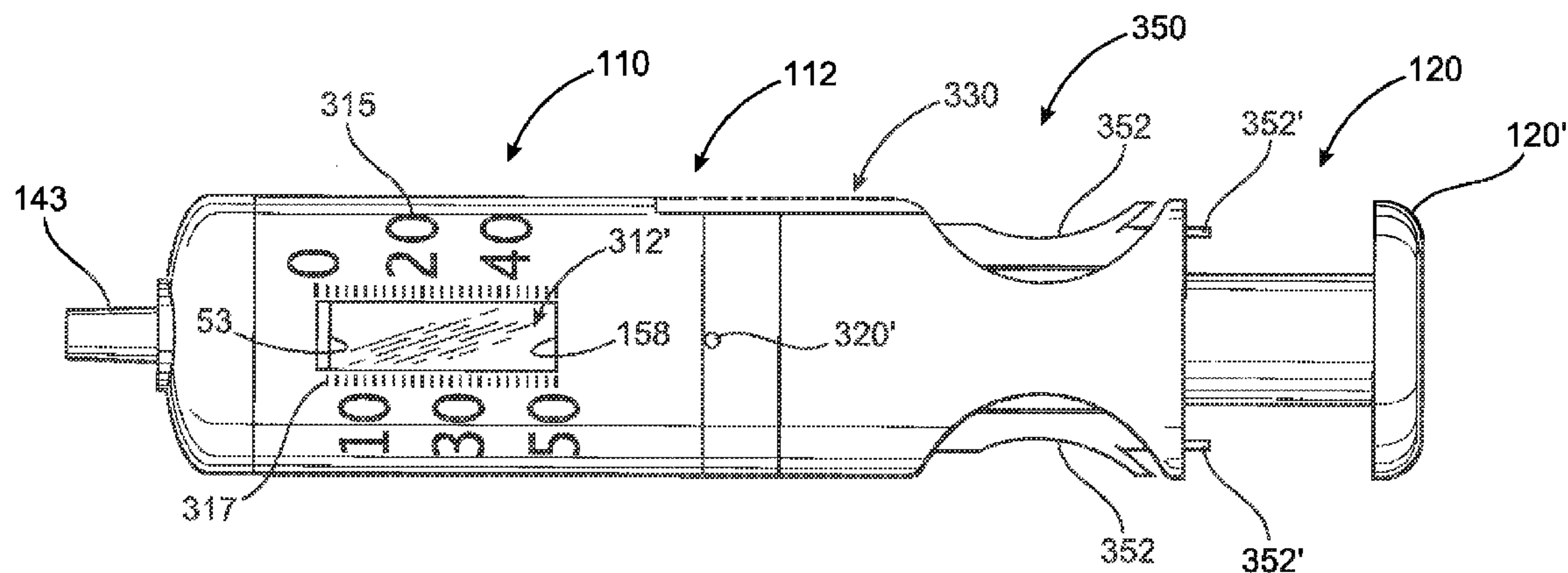
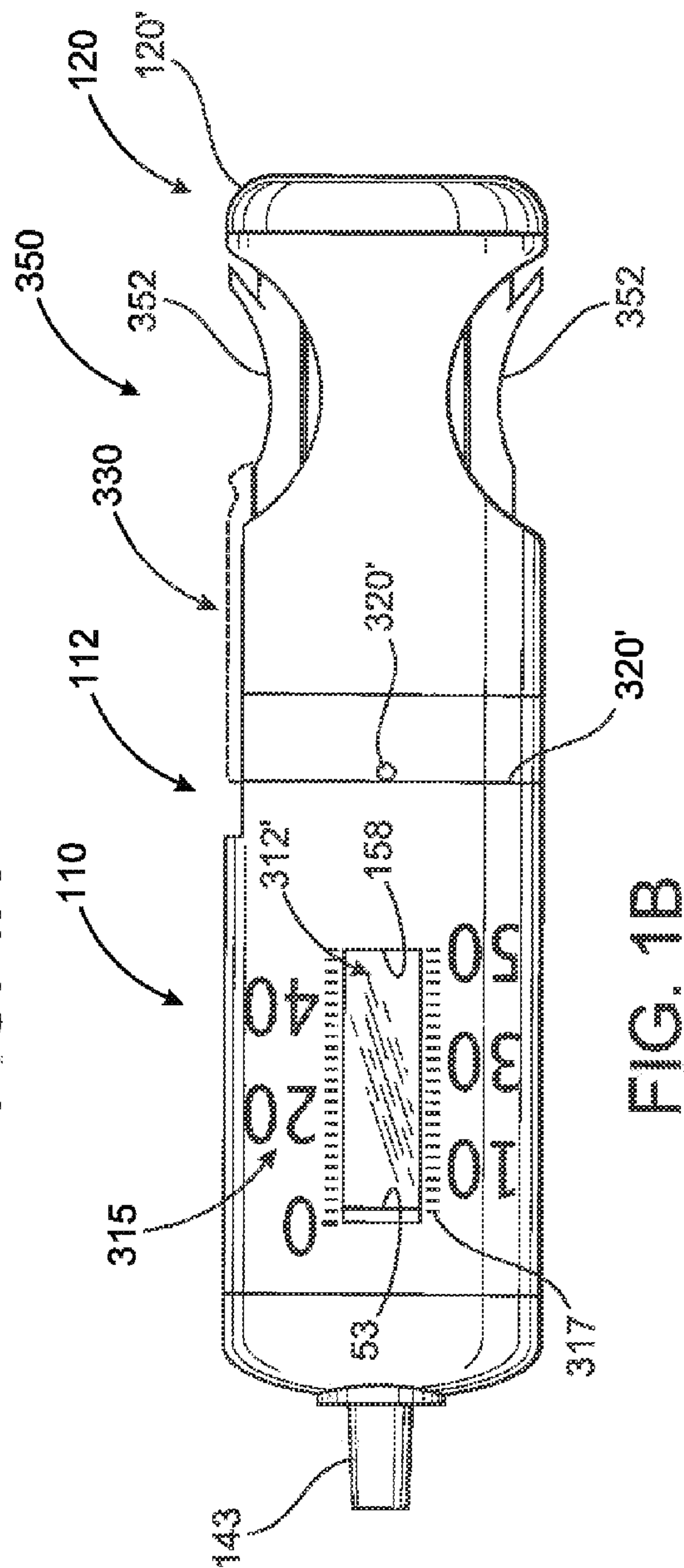
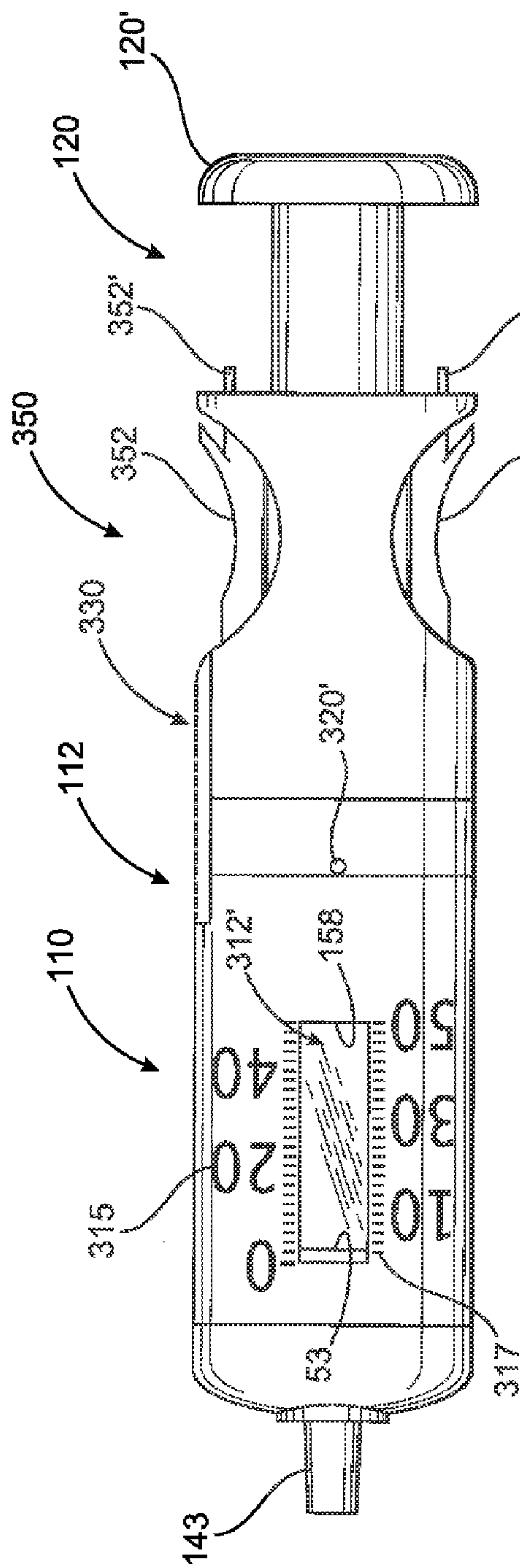


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(19) **United States**(12) **Patent Application Publication**
Lowenstein et al.(10) **Pub. No.: US 2012/0255555 A1**(43) **Pub. Date: Oct. 11, 2012**(54) **INFLATION AND MONITORING ASSEMBLY
FOR A PRESSURE CUFF****Publication Classification**(51) **Int. Cl.**
A61M 16/04 (2006.01)(52) **U.S. Cl.** **128/207.15**(57) **ABSTRACT**

An assembly structured to inflate a retaining or pressure cuff of a medical device of the type associated with artificial airway tube and concurrently monitor pressure therein. A pump assembly is movably connected to a casing and structured to force fluid flow, for inflation of a pressure chamber of the casing. An indicator member is visually accessible through a casing window and is variably positionable dependent on and indicative of existing pressure within the retaining cuff. The existing pressure within the pressure chamber is substantially equivalent to that within the retaining cuff thereby facilitating the variable position of the indicator member being indicative of pressure within the retaining cuff. A junction between the casing and an inflation lumen is structured to allow disconnection and prevent reconnection between the casing and the lumen.

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Sellers**, Portsmouth, NH (US)(21) Appl. No.: **13/421,288**(22) Filed: **Mar. 15, 2012****Related U.S. Application Data**(63) Continuation-in-part of application No. 13/005,359,
filed on Jan. 12, 2011, which is a continuation-in-part
of application No. 12/806,810, filed on Aug. 20, 2010,
which is a continuation-in-part of application No.
12/661,103, filed on Mar. 10, 2010.



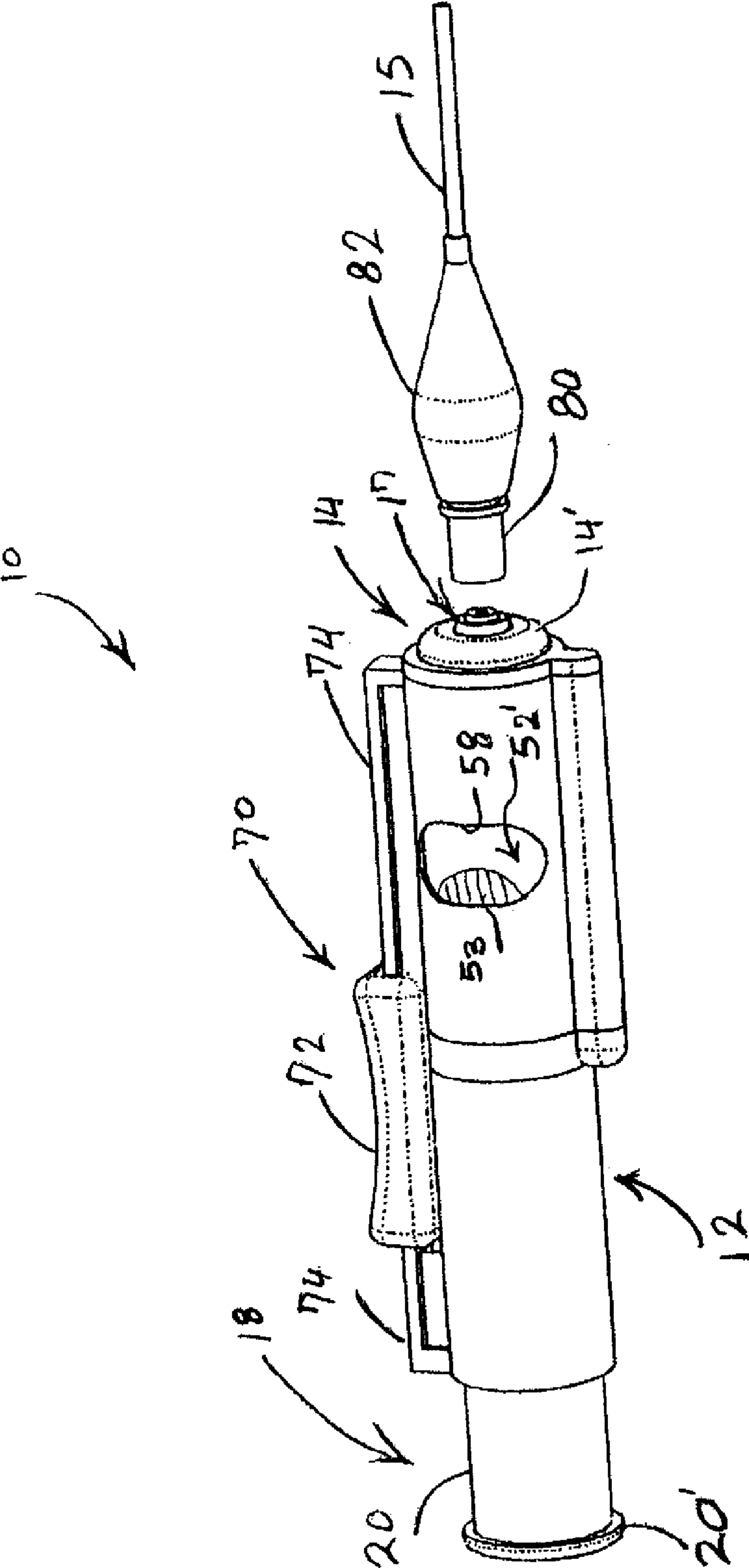


FIG. 1C

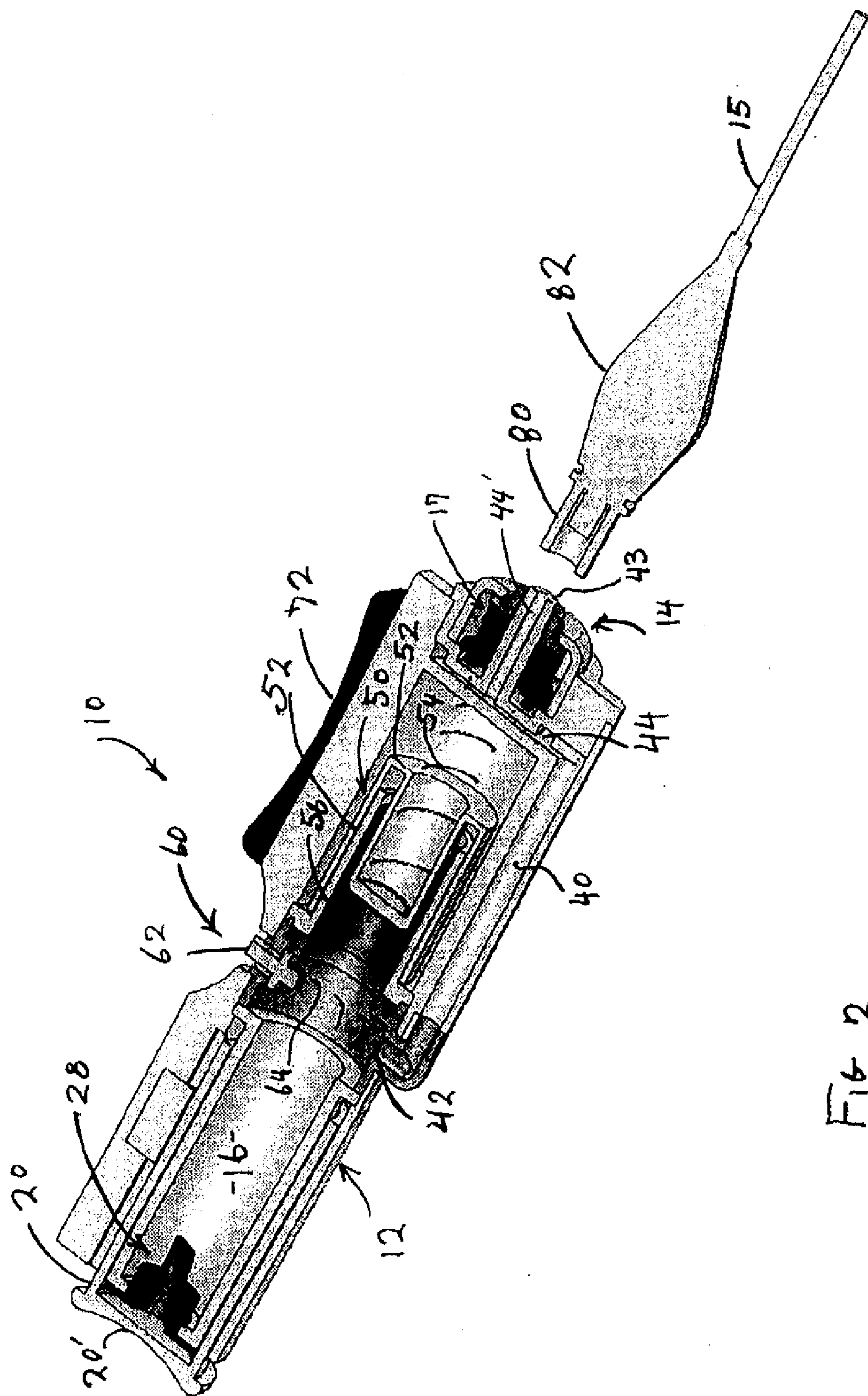
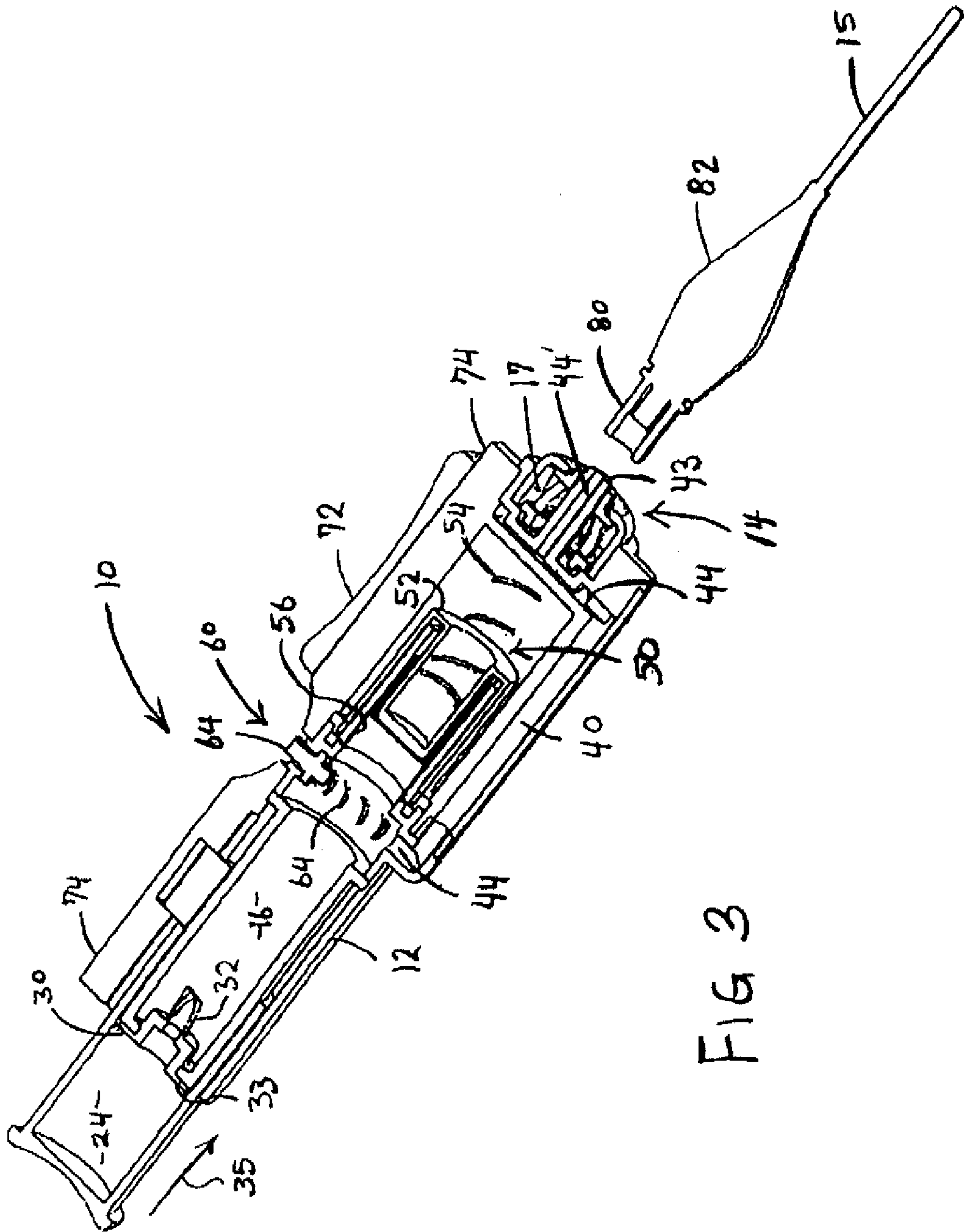


