

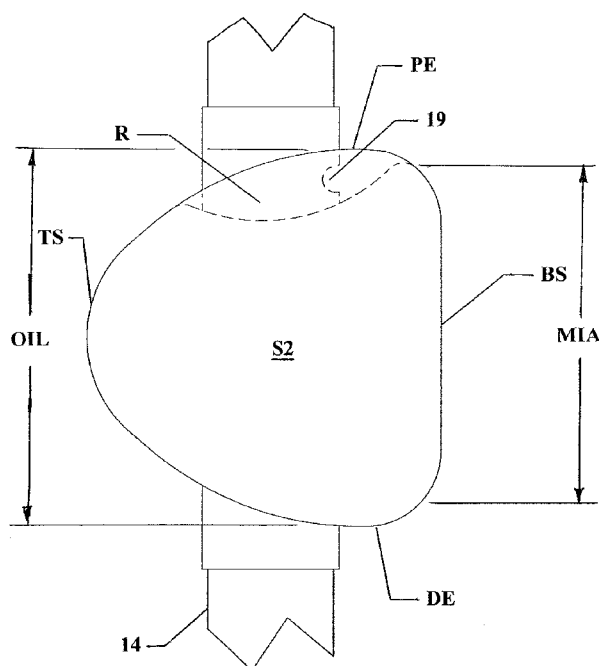


- (51) International Patent Classification:
A61M 16/04 (2006.01)
- (21) International Application Number:
PCT/US2011/065583
- (22) International Filing Date:
16 December 2011 (16.12.2011)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
61/425,584 21 December 2010 (21.12.2010) US
- (71) Applicant (for all designated States except US): **C. R. BARD, INC.** [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **NISHTALA, Vasu** [US/US]; 2269 Bright Water Drive, Snellville, GA 30078 (US). **CICCONE, Paul** [US/US]; 190 Nicklaus Circle, Social Circle, GA 30025 (US). **TERRY, Richard** [US/US]; 1728 Little Brook Drive, Conyers, GA 30094 (US).
- (74) Agent: **WIGHT, Todd, W.**; Rutan & Tucker LLP, 611 Anton Boulevard, Suite 1400, Costa Mesa, CA 92626 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

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- (54) 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

FIG. 4



(57) Abstract: An endotracheal tube includes a main tube with a proximal end and a distal end and an inflatable cuff arranged on the main tube. The inflatable cuff includes a main inflation area. Possible features include at least one generally annular recess or indentation arranged on a proximal end of the cuff, at least one axial recess or indentation arranged in the main inflation area, at least one recess or indentation extending into the main inflation area, at least one suction aperture arranged in the main inflation area, at least one suction aperture arranged in a recess or indentation located in the main inflation area, and at least one suction lumen arranged in a recess or indentation extending into the main inflation area.



SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:**Declarations under Rule 4.17:**

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *of inventorship (Rule 4.17(iv))*

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

**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**

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application No. 61/425,584, 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 suctioning secretions from the trachea while minimizing the possibility of direct suctioning of the tracheal mucosa. This is accomplished using a cuff having one or more recesses or indentations arranged within and/or extending to a main inflation area or inflation plane area of the cuff. In embodiments, one or more suction apertures can be located in the recesses or indentations. In embodiments, the endotracheal tube alternatively and/or additionally utilizes a cuff whose wall has stiffeners and/or different wall thickness sections.

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] Although cuffed endotracheal tubes perform an important service, they can allow secretions to collect proximate the cuff and provide a site for the possible accumulation of pathogens. Various methods have been devised for removing such secretions. For example, a small opening may be provided above the cuff with an associated suction lumen. Fluids and/or solids (e.g., secretions) can be periodically or continuously removed through the opening and lumen by suction.

[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. One example is shown in FIG. 1 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 the tube **T** from the suction aperture **9**. The cuff **8** includes a proximal end and a distal end. 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). Because of this position of the suction aperture 9, it is possible that suction can be applied directly onto the tracheal mucosa wall. This can cause damage to the trachea and cause prolapse of the tissue into the suction aperture. This can, in turn, cause plugging of the suction aperture 9, and thereby prevent suctioning of the secretions or aspirates. In such endotracheal tubes, the suction aperture 9 is thus arranged at about the six o'clock position relative to the plane of curvature of the main tube 4, and when arranged in a patient lying generally horizontally.

[0009] Examples of devices which might overcome the problems associated with locating the suction aperture in the position shown in FIG. 1 include US 5,201,310 to TURNBULL, US 7,089,942 to GREY, US 7,293,561 to MADSEN et al., US 2008/0255951 to GREY, US 2008/0021386 to CLAYTON, US 2008/0047562 to COLBURN et al, and US 2008/0053454 to PASILLAS et al., 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 which a recess or indentation that significantly extends into the cuff area, unlike those known from the above-noted prior art documents. It would also be beneficial to have an endotracheal tube having a cuff which a recess or indentation within which a suction aperture is located. In embodiments, the suction aperture that is placed or located in the cuff recess or indentation reduces the likelihood of direct suctioning of the tracheal mucosa. In this new position, the suction aperture(s) would have the dual advantage of being less likely to directly suction the tracheal wall and could suction the secretions which accumulate or pool immediately adjacent the cuff. In this new position, the suction aperture(s) would also have the advantage of being placed within a proximal recess and/or in an adhered area of the cuff which forms the recess or indentation instead of being spaced by some distance from an end of the cuff. In embodiments, the endotracheal tube alternatively and/or additionally utilizes a cuff that is generally triangular-shaped and/or whose wall has stiffeners and/or different wall thickness sections and/or is fluted in order to prevent folds and/or allow for differential expansion.

SUMMARY OF THE INVENTION

[00011] According to one non-limiting embodiment of the invention, there is provided an endotracheal tube that utilizes the novel way of suctioning secretions from the trachea

while minimizing the possibility of direct suctioning of the tracheal mucosa and which overcomes one or more of the deficiencies noted above.

[00012] In embodiments, the invention can utilize conventional cuffs of the type shown in FIG. 1 and/or of the type disclosed in US 5,201,310 to TURNBULL, US 7,089,942 to GREY, US 7,293,561 to MADSEN et al., US 2008/0255951 to GREY, US 2008/0021386 to CLAYTON, US 2008/0047562 to COLBURN et al, and US 2008/0053454 to PASILLAS et al., and which are modified to include the cuff recess and/or suction aperture configuration 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. 61/425,589, 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;” 2) 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;” and 3) U.S. Provisional Patent Application No. 61/425,599, filed December 21, 2010 with the title “ENDOTRACHEAL TUBE HAVING A CUFF ELASTICALLY EXPANDABLE AND NON-ELASTICALLY EXPANDABLE PORTIONS 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 is generally triangular-shaped and/or whose wall has stiffeners and/or different wall thickness sections and/or is fluted in order to prevent folds and/or allow for differential expansion.

[00015] According to one non-limiting embodiment of the invention, there is provided an endotracheal tube including a main tube comprising a proximal end and a distal end and an inflatable cuff arranged on the main tube. The inflatable cuff includes a main inflation area. At least one of the following is included; at least one generally annular recess or indentation arranged on a proximal end of the cuff, at least one axial recess or indentation arranged on a proximal end of the cuff, at least one recess or indentation arranged in the main inflation area,

at least one recess or indentation extending into the main inflation area, at least one suction aperture arranged in the main inflation area, at least one suction aperture arranged in a recess or indentation located in the main inflation area, at least one suction lumen arranged in a recess or indentation extending into the main inflation area, the cuff being generally triangular-shaped and at least one recess or indentation arranged on a proximal end of the cuff, the cuff being generally cone-shaped and at least one recess or indentation arranged on a proximal end of the cuff, the cuff being generally heart-shaped and at least one recess or indentation arranged on a proximal end of the cuff, the cuff comprising plural cuffs having flutes and/or struts formed in the cuff wall, the cuff having a wall that includes stiffeners, the cuff having a wall with different wall thickness sections, the cuff having flutes, the cuff being structured and arranged to prevent folds, and the cuff being structured and arranged to allow for differential expansion.

[00016] The inflatable cuff may have a generally triangular shape. The inflatable cuff may have a tapered distal end. The inflatable cuff may have a generally circular shape. The inflatable cuff may comprise at least two spaced-apart cuffs. The main inflation area may have an axial length that is between about 40% and about 90% of an overall axial length of the cuff. The main inflation area may have an axial length that is between about 50% and about 80% of an overall axial length of the cuff. The main inflation area may have an axial length that is between about 60% and about 75% of an overall axial length of the cuff.

[00017] The cuff may comprise at least one recess or indentation extending into the main inflation area and is arranged on a proximal end of the cuff. The cuff may comprise at least one recess or indentation extending into the main inflation area, and wherein the at least one recess or indentation is generally triangular or pie-wedge shaped. The cuff may comprise at least one suction aperture arranged in a recess or indentation extending into the main inflation area and wherein the at least one suction aperture has a center axis that intersects a circumference or perimeter of the main inflation area. The cuff may comprise at least one generally annular recess or indentation arranged on a proximal end of the cuff. The cuff may comprise at least one axial recess or indentation arranged on a proximal end of the cuff.

[00018] 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.

[00019] The cuff may be generally triangular-shaped and comprise at least one suction aperture arranged in a recess or indentation extending into the main inflation area and wherein the at least one suction aperture is arranged on a bending plane of the main tube. The endotracheal tube may further comprise at least one inflation lumen generally oriented on a bending plane of the main tube.

[00020] The cuff may be generally cone-shaped and/or tapered and comprise at least one suction aperture arranged in a recess or indentation extending into the main inflation area and wherein the at least one suction aperture is arranged on a bending plane of the main tube.

[00021] The cuff may be one or more generally circular-shaped cuffs and comprise at least one suction aperture arranged in a recess or indentation extending into the main inflation area and wherein the at least one suction aperture is arranged on a bending plane of the main tube.

