United States Patent

[11] **3,565,079**

[72] Inventor **Richard Robert Jackson**
Marblehead, Mass. 01945

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Continuation-in-part of application Ser. No. 427,601, Jan. 25, 1965, now abandoned.

[54] **SELF-INFLATING ENDOTRACHEAL TUBE**
15 Claims, 11 Drawing Figs.

[52] **U.S. Cl.** **128/351**
[51] **Int. Cl.** **A61m 25/00**
[50] **Field of Search** ..... 128/348-—351, 344, 325, 246

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Primary Examiner—Dalton L. Truluck
Attorney—John Noel Williams

ABSTRACT: Endotracheal tubes with cuffs that self-inflate during inspiration and remain inflated during expiration. Shown are distal openings on the outside of the tube into the cuff volume. Also shown is a tube having an opening through its wall into the cuff volume, and a flutter valve to restrict the flow of air. The cuffs shown are substantially larger than the trachea and are of thin film material.

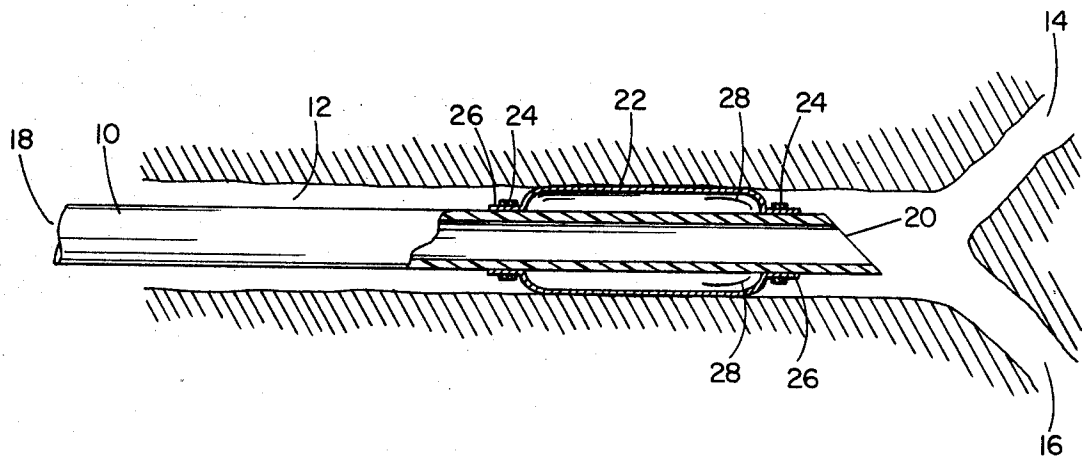
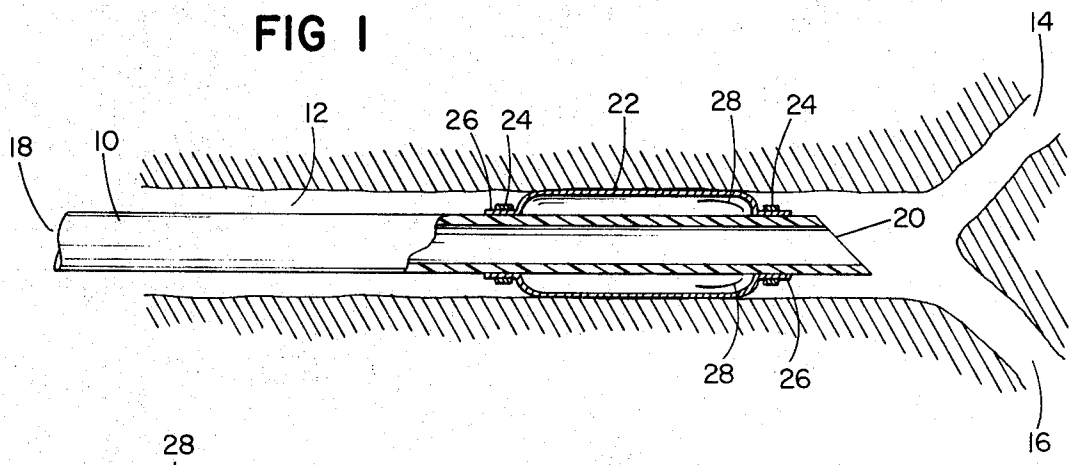


