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(54) Benævnelse: **INJEKTIONSINDRETNING, ISÆR AUTO-INJEKTOR, MED EN NÅLEBESKYTTELSE OG/ELLER OVERBELASTNINGSSIKRING TIL EN PRODUKTBEHOLDER**

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Description

[0001] The invention relates to an injection device for administering a product, preferably a medication. The invention may in particular be used in an auto-injector, wherein it is not limited thereto.

[0002] Known from the prior art are auto-injectors that permit automatic delivery of the product. The needle may be inserted manually or automatically. If inserted manually, the needle pricking movement may be accomplished with the hand of the user in that, for instance, he grasps the injection device and presses it against the injection site, so that the needle is inserted. In the case of automatic insertion, the needle pricking movement is effected by a drive member, such as e.g. a spring element, that drives the needle into the injection site.

[0003] Such injection devices may have an opening from which the needle may be advanced manually or automatically. There are systems in which the opening has a slightly wider diameter than the needle so that access to the needle, e.g. with a finger, and thus accidental pricks are prevented. These embodiments limit the ease of assembling the injection device, however. Furthermore, there are systems in which the opening is dimensioned large enough that simple ease of assembly for the injection device is facilitated. As a rule, in these systems, the opening is large enough for a finger to fit through it, so that there is a risk of pricking the finger.

[0004] In the prior art, for instance in WO 2008113864 A1, injection devices are described with a syringe that is retracted into the housing at the end of the product dispense by means of a retraction spring, to reduce the risk of pricking by the syringe.

[0005] Furthermore known from the prior art are injection devices that receive a product container with the product to be delivered. A needle is or may be attached to the distal end of the product container. There are embodiments in which the product container is attached to the injection device at the proximal end, i.e. the end opposite the needle. Due to the forces occurring when the injection device is employed, it may happen that the attachment of the product container releases, or, in an extreme case, that the product container breaks, so that the product container may fall out of the injection device.

[0006] The invention may be applied in the context of the above-described as well as a number of further injection systems.

[0007] The underlying object of the invention is to create an injection device in which the risk of pricking is avoided, wherein the injection device is to remain simple to assemble.

[0008] The objects are attained using the features of claim 1. Advantageous refinements result from the dependent claims.

[0009] The invention proceeds from an injection device for administering a product, preferably a liquid or fluid product. The product may be, e.g. a medication. The product may be stored in a product container in liquid form or may be stored in the product container in liquid and solid form. In the latter case, this may be a so-called dual-chamber product container in which a liquid active substance is mixed with a solid or powder active substance immediately prior to administration. The injection device may be provided for manual or automatic administration. The injection device is preferably a so-called auto-injector.

[0010] In a first aspect of the invention, the injection device comprises a distal end and a needle, wherein in its starting position the needle is disposed inside the injection device and may be moved into an administering position in which the needle projects beyond the distal end of the injection device. When the injection device is supplied, the needle is disposed in its starting position. In the administering position, the needle projects beyond the distal end of the injection device, preferably by a distance that is approximately equal to the needle insertion depth into the injection site. The distal end of the injection device is provided to be pressed against and around the injection site. The needle may be securely connected to the product container, such as e.g. during production of the product container. In this embodiment the product container may also be called a syringe and at its proximal end may have a flange with which the syringe may be attached in the injection device. Alternatively, the needle may be attached to the product container as a separate part. The product container may also be called a carpule or ampule. Carpule, ampule, and syringe may have, but do not necessarily have to have, a flange at the proximal end, the flange sometimes also being called a finger flange.

[0011] The injection device may have an opening region that is disposed distal to the needle, in particular the tip of the needle, when the needle is in the starting position, and that has a cross-section. With the needle in the starting position, the opening region may extend between the needle or needle tip and the distal end of the injection device. Needle tip shall be understood to be the distal end region of the needle. The opening region may be laterally enclosed by a housing or a trigger element, i.e., preferably in a sleeve-shaped manner about the longitudinal axis of the needle. The opening region may have a cross-section, i.e., a cross-sectional surface area, that is approximately perpendicular to the longitudinal axis of the needle. The cross-section is limited by the element that immediately encloses the cross-section. For example, the opening region may have a constant or variable cross-section across its entire axial length. In an opening region having a plurality of cross-sections with different surface areas, preferably the smallest cross-section is intended when a cross-section is being addressed.

[0012] The injection device may comprise a movable reducing piece. The reducing piece may be moved into the opening region, in particular from a position that is not in the opening region. For example, the movement may be directed along, in particular parallel or transverse to, or in combination transverse to and along, the longitudinal axis. The cross-section of the opening region is reduced due to the movement of the reducing piece into the opening region. The reducing piece may reduce the cross-section of the opening region at the location at which the reducing piece is arranged in the opening region. For example, the reducing piece may have an opening that comprises a cross-section that is smaller than the cross-section of the opening region at the location at which the reducing piece is arranged in the opening region. In the region of the reducing piece, the cross-section of the opening region is preferably dimensioned such that the needle may be moved through the opening region despite the reducing piece arranged in the opening region.

[0013] The opening region may be decreased in size so that access, e.g. with a finger, to the needle is no longer possible through the opening. This reduces the risk of pricking as well as the risk of contaminating the needle.

[0014] The injection device has a removal element, in particular in the form of a cap, that is removably arranged on the injection device, in particular at its distal end. As supplied, the removal element may prevent access to the needle. Once the removal element has been removed, i.e., when the removal element has been taken off the device, access to the opening region may be provided, wherein the opening region is again constricted by the reducing piece so that access to the opening region up to the needle is not possible.

[0015] The reducing piece may be moved from a position arranged in the injection device, this position being in particular proximal to the needle tip, to the opening region. For example, the product container received in the injection device may have a section for receiving the product to be administered, it being possible to move the reducing piece from a position that is disposed axially in the region of the section for receiving the product to be administered into the opening region. The product container may have a plunger that may be moved in the section for receiving the product to be administered, in particular may be moved from a proximal position to a distal position. During this movement, the product is displaced and delivered through the needle. The section for receiving the product to be administered is proximal to the section to which the needle may be or is attached.

[0016] The reducing piece may enclose the product container in part, such as e.g. by segment, but particularly preferred annularly, e.g. in the region of the section to which the needle is attached. For example, the reducing piece may form a passage for the product container.

[0017] In preferred embodiments, the injection device as supplied may be provided with a needle protecting cap that is arranged on the section to which the needle is attached. The needle protecting cap protects the needle from contamination and keeps it sterile. For instance, the product container with the needle protecting cap may be or is used as a finished module in the injection device. The needle protecting cap may be, e.g., a cap made of a flexible, such as, e.g., a rubber-like material, or may be a solid material, such as e.g. a material made of a hard plastic. The latter embodiment is all referred to as a so-called “rigid needle shield.” When the removal element has been removed and the

needle protecting cap has been removed, the needle is exposed in the opening region, the reducing piece nevertheless making it possible to avoid pricking.

[0018] The reducing piece may preferably be fixed in one position in the opening region, such as e.g. in a force and/or form-fit. Clamping the reducing piece in the opening region would be an example of a force-fit. A latching connection, in which the reducing piece or a part of the reducing piece latches into an element enclosing the reducing piece, would be an example of a form-fit connection. To this end, the reducing piece may have cams or catches that are, for example, prestressed elastically and latch into the element enclosing the reducing piece at the desired axial position in the opening region. For example, the part enclosing the reducing piece may have one or a plurality of depressions into which the reducing piece latches. That part enclosing the reducing piece may be, e.g., a housing, a trigger element, or a needle protecting sleeve.

[0019] The opening of the reducing piece preferably has a smaller cross-section than the opening region of the injection device and a larger cross-section than a needle protecting cap arranged on the product container and/or a section for receiving the product to be administered. During assembly this advantageously means that at least the needle protecting cap of the product container may be passed through the opening of the reducing piece; in other embodiments the section for receiving the product to be administered may be passed through, as well.

[0020] In preferred embodiments, the reducing piece is movable relative to a housing, a needle protecting sleeve, a trigger element, and/or the needle. The needle protecting sleeve may in particular be moved over the needle disposed in the administering position in order to re-cover the needle after use. The reducing piece preferably moves with the needle protecting sleeve, especially when the reducing piece has been connected, axially fixed, to the needle protecting sleeve. The trigger element triggers the movement of the needle from its starting position to its administering position. For example, the trigger element may release an energy storage means that displaces the needle, e.g. with the product container. The needle protecting sleeve simultaneously assumes the object of the trigger element. The needle protecting sleeve acting as trigger element may be moved in the proximal direction, e.g. relative to the housing, for instance in that the distal end of the needle protecting sleeve is pressed against the

injection site. The needle protecting sleeve or the trigger element may project beyond the distal end of the housing, wherein when the injection device is pressed against the injection site, the needle protecting sleeve or the trigger element is moved proximally into the housing. For example, after the injection device has been used, the needle protecting sleeve may project beyond the distal end of the housing by a distance that is greater than the distance with which the needle protecting sleeve projects beyond the distal end of the housing prior to triggering.

[0021] Another aspect, which may be pursued by itself or may also be combined with the first aspect, relates to an injection device for administering a product having the product container for receiving the product to be administered. The product container has a tapering region or section that connects, especially distally, to a section for receiving the product. This section may be embodied as a hollow cylinder and/or may displaceably receive a plunger with which the product may be displaced out of the product container. The plunger may preferably be moved through the entire section for receiving the product. At its proximal end, the product container may have a projection extending outward, especially radially, such as e.g. a flange.

