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(54) **INFLATION AND MONITORING ASSEMBLY FOR A PRESSURE CUFF OF AN ENDOTRACHEAL TUBE**

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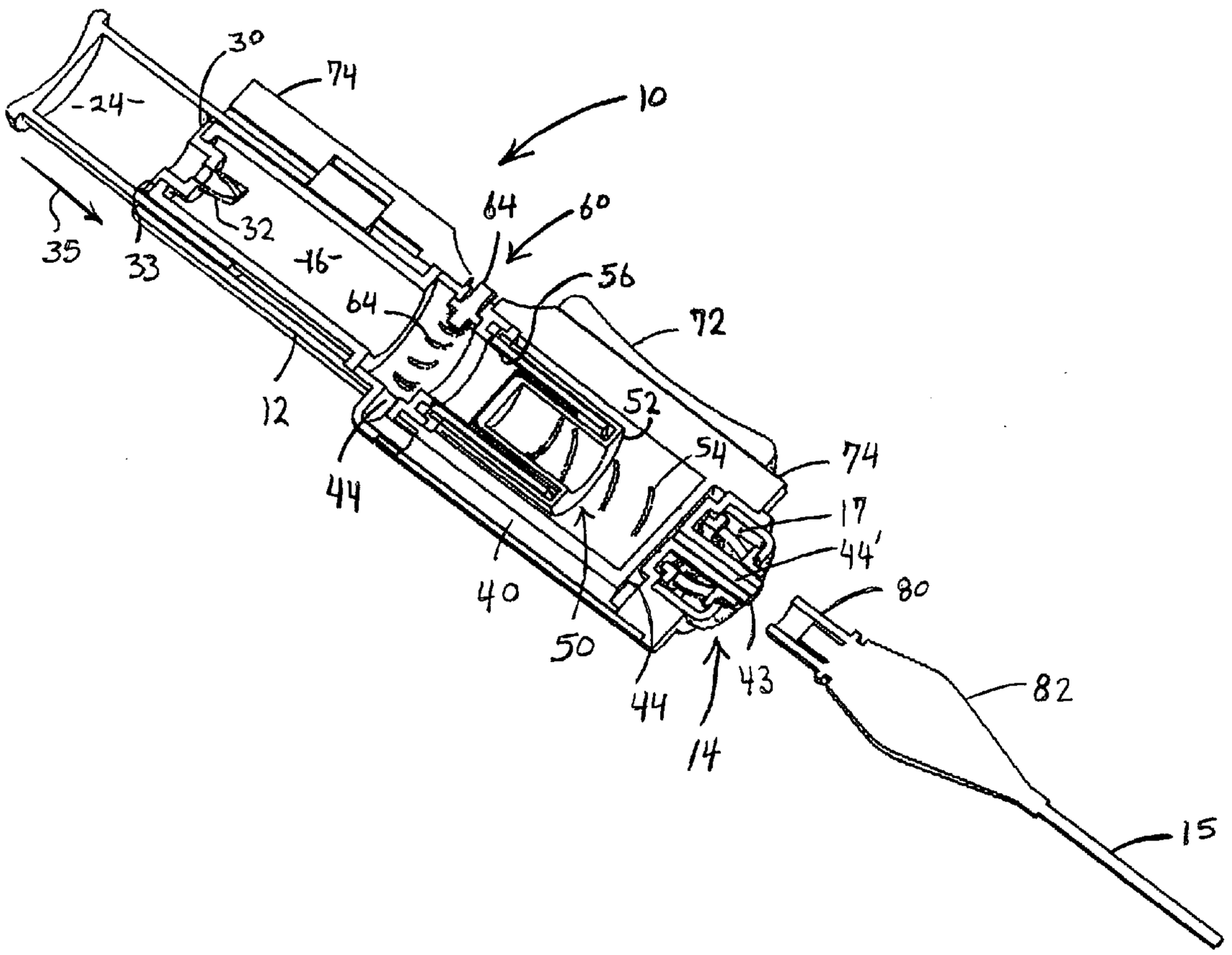
(57) **ABSTRACT**

An assembly structured to inflate a retaining or pressure cuff associated with an artificial airway tube and concurrently monitor pressure therein. A pump assembly is structured to force fluid flow to the retaining cuff, for inflation, through a pressure chamber within a casing of the assemblies. An indicator member is observable through a casing window and is variably positionable dependent on and indicative of existing pressure within the retaining cuff. Existing pressure within the pressure chamber is substantially equivalent to that within the retaining cuff and is thereby indicative of pressure within the retaining cuff. A junction may be disposed in removable interconnecting relation between the casing and an inflation lumen and be structured to prevent reconnection there between.



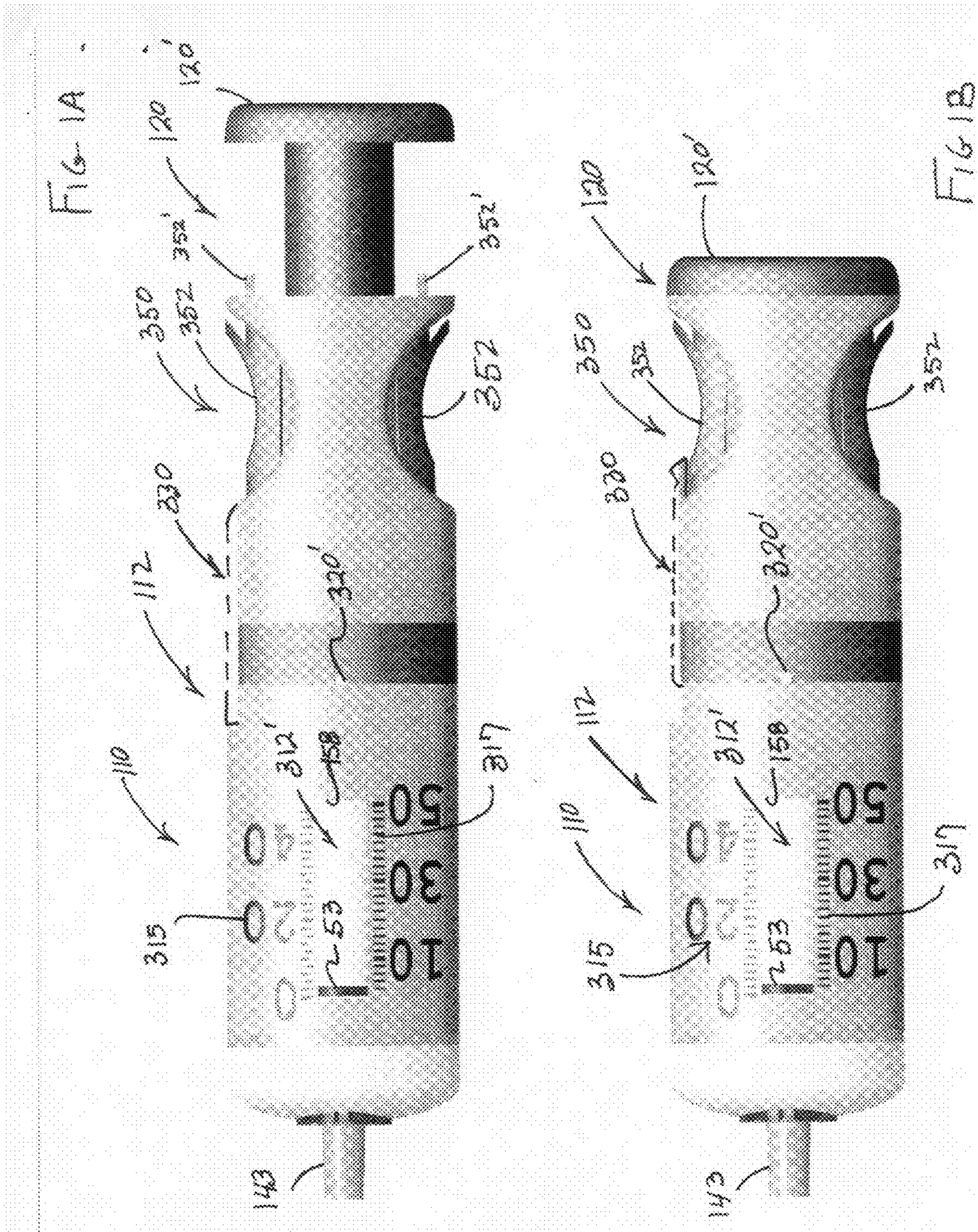


FIG. 1A'
120'
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FIG. 1B
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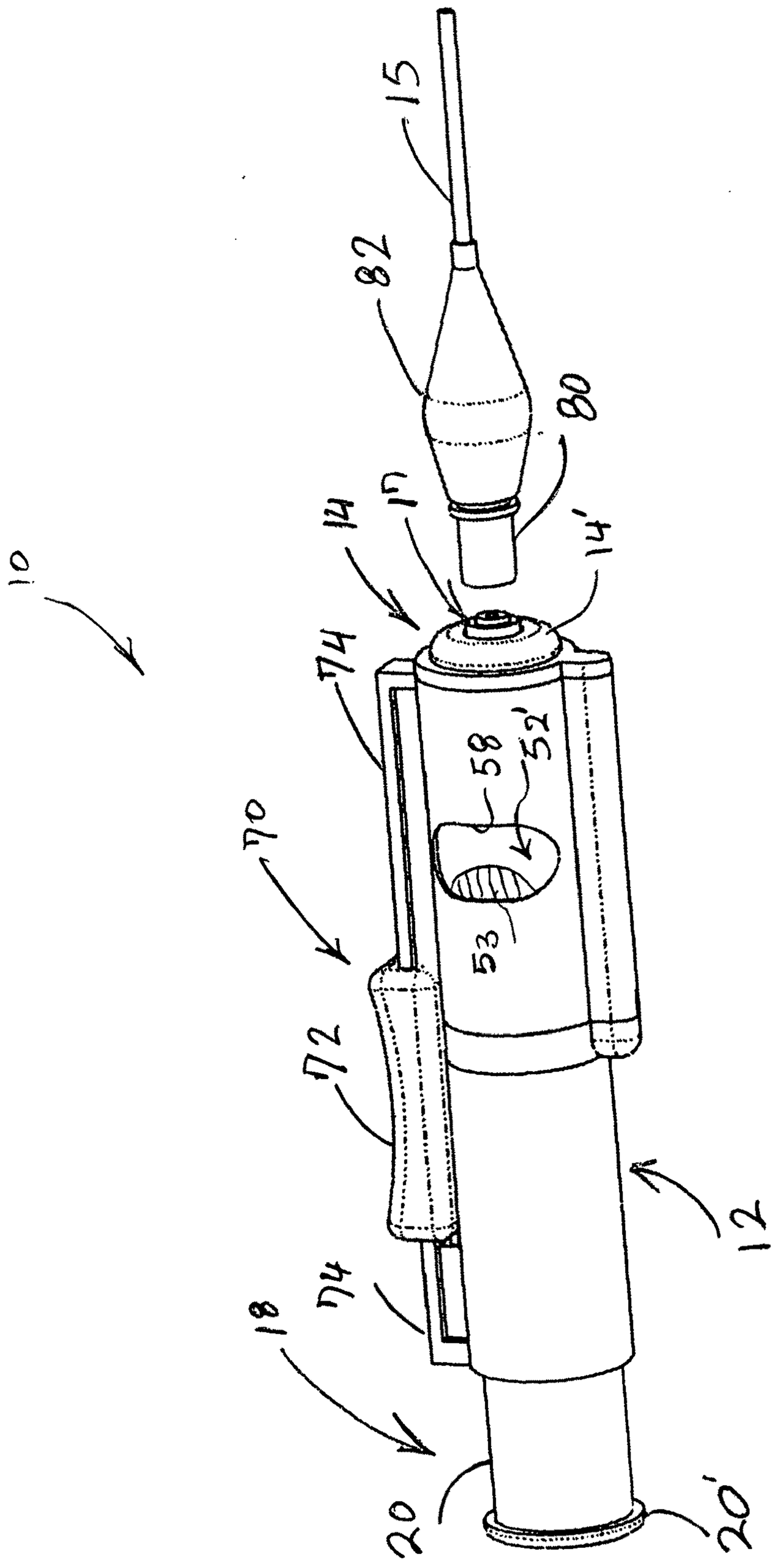

