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DESCRIPTION

Description

TECHNICAL AREA

[0001] The present application relates to a medicament delivery device comprising a safety cap that on the one hand protects a dose delivery member of the medicament delivery device and on the other hand removes protective elements surrounding a medicament delivery member of the medicament delivery device.

BACKGROUND OF INVENTION

[0002] A large number of medicament delivery devices on the market and developed during the last 20 years are arranged with a protective cap at the proximal end thereof that on the one hand protect the proximal end of the medicament delivery device, which proximal end is arranged with a dose delivery member such as an injection needle. The injection needle for instance has to be kept sterile before use, whereby it is surrounded by a covering material such as a sheath of e.g. rubber, creating a so called flexible needle shield or FNS. Further developments in that regard are the so called rigid needle shields or RNS's that have an outer shell of a more rigid material surrounding the flexible inner sheath. The main purpose in any event is to keep the injection needle protected and sterile.

[0003] The safety cap on the other hand usually has two functions, to protect the medicament delivery member and other elements at the proximal end of the medicament delivery device and on the other hand provide an aid for removing the medicament delivery member shield when the medicament delivery device is to be used. It is designed to facilitate for a user to pull off the safety cap and at the same time the medicament delivery member shield.

[0004] A common design of a safety cap comprises a generally tubular outer body releasably attached to an end of the medicament delivery device and often provided with grip means for facilitating the removal. Inside the body, a generally tubular medicament delivery member guard remover is attached. The remover often comprises inclined tongues that grip into the material of the medicament delivery member guard or needle shield so that the needle shield is pulled off when the safety cap is pulled off.

[0005] The body of the safety cap and the remover are arranged with attachment elements. Often the remover is attached to the body of the safety cap by tongues or ledges on an inner

surface of a proximal end wall of the safety cap interacting with grooves or cut-outs or the like on one end of the remover or vice versa. From an assembly perspective, this is not optimal since the remover has to be inserted into body of the safety cap from a distal end and the attachment elements have to inter-connect, where the whole process requires rather tight tolerances and precise alignment of the components in order to properly attach the remover to the body.

[0006] WO2017/102175 discloses a protective cap according to the preamble of claim 1. J There is thus room for improvements regarding manufacture and assembly of safety caps.

BRIEF DESCRIPTION OF INVENTION

[0007] In the present disclosure, when the term "distal" is used, this refers to the direction pointing away from the dose delivery site. When the term "distal part/end" is used, this refers to the part/end of the delivery device, or the parts/ends of the members thereof, which under use of the medicament delivery device is/are located furthest away from the dose delivery site. Correspondingly, when the term "proximal" is used, this refers to the direction pointing to the dose delivery site. When the term "proximal part/end" is used, this refers to the part/end of the delivery device, or the parts/ends of the members thereof, which under use of the medicament delivery device is/are located closest to the dose delivery site.

[0008] The aim of the present application is to remedy the drawbacks of the state of the art devices. This aim is solved by a protective cap arrangement comprising the features of the independent claim. Preferably embodiments of the present application form the subject of the dependent claims.

[0009] According to one aspect, a protective cap to be releasably connected to a medicament delivery device having a medicament delivery member shield. The cap comprises a generally tubular body, a generally tubular medicament delivery member shield remover for removing the medicament delivery member shield. The medicament delivery member shield remover comprises an attachment element. The protective cap comprises a lid attached to the tubular body so that the medicament delivery member shield remover is held in place in this position by the end lid been in contact with the attachment element of the medicament delivery member shield remover. The attachment elements are for holding the generally tubular medicament delivery member shield remover. The lid is attached to said body for holding said medicament delivery member shield remover in fixed position. This provides an easy and effective assembly setup of a safety cap.

[0010] Moreover, the protective cap tubular body comprises an end wall provided with a passage through which said medicament delivery member shield remover protrudes. In this regard, an attachment element comprises radially outwardly extending a circumferential flange with two support surfaces on said medicament delivery member -shield remover proximal end, which support surfaces are positioned between and facing the end wall and the lid. Thus, from

an assembly point of view, it is easy to enter or insert the medicament delivery member guard into the passage from the proximal end of the cap and then attach the lid, providing a protective safety cap with an integrated medicament delivery member shield remover with fewer assembly steps.

[0011] According to a further aspect, the end wall is arranged with a seat or a recess for support surfaces, and the support surfaces may comprise a single circumferential flange as an attachment element or a number of circumferential extensions (not shown) as a plurality of the attachment elements. Also, the lid may be arranged with distally directed arms, which arms are arranged with ledges wherein the arms are designed to fit into openings of the body and the ledges will snap around edges of the openings. In this regard, the arms may be arc-shaped and provided with radially outwardly directed ledges, and that the openings are arc-shaped. Preferably, the openings may be arranged in the end wall. Additionally, the lid may further be arranged with a number of distally directed protrusions or ledges which are to be in contact with the flange or the attachment elements of the medicament delivery member shield remover.

[0012] These and other aspects of, and advantages with, the present invention will become apparent from the following detailed description of the invention and from the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

[0013] In the following detailed description of the invention, reference will be made to the accompanying drawings, of which

Fig. 1 is an exploded view of a medicament delivery device comprising a protective cap according to the application,

Figs. 2, 3 are cross-sectional views of the medicament delivery device of Fig. 1, and

Figs. 4-21 are detailed views of components comprised in the medicament delivery device of Fig. 1.

DETAILED DESCRIPTION OF THE INVENTION

[0014] The medicament delivery device 10 shown in the drawings comprises a generally tubular housing 12 having a proximal end 14 and a distal end 15. Inside the housing a generally transversal wall 16 is arranged, Fig. 4, which wall 16 is provided with a central passage 18. Cut-outs 20 are further arranged on opposite sides of the passage 18. A seat 22 is surrounding the passage 18. Further generally rectangular windows 24 are arranged in the

housing, which windows 24 are arranged with inwardly directed wall sections 26. The proximal parts of the wall sections 26 are attached to or form part of the transversal wall 16. Further, a number of longitudinally extending ribs 30 are arranged on the inner surface of the housing, having inwardly directed protrusions 32 at the proximal end thereof, the function of which will be described below. Moreover, at the distal area of the housing generally radially flexing tongues 34 are arranged, which tongues 34 are arranged with inwardly extending ledges 36 at their free ends.

[0015] Inside the housing, a medicament container holder 38 is arranged coaxially. The medicament container holder 38 comprises a generally elongated tubular body 40 having a distal passage 42 and a proximal passage 44. The proximal passage 44 is arranged with an inwardly directed ledge 46 stretching around the circumference. The body 40 is arranged with two elongated slits 48 on opposite sides of the body. One of the slits 48 extends all the way to the proximal end, connecting the slit with the proximal passage, creating a C-shaped appearance when viewing in the distal direction. The circumferential ledge is further arranged with a number of cut-outs 50, three in the embodiment shown, for providing flexibility of the proximal part of the medicament container holder as will be described. The longitudinal sides of the slits 48 are arranged with outwardly directed ledges 52, which ledges 52 are designed to be in contact with inwardly surfaces 54 surrounding the windows 24 of the housing, for providing orientation and rotational fixation in relation to the housing. The medicament container holder 38 is arranged to accommodate a medicament container 56 that in the embodiment shown is a syringe, having an injection needle 58 as a medicament delivery member attached to a proximal end thereof and a stopper 60 of resilient material that is movable inside the tubular body of the medicament container 56.

