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(54) Benævnelse: **SPRØJTESPIDSKAPPEANORDNING, SPRØJTE MED EN SÅDAN SPRØJTESPIDSKAPPE OG FREMGANGSMÅDE TIL AT FORSEGLE EN SPRØJTECYLINDER**

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DESCRIPTION

Field of Invention

[0001] The present invention generally relates to drug delivery devices and containers, and more specifically relates to a syringe tip cap assembly for securely sealing the tip of a syringe barrel, as well as a syringe and a method of sealing such a syringe with a resilient closure and a syringe tip cap.

Background of Invention

[0002] Conventional syringes, which are typically made of plastic or preferably of glass, comprise a barrel having an open proximal end and an opposite distal end. A cylindrical wall extends between the ends, which defines a substance retaining chamber. An elongate syringe tip projects from the distal end of the syringe barrel and includes a narrow passage which communicates with the substance retaining chamber of the barrel. A plunger may be inserted into the open proximal end of the syringe barrel for sliding fluid-tight engagement with the cylindrical chamber wall. Sliding movement of the plunger in a distal direction urges fluid in the chamber through the passage in the tip for administering the substance. Conversely, sliding movement of the plunger in a proximal direction draws fluid through the passage in the tip and into the chamber of the syringe barrel.

[0003] Such syringes may further include a needle assembly with a needle cannula having a proximal end, a pointed distal end and a lumen extending axially therethrough. The needle assembly also includes a hub which is engageable with mounting means on the syringe barrel for selectively placing the lumen of the needle cannula in fluid communication with the passage through the tip of the syringe barrel. Such a mounting means may be a luer collar disposed in spaced concentric relationship around the tip of the syringe barrel. The luer collar includes an array of threads for threaded engagement with corresponding structure on the hub of the needle. For example, the luer collar may include an array of internal threads which are engageable with projections extending outwardly from the hub of the needle cannula. Syringe barrels formed from plastic may have the luer collar unitarily molded therewith. However, glass syringe barrels may not be easily formed with an integral luer collar. Thus, glass syringe barrels and some plastic syringe barrels may have a separately formed luer collar securely mounted to the tip of the syringe barrel. The luer collar may rely upon a slip fit interengagement, a snap fit or other such secure mounting engagement around the tip of the syringe barrel.

[0004] Medications that are pre-filled into a syringe barrel must be sealed to prevent contamination or loss of the medication. For this purpose, stoppers or closures of an elastomeric material are mounted over the tip at the distal end of the syringe barrel to prevent

leakage and to avoid contamination of the medication. Tip caps according to the prior art have been formed from elastomeric material frictionally and/or resiliently retained in engagement with the tip of the prior syringe barrel and can be removed from the syringe tip shortly prior to usage of the syringe. The hub of the needle assembly may then be securely engaged with the luer collar or other mounting means adjacent the exposed tip of the syringe barrel. For example, the needle hub may be threadedly engaged within the luer collar such that the lumen of the prior needle cannula communicates with the exposed tip of the syringe barrel.

[0005] Such seals must be reliably held on the syringe tip, for sealing the syringe tip over an extended period of time. For this purpose, syringe tip caps are used, which retain the seals in axial direction and are configured to provide evidence of tampering or misuse of a pre-filled syringe.

[0006] One such syringe tip cap is disclosed in US 6,196,998 B1 and comprises an outer cap made of a rigid thermoplastic material, consisting of a proximal sleeve and a distal sleeve. The proximal sleeve is configured to be coupled with the collar, whereas the distal sleeve is configured for engagement with the resilient closure. Between the proximal and distal end, frangible portions are provided that serve as tamper evidence means and prevent a rotation of the distal end relative to the proximal end. As the proximal end is coupled with the collar of the syringe, it is difficult to couple the needle assembly with the collar after breaking the frangible portions for removal of the distal end of the outer cap.

[0007] US 2013/0338603 A1 (corresponding to WO 2012116790 A1) discloses a syringe tip cap according to the preamble of claim 1. The syringe tip cap comprises a distal cap member and a proximal sleeve member, wherein an annular first breaking line is formed between the distal cap member and the proximal sleeve member. Frangible portions, which serve as tamper indicator means, extend across the annular first breaking line, for coupling the distal cap member and the proximal sleeve member. A closure is accommodated inside the syringe tip cap, for closing off the needle attachment piece and forming a seal. The distal cap member surrounds the closure cap. The syringe tip cap is attached to the needle attachment piece by way of a holding ring. The distal cap member and the proximal sleeve member are configured in one piece, which can make manufacturing difficult. When the first breaking line is broken, the distal cap member and the proximal sleeve member are not coupled anymore. Therefore, this syringe tip cap is operated in a significantly different manner.

[0008] A related syringe is disclosed in US 2010/0168678 A1.

[0009] A further syringe cap is disclosed in US 2013/0237911 A1, which has, however, a complicated structure.

[0010] US 2012/0123334 A1 discloses in Figs. 11 to 14 an injection device tip including a single breaking line in the collar of a pen needle member. Once the section(s) of the breaking line is(are) broken, a slot allows the sidewall of the device tip to deflect inwardly or outwardly so that a thread section can engage with another thread section so that the pen needle can more

easily slide axially off threaded section. The device tip is spread apart, which cannot be compared with a pivoting of a distal cap member relative to a proximal cap member. A second breaking line and a hinge in the sense of the present application are not disclosed

[0011] US 5 344 404 A discloses a needle shield that is divided along the longitudinal axis into a plurality of separate needle shield segments. A frangible structure is provided for releasably holding the needle shield segments together and preventing removal of the needle shield from the syringe assembly. Disengagement of the frangible means allows the needle shield segments to separate and come apart to expose the needle cannula and after disengagement, the needle shield segments can no longer by themselves engage the tip of the barrel to shield the needle cannula. A second breaking line and a hinge in the sense of the present application are not disclosed

Summary of Invention

[0012] It is an object of the present invention to provide an enhanced syringe tip cap of a simple configuration that offers tamper evidence means, is configured to reliably hold a resilient closure at a syringe tip for sealing the syringe tip and can be produced easily and at lost costs. It is a further object of the present invention to provide an enhanced method of sealing a syringe using such a syringe tip cap and a syringe comprising such a syringe tip cap.

[0013] The above problems are solved by a syringe tip cap as claimed in claim 1, by a method of sealing a syringe as claimed in claim 13 and 14, respectively, and by a syringe as claimed in claim 15. Further advantageous embodiments are the subject-matter of the dependent claims.

[0014] A syringe tip cap as claimed by claim 1 serves for retaining a resilient closure at a distal end of a syringe tip on which a collar for coupling with a syringe needle is mounted. An annular first breaking line is formed between the distal cap member and the proximal sleeve member, which extends preferably perpendicular to an axial direction of the syringe tip cap / syringe barrel, but may also extend slanted at small angle relative to a direction perpendicular to the axial direction of the syringe tip cap / syringe barrel. The distal cap member is cup-shaped and configured for accommodating and covering a distal end of the resilient closure, and configured for pressing the resilient closure toward the syringe tip. The proximal sleeve member is formed as a tubular sleeve that can be fitted over the syringe tip and comprises a distal end and a proximal end configured to be coupled with the collar, for coupling the syringe tip cap with the distal end of the syringe tip.

[0015] According to the invention, a second breaking line is formed in the proximal sleeve member extending between the distal end and the proximal end of the proximal sleeve member, wherein the distal cap member and the proximal sleeve member of the rigid outer cap are connected with each other via an axial coupling strip, which bridges and disrupts the annular first breaking line, and wherein the frangible portions of the tamper indicator means are weaker than the coupling strip, so that the distal cap member and the proximal sleeve

member of the rigid outer cap can be partially separated by breaking the annular first breaking line and the coupling strip serves as a hinge for pivotally coupling the distal cap member and the proximal sleeve member of the rigid outer cap after the annular first breaking line has been broken.

[0016] By breaking the frangible portions of the annular first breaking line the distal cap member and the proximal sleeve member of the rigid outer cap can be partially separated to provide access to the upper surface of the resilient closure, which may be sufficient to couple the needle assembly with the collar and puncture the resilient closure for administering the medication. The first breaking line is broken preferably by pushing the distal cap member obliquely toward a distal end of the tip cap and pivoting it about the coupling strip. The coupling strip serves thus as a hinge for pivotally coupling the distal cap member and the proximal sleeve member of the rigid outer cap after the annular first breaking line has been broken.

[0017] This procedure for breaking the first breaking line and opening the tip cap for providing access to the resilient closure is convenient for a user and may be performed with one finger only, preferably with a thumb, while holding the syringe barrel with the other fingers of the same hand.

[0018] The second braking line extends substantially perpendicularly to the annular first breaking line, i.e. it may extend in axial direction or extend under a relatively small acute angle relative to the axial direction. Once the first breaking line is broken, the distal cap member may thus be used as a handle or tab to further pull-down the distal cap member in proximal direction. As this pulling direction (nearly) coincides with the direction of the second breaking line, the second breaking line can be broken easily. The syringe tip cap may thus be removed from the syringe tip easily and in a convenient, intuitive manner. The second breaking line preferably extends from the annular first breaking line until the proximal and of the proximal sleeve member, so that the proximal sleeve member may be easily torn-off until the proximal end of the sleeve member. According to a further embodiment, the second breaking line stops before reaching the proximal end of the proximal sleeve member so that, if the second breaking line is broken completely by breaking its frangible portions, the annular proximal end still remains to hold the proximal sleeve member on the syringe barrel, until also this annular proximal end is broken to tear-off the proximal sleeve member completely from the syringe barrel.

[0019] According to a further embodiment, a film hinge or thinner region extending perpendicular to the axial direction of the syringe tip cap is formed in the middle of the coupling strip, just in the center of the annular first breaking line. Thus, the distal cap member may be pivoted precisely about this film hinge at an early stage of opening the syringe tip cap already, for breaking the frangible portions of the annular first breaking line precisely and in a controllable, intuitive manner.

[0020] According to a further embodiment, the second breaking line formed in the proximal sleeve member is followed by a first slot, which is formed in the distal cap member and forms a

first edge of the axial coupling strip. Thus, by continuing pulling the distal cap member toward the proximal end of the syringe barrel, the second breaking line can be broken as well, so that the whole tip cap may then be torn off from the syringe barrel to provide full access to the resilient closure.

[0021] According to a further embodiment, the axial coupling strip is further delimited by a second slot which is formed in the distal cap member and extends in parallel with the first slot, so that the axial coupling strip is rectangular and extends in axial direction of the syringe tip cap. Thus, a pulling tab is automatically formed when pivoting and pulling the distal cap member toward the proximal end of the syringe barrel, which may ease the breaking of the second breaking line.

