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(54) Benevnelse **Autoinjector with a signalling device at the end of the product dispensing**

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Description

The invention relates to an autoinjector which is also often referred to as an autoinjection device with which a product contained in a product container can be automatically dispensed after triggering. The liquid product is in particular a medication. In particular the invention concerns a signaling device which generates an acoustic or tactile signal at the end of product dispensing in order to inform the user about the end of product dispensing.

Autoinjectors are known in the art. Devices are also known which signal the end of product dispensing. An injection device is known from DE 10 2008 037 310 A1 and WO 2010/017650 A1, which has a spring element on the piston rod, that at the end of automatic dispensing radially snaps over ribs on the housing and produces the so-called “end click.”

Injection devices, in particular autoinjectors, which have a needle protection sleeve which is supported on an unstressed needle protection spring are further known from DE 10359694 A1 and WO 2004/047892 A1. During the automatic injection procedure with the needle the needle protection spring is stressed. After removal of the injection device from the injection site the spring which is now stressed can push the needle protection sleeve over the needle tip in the distal direction. An injection device in which a signal spring is stressed by movement of the needle protection sleeve to produce the "end click" is known from EP 2 489 380. WO 2011/043714 discloses a further mechanism for producing an "end click"

A problem of the invention is to provide an autoinjector having a device for generating an acoustic and/or tactile signal, wherein the autoinjector is to be of an inexpensive and operationally reliable design.

The problem is solved with the autoinjector according to claim 1. Advantageous further developments are set forth in the appendant claims, the description and the Figures.

The autoinjector according to the invention has a housing and a product container arranged in the housing. The product container can be in particular a syringe having a syringe body, on the distal end of which an injection needle is fixedly arranged. The preferably cylindrical syringe body surrounds a piston

which is moveable in relation to the syringe body and is pushed towards the distal end for dispensing the product, whereby the liquid product, in particular a medication, that is between the piston and the injection needle, is dispensed from the product container through the injection needle. The syringe body can comprise a flange which can also be referred to as a finger flange at its proximal end, that is to say the rear end or opposite the injection needle. A syringe designed in this way is available as a standard syringe so that an especially adapted syringe does not necessarily have to be developed for the autoinjector. The piston bears sealingly against the inside diameter of the syringe body.

The housing is preferably elongate and forms the longitudinal axis of the autoinjector. The housing is preferably in the shape of a sleeve and/or is cylindrical, in particular circular-cylindrical. The product container is arranged in the housing. For example the container can be arranged displaceably in the housing, that is to say, displaceable in the distal direction relative to the housing for automatic injection so that the needle tip protrudes from an opening at the distal end of the autoinjector and can be automatically pushed into the patient. Optionally, with such a device, the needle tip can be moved into the distal end of the device after product dispensing, in particular the product container can be moved in the proximal direction relative to the housing.

In preferred embodiments the product container is accommodated in the housing in non-displaceable relationship along the longitudinal axis, in particular by means of a product container holder or a syringe holder which axially fixedly holds the product container and is axially fixedly connected to the housing, in particular in latching engagement. Preferably the needle tip protrudes beyond the distal end of the housing in the distal direction. In this way the needle can be injected into the injection site by means of a movement of the housing toward the patient. Preferably a needle protection sleeve is provided, which forms the distal end of the autoinjector and has an opening for the injection needle, wherein the needle can pass through the opening. The needle protection sleeve can be arranged in its starting position relative to the needle tip in such a way that the needle protection sleeve distally protrudes beyond the needle tip or that the needle tip protrudes distally beyond the distal

end of the needle protection sleeve. The needle protection sleeve can be moved in the proximal direction relative to the housing by an actuation stroke from its starting position into an actuated position, in particular it is displaceable into the housing so that the needle emerges or further emerges from the distal end or through the opening of the needle protection sleeve. Preferably the needle protection sleeve can be moved in the distal direction relative to the housing by a needle protection stroke from the actuated position into a needle protection position in which the distal end of the needle protection sleeve protrudes distally beyond the needle tip in order after use of the device or after dispensing of the product is performed to ensure an injury risk due to the exposed needle tip is reduced. The needle protection sleeve can be displaced in the proximal direction for example against the force of a spring which can be referred to as the needle protection spring, wherein the spring which for example is the second spring described hereinafter or a spring separate therefrom can move the needle protection sleeve from the actuated position in the distal direction into the needle protection position. The autoinjector can for example comprise a resiliently arranged locking element which locks the needle protection sleeve in its needle protection position, in particular relative to the housing and blocks a return movement of the needle protection sleeve in the proximal direction or into the housing. The locking element locks the needle protection sleeve at least in such a manner that the needle cannot emerge from the distal end of the needle protection sleeve. The needle protection sleeve can for example be moved from the needle protection position in the proximal direction only to such an extent that the needle tip does not emerge from the distal end of the needle protection sleeve.

The autoinjector further comprises a forward drive member which acts on the piston and in particular bears against the piston at least during product dispensing and a first spring which acts on the drive member such as for example being supported in particular with its distal end against the drive member. The drive member can for example be sleeve-shaped and form a shoulder which is arranged for example in the region of the distal end of the drive member, against which the distal end of the first spring can be supported. The first spring is preferably arranged within the sleeve-shaped drive member.

The spring is preferably a coil spring which acts as a compression spring and is preferably formed of metal. The first spring is so highly prestressed, in particular in the delivery state of the autoinjector, that it or the energy stored therein is sufficient to substantially completely dispense the product out of the product container by the movement of the drive member by a dispensing stroke. The movement of the drive member by the dispensing stroke also moves the piston. If there is a spacing between the piston and the drive member in the delivery state the dispensing stroke of the piston is less than the dispensing stroke of the drive member which is preferred since the piston remains unloaded until used, thereby preventing unwanted premature dispensing of the product. In principle however it is also possible for the drive member to bear against the piston in the delivery state and not only during dispensing of the product. If the drive member already bears against the piston in the delivery state the dispensing stroke of the piston corresponds to the dispensing stroke of the drive member. The proximal end of the first spring which by virtue of its function can also be referred to as the dispensing spring can be supported against the housing or an element fixed with respect to the housing, in particular even an element which is only temporarily axially fixed relative to the housing.

According to the invention the autoinjector comprises a signal element, a signal stop and a second spring. The second spring exerts a spring force on the signal element in a direction opposite the dispensing direction or in the proximal direction. In particular the second spring can be supported for example with its proximal end against the signal element

The second spring can be for example a coil spring acting as a compression spring, which is supported with its proximal end against the signal element. The spring can be supported with its distal end for example against the housing or against an element fixed with respect to the housing. It is particularly preferred for the second spring to be supported with its distal end against the needle protection sleeve or against an element which is displaced with the needle protection sleeve, in particular upon movement of the needle protection sleeve relative to the housing. For example the element can be a switch module or a switch sleeve as described hereinafter. The element can

be arranged in particular kinematically and/or geometrically between the needle protection sleeve and the distal end of the second spring. The advantage here is that the needle protection sleeve can be moved from its actuated position into the needle protection position by means of the second spring. The spring can thus preferably fulfil a double function since it additionally exerts the above-mentioned force on the signal element.

i During a first partial stroke of the dispensing stroke of the drive member or in particular n the delivery state the signal element is coupled axially fixedly to the drive member so that the signal element can be moved together with the drive member along the longitudinal axis and in particular relative to the housing, in particular in the distal direction. The axially fixed coupling to the drive member provides that the signal element is entrained during the movement of the drive member in the dispensing direction while during the first partial stroke of the dispensing stroke and the second spring is stressed. During a second partial stroke of the dispensing stroke the axially fixed coupling between the signal element and the drive member is released. The axially fixed coupling between the signal element and the drive member is thus releasable. When the axially fixed coupling between the signal element and drive member is released - and in particular there are no other couplings between the signal element and a further element as described hereinafter - the signal element can be accelerated by means of the second prestressed spring in a direction opposite the dispensing direction and relative to the drive member and/or the housing. As a result of the signal element being entrained by the drive member by the first partial stroke a spacing which extends for example along the longitudinal axis and which corresponds in particular to the first partial stroke is formed between the signal stop and the signal element. The second spring can accelerate the signal element to that spacing whereby the signal element meets the signal stop at a speed such that an impulse is imparted to the signal element which produces an acoustic (audible) and/or tactile (perceptible) signal.

The signal stop can be formed by the housing or an at least axially fixed element which is preferably also non-rotatably connected to the housing. For example that element can be a closure cap on the proximal end of the housing

and/or can form the proximal end of the autoinjector. Particularly preferably the closure cap can be connected in positively locking relationship or alternatively in friction- or material-locking relationship. Preferably the element is latched to the housing. A separate cap has the advantage that assembly of the device is facilitated, wherein for assembly at least some of the components are introduced into the housing by way of the proximal end which is subsequently closed with the cap. The cap can form a resonance body if the signal stop is arranged on the cap so that the audible impression of the acoustic signal can be changed within certain limits. by the configuration in terms of material thicknesses and cap shapes

The signal element comprises a first engagement element which is in particular resiliently arranged and/or disposed on a resilient arm and which releasably engages in the drive member, in particular in a recess of the drive member. In that way the drive member is axially fixedly coupled to the signal element, the axially fixed coupling between the drive member and the signal element being released when the signal element, in particular the first engagement element, becomes disengaged or is urged out of engagement with the drive member, in particular out of the recess of the drive member. In particular the first engagement element is released from engagement with the drive member at the end of the first partial stroke of the drive member.

Preferably the signal stop is arranged along the longitudinal axis of the autoinjector in such a way that it is in alignment with the signal element. This makes it possible for the signal element to hit against the signal stop with a movement along the longitudinal axis of the autoinjector.

In embodiments with a needle protection sleeve it is preferred that the needle protection sleeve acts on the second spring, wherein for triggering of product dispensing the needle protection sleeve is moveable from its starting position relative to the housing and along the longitudinal axis of the autoinjector in the proximal direction, that is to say in a direction opposite the dispensing direction, in particular by the actuation stroke. In this way the second spring is stressed and also dispensing of the product is triggered, being therefore movement of the drive member in the dispensing direction. The needle protection sleeve is thereby preferably moved from its starting position

into its actuated position by the actuation stroke so that its distal end is pressed against the injection site of the patient, wherein the housing is moved relative to the needle protection sleeve in the direction of the injection site so the needle protection sleeve performs the actuation stroke relative to the housing. In that case the needle protruding from the distal end of the needle protection sleeve is also injected into the injection site. After product dispensing is effected, in particular after for example a short waiting period like for example 3 to 10 seconds, after which the signal was generated by the signal element the autoinjector is removed from the injection site, whereby the needle protection sleeve is moved from its actuated position into the needle protection position relative to the housing by the needle protection stroke, in particular by means of the spring energy stored in the second spring. The removal of the autoinjector from the injection site also causes the needle to be withdrawn from the injection site.

In certain embodiments a switch module can be kinematically arranged between the second spring and the needle protection sleeve, wherein the switch module is entrained in the proximal direction by the needle protection sleeve when the needle protection sleeve is moved from its starting position in the proximal direction or into the actuated position and moves the needle protection sleeve in the distal direction when the spring acting on the switch module moves the switch module in the distal direction. The switch module or a part thereof such as for example a switch sleeve can be integral with the needle protection sleeve or for example positively lockingly connected such as for example snapped on or bearing loosely against the needle protection sleeve. The switch module can comprise a single part or or a plurality of parts, wherein a multipart switch module can comprise at least the switch sleeve and a blocking sleeve. The blocking sleeve is moveable relative to the needle protection sleeve and/or the switch sleeve for example along the longitudinal axis. For example the spring can be supported on the switch sleeve and on the switch sleeve on the needle protection sleeve. It is possible to provide for example a unidirectionally acting locking element between the blocking sleeve and the switch sleeve, that preferably engages the above-mentioned locking element which locks the needle protection sleeve in its needle protection

position, that is formed for example by the blocking sleeve and engages in the switch sleeve, in particular in a recess. The locking element is preferably of such a configuration that during the movement of the switch sleeve relative to the housing in the proximal direction the switch sleeve entrains the blocking sleeve by way of the locking element, in particular during the movement of the needle protection sleeve from its starting position into an actuated position and during its movement relative to the housing in the proximal direction is displaced into a blocking position relative to the blocking sleeve, in particular during the movement of the needle protection sleeve from its actuated position into the needle protection position, wherein in the blocking position the locking element or another locking element such as for example the one mentioned hereinbefore blocks a movement of the switch sleeve relative to the blocking sleeve in the proximal direction. This advantageously prevents the needle protection sleeve from being pushed back into the housing from its needle protection position for renewed release of the needle tip.

For example the switch sleeve can comprise a first recess into which the locking element of the blocking sleeve releasably engages when the needle protection sleeve is moved from its starting position into its actuated position. The switch sleeve can comprise for example a second recess into which the locking element or optionally the other locking element engages when the needle protection sleeve is in its needle protection position. The first and second recesses can be arranged at a spacing relative to one another along the longitudinal axis, which preferably approximately corresponds to the needle protection stroke. It will be appreciated that a reversal of the arrangement of recesses and the locking element or locking elements is also possible, that is to say, the at least one locking element can be formed on the switch sleeve and the at least one recess, that is to say, the first recess and optionally the second recess can be formed on the blocking sleeve.

The locking element and optionally the other locking element can be resiliently arranged in particular each on a resilient arm. Preferably the switch sleeve can surround and/or guide the blocking sleeve.

In preferred embodiments the signal element can comprise a second engagement element which is moveable by the disengagement movement of

the first engagement element, with which the first engagement element disengages from the drive element into an in particular axially fixed engagement with the needle protection sleeve or the switch module, in particular the blocking sleeve. The first engagement element and the second engagement element are preferably matched with one another in such a way that the second engagement element already engages, preferably in axially fixed relationship, into the needle protection sleeve or the switch module when the first engagement element is not yet completely released from engagement with the drive member. That advantageously reliably prevents the first engagement element from already being released from engagement with the drive member when the second engagement element is not yet engaged with the needle protection sleeve or the switch module. The needle protection sleeve or the switch module, in particular the blocking sleeve, can have for example an additional recess, into which the second engagement element of the signal element is engaged for example for axially fixed coupling between the signal element and the signal module, in particular the blocking sleeve or the needle protection sleeve. The drive member can have a recess, into which the first engagement element engages for axially fixed coupling between the drive member and the signal element. Preferably the first engagement element and the second engagement element are formed on a common resilient arm, wherein the first engagement element is directed for example radially in the direction of the longitudinal axis and the second engagement element is directed for example radially away from the longitudinal axis. The first and second engagement elements can preferably be arranged radially between the drive member and the needle protection sleeve or the switch module, in particular the blocking sleeve.

In particular during the dispensing stroke of the drive member, in particular at the end of the first partial stroke, the first engagement element is released from engagement with the drive member and preferably at the same time the second engagement element becomes engaged with the switch module or the needle protection sleeve, in particular with a movement transverse to the longitudinal axis. In particular by virtue of its movement in the dispensing direction the drive member can press the first engagement element

out of the recess of the drive member and the second engagement element into the recess of the needle protection sleeve or the switch module, in particular the blocking sleeve.

In particularly preferred embodiments the needle protection sleeve or the switch module, in particular the blocking sleeve, can hold the first engagement element in engagement with the recess of the drive member, wherein the recess for the second engagement element is moved towards the second engagement element by the displacement of the needle protection sleeve from its starting position to its actuated position relative to the longitudinal axis, wherein the recess in the actuated position of the needle protection sleeve, in particular at the moment the dispensing stroke is implemented is arranged at a spacing from the second engagement element along the longitudinal axis, that corresponds approximately to the first partial stroke of the signal element. The drive member released for the dispensing stroke by actuation of the needle protection sleeve can then be moved by the first partial stroke in the dispensing direction. Preferably the first engagement element is held in engagement with the drive member by the inner circumference of the needle protection sleeve or the switch module, in particular the blocking sleeve, against which the second engagement element bears. At the end of the first partial stroke the second engagement element is in the same position relative to the longitudinal axis as the recess, whereby the second engagement element can move into its recess and the first engagement element can move out of its recess.

The dispensing stroke of the drive member can comprise in particular two phases, namely the first partial stroke and the second partial stroke. During the first partial stroke the first engagement element is in axially fixed engagement with the drive member and the second engagement element is out of axially fixed engagement with the needle protection sleeve or the switch module, in particular the blocking sleeve. During the second partial stroke of the dispensing stroke the second engagement element is in axially fixed engagement with the needle protection sleeve or the switch module, in particular the blocking sleeve, wherein the first engagement element is out of engagement with the drive member, which advantageously causes the drive

member to be moveable by means of the first spring in the distal direction relative to the signal element and/or the signal element to not yet be released for emitting a signal.

It is generally preferred that the drive element moveable in the distal direction relative to the signal element by means of the first spring, in particular by the second partial stroke, when the first engagement element is out of engagement with the drive member and the second engagement element is in engagement with the needle protection sleeve or the switch module.

In preferred embodiments the second engagement element and the recess for the second engagement element can be arranged in the delivery state of the autoinjector along the longitudinal axis approximately at a spacing relative to one another, that corresponds approximately to the sum of the actuation stroke of the needle protection sleeve and the first partial stroke of the drive member, that approximately corresponds to the stroke of the signal element away from the signal stop.

Preferably the drive member can prevent the second engagement element from moving out of the axially fixed engagement with the needle protection sleeve or the switch module when the drive member moves in the distal direction relative to the signal element, in particular during the second partial stroke of the drive member. At the end of the dispensing stroke and/or the second partial stroke the drive member allows the second engagement element to move out of engagement with the needle protection sleeve or with the switch module. When at the end of the second partial stroke the second engagement element has moved out of engagement with the needle protection sleeve or the switch module the second spring accelerates the signal element in a direction opposite the dispensing direction and the signal element hits against the signal stop. Preferably the second engagement element is held in engagement with the needle protection sleeve or the switch module by the outer circumference of the drive member, against which the first engagement element bears.