Fig. 2



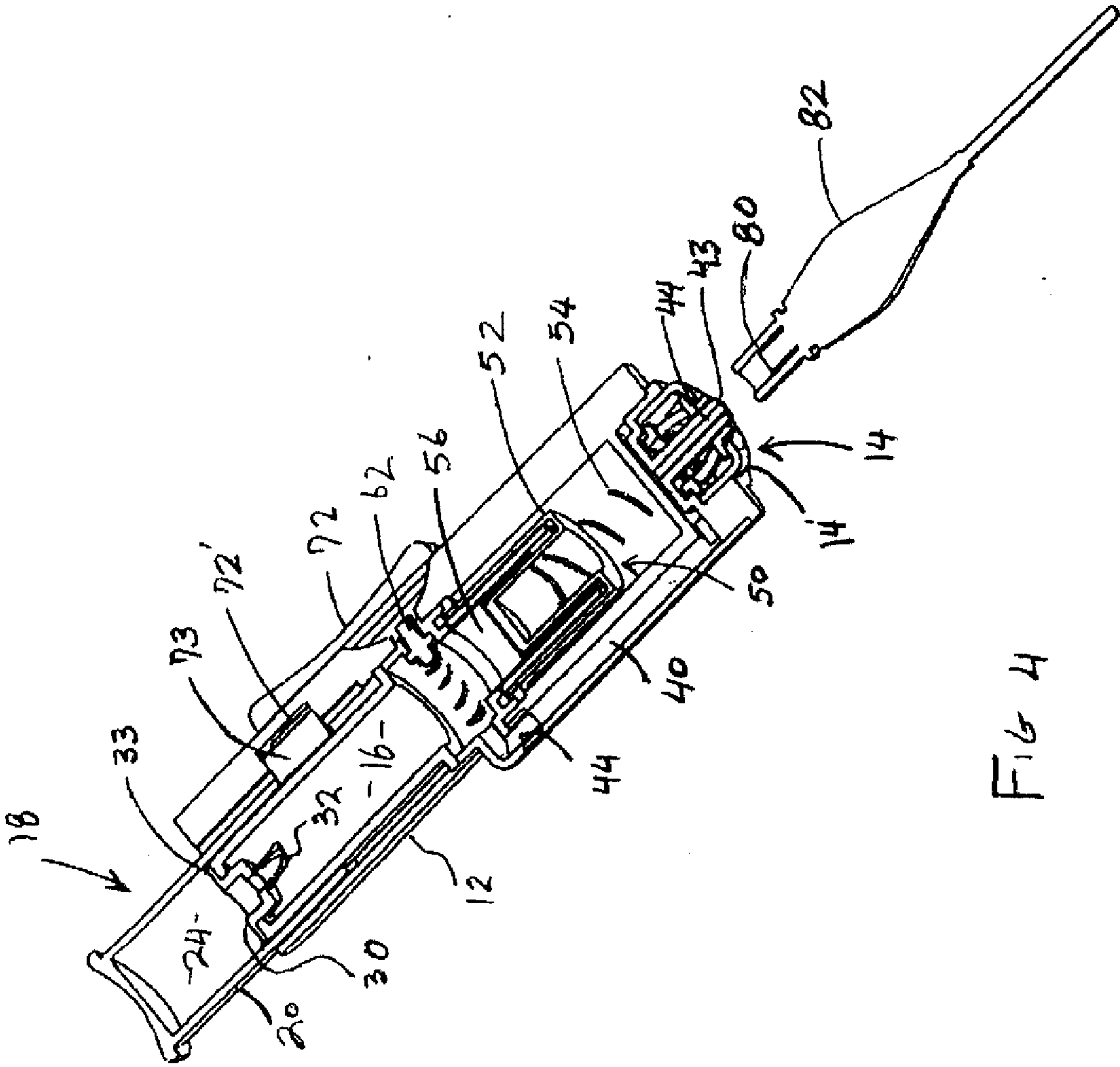
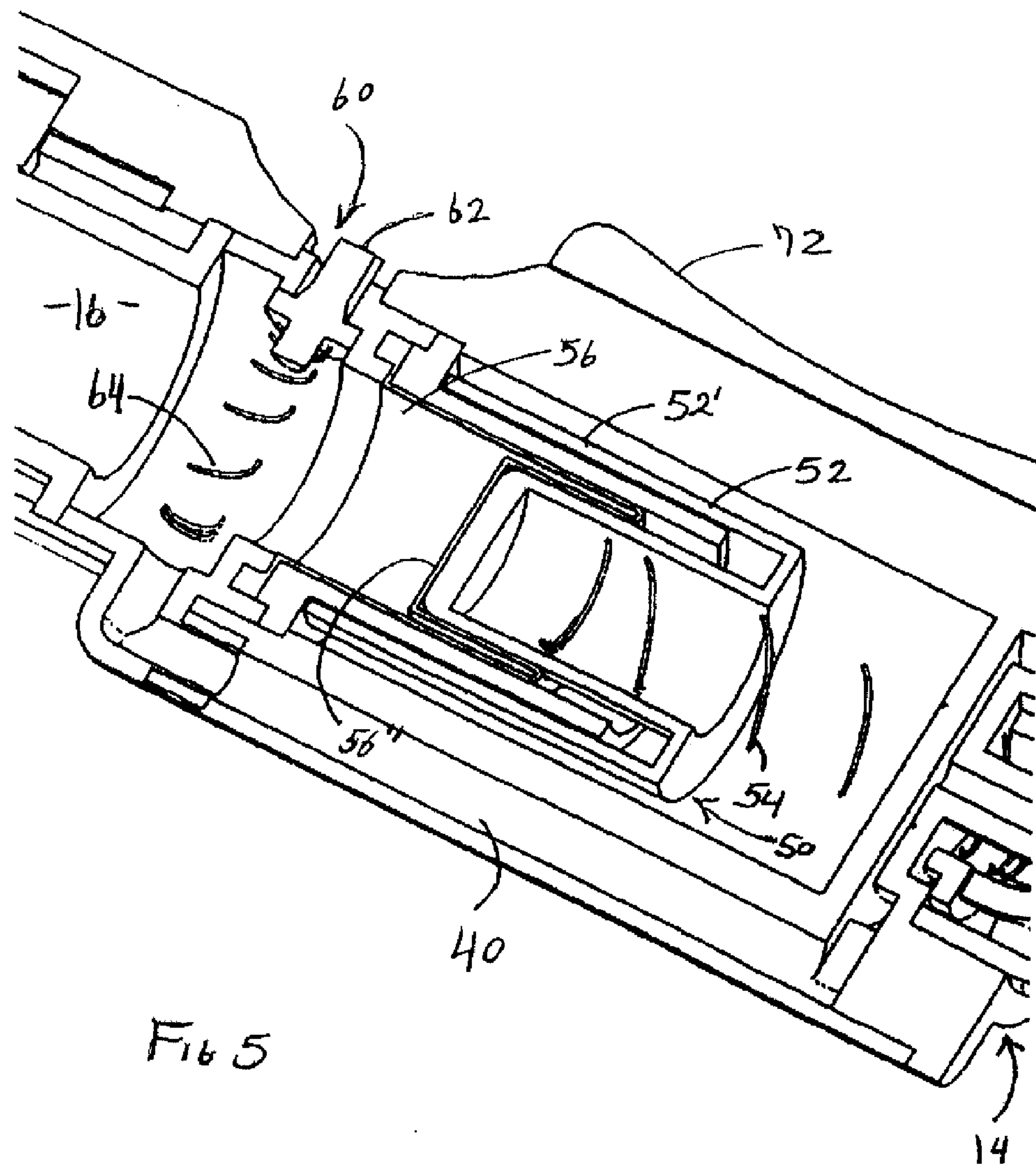


Fig 4



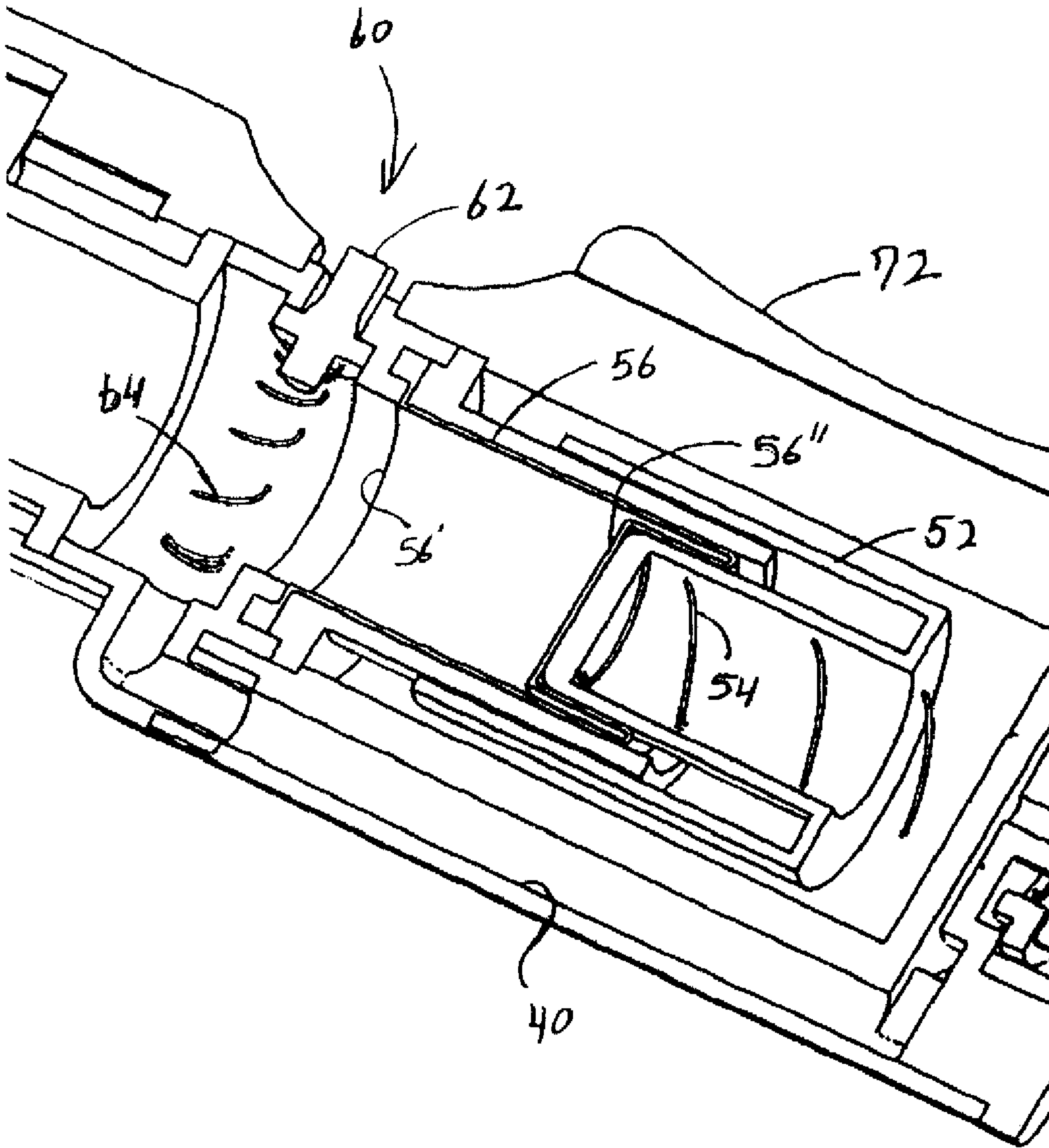


FIG 6

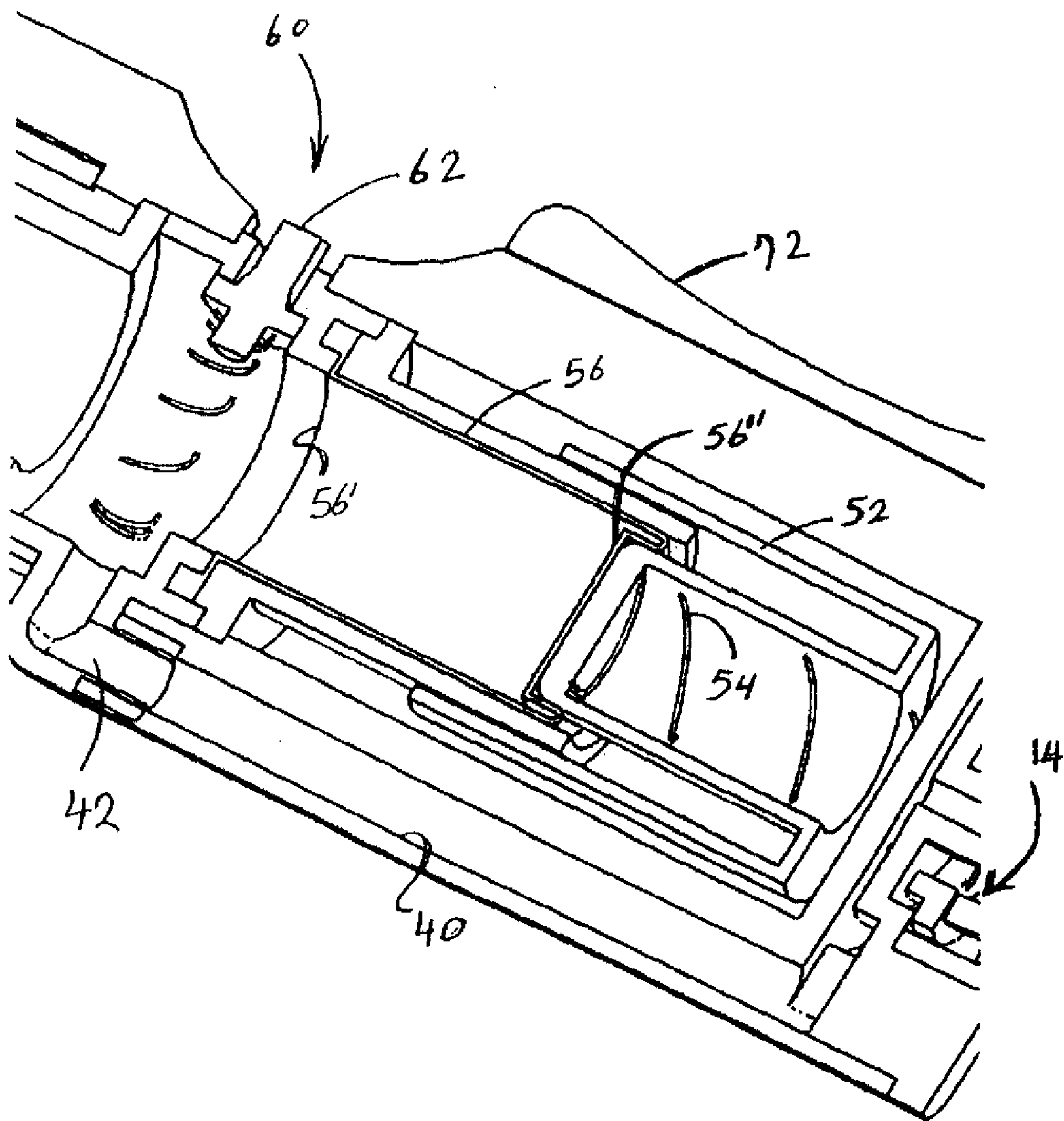


Fig 7

FIG. 8

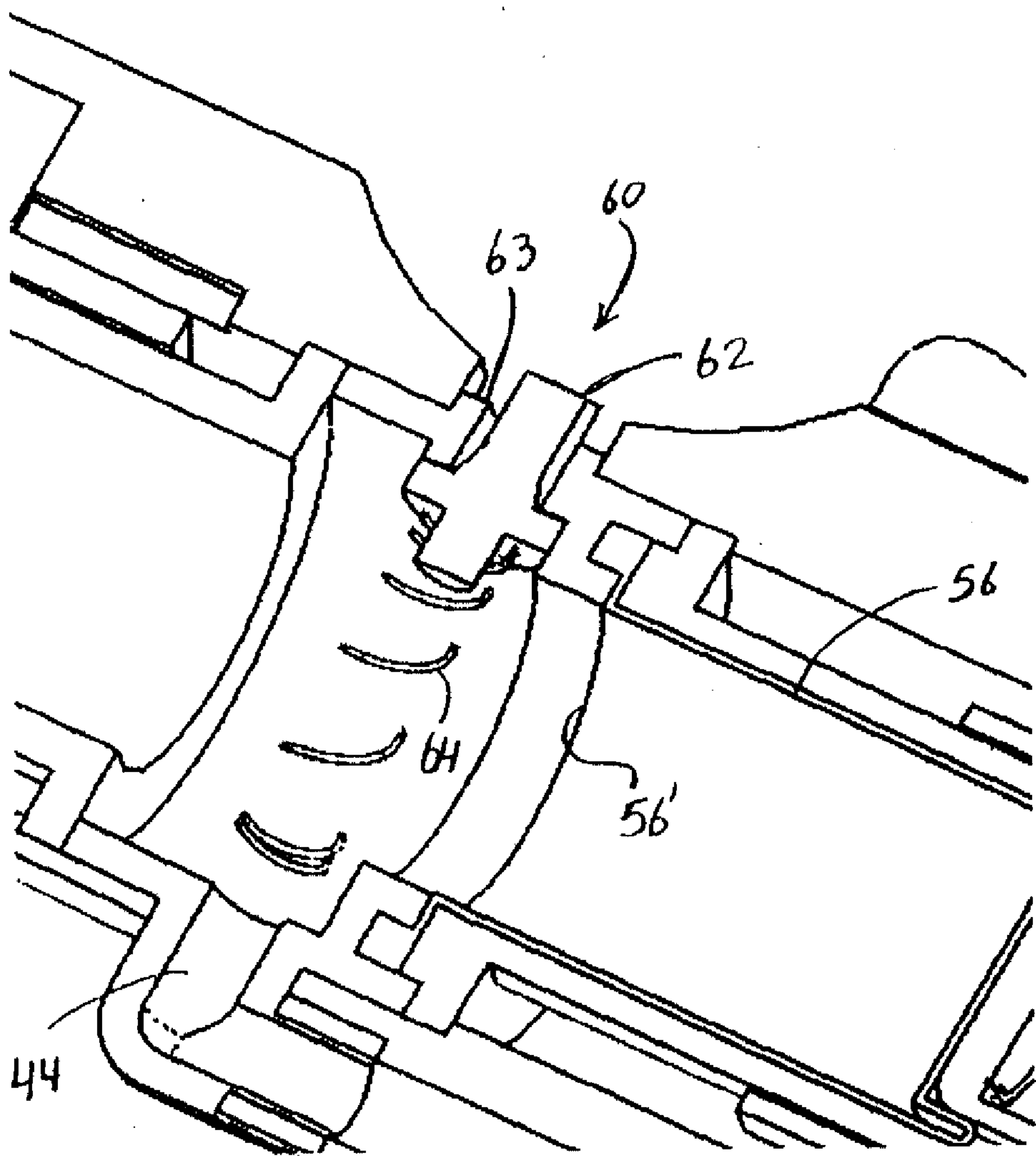
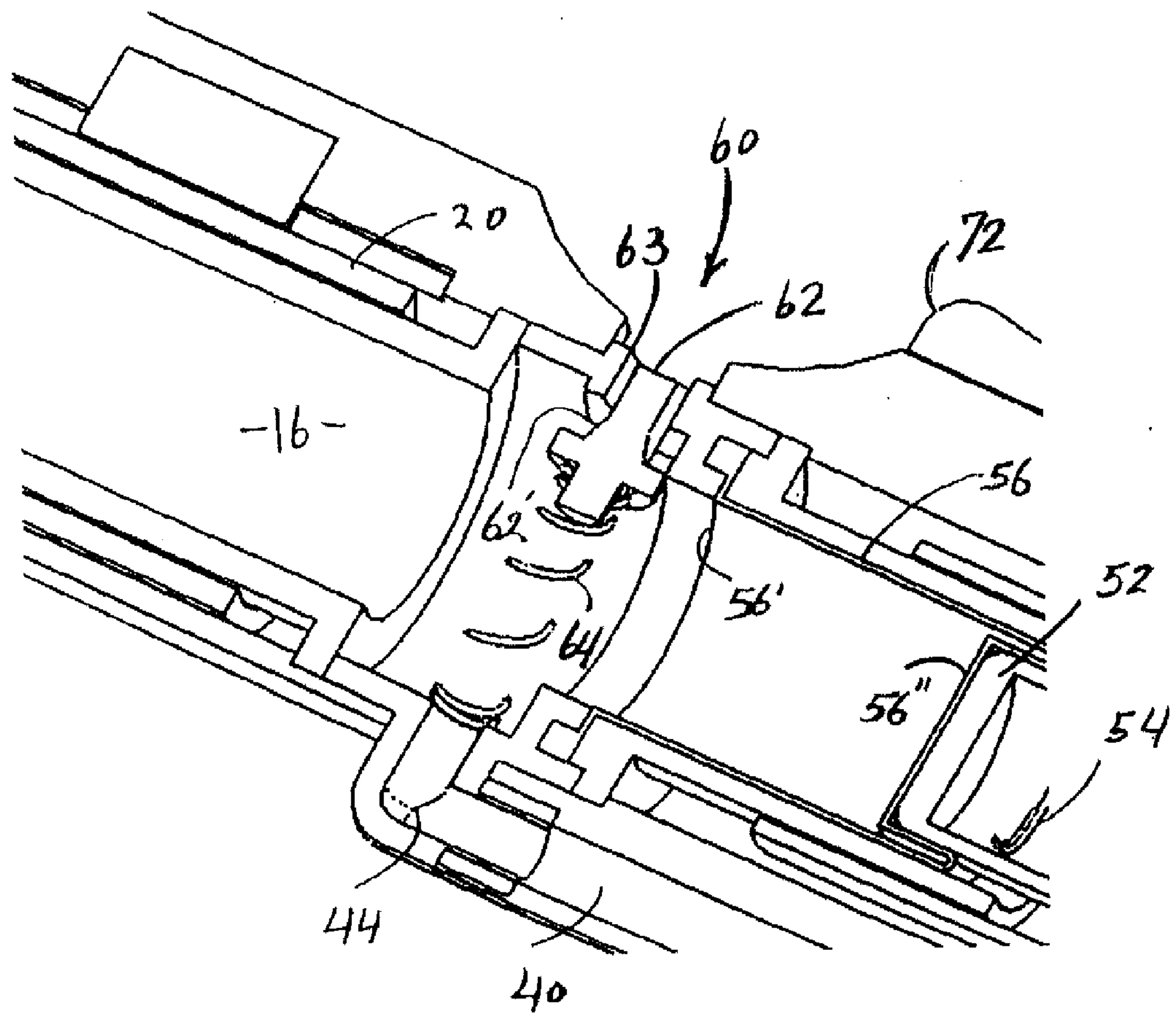


