ved, at sprøjteholderen (4) er frigørligt monteret til huset (2), hvor kanylebeskytteren (3) i den tilbagetrukne position (PR) er indrettet til frigørelse af sprøjteholderen (4) til muliggørelse af proksimal translation af sprøjteholderen (4) i forhold til huset (2).

10. Autoinjektor (1) ifølge ét af kravene 7 til 9,
der er kendetegnet ved, at koblingskappen (6) er indrettet til at blive afkoblet fra stemplet (9) i en forudbestemt anden position (II) defineret af en åbning (2.3), der er dannet i huset (2).

11. Autoinjektor (1) ifølge ét af kravene 7 til 10,
der er kendetegnet ved, at en koblingsgriber (6.1) er anbragt, så den støder mod en skulder (9.1), der er dannet på stemplet (9), til frigørlig kobling af stemplet (9) til koblingskappen (6).

12. Autoinjektor (1) ifølge krav 11,
der er kendetegnet ved, at åbningen (2.3) åbner mulighed for, at koblingsgriberen (6.1) kan afbøjes radialt udad til afkobling af koblingskappen (6) fra stemplet (9) i den anden position (II).

13. Autoinjektor (1) ifølge ét af ovennævnte krav,
der er kendetegnet ved, at drivmidlet (8) er indrettet som en enkelt kompressionsfjeder.

