(19) DANMARK

(10) DK/EP 1755709 T4

Patent- og Varemærkestyrelsen

(12) Oversættelse af ændret europæisk patentskrift

(51) Int.Cl.: ***A 61 M 5/20 (2006.01)***

(45) Oversættelsen bekendtgjort den: **2016-01-18**

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om opretholdelse af patentet i ændret form: **2015-09-30**

(86) Europæisk ansøgning nr.: **05747012.2**

(86) Europæisk indleveringsdag: **2005-05-27**

(87) Den europæiske ansøgnings publiceringsdag: **2007-02-28**

(86) International ansøgning nr.: **GB2005002126**

(87) Internationalt publikationsnr.: **WO2005115510**

(30) Prioritet: **2004-05-28 GB 0412055**

(84) Designerede stater: **AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR**

(73) Patenthaver: **Cilag GmbH International, Gubelstrasse 34, 6300 Zug, Schweiz**

(72) Opfinder: **BARROW-WILLIAMS, Tim, 200 London Road, St Albans, Hertfordshire AL1 1PL, Storbritannien**
HABESHAW, Rosie, 84a Blinco Grove, Cambridge CB1 7TS, Storbritannien

(74) Fuldmægtig i Danmark: **Budde Schou A/S, Hausergade 3, 1128 København K, Danmark**

(54) Benævnelse: **Injektionsindretning**

(56) Fremdragne publikationer:
WO-A-03/041768
DE-A1- 10 137 962
US-A- 4 194 505
US-A- 5 681 291
US-A- 5 704 911
US-A1- 2001 005 781
US-A1- 2002 183 690
US-A1- 2003 196 928
US-B1- 6 203 530
US-B1- 6 939 319
US-A1- 2001 051 789
US-A1- 2003 199 814

DESCRIPTION

Background Technology

[0001] The present invention relates to an injection device of the type that receives a syringe, extends it, discharges its contents and then retracts it automatically. Devices of this general description are shown in WO 95/35126 and EP-A-0 516 473 and tend to employ a drive spring and some form of release mechanism that releases the syringe from the influence of the drive spring once its contents are supposed to have been discharged, to allow it to be retracted by a return spring. The initial action of the drive spring is typically controlled by means of a trigger. Depression of the trigger causes the drive spring to become operative. US 4,194,505 describes an injection device which includes a trigger integrated with a safety element which prevents operation of the trigger when the safety device is engaged.

[0002] US 2001/005781 discloses an autoinjector for replaceable containers of syringe type, comprising a barrel of axially roughly constant cross-section, a front opening with or for an injection needle and at least one movable rear piston, optionally with a plunger connected thereto, inserted in the barrel for the displacement of a container content.

[0003] US 5,704,911 discloses s system which includes a spring actuated needleless hypodermic injector device for injecting medication through the skin.

[0004] WO 03/041768 discloses an anaesthesia syringe that has a control unit for controlling the injection process.

[0005] DE 10137 962 discloses an ampule for an injection device, comprising a plug which closes the chamber holding injection medium, and is penetrated by a hollow needle to produce a channel between the chamber interior and the injection nozzle.

[0006] US 6,939,319 discloses a manually or pneumatic operated injector which includes safety interlock features.

[0007] It is not uncommon for the operation of the trigger to be dependent upon the operation of a safety interlock, to prevent accidental operation. First the safety interlock must be operated, and then the trigger. Market research has shown that it is beneficial for an injector device to provide some form of visual indication that the device is either ready to use or has been used. As ever, the simplest and cheapest way of achieving this is sought.

Summary of the Invention

[0008] The injection devices of the present invention are designed to do this.

[0009] An injection device according to the present invention is defined in claim 1.

[0010] Thus, a device according to this invention provides a visual indication that it is either ready to use or has been used.

[0011] If such a device is ready for use, the trigger will be in its rest position. If it has been used, the trigger will be in its active position. These positions can be discriminated by the user. Moreover, the device incorporates the mechanism for achieving this result into a safety interlock mechanism, in the interests of simplicity. The trigger may comprise a locking member that, in the rest position of the trigger, engages a locking surface of the drive and, in the active position, does not.

