

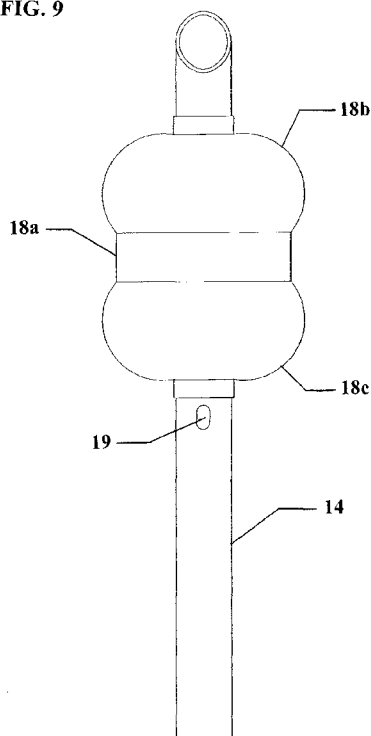


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(54) Title: ENDOTRACHEAL TUBE HAVING A CUFF ELASTICALLY EXPANDABLE AND NON-ELASTICALLY EXPANDABLE PORTIONS AND METHOD OF MAKING AND/OR USING THE SAME

FIG. 9



(57) Abstract: An endotracheal tube includes a main tube having a proximal end and a distal end and an inflatable cuff arranged on the main tube. The cuff has one or more portions or sections that can be elastically expanded and one or more portions or section that are not elastically expandable. A method for intubation using the endotracheal tube includes inserting at least a portion of an endotracheal tube into a trachea, inflating a cuff of the endotracheal tube, and supplying gas into a patient's lungs via the endotracheal tube. A method of making the endotracheal tube includes forming the cuff having one or more portions or sections that can be elastically expanded and one or more portions or section that are not elastically expandable.



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**ENDOTRACHEAL TUBE HAVING A CUFF ELASTICALLY EXPANDABLE AND
NON-ELASTICALLY EXPANDABLE PORTIONS AND METHOD OF MAKING
AND/OR USING THE SAME**

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application No. 61/425,599, filed December 21, 2010, which is incorporated by reference in its entirety into this application.

BACKGROUND OF THE INVENTION

Field of Invention

[0002] The invention relates generally to the field of medical devices, e.g., a medical tube, e.g., an endotracheal (ET) tube, including an inflatable cuff. According to various embodiments, the endotracheal tube utilizes the novel way of providing better sealing cuff which imparts less force to the trachea wall. This is accomplished using a cuff having one or more portions or sections that can be elastically expanded and having one or more portions that are not elastically expandable.

Discussion of Background Information

[0003] Conventional methods of endotracheal intubation involve the insertion of a tubular device, e.g., an endotracheal tube, into the trachea. The endotracheal tube typically passes through the trachea and terminates above the carina, allowing gases to be directed through the tube and into the lungs.

[0004] A primary objective of this type of treatment is the mechanical ventilation of a patient's lungs, which may be required or appropriate due to the subject's medical condition. In order to create the air pressure necessary to artificially ventilate the lungs, the passageways around the tube are typically sealed, which may be accomplished, e.g., using the inflatable cuff. The cuff is typically located within the trachea about 3-5 centimeters above the carina and is then inflated to expand and seal against the wall of the trachea. This prevents gases from being pumped into the lungs from backing up around the tube.

[0005] Standard cuffs for endotracheal tubes are typically molded such that they are larger in a filled or inflated state than a typical trachea. Some cuffs are elastically expandable

so that they can expand elastically in the trachea beyond the initial expanded state. With such cuffs, once the cuff is filled inside the trachea, folds can form in the cuff which allow secretions to pass into the lungs through the folds. One solution to this problem is to use an elastic cuff which has an un-elastically deformed shape that is smaller than the trachea before filling. This cuff is then expanded elastically when filled inside the trachea so as to provide sealing without folds. The problem with this solution is that it typically applies much greater force or pressure to the trachea wall than cuffs that are not expanded elastically. Thus, in turn, can cause pressure necrosis to the trachea wall or vessel lining.

[0006] It is also known that cuffed endotracheal tubes often do not self-center within the trachea upon inflation of the cuff. As a result, the suction openings of a particular tube may not be spaced apart from the tracheal wall. For example, due to the curvature of the tube and/or other factors, the suction opening may be located very near the tracheal wall upon cuff inflation. In some instances, the suction opening may actually contact the tracheal wall. In such situations, the tracheal wall membrane may be drawn into the suction opening upon application of a vacuum, thereby occluding the opening. This may prevent the proper removal of secretions from the subglottic space and/or may cause trauma to the tracheal wall.

[0007] Known endotracheal tubes also incorporate pigtail tubing to connect the cuff inflation lumen to an inflation syringe and a suction lumen to deliver suctioning into the trachea from a suction source. These pigtails typically separate from the main tube at a point below where the main tube is typically cut to fit a particular patient. While the pigtail for cuff inflation is small, the pigtail for suctioning is larger and can cause space issues within the limited space of the patient oral cavity. This is especially the case during, e.g., oral care and inspections.

[0008] With current endotracheal tubes, especially CASS type, the suction aperture is placed on the outer edge or side of the main tube curvature. These ET tubes also use standard cuffs that are typically molded such that they are larger in a filled or inflated state than a typical trachea. One example is shown in FIGS. 1-5 which illustrates an endotracheal tube **1** having a proximal end **2**, a distal end **3**, a main tube **4**, a connector **C** for interfacing with a respiration source, an inflation lumen arranged in the main tube **4**, a cuff **8**, a suction aperture **9**, and optionally a radiopaque stripe. An inflation device **ID** is used to cause inflation of the cuff **8** by passing a gas through a tube **T** and into the main tube **4**. A suction device **SD** (or connector for connecting to the same) is used to create suction at the suction aperture **9** by

allowing gas to pass through an inflation lumen of the tube **4** from the suction aperture **9**. The cuff **8** includes a proximal end and a distal end. In an un-filled or un-inflated position, the cuff **8** has folds **F**. The suction aperture **9** is typically arranged about 8 mm away from the cuff **8** (measured along the axis of the main tube **4**) in order to avoid the portion of the cuff **8** that is glued to the main tube **4**. In this position, the suction aperture **9** is typically positioned where it will be at the lowest point within the trachea (when the patient is inclined).

[0009] Examples of devices which utilize folds in an expanded state and/or which aim to overcome some of the problems discussed above include US 2008/0236593 to NELSON et al., US 2008/0000482 to MAGUIRE et al., US 2007/0296125 to COLBURN et al., US 7,207,972 to FLODIN, US 5,937,861 to AUGUSTINE, US 4,328,056 to SNOOKS, US 4,134,407 to ELAN, US 4,315,505 to CRANDALL et al., and US 6,651,664 to LOMHOLT, each of which is expressly incorporated by reference in its entirety into this application.

[00010] It would be beneficial to have an endotracheal tube having a cuff with properties of both a standard non-elastically filled cuff as well as an elastically expandable one. It would also be beneficial to have an endotracheal tube having a cuff that is blow-molded and/or formed in a manner similar to that of a standard Hi-Lo and/or “micro-cuff” style cuffs, except that the mold is made smaller than a circumference of the trachea so that the cuff is smaller in its filled, but not elastically expanded state than when it is filled and expanded elastically to seal the trachea. In embodiments, it would be beneficial if the mold is configured such that the cuff is formed about 20% smaller than the size of the inner tracheal space that it will seal. When inflated, the cuff will only require an additional elastic expansion of 20% or more to seal the trachea. By reducing the amount of elastic deformation required to seal the trachea, the force imparted to the trachea wall can be reduced significantly. This reduces the likelihood of causing pressure necrosis to the vessel (i.e., trachea) wall.

SUMMARY OF THE INVENTION

[00011] According to one non-limiting embodiment of the invention, there is provided a endotracheal tube utilizing a novel way of providing sealing between the cuff and the tracheal wall, which overcomes one or more of the deficiencies noted above.

[00012] In embodiments, the invention can utilize ET tubes of the type shown in FIG. 1 and/or of the type disclosed in US 2008/0236593 to NELSON et al., US 2008/0000482 to MAGUIRE et al., US 2007/0296125 to COLBURN et al., US 7,207,972 to FLODIN, US 5,937,861 to AUGUSTINE, US 4,328,056 to SNOOKS, US 4,134,407 to ELAN, US 4,315,505 to CRANDALL et al., and US 6,651,664 to LOMHOLT, and which are modified to include the cuff configurations and/or cuff shapes and/or cuff wall configurations disclosed herein.

[00013] In embodiments, the invention can utilize ET tubes, as well as any features thereof, of the type disclosed in three concurrently filed PCT applications, claiming the benefit of priority, respectively, to the following: 1) U.S. Provisional Patent Application No. 61/425,584, filed December 21, 2010 with the title “ENDOTRACHEAL TUBE HAVING A RECESSED CUFF, ONE OR MORE SUCTION APERTURES ARRANGED THEREIN, AND/OR A CUFF HAVING STIFFENERS AND METHOD OF MAKING AND/OR USING THE SAME;” 2) U.S. Provisional Patent Application No. 61/425,589, filed December 21, 2010 with the title “ENDOTRACHEAL TUBE HAVING A RECESSED CUFF AND/OR ONE OR MORE SUCTION APERTURES ARRANGED IN A CUFF RECESS AND METHOD OF MAKING AND/OR USING THE SAME;” and 3) U.S. Provisional Patent Application No. 61/425,593, filed December 21, 2010 with the title “ENDOTRACHEAL TUBE HAVING ONE OR MORE ANGULARLY OFFSET SUCTION APERTURES AND METHOD OF MAKING AND/OR USING THE SAME.” The disclosure of each of these documents is expressly incorporated by reference in its entirety into this application.

[00014] In embodiments, the endotracheal tube can utilize a cuff that has one or more portions or sections that can be elastically expanded and having one or more portions that are not elastically expandable.

[00015] In embodiments, the cuff is molded such that it has a center area or region that is smaller, i.e., in diameter and/or peripherally and/or circumferentially, than the trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are also smaller, i.e., in diameter and/or peripherally and/or circumferentially, than the trachea, but which can expand elastically to seal against the trachea wall. In embodiments, the outer regions can be tapered so as to decrease in size from the center area and towards each end of the cuff.

[00016] In embodiments, the cuff is molded such that it has a center area or region that is larger, i.e., in diameter and/or peripherally and/or circumferentially, than the trachea in its pre-formed (i.e., the circumference of the center region is formed larger in the mold) state and outer areas or regions that are smaller, i.e., in diameter and/or peripherally and/or circumferentially, than the trachea, but which can expand elastically to seal against the trachea wall. In embodiments, the outer regions can be tapered so as to decrease in size from the center area and towards each end of the cuff.

[00017] In embodiments, the cuff is molded such that it has a center area or region that is larger than the trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall. In embodiments, the outer regions can be tapered so as to decrease in size from the center area and towards each end of the cuff.

[00018] In embodiments, the cuff has an area or region that is larger than the trachea in its filled but non-elastically expandable state and one or more other areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall. The area that is larger than the trachea can seal to the trachea without elastic expansion or deformation. Even if the larger area has folds during the sealing to the trachea, the one or more smaller elastically expandable areas seal to the trachea without folds. In embodiments, the larger area is arranged in a center of the cuff and the smaller areas are tapered and are arranged on one or more sides of the center.

[00019] In embodiments, there is provided a cuff for an endotracheal tube that is smaller than the tracheal circumference but larger than the endotracheal tube circumference when it is in the filled but not elastically expanded state. In embodiments, the cuff is made from a material that will expand elastically to allow the cuff to be expanded to fill and seal the trachea. Such materials can include PVC, polyurethane, silicone, as well as blends of these materials and composites and copolymers of the same. In embodiments, the cuff is between about 20% and about 30% smaller than the circumference of the trachea in its filled but un-elastically deformed state.

[00020] According to one non-limiting embodiment of the invention, there is provided an endotracheal tube that includes a main tube comprising a proximal end and a distal end and an inflatable cuff arranged on the main tube. At least one of the following is utilized: the

cuff has one or more portions or sections that can be elastically expanded and one or more portions or section that are not elastically expandable; the cuff has a center area or region that is smaller than a trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall; the cuff has a center area or region that is smaller than a trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are tapered so as to decrease in size from the center area and towards each end of the cuff; the cuff has a center area or region that is larger than the trachea in its pre-formed state and outer areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall; the cuff has a center area or region that is larger than the trachea in its pre-formed state and outer areas or regions that are tapered so as to decrease in size from the center area and towards each end of the cuff; the cuff has a center area or region that is larger than the trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are smaller than the trachea and are tapered so as to decrease in size from the center area and towards each end of the cuff, but which can expand elastically to seal against the trachea wall; the cuff has an area or region that is larger than the trachea in its filled but non-elastically expandable state and one or more other areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall, wherein the area that is larger than the trachea can seal to the trachea without elastic expansion or deformation and the one or more smaller elastically expandable areas seal to the trachea without folds; the cuff has a center area or region that is smaller than a trachea in its pre-formed state and elastically expandable to seal against the trachea wall and outer areas or regions that are smaller than the trachea, but which are not elastically expandable; and the cuff has a larger non-elastically expandable center area and smaller tapered end areas which, upon inflation, can expand elastically to a circumference that is greater than the center area.