[00022] The invention also provides for an endotracheal tube comprising a main tube comprising a proximal end and a distal end and a generally triangular inflatable cuff arranged on the main tube. The inflatable cuff comprises a main inflation area and at least one of at least one generally annular recess or indentation arranged on a proximal end of the cuff, at least one axial recess or indentation arranged on a proximal end of the cuff, at least one suction aperture arranged in a recess or indentation located in the main inflation area, at least one suction lumen arranged in a recess or indentation extending into the main inflation area, the cuff having a wall that includes stiffeners, the cuff having a wall with different wall thickness sections, the cuff having flutes, the cuff being structured and arranged to prevent folds, and the cuff being structured and arranged to allow for differential expansion.

[00023] The invention also provides for an endotracheal tube comprising a main tube comprising a proximal end and a distal end and a generally cone-shaped or tapered inflatable cuff arranged on the main tube. The inflatable cuff comprises a main inflation area and at least one of at least one generally annular recess or indentation arranged on a proximal end of

the cuff, at least one axial recess or indentation arranged on a proximal end of the cuff, at least one suction aperture arranged in a recess or indentation located in the main inflation area, at least one suction lumen arranged in a recess or indentation extending into the main inflation area, the cuff having a wall that includes stiffeners, the cuff having a wall with different wall thickness sections, the cuff having flutes, the cuff being structured and arranged to prevent folds, and the cuff being structured and arranged to allow for differential expansion.

[00024] The invention also provides for an endotracheal tube comprising a main tube comprising a proximal end and a distal end and at least one generally circular-shaped inflatable cuff arranged on the main tube. The inflatable cuff comprises a main inflation area and at least one of at least one generally annular recess or indentation arranged on a proximal end of the cuff, at least one axial recess or indentation arranged on a proximal end of the cuff, at least one suction aperture arranged in a recess or indentation located in the main inflation area, at least one suction lumen arranged in a recess or indentation extending into the main inflation area, the cuff having a wall that includes stiffeners, the cuff having a wall with different wall thickness sections, the cuff having flutes, the cuff being structured and arranged to prevent folds, and the cuff being structured and arranged to allow for differential expansion.

[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 one recess or indentation in the cuff.

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] FIG. 2 shows a side perspective view of an endotracheal tube in accordance with an exemplary embodiment of the invention. The cuff is shown in a substantially inflated configuration;

[00031] FIG. 3 shows an enlarged partial cross-section view of a human trachea and illustrates how it has a generally heart-shape and/or triangular-shape;

[00032] FIG. 4 shows an enlarged partial side-view of the cuff area shown in FIG. 2 in accordance with an exemplary embodiment of the invention;

[00033] FIG. 5 shows an enlarged partial top and side perspective view of the cuff portion shown in FIG. 2 in accordance with an exemplary embodiment of the invention;

[00034] FIG. 6 shows a partial bottom and side perspective view of the cuff portion shown in FIG. 2 and arranged in a trachea in accordance with an exemplary embodiment of the invention;

[00035] FIG. 7 shows a partial top and side perspective view of the cuff portion shown in FIG. 2 and arranged in a trachea in accordance with an exemplary embodiment of the invention;

[00036] FIG. 8 shows a cut-away view of FIG. 7 and shows how the cuff substantially conforms to the generally triangular-shaped trachea in accordance with an exemplary embodiment of the invention;

[00037] FIG. 9 shows a cross-section view of another embodiment of a generally triangular-shaped cuff in accordance with an exemplary embodiment of the invention. This embodiment utilizes a cuff wall having thicker and thinner sections. The thicker sections form struts;

[00038] FIG. 10 shows a side partial cross-section view of another cuff configuration which can be utilized in accordance with an exemplary embodiment of the invention. Instead

of the generally triangular-shaped cuff, this embodiment utilizes a generally cone-shaped cuff;

[00039] FIG. 11 shows a side cross-section view similar to that shown in FIG. 10 and illustrates how the cuff wall can utilize thicker and thinner sections in accordance with an exemplary embodiment of the invention. The thicker sections form struts;

[00040] FIG. 12 shows a side cross-section view similar to that shown in FIG. 11 and illustrates how the cuff wall struts can be oriented circumferentially instead of being generally parallel to the axis of the main tube as in FIGS. 9 and 11;

[00041] FIG. 13 shows a cross-section view of a conventional main tube and which can be used with any of the embodiments disclosed herein in accordance with exemplary embodiments of the invention;

[00042] FIGS. 14-16 show cross-section views of a main tube which can be used with any of the embodiments disclosed herein in accordance with exemplary embodiments of the invention; and

[00043] FIGS. 17 and 18 show enlarged partial side-views of the cuff in both a pre-inflated and inflated configurations in accordance with an exemplary embodiment of the invention. This embodiment utilizes two generally round or spherical cuffs.

DETAILED DESCRIPTION OF THE INVENTION

[00044] 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.

[00045] 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."

[00046] FIGS. 2 and 4-18 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 suction aperture arranged in at least one cuff recess or indentation and/or located as described herein which advantageously suctions secretions from the trachea while minimizing the possibility of direct suctioning of the tracheal mucosa. As used throughout this document, the terms "subject", "patient" or "user" may include any human or other animal. Furthermore, the term "main inflation area" is generally a center portion of the cuff whose axial length substantially corresponds to an area of contact between the cuff and a trachea when the ET tube is arranged in a patient and the cuff is sufficiently or fully inflated. 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.

[00047] With reference to FIGS. 2 and 4-8, there is shown one non-limiting embodiment of an endotracheal tube in accordance with the invention. Like the embodiment shown in FIG. 1, the embodiment of FIG. 2 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**.

[00048] Unlike the ET tube of FIG. 1, however, in embodiments, the invention shown in FIG. 2 (and also Fig. 4) utilizes a generally triangular-shaped cuff **18** which includes a proximal end **PE**, a distal end **DE**, a base side **BS**, a top side **TS**, and two angled sides **S1** and **S2**. A cuff recess or indentation **R** is also provided in an area of the proximal end **PE**. This recess **R** provides the endotracheal tube with a novel way of suctioning secretions from the trachea while minimizing the possibility of direct suctioning of the tracheal mucosa. The recess **R** has a bottom side that is generally arranged within a main inflation area **MIA** (see FIG. 4). In embodiments, the bottom side of the recess **R** is formed by a wall portion of the cuff **18**. The recess or indentation **R** has a closed bottom end that is closer to the distal end **DE** of the cuff **18**, but is open in an axial direction all the way to the proximal end **PE** of the cuff **18**. The recess **R** thus forms a sort-of “crater” area around the main tube **14** in the area of the proximal end **PE**. Since the cuff **18** is generally triangular in shape, the recess **R** can, in embodiments, be a similarly triangularly-shaped crater type recess (when viewed from the axial direction). Other shapes that can facilitate flow into the suction lumen can also be utilized.

[00049] In the recess configuration shown in FIGS. 4, 5 and 7, the space defined by the recess **R** (which if filled would resemble the opposite end **DE** of the cuff **18**) is generally triangular and has a base side which is oriented generally parallel to the base side **BS** of the cuff **18**. As is apparent from FIG. 4, the recess or indentation **R** extends axially from the proximal end **PE** of the cuff **18** into a main inflation area **MIA** of the cuff **18**. In embodiments, the recess or indentation **R** extends axially from the proximal end **PE** into the cuff **18** by an amount that is between about 5% and about 20% of the overall inflation length **OIL**. In embodiments, the recess or indentation **R** extends axially from the proximal end **PE** into the cuff **18** by an amount that is between about 10% and about 15% of the overall inflation length **OIL**. In embodiments, the suction aperture **19** is arranged in the recess **R** so as to suction secretions which accumulate in the recess **R** and/or which accumulate very close to the proximal end **PE** of the cuff **18**. The suction aperture **19** can also be arranged, at least partially, within the main inflation area **MIA**. Alternatively, the suction aperture **19** is arranged outside of the main inflation area **MIA** or fully within the main inflation area **MIA**, but is also arranged within the overall inflation area **OIL** (see FIG. 4). In embodiments, the suction aperture **19** faces the base side **BS** and/or is generally perpendicular to the base side **BS** of the cuff **18**.

[00050] Although FIGS. 4 and 5 show a single suction aperture **19** arranged in the cuff recess **R**, the invention contemplates using plural suction apertures arranged in the recess **R**. In this case, one of the suction apertures can be arranged within the main inflation area **MIA** while another is arranged outside the main inflation area **MIA**. Alternatively, both suction apertures can be arranged within the main inflation area **MIA** or outside the main inflation area **MIA**. In other embodiments, the suction apertures can be arranged circumferentially side-by-side and/or can have different shapes and/or sizes.

[00051] FIG. 4 shows one non-limiting way in which the recess **R** (shown in dashed-line) can be configured in the cuff **18**. As can be seen in FIG. 4, the recess or indentation **R** is essentially defined by the closed bottom side and an open upper side which extends to the proximal end **PE** of the cuff **18**. It is also defined by an outer surface of the main tube **14** between the bottom closed side and the proximal end **PE** or more accurately by the wall portion of the cuff **18** which is adhered to an outer surface of the main tube **14**. The suction aperture **19** is formed through the adhered wall of the cuff **18** and penetrates an outer surface of the main tube **14**. At a distal or bottom end of the recess **R**, the wall of the cuff **18** extends or tapers upwards from the adhered area until it merges with the proximal end **PE** of the cuff **18**. FIG. 5 also shows how the recess **R** is open axially all the way around the main tube **14** as well as in an axial direction from the closed end all the way to the proximal end **PE** of the cuff **18**. In the recess configuration shown in FIGS. 4 and 5, the recess **R** is generally triangular so as to generally correspond to the shape of the cuff **18**. Of course, the recess **R** need not have the same or a corresponding shape as the cuff **18**, and can instead have other annular shapes such as that resembling a circular moat.

[00052] FIG. 8 shows how the generally triangular-shaped cuff **18** can more generally and/or accurately conform to a generally triangular-shaped trachea **T** shown in FIG. 3. This ensures better and/or proper sealing between the cuff **18** and the trachea **T** at a lower inflation pressure.