FIG. 1C

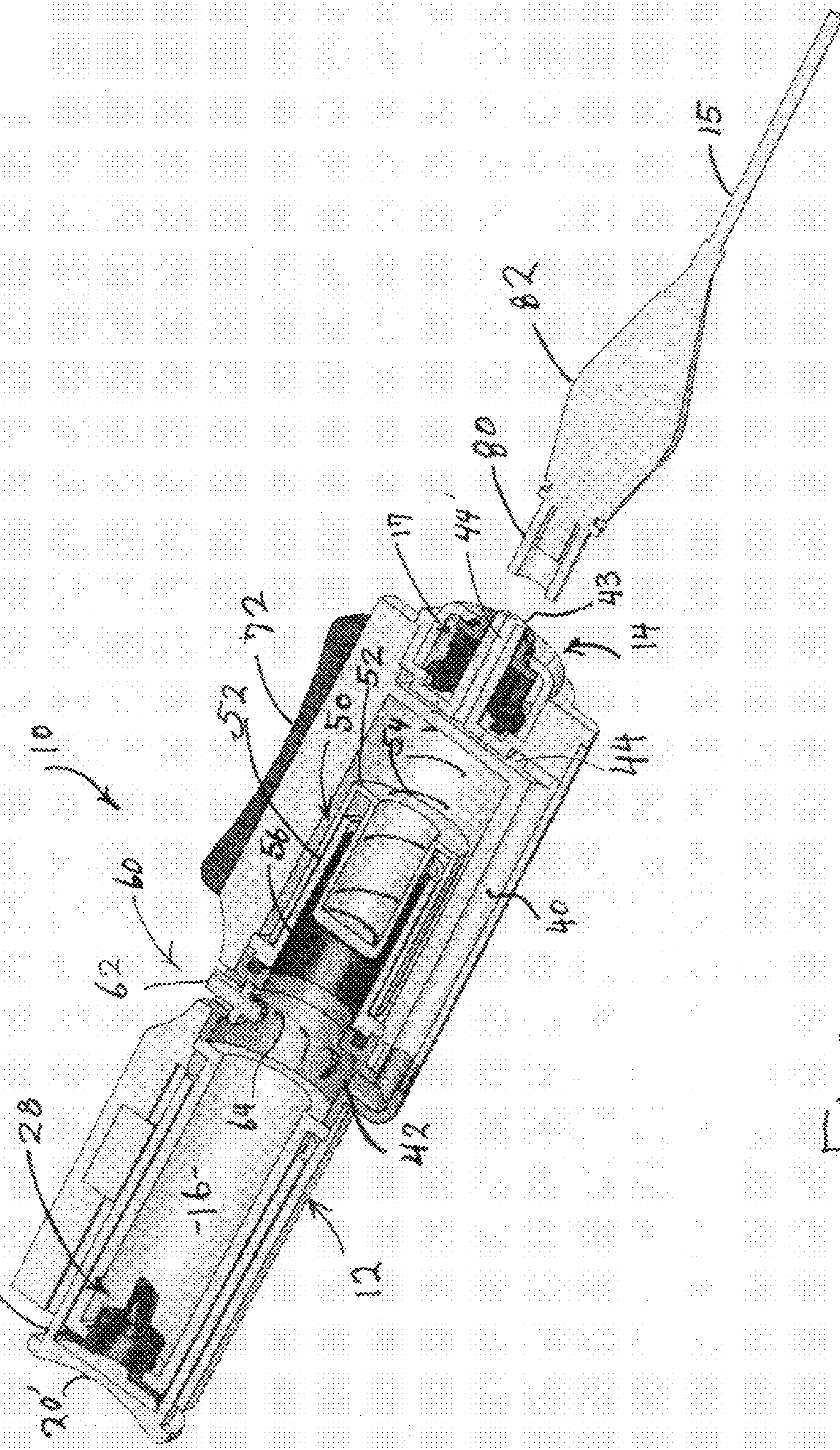
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Fig 2

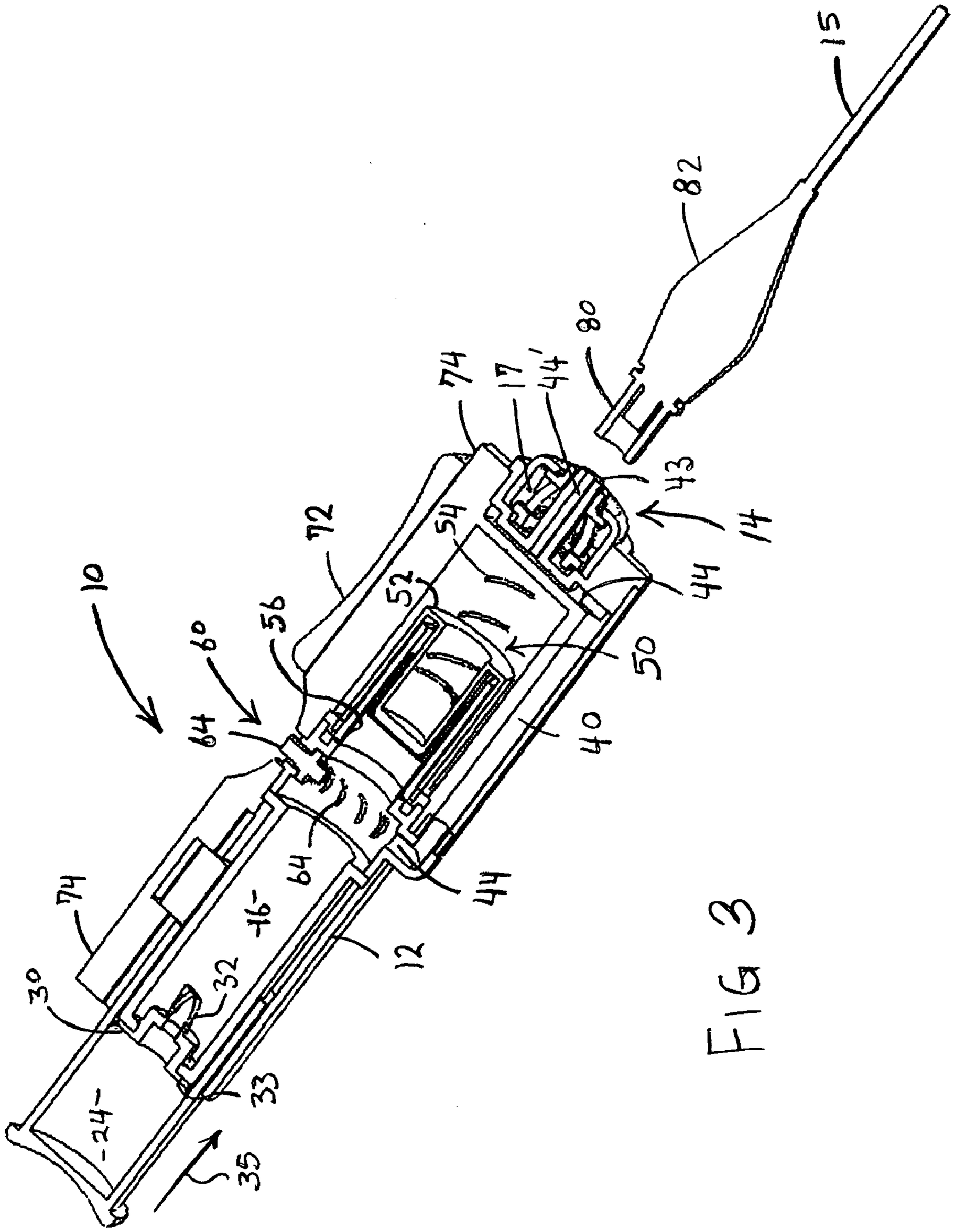
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FIG 3

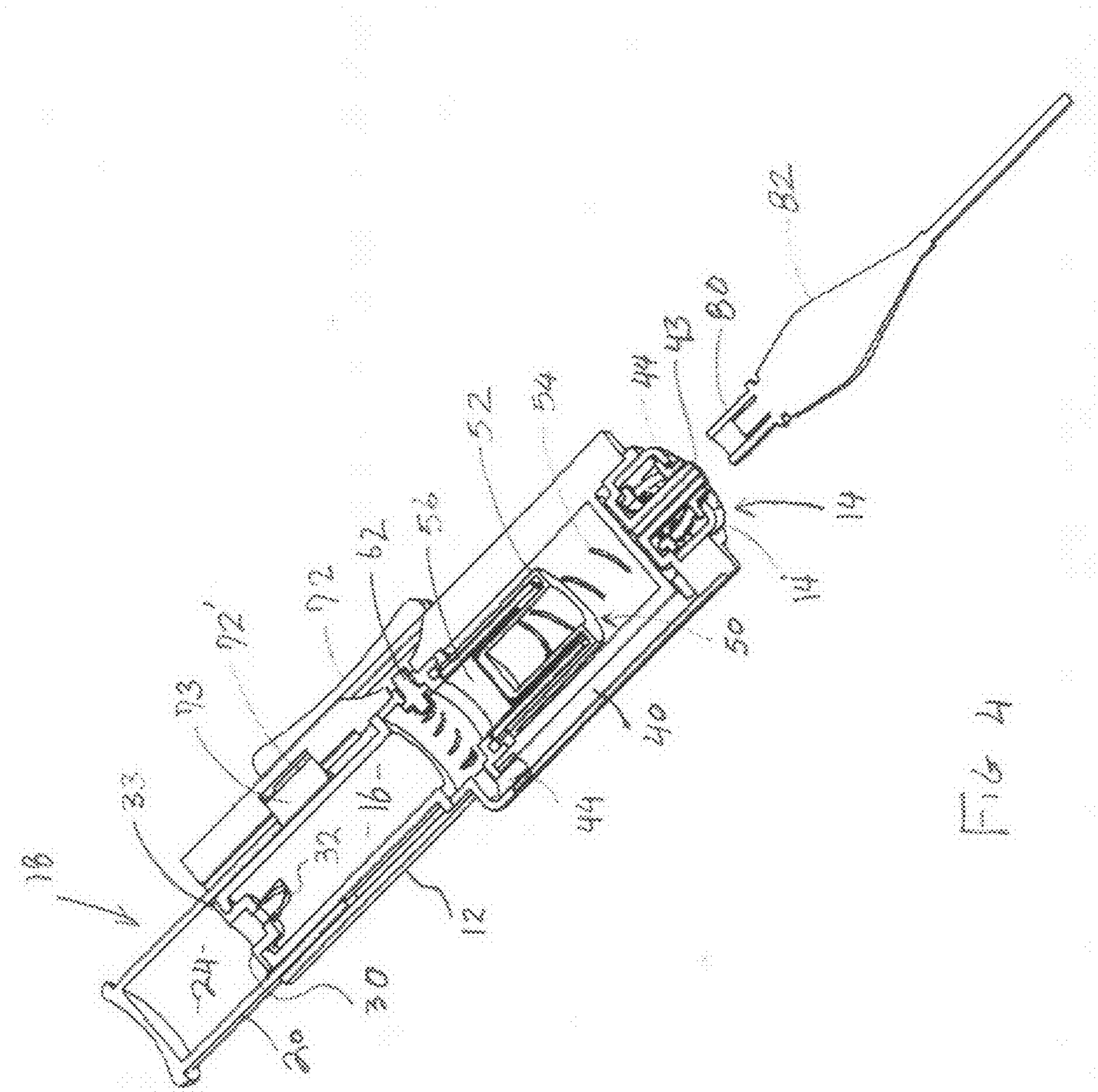
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FIG. 4

