

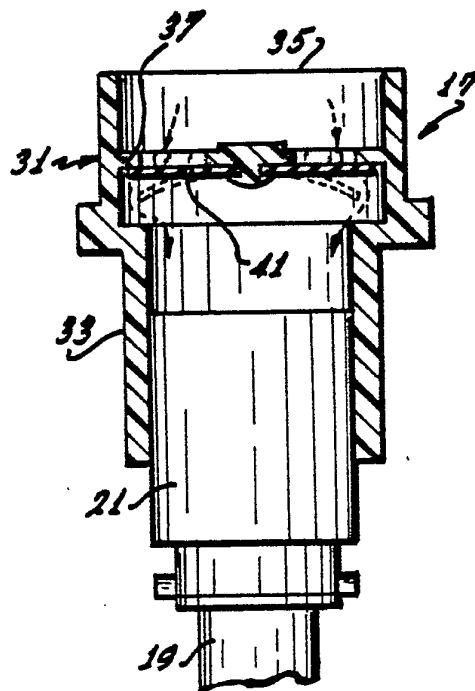


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification<sup>4</sup> :</b>  <b>A61M 16/00</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 86/ 05102</b>  <b>(43) International Publication Date:</b> 12 September 1986 (12.09.86)
<b>(21) International Application Number:</b> PCT/US86/00456 <b>(22) International Filing Date:</b> 27 February 1986 (27.02.86)  <b>(31) Priority Application Number:</b> 709,543 <b>(32) Priority Date:</b> 8 March 1985 (08.03.85) <b>(33) Priority Country:</b> US  <b>(71)(72) Applicant and Inventor:</b> MUIR, David, A. [US/US]; 210 Paseo Picaro, Anaheim, CA 92807 (US).  <b>(74) Agent:</b> STERN, Richard, H.; #800, 2101 L Street, Northwest, Washington, DC 20037 (US).  <b>(81) Designated States:</b> AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).		<b>Published</b> <i>With international search report.</i> <i>With amended claims.</i>

**(54) Title:** TRACHEOSTOMY DEVICE**(57) Abstract**

A tracheostomy device comprising a tube (19) adapted to be at least partially received in a patient's trachea and having a passage extending through the tube. The passage has an inlet (23) adapted to be exposed to ambient air and an outlet (27) adapted to be received in the patient's trachea so that the tube can conduct ambient air to the trachea. A one-way valve (17) is carried by the tube for permitting air flow through the passage from the inlet to the outlet. The one-way valve blocks air flow through the passage from the outlet to the inlet.



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TRACHEOSTOMY DEVICEBACKGROUND OF THE INVENTION

In a tracheotomy, an opening is formed in the lower region of the patient's neck into the trachea. When this is done, ambient air can flow directly from the atmosphere to the lungs.

5           After a tracheotomy, a tracheostomy device is commonly employed to conduct ambient air through the opening in the neck to the trachea. A tracheostomy device typically includes a tube releasably attached at its outer end to the patient and extending through the opening in the neck into  
10           the trachea. The tube may be used alone for this purpose, or the tube may be an inner cannula which is received within an outer cannula.

          A patient with a tracheotomy tends to inhale and exhale through the tracheostomy device. The larynx or voice  
15           box is located above the tracheostomy device and so, when the patient exhales through the device, air flow through the larynx is minimal. Without air flow through the larynx and out through the mouth, speech is difficult or impossible. To aid speech, the patient may place his finger over the opening  
20           in the tracheostomy device whenever he wishes to speak so that he will then exhale through the larynx and mouth to make speech possible. This technique is inconvenient because it requires manual manipulation to close off the tracheostomy device during exhalation to enable speech and opening the  
25           device to enable inhalation. This requires the patient to coordinate manual and breathing functions and cannot be done if the patient does not have adequate use of at least one arm and hand.

SUMMARY OF THE INVENTION

This invention solves these problems by providing a one-way valve carried by a tracheostomy tube. The valve automatically permits the patient to inhale through the tube and substantially reduces or blocks exhalation through the tube. Accordingly, the patient is automatically caused to exhale over the larynx and through the mouth to enable speech. This eliminates the manual manipulation and coordination tasks necessary heretofore and permits speech by a patient who does not have adequate use of his arms.

