(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 December 2009 (23.12.2009)

PCT

(10) International Publication Number
WO 2009/153540 A1

(51) International Patent Classification:
A61M 5/20 (2006.01)

(21) International Application Number:
PCT/GB2009/001445

(22) International Filing Date:
10 June 2009 (10.06.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0811349.0 19 June 2008 (19.06.2008) GB

(71) Applicant *(for all designated States except US)*: **CILAG GMBH INTERNATIONAL** [CH/CH]; Landis + Gyr, Strasse 1, CH-6300 Zug (CH).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **JENNINGS, Douglas, Ivan** [GB/GB]; PA Consulting Group, Cambridge Technology Centre, Melbourn, Hertfordshire SG8 6DP (GB).

(74) Agents: **BRUNNER, John, Michael, Owen** et al.; CARPMAELS & RANSFORD, 43-45 Bloomsbury Square, London WC1A 2RA (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: REUSABLE AUTO- INJECTOR

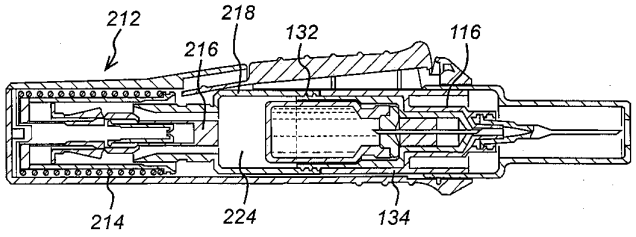


FIG. 5

(57) **Abstract**: An injection device comprises a first sub-assembly (110) comprising a chamber (112) for holding a fluid and a transfer assembly (116) moveably disposed within the chamber. The chamber comprises an exit aperture and an inner surface and the transfer assembly has an outer surface substantially in contact with the inner surface about its perimeter. The transfer assembly is adapted to transfer fluid into the chamber when the transfer assembly is moved within the chamber.

WO 2009/153540 A1

REUSABLE AUTO- INJECTOR

Field of the Invention

This invention relates to an injection device and, in particular, to a re-useable auto-injector device into which a drug may be transferred from a vial prior to subcutaneous injection into a patient.

Background of the Invention

The use of automatic injection devices (commonly known as auto-injectors) to deliver a medicament to a patient has provided many benefits over manual syringes. In particular, auto-injectors have helped to relieve the burden on hospital staff to deliver a drug to a patient because patients are able to use the devices on themselves reliably and safely and in their own home.

Known auto-injectors are described in WO 95/35126 and EP-A-0 516 473. These and similar auto-injectors are typically provided primed (i.e. pre-sprung) and ready to be used for injecting a patient. For these reasons, it is difficult to insert a drug into the auto-injector and, as a consequence, manufacturers of such auto-injectors have typically provided a pre-filled syringe for use in the auto-injector, or a complete auto-injector unit which is pre-filled with a particular drug.

This requires a more complicated and expensive manufacturing process than would be otherwise required for an auto-injector because manufacturers must also obtain and provide the drugs and maintain the facilities for storing and handling them. Furthermore, the manufacturer must operate separate production lines for each drug which is required.

Drugs for medical use are often manufactured and distributed in standard vials. In this way, drugs may be supplied in bulk conveniently and relatively cheaply, regardless of the way in which the drug is finally used.

A significant cost-saving could be made in providing an auto-injector device which is capable of drawing a drug from a standard vial rather than relying on a pre-filled syringe. Not only would such a device benefit the manufacturers, who would no longer have to provide bespoke drug-filled devices, but also hospitals, which would enjoy a simplified inventory system and could make use of the standard vials which are used on a regular basis, and patients, who could be provided with a supply of vials for self administration.

In addition, the use of vials permits the possibility of reusing a greater proportion of an auto-injector device. Typically, auto-injectors are provided in two subassemblies. The first subassembly comprises the operating mechanisms and all other reusable components and the second subassembly contains the injection components that must be replaced each time the device is used.

A major factor in the cost of the second subassembly is the provision of a chamber which is pre-filled with a drug to be injected. As explained above, providing a range of syringes is an expensive and time-consuming aspect of the manufacturing process of an auto-injector. The use of standard vials would enable this cost to be reduced.

Summary of the Invention

The present invention aims to solve the aforementioned problems. Accordingly, an injection device comprises a first sub-assembly comprising a chamber for holding a fluid, said chamber comprising an exit aperture and an inner surface; and a transfer assembly movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter, said transfer assembly being adapted to transfer fluid into the chamber when the transfer assembly is moved within the chamber.

