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(54) **Title:** INTRAOCULAR GAS INJECTOR

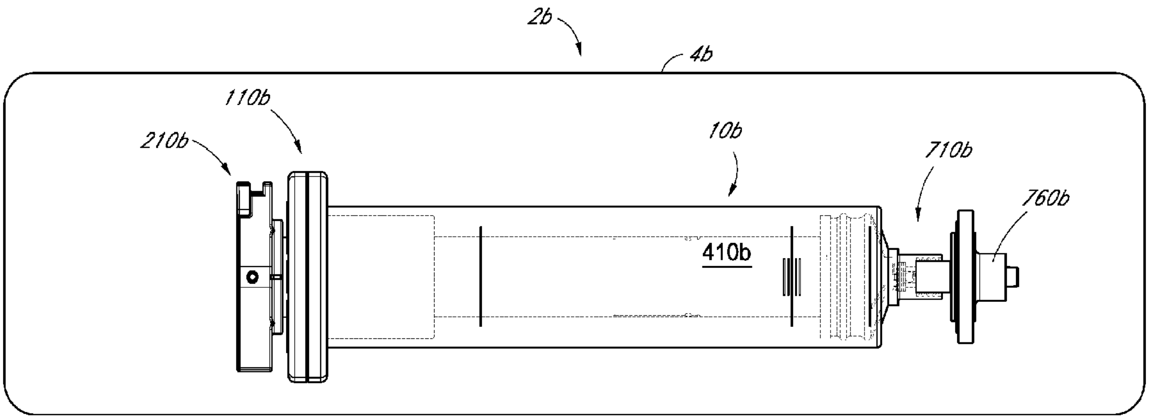

FIG. 2A

(57) **Abstract:** A gas mixture apparatus includes a measurement control system, an activation system, a pressurized chamber with one or more gases, and a mixing chamber. A filter can be preattached to the outlet of the mixture apparatus, allowing excess gas to be discharged therethrough and then atmospheric air to be drawn into the mixture apparatus through the filter for creating a therapeutic gas mixture.

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[Continued on next page]

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INTRAOCULAR GAS INJECTOR

TECHNICAL FIELD

[0001] The inventions disclosed herein generally relate to devices and methods for injecting gases into an eye of an animal.

BACKGROUND OF THE INVENTIONS

[0002] Surgical procedures can require gases or other fluids to be injected into a target area for treatment of certain injuries, disorders and diseases. In the treatment of eye conditions such as macular holes, retinal tears and detachments, part of the surgical procedure can include the injection of gases or other fluids into the eye.

[0003] For example, retinal detachment is an eye disorder involving the separation of the retina from the Retinal Pigment Epithelium (RPE), the tissue that holds the retina in place. Retinal detachment can occur due to a retinal tear, traction on the retina, or inflammation which allows fluid to build up in the subretinal space thereby causing the retina to begin to separate from supporting RPE tissue. This disorder can also occur due to Posterior Vitreous Detachment (PVD), Proliferative Diabetic Retinopathy (PDR), injury, or neovascularization of the fibrous or vascular tissue causing the retina to be detached from the RPE. Such a condition, if not treated immediately, could lead to partial vision loss and potentially even blindness.

[0004] Treatment approaches for uncomplicated retinal detachments may include non-surgical techniques such as pneumatic retinopexy, laser photocoagulation, or cryopexy. More complicated retinal detachments require surgical intervention. Due to the risk of infection, which can potentially cause blindness, such surgeries are performed under sterile conditions in order to significantly reduce the potential for infection. Surgical methods include vitrectomy, which is the removal of the vitreous humor; dissection and removal of membranes, in the case of traction retinal detachments; and photocoagulation or cryopexy, in the case of additional retinal tears. Following such a surgical procedure, an intraocular gas tamponade may be used to hold the retina tissue in contact with the RPE which enables the retina to remain attached during the healing process after the surgical procedure.

[0005] Since intraocular pressure must be maintained relatively constant during the healing process, the gas chosen is typically one that expands at constant pressure (isobaric process). As such, the intraocular gas tamponade can be a gas bubble of air mixed with an expansile gas such as sulfur hexafluoride (SF_6), hexafluroethane (C_2F_6), or octafluoropropane (C_3F_8). The intraocular gas tamponade dissolves over time depending on the gas and concentrations used. For example, sulfur hexafluoride dissolves within 1-2 weeks when mixed with air at a concentration of approximately 20 percent, hexafluoroethane dissolves in approximately 4-5 weeks when mixed with air at a concentration of approximately 16 percent, and octafluoropropane dissolves in approximately 6-8 weeks when mixed with air at a concentration of approximately 12%. Changing the concentrations of these gases affects the duration.

[0006] Current practice involves use of gases contained in separate, multi-dose pressurized containers which are then transferred into a syringe for mixing with air and injection into the patient's eye. Therefore, during a surgical procedure, multiple non-sterile and sterile steps are required in order to fill the syringe with a desired concentration of gas and air. These non-sterile and sterile steps are typically performed by the non-sterile operating room circulating nurse and the sterile scrub technician supporting the surgeon in the sterile field. During a first non-sterile step, the circulating nurse prepares the non-sterile re-usable gas container by setting a pressure regulator connected to the gas container at the proper pressure. During a second step, the scrub tech prepares a sterile syringe by connecting a stopcock, filter, and tubing, in series, onto the syringe. During a third step, the tubing is connected to the gas container. The scrub tech carefully passes the free end of the sterile tubing through the invisible sterile barrier to the awaiting non-sterile circulating nurse. The non-sterile circulating nurse receives the tubing and carefully ensures that he/she does not contaminate the scrub tech nor any other of the sterile surfaces; and connects the tubing to the regulator on the gas container. During a fourth step, the syringe is then filled with gas from the container. The scrub tech and circulating nurse coordinate the opening of the pressurized container valve to release gas through the connected tubing, filter, stopcock, and into the syringe. The pressure of the released gas is sufficient to push the syringe plunger along the length of the syringe barrel and thus fill the syringe with gas. The scrub tech ensures that the gas does not push the plunger out of the open end of the syringe barrel and signals to the circulating nurse to close the gas container valve when the syringe approaches a fully filled condition. During a fifth step, the syringe is then purged of all air and gas in order to ensure that a substantial majority of air which may have been present within the syringe, stopcock, filter, and tubing, prior to filling with gas has been purged. The scrub tech turns the stopcock, to provide a means for the air and gas in the syringe to be released to the atmosphere, presses on the syringe plunger, and empties the syringe of all of its contents. The scrub tech then turns the stopcock in the opposite direction, returning the connection pathway to the tubing and the gas container.

[0007] Steps four and five are repeated several times to further reduce the amount of air that was initially in the syringe, stopcock, filter, and tubing; flushing the majority of the air from the syringe, stopcock, filter, and tubing and purging the system of air. During a sixth step, the syringe is then refilled with gas from the container. The scrub tech detaches the tubing from the filter and signals the circulating nurse to carefully take the tubing, removing it from the sterile field. During a seventh step, the scrub tech does not expel the full contents of the syringe, stopping the plunger such that only a measured volume of gas remains in the syringe. For example, the gas may be expelled such that only 12mL remains within the syringe. During an eighth step, the scrub tech replaces the used filter with a new sterile filter and draws filtered room air into the syringe until the total air/gas mixture in the syringe is at a proper volume for the desired gas concentration.

[0008] For example, atmospheric air may be drawn into the syringe such that the total volume of air and gas is 60mL therefore achieving a concentration of 20 percent. Since the pressurized containers are non-sterile, and the syringe and surgical area are sterile, completing the above-mentioned steps must be performed by at least one party in the non-sterile field (typically the circulating nurse), a second party in the sterile field (typically the scrub tech), and requires the coordination and communication between the two parties.

[0009] The procedure requires a complex set of steps which may increase the potential for errors occurring. An error in one of these steps can result in an improper concentration of gas being used which may result in having either an elevated pressure or reduced retinal tamponade duration thereby potentially causing ischemia or failure of the reattachment surgery, both of which potentially causing blindness. Additionally, the current practice results in a significant amount of wasted gas which is both expensive and harmful to the environment. Thus handling of such gases, especially in pressurized containers containing more than one dose, may present potential danger to the operator if mishandled. As such, some countries may even prohibit storage of these pressurized containers in the operating room.

[0010] While there have been some approaches to improve the current procedure, such as U.S. Patent Number 6,866,142 to Lamborne et al., single-dose containers capable of being placed in the sterile field, and the Alcon® Constellation® system which allows filling and purging of gas, these approaches have been insufficient to address all the potential issues. Another approach is disclosed in US Patent No. 8,986,242 in which a syringe apparatus includes an internal pressurized canister of expansile gas in a volume limiting mechanism. In use, the volume limiting mechanism is set to a volume of expansile gas corresponding to ultimate desired concentration of a gas tamponade which can include an expansile gas and air. The expansile gas is released into the chamber of the syringe until the plunger of the syringe hits the volume limiting mechanism structures and the remaining expansile gas is discharged to the atmosphere. The filter is then attached to the outlet of the syringe mechanism and atmospheric air is drawn into the chamber of the syringe, through the filter, so as to create a mixture of expansile gas and air at the desired concentration for later injection.

[0010a] A reference herein to a patent document or any other matter identified as prior art, is not to be taken as an admission that the document or other matter was known or that the information it contains was part of the common general knowledge as at the priority date of any of the claims.

SUMMARY OF THE INVENTION

[0010b] According to an aspect of the present invention, there is provided a hand-held gaseous injector for delivering therapeutic gas to a patient, comprising: a syringe body with an outlet; a plunger slidably disposed in the syringe body and with the syringe body, defining a first chamber within the syringe body; a second chamber disposed within at least one of the syringe body and the plunger, the second chamber comprising: an internal volume containing at least a first fluid at a pressure greater than that of surrounding atmospheric air; an opening at a first end of the second chamber; and a valve mechanism located adjacent the first end of the second chamber, the valve mechanism configured to seal the opening; a channel and an aperture between the second chamber and the first chamber; an activation system operatively coupled to the second chamber, the activation system being configured to cause the release of the first fluid from the second chamber into the first chamber through

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the channel; an adjustable volume limiter configured to limit movement of the plunger to a plurality of user-selectable positions corresponding to a plurality of volumes of the first chamber; a filter having: a first end connected to the outlet of the syringe body, a second end with a filter orifice, and a filter element disposed between the first end of the filter and the second end of the filter; and a flow restrictor connected to the filter orifice and having a restrictor orifice that is smaller than the filter orifice and configured to restrict a flow of the first fluid from the first chamber through the filter orifice such that the first fluid from the second chamber travels from the second chamber, through the valve mechanism located adjacent the first end of the second chamber, through the first chamber, through the first end of the filter, through the filter, through the second end of the filter with the filter orifice and then through the restrictor orifice of the flow restrictor to an exterior of the hand-held gaseous injector assembly; wherein the flow restrictor is configured to generate back pressure against the flow of the first fluid from the first chamber to expand the first chamber to a desired volume corresponding to a user-selected position of the adjustable volume limiter.

[0010c] According to another aspect of the present invention, there is provided a hand-held gaseous injector assembly, comprising: a syringe body with an outlet; a plunger slidably disposed in the syringe body and with the syringe body, defining a chamber within the syringe body; an adjustable volume limiter configured to limit movement of the plunger to a plurality of user-selectable positions corresponding to a plurality of volumes of the chamber; a filter having a first end connected to the outlet of the syringe body and a second end with a filter orifice; and a flow restrictor connected to the filter orifice and having a restrictor orifice that is smaller than the filter orifice and configured to restrict a flow of fluid from the chamber through the filter orifice such that the fluid leaving the syringe, travels through the first end of the filter, through the filter, through the second end of the filter with the filter orifice and then through the restrictor orifice of the flow restrictor to an exterior of the hand-held gaseous injector assembly; wherein the flow restrictor is configured to generate back pressure against the flow of the fluid from the chamber to expand the chamber to a desired volume corresponding to a user-selected position of the adjustable volume limiter.

[0010d] According to a further aspect of the present invention, there is provided a hand-held gaseous injector assembly, comprising: a syringe body comprising an endwall and an outlet connected to the endwall; a plunger slidably disposed in the syringe body and with the syringe body, defining a first chamber within the syringe body and between the plunger and the endwall, the plunger being disposed at the endwall of the syringe body such that the first chamber comprises a volume definable by movement of the plunger; a second chamber, the second chamber comprising an internal volume containing at least a first fluid at a pressure greater than that of surrounding atmospheric air, wherein the second chamber is fluidically coupled to the first chamber for release of the first fluid from the second chamber to the first chamber; a filter having a first end connected to the outlet of the syringe and a second end with a filter orifice; and a flow restrictor connected to the filter orifice and configured to restrict a flow of the first fluid from the first chamber through the filter orifice, wherein the flow restrictor comprises a restrictor orifice that is smaller than the filter orifice such that the first fluid leaving the syringe body travels through the first end of the filter, through the filter, through the second end of the filter with the filter orifice and then through the restrictor orifice of the flow restrictor to an exterior of the hand-held gaseous injector assembly; wherein the flow restrictor is configured to generate back pressure against the flow of the first fluid from the first chamber to expand the first chamber to a desired volume corresponding to a user-selected position of an adjustable volume limiter of the hand-held gaseous injector assembly.

[0011] It is disclosed that an intraocular gas injector device can be assembled and packaged in a manner that reduces or eliminates manipulations required of a user and can further reduce potential sources of contamination. For example, as noted above with regard to the usage of the devices disclosed in US Patent No. 8,986,242, an expansile gas is provided into an internal mixing chamber of a syringe device, with some excess expansile gas being discharged through the outlet of the syringe. Thereafter, a filter is attached to the outlet of the syringe and atmospheric air is drawn into the mixing chamber, through the filter.

[0012] It is also disclosed that an intraocular gas injection device can include a syringe body, a source of theraputic gas, and a filter preattached to the outlet of the syringe, for example, before the discharge of excess therapeutic gas through the outlet. In some embodiments, the gas injection device having the filter preattached thereto can be packaged in a sterile container for use in a surgical procedure. As such, a user can open the sterile container, remove the intraocular gas injection device and operate it with the filter in place throughout the gas mixing process. For example, with the filter preattached, a user can provide the expansile gas into the mixing chamber of the syringe, at least partially filling the mixing chamber with expansile gas, or another gas of choice, and in some modes of use, allow excess expansile gas to be discharged out of the mixing chamber, through the outlet of the syringe body, and through the filter then to the atmosphere. During such discharge of the excess expansile gas, filtering of the expansile gas would not provide any known, substantial direct beneficial effects. However, using the intraocular gas injector in such a mode, with the filter in place during the discharge of excess expansile gas, provides a reduced risk of contamination of various volumes of space within the device including those between the plunger of the syringe and the filter membrane of the filter device. Further, once the discharge of excess expansile gas is completed, the user can then draw an atmospheric air into the mixing chamber, through the filter, without opening the intermediate volumes of space to the atmosphere. Thus, the intermediate volumes of space between the filter membrane and the plunger of the syringe remain closed to the atmosphere, only receiving atmospheric air that has been filtered through the filter device.

[0013] After the user has drawn in the desired amount of atmospheric air, filtered 01through the filter device, the filter device can be removed and a desired instrument can be attached to the outlet of the syringe. For example, in some embodiments, a user may attach a needle for injecting the mixed expansile gas and atmosphere air into the eye of an animal or patient doe treatment of a detached retina. After attachment of such a needle, the user can flush the needle with the mixed expansile gas and atmospheric air in the mixing chamber. Thus, prior to surgical use, no volume of space between the filter membrane and the syringe plunger would be exposed to unfiltered atmospheric air.

[0014] It is disclosed that filling of a variable volume gas mixer with a fixed amount of source gas can result in an insufficient expansion of the variable volume chamber and thus a failure to produce the desired concentration of mixed gas. Thus, an aspect of at least one of the inventions disclosed herein includes the realization that providing a flow restriction device onto the outlet of a filter which is mounted to the outlet of an intraocular gas injection device can provide beneficial and/or additional back pressure that can be beneficial for better ensuring that the mixing chamber expands to the desired volume of a therapeutic gas or a component of a therapeutic gas, such as an expansile gas.

[0015] It is further disclosed that a flow restrictor attached to the outlet of a downstream filter of an intraocular gas injector can generate an undesirably strong flow restriction during a process of drawing in ambient air or atmospheric air through the filter after the mixing chamber has been filled with therapeutic gas. Thus, an aspect of at least one of the inventions disclosed herein includes the realization that providing a removable flow restrictor to the outlet of a filter of an intraocular gas injection device can provide two beneficial modes of operation; generating a desirable back pressure during discharge of excess therapeutic gas during a filling phase of a mixing chamber, ensuring that the mixing chamber fully expands to the desired volume for containing a desired amount of therapeutic

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gas, then with the flow restrictor is removed, a user can manually expand the mixing chamber and draw atmospheric air through the filter, without the increased difficulty that would be associated with such an operation if the flow restrictor were in place. Thus, an aspect of at least one of the inventions disclosed herein includes an intraocular gas injection device having a downstream filter device and a removable flow restrictor at the downstream end of the filter device.

[0016] It is disclosed that if a filter device is attached to the outlet of the syringe in an operating room, there is potential for foreign materials or contamination to enter the upstream end of the filter device and thus be contained in a volume disposed between the filter membrane and the plunger. Thus, even if some excess expansile gas is subsequently discharged through the filter, such contamination and/or foreign materials may be captured by the filter membrane then subsequently back flushed into the mixing chamber when atmospheric air is drawn in the reverse direction through the filter. Thus, an aspect of at least one of the inventions disclosed herein includes configurations and methods of operation in which the potential for contamination and/or foreign materials to enter volumes of space disposed between the filter membrane and the plunger are reduced.

[0016a] Unless the context requires otherwise, where the terms “comprise”, “comprises”, “comprised” or “comprising” are used in this specification (including the claims) they are to be interpreted as specifying the presence of the stated features, integers, steps or components, but not precluding the presence of one or more other features, integers, steps or components, or group thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIGURE 1A is a schematic diagram of an embodiment of a gas mixing device.

[0018] FIGURE 1B is a further embodiment of a gas mixture apparatus.

[0019] FIGURE 2A is another embodiment of a gas mixture apparatus shown packaged in an enclosed container designed for deployment in a surgical room.

[0020] FIGURE 2B is a schematic side elevational view of the gas mixture apparatus shown in a first phase of operation.

[0021] FIGURE 2C is the gas mixture apparatus shown in a second phase of operation.

[0022] FIGURE 2D is the gas mixture apparatus shown in a third phase of operation.

[0023] FIGURE 3 is an exploded view of the components of the gas mixture apparatus.

[0024] FIGURE 4 is a perspective view of a measurement control system and activation system of the gas mixture apparatus.

[0025] FIGURE 5A is a perspective view of a metering dial of the gas mixture apparatus.

[0026] FIGURE 5B is a sectional view of a metering dial of the measurement control system of Figure 4.

[0027] FIGURE 6 is a perspective view of a plunger body of the measurement control system of Figure 4.

[0028] FIGURE 7 is a perspective view of the activation system of Figure 4.

[0029] FIGURE 8A is a sectional view of the measurement control system and activation system of Figure 4 in a first or "closed" position.

[0030] FIGURE 8B is a sectional view of the measurement control system and activation system of Figure 4 in a second or "open" position.

[0031] FIGURE 9 is a side view of an embodiment of an activation system, pressurized chamber, and first pressure regulation system of the second embodiment of a gas mixture apparatus.

[0032] FIGURE 10 is a sectional view of the activation system, pressurized chamber, and first pressure regulation system of Figure 9 in a first position.

[0033] FIGURE 11 is a sectional view of the activation system, pressurized chamber, and first pressure regulation system of Figure 9 in a second position.

[0034] FIGURE 12 is a sectional view of components including a mixing chamber and second pressure regulation system of the gas mixture apparatus.

[0035] FIGURE 13 is an enlarged sectional view of the mixing chamber and second pressure regulation system of Figure 12.

[0036] FIGURE 14 is an enlarged sectional view of the mixing chamber and second pressure regulation system of Figure 12 with an additional attachment.

[0037] FIGURE 15A is a perspective view of a metering dial of an embodiment of a measurement control system.

[0038] FIGURE 15B is a sectional view of a metering dial of an embodiment of a measurement control system.

[0039] FIGURE 16 is a perspective view of a plunger body of an embodiment of a measurement control system.

[0040] FIGURE 17 is a perspective view of components of an embodiment of an activation system.

[0041] FIGURE 18 is a sectional view of a measurement control system and activation system in a first, "initial", or "pre-activation" position showing operation of an interlock mechanism.

[0042] FIGURE 19 is a sectional view of a measurement control system and activation system in a second or "open" position showing operation of an interlock mechanism.

[0043] FIGURE 20 is a sectional view of a measurement control system and activation system in a third or "closed" position showing operation of an interlock mechanism.

[0044] FIGURE 21 is a sectional view of a measurement control system and activation system in a first, "initial", or "pre-activation" position showing operation of the latch.

[0045] FIGURE 22 is a sectional view of a measurement control system and activation system in a second or "open" position showing operation of the latch.

[0046] FIGURE 23 is a sectional view of a measurement control system and activation system in a third or “closed” position showing operation of the latch.

[0047] FIGURE 24 is an enlarged view of an embodiment of an activation system, pressurized chamber, and a storage member pressure regulation system.

[0048] FIGURE 25A is a sectional view of the embodiment of an activation system, pressurized chamber, and a storage member pressure regulation system of Figure 24 in a first, “initial”, or “pre-activation” position.

[0049] FIGURE 25B is an enlarged view of the embodiment of an activation system, pressurized chamber, and a storage member pressure regulation system of Figure 25A.

[0050] FIGURE 26A is a sectional view of the embodiment of an activation system, pressurized chamber, and a storage member pressure regulation system of Figure 24 in a second or “open” position.

[0051] FIGURE 26B is an enlarged view of the embodiment of an activation system, pressurized chamber, and a storage member pressure regulation system of Figure 26A.

[0052] FIGURE 27A is a sectional view of the embodiment of an activation system, pressurized chamber, and a storage member pressure regulation system of Figure 24 in a third or “closed” position.

[0053] FIGURE 27B is an enlarged view of the embodiment of an activation system, pressurized chamber, and a storage member pressure regulation system of Figure 27A.

[0054] FIGURE 28 is an enlarged view of the embodiment of an activation system, pressurized chamber, and a storage member pressure regulation system of Figure 25A illustrating in more detail an embodiment of a storage member.

[0055] FIGURE 29 is an enlarged view of the embodiment of an activation system, pressurized chamber, and a storage member pressure regulation system of Figure 26A illustrating in more detail an embodiment of a storage member.

[0056] FIGURE 30 is a schematic side elevational view of yet another embodiment of a hand-held gaseous injector assembly, removed from a package and prepared for the introduction of a therapeutic gas or gas component into a mixing chamber and including a flow restrictor connected downstream from a filter device.

[0057] FIGURE 31 is an exploded view of the hand-held gaseous injector device of FIGURE 30.

[0058] FIGURE 32 is a sectional view of an enlarged portion of the injector assembly of FIGURE 30.

[0059] FIGURE 33 is an enlarged side elevational view of a flow restrictor of the embodiment of FIGURE 30.

[0060] FIGURE 34 is an enlarged perspective view of the flow restrictor of FIGURE 30.

[0061] FIGURE 35 is an enlarged cross-sectional view of the flow restrictor of FIGURE 30.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0062] The following detailed description is merely illustrative in nature and is not intended to limit the embodiments of the subject matter or the application and uses of such embodiments. As used herein, the word "exemplary" means "serving as an example, instance, or illustration." Any implementation described herein as exemplary is not necessarily to be construed as preferred or advantageous over other implementations. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the proceeding technical field, background, brief summary, or the following detailed description.

[0063] Certain terminology may be used in the following description for the purpose of reference only, and thus are not intended to be limiting. For example, terms such as "upper", "lower", "above", and "below" refer to directions in the drawings to which reference is made. Terms such as "proximal", "distal", "front", "back", "rear", and "side" describe the orientation and/or location of portions of the component within a consistent but arbitrary frame of reference which is made clear by reference to the text and the associated drawings describing the component under discussion. Such terminology may include the words specifically mentioned above, derivatives thereof, and words of similar import. Similarly, the terms "first", "second", and other such numerical terms referring to structures.

[0064] As used herein, the terms “front” and “distal” refer to the parts of the subject apparatus which are located further away from the user (e.g., surgeon) of the apparatus during an injection operation. As used herein, the terms “rear” and “proximal” refer to the parts of the apparatus which are located closer to the user (e.g., surgeon) of the apparatus during an injection operation.

Apparatus For Mixing Two Gases

[0065] FIGURE 1A illustrates an embodiment of a gas mixture kit **2** that can include a gas mixture apparatus **10** enclosed in a container **4**. The container **4** can be any type of container appropriate for use in containing components of a surgical kit, with a sterilized internal environment, for use in a surgical room, such as within a sterilized field of a surgical room, for use during a surgery. In some such containers, a thermoformed plastic tray includes structures for retaining the components that contain surgical components in a predetermined arrangement and a frangible seal made with a thin membrane-type material. The surgical components, in some embodiments, including the gas mixture apparatus **10** are sterilized and inserted into the container **4** in a sterilized environment, and in some embodiments, with an inert gas sealed therein. Other types of containers can also be used.

[0066] The gas mixture apparatus **10** can be configured to form a therapeutic gas or components for a therapeutic gas. For example, the gas mixture apparatus **10** can be configured to receive a therapeutic gas or a component of a therapeutic gas and a second gas, which can be in some embodiments, atmospheric air, into a mixing chamber for subsequent discharge for therapeutic use. For example, in some embodiments, the gas mixing apparatus **10** can be used for creating a therapeutic gas mixture for injection into a patient, and in some embodiments, the eye of a patient.

[0067] With continued reference to FIGURE 1A, the gas mixture apparatus **10** can comprise a mixing system **310**, a pressure regulation system **710**, and a filter device **760.** The mixing system **310** can include an outer housing **311**, a therapeutic gas source **410**, and a mixing chamber **510**. The mixing chamber **510** can be defined by a portion of the housing **311** and a movable wall, such as a plunger **460**. The plunger **460** can be in the form of a plunger typically provided in a syringe device.

[0068] The mixing system **310** can also include a pressure regulation system **610** disposed between the source **410** and the mixing chamber **510**. The pressure regulation system **610** can include a valve configured to retain the source **410** in a closed condition and, upon actuation, release the contents of the source **410** into the mixing chamber **510**, through the valve **610.**

[0069] The pressure regulation system **710** can be configured to control a flow of gas into an out of the mixing chamber **510**. For example, the pressure regulation system **710** can be configured to allow excess gas, originally from the source **410**, provided into the mixing chamber **510**, to escape to the atmosphere. For example, the pressure regulation system **710** can be configured to controllably release gas from the mixing chamber **510** that is at a pressure greater than atmospheric pressure. Additionally, the pressure regulation system **710** can be configured to allow a gas to enter the mixing chamber **510** when the pressure within the mixing chamber **510** is below atmospheric.

[0070] The filter device **760** can include a filter membrane (not shown) or another filtering device configured to remove particles, foreign materials, or other substances from gases flowing therethrough. The filter device **760** can include an outlet end **761** communicating with the atmosphere. The outlet **761** can be used to discharge gas from the mixing chamber **510,** as well as allow the admission of atmospheric air into the filter device **760** for mixing in the mixing chamber **510.** Optionally, the filter device **760** can include a further flow restrictor **1300** configured to restrict a flow out of and/or into the outlet **761**.

[0071] The kit **2** can be prepared in a sterilized environment, and receive the gas mixture apparatus **10**, with or without the optional flow restrictor **1300**, such that the filter member **760** is attached to the mixing apparatus **310** and sealed within the container **4**. In use, a practitioner can open the container **4** and release a therapeutic gas or gas component from the source **410** into the mixing chamber **510**.

[0072] By way of the introduction of the gas in the mixing chamber **510**, the plunger **460** would move to the left (as viewed in **FIG.** 1A) thereby allowing the volume of the mixing chamber **510** to expand in accordance with the introduction of the therapeutic gas from the source **410** into the mixing chamber **510**. For example, in some embodiments, the source **410** is a pressurized container of a therapeutic gas or component thereof. Thus, the release of the pressurized gas into the mixing chamber **510**, would raise the pressure within the mixing chamber **510**, thereby urging the plunger **460** to move and thereby expand the volume of mixing chamber **510**.

