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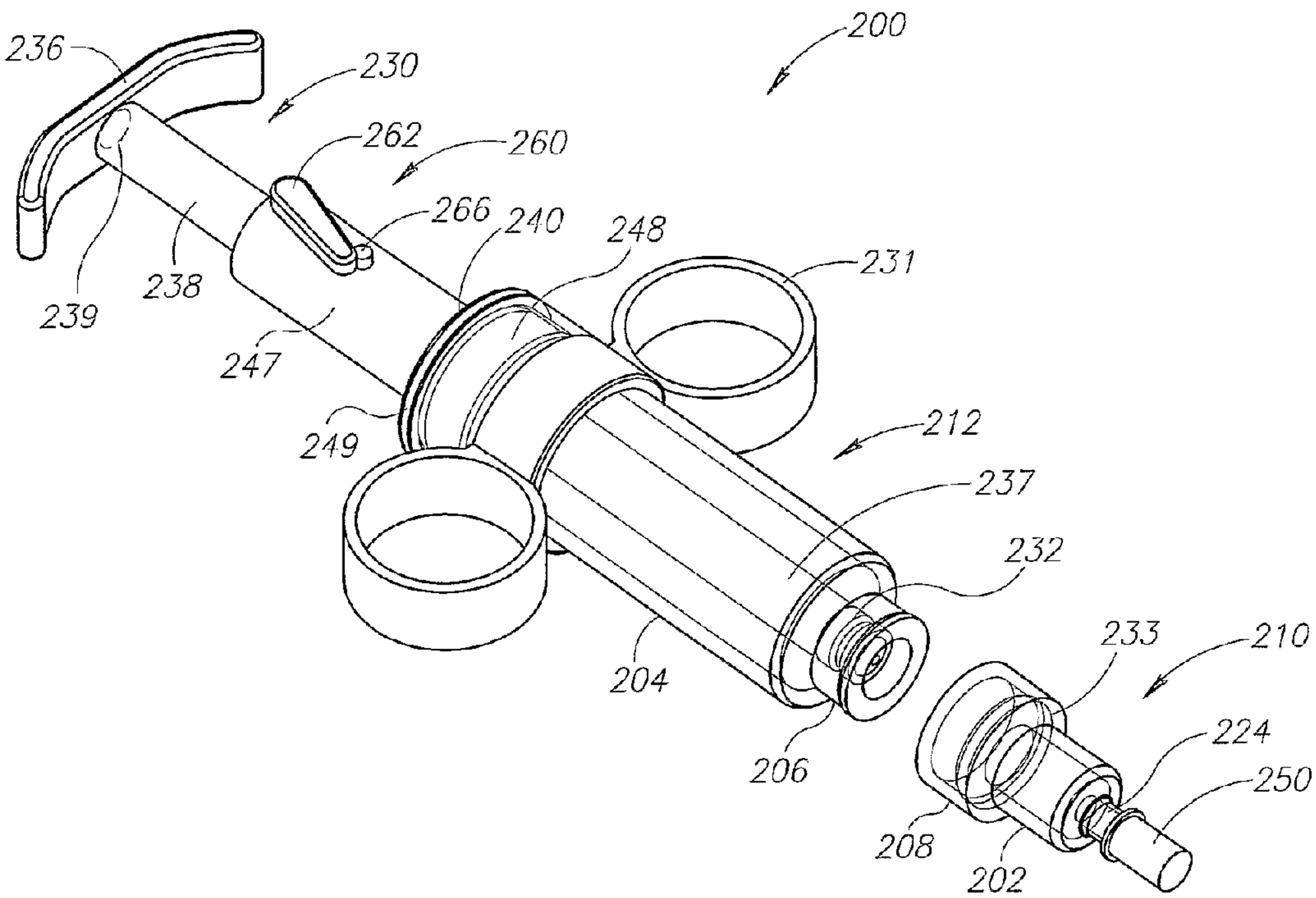

(57) Abrégé/Abstract:
A syringe assembly consists of two basic types of assembly units: a dispensing unit, and a separate, independent plunger unit. The dispensing unit and the plunger unit are assembled together coaxially to form a two-unit syringe assembly for storage or prior to use. At least the dispensing unit is a container for a material to be dispensed and, by inserting one or more extension units between the dispensing unit and the plunger unit, additional compartments may be added. Each extension unit may contain a different component of a formulation in any predetermined quantity. The syringe assembly allows the user to store one or more components of a formulation in separate individual units that can be assembled easily into a single multi-compartment syringe assembly, which can store the multiple components separately until they are ready for use, at which time the components may be mixed to form the formulation.

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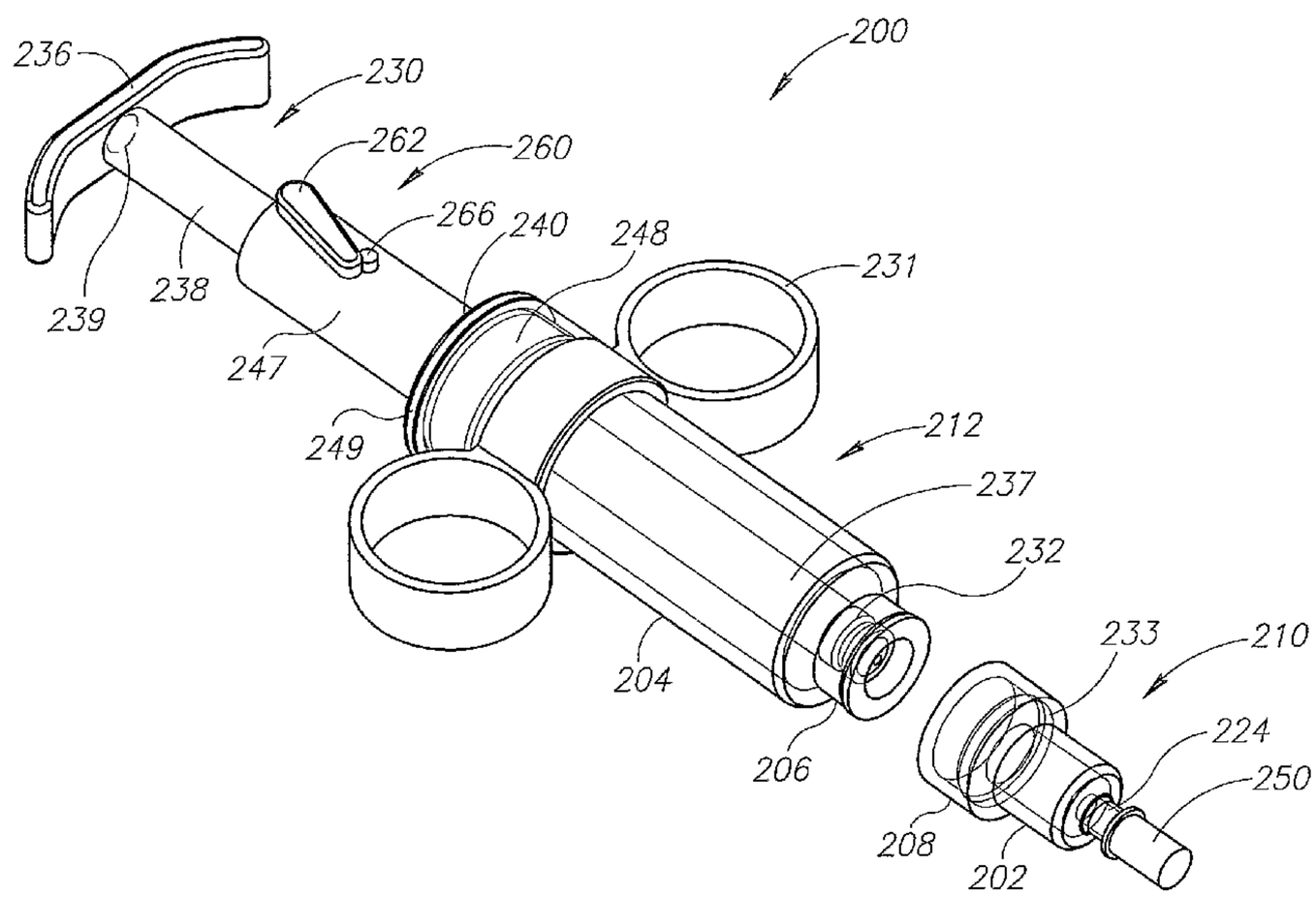
(54) Title: A SYRINGE ASSEMBLY



(57) Abstract: A syringe assembly consists of two basic types of assembly units: a dispensing unit, and a separate, independent plunger unit. The dispensing unit and the plunger unit are assembled together coaxially to form a two-unit syringe assembly for storage or prior to use. At least the dispensing unit is a container for a material to be dispensed and, by inserting one or more extension units between the dispensing unit and the plunger unit, additional compartments may be added. Each extension unit may contain a different component of a formulation in any predetermined quantity. The syringe assembly allows the user to store one or more components of a formulation in separate individual units that can be assembled easily into a single multi-compartment syringe assembly, which can store the multiple components separately until they are ready for use, at which time the components may be mixed to form the formulation.

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A SYRINGE ASSEMBLY

FIELD OF THE INVENTION

This invention relates to syringe assembly systems in general and, in particular, to multi-unit syringe assemblies for separately storing each of one or more components of a formulation in separate containers until ready for dispensing or mixing prior to dispensing.

BACKGROUND OF THE INVENTION

A multi-compartment syringe, allowing the user to store multiple components of a medicament in separate, individually sealed compartments until ready for use is known in the art. A multi-compartment syringe comprising a single multi-compartment barrel, is disclosed in United States Patent number 6,743,194, herein "the '194 Patent", which is assigned to the assignee of the present application. In the '194 Patent, the syringe is a single barreled syringe that may be configured to store two or more components of a medicament or other formulation separately in hermetically sealed compartments until just prior to use. When ready to mix the contents of the pre-filled syringe, the seal(s) partitioning the compartments can be easily unsealed, establishing a two-way flow communication between the compartments so that the contents of each compartment can be mixed to form the medicament.

Thus, the '194 Patent describes and claims a syringe including a syringe body having an opening at each of its top and bottom ends; a shoulder provided between the top and the bottom ends defining a top-compartment sidewall portion between the top end and the shoulder; the shoulder further defining a bottom-compartment sidewall portion between the shoulder and the bottom end; the bottom-compartment sidewall portion having a larger cross-section than the top-compartment sidewall portion; a plunger having a shaft, a distal end, a proximal end, and a plunger head having a smaller cross-section than the bottom-compartment sidewall portion provided at the distal end; the plunger inserted into the syringe body plunger head first through the bottom-end opening; the plunger head configured and adapted to form a seal when the plunger head engages the top-compartment sidewall, wherein the plunger is axially translatable between a first position where the plunger head is sealingly engaged with the top-compartment sidewall dividing the syringe

body into a top compartment and a bottom compartment, and a second position where the plunger head disengages from the top-compartment sidewall establishing a two-way flow communication between the top and bottom compartments; and a bottom closure member having a central aperture in which the plunger shaft is slidably disposed, wherein the bottom closure member is slidable along the plunger shaft between an unsealed position where the bottom-end opening is not sealed and a sealed position sealing the bottom-end opening of the syringe body.

The syringe according to the '194 Patent may be used to form a multi-compartment container for storing a variety of medicaments as, for example, medicaments for human use in the form of a dry powder which are mixed with a liquid to form a liquid formulation shortly before use. Such medicament, for example, may include a variety of drugs, e.g. antibiotics. The shelf life of such mixed dry powder and liquid formulations is limited, and this dictates the need to prepare the formulation only shortly before use. The limited shelf life of the powder and liquid formulation is a result of a loss of activity of an active ingredient in the formula, accelerated oxidation once in solution, etc.

While this syringe has various advantages over conventional syringes, it is a single barreled syringe, requiring either that the compartments be filled in a single location or by the user at the time of use. Additionally, filling the separate compartments of this syringe with different components is cumbersome and limited. Furthermore, it has little flexibility, as in cases where one component may be mixed on one occasion with a second component, while on another occasion, it is preferred to mix the first component with a different component altogether. In addition, if an additional component is required to be added it is not possible to add another compartment to a prepared syringe of defined size and volume.

Another disadvantage of the single body syringe of the '194 Patent is the method of filling the syringe. The syringe is assembled and filled, according to one method, by first orienting the body with the two-compartment embodiment of the syringe in an upright position with its top-end opening pointing upwardly. The plunger is then inserted into the syringe body, plunger-head portion first, until the plunger head engages the top-compartment sidewall. This forms a hermetic seal at the bottom of the top compartment near the shoulder portion. The top compartment is then filled with a first component of a

medicament, preferably a liquid, through the top-end opening and sealed with a suitable top sealing member or assembly.

Alternatively, the top compartment may be filled by inserting the plunger completely to the end of the top compartment, immersing the open top end in the liquid, then drawing the liquid into the top compartment by pulling the plunger back to its sealed position between the compartments. This method is only practical when the first component of the medicament is a liquid.

Next, the syringe device may be turned 180 degrees, with the sealed top end oriented downwardly, so that the bottom-end opening is facing up. The bottom compartment is filled with a second component of the medicament through the bottom-end opening and sealed with the bung. Filling the bottom compartment while the plunger shaft is disposed through the bottom-end opening is cumbersome and poses various constraints on the filling process. The second component may be a liquid or a powdered solid substance. In this embodiment where a bung seals the bottom opening, the second component may be placed in the bottom compartment in a hydrated form and dried using a lyophilization process.

There is a design concern with the prior art multi-compartment syringes that, prior to use, the compartments be hermetically sealed, so as to prevent, over an extended period of time, accidental pre-mature mixing of liquid or liquid vapor of a component in one compartment with a component in a second compartment. Another design concern with such multi-compartment syringes is that the user should be able to readily inspect the component in any of the compartments just prior to use, in order to verify its useful condition. Yet another concern with many of the multi-compartment syringes is the relatively high cost of manufacture.

Accordingly, it would be very desirable to have a multi-compartment syringe which is formed of two or more separate containers capable of separately storing one or more different components, and which can be joined together as desired, depending upon the components required, and which can further be extended *in situ*, if additional components are required. Advantages of such a multi-compartment syringe include the possibility of filling the compartments in different locations and assembling the syringe where and when needed. Additionally, the filling of the separate containers, each having top

and bottom sealable openings, is a much easier and more flexible task. Because each component of a multi-component medicament may be stored in separately sealed containers, the components of a medicament may be stored for longer periods without concerns of accidental mixing. The use of such a syringe may also shorten the time required for administering a medicament which is a solution of two components. Each of the assembly units may be provided in various sizes to accommodate different quantities of each component of a medicament, where appropriate. In particular, the dispensing unit may have a pre-selected volume permitting multiple injections of a pre-selected dose of a medicament. In this case, the medicament may be stored in the plunger unit whereas the dispensing unit may have a pre-selected volume permitting multiple injections of a pre-selected dose of a medicament, which is transferred from the plunger unit into the dispensing unit just prior to injecting of the pre-selected dose.

SUMMARY OF THE INVENTION

The syringe assembly of the present invention consists of two basic types of assembly units: a dispensing unit, and a separate, independent plunger unit. The dispensing unit and the plunger unit are assembled together coaxially to form a two-unit syringe assembly for storage or just prior to use. At least the dispensing unit is a container for a material to be dispensed and, by inserting one or more extension units between the dispensing unit and the plunger unit, additional compartments may be added. Each extension unit may contain a different component of a formulation in any predetermined quantity. For purposes of the present application, the terms component, formulation, medicament, mixture, solution, or any combination thereof, can also be referred to as a material.

The syringe assembly of one embodiment of the invention allows the user to store one or more components of a formulation in separate individual units that can be assembled easily into a single multi-compartment syringe assembly, which can store the multiple components separately until they are ready for use, at which time the components may be mixed to form the formulation just prior to dispensing. Each of the assembly units may be a separate container that may be assembled together readily to form a single multi-unit syringe assembly, with each of the assembly units forming a separate compartment.

It is to be appreciated that, because the volumes of the dispensing unit and the plunger unit may be varied in unlimited combinations, this assembly system provides the flexibility of allowing the user to prepare varying quantities of a given formulation, as well as to prepare a complex formulation with multiple components of varying quantities. Each of the assembly units may be provided in various volumes to accommodate different quantities of each component of a formulation where appropriate. In addition, according to one embodiment of the invention, the dispensing unit may be sized to contain a pre-selected volume of a component or mixture to be dispensed, which is stored in the plunger unit and transferred to the dispensing unit before dispensing. Thus, the dispensing unit may be selected to have the appropriate volume for a fixed dosage of a component or mixture.

Alternatively, the plunger unit need not contain a component to be dispensed or mixed, but may be designed to hold only a plunger, and be arranged to dispense a material from a plurality of dispensing units, which are coupled to the plunger unit one at a time.

Another advantage of using the multi-compartment syringe assembly of this invention over the prior art single barrel multi-compartment syringes is that the assembly provides longer storage-life for the components of a formulation and, in most applications, there is no need for special storage conditions of the assembly and/or components, such as refrigeration. Because each component of a multi-component formulation may be stored in separately sealed containers, the components of a formulation may be stored for longer periods without concerns of accidental mixing.

A dispensing unit may be a container for storing a component of a formulation, or for providing a single, pre-measured dose of a component or mixture, the container having an opening at each end of the container body. The bottom end of the dispensing unit may be adapted and configured to engage a plunger unit in order to assemble a multi-compartment syringe assembly. The top end of the dispensing unit may be adapted and configured to engage a dispensing device, such as a hypodermic needle, or a dosage device, etc.

Both ends of the dispensing unit may typically be sealed so that the dispensing unit's content can be protected from any contamination or spillage during storage. And because these seals must be removed in order to assemble the multi-compartment syringe assembly and dispense the contents, the seals are preferably configured to be readily removed or broken, e.g., a breakable or peelable seal. The breakable or peelable seal may comprise a

membrane where the membrane may be a foil or a non-metallic membrane, such as a plastic or other polymer membrane, and may have a single-layer or a multi-layered laminate structure. Such membrane seal may be heat sealed along the rims of the dispensing unit's open ends so that it may be peeled off to engage a plunger unit or to attach an appropriate dispensing device. The seal may further comprise a screw-on or pressure-closing cap.

A plunger unit is a second container for storing another component of the formulation or a formulation itself, with an opening at each of the top and bottom ends of the container. The top open end of the plunger unit may be adapted and configured for sealing engagement of the bottom opening of the dispensing unit in order to assemble a two-unit syringe assembly. To form a two-compartment syringe assembly, the upper portion of the plunger unit, which may define a joining sleeve, is inserted into a depending flange defining the bottom portion of the dispensing unit, whereby each assembly unit forms a separate unit of the resulting syringe assembly. The diameter of the inner sidewall of the depending flange is sized for receiving and sealingly engaging the upper portion of the plunger unit.

A plunger having a shaft, a distal end, a proximal end, and a plunger head at the distal end is disposed within the plunger unit for dispensing a material stored in any unit of the syringe assembly, or for selectably providing two-way flow communication between the plunger unit and the dispensing unit. Thus, the head of the plunger sits in the joining sleeve of the plunger unit and preferably forms a fluid-tight seal with the inner sidewall surface of the joining sleeve. According to one embodiment of the invention, the diameter of the head of the plunger is smaller than the diameter of the body of the plunger unit, so as to provide a passage between the plunger head and the inside wall of the body of the plunger unit. At the same time, the plunger head is configured and adapted to form a slidable hermetic seal when it engages the inner sidewall of the dispensing unit.

To lock the units to one another, the outer surface of the joining sleeve may be provided with one or more locking elements, which engage mating locking elements on the inner sidewall of the flange of the dispensing unit. An additional sealing washer or other sealing element may be disposed in the upper portion of the depending flange for engagement by the top edge of the joining sleeve to provide a hermetic seal between the dispensing unit and the plunger unit.

According to a preferred embodiment, the plunger head is movable between a sealed position, where it forms a seal between the plunger unit and the dispensing unit, and an unsealed position, whereby a two-flow communication is formed between the dispensing unit and the plunger unit. The sealed state may be established by positioning the plunger head in the joining sleeve of the plunger unit or in the body of the dispensing unit. In the unsealed state, the plunger head is positioned inside the body of the plunger unit, which has a larger diameter than the plunger head.

A closure member having an aperture is also provided at the bottom of the plunger unit. The plunger shaft is slidably disposed within the aperture of the closure member so that the closure member is slidable along the plunger shaft between a sealed position, hermetically sealing the bottom-end opening of the plunger unit, and an unsealed position where the bottom-end opening is not sealed. When the closure member is in its sealed position, it seals the bottom end of the plunger unit and the plunger can be axially translated between its first position and its second position without moving the closure member.. To enable the translation of the plunger without displacing the closure member, the closure member may be configured and adapted so that the friction between the closure member and the sidewall of the syringe body is greater than the friction between the closure member and the plunger shaft. Alternatively, the closure member may have screw threads for screwing onto the body of the plunger unit.