[00053] FIG. 9 shows an enlarged side cross-section view of an exemplary cuff **18'** which can be used on the endotracheal tube shown in FIG. 2. In the embodiment shown in FIG. 9, the generally triangular-shaped cuff **18'** utilizes a cuff wall having wall sections of different thicknesses. The thick portions form struts **S** and function to provide stiffness to the cuff wall. The struts **S** also function to provide the cuff **18'** with flutes in the un-inflated position. The struts **S** can also allow the thinner sections to expand slightly move when the

cuff **18'** is inflated so as to form flutes. The cuff **18'** is also structured and arranged to prevent folds by virtue of the struts **S**. Finally, the cuff **18'** also is structured and arranged to allow for differential expansion because of the struts **S**.

[00054] As is apparent from FIG. 9, the main tube can utilize a non-circular shaped suction lumen and an inflation lumen which are both oriented on the bending plane (i.e., perpendicular to base side **BS**) in the same way as the suction aperture **9** shown in FIG. 1.

[00055] In embodiments, the main tube **14** can be a one-piece member whereby the suction lumen **16** and the inflation lumen **17**, also optionally the radiopaque stripe (not shown), are integrally formed therewith. By way of non-limiting example, the main tube **14** can be made of any medical grade plastic and can be generally circular in cross-section shape. Alternatively, the main tube **14** can have other shapes such as a generally oval shape (see e.g., FIGS. 15 and 16). In embodiments, the ventilation lumen **15** can be generally non-circular in cross-section shape. Alternatively, the ventilation lumen **15** can have other shapes. In embodiments, the suction lumen **16** can be generally oval in cross-section shape. Alternatively, the suction lumen **16** can have other shapes such as circular (see e.g., FIG. 18). In embodiments, the inflation lumen **17** can be generally circular in cross-section shape. Alternatively, the inflation lumen **17** can have other shapes such as, e.g., generally conical with the cone extending towards a long axis of the lumen.

[00056] In embodiments, the suction aperture **19** (and/or the apex thereof) used in the embodiments of FIGS. 2 and 4-9 can be arranged about 8 mm from a bottom surface of the recess **R** and, in embodiments, is arranged on the portion of the cuff **18** that is glued and/or adhered and/or otherwise non-removably secured to the main tube **14**. In these and other embodiments discussed herein, other distances can also be utilized provided they function to remove secretions from within the recess **R** and do not otherwise interfere with the proper functioning or use of the cuff **18** and/or **18'**. In this position, the suction aperture **19** is positioned spaced by and tucked-into the recess **R** from where it will be at the lowest point within the trachea (when the patient is inclined). Because of this position of the suction aperture **19**, it is very unlikely that suction can be applied directly onto the tracheal mucosa wall. With this spaced and tucked-into arrangement of the suction aperture **19**, there is a lower possibility of causing damage to the trachea and prolapse of the tissue into the suction aperture **19**. Furthermore, because of the spaced and/or tucked-into arrangement of the suction aperture **19**, there is a lower likelihood of plugging of the suction aperture **19**, which,

in turn, ensures that suctioning of the secretions or aspirates can continue even if the main tube **14** is in contact with the trachea. The arrangement(s) of FIGS. 2 and 4-9 also advantageously allows suction of the secretions which accumulate or pool immediately adjacent the proximal end **PE** of the cuff **18** and/or on the recess **R**.

[00057] In the embodiment of FIGS. 2 and 4-9, the suction aperture **19** is arranged at about the six o'clock position shown in FIG. 9 (relative to the bending plane). In embodiments, the suction aperture **19** can also be arranged angularly offset so as to point towards one of the corners formed between walls or sides **BS** and **S1** or **S2**. In other embodiments, the suction aperture **19** can be arranged at about the seven o'clock position instead of the six o'clock position shown in FIG. 9. In other embodiments, the suction aperture **19** can also be arranged between about the seven and about the eight o'clock positions.

[00058] FIGS. 10-12 show alternative embodiments of a cuff **28** which is generally cone-shaped and/or heart-shaped instead of generally triangular-shaped. As in the previous embodiments, the embodiments shown in FIGS. 10-12 also utilizes an axial recess **R'** arranged at a proximal end of the cuff **28** and a suction aperture **29** arranged in the recess **R'** and within a main inflation area **MIA**. The cuff **28** is said to be cone-shaped because it tapers down from the proximal end of the cuff **28** to a distal end thereof.

[00059] As can be seen in FIG. 10, the recess or indentation **R'** is essentially defined by the closed bottom side and an open upper side which extends to the proximal end of the cuff **28**. It is also defined by an outer surface of the main tube **24** between the bottom closed side and the proximal end or more accurately by the wall portion of the cuff **28** which is adhered to an outer surface of the main tube **24**. The suction aperture **29** is formed through the adhered wall of the cuff **28** and penetrates an outer surface of the main tube **24**. At a distal or bottom end of the recess **R'**, the wall of the cuff **28** extends or tapers upwards from the adhered area until it merges with the proximal end of the cuff **28**. FIG. 10 also shows how the recess **R'** is open axially all the way around the main tube **24** as well as in an axial direction from the closed end all the way to the proximal end of the cuff **28**. In the recess configuration shown in FIG. 10, the recess **R'** is generally circular so as to generally correspond to the shape of the cuff **28**. Of course, the recess **R'** need not have the same or a corresponding shape as the cuff **28**, and can instead have other shapes that resemble a moat.

[00060] FIG. 11 shows a modification of the cuff shown in FIG. 10. In the embodiment shown in FIG. 11, the cuff **28'** utilizes a cuff wall having wall sections of different thicknesses. The thick portions form struts **S'** and function to provide stiffness to the cuff wall. The struts **S'** also function to provide the cuff **28'** with flutes in the un-inflated position. The struts **S'** can also allow the thinner sections to expand slightly move when the cuff **28'** is inflated so as to form flutes. The cuff **28'** is also structured and arranged to prevent folds by virtue of the struts **S'**. Finally, the cuff **28'** also is structured and arranged to allow for differential expansion because of the struts **S'**. In this embodiment, the struts **S'** are oriented generally parallel to an axis of the main tube **24'** as was the case in the embodiment of FIG. 9.

[00061] FIG. 12 shows another modification of the cuff shown in FIG. 10. In the embodiment shown in FIG. 12, the cuff **28''**, like that of FIG. 11, utilizes a cuff wall having wall sections of different thicknesses. The thick portions form struts **S''** and function to provide stiffness to the cuff wall. The struts **S''** also function to provide the cuff **28''** with flutes in the un-inflated position. The struts **S''** can also allow the thinner sections to expand slightly move when the cuff **28''** is inflated so as to form flutes. The cuff **28''** is also structured and arranged to prevent folds by virtue of the struts **S''**. Finally, the cuff **28''** also is structured and arranged to allow for differential expansion because of the struts **S''**. In this embodiment, the struts **S''** are oriented generally perpendicular or circumferentially relative to an axis of the main tube **24''**.

[00062] FIG. 13 shows a cross-section view of a conventional main tube **4** having a ventilation lumen **5** and a suction lumen **6**, and which can be used with any of the embodiments disclosed herein in accordance with exemplary embodiments of the invention. In embodiments, the dimension "a" can be about 0.441 inches. In embodiments, the area of the ventilation lumen **5** can be about 0.0664 square-inches and the area of the suction lumen **6** can be about 0.0086 square-inches.

[00063] FIG. 14 shows a cross-section view of a non-limiting embodiment of a main tube **14'** having a ventilation lumen **15'** and a suction lumen **16'**, and which can be used with any of the embodiments disclosed herein in accordance with exemplary embodiments of the invention. In embodiments, the dimension "a" can be about 0.404 inches. In embodiments, the area of the ventilation lumen **15'** can be about 0.0676 square-inches and the area of the suction lumen **16'** can be about 0.0032 square-inches.

[00064] FIG. 15 shows a cross-section view of a non-limiting embodiment of a main tube **14''** having a ventilation lumen **15''** and a suction lumen **16''**, and which can be used with any of the embodiments disclosed herein in accordance with exemplary embodiments of the invention. In embodiments, the dimension “a” can be about 0.412 inches. In embodiments, the dimension “b” can be about 0.475 inches. In embodiments, the area of the ventilation lumen **15''** can be about 0.0685 square-inches and the area of the suction lumen **16''** can be about 0.0204 square-inches.

[00065] FIG. 16 shows a cross-section view of a non-limiting embodiment of a main tube **14'''** having a ventilation lumen **15'''** and a suction lumen **16'''**, and which can be used with any of the embodiments disclosed herein in accordance with exemplary embodiments of the invention. In embodiments, the dimension “a” can be about 0.412 inches. In embodiments, the dimension “b” can be about 0.475 inches. In embodiments, the area of the ventilation lumen **15'''** can be about 0.0639 square-inches and the area of the suction lumen **16'''** can be about 0.0191 square-inches.

[00066] FIGS. 17 and 18 show enlarged partial side-views of a two-cuff ET tube in both a pre-inflated (FIG. 17) and inflated (FIG. 18) configurations in accordance with an exemplary embodiment of the invention. This embodiment utilizes two generally round or spherical cuffs **38A** and **38B** and two suction apertures **39**. Each cuff **38A** and **38B**, in embodiments, utilizes struts (not shown) which function to form the cuff flutes shown in FIG. 17. The struts can be oriented generally parallel to an axis of the main tube so as to form the flutes shown FIG. 17. In embodiments, other shapes can be utilized for the cuffs **38A** and **38B** instead of generally spherical.

[00067] 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.

[00068] 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.

[00069] The invention also provides for a method for intubation using the assembly of FIGS. 2 and 4-18, which includes inserting at least a distal portion of the endotracheal tube into a trachea, inflating the cuff, 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.