[0022] According to a further embodiment, the second breaking line is slanted at an acute angle relative to the axial direction of the syringe tip cap, wherein the second breaking line comprises frangible portions extending substantially perpendicular to the axial direction of the syringe tip cap. This acute angle may be of the order of a few degrees only, which may be sufficient to generate forces in a direction perpendicular to the axial direction of the syringe barrel when pulling the distal cap member toward the proximal end of the syringe barrel. These force components act in the same direction as the direction of the frangible portions of the second breaking line and thus help to break the second breaking line more easily and in a controlled manner.

[0023] According to a further embodiment, the proximal sleeve member of the syringe tip cap further comprises a third breaking line, which is preferably also formed by frangible portions that are broken if the third breaking line is broken. Preferably, the second and third breaking lines extend in parallel with each other so that the second and third breaking lines can be broken simultaneously to thereby form a rectangular pulling tab that can be used to more efficiently break the frangible portions of the second and third breaking lines when the distal cap member is pulled-down.

[0024] According to a further embodiment, the distal cap member comprises a step formed at a side wall of the distal cap member opposite to a position wherein the coupling strip bridges the second breaking line. This step precisely guides the movement of a user when pushing the distal cap member for breaking the annular first breaking line. Thus, already when pushing the step obliquely upward toward the distal end of the tip cap, the coupling strip serves as a hinge for pivotally coupling the distal cap member with the proximal sleeve member, which eases the breaking of the frangible portions of the annular first breaking line.

[0025] According to a further embodiment, the step is formed by a vertical side wall extending in the axial direction of the syringe tip cap and a slanted surface, which is slanted relative to a bottom of the distal cap member, so that by pushing the vertical side wall obliquely upward the distal cap member can be pushed from the proximal sleeve member of the rigid outer cap to thereby break the annular first breaking line and partially separate the proximal sleeve member from the rigid outer cap. The vertical side wall significantly eases the pushing of the distal cap

member for breaking the annular first breaking line and thus renders the handling of the syringe tip cap intuitive and user-friendly.

[0026] According to a further embodiment, a pressing member protrudes from an inner surface of the distal cap member of the rigid outer cap at a centre thereof, for pressing the resilient closure toward the syringe tip. This pressing member preferably protrudes from the inner surface over such a distance that the resilient closure can remain seated on the syringe tip and is not sheared off when the distal cap member is pivoted about the coupling strip. By adjusting the axial length of the pressing member, the pressure exerted onto the resilient closure, when the syringe tip cap is mounted, can be adjusted precisely in accordance with individual specifications.

[0027] According to a further embodiment, a transparent portion may be disposed in a side wall of the distal cap member so that a contact region between the pressing member and the resilient closure and/or an upper surface of the resilient closure is visible from outside the syringe tip cap.

[0028] According to a further embodiment, a plurality of locking protrusions is formed on an inner side wall of the proximal end of the proximal sleeve member, which are configured for coupling the syringe tip cap with the distal end of the syringe tip, e.g. for gripping behind an edge of the collar.

[0029] According to a further embodiment, the locking protrusion are formed at equiangular intervals along the inner side wall of the proximal end of the proximal sleeve member, said locking protrusions having slanted insertion surfaces so that the syringe tip cap can be pushed onto the syringe tip more easily.

[0030] According to a further embodiment, the diameter of a circle along which the plurality of locking protrusions is disposed is smaller than a maximum outer diameter of the distal end of the resilient closure to be accommodated in the cup-shaped distal cap member so that the resilient closure can be retained in axial direction inside the cup-shaped distal cap member by the plurality of locking protrusions. This eases the mounting of the resilient closure and of the syringe tip cap on the distal end of a syringe barrel. Particularly, the syringe tip cap together with the resilient closure accommodated therein simply may be pushed in axial direction on the distal end of the syringe barrel to thus mount the syringe tip cap and at the same time to precisely position the resilient closure on the syringe tip, for sealing the syringe tip.

[0031] According to a further embodiment, a plurality of ridges may be formed on an inner surface of the proximal sleeve member, wherein the ridges are disposed at equiangular intervals along the inner surface of the proximal sleeve member and enclose a circle having a diameter, which is substantially equal to an outer diameter of the collar.

[0032] According to a further embodiment, the tip cap further comprises a resilient closure, which is accommodated and axially retained in the cup-shaped distal cap member.

[0033] A further unitary aspect of the present invention is directed to a method of sealing a syringe barrel for administering a liquid containing a pharmaceutical drug, said method comprising the steps of: providing the syringe barrel having a syringe tip at a distal end thereof on which a collar for coupling with a syringe needle is mounted; sealing the syringe tip with a resilient closure; providing a syringe tip cap as outlined in the following; and pushing the syringe tip cap in axial direction on the distal end of the syringe barrel until the proximal end of the syringe tip cap is coupled with the collar and the resilient closure is pressed on the distal end of the syringe tip, for sealing the syringe tip.

[0034] A further unitary aspect of the present invention is directed to a method of sealing a syringe for administering a liquid containing a pharmaceutical drug, said method comprising the steps of: providing the syringe barrel having a syringe tip at a distal end thereof on which a collar for coupling with a syringe needle is mounted; providing a syringe tip cap as outlined in the following, which accommodates and axially retains a resilient closure in the cup-shaped distal cap member; and pushing the syringe tip cap together with the resilient closure in axial direction on the distal end of the syringe barrel until the resilient closure seals the syringe tip, the proximal end of the syringe tip cap is coupled with the collar and the resilient closure is pressed on the distal end of the syringe tip, for sealing the syringe tip.

[0035] A further aspect of the present invention relates to a syringe, wherein a syringe tip cap as outlined in the following is mounted at the distal end of a syringe tip of the syringe barrel, which engages with the collar at the syringe tip and retains a resilient closure at the distal end of the syringe tip, for sealing the syringe tip.

Overview on Drawings

[0036] The invention will now be described by way of example and with reference to the accompanying drawings, from which further features, advantages and problems to be solved will be-come apparent. In the drawings:

Fig. 1
: shows a typical syringe barrel to be sealed by a resilient closure, for use with a syringe tip cap of the present invention;

Figs. 2a and 2b
: show in a perspective front and rear view a syringe barrel with a luer collar and a resilient closure mounted on the syringe tip;

Figs. 3a to 3c
: show a syringe tip cap according to a first embodiment of the present invention in two perspective side views and a perspective bottom view;

Figs. 4a and 4b
: show in a perspective front and rear view the syringe barrel of Figs. 2a and 2b with the syringe tip cap of the first embodiment of the present invention;

Figs. 4c and 4d
: show in a front and rear view the syringe barrel of Figs. 2a and 2b with the syringe tip cap of the first embodiment in an enlarged view;

Figs. 5a to 5c
: show in different perspective top views the condition of a syringe tip cap of the first embodiment of the present invention after breaking a first annular breaking line at a first stage of removing the syringe tip cap from the syringe barrel;

Figs. 6a to 6c
: show in different perspective top views the condition of a syringe tip cap of the first embodiment of the present invention after breaking a second breaking line at a second stage of removing the syringe tip cap from the syringe barrel, subsequent to the first stage of Figs. 5a to 5c;

Figs. 7a and 7b
: show a syringe tip cap according to a second embodiment of the present invention in a perspective side view and a bottom view;

Fig. 7c
: shows in a side view the syringe barrel of Figs. 2a and 2b with the syringe tip cap of the second embodiment in an enlarged view; and

Figs. 8a to 8c
: show in different perspective top views the condition of a syringe tip cap of the second embodiment of the present invention after breaking the second and third breaking lines at a second stage of removing the syringe tip cap from the syringe barrel.

[0037] In the drawings, the same reference numerals designate identical or substantially equivalent elements or groups of elements.

Detailed description of preferred embodiments

[0038] As shown in Fig. 1, the syringe 6 includes a syringe barrel 60 which is formed from glass or plastic and is preferably transparent. The syringe barrel 60 includes a proximal end 61 having a flange 67, a distal end 62 and is a cylindrical body defining a substance receiving chamber which may be pre-filled with a selected dose of medication in either dry or liquid form, as well as other substances such as water or diluent for use in reconstituting a medicament. The distal end 62 of syringe barrel 60 includes a tip 64 having a passage extending therethrough and communicating with the substance receiving chamber. A plunger rod assembly (now shown) may extend into the proximal end 61 of the syringe barrel 60 via the filling opening 68, and include a stopper, which may slide in fluid-tight engagement inside the cylindrical wall. The syringe barrel 60 may be used with a standard needle assembly (not shown), which is generally known from the prior art.

[0039] The syringe barrel 60 generally does not have an integral collar for engaging the

mounting hub of the needle assembly. As shown in Figs. 2a and 2b, for this purpose a collar 4, particularly a luer collar, is mounted to the syringe tip 64 at the distal end 62 of the syringe barrel 60. The collar 4 includes a generally cylindrical body 40, having locking members 43 at a proximal end 42 thereof, configured for engagement with the syringe tip 64, e.g. with a groove or ridge 64 (see Fig. 1) provided on the outer surface of the syringe tip 64.

[0040] The needle assembly may be maintained separate from the syringe barrel 60, and may be mounted to the syringe barrel 60 a short time prior to usage of syringe 6. In this way, the syringe barrel 60 may be pre-filled with medication, and stored in its pre-filled condition prior to mounting needle assembly 30 thereto. To prevent contamination or leakage of medication stored in syringe barrel 60, a resilient closure 5 shown in Figs. 2a and 2b seals the syringe tip 64. The resilient closure 5 is preferably made of an elastomeric material and comprises a cylindrical body (not shown), which is inserted into the syringe tip 64 to seal it. The distal end of the resilient closure 5 is of cylindrical shape and of a larger diameter, which usually corresponds to the outer diameter of syringe barrel 60. On the upper surface 51 of the distal end 50 and annular protrusion 52 is formed that can be used by a pressing member to exert a controlled and uniformly spread pressure onto the resilient closure 5, for pressing the resilient closure 5 in a controlled manner on syringe tip 64.

[0041] In order to keep the resilient closure 5 in place, in a proper engagement with the syringe tip 64 and to prevent a contamination of the resilient closure 5 during storage, a tip cap assembly generally denoted by reference numeral 1 is provided on the syringe tip 64 of the syringe barrel 60, as generally shown in Figs. 4a and 4b.

