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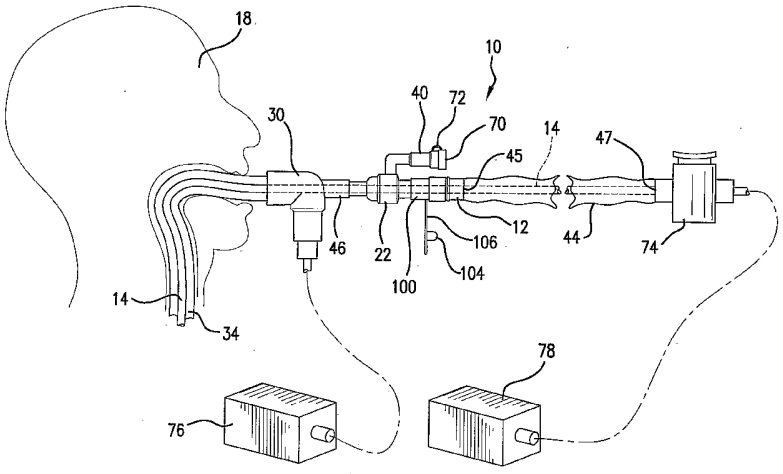
(54) Title: RESPIRATORY APPARATUS HAVING AN INTRODUCTION SECTION CONFIGURED FOR RELEASABLE ATTACHMENT WITH A RESPIRATORY INSTRUMENT



(57) Abstract: A respiratory apparatus includes an instrument introduction section that is adapted for introducing an instrument into an artificial airway of a patient. The instrument introduction section has a distal end and a proximal end with an opening that allows for insertion of the instrument into the instrument introduction section. The instrument is movable through a passageway between the distal and proximal ends. The distal end is configured for releasable attachment with an artificial airway structure that is attached to the patient. Further, a valve is located in the instrument introduction section. The valve has a closed position in which the passageway is at least substantially isolated from the artificial airway of the patient when the instrument is present and is proximal from the valve. The valve at least substantially blocks the passageway of the instrument introduction section when the valve is in the closed position. The valve also has an open position that allows for the instrument to be moved through the instrument introduction section and into the artificial airway of the patient.

WO 2004/101044 A1

RESPIRATORY APPARATUS HAVING AN INTRODUCTION SECTION CONFIGURED FOR RELEASABLE ATTACHMENT WITH A RESPIRATORY INSTRUMENT

Background

A variety of different circumstances exist in which a person may be required to have an artificial airway, such as an endotracheal tube, placed in his or her respiratory system. During surgery, for instance, the artificial airway's primary function is to keep the patient's airway open so that adequate lung ventilation can be maintained during the surgical procedure. Alternatively, with many patients the endotracheal tube will remain in place to sustain mechanical ventilation for a prolonged period.

If an endotracheal tube is to be left in place for any substantial amount of time, it is critical that respiratory secretions be periodically removed. This is usually accomplished with the use of a respiratory suction catheter. As the suction catheter is withdrawn, a negative pressure may be applied to the interior of the catheter to draw mucus and other secretions from the respiratory system.

With conventional closed suction catheter assemblies, for example as the one set forth in U.S. Patent No. 4,569,344 issued to Palmer, which is incorporated by reference herein in its entirety for all purposes, the catheter tube is enveloped by a protective sleeve. The catheter assembly includes a valve mechanism in communication with a vacuum source to control the suctioning process. At its distal or patient end, the closed suction catheter assembly is permanently attached to a manifold, connector, adaptor, or the like.

After the application of negative pressure, the catheter tube may be withdrawn from the artificial airway and, as the catheter tube is pulled back into the protective sleeve, a wiper or seal strips or scrapes a substantial portion of any mucus or secretions from the outside of the catheter tube. However, the distal tip portion of the catheter tube may not pass through the seal or wiper and thus any secretions or mucus on the distal end must be removed by other means. It is desirable to remove these secretions from the catheter tube in order to prevent contamination from infectious agents that may be present in the respiratory

secretions. Patients using artificial airways often have compromised immune systems and are more susceptible to infectious agents.

Several mechanisms exist by which a catheter may be cleaned. For example, a lavage port may be included which enables the clinician to inject liquid into the area surrounding the tip of the catheter after it has been withdrawn from the patient's airway. When liquid is injected and suction is applied, the liquid helps to loosen and remove the secretions from the exterior of the catheter.

One significant problem with simply injecting liquid and applying suction is that the suction also causes a volume of respiratory air to be removed through the catheter. The air that is evacuated potentially disrupts the carefully controlled ventilation cycle and therefore the amount of respiratory air available to the patient may be decreased as a result of catheter cleaning.

Prior respiratory suction catheter apparatuses have been developed in order to allow for cleaning of the distal tip of the catheter without substantially interrupting the airflow to the patient from the ventilator. U.S. Patent No. 6,227,200 B1 issued to Crump et al., which is incorporated by reference herein in its entirety for all purposes, provides in one exemplary embodiment a flap valve that may be used to substantially isolate the distal end of the catheter from the patient's airway during cleaning. The flap valve also has an open position in which the catheter may be inserted through the manifold into the airway of the patient. Current respiratory suction catheter apparatuses incorporate the flap valve and related structure such that these parts are permanently bonded to the manifold.

Although respiratory suction catheter apparatuses are provided with a cleaning mechanism in order to remove mucus and other infectious agents, it is often the case that the catheter itself needs to be regularly replaced in order to insure a more sterile respiratory circuit. Some respiratory suction catheter manufacturers recommend replacement of the suction catheter every 24 hours with a new suction catheter. In the instance when the suction catheter needs to be replaced, the manifold into which the flap valve and related parts are contained, and onto which the suction catheter is attached, is detached from the respiratory circuit. This detachment necessarily interferes with the supply of air to the patient, and increases the chances of ventilator associated complications. The new manifold with attached catheter and valve is then connected to the ventilator

circuit.

Also, it is often the case that the suction catheter is permanently attached to the structure that houses the valve and related cleaning elements. As such, other instruments which may be desired to be advanced into the artificial airway, such as an endoscope or a bronchoscope, can not be advanced through the manifold. Additionally, these other instruments are not capable of being cleaned by the use of the valve and/or cleaning structure due to the presence of the suction catheter and its attachment to the manifold.

Therefore, there is a need in the art for a respiratory apparatus that is capable of effectively cleaning the tip of an instrument without a resulting drop of ventilation air to the patient. Additionally, a need in the art exists in replacing a respiratory apparatus with a new respiratory apparatus without disconnecting the manifold from the ventilation circuit in order to prevent air loss to the patient, and to lower the chances of imparting illness to the patient during the replacement procedure.

Summary

Various features and advantages of the invention will be set forth in part in the following description, or may be apparent from the description, or may be learned from practice of the invention.

The present invention provides for a respiratory apparatus that may be removed from a ventilation circuit of a patient and replaced without having to disconnect an artificial airway structure from the ventilation circuit. An instrument introduction section is present and may be adapted for introducing an instrument into the artificial airway of the patient. The instrument introduction section is provided with a proximal end that may have an opening that allows for insertion of the instrument. The instrument introduction section may have a passageway that extends from the opening in the proximal end to an opening in a distal end. The instrument may be movable through this passageway. The distal end is configured for releasable attachment with an artificial airway structure that is attached to the patient. A valve may be located in the instrument introduction section and may have a closed position in which the passageway is at least substantially isolated from the artificial airway of the patient. The valve may at least substantially block the passageway of the instrument introduction section. The valve may have an

open position that allows for the instrument to be moved through the instrument introduction section and into the artificial airway of the patient.

The present invention also provides for an exemplary embodiment of a respiratory apparatus that includes an artificial airway structure that is attached to an artificial airway of a patient. An instrument introduction section may be present and may be adapted to allow for the introduction of an instrument into the artificial airway. The instrument introduction section may have a proximal end with an opening, and a distal end that is configured for releasable attachment with the artificial airway structure. A passageway is present in the instrument introduction section from the opening in the proximal end to an opening in the distal end. A valve may be located in the instrument introduction section and may at least substantially block the passageway when in a closed position. The valve may have an open position that allows the instrument to be moved through the instrument introduction section. A cleaning section may also be provided in the instrument introduction section, and may be proximal from the valve when the valve is in the closed position. An irrigation port may be in communication with the cleaning section. The irrigation port may be configured for allowing fluid to be transferred therethrough into the cleaning section. A plug may be present and may be engageable with the proximal end of the instrument introduction section. The plug may be adapted to isolate the passageway from the environment by closing the opening in the proximal end.

The present invention also provides for a respiratory apparatus that has an instrument introduction section adapted for introducing an instrument into an artificial airway of a patient. The instrument introduction section may have a proximal end with an opening, and be configured for insertion of the instrument into the instrument introduction section. A distal end is present on the instrument introduction section and may be configured for releasable attachment with an artificial airway structure that is attached to the patient. The distal end may be releasably attached by a friction fit arrangement. A passageway is present from the opening in the proximal end to an opening in the distal end. The instrument may be movable through the passageway. A single flap valve may be located in the instrument introduction section and may have a closed position in which the passageway is at least substantially blocked from the artificial airway of the patient.

The valve may have an open position that allows the instrument to be moved through the instrument introduction section and into the artificial airway of the patient. A cleaning section may be provided in the instrument introduction section and may be proximal from the valve when the valve is in the closed position. An irrigation port may be in communication with the cleaning section. The irrigation port may be configured for allowing fluid to be transferred into the cleaning section. A wiper seal may be located in the instrument introduction section and may be proximal from the cleaning section. A cap may be configured to engage the proximal end of the instrument introduction section. The cap may have an opening that allows for insertion of the instrument into the opening in the proximal end of the instrument introduction section. A plug may be connected to the cap by a tether. The plug may be insertable into the opening in the cap in order to close this opening.

The present invention also provides for an exemplary embodiment of a respiratory apparatus as described above which further has a wiper seal that is located in the instrument introduction section proximal from the valve.

Another exemplary embodiment exists in a respiratory apparatus as described above where the valve is a single flap. Still further, in other exemplary embodiments of the present invention the single flap may have an aperture therethrough. The single flap may be adapted to be opened by insertion of the instrument through the instrument introduction section.

The instrument introduction section may be releasably attached to the artificial airway structure through a variety of mechanisms in various exemplary embodiments of the present invention. For instance, a friction fit arrangement, a threaded engagement, a barb structure, or a clamping ring may be used to releasably attach the instrument introduction section to and from the artificial airway structure.

Brief Description of the Drawings

Fig. 1 is a perspective view of a respiratory apparatus in accordance with the present invention. A patient is shown having an artificial airway and an artificial airway structure attached thereto.

Fig. 2 is a cross sectional elevational view of a respiratory apparatus in accordance with the present invention. The respiratory apparatus is shown located proximate to an artificial airway structure.

Fig. 3 is a cross sectional elevational view of a respiratory apparatus similar to that shown in Fig. 2. Here, the respiratory apparatus is attached to the artificial airway structure.

Fig. 4 is a cross sectional elevational view of a respiratory apparatus in accordance with the present invention. Here, the respiratory apparatus is located proximate to an artificial airway structure that has swiveling ports.

Fig. 5 is a cross sectional elevational view of a respiratory apparatus similar to that shown in Fig. 4. Here, the respiratory apparatus is attached to the artificial airway structure through a friction fit arrangement.

Fig. 6 is a cross sectional elevational view of a respiratory apparatus in accordance with the present invention. The respiratory apparatus is shown located proximate to an artificial airway structure that has an artificial airway structure valve located therein.

Fig. 7 is a cross sectional elevational view of a respiratory apparatus similar to that shown in Fig. 6. Here, the respiratory apparatus is connected to the artificial airway structure through a threaded engagement.

Fig. 8 is a cross sectional elevational view of a respiratory apparatus in accordance with the present invention. A barb is present on the respiratory apparatus which is used to connect the respiratory apparatus to the artificial airway structure.

Fig. 9 is a cross sectional elevational view of a respiratory apparatus similar to that shown in Fig. 8. Here, the respiratory apparatus is shown engaging the artificial airway structure, and a tubular portion of a suction catheter is shown as passing through the respiratory apparatus and the artificial airway structure.

Fig. 10 is a cross sectional elevational view of a respiratory apparatus in accordance with the present invention. Here, the respiratory apparatus is shown as being proximate to an artificial airway structure that has a clamping ring that is used to attach the respiratory apparatus to the artificial airway structure.

Fig. 11 is a cross sectional elevational view of a respiratory apparatus similar to that shown in Fig. 10. Here, the respiratory apparatus is attached to the artificial airway structure.

Fig. 12 is a cross sectional elevational view of a respiratory apparatus in accordance with the present invention. Here, the respiratory apparatus is located proximate to an artificial airway structure that is a neonate Y-manifold.