In preferred embodiments the autoinjector can comprise a holding element, against which for example an end of the first spring, in particular the proximal end of the first spring, is supported. Alternatively the spring can be

supported with its proximal end against the housing or an element fixed with respect to the housing. The holding element itself can be fixed to the housing or arranged moveably relative to the housing. The holding element can comprise a first engagement element which engages into the drive member prior to triggering of dispensing of the product, whereby the drive member is prevented from moving in the dispensing direction relative to the holding element and/or the housing. The engagement of the first engagement element into the drive member is releasable for dispensing of the product. When the engagement is released the drive member is released for movement in the dispensing direction. The first spring can move the drive member relative to the holding element and/or the housing by the dispensing stroke in the dispensing direction. The drive member can have a recess for the first engagement element of the holding element, wherein that coupling between the drive member and the holding element is released when the holding element, in particular the first engagement element, has moved out of engagement with the drive member, in particular the recess of the drive element. In particular the first engagement element can be released from engagement with the drive member by the needle protection sleeve being moved by the actuation stroke from its starting position into the actuated position. For example the first engagement element can be held in axially fixed engagement with the drive member by the needle protection sleeve or the switch module, in particular the blocking sleeve, when the needle protection sleeve is not in its actuated position or in its starting position. For example an inner circumference of the needle protection sleeve or the switch module, in particular the blocking sleeve, can hold the first engagement element in engagement with the drive member, wherein for example a second engagement element which is described hereinafter can bear against the inner circumference.

By the movement of the needle protection sleeve into its actuated position the needle protection sleeve or the switch module, in particular the blocking sleeve, can allow the first engagement element to move out of engagement with the drive member, in particular with a movement transversely to the longitudinal axis of the autoinjector. For example a recess, in particular

for the second engagement element, that is formed on the needle protection sleeve or the switch module, in particular the blocking sleeve, can be arranged relative to the longitudinal axis in the same position as the first and/or the second engagement element so that the first engagement element can move out of engagement with the drive member. For example the drive member can press the first engagement element out of engagement with the drive member when the needle protection sleeve is in its actuated position.

The first engagement element can for example be directed radially relative towards the longitudinal axis and/or arranged on a resilient arm of the holding element.

As mentioned the holding element can have a second engagement element which, by means of the disengagement movement of the first engagement element out of the drive member, is moveable into axially fixed engagement with the needle protection sleeve or with the switch module, in particular the blocking sleeve. The second engagement element can be arranged for example on the arm on which the first engagement element is arranged and/or for example can be directed radially away from the longitudinal axis. The first engagement element and the second engagement element can be matched to each other such that the second engagement element already engages in axially fixed relationship in its recess which is formed by the needle protection sleeve or the switch module, in particular the blocking sleeve, when the first engagement element is not yet completely released from engagement with the drive member. This advantageously provides that the axially fixed connection between the holding element and the needle protection sleeve or the switch module is established before the axially fixed connection between the holding element and the drive member is released and thus a renewed or further pushing back movement of the needle protection sleeve is blocked.

In particular when the second engagement element is in its recess the drive member can move in the distal direction relative to the holding element, in particular as a result of the energy stored in the prestressed spring. The drive member can prevent the second engagement element from moving out of the axially fixed engagement with the needle protection sleeve or the switch

module, in particular the blocking sleeve, when the drive member moves in the distal direction relative to the signal element. Preferably this also applies at the end of the dispensing stroke, in particular also when the second engagement element of the signal element is released from its recess in order to be accelerated by the second spring in a direction opposite to the dispensing direction.

Particularly in embodiments in which the recess for the second engagement element of the holding element is formed by the needle protection sleeve or the switch sleeve it is preferred that the second engagement element moves out of its recess at the end of the dispensing stroke in order to be able to move the needle protection sleeve out of the actuated position into the needle protection position after administration of the product. For that purpose the drive member can have a recess, into which the first engagement element can move, wherein the second engagement element simultaneously moves out of its recess, in particular in order to release the movement of the needle protection sleeve in the distal direction.

In embodiments comprising a switch module having a switch sleeve and a blocking sleeve it is preferable that the second engagement element also remains at the end of the dispensing stroke such that the second engagement element prevents the blocking sleeve from being moved in the distal direction relative to the housing and/or the second engagement element, wherein the switch sleeve and/or the needle protection sleeve are displaceable in the distal direction relative to the blocking sleeve, in particular by virtue of the energy stored in the second spring, whereby the needle protection sleeve is moved in particular into its needle protection position. As already described and noted only for the sake of completeness the locking element can be brought into engagement between the blocking sleeve and the switch sleeve, which prevents the switch sleeve from being displaceable in the proximal direction relative to the blocking sleeve. Preferably a movement of the blocking sleeve in the proximal direction is prevented by the blocking sleeve butting either against the housing or against an element which is fixed with respect to the housing such as for example a mechanism holder or against the signal element.

Another aspect of the invention concerns the configuration of a product container, in particular a tip holder for an autoinjector, in particular for an autoinjector in which the product container is not displaceable relative to the housing and/or for an autoinjector of the above-described type.

The invention is based on a syringe module which is provided in particular for use in an autoinjector. In particular an autoinjector having such a syringe module can be provided. The syringe module comprises a syringe and a syringe holder. The syringe comprises a syringe body, a piston and a needle, wherein the needle is for example non-detachably secured to a needle holding portion of the syringe and the piston is displaceably arranged in a cylindrical portion of the syringe, the syringe body having a tapering portion or region arranged between the needle holding portion and the cylindrical portion. The syringe further comprises a needle protection cap which can be for example a so-called soft needle shield or preferably a rigid needle shield. A soft needle shield is preferably formed by a rubber-elastic plastic, wherein a rigid needle shield is formed of a sleeve of hard plastic, in which a sleeve of a rubber-elastic plastic is arranged. The sleeve made of rubber-elastic plastic and the hard plastic sleeve together form the rigid needle shield. The needle protection cap which covers the needle and is fixed to the needle holding portion extending in particular conically in the direction of the needle tip preferably protects the needle from soiling and keeps it sterile. A gap is formed between the tapering portion and the needle protection cap, in particular the hard plastic sleeve.

The syringe holder comprises at least one engagement element, in particular a shoulder, against which the tapering portion of the syringe is supported in the distal direction and which engages in the gap between the needle protection cap and the tapering portion. Advantageously the fact of the tapering portion bearing against the at least one shoulder prevents the syringe from being able to move in the distal direction relative to the syringe holder.

It is preferred for a gap to exist or be formed between the shoulder and the needle protection cap so that the needle protection cap remains unloaded by the shoulder. This advantageously prevents sterility of the needle from being compromised by unintentional displacement of the needle protection cap by the shoulder.

In preferred embodiments the syringe body can comprise a finger flange on its proximal end, wherein a gap is formed between the finger flange and the syringe body when the tapering portion bears against the shoulder, whereby the finger flange remains substantially without any loading thereon. This advantageously prevents the finger flange from being overloaded and breaking the syringe body.

It is further preferred for the syringe holder to comprise at least one holding element, in particular an outwardly directed projection, with which the syringe holder can be or is axially fixedly connected to a housing of the autoinjector, in particular being snapped on or capable of being snapped on.

In particular the syringe holder can comprise at least one cam which is resiliently arranged in particular on an arm and is arranged for example distally of the holding element. The at least one cam can inhibit or prevent a needle protection sleeve from moving from its starting position into its actuated position such that when a limit force is exceeded exerted on the needle protection sleeve along the longitudinal axis L of the autoinjector the at least one cam is pressed out of engagement with the needle protection sleeve, whereby the needle protection sleeve is abruptly displaceable into its actuated position relative to the housing.

The housing of the autoinjector can for example comprise a holding portion which bears against the syringe holder, in particular against an outside surface or an outer circumference of the syringe holder, and prevents the at least one engagement element from moving transversely to the longitudinal axis away from the longitudinal axis. In particular the holding portion can be ring-shaped and surround the at least one engagement element, preferably two or three or four engagement elements, so that the at least one engagement element is arranged within the holding portion. For assembly and/or insertion of the syringe in the syringe holder the syringe holder is out of engagement with the holding portion of the housing. When the syringe is inserted completely in the syringe holder, in particular the at least one engagement element engages into the gap between the tapering portion and the needle protection cap, the syringe module and/or the syringe holder is brought into engagement with the holding portion so that the at least one engagement element is

prevented from moving out of engagement with the tapering portion transversely to the longitudinal axis, in particular away from the longitudinal axis or outwardly.

In a first variant the at least one engagement element can be formed resiliently, in particular on an arm on the syringe holder, wherein the syringe is pushed with its proximal end an with the needle leading into the syringe holder which is preferably sleeve-shaped, wherein the needle protection cap deflects the at least one engagement element outwardly transversely to the longitudinal axis, that is to say away from the longitudinal axis, wherein if the needle protection cap was moved completely past the at least one engagement element the at least one engagement element snaps into the gap between the tapering region and the needle protection cap. Subsequently the syringe holder with the syringe is moved into engagement with the holding portion of the housing of the autoinjector, whereby the at least one engagement element is held in engagement with the gap between the needle protection cap and the tapering portion and can no longer spring out of this engagement.

In other variants the syringe holder can comprise at least two shell bodies, in particular two half-shells, preferably each comprising such an engagement element, wherein the engagement element can be arranged rigidly, that is to say substantially immovably on the shell body. By joining the at least two shell bodies together the at least one engagement element can be inserted into the gap between the needle protection cap and the tapering portion of the syringe arranged between the shell bodies, whereby the syringe is blocked from moving in the distal direction.

In particular two shell bodies can be connected by way of a pivotable joint, wherein the shell bodies can be pivoted relative to one another from an insertion position in which the syringe can be inserted in the syringe holder into a closing position in which the at least one engagement element engages into the gap between the needle protection cap and the tapering region. The shell bodies can latch or be locked together in the closing position or alternatively bear loosely against each other, wherein the shell bodies can be held together by the holding portion.

Since the shell bodies are preferably formed of plastic such as for example transparent plastic the pivot joint can be a film hinge so that the first and second shell bodies are integrally connected by way of the film hinge.

Alternatively the pivot joint can be a hinge having at least one hinge pin and at least one hinge pin holder in which the hinge pin is arranged, in particular latched, and relative to which the hinge pin is pivotable and/or on which the hinge pin slides during pivoting. For example the first shell body can comprise two hinge pins and the second shell body can comprise two hinge pin holders for the two hinge pins. Preferably the first shell body respectively comprises one hinge pin and one hinge pin holder, wherein the second shell body likewise comprises one hinge pin and one hinge pin holder and the hinge pin of the one shell body is inserted or can be inserted into the hinge pin holder of the other shell body. The advantage here is that the first shell body and the second shell body can be formed in identical fashion and can be quickly joined together so that the tooling costs for production can be reduced.

The pivot axis of the pivot joint can be parallel or transverse, in particular vertical or tilted, relative to the longitudinal axis of the syringe, in particular relative to the injection needle of the syringe. If the pivot axis is parallel to the longitudinal axis it is preferable that the pivot axis is arranged laterally relative to the syringe body. If the pivot axis is arranged transversely to the longitudinal axis it is preferred that the hinge and/or the pivot axis is arranged at the proximal end of the syringe holder.

In preferred embodiments the first and second shell body can be joined together by a linear movement transversely to the longitudinal axis and the at least one engagement element is moved during joining into the gaps between the needle protection cap and the tapering region of the syringe body, in particular by the linear joining movement. The first and second shell bodies can be latched or snapped in place on opposite sides relative to the syringe diameter; alternatively they can loosely bear against one another, wherein the holding portion of the housing of the autoinjector can hold the shell bodies together.

Preferably the first shell body and the second shell body are connected in a joining position in which the syringe can be inserted into the syringe body

by means of at least one, preferably by a plurality of, predetermined breaking points, wherein the at least one predetermined breaking point is broken by pressing the first and the second shell body against each other, wherein the first and second shell bodies are brought into their closed position in which the at least one engagement element engages into the gap between the needle protection cap and the tapering region. Prior to breakage of the at least one predetermined breaking point the first and the second shell body can be integrally joined together, wherein a sleeve-shaped body is formed, by way of the proximal end of which the syringe can be inserted, in particular with the needle or the needle protection cap leading.

It is generally preferred that the first shell body and the second shell body respectively comprise the at least one projection for the connection to the housing and/or the cam to provide resistance when the needle protection sleeve is pushed back.

In further embodiments the first shell body can comprise the at least one engagement element and a lateral opening through which the syringe can be inserted laterally into the first shell body, wherein upon lateral insertion of the syringe into the syringe body the at least one engagement element is inserted into the gap between the needle protection cap and the tapering portion. For example the first shell body can comprise the at least one projection and/or the at least one cam.

Preferably the syringe holder comprises a second in particular sleeve-shaped shell body, into which the first shell body can be inserted together with the syringe and with a movement along the longitudinal axis, in particular by way of the proximal end of the second shell body and preferably with the needle tip or the needle protection cap leading. In the embodiment with the second shell body the second shell body can optionally comprise the at least one projection and/or the at least one cam.

Preferably the second shell body can comprise a translatory motion stop, against which a translatory motion counterpart stop of the first shell body bears so that a displacement of the first shell body received in the second shell body is prevented in the distal direction relative to the second shell body, that is to say in particular when the first shell body is inserted into the second shell

body. The holding portion of the housing can preferably be of such a configuration that the at least one engagement element of the first shell body is held in engagement with the tapering region and preferably also bears against the region of the second shell body in which the translatory motion stop is formed.

In further preferred embodiments the syringe holder can comprise at least one first sleeve-shaped shell body, in particular a sleeve-shaped basic body, and at least one and preferably two pivoting levers, with the pivoting lever being arranged pivotably about a pivot axis on the first shell body by means of a hinge. The pivot axis can preferably extend transversely to the longitudinal direction of the syringe, preferably in skewed relationship with the longitudinal axis of the syringe. The engagement element can be arranged on the pivoting lever and, when there are a plurality of pivoting levers, preferably on each of the pivoting levers, in particular at the end of the pivoting lever remote from the pivotal axis. Preferably the engagement element is arranged at a position distally from the pivot joint. The pivot joint can be a film hinge which connects the pivoting lever and the first sleeve-shaped shell body. Alternatively the pivot joint can be a hinge having at least one hinge pin and at least one hinge pin holder in which the hinge pin is arranged, in particular latched, and relative to which the hinge pin is pivotable and/or along which the hinge pin slides during pivoting. Preferably the pivoting lever can comprise two hinge pins and the sleeve body can comprise two hinge pin holders for the hinge pins of the pivoting lever or vice-versa. When there are a plurality of pivoting levers a plurality of such pivoting pin holders can accordingly be present.

Preferably the holding portion of the housing can act on the at least one pivoting lever, in particular it can bear against the at least one pivoting lever, in such a way that the engagement element is held in engagement with the tapering region of the syringe body. When the syringe is inserted by way of the proximal end of the sleeve body with the needle and/or the needle protection cap leading the at least one engagement element is pivoted outwardly, whereby the needle protection cap can be moved past the at least one engagement element so that the at least one engagement element can engage

into the gap if the gap is in the position of the at least one engagement element relative to the longitudinal axis.

Preferably the cam for the needle protection sleeve can be formed on the pivoting lever. In particular the pivoting lever can be a two-arm pivoting lever, wherein the cam is formed on one arm which preferably protrudes in the proximal direction from the pivot joint and wherein the at least one engagement element is formed on the other arm which preferably protrudes in the distal direction from the pivot joint. When the holding portion of the housing holds the pivoting lever in engagement with the tapering region the pivoting arm on which the cam is arranged can be resiliently deformed when the needle protection sleeve is pushed back.

The invention and the further aspect relating to the invention were described by reference to a number of preferred embodiments. Particularly preferred embodiments are described hereinafter with reference to Figures. The features disclosed in that respect develop the invention individually and advantageously in any combination of features. In the drawings:

Figure 1 is an exploded show of an autoinjector according to an particularly preferred embodiment,

Figures 2a-2c show the autoinjector of Figure 1 in a delivery state, in which Figures 2a to 2c are sectional views the longitudinal axis of the device, wherein the sectional views are at different angles about the longitudinal axis,

Figures 3a-3c show the device and the views from Figures 2a-2c, wherein a needle protection sleeve is in its actuated position,

Figures 4a-4c show the device and the views from Figures 2a-2c, wherein the drive member is shown at the end of a first partial stroke of its dispensing stroke.

Figures 5a-5c show the device and the views from Figures 2a-2c, wherein a drive member is shown at the end of its dispensing stroke,

Figures 6a-6c show the device and the views from Figures 2a-2c, wherein a signal which signals the end of product dispensing is generated,

Figures 7a-7c are the device and the views from Figures 2a-2c, wherein the needle protection sleeve is in its needle protection position.

Figures 8a-8d are perspective views of a multipart syringe holder according to a first variant,

Figures 9a-9c are perspective views of a syringe holder according to a second variant,

Figures 10a-10d are perspective views of a syringe holder according to a third variant,

Figures 11a-11c are perspective views of a syringe holder according to a fourth variant,

Figures 12a-12c are perspective views of a syringe holder according to a fifth variant, and

Figures 8e, 9d, 10e, 11d and 12d are longitudinal sections of the five embodiments in the delivery state and for the embodiments two to five in a position with a partially and a completely inserted syringe respectively.

Reference is now made to Figures 1-7c to describe the structural features and the function of the preferred autoinjector.

The autoinjector has a sleeve-shaped longitudinal housing 2 with a longitudinal axis L and having a closure cap 12 at its proximal end which is connected in positively locking axially and rotationally fixed relationship to the housing 2 and forms the proximal end of the autoinjector. The closure cap 12 is snapped on the housing 2. For that purpose the closure cap 12 comprises a latching element 12a which is latched into a recess 2a on the housing 2, preferably in such a manner that the closure cap 12 cannot or cannot be readily released from the housing 2.

A pull-off cap 4 is arranged on the distal end of the autoinjector in its delivery state (Figures 2a-2c), that can be pulled off or turned off and removed before the autoinjector is used.

A product container 13 in the form of a syringe is accommodated in the housing 2 non-displaceably - except when the autoinjector is assembled - along the longitudinal axis L relative to the housing 2. The product container 13 comprises a sleeve-shaped syringe body surrounding a piston 13b which sealingly bears against the inner circumference of the syringe body. On its distal end the syringe body comprises an injection needle 13a which is in particular non-releasably connected to the syringe body, the distal end of

which is formed by the needle tip. A liquid product, in particular a medication, is disposed within the syringe body between the injection needle 13a and the piston 13b, wherein the liquid product is dispensed through the hollow injection needle 13a from the product container 13 by movement of the piston 13b in a dispensing direction, that is to say in the distal direction or toward the injection needle 13a. The syringe body comprises a so-called finger flange at its proximal end, that projects radially outwardly beyond the outer circumference of the cylindrical syringe body.