The tracheostomy tube has a passage with an inlet adapted to be exposed to ambient or atmospheric air and an outlet adapted to be in the patient's trachea so that the tube can conduct ambient air to the trachea. The one-way valve permits air flow through the passage from the inlet to the outlet and reduces air flow through the passage from the outlet through the inlet to the atmosphere sufficiently to cause adequate air flow along a path which includes the larynx and the nose or mouth to materially facilitate speech. Although it is only necessary for the one-way valve to provide adequate exhalation air to materially facilitate speech, preferably the one-way valve substantially blocks the flow of exhalation air from the outlet of the tube through the inlet.

The tube has opposite ends, and the inlet is preferably substantially at one of the ends. Although the one-way valve can be carried at different locations by the tube, preferably, the one-way valve is mounted on the inlet end of the tube. In a preferred construction, the mounting

means removably mounts the one-way valve on the inlet end of the tube. Consequently, the valve can be removed by the patient or an attendant if it is desired to exhale through the tube.

5           The tracheostomy tube can be an inner cannula adapted to be removably received in an outer cannula. Alternatively, the tracheostomy tube may be an outer cannula which may or may not have an inner cannula.

10           The invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in connection with the accompanying illustrative drawing.

15                           BRIEF DESCRIPTION OF THE DRAWINGS

20           Fig. 1 is an exploded isometric view of a portion of one form of tracheostomy device constructed in accordance with the teachings of this invention.

          Fig. 2 is a view taken generally along line 2-2 of Fig. 1.

25           Fig. 3 is a sectional view taken generally along line 3-3 of Fig. 2 with the components of the tracheostomy device assembled.

          Fig. 4 is an exploded isometric view of a second form of tracheostomy device constructed in accordance with the teachings of this invention.

30           Fig. 5 is a somewhat schematic view illustrating one way in which the tracheostomy device can be used.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figs. 1-3 and 5 show a tracheostomy device 11 which generally comprises a tracheostomy tube in the form of an inner cannula 13, an outer cannula 15 (Fig. 5) and a one-way valve 17. The cannulas 13 and 15 may be conventional. As such, the inner cannula 13 includes a plastic tube 19 and a coupling 21 rotatably mounted on one end of the tube 19. The inner cannula 13 has a passage 23 extending completely through it from an inlet 25 to an outlet 27.

The outer cannula 15 is also in the form of a tube which is sized to receive the tube 19 of the inner cannula 13 therein. The outer cannula 15 has a fixed coupling 29 at its inlet end for at least partially receiving and cooperatively locking with the coupling 21 to lock the inner cannula 13 to the outer cannula 15 in a conventional manner.

Although the one-way valve 17 can be of various different constructions, in the embodiment illustrated, it includes a tubular valve housing 31 having a coupling section 33 which is adapted to slidably receive at least a portion of the coupling 21 with an interference fit so that the one-way valve is retained on the inner cannula 13 by friction. One or both of the engaging surfaces of the coupling 21 and the coupling section 33 can be tapered to facilitate such a friction fit, if desired.

The end of the housing 31 remote from the coupling section 33 terminates in an opening 35. A transverse wall 37 extends across the housing 31 intermediate the opening 35 and the coupling section 33. The wall 37 has a plurality of ports 39 extending through the

wall, and a flexible resilient valve element 41 is suitably attached to a central region of the transverse wall 37 and extends radially outwardly to fully cover each of the ports 39. The valve 17 may be conventional.

5 This invention is particularly adapted for use with a patient having a larynx 43 (Fig. 5) and a tracheotomy which leaves an opening 45 in the patient's neck extending from the atmosphere to the trachea 47. The outer cannula is inserted through the opening 45 to the trachea 47 and is retained on  
10 the patient's neck in any suitable manner, such as by wrapping a cord or flexible element (not shown) about the neck and affixing it to a cuff 49 which is carried by, and forms a portion of, the outer cannula 15. The inner cannula 13 is inserted into the outer cannula 15 and is affixed  
15 thereto in a conventional manner by rotation of the coupling 21 to attach the coupling 21 to the coupling 29. When affixed in this fashion, the outlet 27 terminates within the outer cannula 15 as shown in Fig. 5.

