

[54] **TRACHEOSTOMY TUBE WITH NOVEL RETAINING MEANS**

[76] Inventor: **Precha Eamkaow**, 106 Revere Rd.,
Dewitt, N.Y. 13214

[22] Filed: **Dec. 19, 1973**

[21] Appl. No.: **426,045**

[52] U.S. Cl. **128/351**

[51] Int. Cl. **A61m 16/00**

[58] Field of Search 128/1 R, 2 F, 129, 241,
128/246, 283, 344, 345, 348-351, DIG. 16,
DIG. 26, 341-343

[56] **References Cited**

UNITED STATES PATENTS

2,457,244	12/1948	Lamson.....	128/1 R
2,586,940	2/1952	Graham.....	128/349
3,693,624	9/1972	Shiley et al.	128/351

FOREIGN PATENTS OR APPLICATIONS

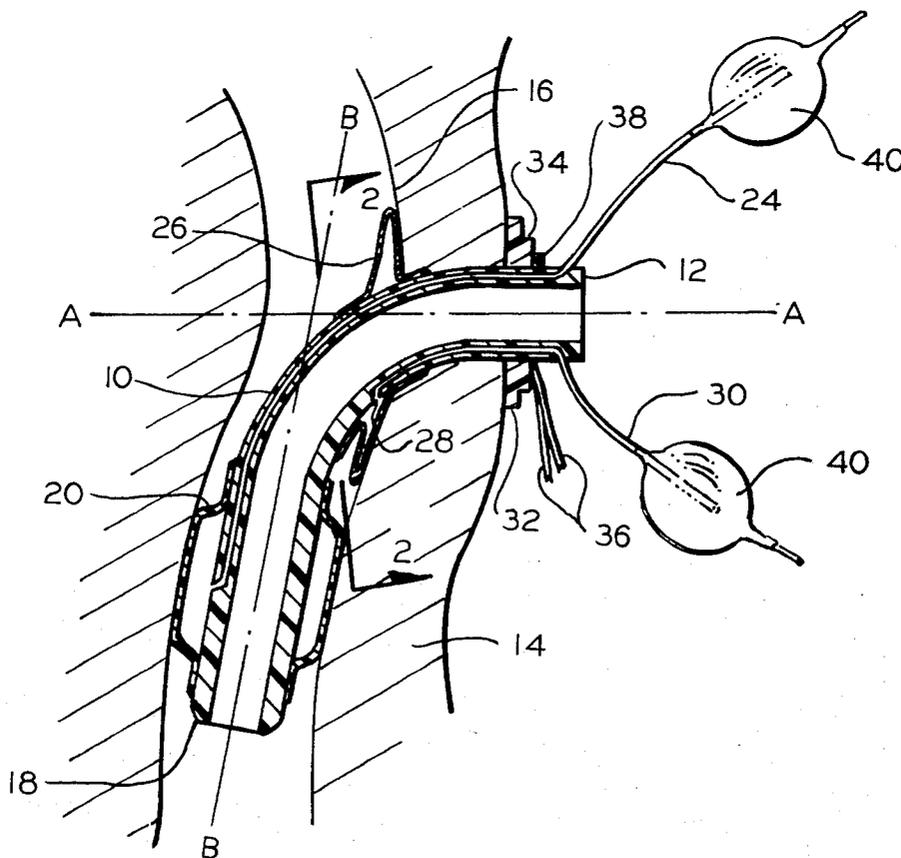
19,196	1907	United Kingdom.....	128/348
--------	------	---------------------	---------