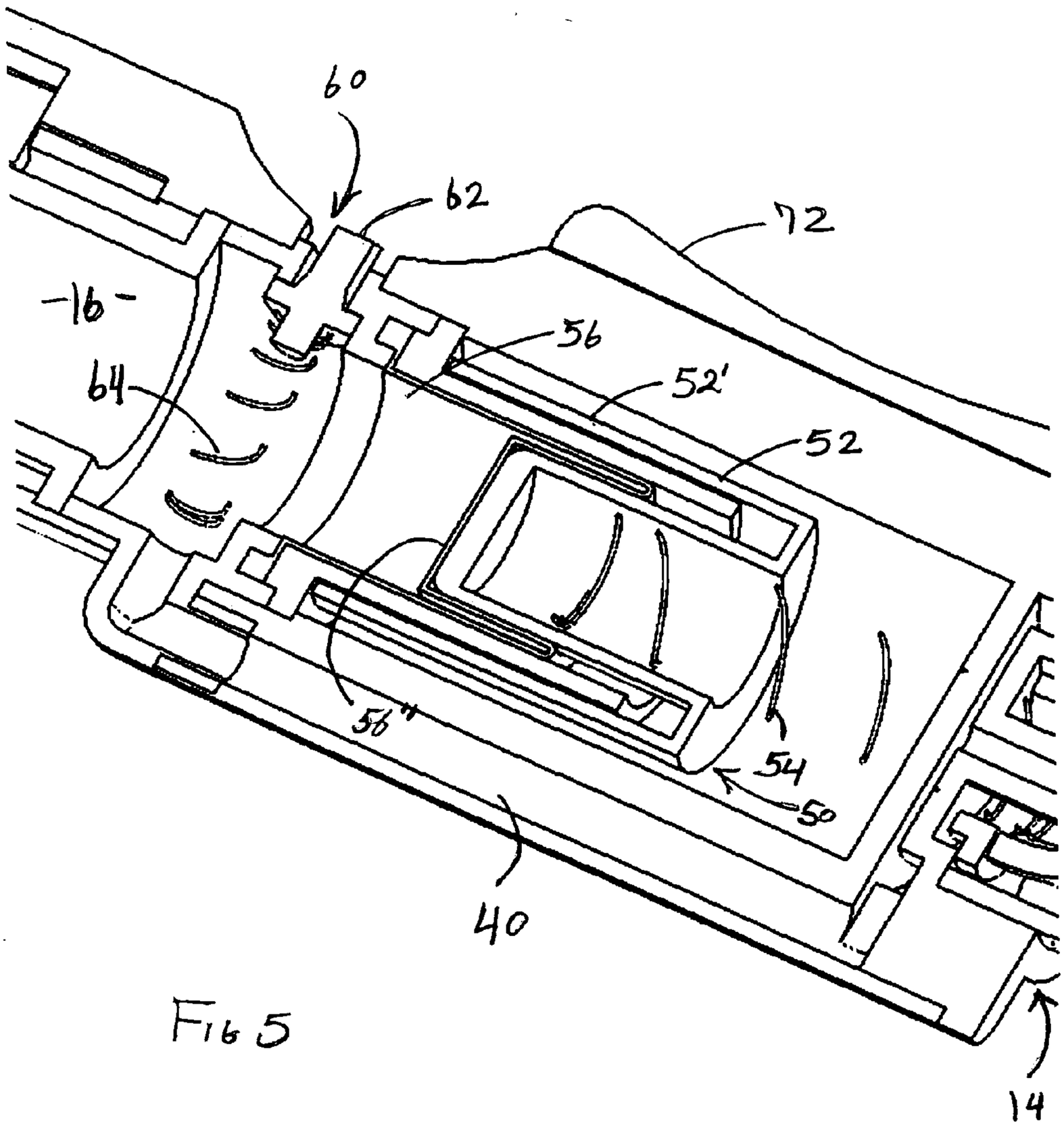


FIG 5

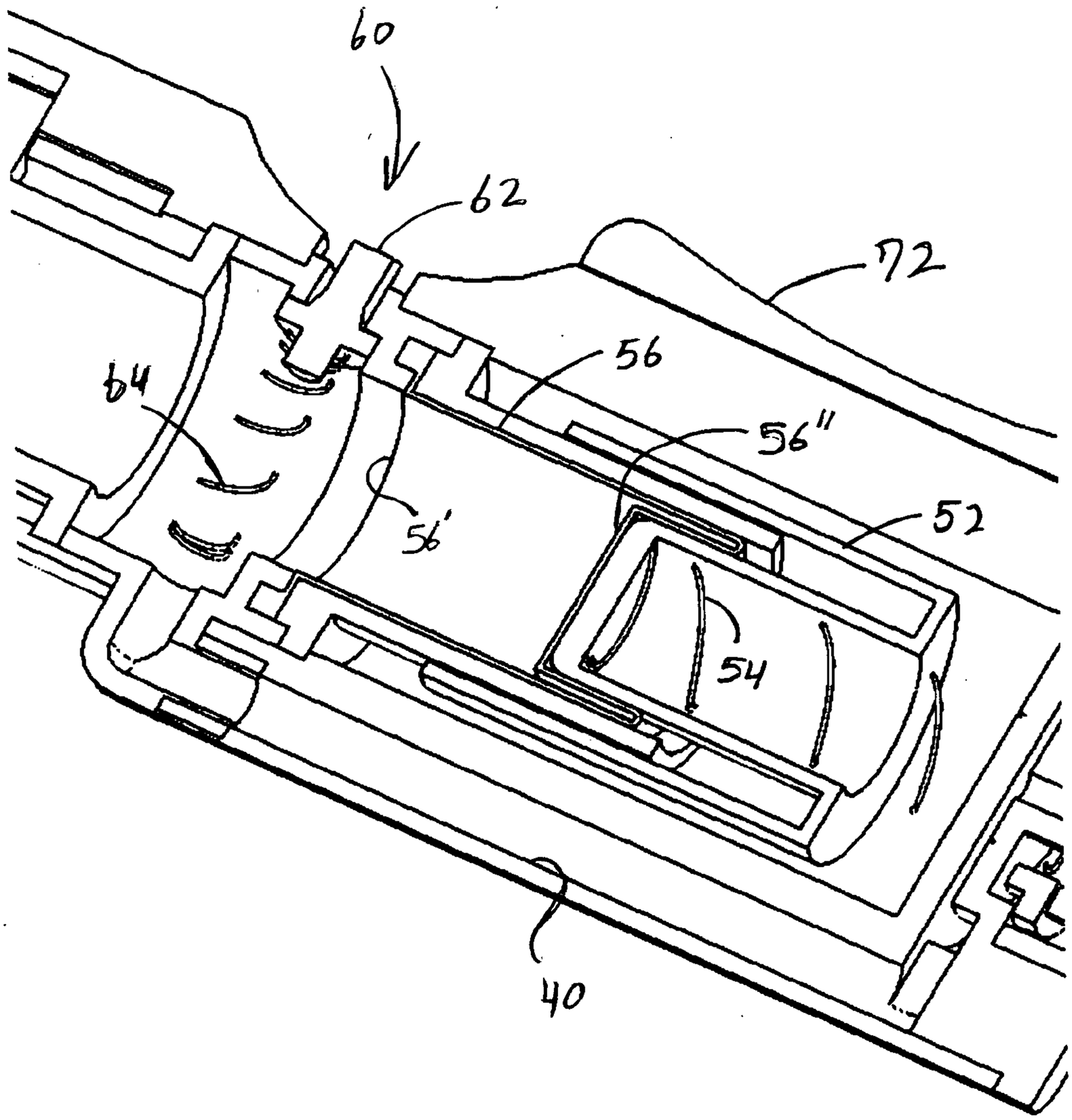


FIG 6

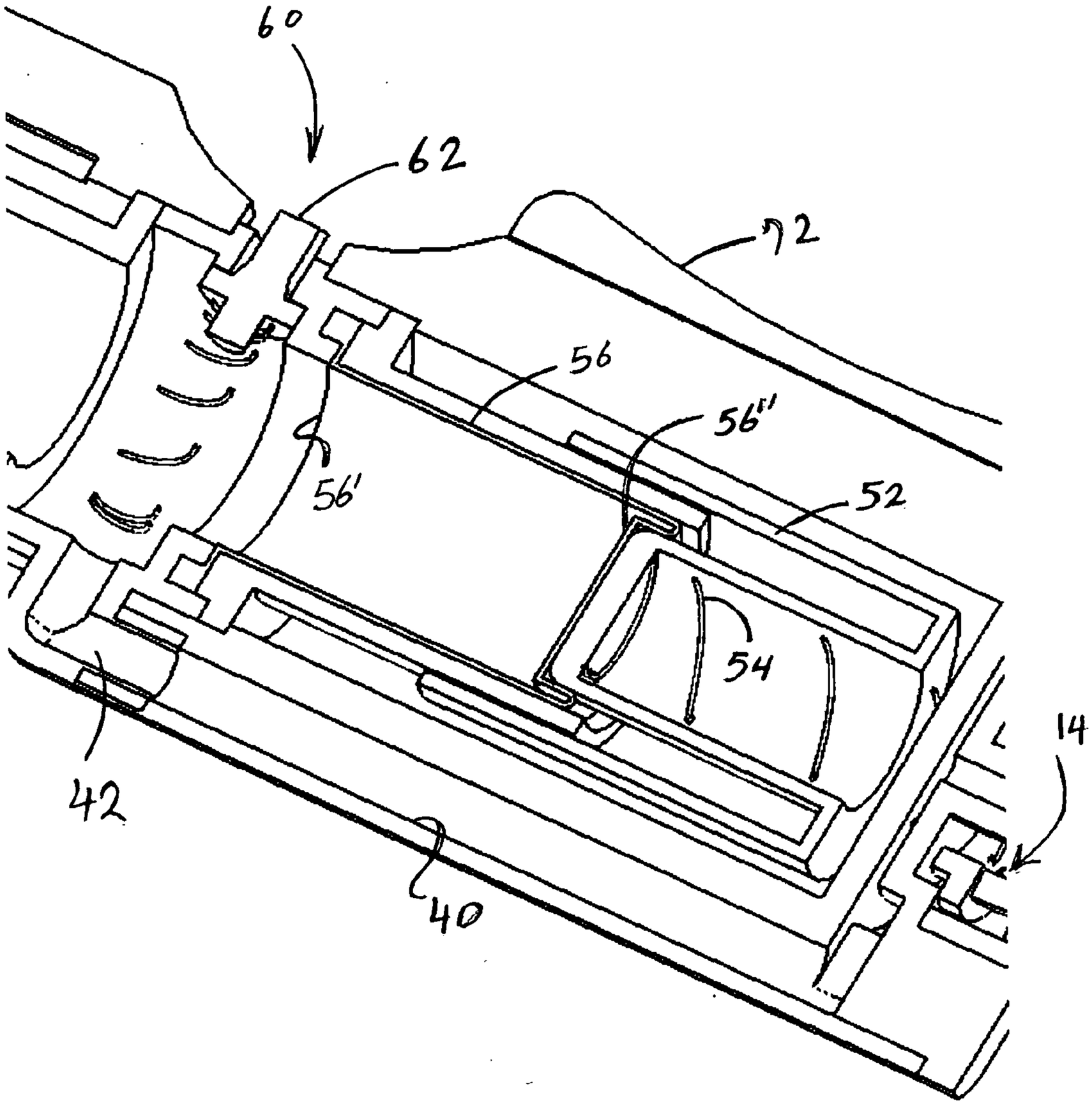


