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(54) **Title:** DEVICE AND METHOD FOR IRRIGATING-EVACUATING A BODY CAVITY

(57) **Abstract:** A device for irrigating a body cavity with fluid is disclosed. The device comprises a manually-operated pump mechanism, configured for delivering a first volume of fluid to the body cavity and delivering a second volume of fluid to the body cavity while concomitantly withdrawing at least said second volume of fluid from the body cavity.

DEVICE AND METHOD FOR IRRIGATING-EVACUATING A BODY CAVITY

RELATED APPLICATIONS

This application claims the benefit of priority from U.S. Application Nos. 61/359,404, filed on June 29, 2010, and 61/406,201, filed on October 25, 2010, the contents of which are incorporated by reference as if fully set forth herein.

FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to a hand-held, and optionally manually-operated, device for irrigating-evacuating a body cavity and specifically, but not exclusively, to a manually operated pumps mechanism which can be used to remove secretions from a subglottic region of an intubated subject.

Intubation involves positioning of a tube, such as an endotracheal tube (ETT) or a tracheostomy tube through the trachea of a subject terminating at a position above the carina, anterior to a position between the second and fourth thoracic vertebrate.

Endotracheal intubation is used to mechanically ventilate the subject's lungs when normal breathing is not supported, or to apply anesthetic gases during surgical intervention.

Tracheostomy is an operative procedure that creates a surgical airway in, anterior to a position between the cervical trachea. The resulting stoma can serve independently as an airway or as a site for a tracheostomy tube to be inserted. This tube allows a person to breathe without the use of their nose or mouth, or being mechanically ventilated when hospitalized or in homecare environment

In order to create enough air pressure to accomplish mechanical ventilation and to prevent escape of gases past the tube, the tubes are sealed against the trachea using, for example, an inflatable cuff.

The inflatable cuff is inflated so as to engage the wall of the trachea and thereby seal the trachea and prevent gases being introduced through the tracheal tube from simply leaking around the tube. While use of an inflatable cuff is important for operability of an ETT, it can also contribute to complications.

Intubated patients can develop pneumonia resulting from an infection of the lungs induced by contaminated, pooled secretions with digestive content bypassing the

epiglottis. To overcome these risks, endotracheal and tracheostomy tubes which enable single lumen suction or double lumen irrigation and suction of such secretions have been developed. Single lumen suction tubes are limited in that the suction often causes direct suction to be exerted on the tracheal mucosa which may then result in damage to the mucosa. Double lumen tubes while being vastly superior in enabling clearance of secretions require the use of complicated and expensive irrigation pumps.

SUMMARY OF THE INVENTION

According to an aspect of some embodiments of the present invention there is provided a device for irrigating a body cavity with fluid. In various exemplary embodiments of the invention the device is a hand-held device. The device comprises a pump mechanism configured for delivering a first volume of fluid to the body cavity and delivering a second volume of fluid to the body cavity while concomitantly withdrawing at least the second volume of fluid from the body cavity. The pump mechanism is optionally and preferably a manually-operated pump mechanism.

According to some embodiments of the invention the pump mechanism is configured to deliver fluid to the body cavity at a first volumetric flow rate and simultaneously withdraw fluid from the body cavity at a second volumetric flow rate, and wherein there is a linear relation between the first and the second volumetric flow rates.

According to some embodiments of the invention the mechanism comprises a first pump and a second pump each being configured for communicating fluid to and from the body cavity, the first pump and the second pump being operatively linked such that operating the second pump to deliver the second volume of fluid into the body cavity activates the first pump to withdraw the at least the second volume of fluid from the body cavity.

According to some embodiments of the invention the mechanism comprises a first pump and a second pump each being configured for communicating fluid to and from the body cavity, the first pump and the second pump being operatively linked such that operating the first pump to withdraw the at least the second volume of fluid from the body cavity activates the second pump to deliver the second volume of fluid into the body cavity.

According to some embodiments of the invention the first and the second pumps are, respectively, a first and a second piston pumps and wherein the first piston of the first pump is operatively linked to a second piston of the second pump.

According to some embodiments of the invention the first piston and the second piston are linked in a manner which enables independent movement of the first piston and the second piston through a preset movement range and linked movement of the first piston and the second piston beyond the preset movement range.

According to some embodiments of the invention movement of the first piston within the preset movement range delivers the first volume of fluid to the body cavity and further wherein movement of the second piston beyond the preset movement range delivers the second volume of fluid and operates the first piston to withdraw the at least the second volume of fluid.

According to some embodiments of the invention the piston pumps are syringes having manually operateable plungers.

According to some embodiments of the invention the piston pumps are aligned parallel to each other such that a withdrawing direction of the first piston pump is opposite to an ejecting direction of the second piston pump.

According to some embodiments of the invention the piston pumps are aligned parallel to each other such that a withdrawing direction of the first piston pump is parallel to an ejecting direction of the second piston pump.

According to some embodiments of the invention the device comprises an actuator member having a first mode in which both the pumps are inoperative, and a second mode in which the actuator member activates the first pump to eject an initial volume of fluid out of the device.

According to some embodiments of the invention the actuator member additionally has a third mode in which the actuator member activates the second pump to eject a further initial volume of fluid out of the device.

According to some embodiments of the invention the actuator member additionally has a fourth mode in which the actuator member simultaneously activates the second pump to deliver fluid into the body cavity and the first fluid pump to withdraw fluid from the body cavity.

According to some embodiments of the invention the actuator member additionally has a fifth mode in which the actuator member activates only the first fluid pump to withdraw fluid from the body cavity.

According to some embodiments of the invention the actuator member is a mechanical member.

According to some embodiments of the invention at least one of the first and the second pumps is a peristaltic pump.

According to some embodiments of the invention the first pump is a container having an under pressure therein.

According to some embodiments of the invention the second pump is a deformable bag.

According to some embodiments of the invention the device comprises a pressure measuring device.

According to some embodiments of the invention the pump mechanism comprises a biomarker therein.

According to an aspect of some embodiments of the present invention there is provided an intubation system comprising the device according to any of claims 1-20, and a tube assembly adapted for being introduced into the body cavity.

According to an aspect of some embodiments of the present invention there is provided a method of irrigating a body cavity with fluid. The method comprises: (a) delivering a first volume of fluid to the body cavity; and (b) delivering a second volume of the fluid and simultaneously withdrawing at least the second volume of the fluid from the body cavity. In various exemplary embodiments of the invention the first and second volumes are delivered manually.

According to some embodiments of the invention the method is effected by a device which comprises a first pump and a second pump each being configured for communicating fluid to and from the body cavity, the first pump and the second pump being operatively linked such that operating the second pump to deliver the second volume of fluid into the body cavity activates the first pump to withdraw the at least the second volume of fluid from the body cavity.

According to some embodiments of the invention the method is effected by a device which comprises a first pump and a second pump each being configured for

communicating fluid to and from the body cavity, the first pump and the second pump being operatively linked such that operating the first pump to withdraw the at least the second volume of fluid from the body cavity activates the second pump to deliver the second volume of fluid into the body cavity

According to some embodiments of the invention (a) is effected by operating the second pump to deliver a first volume of fluid to the body cavity.

According to some embodiments of the invention (b) is effected by manually operating the first pump to deliver a second volume of the fluid to the body cavity thereby operating the second pump to withdraw fluid from the body cavity.

According to some embodiments of the invention the device is connected to the body cavity via a tube having a first line in fluid communication with the first pump and a separate second line in fluid communication with the second pump, and the method comprises: operating the second pump to deliver fluid into the second line, so as to at least fill the second line; operating the first pump to deliver fluid into the first line, so as to at least fill the first line; and simultaneously operating the first pump to withdraw fluid from the first line and the second pump to deliver fluid into the second line.

According to some embodiments of the invention the manually delivering the second volume of the fluid is at a first volumetric flow rate, and the simultaneously withdrawing the at least the second volume of the fluid is at a second volumetric flow rate, and wherein there is a linear relation between the first and the second volumetric flow rates.

According to some embodiments of the invention the method comprises subsequently to the (b), withdrawing fluid from the body cavity without delivering fluid into the body cavity.

According to some embodiments of the invention the body cavity is the trachea. According to some embodiments of the invention the method is executed during tracheotomy intubation. According to some embodiments of the invention the method is executed during oral endotracheal intubation. According to some embodiments of the invention the method comprises connecting the irrigation device to an intubation device which comprises: a flexible tubular body being adapted for being introduced into the trachea of a subject and defining a main lumen; and an inflatable cuff associated with the tubular body and arranged to be located at a location in the patient trachea; the wall

being embedded with at least: (i) two suction lumens with respective openings above the cuff, the openings being arranged laterally with respect to each other within the wall, (ii) a cuff inflation lumen with opening at the cuff, and (ii) an irrigation lumen with opening above the cuff.

According to some embodiments of the invention the body cavity is the ear canal.

According to some embodiments of the invention the body cavity is the intestines.

According to an aspect of some embodiments of the present invention there is provided a device for irrigating a body cavity with fluid. The device comprises two manually-operated syringes having linked plungers, wherein pushing in a first plunger of a first syringe beyond a predetermined travel distance withdraws a second plunger of a second syringe.

According to some embodiments of the invention the two manually-operated syringes are of different volumes and/or plunger stroke length.

According to an aspect of some embodiments of the present invention there is provided a kit. The kit comprises the irrigation device as described herein and an intubation device, wherein the intubation device comprises: a flexible tubular body being adapted for being introduced into the trachea of a subject and defining a main lumen; and an inflatable cuff associated with the tubular body and arranged to be located at a location in the patient trachea; the wall being embedded with at least: (i) two suction lumens with respective openings above the cuff, the openings being arranged laterally with respect to each other within the wall, (ii) a cuff inflation lumen with opening at the cuff, and (ii) an irrigation lumen with opening above the cuff.

According to some embodiments of the invention the wall has a dorsal section and a ventral section at opposite sides of a longitudinal axis of the tubular body, and wherein the openings of the suction lumens are both located at the dorsal section. Preferably, the openings of the suction lumens are separated by a an azimuthal angle which is less than a with respect to the center of a cross-section perpendicular to the longitudinal axis, where a is less than 100° or less than 90° or less than 80° or less than 70° or less than 60° or less than 50° or less than 40° or less than 30° or less than 20°. According to some embodiments of the invention the opening of the irrigation lumen is

located at the ventral section. According to some embodiments of the invention the opening of the evacuation lumens are located at the dorsal section having openings with ducts on the sidereal to enlarge suction ports.

According to some embodiments of the invention the suction lumens are unified to a single conduit external to the tubular body.

According to some embodiments of the invention the tubular body is adapted for oral endotracheal intubation. According to some embodiments of the invention the tubular body is adapted for tracheostomy intubation.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings and images. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

FIGs. 1A-D are schematic illustrations of the stages of operation of a device, according to some embodiments of the present invention.

FIGs. 2A-E are schematic illustrations of the stages of operation a device in embodiments in which the device is connected to an endotracheal tube.

FIGs. 2F-J are schematic illustrations of the stages of operation a device in embodiments in which the device is connected to a tracheostomy tube.

FIGs. 3A-C are schematic illustrations of the stages of operation of a device, specifically showing different barrel and plunger diameters, according to some embodiments of the present invention.

FIGs. 4A-E are schematic illustrations of the stages of operation of the device in embodiments in which the present device is attached to an endotracheal tube and a unidirectional spring is employed.

FIGs. 4F-J are schematic illustrations of the stages of operation of the device in embodiments in which the present device is attached to a tracheostomy tube and a unidirectional spring is employed.

FIGs. 5A-D are schematic illustrations of the stages of operation of an embodiment in which the present device is attached to an endotracheal tube and a bidirectional spring is employed.

FIGs. 5E-H are schematic illustrations of the stages of operation of an embodiment in which the present device is attached to a tracheostomy tube and a bidirectional spring is employed.

FIGs. 6A-G are schematic illustrations of pump mechanisms, according to some embodiments of the present invention.

FIGs. 7A-E are schematic illustrations of a device in embodiments of the invention in which the device comprises an actuator member.

FIGs. 8A and 8B are schematic illustration of a system which comprises a device that including an actuator member and a tube.

FIGs. 9A and 9B are schematic illustrations of a device in embodiments of the invention in which the device comprises a pressure measuring device.

FIG. 10 is a schematic illustration of a pack including two devices, according to some embodiments of the present invention.

FIGs. 11A-B are schematic illustrations and an image of a device and an endotracheal tube, used in experiments performed according to some embodiments of the present invention.

FIG. 12 is a fluoroscopy image of a goat's trachea with the endotracheal tube of the present embodiments before evacuation of the secretions.

FIG. 13 is a fluoroscopy image of the goat's trachea with the endotracheal tube after the evacuation of the secretions using the prototype device of the present embodiments.

FIG. 14 is a fluoroscopy image of the goat's trachea with a conventional tube before a evacuation of the secretions.

FIG. 15 is a fluoroscopy image of the goat's trachea with the conventional tube after the evacuation of the secretions by rinsing followed by suction.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to a hand-held, and optionally a manually-operated, device for irrigating-evacuating a body cavity and specifically, but not exclusively, to a manually operated pump mechanism which can be used to remove secretions from a subglottic region of an intubated subject.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the Examples. The invention is capable of other embodiments or of being practiced or carried out in various ways.

The present inventors have previously described endotracheal tubes which are designed for facilitating removal of secretions from a subglottic region using automated pump mechanisms (see WO2007/066332 which is incorporated herein by reference). Although such endotracheal tube configurations are highly effective in reducing complications associated with migration of secretions into the lungs, the requirement for sophisticated pump mechanisms for operability can be limiting

In efforts of overcoming these requirements, the present inventors devised a manually-operated pump mechanism which is characterized by at least one of:

(i) a simple design - reduces costs of manufacturing and use;

(ii) simple and easy operation - simple to setup and operate, designed to provide operability familiar to medical personnel;

(iii) single use - reduces risk of contaminations and traverses need for sterilization; and

(iv) provides a clear indication of irrigation and of secretions/debris evacuated from an irrigated body cavity.

(v) reducing time and providing more frequent diagnosis by sending the device with evacuated to secretions to laboratory before disposing it.

Thus, according an aspect of some embodiments of the present invention there is provided a device for irrigating and evacuating a body cavity.

As used herein, the term "irrigating" refers to running fluid into and out of the body cavity for the purpose of evacuating secretions, debris and the like.

As used herein, "a body cavity" refers to naturally occurring or artificially formed cavities within tissue structures. One example of a cavity is the space formed below the glottis and above an inflatable cuff of an endotracheal tube or a tracheostomy tube. Other examples including, without limitation, the ear canal, and the intestines.

In embodiments of the invention in which the device is adapted for manually irrigating and evacuating the space defined between the tracheal wall and an endotracheal tube or a tracheostomy tube below the glottis and above the inflatable cuff, the device is termed Manual Aspiration of Subglottic Secretions (MASS) device.

The device of the present embodiments includes a manually-operated pump mechanism capable of delivering a volume of fluid to the body cavity while concomitantly withdrawing a volume of fluid from the body cavity (through suction). Such delivery is typically effected through two fluid lines (delivery and suction) each separately connected to the pump mechanism of the present embodiments at one end, while the opposite end of each fluid line is disposed within the body cavity or connected to a device being in fluid communication with the body cavity (e.g. an endotracheal tube such as that shown in FIGs. 2A-E or FIG. 4A-E or 5A-D or that described in WO2007/066332, or a tracheostomy tube such as that shown in FIGs. 2F-J or FIG. 4F-4J or 5E-5H).

Manually operated pump mechanisms such as syringes are relatively inexpensive to fabricate and easy to operate. However, such mechanisms are typically limited in that each stage of an irrigation procedure (pumping fluid in and pumping fluid out) requires a separate manual operation of the pump piston (syringe plunger). Although mechanical pumps capable of continuous operation (e.g. peristaltic) can be manually operated to circulate a fluid through a cavity they can be difficult to operate and are less suitable for

use in medical applications which require periodic rapid irrigation with low volumes of fluid under sterile conditions.

The manually operated pump mechanism of the present embodiments is configured for delivering a volume of fluid into the cavity while simultaneously or sequentially (or semi-sequentially) withdrawing that volume in a single stage of operation thus enabling rapid and easy irrigation of the body cavity and traversing the limitations of prior art devices such as simple syringes.

During the operation phase in which the pump mechanism delivers fluid to the body cavity and simultaneously withdraw fluid from the body cavity, there is always a linear relation between the volumetric flow rate Q_1 at which the fluid is delivered and the volumetric flow rate Q_2 at which fluid is withdrawn. For example, $Q_2=Q_1$, or $Q_2=aQ_1$ or $Q_2=aQ_1+b$, where *a* and *b* are constants. In some embodiments of the present invention b=0.

The manually operated pump mechanism of the present embodiments is optionally and preferably also configured to enable a priming operation in which a first volume of fluid is first delivered into the cavity without simultaneous withdrawal of that fluid. Such a priming stage fills the suction line and optionally partially fills the body cavity so as to establish a fluid continuum between the pump mechanism and the body cavity and prevent compressible gas voids within suction line.

This feature is particularly important since air filled suction lines can collapse due to tissue occlusion of suction ports. Under suction pressure, tissue sucked into a suction port can cause a suction line to collapse. If the suction line is filled with a fluid such as saline (which unlike air is not compressible) a continuum is created between the pump mechanism and the fluid in the body cavity thereby preventing collapse of the suction line and occlusion of the suction line.

To enable such 'priming' of fluid lines and especially the fluid suction line, the mechanism of the present embodiments enables a two stage operation in which in a first stage (priming) a first volume of fluid is delivered to the body cavity via the irrigation mechanism (without simultaneous fluid withdrawal), followed by a second stage of operation (irrigation using a second fluid line that delivers fluid into the cavity) in which delivery and simultaneous withdrawal of a second (and typically larger) volume of fluid

is effected. Preferably, the second (delivery) line is also primed with fluid prior to delivery and simultaneous withdrawal.

Several configurations of the device of the present embodiments can be used to enable such functionality, one preferred configuration of the present device includes a pump mechanism constructed from two operably linked piston pumps having opposingly operable pistons actuatable via a single manual operation.

Such linked operation can be used to deliver fluid into the body cavity from a first piston pump while simultaneously withdrawing fluid from the body cavity through the second and operatively linked piston pump.

Several piston pump configurations can be used to provide such operability. One configuration which is particularly useful for medical applications is a dual syringe configuration having operatively linked plungers.

A device configuration using two interconnected syringes is easy and inexpensive to manufacture, can be disposed of with ease following a single use (thereby lending itself to medical applications) and provides the treating physician with familiar operability.

FIGs. 1A-D illustrate one embodiment of a dual syringe device which is referred to herein as device **10.**

Device **10** includes two pumps **12,** for example, piston pumps, shown in FIGs. 1A-D as syringes. Each syringe is constructed from a barrel (with nozzle **14** - shown on one syringe) housing a plunger **18** having a seal (not shown) and back stop **34.** Syringes **12** are fabricated using materials and methods well known in the art.

One or both plungers **18** can include a spring element for facilitating plunger withdrawal from the barrel once plunger **18** is pushed in. Sprung plungers enable a greater degree of control over plunger activation and as such can be advantageous in cases where fluid delivery has to be carefully controlled. Spring loaded plunger configurations are well known to the ordinary skilled artisan.

Syringes **12** can be connected using removable or non-removable attachment mechanisms. FIGs. 1A-D illustrate configuration of device **10** in which syringes **12** are attached to a housing **22.** Housing **22** can be fabricated to accommodate syringes of variable sizes, volumes and plunger stroke lengths. The configuration shown in FIGs. 1A-D includes syringes **12** of non identical volumes (asymmetric configuration),

although symmetric configurations in which syringes **26** and **32** are identical can be used in device **10.** In asymmetric configurations, a syringe **12** used for suction **(32)** can be configured to generate a suction volume per plunger **18** stroke (see the configuration of FIGs. 3A-C which is further described hereinunder) which is greater than the delivery volume of syringe **26.** This enables suctioning of the irrigation fluid delivered from syringe **26** as well as any fluid contained in the cavity (e.g. secretions etc).

The volume of each syringe, as well as plunger **18** stroke length are selected according to the irrigation procedure, for example, in the case of subglottic irrigation, each syringe can contain about 2-10 ml deliverable through a plunger stroke length of about 5-10 cm. Other amounts are not excluded from the scope of the present invention. FIGs. 1A-D illustrate syringes **12** in an 'over and under' configuration however, other arrangements such as that of the configuration shown in FIGs. 2A-8B are also envisaged.

As is mentioned hereinabove, device **10** of the present embodiments is configured so as to provide fluid delivery and withdrawal via a single manual operation. To enable such functionality, plungers **18** of syringes **12** are operatively linked via element **23** to move in opposite directions (with respect to the syringe barrels). Thus, when plunger **24** of syringe **26** is pushed into barrel **28** effectively delivering any fluid contained therein (through nozzle **14** - not shown), element **23** draws plunger **30** of syringe **32** out of barrel **32** creating a suction force capable of withdrawing fluid through nozzle **14** (FIGs. 1C-D). Element **23** shown in FIGs. 1A-D is an elongated frame disposed between end stops **34** of syringes **12** and set within grooves in housing **22** (enabling element **23** to slide back and forth). Element **23** can be interchangeable to provide varying functionality.

Operatively connecting plungers **18** via element **23** enables single stage irrigation, however, it negates any independent movement of plungers **18** and thus prevents syringe **26** or **32** from being used to prime a suction line.

Several approaches can be used to enable such functionality. For example, syringe **24** and/or **30** can be removed from housing **22** and used for priming a suction line and/or rinsing lines prior to evacuation , or element **23** can be configured to enable some non-linked movement of plungers **18** through a preset movement range beyond which movement of plungers **18** is linked.

The latter configuration is shown in FIGs. 1A-D, 2A-J and 3A-C. As is seen in FIG. 1A, plunger **30** of syringe **32** is free to move a preset distance without backstop **34** contacting element **23.** Such free movement of plunger **30** enables use of syringe **32** for delivering a preset volume of fluid through nozzle **14** without activating movement of plunger **24;** this enables the priming of a suction line described above. Once plunger **30** is depressed such that backstop **34** engages limiter **36** and delivery of fluid from syringe **32** is complete (FIG. IB), operating plunger **24** of syringe **26** slides element **23** in the direction of backstop **34** of syringe **32** until element **23** contacts backstop **34** of syringe **30** (FIG. 1C), this phase can also include non-linked movement in order to deliver a predetermined amount of fluid for priming the fluid delivery line (with excess fluid delivered into the body cavity). In any case, once element **23** contacts backstop **34** of syringe **32** inward movement of plunger **24** forces plunger **30** out of syringe **32** (FIG. ID) thereby generating simultaneous fluid delivery from syringe **26** and suction in syringe **32.**

Thus, a single operation of pushing in plunger **24** can be used to optionally prime a fluid delivery line and thereafter simultaneously deliver and suction fluid through two separate delivery nozzles.

In the configuration shown in FIGs. 1A-D, element **23** is designed to provide each plunger **18** with some independent movement, it will be appreciated however, that an element **23** which does not enable independent movement of plungers **18** or one that enables more independent movement can also be used.