[00070] The invention also provides for a method of making a device for intubation shown FIGS. 2 and 4-18, and specifically making the at least one suction aperture of the main tube be arranged in a cuff recess. The cuff recess can be formed in various non-limiting ways such as, e.g., by gluing a portion of the proximal end of the cuff to the outer surface of the main tube in a manner which forms the recess. The suction aperture can be formed in the recess by punching it through the adhered area of the cuff in the recess. Alternatively, a blow mold can be created and/or modified so that the cuff has the configurations shown in the drawings.

[00071] The struts in the wall of the cuff(s) can be formed by adding reinforcing layer(s) to the instant surface of the cuff wall and/or removing sections of a multi-layered wall. Alternatively, the wall can be extruded or molded with the struts integrally formed therein.

[00072] 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.

[00073] 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, the inflatable cuff including a main inflation area; and
 - at least one of:
 - at least one generally annular recess or indentation arranged on a proximal end of the cuff;
 - at least one axial recess or indentation arranged on a proximal end of the cuff;
 - at least one recess or indentation arranged in the main inflation area;
 - at least one recess or indentation extending into the main inflation area;
 - at least one suction aperture arranged in the main inflation area;
 - at least one suction aperture arranged in a recess or indentation located in the main inflation area;
 - at least one suction lumen arranged in a recess or indentation extending into the main inflation area;
 - the cuff being generally triangular-shaped and at least one recess or indentation arranged on a proximal end of the cuff;
 - the cuff being generally cone-shaped and at least one recess or indentation arranged on a proximal end of the cuff;
 - the cuff being generally heart-shaped and at least one recess or indentation arranged on a proximal end of the cuff;
 - the cuff comprising plural cuffs having flutes and/or struts formed in the cuff wall;
 - the cuff having a wall that includes stiffeners;
 - the cuff having a wall with different wall thickness sections;
 - the cuff having flutes;
 - the cuff being structured and arranged to prevent folds; and
 - the cuff being structured and arranged to allow for differential expansion.

2. The endotracheal tube of claim 1, wherein the inflatable cuff has a generally triangular shape.
3. The endotracheal tube of claim 1, wherein the inflatable cuff has a tapered distal end.
4. The endotracheal tube of claim 1, wherein the inflatable cuff has a generally circular shape.
5. The endotracheal tube of claim 1, wherein the inflatable cuff comprises at least two spaced-apart cuffs.
6. The endotracheal tube of claim 1, wherein the main inflation area has an axial length that is between about 40% and about 90% of an overall axial length of the cuff.
7. The endotracheal tube of claim 1, wherein the main inflation area has an axial length that is between about 50% and about 80% of an overall axial length of the cuff.
8. The endotracheal tube of claim 1, wherein the main inflation area has an axial length that is between about 60% and about 75% of an overall axial length of the cuff.
9. The endotracheal tube of claim 1, wherein the cuff comprises at least one recess or indentation extending into the main inflation area and is arranged on a proximal end of the cuff.
10. The endotracheal tube of claim 1, wherein the cuff comprises at least one recess or indentation extending into the main inflation area, and wherein the at least one recess or indentation is generally triangular or pie-wedge shaped.
11. The endotracheal tube of claim 1, wherein the cuff comprises at least one suction aperture arranged in a recess or indentation extending into the main inflation area and wherein the at least one suction aperture has a center axis that intersects a circumference or perimeter of the main inflation area.
12. The endotracheal tube of claim 1, wherein the cuff comprises at least one generally annular recess or indentation arranged on a proximal end of the cuff.

13. The endotracheal tube of claim 1, wherein the cuff comprises at least one axial recess or indentation arranged on a proximal end of the cuff.

14. 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.

15. 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.

16. 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.

17. The endotracheal tube of claim 16, wherein the main tube comprises at least one suction lumen that is arranged on a bending plane of the main tube.

18. 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.

19. The endotracheal tube of claim 1, wherein the main tube comprises at least one non-circular suction lumen that is arranged on a bending plane of the main tube.

20. The endotracheal tube of claim 1, wherein the main tube comprises a generally circular cross-section shape.

21. The endotracheal tube of claim 1, wherein the main tube comprises a generally oval cross-section shape.

22. The endotracheal tube of claim 1, wherein the cuff is generally triangular-shaped and comprises at least one suction aperture arranged in a recess or indentation extending into the main inflation area and wherein the at least one suction aperture is arranged on a bending plane of the main tube.

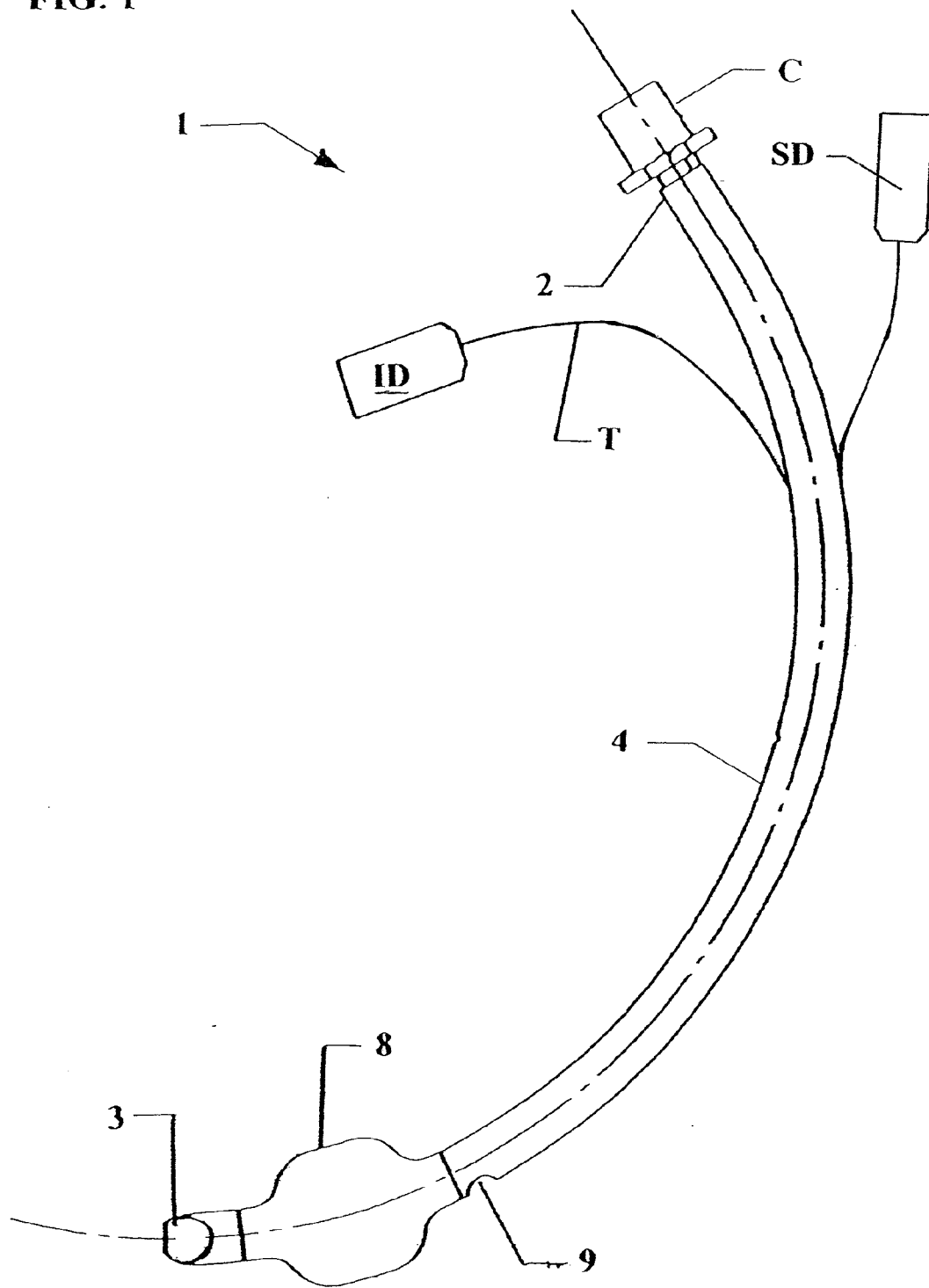
23. The endotracheal tube of claim 1, wherein the cuff is generally cone-shaped and/or tapered and comprises at least one suction aperture arranged in a recess or indentation extending into the main inflation area and wherein the at least one suction aperture is arranged on a bending plane of the main tube.

24. The endotracheal tube of claim 1, further comprising at least one inflation lumen generally oriented on a bending plane of the main tube.
25. An endotracheal tube, comprising:
- a main tube including a proximal end and a distal end;
 - a generally triangular inflatable cuff arranged on the main tube, the inflatable cuff including a main inflation area; and
 - at least one of:
 - at least one generally annular recess or indentation arranged on a proximal end of the cuff;
 - at least one axial recess or indentation arranged on a proximal end of the cuff;
 - at least one suction aperture arranged in a recess or indentation located in the main inflation area;
 - at least one suction lumen arranged in a recess or indentation extending into the main inflation area;
 - the cuff having a wall that includes stiffeners;
 - the cuff having a wall with different wall thickness sections;
 - the cuff having flutes;
 - the cuff being structured and arranged to prevent folds; and
 - the cuff being structured and arranged to allow for differential expansion.

26. An endotracheal tube, comprising:
- a main tube including a proximal end and a distal end;
 - a generally cone-shaped or tapered or heart-shaped inflatable cuff arranged on the main tube, the inflatable cuff including a main inflation area; and
 - at least one of:
 - at least one generally annular recess or indentation arranged on a proximal end of the cuff;
 - at least one axial recess or indentation arranged on a proximal end of the cuff;
 - at least one suction aperture arranged in a recess or indentation located in the main inflation area;
 - at least one suction lumen arranged in a recess or indentation extending into the main inflation area;
 - the cuff having a wall that includes stiffeners;
 - the cuff having a wall with different wall thickness sections;
 - the cuff having flutes;
 - the cuff being structured and arranged to prevent folds; and
 - the cuff being structured and arranged to allow for differential expansion.