Fig 7

Fig. 8

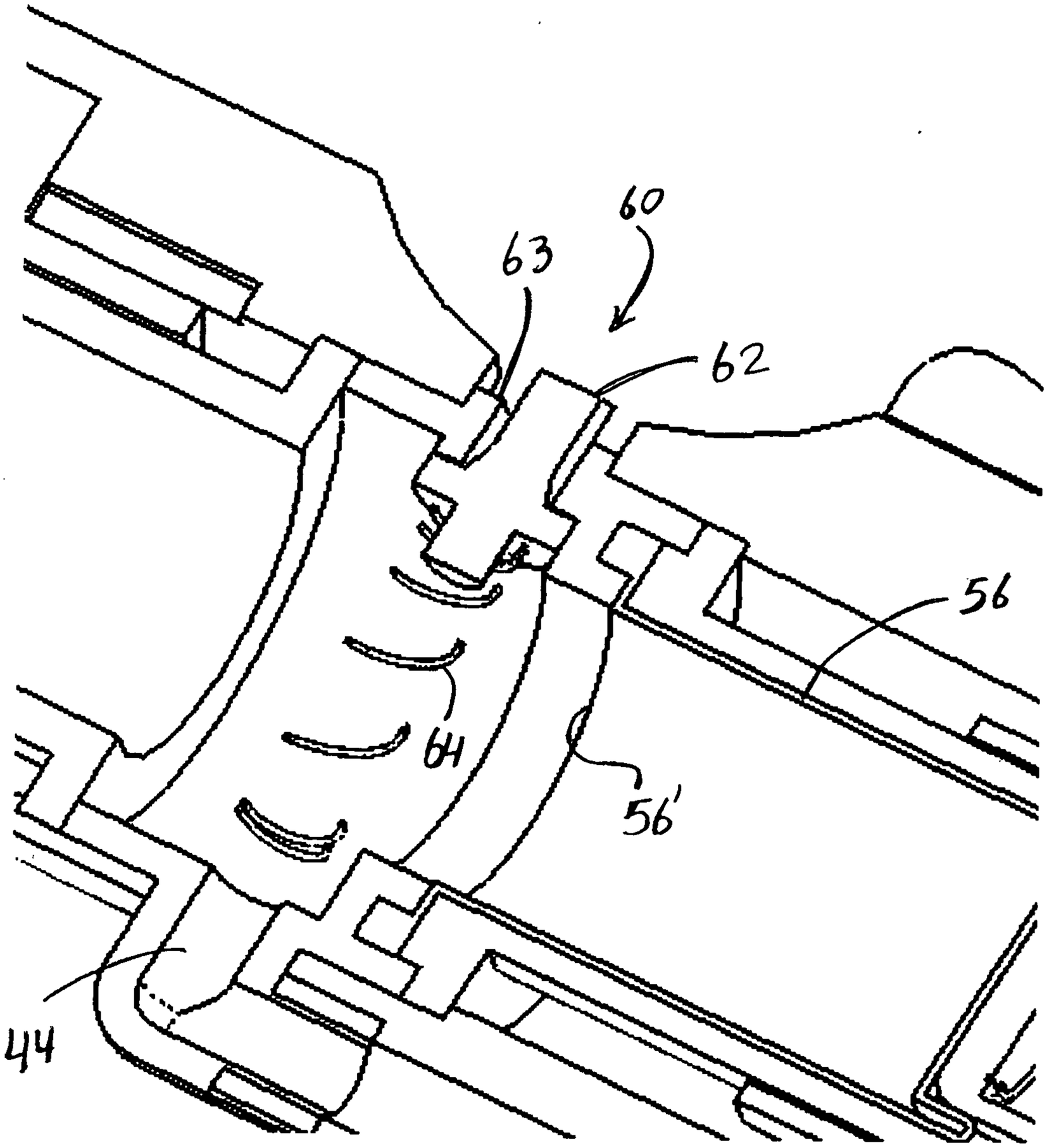
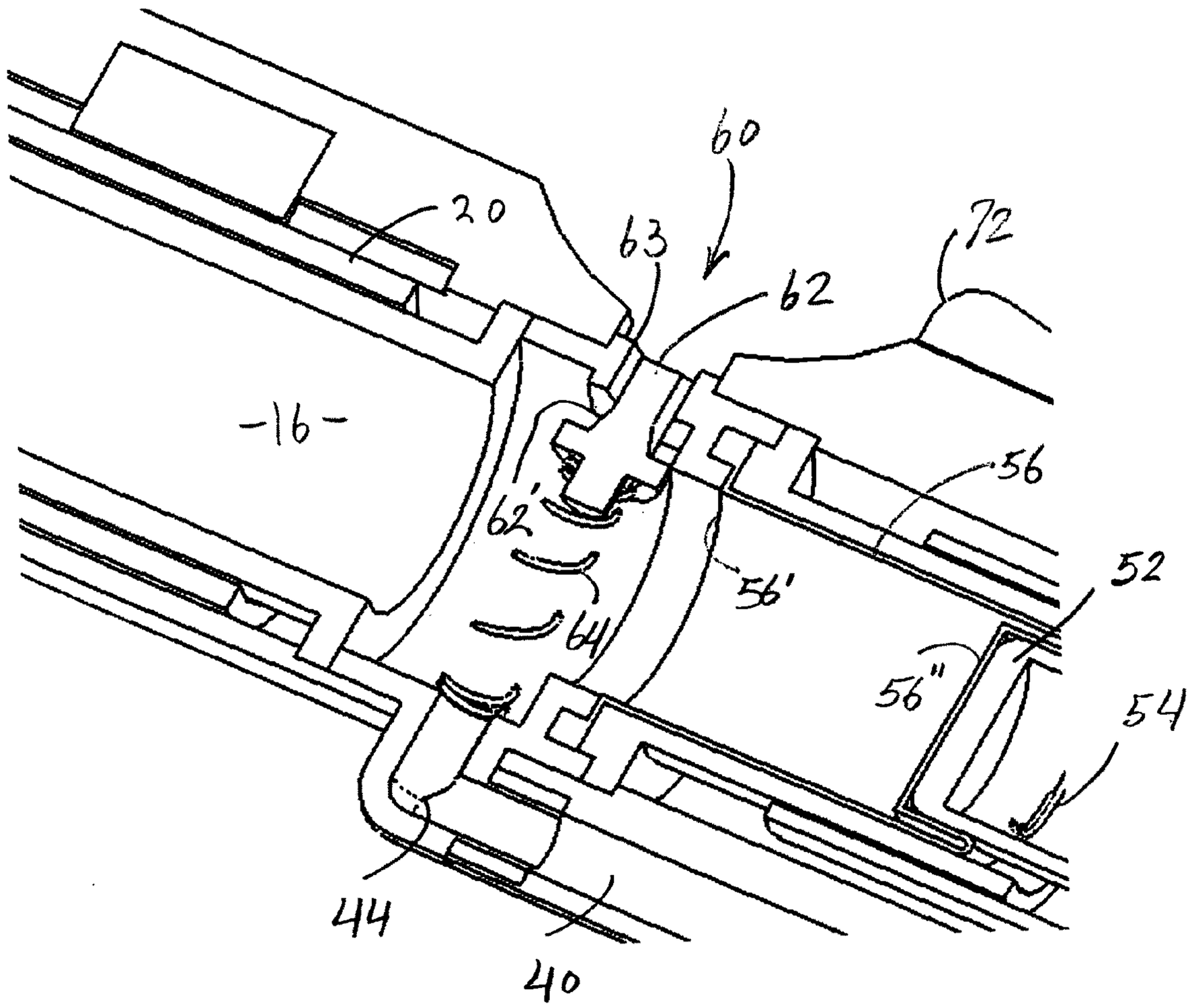


