

[54] **ENDOTRACHEAL TUBE WITH IMPROVED INFLATION RETENTION MEANS**

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[22] Filed: **Apr. 23, 1973**

[21] Appl. No.: **353,243**

[52] U.S. Cl. .... **128/351**, 128/349 B

[51] Int. Cl. .... **A61m 16/00**, A61m 25/02

[58] Field of Search..... 128/349 B, 349 X, 349 BV, 128/351, 246, 344

[56]

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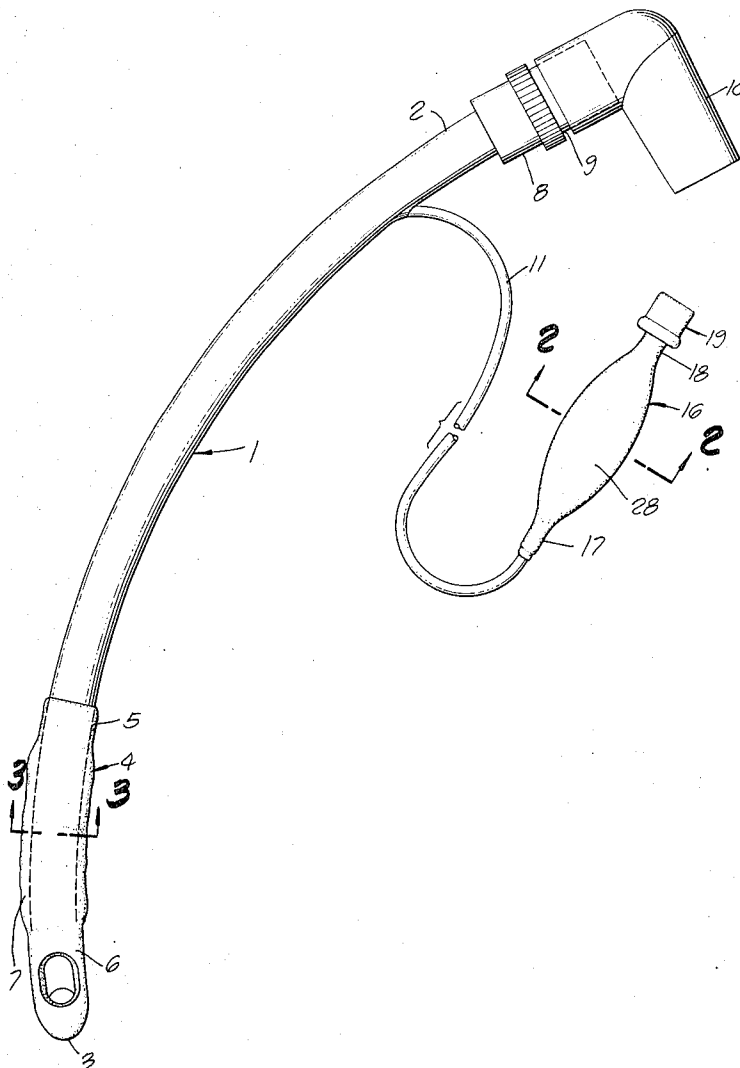
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[57]

### ABSTRACT

A dual-lumen endotracheal tube with a plastisol tracheal balloon of limited stretchability and a highly stretchable latex pilot balloon. These two balloons are connected through an inflation lumen of the endotracheal tube. Injection of 10 to 15 cc. of air into the double balloon system through a special check valve at the pilot balloon expands the pilot balloon substantially more than the tracheal balloon. The pilot balloon forms a high volume low pressure air reservoir gently urging the plastisol tracheal balloon outwardly against a patient's trachea.