Providing an injection device, such as an auto-injector, having a chamber into which a fluid may be transferred by a bespoke transfer assembly has at least two benefits over the prior art. Firstly, manufacturers of auto-injector devices need no longer manufacture a range of pre-filled syringes to be inserted into a reusable sub-assembly. Rather, the

manufacturer may provide instead a single type of sub-assembly in accordance with the present invention into which any variety of drug may be transferred immediately prior to injection. The single type of sub-assembly may be manufactured in bulk, thereby reducing the manufacturing costs.

This advantage leads on to a second benefit whereby the invention may be used in conjunction with any type of container from which a drug may be transferred into the chamber. In particular the invention may be used with standard vials.

Furthermore, the invention allows a greater proportion of the needle assembly to be reused. Whereas known auto-injector systems require pre-filled syringes, the capability of transferring fluid into a chamber within the needle device permits greater scope for reusability.

The volume of the chamber into which the fluid is transferred is defined by the space between the distal end of the transfer assembly and the exit aperture. Consequently, the volume is increased as the stopper is moved away from the exit aperture. The increase in volume causes an initial decrease in pressure in the chamber which thereby draws the fluid into the chamber. Of course, in alternative embodiments, an increase in chamber volume, and a corresponding effect, may be achieved by moving the transfer assembly toward the exit aperture. Other embodiments which achieve an increase in chamber volume to draw fluid into the chamber are also envisaged.

Preferably, the transfer assembly is adapted to transfer fluid into the chamber when the transfer assembly is moved with respect to the chamber away from the exit aperture.

Optionally, the transfer assembly is adapted to receive a fluid container. In such an embodiment, the assembly may be further adapted to transfer fluid from the container into the chamber when it is moved, with respect to the chamber, away from the exit aperture. Using containers as a source of fluid provides additional benefits. It is straightforward to obtain, install and replace a container of fluid to be injected, and different fluids can be provided without any modification of the device. Other methods

of providing a fluid source are contemplated, but inserting a fluid container directly into the transfer assembly is straightforward and reduces number of components required. Other approaches, such as providing a fluid pathway to a container situated elsewhere on the device, may provide additional benefits in terms of accessibility, for example.

Suitable containers may include any container configured to contain a drug and interface in some manner with the transfer assembly. Thus, a standard vial used to contain and transport fluid medicaments may be used in combination with this invention. In this manner, the cost of providing an auto-injector system is greatly reduced as the process of transferring the drug into a syringe may be performed entirely by the patient, and standard vials are easy to obtain and low in cost.

In certain embodiments, the transfer assembly may comprise a hollow fluid transfer needle adapted to engage the fluid container to form a fluid pathway from the container into the chamber through the hollow needle. Alternatively, the needle may comprise a fluid passageway including a unidirectional valve. This would enable transfer into, but not out of, the chamber.

Typically, containers used to contain drugs are provided with piercable foil or rubber caps. A hollow needle, provided on the transfer assembly and configured to pierce the cap, may form part of the fluid conduit between the container and the chamber. Of course, a needle is merely preferred. Other means may be provided according to the particular configuration of the container. For example, if the container were to comprise a valve, the means for transferring fluid into the chamber may comprise a hollow passage connected to the valve by a fluid tight seal. Other embodiments comprising a means for transferring fluid from the container are also envisaged.

Optionally, the transfer assembly may comprise a stopper for blocking fluid movement out of the transfer assembly. In such embodiments, the fluid transfer needle is adapted to pierce the stopper to deliver fluid through the stopper into the chamber. The stopper provides additional benefits in maintaining a seal between the transfer assembly and the

chamber. It also prevents fluid from being transferred out of the chamber, other than through the exit aperture.

In certain embodiments, the transfer assembly includes a grip attached to the fluid transfer needle and movably disposed within the transfer assembly. The grip is adapted to move with the container as the container is inserted into the transfer assembly, thereby moving the fluid transfer needle into fluid communication with the chamber towards the exit aperture. Such embodiments improve the ease with which a fluid conduit between the container and the chamber is established. Preferably, the needle protrudes sufficiently from the grip to penetrate the cap of the container when the container is engaged with the transfer assembly. By pushing the container into the transfer assembly, the cap of the container may abut the grip and drive it, along with the needle, within the transfer assembly such that the needle pierces the stopper.