[00021] The cuff may be smaller than a tracheal circumference but larger than a circumference of the main tube when it is in a filled but not elastically expanded state. The cuff may be made from a material that expands elastically to allow the cuff to be expanded to fill and seal the trachea. The material may comprise one of PVC, polyurethane, silicone, blends thereof, composites thereof, and copolymers thereof. The cuff, in its filled but unelastically deformed state, may be between about 20% and about 30% smaller than a circumference of the trachea. The inflatable cuff may have tapered distal and proximal ends.

The inflatable cuff may have a generally circular cross-sectional shape. The inflatable cuff may comprise at least two spaced-apart elastically expandable sections.

[00022] A center area or region may have an axial length that is between about 10% and about 25% of an overall axial length of the cuff. A non-elastically expandable section of the cuff may have an axial length that is between about 10% and about 25% of an overall axial length of the cuff.

[00023] The inflatable cuff may be arranged on the main tube and spaced from the distal end by an amount that is less than a spacing from the proximal end. The main tube may comprise at least one integrally formed suction lumen which extends to at least one suction aperture. The main tube may comprise at least one integrally formed inflation lumen which extends to at least one aperture for inflating the cuff. The main tube may comprise at least one suction lumen that is arranged on a bending plane of the main tube. The main tube may comprise at least one non-circular suction lumen that is arranged on a bending plane of the main tube. The main tube may comprise a generally circular cross-section shape. The main tube may comprise a generally oval cross-section shape. The endotracheal tube may further comprise at least one inflation lumen generally oriented on a bending plane of the main tube.

[00024] The invention also provides for an endotracheal tube comprising a main tube comprising a proximal end and a distal end and an inflatable cuff arranged on the main tube. At least one of the following can be utilized: the cuff has a center area or region that is smaller than a trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall, the cuff has a center area or region that is smaller than a trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are tapered so as to decrease in size from the center area and towards each end of the cuff; the cuff has a center area or region that is larger than the trachea in its pre-formed state and outer areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall, the cuff has a center area or region that is larger than the trachea in its pre-formed state and outer areas or regions that are tapered so as to decrease in size from the center area and towards each end of the cuff; the cuff has a center area or region that is larger than the trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are smaller than the trachea and are tapered so as to decrease in size from the center area and

towards each end of the cuff, but which can expand elastically to seal against the trachea wall; the cuff has a center area or region that is smaller than a trachea in its pre-formed state and elastically expandable to seal against the trachea wall and outer areas or regions that are smaller than the trachea, but which are not elastically expandable; and the cuff has a larger non-elastically expandable center area and smaller tapered end areas which, upon inflation, can expand elastically to a circumference that is greater than the center area.

[00025] The invention also provides for a method for intubation using the endotracheal tube described above, wherein the method comprises inserting at least a portion of an endotracheal tube into a trachea, inflating a cuff of the endotracheal tube, and supplying gas into a patient's lungs via the endotracheal tube.

[00026] The method may further comprise suctioning matter through the at least one suction aperture.

[00027] The invention also provides for a method of making the endotracheal tube described above, wherein the method comprises forming at least cuff that has one or more portions or sections that can be elastically expanded and having one or more portions that are not elastically expandable.

BRIEF DESCRIPTION OF DRAWINGS OF THE EXEMPLARY EMBODIMENTS

[00028] The present invention is further described in the detailed description which follows, in reference to the noted plurality of drawings by way of non-limiting examples of exemplary embodiments of the present invention, in which like reference numerals represent similar parts throughout the several views of the drawings, and wherein:

[00029] FIG. 1 shows a side perspective view of an endotracheal tube of the type conventionally used in intubation in a bent or use configuration and with the cuff inflated;

[00030] FIGS. 2 and 3 show side views (rotated 90 degrees to one another) of a distal end portion of the endotracheal tube of FIG. 1 with the cuff being filled or inflated;

[00031] FIGS. 4 and 5 show a side and a cross-section view of a distal end portion of the endotracheal tube of FIG. 1 with the cuff being un-filled or un-inflated and illustrating its folds;

[00032] FIGS. 6 and 7 show side views (rotated 90 degrees to one another) of a distal end portion of an endotracheal tube in accordance with an exemplary embodiment of the invention. The cuff is shown in a partial and/or initial inflated or filled position;

[00033] FIG. 8 shows an enlarged partial side cross-section view of the cuff portion shown in FIGS. 6 and 7 in accordance with an exemplary embodiment of the invention;

[00034] FIG. 9 shows a view similar to that of FIG. 6 except that the cuff is further and/or fully inflated to cause elastic expansion and/or elastic deformation of the outer portions of the cuff in accordance with an exemplary embodiment of the invention. The center area of the cuff is not enlarged (i.e., does not expand with further inflation pressure inside the cuff) because it is not elastically expandable;

[00035] FIGS. 10 and 11 show a side and a cross-section view of a distal end portion of the endotracheal tube of FIGS. 6-9 with the cuff being un-filled or un-inflated and illustrating its folds;

[00036] FIG. 12 shows the endotracheal tube of FIGS. 6 and 7 inside a trachea in accordance with an exemplary embodiment of the invention. This embodiment utilizes a cuff that is smaller in circumference in a filled but not elastically expanded state;

[00037] FIG. 13 shows the endotracheal tube of FIG. 12 in a fully expanded state and illustrating how the elastically expanded sections expand to provide sealing to the trachea in accordance with an exemplary embodiment of the invention;

[00038] FIG. 14 shows an embodiment similar to that of FIGS. 6 and 7 arranged in a trachea in accordance with an exemplary embodiment of the invention. This embodiment utilizes a cuff that is larger than the trachea in a filled and not elastically expandable state;

[00039] FIG. 15 shows the endotracheal tube of FIG. 14 in a fully expanded state and illustrating how the elastically expanded sections expand to provide sealing to the trachea in accordance with an exemplary embodiment of the invention;

[00040] FIG. 16 shows side view of a distal end portion of an endotracheal tube in accordance with another exemplary embodiment of the invention. The cuff is shown in a fully inflated or filled position;

[00041] FIG. 17 shows the distal end portion of FIG. 16 and illustrates the elastically expandable sections before they are elastically expanded in accordance with an exemplary embodiment of the invention. FIG. 7 also illustrates how the elastically expandable and non-elastically expandable sections are not visually discernable when the cuff is partially filled and/or inflated to an initial state;

[00042] FIG. 18 shows side view of a distal end portion of an endotracheal tube in accordance with another exemplary embodiment of the invention. The cuff is shown in a fully inflated or filled position;

[00043] FIG. 19 shows the distal end portion of FIG. 18 and illustrates the elastically expandable sections before they are elastically expanded in accordance with an exemplary embodiment of the invention. FIG. 19 also illustrates how the elastically expandable and non-elastically expandable sections are visually discernable (one section with crosshatching and other sections without crosshatching) when the cuff is partially filled and/or inflated to an initial state;

[00044] FIG. 20 shows an enlarged partial side cross-section view of a cuff portion of an endotracheal tube in accordance with another exemplary embodiment of the invention. This embodiment illustrates how the center non-elastically expandable section is formed by a thicker wall thickness than the outer elastically expandable sections;

[00045] FIG. 21 shows an enlarged partial side cross-section view of a cuff portion of an endotracheal tube in accordance with another exemplary embodiment of the invention. This embodiment illustrates how the center non-elastically expandable section is formed by using a reinforcing ring and/or layer of non-elastically expandable material over a center section of the cuff so as to prevent the center area from expanding elastically; and

[00046] FIG. 22 shows a side view of a distal end portion of an endotracheal tube in accordance with another exemplary embodiment of the invention. In this embodiment, the center area is elastically expandable when the cuff is in the fully inflated state and the outer areas of the cuff are not elastically expandable in the fully inflated position.

DETAILED DESCRIPTION OF THE INVENTION

[00047] The following description should be read with reference to the drawings, in which like elements in different drawings are identically numbered. The drawings, which are

not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. The detailed description illustrates by way of example, not by way of limitation, the principles of the invention. This description will enable one skilled in the art to make and use the invention, and describes several embodiments, adaptations, variations, alternatives and uses of the invention, including what is presently believed to be the best mode of carrying out the invention.

[00048] As used herein, the reference terms "proximal" and "distal" (proximal being closer than distal) refer to proximity with respect to a health care professional inserting the endotracheal tube into a patient. For example, the region or section of the endotracheal tube that is closest to the health care professional during insertion is referred to herein as "proximal," while a region or section of the endotracheal tube closest to the patient's lungs is referred to as "distal."

[00049] FIGS. 6-22 show non-limiting or exemplary embodiments of the invention wherein like numbers refer to same and like parts. Different embodiments generally utilize reference numbers increased by ten for similar/comparable features. For example, devices labeled with 4, 14, 24, 34, etc., all relate to comparable devices, i.e., a main tube. The present invention broadly relates to medical tubes (e.g., endotracheal, tracheostomy, or oropharyngeal tubes or other tubes or catheters) adapted to be intubated into one or more passageways (e.g., the trachea and/or pharynx) of a patient, subject or user in connection with a medical procedure. For example, certain embodiments are directed toward endotracheal tubes inserted into a subject's trachea to facilitate mechanical ventilation of the lungs. Certain embodiments include tubes having an improved configuration for periodic removal of fluids and/or solids that collect adjacent an inflatable cuff used to seal, secure, and/or position the tube against the tracheal wall. The endotracheal tube of the invention, in embodiments, includes at least one cuff that has one or more portions or sections that can be elastically expanded and having one or more portions that are not elastically expandable that advantageously seals to the trachea while minimizing the possibility of causing injury to the tracheal mucosa. As used throughout this document, the terms "subject", "patient" or "user" may include any human or other animal. Furthermore, the term "non-elastically expandable" in relation to a cuff section, area or portion generally means that the cuff can inflate and expand upon inflation, but the wall does not significantly expand elastically or experience significant deformation. An example, would be a foil (e.g., Mylar®) balloon which expands

upon inflation, but does not experience significant elastic expansion when pressure is increased. The term “elastically expandable” in relation to a cuff section, area or portion generally means that the cuff can inflate and expand upon inflation. However, the wall also experiences deformation, i.e., thinning, like a rubber band and therefore expands elastically when pressure in the cuff is increased. An example, would be a rubber or latex balloon which expands upon inflation, and also experience significant elastic expansion when pressure is increased. Additionally, the term “overall inflatable length” is generally an axial length of the portion of the cuff which can be inflated and which generally excludes the portions of the cuff which are adhered to the main tube and which project out beyond the portion of the cuff which can be inflated.

[00050] With reference to FIGS. 6-13, there is shown one non-limiting embodiment of an endotracheal tube in accordance with the invention. Like the embodiment shown in FIGS. 1-5, the embodiment of FIGS. 6-13 has a proximal end, a distal end, a main tube **14**, a connector for interfacing with a respiration source, an inflation lumen, a cuff **18**, a suction aperture **19**, and optionally a radiopaque stripe. An inflation device is used to cause inflation of the cuff **18** by passing a gas through a tube and into the main tube **14**.

[00051] Unlike the ET tube of FIGS. 1-5, however, in embodiments, the invention shown in FIGS. 6-13 utilizes a cuff **18** which includes a center section or area **18a** having different expansion characteristics from that of a distal section or area **18b** and a proximal section or area **18c**. In embodiments, the section **18a** is non-elastically expandable so that once the cuff **18** is initially inflated (see FIGS. 6-8), a pressure increase inside the cuff **18** will not cause the section **18a** to significantly expand circumferentially (see FIG. 9). The sections **18b** and **18c**, in contrast, are elastically expandable so that once the cuff **18** is initially inflated (see FIGS. 6-8), a pressure increase inside the cuff **18** will cause the sections **18b** and **18c** to significantly expand circumferentially (see FIG. 9).

[00052] In embodiments, the center section **18a** can be made non-elastically expandable relative to sections **18b** and **18c** by making the section **18a** so as to have a thicker wall as shown in FIG. 8. In embodiments, the center section **18a** can also be made non-elastically expandable relative to sections **18b** and **18c** by making the section **18a** have different, i.e., greater, tensile properties relative to sections **18b** and **18c**. In embodiments, the center section **18a** can also be made non-elastically expandable relative to sections **18b** and **18c** by subjecting the section **18a** to a heat treatment process different from that of

sections **18b** and **18c**. In embodiments, the center section **18a** can also be made non-elastically expandable relative to sections **18b** and **18c** by adding reinforcing material and/or layers to an inside surface of the section **18a** which results in this section having different, i.e., greater, tensile properties than that of sections **18b** and **18c**.