**6 Claims, 10 Drawing Figures**



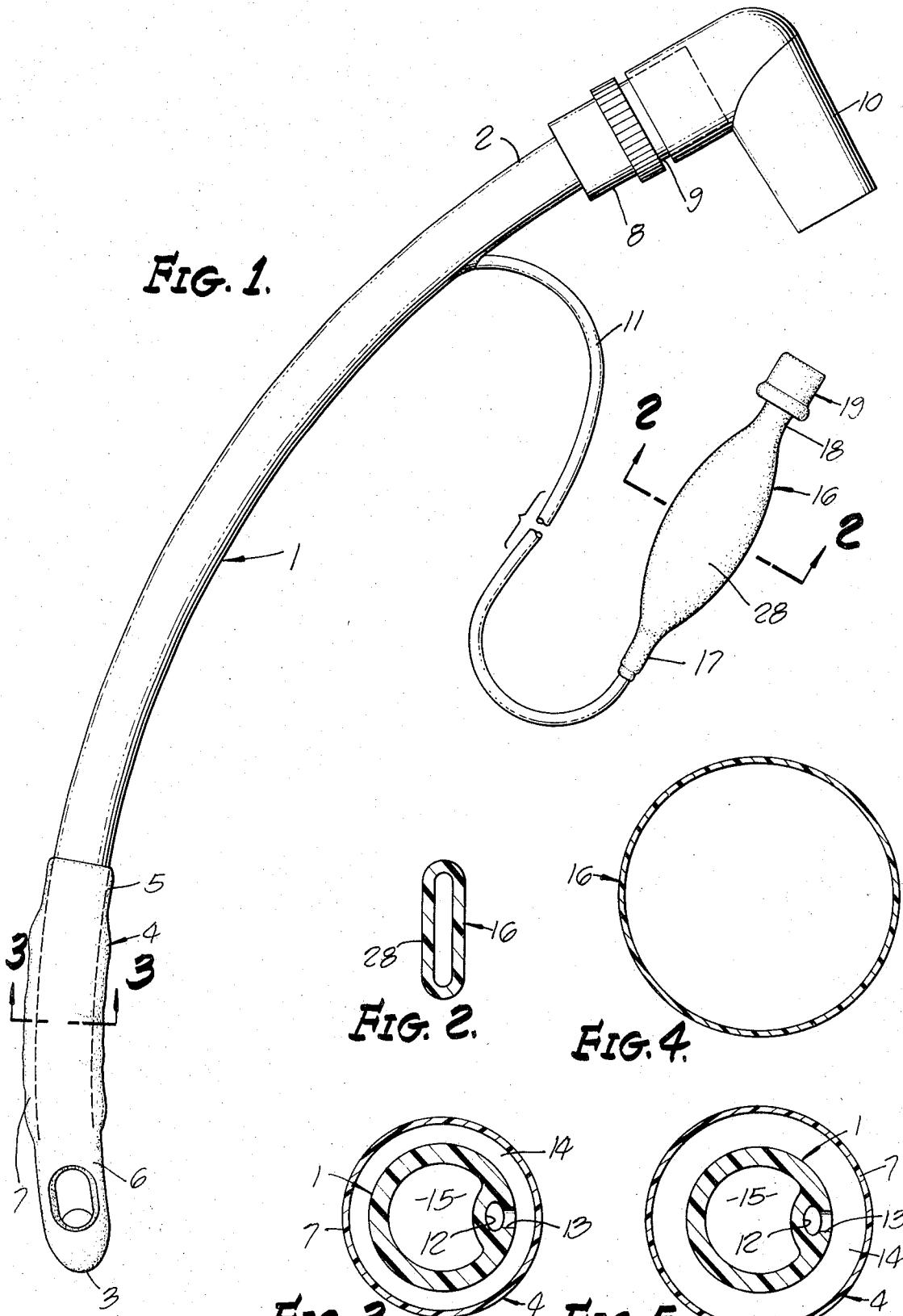


FIG. 6.