[0042] The tip cap 1 is generally cup-shaped and suited to fully accommodate at least the distal end 50 of the resilient closure 5, for preventing a contamination of the distal end 50. The tip cap 1 is made of a rigid or sufficiently stiff plastic material, preferably by plastic injection molding. The tip cap 1 generally is a tubular member and preferably has a closed upper surface 20 at a distal end thereof, for covering the entire distal end of closure 5. More specifically, the tip cap 1 consists of a distal cap member 2 and a proximal sleeve member 3 that are connected with each other via frangible, web-like portions 11 disposed along a first annular breaking line 10 formed between the distal cap member 2 and the proximal sleeve member 3. These frangible, web-like portions 11 serve as tamper indicator means, as outlined below in more detail.

[0043] As shown in Figs. 3a to 3c, the distal cap member 2 of the first embodiment of the present invention is generally cup-shaped, for fully accommodating the entire distal end of the resilient closure. When mounted on the distal end of syringe barrel 60, the annular first breaking line 10 is preferably below the position of the distal end 50 of closure 5, to provide full access to the closure 5 once the annular first breaking line 10 is broken and the distal cap member 2 is partially separated from the proximal sleeve member 3, as outlined below in more detail.

[0044] As shown in Fig. 3a, the distal cap member 2 is a cup-shaped cylindrical body having a

closed upper surface 20, which is surrounded by a rounded upper rim 21 connecting with the circumferential side wall. The inner diameter of the distal cap member 2 is slightly larger than the outer diameter of the distal end 50 of closure 5 so that the closure 5 can be easily inserted and accommodated with radial play inside the distal cap member, when it is not compressed.

[0045] The annular first breaking line 10 is not fully circumferential, but disrupted by a coupling strip 29, which bridges the annular first breaking line 10 and couples the distal cap member 2 with the proximal sleeve member 3. The frangible portions 11 are weaker than the axial coupling strip 29. Hence, when the frangible portions 11 are broken by tilting the distal cap member 2 about coupling strip 29, the coupling strip 29 will continue coupling the distal cap member 2 with the proximal sleeve member 3. Thus, after breaking the annular first breaking line 10, the distal cap member 2 and the proximal sleeve member 3 will be separated only partially, but remain coupled with each other via coupling strip 29. The coupling strip 29 will thus serve as a hinge for pivotally coupling the distal cap member 2 and the proximal sleeve member 3 of the rigid outer cap 1 after the annular first breaking line 10 has been broken.

[0046] In order to ease a breaking of the annular first breaking line 10, a handling section is formed at the distal cap member 2 at a position opposite to the coupling strip 29 and slightly offset toward the distal end 20 of the distal cap member 2, so that a pivoting force will be exerted on the distal cap member 2 when operating the handling section, to ease a pivoting of the distal cap member 2 about the hinge formed by the coupling strip 29. More specifically, this handling section may be formed by a stepped portion on the outer surface of the distal cap member 2, as shown in Fig. 3a. This stepped portion is formed by a planar, vertical side wall 23, which extends from the distal end 20 toward the step 25, which is a substantially horizontal surface near the proximal end 26 of the distal cap member 2 and is connected with the vertical side wall 23 via a rounded horizontal edge 24. This stepped portion can be operated easily by a finger, preferably by a thumb, while holding the syringe barrel 60 with a hand. It is preferred to operate the tip cap 1 with only one hand, in which case the syringe barrel 60 will be held with the fingers of one hand, while the stepped portion will be pushed radially inward and toward the distal end 20 under an acute angle with respect to an axial middle line of the syringe barrel 60 so that a pivoting force will be exerted onto the distal cap member 2, which will finally break the frangible portions 11 of the first annular breaking line 10 and will finally result in the condition shown in Figs. 5a to 5c.

[0047] As shown in Fig. 3b, the rectangular coupling strip 29 of the distal cap 2 is integrally connected with an opposite, rectangular coupling strip 39 of the proximal sleeve 3. More specifically, the coupling strips 29, 39 have a wedge-shaped profile, if viewed in a cross-sectional view, so that a film hinge is formed at the region where the two coupling strips 29, 39 are connected with each other. As shown in Fig. 3b, this film hinge is at the center of the first breaking line 10 and thus eases and guides the pivoting of the distal cap 2 about the proximal sleeve 3.

[0048] As shown in Fig. 3b, the coupling strip 29 is laterally delimited by two rectangular slots 28a, 28b and 37b, 38, respectively, which both extend in axial direction and are formed in the

side wall of both the distal cap member 2 and the proximal sleeve member 3. More specifically, a first slot 28a is formed at a first side of the coupling strip 29 in the distal cap member 2 and a second slot 28b is formed at a second side of the coupling strip 29, in parallel with the first slot 28a. Directly opposite to these two slots 28a, 28b two corresponding slots 37b, 38 are formed at the distal end 31 of the proximal sleeve member 3. The first slot 37b communicates with a second breaking line 35 formed in the proximal sleeve member 3, extending between the distal end 31 and proximal end 30 thereof. Web-shaped second frangible portions 36 extend horizontally across the second breaking line 35. It is noted that the second breaking line 35 preferably extends under an acute angle with respect to the axial direction, preferably at an angle in the range between 45 degrees and 5 degrees, more preferably at an angle in the range between 30 degrees and 5 degrees and even more preferably at an angle in the range between 20 degrees and 10 degrees. It is also noted that the first slot 37b of the proximal sleeve member 3 extends in axial direction and can be considered as an extension of the first slot 28a of distal cap member 2.

[0049] As indicated by the dashed lines in Fig. 4d, the slot 38 in the proximal sleeve member 3 opposite to the axial slot 28b is optional any may also be omitted.

[0050] As shown in Fig. 3c, a plurality of locking protrusions 34 is formed on the inner surface of the proximal sleeve member 3 at a proximal end 30 thereof. The locking protrusions 34 are preferably disposed at equiangular distances to each other and protrude in radial direction inwards and each have an upper surface (not shown), which extends substantially perpendicularly to the side wall of proximal sleeve member 3, and a slanted insertion surface, which is directed toward the proximal end 30 for guiding the tip cap 1 when it is pushed over the distal end of the collar 4, as outlined below in more detail. After the tip cap 1 has been mounted on the syringe tip, the locking protrusions 34 grip behind the distal end of the collar 4, for coupling the tip cap 1 with the syringe 6.

[0051] As shown in Fig. 3c, a plurality of axial ridges 32 is formed on the inner side wall 33 of proximal sleeve member 3 and disposed at a distance to the locking protrusions 34 and at equiangular intervals along the inner side wall 33 of proximal sleeve member 3. The ridges 32 enclose a circle having a diameter, which is substantially equal to an outer diameter of the collar 4 and/or the syringe 6, so that the collar 4 and/or the syringe 6 may abut with these ridges 32 in a mounted position. The ridges 32 serve for precisely centering the syringe in the tip cap 1 and for reducing friction when mounting the tip cap 1.

[0052] In the following, two methods according to the present invention for mounting the tip cap 1 on the syringe tip and sealing a syringe are described with reference to Figs. 1 to 3c. According to a first embodiment of the method, first the resilient closure 5 is put on the syringe tip 64. Afterwards, the tip cap 1 is pushed on the distal end 62 of the syringe barrel 60, until the slanted insertion surfaces of the locking protrusions 34 get in contact with the distal edge of the collar 4. Then, the tip cap 1 is further pushed onto the distal end of syringe barrel 60 so that the front ends of the locking protrusions 34 slide over the outer surface of collar 4, until the locking protrusions 34 grip behind the proximal end of collar 4 to thereby retain the tip cap 1 on

syringe barrel 60. In this position, the distal end 20 of tip cap 1 may slightly compress the resilient closure 5 and press it on syringe tip 64 to seal the syringe tip 64 safely. For exerting a controlled pressure on the upper surface 51 of the resilient closure 5 and properly spread this pressure over the upper surface 51, a cylindrical protrusion 27 (see Fig. 5a and Fig. 7b) may be formed on the inner surface of the distal end 20 of the distal cap member 2, in which case the pressure exerted on the upper surface 51 of the resilient closure 5 may be controlled by the axial length of the cylindrical protrusion.

[0053] According to a second embodiment of the method, first the resilient closure 5 is inserted into the tip cap 1. Because the diameter of a circle along which the plurality of locking protrusions 34 is disposed on the inner side wall 33 of proximal sleeve member 3 is smaller than a maximum outer diameter of the distal end 50 of the resilient closure 5 the resilient closure 5 is retained in axial direction inside the cup-shaped distal cap member 2 by the plurality of locking protrusions 34. Afterwards, the syringe tip cap 1 together with the resilient closure 5 are pushed in axial direction on the distal end 62 of syringe barrel 60 until the slanted insertion surfaces of the locking protrusions 34 get in contact with the distal edge of the collar 4. Then, the tip cap 1 is further pushed onto the distal end of syringe barrel 60 in the same manner as outlined in the previous section, until the locking protrusions 34 grip behind the proximal end of collar 4 to thereby retain the tip cap 1 on syringe barrel 60.

[0054] Because the resilient closure 5 is fully accommodated in the cup-shaped distal cap member 2, particles from outside cannot contaminate the upper surface 51 of the resilient closure 5. Figs. 4a and 4b show the syringe 6 with the syringe tip cap 1 according to the present invention mounted at the distal end of syringe 6. Figs. 4c and 4d show the syringe 6 with the syringe tip cap 1 according to the present invention mounted at the distal end of syringe 6 in an enlarged partial view.

[0055] For permitting a visible inspection of the contact area between the pressing member 27 (see Fig. 5a) on the inner surface of the distal end 20 and the upper surface 51 of the resilient closure 5, a transparent window (not shown) may be provided in a side wall of the distal cap member 2, particularly in the vertical side wall 23, so that the upper surface 51 of resilient closure 5 and/or the upper surface 51 of the resilient closure 5 is visible from outside the syringe tip cap 1. This transparent window may be integrally formed with the tip cap 1, particularly by two-component plastic injection molding.

[0056] In the following, a process for giving access to the resilient closure 5 by partially separating the distal cap member 2 from the proximal sleeve member 3 and even for completely removing the tip cap 1 will be described with reference to Figs. 4a to 6c.

[0057] At a first stage, a force directed obliquely toward the distal end of the syringe 6 is exerted on the distal cap member 2 by a user, particularly by pushing the vertical side wall 23 obliquely upward toward the distal end with the thumb of the user. This force will finally break the frangible portions 11 of the first annular breaking line 10 which hence serve as a tamper indicator means to provide such tamper evidence, as an integral and unmistakable evidence of

tampering with the syringe barrel 60 and the medication therein. When the annular first breaking line 10 is broken, the distal cap member 2 is pivoted about the coupling strip 29, which is disposed opposite to the vertical side wall, until the condition shown in Figs. 5a to 5c is reached. In this condition access is gained to the upper surface 51 of the resilient closure 5, which may be sufficient for administering the medication inside syringe barrel 60.

