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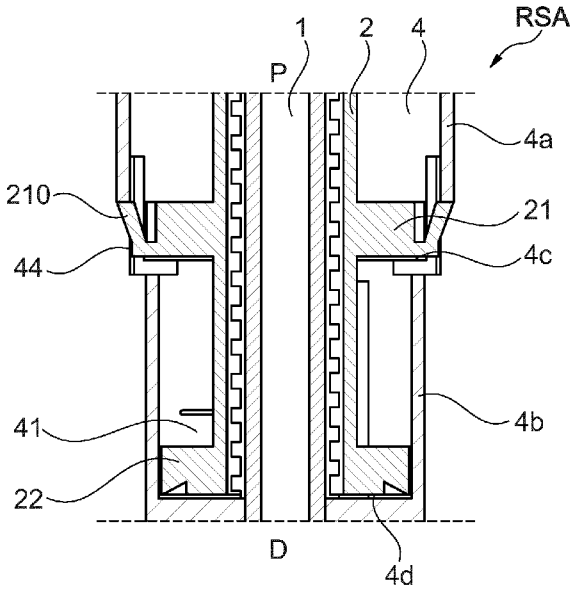

Fig. 48

(57) Abstract: The invention relates to a drive subassembly (RSA) for a drug delivery device, comprising - a housing element (4), - a drive member (2) arranged rotatably with respect to the housing element (4), - an energy member (3) configured to provide energy in order to induce a torque onto the drive member (2) tending to rotate the drive member (2) in a first rotational direction, wherein - the drive subassembly (RSA) has a first and a second locked state, - in the first locked state, a first rotation-locking mechanism prevents a movement of the drive member (2) in the first rotational direction induced by the energy member (3), - in the second locked state, a second rotation-locking mechanism prevents a rotation of the drive member (2) in the first rotational direction induced by the energy member (3) and an axial- locking mechanism prevents an axial movement of the drive member (2), - the drive subassembly

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(RSA) is configured to be switched from the second locked state into the first locked state by releasing the axial-locking mechanism and moving the drive member (2) in an axial direction. Furthermore, the invention relates to an arrangement comprising such a drive subassembly, a method for assembling a drug delivery device, a container-holder subassembly for a drug delivery device, a kit and a drug delivery device.

Title

Drive subassembly for a drug delivery device, arrangement, method for assembling a drug delivery device, container-holder subassembly for a drug delivery device, kit and drug delivery device

Technical field

A drive subassembly for a drug delivery device is provided. Furthermore, an arrangement comprising such a drive subassembly, a method for assembling a drug delivery device, a container-holder subassembly for a drug delivery device, a kit and a drug delivery device are provided.

Background

Administering an injection is a process which presents a number of risks and challenges for users and healthcare professionals, both mental and physical. A drug delivery device may aim to make self-injection easier for patients. A conventional drug delivery device may provide the force for administering the injection by a spring, and trigger button or another mechanism may be used to activate the injection. Drug delivery devices may be single-use or reusable devices.

There remains a need for an improved drive subassembly for a drug delivery device, an improved arrangement with such a drive subassembly, an improved method for assembling a drug delivery device, an improved container-holder for a drug delivery device, a kit and an improved drug delivery device.

Summary

One object to be achieved is to provide an improved drive subassembly for a drug delivery device. Further objects to be achieved are to provide an improved arrangement, an improved method for assembling a drug delivery device, an improved container-holder subassembly for a drug delivery device, and improved kit and an improved drug delivery device. These objects are achieved, inter alia, by the subject-matter of claims 1, 7, 8, 10 and 15. Advantageous

embodiments and further developments are subject of the dependent claims and are also presented in the following description and the figures.

Firstly, the drive subassembly for a drug delivery device is specified.

According to at least one embodiment, the drive subassembly comprises a housing element. The housing element may be hollow and/or elongated. The housing element may be a sleeve, e.g. a cylindrically-shaped sleeve. Particularly, the housing element may be a holder for an energy member such as a drive spring, i.e. an element in which an energy member can be stored. The energy member may be secured to the housing element, e.g. by fixing one end of the drive spring to the housing element.

According to at least one embodiment, the drive subassembly comprises a drive member. The drive member may be arranged rotatably and/or axially movable with respect to the housing element. The drive member may be hollow and/or elongated. The drive member may be a sleeve. For example, the drive member is a rotating collar. The drive member may be configured to be rotated in only one or two opposite rotational directions. The rotational axis of the drive member may define or coincide with a longitudinal axis of the drive subassembly or of the drug delivery device. The drive member may be secured to the energy member, e.g. by fixing a further end of the drive spring to the drive member.

According to at least one embodiment, the drive subassembly comprises an energy member configured to provide energy in order to induce a torque onto the drive member, preferably to drive the drive member. The torque may tend to rotate the drive member in a first rotational direction. In other words, the energy member may be configured to provide energy in order to rotate the drive member relative to the housing element in a first rotational direction. A rotation of the drive member induced by the energy member may be configured to induce a drug delivery process, particularly, when the drive subassembly is assembled into a drug delivery device. The drive member may, e.g., be a plunger rod configured to be directly driven by the energy member or may be a transfer member configured to transfer energy from the drive member to a plunger rod.

The energy member may be a drive spring, e.g. a torsion drive spring, particularly a spiral torsion spring or clock spring or power spring, or another component configured to induce a torque, e.g. a gas cartridge or an electric motor. The drive spring may be formed of metal, e.g. steel. The longitudinal axis may run through the center of the drive spring.

Here and in the following, if not stated otherwise, a movement of a member or element or feature is to be understood as a movement with respect to the housing element.

According to at least one embodiment, the drive subassembly has a first and a second locked state.

According to at least one embodiment, in the first locked state, a first rotation-locking mechanism prevents a movement of the drive member in the first rotational direction induced by the energy member. For example, in the first locked state, the drive member is coupled to the housing element via a first rotation-lock interface, wherein the first rotation-lock interface prevents a movement of the drive member in the first rotational direction induced by the energy member.

According to at least one embodiment, in the second locked state, a second rotation-locking mechanism prevents a rotation of the drive member in the first rotational direction induced by the energy member. Moreover, in the second locked state, an axial-locking mechanism may prevent an axial movement of the drive member. Particularly, the axial-locking mechanism may prevent an axial movement of the drive member in a proximal direction and/or a distal direction.

For example, in the second locked state, the drive member is coupled to the housing element via a second rotation-lock interface preventing a rotation of the drive member in the first rotational direction induced by the energy member and is coupled to the housing element via an axial-lock interface preventing a movement of the drive member in one or both axial directions.

In the first locked state and/or in the second locked state, the energy member may already induce a torque onto the drive member.

According to at least one embodiment, the drive subassembly is configured to be switched from the second locked state into the first locked state by releasing the axial-locking mechanism and moving the drive member in an axial direction, e.g. in proximal direction. The movement in axial direction after releasing the axial-locking mechanism may release the second rotation-locking mechanism and may lock the first rotation-locking mechanism. The drive subassembly may be configured such that the second rotation-locking mechanism can only be released by a movement of the drive member in an axial direction. For example, during movement in axial direction, the first rotation-locking mechanism is locked before the second rotation-locking mechanism is completely released. By way of example, the first rotation-lock interface is established before the second rotation-lock interface is completely resolved.

The first locked state may also be called primed state. The second locked state may also be called pre-primed state. During assembling a drug delivery device, the second locked state may be a state prior to the first locked state. The drive subassembly may also have a released state into which the drive subassembly switches from the first locked state when releasing the first rotation-locking mechanism. In the released state, the drive member rotates in the first rotational direction induced by the energy member, e.g. by at least 360°. The drive member may also move axially, e.g. in proximal direction, in the released state. When the drive subassembly is assembled into a drug delivery device, the released state may be a state in which a drug is administered due to the rotation of the drive member.

In at least one embodiment, the drive subassembly for a drug delivery device comprises a housing element, a drive member arranged rotatably with respect to the housing element and an energy member configured to provide energy in order to induce a torque onto the drive member tending to rotate the drive member in a first rotational direction. The drive subassembly has a first and a second locked state. In the first locked state, a first rotation-locking mechanism prevents a movement of the drive member in the first rotational direction induced by the energy member. In the second locked state, a second rotation-locking mechanism prevents a rotation of the drive member in the first rotational direction induced by the energy member and an axial-locking mechanism prevents an axial movement of the drive member. The drive subassembly is configured to be switched from the second locked state into the first locked state by releasing the axial-locking mechanism and moving the drive member in an axial direction.

With such a drive subassembly an easy an improved assembling of a drug delivery device may be achieved.

The drug delivery device and/or the subassemblies for the drug delivery device specified herein may each be elongated and/or may each comprise a longitudinal axis, i.e. a main extension axis. A direction parallel to the longitudinal axis is herein called an axial direction. By way of example, the drug delivery device and/or the subassemblies may be cylindrically-shaped.

Furthermore, the drug delivery device and/or the subassemblies may comprise a longitudinal end, which may be provided to face or to be pressed against a skin region of a human body. This end is herein called the distal end. A drug or medicament may be supplied via the distal end. The opposing longitudinal end is herein called the proximal end. The proximal end is, during usage, remote from the skin region. The axial direction pointing from the proximal end to the distal end is herein called distal direction. The axial direction pointing from the distal end to

the proximal end is herein called proximal direction. A distal end of a member or element of the drug delivery device and/or of the subassemblies is herein understood to be the end of the member/element located most distally. Accordingly, the proximal end of a member or element is herein understood to be the end of the element/member located most proximally.

In other words, "distal" is used herein to specify directions, ends or surfaces which are arranged or are to be arranged to face or point towards a dispensing end of the drug delivery device or components thereof and/or point away from, are to be arranged to face away from or face away from the proximal end. On the other hand, "proximal" is herein used to specify directions, ends or surfaces which are arranged or are to be arranged to face away from or point away from the dispensing end and/or from the distal end of the drug delivery device or components thereof. The distal end may be the end closest to the dispensing end and/or furthest away from the proximal end and the proximal end may be the end furthest away from the dispensing end. A proximal surface may face away from the distal end and/or towards the proximal end. A distal surface may face towards the distal end and/or away from the proximal end. The dispensing end may be a needle end where a needle unit is or is to be mounted to the device, for example.

A direction perpendicular to the longitudinal axis and/or intersecting with the longitudinal axis is herein called radial direction. An inward radial direction is a radial direction pointing towards the longitudinal axis. An outward radial direction is a radial direction pointing away from the longitudinal axis.

The terms "angular direction", "azimuthal direction" or "rotational direction" are herein used as synonyms. Such a direction is a direction perpendicular to the longitudinal axis and perpendicular to the radial direction.

An element or member or feature being rotationally, axially or radially fixed with respect to another element or member or feature means that a relative movement in rotational direction or axial direction or radial direction between the two elements/members/features is not possible or prevented.

The terms "protrusion" and "boss" are used as synonyms herein. The term "recess" may particularly stand for an indentation or a cut-out or opening or hole.

The drive subassembly specified herein may be configured to be assembled together with a further subassembly into a drug delivery device. The drive subassembly may, in particular, be a rear subassembly to be arranged proximally with respect to a front subassembly.

According to at least one embodiment, the drive subassembly comprises a plunger rod being arranged axially movable, i.e. in only one or two opposite axial directions, movable with respect to the housing element. The plunger rod may be hollow or solid. The plunger rod may be cylindrically-shaped, e.g. hollow cylindrically-shaped. In case the plunger rod is hollow, further elements or members, e.g. other than an energy member, may be received in the plunger rod.

According to at least one embodiment, the drive member and the plunger rod are operatively coupled such that a rotation of the drive member in the first rotational direction is converted into a movement of the plunger rod in distal direction. The plunger rod and the drive member may be operatively coupled by a gear, e.g. a threaded interface, transforming a rotational movement of the drive member into an axial movement of the plunger rod. In this case, the drive member is particularly a transfer member. The threaded interface may be formed directly between the plunger rod and the drive member. The threaded interface may transform the rotational movement of the drive member into an axial movement of the plunger rod. The plunger rod may comprise a thread engaged with a thread of the drive member. The thread of the plunger rod may be an external thread, the thread of the drive member may be an internal thread, or vice versa. The drive member may be axially secured to the housing element, e.g. via the energy member. For example, the drive member is secured to the housing element such that, in the released state, a force necessary for moving the drive member in one or both axial directions, particularly in the proximal direction, is greater than a force necessary to axially move the plunger rod.

According to at least one embodiment, the plunger rod is rotationally fixed to the housing element via a splined interface. The splined interface may be formed directly between the plunger rod and the housing element. For example, the plunger rod has a splining element and the housing element has a splining element, e.g. complementarity to and/or mating with the splining element of the plunger rod. The splining elements of the plunger rod and the housing element may engage with each other, e.g. form-lockingly, thereby preventing the rotation of the plunger rod with respect to the housing element. One of the splining elements of the housing element and of the plunger rod may be a groove and the other one of the splining elements of the housing element and the plunger rod may be a protrusion. The protrusion may then engage or project into the groove thereby preventing rotation of the plunger rod. The groove may extend parallel to the longitudinal axis. For example, the groove is formed in the plunger rod and the protrusion is part of the housing element, e.g. integrally formed with the housing element.

Preferably, the splined interface is in close proximity to the threaded interface, e.g. with a distance of at most 1 cm or at most 0.5 cm or at most 0.2 cm. This is beneficial since the torque on the plunger rod is resolved over a short distance reducing the stresses within the plunger rod.

The housing element and/or the plunger rod and/or the drive member may comprise or consist of a plastic. Each of them may be formed in one piece, i.e. be of a unitary construction or integrally formed. Each of them may have a main extension direction parallel the longitudinal axis. The longitudinal axis may run through one or more or every of the mentioned elements/members, e.g. through the center thereof.

The plunger rod may be received in the drive member so that the drive member circumferentially surrounds, e.g. completely circumferentially surrounds, at least a portion of the plunger rod. The drive member may be received in the housing element and/or the energy member so that at least a portion of the drive member is circumferentially surrounded, e.g. completely circumferentially surrounded, by the housing element and/or the energy member. The energy member may be received in the housing element so that at least a portion of the energy member is circumferentially surrounded, e.g. completely circumferentially surrounded, by the housing element.

According to at least one embodiment, the first rotation-locking mechanism comprises a first rotation-lock element rotationally and/or axially fixed with respect to the drive member and a second rotation-lock element rotationally and/or axially fixed with respect to the housing element. The two rotation-lock elements of the first rotation-locking mechanism may be configured to engage with each other. The first rotation-lock element may be a part of the drive member. The second rotation-lock element may be a part of the housing element.

According to at least one embodiment, at least one of the first and the second rotation-lock elements of the first rotation-locking mechanism, e.g. the second rotation-lock element, is a displaceable rotation-lock element. For example, the displaceable rotation-lock element is displaceable in a second direction other than the first rotational direction. The second direction may be a direction perpendicular to the first rotational direction, e.g. a radial direction, particularly the outward radial direction. The other rotation-lock element of the first rotation locking mechanism may be arranged to be not moveable in the second direction, i.e. fixed in the second direction.

According to at least one embodiment, the displaceable rotation-lock element of the first rotation-locking mechanism is orientated circumferentially. This means, a main extension direction of the displaceable rotation-lock element is along an angular direction. The displaceable rotation-lock element may be elongated. For example, the displaceable rotation-lock element may be a flexible, particularly a resilient arm. One end of the displaceable rotation-lock element may be radially, preferably also rotationally and/or axially, fixed with respect to the housing element and the end of the displaceable rotation-lock element remote from the one end, e.g. as seen along the extension of the displaceable element and/or in the angular direction, may not be radially fixed with respect to the housing element, i.e. it may be a free end, and is therefore displaceable in radial direction. The free end may face in the angular direction. In other words, the displaceable element may be pivotally connected to or integrated into the housing element, e.g. a main body thereof.

According to at least one embodiment, the first rotation-lock element and the second rotation-lock element of the first rotation-locking mechanism are engaged in the first locked state. For example, in a first position of the displaceable rotation-lock element, the rotation-lock elements of the first rotation-locking mechanism are engaged.

According to at least one embodiment, the engagement of the first and the second rotation-lock elements of the first rotation-locking mechanism prevents an energy member induced movement of the drive member in the first rotational direction. In other words, the engagement may establish a rotation-lock interface.

According to at least one embodiment, a displacement of the displaceable rotation-lock element in the second direction disengages the first rotation-lock element and the second rotation-lock element of the first rotation-locking mechanism and releases the first rotation-locking mechanism such that a movement of the drive member in the first rotational direction induced by the energy member is enabled. For example, in a second position of the displaceable rotation-lock element, the two rotation-lock elements of the first rotation-locking mechanism may be disengaged to release the first rotation-locking mechanism and to enable rotation of the drive member. The second position may be a position downstream along the second direction with respect to the first position.

According to at least one embodiment, the axial-locking mechanism comprises a first axial-lock element axially and/or rotationally fixed with respect to the drive member and a second axial-lock element rotationally and/or axially fixed with respect to the housing element. The first axial-

lock element of the axial-locking mechanism may be a part of the drive member. The second axial-lock element of the axial-locking mechanism may be a part of the housing element.

According to at least one embodiment, at least one of the first axial-lock element and the second axial-lock element, e.g. the first axial-lock element, may be a displaceable element displaceable in a third direction, e.g. in radial direction, particularly in inward radial direction. The other axial-lock element may be fixed in the third direction. The displaceable axial-lock element may be oriented in the axial direction. The displaceable axial-lock element may be a pivotable or flexible or resilient arm. The other axial-lock element, e.g. the second axial-lock element, may comprise a recess.

According to at least one embodiment, the two axial-lock elements of the axial-locking mechanism are engaged in the second locked state. For example, in the second locked state, the displaceable axial-lock element may project into the recess of the other axial-lock element.

According to at least one embodiment, the engagement of the axial-lock elements of the axial-locking mechanism prevents switching from the second locked state into the first locked state. Particularly, the engagement prevents an axial movement, e.g. a proximal movement, of the drive member. For example, when trying to move the drive member in an axial direction, the displaceable axial-lock element projecting into the recess contacts an edge of the other axial-lock element delimiting the recess.

According to at least one embodiment, a displacement of the displaceable axial-lock element in the third direction disengages the first axial-lock element and the second axial-lock element and enables a movement of the drive member in an axial direction, e.g. in the proximal direction. For example, in a first position of the displaceable axial-lock element, the two axial-lock elements are engaged and in a second position of the displaceable axial-lock element, which may be arranged downstream of the first position along the third direction, the two axial-lock elements are disengaged.

According to at least one embodiment, the second rotation-locking mechanism comprises a first rotation-lock element rotationally and/or axially and/or radially fixed with respect to the drive member and a second rotation-lock element rotationally and/or axially and/or radially fixed with respect to the housing element. The first rotation-lock element of the second rotation-locking mechanism may be part of the drive member. The second rotation-lock element of the second rotation-locking mechanism may be part of the housing element, e.g. a main body of the housing element.

According to at least one embodiment, the first and the second rotation-lock elements of the second rotation-locking mechanism are engaged in the second locked state. For example, the second-rotation locking mechanism is configured such that the two rotation-lock elements can only be disengaged by an axial movement of the drive member.

According to at least one embodiment, the engagement of the first and the second rotation-lock elements of the second rotation-locking mechanism prevents an energy member induced movement of the drive member in the first rotational direction. In other words, the engagement of the two rotation-lock elements of the second rotation-locking mechanism may establish a rotation-lock interface.

According to at least one embodiment, the first rotation-lock element of the first rotation-locking mechanism is also the first rotation-lock element of the second rotation-locking mechanism.

According to at least one embodiment, the drive subassembly is configured such that when switched from the second locked state into the first locked state, the first rotation-lock element is moved in an axial direction, e.g. in the proximal direction.

According to at least one embodiment, the drive subassembly is configured such that during movement in axial direction, the first rotation-lock element engages with the second rotation-lock element of the first rotation-locking mechanism before being completely disengaged from the second rotation-lock element of the second rotation-locking mechanism.

According to at least one embodiment, the first rotation-lock element of the first rotation-locking mechanism comprises a locking feature, the first rotation-lock element of the second rotation-locking mechanism comprises a locking feature, the second rotation-lock element of the first rotation-locking mechanism comprises a locking feature and the second rotation-lock element of the second rotation-locking mechanism comprises a locking feature. The locking feature of a displaceable rotation-lock element may be arranged closer to a free end than to an end fixed with respect to the housing element or the drive member.

According to at least one embodiment, the locking features of the second rotation-lock elements are both protrusions and the locking features of the first rotation-lock elements are both recesses or vice versa. The protrusion(s) may be radially, e.g. radially inwardly, oriented.

According to at least one embodiment, when the rotation-lock elements are engaged in the first and the second locked state, the respective protrusion projects into the respective recess.

According to at least one embodiment, the locking feature of the first rotation-lock element of the first rotation-locking mechanism is arranged downstream of, e.g. directly behind, the locking feature of the first rotation-lock element of the second rotation-locking mechanism in an axial direction, particularly in the proximal direction. Said locking features may be aligned or may overlap in rotational and/or radial direction. In other words, the locking features of the second rotation-lock elements of the two rotation-locking mechanisms may be angularly and/or radially aligned and axially offset from one another. At least a section of the locking feature of the second rotation-lock element of the first rotation-locking mechanism may have the same radial extension as and/or the same extension in angular direction as or may even be formed identically with the locking feature of the second rotation-lock element of the second rotation-locking mechanism. Said locking features may also have free ends which are radially aligned. This facilitates an engagement of the same first rotation-lock element with the two different second rotation-lock elements of both rotation-locking mechanisms.

According to at least one embodiment, the drive member comprises a first portion, also called axial-lock portion, and a second portion, also called rotation-lock portion, which are axially offset. The diameter in the first portion may be greater than in the second portion. The first portion may be arranged proximally with respect to the second portion. The first rotation-lock elements of the first and second rotation-locking mechanism may be part of or may be formed by the second portion. The first axial-lock element of the axial-locking mechanism may be part of or may be formed by the first portion. The first and/or the second portion may be disc-shaped.

According to at least one embodiment, a third portion, also called connection portion, of the drive member is arranged between the first portion and the second portion. The third portion may have a smaller diameter than each of the first portion and the second portion. For example, the third portion may be a shaft, e.g. with cylindrical shape. The first and/or the second and/or the third portion may, at least in the first and/or second locked state, be arranged inside the housing element, i.e. be circumferentially surrounded by the housing element. Moreover, at least in the first and/or second locked state, the plunger rod may overlap with one, some or all of the first, second and third portion of the drive member in axial direction.

According to at least one embodiment, the drive subassembly comprises a housing in which the drive member and the energy member are received, e.g. circumferentially, particularly completely circumferentially, surrounded by the housing. Also the plunger rod may be received

in the housing. Particularly, the drive member and/or the energy member and/or the plunger rod may be completely received in the housing, e.g. such that the housing completely covers that drive member and/or the energy member and/or the plunger when viewed along a radial direction.

According to at least one embodiment, the housing element is fixed or configured to be fixed to the housing. The housing element may also be integrated in the housing. The housing is preferably axially and rotationally, preferably also radially, fixed with respect to the housing element. The housing element may be part of the housing, e.g. integrally formed with the housing, or maybe a separate element. The housing element may be received, e.g. completely received in the housing.

The housing may comprise or consist of plastic and/or may be formed in one piece. The housing may be hollow and/or elongated and/or hollow cylindrically-shaped. The housing may be a sleeve.

According to at least one embodiment, the housing axially projects beyond the drive member and/or the energy member and/or the plunger rod. For example, the housing projects beyond the drive member and/or the energy member and/or the plunger rod in distal direction and/or in proximal direction.

According to at least one embodiment, the housing is configured to hold or receive a medicament container, e.g. a syringe. The housing may be configured to hold the medicament container such that the medicament container is axially and/or rotationally and/or radially fixed with respect to the housing. For example, the housing is configured such that, when a medicament container with a needle is received in the housing, only the needle projects beyond the housing in distal direction.

According to at least one embodiment, the housing has a length of at least 75 % or at least 80 % of the length of the drug delivery device. For example, the length of the housing is greater, e.g. at least 1.5 times as great or at least two times as great, as the length of the drive member and/or the energy member and/or the plunger rod. Herein, the length is measured along the longitudinal axis.

According to at least one embodiment, the housing provides an outer surface of the drive subassembly configured to be grabbed by a user. In other words, the housing is the outermost member of the drive subassembly and/or of the drug delivery device in outward radial direction.

Next, the arrangement is specified.

According to at least one embodiment, the arrangement comprises a drive subassembly specified herein. This means, all features disclosed for the drive subassembly are also disclosed for the arrangement and vice versa.

According to at least one embodiment, the arrangement comprises a release subassembly configured to be connected with the drive subassembly in order to assemble a drug delivery device. For example, the drive subassembly and the release subassembly are configured to be telescoped with or into each other. The release subassembly may be a front subassembly configured to be located distally with respect to the drive subassembly.

According to at least one embodiment, the drive subassembly is in the second locked state, particularly before the subassemblies are connected to each other.

According to at least one embodiment, the release subassembly comprises a release element configured to release the axial-locking mechanism of the drive subassembly when telescoping the drive subassembly and the release subassembly. Particularly, the release element may be configured to displace the displaceable axial-lock element in the third direction, e.g. the inward radial direction, in order to disengage the axial-lock elements. The release element may be configured to release the axial-locking mechanism automatically during telescoping the drive subassembly and the release subassembly so that a further release step after telescoping is not necessary.

According to at least one embodiment, the release subassembly comprises a push element configured to push the drive member in an axial direction, particularly in proximal direction, when telescoping the drive subassembly and the release subassembly for switching the drive subassembly from the second locked state into the first locked state. The push element may be configured to push the drive member automatically during telescoping the drive subassembly and the release subassembly so that a further step of moving the drive member after telescoping is not necessary.

The release element and/or the push element may be located in the region of an axial end of the release subassembly, e.g. in the region of the proximal end of the drive subassembly. The release element and/or the push element may be axially and/or rotationally and/or radially fixed

to a container-holder of the release subassembly. The release element and/or the push element may be part of the container-holder.

The release element and the push element may be arranged such that when telescoping or connecting the drive subassembly and the release subassembly, the release element first releases the axial-locking mechanism and after that, e.g. immediately after that, the push element pushes the drive member in an axial direction, particularly in the proximal direction.

In other words, the arrangement may be configured such that the release of axial-locking mechanism and/or the movement of the drive member in axial direction for switching from the second locked state into the first locked state happens automatically during telescoping or assembling.

Next, the method for assembling a drug delivery device is specified.

According to at least one embodiment, the method comprises a step in which a drive subassembly specified herein is provided. This means, all features disclosed for the drive subassembly are also disclosed for the method and vice versa. In this step, the drive subassembly is in the second locked state.

According to at least one embodiment, the method comprises a step, in which a release subassembly is provided. The release subassembly may be the release subassembly of the arrangement specified herein. This means, all features disclosed for the release subassembly of the arrangement are also disclosed for the release subassembly of the method and vice versa.

According to at least one embodiment, the method comprises a step of connecting, particularly telescoping, the release subassembly and the drive subassembly, wherein during connecting or telescoping, the release subassembly releases the axial-locking mechanism and pushes the drive member in an axial direction, particularly in the proximal direction, so that the drive subassembly is switched from the second locked state into the first locked state. For example, the drive member is moved by at least 2 mm or at least 5 mm or at least 10 mm and/or at most 30 mm or at most 20 mm in axial direction when switching from the second locked state into the first locked state.

According to at least one embodiment, when telescoping the release subassembly and the drive subassembly, the release element pushes the displaceable axial-lock element in the third

direction, whereby the displaceable axial-lock element disengages from the other axial-lock element.

According to at least one embodiment, when telescoping the release subassembly and the drive subassembly, the push element pushes the drive member in an axial direction thereby switching the drive subassembly from the second locked state into the first locked state.

According to at least one embodiment, the release subassembly comprises a support element. The support element may be a release member, particularly a needle shroud, or part of such a release member, e.g. a wall portion of the release member.

According to at least one embodiment, when telescoping the release subassembly and the drive subassembly, the support element is brought into a support position in which the support element holds the displaceable rotation-lock element of the first rotation-locking mechanism in a first position. In the first position, the displaceable rotation-lock element is arranged to engage or is engaged with the other rotation-lock element of the first rotation-locking mechanism. Particularly, in the support position, the support element is aligned or overlaps with the displaceable rotation-lock element of the first rotation-locking mechanism in axial and/or rotational direction. The support element in the support position may be configured to prevent a disengagement of the rotation-lock elements of the first rotation-locking mechanism by a displacement of the displaceable rotation-lock element. The support element in the support position may be located radially outwardly with respect to the displaceable rotation-lock element of the first rotation-locking mechanism.

For example, the support element is brought into the mentioned support position before the second rotation-locking mechanism is completely released and/or before the first rotation-locking mechanism is locked.

Next, the container-holder subassembly for a drug delivery device is specified.

The container-holder subassembly may be the release subassembly specified herein. Accordingly, all features disclosed for the container-holder subassembly are also disclosed for the release subassembly and vice versa. The container-holder subassembly may be a front subassembly configured to be arranged distally to a rear subassembly, e.g. the drive subassembly specified herein.

According to at least one embodiment, the container-holder subassembly comprises a needle shroud configured to cover a needle of a medicament container. The needle shroud may be configured to circumferentially surround the needle and to, at least in an extended position, project beyond the needle in distal direction.

According to at least one embodiment, the container-holder subassembly comprises a container holder configured to hold a medicament container. The container holder may be configured to hold the medicament container such that the medicament container is axially and/or rotationally and/or radially fixed with respect to the container holder.

The needle shroud and/or the container holder may comprise or consist of a plastic. The needle shroud and/or the container holder may each be formed in one piece. The needle shroud and/or the container holder may be elongated. A main extension direction of the needle shroud and/or the container holder may run parallel to a longitudinal axis of the container-holder subassembly.

According to at least one embodiment, the needle shroud and the container holder are coupled to each other so that the needle shroud is movable with respect to the container holder in axial direction, i.e. in only one or both axial directions. Particularly, the needle shroud may be axially moveable relative to the container holder between an extended position, configured to cover the needle such that the needle does not project beyond the needle shroud in distal direction, and a retracted position, configured such that the needle projects beyond the needle shroud in distal direction.

According to at least one embodiment, the container-holder subassembly is configured to be inserted into a housing for a drug delivery device, particularly into a sleeve-shaped housing, e.g. into the housing of the drive subassembly specified above. For example, the container-holder subassembly is configured such that when inserted into the housing, at least the container holder is completely received in the housing and, e.g., does not project from the housing in distal and/or proximal direction. When inserted into the housing, the container-holder subassembly may be circumferentially surrounded, e.g. completely circumferentially surrounded, by the housing.

In at least one embodiment, the container-holder subassembly for a drug delivery device comprises a needle shroud configured to cover a needle of a medicament container and a container holder configured to hold a medicament container. The needle shroud and the container holder are coupled to each other so that the needle shroud is movable with respect to the container holder in an axial direction. The container-holder subassembly is configured to be

inserted into a housing for a drug delivery device. Particularly, the container-holder subassembly may be inserted into the housing as one entity and/or may be preassembled before it is guided into the housing. The housing may be the housing element of the drive subassembly and/or the housing of the drug delivery device. The drive subassembly and the container-holder subassembly may be assembled or connected to each other, e.g. to form the drug delivery device. The connection between the container-holder subassembly and the drive assembly may be permanent or irreleasable.

According to at least one embodiment, an outer surface of the container-holder subassembly is at least partially formed by the container holder and/or the needle shroud. Particularly, the container holder and/or the needle shroud may be freely accessible from a radial direction. This means, when viewed in inward radial direction, at least a portion of the container holder and/or the needle shroud may be exposed, i.e. not covered by other elements. Such a configuration allows to check the position of a medicament container held or received in the container holder. In at least one axial position along the axial extension of the container-holder subassembly, the outer perimeter or boundary of the container-holder subassembly may be defined by at least one portion of the needle shroud, e.g. one arm, and at least one portion of the container holder, e.g. at least one arm or a body thereof. Portions of the container holder and portions of the needle shroud may be alternatingly disposed in the rotational or angular direction when traveling along the outer perimeter or boundary of the container-holder subassembly in the rotational or angular direction in the at least one axial position.

According to at least one embodiment, the container-holder subassembly further comprises a medicament container. The medicament container may comprise a needle. Particularly, the medicament container is received in the container holder. The needle may form the distal end of the medicament container. The needle may distally project from the container holder.

The medicament container may be a syringe, e.g. a prefilled syringe. The container holder may also be referred to as syringe holder. The medicament container may be arranged axially and/or rotationally and/or radially fixed with respect to the container holder, i.e. it is not moved with respect to the container holder during the intended usage of the drug delivery device or of the container-holder subassembly. An end of the medicament container opposite the needle may be sealingly closed by a movable member, e.g. a stopper or piston. The medicament container may comprise a drug or medicament, e.g. a liquid drug or medicament.

According to at least one embodiment, the medicament container is freely accessible from a proximal side of the container-holder subassembly. This means, when viewed from the proximal

side of container-holder subassembly along the axial direction, the medicament container is visible or exposed, i.e. not completely covered by other elements of the container-holder subassembly.

According to at least one embodiment, the container holder and the needle shroud are rotationally fixed with respect to each other. Particularly, the container holder and the needle shroud may be coupled to each other by a rotation-lock interface.

According to at least one embodiment, the container holder comprises a first rotation-lock feature and the needle shroud comprises a second rotation-lock feature. The container holder may comprise several, e.g. two or more, first rotation-lock features. Likewise, the needle shroud may comprise several, e.g. two or more, second rotation-lock features. The rotation-lock features may be arranged rotationally symmetrically at the container holder or the needle shroud, respectively. All features disclosed here and in the following for one first rotation-lock feature or one second rotation-lock feature are also disclosed for further first rotation-lock features or second rotation-lock features, respectively.

One of the first and second rotation-lock features may be a protrusion and the other one may be a recess. The protrusion may protrude in a radial direction. For example, the protrusion and/or the recess may be elongated. A main extension direction of the protrusion and/or the recess may extend along the longitudinal axis, respectively. In other words, the protrusion may be a rib and the recess may be a slit or slot. The recess may be longer than the protrusion in order to allow a relative axial movement of the needle shroud and the container holder.

According to at least one embodiment, the two rotation-lock features are engaged with each other and the engagement prevents a rotation of the container holder and the needle shroud with respect to each other. Particularly, the protrusion may project into the recess.

According to at least one embodiment, the container-holder subassembly further comprises a shroud spring coupled to the needle shroud and the container holder. The shroud spring may be configured such that it induces a restoring force acting in distal direction on the needle shroud when the needle shroud is moved in proximal direction with respect to the container holder. Particularly, one end of the shroud spring, e.g. a distal end of the shroud spring, may be coupled or fixed or secured to a distal portion of the needle shroud and a further end, e.g. a proximal end, of the shroud spring may be coupled or fixed or secured to a distal portion of the container holder.

The distal portions of the container holder and/or of the needle shroud may be cylindrically-shaped portions, e.g. hollow cylindrically-shaped portions. The distal portion of the container holder may be located further proximal than the distal portion of the needle shroud.

According to at least one embodiment, the needle shroud comprises two arms, e.g. exactly two arms, extending from a first portion of the needle shroud, e.g. the distal portion, in proximal direction. The two arms of the needle shroud may be arranged with a rotational symmetry, e.g. a 2-fold rotational symmetry, around the longitudinal axis. The two arms of the needle shroud may be spaced from each other in rotational direction.

According to at least one embodiment, the container holder comprises two arms, e.g. exactly two arms, extending from a first portion of the container holder, e.g. the distal portion or a support portion, in proximal direction. The two arms of the container holder may be arranged with a rotational symmetry, e.g. a 2-fold rotational symmetry, around the longitudinal axis. The two arms of the container holder may be spaced from each other in rotational direction.