[00053] As is shown in FIGS. 10 and 11, the cuff **18** can have folds **F** when it is uninflated. However, once it is initially inflated (see FIGS. 6-8), each section **18a**, **18b** and **18c** of the cuff **18** can assume the configuration of that used in conventional cuffs (see, e.g., FIGS. 2-3). However, unlike conventional cuffs, the inventive cuff **18** utilizes section **18b** and **18c** which can experience further expansion, i.e., elastic expansion (see, e.g., FIG. 9) when the pressure is increased within cuff **18**. At the same time, the cuff **18** utilizes a center section **18a** that does not expand significantly when pressure is increased in the cuff **18**.

[00054] As is apparent from FIGS. 12 and 13, the cuff **18** has the advantage that it can be inflated to the initial configuration shown in FIGS. 6 and 7 while in the trachea **T** without sealing to the trachea **T** (see FIG. 12). However, when the cuff **18** is further inflated beyond the initial configuration shown in FIGS. 6 and 7, the sections **18b** and **18c** experience further expansion, i.e., elastic expansion, and provide sealing to the trachea **T** (see FIG. 13). Furthermore, this occurs without the center section **18a** expanding significantly when pressure is increased in the cuff **18**. An advantage of this configuration is that it can provide sealing between the cuff **18** and the trachea **T** with less pressure exerted on the trachea wall as compared to conventional cuffs of the type shown in FIGS. 1-5.

[00055] With reference to FIG. 14, there is shown another non-limiting embodiment of an endotracheal tube in accordance with the invention. Like the embodiment shown in FIGS. 1-5, the embodiment of FIG. 6-13 has a proximal end, a distal end, a main tube **24**, a connector for interfacing with a respiration source, an inflation lumen, a cuff **28**, a suction aperture **29**, and optionally a radiopaque stripe. An inflation device is used to cause inflation of the cuff **28** by passing a gas through a tube and into the main tube **24**.

[00056] Unlike the ET tube of FIGS. 1-5, however, in embodiments, the invention shown in FIGS. 14-15, like that of FIGS. 6-13, utilizes a cuff **28** which includes a center section or area **28a** having different expansion characteristics from that of a distal section or area **28b** and a proximal section or area **28c**. In embodiments, the section **28a** is non-elastically expandable so that once the cuff **28** is initially inflated, a pressure increase inside

the cuff **28** will not cause the section **28a** to significantly expand circumferentially, except to the extent that it is arranged in a trachea **T** that is smaller in size than the initially inflated section **28a** (see FIG. 14). The sections **28b** and **28c**, in contrast, are elastically expandable so that once the cuff **28** is initially inflated, a pressure increase inside the cuff **18** will cause the sections **28b** and **28c** to significantly expand circumferentially.

[00057] In embodiments, as with the previously described embodiment, the center section **28a** can be made non-elastically expandable relative to sections **28b** and **28c** by making the section **28a** so as to have a thicker wall (similar to that shown in FIG. 8). In embodiments, the center section **28a** can also be made non-elastically expandable relative to sections **28b** and **28c** by making the section **28a** have different, i.e., greater, tensile properties relative to sections **28b** and **28c**. In embodiments, the center section **28a** can also be made non-elastically expandable relative to sections **28b** and **28c** by subjecting the section **28a** to a heat treatment process different from that of sections **28b** and **28c**. In embodiments, the center section **28a** can also be made non-elastically expandable relative to sections **28b** and **28c** by adding reinforcing material and/or layers to an inside surface of the section **28a** which results in this section having different, i.e., greater, tensile properties than that of sections **28b** and **28c**.

[00058] As is suggested in FIG. 14, the cuff **28** can have folds **F** when it is un-inflated. However, once it is initially inflated, each section **28a**, **28b** and **28c** of the cuff **28** can assume the configuration of that used in conventional cuffs such that the folds **F** do not disappear when the cuff **28** is initially inflated in the trachea **T** (see FIG. 14). However, unlike conventional cuffs, the inventive cuff **28** utilizes section **28b** and **28c** which can experience further expansion, i.e., elastic expansion when the pressure is increased within cuff **28** (see FIG. 15). As is apparent from FIG. 15, this further or elastic expansion of the section **28b** and **28c** eliminates the folds **F** in these sections and provide sealing to the trachea **T** even though folds **F** still exist in the center section **28a**. Furthermore, even if the center section **28a** expands further to the point of eliminating the folds **F** in section **28a**, the section **28a** does not expand significantly beyond the point of fold elimination when pressure is increased in the cuff **28** due to the fact that section **28a** is made non-elastically expandable.

[00059] As is apparent from FIGS. 14 and 15, the cuff **28** has the advantage that it can be inflated to the initial configuration shown in FIG. 14 while in the trachea **T** without providing proper sealing to the trachea **T**, i.e., the folds **F** will form leakage points. However,

when the cuff **28** is further inflated beyond the initial configuration shown in FIG. 14, the sections **28b** and **28c** experience further expansion, i.e., elastic expansion, and provide sealing to the trachea **T** (see FIG. 15). Furthermore, this can occur with or without the center section **28a** expanding significantly when pressure is increased in the cuff **28**. An advantage of this configuration is that it can provide sealing between the cuff **28** and the trachea **T** with less pressure exerted on the trachea wall as compared to conventional cuffs of the type shown in FIGS. 1-5.

[00060] FIGS. 16-17, show how, in embodiments, the cuff **38** can have elastically expandable sections **38b** and **38c** and a non-elastically expandable section **38a** need not be visually discernable when the cuff **38** is partially filled and/or inflated to an initial state (see FIG. 17). The elastically expandable sections **38b** and **38c** and the non-elastically expandable section **38a** would be discernable only when the cuff **38** experiences further inflation (see FIG. 16).

[00061] FIGS. 18-19, show how, in embodiments, the cuff **48** can have elastically expandable sections **48b** and **48c** and a non-elastically expandable section **48a** which are visually discernable (as represented by the crosshatching) when the cuff **48** is partially filled and/or inflated to an initial state (see FIG. 19). The elastically expandable sections **48b** and **48c** and the non-elastically expandable section **48a** remain visually discernable when the cuff **48** experiences further inflation (see FIG. 18).

[00062] With reference to FIG. 20, in embodiments, as with the previously described embodiments, the cuff **58** can also utilize a center section **58a** that is made non-elastically expandable relative to sections **58b** and **58c** by making the section **58a** so as to have a thicker wall. In embodiments, the center section **58a** can also be made non-elastically expandable relative to sections **58b** and **58c** by making the section **58a** have different, i.e., greater, tensile properties relative to sections **58b** and **58c**. In embodiments, the center section **58a** can also be made non-elastically expandable relative to sections **58b** and **58c** by subjecting the section **58a** to a heat treatment process different from that of sections **58b** and **58c**. In embodiments, the center section **58a** can also be made non-elastically expandable relative to sections **58b** and **58c** by adding reinforcing material and/or layers to an outside surface of the section **58a** which results in this section having different, i.e., greater, tensile properties than that of sections **58b** and **58c**. In this latter case, the cuff **58** would more advantageously be used in the manner depicted in FIGS. 12 and 13 so that the center section **58a** does not exert substantially

pressure on the trachea wall under full inflation pressure and/or when the sections **58b** and **58c** experience elastic expansion.

[00063] With reference to FIG. 21, in embodiments, as with the previously described embodiments, the cuff **68** can also utilize a center section **68a** that is made non-elastically expandable relative to sections **68b** and **68c** by making the section **68a** so as to have a thicker wall. In embodiments, the center section **68a** can also be made non-elastically expandable relative to sections **68b** and **68c** by adding a different reinforcing material and/or one or more layers to an outside surface of the section **68a** which results in this section having different, i.e., greater, tensile properties than that of sections **68b** and **68c**. In this latter case, the cuff **68** would more advantageously be used in the manner depicted in FIGS. 12 and 13 so that the center section **68a** does not exert substantially pressure on the trachea wall under full inflation pressure and/or when the sections **68b** and **68c** experience elastic expansion.

[00064] With reference to FIG. 22, there is shown another non-limiting embodiment of an endotracheal tube in accordance with the invention. Like the embodiment shown in FIGS. 1-5, the embodiment of FIG. 22 has a proximal end, a distal end, a main tube **74**, a connector for interfacing with a respiration source, an inflation lumen, a cuff **78**, a suction aperture, and optionally a radiopaque stripe. An inflation device is used to cause inflation of the cuff **78** by passing a gas through a tube and into the main tube **74**.

[00065] Unlike the ET tube of FIGS. 1-5, however, in embodiments, the invention shown in FIG. 22 utilizes a cuff **78** which includes a center section or area **78a** having different expansion characteristics from that of a distal section or area **78b** and a proximal section or area **78c**. In embodiments, the section **78a** is elastically expandable so that once the cuff **78** is initially inflated, a pressure increase inside the cuff **78** will cause the section **78a** to significantly expand circumferentially (see FIG. 22). The sections **78b** and **78c**, in contrast, are non-elastically expandable so that once the cuff **78** is initially inflated, a pressure increase inside the cuff **78** will not cause the sections **78b** and **78c** to significantly expand circumferentially (see FIG. 22).

[00066] In embodiments, the sections **78b** and **78c** can be made non-elastically expandable relative to section **78a** by making the sections **78b** and **78c** so as to have a thicker wall. In embodiments, the sections **78b** and **78c** can also be made non-elastically expandable relative to section **78a** by making the sections **78b** and **78c** have different, i.e., greater, tensile

properties relative to section **78a**. In embodiments, the sections **78b** and **78c** can also be made non-elastically expandable relative to section **78a** by subjecting the sections **78b** and **78c** to a heat treatment process different from that of section **78a**. In embodiments, the sections **78b** and **78c** can also be made non-elastically expandable relative to section **78a** by adding reinforcing material and/or layers to an inside surface of the sections **78b** and **78c** which results in these sections having different, i.e., greater, tensile properties than that of section **78a**. Alternatively, in embodiments, the sections **78b** and **78c** can also be made non-elastically expandable relative to section **78a** by adding reinforcing material and/or layers to an outside surface of the sections **78b** and **78c** which results in these sections having different, i.e., greater, tensile properties than that of section **78a**.

[00067] In embodiments, the suction aperture, e.g., aperture **19**, used in the embodiments can be arranged about 8 mm from an end of the cuff and, in embodiments, is arranged on the portion of the cuff that is glued to the main tube. In these and other embodiments discussed herein, other distances can also be utilized provided they function to remove secretions and do not otherwise interfere with the proper functioning or use of the cuff.

[00068] In embodiments, the main tube can be a one-piece member whereby the suction lumen and the inflation lumen, also optionally the radiopaque stripe (not shown), are integrally formed therewith. By way of non-limiting example, the main tube can be made of any medical grade plastic and can be generally circular in cross-section shape. Alternatively, the main tube can have other shapes such as oval. In embodiments, the ventilation lumen can be generally non-circular in cross-section shape. Alternatively, the ventilation lumen can have other shapes. In embodiments, the suction lumen can be generally oval in cross-section shape. Alternatively, the suction lumen can have other shapes such as circular. In embodiments, the inflation lumen can be generally circular in cross-section shape. Alternatively, the inflation lumen can have other shapes.

[00069] The main tube member may, in embodiments, be constructed from a suitable polymeric material, such as polyvinyl chloride, polyethylene or polypropylene, with PVC being advantageous. The components of the assembly disclosed herein can also be made from various well-known materials. The components the main tube can be molded or extruded according to well-known manufacturing techniques.

[00070] Materials commonly used to make the main tube member include, but are not limited to thermoplastic polymers and thermoplastic elastomers (TPE). In embodiments, materials which are environmentally green in nature and have no extractables can be utilized. Other materials include, but are not limited to natural rubber latexes (available, for example, from Guthrie, Inc., Tucson, Ariz.; Firestone, Inc., Akron, Ohio; and Centrotrade USA, Virginia Beach, Va.), silicones (available, for example, from GE Silicones, Waterford, N.Y., Wacker Silicones, Adrian, Mich.; and Dow Corning, Inc., Midland, Mich.), polyvinyl chlorides (available, for example, from Kaneka Corp., Inc., New York, N.Y.), polyurethanes (available, for example, from Bayer, Inc., Toronto, Ontario, Rohm & Haas Company, Philadelphia, Pa.; and Ortec, Inc., Greenville, S.C.), plastisols (available, for example, from G S Industries, Bassett, Va.), polyvinyl acetate, (available, for example from Acetex Corp., Vancouver, British Columbia) and methacrylate copolymers (available, for example, from Heveatex, Inc., Fall River, Mass.). Any combination of the foregoing materials may also be used in making ET tubes.

