

(19) **DANMARK**



Patent- og  
Varemærkestyrelsen

(10) **DK/EP 2585135 T3**

(12) Oversættelse af  
europæisk patentskrift

- 
- (51) Int.Cl.: **A 61 M 5/20 (2006.01)** **A 61 M 5/00 (2006.01)**
- (45) Oversættelsen bekendtgjort den: **2021-04-06**
- (80) Dato for Den Europæiske Patentmyndigheds  
bekendtgørelse om meddelelse af patentet: **2021-01-20**
- (86) Europæisk ansøgning nr.: **11727478.7**
- (86) Europæisk indleveringsdag: **2011-06-27**
- (87) Den europæiske ansøgnings publiceringsdag: **2013-05-01**
- (86) International ansøgning nr.: **EP2011060726**
- (87) Internationalt publikationsnr.: **WO2012000939**
- (30) Prioritet: **2010-06-28 EP 10167506**
- (84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV  
MC MK MT NL NO PL PT RO RS SE SI SK SM TR**
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- (54) Benævnelse: **AUTOINJEKTOR**
- (56) Fremdragne publikationer:  
**WO-A1-2009/062508  
US-A- 5 267 963  
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US-B2- 7 717 877**



# DESCRIPTION

## Technical Field

**[0001]** The invention relates to an auto-injector for administering a dose of a liquid medicament according to the preamble of claim 1.

## Background of the Invention

**[0002]** Administering an injection is a process which presents a number of risks and challenges for users and healthcare professionals, both mental and physical.

**[0003]** Injection devices (i.e. devices capable of delivering medicaments from a medication container) typically fall into two categories - manual devices and auto-injectors.

**[0004]** In a manual device - the user must provide the mechanical energy to drive the fluid through the needle. This is typically done by some form of button / plunger that has to be continuously pressed by the user during the injection. There are numerous disadvantages to the user from this approach. If the user stops pressing the button / plunger then the injection will also stop. This means that the user can deliver an underdose if the device is not used properly (i.e. the plunger is not fully pressed to its end position). Injection forces may be too high for the user, in particular if the patient is elderly or has dexterity problems.

**[0005]** The extension of the button/plunger may be too great. Thus it can be inconvenient for the user to reach a fully extended button. The combination of injection force and button extension can cause trembling / shaking of the hand which in turn increases discomfort as the inserted needle moves.

**[0006]** Auto-injector devices aim to make self-administration of injected therapies easier for patients. Current therapies delivered by means of self-administered injections include drugs for diabetes (both insulin and newer GLP-1 class drugs), migraine, hormone therapies, anticoagulants etc.

**[0007]** Auto-injectors are devices which completely or partially replace activities involved in parenteral drug delivery from standard syringes. These activities may include removal of a protective syringe cap, insertion of a needle into a patient's skin, injection of the medicament, removal of the needle, shielding of the needle and preventing reuse of the device. This overcomes many of the disadvantages of manual devices. Injection forces / button extension, hand-shaking and the likelihood of delivering an incomplete dose are reduced. Triggering may be performed by numerous means, for example a trigger button or the action of the needle reaching its injection depth. In some devices the energy to deliver the fluid is provided by a

spring.

**[0008]** US 2002/0095120 A1 discloses an automatic injection device which automatically injects a pre-measured quantity of fluid medicine when a tension spring is released. The tension spring moves an ampoule and the injection needle from a storage position to a deployed position when it is released. The content of the ampoule is thereafter expelled by the tension spring forcing a piston forward inside the ampoule. After the fluid medicine has been injected, torsion stored in the tension spring is released and the injection needle is automatically retracted back to its original storage position.

**[0009]** WO 2009/062508 A1 discloses a disposable auto injector having a housing for accommodation of a syringe with a needle movably positioned in the housing between a first position in which the needle is inside the housing and a second position in which the needle protrudes outside the housing, a driver positioned laterally in relation to the syringe and configured for applying a force to the syringe thereby moving the syringe from the first position to the second position, a first injection lock configured in a locked state for preventing syringe movement from the first position to the second position and an injection trigger member configured for releasing the first injection lock to an unlocked state wherein the first injection lock comprises a rotatable release shaft; configured for rotation between a first angular position in which it prevents movement of the syringe from the first position to the second position and a second angular position in which position does not prevent movement of the syringe from the first position to the second position.

**[0010]** US 7,717,877 discloses an injector being automatic in that the needle is inserted into the injection site (e.g., a patient's skin) with user or caregiver assistance, the delivery is automatically initiated upon needle insertion, and the needle is retracted automatically after the end of delivery. Preferably the needle is not seen by the user prior to, during or after injection. Prior to and after injection, the needle is hidden in the device so as to avoid any potential injury or health risk to the user or health care provider. The injector includes a housing and a shield arranged to slide relative to the housing and a driver moving during drug delivery. The housing and shield form a cartridge enclosure. The cartridge is shielded and locked after delivery is completed. A needle-locking mechanism can be used in any number of pen-like injectors or safety needles.

**[0011]** US 5,267,963 discloses an automatic injection device which, upon activation by the user, automatically extends a syringe with needle, delivers medication through the needle, and retracts the needle, thus keeping the needle hidden from view.

**[0012]** The spring means is a single compression spring arranged to be grounded at a distal end in the housing for advancing the needle and for injecting the dose of medicament via a plunger and wherein the compression spring is arranged to have its ground in the housing switched to its proximal end for retracting the syringe.

## **Summary of the Invention**

**[0013]** It is an object of the present invention to provide an improved auto-injector.

**[0014]** The object is achieved by an auto-injector according to claim 1.

**[0015]** Preferred embodiments of the invention are given in the dependent claims.

**[0016]** In the context of this specification the term proximal refers to the direction pointing towards the patient during an injection while the term distal refers to the opposite direction pointing away from the patient.

**[0017]** According to the invention, an auto- injector for administering a dose of a liquid medicament comprises:

- an elongate housing arranged to contain a syringe with a hollow needle and a stopper for sealing the syringe and displacing the medicament, the housing having a distal end and a proximal end with an orifice intended to be applied against an injection site, wherein the syringe is slidably arranged with respect to the housing,
- spring means capable of, upon activation:
  - pushing the needle from a covered position inside the housing into an advanced position through the orifice and past the proximal end,
  - operating the syringe to supply the dose of medicament, and
  - retracting the syringe with the needle into the covered position after delivering the medicament,
- activating means arranged to lock the spring means in a pressurized state prior to manual operation and capable of, upon manual operation, releasing the spring means for injection.