FIG 9



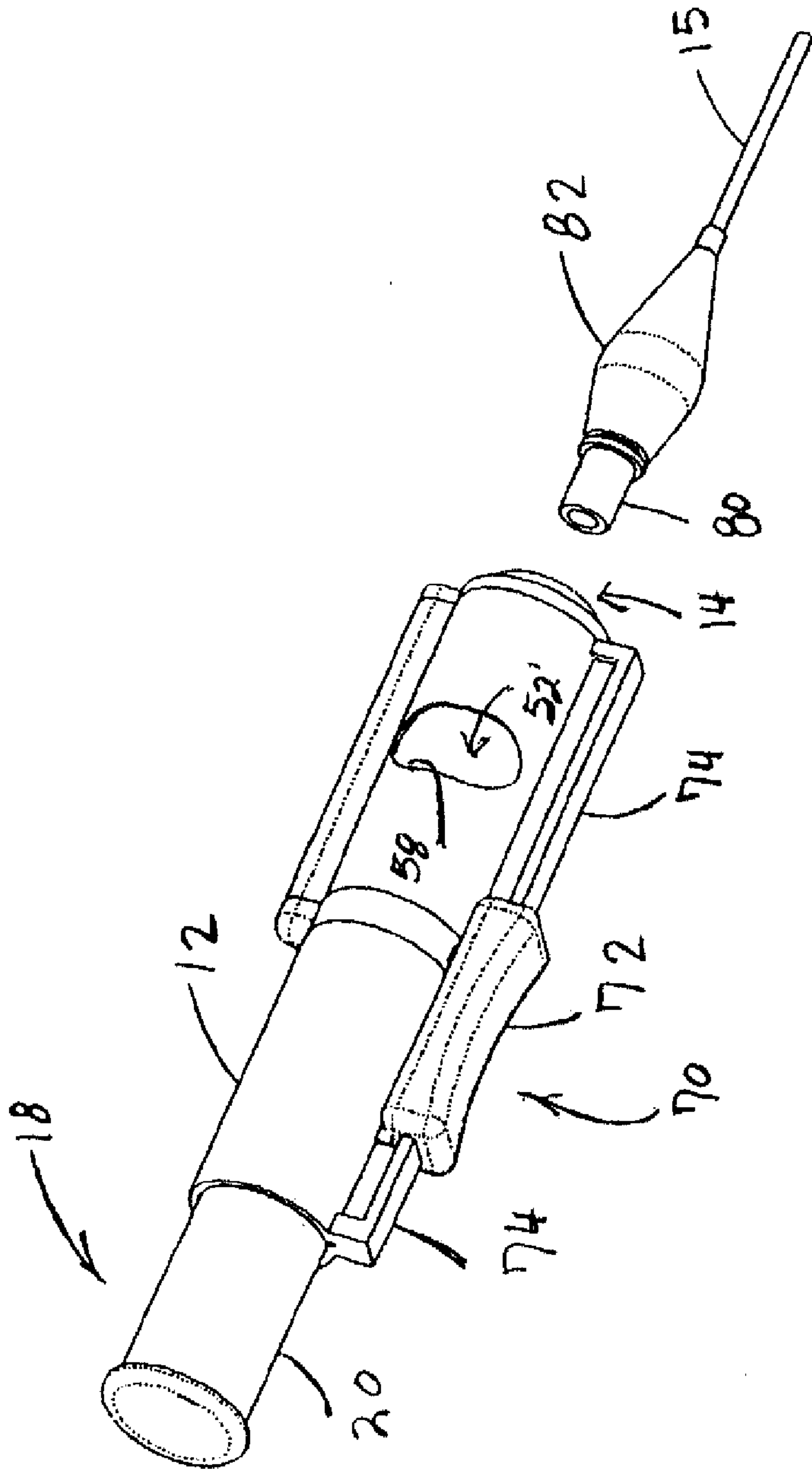


FIG. 10

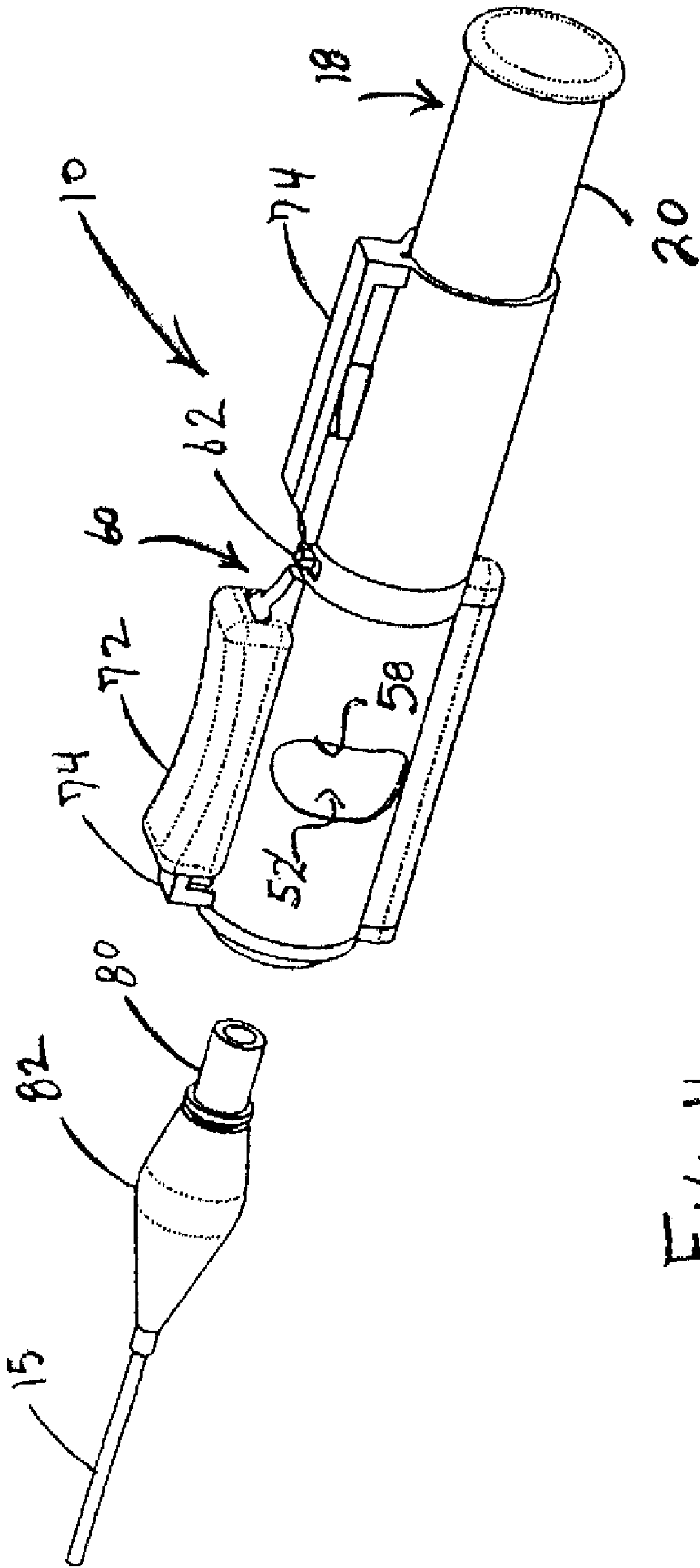


FIG 11

Fig 12

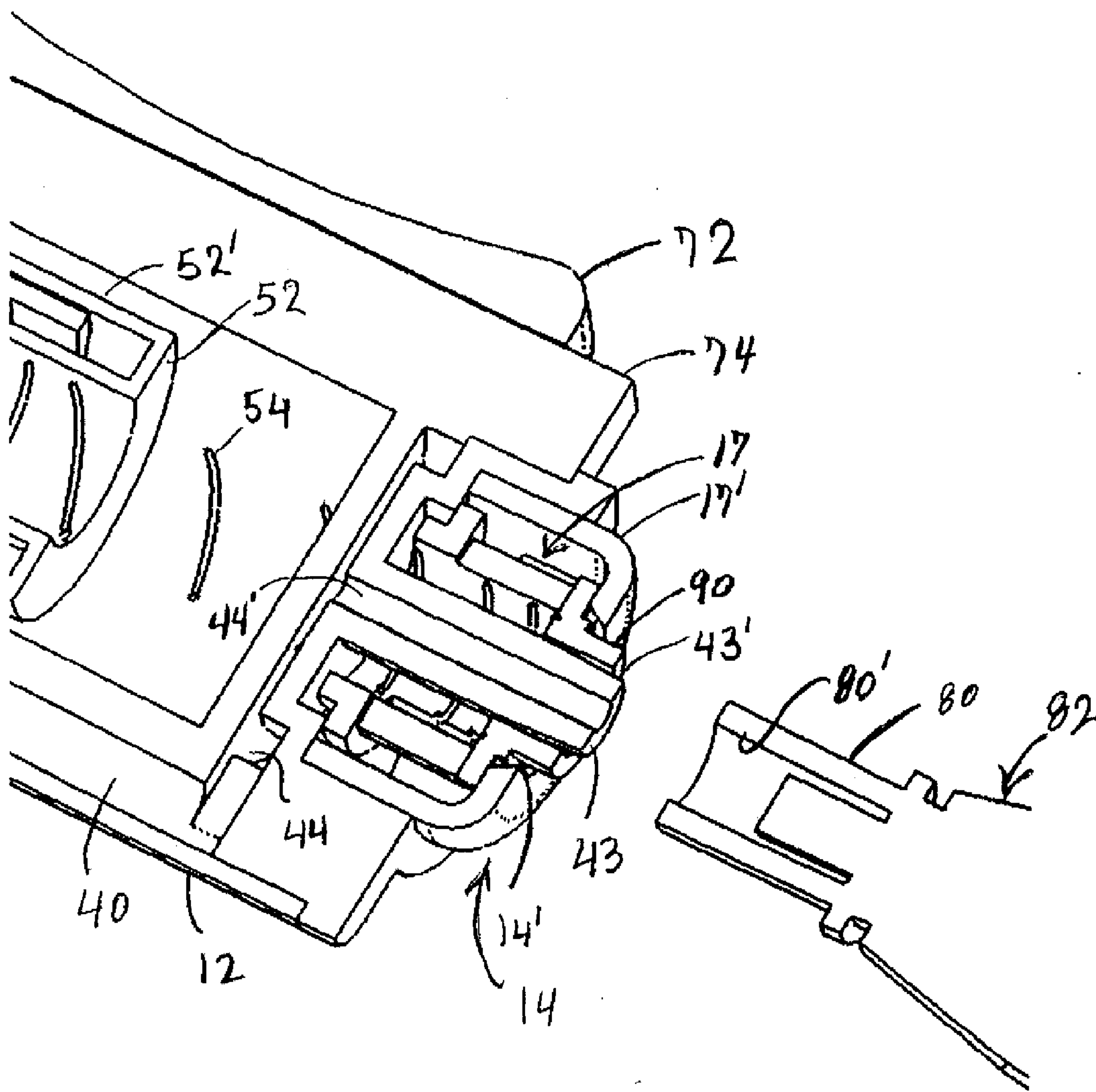
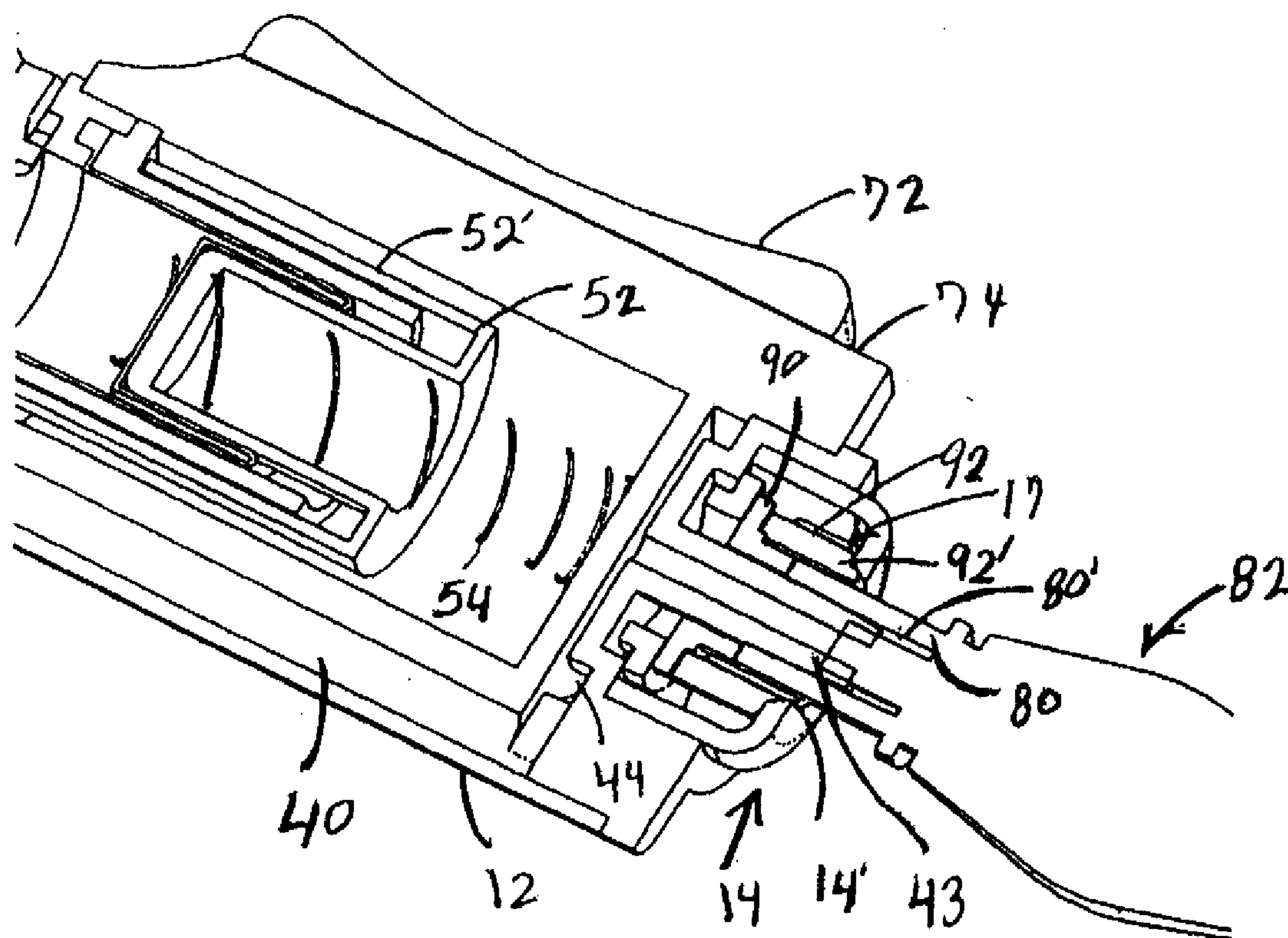
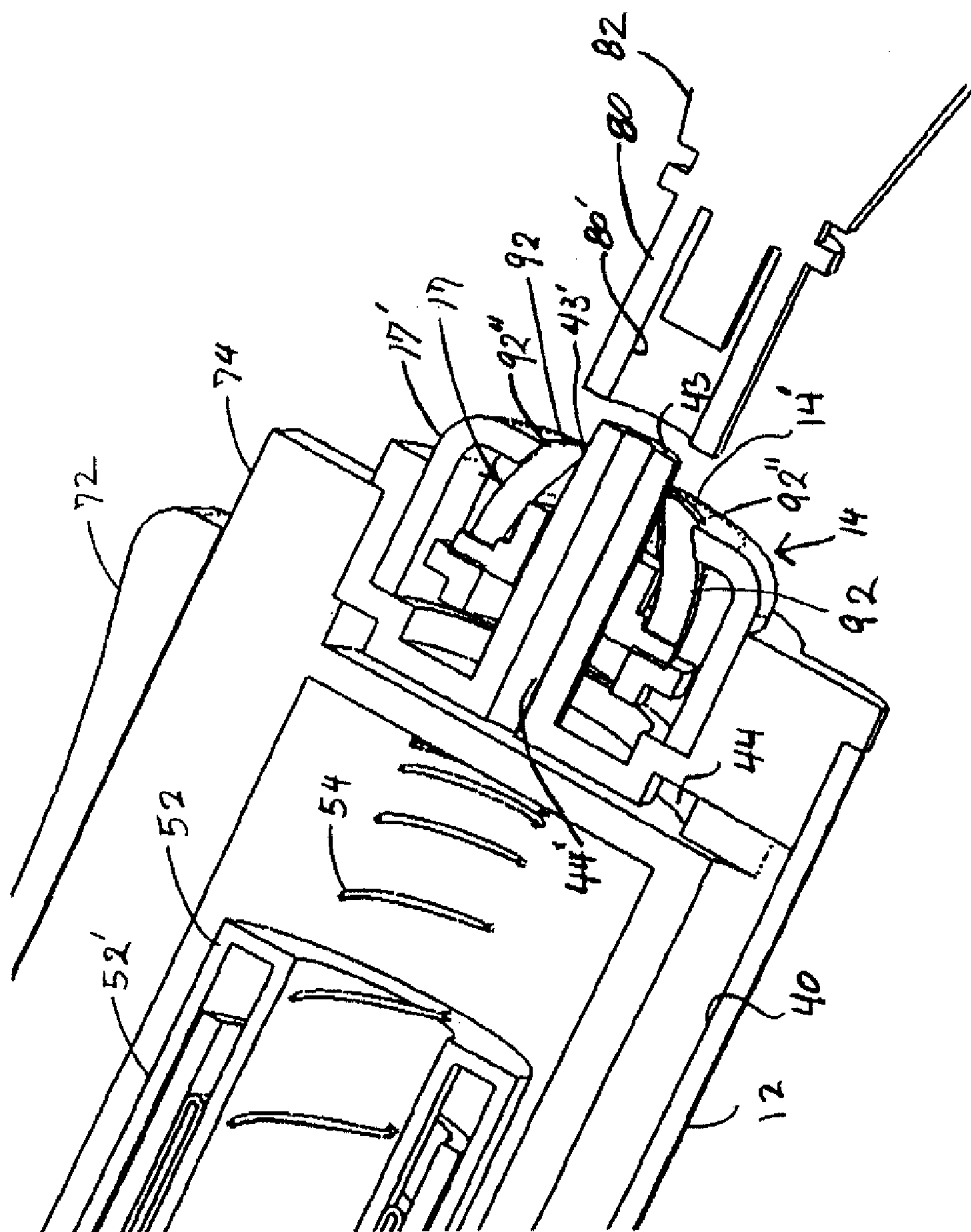


FIG 13





F16 14

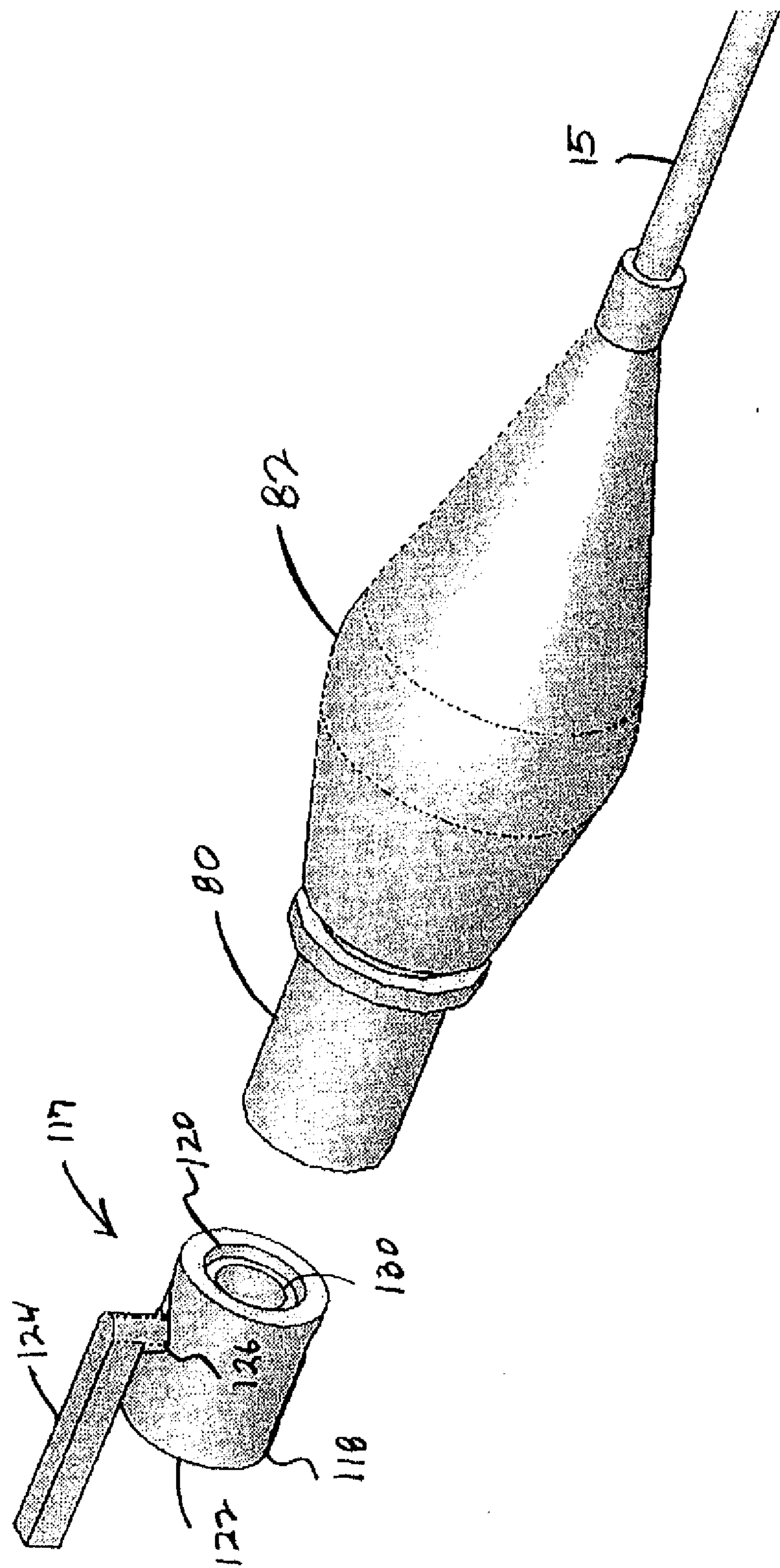
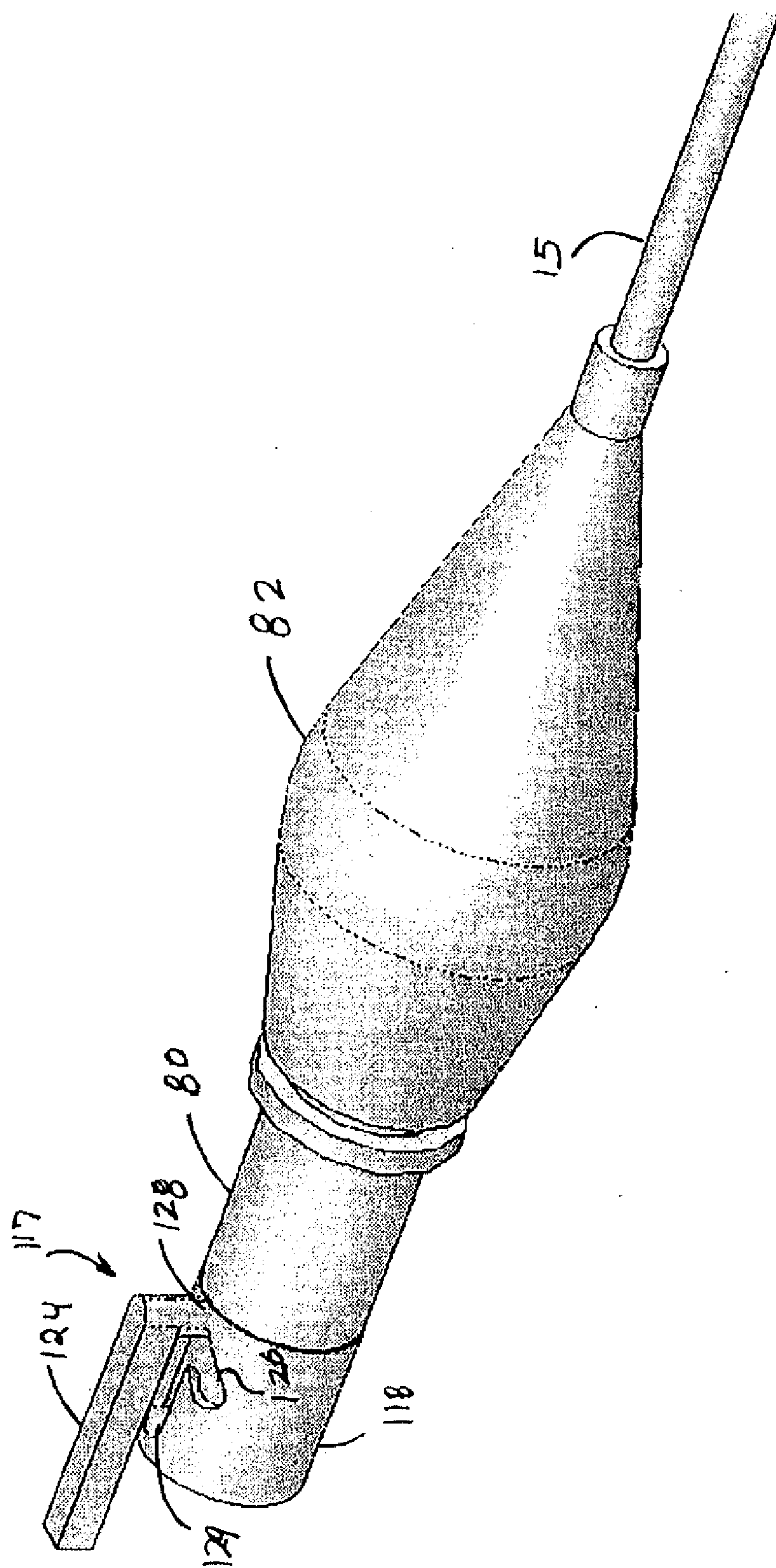