DRAWINGS

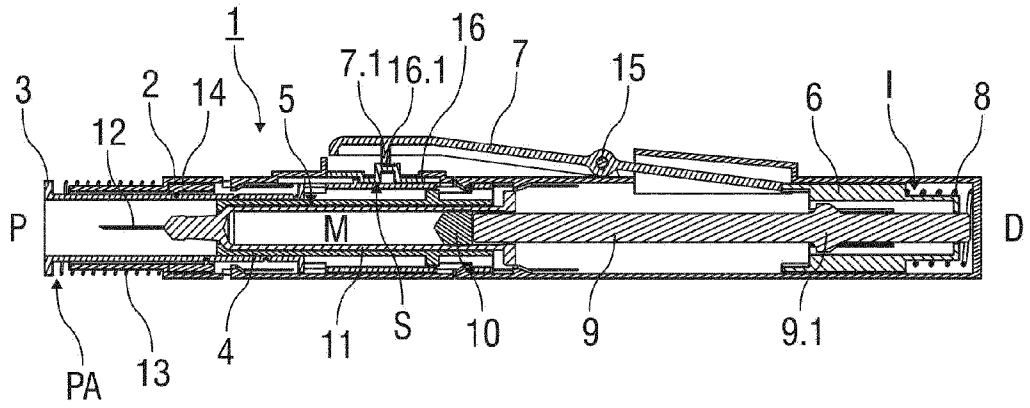

FIG 1A

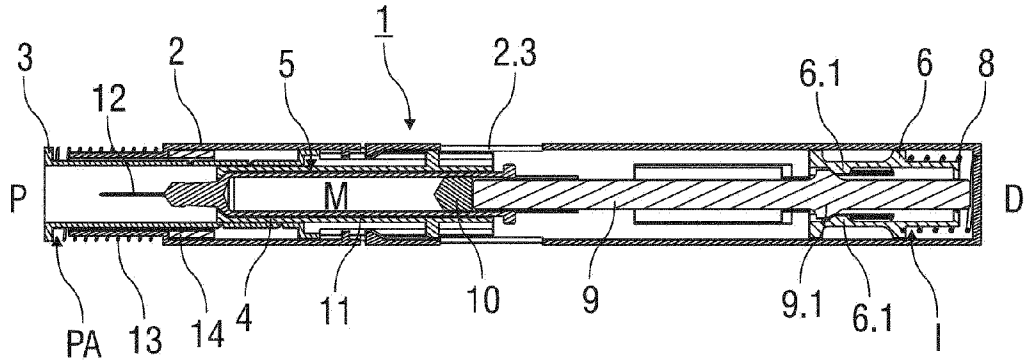

FIG 1B

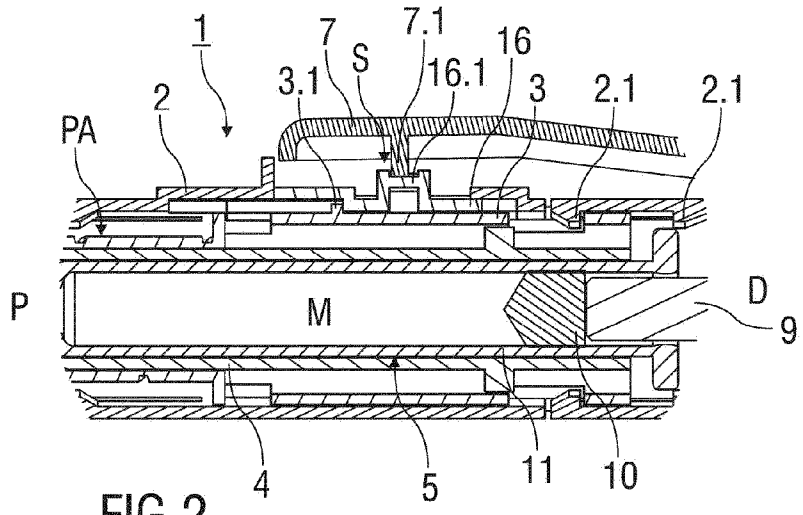

FIG 2

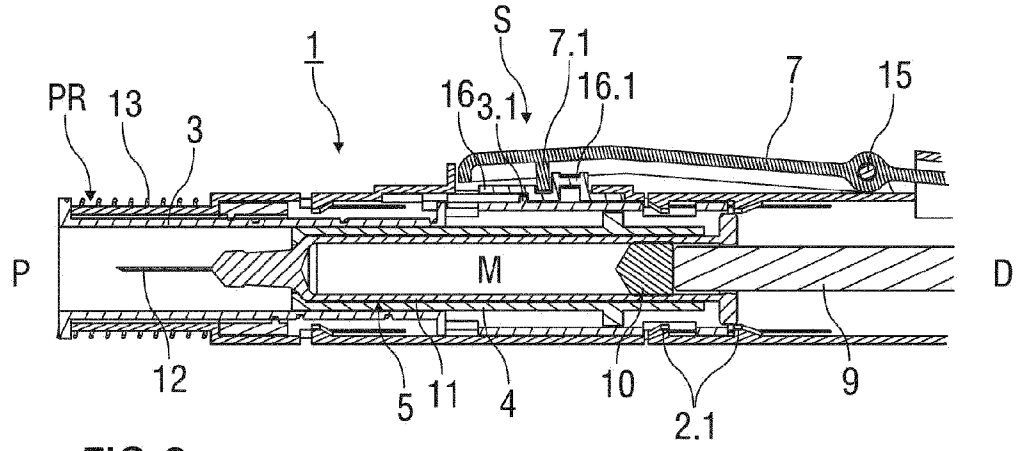