FIG 1



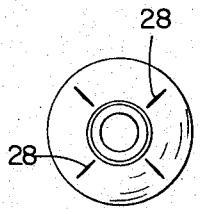
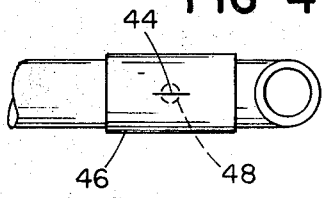


FIG 2

FIG 4



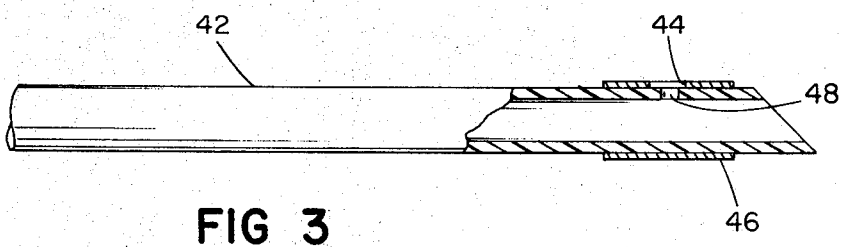


FIG 3

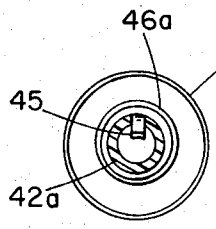


FIG 6

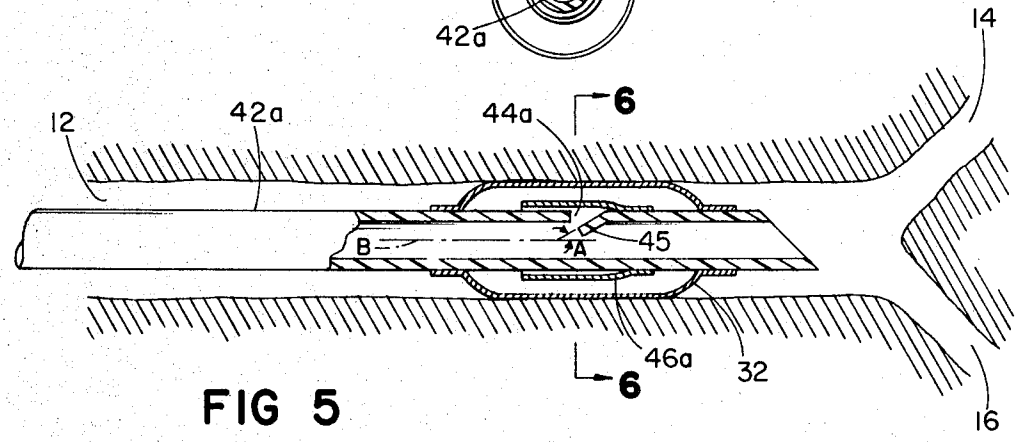
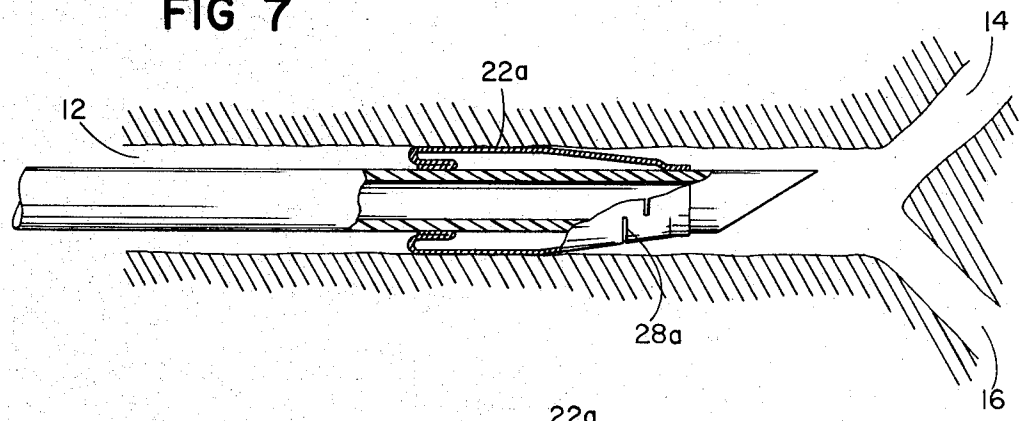