FIG 9



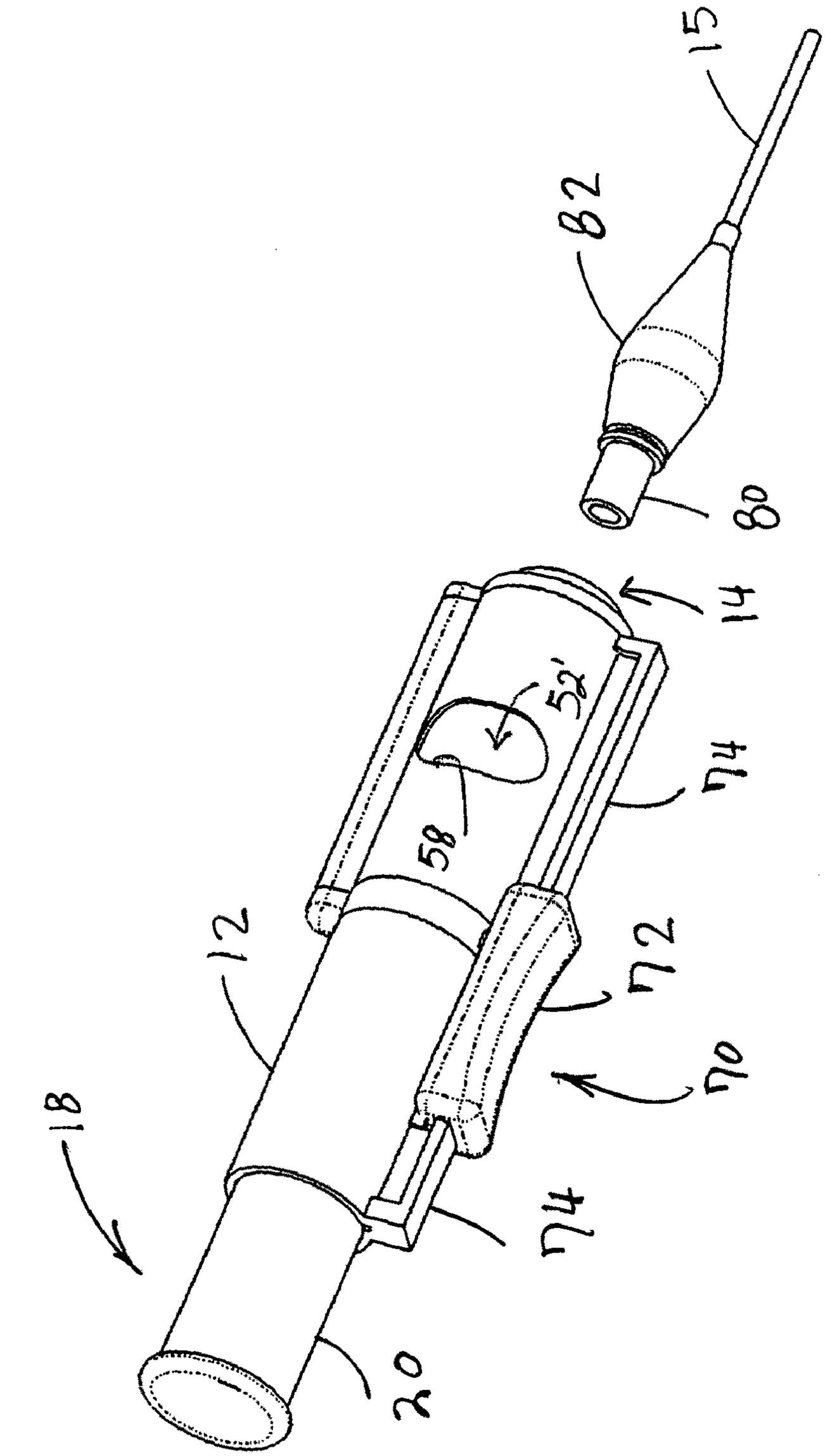


FIG. 10

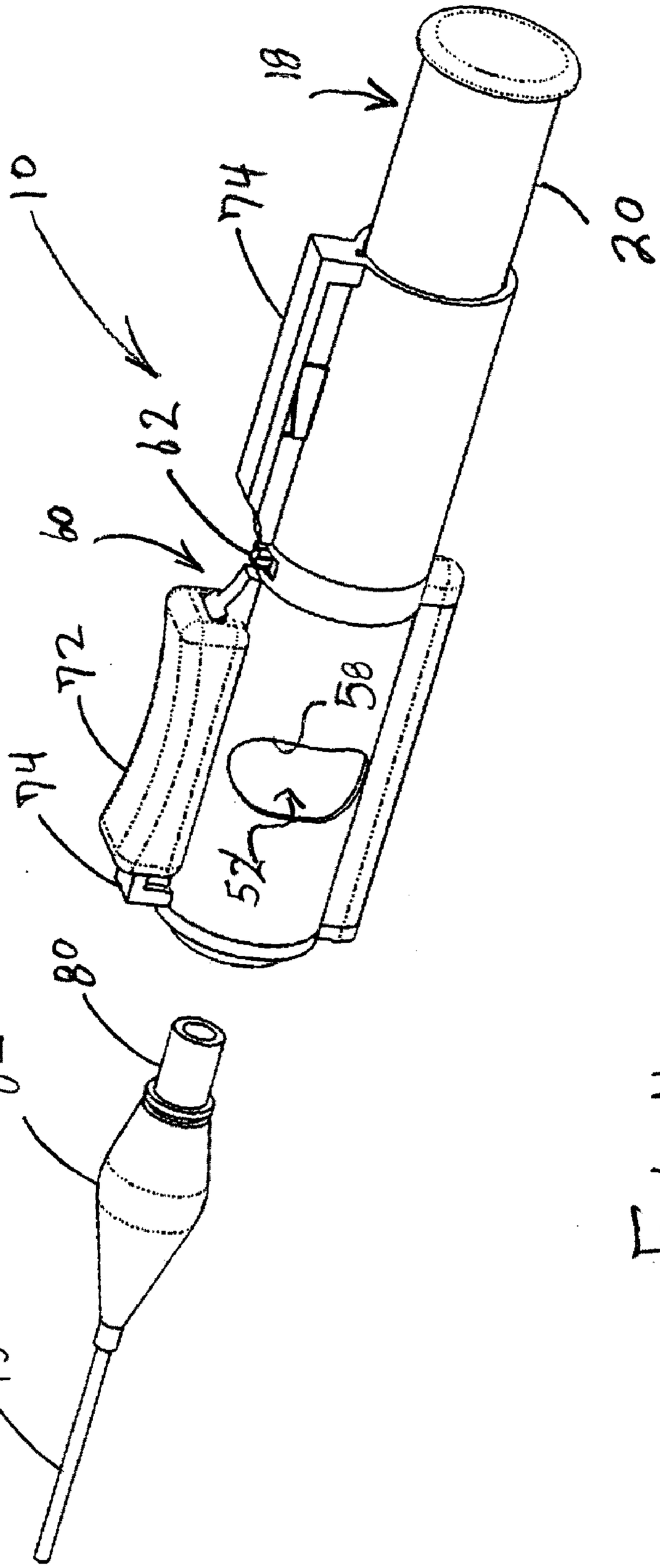


FIG 11

Fig 12

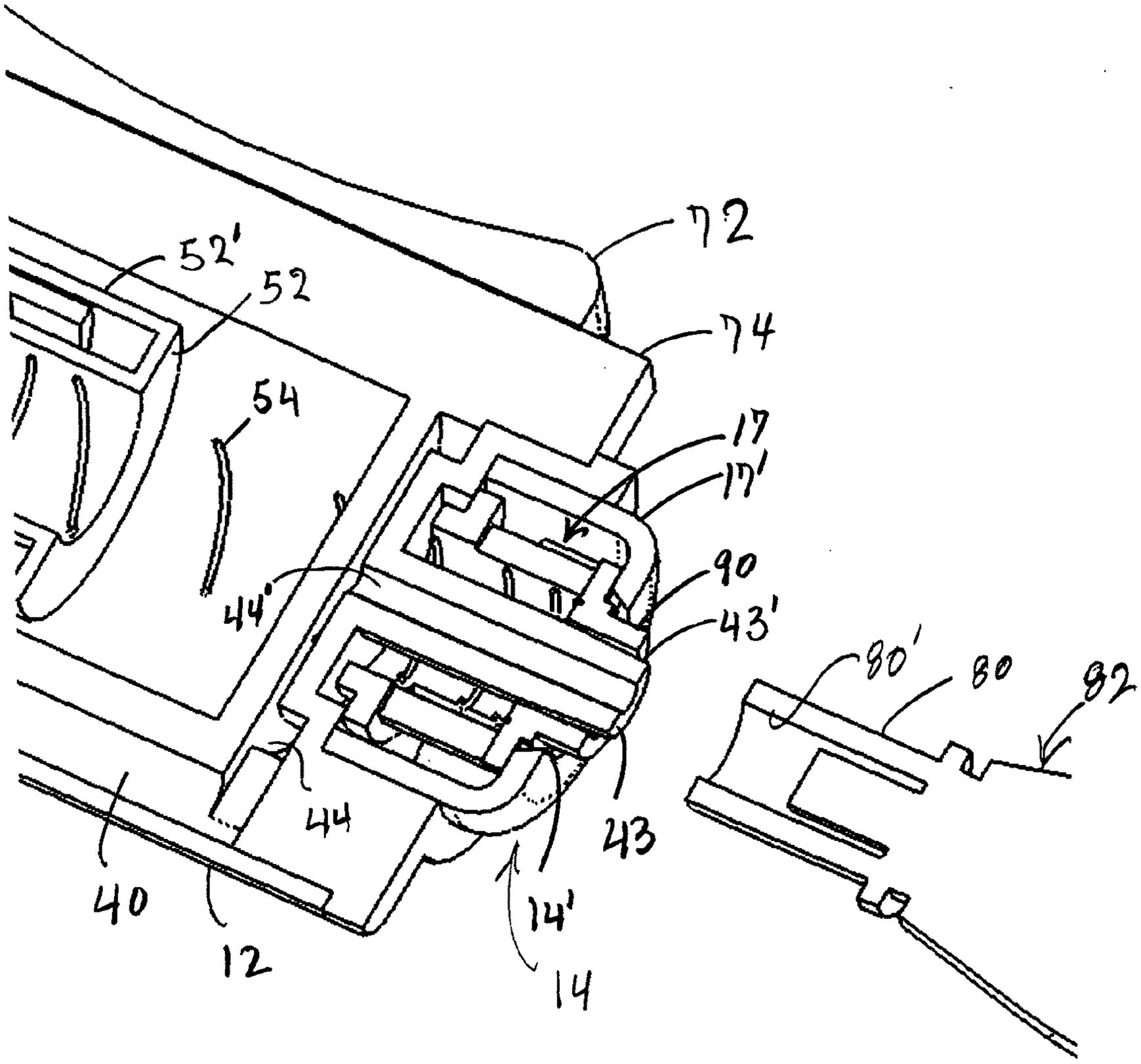
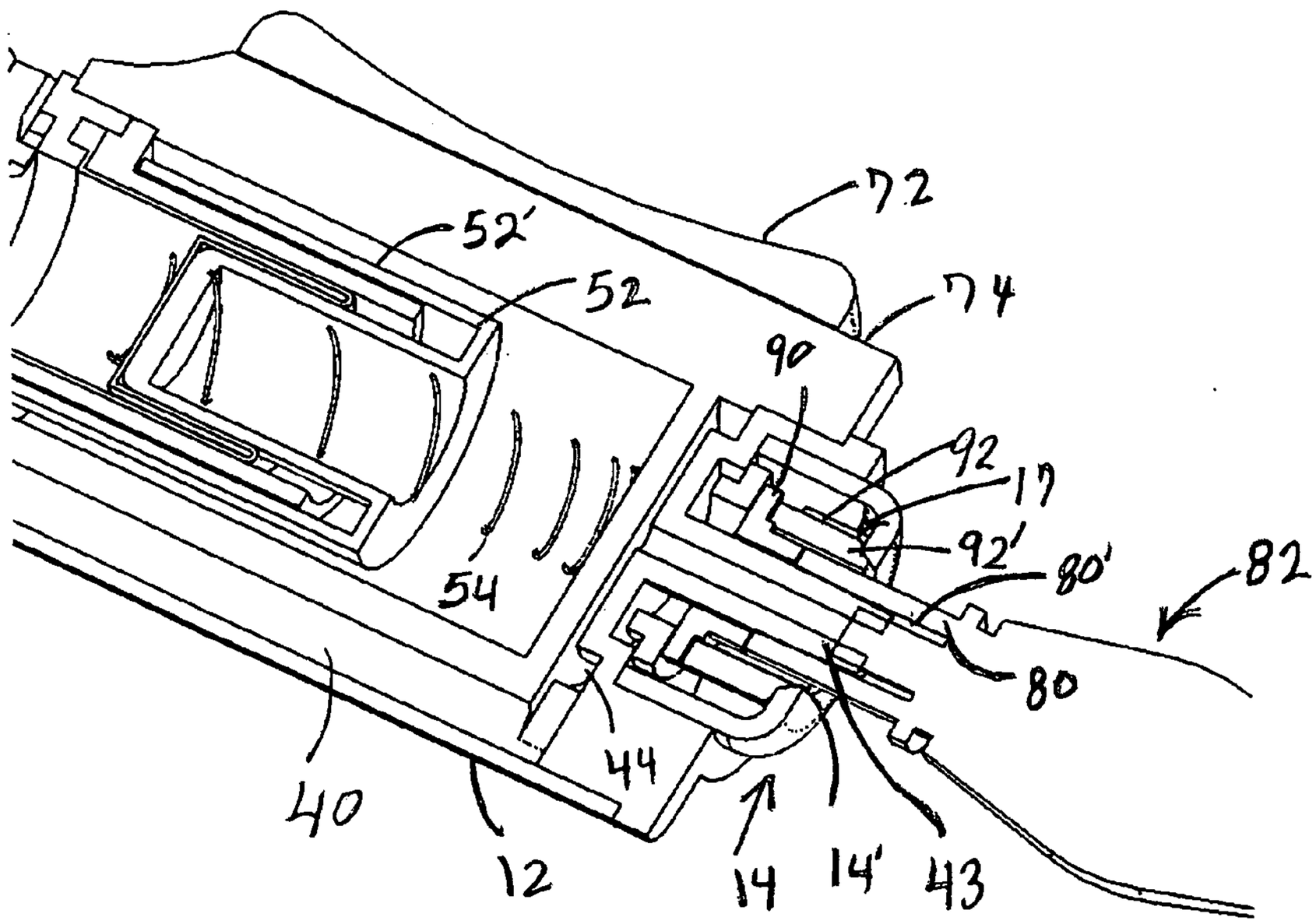