[0012] The interlock member may comprises a primary member, the locking position of the interlock member being one in which the primary member projects from the discharge opening and the releasing position being one in which the primary member does not project from the discharge opening or projects from it to a lesser extent. This means that the interlock member may be moved from its locking position to its releasing position by bringing the end of the injection device into contact with the skin at the injection site. Apart from anything else, this ensures that the injection device is optimally positioned relative to the injection site before the injection cycle can begin. A primary member in the form of a sleeve allows a relatively large area to contact the skin and allows the discharge nozzle of the syringe to be advanced and retracted within it. In the case of a hypodermic syringe, the sleeve will shroud the needle from view, which is a good idea for the squeamish, particularly those who have to administer to themselves.

[0013] The locking of the trigger in its rest position may be achieved as follows. The trigger and the interlock member include a

projection and an aperture, the projection being in register with the aperture when the interlock member is in its releasing position, but not otherwise. This allows the trigger to move from its rest position to its active position by movement of the projection into the aperture. The projection may be on the trigger and the aperture is in the interlock member.

Brief Description of the Drawings

[0014] The invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 shows in section an injection device of the type to which the present invention is applicable;

Figure 2 shows in sectional schematic how that device may be modified in accordance with the invention;

Figure 3 is a cut-away view of the modified injection device; and

Figure 4 shows in section a preferred injection device.

Detailed Description

[0015] Fig. 1 shows an injection device 110 having a housing 112 that contains a hypodermic syringe 114 of conventional type, including a syringe body 116 terminating at one end in a hypodermic needle 118 and at the other in a flange 120. The conventional plunger that would normally be used to discharge the contents of the syringe 114 manually have been removed and replaced with a drive element 134, terminating in a bung 122. The bung 122 constrains a drug 124 to be administered within the syringe body 116. Whilst the syringe illustrated is of hypodermic type, this need not necessarily be so. Transcutaneous or ballistic dermal and subcutaneous syringes may also be used with the injection device of the present invention. As illustrated, the housing includes a return spring 126 that biases the syringe 114 from an extended position in which the needle 118 extends from an aperture 128 in the housing 112 to a retracted position in which the discharge nozzle 118 is contained within the housing 112. The return spring 126 acts on the syringe 114 via a syringe carrier 127.

[0016] At the other end of the housing is an actuator, which here takes the form of a compression drive spring 130. Drive from the drive spring 130 is transmitted via a multi-component drive to the syringe 114 to advance it from its retracted position to its extended position and discharge its contents through the needle 118. The drive accomplishes this task by acting directly on the drug 124 and the syringe 114. Hydrostatic forces acting through the drug and, to a lesser extent, static friction between the drive element 134 and the syringe body 116 initially ensure that they advance together, until the return spring 126 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion.

[0017] The multi-component drive between the drive spring 130 and the syringe 114 consists of three principal components. A drive sleeve 131 takes drive from the drive spring 130 and transmits it to flexible latch arms 133 on a first drive element 132. This in turn transmits drive via flexible latch arms 135 to a second drive element, the drive element 134 already mentioned.

[0018] The first drive element 132 includes a hollow stem 140, the inner cavity of which forms a collection chamber 142 in communication with a vent 144 that extends from the collection chamber through the end of the stem 140. The second drive element 134 includes a blind bore 146 that is open at one end to receive the stem 140 and closed at the other. As can be seen, the bore 146 and the stem 140 defining a fluid reservoir 148, within which a damping fluid is contained.

[0019] A trigger (not shown) is provided that, when operated, serves to decouple the drive sleeve 131 from the housing 112, allowing it to move relative to the housing 112 under the influence of the drive spring 130. The operation of the device is then as follows.