FIG 5

FIG 7



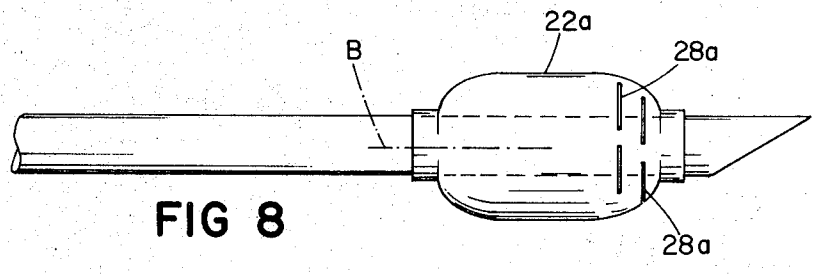


FIG 8

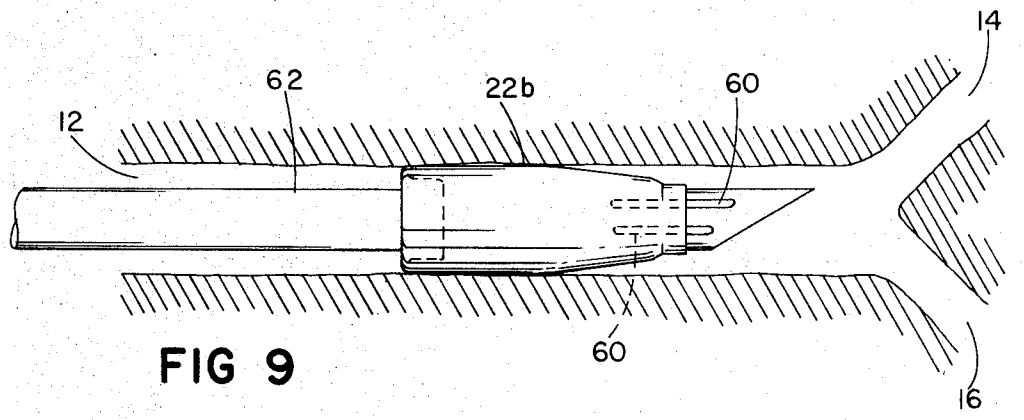
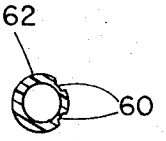


FIG 9

FIG 11



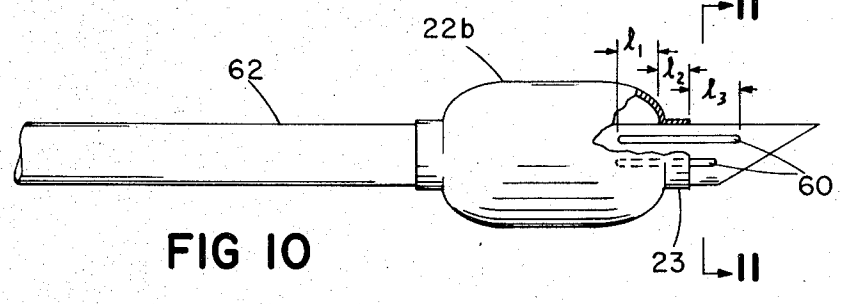


FIG 10

SELF-INFLATING ENDOTRACHEAL TUBE

This application is a continuation-in-part of my copending application of the same title, Ser. No. 427,601, filed Jan. 25, 1965, now abandoned.

The present invention relates generally to medical and surgical equipment and is more particularly concerned with the provision of means for maintaining normal breathing of of the patient during surgical operations and the like.

A primary object of the instant invention is the provision of a novel and improved endotracheal tube.

An important object of the instant invention is the provision of an endotracheal tube having a self-inflating cuff.

Another object of this invention is the provision of an endotracheal tube having a self-inflating cuff that automatically inflates during inspiration through the tube and which remains inflated during expiration therethrough.

Another object is the provision of an endotracheal tube having a self-inflating cuff that makes a good seal with the wall of the trachea but which nevertheless minimizes the likelihood of trauma at the area of the trachea wall where the seal is made.

