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(54) Title: TRACHEAL TUBES, ASSEMBLIES AND METHODS

(57) Abstract: A tracheal tube has a sealing cuff (4, 61) with an expulsion chamber (5, 75) at its machine end. The expulsion chamber has a relatively small volume and has a ring of small openings (13, 71) around its upper end. A conduit (9, 79) connects the expulsion chamber (5, 75) to a resuscitation bag (12) so that a rapid, large volume of air can be supplied to the chamber, thereby creating air jets directed upwardly through the openings (13, 71) around its upper end to blow secretions up the trachea.

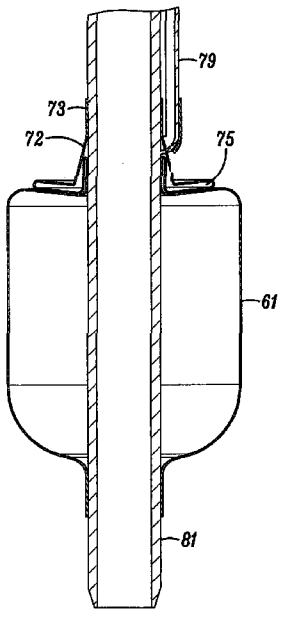

FIG. 9

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Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

TRACHEAL TUBES, ASSEMBLIES AND METHODS

This invention relates to tracheal tubes of the kind having sealing means on its outer surface towards its patient end adapted to form a seal with the wall of a trachea.

Tracheal tubes are used to enable ventilation, respiration or spontaneous breathing of a patient. Endotracheal tubes are inserted via the mouth or nose so that one end locates in the trachea and the other end locates outside the patient. Tracheostomy tubes are inserted into the trachea via a surgically-formed opening in the neck. It is common practice for such tubes to include a sealing member close to the patient end of the tube that forms a seal between the outside of the tube and the tracheal wall. In this way gas flow into the lungs is confined along the bore of the tube and cannot flow between the outside of the tube and the trachea. Usually the sealing member is in the form of a hollow annular cuff that can be inflated and deflated via a small bore inflation line opening into the interior of the cuff and extending rearwardly towards the machine end of the tube where it can be connected with a syringe or the like to supply air or liquid via the inflation line to or from the inside of the cuff.

One problem with cuffed tracheal tubes is that secretions can collect above the cuff between the tube and the wall of the trachea. These secretions can provide a site for bacterial growth. It is important, therefore, to minimise the amount of secretions that leak past the cuff during use such as by special design of the cuff shape and material and by control of the cuff inflation pressure. It is also important to minimize the amount of secretions released into the trachea when the cuff is deflated prior to removing the tube from the trachea. Cuffed tubes are available with a suction channel opening above the cuff to enable secretions to be periodically removed, such as described in US4607635 which describes a tracheal tube having a channel open at various locations along its length and through which a suction catheter can be inserted to remove secretions at any desired location above the cuff. US4305392 describes a tracheal tube with a bulbous chamber above the cuff in which secretions are collected for removal through a suction lumen extending through the wall of the tube. US4840173 describes a catheter having a suction tube projecting over the proximal collar of the cuff to increase the amount of secretions that can be collected. GB2250440

describes a tube where the upper end of the cuff is everted within the cuff so that it does not provide any obstruction to locating a suction opening as close as possible to the cuff. JP-A-10005340 describes a tube with two suction lumens linked by a gutter where they open on the side of the tube. US6796309 describes a tracheal tube with a gutter extending around the tube from the suction opening. US5819723 describes a tracheal tube with suctioning above the cuff and with an irrigating lumen that opens on the outside wall of the tube to deliver liquid above the cuff to help loosen the secretions for suctioning. US2018/0296782 describes a tube with two sealing cuffs separated from one another by a cavity from which fluid can be aspirated via a lumen opening into the cavity.

It has also been proposed to use positive pressure to expel secretions by rapidly applying an elevated pressure to the main bore of the tracheal tube using a self-inflating resuscitation bag while at the same time deflating the sealing cuff so that the air delivered by the bag is forced rearwardly in a cephalic direction around the outside of the tracheal tube. In this way, secretions are blown away from the respiratory passages. See: "Evaluation of the Safety and Effectiveness of the Rapid Flow Expulsion Maneuver to Clear Subglottic Secretions in Vitro and Vivo" by Jie Li et al Respiratory Care – April 4, 2017. A problem with this technique is that it relies on coordinating the deflation of the cuff with the administration of the rapid expulsion pulse. US5544648 describes a tube having a sleeve attached to its outside that opens at its rear end so that gas supplied to the sleeve blows rearwardly along the trachea away from the respiratory passages. This arrangement does not suggest how such an arrangement could be used in conjunction with a sealing cuff.