[0016] The medicament delivery device further comprises a medicament delivery member guard 62, Figs. 1 and 7. The medicament delivery member guard 62 comprises a proximal generally tubular body 64 provided with a central passage 66 in a transversal end wall 68. Two oppositely positioned arms 70 are arranged to the distal area of the body 64 and extending in the distal direction. The arms 70 are arranged with longitudinal slits 72 which are to cooperate with the longitudinal ribs 30 of the interior of the housing. At the distal end of the arms 70, outwardly directed ledges 74 are provided. Further on the inner surface of the arms 70, inwardly directed protrusions 76 are arranged, the function of which will be described. A medicament delivery member guard spring 78 is further arranged between a distally directed surface of the transversal end wall 68 of the medicament delivery member guard 62 and a proximally directed surface of the wall 16. In this regards, proximally directed support protrusions 80, Figs. 3b and 12, are provided on the wall 16 for supporting the medicament delivery member guard spring 78 and preventing it from accidentally interacting with the arms 70 of the medicament delivery member guard 62.

[0017] The medicament delivery device 10 shown also comprises a power pack or drive unit 82. The power pack 82 comprises an actuator 84 provided with a distal portion forming an end cap 86 of the medicament delivery device when the actuator is connected to the housing. The proximal part of the actuator 84 comprising a generally elongated tubular body 88. A

transversal support surface 90 is arranged in the area between the end cap 86 and the body 88, which support surface 90 is designed to cooperate with the ledges 36 of the tongues 34 on the housing 12 for locking the actuator 84 to the housing 12 as seen in Fig 8. The body 88 is further arranged with proximally directed arms 92 that are flexible in a generally radial direction. The free ends of the arms 92 are provided with inwardly directed protrusions 94. These inwardly directed protrusions 94 are arranged to fit into and cooperate with recesses 95 in an elongated plunger rod 96, which plunger rod 96 is intended to fit into and be coaxial with the body 88 of the actuator 84.

[0018] Further, a drive spring 98 is arranged inside the plunger rod 96 as well as a bracket 100 having a transversal distal part 102 and two proximally extending arms 104 on either side of, and outside, the drive spring 98. The ends of the arms 104 are arranged with outwardly extending ledges 106, which ledges 106 are to be in contact with proximally directed edge surfaces 108 of the body 88 of the actuator 84. Inside the drive spring 98 a guide rod 110 is arranged, provided with a disk 112 at its distal end. The drive spring 98 is thus arranged between a proximal end wall 114 of the plunger rod 96 and the transversal distal part 102 of the bracket 100 via the disk 112 of the guide rod 110, Fig. 2. Further, at the proximal end of the body 88, arc-shaped support elements 116 are arranged, which are flexible in the generally longitudinal direction and are intended to be in contact and support the medicament container 56 in the distal direction.

[0019] Moreover, the free ends of the arms 92 of the body 88 are arranged with outwardly directed protrusions 118 that are intended to cooperate with inner surfaces 120 of a generally tubular rotator 122 that is arranged outside and coaxial with the body 88 of the actuator 84. The inner surface 120 of the rotator 122 is arranged with longitudinally extending grooves 124, Fig. 9, the function of which will be described below. The outer surface of the rotator 122 is arranged with guide ledges or ribs 126, where some are extending in the longitudinal direction 126l and some are inclined 126i in relation to the longitudinal direction as will be explained. Adjacent one longitudinal guide rib 126l, a proximally directed tongue 128 is arranged, which tongue 128 is flexible in the generally radial direction, and where the free end of the tongue 128 is arranged with an outwardly directed, wedge-shaped, protrusion 130.

[0020] The medicament delivery device 10 is further arranged with a safety cap 132, Figs. 1 and 10, comprising a generally tubular body 134 having a distal passage 136. In order to provide a good fit between the safety cap 132 and the medicament delivery device 10, the inner surface of the body 134 of the safety cap 132 may be arranged with a circumferential ledge 138, which ledge 138 is arranged to interact with protrusions 140, Fig. 7, on the outer surface of the body 64 of the medicament delivery member guard 62 as seen in Fig. 14. The body 134 of the safety cap 132 is further arranged with a distally directed end surface 135, Figs. 11 and 14, that acts as an abutment surface against a proximally directed end surface 137, Figs. 5 and 14, of the housing 12, which end surface 137 also acts as an abutment surface such that the surfaces 135, 137 provide a specific position of the protection safety cap 132 when mounted onto the medicament delivery device 10.

[0021] Moreover, the body 134 of the safety cap 132 is arranged with a proximal end wall 142, which end wall 142 is arranged with a central circular passage 144. Radially outside the central passage 144 are two oppositely positioned arc-shaped openings 146. Alternatively, only one opening of a suitable shape can be provided (not shown here). A generally tubular medicament delivery member shield remover 148 is to be positioned in the central passage 144 of the end wall 142, wherein the medicament delivery member shield remover 148 will extend into the body 134 of the safety cap 132. The proximal end of the medicament delivery member shield remover 148 is arranged with an outwardly extending ledge 150, which ledge or flange 150 is arranged to be seated in a seat or a recess 152 in the end wall 142 of the body 134. The medicament delivery member shield remover 148 is held fixed in place in this position by an end lid 154. The end lid 154 is arranged with a couple of distally directed arc-shaped arms 156 as illustrated in Fig. 11, provided with radially outwardly directed ledges 158, wherein the arms 156 are designed to fit into the arc-shaped openings 146 of the body 134 and the ledges 158 will snap around edges of the arc-shaped openings 146, locking the end lid 154 to the body 134 of the safety cap 132. Alternatively, only one distally directed arm of a suitable shape or an arm comprising a couple of flexible fingers (now shown) can be arranged. The end lid 154 is further arranged with one or a number of distally directed protrusions or ledges 160 which are to be in contact with the ledge 150 of the medicament delivery member shield remover 148, holding it in place in the recess 152, see Fig. 12.

[0022] The end lid 154 is arranged with further protrusions 162 at the edge of the end lid 154 that are in contact with the end wall 142 of the body 134, creating a space 164 between the body 134 and the end lid 154, Fig. 13. The diameter of the end lid 154 is further chosen such in relation to the proximal edge of the body 134 such that gaps 166 are created around the circumference. The design provides an air passage through the protective safety cap 132, as seen by the arrow in Fig. 15, preventing possible suffocation should a child for example put the safety cap 132 in the mouth. Moreover, the distal end of the medicament delivery member shield remover 148 is arranged with generally proximally and inwardly inclined tongues 168 that are designed to be in contact with and engage a medicament delivery member shield 170 such as a rigid needle shield or a flexible needle shield, covering the medicament delivery member such as the injection needle 58.

[0023] Also, the protective safety cap has a facilitated assembly procedure in that the medicament delivery member shield remover 148 is simply entered into the central passage 144 of the end wall 142 of the body 134 from the proximal side until the ledge 150 is seated in the recess 152 in the end wall 142. Then the end lid 154 is simply pushed onto the proximal end of the body 134 such that the arms 156 fit into the openings and the ledges 158 snap around the edges of the openings 146 of the body 134. A very simple, fast and effective assembly way of the protective safety cap is obtained by the solution.

[0024] The medicament delivery device according to the drawings is intended to function as follows. The medicament delivery device is delivered to a user with the safety cap 132 attached to the proximal end of the medicament delivery device. The medicament delivery member guard 62 is in an extended position in relation to the housing 12 such that when the abutment

surface 135 of the safety cap 132 is in contact with the abutment surface 137 of the housing, the circumferential ledge 138 is distally of, and in contact with, the protrusions 140 of the medicament delivery member guard 62 as seen in Fig. 14. This provides a very secure fit, reducing the risk for premature release of the safety cap 132.

[0025] The medicament delivery device is generally activated by the medicament delivery member guard 62 being pushed into the housing 12 when the proximal end of the medicament delivery device is pressed against a dose delivery site, as will be described. This may happen accidentally if the medicament delivery device is dropped against a hard surface such as a floor. Now there is a risk that the medicament delivery device 10 is activated in that the medicament delivery member guard 62 may be moved in relation to the housing 12 due to the impact forces, which might trigger the medicament delivery device. This risk is reduced and minimized in that the medicament delivery member guard 62 is held by the engagement with the safety cap 132 by the protrusions 140 interacting with the ledge 138.

