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Reusable auto-injector

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ABSTRACT

An injection device comprises a first sub-assembly and second assembly. The first sub-assembly comprises: a chamber for holding a fluid, said chamber comprising an inner surface and an exit aperture; a stopper movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter; and an adapter adapted to transfer fluid into the chamber, the adapter comprising means for moving the stopper through the chamber and a conduit for transferring fluid into the chamber when the stopper is moved away from the exit aperture. The second sub-assembly comprises: a releasable drive mechanism, said drive mechanism comprising an elongate shaft which is driven against the stopper upon activation of the drive mechanism. The adapter is configured to be inserted within the shaft.

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COMPLETE SPECIFICATION
STANDARD PATENT

Invention Title: **Reusable auto-injector**

The following statement is a full description of this invention, including the best method of performing it known to us:

REUSABLE AUTO-INJECTOR

Field of the Invention

This invention relates to an injection device, for example, a re-useable auto-injector 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.

Reference to any prior art in the specification is not, and should not be taken as, an acknowledgment or any form of suggestion that this prior art forms part of the common general knowledge in Australia or any other jurisdiction or that this prior art could reasonably be expected to be ascertained, understood and regarded as relevant by a person skilled in the art.

Summary of the Invention

The present invention aims to solve or at least ameliorate one or more of the aforementioned problems.

A first aspect of the present invention provides an injection device comprising:

a first sub-assembly comprising:

a chamber for holding a fluid, said chamber comprising an inner surface and an exit aperture; a stopper movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter; and

an adapter adapted to transfer fluid into the chamber, the adapter comprising means for moving the stopper through the chamber and a conduit for transferring fluid into the chamber when the stopper is moved away from the exit aperture; and

a second sub-assembly comprising:

a releasable drive mechanism, said drive mechanism comprising an elongate shaft which is driven against the stopper upon activation of the drive mechanism; and

wherein the adapter is configured to be inserted within the shaft.

A second aspect of the present invention provides a method for introducing a fluid into an injection device according to any preceding claim, wherein the adapter comprises a hollow needle, said method comprising the steps of:

connecting said adapter to said stopper;

piercing said stopper with said needle; and

drawing said adapter and said stopper through said fluid container, thereby drawing a fluid through said needle into said syringe.

A third aspect of the present invention provides an injection kit comprising:

a first sub-assembly for an injection device comprising:

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

a stopper movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter; and

an adapter adapted to transfer fluid into the chamber, the adapter comprising means for moving the stopper through the chamber and a conduit for transferring fluid into the chamber when the stopper is moved away from the exit aperture; and

a second sub-assembly for an injection device comprising:

a releasable drive mechanism, said drive mechanism comprising an elongate shaft which is driven against the stopper upon activation of the drive mechanism; and

wherein the adapter is configured to be inserted within the shaft.

Also described herein is an injection device comprises a first sub-assembly comprising a chamber for holding a fluid, said chamber comprising an inner surface and an exit aperture; a stopper movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter; and an adapter adapted to transfer fluid into the chamber.

Providing an injection device, such as an auto-injector, having a chamber into which a fluid may be transferred by a bespoke adapter 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 adapter may comprise means for moving the stopper through the chamber; and means for transferring fluid into the chamber when the stopper is moved away from the exit aperture. The stopper may be provided at the distal end of the adapter.

Providing an adapter has the additional benefit of removing the need to disassemble the auto-injector to provide fluid directly into the chamber from which it is injected. An adapter which is configured to transfer fluid into the chamber enables a user to provide a fluid to be injected at a convenient location.

In the embodiments set out above, the volume of the chamber into which the fluid is transferred is defined by the space between the stopper and the exit aperture. Consequently, the volume is increased as the stopper is moved away from the exit aperture. The increase in volume causes a 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 a stopper toward the exit aperture. Other embodiments which achieve an increase in chamber volume to draw fluid into the chamber are also envisaged.

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

The adapter may be adapted to receive a fluid container and transfer the fluid from the container to the chamber. Suitable containers may include any container configured to contain a drug and interface in some manner with the adapter. 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. The container may be provided at the proximal end of the adapter.

It will be appreciated that the convenience of providing a fluid container such as a vial in communication with the adapter renders the transfer of fluid into the chamber

particularly straightforward. In some embodiments, the adapter may extend outside of the injection device such that the fluid container may simply be pushed onto the adapter to create a fluid conduit between the container and the chamber.

In some embodiments, the means for transferring fluid into the chamber may comprise a hollow fluid transfer needle adapted to engage the fluid container to transfer fluid from the fluid container through the hollow needle, as the stopper is moved away from the exit aperture. 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 needle, provided on the adaptor 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.

The hollow needle may be adapted to pierce the stopper to deliver fluid through the stopper into the chamber. In such an embodiment, the hollow needle may extend for the length of the adapter - from the container, at the proximal end, to the chamber, at the distal end - to provide a complete fluid conduit there-between. An additional benefit of this embodiment is that the force of engaging a container with the hollow needle at the proximal end may also be transferable through the hollow needle and thus sufficient to pierce the stopper at the distal end.

Alternatively, in place of such a needle, the adapter may comprise a separate second needle, adapted to pierce the stopper to permit fluid to be transferred into the chamber. In such an embodiment, it may be necessary to provide a means for driving the second needle through the stopper. Of course, the second needle may be substituted for a tube

or similar means for transferring fluid. Such means may comprise a valve to permit fluid to be transferred into but not out of the chamber.

In preferred embodiments, the adapter comprises a fluid pathway to transfer fluid from the container to the chamber. In the case where the adaptor comprises a single hollow needle extending the length of the adaptor, the fluid pathway is through the needle. However, in the case where there is no such single conduit, the adaptor may provide a fluid pathway between the container and the chamber to transfer the fluid. The pathway may be a hollow passage or a tube, for example.