Fig. 13 is a cross sectional elevational view of a respiratory apparatus similar to that shown in Fig. 12. Here, the respiratory apparatus is connected to the artificial airway structure through a fiction fit arrangement.

Fig. 14 is a top plan view of an alternative cap and plug assembly in accordance with the present invention.

Fig. 15 is a cross sectional view taken along line A-A in Fig. 14.

Fig. 16 is a cross sectional view taken along line B-B in Fig. 14.

Detailed Description

Reference will now be made in detail to embodiments of the invention, one or more examples of which are illustrated in the drawings. Each example is provided by way of explanation of the invention, and is not meant as a limitation of the invention. For example, features illustrated or described as part of one embodiment can be used with another embodiment to yield still a third embodiment. It is intended that the present invention include these and other modifications and variations.

As used herein, proximal refers generally to the direction towards a medical caregiver. Also, distal refers generally to the direction towards a patient.

The present invention provides for a respiratory apparatus 10 that may be removed from the ventilation circuit of a patient 18 and replaced without having to disconnect an artificial airway structure 30 from the ventilation circuit.

Referring to Fig. 1, the present invention may be used in conjunction with a variety of instruments that are placed into an artificial airway 34 of a patient 18. By way of example, the present invention is shown as being used in conjunction with a suction catheter 12 and related apparatus. A ventilator 76 may be in communication with the artificial airway 34 through an artificial airway structure 30. The artificial airway structure 30 is sometimes known in the art as a manifold. The

ventilator 76 may provide air to and remove air from the patient 18 through the artificial airway 34.

If the artificial airway 34 is left in the patient 18 for any substantial amount of time, respiratory secretions may build up in the lungs of the patient 18. As such, these secretions may need to be removed in order to ensure that adequate lung ventilation of the patient 18 is maintained. These secretions may be removed through use of the suction catheter 12. The suction catheter 12 has a tubular portion 14 that may be extended through the artificial airway 34 into the lungs of the patient 18. A vacuum source 78 may be in communication with the ventilating circuit, and more specifically in communication with the suction catheter 12. A medical caregiver may actuate a suction valve 74 thereby applying a vacuum pressure to the tubular portion 14 of the suction catheter 12. Upon doing so, respiratory secretions in the patient 18 and in the artificial airway 34 may be removed.

Respiratory secretions may sometimes remain on the tubular portion 14 of the suction catheter 12 or transfer onto other portions of the ventilator circuit. These respiratory secretions are undesirable in that they provide a breeding ground for pathogens and other harmful agents that may harm the patient 18. It is therefore the case that the suction catheter 12 and/or other components of the ventilation circuit may be cleaned in order to remove any residual respiratory secretions. However, in order to ensure a lower risk of contamination to the patient 18, it may be common practice to remove and replace the suction catheter 12 and/or other components in the ventilation circuit after some amount of set time has passed, for instance after 24 or 72 hours of use.

The suction catheter 12 is shown with a flexible plastic sleeve 44. The sleeve 44 is present in order to contain and isolate respiratory secretions that accumulate on the tubular portion 14 of the suction catheter 12 as the tubular portion 14 is withdrawn from the ventilation circuit. The sleeve 44 may be provided on either end with sealing connections 45 and 47 that attach the sleeve 44 to the suction catheter 12.

In previous devices, the artificial airway structure 30 was detachable from the artificial airway 34 so that a new artificial airway structure 30 could be incorporated into the ventilation circuit. This break in the ventilation circuit

interrupted the flow of air to the patient 18 and increased the chances of ventilator associated complications. In the present invention, the respiratory apparatus 10 may be removably attached to the artificial airway structure 30. In this instance, upon removing the respiratory apparatus 10, the artificial airway structure 30 may remain in place and allow for communication between the ventilator 76 and the artificial airway 34. As such, air may still be provided to the patient 18 during removal of the respiratory apparatus 10. A new respiratory apparatus 10 may be reattached to the same artificial airway structure 30. The suction catheter 12 may be releasably attachable to the respiratory apparatus 10, and may or may not be replaced with a new suction catheter 12 during replacement of the respiratory apparatus 10.

The respiratory apparatus 10 in accordance with the present invention may be used in combination with a variety of artificial airway structures 30. For instance, in one exemplary embodiment of the present invention as shown in Fig. 10, the respiratory apparatus 10 may be used with a T-piece artificial airway structure 30. A port 90 is present and may be attached to the artificial airway 34 (Fig. 1). The port 90 therefore allows for communication between the artificial airway structure 30 and the artificial airway 34. Air from the ventilator 76 (Fig. 1) may be provided to and from the artificial airway structure 30 through a port 92. The port 92 may be attached to a pair of ventilation tubes via a connector (not shown). An additional port 94 on the artificial airway structure 30 may be provided opposite the port 92. The port 94 is typically covered with a cap 68 which is removed when "blow-by" is desired to wean the patient 18 (Fig. 1) from forced ventilation. An additional port 46 may be configured to engage the respiratory apparatus 10 such that the respiratory apparatus 10 may be removably attached to the artificial airway structure 30.

The respiratory apparatus 10 is shown in greater detail in Fig. 2. The respiratory apparatus 10 includes an instrument introduction section 22 to which an instrument such as the suction catheter 12 (Fig. 1) may be attached in any suitable manner. The instrument introduction section 22 has a passageway 24 extending therethrough. The tubular portion 14 (Fig. 1) of the suction catheter 12 may be advanced through the passageway 24, through an opening 98 in the distal end 28 of the instrument introduction section 22 and into the artificial airway

structure 30, and eventually advanced into the artificial airway 34 (Fig. 1). Upon retraction of the tubular portion 14 from the patient 18, respiratory secretions may be present on the surface of the tubular portion 14. A wiper seal 36 may be provided in the instrument introduction section 22. The wiper seal 36 may be a resilient member having an aperture therethrough that allows for the tubular portion 14 to pass. The wiper seal 36 desirably tightly engages the tubular portion 14 as the tubular portion 14 is retracted into the proximal end 26 of the instrument introduction section 22. Respiratory secretions present on the surface of the tubular portion 14 may be removed by contact with the wiper seal 36.

The instrument introduction section 22 may also be provided with a cleaning section 38. In one exemplary embodiment, the cleaning section 38 may be defined by a cleaning section member 86. Additionally or alternatively, the cleaning section 38 may be defined on one end by a valve 32. Further, the cleaning section 38 may alternatively be defined by any portion of the instrument introduction section 22. The valve 32 shown in Fig. 2 is a single flap that is hingedly attached to an annular ring 31 housed within instrument introduction section 22. The hinge on the valve 32 may provide both a bias force and a pivoting location. Use of such a valve 32 is disclosed in U.S. Patent 6,227,200 B1 issued to Crump et al., the entire disclosure of which is incorporated by reference herein in its entirety for all purposes. The valve 32 may at least substantially block the passageway 24.

As can be seen in Fig. 9, the tubular portion 14 of the suction catheter 12 may have a distal end 16 with a distal opening 82. A lumen 20 extends through the tubular portion 14 and allows for respiratory secretions and other fluids to be transferred through the distal opening 82 and into the lumen 20 by the vacuum source 78 (Fig. 1). The tubular portion 14 of the suction catheter 12 may be cleaned by positioning the distal end 16 of the suction catheter 12 either against the valve 32 and/or within the cleaning section 38. Upon so positioning, a vacuum can be effected upon the lumen 20 and lavage or other cleaning solution may be injected into the cleaning section 38. Application of the vacuum causes the valve 32 to be forced against the distal end 16 of the tubular portion 14. However, it is to be understood that injection of lavage or other cleaning solutions and/or

application of a vacuum may be performed in other instances not associated with cleaning of the tubular portion 14.

Although described as contacting the distal end 16 of the tubular portion 14, in certain exemplary embodiments of the present invention, the valve 32 need not contact the distal end 16 of the tubular portion 14 in order to effectively clean the tubular portion 14. For instance, the valve 32 may be urged against the cleaning section member 86 during cleaning of the tubular portion 14.

The tubular portion 14 may also be provided with at least one side opening 84. This arrangement allows for turbulent flow to be established within the cleaning section 38 during suctioning causing the lavage solution to break up and remove any respiratory secretions present on the tubular portion 14. Respiratory secretions may be removed through the side opening 84 and/or the distal opening 82. The valve 32 may be provided with an aperture 42 therethrough. The presence of the aperture 42 may help to establish a more desirable turbulent fluid flow within the cleaning section 38. In one exemplary embodiment of the present invention, the aperture 42 may be about 0.03 inches in diameter.

An irrigation port 40 may be attached to the instrument introduction section 22 in order to allow for the injection of the lavage solution. A container (not shown) holding the lavage solution may have an outlet inserted into the irrigation port 40. Lavage may then be dispensed from this container into the irrigation port 40 which may be in communication with the cleaning section 38. The irrigation port 40 may also be provided with an irrigation cap 70 that may be connected to the irrigation port 40 by way of a tether 72. The irrigation cap 70 may be placed onto the irrigation port 40 in order to close the irrigation port 40 when not in use.

In certain exemplary embodiments of the present invention, the cleaning section member 86 may be configured such that a small amount of space is present between the tubular portion 14 of the suction catheter 12 and the cleaning section member 86. In certain exemplary embodiments of the present invention, this space may be between about 0.005 and about 0.015 inches. This space provides two advantages. First, if lavage is needed to be provided to the patient 18, injection of lavage through the irrigation port 40 and then into the cleaning section 38 causes a stream of lavage solution to be directed out of the instrument introduction section 22 and into the patient 18. Second, as the tubular portion 14

is withdrawn the close proximity between the tubular portion 14 and the cleaning section member 86 may help to wipe any heavy layers of respiratory secretions from the outside of the tubular portion 14 of the suction catheter 12.

Employment of the valve 32 is advantageous in that the tubular portion 14 of the suction catheter 12 may be cleaned without causing a pressure loss to the ventilation circuit. This is because the valve 32 at least substantially isolates the portion of the respiratory apparatus 10 proximal the valve 32 from the remainder of the ventilation circuit. In one exemplary embodiment of the present invention, the valve 32 may be provided with one or more projections 88. Fig. 9 shows the respiratory apparatus 10 engaged with the artificial airway structure 30. In this case, the artificial airway structure 30 is a neonate manifold. The tubular portion 14 of the suction catheter 12 is shown as being advanced through the instrument introduction section 22, the artificial airway structure 30, and out of the port 90 eventually enabling entry of the artificial airway 34 (Fig. 1) of the patient 18 (Fig. 1). The valve 32 may be opened by insertion of the tubular portion 14 through the instrument introduction section 22. The projection 88 may be configured to minimize valve 32 contact with the surface of the tubular portion 14. This contact helps to reduce contamination of respiratory secretions from the tubular portion 14 onto the valve 32 and related components due to the minimized contact afforded by the projections 88. Additionally, in certain exemplary embodiments, this contact may help to ensure the structural integrity of the valve 32 and may minimize any unnecessary bending or stress on the valve 32.

In one exemplary embodiment of the present invention, the valve 32 may be biased towards the closed position. Although shown in Fig. 9 as being attached to an annular ring 31, the valve 32 may alternatively be attached, for example, directly onto a wall of the instrument introduction section 22. The valve 32 may be configured to be closed once the tubular portion 14 is positioned proximally from the valve 32, or alternatively the valve 32 may be configured to be closed upon the proximal positioning of the tubular portion 14 from the valve 32 and application of vacuum through the lumen 20 in order to draw the valve 32 into a closed position.

The valve 32 need not be a single flap in other exemplary embodiments of the present invention nor need it have the annular ring 31, nor need it have the aperture 42, or the projection 88. It is to be understood that the configuration of

the valve 32 shown in the drawings is only a desired embodiment, and other configurations of the valve 32 are possible in accordance with the present invention. For instance, the valve 32 may be one, two, three, or more flaps that are biased towards a closed position and opened by insertion of the tubular portion 14 of the suction catheter 12 or any other suitable instrument through the instrument introduction section 22.

Referring back to Fig. 2, the instrument introduction section 22 is provided with a proximal end 26 and a distal end 28. The proximal end 26 may be releasably attached to the suction catheter 12 through a variety of means commonly known in the art. For instance, these two components may be friction fit to one another, clamped to one another, or connected through a threaded engagement. Other suitable connections such as a snap fit, a latch, a boss and detent, etc. may be used. The distal end 28 of the instrument introduction section 22 may be configured for being releasably attachable to a port 46 on the artificial airway structure 30. Engagement of the distal end 28 of the instrument introduction section 22 and the port 46 is shown in Fig. 3. In this exemplary embodiment, the distal end 28 may be friction fit onto the port 46. This provides for a secure attachment between the respiratory apparatus 10 and the artificial airway structure 30, but also allows for the disengagement of these two components once the desire to replace the respiratory apparatus 10 is present. The artificial airway structure 30 shown in Fig. 3 may be provided with an additional port 80 onto which the respiratory apparatus 10 may be attached in other exemplary embodiments. Additionally, in yet other exemplary embodiments of the present invention, two respiratory apparatuses 10 may be employed such that their respective distal ends 28 are engageable with the port 46 and the port 80.

