This invention relates generally to surgical appliances and more particularly to tracheotomy tubes and the like. For people whose natural air passage has become obstructed either by injury, disease or the insertion of foreign bodies thereto, it is a common practice for surgeons to make an incision near the base of the patient's throat to establish communication between the atmosphere and the patient's trachea or windpipe. The operation of opening the trachea and inserting a tube into the trachea in order to provide a means of breathing when the natural passage is obstructed is called a "tracheotomy." The tube is known as a "tracheotomy tube." The insertion of a tracheotomy tube into the trachea through the incision facilitates the passage of air into the trachea thereby permitting the patient to breathe.

There are also instances when a person's larynx becomes diseased and must be removed by surgery. When this occurs, the patient loses the power of speech. In this instance an incision is also made in the throat for reception of a tracheotomy tube in the trachea, an artificial larynx being connected to the tube to enable the afflicted person to speak again.

Tracheotomy tubes of the type generally used are curvilinear and come in pairs, one being telescopically inserted within the other. The outer tube is generally inserted through the incision or tracheotomy and, by virtue of its curvilinear configuration, extends downwardly into the trachea. Generally the tracheotomy tube is held in place by a neck band. The inner tube or cannula is then slid telescopically into the outer tube and to prevent its accidental removal therefrom, such as by coughing or otherwise, some sort of locking means is usually employed to hold the two tubes together. The outer tube generally remains in the trachea for relatively long periods while the inner tube is frequently removed for cleaning.

Tracheotomy tubes of this conventional design suffer from the disadvantage that they constantly reside in the trachea and, as a result of body movement, constantly rub and irritate the delicate ciliated epithelium which line the trachea. Furthermore, utilization of normal functions to expatriate mucous and the like from the trachea is substantially precluded.

As practiced heretofore, such tubes have been made of sterling silver or silver-plated brass or stainless steel which gives rise to still further objectionable features. For example, tubes manufactured from these materials are comparatively heavy and hence cause the patients who wear them considerable discomfort. To reduce the weight of such tubes, it has been proposed to make them of such material as aluminum and hard rubber. However, aluminum tubes become roughened by boiling during sterilization and also by contact with the glandular secretions of the human throat. This results in the formation of granulations which in time lead to stenosis. Hard rubber tubes have not only the disadvantage that they cannot be boiled safely as the walls of such tubes are too thick than they leave too little lumen. Moreover, hard rubber tubes like many of the metallic tubes are irritating to the users' tissues. Other disadvantages of metallic tubes are that they are expensive to fabricate, they are difficult to clean and sterilize, they easily become deformed or damaged, and when the tubes are plated, the plate eventually wears off so that the tubes require constant replating.

Another disadvantage of the curvilinear tubes which have heretofore been utilized almost exclusively in tracheotomy operations arises from the fact that even though a concerted effort is made to bevel the leading edge, the columnar ciliated epithelium which internally line the trachea are frequently irritated and harmed during the insertion of the tube with the result that the proper functioning of the cilia is significantly reduced and even eliminated.

The proper function of the cilia is extremely important since the cilia form one segment of a continuous field of upward stroking lashes which normally carry mucus and other inspired matter from the lungs to the larynx where it can be coughed up. The insertion and interference with these cilia therefore is a defect of the current tubes which it would be desirable to avoid.

Another disadvantage of the curved tube is that it is being inserted down into the trachea will, when plugged with mucus or other inspired material, obstruct the entire tracheal passage thereby making breathing exceedingly difficult and if not properly attended to provides a serious threat to the life of the wearer.

A still further disadvantage of the curvilinear tube arises from the fact that its cooperating, and consequently also curvilinear, inner cannula must be literally custom-made in order to assure proper fit to avoid leakage and to compensate for the vagaries of positioning the "bend" in the outer cannula. Thus, if either of the cannula of the matched pair should become even slightly dented, deformed or otherwise damaged, or if one should become lost, the entire set is useless. Further, in sterilization, the bent nature of the cannula pair requires the exercise of extreme care to avoid the interchanging of non-complementary cannula.

Another form of tracheotomy tube has been recently described and comprises segmented helically wound inner and outer layers interlocked to provide a flexible tube capable of bending in all directions. This tube likewise is fraught with serious disadvantages because the plurality of interlocking surfaces are easily clogged and corroded, and because the flexible contour is readily deformed by the impingement of foreign matter or bodies on any portion of the tube.