To secure a container when it is engaged with the transfer assembly, there may be provided a port having an opening adapted to receive and secure the container. The port is preferably situated at the opposite end of the transfer assembly to the end proximal the exit aperture.

In certain embodiments, the transfer assembly may be adapted to move away from the exit aperture within the chamber upon actuation of a mechanism, thereby drawing fluid into the chamber. Preferably, the mechanism is actuated by the user and the actuator in question is easily accessible on the device. More preferably, actuation is achieved by actuating part of a housing of the injector. In one embodiment, the transfer assembly is adapted to move away from the exit aperture upon rotation of the first sub-assembly. This actuation is merely preferred, however, and any mechanism which causes the transfer assembly to be moved within the chamber may be used.

In other embodiments, the injection device comprises a second sub-assembly. Optionally, the first sub-assembly and the transfer assembly are detachable from the second sub-assembly. Detachability enables certain parts of the device to be reused and others to be replaced. Preferably, the second sub-assembly is reusable. Whereas the

first sub-assembly may comprise components which must be disposed of for hygiene reasons, or because they are spent, the second sub-assembly may comprise the drive mechanism which operates the needle device.

In the above embodiment, the transfer assembly may comprise a first thread and the second sub-assembly may comprise a second thread engageable with the first thread. The provision of the threads enables the first sub-assembly to be adapted to rotate with respect to the second sub-assembly. As a result of the rotation, the second sub-assembly moves the transfer assembly within the chamber away from the exit aperture.

In other embodiments, the transfer assembly is further adapted to expel fluid held within the chamber when the transfer assembly is moved toward the exit aperture.

Brief Description of the Drawings

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

Figure 1 is a side view of a first sub-assembly for use in an auto-injector according to the present invention;

Figure 2 is a side view of the first sub-assembly of Figure 1 engaged with a vial;

Figure 3 is a second side view of the first sub-assembly engaged with the vial;

Figure 4 is a side view of the first sub-assembly being engaged with a second sub-assembly for use in an auto-injector according to the present invention;

Figure 5 is a side view of an auto-injector according to the present invention comprised of the first and second sub-assemblies;

Figure 6 is a side view of the auto-injector which has been primed by transferring fluid from the vial into the chamber;

Figure 7 is a side view of the auto-injector having been actuated to expose a needle and inject the fluid; and

Figure 8 is a side view of the auto-injector wherein the needle has been retracted following activation.

Detailed Description of the Drawings

Figures 1 to 3 illustrate a first sub-assembly 110 of an injection device 100 according to the present invention.

The first sub-assembly 110 comprises a chamber 112 for holding a fluid. The chamber 112 comprises an exit aperture 114 and an inner surface. A transfer assembly 116 is moveably disposed within the chamber 112 and has an outer surface substantially in contact with the inner surface about its perimeter. The transfer assembly 116 is adapted to transfer fluid into the chamber when the transfer assembly 116 is moved within the chamber 112, as will be described in more detail below.

The first sub-assembly 110 further comprises a support structure 134 which defines the outer perimeter of the chamber 112 and contains the transfer assembly 116. The transfer assembly 116 is configured to move within the support structure 134.

In fluid communication with the exit aperture 114 is an injection needle 136. The injection needle is configured to pierce the skin of a patient and subcutaneously inject a fluid.

The transfer assembly 116 comprises proximal and distal ends. As depicted in Figure 1, the distal end of the transfer assembly 116 is substantially in contact with the exit aperture 114.

At its proximal end, the transfer assembly comprises a port 126 adapted to receive a vial 120 comprising a cap 122 and containing a fluid 124. The port 126 is sized to accept the vial 120 and secure it within the transfer assembly 116.

At its distal end, the transfer assembly 116 comprises a stopper 128 for blocking fluid movement into and out of the transfer assembly 116. The stopper 128 is made out of rubber but other pliable materials may also be used.

The transfer assembly 116 further comprises a hollow fluid transfer needle 118. The transfer needle 118 extends from the port 126 to a position adjacent the stopper 128 and comprises proximal and distal ends configured to pierce the vial cap 120 and the stopper 128 respectively.

Surrounding the needle 118 and attached thereto is a grip 130. The grip 130, along with the needle 118, are moveable within the transfer assembly 116. As shown in Figure 1, the grip 130 protrudes into the port 126.