FIG 13



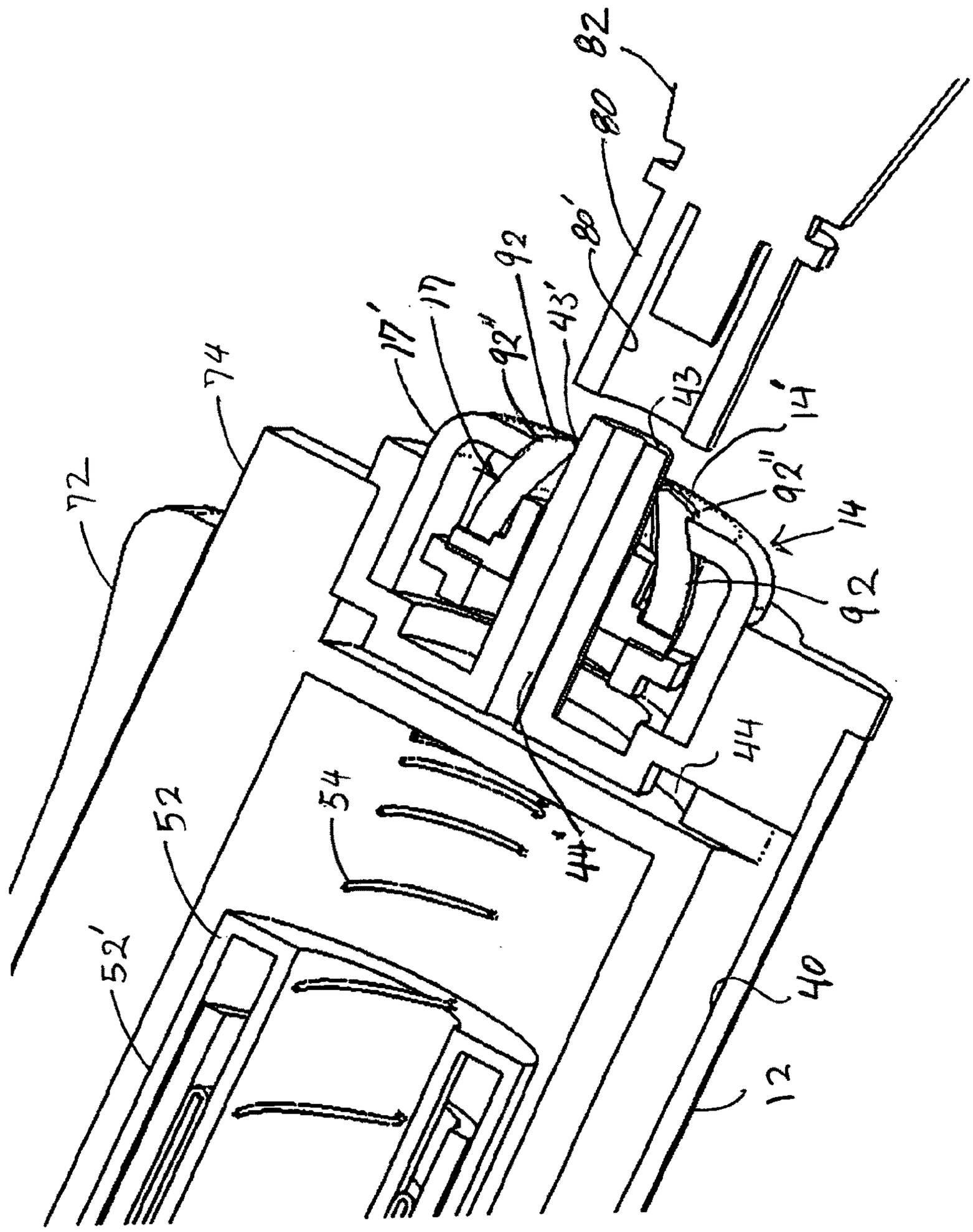


FIG 14

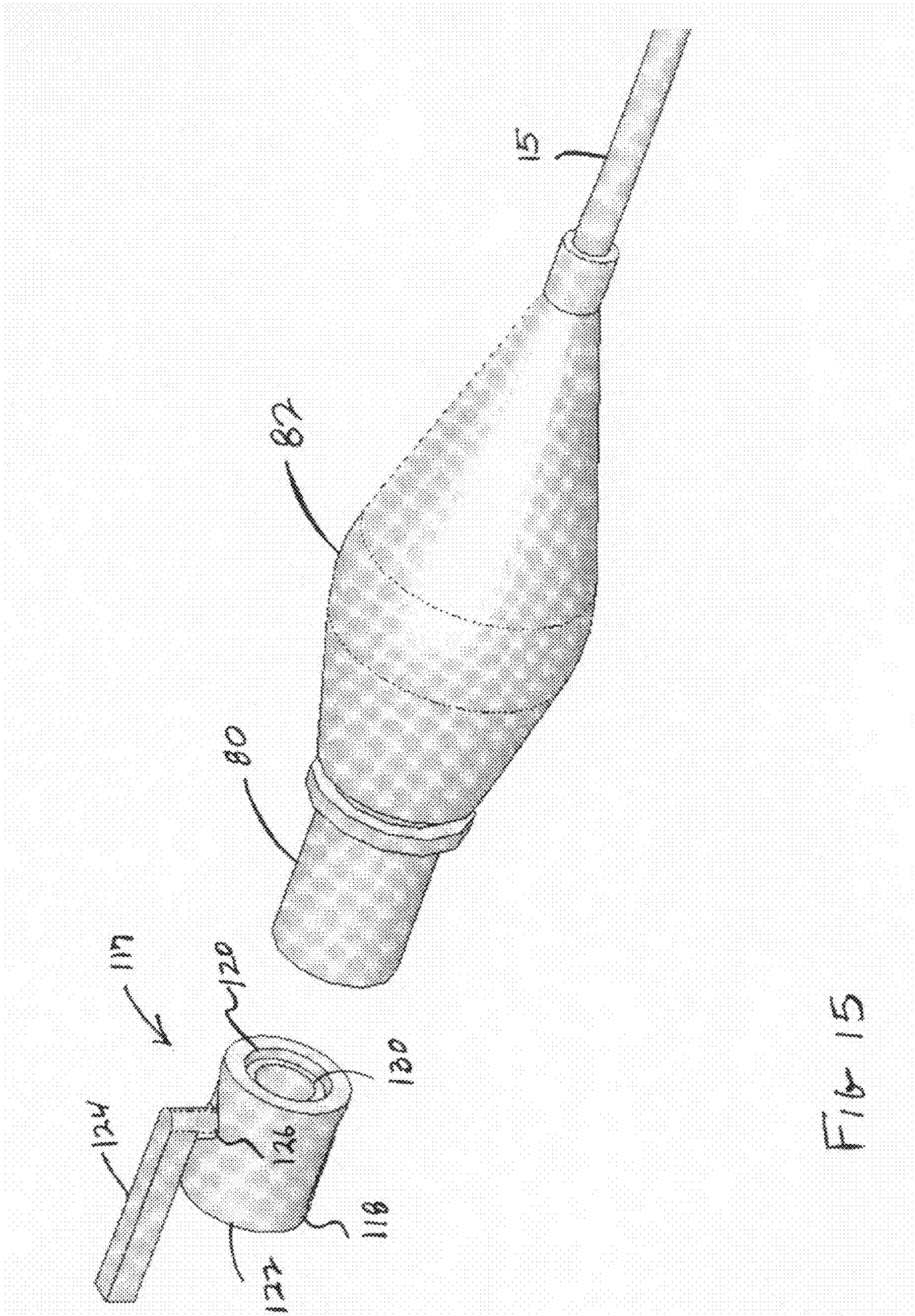


Fig 15

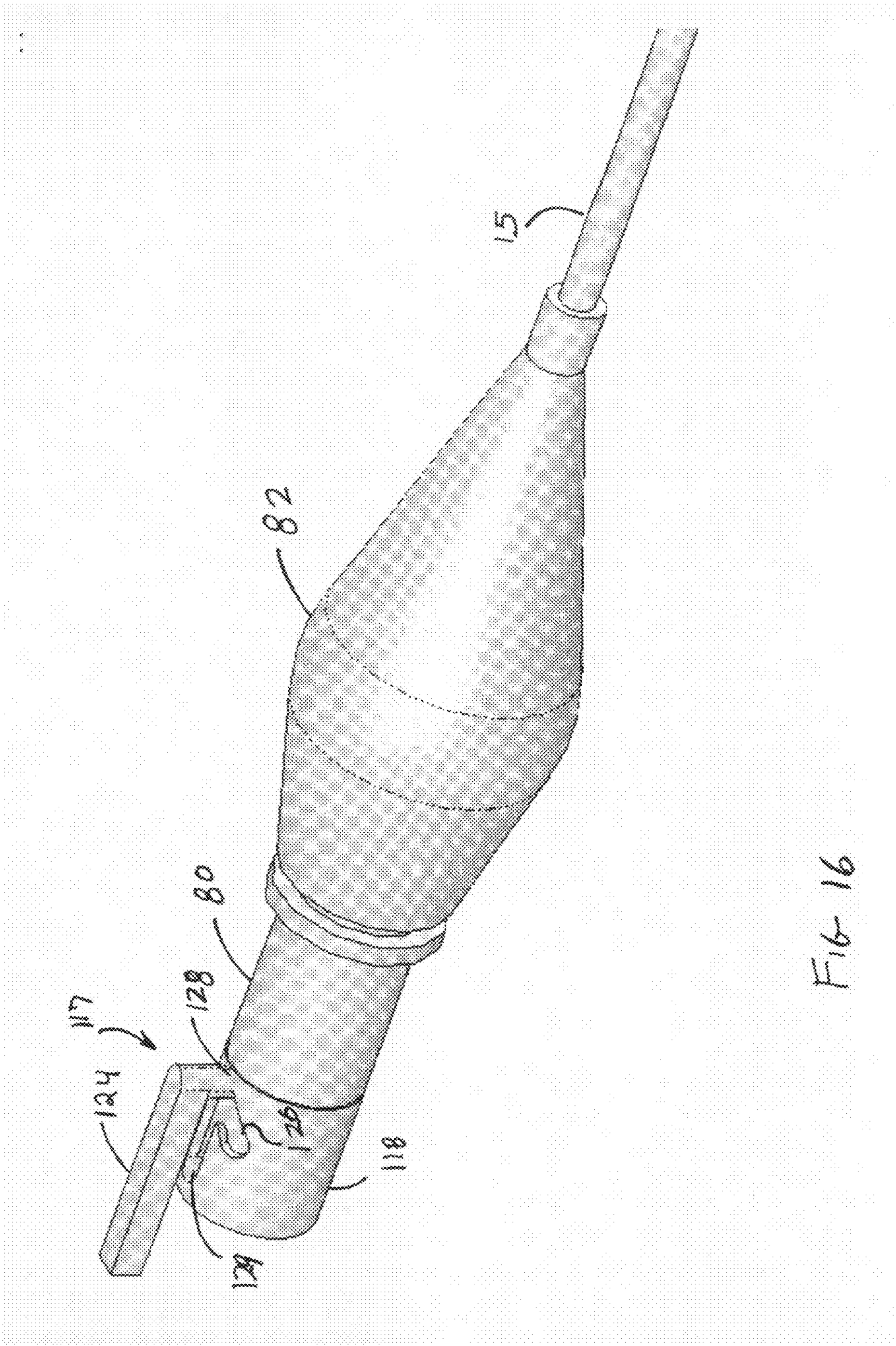


FIG. 16

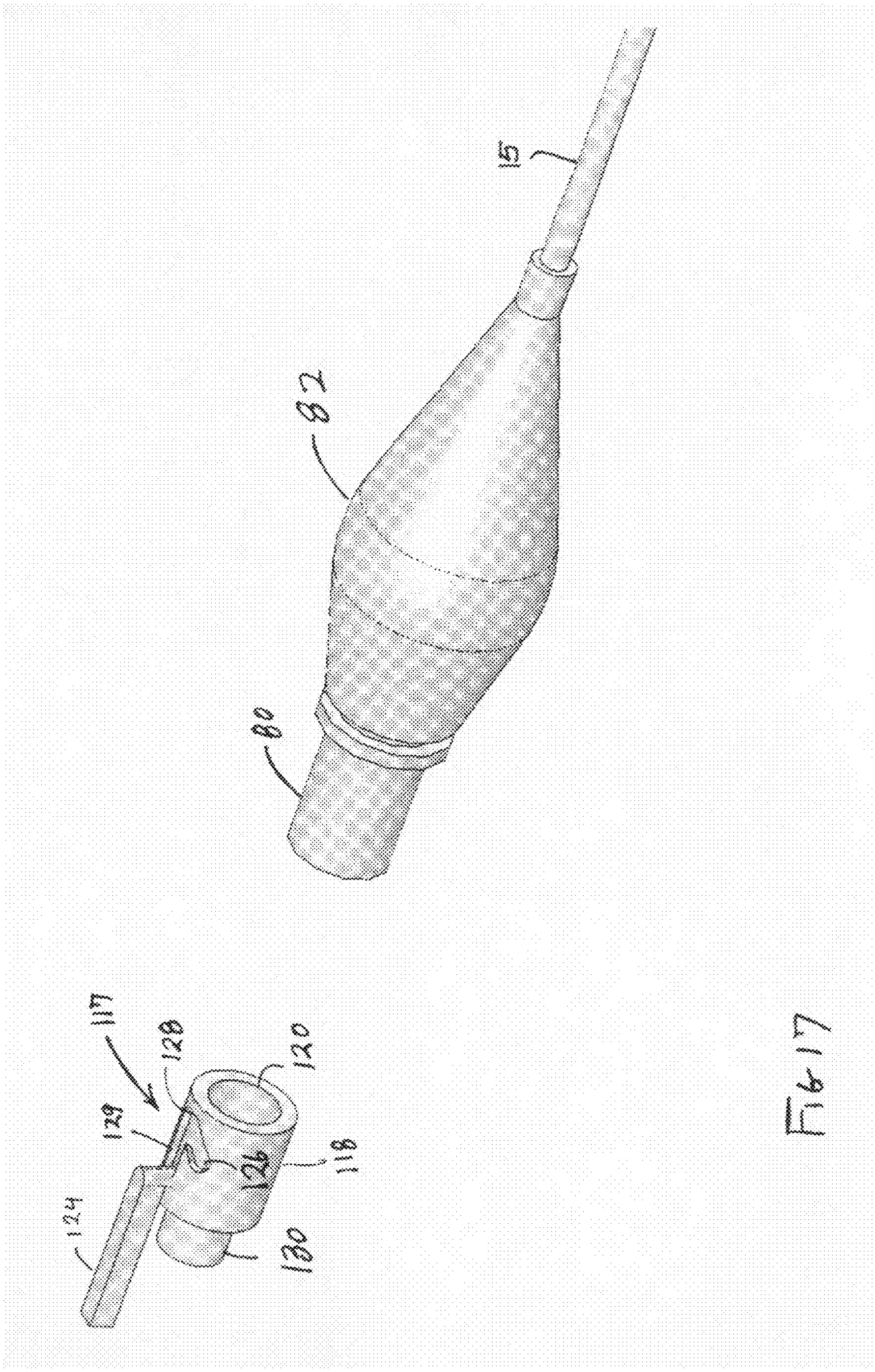


FIG 17

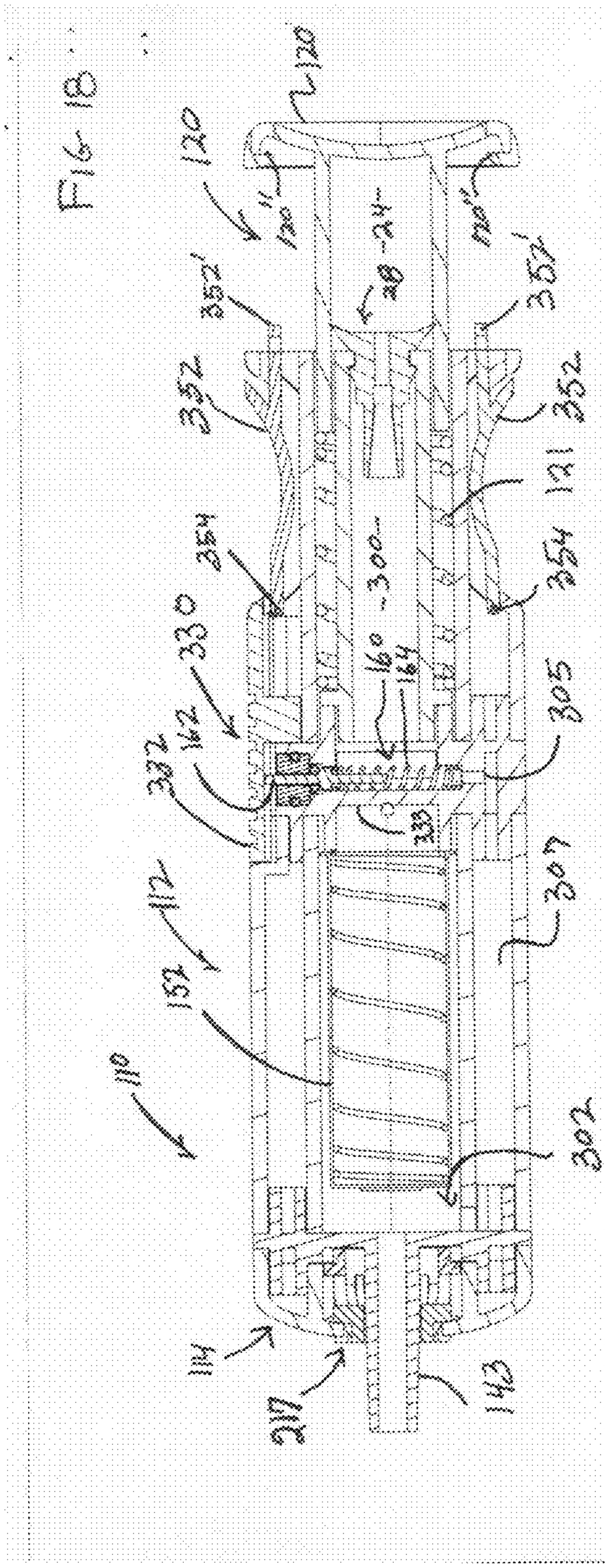


FIG 18
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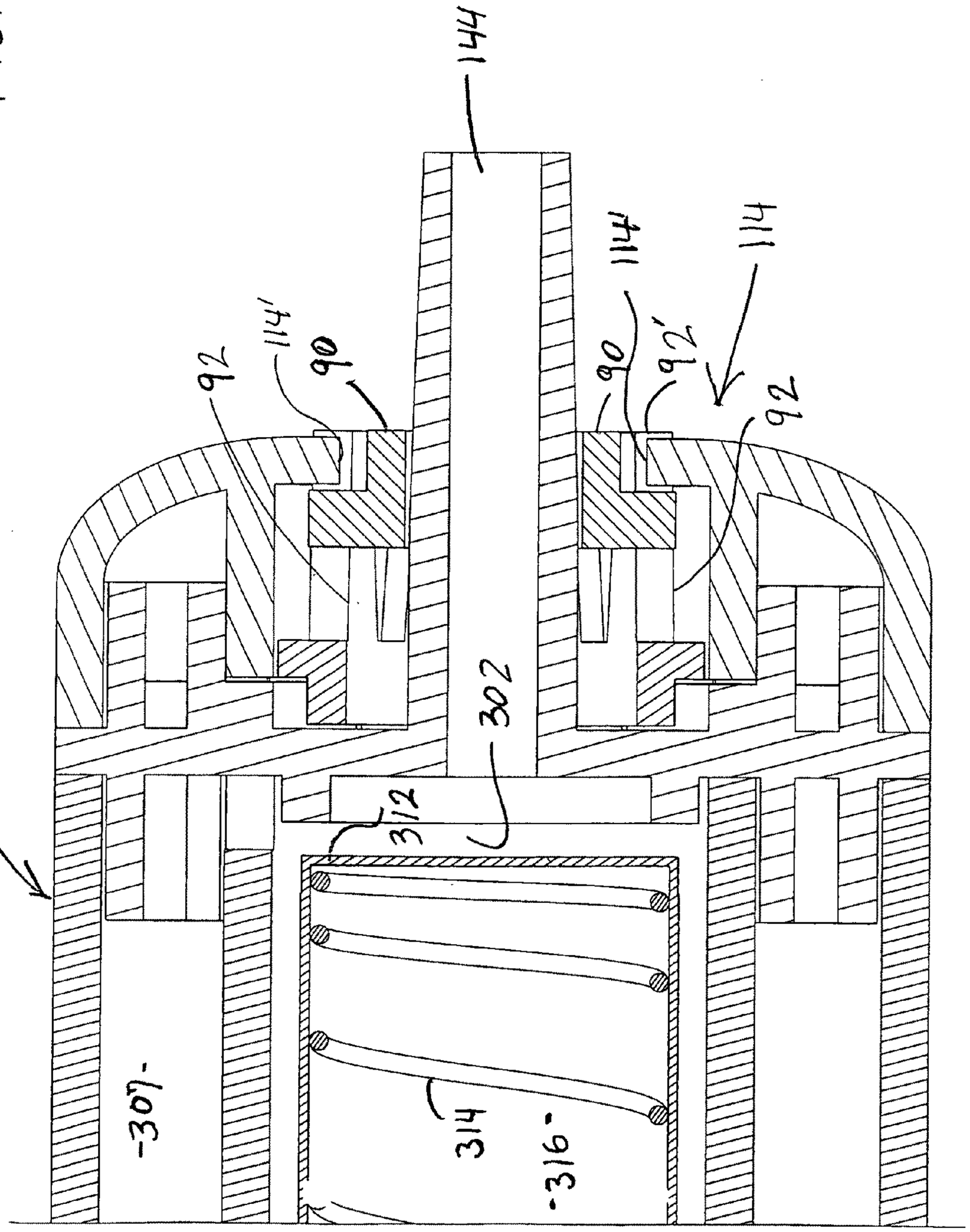
Fig. 20



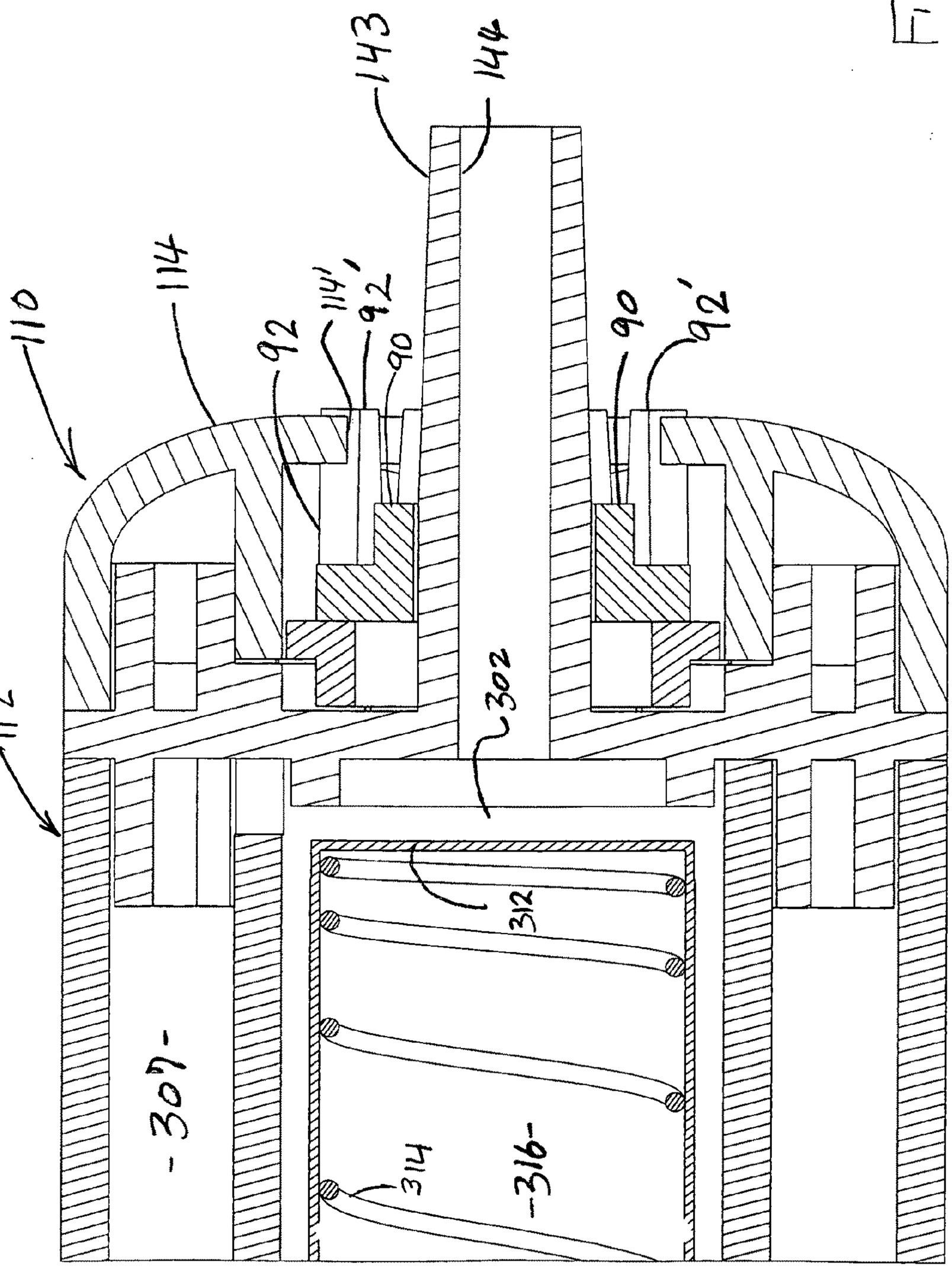


FIG 21

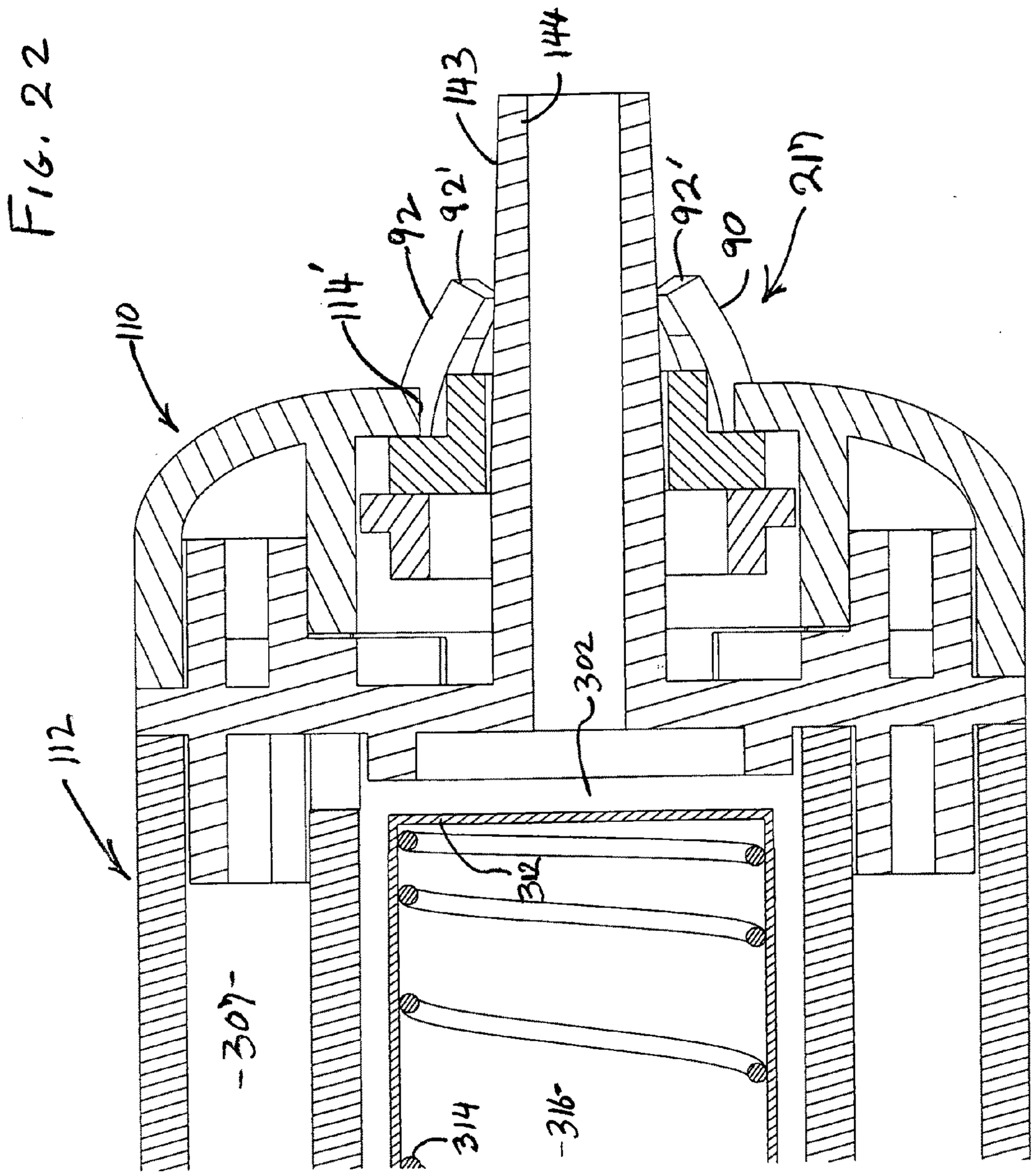


FIG. 22

INFLATION AND MONITORING ASSEMBLY FOR A PRESSURE CUFF OF AN ENDOTRACHEAL TUBE

CLAIM OF PRIORITY

[0001] The present application is a continuation-in-part application of previously filed, now pending application having Ser. No. 12/661,103, filed on Mar. 10, 2010 incorporated herein by reference in its 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 a retaining cuff associated with an endotracheal tube and/or tracheostomy tube including a casing having a pump assembly operative to inflate the retaining cuff. An indicator assembly is readily observable and variably positioned on the casing in response to the existing pressure of the cuff. The casing may be alternately structured for fixed or removable securement to an inflating lumen communicating with the cuff. Moreover, when removably secured the casing may be further structured to prevent reconnection to the lumen, once disconnection from the lumen has occurred. The casing includes a relief valve assembly to avoid over pressurization of the cuff.

[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 re-positioned, 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 re-use of the device is prevented to avoid cross-contamination of infection from patient to patient.

SUMMARY OF THE INVENTION

[0009] The present invention is directed to an assembly structured to inflate and monitor the pressure within a retaining or pressure cuff of the type associated with an artificial airway tube such as, 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.

[0010] 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.

[0011] 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 in the form of a plunger movably connected to the casing between and 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. 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, the 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, where the forced fluid flow travels to the retaining cuff. The cuff is thereby inflated and pressurized. While a preferred embodiment of the present invention comprises the pump assembly structured as an integrated and/or permanent part of the casing, it is noted that the removable pump assembly, having similar operative and structural characteristics as the plunger, etc., can be removably connected to the casing without departing from the spirit and scope of the present invention.

[0012] 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. As a result of the existing pressure within the pressure chamber being 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, which as set forth above, is the equivalent of the pressure within the cuff.