[0058] To gain full access to the entire resilient closure 5, the tip cap 1 may also be removed completely, which will be described with reference particularly to Figs. 6a to 6c in the following.

[0059] For tearing off the tip cap 1 completely, the user may proceed further by gripping the distal end of syringe 6 with two fingers of one hand, particularly with the thumb and forefinger, and gripping the distal cap member 2 with two fingers of the other hand, particularly with the thumb and forefinger of the other hand. The user will continue tearing the distal cap member 2 into the same direction as previously pushing the distal cap member 2. In this condition, the distal cap member 2 will further pivot about the coupling strip 29 opposite to the vertical side wall 23. Finally, the distal cap member 2 is pivoted to such an extent about the coupling strip 29 that the coupling strip 29 basically serves as shackle to ease breaking the second breaking line 35 and completely tearing off the tip cap 1. This function is enhanced, because the two axial slots 37b and 38 that delimit the coupling strip 29 in the side wall of the proximal sleeve 3 enable pulling the coupling strip 29 a distance away from the side wall of the proximal sleeve member 3. Finally, the coupling strip 29 can be pulled in axial direction toward the proximal end of the proximal sleeve member 3, because the slot 37b serving as the distal end of the second breaking line 35 also extends in axial direction.

[0060] Then, the user continues pulling the coupling strip 29 toward the proximal end 30 of proximal sleeve member 3 so that one frangible portion 36 of the second breaking line 35 after the other is finally broken, as shown particularly in Fig. 6b, so that the proximal sleeve 3 can be unwound finally from the distal end of syringe 6, as shown particularly in Fig. 6c. That rim of the second breaking line 35 that is provided on the same side of the second breaking line 35 as the coupling strip 29 may thus serve as a pulling tab 13, as shown in Fig. 6c, for further pulling the proximal sleeve member and unwind the proximal sleeve member 3 from the distal end of the syringe 6. For this purpose, the user may grip the side of the proximal sleeve member 3 opposite to this pulling tab 13 and continue pulling the coupling strip 29, until all frangible portions 36 of the second breaking line 35 are broken and the proximal sleeve member 3 is finally unwound from the distal end of the syringe 6. Then, full access is gained to the resilient closure 5 on the distal end of syringe 6, for further handling, such as puncturing the closure 5 with a needle etc.

[0061] To enable the above handling of the tip cap 1, the material of the tip cap 1 should be sufficiently flexible, particularly in the region of the coupling strip 29 bridging the annular first breaking line 10.

[0062] Figs. 7a and 7b show a syringe tip cap 1 according to a second embodiment of the present invention. As shown in Fig. 7a, the second breaking line 35a extends basically in the

axial direction of the syringe tip cap 1, but stops a short distance before reaching the proximal end 30 of the proximal sleeve member 3. According to this second embodiment, a third breaking line 35b extends in parallel with the second breaking line 35a, and may extend until the proximal end 30. Both the second and third breaking line 35a, 35b are formed by a linear groove which is bridged by web-shaped frangible portions 36 that are broken when breaking the second and third breaking line 35a, 35b. The second and third breaking line 35a, 35b is each followed by a respective short slot 28a, 28b formed in the distal cap member 2 at an opposite side of the annular first breaking line 10. As shown in Fig. 7a, the coupling strip 29 does not necessarily comprise a hinge as for the above first embodiment. Of course, such a hinge may be provided also in the second embodiment.

[0063] Once the annular first breaking line 10 is broken and the distal cap member 2 is pulled down toward the proximal end 30 the frangible portions 36 of the second and third breaking line 35a, 35b are broken, one after the other, so that a pulling tab of rectangular shape is formed between the second and third breaking line 35a, 35b, which acts as a lever for more efficiently break the second and third breaking line 35a, 35b when the distal cap member 2 is pulled down further toward the proximal end 30. Figs. 8a to 8c show this pulling tab 13 at the second stage of removing the syringe tip cap 1 from the syringe barrel 60 by pulling down the distal cap member 2 toward the proximal end 30.

[0064] Fig. 7c shows the syringe tip cap 1 of the second embodiment in a rear side view, when mounted on the syringe barrel 60. Of course, the second and third breaking line 35a, 35b may also extend under an acute angle relative to the axial direction of the syringe tip cap 1, just as in the case of the first embodiment described above.

[0065] Fig. 7b shows a bottom view of the syringe tip cap 1 of the second embodiment. The pressing member formed in the bottom of the cap 1 consists of two concentric circular protrusions 27a, 27b, which may be of identical height, but which may also have different heights. The diameter of the outer pressing member 27b may be similar or slightly smaller than the diameter of protrusion 52 (see Figs. 2a and 2b) of the resilient closure. The inner pressing member 27a is used to exert a controlled pressure at a central part of the upper surface 51 of resilient closure 5. The cooperation of the inner and outer pressing member 27a, 27b ensures a reliable sealing of the ejection opening 66 (see Fig. 1) of syringe barrel 60.

[0066] While the preferred embodiments of the present invention have been described so as to enable one skilled in the art to practice the device of the present invention, it is to be understood that variations and modifications may be employed without departing from the concept and intent of the present invention as defined in the appended claims. Accordingly, the preceding description is intended to be exemplary and should not be used to limit the scope of the invention. The scope of the invention should be determined only by reference to the appended claims.

List of reference numerals

[0067]

1
: syringe tip cap

2
: distal cap member

3
: proximal sleeve member

4
: collar

5
: resilient closure

6
: syringe

10
: annular first breaking line

11
: frangible portion / coupling web

12
: gap

13
: pulling tab

20
: upper surface / distal end

21
: rounded upper rim

22
: edge

23
: vertical side wall

24
: edge

25
: step / slanted surface

26
: proximal end

27
: pressing member

27a
: outer pressing member

27b
: inner pressing member

28a
first slot
28b
second slot
29
coupling strip

30
proximal end
31
distal end
32
inner ridge
33
inner side wall
34
locking protrusion
35
second breaking line
35a
second breaking line
35b
third breaking line
36
frangible portion / coupling web
37a
proximal end of second breaking line
37b
distal end of second breaking line
38
slot
39
coupling strip

40
cylindrical body
41
ridge
42
proximal end of collar 4
43
locking member

50
distal end of resilient closure 5

51
upper surface
52
protrusion
53
step

60
syringe barrel
61
proximal end
62
distal end
63
tip shoulder
64
syringe tip
65
groove
66
ejection opening
67
flange
68
filling opening

REFERENCES CITED IN THE DESCRIPTION

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Patentkrav

1. Sprøjtespidskappe til at fastholde en elastisk lukning (5) ved en distal ende af en sprøjtespids, hvorpå en krave (4) til at koble med en sprøjtenål er monteret, omfattende:

en stiv ydre kappe (1), der har et distalt kappeelement (2) og et proksimalt hylsterelement (3), hvor en ringformet første brudlinje (10) er dannet mellem det distale kappeelement (2) og det proksimale hylsterelement (3); manipulationsindikatororgan omfattende skrøbelige dele (11), som brydes, når den ringformede første brudlinje (10) brydes; hvor

det distale kappeelement (2) er kopformet til at akkommodere og dække en distal ende af den elastiske lukning (5), og konfigureret til at presse den elastiske lukning mod sprøjtespidsen; og

det proksimale hylsterelement (3) omfatter en distal ende (31) og en proksimal ende (30) konfigureret til at blive koblet med kraven (4), til at koble sprøjtespidskappen med den distale ende af sprøjtespidsen;

kendetegnet ved at

det proksimale hylsterelement (3) omfatter en anden brudlinje (35; 35a), der strækker sig mellem den distale ende og den proksimale ende af det proksimale hylsterelement;

det distale kappeelement (2) og det proksimale hylsterelement (3) af den stiv ydre kappe er forbundne med hinanden via en aksial koblingsstrimmel (29), som slår bro over og afbryder den ringformede første brudlinje; og de skrøbelige dele (11) af manipulationsindikatororganet er svagere end koblingsstrimlen (29), således, at

det distale kappeelement (2) og det proksimale hylsterelement (3) af den stive ydre kappe kan delvist adskilles ved at bryde den ringformede første brudlinje (10) og

koblingsstrimlen (29) fungerer som en hængsel til at drejeligt koble det distale kappeelement (2) og det proksimale hylsterelement (3) af den stive ydre kappe efter den ringformede første brudlinje (10) er brudt.

2. Sprøjtespidskappe ifølge krav 1, hvor den anden brudlinje (35; 35a) er efterfulgt af en første slids (28a), som er dannet i det distale kappeelement (2) og

danner en første kant af den aksiale koblingsstrimmel (29).

3. Sprøjtespidskappe ifølge krav 2, hvor den aksiale koblingsstrimmel (29) er yderligere begrænset af en anden slids (28b), som er dannet i det distale kappeelement (2), og strækker sig parallelt med den første slids (28a), således, at den aksiale koblingsstrimmel er rektangulær og strækker sig i aksial retning af sprøjtespidskappen.

4. Sprøjtespidskappe ifølge et hvilket som helst af de foregående krav, hvor den anden brudlinje (35; 35a) er skråtstillet ved en spids vinkel i forhold til den aksiale retning af sprøjtespidskappen, hvor den anden brudlinje omfatter skrøbelige dele (36), der strækker sig i alt væsentligt vinkelret på den aksiale retning af sprøjtespidskappen.

5. Sprøjtespidskappe ifølge et hvilket som helst af de foregående krav, yderligere omfattende en tredje brudlinje (35b), idet nævnte anden brudlinje (35a) og nævnte tredje brudlinje (35b) omfatter skrøbelige dele (36), som brydes, når den anden brudlinje og tredje brudlinje brydes, hvor den anden brudlinje og tredje brudlinje fortrinsvis strækker sig parallelt med hinanden.

6. Sprøjtespidskappe ifølge et hvilket som helst af de foregående krav, hvor det distale kappeelement (2) omfatter en trindel dannet ved en sidevæg af det distale kappeelement modstående en position, hvor koblingsstrimlen (29) slår bro over den anden brudlinje (35), hvor
trindelen er dannet af en vertikal sidevæg (23), der strækker sig i den aksiale retning af sprøjtespidskappen og en overflade (25), der strækker sig radialt indad vinkelret på eller skråtstillet i forhold til den aksiale retning, således, at ved at skubbe den vertikale sidevæg (23) skævt opad mod en distal ende af sprøjtespidskappen, da kan det distale kappeelement (2) adskilles fra det proksimale hylsterelement (3) af den stive ydre kappe for derved at bryde den ringformede første brudlinje (10) og delvist adskille det proksimale hylsterelement fra den stive ydre kappe.