Although the configurations shown in FIGs. 1A-8B include two opposingly mounted syringes (whether end to end or over and under), wherein the withdrawing direction of one syringe is parallel to the ejecting direction of the other syringe, this need not necessarily be the case since, in some embodiments the syringes are mounted in the same direction (i.e. nozzles on the same side of device **10),** wherein the withdrawing direction of one syringe is opposite io the ejecting direction of the other syringe. Such configurations can employ an element **23** configured to translate movement of one plunger **18** to opposite movement of another plunger **18.** For example, element **23** can be a beam attached at ends thereof to plungers **18** and to a hinged element in the middle thereby functioning as a seesaw between the two plungers, or cog-wheel that connects two opposite 23 elements.

Device **10** of the present embodiments can be used for irrigating body cavities such as tissue voids filled with pus, by clearing the pus while preventing shrinkage of surrounding tissue by filling the void created with antiseptic or other therapeutic fluid. The present device can also be used to clear obstructions in vessels such as urinary. Opposite sides of the vessel can be connected to delivery and fluid lines and simultaneously rinsed and suctioned with saline or a therapeutic fluid to clear and suction out an obstruction.

Automatic irrigation systems and pumps are limited in that they may cause a collapse of a cavity due to large and rapid suction pressures. By providing manual control over irrigation and suction, the present embodiments enable an operator to carefully control irrigation and suction and thus clear cavities of accumulated fluids and debris without compromising the integrity of the cavity or damaging tissue surrounding and defining such cavity.

One preferred use for the present device is irrigation of a subglottic region in intubated patients, either during oral endotracheal intubation or during tracheostomy intubation. In such cases, the present device preferably forms a part of a system which also includes an endotracheal or tracheostomy tube having at least two separate fluid lines. One example of a suitable endotracheal tube is described in WO2007/066332 which is incorporated herein by reference.

FIGs. 2A-J illustrate an intubation system **50** which comprises device **10** connected to a tube **60** through fluid delivery line **52** and a suction line **54.** Tube **60** can be an endotracheal tube, as schematically illustrated in FIGs. 2A-E or a tracheostomy tube as schematically illustrated in FIGs. 2F-J. Tube **60** includes cuff **62,** fluid suction port **66** and fluid delivery port **68.** Ports **66** and **68** are in fluid communication with external suction tube **54** and external delivery tube **52** respectively.

Device **10** of FIGs. 2A-J comprises syringes **12** which are connected back to back with plungers **18** interconnected via element **23.**

Element **23** in this case is a strut which is compressible to a folded configuration of a predetermined length or stretched to a linear configuration of a predetermined length. This length change in element **23** provides each plunger **18** with a preset range of independent movement.

FIGs. 2A and 2F illustrate system **50** in the initial state. Syringe **32** is filled with about 4 ml of a rinsing solution (saline or/and diluting fluid or/and antiseptic fluid), while syringe **26** is filled with about 12 ml of the same solution. Other amounts are not excluded from the scope of the present invention. Element **23** is shown in the compressed state thus allowing independent movement of plungers **24** and **30.**

FIGs. 2B-C and 2G-H illustrate priming of suction line **54** via actuation of plunger **30** (arrow FIGs. 2B and 2G); excess rinsing solution fills subglottic region **70.** FIGs. 2C and 2H illustrate priming of rinsing line **52** via actuation of plunger **24;** excess rinsing fills subglottic region **70.** Once plungers **24** and **30** are fully actuated in, element **23** straightens (FIGs. 2C and 2H). Now plunger **24** is actuated (arrow FIGs. 2C and 2H) to deliver rinsing solution from syringe **26** and at the same time draw out plunger **30** (FIGs. 2D and 21) creating suction in syringe **32.** Concomitant delivery and suction irrigates subglottic region **70** and removes any secretions accumulated in this cavity into syringe **32** (FIGs. 2E and *25).* Device **10** can then be disconnected from lines **52** and **54** which are then capped. Device **10** can then be disposed of or sent to laboratory for diagnosis purposes and replaced with a new device **10** if additional irrigation/evacuation is needed.

Device **10** depicted in FIGs. 2A-J employs a symmetric syringe configuration which, at the concomitant delivery-suction phase, suctions a volume of fluid which is identical to that delivered.

The configuration shown in FIGs. 3A-C employs syringes **12** of different barrel and plunger diameters - syringe **32** has a larger barrel diameter (and hence larger volume per stroke length of plunger **18)** than that of syringe **26.**

Such an asymmetric syringe configuration enables syringe **32** of device **10** to suction a larger volume of fluid than that delivered by syringe **26** of device **10** during the concomitant delivery-suction phase (FIG. 3C). This enables device **10** to more effectively clear fluids from a cavity, especially one which includes excess volume of natural secretions (e.g. subglottic cavity).

Device **10** of FIGs. 3A-C incorporates an element **23** configuration which enables independent movement of syringe **32** through a locked tongue and groove configuration. This configuration of element **23** enables limited movement of tongue **25** in groove **27.** As is shown in FIGs. 3A-C, once syringe **32** is completely pushed in,

tongue **25** moves out of groove **27** to a locked position (FIGs. 3B), pushing in plunger **24** of syringe **26** draws out plunger **30** of syringe **32** generating a suction force in syringe **32.** It will be appreciated that in this configuration plunger **30** can be modified to include a spring such that the step of priming, in which plunger **30** is pushed in, loads the spring (e.g. compresses it) and locks element **23** with the spring loaded. Releasing element **23** releases the spring and automatically withdraws plunger **30** thereby automatically pushing in plunger **24.**

FIGs. 4A-J illustrate the stages of operation of embodiments of the present device, in which the device comprises a spring that is stretched when a lock is release. FIGs. 4A-E illustrate a system in which the device is connected to an endotracheal tube and FIGs. 4F-J illustrate a system in which the device is connected to an tracheostomy tube. The spring facilitates automatic of the suction lines, wherein the operator pushes the lever only in one direction to the end. The spring can be unidirectional or bidirectional. In the illustrations of FIGs. 4A-J a unidirectional spring is employed.

FIGs. 4A and 4F illustrate system **50** in the initial state. The syringe is filled with, e.g., 4 ml of rinsing solution while the other syringe is filled with, e.g., 12 ml of the same solution, as further detailed hereinabove. Other amounts are not excluded from the scope of the present invention. FIGs. 4B-C and 4G-H illustrate priming of the suction line (FIGs. 4B and 4G), and rinsing line (FIGs. 4C and 4H), as further detailed hereinabove. FIGs. 4D and 41 illustrate the simultaneous rinsing (via the rinsing line) and suction (via the suction line). Concomitant delivery and suction irrigates the subglottic region and removes any secretions accumulated in this cavity (FIGs. 4E and 4J).

FIGs. 5A-H illustrate the stages of operation of the device in embodiments in which the device comprises a bidirectional spring that is stretched when a lock is release. FIGs. 5A-D illustrate a system in which the device is connected to an endotracheal tube and FIGs. 5E-H illustrate a system in which the device is connected to an tracheostomy tube.

FIGs. 5A-B and 5E-F illustrate system **50** in the initial state. The syringe is filled with, e.g., 4 ml of rinsing solution while the other syringe is filled with, e.g., 12 ml of the same solution, as further detailed hereinabove. Other amounts are not excluded from the scope of the present invention. FIGs. 5C and 5G illustrate a generally simultaneous

priming of the suction line and rinsing line by the bidirectional spring and FIGs. 5D and 5H illustrate the simultaneous rinsing (via the rinsing line) and suction (via the suction line).

The configurations described above utilize two syringe-type piston pumps to enable one step irrigation (fluid delivery and concomitant suction). The dual syringe configurations exemplified herein are preferred for their simplicity of design, low cost construction and flexibility and ease of use.

It will be appreciated however, that other configurations utilizing piston type pumps can also be utilized to achieve the same functionality. For example, a configuration which includes crank, cam or cog-wheel driven pistons of opposing or parallel direction (within barrels) can be used to provide concomitant delivery and suction as described above.

Representative examples of several configurations suitable for some embodiments of the present invention are illustrated in FIGs. 6A-G.

FIGs. 6A and 6B are schematic illustrations of device **10** in embodiment of the invention in which device **10** comprises a syringe **62** and a container **64,** which is optionally and preferably a bag. Syringe **62** can primarily serve for withdrawing fluid from the body cavity and container **64** can serve for delivering fluid into the body cavity. Thus, container **64** is preferably filled with fluid. Container **64** is preferably a deformable bag, ***e.g.,*** a disposable bag, which can be made of any material such as polyester, polyethylene terephthalate (PET), copolyethylene terephthalate (CoPET), polybutylene terephthalate (PBT) and the like.

The embodiments in FIGs. 6A and 6B will now be described with reference to FIGs. 6E and 6F.

FIG. 6E is a cut view of the embodiment shown in FIG. 6A. Bag **64** is external to syringe **62** but is encapsulated with it in housing **22,** within a compartment having a movable oblique element **65.** The plunger **63** of syringe **62** comprises or is connected to an extension **67** which engages element **65.** When plunger **63** is pulled, syringe **62** withdraws fluid out of the body cavity while at the same time extension **67** slides on oblique element **65** forcing it to apply pressure on bag **64,** thereby delivering the fluid out of bag **64,** simultaneously with the withdrawal of fluid by syringe **62.**

FIG. 6F is a cut view of the embodiment shown in FIG. 6B. Bag 64 is disposed within the barrel 71 of syringe 62, while the plunger 63 is in its pushed position. Bag 64 is disposed such that the tip 69 of plunger 63 is between bag 64 and the nozzle 73 of barrel 71. When plunger 63 is pulled, syringe 62 withdraws fluid out of the body cavity through nozzle 73 while squiring bag 64, thereby delivering the fluid out of bag 64, through a second nozzle 75 which may be disposed laterally to nozzle 73, or, is illustrated in FIG. 6F, circumferential with respect to nozzle 73.

FIG. 6C is a schematic illustration of device 10 in embodiment of the invention in which device 10 comprises two syringes 62 and 66, wherein syringe 66 is a conventional syringe and syringe 62 is a specially designed syringe. This embodiment is better illustrated in FIG. 6G which is a cut view of the embodiment shown in FIG. 6C.

Syringe 62 is filled with fluid (not shown in FIG. 6G). The plunger 63 of syringe 62 is mounted, or being formed, with an extension element 77 than engages the plunger 79 of syringe 66. When plunger 79 is pulled, syringe 66 withdraws fluid out of the body cavity while at the same time element 77 causes plunger 63 to move at the ejecting direction of syringe 62, thereby delivering the fluid out of syringe 62.

FIG. 6D is a schematic illustration of a peristaltic pump 68 which can be used for one or both pumps of device 10. Peristaltic pumps, which are known *per se*, pump the fluid in a wave-like pattern by sequential deformation and occlusion of several points along the length of a resilient deformable tube 70 which carries the fluid. Operation of such a pump typically involves a mechanical interaction between a portion of resilient tube 70 and a peristaltic mechanism 72 that creates a wave-like deformation along the resilient tube. In various exemplary embodiments of the invention peristaltic pump 68 is manually operated.

Also contemplated, are embodiments in which the device comprises a syringe and a vacuum tube.

FIGs. 7A-E are schematic illustrations of device 10 in embodiments of the invention in which device 10 comprises an actuator member 74, and two piston pumps (shown as syringes 32 and 26) which are arranged within housing 22.

Actuator member 74 is preferably a mechanical member, and can be in the form of, for example, a safety hatch or the like. In various exemplary embodiments of the

invention member **74** is being operated manually without the use of any other drive means such as an electrical or magnetic motor or an acoustical transducer.

Pump **26** and pump **32** are optionally and preferably initially filled with respective initial volumes **76** and **78** of fluid, ***e.g.,*** irrigation liquid. Typically, volume **76** is 5 cc, and volume **78** is 10 cc, but other amounts are not excluded from the scope of the present invention.

Member **74** has a first mode (FIG. 7A) in which both pumps are inoperative. In this mode member **74** serves as a safety hatch, and device **10** can be shifted from one location to the other without the risk of accidental operation. In the representative example of FIG. 7A, which is not considered to be limiting, in the first mode, member **74** assumes an orientation which is perpendicular to symmetry axis of the piston pumps. Member **74** also has a second mode in which actuator member activates pump **32** to eject an initial volume **76** of fluid out of the device. In this mode, volume **78** of pump **26** is still filled with fluid. Switching from the first mode to the second mode can be, for example, by rotating member **74** by 90° to assume an orientation which is generally parallel to the symmetry axis of the piston pumps (FIG. 7B). The rotation generates a force applied by the tip of member **74** on the piston of pump **32,** which ejects the fluid in volume **76.**

In various exemplary embodiments of the invention member **74** also has a third mode, in which member **74** activates pump **26** to eject an initial portion of the fluid in volume **78** out of the device. Typically, about 2cc are ejected in the third mode of member **74.** Other amounts are not excluded from the scope of the present invention Switching from the second mode to the third mode can be, for example, by pulling member **74** outwardly (see arrow **80).** A linkage member **82** which is connected to actuator member **74** extends from member **74** to the piston of pump **26.** An engaging element **84** at the part of member **82** which is close to pump **26** engages the piston and pushes it in the ejection direction of pump **26,** thereby ejecting part of the fluid in volume **78** (FIG. 7C).

In various exemplary embodiments of the invention member **74** also has a fourth mode, in which member **74** simultaneously activates pump **26** to deliver fluid into the body cavity and pump **32** to withdraw fluid from the body cavity. Typically, all the remaining fluid in volume **78** (about 8cc in the present example) are ejected in the third

mode of member **74.** Switching from the third mode to the fourth mode can be, for example, by pulling member **74** further outwardly (FIG. 7D). Engaging element **84** continues to push the piston of pump **26** in its ejecting direction (direction **80** in the present example) while a lever mechanism **86** pulls the piston of pump **32** in its withdrawing direction (in the present example, also direction **80).** Thus, in simultaneous manner, fluids enter pump **26** and exit pump **26.**

In various exemplary embodiments of the invention member **74** also has a fifth mode, in which member **74** activates only pump **32** to withdraw fluid from the body cavity. Switching from the fourth mode to the fifth mode can be, for example, by pulling member **74** further outwardly (FIG. 7E), to effect a motion of the piston of pump **32** (via lever mechanism **86)** withdrawing direction **80** thereby facilitating withdrawal of fluids into the device. Since pump **26** does not contain any fluid once member **74** enters its fourth mode, the further pulling of member **74** after the fourth mode does not affect pump **26.**

A device **10** which includes actuator member **74,** can be implemented in system **50** described above. FIGs. 8A and 8B are schematic illustration of system **50** in embodiments of the present invention in which device **10** including member **74** is connected to tube **60.** FIG. 8A show system **50** in embodiments in which tube **60** is adapted for being introduced into the trachea (either orally or in a tracheostomy procedure), and FIG. 8B shows system **50** in embodiments in which tube **60** is adapted for being inserted into the ear canal. The skilled person, provided by the details provided herein, will know how to adjust the drawings for embodiments in which tube **60** is introduced into other cavities, ***e.g.,*** the intestines.

Reference is now made to FIGs. 9A and 9B which are schematic illustrations of device **10** in embodiments of the invention in which device **10** comprises an analog (FIG. 9A) or digital (FIG. 9B) pressure measuring device **90.** Device **90** can be mounted, for example, onto housing **22** of device **10.** Device **90** comprises an inlet **92** which can be connected, for example, to the cuff inflation line of tube **60** (not shown, see **94** in FIGs. 2A-J, 4A-J, 5A-H and 8A), for determining the inflation pressure of the cuff. This embodiment is particularly useful when the intubated subject is connected to a ventilation or anesthetic machine which does not provide indication of cuff inflation pressure. Measuring device can be of any type known in the art, including, without

limitation, a device incorporating a pressure sensor, ***e.g.,*** a piezoelectric or a piezoresistive element, a manometer, ***e.g.,*** a capacitance manometer, a mercury manometer, a flow meter, and the like.

The device of the present embodiments may, if desired, be presented in a pack, such as an FDA-approved kit. The pack may, for example, comprise metal or plastic foil, such as a blister pack. The pack may be a disposable pack. The pack may be accompanied by instructions for administration. The pack may also be accompanied by a notice in a form prescribed by a governmental agency regulating the manufacture, use, or sale of pharmaceuticals, which notice is reflective of approval by the agency of the form of the compositions for human or veterinary administration. Such notice, for example, may include labeling approved by the U.S. Food and Drug Administration for prescription drugs or of an approved product insert.

A representative example of a pack according to some embodiments of the present invention is illustrated in FIG. 10. Showing a pack **100** with two devices **10.** For example, the device shown in FIG. 7A-F can be installed within an automatic syringe pump that replaces the manual activation by configured external electric piston that pulls the safety hatch and draws the evacuation plunger in a programmed mode. The automatic device can include one or more devices connected to same lumens.

The device of the present embodiments optionally and preferably includes therein one or more types of substances that are capable of providing indication of presence of a disease. Preferably, the substance or substances are incorporated in the pump that serves for withdrawing fluid from the body cavity. The substance can change its property, for example, optical property ***(e.g.,*** color) when contacted with diseased secretions. The substance can comprise for example, a functional group that react with the disease of interest and provides indication of its existence. The substance can also be a biological marker, such as, but not limited to, cells, proteins, enzymes, nucleic acids, carbohydrate markers, cell surface markers, circulating antibodies, secretory antibodies, cell-associated antibodies, intracellular markers, morphological markers, functional parameters (e.g. enzymatic activity), pH, cytokines and chemokines, viral markers, bacteria, fungi, protozoa, nematodes and parasites.

According to some embodiments of the present invention there is provided a method suitable for irrigating a body cavity with fluid. Generally, the method comprises

manually delivering a first volume of fluid to the body cavity, and manually delivering a second volume of the fluid and simultaneously withdrawing at least second volume of the fluid from the body cavity. The method can be effected, for example, by a device that includes manually-operated pump mechanism as further detailed hereinabove, ***e.g.,*** device **10.**

In various exemplary embodiments of the invention the method delivers fluid is at volumetric flow rate Q_1, and simultaneously withdraws fluid at volumetric flow rate Q_2, wherein there is a linear relation between Q_1 and Q_2, as further detailed hereinabove.

The method is optionally and preferably executed using a device which is connected to the body cavity via a tube having a first line in fluid communication with the first pump of the device and a separate second line in fluid communication with the second pump of the device. The following protocol is preferably, but not necessarily employed. The second pump is operated to deliver fluid into the second line, so as to at least fill second line. The first pump is operated to deliver fluid into the first line, so as to at least fill first line. Once the lines are filled, the first pump is operated to withdraw fluid from the first line and the second pump is simultaneously operated to deliver fluid into the second line. Subsequently, the first pump is operated to withdraw fluid from the first line while the second pump remains inoperative.

As used herein the term "about" refers to ± 10 %.

The word "exemplary" is used herein to mean "serving as an example, instance or illustration." Any embodiment described as "exemplary" is not necessarily to be construed as preferred or advantageous over other embodiments and/or to exclude the incorporation of features from other embodiments.

The word "optionally" is used herein to mean "is provided in some embodiments and not provided in other embodiments." Any particular embodiment of the invention may include a plurality of "optional" features unless such features conflict.

The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean "including but not limited to".

The term "consisting of means "including and limited to".

The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional

ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular form "a", "an" and "the" include plural references unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

Throughout this application, various embodiments of this invention may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to ***4,*** from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral) within the indicated range. The phrases "ranging/ranges between" a first indicate number and a second indicate number and "ranging/ranges from" a first indicate number "to" a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals therebetween.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Various embodiments and aspects of the present invention as delineated hereinabove and as claimed in the claims section below find experimental support in the following examples.

EXAMPLES

Reference is now made to the following examples, which together with the above descriptions illustrate some embodiments of the invention in a non limiting fashion.

A prototype MASS device and an FDA/CE approved endotracheal tube were manufactured and tested according to some embodiments of the present invention. The prototype MASS device and the endotracheal tube are illustrated in FIGs. 11A-B.

The prototype MASS device included two opposingly mounted syringes with their plungers linked such that they can operate simultaneously, as described in greater detail above.

The endotracheal tube included a main lumen, two suction lumens embedded in the wall of the main lumen at the dorsal side of the tube with distal openings above the cuff, and an irrigation lumen embedded in the wall of the main lumen at the ventral side of the tube and having an opening above the cuff. The embedded suction lumens were unified to one external lumen. A cross section of the tube is illustrated in FIG. 11B.

Material and Methods

Experiment 1

Evacuation of Secretions using of the Prototype MASS device

A goat was anesthetized (Ketamine and Isofluran) and intubated with the endotracheal tube. Sealing was validated by above cuff $C0_2$ reading, as disclosed, for example, in Efrati, MD et al., "Optimization of Endotracheal Tube Cuff Filling by Continuous Upper Airway Carbon Dioxide Monitoring," Anesth. Analg; vol. 101, pp. 1081-1088 (2005). $C0_2$ was monitored through the vent lumen of the tube. A partial $C0_2$ pressure of less than 1 mmHg, was considered as indicative of adequate sealing.

Contrast medium (OMNIPAQUE- IOHEXOL 350 mgI/ml) was used for simulation of above cuff fluid. 5cc of contrast medium were injected via the suction lumen under fluoroscopy recording.

The prototype MASS device was used for synchronized irrigation and suction. lOcc of Saline were used for irrigation. The entire irrigation/suction procedure was monitored and recorded by fluoroscopy. The amount of the evacuated fluids were measured and recorded.

The above procedure was repeated with following cuff pressures of 45, 40, 35, 30, 25, 20, 15, 10 and 5 mmHg. At 5mmHg a leakage above the cuff was detected by above cuff $C0_2$ readings.

Experiment 2

Evacuation of Secretions using conventional technique (rinsing followed by suction)

In this experiment the same endotracheal tube (FIG. 11) was used. The cuff pressure was set to 20 mmHg and the ealing was validated by above cuff $C0_2$ as described above. Contrast medium (OMNIPAQUE- IOHEXOL 350 mgl/ml) was used for simulation of above cuff fluid/ secretions: 5cc of contrast medium were injected via the suction lumen. lOcc of saline were injected via the suction lumen. Secretions were evacuated using a 20cc syringe. The amount of the evacuated fluids were measured and recorded.

The experiment was repeated for the following cuff pressures: 15, 10, and 5 mmHg. At 5mmHg a leakage above the cuff was detected by above cuff $C0_2$ readings.

Experiment 3

Evacuation of Secretions using a conventional Hi-Lo® Evac tube

The goat was intubation with a Hi-Lo Evac endotracheal tube (I.D 8.0 Polyurethane cuff; Evac, Mallinckrodt, USA). The cuff pressure was set to 20 mmHg and sealing was validated by above cuff $C0_2$ reading as further detailed hereinabove. The $C0_2$ readings were done through the suction lumen. Contrast medium (OMNIPAQUE- IOHEXOL 350 mgl/ml) was used for simulation of above cuff fluid/secretions. 5cc of contrast medium were injected via the suction lumen under fluoroscopy recording. lOcc of saline were injected via the suction lumen. Secretions were evacuated with a 20 cc Syringe. The entire irrigation/suction procedure was monitored and recorded by fluoroscopy. The amount of the evacuated fluids were

measured and recorded. The experiment was repeated with the following cuff pressure 20, 15, 10 and 5 mmHg.

Results

The results of Experiment 1 are summarized in Table 1.