Fig 15



F16-16

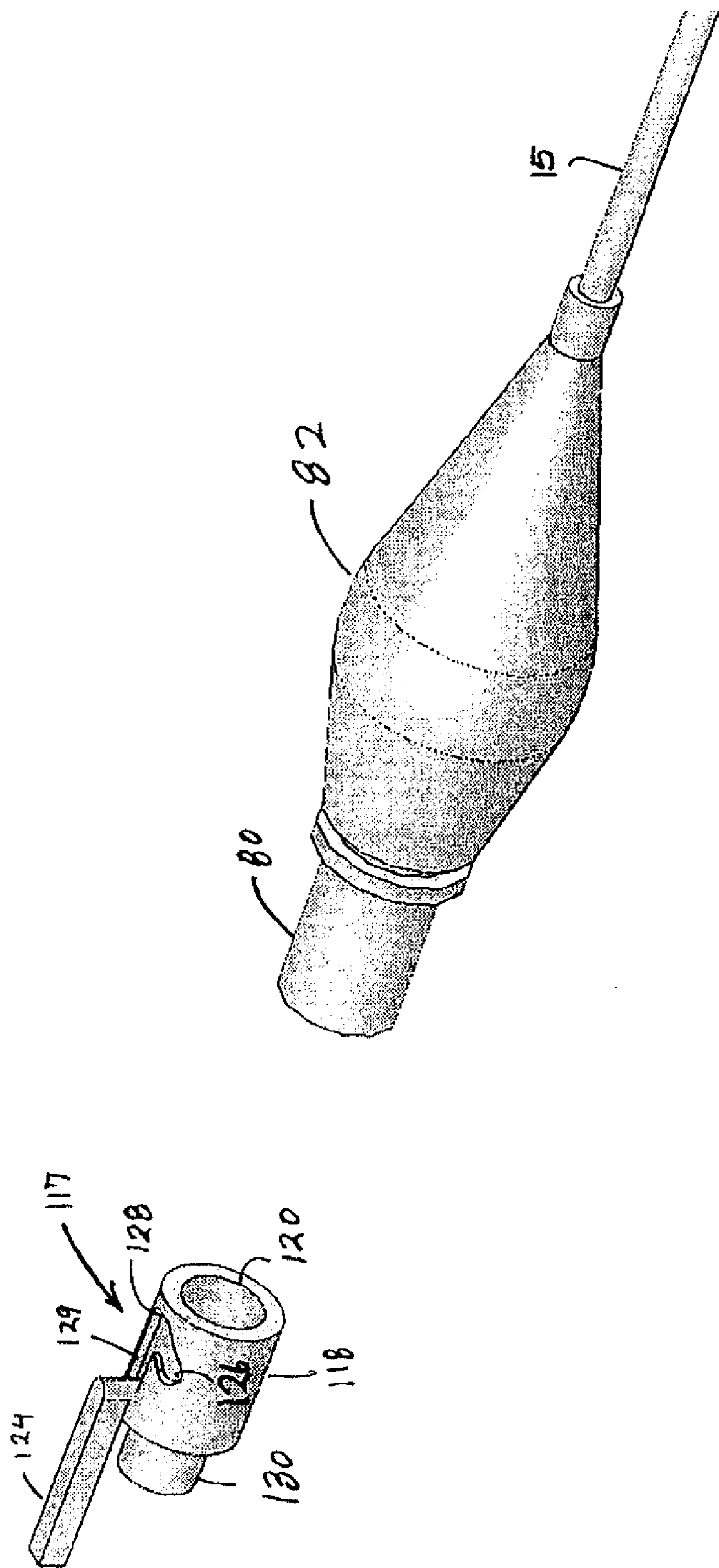


Fig 17

FIG 18

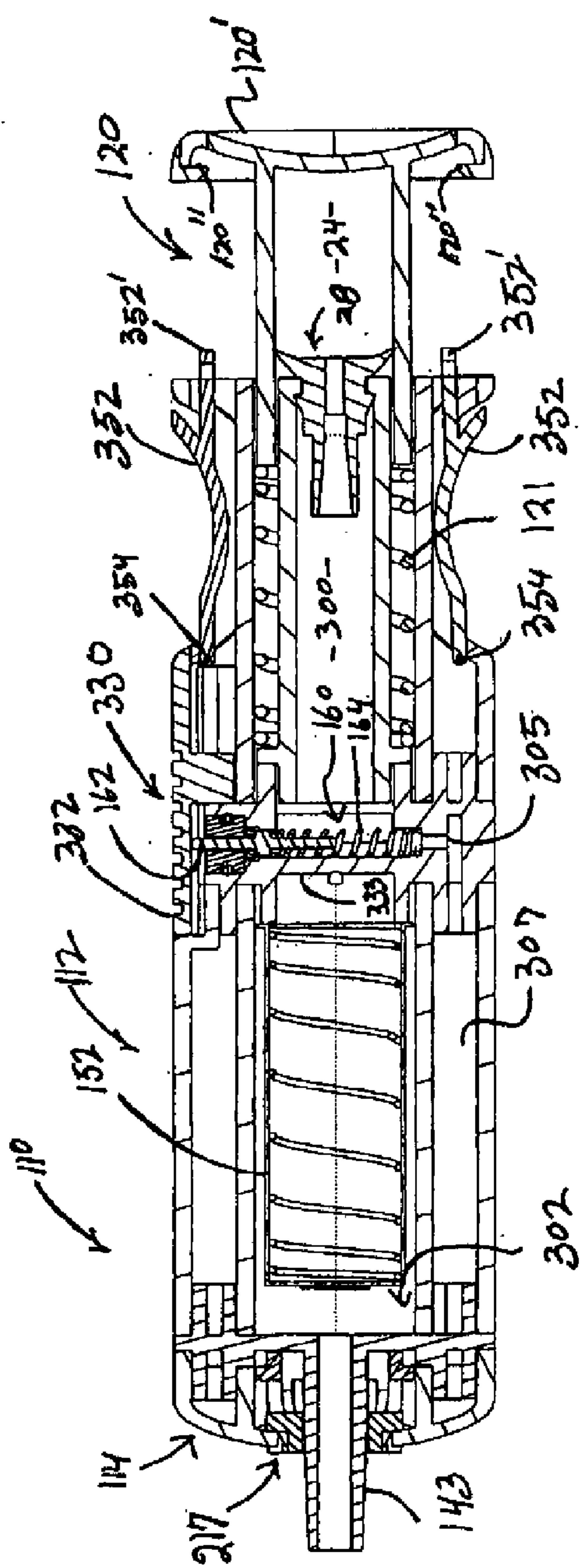


FIG 19

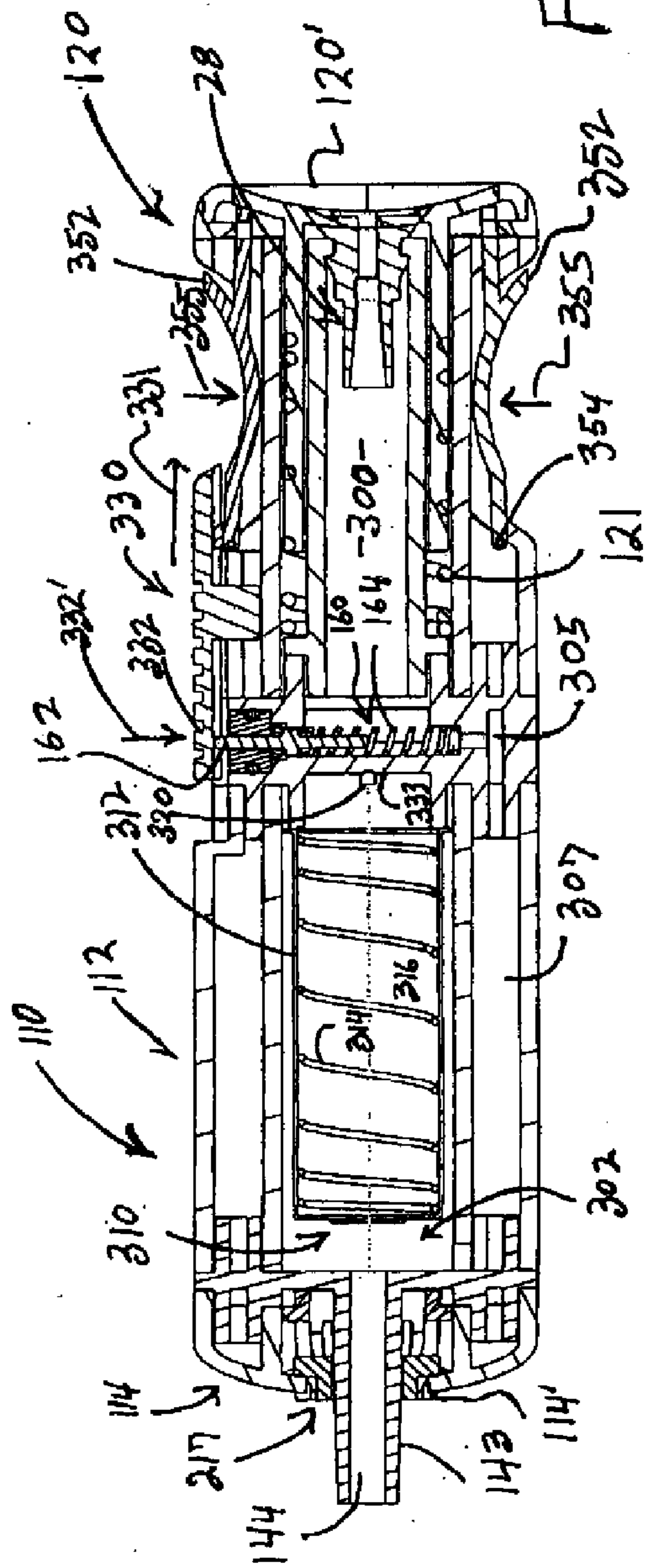
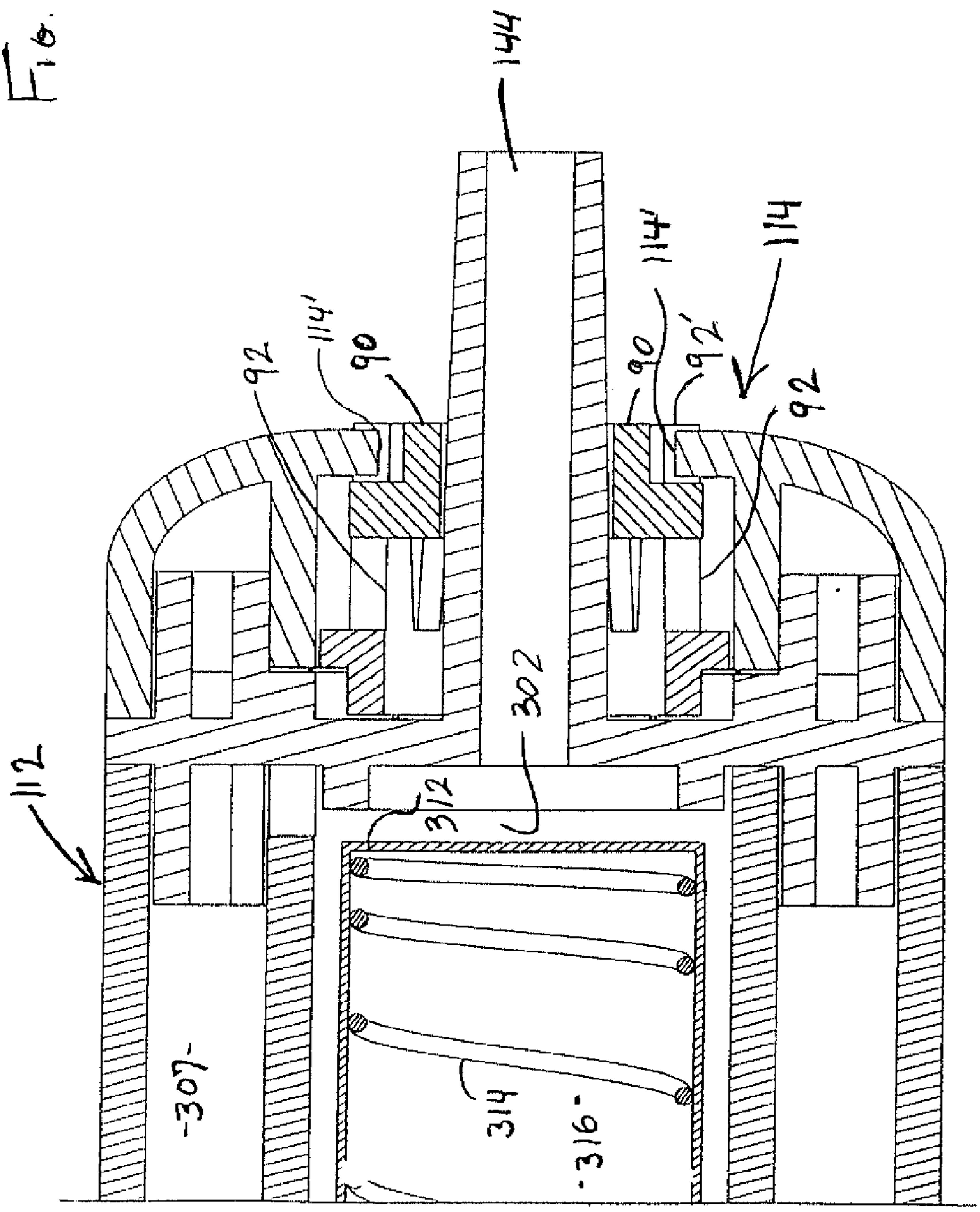
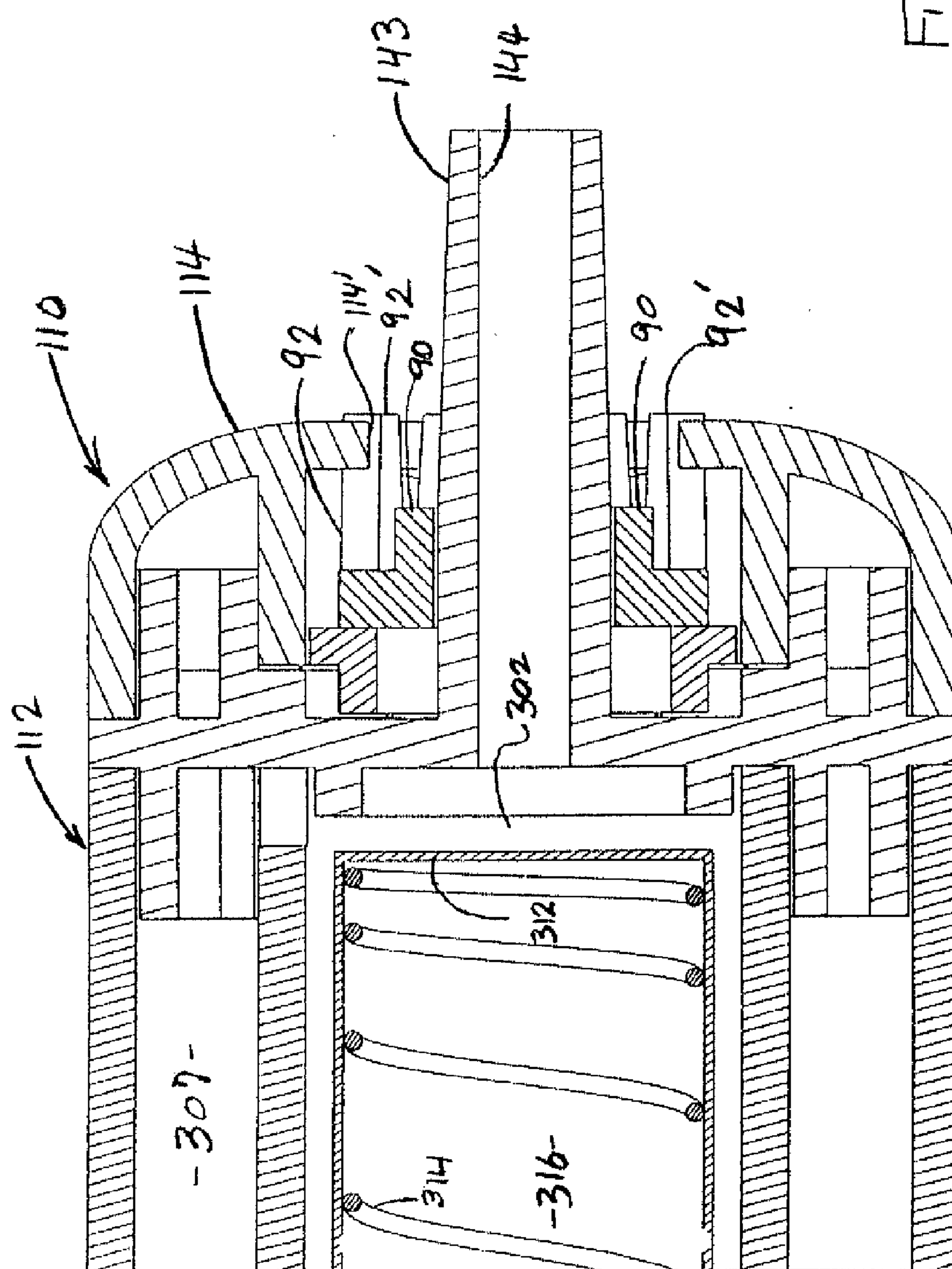
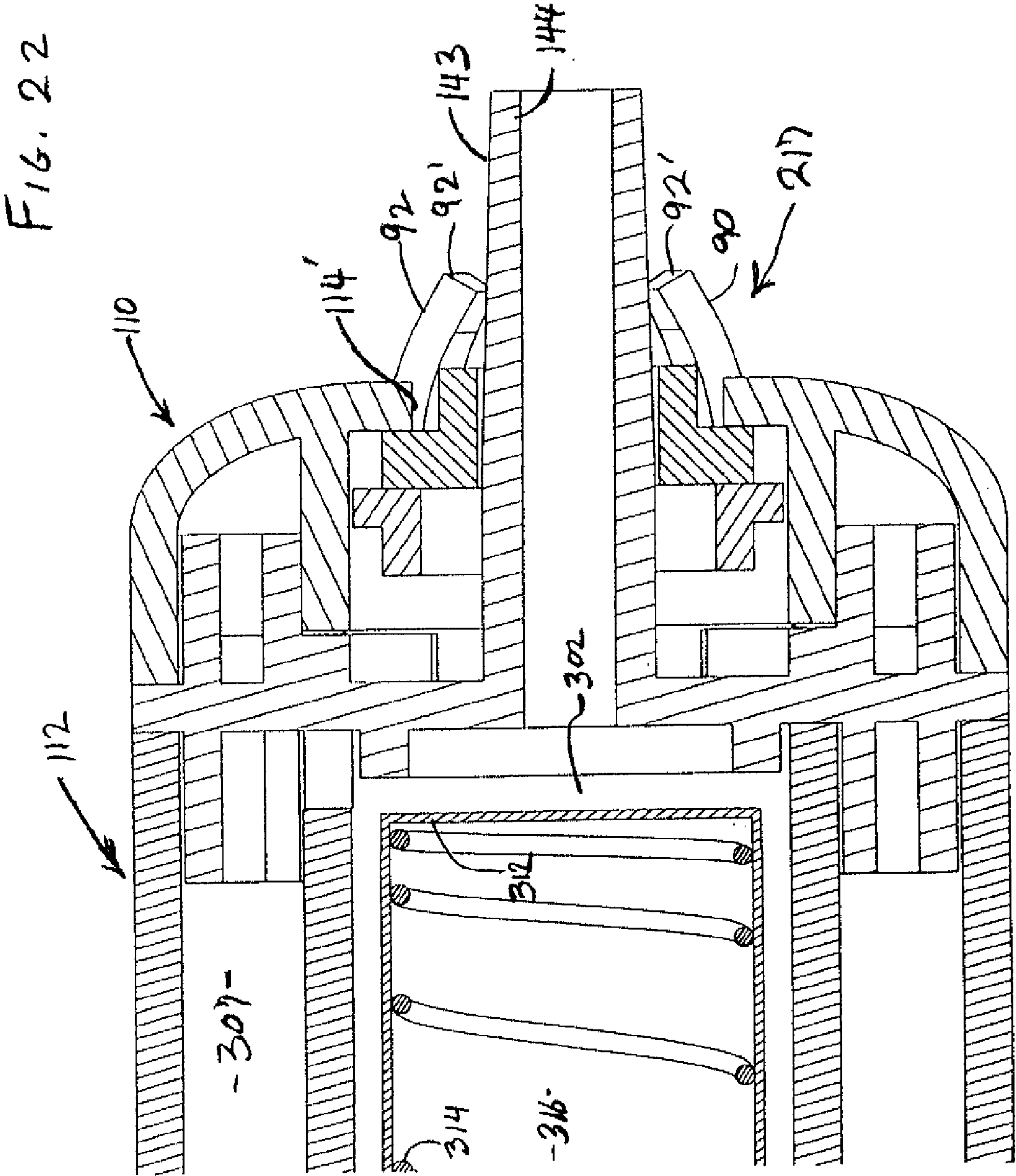


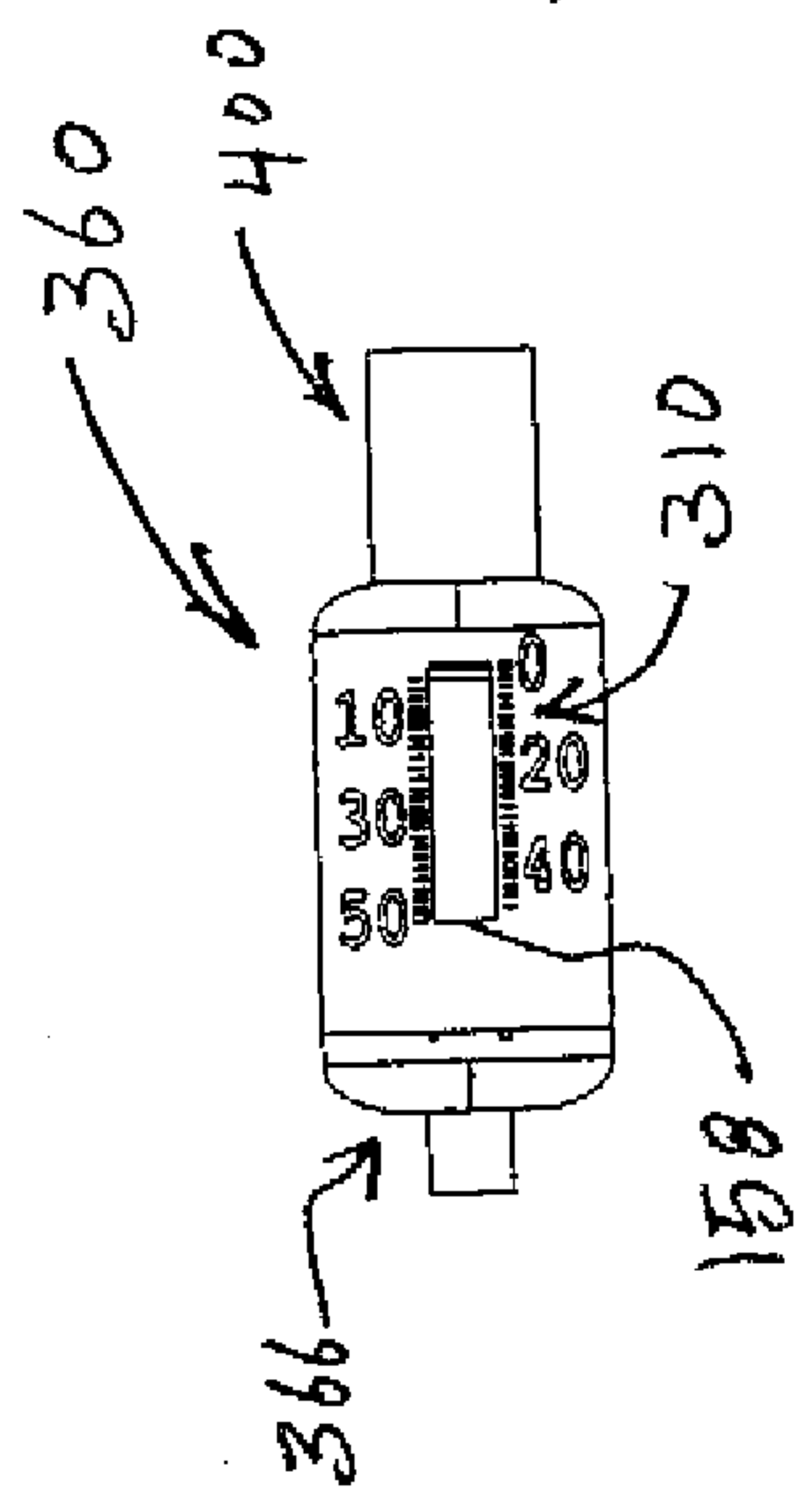
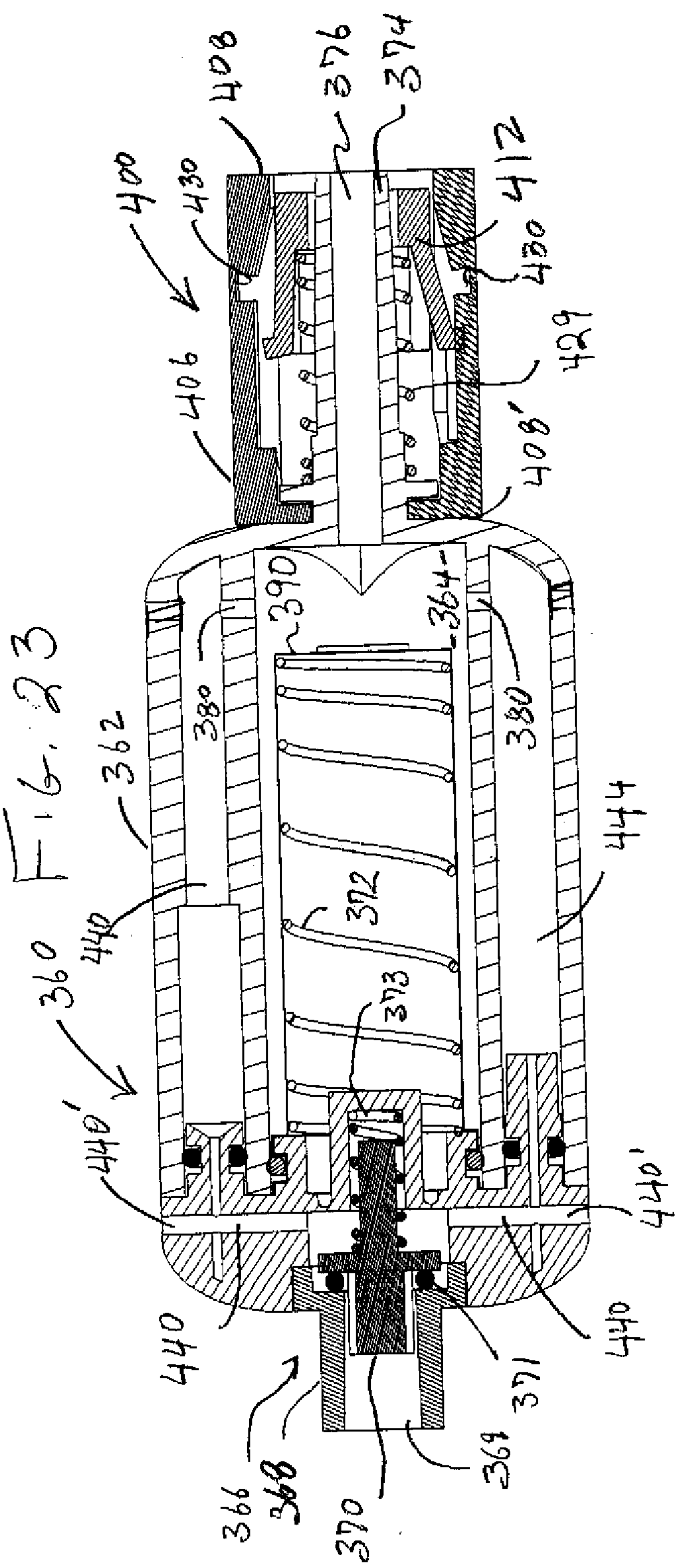
Fig. 20