The first rotation-lock feature of the container holder may be arranged in the first portion of the container holder, particularly in a support portion of the container holder. The first portion of the container holder may be cylindrically-shaped, e.g. hollow cylindrically-shaped. The support portion may be arranged axially between the distal portion and the arms of the container holder.

The second rotation-lock feature of the needle shroud may be arranged in an arm of the needle shroud. The arms of the needle shroud may be aligned or may overlap with the first portion of the container holder in axial and/or rotational direction.

According to at least one embodiment, the arms of the needle shroud are arranged between the arms of the container holder in angular direction. Particularly, at least a portion of the outer surface of the container-holder subassembly may alternatingly be formed by the arms of the needle shroud and the arms of the container holder when viewed along the angular direction. The arms of the needle shroud and the container holder may overlap in axial direction.

According to at least one embodiment, the container holder, particularly the arms of the container holder, project beyond the needle shroud, particularly beyond the arms of the needle shroud, in proximal direction. The arms of the container holder may comprise or may form the release element and/or the push element specified above. The release element and/or the push element may be formed in the region of the proximal end of the arms of the container holder.

The arms of the container holder and/or the arms of the needle shroud may form the proximal end of the container holder or the needle shroud, respectively.

According to at least one embodiment, the container holder comprises at least one window through which a medicament container held in the container holder can be observed. The window may be formed in an arm of the container holder or in the first portion of the container holder, e.g. in the support portion. For example, the container holder comprises several windows. The window(s) may have an elongated shape, e.g. an oval shape. A main extension direction of the window(s) may run along the longitudinal axis. In angular direction, the windows may be formed between the first rotation-lock features.

According to at least one embodiment, the container holder comprises a snap feature. The snap feature may be arranged next to the window. The snap feature may be configured for axially and/or rotationally and/or radially fixing the container holder to the housing. For example, the snap feature is arranged at the proximal end and/or at the distal end of the window. The snap feature may be a protrusion protruding in radial outward direction.

The container holder may comprise several such snap features, e.g. for each window two snap features arranged at the distal and proximal end thereof.

The snap feature(s) may be configured to engage with corresponding snap feature(s) of the housing. The snap feature(s) of the housing may be protrusions or recesses.

According to at least one embodiment, the container-holder subassembly comprises a cap arranged at the distal end of the container-holder subassembly. The cap may be configured to cover a distal portion of the needle shroud.

According to at least one embodiment, the cap is releasably coupled to the needle shroud. For example, the cap is coupled to the distal portion of the needle shroud and may completely cover the distal portion of the needle shroud when coupled to the needle shroud.

Next, the kit is specified. The kit may comprise the drive subassembly specified herein and the container-holder subassembly specified herein. The drive subassembly and the container-holder subassembly may be configured to be telescoped with each other or coupled to each in order to assemble a drug delivery device. The drive subassembly and the container-holder subassembly may be assembled to a drug delivery device with the method specified herein.

Next, the drug delivery device specified.

The drug delivery device may be an auto-injector. The drug delivery device may comprise a drive subassembly as specified herein and/or a container-holder subassembly as specified herein. The drive subassembly and the container-holder subassembly may be coupled to each other and fixed, e.g. axially and/or rotationally fixed, to each other. The drive assembly and the container-holder subassembly may be permanently or irreleasably connected to one another. The drug delivery device may comprise a medicament container, e.g. a syringe. The medicament container may be received in the container holder. The drug delivery device may be configured to empty the medicament container when the first rotation-locking mechanism is released. In other words, the medicament container may comprise medicament in an amount sufficient for just one drug delivery operation. The drug delivery operation may be performed when the drug delivery device has been switched from the first locked state into a released state. The drug delivery device may be a single use device and/or a disposable device.

Hereinafter, the subassemblies for a drug delivery device, the method for assembling a drug delivery device and the drug delivery device described herein will be explained in more detail with reference to drawings on the basis of exemplary embodiments. Same reference signs indicate same elements in the individual figures. However, the size ratios involved are not necessarily to scale, individual elements may rather be illustrated with exaggerated size for a better understanding.

Brief description of the drawings

Figures 1 to 6 show a first exemplary embodiment of the drug delivery device in different views,

Figure 7 to 12 show different positions during usage of the drug delivery device according to the first exemplary embodiment,

Figure 13 shows the drug delivery device according to the first exemplary embodiment in an exploded view,

Figures 14 to 16 show subassemblies of the drug delivery device according to the first exemplary embodiment in more detail,

Figures 17 to 22 show a second exemplary embodiment of the drug delivery device in different views,

Figures 23 and 24 show subassemblies of the drug delivery device according to the second exemplary embodiment in exploded views,

Figures 25 to 27 show a part or arrangement of the drug delivery device according to the first and second exemplary embodiment in different positions during usage for illustrating an exemplary embodiment of a drive mechanism,

Figures 28 to 33 show sections of the drug delivery device according to the first and second exemplary embodiment in different positions during usage for illustrating an exemplary embodiment of a first locking mechanism and the release of the first locking mechanism,

Figures 34 to 38 show sections of the drug delivery device according the first and second exemplary embodiment in different positions during usage for illustrating a first exemplary embodiment of a third locking mechanism,

Figures 39 and 40 show sections of the drug delivery device in different positions during usage for illustrating a second exemplary embodiment of the third locking mechanism,

Figures 41 and 42 show sections of the drug delivery device according to the first and second exemplary embodiment in different positions during usage for illustrating an exemplary embodiment of a drop protection mechanism,

Figure 43 shows the different subassemblies of the drug delivery device according to the first exemplary embodiment and a step during assembling a drug delivery device,

Figures 44 to 46 show sections of the front subassembly of the drug delivery device according to the first exemplary embodiment,

Figures 47, 48 and 50 to 53 show different positions in an exemplary embodiment of a method for assembling the drug delivery device according to the first exemplary embodiment,

Figure 49 shows an isolated drive spring holder of the drug delivery according to the first and second exemplary embodiments,

Figures 54 to 56 show an exemplary embodiment of a feedback mechanism in different positions,

Figures 57 to 62 show a third exemplary embodiment of a drug delivery device in different views,

Figure 63 shows the drug delivery device according to the third exemplary embodiment after usage,

Figure 64 shows different subassemblies of the drug delivery device according to the third exemplary embodiment,

Figures 65 and 66 show the subassemblies of the drug delivery device according to the third exemplary embodiment in exploded views,

Figures 67 to 70 show sections of the drug delivery device according to the third exemplary embodiment in different positions during usage for illustrating a locking mechanism,

Figures 71 to 73 show different positions during assembling the drug delivery device according to the third exemplary embodiment.

Description of exemplary embodiments

1. First exemplary embodiment of a drug delivery device

Figures 1 and 2 show side views of a first exemplary embodiment of the drug delivery device 1000. Figure 1 shows a first view of the drug delivery device 1000 and figure 2 shows a second view in which the device 1000 is rotated by 90° around a longitudinal axis A compared to the first view.

Figures 1 and 2 also indicate the coordinate system used herein for specifying positions of members or elements or features. The distal direction D and proximal direction P run parallel to the longitudinal axis A. The longitudinal axis A is a main extension axis of the device 1000. The radial direction R is a direction perpendicular to the longitudinal axis A and intersecting with the longitudinal axis A. The azimuthal direction C, also referred to as angular direction or rotational direction, is a direction perpendicular to the radial direction R and to the longitudinal axis A. The different directions and axes will not be indicated in every of the following figures in order to increase the clarity of the figures.

The drug delivery device 1000 according to the first exemplary embodiment is an auto-injector. The auto-injector 1000 comprises a housing 100. A cap 110 is removably attached or coupled to the housing 100 at a distal end of the housing 100. The housing 100 may be formed in one piece and may extend from the cap 110 to the proximal end of the auto-injector 1000. The housing 100 is a cylindrically-shaped sleeve.

As can be further seen in figures 1 and 2, the housing 100 comprises windows 120 through which a medicament container inside the housing 100 can be investigated. For example, the fill level of the drug inside the medicament container or the advancement of a stopper in the medicament container or the drug clarity or the degradation of the drug can be observed through the windows 120.

Figures 3 and 4 show the auto-injector 1000 in the same views as in figures 1 and 2, but now the cap 110 and the housing 100 are indicated semi-transparent so that further details of the auto-injector 1000, which are normally completely surrounded and hidden by the housing 100 and the cap 110, are visible. It can be seen that the auto-injector 1000 further comprises a transfer member 2, also referred to as moveable member 2 or drive member 2, respectively, in the form of a rotating collar 2, an energy member 3 in the form of a torsion drive spring 3, particularly a spiral torsion drive spring (also commonly referred to as clock spring or power spring), and a housing element 4 in the form of a drive spring holder 4.

The drive spring holder 4 is fixed to the housing 100 so that the drive spring holder 4 can neither be rotated nor axially nor radially moved with respect to the housing 100. For example, the drive spring holder 4 is fixed with help of clips (not shown) to the housing 100. Alternatively, the drive spring holder 4 may be part of the housing 100, e.g. integrally formed with the housing 100. The drive spring holder 4 is received in the housing 100. The housing 100 circumferentially completely surrounds the drive spring holder 4.

The torsion drive spring 3 is connected to the drive spring holder 4 at a connection point. At a further connection point, the torsion drive spring 3 is connected to the rotating collar 2. The connection points are not visible in the figures. The rotating collar 2 is arranged axially and rotationally movable with respect to the drive spring holder 4. The torsion drive spring 3 circumferentially surrounds a portion of the rotating collar 2. When the torsion drive spring 3 is biased, it induces a torque onto the rotating collar 2. This torque results in a rotation of the rotating collar 2 with respect to the drive spring holder 4, if the rotating collar 2 is not prevented from rotating by a locking mechanism (see explanations further down below). The rotational axis of the rotating collar 2 may define or coincide with the longitudinal axis A.

The auto-injector 1000 further comprises a release member 5 or protection member 5, respectively, in the form of a needle shroud 5 and a medicament container holder 6 in the form of a syringe holder 6. The syringe holder 6 may be axially and preferably also rotationally fixed with respect to the housing 100. The syringe holder 6 is configured to hold a syringe. The syringe holder 6 comprises windows 60 which overlap/ are aligned with the windows 120 in the housing 100. In this way, the syringe or medicament container can be observed through the windows 60, 120.

The needle shroud 5 is arranged axially movable with respect to and telescopically coupled to the housing 100 or the drive spring holder 4, respectively. Particularly, the needle shroud 5 can be moved from an extended position, which is the position shown in figure 3 and 4, in the proximal direction P, into a retracted position (see figures 7 and 8). This will be explained in more detail further below.

The needle shroud 5 and the syringe holder 6 are moveably coupled to each other via a shroud spring 7. One end of the shroud spring 7 is connected to the syringe holder 6 and the other end of the shroud spring 7 is connected to the needle shroud 5. The coupling is such that a movement of the needle shroud 5 in the proximal direction P with respect to the syringe holder 6 results in a compression of the shroud spring 7 inducing a force onto the needle shroud 5 pointing in distal direction D.

Figures 5 and 6 show the auto-injector 1000 in two cross-sectional views, the views again being rotated by 90° with respect to each other around the longitudinal axis. The cutting plane comprises the longitudinal axis A. In this view, it can be seen that the auto-injector 1000 further comprises a plunger rod 1. The plunger rod 1 is to a main part arranged inside the rotating collar 2 and is circumferentially surrounded by the rotating collar 2. Only a small portion of the plunger rod 1 (less than 50 % of its length) projects out of the rotating collar 2 in distal direction D. In proximal direction P, the rotating collar 2 is closed and the plunger rod 1 does not project beyond the proximal end of the rotating collar 2. The plunger rod 1 is longer, measured along the longitudinal axis A, than the rotating collar 2.

The housing 100, the housing element 4, the plunger rod 1, the rotating collar 2, the needle shroud 5, the syringe holder 6 and the cap 110 may all comprise or consist of plastic. All these members may each be formed in one piece. The drive spring 3 and the shroud spring 7 may comprise or consist of a metal, e.g. steel.

It can be seen in figures 5 and 6 that a medicament container 8, in the present case a syringe 8, is arranged in the syringe holder 6. This syringe 8 may be arranged axially and/or rotationally and/or radially fixed with respect to the syringe holder 6 and/or with respect to the housing 100. The syringe 8 comprises a cartridge 81 filled with a drug, a needle 80 and a stopper 82. The needle 80 is arranged at a distal end of the syringe 8. The stopper 82 seals the cartridge 81 in proximal direction P. When moving the stopper 82 in the distal direction D, the drug stored in the cartridge 81 is pressed out of the syringe 8 through the needle 80.

In figures 5 and 6 it can be further seen that the needle 80 is covered by a needle shield 83 which encapsulates the needle 80 and projects beyond the needle 80 in distal direction D. The needle shield 83 may be formed of a rubber material. The cap 110 is connected to a grabber 111. The grabber 111 is retained within the cap 110 with a one or more bosses. The grabber 111 is coupled with the needle shield 83. The grabber 111 may be formed of a metal and may comprise barbs, which engage into the material of the needle shield 83.

When the cap 110 is removed from the housing 100, the grabber 111 pulls of the needle shield 83 from the needle 80. Afterwards, the needle 80 is circumferentially only surrounded by the retractable needle shroud 5.

Figures 7 and 8 show the auto-injector 1000 in the two cross-sectional views during usage. A first position during usage is shown in which the cap 110, the grabber 111 and the needle shield 83 have been removed from the housing 100. The needle shroud 5 projects from the housing 100 in distal direction D.

In the position of figures 7 and 8, the distal end of the auto-injector 1000 formed by the needle shroud 5 may be pressed against a body, e.g. a human body. As a consequence of that, the needle shroud 5 moves from its extended position in the proximal direction P with respect to the housing 100. This results in the needle 80 being exposed and projecting in distal direction D beyond the needle shroud 5 so that it can now pierce or is already pierced into the tissue of the body.

In the position of figures 7 and 8, the auto-injector 1000 is still in a first locked state, also referred to as pre-released state or initial state, (like in the previous figures), in which the torsion drive spring 3 is biased and induces a torque onto the rotating collar 2. A first locking mechanism (also referred to as first rotation-locking mechanism), however, prevents the rotating collar 2 from a rotational movement. The first locking mechanism will be explained in more detail further below.

In the first locked state, a proximal end of the rotating collar 2 is axially spaced from a proximal end-stop of the housing 100. This allows an axial movement of the rotating collar 2 in proximal direction P. Moreover, in the first locked state, a distal end of the plunger rod 1 is axially spaced from the stopper 82 of the syringe 8. Thus, the plunger rod 1 can axially move in the distal direction D for a predetermined distance before hitting the stopper 82.

Figures 9 and 10 show the two cross-sectional views of the auto-injector 1000 in a second position during usage. The auto-injector 1000 is now in a released state. The needle shroud 5 has been further moved in the proximal direction P into a retracted position. This has released the first locking mechanism so that the rotating collar 2 was no longer prevented from rotating. The torque induced by the torsion drive spring 3 onto the rotating collar 2 forces the rotating collar 2 to rotate in a first rotational direction (clockwise or counterclockwise). A drive mechanism, which will be explained in more detail further below, has converted the rotation of the rotating collar 2 into an axial movement of the plunger rod 1 in the distal direction D. After having moved the predetermined distance in the distal direction D, the plunger rod 1 has hit the stopper 82 of the syringe 8 and can now push the stopper 82 in distal direction D which results in the drug in the cartridge 81 being pressed out through the needle 80 into the tissue.

As indicated in figures 9 and 10, the rotating collar 2 does not only rotate but also moves in proximal direction P until the proximal end of the rotating collar 2 hits the proximal end-stop of the housing 100. The end-stop comprises is a protrusion 101 which tapers in distal direction D. The protrusion 101 may be a cone. The proximal end of the rotating collar 2 comprises an indentation 200. For example, the surface of the proximal end of the rotating collar 2 is concavely shaped. The protrusion 101 can penetrate into the indentation 200 when the proximal end of the rotating collar 2 hits the end-stop of the housing 100. The protrusion 101 and the indentation 200 may each be designed rotationally symmetric or circular symmetric with respect to the rotational axis of the rotating collar 2. In this way, a low friction interface is formed between the housing 100 and the rotating collar 2 so that a low friction rotation of the rotating collar 2 is enabled also when the proximal end of the rotating collar 2 abuts against the housing 100. Particularly, the radius at which the friction between the rotating collar 2 and the end-stop acts is approaching zero or is zero, therefore the resulting torque from the friction also tends to zero significantly reducing losses allowing a reduced spring force and/or enhance injection performance.

Figures 11 and 12 show two cross-sectional views of the auto-injector 100 in a third position during usage. The torsion drive spring 3 has further induced torque onto the rotating collar 2,

which, although abutting against the end-stop of the housing 100, has further rotated and has thereby forced the plunger rod 1 to move further in distal direction D. The plunger rod 1 has pushed the stopper 82 further in distal direction D so that a predetermined dose of the drug was supplied through the needle 80, e.g. into the tissue. Between the described first and third position, the rotating collar 2 has, e.g., rotated several times around its rotational axis.

In figures 11 and 12, the auto-injector 1000 is in a third locked state or post-released state, in which the needle shroud 5 is again in its extended position so that it circumferentially surrounds the needle 80 and so that the needle 80 does no longer distally project beyond the needle shroud 5. The movement of the needle shroud 5 in the extended position happens automatically due to the force induced by the shroud spring 7 which has been compressed when moving the needle shroud 5 out of the extended position towards the retracted position.

In the third locked state of the auto-injector 1000 shown in figures 11 and 12, the needle shroud 5 cannot be moved back into the retracted position due to a third locking mechanism which will be explained in more detail further below.

Figure 13 shows the auto-injector 1000 of the previous figures in an exploded view. The auto-injector 1000 comprises a release subassembly FSA or front subassembly FSA, respectively, a drive subassembly RSA or rear subassembly RSA, respectively, and the syringe 8. For assembling the auto-injector 1000, the syringe 8 is inserted into the front subassembly FSA or the rear subassembly RSA and afterwards the front subassembly FSA is inserted into the rear subassembly RSA. Assembling of the auto-injector 1000 will be explained in more detail further below.

Figure 14 shows the front subassembly FSA in a more detailed side view. The syringe holder 6 comprises two elongated arms 6b which extend axially and which are spaced from one another along the angular direction. The needle shroud 5 also comprises two elongated arms 5b which extend axially and which are spaced from one another along the angular direction. The needle shroud 5 and the syringe holder 6 are inserted into each other such that the arms 5b of the needle shroud 5 are located between the arms 6b of the syringe holder 6 along the angular direction. Furthermore, it can be seen that the arms 6b of the syringe holder 6 project beyond the arms 5b of the needle shroud 5 in proximal direction P.

The distal end of the syringe holder 6 is formed by a distal portion 6a in the form of a cylindrically-shaped portion 6a. This portion 6a is configured to hold the shroud spring 7. The cylindrically-shaped portion 6a is inserted into the shroud spring 7 so that an edge of the syringe

holder 6 abuts against the proximal end of the shroud spring 7. The shroud spring 7 circumferentially surrounds the cylindrically-shaped portion 6a of the syringe holder 6. The shroud spring 7 may be fixed to the cylindrically-shaped portion 6a, e.g. by a glue or a mechanical radial interference with the proximal coil of the shroud spring 7.

Figure 15 shows the front subassembly FSA in an exploded view. It comprises the cap 110, the grabber 111, the needle shroud 5, the shroud spring 7 and the syringe holder 6. The needle shroud 5 also comprises a distal portion 5a in the form of a cylindrically-shaped portion 5a forming the distal end of the needle shroud 5. The cylindrically-shaped portion 5a is configured to hold the shroud spring 7. This cylindrically-shaped portion 5a is shaped as a hollow cylinder so that the shroud spring 7 can be inserted into this portion 5a an so that the distal end of the shroud spring 7 abuts against a bottom area of the cylindrically-shaped portion 5a. The shroud spring 7 may be fixed to the cylindrically-shaped portion 5a, e.g. by a glue or a mechanical radial interference with the distal coil of the shroud spring 7. In this way, the needle shroud 5, the shroud spring 7 and the syringe holder 6 are coupled such that a movement of the needle shroud 5 in proximal direction P with respect to the syringe holder 6 results in a compression of the shroud spring 7. The shroud spring 7 could also be held in place by a coupling/snap between the needle shroud 5 and the syringe holder 6 at the most extended positions, e.g. by the features 54 and 61 explained further below.

As can further be seen in figure 15, the syringe holder 6 comprises a support portion 6c, which is located proximally with respect to the cylindrically shaped portion 6a and which is located between the arms 6b and the cylindrically shaped portion 6a. After inserting the syringe holder 6 into the needle shroud 5, the arms 5b of the needle shroud 5 cover the support portion 6c, i.e. are located radially outwardly with respect to the support portion 6c.

Figure 16 shows the rear subassembly RSA in an exploded view. The rear subassembly RSA comprises the housing 100, the torsion drive spring 3, the rotating collar 2, the plunger rod 1 and the drive spring holder 4. The drive spring holder 4, the rotating collar 2 and the housing 100 each have the form of a sleeve. When assembling the rear subassembly RSA, the plunger rod 1 is inserted into the rotating collar 2, the rotating collar 2 is inserted into the torsion drive spring 3 and is fixed to the torsion drive spring 3 at one connection point. The torsion drive spring 3 is inserted into the drive spring holder 4 and is connected to the drive spring holder 4 at a further connection point. The drive spring holder 4 is inserted into the housing 100.

2. Second exemplary embodiment of a drug delivery device

Figures 17 and 18 show a second exemplary embodiment of a drug delivery device 1000 which is again an auto-injector 1000. Like figures 1 and 2, figure 17 and 18 show the auto-injector 1000 in two different views rotated with respect to each other by 90° around the longitudinal axis A.

Figures 19 and 20 show the auto-injector 1000 of figures 17 and 18 in the same rotated views but with a semi-transparent housing 100.

Figures 21 and 22 show the auto-injector 1000 of figures 17 and 18 in the same rotated views but now in cross-sectional view with the crossing plane comprising the longitudinal axis.

One difference between the auto-injector 1000 according to the second exemplary embodiment and the auto-injector according to the first exemplary embodiment is that, in the second exemplary embodiment, the housing 100 now comprises two parts instead of one part. A first part forming the distal part of the housing 100 and a second part forming the proximal part of the housing 100. The two parts of the housing 100 are connected to each other, e.g. with help of clips (not shown). For example, the two parts of the housing 100 are fixed to each other such that they are neither axially nor rotationally nor radially movable with respect to each other.

Figure 23 shows a front subassembly FSA of the auto-injector 1000 according to the second exemplary embodiment in an exploded view. The first part of the housing 100 is assigned to the front subassembly FSA. The needle shroud 5 may be inserted into this first part of the housing 100. The shroud spring 7 is connected to the needle shroud 5 and the first part of the housing 100 so that a movement of the needle shroud 5 in proximal direction with respect to the first part of the housing 100 results in a compression of the shroud spring 7. In difference to the first exemplary embodiment, the auto-injector according to the second exemplary embodiment does not comprise a syringe holder with two arms spaced in angular direction. Instead of such a syringe holder, the first part of the housing 100 is configured to hold a medicament container, e.g. in an axially and/or rotationally fixed manner. The first part of the housing 100 circumferentially completely surrounds the needle shroud 5.

An exploded view of the rear subassembly RSA of the auto-injector 1000 according to the second exemplary embodiment is shown in figure 24. This rear subassembly is basically identical to the rear subassembly RSA of the first exemplary embodiment. Only the second part of the housing 100 assigned to the rear subassembly RSA may be shorter than the housing 100 of the first exemplary embodiment.

3. Drive Mechanism

The conversion of the rotational movement of the rotating collar 2, induced by the torsion drive spring 3, into an axial movement of the plunger rod 1 (drive mechanism) is explained in more detail in the following in connection with figures 25 to 27.

Figures 25 and 26 show a part or arrangement of the auto-injector 1000 of the first and second exemplary embodiment in different positions during usage. The shown part comprises the rear subassembly (only the housing is not shown) and a syringe 8. In figure 25, the auto-injector 1000 is in the first locked state and in figure 26 the auto-injector is in the released state.

As can be seen in figures 25 and 26, the drive spring holder 4 comprises two hollow sections 4a, 4b, which may both be hollow cylindrically-shaped. The two sections 4a, 4b are arranged behind each other along the longitudinal axis. The first section 4a is located more proximally and has a greater inner diameter and a greater outer diameter than the second section 4b.

The rotating collar 2 is received in the drive spring holder 4. A proximal end of the rotating collar 2 projects out of the drive spring holder 4 in proximal direction P. The rotating collar 2 comprises a shaft 20, and two portions 21, 22 with larger diameters than the shaft 20. The two portions 21, 22 are axially spaced from one another and are connected via the shaft 20. In this exemplary embodiment, the two portions 21, 22 are disc-shaped but other shapes might also be possible. The first portion 21 has a greater diameter than the second portion 22. The first portion 21 is located in the first section 4a of the drive spring holder 4 and the second portion 22 is located in the second section 4b of the drive spring holder 4. The diameters of the portions 21, 22 are substantially the same as the inner diameters of the assigned sections 4a, 4b but sufficiently smaller to allow a rotation of the rotating collar 2 with respect to the drive spring holder 4. Moreover, the diameter of the first portion 21 is greater than the inner diameter of the second section 4b which limits the axial movement of the rotating collar 2 in distal direction D.

As can be further seen in figure 25, in the first locked state, the second portion 22 is offset in proximal direction P from a second bottom ring 4d of the drive spring holder 4. Likewise, the first portion 21 is offset in proximal direction P from a first bottom ring 4c of the drive spring holder 4.

The torsion drive spring 3 is received in the first section 4a and is fixed to the first section 4a at a connection point. The rotating collar 2 is received in the torsion drive spring 3 so that the torsion drive spring 3 circumferentially surrounds the shaft 20 of the rotating collar 2 at a proximal side of the first section 21. The shaft 20 of the rotating collar 2 is connected to the

torsion drive spring 3 at a further connection point. The first portion 21 is offset with respect to the torsion drive spring 3 in distal direction D. In the first locked state, shown in figure 25, the torsion drive spring 3 is biased and induces a torque onto the rotating collar 2. The rotating collar 2 is prevented from a rotation with help of the first locking mechanism explained further below.

The plunger rod 2 is received in the rotating collar 2. In the first locked state, a portion of the plunger rod 1 projects from the rotating collar 2 in distal direction D. The stopper 82 of the syringe 8 is offset from the distal end of the plunger rod 1 in distal direction D.

Figure 26 shows the part or arrangement of the auto-injector in the released state. The first locking mechanism has been released so that the rotating collar 2 was no longer prevented from rotating. Due to the torque induced by the drive spring 3, the rotating collar 2 rotates in a first rotational direction (clockwise or anti-clockwise) inside the drive spring holder 4. The rotating collar 2 and the plunger rod 1 are operatively coupled via a threaded interface. In the present case, the plunger rod 1 comprises an external thread 11 and the rotating collar 2 comprises an internal thread (not visible) engaging with the external thread 11 of the plunger rod 1. The coupling via the threaded interface is such that the rotation of the rotating collar 2 in the first rotational direction is converted into a movement of the plunger rod 1 in distal direction D.

During the axial movement of the plunger rod 1 induced by the rotation of the rotating collar 2, the plunger rod 1 itself does not rotate. This is realized by a coupling between the plunger rod 1 and the drive spring holder 4 via a splined interface. This is further illustrated in figure 27 showing a three-dimensional view of the part/arrangement of the auto-injector. The splined interface is realized by protrusions 40 of the drive spring holder 4 projecting in distal direction D from the second bottom ring 4d and engaging with or projecting into grooves 10 of the plunger rod 1, respectively. The grooves 10 extend along the longitudinal axis A, i.e. run essentially parallel to the longitudinal axis A. The grooves 10 are arranged opposite each other on the plunger rod 1. Instead of two grooves, as shown in figure 27, one groove and one corresponding protrusions 40 may be sufficient. However, more than two grooves 10 and associated protrusions 40 may also be used.

In the exemplary embodiments, the splined interface is in close proximity to the threaded interface, e.g. with a distance of at most 1 cm or at most 0.5 cm. This is beneficial since the torque on the plunger rod 1 is resolved over a short distance reducing the stresses within the plunger rod 1. The plunger rod 1 is often a small member likely to deform.

As can be further seen in figure 26, the rotating collar 2 does not only rotate but also moves axially in the proximal direction P, as already mentioned before. The movement in proximal direction P preferably starts immediately when the rotation is started. In this way the needle shroud 5 may reextend upon premature removal from the skin. The break loose force of the stopper 82 is typically 5 N or more. The ability of the torsion drive spring 3 to resolve axial loads may be smaller than this.

In the released state, the plunger rod 1 pushes the stopper 82 in distal direction D until the stopper 82 hits against a bottom region of the cartridge 81. A further distal movement of the stopper 82 and the plunger rod 1 is then prevented. After movement of the plunger rod 1 and the rotating collar 2 is finished, a portion of the plunger rod 1 is still received in the rotating collar 2.

An example of the dimensions of the plunger rod 1 is as follows: The plunger rod 1 has a diameter of 8.0 mm and the pitch of the outer thread is 3.17 mm. The coefficient of friction is 0.3. The mean contact radius, i.e. the position of the threaded face from the central axis of the plunger rod 1, is 3.75 mm.

An example of the torsion drive spring is 3 as follows: The material is polished and blued SAE 1095 steel. The height of the torsion drive spring is 12.0 mm, the thickness of the material is 0.168 mm, the length is 840.749 mm, the outer diameter is 20.0 mm, the arbor diameter is 10.0 mm. The bending stress limit is 2000 $N \cdot mm^{-2}$, the Youngs Modulus is 20000 $N \cdot mm^{-2}$, the number of revolutions before being biased is 3.

In general, the following conditions for the torsion drive spring turned out to be advantageous: The arbor diameter is between 12 to 25 times the thicknesses of the material. The length is between 5000 to 15000 times the thickness. The area of the torsion drive spring 3 is half the area of the drive spring holder 4 (e.g. in the first section 4a) +- 10%. The bending stress for tempered polished and blued SAE 1095 steel should not exceed 2000 MPa.

An example of the used syringe 8 might be as follows: The drug inside the cartridge 81 has a volume of 2 ml. The viscosity of the material is 50 cP at room temperature. The inner needle diameter is 0.29 mm. The inner cartridge diameter is 8.65 mm. The friction of the stopper 82 is 10 N. The stopper gap, i.e. the initial clearance between the proximal end of the stopper 82 and the distal end of the plunger rod 1, is 2 mm.

4. First locking mechanism and release of the first locking mechanism

The previously mentioned first locking mechanism or first rotation-locking mechanism, respectively, and how it is released is described in further detail in the following in connection with the figures 28 to 33.

Figure 28 illustrates a cross-sectional view of the auto-injector 1000 of the first and second exemplary embodiment with the cutting plane being perpendicular to the longitudinal axis A and running through the second portion 22 of the rotating collar 2. As can be seen, the drive spring holder 4 comprises a displaceable element 41 in the form of a resilient arm (see also figures 27 and 49). The resilient arm 41 is integrally formed with the drive spring holder 4 and is arranged in the second section 4b of the drive spring holder 4. The resilient arm 41 is oriented circumferentially, i.e. a main extension direction of the resilient arm 41 is along the angular direction C. One end of the resilient arm 41 is connected to the drive spring holder 4, the other end is free and movable in radial direction R.

The resilient arm 41 comprises a protrusion 410 projecting radially inwardly, i.e. in a radial direction pointing towards the longitudinal axis A. The protrusion 410 tapers radially inwardly. The protrusion 410 comprises a beveled surface 410a, which essentially runs parallel to the longitudinal axis A and which is tilted with respect to the radial direction R and with respect to the angular direction C. For example, the angle α between the beveled surface 410a and the radial direction R is at least 10° and at most 80°, preferably between 30° and 55°.

In the first locked state, shown in figure 28, the resilient arm 41 is in a first radial position in which the protrusion 410 engages or projects into a recess 220 of the second portion 22 of the rotating collar 2, respectively. In this way a rotation-lock interface is formed, coupling the resilient arm 41 and the rotating collar 2 and preventing the rotating collar 2 from a rotation.

The first radial position may be the relaxed position of the resilient arm 41 which it would occupy if no further forces pointing radially inwardly and radially outwardly were acting on the resilient arm 41. Alternatively, the resilient arm 41 may be biased in the first radial position, such that the first radial position is a stressed position of the resilient arm 41.

As long as the resilient arm 41 is in the first radial position in which the protrusion 410 projects into the recess 220, a rotation of the rotating collar 2 in the first rotational direction induced by the torsion drive spring 3 is prevented. However, the torque acting on the rotating collar 2 presses a surface of the second portion 22 delimiting the recess 220 against the beveled

surface 410a of the protrusion 410 of the resilient arm 41. This results in a force trying to move the resilient arm 41 radially outwardly from the first radial position into a second radial position. In other words, the torque induced by the torsion drive spring 3 biases the resilient arm 41 radially outwardly. If a movement in radial outward direction would be allowed, the first locking mechanism would be released automatically and the auto-injector 1000 would transfer into the released state.

In the first locked state, an arm 5b of the needle shroud 5 is located at the height of, i.e. axially overlapping or aligned with, the resilient arm 41 and prevents the resilient arm 41 from moving radially outwardly out of and away from the first radial position. Indeed, the resilient arm 41 abuts against the needle shroud 5 in outward radial direction such that an outward radial movement is blocked. The resilient arm 41 comprises a further protrusion 411 which projects radially outwardly and which abuts against the needle shroud 5. An outward radial movement of the needle shroud 5 is prevented, e.g. by the housing 100 circumferentially surrounding the needle shroud 5.

Figure 29 shows a section of the auto-injector 1000 in the same state as in figure 28 but now in a cross-sectional view with the longitudinal axis lying in the cutting plane. There it can be seen that the arm 5b of the needle shroud 5 in fact comprises a first section 50a, namely a wall portion, and a second section 50b, namely a recess, e.g. a cut-out. The recess 50b is offset in distal direction D with respect to the wall portion 50a. In the first locked state, the needle shroud 5 is in its extended position, in which the wall portion 50a blocks the outward radial movement of the resilient arm 41.

Figure 29 further indicates that the needle shroud 5 can be moved from its extended position into a retracted position which would result in an overlap or alignment between the recess 50b and the resilient arm 41 in axial direction and rotational direction. Movement of the needle shroud 5 in proximal direction P requires a force, also called activation force, which includes the force needed to compress the shroud spring 7 and the friction force resulting from the resilient arm 41 being pressed against the needle shroud 5.

As an numerical example: Assuming a torque induced by the torsion drive spring 3 onto the rotating collar 2 of 102 Nmm, a radius at which the rotating collar 2 abuts against the protrusion 410 of 7.5 mm and an angle α of 39° would result in a force on the resilient arm 41 in radial direction of about 10.57 N. Assuming a friction coefficient of 0.3, the friction force would be about 3.17 N. Assuming further that the force for compressing the shroud spring 7 is about 6 N, the activation force would be about 9 N.

Figures 30 and 31 show sections of the auto-injector 1000 which corresponds to the sections shown in figures 28 and 29. Now the needle shroud 5 has been moved in its retracted position (by overcoming the activation force). This movement releases the first locking mechanism so that the auto-injector 1000 is switched from the first locked state into the released state. As the recess 50b of the needle shroud 5 is now at the height of the resilient arm 41, the outward radial movement of the resilient arm 41 is no longer blocked. The resilient arm 41 automatically – induced by the torque on the rotating collar 2 – leaves its first radial position and deflects into a second radial position in which the protrusion 410 no longer projects into the recess 220, thus the rotation-lock interface is resolved and the first locking mechanism is released. As a result of this, the rotation of the rotating collar 2 is no longer prevented. The rotating collar 2 starts to rotate (see figure 30) due to the force induced by the drive spring 3, thereby forcing the plunger rod 1 into an axial movement.