Figure 2 illustrates the first sub-assembly 110 engaged with the vial 120. As illustrated, the vial 120 has been engaged with the port 126 to enable the proximal end of the needle 118 to pierce the cap 122 of the vial 120, extend into the fluid 124, and form a first part of a fluid conduit between the vial 120 and the chamber 112.

Once engaged within the port, the cap 122 of the vial 120 abuts the grip 130 attached to the needle 118. The grip 130 is positioned on the needle 118 a sufficient distance from its proximal end to enable the needle 118 to pierce the cap 122 to gain access to the fluid.

As shown in Figure 3, further engagement of the vial 120 causes the cap 122 to exert a force on the grip 130 and move it, along with the needle 118, through the transfer assembly 116. This movement causes the distal end of the needle 118 to pierce the

stopper 128 to form a second part of the fluid conduit between the vial 120 and the chamber 112.

In this manner, engagement of the vial 120 with the transfer assembly 116 creates a complete fluid pathway between the vial 120 and the chamber 112, allowing fluid to be transferred there-between.

In the configuration of Figure 3, the first sub-assembly 110 is adapted to transfer fluid from the vial 120 to the chamber 112. A fluid conduit exists, by virtue of the hollow needle which has pierced the cap and the stopper, between the vial 120 and the chamber 112. Movement of the transfer assembly 116 away from the exit aperture 114 of the chamber 112 will transfer fluid from the vial 120, through the needle and into the chamber 112.

Figures 4 to 8 show the engagement of the first sub-assembly 110 with a second sub-assembly 210. Once engaged, the two sub-assemblies form an auto-injector.

The second sub-assembly 210 comprises a housing 220 and a trigger mechanism 222. Within the housing 220 there is a drive means 212 comprising a spring 214, a drive rod 216 and an engagement mechanism 218 for engaging the transfer assembly 116 to transfer fluid from the vial 120 to the chamber 112.

As can be seen in Figure 4, the transfer assembly 116 comprises a first thread 132 disposed on an outer surface of the assembly 116. The engagement mechanism 218 comprises a second thread (not shown) on an inner surface of the mechanism 218. The second thread is configured to be engageable with the first thread 132.

The second sub-assembly 210 is engaged with the first sub-assembly 110 by sliding the first sub-assembly 110 within the second sub-assembly 210 through an opening at the distal end of the second sub-assembly. The vial 120 and the transfer assembly 116 are configured to fit within the engagement mechanism 218 to bring the first and second threads into engagement. To assist proper alignment, the proximal end of the support

structure 134 is brought into contact with the distal end of the engagement mechanism 218 when the first and second sub-assemblies 110, 210 are fully engaged, as shown in Figure 5.

A recess 224 in the engagement mechanism 218 provides a space into which the vial 120 and the transfer assembly may be moved to transfer fluid from the vial to the chamber. Movement is effected by rotation of the first sub-assembly 110 in relation to the second sub-assembly 210. Rotation of the first sub-assembly 110 causes the first thread of the transfer assembly 116 to rotate in relation to the second thread of the engagement mechanism 218, thereby moving the transfer assembly 116 away from the exit aperture of the chamber 112 into the recess 224 in the engagement mechanism 218.

Figure 6 illustrates the injection device 100 wherein the transfer assembly 116 and the vial 120 have been retracted into the recess by virtue of the operation of the interconnecting first and second threads 132. As the transfer assembly 116 moves away from the exit aperture 114, the available volume of the chamber 112 increases. In the configuration depicted in Figure 6, the chamber 112 is substantially at its maximum volume.

As the volume of the chamber increases, the pressure of that volume decreases, and the pressure difference between the vial and the chamber causes fluid to be drawn from the vial, through the needle into the chamber 112. As shown, the injection device 100 is primed to enable injection of the fluid from the chamber 112, through the exit aperture into a patient.

Figures 6 to 8 illustrate the injection of the fluid, having been transferred from the vial 120 to the chamber 112, from the chamber 112 to the patient.

The auto-injector comprises a trigger 222 configured to actuate the drive means 212. Upon actuation, the drive means 212 is configured to perform two distinct steps to inject the fluid into the patient. Firstly, the drive means is configured to extend the injection assembly (comprising the drive rod 216, the engagement mechanism 218, the transfer

assembly 116, the vial 120, the support structure 134, the chamber 112, the exit aperture 112 and the delivery needle 136) toward the patient in relation to the housing 220. This step exposes at least part of the delivery needle 136 outside the housing 222, as shown in Figure 6. The support structure 134 comprises an arm 138 which abuts a flange 140 of the first sub-assembly, to prevent the injection assembly from extending further than a desired point.