In a three- or more compartment syringe assembly according to the invention, one or more extension units are provided and adapted to be affixed between the dispensing unit and the plunger unit. Each extension unit includes a substantially cylindrical sidewall portion having a sealable opening at each end. According to a preferred embodiment, the diameter of the sidewall portion of the extension unit will be larger than the diameter of the dispensing unit but smaller than the diameter of the plunger unit. The top end of the extension unit may be adapted and configured to engage the bottom end of the dispensing unit, and the bottom end of the extension unit may be adapted and configured to engage the top end of a plunger unit, in order to assemble a multi-compartment syringe assembly. The top and bottom seals are coupled to permit them to slide in tandem inside the syringe assembly.

The syringe assembly may be filled and assembled in a number of ways, according to the particular embodiment. First, the dispensing unit, which constitutes the top compartment, is filled with a desired component, if any. The dispensing unit may be filled through the top-end opening and sealed with a suitable topsealing member, if desired. Alternatively, the top end opening may be sealed first, and the dispensing unit rotated through 180 degrees to permit filling through its larger, bottom end opening. Then this sealable opening is sealed hermetically, permitting the dispensing unit to be stored until needed. The first component may be a liquid, a gel, or a powdered solid substance.

It is a particular feature of the present invention that the component stored in the dispensing unit conveniently may be a powdered solid component. The dispensing unit may be easily filled with a powdered substance through the relatively large bottom-end opening of the dispensing unit. It will be appreciated that it is much easier to inspect a powdered component when it is in the dispensing unit, since the material can be easily viewed through the transparent syringe body, without interference from the plunger shaft, and the state of the component can be determined before use. Thus, the syringe also provides easily viewed tamper evidence. Furthermore, as described below, the assembled syringe assembly of the present invention provides double protection against liquid leakage from one compartment to a second compartment.

Alternatively, the dispensing unit may be a disposable ampoule, for holding a single dose of a medicament for dispensing by the plunger unit.

Next, if desired, the plunger unit is filled. The top-end opening is sealed by a removable seal. The plunger unit is now filled through the bottom-end opening. The plunger head is inserted into the bottom end of the plunger unit, and the closure member is slid along the plunger shaft until it seals the bottom-end opening of the plunger unit. The plunger unit is now rotated through 180 degrees to permit the component to pass around the plunger head towards the bottom portion of the plunger unit. The plunger is now pushed through the plunger unit until the plunger head sealingly engages the inside wall of the joining sleeve. The plunger unit may now be stored until needed.

The second component may be a liquid, gel or a powdered solid substance. To prevent any degradation of a liquid component from prolonged exposure to air during storage, the compartment holding the liquid may be sized to fill completely with the liquid

component, minimizing or eliminating any air pockets inside the compartment. Alternatively, any unfilled space in the compartment may be filled with a material, such as nitrogen gas for example, which is inert with the first component.

According to one embodiment of the invention, where a bung seals the bottom opening of the plunger unit, the second component may be placed in the plunger unit in a hydrated form and dried using a lyophilization process. Before the lyophilization process begins, the bung is brought close to the sealable opening so that it almost fits into the sealable opening, and the substantial portion of the bung remains outside the sealable opening. The vacuum created in the plunger unit during the lyophilization process pulls the bung completely into the sealable opening, sealing the bottom-end opening. It will be appreciated that this process can also be performed with a component in a dispensing unit having a bung as a bottom end seal.

At the time of assembling the syringe assembly, the dispensing unit is coupled to the plunger unit, as by means of mating locking elements in the plunger head and the bottom end seal of the dispensing unit. Thus, the bottom end seal of the dispensing unit forms an integral part of the plunger head. Once assembled, this syringe assembly operates like a single barrel, multi-compartment syringe.

The present invention also provides processes for preparing multi-unit syringe assemblies. The process includes:

(a) providing a dispensing unit having a dispensing unit body and a sealable opening at each of its top and bottom ends;

(b) providing a separate, independent plunger unit having a plunger unit body and a sealable opening at each of its top and bottom ends;

(c) placing a plunger within the plunger unit, the plunger having a plunger head adapted to form a seal closing the top opening of the plunger unit, and

(d) coupling the dispensing unit coaxially to the plunger unit to form a two-unit syringe assembly.

The process may further include providing at least one independent extension unit having a cylindrical body and sealable openings at it top and bottom end, and coupling the extension unit between the dispensing unit and the plunger unit to form a three- or more unit syringe assembly.

The process may further include the steps of filling the dispensing unit and/or the plunger unit before coupling the units to form the syringe assembly. Alternatively, the process may further include the steps of filling the dispensing unit and/or the plunger unit after coupling the units to form the syringe assembly.

The present invention also provides processes for preparing multi-unit syringe assemblies for holding and storing one or more components of a formulation separately until the units are assembled into a single multi-unit syringe for dispensing the formulation or for mixing the contents of the compartments prior to dispensing. The process includes:

(a) providing a dispensing unit having a housing and an opening at each of its top and bottom ends;

(b) sealing one end of the dispensing unit;

(c) introducing a first component of a formulation, if there is more than one, into the dispensing unit through the other end and sealing that end;

(d) providing a separate, independent plunger unit having a plunger unit body and an opening at each of their top and bottom ends;

(e) placing a plunger within the plunger unit, the plunger having a plunger head adapted to form a seal closing the top opening of the plunger unit,the plunger head movable between a sealed position and an unsealed position; the plunger being placed in the plunger unit in the sealed position; (f) introducing a different component of the formulation, or a medicament if there is only one, into the plunger unit through the sealable filling opening of the plunger unit; and

(g) sealing the sealable filling opening.

Once the dispensing units and the plunger units are prepared and sealed, they can be stored for extended periods of time until they are ready to be assembled into a single multi-compartment syringe to dispense the contents of the plunger unit or the dispensing unit, or to mix the contents of both units into a formulation for dispensing.

After the user has assembled the filled assembly units into a multi-compartment syringe and mixed and dispensed the contents of the syringe, the assembly units, particularly the plunger unit, can be reused. The assembly units may be disassembled and then refilled, or different dispensing units may be affixed, one at a time, to the plunger unit, for dispensing the contents of the dispensing units.

Furthermore, the assembly units, according to one embodiment of the present invention, may be filled and pre-assembled into a multi-compartment syringe and then stored as an assembly until the contents of each unit are ready to be mixed and dispensed. It is to be appreciated that in the assembled state, each dispensing unit and plunger unit forms a separate compartment of the multi-compartment syringe, preventing the contents of the units from mixing prematurely.

The syringe assembly of the present invention is also useful for providing multiple injections of a pre-selected dosage of a single medicament. In this case, the plunger unit may be filled with the desired medicament and sealed with the plunger head. The dispensing unit may consist of an empty container of a pre-selected volume for holding the pre-selected dosage, which is filled from the plunger unit when the plunger head is moved to the unsealed position, permitting flow communication between the plunger unit and the dispensing unit. When the dispensing unit is full, the plunger head is moved to the sealed position, and the pre-selected dosage is ready for dispensing.

The syringe assembly of one embodiment of the present invention permits multiple use of the plunger unit with an unlimited number of dispensing units, one at a time. According to this embodiment, the plunger unit does not contain a component of the medicament, and merely serves to press a bottom end seal of the dispensing unit so as to dispense the contents of the dispensing unit. Additionally, a single plunger unit can be used repeatedly with a combination of extension units with dispensing units, for dispensing, or for mixing and then dispensing, the components in the combined extension and dispensing units.The invention will now be illustrated in some specific embodiments directed to two and three-compartment syringe assemblies, fitted with a hypodermic needle as the dispensing device. It will be appreciated by one of ordinary skill in the art that the same principle is also applicable to form containers with additional separate components, and containers for other applications and areas where it is desired to store components of multiple-component formulations separately in individual containers and then assemble the individual assembly units into a single multi-compartment syringe which will store the components separately in such multi-compartment containers which may later be mixed to form and dispense the formulation.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an embodiment of the syringe assembly of the invention in a non-assembled state, having two compartments where the syringe bodies are illustrated as being translucent in order to show the internal structures of the syringe;

Fig. 2 is a partial sectional view of the syringe assembly of **Fig. 1**;

Fig. 3 is a perspective view of the syringe assembly of **Fig. 1**, when the two compartments have been assembled to form a single syringe;

Fig. 4 is a partial sectional view of the syringe assembly of **Fig. 3**, where the sealing elements of the two compartments have been joined to one another;

Fig. 5 is a perspective view of the syringe assembly of **Fig. 1**, illustrating the syringe assembly in an interim stage in the process of filling and assembling the syringe assembly, where the dispensing and plunger units have been filled with desired substances and sealed;

Fig. 6 is a perspective view of the syringe assembly of **Fig. 5**, showing the fully assembled syringe, where the cap has been removed from the top-end opening and replaced with a hypodermic needle for dispensing the medicament;

Fig. 7 is a partial sectional view of the syringe assembly of **Fig. 6**, where the plunger has been retracted into the plunger unit so that the two compartments are in communication with one another allowing the contents of the two compartments to mix;

Fig. 8 is a partial sectional view of the syringe assembly of **Fig. 7**, where the plunger has been pushed into the dispensing unit for dispensing the mixed medicament, which is now in the dispensing unit;

Fig. 9 is a perspective view of the syringe assembly of **Fig. 7**, where the plunger is in a fully depressed position after the medicament in the dispensing unit has been completely dispensed.

Fig. 10A is a perspective view of another embodiment of the syringe assembly of the invention in a non-assembled state, having two compartments particularly for use as a multi-dose syringe;

Fig. 10B is an exploded view of the syringe assembly of **Fig. 10A;**

Fig. 11A is a plan view of the syringe assembly of **Fig. 10** when the two compartments have been assembled to form a single syringe;

Fig. 11B is a sectional view of the syringe assembly of **Fig. 11A** taken along line A-A;

Fig. 12 is a partially cut away perspective view of the syringe assembly of **Fig. 11A**, where the plunger has been withdrawn to permit flow communication between the plunger unit and the dispensing unit;

Fig. 13 is a perspective view of the syringe assembly of **Fig. 11A**, where the plunger is in a fully depressed position after the dose of the medicament in the dispensing unit has been completely dispensed.

Fig. 14 is a perspective view of an embodiment of the syringe assembly of the invention in a non-assembled state, having three compartments where the syringe separate units are illustrated as being translucent in order to show the internal structures of each of the units of the syringe;

Fig. 15 is a partial sectional view of the assembled syringe assembly of **Fig. 14**, where the plunger is in the sealed position; and

Fig. 16 is a partial sectional view of the assembled syringe assembly of **Fig. 14**, where the plunger has been withdrawn so that the plunger head and the second extension bung are in the plunger unit and the first extension bung is in the extension unit, so that the three compartments are in communication with one another allowing the contents of the three compartments to mix;

Fig. 17 is a perspective view of another embodiment of the syringe assembly of the invention in a non-assembled state; and

Fig. 18 is a perspective view of the syringe assembly of **FIG. 18** in an assembled state.

The drawings are only schematic and are not necessarily to scale.

DETAILED DESCRIPTION OF THE INVENTION

Some examples of the syringe assemblies of the present invention are provided to illustrate various specific configurations and examples of the invention. The invention should not be regarded as being limited to these embodiments. The syringe assemblies may also be used for different uses, e.g., a syringe assembly of two or more units used as compartments for medicinal formulations, dietary powders to be reconstituted with a liquid or other mixtures wherein one compartment contains one component and the other compartment contains another component to be mixed to form a formulation. Alternatively, a syringe assembly according to the present invention is formed of a plunger unit and a dispensing unit, wherein the plunger unit holds a medicament and the dispensing unit is adapted to hold a pre-selected dose of the medicament for administering it. According to a preferred embodiment, using a dispensing unit of a small volume relative to the volume of the plunger unit, allows the user to repeat the administering of the pre-selected dose until the entire medicament has been dispensed. Alternatively, a syringe assembly may be formed of a plunger unit adapted to be coupled to a plurality of dispensing units, one after the other, for dispensing a medicament from the dispensing units by the plunger unit.

FIGS. 1 and **2** illustrate a syringe assembly **2** in a non-assembled state, including a dispensing unit **10** with a body **12**, a top opening **16** and a bottom opening **18**. Preferably, body **12** is substantially cylindrical. The bottom portion of body **12** may define a depending flange **14** adapted and configured for a sealed locking engagement with a plunger unit **30**.

The top portion of body **12** may define an open ended nipple **20** with top-end opening **16**. Nipple **20** may be adapted and configured for attaching an appropriate dispensing device, e.g. a hypodermic needle (not shown). For illustrative purposes, in this embodiment dispensing unit **10** is provided with a screw thread for sealing attachment of a removable screw cap **19** (shown in **Fig. 2**) or a dispensing device. It will be appreciated that the top portion **17** of body **12** may be sealed, for example, by a removable cover member (not shown). According to one embodiment, the cover member is provided with a screw thread on a first end for sealing attachment to body **12** having matching screw threads (not shown), and a screw thread on a second end for sealing attachment of a desired dispensing

device having matching screw threads (not shown). Alternatively, the cover member may be replaceable by a dispensing device.

Dispensing unit **10** may be empty or may be filled with a medicament or a component of a formulation, which may typically be a liquid, a powdered substance, or a gel, etc. During the storage of the dispensing unit **10**, the top and bottom openings **16** and **18** respectively, may be sealed to prevent contamination or spoilage of the contents of the dispensing unit or spillage thereof. Opening **16** may be sealed with a membrane (not shown) with or without cap **19**. Opening **18** may also be sealed with a membrane (not shown) or with other suitable sealing methods (e.g., screw caps, or a bung **22**). The seals are preferably readily removable so that a plunger unit **30** and a dispensing unit **10** may be assembled into a multi-compartment syringe for dispensing, and possibly mixing, of a formulation. The sealing membranes may be foils or non-metallic membranes, and may have a single or a multi-layered structure. The membranes are preferably heat sealed to the open ends of the dispensing unit in such manner that they may be peeled off.

Syringe assembly **2** further includes a plunger unit **30** which is engaged with dispensing unit **10** to form a two-compartment syringe assembly. Plunger unit **30** has a body **50**. Preferably, body **50** is substantially cylindrical. The top portion of body **50** defines a neck portion having an inner sidewall diameter smaller than the inner sidewall diameter of body **50** and an outer sidewall diameter smaller than the inner sidewall diameter of flange **14**, and forming a joining sleeve **34,** having a top opening **32.** When plunger unit **30** and dispensing unit **10** are assembled, joining sleeve **34** is inserted into flange **14** of dispensing unit **10**. The outer sidewall of joining sleeve **34** maybe provided with two or more slightly slanted, peripherally extending ribs **33** configured for locking engagement with at least two matching ribs **36** peripherally extending from the inner sidewall of the flange **14** of the dispensing unit **10**. This provides a friction-fitting joint between the inner sidewall of flange **14** and the outer sidewall of joining sleeve **34**. A sealing washer **13** or other sealing element is provided in the upper portion of flange **14** for engagement by the top edge of the joining sleeve **34**, to provide a hermetic seal between the dispensing unit and the plunger unit in the assembled syringe. The internal diameter of sealing washer **13** is substantially equal to the inner sidewall diameter of body **12**.

Plunger unit **30** also includes a plunger **44.** The plunger **44** may be axially displaced between a sealed position and an unsealed position. The plunger **44** consists of a user manipulable plunger shaft **41**, having a distal end **45** and a proximal end **47** and is provided with a substantially cylindrical plunger head **64** at distal end **45.** The outer diameter of the plunger head **64** is substantially the same as the inner sidewall diameter of joining sleeve **34,** and substantially the same as the inner sidewall diameter of dispensing unit body **12**. Thus, in the sealed position, plunger head **64** sealingly engages the inner sidewall surface of joining sleeve **34** thereby closing opening **32** in a fluid-tight manner, and forming a hermetically sealed partition between dispensing unit **10** and plunger unit **30.** In an unsealed position, plunger head **64** is axially retracted inside the compartment defined by plunger unit body **50**, where the inner sidewall diameter is larger than the outer diameter of plunger head **64**, which allows the component in this compartment to flow around plunger head **64**. Plunger head **64** is preferably made of an elastomer having characteristics (e.g. hardness, elasticity, etc.) that is suitable to provide the desired sealing quality. The particular elastomer selected for the plunger head **64** should also be chemically inert with respect to the particular medicament or components with which plunger head **64** may come in contact. A thumb rest **49** may be provided on proximal end **47** of plunger **44** with which a user may urge the plunger **44** into the syringe assembly **2** to dispense of its contents. In the unsealed position, plunger head **64** is disengaged from sealable opening **32**, allowing a two-way flow-communication between the compartment defined by body **50** and the compartment defined by body **12**, through opening **32**. The diameter of the inner sidewall of body **12** is sized for receiving and sealably engaging plunger head **64**.

According to one embodiment, illustrated in **Fig. 1**, dispensing unit seal **22** is a bung having substantially the same outer diameter as body **12** of dispensing unit **10**. Bung **22** is adapted and configured to lockingly engage plunger head **64**. Preferably, the locking mechanism is a bayonet lock. As illustrated, the bayonet locking mechanism includes an elongated locking member **39** fitted to pass through a matching recess **43** in plunger head **64** and lock one to the other by turning the assembly units, or either one of them, relative to one another, simultaneously with locking flange **14** to joining sleeve **34**. It will be appreciated that the locking mechanism is preferably releasable.

The syringe assembly **2** also includes a threaded closure element **38** for sealing the bottom-end opening **50b** of the plunger unit **30.** The closure element **38** is sized to receive the bottom end of the body **50** of plunger unit **30,** and is provided with screw threads **40** along its inner sidewall, shown in **Fig. 2**. Body **50** is provided with mating screw threads (not shown) near its bottom end so that the closure member **38** can be screwed onto body **50** and seal the bottom opening of the plunger unit **30**. Closure member 38 mechanically prevents accidental or unwanted removal of plunger **44** out of plunger unit **30.**

Closure element **38** has a central aperture along its longitudinal axis so that plunger **44** is received through the central aperture of closure element **38** which can be moved up and down the plunger shaft **41** until it abuts against a protruding flange **51** near the bottom-end opening **50b** of body **50.** Closure element **38** preferably includes a sealing washer (not shown) for sealingly engaging the bottom-end opening **50b** of the plunger unit. Part of the inner surface of closure element **38** adjacent the central aperture may be provided with a plurality of inner sealing ribs (not shown), or a plurality of grooves **43** for receiving o-rings **42**, or other annular seals, for sealingly engaging the plunger shaft **41.** These annular seals may be configured to form hermetic seals with the mating surface through compression. The bottom closure element **38** may be made of a single material or formed as a composite, but preferably at least the sealing ribs or the o-rings which sealingly engage plunger shaft **41**, and the inside surface of closure element **38** which sealingly engage the body **50,** are made from an elastomer.

When the closure element **38** is positioned in its sealed position, preferably plunger **44** can be withdrawn partially from plunger unit **30** without dislodging closure element **38** from its sealed position in the bottom-end opening **50b** of body **50** of the plunger unit. This allows the plunger head **64** to be disengaged from the sealable opening **32** of joining sleeve **34** to establish communication between the plunger unit and the dispensing unit without unsealing the bottom-end opening of the plunger unit.

According to another embodiment of the present invention, closure element may be a bung (not shown). To enable the translation of plunger **44** without dislodging the closure element **38** where it is a bung, from its sealed position, closure element **38** may be configured and adapted so that the friction between the outer surface of closure element **38** and the inner sidewall of body **50** is greater than the friction between closure element **38** and

the plunger shaft **41**. In this embodiment, the frictional forces between closure element **38** and the plunger unit body **50** and plunger shaft **41** may be controlled by varying the number of the sealing elements at each sealing surface. Alternatively, it will be obvious to one of ordinary skill in the art that the same result could be achieved by many other methods. For example, the dimensions of the sealing elements, such as their widths and thicknesses, may be varied to achieve the desired frictional forces at each sealing interface without necessarily varying the number of the sealing elements.

According to one embodiment of the invention, illustrated in **Figs. 1** and **2**, bottom opening **18** of dispensing unit **10** is sealed by a bung **22**, adapted and constructed to frictionally seat in body **12** and provide a bottom-end seal of the dispensing unit compartment. Similarly, the top-end opening **32** of plunger unit **30** is sealed by plunger head **64**, adapted and constructed to frictionally seat in joining sleeve **34** and seal the plunger compartment.