The product container 13 is accommodated in a product container holder which is referred to as a syringe holder 1 in such a way that it is secured at least against a movement along the longitudinal axis L in the distal direction relative to the syringe holder 1. As can best be seen from Figure 2a the syringe holder 1 is connected to the housing 2 in positively locking relationship, in particular being latched in place. For that purpose the housing 2 comprises recesses into which latching elements engage, that are formed at the proximal end of the syringe holder 1. The syringe holder 1 comprises at least one inwardly projecting shoulder 1b on which a tapering portion of the product container 13 is supported, which is distal relative to the cylindrical syringe body portion which guides the piston 13b.

In order to prevent the product container 13 being displaceable in the proximal direction relative to the syringe holder 1 the proximal end of the product container 13 is pressed into engagement with the shoulder 1b by a holder acting on the syringe body. The holder is formed by a holder spring portion 5c of a mechanism holder 5. The mechanism holder 5 is arranged, in particular non-displaceably and/or non-rotatably relative to the housing 2 along the longitudinal axis L. The sleeve-shaped mechanism holder 5 can be snapped on the housing 2. By means of the holding spring portion 5c longitudinal differences of the product holder 13 which can arise as a result of manufacturing tolerances can be compensated for, ensuring a fixed fit of the product holder 13 on the shoulder 1b.

The product container 13 is arranged relative to the housing 2 such that the needle tip projects distally beyond the distal end of the housing 2. In the starting or delivering position of the autoinjector, that is to say when the pull-

off cap 4 is arranged on the autoinjector the needle 13a is covered by a needle cover cap 14 which in the example shown is in the form of a so-called rigid needle shield known to the man skilled in the art or alternatively a soft needle shield in order to protect the needle 13a from soiling and/or to keep the needle 13a and the medication sterile. The rigid needle shield 14 is arranged on a needle holding portion of the syringe body, wherein the tapering portion of the syringe body is located between the needle holding portion and the cylindrical portion of the syringe body. The shoulder 1b is arranged between the syringe body and the proximal end of the rigid needle shield 14, in particular such that between the rigid needle shield 14 and the shoulder 1b a gap – although also smaller - is formed in order to prevent the shoulder 1b from exerting a force on the rigid needle shield 14, which could for example compromise the sterility of the needle 13a or the liquid product. The pull-off cap 4 is removably snapped onto the housing 2 or a needle protection sleeve 3, wherein said is released when the pull-off cap 4 is removed from the housing 2 or the needle protection sleeve 3. The snapping engagement is formed in the example shown by a snapping geometry 3b of the needle protection sleeve 3 and a snap hook 4a of the pull-off cap 4 (Figure 2b). Those hooks 4a further secure the pull-off cap 4 against a proximal movement relative to the housing 2 by being fixedly supported on the housing 2 or on a distal front side on the syringe holder 1. The pull-off cap 4 also comprises in particular a snap hook 4a with at least one snap portion 4b which engages in to a gap between the syringe body, in particular in its tapering region, and the proximal end of the rigid needle shield 14. When the pull-off cap 4 is removed from the autoinjector the snap portion 4b latches into the proximal end of the rigid needle shield 14, whereby the rigid needle shield 14 becomes detached from the product holder 13 and is removed together with the cover cap 4 from the autoinjector.

The autoinjector comprises a needle protection sleeve 3 which can be displaced relative to the housing 2 and along the longitudinal axis L by an actuation stroke H_B in the proximal direction into an actuated position in order to trigger dispensing of the product. In the starting position of the needle protection sleeve 3 as is shown in Figures 2a-2c, wherein the pull-off cap 4 is removed the distal end of the needle protection sleeve 3 protrudes distally

beyond the needle tip of the needle 13a so that access to the needle tip is initially prevented. By displacement of the needle protection sleeve 3 by the actuation stroke H_B the needle protection sleeve 3 is moved by such a distance in the proximal direction that the needle 13a projects from the distal end of the needle protection sleeve 3, in particular with a length corresponding to the injection depth of the needle into the injection site. Preferably the needle 13a should project beyond the distal end of the needle protection sleeve 3 to such an extent that a subcutaneous injection can be performed. In particular the housing 2 can form a stop 2c, against which the needle protection sleeve 3 bears when it is in the actuated position.

After the injection the needle protection sleeve 3 can be displaced relative to the housing 2 along the longitudinal axis L by a needle protection stroke H_N in the distal direction from the actuated position and into a needle protection position (Figures 7a-7c). In the needle protection position the distal end of the needle protection sleeve 3 projects distally beyond the needle tip so that access to the needle tip is prevented and the risk of injury is reduced. As described hereinafter the needle protection sleeve 3 can be blocked against being pushed back again from the needle protection position.

The syringe holder 1 has a projection 1a facing radially outwardly, wherein the projection 1a engages in a slit-shaped recess of the needle protection sleeve 3 between the housing 2 and the syringe holder 1. In the starting position of the needle protection sleeve 3 (Figures 2a-2c) and/or in the needle protection position of the needle protection sleeve 3 (Figures 7a-7c) the needle protection sleeve 3, in particular the proximal end of the slit-shaped recess bears against the projection 1a, thereby preventing movement of the needle protection sleeve 3 in the distal direction. A cam 1c which is resiliently arranged on the syringe holder 1 and formed by the syringe holder 1 can engage into that slit-shaped recess or alternatively into another recess of the needle protection sleeve 3. The cam 1c is designed in such a way that upon an attempt to move the needle protection sleeve 3 from the starting position into the actuated position the cam 1c initially prevents movement of the needle protection sleeve 3, wherein the cam 1c is pressed out when the force applied to the needle protection sleeve 3 for pushing it back exceeds a certain

threshold value, whereby the needle protection sleeve 3 is abruptly pushed back into the actuated position. In this way the needle 13a can be abruptly inserted into the injection site. For inserting the needle 13a and/or for displacing the needle protection sleeve 3 into the actuated position the distal end of the needle protection sleeve 3 is applied to the injection site, the housing 2 then being pressed in the direction of the injection site, in which case if the pressing force exceeds the above-mentioned threshold value the housing 2 is abruptly moved toward the injection site and the needle protection sleeve 3 is displaced into the actuated position relative to the housing 2.

The housing 2 comprises a ring-shaped holding portion or ring portion 2b which in particular circularly surrounds the distal end of the syringe holder 1 and bears against it, whereby the at least one shoulder 1b is held in engagement with the tapering region of the syringe body. The housing 2 further comprises a translatory motion stop in the form of a holding shoulder 2e in the region of the holding portion 2b, that prevents the syringe holder 1 from being displaceable in the distal direction relative to the housing 2 when the syringe holder 1 bears against the holding shoulder 2e. This also advantageously applies to the variants described.

The autoinjector also comprises a sleeve-shaped drive member 7 which forms an inwardly projecting shoulder at its distal end on which a first spring 9 is supported, that can also be referred to as the dispensing spring. The first spring 9 is arranged within the sleeve-shaped drive member 7. The first spring 9 is a coil spring acting as a compression spring which is prestressed in the starting or delivery state of the autoinjector with so much energy that it can dispense the product contained in the product container 13, in particular completely out of the product container 13 by displacement of the drive member 7 by a dispensing stroke H_A. In the delivery state of the device there is a spacing between the piston 13b and the distal end of the drive member 7 so that the drive member 7 hits the piston 13b and entrains it in the dispensing direction only while the dispensing stroke H_A is being executed.

The first spring 9 is supported with its proximal end on a holding element 6 comprising in this example two arms 6c, wherein arranged on each arm 6c are a first engagement element 6a and a second engagement element 6b. The

first engagement element 6a faces radially toward the longitudinal axis L and the second engagement element 6b faces radially away from the longitudinal axis L. The first engagement element 6a engages into a first recess 7a which is formed by the drive element 7 whereby movement of the drive member 7 is prevented in the distal direction or in the dispensing direction relative to the holding element 6. In that way the first spring 9 is held in its stressed state. The holding element 6 comprises a guide pin 6d which is inserted through the proximal end of the first spring 9 into the core of the spring 9. The guide pin 6d prevents lateral outward bending of the first spring 9 during and at the end of the dispensing stroke H_A of the drive member 7.

The autoinjector has a switch module 8, 15 having a switch sleeve 15 and a blocking sleeve 8 surrounded by the switch sleeve 15. In the delivery state of the device the first engagement element 6a is held in engagement with the first recess 7a by the inner circumference of the blocking sleeve 8 which bears against the second engagement element 6b.

The switch sleeve 15 is connected to the proximal end 3a of the needle protection sleeve 3 or at least bears against the proximal end 3a of the needle protection sleeve 3. A second spring 10 within which the first spring 9 is disposed and which preferably at least partially surrounds the switch sleeve 15 and the blocking sleeve 8 is supported with its distal end on the switch sleeve 15. A part of the switch sleeve 15 is thus arranged between the needle protection sleeve 3 and the distal end of the second spring 10. The second spring 10 is a metal spring acting as a compression spring and is in the form of a coil spring. The second spring 10 is supported with its proximal end on a signal element 11, in particular on a projection 11c which engages axially displaceably and non-rotatably into the housing 2 and which extends through a slit-shaped groove 5b of the mechanism holder 5. The second spring 10 thus also surrounds the mechanism holder 5 at least partially and preferably completely.

The switch element 15 comprises a recess 15a into which a locking element 8a of the blocking sleeve 8 engages. The locking element 8a is sawtooth-shaped and projects radially away from the longitudinal axis L. The locking element 8a is resiliently arranged on an arm formed by the blocking

sleeve 8. By movement of the switch sleeve 15 in the proximal direction the blocking sleeve 8 is entrained in the proximal direction by way of the engagement of the locking element 8a.

By displacement of the needle protection sleeve 3 into the actuated position the switch sleeve 15 is likewise entrained by the actuation stroke H_B, whereby the second spring 10 is stressed. If the needle protection sleeve 3 is not completely displaced into the actuated position the second spring 10 can move the switch sleeve 15 and the needle protection sleeve 3 back into the starting position again, wherein the blocking sleeve 8 is also entrained by the switch sleeve 15 by way of the engagement of the locking element 8a.

In the delivery state or prior to triggering of product dispensing the sleeve-shaped signal element 11 is in axially fixed engagement with the drive member 7. The signal element 11 comprises a first engagement element 11a which engages into a recess 7b of the drive member 7 and a second engagement element 11b. The first engagement element 11a and the second engagement element 11b are resiliently arranged on the end of an arm 11d. The signal element 11 comprises two such arms 11d with a first engagement element 11a and a second engagement element 11b. The first engagement element 11a faces radially toward the longitudinal axis L and the second engagement element 11b faces radially away from the longitudinal axis L. In the delivery state the first engagement element 11a is held by the inner circumference of the blocking sleeve 8 in axially fixed engagement with the drive member 7. The second engagement element 11b bears against the inner circumference of the blocking sleeve 8. The closure cap 12 has a signal stop 12b, against which the signal element 11 can hit to produce a signal and preferably bears against the signal element 11 in the delivery state of the device.

To administer the product from the product container 13 the pull-off cap 4 is removed from the autoinjector together with the rigid needle shield 14. The distal end of the needle protection sleeve 3 is applied to the injection site of a patient, in which case the housing 2 is displaced toward the injection site whereby the needle protection sleeve 3 moves by the actuation stroke H_B from its starting position into the actuated position in the proximal direction relative

to the housing 2. In that way the second spring 10 is stressed, wherein the switch sleeve 15 is entrained by the needle protection sleeve 3 by the actuation stroke H_B. The blocking sleeve 8 has a first recess 8b which as shown in Figures 3a-3c is brought to the position of the second engagement element 6b of the holding element 6 by movement of the blocking sleeve 8 by the actuation stroke H_B along the longitudinal axis L. In that way the first engagement element 6a is moved out of engagement with the drive member 7 with a movement transversely towards and away from the longitudinal axis L, wherein at the same time the second engagement element 6b is moved into engagement with the blocking sleeve 8, in particular with its first recess 8b. This releases the drive member 7 for movement in the dispensing direction by the dispensing stroke H_A.

Since the axially fixed coupling between the drive member 7 and the holding element 6 is now released the holding element 6 which is moveable by least by a distance relative to the housing 2 and along the longitudinal axis L can be moved by the first spring 9 in the proximal direction, wherein the holding element 6 entrains the blocking sleeve 8 by a start signal stroke H_K (Figure 3c) by way of engagement of the second engagement element 6b in the recess 8b, whereby the blocking sleeve 8 hits against a start signal stop 5a which is formed by the mechanism holder 5 and thereby emits an acoustic and/or tactile signal which signals to the user of the device that dispensing of the product has started. The movement of the blocking sleeve 8 by the actuation stroke H_B releases the locking element 8a for a movement transversely to and towards the longitudinal axis L since the mechanism holder 5 comprises an indentation 5d which permits such movement of the locking element 8a when the blocking sleeve 8 was displaced by the actuation stroke H_B or when the needle protection sleeve 3 is in its actuated position.

As the signal element 11 is still axially fixedly connected to the drive member 7 it is entrained in the dispensing direction by a first partial stroke H_S of the dispensing stroke H_A, wherein the signal element 11 is moved by approximately the first partial stroke H_S away from the signal stop as can best be seen from Figure 4c. At the end of the first partial stroke H_S during which the first and second engagement elements 11a 11b are moved relative to the

blocking sleeve 8 the first engagement element 11a is urged out of its engagement with the drive member 7, wherein the second engagement element 11b is at the same time moved into the second recess 8c of the blocking sleeve 8 with a movement transverse to the longitudinal axis L and radially away from the longitudinal axis L. That prevents the signal element 11 from moving in the proximal direction relative to the housing 2 or the blocking sleeve 8. The second engagement element 11b is held by the outer circumference of the drive member 7 in engagement with the recess 8c (Figure 4a) when the drive member 7 is moved by its second partial stroke of the dispensing stroke H_A. The outer circumferential surface of the drive member 7 holds the second engagement element 6b in engagement with the first recess 8b of the blocking sleeve 8 as can best be seen from Figure 4b. At the end of the dispensing stroke H_A the drive member 7 releases the second engagement element 11b from engagement with the blocking sleeve 8, whereby the second engagement element 11b is moved out of engagement with the recess 8c, in particular towards the longitudinal axis L, so that the second spring 10 accelerates the signal element 11 in opposite relationship to the dispensing direction, that is to say in the proximal direction so that when the signal element 11 encounters the signal stop 12b an acoustic and/or tactile signal is generated.

As can best be seen from Figure 5b the engagement of the second engagement element 6b in the first recess 8b remains, whereby a movement of the blocking sleeve 8 in the distal direction relative to the housing 2 is prevented.

By removal of the autoinjector from the injection site the second spring 10 can move the switch sleeve 15 and the needle protection sleeve 3 from the actuated position into the needle protection position by the needle protection stroke H_N, wherein the locking element 8a is urged out of engagement with the recess 15a and the switch sleeve 15 is moved in the distal direction relative to the blocking sleeve 8. When the needle protection sleeve 3 is in its needle protection position the locking element 8a snaps into engagement with the switch sleeve 15, wherein the locking element 8a prevents the needle protection sleeve 3 from being pushed back into its actuated position. Upon an

attempt to push back the needle protection sleeve 3 from the needle protection position into the actuated position the switch element 15 hits against the locking element 8a, which prevents movement of the needle protection sleeve 3 into the actuated position. For that purpose the blocking sleeve 8 is supported axially against the start signal stop 5a of the mechanism holder 5.

Various embodiments of a syringe holder are shown hereinafter, which can be used with an autoinjector, preferably but not necessarily an autoinjector of the above described kind.

The syringe module of Figures 8a to 8d has a first shell body or sleeve body 103 which laterally has an opening and at least one, that is to say in the example shown two shoulder-shaped engagement elements 1b which project inwardly, that is to say towards the longitudinal axis of the sleeve body 103. The sleeve body 103 further comprises a translatory motion counterpart stop 1k facing in the distal direction. For assembling the syringe 13 (Figure 8b) it is inserted laterally into the sleeve body 103, that is to say with a movement transversely to the longitudinal axis, whereby the at least one engagement element 1b is inserted into the gap between the needle protection cap 14 and the tapering portion of the syringe body of the syringe 13.

The syringe module further has a second shell body, in particular a sleeve body 104 (Figure 8c) which is open at its proximal end and at its distal end comprises at least one, that is to say in the example shown two translatory motion stops 1m projecting radially inwardly. Like the syringe holder 1 in the embodiment in Figures 1 to 7c the sleeve body 104 has at least one cam 1c, namely two cams 1c and at least one projection 1a, namely two projections 1a. The cam 1c is arranged resiliently on the sleeve body 104 by way of an arm.

The unit consisting of the syringe 13, the needle protection cap 14 and the first sleeve body 103 is inserted into the second sleeve body 104 (Figure 8c) by way of the proximal end along the longitudinal axis with the needle protection cap 14 leading (Figure 8b), wherein the translatory motion counterpart stop 1k hits the translatory motion stop 1m when the unit 13, 14, 103 has been completely inserted into the sleeve body 104 (Figure 8d). The unit shown in Figure 8d is then moved in the housing 2 of the autoinjector in

such a way for assembly that the holding portion 2b, in particular the annular holding portion or ring portion, bears against at least the first sleeve body 103, at least in the region of the engagement element 1b, so that the engagement element 1b is held in engagement with the tapering portion of the syringe body. The holding portion 2b can further also bear against the second sleeve body 104, in particular in the region on which the at least one translatory motion stop 1m is formed in order to keep the translatory motion stop 1m in engagement with the translatory motion counterpart stop 1k.

In the embodiment shown in Figures 9a-9c the syringe module, in particular the syringe holder 1, comprises a first shell body 101 and a second shell body 102 each in the form of a half-shell. Each of the shell bodies 101 102 comprises a cam 1c and a projection 1a in the manner described herein.