**[0018]** According to the invention the spring means is a single drive spring in the shape of a compression spring arranged to be grounded at a distal end in the housing for advancing the needle and for injecting the dose of medicament. The force of the drive spring is forwarded to the needle and/or the syringe via a plunger. The drive spring is arranged to have its ground in the housing switched to its proximal end for retracting the syringe when the injection of the medicament is at least nearly finished.

**[0019]** The single drive spring is used for inserting the needle, fully emptying the syringe and retracting the syringe and needle to a safe position after injection. Thus a second spring for withdrawing the syringe and needle, which is a motion with an opposite sense compared to advancing the syringe and injecting the dose, is not required. While the distal end of the drive spring is grounded the proximal end moves the syringe forward for inserting the needle and carries on to the injection by pushing on the stopper. When the injection is at least nearly finished the drive spring bottoms out at its proximal end, resulting in the proximal end being

grounded in the housing. At the same time the distal end of the drive spring is released from its ground in the housing. The drive spring is now pulling the syringe in the opposite direction.

**[0020]** According to the invention the activating means is arranged as a trigger button laterally arranged on the housing. A lateral trigger button can be easier to operate for people with dexterity problems.

**[0021]** The auto-injector according to the invention has a particularly low part count compared to most conventional auto-injectors. The use of just one drive spring reduces the amount of metal needed and thus consequently reduces weight and manufacturing costs.

**[0022]** The trigger button is preferably pivoted in the housing and arranged to be rotated when operated.

**[0023]** An interlock sleeve may be telescoped in the proximal end of the housing, the interlock sleeve translatable in longitudinal direction between a proximal position and a distal position and biased in proximal direction in a manner to protrude from the housing in the proximal position. The interlock sleeve is arranged to be translated from its proximal position into an intermediate position when pressed against the injection site. The trigger button is arranged to push the interlock sleeve from the intermediate position into the distal position thus releasing the drive spring. Before the syringe and needle translate in proximal direction the activating means, i.e. the lateral trigger button has to be operated so as to release the drive spring. The probability for inadvertent operation of the auto-injector thus decreases due to the requirement of two user actions, pressing the auto-injector against the injection site and operating the trigger button.

**[0024]** In its proximal position the interlock sleeve may be arranged to hold the trigger button in a depressed position, e.g. flush with the housing. Translation of the interlock sleeve into the intermediate position causes the trigger button to emerge from the housing into a ready position. This provides a sequenced operation in a manner that the trigger button cannot be operated before the interlock sleeve is pressed against the injection site.

**[0025]** It is desirable to trigger the retraction of the needle when the contents of the syringe have been entirely delivered to the patient, i.e. when the stopper has bottomed out in the syringe. Automatically triggering the retraction when the stopper exactly reaches the end of its travel is a problem due to tolerances when manufacturing the syringe and stopper. Due to these tolerances the position of the stopper at the end of its travel relative to the retracting means is not repeatable. Consequently, in some cases the stopper would prematurely bottom out so the retraction would not be triggered at all. In other cases the retraction would be triggered before the stopper bottomed so residual medicament would remain in the syringe.

**[0026]** The retraction could automatically be triggered a certain amount of time or travel before the stopper bottoms out in the syringe. However this reliable retraction would be traded off for residual medicament in the syringe.

**[0027]** Thus, in a preferred embodiment the interlock sleeve is furthermore arranged to prevent release of the distal ground of the drive spring when in its intermediate and/or distal position. This means, the drive spring remains distally grounded as long as the auto-injector is kept pressed against the injection site so the needle retraction can only start when the auto-injector is removed from the injection site and the interlock sleeve consequently returns into its proximal position and thus releases the distal ground.

**[0028]** A retraction sleeve may be axially movable arranged in the housing, wherein the drive spring is arranged inside the retraction sleeve with its distal end bearing against a distal end face and with its proximal end bearing against a thrust face of a decoupling member. A resilient lug on the interlock sleeve is arranged to be engaged with the retraction sleeve by the trigger button being depressed when the interlock sleeve is in its intermediate or distal position so as to prevent the retraction sleeve from translating in distal direction. Thus, when the interlock sleeve is pressed against the injection site, the retraction sleeve is kept from retracting. Only after removal of the auto-injector from the injection site and consequent translation of the interlock sleeve into its proximal position the retraction sleeve may translate in distal direction and retract the needle into the housing.

**[0029]** The lug may be engaged between two ramps on the trigger button in such a manner that the trigger button is pulled into the depressed position upon translation of the interlock sleeve into its proximal position by the lug sliding along the first ramp. The trigger button is pushed into its ready position by the lug sliding along the second ramp.

**[0030]** A third ramp may be arranged on the interlock sleeve for being engaged by a pin on the trigger button when the trigger button is being pressed when the interlock sleeve is in its intermediate position. When the trigger button is being pressed the pin slides along the third ramp and translates the interlock sleeve into its distal position for triggering the injection.

**[0031]** A tubular syringe carrier may be arranged for holding the syringe and supporting it at its proximal end. Supporting the syringe at the proximal end is preferred over support at the finger flanges since the finger flanges are more frangible under load while the proximal or front end of the syringe is more robust. The syringe and the syringe carrier are arranged for joint axial translation. The syringe carrier is telescoped in the interlock sleeve.

**[0032]** In a preferred embodiment at least one latch is provided for axially fixing the retraction sleeve in a maximum proximal position. The decoupling member is arranged to decouple the latch when being moved in proximal direction nearly into a maximum proximal position. When decoupled, the retraction sleeve is allowed to move in distal direction and retract the needle by means of the spring force which is no longer grounded at its distal end. Thus, retraction can only occur if the latches have been released and if the auto-injector has been removed from the injection site.