[0022] An attaching section for the needle may be arranged or connected distal to the tapering region of the product container. The attaching section may be embodied such that a needle may be attached to the product container and/or is detachable from the product container. The needle is preferably arranged securely on the attaching section.

[0023] The needle is exposed, at least immediately prior to administration. When the product container is as supplied or the injection device is as supplied, the needle may be enclosed by the needle protecting cap, which is preferably attached to the attaching section for the needle, in particular in a force-fit and/or form-fit, e.g. by being placed thereover and/or by means of frictional engagement. The needle protecting cap may be removable, completely or at least partially, for releasing the needle from the product container. The needle protecting cap may be a so-called “rigid needle shield” or a simple rubber cap. For example, in the case of a “rigid needle shield” for exposing the needle, only a part of the needle protecting cap may be removed, another part of the “rigid needle shield” remaining on the product container, in particular on the attaching section. The remaining and removable part of the “rigid needle shield” may be

connected, e.g. by means of a material-fit or form-fit connection, in particular to a predetermined breaking point that may be detached during destruction.

[0024] The injection device may have a movable holding member that may be moved out of a position in which it does not fulfill any holding function for the product container into a position in which it fulfills a holding function for the product container. The holding member may preferably in particular be moved distally in front of the tapering region, in particular a shoulder of the product container. In the position in which it fulfills the holding function, the holding member may, but does not have to, touch the product container, so that there may be an interval between the tapering region and the holding member as measured axially. If the holding member touches the product container, this may divert a force exerted on the product container by removing the needle cover cap. If there is an interval between the holding member and the tapering region, the holding member may prevent the product container from falling out of the injection device if the attaching device with which the product container is normally received in the injection device fails. The attaching device may be embodied e.g. by means of the flange arranged at the proximal end of the product container, which is positioned e.g. against the proximal end of a product container holder. If the flange were to break, for whatever reason, the holding member would prevent the product container from falling out of the injection device.

[0025] The holding member may be displaced from a first position into the holding position. In the first position, the holding member may be disposed lateral to the product container, in particular the section for receiving the product. In the first position, the holding member may be arranged such that the tapering region of the product container is able to pass by the holding member. The holding member may preferably be guided, at least by section, along the section for receiving a product.

[0026] For example, during the movement into the holding position, the holding member may execute a radial movement with respect to the longitudinal axis of the product container. To this end, the holding member may execute a radial movement as a whole or preferably in part. The holding member may be deformed, in particular partially deformed when it is moved into the holding position. The deformation may be elastic

and/or plastic. The holding member may in particular be pivoted towards the longitudinal axis.

[0027] The injection device may particularly preferably have a means with which the holding member can execute a combined axial and radial movement during the movement into the holding position. Such a means may be, e.g. a part of a gearing or a gearing surface or a guide track or the like. For example, a gearing surface may be provided that forces the holding member during its axial movement towards the longitudinal axis with respect to the longitudinal axis of the product container. The gearing surface may force the holding member, in particular displace and/or pivot and/or deform the holding member, at least partially or completely into the holding position.

[0028] The means for deflecting the holding member, such as e.g. the gearing surface, may be arranged or formed e.g. on an element that encloses the product container. The element is preferably a product container holder. The product container holder may form a passage for the product container, in particular may be sleeve-shaped and enclose the product container. The holding member is preferably in particular arranged radially between the product container and the product container holder. Thus the product container holder may enclose both the holding member and the product container. During the movement into the holding position, the holding member may be movably arranged relative to the product container and/or to the product container holder. For example, product container holder, holding member, product container, and in particular also the housing of the injection device may be arranged concentrically with one another.

[0029] At its distal end, the product container holder may have an opening that permits a part of the product container to be inserted through it. The opening is in particular large enough that the product container with a needle protecting cap attached to it may be inserted through it. The opening may be, but does not have to be, large enough that the section for receiving the product to be administered would pass through the opening. The means for deflecting the holding member is preferably arranged at the distal end of the product container holder, which in particular is formed using the circumference of the product container holder. The means for deflecting may have a surface inclined towards the longitudinal axis.

[0030] The holding member may enclose the product container across its circumference. The holding member may in particular comprise a plurality of tongues that, due to material deformation, may be moved in front of the tapering region of the product container. In preferred embodiments, the tongues may be intended when the issue is a holding member that may be moved in front of the tapering region of the product container. This means that it is not the entire holding member that must be able to be moved in front of the tapering region, but only a part of the holding member. For example, the holding member may have an annular base from which the at least one tongue extends, in particular towards the longitudinal axis.

[0031] It is particularly preferred that the holding member is latched or latchable in front of the tapering region of the product container against a further movement relative to the product container. To this end, for example, the at least one tongue or the annular base or another part of the holding member may have a latching element that preferably engages in the part surrounding the latching element, in particular the product container holder. For example, the latching element of the tongue may engage in the deflecting means for the holding member or the tongue.

[0032] The injection device may have at least one engaging member that is coupled in a force-fit and/or in a form-fit to at least one of reducing piece and holding member, so that given an axial movement of the at least one engaging member the reducing piece and/or the holding member may be carried along. The at least one engaging member may preferably be moved in the distal direction. During this movement, it may carry along the engaging member, at least by section. To this end the engaging member may have strips that preferably extend from the annular base, in particular in the longitudinal direction, and preferably in the same direction as the at least one tongue. In preferred embodiments, the at least one engaging member may be moved in the distal direction and during this movement carries along the holding member, at least by section, there being no relative movement between holding member and the at least one engaging member during this carrying along. To this end, the at least one engaging member may engage in the at least one strip of the holding member. The holding member and the at least one engaging member may be moved with one another until the engaging

member has been moved in front of the product container. A further movement of the at least one engaging member is preferably possible relative to the holding member.

[0033] During the movement of the holding member, the reducing piece may move along with the holding member, for example in that it is supported against the holding member. Alternatively or in addition, the reducing piece may move along with the at least one engaging member, for example in that the engaging member engages in the reducing piece. During the movement of the at least one engaging member in the distal direction, the needle protecting cap may preferably be removed from the product container, wherein this may occur prior to, after, or while the reducing piece and/or the holding element are being carried along.

[0034] The at least one engaging member may be formed on a removal element, in particular a cap, in particular on one or a plurality of arms extending in the longitudinal direction that resiliently bear the at least one engaging member transverse to the longitudinal axis. When the removal element is removed from the injection device, therefore, the following steps may be executed:

- Removal of the needle protecting cap; and/or
- Carrying along of the holding member so that its tongues move in front of the shoulder of the product container; and/or
- Carrying along of the reducing piece into a position in which it reduces the cross-section of the opening region and thus prevents access to the needle.

[0035] In general the injection device may comprise at least one of the following features:

- a needle protecting sleeve acting as a trigger element for triggering an insertion movement of a needle, wherein the needle protecting sleeve for triggering the needle insertion movement may be displaced in the proximal direction relative to the housing of the injection device and may be displaced in the distal direction beyond the needle disposed in the administering position;
- an elasticity means, in particular a spring, against which the trigger element is displaceable for triggering, and with which the trigger element may be displaced in the distal direction beyond the needle disposed in the administering position;

- a driven member that may be displaced in the distal direction by a drive member, in particular an advancing spring, in order to displace the product container for an administering movement and/or to move a plunger in the product container in order to deliver a product;
- a blocking member that may be selectively caused to engage with the driven member or the trigger element in order to prevent an axial movement by the part with which the blocking member is engaged.

[0036] The invention was described using a number of embodiments. The invention is explained in the following using a preferred example. The features disclosed here, both individually and in combination, refine the subject matter of the invention.

Figure 1	depicts two components of the injection device prior to final assembly;
Fig. 2a	depicts the individual parts of the injection device in a perspective elevation;
Fig. 2b	is an enlarged view of three parts from the view in Figure 2a;
Fig. 2c	depicts an arrangement of the three parts from Figure 2b as supplied;
Figures 3a and 3b	depict longitudinal sections of the injection device with seated removal element, Figure 3b being a view rotated 90° about the longitudinal axis with respect to Figure 3a;
Figures 4a and 4b	depict longitudinal sections of the injection device as supplied and from which the removal element has been removed, Figure 4b being a view rotated 90° about the longitudinal axis with respect to Figure 4a;
Figures 5a and 5b	depict longitudinal sections of the injection device after being triggered, Figure 5b being a view rotated 90° about the longitudinal axis with respect to Figure 5a;

Figures 6a and 6b depict longitudinal sections of the injection device following the insertion sequence and prior to the delivery sequence, Fig. 6b being a view rotated 90° about the longitudinal axis with respect to Figure 6a;

Figures 7a and 7b depict longitudinal sections of the injection device following a delivery sequence, Figure 7b being a view rotated 90° about the longitudinal axis with respect to Figure 7a; and,

Figures 8a and 8b depict longitudinal sections of the injection device with a needle protecting sleeve in its needle protecting position, Figure 8b being a view rotated 90° about the longitudinal axis with respect to Figure 8a.

