PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:
A61M 16/00, A62B 9/06	A1	WO 93/17744
		(43) International Publication Date: 16 September 1993 (16.09.93)

(21) International Application Number: PCT/US93/01947

(22) International Filing Date: 4 March 1993 (04.03.93)

(30) Priority data:
849,168 10 March 1992 (10.03.92) US

(71) Applicant: DUKE UNIVERSITY [US/US]; 001 Allen Building, Durham, NC 27708-0083 (US).

(72) Inventor: MACINTYRE, Neil, R. ; 3920 Wentworth Drive, Durham, NC 27707 (US).

(74) Agent: JENKINS, Richard, E.; 3101 Petty Road, Suite 1510 University Tower, Durham, NC 27707 (US).

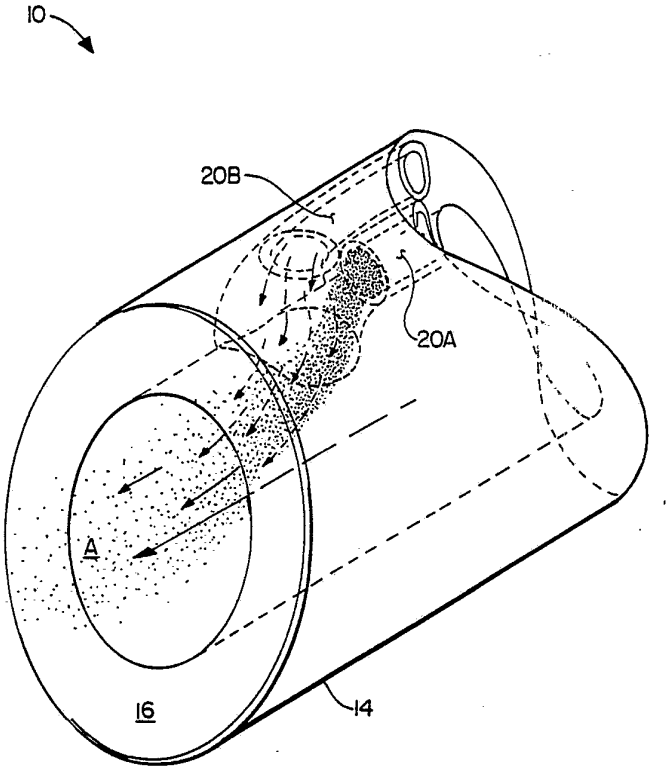
(81) Designated States: AT, AU, BB, BG, BR, CA, CH, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).

Published
With international search report.
With amended claims.

(54) Title: ENDOTRACHEAL TUBE HAVING AEROSOL GENERATING MEANS

(57) Abstract

An endotracheal tube (10) adapted for aerosol generation at the distal end (14) thereof and which is a modification of existing endotracheal tubes. The improved tube (10) incorporates first (20A) and second (20B) conduits along the length thereof in order to deliver a liquid to be aerosolized and a high velocity gas at the distal end (14) of the endotracheal tube (10) so as to create an aerosol within the lungs. The distal end of the gas conveying catheter (20B) is configured to direct the high velocity gas transported therethrough across the pathway of the liquid solution exciting the distal end of the first conduit (20A) to facilitate the creation of an aerosol for high efficiency delivery of the liquid solution.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	**FR**	France	**MR**	Mauritania
AU	Australia	**GA**	Gabon	**MW**	Malawi
BB	Barbados	**GB**	United Kingdom	**NL**	Netherlands
BE	Belgium	**GN**	Guinea	**NO**	Norway
BF	Burkina Faso	**GR**	Greece	**NZ**	New Zealand
BG	Bulgaria	**HU**	Hungary	**PL**	Poland
BJ	Benin	**IE**	Ireland	**PT**	Portugal
BR	Brazil	**IT**	Italy	**RO**	Romania
CA	Canada	**JP**	Japan	**RU**	Russian Federation
CF	Central African Republic	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CG	Congo			**SE**	Sweden
CH	Switzerland	**KR**	Republic of Korea	**SK**	Slovak Republic
CI	Côte d'Ivoire	**KZ**	Kazakhstan	**SN**	Senegal
CM	Cameroon	**LI**	Liechtenstein	**SU**	Soviet Union
CS	Czechoslovakia	**LK**	Sri Lanka	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**MC**	Monaco	**UA**	Ukraine
DK	Denmark	**MG**	Madagascar	**US**	United States of America
ES	Spain	**ML**	Mali	**VN**	Viet Nam
FI	Finland	**MN**	Mongolia		