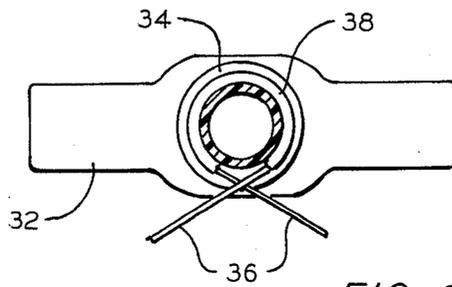
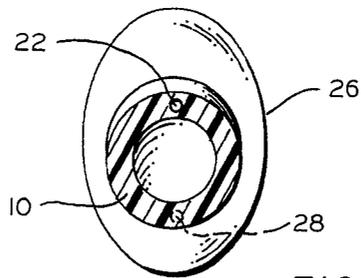
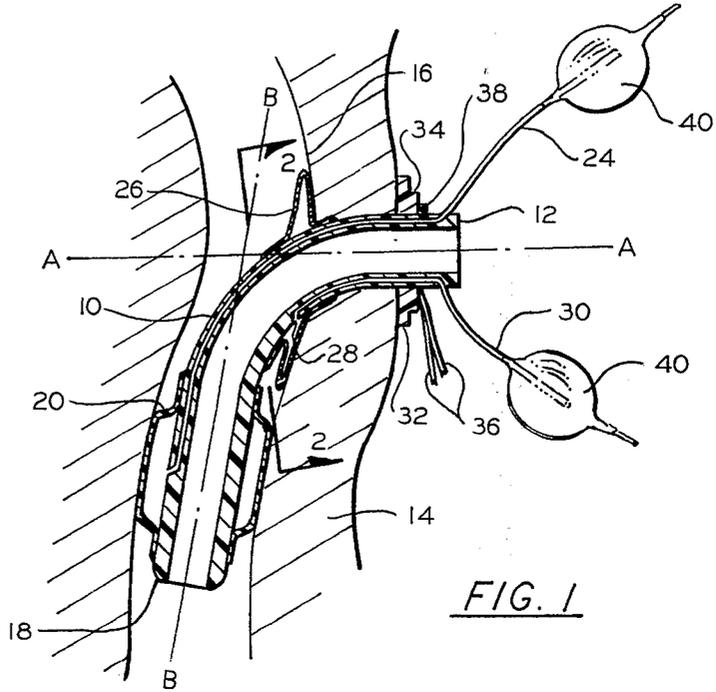
Primary Examiner—Richard A. Gaudet
Assistant Examiner—Rick Opitz
Attorney, Agent, or Firm—Charles S. McGuire

[57] **ABSTRACT**

A tracheostomy tube for insertion through the soft tissue of the neck and an opening in the tracheal wall, and having an inflatable cuff to seal the tube within the trachea as well as a second inflatable device surrounding the tube at a point closely adjacent the opening through which the tube passes on the inside of the trachea. The second device is inflatable to a diameter greater than the opening to prevent withdrawal of the tube until the second device has been deflated. An adjustable shield for securing the tube on the outside of the neck is also provided.

8 Claims, 3 Drawing Figures





TRACHEOSTOMY TUBE WITH NOVEL RETAINING MEANS

BACKGROUND OF THE INVENTION

This invention relates to tracheostomy tubes and, more particularly, to novel and improved means of retaining such tubes in position with the trachea.

It is a common practice to create an artificial airway directly through the neck and into the trachea to permit respiration without passing through the nose or mouth. An opening is made through the soft tissue of the neck and the tracheal wall through which a hollow tube is inserted to conduct air from the front of the neck directly into the trachea.

It is also common practice to provide means for sealing the tube to the inner wall of the trachea to prevent leakage of air around the tube away from the lungs. That is, the sealing means are engaged between the outside of the tube and the inside of the trachea to provide a sealed passageway between the outer end of the tube and the lungs. A flange or shield is normally affixed to the outer end of the tube to prevent insertion past the desired point. The device may be secured in place by a cord tied around the patient's neck from each side of the shield to prevent inadvertent dislodgement.

It has been found, however, that in tracheostomized patients with chronic wasting diseases, senility, mental problems, semicoma or coma, the tube sometimes is dislodged from the trachea accidentally or intentionally, resulting in serious respiratory insufficiency or death. Thus, conventional means of securing the tube in position are not satisfactory in such cases. Also, the cord around the patient's neck may cause irritation and pain, as well as being unsanitary and interfering with circulation in patients who have undergone operative procedures on the neck.

The aforementioned means providing a seal between the tube and inner tracheal wall is commonly in the form of a cuff surrounding the tube which may be filled with air to lodge within the tracheal lumen. If the cuff remains inflated for a long period, exerting outward pressure on the trachea, stricture or necrosis of the tracheal lumen sometimes results. Deflation of the cuff, however, creates the possibility of dislodgement of the tube from the tracheal lumen.

It is a principal object of the present invention to provide a tracheostomy tube having novel and improved means for securing the tube within the trachea.

A further object is to provide a simple and effective structure forming an artificial airway through the throat and into the trachea which cannot be inadvertently withdrawn or inserted too far, and without tying a cord around the patient's neck.

Another object is to provide a tracheostomy tube having novel adjustment means for selectively affixing the outer shield at any desired point along the tube to compensate for different thicknesses of soft tissue between the outside of the neck and the trachea.

