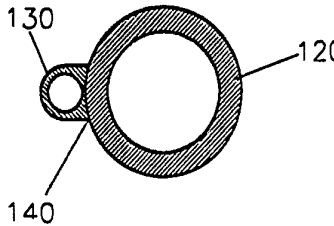




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US96/09185 (22) International Filing Date: 6 June 1996 (06.06.96) (30) Priority Data: 08/476,005 7 June 1995 (07.06.95) US (71) Applicant: MALLINCKRODT MEDICAL, INC. [US/US]; 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, MO 63134 (US). (72) Inventors: PRICHARD, Cheryl, B.; 312 Lazy Branch Drive, St. Peters, MO 63376 (US). TAYLOR, Geraldine; Bal- linamore Bridge, Ballinaloe County, Galway (IE). MA- HONEY, Michael, R.; 101 Rue Grand, Lake St. Louis, MO 63367 (US). (74) Agents: HEY, David, A. et al.; Mallinckrodt Medical, Inc., 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, MO 63134 (US).</p>		<p>(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i></p>
<p>(54) Title: IMPROVED TRACHEOSTOMY TUBES</p>		
<p>(57) Abstract</p>		
<p>A tracheostomy tube (100) comprising a first tube (120) having a cylindrical cross section bonded to a second tube (130) having a D-shaped cross section. The tracheostomy tube of the present invention presents a lower profile and is therefore more comfortable for the patient. Further, the tracheostomy tube of the present invention allows for greater flow rates or suction rates when compared to prior art tracheostomy tubes comprised of two cylindrical tubes.</p> <div style="text-align: right;">  </div>		

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Improved Tracheostomy TubesBackground

The present invention relates to tracheostomy tubes which are used as an alternate airway passage for patients. In particular, the present invention relates to tracheostomy tubes which have an additional lumen and methods of making them.

Tracheostomy tubes have been used for some time to provide a bypass supply of air or mixture of gases to a patient having an obstruction in the larynx or the pharynx area of the throat. The distal end of the tracheostomy tube is inserted through an incision or stoma in the patient's neck below the obstructed area. An inflatable cuff near the distal end of the tracheal tube is inflated to securely position the tube within the trachea of the patient. The proximal end of the tracheostomy tube remains outside the trachea in communication with ambient air or with a ventilator and permits passage of air into the trachea.

Tracheostomy tubes are often used following a surgical procedure in the larynx or pharynx to aid the patient in breathing during the surgical recovery period. In these cases, the tracheostomy tube is intended to be used for a relatively short period of time until the patient can resume breathing normally. In other cases, tracheostomy tubes are used for extended periods of time or may be permanent.

In all cases, it is necessary to periodically clean the area of the tube above the cuff of the tracheostomy tubes of mucus and other secretions which build up in the trachea.

When tracheostomy tubes are used, it is often desirable to have an additional lumen, wherein the main lumen provides the airway passage and the additional lumen provides a means for introduction of medicants and a means for suctioning of secretions which may collect in the patient's airway above the

cuff. The inclusion of an additional lumen is important, as it allows for suctioning, while maintaining the main lumen for breathing. This is especially important when the normal airway passages of the patient are completely blocked.

5 Prior art tracheostomy tubes having an additional lumen have been comprised of two tubes, each having a cylindrical cross-section, bonded together. Such a prior art tube is shown in Figs. 1 and 2 wherein the tracheostomy tube, generally designated by reference numeral 10, comprises a first tube 20, bonded to a
10 second tube 30. The tube 10, includes an inflatable cuff 50, formed near the distal end and surrounding the first tube 20. The second tube 30, extends to just above the cuff 50, and includes openings 35, which may be used to admit medicants above the cuff 50, or to suction material from above the cuff 50.
15 Prior art tubes of this type have a number of disadvantages, including the use of two cylindrical tubes 20, 30, which creates a tracheostomy tube having a relatively large and non-symmetrical overall cross-section. This can create discomfort for the patient, especially in the stoma area. Further, as best shown
20 in Fig. 2, the first tube 20, and second tube 30, must be bonded together by bond seams 40, 45, which run the entire length of the second tube 30. The bond seams 40, 45, necessarily are wedge shaped to create a sufficient bond between the tubes 20, 30, and to present a more even and consistent outside diameter for the
25 tracheostomy tube 10. However, the bond seams 40, 45, can still cause discomfort to the patient and add considerably to the expense and processing required to form the tracheostomy tube.