7. Sprøjtespidskappe ifølge et hvilket som helst af de foregående krav, hvor et presseelement fremspringer fra en indre overflade af det distale kappeelement (2)

af den stive ydre kappe ved en midte deraf, til at presse den elastisk lukning mod sprøjtespidsen.

8. Sprøjtespidskappe ifølge krav 7, hvor en gennemsigtig del er tilvejebragt i en sidevæg af det distale kappeelement (2) således, at et kontaktområde mellem presseelementet og den elastiske lukning og/eller en øvre overflade af den elastiske lukning er synlig fra uden for sprøjtespidskappen.

9. Sprøjtespidskappe ifølge et hvilket som helst af de foregående krav, hvor en flerhed af låsningsfremspring (34) er dannet på en indre sidevæg af den proksimale ende (30) af det proksimale hylsterelement (3), som er konfigureret til at gribe bag ved en kant af kraven, til at koble sprøjtespidskappen med den distale ende af sprøjtespidsen, hvor låsningsfremspringet (34) er fortrinsvis dannet ved ligevinklede intervaller langs den indre sidevæg af den proksimale ende (30) af det proksimale hylsterelement (3), idet nævnte låsningsfremspring har skråtstillet indsættelsesoverflader således, at sprøjtespidskappen kan skubbes på sprøjtespidsen.

10. Sprøjtespidskappe ifølge krav 9, hvor diameteren af en cirkel langs hvilken flerheden af låsningsfremspring (34) er anbragt, er mindre end en maksimal ydre diameter af den distale ende (50) af den elastiske lukning (5) til at blive akkommoderet i det kopformede distale kappeelement (2) således, at den elastiske lukning fastholdes i aksial retning inden i det kopformede distale kappeelement af flerheden af låsningsfremspring.

11. Sprøjtespidskappe ifølge et hvilket som helst af de foregående krav, hvor en flerhed af ribber (32) er dannet på en indre overflade af det proksimale hylsterelement, hvor ribberne er anbragt i en afstand til låsningsfremspringet (34) og ligevinklet intervaller langs den indre overflade af det proksimale hylsterelement (3) og omslutter en cirkel, der har en diameter, som er i alt væsentligt lig med en ydre diameter af kraven (4) og/eller af sprøjten.

12. Sprøjtespidskappe ifølge et hvilket som helst af de foregående krav, yderligere omfattende en elastisk lukning (5), som er akkommoderet og aksialt

fastholdt i det kopformede distale kappeelement (2).

13. Fremgangsmåde til at forsegle en sprøjtecylinder til at indgive en væske indeholdende et farmaceutisk lægemiddel, omfattende trinnene:

at tilvejebringe sprøjtecylinderen (6), som har en sprøjtespids (64) ved en distal ende deraf, hvorpå en krave (4) til at koble med en sprøjtenål er monteret;

at forsegle sprøjtespidsen (64) med en elastisk lukning (5);

at tilvejebringe en sprøjtespidskappe (1) ifølge et hvilket som helst af de foregående krav; og

at skubbe sprøjtespidskappen (1) i aksial retning på den distale ende af sprøjtecylinderen (6) indtil den proksimale ende (3) af sprøjtespidskappen (1) er koblet med kraven (4) og den elastiske lukning (5) presses på den distale ende af sprøjtespidsen (64), til at forsegle sprøjtespidsen.

14. Fremgangsmåde til at forsegle en sprøjte til at indgive en væske indeholdende et farmaceutisk lægemiddel, omfattende trinnene:

at tilvejebringe sprøjtecylinderen (6), der har en sprøjtespids (64) ved en distal ende deraf, hvorpå en krave (4) til at koble med en sprøjtenål er monteret;

at tilvejebringe en sprøjtespidskappe (1) ifølge et hvilket som helst af kravene 1 til 12, som akkommoderer og aksialt fastholder en elastisk lukning (5) i det kopformede distale kappeelement (2); og

at skubbe sprøjtespidskappen (1) sammen med den elastiske lukning (5) i aksial retning på den distale ende af sprøjtecylinderen, indtil den elastiske lukning forsegler sprøjtespidsen (64), den proksimale ende af sprøjtespidskappen (1) er koblet med kraven (4) og den elastiske lukning (5) presses på den distale ende af sprøjtespidsen (64), til at forsegle sprøjtespidsen.

15. Sprøjte omfattende:

en sprøjtecylinder (6), der har et stofmodtagelseskammer og en sprøjtespids (64), der fremspringer fra en distal ende af sprøjtecylinderen med en fluidgennemgang, der strækker sig gennem nævnte sprøjtespids;
en krave (4), der koncentrisk omgiver sprøjtespidsen, til at koble med en sprøjtenål; og
en elastisk lukning (5), der har modstående proksimale og distale ender, idet nævnte proksimale ende definerer en spidsindgrebsdel til at forseglingsmæssigt indgribe sprøjtespidsen til at forsegle et stof indeholdt i stofmodtagelseskammeret af sprøjtecylinderen (6);
kendetegnet ved at
en sprøjtespidskappe (1) ifølge et hvilket som helst af kravene 1 til 12 er monteret ved den distale ende af en sprøjtespids (64), som indgriber med kraven (4) og fastholder den elastiske lukning (5) ved den distale ende af sprøjtespidsen (64), til at forsegle sprøjtespidsen.