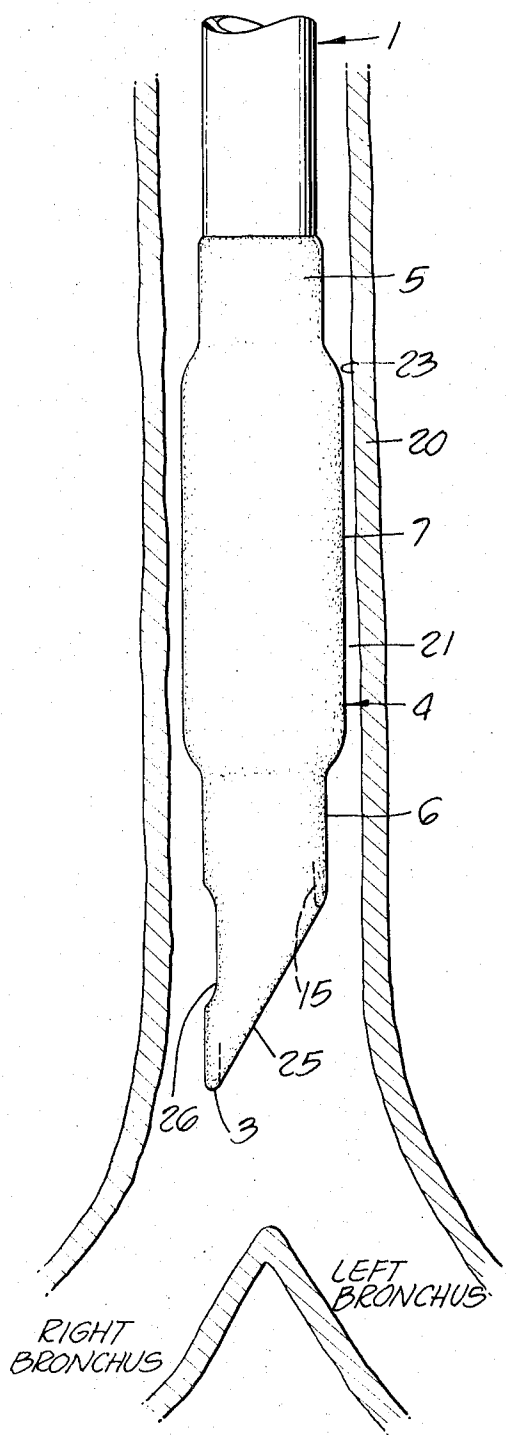
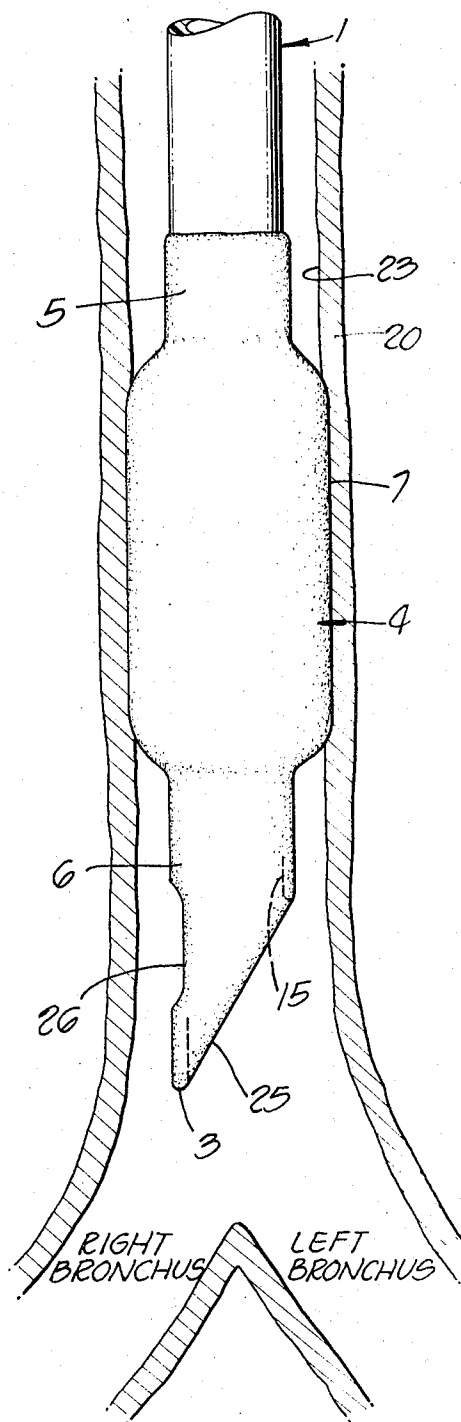
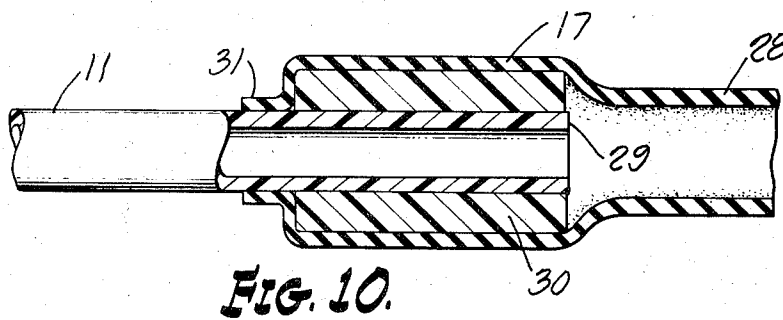