[0020] Initially, the drive spring 130 moves the drive sleeve 131, the drive sleeve 131 moves the first drive element 32 and the first drive element 132 moves the second drive element 134, in each case by acting through the flexible latch arms 133, 135. The second drive element 134 moves and, by virtue of static friction and hydrostatic forces acting through the drug 124 to be administered, moves the syringe body 116 against the action of the return spring 126. The return spring 126 compresses and the hypodermic needle 118 emerges from the exit aperture 128 of the housing 112. This continues until the return spring 126 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion. Because the static friction between the second drive element 134 and the syringe body 116 and the hydrostatic forces acting through the drug 124 to be

administered are not sufficient to resist the full drive force developed by the drive spring 130, at this point the second drive element 134 begins to move within the syringe body 116 and the drug 124 begins to be discharged. Dynamic friction between the second drive element 134 and the syringe body 116 and hydrostatic forces acting through the drug 124 to be administered are, however, sufficient to retain the return spring 126 in its compressed state, so the hypodermic needle 118 remains extended.

[0021] Before the second drive element 134 reaches the end of its travel within the syringe body 116, so before the contents of the syringe have fully discharged, the flexible latch arms 135 linking the first and second drive elements 132, 134 reach a constriction 137 within the housing 112. The constriction 137 moves the flexible latch arms 135 inwards from the position shown to a position at which they no longer couple the first drive element 136 to the second drive element 134, aided by the bevelled surfaces on the constriction 137. Once this happens, the first drive element 136 acts no longer on the second drive element 134, allowing the first drive element 132 to move relative to the second drive element 134.

[0022] Because the damping fluid is contained within a reservoir 148 defined between the end of the first drive element 132 and the blind bore 146 in the second drive element 134, the volume of the reservoir 146 will tend to decrease as the first drive element 132 moves relative to the second drive element 134 when the former is acted upon by the drive spring 130. As the reservoir 148 collapses, damping fluid is forced through the vent 144 into the collection chamber 142. Thus, once the flexible latch arms 135 have been released, the force exerted by the drive spring 130 does work on the damping fluid, causing it to flow though the constriction formed by the vent 144 and also acts hydrostatically through the fluid and through friction between the first and second drive elements 132, 134, thence via the second drive element 134. Losses associated with the flow of the damping fluid do not attenuate the force acting on the body of the syringe to a great extent. Thus, the return spring 126 remains compressed and the hypodermic needle remains extended.

[0023] After a time, the second drive element 134 completes its travel within the syringe body 116 and can go no further. At this point, the contents of the syringe 114 are completely discharged and the force exerted by the drive spring 130 acts to retain the second drive element 134 in its terminal position and to continue to cause the damping fluid to flow though the vent 144, allowing the first drive element 132 to continue its movement.

[0024] Before the reservoir 148 of fluid is exhausted, the flexible latch arms 133 linking the drive sleeve 131 with the first drive element 132. reach another constriction 139 within the housing 112. The constriction 139 moves the flexible latch arms 133 inwards from the position shown to a position at which they no longer couple the drive sleeve 131 to the first drive element 132, aided by the bevelled surfaces on the constriction 139. Once this happens, the drive sleeve 131 acts no longer on the first drive element 132, allowing them to move relative each other. At this point, of course, the syringe 114 is released, because the forces developed by the drive spring 130 are no longer being transmitted to the syringe 114, and the only force acting on the syringe will be the return force from the return spring 126. Thus, the syringe 114 is now returned to its retracted position and the injection cycle is complete.

[0025] All this takes place, of course, only once the cap 111 has been removed from the end of the housing 112. As can be seen from fig. 3, the end of the syringe is sealed with a boot 123. The central boss 121 of the cap that fits within the sleeve 119 when the cap 111 is installed on the housing 112, is hollow at the end and the lip 125 of the hollow end is bevelled on its leading edge 157, but not its trailing edge. Thus, as the cap 111 is installed, the leading edge 157 of the lip 125 rides over a shoulder 159 on the boot 123. However, as the cap 111 is removed, the trailing edge of the lip 125 will not ride over the shoulder 159, which means that the boot 123 is pulled off the syringe 114 as the cap 111 is removed.

