

[54] **PRESSURE REGULATED INFLATABLE CUFF FOR AN ENDOTRACHEAL OR TRACHEOSTOMY TUBE**

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[56] **References Cited**

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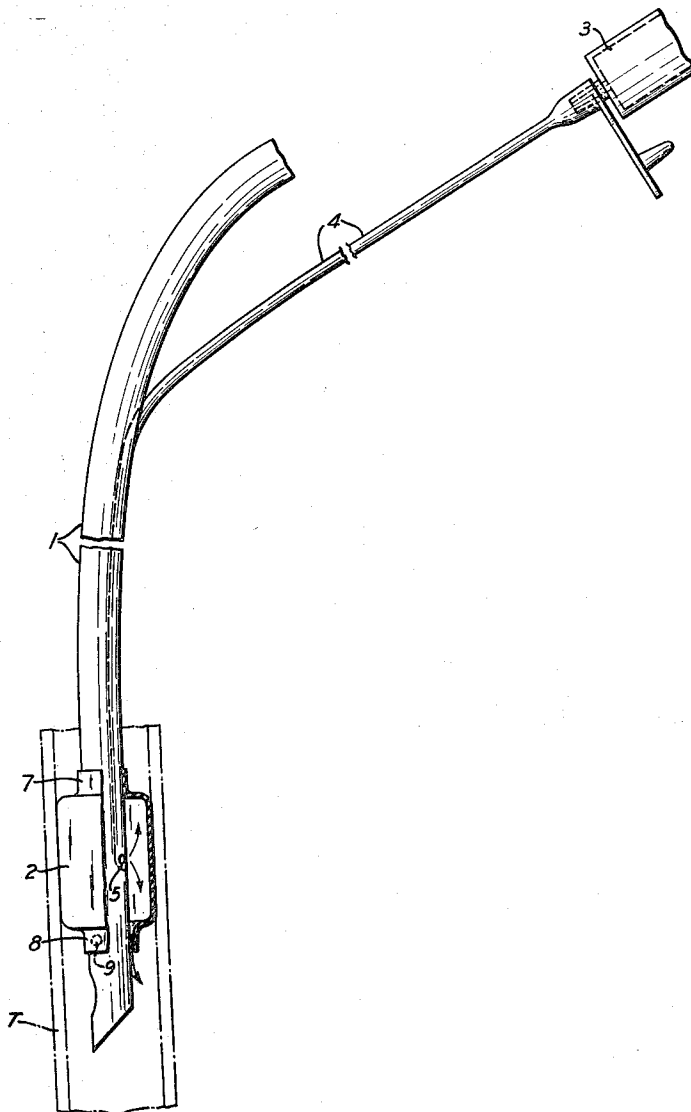
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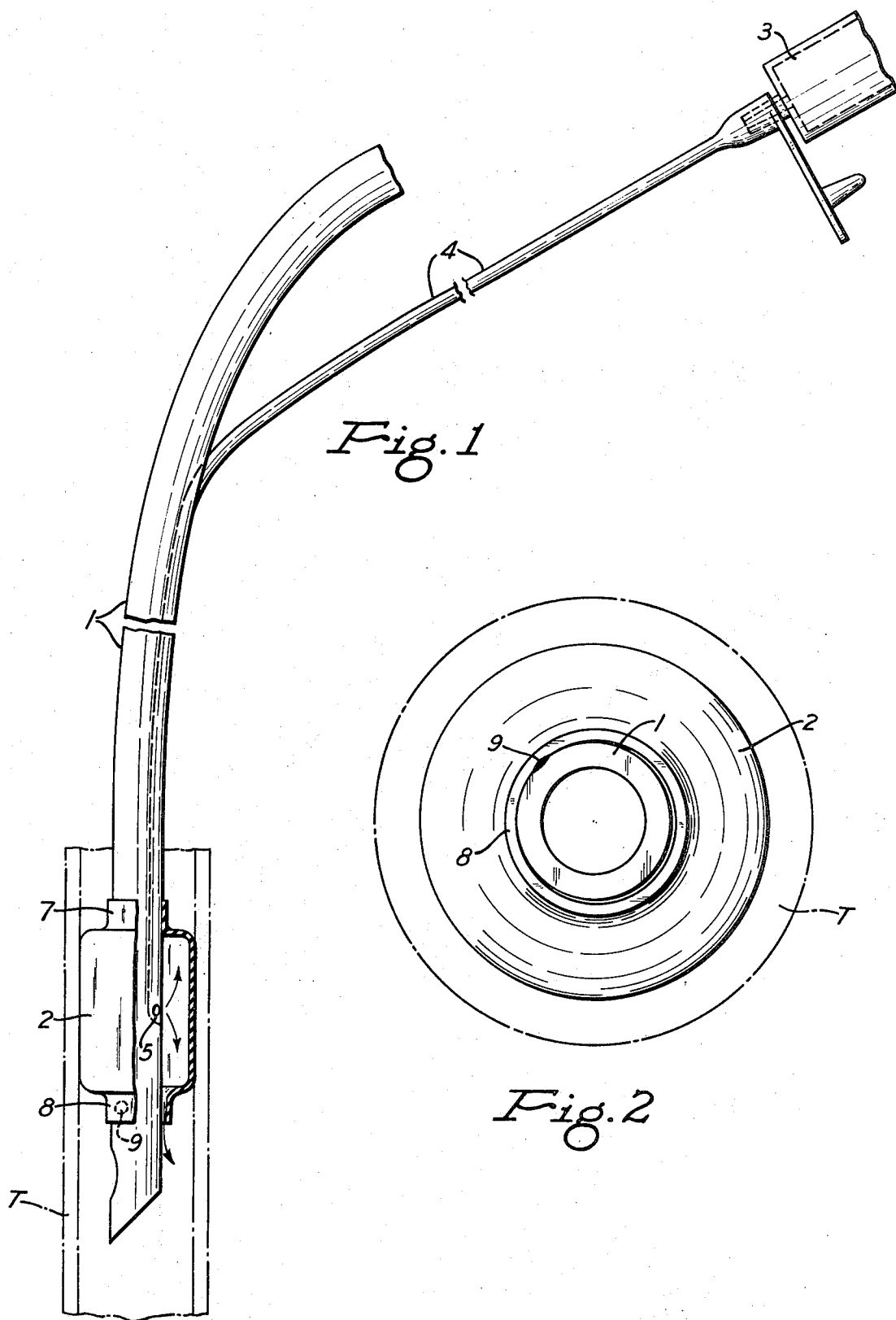
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[57] **ABSTRACT**