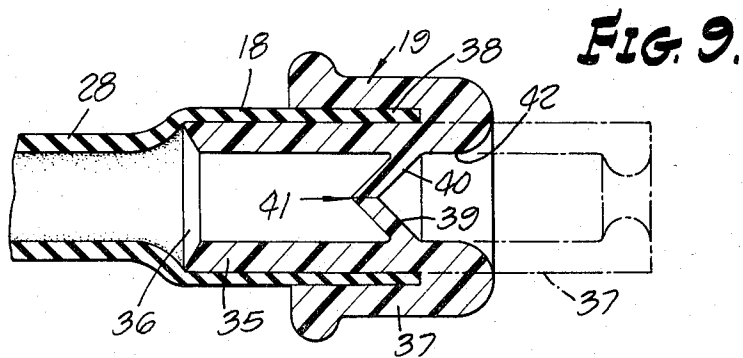
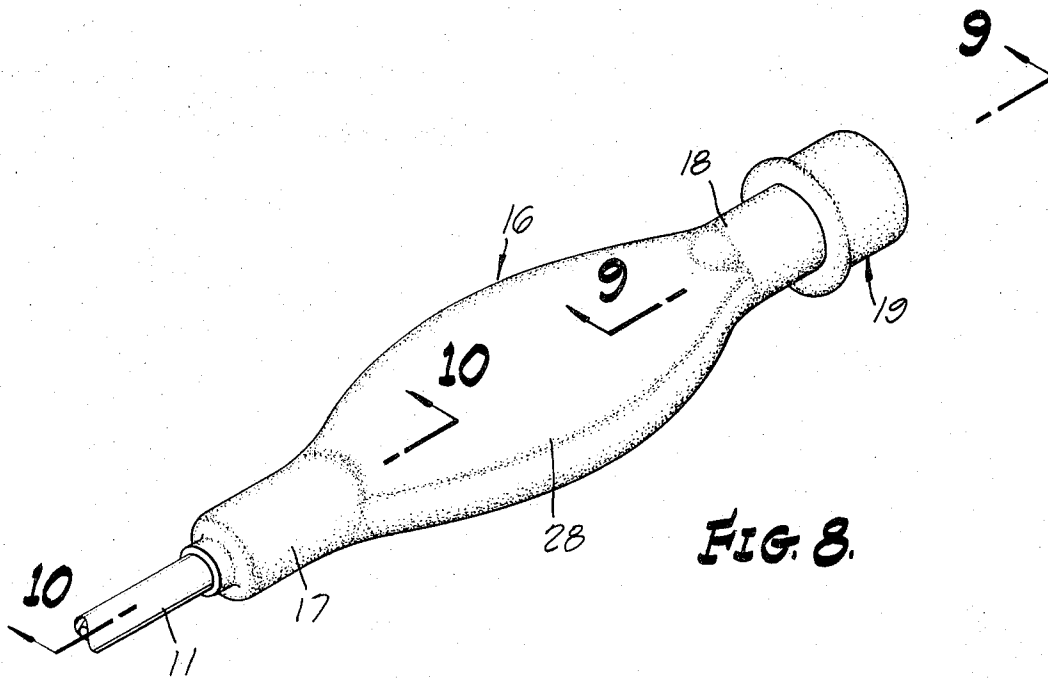