[0026] Figs. 2 and 3 show the device may be further modified. Although figs. 2 and 3 differ from fig. 1 in some details, the principles now discussed are applicable to the device shown in fig. 1. As can be seen, the device includes a trigger 300 having a button 302 at one end and a pair of lugs 304 that cooperate with pins (not shown) on the inside of the housing 112 to allow the trigger to pivot about an axis through the two lugs 304. The main body portion of the trigger 300, to which both the button 302 and the lugs 304 are affixed, forms a locking member 306. In the position shown, the end of the locking member 306 remote from the button 302 engages the end of the drive sleeve 131, against which the drive spring 130 acts and which in turn acts upon the multi-component drive previously discussed. This prevents the drive sleeve 131 from moving under the influence of the drive spring 130. When the button 302 is depressed, the trigger 300 pivots about the lugs 304, which lifts the end of the locking member 306 from its engagement with the drive sleeve 131, now allowing the drive sleeve 131 to move under the influence of the drive spring 130.

[0027] Fig. 3 shows the exit aperture 128 in the end of the housing 112, from which the end of the sleeve 119 can again be seen to emerge. As is shown in fig. 2, the sleeve 119 is coupled to a button lock 310 which moves together with the sleeve 119. The trigger includes a stop pin 312 and the button lock 310 includes an stop aperture 314 which, as shown in fig. 2, are out of

register. They can, however, be brought into register by inward movement of the sleeve 119, which results in a corresponding movement of the button lock 310. Whilst the stop pin 312 and the stop aperture 314 are out of register, the button 302 may not be depressed; once they are in register, it may. The trigger 300 also includes a flexible, barbed latching projection 316 and the button lock 310 also includes a latching surface 318 with which the latching projection 316 engages when the button is depressed. Once the latching projection 316 has latched with the latching surface 318, the trigger 300 is permanently retained with the button 302 in its depressed position.

[0028] Thus, movement of the sleeve 119 in a direction into the housing 112, or in other words depression of the projecting end of the sleeve, brings the stop pin 312 into register with the stop aperture 314, allowing the trigger button 302 to be depressed, whereupon it is retained in its depressed position by the latching projection 316 and the latching surface 318. The sleeve 119 may be depressed by bringing the end of the injection device into contact with the skin at an injection site which, apart from anything else, ensures it is properly positioned before the injection cycle begins.

[0029] Figure 4 shows a preferred injection device 210 to which the improvements described above with reference to figures 2 and 3 are applied. Again, a housing 212 contains a hypodermic syringe 214. The syringe 214 is again of conventional type, including a syringe body 216 terminating at one end in a hypodermic needle 218 and at the other in a flange 220, and a rubber bung 222 that constraints a drug 224 to be administered within the syringe body 216. The conventional plunger that would normally be connected to the bung 222 and used to discharge the contents of the syringe 214 manually, has been removed and replaced with a multi-component drive element as will be described below. Whilst the syringe illustrated is again of hypodermic type, this need not necessarily be so. As illustrated, the housing includes a return spring 226 that biases the syringe 214 from an extended position in which the needle 218 extends from aperture 228 in the housing 212, to a retracted position in which the hypodermic needle 218 is contained within the housing 212. The return spring 226 acts on the syringe 214 via a sleeve 227.

[0030] At the other end of the housing is a compression drive spring 230. Drive from the drive spring 230 this transmitted via the multi-component drive to the syringe 214 to advance it from its retracted position to its extended position and discharge its contents through the needle 218. The drive accomplishes this task by acting directly on the drug 224 and the syringe 214. Hydrostatic forces acting through the drug 224 and, to a lesser extent, static friction between the bung 222 and the syringe body 216 initially ensure that they advance together, until the return spring 226 bottoms out or the syringe body 216 meets some other obstruction that retards its motion.

[0031] The multi component drive between the drive spring 230 and the syringe 214 again consists of three principal components. The drive sleeve 231 takes drive from the drive spring 230 and transmits it to flexible latch arms 233 on a first drive element 232. These elements are shown in detail "A". The first drive element 232 in turn transmits drive via flexible latch arms 235 to a second drive element 234. These elements are shown in detail "B". As before, the first drive element 232 includes a hollow stem 240, the inner cavity of which forms a collection chamber 242. The second drive element 234 includes a blind for 246 that is open at one end to receive the stem 240 and closed at the other. As can be seen, the bore 246 and the stem 240 define a fluid reservoir 248, within which a damping fluid is contained.