[00071] The invention also provides for a method for intubation using the assembly of FIGS. 6-22, which includes inserting at least a distal portion of the endotracheal tube into a trachea, inflating the cuff until it provides sealing to the trachea as disclosed herein, and supplying gas into a patient's lungs via the endotracheal tube. The method can further include suctioning matter through the one or more suction apertures located in a cuff recess.

[00072] The invention also provides for a method of making a device for intubation shown FIGS. 6-22, and specifically making and/or assembling on the main tube a cuff of the type disclosed herein. The cuff can be formed in various non-limiting ways such as, e.g., by blow molding, so as to have the different and/or elastically and non-elastically expandable sections. In embodiments, a blow mold can be created and/or modified so that the cuff has the configurations shown in the drawings.

[00073] The wall of the cuff(s) can be formed by adding reinforcing layer(s) to certain surface(s) of the cuff wall and/or removing sections of a multi-layered wall. Alternatively, the wall can be extruded or molded with different and/or elastically and non-elastically expandable sections formed therein.

[00074] The invention has been described and specific examples of the invention have been portrayed. While the invention has been described in terms of particular variations and

illustrative figures, those of ordinary skill in the art will recognize that the invention is not limited to the variations of figures described. In addition, where methods and steps described above indicate certain events occurring in certain order, those of ordinary skill in the art will recognize that the ordering of certain steps may be modified and that such modifications are in accordance with the variations of the invention. Additionally, certain of the steps may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Therefore, to the extent there are variations of the invention, which are within the spirit of the disclosure or equivalent to the inventions found in the claims, it is the intent that this patent will cover those variations as well. Finally, all publications and patent applications cited in this specification are herein incorporated by reference in their entirety as if each individual publication or patent application were specifically and individually put forth herein.

[00075] It is noted that the foregoing examples have been provided merely for the purpose of explanation and are in no way to be construed as limiting of the present invention. While the present invention has been described with reference to an exemplary embodiment, it is understood that the words which have been used herein are words of description and illustration, rather than words of limitation. Changes may be made, within the purview of the appended claims, as presently stated and as amended, without departing from the scope and spirit of the present invention in its aspects. Although the present invention has been described herein with reference to particular means, materials and embodiments, the present invention is not intended to be limited to the particulars disclosed herein; rather, the present invention extends to all functionally equivalent structures, methods and uses, such as are within the scope of the appended claims.

CLAIMS

What is claimed is:

1. An endotracheal tube, comprising:
 - a main tube including a proximal end and a distal end;
 - an inflatable cuff arranged on the main tube; and
 - at least one of:
 - the cuff having one or more portions or sections that can be elastically expanded and one or more portions or section that are not elastically expandable;
 - the cuff having a center area or region that is smaller than a trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall;
 - the cuff having a center area or region that is smaller than a trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are tapered so as to decrease in size from the center area and towards each end of the cuff;
 - the cuff having a center area or region that is larger than the trachea in its pre-formed state and outer areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall;
 - the cuff having a center area or region that is larger than the trachea in its pre-formed state and outer areas or regions that are tapered so as to decrease in size from the center area and towards each end of the cuff;
 - the cuff having a center area or region that is larger than the trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are smaller than the trachea and are tapered so as to decrease in size from the center area and towards each end of the cuff, but which can expand elastically to seal against the trachea wall;
 - the cuff having an area or region that is larger than the trachea in its filled but non-elastically expandable state and one or more other areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall, wherein the area that is

- larger than the trachea can seal to the trachea without elastic expansion or deformation and the one or more smaller elastically expandable areas seal to the trachea without folds;
- the cuff having a center area or region that is smaller than a trachea in its pre-formed state and elastically expandable to seal against the trachea wall and outer areas or regions that are smaller than the trachea, but which are not elastically expandable;
- the cuff having a larger non-elastically expandable center area and smaller tapered end areas which, upon inflation, can expand elastically to a circumference that is greater than the center area;
- the cuff having a center area or region that is peripherally and/or circumferentially smaller than a trachea in its pre-formed state and elastically expandable to seal against the trachea wall and outer areas or regions that are peripherally and/or circumferentially smaller than the trachea, but which are not elastically expandable; and
- the cuff having a peripherally and/or circumferentially larger non-elastically expandable center area and peripherally and/or circumferentially smaller tapered end areas which, upon inflation, can expand elastically to a circumference that is greater than the center area.

2. The endotracheal tube of claim 1, wherein the cuff is smaller than a tracheal circumference but larger than a circumference of the main tube when it is in a filled but not elastically expanded state.

3. The endotracheal tube of claim 1, wherein the cuff is made from a material that expands elastically to allow the cuff to be expanded to fill and seal the trachea.

4. The endotracheal tube of claim 3, wherein the material comprises one of PVC, polyurethane, silicone, blends thereof, composites thereof, and copolymers thereof.

5. The endotracheal tube of claim 3, wherein the cuff, in its filled but un-elastically deformed state, is between about 20% and about 30% smaller than a circumference of the trachea.

6. The endotracheal tube of claim 1, wherein the inflatable cuff has tapered distal and proximal ends.
7. The endotracheal tube of claim 1, wherein the inflatable cuff has a generally circular cross-sectional shape.
8. The endotracheal tube of claim 1, wherein the inflatable cuff comprises at least two spaced-apart elastically expandable sections.
9. The endotracheal tube of claim 1, wherein a center area or region has an axial length that is between about 10% and about 25% of an overall axial length of the cuff.
10. The endotracheal tube of claim 1, wherein a non-elastically expandable section of the cuff has an axial length that is between about 10% and about 25% of an overall axial length of the cuff.
11. The endotracheal tube of claim 1, wherein the inflatable cuff is arranged on the main tube and spaced from the distal end by an amount that is less than a spacing from the proximal end.
12. The endotracheal tube of claim 1, wherein the main tube comprises at least one integrally formed suction lumen which extends to at least one suction aperture.
13. The endotracheal tube of claim 1, wherein the main tube comprises at least one integrally formed inflation lumen which extends to at least one aperture for inflating the cuff.
14. The endotracheal tube of claim 1, wherein the main tube comprises:
 - at least one suction lumen that is arranged on a bending plane of the main tube; and/or
 - at least one non-circular suction lumen that is arranged on a bending plane of the main tube.
15. The endotracheal tube of claim 1, wherein the main tube comprises:
 - a generally circular cross-section shape; or
 - a generally oval cross-section shape.

16. The endotracheal tube of claim 1, further comprising at least one inflation lumen generally oriented on a bending plane of the main tube.

17. An endotracheal tube comprising:

a main tube comprising a proximal end and a distal end;

an inflatable cuff arranged on the main tube; and

at least one of:

the cuff having a center area or region that is smaller than a trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall;

the cuff having a center area or region that is smaller than a trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are tapered so as to decrease in size from the center area and towards each end of the cuff;

the cuff having a center area or region that is larger than the trachea in its pre-formed state and outer areas or regions that are smaller than the trachea, but which can expand elastically to seal against the trachea wall;

the cuff having a center area or region that is larger than the trachea in its pre-formed state and outer areas or regions that are tapered so as to decrease in size from the center area and towards each end of the cuff;

the cuff having a center area or region that is larger than the trachea in its pre-formed state and non-elastically expandable and outer areas or regions that are smaller than the trachea and are tapered so as to decrease in size from the center area and towards each end of the cuff, but which can expand elastically to seal against the trachea wall;

the cuff having a center area or region that is smaller than a trachea in its pre-formed state and elastically expandable to seal against the trachea wall and outer areas or regions that are smaller than the trachea, but which are not elastically expandable;

the cuff having a larger non-elastically expandable center area and smaller tapered end areas which, upon inflation, can expand elastically to a circumference that is greater than the center area;

the cuff having a center area or region that is peripherally and/or circumferentially smaller than a trachea in its pre-formed state and elastically expandable to seal against the trachea wall and outer areas or regions that are peripherally and/or circumferentially smaller than the trachea, but which are not elastically expandable; and

the cuff having a peripherally and/or circumferentially larger non-elastically expandable center area and peripherally and/or circumferentially smaller tapered end areas which, upon inflation, can expand elastically to a circumference that is greater than the center area.

18. A method for intubation using the endotracheal tube of any one of claims 1-17, the method comprising:

inserting at least a portion of an endotracheal tube into a trachea;

inflating a cuff of the endotracheal tube; and

supplying gas into a patient's lungs via the endotracheal tube.

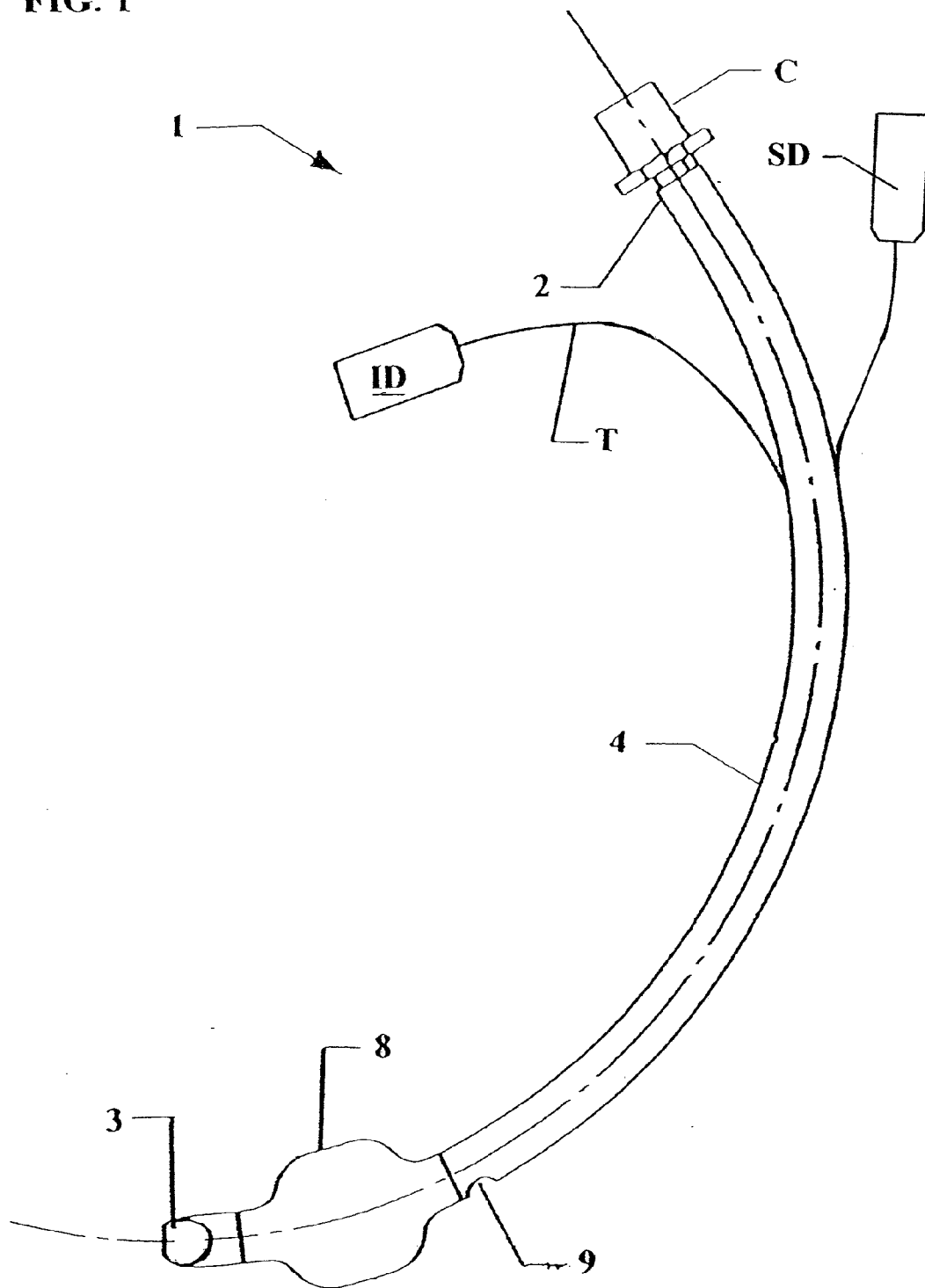
19. The method of claim 18, further comprising suctioning matter through the at least one suction aperture.

20. A method of making the endotracheal tube of any one of claims 1-17, the method comprising:

forming the cuff having one or more portions or sections that can be elastically expanded and one or more portions or section that are not elastically expandable.