20 The one-way valve 17 is removably mounted on the inlet end of the inner cannula 13 by virtue of the friction fit between the coupling section 33 and the coupling 21 as shown in Fig. 3. When installed in this fashion, the one-way valve 17 permits air flow through the passage 23 from the atmosphere to the trachea, and it substantially completely  
25 blocks air flow through the passage from the trachea through the passage 23 to the atmosphere. Accordingly, when the patient inhales, ambient or atmospheric air is supplied through the one-way valve 17 and the passage 23 to the trachea 47. However, when the patient exhales, there is  
30 essentially no air flow through the passage 23 to the atmosphere. Rather, exhalation air is forced along a path

which includes the larynx 43 and the nose 51 and/or the mouth 53 to the atmosphere. Because the exhalation air flows over the larynx 43 and out the mouth 53, the patient is automatically enabled to speak. The one-way valve 17 can be manually removed from the inner cannula 13 when desired.

Fig. 4 shows the use of a one-way valve 17a with a tracheostomy tube in the form of an outer cannula 15a. Portions of the embodiment of Fig. 4 corresponding with portions of the embodiment of Figs. 1-3 and 5 are designated by corresponding reference numerals followed by the letter "a."

The outer cannula 15a is of the type which does not utilize an inner cannula. Thus, the outer cannula 15a has a passage 101 extending through it from an inlet 103 to an outlet 105. The outer cannula 15a also has a cuff 49a for use in removably attaching the outer cannula 15a to the neck of a patient. The outer cannula 15a also includes a tube 107 and an enlarged head 109.

The one-way valve 17a may be identical to the one-way valve 17, except that the coupling section 33a is sized to frictionally receive the head 109 to removably mount the one-way valve on the outer cannula 15a. The embodiment of Fig. 4 may be used in the same manner as described above.

The one-way valves 17 and 17a can be used with many different tracheostomy tubes, and the tracheostomy tubes described herein are merely illustrative. Also, the one-way valve can be of various different constructions which will carry out the basic functions described herein.

Although exemplary embodiments of the invention have been shown and described, many changes, modifications and substitutions may be made by one having ordinary skill in



the art without necessarily departing from the spirit and scope of this invention.

## CLAIMS

1. A tracheostomy speaking device comprising:

a tracheostomy tube having an outer end portion adapted to be at least partially received in a patient's trachea, said tracheostomy tube having a passage extending therethrough;

5 said passage having an inlet at said outer end portion adapted to be exposed to ambient air and an outlet adapted to be in the patient's trachea whereby the tube can conduct ambient air to the patient's trachea;

10 a one-way valve including a tubular valve housing slidably cooperating with the outer end portion of the tube to form a friction fit therewith to removably mount the valve housing on the outer end portion of the tube with said friction fit whereby the valve housing can be installed on and removed from the outer end portion of the tube; and

15 said one-way valve including a valve carried by said tubular valve housing for permitting air flow through said passage from said inlet to said outlet and for blocking air flow through said passage from said outlet through said inlet to the atmosphere sufficiently to cause adequate air flow along a path which in-  
20 cludes the larynx and the nose or mouth to materially facilitate speech by the patient.

2. A device as defined in claim 1 including an outer cannula adapted to extend from ambient air into the patient's trachea and said tube is an inner cannula removably received within the outer cannula.

3. A device as defined in claim 1 wherein the valve housing and the outer end of the tube have engaging surfaces and at least one of the engaging surfaces is tapered.

4. A device as defined in claim 1 wherein said valve includes a transverse wall extending across the valve housing intermediate the ends thereof whereby the transverse wall is recessed inwardly from both ends of the valve housing, said  
5 transverse wall having a port therein and the valve includes a flexible resilient valve element coupled to the transverse wall.

5. A device as defined in claim 1 wherein said inner end of said tube includes a coupling and said valve housing includes a coupling section which slidably receives said coupling with said friction fit.

6. A device as defined in claim 1 wherein the valve housing and the outer end of the tube have engaging surfaces and at least one of the engaging surfaces is tapered, said valve includes a transverse wall extending across the valve housing  
5 intermediate the ends thereof whereby the transverse wall is recessed inwardly from both ends of the valve housing, said transverse wall having a port therein and the valve includes a flexible resilient valve element coupled to the transverse wall.