In the view shown in Figure 9a the first shell body 101 and the second shell body 102 are integrally connected to each other by way of a plurality of predetermined breaking points, wherein the first and second shell body 101, 102 assume an insertion position relative to each other. The syringe 13 is inserted in the distal direction with the needle protection cap 14 leading (Figure 9b) by way of the proximal end of the bodies 101, 102 shown in Figure 9a until the gap between the tapering portion and the needle protection cap 14 along the longitudinal axis L is in the same position as the at least one engagement element 1b. In the example shown each of the first and second shell bodies 101, 102 comprises an engagement element 1b. By pressing the first and second shell bodies 101, 102 against each other transversely to the longitudinal axis L the predetermined breaking points are broken, the first and second shell bodies 101, 102 latching together in a positively locking relationship and the engagement elements 1b moving into the gap. As already described the region of the first and second shell bodies 101, 102 on which the engagement element 1b is formed can be surrounded by the holding portion 2b of the housing 2, whereby the engagement elements 1b are held in engagement with the tapering region of the syringe body. Particularly preferably upon insertion of the syringe 13 transversely to the longitudinal axis the shell bodies 101, 102 can move into the insertion position against the resilient force of the arms which carry the projection 1a and/or the cam 1c. As

described here too the engagement elements 1b can be subsequently brought into and held in engagement by the holding portion 2b of the housing 2 with the tapering portion of the syringe body 13. Alternatively or additionally the first shell body 101 and the second shell body 102 can latch together in the closed position (Figure 9c) in which the engagement elements 1b engage into the gap.

In the embodiment shown in Figures 10a-10d the syringe holder 1 comprises a first shell body 101 and a second shell body 102, each in the form of a half-shell and in particular are of an identical configuration so that tooling costs can be reduced.

Each of the first and second shell bodies 101, 102 comprises a cam 1c and a projection 1a in the manner described. Furthermore each of the first and second shell bodies 101 102 has an engagement element 1b at its distal end.

Each of the shell bodies 101, 102 has a hinge pin 1e and a hinge pin holder 1f (Figure 10a), wherein the hinge pin 1e of the one shell body 101, 102 is inserted into the hinge pin holder 1f of the other shell body 102, 101 (Figure 10b) so that the first and second half-shells 101, 102 pivotable relative to each other about the pivot axis of the pivot joint 1e 1f which is formed by the hinge pin 1e and the hinge pin holder 1f, namely between an insertion position (Figure 10c) and a closed position (Figure 10d). The syringe 13 is inserted together with the needle protection cap 14 by way of the proximal end of the syringe body 1 with the needle protection cap 14 being moved past the engagement element 1b, wherein the first shell body 101 and the second shell body 102 are pivoted relative to each other when the gap between the needle protection cap 14 and the tapering region of the syringe body is in the same position as the engagement elements 1b relative to the longitudinal axis L. As a result the engagement elements 1b engage into the above-mentioned gap. As described the engagement elements 1b can be held in engagement with the tapering portion of the syringe body by the holding portion 2b of the housing 2. Alternatively or additionally the first shell body 101 and the second shell body 102 can latch together in the closed position (Figure 10d) in which the engagement elements 1b engage into the gap.

Figures 11a to 11c show an embodiment of the syringe holder 1 which has a first sleeve body 103 and two pivoting arms 1h. The projection 1a is formed on the sleeve body 103. The sleeve body 103 forms two hinge pin holders 1g for each of the pivoting arms 1h, in which a hinge pin 1i of the pivoting lever 1h is respectively arranged. Each of the pivoting levers 1h forms two hinge pins 1i which are latched to the hinge pin holder. The pivoting pin 1i is rotatable relative to the pivoting pin holder 1g and can slide on the hinge pin holder 1g. The pivoting lever 1h comprises a lever portion facing in the distal direction, wherein at the distal end of that lever portion the engagement element 1b formed by the pivoting lever 1h is formed for engagement into the gap between the needle protection cap 14 and the tapering portion of the syringe body.

The pivoting lever 1h shown in the example is double-armed, wherein the lever portion protruding from the pivot joint 1g 1i in the opposite direction to the arm which forms the engagement element 1b forms the cam 1c.

The syringe 13 is introduced with the needle protection cap 14 leading by way of the proximal end of the sleeve body 103 into the sleeve body 103, the needle protection cap 14 being moved past the engagement elements 1b until the gap between the tapering region of the syringe body and the needle protection cap 14 are in the same position relative to the longitudinal axis as the engagement elements 1b. By pivotal movement of the pivoting lever 1h the engagement elements 1b are pivoted into the gap or towards the longitudinal axis. The unit shown in Figure 11c is then arranged in the housing 2 of the autoinjector in such a way that the holding portion 2b fixes the pivoting lever 1h such that the engagement elements 1b are held in engagement with the tapering portion of the syringe body. The arm on which the cam 1c is formed is resiliently deformable relative to the arm on which the engagement element 1b is formed, whereby the cam 1c can perform the intended function of the needle protection sleeve 3. In particular the cam 1a serves as a stop for the needle protection sleeve 3, wherein the needle protection sleeve 3 bears against the cam 1a when the needle protection sleeve is in its starting position and/or in its needle protection position.

In the fifth embodiment shown in Figures 12a-12d the syringe module, in particular the syringe holder 1, comprises a sleeve body 103. The sleeve body 103 comprises in particular two cams 1c and in particular two projections 1a in the manner shown here.

In this variant the at least one engagement element can be formed resiliently in the form of a shoulder 1b, in particular on a resilient arm 1h on the syringe holder, wherein the syringe 13 is inserted by way of the proximal end with the needle leading into the syringe holder which is preferably sleeve-shaped, wherein the needle protection cap 14 outwardly deflects the at least one engagement element 1b transversely to the longitudinal axis, that is to say away from the longitudinal axis, wherein when the needle protection cap 14 was moved completely past the at least one engagement element 1b the at least one engagement element 1b snaps into the gap between the tapering region of the syringe 13 and the proximal end of the needle protection cap 14. The unit shown in Figure 12c is then accommodated in the housing 2 of the autoinjector in such a way that the holding portion 2b fixes the arm 1h in such a way that the engagement elements 1b are held in engagement with the tapering portion of the syringe body 13 in a force-locking or positively locking relationship and no longer resiliently move out of such engagement.

Figures 8e, 9d, 10e, 11d and 12d show longitudinal sections of the five embodiments in the delivery state and for the embodiments two to five after a respective assembly step of fitting the syringe into the autoinjector in a respective position with a partially and a completely inserted syringe. With a completely inserted syringe the at least one snap portion 4b comprising the pull-off cap 4 also engages into the gap between the syringe body 13 and in particular in its tapering region and the proximal end of the rigid needle shield 14 (Figure 2a, 2b).

The at least one engagement element 1b is pushed into the region of the holding portion 2b together with the syringe holder 1 by an assembly stroke H_M which in particular is performed as the last assembly step in the axial direction so that a force-locking or positively locking connection is produced, which prevents the at least one engagement element 1b from coming out of engagement with the tapering portion of the syringe body 13 transversely to

the longitudinal axis, in particular away from the longitudinal axis L or outwardly. Furthermore by virtue of that assembly stroke the pull-off cap 4 is moved into its distal position which it assumes in the delivery state of the autoinjector, wherein the pull-off cap 4 is moved through the syringe holder 1 by means of the at least one snap hook 4a which is supported on the syringe holder 1.

List of references

1 syringe holder
1a projection/holder
1b shoulder/engagement element
1c cam
1e hinge pin
1f hinge pin holder
1g hinge pin holder
1i hinge pin
1h pivoting lever/arm
1k translatory motion counterpart stop
1m translatory motion stop

2 housing
2a recess
2b ring portion/holding portion
2c actuating stop
2e holding shoulder

3 needle protection sleeve
3a proximal end
3b snap geometry

4 pull-off cap
4a snap hook
4b snap portion

5 mechanism holder
5a start signal stop
5b groove
5c holding spring portion
5d recess

6 holding element
6a first engagement element
6b second engagement element
6c arm
6d guide pin

7 drive member
7a first recess
7b second recess
8 blocking sleeve
8a locking member
8b first recess
8c second recess

9 first spring/dispensing spring
10 second spring/needle protection spring
11 signal element
11a first engagement element
11b second engagement element
11c projection
11d arm

12 closure cap
12a latching element
12b signal stop

13 product container/syringe
13a needle
13b piston

14 rigid needle shield/needle protection cap

15 switch sleeve
15a recess

101 first shell body/half-shell
102 second shell body/half-shell
103 first shell body/sleeve body
104 second shell body/sleeve body

H_A dispensing stroke
H_B actuation stroke
H_S signal stroke/first partial stroke
H_K start signal stroke
H_N needle protection stroke
H_M mounting stroke

L longitudinal axis

Patentkrav

1. Autoinjektor med en lengdeakse (L) for frigivelse av et flytende produkt, omfattende:

a) et hus (2) og en produktbeholder (13), spesielt sprøyte som har et forskyvbart stempel (13b), anordnet i huset (2), hvor stempelet (13b) for frigivelse av produktet inneholdt i produktbeholderen (13), er forskyvbart i en frigivelsesretning,

b) et fremdriftsledd (7) som under produktfrigivelsen virker inn på stempelet (13b), og en første fjær (9) som virker inn på fremdriftsleddet (7), hvor den første fjæren (9) er så sterkt forspent at den kan frigi produktet fra produktbeholderen (13) ved forskyvning av fremdriftsleddet (7) med et frigivelsesslag (H_A) og av stempelet (13b),

karakterisert ved

c) et signalledd (11), et signalanslag (12b) og en andre fjær (10) som utøver en fjærkraft på signalleddet (11) som virker motsatt av frigivelsesretningen, hvor signalleddet (11) under et første delslag (Hs) av frigivelsesslaget (H_A) via et første inngrepsledd (11a) er koblet aksialfast med fremdriftsleddet (7), slik at signalleddet (11) tas med under forskyvningen av fremdriftsleddet (7) i frigivelsesretningen og den andre fjæren (10) spennes, og hvor ved løsnet aksialfast kobling mellom signalleddet (11) og fremdriftsleddet (7), signalleddet (11) ved hjelp av den andre fjæren (10) kan akselereres motsatt frigivelsesretningen og relativt til fremdriftsleddet (7) eller/og huset (2), hvorved signalleddet (11) akselerert av den andre fjæren (10), slår mot signalanslaget (12b), og et akustisk og/eller taktilt signal genereres.

2. Autoinjektor ifølge krav 1, **karakterisert ved at** det første inngrepsleddet (11a) griper løsbart inn i fremdriftsleddet (7), hvorved fremdriftsleddet (7) er aksialfast koblet med signalleddet (11), hvor den aksialfaste koblingen mellom fremdriftsleddet (7) og signalleddet (11) er løsnet når det første inngrepsleddet (11a) er rykket ut eller trykket ut av inngrepet med fremdriftsleddet (7).

3. Autoinjektor ifølge et av de foregående kravene, **karakterisert ved at** signalanslaget (12b) er dannet av huset (2) eller et element (12) som er forbundet med huset (2) i det minste aksialfast, og at signalanslaget (12b) er anordnet langs autoinjektorens lengdeakse (L) i flukt med signalleddet (11).

4. Autoinjektor ifølge et av de foregående kravene, **karakterisert ved at** produktbeholderen (13) er ikke-forskyvbart mottatt i huset langs autoinjektorens lengdeakse (L).

5. Autoinjektor ifølge et av de foregående kravene, **karakterisert ved** en nålebeskyttelseshylse (3) som virker inn på den andre fjæren (10), og som til utløsningen av produktfrigivelsen kan forskyves fra dens utgangsposisjon relativt til huset (2) og langs autoinjektorens lengdeakse (L) i en proksimal retning med et betjeningsslag (H_B), hvorved den andre fjæren (10) spennes og produktfrigivelsen utløses.

6. Autoinjektor ifølge krav 5, **karakterisert ved** en koblingsmodul (8, 15) som er anordnet kinematisk eller/og geometrisk mellom den andre fjæren (10) og nålebeskyttelseshylsen (3), hvor koblingsmodulen (8, 15) tas med av nålebeskyttelseshylsen (3) i den proksimale retningen når nålebeskyttelseshylsen (3) forskyves fra sin utgangsposisjon i den proksimale retningen.

7. Autoinjektor ifølge krav 6, **karakterisert ved at** signalleddet (11) har et andre inngrepsledd (11b) som kan beveges ved utrykksbevegelsen av det første inngrepsleddet (11a) ut av fremdriftsleddet (7) i et aksialfast inngrep med nålebeskyttelseshylsen (3) eller koblingsmodulen (8, 15), hvor det første inngrepsleddet (11a) og det andre inngrepsleddet (11b) er avstemt til hverandre på en slik måte at det andre inngrepsleddet (11b) allerede griper aksialfast inn i nålebeskyttelseshylsen (3) eller koblingsmodulen (8, 15) når det første inngrepsleddet (11a) ikke ennå er fullstendig løsnet fra inngrepet med fremdriftsleddet (7).

8. Autoinjektor ifølge krav 7, **karakterisert ved at** fremdriftsleddet (7) ved hjelp av den første fjæren (9) kan beveges relativt til signalleddet (11) i den distale retningen når det første inngrepsleddet (11a) er ute av inngrep med fremdriftsleddet (7) og det andre inngrepsleddet (11b) er i inngrep med nålebeskyttelseshylsen (3) eller koblingsmodulen (8, 15).

9. Autoinjektor ifølge krav 7 eller 8, **karakterisert ved at** fremdriftsleddet (7) hindrer det andre inngrepsleddet (11) i å rykke ut av det aksialfaste inngrepet med nålebeskyttelseshylsen (3) eller koblingsmodulen (8, 15) når fremdriftsleddet (7) beveger seg relativt til signalleddet (11) i distal retning, hvor fremdriftsleddet (7) på slutten av frigivelsesslaget (H_A) tillater at det andre inngrepsleddet (11b) rykker ut av inngrepet med nålebeskyttelseshylsen (3) eller koblingsmodulen (8, 15), hvorved signalleddet (11) blir akselerert av den andre fjæren (10) motsatt frigivelsesretningen og slår mot signalanslaget (12b).

10. Autoinjektor ifølge et av de foregående kravene, **karakterisert ved** et holdeelement (6) som en ende på den første fjæren (9) støtter seg på, og som har et første inngrepsledd (6a), hvor det første inngrepsleddet (6a) for utløsningen av produktfrigivelsen griper inn i fremdriftsleddet (7), hvorved fremdriftsleddet (7) hindres i å bevege seg relativt til holdeelementet (6) i frigivelsesretning, hvor dette inngrepet av det første inngrepsleddet (6a) for produktfrigivelsen kan løsnes, slik at den første fjæren (9) kan forskyve fremdriftsleddet (7) relativt til holdeelementet (6) i frigivelsesretningen.

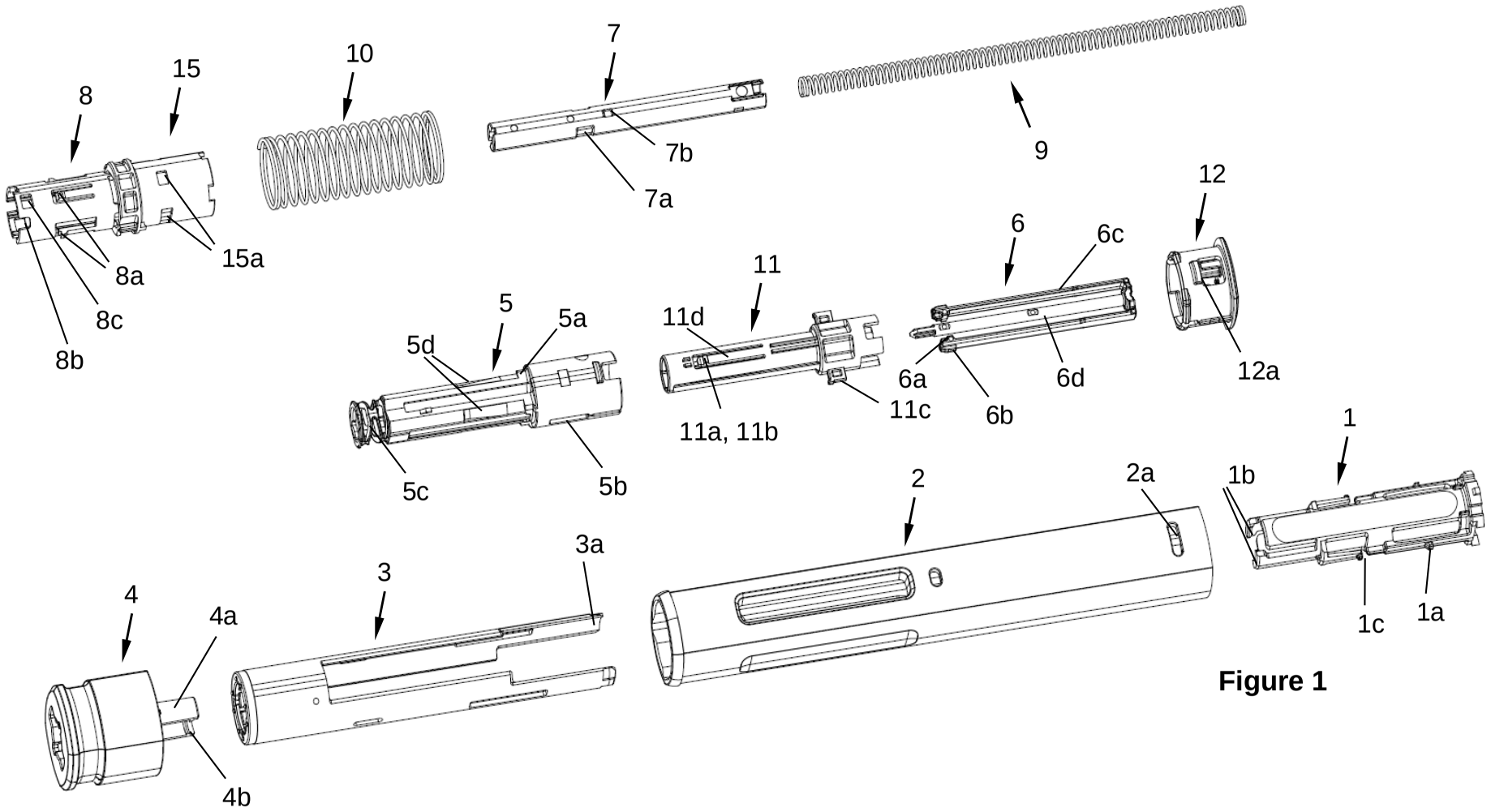
11. Autoinjektor ifølge kravene 10 og 6, **karakterisert ved at** holdeelementet (6) har et andre inngrepselement (6b) som ved det første inngrepselementets (6a) utrykksbevegelse kan beveges ut av fremdriftsleddet (7) i et aksialfast inngrep med nålebeskyttelseshylsen (3) eller koblingsmodulen (8, 15), hvor det første inngrepselementet (6a) og det andre inngrepselementet (6b) er avstemt til hverandre på en slik måte at det andre inngrepselementet (6b) allerede griper aksialfast inn i nålebeskyttelseshylsen (3) eller koblingsmodulen (8, 15) når det første inngrepselementet (6a) ikke ennå er fullstendig løsnet fra inngrepet med fremdriftsleddet (7).