[0037] First, with respect to Figures 2a through 2c, the individual parts of an injection device, which especially form an auto-injector, shall be described. The injection device comprises a sleeve-shaped housing 1, a needle protecting sleeve 2 that is received, longitudinally displaceable, in the housing 1 and simultaneously acts as a trigger element, a product container 5 having a needle protecting cap 6 detachable attached thereto, a product container holder 4 that receives the product container 5 and has means 4a for deflecting, a removal element 3 that has engaging members 3a, 3d, a drive member 8 in the form of a spiral coiled spring, acting as a compression spring, that supplies the energy for insertion and delivery sequences, a driven member 7 that acts on the product container 5, a holding element 10 that holds the drive member 8 in a clamped condition until the injection device has been triggered and that is connected, axially fixed, to the housing 1, in particular is snapped therein, and a spring element 9 that supplies the energy for displacing the needle protecting sleeve 2 into the needle protecting position. In addition, the injection device comprises a holding member 12 that permits simple assembly and can still prevent the product container from falling out of the injection device, and a reducing piece 11 that provides access protection in order to prevent pricking on the device. The preferred embodiment illustrated here includes both the holding member 12 and the reducing piece 11. In principle, the injection device may be equipped with only one of the two aforesaid parts.

[0038] Figure 1 illustrates the auto-injector prior to a final assembly. During final assembly, the auto-injector is in two components, specifically component A, which essentially comprises the housing, the needle protecting sleeve 2, and the drive unit, already prestressed, and a component B, which essentially comprises the product container 5, the product container holder 4, the removal element 3, and at least one of the holding member 12 or the reducing piece 11. This separation into components has the advantage that the components may be preassembled at a location different from the final assembly and integration of the product container. For example, the component A and the component B without the product container may be delivered from a first location to a second location, the product container 5, along with needle protecting cap 6, being inserted or introduced at a second location into the product container holder 4 via an opening at the proximal end of the product container holder 4 into the combination comprising product container holder 4 and reducing element 3 with the needle protecting cap 6. The holding member 12 and the reducing piece 11 each have an opening 11d; 12d that is large enough to insert the needle protecting cap 6 of the product container 5 through the openings 11d; 12d. Holding member 12 and reducing piece 11 are each arranged in a first position and are each displaced into second positions when the removal element 3 is removed from the injection device. Thus simple integration of the product container 5 including needle protecting cap 6 into the other parts of component B is possible.

[0039] The completely assembled component B may now be introduced via an opening at the distal end of the trigger element 2 into the component A, where it is attached to the housing 1 in an axially fixed but detachable manner with an attaching member 4b of the product container 4, which in this example is embodied as a snap-in element. Another advantage of the separation into components is that a plurality of components A,B may be delivered from the first location to the second location, and only at the second location is it decided which medication is to be used in the injection device. This increases the application flexibility of the injection device.

[0040] Figures 3a and 3b depict the injection device in a final assembled supply status. See also Figures 2a through 2c for the illustration of the individual parts. The product container 5 is displaceably borne in the housing 1. The product container 5 is received

in the product container holder 4 so that the former may not be moved in particular in the distal direction relative to the product container holder 4. This is effected using a finger flange 5d that is formed on the proximal end of the product container 5 and that projects radially outward and engages the proximal end face of the product container holder 4. The reservoir part 5a of the product container 5 accommodates the product to be administered. Received in the hollow cylindrical reservoir part 5a is a plunger 5f that is positioned sealingly against the inner wall of the reservoir part 5a and for product delivery is displaceable towards needle 5e relative to the reservoir part 5a. The needle 5e is non-detachably attached to an attaching section 5c of the product container 5. The attaching section 5c is attached distally to the reservoir part 5a. The reservoir part 5a transitions by means a shoulder 5b to the attaching section. The shoulder 5b thus forms a tapering region in front of which or at which at least part of the holding member 12 is later moved. In order to protect the needle 5e from contamination and keep it sterile, the needle protecting cap 6 is arranged on the attaching section 5c and over the needle 5e. The needle protecting cap 6 is attached in a force-fit and/or in a form-fit to the attaching section 5c of the product container 5. Between the shoulder 5b of the product container 5 and the proximal end or the proximal end face of the needle protecting cap 6 is a gap that is at least large enough that at least one or both of the engaging members 3a, 3d and a part of the holding member 12 can engage in the gap.

[0041] The holding member 12 and the reducing piece 11 are shown in detail in particular in Figures 2b and 2c. The reducing piece 11 has an annular base 11c. The annular base 11c comprises a passage or opening 11d that is dimensioned such that the needle protecting cap 6 may be inserted or moved therethrough, at least in part, preferably completely. On the other hand, the opening 11d is dimensioned such that a human finger preferably will not pass through it. The cross-section of the opening 11d is smaller than the cross-section of the opening region 13 (Fig. 3a), wherein the cross-section of the opening region is reduced or decreased by arranging the reducing piece 11 in the opening region 13. The annular base 11c furthermore has recesses 11a that are formed in particular as a passage and lateral to the opening 11d. The recesses 11a may be separate from the opening 11d or, as is shown here, connected to the opening

11d. The recesses 11a each permit an arm 3b that is formed on the at least one engaging member 3a, 3d to pass through.

[0042] The reducing piece 11 has a plurality of projections that extend proximally from the annular base 11c and that form stops or latching elements 11e, 11f for the same or different purposes. To this end the projections may be embodied with the same length or different lengths.

[0043] The latching element 11e may, but does not have to, act as a stop at the holding member 12, in particular at its annular base 12c. The stop causes the reducing piece 11 to be carried along by the holding member 12 when the holding member 12 moves in the distal direction. If the latching element 11e is not acting as a stop, the reducing piece 11 may be carried along by the at least one engaging member 3a, 3d.

[0044] The locking elements 11e, 11f latch axially fixed with the needle protecting sleeve 2 when the reducing piece 11 is in its second position, i.e. in the opening region 13. Because it is latched, axially fixed, to the needle protecting sleeve 2, the reducing piece 11 also performs the movements of the needle protecting sleeve 2. In the example illustrated, the reducing piece 11 has two latching elements 11e and two latching elements 11f, the latching elements 11e being formed on projections that are longer than the projections on which the latching elements 11f are formed. For example, the latching elements 11e may block the axial movement in the distal direction and the latching elements 11f may block the movement of the reducing piece 11 relative to the needle protecting sleeve 2 in the proximal direction. Thus, as is generally preferred, it is achieved that the reducing piece 11, relative to the needle protecting sleeve 2, is not movably connected to the needle protecting sleeve 2 in both axial directions.

[0045] The holding member 12 has an annular base 12c from which tongues 12a and strips 12e project. The tongues 12a are flexibly, in particular bendable, in particular elastically or plastically deformable towards the center or longitudinal axis of the holding member 12. The tongues 12a each have, in particular at their distal end, a locking member 12b that later can latch with the deflecting means 4a.

[0046] The strips 12e each have a groove 12f that extends longitudinally. The grooves allow engaging members 3a, alternatively 3d, to engage the removal element 3. The grooves 12f are continuous, but could also be blind grooves. The arms 3b engage

through the recesses 11a of the reducing piece 11 so that at least one engaging member 3a can engage in the groove 12f.

[0047] The annular base 12c forms a passage or an opening 12d that is large enough for the needle protecting cap 6 to be passed or moved therethrough. Preferably the latching members 12b in their non-deformed state do not obstruct the passage for the needle protecting cap 6.

[0048] The deflecting means 4a is resiliently arranged on the product container holder 4, specifically by means of an arm 4g. This arrangement has advantages for assembly. As may be seen from Figure 1, the product container 5 is inserted into the product container holder 4 open in the circumferential direction. Since the product container holder 4, prior to the final assembly, is open in the circumferential direction, the deflecting means 4a may move resiliently outward and thus allow the needle protecting cap 6 through, without increased assembling force being necessary and without there being a risk of jamming. However, due to the subsequent reduction in cross-section because of the holding member 12, it is possible that the deflecting means 4a does not need to move resiliently outward, because at first the passage is large enough for the needle protecting sleeve 6. Therefore the deflecting means does not necessarily have to be resilient, but may also be arranged rigidly. Having undergone final assembly, such as e.g. in Figures 3a and 3b, the deflecting means 4a may not move resiliently outward, because the product container holder 4 is enclosed by the needle protecting sleeve, wherein the needle protecting sleeve 2 on its inside forms a holding section 2c that prevents the deflecting means 4a from making a movement radially outward.

[0049] The product container holder 4 has an outwardly oriented attaching member 4b in the form of a recess, the attaching member 4b engaging in a projection 1a formed on the inner circumference of the housing and thus forming a form-fit locking mechanism. However, this locking mechanism may be released during use of the injection device. The locking mechanism causes the product container holder 4 to be coupled, axially fixed, to the housing 1, so that the product container 5 also cannot be moved relative to the product container holder 4 in the distal direction due to the finger flange 5d being engaged on the proximal end face of the product container holder 5.

[0050] The needle protecting sleeve 2 is guided on the inner circumference of the housing 1. The needle protective sleeve 2 is disposed in particular radially between the product container holder 4 and the housing 1. In principle the needle protecting sleeve 2 is displaceable relative to the housing 1, the needle protecting sleeve 2 as delivered being axially fixed relative to the housing 1. To this end, the needle protecting sleeve 2 has an engaging member 2a that engages in a form-fit in an engaging counter-member 1b on the inside of the housing 1. The engaging member 2a is resiliently borne and may be moved transverse to the longitudinal axis of the injection device. The resilient arrangement is formed by an arm at the end of which the engaging member 2a is formed.