27. An endotracheal tube, comprising:
a main tube including a proximal end and a distal end;
at least one generally circular-shaped inflatable cuff arranged on the main tube, the inflatable cuff including a main inflation area; and
at least one of:
at least one generally annular recess or indentation arranged on a proximal end of the cuff;
at least one axial recess or indentation arranged on a proximal end of the cuff;
at least one suction aperture arranged in a recess or indentation located in the main inflation area;
at least one suction lumen arranged in a recess or indentation extending into the main inflation area;
the cuff having a wall that includes stiffeners;
the cuff having a wall with different wall thickness sections;
the cuff having flutes;
the cuff being structured and arranged to prevent folds; and
the cuff being structured and arranged to allow for differential expansion.
28. A method for intubation using the endotracheal tube of any one of claims 1-27, 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.
29. The method of claim 28, further comprising suctioning matter through the at least one suction aperture.
30. A method of making the endotracheal tube of any one of claims 1-27, the method comprising forming at least one recess or indentation in the cuff.

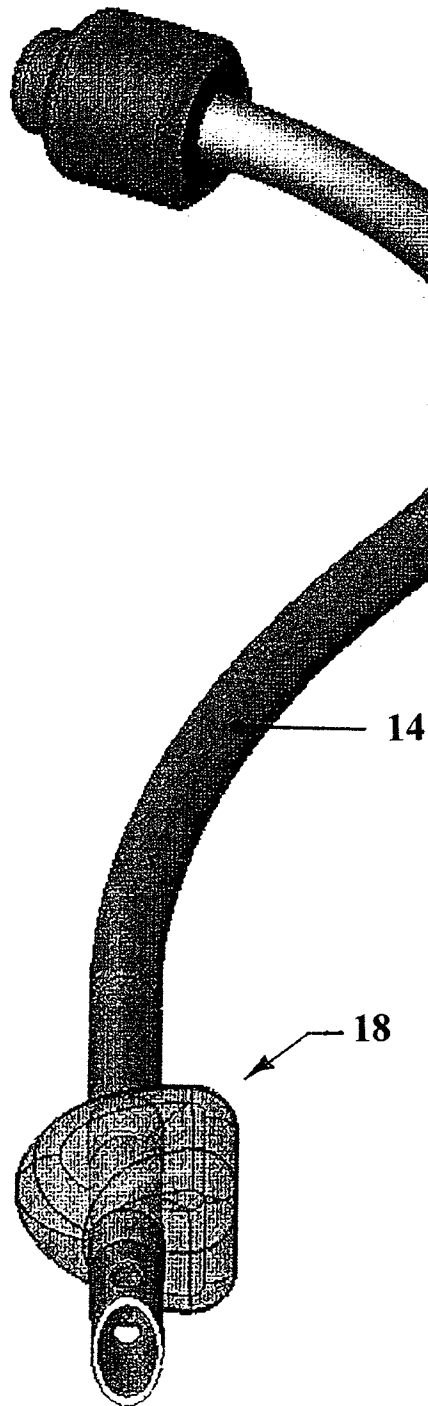
FIG. 1



PRIOR ART

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FIG. 2



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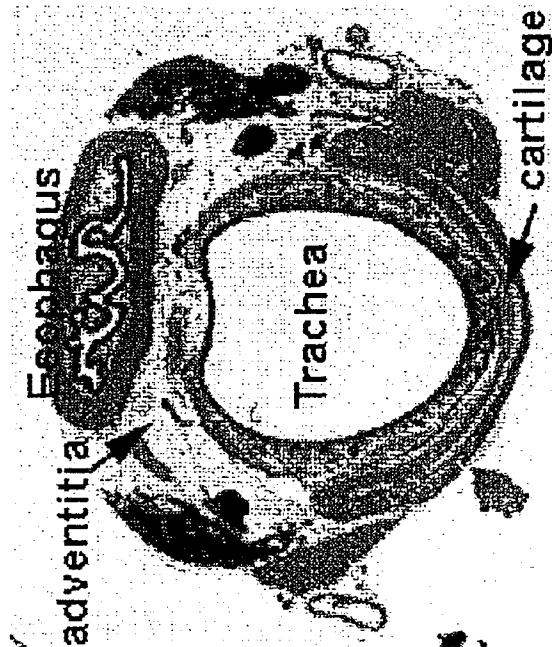