[0032] A trigger as described above with reference to figures 2 and 3 is provided in the middle of the housing 212. The trigger, one operated, serves to decouple the drive sleeve 231 from the housing 212 allowing it to move relative to the housing 212 under the influence of the drive spring 230. The operation of the device is then as follows.

[0033] Initially, the drive spring 230 moves the drive sleeve 231, the drive sleeve 231 moves the first drive element 232 and the first drive element 232 moves the second drive element 234, in each case by acting through the flexible matching arms 233, 235. The second drive element 234 moves and, by virtue of static friction and hydrostatic forces acting through the drug 224 to be administered, moves the syringe body 216 against the action of the return spring 226. The return spring 226 compresses and the hypodermic needle 218 emerges from the exit aperture 228 of the housing 212. This continues until the return spring 226 bottoms out or the syringe body 216 meets some other obstruction that retards its motion. Because the static friction between the bung 222 and the syringe body 216 and the hydrostatic forces acting through the drug 224 to be administered are not sufficient to resist the full drive force developed by the drive spring 230, at this point the second drive element 234 begins to move within the syringe body 216 and the drug 224 begins to be discharged. Dynamic friction between the bung 222 and the syringe body 216 and hydrostatic forces acting through the drug 224 to be administered are, however, sufficient to retain the return spring 226 in its compressed state, so the hypodermic needle 218 remains extended.

[0034] Before the second drive element 234 reaches the end of its travel within the syringe body 216, so before the contents of the syringe have fully discharged, the flexible latch arms 235 linking the first and second drive elements 232, 234 reach a constriction 237. The constriction 237 is formed by a component 262 that is initially free to move relative to all other components, but that is constrained between the syringe flange 220 and additional flexible arms 247 on the second drive element 234. These

additional flexible arms 247 overlie the flexible arms 235 on the first drive element 232, by means of which drive is transmitted to the second drive element 234. Figure 3 illustrates the injection device 210 at the position where the additional flexible arms 247 are just making contact with the constriction 237 in the component 262.

[0035] The constriction 237 moves the additional flexible arms 247 inwards, aided by the bevelled surfaces on both, and the additional flexible arms 247 in turn move the flexible arms 235, by means of which drive is transmitted from the first drive element 232 to the second drive element 234, inwards from the position shown to a position at which they no longer couple the first and second drive elements together. Once this happens, the first drive element 232 acts no longer on the second drive element 234, allowing the first drive element 232 to move relative to the second drive element 234.

[0036] Because the damping fluid is contained within a reservoir 248 defined between the end of the first drive element 232 and the blind bore 246 in the second drive element 234, the volume of the reservoir 248 will tend to decrease as the first drive element 232 moves relative to the second drive element 234 when the former is acted upon by the drive spring 230. As the reservoir 248 collapses, damping fluid is forced into the collection chamber 242. Thus, once the flexible latch arms 235 have been released, the force exerted by the drive spring 230 does work on the damping fluid, causing it to flow into the collection chamber 242, and also acts hydrostatically through the fluid and through friction between the first and second drive elements 232, 234, thence via the second drive element 234. Losses associated with the flow of the damping fluid do not attenuate the force acting on the body of the syringe to a great extent. Thus, the return spring 226 remains compressed and the hypodermic needle remains extended.

[0037] After a time, the second drive element 234 completes its travel within the syringe body 216 and can go no further. At this point, the contents of the syringe 214 are completely discharged and the force exerted by the drive spring 230 acts to retain the second drive element 234 in its terminal position and to continue to cause the damping fluid to flow into the collection chamber 142, allowing the first drive element 232 to continue its movement.