[0026] . The user may now press the proximal end of the medicament delivery device 10 against the dose delivery site, whereby the medicament delivery member guard 62 is pushed into the housing 12, causing a penetration by the injection needle 58. The movement of the medicament delivery member guard 62 will cause its protrusions 76 at the distal end to slide in relation to the rotator 122. When the protrusions 76 reach the inclined guide ribs 126i of the rotator 122, the rotator 122 will rotate in relation to the actuator 84, which in turn causes the outwardly protrusions 118 of the arms 92 of the actuator 84 to be moved in position with the longitudinal grooves 124 on the inner surface 120 of the rotator 122. The arms 92 are thereby free to move radially outwards, whereby the engagement between the inwardly directed protrusions 94 and the recesses 95 of the plunger rod 96 is removed, releasing the plunger rod 96. The plunger rod 96 is then urged in the proximal direction by the force of the drive spring 98. The plunger rod 96 will now act on and move the stopper 60 of the medicament container 56 in the proximal direction, expelling a dose of medicament through the injection needle 58. At the end of the injection sequence, the distal end of the plunger rod 96 will pass the bracket 100 whereby the arms 104 of the bracket 100 are free to move radially inwards, wherein the ledges 106 are moved out of contact with the surfaces 108 of the actuator 84. Because the distal end of the drive spring 98 is in contact with the transversal distal part 102 of the bracket 100 via the disk 112 of the guide rod 110 and since the drive spring 98 has a residual force, the bracket 100 will be forced suddenly in the distal direction until the distal end of the bracket 100 hits an end wall of the actuator 84, causing a tactile and audible signal to the user that the injection sequence is completed and that it is safe to remove the medicament delivery device from the dose delivery site.

[0027] The user can now remove the medicament delivery device 10 whereby the medicament delivery member guard 62 is pushed in the proximal direction by the medicament delivery guard spring 78. This will cause the protrusions 76 of the medicament delivery member guard 62 to move such that they come in contact with and pass the wedge-shaped protrusions 130 of the tongues 128 of the rotator 122. The passing of the protrusions 130 will cause a locking of the medicament delivery member guard 62 in the extended position, covering the injection

needle 58, in turn preventing accidental injuries on the injection needle 58. The medicament delivery device can now be discarded.

[0028] Regarding the securing of the medicament delivery member guard 62 it is to be understood that several other alternatives are feasible. Instead of discrete protrusions on the outer surface of the medicament delivery member guard 62, there could for example be a continuous protrusion 180 running along the circumference as seen in Fig. 16. As an alternative, there could be a recess in the medicament delivery member guard 62 and protrusions on the inner surface of the body of the safety cap 132. It is to be understood that the recesses in the medicament delivery member guard 62 could either be continuous 182 as seen in Fig. 17 or discrete 184 as seen in Fig. 18. As a further alternative, the protrusion on the inner surface of the safety cap 132 may be discrete 186 instead of continuous, Fig. 19. As yet an alternative there may be recesses on the inner surface of the safety cap 132, either continuous 188, Fig. 20 or discrete 190, Fig. 21. As understood there are many variants that may be combined in order to obtain the desired function of enhanced safety against accidental activation.

[0029] It is to be understood that the embodiment described above and shown in the drawings is to be regarded only as a one non-limiting example that may be modified in many ways within the scope of the patent claims.

REFERENCES CITED IN THE DESCRIPTION

Cited references

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- [WO2017102175A \[0006\]](#)

PATENTKRAV

1. Beskyttelseshætte (132) til aftagelig forbindelse til en lægemiddelindgivelsesanordning (10) med en lægemiddelindgivelseselement-manchet (170), hvilken hætte (132) omfatter et generelt rørformet legeme (134) og en
5 generel rørformet lægemiddelindgivelseselement-manchetfjerner (148) til fjernelse af lægemiddelindgivelseselement-manchetten (170), hvor lægemiddelindgivelseselement-manchetfjerner (148) omfatter et fastgørelseselement (150) på den proksimale ende, og beskyttelseshætten (132) omfatter et låg (154), der er fastgjort på den proksimale ende af det rørformede
10 beskyttelseshættelegeme (134) på en sådan måde, at lægemiddelindgivelseselement-manchetfjerner (148) holdes på plads i denne position af endelåget (154), der er i kontakt med lægemiddelindgivelseselement-manchetfjernerens (148) fastgørelseselement (150),

hvor det rørformede legeme (134) omfatter en endevæg (142), der er
15 forsynet med en gennemføring (144), gennem hvilken lægemiddelindgivelseselement-manchetfjerner (148) stikker frem, og i det mindste en åbning (146),

hvor fastgørelseselementet (150) omfatter radialt udadforløbende støtteflader på lægemiddelindgivelseselement-manchetfjerner (148), hvilke støtteflader er
20 positioneret mellem endevæggen (142) og låget (154),

hvor endevæggen (142) er indrettet med et leje, dvs. en forsænkning (152) til støttefladerne; **kendetegnet ved, at** endelåget (154) yderligere er indrettet med et eller flere distalt rettede fremspring (160), hvor det ene eller flere fremspring (160) er i kontakt med lægemiddelindgivelseselement-manchetfjernerens (148)
25 fremspringende kant (150) på en sådan måde, at lægemiddelindgivelseselement-manchetfjerner (148) holdes på plads i forsænkningen (152).

2. Beskyttelseshætte (132) ifølge krav 1, hvor støttefladerne omfatter en periferisk flange (150).

3. Beskyttelseshætte (132) ifølge et hvilket som helst af de foregående
30 krav, hvor låget (154) er indrettet med i det mindste en distalt rettet arm (156),

hvilken arm (156) er indrettet med en fremspringende kant (158), hvor armen (156) er udformet til at passe i legemets (134) åbning (146), og den fremspringende kant (158) vil snaplukke om åbningens (146) kanter og låse låget (154) til hættens (132) legeme (134).

5 4. Beskyttelseshætte (132) ifølge krav 3, hvor armene (156) er bueformede og forsynet med radialt udadrettede fremspringende kanter (158), og åbningerne (146) er bueformede.

5. Beskyttelseshætte (132) ifølge krav 4, hvor låget (154) yderligere er indrettet med et antal distalt rettede fremspring eller fremspringende kanter
10 (160), der skal være i kontakt med lægemiddelindgivelseselement-
manchetfjernerens (148) flange (150).

6. Lægemiddelindgivelsesanordning (10) omfattende et generelt tubeformet hus (12), yderligere omfattende beskyttelseshætten (132) ifølge et hvilket som helst af de foregående krav.

15 7. Lægemiddelindgivelsesanordning (10) ifølge krav 6, omfattende, i huset (12), en lægemiddelbeholderholder (38), der er anbragt koaksialt og rummer en lægemiddelbeholder (56) med et lægemiddelindgivelseselement (58), der er fastgjort til en proksimal ende deraf, og en lægemiddelindgivelseselement-
manchet (170), der dækker lægemiddelindgivelseselementet (58) og skal fjernes,
20 når hætten (132) fjernes.

8. Fremgangsmåde til montering af en beskyttelseshætte (132) ifølge et hvilket som helst af de foregående krav, **kendetegnet ved:**

- forsyning af lægemiddelindgivelseselement-manchetfjernerens (148) proksimale ende med en udadforløbende fremspringende kant (150);
- 25 - indførelse af lægemiddelindgivelseselement-manchetfjernereren (148) i en midtstillet gennemføring (144) i beskyttelseshættelegemets (134) endevæg (142) fra den proksimale side, indtil den fremspringende kant (150) er lejret i forsænknings (152) i endevæggen (142);
- tilvejebringelse af et låg (154) og

- skubning af låget (154) over på legemets (134) proksimale ende på en sådan måde, at lægemiddelindgivelseselement-manchetfjerner (148) holdes på plads i denne position af endelåget (154).