The respiratory apparatus 10 is shown in Fig. 5 as being provided with a cap 100 placed on the proximal end 26 of the instrument introduction section 22. An opening 102 in the cap 100 may be provided through which the suction catheter 12 may be passed prior to being passed through an opening 96 in the proximal end 26 of the instrument introduction section 22. The opening 102 may be sized so that various instruments may be used in conjunction with the respiratory apparatus 10. The opening 102 may be closed by a plug 104 that is

desirably connected to the cap 100 by way of a tether 106. Fig. 5 shows an exemplary embodiment where the plug 104 is inserted into the opening 102 (Fig. 4), hence acting to close the opening 96 in the proximal end 26 of the instrument introduction section 22. Closing off the opening 96 may help to prevent contamination of the respiratory apparatus 10 by contaminants in the environment when instruments are not being used in conjunction with the respiratory apparatus 10. Additionally, during mechanical ventilation of the patient 18, it is advantageous to close the opening 96 so that positive end expiratory pressure can be maintained in the ventilation circuit. Although it is also possible to maintain the positive end expiratory pressure through the use of the valve 32 or a PEEP seal (not shown), the use of the plug 104 to close off the proximal end 26 provides for an alternative or supplemental way of maintaining the positive end expiratory pressure. As suggested above, the cap 100 need not be provided on the respiratory apparatus 10. For instance, Fig. 9 illustrates an exemplary embodiment that does not have such a cap 100 present.

Figs. 14-16 show an alternative arrangement of the cap 100 and the plug 104 in accordance with an exemplary embodiment of the present invention. Here, an attachment member 114 is present and may be attached to any component of the respiratory apparatus 10, for example the proximal end 26. The cap 100 is shown as being connected to the attachment member 114 by way of the tether 106, while the plug 104 is connected to the attachment member 114 by a separate plug tether 116. The cap 100 may be placed over a portion of the respiratory apparatus 10, for instance the opening 96. Further, when desired, the plug 104 may be placed within the opening 102 in the cap 100.

Fig. 4 shows an alternate exemplary embodiment of the present invention where the cap 100 with the attachment member 114 may be attached to the port 46 of the artificial airway structure 30. The plug 104 may be inserted into the cap 100 in order to close off the port 46. Fig. 5 shows the cap 100 and plug 104 removed in order to allow attachment of the respiratory apparatus 10 to the artificial airway structure 30. In other exemplary embodiments of the present invention, however, the distal end 28 of the respiratory apparatus 10 may be inserted into the port 46 of the artificial airway structure 30 without removing the cap 100 from the port 46.

As shown in Fig. 3, the port 46 is in axial alignment with a swiveling port 62 that may be further attached to the artificial airway 34 (Fig. 1). A rotating member 60 may be provided on the artificial airway structure 30 that allows for the rotation of the ports 46 and 80 such that port 80 may be axially aligned with the swiveling port 62, hence moving port 46 out of axial alignment with port 62. This type of artificial airway structure 30 is disclosed in U.S. Patent No. 5,735,271 to Lorenzen et al., the entire disclosure of which is incorporated by reference herein in its entirety for all purposes. The artificial airway structure 30 has another swiveling port 64 located thereon that is in communication with the ventilator 76. These two swiveling ports 62 and 64 are provided with a swiveling feature so that the tubing and/or structure connected to them more easily moves when various parts of the ventilation circuit are manipulated or moved. This helps to reduce stress imparted onto the patient 18 (Fig. 1) brought about by movement of the ventilation circuit. The swiveling ports 62 and 64 may be constructed, for instance, as those disclosed in U.S. Patent No. 5,694,922 to Palmer, the entire disclosure of which is incorporated by reference herein in its entirety for all purposes.

Another exemplary embodiment of the present invention is shown in Fig. 4. Here, the respiratory apparatus 10 may be substantially similar to the respiratory apparatus 10 described above with respect to the exemplary embodiment shown in Fig. 2. However, the artificial airway structure 30 to which the respiratory apparatus 10 may be removably attached is in this instance an elbow manifold that has a pair of swiveling ports 62 and 64. Fig. 5 shows the respiratory apparatus 10 attached to the artificial airway structure 30 in much the same way as discussed above in respect to the exemplary embodiment shown in Fig. 3, that being a friction fit arrangement between the port 46 and the distal end 28 of the instrument introduction section 22. It is to be understood that the present invention is not limited to a particular amount of friction between the port 46 and the distal end 28 of the instrument introduction section 22. For instance these two parts may be tightly fit with respect to one another such that a medical caregiver must provide a large amount of force in order to remove the distal end 28 of the instrument introduction section 22 from the port 46. Conversely, these two parts may be fit together such that only a small amount of force is needed to remove the distal end 28 of the instrument introduction section 22 from the port 46. The present

invention is to be understood as encompassing exemplary embodiments of the respiratory apparatus 10 that may be fit onto the artificial airway structure 30 with varying degrees of friction between these two components.

Although shown as being inserted (in Figs. 3, 5, 7, 9, 11, and 13) within the port 46, the distal end 28 of the instrument introduction section 22 may in other exemplary embodiments be sized to fit around the port 46. Additionally, other friction fit arrangements between the port 46 and the distal end 28 are possible in accordance with the present invention as is commonly known in the art.

Yet another exemplary embodiment of the present invention is disclosed in Fig. 6. Here, the artificial airway structure 30 may be an elbow manifold that has ports 90 and 92 located thereon that do not include the swiveling feature. These two ports 90 and 92 form part of the ventilation circuit that provides air to and from the patient 18 (Fig. 1) through the port 90 and provides air to and from the ventilator 76 (Fig. 1) through the port 92. As stated, the respiratory apparatus 10 may be disengaged from the artificial airway structure 30 without the need to remove the artificial airway structure 30 from the remainder of the ventilation circuit. This helps to ensure that air is still provided to the patient 18 (Fig. 1) during replacement of the respiratory apparatus 10. However, it may be the case that a small amount of air is lost due to the opening in the port 46 once the respiratory apparatus 10 is disengaged therefrom. In order to further minimize the loss of positive end expiratory pressure, the artificial airway structure 30 may be provided with an artificial airway structure valve 66.

The artificial airway structure valve 66 may prevent air loss during removal of the respiratory apparatus 10 by sealing off the port 46. The artificial airway structure valve 66 may take any design commonly known in the art. For instance, as disclosed in Fig. 6, the artificial airway structure valve 66 may be a single flap that is substantially similar to the valve 32 of the instrument introduction section 22. The artificial airway structure valve 66 may be biased towards a closed position, and may be opened upon the insertion of the tubular portion 14 (Fig. 1) through the port 46 and into the port 90. Although shown as being a single flap, the artificial airway structure valve 66 may also be a plurality of flaps. Additionally, the artificial airway structure valve 66 may be a mechanism that does not have flaps but yet

still provides for a closed port 46 during disengagement of the respiratory apparatus 10 from the artificial airway structure 30.

Additionally, the valve 32 and the artificial airway structure valve 66 may be of the other configurations in other exemplary embodiments of the present invention. For instance, configurations disclosed in commonly owned U.S. Patent 6,227,200 B1 issued to Crump et al., may be employed which may be a twisting membrane, a duckbill arrangement, or a dual membrane configuration having offset apertures.

The artificial airway structure valve 66 may be configured such that it is closed during disengagement of the respiratory apparatus 10, but opened upon insertion of the distal end 28 of the instrument introduction section 22 into the port 46. Additionally, the artificial airway structure valve 66 may be configured to be opened by insertion of the tubular portion 14 (Fig. 1) through the port 46 and into the artificial airway structure 30. In this instance, it may be the case that the artificial airway structure valve 66 is also in need of cleaning due to contact with respiratory secretions from the tubular portion 14. In this instance, the distal end 16 (Fig. 1) of the tubular portion 14 may be located proximate to the artificial airway structure valve 66 and lavage solution may be injected into this location through the irrigation port 40. Vacuum may be applied to the lumen 20 of the tubular portion 14 and respiratory secretions present may then be removed via a process substantially the same as the cleaning procedure with respect to the valve 32.

Additionally, other ways of releasably attaching the respiratory apparatus 10 to the artificial airway structure 30 are possible in accordance with the present invention. Figs. 6 and 7 show a threaded engagement where the distal end 28 of the instrument introduction section 22 may have external threading 48 located thereon. The port 46 may have internal threading 50 located therein and is configured to mate with the external threading 48. Fig. 7 shows the threaded engagement between the respiratory apparatus 10 and the artificial airway structure 30. In order to effect this attachment, the medical caregiver needs to rotate the respiratory apparatus 10 and the artificial airway structure 30 with respect to one another.

Another configuration for releasably attaching the respiratory apparatus 10 to the artificial airway structure 30 is disclosed in Fig. 8. Here, the artificial airway structure 30 is a neonate manifold having a plurality of ports. Three such ports are labeled 46, 90, and 92. The port 92 may provide access to and from the ventilator 76 (Fig. 1), and the port 90 may provide access to and from the artificial airway 34 (Fig. 1) of the patient. The port 46 may be configured to be releasably engageable with the distal end 28 of the respiratory suction catheter apparatus 10. The distal end 28 may be provided with a barb 52 that extends from the distal end 28. The barb 52 and the distal end 28 may be force fit into the port 46 and slid distally. The port 46 may be provided on one end with a receiving area 54 that is designed so as to receive the barb 52. As the barb 52 is moved into the receiving area 54, the distal end 28 of the instrument introduction section 22 is retained in the port 46. This engagement is shown in Fig. 9. In order to remove the respiratory apparatus 10 from the artificial airway structure 30, the medical caregiver may provide a force tending to separate these two components. This force will be enough to compress the barb 52 and/or deform the distal end 28 such that they may be slid out of the port 46 and effect disengagement of the respiratory apparatus 10.

Yet another exemplary embodiment of the present invention is shown in Fig. 10. Here, the artificial airway structure 30 may be a T-piece manifold, having the port 46 located thereon in order to be releasably attached to the distal end 28 of the respiratory suction catheter apparatus 10. A clamping ring 56 may be provided and surrounds the exterior of the port 46. The clamping ring 56 may be a single piece of material, for instance metal or medical grade plastic, that exhibits at least a slight amount of flexibility. The clamping ring 56 has holes (not shown) on either end through which a screw 58 may be positioned. The distal end 28 of the instrument introduction section 22 may be inserted into the port 46 as shown in Fig. 11, and the screw 58 may be turned such that the two ends of the clamping ring 56 are urged towards one another. This in turn causes the port 46 to be compressed such that it is forced against the distal end 28 of the instrument introduction section 22 causing a secure attachment between the respiratory apparatus 10 and the artificial airway structure 30. Additionally, a nut (not shown) may engage the screw 58 and may also be used to effect the constriction of the clamping ring 56 as is commonly known in the art. The screw 58 may be loosened

in order to separate the two ends of the clamping ring 56 from one another. This loosens the connection between the distal end 28 and the port 46 and allows for the respiratory apparatus 10 to be removed from the artificial airway structure 30.

An additional exemplary embodiment of the present invention is shown in Fig. 12. Here, the respiratory apparatus 10 is configured substantially the same as the respiratory apparatus 10 of Fig. 2. However, the artificial airway structure 30 onto which it is releasably attached is shown as a neonate Y-manifold. Fig. 13 shows the distal end 28 of the respiratory apparatus 10 being connected to the port 46 on the artificial airway structure 30 through a friction fit arrangement as previously described. Ports 90 and 92 of the artificial airway structure 30 allow for communication between the ventilator 76 and the artificial airway 34. A tapered adaptor 112 may be retained within the port 90 in order to allow for connection of the respirator apparatus 10 to tubing or other components of the respiratory circuit. The tapered adaptor 112 may or may not be permanently attached to the port 90. Alternatively, the artificial airway structure 30 itself may be tapered, hence eliminating the need for the tapered adaptor 112 in other exemplary embodiments of the present invention.

In accordance with the present invention, the respiratory apparatus 10 may be sized such that it may be attached to a variety of artificial airway structures 30. As such, the present invention includes various sizes of the respiratory apparatus 10 along with various sizes and configurations of the artificial airway structure 30. The examples of which described herein are only exemplary embodiments of the present invention and do not limit the present invention. Additionally, various ways of releasably attaching the distal end 28 of the introduction section 22 to the artificial airway structure 30 are possible in accordance with the present invention, the mechanisms disclosed herein being only exemplary embodiments.