7. A one-way valve removably attachable to an outer end of a tracheostomy tube for use in allowing a patient to inhale through the one-way valve and to exhale along a path which includes the larynx and nose or mouth to materially facilitate speech by  
5 the patient, said one-way valve comprising:

4 a tubular valve housing slidably cooperable with the outer end portion of the tracheostomy tube to form a friction fit therewith to removably mount the valve housing on the outer end portion of the tracheostomy tube with said friction fit whereby  
7 10 the valve housing can be installed on and removed from the outer end portion of the tracheostomy tube; and

a valve carried by the tubular valve housing for permitting air flow through the valve housing in one direction so that the patient can inhale when the tubular valve housing is mounted on the tracheostomy tube and for substantially blocking air flow through the tubular valve housing in the other direction so that the patient can exhale along a path which includes the larynx and nose or mouth to materially facilitate speech by the patient when the tubular valve housing is mounted on the tracheostomy tube.

8. A valve as defined in claim 7 wherein the valve housing has a tapered engaging surface for engaging the outer end portion of the tube and forming said friction fit.

9. A valve as defined in claim 7 including a transverse wall extending across the valve housing intermediate the ends thereof whereby the transverse wall is recessed inwardly from both ends of the valve housing, said transverse wall having a port therein and the valve includes a flexible resilient valve element coupled to the transverse wall.

10. A valve as defined in claim 9 wherein the valve housing has a tapered engaging surface for engaging the outer end portion of the tube and forming said friction fit.

11. A method of facilitating speech by a patient having a larynx and a tracheostomy tube with an outer end portion and wherein the tube extends through an opening in a patient's neck into the trachea to supply ambient air from the atmosphere to the patient's trachea, said method comprising:

providing a one-way valve which includes a tubular valve housing sized to fit over the outer end portion of the tube with a friction fit and a valve carried by the housing;

10       sliding the valve housing over the outer end portion of the tube to removably attach the valve housing to the tube with a friction fit so that the patient can inhale through the one-way valve and exhale along a path which includes the larynx and the nose or mouth to materially facilitate speech; and

15       overcoming said friction fit to remove the valve housing from the outer end of the tube.

## AMENDED CLAIMS

[received by the International Bureau on 08 July 1986 (08.07.86);  
original claims 1-11 replaced by amended claims 12-28 (9 pages)]

12. In a tracheostomy tube valve assembly for use with a tracheostomy tube inserted into the throat of a person, said assembly including:

a hollow housing having

a longitudinal axis in approximately the direction of air flow through said assembly,

an inlet and an outlet that are longitudinally spaced from one another, and

inner walls that enclose a generally convex transverse cross-sectional shape between said inlet and said outlet;

a closure system for permitting air to enter said housing via said inlet and for obstructing air from exiting said housing via said inlet, said closure system being

located within said housing between said inlet and said outlet,

adapted to obstruct air flow through said inlet when pressure at said outlet is greater than at said inlet, and

adapted not to prevent airflow through said inlet when pressure at said inlet is greater than at said outlet; and means for mounting said housing at its outlet to said tracheostomy tube,

whereby said outlet is connected to said tracheostomy tube; air is permitted to enter said tracheostomy tube from said housing when said person inhales or pressure at said inlet greater than at said outlet is otherwise provided; and air is obstructed from exiting said tracheostomy tube via said housing when said person exhales or pressure at said outlet greater than at said inlet is otherwise provided;

the improvement comprising:

a first closure means for permitting air to enter said housing via said inlet and for preventing air from exiting said housing via said inlet, said first closure means including a disk shaped member located in a plane transverse to said longitudinal axis; fabricated from thin, flat, flexible material; and having radial planar dimensions smaller than those of said transverse cross-sectional shape but otherwise being approximately congruent to said transverse cross-sectional shape;

a support means for supporting said first closure means, said support means mounted to said housing; adapted to contact and support said first closure means at an interior location in said disk shaped member; and

adapted to permit said disk shaped member to bend concavely toward said outlet and around said support means when pressure lower at said outlet than at said inlet is provided; and

a second closure means for cooperating with said first closure means in permitting air to enter said housing via said inlet and preventing air from exiting said housing via said inlet, said disk shaped member being located within said housing between said second closure means and said outlet, and said second closure means including a barrier means

having an outer lateral surface that contacts said inner walls of said housing,

having a flat, transverse surface immediately adjacent to said disk shaped member, extending inwardly from said inner walls of said housing to a sufficient extent as to come wholly within the longitudinal projection of the perimeter of said disk shaped member,

having a longitudinal port located wholly within said longitudinal projection of said perimeter, and

thereby both preventing air flow past said disk shaped member from said outlet toward said inlet when pressure is not greater at said inlet than at said outlet, and permitting air flow from said inlet toward said outlet when pressure is greater at said inlet than at said outlet.