Figure 32 and 33 show sections of the auto-injector 1000 which corresponds to the sections shown in figures 28 and 29. Now, the auto-injector 1000 is switched into a third locked state or post-released state. For example, the distal end of the auto-injector 1000 has been removed from the body so that the needle shroud 5 automatically moves from the retracted position back into the extended position induced by the shroud spring 7.

The protrusion 411 of the resilient arm 41 comprises a slide feature 411a in the form of a beveled surface 411a. The beveled surface 411a and the longitudinal axis may include, e.g., an angle between 10° and 80° inclusive. An edge of the needle shroud 5 delimiting the recess 50b in proximal direction P may contact this beveled surface 411a when the needle shroud 5 moves in distal direction D. Due to the beveled surface 411a, the resilient arm 41 is pushed radially inwardly when the edge hits the protrusion 411. In this way, the movement of the needle shroud 5 back into the retracted position is possible without the needle shroud 5 jamming up with the resilient arm 41. The slide feature may additionally or alternatively be formed in the needle shroud 5 (see figures 39 and 40).

In the case the resilient arm 41 indeed abuts against the edge of needle shroud 5 when the needle shroud 5 is moved in distal direction D, the movement of the resilient arm 41 in inward radial direction is possible, since the rotating collar 2, particularly the second portion 22 of the rotating collar 2, has moved in proximal direction P. Thus, the second portion 22 is now offset in proximal direction P with respect to the resilient arm 41. For this reason, it is particularly beneficial if the rotating collar 2 moves in the proximal direction immediately when the plunger rod 1 starts to move in distal direction, i.e. before the plunger rod 1 hits the stopper 82. If the

user lifts the auto-injector 1000 early from the skin, e.g. before the drug is started to be administered, the needle shroud 5 can then still move back in distal direction and the third locking mechanism explained below can be activated.

5. Third locking mechanism / post-released locking mechanism

A third locking mechanism or post-released locking mechanism, respectively, is described in further detail in the following in connection with the figures 34 to 40.

Figures 34 to 38 illustrate a first exemplary embodiment of the third locking mechanism. This mechanism is configured to prevent the needle shroud 5 from being moved from the extended position into the retracted position after the drug has been delivered or after the autoinjector has once been activated. Thus, the risk of injuries due to an exposed needle may be reduced. This third locking mechanism may be used in all exemplary embodiments of the auto-injector 1000 described herein.

Figure 34 shows again a cross-sectional view of a section of the auto-injector 1000 with the cutting plane comprising the longitudinal axis A. However, the cutting plane is rotated compared to what is shown in, e.g. figure 33 (see figure 38 for a perspective view). It can be seen in figure 34 that the arm 5b of the needle shroud 5 comprises a first stop feature 51 in the form of a displaceable element 51 which is located at the proximal end of the arm 5b. The displaceable element 51 is a resilient arm 51 which is integrally formed with the rest of the needle shroud 5 and, therefore, is axially and rotationally fixed to the rest of the needle shroud 5. Thus, the resilient arm 51 moves in axial direction when the needle shroud 5 is moved in axial direction.

As can be seen in figure 38, the resilient arm 51 is located on the same height as the wall portion 50a when seen along to the longitudinal axis A and is arranged offset from the wall portion 50a in the angular direction C.

Simultaneously to extending in proximal direction P, the resilient arm 51 also extends radially inwardly, i.e. a main extension direction of the resilient arm 51 has a component along the proximal direction P and a component along the inward radial direction. Thus, a proximal end of the resilient arm 51 is located further radially inwardly than a distal end of the resilient arm 51. The proximal end of the resilient arm 51 is free and displaceable in the radial direction. The distal end of the resilient arm 51 is connected to the rest of the needle shroud 5. A kink is formed between the distal end of the resilient arm 51 and the rest of the needle shroud 5.

In figure 34, the auto-injector 1000 is in the first locked state (also referred to as initial state or pre-released state), in which a rotation of the rotating collar 2 is blocked by the first locking mechanism as described before. The resilient arm 51 is in a first radial position, which may be a biased position of the resilient 51. The resilient arm 51 is held in the first radial position and is prevented from moving radially inwardly by the second portion 22 of the rotating collar 2. In the present case, the drive spring holder 4 comprises a recess 43, namely a cut-out 43, into which the resilient arm 51 projects. The resilient arm 51 abuts against the second portion 22 in inward radial direction.

Figure 35 shows a section of the auto-injector 1000 in a position during usage, when the needle shroud 5 is moved from its extended position into the retracted position so that the auto-injector 1000 switches into the released state. Together with the needle shroud 5, the resilient arm 51 has moved in proximal direction P such far that the second portion 22 of the rotating collar 2 does no longer hold the resilient arm 51 in the first radial position. This allowed the resilient arm 51 to move radially inwardly into a second radial position. In the released state of the auto-injector 1000 and the needle shroud 5 being in the retracted position, the resilient arm 51 is offset with respect to the second portion 22 in proximal direction P.

In the released state of the auto-injector 1000, the rotating collar 2 moves in proximal direction P from a nonlocking position into a locking position, as it is indicated in figure 35.

Figure 36 shows a section of the auto-injector 1000 in a third locked state, also referred to as post-released state, which is a state after usage, i.e. after the drug has been dispensed. The third locked state is a state after the released state. In this third locked state, the needed shroud 5 is again in its extended position. As can be seen in figure 36, the second portion 22 has moved in proximal direction P such far that the resilient arm 51 is now offset in distal direction D with respect to the second portion 22 so that the second portion 22 can no longer hold the resilient arm 51 in the first radial position. Therefore, in the third locked state, the resilient arm 51 is in the second radial position. When trying to move the needle shroud 5 from the extended position towards the retracted position, the resilient arm 51 in the second radial position hits against a second stop feature 22a, namely a surface of the second portion 22 which runs essentially perpendicularly to the longitudinal axis and faces in distal direction D. This prevents a further movement of the needle shroud 5 in proximal direction P. For example, the auto-injector 1000 is configured such that, in the third locked state, the resilient arm 51 hits against the surface 22a of the second portion 22 when moving the needle shroud 5 in proximal direction P before the needle is exposed.

When the resilient arm 51 hits against the surface 22a of the second portion 22, a lock interface is formed between the resilient arm 51 and the surface 22a. For this purpose, a recess 221 or notch 221 is formed in the surface 22a which engages with the proximal end of the resilient arm 51 when the resilient arm 51 hits against the surface 22a. The recess 221 is delimited by a beveled surface 221a which is tilted with respect to the longitudinal axis A and the radial direction. For example, an angle between the beveled surface 221a and the longitudinal axis and/or the radial direction is between 10° and 80° inclusive. When the proximal end of the resilient arm 51 engages into the recess 221, the resilient arm 51 hits against the beveled surface 221a and slides along the beveled surface 221a thereby being forced to move radially inwardly. The recess 221 with the beveled surface 221a thus prevents the resilient arm 51 from sliding along the surface 22a in outward radial direction.

The surface 22a of the second portion 22 may circumferentially extend around the longitudinal axis and/or the rotational axis of the rotating collar 2 by at least 270° and may have a constant geometrical form along its extension along the angular direction. In this way, the functionality of the third locking mechanism is almost independent on how far the rotating collar 2 has rotated in the released state.

As can be further seen in figures 34 to 36, the resilient arm 51 comprises a slide feature 51a in the form of a ramp 51a. During movement of the needle shroud 5 from the retracted position into the extended position, the ramp 51 hits against a proximal edge of the second portion 22. The ramp 51a is designed such that it forces the resilient arm 51 to slide along the edge of the second portion 22 so that the resilient arm 51 is pushed radially outwardly. This allows the resilient arm 51 to pass the second portion 22 without being jammed up with the second portion 22. After having passed the second portion 22 during movement towards the extended position, the resilient arm 51 springs back into the second radial position.

Figure 37 shows the auto-injector 1000 in a cross-sectional view in the third locked state. As can be seen, the needle shroud 5 cannot be moved such far in proximal direction P that the needle 80 is exposed because the resilient arm 51 hits against the surface 22a of the second portion 22 before.

Figures 39 and 40 illustrate a second exemplary embodiment of the third locking mechanism. Also this exemplary embodiment of the third locking mechanism may be used in all exemplary embodiments of the auto-injector described herein.

The main difference to the first exemplary embodiment is that, in the third locked state of the auto-injector 1000, when moving the needle shroud 5 towards the retracted position, the resilient arm 51 does not hit against a stop feature axially fixed to the rotating collar 2 but against a stop feature 40a axially fixed to the drive spring holder 4. The stop feature 40a is formed by an edge of the drive spring holder 4. The edge 40a delimits a recess/cut-out in the drive spring holder 4 in proximal direction P.

A flap 46, which is axially fixed to the drive spring holder 4, e.g. integrally formed with the drive spring holder 4, partially fills this recess. A distal end of the flap 46 is connected to the drive spring holder 4 and a proximal end of the flap 46 is free and displaceable in radial direction. The proximal end of the flap 46 is spaced from the edge 40a by a small gap.

In the first locked state, when the needle shroud 5 is still in the extended position, the rotating collar 2, particularly the second portion 22 of the rotating collar 2, abuts against the flap 46 of the drive spring holder 4 in outward radial direction and holds the flap 46 in a first radial position, in which the flap 46 substantially terminates flush with the edge 40a in outward radial direction. The second portion 22 prevents the flap 46 from being displaced in the inward radial direction. On the other hand, the flap 46 abuts against the resilient arm 51 of the needle shroud 5. In the first radial position of the flap 46, the flap 46 holds the resilient arm 51 in its first radial position.

When now moving the needle shroud 5 in proximal direction P, the resilient arm 51 can pass the edge 40a without jamming up with the edge 40a, since the flap 46 terminates flush with the edge 40a and since the flap 46 is held in its first radial position by the second portion 22. Moving the needle shroud 5 further into its retracted position releases the first locking mechanism, the auto-injector 1000 switches from the first locked state into the released state and the rotating collar 2 together with the second portion 22 moves in proximal direction P into a locking position. The needle shroud 5 being in its retracted position is shown in figure 39.

When moving the needle shroud 5 back from its retracted position into the extended position, the resilient arm 51 passes the edge 40a and stops at the height of the flap 46. This position is shown in figure 40. The auto-injector 1000 is now in the third locked state. The resilient arm 51 and optionally also the flap 46 may be biased in inward radial direction. Thus, the resilient arm 51 and the flap 46 move radially inwardly and each reach a second radial position. This is possible because the elements are no longer held by the second portion 22 of the rotating collar 2 in their respective first radial position.

The flap 46 being in the second radial position does no longer terminate flush with the edge 40a of the drive spring holder 4. Thus, when moving the needle shroud 5 from the extended position towards the retracted position, the resilient arm 51 will hit against the edge 40a which prevents a further movement of the needle shroud 5 in proximal direction P.

6. Drop protection mechanism

An exemplary embodiment of a drop protection mechanism is described in further detail in the following in connection with the figures 41 and 42. The drop protection mechanism shall prevent the release of the first locking mechanism when the auto-injector 1000 is unintentionally dropped. In fact, when the auto-injector 1000 of the exemplary embodiments described herein is in the first locked state, a movement of the rotating collar 2 in proximal direction P would result in a release of the first locking mechanism.

Figure 41 shows a section of the auto-injector 1000 of the first and second exemplary embodiments in cross-sectional view illustrating a first part of the drop protection mechanism. In the first locked state of the auto-injector 1000 and when the needle shroud 5 is still in the extended position (initial position), the second portion 22 and the resilient arm 41 engage with each other (protrusion 410 projects into recess 220) and this engagement is retained by the needle shroud 5 holding the resilient arm 41 in its radial position as explained in connection with the first locking mechanism. The engagement, however, also establishes an axial-lock interface preventing the rotating collar 2 from an axial movement at least in proximal direction P.

For this purpose, the protrusion 410 of the resilient arm 410 is a stepped protrusion having two section 410b, 410c (see also figure 49). The recess 220 in the second portion 22 of the rotating collar 2 is a stepped recess also having two sections 220b, 220c. The sections 410b, 410c are connected by a surface 410d running essentially perpendicularly to the longitudinal axis. The sections 220b, 220c are also connected by a surface 220d running essentially perpendicularly to the longitudinal axis. The surface 220d is located more distally than the surface 410d. These surfaces 220d, 410d abut or hit against each other when the rotating collar 2 is moved in proximal direction P and, in this way, the rotating collar 2 is prevented from moving in proximal direction P as long as the protrusion 410 projects into the recess 220.

The first part of the drop protection mechanism described in connection with figure 41 could, however, be released when the needle shroud 5 would unintentionally be moved in proximal direction P. Therefore, in one exemplary embodiment, the drop protection mechanism comprises a second part illustrated in connection with figure 42.

Figure 42 shows a section of the auto-injector in a cross-sectional view with the cutting plane running parallel to the longitudinal axis A. Shown is the distal end of the auto-injector with the cap 110 still being coupled to the housing 100. The cap 110 is in its most proximal position and cannot be moved further in proximal direction P with respect to the housing 100 since it hits against the housing 100 when moved in this direction. The cap 110 comprises a radially displaceable cap-lock element 110a, namely a resilient arm 110a, with a protrusion 110b protruding radially inwardly and engaging into a cap-lock element 52, namely a recess 52, particularly a cut-out 52, in the needle shroud 5.

In figure 42, the auto-injector 1000 is shown when it is dropped which results in a proximal movement of the needle shroud 5. The needle shroud 5, particularly an edge of the needle shroud 5 delimiting the recess 52 in distal direction D, hits against the protrusion 110b due to its proximal movement. This prevents a further movement of the needle shroud 5 in proximal direction P as long as the cap 110 is coupled to the housing 100. Thus, the needle shroud 5 cannot reach the retracted position in which it would no longer hold the resilient arm 41 in its radial position.

In the position shown in Figure 42, the resilient arm 110a cannot or only slightly be moved in outward radial direction as the housing 1000 circumferentially surrounds the resilient arm 110a and abuts or almost abuts against the resilient arm 110a thereby preventing an outward radial movement of the resilient arm 110a.

The protrusion 110b is located at a proximal end of the resilient arm 110a of the cap 110. Normally, when the drug delivery device is not dropped, the edge of the needle shroud 5 delimiting the recess 52 in distal direction D is located further distal as to what is shown in figure 42. When removing the cap 110, the cap 110 is moved in distal direction D until the protrusion 110b hits against said edge of the recess 52. The resilient arm 110a can then move in radial outward direction, because in this position of the cap 110, the housing 100 does not prevent the resilient arm 110a from being moved radially outwardly. The resilient arm 110a can disengage from the recesses 52 and the cap 110 can be completely removed. The protrusion 110b has a beveled surface (slide feature) which hits against the edge of the recess 52 and thereby forces the resilient arm 110a to deflect radially outwardly when the cap 110 is moved in distal direction D.

7. Subassemblies, assembling and second locking mechanism

Figure 43 shows the front subassembly FSA (also referred to as release subassembly FSA or container-holder subassembly FSA) and the rear subassembly RSA (also referred to as drive subassembly RSA) of the auto-injector according to the first exemplary embodiment in an exploded view as well as a position during assembling the front subassembly FSA and the rear subassembly RSA to an auto-injector 1000. These figures correspond to the figures 13, 15 and 16. It is therefore mainly referred to the description in connection with these figures.

What can be seen in figure 43 is that the support portion 6c of the syringe holder 6 comprises a first rotation-lock features 61 in the form of protrusions 61 or ribs 61 which protrude in outward radial direction and which have a main extension direction along the longitudinal axis. These ribs 61 are configured to engage with second rotation-lock features 54 in the form of recesses 54, particularly slots 54, in the arms 5b of the needle shroud 5. The recesses 54 are also elongated with a main extension direction along the longitudinal axis and are longer than the ribs 61 so that, when engaged, a relative axial movement between the needle shroud 5 and the syringe holder 6 is possible.

Figure 44 shows the front subassembly FSA in perspective view. As previously described, the needle shroud 5 comprises two arms 5b which are positioned, along the angular direction, between two arms 6b of the syringe holder 6. The arms 6b of the syringe holder 6 project beyond the arms 5b of the needle shroud 5 in proximal direction P. The needle shroud 5 and the syringe holder 6 are coupled by the shroud spring 7 and the rotation-lock features 61, 54 so that the needle shroud 5 can be moved axially but not rotationally with respect to the syringe holder 6.

In figure 45, a section of the front subassembly FSA of figure 44 is shown. Windows 60 are formed in the arms 6b of the syringe holder 6, through which a syringe or medicament container located inside the syringe holder 6 can be investigated. The windows 60 are delimited by a wall portion 60a of the syringe holder 6. The diameter of the windows 60 decreases in inward radial direction.

The syringe holder 6 further comprises snap features 62, namely ribs, protruding in outward radial direction. A respective snap feature 62 is located at the distal end and at the proximal end of the window 60. The snap features 62 are configured to engage with the housing 100 to fix the syringe holder 6 to the housing 100 such that an axial and a rotational movement of the syringe holder 6 with respect to the housing 100 is prevented. The housing 100 and the syringe holder 6 can be permanently and irreleasably connected in this way.

In figure 45, the ribs 61 project into the recesses 54 allowing an axial movement of the needle shroud 5 with respect to the syringe holder 6 but preventing a rotational movement of the needle shroud 5 with respect to the syringe holder 6. For that purpose, the width of the recesses 54 might be substantially as great as the width of the ribs 61.

Figure 46 shows a detailed view of the distal end of the front subassembly FSA with the cap 110 attached to the needle shroud 5. The protrusions 110b of the resilient arms 110a project into the recesses 52 of the needle shroud 5 so that the cap 110 is loosely held in position with respect to the needle shroud 5.

Figure 47 shows a section of the rear subassembly RSA in perspective view. Figure 48 shows the rear subassembly RSA in cross-sectional view with the longitudinal axis A running in the cutting plane. Figure 50 shows the rear subassembly RSA in a cross-sectional view with the cutting plane running perpendicularly to the longitudinal axis A. An exemplary embodiment of the second locking mechanism is illustrated on the basis of these figures.

As can be seen in figure 47, a recess 44, particularly a cut-out, is formed in the first section 4a of the syringe holder 4. The first portion 21 of the rotating collar 2 comprises a displaceable axial-lock element 210 in form of a resilient arm 210 or clip 210. The resilient arm 210 is displaceable in radial direction. The resilient arm 210 is configured to project into the recess 44 when it is in a first radial position. In this case, the rear subassembly RSA is in a second locked state. The engagement of the resilient arm 210 and the recess 44 establishes an axial-lock interface and prevents a proximal movement of the rotating collar 2 with respect to the drive spring holder 4, because, when moving the rotating collar 2 in proximal direction P, the resilient arm 210 hits against an edge of the drive spring holder 4 delimiting the recess 44 in proximal direction P. This is one part of the second locking mechanism, also referred to as axial-locking mechanism.

As can be seen in figure 48, in the second locked state, the second portion 22 of the rotating collar 2 abuts against the second bottom ring 4d of the drive spring holder 4. The first portion 21 of the rotating collar 2 abuts against the first bottom ring 4c of the drive spring holder 4.

The second locking mechanism comprises also a protrusion 45 (see also figure 49) which is part of the second portion 4b of the drive spring holder 4 protruding radially inwardly. The protrusion 45 is not movable in any direction with respect to the rest of the drive spring holder 4. The protrusion 45 may have the same form as the first section 410b of the protrusion 410 of the resilient arm 41. The protrusion 45 is offset in distal direction D with respect to the resilient arm

41 or the protrusion 410, respectively. Furthermore, the second locking mechanism comprises the second section 22 of the rotating collar 2 with the above described recess 220 forming also part of the previously described first locking mechanism.

In the second locked state, the protrusion 45 projects into the recess 220 (see figure 50) thereby establishing a rotation-lock interface. This engagement prevents a rotation of the rotating collar 2 (the biased torsion drive spring 3 may already induce a torque onto the rotating collar 2 in the second locked state). This is another part of the second locking mechanism, also referred to a second rotation-locking mechanism.

The second rotation-locking mechanism does not need the needle shroud 5 for retaining the second locked state as the protrusion 45 is not displaceable in radial direction. Thus, as long as the rotating collar 2 is not moved in proximal direction P, a rotation of the rotating collar 2 is not possible.

Figure 51 shows a position in the assembly of the auto-injector, in which the rear subassembly and the front subassembly of the previous figures are telescoped into each other. Figure 52 shows the same position in the assembling as figure 51 but in a cross-sectional view.

As can be seen in figure 52, the arms 6b of the syringe holder 6 each comprise or form at their proximal ends a push element 63 and a release element 64. The release element 64 protrudes beyond the push element 63 in proximal direction P. Moreover, the push element 63 is offset in inward radial direction with respect to the release element 64. When being telescoped into each other, the release element 64 first hits against the resilient arm 210 and forces the resilient arm 210 to move radially inwardly so that the axial-locking mechanism is released. This is realized by the resilient arm 210 having a beveled surface tilted with respect to the longitudinal axis so that a force acting on the beveled surface in proximal direction P pushes the resilient arm 210 in inward radial direction.

At the same time or later during telescoping the rear subassembly into the front subassembly, the push element 63 hits against the first section 21 of the rotating collar 2 and pushes the rotating collar 2 in proximal direction P (see also figure 53). This results in a release of the second rotation-locking mechanism and a transfer from the second locked state into the first locked state. The first locked state is occupied because the pushing of the rotating collar 2 in proximal direction P is accompanied with the needle shroud 5 being brought in the position where it holds the resilient arm 41 in its first radial position. Pushing the rotating collar 2 in proximal direction P during assembly has as a consequence that the recess 220 in the second

portion 22 disengages with the protrusion 45 but before engages with the protrusion 410 of the resilient arm 41 (see also figure 49).

8. Feedback mechanism

Figures 54 to 56 illustrate an exemplary embodiment of a feedback mechanism. Such a feedback mechanism can be used in any one of the exemplary embodiments of a drug delivery device described herein.

Figure 54 shows a section of an exemplary embodiment of a drug delivery device/auto-injector 1000 with such a feedback mechanism. In figure 54, the auto-injector 1000 may be in the first locked state (initial state).

The feedback mechanism comprises a plunger rod 1 received in a rotating collar 2. The rotating collar 2 may be designed as described in connection with the previous figures. Particularly, the rotating collar 2 is a sleeve. The plunger rod 1 is hollow, e.g. hollow cylindrically-shaped. A feedback energy member 14 in the form of a spring 14, e.g. compression spring, is received in the plunger rod 1, i.e. in a cavity thereof. Furthermore, a feedback element 12 in the form of a piston 12 is received in the plunger rod 1. The spring 14 is connected to the piston 12 and to the plunger rod 1 and is compressed. The spring 14 induces a force onto the piston 12 pointing in proximal direction P, i.e. the piston 12 is biased in proximal direction P relative to the plunger rod 1.

The plunger rod 1 comprises displaceable arms 13 oriented in axial direction. The displaceable arms 13 may be resilient arms 13 and are located at the proximal end of the plunger rod 1. The displaceable arms 13 each comprise a stop feature 130 in the form of a protrusion 130 at their respective proximal end. The displaceable arms 13 together with their protrusions 130 are each displaceable in radial direction. The displaceable arms 13 are each in a first radial position. They may be biased in the outward radial direction. However, the displaceable arms 13 are held in the first radial position by a sidewall of the rotating collar 2 circumferentially surrounding the plunger rod 1 at least at the height of the displaceable arms 13.

The protrusions 130 of the displaceable arms 13 project into the cavity of the plunger rod 1. The proximal end of the piston 12 abuts against the protrusions 130. This prevents a movement of the piston 12 in proximal direction P driven by the spring 14 beyond the protrusions 130.

As visible in figure 54, the piston 12 and the protrusions 130 each comprise slide features in the form of beveled surfaces tilted with respect to the longitudinal axis and the radial direction. The piston 12 and the protrusions 130 abut against each other at the beveled surfaces which biases the protrusions 130 or the displaceable arms 13, respectively, in outward radial direction.

Figure 55 shows the auto-injector 1000 in the released state. The torsion drive spring induces a torque onto the rotating collar 2 which starts rotating in a first rotational direction and thereby the plunger rod 1 is moved in distal direction D. The biased spring 14 and the piston 12 move together with the piston rod 1 in distal direction D. During the movement, the displaceable arms 13 of the plunger rod 1 are held in the first radial position by the sidewall of the rotating collar 2 still circumferentially surrounding the resilient arms 13.

In a region of the distal end of the rotating collar 2, namely in the region between the first section 21 and the second section 22, the side wall of the rotating collar 2 is interrupted by a recess 23. When the plunger rod 1 reaches a feedback position, the displaceable arms 13 or the protrusions 130, respectively, axially and rotationally overlap with this recess 23. Thus, the displaceable arms 13 are no longer held in the first radial position. As they are biased radially outwardly, the displaceable arms 13 leave the first radial position and move in outward radial direction into a second radial position. In the second radial position, the piston 12 is no longer prevented from moving in proximal direction P relative to the plunger rod 1 driven by the spring 14 beyond the protrusions 130. This is illustrated in figure 56.

In figure 56, it can be seen that the piston 12, due to the force induced by the spring 14, moves in proximal direction P, thereby leaves the plunger rod 1 and finally hits against a proximal end 201 of the rotating collar 2 forming an impact feature 201. This hit may cause an audible and/or tactical feedback which indicates the user the end of the drug delivery process. For example, the auto-injector is designed such that the piston 12 hitting the impact feature 201 creates a noise of at least 20 dB.

9. Third exemplary embodiment of a drug delivery device

Figures 57 and 58 show a third exemplary embodiment of a drug delivery device 1000. Figure 57 is a side view and figure 58 is a side view rotated by 90° around the longitudinal axis A with respect to figure 57. The drug delivery device 1000 is an auto-injector.

The auto-injector 1000 comprises a housing 100 with a window 120. The window 120 may be used for inspecting the fill level of a medicament container or a syringe or a progress of a stopper inside the housing 100 or the drug clarity or the degradation of the drug.

The auto-injector 1000 further comprises a protection member 5 in the form of a needle shroud 5 which is telescopically coupled to the housing 100 and is axially movable with respect to the housing 100.

Figures 59 and 60 show the auto-injector 1000 of figures 57 and 58 in the same views but now with the housing 100 being indicated semi-transparent which allows to see further members and elements of the auto-injector 1000. It can be seen, that the auto-injector 1000 further comprises a rear cap 102 which closes the housing 100 at the proximal end. Furthermore, the auto-injector 1000 comprises a drive spring holder 4, which is hollow, e.g. a sleeve. A torsion drive spring 3 is received in the drive spring holder 4. The torsion drive spring may be a spiral torsion spring. A rotating collar 2 is received in the torsion drive spring 3 and the drive spring holder 4. Moreover, a moveable member 9, also referred to as activation element 9, in the form of an activation collar 9 is provided. The activation collar 9 is releasably axially coupled to the needle shroud 5 so that an axial movement of the needle shroud 5 induces an axial movement of the activation collar 9. The activation collar 9 is located downstream of the torsion drive spring 3 in distal direction D and circumferentially surrounds a portion of the rotating collar 2.

Furthermore, the auto-injector 1000 comprises a shroud spring 7 which couples the needle shroud 5 to the housing 100. The coupling via the shroud spring 7 is such that a proximal movement of the needle shroud 5 with respect to the housing 100 compresses the shroud spring 7. This compression biases the needle shroud 5 in distal direction D relative to the housing 100.

Figure 61 and 62 show the auto-injector 1000 of figures 57 and 58 in the same views but now in a cross-sectional view with the cutting plane comprising the longitudinal axis A. In this view, it can be seen that the auto-injector 1000 further comprises a plunger rod 1. The plunger rod 1 is to a main part received in the rotating collar 2 and is circumferentially surrounded by the rotating collar 2. Only a small portion of the plunger rod 1 (less than 50 % of its length) projects out of the rotating collar 2 in distal direction D. In proximal direction P, the rotating collar 2 is closed and the plunger rod 1 does not project beyond the proximal end of the rotating collar 2. The plunger rod 1 is longer, measured along the longitudinal axis, than the rotating collar 2.

The housing 100, the housing element 4, the plunger rod 1, the rotating collar 2, the needle shroud 5 and the activation element 9 may all comprise or consist of plastic. All these members may each be formed in one piece. The drive spring 3 and the shroud spring 7 may comprise or consist of a metal, e.g. steel.

It can be seen in figures 61 and 62 that a medicament container 8, in the present case a syringe 8, is arranged in the housing 100. This syringe 8 may be arranged axially and/or rotationally and/or radially fixed with respect to the housing 100. The syringe 8 comprises a cartridge 81 filled with a drug, a needle 80 and a stopper 82. The needle 80 is arranged at a distal end of the syringe 8. The stopper 82 seals the cartridge 81 in proximal direction P. When moving the stopper 82 in the distal direction D, the drug stored in the cartridge 81 is pressed out of the syringe 8 through the needle 80.

In figures 61 and 62 it can be further seen that the needle 80 is covered by a needle shield 83 which encapsulates the needle 80 and projects beyond the needle 80 in distal direction D. The needle shield 83 may be removed before using the auto-injector 1000.

For using the auto-injector 1000, the distal end of the auto-injector 1000 formed by the needle shroud 5 may be pressed against a body, e.g. a human body. As a consequence of that, the needle shroud 5 moves from its extended position in the proximal direction P with respect to the housing 100. This results in the needle 80 being exposed and projecting in distal direction D so that it can now pierce into the tissue of the body.

In the position shown in figure 61 and 62, the auto-injector 1000 is still in an initial state, in the following referred to as locked state, in which the torsion drive spring 3 is biased and induces a torque onto the rotating collar 2. A locking mechanism, however, prevents the rotating collar 2 from a rotational movement. The locking mechanism will be explained in more detail further below.

In the locked state, a proximal end of the rotating collar 2 may be axially spaced from a proximal end-stop of the housing 100. This allows an axial movement of the rotating collar 2 in proximal direction P. Moreover, in the locked state, a distal end of the plunger rod 1 is axially spaced from the stopper 82 of the syringe 8. Thus, the plunger rod 1 can axially move in the distal direction D for a predetermined distance before hitting the stopper 82.

The needle shroud 5 may be moved in the proximal direction P into a retracted position. This releases the locking mechanism so that the rotating collar 2 is no longer prevented from

rotating. The auto-injector switches from the locked state into a released state. The torque induced by the torsion drive spring 3 onto the rotating collar 2 forces the rotating collar 2 to rotate in a first rotational direction (clockwise or counterclockwise). For example, the rotating collar 2 rotates several times around its rotational axis. A drive mechanism, e.g. the drive mechanism described before, converts the rotation of the rotating collar 2 into an axial movement of the plunger rod 1 in the distal direction D. After having moved the predetermined distance in the distal direction D, the plunger rod 1 hits the stopper 82 of the syringe 8 and can now push the stopper 82 in distal direction D which results in the drug in the cartridge 81 being pressed out through the needle 80 into the tissue.

The rotating collar 2 may not only rotate but also moves in proximal direction P until the proximal end of the rotating collar 2 hits the proximal end-stop of the housing 100. The end-stop comprises is a protrusion 101 which tapers in distal direction D. The protrusion 101 may be a cone. The proximal end of the rotating collar 2 comprises an indentation 200. For example, the surface of the proximal end of the rotating collar 2 is concavely shaped. The protrusion 101 can penetrate into the indentation 200 when the proximal end of the rotating collar 2 hits the end-stop of the housing 100. The protrusion 101 and the indentation 200 may each be designed rotationally symmetric or circular symmetric with respect to the rotational axis of the rotating collar 2. In this way, a low friction interface is formed between the housing 100 and the rotating collar 2 so that a low friction rotation of the rotating collar 2 is enabled also when the proximal end of the rotating collar 2 abuts against the housing 100. Particularly, the radius at which the friction between the rotating collar 2 and the end-stop acts is approaching zero or is zero, therefore the resulting torque from the friction also tends to zero significantly reducing losses allowing a reduced spring force and/or enhance injection performance.

Figure 63 shows the auto-injector 1000 according to the third exemplary embodiment in a cross-sectional view and after usage. The plunger rod 1 has hit the stopper 82 and has pushed the stopper 82 into distal direction D. As a consequence, the drug in the cartridge 82 was pushed through the needle 80 out of the syringe 8. For example, the drug was thereby injected into the tissue of the body.

Figure 64 shows different subassemblies of the auto-injector 1000 according to the third exemplary embodiment. The auto-injector 1000 comprises a front subassembly FSA. The front subassembly FSA comprises the housing 100, the needle shroud 5 and the shroud spring 7 coupling the housing 100 and the needle shroud 5.

The auto-injector 1000 further comprises a rear subassembly RSA, with the plunger rod 1, the rotating collar 2, the torsion drive spring 3, the drive spring holder 4 and the activation collar 9.

When assembling the front subassembly FSA and the rear subassembly RSA, a syringe 8 is first telescoped into the housing 100 of the front subassembly FSA and then the rear subassembly RSA is telescoped into the housing 100. Finally the rear cap 102 is attached to the proximal end of the housing 100 and may be fixed to the housing 100 via a clip.

Figure 65 shows the front subassembly FSA in an exploded view. The needle shroud 5 comprises a distal portion 5a which is shaped hollow cylindrically and into which the shroud spring 7 can be telescoped. Furthermore, the needle shroud 5 comprises two arms 5b extending from the cylindrically shaped portion 5a in proximal direction P.

Figure 66 shows the rear subassembly RSA in an exploded view.

9.1 Drive mechanism of the drug delivery device according to the third exemplary embodiment

The drive mechanism of the auto-injector according to the third exemplary embodiment may be designed as the previously described drive mechanism.

9.2 Locking mechanism of the drug delivery device according to the third exemplary embodiment

Figure 67 shows sections of the auto-injector 1000 according to the third exemplary embodiment in the locked state.

The upper part of figure 67, above the horizontal dashed line, shows a section of the auto-injector 1000 in a side view. The lower part of figure 67, below the dashed line, shows a section of the auto-injector in a side view rotated by 90° around the longitudinal axis A with respect to the upper part.

Figure 70 shows the auto-injector 1000, e.g. also in the locked state, in a cross-sectional view with the crossing plane being perpendicular to the longitudinal axis A.

Considering first figure 67, the needle shroud 5 comprises a coupling feature 53 in the form of a resilient arm 53 with a protrusion projecting radially inwardly. The activation collar 9 has a coupling feature 92 in the form of a recess 92 or opening 92. The protrusion of the resilient arm

92 projects into the recess 92. In this way, the needle shroud 5 and the activation collar 9 are axially coupled so that an axial movement of the needle shroud 5 induces an axial movement of the activation collar 9.

In the lower part of figure 67 it can be seen that the recess 92 is L-shaped and comprises two sections being adjacent to each other in the angular direction. In the locked state shown in figure 67, the resilient arm 53 engages into a first section of the recess 92. The first section of the recess 92 is bordered in proximal direction P and distal direction D by edges of the activation collar 9. Thus, an axial movement of the needle shroud 5 in proximal direction P and distal direction D results in the protrusion of the resilient arm 53 hitting either one of these edges. As a consequence, the activation collar 9 is forced to move in distal direction D when the needle shroud 5 is moved in distal direction D and the activation collar 9 is forced to move in proximal direction P when the needle shroud 5 is moved in proximal direction P. In other words, the needle shroud 5 is coupled to the activation collar 9 in proximal direction P and distal direction D.

On the other hand, the second section of the recess 92 is delimited by an edge of the activation collar 9 only in proximal direction P. In distal direction D, the second section of the recess 92 is open and not delimited by an edge of the activation collar 9. Thus, if the protrusion of the resilient arm 53 would engage into the second section of the recess 92, the protrusion would hit against an edge of the activation collar 9 when moving the needle shroud 5 in proximal direction P which would force the activation collar 9 to also move in proximal direction P. A movement of the needle shroud 5 in distal direction D, however, would result in a disengagement of the resilient arm 53 and the recess 92.