Although embodiments of the present invention have been described as being used in connection with a suction catheter 12 as shown in Fig. 1, it is to be understood that the instrument may be something other than a suction catheter 12 in accordance with other exemplary embodiments of the present invention. For instance, Fig. 11 shows the respiratory apparatus 10 having a bronchoscope 108 inserted therethrough. The bronchoscope 108 may be inserted through the passageway 24, into the artificial airway structure 30, and into the artificial airway

34 of the patient 18 (Fig. 1). Also, the bronchoscope 108 may be cleaned in much the same way as describe above with respect to the suction catheter 12. For instance, the tip of the bronchoscope 108 may be positioned proximate to the valve 32, lavage solution may be injected into the cleaning section 38, and suction may be applied through the bronchoscope 108 so that respiratory sections are removed from the surface of the bronchoscope 108. Alternatively, other suitable instruments, such as an endoscope, may be used in conjunction with the respiratory apparatus 10. The respiratory apparatus 10 therefore allows for different instruments to be placed therethrough and to be able to be cleaned by insertion of lavage solution and/or application of suction to the instrument. The respiratory apparatus 10 allows for different types of instruments to be inserted into the artificial airway 34 without having to disconnect the artificial airway structure 30 and cause the aforementioned interruption in ventilation air to the patient. Additionally, the valve 32 may act to maintain positive end expiratory pressure when in the closed position. It is to be understood that the present invention is not limited to a respiratory apparatus 10 that is used in conjunction with a suction catheter 12, but may be used with any suitable instrument that is to be inserted into the artificial airway 34. Therefore, different types of instruments may be interchanged with the respiratory apparatus 10.

It should be understood that the present invention includes various modifications that can be made to the embodiments of the respiratory apparatus described herein as come within the scope of the appended claims and their equivalents.

Claims

What is claimed is:

1. A respiratory apparatus, comprising:

an instrument introduction section adapted for introducing an instrument into an artificial airway of a patient, the instrument introduction section comprising:

a proximal end with an opening, the proximal end configured for insertion of the instrument into the instrument introduction section;

a distal end configured for releasable attachment with an artificial airway structure attached to the patient; and

a passageway from the opening in the proximal end to an opening in the distal end such that the instrument is moveable through the passageway; and

a valve located in the instrument introduction section, the valve having a closed position in which the passageway is at least substantially blocked from the artificial airway of the patient, the valve having an open position allowing the instrument to be moved through the instrument introduction section and into the artificial airway of the patient.

2. The respiratory apparatus of claim 1, further comprising:

a cap configured to engage the proximal end of the instrument introduction section, the cap having an opening allowing for insertion of the instrument into the opening in the proximal end of the instrument introduction section.

3. The respiratory apparatus of claim 1, further comprising a plug configured to engage the proximal end of the instrument introduction section to close the opening in the proximal end of the instrument introduction section.

4. The respiratory apparatus of claim 1, wherein the instrument is selected from the group consisting of a suction catheter, an endoscope, and a bronchoscope.

5. The respiratory apparatus of claim 1, wherein the instrument is a suction catheter, the proximal end of the instrument introduction section configured for releasable attachment with the suction catheter, the suction catheter having a tubular portion advanceable through the passageway of the instrument introduction section.

6. The respiratory apparatus of claim 1, further comprising a wiper seal located in the instrument introduction section proximal from the valve.

7. The respiratory apparatus of claim 1, further comprising:

a cleaning section located in the instrument introduction section proximal from the valve; and

an irrigation port in communication with the cleaning section, the irrigation port configured for allowing fluid to be transferred therethrough into the cleaning section.

8. The respiratory apparatus of claim 1, wherein the valve is a single flap.

9. The respiratory apparatus of claim 8, wherein the single flap has an aperture therethrough, the single flap is adapted to be opened by insertion of the instrument through the instrument introduction section.

10. The respiratory apparatus of claim 1, wherein the valve is biased towards the closed position.

11. The respiratory apparatus of claim 1, wherein the distal end of the instrument introduction section is releasably attachable to the artificial airway structure by a friction fit arrangement.

12. The respiratory apparatus of claim 1, wherein the distal end of the instrument introduction section has threading thereon for being releasably attachable to the artificial airway structure by a threaded engagement.

13. The respiratory apparatus of claim 1, wherein the distal end of the instrument introduction section has at least one barb located thereon for being releasably attachable to the artificial airway structure.

14. The respiratory apparatus of claim 1, further comprising a clamping ring engageable with the distal end of the instrument introduction section and adapted to releasably attach the instrument introduction section to the artificial airway structure.

15. The respiratory apparatus of claim 1, wherein the artificial airway structure is selected from the group consisting of a rotatable manifold, an elbow manifold, a T-manifold, and a Y-manifold.

16. The respiratory apparatus of claim 1, wherein the artificial airway structure has a valve located therein for preventing air loss.

17. The respiratory apparatus of claim 1, further comprising;

a cap configured to engage the proximal end of the instrument introduction section, the cap having an opening that allows for insertion of the instrument into the opening in the proximal end of the instrument introduction section; and

a plug having a plug tether, the plug insertable into the opening in the cap to close the opening in the cap.

18. The respiratory apparatus of claim 1, further comprising:

a cap configured to engage a port of the artificial airway structure, the cap having an opening that allows for insertion of the instrument into the artificial airway structure; and

a plug having a plug tether, the plug insertable into the opening in the cap to close the opening in the cap.

19. The respiratory apparatus of claim 1, further comprising a positive end expiratory pressure cap adapted to close the proximal end of the instrument introduction section.

20. A respiratory apparatus, comprising:

an artificial airway structure attached to an artificial airway of a patient;

an instrument introduction section adapted for introducing an instrument into the artificial airway of the patient, the instrument introduction section comprising:

a proximal end with an opening;

a distal end configured for releasable attachment with the artificial airway structure; and

a passageway from the opening in the proximal end to an opening in the distal end;

a valve located in the instrument introduction section and at least substantially blocking the passageway when in a closed position, the valve having an open position allowing the instrument to be moved through the instrument introduction section;

a cleaning section provided in the instrument introduction section proximal from the valve when the valve is in the closed position;

an irrigation port in communication with the cleaning section, the irrigation port configured for allowing fluid to be transferred therethrough into the cleaning section; and

a plug engageable with the proximal end of the instrument introduction section, the plug adapted to isolate the passageway from the environment by closing the opening in the proximal end.

21. The respiratory apparatus of claim 20, further comprising a wiper seal located in the instrument introduction section proximal from the valve.

22. The respiratory apparatus of claim 20, wherein the valve is a single flap.

23. The respiratory apparatus of claim 22, wherein the single flap has an aperture therethrough, the single flap is adapted to be opened by insertion of the instrument through the instrument introduction section.

24. The respiratory apparatus of claim 20, wherein the valve is biased towards the closed position.

25. The respiratory apparatus of claim 20, wherein the distal end of the instrument introduction section is releasably attachable to the artificial airway structure by a friction fit arrangement.

26. The respiratory apparatus of claim 20, wherein the distal end of the instrument introduction section has threading thereon for being releasably attachable to said artificial airway structure by a threaded engagement.

27. The respiratory apparatus of claim 20, wherein the distal end of the instrument introduction section has at least one barb located thereon for being releasably attachable to the artificial airway structure.

28. The respiratory apparatus of claim 20, further comprising a clamping ring engageable with the distal end of the instrument introduction section and adapted to releasably attach the instrument introduction section to the artificial airway structure.

29. The respiratory apparatus of claim 20, wherein the artificial airway structure is selected from the group consisting of a rotatable manifold, an elbow manifold, a T-manifold, and a Y-manifold.

30. The respiratory apparatus of claim 20, further comprising a cap configured to engage the proximal end of the instrument introduction section, the cap having an opening allowing for insertion of the instrument into the opening in the proximal end of the instrument introduction section.

31. The respiratory apparatus of claim 20, wherein the instrument is selected from the group consisting of a suction catheter, an endoscope, and a bronchoscope.

32. The respiratory apparatus of claim 20, wherein the instrument is a suction catheter, the proximal end of the instrument introduction section configured for releasable attachment with the suction catheter, the suction catheter having a tubular portion advanceable through the passageway of the instrument introduction section.

33. The respiratory apparatus of claim 20, wherein the artificial airway structure has a valve located therein for preventing air loss.

34. The respiratory apparatus of claim 20, further comprising:

a cap configured to engage the proximal end of the instrument introduction section, the cap having an opening that allows for insertion of the instrument into the opening in the proximal end of the instrument introduction section; and

a plug tether connected to the plug, and wherein the plug is insertable into the opening in the cap to close the opening in the cap while at the same time adapted to isolate the passageway of the instrument introduction section from the environment by closing the opening in the proximal end and the opening in the cap.

35. A respiratory apparatus, comprising:

an instrument introduction section adapted for introducing an instrument into an artificial airway of a patient, the instrument introduction section comprising:

a proximal end with an opening configured for insertion of the instrument into the instrument introduction section;

a distal end configured for releasable attachment with an artificial airway structure attached to the patient, the distal end being releasably attached by a friction fit arrangement; and

a passageway from the opening in the proximal end to an opening in the distal end such that the instrument is movable through the passageway;

a single flap valve located in the instrument introduction section, the single flap valve having a closed position in which the passageway is at least substantially blocked from the artificial airway of the patient, the valve having an open position allowing the instrument to be moved through the instrument introduction section and into the artificial airway of the patient;

a cleaning section provided in the instrument introduction section proximal from the valve when the valve is in the closed position;

an irrigation port in communication with the cleaning section, the irrigation port configured for allowing fluid to be transferred therethrough into the cleaning section;

a wiper seal located in the instrument introduction section and proximal from the cleaning section;

a cap configured to engage the proximal end of the instrument introduction section, the cap having an opening allowing for insertion of the instrument into the opening in the proximal end of the instrument introduction section; and

a plug connected to the cap by a tether, the plug insertable into the opening in the cap to close the opening in said cap.