Description

Endotracheal Tube Having Aerosol Generating Means

Technical Field

The present invention relates generally to endotracheal tubes, and more particularly to an endotracheal tube designed to allow for the generation of an aerosol at the distal end thereof for direct delivery to the lungs.

Related Art

Aerosol delivery to the lungs is an important therapeutic modality in respiratory medicine. Through aerosols a variety of solutions can be delivered directly to the lung tissue for various purposes such as to dilate airways, treat infections and to replace surfactant. Conventional aerosol generators are of the "jet" variety wherein a jet of gas is placed over the solution to be aerosolized and particles of about 1.0-5.0 micrometers are created. Unfortunately, actual lung delivery of aerosolized solutions from these devices is quite low. As is well known to those skilled in the art, even with the best of technique, standard aerosolization devices (nebulizers) with appropriate mouthpieces deliver only about 5.0-20.0% of their material into the lungs, and the remainder is wasted in the mouth or exhaled back out into

the environment.

The inadequacies of conventional aerosol delivery to the lungs is made even worse when an endotracheal tube is placed into a patient's airway and connected to a mechanical ventilator at the proximal end thereof. Once this procedure is accomplished, aerosol delivery through the tube (which is typically about 6.0-10.0 millimeters in diameter and about 30.0 centimeters long) is reduced to less than 5% since the tube is narrow and bent and many times is partially filled with mucus or other respiratory secretions. All of the circumstances serve as a significant barrier to aerosol delivery into the lungs when a patient has been intubated with an endotracheal tube. Therefore, it is a common practice to substantially increase the solution dose being applied by a nebulizer to an endotracheal tube to compensate for the fact that the endotracheal tube will limit aerosol delivery and deposition within the lungs. Thus, there is a long-felt need for a device which will provide for increased aerosol delivery to mechanically ventilated patients with endotracheal tubes (intubated patients) since such a device would provide higher efficacy of aerosol delivery and would be very cost effective in use.

A number of attempts have been made to overcome the shortcomings inherent in the use of conventional nebulizers to deliver an aerosol through an endotracheal tube to the lungs of a mechanically ventilated patient. The most common approach to the problem is the

aforementioned increase in the aerosolized solution in order to compensate for the fact that 90-95% of the solution will not actually be introduced into the lungs. Also, metered dose inhalers of the type which generate aerosols from pressurized canisters have been advocated for use. However, since these devices generate similar aerosol particle characteristics, these devices also have shown only nominal improvement in lung deposition of the aerosolized solution.

A variety of techniques placing the nebulizer at different points in the ventilator circuitry have also proved to be of only minimal benefit. In further efforts to overcome the shortcomings of conventional aerosol delivery to the lungs of an intubated patient, catheters have been developed to deliver aerosols which are generated at the proximal end of the endotracheal tube and delivered at the distal end thereof. Unfortunately, as is well known to those skilled in this art, these catheters usually cause the aerosol particles introduced at the proximal end to coalesce during the passage to the distal end and the aerosolized solution thus tends to drip from the distal end. Consequently, delivery of the solution to lung tissue beyond the airways is substantially defeated by this phenomenon.

Therefore, the search continues for an endotracheal tube which is capable of delivering an aerosolized solution with a high degree of efficacy into the lungs of an intubated patient.