[0051] The removal element 3 seals the distal end of the injection device, at least partially. In particular, the removal element 3 prevents access to the needle protecting sleeve 2 that projects beyond the distal end of the housing 1. The removal element 3 is attached to the housing 1 in a force-fit, specifically by means of a sleeve-shaped extension that encloses the distal end of the housing 1. Alternatively or in addition, the removal element 3 may be attached in a form-fit to the distal end of the injection device, such as e.g. to the housing 1 or the needle protecting sleeve 2 or via the engagement of the engaging member 3a in the product container holder 4, in particular in its recess 4f. The removal element 3 furthermore has a sleeve-shaped holding section 3c that, when the injection device is supplied, is disposed axially at the elevation of the engaging member 2a on the inner circumference of the needle protecting sleeve 2 in order to prevent the engaging member 2a from moving inward, and thus ensures that, as delivered, i.e. with the removal element 3 in place, the needle protecting sleeve 2 is prevented from moving relative to the housing 1. Thus the needle protecting sleeve 2 may be reliably prevented from moving relative to the housing 1, such as e.g. if the injection device falls and the needle protecting sleeve 2 were to move relative to the housing 1 due to inertia. The engaging member 2a thus acts primarily as a transport safety mechanism. The removal element 3 forms an annular gap, specifically between the outer sleeve, which is attached to the circumference of the housing 1, and the inner sleeve, which has the holding section 3c. When the removal element is seated, some of the housing 1 and some of the needle protecting sleeve 2 are disposed in the annular

gap, preferably also the engaging member 2a and the engaging counter-member 1b formed by the housing. The holding section 3c, in particular its proximal end, also forms an assembly aid for preassembling the component B in that, for example, the reducing piece 11, in particular the annular base 11e, can be supported on the proximal end of the removal element 3 or of the holding section 3c and optionally at least one of the holding member 12 or the product container holder 4 on the reducing piece 11.

[0052] At least one engaging member 3a, 3d is formed on the removal element 3 and is resiliently movable transverse to the longitudinal axis of the injection device via the arm 3b. During preassembly of the component B and also as the injection device is supplied, the recess 4f formed on the product container holder 4 is disposed longitudinally at the elevation of the engaging member 3a, so that the engaging member 3a can move resiliently radially outward into the recess. When inserting the product container 5 into the combination of product container holder 4 and removal element 3 during assembly of the component B (Figure 1), the engaging member 3a moves resiliently into the recess 4f if the needle protecting cap 6 fits the engaging member 3a. Furthermore, the engaging member 3a moves resiliently into the recess 4f if the product container 5 is inserted completely into the product container holder 4, because in this case the engaging member 3a is positioned against the distal end region, in particular laterally against the reservoir part 5a of the product container 5. Alternatively, in this state, the engaging member 3a or another engaging member 3d can engage in the gap between needle protecting cap 6 and shoulder 5b. The engaging member 3a projects, relative to the outer circumference of the sleeve-shaped section that forms the holding section 3c, radially outward and thereby forms a type of gearing surface, the function of which shall be described later.

[0053] The engaging member 3d projects, with respect to the inner circumference of the sleeve-shaped section that forms the holding section 3c, inward and is preferably hook-shaped and dimensioned such that it can engage in the gap between needle protecting cap 6 and shoulder 5b during the course of the injection device being used.

[0054] Since in the embodiments illustrated the engaging members 3a, 3d are arranged at approximately the same axial position, they can form a joint engaging member. In principle the engaging members 3a and 3d may be arranged at different axial positions.

[0055] Finally, the removal element 3 has another radially outwardly directed projection that makes it easier for the user of the injection device to grip the removal element 3 and exert an axial force on the removal element 3.

[0056] When a product container 5 is completely inserted in the product container holder 4, the projection 5d may be positioned longitudinally against the proximal end of the product container holder 4.

[0057] The spring element 9 is supported at its proximal end on the holding element 10, and thus is axially fixed relative to the housing 1, and at its distal end 9 is supported on the proximal end of the needle protecting sleeve 2. The spring element 9 is prestressed and acts on the needle protecting sleeve 2 with a force acting in the distal direction, wherein the needle protecting housing is blocked from moving in the distal direction both in the starting position and immediately after the removal of the removal element 3 (Figures 4a and 4b).

[0058] The holding element 10 seals the proximal end of the housing 1 and is connected to the housing 1 rotation-fast and axially fixed, in particular is snapped thereto. The holding element 10 could just as well be formed integrally with the housing 1, wherein it is advantageous to design holding element 10 and housing 1 in multiple parts because this facilitates production of the individual parts and assembly of the injection device.

[0059] The holding element 10 has at least one, in this case two, resilient arms 10b that extend in the longitudinal direction of the injection device and form a blocking member 10a at its distal end. The blocking member 10a may be moved transverse to the longitudinal axis of the injection device. The blocking member 10a forms one projection that with respect to the arm 10b is inwardly oriented, in a form-fit, and one projection that is outwardly oriented. The inwardly oriented projection engages a shoulder 7b formed by the driven member 7, thereby preventing the driven member 7 from moving in the distal direction. The outwardly oriented projection of the blocking member 10a is positioned against an inwardly oriented surface of the needle protecting sleeve 2 so that the blocking member is kept engaged with the shoulder 7b and radially outward movement of the locking member 10a is prevented. The arms 10b are formed with their proximal ends against a sleeve-shaped section of the holding member 10.

[0060] The arm 10b, together with the sleeve-shaped section of the holding member 10, extends across the entire length of a sleeve-shaped section of the driven member 7. In particular the arm 10b, including locking member 10a and sleeve-shaped section, is longer than the sleeve-shaped section of the driven member 7. The drive member 8, in the form of a prestressed spiral coil compression spring, is received within the sleeve-shaped section of the driven member 7. The spring element 8 is supported at its proximal end on the holding element 10 and at its distal end on the distal end of the sleeve-shaped section of the driven member 7, which also forms the shoulder 7b. Two arms that extend in a fork and that at each of their distal ends form a contact element 7a project from the distal end of the sleeve-shaped section of the driven member 7. The contact elements 7a have beveled surfaces that in the longitudinal direction are disposed in alignment with the housing wall of the reservoir part 5a of the product container 5. The effect of this is that, given a movement of the driven member 7 in the distal direction, the beveled surfaces of the contact elements 7a move against a stop with the proximal end of the product container 5.

[0061] The functioning of the injection device shall be described in the following. Proceeding from the injection device as supplied, illustrated in Figures 3a and 3b, the user of the device grasps the housing 1 with one hand and grasps the removal element 3 with the other hand. To remove the removal element 3, the user pulls on the removal element 3 so that the latter is removed from the housing 1. When the removal element 3 is removed, the engaging members 3d are in or travel into the gap between needle protecting cap 6 and shoulder 5b and finally to a stop with the proximal end face of the needle protecting cap 6. Furthermore, when the removal element 3 is removed, the engaging members 3a move out of the recesses 4f but remain in the grooves 12f. The engaging members 3a, 3d are ultimately prevented from moving radially outward by the inside of the product container holder 4c, the engaging members 3d even being forced into engagement in the gap or in the end face of the needle protecting cap. To this end, the radially outward engaging member 3a is advantageous, since it forms a gearing surface that slides out of the recess 4f on the product container holder 4 during the movement of the engaging member 3a and thus, using the holding section formed by the inside of the product container holder 4, ensures that the engaging member 3d

engages in the needle protecting cap 6. As the removal movement for the removal element 3 continues, the engaging members 3d carry the needle protecting cap 6 along, so that the latter is removed from the product container 5, and unlatches the engaging member 3a from the strip 12e or groove 12f, since the support for the engaging member 3a inward is now gone. The outer force added to the product container with the removal movement may be conveyed from the shoulders 5b of the product container 5 via the deformed tongues 12a to the product container holder 4 and from the product container holder 4 via the engagement 4b, 1a into the housing 1. Alternatively or in addition, the outer force may be conveyed from the finger flange 5d onto the product container holder and from there via the engagement 4b into the housing 1. In the first alternative, the projection 5d of the product container 5 remains unloaded, so that damage to the product container 5 is prevented. As the removal movement for the removal element 3 continues, the engaging member 3a unlatched from the groove 12f engages the annular base 11c and carries the reducing piece 11 along with it. Removing the removal element 3 also releases the engaging member 2a of the needle protecting sleeve 2 for a movement inward, since during this removal the holding section 3c is also removed.

[0062] Due to the engaging member 3d engaging in the needle protecting cap 6, it is furthermore assured that the engaging member 3a remains in the grooves 12f. During the movement removing the removal element 3, the engaging member 3a strikes the distal end of the groove 12f. The holding member 12 is carried along by the removal element 3. Due to the latching element 11e striking the holding member 12, the reducing piece 11 is also carried along out of its first position, which it assumes when completely assembled. The tongue 12a is deflected or deformed in the distal direction to the longitudinal axis by the deflecting means 4a when the holding member 12 is carried along or moved. The deformed tongue 12a is then disposed in front of the shoulder 5b, in particular between needle protecting cap 6 and shoulder 5b. The deformed tongue 12a locks with the locking member 12b, which projects radially outward from the tongue 12a, with the deflecting means 4a or with the product container 4. The holding member 12 is thus axially fixed relative to the product container holder 4.

[0063] The reducing piece 11 that is carried along by the removal element 3, in particular using the holding member 12 and/or the engaging member 3a, latches, axially

fixed, with its latching elements 11e and 11f with the needle protecting sleeve 2, such as e.g. may be seen in Figures 4a and 4b.