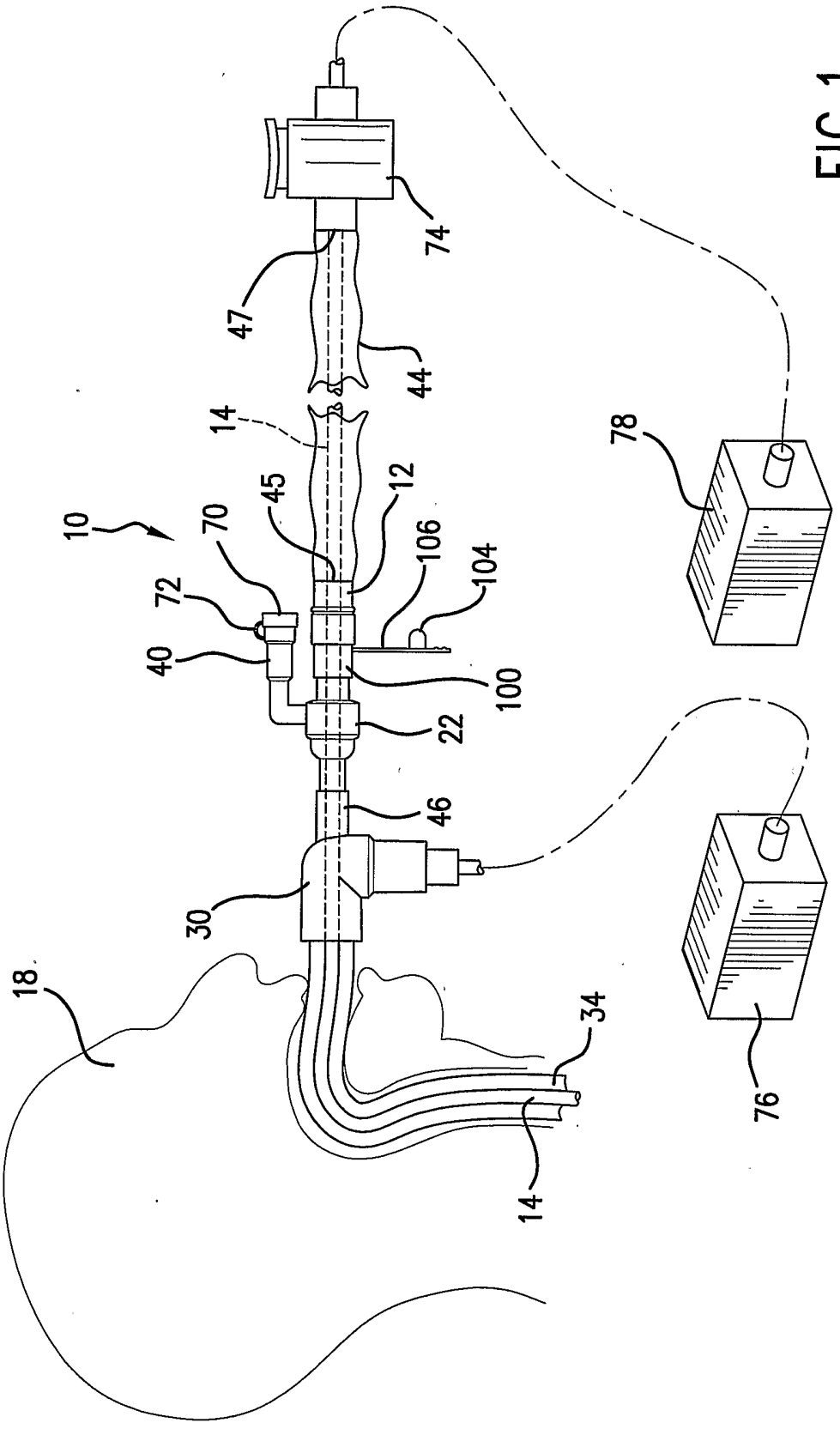


FIG.1

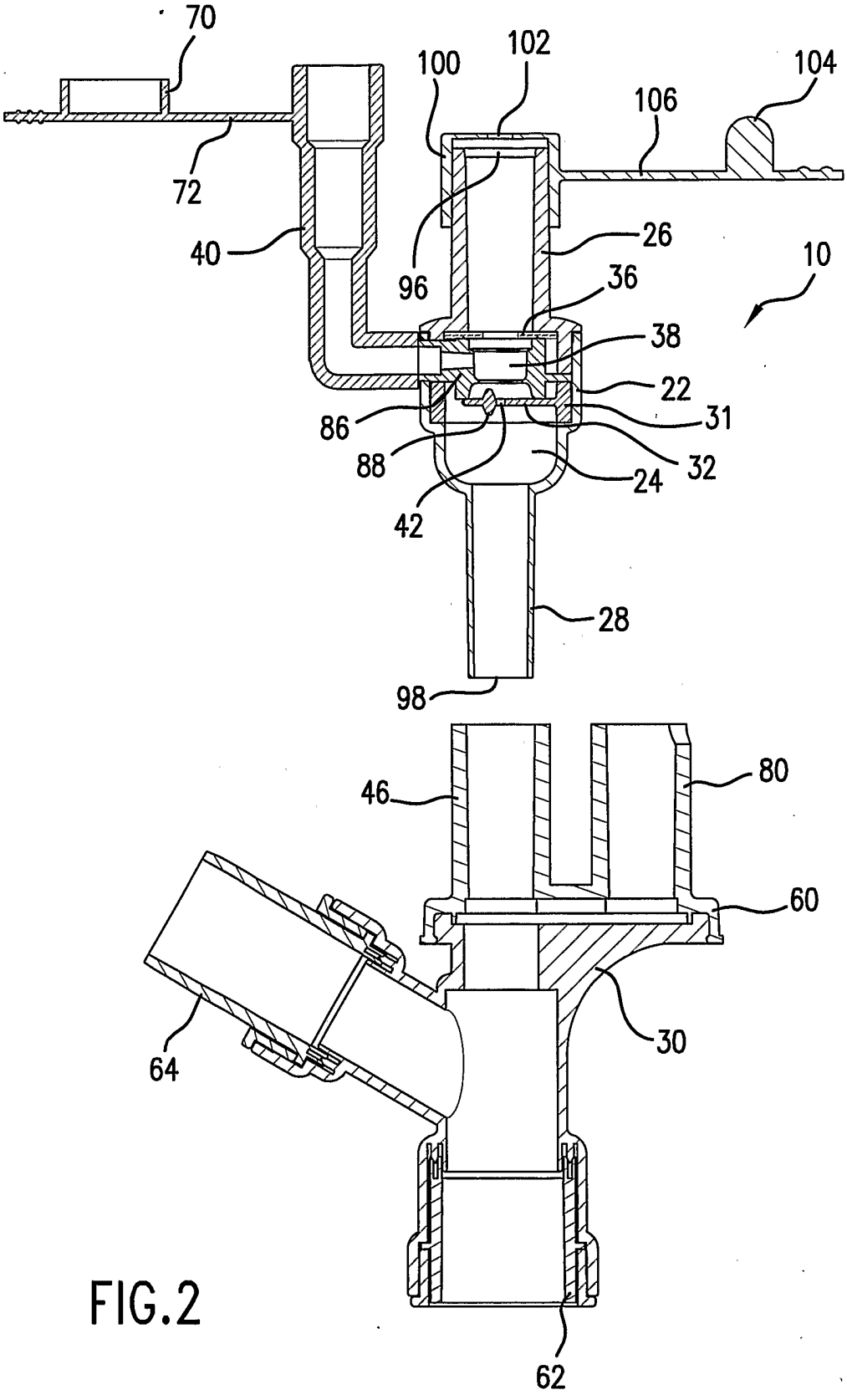

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FIG.2

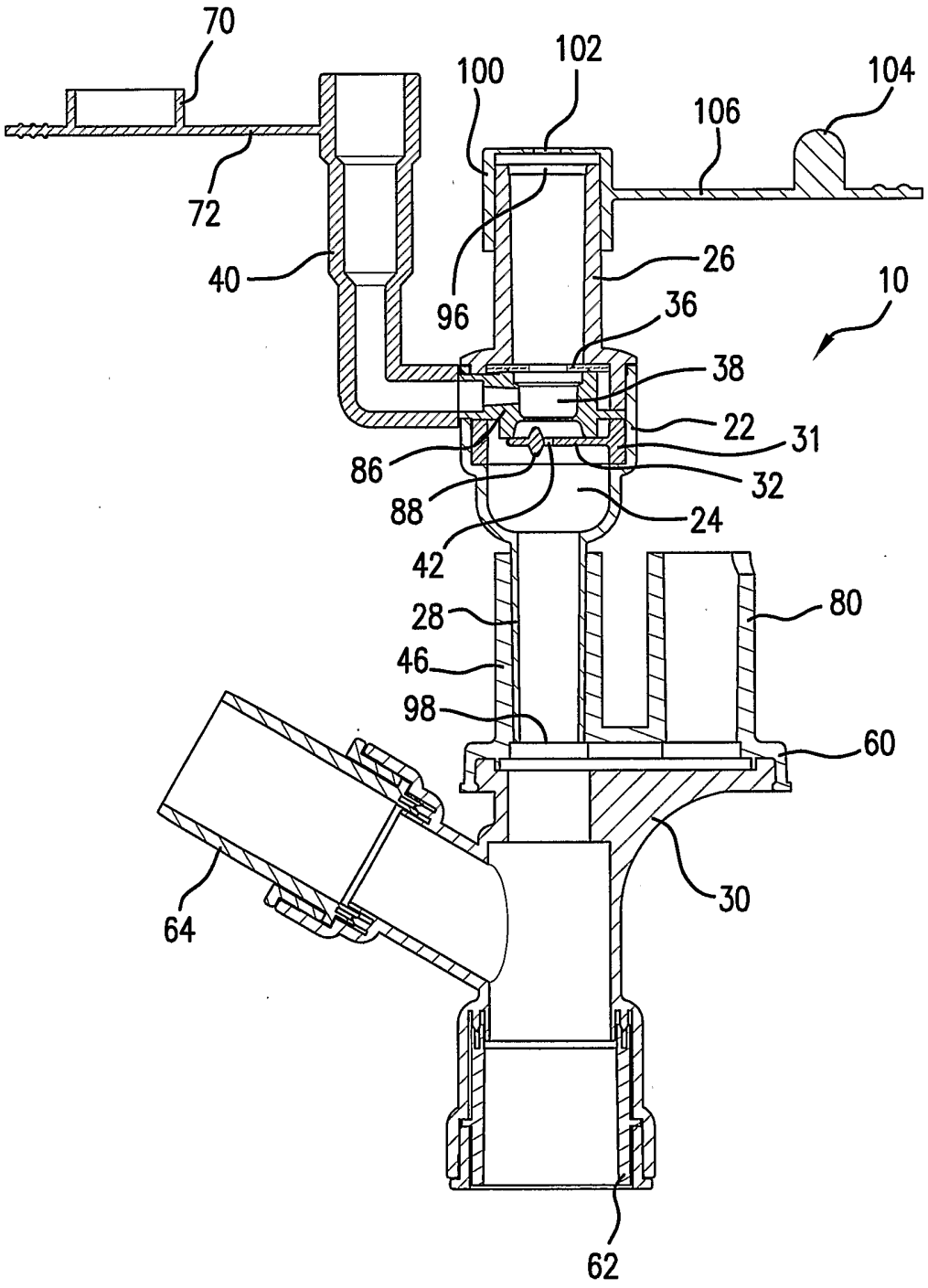
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FIG.3

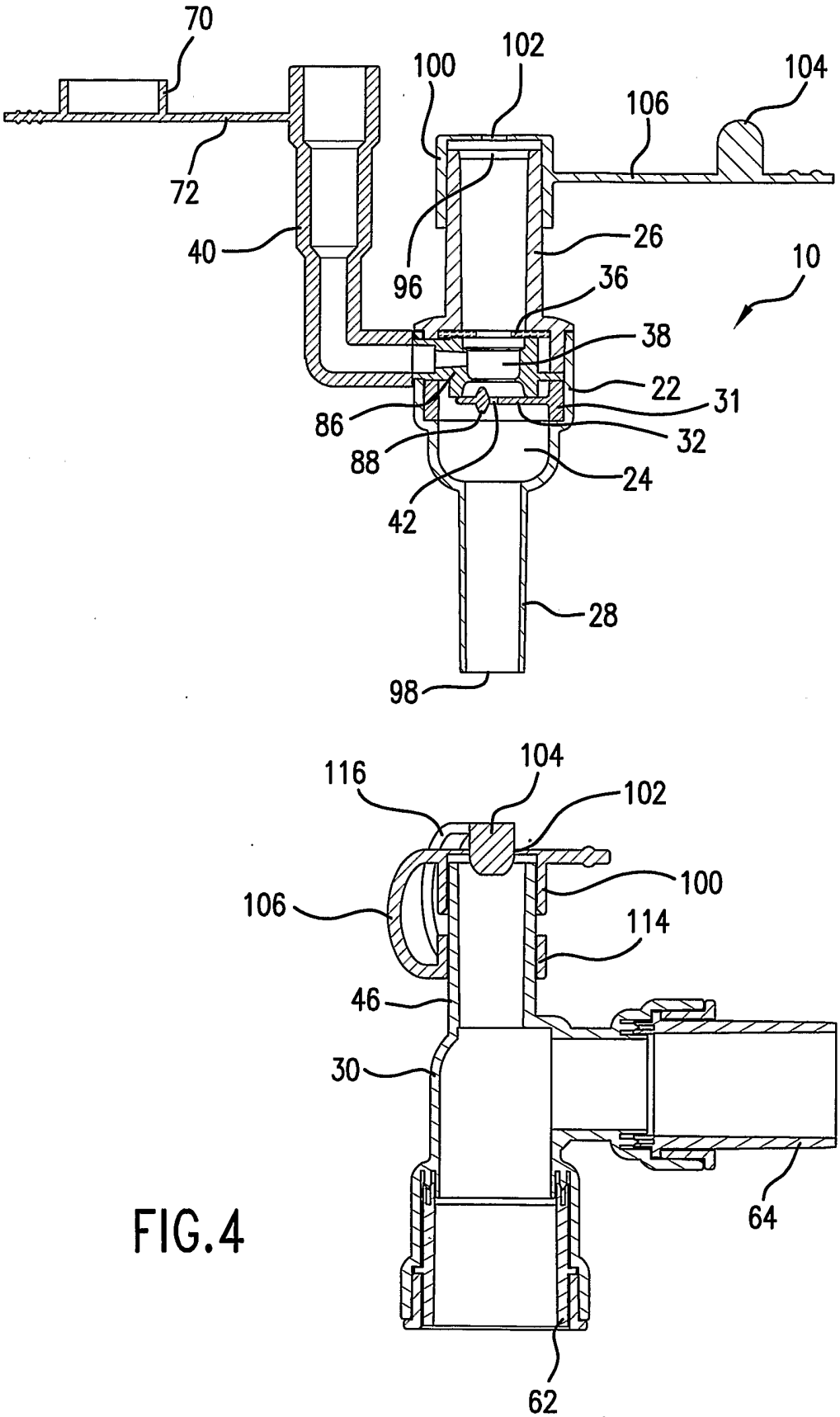
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FIG.4