DRAWINGS

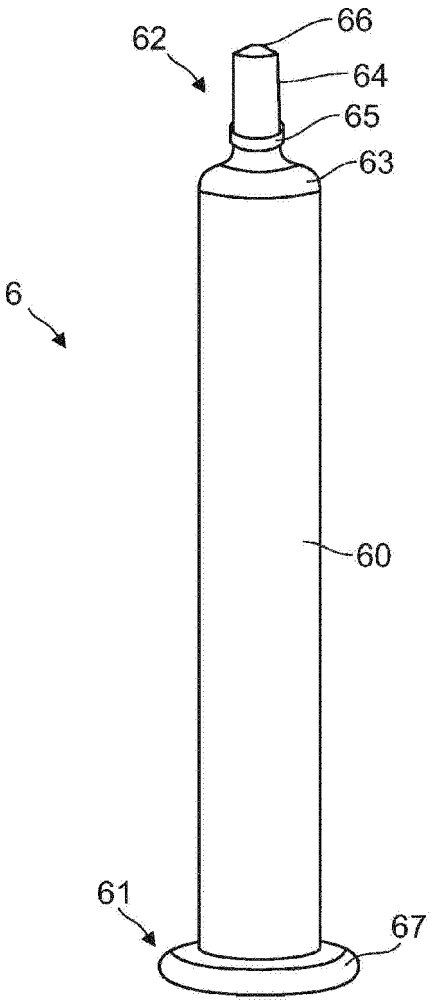


Fig. 1

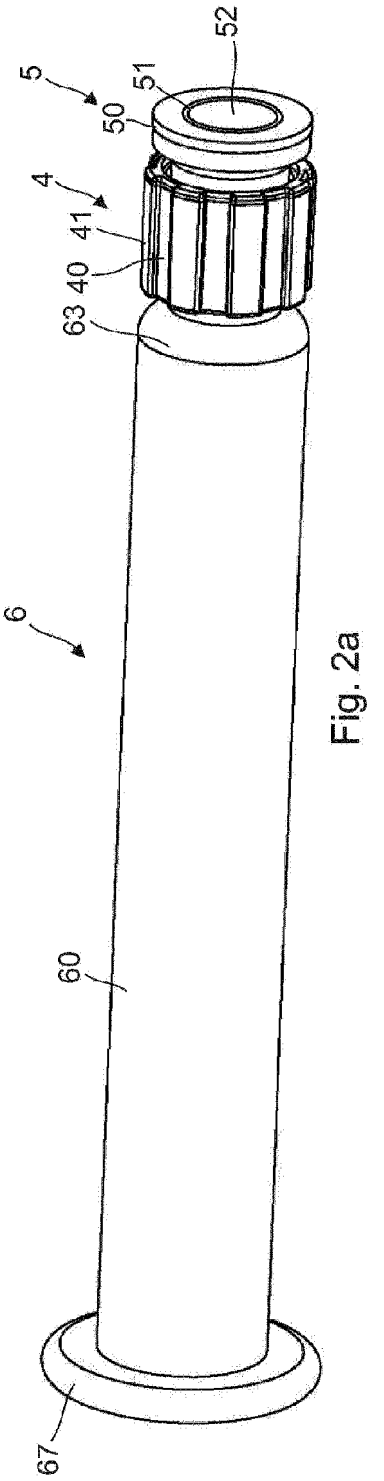


Fig. 2a

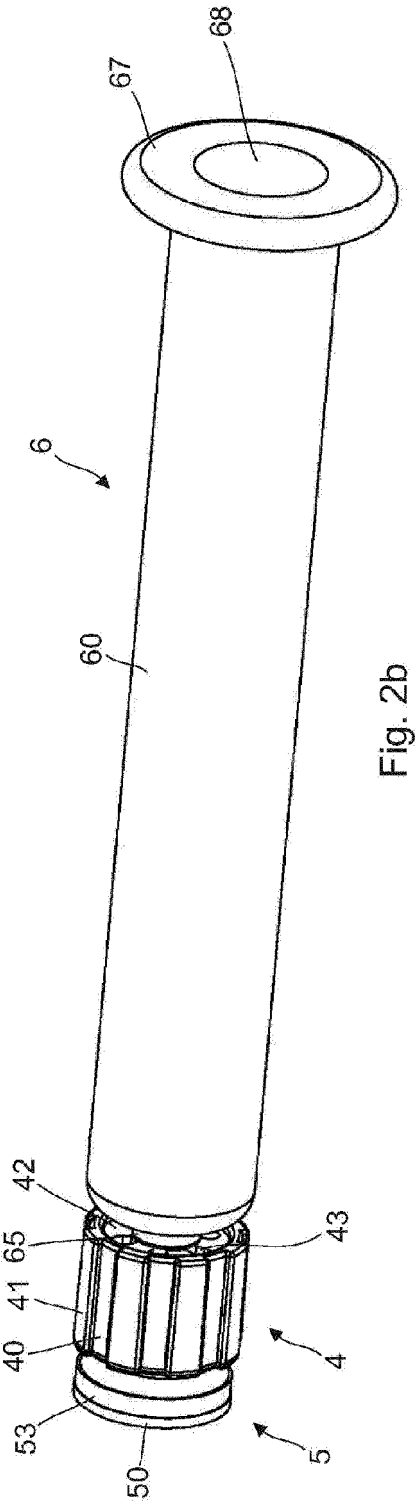


Fig. 2b

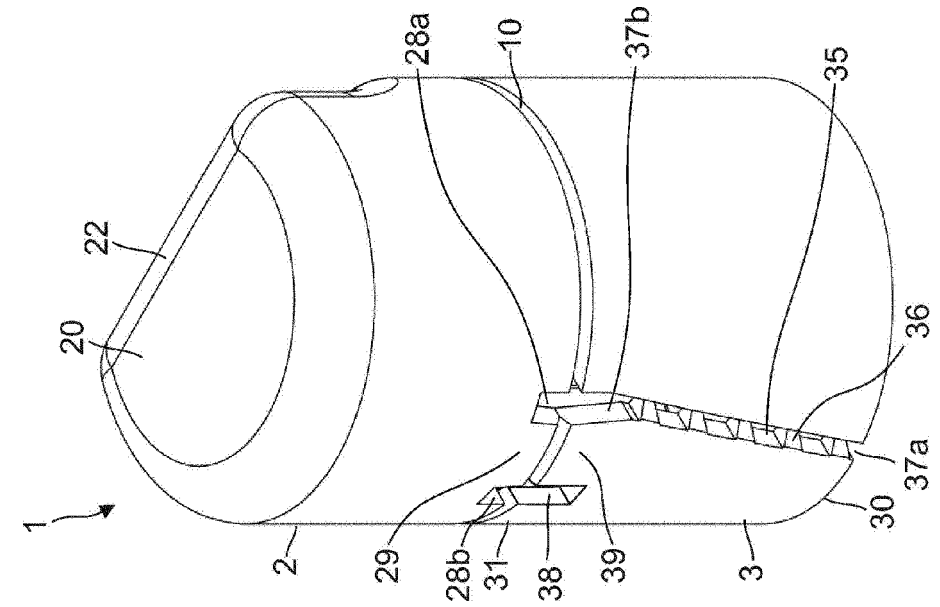
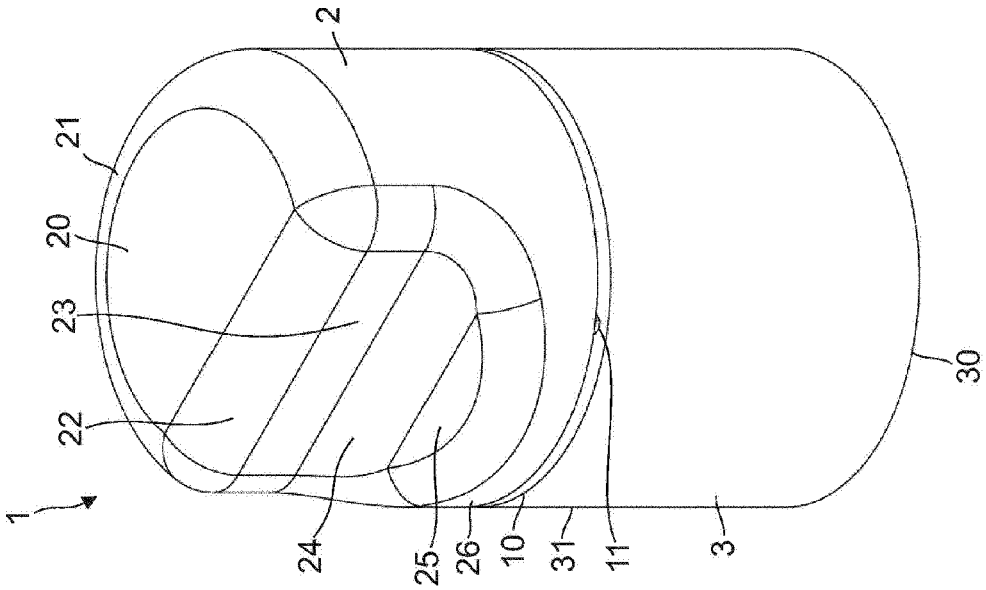

28a
10
37b
35
22
20
36
37a
30
1
2
29
28b
31
38
39
3

Fig. 3b


2
21
20
23
22
30
1
24
25
26
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31
11
3

Fig. 3a

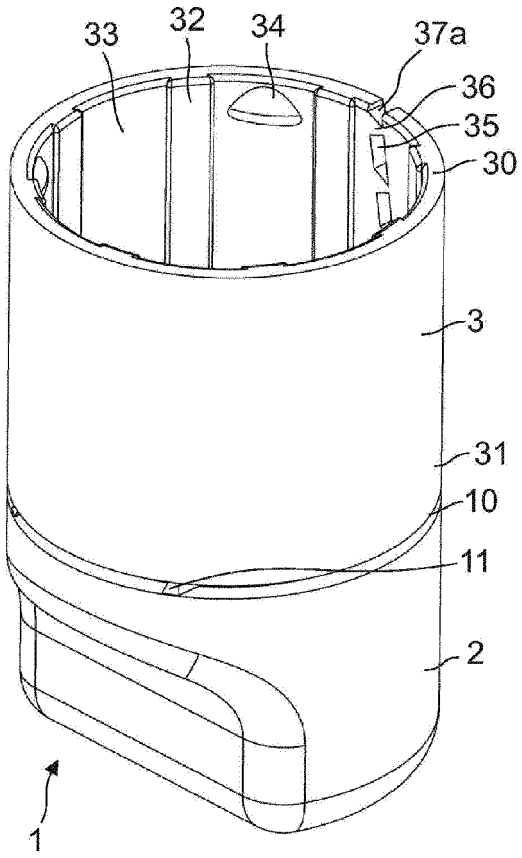

Fig. 3c

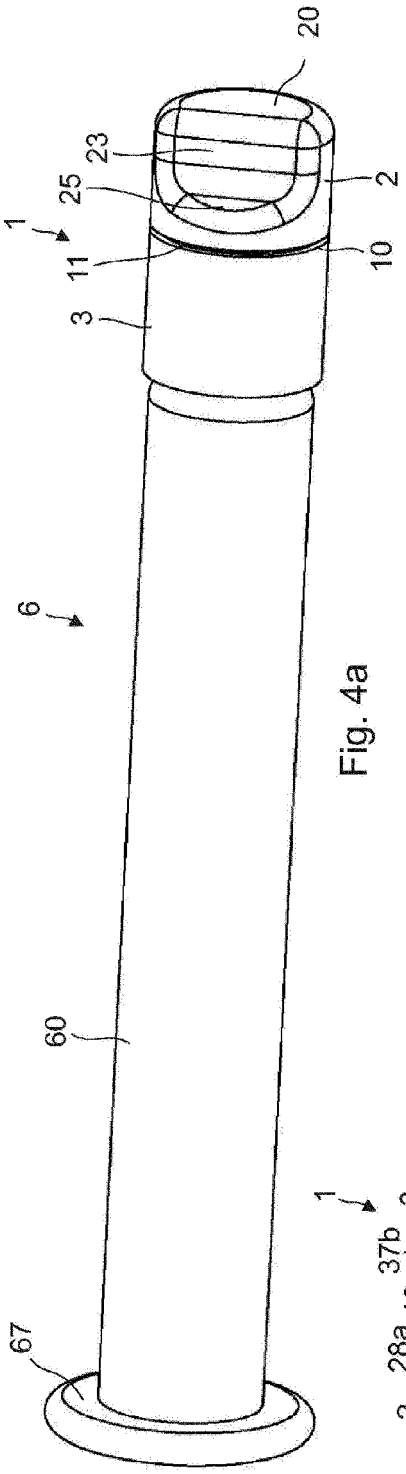
20
23
25
2
1
11
10
3
6
60
67

Fig. 4a

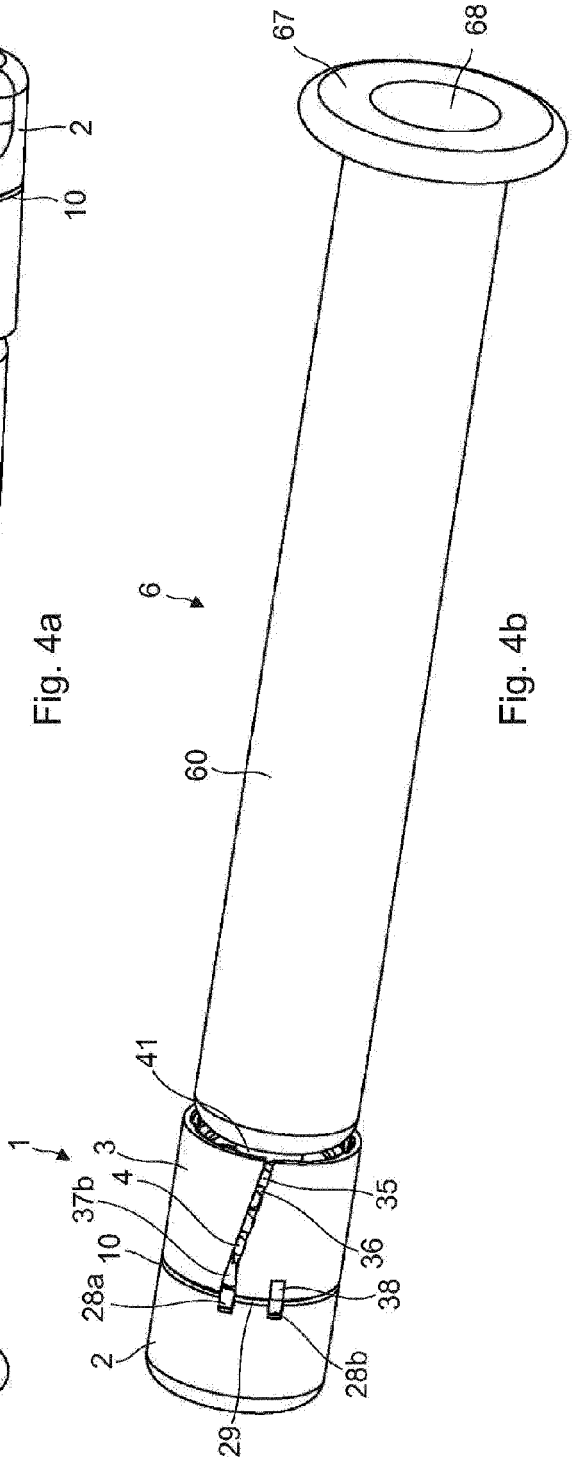
67
68
6
60
41
1
3
4
37b
10
28a
2
29
35
36
38
28b