It is an object of the present invention to provide alternative tracheal assembly and method of manufacture.

According to one aspect of the present invention there is provided a tracheal tube of the above-specified kind, characterised in that the tube includes an expulsion chamber adjacent with the machine end of the sealing means, that the expulsion chamber has a plurality of openings around the tube facing away from its patient end, and that the assembly includes an expulsion conduit opening at one end into the expulsion chamber and arranged at its opposite end for connection with a source of expulsion fluid so that expulsion fluid can be

delivered rapidly to the expulsion chamber while the sealing means maintains a seal with the trachea on the patient side of the expulsion chamber such that the expulsion fluid flows into the expulsion chamber and out through the openings causing secretions above the expulsion chamber to be displaced away from the patient end of the tube.

The sealing means preferably includes an inflatable sealing means. The expulsion chamber may be attached with a machine end of the sealing means. The sealing means and expulsion chamber may be moulded together as a one-piece, unitary construction.

According to another aspect of the present invention there is provided a method of manufacturing a tracheal tube including the steps of providing a shaft for the tube, moulding a one-piece unitary moulding having a sealing cuff and an expulsion chamber arranged coaxially of one another and joined with one another by a tubular extension, the expulsion chamber having a plurality of expulsion openings arranged around its machine end face, and displacing the expulsion chamber and sealing cuff towards one another such that the tubular extension extends into the interior of the expulsion chamber and the expulsion chamber contacts the machine end surface of the sealing cuff.

The method may include the step of bonding the expulsion chamber with the machine end surface of the sealing cuff. The moulding is preferably assembled on the shaft before bonding the expulsion chamber with the sealing cuff.

According to a further aspect of the present invention there is provided a tracheal tube made by a method according to the above other aspect of the present invention.

According to a further aspect of the present invention there is provided an assembly of a tracheal tube according to the above one or further aspect of the present invention and a source of expulsion fluid connected with the expulsion conduit.

According to another aspect of the present invention there is provided an assembly of a tracheal tube of the above-specified kind and a source of expulsion fluid connected with the expulsion conduit.

The source of expulsion fluid is preferably a self-inflatable resuscitation bag.

Two forms of tracheal assembly and a method of manufacture will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a side elevation view of a first form of the tracheal assembly in use;

Figure 2 is a side elevation view of the first form of assembly;

Figure 2A is an enlarged, cut-away, perspective view showing the expulsion chamber in more detail;

Figure 3 is a side elevation view of a moulding used in a second form of assembly;

Figure 4 is a side elevation view of a part of the moulding of Figure 3 to an enlarged scale;

Figure 5 is a side elevation sectional view of the moulding of Figures 3 and 4 assembled on the shaft of a tracheal tube at a preliminary stage of manufacture;

Figure 6 is a partly cut away perspective view of the assembly of Figure 5;

Figure 7 is a side elevation view of a part of the assembly at a subsequent stage of manufacture;

Figure 8 is a side elevation view of the part of the assembly at the final stage of manufacture, omitting the tube; and

Figure 9 is a side elevation view of the part shown in Figure 8 assembled on a tube.

With reference first to Figure 1 there is shown a first form of a tracheostomy tube assembly having a curved shaft 1 with a patient end 2 for location in the trachea T and a machine end 3 that projects through a tracheostomy stoma on the neck surface. The tracheostomy tube assembly also includes a sealing cuff 4 close to its patient end 2 and an expulsion chamber 5 bonded to the machine side of the cuff. The sealing cuff 4 communicates with the patient end of an inflation lumen 6 extending rearwardly along the shaft 1 within the thickness of its wall and joined with one end of an inflation line 7 towards the machine end of the shaft 1. The opposite end of the inflation line 7 is joined with a combined inflation indicator, valve and connector 8 of a conventional kind. The expulsion chamber 5 is described in detail later, its interior being in communication with an expulsion fluid line 9 of a larger internal diameter than the cuff inflation line 7 and extending externally along the shaft 1. At its machine end the expulsion fluid line 9 is terminated by a 15 mm male connector 10 adapted to receive a mating female coupling 11 on a conventional self-inflating resuscitation bag 12. The expulsion chamber 5 has a ring of several (typically around eight) expulsion openings or ports 13 spaced from one another around the shaft 1 and facing upwardly, that is, away from the patient end, outwardly of the respiratory passages and generally parallel with the axis of the shaft. In this way, when the resuscitation bag 12 is squeezed forcefully a large volume of air is rapidly driven along the expulsion fluid line 9 to the interior of the expulsion chamber 5. The air forced into the expulsion chamber 5 immediately flows out through the openings 13 to form a ring of air jets around the shaft 1 that forces any secretions above the expulsion chamber 5 upwardly and outwardly of the respiratory passages, away from the sealing cuff 4.