[0073] The pressure regulation system **710** can include a valve mechanism configured to open when subject to pressures greater than atmosphere and, simultaneously, provide a flow restriction thereby creating some back pressure sufficient to cause the plunger **460** to move and allow the mixing chamber **510** to expand. When the plunger **460** has moved sufficiently to allow the mixing chamber **510** to expand to the desired volume of therapeutic gas, the pressure regulation device system **710** will allow the release of the remaining excess gas from the source **410** to flow out through the filter device **760** and the outlet **761**. As excess gas flows through the filter device **760**, the upstream side of the filter device **760** would not be expected to capture any foreign materials or contaminants as all interior spaces within the device **10** would have been presterilized and stored in a sterilized environment within the container **4**. Thus, during the discharge of excess gas from the mixing chamber **510**, the filter device **760** would not likely serve any desired filtering functions.

[0074] After the chamber **510** has been filled with the desired volume of therapeutic gas or component thereof, the plunger **460** can be manually moved, for example, toward the left (as viewed in **FIG.** 1A), so as to draw atmospheric air into the outlet **761**, through the filter device **760**, through the pressure regulation system **710** and into the mixing chamber **510**. As such, the filter device **760** can capture foreign material and/or other undesirable gases that may be present in the atmosphere from entering and prevent those substances from entering the mixing chamber **510**.

[0075] The plunger **460** can be moved to a desired location corresponding to the desired mixture of gases from the source **410** and atmospheric air. After the desired mixture has been formed in the mixing chamber **510**, the user can remove the filter **760**, and attach a delivery device (not shown), such as a hypodermic needle to the pressure regulation device **710**, for further discharge.

[0076] For example, in the context of using the device **10** for mixing expansile gas from the source **410** with atmospheric air for the treatment of a detached retina, a user may attach a hypodermic needle to the downstream side of the pressure regulation system

710, in the illustrated location of the filter device **760**. With the needle attached as such, a user can manually move the plunger **460** to the right (as viewed in **FIG.** 1A) and flush the hypodermic needle with uncontaminated mixed gas from within the mixing chamber **510**, then continue the procedure for providing therapy to a patient, for example, by introducing a bubble of mixed expansile gas and atmospheric air from the mixing chamber **510** into the eye of a patient.

[0077] In some embodiments, as described above, the device **10** can include a flow restrictor **1300**. The flow restrictor **1300** can provide additional restriction of flow out of and into the outlet **761**. Thus, during the addition of therapeutic gas into the mixing chamber **510**, the flow restrictor **1300** can provide additional back pressure and thus assurance that sufficient positive pressure will be generated in the mixing chamber **510** so as to move the plunger **460** (to the left) and thus allow the mixing chamber **510** to fully expand to the desired volume associated with the desired final concentration of the mixture in the mixing chamber **510.**

[0078] FIGURE 1B illustrates a further embodiment of the gas mixture kit **2**, identified generally by the reference numeral **2a**. The kit **2a** includes a gas mixture apparatus **10a** contained within a container **4a**. As described above with reference to the container **4**, the container **4a** can contain the system **10a** in a sterilized state for opening and use in a surgical environment. The gas mixture apparatus **10a** can comprise a measurement control system **110a**, an activation system **210a**, and a mixing system **310a** configured to create a mixture of two or more gases at a desired concentration ratio, and a preattached filter **760a**. Further, optionally, the kit **2a** can include a removable flow restrictor **1300** attached to an outlet **761a** of the filter device **760a**. The mixing system **310a** can also optionally include a pressurized chamber **410a** and a mixing chamber **510a**.

[0079] The mixing system **310a** can also include a pressure regulation system to enhance the operation of the mixing system **310a**. In some embodiments, the mixing system **310a** additionally includes a first pressure regulation system **610a** and a second pressure regulation system **710a**.

[0080] The measurement control system **110a** can be in the form of a metering mechanism contained within the mixing system **310a** to control certain aspects of the devices contained therein. In some embodiments, the measurement control system **110a** can be a variable and user-adjustable device. The activation system **210a** can be operatively coupled to the pressurized chamber **410a** in order to activate operation of the device and commence the mixing of gases within the mixing system **310a**.

[0081] The optional pressurized chamber **410a** can contain at least one of the two or more gases to be mixed within the mixing system **310a**. In some embodiments, the gas contained within the pressurized chamber **410a** can be at a pressure higher than surrounding ambient conditions. Additionally, the pressurized chamber **410a** can contain gases at concentrations different from that in the atmosphere. The pressurized chamber **410a** can be configured such that it is in fluid communication with the first pressure regulation system **610a**. In other embodiments, the pressurized chamber **410a** can be in direct fluid communication with the mixing chamber **510a**. The pressurized chamber **410a** can be configured such that it is internally contained within an injector apparatus. The pressurized chamber **410a** can also be configured such that it is external to the injector apparatus. The first pressure regulation system **610a** can be configured to maintain a pre-configured pressure differential between the pressurized chamber **410a** and the mixing chamber **510a**.

[0082] The mixing chamber **510a** can be configured to receive gas from the pressurized chamber **410a** either directly or via the first pressure regulation system **610a**. In some embodiments, the mixing chamber **510a** can additionally be configured to receive a second gas to be mixed from outside the mixing system **310a** such as an external gas container or the atmosphere. The mixing chamber **510a** can be configured such that it is in fluid communication with the second pressure regulation system **710a** at a mixing chamber **510a** exit point. In other embodiments, the mixing chamber **510a** can be in direct fluid communication with the atmosphere at a mixing chamber exit point. Examples of each of these subsystems are described separately below.

[0083] In some embodiments, the measurement control system **110a** is configured to control concentrations of the gas within the gas mixture apparatus **10a**. In some embodiments, the measurement control system **110a** is operatively coupled with the mixing system **310a**. Preferably, the measurement control system **110a** is operatively coupled with either the pressurized chamber **410a** or the mixing chamber **510a** such that the measurement control system **110a** can modify variable aspects of the pressure chamber **410a** and/or the mixing chamber **510a**.

[0084] In some embodiments, the measurement control system **110a** is capable of controlling characteristics such as, but not limited to, the volume of gas contained within the mixing chamber **510a**. Other characteristics, such as pressure, are also contemplated as being controllable by the measurement control system **110a**. Preferably, the measurement control system **110a** is variable such that a user can be able to select a desired concentration ratio of gas that can be expelled from the gas mixture apparatus **10a**. This advantageously allows a user to have only a single gas mixture apparatus **10a** for a wide range of desired concentration ratios. As such, the measurement control system **110a** can include user-operable switches such as dials which vary the operation of components within the mixing system **310a** such as the pressurized chamber **410a**, the mixing chamber **510a**, the first pressure regulation system **610a**, and the second pressure regulation system **710a**.

[0085] The pressurized chamber **410a** can be configured to store one or more gases within an interior space of the pressurized chamber **410a** for a period of time prior to mixing the two or more gases in the gas mixture apparatus **10a**. The conditions within the interior space is configured to be different than those of atmospheric conditions and therefore the interior space should generally reduce the release of such gases out of the interior space or reduce the entry of non-stored gases into the interior space until mixing of the two or more gases is to be performed.

[0086] In some embodiments, the one or more gases within the interior space are at a higher pressure than ambient atmospheric conditions. Additionally, the one or more gases can also be gases at concentrations different than those at ambient atmospheric conditions. In some embodiments, the interior space can be divided into separate subsections or portions for holding one or more gases. These separate portions of the interior space can therefore be kept at different pressures and/or different concentrations of gases.

[0087] In some embodiments, the gases can additionally be placed in different structural units within the interior space. Such structural units can be used to more effectively reduce the release of stored gases and/or reduce the entry of non-stored gases. In some embodiments, the stored gases of the pressurized chamber **410a** are pre-loaded from the time of manufacture. In other embodiments, it is contemplated that the contents of the pressurized chamber **410a** can be loaded by a user of the gas mixture apparatus **10a**. For example, the stored gases can be contained in a removable cartridge-like device which can advantageously facilitate the replacement of such gases.

[0088] In some embodiments, the activation system **210a** is configured to activate the operation of the gas mixture apparatus **10a** and commence the process of mixing the two or more gases within the mixing system **310a**. As such, the activation system **210a** is operatively coupled to the mixing system **310a** and can be coupled to both the mixing chamber **310a** and the pressurized chamber **410a**. The activation system can cause the pressurized chamber **410a** to activate and release gases contained therein into the mixing chamber **510a**. In some preferred embodiments, the activation system **210a** can cause the pressure within the pressurized chamber **410a** to increase such that the first pressure regulation system **610a** is activated thereby allowing fluid flow from the pressurized chamber **410a** into the mixing chamber **510a**. The activation system **210a** can include a device configured to activate a separate portion of the pressurized chamber **410a** that contains higher pressure gas than the remainder of the pressurized chamber **410a** such that the pressure within a separate section of the pressurized chamber **410a** increases. In a preferred embodiment, the activation system **210a** can open a sealed device within the mixing chamber **510a** to release pressurized gas and thereby release pressure throughout the pressurized chamber **410a**. In such embodiments, the activation system **210a** can include a puncturing device capable of piercing the seal. Other devices and techniques can also be used. Use of an activation system **210a** provides advantages by allowing the gas mixture apparatus **10a** to potentially be pre-filled prior to use and safely stored.

[0089] The activation system **210a** can also be operably coupled to the mixing chamber **510a** allowing a user to manually vary certain aspects of the device. In some embodiments, the activation system **210a** can be used to modify the volume of the mixing chamber **510a**. The activation system **510a** can also be used to modify the pressure of the mixing chamber **510a**.

[0090] In some embodiments, the first pressure regulation system **610a** is configured to serve as a separation mechanism between both the pressurized chamber **410a** and the mixing chamber **610a**. The first pressure regulation system **610a** can activate upon reaching a pre-configured pressure differential between both the pressurized chamber **410a** and the mixing chamber **510a**. In some preferred embodiments, the first pressure regulation system **610a** can be comprised of at least one valve assembly. The valve assembly can open when pressure within a portion of the pressurized chamber **410a** is higher than the pressure in the mixing chamber **510a**. The valve assembly can be a check valve, clack valve, non-return valve, or one-way valve. Such valves can also include ball check valves, diaphragm check valves, swing check valves, stop-check valves, lift-check valves, in-line check valves, and duckbill valves. Other pressure regulation mechanisms can also be used. Additionally, it is contemplated that first pressure regulation system **610a** can also be activated by other means other than pressure differentials across the system **610a**.

[0091] In some embodiments, the mixing chamber **510a** is configured to serve as a space within which the two or more gases can be mixed to obtain a desired concentration ratio of the gases. The mixing chamber **510a** can be configured to have a variable volume, adjustable upon use of the activation mechanism. The mixing chamber **510a** can receive the gases to mix solely from the pressurized chamber or from gases already existing within the mixing chamber **510a**. The mixing chamber **510a** can also receive gases from secondary sources. In some embodiments, the mixing chamber **510a** can receive air from the atmosphere to mix with the gases received from the pressure chamber **310a** and/or gases already existing within the mixing chamber **510a**.

[0092] In some embodiments, the second pressure regulation system **710a** is configured to serve as a separation mechanism between both the mixing chamber **510a** and the surrounding atmosphere. The second pressure regulation system **710a** can activate upon reaching a pre-configured pressure differential between both the mixing chamber **510a** and the surrounding atmosphere. In some preferred embodiments, the second pressure regulation system **710a** can be comprised of at least one valve assembly. The valve assembly can open when pressure in the mixing chamber **510a** is higher than the pressure in the surrounding atmosphere. The valve assembly can be a check valve, clack valve, non-return valve, or one-way valve. Such valves can also include ball check valves, diaphragm check valves, swing check valves, stop-check valves, lift-check valves, in-line check valves, and duckbill valves. Other pressure regulation mechanisms can also be used. Additionally, it is contemplated that second pressure regulation system **710a** can also be activated by other means other than pressure differentials across the system **710a**.

[0093] The kit **2a** can also include a filter device **760a** attached to an outlet of the mixing chamber **510a** and/or an outlet of the second pressure regulation system **710a**. The filter device **760a** can include an outer housing and an internal filtering component, such as a membrane with a desired porosity or aperture size, for filtering out undesired foreign particles, substances, and/or gases. The filter device **760a** can include an outlet **761a** communicating with the atmosphere. During assembly of the kit **2a**, the mixing device **10a**, with the components **110a**, **210a**, **310a**, **410a**, **510a**, **610a**, **710a**, and the filter device **760a** attached in a sterilized packaging room and sealed within the container **4a** in a sterilized state, and optionally, packed with a sterilized, inert gas. Thus, all of the empty internal volumes within and between the components **110a**, **210a**, **310a**, **410a**, **610a**, **510a**, **710a**, and **760a** will be either sterilized and/or filled with an inert gas within the sealed package **410a**. Optionally, as noted above, the kit **210a** can also include an additional flow restrictor **1300** attached to the outlet **761a** of the filter device **760a**.

Operational Overview

[0094] With reference to **FIGS. 2A–2D**, the operation of an embodiment of a gas mixture apparatus **10b** is illustrated. With reference to **FIG. 2A**, the apparatus **10b** can be in an initial phase with the activation system **210b** in a first or “closed” position and contained in the package **4b**. In this phase, the device **10b** is in a fully sterilized state, with all internal volumes, including those between the filter element of the filter device **760** and the plunger **460** (not shown) sterilized and/or filled with a sterilized inert gas.

[0095] A practitioner or other user can remove the device **10b** from the package **4b** and use the measurement control system **110b** to select the desired concentration of therapeutic gas for mixing. Then, the user can use the activation system **210b** to release gas from the gas source **410b** into the mixing chamber **510b.**

[0096] For example, with reference to **FIG.** 2B, gas contained within the pressurized chamber **410b** can be released and, in embodiments containing a first pressure regulation system, the first pressure regulation system can open in response to a change in pressure within the chamber. As such, fluid can flow from the pressurized chamber into the mixing chamber **510b** thereby causing an increase in the volume of the mixing chamber **510b**. However, due to components of the measurement control system **110b**, the plunger **460b** of the mixing chamber **510b** is stopped at the user-selected first volume and cannot expand beyond this first volume. This first volume can be set based on the desired concentration of the injectable volume. During this first phase of operation, excess gas can also be bled from the mixing chamber **510b** via the second pressure regulation system **710b**. Once the mixing chamber has reached this first volume, the first phase of operation is complete and the second phase of operation begins.

[0097] During the second phase of operation, the mixing chamber **510b** can remain at the first volume while pressure within the mixing chamber **510b** is bled from the system via the filter **760** and the second pressure regulation system **710b**. By overfilling the mixing chamber **510b** with the desired gas, and then bleeding off that gas, this helps to ensure that any amount of atmospheric gas or inert gas provided into the container at the time of packaging within the mixing chamber **510b**, which may have been contained in the mixing chamber **510b** prior to activation, is substantially purged from the mixing chamber **510b** and displaced by the gas originally contained in the pressurized chamber. Once the pressure within the mixing chamber **510b** has reached a configured value based on the configuration of the second pressure regulation system **710b**, bleeding of the gas within the mixing chamber **510b** ceases and the second phase of operation is complete.

[0098] During a third phase of operation, as shown in **FIG. 2C**, once sufficient time has elapsed for the gas to reach ambient pressure, the user can then set the activation system **210b** to the first or "closed" position thereby unlocking the measurement control system **110b**. The user can then manually expand the volume of the mixing chamber **510b** to the injectable volume. As the user manually expands the volume of the mixing chamber **510**, ambient air is drawn from the atmosphere, through the filter device **760b**, and into the mixing chamber **510b**. The filter **760b** thereby can filter out foreign particulates or gases from the ambient air before that air enters chamber **510b**.

[0099] Once the third phase is complete, with reference to **FIG.** 2D, the filter device **760b** can be removed and an additional device configured for the delivery of the therapeutic gas in the mixing chamber **510b**, can be attached (not shown). For example, a hypodermic needle could be attached to the device **10b** for supporting therapeutic delivery of the therapeutic gas within the mixing chamber **510b** to a patient. In some embodiments, the gas within the mixing chamber **510b** can be a mixture of expansile gas and filtered atmospheric air for the treatment of detached retinas. In such a scenario, a hypodermic needle attached to the device can be purged of any gas that may exist therein by depression of the plunger for **460b** to discharge some of the gas from the mixing chamber **510b** through the hypodermic needle. Thereafter, the needle can be inserted into a patient's eye and gas from the mixing chamber **510b** can be used to generate one or more gas bubbles within the patient's eye for treatment of a detached retina. Other uses are also possible.

[0100] In other embodiments, a fewer or greater number of phases of operation can be performed. In some embodiments, only a single phase of operation can be performed. For example, the pressurized chamber **410a** can contain a gas at a pre-set concentration level. During the single phase of operation, the user can activate the apparatus **10b** such that a gas or fluid flows from the pressurized chamber **410a** and into a second chamber, such as the mixing chamber **510a**, until the chamber reaches a configured volume. The gas or fluid can also be expelled or bled off using a pressure regulation system until a desired pressure is achieved within the chamber. After expelling the gas, the apparatus **10b** can be ready for use. As should be apparent to one of skill in the art, in such an embodiment, little to no mixing may in fact be performed.

System Overview

[0101] With reference to **FIG. 3**, components of an embodiment of a gas mixture apparatus **10b** are shown which comprise a measurement control system **110b**, an activation system **210b**, a pressurized chamber **410b**, a mixing chamber **510b**, a first pressure regulation system **610b**, and a second pressure regulation system **710b**. The measurement control system **110b** can comprise a metering dial **120** and a plunger body **160** which can be inserted into the metering dial **120**. The activation system **210b** can comprise an actuation rod **220** and activation switch **260**. The activation system **210b** can be operatively coupled to the measurement control device **110b** to control the operation of the gas mixture apparatus **10b**. The activation system **210b** can be inserted into the plunger body **160**.

[0102] The pressurized chamber **410b** can be comprised of a housing **420**, a canister **436** containing a gas, a release mechanism **444** to release the gas contained within the canister **436**, a filter **448** to reduce the amount of non-gas or bacteria material flowing out of the housing **420**, and a plunger seal **460**. The mixing chamber **510b** can be comprised of a syringe body **520**. The first pressure regulation system **610b** can comprise a valve body and associated valve components. The second pressure regulation system **710b** can also comprise associated valve components.

Measurement Control System and Activation System

[0103] With reference to **FIG. 4**, an embodiment of a combined measurement control system **110b** and activation system **210b** is shown. The measurement control system **110b** can comprise a metering dial **120** and a plunger body **160**. The activation system can comprise an actuation rod **220** (shown in **FIG.** 7) and an activation switch **260**.

[0104] With reference to **FIGS. 5A and 5B**, an embodiment of a metering dial **120** of the gas mixture apparatus **10b** is shown which is configured to allow a user of the apparatus **10b** to selectively vary the concentration of an injectable volume. The metering dial **120** is comprised of two structural components – a metering body **122** and a metering cap **124** which can be coupled to the metering body **122** so as to allow the metering dial **120** to be releasably attached to another component of the apparatus **10b**. This can advantageously facilitate assembly of the apparatus and, in some embodiments which are reusable, can facilitate disassembly for resterilization. In some embodiments, the metering cap **124** can be releasably attached to the metering body **122** using fasteners such as screws, rivets, clips, and other fastening mechanisms known in the art. Attachment of the metering cap **124** to the metering body **122** can form an annular slot **126** and an annular lip **128** such that the metering dial **120** can be attached to another component of the apparatus **10b**. For example, the annular slot **126** and annular lip **128** can correspond to a flange **526** located on the syringe body **520**.

[0105] The metering body **122** can have a generally cylindrical member **130** with a flange **132** at the top end and a channel **134** substantially centered on the cylindrical member **130** and running throughout the entire meter body **122**. Since the meter body **122** is configured to control the concentration of the gas in the injectable volume, the meter body **122** can include metering indicators **136** along a surface viewable by a user of the apparatus **10b** in a fully assembled state. In the illustrated embodiment, the metering indicators **136** are located on a top surface of the flange **132** although any location which can be viewed by the user can be used. The metering indicators **136** can provide the user of the device with information regarding the operation of the apparatus **10b**. In the illustrated embodiment, the metering indicators **136** show a range of numbers from 18, 19, 20, 21, and 22 corresponding to concentrations of sulfur hexafluoride (SF_6) which would be produced in the injectable volume if the apparatus **10b** is activated. As should be apparent to one of skill in the art, the ranges used can depend upon the gas used and the application for the gas. Furthermore, in some embodiments, this range can be further divided to provide enhanced control over the desired concentration.

[0106] The metering body **122** can have slots **138**, slot 138, and variable stops **142** corresponding to the metering indicators **136**. In the illustrated embodiment, the metering body **122** has five separate slots **138** located along an inner surface of the channel **134** which correspond to the five integer values stated above. In other embodiments, the metering body **122** can have fewer or greater slots than the number of values provided by the metering indicators **136**.

[0107] Corresponding with each of these slots **138** are variable stops **142** which extend inwardly from the slots **138**. As illustrated above, these variable stops **142** can be in the form of surfaces extending from the top surface of the flange **132** having lower end surfaces **142a** disposed at set distances spaced from the bottom end of the tubular body **130**. In some embodiments, the variable stops **142** need not extend from the top surface but instead are minor protrusions with lower end surfaces **142a** disposed at set distances towards the bottom end of the cylindrical member **130**. These variable stops **142** are configured to interact with components contained in the plunger body **160** such as a latch **228**, or the plunger body **160** itself to control the expansion volume of the mixing chamber **510b** during a first and second phase of operation by limiting the rearward extension of the plunger body **160** during these phases (see **FIG. 2B**). As such, the variable stops **142** extend different distances depending upon the concentration to which the stop **142** corresponds. For example, a concentration of 21 percent extends downwardly a lesser distance than a concentration of 20 percent thereby allowing the mixing chamber **510b** to hold a larger amount of the first gas. The end of the third phase of operation (FIGURE 2C) prior to the addition of filtered ambient air during the fourth phase (FIGURE 2D). As such, when a concentration of 21 percent is chosen, the plunger body **160** can be allowed to extend rearwardly a greater distance thereby allowing a greater expansion of the mixing chamber **510b** during the first phase of operation. Therefore, as should be apparent, the variable stops **142** are used to control the first expansion volume of the first phase of operation.

[0108] On both sides of slots **138** are slot 138 which extend inward from an inner surface of the channel **134**. In some embodiments, the slot 138 extend inwardly from the inner surface of the channel **134** a greater distance than the variable stops **142**. The slot 138 can be configured to prevent the apparatus **10b** from switching to a different concentration value once the apparatus **10b** has been activated. This can be particularly important in applications where a specific concentration of gas can be necessary and any minor change in this value can have significantly adverse effects. In the illustrated embodiment, the slot 138 are configured to substantially reduce the likelihood that the plunger body **160** will rotate to a different variable stop **142** during at least the first two phases of operation. In certain embodiments, these rails can be removed if a constantly variable metering device is desired. In such an embodiment, the variable stop **142** could instead have a ramp shape rather than have multiple steps.

[0109] Metering body **122** can additionally include a ratchet pawl **144** along an inner surface of channel **134** which extends inwardly toward the center of the channel **134**. The ratchet pawl **144** can be hinged and configured such that the ratchet pawl **144** is movably deformable and provides resistance during deformation. This ratchet pawl **144** can correspond to features located on the plunger body **160** to facilitate proper orientation with respect to the selected concentration. Such a mechanism can additionally provide tactile feedback to a user of the device indicating that the proper alignment has been achieved. This tactile feedback can advantageously reduce the likelihood of activation in an improper orientation. Other types of feedback mechanisms and alignment mechanisms can also be used.

[0110] With reference to **FIG. 6**, an embodiment of a plunger body **160** is shown which comprises a generally tubular frame **162**, a handle **164** at one end of the plunger body **160**, a selector ring **166** located therebetween, and a channel **168** centered on the tubular frame **162** and running throughout the entire length of the plunger body **160**. The tubular frame **162** is configured to be slidably translatable and partially slidably rotatable within the channel **134** of the metering dial **120**.

[0111] The tubular frame **162** has a retention mechanism **170** in the form of a clip which is hingedly attached to the tubular frame **162**. The retention mechanism **170** can be configured to retain a component such as a housing **420** of the pressurized chamber **410b**. The retention mechanism **170** advantageously allows the component to be attached without the use of tools thereby facilitating the process of assembling the entire device. Additionally, the retention mechanism **170** can also be configured such that the component can be removed from the tubular frame **162** thereby allowing the apparatus **10b** to be reused or, in other embodiments which allow for reuse of the apparatus **10b**, facilitating the process of resterilization if such a process is used for the device. Other types of retention mechanisms can also be used in lieu of the clips shown in the illustrated embodiment and can include fasteners such as screws.

[0112] Tubular frame **162** can additionally comprise a guide **172** which extends outward from the outer surface of the tubular frame **162**. The guide **172** can run from the bottom end of the tubular frame **162** to a distance toward the top end of the tubular frame **162**. The guide 172 is configured to fit within the slots **138** and slot 138 located along the inner surface of the channel **134** of the metering body **122**. As such, the guide 172, when positioned between the slot **138**, can prevent the plunger body **160** from rotating. This advantageously can prevent the plunger body **160** from moving to a different variable stop **142** after commencing the first phase of operation and thereby reduce the risk of an improper concentration in the injectable volume. The guide 172 is preferably sized such that, when the plunger body **160** is fully inserted, the guide 172 is only slightly below the slot 138 such that the plunger body **160** can rotate freely to different concentration values during the initial phase of operation (see **FIG. 2A**). However, because the guide 172 is only slightly below the slot 138, once extended a short distance, the guide 172 can become locked within the selected rail **140**. This positioning advantageously allows the guide 172 to lock shortly after activation of the apparatus **10b**. Furthermore, the guide 172 preferably extends outward from the tubular frame **162** only a sufficient distance such that it can contact the slot 138 but not enough such that it contacts the variable stops **142** located between the slot 138. This can therefore allow the guide 172 to not be interfered by the variable stops **142** during operation.

[0113] Tubular frame **162** can additionally comprise a latch aperture **174** configured to allow a latch **228** (FIGURE 7) located on the activation rod **220** to protrude outward from the tubular frame **162**. The latch aperture **174** is preferably centered just above the top-most portion of the guide 172. As will be discussed in detail below, in a first or "closed" position, the latch **228** is retracted such that it does not extend beyond the guide 172 and thus would not contact a variable stop **142** (see **FIG. 8A**). When in a second position, the latch **228** extends outwardly from the tubular frame **162** beyond the guide 172 such that the latch **228** can contact the variable stops **140** such as the lower surfaces **142a** thereby preventing further extension of the plunger body **160** while the latch is in the second position (see **FIG. 8B**). As such, the volume to which the chamber **510b** can expand is limited by the latch **228** and the surface **142a**. In some embodiments, the latch aperture **174** can be placed such that, if the plunger body **160** is improperly oriented within the metering dial **120** during an initial phase of operation (shown in **FIG. 2A**), the latch **228** can be prevented from extending outward into the second or "open" position by a rail **140** of the metering dial **120**. This can advantageously prevent the apparatus **10b** from activating when improperly oriented.

[0114] Tubular frame **162** can additionally include ratchet slots **176** in the form of cut-outs located along its outer surface. The ratchet slots **176** are configured to receive the ratchet pawl **144** of the metering body **122** thereby providing a mechanism for ensuring that the plunger body **160** is properly oriented within the metering body **122** by providing resistance against rotation when the pawl **144** is received within one of the ratchet slots **176**. Furthermore, advantageously, at each point where the ratchet pawl **144** is received within the ratchet slots **176**, a user of the apparatus **10b** can also receive tactile feedback when the plunger body **160** is properly oriented within the metering body **120**.

[0115] With continued reference to FIGURE 6, ring **166** can include an annular protrusion extending from the outer surface of the tubular frame **162**. The selector ring **166** can additionally include a selector indicator **178** which can take the form of a minor protrusion located on the selector ring **166**. Selector indicator **178** can correspond to and be alignable with the metering indicators **136** located on the metering body **122** (**FIG. 5A**) to indicate the concentration level that will be obtained when the plunger body **160** is oriented in that position which corresponds to the alignment of the latch **228** with a corresponding surface **142a**. Such a system can advantageously provide a user of the device with easily viewed information regarding the selected concentration level. The selector indicator **178** can advantageously be colored to facilitate use of the apparatus **10b**.