Figs. 3 and **4** illustrate a fully assembled syringe assembly **100**, which is substantially similar to the syringe assembly **2** of **Fig. 1**, with plunger unit **112** and dispensing unit **110** in their sealed configuration, each holding a component of a formulation. Plunger head **132** lockingly engages a bung **103** sealing bottom-end opening **116** (see **Fig 5**) of dispensing unit **110.** Plunger **130** is positioned inside plunger unit **112** so that the whole plunger head **132** sealingly engages joining sleeve **125** (see **Fig 5**), thereby sealing the sealable opening **124** (see **Fig. 5**) of plunger unit **112**. Thus, dispensing unit **110** and plunger unit **112** form a single syringe assembly, temporarily partitioned by plunger head **132** and bung **103** lockingly engaged to one another**.** The seal formed by the plunger head **132** and bung **103** against the inner sidewalls of bodies **104** and **102**, respectively, may be hermetic so that two components of a medicament or other formulation may be stored separately in each compartment until ready to be mixed. Disengaging plunger head **132** from joining sleeve **125** by retracting plunger **130** would allow a two-way flow-communication between the compartment defined by plunger unit **112** and the compartment defined by dispensing unit **110**.

In this fully assembled and ready-for-storage configuration, closure element **108** sealingly engages the bottom-end of body **104** of the plunger unit **112,** plunger head **132**

hermetically sealing the top-end opening **124** (see **Fig 5**) of the plunger unit **112**, and bung **103** hermetically sealing the bottom-end opening **116** of dispensing unit **110**.

The top-end opening of nipple **114** of the dispensing unit is removably sealed with a top sealing member **115** or an assembly which is configured to be removable when desired; for example, when the contents of the syringe assembly **100** have been mixed and are ready to be dispensed. Top sealing member **115** may be a cap as shown in **Fig 3**. In this embodiment, top sealing member **115** is a screw cap. Cap **115** is provided with screw threads (not shown) and nipple **114** of dispensing unit **102** is also provided with screw threads so that cap **115** can be screwed onto dispensing unit **102** to seal the top end opening of nipple **114.**

It will be apparent to those skilled in the art that top sealing member **115** and nipple **114** may be configured to sealingly engage each other in a variety of ways that may be appropriate and suitable for a particular application. For example, the top sealing member **115** may be a foil or a membrane (not shown) made of a suitable material that may be heat sealed along the top rim of nipple **114**. The heat sealed membrane may be peeled away to unseal the top-end opening of nipple **114** when the syringe assembly **100** is ready to be used.

In a typical intended use, a dispensing unit **110** would be sealingly engaged to the top end of a plunger unit **112** whereby the dispensing unit and the plunger unit form the upper and lower compartments of a two-compartment syringe assembly respectively. The two-compartment syringe may be assembled without breaking the seal formed by plunger head **106** and bung **103**, and may be used to store the components in assembled fashion and later controllably remove the seal by retracting plunger shaft **130** and unsealing top-end opening **124** of plunger unit **112**, and bottom-end opening **116** of dispensing unit **110**, to mix the components and form the formulation. Since the outer surface of plunger head **106** has a smaller diameter than plunger unit body **104**, axially moving the locked plunger head **106** and bung **103** inside body **104** provides two-way flow communication around the plunger head, thereby allowing the components of the two-compartment syringe assembly to mix.

Fig. 5 is a perspective illustration of the syringe assembly **100** in an interim stage in the process of filling and assembling the syringe assembly, where the dispensing and plunger units have been filled independently with desired substances and sealed. The dispensing unit **110** has been filled with the first component of a medicament. The top-end

opening of a nipple **114** has been sealed with a cap **115** and the opposite end by a bung **103.** The plunger unit **112** has been filled with the second component of a medicament. The bottom-end opening **126** has been sealed with a closure element **108** and the opposite end by a plunger head **106.**

The process of filling and assembling the syringe assembly **100** will now is described with the aid of **Figs. 5** and **6**. A plunger **130** is positioned inside the plunger unit body **104** in the sealed position, and plunger head **106** seals top-end opening **124** of plunger unit **112.** The compartment defined by the plunger unit body **104** may be filled with a component of a formulation through sealable filling opening **126** on the bottom side of the plunger unit **112.** Sealable filling opening **126** may then is sealed with closure member **108.**

Alternatively, the compartment defined by the plunger unit body **104** may be more conveniently filled by sealing top end opening **124** with a foil or a non-metallic membrane having a single or multi-layered structure. The plunger unit may now be rotated through 180 degrees and filled through sealable bottom end opening **126**. Closure member **108** is mounted about shaft **138** of plunger **130.** Plunger **130** may now be positioned inside the plunger unit body **104** and the plunger unit sealed by closure member **108.**

Yet another option is to position plunger **130** inside the plunger unit body **104** where plunger head **106** is in the unsealed position, and sealably close closure member **108.** The plunger unit is now filled through the top end opening **124** and the plunger head **106** is moved to a sealing position inside joining sleeve **125** of plunger unit **112**. This is possible due to the fact that the outer diameter of the plunger head is smaller than the inner sidewall diameter of plunger unit body **104.**

The dispensing unit may be filled as follows. The bottom-end opening **116** of a dispensing unit **110** is sealed by a bung **103.** The dispensing unit **110** can be filled with a desired component of a medicament through the top-end opening of nipple **114**. Once the dispensing unit **110** is filled, it may be sealed by closing the nipple **114,** as with a screw cap **115**.

According to another embodiment, the top opening of the dispensing unit body **102** is sealed by a threaded cover member (not shown) provided with a screw thread on a first end for sealing attachment to body **102**, and a screw thread on a second end for sealing attachment of a desired dispensing device. In this embodiment, the bottom-end opening **116**

of a dispensing unit **110** is sealed by a bung **103**, and the threaded cover member removed. The dispensing unit may now easily be filled through the top opening, and the closed by the threaded cover member.

Alternatively, the top-end opening of nipple **114** of dispensing unit **110** is sealed, as with cap **115.** The dispensing unit **110** is now oriented in an upside down position with its bottom-end opening **116** pointing upwardly. The dispensing unit **110** can now be easily filled with a desired component of a medicament through the relatively large bottom-end opening **116**. This embodiment is particularly suitable for storing a powdered component in the dispensing unit, since its translucent or transparent sidewall permits easy viewing of the component before use, to permit the user to inspect the physical condition of the component in the dispensing unit prior to use. Once the dispensing unit **110** is filled, it may be sealed by inserting a bung **103** into bottom-end opening **116**. The dispensing unit may now be stored until required for assembly prior to use.

According to another filling option, the syringe assembly is first assembled, by coupling the dispensing unit to the plunger unit. In this case, a plunger **130** having a plunger head **106** sized to fit the inner sidewall of body **102** is pushed into body **102** of dispensing unit **110.** Top-end opening **114** is opened or fitted with a hypodermic needle **117**. The dispensing unit **110** may then be filled from a conventional medicament bottle by immersing the open top end in the first component liquid, then drawing the liquid into the dispensing unit by retracting plunger **130** back to withdraw a desired quantity. The dispensing unit **110** may be dimensioned so that when the plunger is withdrawn back to the filled position, the dispensing unit **110** will be filled with a predetermined desired amount of the first component. In this case, plunger unit **112** may be filled before assembly of the syringe assembly. Alternatively, after filling the dispensing unit, closure element **108** is opened and moved along the shaft of the plunger so that the plunger unit may be filled through the bottom end opening. Once it is filled, plunger unit **112** may be sealed by closure element **108**.

To prevent any degradation of a liquid component from prolonged exposure to air during storage, the plunger unit or the dispensing unit may be filled completely with the liquid component, minimizing or eliminating any air pockets inside the unit when sealed. Alternatively, the filling process may be conducted under a vacuum or an inert gas

environment so that even if the unit is not completely filled with the liquid component, there would not be any air trapped inside the unit after being sealed.

It will be appreciated that the dispensing and plunger units of the invention may be filled with different components and in different locations, and can be sealed and stored separately prior to assembly and use.

Fig. 6 illustrates the fully assembled syringe assembly **100** ready for use. The syringe assembly **100** now consists of two completely sealed compartments – the dispensing unit **110** and the plunger unit **112** – where each compartment is holding a component of a medicament, coupled together until ready to be mixed just prior to use. Coupling of the two units, according to the illustrated embodiment, is as follows. Sealing washer **13** (see **Fig. 1**) is disposed in depending flange **118.** Joining sleeve **125** of the plunger unit **112** is inserted into depending flange **118** of the dispensing unit **110**. At the same time, the bayonet locking mechanism **39** (See **Fig. 1**) on bung **103** engages matching recess 43 (See **Fig. 1**) in plunger head **106**. The dispensing unit is now rotated relative to the plunger unit, in order to seal the separate units to form a single syringe assembly. As can be seen in **Fig. 6**, the peripherally extending ribs **113** on joining sleeve **125** of body **104** of the plunger unit **112** have been rotated to engage two matching ribs **111** peripherally extending from the inner sidewall of the flange **118** of the dispensing unit **110**, and the plunger head **106** lockingly engages the bung **103.**

In the embodiment where the bottom end opening of the dispensing unit is sealed by a membrane or laminate, assembly of the syringe assembly is accomplished by removing the seal from the bottom end of the dispensing unit, when in an upside down position, and locking the two units together, as described above. Plunger head **106** positioned inside joining sleeve **125** provides a sealed partition between the two compartments of the syringe assembly, preventing flow communication between the two units until ready for dispensing.

Then, as shown in **Fig. 6**, cap **115** may be removed and a syringe needle **117** may be attached to the top-end opening of nipple **114.** Depending on the application, other dispensing apparatus may be attached to the top-end opening to dispense the medicament or any other formulation.

The process involved in preparing and dispensing the medicament from the two components stored in the syringe assembly **100** will now be described with reference to

Figs. 7-9. In order to mix the two components of a medicament stored in the syringe assembly **100**, the plunger **130** is first retracted so that the plunger head **132** disengages from the joining sleeve **125,** as illustrated in **Fig. 7**. It will be appreciated that withdrawing the plunger **130** moves the plunger head **132** and bung **103** lockingly engaged to the plunger head, into the plunger unit whose body **104** has a larger inner sidewall diameter than the inner sidewall diameter of the joining sleeve in which it was sealingly seated, thereby permitting two-way flow communication between the plunger unit and the dispensing unit. As known, the retraction of plunger **130** may be limited by a vacuum force that it may create inside syringe assembly **100**. However, since achieving the flow communication between the two units of the syringe plunger head **132** needs to be retracted a relatively short distance, such vacuum force is negligible.

Once a two-way flow communication is established, a medicament or medicaments in the dispensing unit **110** and the plunger unit **112** are free to flow around the plunger head **132** in and out of both units. During this procedure, the closure element **108** remains in place in its sealed position.

By withdrawing the plunger head **132,** together with bung **103,** from the joining sleeve **125** and the dispensing unit body **102** respectively, the two compartments are now in communication with one another so that the contents of the two compartments can mix.

According to one embodiment of the invention, the withdrawal of plunger **130** is limited by a stopper element (not shown) on the plunger shaft **138**. As the plunger **130** is withdrawn, the stopper element abuts against the shoulder **134** of closure element **108** and limits the travel of the plunger **130.** Typically, the syringe assembly **100** would be shaken vigorously to mix the contents of the syringe assembly **100**. The presence of the substantial portion of the plunger shaft **138** inside the plunger unit **112** enhances the mixing of the contents by functioning as an agitator during the shaking. This agitating function of the plunger shaft **138** may be further enhanced by providing vanes **131** in the portion of the plunger shaft that is positioned within the plunger unit **112**.

When the contents of the syringe assembly **100** are completely mixed and the medicament is ready for dispensing, the syringe assembly **100** is oriented so that the dispensing unit is pointing downward. This will cause the medicament to drain into the dispensing unit **110.** The volume of the two components of the medicament preferably is

controlled so that the mixed medicament would fit completely inside the dispensing unit **110** without overflowing into the plunger unit **112**. This minimizes any portion of the medicament from being wasted.

As seen in **Fig. 8**, the plunger **130** lockingly engaged to bung **103** is now pressed through joining sleeve **125** into the dispensing unit **110** for dispensing the mixed medicament, which is now in the dispensing unit. To completely dispense the medicament contained in the dispensing unit **120**, the plunger **130** is fully depressed into the dispensing unit **110** as illustrated in **Fig. 9**.

Once the medicament has been dispensed, the needle **119** may be disposed of in any conventional manner, and the syringe assembly may also be discarded. Alternatively, the plunger unit **112** may be separated from the dispensing unit **110**, by rotating so as to release the locking elements **111** and **113** from each other, and either or both units may be sterilized and re-used. It will be appreciated by those of ordinary skills in that art, that in order to depress **130** all the way from the plunger through the dispensing unit, air must enter the syringe assembly behind the axially moving plunger head **132**. As will be further described herein below, shaft **138** is provided with a longitudinal groove allowing air from outside the syringe assembly to enter the plunger unit as the medicament is being displaced by the plunger head through joining sleeve **125** and body **102** of the dispensing unit. When this process takes place, the medicament is no longer present in body **104** of the plunger unit, thus it cannot leak out of the syringe assembly through the groove in shaft **138**.

Figs. 10A and **10B** illustrate another embodiment of a two-compartment syringe assembly particularly suited for providing multiple injections of a pre-selected dosage. This two-compartment syringe assembly **200** comprises a dispensing unit **210** having a substantially cylindrical body **202** including openings at top and bottom ends, and a plunger unit **212** having a substantially cylindrical body **204** including openings at top and bottom ends. Inner sidewall of body **202** having one diameter and inner sidewall body **204** having a larger diameter. The top-end opening of the plunger unit **212** defines a protruding neck serving as a joining sleeve **206** having inner sidewall of smaller diameter than the inner sidewall of plunger unit body **204**. The bottom-end opening of the dispensing unit **210** defines a depending flange **208** sized to snugly engage the outer sidewall surface of the joining sleeve **206** of the plunger unit, thereby to join the two units together.

The syringe assembly **200** further comprises a plunger **230** having a plunger head **232** at its distal end **237.** When the plunger **230** is inserted inside the plunger unit **212**, the plunger head **232** sealingly engages the inner sidewall of joining sleeve **206** and seals the top-end opening of the plunger unit **212**. A sealing washer **233** may be provided in the bottom-end opening of the dispensing unit **210** to provide a hermetic seal to prevent leakage between the dispensing unit **210** and the plunger unit **212**. The plunger **230** may be provided with a thumb rest **236** near the proximal end **239** of the plunger shaft **238** that can also be used to withdraw the plunger **230** from the syringe. Such thumb rest **236** will be useful also when pressing the plunger **230** into the syringe. If desired, retaining rings **231** may be provided about plunger unit **212** for engagement by the fingers of the user during dispensing. A bottom closure member **240** for sealing the bottom end opening of the plunger unit **212** is also provided. Bottom closure member **240** is slidably mounted on the plunger **230** and is movable along plunger shaft **238** between the plunger's proximal end **239** and the bottom end opening of plunger unit body **204.** The bottom closure member **240** is illustrated in detail in **Fig. 10B**. The bottom closure member **240** further comprises a base portion **247** and a radial flange **249** adjacent a bung portion **248**.

The bottom closure member **240** has a central aperture **246** for slidably receiving the plunger shaft **238.** The sidewall of the central aperture **246** is configured with at least one sealing rib (not shown) so that an appropriate seal is maintained at the interface between the plunger shaft **238** and the bottom closure member **240.**

The bung portion **248** is sized to seat inside the bottom end of the plunger unit **212** and sealingly engage the plunger unit body **204** along its inner sidewall. The bung portion **248** is prevented from excess movement by radial flange **249**, which is adapted to seat against the bottom open end of body **204.** The bottom closure member **240** may be made of a single material or formed as a composite, but preferably at least the sealing ribs **242** and the bung portion **248** that sealingly engages the plunger unit body are made from an elastomer.

Preferably, a locking mechanism **260** is provided to prevent inadvertent movement of plunger **230** relative to the plunger unit **212**. Locking mechanism **260** includes a pivotable screw **262** arranged to seat in a threaded aperture **264** in the base portion **247** of bottom closure member **240**. A stopper pin **266** is affixed to the base **247** to limit the range of

motion of pivotable screw **262**. A step-shaped groove **270** is provided in the plunger shaft **238**. Groove **270** extends longitudinally along shaft **238**, turns 90 degrees and continues horizontally about the circumference of the shaft, and then turns again 90 degrees and extends lengthwise along another side of the shaft **238**. Pivotable screw **262** seats in groove **270** and permits or prevents movement of the plunger, depending upon the depth to which it is screwed into the bottom closure member. Thus, when the pivotable screw **262** is screwed into the closure member, it presses against shaft **238**, preventing its movement. When it is desired to withdraw or press the plunger, the pivotable screw **262** is unscrewed until it is stopped by stopper pin **266**, which releases the pressure on the shaft and frees the screw within the aperture **264**. The plunger shaft is now restricted to movement where the screw **262** slides along groove **270.** Groove **270** also permits for air to enter the syringe when the plunger **230** is pressed so as to prevent vacuum from being created while plunger head **232** slides towards the top end opening of a nipple **224** of the dispensing unit.

Nipple **224** is preferably sealed with a removable closure. In this embodiment, nipple **224** is sealed with a screw cap **250**. The screw cap is provided with screw threads (not shown) and nipple **224** is provided with mating threads so that the screw cap **250** can be screwed onto the nipple top-end opening.

The desired quality of the seals produced by the screw cap **250** and the bottom closure member **240** and sealing washer **233**, will be dictated by the particular application for the syringe assembly such as the particular substance stored in each compartment of the syringe. For example, the seals may be hermetic or non-hermetic but liquid tight.

Alternatively, nipple **224** may be sealed with any other appropriate sealing methods. For example, nipple **224** may be heat sealed along its rim with a foil membrane made of an appropriate material that can be peeled away to dispense the contents of the syringe.

According to one embodiment of the invention, the bottom-end opening of dispensing unit **210** may also be sealed, either when the unit is empty to prevent contamination, or after being filled with a quantity of a component of a medicament.

According to a preferred embodiment, the dispensing unit **210** is not filled in advance, but has a pre-selected volume suitable for a single dosage of a medicament of which multiple, same dosages must be provided. It will be appreciated that dispensing unit

210 can be readily exchanged to provide any desired volume suitable for the required dosage.

All components of the syringe assembly **200** are preferably provided in sterile condition to prevent any contamination of the medicament or formulation to be stored in the syringe assembly **200.** Of course, if required, the filling and assembly operation itself may be conducted in a sterile environment.

Next, **Figs. 11A-13** will be utilized to illustrate the process involved in filling the syringe assembly **200** for storage and also measuring a single pre-selected dose of the contents of the syringe assembly **200** and preparing it for dispensing. **Figs. 11A** and **11B** are respective plan and sectional view of the syringe assembly **200** when the plunger unit and the dispensing unit have been assembled to form a single syringe assembly. It will be appreciated that, for a multi-dose syringe, the plunger unit **212** will be able to hold a relatively large volume of medicament, for example 10 cc, while the dispensing unit **210** will hold only a single, preferably precisely-measured dose, of say 1 cc.

In **Figs. 11A** and **11B**, a medicament **20** introduced into the plunger unit **212** is a liquid. The bottom closure member **240** is removed from the bottom-end opening **226** of plunger unit **212** to its unsealed position (if not already in its unsealed position) and may be positioned near the proximal end **239** of the plunger **230** to facilitate the filling of the plunger unit **212.**

Next, the plunger unit **212** is filled with a medicament **20** through the bottom opening **226.** During this process, the plunger **230** is maintained in its position so that the plunger head **232** remains engaged with the joining sleeve **206** of body **204**, confining the medicament **20** within the plunger unit **212**.

After a desired amount of the medicament **20** is introduced into the plunger unit **212**, the bottom opening **226** is sealed by sliding the bottom closure member **240** along the plunger shaft **238** towards its distal end **237** and snap-fitting the bottom closure member **240** onto the bottom-end opening of plunger unit **212. Fig. 11B** illustrates the syringe assembly **200** after the bottom closure member **240** has been fitted into its sealed position. The medicament **20** is kept in the compartment within the plunger unit **212** and may be stored until ready to be measured and dispensed. It will be appreciated that the locking mechanism

260 is in the locking configuration, where pivotable screw **262** engages groove **270** in the plunger shaft **238.**

Fig. 12 is a partially cut away illustration of the syringe assembly **200** in a configuration where flow communication exists between the plunger unit and the dispensing unit. The plunger **230** has been withdrawn so that the plunger head **232** is no longer sealingly engaging joining sleeve **206** but lies within the plunger unit **212.** The plunger **230** may be provided with stopper tabs **234** that limit the travel of the plunger **230** when it is being withdrawn to prevent any compromise of the seal between the plunger shaft **238** and the bottom closure member **240.** Because the inner sidewall of plunger unit body **204** is of a larger diameter than the outer diameter of plunger head **232**, dispensing unit **210** and plunger unit **212** are in flow communication with one another. In this way, medicament **20** flows into and fills the pre-sized compartment **205** in dispensing unit body **202**.