[0064] Figures 4a and 4b depict the injection device from which the removal element 3 has been removed. The device is now ready for use. To this end, the user of the device grasps the housing 1 and presses the distal end of the injection device, formed by the needle protecting sleeve 2, against the injection site. Because of this, the engaging member 2a slides out of engagement with the attaching counter-member 1b of the housing 1 so that the engaging member 2a is deflected inward. A relative movement between the needle protecting sleeve 2 and the rest of the injection device occurs in which the needle protecting sleeve 2 is pushed via a ramp-like gearing surface 4e of the product container holder 4, so that the product container 4 is disengaged from the projection 1a of the housing 1 in that the attaching member 4b is deflected inward. Furthermore, when the needle protecting sleeve 2 is displaced, the spring element 9 is stressed about the displacement path and a recess 2d formed by the needle protecting sleeve 2 is axially brought to the elevation of the blocking member 10a. Due to the pushing in of the needle protecting sleeve 2, the needle insertion sequence, and, in the broader sense, the delivery sequence, is triggered. The needle protecting sleeve 2 may thus also be called the trigger element 2.

[0065] Figures 5a and 5b illustrate the injection device in a condition in which the needle protecting sleeve 2 is pushed in for triggering. The attaching member 4b is not engaged with the engaging member 1a, so that it is released for an axial movement relative to the housing 1.

[0066] The blocking member 10a may now be deflected into the recess 2d, wherein the former, engaged with the needle protecting sleeve 2, blocks a movement by the needle protecting sleeve 2 in the distal direction. At the same time as the movement into the recess 2d, the blocking member 10a releases the shoulder 7b, so that the prestressed drive member 8 can move the driven member 7 in the distal direction. The part of an overall movement described in the following is called the insertion sequence. During this movement, the contact elements 7a move to a stop at the proximal end of the product container 5, so that the latter is displaced in the distal direction, specifically until the needle 5e emerges through the opening 11d, consistent with the desired insertion

depth, beyond the distal end of the injection device, as is illustrated in Figures 6a and 6b. As soon as the needle 5e has moved the appropriate distance out of the distal end of the injection device, a second attaching member 4d formed by the product container holder 4 strikes the projection 1a of the housing 1, so that the advancing movement of the needle 5e is stopped. This terminates the insertion sequence.

[0067] Due to the beveled surfaces of the contact elements 7a and the continuing force of the drive member 8, the contact elements 7a slide on the proximal end of the project container 5 so that they are deflected inward, in particular towards one another and/or into the reservoir section 5a and thus travel to a stop with the plunger 5f. This starts the delivery sequence, because the force of the drive member 8 displaces the plunger 5f towards needle 5e, so that the product contained in the product container 5 is delivered via the needle 5e.

[0068] Figures 7a and 7b illustrate the injection device at the end of the product delivery sequence, in particular with contact elements 7a deflected into the reservoir part 5a.

[0069] During the insertion and delivery sequences, the sleeve-shaped section of the driven member 7 prevents the blocking members 10a from disengaging from the recesses 2d of the trigger element. At the end of the product delivery sequence, the blocking members 10a may disengage from the recess 2d, since the driven member 7 has moved completely past the blocking members 10a.

[0070] After the user has removed the injection device from the injection site a few seconds after the finished product delivery sequence, the spring element 9 presses the needle protecting sleeve 2 in the distal direction, so that the blocking members 10a are disengaged from the recesses 2d. Furthermore, the needle protecting sleeve 2, along with the reducing piece 11, is displaced beyond the distal end of the needle 5e, as illustrated in Figures 8a and 8b.

[0071] To prevent the needle protecting sleeve 2 from being pushed back into the housing 1, the needle protecting sleeve 2 has a blocking member 2c that engages in the projection 1c of the housing 1 in a form-fit, preferably in a non-releasable manner, i.e. it can only be released by extreme force or destruction. Thus under normal circumstances it is no longer possible to move the needle protecting sleeve 2 back into the housing 1. Due to the cross-section, reduced in size by the reducing piece, in the opening region, it

is not possible to insert, e.g. a finger, into the distal end of the injection device. The risk of injury with the used device is thus reduced.

Patentkrav

1. Injektionsindretning til administration af et produkt der omfatter:

a) et hylsterformet hus (1)

b) et nålebeskyttelseshylster (2) der er optaget forskydeligt i længderetningen i huset og samtidig tjener som udløserelement,

c) en holder til en produktbeholder (4) der optager en produktbeholder (5) med en nålebeskyttelseshætte (6), som er aftageligt fastgjort derpå,

d) et fradriftselement (7) der virker på produktbeholderen,

e) et fratrækningselement (3) med indgrebselementer (3a/3d) til at trække nålebeskyttelseshætten (6) fra produktbeholderen (5), hvor

f) nålebeskyttelseshylsteret (2) er aksialt fastgjort i udleveringstilstanden af injektionsindretningen i forhold til huset (1) og omfatter dertil et indgrebselement (2a), som indgriber på en formtilpasset måde i et modindgrebselement (1b) på indersiden af huset og kan bevæges på tværs af længdeaksen,

g) fratrækningselementet (3) omfatter en holdesektion (3c), som i udleveringstilstanden er placeret aksialt på niveau med indgrebselementet (2a) på den indvendige omkreds af nålebeskyttelseshylsteret (2) for at forhindre en bevægelse af indgrebselementet (2a) indad og således at sikre, at en bevægelse af nålebeskyttelseshylsteret (2) i forhold til huset (1) i udleveringstilstanden forhindres, og at

h) holdesektionen (3c) fjernes ved at trække i fratrækningselementet (3) og indgrebselementet (2a) på nålebeskyttelseshylsteret (2) frigives til en bevægelse indad,

kendetegnet ved, at

i) nålebeskyttelseshylsteret (2) omfatter et spærreelement (2c), som går i indgreb på en formtilpasset måde med et fremspring af huset for at forhindre at nålebeskyttelseshylsteret (2) skubbes tilbage ind i huset (1), efter at nålebeskyttelseshylsteret (2) er blevet skubbet ud over den distale ende af en nål (5e) af produktbeholderen (5) ved afslutningen af en dispensering af et produkt.

2. Injektionsindretningen ifølge krav 1, **kendetegnet ved, at** fratrækningselementet (3) danner en ringformet spalte mellem det ydre hylster, der er fastgjort på omkredsen af huset (1), og det indre hylster der omfatter holdesektionen (3c), hvilket fratrækningselement i den fastgjorte tilstand befinder sig i den ringformede spalte i en del af huset (1) og en del af nålebeskyttelseshylsteret (2), fortrinsvis også indgrebsdelen (2a) og modindgrebsdelen (1b).

3. Injektionsindretning ifølge krav 1 eller 2, **kendetegnet ved, at** indgrebselementet (2a) er fjedermonteret og kan bevæges på tværs af længdeaksen af injektionsindretningen.

4. Injektionsindretning ifølge et hvilket som helst af kravene 1 til 3, **kendetegnet ved, at** fremdriftselementet (8) er en forspændt trykfjeder og er optaget inden i en hylsterformet sektion af fradriftselementet (7).

5. Injektionsindretning ifølge et hvilket som helst af kravene 1 til 4, **kendetegnet ved, at** et fjederelement (9) tilfører energi til en forskydning af nålebeskyttelseshylsteret til en nålebeskyttelsesposition.

6. Injektionsindretning ifølge et hvilket som helst af kravene 1 til 5, **kendetegnet ved, at** fradriftselementet (7) er forskydeligt af et fremdriftselement (8), især en fremføringsfjeder, i distal retning for at forskyde produktbeholderen (5) til en automatisk indstikningsbevægelse af nålen.

7. Injektionsindretning ifølge et hvilket som helst af kravene 1 til 5, **kendetegnet ved, at** den er beregnet til manuel indstikning.