Therefore, there remains a need in the art for improvements to double lumen tracheostomy tubes.

30 Objects Of The Invention

It is one object of the present invention to provide a lower

profile two lumen tracheostomy tube.

It is a further object of the present invention to provide a two lumen tracheostomy tube which can be more easily manufactured than those of the prior art.

5 Summary Of The Invention

The above objects and others, are accomplished according to the present invention by providing a tracheostomy tube comprised of a first tube having a cylindrical cross-section bonded to a second tube initially having a "D" shaped cross-section.

10 Brief Description Of The Drawings

Fig. 1 is a plan view of a tracheostomy tube as known in the prior art.

Fig. 2 is a cross sectional view taken along line A-A of Fig. 1, of a tracheostomy tube as known in the prior art.

15 Fig. 3 is a plan view of a tracheostomy tube according to one embodiment of the present invention.

Fig. 4 is an cross sectional view taken along line B-B of Fig. 3, of a tracheostomy tube according to one embodiment of the present invention.

20 Fig. 5 is a cross sectional view of the "D" shaped second tube of the tracheostomy tube according to the present invention.

Fig. 6A and 6B are cross sectional views showing progressive stages of the manufacture of a tracheostomy tube according to one embodiment of the present invention.

Detailed Description Of The Invention

Fig. 3 is a plan view of a tracheostomy tube generally designated by reference numeral 100, according to one embodiment of the present invention. In particular, tracheostomy tube 100, comprises a first tube 120, having a generally cylindrical cross-section, and a second tube 130, having a D-shaped cross-section, bonded to the first tube 120. The tube 100, includes an inflatable cuff 150, formed near the distal end and surrounding the first tube 120. The second tube 130, extends to just above the cuff 150, and includes openings 135, which may be used to admit medicants above the cuff 150, or to suction material from above the cuff 150.

Fig. 4 is an cross sectional view taken along line B-B of Fig. 3, of a tracheostomy tube according to the present invention, showing the overall profile comprising first tube 120, and second tube 130, bonded together along seam 140.

As will be apparent from a review of Figs. 3 and 4, the tracheostomy tube 100, according to the present invention overcomes all of the disadvantages noted above with respect to the prior art. In particular, tracheostomy tube 100, presents a much smaller overall cross-section which reduces discomfort for the patient, especially in the stoma area. Further, the seam 140, is much smaller and less intrusive, virtually eliminating one source of discomfort for the patient. The seam 140, actually comprises only a thin layer of adhesive between the tubes 120, 130, but achieves a greater binding strength therebetween than with the wedge shaped seam of the prior art.

As can be seen in Figs. 3 and 4, first tube 120, has a substantially larger cross sectional area than that of second tube 130. Any appropriate sized tubes may be used according to the present invention, but sizes should be picked to present the

lowest overall profile which still maintains the desired air supply capabilities through the first tube 120, and provides the desired medicant delivery or suctioning capabilities through the second tube 130. In particular, first tube 120, may be of any standard size used for tracheostomy tubes, e.g. having inside diameters in the range of 5.0 mm to 10.0 mm and outside diameters in the range of 7.0 mm to 13.3 mm. The second tube 130, may have the same size for all uses and has an inside diameter of about 0.075 mm to 0.08 mm. The outside diameter of the second tube 130, has two dimensions, the first extending from the flat side to the curved side of the D shape and being about 0.128 mm, and the second extending from side to side of the D shape and being about 0.143 mm.