Secondly, the drive means is configured to drive the transfer assembly 116 towards the exit aperture 114. As the transfer assembly is moved, the available volume inside the chamber decreases and the fluid within the chamber 112 is forced out of the exit aperture 114. The force required to pass fluid through the exit aperture 114 is less than that required to pass fluid back into the transfer needle 118. Consequently, the fluid passes from the chamber 112, through the exit aperture 114 and the injection needle 136 into the patient.

As shown in Figure 7, the second step is performed by the drive rod 216 which extends toward the patient in relation to the housing 220. The drive rod 216 contacts the vial 120 and drives it, along with the transfer assembly 116, through the chamber 112 to exert a pressure on the fluid in the chamber 112. When the pressure is sufficient, the fluid is driven out of the chamber 112, through the injection needle 136, into the patient.

Following injection of the fluid, the drive means 212 is configured to retract the needle assembly, including the needle 136, back into the housing, as depicted in Figure 8.

Once the fluid has been injected, the second sub-assembly 210 may be disassembled from the first sub-assembly 110 and reused. The first sub-assembly 110 may be discarded and a new first sub-assembly 110 provided for subsequent injections, or may be sterilised for reuse.

It will be appreciated that modifications may be made to the embodiment described without departing from the scope of the invention, as defined in the appended claims.

Claims

1. An injection device comprising:

a first sub-assembly comprising:

a chamber for holding a fluid, said chamber comprising an exit aperture and an inner surface; and

a transfer assembly movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter, said transfer assembly being adapted to transfer fluid into the chamber when the transfer assembly is moved within the chamber.

2. The injection device of claim 1, wherein the transfer assembly is adapted to transfer fluid into the chamber when the transfer assembly is moved with respect to the chamber away from its exit aperture.

3. The injection device of claim 1 or claim 2, wherein the transfer assembly is adapted to receive a fluid container and transfer fluid from the container into the chamber when the transfer assembly is moved with respect to the chamber.

4. The injection device of claim 3, wherein the transfer assembly comprises a hollow fluid transfer needle adapted to engage the fluid container to form a fluid pathway from the container into the chamber through the hollow needle.

5. The injection device of claim 4, wherein the transfer assembly further comprises:

a stopper for blocking fluid movement out of the transfer assembly; and wherein

the fluid transfer needle is adapted to pierce the stopper to deliver fluid through the stopper into the chamber.

6. The injection device of claim 5, further comprising a grip attached to the fluid transfer needle and movably disposed within the transfer assembly;

wherein the grip is adapted to move with the container as the container is inserted into the transfer assembly, thereby moving the fluid transfer needle into fluid communication with the chamber towards the exit aperture.

7. The injection device of any one of claims 3 to 6, wherein the transfer assembly further comprises a port having an opening adapted to receive and secure the container at the opposite end to the exit aperture.

8. The injection device of any preceding claim, wherein the transfer assembly is adapted to move away from the exit aperture within the chamber upon rotation of the first sub-assembly, thereby drawing fluid into the chamber.

9. The injection device of claim 8, further comprising a second sub-assembly; wherein

the transfer assembly comprises a first thread;

the second sub-assembly comprises a second thread engageable with the first thread; and

the first sub-assembly is adapted to rotate with respect to the second sub-assembly and the second sub-assembly is adapted to move the transfer assembly within the chamber away from the exit aperture.

10. The injection device of any preceding claim, wherein the transfer assembly is further adapted to expel fluid held within the chamber when the transfer assembly is moved toward the exit aperture.

11. The injection device of any preceding claim, further comprising an injection needle in fluid communication with the exit aperture.

12. The injection device of claim 11 further comprising a releasable drive mechanism which, upon activation, is adapted to:

(a) move the chamber and the injection needle from a retracted position in which the needle is wholly inside a housing of the injection device to an extended position in which the needle is at least partially outside the housing; and

(b) subsequently move the transfer assembly within the chamber toward the exit aperture to expel fluid out of the injection needle.

13. The injection device of claim 12, further comprising a retraction mechanism adapted to retract the injection needle into the housing after the fluid has been expelled.

14. The injection device of claim 9, or claims 10 to 13 when dependent on claim 9, wherein:

the first sub-assembly and the transfer assembly are detachable from the second sub-assembly; and

the second sub-assembly is reusable.