Disclosure of the Invention

The present invention comprises an endotracheal tube for aerosol delivery of a selected liquid solution to the lungs. The tube comprises a tubular member for ventilating a patient which has a distal end for insertion into the trachea and a proximal end adapted for introduction of a breathable gas. A first conduit is provided for delivery of a selected liquid solution to the lungs and has a proximal end terminating adjacent the proximal end of the tubular member and a distal end terminating adjacent the distal end of the tubular member. A second conduit is provided for high velocity delivery of a gas and has a proximal end terminating adjacent the proximal end of said tubular member and a distal end terminating adjacent the distal end of the tubular member. The distal end of the second conduit is configured so as to direct the high velocity gas flow across the pathway of the liquid solution exiting the distal end of the first conduit so as to create an aerosol. Most suitably both the first and second conduits are embedded adjacent each other in the wall of the tubular member and are positioned inwardly from the distal end thereof a distance of between about 1.0-2.0 centimeters.

It is therefore the object of this invention to provide an improved endotracheal tube which eliminates the problems described above.

More specifically, it is the object of the present invention to provide an endotracheal tube which generates

a jet aerosol at the distal end thereof so as to assure high efficiency aerosol delivery of a desired medication to the lungs.

It is yet another object of the present invention to provide an endotracheal tube which provides enhanced aerosol delivery of a selected medication to the lungs so as to reduce the amount of medication needed for the treatment.

Some of the objects of the invention having been stated, other objects will become evident as the description proceeds, when taken in connection with the accompanying drawings described below.

Description of the Drawings

Figure 1 is a perspective view, with parts broken away for clarity, of an endotracheal tube incorporating a preferred embodiment of the invention.

Figure 2 is a vertical cross-sectional view taken along line 2-2 of Figure 3.

Figure 3 is a horizontal cross sectional view taken along line 3-3 of Figure 2.

Figure 4 is an enlarged fragmentary view of the distal end of the endotracheal tube shown in Figure 1.

Best Mode for Carrying Out the Invention

The invention described herein is a modification of a commonly used medical device called an endotracheal tube which possesses significant advantages thereover by providing the ability to generate an aerosol at the distal

end thereof for enhanced delivery of a medication to the lungs.

Referring to Figures 1-4, an endotracheal tube 10 in accordance with the present invention is shown having a proximal end 12, a distal end 14, and a side wall 16 (see Figures 2-4). The proximal end 12 typically includes a conventional coupling device 18 for attachment to ventilating equipment or other medical equipment as known to those skilled in this art. Endotracheal tube 10 of the present invention may most suitably be extruded from polyvinyl chloride or other suitable flexible plastic-type material.

Endotracheal tube 10 includes two side-by-side small diameter catheters, 20A, 20B, which are embedded in wall 16 of the tubular member. Small diameter catheters 20A, 20B, extend adjacent each other substantially along the length of endotracheal tube 10 in embedded relationship to side wall 16 (see Figures 2-4). The proximal ends of catheters 20A, 20B, extend outwardly and are spaced apart from wall 16 adjacent proximal end 12 of endotracheal tube 10 (see Figure 1) and, most suitably, the distal ends thereof terminate about 1.0-2.0 centimeters short of distal end 14 of endotracheal tube 10 and in fluid communication with the internal passageway thereof (see Figure 4). Although the preferred embodiment shown in Figures 1-4 of the drawings depicts catheters 20A, 20B as embedded within wall 16 of endotracheal tube 10, applicant contemplates that suitable first and second lumens could

also be incorporated in wall 16 of the tube during the manufacturing process and suitable proximal and distal ends fitted to both lumens as an alternative to the two small diameter catheters 20A, 20B provided in the preferred embodiment shown herein.