Furthermore, it can be seen in figure 67 that the activation collar 9 is coupled to the drive spring holder 4 via a first rotation-lock interface. The first rotation-lock interface prevents a rotation of the activation collar 9 with respect to the drive spring holder 4. On the other hand, as can be seen in figure 70, the rotating collar 2 and the activation collar 9 are coupled via a second rotation-lock interface. The second rotation-lock interface prevents a rotation of the rotating collar 2 with respect to the activation collar 9. Thus, in sum, a rotation of the rotating collar 2 with respect to the drive spring holder 4 is prevented by the two rotation-lock interfaces.

The first rotation-lock interface is established by a slit 91a in the activation collar 9 and a rib 47 of the drive spring holder 4 engaging into the slit 91. The rib 47 and the slit 91 are each elongated with a main extension direction along the longitudinal axis. As can be seen in figure 67, the slit 91a is a first section of a recess 91 in the activation collar 9. The recess 91 also

comprises a second section 91b adjoining the slit 91a in distal direction D. The slit 91 has a smaller width, measured along the angular direction, than the second section 91b. The width of the second section 91b first increase in direction away from the slit 91a and then has a constant width. In this region of increasing width, the second section 91b is delimited by a beveled surface 91c of the activation collar 9 which is tilted with respect to the longitudinal axis and the rotational direction. This beveled surface 91c realizes a slide feature. In the locked state, shown in figure 67, the rib 47 engages into the slit 91a of the recess 91.

As can be seen in figure 70, the second rotation-lock interface is realized by a protrusion 93 of the activation collar 9 and a protrusion 24 of the rotating collar 2 abutting against each other in angular direction. The protrusion 93 of the activation collar 9 projects radially inwardly and the protrusion 24 of the rotating collar 2 projects radially outwardly. The protrusions 24, 93 abut against each other such that a rotation of the rotating collar 2 induced by the biased torsion drive spring 3 with respect to the activation collar 9 is prevented or blocked by the activation collar 9.

Figure 68 shows the autoinjector 1000 in a position in which the needle shroud 5 has been moved from its extended position proximally towards the retracted position. The needle shroud 5 is now in an intermediate position between the extended position and the retracted position. In this intermediate position, the rib 47 is transferred from the slit into the second section 91b. Due to the force induced by the drive spring 3, the beveled surface 91c is pressed against the rib 47 and the rib 47 slides along the beveled surface 91c whereby the activation collar 9 rotates with respect to the drive spring holder 4 and with respect to the needle shroud 5 by a predetermined angle in the first rotational direction. This rotation happens automatically, as the torque induced by the torsion drive spring 3 is transferred via the rotating collar 2 to the activation collar 9 (via the second rotation-lock interface). After the rotation by the predetermined angle, an edge of the activation collar 9 running parallel to the longitudinal axis and delimiting the second section 91b of the recess 91 in angular direction hits against the rib 47. A further rotation of the activation collar 9 with respect to the drive spring holder 4 in the first rotational direction is then prevented.

However, the rotation of the activation collar 9 by the predetermined angle in the first rotational direction has as a consequence that the resilient arm 53 of the needle shroud 5 now engages into the second section of the recess 92 of the activation collar 9 which results in a decoupling of the activation collar 9 and the needle shroud 5in distal direction D. In other words, the coupling of the needle shroud 5 and the activation collar 9 in distal direction D is released.

Figure 69 shows the auto-injector 1000 in a position in which the needle shroud 5 has been further moved in proximal direction P into the retracted position which has also forced the activation collar 9 to further move in proximal direction P. In this retracted position of the needle shroud 5, the needle 80 of the auto-injector 1000 may be exposed allowing the needle 80 to pierce into a tissue of a body. In the retracted position of the needle shroud 5, the second rotation-lock interface between the activation collar 9 and the rotating collar 2 is released, i.e. the protrusion 24 and the protrusion 93 are now axially offset and do not abut against each other any longer so that the auto-injector 1000 transfers into the released state in which the rotation of the rotating collar 2 with respect to the activation collar 9 and with respect to the drive spring holder 4 is enabled. The rotating collar 2 rotates in the first rotational direction and thereby drives the plunger rod 1 in distal direction D which results in a delivery of the drug through the needle 80 (see description above).

Furthermore, the movement of the activation collar 9 further in proximal direction P had as a consequence that a second coupling feature 90 of the activation collar 9, namely a clip 90, has engaged into a coupling feature 48 of the drive spring holder 4, namely a recess 48. The engagement between the clip 90 and the recess 48 is such that a movement of the activation collar 9 in distal direction D is prevented. When moving the needle shroud 5 from the retracted position back towards or into the extended position, the activation collar 9 does not and cannot follow. A movement of the needle shroud 5 in distal direction D relative to the activation collar 9 is enabled since the resilient arm 53 engages into the second section of the recess 92 as described above.

Figure 71 to 73 show different positions during assembling the auto-injector 1000 according to the third exemplary embodiment. The rear subassembly is telescoped into the front subassembly.

Figure 71 shows a first position, in which the needle shroud 5 of the front subassembly and the activation collar 9 of the rear subassembly are not yet coupled to each other. Figure 71 is a side view of the auto-injector 1000 during assembling.

Figure 72 shows the position of figure 71 in a cross-sectional view. It can be seen, that the resilient arm 53 of the needle shroud 5 has a slide feature in form of a beveled surface. The beveled surface is designed such that, when the beveled surface hits the distal end of the activation collar 9, a force is created pushing the resilient arm 53 in outward radial direction. The rear subassembly and the front subassembly can then further be telescoped into each other and as soon as the protrusion of the resilient arm 53 axially and rotationally overlaps with the

recess 92 of the activation collar 9, it slips into this recess 92. In this way, a coupling between the activation collar 9 and needle shroud 5 is obtained.

Figure 73 shows the auto-injector after coupling of the needle shroud 5 and the activation collar 9.

Further explanations and definitions

The terms “drug” or “medicament” are used synonymously herein and describe a pharmaceutical formulation containing one or more active pharmaceutical ingredients or pharmaceutically acceptable salts or solvates thereof, and optionally a pharmaceutically acceptable carrier. An active pharmaceutical ingredient (“API”), in the broadest terms, is a chemical structure that has a biological effect on humans or animals. In pharmacology, a drug or medicament is used in the treatment, cure, prevention, or diagnosis of disease or used to otherwise enhance physical or mental well-being. A drug or medicament may be used for a limited duration, or on a regular basis for chronic disorders.

As described below, a drug or medicament can include at least one API, or combinations thereof, in various types of formulations, for the treatment of one or more diseases. Examples of API may include small molecules having a molecular weight of 500 Da or less; polypeptides, peptides and proteins (e.g., hormones, growth factors, antibodies, antibody fragments, and enzymes); carbohydrates and polysaccharides; and nucleic acids, double or single stranded DNA (including naked and cDNA), RNA, antisense nucleic acids such as antisense DNA and RNA, small interfering RNA (siRNA), ribozymes, genes, and oligonucleotides. Nucleic acids may be incorporated into molecular delivery systems such as vectors, plasmids, or liposomes. Mixtures of one or more drugs are also contemplated.

The drug or medicament may be contained in a primary package or “drug container” adapted for use with a drug delivery device. The drug container may be, e.g., a cartridge, syringe, reservoir, or other solid or flexible vessel configured to provide a suitable chamber for storage (e.g., short- or long-term storage) of one or more drugs. For example, in some instances, the chamber may be designed to store a drug for at least one day (e.g., 1 to at least 30 days). In some instances, the chamber may be designed to store a drug for about 1 month to about 2 years. Storage may occur at room temperature (e.g., about 20°C), or refrigerated temperatures (e.g., from about -4°C to about 4°C). In some instances, the drug container may be or may include a dual-chamber cartridge configured to store two or more components of the pharmaceutical formulation to-be-administered (e.g., an API and a diluent, or two different drugs) separately,

one in each chamber. In such instances, the two chambers of the dual-chamber cartridge may be configured to allow mixing between the two or more components prior to and/or during dispensing into the human or animal body. For example, the two chambers may be configured such that they are in fluid communication with each other (e.g., by way of a conduit between the two chambers) and allow mixing of the two components when desired by a user prior to dispensing. Alternatively or in addition, the two chambers may be configured to allow mixing as the components are being dispensed into the human or animal body.

The drugs or medicaments contained in the drug delivery devices as described herein can be used for the treatment and/or prophylaxis of many different types of medical disorders. Examples of disorders include, e.g., diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism. Further examples of disorders are acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis. Examples of APIs and drugs are those as described in handbooks such as Rote Liste 2014, for example, without limitation, main groups 12 (anti-diabetic drugs) or 86 (oncology drugs), and Merck Index, 15th edition.

Examples of APIs for the treatment and/or prophylaxis of type 1 or type 2 diabetes mellitus or complications associated with type 1 or type 2 diabetes mellitus include an insulin, e.g., human insulin, or a human insulin analogue or derivative, a glucagon-like peptide (GLP-1), GLP-1 analogues or GLP-1 receptor agonists, or an analogue or derivative thereof, a dipeptidyl peptidase-4 (DPP4) inhibitor, or a pharmaceutically acceptable salt or solvate thereof, or any mixture thereof. As used herein, the terms “analogue” and “derivative” refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, by deleting and/or exchanging at least one amino acid residue occurring in the naturally occurring peptide and/or by adding at least one amino acid residue. The added and/or exchanged amino acid residue can either be codable amino acid residues or other naturally occurring residues or purely synthetic amino acid residues. Insulin analogues are also referred to as "insulin receptor ligands". In particular, the term „derivative” refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, in which one or more organic substituent (e.g. a fatty acid) is bound to one or more of the amino acids. Optionally, one or more amino acids occurring in the naturally occurring peptide may have been deleted and/or replaced by other amino acids, including non-codeable amino acids, or amino acids, including non-codeable, have been added to the naturally occurring peptide.

Examples of insulin analogues are Gly(A21), Arg(B31), Arg(B32) human insulin (insulin glargine); Lys(B3), Glu(B29) human insulin (insulin glulisine); Lys(B28), Pro(B29) human insulin (insulin lispro); Asp(B28) human insulin (insulin aspart); human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin.

Examples of insulin derivatives are, for example, B29-N-myristoyl-des(B30) human insulin, Lys(B29) (N- tetradecanoyl)-des(B30) human insulin (insulin detemir, Levemir®); B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl- ThrB29LysB30 human insulin; B29-N-(N-palmitoyl-gamma-glutamyl)-des(B30) human insulin, B29-N-omega-carboxypentadecanoyl-gamma-L-glutamyl-des(B30) human insulin (insulin degludec, Tresiba®); B29-N-(N-lithocholyl-gamma-glutamyl)-des(B30) human insulin; B29-N-(ω-carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(ω-carboxyheptadecanoyl) human insulin.

Examples of GLP-1, GLP-1 analogues and GLP-1 receptor agonists are, for example, Lixisenatide (Lyxumia®), Exenatide (Exendin-4, Byetta®, Bydureon®, a 39 amino acid peptide which is produced by the salivary glands of the Gila monster), Liraglutide (Victoza®), Semaglutide, Taspoglutide, Albiglutide (Syncria®), Dulaglutide (Trulicity®), rExendin-4, CJC-1134-PC, PB-1023, TTP-054, Langlenatide / HM-11260C (Efpeglenatide), HM-15211, CM-3, GLP-1 Eligen, ORMD-0901, NN-9423, NN-9709, NN-9924, NN-9926, NN-9927, Nodexen, Viador-GLP-1, CVX-096, ZYOG-1, ZYD-1, GSK-2374697, DA-3091, MAR-701, MAR709, ZP-2929, ZP-3022, ZP-DI-70, TT-401 (Pegapamodtide), BHM-034. MOD-6030, CAM-2036, DA-15864, ARI-2651, ARI-2255, Tirzepatide (LY3298176), Bamadutide (SAR425899), Exenatide-XTEN and Glucagon-Xten.

An example of an oligonucleotide is, for example: mipomersen sodium (Kynamro®), a cholesterol-reducing antisense therapeutic for the treatment of familial hypercholesterolemia or RG012 for the treatment of Alport syndrom.

Examples of DPP4 inhibitors are Linagliptin, Vildagliptin, Sitagliptin, Denagliptin, Saxagliptin, Berberine.

Examples of hormones include hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists, such as Gonadotropine (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, and Goserelin.

Examples of polysaccharides include a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra-low molecular weight heparin or a derivative thereof, or a sulphated polysaccharide, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium. An example of a hyaluronic acid derivative is Hylan G-F 20 (Synvisc®), a sodium hyaluronate.

The term “antibody”, as used herein, refers to an immunoglobulin molecule or an antigen-binding portion thereof. Examples of antigen-binding portions of immunoglobulin molecules include F(ab) and F(ab')2 fragments, which retain the ability to bind antigen. The antibody can be polyclonal, monoclonal, recombinant, chimeric, de-immunized or humanized, fully human, non-human, (e.g., murine), or single chain antibody. In some embodiments, the antibody has effector function and can fix complement. In some embodiments, the antibody has reduced or no ability to bind an Fc receptor. For example, the antibody can be an isotype or subtype, an antibody fragment or mutant, which does not support binding to an Fc receptor, e.g., it has a mutagenized or deleted Fc receptor binding region. The term antibody also includes an antigen-binding molecule based on tetravalent bispecific tandem immunoglobulins (TBTI) and/or a dual variable region antibody-like binding protein having cross-over binding region orientation (CODV).

The terms “fragment” or “antibody fragment” refer to a polypeptide derived from an antibody polypeptide molecule (e.g., an antibody heavy and/or light chain polypeptide) that does not comprise a full-length antibody polypeptide, but that still comprises at least a portion of a full-length antibody polypeptide that is capable of binding to an antigen. Antibody fragments can comprise a cleaved portion of a full length antibody polypeptide, although the term is not limited to such cleaved fragments. Antibody fragments that are useful in the present invention include, for example, Fab fragments, F(ab')2 fragments, scFv (single-chain Fv) fragments, linear antibodies, monospecific or multispecific antibody fragments such as bispecific, trispecific, tetraspecific and multispecific antibodies (e.g., diabodies, triabodies, tetrabodies), monovalent or multivalent antibody fragments such as bivalent, trivalent, tetravalent and multivalent antibodies, minibodies, chelating recombinant antibodies, tribodies or bibodies, intrabodies, nanobodies, small modular immunopharmaceuticals (SMIP), binding-domain immunoglobulin

fusion proteins, camelized antibodies, and VHH containing antibodies. Additional examples of antigen-binding antibody fragments are known in the art.

The terms “Complementarity-determining region” or “CDR” refer to short polypeptide sequences within the variable region of both heavy and light chain polypeptides that are primarily responsible for mediating specific antigen recognition. The term “framework region” refers to amino acid sequences within the variable region of both heavy and light chain polypeptides that are not CDR sequences, and are primarily responsible for maintaining correct positioning of the CDR sequences to permit antigen binding. Although the framework regions themselves typically do not directly participate in antigen binding, as is known in the art, certain residues within the framework regions of certain antibodies can directly participate in antigen binding or can affect the ability of one or more amino acids in CDRs to interact with antigen.

Examples of antibodies are anti PCSK-9 mAb (e.g., Alirocumab), anti IL-6 mAb (e.g., Sarilumab), and anti IL-4 mAb (e.g., Dupilumab).

Pharmaceutically acceptable salts of any API described herein are also contemplated for use in a drug or medicament in a drug delivery device. Pharmaceutically acceptable salts are for example acid addition salts and basic salts.

Those of skill in the art will understand that modifications (additions and/or removals) of various components of the APIs, formulations, apparatuses, methods, systems and embodiments described herein may be made without departing from the full scope and spirit of the present invention, which encompass such modifications and any and all equivalents thereof.

An example drug delivery device may involve a needle-based injection system as described in Table 1 of section 5.2 of ISO 11608-1:2014(E). As described in ISO 11608-1:2014(E), needle-based injection systems may be broadly distinguished into multi-dose container systems and single-dose (with partial or full evacuation) container systems. The container may be a replaceable container or an integrated non-replaceable container.

As further described in ISO 11608-1:2014(E), a multi-dose container system may involve a needle-based injection device with a replaceable container. In such a system, each container holds multiple doses, the size of which may be fixed or variable (pre-set by the user). Another multi-dose container system may involve a needle-based injection device with an integrated non-replaceable container. In such a system, each container holds multiple doses, the size of which may be fixed or variable (pre-set by the user).

As further described in ISO 11608-1:2014(E), a single-dose container system may involve a needle-based injection device with a replaceable container. In one example for such a system, each container holds a single dose, whereby the entire deliverable volume is expelled (full evacuation). In a further example, each container holds a single dose, whereby a portion of the deliverable volume is expelled (partial evacuation). As also described in ISO 11608-1:2014(E), a single-dose container system may involve a needle-based injection device with an integrated non-replaceable container. In one example for such a system, each container holds a single dose, whereby the entire deliverable volume is expelled (full evacuation). In a further example, each container holds a single dose, whereby a portion of the deliverable volume is expelled (partial evacuation).

The invention described herein is not limited by the description in conjunction with the exemplary embodiments. Rather, the invention comprises any new feature as well as any combination of features, particularly including any combination of features in the patent claims, even if said feature or said combination per se is not explicitly stated in the patent claims or exemplary embodiments.

Reference numerals

1	plunger rod
2	rotating collar
3	torsion drive spring
4	drive spring holder
4a	first section of drive spring holder 4
4b	second section of drive spring holder 4
4c	first bottom ring of drive spring holder 4
4d	second bottom ring of drive spring holder 4
5	needle shroud
5a	cylindrically-shaped portion
5b	arm
6	medicament container holder/ syringe holder
6a	cylindrically-shaped portion
6b	arm
6c	support portion
7	shroud spring
8	medicament container/syringe
9	activation collar
10	groove
11	external thread
12	piston
13	displaceable arm
14	feedback energy member/ spring
20	shaft
21	first portion
22	second portion
22a	surface
23	recess
24	protrusion
40	protrusion
40a	edge in drive spring holder 4
41	resilient arm
43	recess
44	recess
45	protrusion

46	flap
47	rib
48	recess
50a	wall portion
50b	recess
51	resilient arm
51a	ramp
52	recess
53	resilient arm
54	recess
60	window
60a	wall portion
61	rib
62	snap feature
63	push element
64	release element
80	needle
81	cartridge
82	stopper
83	needle shield
90	clip
91	recess
91a	slit/first section of recess 91
91b	second section of recess 91
91c	tilted surface
92	recess
93	protrusion
100	housing
101	protrusion
102	rear cap
110	cap
110a	resilient arm
110b	protrusion
111	grabber
120	window
130	protrusion
200	indentation

201	impact feature
210	resilient arm/ clip
220	recess
220b	first section of recess 220
220c	second section of recess 220
220d	surface of recess 220
221	recess
221a	beveled surface
410	protrusion
410a	beveled surface
410b	first section of protrusion 410
410c	second section of protrusion 410
410d	surface of protrusion 410
411	protrusion
411a	beveled surface
1000	drug delivery device / auto-injector
FSA	front sub assembly
RSA	rear sub assembly
α	angle
D	distal direction
P	proximal direction
A	longitudinal axis/ axial direction
R	radial direction
C	azimuthal/rotational/angular direction

Claims

1. Drive subassembly (RSA) for a drug delivery device, comprising
- a housing element (4),
- a drive member (2) arranged rotatably with respect to the housing element (4),
- an energy member (3) configured to provide energy in order to induce a torque onto the drive member (2) tending to rotate the drive member (2) in a first rotational direction, wherein
- the drive subassembly (RSA) has a first and a second locked state,
- in the first locked state, a first rotation-locking mechanism prevents a movement of the drive member (2) in the first rotational direction induced by the energy member (3),
- in the second locked state, a second rotation-locking mechanism prevents a rotation of the drive member (2) in the first rotational direction induced by the energy member (3) and an axial-locking mechanism prevents an axial movement of the drive member (2),
- the drive subassembly (RSA) is configured to be switched from the second locked state into the first locked state by releasing the axial-locking mechanism and moving the drive member (2) in an axial direction.

2. Drive subassembly (RSA) according to claim 1, further comprising
- a plunger rod (1) being arranged axially movable with respect to the housing element (4),
- wherein the drive member (2) and the plunger rod (1) are operatively coupled such that a rotation of the drive member (2) in the first rotational direction is converted into a movement of the plunger rod (1) in distal direction (D).

3. Drive subassembly (RSA) according to claim 1 or 2, wherein
- the first rotation-locking mechanism comprises a first rotation-lock element (22) rotationally and axially fixed with respect to the drive member (2) and a second rotation-lock element (41) rotationally and axially fixed with respect to the housing element (4),
- at least one of the first (22) and the second (41) rotation-lock elements of the first rotation-locking mechanism is a displaceable rotation-lock element being displaceable in a second direction,
- the first rotation-lock element (22) and the second rotation-lock element (41) of the first rotation-locking mechanism are engaged in the first locked state,
- the engagement of the first (22) and the second (41) rotation-lock elements of the first rotation-locking mechanism prevents an energy member (3) induced movement of the drive member (2) in the first rotational direction,

- a displacement of the displaceable rotation-lock element (41) in the second direction disengages the first rotation-lock element (22) and the second rotation-lock element (41) of the first rotation-locking mechanism and releases the first rotation-locking mechanism such that a movement of the drive member (2) in the first rotational direction induced by the energy member (3) is enabled.

4. Drive subassembly (RSA) according to any one of the preceding claims, wherein
- the axial-locking mechanism comprises a first axial-lock element (210) axially and rotationally fixed with respect the drive member (2) and a second axial-lock element (4a) rotationally and axially fixed with respect to housing element (4),
- at least one of the first axial-lock element (210) and the second axial-lock element (4a) is a displaceable axial-lock element being displaceable in a third direction,
- the two axial-lock elements (210, 4a) of the axial-locking mechanism are engaged in the second locked state,
- the engagement of the axial-lock elements (210, 4a) of the axial-locking mechanism prevents switching from the second locked state into the first locked state,
- a displacement of the displaceable axial-lock element (210) in the third direction disengages the first axial-lock element (210) and the second axial-lock element (4a) and enables a movement of the drive member (2) in an axial direction,
- the second rotation-locking mechanism comprises a first rotation-lock element (22) rotationally and axially fixed with respect to the drive member (2) and a second rotation-lock element (4b) rotationally and axially fixed with respect to the housing element (4),
- the first (22) and second (4b) rotation-lock elements of the second rotation-locking mechanism are engaged in the second locked state,
- the engagement of the first (22) and the second (4b) rotation-lock elements of the second rotation-locking mechanism prevents an energy member (3) induced movement of the drive member (2) in the first rotational direction.

5. Drive subassembly (RSA) according to claims 3 and 4, wherein
- the first rotation-lock element (22) of the first rotation-locking mechanism is also the first rotation-lock element (22) of the second rotation-locking mechanism,
- the drive subassembly (RSA) is configured such that
    - when switched from the second locked state into the first locked state, the first rotation-lock element (22) is moved in an axial direction,
    - during movement in axial direction, the first rotation-lock element (22) engages with the second rotation-lock element (41) of the first rotation-locking mechanism before being

completely disengaged from the second rotation-lock element (4b) of the second rotation-locking mechanism.

6. Drive subassembly (RSA) according to any one of the preceding claims, further comprising,
- a housing (100) in which the drive member (2) and the energy member (3) are received, wherein
- the housing element (4) is fixed to or integrated in the housing (100),
- the housing (100) axially projects beyond the drive member (2) and/or the energy member (3).
- the housing (100) is configured to receive a medicament container (8),
- the housing (100) has length of at least 75 % of the drug delivery device,
- the housing (100) provides an outer surface of the drive subassembly (RSA) configured to be grabbed by a user.

7. Arrangement comprising a drive subassembly (RSA) according to any one of the preceding claims and a release subassembly (FSA) configured to be telescoped with the drive subassembly (RSA) in order to assemble a drug delivery device, wherein
- the drive subassembly (RSA) is in the second locked state,
- the release subassembly (FSA) comprises a release element (64) configured to release the axial-locking mechanism of the drive subassembly (RSA) when telescoping the drive subassembly (RSA) and the release subassembly (FSA),
- the release subassembly (FSA) comprises a push element (63) configured to push the drive member (2) in an axial direction when telescoping the drive subassembly (RSA) and the release subassembly (FSA) for switching the drive subassembly (RSA) from the second locked state into the first locked state.

8. Method for assembling a drug delivery device (1000), comprising:
- providing a drive subassembly (RSA) according to any one of claims 1 to 6, wherein the drive subassembly (RSA) is in the second locked state,
- providing a release subassembly (FSA),
- telescoping the release subassembly (FSA) and the drive subassembly (RSA), wherein during telescoping, the release subassembly (FSA) releases the axial-locking mechanism and pushes the drive member (2) in an axial direction so that the drive subassembly (RSA) is switched from the second locked state into the first locked state.

9. Method according to claim 8, wherein
- the drive subassembly (RSA) is a drive subassembly (RSA) according to claims 3 and 4,

- the release subassembly (FSA) is a release subassembly (FSA) as specified in claim 7, wherein
- when telescoping the release subassembly (FSA) and the drive subassembly (RSA), the release element (64) pushes the displaceable axial-lock element (210) in the third direction, whereby the displaceable axial-lock element (210) disengages from the other axial-lock element (4a), and the push element (63) pushes the drive member (2) in an axial direction thereby switching the drive subassembly (RSA) from the second locked state into the first locked state,
- the release subassembly (FSA) comprises a support element (5),
- during telescoping the release subassembly (FSA) and the drive subassembly (RSA), the support element (5) is brought into a support position in which the support element (5) holds the displaceable rotation-lock element (41) of the first rotation-locking mechanism in a first position in which the displaceable rotation-lock element (41) is arranged to engage with the other rotation-lock element (22) of the first rotation-locking mechanism.

10. Container-holder subassembly (FSA) for a drug delivery device, comprising
- a needle shroud (5) configured to cover a needle of a medicament container,
- a container holder (6) configured to hold a medicament container, wherein
- the needle shroud (5) and the container holder (6) are coupled to each other so that the needle shroud (5) is moveable with respect to the container holder (6) in axial direction,
- the container-holder subassembly (FSA) is configured to be inserted into a housing for a drug delivery device.

11. Container-holder subassembly (FSA) according to claim 10, wherein
- an outer surface of the container-holder subassembly (FSA) is at least partially formed by the container holder (6) and/or the needle shroud (5),
- a medicament container (8) with a needle (80) is received in the container holder (6), wherein
- the medicament container (8) is freely accessible from a proximal side of the container-holder subassembly (FSA).

12. Container-holder subassembly (FSA) according to claim 10 or 11, wherein
- the container holder (6) and the needle shroud (5) are rotationally fixed with respect to each other,
- the container holder (6) comprises a first rotation-lock feature (61) and the needle shroud (5) comprises a second rotation-lock feature (54),
- the two rotation-lock features (54, 61) are engaged with each other and the engagement prevents a rotation of the container holder (6) and the needle shroud (5) with respect to each other.

13. Container-holder subassembly (FSA) according to any one of claims 10 to 12, further comprising
- a shroud spring (7) coupled to the needle shroud (5) and the container holder (6) and configured such that it induces a restoring force acting in distal direction (D) on the needle shroud (5) when the needle shroud (5) is moved in proximal direction (P) with respect to the container holder (6).

14. Container-holder subassembly (FSA) according to any one of claims 10 to 13, wherein
- the needle shroud (5) comprises two arms (5b) extending from a first portion (5a) of the needle shroud (5) in proximal direction (P),
- the container holder (6) comprises two arms (6b) extending from a first portion (6a, 6c) of the container holder (6) in proximal direction (P), wherein
- the arms (5b) of the needle shroud (5) are arranged between the arms (6b) of the container holder (6) in angular direction,
- the container holder (6) comprises at least one window (60) through which a medicament container held in the container holder (6) can be observed,
- the container holder (6) comprises a snap feature (62) arranged next to the window (60) for axially and/or rotationally fixing the container holder (6) to the housing,
- the container-holder subassembly (FSA) comprises a cap (110) arranged at the distal end of the container-holder subassembly (FSA), and
- the cap (110) is releasably coupled to the needle shroud (5).

15. Container-holder subassembly (FSA) according to any one of claims 10 to 13, wherein
- the needle shroud (5) comprises two arms (5b) extending from a first portion (5a) of the needle shroud (5) in proximal direction (P),
- the container holder (6) comprises two arms (6b) extending from a first portion (6a, 6c) of the container holder (6) in proximal direction (P), and
- the arms (5b) of the needle shroud (5) are arranged between the arms (6b) of the container holder (6) in angular direction.

16. Container-holder subassembly (FSA) according to any one of claims 10 to 13, wherein
- the container holder (6) comprises at least one window (60) through which a medicament container held in the container holder (6) can be observed, and
- the container holder (6) comprises a snap feature (62) arranged next to the window (60) for axially and/or rotationally fixing the container holder (6) to the housing.

17. Container-holder subassembly (FSA) according to any one of claims 10 to 13 and 16, wherein
- the container-holder subassembly (FSA) comprises a cap (110) arranged at the distal end of the container-holder subassembly (FSA), and
- the cap (110) is releasably coupled to the needle shroud (5).

18. Container-holder subassembly (FSA) according to any one of claims 10 to 17, wherein the housing has a length of at least 75 % of the length of the drug delivery device

19. Kit comprising a drive subassembly (RSA) according to any one of claims 1 to 6 and a container-holder subassembly (FSA) according to any one of claims 10 to 18.

20. A drug delivery device comprising:
- a housing,
- a drive subassembly of any one of claims 1 to 6, and
- a medicament container.

21. A drug delivery device comprising:
- a housing,
- a container-holder subassembly of any one of claims 10 to 18, and
- a medicament container,
wherein the medicament container comprises medicament in an amount sufficient for just one drug delivery operation.

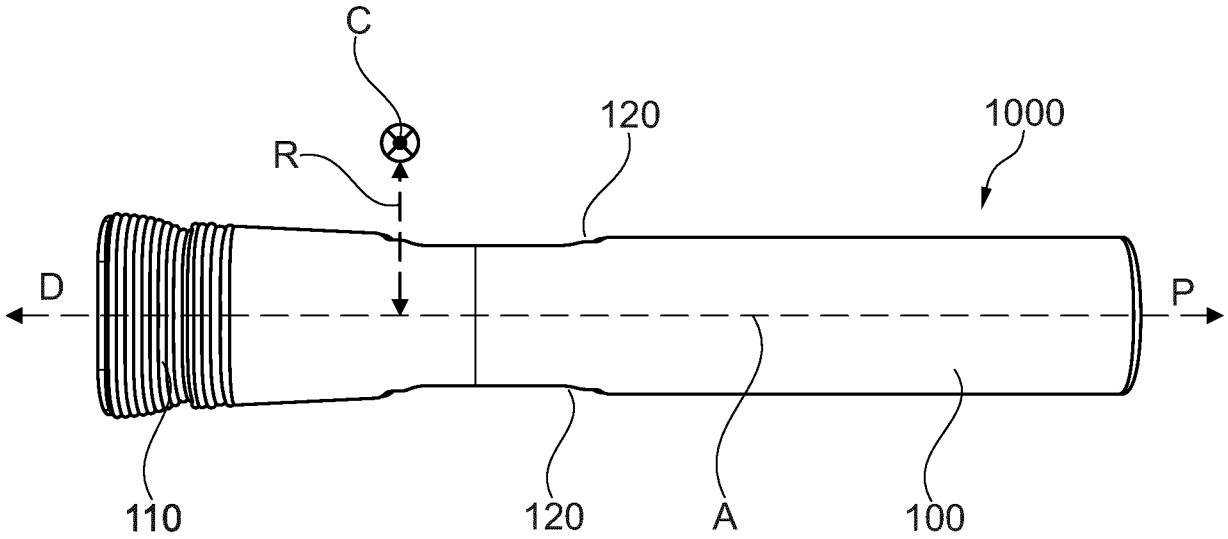

Fig. 1

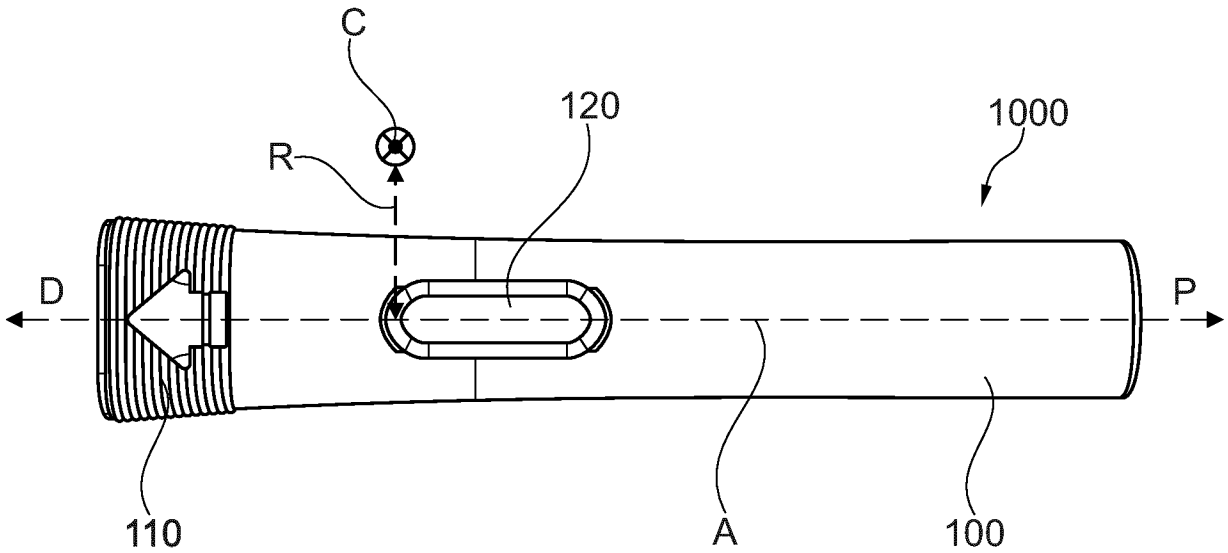

Fig. 2

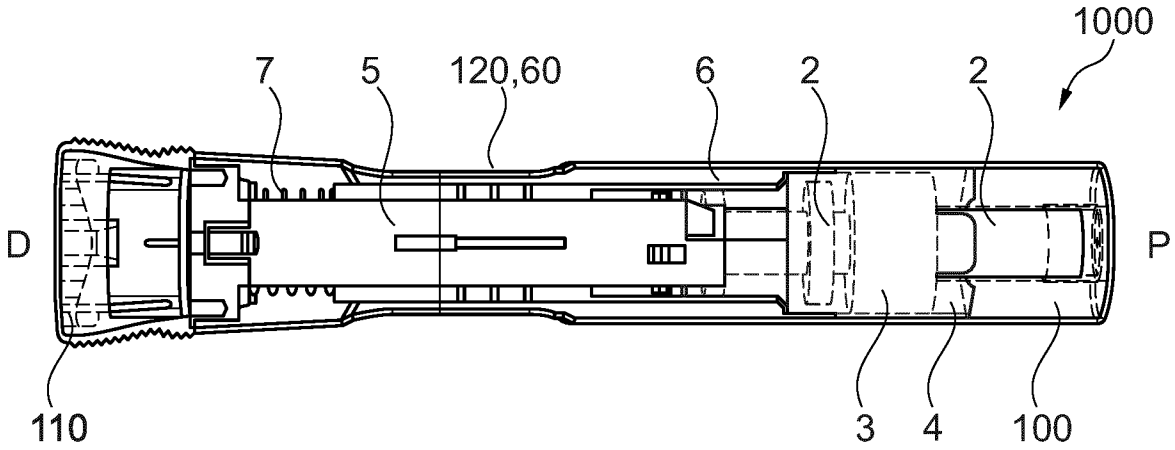

Fig. 3

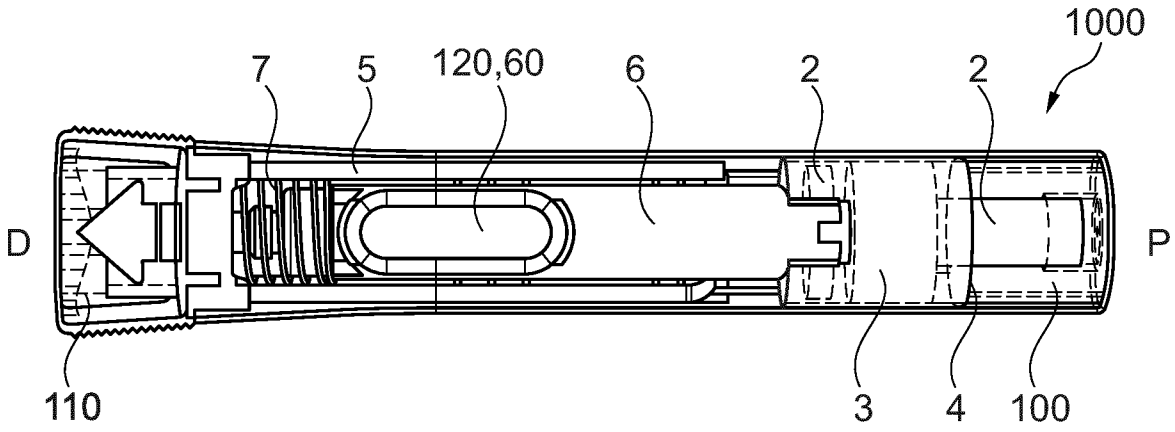

Fig. 4

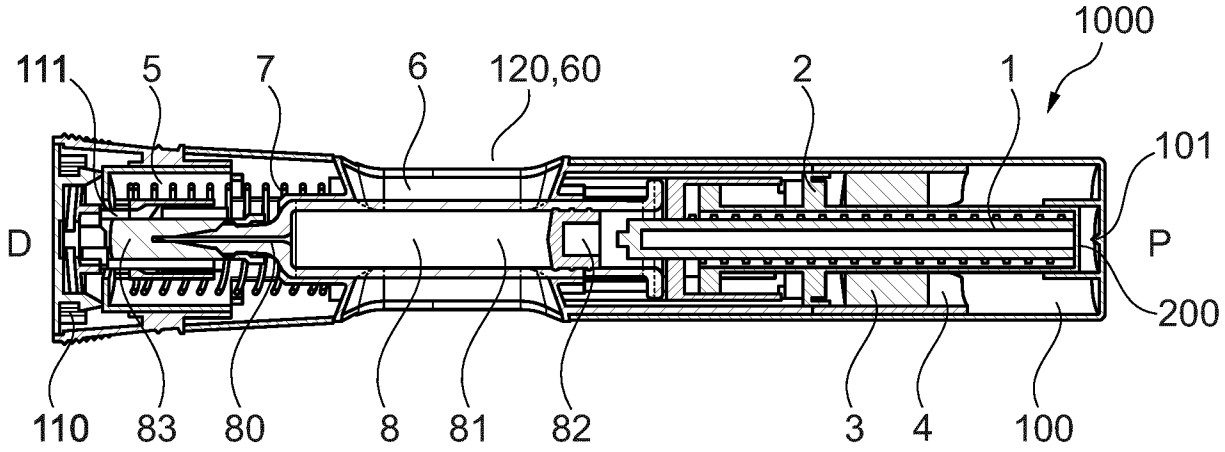
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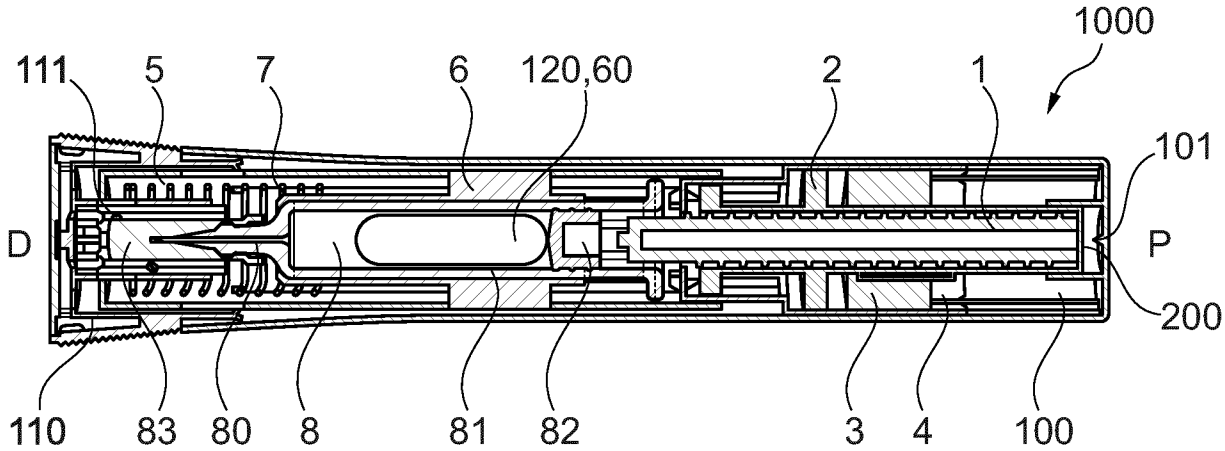
Fig. 5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3
4
100