FIG. 3

FIG. 4

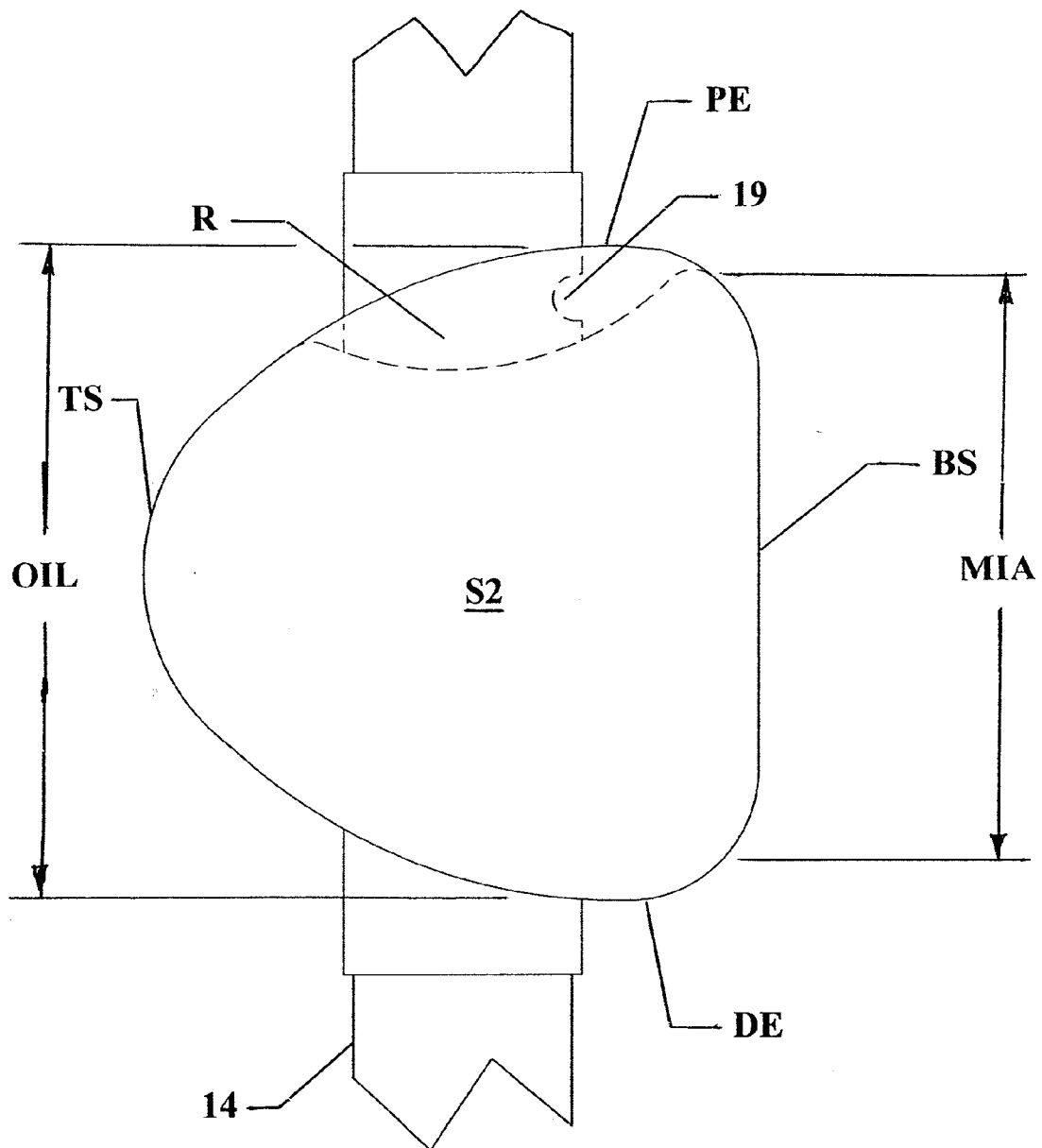


FIG. 5

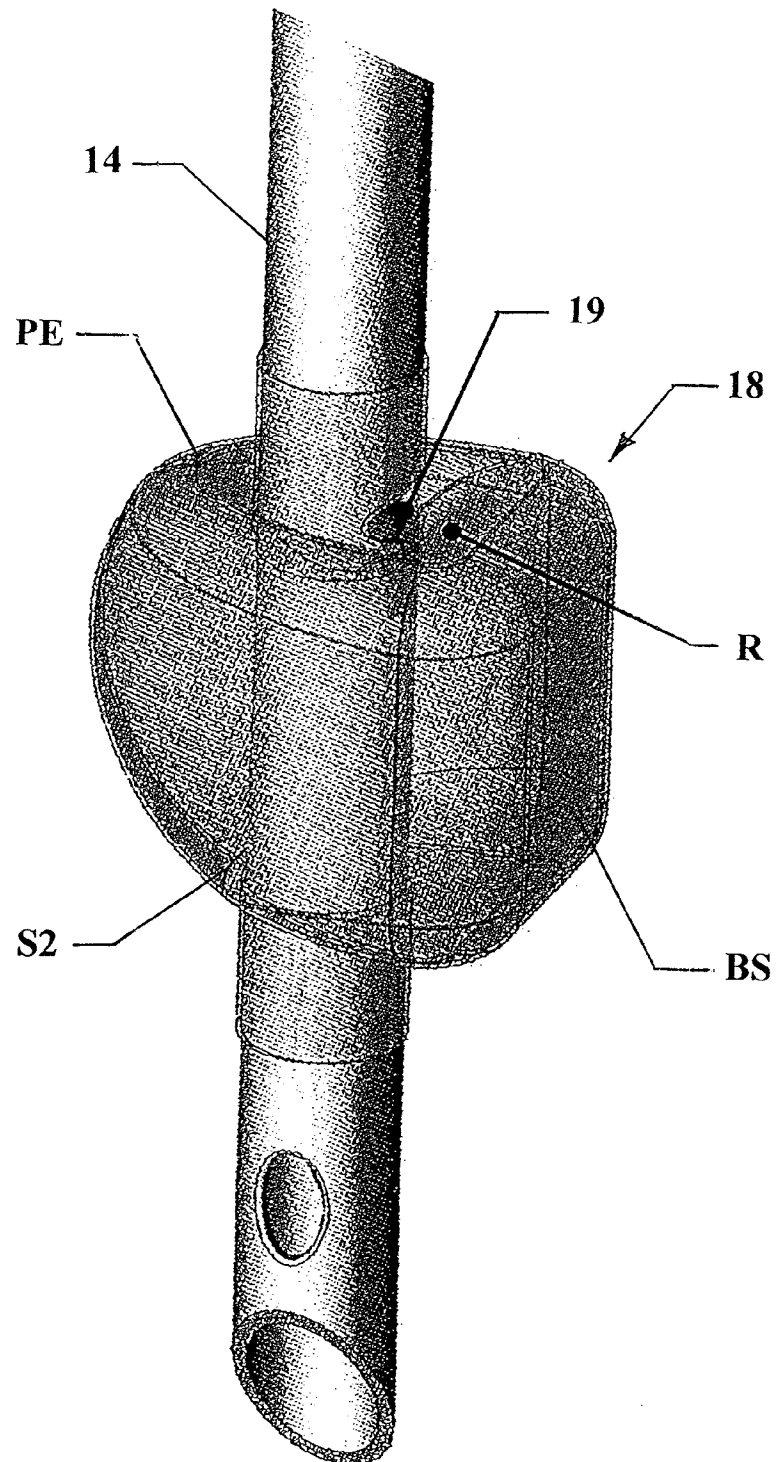


FIG. 6

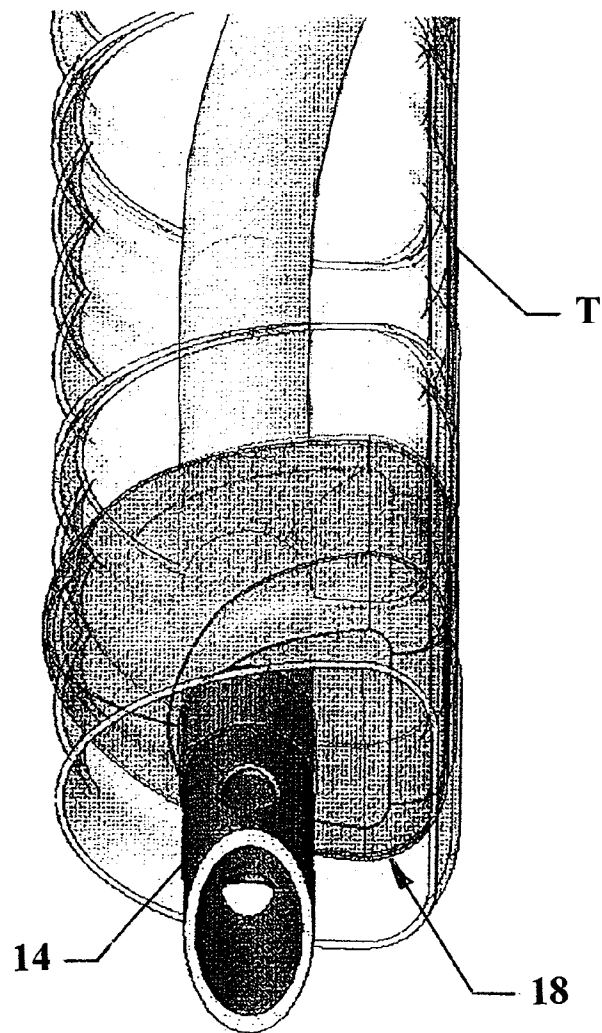
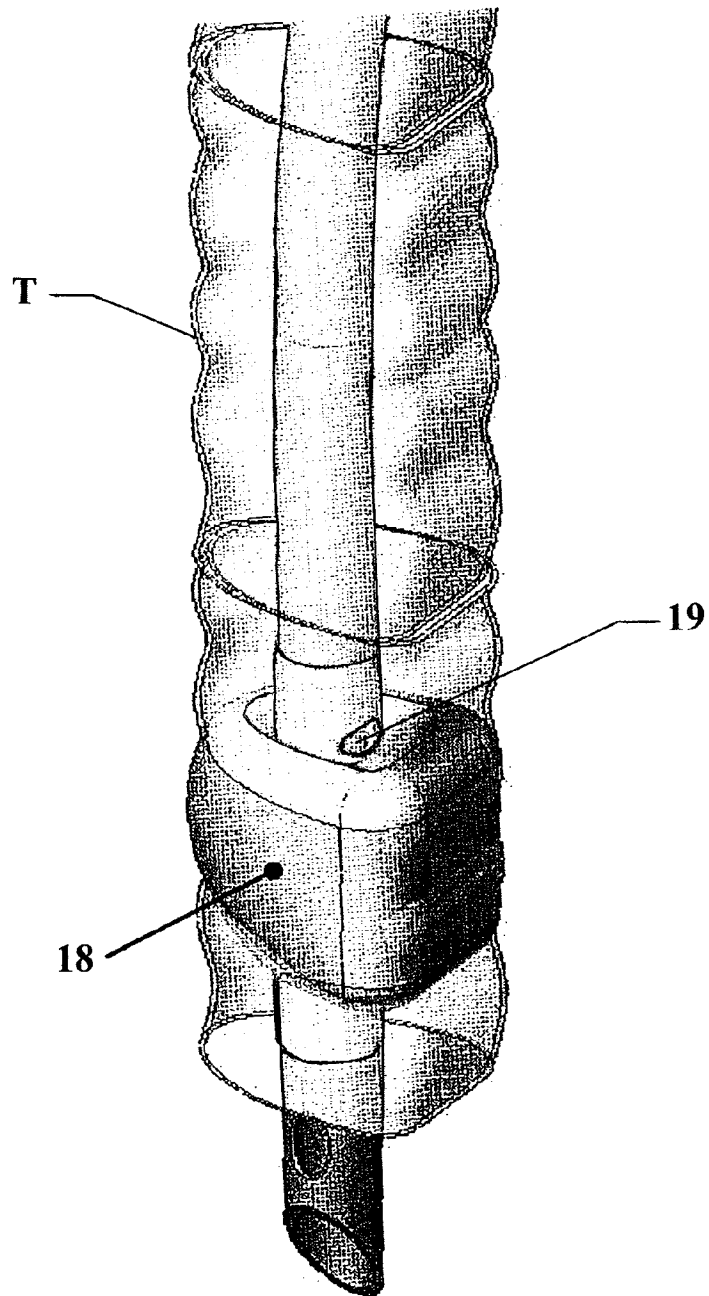


FIG. 7



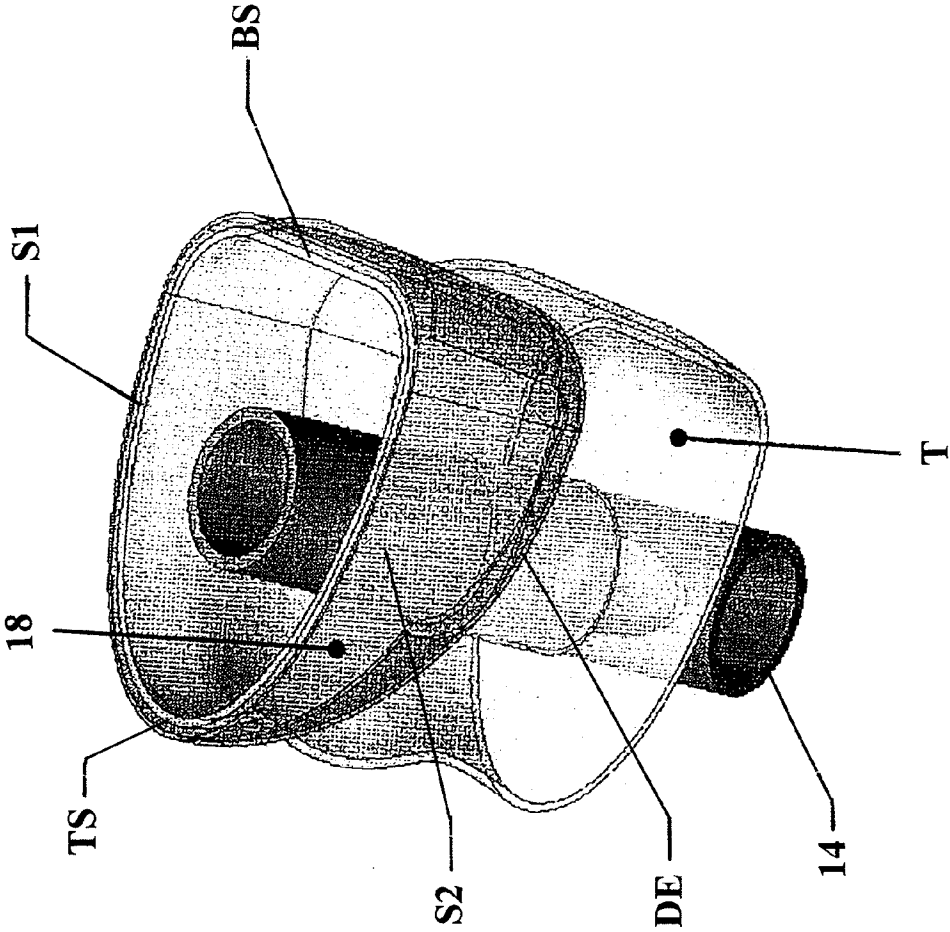
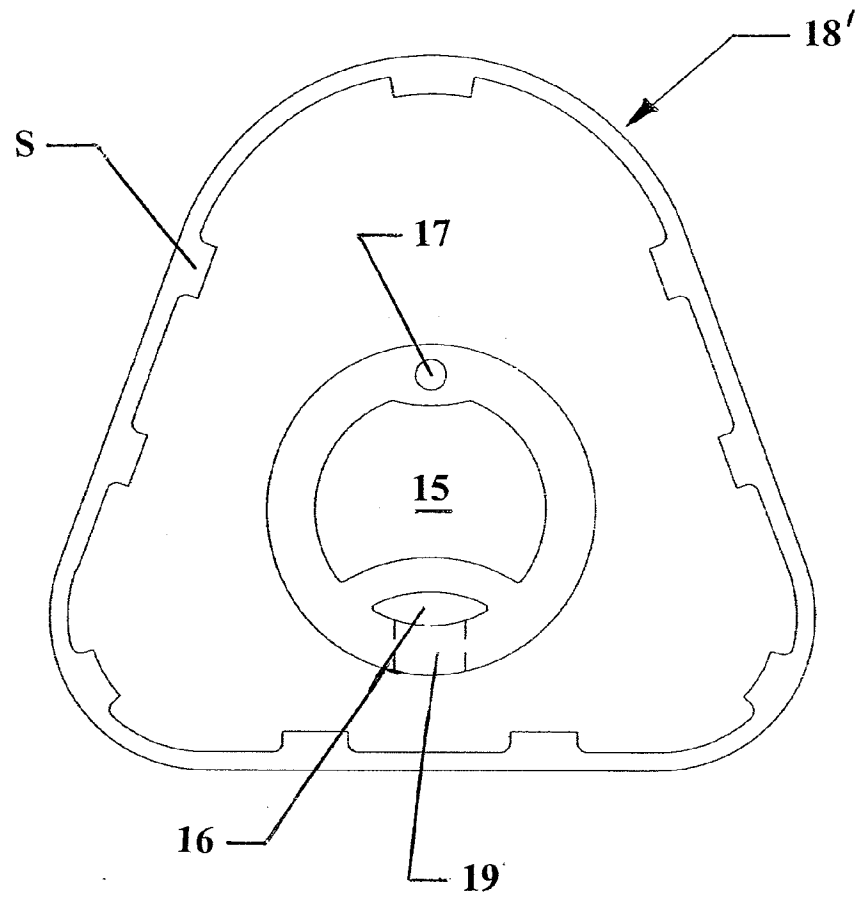