A further object of the instant invention is the provision of a self-inflating endotracheal tube having novel and improved structural means for automatically causing inflation of the inflatable cuff during inspiration of the patient and for maintaining the cuff inflated during expiration.

Another object is the provision of an endotracheal tube of the character described that is relatively simple and inexpensive to manufacture and which therefore may be disposable after use.

Other object, features and advantages of the invention will become apparent as the description thereof proceeds when considered in connection with the accompanying illustrative drawings.

In the drawings which illustrate the best mode presently contemplated for carrying out the instant invention:

FIG. 1 is a fragmentary elevational view, partly in section, showing an endotracheal tube embodying the instant invention in operation position within the trachea of a patient;

FIG. 2 is a right-hand end view of the tube shown in FIG. 1;

FIG. 3 is a fragmentary elevational view, partly in section, of a further modified endotracheal tube, with the cuff removed for convenience of illustration;

FIG. 4 is a top plan view of a portion of the tube illustrated in FIG. 3;

FIG. 5 is a view of another embodiment in operation within the trachea and

FIG. 6 is a cross-sectional view taken on line 6–6 of this embodiment;

FIG. 7 is a view of another embodiment in operation within the trachea;

FIG. 8 is a side view of this embodiment;

FIG. 9 is a view of another embodiment in operation within the trachea;

FIG. 10 is a side view, partly in cross section of this embodiment; and

FIG. 11 is a cross-sectional view taken on line 11–11 of FIG. 10.

Although the instant invention is illustrated and described in connection with an endotracheal tube, it will be understood that all forms of the invention hereinafter described function equally as well in connection with tracheotomy tubes used as an artificial airway in the neck to create a direct passage for air to enter the trachea without passing through the mouth, as is well known in the art. Thus, it will be understood that all reference in the specification and claims herein to endotracheal tubes, applies equally to tracheotomy tubes, and hence, for the purpose of this application, the term endotracheal tube is construed broadly as covering tracheotomy tubes as well.

Referring now to the drawings, and more particularly to FIGS. 1 and 2 thereof, there is shown an endotracheal tube 10 in operative position in the trachea 12 of a patient, having passages 14 and 16 leading to the left and right lungs of the patient. The tube 10 is of conventional construction in that it

comprises a hollow open-ended tube of any flexible nontoxic material, such as certain well known types of plastic that are used for this purpose. The tube 10 has a proximal end 18 and a distal end 20, the latter terminating in a beveled form, as is well known and conventional in the art.

Secured to the tube 10 adjacent its distal end 20 is an inflatable cuff or balloon 22, said cuff being generally tubular in configuration and being constructed of any suitable flexible film material, such as extremely thin latex, e.g. of less than .002 inch thickness. The cuff 22 is secured to the tube 10 by any suitable means, such as, for example, by winding silk suture 24 around opposite hub portions 26 of the cuff so as to tightly bind the cuff to the tube in airtight relation with respect thereto. In the form of my invention illustrated in FIGS. 1 and 2, it is important to note that there is no communication between the interior of tube 10 and the interior of cuff 22. Expressed differently, the wall of the tube 10 is imperforate. It is also important to note that the length of the cuff is preferably short relative to the overall length of the tube within the trachea. Furthermore, the diameter of the cuff 22 is substantially larger than the diameter of the trachea 12, e.g. of 1 ½ inch diameter in comparison to a trachea of three-fourths inch diameter, and even though this may result in some folding of the cuff 22 on itself when inflated, this is not detrimental in any way, since the extreme thinness of the material of which cuff 22 is constructed enables the cuff to easily fold upon itself, even at low pressures, while at the same time maintaining a good airtight seal with the surrounding trachea. The cuff 22 is provided with a series of radially spaced slits 28, located adjacent the distal end of the cuff, the purpose of said slits now to be described.

In operation and use, the endotracheal tube 10 is inserted into the trachea in the usual manner, using sterile lubricant to facilitate introduction. The fact that the cuff 22 is not inflated during introduction of the tube 10 further facilitates its insertion into the trachea. Once the tube 10 has been positioned in the patient's trachea, the pressure differential which exists between the patient's lungs and the patient's throat, when respiration is being assisted by the anesthesiologist, will automatically cause inflation of the cuff 22. Expressed differently, the pressure in the patient's lungs is relatively high as compared to the relatively low or atmospheric pressure that exists in the trachea 12 surrounding tube 10. As a result of this pressure differential, and the preferred character of the cuff, i.e. its high flexibility, its oversize shapes relative to the trachea, and its short length, the relatively high pressure air is forced through slits 28 to inflate cuff 22, thereby creating an effective seal between the cuff and the surrounding wall of the trachea. The effectiveness of this seal is further enhanced by the adhesion of the thin latex cuff 22 to the surrounding portion of the trachea, said adhesion being caused by mucus normally present on the wall of the trachea.