[0116] The handle **164** can extend in a radial direction relative to the longitudinal axis of the tubular frame **162**. Handle **164** can be shaped such that a user of the apparatus **10b** can grasp the handle **164** and use the handle to either further extend the plunger body **160** rearward and out of the apparatus **10b** or further depress the plunger body **160** frontward into the apparatus **10b**. Handle **164** can additionally include an aperture **180** for receiving a coupling mechanism for the activation switch **260**. The activation switch **260** can thereby rotate about the coupling mechanism in order to operate the actuation rod **220** located within the plunger body **160**.

[0117] With reference to **FIG.** 7, an embodiment of an activation system **210b** is shown which comprises an actuation rod assembly **220** and an activation switch **260**. The actuation rod assembly **220** has a generally elongate body with an actuator pin **222** at a first end, an actuator stem **224** at a second end, and a latch movement portion **226** located in an intermediate portion. The actuator pin **222** is configured to be received within a housing **420** of the pressurized chamber **410b** and activate the release of gas contained therein when in a second or "open" position.

[0118] The actuator stem **224** is configured to abut and follow the contoured surface **262** (**FIG. 9**) of the activator switch **260**. The actuator stem **224** is also preferably shaped such that the cross-sectional profile matches the cross-sectional profile in a top portion of the channel **169** (as shown in **FIG. 8**) located near the handle **164** of the plunger body **160**. Preferably, the cross-sectional profile is not substantially circular such that the actuator rod **220** is substantially prevented from rotating within the channel **168** of the plunger body **160**. The latch movement portion **226** is shaped such that the latch **228** is translated when the latch **228** slidably translates along the latch movement portion **226** of the actuation rod **220**. As such, the latch **228** has an aperture **230** which has a cross-sectional shape similar to that of the cross-sectional shape of the latch movement portion **226**.

[0119] The activator switch **260** is configured to translate the actuator rod **220** through portions of the plunger body **160** and through the housing **420** of the pressurized chamber **410b** to activate the release of gas contained therein. As such, the activator switch **260** can include a cam with a contoured profile **262** along the surface configured to contact the actuator stem **224**. Activator switch **260** can also have an aperture **264** configured to receive a pin **266** such that the activator switch **260** can rotate about the pin **266**. In the illustrated embodiment, the activator switch **260** is shown in a first or “closed” position. In this first position, the distance between the pin **266** and the contoured surface **262** in contact with the actuator stem can be a reduced distance such that the actuator rod remains in a first or “closed” position.

[0120] When rotated about the pin **266** to a second or “open” position, the distance between the pin **266** and the contoured surface **262** in contact with the actuator stem **224** is increased distance thereby translating the actuator rod **220** to a second or “open” position further into the housing **420** of the pressurized chamber **410b**. As will be described below in greater detail with respect to **FIGS. 10** and **11**, movement into the second or “open” position can be configured to release gas in the pressurized chamber **410b**. The activator switch **260** can preferably be any type of switch that can remain in a first or second position without the user needing to maintain the switch in that position. In the illustrated embodiment, a rotating lever is used. Other switches can also be used such as a screw, latch, spring loaded pin, or any other switch known in the art.

[0121] With reference to **FIGS. 8A** and **8B**, an illustration of the operation of the activation system **210b** is shown which includes some components of the measurement control system **110b** and the activation system **210b**. As shown here, the latch **228** is contained within the latch aperture **174** such that the latch cannot translate toward a front end or rear end of the plunger body **160**. As such, when the actuator rod **220** translates in a frontward or rearward direction, the latch **228** must follow the profile of the latch movement portion **226** of the actuator rod **220**. As such, this provides the advantage of coupling movement of the latch **228** in the second position when the activator switch **260** and thus the actuator rod **220** are in a corresponding second position. Furthermore, because movement of the latch **228** is coupled with movement of the other activator switch **260** and actuator rod **220**, if the latch **228** is prevented from moving into the second position, the activator switch **260** and activator rod **220** are also prevented from moving into the second position. Note that, as described above, while in the second or "open" position, the latch **228** can protrude from the plunger body **160** thereby restricting extension of the plunger body **160** as shown in **FIG. 8B**.

Pressurized Chamber and First Pressure Regulation System

[0122] With reference to **FIG. 9**, an embodiment is shown including some components of both the activation system **210b**, the pressurized chamber **410b** of the mixing system **310b**, and the first pressure regulation system **610b** of the mixing system **310b**. As illustrated, the pressurized chamber **410b** can have a housing **420** with an annular slot **422** located near a first end of the housing **420**. The annular slot **422** can be configured to receive the retention mechanism **170** located on the plunger body **160**. Housing **420** can also have a plunger seal **460** located at a second end of the housing **420**. The plunger seal **460** is configured to provide an airtight seal for defining the mixing chamber **510b**.

[0123] With reference to **FIG. 10**, which is a sectional view of the pressurized chamber **410b** and the first pressure regulation system **610b**. The annular slot **422** is located at the first or rearward end and a conical or frusto-conical surface **424** located at the second or frontward end corresponding to the shape of the plunger seal **460**. Housing **420** can additionally be shaped such that it has an annular protrusion **426** and an annular slot **428** configured to receive a lip **462** of the plunger seal **460**. This configuration advantageously ensures that the plunger seal **460** remains connected to the housing **420** and forms a seal to prevent the leakage of any gas contained in the housing body **420**. Lip **462** of the plunger seal **460** can fit snugly within the annular slot **428** of the housing **420** to provide an enhanced seal.

[0124] An interior space **430** is substantially enclosed by the housing **420** and can be separated into a first separate portion **432** and a second separate portion **434**. Contained within the second separate portion **434** of the housing **420** can be a third separate portion in the form of a structural unit such as a canister **436**. This canister can contain the gases for mixing into the mixing chamber **510b**. Provision of the gases in a canister is advantageous as it facilitates manufacturing of the apparatus **10b** as it can allow the canisters to be manufactured separately from other components of the pressurized chamber **410b**. In some embodiments where the apparatus **10b** is reusable, canisters can be replaced.

[0125] The canister **436** has a first or rearward end in contact with the actuator pin **222** and a sealed second or frontward end **437**. At one end of the canister **436** is a seal **438** which substantially reduces leakage of any gas from the first separate portion **432** to the second separate portion **434**. This advantageously reduces the likelihood of gases from leaking out of the actuator aperture **440** and out of the apparatus **10b**.

[0126] The housing **420** can also include a biasing mechanism **442**, such as a spring, which exerts a force on the seal in a direction away from the second end of the housing **420**. In the illustrated embodiment, the biasing mechanism **442** is located in the first separate portion **432**. This reduces the likelihood of the canister **436** moving into the first separate portion **432** and potentially releasing the gas contained therein without having been activated by the user. Furthermore, biasing mechanism **442** can also provide a counter-force against activation such that a user cannot accidentally activate the device. The biasing mechanism **442** can be configured to exert a sufficient force such that, after the first and second phases of operation are complete and the activation switch **160** is returned to a first or "closed" position, the biasing mechanism **442** exerts sufficient force such that actuator rod **220** is returned to its first or "closed" position thereby causing the latch **228** to return to its first or "closed" position. Once latch **228** returns to its first or "closed" position, the extension of the plunger body **160** is no longer limited and the third phase of operation can commence. If the biasing mechanism **442** does not exert sufficient force on the actuator rod **220**, entering into the third phase of operation could be more difficult.

[0127] Housing **420** can also have a release mechanism **444**, such as a needle or a pilot tip as illustrated in this embodiment of the apparatus **10b**, which can be configured to puncture the sealed second end **437** of the canister **436** to release gas into the first separate portion **432** through the release mechanism **444** due to a channel **446** running axially through release mechanism **444**. Due to the high pressure in the first separate portion **432**, the first pressure regulation system **610b** can open allowing the gas to escape to the front of the plunger seal **460** and into the mixing chamber **510b**. In some embodiments, a filter **448** can be placed along the flow path such that there is a reduced likelihood of foreign materials entering into the mixing chamber **510b**. In some embodiments, the filter **448** can be configured to filter out bacteria.

[0128] Plunger seal **460** is configured to partially define the injectable volume of the mixing chamber **510b** by creating a seal for the mixing chamber **510b**. Plunger seal **460** can have a generally cylindrical body with annular protrusions **464** configured to contact an inner surface of the mixing chamber **510b** and a conical or frustoconical face **466** at a frontward end. The frustoconical face **466** can additionally comprise an aperture **468** centered about the cylindrical body configured to receive components of the first pressure regulation system **610b**. Furthermore, the body can also have an opening **470**, defined by the lip **462**, on the rearward end configured to receive the housing **420**.

[0129] With continued reference to **FIG. 10**, an embodiment of the first pressure regulation system **610b** is shown in a first or "closed" position. The first pressure regulation system **610b** can comprise a valve body **620** comprising multiple apertures **622** at one end, a valve stem **624** running through the valve body **620** with a seat **626** at a rear end configured to contact the biasing mechanism **628** and a head **630** at a front end configured to contact a sealing ring **632**.

[0130] During operation, the biasing mechanism **628** can exert a biasing force against the seat **626** in a rearward direction such that the head **630** is biased against the sealing ring **632** and valve body **620** thereby reducing or preventing the flow of gas through the valve body **620** and ultimately into the mixing chamber **510b**. Due to the orientation of the biasing mechanism **628**, the first pressure regulation system **610b** remains closed until pressure within the pressurized chamber **410b** exceeds a threshold value. This threshold value can be configured by changing the amount of force necessary to compress the biasing mechanism **628**.

[0131] With reference to **FIG. 11**, an embodiment of the first pressure regulation system **610b** is shown in an "open" position in which pressure within the pressurized chamber **410b** exceeds the pressure within the mixing chamber **510b**. In some preferred embodiments, the difference in pressure is substantial. Due to this pressure differential, sufficient force is placed upon the valve components causing the biasing mechanism **628** to be overcome thereby allowing gas to flow out of the valve body **620** and into the mixing chamber **510b**.

[0132] This configuration for the first pressure regulation system **610b** is advantageous due to the multiple phases of operation of the apparatus **10b**. During the first and at least part of the second phase of operation, the pressure differential causes the valve to remain open. However, once the pressure differential is insufficient to overcome the threshold value, the valve remains in a closed position preventing any additional gas from flowing into the mixing chamber and potentially disrupting the calculated pressures/concentrations.

[0133] With reference to **FIG. 12**, an embodiment of a mixing chamber **510b** is shown comprising a syringe body **520**, a second pressure regulation system **710b**, and various components of the above-mentioned systems. Syringe body **520** can be a cylindrical body, and can include an aperture **522** at the rear end, and a threaded nozzle **524** at the front end. Syringe body also has flange **526** configured to be engaged with the metering device **120**. The mixing chamber **510b** can be defined by the inner walls of the syringe body **520** and the plunger seal **460**. Furthermore, the syringe body can include indicators **528** along its outer surface corresponding to a chosen concentration. These indicators **528** can advantageously provide visual confirmation to the user of a selected concentration.

[0134] With reference to **FIG. 13**, an embodiment of the second pressure regulation system **710b** is shown comprising a valve body **720** which can include a ball **722**, a biasing mechanism **724**, a seat **726**, and a sealing mechanism **728**. The second pressure regulation system **710b** can also comprise a second biasing mechanism **730** and a pin actuator **732**.

[0135] The valve body **720** can be translatable within the interior space **734** near the nozzle **524** of the syringe body **520**. In some embodiments, due to the second biasing mechanism **730**, the valve body **720** is translated such that a flange **735** of the valve body **720** is pressed against the inner lip **736** of the nozzle **524**. Furthermore, biasing mechanism **724** can seal and prevent flow through the valve body **720** until a sufficient force is placed on the ball **722** to overcome the biasing force. This can occur when the pressure differential between the mixing chamber **510b** and the atmosphere is beyond a threshold value.

[0136] During operation, the second pressure regulation system **710b** is opened during first and second phases of operation due to the increased pressure contained in the mixing chamber **510b**. Once the pressure differential is insufficient to cause valve body **720** to open, the second phase of operation is complete and the user can move proceed to the third phase of operation.

[0137] With reference to **FIG. 14**, a filter **760** is attached to an outlet of the second pressure regulation system **710b**. The filter **760** has a first open end **762** with a flange **764** configured to engage with the threads on the interior of the threaded nozzle **524**, a second open end **766**, and a filter element **768** located therebetween. As such, gas can pass in both directions between the first open end **762** to the second open **766** and be filtered in the process.

[0138] In some embodiments, the inner surface of the first open end **762** tapers in the direction of the second open end **766** such that the shape corresponds to the shape of valve body **720**. As the attachment **760** is threaded into the threaded nozzle **524**, the attachment **760** engages the valve body **720** and translates the valve body **720**, against the biasing force of the second biasing mechanism **730** towards the rear end of the syringe body **520**. This causes the ball **722** to contact the pin actuator **732** thereby causing the ball to move away from the inner surface of the valve body **720** to thereby allow gas to flow through the valve body **720** in either direction. This configuration can allow the mixing chamber **510b** to be further expanded at ambient pressure and for filtering air drawn into the mixing chamber **510b**. In this position, the third phase of operation can therefore be performed. Once the third phase of operation is completed, the filter **760** can be removed. Due to the force of the second biasing mechanism **730**, the valve body **720** can be translated away from pin actuator **732** such that the valve body **720** remains closed until a user decides to use the therapeutic gas within the mixing chamber **510** by, for example, by attaching an injection needle for injection of the therapeutic gas into a patient.

<u>Embodiment of Measurement Control System and Activation System</u>

[0139] **FIGS. 15-31** illustrate additional embodiments of components of a measurement control system of the apparatus.

[0140] **FIGS. 15A** and **15B** illustrate an embodiment of a metering dial **820** which can be configured to allow a user of the device to select a concentration of fluid for an injectable volume. Similar to other embodiments, the metering dial **820** can include two components such as a metering body **822** and a metering cap **824** which can be removably attached to the metering body **822**.

[0141] With continued reference to **FIG. 15A** and **FIG. 15B**, the metering body **822** can have a generally cylindrical member **830** with a flange **832** located at top portion of the metering body **822**. The metering body **822** can include a channel **834** substantially centered on the cylindrical member **830** and running throughout the entire metering body **822**. In some embodiments, such as that illustrated in **FIG. 15A**, the generally cylindrical member **830** can include additional surface features, such as an increased diameter portion **831**, which can potentially be keyed to the device into which it is inserted.

[0142] As with other embodiments of metering dials or similar metering mechanisms, this embodiment can also include metering indicators **836** located along a surface of the metering body **822**. In this illustrated embodiment the metering indicators **836** are located on a top surface of the flange **832** although any other viewable location can be used such as, for example, along the perimeter portion of the flange **832**. In the illustrated embodiment, the metering indicators **836** show a range of numbers from 18, 19, 20, 21, and 22 corresponding to concentrations of sulfur hexafluoride (SF_6) which can be produced in an injectable volume of the assembly.

[0143] As with other embodiments of metering dials and other metering mechanisms, the metering body **822** can have slots **838**, rails **840**, and variable stops corresponding to the metering indicators **836**.

[0144] The operation of the variable stops of the illustrated embodiment of the metering dial **820** can be similar to that of other embodiments of metering dials and metering mechanisms. The variable stops can be configured to interact with components contained within the plunger body **860**, such as a latch **928** or similar protruding structure, to control expansion of a chamber for an injectable volume during at least some phases of operation. In some embodiments, the variable stops can perform this task by limiting the rearward extension of the plunger body **860** during different phases. As such, the variable stops extend different distances depending upon the concentration to which the stop corresponds.

[0145] With reference to **FIG. 16**, an embodiment of a plunger body **860** is shown which can include a generally tubular frame **862**, a handle **864** at one end of the plunger body **860**, a selector member **866** located there between, and a channel **868** centered on the tubular frame **862** which can run throughout the entire length of the plunger body **860** or which can run throughout at least a part of the length of the tubular frame **862**. The tubular frame **862** can be configured to slidably translate and slidably rotate within a channel of a metering dial.

[0146] With continued reference to **FIG. 16**, the tubular frame **862** can include a latch aperture **874** configured to allow a latch **928** located on the activation rod **920** and contained within the channel **868** to protrude outwardly from the tubular frame **862**. As shown in the illustrated embodiment, the latch aperture **874** can be centered just above the topmost portion of the guard **872**. In other embodiments, the latch aperture **874** can also be located at different positions along the tubular frame **862** and can contain more than one latch aperture if multiple latches are used.

[0147] As described in greater detail below, in a first, "initial", or "pre-activation" position, the latch **928** can be sized so as to not extend beyond the guard **872** and thus not contact a variable stop or similar structure. When in a second or "open" position, the latch **928** can extend outwardly from the tubular frame **862** beyond the guard **872** such that the latch **928** can contact the variable stops or similar structures thereby preventing or significantly reducing the likelihood of further extension of the plunger body **860** while the latch is in the second position.

[0148] With continued reference to **FIG. 16, 25a and 25b**, an activator switch **960** can be configured to translate the actuator rod **920** through the plunger body **860** towards the first housing member **1020** to activate a mechanism for releasing the gas contained therein. As such, the activator switch **960**, like the activator switch of other embodiments, can be a cam with a contoured profile **962** located along the surface configured to contact the actuator body **922**. Activator switch **960** can additionally include an aperture **964** configured to receive a pin such that the activator switch **960** can rotate about the pin. It should be appreciated by a person of skill in the art that the activation switch **960** can preferably be any type of switch that can remain in a first, second, or more positions without the user needing to maintain the switch in that position. In the illustrated embodiment, a rotating lever is used. Other switches can also be used such as a screw, latch, spring loaded pin, or any other switch known in the art.

[0149] With reference to **FIG. 18**, the activator switch **960** is shown in a first, “initial”, or “pre-activation” position. For example, this can be a position prior to a first phase of operation. In this first position, the distance between the pin **966** and the contoured surface **962** in contact with the actuator body **922** can be a first distance such that the actuator body **922** is located at a first distance from the end of the tubular frame **862** of the plunger body **860**.

[0150] As shown in **FIG. 19**, in some embodiments, the activator switch **960** can be rotated towards a more vertically oriented position, a second or “open” position, in which the distance from the pin **966** to the contoured surface **962** in contact with the actuator body **922** can be a second distance such that the actuator body **922** is located at a second distance from the end of the tubular frame **862** of the plunger body **860**. This can correspond to the position of the activation switch **960** during a first and second phase of operation. In some embodiments, the second distance can be greater than the first distance. As will be described in more detail with respect to **FIGS. 25-27**, this can cause the actuator body **922** to translate towards the first housing member **1020** of the pressurized chamber. This translation can activate the release of fluid or gas contained in the pressurized chamber.

[0151] As shown in **FIG. 20**, in some embodiments, the activation switch **960** can also be rotated towards a more horizontally-oriented position, a third or “closed” position, in which the distance from the pin **966** to the contoured surface **962** in contact with the actuator body **922** can be a third distance such that the actuator body **922** is located at a third distance from the end of the tubular frame **862** of the plunger body **860**. This can correspond to a third phase of operation and/or a final phase prior to injection of the injectable volume into a patient. This third distance can be less than or equal to the first and/or second distances. In some embodiments, rotation towards the third position can cause the actuator body **922** to translate away from the first housing member **1020** of the pressurized chamber such that no fluid or gas is released from the pressurized chamber.

[0152] Optionally, an interlock mechanism can be included to control and limit the movement of the activation switch **960**.

[0153] With reference to **FIGS. 21-23**, operation of an embodiment of the activation system is shown. As shown in the illustrated embodiment, and similar to other embodiments, the latch **928** can be contained within the latch aperture **874** such that the latch cannot translate toward a front end or rear end of the plunger body **860**. In such an embodiment, when the actuator rod **920** translates in a frontward or rearward direction, the latch **928** is configured to follow the profile of the latch movement portion **926** of the actuator rod **920**.

[0154] **FIG. 21** shows the embodiment in a first, "initial", or "pre-activation" position. As shown here, the latch **928** can be positioned such that it outwardly protrudes from the plunger body **860** sufficiently such that, if extended rearwardly, the latch **928** would contact a variable stop located on the metering body **922** and prevent any further extension. In other embodiments, when in the first position, the latch **928** can be configured so as to not outwardly protrude from the body **860** to prevent such extension. When moved to the second or "open" position, as shown in **FIG. 22**, the latch **928** can sufficiently outwardly protrude from the plunger body **860** such that the latch **928** can contact the variable stop or similar structure located on the metering dial **820** thereby preventing any further rearward extension. When rotated to the third or "closed" position, as illustrated in **FIG. 23**, the latch **928** can be sufficiently retracted within the latch aperture **874** such that the latch **928** no longer contacts the variable stop or similar structure located on the metering dial **820** thereby allowing the plunger body **860** to be further extended rearwardly.

[0155] With continued reference to **FIGS. 21–23**, a ratcheting member **886** such as a pawl can be attached to the plunger body **860**. The ratcheting member **886** can be hinged and configured such that the ratcheting member **886** is movably deformable and provides resistance during deformation. The ratcheting member **886** can correspond to features located on the plunger body metering dial **820**, such as notches **842**, **FIG. 15b** to facilitate proper orientation with respect to the selected concentration. In order to allow inward deformation of the ratcheting member **886**, the actuator body **924** can include a recess or indentation **980**. This recess **980** can be configured such that the ratcheting member **886** is allowed to inwardly deform only in the first and third positions whereas the ratcheting member **886** is restricted from deforming inwardly while in the second position. This can provide a means of reducing the likelihood that the plunger body **860** can be rotated during operation of the device.

Embodiment of Pressurized Chamber

[0156] With reference to **FIGS. 24–25B**, an embodiment of a pressurized chamber is shown along with components of an activation system. As illustrated, the pressurized chamber can have a two-part housing with a first housing member **1020** and a second housing member **1022** which are translatable with respect to each other. As shown in the illustrated embodiment, the two members **1020, 1022** can have a generally cylindrical shape such that some or all portions of the two members **1020, 1022** can be received within a channel **868** of the plunger body **860**. In some embodiments, the two members **1020**, **1022** can be detached from one another to allow free translation of the two members **1020, 1022**. In other embodiments, the two-part housing can be attached while still allowing translation of the members **1020, 1022** with respect to each other. Such attachment can be used to increase the stability of the two members **1020, 1022.**

[0157] As shown in the illustrated embodiment and similar to other embodiments of the pressurized chamber, an annular slot **1024** can be located on the second housing member **1022**. In the illustrated embodiment, the annular slot **1024** is located at an end opposite the first housing member **1020** however other possible locations can be chosen. The annular slot **1024** can be sized and configured to receive the retention wings **870 FIG. 25A** of the plunger body **860** allowing the second housing member **1022** to be fastened to the plunger body **860** using a snap-fit connection. To facilitate insertion of the second housing member **1022** into the channel **868** of the plunger body **860**, the inserted end portion can be slightly tapered. In some embodiments, the second housing member **1022** can be removably attached to the plunger body **860** thereby allowing replacement of certain parts contained therein. For example, in some embodiments, a storage member **1030** or canister can be contained within the two-part housing. The two-part housing can also have a plunger end **1060** with a plunger seal **1061** such as a rubber O-ring configured to sealingly contact the syringe body **1120** and form a seal for defining a chamber to contain an injectable volume, such chamber potentially serving as a mixing chamber. Other types of sealing members can be used around the plunger end **1060** to form such a seal.

[0158] **FIGS. 25A** and **25B** are cross-sectional views of the embodiment shown in **FIG. 24** when the apparatus is in a first, "initial", or "pre-activation" position. As illustrated more clearly in **FIG. 25B**, in the first position, the rod biasing member **924**, such as a helical spring, can be in contact with both the actuator body **922** and the first housing member **1020**; however, the actuator body **922** may not be in direct contact with the first housing member **1020**. In the first position, the rod biasing member **924** can exert a force in a frontward direction upon the first housing member **1020** and a force in a rearward direction upon the actuator body **922** such that the actuator body **922** remains in contact with the activation switch **960**. In this position, the frontward force upon the first housing member **1020** can cause the first housing member **1020** to apply a force upon a storage member **1030** contained therein as the first housing member **1020** attempts to translate towards the second housing member **1022**. Preferably, in the first position, the force applied by the first housing member **1020** upon the storage member **1030** will be insufficient to translate the storage member **1030** towards the second housing member **1022** due to mechanisms contained in the storage member **1030** (as will be discussed in further detail in **FIGS. 28-29**). As such, while in the first position, any gas or fluid contained within the storage member **1030** will remain contained within the storage member **1030**.

[0159] **FIGS. 26A** and **26B** are cross-sectional views of the embodiment shown in **FIG. 24** when the apparatus is in a second or "open" position. As illustrated more clearly in **FIG. 26B**, while in the second position, both the actuator body **922** and the rod biasing member **924** can be directly in contact with the first housing member **1020**. Due to this direct contact, a more significant force can be applied to the first housing member **1020** such that the first housing member **1020** can translate in a frontward direction thereby causing the storage member **1030** to translate in a frontward direction. This frontward translation of the storage member **1030** can then activate the release of gas from the storage member **1030**. In other embodiments, the actuator body **922** need not directly contact the first housing member **1020** since, in such embodiments, the increase in force applied by the rod biasing member **924** due to compression of the rod biasing member **924** can be sufficient to cause the first housing member **1020** to translate in a frontward direction to cause the activation of the release of gas from the storage member **1030**.

[0160] **FIGS. 27A** and **27B** are cross-sectional views of the second embodiment shown in **FIG. 24** when the apparatus is in a third or "closed" position. As illustrated in **FIG. 27B**, while in the third position, the actuator body **922** is in contact with the first housing member **1020**. Furthermore, in some embodiments, due to the reduced distance between the pin **966** and the contoured surface **962**, the force exerted by the rod biasing member **924** on the actuator body **922** in a rearward direction can cause the actuator body **922** to translate towards the contoured surface **962** such that the actuator body **922** remains in contact with the activation switch **960**. This expansion of the rod biasing member **924** results in a reduction of force exerted by the rod biasing member **924** upon the first housing member **1020**. As a result of this reduced force, and as a result of other mechanisms located within the storage member **1030** or canister, the storage member **1030** can be restored to a closed state thereby preventing any additional gas from being released into the chamber to contain the injectable volume, which can also serve as a mixing chamber.

[0161] **FIG. 28** is a sectional view of an embodiment of a pressurized chamber. The first and second housing members **1020, 1022** have contained therein a storage member **1030** or canister, such as a microcylinder, which contains a fluid such as gas. In some embodiments, the second member **1022** has at an end opposite the first member **1020** a conical or frusto-conical surface forming the plunger end **1060**. In some embodiments, the second member **1022** and the plunger end **1060** form an integral unit. The plunger end **1060** can have an annular slot configured to receive a plunger seal **1061** such as a rubber O-ring to form a chamber for the injectable volume, which can also serve as a mixing chamber.

[0162] The first housing member **1020** can include a recessed portion **1026** or indented portion configured to contact and receive a first end of the storage member **1030**. The shape of the recessed portion **1026** should preferably correspond to the shape of the first end of the storage member **1030**. In other embodiments, the first housing member **1020** may not include a recessed portion **1026**. The second housing member **1022** can include an interior space **1028** sized and configured to receive a second end of the storage member **1030**. In some embodiments, the interior space **1028** can include a housing seal **1029** in contact with the second end of the storage member **1030**. In some embodiments, the housing seal **1029** creates a sufficient seal such that little to no gas leaks rearward through the interior space **1028.** In some embodiments, the interior space **1028** can also provide a generally snug fit around the storage member **1030** to ensure that the storage member **1030** generally only translates in a frontward and rearward direction. This advantageously reduces the likelihood of the seal between the second end of the storage member **1030** and the housing seal **1029** from being broken.

[0163] With continued reference to **FIG. 28**, the storage member **1030**, such as the illustrated canister or microcylinder, can include a body portion **1040** and a head **1042**. As shown in the illustrated embodiment, the body portion **1040** can have a generally cylindrical shape with a semi-spherical first end. The body portion **1040**, in conjunction with the head **1042,** can form an internal volume **1041** to contain a fluid such as a gas in either gaseous or liquid form, or a combination of both, at a first pressure and concentration which can be different than atmospheric gas. For example, such gases can include, but are not limited to, expansile gases, ophthalmic gases such as SF_6, C_3F_8, C_2F_6, or similar gases, propellant gases such as CO_2, refrigerant gases such as N_20, and other various types of gases. The size of the interior space **1041** can be chosen such that a unit or single-use dose can be contained within the volume. Other shapes can be chosen for the body portion **1040**.