Fig. 5 is a cross sectional view of a second tube 130, as described above with reference to Figs. 3 and 4. The second tube 130, initially has a "D" shaped profile which provides a bonding surface 138, for bonding to the exterior of the first tube 120 (Figs. 3 and 4). It is noted that the lumen 160, of the second tube 130, is not compromised by the "D" shape profile, but rather retains a substantially cylindrical cross section. This is important in providing adequate flow rates of medicants, and to allow for adequate suctioning of material from above the cuff.

As best shown in Figs. 6A and 6B, the process of making a tracheostomy tube according to the present invention is simplified and improved. Fig. 6A shows a first step wherein as tubes 120 and 130, are initially present as two separate tubes. It will be recognized that tube 130 has a D-shaped cross-section. An adhesive may be applied to one or both outer surfaces on tubes 120, 130, which will create the seam 140 (Fig. 4). To avoid an excess of adhesive being applied, the adhesive is preferably applied only to the bonding surface 138, of the D-shaped tube 130.

The tubes 120, 130, are then attached to each other as shown in Fig. 6B. by any suitable bonding procedure, such as solvent or chemical bonding, during which the D-shaped tube 130, conforms to the shape of the cylindrical tube 120.

5 As noted above, the lumen of the "D" shaped tube retains a substantially cylindrical cross section. Advantageously, it has been found that the "D" shaped second tube according to the present invention actually allows greater flow rates or suctioning rates than provided by the prior art, while still
10 presenting the lower profile. This can be extremely advantageous when it is necessary to supply medicants to or to suction secretions from the airway of the patient, because such can be done more quickly.

The tracheostomy tube of the present invention can be formed
15 of any suitable material which provides enough stiffness to allow easy insertion into the trachea of the patient, and enough flexibility to avoid undue stress and damage to the trachea. For example, the tracheostomy tube may be advantageously formed of flexible plastic materials, such as plasticized polyvinyl
20 chloride, polyurethane or silicone.

The individual tubes of the tracheostomy tube according to the present invention may be formed by extrusion techniques, although one skilled in the art will recognize that other methods of manufacture can also be carried out. As will further be
25 understood by one skilled in the art, tracheostomy tubes will vary in size in order to accommodate different patients and clinical needs. The present invention is equally applicable to all sizes and shapes of tracheostomy tubes.

The foregoing has been a description of certain preferred
30 embodiments of the present invention, but is not intended to limit the invention in any way. Rather, many modifications,

variations and changes in details may be made within the scope of the present invention.

What is claimed is:

1. A tracheostomy tube, comprising
a first tube having a cylindrical cross-section; and
a second tube having a D-shaped cross-section;
wherein said first tube and said second tube are bonded
together.
2. A tracheostomy tube according to claim 1, wherein said
second tube conforms to the shape of said first tube.
3. A tracheostomy tube according to claim 1, wherein said
first tube has an inside diameter in the range of 5.0 mm
to 10.0 mm, and said second tube has an inside diameter
in the range of 0.075 mm to 0.080 mm.
4. A tracheostomy tube, comprising
a first tube having a cylindrical cross-section;
an inflatable cuff surrounding said first tube near the
distal end of said first tube; and
a second tube having a D-shaped cross-section bonded to
said first tube from the proximal end of the first tube
to just above said inflatable cuff, and having opening
formed at a location just above said cuff which allow
medicants to be delivered to the exterior of said
tracheostomy tube and allow secretions to be suctioned
away from the exterior of said tracheostomy tube above
said cuff.
5. A method of making a tracheostomy tube, comprising
providing a first tube having a cylindrical cross-
section;
providing a second tube having a D-shaped cross-section,
such that said second tube has a flat portion and a
rounded portion;

- applying an adhesive on at least one portion of one of said first or second tubes;
attaching the flat portion of said second tube to an outside surface of said first tube; and
bonding said second tube to said first tube such that said flat portion of said second tube conforms to said outside surface of said first tube and creates a bonding seam therebetween.
6. A method according to claim 3, wherein said step of applying an adhesive includes the step of applying an adhesive to said flat portion of said second tube.