To dispense a single dose of the medicament, the syringe assembly **200** is placed in an orientation illustrated in **Fig. 12** with its dispensing end pointing down and the plunger end pointing up. This causes the medicament (not shown) to completely fill compartment **205** in the dispensing unit **210.** The plunger head **232** is then pressed back into joining sleeve **206**, thereby sealing a single dosage in the dispensing unit **210**, and the syringe assembly **200** may be used to administer the dosage like a standard syringe. Prior to administering of the dosage, the user may position the syringe assembly **200** in a top end up orientation for allowing any air trapped in the dispensing unit **210** to rise. The screw cap **250** (see **Fig 11B**) may then be removed to attach an appropriate dispensing device to the top end of the syringe assembly **200.** For example, a hypodermic needle **252** may be attached to the syringe assembly **200** at the top end, as shown in **Fig. 12**. Once an appropriate dispensing device is attached, the plunger **230** is pressed further into syringe body **202**.

Fig. 13 is a perspective view of the syringe assembly of **Fig. 10**, where plunger **230** is in a fully depressed position after the medicament in the dispensing unit has been completely dispensed. As the plunger head **232** advances further into the dispensing unit **210**, the increase in the volume of the plunger unit **212** will create a low pressure condition in the plunger unit **212** and may interfere with the dispensing process. To alleviate this concern, groove **270** on plunger shaft **238** provides an air vent channel. As the plunger

advances further into the dispensing unit **210,** groove **270** will break the seal between the bottom closure member **240** and the plunger shaft **238** and allow outside air to vent into the plunger unit **212.**

Figs. 14-16 illustrate another embodiment of the invention, a syringe assembly **300** having three separate units for separately storing up to three different components of a medicament or a formulation, each in separate compartments until ready for use, wherein the components may be mixed to form the medicament. The syringe assembly **300** has three units – a plunger unit **312**, a dispensing unit **310**, and an extension unit **311** adapted to be affixed between the dispensing unit and the plunger unit.

The syringe assembly **300** has three main body sections, a dispensing unit body **102**, an extension unit body **316**, and a plunger unit body **104**, with the inner sidewall diameter of the syringe body increasing progressively with each section. In other words, the inner sidewall diameter of the plunger unit body **104** is larger than the inner sidewall diameter of extension unit body **316**, which, in turn, is larger than the inner sidewall diameter of the dispensing unit body **102.**

The dispensing unit **310** is substantially similar to dispensing unit **110** of **Fig. 1**, and the plunger unit **312** is substantially similar to plunger unit **112** of **Fig. 1**, so they will not be described in detail again, rather like elements have like reference numerals.

Extension unit **311** has two open ends: a top-end opening of body **316** defining a neck portion having an inner sidewall diameter smaller than the inner sidewall diameter of body **316,** and forming a joining sleeve **319,** having a top-end opening **318;** and a bottom-end opening of body **316** defining a depending flange portion **328** having a bottom-end opening **322**. Joining sleeve **319** is adapted and configured to sealingly seat within a depending flange portion **304** of dispensing unit **310**, and snuggly fit its outer sidewall, while joining sleeve **125** is adapted and configured to sealingly seat within depending flange portion **328** of extension unit **311**, and snuggly fit its outer sidewall, thus assembling the syringe assembly. A sealing element (not shown) is disposed in an upper portion of each of flange portion **304** and depending flange portion **328**, for engagement by a top edge of said joining sleeve to provide hermetic seals between the dispensing unit and the extension unit and the plunger unit, respectively.

Extension unit **311** includes a substantially cylindrical body **316,** having a sealable opening at each end. A first extension bung **320** is positioned in joining sleeve **319** of the extension unit **311** adjacent the dispensing unit, for a sealing engagement with inner sidewall of a joining sleeve **319**. A second extension bung **324** is positioned in body **316** at the bottom end opening **322** of extension unit **311** adjacent the plunger unit, for sealing engagement with inner sidewall of body **316**. First extension bung **320** is adapted and configured to be affixed to a bung **364** positioned in body **102** of the dispensing unit **310**, for a sealing engagement with inner sidewall of body **102**. Second extension bung **324** is adapted and configured to be affixed to a plunger head **132** positioned in body **104** of the plunger unit **312**, for a sealing engagement with inner sidewall of joining sleeve **125**. A connecting rod **326** couples the first extension bung **320** with the second extension bung **324** to permit them to slide in tandem inside the syringe assembly.

Bung **364** at the bottom end opening of dispensing unit **310** is adapted and configured to sealingly engage body **102** and seal the bottom end opening **325** of the dispensing unit compartment. Bung **364** includes a locking member **378**. Bung **320** includes a matching opening **380**, complementary to the locking member **378** of bung **364** for a locking engagement. Similarly, bung **324** at the bottom end opening of extension unit **316** is adapted and configured to sealingly engage body **316** and seal the bottom end opening **322** of the extension unit compartment. Bung **324** includes a locking member **382**. Joining sleeve **125** of top-end opening **124** of plunger unit **312** is sealed by plunger head **132**, adapted and configured to sealingly engage body **104** and seal the plunger unit compartment. Plunger head **132** includes a matching opening **327** complementary to the locking member **382** of bung **324** for a locking engagement. Joining sleeve **125** further includes at least two slightly slanted, peripherally extending ribs (not shown in **Fig 14-16** but are substantially the same as extending ribs **33** shown n in **Fig. 1**) configured for locking engagement with at least two matching ribs (not shown in **Fig 14** but is substantially the same as matching ribs **36** shown in **Fig. 1**) peripherally extending from the inner sidewall of flange portion **328** of extension unit **311**. In a similar fashion, joining sleeve **319** of body **316** of extension unit **311** includes at least two slightly slanted, peripherally extending ribs (not shown) configured for locking engagement with at least two matching ribs (not shown) peripherally extending from the inner sidewall of depending flange portion **304** of dispensing unit **310**.

Fig. 15 is a cutaway illustration of the fully assembled syringe assembly **300** in a ready-for-storage configuration. Plunger **340** is positioned inside body **104** of plunger unit **312**, so that plunger head **132** sealingly engages the inner sidewall of joining sleeve **125**, and lockingly engages second extension bung **324**. Bung **324** sealingly engages the inner sidewall of body **316** of extension unit **311.** First extension bung **320** sealingly engages the inner sidewall of joining sleeve **319** of extension unit **311**, and lockingly engages bung **364** which in turn sealingly engages the inner sidewall of body **102** of dispensing unit **310**. In this storage configuration, plunger head **132** and lockingly engaged second extension bung **324** form a partition between the compartment in plunger unit **312** and the compartment in extension unit **311**, while first extension bung **320** and lockingly engaged bung **364** form a partition between the compartment in extension unit **311** and the compartment in dispensing unit **310**. The seal formed by the plunger head **132** in joining sleeve **125** is hermetic so that the component stored in the compartment of plunger unit **312** and the component stored in the compartment of extension unit **311** may be kept separate until ready to be mixed. The seal formed by the second extension bung **320** in joining sleeve **319** serves the same function between the compartment of extension unit **311** and the compartment of dispensing unit **310**.

First extension bung **320** is preferably made from elastomer and may have a composite structure including seal forming portions, i.e., sealing ribs (not shown) made from one or more elastomers. The rest of bung **320** may be made from any material suitable to maintain the structural shape of bung **320** and chemically compatible with the elastomer portions. The diameter of bottom portion **369** of bung **320** is substantially the same as the diameter of joining sleeve **319** and body **102** of dispensing unit **310** so that bung **320** can be moved through dispensing unit **310** to form a seal with the inside surface of the compartment in body **102**.

Second extension bung **324** is positioned within body **316** sealing the bottom-end opening of extension unit **311**. Second bung **324** is coupled to plunger head **132** to permit them to slide in tandem inside the syringe assembly.

The process of filling and assembling the syringe assembly **300** will is now described. Plunger unit **312** and dispensing unit **310** shown in **Fig. 14** and **15** may be separately filled substantially in the same manner as plunger unit **112** and dispensing unit

110 of **Figs. 5** and **6** may be separately filled, as described in detail above. Thus, the process of filling them will not be described in detail again.

To separately fill extension unit **311** shown in **Fig. 14**, first extension bung **320** coupled to connecting rod **326** is positioned inside joining sleeve **319** of the extension unit **311**, and first extension bung **320** seals top-end opening **318** of extension unit **311**. The compartment defined by extension unit body **316** may be filled with a component of a formulation through sealable filling opening **322** on the bottom side of the extension unit. Sealable filling opening **322** may then be sealed by second extension bung **324**.

Alternatively, the compartment defined by extension unit body **316** may be more conveniently filled by sealing top end opening **318** with a foil or a non-metallic membrane having a single or multi-layered structure. The extension unit may now be rotated through 180 degrees and filled through the sealable bottom end opening **322**. First extension bung **320** and second extension bung **324** coupled by connecting rod **326** may now be positioned inside the extension unit body **316** whereby the bottom-end opening of the extension unit is sealed by second extension bung **324**.

It will be appreciated that the dispensing unit, extension unit, and plunger unit of the invention may be separately filled with different components and in different locations, and can be sealed and stored separately prior to assembly and use.

Syringe assembly **300** as illustrated in **Figs. 14** and **15** consists of three completely sealed compartments – the dispensing unit **310,** the extension unit **311**m and the plunger unit **312** – where each compartment may be holding a component of a medicament, coupled together. The coupling of the three units, according to the illustrated embodiment, is as follows. A sealing washer (not shown) is disposed in depending flange **328.** Joining sleeve **125** of the plunger unit **312** is inserted into depending flange **328** of extension unit **311**. At the same time, locking member **382** on second extension bung **324** engages the matching opening **327** in plunger head **132**. The extension unit is then rotated relative to the plunger unit, in order to sealingly couple these two separate units. Similarly, a sealing washer (not shown) is disposed in depending flange **304** of dispensing unit **310.** Joining sleeve **319** of extension unit **311** is inserted into depending flange **304** of dispensing unit **310**. At the same time, locking member **378** on bung **364** engages the matching opening **380** in bung **320**. The dispensing unit is then rotated relative to the plunger unit and extension unit already

sealingly coupled to each other, in order to sealingly couple the dispensing unit to the other two units of the syringe assembly. It will be appreciated that syringe assembly **300** may be assembled in a substantially similar fashion starting from sealingly coupling the extension and dispensing units.

Peripherally, extending ribs (not shown in **Figs. 14-16**) on joining sleeve **125** of the plunger unit **312** (for example, as illustrated in **Fig. 6**) have been rotated to engage two matching ribs peripherally extending from the inner sidewall of depending flange portion **328** of the extension unit **311** (not shown in **Figs. 14-16**). In a substantially similar fashion, peripherally extending ribs (not shown in **Figs. 14-16**) on joining sleeve **319** of extension unit **311** (for example, as illustrated in **Fig. 6**) have been rotated to engage two matching ribs peripherally extending from the inner sidewall of depending flange portion **304** of dispensing unit **310** (not shown in **Figs. 14-16**).

In the embodiment where the bottom end opening of the dispensing unit is sealed by a membrane or laminate, assembly of the assembling of the syringe assembly is accomplished by removing the seal from the bottom end of the dispensing unit, when in an upside down position, and locking the extension unit and the dispensing unit together, as described above. Bung **320** positioned inside joining sleeve **319** provides a seal between the two compartments of the extension and dispensing units of the syringe assembly, preventing flow communication between these two units until ready for dispensing.

Then, a cap **370** may be removed and a syringe needle (not shown) may be attached to the top-end opening of dispensing unit **310.** Depending on the application, other dispensing apparatus may be attached to the top-end opening to dispense the medicament or any other formulation.

The process involved in preparing and dispensing the medicament from the two components stored in the syringe assembly **300** will now be described with reference to **Figs. 14-16**. In order to mix the three components of a medicament stored in the syringe assembly **300**, the plunger **340** lockingly coupled to second bung **324** which in turn is coupled to first extension bung **320** via connecting rod **326**, which in turn is lockingly coupled to bung **364**, is first drawn back towards the proximal end **376** of the plunger **340**, so that the plunger head **132** disengages from the joining sleeve **125,** second extension bung **324** disengages from body **316,** first extension bung **320** disengages from joining sleeve **319**,

and bung **364** disengages from body **102**, simultaneously, as illustrated in **Fig. 16**. It will be appreciated that withdrawing the plunger **340** moves both plunger head **132** and lockingly coupled second extension bung **324** into the plunger unit whose body **104** has an inner sidewall diameter larger than the joining sleeve **125** and body **316** of the extension unit in which they were sealingly seated, respectively, thereby permitting a two-way flow communication between the plunger unit and the extension unit. Simultaneously, both first extension bung **320** and lockingly coupled bung **364** move into the extension unit whose body **316** has an inner sidewall diameter larger than the joining sleeve **319** and the body **102** of the dispensing unit, in which they were sealingly seated, thereby permitting a two-way flow communication between the extension unit and the dispensing unit. Thus, a component or components of a medicament in the dispensing unit **310**, the extension unit **311**, and the plunger unit **310** are now free to flow around the plunger head **132** coupled to second extension bang **324**, and first extension bung **320** coupled to bung **364**, in the assembled syringe. During this procedure, closure element **372** shown in **Fig. 16** as a bung remains in place in its sealed position.

Thus, by withdrawing the plunger **340**, the three compartments have come into two-way flow communication with one another so that the contents of the three compartments can mix.

Typically, the syringe assembly **300** would be shaken vigorously to mix the contents of the syringe assembly **300**. The presence of a substantial portion of plunger shaft **374** inside the plunger unit **312** and a substantial portion of connecting rod **326** inside the extension unit **311** enhances the mixing of the contents by functioning as agitators during the shaking. This agitating function of plunger shaft **374** and connecting rod **326** may be further enhanced by providing vanes (not shown) in the portions of the plunger shaft that is positioned within the plunger unit and the connecting rod that is positioned within the extension unit.

Once the contents of the syringe assembly **300** are completely mixed and the medicament is ready for dispensing, the syringe assembly **300** is oriented so that the dispensing unit is pointing downward. This will cause the medicament to drain into the dispensing unit **310.** The volume of the three components of the medicament preferably is

controlled so that the mixed medicament would fit completely inside the dispensing unit **310** without overflowing. This minimizes any portion of the medicament from being wasted.

Next, while maintaining the dispensing unit oriented downwardly, the plunger **340** is pushed down until first extension bung **320** sealingly engages body **102** of dispensing unit **310.** The syringe assembly **300** then may be turned into the orientation with the top end of the syringe assembly pointing upwardly. Then, cap **370** may be removed and a hypodermic needle (not shown) may be attached to the top-end opening of dispensing unit **310**. In this configuration, the syringe assembly **300** operates similarly to a standard syringe. To completely dispense the medicament contained in the dispensing unit **310**, the plunger **340** is fully depressed into the syringe assembly **300**. It would be apparent to one of ordinary skill in the art that the syringe assembly **300** may be provided with a dispensing apparatus other than a hypodermic needle for dispensing the medicament or any other solution.

It will further be appreciated by, that more than one extension unit may be utilized to assemble a syringe assembly of a desired number of compartments.

Referring now to **Fig. 17** there is shown according to another embodiment of the invention a two-unit syringe assembly **400** in a non-assembled state, including a dispensing unit **410** including a body **402** having bottom and top end sealable openings. Preferably, body **402** is substantially cylindrical. The bottom portion of body **402** may define a depending flange **404** adapted and configured for a locking engagement with a plunger unit **412**. Bottom end opening of body **402** may be adapted and configured for a sealing engagement with a bung **408**.

The top portion of body **402** may define an open ended nipple **406** with a top-end opening. Nipple **406** may be adapted and configured for attaching an appropriate dispensing device, e.g. a hypodermic needle (not shown). Since dispensing unit **410** is substantially similar to dispensing unit **110** of **Fig. 1**, it will not be described in detail again.

Syringe assembly **400** further includes a plunger unit **412** which is engaged with dispensing unit **410** to form a two-unit syringe assembly. Plunger unit **412** has a body **414**. Preferably, body **414** is substantially cylindrical. Plunger unit **412** also includes a plunger **416.** Once plunger and dispensing units are assembled, plunger **416** may be axially displaced in the syringe assembly. Plunger **416** consists of a user manipulable plunger shaft **418**, having a proximal end **420** and a distal end **422** and is provided with a substantially

cylindrical plunger head **424** at distal end **422.** It is a particular feature of this embodiment of the invention that plunger unit **412** is adapted and configured for holding only plunger **416** and allowing it to axially move through the syringe assembly, and does not contain a component or formulation for mixing or dispensing. Thus, plunger unit **412** need not be sealed and plunger head **424** need not engage sealingly the inner sidewall of body **414** or the inner sidewall of body **402**, as in other embodiments of the invention described herein above.

Bung **408** is adapted and configured for a sealing engagement with the inner sidewall of dispensing unit body **402** in a fluid-tight manner, forming a hermetically sealed partition between dispensing unit **410** and plunger unit **412**. It will be appreciated that sealing bung **408** is configured and adapted for sliding engagement with the inner sidewall of dispensing unit body **402**, and slides therealong during dispensing of the contents of the dispensing unit, while maintaining the seal. Also, bung **408** and plunger head **424**, and dispensing unit **410** and plunger unit **412** are adapted and configured for a locking engagement with one another, respectively, during the assembly procedure, in the same fashion as described herein above. The upper portion of the plunger unit body **414** functions like the joining sleeve **34** in **Fig. 1** described above, and lockingly engages the depending flange **404** of the dispensing unit.

According to another particular feature of the embodiment described in **Fig. 17**, the inner sidewall diameter of plunger unit body **414** is smaller than the inner sidewall diameter of dispensing unit body **404**. Thus, when the syringe is assembled, plunger head **424** can move into dispensing unit body **402** during the dispensing procedure, but bung **408** cannot move into plunger unit body **414** when plunger **416** is retracted by the user. One advantage of the syringe assembly according to this embodiment of the invention is that the medicament may be hermetically stored in the dispensing unit very much like in an ampoule as known, then just prior to use the plunger and dispensing units are assembled, cap **426** is removed, a hypodermic needle (not shown) is coupled to nipple **406**, and the syringe assembly is ready for action. This procedure is a fast and efficient way to administer a medicament as it eliminates the need to first draw the medicament from the ampoule into the syringe before dispensing. Another advantage of the syringe assembly according to this embodiment is that the plunger unit can be used repeatedly for dispensing a medicament or a solution from any number of dispensing units without the need to clean or sterilize it before

each use. Another advantage is that, as manufacturing of a dispensing unit is cheaper than manufacturing of a plunger unit, the use of only one plunger unit for dispensing the medicament or the solution from a large number of dispensing units significantly reduces the costs of administering medicaments.

Furthermore, this embodiment can be used for drawing blood samples for testing. Once plunger unit **412** and dispensing unit **410** are assembled to form syringe assembly **400** as illustrated in **Fig. 18**, plunger **416** is pushed into the syringe, moving plunger head **424,** and bung **408** lockingly engaged thereto, to the top end of dispensing unit body **402**. A hypodermic needle **430,** which may be coupled to the syringe assembly **400,** is inserted into a vein, and blood may flow into dispensing unit **410** via needle **430** when the plunger **416** is withdrawn. When bung **408** abuts against the top rim **428** of plunger unit body **414** (as shown in **Fig. 17**) and hermetically seals the bottom end of dispensing unit body **402**, the dispensing unit may be safely removed from the plunger unit and a new dispensing unit may be coupled thereto for drawing a new sample of blood. It will be appreciated that as no part of the plunger unit **412** comes into contact with the blood, plunger unit **412** may be used repeatedly with any number of dispensing units. **Fig. 18** further includes a stop member **432** which abuts against closure member **434** thus preventing accidental or unwanted removal of plunger **416** out of plunger unit **412**.

According to yet another embodiment of the present invention, the plunger unit **412** as shown in **Figs. 17** and **18** can be coupled to an extension unit **311** and a dispensing unit **310** both as shown in **Figs. 14-16**, to form a syringe assembly that can be used for separately storing two components, mixing and dispensing the solution formed, in one or several pre-set dosages. For that purpose, extension unit **311** is adapted and configured to disengage first extension bung **320** and lockingly coupled bung **364** from joining sleeve **319**, allowing a two-way flow-communication between the compartment defined by body **316** of the extension unit and the compartment defined by body **102** of the dispensing unit, while at the same time, second extension bung **324** lockingly coupled to plunger head **132** maintains a sealing engagement with bottom end opening **322** of the extension unit, when plunger **340** is withdrawn. According to one embodiment, bung **324** is sized to keep opening **322** sealed longer than bung **320** can keep joining sleeve **319** sealed when sliding in tandem inside the syringe assembly upon withdrawing of the plunger. Preferably, bung **324** is longer than bung

320. Alternatively, connecting rod 326 may be sized to keep bung 324 away from bottom end opening 322 at a distance substantially equal to the distance necessary for bung 320 to slide out of joining sleeve 319 when plunger 340 is withdrawn, for allowing a flow-communication between the extension unit and the dispensing unit. It will be appreciated by one of ordinary skill in the art that the two-way flow-communication established between the extension unit and dispensing unit can be used to mix two components stored separately in these units and dispense the solution through the top end opening of the dispensing unit, or to allow a pre-set dosage of a component or solution stored in the extension unit to pass and fill the dispensing unit pre-sized to hold the dosage, and dispense the dosage. This procedure can be repeated until the component or solution is completely dispensed.