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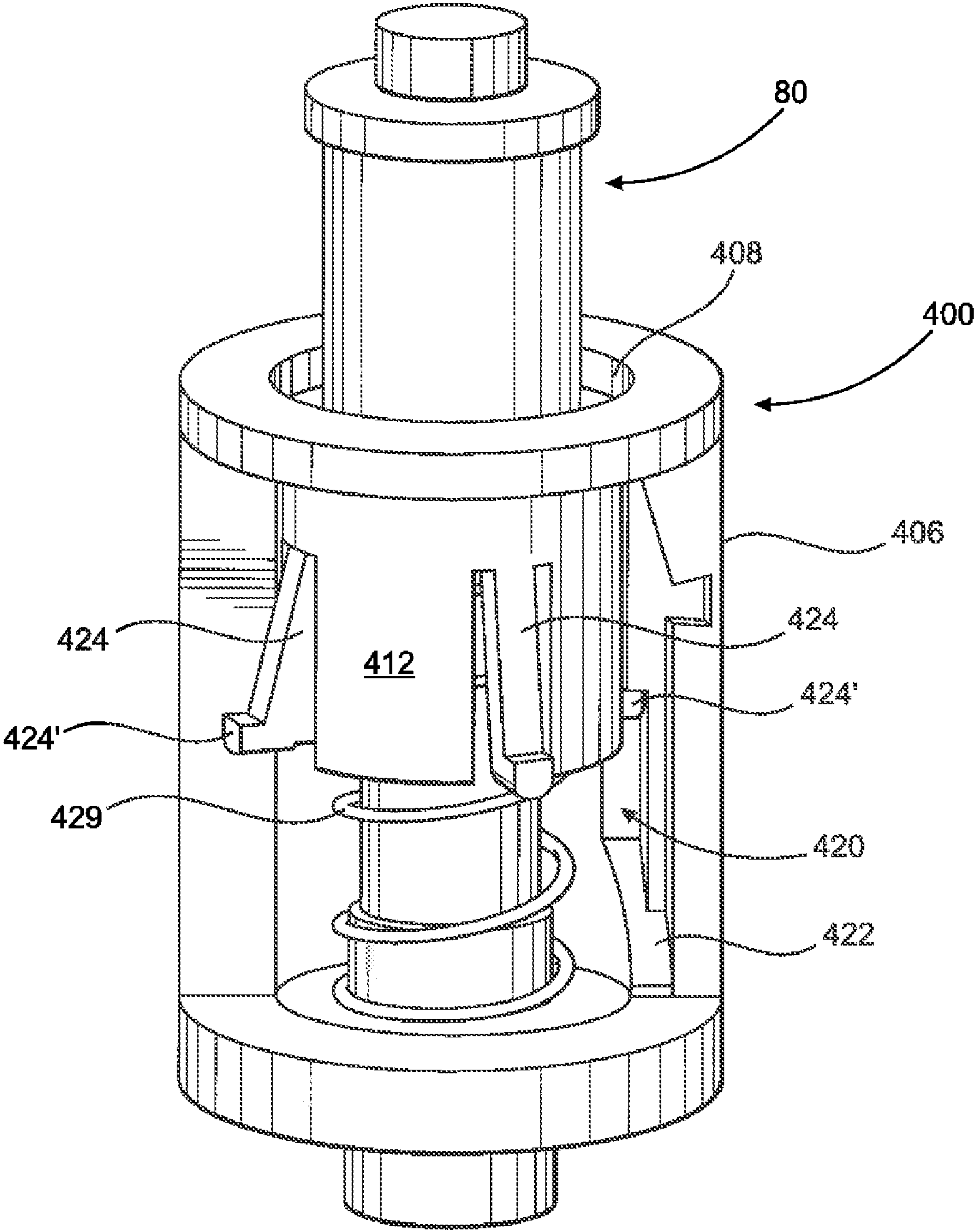


FIG. 25

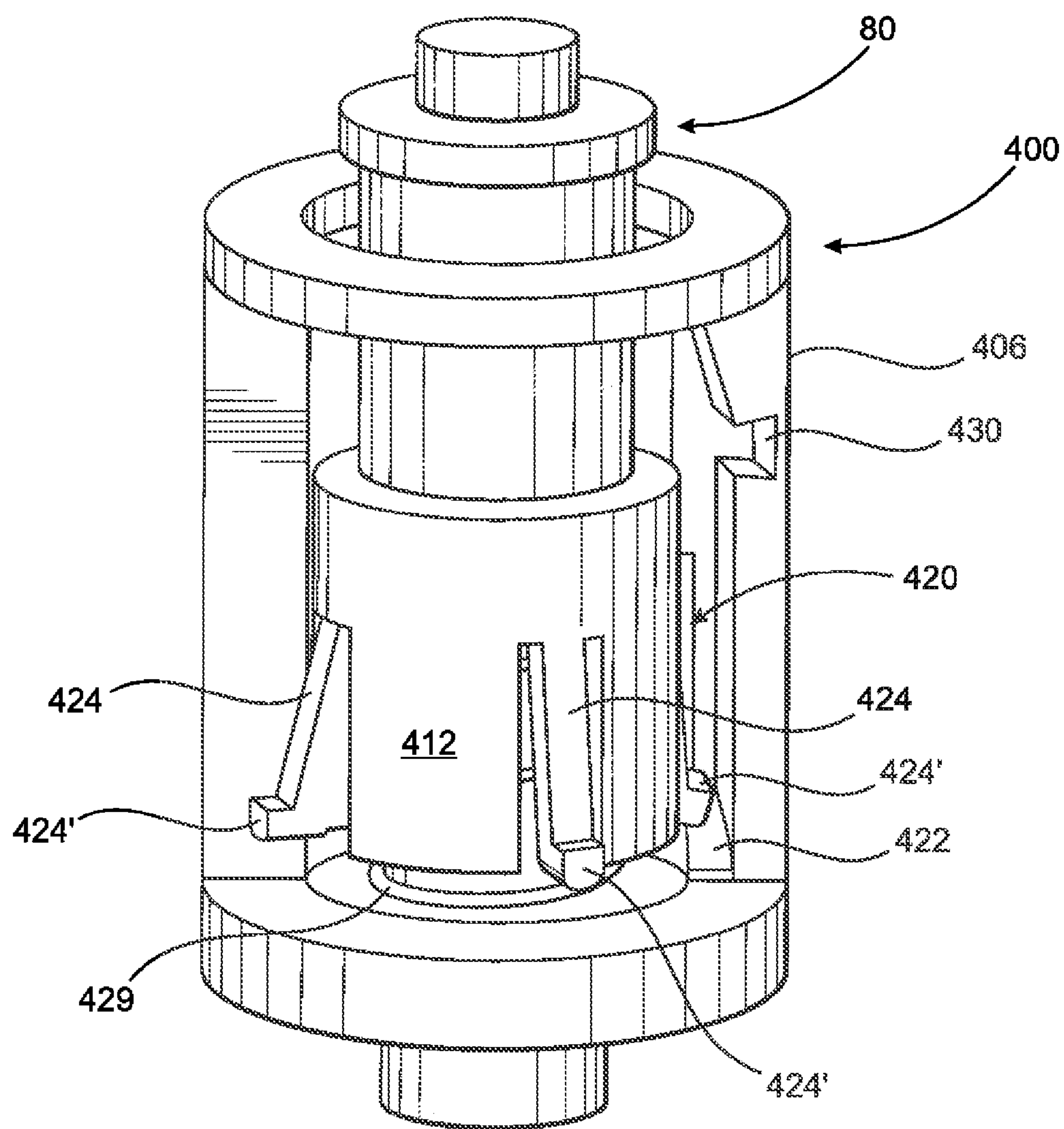


FIG. 26

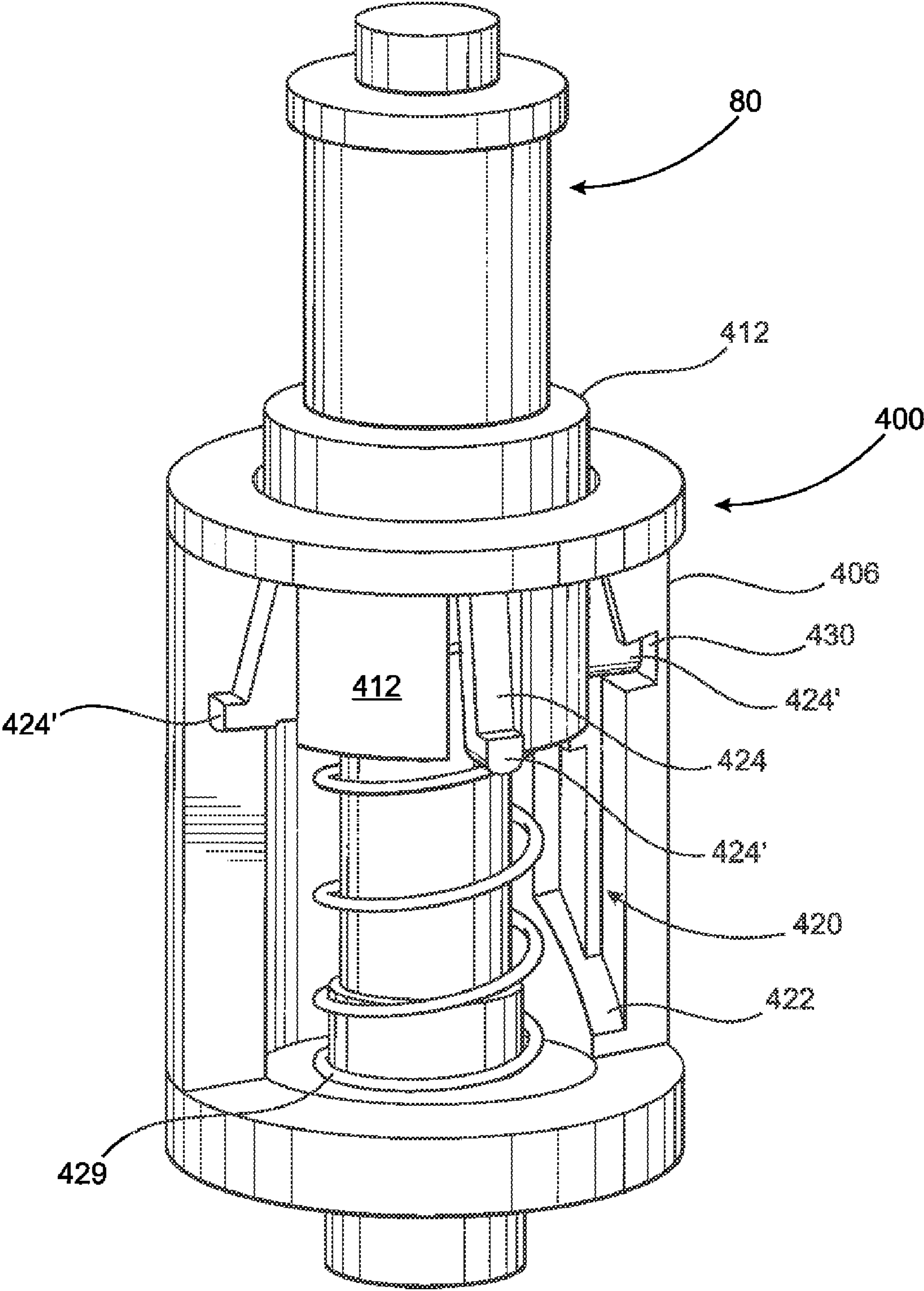


FIG. 27

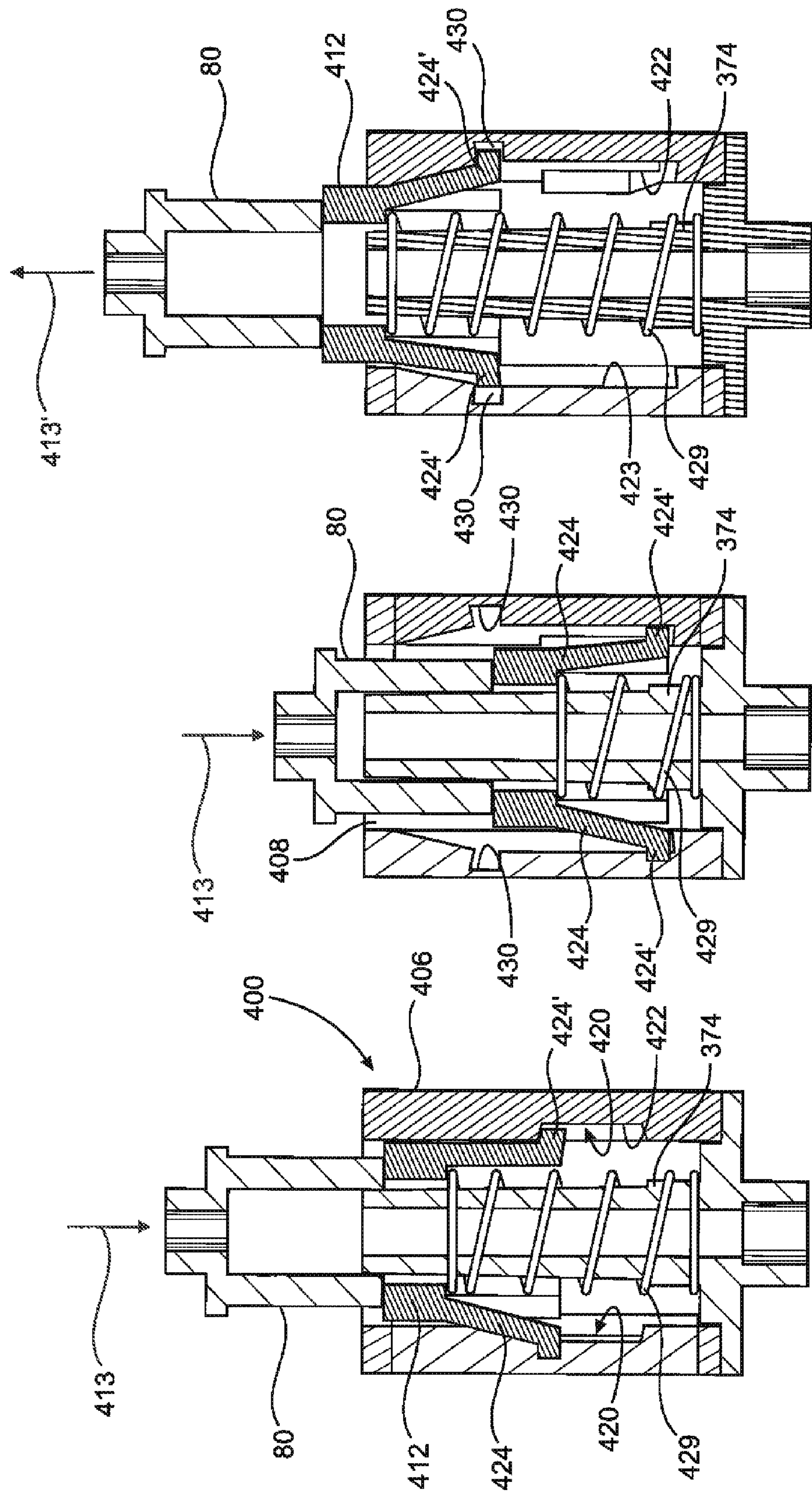


FIG. 28

FIG. 29

FIG. 30

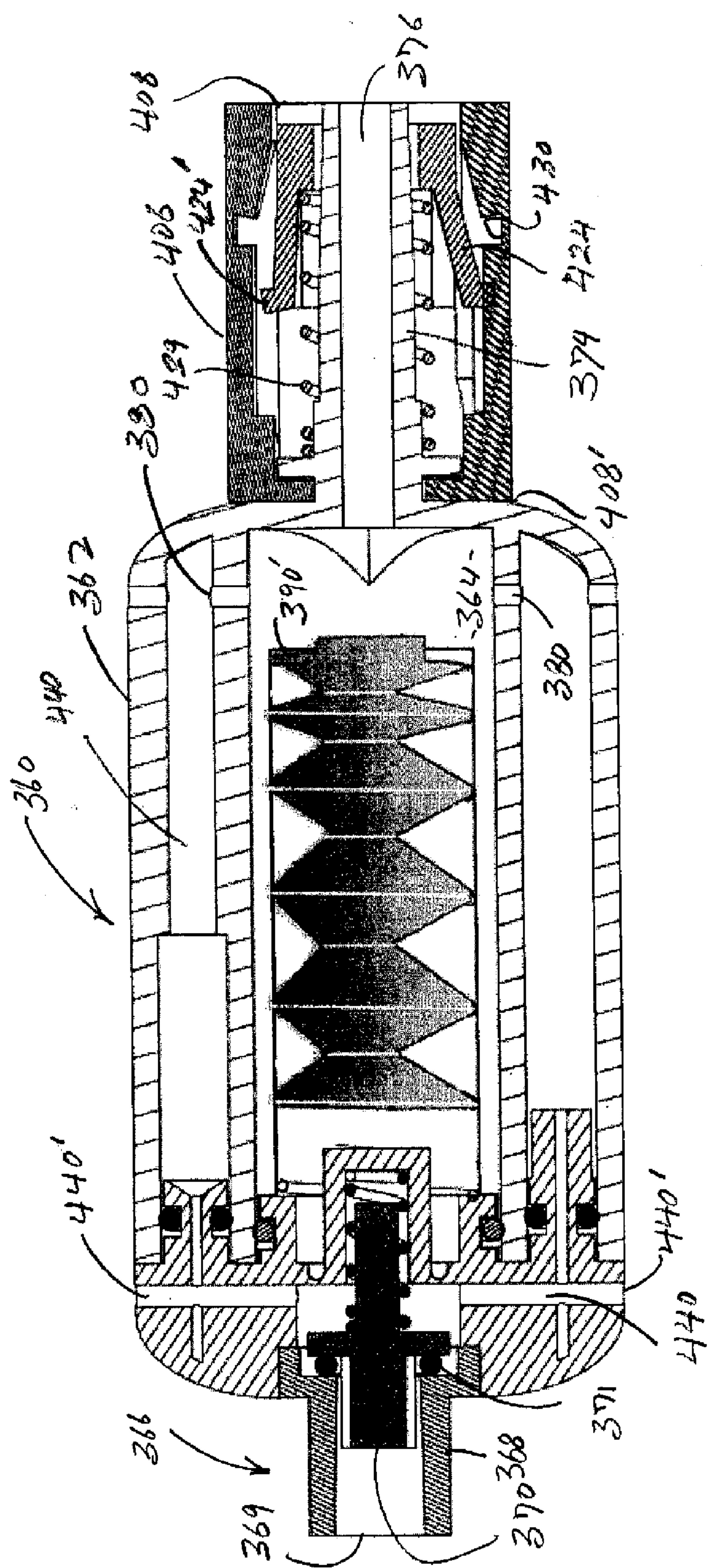


FIG 31

INFLATION AND MONITORING ASSEMBLY FOR A PRESSURE CUFF

CLAIM OF PRIORITY

[0001] The present application is a continuation-in-part application of previously filed, now pending application having Ser. No. 13/005,359, filed on Jan. 12, 2011, which is a continuation-in-part application of previously filed, now pending application having Ser. No. 12/806,810, filed on Aug. 20, 2010, which is a continuation-in-part application of previously filed, now pending application having Ser. No. 12/661,103, filed on Mar. 10, 2010 all of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention is directed to an assembly structured to inflate and continuously monitor pressure within an inflatable cuff, such as a retaining cuff for an endotracheal tube and/or tracheostomy tube. A casing and a pump assembly are collectively operative to inflate the cuff and monitor existing pressure therein. The casing may be alternately structured for fixed or removable securement to either or both the pump assembly and an inflating lumen communicating with the cuff. Moreover, when removably secured the casing may be prevented from being reconnected to the pump assembly and/or the lumen, once disconnection has occurred.

[0004] 2. Description of the Related Art

[0005] The use of endotracheal tubes is well known in the medical profession. In practice, the tube is inserted through the mouth, nose or tracheotomy of the patient into the trachea and is structured, when properly positioned, to facilitate ventilation from a ventilator or the like.