13. The assembly of claim 12 wherein said generally convex transverse cross-sectional shape is a circle;



said disk shaped member  
is a circular disk, and  
at approximately its center contacts  
said supporting member;  
said barrier means includes a circular ring  
with  
an outer diameter substantially  
equal to said circle, and  
an inner diameter less than the  
diameter of said disk; and  
said circle, said disk, and said ring are ap-  
proximately concentric.

14. The assembly of claim 13 wherein the ratio of the diameter of said circular disk to the thickness of said circular disk is greater than approximately 40.

15. The assembly of claim 14 wherein the ratio of the diameter of said circular disk to the thickness of said circular disk is approximately 50.

16. The assembly of claim 13 wherein  
said ring is affixed to and is approximately  
coplanar with said support member,  
said circular disk is mounted between said  
support member and a supporting disk,  
said supporting disk has a diameter smaller  
than the diameter of circular disk, and  
said supporting disk is the only physical  
obstruction to said circular disk's  
bending concavely toward said outlet.

17. The assembly of claim 16 wherein said support-  
ing disk has a diameter less than approximately 35% of  
the diameter of said circular disk.

18. The assembly of claim 17 wherein said supporting disk has a diameter approximately 27% of the diameter of said circular disk.

19. The assembly of claim 16 wherein said support member includes a plurality of radial members joined at the center of said ring and extending therefrom to its periphery, whereby motion of said circular disk away from said transverse plane and toward said inlet is prevented.

20. The assembly of claim 19 wherein a riveting means is mounted to said radial members at the junction thereof, is disposed longitudinally within said housing, passes through the center of said circular disk, is fastened to the center of said supporting disk, and thereby sandwiches said circular disk between said radial members and said supporting disk.

21. The assembly of claim 19 wherein there are four radial members spaced at approximately right angles.

22. The assembly of claim 12 wherein said disk shaped member is longitudinally spaced from said outlet, and a tube receiving means

is located within said housing between said outlet and said disk shaped member,

has a longitudinal axis in approximately the same direction as the longitudinal axis of said housing,

has an outer portion affixed to and integral with said inner walls of said housing, and

has a longitudinally tapered inner surface with a circular transverse section, said taper being such that said circular transverse section has

a greater diameter at the end of said tube receiving means that is closer to said outlet; and

said inner surface extends longitudinally toward said disk shaped member from said outlet to an inside edge of said inner surface, said inside edge being longitudinally spaced from the maximum point to which said disk shape member bends toward said outlet.

23. A method of facilitating the speech of a person having a larynx and a tracheostomy tube, comprising providing said tube with the improved tracheostomy tube valve assembly of claim 12.

24. A method of promoting the evaporation, and decreasing the accumulation, of oral and nasal secretions in a person having a tracheostomy tube, comprising providing said tube with the improved tracheostomy tube valve assembly of claim 12.

25. A method of increasing olfactory sensations in a person having a tracheostomy tube, comprising providing said tube with the improved tracheostomy tube valve assembly of claim 12.

26. A method of improving pulmonary ventilation in a person having a tracheostomy tube, comprising providing said tube with the improved tracheostomy tube valve assembly of claim 12.

27. A method of lessening resistance to air flow in a tracheostomy tube valve assembly that includes a hollow housing having a longitudinal axis in approximately the direction of air flow through said assembly, an inlet and an outlet that are longitudinally spaced from one another, and inner walls that enclose a gener-

ally convex transverse cross-sectional shape between said inlet and said outlet; a closure system for permitting air to enter said housing via said inlet and for preventing air from exiting said housing via said inlet, said closure system being located within said housing between said inlet and said outlet, adapted to obstruct air flow through said inlet when pressure at said outlet is greater than at said inlet, and adapted not to prevent airflow through said inlet when pressure at said inlet is greater than at said outlet; and means for mounting said housing to said tracheostomy tube; whereby said outlet is connected to said tracheostomy tube, air is permitted to enter said tracheostomy tube from said housing when said person inhales or pressure at said inlet greater than at said outlet is otherwise provided, and air is obstructed from exiting said tracheostomy tube via said housing when said person exhales or pressure at said outlet greater than at said inlet is otherwise provided; said method comprising providing said assembly with:

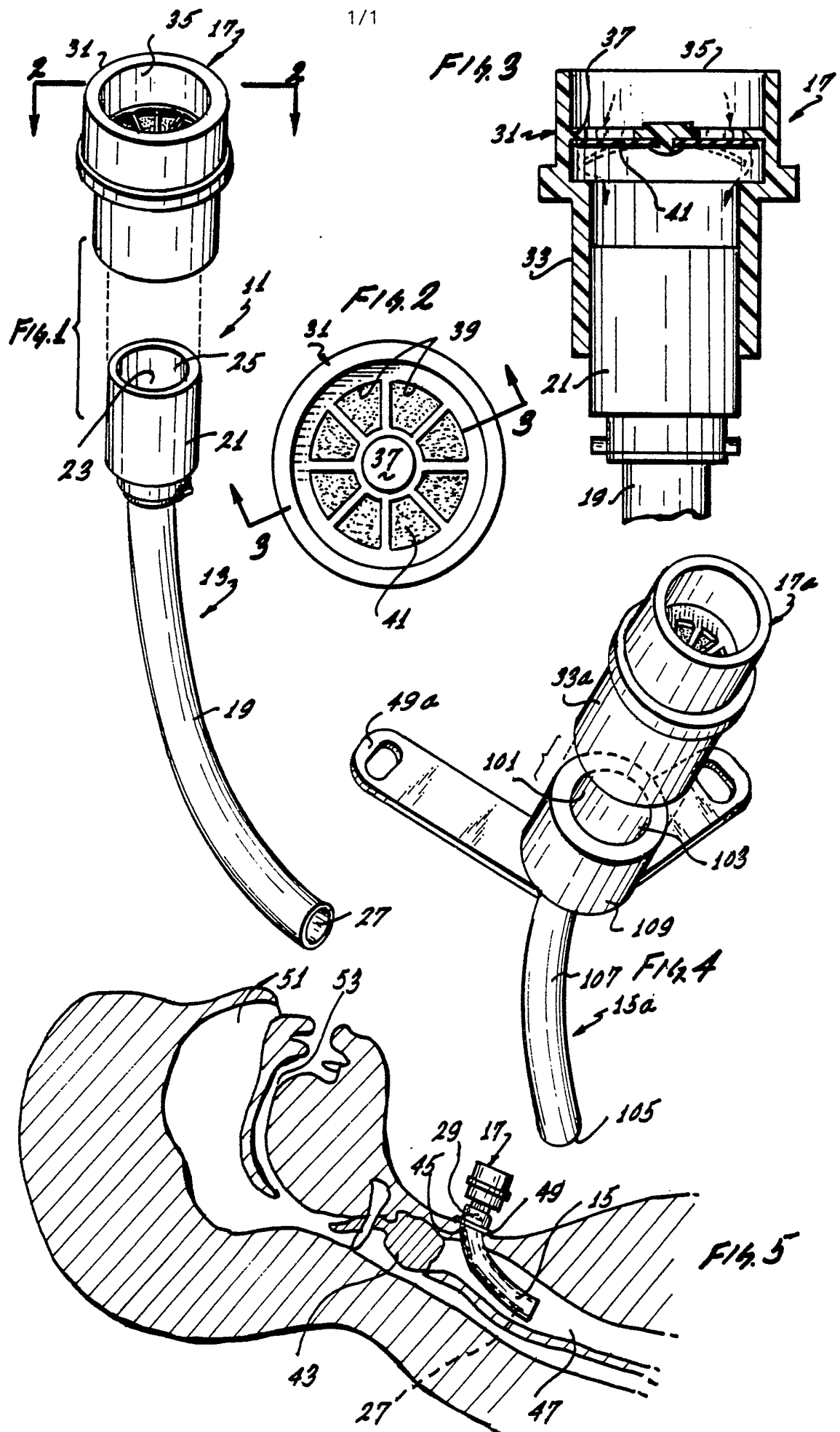
a first closure means for permitting air to enter said housing via said inlet and for preventing air from exiting said housing via said inlet, said first closure means including a disk shaped member  
located in a plane transverse to said longitudinal axis;  
fabricated from thin, flat, flexible material;  
and  
having radial planar dimensions smaller than those of said transverse cross-sectional shape but otherwise being approximately congruent to said transverse cross-sectional shape;