In an alternative embodiment, the auto-injector comprises a second sub-assembly comprising a releasable drive mechanism. The mechanism may comprise an elongate shaft which is driven against the stopper upon activation of the drive mechanism. As will be appreciated, in addition to its role in transferring fluid into the chamber, the stopper may also assist in performing the function of ejecting the fluid from the injection device into the patient.

The first sub-assembly may be detachable from the second sub-assembly. This is of particular benefit if the second sub-assembly is reusable. As explained above, in providing two detachable sub-assemblies, the second sub-assembly, comprising the drive mechanisms of the auto-injector may be reused, whereas the first sub-assembly, having been brought into contact with a drug and the patient, may be disposed of.

Of course, due to the nature of the invention, the first sub-assembly may also be reused if required. Following the expulsion of a drug into the patient, further fluid may be transferred into the first sub-assembly for injection into the same patient, as described above. This would reduce the long term cost of the auto-injector still further, as the only components requiring replacement would be the vial and the drug. In such circumstances, it may be advantageous to sterilise the first sub-assembly to prevent contamination.

In embodiments comprising a second sub-assembly, the adapter may be configured to be inserted within the shaft to provide the fluid pathway. Thus, the shaft may perform its function of driving the stopper to eject the fluid from the injection device, whilst the adapter may provide a fluid conduit to the stopper such that a fluid may be transferred into the chamber.

Optionally, the adapter is removably attachable to the stopper. Whereas the stopper must remain functional inside the auto-injector once the fluid has been transferred into the chamber, the adapter may have no further purpose. Thus it may be advantageous to remove the adapter from the stopper prior to injection. The adapter and the stopper may comprise inter-engagable threads to permit such a removable attachment. Of course, other removable engagement means, such as clips or detents, may be used instead.

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 an auto-injector according to a first embodiment;

Figure 2 is a side view of the first embodiment wherein a vial has been engaged with an adapter of the auto-injector;

Figure 3 is a side view of the first embodiment wherein a vial has been further engaged with an adapter of the auto-injector;

Figure 4 is a side view of the first embodiment wherein a fluid has been drawn into the auto-injector;

Figure 5 is a side view of the first embodiment wherein the adapter has been removed from the auto-injector;

Figure 6 is a side view of a first sub-assembly connected to an adapter in accordance with a second embodiment of the invention;

Figure 7 is a side view of the second embodiment wherein a fluid has been drawn into the first sub-assembly and the adapter has been removed; and

Figure 8 is a side view of the second embodiment wherein the first sub-assembly in engaged with a second sub-assembly.

Detailed Description of the Drawings

Figures 1 to 5 illustrate an auto-injector 110 according to a first embodiment of the present invention.

The auto-injector 110 comprises a drive means 111 coupled to a plunger disposed within a syringe. The plunger comprises a stopper 112 disposed within a chamber 116 having an inner surface. The stopper 112 is movable within the chamber 116 and has an outer surface which is substantially in contact with the inner surface about its periphery. The stopper is made from a pliable material. In the embodiment, the material is rubber, but other pliable materials may also be used. The contact between the stopper and the chamber forms a fluid tight and air tight seal.

At the distal end of the chamber 116 there is provided an exit aperture 114 in communication with an injection needle 115. When the auto-injector is primed and ready to inject a medicament into a patient, the operation of the device is as follows. Upon activation, the drive means 111 is configured to expose the injection needle 115 outside the casing of the auto-injector 110 and subsequently move the plunger 112 within the chamber 116 towards the exit aperture 114 to expel the contents of the chamber 116 through the exit aperture 114.

The auto-injector comprises a removable cap 140 including a sheath 142 disposed over the injection needle 115. The sheath 142 protects the injection needle 115 and provides

a substantially fluid tight and air tight seal over the tip of the injection needle 115, to prevent fluid ingress or egress or other contamination.

In the auto-injector of Figures 1 to 3, the stopper 112 abuts the exit aperture 114. The available volume of the chamber 116 into which a fluid may be transferred is minimal and, accordingly, the chamber 116 is substantially empty. When the stopper 112 is positioned away from the exit aperture 114 (see Figures 4 and 5), the available volume of the chamber 116 is at or substantially at its greatest. As shown, the chamber 116 is suitable for holding a fluid and, immediately prior to injection, contains a drug to be injected.

Referring to Figure 1 in more detail, the auto-injector comprises an adapter 118 removably attached to the stopper 112.

The adapter 118 can be: provided in a kit which includes the auto-injector 110 and a vial 132 of drug to be administered (see below), provided preinstalled in the auto-injector 110, or provided separately for insertion into the auto-injector 110 by a user.

The adapter 118 and the stopper 112 comprise interconnecting threads 120 such that the adapter 118 may be removed from the stopper 116 by unscrewing the adapter 118. The adapter comprises an elongate shaft 122 having proximal and distal ends. The stopper 112 is attached to the adapter 118 at the distal end of the elongate shaft 122. At the proximal end of the adapter 118 is a handle 124. Disposed at the handle 124 is a port 126 configured to receive a vial 132 having a cap 134. The handle 124 is attached to the elongate shaft and enables a user to move the adaptor 118 within the auto-injector, thereby moving the stopper 112 within the chamber 116.