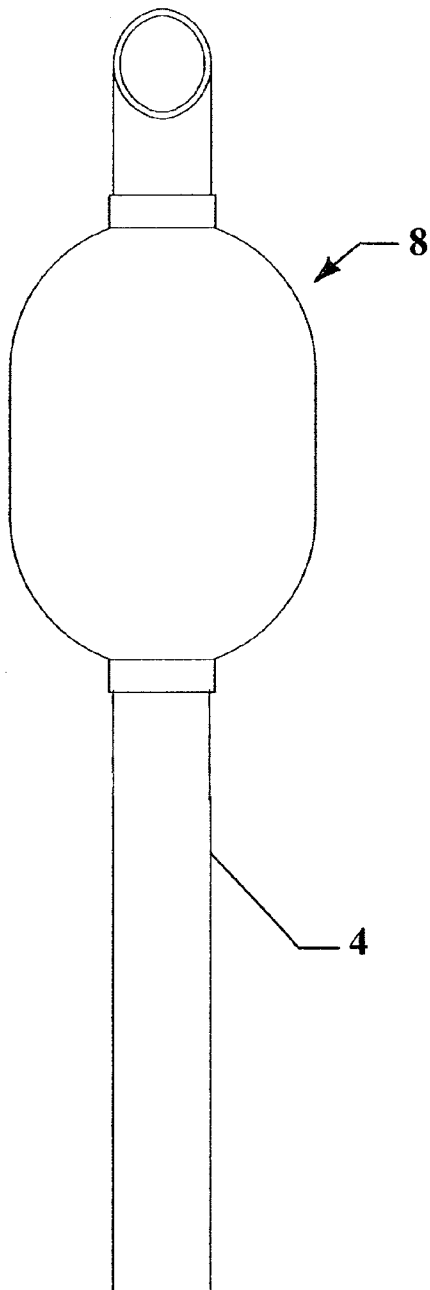
1/16

FIG. 1



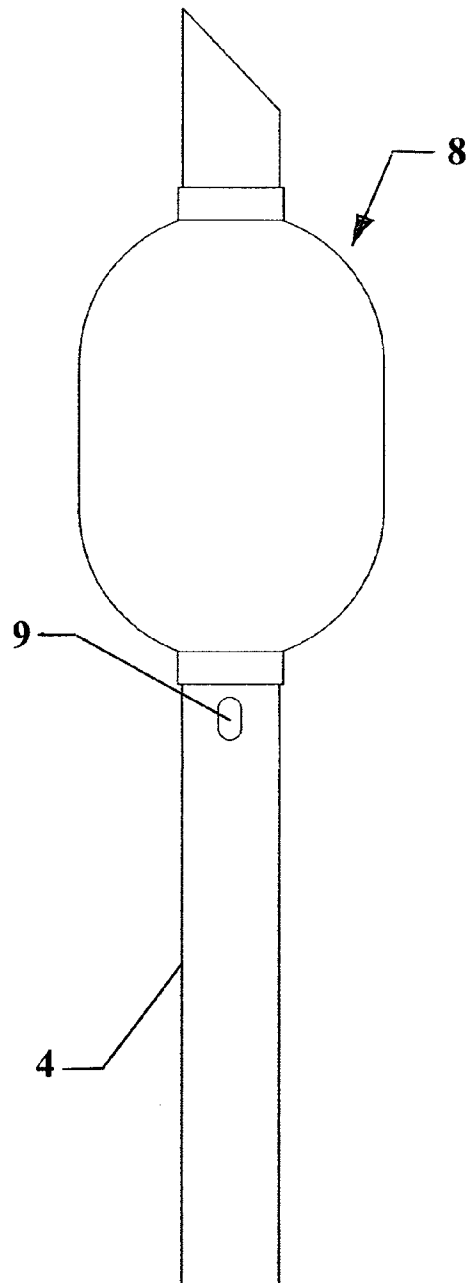
PRIOR ART

FIG. 2



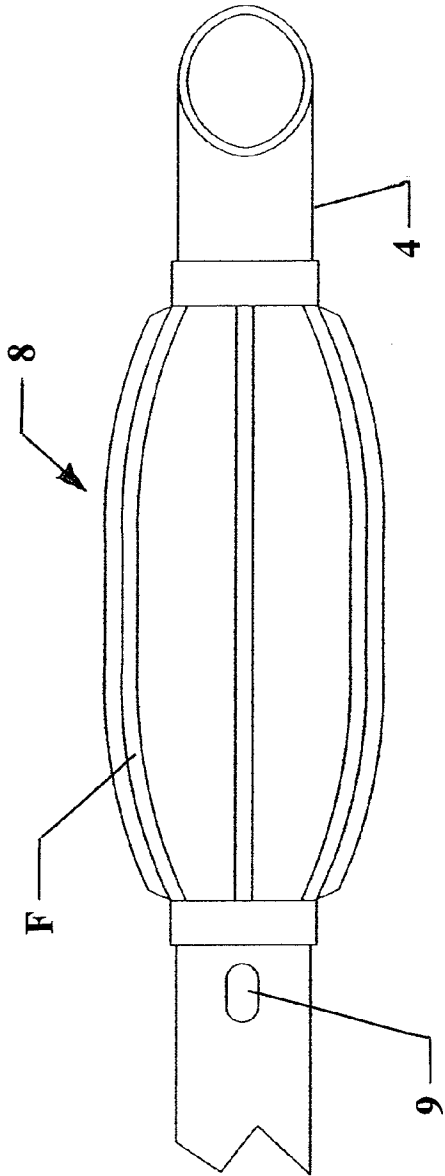
PRIOR ART

FIG. 3



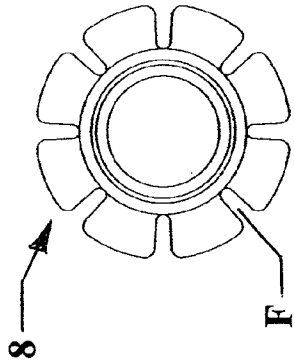
PRIOR ART

FIG. 4



PRIOR ART

FIG. 5



PRIOR ART

FIG. 6

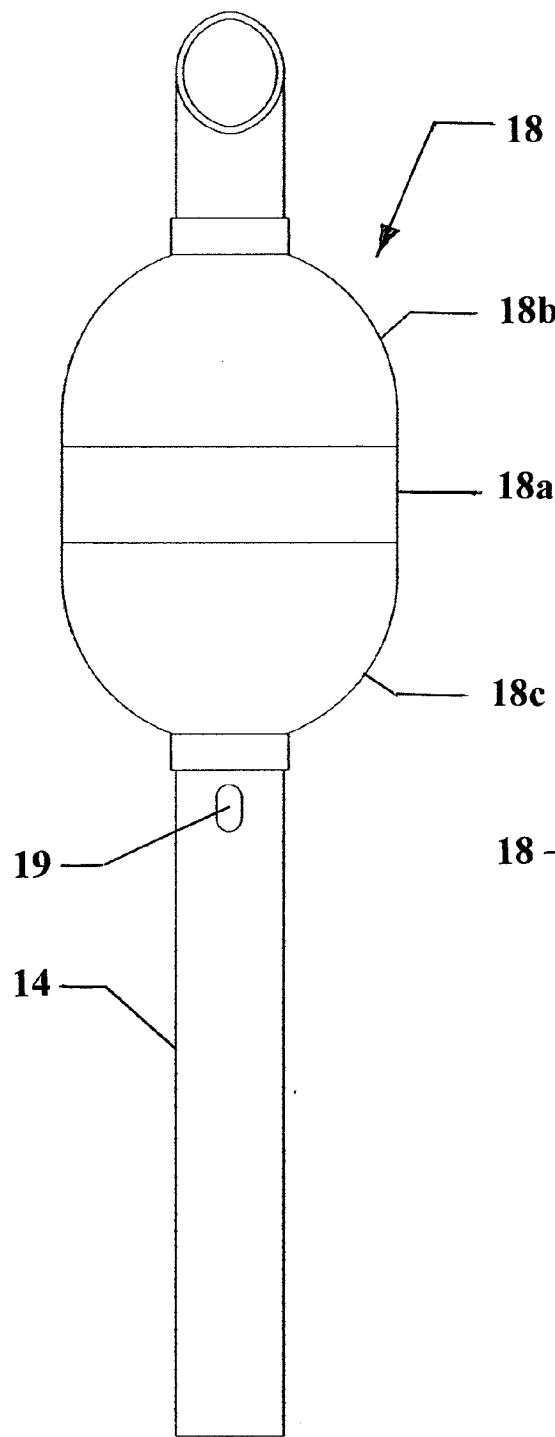
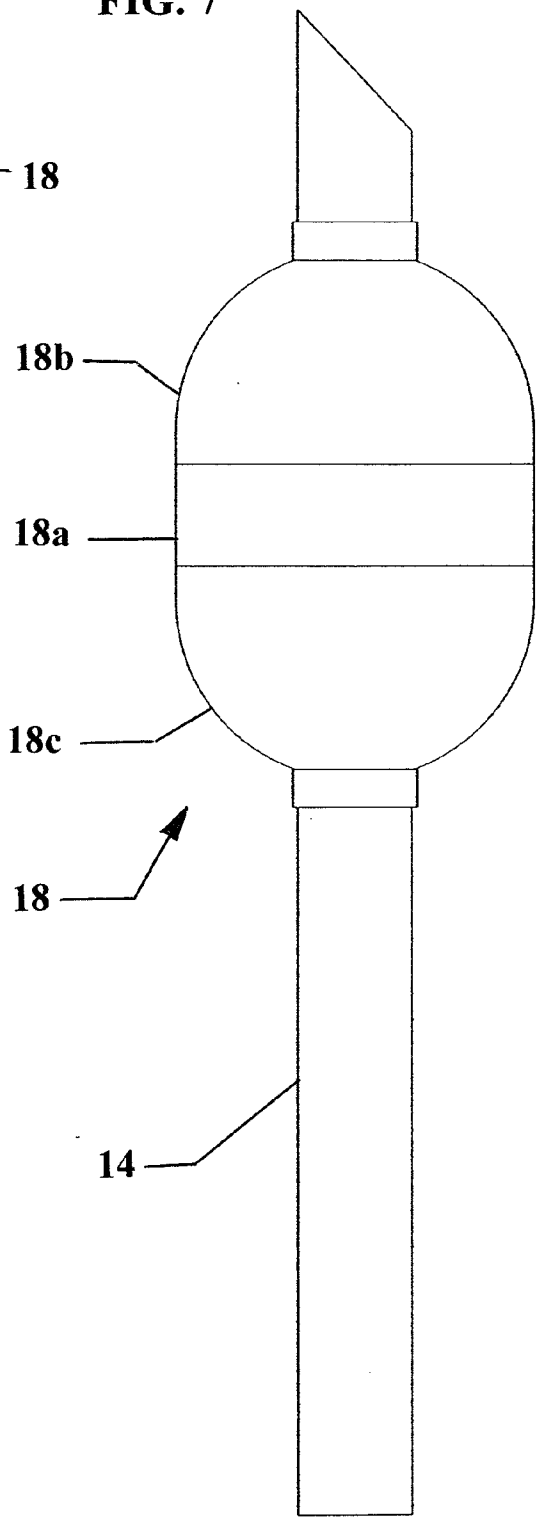