[0038] A flange 270 on the rear of the second drive element 234 normally retains the flexible arms 233 in engagement with the drive sleeve 231. However, before the reservoir 248 of damping fluid is exhausted, the flexible latch arms 233 linking the drive sleeve 231 with the first drive element 232 move sufficiently far forward relative to the second drive element 234 that the flange 270 is brought to register with a rebate 272 in the flexible arms 233, whereupon it ceases to be effective in retaining the flexible arms 233 in engagement with the drive sleeve 231. Now, the drive sleeve 231 moves the flexible latch arms 233 inwards from the position shown to a position at which they no longer couple the drive sleeve 231 to the first drive element 232, aided by the bevelled latching surfaces 274 on the flexible arms 233. Once this happens, the drive sleeve 231 acts no longer on the first drive element 232, allowing them to move relative to each other. At this point, of course, the syringe 214 is released, because the forces developed by the drive spring 230 are no longer being transmitted to the syringe 214, and the only force acting on the syringe will be the return force from the return spring 226. Thus, the syringe 214 now returns to its retracted position and the injection cycle is complete.

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.

Patent documents cited in the description

- WO9535126A [0001]
- EP0516473A [0001]
- US4194505A [0001]
- US2001005781A [0002]
- US5704911A [0003]
- WO03041768A [0004]
- DE10137962 [0005]
- US6939319B [0006]

PATENTKRAV

1. Injektionsindretning (110) omfattende:

et hus (112) indrettet til at modtage en sprøjte (114) med en udløbsdyse;

et drev, som påvirkes og atter påvirker sprøjten (114);

en udløser (300), som kan bevæges fra en hvileposition, i hvilken den forårsager, at drevet tilbageholdes, til en aktiv position, i hvilken den ikke længere forårsager, at drevet således tilbageholdes, hvorved den tillader, at indholdet afgives igennem udløbsdysen; og

et låseelement (310), som er bevægeligt imellem en låsende position, i hvilken det forhindrer bevægelse af udløseren fra dennes hvileposition til dens aktive position, og en frigørende position, i hvilken den tillader bevægelse af udløseren fra dennes hvileposition til dens aktive position, hvilken indretning har en indikator til at vise, at den er blevet brugt, som tilvejebringes ved, at udløseren fastholdes i sin aktive position, og aktiveres ved, at udløseren bevæger sig til sin aktive position,

kendetegnet ved, at udløseren tilbageholdes i sin aktive position af udløseren (300) og låseelementet (310), som omfatter et låsefremspring (316) og en tilsvarende låseflade (318), imod hvilken låsefremspringet låser, når udløseren er i sin aktive position.

2. Injektionsindretning (110) ifølge krav 1, i hvilken udløseren omfatter et låseelement (306), som, i hvilepositionen for udløseren, er i indgreb med en låseflade i drevet, men ikke i den aktive position.

3. Injektionsindretning (110) ifølge krav 2, i hvilken låseelementet omfatter et primært element (119), låsepositionen for låseelementet er én, i hvilken det primære element stikker ud fra udløbsåbningen (128), og den frigørende position er én, i hvilken det primære element ikke stikker ud fra udløbsåbningen eller stikker ud fra denne i mindre udstrækning.

4. Injektionsindretning (110) ifølge krav 3, i hvilken det primære element er en bøsning.

5. Injektionsindretning (110) ifølge ethvert af de foregående krav, i hvilken udløseren og låseelementet omfatter et fremspring (312) og en åbning (314), idet fremspringet er ud for åbningen, når låseelementet er i sin frigørende position, men ikke i øvrigt, hvorved