Table 1

Experiment 1				
Test	Cuff pressure (mmHg)	Fluid leakage into lung detection (Y/N)	Fluid Evacuated (cc)	CO2 (mmHg)
1	45	N	15	0.8
2	40	N	15	0.9
3	35	N	15	0.6
4	30	N	15	0.54
5	25	N	16	0.7
6	20	N	15	0.6
7	15	N	15	0.55
8	10	N	17	0.5
9	5	Y	11	7.43 (max)
10	5	Y	13	7.43 (max)

FIG. 12 is a fluoroscopy image of the goat's trachea with the endotracheal tube of the present embodiments before the evacuation of the secretions. The secretions (dark regions) and cuff (central region) are bordered on the image.

FIG. 13 is a fluoroscopy image of the goat's trachea with the endotracheal tube after the evacuation of the secretions using the prototype MASS device of the present embodiments. As shown, the secretions have been removed by their entirety.

Table 1 and FIGs. 12 and 13 demonstrate that after the MASS procedure (Experiment 1) no leakage around the cuff was detected by fluoroscopy and the whole amount of fluids that were rinsed and the amount of contrast medium were aspirated. The prototype MASS device of the present embodiments with its related synchronized rinsing/suction procedure assured a comprehensive evacuation of secretions from above the cuff.

The results of Experiment 2 are summarized in Table 2.

Table 2

Experiment 2				
Test	Cuff pressure (mmHg)	Fluid leakage into lung detection (Y/N)	Fluid Evacuated (cc)	CO2 (mmHg)
11	20	N	15	0.78
12	15	N	15	0.6
13	10	N	15	0.6
14	5	Y	2	7.43

Table 2 demonstrates that employing rinsing followed by suction in the endotracheal tube resulted in complete evacuation of secretions above the cuff.

The results of Experiment 3 are summarized in Table 3.

Table 3

Experiment 3				
Test	Cuff pressure (mmHg)	Fluid leakage into lung detection (Y/N)	Fluid Evacuated (cc)	CO2 (mmHg)
15	20	N	11	0.5
16	20	N	11	0.5
17	15	N	12	0.7
18	10	N	13	0.6
19	5	N	11	0.7

FIG. 14 is a fluoroscopy image of the goat's trachea with the Hi-Lo® Evac tube before the evacuation of the secretions. The secretions (dark regions) and cuff (central region) are bordered on the image.

FIG. 15 is a fluoroscopy image of the goat's trachea with the Hi-Lo® Evac tube after the evacuation of the secretions by rinsing followed by suction. The secretions (dark regions) and cuff (central region) are bordered on the image.

Table 3 and FIGs. 14 and 15 demonstrate that employing rinsing followed by suction in the Hi-Lo® Evac tube resulted in only partial evacuation of secretions leaving diluted secretions above the cuff at the end of the procedure.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations

will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

WHAT IS CLAIMED IS:

1. A device for irrigating a body cavity with fluid comprising a manually-operated pump mechanism configured for delivering a first volume of fluid to the body cavity and delivering a second volume of fluid to the body cavity while concomitantly withdrawing at least said second volume of fluid from the body cavity.

2. The device of claim 1, wherein said pump mechanism is configured to deliver fluid to the body cavity at a first volumetric flow rate and simultaneously withdraw fluid from the body cavity at a second volumetric flow rate, and wherein there is a linear relation between said first and said second volumetric flow rates.

3. The device according to any of claims 1 and 2, wherein said mechanism comprises a first pump and a second pump each being configured for communicating fluid to and from the body cavity, said first pump and said second pump being operatively linked such that operating said second pump to deliver said second volume of fluid into the body cavity activates said first pump to withdraw said at least said second volume of fluid from the body cavity.

4. The device according to any of claims 1 and 2, wherein said mechanism comprises a first pump and a second pump each being configured for communicating fluid to and from the body cavity, said first pump and said second pump being operatively linked such that operating said first pump to withdraw said at least said second volume of fluid from the body cavity activates said second pump to deliver said second volume of fluid into the body cavity.

5. The device according to any of claims 3 and 4, wherein said first and said second pumps are, respectively, a first and a second piston pumps and wherein said first piston of said first pump is operatively linked to a second piston of said second pump.

6. The device of claim 5, wherein said first piston and said second piston are linked in a manner which enables independent movement of said first piston and said

second piston through a preset movement range, and linked movement of said first piston and said second piston beyond said preset movement range.

7. The device according to claim 6, wherein movement of said first piston within said preset movement range delivers said first volume of fluid to the body cavity and further wherein movement of said second piston beyond said preset movement range delivers said second volume of fluid and operates said first piston to withdraw said at least said second volume of fluid.

8. The device according to any of claims 5-7, wherein said piston pumps are syringes having manually operateable plungers.

9. The device according to any of claims 5-8, wherein said piston pumps are aligned parallel to each other such that a withdrawing direction of said first piston pump is opposite to an ejecting direction of said second piston pump.

10. The device according to any of claims 5-8, wherein said piston pumps are aligned parallel to each other such that a withdrawing direction of said first piston pump is parallel to an ejecting direction of said second piston pump.

11. The device according to any of claims 3-8, further comprising an actuator member having a first mode in which both said pumps are inoperative, and a second mode in which said actuator member activates said first pump to eject an initial volume of fluid out of the device.

12. The device according to claim 11, wherein said actuator member additionally has a third mode in which said actuator member activates said second pump to eject a further initial volume of fluid out of the device.

13. The device according to claim 12, wherein said actuator member additionally has a fourth mode in which said actuator member simultaneously activates

said second pump to deliver fluid into the body cavity and said first fluid pump to withdraw fluid from the body cavity.

14. The device according to claim 13, wherein said actuator member additionally has a fifth mode in which said actuator member activates only said first fluid pump to withdraw fluid from the body cavity.

15. The device according to any of claims 11-14, wherein said actuator member is a mechanical member.

16. The device according to any of claims 3 and 4, wherein at least one of said first and said second pumps is a peristaltic pump.

17. The device according to any of claims 3 and 4, wherein said first pump is a container having an under pressure therein.

18. The device according to any of claims 3 and 4, wherein said second pump is a deformable bag.

19. The device according to any of claims 1-18, further comprising a pressure measuring device.

20. The device according to any of claims 1-19, wherein said pump mechanism comprises a biomarker therein.

21. An intubation system comprising the device according to any of claims 1-19, and a tube assembly adapted for being introduced into the body cavity.

22. A method of irrigating a body cavity with fluid comprising:

(a) manually delivering a first volume of fluid to the body cavity; and

(b) manually delivering a second volume of the fluid and simultaneously withdrawing at least said second volume of the fluid from the body cavity.

23. The method according to claim 22, being effected by a device which comprises a first pump and a second pump, said device being connected to the body cavity via a tube having a first line in fluid communication with said first pump and a separate second line in fluid communication with said second pump, wherein the method comprises:

operating said second pump to deliver fluid into said second line, so as to at least fill said second line;

operating said first pump to deliver fluid into said first line, so as to at least fill said first line; and

simultaneously operating said first pump to withdraw fluid from said first line and said second pump to deliver fluid into said second line.

24. The method according to any of claims 22-23, further comprising subsequently to said (b), withdrawing fluid from the body cavity without delivering fluid into the body cavity.

25. The method according to any of claims 22-23, wherein the body cavity is the trachea.

26. The method according to claim 25, being executed during tracheotomy.

27. The method according to claim 25, being executed during oral endotracheal intubation.

28. The method according to any of claims 22-23, wherein the body cavity is the ear canal.

29. The method according to any of claims 22-23, wherein the body cavity is the intestines.

30. A device for irrigating a body cavity with fluid comprising two manually-operated syringes having linked plungers, wherein pushing in a first plunger of a first

syringe beyond a predetermined travel distance withdraws a second plunger of a second syringe.

31. The device of claim 30, wherein said two manually-operated syringes are of different volumes and/or plunger stroke length.

32. A kit, comprising, the device according to any of claims 1-20, 30 and 31, and an intubation device, wherein said intubation device comprises:

a flexible tubular body being adapted for being introduced into the trachea of a subject and defining a main lumen; and

an inflatable cuff associated with said tubular body and arranged to be located at a location in the patient trachea;

said wall being embedded with at least:

(i) two suction lumens with respective openings above said cuff, said openings being arranged laterally with respect to each other within said wall,

(ii) a cuff inflation lumen with opening at said cuff, and

(ii) an irrigation lumen with opening above said cuff.

33. The kit of claim 32, wherein said wall has a dorsal section and a ventral section at opposite sides of a longitudinal axis of said tubular body, and wherein said openings of said suction lumens are both located at said dorsal section.

34. The kit according to any of claims 32 and 33, wherein said wall has a dorsal section and a ventral section at opposite sides of a longitudinal axis of said tubular body, and wherein said opening of said irrigation lumen is located at said ventral section.

35. The kit according to any of claims 32-34, wherein said suction lumens are unified to a single conduit external to said tubular body.

36. The kit according to any of claims 32-34, being adapted for oral endotracheal intubation.

37. The kit according to any of claims 32-34, being adapted for tracheostomy intubation.

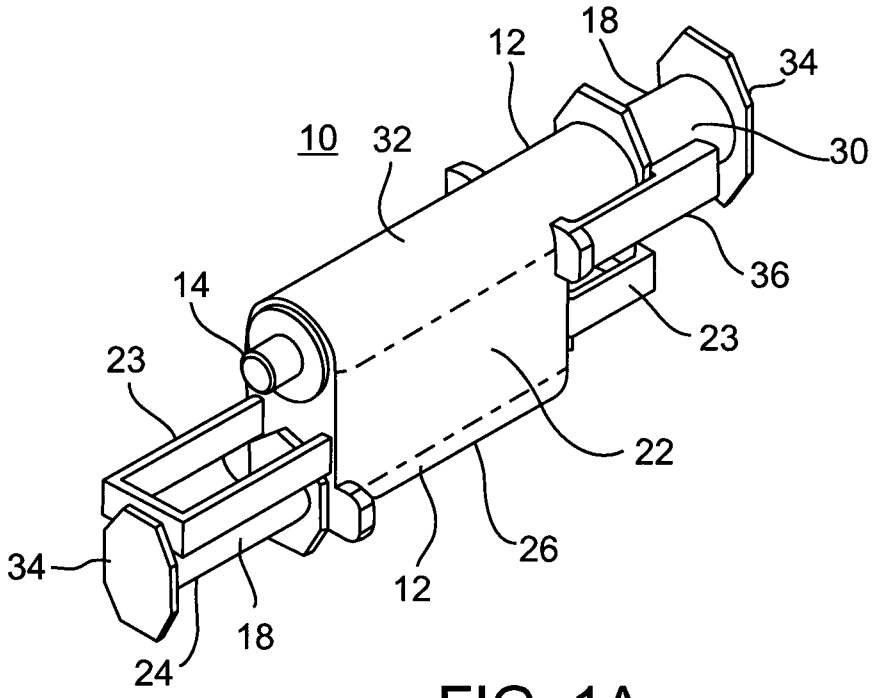
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FIG. 1A

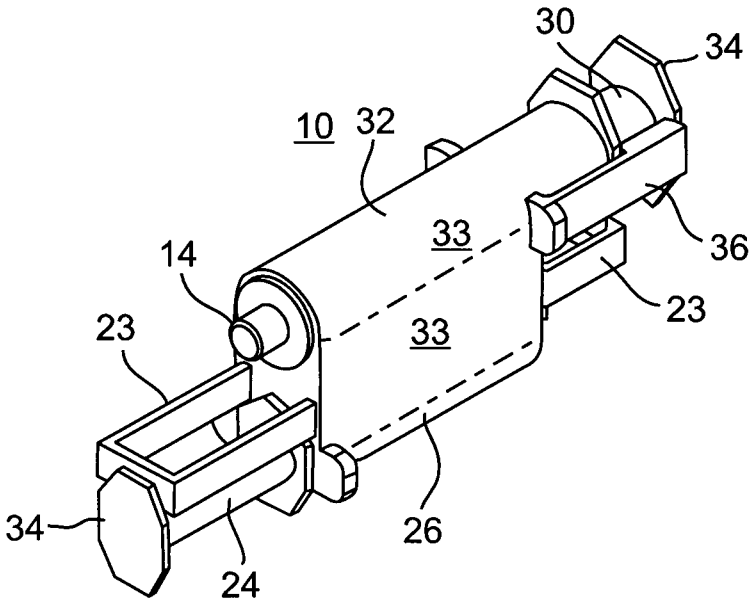
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FIG. 1B

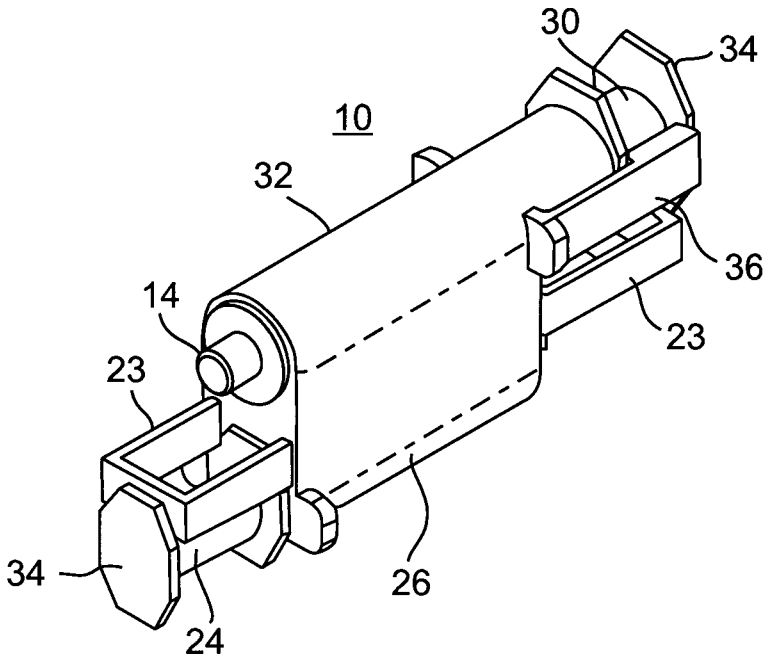

FIG. 1C

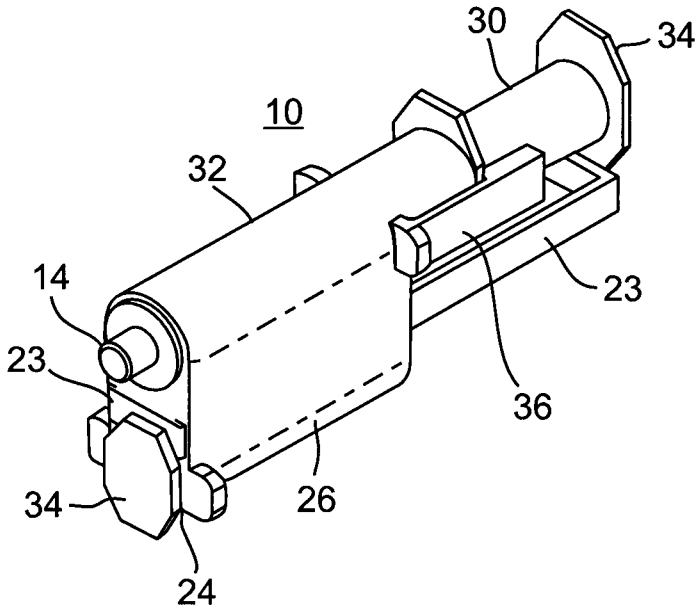

FIG. 1D

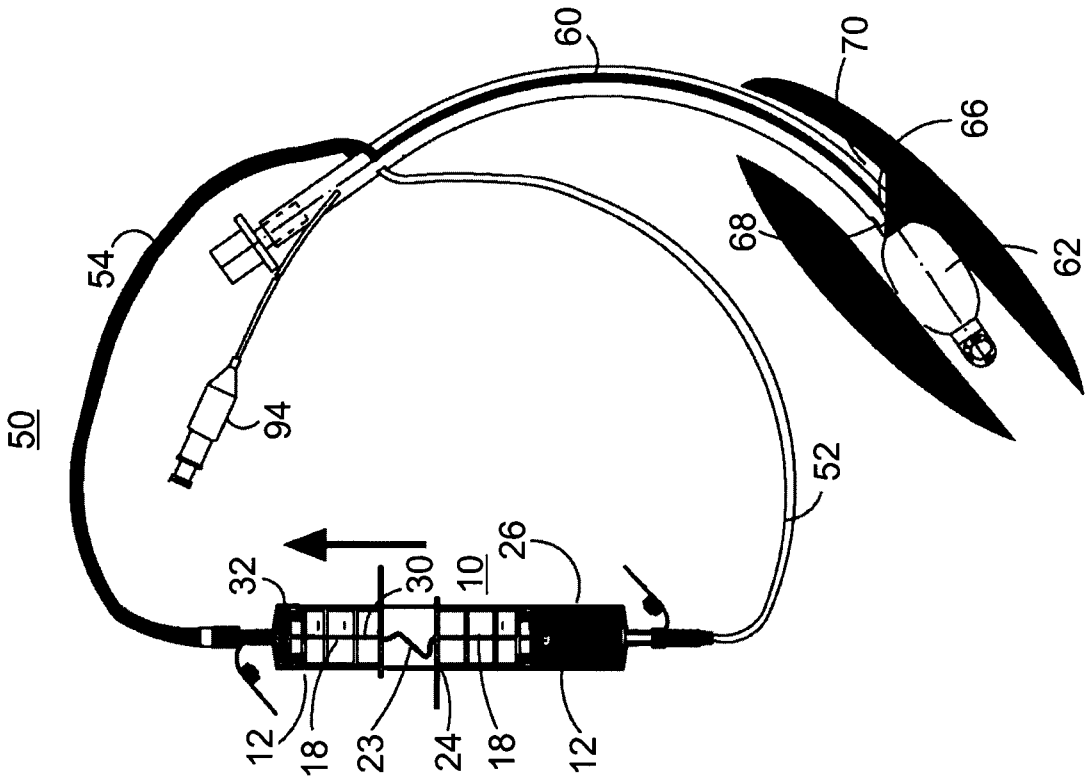
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FIG. 2B

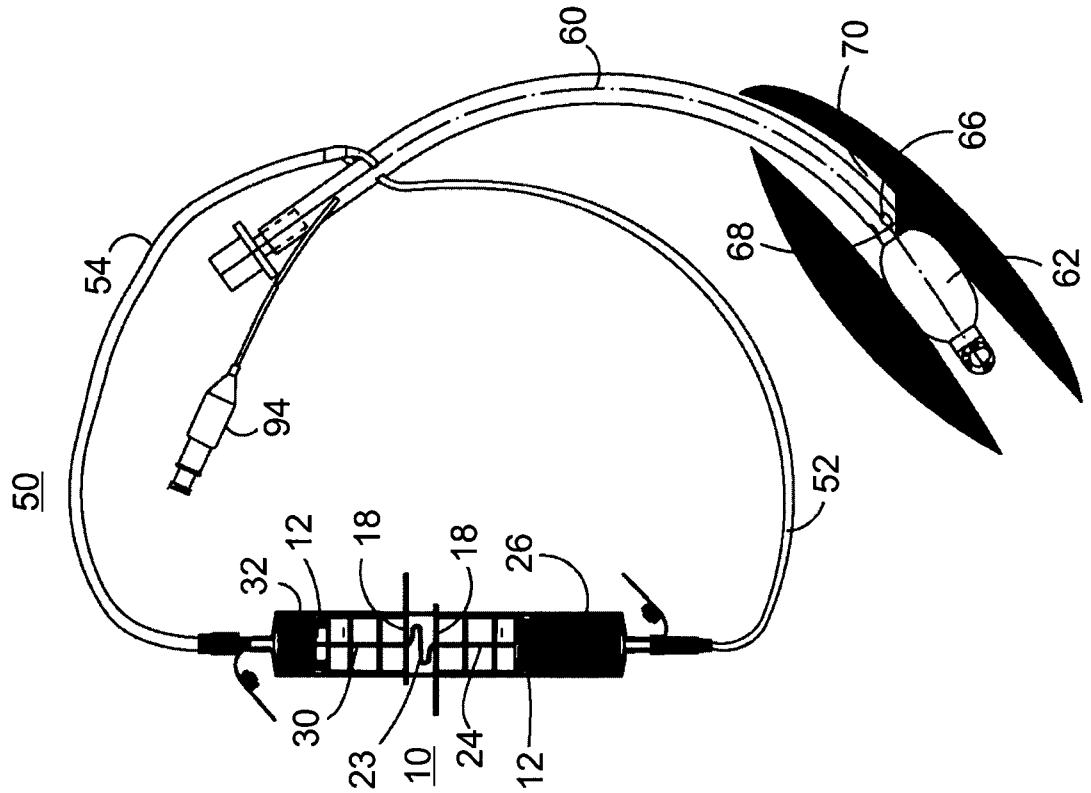
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FIG. 2A

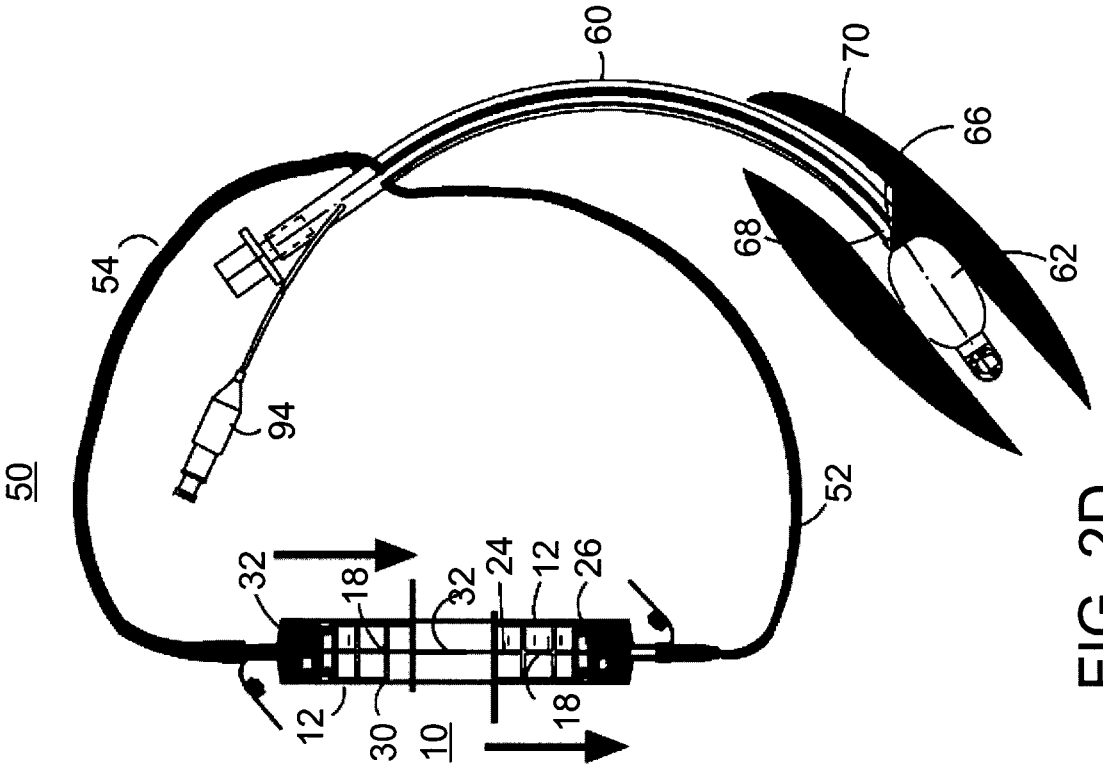
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FIG. 2D