**[0033]** Preferably the plunger is arranged for pushing the syringe and/or the stopper in

proximal direction. At least one but preferably two or more resilient decoupling arms are arranged at the decoupling member. The decoupling arms exhibit inner ramped surfaces bearing against a first shoulder of the plunger in proximal direction. The resilient decoupling arms are supportable by an inner wall of the retraction sleeve in order to prevent the decoupling arms from being flexed outward and slip past the first shoulder. In this state the plunger may be pushed in proximal direction by the decoupling member pushing against the first shoulder in order to insert the needle and inject the dose. At least one aperture is arranged in the retraction sleeve allowing the decoupling arms to be flexed outward by the first shoulder thus allowing the first shoulder to slip through the decoupling arms in proximal direction. This may happen when the injection is at least nearly finished. The decoupled plunger allows the syringe and needle to be retracted since it is no longer bearing against the decoupling member.

**[0034]** The syringe may be arranged for joint axial movement with a syringe holder which is slidably arranged in the retraction sleeve. The syringe holder is provided with at least two resilient syringe holder arms arranged distally, the syringe holder arms having a respective inclined surface for bearing against a second shoulder, which is arranged at the plunger proximally from the first shoulder. The syringe holder arms are supportable by an inner surface of the housing in order to prevent them from being flexed outward. Thus, when the trigger button is pressed the spring force forwarded by the plunger does not yet press against the stopper but against the syringe for forwarding it. Consequently, a so called wet injection is avoided, i.e. the liquid medicament is not leaking out of the hollow needle before the needle is inserted. A widened portion is provided in the housing for allowing the syringe holder arms to flex outwards when the syringe holder has nearly reached a maximum proximal position thus allowing the second shoulder to slip through the syringe holder arms and to switch load of the drive spring from the syringe to the stopper. This allows for defining the moment to start injecting the medicament.

**[0035]** The syringe holder may have at least one stop for being engaged by a resilient first clip on the housing in a manner to prevent translation of the syringe holder in proximal direction. The first clip may be arranged to decouple from the stop upon translation of the interlock sleeve into its distal position in order to release the drive spring and start the injection.

**[0036]** Usually the hollow needle is equipped with a protective needle shield for keeping the needle sterile and preventing it from being mechanically damaged. The protective needle shield is attached to the needle when the auto-injector or the syringe is assembled.

**[0037]** Preferably a cap is provided at the proximal end of the housing. A sheet metal clip is attached to the cap for joint axial movement and independent rotation. The sheet metal clip is arranged to extend through an orifice into the interlock sleeve when the cap is attached to the interlock sleeve. The sheet metal clip incorporates at least two barbs snapped into a circumferential notch or behind a shoulder of the protective needle shield. This allows for automatically engaging the sheet metal clip with the protective needle shield during assembly. When the cap is removed from the interlock sleeve in preparation of an injection the protective

needle shield is reliably removed without exposing the user too high a risk to injure themselves.

**[0038]** The cap may be attachable to the housing by a screw connection. This allows for a low force removal of the protective needle shield.

**[0039]** The housing may have at least one viewing window for inspecting the syringe.

**[0040]** The auto-injector may preferably be used for subcutaneous or intra-muscular injection, particularly for delivering one of an analgetic, an anticoagulant, insulin, an insulin derivate, heparin, Lovenox, a vaccine, a growth hormone, a peptide hormone, a proteine, antibodies and complex carbohydrates.

**[0041]** The cap with the sheet metal spring may also be applied with other auto-injectors and injection devices.

**[0042]** Further scope of applicability of the present invention will become apparent from the detailed description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the scope of the invention as defined by the appended claims will become apparent to those skilled in the art from this detailed description.

### **Brief Description of the Drawings**

**[0043]** The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only, and thus, are not limitive of the present invention, and wherein:

Figure 1

are two longitudinal sections of an auto-injector with a single drive spring for advancing a syringe with a needle, injecting a dose of medicament and retracting the syringe and needle, the auto-injector as-delivered,

Figure 2

is a longitudinal section of the auto-injector with a skin interlock sleeve translated in distal direction and a lateral trigger button ready to be operated, and

Figure 3

is a detail of the auto-injector with the trigger button depressed.

**[0044]** Corresponding parts are marked with the same reference symbols in all figures.

### **Detailed Description of Preferred Embodiments**

**[0045]** Figure 1 shows two longitudinal sections in different section planes of an auto-injector 1, the different section planes approximately 90° rotated to each other. The auto-injector 1 comprises an elongate housing 2. A syringe 3, e.g. a Hypak syringe, with a hollow needle 4 is arranged in a proximal part of the auto-injector 1. When the auto-injector 1 or the syringe 3 is assembled a protective needle shield may be attached to the needle (not illustrated). A stopper 6 is arranged for sealing the syringe 3 distally and for displacing a liquid medicament M through the hollow needle 4. The syringe 3 is held in a tubular syringe carrier 7 and supported at its proximal end therein. A single drive spring 8 in the shape of a compression spring is arranged in a distal part of the auto-injector 1. A plunger 9 is arranged for forwarding the spring force of the drive spring 8.

**[0046]** Inside the housing 2 a retraction sleeve 10 is slidably arranged. Before the injection is triggered the retraction sleeve 10 is in a maximum proximal position and prevented from moving in distal direction D by means of stops 11 caught behind latches 12 in the housing 2. A distal end of the drive spring 8 bears against an end face 13 of the retraction sleeve 10. Due to the stops 11 and latches 12 the force of the drive spring 8 is reacted into the housing 2. The proximal end of the drive spring 8 bears against a decoupling member 14 arranged around the plunger 9.

**[0047]** The decoupling member 14 comprises a thrust face 17 for bearing against a proximal end of the drive spring 8. Proximally from the thrust face 17 two or more resilient decoupling arms 18 are provided at the decoupling member 14, the decoupling arms 18 having inner ramped surfaces bearing against a first shoulder 19 in the plunger 9 in proximal direction P. The resilient decoupling arms 18 are supported by an inner wall of the retraction sleeve 10 in this situation so they cannot flex outward and slip past the first shoulder 19.

**[0048]** The syringe carrier 7 is engaged for joint axial movement with a syringe holder 22 which is slidably arranged in the retraction sleeve 10. The syringe holder 22 is provided with two or more resilient syringe holder arms 23 arranged distally. The syringe holder arms 23 have a respective inclined surface for bearing against a second shoulder 24 in the plunger 9 arranged proximally from the first shoulder 19. In the initial position shown in figure 1 the syringe holder arms 23 are supported by an inner surface (not illustrated) of the housing 2 so they cannot flex outward and the second shoulder 24 cannot slip through. In order to support the syringe holder arms 23 at the housing 2 a respective number of apertures are provided in the retraction sleeve 10.