[0013] More specifically, the indicator member can be accurately described as being "variably positioned" within the casing dependent on and indicative 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 in both the pressure chamber and the retaining cuff.

[0014] 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 limited 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.

[0015] 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.

[0016] 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.

[0017] 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

[0018] 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:

[0019] FIG. **1**A 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.

[0020] FIG. **1**B is a front view of the embodiment of FIG. **1**A in a closed or compressed orientation.

[0021] FIG. **1**C 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.

[0022] FIG. **2** is a perspective view in longitudinal section of the embodiment of FIG. **1**C represented in a different operative orientation.

[0023] FIG. **3** is a longitudinal sectional view of the embodiment of FIGS. **1**C and **2** in an operative orientation.

[0024] FIG. **4** is a longitudinal sectional view of the embodiment of FIGS. **1***c*, **2** and **3** in yet a different stage of operation.

[0025] FIGS. **5-7** are detailed longitudinal sectional views of an indicator assembly of the embodiment of FIGS. **1**C and **2-4**, in successively different stages of operation.

[0026] FIG. **8** is a detailed longitudinal sectional view in partial cutaway of a pressure relief assembly associated with the embodiment of FIGS. **1**C and **2-7**.

[0027] 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.

[0028] FIG. **10** is a perspective view in partially exploded form of the embodiment of FIGS. **1**C 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**.

[0029] FIG. **11** is a perspective view in exploded form of the restriction assembly of the embodiment of FIG. **10** in a non-restricting position.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] FIG. **15** is a perspective view in exploded form of the yet another embodiment of a connection assembly.

[0034] FIG. **16** is a perspective view of the embodiment of FIG. **15** wherein the connection assembly has established a connection with an inflating lumen.

[0035] 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.

[0036] FIG. **18** is a longitudinal sectional view of the embodiment of FIG. **1**A.

[0037] FIG. **19** is a longitudinal sectional view of the embodiment of FIG. **1**B.

[0038] FIG. **20** is a detail view in partial cutaway of a connection assembly associated with an entry port of the embodiment of FIGS. **1**A, **1**B, and structurally and operationally similar to that represented in FIGS. **12-14**.

[0039] FIG. **21** is a detail view in partial cutaway of the embodiment of FIG. **20** in a different, operative orientation.

[0040] FIG. **22** is a detail view in partial cutaway of the embodiment of FIGS. **20** and **21** in a closed, obstructing orientation.

[0041] Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0042] 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 the type associated with an endotracheal tube.

[0043] 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 proximal 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 inflating 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.

[0044] With primary reference to FIGS. **1**C 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 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. **1**C, **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.

[0045] 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.

[0046] 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. **1**C, **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**.

[0047] 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'** is 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 represented 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**.

[0048] 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**.

[0049] While a 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 operative with the casing **12** without departing from the spirit and scope of the present invention.

[0050] 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**.

[0051] 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 features 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.

[0052] 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**.

[0053] 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**.

[0054] 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**.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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**.

[0059] 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. **1**C, **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.

[0060] 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**.

[0061] 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**.

[0062] 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.

[0063] 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'**.

[0064] 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.

[0065] 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 us 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.

[0066] 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.

[0067] 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**.

[0068] 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**.

[0069] As represented in FIGS. **1**A, **1**B 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. **1**C-**14**, described above. However, the assembly **110** includes additional structure and operative features which are distinguishable from the assembly **10**, wherein such distinguishing features are described in greater detail hereinafter.

[0070] More specifically, the structure of FIGS. **1**A, **1**B 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**.

[0071] 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. **1**A and **18** and a compressed orientation as represented in FIGS. **1**B 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. **1**A 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**.

[0072] 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. **1**A and **18** and the inwardly compressed position of FIGS. **1**B 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**.

[0073] With further reference to FIGS. **1**A, **1**B, **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.

[0074] 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. **1**A and **1**B 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.

[0075] 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 indictor 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**.

[0076] With further reference to the embodiments of FIGS. **1**A, **1**B, **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. **1**A 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. **1**A 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'**.

[0077] Yet additional structural and operative features included in the additional preferred embodiment of FIGS. **1**A, **1**B, **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. **1**B 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.

[0078] 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**.

[0079] 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**.

[0080] 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.

[0081] 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.

[0082] Now that the invention has been described,

What is claimed is:

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

a casing including an interior pressure chamber disposed in fluid communication with the retaining cuff; said pressure chamber including a multi-chamber construction comprising at least a first chamber and a second chamber,

a plunger connected to said casing and movable within said first chamber between an extended position and a compressed position,

said plunger structured to force fluid flow to the retainer cuff sequentially through said first chamber and said second chamber,

a valve assembly disposed in fluid regulating relation between said first chamber and said plunger,

a fluid channel disposed in direct fluid communication with said second chamber and structured to deliver fluid flow to the retaining cuff,

an indicator assembly movably disposed within said second chamber in exposed, fluid communication with said fluid channel, said indicator assembly including an indicator member, said indicator member variably positionable on said casing dependent on and indicative of existing pressure within at least said second chamber, and

said second chamber and fluid channel disposed in fluid communication with the retaining cuff, wherein said existing pressure within said second chamber is substantially equivalent to the pressure within the retaining cuff.

2. An assembly as recited in claim **1** wherein said indicator assembly further comprises a reaction member movably disposed in fluid communication within said second chamber and in driving relation to said indicator member; said variable positioning of said indicator member being dependent on disposition of said reaction member and existing pressure within said second chamber being exerted on said reaction member.

3. An assembly as recited in claim **2** wherein said reaction member is connected to said indicator member and movable therewith within said second chamber, said casing including a window disposed in visually accessible relation to said variably positionable indicator member.

4. An assembly as recited in claim **2** wherein said indicator assembly further comprises a biasing structure disposed in biasing engagement with said reaction member; said reaction member biasingly mounted in normally opposing relation to said existing pressure within said second chamber.

5. An assembly as recited in claim **4** wherein said reaction member and said biasing structure are disposed within said second chamber in physically segregated relation to said first chamber.

6. An assembly as recited in claim **5** wherein said reaction member includes a hollow interior, said biasing structure disposed within said hollow interior, said reaction member movable between an outwardly extended orientation and a compressed orientation; a vent structure fluidly interconnecting said hollow interior of said reaction member to an exterior of said casing, said vent structure disposed and structured to regulate fluid flow into and out of hollow interior upon movement of said reaction member between said extended orientation and said compressed orientation.

7. An assembly as recited in claim **1** said valve assembly comprising a first valve member and a second valve member cooperatively disposed and structured to regulate fluid flow from an exterior of said casing into at least said first chamber, through an interior of said plunger.

8. An assembly as recited in claim **7** wherein said first and second valve members each comprise a one way valve structure concurrently operable in interconnecting relation between said plunger interior and said first chamber; said first and second valve members alternately disposed in an open position and a closed position to regulate fluid flow from an exterior of said casing into said first chamber, through said interior of said plunger.

9. An assembly as recited in claim **1** further comprising a relief valve assembly operably accessible from an exterior of said casing and disposed in regulating relation to pressure within said pressure chamber; a shield assembly movably mounted on said casing and disposable in access restricting relation to said relief valve assembly.

10. An assembly as recited in claim **9** said shield assembly including an activating portion deformable into activating relation with said relief valve assembly; said shield assembly selectively disposable between a closed, valve shielding position and an open valve activating position.

11. An assembly as recited in claim **1** further comprising a retaining assembly connected to said casing and disposable into and out of retaining relation to said plunger.

12. An assembly as recited in claim **11** said retaining assembly including at least one retaining member, said one retaining member including one end disposable into and out of retaining engagement with said plunger.

13. An assembly as recited in claim **12** wherein said one retaining member is movable relative to said casing and into and out of retaining engagement with said plunger.

14. An assembly as recited in claim **13** wherein said one retaining member is pivotally connected to said casing and normally biased into said retaining engagement with said plunger.

15. An assembly as recited in claim **11** wherein said retaining assembly comprises two substantially oppositely disposed elongated retaining members each including one end disposable into and out of retaining engagement with said plunger; each of said retaining members manually positionable towards and away from said casing and into and out of retaining engagement with said plunger.

16. An assembly as recited in claim **1** further comprising a connection assembly disposed in interconnecting relation between said casing and an inflation lumen of the retaining cuff; said connection assembly disposable between a connect orientation and a disconnect orientation.

17. An assembly as recited in claim **16** wherein said retaining assembly comprises a retaining member and a gripping structure movably disposed relative to one another and to an entry port of said casing; said retaining member disposed in receiving relation to a connector of the retaining cuff and movable relative to said gripping structure upon receipt of the connecting member.

18. An assembly as recited in claim **17** wherein said gripping structure is disposed to extend outwardly through said receiving port in entry obstructing relation thereto upon removal of the connector member associated with the retaining cuff.

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

a casing including an interior pressure chamber disposed in fluid communication with the retaining cuff;

a plunger movably connected to said casing and disposed and structured to force fluid flow to the retainer cuff through said pressure chamber,

at least one pressure relief valve accessible from an exterior of said casing and structured to regulate pressure within said pressure chamber;

a shield assembly mounted on said casing and movable between a closed, valve shielding position and an open, valve activating position;

said shield assembly including an activating portion positionable into activating engagement with said pressure relief valve when in said open, valve activating position, and

an indicator assembly movably disposed within said pressure chamber and including an indicator member observable and variably positionable on said casing, dependent on and indicative of existing pressure within said pressure chamber.

20. An assembly structured to inflate and monitor pressure within a retaining cuff, said assembly comprising:

a casing including an interior pressure chamber disposed in fluid communication with the retaining cuff;

said casing comprising an integrated pump assembly including a plunger, said plunger movable within said pressure chamber between an extended position and a compressed position and structured to force fluid flow to the retainer cuff through said pressure chamber,

a valve assembly disposed in fluid regulating relation between said pressure chamber and said plunger, and

an indicator assembly movably disposed within said pressure chamber and including an indicator member, said indicator member observable and variably positionable on said casing dependent on and indicative of existing pressure within said pressure chamber.

21. A single-use assembly structured to introduce fluid into a medical device, said single-use assembly comprising:

a casing including an interior pressure chamber disposed in fluid communication with the medical device and an entry port connectable to the medical device;

a connection assembly structured for a single use of said casing and disposed adjacent said entry port in interconnecting relation between said casing and the medical device; said connection assembly disposable between a connect orientation and a disconnect orientation, and

said disconnect orientation at least partially defined by at least a portion of said connection assembly disposed in obstructing relation to a reconnection of a medical device to said entry port.

22. An assembly as recited in claim **21** further comprising a connection assembly disposed in interconnecting relation between said casing and an inflation lumen of the retaining cuff; said connection assembly disposable between a connect orientation and a disconnect orientation.

23. An assembly as recited in claim **21** wherein said retaining assembly comprises a retaining member and a gripping structure movably disposed relative to one another and to said entry port of said casing; said retaining member disposed in receiving relation to a connector of the medical device and movable relative to said gripping structure upon receipt of the connecting member.

24. An assembly as recited in claim **23** wherein said gripping structure is disposed to extend outwardly through said entry port in entry obstructing relation thereto upon removal of the connector member associated with the medical device.

25. An assembly structured to inflate and monitor pressure within a retaining cuff, said assembly comprising:

a casing including an interior pressure chamber disposed in fluid communication with the retaining cuff and an entry port connectable to an inflation lumen of the retaining cuff;

said casing comprising an integrated pump assembly movable within said pressure chamber and structured to force fluid flow to the retainer cuff through said pressure chamber,

a valve assembly disposed in fluid regulating relation between said pressure chamber and said pump assembly,

a retaining assembly including at least one retaining member movably connected to said casing and disposable into and out of retaining relation to said plunger, said one retaining member manually positionable out of retaining engagement with said plunger, and

an indicator assembly movably disposed within said pressure chamber and including an indicator member, said indicator member observable and variably positionable

on said casing dependent on and indicative of existing pressure within said pressure chamber.

26. An assembly structured to inflate and monitor pressure within a retaining cuff, said assembly comprising:

a casing including an interior pressure chamber disposed in fluid communication with the retaining cuff; said pressure chamber including a multi-chamber construction comprising at least a first chamber and a second chamber,

said casing including an integrated plunger movably connected to said casing within said pressure chamber and structured to force fluid flow to the retainer cuff sequentially through said first chamber and said second chamber,

an indicator assembly movably disposed within said pressure chamber and including an indicator member observable and variably positionable on said casing dependent on and indicative of existing pressure within at least said second chamber, and

a reaction member movably disposed in fluid communication within said second chamber in physically segregated relation to said first chamber and in driving relation to said indicator member; said variable positioning of said indicator member being dependent on disposition of said reaction member and existing pressure within said second chamber being exerted on said reaction member.

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