The adapter 118 further comprises a hollow needle 128 which extends through, and is moveable longitudinally within, the shaft 122. The needle 128 has proximal and distal ends corresponding to the proximal and distal ends of the shaft 122. At the proximal end, the needle 128 extends into the port 126. Fixed to the needle 128 at its proximal end is a grip 130. The grip 130 is moveable within the port 126, in conjunction with the

needle 128. At its distal end, the needle 128 is adjacent the stopper 112. The needle 128 is configured to be capable of piercing both the stopper 112, at the distal end, and the cap 134, at the proximal end, when a container is engaged with the adapter 118.

The vial 132 contains a drug 136 to be injected into the patient. As can be seen in Figure 2, when the vial 132 is engaged with the port 126 to a first position wherein the proximal end of the needle pierces the cap 134 of the vial 132, thereby creating a fluid conduit between the vial 132 and the hollow needle 128. The port 126 comprises a detent 138 configured to secure the vial 132 in this position within the port 126 such that the cap 134 abuts the grip 130.

The vial 132 may be further engaged further within the port 126 to a second position, as shown in Figure 3. In moving the vial 132 from the first position to the second position, the vial pushes on the grip 130 which moves within the port 126 towards the exit aperture 114. As the grip is attached to the needle, movement of the grip causes a corresponding movement of the needle. As the needle 128 moves towards the exit aperture 114, it pierces the stopper 112, thereby completing the fluid conduit from the vial 132 through the needle 128 to the chamber 116. At this stage, however, the fluid remains within the vial 132.

Figure 4 demonstrates the process of transferring the fluid from the vial 132 to the chamber 116. Once the needle 128 has pierced both the cap 134 and the stopper 112, a user may draw the adapter 118 through auto-injector, thereby drawing the stopper 112 through the chamber 116 away from the exit aperture 114.

As the stopper 112 moves away from the exit aperture 114, the available volume in the chamber 116 increases. As the injection needle 115 is sealed by the sheath 142 of the removable cap 140, thereby preventing ingress of fluid into the chamber 116 through the exit aperture 114, the pressure of that volume decreases and the pressure difference between the vial 132 and the chamber 116 causes fluid to be drawn from the vial 132, through the fluid transfer needle 128 and into the chamber 116.

Figure 5 illustrates the auto-injector after substantially all of the fluid from the vial 132 has been transferred into the chamber. The adapter 118 is removed from the stopper 112, and the adapter 118, along with the fluid transfer needle 128, is withdrawn from the auto-injector 110. As the stopper is pliable, the aperture formed by the fluid transfer needle 128 is substantially sealed after the fluid transfer needle 128 is removed.

The auto-injector 110 now contains a drug to be administered.

Figures 6 to 8 illustrate a kit 200 according to a second embodiment of the present invention.

Figure 6 shows a first sub-assembly 210 suitable for use in an auto-injector. As with the first embodiment, the first sub-assembly 210 comprises a plunger disposed within a syringe. The plunger comprises a stopper 222 disposed within a chamber 224 having an inner surface. At the distal end of the chamber 224 there is provided an exit aperture 226 in communication with an injection needle (not shown). The stopper 222 and the chamber 224 are in accordance with the stopper and the chamber of the first embodiment.

The first sub-assembly comprises a removable cap 212 in accordance with the cap of the first embodiment. The first sub-assembly 210 also comprises an adapter 214 removably attached to the stopper 222. The adapter 214 is in accordance with the adapter of the first embodiment. The adapter comprises a handle 216 and a fluid transfer needle (not shown). Disposed at the handle 216 is a port 218 configured to receive a vial 220. The port 218 is in accordance with the port of the first embodiment.

As with the first embodiment, a user may engage the vial 220 with the port 218 such that the fluid transfer needle pierces the cap of the vial. Further engagement causes the fluid transfer needle to pierce the stopper 222 to create a fluid conduit from the vial 220 through the needle to the chamber 224.

As shown in Figure 7, a user draws the adapter 214 through the first sub-assembly 210, thereby drawing the stopper 222 through the chamber 224 away from the exit aperture 226. As with the first embodiment, the available volume of the chamber 224 into which a fluid may be transferred increases as the stopper 222 is moved away from the exit aperture 226. As the volume increases, the pressure of that volume decreases, thereby drawing fluid from the vial through the needle into the chamber 224. Once the fluid has been transferred, the adapter is removed from the stopper 222 and the adapter, along with the fluid transfer needle, is withdrawn.

Referring now to Figure 8, once the first sub-assembly 210 is primed, it is inserted into an open aperture 311 on a second sub-assembly 310. The second sub-assembly 310 comprises a drive mechanism which is configured to operate on the components of the first sub-assembly 210 as follows.

Once engaged, the first 210 and second 310 sub-assemblies form an injection device which is primed and ready to use in an identical state to the auto-injector 110 of the first embodiment when it has been filled with a drug. Indeed, the auto-injector 110 of the first embodiment comprises the first and second sub-assemblies 210, 310, but in the first embodiment, these sub-assemblies have been assembled prior to loading of the drug.

Thus, in both the first and second embodiments, activation of a release mechanism 320 of the second sub-assembly 310 releases a drive mechanism, in the form of drive spring 322 acting on the driving mechanism, to cause the needle to be exposed outside of the auto-injector to pierce the skin of a patient and the stopper 112 to be driven through the chamber 116 to inject the patient with the fluid. After all the fluid has been expelled, the needle is subsequently retracted by a retraction mechanism 324 so that it is wholly within the assembled auto-injector 110.

Once the fluid has been injected, the second sub-assembly 310 may be disassembled from the first sub-assembly 210 and reused. The first sub-assembly 210 may be discarded and a new first sub-assembly 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.