[0164] The head **1042** can have a generally tubular shape with an outer diameter matching the inner diameter of the body portion **1040**. The head **1042** can have an internal channel and a flange **1044**. As shown in the illustrated embodiment, the first end of the head **1042** can have an opening with a diameter that matches the diameter of the channel and the second end of the head can have an opening **1046** with a diameter that is less than the diameter of the channel. In some embodiments, the body portion **1040** and the head **1042** can be separate components which are later attached. This potentially advantageously allows for the assembly of internal components of the head **1042** prior to assembly. Once all components are assembled within the head **1042**, the head **1042** can be received within the body portion **1040** and fastened using devices and mechanisms such as adhesives, welding, or the like. In some embodiments, such as that illustrated in **FIG. 28**, the flange **1044** can abut the body portion **1040** and adhered or welded along this surface. In other embodiments, the body portion **1040** and head **1042** can form an integral unit.

[0165] The head **1042** can contain a storage member pressure regulation system, which can form part of a first pressure regulation system, and which can take the form of an internal valve mechanism within the channel. The internal valve mechanism can include a retaining ring **1048**, a valve seat **1050**, an internal biasing member or mechanism **1052** such as a spring, a valve piston **1054**, and a piston seal **1056**. The retaining ring **1048** can be placed within an annular slot **1058** located on the head **1042**. The retaining ring **1048** can be made of an elastic material such that the retaining ring can be deformed prior to fitting into slot **1058**. The valve seat **1050** can be placed between the retaining ring **1048** and the second end of the head **1042**. In some embodiments, the valve seat **1050** can be a ring having an outer diameter approximately equal to the internal diameter of the head **1042**.

[0166] The valve piston **1054** can have a generally cylindrical shape and be placed between the seat **1050** and the second end of the head **1042.** The outer diameter of the valve piston **1054** can be chosen to be approximately equal to the internal diameter of the head **1042.** As shown in the illustrated embodiment, the valve piston can include an annular slot configured to receive the piston seal **1056,** fluid pathways **1055** or channels located along the perimeter of the piston, and a protrusion **1057**. The fluid pathways **1055** can be configured to allow fluid to pass between the valve piston **1054** and the head **1042.** In the illustrated embodiment, a total of four fluid pathways are included; however, fewer or greater numbers of pathways can be used. In some embodiments, the protrusion **1057** can be a cylindrical member having a smaller diameter that corresponds to the diameter of the opening **1046**. The protrusion **1057** can be configured to fit within the opening **1046**. In some embodiments, the protrusion **1057** can be flush with the end surface of the head **1042**. In other embodiments, the protrusion **1057** can be recessed within the opening or extend beyond the end surface. A biasing mechanism **1052** can be placed between the seat **1050** and the piston **1054** to apply a force on the valve piston **1054** in a frontward direction such that a seal is formed between the piston seal **1056** and the head **1042**. In other embodiments, other types of valve designs can be used such as a ball valve, poppet valve, or any other valve mentioned herein or known in the art.

[0167] In some embodiments, the internal biasing mechanism **1052** can be configured such that, when an activation switch is in a first or "pre-activation" position, the internal valve mechanism will not open as a result of any forces applied to it such as the force applied to the storage member **1030** via the first housing member **1020** as a result of the rod biasing mechanism **924**. In some embodiments, the internal biasing mechanism **1052** can be configured such that, when an activation switch is in a second or "open" position, the internal valve mechanism will open as a result of forces applied to it. In some embodiments, the internal biasing mechanism **1052** can be configured such that, when an activation switch is in a third or "closed" position, the internal valve mechanism will not open as a result of any forces applied to it such as the force applied to the storage member **1030** via the first housing member **1020** as a result of the rod biasing mechanism **924**.

[0168] In some embodiments, the storage member **1030** can include other structures such as filters integrated in portions of the storage member **1030** such as the head **1042**. The storage member **1030** can include membranes or other sealing structures placed over the head **1042** and over the opening **1046** to provide an additional seal which can advantageously extend the shelf life of the storage member **1030**. The membrane or sealing structure can be punctured by a protruding member, such as a pin **1059**, or any other similar release mechanism. In some embodiments, the release mechanism can be a porous material, for example, known as "frit". The storage member **1030** can also include additional valve members which can serve as a relief valve to reduce the likelihood of rupturing if the pressure contained within the storage member **1030** exceeds certain operational limits. The storage member **1030** can also be configured to rupture in a controlled manner to reduce the likelihood of catastrophic failure.

[0169] In some embodiments, the storage member **1030**, and the internal components such as the internal valve, is manufactured from materials that are both small and light-weight. The material can also be flexible. In some embodiments, the materials and dimensions of the storage member **1030** can be chosen such that the storage member **1030** resists diffusion of gas through the walls of the storage member **1030**. This can provide the advantage of increasing storage life of the storage member **1030** when a gas is contained therein. In some embodiments, the length of the storage member **1030** from a rearward most end of the body **1040** and a frontward most end of the head **1042** can range from approximately 15mm to approximately 65mm, from approximately 20mm to approximately 45mm, and from approximately 25mm to approximately 35mm, such as 29mm. In some embodiments, the outer diameter of the body **1040** can range from approximately 4mm to approximately 25mm, from approximately 6mm to approximately 20mm, and from approximately 8mm to approximately 15mm, such as 9.5mm. In some embodiments, the outer diameter of the head **1042**, not including a flange portion can range from approximately 2mm to approximately 20mm, from approximately 4mm to approximately 15mm, and from approximately 6mm to approximately 10mm, such as 7.5mm.

[0170] With continued reference to **FIG. 28**, the pin **1059** which can serve as a release mechanism, can be located within a channel **1062**. The release mechanism **1059** can be substantially centered over the protrusion **1057** of the valve piston **1054** and have a diameter which matches the diameter of the opening **1046** and can define through passages (not shown). As illustrated in **FIG. 29,** during operation, when the storage member **1030** is translated in a frontward direction towards the release mechanism **1059**, the release mechanism **1059** remains stationary such that the release mechanism **1059** can cause the valve piston **1056** to unseat from the head **1042** thereby allowing the flow of fluid from the storage member **1030**, past the pathways **1055** and the release mechanism **1059**, and through the channel **1062** where it ultimately can flow into a chamber for the injectable volume, such as a mixing chamber. In some embodiments, the release mechanism **1059** can include internal or external channels or can be made out of a porous material such that the release mechanism **1059** itself serves as a preliminary filtering mechanism for fluid flowing through channel **1062**. In some embodiments, filters can be added between the release mechanism **1059** and the end of the channel **1062** or at any other location to filter out materials.

[0171] With reference to **FIGS. 30–32**, a further embodiment of a surgical kit **2c** is illustrated as including a container **4c** with a gas mixing device **10c.** The gas mixing device **10c** can include the same or similar components described above with reference to gas mixing devices **10, 10a, and 10b,** except as noted below.

[0172] The mixing device **10c** can include a chamber for an injectable volume, such as a mixing chamber, which can include a syringe body **1120**, a syringe pressure regulation system, which can form part of a second pressure regulation system, and various components of the above-mentioned systems. Syringe body **1120** can have a cylindrical body and a nose **1122** at a front end.

[0173] In some embodiments, a threaded nozzle **1124**, which can include multiple components of a pressure regulation system, can be removably attached to the nose **1122** of the syringe body **1120**. This can advantageously facilitate assembly of the apparatus by allowing the pressure regulation system to be assembled within the smaller nozzle **1124** prior to being incorporated with the syringe body **1120**. The nozzle **1124** can be attached to the nose **1122** using multiple fastening devices and means such as screws, adhesives, snap fits, welding, or the like. The chamber for an injectable volume can be defined by the inner walls of the syringe body **1120** and the plunger seal **1061**. Furthermore, as with other embodiments of the syringe, the syringe body **1120** can also include indicators along its outer surface corresponding to a chosen concentration and a flange at a rear end of the body **1120** configured to be attached to a metering dial. Optionally, the surgical kit **2c** can include a flow restrictor **1300** connected to the **761c** of the filter device **760c**.

[0174] With continued reference to **FIGS. 30–32**, an embodiment of the syringe pressure regulation system is shown comprising a valve body **1220**, a valve end **1222**, a valve piston **1224**, a piston seal **1226**, a piston biasing member or mechanism **1228**, a valve biasing member or mechanism **1230**, and a valve end seal **1232**. Similar to other embodiments of the pressure regulation system, the valve body **1220** and valve end **1222** can slidingly translate within the threaded nozzle **1124**.

[0175] In a first position, such as that illustrated in **FIG. 32**, the valve end **1222** can rest against a shoulder **1234** of the threaded nozzle **1124** due to force exerted by the valve biasing member **1230** on the valve body **1220** and valve end **1222** in a frontward direction. In the first position, the valve piston **1224** and valve seal **1226** can form a seal and limit, or prevent, the passage of fluid through the valve body **1220**. However, when the pressure in the chamber for an injectable volume increases beyond a threshold value to overcome the biasing force exerted by the piston biasing member **1228**, the valve piston **1224**

can be translated in a frontward direction against the force applied by the piston biasing member **1228** and fluid can pass through the valve body **1220** and valve end **1222** and into the atmosphere. Once the pressure reduces back to a threshold value, the equilibrium of forces allows the valve piston **1224** and valve seal **1226** to once again sealingly contact the valve body **1220**.

[0176] In a second position, the valve body **1220** and valve end **1222** can be translated in a rearward direction against the valve biasing member **1230**. For example, this can be accomplished by applying a force in the rearward direction upon the valve end **1222**. In the second position, contact between the valve piston **1224** and an internal protruding member **1126** of the syringe body **1120** can cause the valve piston **1224** to move in a rearward direction relative to the valve body **1220** and valve end **1222** such that the valve piston **1224** no longer sealingly contacts the valve body **1220**. This could, in some embodiments, allow the passage of fluid to and from the chamber for an injectable volume. In some embodiments, the pressure regulation system can be forced into a second position when an inline filter **760c** is threaded onto the threaded nozzle **1124**. Other types of attachments, such as stopcocks, valves, tubing, or the like, can also be attached to the threaded nozzle **1124**.

[0177] With reference to **FIGS. 32-35**, the flow restrictor **1300c** can be in the form of a cap configured to engage the outlet and **761c** of the filter device **760c**. For example, the flow restrictor **1300c** can include a threaded end **1302** configured to engage threads on an inner surface of the outlet **761c**. Additionally, the flow restrictor **1300c** can include optional finger grips **1304** configured to facilitate gripping with fingers so as to ease removal of the flow restrictor **1300c** when wearing surgical gloves.

[0178] The flow restrictor can also include a flow restricting port **1306**. In some embodiments, a minimum diameter of the port **1306** can be smaller than the smallest diameter of an outlet opening **1308** of the outlet **761c** (**FIG. 30**). Thus, a minimum cross• sectional area of the outlet port **1306** can be smaller than a minimum cross-sectional area of the outlet opening **1308**. As such, as described above with reference to **FIG. lA** and the flow restrictor **1300c**. With continued reference to **FIG. 30**, an operating, the mixing device **10c** can be packaged in container **4c** forming the surgical kit **2c**. As with the other mixing devices **10, 10a, 10 and 10b,** the mixing device **10c** can be packaged in the container **4c** with the filter device **760c** preattached in a sterilized condition and optionally can also include the flow restrictor **1300.**

[0179] In use, a practitioner or other user can remove the mixing device **10c** from the package **4c** having the filter **760c** preattached. The user can then provide a therapeutic gas and/or component thereof into the mixing chamber of the device **10c** which would move the plunger **1061** in a direction away from the filter device **760c** (as viewed in **FIG. 30**) until the plunger **1061** has been moved to a position corresponding to the desired volume of therapeutic gas which would provide a desired mixed gas concentration. After the plunger **1061** has been moved to the desired position, excess therapeutic gas can be discharged through the filter device **760c.** As such, because the filter device **760c** is preattached to the mixing device **10c**, at no time will any unfiltered atmospheric air reside in any open volumes between the filter member **763** of the filter device **760c** and the plunger 1061. Thus, during discharge of the therapeutic gas through this filter device **760c**, no contaminants, foreign matter, or undesirable gases will be captured on the upstream side of the filter member **763**.

[0180] After the desired volume of therapeutic gas or a component thereof is contained in the mixing chamber, a user can manually further move the plunger **1061** in a direction away from the filter device **760c** and thereby draw atmospheric air in through the outlet **761c** of the filter device **760c,** through the filter member **763,** and into the mixing chamber. As such, the filter member **763** can filter out any particulates, foreign matter, or undesirable gases and prevent such from entering the mixing chamber. After the mixing chamber is expanded to the desired volume and thereby forming a desired concentration of a therapeutic mixture, the filter device **760c** can be removed and a further delivery device can be connected in its place. For example, a hypodermic needle can be attached in place of the filter device **760c** for delivery of a therapeutic gas.

[0181] As noted above, the mixing device **10c** can optionally be packaged in the container **4c** with the flow restrictor **1300c** preattached. Having the flow restrictor **1300c** preattached provides an optional additional benefit of providing additional back pressure during discharge of excess gas which can thereby help ensure the plunger **1061** is pushed fully against any limiting device for defining a predetermined volume of therapeutic gas or a component of therapeutic gas within the syringe body **1120.**

[0182] In some embodiments, the pressurized chamber can be external to the apparatus. In such embodiments, the pressurized chamber can be a tank or other canister containing the gas in liquid or gaseous (or a combination) form. In some embodiments, the tank can be attached to the threaded nozzle via tubing or other mechanisms. The connection between the threaded nozzle and tubing can cause the pressure regulation system located on the apparatus to be forced open thereby allowing the gas from the tank to be input into the chamber. In some embodiments, introduction of the gas from the tank can be performed during a first phase of operation. As such, the gas from the tank can fill the apparatus with gas until the apparatus reaches a configured first volume. In some embodiments, the tank can have a regulator such that the apparatus is filled with gas at a regulated pressure. The connection can then be removed from the threaded nozzle, allowing the valve to function normally. In some embodiments, since the gas can be at a higher pressure than atmospheric air and can exceed a threshold value for the pressure regulation system, the gas can be expelled or bled from the system until a configured pressure is achieved in the apparatus. Once the configured pressure is achieved in the apparatus, the remaining phases of operation can then be completed in a similar manner to those in the above-described embodiments.

[0183] The foregoing description is that of an apparatus and method for mixing and/or injecting gases having certain features, aspects, and advantages in accordance with the present inventions. Various changes and modifications also can be made to the above-described gas mixture apparatus and method without departing from the spirit and scope of the inventions. Thus, for example, those skilled in the art will recognize that the invention can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objects or advantages as can be taught or suggested herein. In addition, while a number of variations of the invention have been shown and described in detail, other modifications and methods of use, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments can be made and still fall within the scope of the invention. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed gas mixture apparatus.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A hand-held gaseous injector for delivering therapeutic gas to a patient, comprising:

a syringe body with an outlet;

a plunger slidably disposed in the syringe body and with the syringe body, defining a first chamber within the syringe body;

a second chamber disposed within at least one of the syringe body and the plunger, the second chamber comprising:

an internal volume containing at least a first fluid at a pressure greater than that of surrounding atmospheric air;

an opening at a first end of the second chamber; and

a valve mechanism located adjacent the first end of the second chamber, the valve mechanism configured to seal the opening;

a channel and an aperture between the second chamber and the first chamber;

an activation system operatively coupled to the second chamber, the activation system being configured to cause the release of the first fluid from the second chamber into the first chamber through the channel;

an adjustable volume limiter configured to limit movement of the plunger to a plurality of user-selectable positions corresponding to a plurality of volumes of the first chamber;

a filter having:

a first end connected to the outlet of the syringe body,

a second end with a filter orifice, and

a filter element disposed between the first end of the filter and the second end of the filter; and

a flow restrictor connected to the filter orifice and having a restrictor orifice that is smaller than the filter orifice and configured to restrict a flow of the first fluid from the first chamber through the filter orifice such that the first fluid from the second chamber travels from the second chamber, through the valve mechanism located adjacent the first end of the second chamber, through the first chamber, through the first end of the filter, through the filter, through the second end of the filter with the filter orifice and then through the restrictor orifice of the flow restrictor to an exterior of the hand-held gaseous injector assembly;

wherein the flow restrictor is configured to generate back pressure against the flow of the first fluid from the first chamber to expand the first chamber to a desired volume corresponding to a user-selected position of the adjustable volume limiter.

2. The hand-held gaseous injector assembly of Claim 1, wherein the filter is removably connected to the syringe body.

3. The hand-held gaseous injector assembly of Claim 1 or Claim 2, wherein the flow restrictor comprises a lumen having a first end configured to receive the first fluid from the filter orifice and a second end comprising the restrictor orifice, wherein the lumen tapers between the first end of the lumen and the second end of the lumen.

4. A hand-held gaseous injector assembly, comprising:

a syringe body with an outlet;

a plunger slidably disposed in the syringe body and with the syringe body, defining a chamber within the syringe body;

an adjustable volume limiter configured to limit movement of the plunger to a plurality of user-selectable positions corresponding to a plurality of volumes of the chamber;

a filter having a first end connected to the outlet of the syringe body and a second end with a filter orifice; and

a flow restrictor connected to the filter orifice and having a restrictor orifice that is smaller than the filter orifice and configured to restrict a flow of fluid from the chamber through the filter orifice such that the fluid leaving the syringe, travels through the first end of the filter, through the filter, through the second end of the filter with the filter orifice and then through the restrictor orifice of the flow restrictor to an exterior of the hand-held gaseous injector assembly;

wherein the flow restrictor is configured to generate back pressure against the flow of the fluid from the chamber to expand the chamber to a desired volume corresponding to a user-selected position of the adjustable volume limiter.

5. The hand-held gaseous injector assembly of Claim 4, further comprising a filling mechanism configured to direct the fluid into the chamber.

6. The hand-held gaseous injector assembly of Claim 4 or Claim 5, wherein the filter is removably connected to the syringe body.

7. The hand-held gaseous injector assembly of any one of claims 4 to 6, wherein the flow restrictor comprises a lumen having a first end configured to receive fluid from the filter orifice and a second end comprising the restrictor orifice, wherein the lumen tapers from a larger size at the first end of the lumen to a smaller size at the second end of the lumen.

8. The hand-held gaseous injector assembly of any one of claims 4 to 7, further comprising a valve mechanism having a first position and a second position, the valve mechanism configured to prohibit of the flow of the fluid from the first chamber when in the first position and to permit the flow of the fluid from the chamber when in the second position.

9. A hand-held gaseous injector assembly, comprising:

a syringe body comprising an endwall and an outlet connected to the endwall;

a plunger slidably disposed in the syringe body and with the syringe body, defining a first chamber within the syringe body and between the plunger and the endwall, the plunger being disposed at the endwall of the syringe body such that the first chamber comprises a volume definable by movement of the plunger;

a second chamber, the second chamber comprising an internal volume containing at least a first fluid at a pressure greater than that of surrounding atmospheric air, wherein the second chamber is fluidically coupled to the first chamber for release of the first fluid from the second chamber to the first chamber;

a filter having a first end connected to the outlet of the syringe and a second end with a filter orifice; and

a flow restrictor connected to the filter orifice and configured to restrict a flow of the first fluid from the first chamber through the filter orifice, wherein the flow restrictor comprises a restrictor orifice that is smaller than the filter orifice such that the first fluid leaving the syringe body travels through the first end of the filter, through the filter, through the second end of the filter with the filter orifice and then through the restrictor orifice of the flow restrictor to an exterior of the hand-held gaseous injector assembly;

wherein the flow restrictor is configured to generate back pressure against the flow of the first fluid from the first chamber to expand the first chamber to a desired volume corresponding to a user-selected position of an adjustable volume limiter of the hand-held gaseous injector assembly.

10. The hand-held gaseous injector assembly of Claim 9, wherein the adjustable volume limiter is configured to limit movement of plunger to a plurality of user-selectable positions corresponding to a plurality of volumes of the first chamber.

11. The hand-held gaseous injector assembly of Claim 9 or Claim 10, further comprising a filling mechanism configured to direct the first fluid into the first chamber.

12. The hand-held gaseous injector assembly of any one of claims 9 to 11, wherein the filter is removably connected to the syringe body.

13. The hand-held gaseous injector assembly of any one of claims 9 to 12, wherein the flow restrictor comprises a lumen having a first end configured to the first receive fluid from the filter orifice and a second end comprising the restrictor orifice, wherein the lumen tapers between the first end of the lumen and the second end of the lumen.

14. The hand-held gaseous injector assembly of any one of claims 9 to 13, further comprising a valve mechanism configured to move between a first position and a second position, the valve mechanism configured to prohibit the flow of the first fluid from the first chamber when in the first position and to permit the flow of the first fluid from the first chamber when in the second position.

15. The hand-held gaseous injector assembly of Claim 14, wherein the valve mechanism comprises a valve body, a piston, a seal, a valve biasing member, and an internal protruding member.

16. The hand-held gaseous injector assembly of Claim 14 or Claim 15, wherein the filter is removably connected to the syringe body, the filter being configured to engage

the valve mechanism when coupled to the syringe body so as to transition the valve mechanism from the first position to the second position.

17. The hand-held gaseous injector assembly of Claim 11, wherein the second chamber comprises an opening at a first end of the first chamber and an internal valve mechanism located adjacent the first end of the second chamber, the internal valve mechanism configured to seal the opening.

18. The hand-held gaseous injector assembly of Claim 17, wherein the internal valve mechanism comprises a piston, a seal, and a biasing member, the internal valve mechanism configured to seal the opening at least prior to activation of the hand-held gaseous injector assembly.

19. The hand-held gaseous injector assembly of any one of the preceding claims, wherein the flow restrictor is a cap configured to removably engage an outlet of the filter.

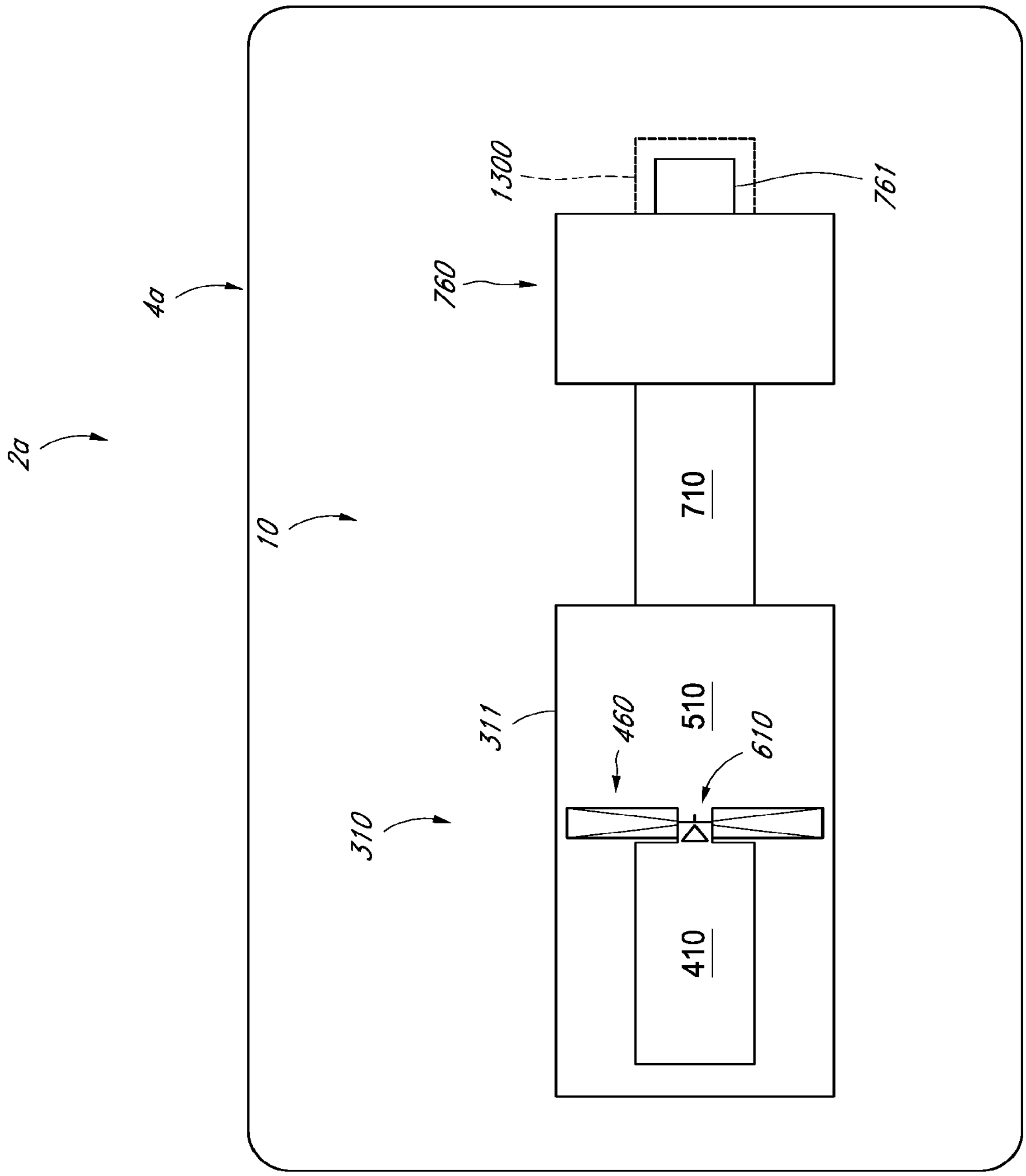


FIG. 1A

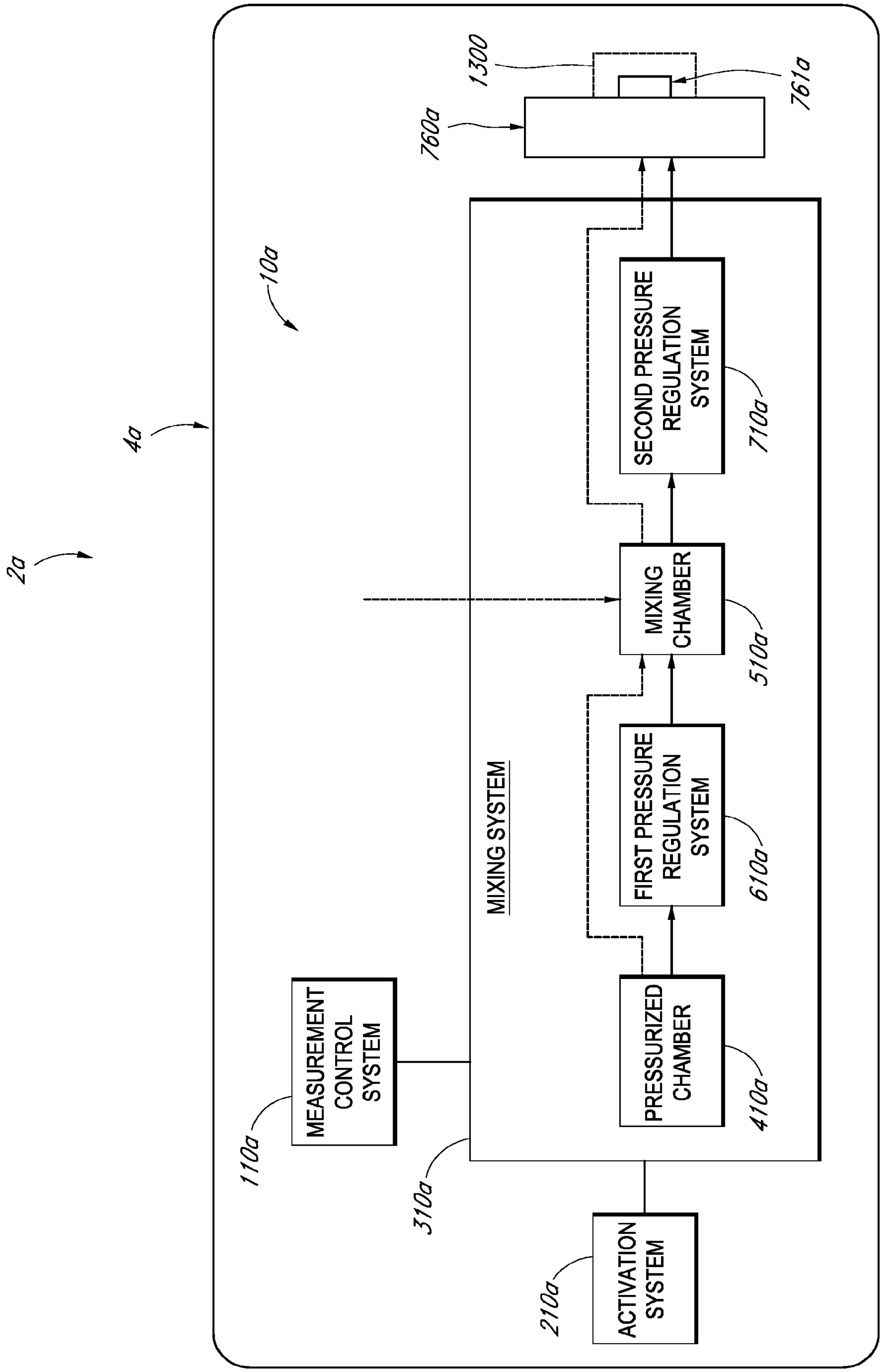

2a
4a
10a
MEASUREMENT CONTROL SYSTEM
110a
ACTIVATION SYSTEM
210a
MIXING SYSTEM
310a
PRESSURIZED CHAMBER
410a
FIRST PRESSURE REGULATION SYSTEM
610a
MIXING CHAMBER
510a
SECOND PRESSURE REGULATION SYSTEM
710a
760a
761a
1300