FIG. 7



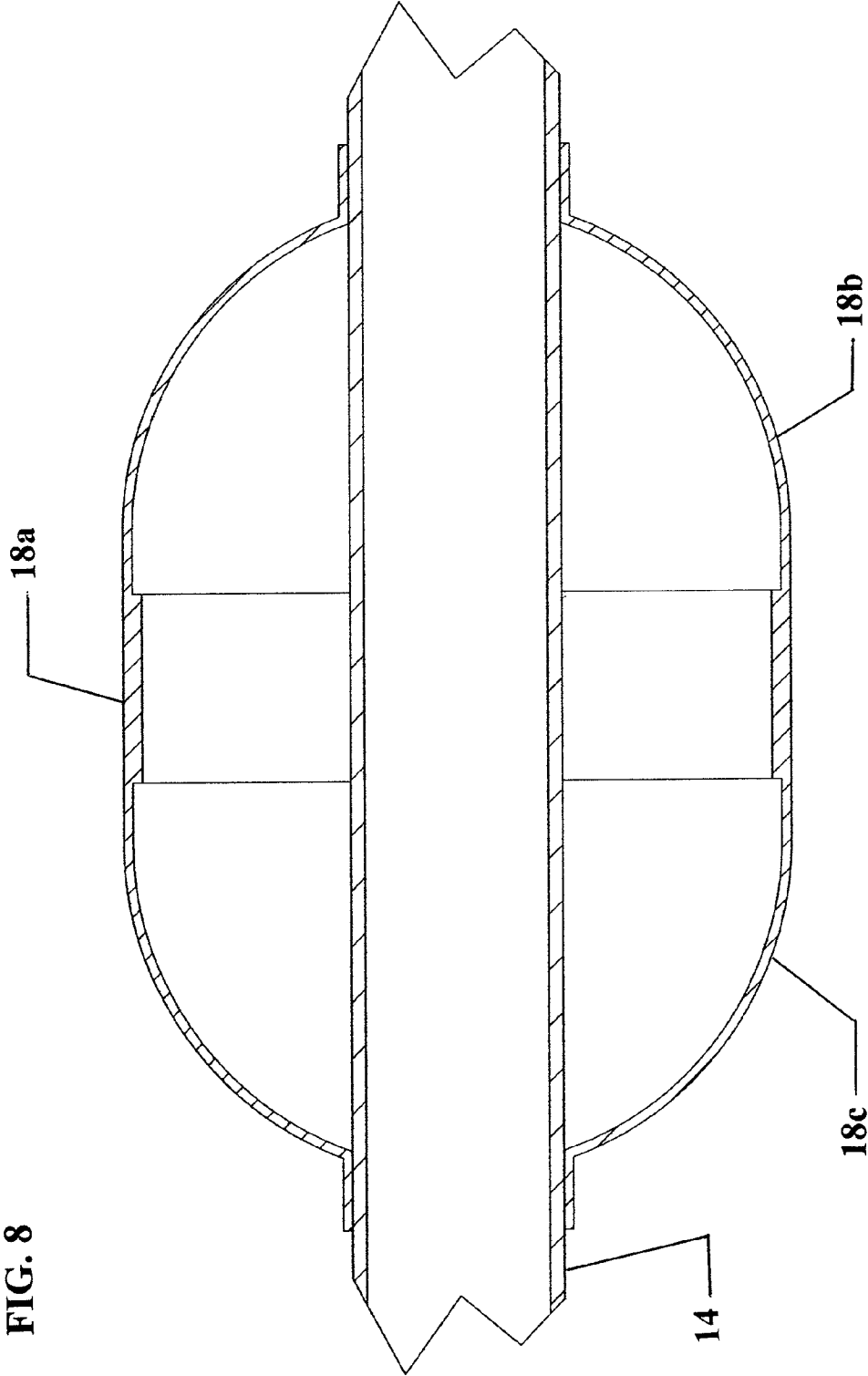


FIG. 9

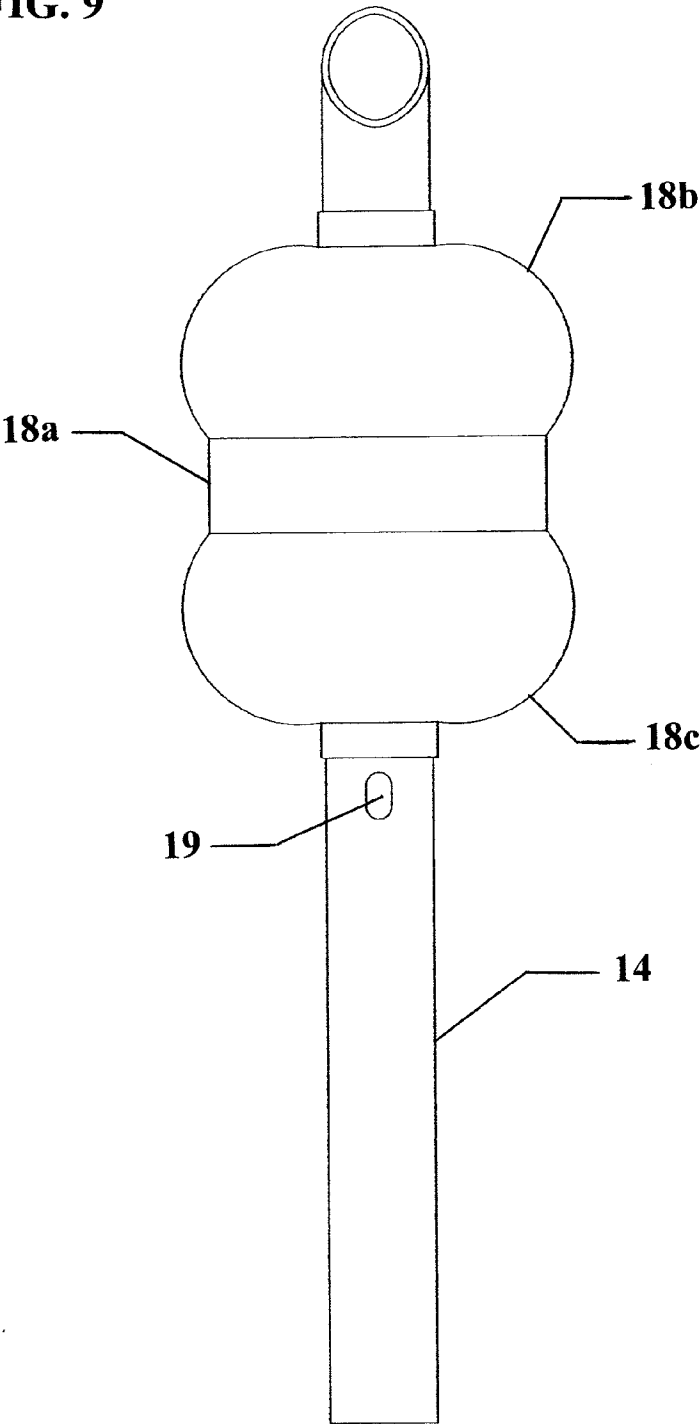


FIG. 11

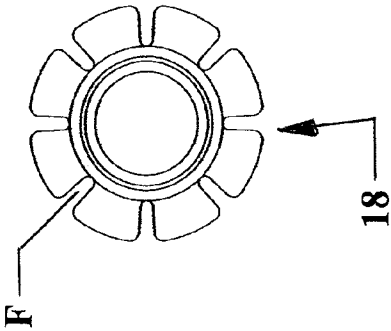


FIG. 10

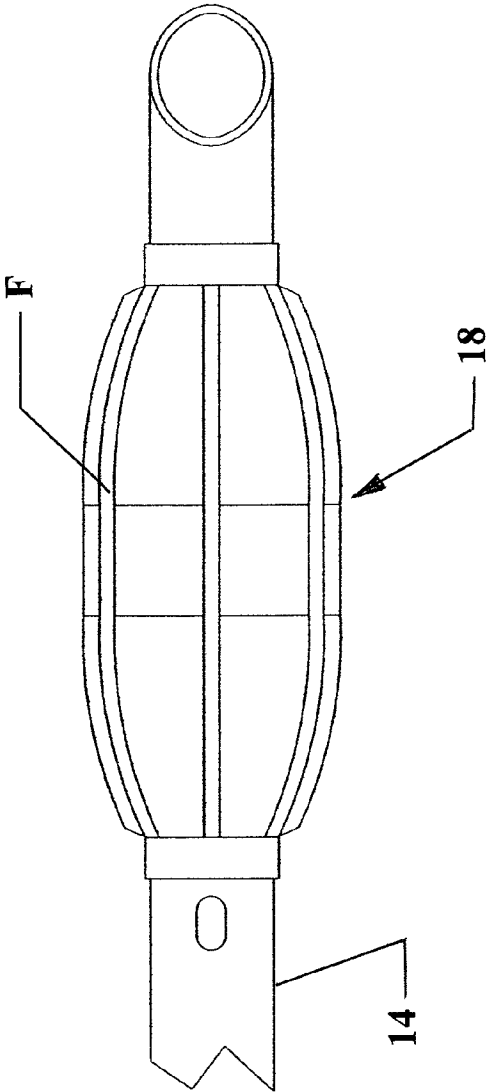


FIG. 12

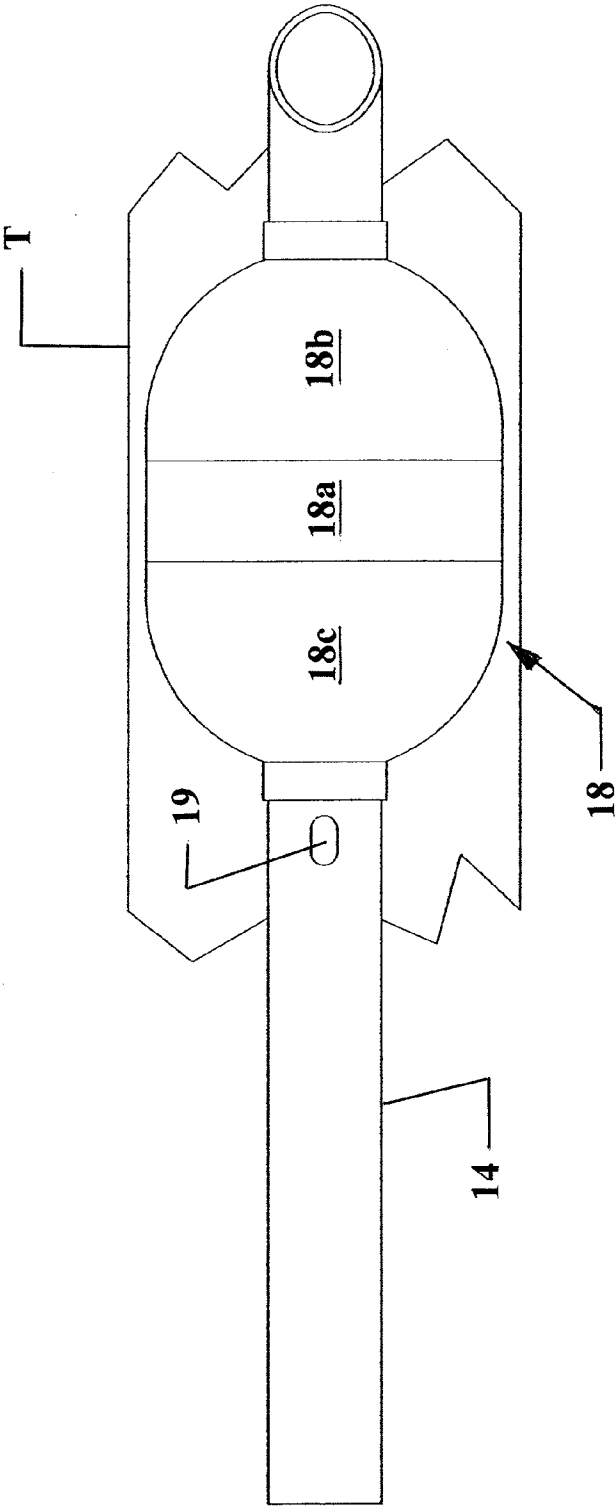


FIG. 13

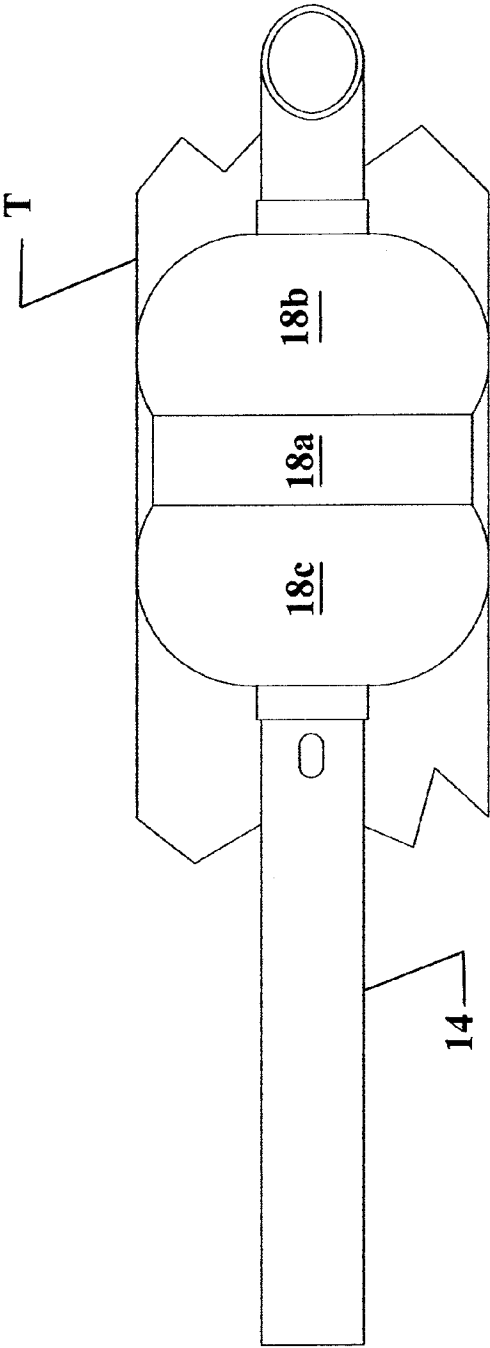


FIG. 14