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The claims defining the invention are as follows:

1. An injection device comprising:

a first sub-assembly comprising:

a chamber for holding a fluid, said chamber comprising an inner surface and an exit aperture; a stopper movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter; and

an adapter adapted to transfer fluid into the chamber, the adapter comprising means for moving the stopper through the chamber and a conduit for transferring fluid into the chamber when the stopper is moved away from the exit aperture; and

a second sub-assembly comprising:

a releasable drive mechanism, said drive mechanism comprising an elongate shaft which is driven against the stopper upon activation of the drive mechanism; and

wherein the adapter is configured to be inserted within the shaft.

2. The injection device of claim 1, wherein the adapter is adapted to receive a fluid container and transfer the fluid from the container to the chamber.

3. The injection device of claim 2, wherein the conduit for transferring fluid into the chamber comprises a hollow fluid transfer needle adapted to engage the fluid container to transfer fluid from the fluid container through the hollow needle, as the stopper is moved away from the exit aperture.

4. The injection device of claim 3, wherein the hollow needle is adapted to pierce the stopper to deliver fluid through the stopper into the chamber.

5. The injection device of any preceding claim, wherein the adapter is removably attachable to the stopper.

6. The injection device of claim 5, wherein the adapter and the stopper comprise inter-engagable threads to permit removable attachment.

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

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

9. The injection device of claim 8, wherein the releasable drive mechanism is, upon activation, 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 stopper within the chamber toward the exit aperture to expel fluid out of the injection needle.

10. The injection device of claim 9, further comprising a retraction mechanism adapted to retract the injection needle into the housing after the fluid has been expelled.

11. The injection device of any preceding claim, wherein:

the first sub-assembly is detachable from the second sub-assembly; and

the second sub-assembly is reusable.

12. A method for introducing a fluid into an injection device according to any preceding claim, wherein the adapter comprises a hollow needle, said method comprising the steps of:

connecting said adapter to said stopper;

piercing said stopper with said needle; and

drawing said adapter and said stopper through said fluid container, thereby drawing a fluid through said needle into said syringe.

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13. An injection kit comprising:

a first sub-assembly for an injection device comprising:

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

a stopper movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter; and

an adapter adapted to transfer fluid into the chamber, the adapter comprising means for moving the stopper through the chamber and a conduit for transferring fluid into the chamber when the stopper is moved away from the exit aperture; and

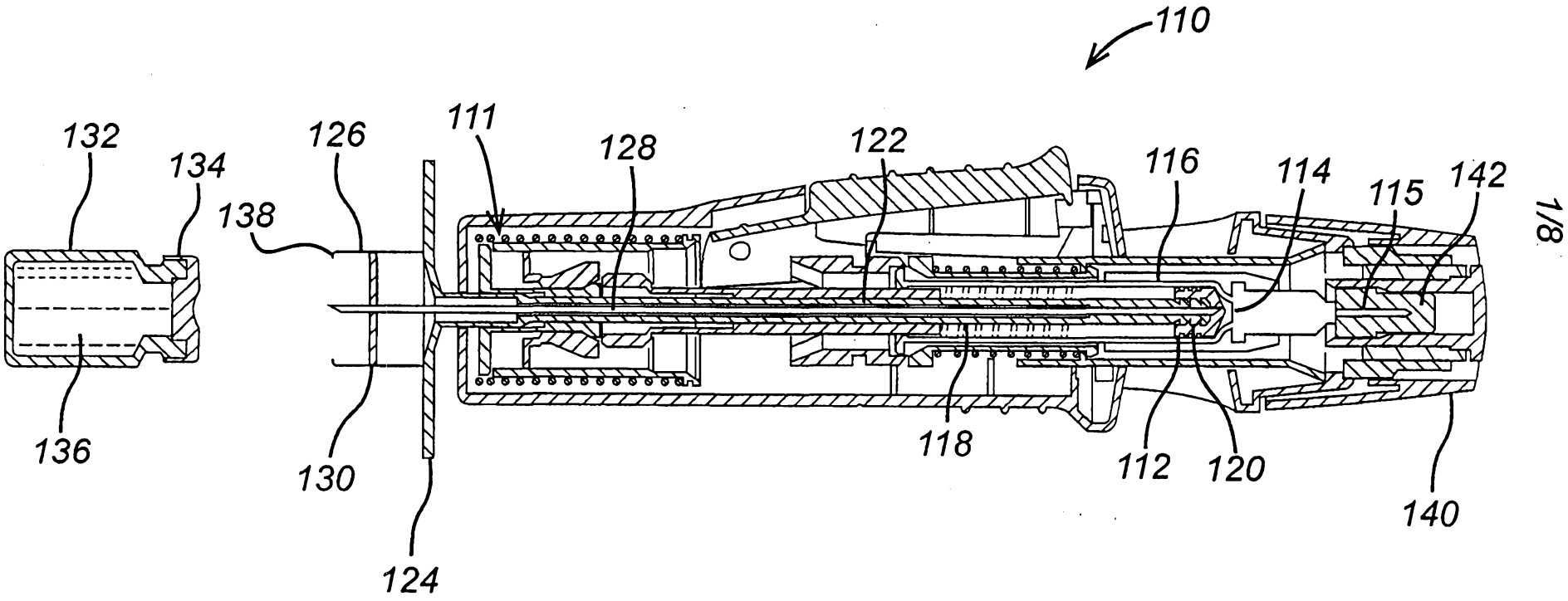
a second sub-assembly for an injection device comprising:

a releasable drive mechanism, said drive mechanism comprising an elongate shaft which is driven against the stopper upon activation of the drive mechanism; and

wherein the adapter is configured to be inserted within the shaft.