FIG. 1B

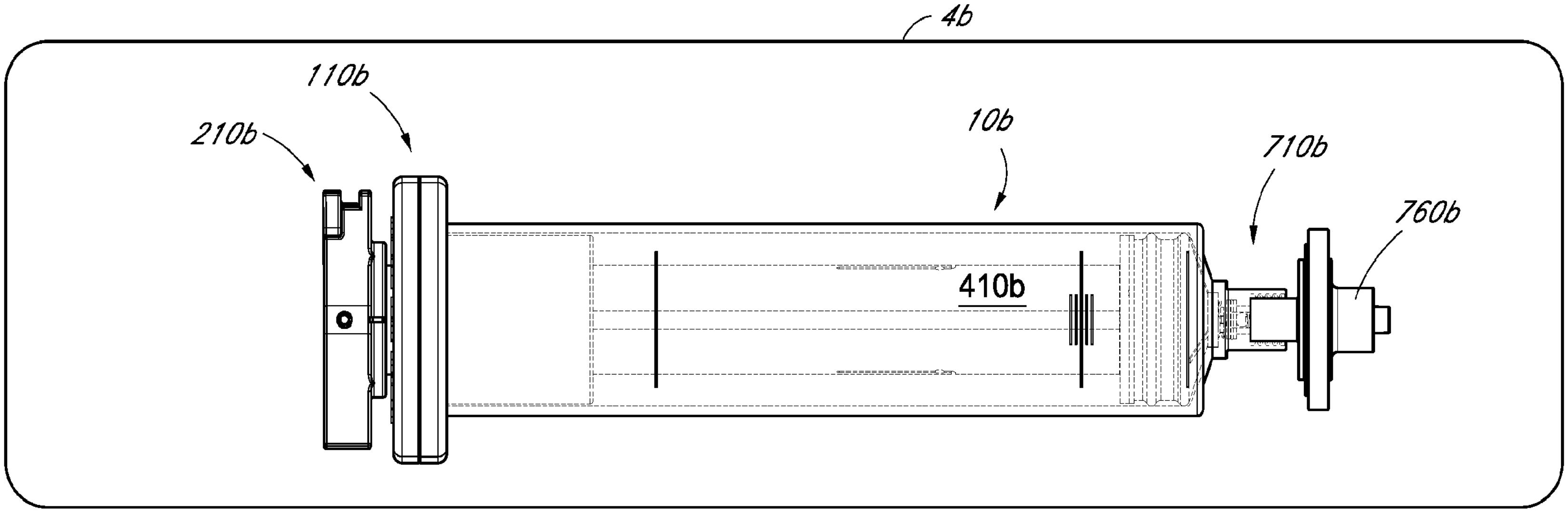


FIG. 2A

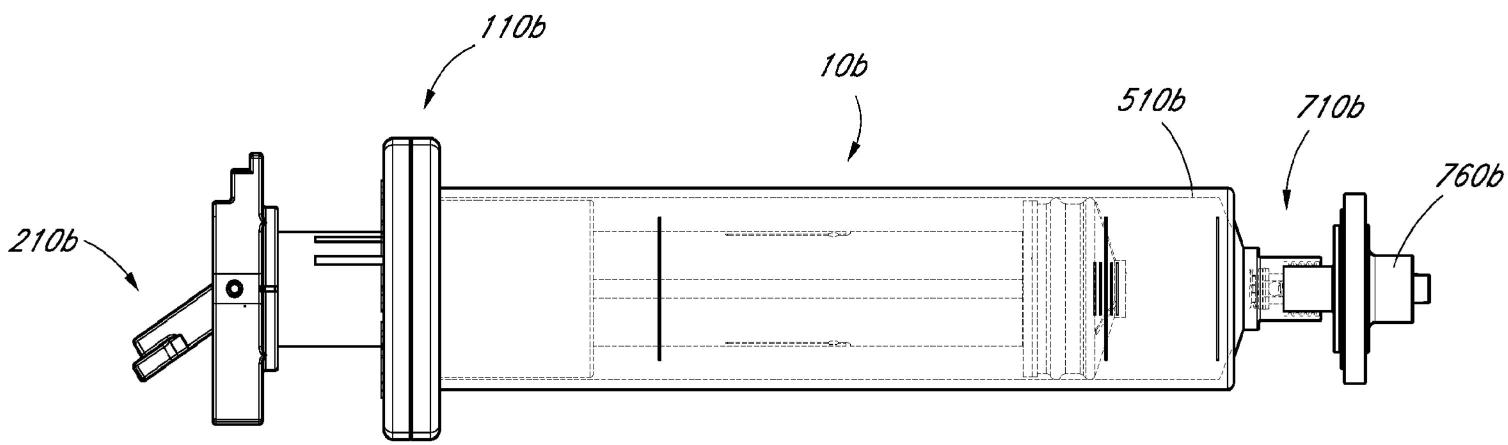


FIG. 2B

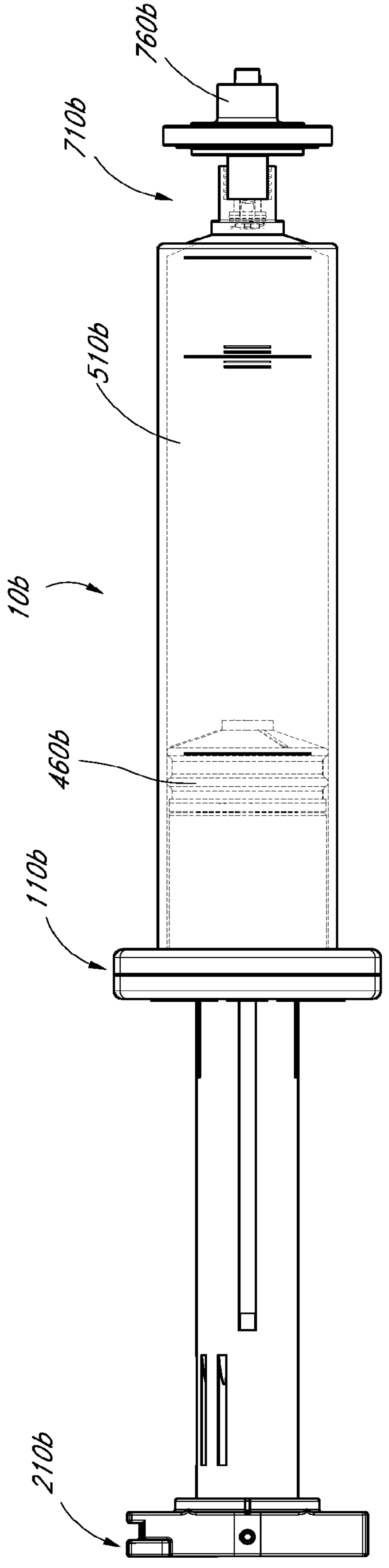


FIG. 2C

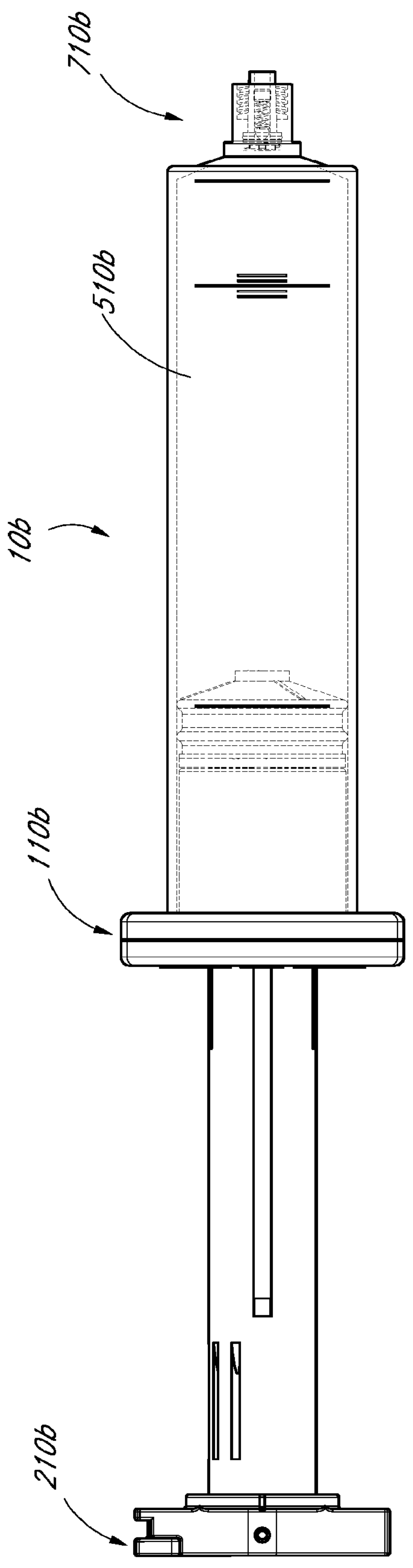
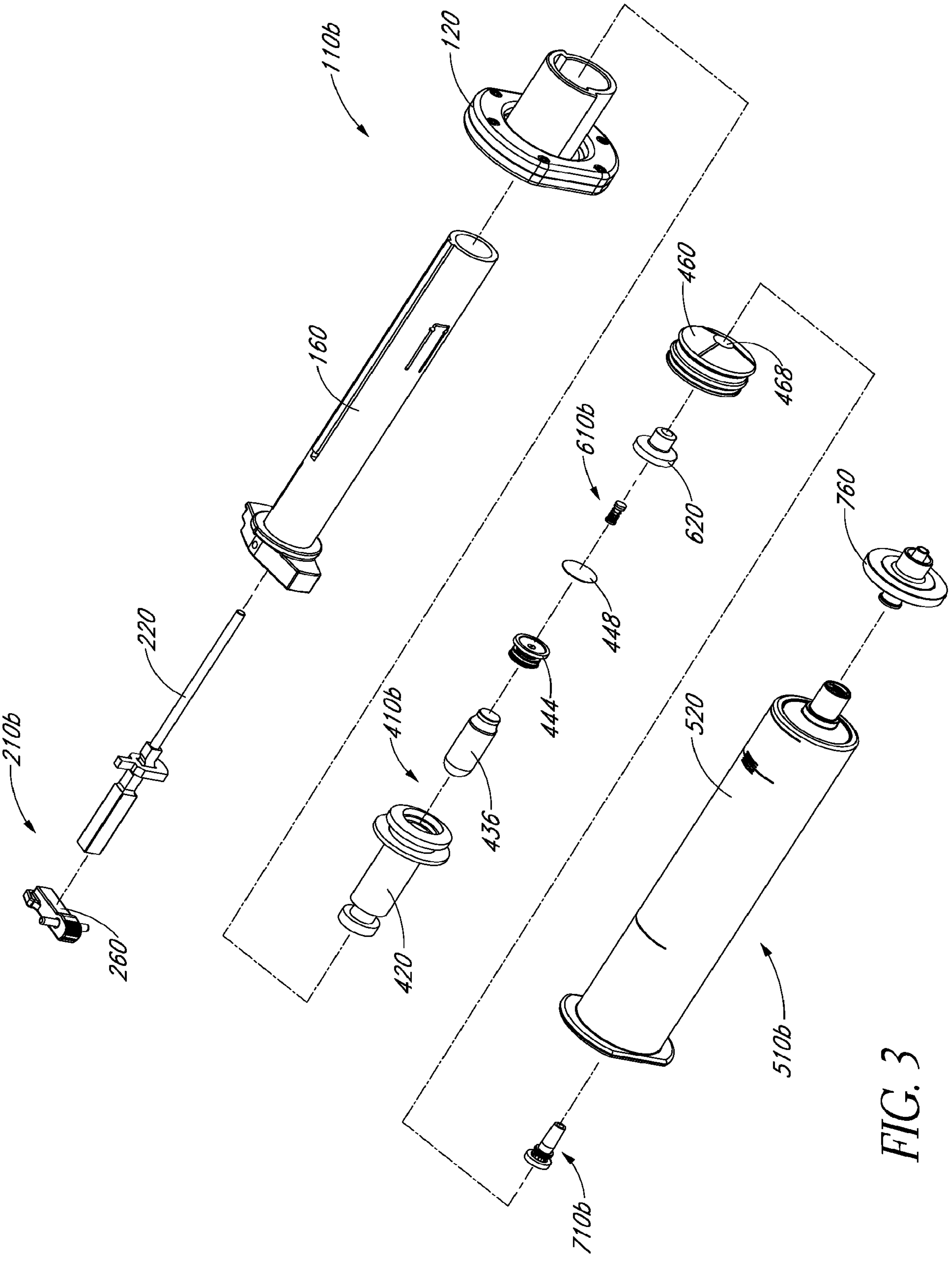


FIG. 2D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410b
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436
260
420
510b
710b

FIG. 3

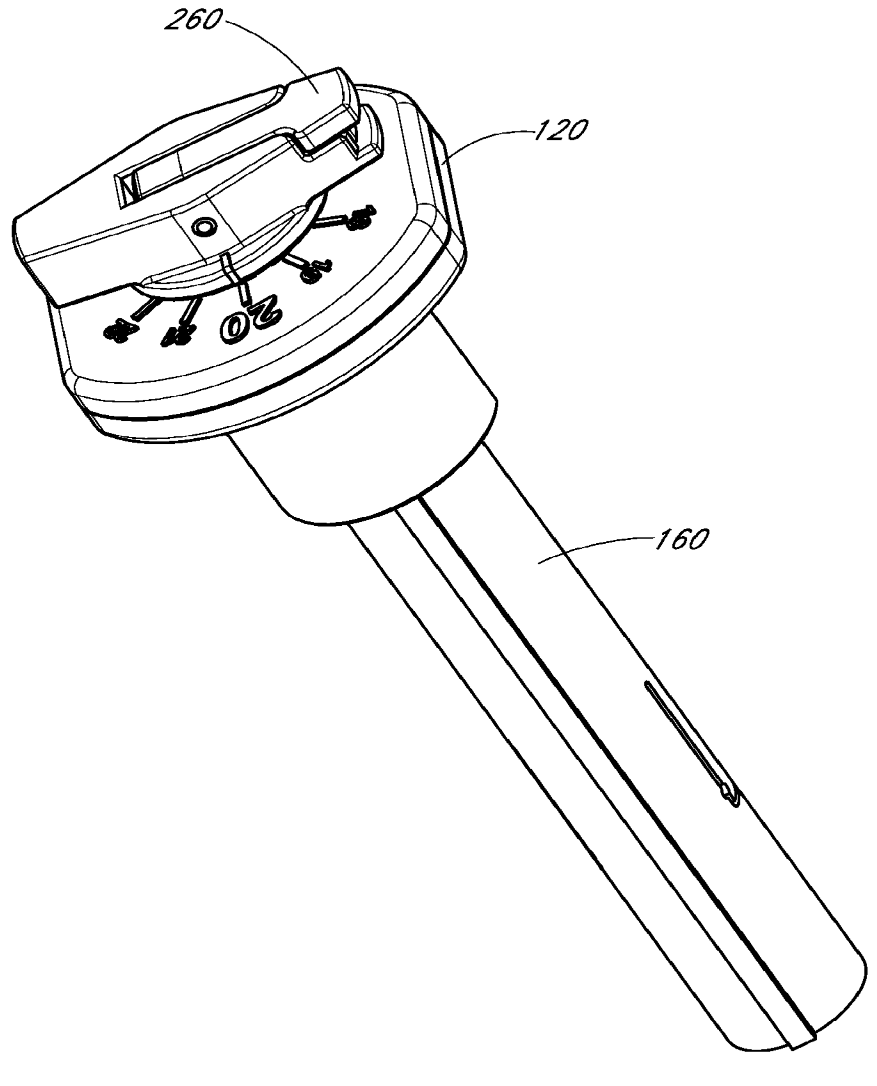

FIG. 4

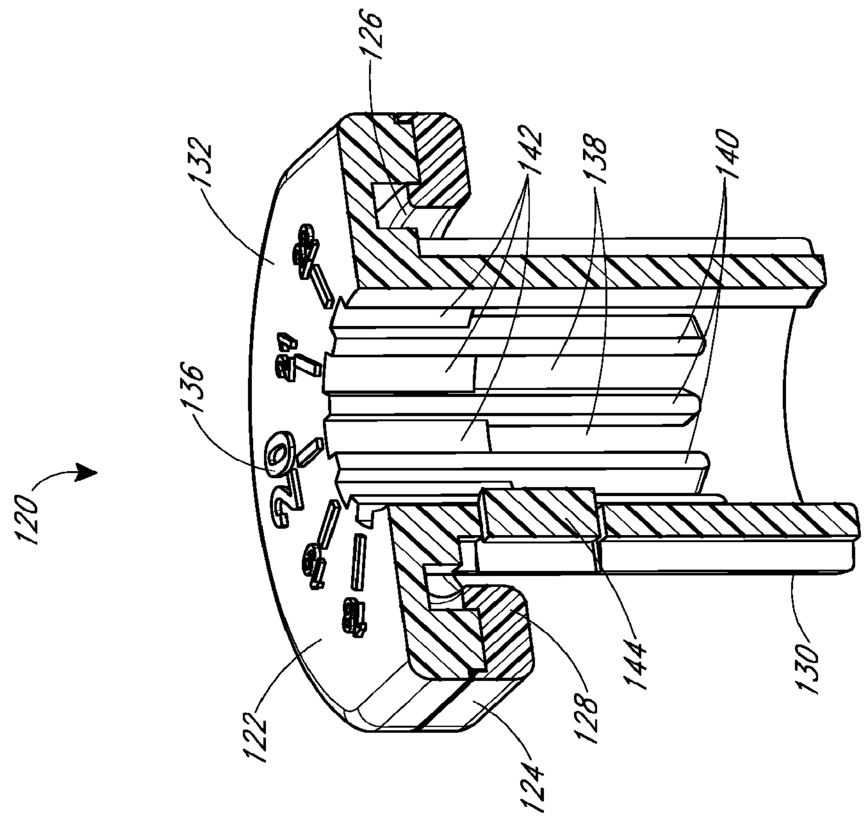
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FIG. 5B

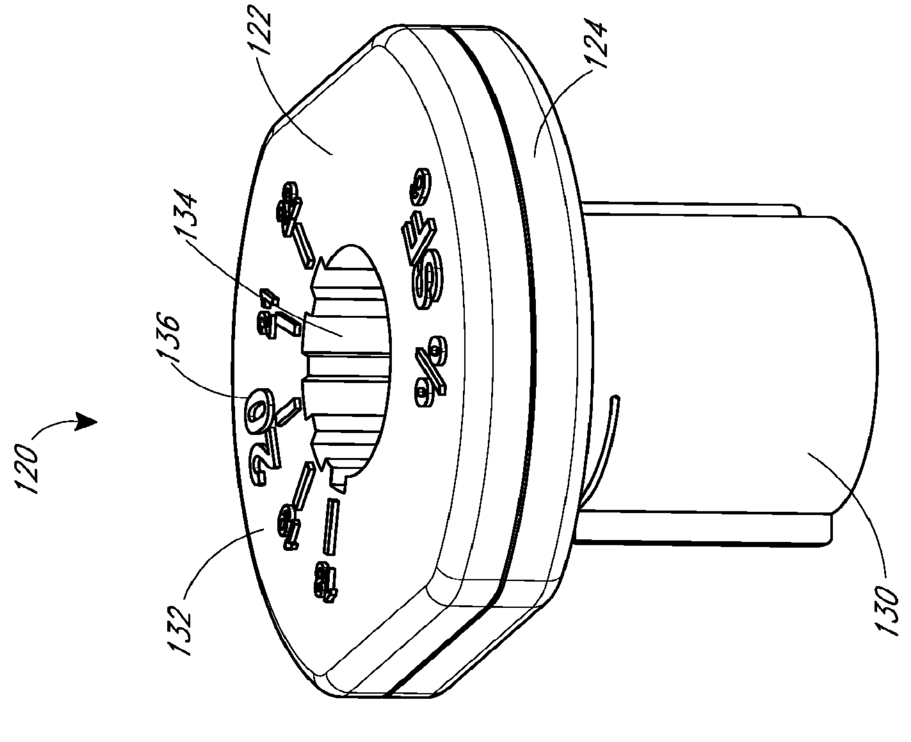
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FIG. 5A

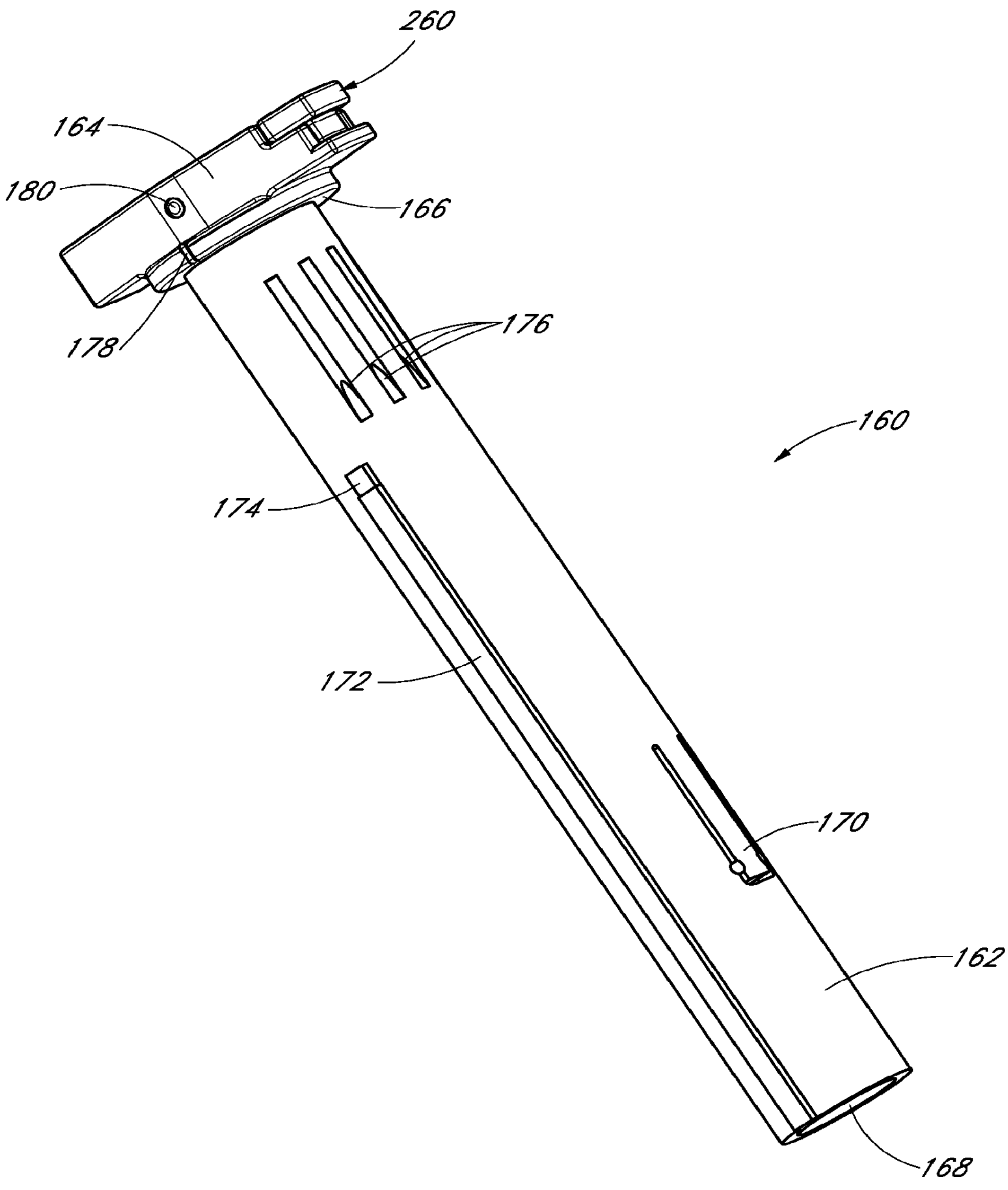


FIG. 6

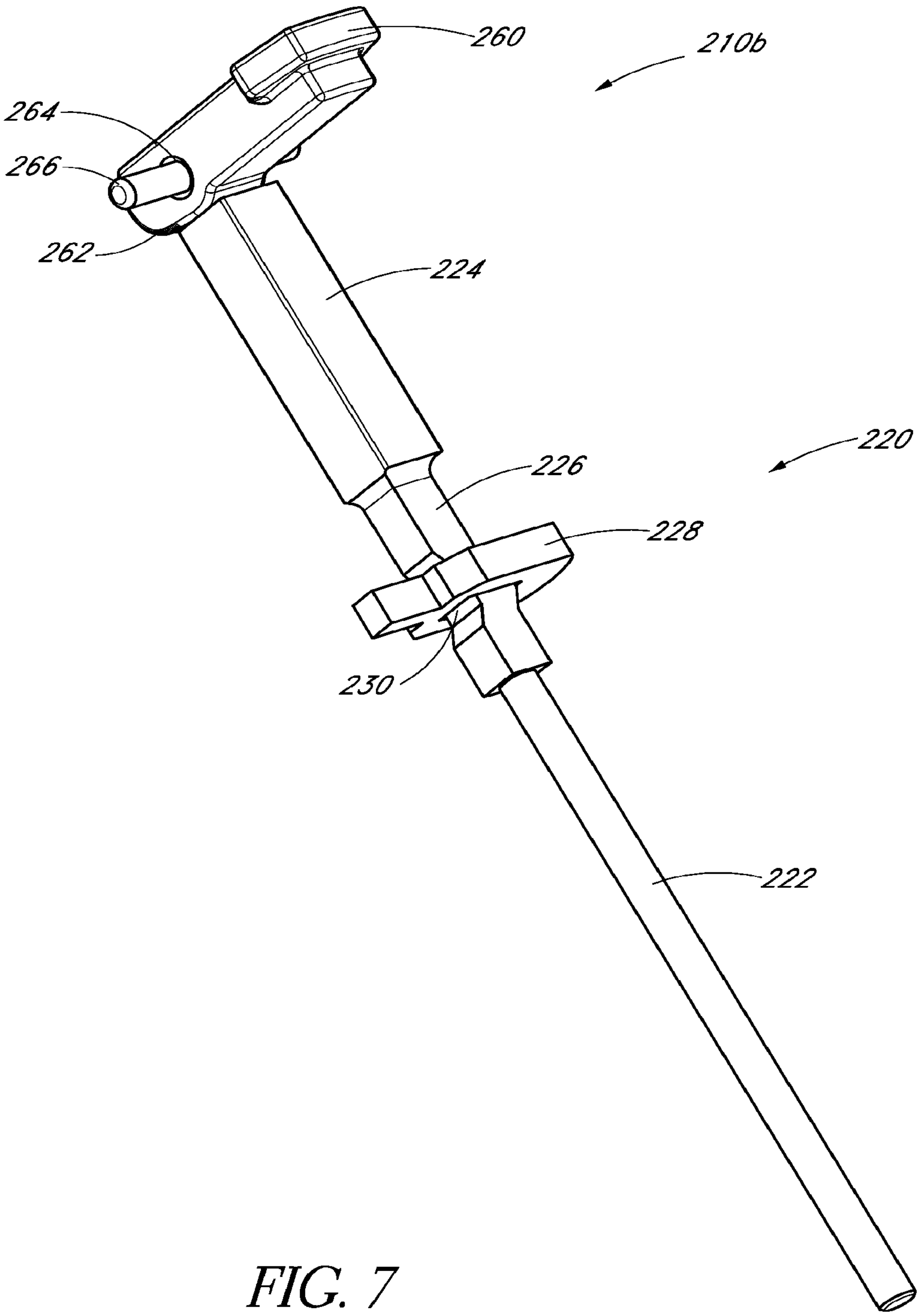
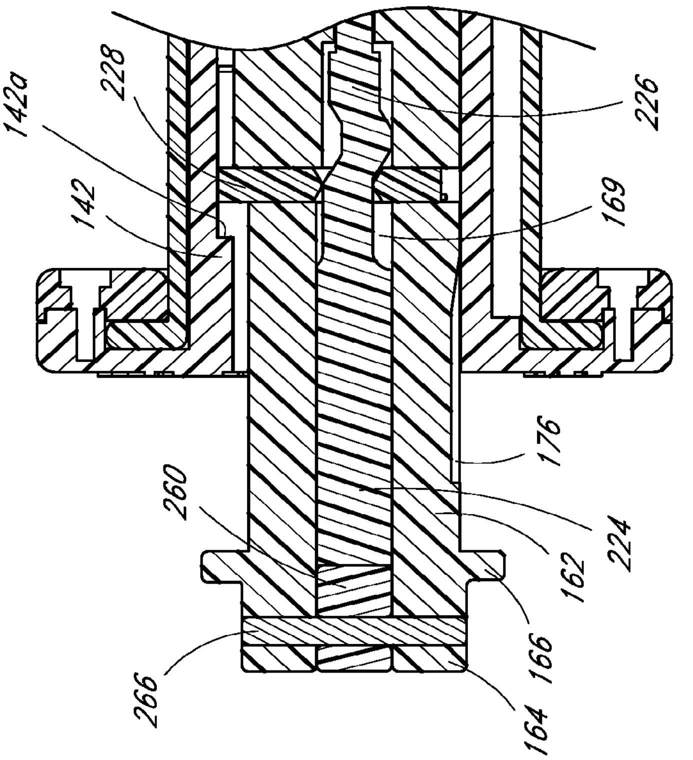