12. Autoinjektor ifølge krav 11, **karakterisert ved at** fremdriftsleddet (7) hindrer det andre inngrepselementet (6b) i å rykke ut av det aksialfaste inngrepet med nålebeskyttelseshylsen (3) eller koblingsmodulen (8, 15) når fremdriftsleddet (7) beveger seg relativt til signalleddet (11) i distal retning og blir stående på slutten av frigivelsesslaget (H_A).

13. Autoinjektor ifølge krav 12, **karakterisert ved at** koblingsmodulen (8, 15) har en koblingshylse (15) og sperrehylse (8), hvor sperrehylsen (8) har et unidireksjonelt virkende låseledd (8a) som griper inn i koblingshylsen (15), hvor koblingshylsen (15) ved sin bevegelse relativt til huset (2) i proksimal retning tar med sperrehylsen (8) via låseleddet (8a) og ved sin bevegelse relativt til huset (2) i proksimal retning forskyves relativt til sperrehylsen (8) i en ytterligere sperreposisjon i hvilken låseleddet (8a) sperrer for en bevegelse av koblingshylsen (15) relativt til sperrehylsen (8) i den proksimale retningen.

14. Autoinjektor ifølge et av kravene 5 til 13, **karakterisert ved at** nålebeskyttelseshylsen (3) etter produktfrigivelsen, når fremdriftsleddet (7) er forskjøvet med frigivelsesslaget (H_A) i den distale retning, kan forskyves fra den andre fjæren (10) relativt til huset (2) i den distale retningen, spesielt med et nålebeskyttelsesslag (H_N) i en nålebeskyttelsesposisjon, der nålebeskyttelseshylsen (3) står distalt over nålespissen til en injeksjonskanyle (13a) til produktbeholderen (13).

15. Autoinjektor ifølge krav 14, **karakterisert ved** et låseledd (8a) som låser nålebeskyttelseshylsen (3) i dens nålebeskyttelsesposisjon relativt til huset (2) mot tilbakeskyving i den proksimale retningen i det minste slik at nålespissen ikke kan tre ut av nålebeskyttelseshylsens (3) distale ende.


8
15
10
7
9
12
6
6c
11
5
5a
11d
5d
8a
15a
7b
8c
7a
6a
6d
12a
8b
11a, 11b
11c
6b
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5b
2
2a
1
1b
3a
3
4
4a
1c
1a
4b

Figure 1

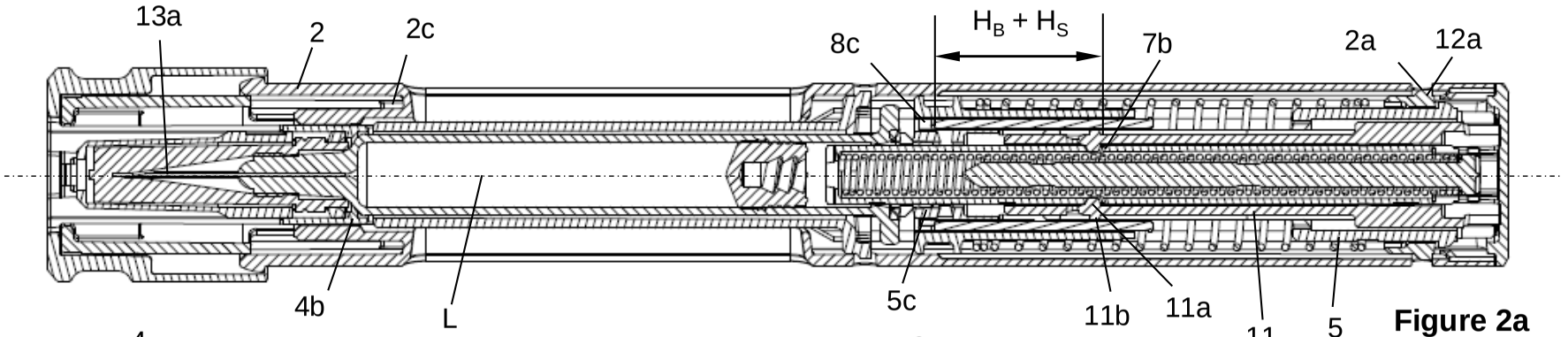


Figure 2a

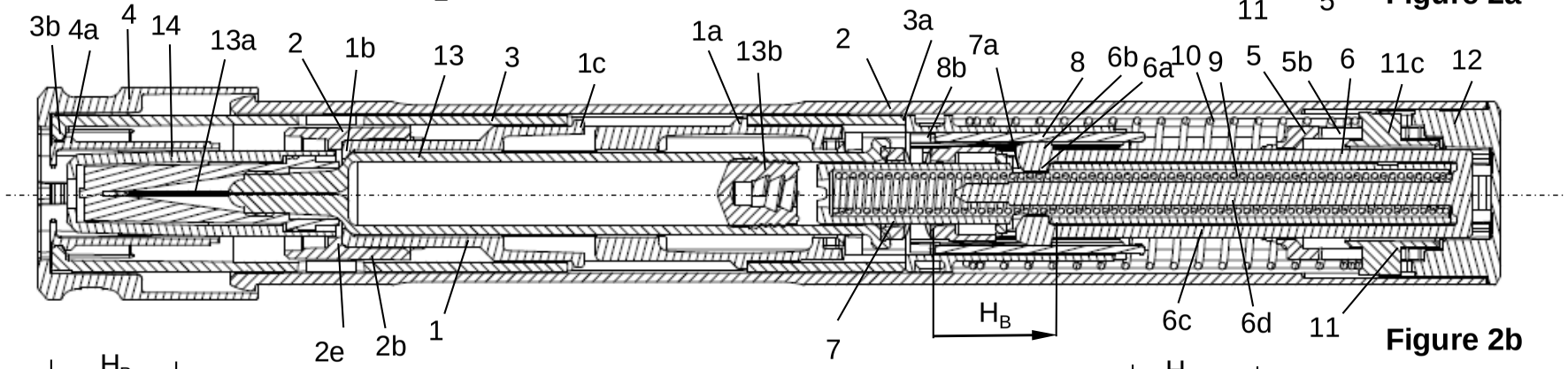


Figure 2b

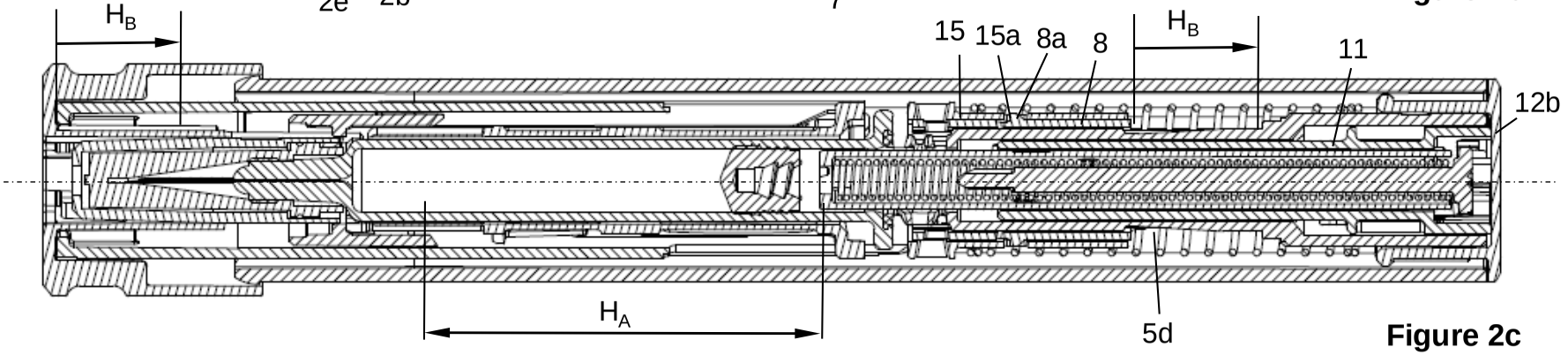
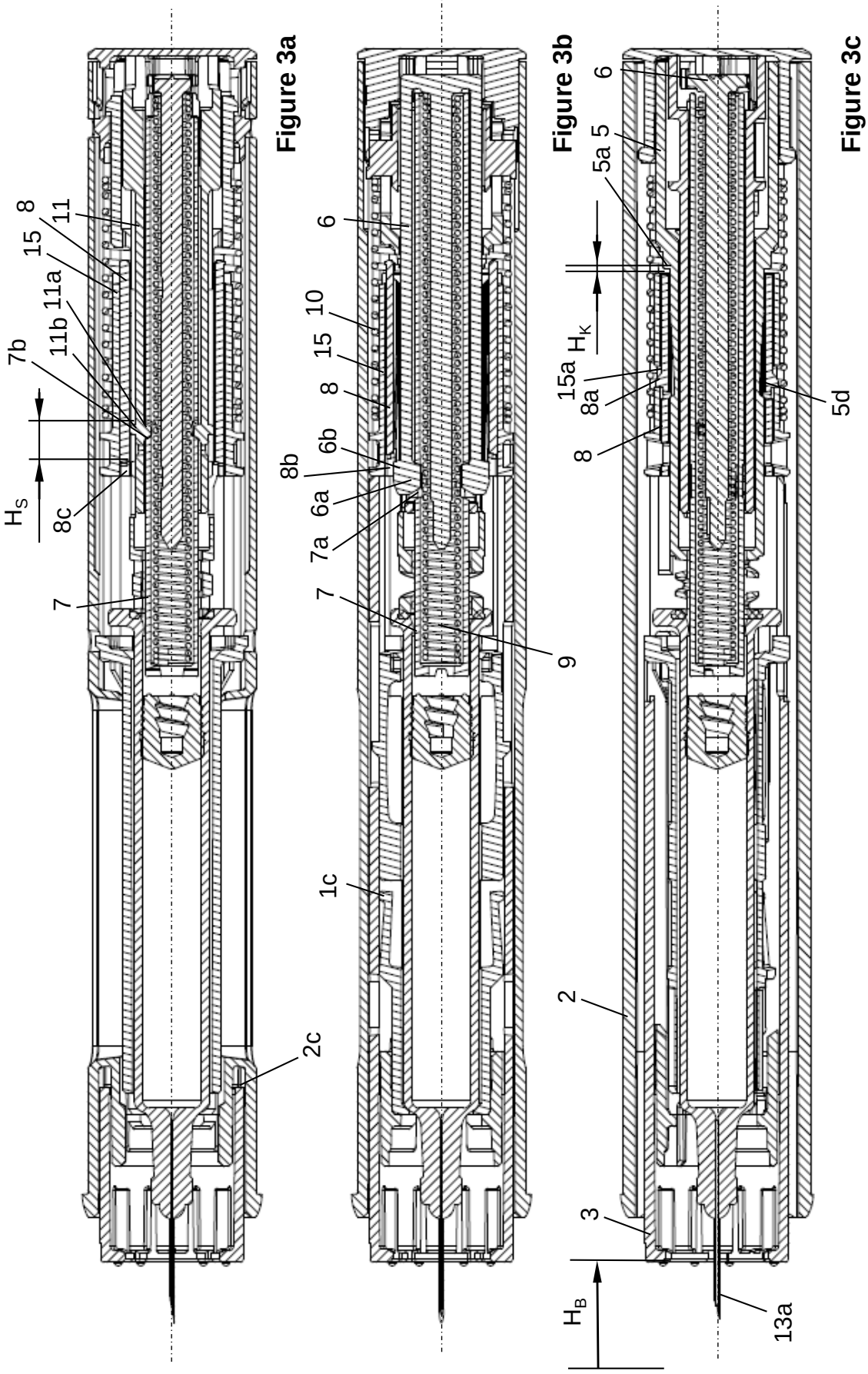


Figure 2c


8
11
15
11a
11b
7b
H_S
8c
7
2c
Figure 3a
6
10
15
8
6b
8b
6a
7a
7
9
1c
Figure 3b
6
5
5a
H_K
15a
8a
8
5d
2
3
H_B
13a
Figure 3c