14. The injection kit of claim 13, further comprising a vial of fluid to be transferred for connection to the adapter.

FIG. 1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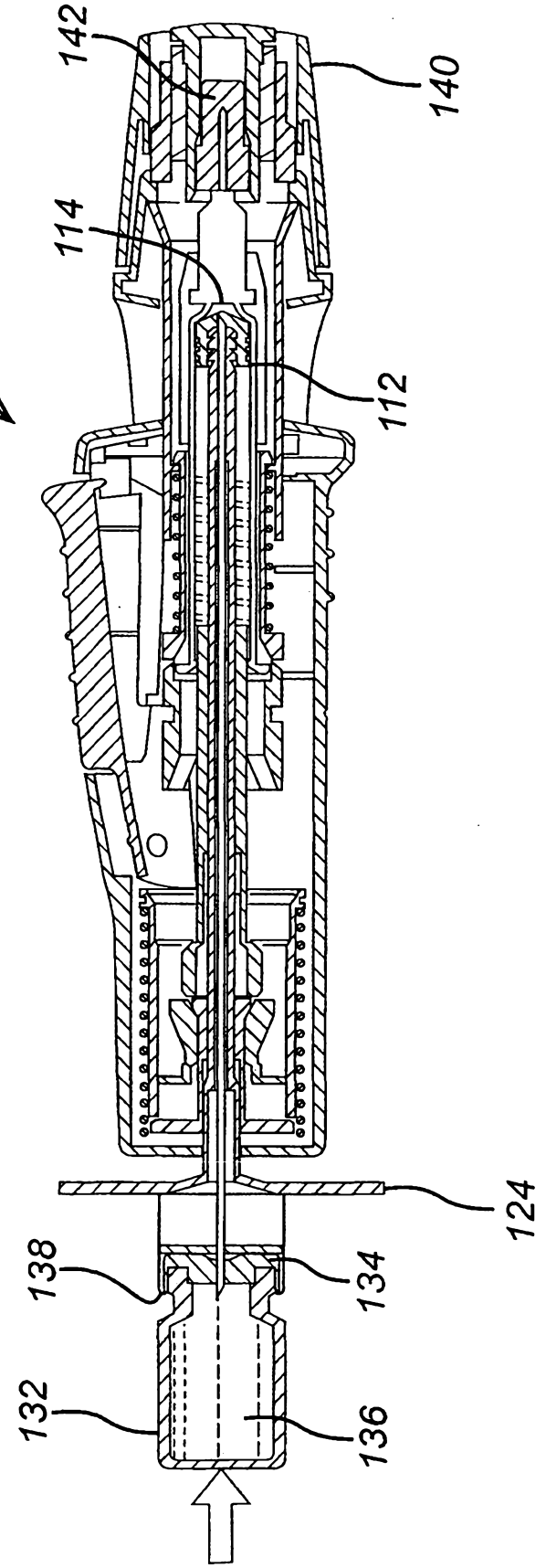