**[0049]** Two resilient first clips 2.1 are arranged in the housing 2 which engage stops 22.1 on the syringe holder 22 so as to prevent translation of the syringe holder 22, the syringe carrier 7, the syringe 3 and the needle 4 in proximal direction P. Since the syringe holder arms 23 are kept from flexing out, the load of the drive spring 8 is statically resolved through the decoupling member 14, the plunger 9 and the syringe holder 22 into the first clips 2.1 in the housing 2.

**[0050]** A lateral trigger button 20 is arranged laterally on the housing 2 with a pivot 20.1 near its proximal end. In the as delivered configuration in figure 1 the trigger button 20 is flush with the housing 2 so it cannot be depressed.

**[0051]** A skin interlock sleeve 25 is telescoped in the proximal end P of the housing 2. An interlock spring 26 for biasing the interlock sleeve 25 in proximal direction P is arranged between the housing 2 and the interlock sleeve 25. The syringe carrier 7 is telescoped in a proximal portion 25.1 of the interlock sleeve 25. A distal portion 25.2 of the interlock sleeve 25 has a greater diameter than the proximal portion 25.1. The syringe holder 22 is telescoped in the distal portion 25.2. The distal portion 25.2 exhibits a lug 25.3 and a third ramp 25.4 for interacting with the trigger button 20. The lug 25.3 is caught between two ramps 20.2, 20.3 arranged inwardly in the trigger button 20.

**[0052]** In order to start an injection the proximal end P of the auto-injector 1 has to be pressed against the injection site, e.g. a patient's skin. As a result the interlock sleeve 25 translates in distal direction D into the housing 2 (see figure 2) until the interlock sleeve 25 is flush with the proximal end P of the housing 2. The lug 25.3 also moves in distal direction D along the second ramp 20.3 of the trigger button 20 thus rotating the trigger button outwardly in such a manner that the trigger button 20 laterally emerges from the housing 2 (see fig. 2).

**[0053]** The trigger button 20 has now been moved to a position where if pushed it will release the drive spring 8 in order to insert the needle 4 into the injection site and to inject the medicament M.

**[0054]** If the auto-injector 1 is removed from the injection site without operating the trigger button 20 the interlock sleeve 25 will translate back into its proximal position under load of the interlock spring 26. The lug 25.3 will slide along the first ramp 20.2 and pull the trigger button 20 back into the position as in figure 1.

**[0055]** The lug 25.3 is resiliently arranged in the interlock sleeve 25 in such a manner that it may be pushed radially inwards. As long as the interlock sleeve 25 is in its proximal position as in figure 1 the lug 25.3 is prevented from flexing inwards by the retraction sleeve 10. When the interlock sleeve 25 is pushed into the housing 2 as in figure 2 the lug 25.3 reaches an aperture 10.1 in the retraction sleeve 10 allowing it to flex inwards. If the interlock sleeve 25 is kept pressed against the injection site and the trigger button 20 is being depressed the lug 25.3 will be pushed inwards through the aperture 10.1. The resilience of the lug 25.3 has to be chosen so as to ensure that the force required to keep the interlock sleeve 25 pressed does not exceed a convenient level for the user since the counteracting force is the sum of the spring force of the interlock spring 26 and the force created by the lug 25.3 trying to slide along the second ramp 20.3.

**[0056]** When the lug 25.3 has entered the aperture 10.1 the skin interlock sleeve 25 is prevented from returning into its proximal position.

**[0057]** If the trigger button 20 was depressed with the interlock sleeve 25 only partially translated into the housing 2 the lug 25.3 would not yet have reached the aperture 10.1 so it could not flex inwards. Instead, depressing the trigger button 20 would force the interlock sleeve 25 back into its proximal position due to the engagement of the lug 25.3 with the second ramp 20.3.

**[0058]** When the trigger button 20 is pushed in the situation shown in figure 2, the lug 25.3 is pushed radially inwards. A pin 20.4, inwardly arranged on the trigger button 20, is pressed against the third ramp 25.4 in such a manner that the interlock sleeve 25 is translated further in distal direction D into the housing 2, as shown in Figure 3. This movement will result in a further flexing of the lug 25.3, as it slides along the second ramp 20.3. This position cannot be reached by just pushing the interlock sleeve 25 against the injection site. A distal end of the distal portion 25.2 now reaches the clips 2.1 and pushes them outwards thus decoupling the syringe holder 22 from the housing 2 and releasing the drive spring 8.

**[0059]** The second shoulder 24 pushes the syringe holder 22, syringe carrier 7 and syringe 3 forward in proximal direction P while no load is exerted onto the stopper 6. The hollow needle 4 appears from the proximal end P and is inserted into the injection site.

**[0060]** The forward movement continues until the syringe holder 22 bottoms out at a front face 35 of the retraction sleeve 10. The travel from the initial position up to this point defines an injection depth, i.e. needle insertion depth.

**[0061]** When the syringe holder 22 has nearly bottomed out, the resilient syringe holder arms 23 have reached a widened portion 2.2 of the housing 2 where they are no longer supported by the inner wall of the housing 2. However, since the force required to insert the needle 4 is relatively low the second shoulder 24 will continue to drive forward the syringe holder 22 until proximal travel is halted at the front face 35. At this point the syringe holder arms 23 are flexed out by the continued force of the second shoulder 24 and allow it to slip through. Now the plunger 9 no longer pushes against the syringe holder 22 but against the stopper 6 for expelling the medicament M from the syringe 3 and injecting it into or through the patient's skin.

**[0062]** When the stopper 6 has nearly bottomed out in the syringe 3 the decoupling member 14 has reached a position where it pushes against the latches 12 in a manner to decouple the retraction sleeve 10 from the housing 2. Thus the drive spring 8 is no longer grounded with its distal end in the housing 2 by the latches 12. Instead, as soon as the decoupling member 14 has bottomed out at a second abutment 33 in the housing 2 the proximal end of the drive spring 8 gets grounded in the housing 2 while its distal end is pulling the retraction sleeve 10 in distal direction D.