FIG. 8

FIG. 9



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FIG. 10

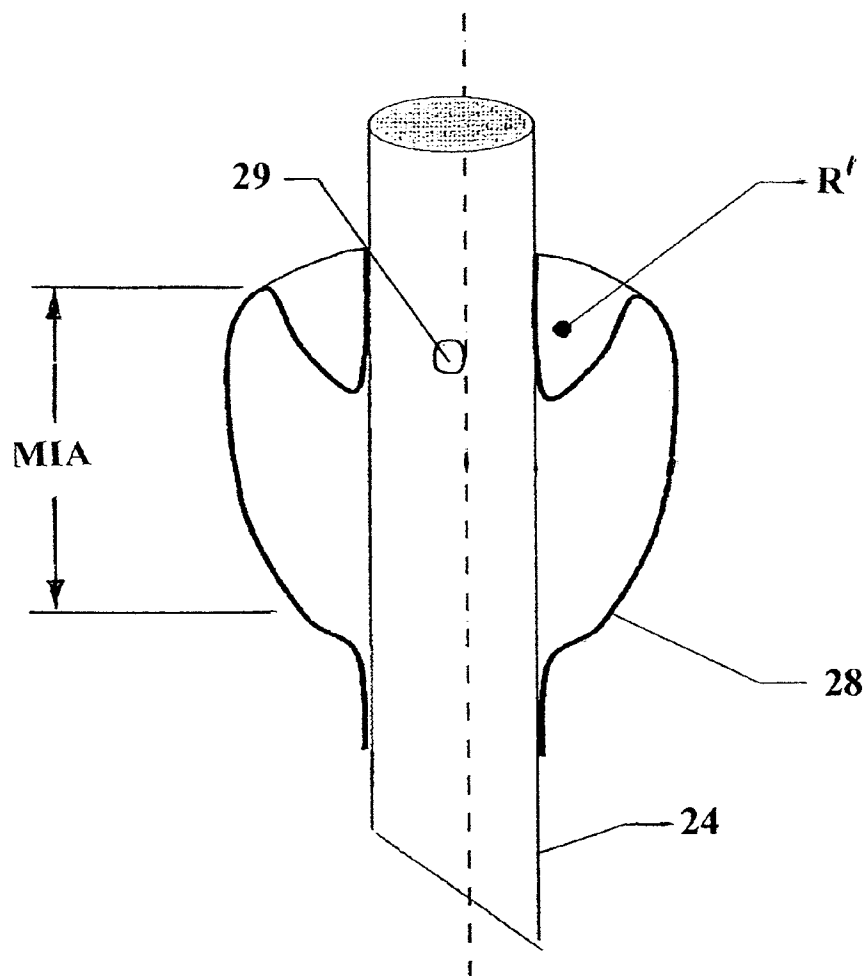


FIG. 11

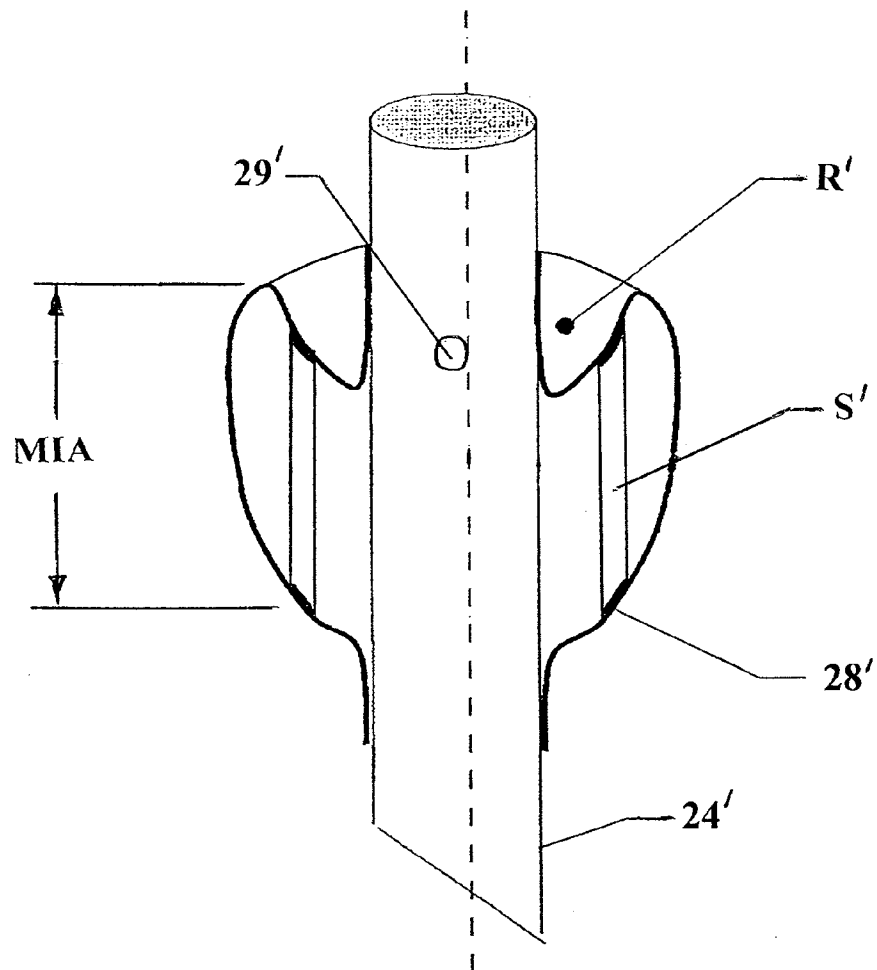
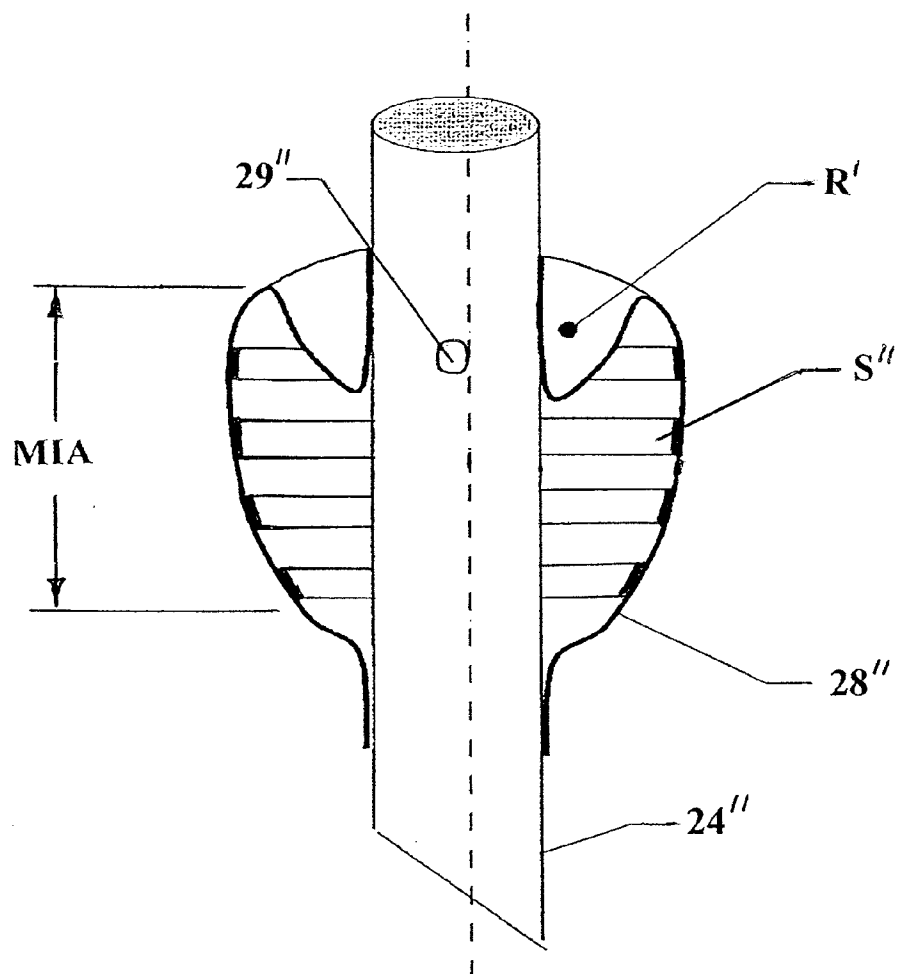
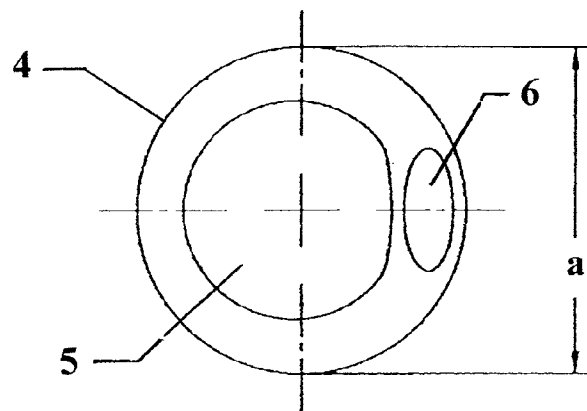