It will be appreciated that the relative diameters of the sidewalls of the plunger unit and the dispensing unit of this embodiment are such as to provide a barrier against sliding of the bung out of the dispensing unit. Alternatively, such a barrier can be provided in any other known manner. This barrier will prevent inadvertent leakage of contact between material in the dispensing unit and the plunger, and prevent contamination of the plunger unit, allowing the user to re-use the plunger unit without a need for cleaning or sterilization..

Most of the seals discussed herein in reference to the various embodiments of the multi-compartment syringe assembly are described as hermetic seals. However, the quality of the seals may be hermetic or non-hermetic as the particular application for the syringe assembly necessitates. The quality of the particular seal in the syringe assembly can be controlled by selecting appropriate materials for the components that form the seal. The particular physical arrangement or configuration of the components selected will also affect the quality of the seal. For example, in the embodiment of the syringe assembly where the top-end opening is sealed with a heat sealed membrane, the membrane may be selected from a variety of materials of having varying permeability with respect to air or the particular substance placed inside the dispensing unit to achieve the desired seal quality at the top-end opening.

It should be emphasized that the above described embodiments of the present invention are merely specific examples. In addition, components and formulations other than medicaments may be administered with the syringe. Various modifications may be

made by those skilled in the art which will embody the principles of the invention and fall within the spirit and the scope thereof.

CLAIMS

1. A syringe assembly comprising:

a dispensing unit including a substantially cylindrical dispensing unit body having top and bottom sealable open ends;

a separate, independent plunger unit including a substantially cylindrical plunger unit body having a top open sealable end defining a joining sleeve, a bottom sealable open end, and an inner sidewall diameter that is larger than the diameter of said joining sleeve;

said joining sleeve having an inner sidewall diameter which is substantially the same as an inner sidewall diameter of said dispensing unit body;

a plunger disposed in the bottom open end of said plunger unit body, the plunger having a shaft and a plunger head;

said plunger head having an outer diameter which is substantially the same as the inner sidewall diameter of said joining sleeve;

wherein said bottom open end of said dispensing unit is adapted and configured for coaxial locking engagement with said top open end of said plunger unit to form a multi-unit syringe assembly; and

wherein said plunger head seals said plunger unit when it sealingly engages the joining sleeve, and allows two-way flow communication between said dispensing unit and said plunger unit when said plunger head is retracted into the plunger unit body and disengages said joining sleeve.

2. The syringe assembly according to claim 1, wherein a lower portion of said dispensing unit defines a depending flange, said depending flange and said joining sleeve being adapted and configured for locking engagement with one another.

3. The syringe assembly according to claim 1 or 2, wherein:

said dispensing unit further comprises a sealing element disposed in an upper portion of said depending flange, for engagement by a top rim of said joining sleeve, to provide a hermetic seal between the dispensing unit and the plunger unit.

4. The syringe assembly according to claim 2 or claim 3, further comprising a seal for sealing the open bottom end of said dispensing unit.

5. The syringe assembly according to claim 4, wherein said seal is a bung, said bung and said plunger head having a locking mechanism for releasably locking said bung to said plunger head, whereby said bung moves together with said plunger head in said syringe assembly.

6. The syringe assembly according to claim 2 or 3, wherein said dispensing unit body is sized to hold a pre-selected volume of a material stored in said plunger unit, for repeatedly dispensing a single dose at a time of said material.

7. The syringe assembly according to any of claims 1 to 6, and further comprising:

at least one extension unit, having a substantially cylindrical body, having an inner sidewall diameter larger than an inner sidewall diameter of said dispensing unit, and sealable top and bottom open ends;

a first extension bung sealably engaging an inner sidewall of said joining sleeve;

a second extension bung sealably engaging the sealable bottom end; and

a connecting rod coupling said first and second extension bungs;

wherein said extension unit is adapted and configured to sealingly engage said dispensing unit, and said extension unit is adapted and configured to engage said plunger unit to form a multi-unit syringe assembly.

8. The syringe assembly according to claim 7, wherein:

a top portion of said extension unit defines a joining sleeve;

a lower portion of said extension unit defines a depending flange;

the joining sleeve of said extension unit is adapted and configured to engage the depending flange of said dispensing unit; and

the depending flange of said extension unit is adapted and configured to engage the joining sleeve of said plunger unit.

9. The syringe assembly according to claim 8, further comprising:

a sealing element disposed in an upper portion of the depending flange in said dispensing unit, for sealing engagement by a top rim of the joining sleeve in said extension unit, to provide a hermetic seal between the dispensing unit and the extension unit.

10. The syringe assembly according to claim 8 or 9, further comprising:

a sealing element disposed in an upper portion of the depending flange in said extension unit, for sealing engagement by a top rim of the joining sleeve in said plunger unit, to provide a hermetic seal between the extension unit and the plunger unit.

11. The syringe assembly according to either of claims 1-2, wherein:

said dispensing unit further comprises a bung disposed in the sealable bottom opening of said dispensing unit; and

said plunger unit has an inner sidewall diameter smaller than said bung.

12. The syringe assembly according to claim 1 or 2, and further comprising:

at least one extension unit, having a substantially cylindrical body, having an inner sidewall diameter larger than an inner sidewall diameter of said dispensing unit, and sealable top and bottom open ends;

a first extension bung sealably engaging an inner sidewall of said joining sleeve;

a second extension bung sealably engaging the sealable bottom end; and

a connecting rod coupling said first and second extension bungs; and

said plunger unit has an inner sidewall diameter smaller than said second extension bung;

wherein said extension unit is adapted and configured to sealingly engage said dispensing unit, said extension unit is adapted and configured to engage said plunger unit to form a multi-unit syringe assembly, and said second extension bung is longer than said first extension bung so as to maintain sealing engagement with the bottom end of the extension unit while the first extension bung is disengaged from the joining sleeve of the extension unit when sliding in tandem inside the syringe assembly upon withdrawing of the plunger.

13. The syringe assembly according to claim 12, further comprising:

a sealing element disposed in an upper portion of the depending flange in said dispensing unit, for sealing engagement by a top rim of the joining sleeve in said extension unit, to provide a hermetic seal between the dispensing unit and the extension unit.

14. The syringe assembly according to claim 11, further comprising a locking mechanism for releasably locking said bung to said plunger head, whereby said plunger head and said lockingly engaged bung move together in said syringe assembly to dispense material from said dispensing unit.

15. The syringe assembly according to claim 12 or claim 13, further comprising a locking mechanism for releasably locking said second extension bung to said plunger head, whereby said plunger head, lockingly engaged to said second extension bung connected by the connecting rod to said first extension bung, move together in the syringe assembly to dispense material from said dispensing unit.

16. The syringe assembly according to any of claims 1 to 15, and further comprising a closure member for sealing the bottom end opening of said plunger unit, said closure member having a central aperture for receiving said plunger shaft.

17. The syringe assembly according to claim 16, wherein said closure member includes sealing elements for hermetically sealing the bottom end opening of said plunger unit and for hermetically sealing said plunger shaft.

18. The syringe assembly according to claim 17, wherein said closure member includes a bung sealingly engaging the bottom end opening of said plunger unit, said bung having a central aperture for sealingly engaging said plunger shaft.

19. The syringe assembly according to any of claims 1 to 18, and further comprising a locking mechanism for locking the plunger relative to said plunger unit body.

20. The syringe assembly according to claim 19, wherein said locking mechanism includes a pivotable screw arranged to seat in a step-shaped groove in the plunger shaft and selectably permits movement of the plunger, depending upon the depth to which it is screwed into the shaft.

21. The syringe assembly according to claim 20, wherein said groove extends longitudinally along the plunger shaft, turns 90 degrees and continues horizontally about the circumference of the plunger shaft, and then turns again 90 degrees and extends lengthwise along another side of the plunger shaft, said groove extending into said plunger unit body when said plunger is pushed into said syringe assembly.

22. The syringe assembly according to either of claims 20 or 21, and further comprising a stopper pin to limit the range of motion of the pivotable screw.

23. The syringe assembly according to any of claims 1 to 22, wherein a top portion of said dispensing unit body defines an open ended nipple, said nipple being adapted and configured for attaching a dispensing device.

24. The syringe assembly according to any of claims 1 to 23, wherein the top end opening of said dispensing unit body is sealed by a removable cover member.

25. A process for preparing a syringe assembly comprising:

(a) providing a dispensing unit having a dispensing unit body and a sealable opening at each of its top and bottom ends;

(b) providing a separate, independent plunger unit having a plunger unit body and a top open sealable end defining a joining sleeve having an inner sidewall diameter which is substantially the same as an inner sidewall diameter of said dispensing unit body, a bottom sealable open end, and an inner sidewall diameter that is larger than the diameter of said joining sleeve;

(c) placing a plunger within the plunger unit, the plunger having a shaft and a plunger head having an outer diameter which is substantially the same as the inner sidewall diameter of said joining sleeve; and

(d) coupling the dispensing unit coaxially to the plunger unit to form a two-unit syringe assembly;

wherein said plunger head seals said plunger unit when it sealingly engages the joining sleeve, and allows two-way flow communication between said dispensing unit and said plunger unit when said plunger head is retracted into the plunger unit body and disengages said joining sleeve.

26. The process according to claim 25, further comprising:

a. providing at least one independent extension unit having a cylindrical body and sealable openings at its top and bottom end; and

b. coupling the extension unit between the dispensing unit and the plunger unit to form a three- or more unit syringe assembly.

27. The process according to claim 25, further comprising the step of filling the dispensing unit before coupling the units to form the syringe assembly.

28. The process according to claim 27, further comprising the step of filling the dispensing unit and the extension unit before coupling the units to form the syringe assembly.

29. The process according to claim 25, further comprising the step of filling the dispensing unit after coupling the units to form the syringe assembly.

30. The process according to claim 26, further comprising the step of filling the dispensing unit and the extension units after coupling these units to one another and before coupling the plunger unit to form the syringe assembly.

31. A process for preparing a syringe assembly comprising:

(a) providing a dispensing unit having a housing and an opening at each of its top and bottom ends;

(b) sealing one end of the dispensing unit;

(c) introducing a first component of a formulation, if there is more than one, into the dispensing unit through the other end and sealing that end;

(d) providing a separate, independent plunger unit having a plunger unit body and a top open sealable end defining a joining sleeve having an inner sidewall diameter which is substantially the same as an inner sidewall diameter of said dispensing unit body, a bottom sealable open end, and an inner sidewall diameter that is larger than the diameter of said joining sleeve;

(e) placing a plunger within the plunger unit, the plunger having a plunger head adapted to form a seal closing the top opening of the plunger unit, the plunger head movable between a sealed position and an unsealed position, said unsealed position providing two-way flow communication between said plunger unit and said dispensing unit; the plunger being placed in the plunger unit in the sealed position;

(f) introducing a different component of the formulation, or a medicament if there is only one, into the plunger unit through the sealable filling opening of the plunger unit; and

(g) sealing the sealable filling opening,

so as to hold and store one or more components of a formulation separately until said units are assembled into a single multi-unit syringe for dispensing the formulation or for mixing the contents of the compartments prior to dispensing.

32. The process according to claim 25, wherein no component is introduced into said dispensing unit, rather said dispensing unit is formed with a body sized to hold a pre-selected volume of a material stored in said plunger unit, for repeatedly dispensing a single dose at a time of said material.

33. The process according to any of claims 25 to 32, wherein:

the step of providing a dispensing unit includes providing a dispensing unit including a bung disposed in the sealable bottom opening of said dispensing unit; and

the step of providing a plunger unit includes providing a plunger unit having an inner sidewall diameter smaller than said bung,

providing a locking mechanism for releasably locking said bung to said plunger head, whereby said plunger is enabled to push said bung to dispense material in said dispensing unit.

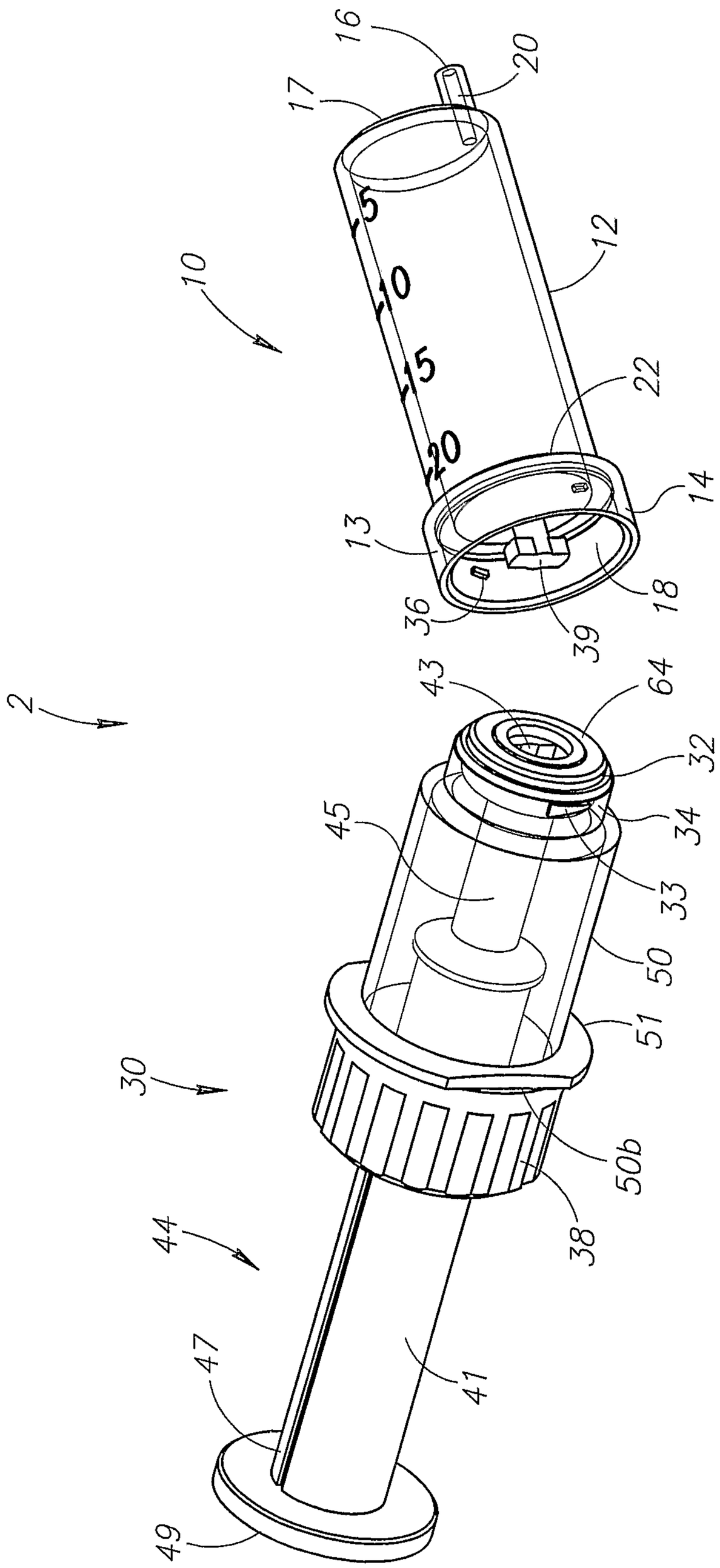
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FIG.1