Other objects will in part be obvious and will in part appear hereinafter.

SUMMARY OF THE INVENTION

In the disclosed form, the present invention includes a hollow tube for insertion through an opening in the patient's neck and into the trachea with two inflatable balloons affixed around the outer periphery of the tube

at spaced points thereon. One of the balloons is in the form of the usual tracheal cuff which expands to form a seal between the tube and the tracheal lumen. The second balloon is in the form of a flat collar which encircles the tube inside the trachea closely adjacent the opening, or stoma, through which tube extends. The second balloon does not engage the inside of the trachea, but inflates to a diameter larger than the tracheal stoma so that the tube cannot be withdrawn. Separate air lines are provided for inflating the first and second balloons.

A separate shield is provided for engaging the outer end of the tube adjacent the patient's neck. An opening in the shield of about the same diameter as the tube allows the shield to be slid onto the tube until it engages the patient's neck. Flexible straps on the shield are then tightened about the tube to secure the two in the proper relative position. The tube then can be neither withdrawn, until the balloons are deflated, nor inserted further, until the shield is re-adjusted. No strap or cord around the patient's neck is necessary to retain the tube in position.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a side elevational view of a tracheostomy tube embodying the present invention shown in position in a patient's neck and trachea which are shown in section;

FIG. 2 is a sectional view taken on the line 2—2 of FIG. 1; and

FIG. 3 is a front view of the outer end of the tube and adjustable shield.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A tracheostomy tube constructed according to a preferred form of the invention is shown in FIG. 1 as it would appear when in use. Hollow tube 10 extends from proximal end 12, on the outside of the patient's throat, through openings made for such purpose in soft tissue 14 and tracheal wall 16, to distal end 18 directed downwardly within the tracheal tube. In accordance with usual medical nomenclature, the tubular portion of the trachea is hereinafter termed the tracheal lumen, and the opening in the tracheal wall through which tube 10 extends is referred to as the stoma.

The provision of tubes through the throat forming artificial airways to the trachea is well known, as are medical techniques for insertion of such tubes. A flexible plastic shaft having a tapered end extending out of end 18 of tube 10 is commonly provided to assist in inserting the tube into its final position. The flexible shaft is withdrawn from tube 10 after insertion. Since this technique is well known and forms no part of the present invention, the flexible shaft is not shown, and tube 10 is not shown prior to insertion into the trachea.

Tube 10 is bent between ends 12 and 18 so that it may extend inwardly, through the soft tissue and tracheal stoma, and then downwardly within the tracheal lumen. For convenience, the axis of the inwardly extending portion of the tube is labeled A—A, and the axis of the downwardly extending portion B—B. The angle between the two axes is normally slightly greater than 90°.

In order that the tube effectively serve its intended purpose, it is necessary to form a seal between the external surface of tube 10 and the tracheal lumen. It is

conventional to accomplish this function by an inflatable device encircling the tube, commonly known as a tracheal cuff. Such an inflatable cuff is shown in FIG. 1, denoted by reference numeral 20 and connected by passageway 22 within the wall of tube 10 to thin inflating tube 24. Thus, by injecting air through tube 24, cuff 20 is inflated to engage the tracheal lumen and form the necessary seal after tube 10 is in its final position.

Cuff 20 is shown as an example of suitable means for providing the lumen seal. Other known means may be used, such as self-inflating cuffs, normally inflated cuffs which are forced to a deflated condition during insertion, and non-inflatable means such as the resilient flanges disclosed in U.S. Pat. No. 3,659,611. In addition to the conventional lumen sealing means, the present invention includes an inflatable device termed the stoma balloon and denoted by reference numeral 26. Passageway 28 through the inwardly extending portion of the wall of tube 10 connects stoma balloon 26 with inflating tube 30. Stoma balloon 26 encircles the portion of tube 10 on axis A—A closely adjacent its intersection with axis B—B. In the disclosed form, balloon 26 forms a relatively flat collar about tube 10, being sealed thereto at points spaced along the tube by less than the longest radius of the balloon. Thus, after insertion of tube 10 with both cuff 20 and balloon 26 in the deflated condition, balloon 26 is positioned inside the trachea closely adjacent the tracheal stoma. Injection of air through tube 30 inflates stoma balloon 26 to a diameter larger than that of the tracheal stoma whereby tube 10 cannot be withdrawn until balloon 26 is deflated. Air pressure within both cuff 20 and balloon 26 is monitored in conventional fashion by small bladders 40.