FIG. 12



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FIG. 13



PRIOR ART

FIG. 14

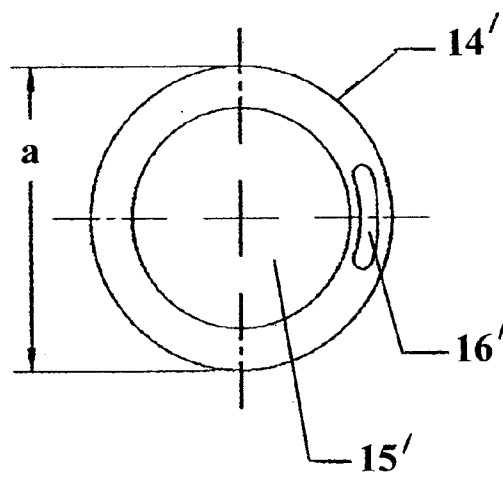


FIG. 16

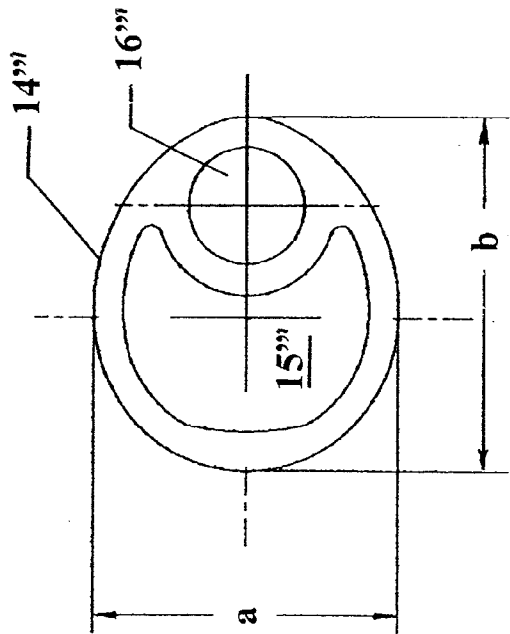


FIG. 15

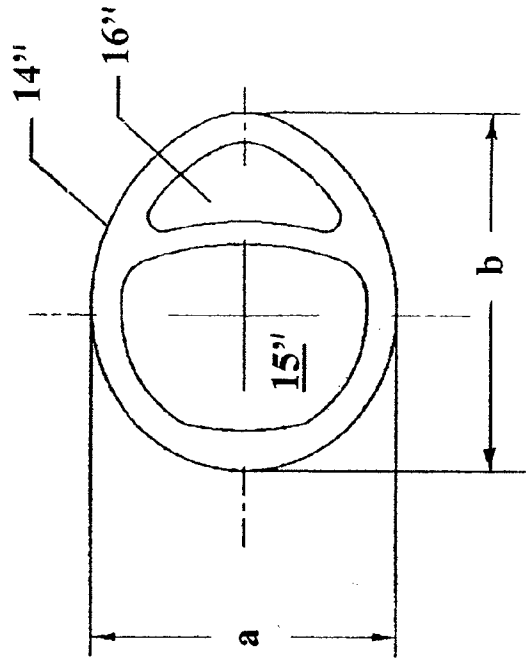


FIG. 17

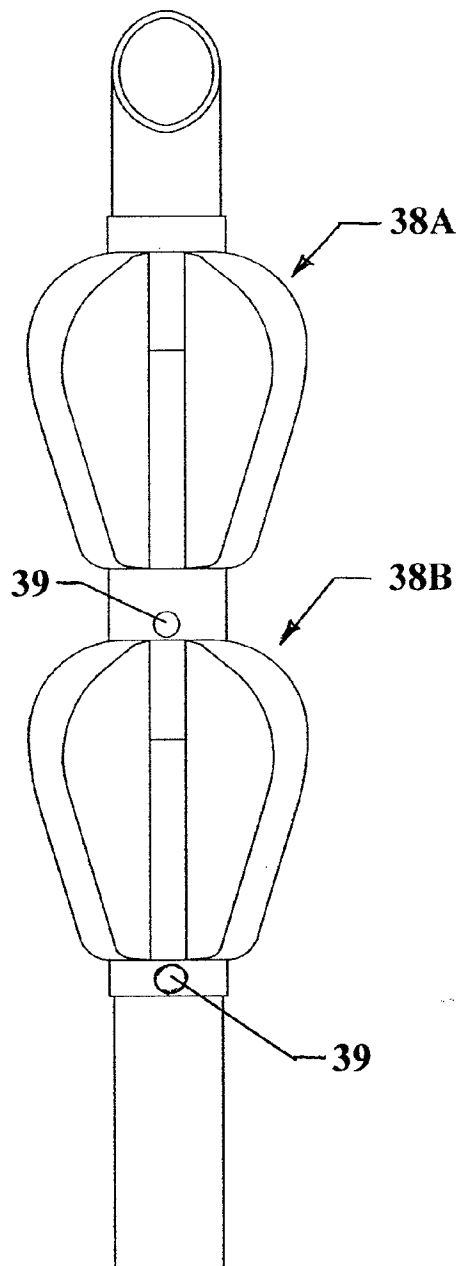
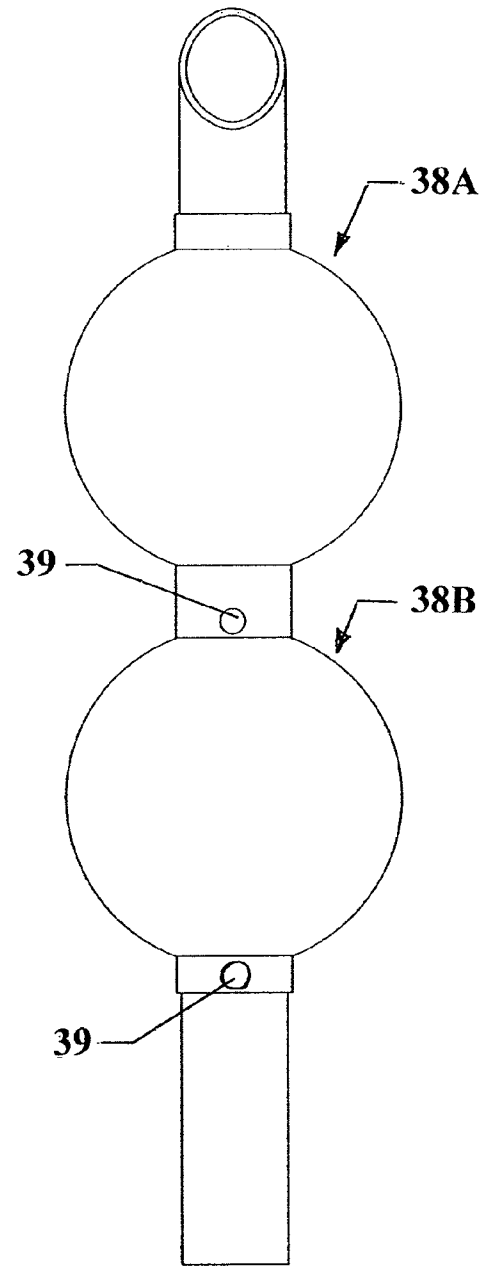


FIG. 18



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2011/065583

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 16/04 (2012.01)

USPC - 604/103.06

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, 16/04 (2012.01)

USPC - 128/200.26, 207.15; 604/101.05, 103.06, 103.07, 103.09

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/0110468 A1 (NELSON et al) 15 May 2008 (15.05.2008) entire document	1-25
Y	US 2008/0021386 A1 (CLAYTON) 24 January 2008 (24.01.2008) entire document	1-25
Y	US 6,152,136 A (PAGAN) 28 November 2000 (28.11.2000) entire document	1-24
Y	US 5,499,625 A (FRASS et al) 19 March 1996 (19.03.1996) entire document	1-24
Y	US 6,544,224 B1 (STEESE-BRADLEY) 08 April 2003 (08.04.2003) entire document	1-25
Y	US 4,796,629 A (GRAYZEL) 10 January 1989 (10.01.1989) entire document	1-25
Y	US 2009/0264822 A1 (JOHNSON) 22 October 2009 (22.10.2009) entire document	1-25

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


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"O" document referring to an oral disclosure, use, exhibition or other means

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Date of the actual completion of the international search

30 March 2012

Date of mailing of the international search report

13 APR 2012

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774