FIG. 7.





## ENDOTRACHEAL TUBE WITH IMPROVED INFLATION RETENTION MEANS

### BACKGROUND

Endotracheal tubes are a common way of administering inhalant anesthetics to a patient such as during surgery. Some physicians prefer an endotracheal tube over a mask or nasal cannula because the lower dispensing end of the endotracheal tube is right at the branch of the bronchial system leading directly to the lungs. To be effective, the inhalant anesthetic must be absorbed by the patient's lungs and many physicians want to dispense it very near to the base of the lungs.

To properly dispense the anesthetic gases into the trachea at the base of the lungs, the tracheal tube must be sealed against the inner lining of the trachea. This is to prevent anesthesia gases from escaping between the endotracheal tube and the tracheal lining where the gases can be discharged from the patient's mouth. To prevent this an endotracheal tube usually includes an inflatable balloon adjacent its lower dispensing end. The tracheal lining is a tender area of the body and the physician desires to make the seal with as small a force as possible to insure that the trachea is not damaged.

Trachea sealing balloons were originally made of a rubber or latex material so that they were highly stretchable and could be inflated outwardly against the trachea. These rubber sealing cuffs did have some disadvantages in that the rubber often included vulcanizing and accelerating agents that could irritate the membrane lining of the trachea. Also being of highly stretchable rubber material the tracheal sealing balloon would sometimes longitudinally stretch to shift either upwardly or downwardly along a dual-lumen insertion tube of the endotracheal tube. When the balloon was sealed against the trachea this shifting caused the lower end of the dual-lumen insertion tube to move relative to the trachea.

To overcome some of the problems with the rubber tracheal balloons of the past, the plastisol endotracheal balloons were developed. These were plastisol dipped balloons often of polyvinyl chloride plastisol that were formed on a mandrel and later secured to a dual-lumen tube. These plastisol endotracheal balloons were free of the vulcanizing and accelerating agents of the previous rubber endotracheal balloons and also reduced the stretch shifting of the balloon longitudinally along the dual-lumen insertion tube.

With endotracheal tubes having rubber or plastisol balloons there was a problem of knowing just when and to what extent the tracheal balloon was inflated. During use the tracheal cuff was inside the patient's trachea where the physician could not see it. To remedy this situation the endotracheal tube manufacturers began including a side branch tube that had a secondary inflatable pilot balloon outside the patient. The pilot balloon was coupled to the tracheal balloon through the inflation lumen of the endotracheal tube. Thus they formed a system of two balloons, one of which was visible and outside the patient.

It was believed to obtain an accurate reading of the condition of the invisible tracheal balloon both the balloons had to be made of the same material. Thus a rubber tracheal balloon was coupled to a rubber pilot balloon, and likewise a plastisol tracheal balloon was cou-

pled to a plastisol pilot balloon. The thinking was that a pilot balloon of the same material as the tracheal balloon could be squeezed or observed and the condition of the hidden endotracheal balloon indicated. There was a balance in stretch characteristics between the two coupled balloons.

### SUMMARY OF THE INVENTION

We have found that balanced stretch characteristics between an endotracheal balloon and a pilot balloon is not required for good visual and touch indication of the condition of the concealed endotracheal balloon. On the contrary, the similar materials of the endotracheal balloon and pilot balloon has a disadvantage. Particularly with a plastisol endotracheal balloon, the plastisol pilot balloon has an inflation resistance because it is of limited stretchability. This inflation resistance causes a greater pressure to build up in the endotracheal balloon inside the patient. This creates additional outward force to be placed on the tracheal lining than is necessary for sealing. The reason for the additional air pressure inside the plastisol pilot balloon is to expand the plastisol pilot balloon of limited stretchability to provide a clear visual indication of the condition of the endotracheal balloon.

We have overcome this problem by creating an endotracheal tube with an endotracheal balloon and a pilot balloon that have walls of substantially different materials and stretch characteristics. The endotracheal balloon fitting inside the patient has a wall of a polyvinyl chloride plastisol material that has limited stretchability. This plastisol endotracheal balloon can expand outwardly slightly to make a good seal against the inner surface of the trachea. The wall of the balloon however does not circumferentially expand more than 50 percent from its normal uninflated condition before it reaches its elastic limit. Therefore, the balloon wall is always circumferentially expanded less than 50 percent from its unstretched condition during normal use to seal against a patient's trachea. Because the tracheal balloon is not highly stretchable, the dual-lumen insertion tube does not longitudinally shift relative to the balloon.

Coupled with the plastisol endotracheal balloon is a highly elastic latex pilot balloon. The pilot balloon has a wall that circumferentially stretches substantially more than 50 percent from its uninflated condition. The latex balloon wall can normally expand circumferentially 800 percent to 1,000 percent before reaching its elastic limit. This creates an unbalanced stretch between the two coupled balloons when both are subjected to a common internal pressure. Therefore the latex pilot balloon can be inflated with low pressure air to a large bulbous reservoir that exerts a low pressure expansion force on the plastisol tracheal balloon of limited stretchability.