**[0063]** Just before the decoupling member 14 decouples the retraction sleeve 10 from the housing 2 the decoupling arms 18 reach an aperture 10.1, 10.2 in the retraction sleeve 10 so they are no longer kept from being flexed outward. The decoupling arms 18 are thus pushed

outward by the first shoulder 19 pushing against its ramped surfaces so the first shoulder 19 can slip through in distal direction D as soon as the decoupling member 14 has hit the second abutment 33.

**[0064]** Although the latches 12 are disengaged now, the retraction sleeve 10 may not yet slide in distal direction D because of the lug 25.3 engaged in the aperture 10.1 so the retraction sleeve 10 is trying to pull the interlock sleeve 25 in distal direction D which is prevented by the third ramp 25.4 distally abutting against the housing 2.

**[0065]** If the auto-injector 1 is taken away from the injection site and the user releases the trigger button 20 the lug 25.3 re-emerges from inside the retraction sleeve 10 so the retraction sleeve 10 gets disengaged from the interlock sleeve 25 and may now translate in distal direction D. A spring means may be arranged for actively pulling the trigger button 20 outwards in this situation. In an alternative embodiment the lug 25.3 may project outwards with an inclination in proximal direction P so as to allow the retraction sleeve 10 to push it outwards on retraction.

**[0066]** The syringe holder 22 is taken along in distal direction D by the retraction sleeve 10, e.g. by a front face 35. Thus the syringe 3 and needle 4 are retracted into a safe position inside the housing 2, e.g. into the initial position. The plunger 9, no longer bearing against the decoupling arms 18 is pulled back, too.

**[0067]** The housing 2 may have at least one viewing window for inspecting the syringe 3.

**[0068]** The auto-injector 1 may preferably be used for subcutaneous or intra-muscular injection, particularly for delivering one of an analgetic, an anticoagulant, insulin, an insulin derivate, heparin, Lovenox, a vaccine, a growth hormone, a peptide hormone, a proteine, antibodies and complex carbohydrates.

## **List of References**

**[0069]**

- 1  
auto-injector
- 2  
housing
- 2.1  
first clip
- 2.2  
widened portion
- 3  
syringe

|      |                   |
|------|-------------------|
| 4    | hollow needle     |
| 6    | stopper           |
| 7    | syringe carrier   |
| 8    | drive spring      |
| 9    | plunger           |
| 10   | retraction sleeve |
| 10.1 | aperture          |
| 10.2 | aperture          |
| 11   | stop              |
| 12   | latch             |
| 13   | end face          |
| 14   | decoupling member |
| 17   | thrust face       |
| 18   | decoupling arm    |
| 19   | first shoulder    |
| 20   | trigger button    |
| 20.1 | pivot             |
| 20.2 | first ramp        |
| 20.3 | second ramp       |
| 20.4 | pin               |
| 22   | syringe holder    |
| 22.1 | stop              |

|      |                                  |
|------|----------------------------------|
| 23   |                                  |
|      | syringe holder arm               |
| 24   |                                  |
|      | second shoulder                  |
| 25   |                                  |
|      | interlock sleeve                 |
| 25.1 |                                  |
|      | proximal portion                 |
| 25.2 |                                  |
|      | distal portion                   |
| 25.3 |                                  |
|      | lug                              |
| 25.4 |                                  |
|      | third ramp                       |
| 26   |                                  |
|      | interlock spring                 |
| 32   |                                  |
|      | first abutment                   |
| 33   |                                  |
|      | second abutment                  |
| 35   |                                  |
|      | front face                       |
| D    |                                  |
|      | distal end, distal direction     |
| M    |                                  |
|      | medicament                       |
| P    |                                  |
|      | proximal end, proximal direction |

## **REFERENCES CITED IN THE DESCRIPTION**

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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- US5267963A [0011]

## Patentkrav

1. Autoinjektor (1) til indgivelse af en dosis af flydende lægemiddel (M), hvilken autoinjektor omfatter:

- 5 - et aflangt hus (2), der er indrettet til at indeholde en sprøjte (3) med en hul kanylen (4) og en prop (6) til forsegling af sprøjten (3) og fortrængning af lægemidlet (M), idet huset (2) har en distal ende (D) og en proksimal ende (P) med en åbning, der er beregnet til at påtrykkes mod et injektionssted, hvor sprøjten (3) er glideligt indrettet i forhold til huset (2),
- 10 - et fjedermiddel (8), som efter aktivering er i stand til:
- at skubbe kanylen (4) fra en tildækket position inden i huset (2) til en fremtrukket position gennem åbningen og forbi den proksimale ende (P),
  - at betjene sprøjten (3) for at afgive dosen af lægemiddel (M), og
  - at trække sprøjten (3) med kanylen (4) tilbage i den tildækkede position efter afgivelse af lægemidlet (M),
- 20 - et aktiveringsmiddel (20), der er indrettet til at låse fjedermidlet (8) i en tryksat tilstand forud for manuel betjening, og som er i stand til efter manuel betjening at frigøre fjedermidlet (8) med henblik på injektion, hvor fjedermidlet (8) er en enkelt drivfjeder (8) i form af en kompressionsfjeder, der er indrettet til at være grundfæstet i den distale ende i huset (2), for at bevæge kanylen (4) fremad og for at indsprøjte dosen af lægemiddel (M) via et stempel (9), og hvor drivfjederen (8) er indrettet til at få sin grundfæstning i huset (2) skiftet til dets proksimale ende for
- 25 at trække sprøjten (3) tilbage, kendetegnet ved, at aktiveringsmidlet (20) er indrettet som en udløsningsknap (20), der er indrettet på siden af huset (2).
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2. Autoinjektor (1) ifølge krav 1, kendetegnet ved, at udløsningsknappen (20) er pivoteret i huset (2) og indrettet til at drejes, når den betjenes.

3. Autoinjektor (1) ifølge et af kravene 1 eller 2,

kendetegnet ved, at en interlock-bøsning (25) er teleskopisk anbragt i den proksimale ende (P) af huset (2), idet interlock-bøsningen (25) er forskydelig i længderetningen mellem en proksimal position og en distal position og  
5 skråtstillet i en proksimal retning (P), på en sådan måde at den rager ud af huset (2) i den proksimale position, hvor interlock-bøsningen (25) er indrettet til at forskydes fra sin proksimale position til en mellemliggende position, når den trykkes mod injektionsstedet, hvor udløsningsknappen (20) er  
10 indrettet til at skubbe interlock-bøsningen (25) fra den mellemliggende position til den distale position, hvorved drivfjederen (8) frigøres.