9. Fremgangsmåde til montering af en beskyttelseshætte (132) ifølge krav

5 8, **kendetegnet ved:**

- forsyning af låget (154) med et par distalt rettede arme (156) med radiale udadrettede fremspringende kanter (158);

- tilvejebringelse af åbningerne (146) på legemet (134);

- indpasning af armene (156) i åbningerne (146) på en sådan måde, at de fremspringende kanter (158) snaplukker om kanterne af legemets (134) åbninger (146).

10. Fremgangsmåde til montering af beskyttelseshætten (132) ifølge krav 9, **kendetegnet ved:**

- tilvejebringelse af åbningerne (146) i bueform;

- 15 - tilvejebringelse af armene (156), hvor armene (156) er udformet til at passe ind i legemets (134) bueformede åbninger (146).

DRAWINGS

Drawing

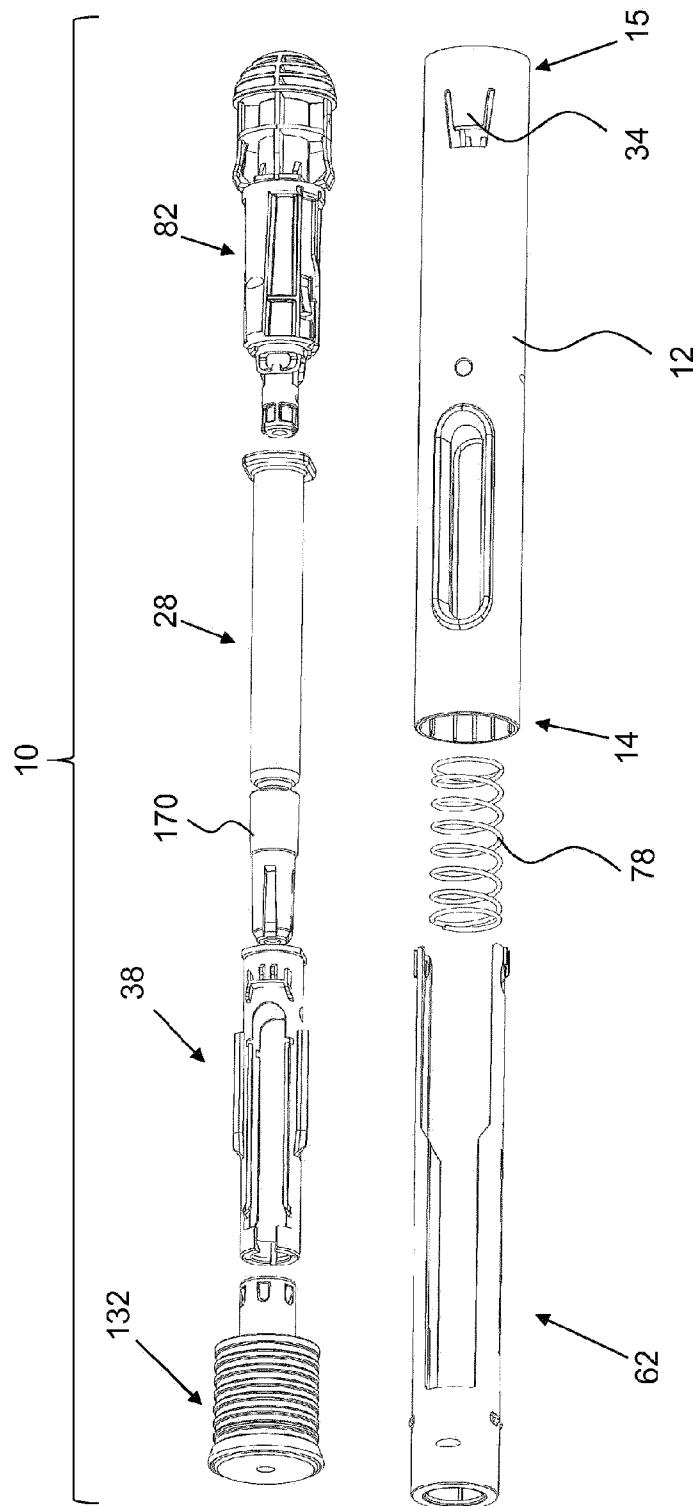
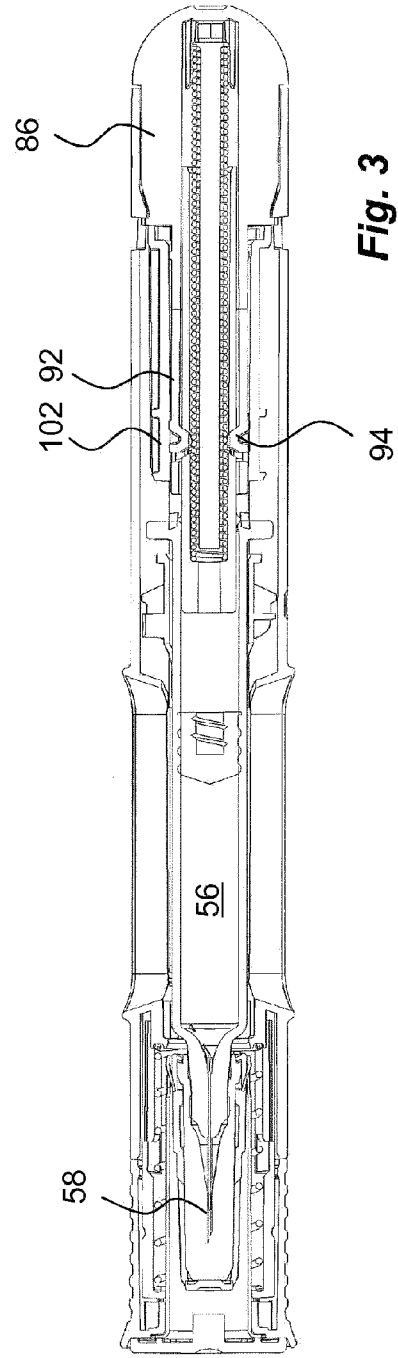
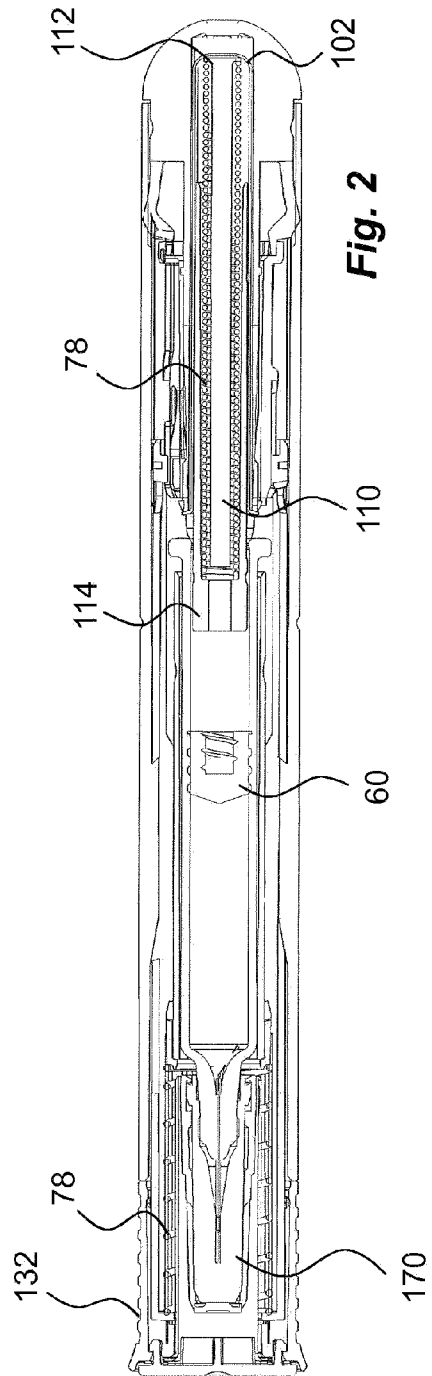