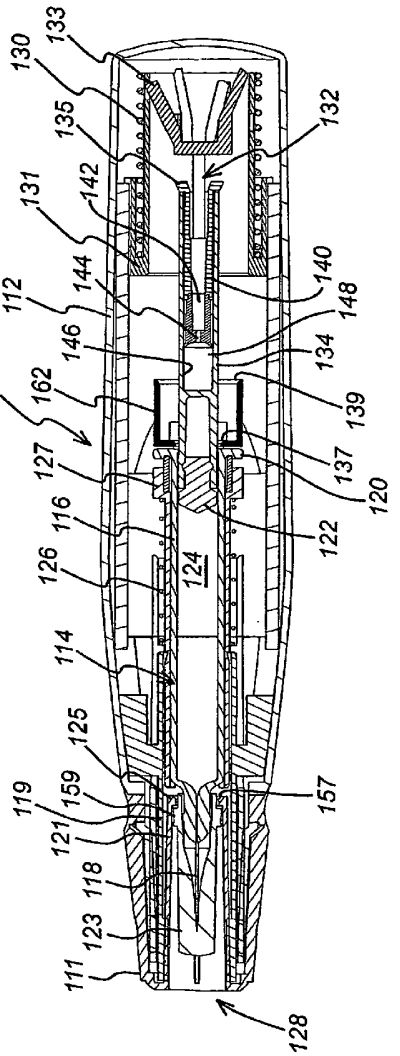
den tillader, at udløseren bevæger sig fra sin hvileposition til sin aktive position ved bevægelse af fremspringet ind i åbningen.