[0006] As conventionally used, the endotracheal tube and/or tracheostomy tube includes a coupling structure at the proximal or outer end thereof which connects the lumen of the endotracheal and/or tracheostomy tube to the source of ventilation. The endotracheal and/or tracheostomy tube commonly includes an inflatable, pressure or retaining cuff which is generally disposed in surrounding relation to the distal end of the tube. In use, the cuff is inflated and thereby serves to secure or stabilize the position of the tube as it expands radially outward into confronting relation to the walls of the trachea. As a result, the inflated cuff serves to stabilize the position of the endotracheal tube and also establishes a seal within the trachea. As conventionally structured, a conduit is associated with the tube and includes an interior, inflating lumen used to inflate the cuff when the endotracheal tube is properly positioned within the trachea. Dependent on the structure and use of the endotracheal tube, the inflating line or conduit may be integrally formed on or within the primary wall of the tube itself. As such, the cuff is manually inflated by an appropriate inflation assembly such as, but not limited to, a separate, removable syringe connected in fluid communication with the inflating lumen. Moreover, the cuff is inflated to a pressure which accomplishes the above noted seal with the interior of the trachea, as well as effect the aforementioned stabilization of the endotracheal and/or tracheostomy tube.

[0007] The importance of under inflation, over inflation and/or excessive pressurization of the retaining cuff is well recognized, due to the potential of resulting injury and/or trauma to the patient. Accordingly, when the pressure within the cuff is too low, the sealing function thereof cannot be fully

achieved resulting in possible leakage of saliva, air, etc. into the trachea. However, an over pressurization of the cuff may result in reduced blood flow to tracheal tissue, tracheal ischemic conditions, and cause ulcers, bleeding and tracheal stenosis or tracheomalacia after removal of the tube, which can lead to the need for tracheal repair surgery or even a tracheal transplant. Accordingly, it is important to maintain the inner pressure of the cuff, depended on its structure and design, within predetermined ranges in order to affect both the above noted fluid seal with the trachea as well as stabilization of the endotracheal tube within the trachea.

[0008] Known attempts to overcome problems of the type set forth above have resulted in the provision of various types of pressure gauges or other pressure monitoring devices connected in fluid communication with the inflating lumen and with the pressure or retaining cuff itself. However, many of these known or conventional attempts to accurately monitor cuff pressure have resulted in less than accurate or satisfactory results. Accordingly, while known monitoring devices may be at least minimally effective for their intended function, they have been found to be relatively bulky, cumbersome, costly, and/or less than efficient. Indeed, because of these factors, monitoring devices are often not available at the bed side and ET cuff pressure monitoring is often inadequately addressed, both initially as well as after the patient is intubated. Moreover, even if a one time, initial pressure identification is achieved, such is inadequate because the pressure can change over time, such as when the patient is moved or the endotracheal tube is repositioned, or when ventilation settings are adjusted. As a result, there is a need in the medical profession for an assembly structured to properly inflate and continuously monitor the pressure within a retaining or pressure cuff of an endotracheal and/or tracheostomy tube. Further, the inflating and monitoring functions of a proposed monitoring assembly should preferably be carried out by a single unit which may be incorporated within the endotracheal tube assembly or alternatively may be connected thereto. As such, the monitoring of the pressure within the retaining cuff should be effectively accomplished by a mere visual observation of the preferred assembly, without requiring repeated attachment and removal of a pressure monitor and/or inflating device. In addition, such a preferred monitoring and inflating assembly should be easily operable, and in certain preferred embodiments may be structured to be used as a single use device, which is not integrated into the endotracheal tube, but readily connectable to an inflation lumen of the tube and subsequently detachable there from, but further wherein reconnection of the monitoring assembly is prevented so that reuse of the device is prevented to avoid cross-contamination of infection from patient to patient.

[0009] Further, in addition to its applicability within the pressure cuff associated with an endotracheal tube, it is also recognized that such a structure would be highly beneficial for use within a variety of different medical devices, including the pressure cuffs, often referred to as balloons or bladders, used in balloon kyphoplasty, balloon sinuplasty, coronary or vascular balloon angioplasty and/or the delivery of stents, balloon esophageal dilation, and the dilation of strictures and sphincters, balloon dilatation of the nephrostomy tract, and/or Swan Ganz catheters, among other medical devices.

SUMMARY OF THE INVENTION

[0010] The present invention is directed to an assembly structured to inflate and monitor the pressure within a retain-

ing or pressure cuff, such as of the type associated with an artificial airway tube including for example, but not limited to, an endotracheal and/or a tracheostomy tube. In typical fashion, the retaining or pressure cuff is connected to or associated with the distal end of the endotracheal tube and is radially expanded, such as by inflation and pressurization. When inflated the cuff serves to retain the associated tube in an intended position within the trachea of a patient and form a seal therewith. It is emphasized that while the structural and operative features of the assembly of the present invention are applicable for use with a retaining/pressure cuff, associated with the aforementioned artificial airway tube(s), it is not intended to be limited to such use. More specifically, the inflation and monitoring assembly of the present invention can be used to perform the intended and described functions when operatively associated with retaining or pressure cuffs used for a plurality of other purposes.

[0011] Accordingly, the assembly of the present invention is structured to efficiently inflate the retaining or pressure cuff so as to orient it in a retaining, sealing position within the trachea. During and subsequent to inflation, the assembly of the present invention is structured to monitor the existing pressure within the cuff in order to avoid under inflation, over inflation and/or over pressurization thereof. More specifically, the assembly of the present invention comprises a casing which is connected to the inflating lumen of the endotracheal tube, leading to the retaining cuff, by means of a connection assembly. In at least one preferred embodiment of the present invention, the connection assembly is structured to selectively assume a connect orientation or a disconnect orientation. When in the connect orientation the connection assembly is disposed or oriented to connect to the inflating lumen and establish and maintain fluid flow between the casing of the assembly and the interior of the retaining cuff. However, when in the disconnect orientation, the connection assembly is structured to allow disconnection and removal of the casing from the inflation lumen and further structured to prevent reconnection therebetween. Therefore, at least one preferred embodiment of the present invention comprises a single-use inflation and monitoring assembly. As a result, once the casing of the assembly is disconnected from the inflating lumen, it is not reusable at least to the extent of being reconnected to the inflating lumen. However, structural modifications of the connection assembly may be included in an additional preferred embodiment, wherein the inflation and monitoring assembly of the present invention may be fixedly and/or permanently connected to the inflation lumen and be used therewith as an integrated unit.

[0012] Additional structural and operative features associated with the inflation and monitoring assembly of the present invention include the existence of a pressure chamber on the interior of the casing. In addition, a pump assembly preferably, but not exclusively, in the form of a plunger is connected to the casing and movable between an outwardly extended position and an inwardly directed, compressed position. Therefore, the pump assembly of the present invention is structured for selective manipulation to direct fluid flow from an exterior of the casing into the pressure chamber and therefrom through a remainder of the casing and into the inflating lumen attached to the casing.

[0013] A valve assembly is operatively disposed in flow regulating relation between the pump assembly and the interior of the pressure chamber. The valve assembly includes a first valve structure serving to regulate fluid flow from an

exterior of the casing into the interior of the pump plunger, as the plunger is drawn or forced into the outwardly extended position. In contrast, a second valve structure of the valve assembly is structured to regulate fluid flow from the interior of the plunger into the interior of the pressure chamber. The inward movement of the plunger into a compressed position forces air or fluid flow through the pressure chamber and predetermined remaining portions of the casing, through the connection assembly and into the inflating lumen, through which the forced fluid flow travels to the retaining cuff. The cuff is thereby inflated and pressurized.

[0014] One preferred embodiment of the present invention comprises the pump assembly structured as an integrated and/or permanent part of the casing. However, it should be noted that a source of air or other fluid used to pressurize or inflate the retaining cuff may be removably attached to the casing of the monitoring assembly. Such a source of pressurizing and/or inflating fluid may comprise, but is not limited to, a pump assembly which may or may not have similar operative and/or structural characteristics as the plunger described herein. Accordingly, a removable pump assembly or other source of inflating fluid can be removably connected to the casing without departing from the spirit and scope of the present invention.

[0015] The assembly of the present invention further includes an indicator assembly comprising an indicator member movably connected to and variably positioned within the casing. The indicator assembly is disposed in direct fluid communication with the interior of the pressure chamber and as a result the position of the indicator member is directly influenced by the existing pressure within the pressure chamber. Moreover, due to the establishment of fluid communication between the interior of the pressure chamber and the interior of the retaining cuff, the existing pressure in the pressure chamber and the retaining cuff will be substantially equivalent. In that the existing pressure within the pressure chamber is exerted on the indicator member, the indicator member is “variably positioned” within the casing dependent on the magnitude of the existing pressure within the pressure chamber. Due to the fact that the existing pressure within the pressure chamber is equivalent to the pressure within the retaining cuff, the variable positioning of the indicator member will be dependent on and indicative of the existing pressure within the retaining cuff.

[0016] Other operative and structural features include a window disposed on the casing to facilitate the visual observation of at least a portion of the indicator member. As a result, personnel may easily and efficiently monitor the pressure within the cuff by visually determining the position of the indicator member within the casing. Moreover, the portion of the indicator member viewable through the window may include informative alpha/numeric indicia, color coding, etc. which provides the observer with a clear and easily determinable visual indication as to an acceptable or non-acceptable pressure level within the retaining cuff. In addition, in order to further facilitate the visual observation of the pressure reading, the window may incorporate a magnifying lens or similar structure to make viewing easier. Yet additional embodiments of the present invention may include an LED or other appropriate digital readout, as well as an audible and/or visual warning in the event of an over inflation condition of the cuff. Also, the inflation and monitoring assembly may be structured to facilitate locating and/or using it when in a darkened room. Such features may include, but are not lim-

ited to, the illumination or “glowing” of the casing and/or other components of the assembly when it is used or stored in a darkened area.

[0017] Additional structural and operative features of the inflation and monitoring assembly of the present invention include a pressure relief valve assembly including at least one relief valve mounted on the casing in an exteriorly accessible location. Further, the pressure relief valve is disposed in direct fluid communication with the interior of the pressure chamber and in regulating relation to fluid flow vented from the pressure chamber to an exterior of the casing. As a result, the selective manipulation of the relief valve will cause a “bleeding” or venting of air or fluid from within the pressure chamber to the exterior of the casing. As a result the pressure within both the pressure chamber and the retaining cuff may be reduced when it is determined that such pressure is excessive. In addition, the structuring of the relief valve may be tapered or otherwise appropriately structured to provide for a gradual bleeding or release of pressure from within the pressure chamber.

[0018] In order to avoid inadvertent venting or release of the pressure within the pressure chamber and retaining cuff, alternately structured embodiments of the inflating and monitoring assembly of the present invention include a restricting assembly or shield assembly. Each of these assemblies is selectively positionable on the casing, so as to restrict inadvertent access to the pressure relief valve. In addition, the restricting assembly is structured to removably lock or otherwise restrictively engage the plunger of the pump assembly in order to restrict its movement and intended operation. In contrast, the shield assembly is movably mounted on the casing and selectively disposable between a closed, valve shielding position and an open, valve activating position relative to the relief valve. In addition, the shield assembly includes an activating portion deformable or otherwise disposable into activating relation and/or engagement with the pressure relief valve, when the shield assembly is in the open, valve activating position.

[0019] It should be noted that in the above described embodiments of the present invention the pump assembly defining the source of inflating fluid is generally represented as being permanently or fixedly attached to the casing. However, in at least one embodiment a source of fluid used to pressurize and inflate the retaining cuff may be removably attached to the casing of the monitoring assembly. In addition, the removable source of pressurizing or inflating air or other fluid may comprise, but is not limited to, a pump assembly which may be similarly operative to direct air into and through the casing for purposes of inflating or pressurizing the retaining cuff. Also, in this additional preferred embodiment the casing includes an adaptor assembly structured to define a single use connection between the casing and the inflating lumen associated with the retaining cuff.

[0020] It is emphasized that while this preferred embodiment is described in detail as establishing a single use connection with an inflating lumen for a retaining cuff, this embodiment could be used for the establishment of a single use connection between different medical devices. By way of example only, the adaptor assembly could be an effective in defining a single use connection between different but cooperatively structured medical devices especially, but not limited to, where one of the devices includes a luer type connector, as should be apparent from the following detailed description.

[0021] The additional preferred embodiment of the present invention includes an adaptor assembly structured to define a single use connection between the casing and the inflating lumen for the retaining cuff. Moreover, the adaptor assembly includes a housing which may be removably or fixedly connected to the casing. In addition, the outlet port connector of the casing is received within the interior of the adaptor in cooperative relation with a restrictor. The restrictor is movable within the interior of the adaptor and in cooperative relation with the outlet port connector of the casing and in receiving relation to a connector associated with the inflating lumen and retaining cuff. Cooperative structuring between the restrictor and the adaptor serve to facilitate the movement of the restrictor between a receiving position, an operative position and an inoperative position. Therefore, the restrictor may be forced to move from the receiving position into the operative position a sufficient force to accomplish the connection of the inflating lumen connector and the outlet port connector. The directed force may be exerted on the restrictor by a forced movement or positioning of the connector of the inflating lumen **15**. As set forth above, once the restrictor is in the operative position, the inflating lumen connector will or can be disposed in sealing or mating engagement with the outlet port connector. The aforementioned path of fluid flow is thereby established between the inflating lumen, the interior of the casing and eventually the retaining cuff.

[0022] Additional structural and operative features associated with the adaptor assembly include the provision of an orienting assembly connected to or mounted on the adaptor as well as portions of the restrictor. More specifically, the orienting assembly includes a track structure which preferably includes a curved and/or angular configuration and may include curved and/or angular ramp portions. In addition, the orienting assembly includes at least one but preferably a plurality of orienting members connected to the restrictor and extending at least partially outward there from. The one or more orienting members may be formed of a flexible material having sufficient resiliency to be normally biased into engagement with the track structure.

[0023] In addition, the adaptor assembly includes the provision of a retaining structure **430** which may include a plurality of independent and/or spaced apart recesses or other appropriately configured grooves or recesses. The retaining structure may be a part of the track structure and as such may be disposed in communicating relation with an appropriately configured track segment which facilitates the movement of the restrictor from the operative position into the inoperative position. Therefore, upon release of the directed force on the restrictor by the inflating lumen connector, the one or more orienting members travel along the track segment(s) until they engage or are at least partially disposed in a retained relation with the retaining structure.

[0024] When so positioned, the orienting members will be substantially fixed within or relative to the retaining structure. As a result, when the restrictor is in the inoperative position, it is disposed in obstructing relation to the inflating lumen connector, thereby preventing or restricting the positioning of the restrictor by the connector into the operative position. Moreover, the obstructing position of the restrictor will restrict the inflating lumen connector from entering the adaptor housing to a position where the connector can establish the aforementioned path of fluid flow with the outlet port connector of the casing. Therefore, the adaptor assembly including the provision of the retaining structure and the interaction

thereof with the orienting assembly will define a single use connection between the retaining cuff and the inflating lumen. However, it is again emphasized that the adaptor assembly including the provision of the retaining structure and the interaction thereof with the orienting assembly could be effective in defining a single use connection between different but cooperatively structured medical devices especially, but not limited to, where one of the devices includes a luer type connector.

[0025] Other features associated with the restrictor include it being color coded so as to provide a clear indication that the adaptor assembly is in fact a single use device. Such color coding may also be used independently of or in combination with appropriate indicia to provide a further visual indication that the adaptor assembly has been previously used and/or is no longer usable.

[0026] As set forth above, at least one embodiment of the adaptor assembly is structured to establish a single use connection of the removal fluid source with the casing. Accordingly, additional structural and operative features of the adaptor assembly may include a retaining structure disposed within the housing in engageable relation with the restrictor. The retaining structure is cooperatively structured with the restrictor so as to fixedly maintain the restrictor in the aforementioned inoperative position. Moreover, the inoperative position may be more specifically defined by the restrictor being fixed in an obstructing position relative to the discharge portion of the removable fluid source. This obstructing position will prevent connection of the discharge portion of the fluid source and the outlet port of the casing, thereby preventing the establishment of the aforementioned path of fluid flow. The obstructing position of the restrictor being fixed will also prevent the pump assembly from forcing movement of the restrictor into the aforementioned operative position within the housing.

[0027] These and other objects, features and advantages of the present invention will become clearer when the drawings as well as the detailed description are taken into consideration.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] For a fuller understanding of the nature of the present invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which:

[0029] FIG. 1A is a front view of one preferred embodiment of the inflating and pressure monitoring assembly of the present invention in an assembled, ready to use, extended orientation associated with an endotracheal tube pressure cuff.

[0030] FIG. 1B is a front view of the embodiment of FIG. 1A in a closed or compressed orientation.

[0031] FIG. 1C is a perspective view of another preferred embodiment of the inflating and pressure monitoring assembly of the present invention in an assembled form separated from but connectable to an inflating lumen for an endotracheal tube.

[0032] FIG. 2 is a perspective view in longitudinal section of the embodiment of FIG. 1C represented in a different operative orientation.

[0033] FIG. 3 is a longitudinal sectional view of the embodiment of FIGS. 1C and 2 in an operative orientation.

[0034] FIG. 4 is a longitudinal sectional view of the embodiment of FIGS. 1C, 2 and 3 in yet a different stage of operation.

[0035] FIGS. 5-7 are detailed longitudinal sectional views of an indicator assembly of the embodiment of FIGS. 1C and 2-4, in successively different stages of operation.

[0036] FIG. 8 is a detailed longitudinal sectional view in partial cutaway of a pressure relief assembly associated with the embodiment of FIGS. 1C and 2-7.

[0037] FIG. 9 is a detailed longitudinal sectional view of the embodiment of FIG. 8, wherein the pressure relief assembly is in an open, venting orientation.

[0038] FIG. 10 is a perspective view in partially exploded form of the embodiment of FIGS. 1C and 2-9 wherein a restriction assembly is disposed in access restricting relation to the pressure relief assembly of the embodiment of FIGS. 8 and 9.

[0039] FIG. 11 is a perspective view in exploded form of the restriction assembly of the embodiment of FIG. 10 in a non-restricting position.

[0040] FIG. 12 is a detailed exploded view in partial cutaway and section of a connection assembly of the present invention structured to facilitate connection to an inflating lumen.

[0041] FIG. 13 is a detailed sectional view in partial cutaway of the embodiment of FIG. 12 wherein the connection assembly establishes a removable connection to the remainder of the flushing assembly of the present invention.

[0042] FIG. 14 is an exploded view in partial cutaway and section, wherein the inflating lumen has been removed from a remainder of the assembly of the present invention and wherein the connection assembly is structured to define a single-use device of the assembly of the present invention.

[0043] FIG. 15 is a perspective view in exploded form of the yet another embodiment of a connection assembly.

[0044] FIG. 16 is a perspective view of the embodiment of FIG. 15 wherein the connection assembly has established a connection with an inflating lumen.

[0045] FIG. 17 is a perspective view in partial cutaway and exploded form of the embodiment of FIGS. 15 and 16, wherein the connection assembly is disconnected from the inflating lumen, once having been connected thereto.

[0046] FIG. 18 is a longitudinal sectional view of the embodiment of FIG. 1A.

[0047] FIG. 19 is a longitudinal sectional view of the embodiment of FIG. 1B.

[0048] FIG. 20 is a detail view in partial cutaway of a connection assembly associated with an entry port of the embodiment of FIGS. 1A, 1B, and structurally and operationally similar to that represented in FIGS. 12-14.

[0049] FIG. 21 is a detail view in partial cutaway of the embodiment of FIG. 20 in a different, operative orientation.

[0050] FIG. 22 is a detail view in partial cutaway of the embodiment of FIGS. 20 and 21 in a closed, obstructing orientation.

[0051] FIG. 23 is a longitudinal sectional view of another preferred embodiment of an inflating and pressure monitoring assembly of the present invention.

[0052] FIG. 24 is an exterior view of the embodiment of FIG. 23.

[0053] FIG. 25 is an interior perspective view in partial cutaway of an adaptor assembly included in the embodiment of FIGS. 23 and 24, wherein the adaptor assembly is in a "receiving position".

[0054] FIG. 26 is an interior perspective view in partial cutaway of the adaptor assembly of FIG. 25 in an “operative position”.

[0055] FIG. 27 is an interior perspective view in partial cutaway of the embodiments of FIGS. 25 and 26 in an inoperative position.

[0056] FIG. 28 is a longitudinal sectional view of the embodiments of FIGS. 25-27 in the receiving position as represented in FIG. 25.

[0057] FIG. 29 is a longitudinal sectional view of the embodiments of FIGS. 25-28 in the operative position as represented in FIG. 26.

[0058] FIG. 30 is a longitudinal sectional view of the embodiments of FIGS. 25-29 in the inoperative position as represented in FIG. 27.

[0059] FIG. 31 is a longitudinal sectional view of yet another preferred embodiment of an inflating and pressure monitoring assembly of the present invention, similar to the embodiment of FIG. 23.

[0060] Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0061] As shown in the accompanying drawings, the present invention is directed to an inflation and pressure monitoring assembly generally indicated as 10. The assembly 10 structured to inflate and monitor the pressure within a retaining cuff or pressure cuff of a medical device, including in the preferred embodiment the type associated with an endotracheal tube. It is understood, however, that the pressure cuff, often referred to as a balloon in some devices, could be included as part of medical devices used in balloon kyphoplasty, balloon sinuplasty, coronary or vascular balloon angioplasty and/or the delivery of stents, balloon esophageal dilation, and the dilation of strictures and sphincters, balloon dilatation of the nephrostomy tract, and/or Swan Ganz catheters, among other medical devices.

[0062] More specifically, the assembly 10 includes a generally elongated casing 12 having a distal end generally indicated as 14 structured to be interconnected to an inflation lumen 15, which will be described in greater detail hereinafter, by means of a connection assembly 17. The connection assembly 17 is accessible through a receiving port 14' associated with the distal end 14 of the casing 12, and will be described hereinafter with primary reference to FIGS. 12 through 17. As such, the assembly 10 is intended to be interconnected in fluid communication with the inflation lumen 15 and in turn is thereby disposed in direct fluid communication with the interior of the retaining or pressure cuff associated with the inner or distal end of the endotracheal tube and not shown for purposes of clarity.

[0063] With primary reference to FIGS. 1C and 2-4, the casing 12 includes an at least partially hollow interior more specifically defined by a pressure chamber 16. A pump assembly generally indicated as 18 is preferably in the form of a plunger 20 having an outer end 20' and an elongated stem or barrel portion. The pump assembly 18 and specifically including the plunger 20 includes a hollow interior 24 extending along substantially the entire length or at least a majority of the length of the plunger 20. The plunger 20 is movably connected to the casing 12 and is selectively disposed between an inwardly directed compressed position as represented in FIG. 2 and an outwardly directed, extended position

as represented in FIGS. 1C, 3 and 4. Moreover, manipulation of the plunger 20 of the pump assembly 18 will force fluid flow from an exterior of the casing 12 into the pressure chamber 16 and through predetermined portions of the casing 12 to the inflation lumen 15, thereby serving to inflate and pressurize the retainer cuff.

[0064] In order to regulate fluid flow to the retainer cuff and maintain a predetermined, acceptable pressure level therein, a valve assembly 28 is associated with the pump 18 and specifically the plunger 20. The valve assembly 28 is disposed in fluid regulating, interconnecting relation between the pressure chamber 16 and the interior 24 of the plunger 20. As such, the valve assembly 28 is disposed and structured to regulate fluid flow from an exterior of the casing 12 into the interior 24 of the plunger 20 and therefrom into the pressure chamber 16. More specifically, the valve assembly 28 includes a first valve structure 30 and a second valve structure 32 both structured in the form of one-way valves. In at least one preferred embodiment of the present invention, the first one-way valve structure 30 and the second one-way valve structure 32 are integrally or fixedly attached and cooperatively operational so as to regulate fluid flow from the exterior of the casing 12, into the pressure chamber 16 and therefrom into the inflation lumen 15 and into the retaining cuff associated with the endotracheal tube.