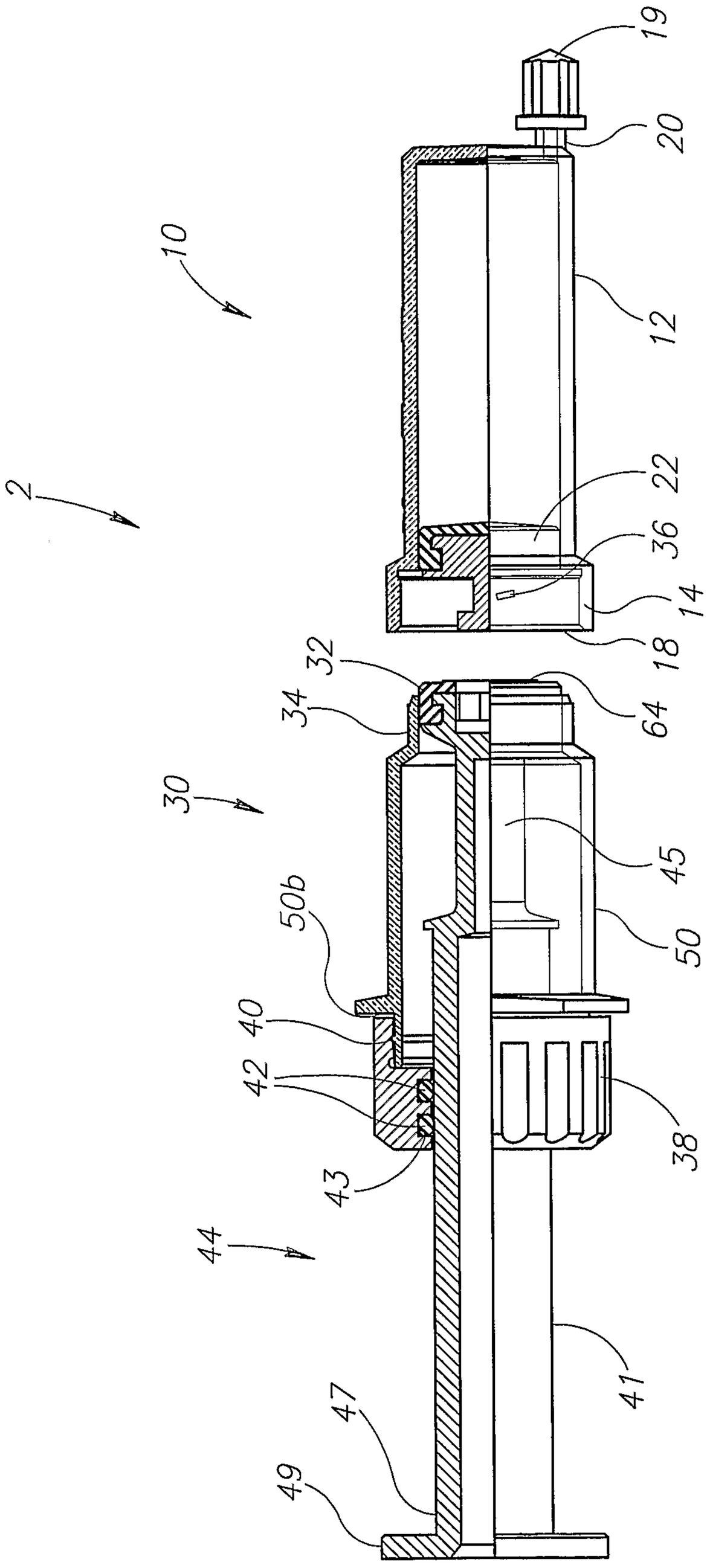

FIG.2

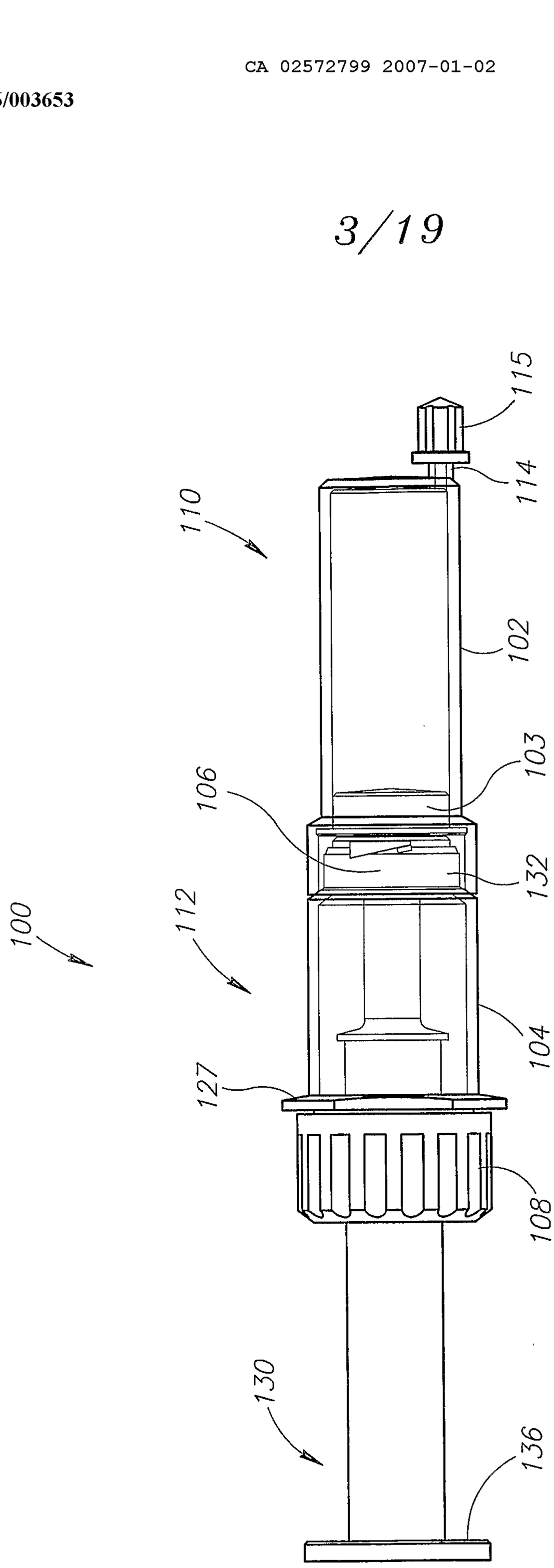

FIG.3

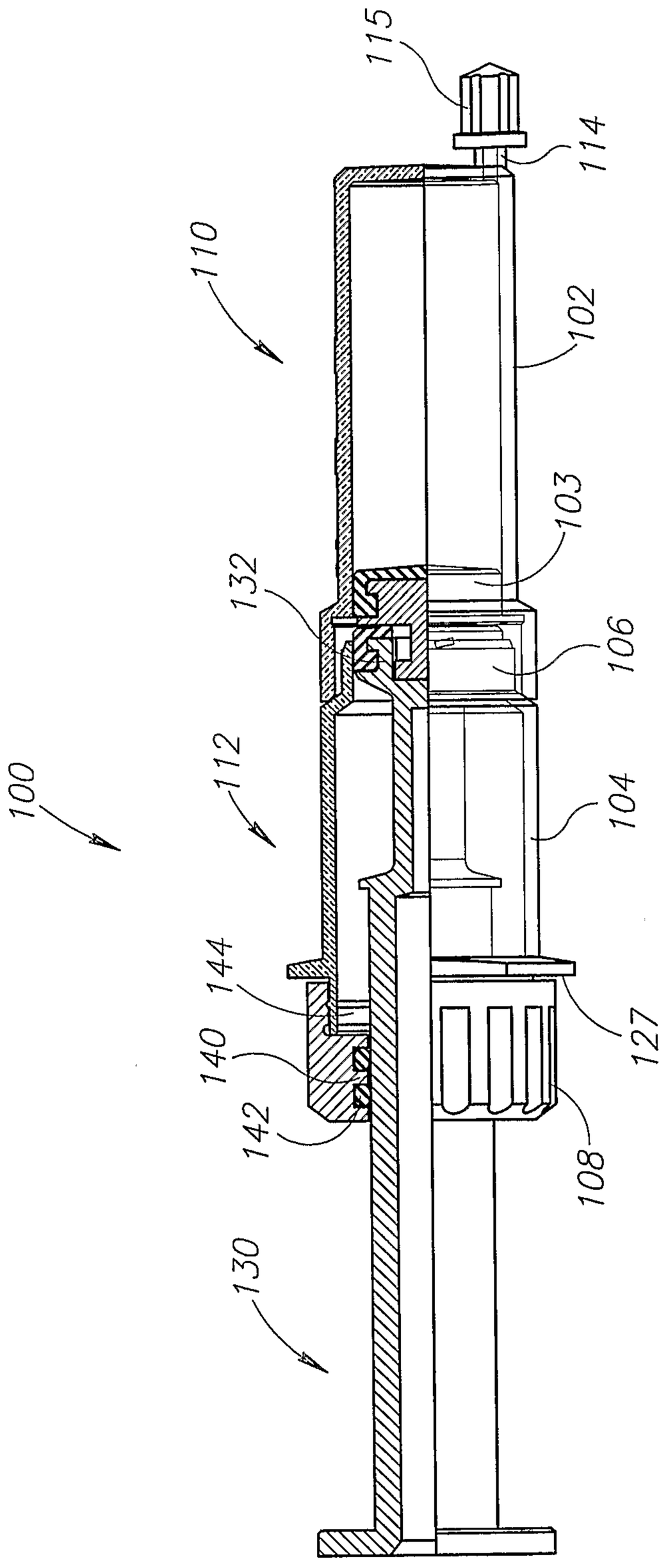

FIG.4

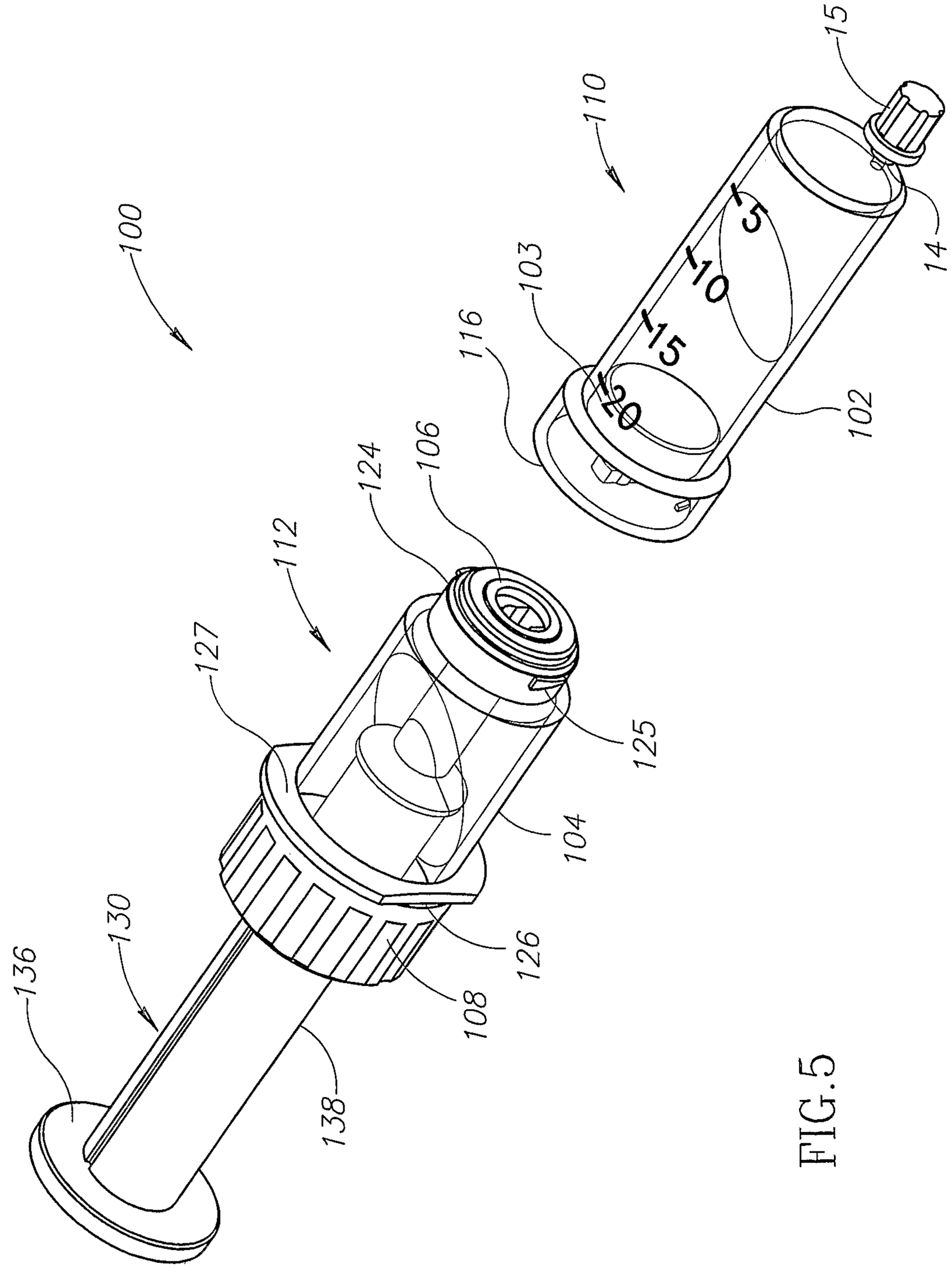
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FIG.5

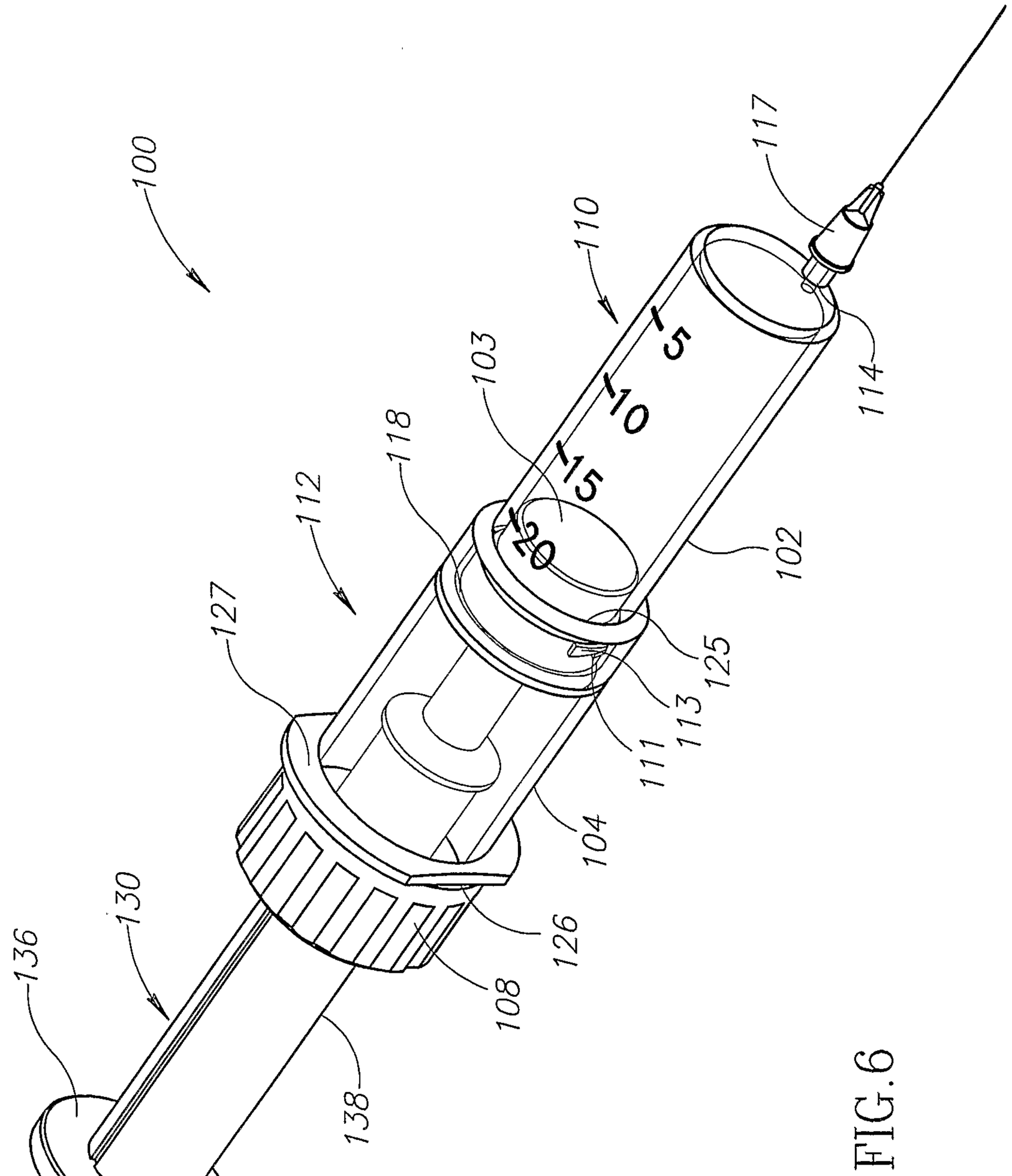
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FIG.6

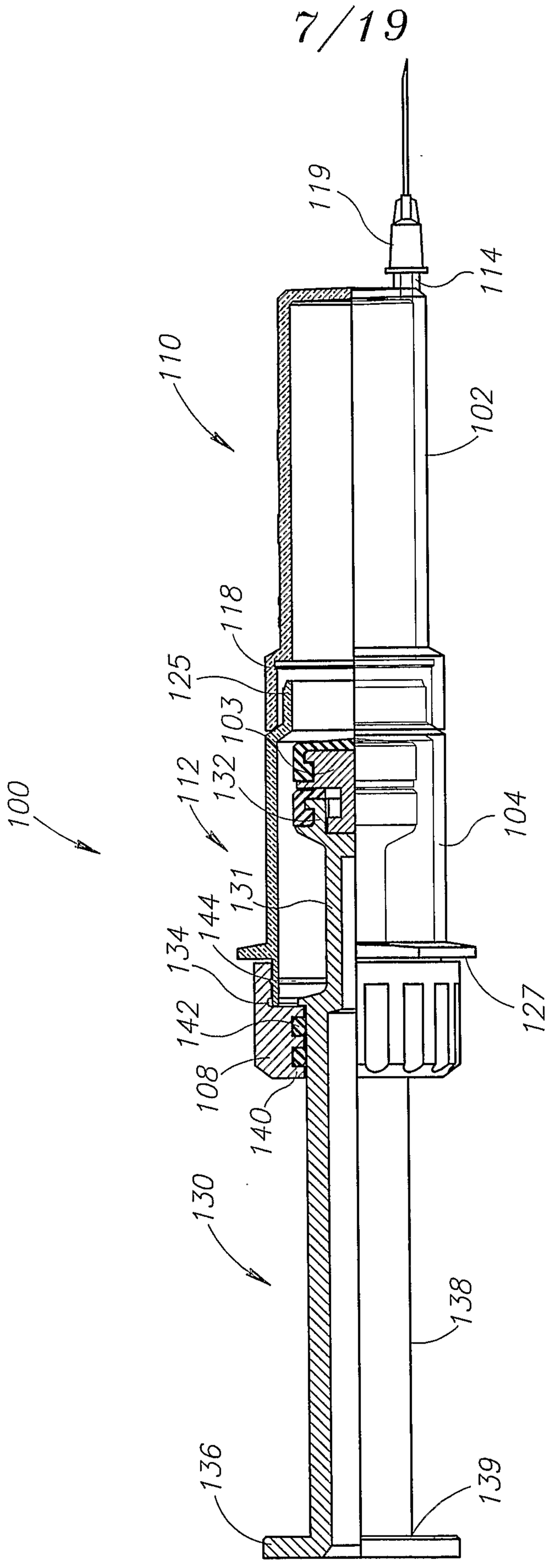
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FIG.7