Fig. 6

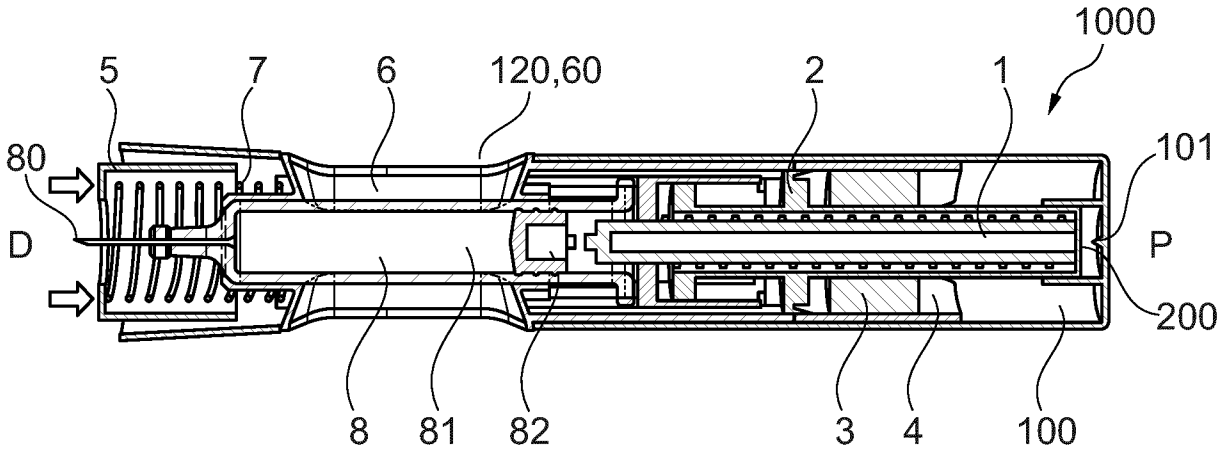

1000
5
7
6
120,60
2
1
80
101
D
P
200
8
81
82
3
4
100

Fig. 7

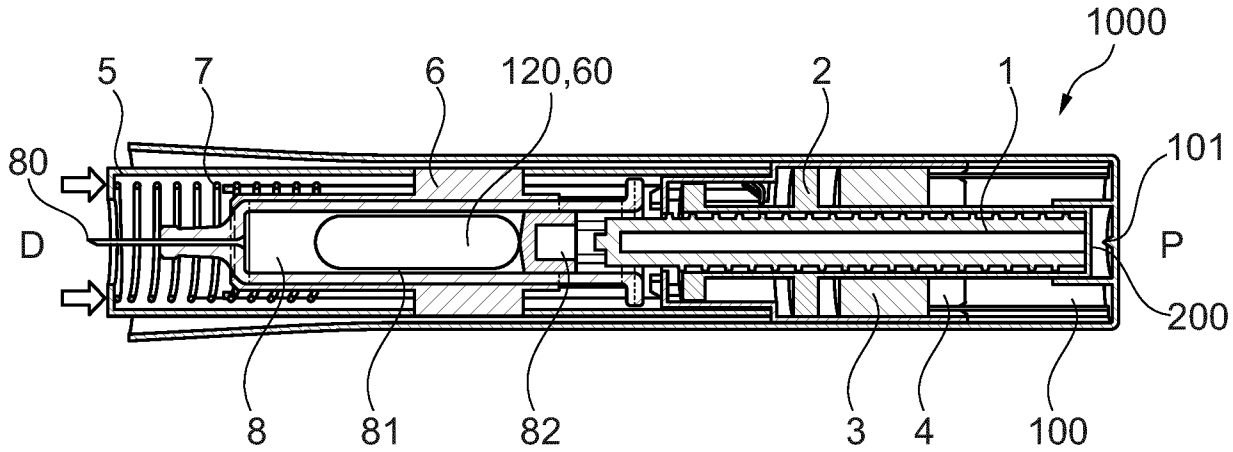

1000
5
7
6
120,60
2
1
80
101
D
P
200
8
81
82
3
4
100

Fig. 8

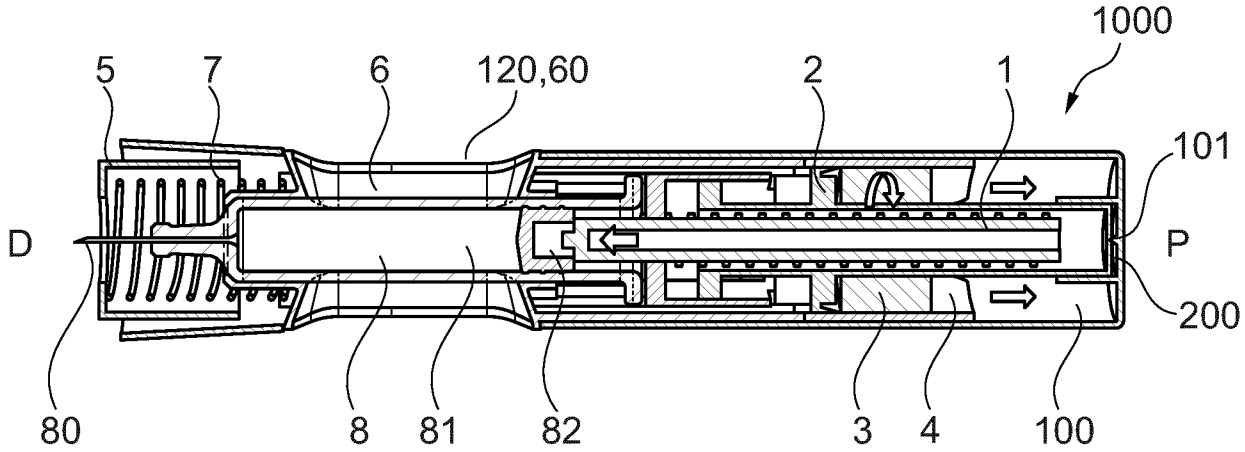

1000
5
7
6
120,60
2
1
101
D
P
200
80
8
81
82
3
4
100

Fig. 9

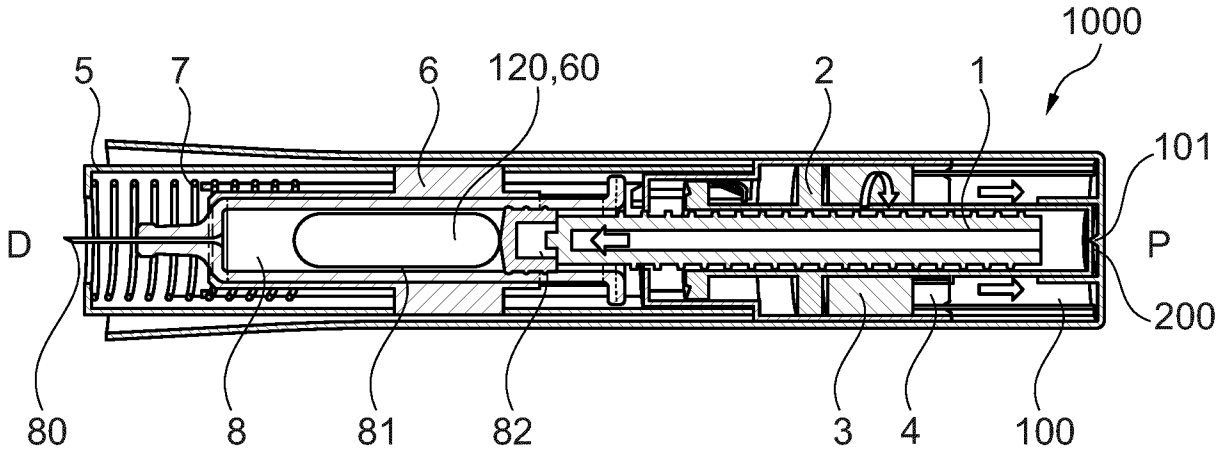

1000
5
7
6
120,60
2
1
101
D
P
200
80
8
81
82
3
4
100

Fig. 10

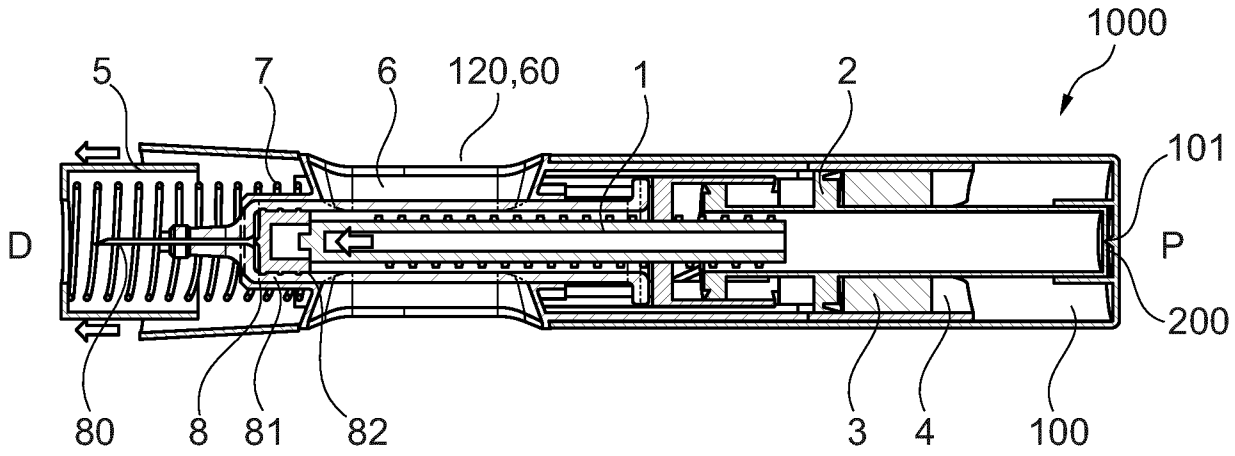

1000
5
7
6
120,60
1
2
101
D
P
200
80
8
81
82
3
4
100

Fig. 11

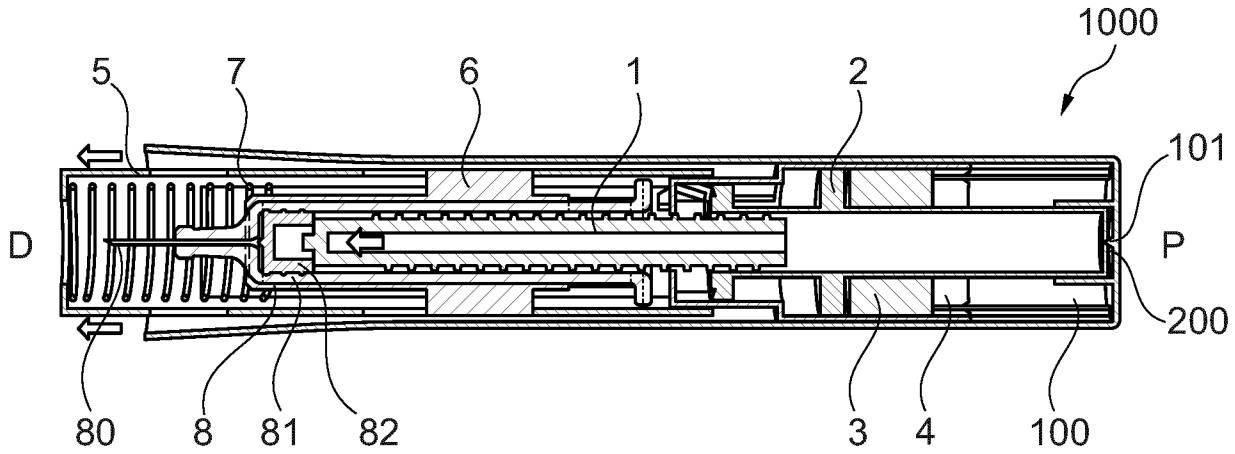

1000
5
7
6
1
2
101
D
P
200
80
8
81
82
3
4
100

Fig. 12

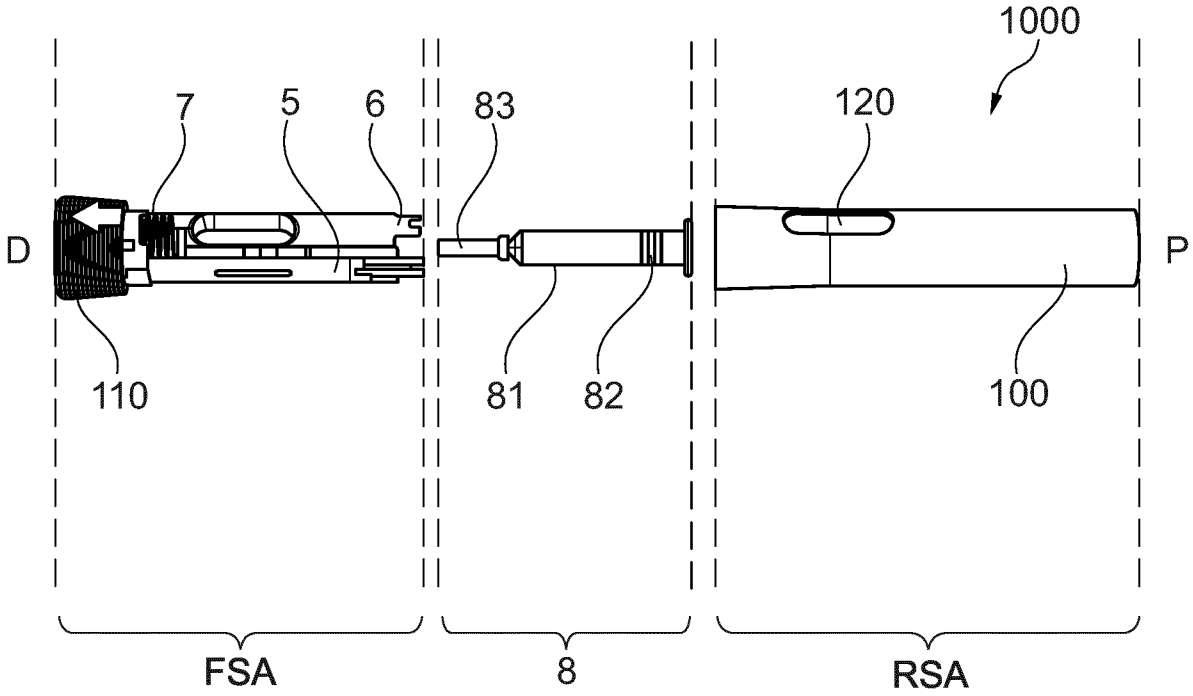

1000
7
5
6
83
120
D
P
110
81
82
100
FSA
8
RSA

Fig. 13

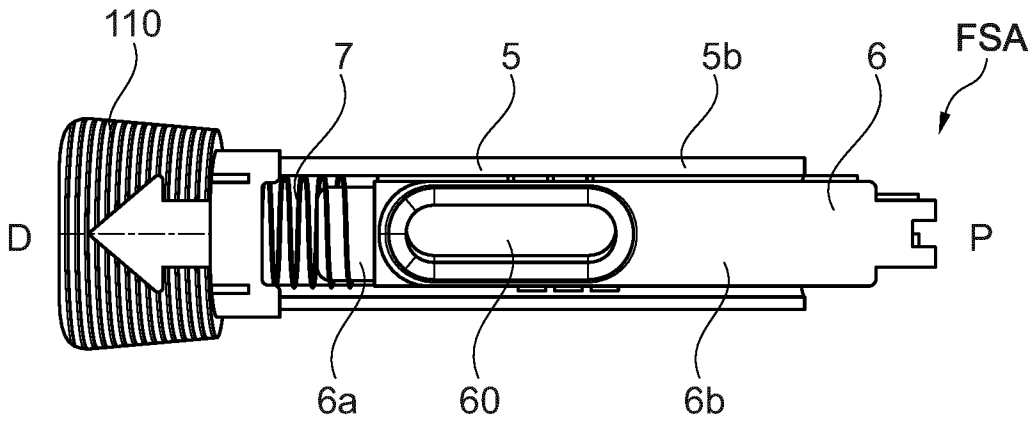

110
7
5
5b
6
FSA
D
P
6a
60
6b

Fig. 14

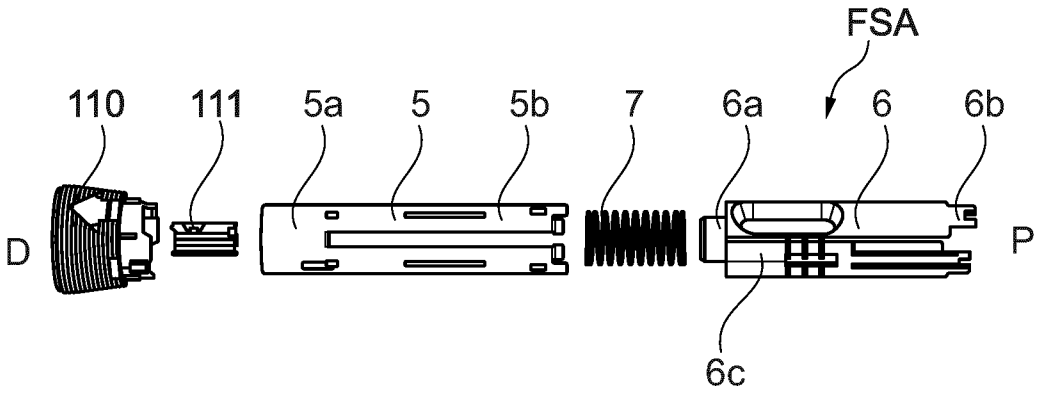


Fig. 15

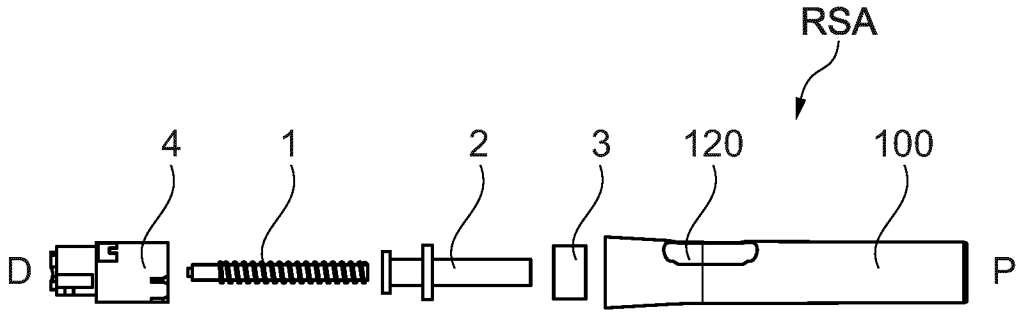


Fig. 16

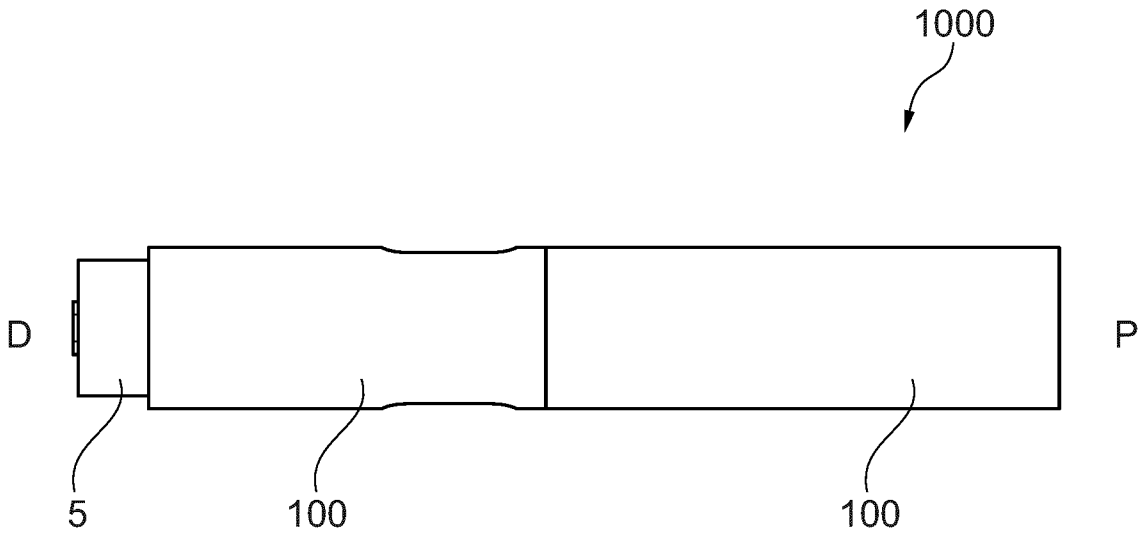


Fig. 17

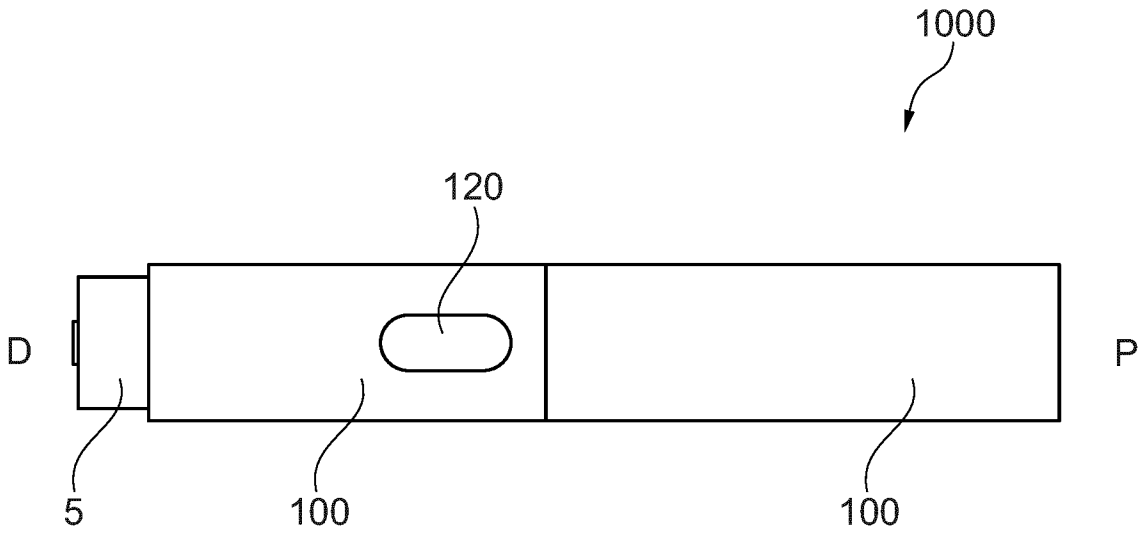


Fig. 18

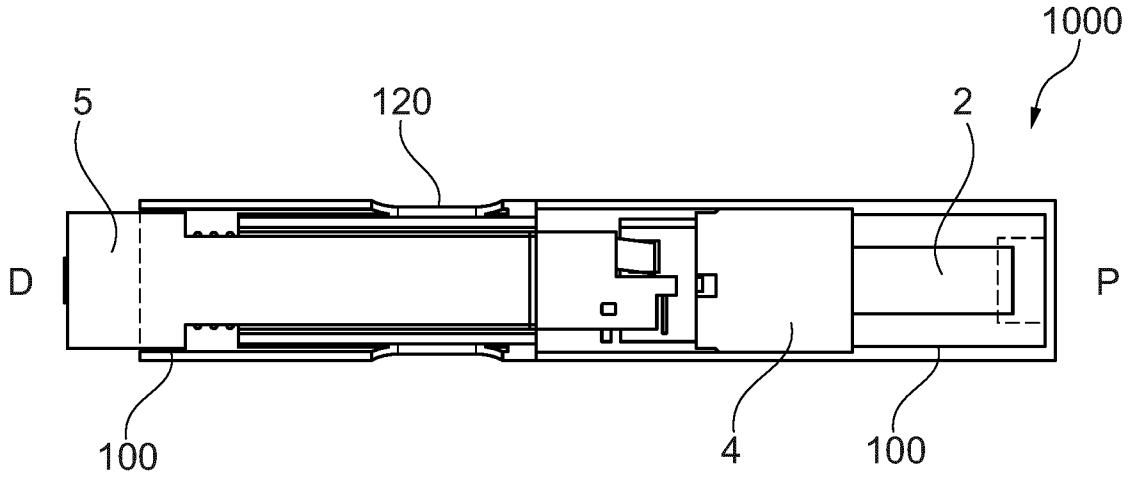


Fig. 19

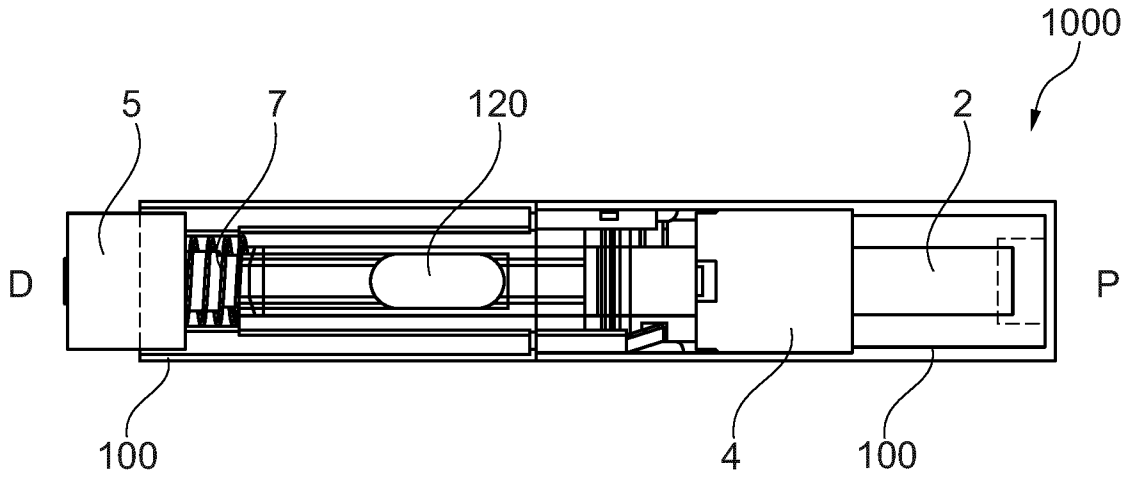


Fig. 20

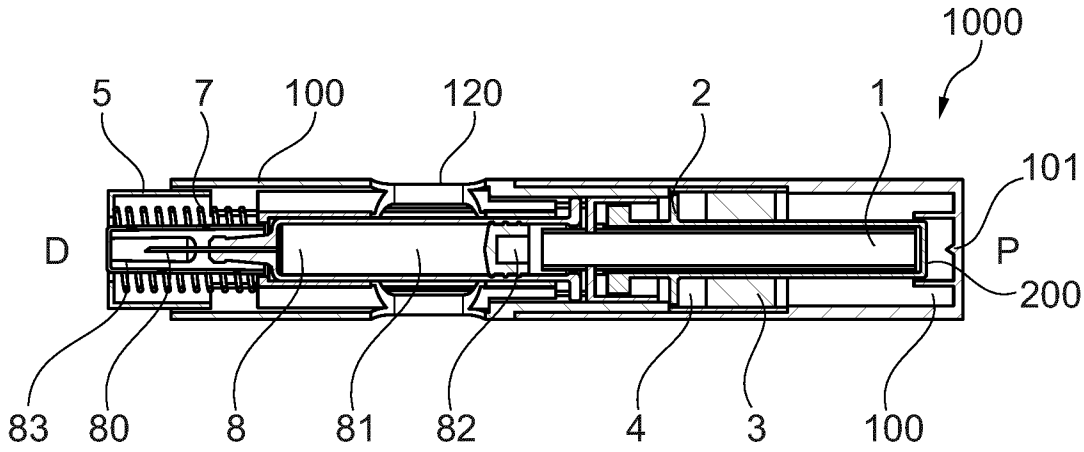

1000
5
7
100
120
2
1
101
D
P
200
83
80
8
81
82
4
3
100

Fig. 21

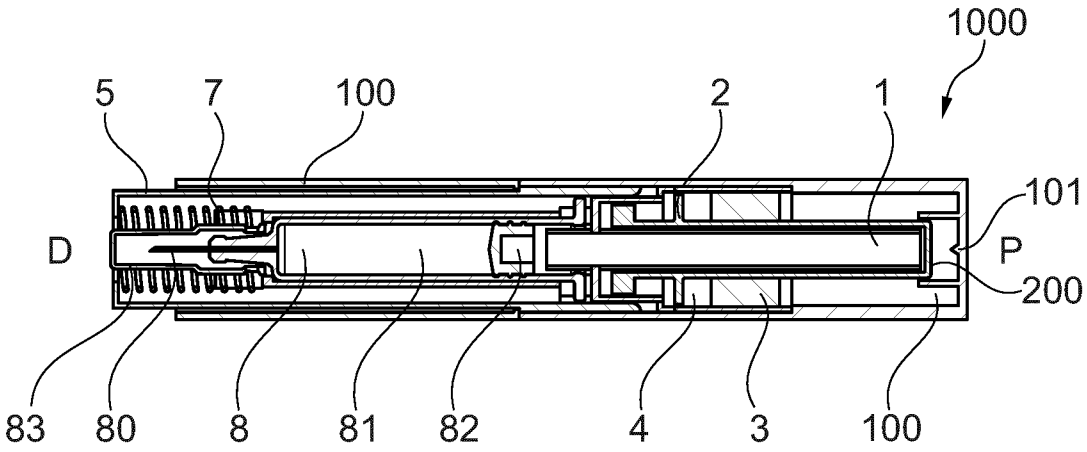

1000
5
7
100
2
1
101
D
P
200
83
80
8
81
82
4
3
100

Fig. 22

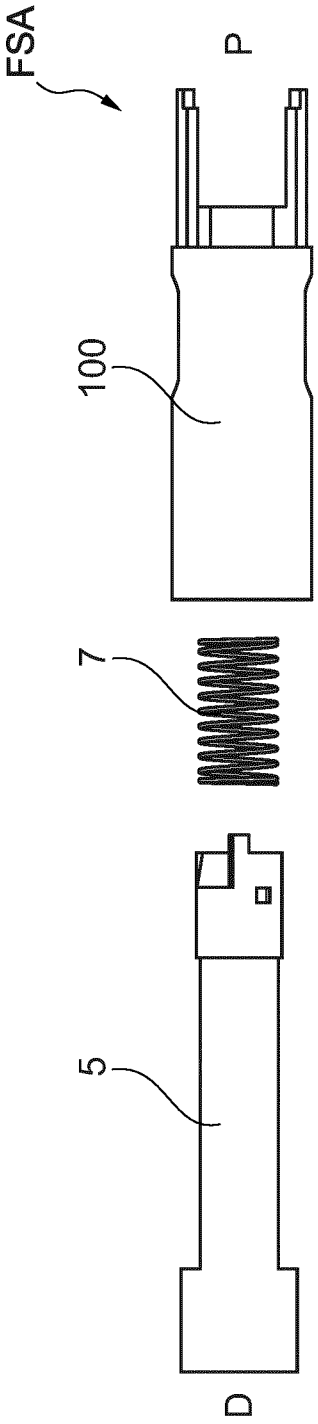


Fig. 23