[0065] In operation, when in the compressed position of FIG. 2, the valve assembly 28 is effectively inoperable since there is no forced or intended fluid flow through the casing 12. However, a withdrawal or outward positioning of the plunger 20 into the extended position, as represented in FIGS. 1C, 3 and 4, will result in the first one-way valve structure 30 opening thereby allowing air to be drawn into the interior 24 of the plunger 20 about the periphery of the first one-way valve structure 30, such as at 33. During the filling of the interior 24 of the plunger 20, the second one-way valve structure 32 will remain closed, thereby preventing fluid flow from the interior of the pressure chamber 16 into the interior 24 of the plunger 20. However, once the plunger 20 is forced inwardly into the casing 12 and toward and into the compressed position of FIG. 2, the inwardly directed force, indicated by directional arrow 35 in FIG. 3, will cause a closing of the first one-way valve structure 30 and a concurrent opening of the second one-way valve structure 32. As a result, the air or other fluid collected within the interior 24 of the plunger 20 will be forced through the second one-way valve structure 32 into the pressure chamber 16. Accordingly, it should be apparent that the first and second one-way valve structures 30 and 32 will automatically and alternatively be disposed in an opened/closed position as the plunger 20 is withdrawn out into its extended position and subsequently forced inwardly into its compressed position as represented in FIGS. 2-4.

[0066] Therefore, the air or other fluid forced into the pressure chamber 16 will pass into a delivery channel 40 having an entrance 42 communicating directly with the interior of the pressure chamber 16. An exit or delivery end of the channel 40 is designated as 44, wherein an end most channel segment 44' will deliver a forced fluid flow through the connecting assembly 17 directly to the connecting collar 80 of the hub 82, of the inflating lumen 15. The end channel segment 44' passes through the connecting assembly 17 and is disposed in fluid communication with the connecting collar 80 through the receiving port 14' associated with the distal end 14 of the casing 12. As set forth above, the distal end 14 may be removably connected to the inflating lumen 15, as primarily repre-

sented in FIGS. 12-14, by an interconnection between the connecting assembly 17 and the connecting collar 80 and hub 82, as will be described in greater detail hereinafter with primary reference to FIGS. 12-15.

[0067] Therefore, it should be apparent that a forced fluid flow from the interior of the plunger 20 into the pressure chamber 16 will serve to deliver a predetermined quantity of air or other inflating fluid through the pressure chamber 16 and into and along the length of the channel 40. Such fluid flow will continue to pass through the exit end 44 and channel segment 44' of the channel 40 and exit from the casing 12 through the receiving port 14'. Therefore the pressure chamber 16 and the interior of the retaining or pressure cuff will normally be maintained in fluid communication with one another. As a result the "existing pressure" within the pressure chamber 16 will be the same as the pressure within the inflated retainer cuff, as long as the casing 12 is operatively connected to the inflating lumen 15.

[0068] While at least one preferred embodiment of the present invention comprises the pump assembly 18 structured as an integrated and/or permanent part of the casing 12, it is noted that the a removable pump assembly, having similar operative and structural characteristics such as, but not limited to, a removably connected syringe type assembly, can be removably connected to the casing 12 without departing from the spirit and scope of the present invention.

[0069] Another feature of at least one preferred embodiment of the present invention is the provision of an indicator assembly generally indicated as 50 represented in different stages of operation in FIGS. 5-7, dependent on the magnitude of the "existing pressure" within the pressure chamber 16 and accordingly, within the retaining cuff. More specifically, the indicator assembly 50 includes an indicator member 52 movably disposed on and more specifically within the casing 12 in direct fluid communication with the pressure chamber 16. Accordingly, any existing pressure within the pressure chamber 16 will be cause a force to be exerted on the indicator assembly 50 and more specifically on the indicator member 52. As also represented, the movement of the indicator member 52 is at least partially the result of it being biasingly mounted or disposed within the interior of the casing 12. Such a biased mounting or connection of the indicator member 52 is accomplished through the provision of a biasing member 54 preferably, but not necessarily, including at least one spring. As such, the biasing member 54 typically biases the indicator member 52 in a direction towards the pressure chamber 16 and against or in confronting relation with the bladder 56 defining an interconnecting member, which is associated with the with the indicator assembly 50, as explained in greater detail hereinafter. Accordingly, the biasing member 54 biases the indicator member 52 against the existing force present within the pressure chamber 16.

[0070] Therefore, as a result of the forces concurrently exerted on the indicator member 52 by the biasing member 54 and the existing pressure within the pressure chamber 16, the indicator member 52 is "variably positioned" within the interior of the casing. The biasing force exerted on the indicator member 52 by the biasing member 54 and may be predetermined and as such relatively constant or at least predictable. Accordingly, the movement of the indicator member 52 and its variable position within the casing 12 is directly dependent on the magnitude of the existing pressure within the pressure chamber 16 and the resulting variable force exerted on the indicator member 52. Additional structural and operative fea-

tures of the indicator assembly 50 include the aforementioned interconnecting member in the form of the bladder 56, formed of a flexible material. The bladder 56 includes an open end 56' disposed and dimensioned to establish direct fluid communication with the interior of the pressure chamber 16. The opposite end or other appropriate portion as at 56" is connected to or is otherwise disposed in confronting, driving relation to a corresponding portion of the indicator member 52. Any existing pressure within the pressure chamber 16 will result in a proportional force being exerted on the flexible material bladder 56 and transferred to the indicator member 52 and against the biasing force exerted on the indicator member 52 by the biasing member 54. Therefore, the existing pressure within the pressure chamber 16 will exert a variable force on the bladder 56 and thereby on the indicator member 52 and against the biasing member 54, depending on the magnitude of this existing force.

[0071] With primary reference to FIGS. 5-7 and a comparison of the position of the indicator member 52 in these Figures, it is clearly demonstrated that the variable position of the indicator member 52 will be dependent on the force exerted on the bladder 56 and indicator member 52 based on the magnitude of the existing pressure within the pressure chamber 16 and the counteracting force exerted on the indicator member 52 by the biasing member 54.

[0072] More specifically, FIG. 5 represents one operative position of the indicator member 52, wherein a first, relatively smaller amount of force is exerted on the indicator member 52 due to a smaller magnitude of existing pressure within the pressure chamber 16. However this relatively smaller force is still adequate to at least partially overcome the biasing force exerted on the indicator member 52 by the biasing member 54. In contrast, the position of the indicator member 52 indicates that the magnitude of the existing pressure within the pressure chamber 16 has significantly increased and is proportionately greater than the biasing force exerted on the indicator member 52 by the biasing member 54 in that the indicator member 52 is forced more closely to the proximal end 14 and against the biasing member 54. Moreover, FIG. 7 represents an even greater increase in the force being exerted on the bladder 56 and indicator member 52, due to a significantly greater increase in the magnitude of the existing pressure within the pressure chamber 16. As a result, the position of the indicator 52 has again varied as it is forced even more closely to the proximal end 14 of the casing 12.

[0073] Accordingly, it is again emphasized that the existing pressure within the pressure chamber 16 will be substantially equivalent to the existing pressure within the retaining cuff associated with the endotracheal tube when it is inflated. This is due to the open line of fluid communication between the pressure chamber 16 and the interior of the retainer cuff once inflated and when the pump assembly 18 specifically including the plunger 20 is in its compressed position as represented in FIG. 2. Therefore, the variable position of the indicator member 52 within the casing 12 is indicative of the magnitude of pressure within the retaining cuff as well as the pressure chamber 16.

[0074] Additional features associated with the indicator assembly 50 preferably include the provision of indicating indicia 53 present on the exterior surface 52' of the indicator member 52. Further, the casing 12 includes a window or like structure 58 which facilitates a visual observation of the exterior surface 52' of the indicator member 52 as well as the indicating indicia disposed thereon. Such indicating indicia

53 may be in the form of a color coded segment or segments on the exterior surface **52'** and/or any type of other appropriate markings which are disposed and structured to facilitate a clear visual indication of an adequate or proper pressure within the pressure chamber **16** and accordingly within the retaining cuff. By way of example only, a color coded portion may exist on the exterior surface **52'** which will provide an individual, having visual access to the window **58**, with a clear indication that at least the minimum or adequate amount of pressure exists within the retainer cuff. Such color coding may include a “red” surface area segment which will quickly inform an observer that the retainer cuff may be over inflated or include excess pressure on the interior thereof.

[0075] In addition, a magnifying lens or other magnifying structure may be included in or as part of the window **58**, in order to further facilitate the visual observation of the indicating indicia **53** on the surface **52'**. Yet additional embodiments of the present invention may include an LED or other appropriate digital readout, as well as an audible and/or visual warning, associated with the exterior of the casing **12**, such as in the vicinity of the window **58**, in the event of an over inflation condition of the cuff.

[0076] In order to properly inflate, monitor and if necessary regulate the existing pressure within the pressure chamber **16** and accordingly within the retainer cuff, at least one preferred embodiment of the present invention includes a pressure relief assembly generally indicated as **60**, as represented in FIGS. **8** and **9**. The pressure relief assembly **60** includes a pressure relief valve **62**, disposed in fluid sealing relation to the interior surfaces of the vent port or opening **63**, wherein the valve **62** is accessible from the exterior of the casing **12** as represented. Further, the pressure relief valve **62** may be normally maintained in a closed position, as clearly represented in FIG. **8**, due to the provision of a biasing member **64** in the form of one or more biasing springs. The biasing member **64** is disposed and structured to maintain the pressure relief valve **62** in a closed orientation unless an external, depressing pressure or force is applied thereto. As a result, in situations where the retainer cuff becomes over inflated or overly pressurized, the relief valve **62** may be depressed or otherwise manipulated to open the relief valve **62** thereby venting the existing pressure from within the pressure chamber **16**. This in turn will cause a change in the force exerted on the indicator member **52** and result in a position change of the indicator member **52** in a direction toward the pressure chamber **16**. Such variable positioning of the indicator member **52** will be observable through the window **58** in the casing **12** as represented throughout the accompanying Figures relating to this embodiment. In addition, the structuring of the relief valve **62** may include a substantially tapered configuration, as at **62'** in FIGS. **8** and **9**, or other appropriate structural configuration to accomplish sealing engagement with the interior surfaces of the vent port or opening **63**. This preferably tapered structure provides for a gradual bleeding or release of pressure from within the pressure chamber.

[0077] The provision of a pressure relief assembly **60** may be necessary and/or desirable to maintain an adequate control of the existing pressure within the pressure chamber **16**. However, care must be taken to avoid or prevent any inadvertent venting of the existing pressure within the pressure chamber **16**. Accordingly, at least one preferred embodiment of the present invention includes a restricting assembly generally indicated as **70**. The restricting assembly **70** includes a finger

manipulated slide structure **72** movable along the exterior of the casing **12**, such as along the one or more rails **74**.

[0078] With primary reference to FIGS. **2**, **3** and **11**, the finger manipulated slide member **72** is disposed along an exterior portion of the casing **12** in spaced relation from the pressure relief assembly **60**, thereby allowing clear access to the pressure relief valve **62**. However, in contrast, FIGS. **1C**, **4** and **10** represent the position of the restricting slide member **72** in the position which restricts access to the pressure relief assembly **60** and in particular the pressure relief valve **62**. As a result, the pressure relief valve **62** cannot be inadvertently or purposefully depressed thereby restricting an inadvertent venting of the pressure chamber **16** while the slide member **72** is in the restricting position.

[0079] As also noted in FIG. **4**, when the slide member **72** is in the restricting position as indicated, a portion thereof as at **72'** engages a lock or blocking structure **73** which may be selectively disposed into blocking or interruptive engagement with an end portion of the plunger **20**, thereby preventing it from being forced inwardly into the aforementioned compressed position as represented in FIG. **2**. As a result, the restricting assembly **70**, specifically including the restricting slide member **72** is disposable on the casing **12** in movement restricting relation to the pump assembly **18** and in particular, the plunger **20**. As also indicated in the embodiment of FIG. **4**, the structure, dimension and configuration of the restricting member **72** may be such as to concurrently restrict movement of the plunger **20** as well as access to the pressure relief valve **62** of the pressure relief assembly **60**.

[0080] With primary reference to FIGS. **12-14**, yet another preferred embodiment of the inflating and monitoring assembly **10** of the present invention comprises a connecting assembly **17**. The structural and operative features of the connecting assembly **17** are such as to allow for only a single-use of the casing **12** and the various operative components associated therewith. More specifically, the connecting assembly **17** is directly associated with the distal end **14** of the casing **12** and is accessible through the receiving or connecting port **14'**. As such, the receiving or connecting port **14'** is dimensioned and configured to receive a connecting collar or like structure **80** associated with the hub **82** of the inflating lumen **15**. The connecting collar **80** may be, but is not limited to, a luer type connector structured for connection to a cooperatively disposed and structured male luer type connector **43**. The connecting collar **80** is dimensioned and configured to pass through the connecting port **14'**, as represented in FIG. **13**. Once so positioned, a retaining member **90** associated with the connecting assembly **17** is forced back into non-retaining relation with a gripping structure **92**, as also represented in FIG. **13**.

[0081] Although not specifically represented, the gripping structure **92** is associated with an appropriate biasing structure, which is disposed to bias the gripping structure **92** in a direction towards the connecting port **14'**. Further, the retaining member **90**, while being initially disposed adjacent to and/or extending outwardly from the port **14'**, is movable on or relative to the gripping structure **92** in direction away from the port **14**, as the collar **80** passes through the port **14'** and engages the retaining member **90**. Accordingly, a comparison of FIGS. **12** and **13**, clearly indicate that the retaining member **90** may be initially disposed, along with the other components of the connecting assembly **17**, into a “connect position”. However, upon entry of the collar **80** through the receiving port **14'**, the retaining member **90** is forced back away from

the gripping structure 92, against the force exerted thereon by the aforementioned biasing structure. Advancement of the collar 80 through the port 14' and on to the male luer type fitting or like connector 43 accomplishes a frictional or other confronting engagement between the interior surface 80' of the hub 80, and an exterior preferably tapered surface 43' of the male connecting member 43. As a result, a fluid tight seal and connection is established between the interior surface 80' of the hub 80 and the exterior surface 43' of the nozzle or male luer type fitting.

[0082] With primary reference to FIGS. 13 and 14, a single use structuring of the connecting assembly 17 is demonstrated. More specifically, as the retaining member 90 is forced inwardly into the interior of the connecting assembly housing 17' it is effectively removed from a retaining relation to the outermost end 92' of the gripping member 92. Accordingly, as the casing 12 is disconnected from the inflating lumen 15, the collar 80 will be withdrawn from the interior of the connecting assembly housing 17', while the retaining member 90 will remain in the position represented in FIG. 14. However, due to the biasing force exerted on the gripping structure 92, as set forth above, the end 92' will be forced out of the connecting port 14' as indicated. As a result, the end 92' will assume a blocking or disconnect orientation due in part to a latching structure 92" formed on the outer surface of the end 92'. This latching structure 92" will overlap and effectively be latched onto the outer periphery of the connecting aperture 14' and thereby prevent the end 92 from passing back through the connecting aperture 14' into the interior of the connection assembly housing 17'.

[0083] As a result, it will be impossible or extremely difficult for the casing 12 to be reconnected to the hub 82 or collar 80 of the inflating lumen 15 once it has been disconnected there from, due at least in part to the fact that the collar 80 will not be able to be inserted back through the receiving or connecting port 14' into engagement with the male connector 43. It should be apparent therefore, that in the embodiment of FIGS. 12-14, the casing 12 can be easily and quickly removed from its operative connection to the inflating lumen 15 but once removed or disconnected cannot then be reconnected, as set forth above.

[0084] In addition to the above, at least one embodiment of the connection assembly 17 comprises the retaining member 90 and the gripping member 92 being of different, contrasting colors thereby clearly indicating whether the assembly 10 and the casing 12 is in the connect orientation and ready for use or in the disconnect orientation and has already been used. More specifically, as represented in FIG. 12 the casing 12 and the connection assembly 17 are in the connect orientation and have not been used in that the connection assembly 17 has not yet been connected to the collar 80 of the inflating lumen 15. As a result, the retaining member 90 is clearly visible through the connecting aperture 14'. In contrast, FIG. 14 represents the casing 12 and connection assembly 17 being in the disconnect orientation, wherein the collar 80 and connection assembly 17 having been disconnected from one another. Moreover, after use the gripping member 92 is clearly visible through the connecting aperture 14' and the retaining member 90 can no longer be seen. Accordingly, the production of the retaining member 92 and the gripping member in contrasting colors such as, but not limited to, green for the retaining member 90 and red for the gripping member 92, will provide a clear and readily observable indication as to whether or not the casing 12 has or has not been used.

[0085] As set forth above, the embodiment represented in FIGS. 12-14 is structured to accomplish a "single-use" inflation and monitoring assembly 10. However, structural modifications representing yet another embodiment of the present invention include the casing 12 being integrally, fixedly and/or at least partially permanently connected to the inflation lumen 15 such as by the interconnecting hub 82 and collar 80. In such an additional preferred embodiment, the structural and operative features of the connecting assembly 17 may be cooperatively modified along with the collar 80 and the hub 82 to accomplish the integration of the casing 12, collar 80 and hub 82 as a single unit.

[0086] With primary reference to FIGS. 15-17, yet another embodiment of the connection assembly is generally indicated as 117. While not directly disclosed, the connection assembly 117 is dimensioned and configured for insertion within the connection shell or housing 17' by being inserted through the connecting or receiving port 14'. Moreover, the connection assembly 117 includes a connection housing 118 having an open proximal end as at 120 and an open distal end as 122. When in a connect orientation, as represented in FIG. 15, member 124 is initially positioned in track segment 126. Upon engagement with the connecting collar 80 of the inflating lumen 15, the indicator member 24 will automatically be forced into the intermediate orientation represented in FIG. 16. As such, the indicator member 24 will be forced out of the track segment 26 and be disposed as at a junction area 128 between the two track segments 126 and 129. Interaction between the connecting collar 80 and interior member 130 will cause the automatic disposition of the member 124 into the orientation or position represented in FIG. 16. Accordingly, the connection assembly 117 is designed to facilitate interconnection between the connecting collar 80 and end 120 of the connection housing 118 by being disposed in confronting engagement therewith or passing into the interior of the open end 120 into engaging relation with the interior member 130.

[0087] Structural features of the connection assembly 117 further provide for the removal or disconnection of the hub 180 from the connection assembly 117 as represented in FIG. 17. Accordingly, once a disconnection occurs between the connecting collar 80 the member 130, due to a biased connection and/or structure, will be forced outwardly through the opposite open end 122 concurrent to the movement or passage of the member 124 passing along the track segment 129 to an inner most end thereof, as also represented in FIG. 17. Therefore, the connection assembly 117, as represented in FIG. 17, at least partially defines a disconnect orientation or position of the connection assembly 117 in that the protrusion of the member 130 outwardly from the interior of the connection housing 118 will prevent reconnection of the connecting hub with or into interior of the housing 118. As a result, the connection assembly 117 is thereby structured to facilitate the casing 12 being structured as a "single-use" device due to the fact that the connection assembly 117 will not allow reconnection with the connecting collar 80 of the inflating lumen 15.

[0088] As represented in FIGS. 1A, 1B and 18-22, the present invention comprises yet another preferred embodiment of the inflation and pressure monitoring assembly and is generally indicated as 110. The assembly 110 is structurally and functionally similar to the inflation and monitoring assembly 10, as represented at least in FIGS. 1C-14, described above. However, the assembly 110 includes addi-

tional structure and operative features which are distinguishable from the assembly 10, wherein such distinguishing features are described in greater detail hereinafter.

[0089] More specifically, the structure of FIGS. 1A, 1B and 18-22 comprises a “single-use” inflation and monitoring assembly 110. However, structural modifications which may be associated with the assembly 110 may facilitate the casing 112 being integrally, fixedly and/or at least partially permanently connected to the inflation lumen 15, such as by the interconnecting hub 82 and collar 80. Moreover, the elongated casing 112 has a distal end 114 which includes a connection assembly 217 structured to removably interconnect the casing 112 to an inflation lumen 15 (see FIG. 2) as well as the hub 82 and collar 80 which is also described above. Moreover, the connection assembly 217 is accessible through the receiving port 114' and will be described in greater detail hereinafter with specific reference to FIGS. 20-22.

[0090] As best represented in FIGS. 18 and 19, the casing 112 includes a pressure chamber comprising a multi-chamber construction including a first chamber 300 and a second chamber 302. In addition, the casing 112 comprises an integrated pump assembly preferably in the form of a plunger 120 also integrated into and at least partially defining the structure of the casing 112. The integration of the pump assembly and plunger 120 into the casing 112, as a part thereof, overcomes the disadvantages of requiring a separate, pump assembly, plunger, etc. removably associated with the casing. The plunger 120 includes a hand manipulated end portion or knob 120' and a hollow interior 24 which is directly associated with a valve assembly 28. The plunger 120 is disposable between an open, outwardly extended, ready to use orientation or position, as demonstrated in FIGS. 1A and 18 and a compressed orientation as represented in FIGS. 1B and 19. As explained in greater detail hereinafter, the plunger 120 may be retained in such a closed or compressed position. The plunger 120 is normally biased by biasing structure 121 into the orientation of FIGS. 1A and 18. The operation or reciprocal movement of the plunger 120 serves to pressurize both the first chamber 300 and the second chamber 302 through appropriate channeling 305, 307.

[0091] Although not specifically represented, the fluid connection between the first and second chambers 300 and 302 respectively is disposed within the casing 112 and establishes fluid communication there between. Upon reciprocal movement of the plunger 120 between the extended position of FIGS. 1A and 18 and the inwardly compressed position of FIGS. 1B and 19, fluid flow will be forced from the first chamber 300 sequentially into the second chamber 302 and eventually out to the retaining cuff by means of the lumen 15, hub 82 and connecting collar 80 as represented in FIG. 2. The sequential passage of pressurized fluid, upon manipulation of the plunger 120 will establish the aforementioned sequential pressurization or fluid flow from the first chamber 300 to the second chamber 302 through the connecting channels 305 and 307. In addition, the connector or luer fitting 143 includes an interior fluid channel 144 which is connected in direct fluid communication with the interior of the second chamber 302. Accordingly, the sequential pressurization of the second chamber 302 through the manipulation of the plunger 120 will force fluid flow from the second chamber 302 through the lumen or flow channel 144 of the connecting luer type fitting or conduit 143. Therefore it is clearly established that the fluid channel 144 is disposed in direct fluid communication with the second chamber 302.

[0092] With further reference to FIGS. 1A, 1B, 18, 19, this additional preferred embodiment includes an indicator assembly generally indicated as 310 and including a reaction member 312. The reaction member 312 includes a collapsible or flexible construction which facilitates it being disposed between the outwardly extended position as represented in FIGS. 18 and 19 and an inwardly, at least partially compressed orientation (not shown for purposes of clarity). A biasing structure 314 is disposed within the hollow interior 316 of the reaction member 312. The biasing structure 314 is disposed to biasingly engage and thereby biasingly mount or position the reaction member 312 into the extended position as represented in FIGS. 18 and 19. As such the reaction member 312 is biased against any pressure build up within the second chamber 302. Therefore, an increase or maintenance in the pressure within the second chamber to a predetermined level will variably position the reaction member into a compressed orientation dependent on the degree of pressure.

[0093] Moreover, the reaction member 312 is connected to or considered a part of the indicator 312' which is visually observable through a window 158 formed on the exterior of the casing 112. Accordingly, viewing of the exterior of the casing in the area disclosed in FIGS. 1A and 1B allows an observer to determine the position of a marker 53 as it moves within the window 158 relative to informative indicia 315 and 317. The indicated indicia are indicative of the existing pressure within at least the second chamber 302 and the retaining cuff by virtue of the establishment of fluid pressure therebetween through the fluid channel 144. Accordingly, the reaction member 312 will move against the biasing force exerted thereon by the biasing structure 314 as the pressure within the second chamber 302 builds. Again the pressure within the second chamber 302 is substantially equivalent to that maintained within the retaining cuff. Accordingly, the variable movement of the reaction member 312 into its various compressed orientations will result in movement of the marker 53 which is connected to the reaction member 312/indicator member 312'. The variable movement of the marker 53 will be viewable through the window 158, as set forth above.