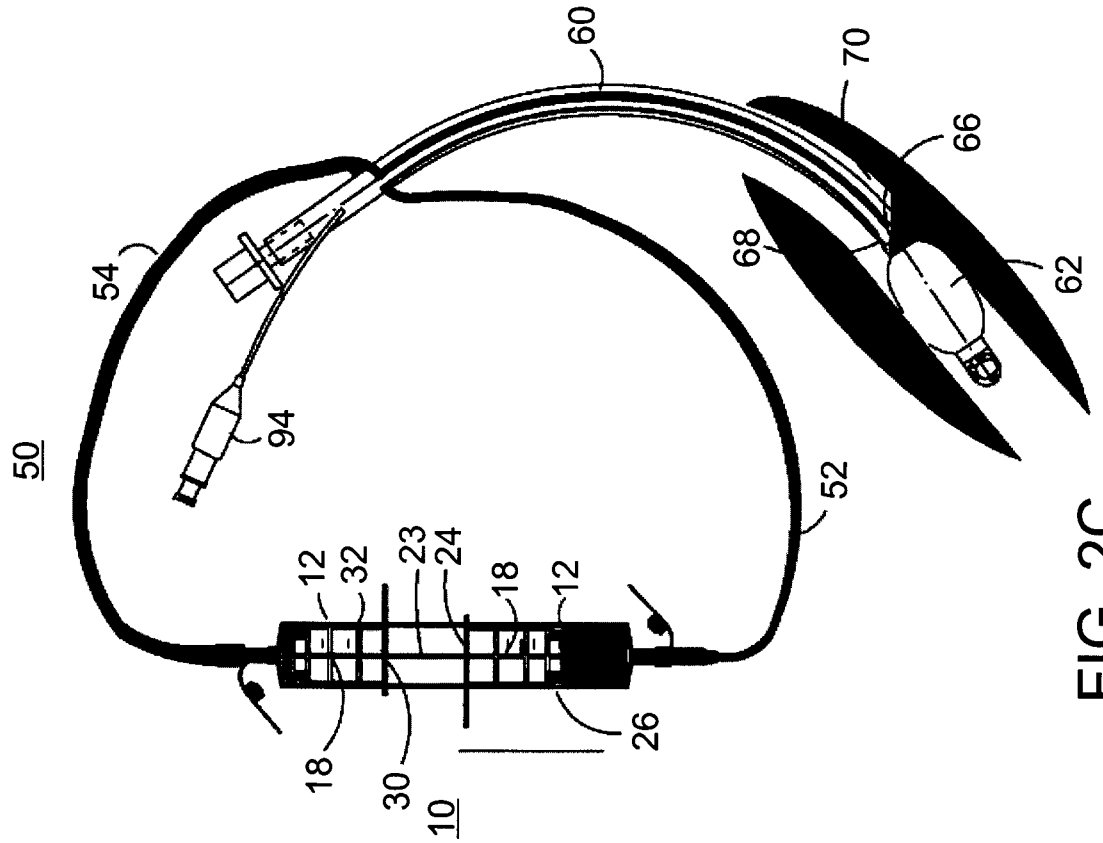
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FIG. 2C

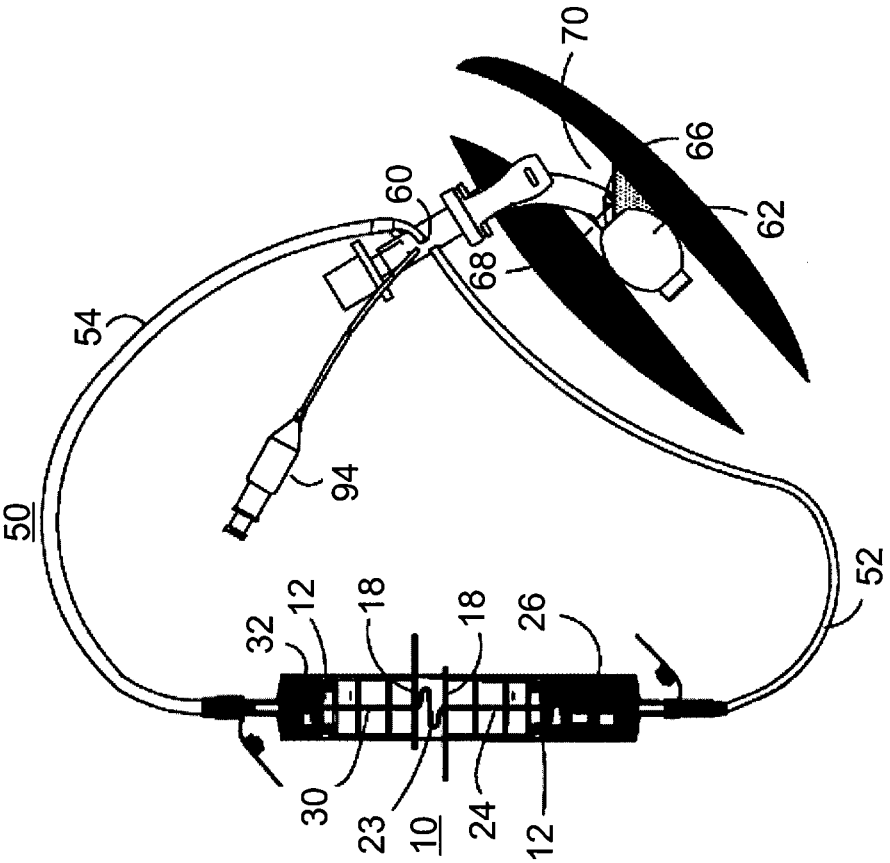
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FIG. 2F

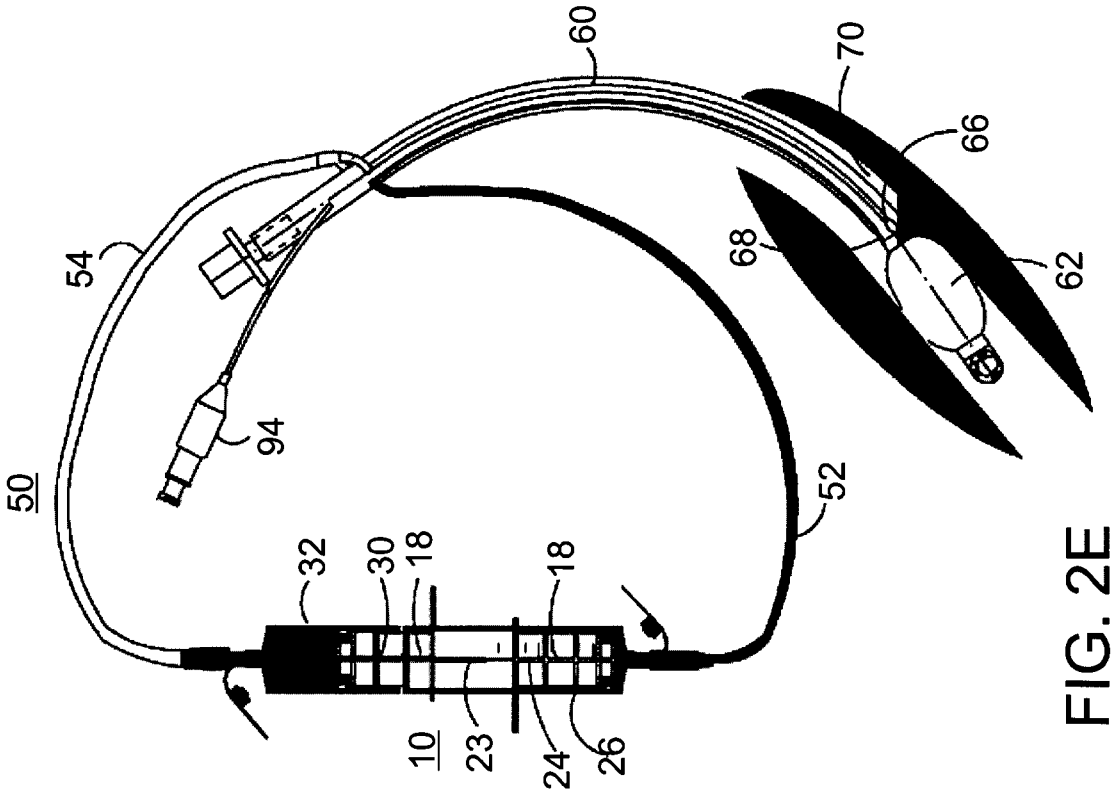
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FIG. 2E

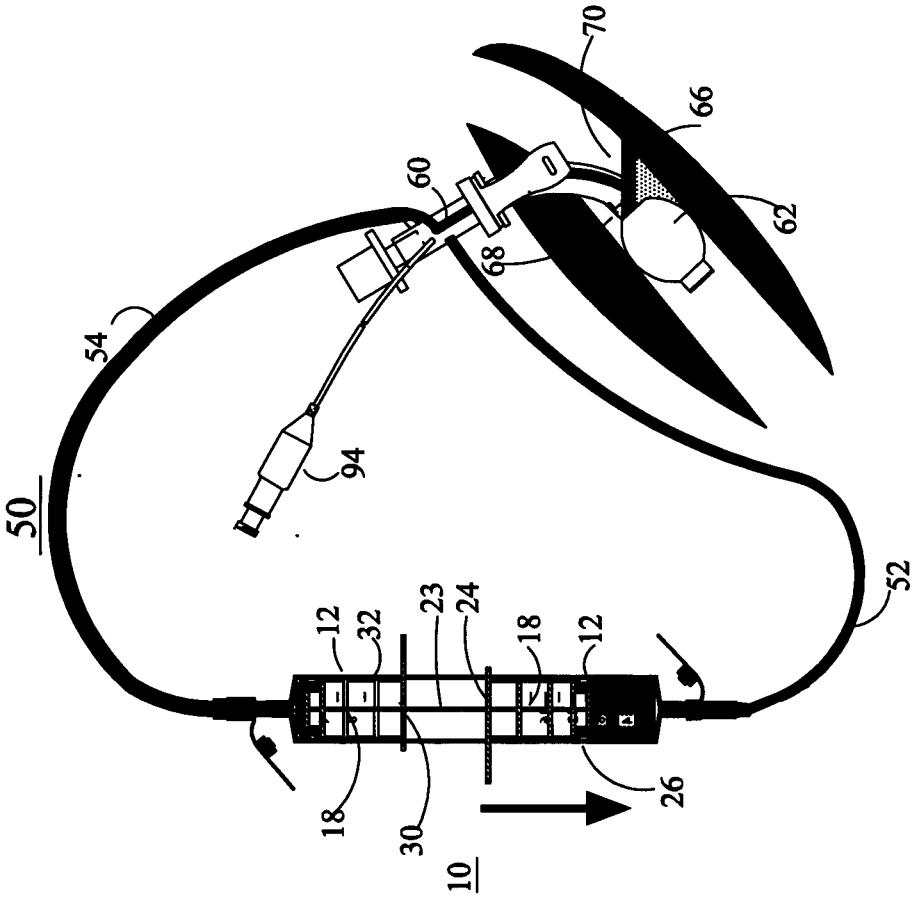
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Fig. 2H

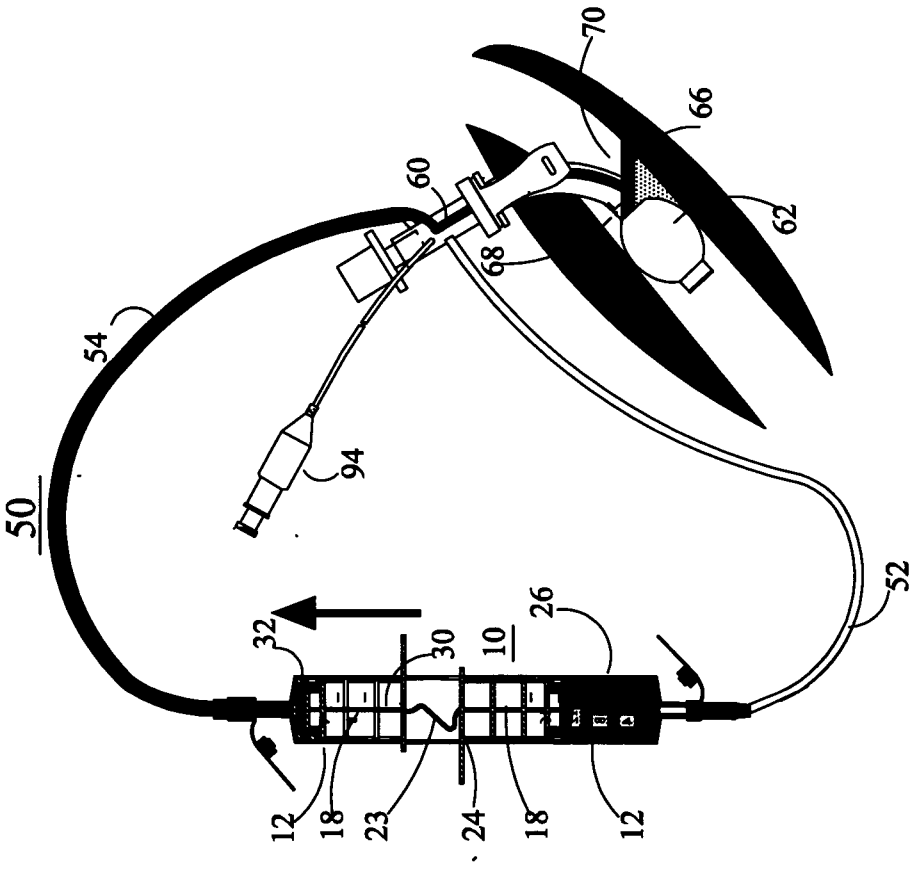
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Fig. 2G

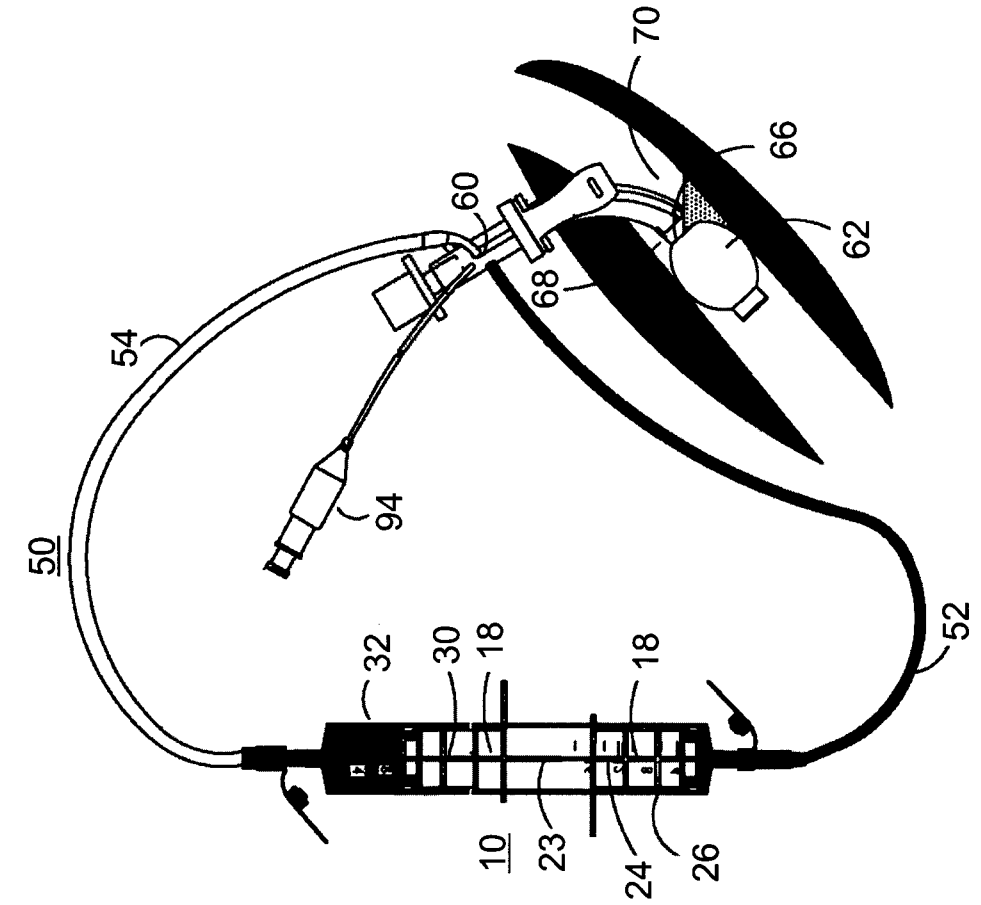
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FIG. 2J

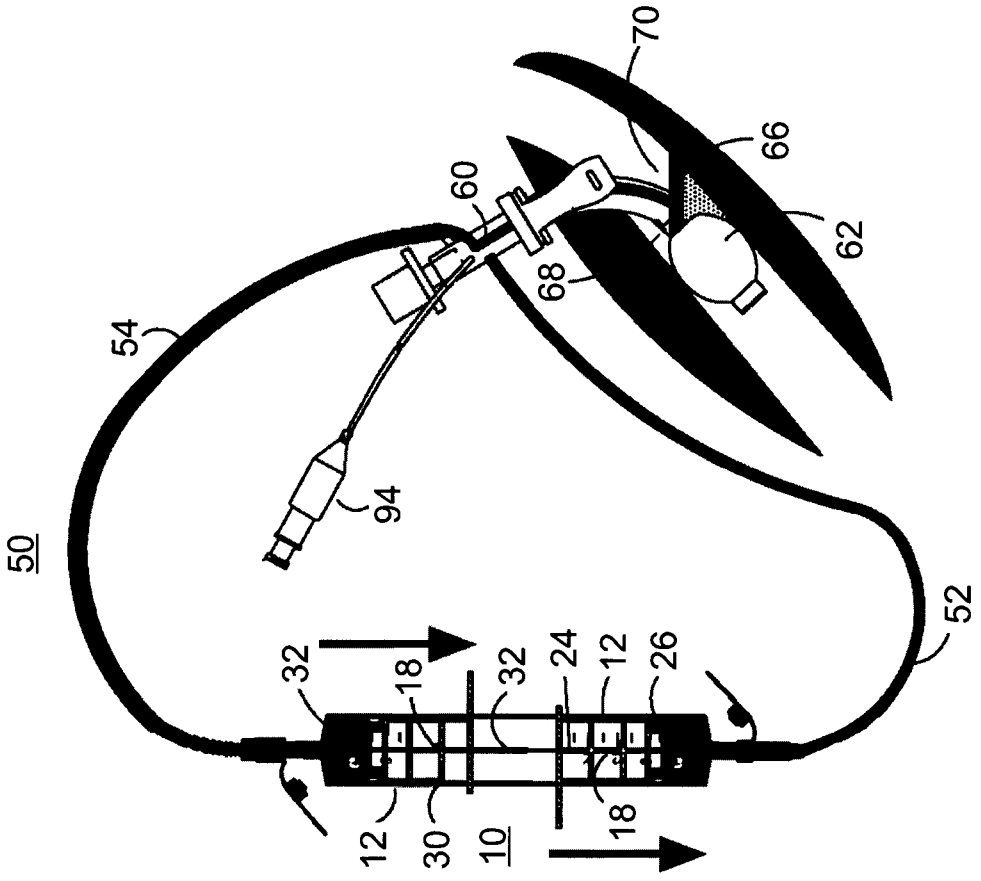
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FIG. 2I