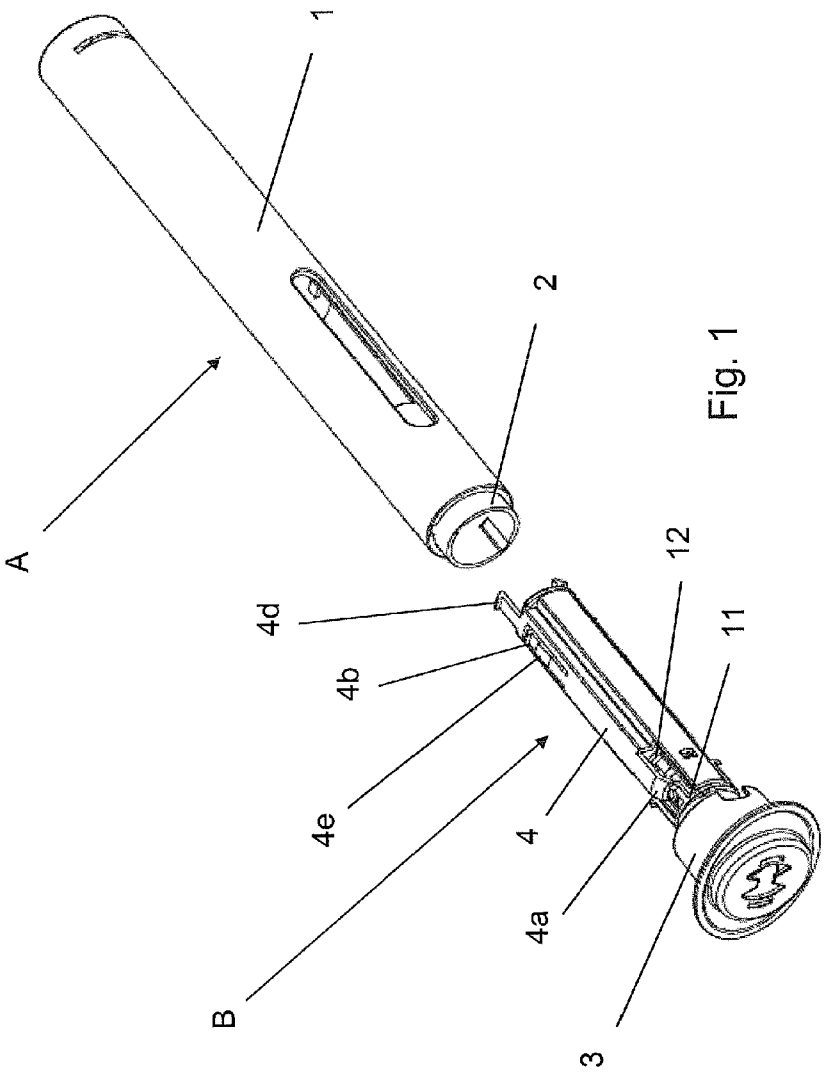


Fig. 1

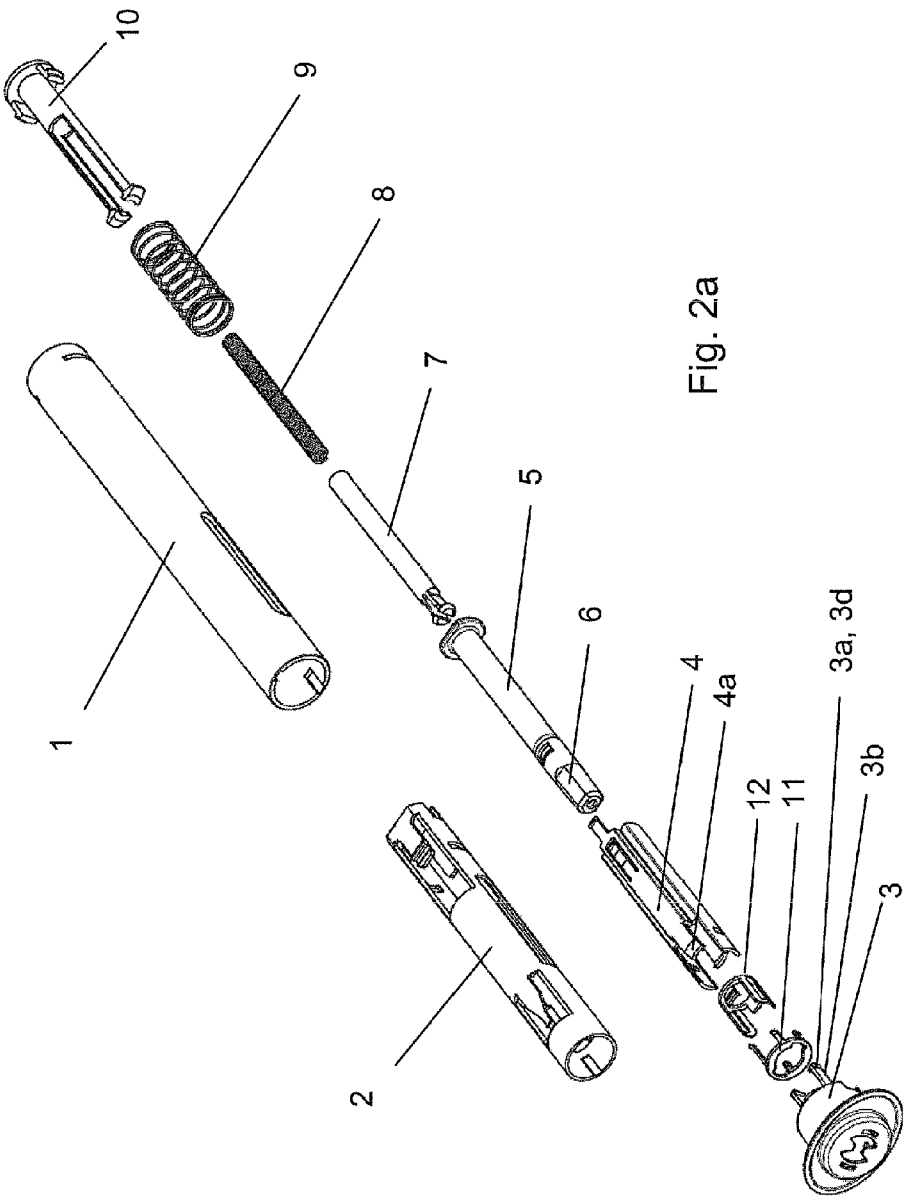
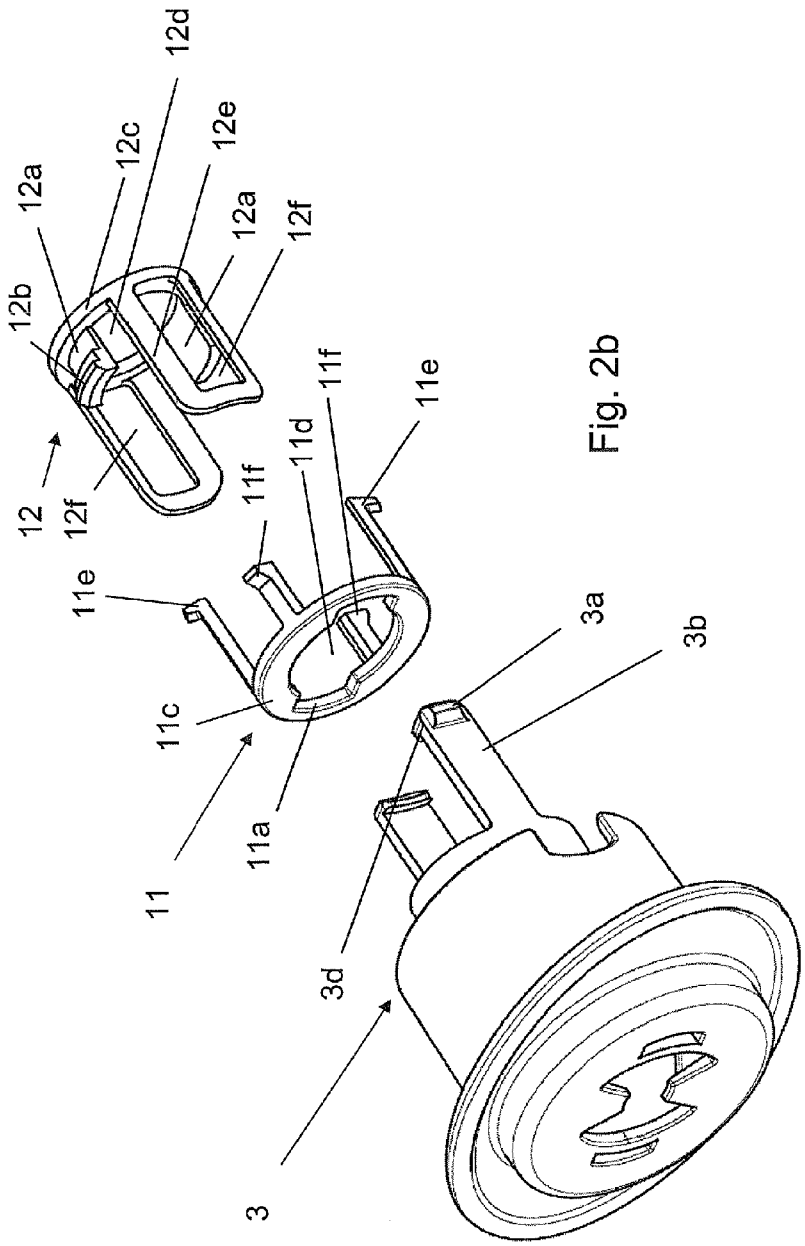


Fig. 2a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12c
12e
12a
12a
12f
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12
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11a
3a
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3d
3