As is indicated above there is a tendency for air to flow from the distal end of the endotracheal tube and the lungs outwardly along the outside of the endotracheal tube. This tendency exists both for inspiration and expiration when the patient is being assisted by the use of a breathing bag. The cuff initially causes partial blockage of this air, so that the pressure at the distal side of the cuff approaches that within the lungs, and the pressure on the proximal side approaches atmospheric. Accordingly, air enters the cuff through the slits and acts to distend the proximal wall of the cuff. This improves the blockage, and increases the pressure differential across the cuff. Also, air passing through the constriction defined by the tracheal wall and the cuff may increase in speed, and produce a venturi effect to assist in drawing the flexible film wall of the cuff toward the tracheal wall. In any event further entry of air and progressive distention of the cuff occurs until the limits of the trachea are reached and a substantially perfect seal achieved, all occurring in a fraction of a second.

Thus it will be seen that the cuff 22 automatically inflates immediately and effectively as soon as assisted or controlled respirations are initiated to the patient. The cuff remains in-

flated during expiration through tube **10** as a result of the air pressure in the lungs being greater than that at the distal end of the tube (the only relaxation of the cuff may occur upon completion of expiration and even this can be prevented by a valve on the ventilator which prevents the pressure in the tube from dropping to atmospheric pressure). Passage of air into and out of the patient's lungs may therefore be effectively controlled during surgical procedures. The extreme thinness of the cuff **22** minimizes the likelihood of trauma at the portion of the trachea at which the seal is made. Furthermore, the self-inflating characteristics of the endotracheal tube prevent over- or under-inflation of the cuff, this being of particular importance where the tube is being used in connection with a tracheotomy.

The seal formed by cuff is not normally sufficiently effective to prevent the passage of secretions and blood through the trachea, although, as hereinbefore stated, the seal is sufficiently effective to enable good respiratory control to be achieved.

Referring now to FIGS. **3** and **4**, a further modified form of my invention is illustrated. In this form, the tube **42** is provided with an opening **48** communicating with the interior of the cuff (not shown). A flexible sheet **46** is secured over opening **48** and is provided with a slit **44** in registry with said opening. Thus, the sheet **46** and slit **44** act, in effect, as a flutter valve for permitting inflation of the cuff and at the same time maintaining sufficient inflation during expiration so as to retain an effective seal. More specifically, as high pressure air is introduced to the patient through tube **42**, it will pass through opening **44** to inflate the cuff. When the pressure in the cuff equalizes the pressure inside of tube **42**, the cuff will be inflated, and no further air will pass therein. When pressure inside of tube **42** commences to drop, air will commence to slowly exit from the cuff through slit **44**; however, this exit will be sufficiently delayed by the aforedescribed valve or slit so as to maintain an effective seal until the inspiratory phase of the cycle begins once again. This form of my invention is particularly applicable to tracheotomy tubes since the air pressure in the cuff is maintained at a more constant level than in the case in the aforedescribed forms of the invention. This constant seal prevents passage of blood or secretions or food into the lung of the patient, an ever-present danger where prolonged artificial respiration via tracheotomy is being performed.

A preferred form of my invention using a flutter valve is shown in FIGS. **5** and **6**. In this case the flutter valve **46*a*** is formed by a loose-fitting thin rubber tube surrounding the endotracheal tube **42*a***. The distal end of the opening **44*a*** is defined by a portion or tab **45** of the endotracheal tube **42*a*** that extends at an angle A inwardly toward the tube axis B. This portion forms an air scoop for air passing through the tube on inspiration. It has been found that this air scoop is effective to direct the air through the valve and into the cuff **32**. In particular it makes the initial inflation of the cuff occur with less air flow and pressure in the tube than is the case with the embodiment of FIGS. **3** and **4**.