An elastic cuff encircles a tracheostomy or endotracheal tube near its distal end and has opposite ends fitting tightly against the tube, with the proximal end of the cuff sealed to the tube. A tubule with a distal end opening into the inside of the cuff extends therefrom outwardly along the tube and has an outer end for air under pressure for inflating the cuff. The distal end of the cuff forms a check valve stretchable radially away from the tube by excessive air pressure in the cuff if the air delivered thereto through said tubule results in a pressure drop across the valve exceeding a predetermined amount, whereupon the pressure drop will be reduced to that predetermined amount.

5 Claims, 2 Drawing Figures





PRESSURE REGULATED INFLATABLE CUFF FOR AN ENDOTRACHEAL OR TRACHEOSTOMY TUBE

A hospital patient requiring intermittent positive pressure ventilation may have a tube inserted in his trachea by way of the mouth or nose or by way of a surgically created opening into his trachea. The distal end of the tube is encircled by an inflatable cuff to provide a seal against the wall of the trachea. In making sure that such a seal is adequate, there is a tendency to over-inflate the cuff so that it may press too tightly against the tracheal wall. Besides discomfort, this can cause serious complications, such as dilation of the trachea, blockage of circulation, and necrosis of that portion of the trachea around the cuff. Various ways have been proposed to prevent overpressurizing of such cuffs, but most of them have not been successful or have been so complicated that they have not been used properly.

It is an object of this invention to provide an endotracheal or tracheostomy tube with an inflatable cuff that will produce a safe pressure controlled good seal against the tracheal wall that will protect against aspiration during all phases of the ventilatory cycle. Another object is to provide such a cuff that will automatically prevent overpressurization. A further object is to provide a cuff which will automatically cycle its internal pressure in synchronous response to airway pressure.

The preferred embodiment of the invention is illustrated in the accompanying drawings, in which

FIG. 1 is a side view of an endotracheal tube, with an overpressurized cuff shown partly in section and excessive air escaping from it; and

FIG. 2 is an enlarged view of the cuff from the distal end of the tube.

Referring to FIG. 1 of the drawings, a flexible breathing tube 1 that is adapted to be inserted in the trachea in a well-known manner has an outer or proximal end that is exposed for connection to breathing apparatus (not shown) by which air can be forced into the lung periodically. The tube is encircled near its inner or distal end by an elastic cuff 2, preferably about five centimeters long and three centimeters in diameter when inflated but unstretched and unpressurized. The opposite ends of the cuff have a much smaller diameter than the area between them and normally both fit tightly against the tube. The cuff can be inflated by air forced into it by means of a syringe 3 or the like, temporarily connected to the outer end of a very small diameter tube or tubule 4 that extends along the main tube and into the inside of the cuff. In one make of endotracheal tube the tubule is molded into the wall of the tube and has an outlet 5 from its distal end into the cuff. After the cuff has been inflated, the syringe is removed and the outer end of the tubule is clamped or plugged to maintain the desired air pressure in the cuff.