The expulsion process simulates a cough. The secretions driven up the trachea "T" may be removed by the patient swallowing or spitting into a bowl. Alternatively, if the patient is unable to do this himself the secretions may be removed by a clinician immediately following expulsion using a Yankauer or similar suction tube inserted through the mouth and into the pharynx.

The construction of the expulsion chamber 5 is shown more clearly in Figures 2 and 2A. Opposite ends 41 and 42 of the sealing cuff 4 both have a domed, almost hemispherical shape. The expulsion chamber 5 is formed by a flexible domed cap 50 enclosing the upper, machine end 42 of the sealing cuff 4 and sealed around its lower, patient end edge 51 with the outside of the sealing cuff at the boundary between its upper domed end 42 and its cylindrical central portion 43. The upper, machine end of the cap 50 is formed into a cylindrical collar 52 bonded onto the outside of the machine end collar 44 of the sealing cuff 4. The expulsion ports 13 are formed in the domed cap 50. The cap 50 and machine end 42 of the sealing cuff 4 form between them a thin, tapering, domed shell-like expulsion chamber 5 with a relatively small volume compared with that of the sealing cuff 4 and compared with the volume of the resuscitation bag 12. In this way, when the resuscitation bag 12 is squeezed to expel secretions the air flows through the expulsion line 9 and into the small volume of the expulsion chamber 5. This causes a small expansion of the chamber 5 because of the resilience of the material of the cap 50 and the compressibility of the air volume in the sealing cuff 4 but most of the air supplied to the chamber will immediately jet out through the expulsion ports 13 and be directed parallel to the axis of the shaft 1 away from its patient end 2.

This arrangement enables secretions to be removed without the need to interrupt the seal between the tube and the trachea.

An alternative, second form of assembly is shown in Figures 3 to 9 where the sealing cuff and expulsion chamber are formed as a one-piece, unitary silicone moulding 60. Figures 3 and 4 show this moulding 60 before further assembly operations, that is, before it is assembled on a shaft 81. The moulding 60 comprises a relatively large volume sealing cuff 61 having a domed lower or patient end 62 that continues as a patient end collar 63. The upper end 64 of the cuff 61 is substantially flat with a slight concave dished machine end surface 65. Centrally of the surface 65 the moulding continues as a short tubular extension 66 of approximately the same diameter as the collar 63. The upper end of the extension 66 continues as a radially-enlarged dish-shape formation 67, which provides the eventual expulsion chamber and is arranged coaxially of the sealing cuff 61. The formation 67 has a circular section with a tapered base portion 68, an outwardly flared side wall 69 and an

inwardly tapered upper or machine end face 70 formed with a series of several expulsion openings or ports 71 around its circumference. Centrally of the upper face 70 extends an axial tapered sleeve 72 that is terminated by a cylindrical collar portion 73.

The moulding 60 in the form described above is slid on to the patient end 80 of the tracheostomy tube shaft 81 with the patient end collar 63 spaced a short distance from the patient end of the shaft, as shown in Figures 5 and 6. The shaft 81 is preferably coated with an adhesive or solvent along its patient end to help lubricate sliding the moulding 60 into the correct position and to form an eventual bond and seal between the outside of the shaft and the moulding. The next step is to apply a layer of a silicone adhesive to the upper dished surface 65 on the sealing cuff 61. Then, as shown in Figures 7 and 8, the upper, machine end of the moulding 60 is slid down in the direction of the patient end 80 of the shaft 81. As this happens the tubular extension 66 pushes up the tapered base portion 68 so that it snaps from having a concave shape (when viewed from above) to a convex shape. Further displacement of the upper end of the moulding 60 flattens the side wall 69 against the upper surface 65 of the sealing cuff 61 and against the adhesive on that surface, as shown in Figure 8. When fully displaced, the upper end of the tubular extension 66 contacts the inside of the tapered sleeve 72, the upper face 70 of the formation 67 lying substantially flat and closely spaced from the lower part of the formation now in contact with the upper surface 65 of the sealing cuff 61. In this way a small interior volume or expulsion chamber 75 is defined between the inner surfaces of the upper face 70, the upper surface of the base of the formation 67 adhered to the upper face of the sealing cuff and externally of the outer surface of the tubular extension 66. When the adhesive has cured and the moulding 60 is securely retained in this compressed state on the tube shaft 81 connection is made to the expulsion chamber 75 by the patient end of an expulsion line 79 (Figure 9). The small volume of the expulsion chamber 75 ensures that when air or other expulsion fluid is delivered to the chamber this immediately jets out forcefully from the chamber via the ports 71. The ports 71 are arranged to face upwardly, towards the machine end of the shaft 81, so that the expulsion jets are directed parallel to the axis of the shaft 81, thereby blowing any secretions collected on the upper machine end of the sealing cuff 61 rearwardly up the trachea.