15. A method of priming an injection device having a transfer assembly, comprising:

inserting a container into the transfer assembly of the injection device, the injection device comprising a chamber having an exit aperture, the transfer assembly comprising a hollow needle and being movably disposed within the chamber;

piercing the container with the hollow needle to form a fluid conduit between the container and the chamber; and

moving the transfer assembly within the chamber, thereby drawing fluid from the container into the chamber.

FIG. 1

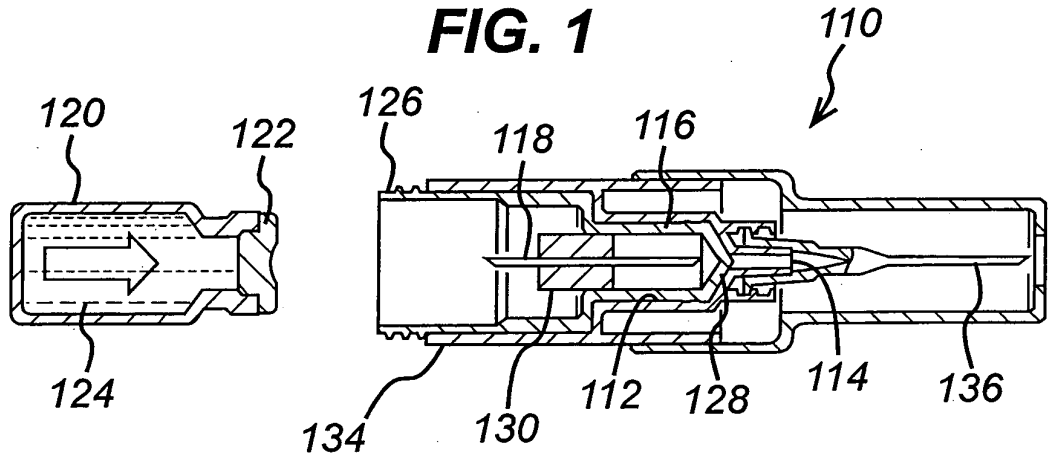


FIG. 2

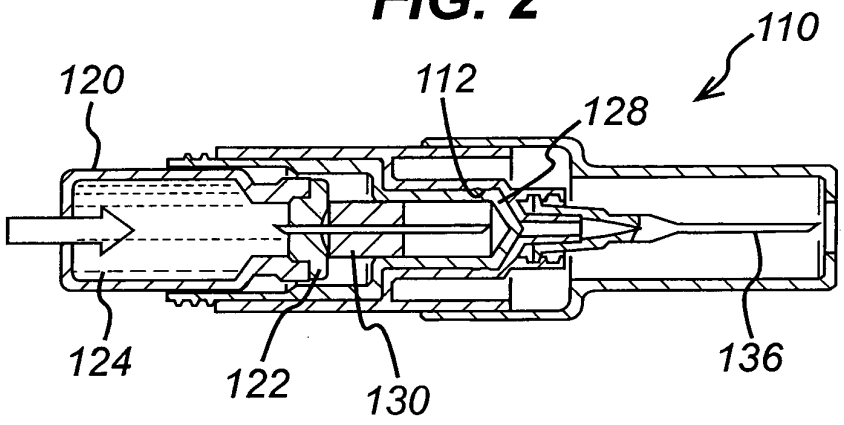
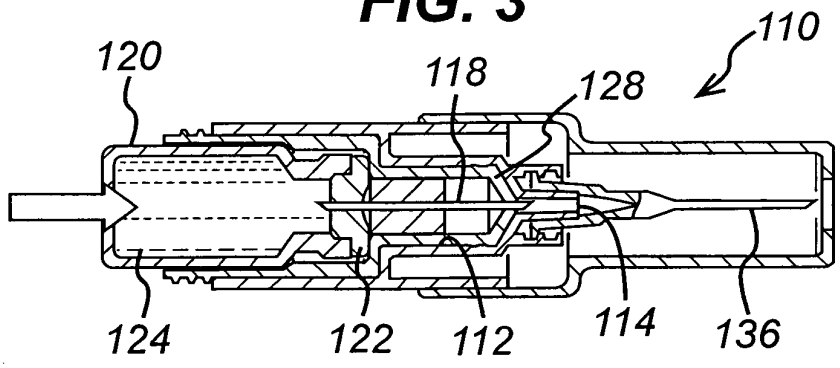