6. Injektionsindretning (110) ifølge krav 5, i hvilken fremspringet er på udløseren, og åbningen er i låseelementet.

7. Injektionsindretning (110) ifølge ethvert af de foregående krav, i hvilken låsefremspringet er på udløseren.

DRAWINGS

FIG. 1



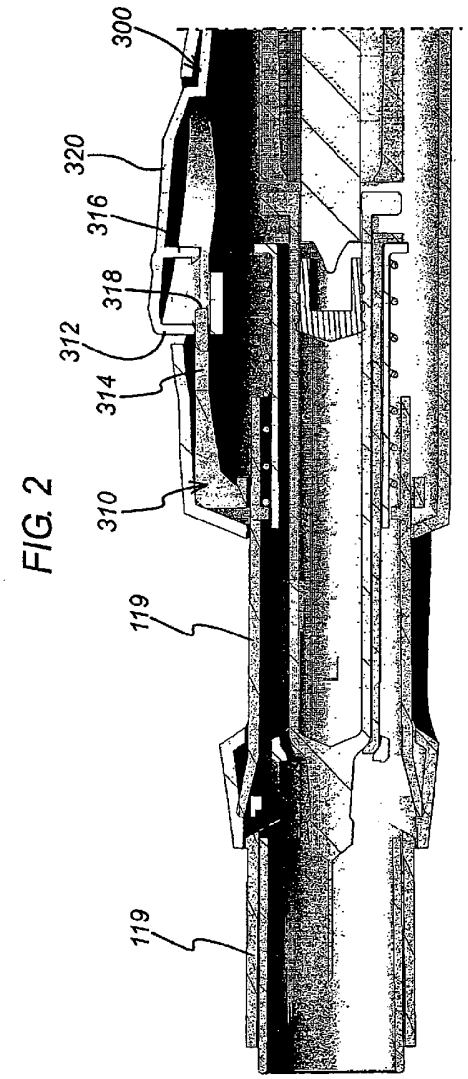


FIG. 2

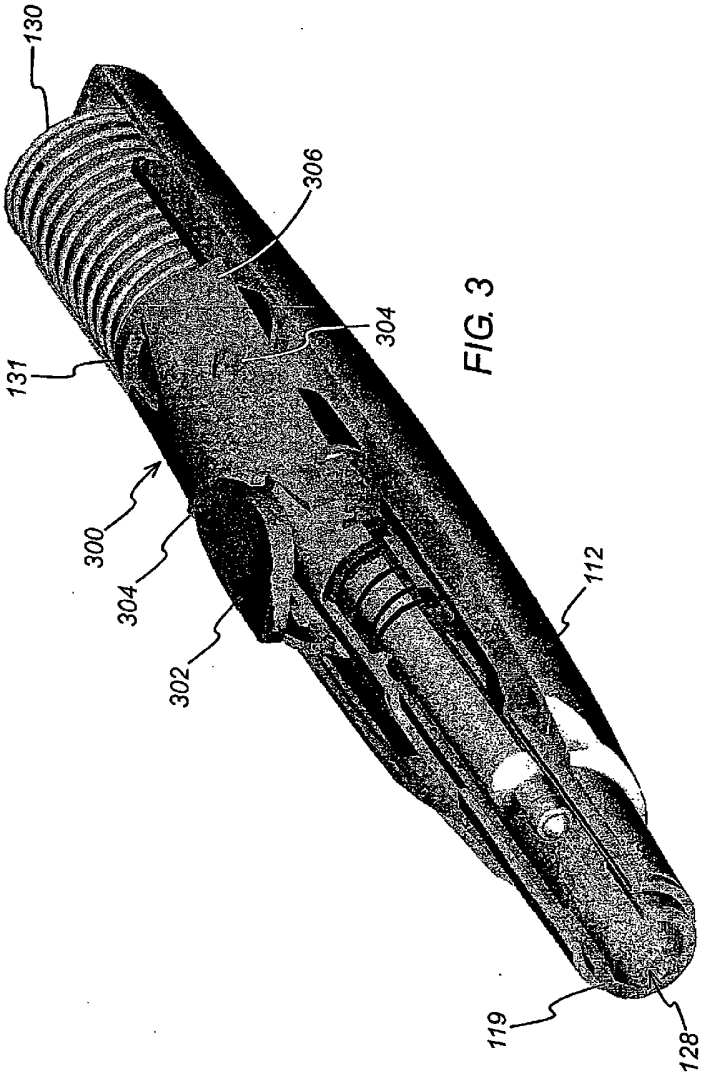


FIG. 3

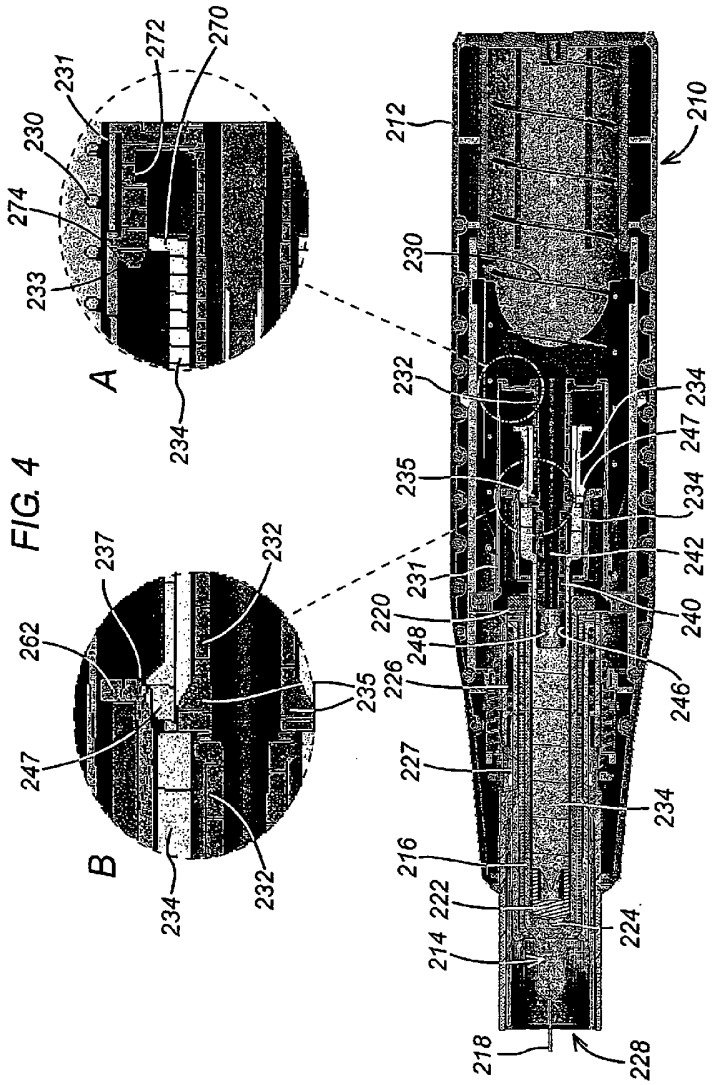

A
B
210
212
230
231
232
233
234
235
237
242
246
247
248
262
270
272
274
220
226
227
216
222
224
214
218
228

FIG. 4