a support means for supporting said first closure means,  
said support means  
mounted to said housing;  
adapted to contact and support said first  
closure means at an interior location in  
said disk shaped member; and  
adapted to permit said disk shaped member to  
bend concavely toward said outlet and  
around said support means when pressure  
lower at said outlet than at said inlet  
is provided; and  
a second closure means for cooperating with said first  
closure means in permitting air to enter said hous-  
ing via said inlet and preventing air from exiting  
said housing via said inlet, said disk shaped mem-  
ber being located within said housing between said  
second closure means and said outlet, and said sec-  
ond closure means including a barrier means  
having an outer lateral surface that contacts  
said inner walls of said housing,  
having a flat, transverse surface immediately  
adjacent to said disk shaped member, ex-  
tending inwardly from said inner walls of  
said housing to a sufficient extent as to  
come wholly within the longitudinal pro-  
jection of the perimeter of said disk  
shaped member,  
having a longitudinal port located wholly  
within said longitudinal projection of  
said perimeter,  
thereby both preventing air flow past said  
disk shaped member from said outlet to-  
ward said inlet when pressure is not  
greater at said inlet than at said out-  
let, and permitting air flow from said  
inlet toward said outlet when pressure is

greater at said inlet than at said outlet.

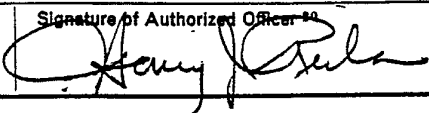
28 . A method of making a tracheostomy tube valve assembly resistant to the accumulation of body secretions comprising providing said assembly with the improved apparatus described in claim 12.

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# INTERNATIONAL SEARCH REPORT

International Application No PCT/US86/00456

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) <sup>3</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
N. Cl. 128/200.26		
IPC <sup>4</sup> A61M 16/00		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>4</sup>		
Classification System	Classification Symbols	
U.S.	128/200.26, 207.14, 207.15, 207.16, 207.17, 912 623/9 3/1.3	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>5</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>14</sup>		
Category *	Citation of Document, <sup>15</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No. <sup>18</sup>
X,Y	US, A, 3,137,299 16 June 1964 Tabor	1-11
X,Y	US, A, 3,844,290 29 October 1974 Birch et al	1-11
Y	US, A, 4,029,105 14 June 1977 Faust	3,6,8,10
Y	US, A, 4,416,273 22 November 1983 Grimes	3,6,8,10
Y,P	US, A, 4,506,665 26 March 1985 Andrews et al	3,6,8,10
Y,P	US, A, 4,510,933 16 April 1985 Wendt et al	3,6,8,10
A	US, A, 4,040,428 09 August 1977 Clifford	
A	US, A, 4,325,366 20 April 1982 Tabor	
A	US, A, 3,693,624 26 September 1972 Shiley et al	
A	"BNGNA <sup>TM</sup> Low Resistance Voice Prosthesis" Advertisement of Bivona Surgical, Inc. 5700 West 23rd Avenue, Gary, Indiana 46406.	
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: <sup>15</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&amp;" document member of the same patent family</p> </div> </div>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search <sup>2</sup>		Date of Mailing of this International Search Report <sup>3</sup>
31 March 1986		04 APR 1986
International Searching Authority <sup>1</sup>		Signature of Authorized Officer <sup>20</sup>
ISA/US		



## III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, <sup>16</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No <sup>18</sup>
A	Blom et al, "Introducing the American V. Mueller Voice Restoration System", Number BE02108301, 1983, American Hospital Supply Corporation, 6600 West Touhy Avenue, Chicago, Illinois, USA 60648.	
A	Blom et al, "Tracheostoma Valve For Post Laryngectomy Voice Rehabilitation", Ann Otol Rhinol Laryngol 91: 1982, Pages 576-578.	
A	"For All Your Tracheostomy Needs", Publication of Shiley Incorporated, 1984, Shiley Inc.	