FIG. 3



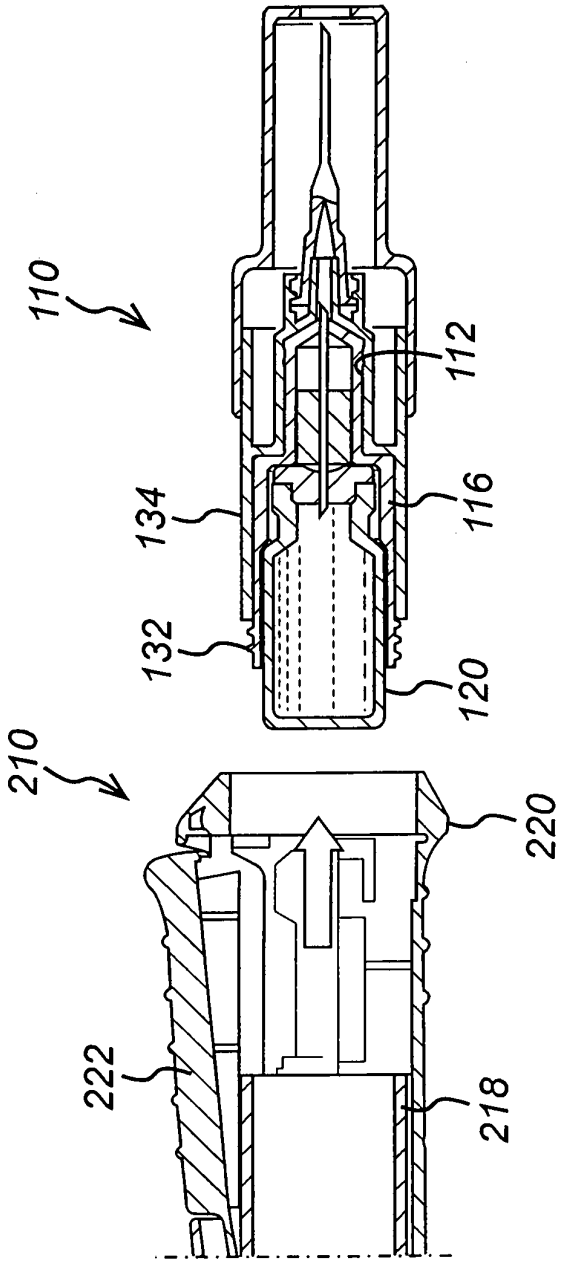

110
112
134
116
132
120
210
220
222
218

FIG. 4

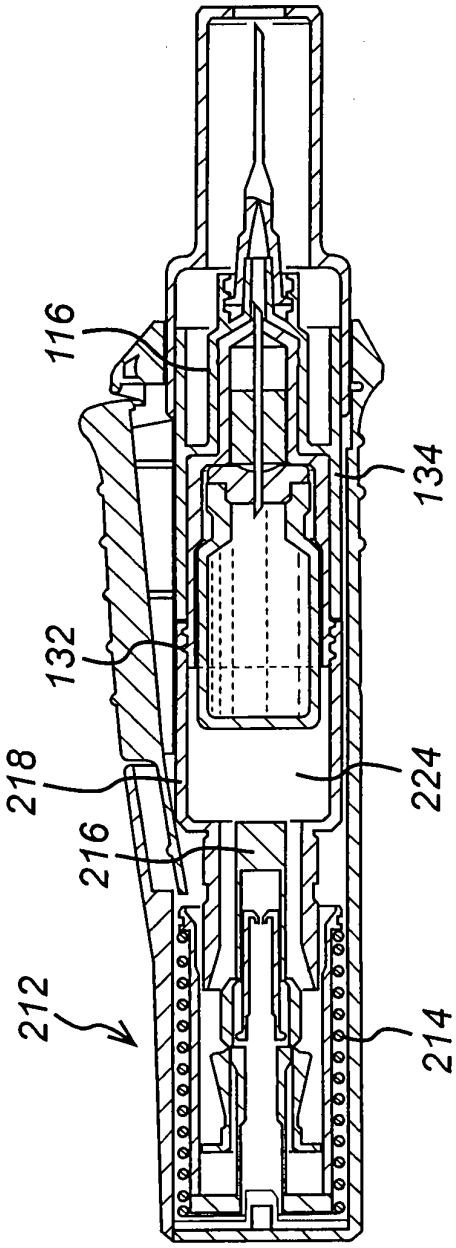

116
134
132
218
224
216
212
214

FIG. 5