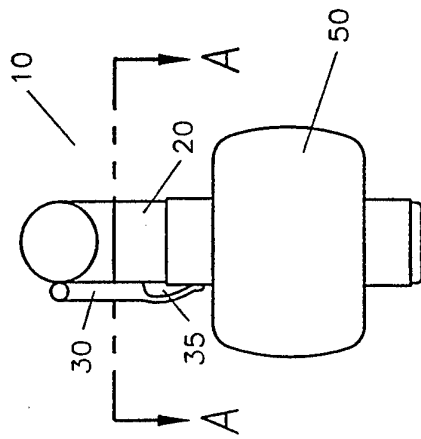


Figure 1

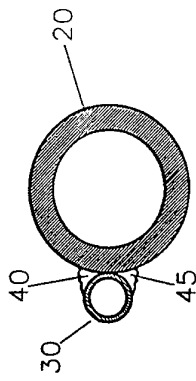


Figure 2

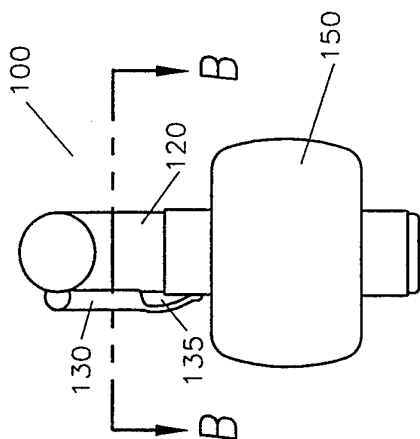


Figure 3

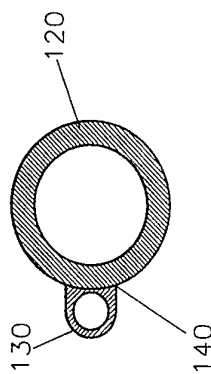


Figure 4

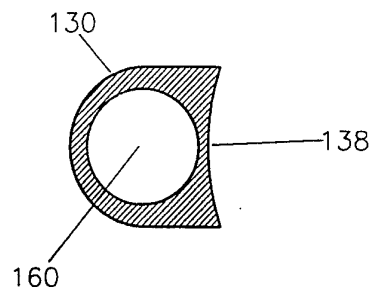


Figure 5

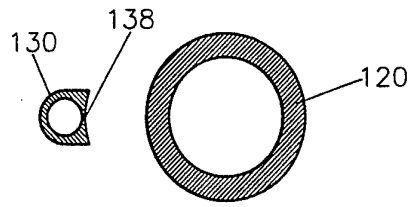


Figure 6A

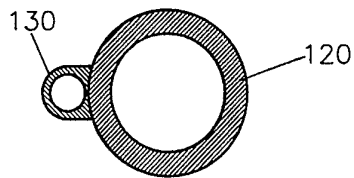


Figure 6B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/09185

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 16/00; A62B 9/06

US CL :128/200.26, 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)

U.S. : U.S. CL. 128/200.26, 207.14

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

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

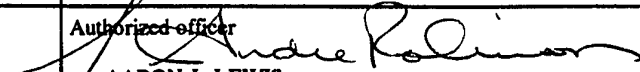
C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,067,497 (GREEAR ET AL.) 26 November 1991, see column 8 lines 54-47.	1-6
Y	US, A, 5,311,864 (HUERTA) 17 May 1994, see Fig. 1.	1-6

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

* Special categories of cited documents:	"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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Date of the actual completion of the international search 07 AUGUST 1996	Date of mailing of the international search report 04 SEP 1996
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