It is found that after initial inflation the cuff **32** remains inflated throughout the breathing cycle. It may be withdrawn from the trachea while still inflated due to its extreme pliability and the relatively low pressure of inflation (no higher than the pressure of the ventilator). Where desired, the flutter valve **46*a*** may be provided with a slit or other means by which air can leave as the cuff is withdrawn from between the vocal chords.

A preferred form of my invention using slits in the cuff is shown in FIGS. **7** and **8**. The slits **28*a*** in this embodiment extend transversely of the axis B of the tube there being two rows located at the distal end of the cuff **22*a***. It is found that these slits are readily opened (as shown in FIG. **7**) by the effect of ventilator air pressure and readily admit the cuff-inflating air. FIG. **7** also shows that the inflating air concentrates in the proximal end of the cuff. According to observations of the endotracheal tube when disposed in a glass cylinder, it is found that the cuff **22*a*** assumes the form shown when, as preferred, the cuff is oversize relative to the trachea and of such flexibility (e.g. less than .002 inch thick latex film) as to be capable of folding upon itself. In this teardrop form the cuff extends from its proximal point of attachment first toward the proximal end of the tube, then reverses, quickly attaining the maximum diameter and then tapers slowly toward its distal point of attachment. Sealing against the tracheal wall is thus accomplished at the proximal end of the cuff, and the bulk of the cuff in that region provides amply for self-adjustment of the cuff to the contour of the trachea.

So long as the openings in the cuff are in the vicinity of the distal end of the cuff (that is, not in the proximal portions) self inflation is possible. According to the presently preferred embodiment the openings are formed in the outer wall of the distal portion of the endotracheal tube itself. Referring to FIGS. **9—11** a series of elongated grooves **60** are formed in the outer surface of the endotracheal tube **62**, distributed about the circumference of the tube. These grooves extend in the direction of the length of the tube, in this embodiment in excess of one-half inch.

The distal end of the cuff **22*b*** is secured to the tube **62** by a hub margin **23** of reduced diameter. This margin **23** is so sized and positioned that a portion, 1_1 of each groove **60** lies within the cuff **22*b***, on the proximal side of margin **23**, and another portion, 1_3, lies on the distal side of the margin, beyond the cuff. Thus there are provided openings in the vicinity of the distal end of the cuff which admit backflow of air flowing along the outside of the tube. The cuff accordingly inflates, as shown in FIG. **10**, in the form similar to that of FIG. **8**.

It has been suggested by others for ease of manufacture that a separate tip member be molded with properly sized grooves, and adhesively secured to the tube proper. Embodiments following this suggestion have been tested and have been found to produce a very good seal.

It is preferred for the embodiments of FIGS. **5—10** that the cuff be provided with reduced diameter hubs at each end, these hubs being adhesively secured to the tube. Where the cuff is latex and the tube plastic an adhesive marketed as "Eastman 910" is found effective.

In the embodiments of FIGS. **5** and **6** a substantially airtight seal is formed at both ends. In the embodiments of FIGS. **7—11** the hub at the proximal end is sealed substantially airtight, and at the distal end is secured sufficiently strongly to resist being dislodged as the tube is inserted between the vocal chords, into the trachea. In some instances elastic stretching of the cuff to fit the tube may prove sufficient to provide the desired seal and attachment.

In the embodiment of FIGS. **1**, **2**; **7**, **8**; and **9—11** the cuff is shown without openings. Thus communication between the cuff and the inside of the tube is prevented during respiration. An opening covered with a flutter valve and scoop as shown in FIGS. **5** and **6** could alternatively be provided in the other embodiments (albeit at extra expense), and still the tube would be operationally imperforate during the respiration period, and hence within the scope of the invention.

Other modifications of the specific details are possible within the spirit and scope of the claims.

As will be seen, all forms of the present invention provide for automatic inflation of the cuff during the inspiratory phase of the respiration cycle, and at the same time, the cuff is maintained sufficiently inflated during expiration to retain an effective seal. The simplicity of construction of the various forms of the instant invention hereinbefore described make it feasible for the tubes to be disposable after each use.