FIG. 7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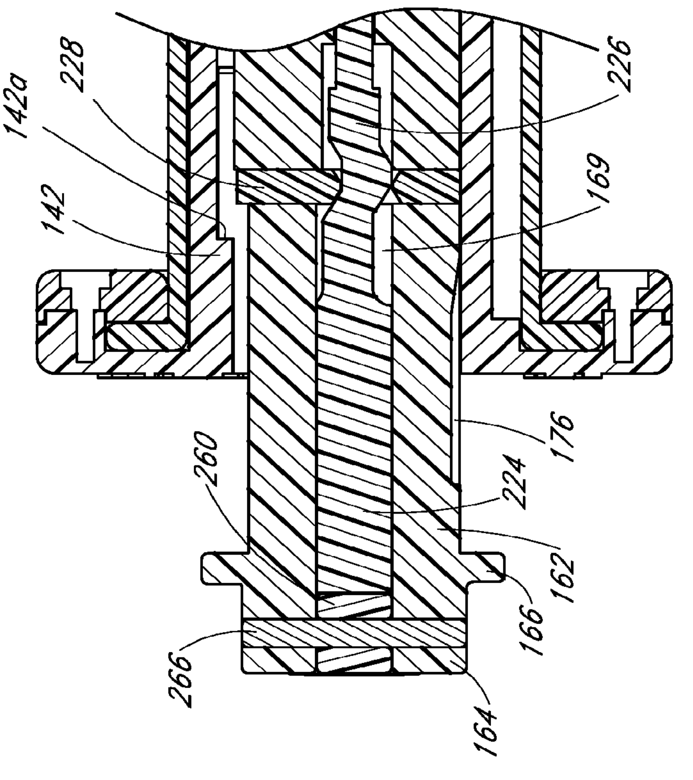
164

FIG. 8B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164

FIG. 8A

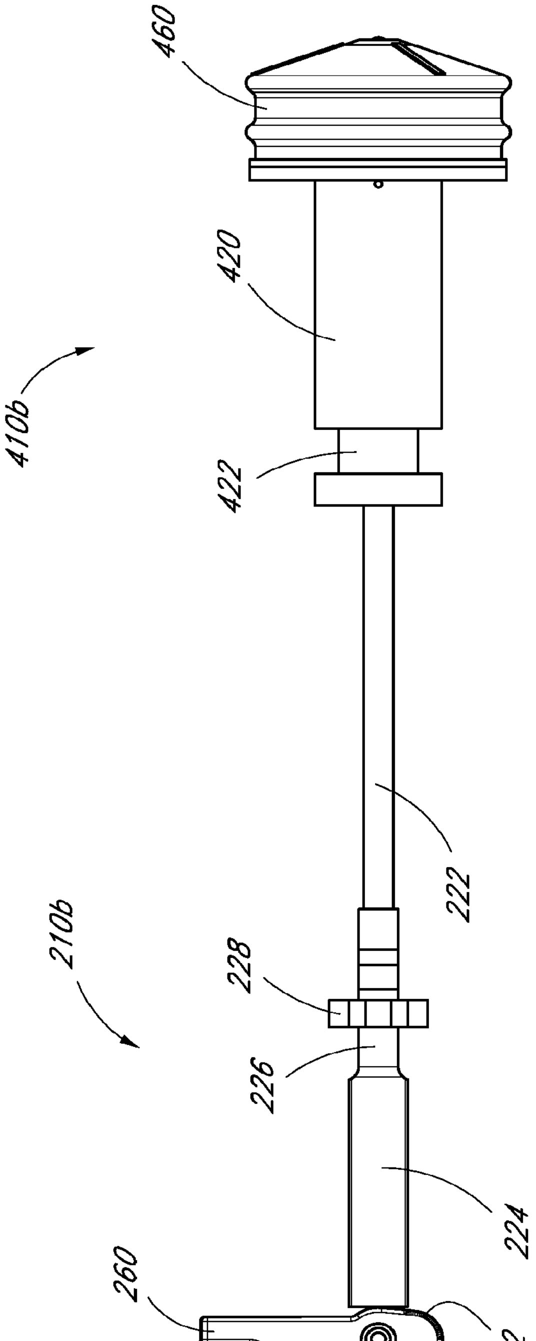

FIG. 9

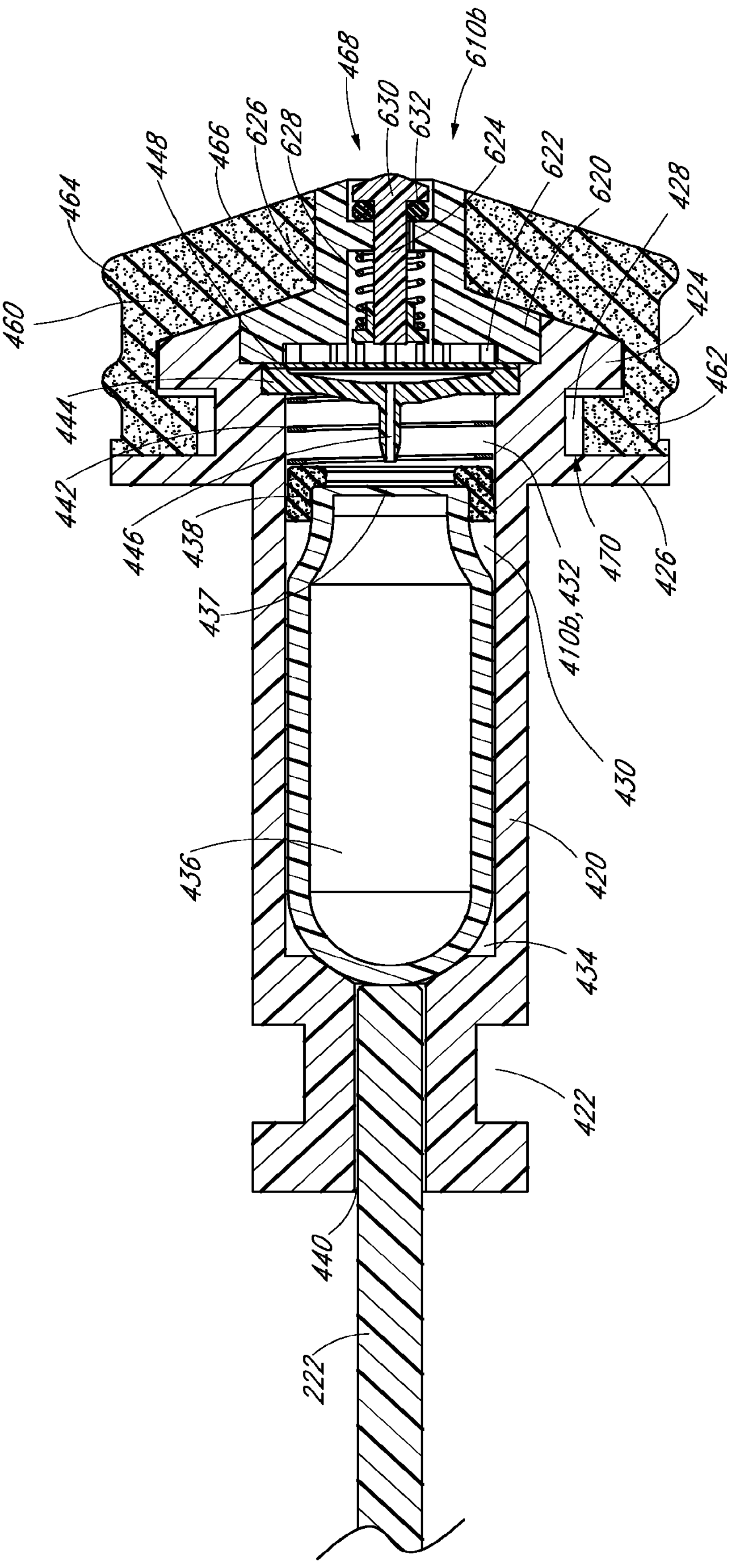
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FIG. 10

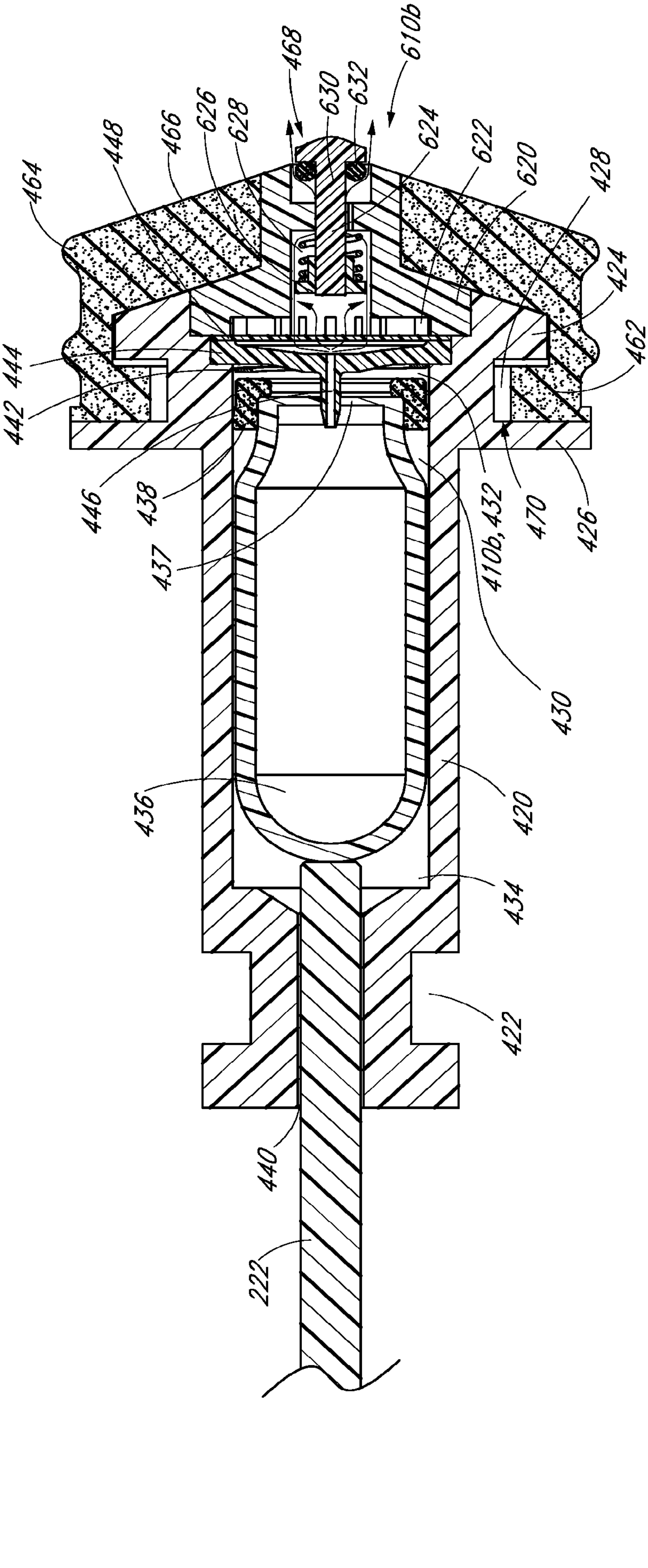
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FIG. 11