Accordingly, one of the primary objects of the present invention is to provide an improved tracheotomy tube which is free of all of the aforementioned disadvantages of prior art tracheotomy tubes.

Another object of the present invention is to provide an improved tracheotomy tube which can be made from a single material which is easier to handle and will maintain substantially permanently that position without entering into or actually obstructing the normal passages of the trachea.

Still other objects of the present invention are to provide an improved tracheotomy tube which affords complete freedom of motion to the wearer's head and neck, which enables the patient to exhale in a normal fashion, which is self-purging by the patient's normal biological functions of keeping the mucus and phlegm that otherwise collect on and within the submucous tissue of the trachea discharged into a normal fashion, and which do not engage and therefore do not irritate extensive portions of the patient's ciliated epithelium. It is another object of the present invention to provide an improved tracheotomy tube which can easily and readily be cleaned in a simplified fashion.

Another object of the present invention is to provide an improved tracheotomy tube structure in which the utilization of inner cannulas is greatly simplified and
the maintenance of a tight seal between the inner and outer cannulas is substantially assured whereupon the mucous secretions or other body fluids are prevented from escaping between the two cannula walls.

Still another and very important object of the present invention is the provision of an improved tracheotomy tube structure wherein the tubes can be interchanged with corresponding tubes of like design with equal effectiveness.

Another object of the present invention is the provision of an improved tracheotomy tube structure which has increased strength by avoiding curvilinear portions, is more compact, and may be made of significantly lesser weight with the attendant advantages to the wearer.

Still another object of the present invention is to provide an improved tracheotomy tube structure which lends itself to the fabrication with modern plastic materials which can if desired be tinted or otherwise made to conform with the skin textures of the wearer and will thereby be relatively inconspicuous.

Still another object of the present invention is to provide an improved tracheotomy tube with valving means providing to permit the ingress but not the egress of air into the trachea which means may be readily removed for purposes of cleaning and adjustment or other inspection of the cannula.

A still further object of the present invention is the provision of an improved tracheotomy tube structure in which a pair of spaced flanges adjacent the inner end of the tube coax with the trachea rings themselves to maintain the tube in its installed position in the patient.

These, and still other objects as shall hereinafter appear, are fulfilled to a remarkably unexpected extent by tracheotomy tubes embodying the present invention in a manner which can be readily discerned from the following detailed description of an exemplary embodiment of the invention, especially when considered in conjunction with the attached drawings in which:

FIG. 1 is a cross section, partially in phantom, of a tracheotomy tube embodying the present invention;

FIG. 2 is a cross section of the valve cap shown in phantom in FIG. 1;

FIG. 3 is an end view of the valve cap of FIG. 2;

FIG. 4 is an end view of the tracheotomy tube of FIG. 1;

FIG. 5 is an enlarged elevation of a trochar for use with the cannula of FIG. 1;

FIG. 6 is a side view, partially in section, of my tracheotomy tube in place on a patient, and illustrates the position of the tracheotomy tube relative to the trachea; and

FIG. 7 is a front view of a patient wearing a tracheotomy tube in accordance with the present invention.

Referring more particularly to the drawings wherein a tracheotomy tube exemplifying the present invention is illustrated an identified by the general reference numeral 10.

Tracheotomy tube 10, as shown, comprises a generally cylindrical tube 11 (hereinafter called "outer cannula 11") having a proximal end 12, distal end 13, a first body portion 14 and a second body portion 15.

Body portion 14 is cylindrical, having an outside diameter of a first dimension, and forms a major part of the overall length of cannula 11, commencing at distal end 13. Second body portion 15 is likewise cylindrical, having an outside diameter of a second dimension which is slightly larger than the outside diameter of the first portion. The second body portion 15 lies contiguous with first body portion 14 and extends therefrom to proximal end 12. The internal diameter of both body portions is the same.

Second body portion 15 is provided with a channel 16 approximately in the middle thereof whereupon the body portion 15 is divided into two spaced substantially identical flange members herein referred to as anterior flange 17 and posterior flange 18, the full significance of which shall hereinafter be described in detail.

Adjacent distal end 13, cannula 11 is provided with a plurality of threads 19. Adjacent proximal end 20, 1 end 20, 1 are positioned in coplanar relationship to each other and have openings 22, 23, respectively, defined therethrough.