FIG. 2

FIG. 3

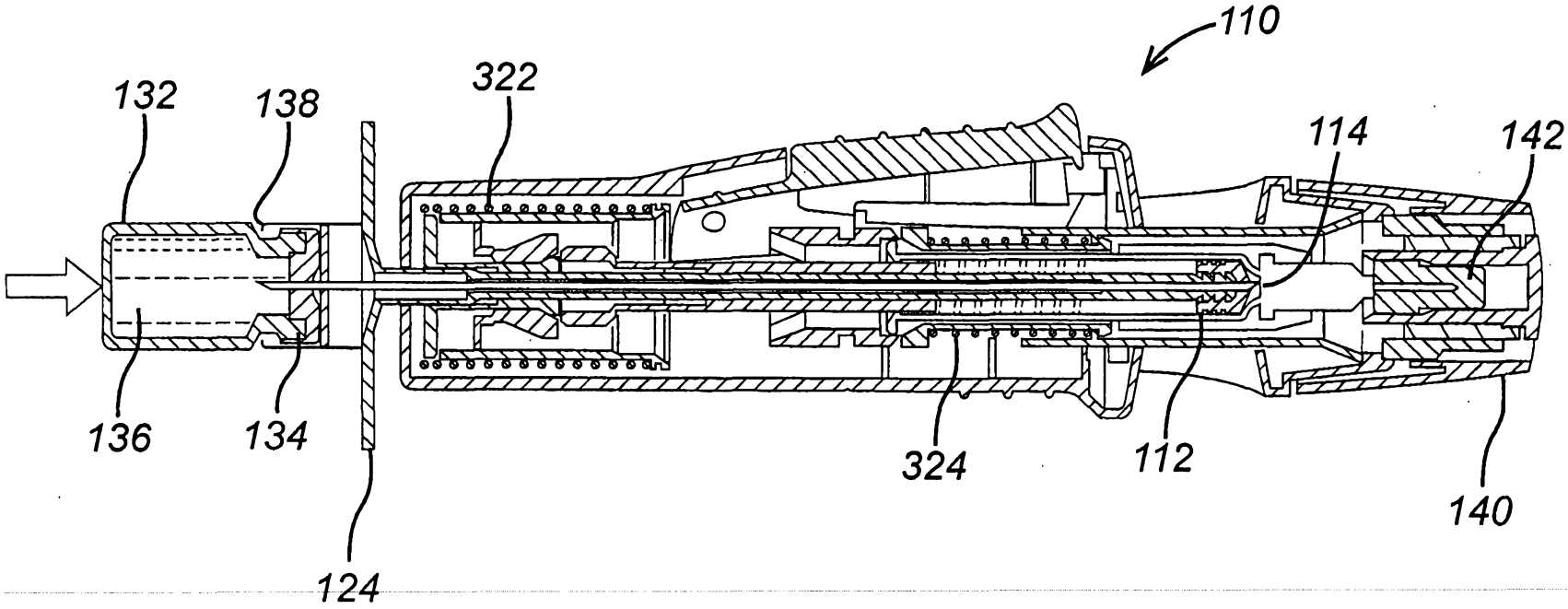

FIG. 4

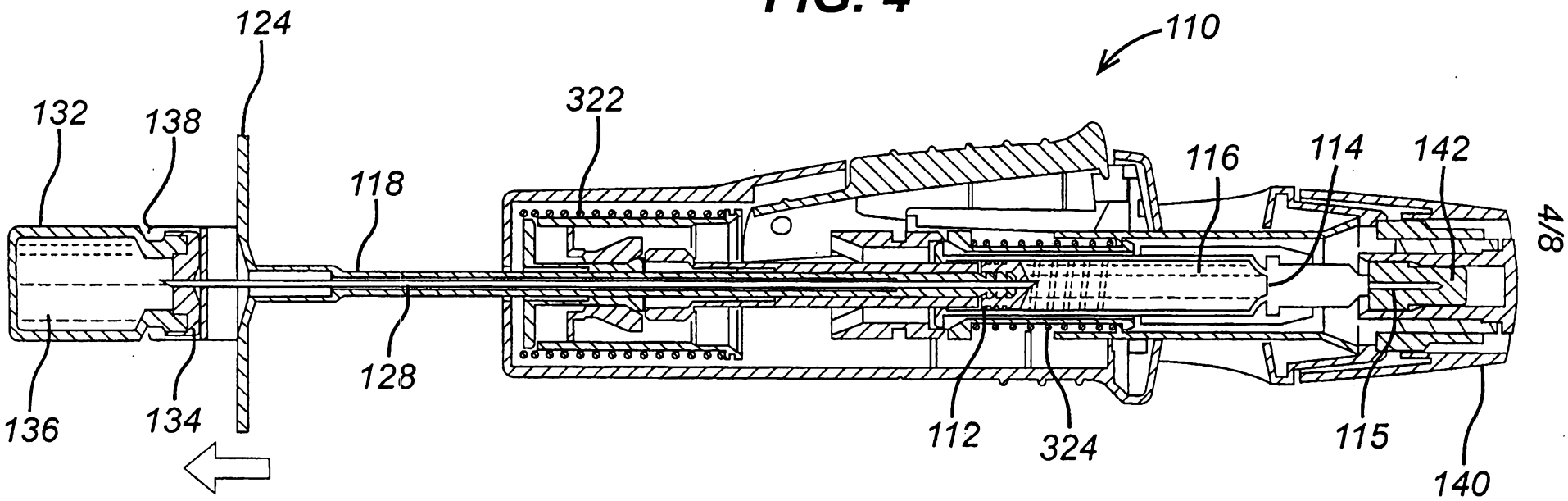

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FIG. 5