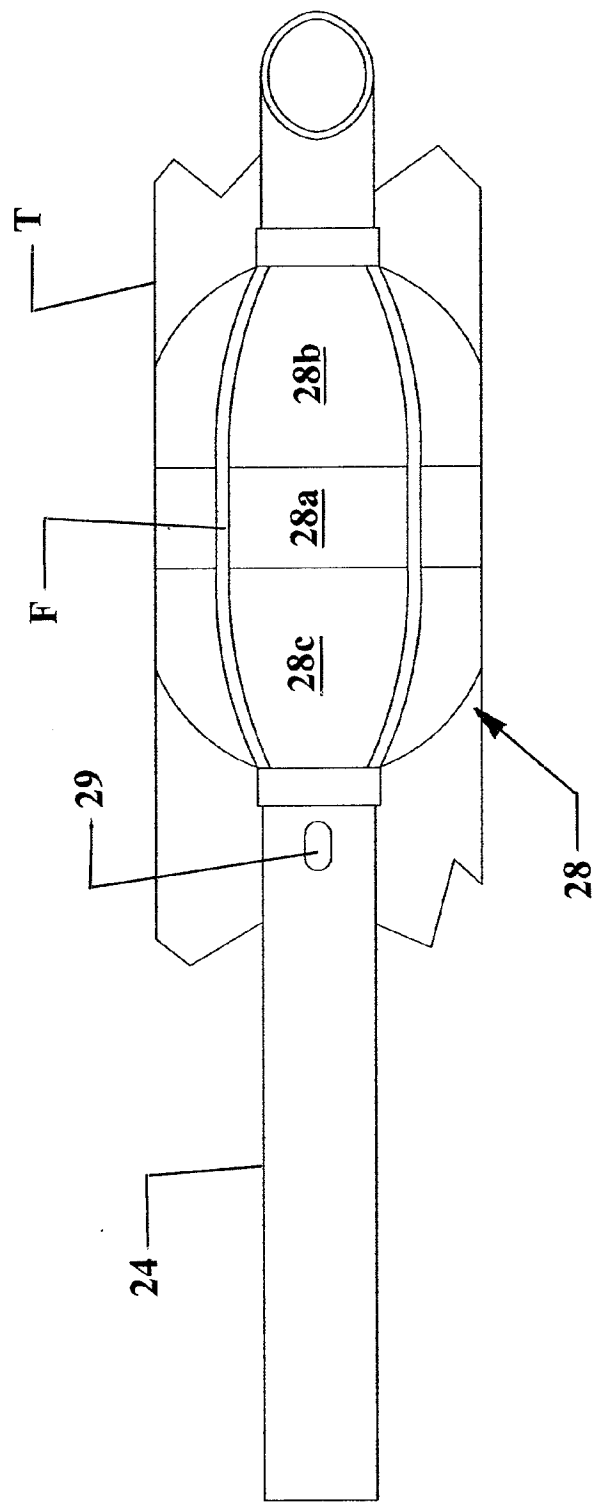
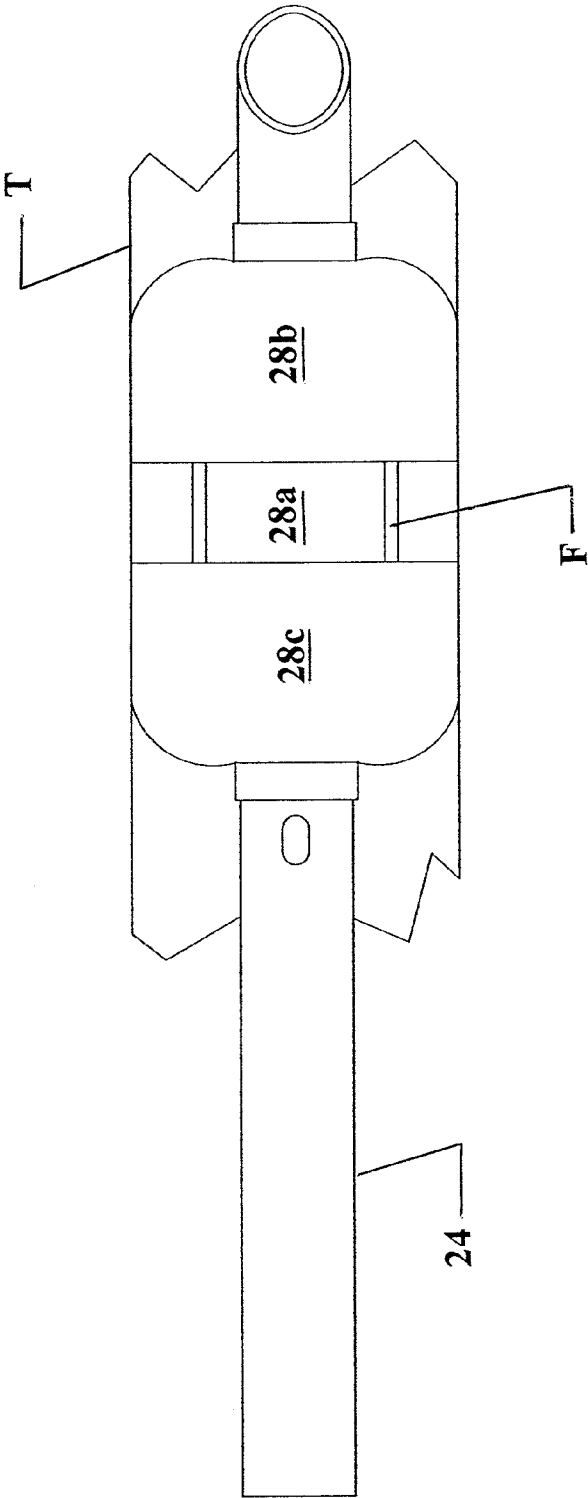


FIG. 15



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FIG. 16

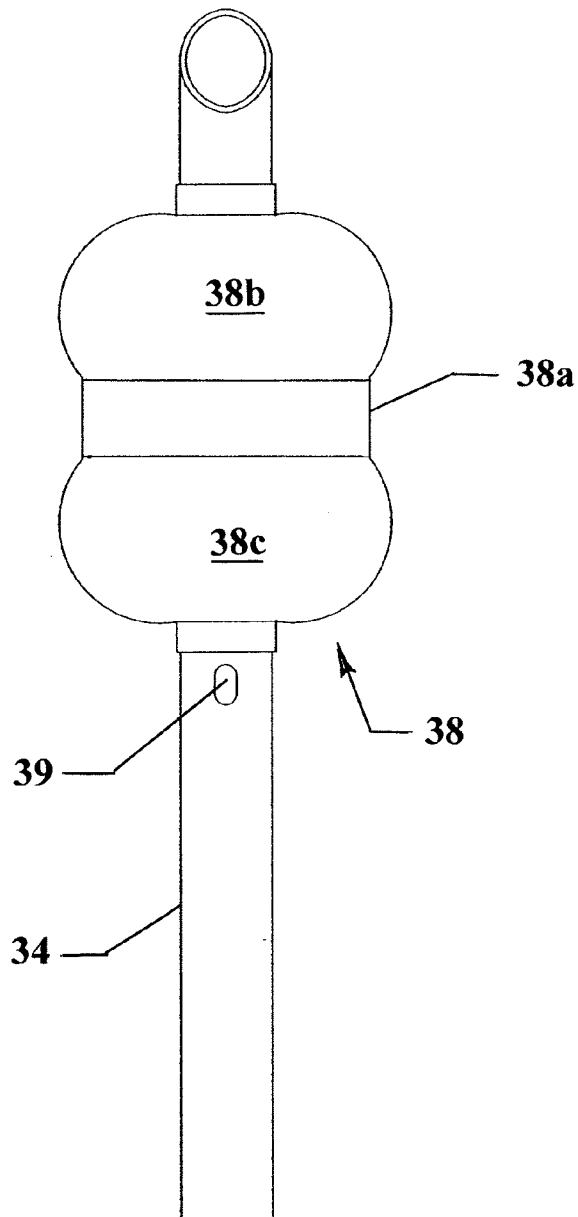


FIG. 17

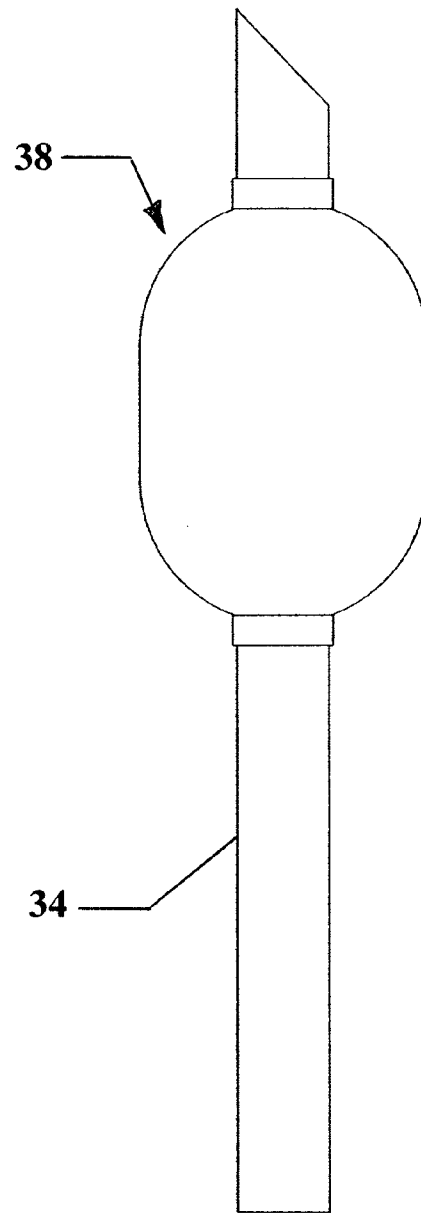


FIG. 18

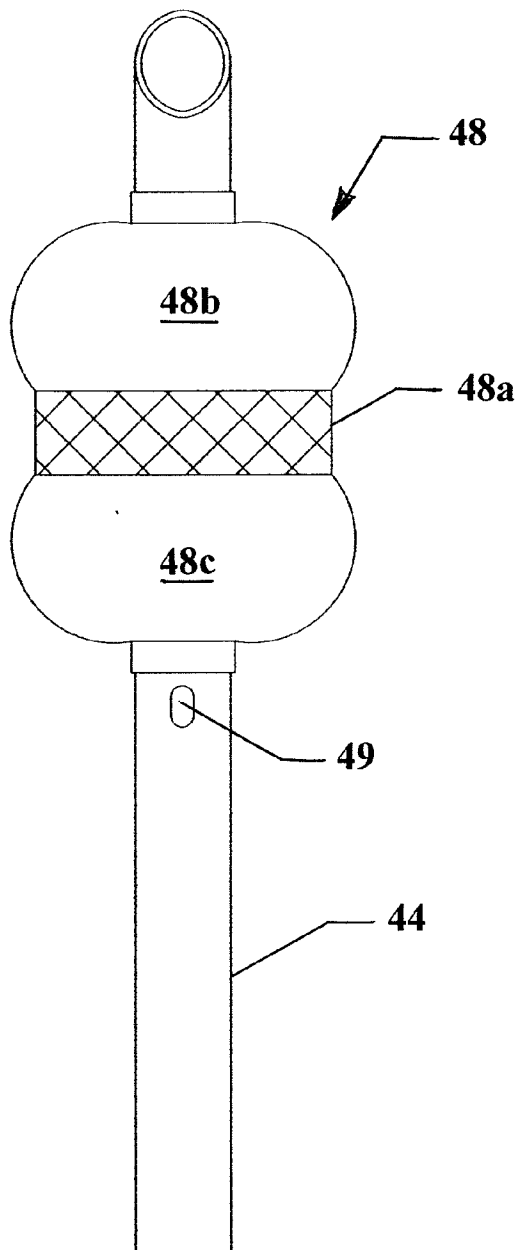
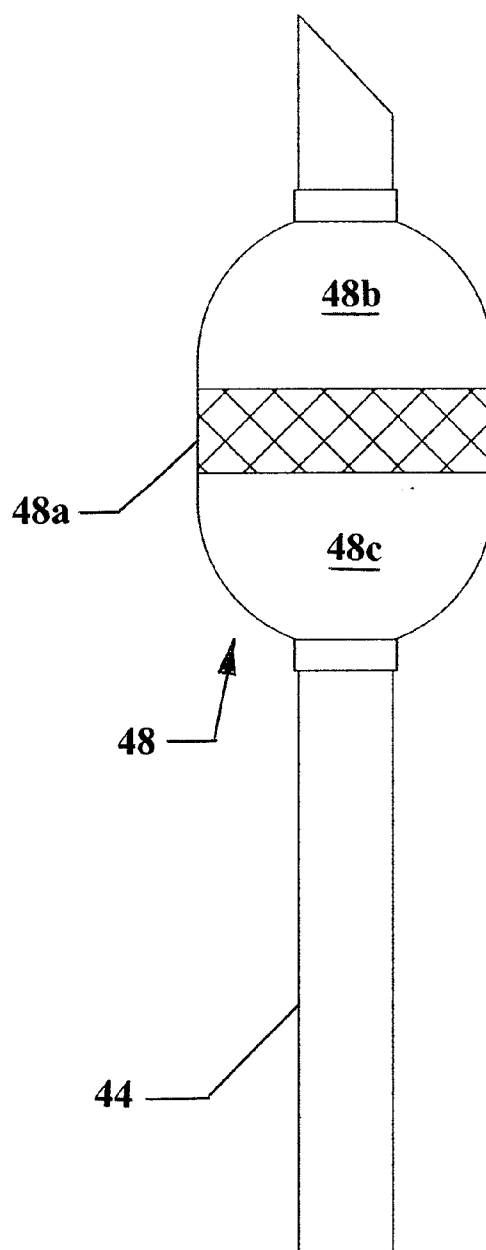