[0094] Other structural features associated with the indicator assembly 110 include the hollow interior 316 as well as the reaction member 312 itself being physically isolated from the first chamber 300, such as by partition structure 333 in order to better provide an accurate response by substantially equivocating the pressure within the second chamber 302 to the pressure within the retaining cuff. However, the indicator assembly 310 further includes a vent structure 320 disposed in fluid communication between the interior 316 of the reaction member 312 and an exterior of the casing 112, as represented at 320'. Vent structure 320 is disposed and structured to regulate fluid flow into and out of the hollow interior 316 as the reaction member 312 moves with and against the biasing force of the biasing structure 314. More specifically, a build up of the pressure within the second chamber 302 will force the reaction member 312 into a compressed orientation thereby forcing fluid from within the hollow interior 316 out through the vent 320. Movement of the reaction member 312 in the opposite, outwardly extended position, upon absence of significant pressure within the chamber 302 will allow air or fluid to be drawn into the interior 316 through the vent structure 320.

[0095] With further reference to the embodiments of FIGS. 1A, 1B, 18 and 19, the inflation and monitoring assembly 110 further includes a shield assembly generally indicated as 330.

The shield assembly 330 is movable on the exterior of the casing 112 by manipulation of the fingers of the user of the casing 112. More specifically, as represented in FIGS. 1A and 18, the shield assembly 330 is disposed in closed orientation and as such is disposed in shielding relation to the relief valve assembly 160 including the valve stem 162. The shielding assembly 130 once in the closed position of FIGS. 1A and 18 restricts access to the valve stem 162 such that the relief valve 160 can not be depressed against the biasing force exerted by the biasing member 164 and opened. The relief valve 160 therefore remains closed so as to maintain the pressure within the first chamber 300. However, movement of the shield assembly 330 in accord with directional arrow 331 serves to dispose the shield assembly 330 in at least a partially open orientation. As such, the shield assembly 330 includes an activating portion 332 formed of an at least partially flexible or otherwise deformable material. Therefore, a downward pressure, exerted by the fingers of the user, on the activating portion 332 will serve to engage and force open the valve stem 162 thereby allowing at least partial release of the pressure from within the pressure through the first chamber 300. Accordingly, the activating portion 332 of the shield assembly 330 is at least partially deformable, as schematically indicated at 332' by exerting a downwardly or inwardly directed pressure as also schematically indicated at 332'.

[0096] Yet additional structural and operative features included in the additional preferred embodiment of FIGS. 1A, 1B, 18 and 19 include the provision of a retaining assembly 350 disposed at least partially on and accessible from an exterior of the casing 112. More specifically, the retaining assembly 350 is disposed and structured to fixedly or removably retain the plunger 118, including the plunger head 118', into the closed position represented in FIGS. 1B and 19. The retaining assembly 315 includes at least one but preferably two oppositely disposed retaining members 352. Moreover, each of the retaining members 352 are movably, flexibly or pivotally connected to the casing, as at 354, such that they may be forced inwardly in accord with directional arrows 355, by the fingers of the hand of the user. However, a natural orientation of the retaining members 352 is an outwardly disposed position, as represented in FIG. 18, due at least in part to an inherent or structural biasing force being exerted thereon.

[0097] In addition, each of the retaining members 352 include a free end portion 352' which are cooperatively structured with correspondingly disposed parts of the plunger head 120', as at 120". When the one or more retaining members 352 are in the orientation represented in FIG. 19, an inwardly forced positioning of the plunger head 120' will cause a locking engagement between the ends 352' and the portions 120" of the plunger head 120'. Release of the one or more retaining members 352 and the corresponding ends associated therewith from locking or retaining engagement from the plunger head 120' can be accomplished by an inward force on the one or more retaining members 352, as schematically represented at 355.

[0098] With primary reference to FIGS. 20-22, the additional preferred embodiment of the inflation and monitoring assembly 110 includes a connection assembly 217. The connection assembly 217 is structurally and operationally similar and in some instances identical to the connection assembly 17 as represented in FIGS. 12-14, and described above. More specifically, the connection assembly 217 includes a retaining member 90 and a gripping structure 92 disposed within the

receiving port 114' associated with the corresponding end 114 of the casing 112. Moreover, the retaining member 190 is movable relative to the gripping portion 92 as the collar 80, associated with the lumen 15 (see FIGS. 12-14), is disposed into and through the entry port 114'. Such movement will cause an inward movement of the retainer member 90 relative to the gripping portion 92.

[0099] As also set forth above, the connecting portion 217 is intended to be of a single use construction. Upon the inward forced movement of the retaining member 90 it is removed from its retaining relation to the outermost end 92' of the gripping structure 92. The inward forced travel of the retaining member 90 is caused by the insertion thereof of the collar 80, as described in detail with reference to FIG. 13. However, upon the removal of the collar 80, the end 92' of the gripping structure will be forced out through the port 114' as clearly demonstrated in FIG. 22. As a result, the end 92' will assume a blocking and disconnect orientation. As a result, it will be extremely difficult, if not impossible, for the casing 112 to be reconnected to a hub 82 or collar 80 of an inflating lumen 15 once it has been disconnected.

[0100] As described in detail with the above noted embodiments, a source of inflating air or fluid used to inflate and pressurize the retaining cuff may take a variety of forms such as, but not limited to a syringe or like pump assembly. It is also indicated the pump assembly or source of inflating fluid may or may not be fixedly attached to the remainder of the inflating and monitoring assembly. Accordingly, the present invention includes an additional preferred embodiment, represented in FIGS. 23-31, wherein the pump assembly, syringe or other source of inflating fluid is not necessarily permanently connected to the remainder of the inflating an monitoring assembly 360.

[0101] As such, the inflating and monitoring assembly 360 includes a casing 362 having at least one pressure chamber 364. The pressure chamber 362 is disposed in fluid communication with a pump assembly or source of inflating fluid, which may be removably or fixedly connected to an inlet portion 366 of the casing 362. More specifically in the embodiment of FIG. 23, the inlet portion 366 includes a connector 368 directly associated with a valve assembly 370. The valve assembly 370 is normally biased into a closed or sealing position relative to a flow path 369 disposed, configured and structured to be connected to the discharge portion of the syringe, pump assembly, or other source of inflating fluid (not shown). As further represented, the valve assembly 370 is maintained in a sealed, closed orientation due to the cooperative positioning and structuring of the seal member 371 and biasing member 372.

[0102] Somewhat similar to the operative and structural features of at least some of the preferred embodiments of FIGS. 1-22, the pressure chamber 364 is disposed in fluid communication with the inflating and/or pressurizing air forced into the casing 362 by operation of the pump assembly, syringe, etc. A connecting channel or passage 440 is in direct communication with the inlet portion 366 as well as channel or passage segments 440'. As indicated, channels or passages 444 continue passage of the inflating or pressurizing fluid from the valve assembly 369 into the interior of the pressure chamber 364. The inflating air, once passing into the pressure chamber 364, interacts with the diaphragm 390. The diaphragm 390 is cooperatively disposed and structured with a

biasing member 373 and therefore is operatively structured similar to the equivalent or corresponding structures of the embodiments of FIGS. 1-22.

[0103] An additional structural modification is represented in FIG. 31 and includes the use of a collapsible bellows structure 390' as an operative substitution for the diaphragm 390, as described with reference to FIG. 23. The inflating air, once passing into the pressure chamber 364, interacts with the bellows 390' and is therefore operative in the same manner as the diaphragm 390. In addition, the bellows 390' may be independently biased, as with diaphragm 390, or include and inherent bias. In either case the bellows 390' will be normally biased in the outwardly extended orientation, as represented in FIG. 31 and be collapsible upon the increase in pressure within the pressure chamber 364, due to the inflow of inflating air.

[0104] In addition, an outlet port of the casing 362 may be in the form of a male luer type connector 374 including an interior lumen 376. As set forth in greater detail hereinafter the connector structure 374 and the interior lumen 376 may at least partially define a path of fluid flow of the cuff inflating air. More specifically, the inflating air passes from the pressure chamber 364 into a connecting collar or connector 80 associated with the inflating lumen 15 and hub 82. As clearly represented in the embodiment of FIG. 2, the connector 80, hub 82 and inflating lumen 15 are connected to or otherwise directly associated with the retaining cuff as described above. Further, the connector 80 may be in the form of a female luer connector and once disposed in sealing or mating engagement with the male luer type connecting member 374, serves to at least partially define a path of fluid flow from the casing 362 through the inflating lumen 15 to the retaining cuff. As also emphasized in the above noted embodiments, this established path of fluid flow will result an equal pressure within the pressure chamber 364 and the inflated retaining cuff. As a result, a monitoring of the pressure of the inflated retaining cuff can be accurately monitored through the provision of an indicator assembly 310.

[0105] Further with regard to the embodiments of FIGS. 23, 24 and 31 the indicator assembly 310 and is directly associated with the operative features of the diaphragm 390. As described above with the embodiments of FIG. 1A and 1B, the casing 362 includes a window 158 and a plurality of pressure indicating indicia formed on the exterior surface thereof. The diaphragm 390 and the bellows 390' are cooperatively structured to serve as part of the indicator assembly 310 thereby providing an indication of the pressure within the pressure chamber 364 and as a result the substantially equivalent pressure within the retaining cuff. Therefore the substantially equivalent pressures within the pressure chamber 364 and the retaining cuff is due to the fluid communicating interconnection between the casing 362 and the inflating lumen 15, by virtue of the connector 80 and connector 374 being disposed in mating engagement with one another, as also described above.

[0106] Another structural and operative feature of the additional preferred embodiment of FIGS. 23-31 includes the provision of an adaptor assembly 400. Moreover, the adaptor assembly 400 is structured to define a single use connection between the retaining cuff, via the connector 80 of the inflating lumen 15, as represented in FIG. 2. Moreover, the adaptor assembly 400 includes a housing 406 having an at least partially hollow interior and an at least partially outer open end 408. The opposite end 408' of the adaptor or housing 406 may

be removably or fixedly connected to the casing 362. In addition, the outlet port connector 374 of the casing 362 is received within the interior of the adaptor housing 406 in cooperative relation with a restrictor 412. As set forth above, in at least one embodiment of the present invention, the outlet port comprising the connector 374 may be in the form of a male luer connector structured to establish a path of fluid flow with the connector 80 of the inflating lumen 15. As also indicated the connector 80 may be in the form of a female luer connector so as to establish sealing engagement with the outlet port connector 374 in the form of a male luer connector. As a result, mating engagement (see FIG. 29) between the corresponding luer connectors of the outlet port connector 374 and connector 80 collectively define a luer type coupling or fastener and the path of fluid from the interior of the casing 360 into and through the inflating lumen 15.

[0107] Additional features of the adaptor assembly 400 include a restrictor 412 movable within the interior of the adaptor housing 406. As such the restrictor 412 preferably, but not necessarily, at least partially surrounds the outlet port connector 374 and is disposed in at least partially receiving relation to the 80 as clearly represented. Cooperative structuring between the restrictor 412 and the adaptor housing 406, including interior portions thereof, serve to facilitate the movement of the restrictor 412 between a receiving position; as represented in FIGS. 25 and 28, an operative position; as represented in FIGS. 26 and 29 and an inoperative position; as represented in FIGS. 27 and 30. As also schematically represented in FIGS. 28-29, the restrictor 412 may be movably forced from the receiving position of FIGS. 25 and 28 into the operative position of FIGS. 26 and 29 by a directed force 413 sufficient to accomplish the connection of the connector 80 to the outlet port or male luer connector 374. The inwardly or axially directed force 413 is exerted on the restrictor 412 by a forced movement or positioning of the connector 80 of the lumen 15, while engaging a corresponding portion or end of the adaptor housing 406. As set forth above, once in the operative position of FIGS. 26 and 29, the connector 80 is disposed in sealing or mating engagement with the outlet port connector 374. The aforementioned path of fluid flow is thereby established between the lumen 15, into the interior of the casing 362 and eventually to the retaining cuff.

[0108] Additional structural and operative features associated with the adaptor assembly 412 include the provision of an orienting assembly connected to or mounted on both interior portions of the adaptor housing 406 and portions of the restrictor 412. More specifically, the orienting assembly includes a track structure generally indicated as 420 formed on interior wall surfaces of the housing 406 or other appropriate portions thereof. The track structure 420 preferably includes a curved and/or angular configuration and may include a curved and/or angular ramp member 422. In addition, the orienting assembly includes at least one but preferably a plurality of orienting members 424 connected to a remainder of the restrictor assembly 412 and extending at least partially outwardly there from. Additionally, in at least one structural modification or additional embodiment, the orienting assembly includes one or more orienting members 424. The orienting members 424 preferably, but not necessarily, are formed of a flexible material having sufficient resiliency to be normally biased outwardly from the remainder of the restrictor 412 into engagement with the track structure 420.

[0109] The one or more orienting members 424 will be disposed into movable engagement with at least a portion of the track structure 420 and will “follow” the curved or angular path of the portion of the track structure 420 which the orienting members 424 engage. As such, a forced positioning of the restrictor 412 by an inward and/or axial movement 413 of the connector 80 (or relative axial movement therebetween) will result in the axial travel of the restrictor 412 from the receiving position to the operative position and a concurrent predetermined reorientation of the restrictor 412. Such a predetermined reorientation of the restrictor 412 concurrently to its axial movement within the interior of the housing 406 is caused by the movable interaction between and the “following” of the one or more orienting members 424 along the track assembly 420. As clearly indicated, the connection of the orienting members 424 with the remainder of the restrictor 412 will result in a corresponding “reorientation” of the remainder of the restrictor 412 as it is forced from the receiving position into the operative position. Moreover, it is to be noted that the disposition of the track structure 420 extends about and along portions of the interior surface of the adaptor housing 406. This disposition as well as the curved and/or angular configuration of at least portions of track assembly 420 and/or the provision of one or more ramps 422 will cause a rotation and/or a “rotational reorientation” of the restrictor 412 within the interior of the housing 406, concurrently to its travel from the receiving position to the operative position. Such a rotational reorientation is further due to the interaction of the one or more orienting members 424 with the track structure 420.

[0110] As also represented in FIGS. 23-31, the adaptor assembly 400 includes a biasing structure 429 disposed within the interior of the housing 406 in biasing relation or engagement with the restrictor 412. The disposition of the biasing structure 429 is such as to normally bias the restrictor 412 outwardly or towards the open end 408 of the adaptor housing 406 and into the inoperative position, as represented in FIGS. 27 and 30. Accordingly, the removal or detachment of the connector 80 from the casing 362 and adaptor housing 406, as indicated by directional arrow 413' in FIG. 30, will result in a lessening or removal of the axial force 413. In turn this will allow the biasing structure 429 to force the restrictor 412 into the aforementioned inoperative position, as represented in FIGS. 27 and 30. Further facilitating the disposition of the restrictor 412 in the inoperative position is the continued movable engagement of the one or more restrictors 424 with a corresponding portion of the track assembly 420 on interior portions of the housing 406. As such, the corresponding portions of the track assembly 420 will allow the one or more orienting members 424 to be unobstructed in the travel of the restrictor 412 within the housing, from the operative position of FIG. 29 into the inoperative position of FIG. 30.

[0111] Additional structural features which may be associated with one or more preferred embodiments of the adaptor assembly 400 include the provision of a retaining structure 430. The retaining structure 430 is also preferably formed on the interior of the housing 406. The retaining structure 430 may comprise a plurality of independent and/or spaced apart recesses or alternatively an annular, semi-annular or other appropriately configured groove or recess, as represented in at least FIGS. 29 and 30. Moreover, the retaining structure 430 may be a part of the track structure 420 and as such may be disposed in communicating relation with a linear or other appropriately configured track segment 423. Therefore, upon

release of the inwardly directed force 413, such as at 413', exerted on the restrictor 412 by the connector 80, the one or more orienting members 424 may travel along the track segment(s) 432 until the distal ends or projected portions 424' engage or are at least partially disposed in a retained relation with the retaining structure 430.

[0112] When so positioned, the structured disposition or inherent outward biasing feature of the orienting members 424 will cause the distal ends 424' thereof to be substantially fixed within or relative to the retaining structure 430. Therefore, when the restrictor 412 is in the inoperative position, it is disposed in obstructing relation to the connector 80, thereby preventing or restricting the forced positioning of the restrictor 412 by the connector 80 into the operative position. Moreover, the obstructing position of the restrictor 412 will restrict the connector 80 from entering the adaptor housing 406 to a position where the connector 80 can establish the aforementioned path of fluid flow with the outlet port or male connector 374. Therefore, the adaptor assembly 400 of the present invention, through the provision of the retaining structure 430 and the interaction thereof with the one or more orienting members 424 can be said to define a single use connection between the retaining cuff via the connector 80 of the inflating lumen 15.

[0113] However, it is again emphasized that the adaptor assembly 400 including the provision of the retaining structure 430 and the interaction thereof with the orienting assembly, as described herein, could be effective in defining a single use connection between different but cooperatively structured medical devices especially, but not limited to, where one of the devices includes a luer type connector.

[0114] As represented in FIGS. 25-27 other features associated with the restrictor 412 include it being color coded so as to provide a clear indication that the adaptor assembly 400 is in fact a single use device. Such color coding may also be used independently of or in combination with appropriate indicia to provide a further visual indication that the adaptor assembly has been previously used and is no longer usable.

[0115] Since many modifications, variations and changes in detail can be made to the described preferred embodiment of the invention, it is intended that all matters in the foregoing description and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense. Thus, the scope of the invention should be determined by the appended claims and their legal equivalents.

[0116] Now that the invention has been described,

What is claimed is:

1. An assembly structured to inflate and monitor pressure within a retaining cuff of a medical device, said assembly comprising:

a casing including an interior pressure chamber and an outlet port disposable in fluid communication with the retaining cuff,

said casing structured for connecting an inflating fluid source in fluid communication with said pressure chamber,

an adapter disposed on said casing and structured to define a single use connection between said casing and a connector to the retaining cuff,

said adapter including a restrictor movably disposed therein in receiving relation to the connector,

said restrictor movable within said adapter between a receiving position, an operative position and an inoperative position,

said operative position comprising a path of fluid flow from said casing to the retaining cuff via said outlet port and the connector to the retaining cuff, and

said inoperative position comprising said restrictor disposed in obstructing relation to the connector and an establishment of said path of fluid flow.

2. An assembly as recited in claim **1** wherein said inoperative position further comprises a substantially fixed disposition of said restrictor in said obstructing relation to the connector.

3. An assembly as recited in claim **2** wherein said fixed disposition of said restrictor is at least partially defined by a retaining engagement of said restrictor with interior portions of said adaptor.

4. An assembly as recited in claim **1** further comprising an orienting assembly at least partially defined by cooperative structuring of said restrictor and said adaptor; said orienting assembly structured for reorientation of said restrictor concurrently to and independently of movement of said restrictor between said receiving and operative positions.

5. An assembly as recited in claim **4** wherein said cooperative structuring comprises at least a portion of said restrictor disposed in movable engagement with interior portions of said adaptor at least during movement said restrictor between said receiving and operative positions.

6. An assembly as recited in claim **5** wherein said interior portions are disposed and configured to at least partially define a rotational reorientation of said restrictor relative to said adaptor.

7. An assembly as recited in claim **4** wherein said orienting assembly comprises a track structure disposed within said adaptor and at least one orienting member connected to said restrictor and movable therewith; said one orienting member disposed in engaging relation with said track structure and movable along at least a portion of a length of said track structure.

8. An assembly as recited in claim **7** wherein said track structure comprises an at least partially curved configuration.

9. An assembly as recited in claim **7** wherein said track structure includes an angularly oriented ramp portion disposed in engaging relation with said orienting member concurrent to movement of said restrictor between said receiving and operative positions.

10. An assembly as recited in claim **7** wherein said track structure and said one orienting member are cooperatively structured for rotational reorientation of said restrictor concurrently to axial movement thereof, relative to said adaptor, between said receiving and operative positions.

11. An assembly as recited in claim **7** further comprising a retaining structure disposed in engageable relation with said one orienting member and cooperatively structured therewith to fixedly retain said restrictor in said inoperative position.

12. An assembly as recited in claim **11** wherein said track structure and said one orienting member are cooperatively disposed and structured for rotational reorientation of said restrictor concurrently to axial movement thereof, within said adaptor, between said receiving and operative positions.

13. An assembly as recited in claim **12** wherein said one orienting member is at least partially formed of a flexible material; said flexible material including sufficient resiliency to normally bias said orienting member into said engaging relation with said track structure.

14. An assembly as recited in claim **7** wherein said orienting assembly comprises a plurality of orienting members

each concurrently disposable in movable engagement with said track structure and cooperatively structured therewith for rotational reorientation of said restrictor concurrently to axial movement thereof between said receiving and operative positions.

15. An assembly as recited in claim **1** further comprising a biasing member disposed within said adaptor and structured to normally bias said restrictor into said inoperative position.

16. An assembly as recited in claim **15** wherein said restrictor and said housing are cooperatively structured to force disposition of said restrictor from said receiving position to said operative position upon an insertion of the connector into said adaptor.

17. An assembly as recited in claim **1** wherein said adaptor and said restrictor are cooperatively structured to concurrently receive a first luer fastener defining the connector and a second luer fastener defining said outlet port; said operative position comprising an operative connection of said first and second luer fasteners and an establishment of said path of fluid flow.

18. An assembly as recited in claim **1** further comprising an indicator assembly movably disposed on said casing in fluid communication with said pressure chamber, said indicator assembly including an indicator member variably positionable on said casing dependent on and indicative of existing pressure within said pressure chamber and the retaining cuff.

19. An assembly structured to inflate and monitor pressure within a retaining cuff of a medical device, said assembly comprising:

a casing including an interior pressure chamber and an outlet port disposable in fluid communication with the retaining cuff,

said casing structured for connecting an inflating fluid source in fluid communication with said pressure chamber,

an adapter disposed on said casing and structured to define a single use connection between said casing and a connector to the retaining cuff,

said adapter including a restrictor movably disposed therein in receiving relation to the connector,

said restrictor movable within said housing between a receiving position, an operative position and an inoperative position,

an orienting assembly disposed within said housing and structured for a predetermined reorientation of said restrictor concurrently to independent movement of said restrictor at least between said receiving and operative positions,

said operative position at least partially defining a path of fluid flow between said casing and the retaining cuff through said outlet port and the connector,

said inoperative position comprising said restrictor disposed in obstructing relation to entry of the connector into said operative position, and

a retaining structure disposed within said adaptor in engageable relation with said restrictor and cooperatively structured therewith to fixedly dispose said restrictor in said inoperative orientation.

20. An assembly as recited in claim **19** wherein said orienting assembly comprises a track structure and at least one orienting member cooperatively structured for rotational reorientation of said restrictor concurrently to axial movement thereof between said receiving and operative positions.

21. An assembly as recited in claim **20** wherein said track structure is disposed within said adaptor and said at least one orienting member is connected to said restrictor and movable therewith; said one orienting member disposed in engaging relation with said track structure and movable along at least a portion thereof concurrently to said restrictor moving between said receiving position and said operative position.

22. An assembly as recited in claim **19** further comprising an indicator assembly movably disposed and visually accessible on said casing in fluid communication with said pressure chamber, said indicator assembly including an indicator member variably positionable on said casing dependent on and indicative of existing pressure within said pressure chamber and the retaining cuff.

23. An adapter assembly structured to establish a one time connection of a port of a first medical device to a second medical device, said adapter assembly comprising:

a housing connected to the second medical device,
a restrictor disposed within said housing in receiving relation to the port of the first medical device,
said restrictor movable within said housing between a receiving position and an operative position,
said operative position at least partially defining a path of fluid flow from the port of the first medical device to the second medical device,
said restrictor cooperatively structured with said housing for further movement into an inoperative position, and
said inoperative position comprising said restrictor at least partially disposed within said housing in obstructing relation to the port of the first medical device.

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