### THE DRAWINGS

FIG. 1 is a side elevational view of the endotracheal tube showing the tracheal balloon and pilot balloon in their natural uninflated condition;

FIG. 2 is an enlarged sectional view taken along line 2—2 of FIG. 1;

FIG. 3 is an enlarged sectional view taken along line 3—3 of FIG. 1;

FIG. 4 is a view similar to FIG. 2, but showing the pilot balloon in inflated condition;

FIG. 5 is a sectional view similar to FIG. 3, but showing the tracheal balloon in an inflated condition;

FIG. 6 is a front elevational view of a forward section of the endotracheal tube showing its position in the trachea with the tracheal balloon in a normal uninflated condition;

FIG. 7 is a view similar to FIG. 6, but showing the tracheal balloon inflated against the trachea lining;

FIG. 8 is a perspective view of the pilot balloon of the endotracheal tube;

FIG. 9 is a sectional view taken along line 9—9 of FIG. 8; and

FIG. 10 is a sectional view taken along line 10—10 of FIG. 8.

#### DETAILED DESCRIPTION

Referring to these drawings, FIG. 1 shows the complete endotracheal tube prior to insertion into a patient's trachea. The endotracheal tube includes a dual-lumen insertion tube 1 that extends between a rear end 2 and a forward end 3. Adjacent a forward end of the endotracheal tube is a main balloon 4 for sealing against a trachea. This tracheal balloon includes a rear collar 5 and a forward collar 6 permanently bonded to the dual-lumen tube 1. Centrally located between collars 5 and 6 is a permanently enlarged central portion 7.

At the upper end of the dual-lumen tube formed of extruded flexible polyvinyl chloride is connected a rigid adapter 8 with a tapered section 9. Fitted on this tapered section 9 is an elbow coupling 10 which is for connecting with an anesthesia machine. Such anesthesia machine (not shown) feeds the proper mixture of anesthesia gases through a main lumen of the insertion tube to the patient.

Adjacent an upper end of the dual-lumen tube 1 is a side branch tube 11 that joins with an inflation lumen 12 (see FIG. 3) of the dual-lumen tube. Inflation lumen 12 extends forwardly along the dual-lumen tube to a port 13 beneath enlarged central portion 7. Port 13 communicates with an interior annular air space 14 between the enlarged section 7 and the dual-lumen tube 1. Preferably the inflation lumen 12 is formed within a wall portion of dual-lumen 1 which wall portion defines both the inflation lumen 12 and a main lumen 15.

At an outer end of side branch tube 11 is connected a highly stretchable latex rubber pilot balloon 16. This balloon has an elongated shape with a front collar 17 and a rear collar 18 at a rearward end. An inflation check valve 19 connects with rear collar 18. Both the check valve 19 and front connector at collar 17 will be discussed in more detail later in the specification.

As seen in FIG. 1, the main tracheal sealing balloon 4 and pilot balloon 16 are coupled together through inflation channel or lumen 12. Thus the air pressure in the two balloons are equalized. However, an important feature of this invention is that although their pressures are equalized, their stretch characteristics differ widely and create an unbalanced system relative to elongation of the walls of the two balloons at a given pressure.

As shown in FIG. 2, the pilot balloon has a thin flattened shape at its center section in its normally uninflated condition. In FIG. 3, the polyvinyl chloride plastisol tracheal sealing balloon central portion 4 in its uninflated condition is spaced outwardly a distance from the exterior wall of the dual-lumen tube 1. The purpose of this is so that the enlarged central portion 7 of the

tracheal sealing balloon more closely approaches the diameter of the patient's trachea in its uninflated condition. Therefore the degree of inflation of central portion 7 is greatly reduced when the balloon is expanded to seal against the patient's trachea.

FIGS. 4 and 5 illustrate the substantially different stretch characteristics of the highly stretchable rubber pilot balloon and the plastisol trachea sealing balloon 4. When 10 to 15 cc. of air are injected into the pilot balloon 16 through check valve 19, the pilot balloon being highly stretchable with less force expands to a very large shape. Being of latex rubber its percent elongation in a given wall section of pilot balloon 16 can reach 800 percent to 1,000 percent or more before rupturing. Thus, the pilot balloon serves as a low pressure, high volume air reservoir for inflating the tracheal sealing balloon 4. As shown in FIG. 5, the plastisol endotracheal balloon 4 has a very limited stretchability and in a given wall section the circumference of an annular section of its wall expands less than 50 percent. On the other hand, during normal use, the circumference of an annular section of the pilot balloon wall may expand to 400 percent and still maintain a low pressure system between the two balloons. During normal use, the pressure in the coupled balloons might be 5 to 10 psi above atmospheric and the capacity of the pilot balloon expand from a capacity of 1 to 3 cc. at its uninflated condition to a capacity of 25 cc. when inflated.