FIG 3

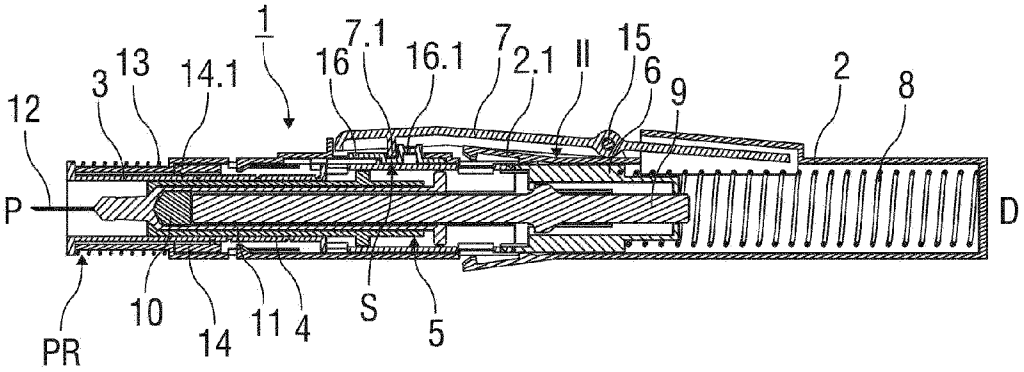

FIG 4A

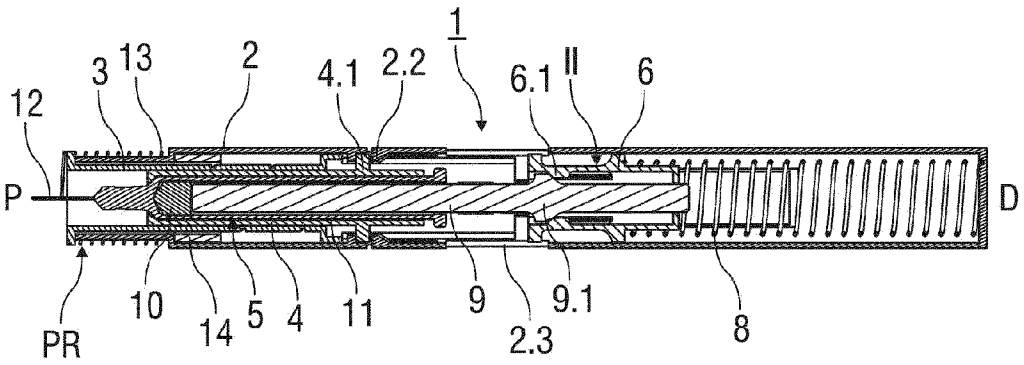

FIG 4B

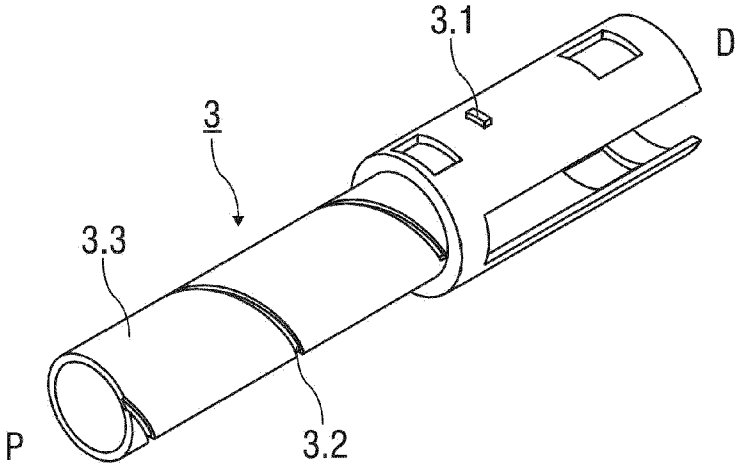

FIG 5