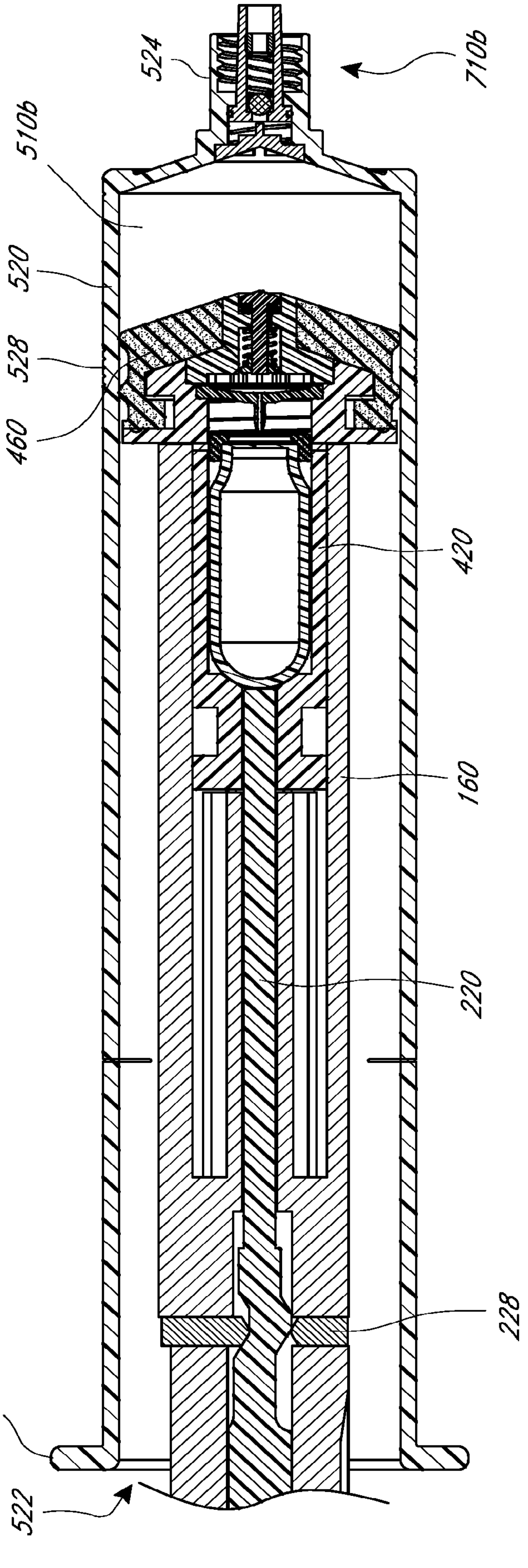


FIG. 12

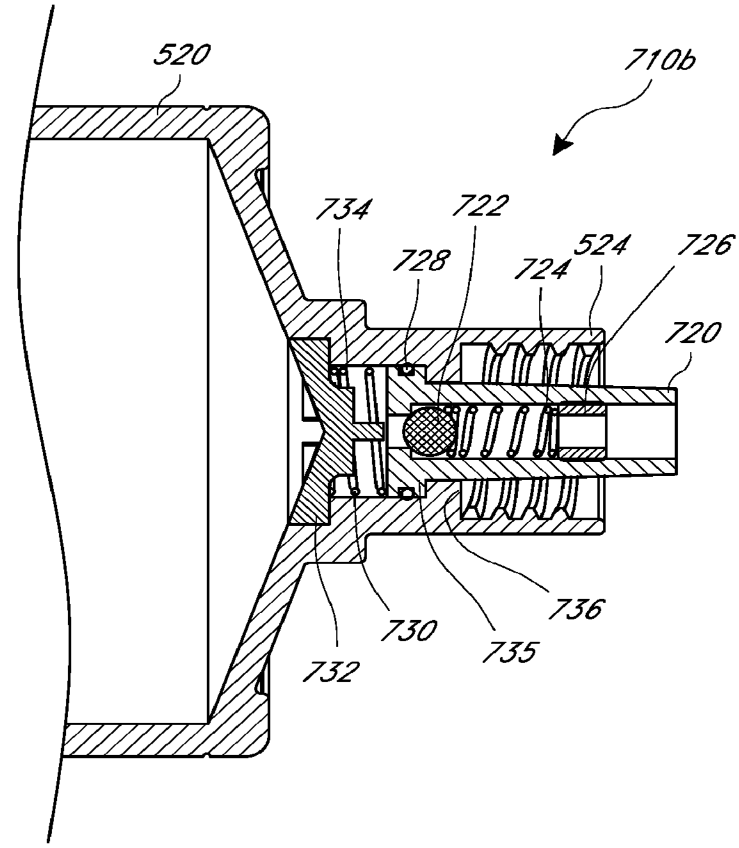


FIG. 13

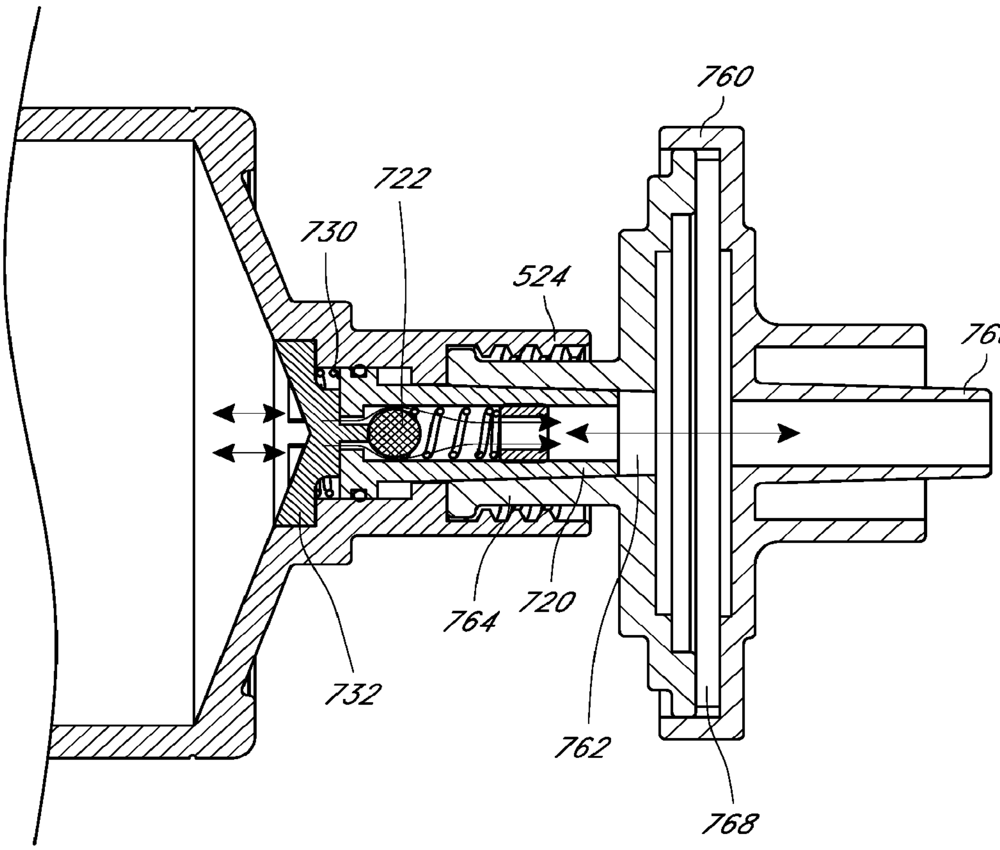


FIG. 14

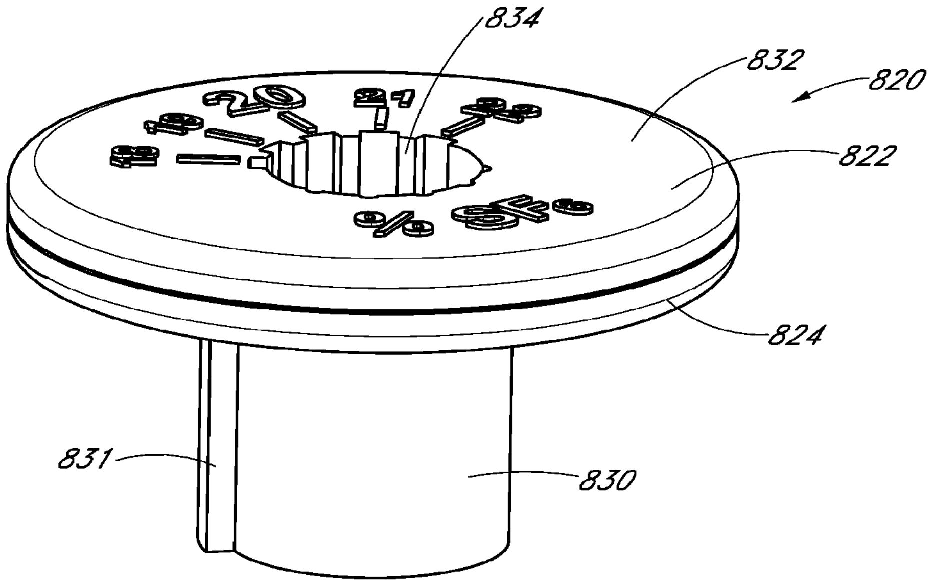


FIG. 15A

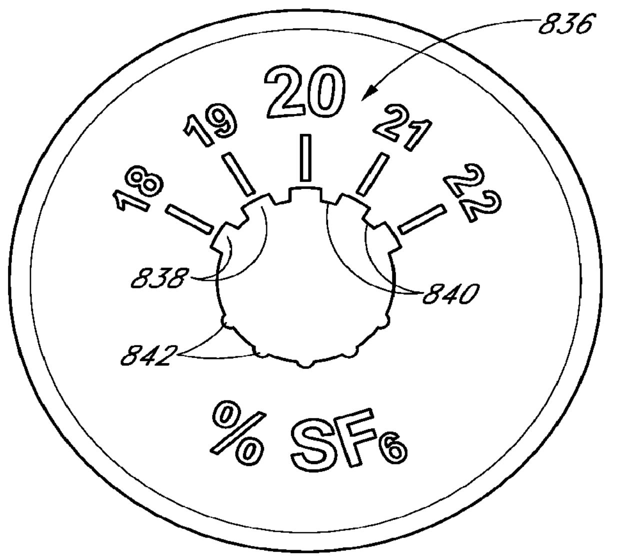


FIG. 15B

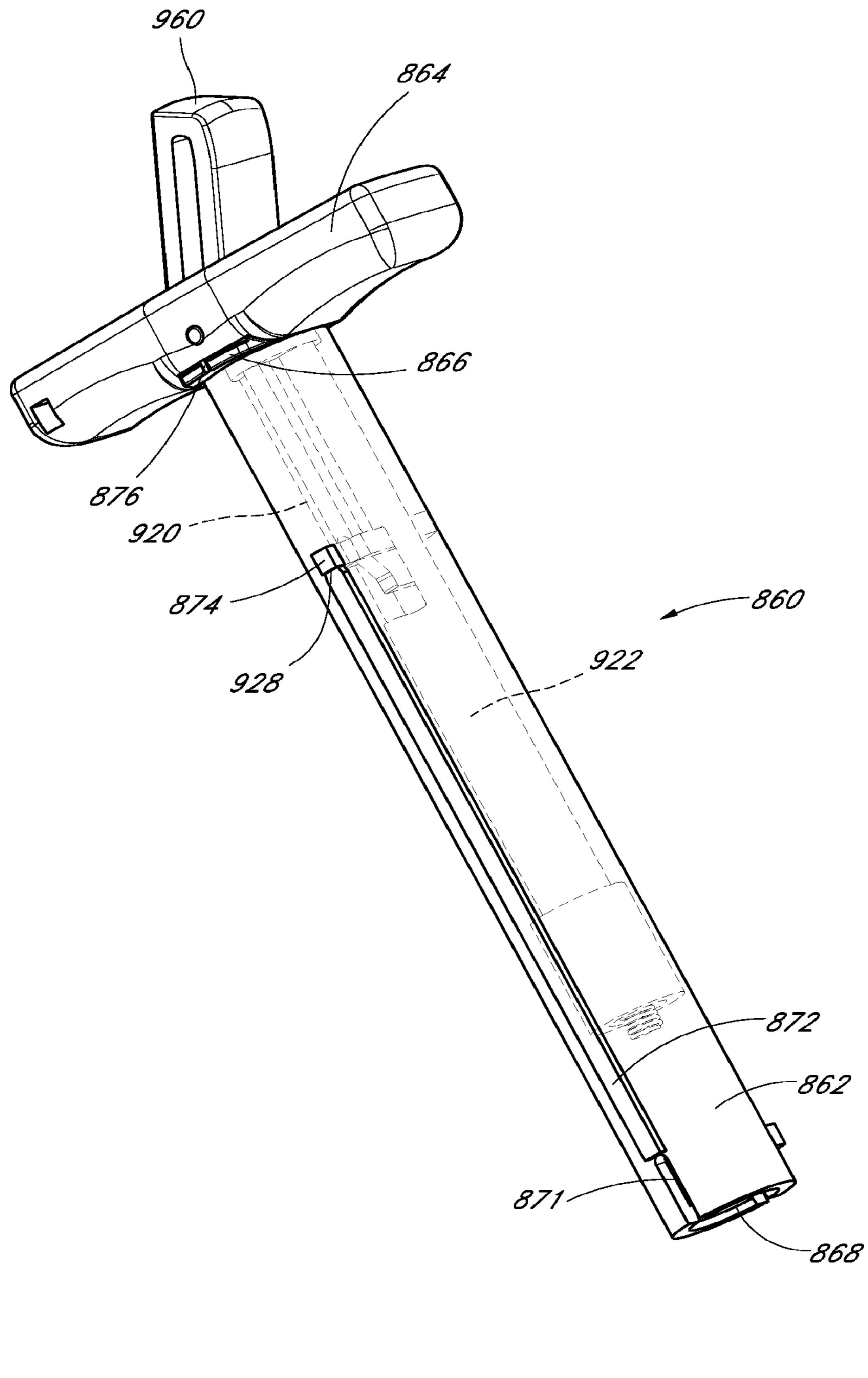


FIG. 16

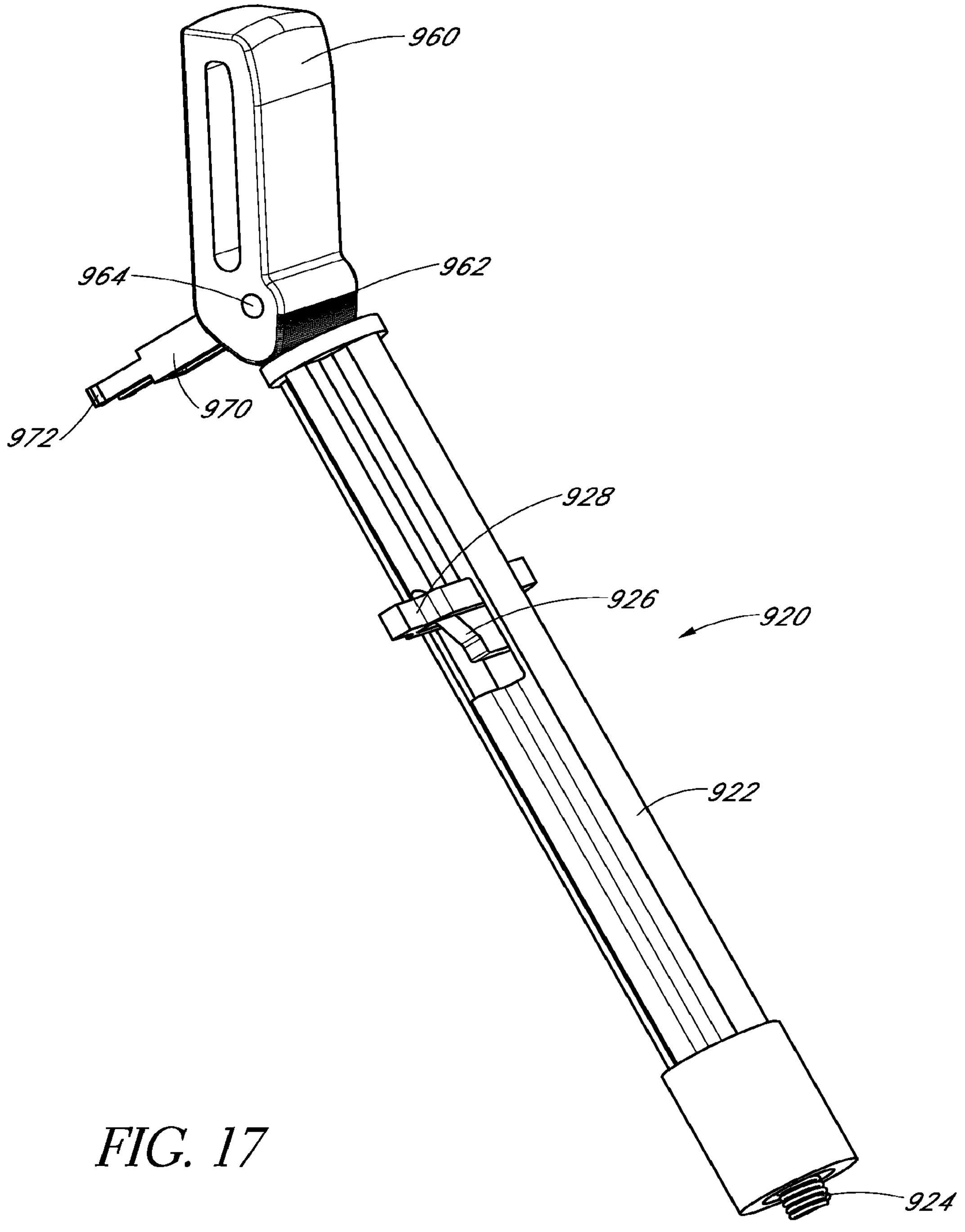


FIG. 17

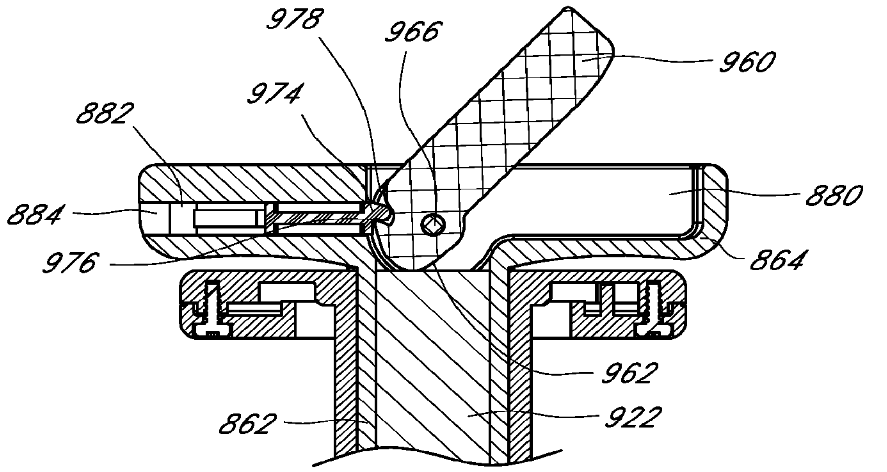


FIG. 18

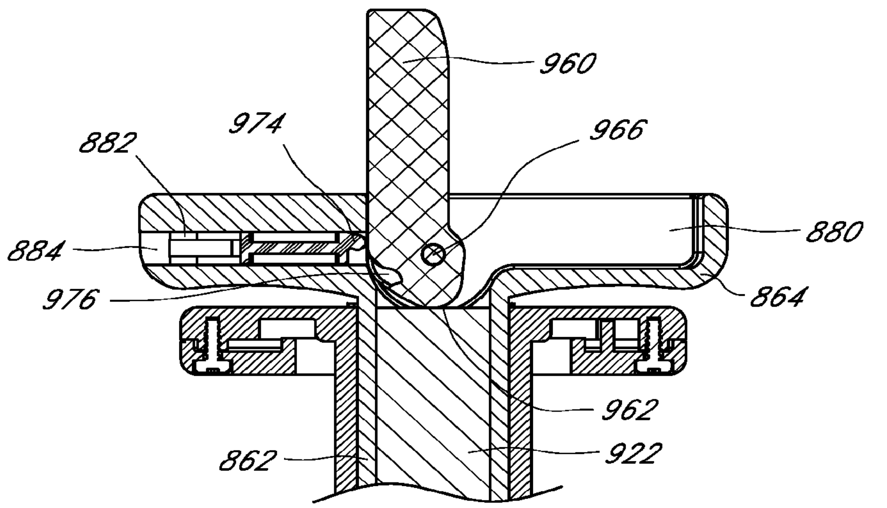


FIG. 19

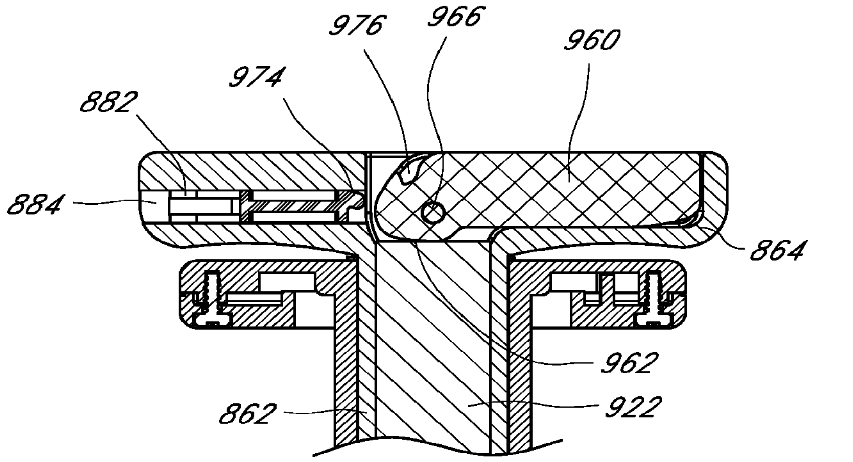


FIG. 20

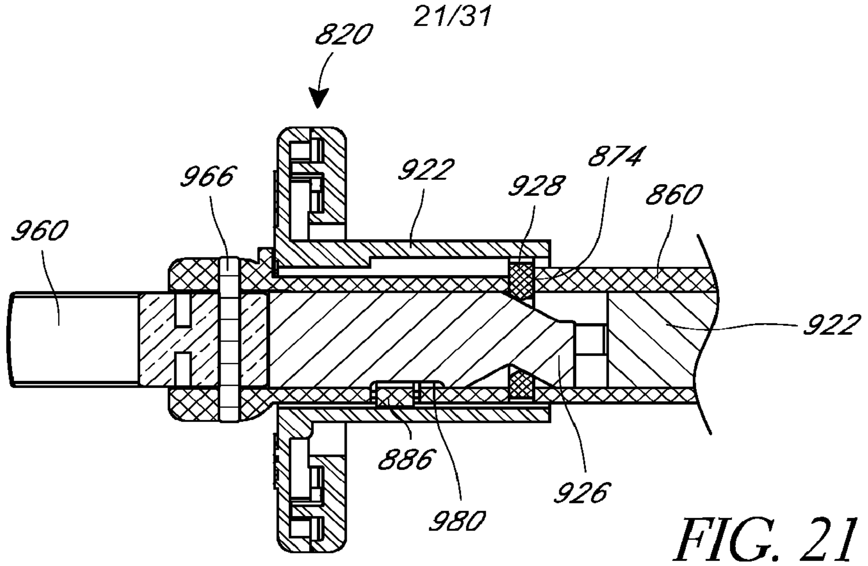


FIG. 21

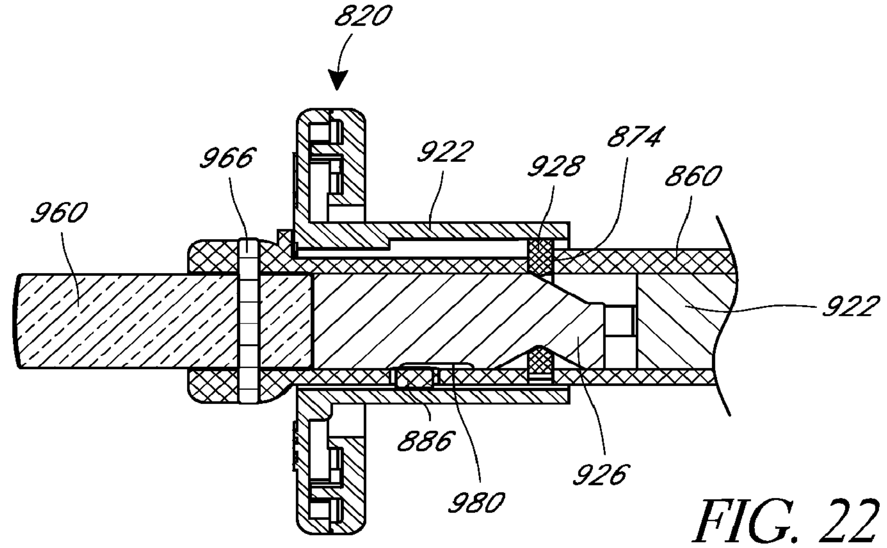


FIG. 22

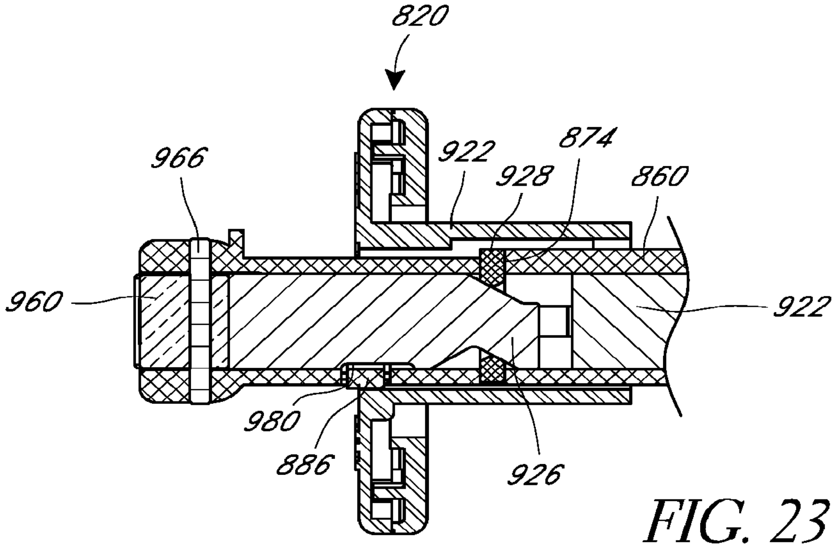


FIG. 23

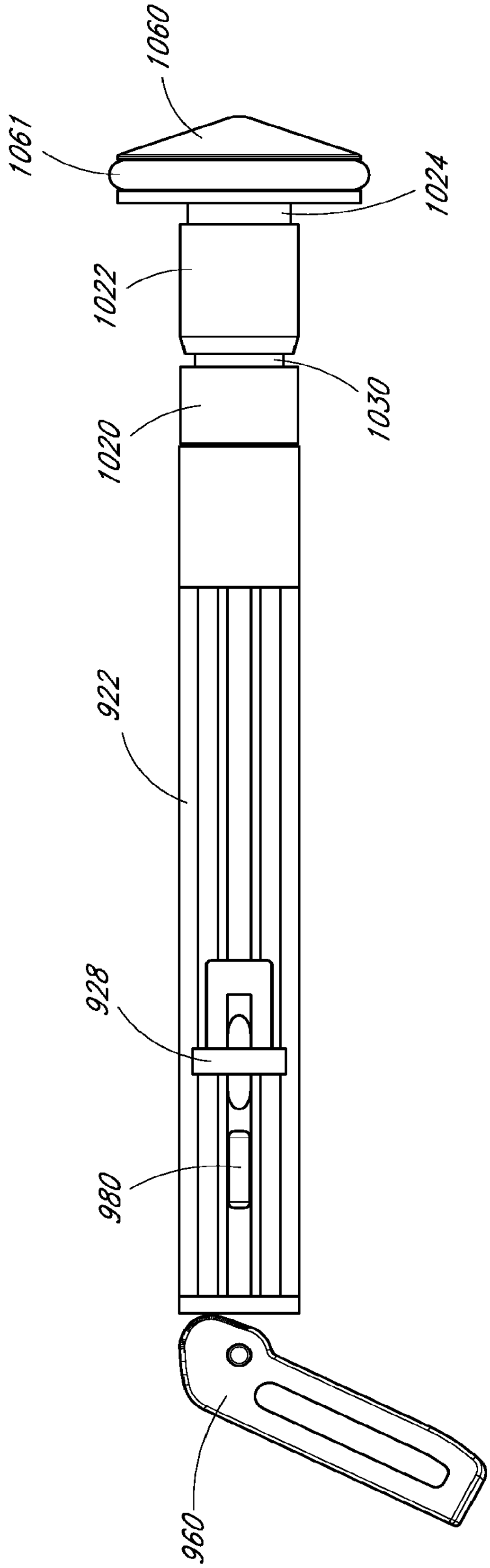


FIG. 24

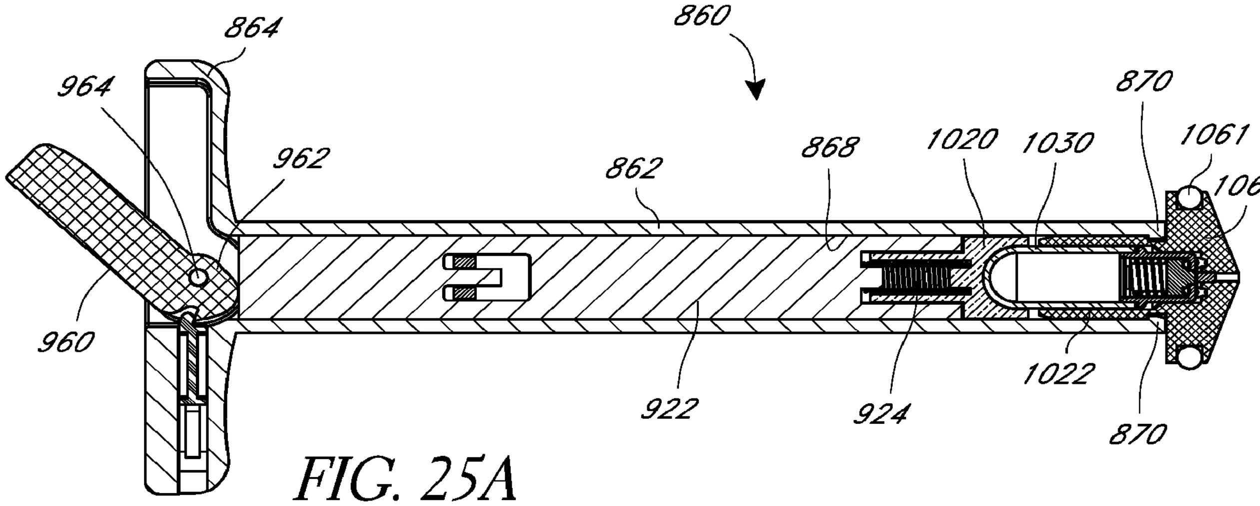


FIG. 25A

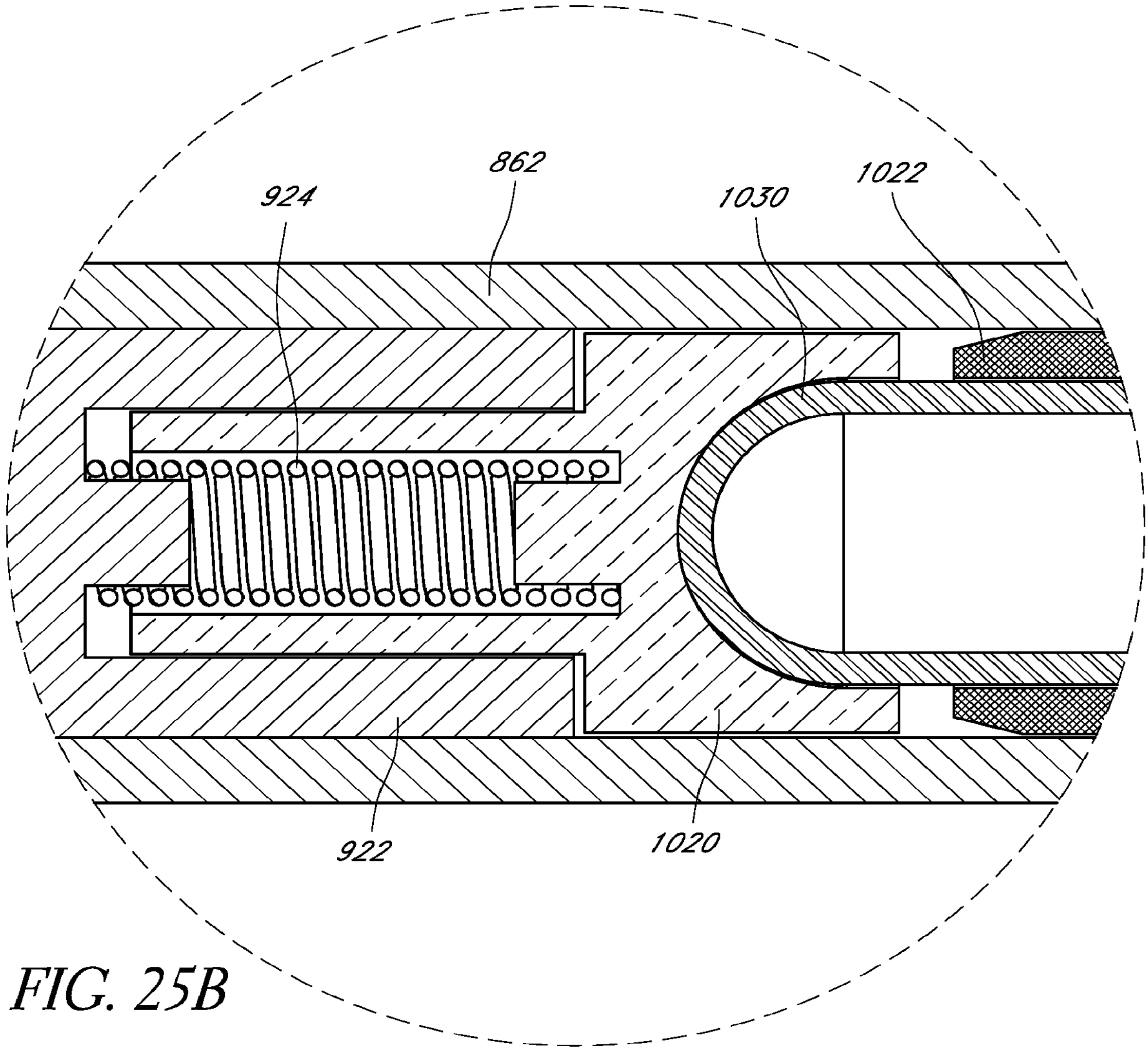


FIG. 25B