Because the plastisol endotracheal balloon 4 has a wall with a relatively low percent elongation at its elastic limit, i.e., less than 50 percent elongation, the center section 7 will not materially stretch longitudinally to shift its position along dual-lumen tube 1. Thus, when the plastisol balloon 4 is locked against a patient's trachea, this also locks the dispensing forward tip 3 at a given location at the base of the lungs. If balloon 4 were highly stretchable, as is the latex pilot balloon 16, the dual-lumen tube 1 could longitudinally shift in the trachea, because of a stretch and rolling effect of a latex balloon on the dual-lumen tube.

With reference to FIGS. 6 and 7, the forward portion of the endotracheal tube is shown in a patient's trachea 20. In FIG. 6, the endotracheal tube has just been inserted in trachea 20 and is in its normal uninflated condition. It is noted that there is an annular space 21 between the enlarged central portion 7 of the trachea balloon and an inner lining 23 of the trachea.

When the endotracheal tube is inserted into the trachea as in FIG. 6, the physician properly locates the end 3 at the desired depth in the trachea, usually immediately above the branched fork of the left and right bronchus. As shown in FIG. 6, the left bronchus is on the right side of FIG. 6 and the right bronchus is on the left side of FIG. 6. This is because the viewer is facing the patient that is shown in sectional view. In FIGS. 6 and 7, the open forward end 25 is defined by a lip angularly biased relative to a longitudinal axis of the dual-lumen tube and end 25 is positioned to direct gases to the left bronchus. Physicians prefer to have the very large diagonal opening 25 directed to the left bronchus. The smaller opening 26 is directed to the right bronchus. This is because it is more difficult to get anesthetic gases into the left bronchus. The reason for this is that a patient's anatomy is not symmetrical in this area.

After the endotracheal tube is positioned as in FIG. 7, the physician regulates the anesthesia machine to administer gaseous anesthesia mixture, air, or other gas in through the main lumen 15 of the dual-lumen tube. While gas is flowing in the main lumen 15 of the dual-lumen tube it can exit through forward end 25 and side port 26. The physician then begins slowly inflating the pilot balloon 16 with air from a hypodermic syringe inserted into check valve 19. As this occurs, a central portion 7 of the endotracheal balloon 4 begins expanding until it contacts the lining of the trachea, as shown in FIG. 7. The physician listens for a hissing noise indicating the passage of expelled air past the endotracheal balloon 4. When this hissing noise stops the balloon is inflated against the trachea. The physician can then insert a small additional amount of air to insure that anesthesia gases will not leak past the endotracheal balloon 4.

When the two balloons are so inflated, usually with 5 to 10 psi air pressure, the pilot balloon 4 will exhibit a substantially enlarged condition as illustrated generally at FIG. 4. Thus, as the patient breathes or moves his trachea to slightly contract and expand the air will be shifted in and out slightly from the highly stretchable pilot balloon 16. Thus the coupled two balloon system, (a plastisol balloon with high stretch resistance and a latex rubber balloon with a very low stretch resistance) provides a low pressure inflation retention means for gently urging the endotracheal balloon against the trachea. As shown in FIG. 7, the stretch resistance of the endotracheal balloon 4 keeps the dual-lumen tube 1 from shifting up and down relative to the branched tubes leading to the lungs. This gives the physician a very accurate control of the outlet end and the depth it is located in the trachea.

With reference to this highly stretchable latex rubber pilot balloon, FIG. 8 shows the balloon in perspective view. The balloon has a flattened central body section 28 with forward collar section 17 and rearward collar section 19. At FIG. 10, the side branch tube 11 leading from the inflation channel or lumen 12 has an upper end 29. Fitting around the branch tube 11 adjacent end 29 is a rigid thermoplastic collar. This thermoplastic collar 30 is permanently bonded to branch tube 11. It can be bonded by cement, solvent sealing, etc. The forward latex collar 17 is physically stretched over rigid collar 30 and assumes a neck down retention section 31 adjacent its forward end. Thus the inflation pilot balloon is permanently locked in an air tight joint to the side branch tube 11.