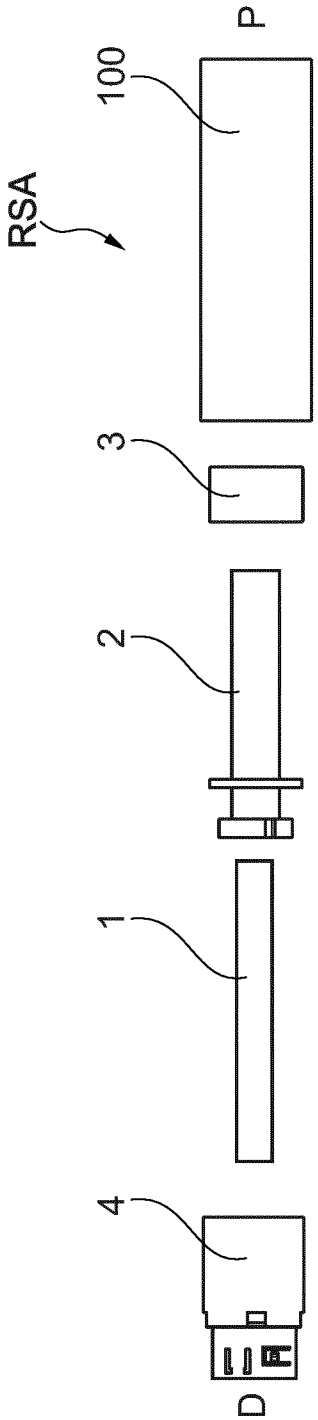


Fig. 24

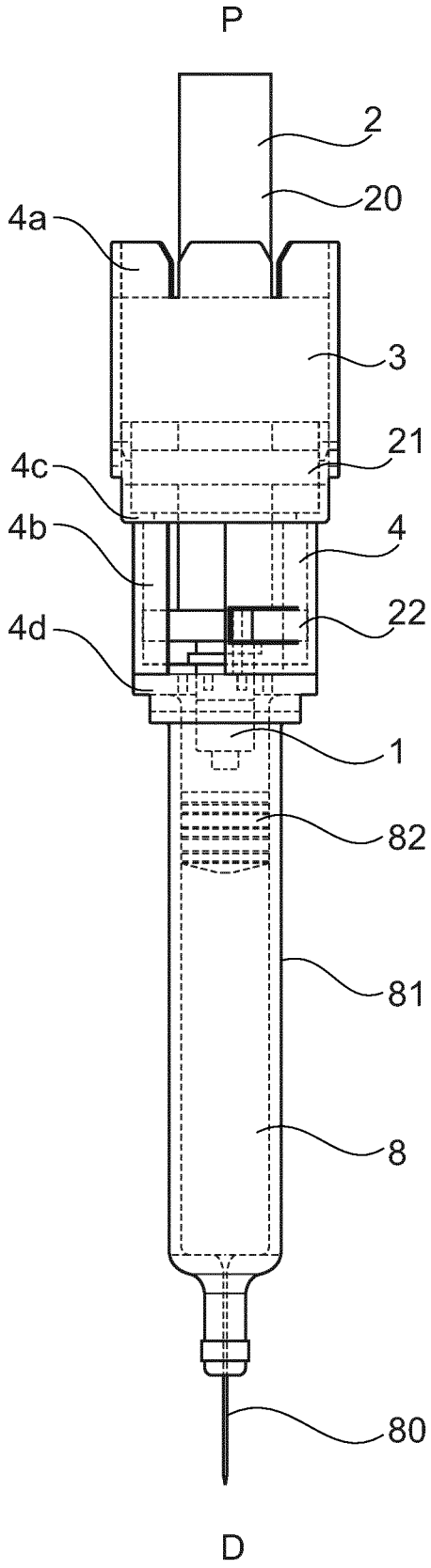

P
2
20
4a
3
21
4c
4b
4
4d
22
1
82
81
8
80
D

Fig. 25

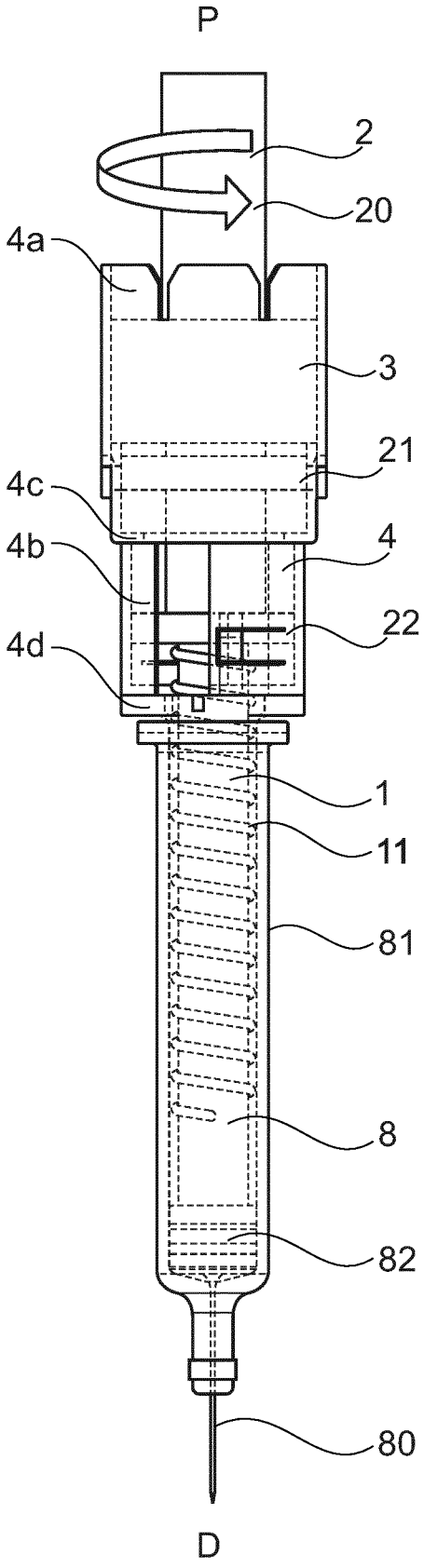

P
2
20
4a
3
21
4c
4b
4
4d
22
1
11
81
8
82
80
D

Fig. 26

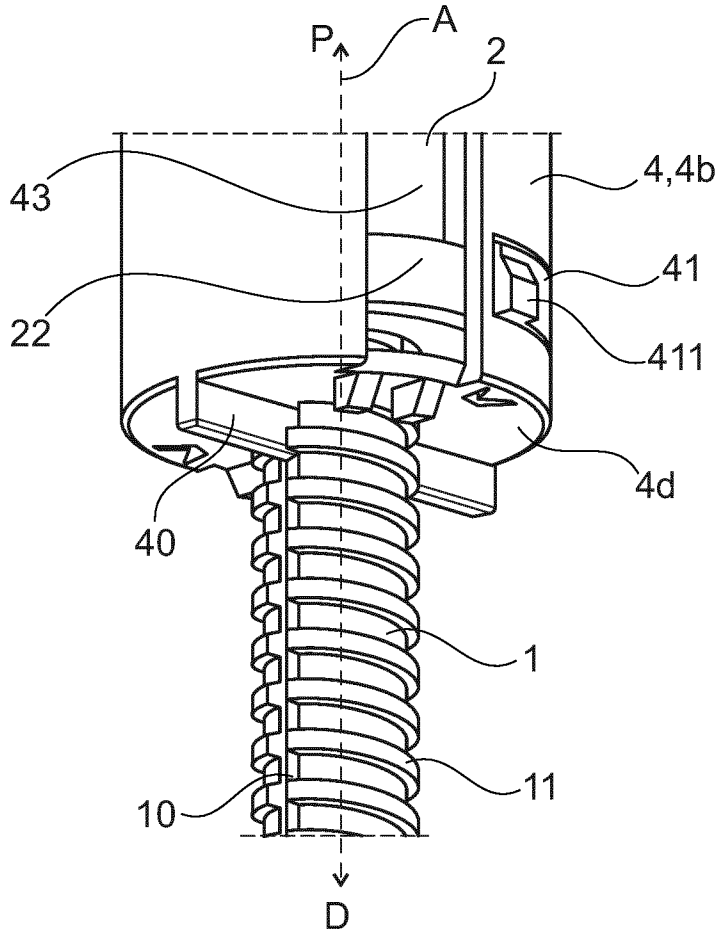

P
A
2
43
4,4b
41
22
411
4d
40
1
11
10
D

Fig. 27

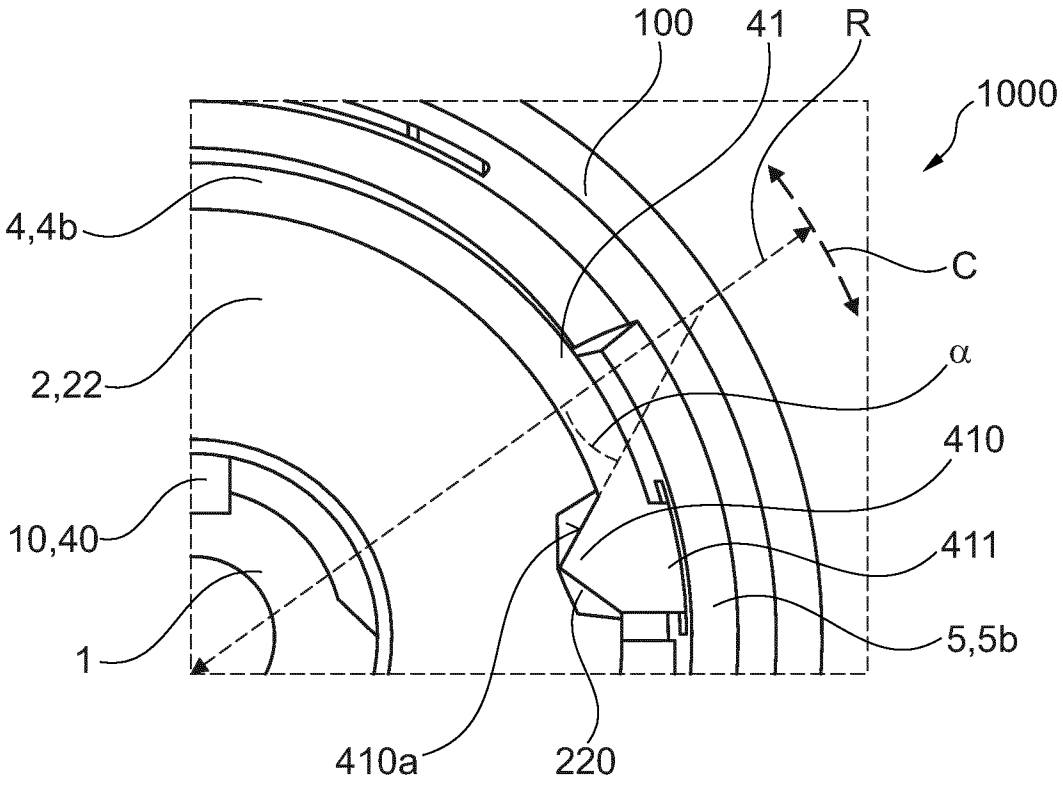

100
41
R
1000
4,4b
C
α
2,22
410
10,40
411
5,5b
1
410a
220

Fig. 28

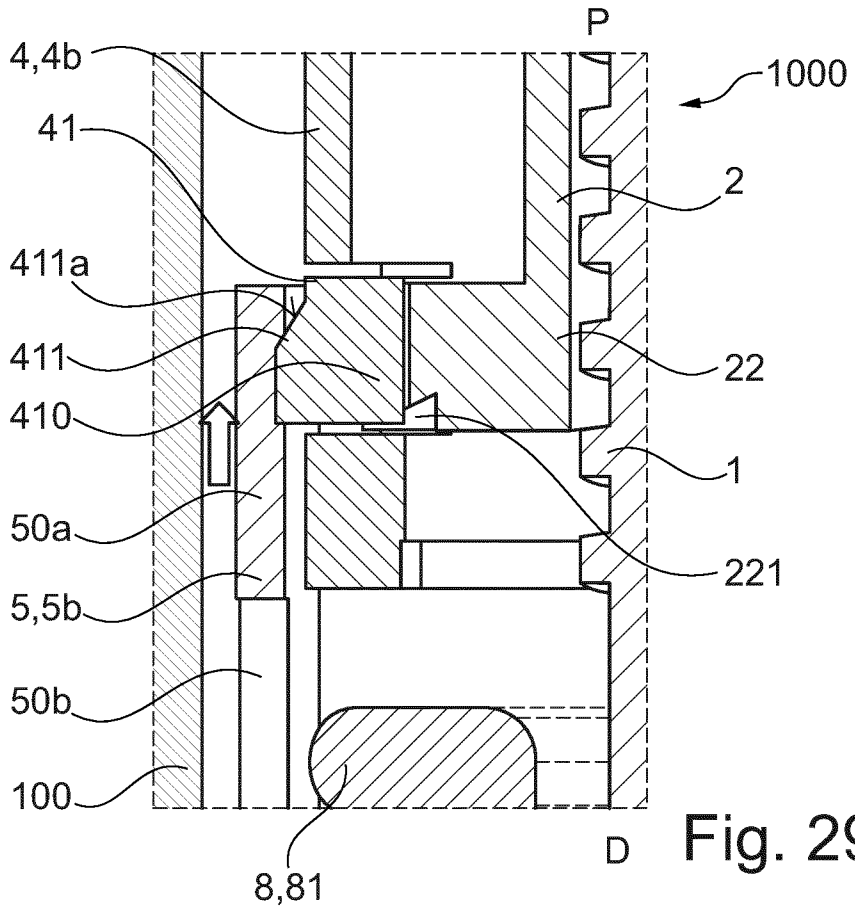

P
4,4b
1000
41
2
411a
411
22
410
1
50a
221
5,5b
50b
100
D
8,81

Fig. 29

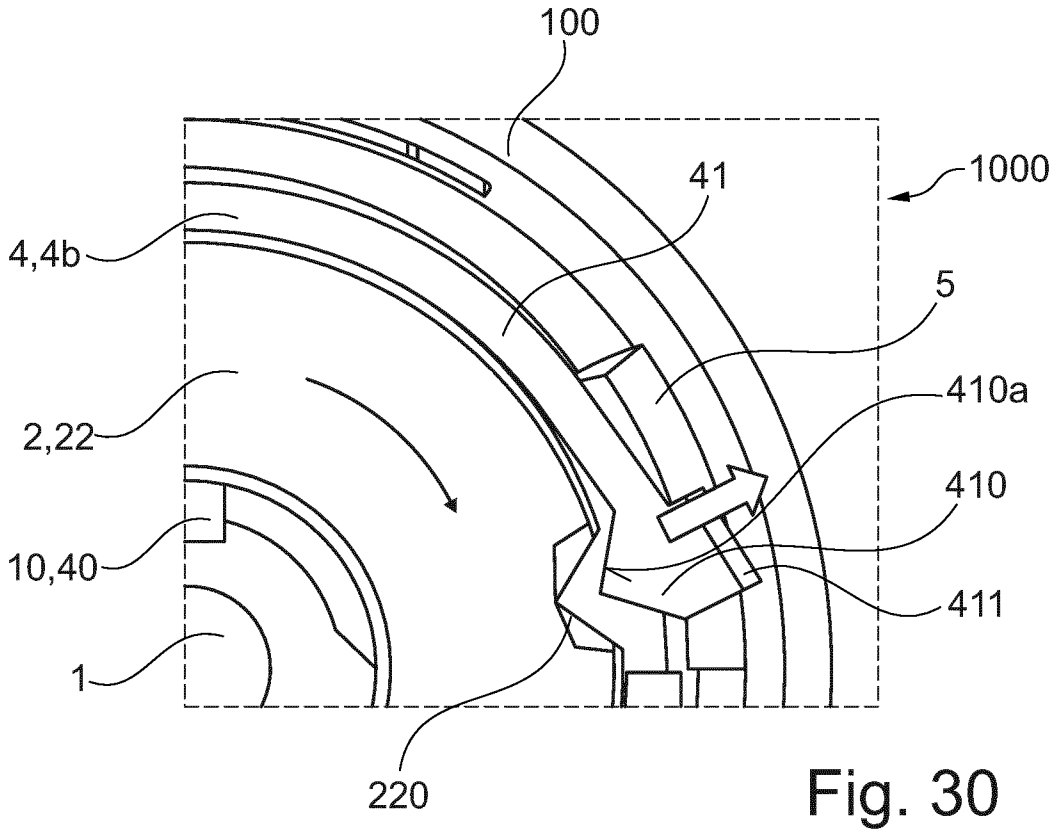

100
41
1000
4,4b
5
410a
2,22
410
10,40
411
1
220

Fig. 30

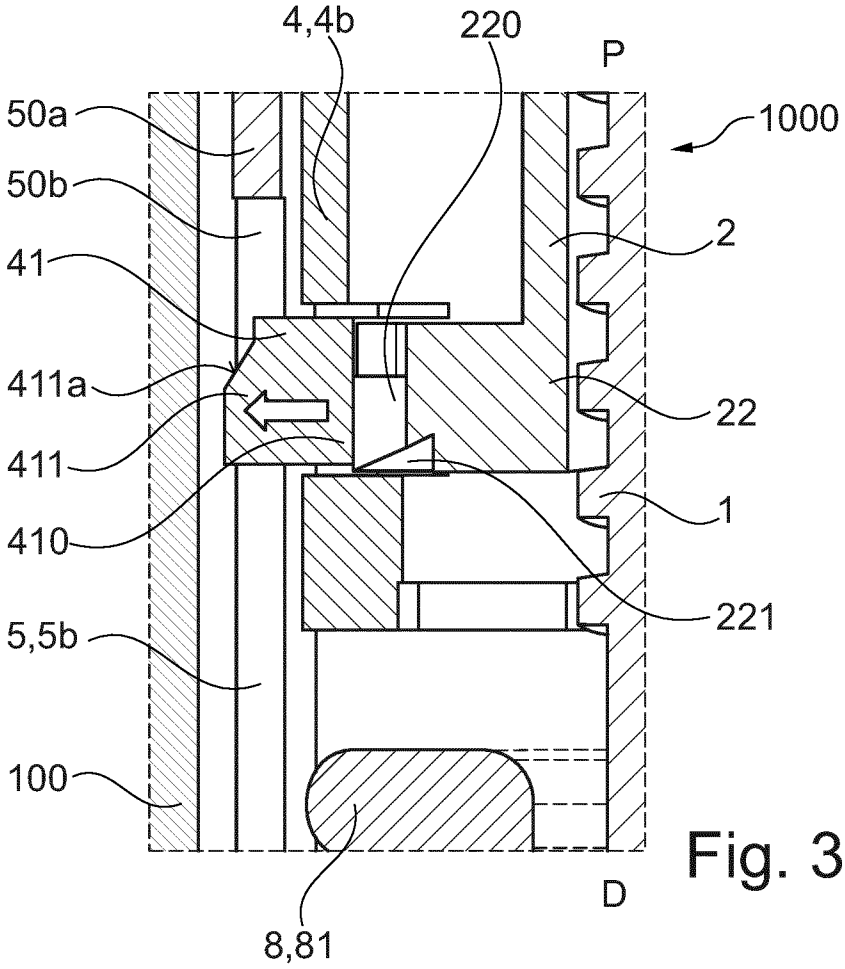

4,4b
220
P
50a
1000
50b
2
41
411a
22
411
1
410
221
5,5b
100
D
8,81

Fig. 31

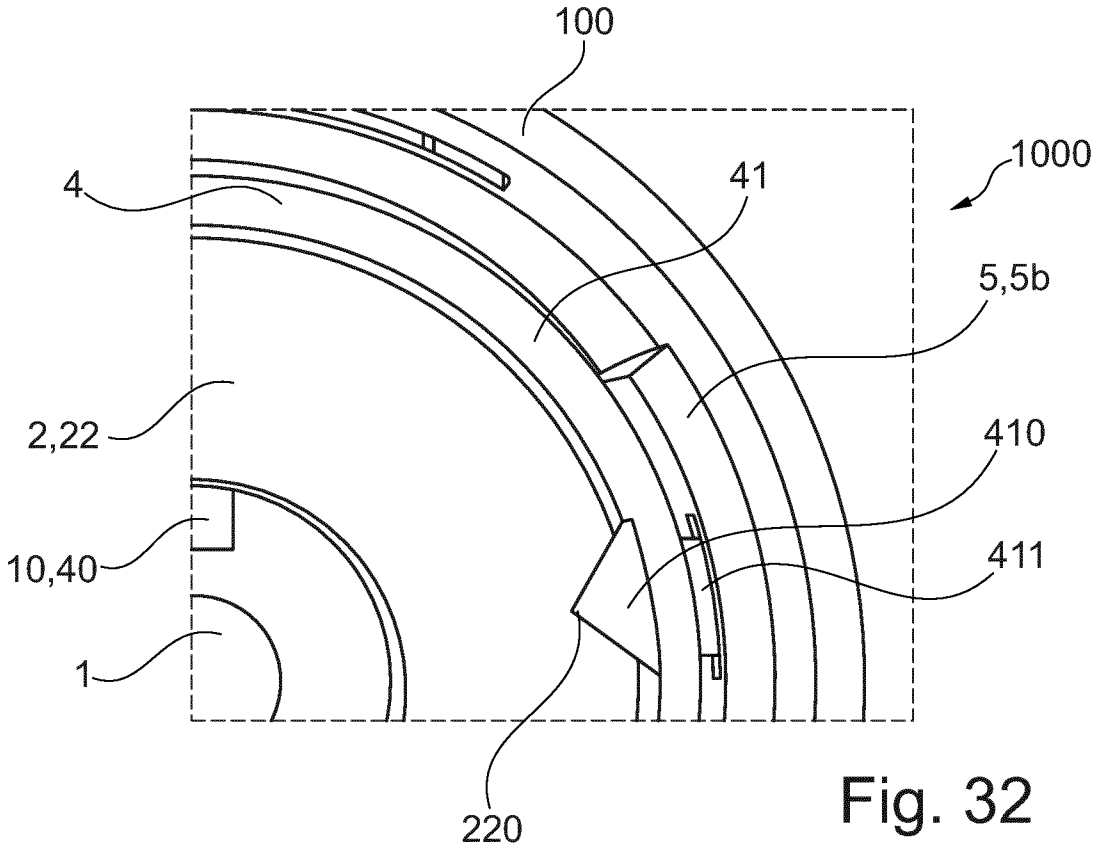

100
4
41
1000
5,5b
2,22
410
10,40
411
1
220

Fig. 32

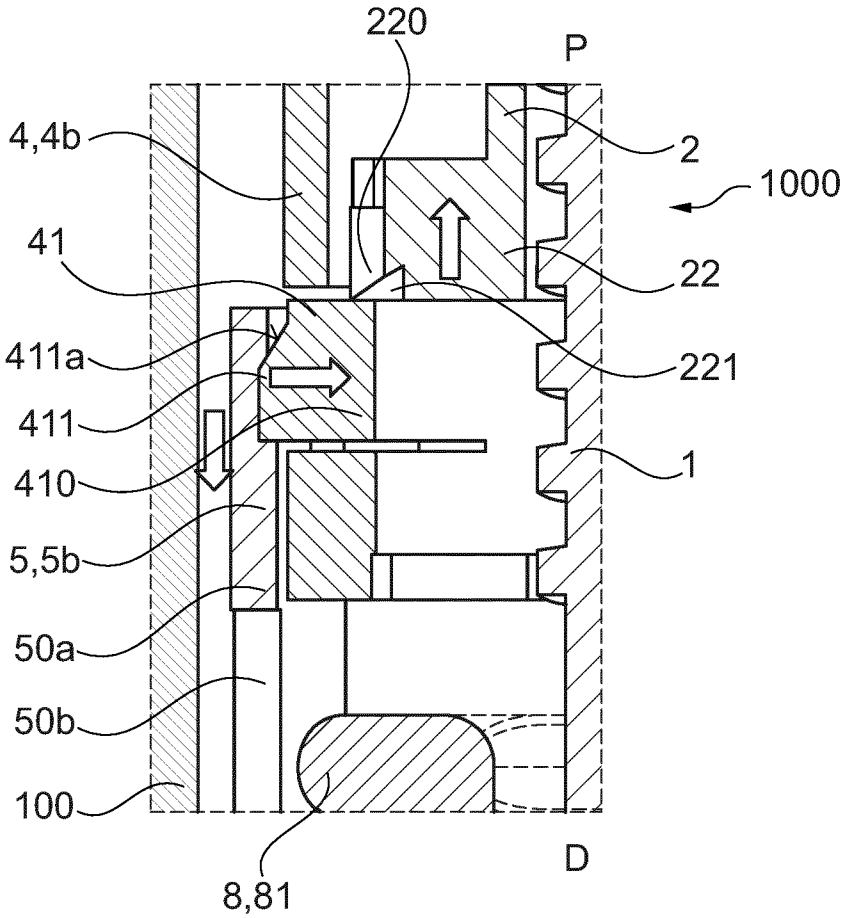

220
P
4,4b
2
1000
41
22
411a
221
411
1
410
5,5b
50a
50b
100
D
8,81

Fig. 33

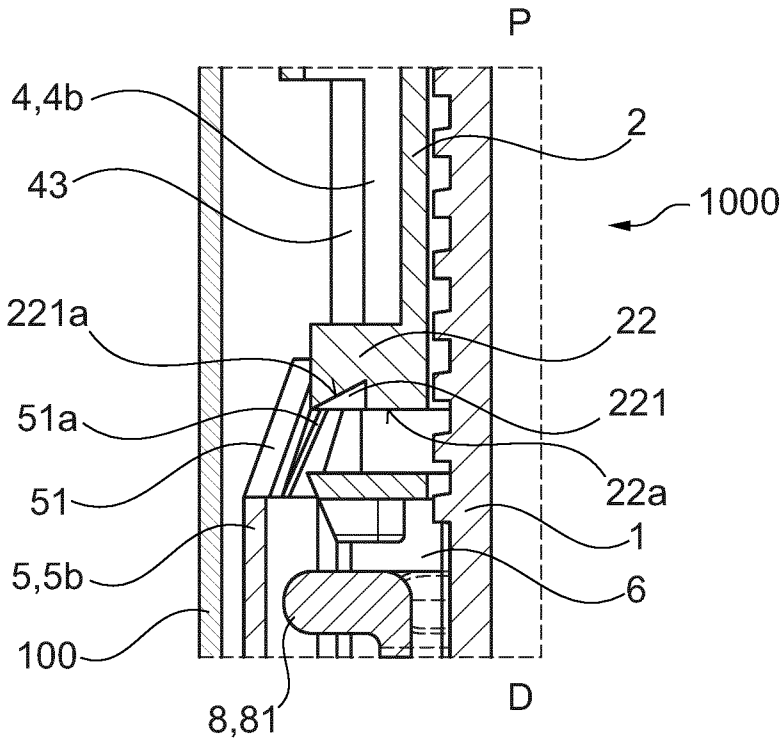

P
4,4b
2
43
1000
221a
22
221
51a
22a
51
1
5,5b
6
100
D
8,81

Fig. 34

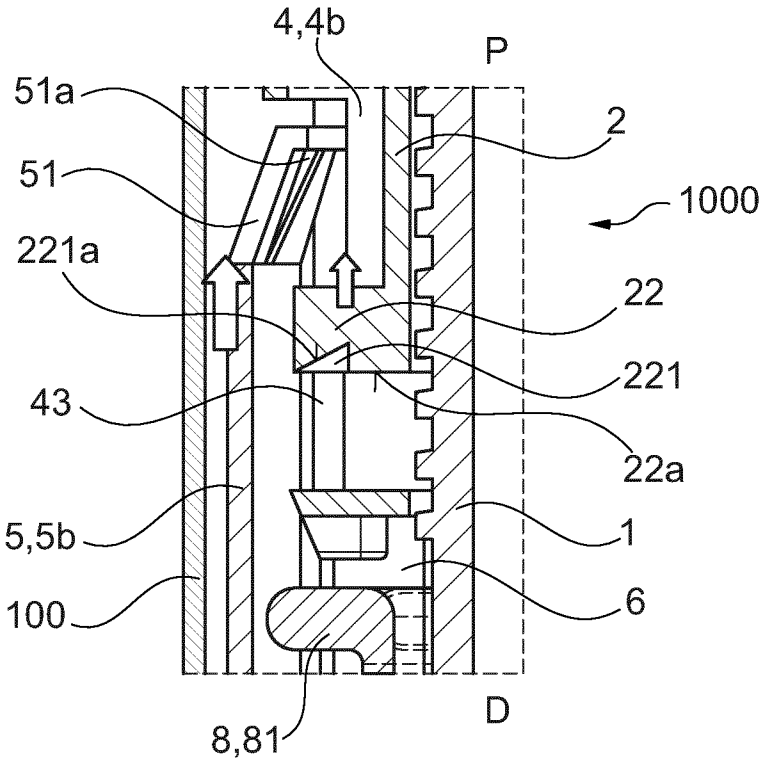

4,4b
P
51a
2
51
1000
221a
22
221
43
22a
5,5b
1
100
6
D
8,81

Fig. 35

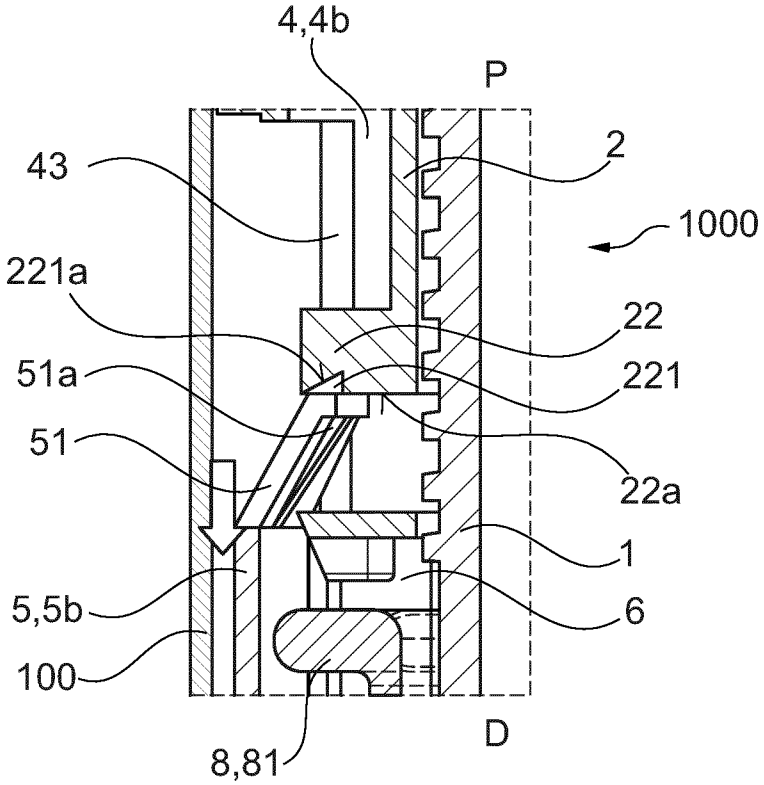

4,4b
P
43
2
1000
221a
22
51a
221
51
22a
1
5,5b
6
100
D
8,81

Fig. 36

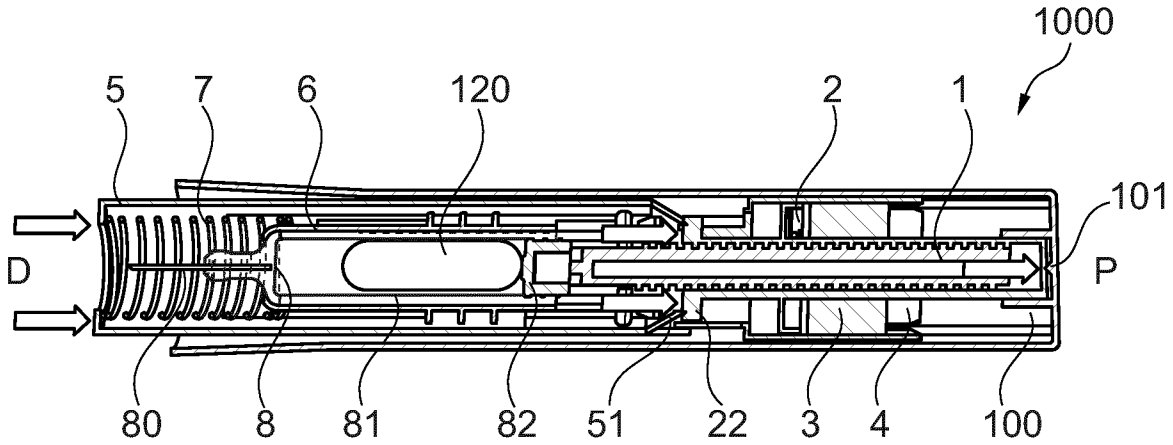

1000
5
7
6