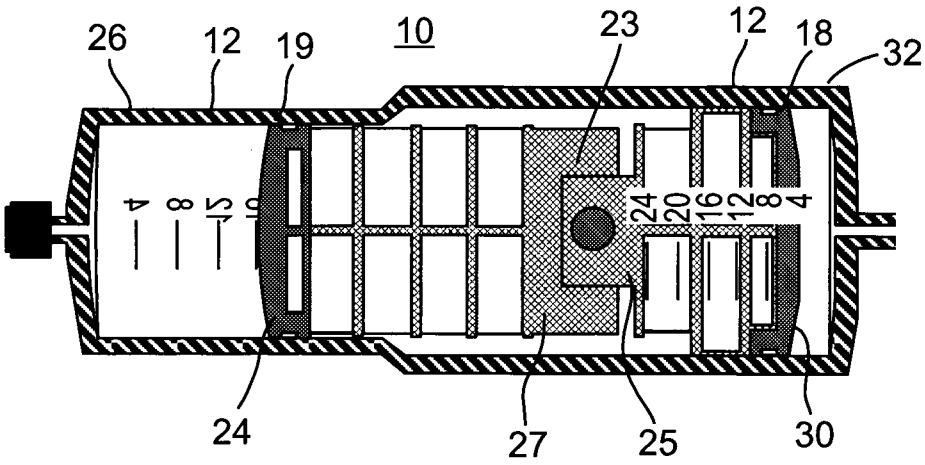

FIG. 3A

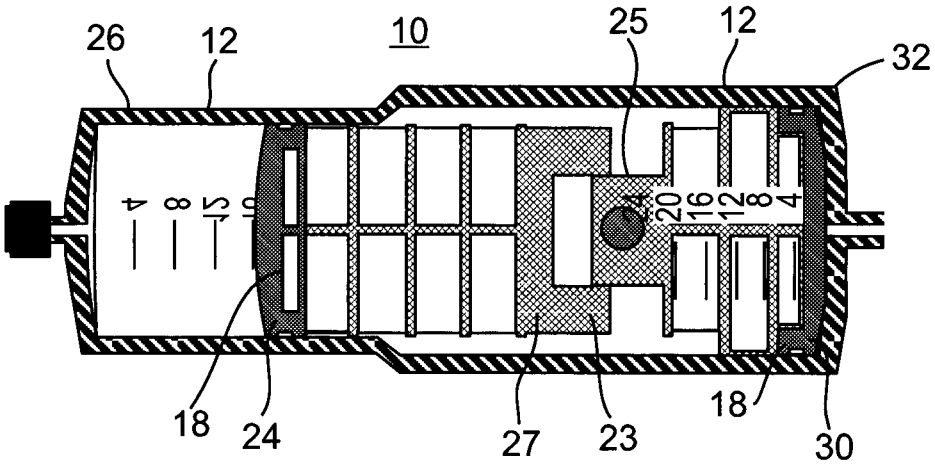

FIG. 3B

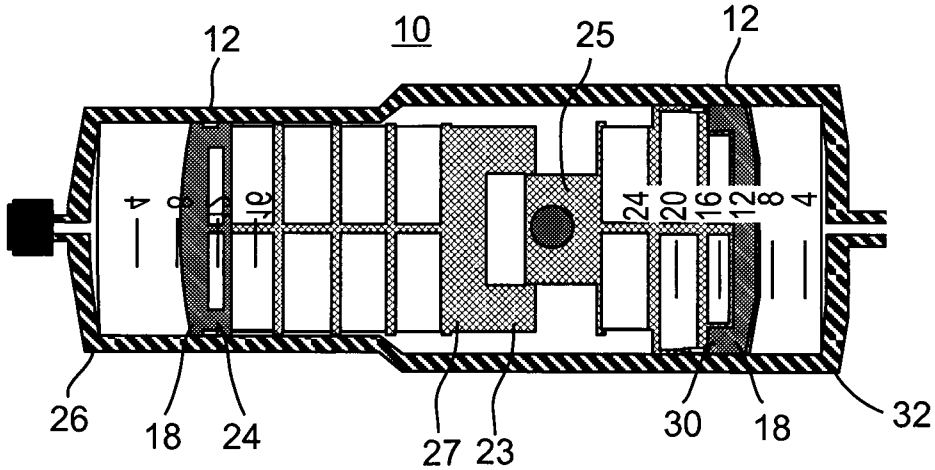

FIG. 3C

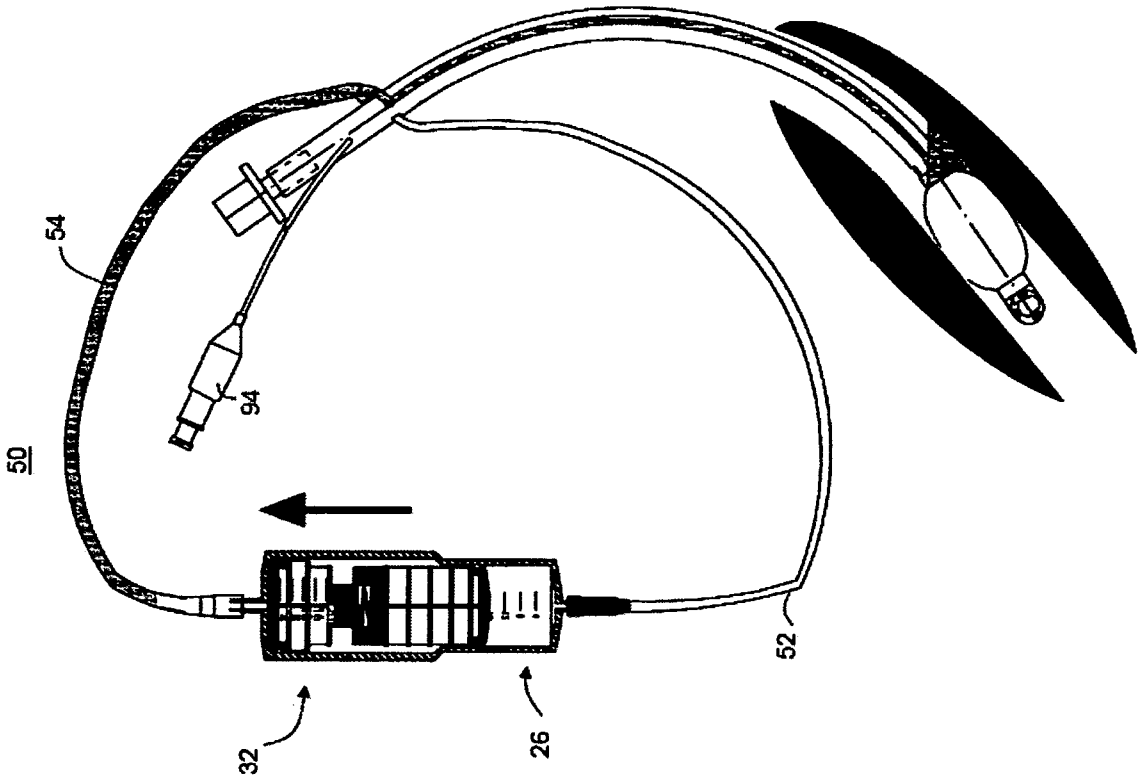

FIG. 4B

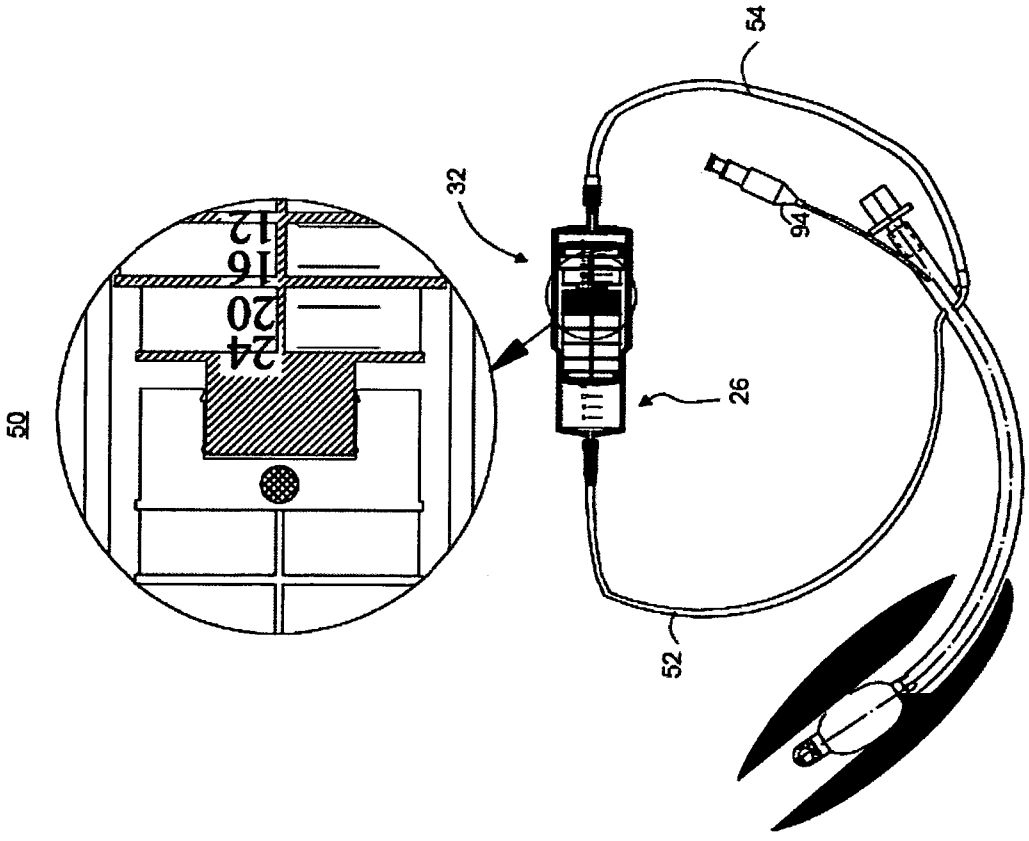

FIG. 4A

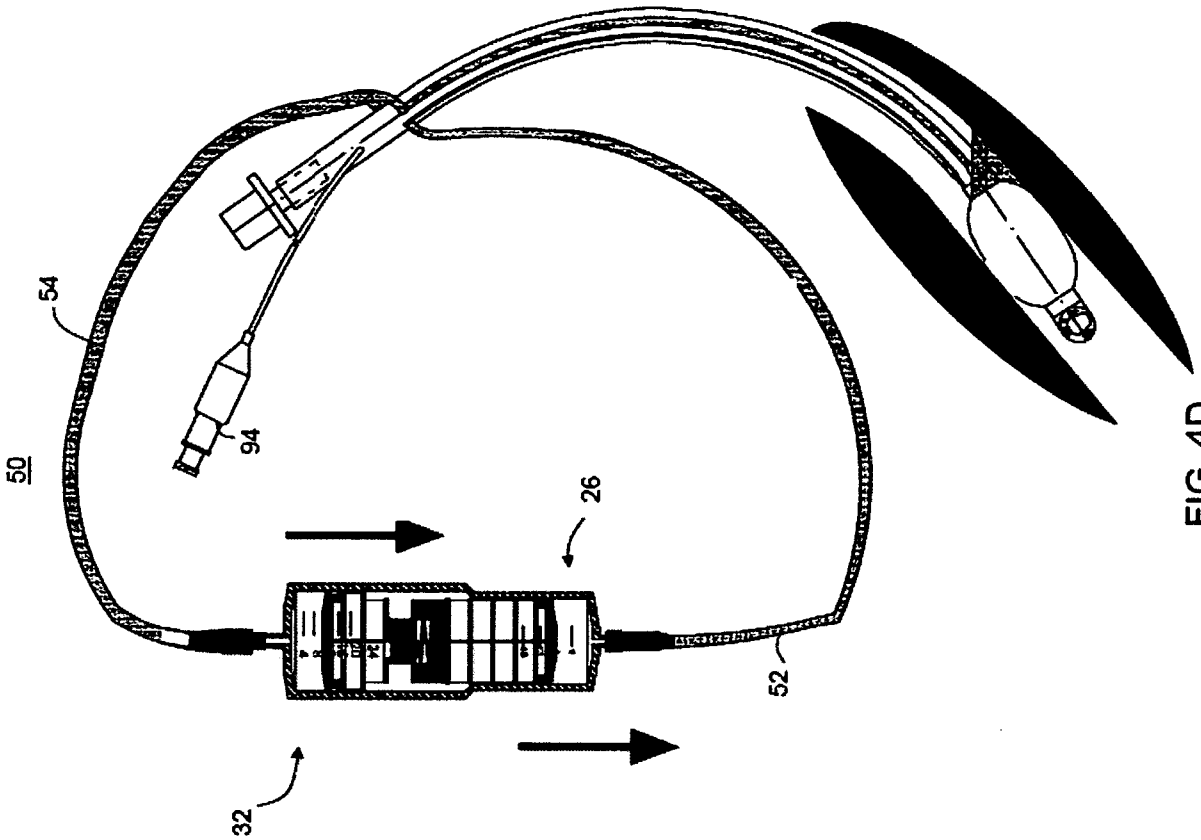

FIG. 4D

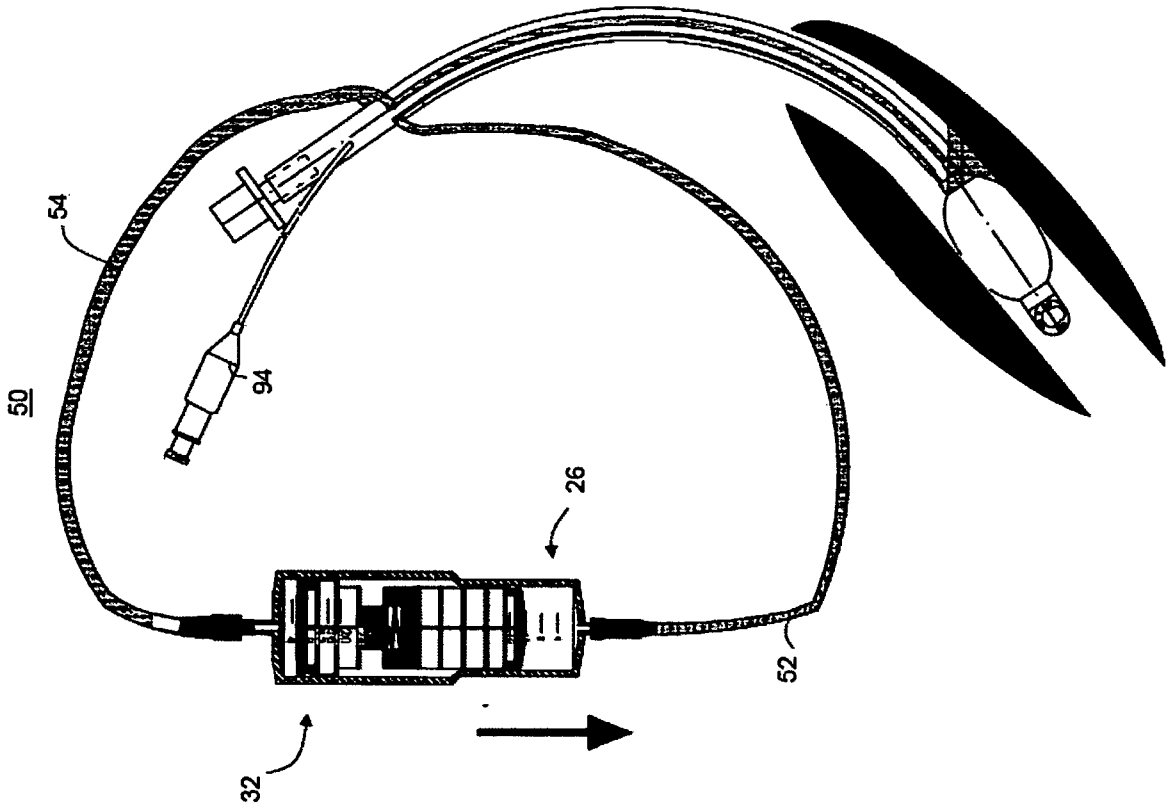

FIG. 4C

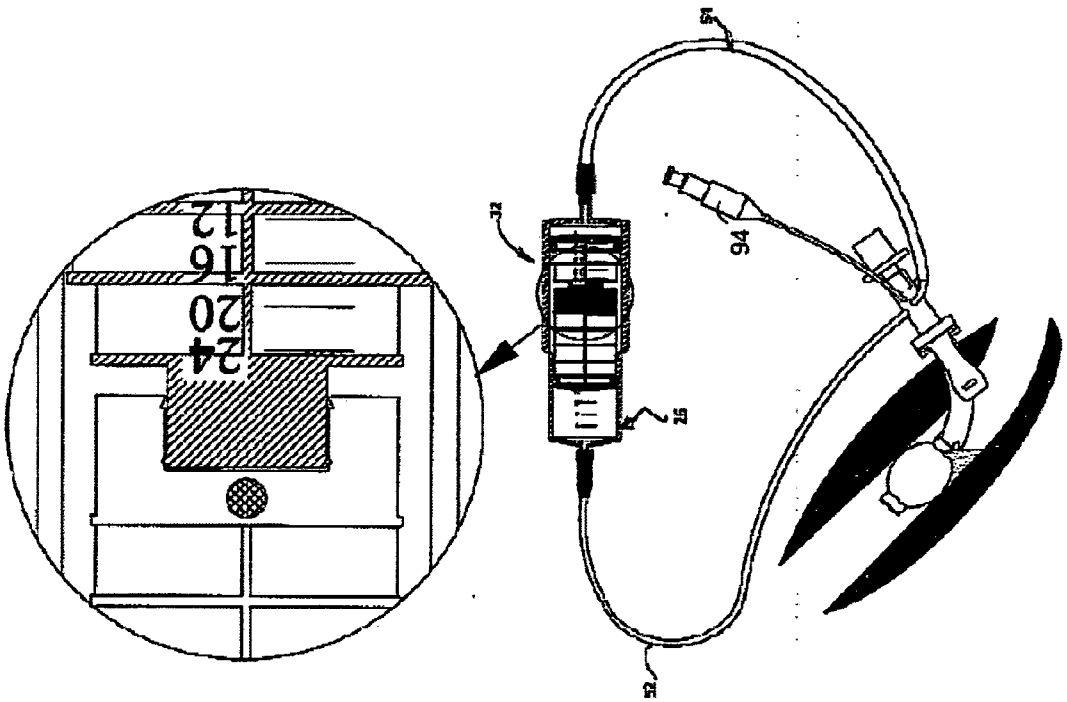

FIG. 4F

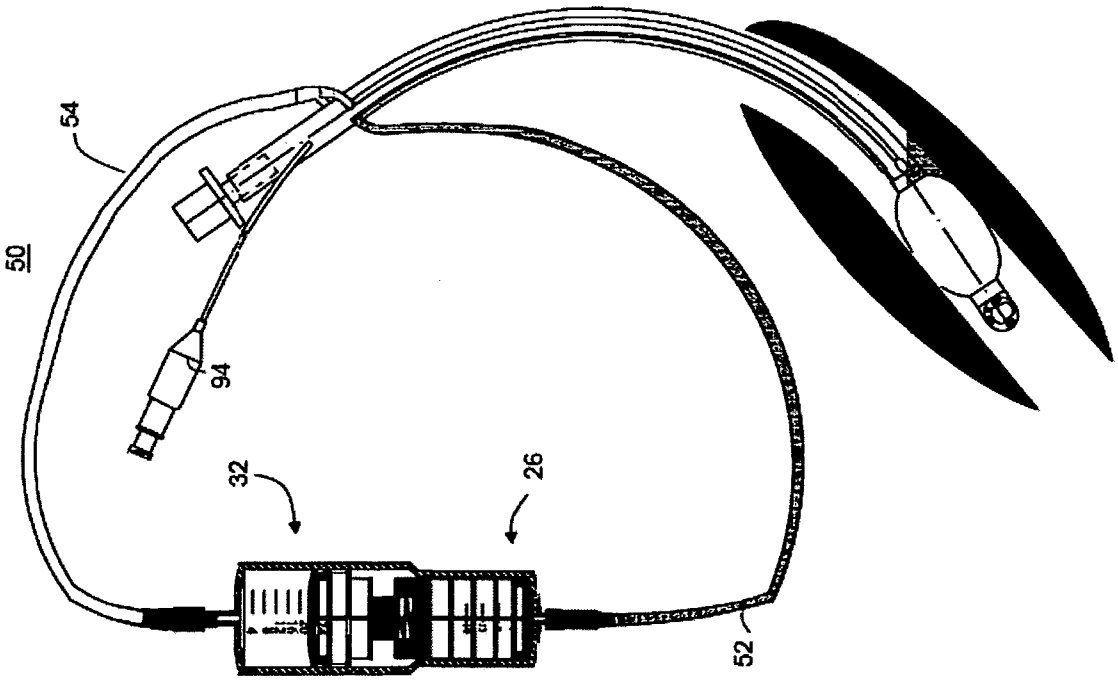

FIG. 4E

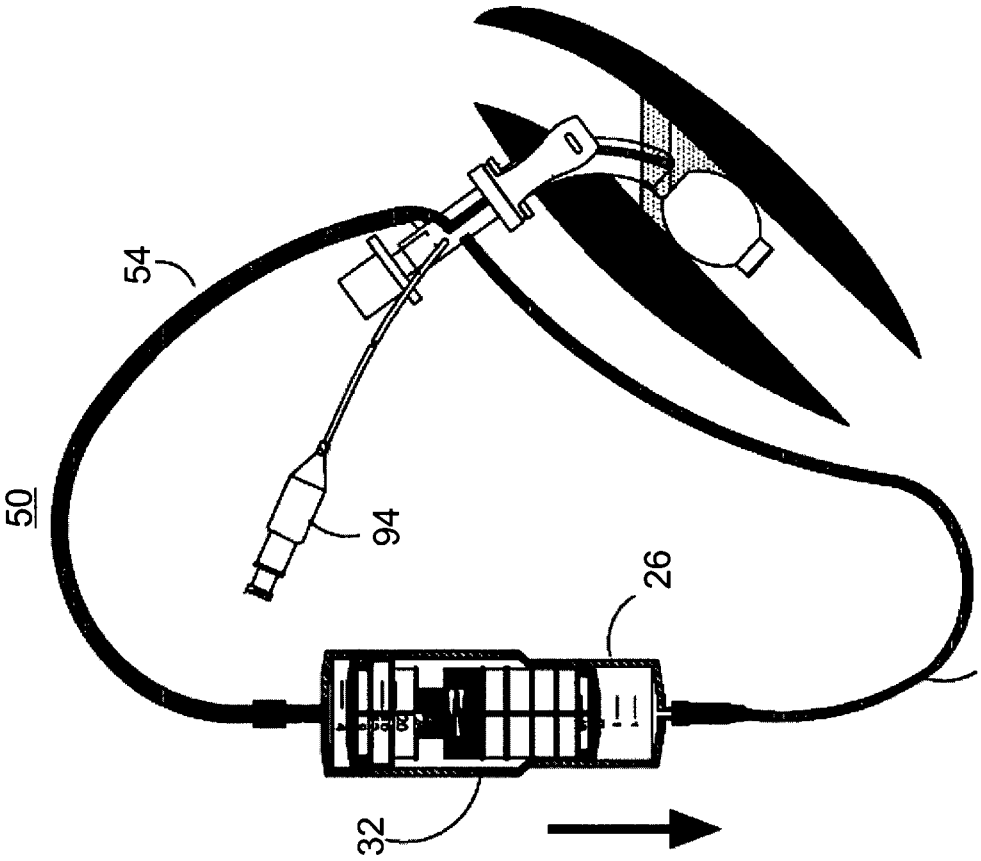

FIG. 4H

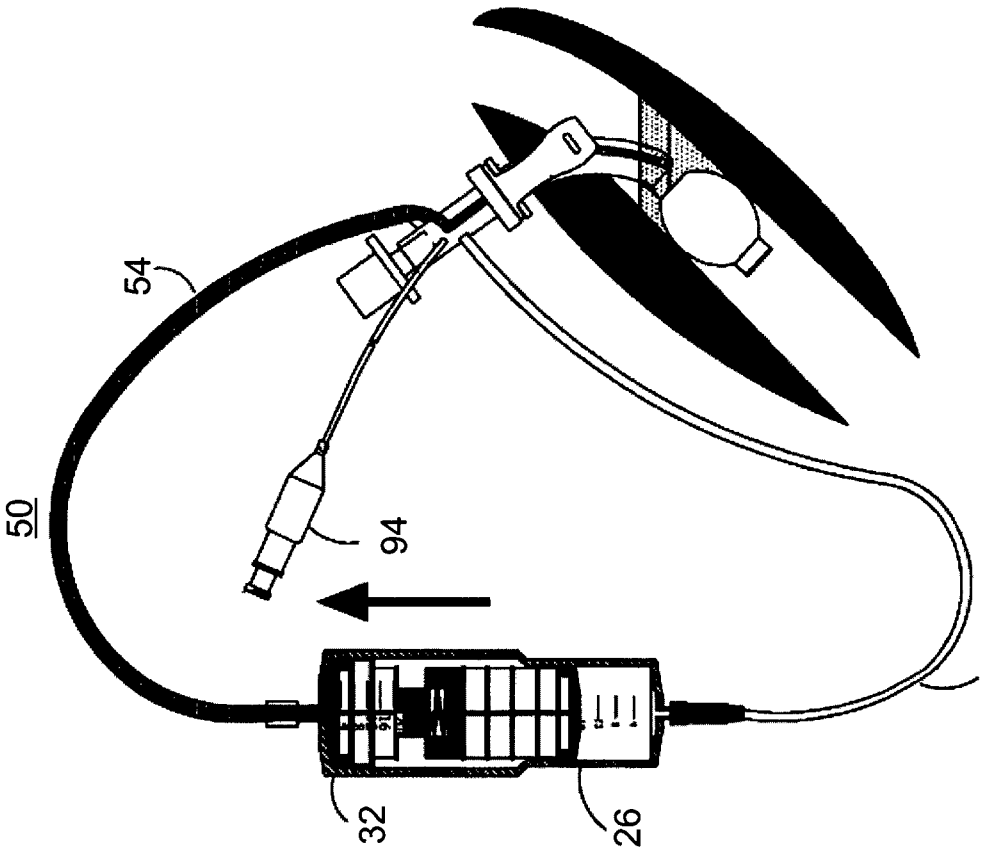

FIG. 4G

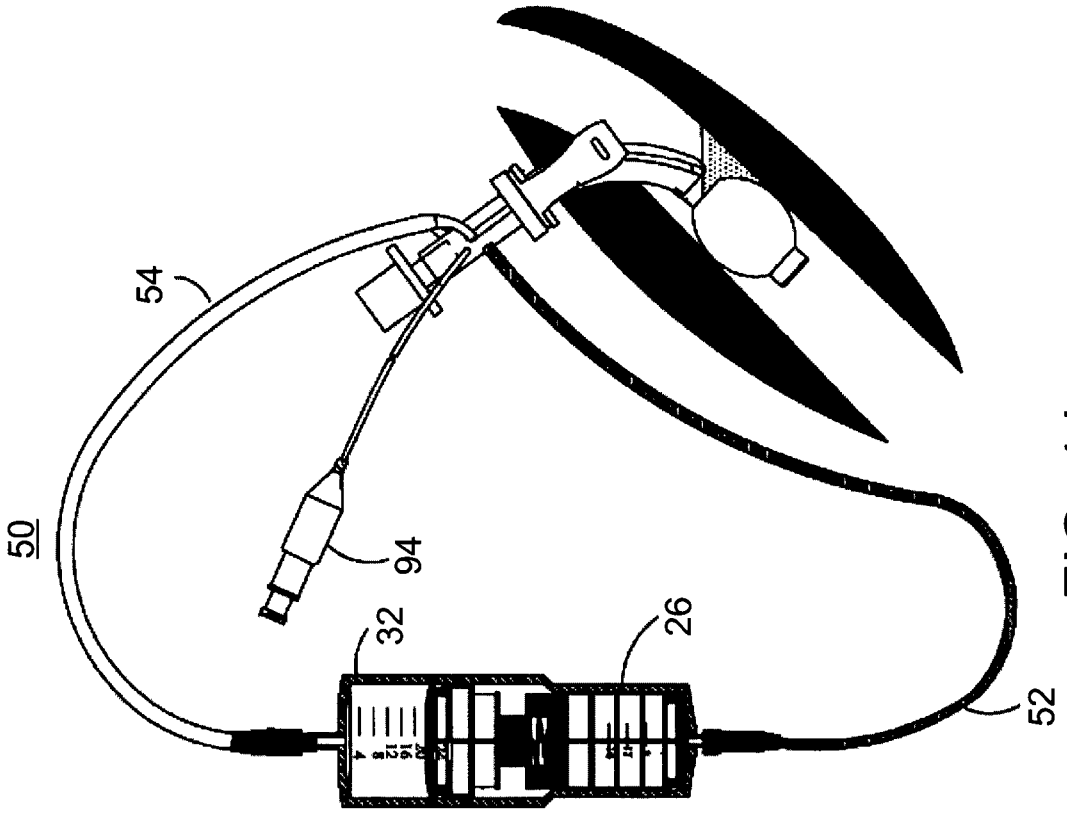

FIG. 4J

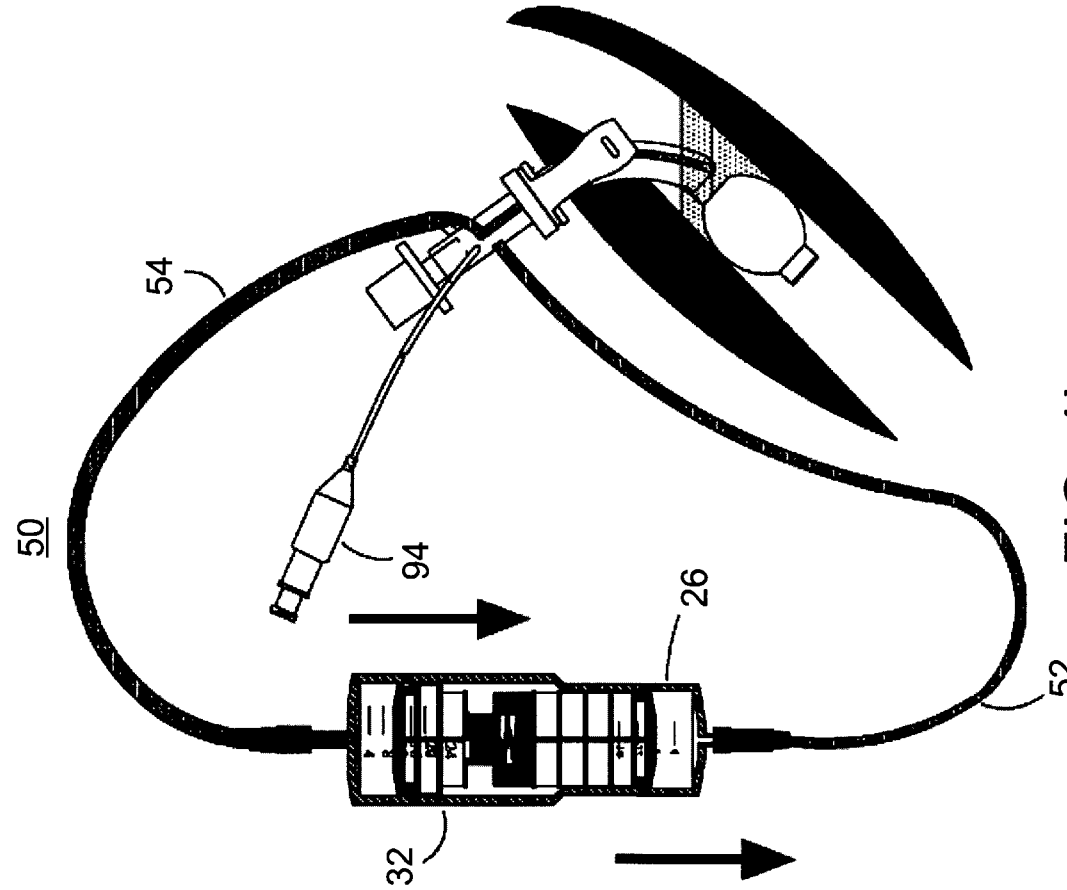

FIG. 4I

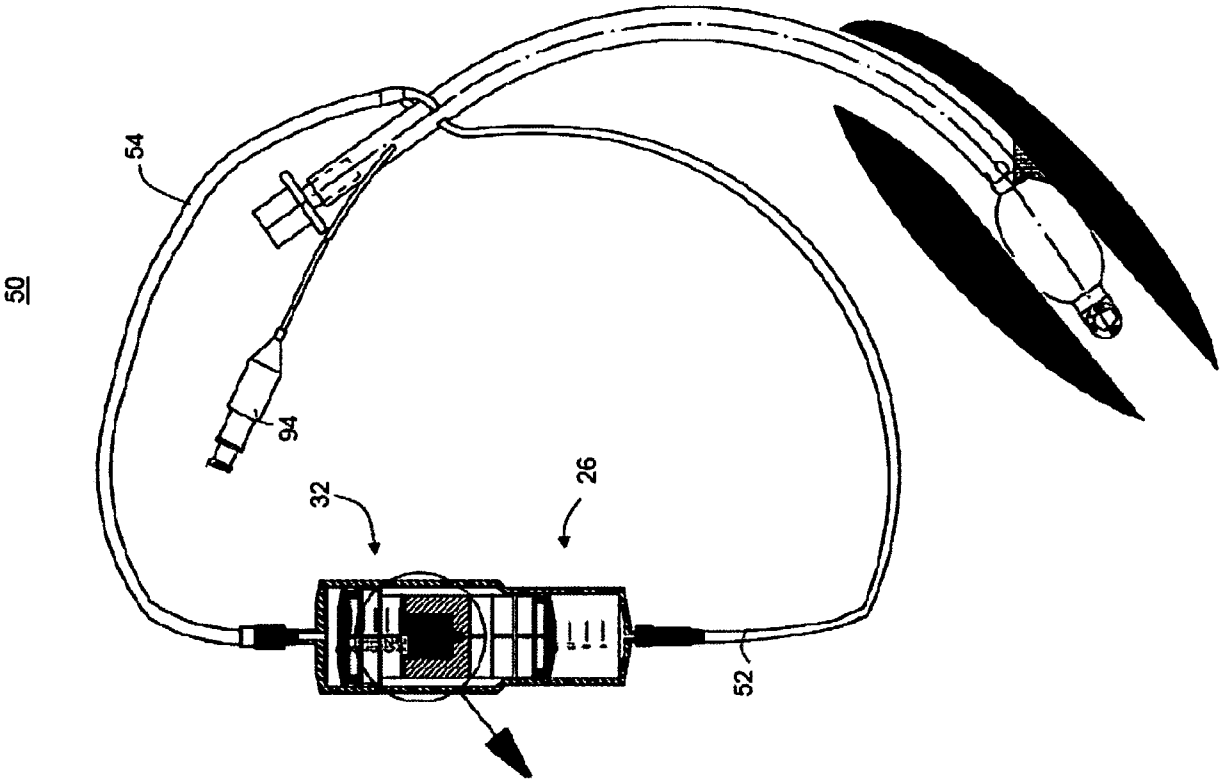

FIG. 5B

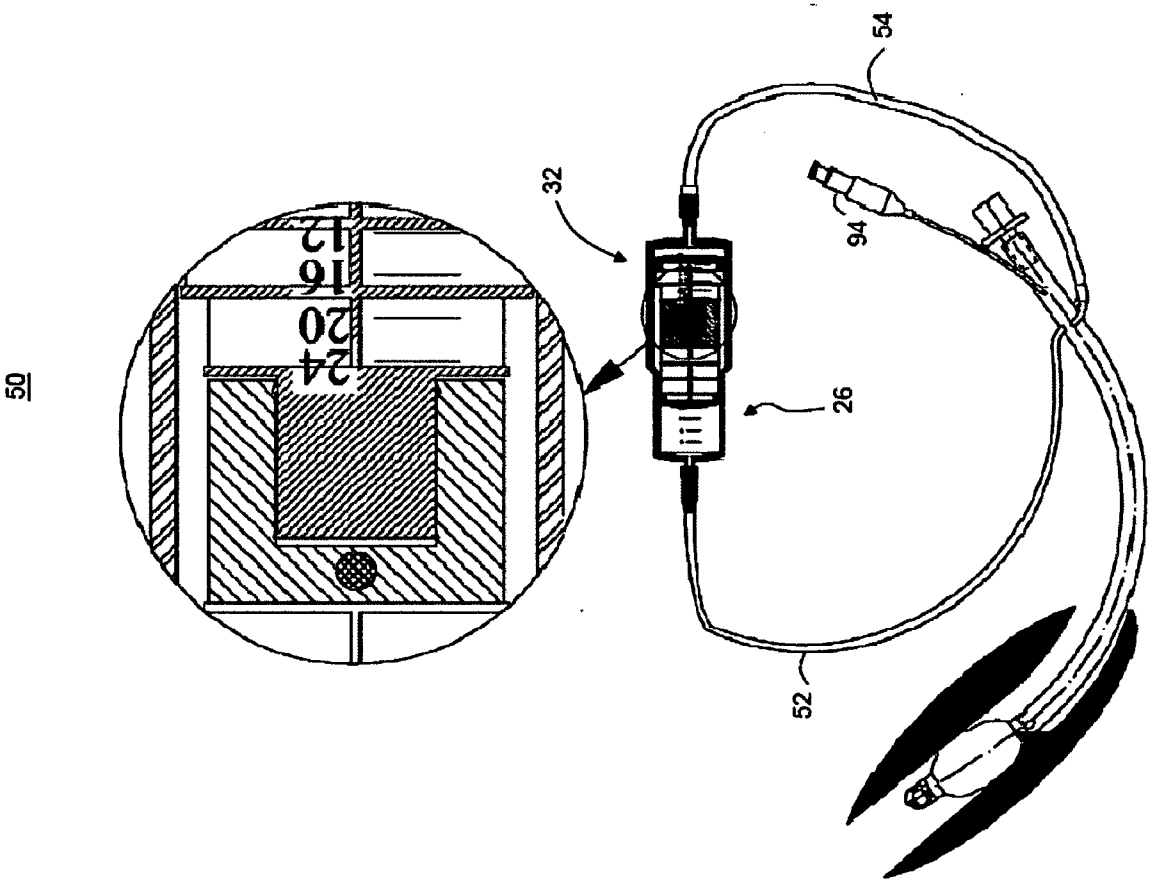

FIG. 5A

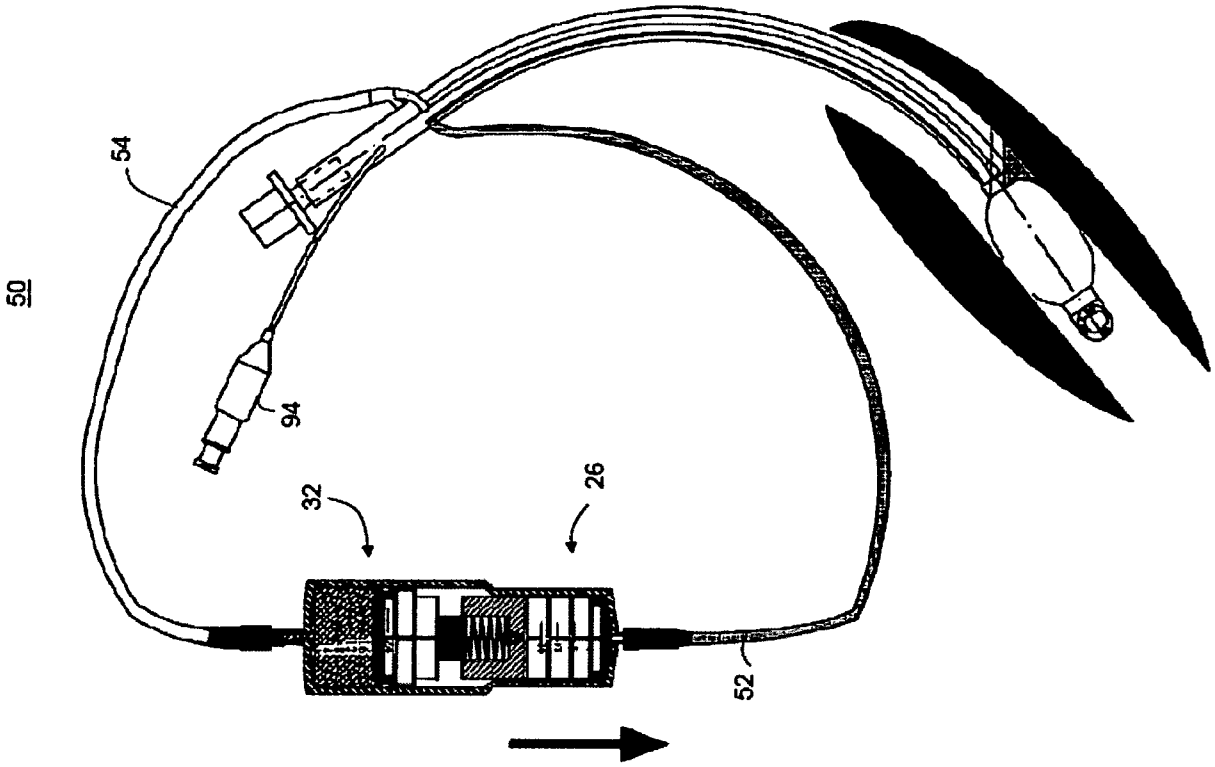

FIG. 5D

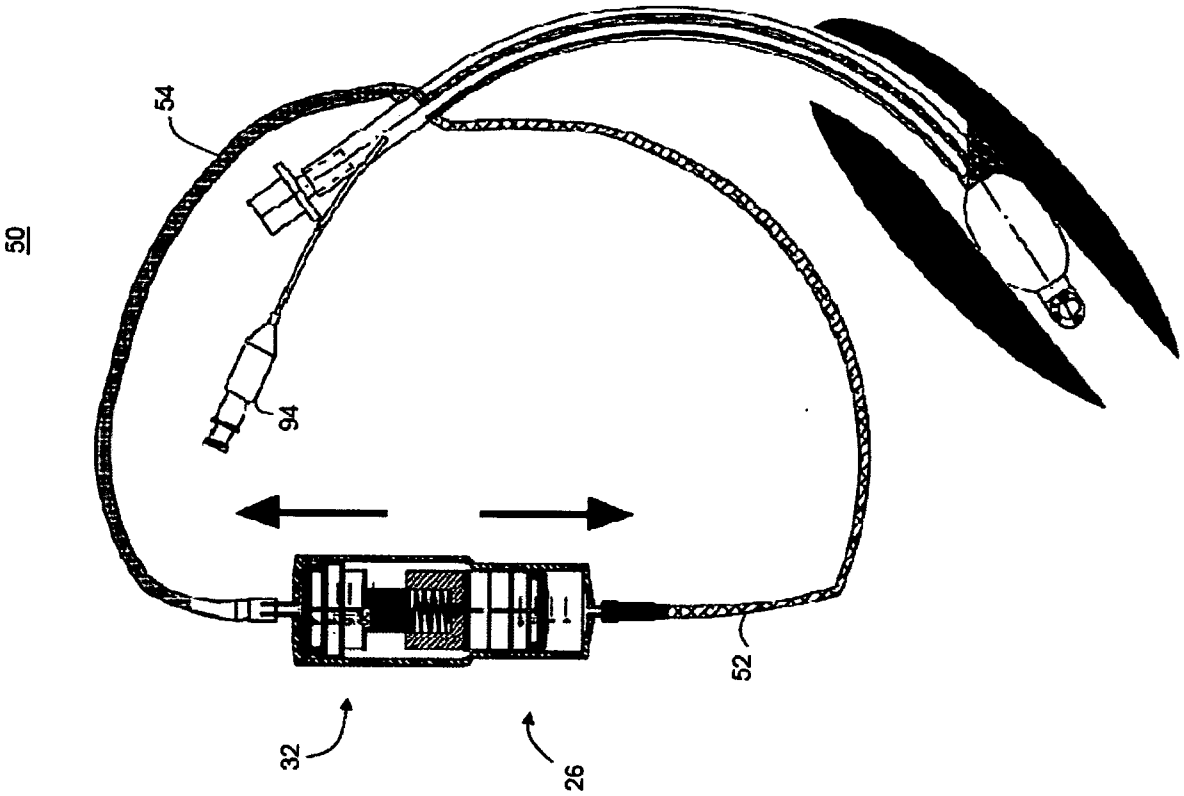

FIG. 5C

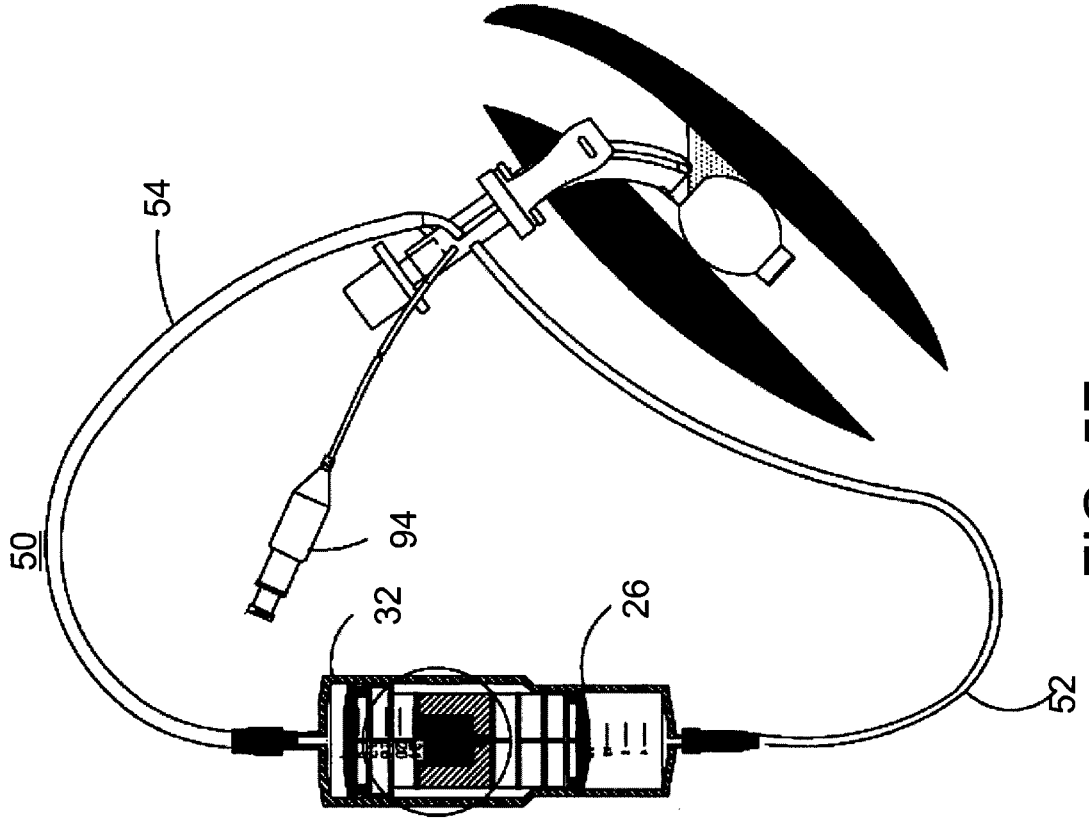

FIG. 5F

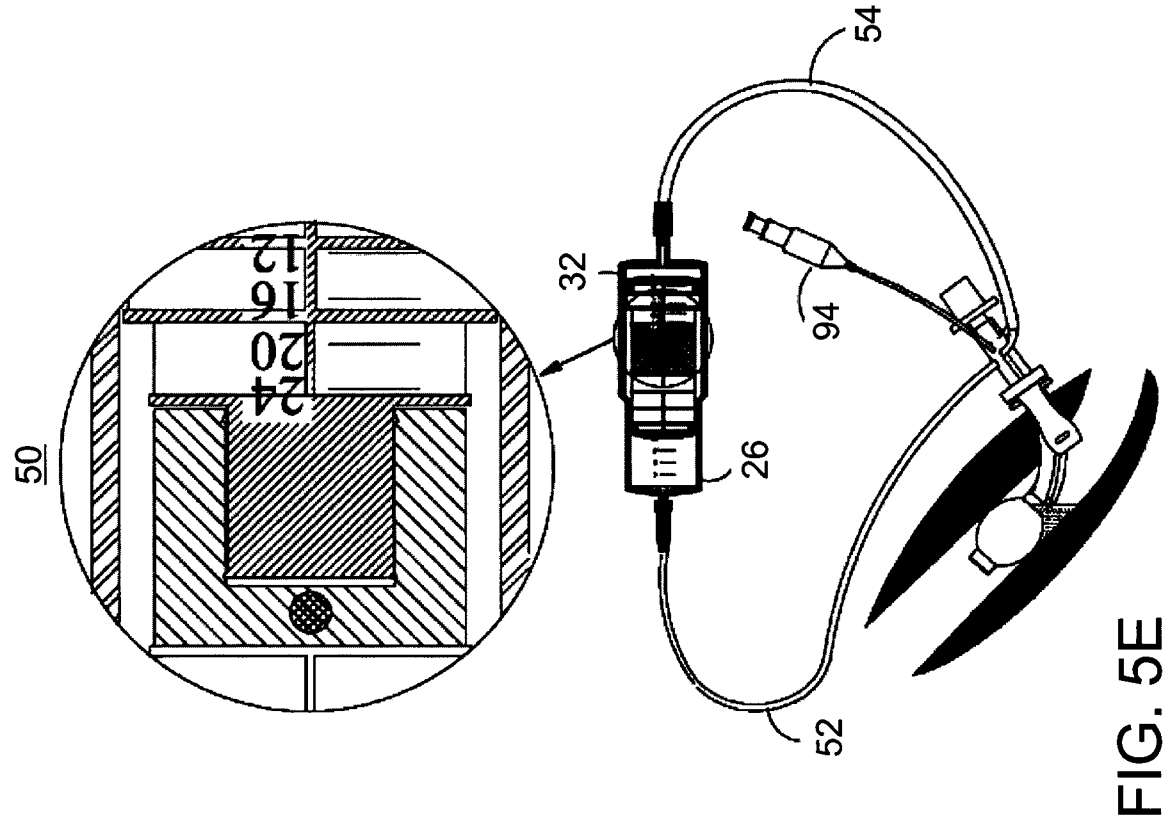

FIG. 5E

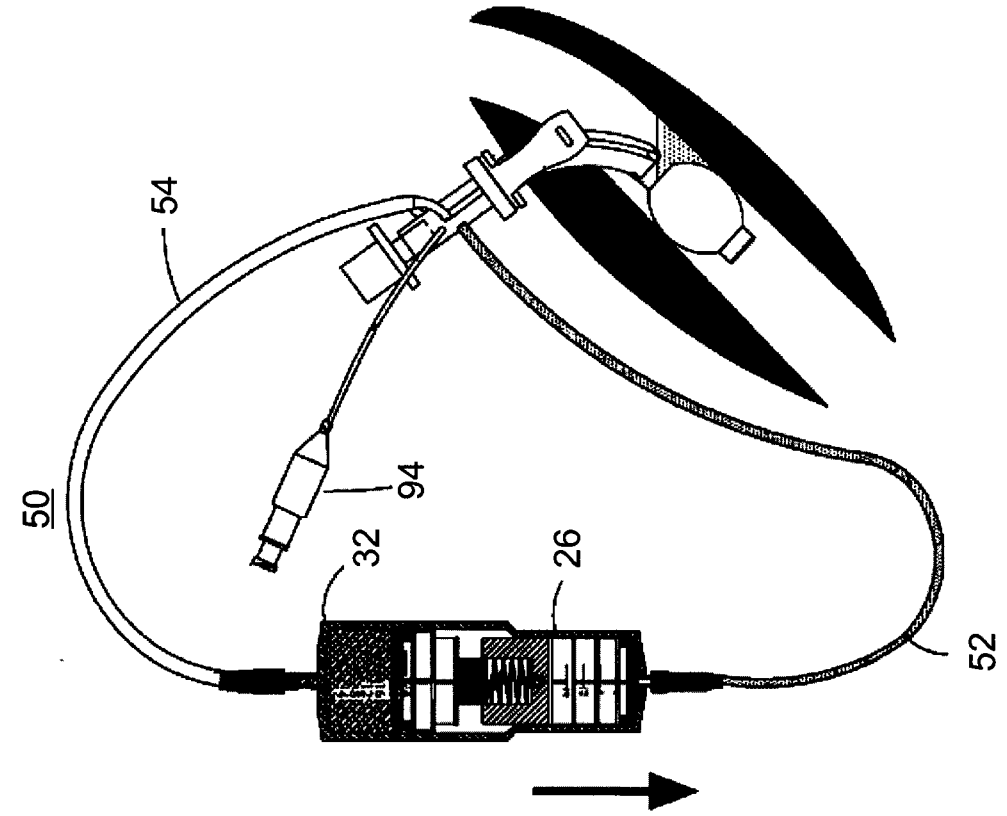