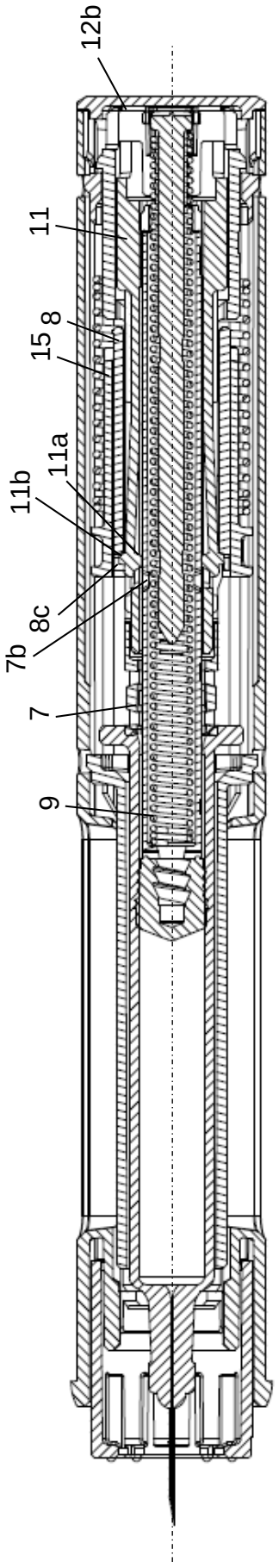


Figure 4a

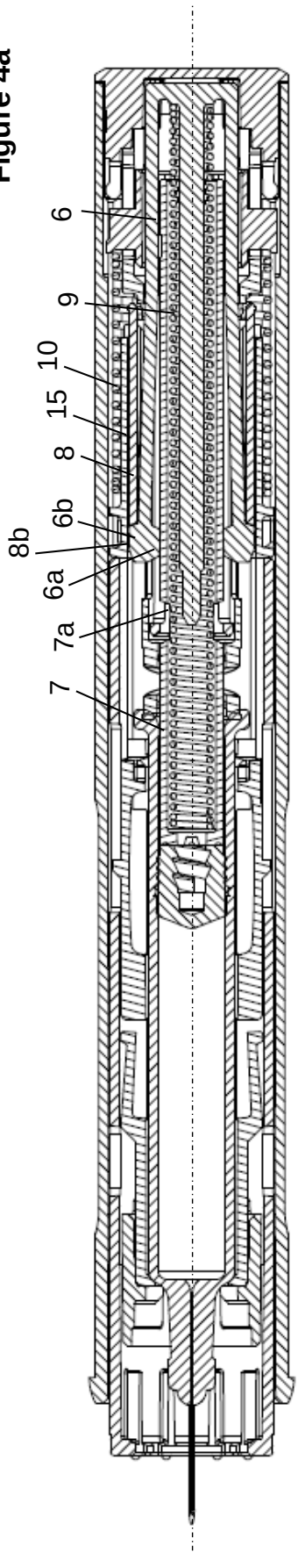


Figure 4b

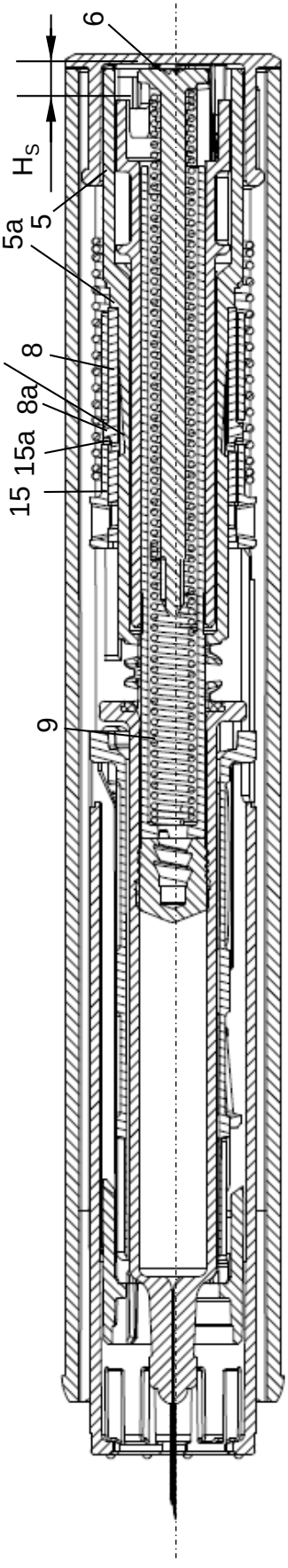


Figure 4c

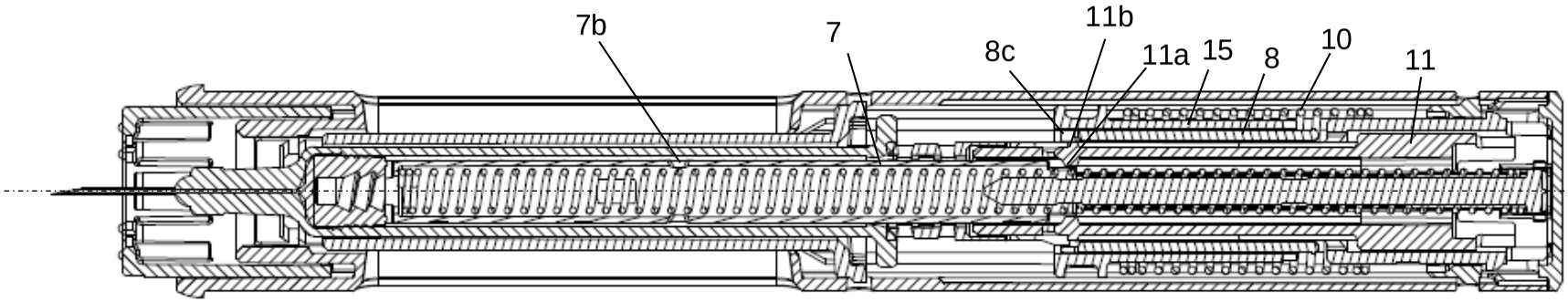


Figure 5a

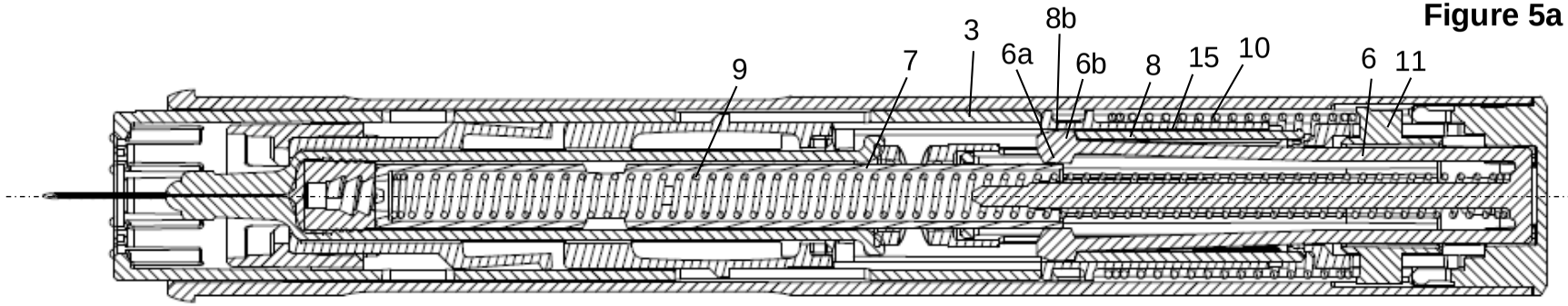


Figure 5b

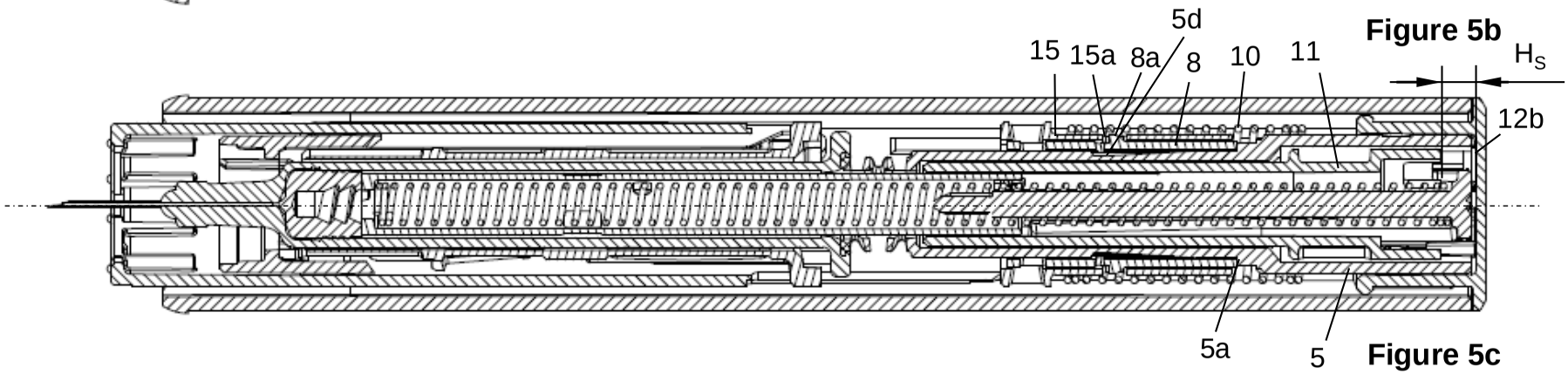


Figure 5c

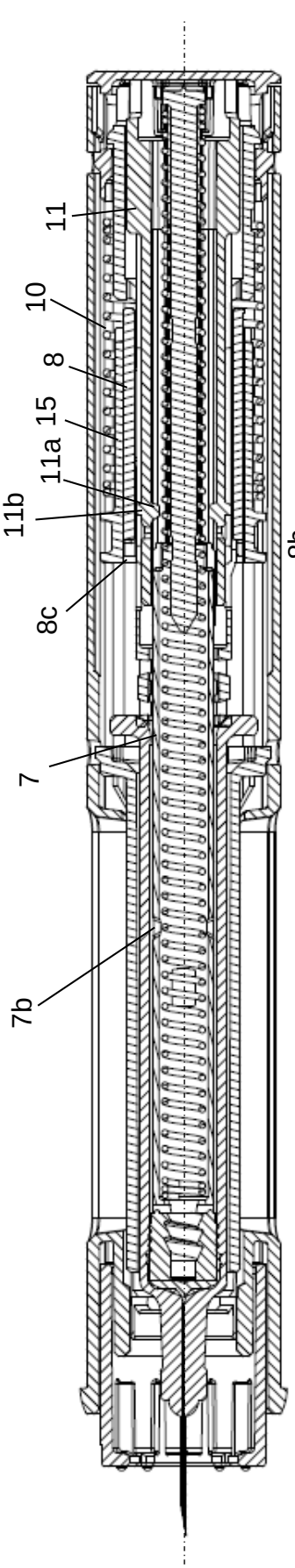


Figure 6a

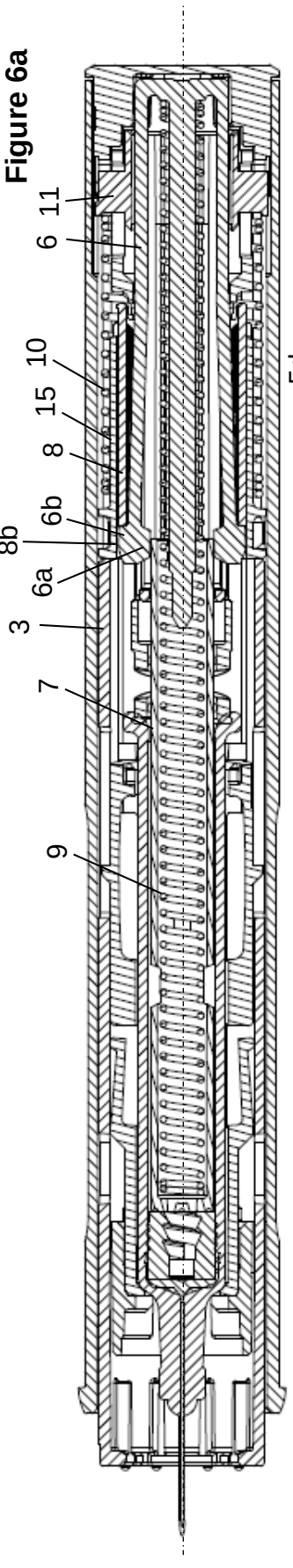


Figure 6b

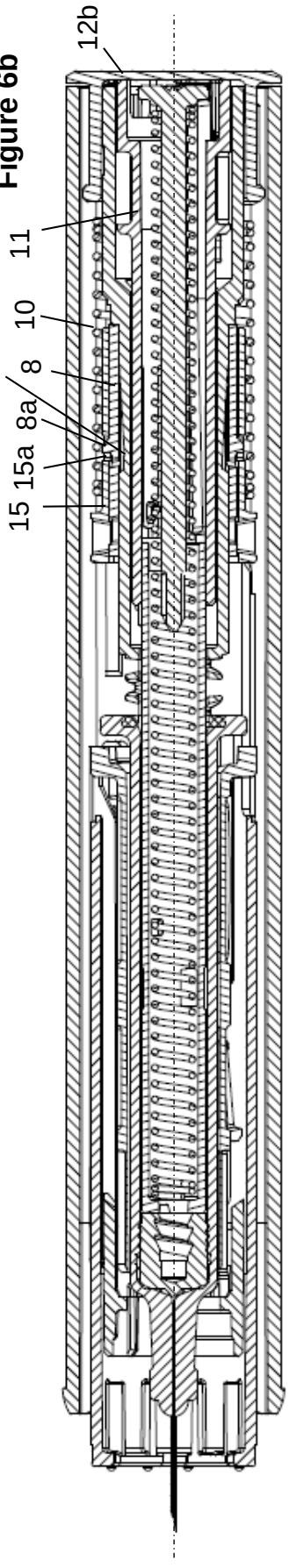


Figure 6c

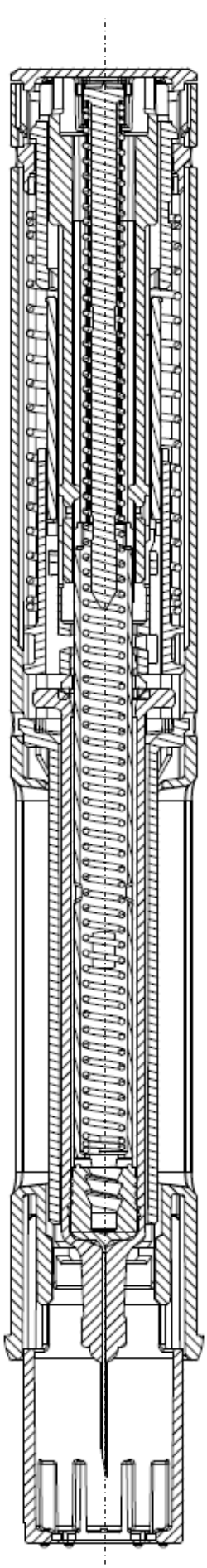


Figure 7a

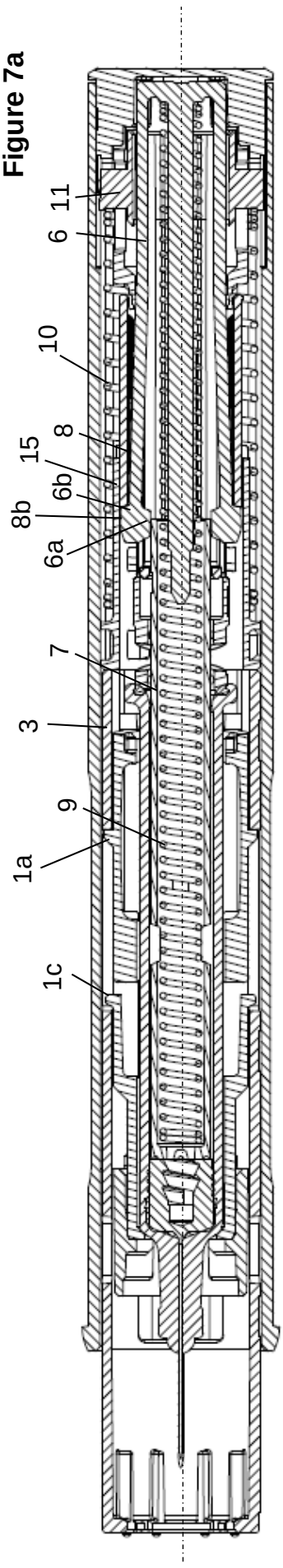


Figure 7b

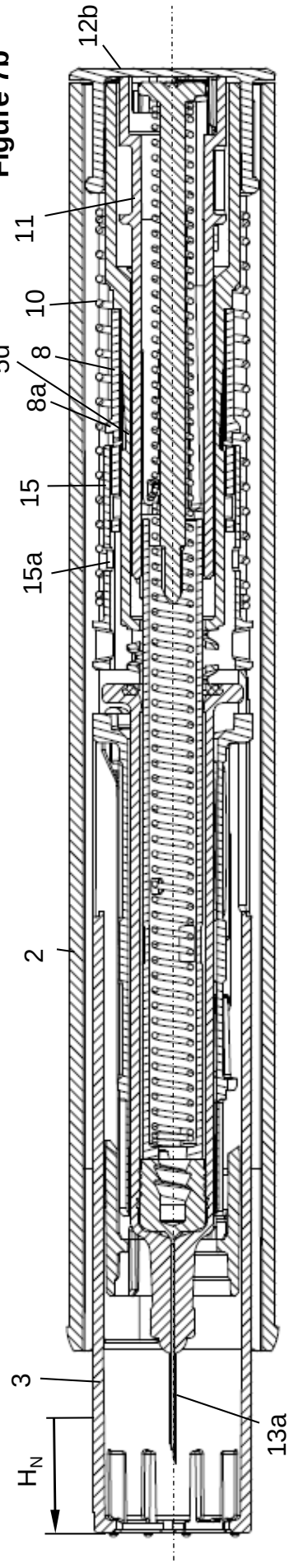