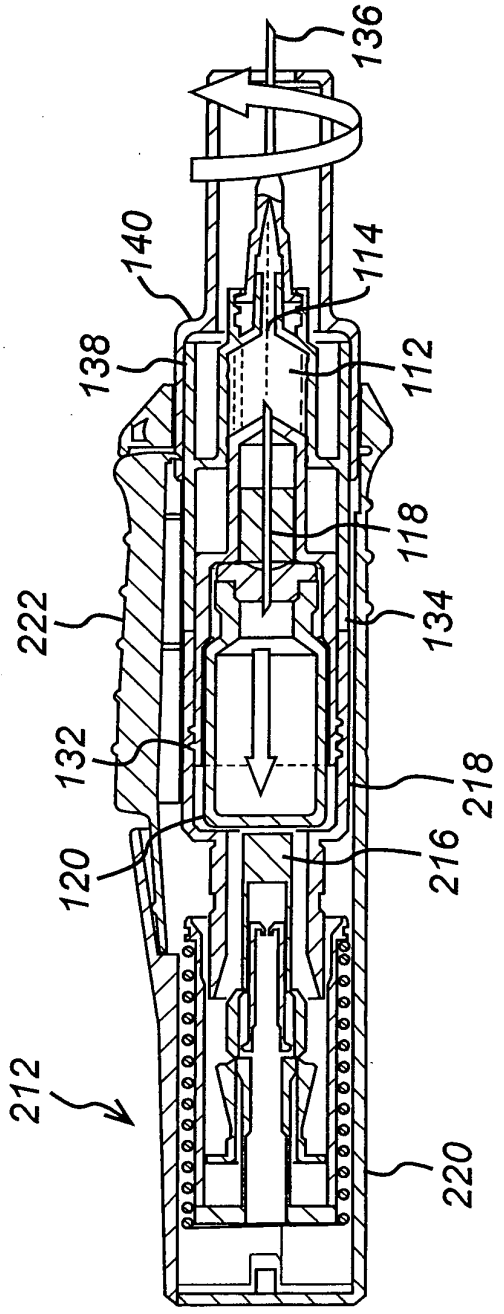

136
140
114
138
112
118
222
134
132
218
120
216
212
220

FIG. 6

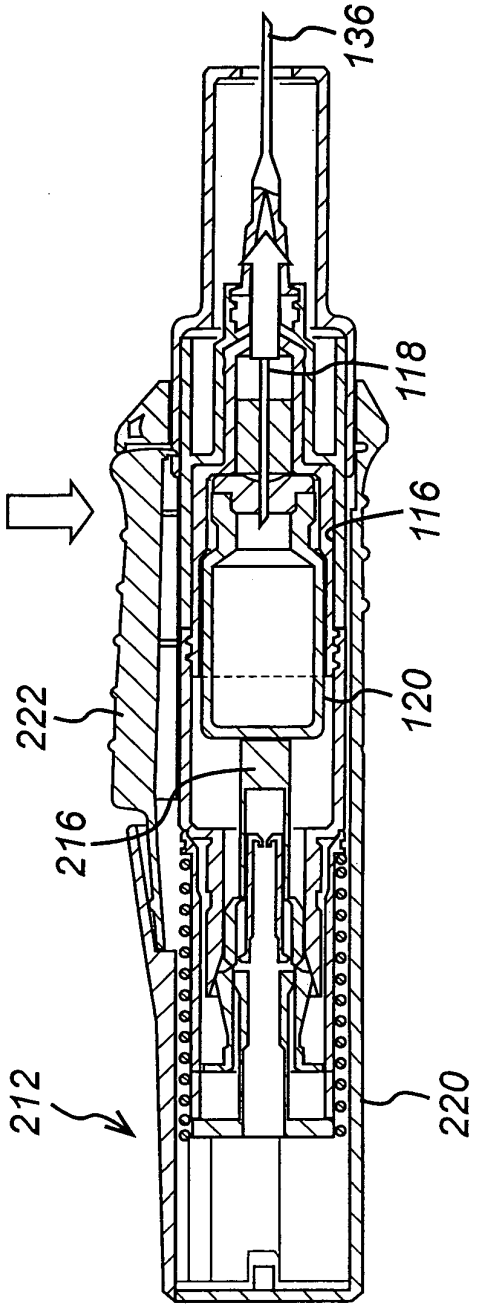

136
118
116
222
120
216
212
220

FIG. 7

FIG. 8