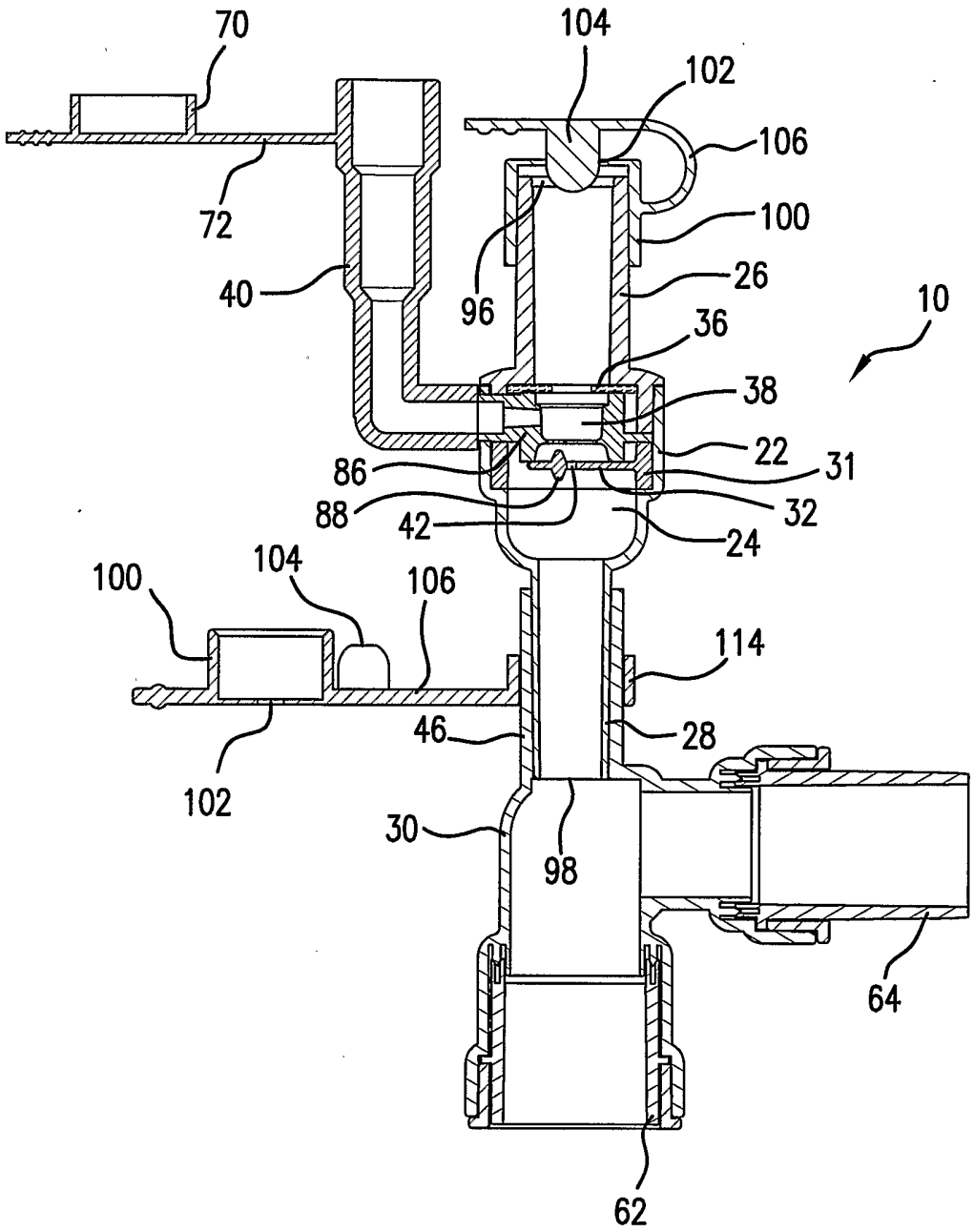
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FIG.5

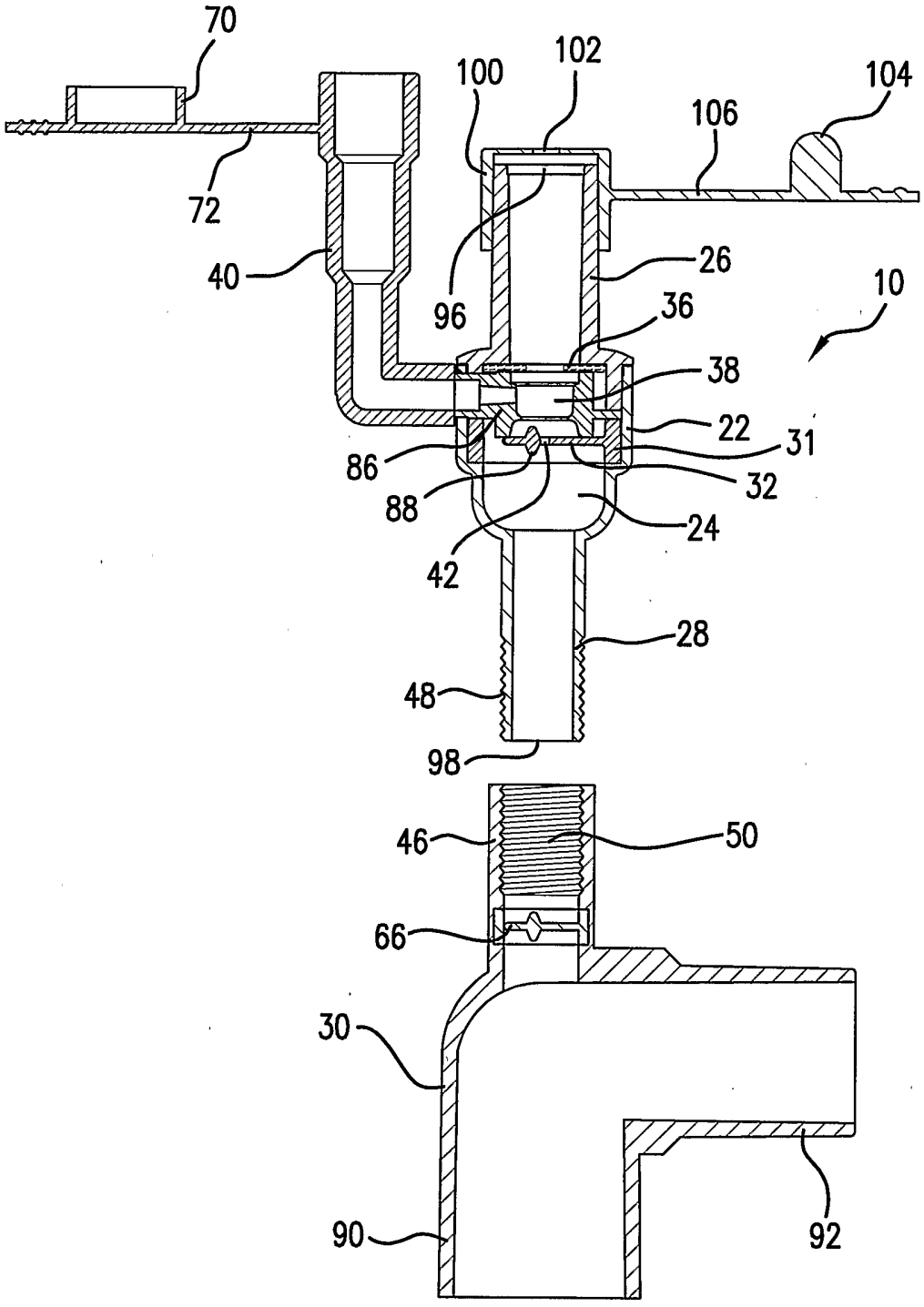
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FIG.6

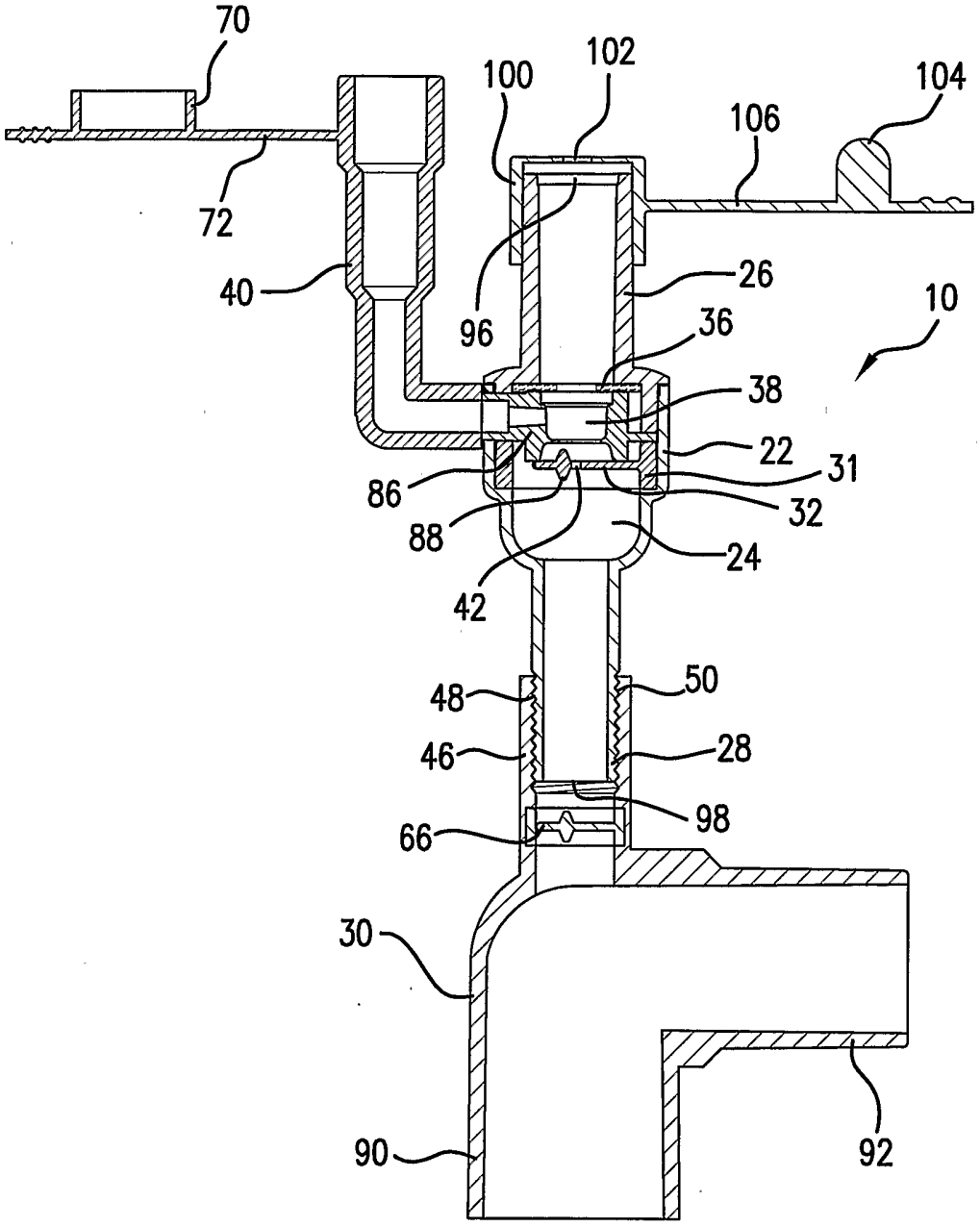
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FIG.7