Turning now to FIG. 3, tube 10 is retained on the outside of patient's throat by shield 32, preferably constructed of somewhat flexible plastic. The shield is not directly attached to tube 10, but has a central opening of about the same diameter as the outside of tube 10 through which end 12 passes. Boss 34, formed integrally with shield 32, encircles this opening. Flexible straps 36 are affixed to opposite ends of collar 38 which partially encircles and extends outwardly from boss 34.

After insertion of tube 10 into the trachea stoma balloon 26 is inflated and the tube is pulled outwardly to insure that balloon 26 is firmly engaged against the tracheal wall around the stoma. Cuff 20 is then inflated to seal the trachea around tube 10. Shield 32 is placed over end 12 and slid along tube 10 until it engages the patient's throat. Flexible straps 36 are then pulled tightly together and secured by any convenient means so that collar 38, being somewhat flexible, is deformed into frictional engagement with tube 10 to maintain shield 32 firmly in position thereon. For example, the straps may be merely tied either below or above the tube, or may be provided with cooperable engagement means such as mutually engageable notches in the edges of the straps, openings in one strap engageable by a projection on the other, etc.

Thus, the disclosed tube device may be secured firmly in place with neither undue discomfort to the patient nor the possibility of being dislodged. The stoma balloon in the disclosed embodiment is somewhat elongated in the vertical direction since its width is limited by the extent to which it can extend laterally of the tracheal lumen. The stoma balloon may take forms other than that of an inflatable device as long as it is movable

between extended and retracted positions with respect to the outside of the tube. Such movement must, of course, be effected while the balloon, or equivalent retaining means, is within the trachea. Since the tracheal cuff is no longer used as a retaining means, it need be inflated only to the extent necessary to maintain the seal, thereby reducing the possibility of stricture or necrosis resulting from prolonged periods of tight engagement.

It is essential to maintain a seal around the tube in cases such as those where a respirator is connected to the outer end of the tube, to prevent air leakage, or where necessary to prevent aspiration; otherwise, inflation of cuff 20 may be omitted.

What is claimed is:

1. A tube device for introduction into the trachea to form an artificial airway through a patient's throat, said device comprising, in combination:

a. a hollow tube having open ends and a bend intermediate of said ends to form portions lying along first and second linear, intersecting axes, said tube being constructed and arranged for insertion of one end thereof through a tracheal stoma and into the tracheal lumen with said first axis disposed generally coaxial with the tracheal lumen and said second axis extending through the stoma;

b. impermeable means attached to the portion of said tube lying along said first axis and inflatable from a retracted to an extended position to effect a seal between, said tube and lumen;

c. inflatable retaining means attached to the portion of said tube lying along said second axis closely adjacent said bend, and movable with respect thereto between retracted and extended positions, said tube and retaining means having a combined dimension laterally of said second axis when retracted allowing insertion of said tube and retaining means through the stoma, and a combined dimension laterally of said second axis when extended preventing withdrawal of said tube through the stoma;

d. means for selectively inflating said impermeable means and said retaining means between said retracted and extended positions while inside the patient's trachea; and

e. a shield substantially wider than the diameter of said tube, and adjustably positionable along the length of the portion of said tube lying along said second axis outside the stoma, whereby the tissue may be engaged between said retaining means and said shield to fix the position of said tube.

2. The invention according to claim 1 wherein said impermeable means comprise a selectively inflatable and deflatable tracheal cuff.

3. The invention according to claim 1 wherein said retaining means comprises an inflatable balloon sealed to said tube and connected by a closed passageway, through which air may pass to and from the interior of said balloon, to a tube for the passage of air to and from said balloon.

4. The invention according to claim 3 wherein said balloon is annular and is sealed to said tube around the periphery thereof at two positions spaced along said tube by a distance less than the radius of said balloon means, whereby the latter forms a relatively flat collar around said tube when inflated.

5

5. The invention according to claim 1 wherein said shield includes an opening of substantially the same diameter as said tube, and means movable into frictional engagement with said tube for fixing the position of said shield on said tube.

6. The invention according to claim 5 wherein said movable means surround said opening in said shield.

7. The invention according to claim 6 wherein said

6

movable means comprise a pair of flexible straps.

8. The invention according to claim 7 wherein said flexible straps extend from opposite ends of a collar partially surrounding said opening and extending from one side of said shield, said collar being radially deformable into frictional engagement with said tube by tightening said straps.

* * * * *

10

15

20

25

30

35

40

45

50

55

60

65