Fig. 1



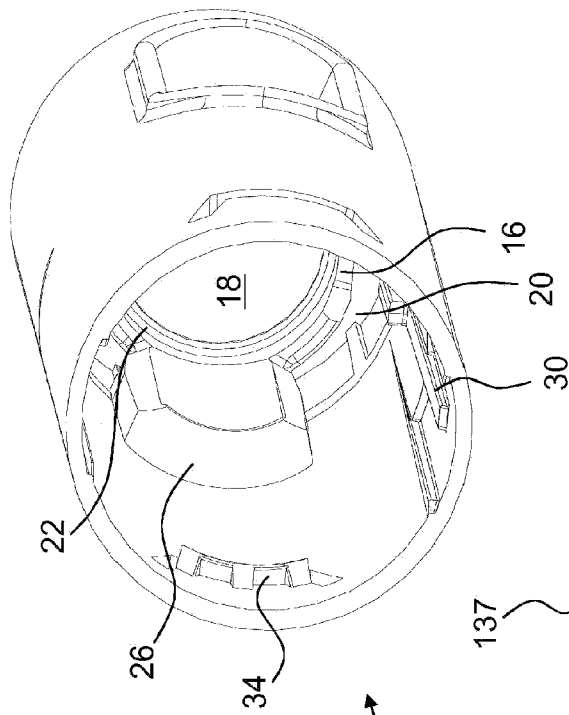


Fig. 4

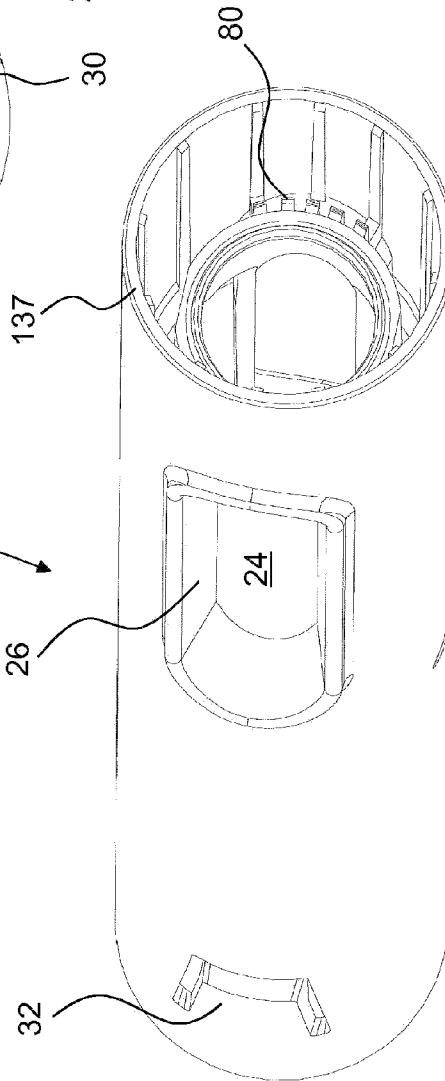
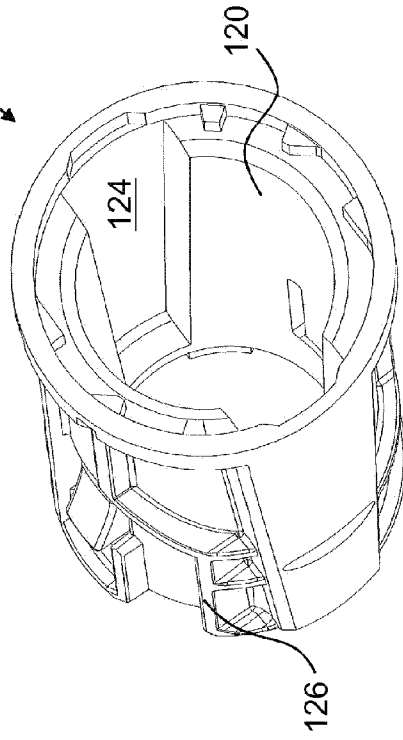
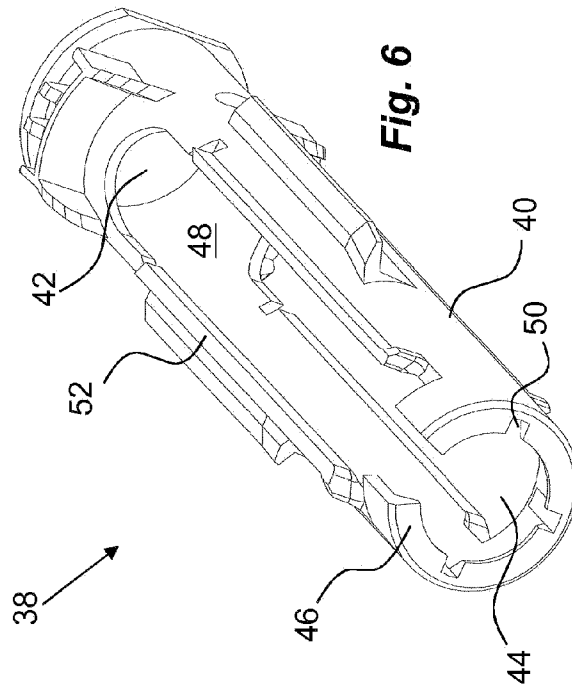
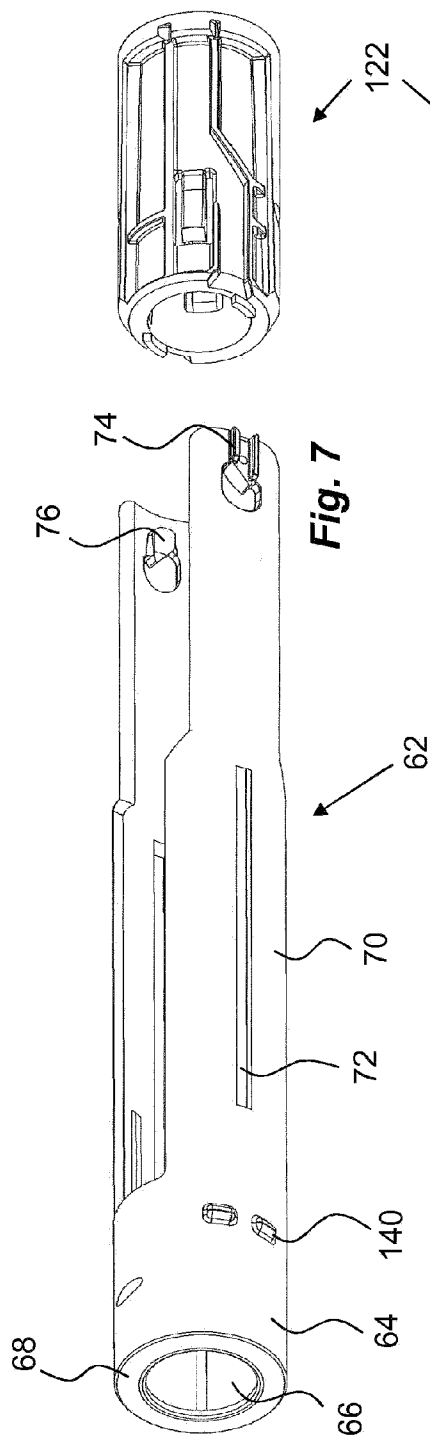