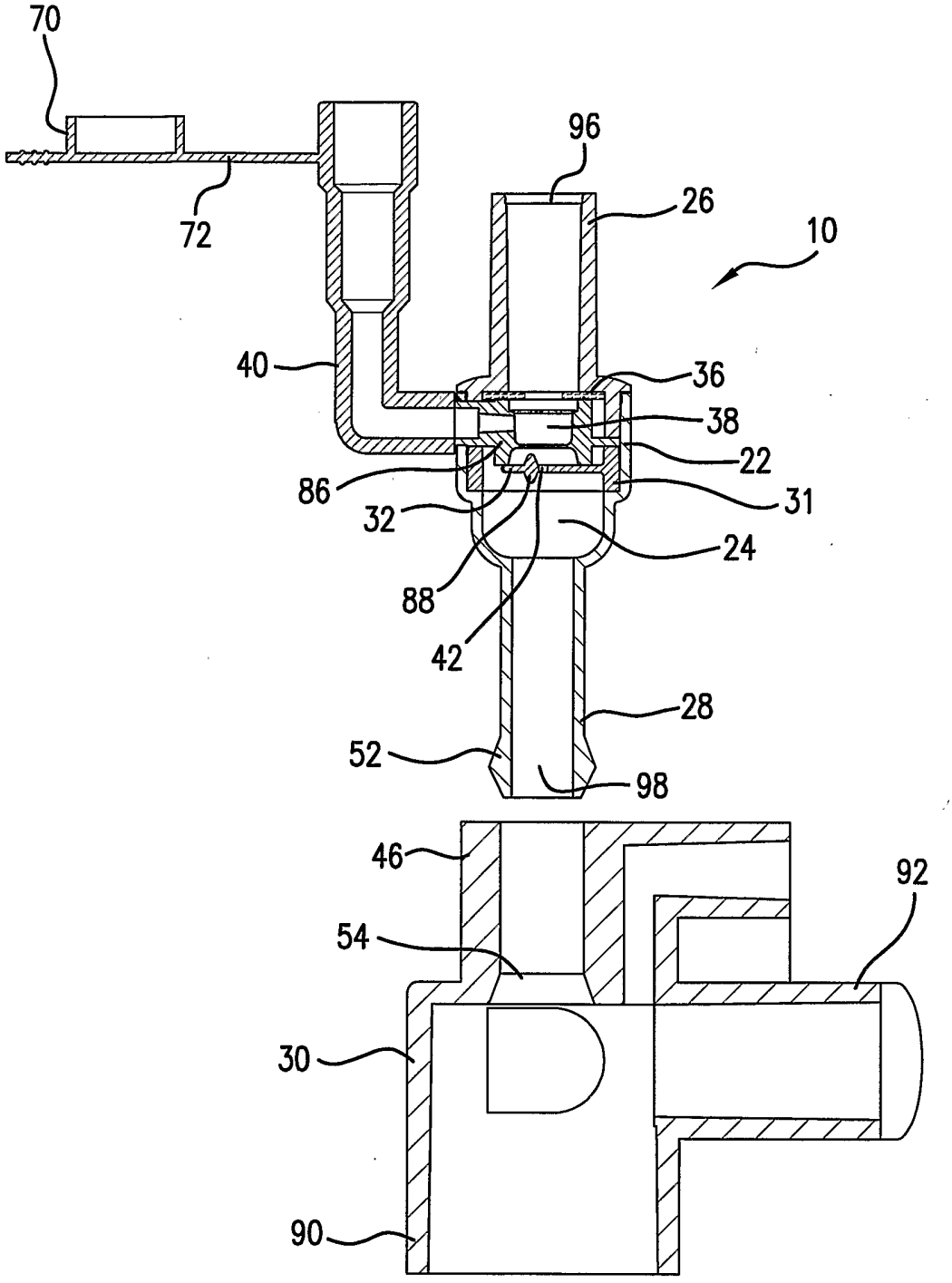

FIG.8

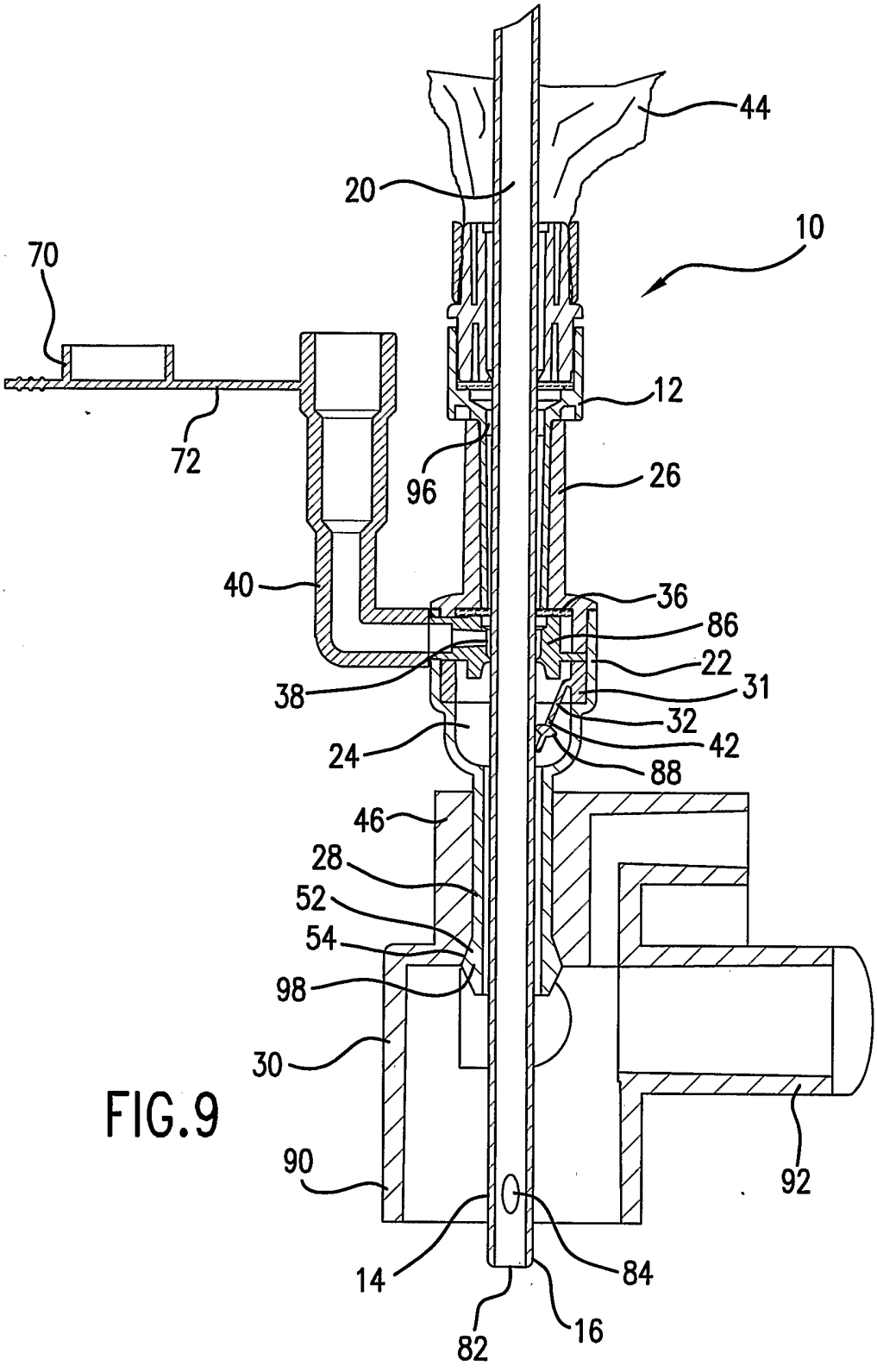
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FIG.9

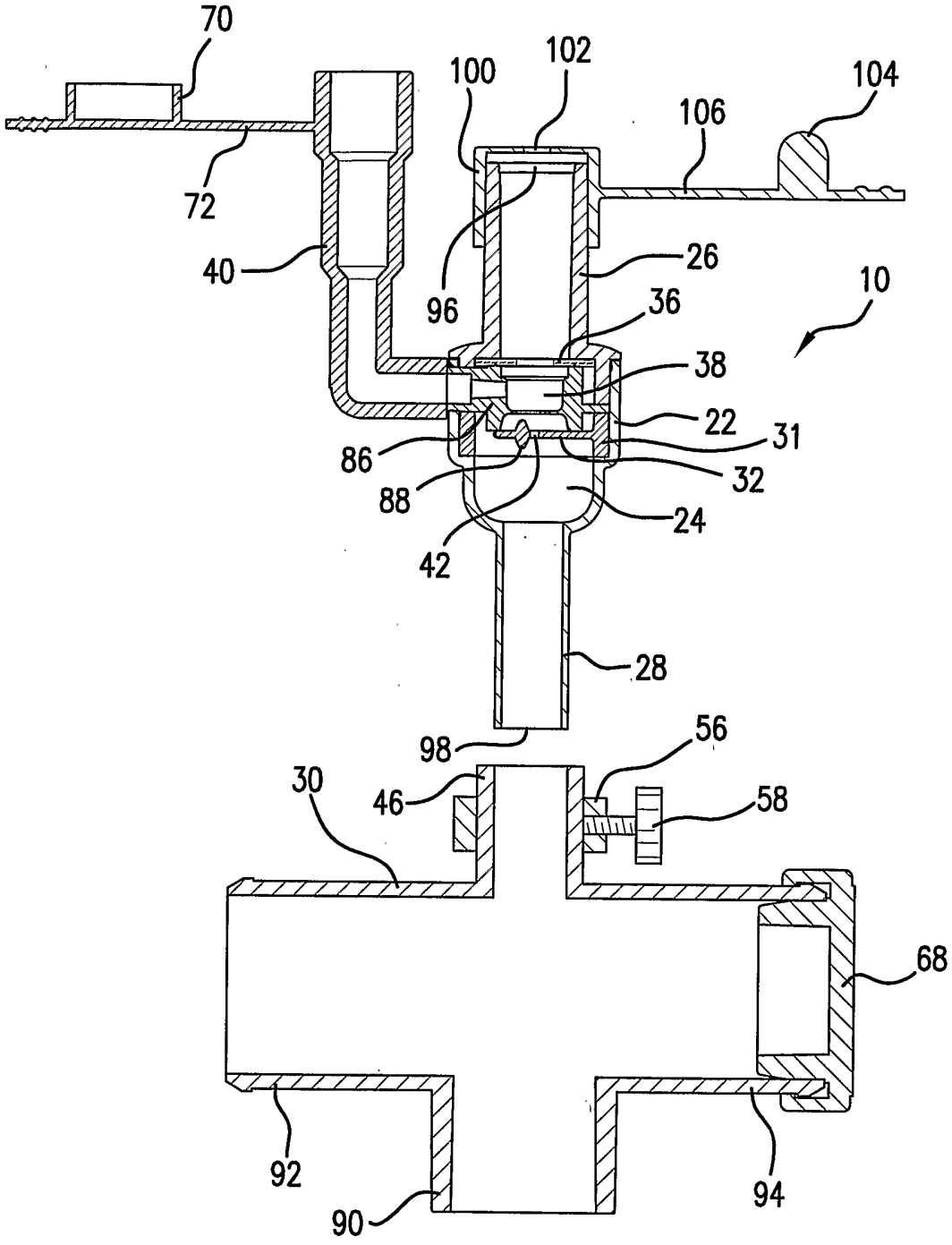
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FIG.10

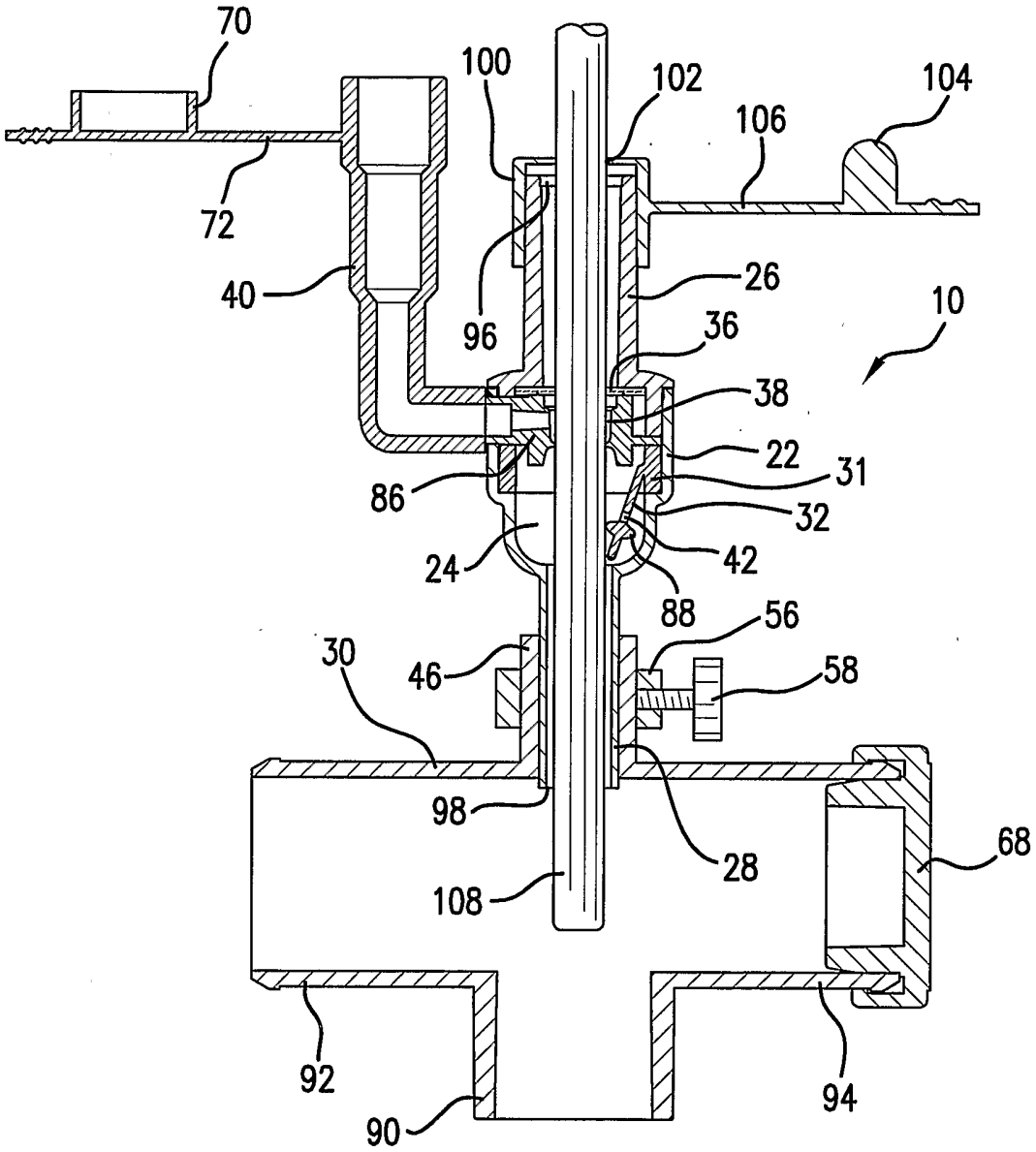
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FIG.11