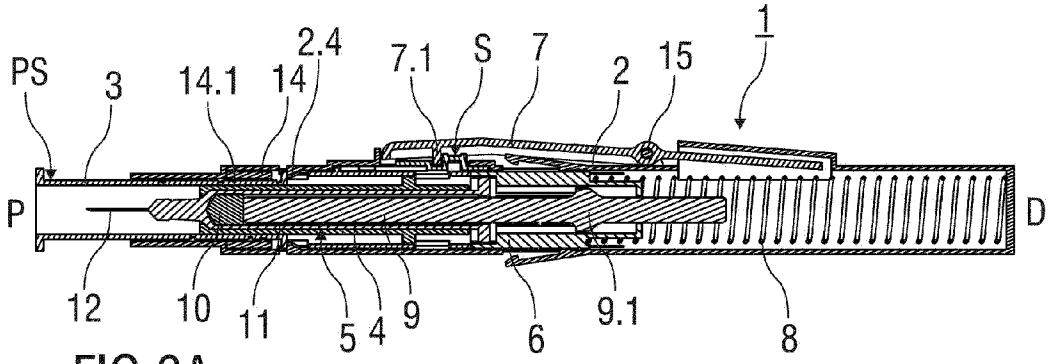

FIG 6A

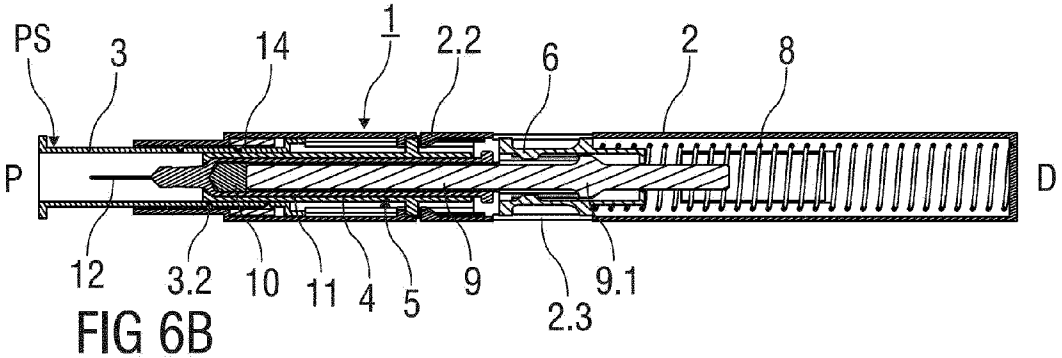

FIG 6B

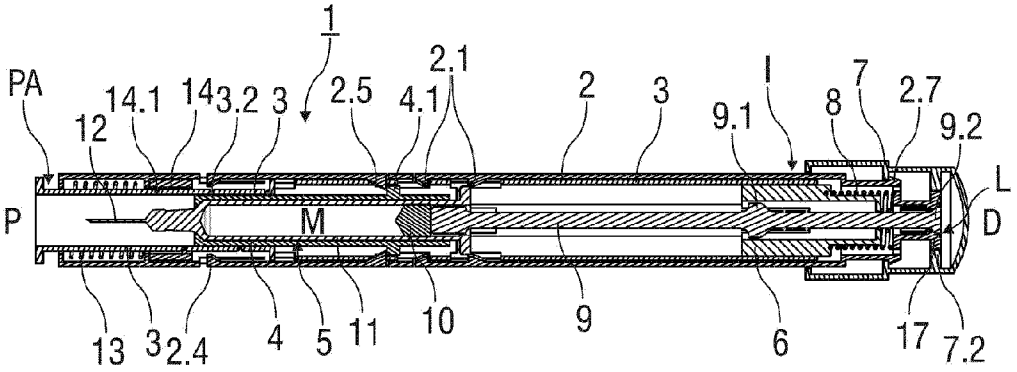

FIG 7A

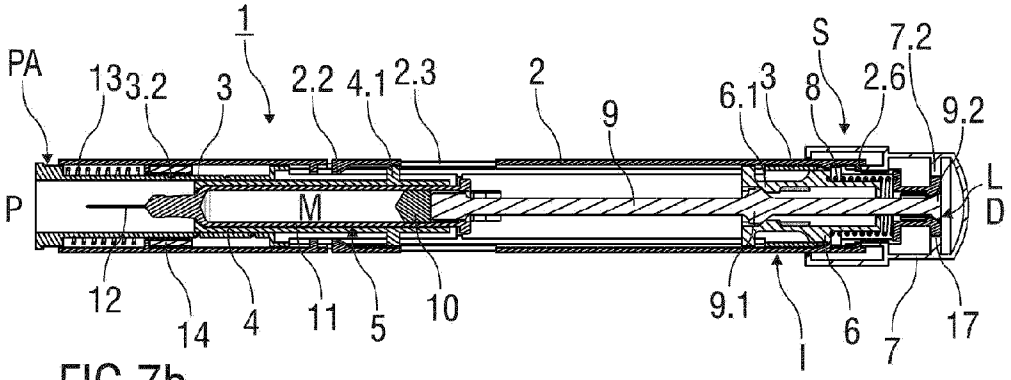

FIG 7b