FIG. 5H

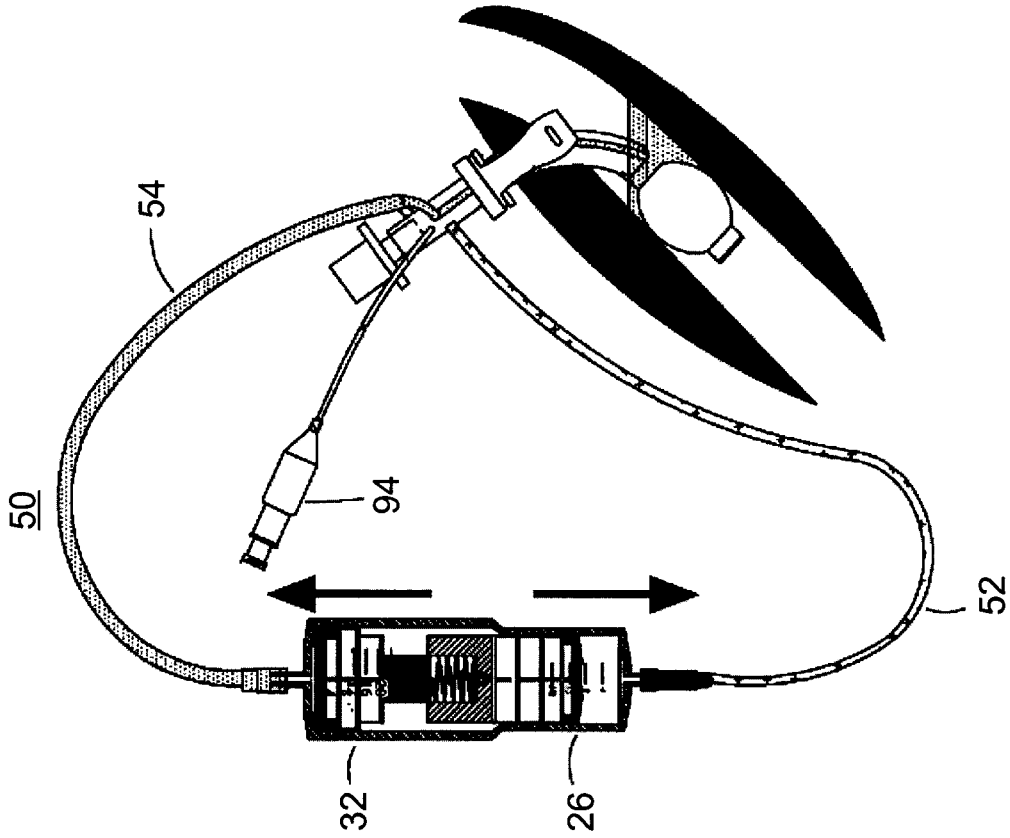

FIG. 5G

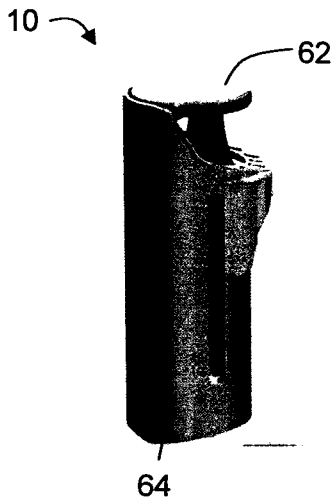

FIG. 6A

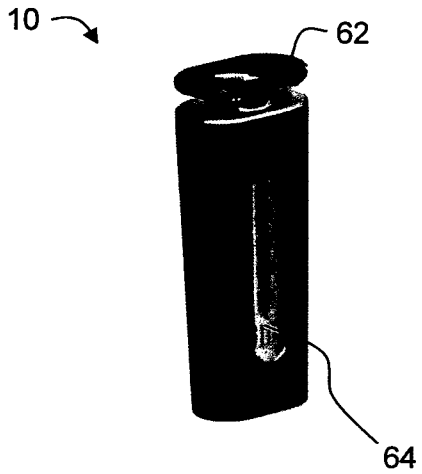

FIG. 6B

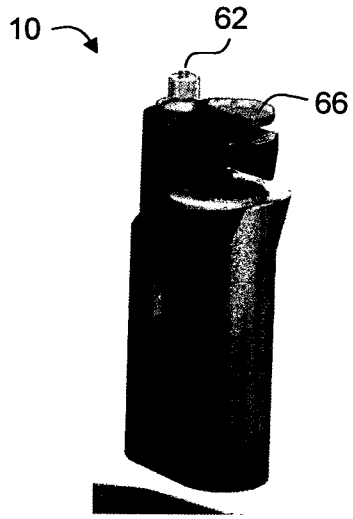

FIG. 6C

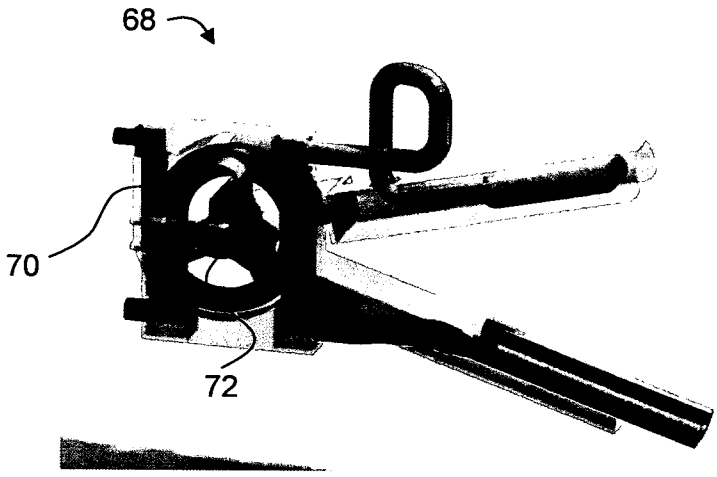

FIG. 6D

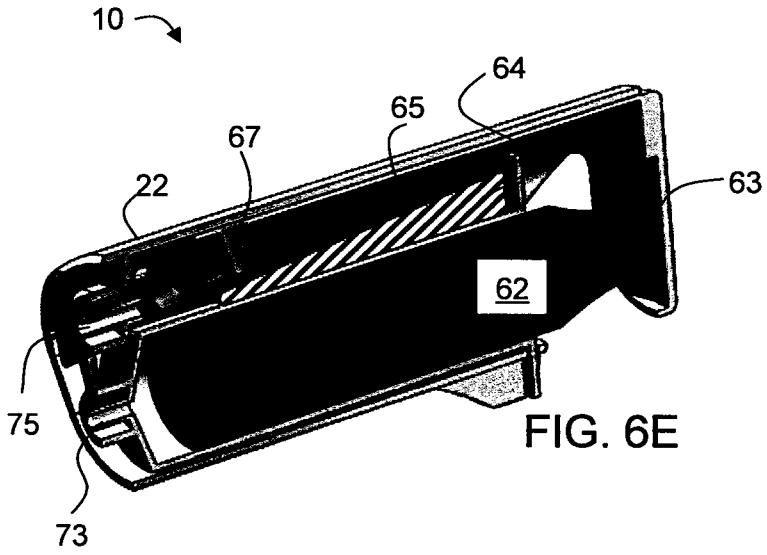

FIG. 6E

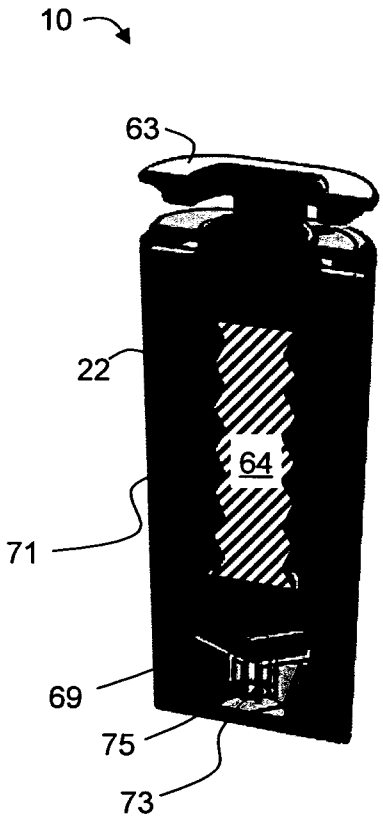

FIG. 6F

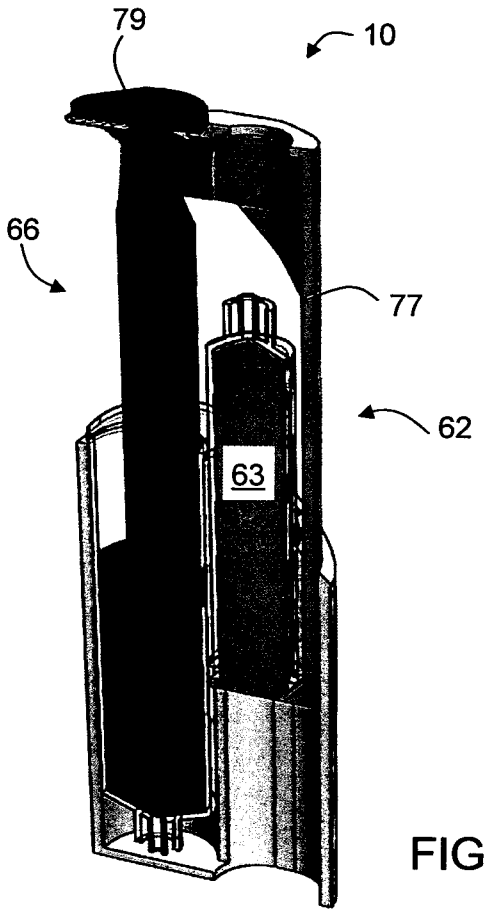

FIG. 6G

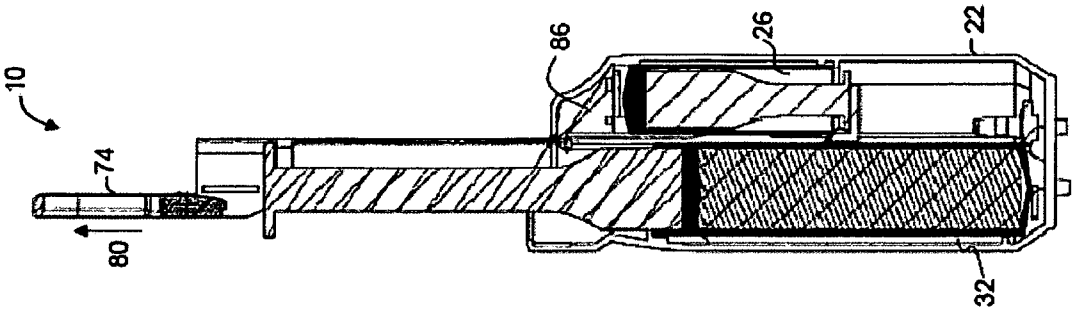

FIG. 7E

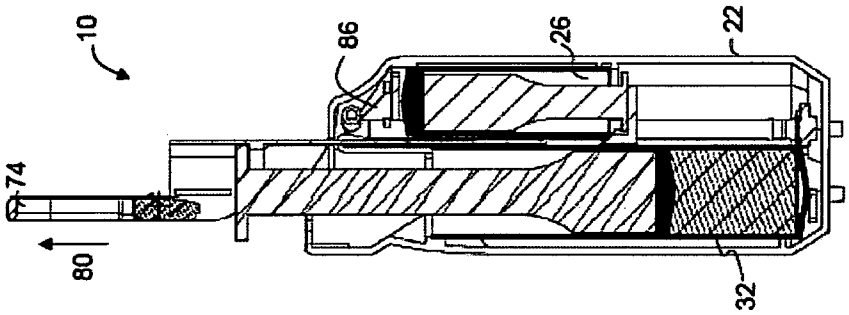

FIG. 7D

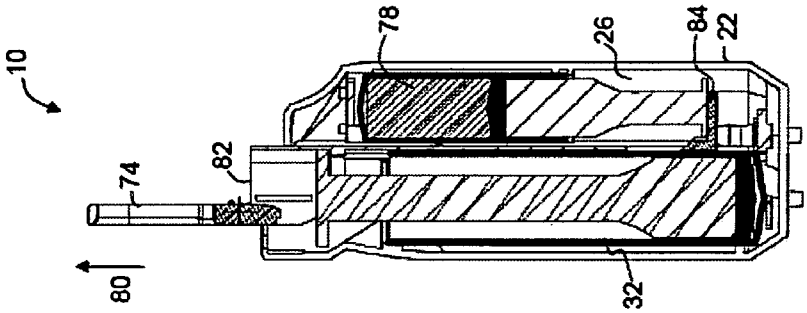

FIG. 7C

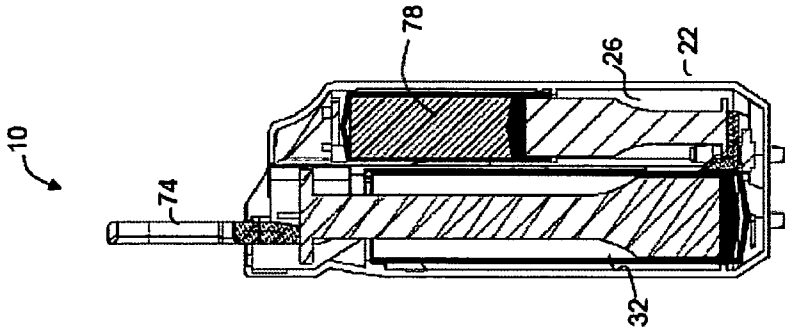

FIG. 7B

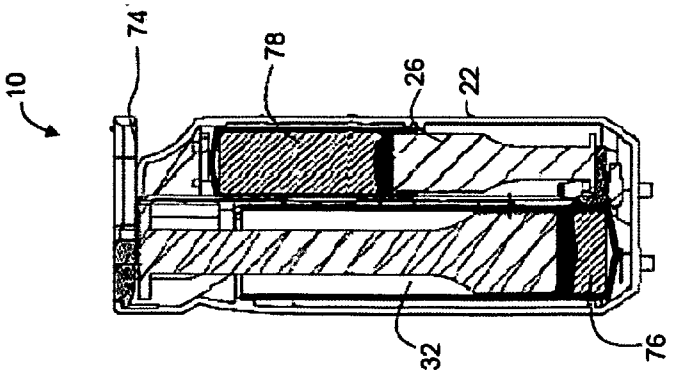

FIG. 7A

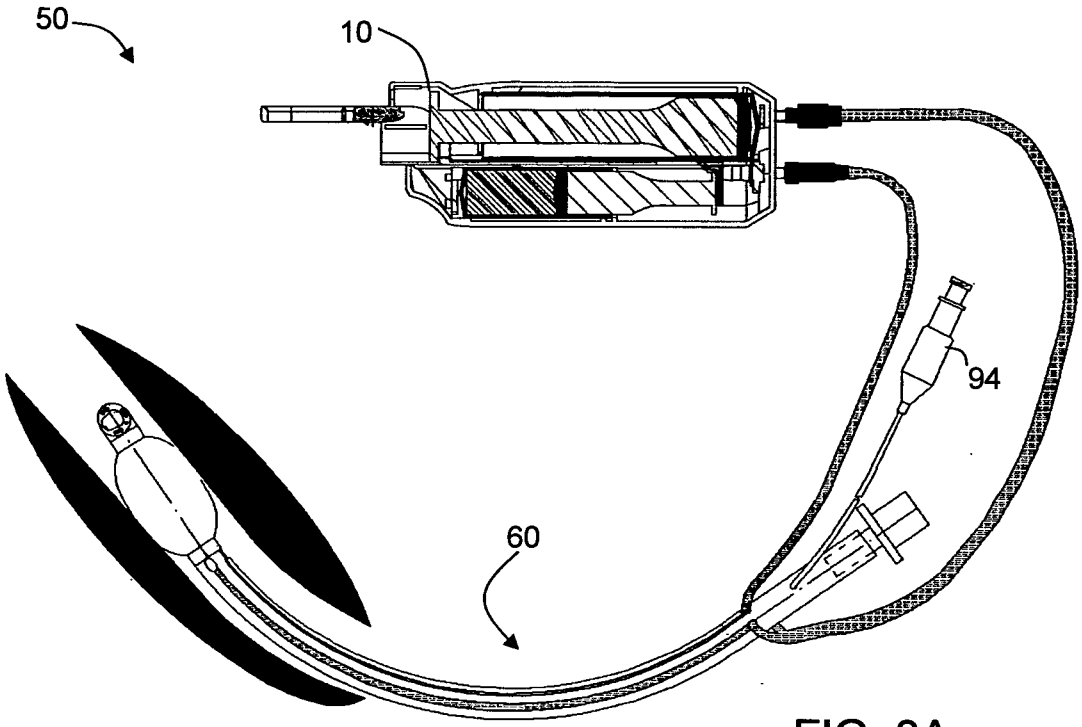

FIG. 8A

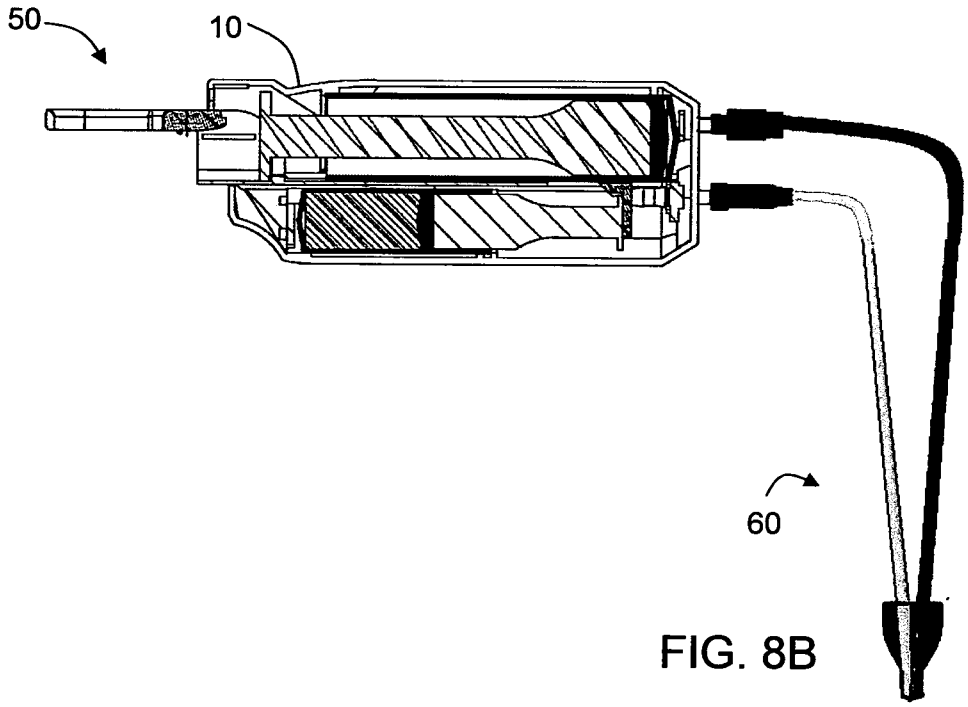

FIG. 8B

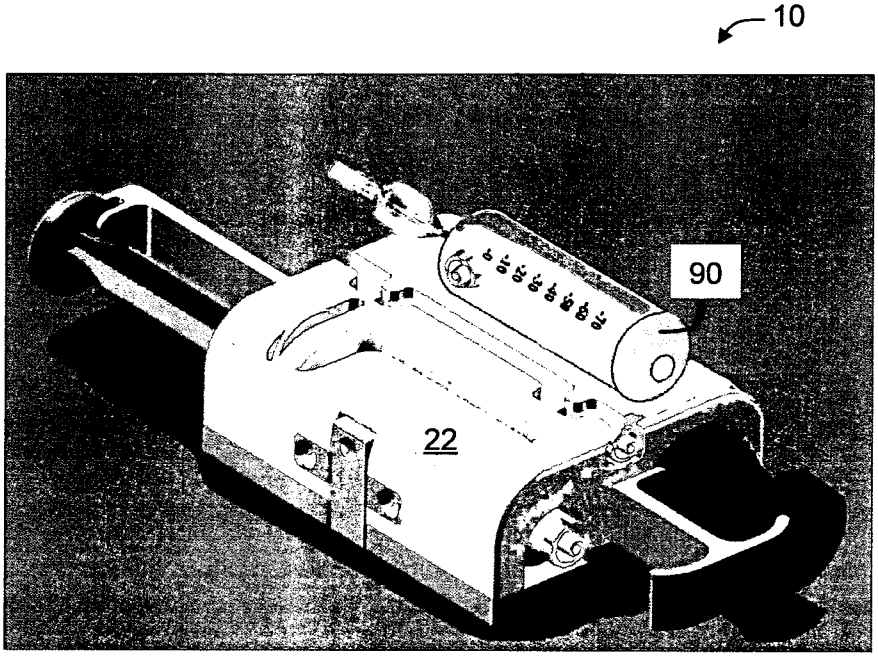

FIG. 9A

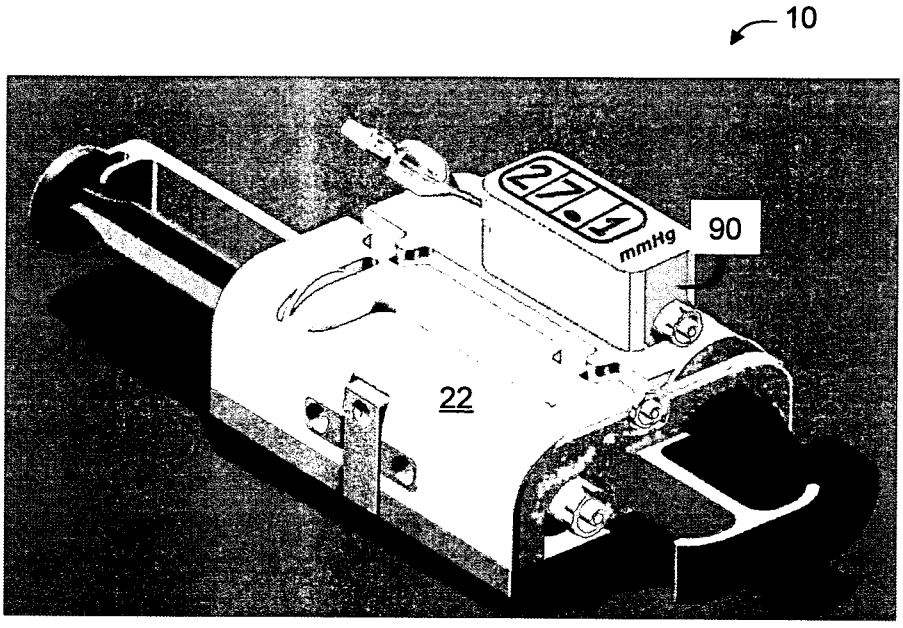

FIG. 9B

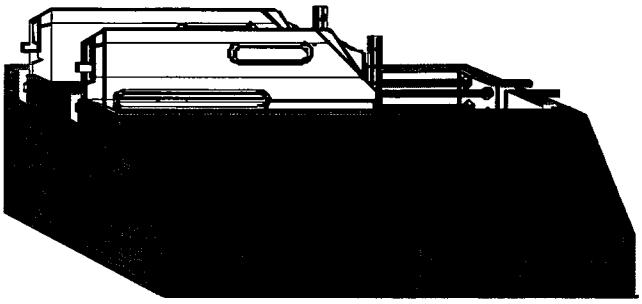

FIG. 10

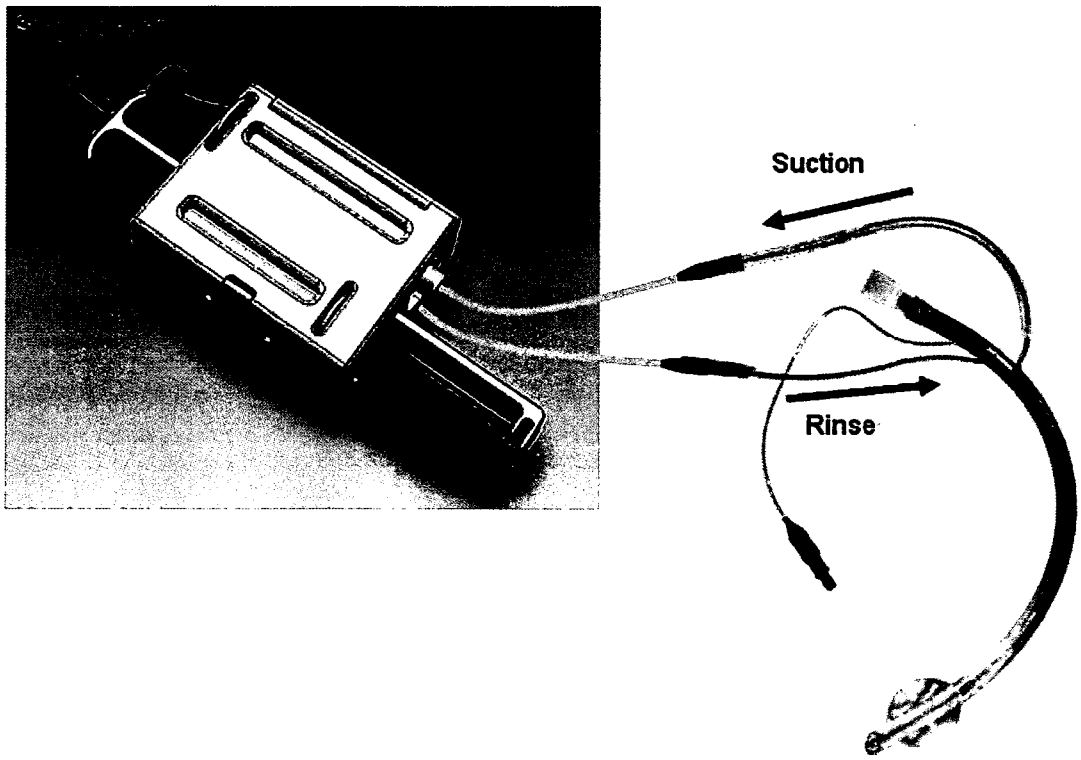

FIG. 11A