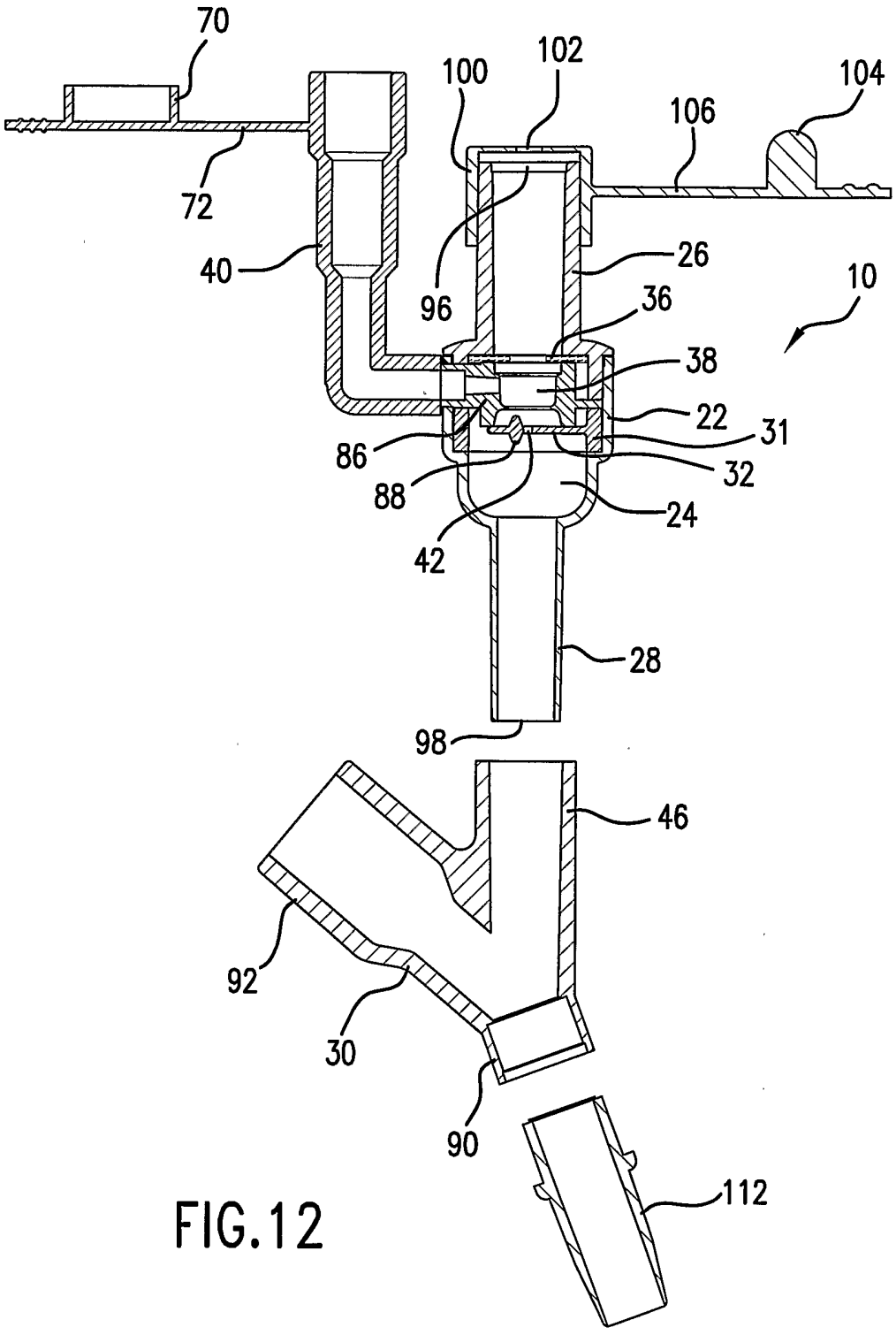
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FIG.12

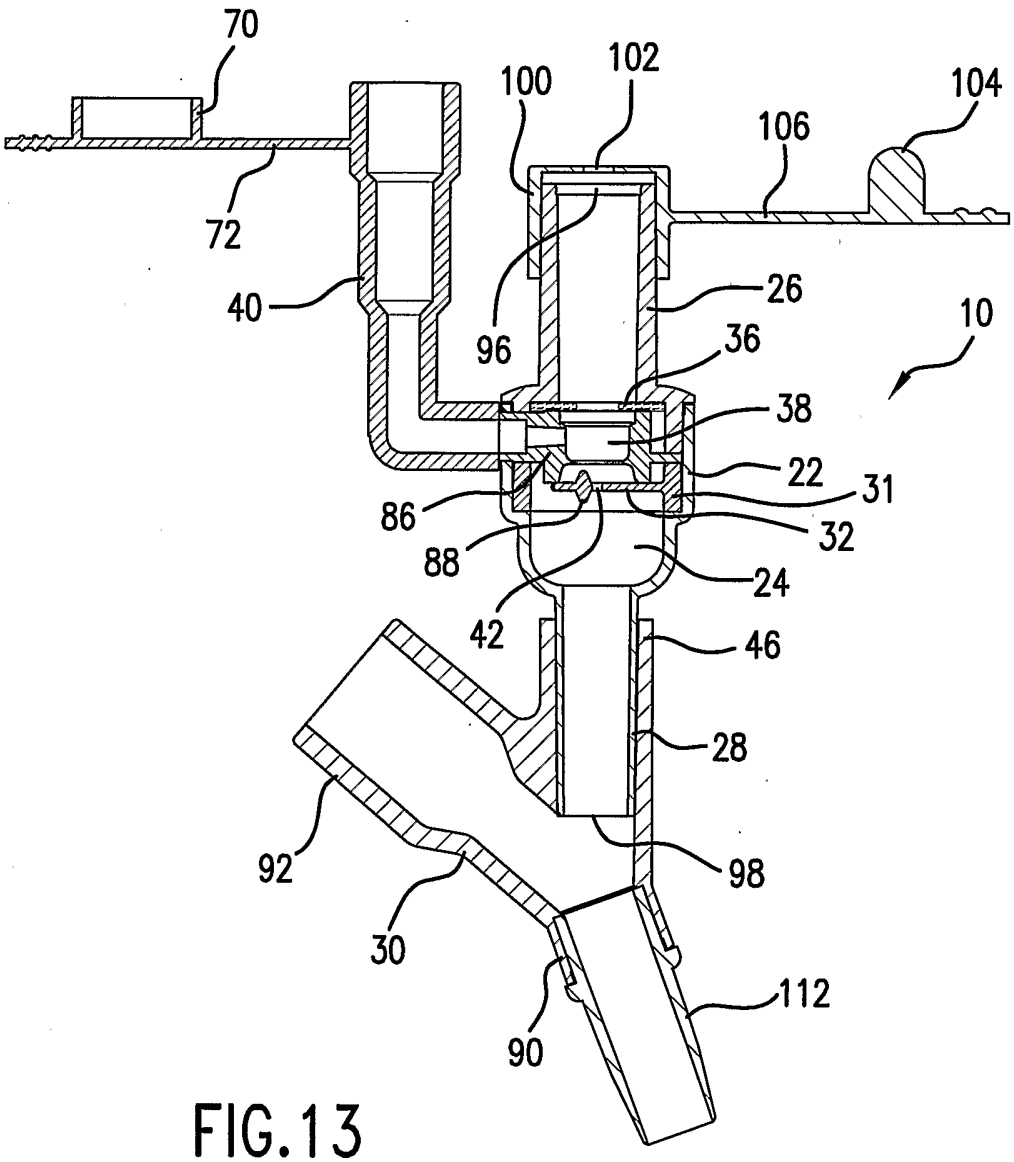
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FIG.13

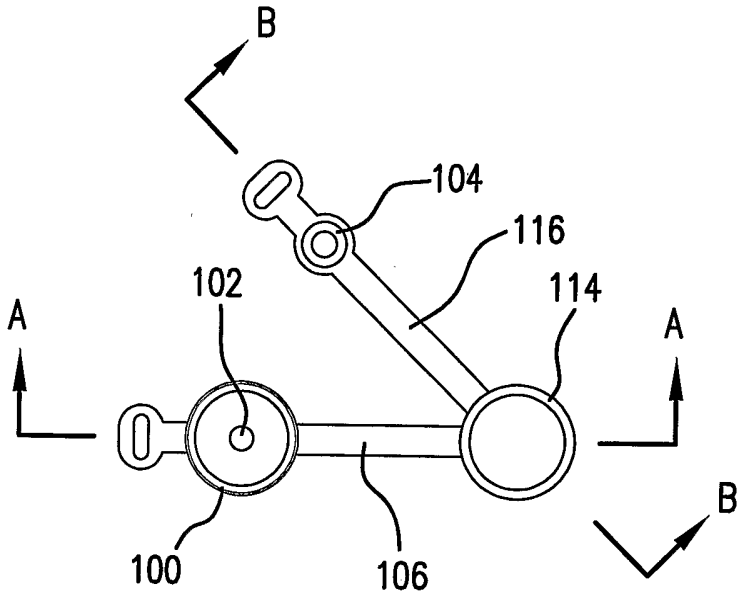

FIG.14

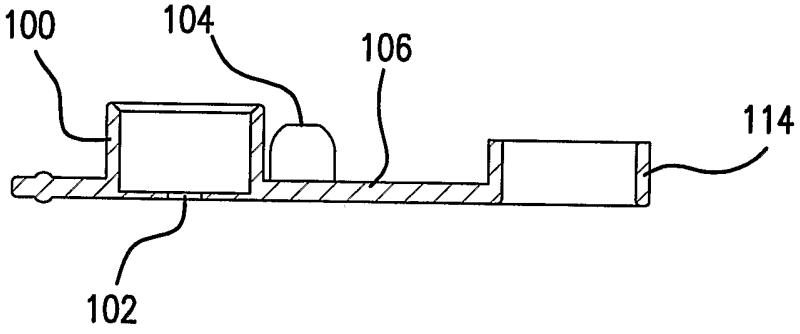

FIG.15

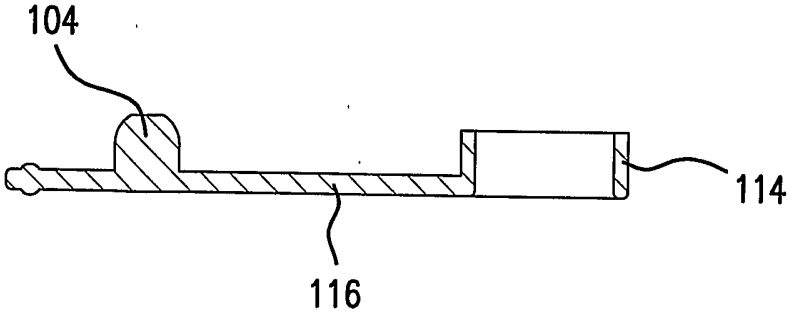

FIG.16

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/001412

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M16/00 A61M16/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/45779 A (BALLARD MED PROD) 28 June 2001 (2001-06-28) page 12, line 1 -page 17, line 4 page 21, line 15 -page 23, line 16 page 24, line 6 - line 11 page 25, line 13 -page 26, line 4	1-11,15, 16, 19-25, 29-33
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
3 June 2004	18/06/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Vänttinen, H

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/001412

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