120
2
1
101
D
P
80
8
81
82
51
22
3
4
100

Fig. 37

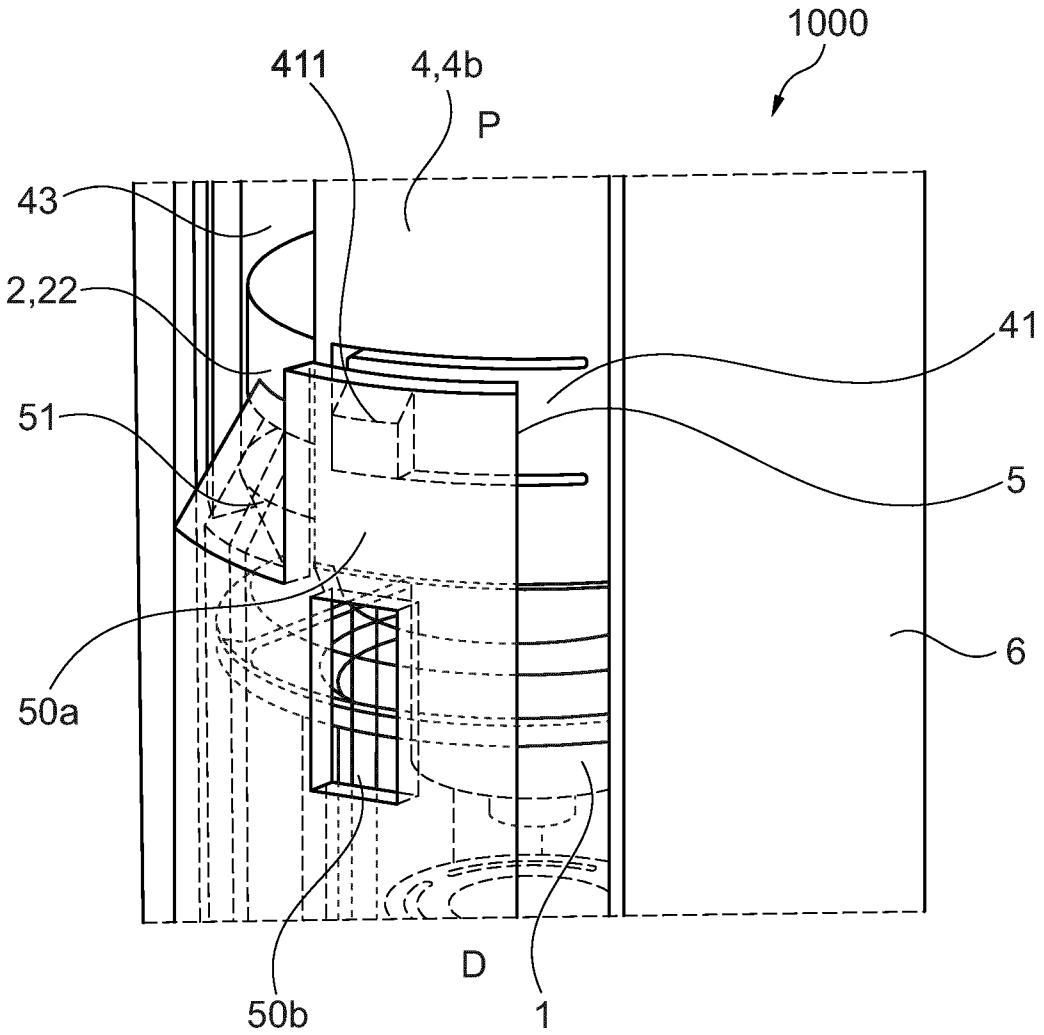

1000
411
4,4b
P
43
2,22
41
51
5
6
50a
D
50b
1

Fig. 38

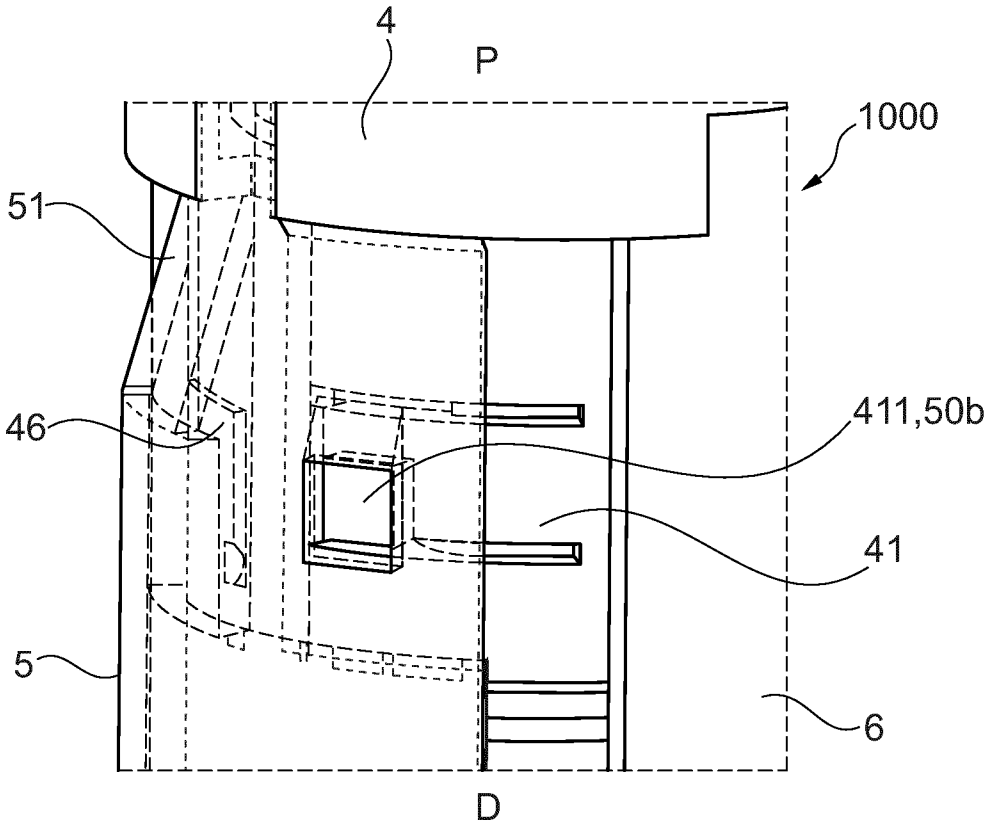


Fig. 39

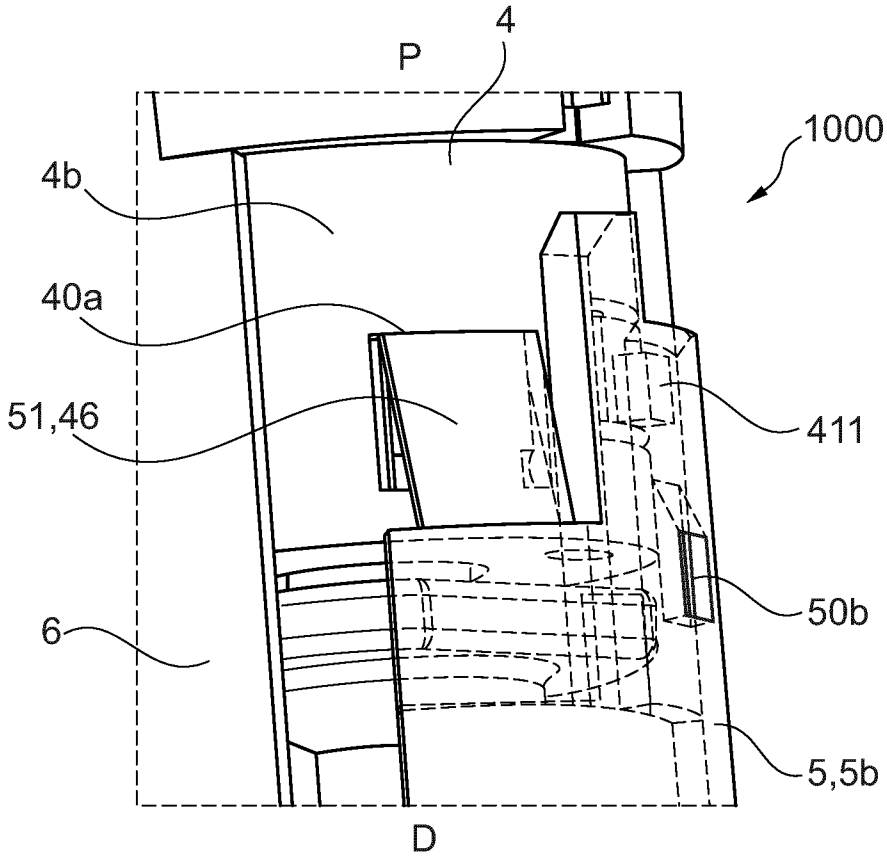


Fig. 40

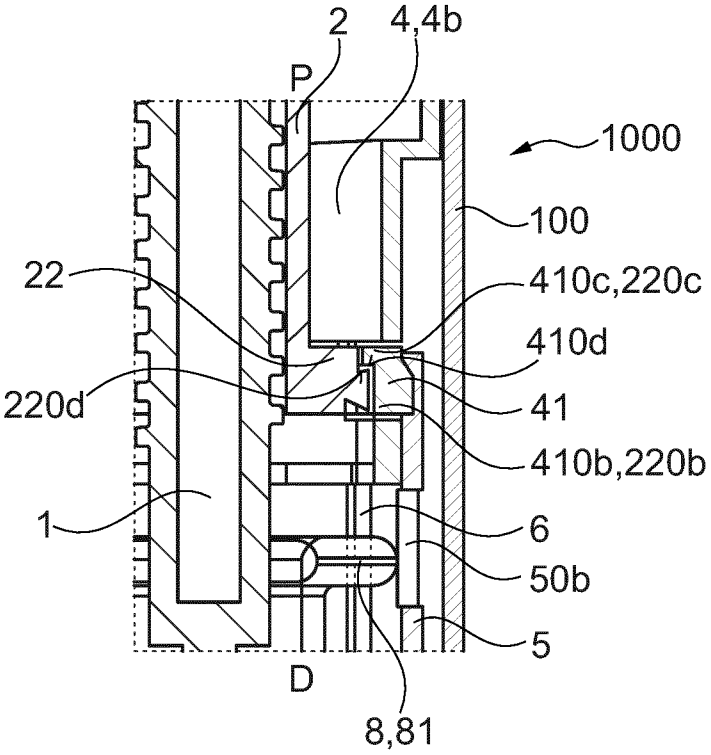

2
4,4b
P
1000
100
22
410c,220c
410d
220d
41
410b,220b
1
6
50b
5
D
8,81

Fig. 41

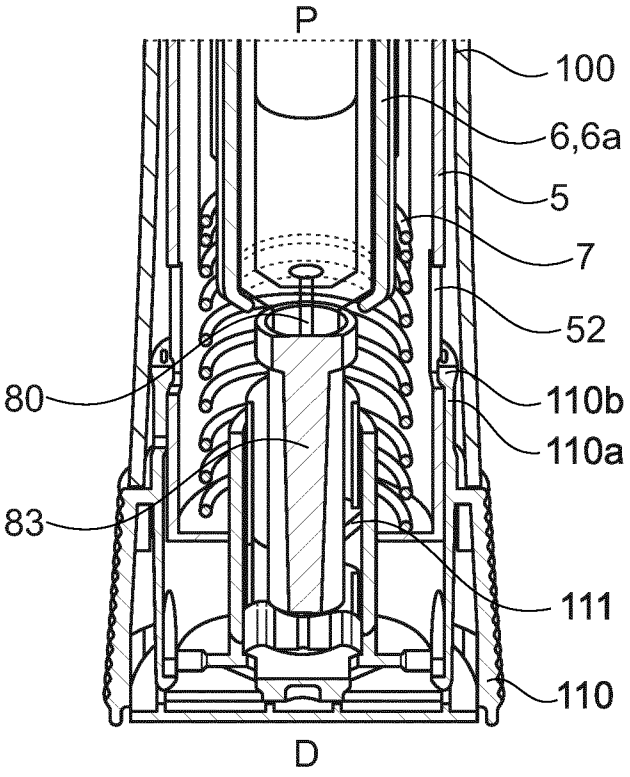

P
100
6,6a
5
7
52
80
110b
110a
83
111
110
D

Fig. 42

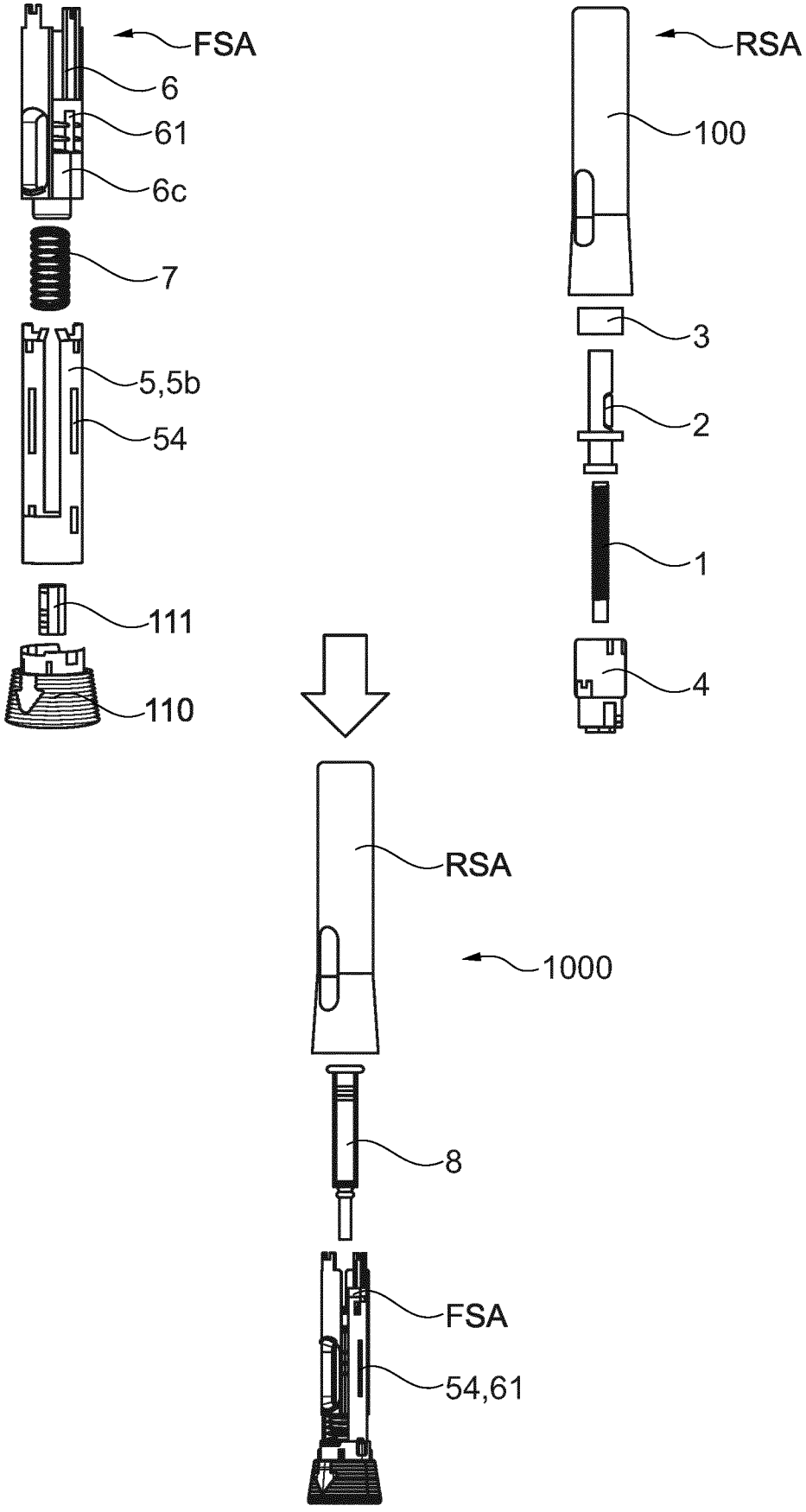


Fig. 43

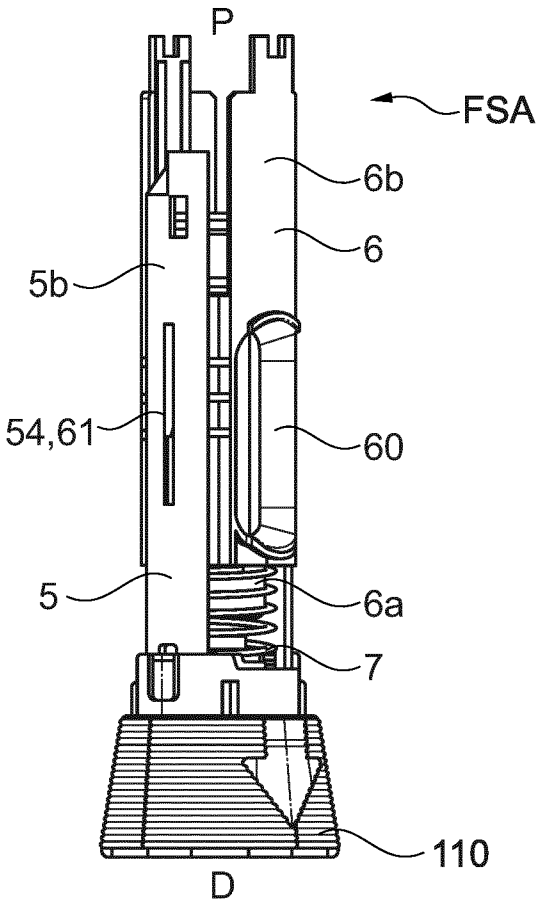


Fig. 44

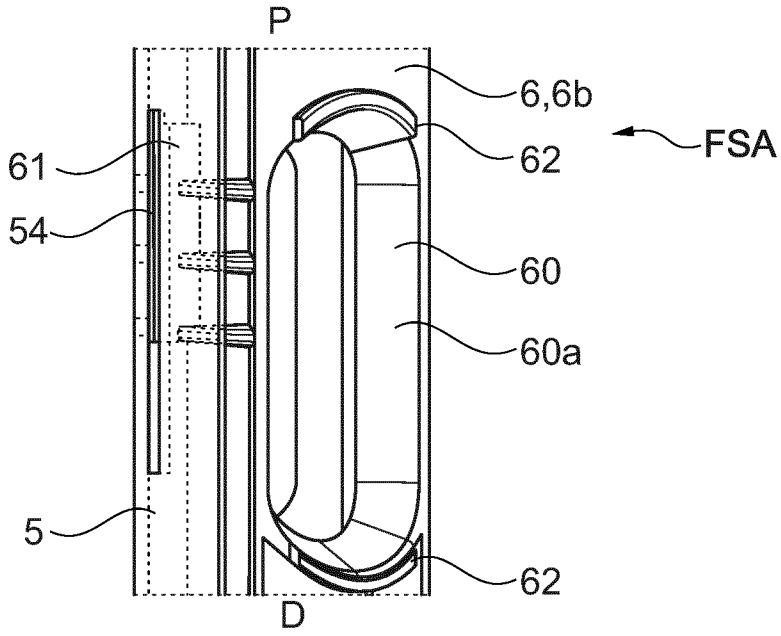


Fig. 45

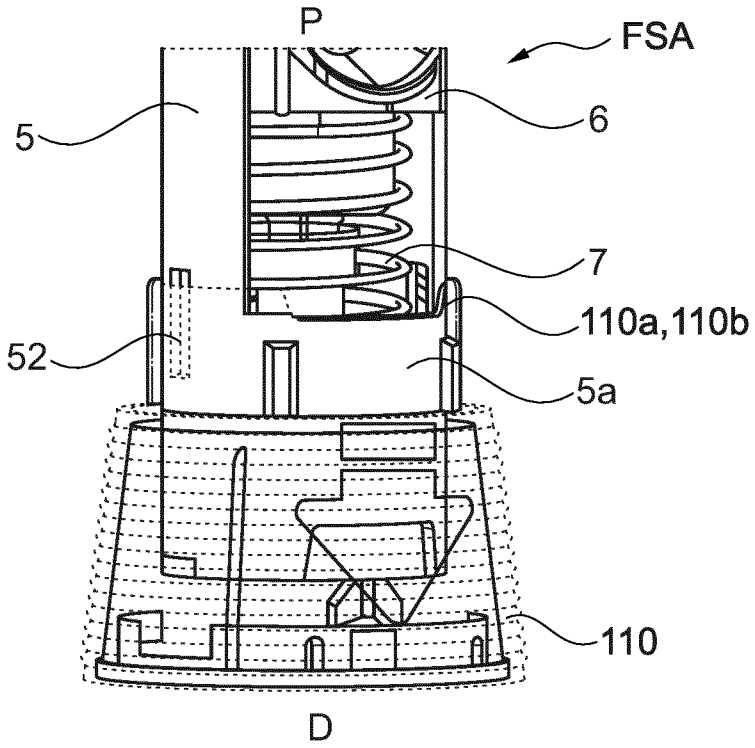


Fig. 46

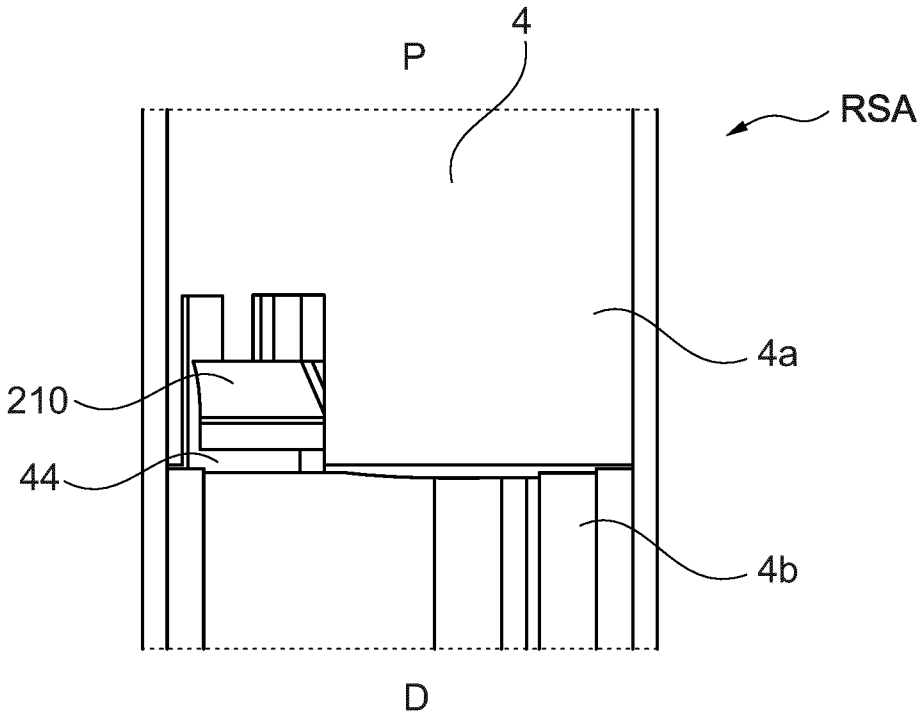


Fig. 47

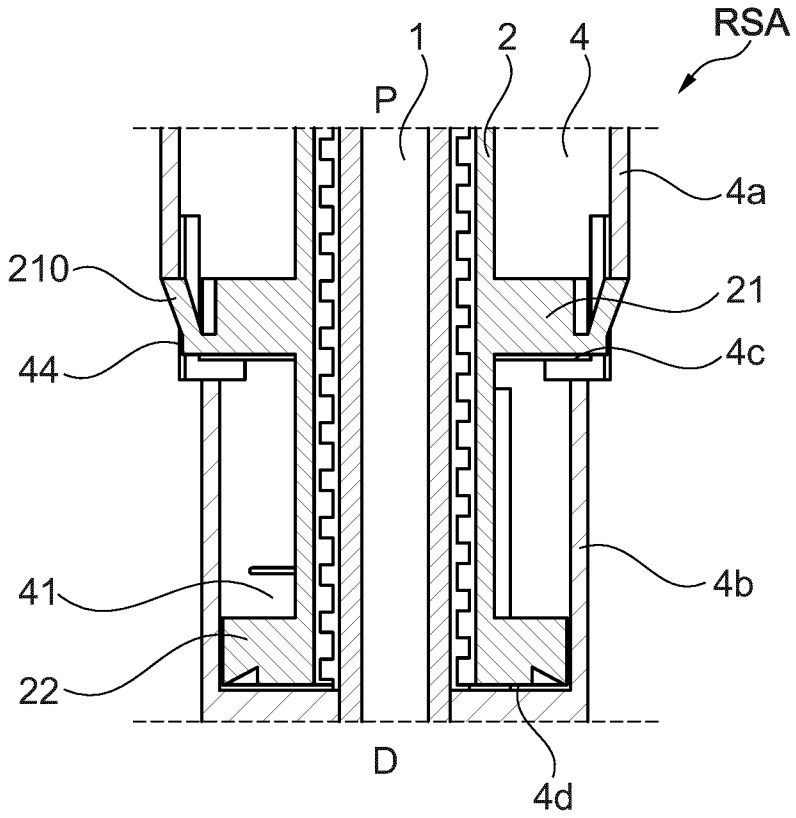

RSA
1
2
4
P
4a
210
21
44
4c
41
4b
22
D
4d

Fig. 48

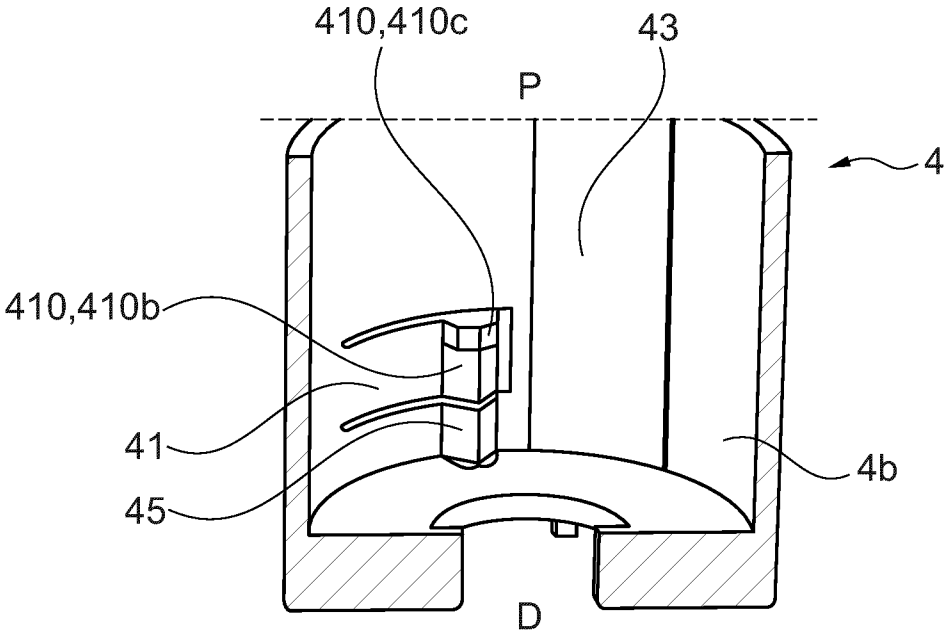

410,410c
43
P
4
410,410b
41
4b
45
D

Fig. 49

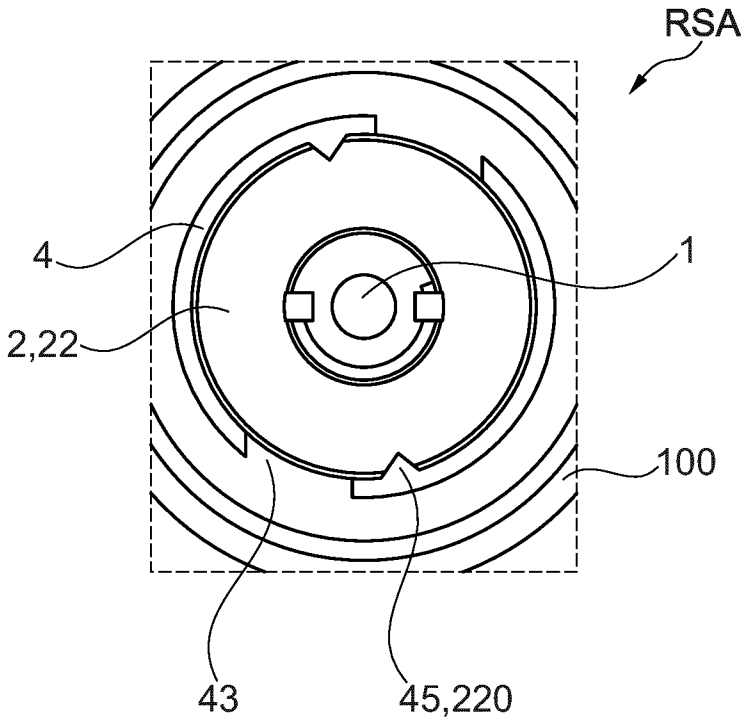


Fig. 50

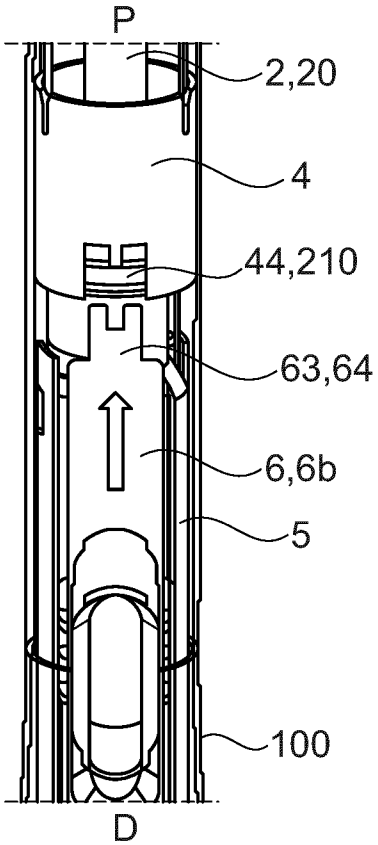


Fig. 51

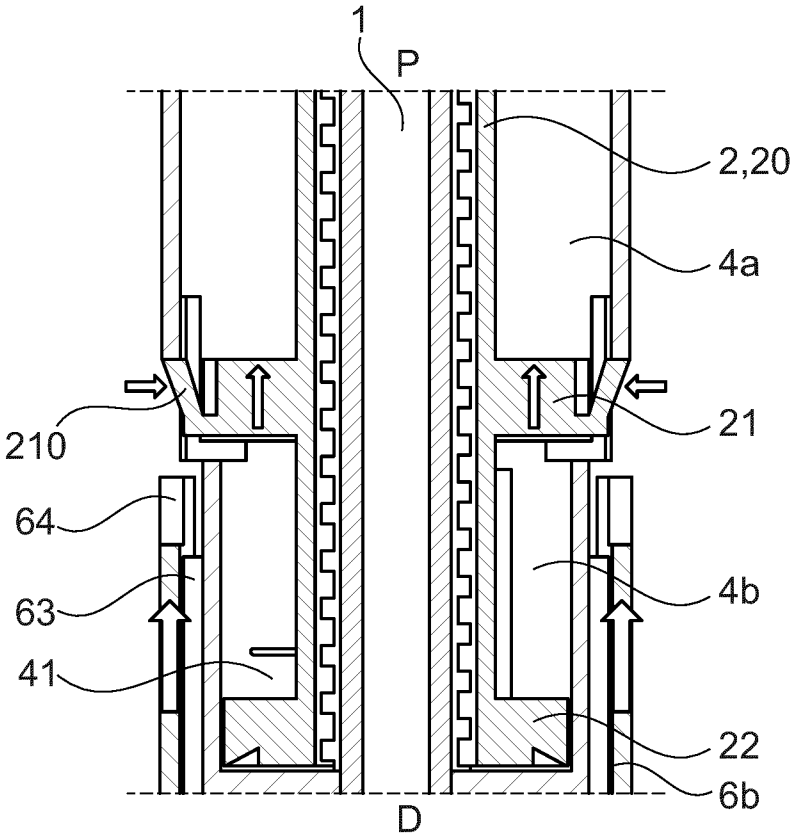

1
P
2,20
4a
21
210
64
63
4b
41
22
6b
D

Fig. 52

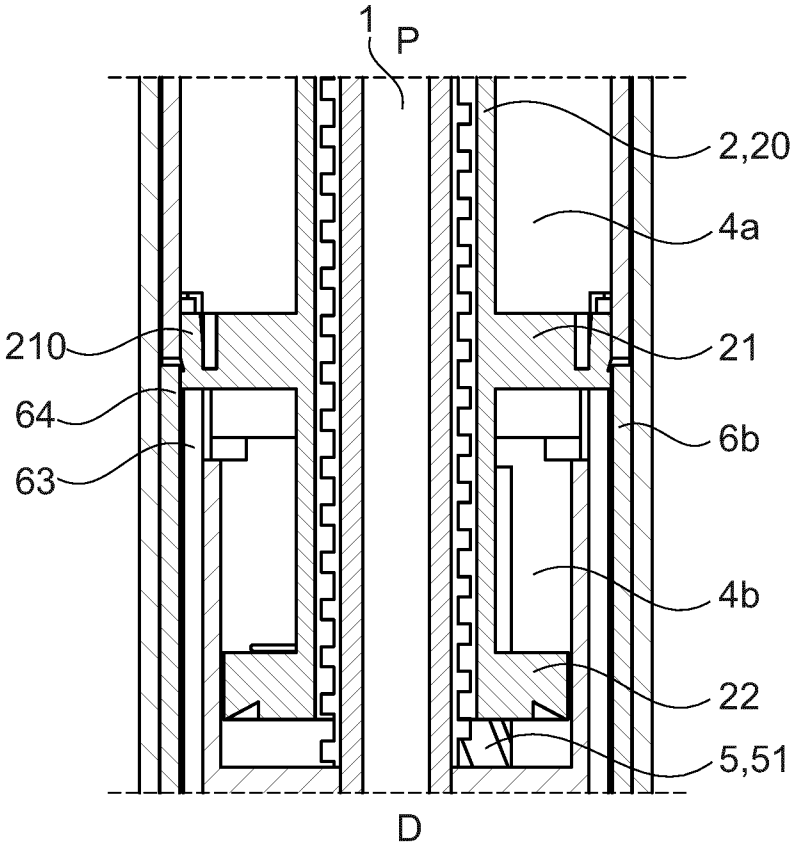
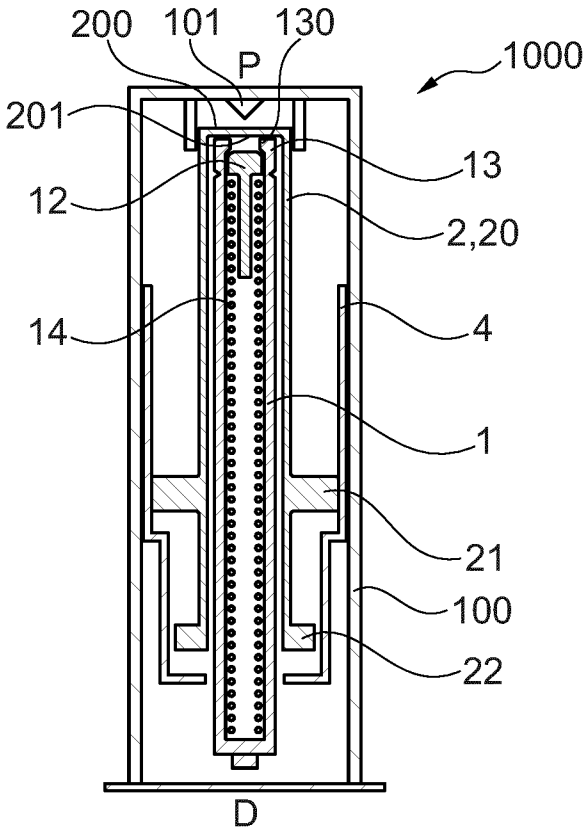

1
P
2,20
4a
210
21
64
6b
63
4b
22
5,51
D

Fig. 53


200
101
130
P
1000
201
13
12
2,20
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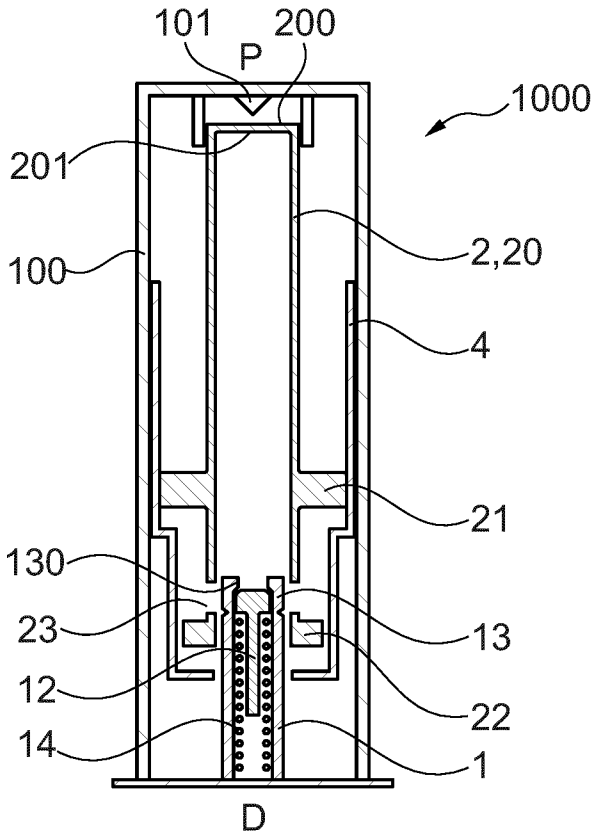
21
100
22
D