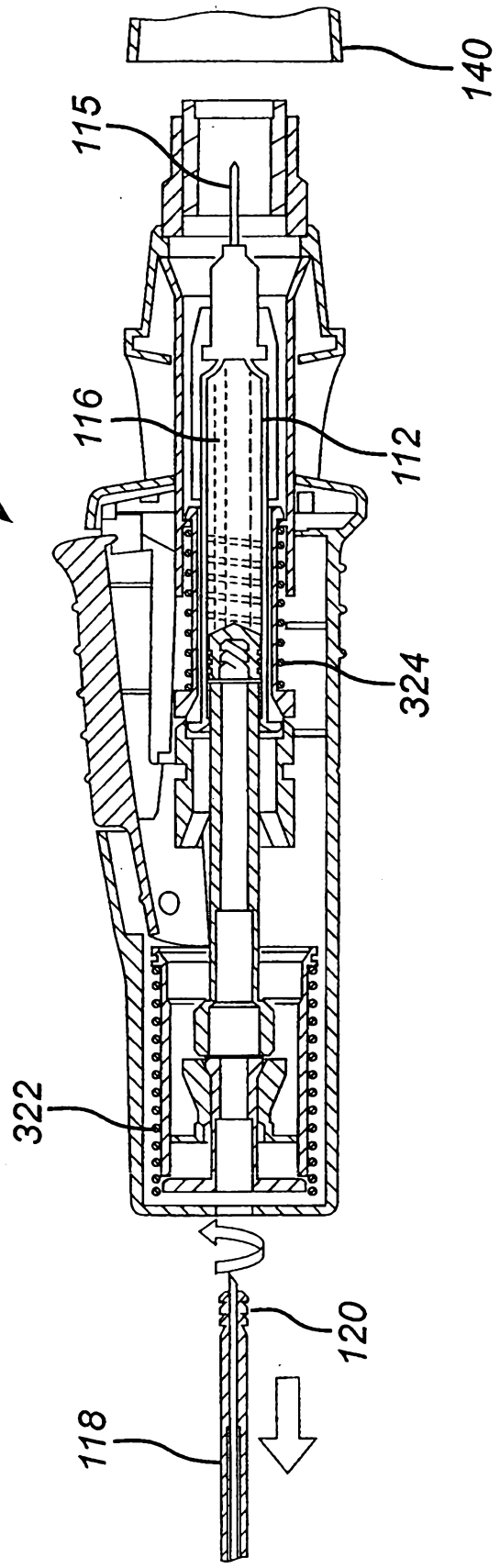


FIG. 6

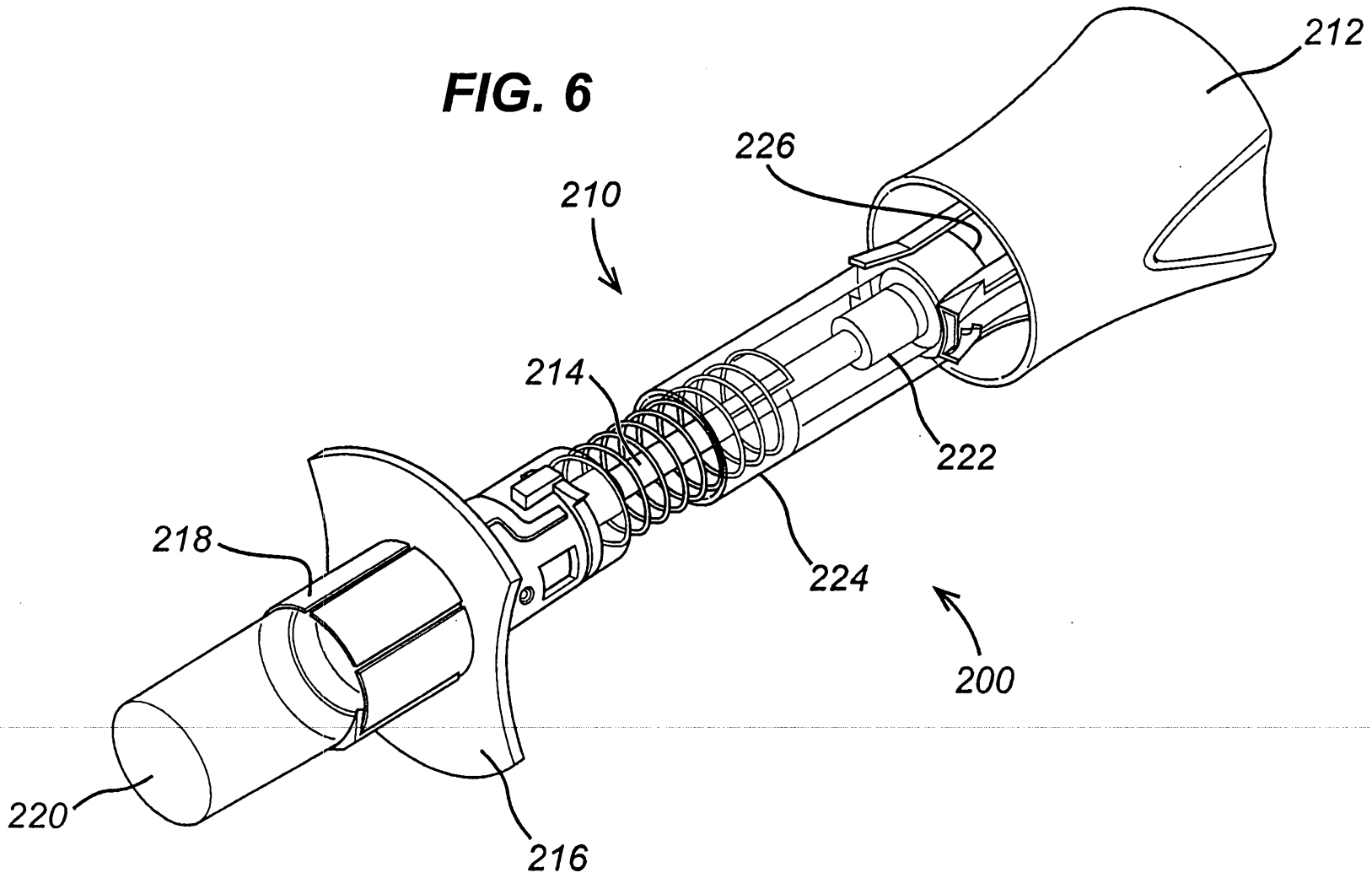
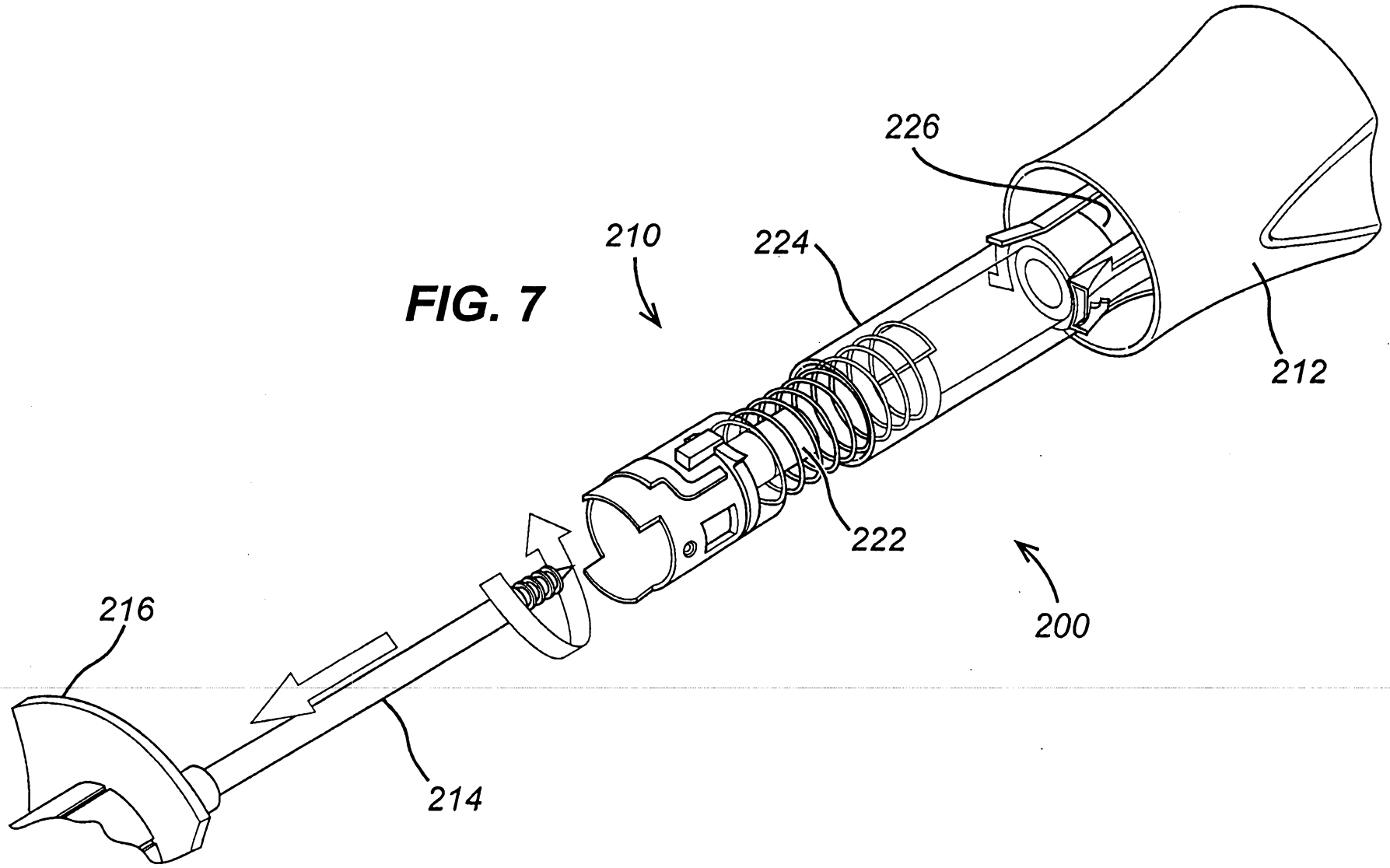