Making the expulsion chamber 75 and sealing cuff 61 as a single component 60 avoids any risk of leakage or separation of components and keeps manufacturing and assembly costs to a minimum.

Other sources of expulsion fluid could be used in place of a self-inflating resuscitation bag, such as, for example, a large volume syringe or a source of compressed gas. Instead of using a gas as the expulsion fluid it would be possible to use a liquid, providing provision was made to remove the liquid from the trachea. The invention is not confined to tracheostomy tubes but could be used with other cuffed tracheal tubes, such as endotracheal tubes.

CLAIMS

1. A tracheal tube having sealing means (4, 61) on its outer surface towards its patient end (2) adapted to form a seal with the wall of a trachea, characterised in that the tube includes an expulsion chamber (5, 75) adjacent with the machine end of the sealing means (4, 61), that the expulsion chamber (5, 75) has a plurality of openings (13, 71) around the tube facing away from its patient end (2), and that the assembly includes an expulsion conduit (9, 79) opening at one end into the expulsion chamber (5, 75) and arranged at its opposite end for connection with a source (12) of expulsion fluid so that expulsion fluid can be delivered rapidly to the expulsion chamber (5, 75) while the sealing means (4, 61) maintains a seal with the trachea on the patient side of the expulsion chamber such that the expulsion fluid flows into the expulsion chamber (5, 75) and out through the openings (13, 71) causing secretions above the expulsion chamber to be displaced away from the patient end (2) of the tube.

2. A tracheal tube according to Claim 1, characterised in that the sealing means includes an inflatable sealing means (4, 61).

3. A tracheal tube according to Claim 1 or 2, characterised in that the expulsion chamber (5, 75) is attached with a machine end of the sealing means (4, 61).

4. A tracheal tube according to any one of the preceding claims, characterised in that the sealing means (61) and expulsion chamber (75) are moulded together as a one-piece, unitary construction (60).

5. A method of manufacturing a tracheal tube including the steps of providing a shaft (81) for the tube, moulding a one-piece unitary moulding (60) having a sealing cuff (61) and an expulsion chamber (75) arranged coaxially of one another and joined with one another by a tubular extension (66), the expulsion chamber (75) having a plurality of expulsion openings (71) arranged around its machine end face (70), and displacing the expulsion chamber (75) and sealing cuff (61) towards one another such that the tubular extension (66) extends into the interior of the expulsion chamber (75)

and the expulsion chamber (75) contacts the machine end surface (65) of the sealing cuff (61).

6. A method according to Claim 5, characterised in that the method includes the step of bonding the expulsion chamber (75) with the machine end surface (65) of the sealing cuff (61).

7. A method according to Claim 6, characterised in that the moulding (60) is assembled on the shaft (81) before bonding the expulsion chamber (75) with the sealing cuff (61).

8. A tracheal tube made by a method according to any one of Claims 5 to 7.

9. An assembly of a tracheal tube according to any Claims 1 to 4 or Claim 8 and a source (12) of expulsion fluid connected with the expulsion conduit.

10. An assembly according to Claim 9, characterised in that the source of expulsion fluid is a self-inflatable resuscitation bag.