Figure 7c

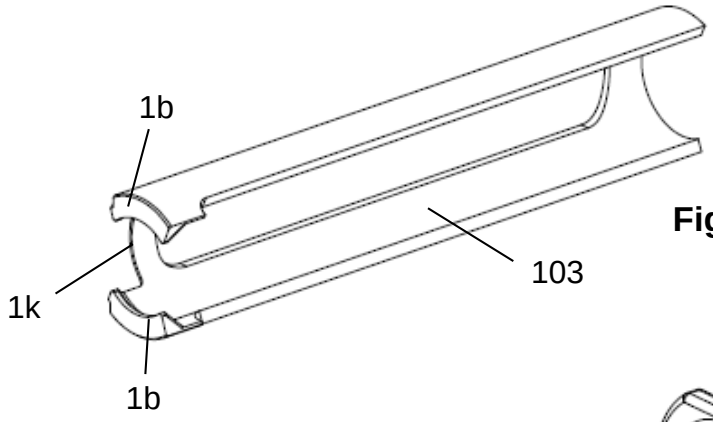


Figure 8a

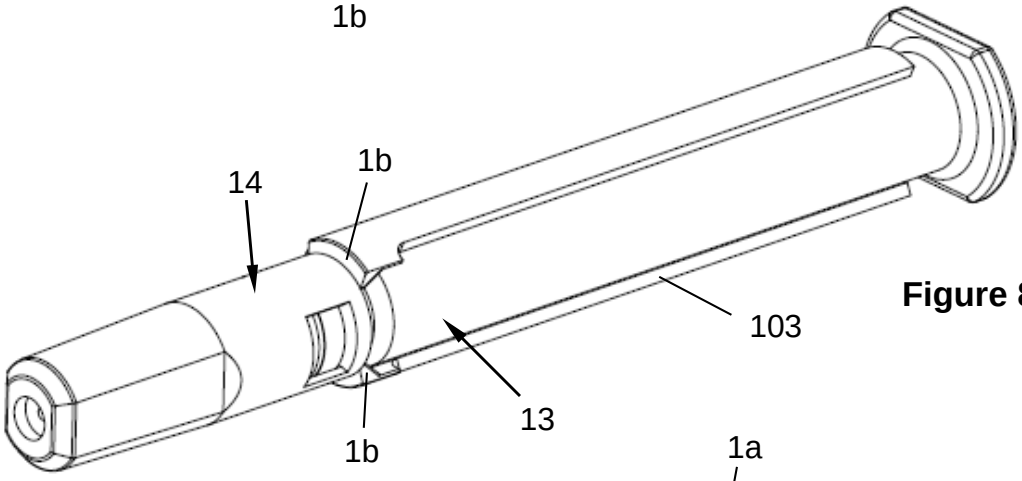


Figure 8b

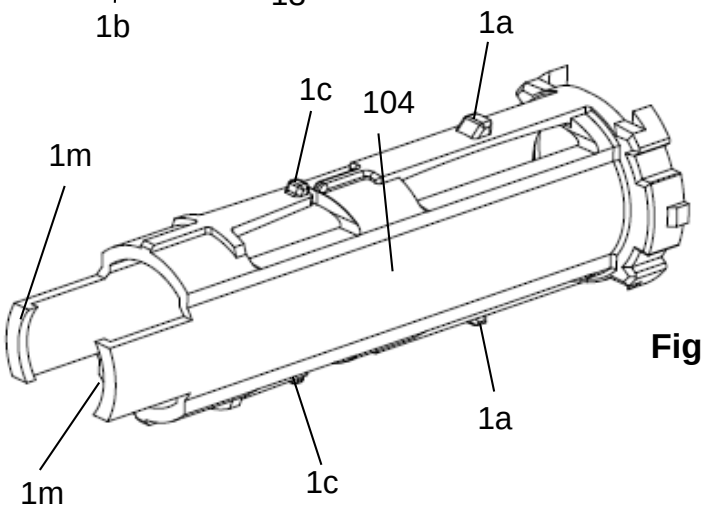


Figure 8c

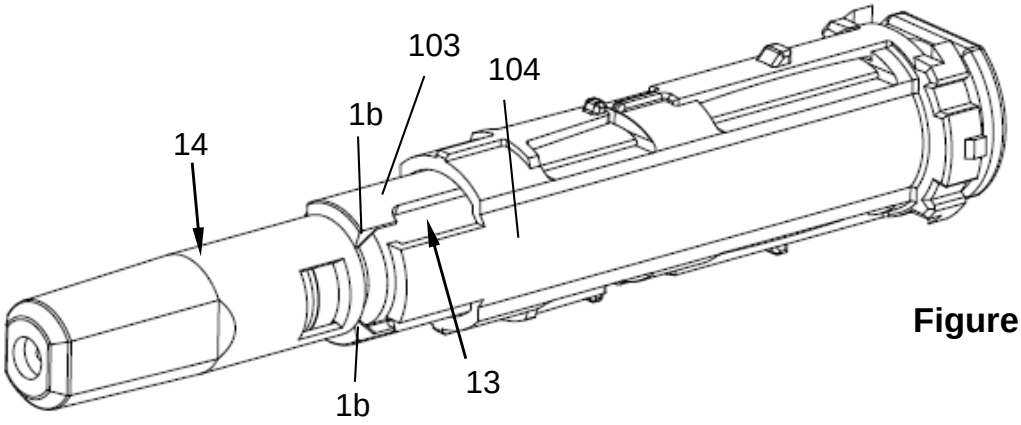


Figure 8d

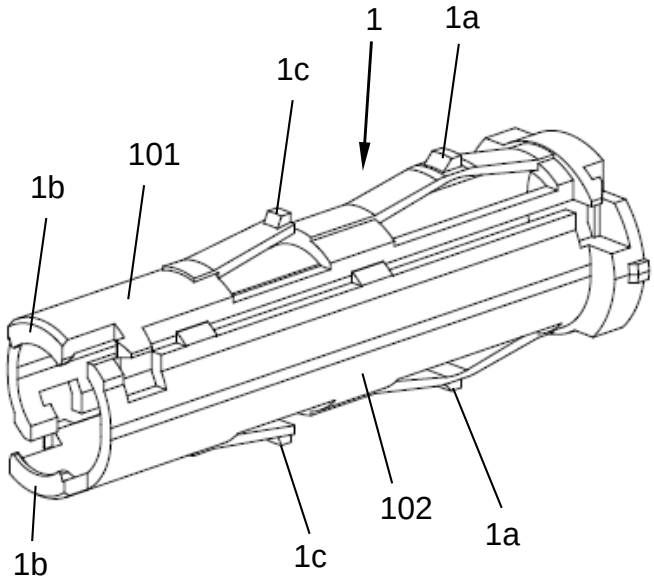


Figure 9a

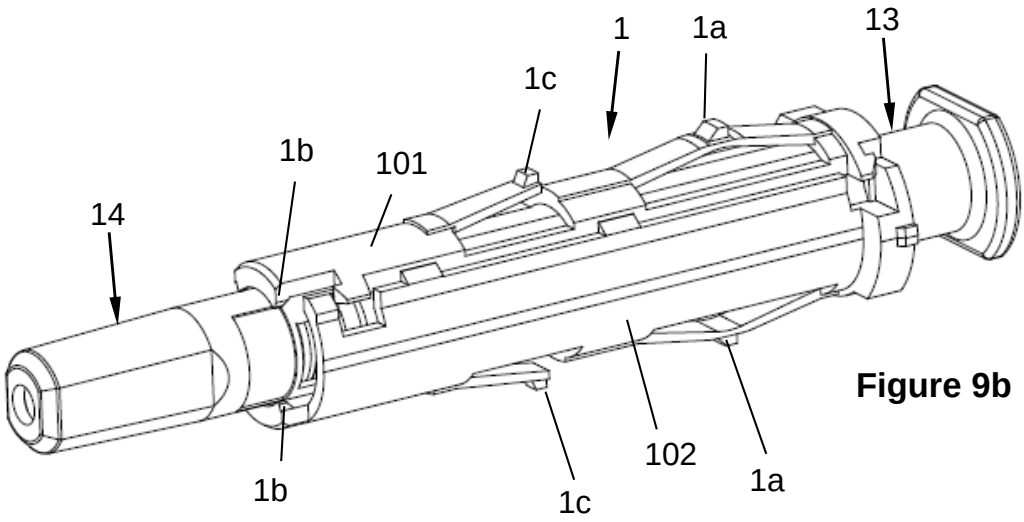


Figure 9b

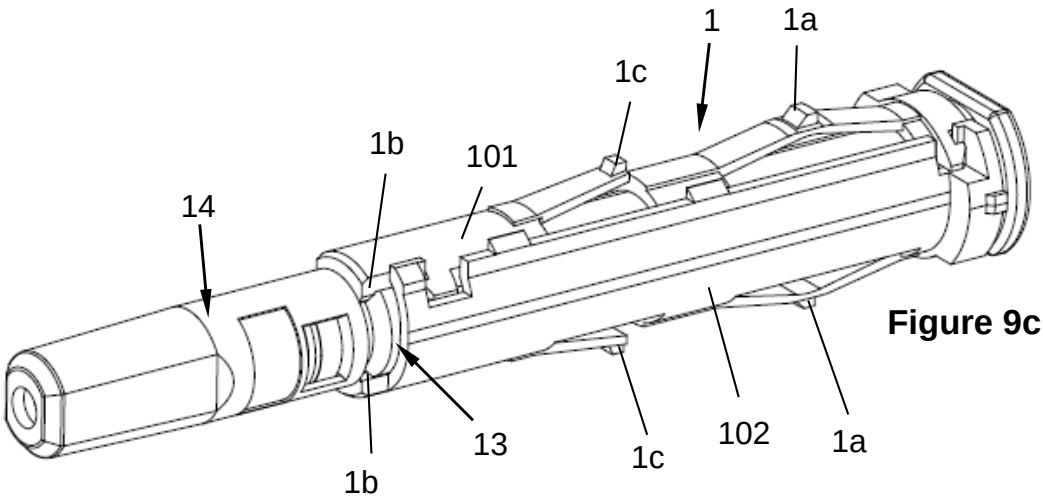


Figure 9c

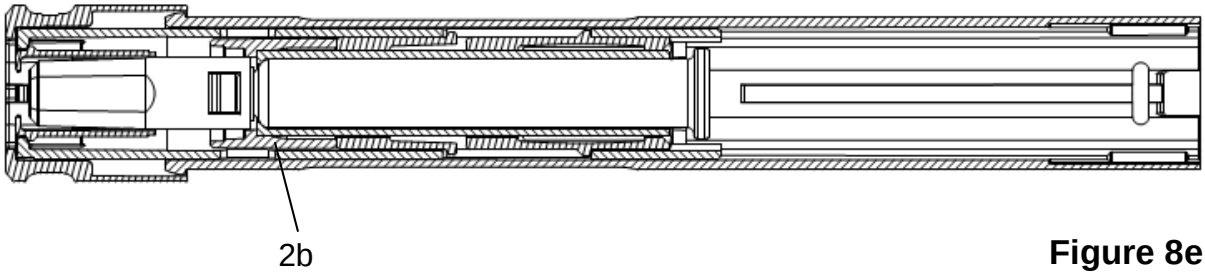


Figure 8e

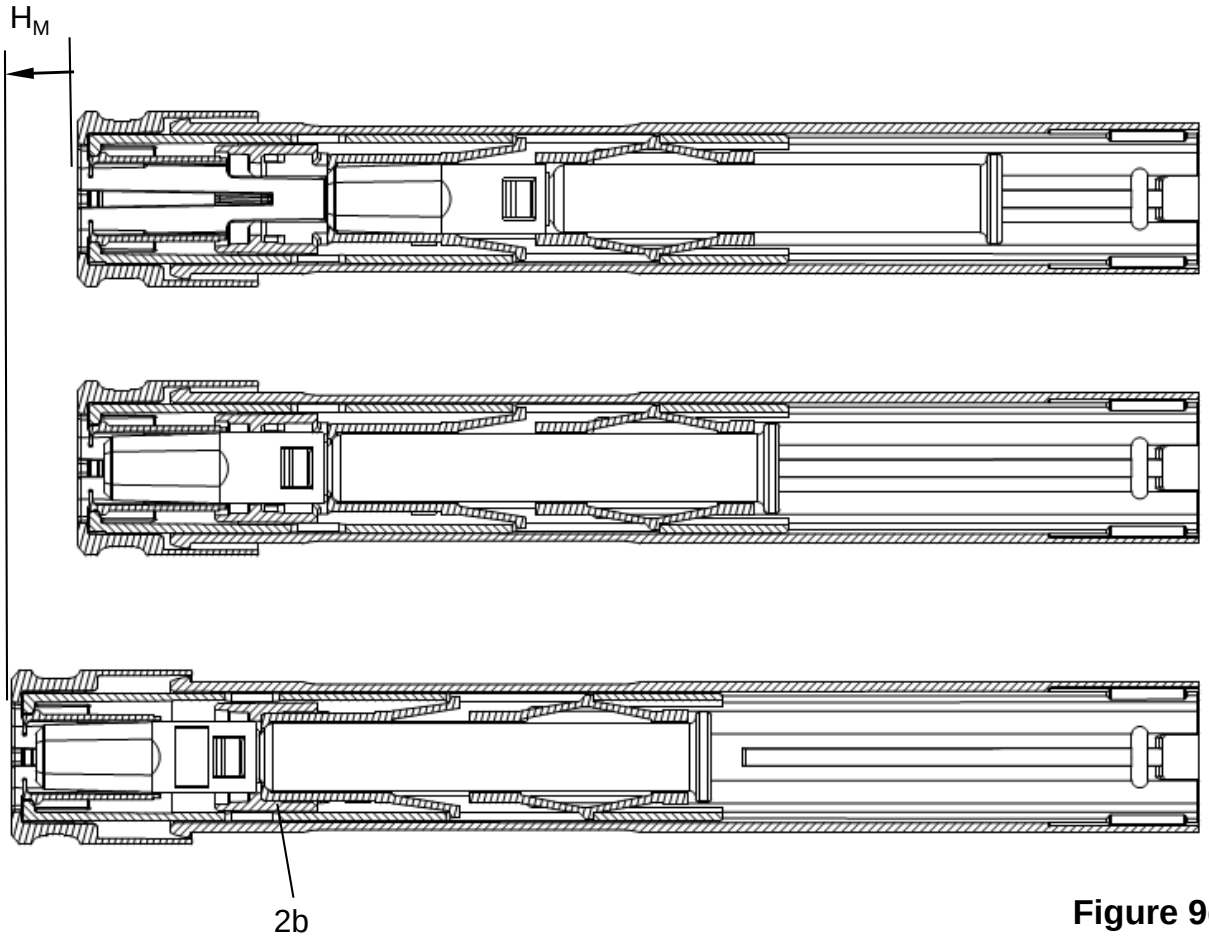


Figure 9d

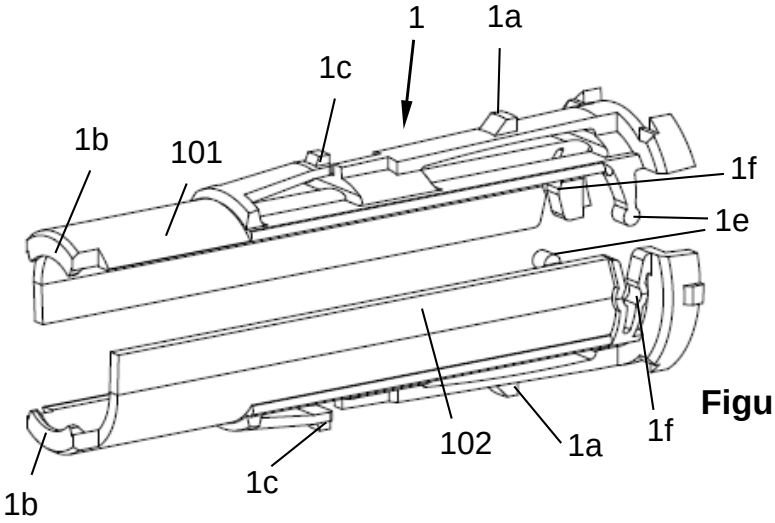


Figure 10a

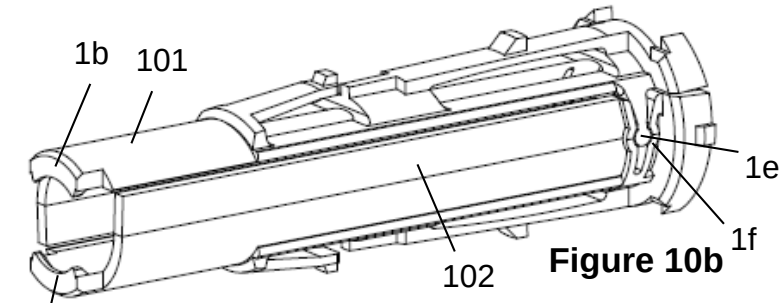