4. Autoinjektor (1) ifølge krav 3, kendetegnet ved, at  
15 interlock-bøsningen (25) i sin proksimale position er indrettet til at holde udløsningsknappen (20) i en nedtrykket position, hvor forskydning af interlock-bøsningen (25) til den mellemliggende position får udløsningsknappen til at komme frem af huset (2) til en klar-position.

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5. Autoinjektor (1) ifølge et af kravene 3 eller 4, kendetegnet ved, at interlock-bøsningen (25) i sin mellemliggende og/eller distale position er indrettet til at forhindre frigørelse af drivfjederens (8) distale  
25 grundfæstning.

6. Autoinjektor (1) ifølge et af kravene 3 til 5, kendetegnet ved, at en tilbagetrækningsbøsning (10) er aksialt bevægeligt indrettet i huset (2), hvor drivfjederen (8) er  
30 indrettet inden i tilbagetrækningsbøsningen (10) med sin distale ende liggende an mod en distal endeflade (13) og med sin proksimale end liggende an mod en trykflade (17) af en afkoblingsdel (14), hvor en elastisk flap (25.3) på interlock-bøsningen (25) er indrettet til at bringes i indgreb med  
35 tilbagetrækningsbøsningen (10), ved at udløsningsknappen (20) trykkes ned, når interlock-bøsningen (25) er i sin mellemliggende eller distale position, således at tilbagetrækningsbøsningens (10) forskydning i distal retning

(D) forhindres.

7. Autoinjektor (1) ifølge krav 6, kendetegnet ved, at flappen (25.3) er i indgreb mellem to skråplaner (20.2, 20.3) på udløsningsknappen (20) på en sådan måde, at udløsningsknappen (20) trækkes ind i den nedtrykkede position efter interlock-bøsningens (25) forskydning til sin proksimale position, ved at flappen (25.3) glider langs det første skråplan (20.2), og at udløsningsknappen (20) skubbes til sin klar-position, ved at flappen (25.3) glider langs det andet skråplan (20.3).

8. Autoinjektor (1) ifølge et af kravene 3 til 7, kendetegnet ved, at et tredje skråplan (25.4) er indrettet på interlock-bøsningen (25) til at blive bragt i indgreb af en tap (20.4) på udløsningsknappen (20), når der trykkes på udløsningsknappen (20) med interlock-bøsningen (25) i sin mellemliggende position, således at tappen (20.4) glider langs det tredje skråplan (25.4) og forskyder interlock-bøsningen (25) til dens distale position.

9. Autoinjektor (1) ifølge et af de foregående krav, kendetegnet ved, at en rørformet sprøjtebærer (7) er indrettet til at holde sprøjten (3) og understøtte den i dens proksimale ende, idet sprøjten (3) og sprøjtebæreren (7) er indrettet med henblik på fælles aksial forskydning, hvor sprøjtebæreren (7) er teleskopisk anbragt i interlock-bøsningen (25).

10. Autoinjektor (1) ifølge et af kravene 6 til 9, kendetegnet ved, at mindst en klinke (12) er tilvejebragt til at fastholde tilbagetrækningsbøsningen (10) aksialt i en maksimalt proksimal position, hvor afkoblingsdelen er indrettet (14) til at afkoble klinken (12), når den bevæges i proksimal retning (P) til næsten en maksimalt proksimal position, hvorved tilbagetrækningsbøsningen (10) tillades at bevæge sig i distal retning (D) og trække kanylen (4) tilbage.

11. Autoinjektor (1) ifølge et af kravene 6 til 10,

kendetegnet ved, at mindst to elastiske afkoblingsarme (18) er indrettet ved afkoblingsdelen (14), idet afkoblingsarmene (18) har indre skrånende overflader, der ligger an mod en første ansats (19) af stemplet (9) i proksimal retning (P), hvor de elastiske afkoblingsarme (18) kan være båret af en indervæg af tilbagetrækningsbøsningen (10) for at forhindre afkoblingsarmene (18) i at blive bøjet udad og glide forbi den første ansats (19), og hvor mindst en åbning (10.1, 10.2) er indrettet i tilbagetrækningsbøsningen (10) for at tillade afkoblingsarmene (18) at blive bøjet udad af den første ansats (19), hvorved den første ansats (19) tillades at glide gennem afkoblingsarmene (18) i proksimal retning (P), hvor stemplet (9) er indrettet til at skubbe sprøjten (3) og/eller proppen (6) i proksimal retning (P).