At an opposite upper end of the rubber pilot balloon 16 is a check valve system shown in FIG. 9. This check valve system has a tubular rubber body 35 with a forward end 36. The check valve has an integral inverted skirt 37. This skirt is formed from a longitudinal extension of body 35 as shown in dotted line in FIG. 9. This skirt is then expanded outwardly and stretched down over an outside surface of body 35. This creates an annular gripping section at 38 that securely locks to an end portion of collar 19.

Within the tubular body 35 are located a pair of converging flap portions 39 and 40 that are integral with the body 35 and converge toward the pilot balloon 28. There is a slit or openable section 41 between these two flaps 39 and 40. Thus, when a tapered tip portion (Luer adapter) of a hypodermic syringe is inserted into syringe retention pocket 42 and a plunger moved for-

wardly, air is forced through slit 41. When the rubber pilot balloon is expanded as shown in FIG. 4, the back pressure from the latex pilot balloon will force the check valve slit into a closed position because of the angular slant of flaps 39 and 40. To deflate the latex pilot balloon, the tip of a hypodermic syringe (not shown) is inserted into pocket 42 to a depth sufficient to expand apart reeds 39 and 40. Thus slit 41 opens and air can be withdrawn by the syringe. To get good valving action between flaps 39 and 40, the rubber valve is of natural or synthetic rubber of a Shore A hardness of 35.

In the foregoing specification a specific embodiment has been used to describe the invention. However, it is understood by those skilled in the art that certain modifications can be made to this embodiment without departing from the spirit and scope of the invention.

We claim:

1. In a medical device for insertion into a body passage, comprising, in combination:
  - an administration tube for insertion in a body passage; said tube including a main balloon circumposed about said tube for inflation and retaining the tube in a relatively fixed position within a body passage during medical treatment;
  - a branch tube connected at an inner end to the interior of said main balloon for inflating the balloon from outside the body passage;
  - pilot balloon means connected in series to the main balloon through an outer end of the branch tube for access outside the body passage;
  - said pilot balloon means comprising an elastic material having expansion properties appreciably greater than the corresponding inflation characteristics of the main balloon whereby inflation of the main balloon causes radical exaggerated inflation of the pilot balloon for immediately apprising a user of the inflated condition of the main balloon in a body passage; and
  - inflation valve means connected in series to the pilot balloon for permitting inflation pressure to be administered to the balloons; the improvement including means for permitting the central portion of the pilot balloon to freely expand longitudinally and laterally when inflated, said means comprising a pilot balloon having a free central portion communicating at one end with an elastic collar of reduced cross-section, said branch tube having bonded to the outer end thereof an enlarged, rigid collar, said elastic collar being stretched in circumposed, air-tight relationship around said bonded collar for obviating the use of adhesives and bonding of the pilot balloon collar to said bonded collar and branch tube.
2. The combination as claimed in claim 1 in which said pilot is stretchingly engaged completely over said bonded collar and a portion of the branch tube depending therefrom.
3. The combination as claimed in claim 2 in which said inflation valve means comprises a rear collar portion of said pilot balloon, a tubular elastic body sealed to the rear collar and including a pair of integral, valve flaps converging inwardly and downwardly from the inner wall surface of the tubular body and include free abutting edge portions normally biased toward each other and forming a one-way valve, said flaps freely diverging from the inner surface of the tubular body

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whereby pressure inside the pilot balloon biases the flaps to a "closed" condition to trap air therein, and ready entry of inflation means beyond the flaps is permitted.

4. The combination as claimed in claim 3 in which said tubular body includes an integral elastic skirt projecting beyond said elastic flaps, said skirt being inverted into circumposed relation about said rear collar of the pilot balloon circumposed on the outer surface of the tubular body.

5. The combination as claimed in claim 4 in which

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said skirt includes a terminal, integral, thickened annular collar circumposed intermediately about said outer collar of the pilot balloon, below the connection between the valve flaps and said tubular body.

6. The combination as claimed in claim 5 in which said pilot balloon comprises a rubber material having a low stretch resistance, and the main balloon comprises a polyvinyl chloride plastisol material having a high stretch resistance.

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