Fig. 4b

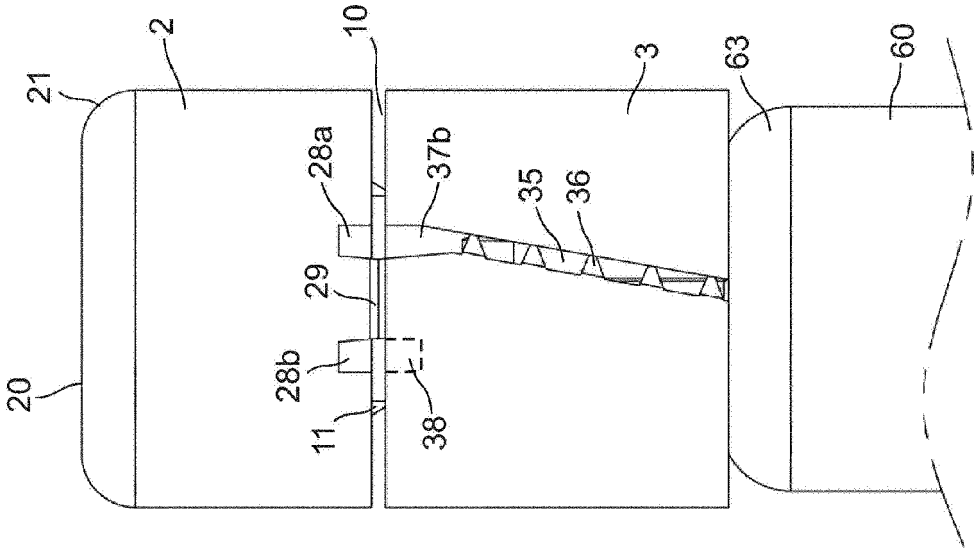
21
2
10
3
63
60
28a
37b
35
36
29
28b
20
11
38