FIG. 7



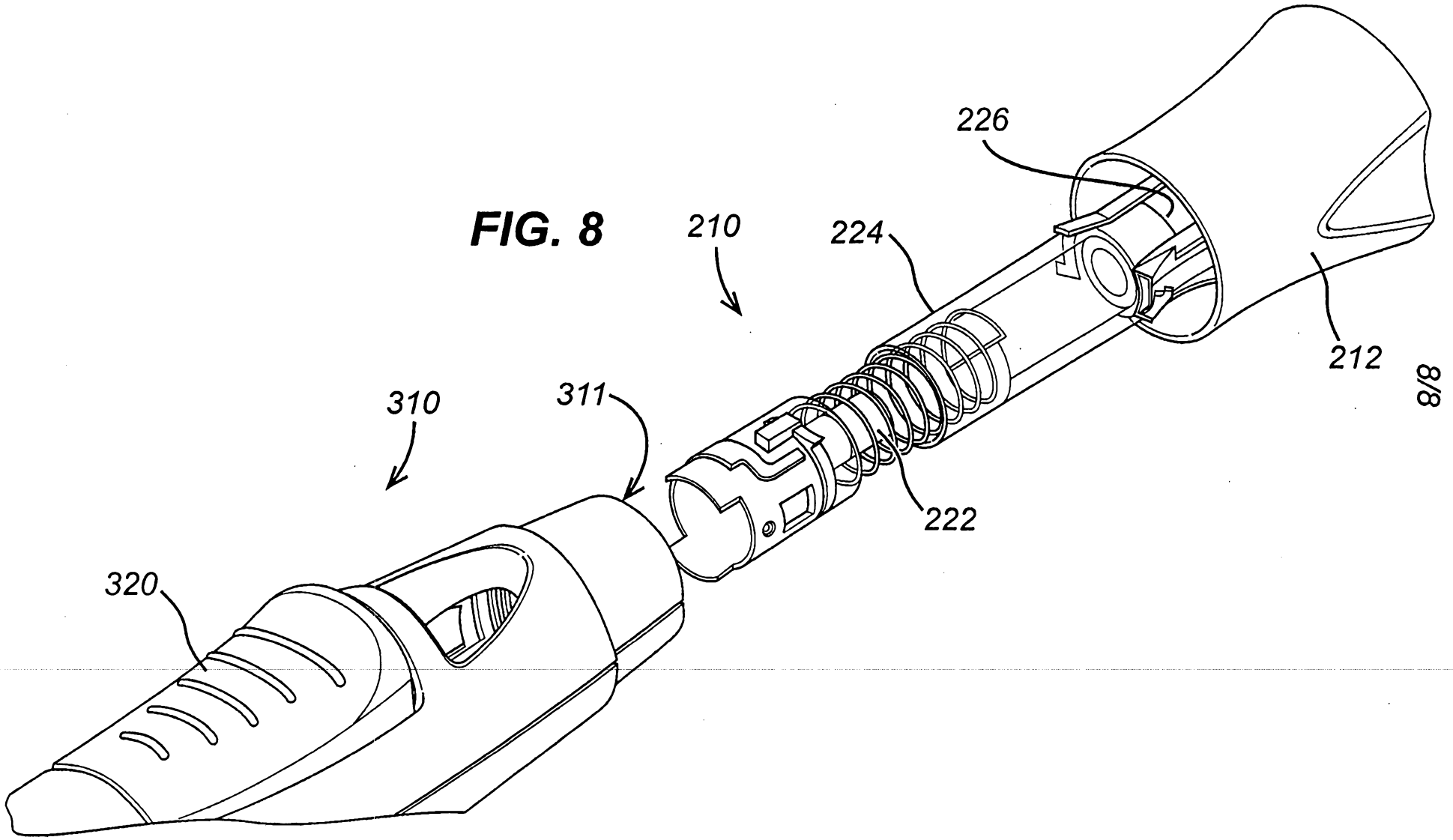


FIG. 8