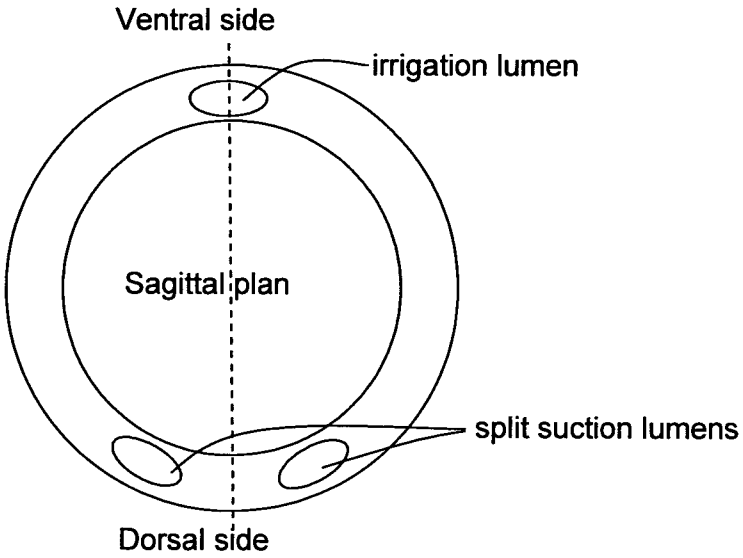

FIG. 11B

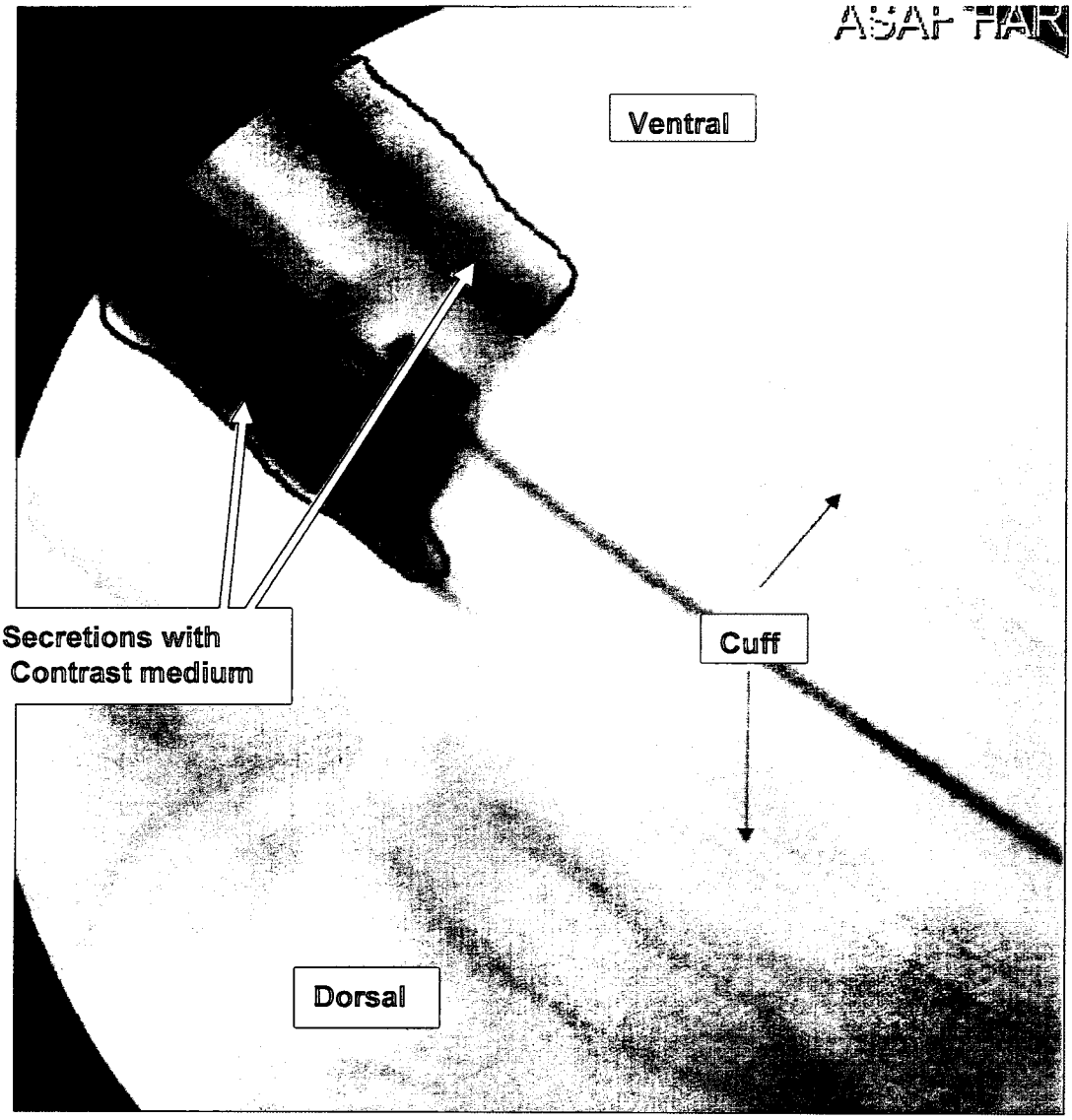
ASAHI-TAR
Ventral
Secretions with
Contrast medium
Cuff
Dorsal

FIG. 12

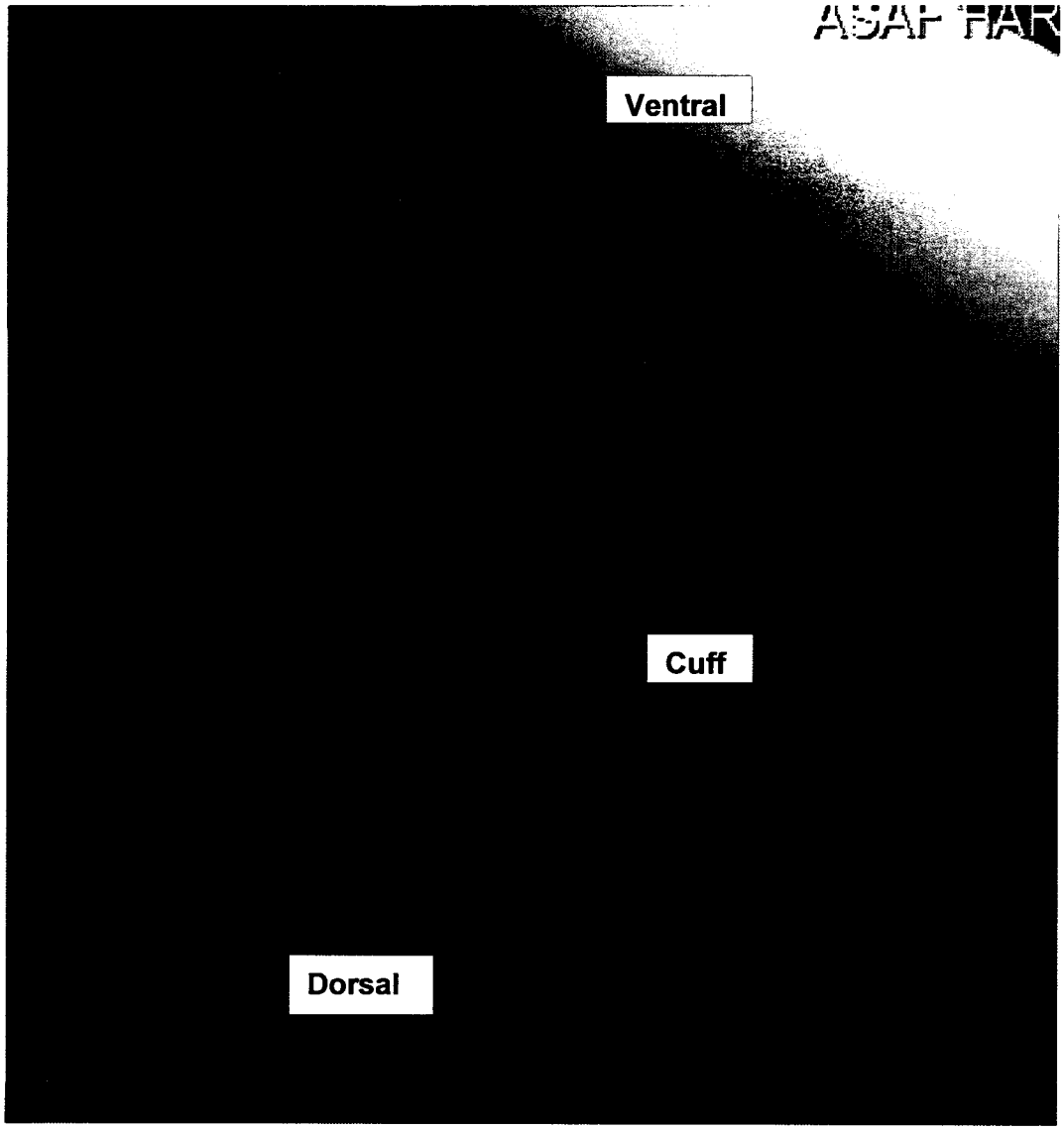

FIG. 13

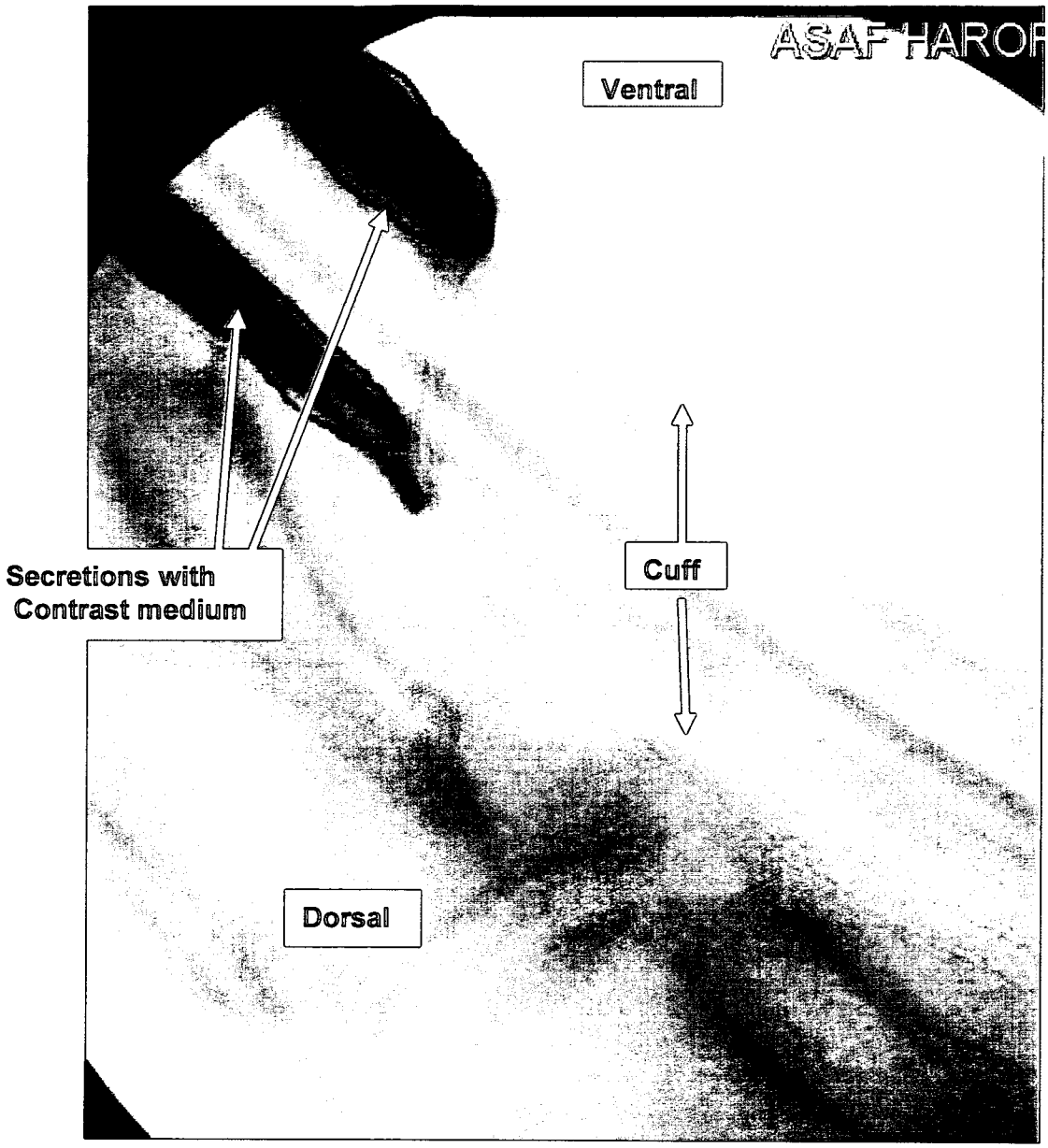
ASAF HAROF
Ventral
Secretions with
Contrast medium
Cuff
Dorsal

FIG. 14

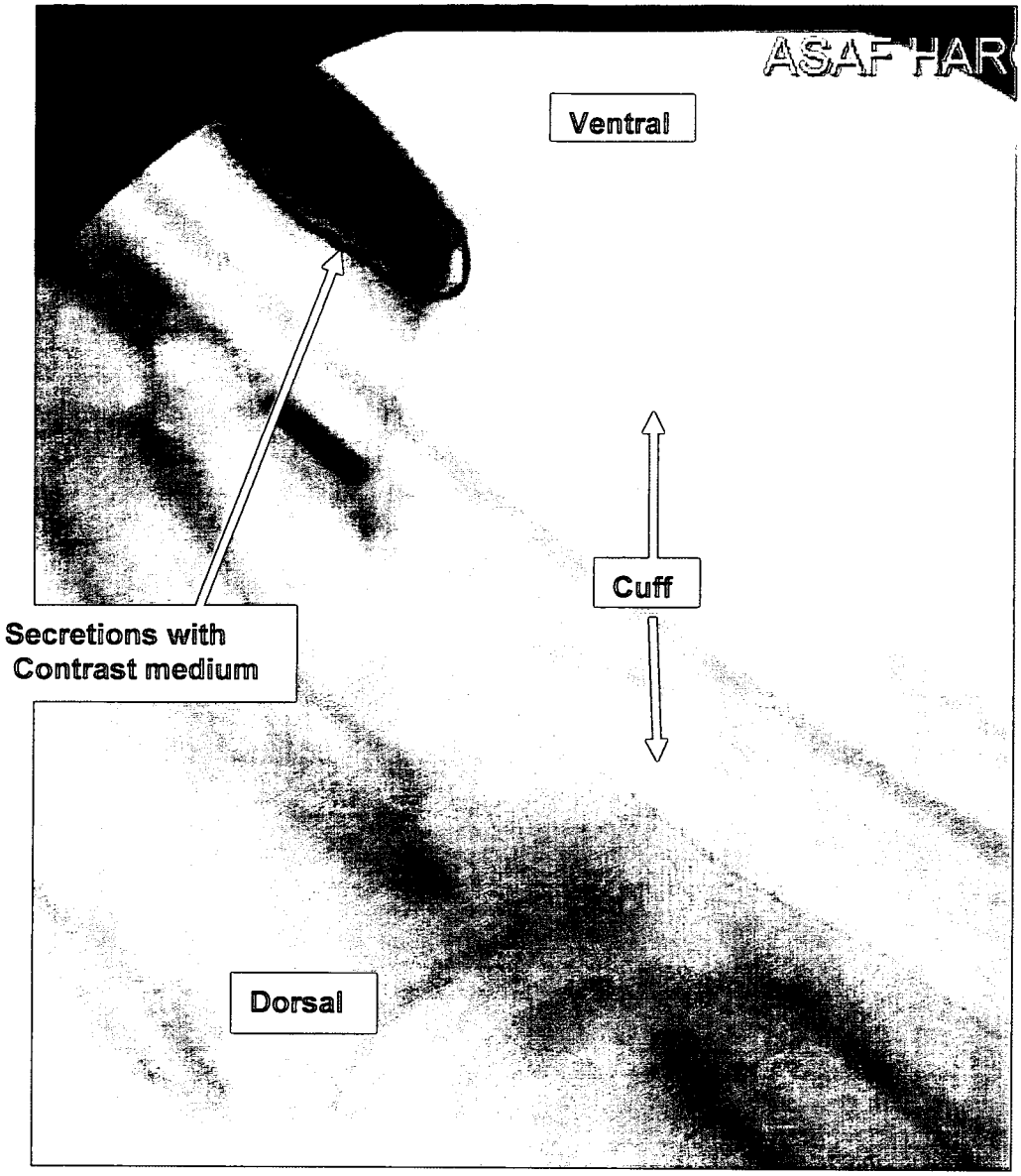

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2011/000520

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00 A61M31/00
ADD.

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)
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)
EPO-Internal , BIOSIS, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2003/069549 Al (MACMAHON JOHN M [US] ET AL) 10 Apri l 2003 (2003-04-10) paragraphs [0015] , [0029] , [0035] , [0038] , [0068] - [0070] , [0072] - [0079] , [0087] - [0088] ; f i gures 4A, 4B, 5A, 5B, 6, 7, 11, 12A, 12B, 13A, 13B, 16 -----	1-11 , 15-21 , 30,31 32-37
X	US 4 909 783 A (MORRISON DAVID P [US]) 20 March 1990 (1990-03-20) col umn 1, l i nes 9-14; f i gures 1-4 col umn 5, l i nes 4-17 col umn 5, l i nes 56-60 col umn 3, l i nes 64-66 col umn 4, l i nes 23-30 col umn 4, l i nes 40-53 ----- -/-- ·	1-5 , 8-11 ,21 , 30,31

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 November 2011	30/11/2011

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, Fax: (+31-70) 340-3016	Landre, Jul i en

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2011/000520

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	WO 92/07602 A1 (MALLINCKRODT MEDICAL INC [US]) 14 May 1992 (1992-05-14) abstract; claims 1-3, 5; figure 2 page 4, lines 14-22 page 5, lines 9-27 page 6, lines 4-7 page 7, lines 8-12	32-37
X	US 5 957 883 A (LIN P0-KANG [TW]) 28 September 1999 (1999-09-28) the whole document	1-5,8,9, 21,30

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Information on patent family members

International application No
PCT/IL2011/000520

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