Fig. 5



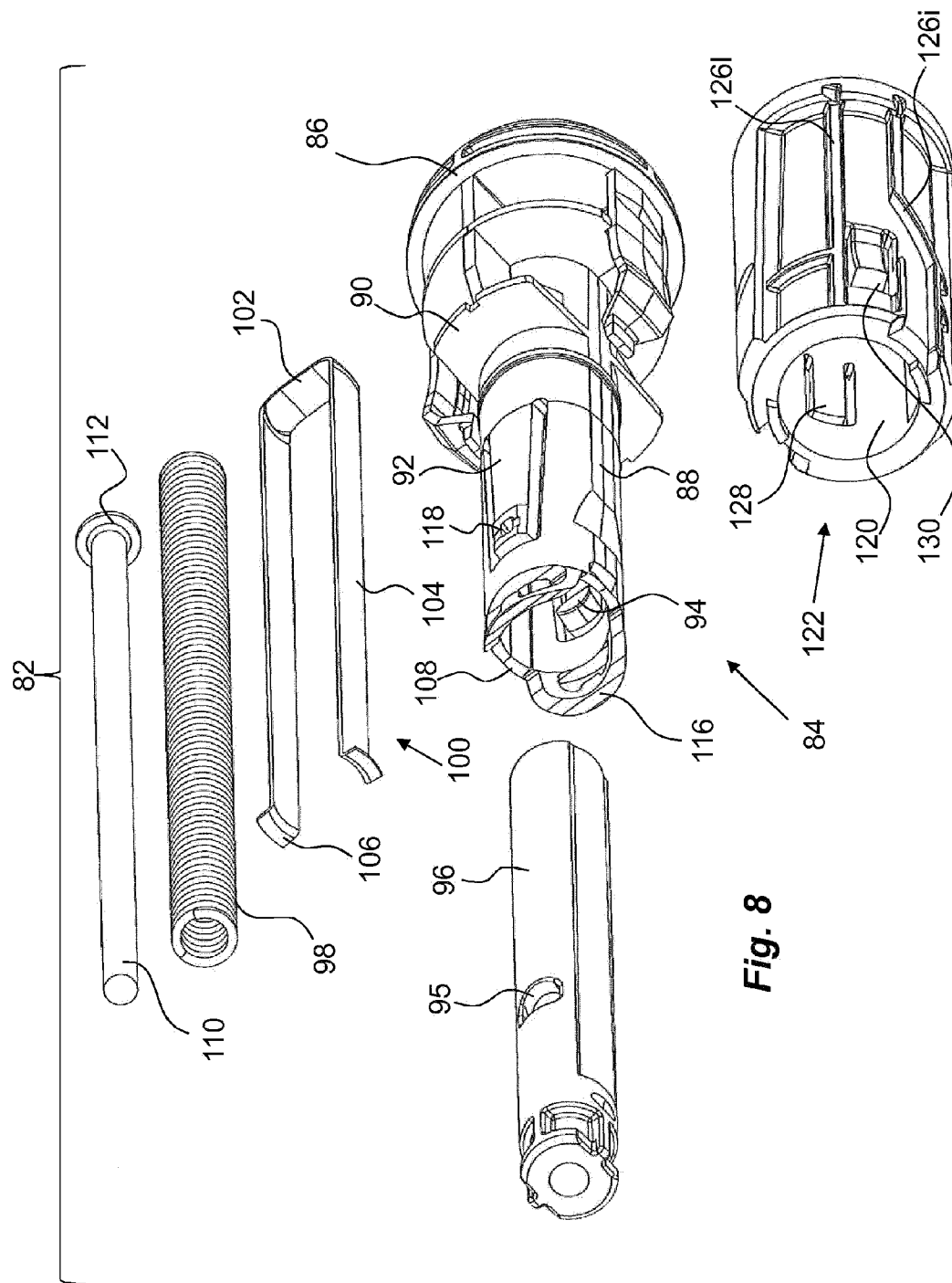
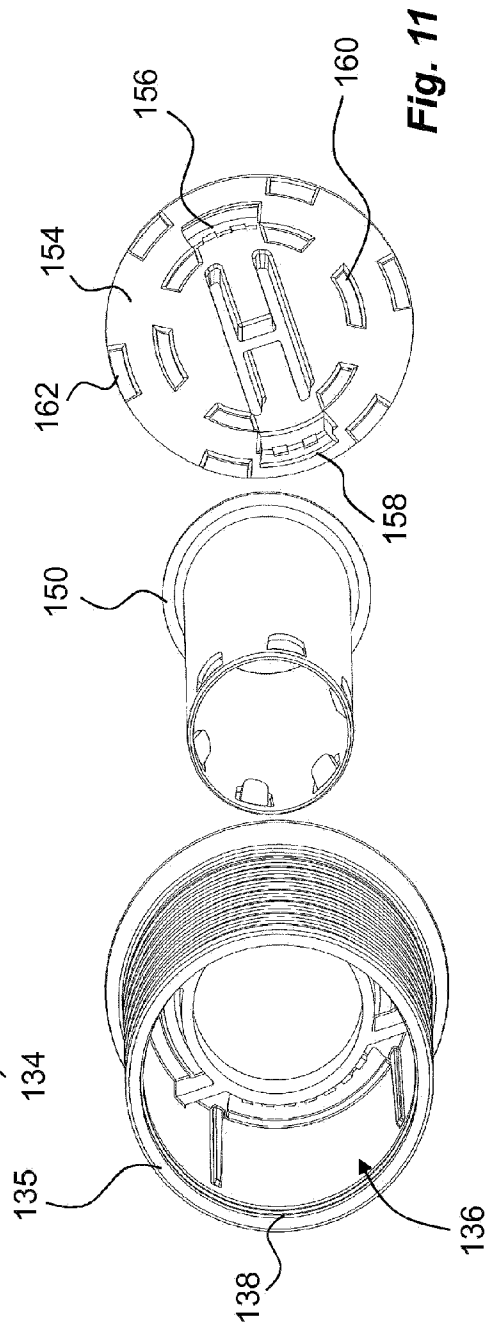