Fig. 2b

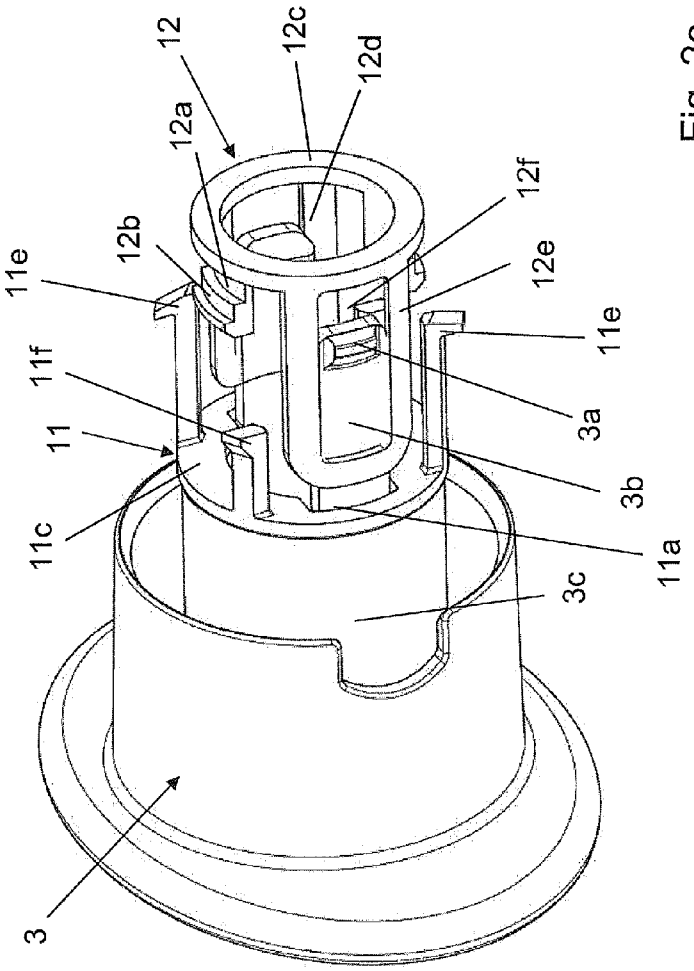
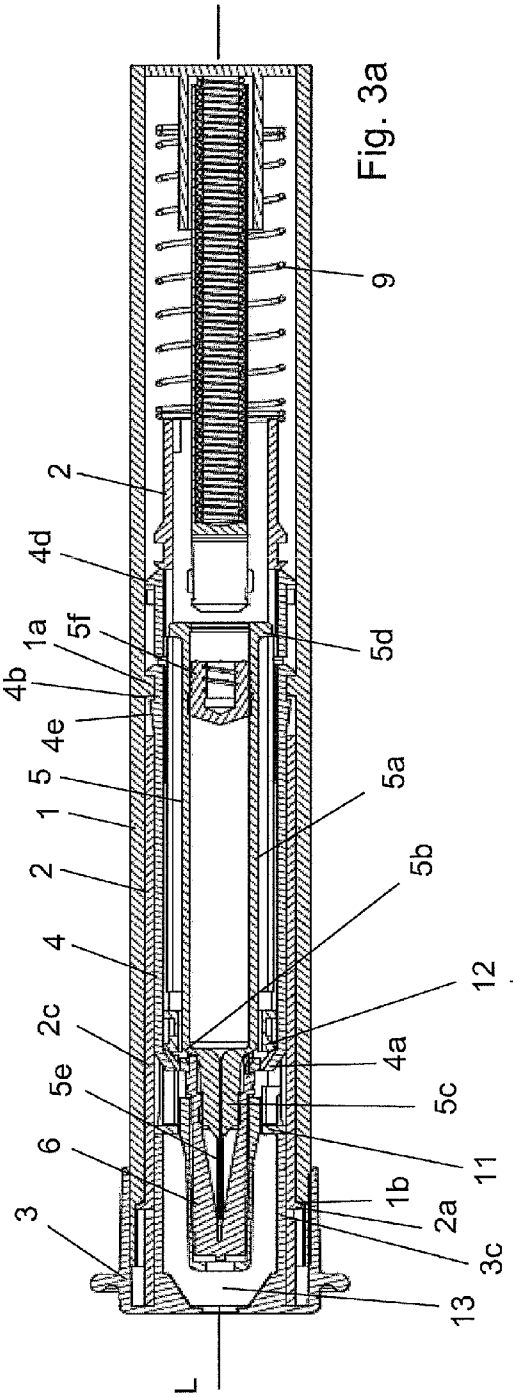


Fig. 2c


L
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4
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4e
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1a
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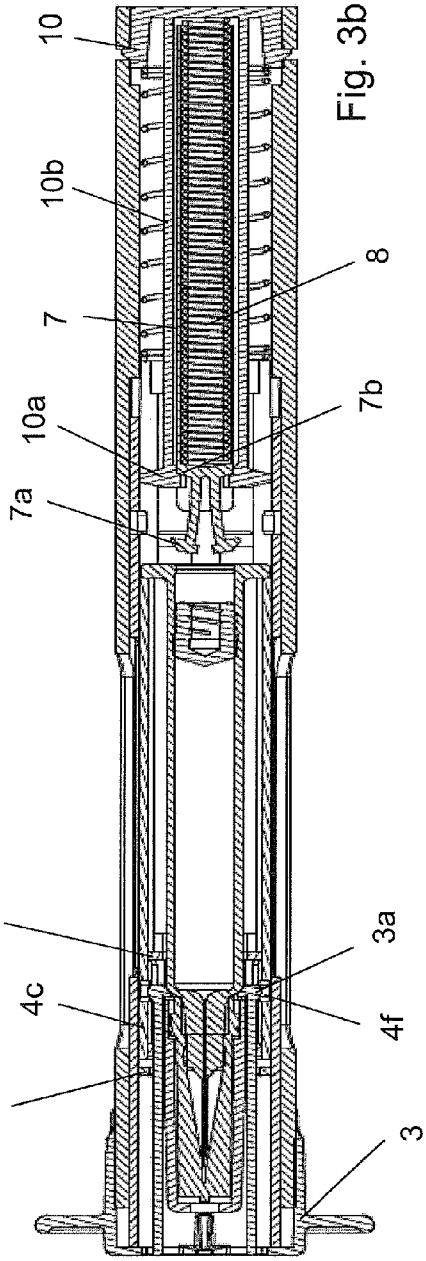
3c
13

Fig. 3a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4c
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Fig. 3b