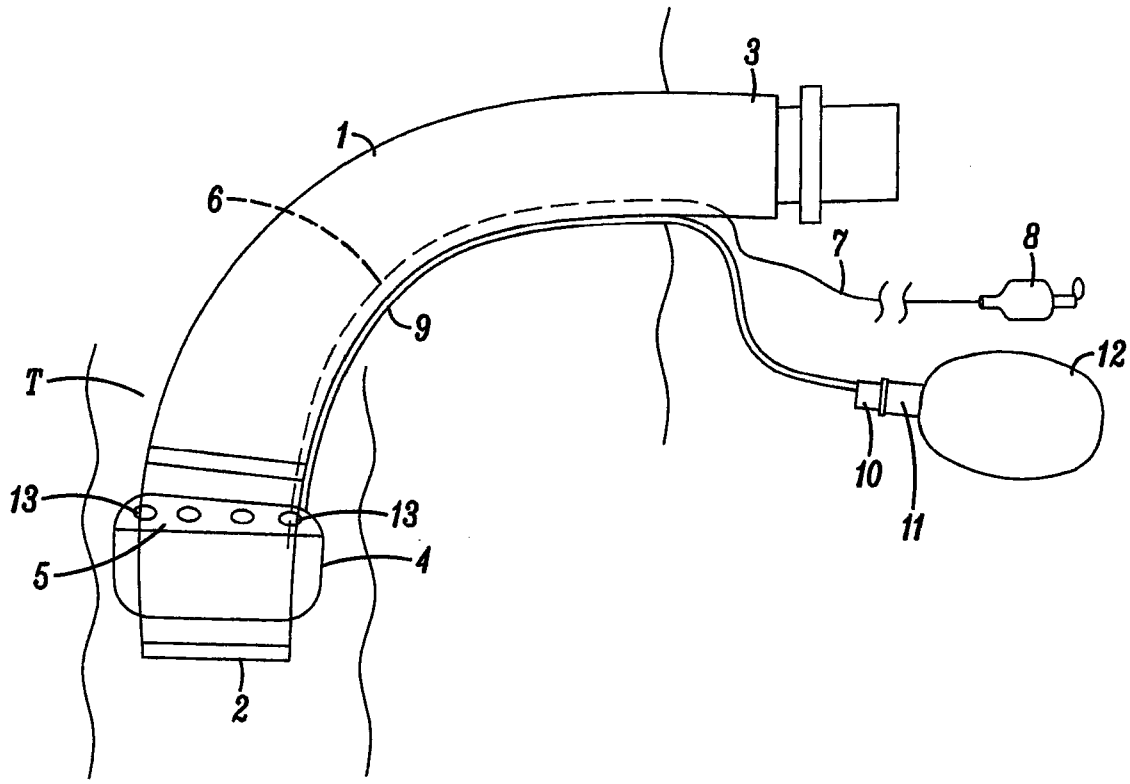

FIG. 1

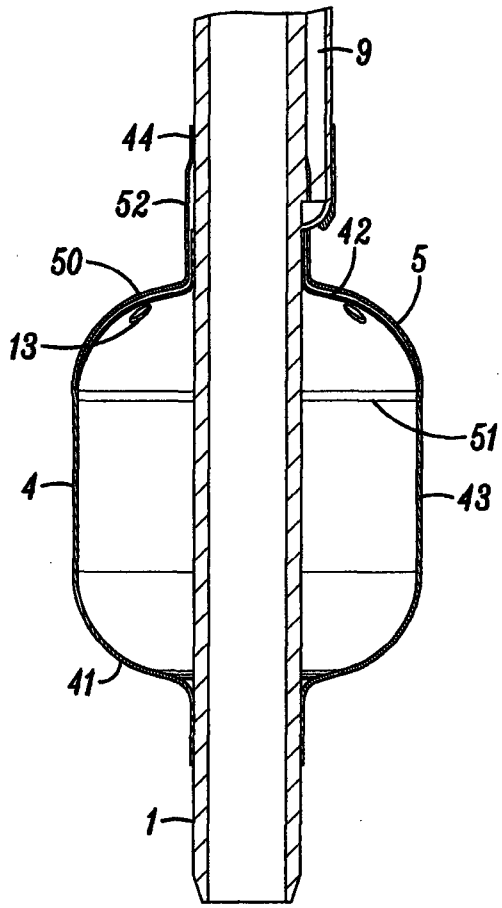

FIG. 2

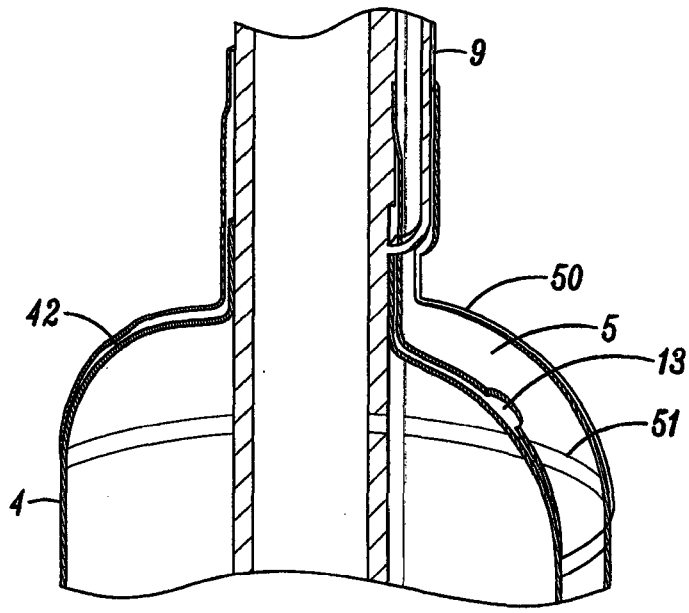

FIG. 2A

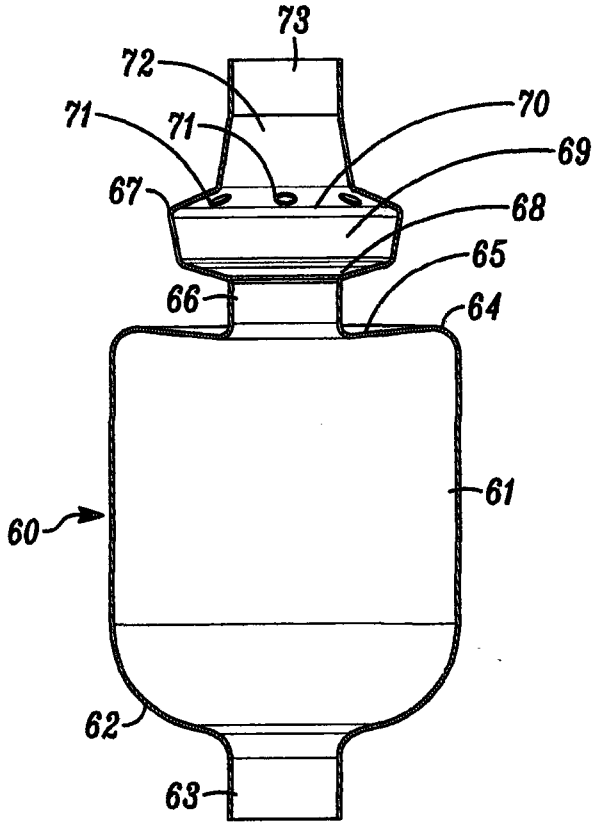

FIG. 3

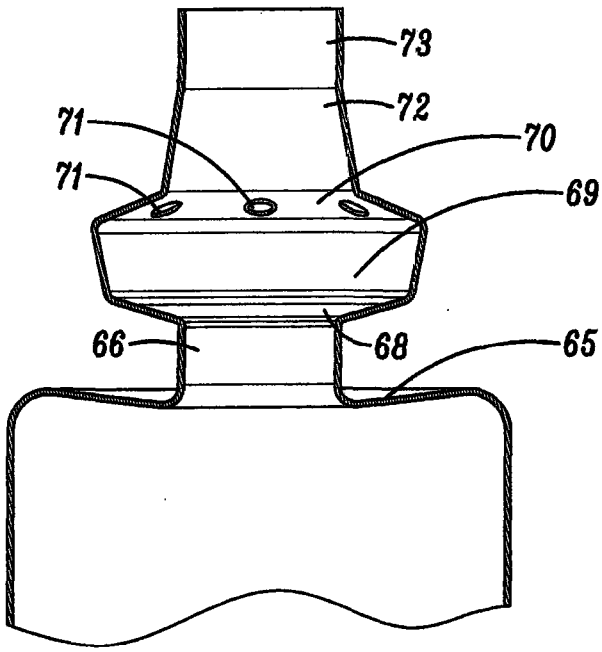

FIG. 4

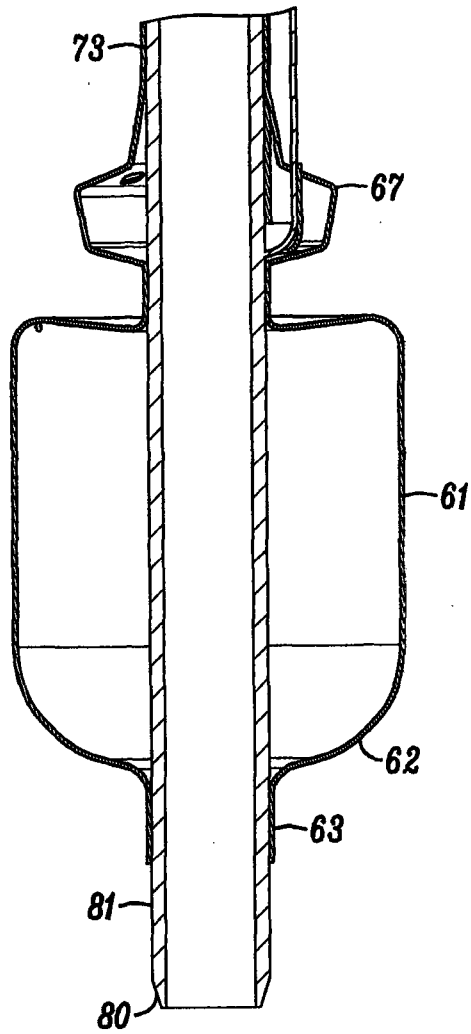

FIG. 5

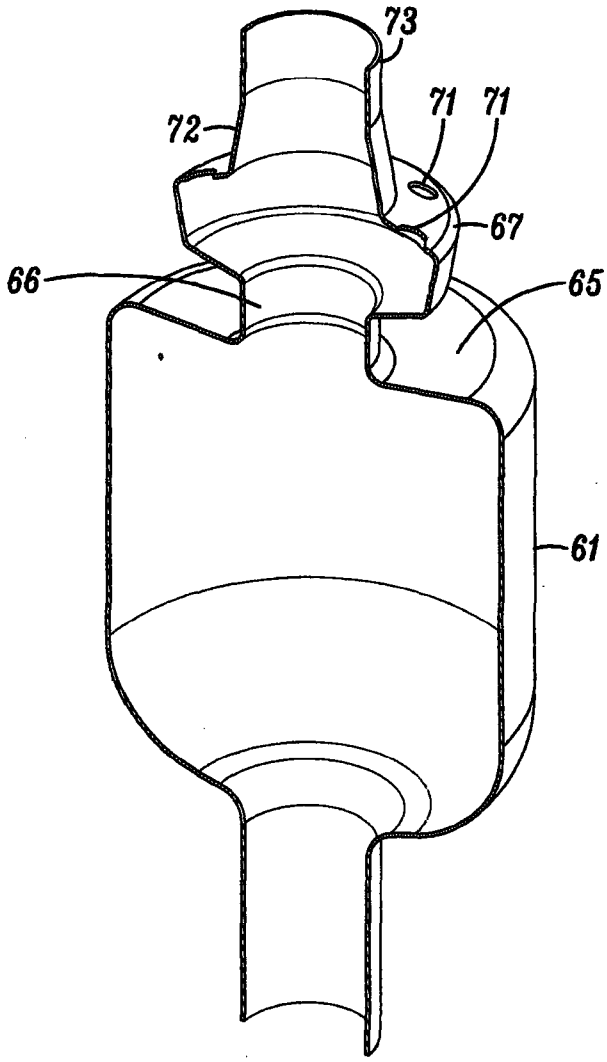

FIG. 6

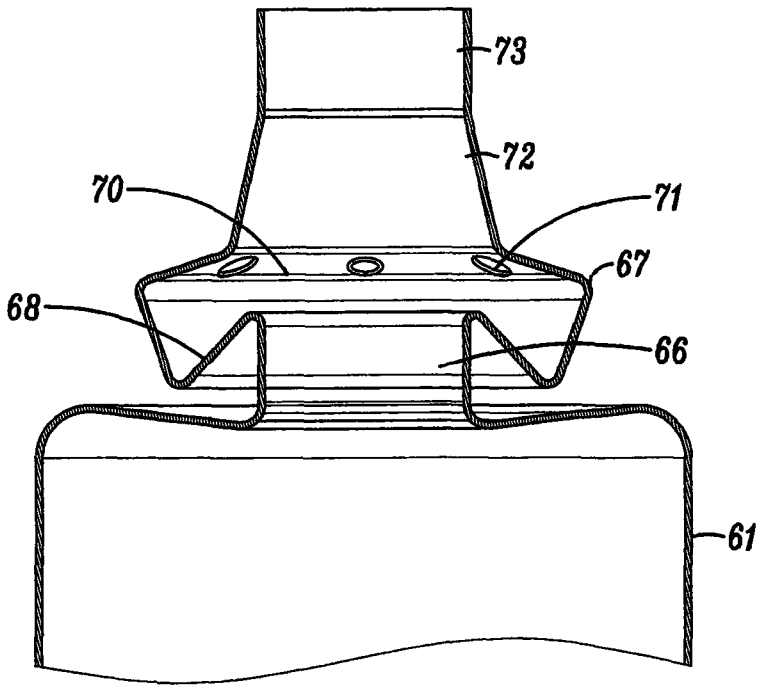

FIG. 7

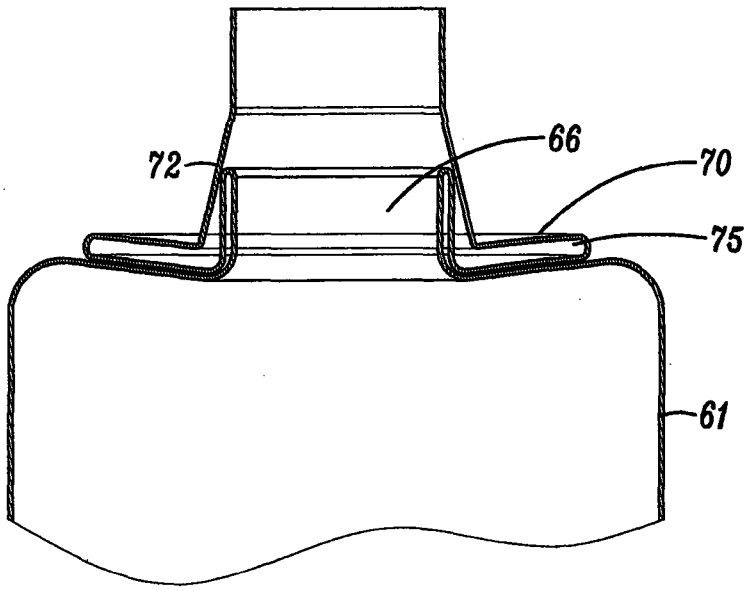

FIG. 8

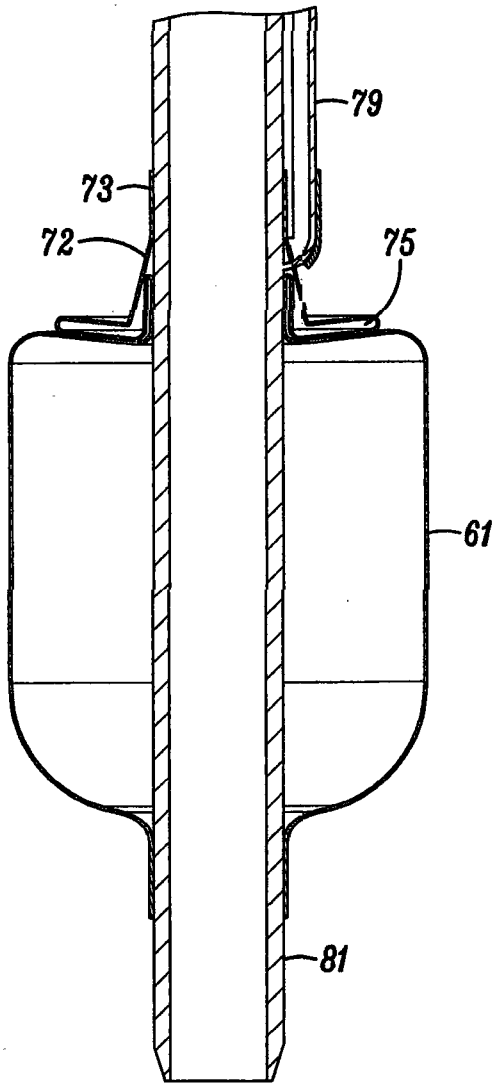

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2019/000089

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/00 A61M16/04
ADD.