Fig. 54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D

Fig. 55

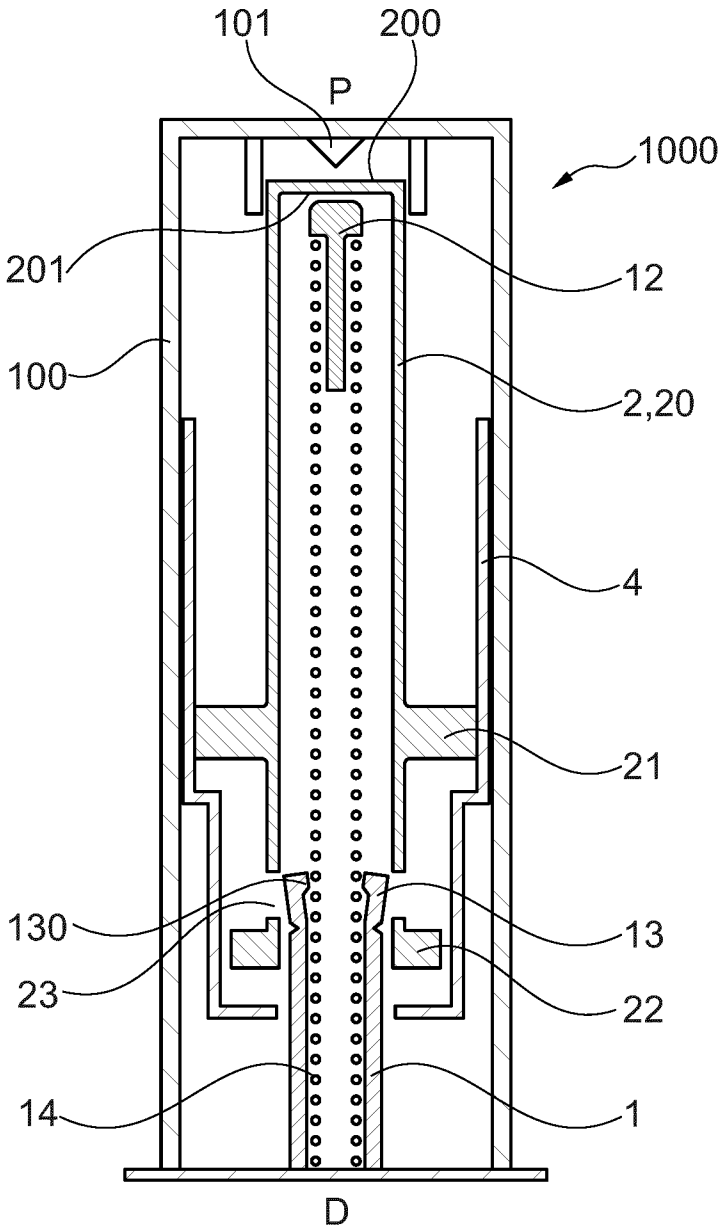

Fig. 56

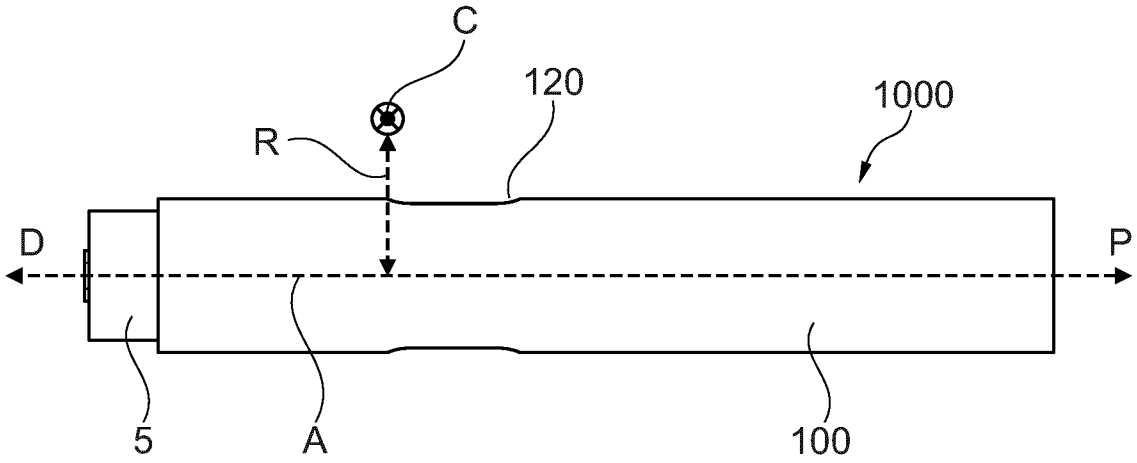

Fig. 57

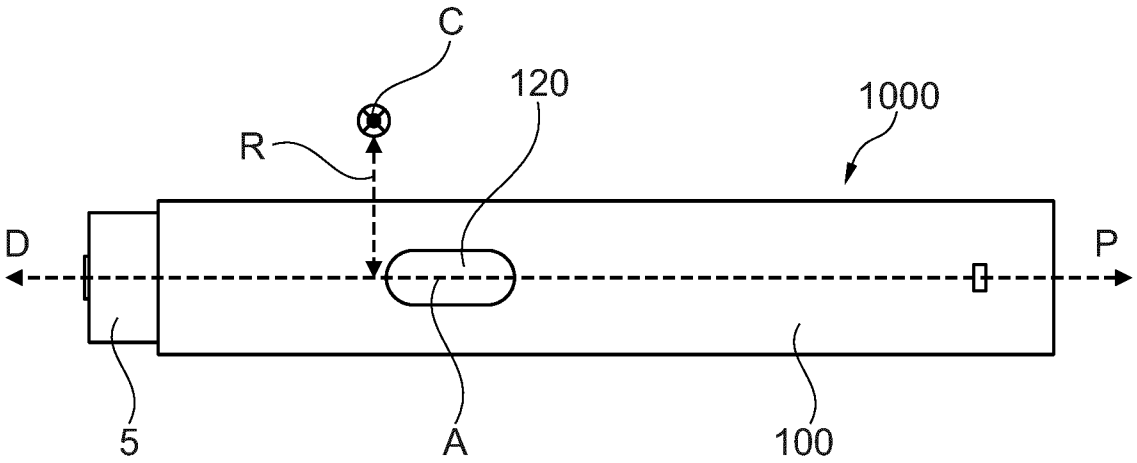

Fig. 58

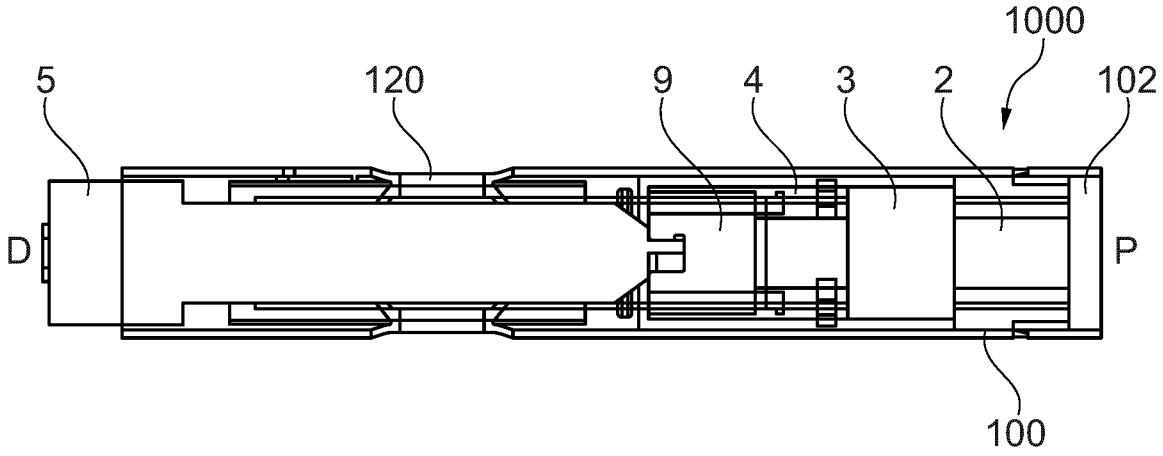

Fig. 59

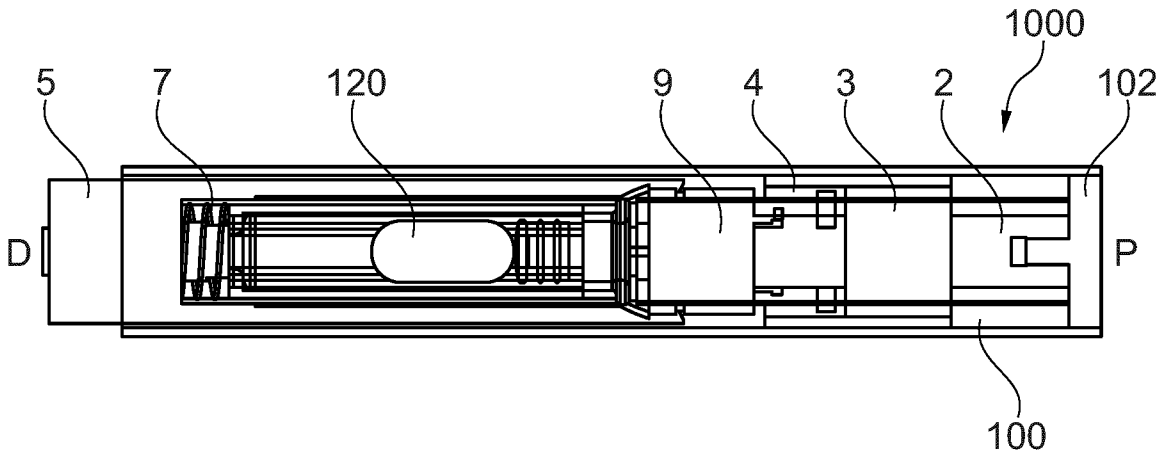

Fig. 60

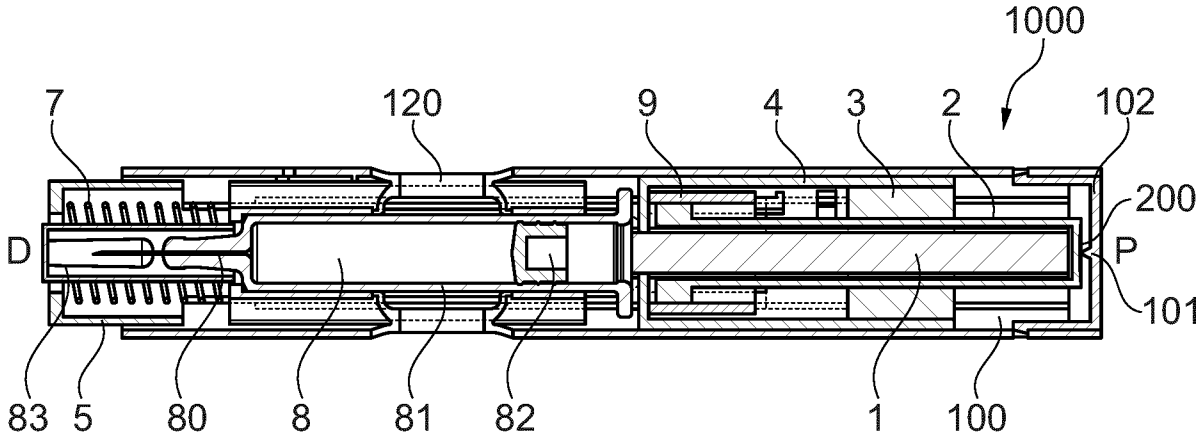
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Fig. 61

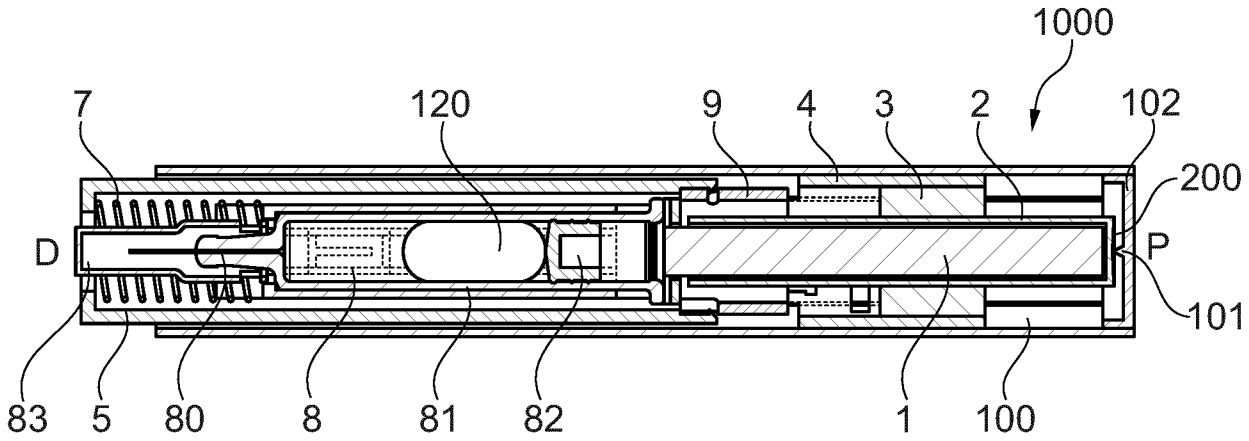
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Fig. 62

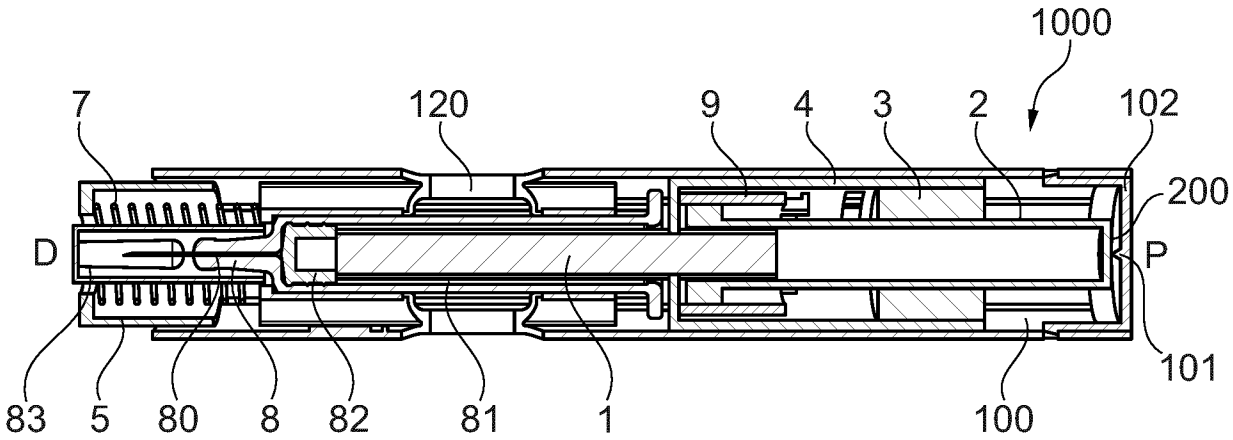
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Fig. 63

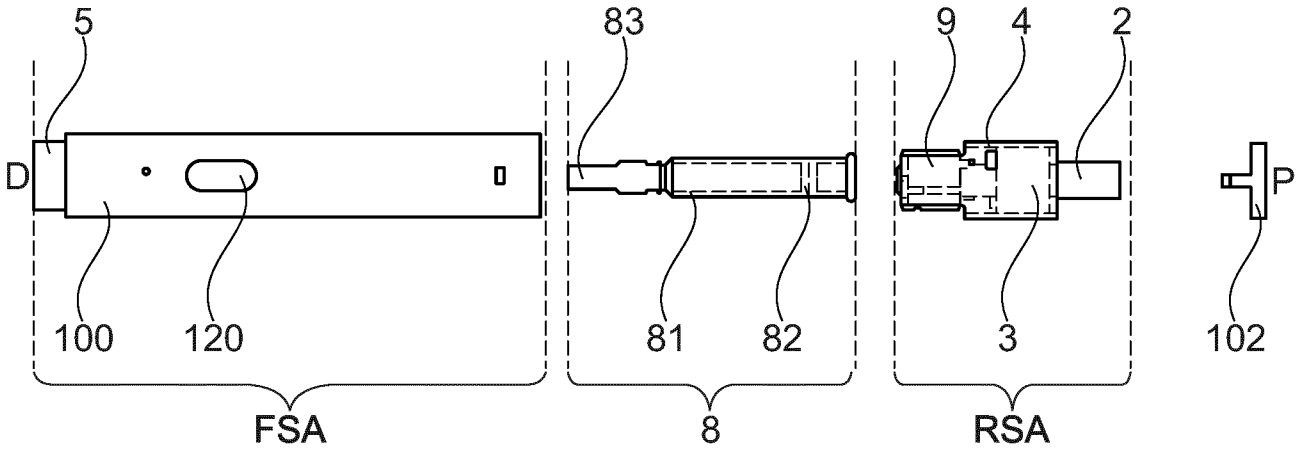
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Fig. 64

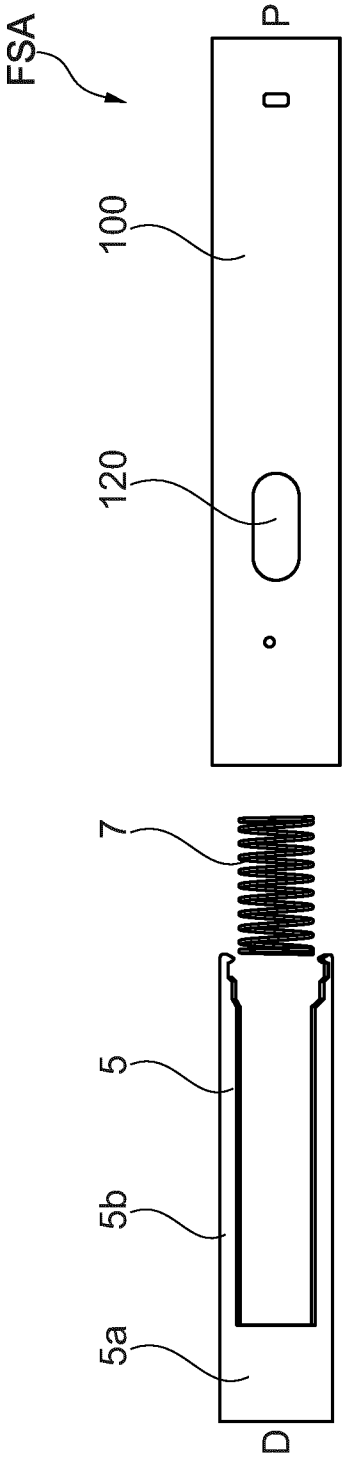


Fig. 65

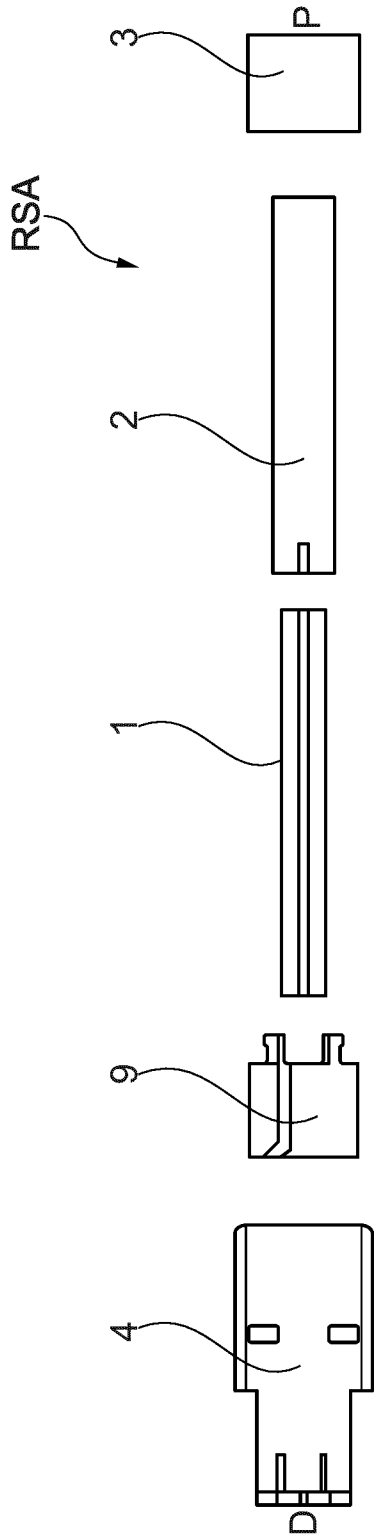
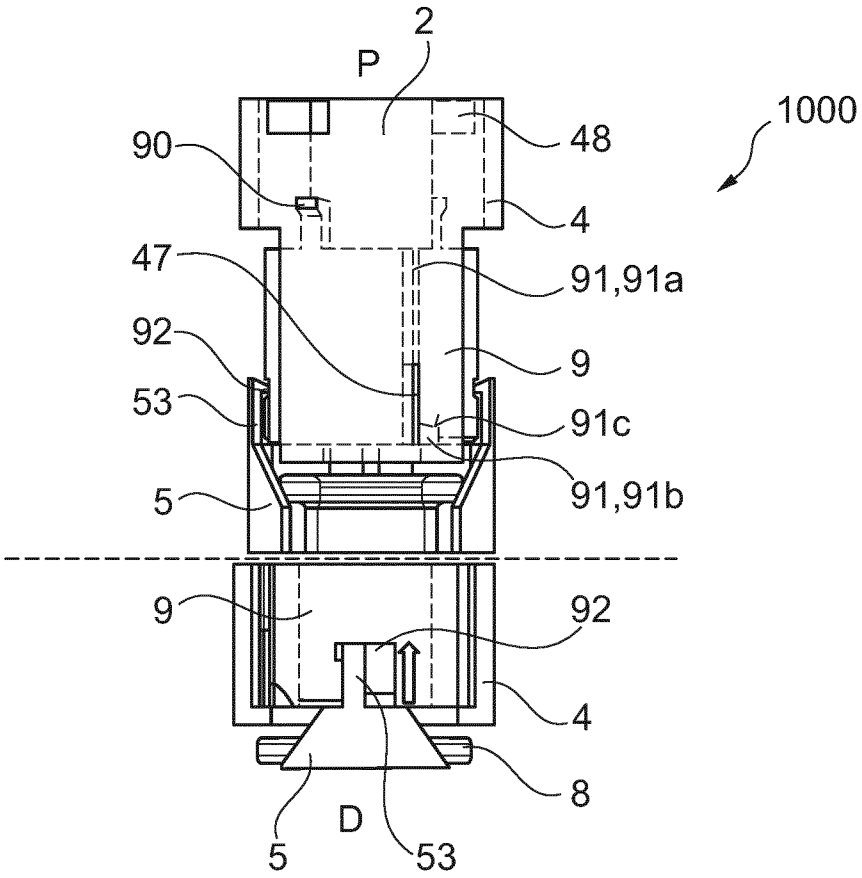


Fig. 66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D
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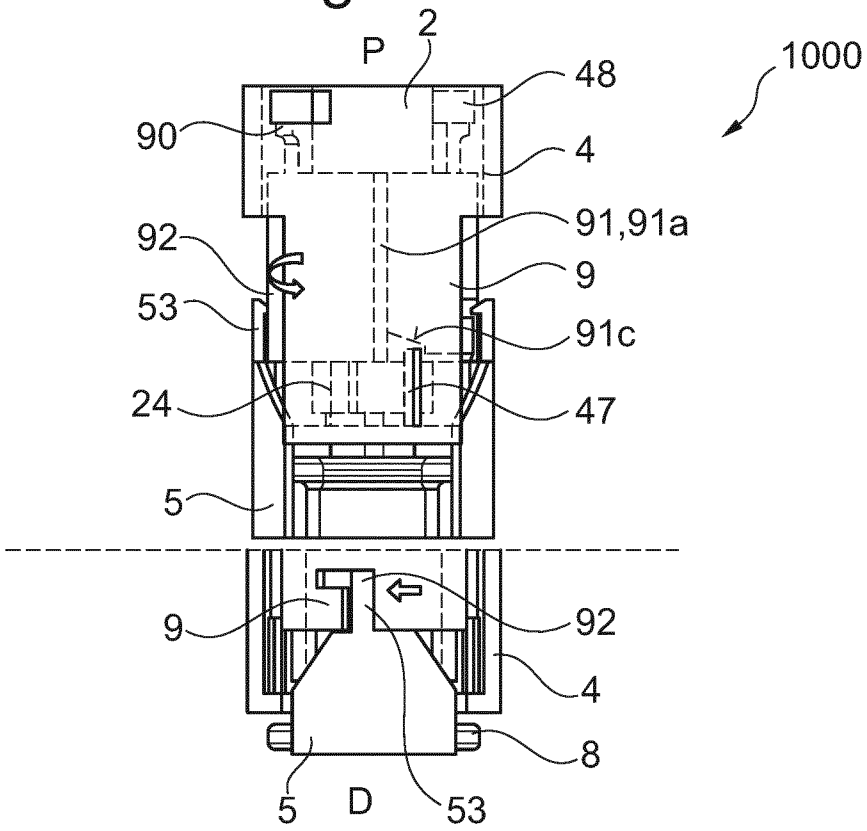
53

Fig. 67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D
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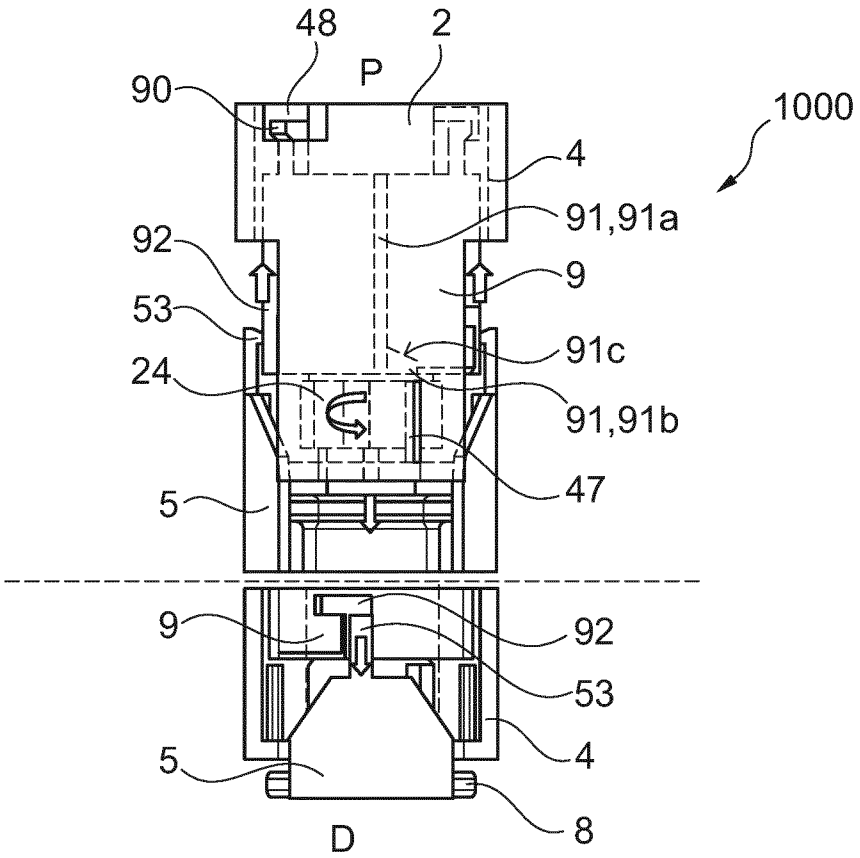
Fig. 68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5
8
D

Fig. 69

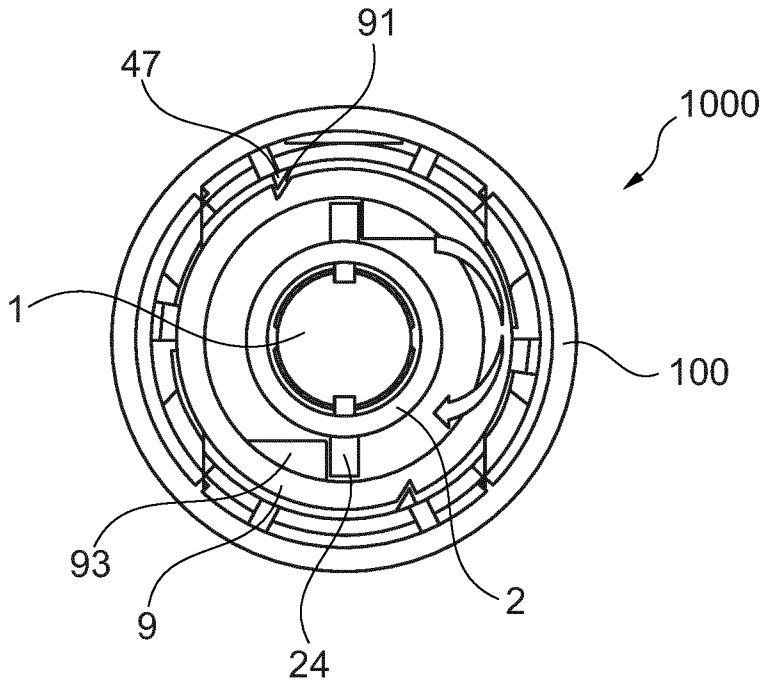
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Fig. 70

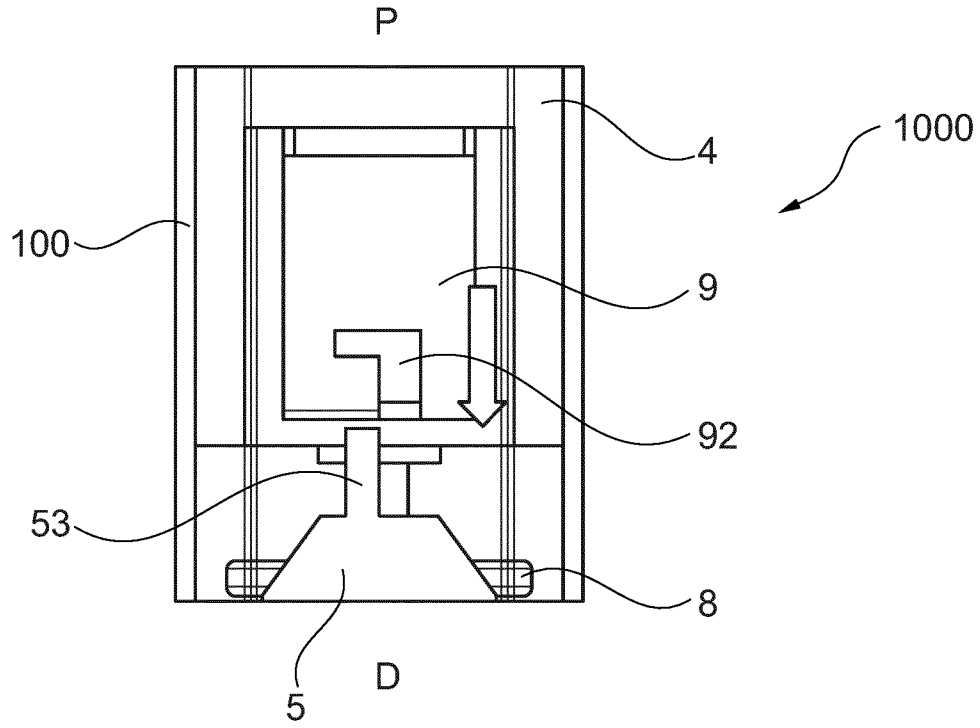

Fig. 71

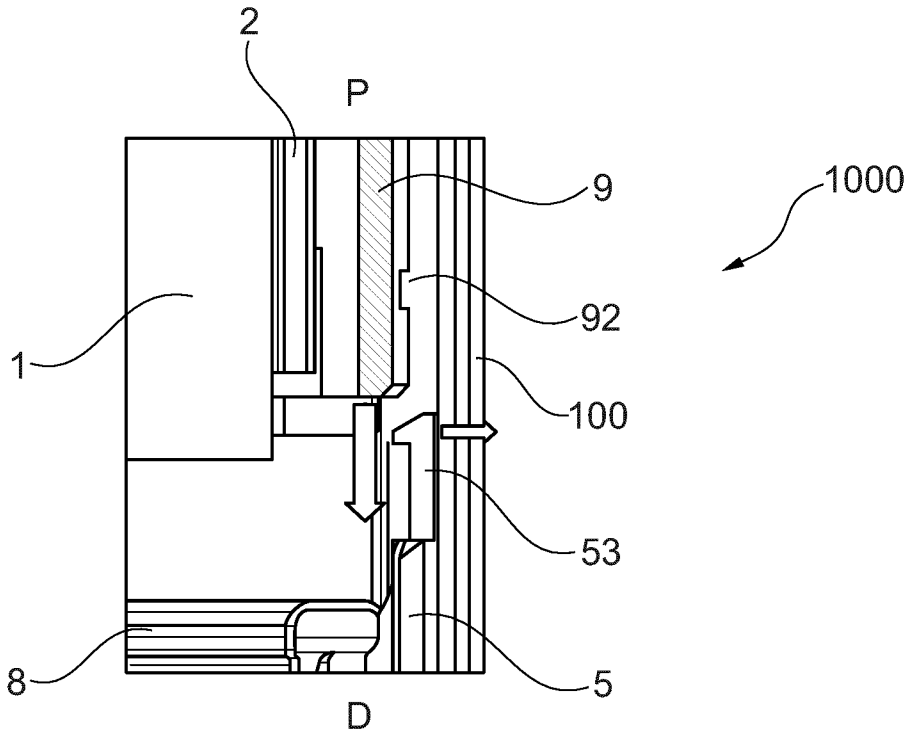

Fig. 72

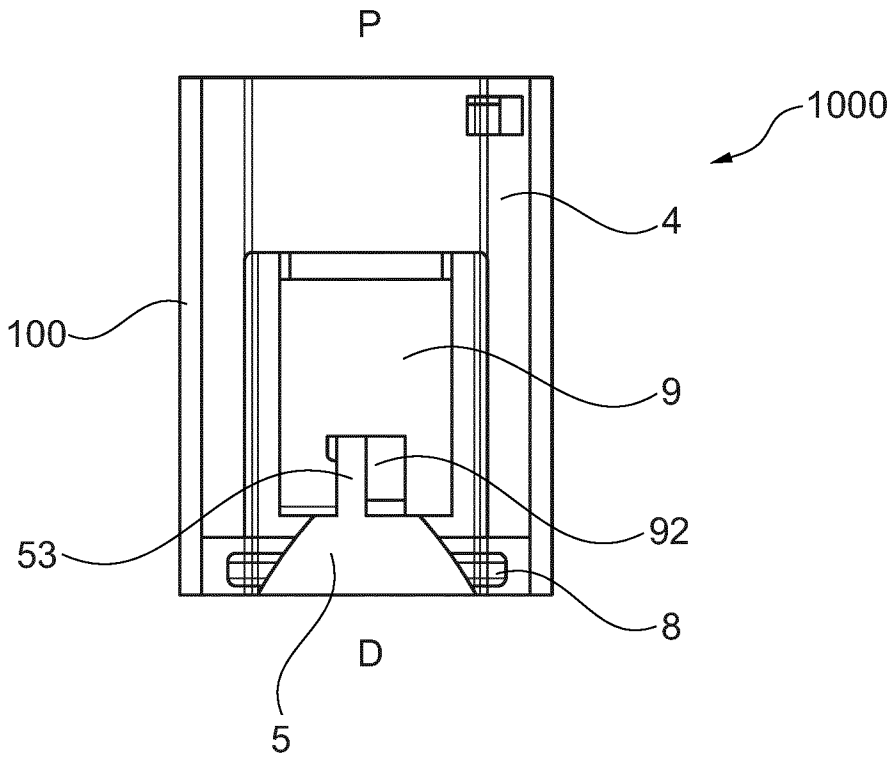

Fig. 73

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2021/083842

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/315 A61M5/32
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2016/287812 A1 (NIELSEN CHRISTIAN HOEJRIS [DK] ET AL) 6 October 2016 (2016-10-06) figures 1-7 paragraphs [0092]-[0094], [0104]-[0106]	1-9,19, 20
A	US 2018/126088 A1 (RADMER BO [DK] ET AL) 10 May 2018 (2018-05-10) figures 1-7 paragraphs [0059]-[0061]	1-9,19, 20
X	WO 2015/090320 A2 (CPU INNOVATION [DK]) 25 June 2015 (2015-06-25)	10-13, 15,17, 18,21
A	figures 1-12 page 18 lines 21-30	14,16

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 May 2022	18/05/2022

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Delmotte, Pierre

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2021/083842

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9, 19, 20

Drive subassembly

---

2. claims: 10-18, 21

Container-holder subassembly

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2021/083842

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016287812 A1	06-10-2016	CN 105705183 A	22-06-2016
		EP 3068466 A1	21-09-2016
		JP 2016535656 A	17-11-2016
		US 2016287812 A1	06-10-2016
		WO 2015071289 A1	21-05-2015
US 2018126088 A1	10-05-2018	CN 107567341 A	09-01-2018
		EP 3294385 A1	21-03-2018
		JP 2018515232 A	14-06-2018
		US 2018126088 A1	10-05-2018
		WO 2016180873 A1	17-11-2016
WO 2015090320 A2	25-06-2015	NONE	