I claim:

1. A self-inflating endotracheal tube comprising an elongated, flexible, open-ended hollow tube having a proximal and distal end, an inflatable cuff secured to said tube adjacent the distal end thereof, and means for automatically causing inflation of said cuff in response to inspiration through said tube and for maintaining said cuff inflated during expiration therethrough, the portion of said tube extending through said cuff being imperforate and said means comprising openings in

the vicinity of the distal end of said cuff adapted to receive a backflow of air flowing along the outside of said tube.

2. The endotracheal tube of claim 1 further characterized in that the said cuff is generally tubular in configuration and has a diameter substantially larger than that of the trachea in which the tube is adapted to be inserted.

3. The endotracheal tube of claim 2 further characterized in that said cuff is of thin, film material.

4. The endotracheal tube of claim 1 further characterized in that said cuff is of thin film material sized and shaped to permit it to fold upon itself when inflated in the trachea into a substantial teardrop configuration with the large end of the teardrop near the proximal end.

5. A self-inflating endotracheal tube comprising an elongated, flexible, open-ended hollow tube having a proximal and distal end, an inflatable cuff secured to said tube adjacent the distal end thereof, and means for automatically causing inflation of said cuff in response to inspiration through said tube and for maintaining said cuff inflated during expiration therethrough, the portion of said tube extending through said cuff being constructed to prevent flow of air from within said cuff to the interior of said tube when the pressure in said cuff is higher, said means comprising openings in the vicinity of the distal end of said cuff adapted to receive a backflow of air flowing along the outside of said tube and said cuff being of thin film material and sized and shaped to permit it to fold upon itself when inflated in the trachea into a substantial teardrop configuration with the large end of the teardrop near the proximal end.

6. The endotracheal tube of claim 5 wherein said openings comprise, at least in part, passages defined beneath the distal end of the cuff.

7. The endotracheal tube of claim 6 further characterized in that said passages comprise grooves in the outer surface of the distal end of the endotracheal tube.

8. The endotracheal tube of claim 7 wherein said grooves are distributed around the circumference of the tube, a reduced diameter hub portion of the cuff secured about said grooves, the grooves being longer than the axial length of the hub and having portions lying beyond said hub on both sides thereof.

9. A self-inflating endotracheal tube comprising an elongated, flexible, open-ended hollow tube having a proximal and distal end, and an inflatable cuff secured to said tube adjacent the distal end thereof, said cuff having at least one slit therein, said slit located in the distal portion of said cuff for entry of air from the trachea, the portion of said tube extending through said cuff being imperforate.

10. The endotracheal tube of claim 9 further characterized in that said cuff is of thin, flexible film material.

11. The endotracheal tube of claim 10 further characterized in that the said cuff is generally tubular in configuration and has a diameter substantially larger than that of the trachea in which the tube is adapted to be inserted.

12. The endotracheal tube of claim 9 wherein said slits are elongated and extend generally parallel to the axis of the hollow tube.

13. The endotracheal tube of claim 9 wherein said slits are elongated and extend generally perpendicular to the axis of the hollow tube.

14. An endotracheal tube comprising an elongated, flexible open-ended hollow tube having a proximal and a distal end, said tube being provided with a generally radially extending aperture therethrough adjacent the distal end thereof, an inflatable cuff overlying said aperture and sealed to the tube at its ends on either side of the aperture whereby to form a fluid chamber intermediate the walls of the tube and cuff, and a flexible sheet secured over said opening and having a slit therein in registry with said opening, said flexible sheet being oriented so that when the pressure of the fluid within the hollow tube increases above that in the chamber, the slit in the flexible sheet will open and the fluid will flow into the chamber, thereby inflating the cuff, said flexible sheet thereafter operating to restrict fluid flow out of the cuff.

15. An endotracheal tube comprising an elongated, flexible open-ended hollow tube having a proximal and a distal end, said tube being provided with a generally extending aperture therethrough adjacent the distal end thereof, an inflatable cuff overlying said aperture and sealed to the tube at its ends on either side of the aperture whereby to form a fluid chamber intermediate the walls of the tube and cuff, a flexible check valve on the hollow tube and normally covering the aperture, an air scoop member positioned to divert air moving toward the distal end into said aperture and thus through said check valve into said cuff, said flexible check valve being oriented so that when the pressure of the fluid within the hollow tube increases above that in the chamber, the flexible check valve will open and the fluid will flow into the chamber, thereby inflating the cuff, said check valve thereafter operating to restrict fluid flow out of the cuff.