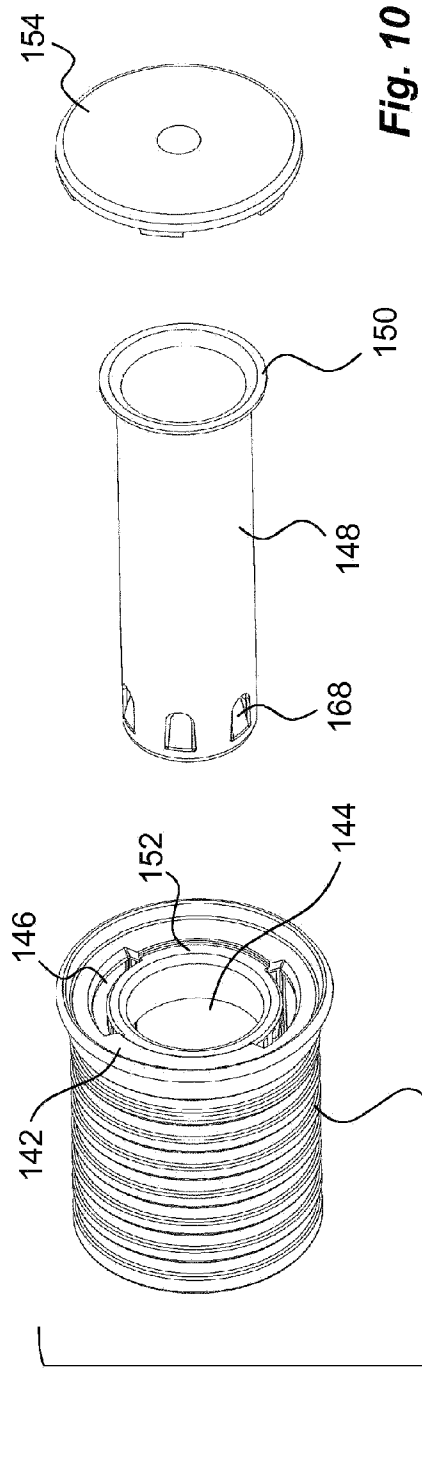
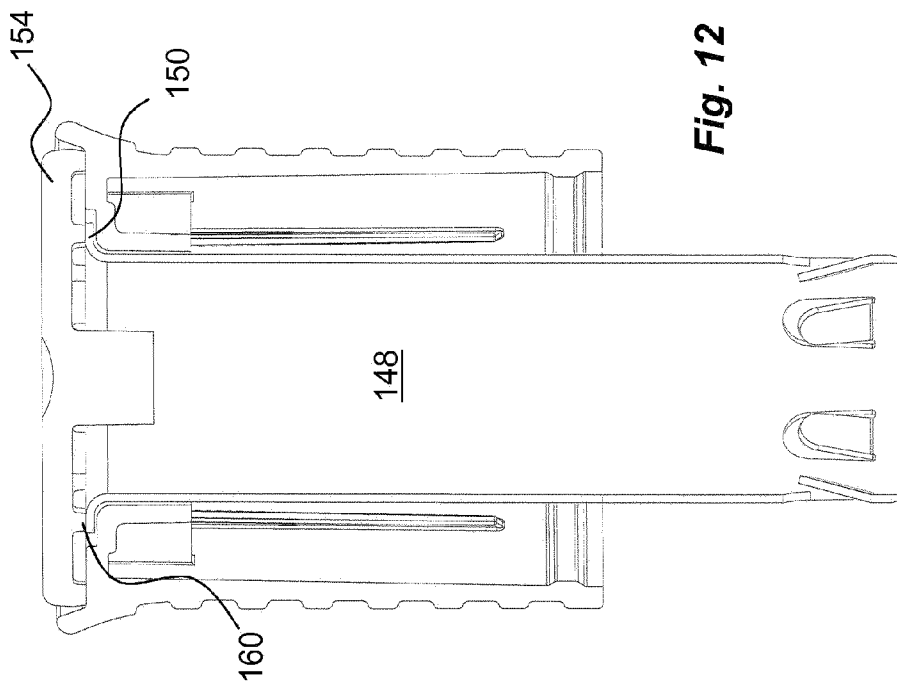
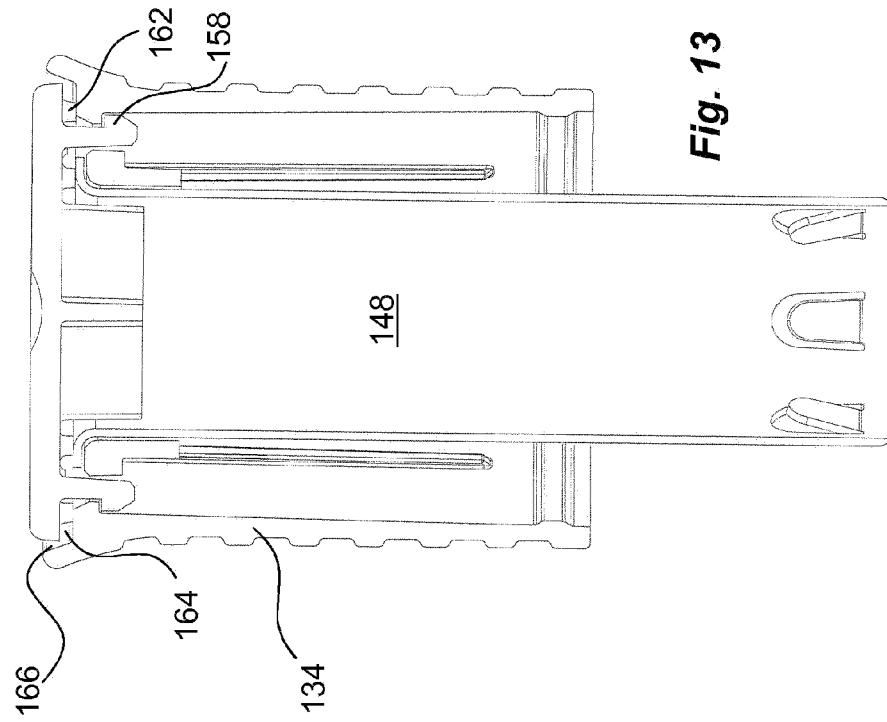