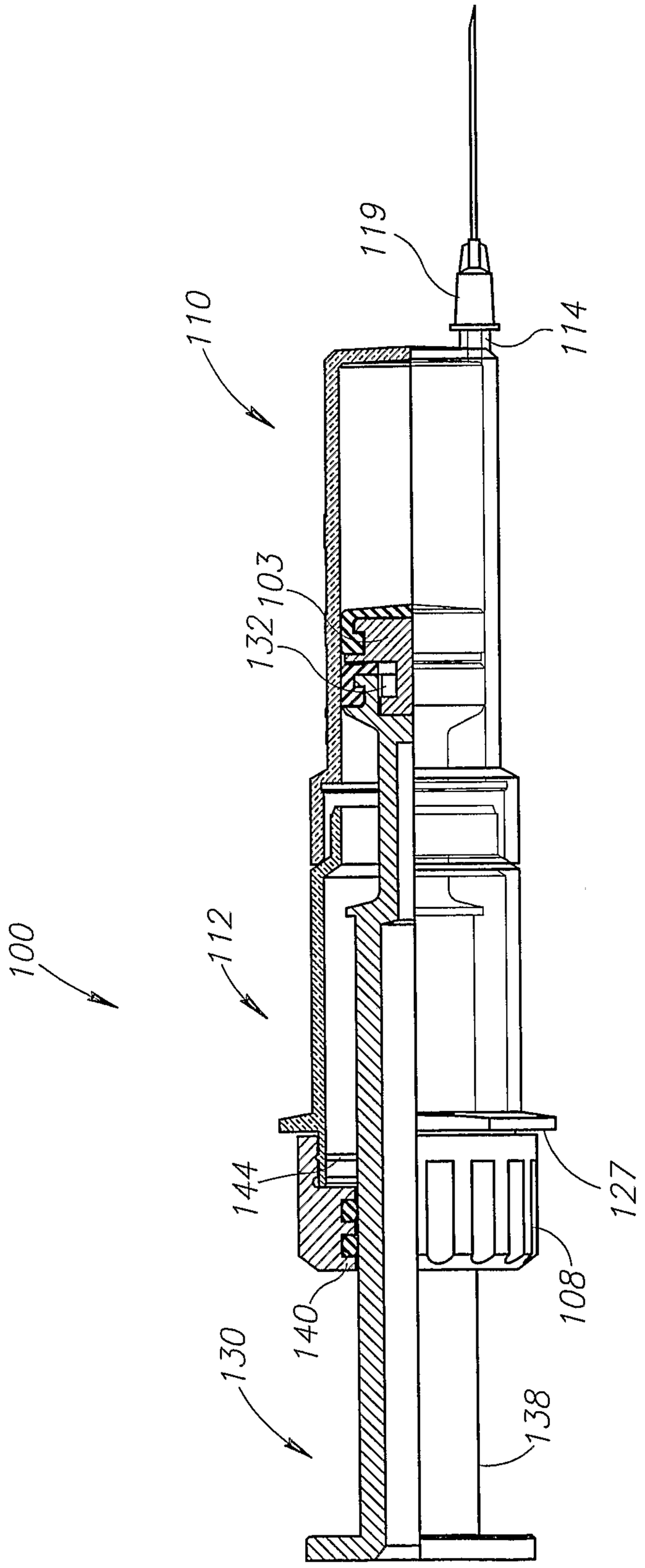

FIG.8

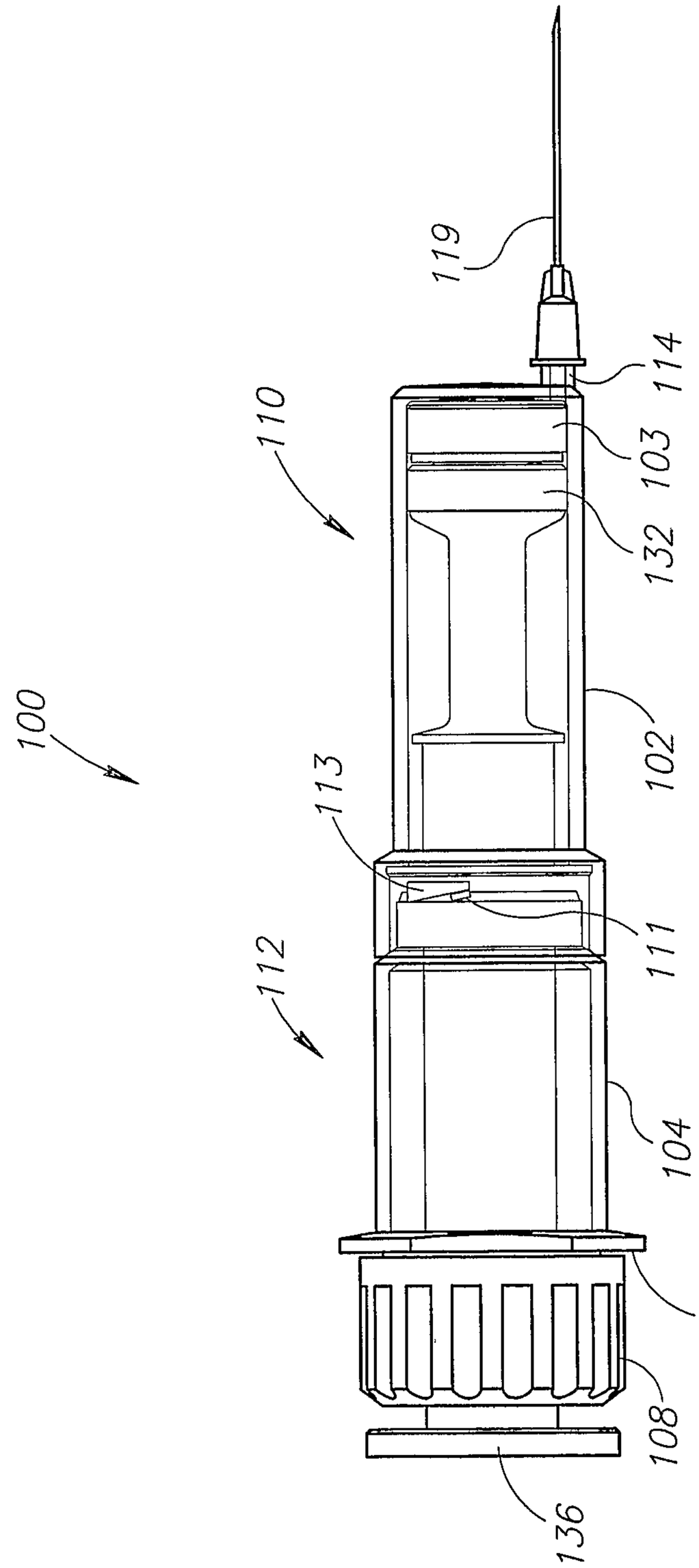

FIG.9

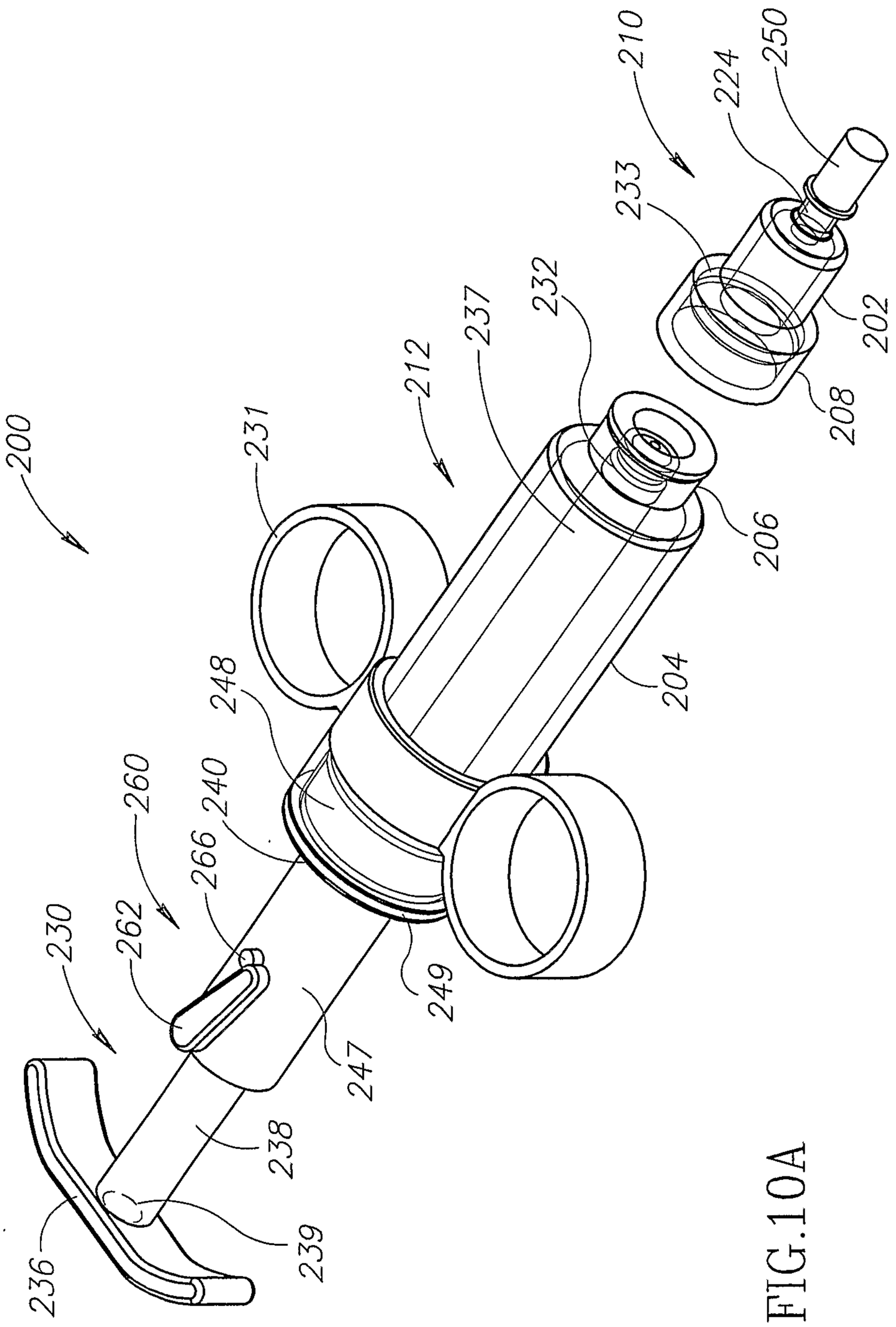
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FIG.10A

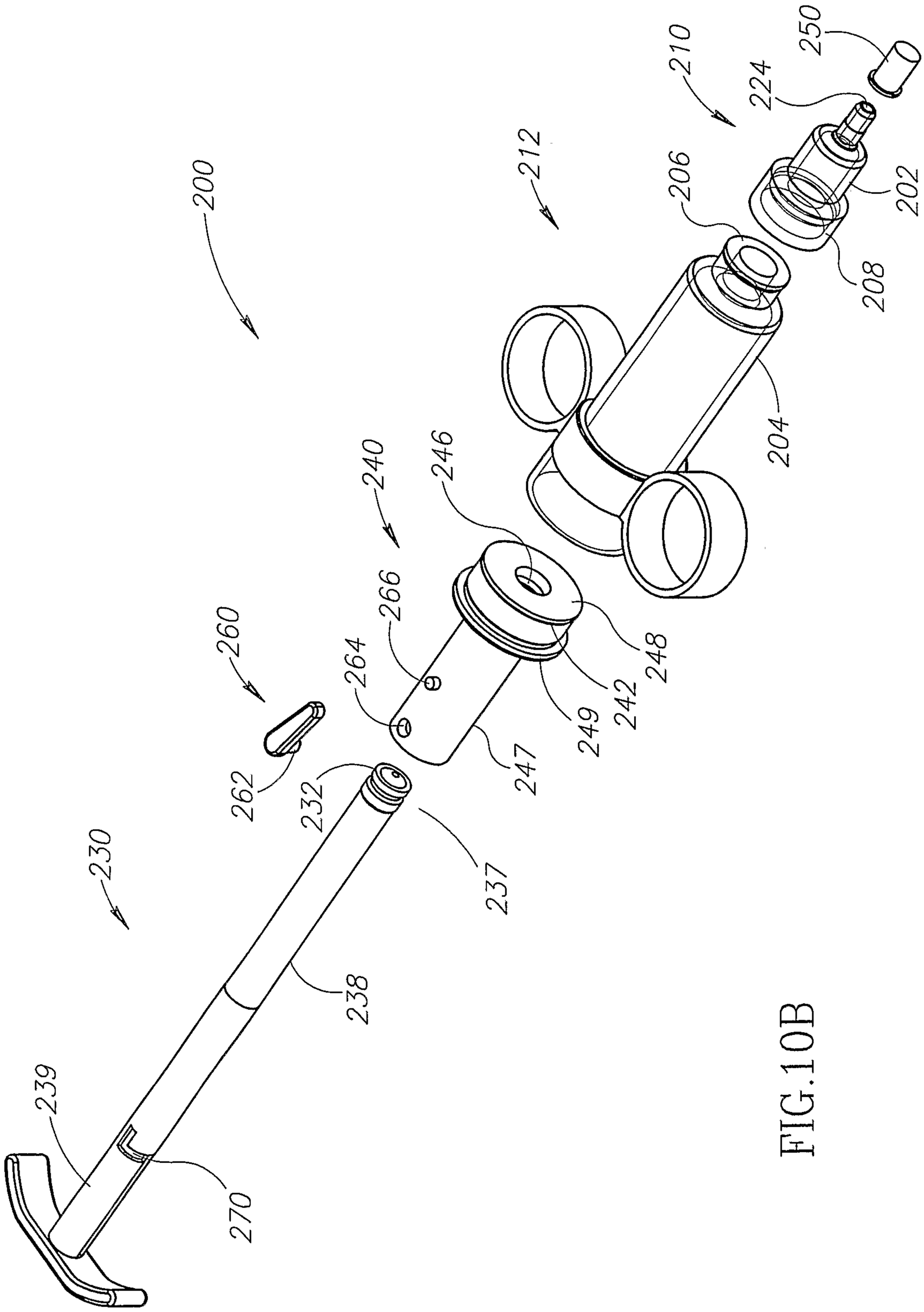
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FIG.10B

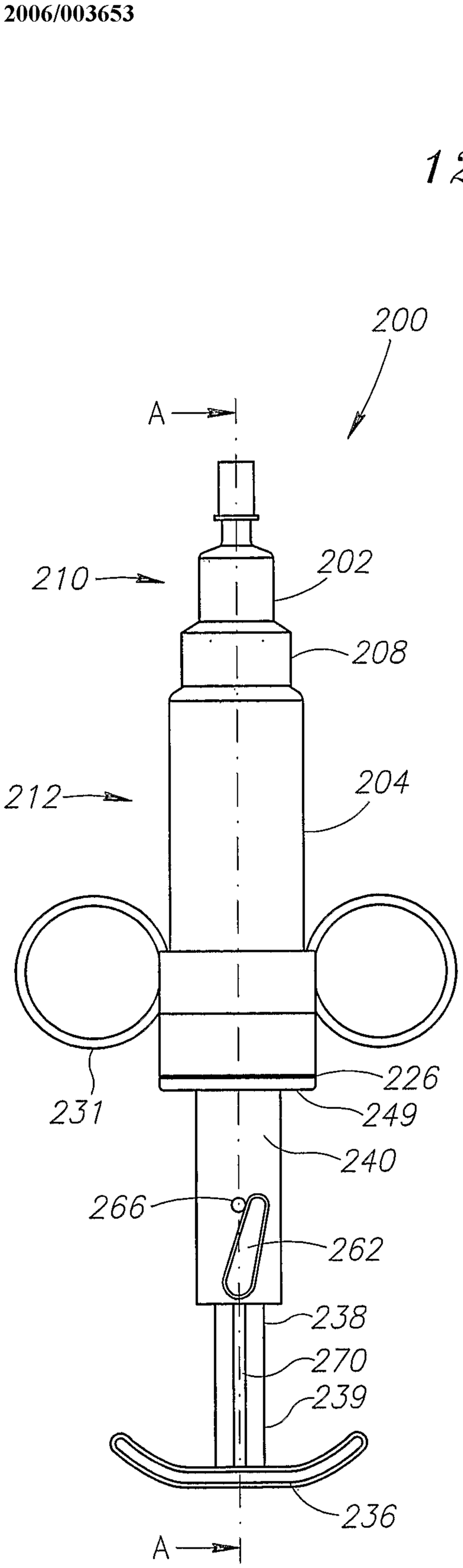

FIG.11A

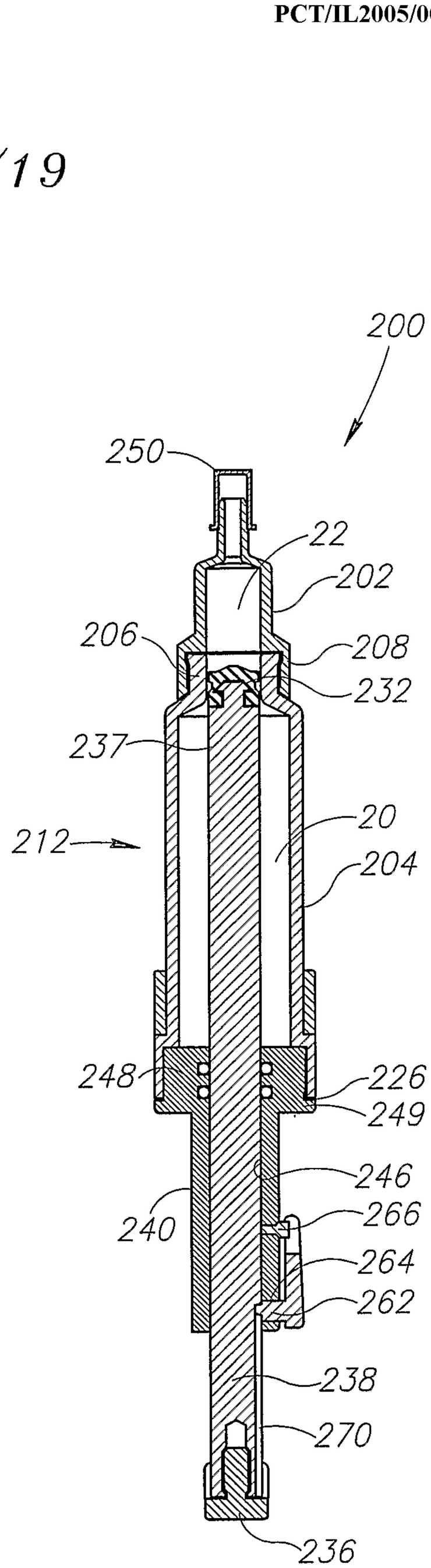

FIG.11B

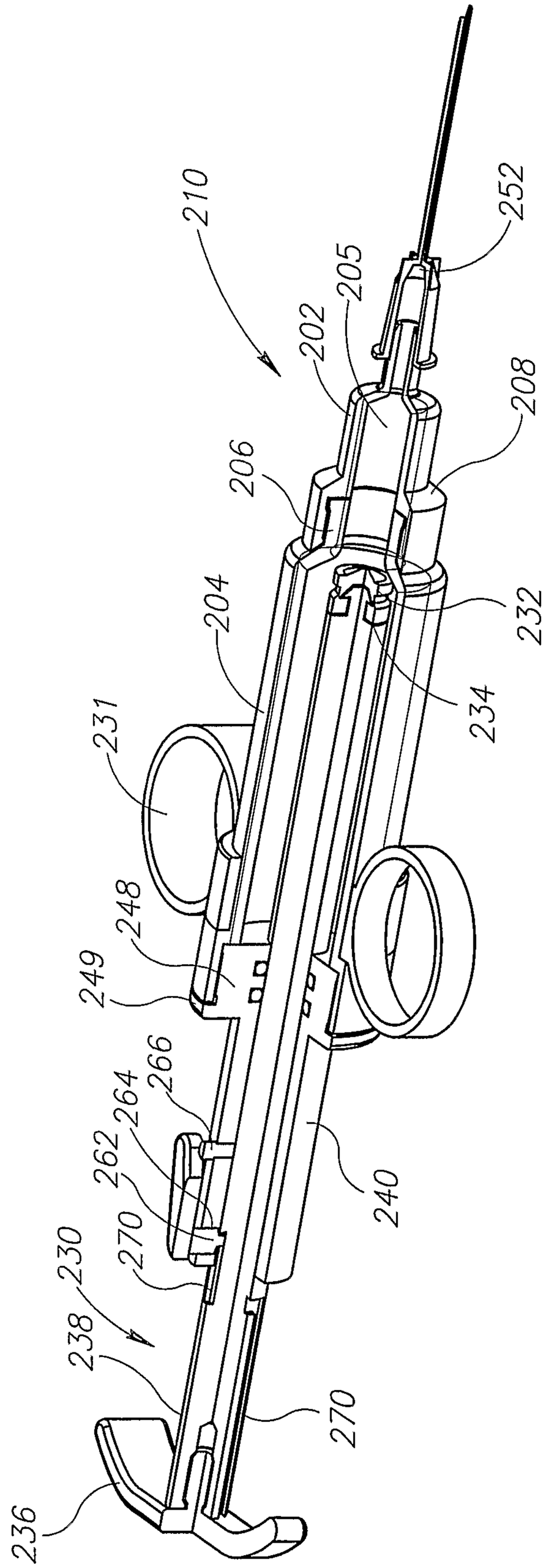
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FIG.12

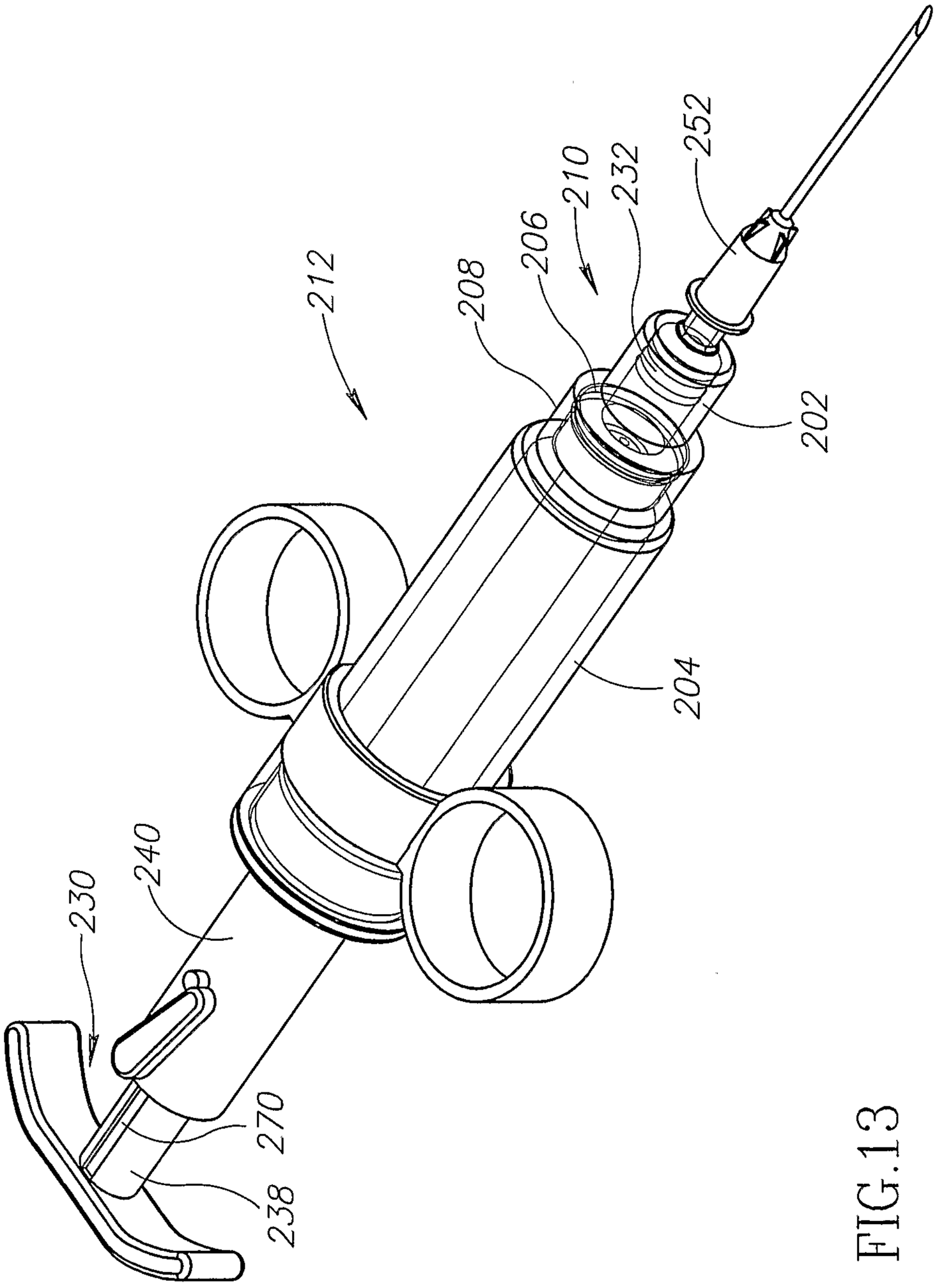

FIG.13

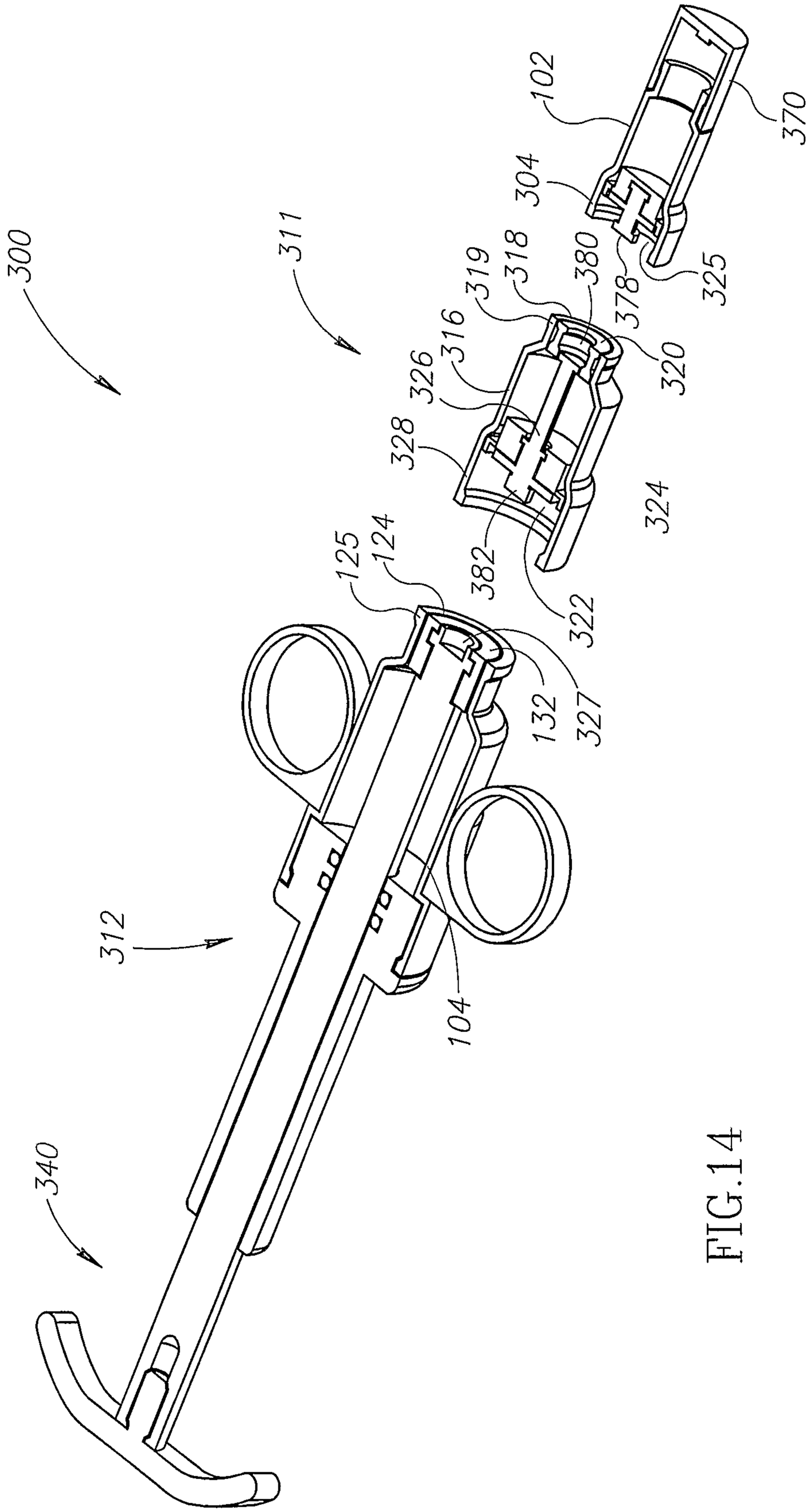
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FIG.14