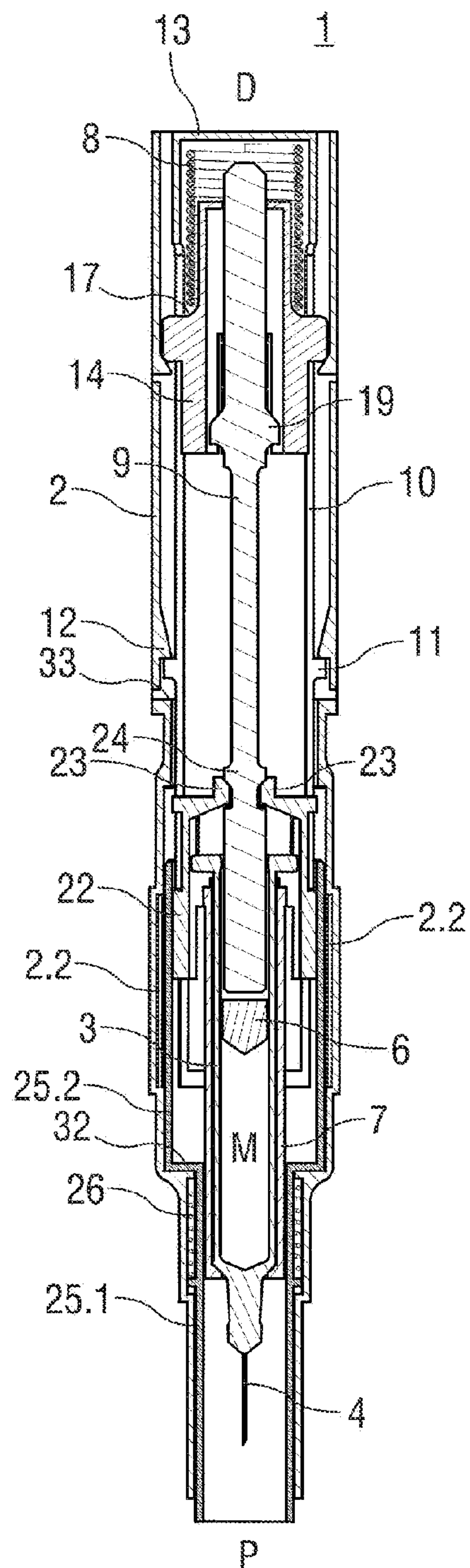
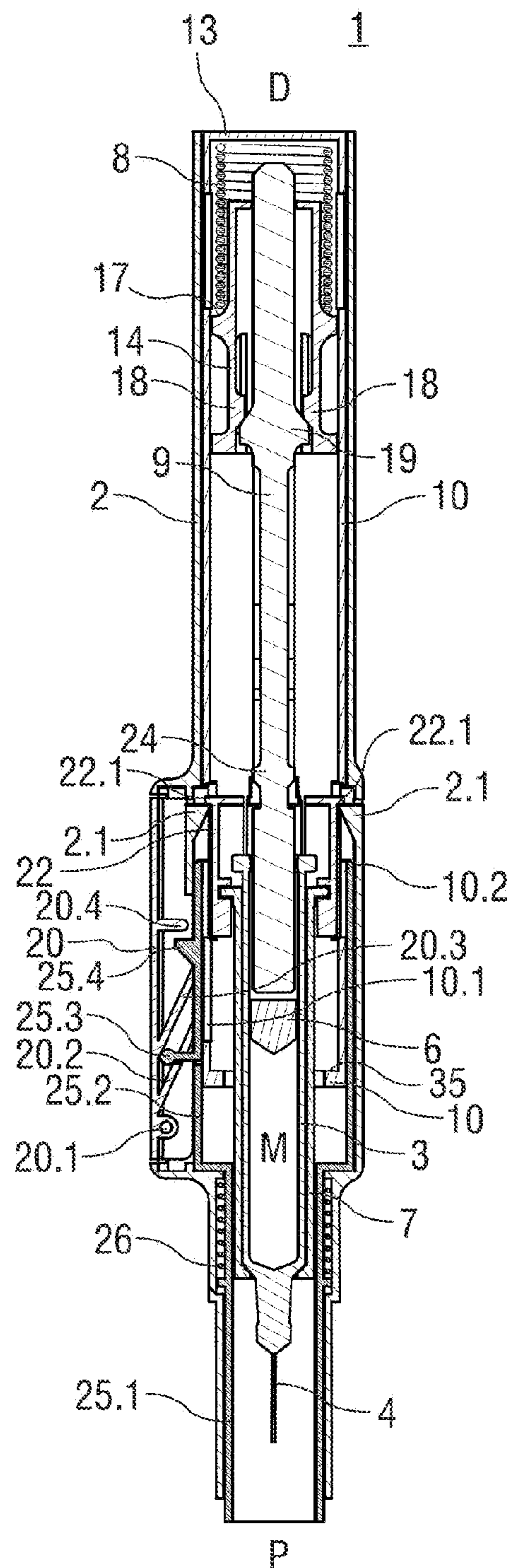
12. Autoinjektor (1) ifølge et af kravene 6 til 11, kendetegnet ved, at sprøjten (4) er indrettet med henblik på fælles aksial bevægelse med en sprøjteholder (22), som er glideligt indrettet i tilbagetrækningsbøsningen (10), hvor sprøjteholderen (22) er udstyret med mindst to distalt indrettede elastiske sprøjteholderarme (23), idet sprøjteholderarmene (23) har en henholdsvis hældende overflade til at ligge an mod en anden ansats (24), som er indrettet ved stemplet (9) proksimalt i forhold til den første ansats (19), hvor sprøjteholderarmene (23) kan være båret af en inderflade af huset (2) for at forhindre dem i at blive bøjet udad, og hvor en udvidet del (2.2) er tilvejebragt i huset (2) for at tillade sprøjteholderarmene (23) at bøje udad, når sprøjteholderen (22) næsten har nået en maksimalt proksimal position, hvorved den anden ansats (24) tillades at glide gennem sprøjteholderarmene (23) og skifte drivfjederens (8) påvirkning fra sprøjten (3) til proppen (6).

13. Autoinjektor (1) ifølge krav 12, kendetegnet ved, at sprøjteholderen (22) har mindst et stop (22.1) til at bringes i indgreb af en første elastisk clips (2.1) på huset (2) på en måde, der forhindrer forskydning af sprøjteholderen (22) i proksimal retning (P), hvor den første clips (2.1) er

indrettet til at afkoble fra stoppet (22.1) efter interlock-bøsningens (25) forskydning til sin distale position.

14. Autoinjektor (1) ifølge et af kravene 3 til 13, 5 kendetegnet ved, at en hætte er tilvejebragt i den proksimale ende (P) af huset (2), hvor en blikclips er fastgjort til hættens med henblik på fælles aksial bevægelse og uafhængig rotation, idet blikclipsen er indrettet til at strække sig gennem en åbning ind i interlock-bøsningen (25), når hættens 10 fastgjort til interlock-bøsningen (25), hvor blikclipsen indbefatter mindst to pigge, der er klikket ind i en omkredsnot eller bag en ansats af en beskyttende kanyleafskærmning, der er fastgjort til den hule kanyle (4).
- 15 15. Autoinjektor (1) ifølge krav 14, kendetegnet ved, at hættens kan fastgøres til interlock-bøsningen (25) ved hjælp af en skrueforbindelse.