In use, a desired aerosol medication solution would be mixed and placed into a bag so that the solution could be pumped through fluid catheter 20A at a constant rate selected by a clinician. Catheter 20B would be attached to a gas source so as to provide a suitable high velocity gas such as at the distal end thereof. As best seen in Figure 4 of the drawings, the distal end of the gas-conveying small catheter 20B is formed with an exit aperture formed so as to direct the gas across the pathway of the liquid exiting from small diameter catheter 20A and to produce an aerosol A (see Figure 4) in the trachea at the entrance to the lungs. The distal ends of both catheters 20A and 20B are most suitably formed so as to be in fluid communication with the internal passageway of endotracheal tube 10 at or near the distal end thereof. By producing the aerosol at this location as opposed to previously known techniques of introducing an aerosol at the proximal end of an endotracheal catheter, a virtual 100% efficiency of delivery of the desired medication aerosol solution to the lungs is assured and the amount of medication needed for a given treatment is significantly reduced from what is normally utilized.

In order to prevent lung injury from the high

velocity gas flow from catheter 20B, the distal ends of catheters 20A, 20B, are most suitably about 1.0-2.0 centimeters short of distal end 14 of the endotracheal tube although other configurations of catheters 20A, 20B for producing aerosol A at distal end 14 of tube 10 are contemplated as within the scope of applicant's invention. In order to optimize performance of endotracheal tube 10, one skilled in the art would need to suitably adjust gas flow from catheter 20B, fluid flow from catheter 20A, the diameters of catheters 20A, 20B and the angle of intersection of the gas emitted by the distal end of catheter 20B with the liquid emitted at the distal end of catheter 20A in order to provide an aerosol particle size of about 1.0-5.0 micrometers. Also, in view of the reduced use of medication resulting from use of applicant's inventive endotracheal tube 10, appropriate dosing adjustments would have to be made by clinicians during use thereof.

It will be understood that various details of the invention may be changed without departing from the scope of the invention. Furthermore, the foregoing description is for the purpose of illustration only, and not for the purpose of limitation--the invention being defined by the claims.

Claims

What is claimed is:

1. An endotracheal tube for aerosol delivery of a selected liquid solution to the lungs comprising:

a tubular member for ventilating a patient comprising a distal end for insertion into the trachea of a patient and a proximal end adapted for introduction of a breathable gas into said tubular member;

a first conduit for delivery of a selected liquid solution to the lungs having a proximal end terminating adjacent the proximal end of said tubular member and a distal end terminating adjacent the distal end of said tubular member, said first conduit extending substantially along the length of said tubular member; and

a second conduit for high velocity delivery of a gas having a proximal end terminating adjacent the proximal end of said tubular member and a distal end terminating adjacent the distal end of said tubular member, said second conduit extending substantially along the length of said tubular member and the distal end thereof being configured so as to direct said high velocity gas across the pathway of said liquid solution exiting the distal end of said first conduit so as to create an aerosol.

2. An endotracheal tube according to claim 1 wherein

said first and second conduits are embedded within the wall of said tubular member.

3. An endotracheal tube according to claim 2 wherein said first and second conduits are positioned adjacent each other within the wall of said tubular member.

4. An endotracheal tube according to claim 1 wherein said first and second conduits terminate between about 1.0-2.0 centimeters before the distal end of said tubular member and in fluid communication with the internal passageway defined by said tubular member.

5. An endotracheal tube according to claim 1 wherein said endotracheal tube creates an aerosol at the distal end thereof having a particle size between about 1.0-5.0 micrometers.

6. An endotracheal tube for aerosol delivery of a selected liquid solution to the lungs comprising:

a tubular member for ventilating a patient comprising a distal end for insertion into the trachea of a patient and a proximal end adapted for introduction of a breathable gas into said tubular member;

a first conduit for delivery of a selected liquid solution to the lungs having a proximal end terminating adjacent the proximal end of said tubular member and a distal end terminating adjacent the distal end of said tubular member, said first conduit extending substantially along the length of said tubular member and being

embedded within the wall thereof; and

a second conduit embedded within the wall of said tubular member adjacent said first conduit for high velocity delivery of a gas and having a proximal end terminating adjacent the proximal end of said tubular member and a distal end terminating adjacent the distal end of said tubular member, said second conduit extending substantially along the length of said tubular member and the distal end thereof being configured so as to direct said high velocity gas across the pathway of said liquid solution exiting the distal end of said first conduit so as to create an aerosol.