FIG. 19



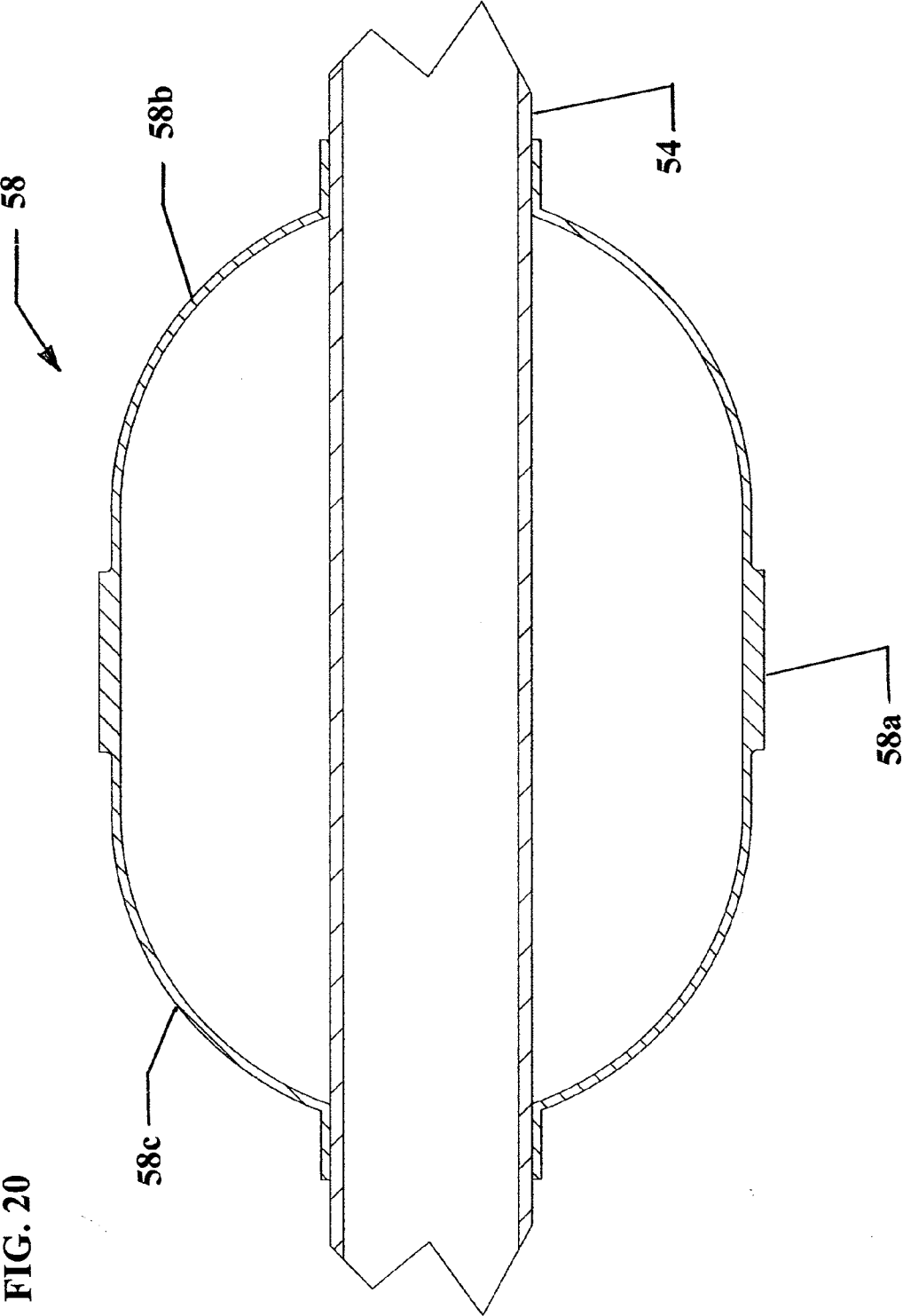


FIG. 21

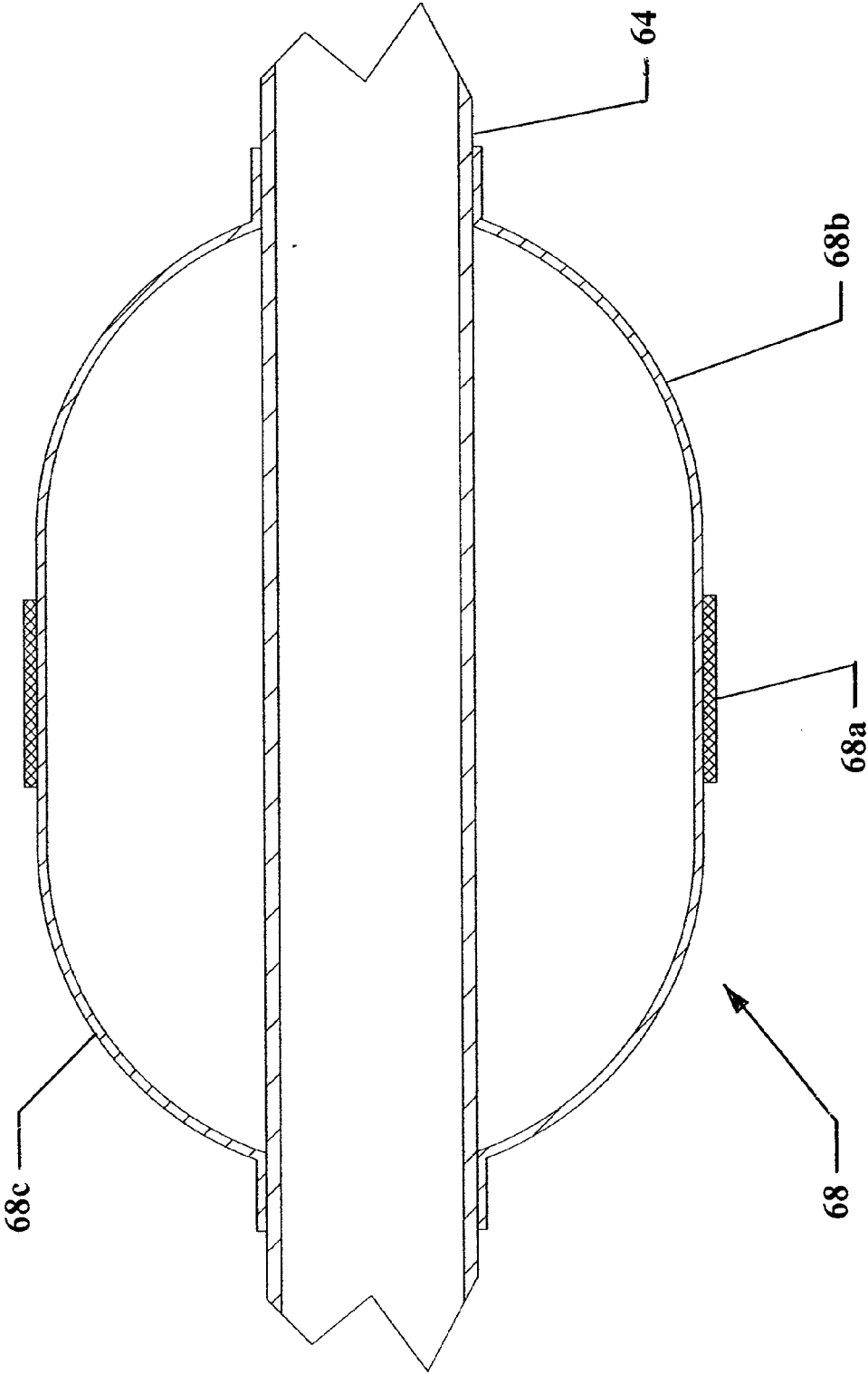
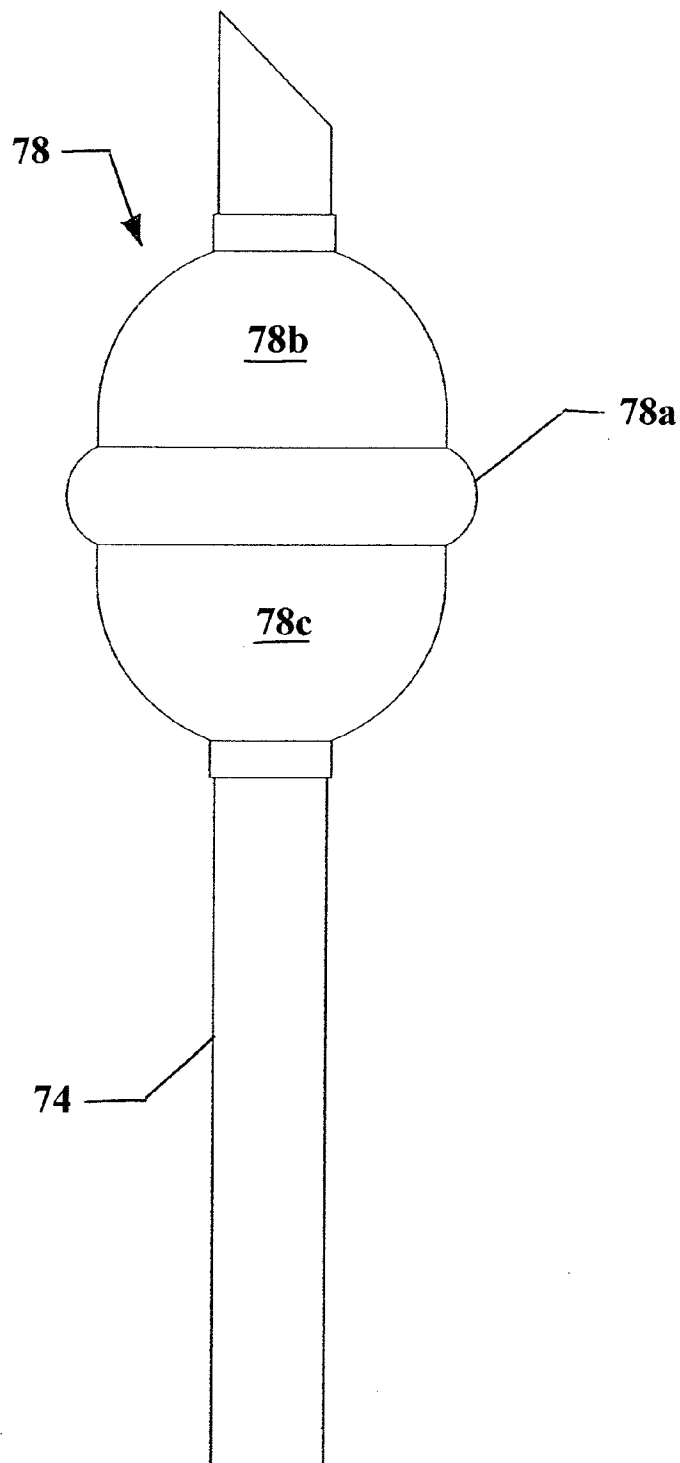


FIG. 22



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2011/065618

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/00 (2012.01)

USPC - 128/207.14

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61M 16/00, 25/00; B29C 1/14, 39/14 (2012.01)

USPC - 116/270; 128/207.14, 207.15, 351; 264/138, 562

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 practicable, search terms used)

PatBase, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,134,407 A (ELAM) 16 January 1979 (16.01.1979) entire document	1-19
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Y		20
Y	US 3,725,522 A (SHERIDAN et al) 03 April 1973 (03.04.1973) entire document	20
A	US 2007/0296125 A1 (COLBURN et al) 27 December 2007 (27.12.2007) entire document	1-20
A	US 2008/0000482 A1 (MAGUIRE et al) 03 January 2008 (03.01.2008) entire document	1-20

☐ Further documents are listed in the continuation of Box C.


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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

30 March 2012

Date of mailing of the international search report

13 APR 2012

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