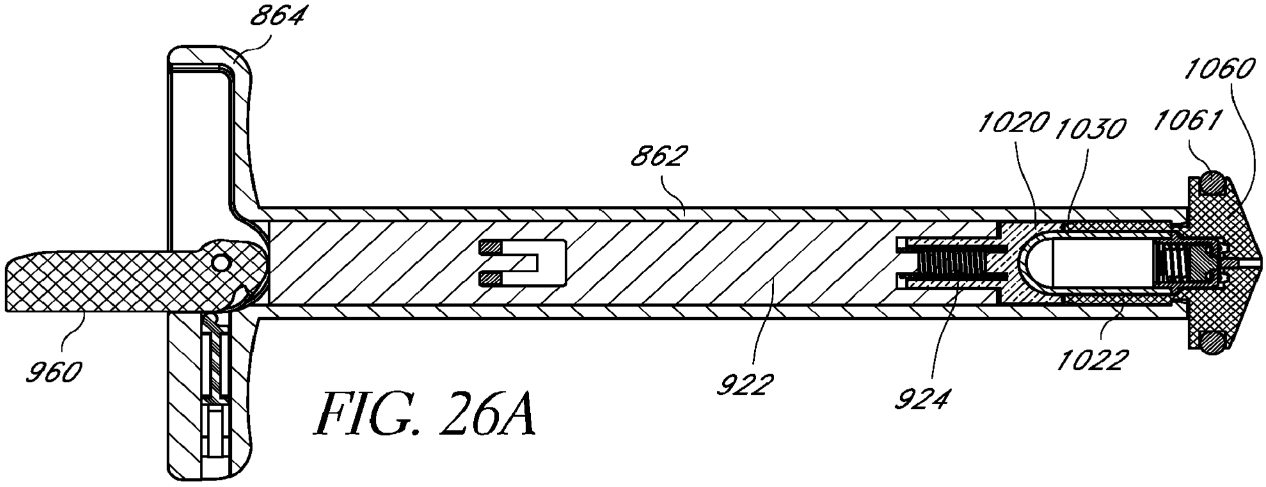


FIG. 26A

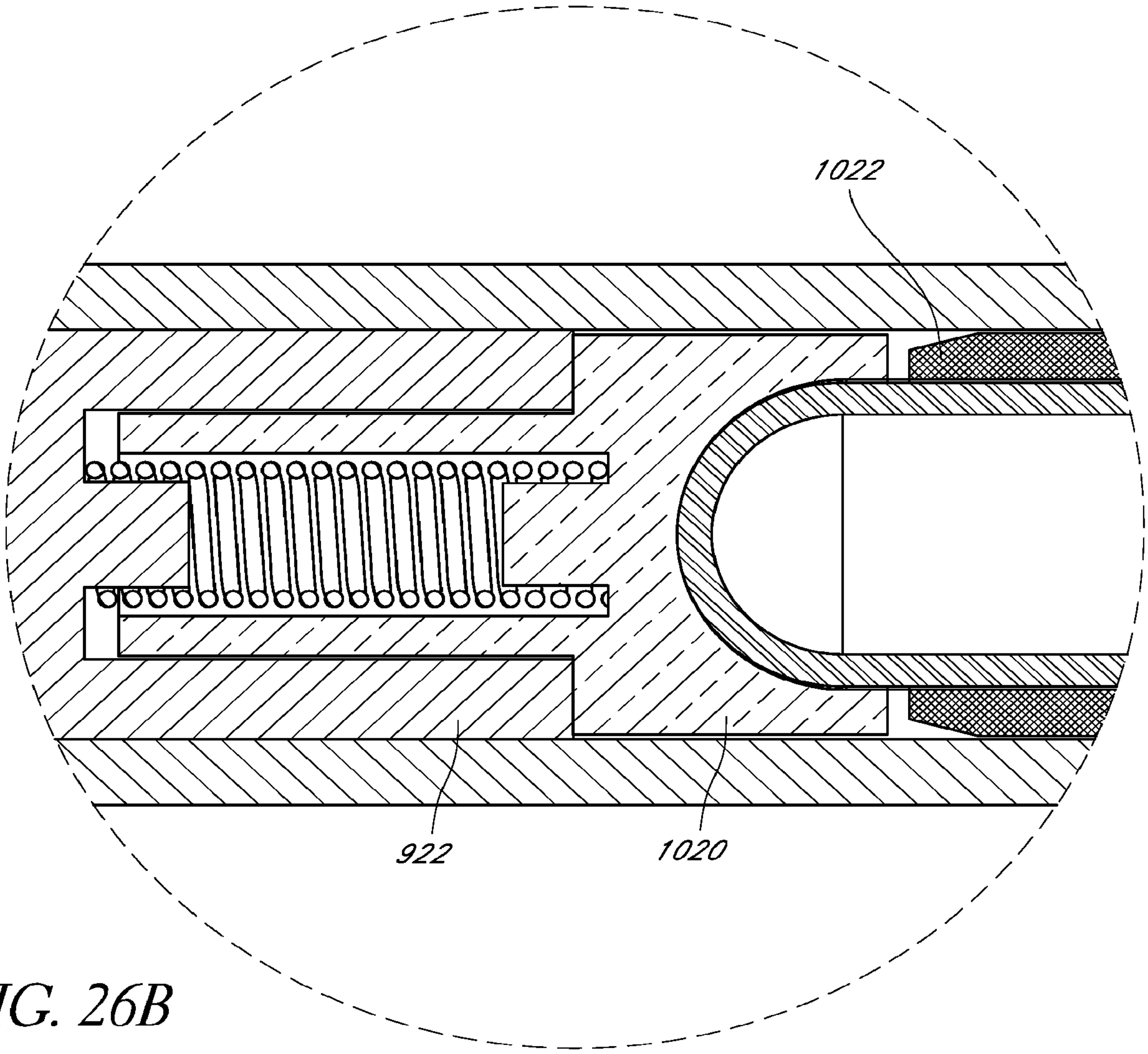


FIG. 26B

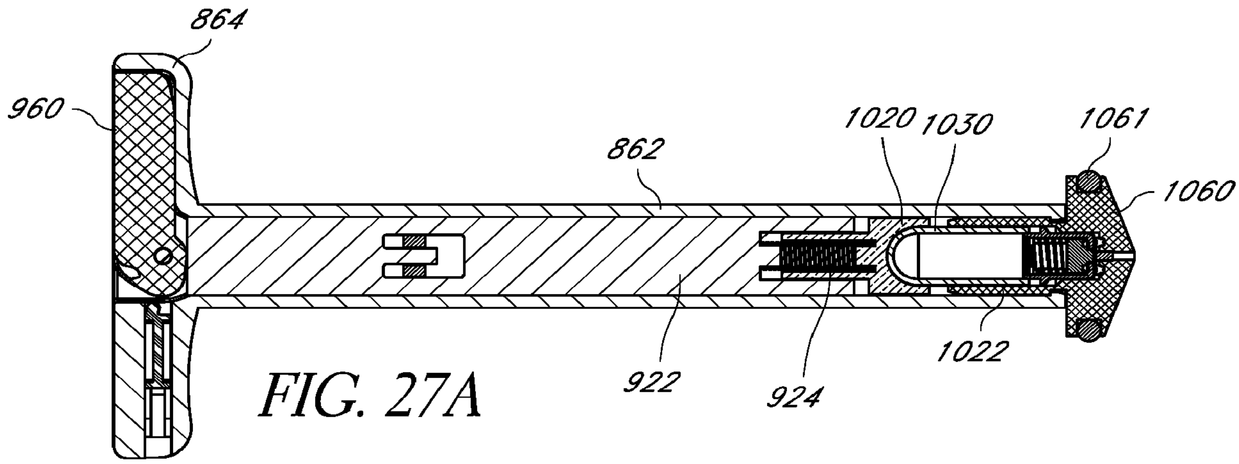


FIG. 27A

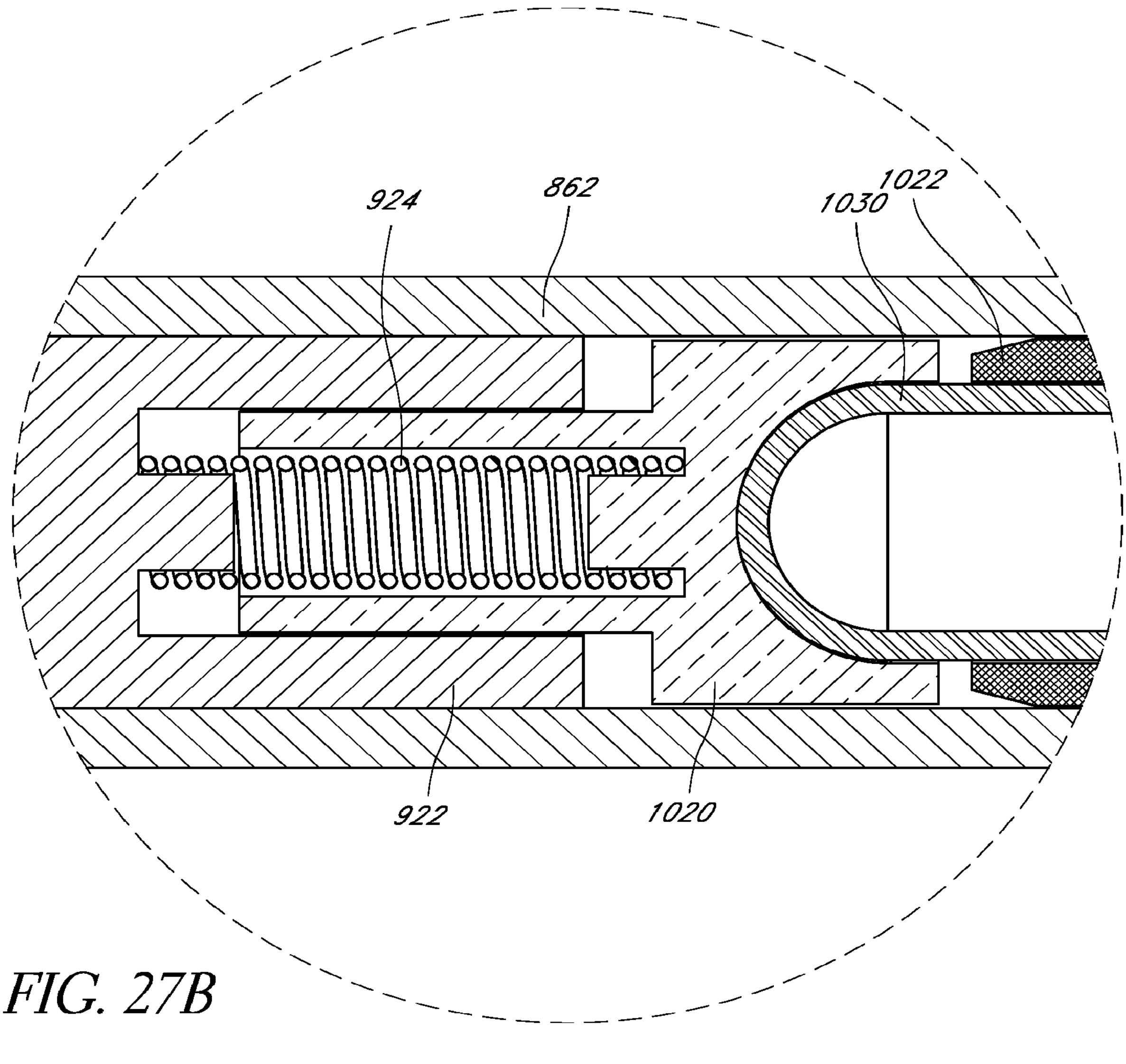
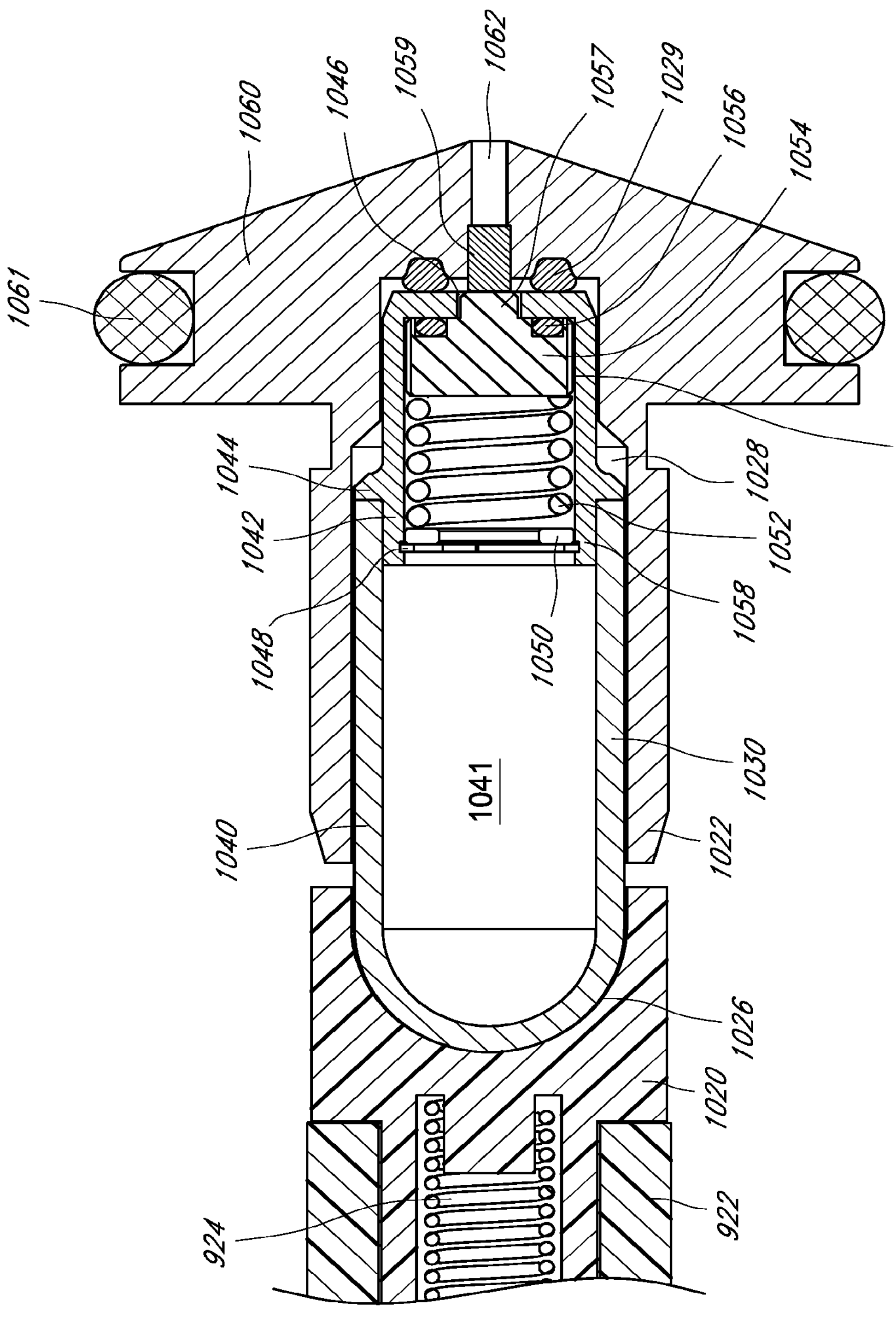


FIG. 27B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924
922

FIG. 28

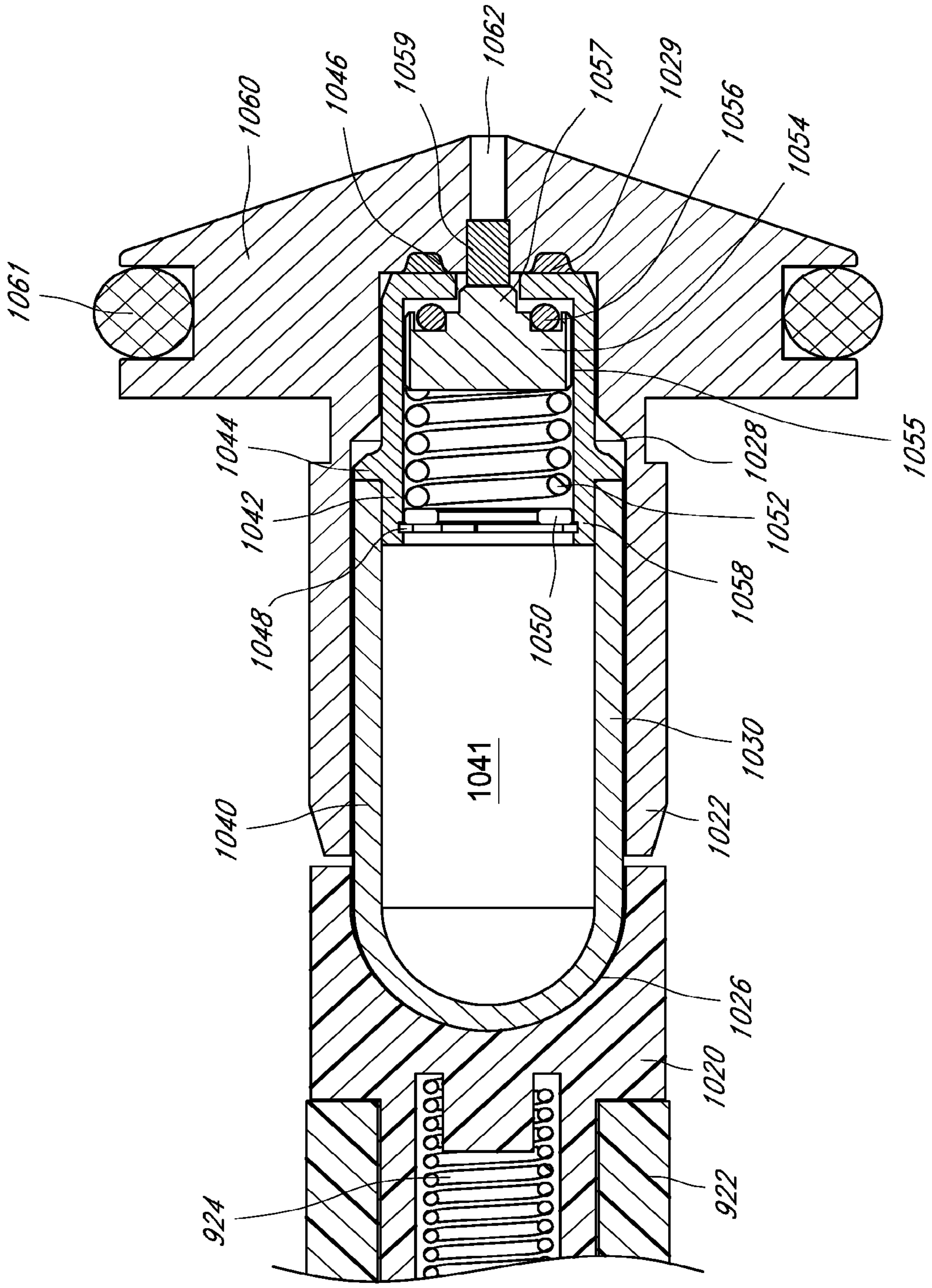
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FIG. 29

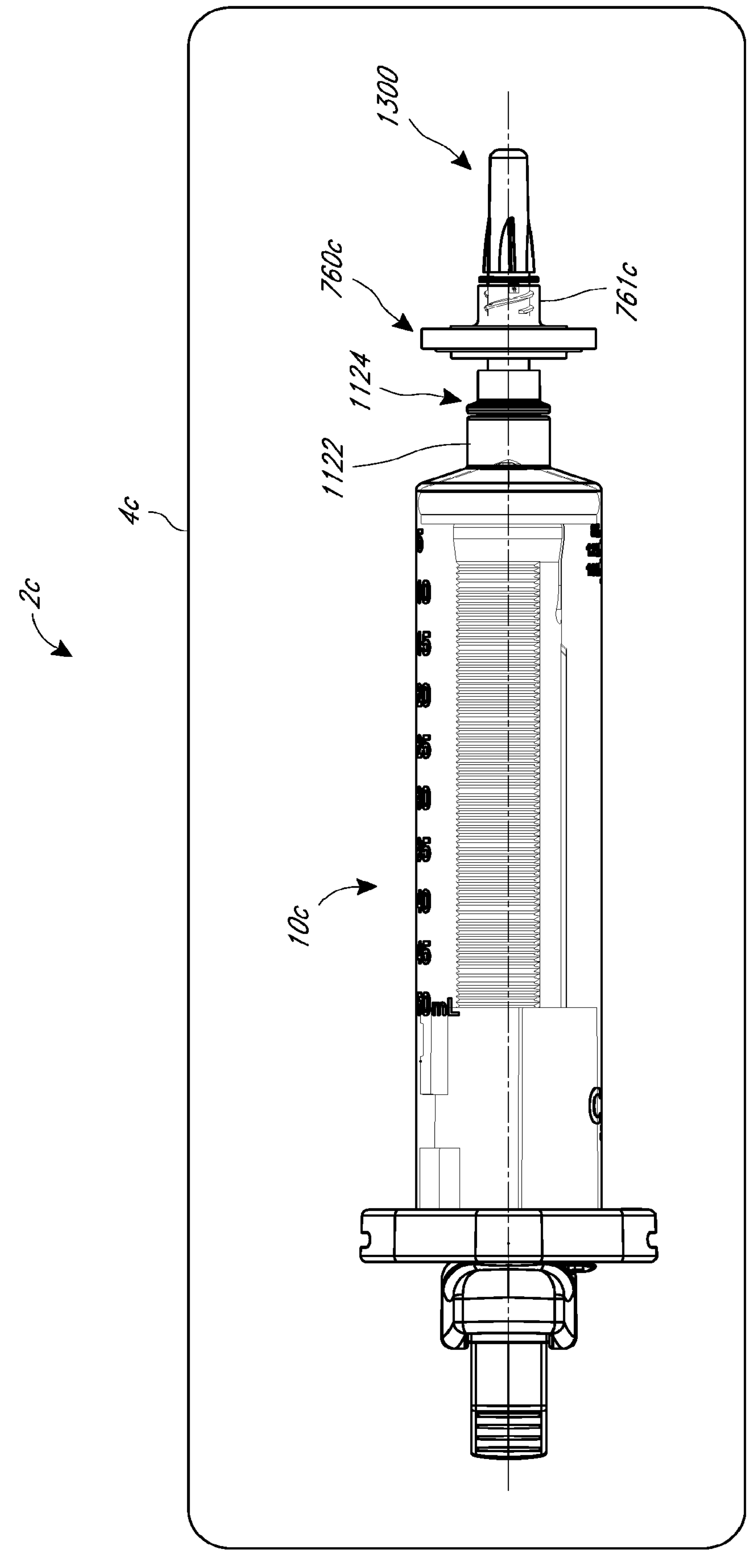
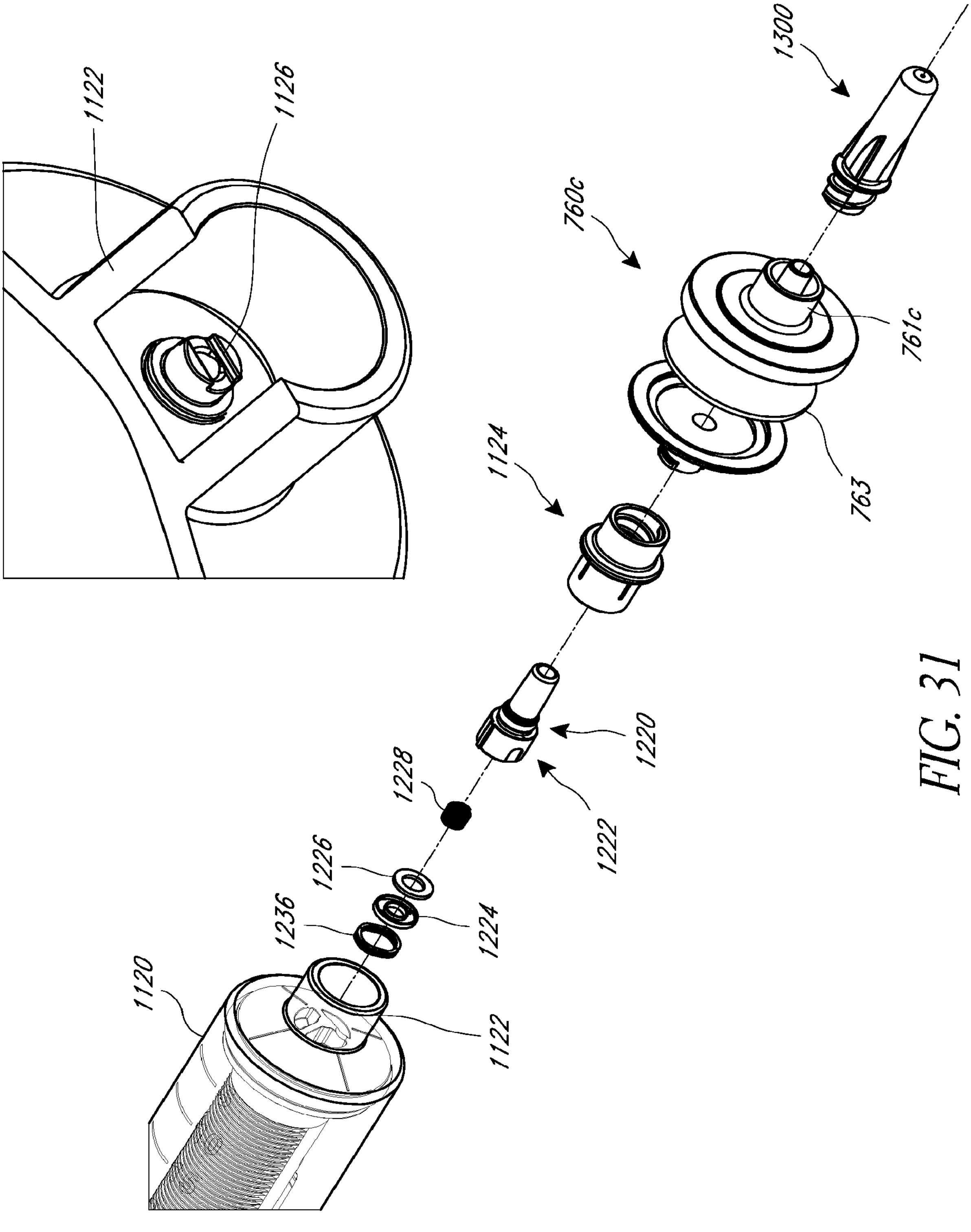


FIG. 30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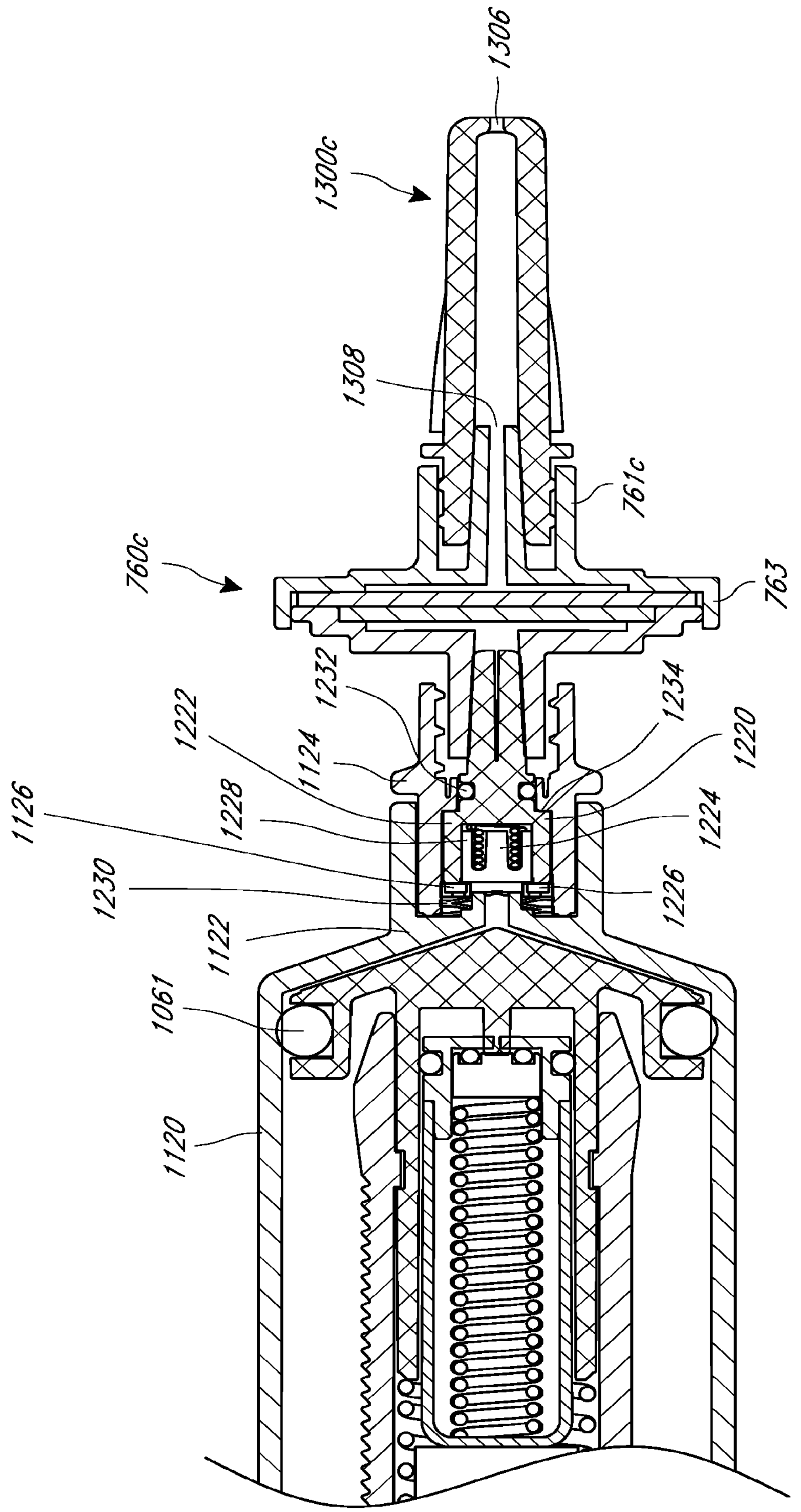
1122

FIG. 31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1061
1120

FIG. 32

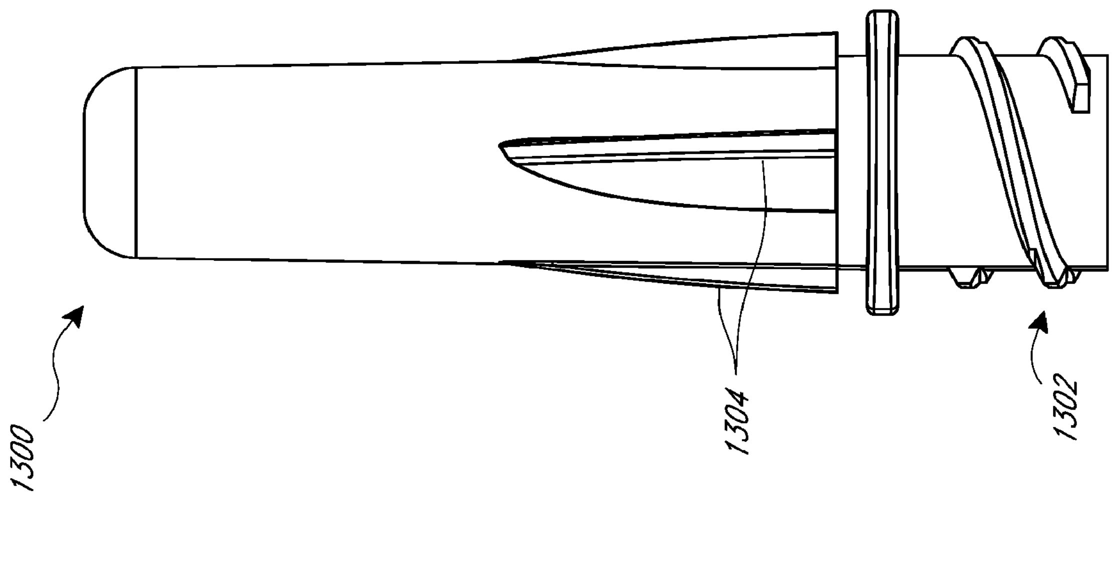

FIG. 33

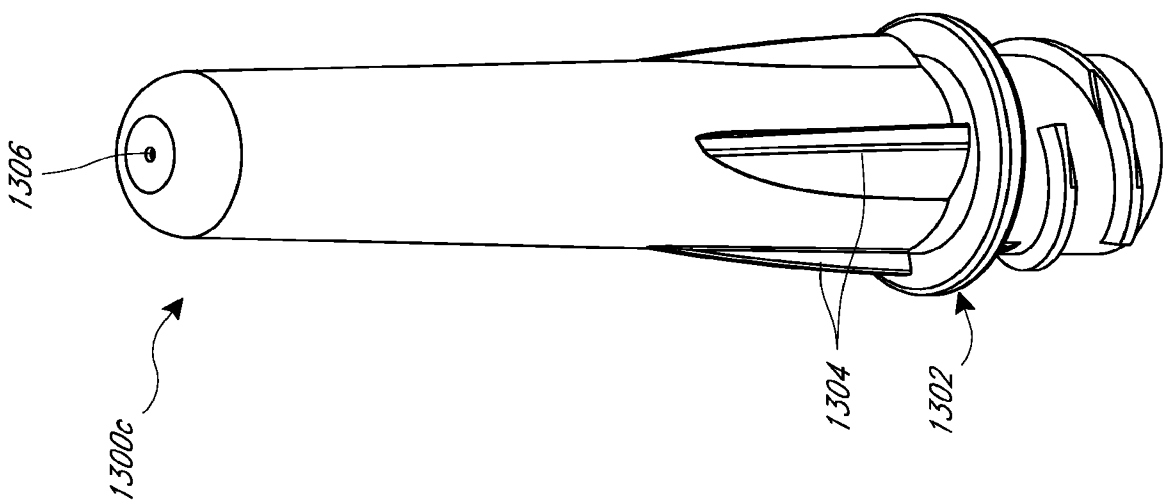

FIG. 34

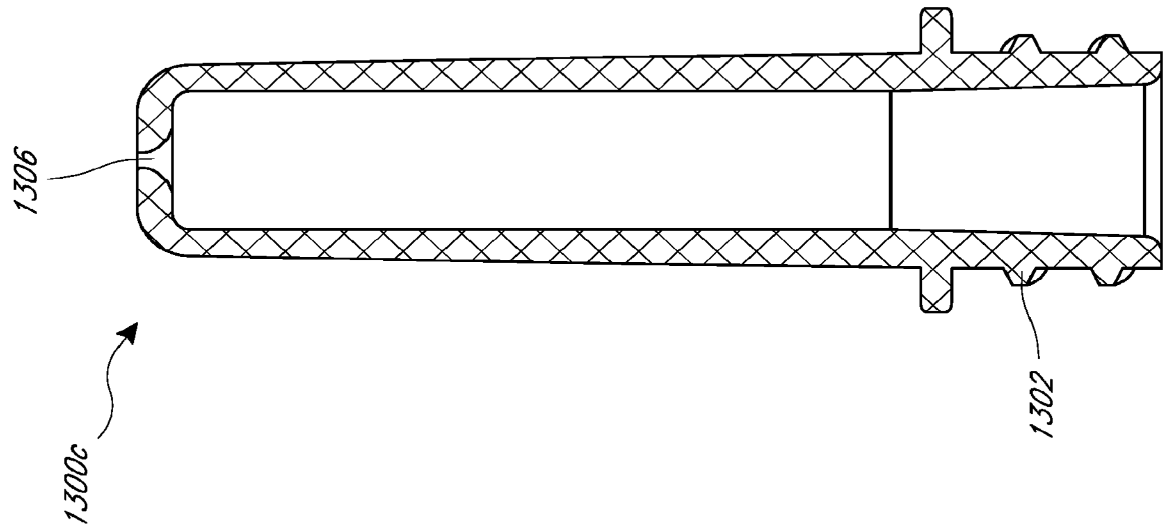

FIG. 35