Fig. 8





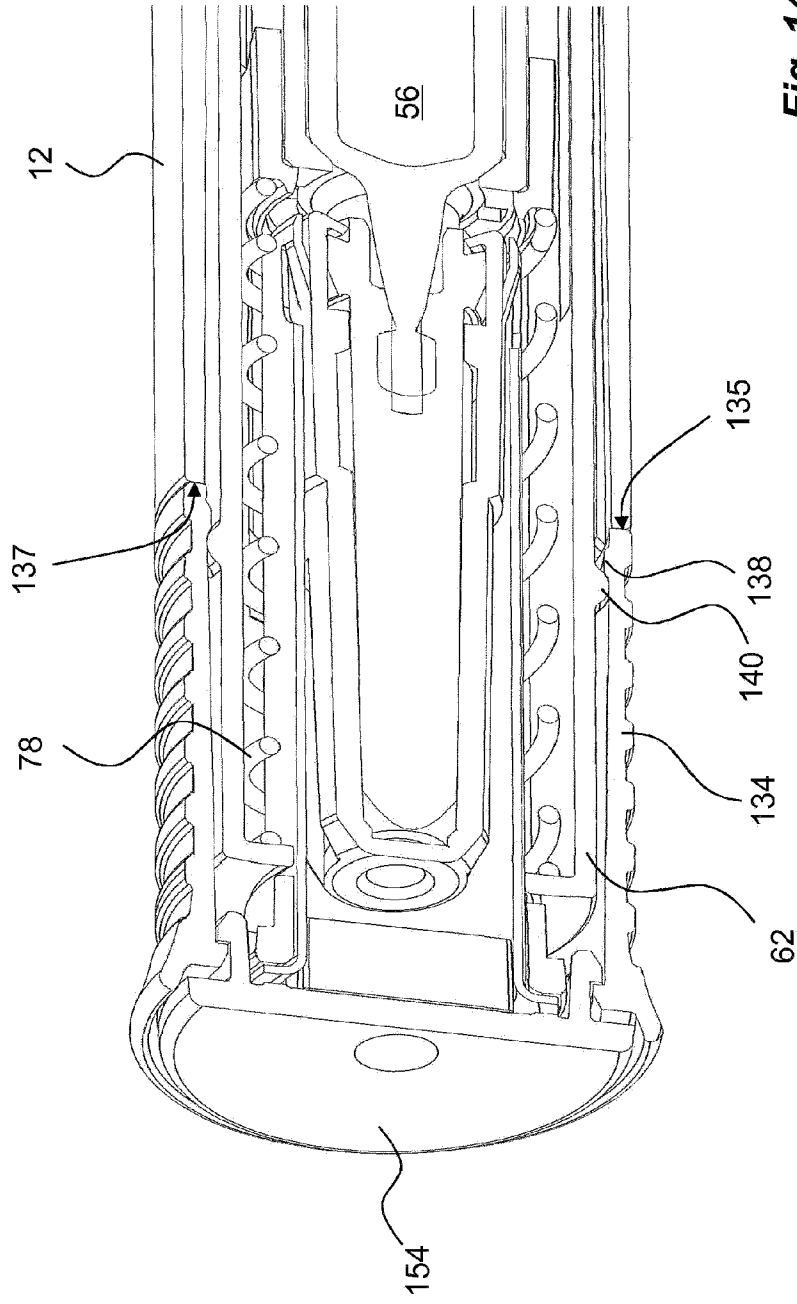


Fig. 14

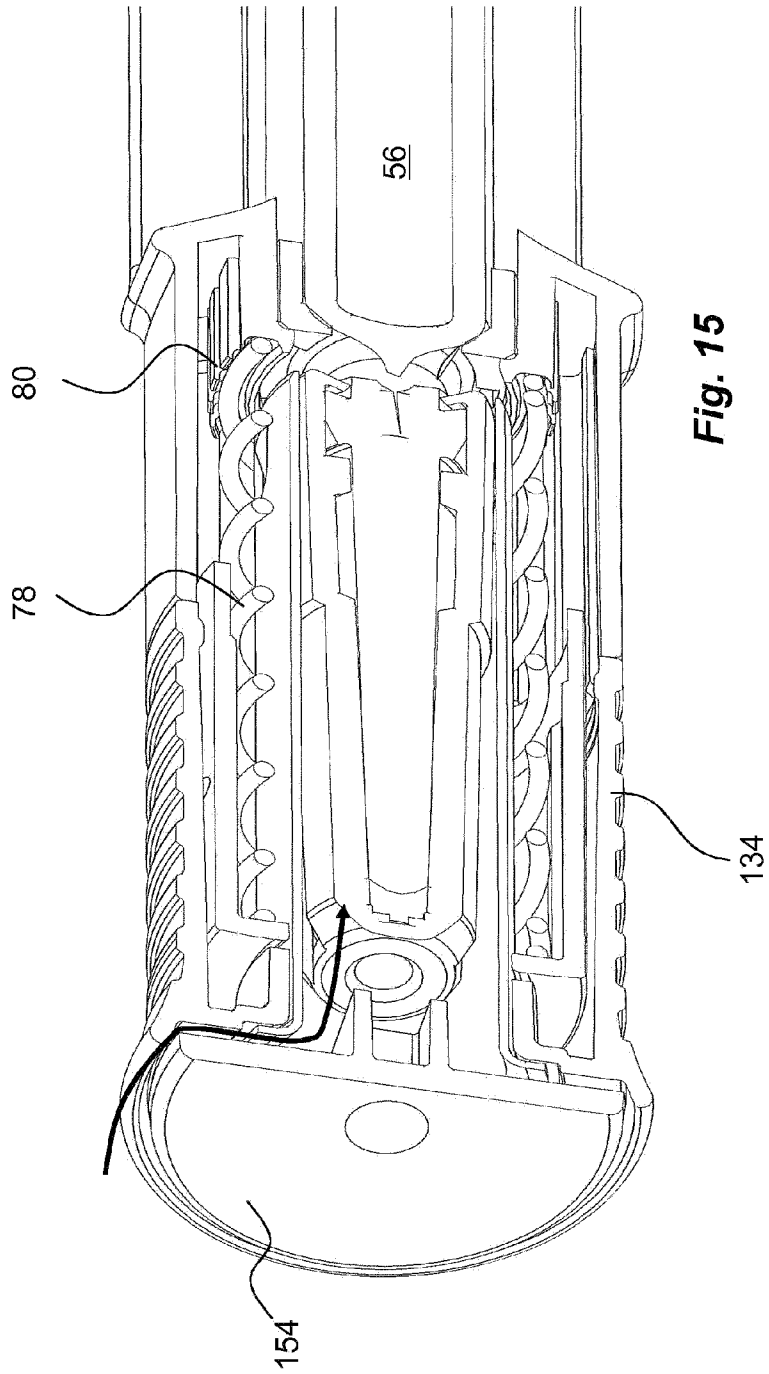


Fig. 15

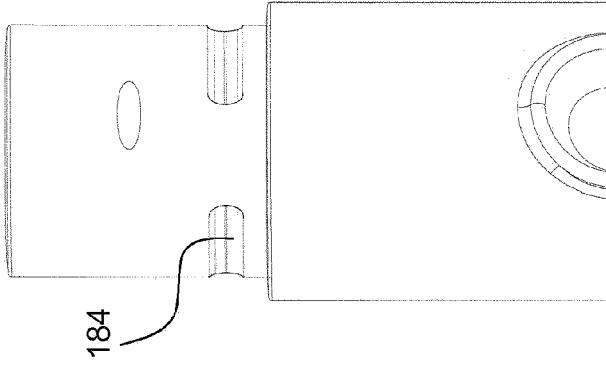


Fig. 16

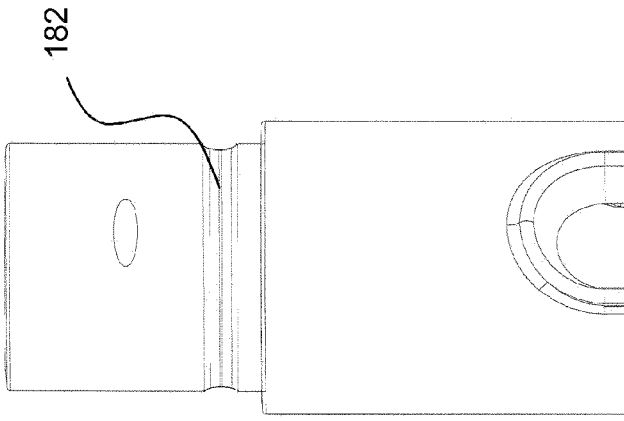


Fig. 17

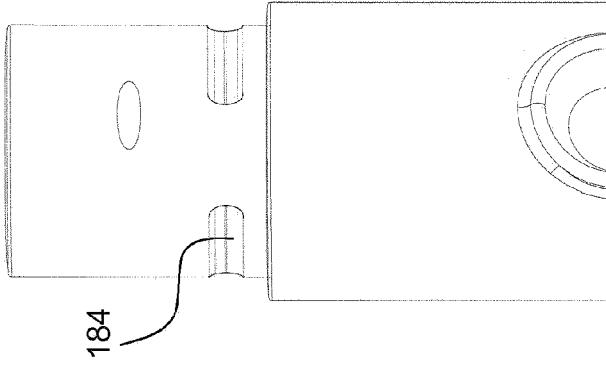


Fig. 18

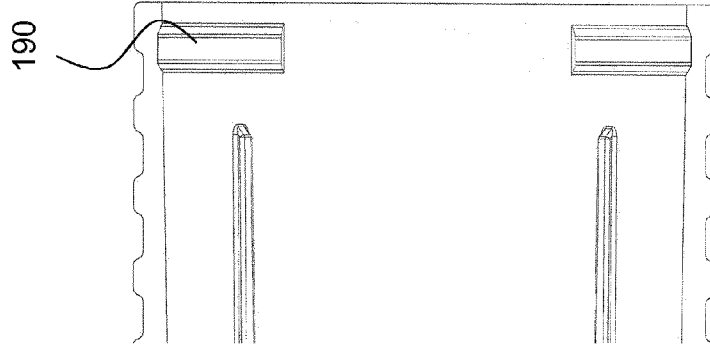


Fig. 21

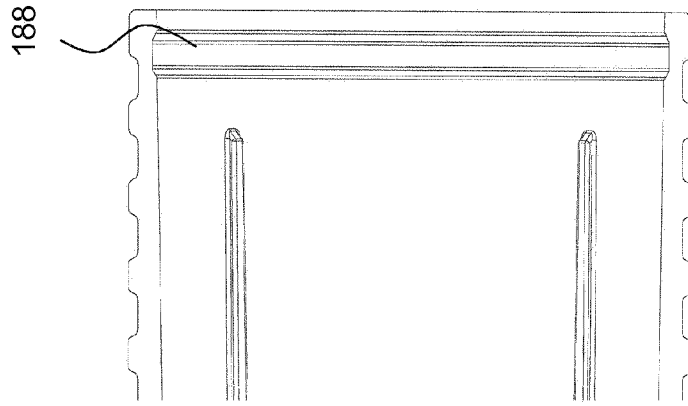


Fig. 20

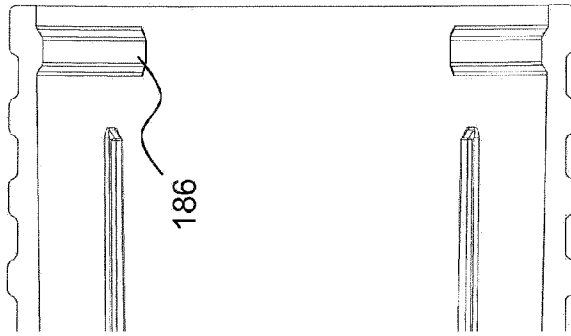


Fig. 19