Fig. 4d

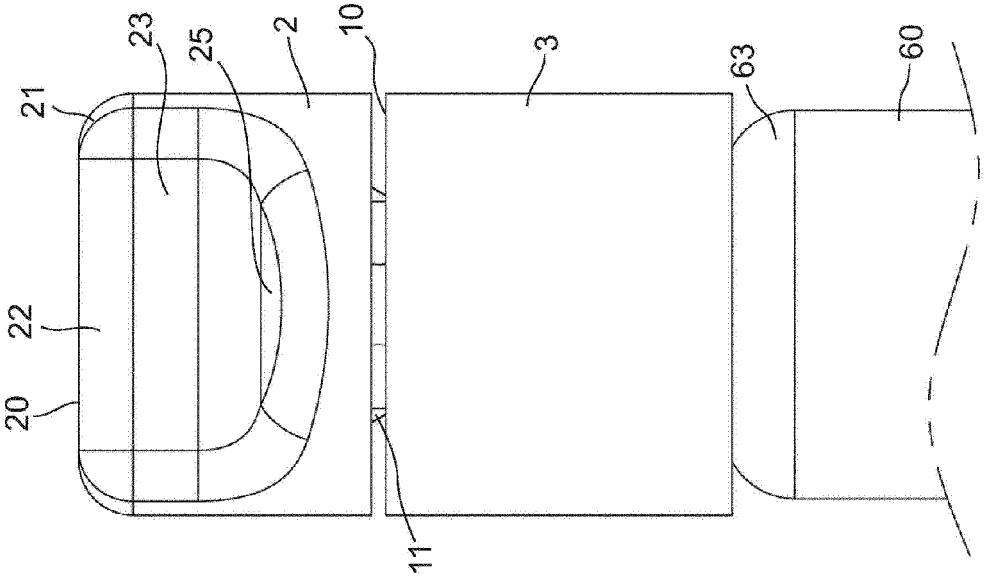
23
25
2
10
3
63
60
21
22
20
11

Fig. 4c

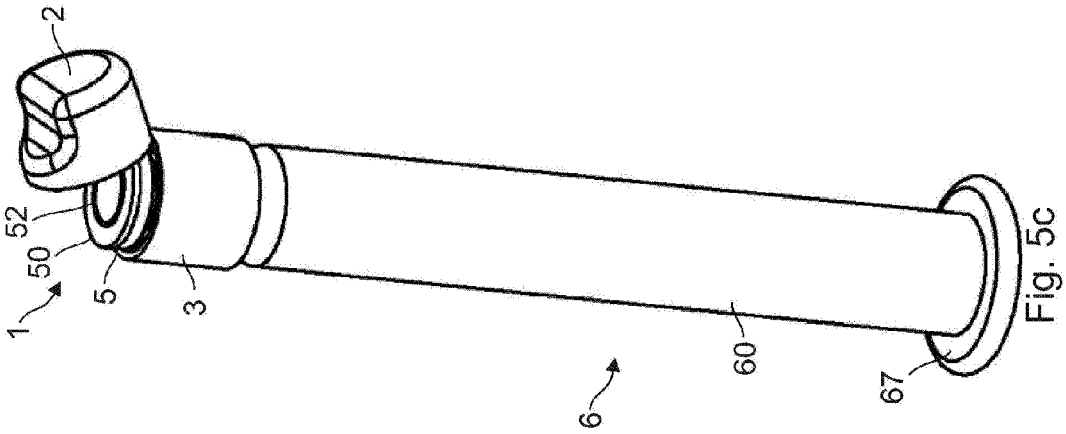

Fig. 5c

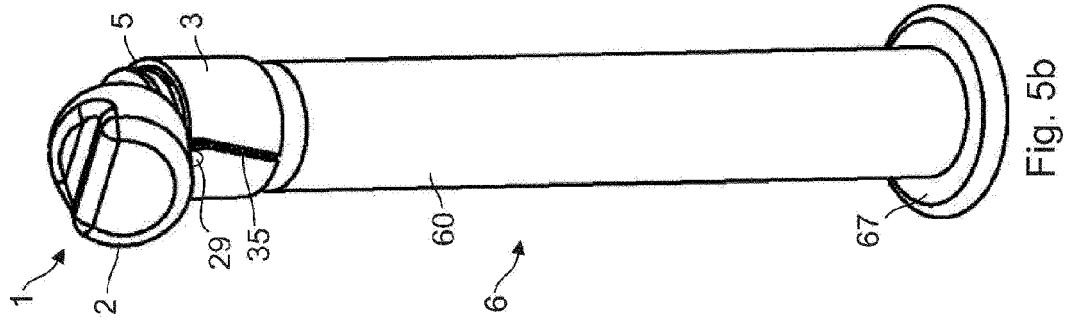

Fig. 5b

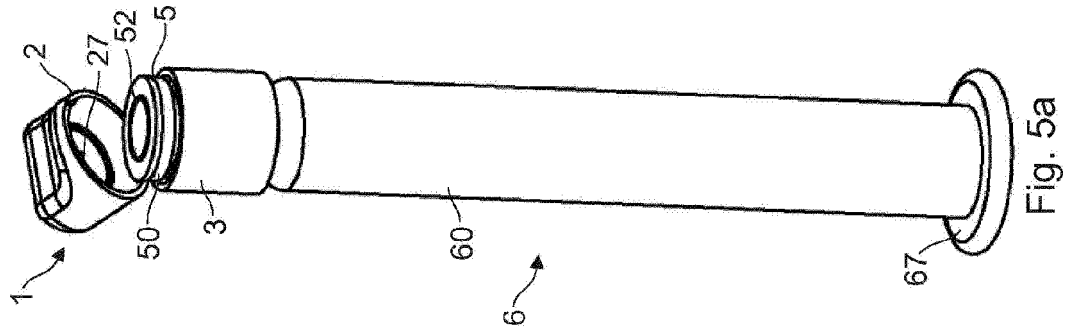

Fig. 5a

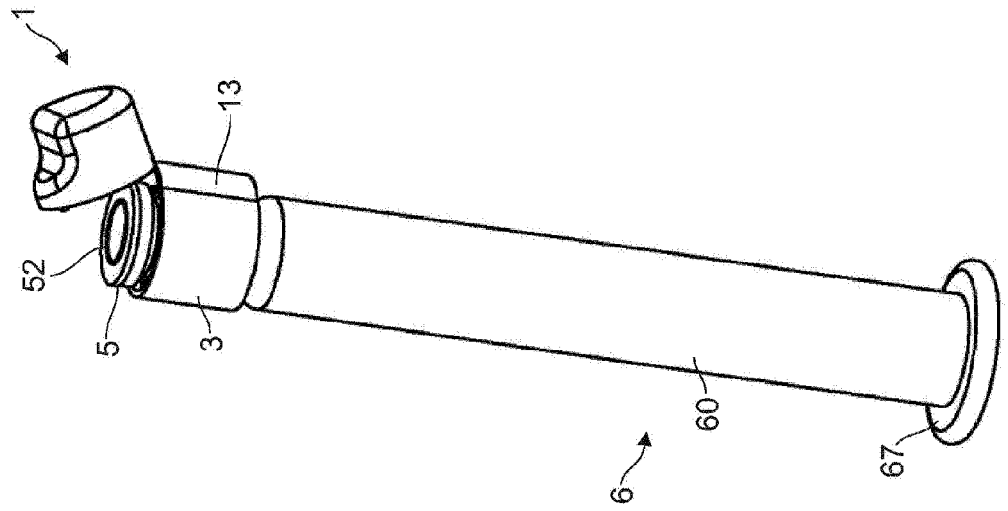

Fig. 6c

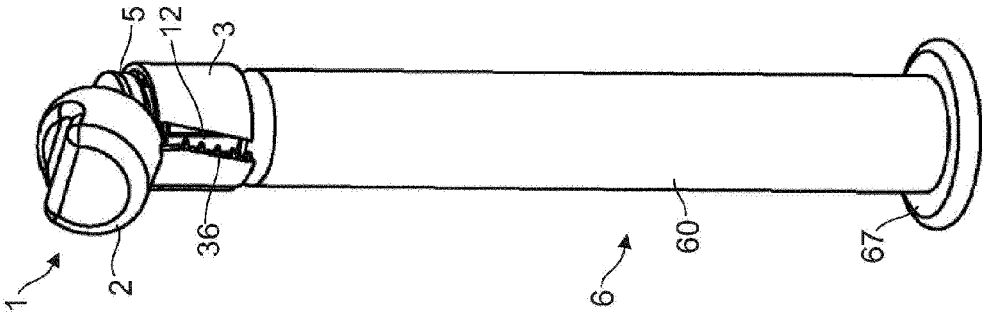

Fig. 6b

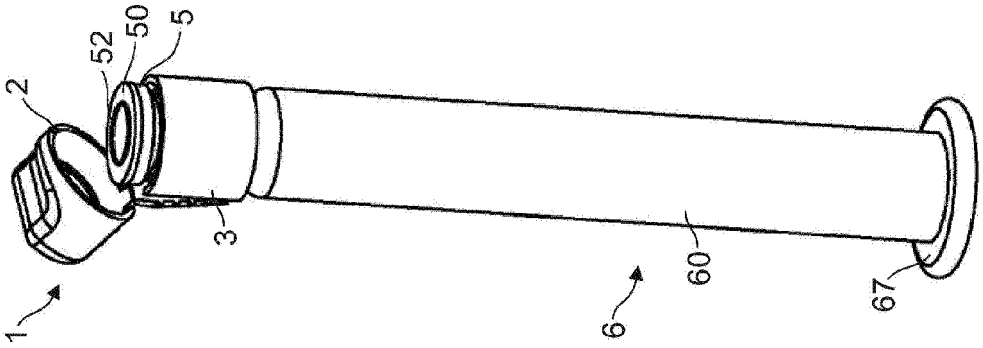

Fig. 6a

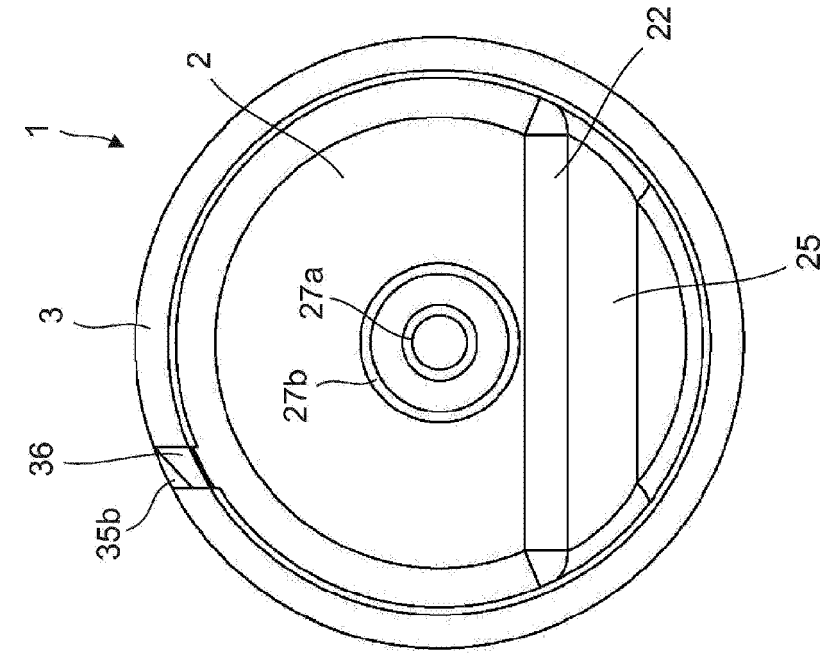

Fig. 7b

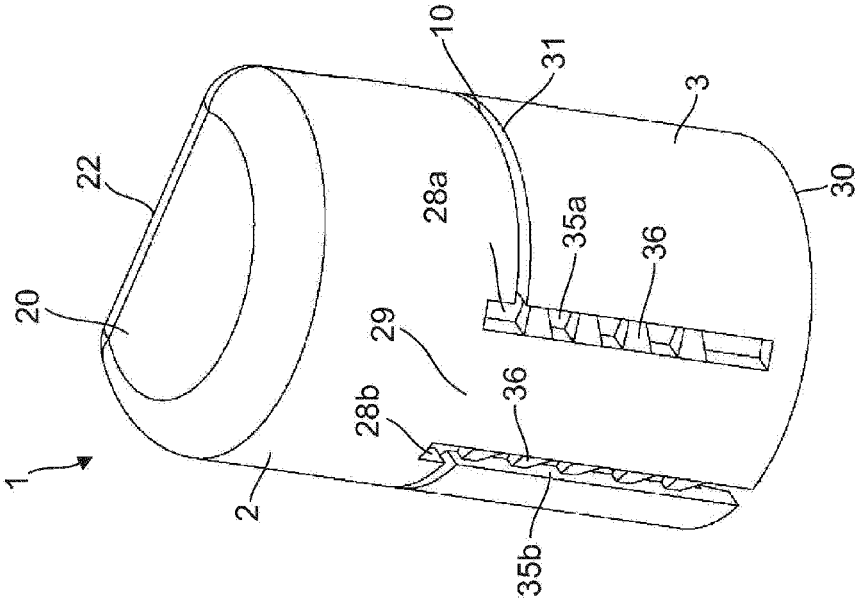

Fig. 7a

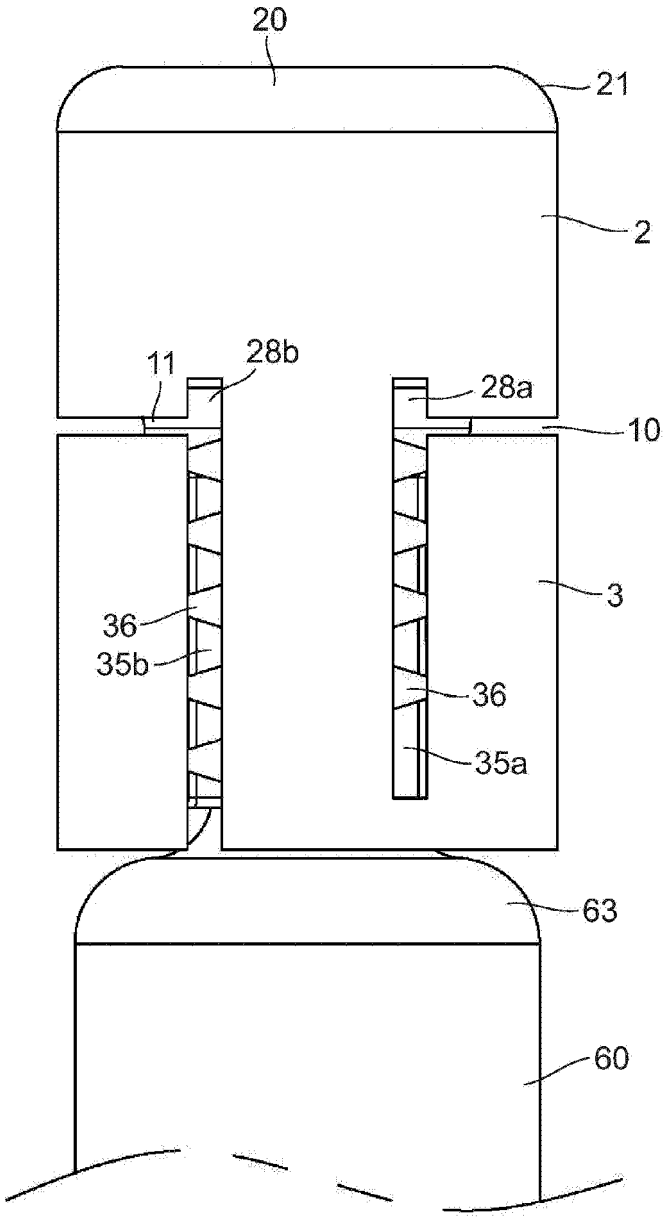

Fig. 7c

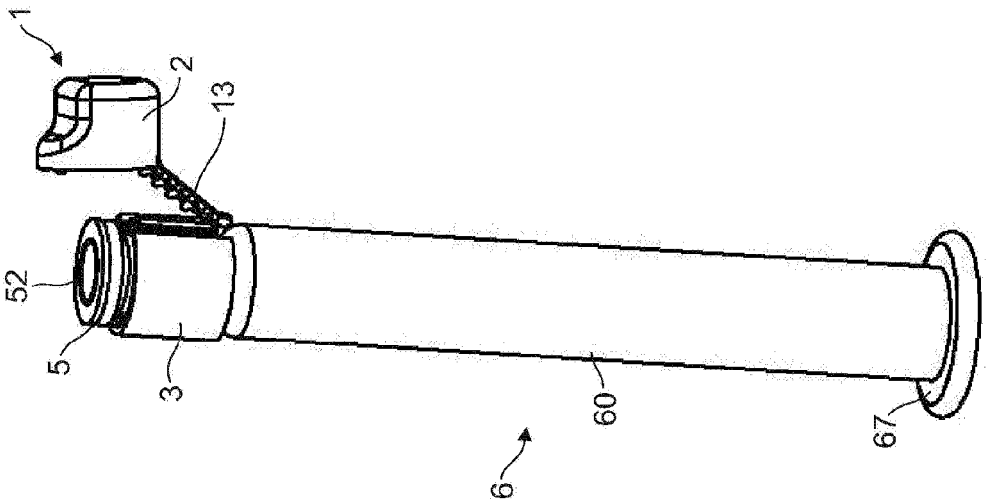

Fig. 8c

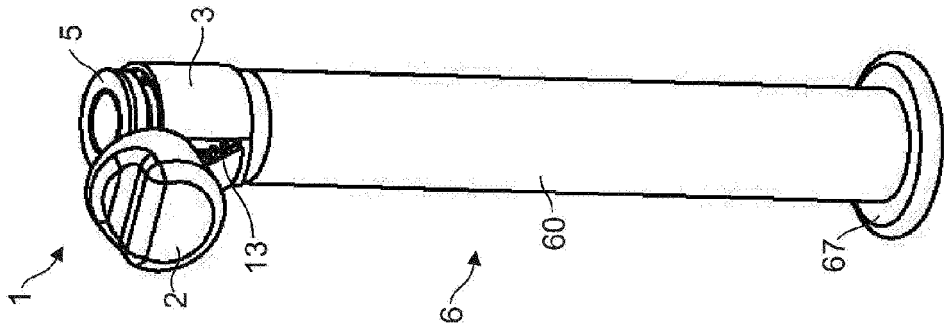

Fig. 8b

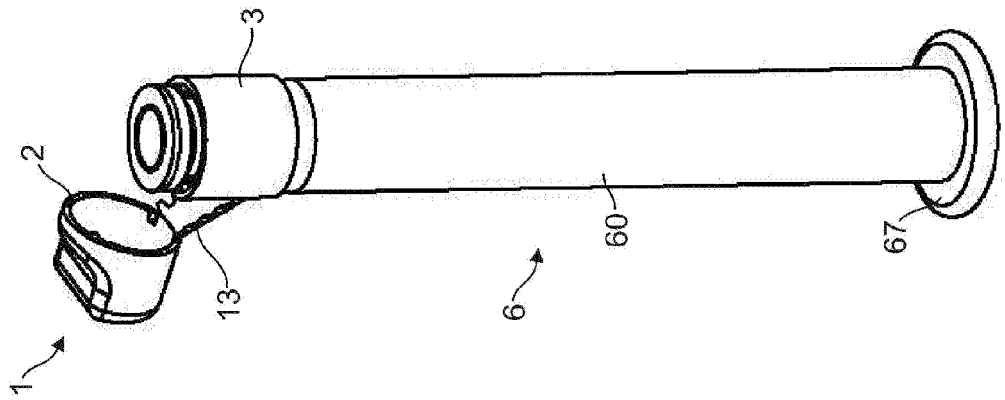

Fig. 8a