It is a feature of this invention that the cuff cannot be overinflated except momentarily. Accordingly, although the proximal end 7 of the cuff is sealed against the tube, such as by an adhesive, the major portion of the distal end 8 of the cuff is not attached to the tube. It need be tacked to the tube at only one or two points to prevent it from sliding along the tube. For example, a stitch or a spot of adhesive 9 may hold the end of the cuff in place. The rest of the distal end of the cuff is free to be stretched radially away from the tube in case the air pressure in the cuff is excessive. Consequently, the distal end of the cuff serves as a check valve. In this

connection it should be noted that it is not the air pressure alone inside the cuff that is the determining factor regarding opening the valve, but it is the pressure gradient or drop across the check valve; that is, the difference in air pressure between the inside of the cuff and the air pressure in the trachea below the cuff. This pressure drop exists only during exhalation, when the pressure in the lungs drops to approximately zero. If the pressure inside the cuff at that time is greater than the cuff is designed for, the excess pressure will be relieved because it will stretch the check valve 8 radially away from the tube sufficiently to allow air to escape from the cuff until the intracuff pressure is back to a safe value.

During inflation of the lungs by the breathing apparatus, the pressure drop across the check valve becomes zero because the air pressure in the trachea below the cuff and the air pressure inside the cuff are equalized. In other words, as the air pressure in the trachea below the cuff starts to exceed the normal pressure within the cuff, the lower end portion of the cuff is compressed and that reduces the internal volume of the cuff and causes the intracuff pressure to increase to balance the air pressure in the trachea. The check valve is held closed by the increased air pressure around it. There is thus no danger of cuff deflation when high airway pressures are necessary for patient ventilation. Although at this time the pressure of the cuff against the wall of the trachea is increased, it has no more injurious effect on that wall than the pressure of the air against it below the cuff.

It will be seen that it is absolutely necessary that it be the distal or lower end of the cuff that serves as the check valve to permit excessive air pressure to escape from the cuff. If this valve were formed by the upper end of the cuff instead, during inflation of the lungs the air pressure in the trachea below the cuff would squeeze the air out of the upper end of the cuff and thereby deflate it.

To control the opening of the check valve formed by the distal end of the cuff, it has been found best to make that end in the form of a cylindrical band as shown, so that an appreciable area of the tube will be engaged by the cuff, rather than providing merely line contact between them. The band may be about 5 mm long, although it may be provided with pleats that extend from its inner edge part way out to its free outer edge so that the inner area of the band will expand and separate from the tube easily as overinflation starts to occur, whereby the threshold pressure for cuff decompression is controlled more exactly. It also has been found best to design the cuff so that a pressure drop across the check valve that does not exceed about 20 mm of mercury during exhalation will not open the valve. If, due to too much air being forced into the cuff through the tubule, the pressure drop becomes greater than that, the check valve will open and permit enough air to escape from the cuff to reduce the pressure drop to 20 mm of mercury. Even if positive-negative pressure ventilation is used, the valve will remain closed if the resting intracuff pressure is 15 mm of mercury and the negative pressure during the negative phase of ventilation does not exceed 5 mm of mercury.

The cuff and tube should be made of materials that will not stick together where the distal end of the cuff engages the tube. If rubber is found to present such a

problem, the tube and/or cuff can be made of some such material as Dow Corning's Silastic.

Another important advantage of this cuff is that if the patient is not being ventilated effectively and if he is capable of making inspiration efforts of sufficient magnitude, he can actually suck the air out of the cuff through the check valve and thereby collapse the cuff so that he can inhale around it.

With this cuff the intracuff pressure is independent of the skills of those who may inflate the cuff, because the check valve will automatically take care of too much air pressure in the cuff. Consequently, the pressure of the cuff against the wall of the trachea likewise is controlled automatically.

According to the provisions of the patent statutes, I have explained the principle of my invention and have illustrated and described what I now consider to represent its best embodiment. However, I desire to have it understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically illustrated and described.

I claim:

1. The combination with an endotracheal or tracheostomy tube having distal and proximal ends, of an elastic cuff encircling the tube near its distal end and having opposite ends fitting tightly against the tube with the proximal end of the cuff sealed to the tube,

and a tubule extending from the cuff outwardly along said tube and having a distal end communicating with the inside of the cuff, the proximal end of the tubule having an inlet for air under pressure for inflating the cuff, and the distal end of the cuff forming a check valve stretchable radially away from the tube by excessive air pressure in the cuff if the air delivered thereto through said tubule results in the pressure drop across said valve exceeding a predetermined amount, whereby said pressure drop will be reduced to said predetermined amount.

2. The combination recited in claim 1, including means tacking said distal end of the cuff to the tube to prevent it from sliding along the tube.

3. The combination recited in claim 1, in which said distal end of the cuff is in the form of a cylindrical band.

4. The combination recited in claim 1, in which said distal end of the cuff is in the form of a cylindrical band secured at at least one point to the tube to prevent it from sliding along the tube.

5. The combination recited in claim 1, in which said distal end of the cuff is in the form of a cylindrical band provided with pleats extending outwardly across the band to points spaced inwardly from the outer edge of the band.

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