7. An endotracheal tube according to claim 6 wherein said first and second conduits terminate between about 1.0-2.0 centimeters before the distal end of said tubular member and in fluid communication with the internal passageway defined by said tubular member.

8. An endotracheal tube according to claim 6 wherein said endotracheal tube creates an aerosol at the distal end thereof having a particle size between about 1.0-5.0 micrometers.

AMENDED CLAIMS

[received by the International Bureau on 27 July 1993 (27.07.93);
original claims 1 and 6 amended; new claims 9 and 10 added;
other claims unchanged (4 pages)]

1. An endotracheal tube for aerosol delivery of a selected liquid solution to the lungs comprising:

a tubular member for ventilating a patient comprising a distal end for insertion into the trachea of a patient and a proximal end adapted for introduction of a breathable gas into said tubular member;

a first conduit for delivery of a selected liquid solution to the lungs having a proximal end terminating adjacent the proximal end of said tubular member and a distal end terminating adjacent the distal end of said tubular member, said first conduit extending substantially along the length of said tubular member; and

a second conduit for high velocity delivery of a gas having a proximal end terminating adjacent the proximal end of said tubular member and a distal end terminating adjacent the distal end of said tubular member, said second conduit extending substantially along the length of said tubular member and the distal end thereof being substantially adjacent the distal end of the first conduit and being configured so as to direct said high velocity gas across the pathway of said liquid solution exiting the distal end of said first conduit so as to create an

aerosol.

2. An endotracheal tube according to claim 1 wherein said first and second conduits are embedded within the wall of said tubular member.

3. An endotracheal tube according to claim 2 wherein said first and second conduits are positioned adjacent each other within the wall of said tubular member.

4. An endotracheal tube according to claim 1 wherein said first and second conduits terminate between about 1.0-2.0 centimeters before the distal end of said tubular member and in fluid communication with the internal passageway defined by said tubular member.

5. An endotracheal tube according to claim 1 wherein said endotracheal tube creates an aerosol at the distal end thereof having a particle size between about 1.0-5.0 micrometers.

6. An endotracheal tube for aerosol delivery of a selected liquid solution to the lungs comprising:

a tubular member for ventilating a patient comprising a distal end for insertion into the trachea of a patient and a proximal end adapted for introduction of a breathable gas into said tubular member;

a first conduit for delivery of a selected liquid solution to the lungs having a proximal end terminating adjacent the proximal end of said tubular member and a distal end terminating adjacent the distal end of said tubular member,

said first conduit extending substantially along the length of said tubular member and being embedded within the wall thereof; and

a second conduit embedded within the wall of said tubular member adjacent said first conduit for high velocity delivery of a gas and having a proximal end terminating adjacent the proximal end of said tubular member and a distal end terminating adjacent the distal end of said tubular member, said second conduit extending substantially along the length of said tubular member and the distal end thereof being substantially adjacent the distal end of the first conduit and being configured so as to direct said high velocity gas across the pathway of said liquid solution exiting the distal end of said first conduit so as to create an aerosol.

7. An endotracheal tube according to claim 6 wherein said first and second conduits terminate between about 1.0-2.0 centimeters before the distal end of said tubular member and in fluid communication with the internal passageway defined by said tubular member.

8. An endotracheal tube according to claim 6 wherein said endotracheal tube creates an aerosol at the distal end thereof having a particle size between about 1.0-5.0 micrometers.

9. An endotracheal tube according to claim 1

wherein the distal end of said second conduit is less than 2 centimeters from the distal end of the first conduit.