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 305 392 A (CHESTER MARTIN H) 15 December 1981 (1981-12-15) cited in the application	1-3,9
Y	the whole document, and especially column	10
A	3 lines 30-34, claim 7 and figures 1-4	4-8

A	WO 2012/052908 A1 (ETVIEW LTD [IL]; DAHER ELIAS [DE]) 26 April 2012 (2012-04-26) the whole document, and especially the figures	1-10

A	US 5 501 215 A (HUERTA CHRISTINE M [US]) 26 March 1996 (1996-03-26) the whole document, and especially the figures	1-10

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
5 September 2019	16/09/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Azaïzia, Mourad

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 327 721 A (GOLDIN JACK ET AL) 4 May 1982 (1982-05-04) the whole document, and especially the figures	1-10
A	GB 1 040 425 A (RAYMOND PESTY) 24 August 1966 (1966-08-24) the whole document, and especially the figures	1-10
A	US 3 173 418 A (BARAN OSTAP E) 16 March 1965 (1965-03-16) the whole document, and especially the figures	1-10
Y	JIE LI ET AL: "Evaluation of the Safety and Effectiveness of the Rapid Flow Expulsion Maneuver to Clear Subglottic Secretions in Vitro and in Vivo", RESPIRATORY CARE, vol. 62, no. 8, 4 April 2017 (2017-04-04), pages 1007-1013, XP055617541, US ISSN: 0020-1324, DOI: 10.4187/respcare.05348 cited in the application the whole document, and especially figures 1-3	10
A	WO 2016/189427 A1 (UNIVERSITA' DEGLI STUDI DI MILANO-BICOCCA [IT]) 1 December 2016 (2016-12-01) the whole document, and especially the figures	1-10
A	US 2008/053454 A1 (PASILLAS PEDRO VELAZCO [MX] ET AL) 6 March 2008 (2008-03-06) the whole document, and especially the figures	1-10
A	GB 2 335 362 A (SMITHS INDUSTRIES PLC [GB]) 22 September 1999 (1999-09-22) the whole document, and especially the figures	1-10

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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