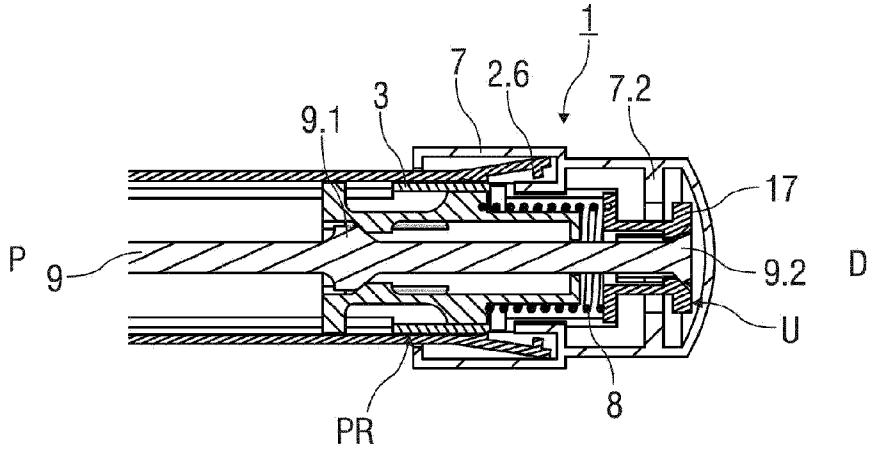

FIG 8

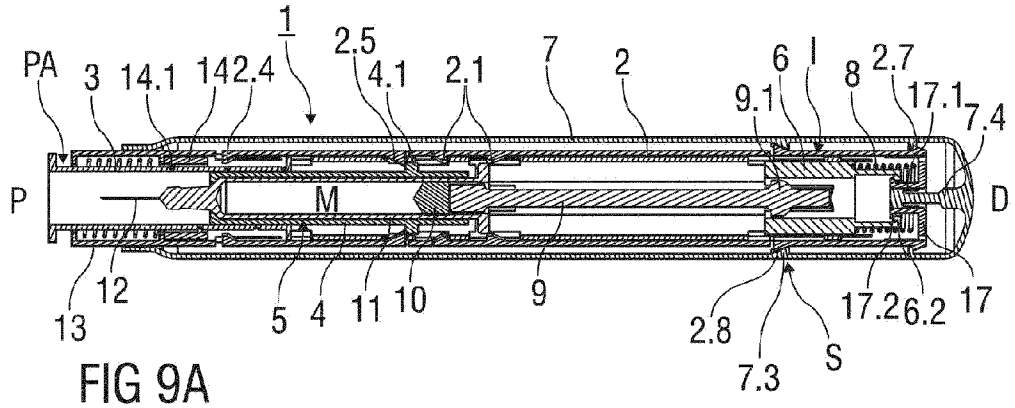

FIG 9A

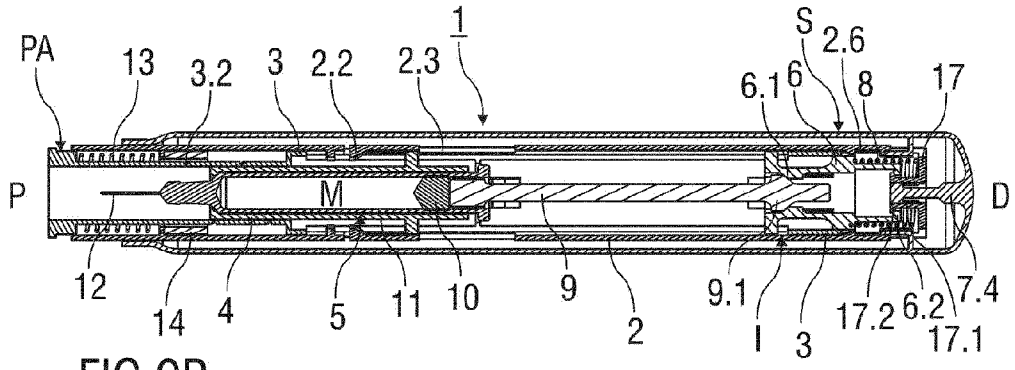

FIG 9B

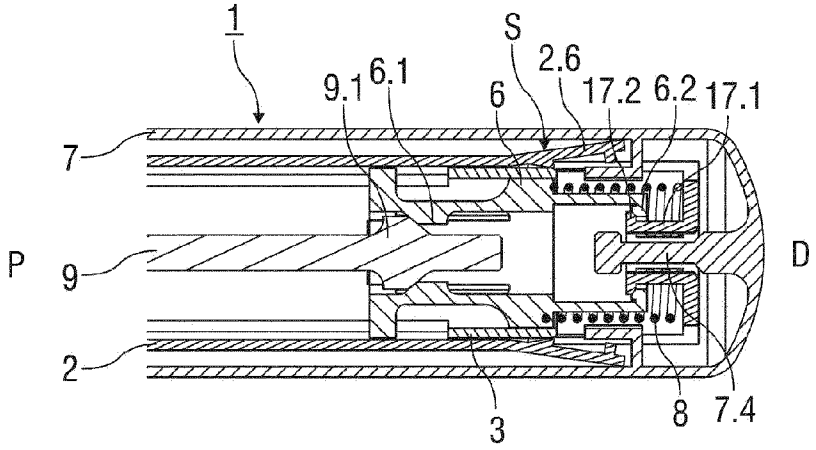

FIG 10