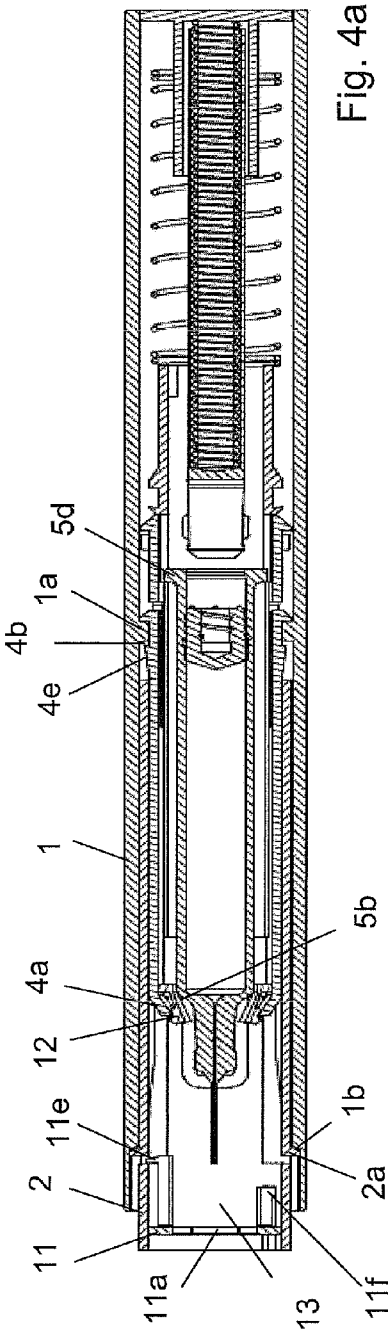

Fig. 4a

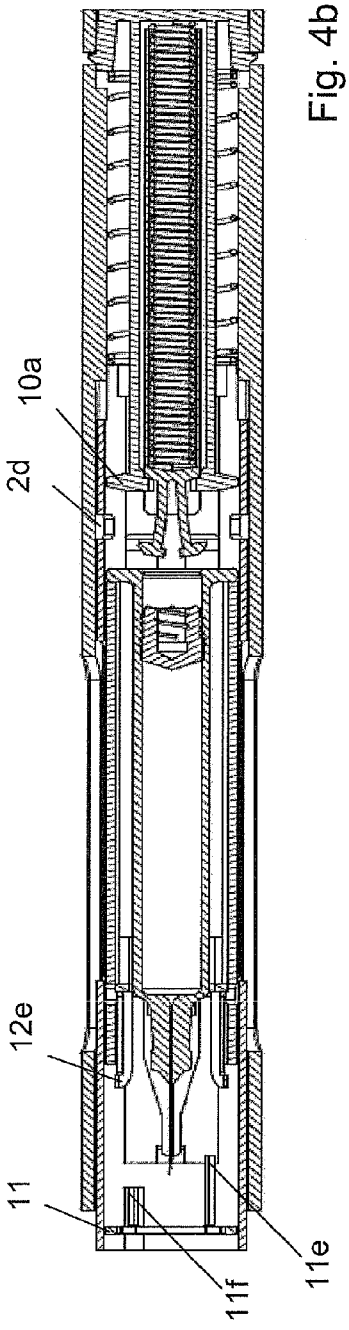

Fig. 4b

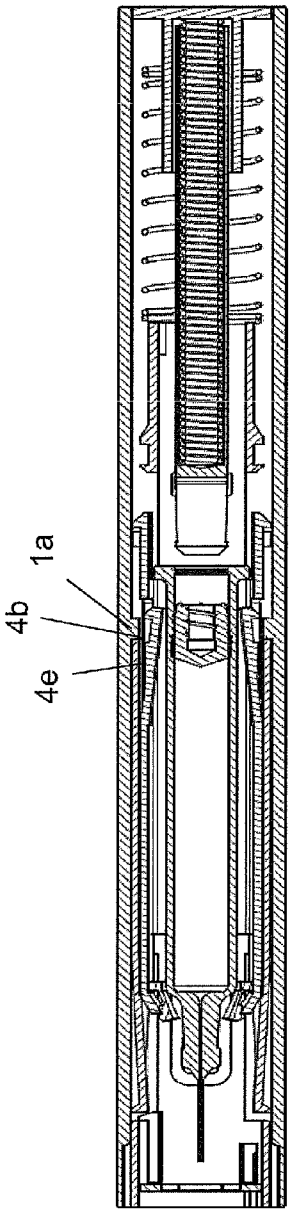

Fig. 5a

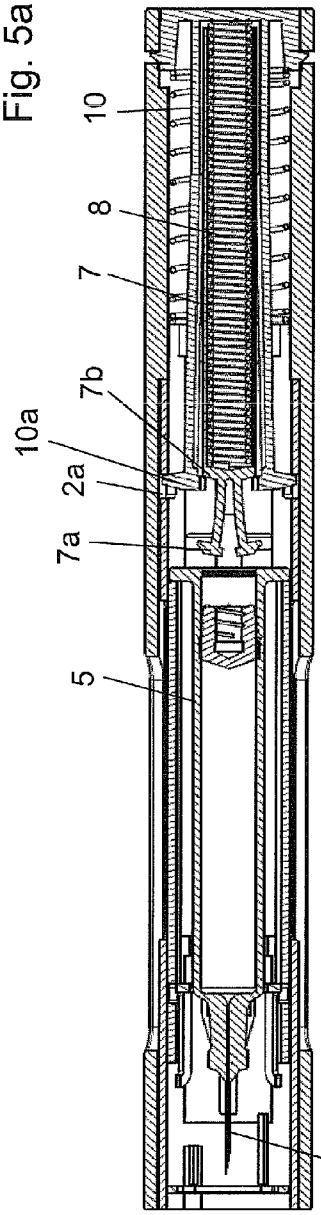

Fig. 5b

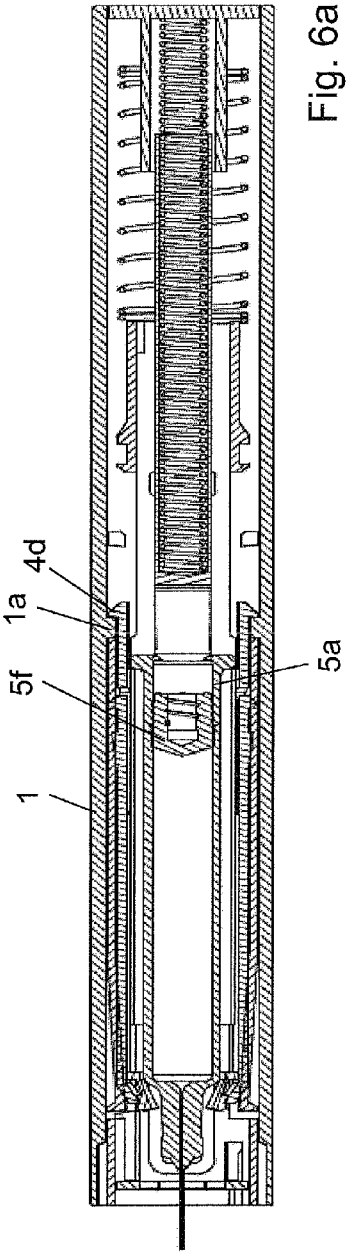

Fig. 6a

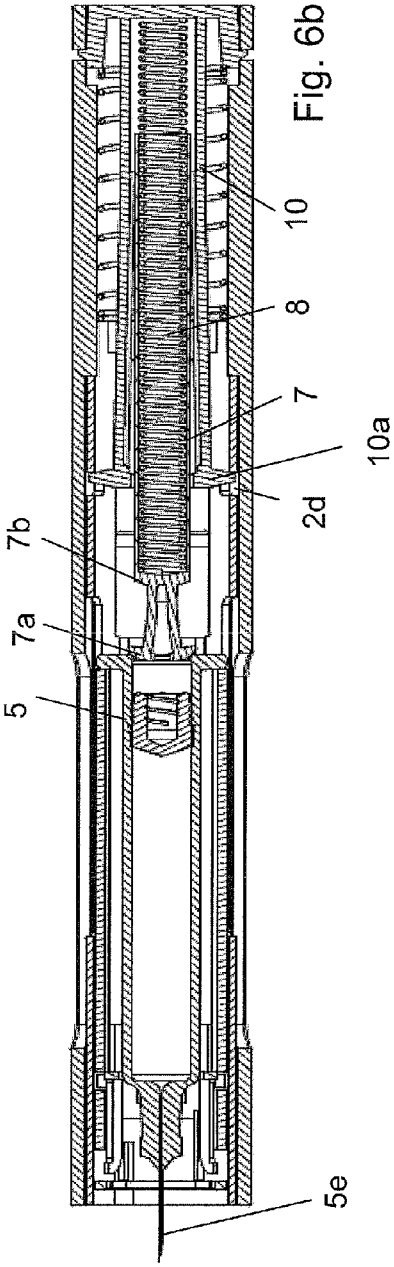

Fig. 6b

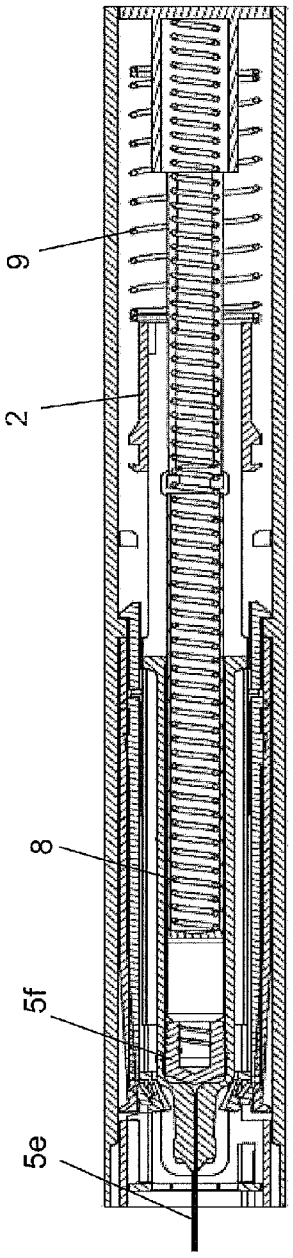

Fig. 7a

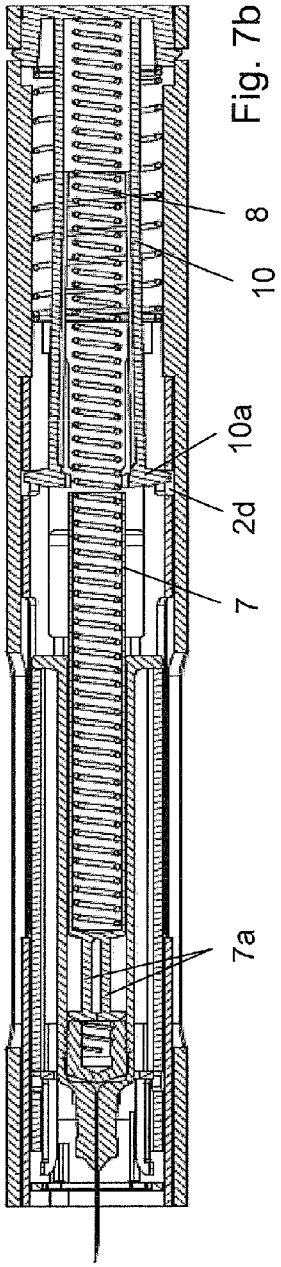

Fig. 7b

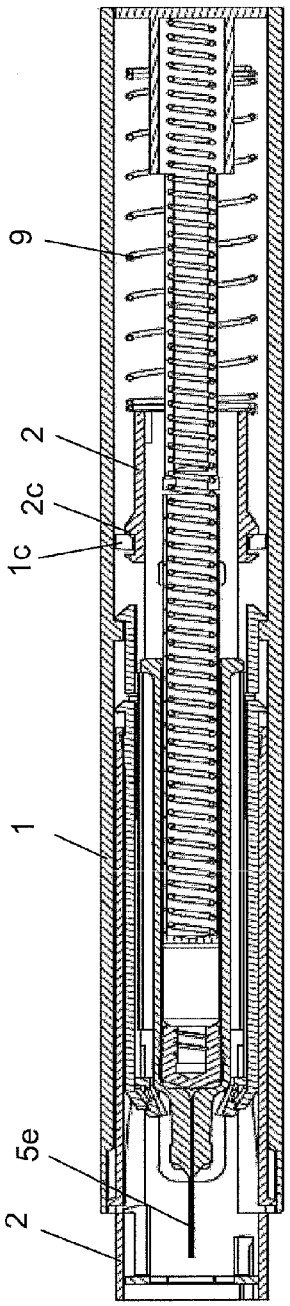

Fig. 8a

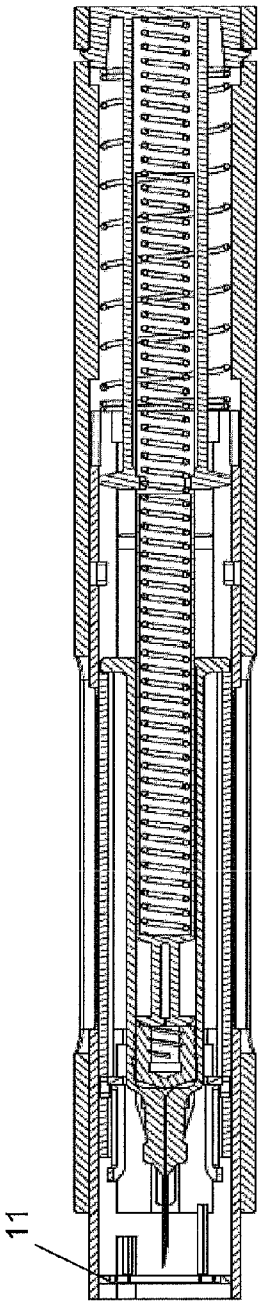

Fig. 8b