10. An endotracheal tube according to claim 6 wherein the distal end of said second conduit is less than 2 centimeters from the distal end of the first conduit.

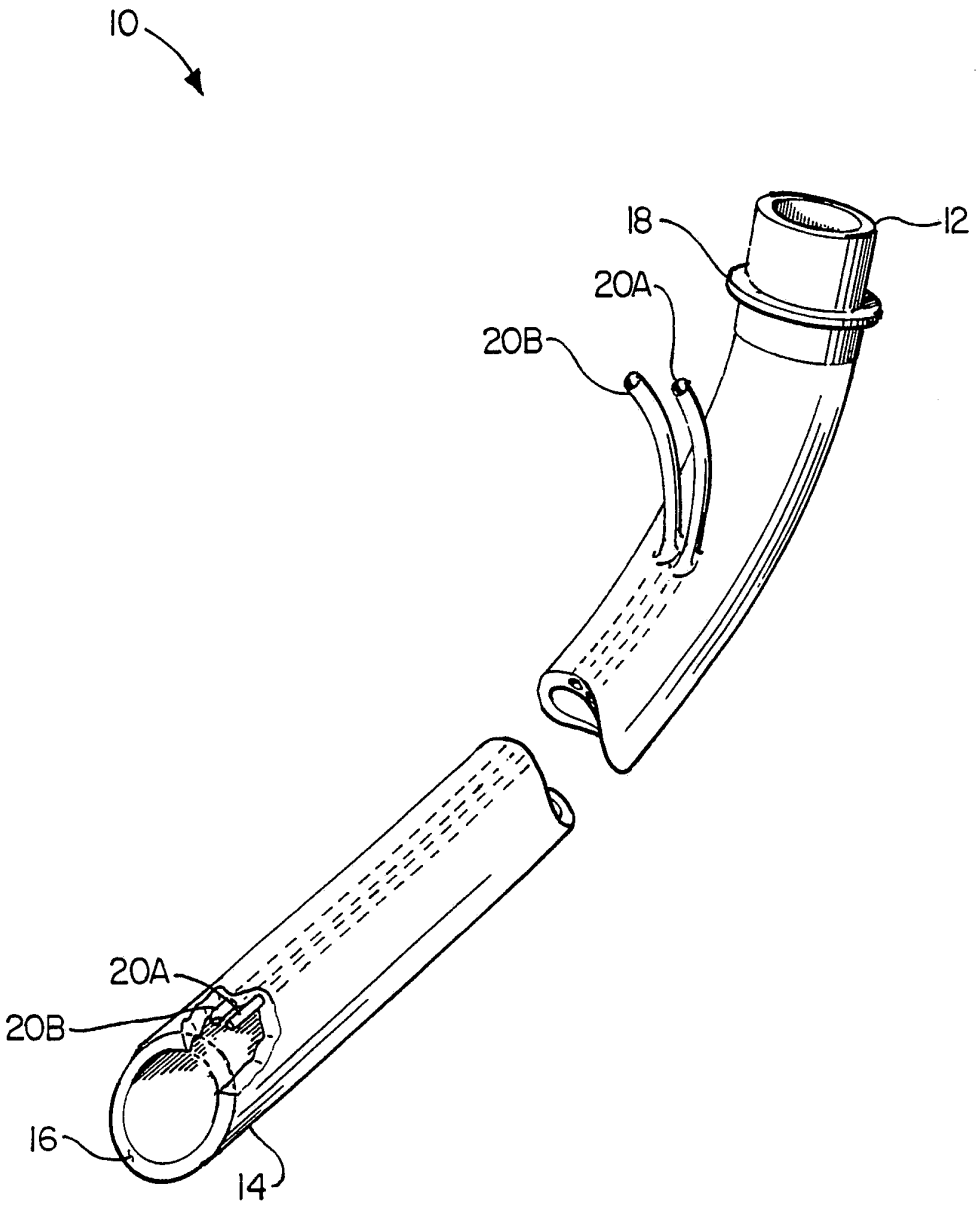


FIG. 1

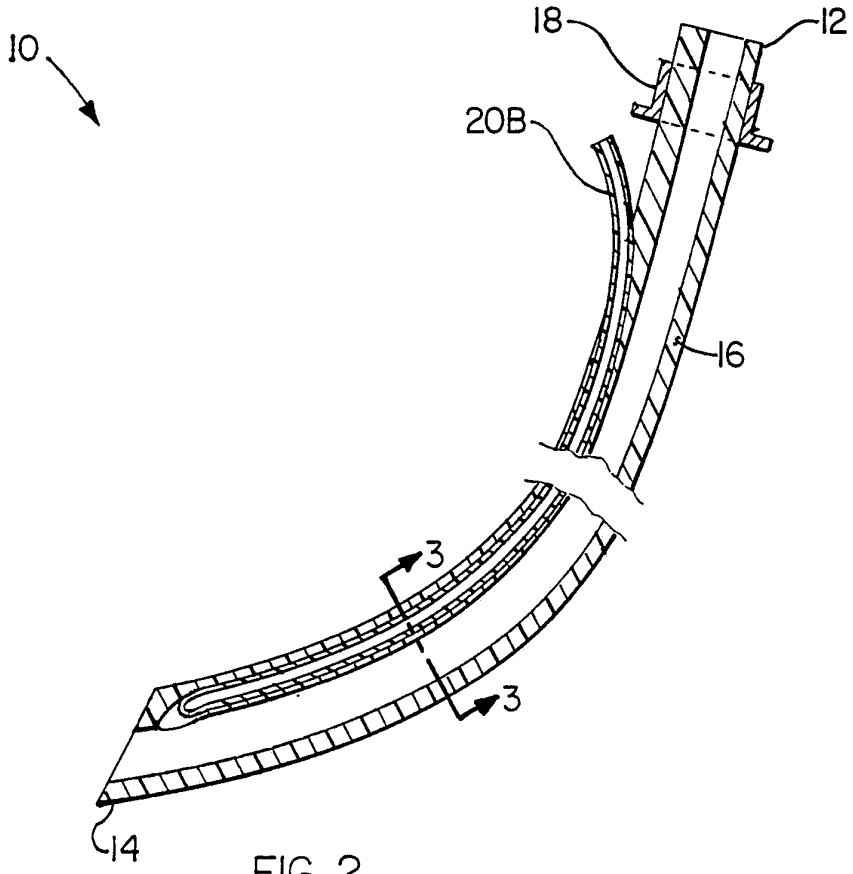


FIG. 2

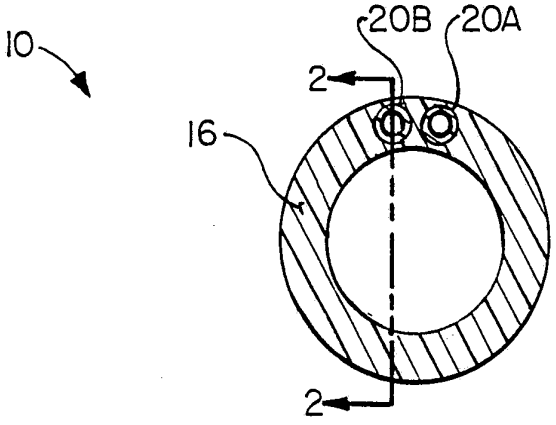


FIG. 3

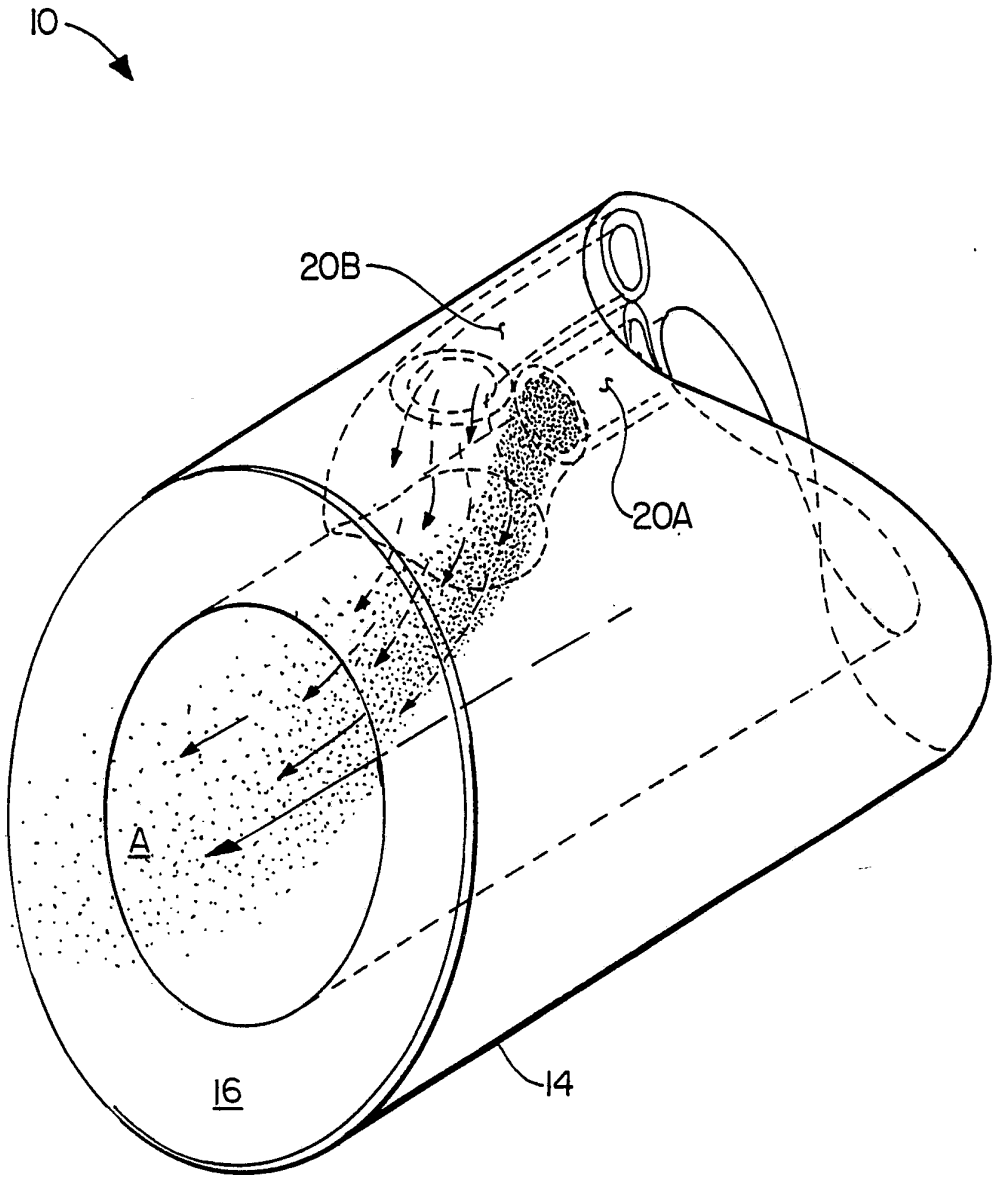


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/01947

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 16/00; A62B 9/06
US CL :128/207.14

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/207.14,911,912,200.14,203.12

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)

none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A, 4,584,998 (McGrail) 29 April 1986. See entire document.	1-3,6 4,5,7,8

☐ 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
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 16 APRIL 1993	Date of mailing of the international search report 08 JUN 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer KIMBERLY L. ASHER Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992)★