Figure 10b

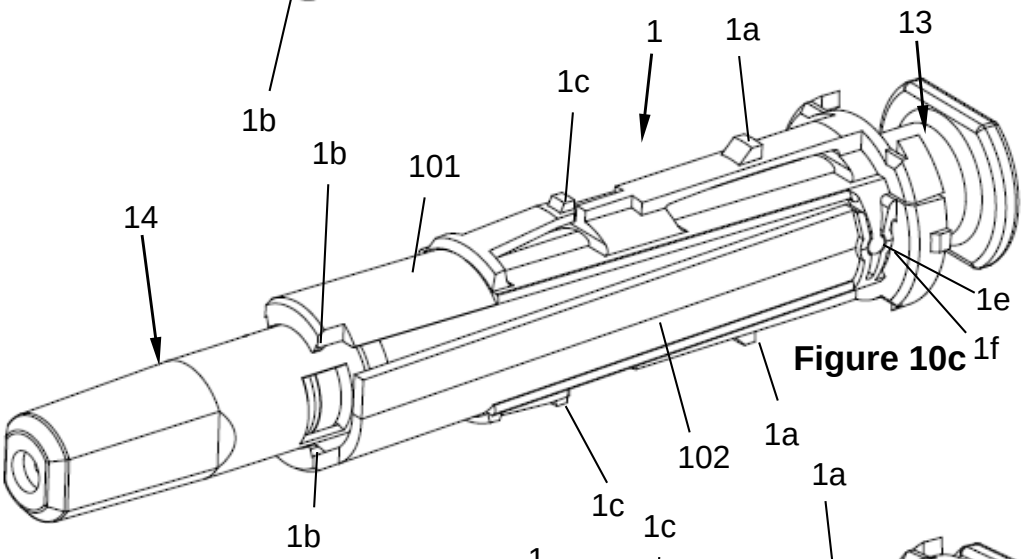


Figure 10c

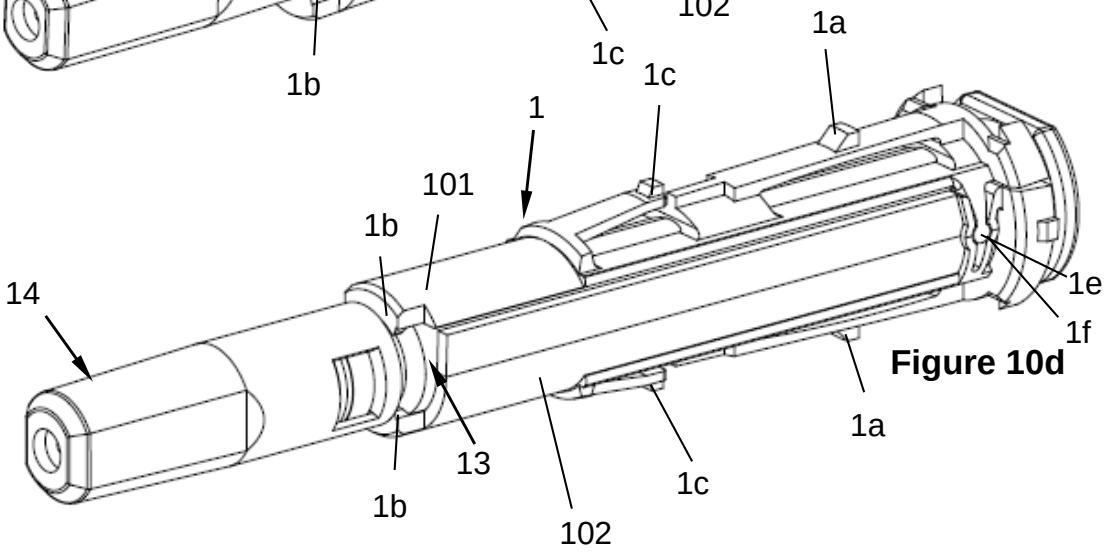


Figure 10d

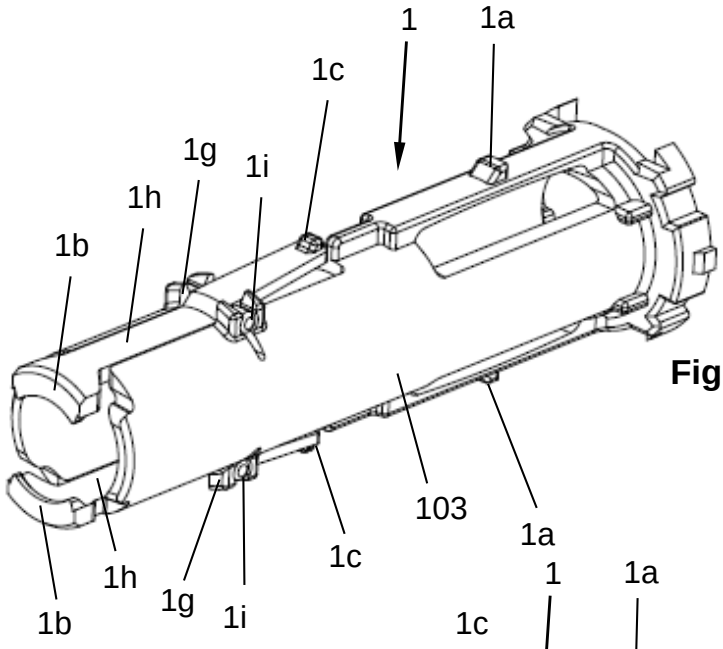


Figure 11a

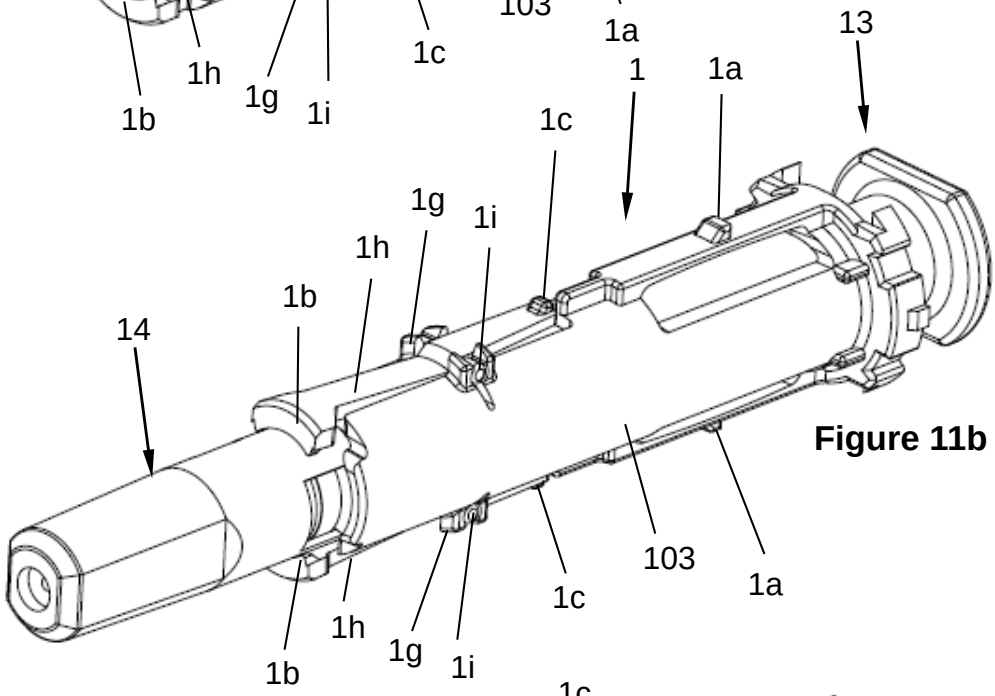


Figure 11b

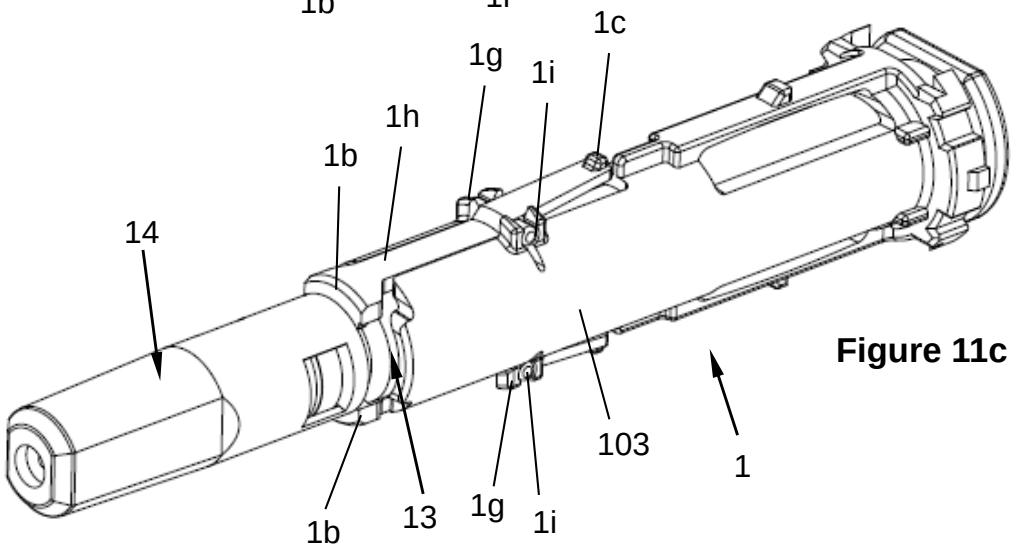


Figure 11c

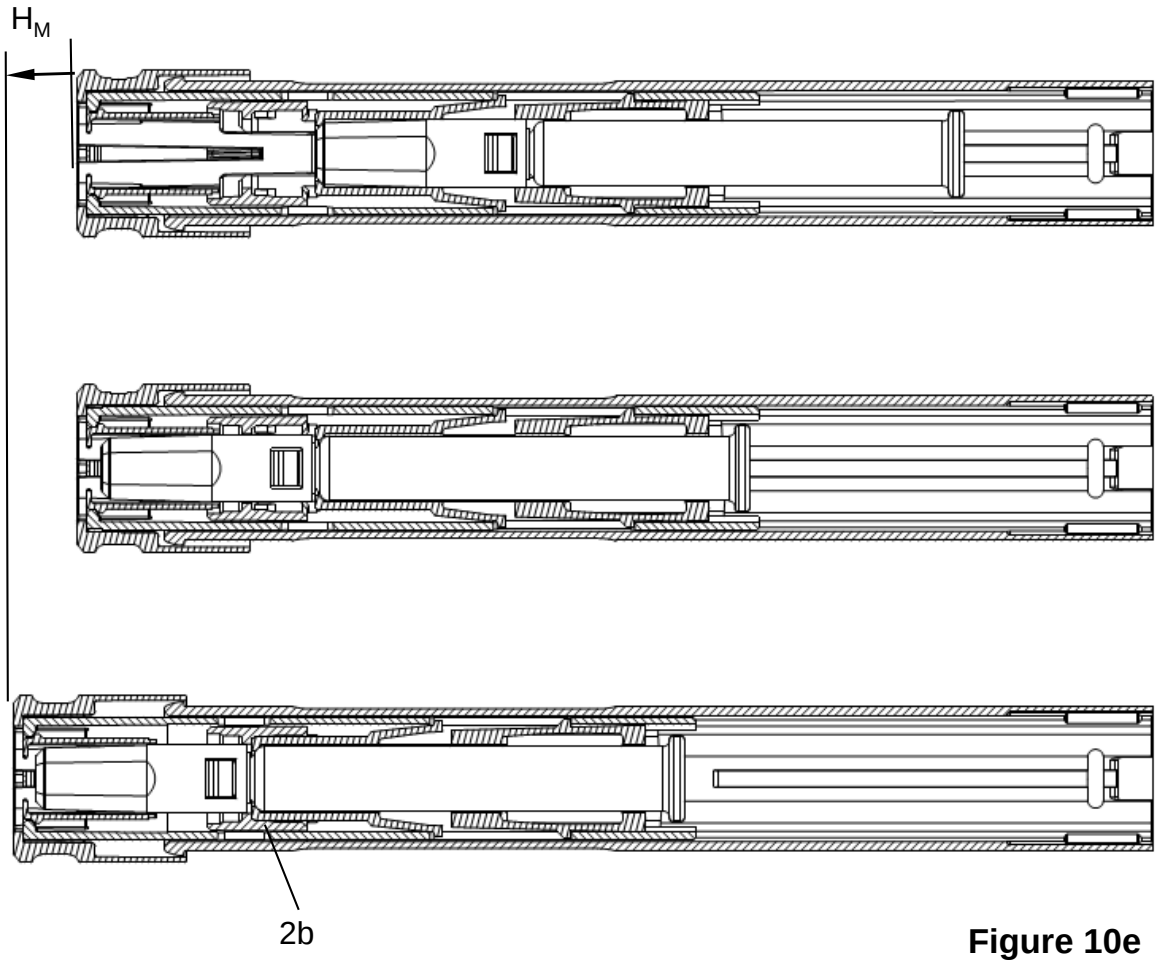


Figure 10e

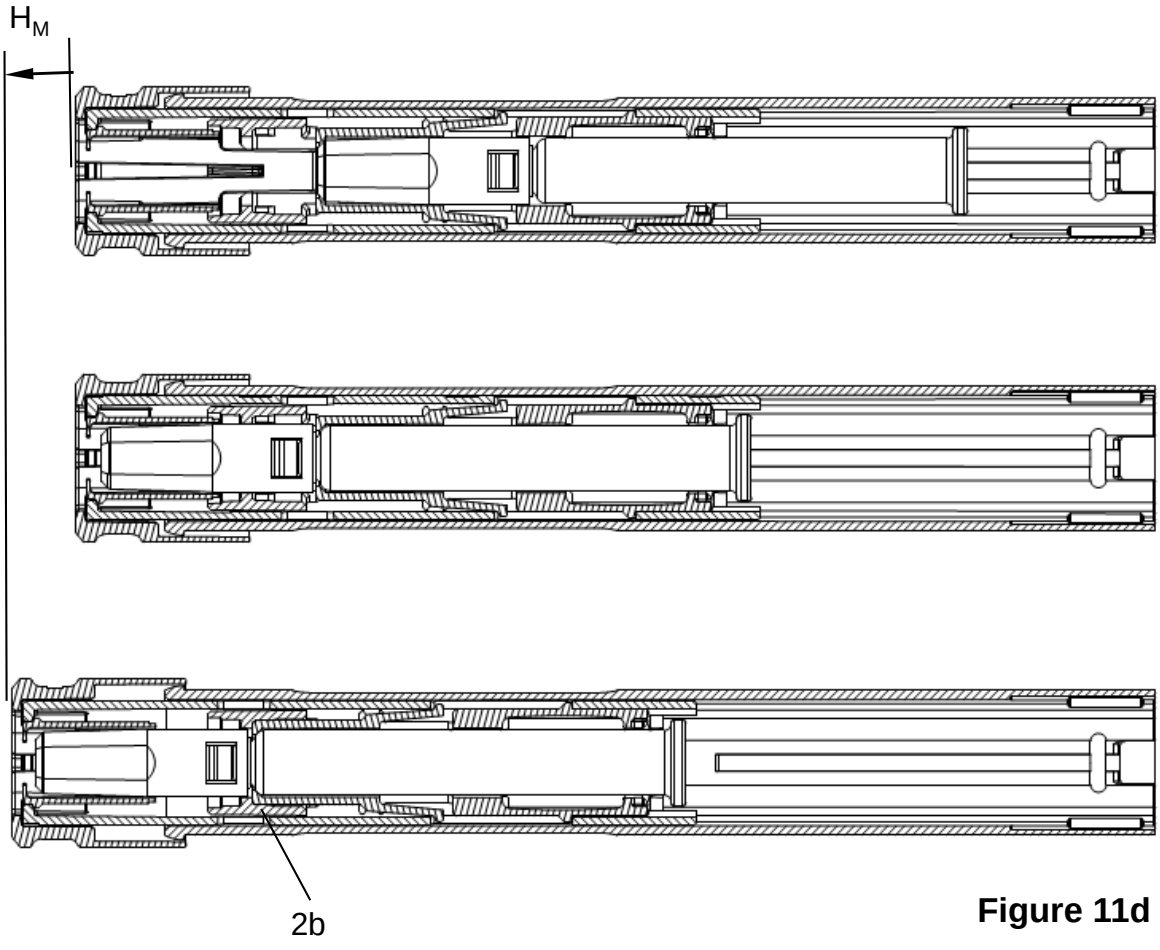


Figure 11d

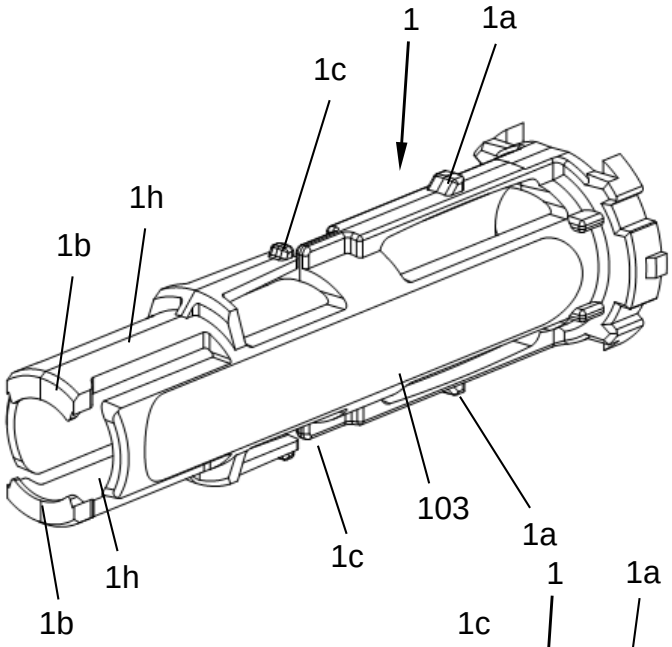


Figure 12a

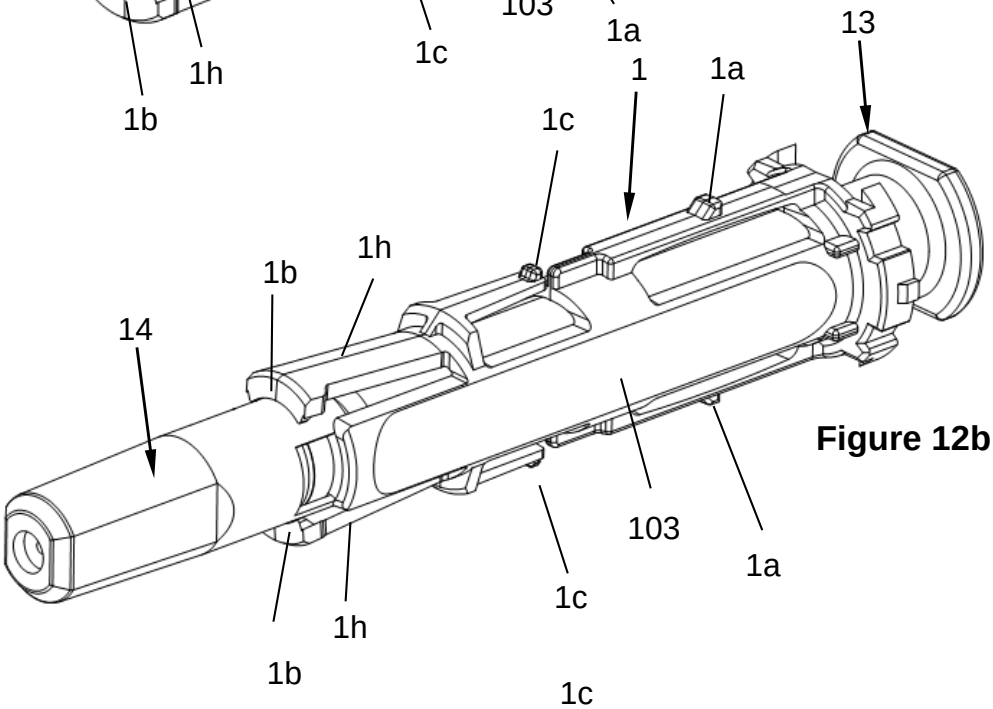


Figure 12b

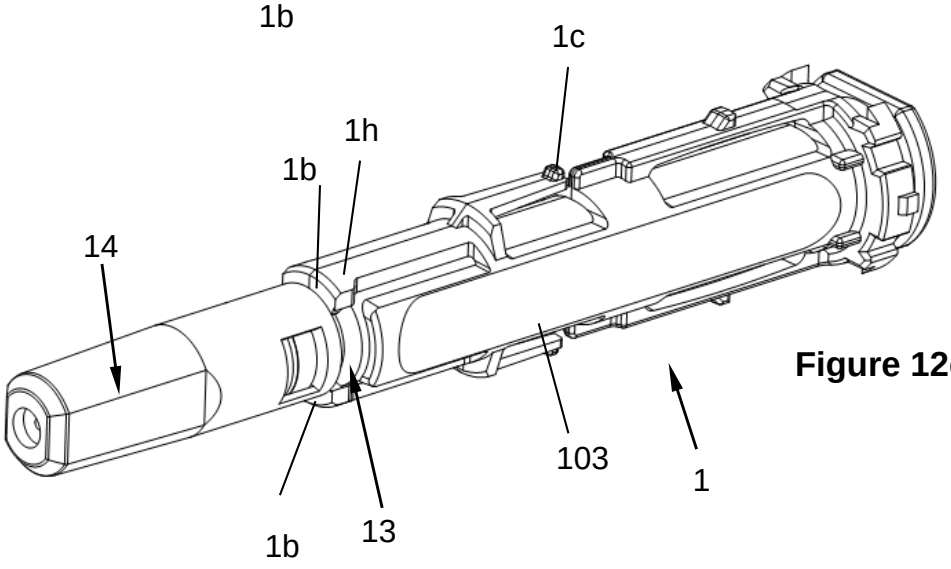


Figure 12c

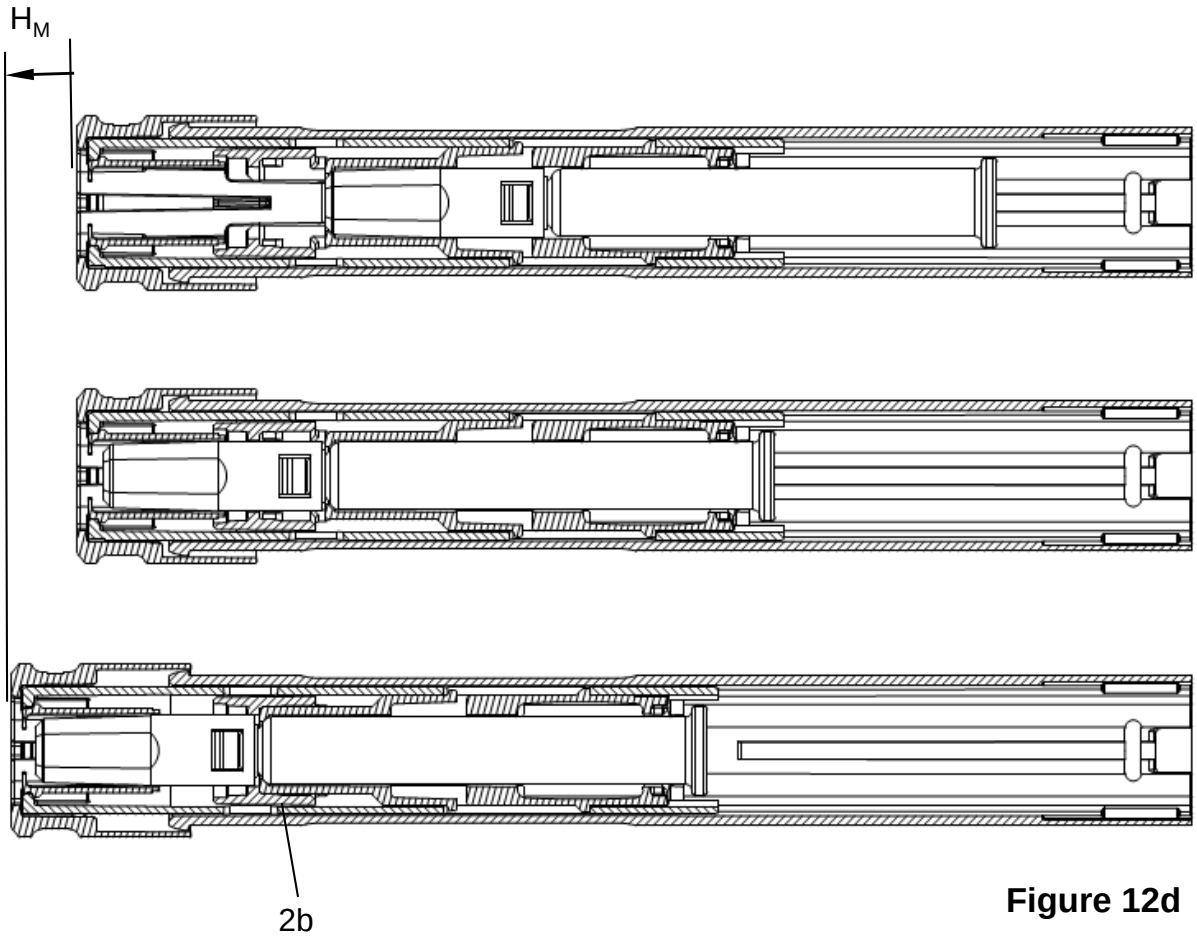


Figure 12d