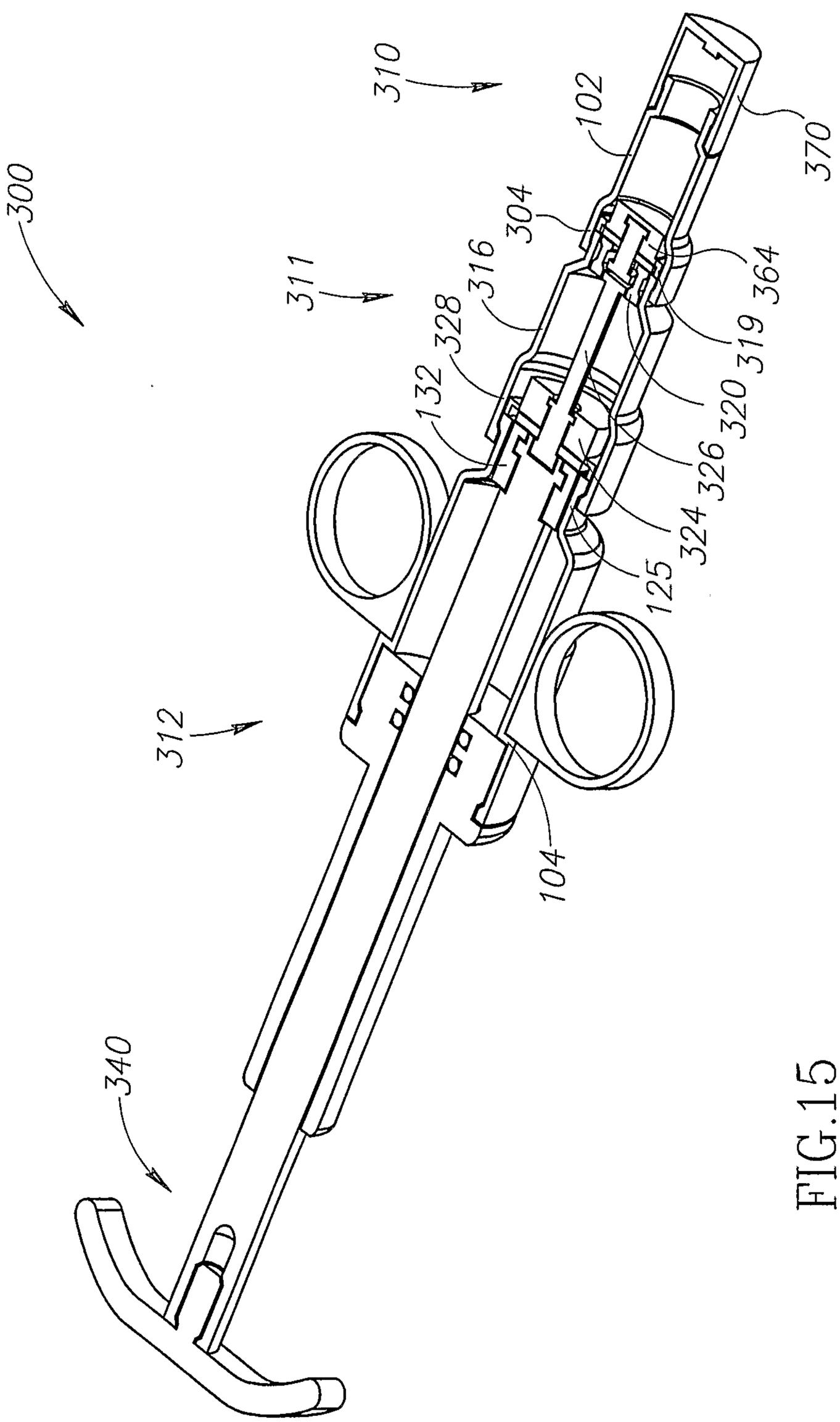
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FIG.15

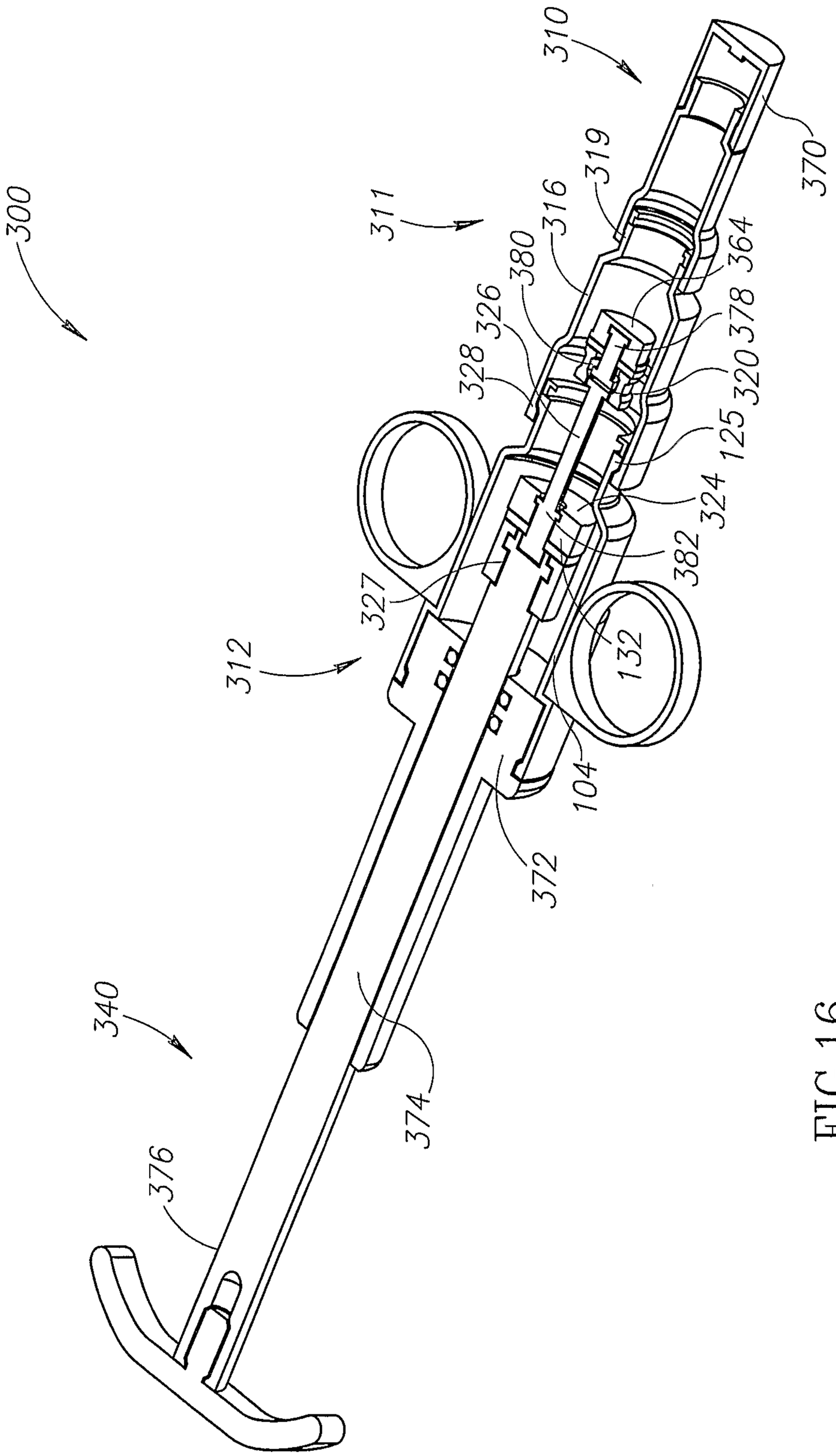
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FIG.16

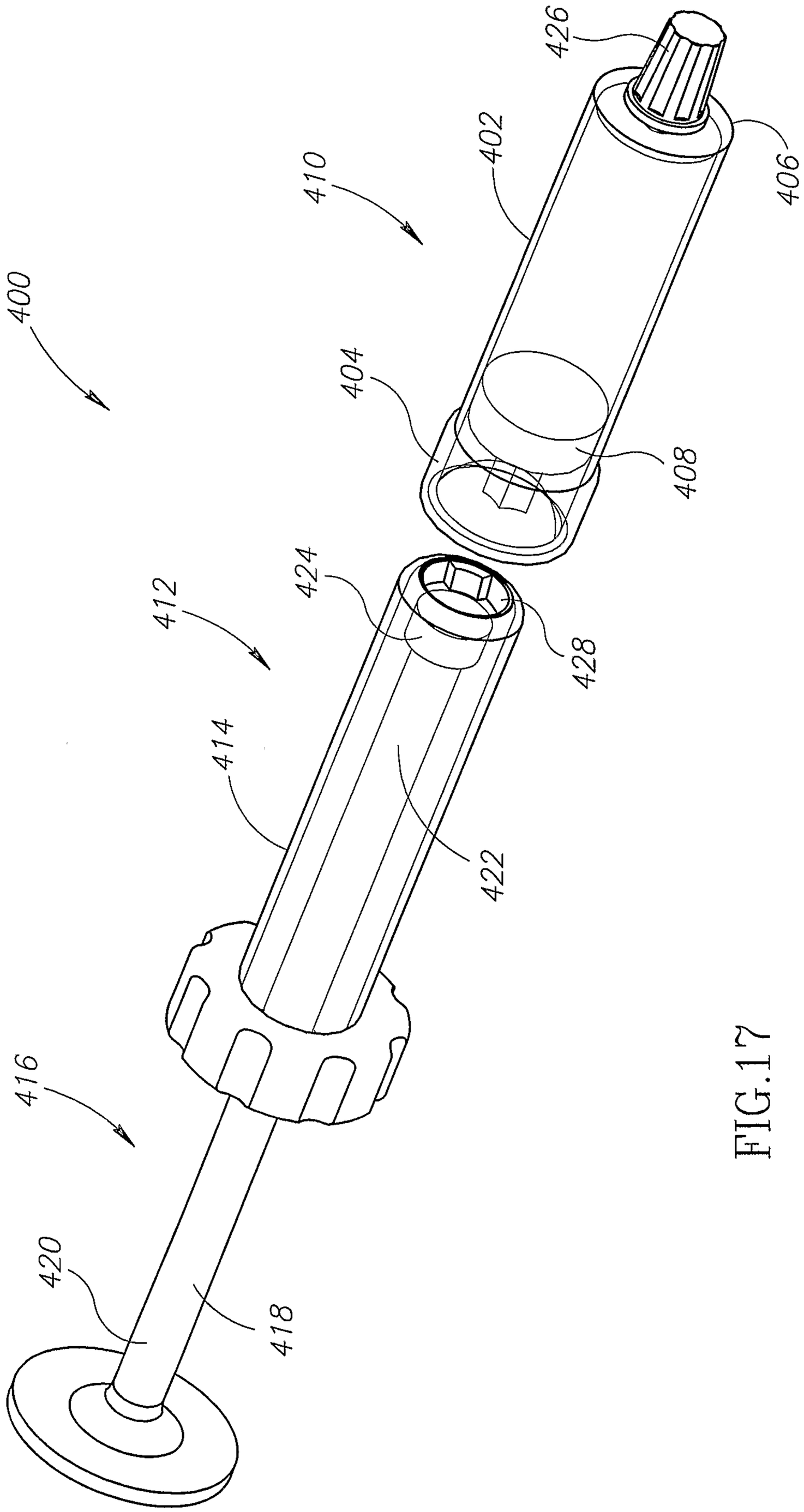


FIG.17

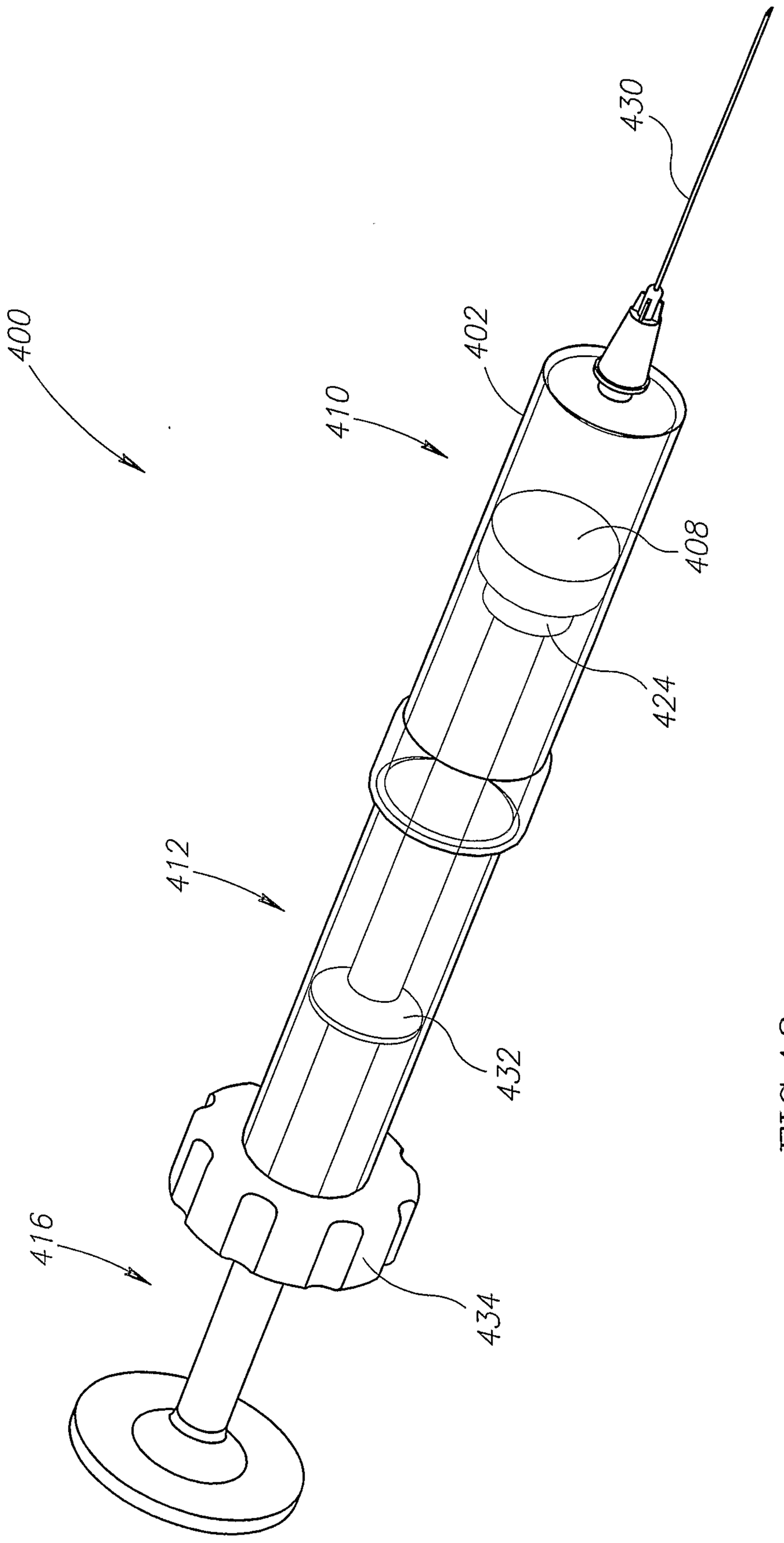
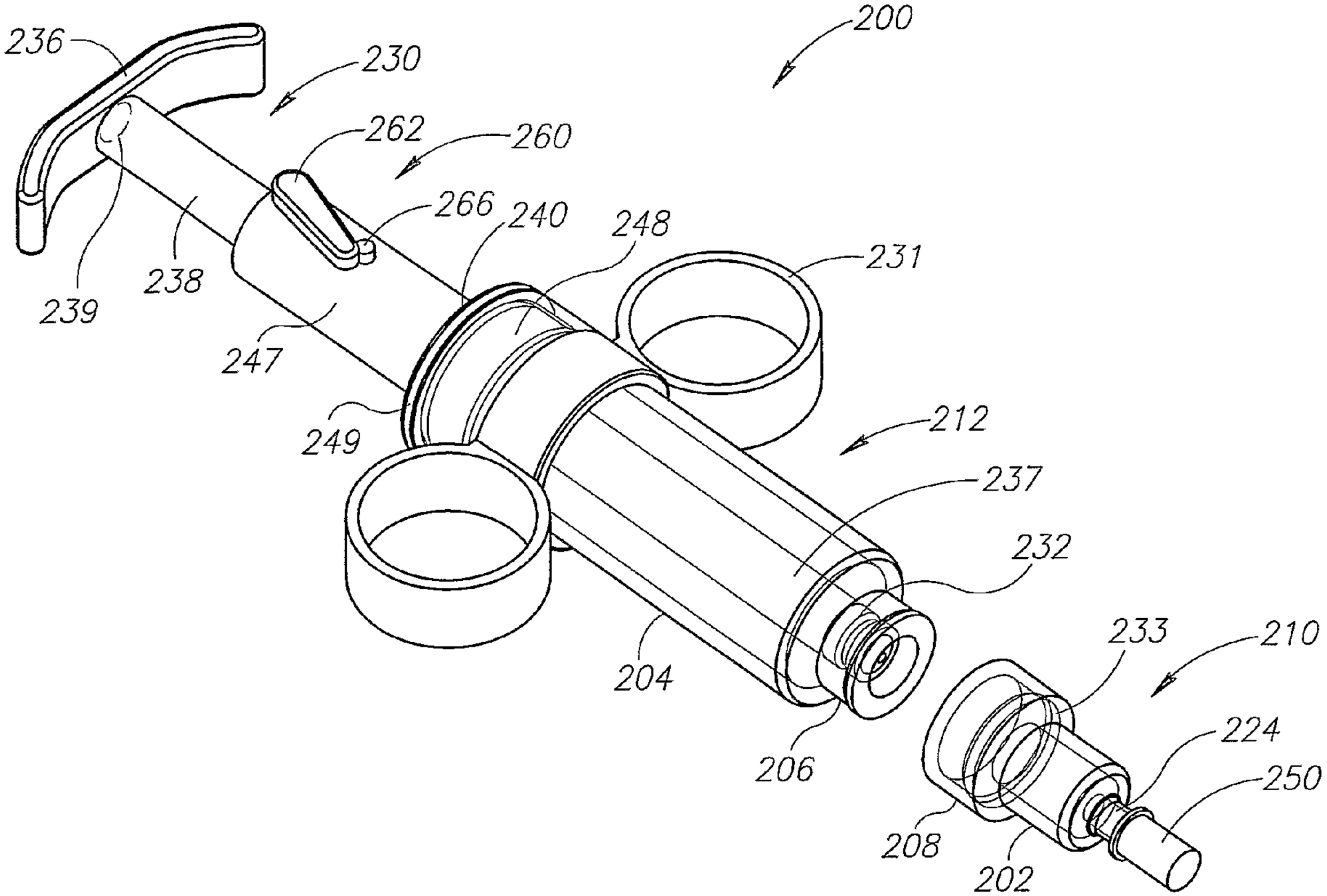


FIG.18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