# DRAWINGS



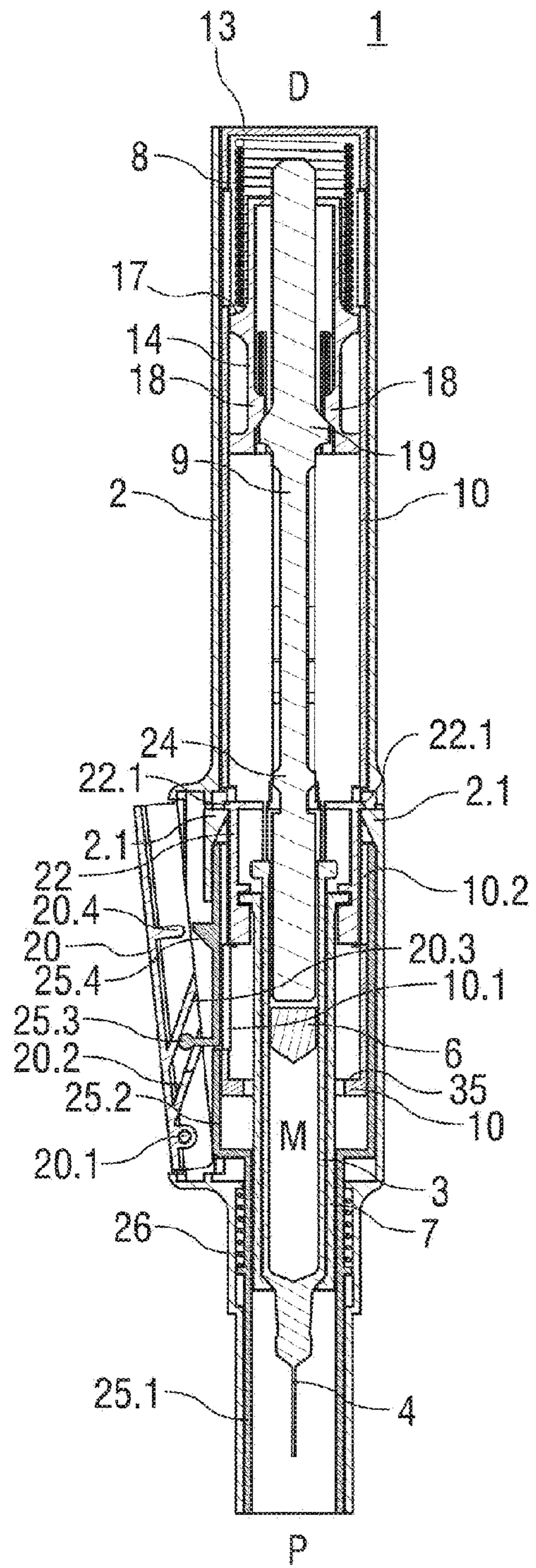


FIG 2

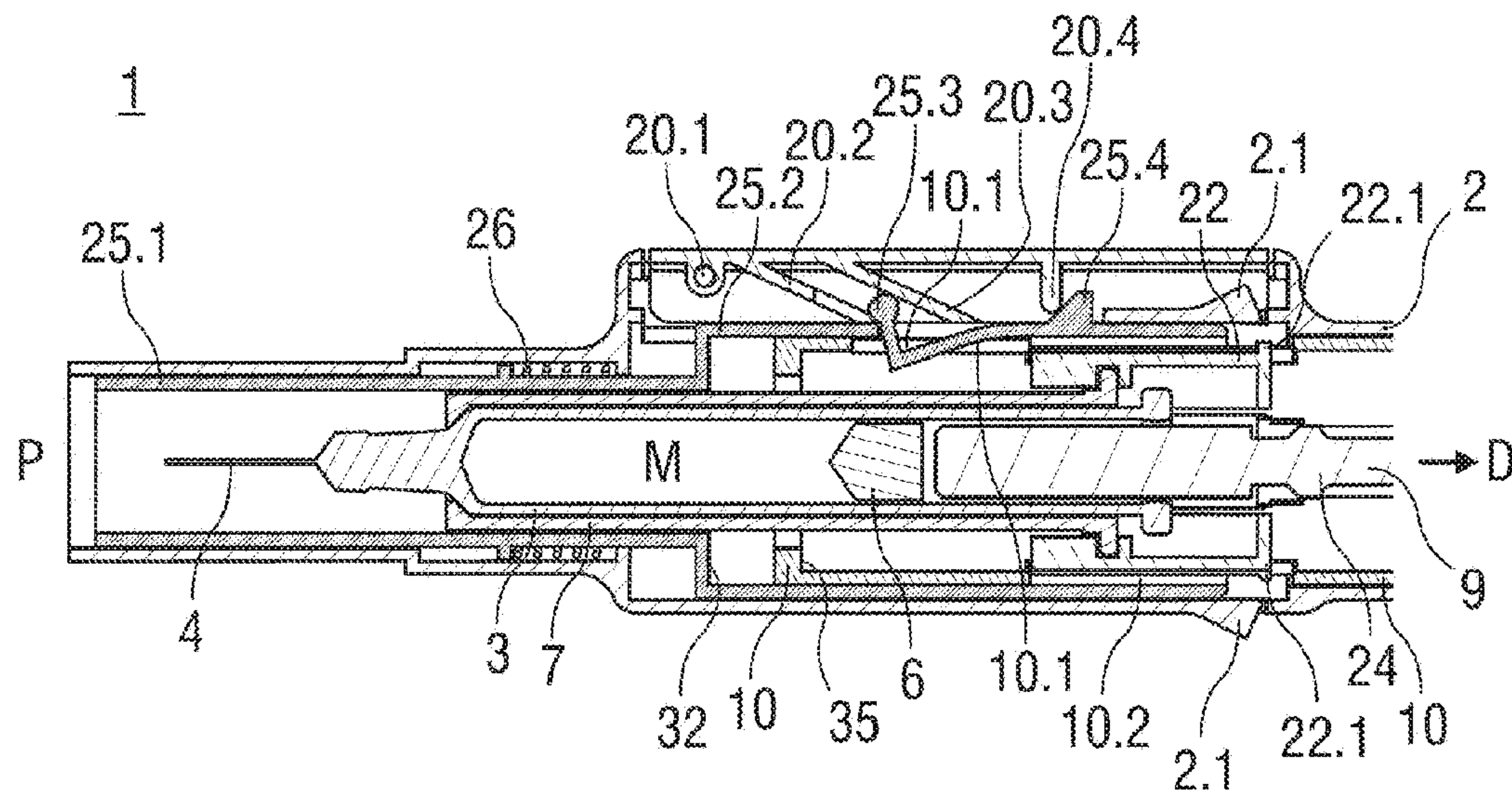


FIG 3