In the embodiment of FIG. 1, an inner cannula 27 is telescopically inserted within the outer cannula 11 but extends from proximal end 28, coterminal with proximal end 12 of outer cannula 11, to a distal flange 29. Distal flange 29, when cannula 27 is inserted completely into cannula 11, overlaps a portion of the annular distal end 13 of outer cannula 11 in intimate engagement therewith.

A valve cap 31, shown in phantom in FIG. 1 and in detail in FIG. 2, is provided internally with threads 32 which cooperatively engage threads 19 of the outer cannula 11 to advance and secure valve cap 31 in the position shown in FIG. 1. Valve cap 31 further comprises thin membrane 33 secured by a suitable axially slidable holder such as pin 34 to support member 35 which substantially bisects cylindrical top surface 36 and is in turn supported by cap side wall 37. Member 35 further coacts with side wall 37 to define air inlets 38 and 39. Intermediate internal threads 32 and diaphragm 33, on the inner surface of the side wall, and the expanding seat means 40 is provided for engaging flange 29 of inner cannula 27 and holding it in place when valve cap 31 is advanced all the way on threads 19.

Referring to FIG. 5, a obturator 41 is shown which comprises a straight shank portion 42 carrying a lead portion 43 having an arcuately curved face 44 and, at its base, a diameter substantially identical to the internal diameter of outer cannula 11. The full function of face 44 shall be hereinafter more fully described.

At its other end shank portion 42 carries a radially extending detent 45. Detent 45 is provided with a cross diametrical dimension which is sufficiently larger than the inner diameter of cannula 11 to prevent the passage of detent 45 thereinto. Lead portion 43 and detent 45 are secured to shank portion 42 in any suitable fashion such, for example, by having a sleeve 46 which is force-fit to the end of the shank portion 42.

In the manufacture of a tracheotomy tube in accordance with the present invention, any suitable non-corrosive and durable material may be utilized for forming the outer cannula 11. Thus conventional surgical steels and alloys may be employed although it has been found that several of the new plastics such, for example, as "mylron" and "Lucite" are quite satisfactory and will readily withstand sterilization and such other abuses it might encounter together with the corrosive action of the body fluids. In addition, the synthetic resins, such as those commercially available from Du Pont under the trade name "nylon" are light in weight, extremely tough, and yet are resilient to an advantageous degree. In addition, the resins lend themselves readily to fabrication by molding whereas most metals require refined machining.

From the foregoing it becomes apparent that a tracheotomy tube quite unlike any heretofore known has been described in which a relatively short straight tubular member having spaced anterior and posterior flanges adjacent its proximal end, detachable valve means in threaded engagement at its distal end, and coplanar wing members intermediate said posterior flange and said valve means, is utilized to permit a patient with tracheal difficulties to breathe and which, as shall now be described, completely avoids passing axially in the trachea the devices which have been heretofore. Further, the detachable valve cap permits the ready removal of the valve cap from the distal end of the tube thereby permitting the cannula to be readily sucked out or otherwise cleaned as the need arises,
The use of the tube of the present invention shall now be described, special reference being had to FIGS. 6 and 7 which show the tracheotomy tube 10 as it appears when it is operatively installed on a patient. Thus tube 10, as shall be detailed herinafter, extends to the trachea 45 through an incision (tracheotomy) in the patient's neck 48 and is partially maintained in this position by a suitable securing means such, for example, as tie cord 49 extending between the openings 22 and 23 defined in wing members 20 and 21, respectively around the rear of the patient's neck. Wing members 20, 21 rest on the outer skin of the patient's neck where they are held reasonably secure although comfortably loose by the action of the securing means 49.

When tube 10 is in position in the patient, it will be further secured by the coaction of anterior flange 17 and posterior flange 18 with the trachea 47. It should be especially noticed that the small radially extending annular surface 50 of anterior flange 17 is the only portion of the tube which comes in contact with the inner wall of the trachea whereupon constant irritation of the ciliated lining which was heretofore characteristic of tracheotomy tubes is eliminated. Upon installation, and usually never exceeding about two air hours, the living tissue of the trachea literally grows into channel 16 and flanges 17, 18 coat therewith to provide enhanced stability to the tube.

The action of the flutter valve in valve cap 31 permits the patient to take in air through inlets 36 and 39, the force of the incoming air causing the diaphragm 33 and pin 34 to move axially away from surface 36 and permit passage of the air. Any attempt to expire through the tube is prevented, however, since the force of expired air causes the diaphragm 33 and pin 34 to slide axially toward and into sealed engagement with the top of valve cap 31 by virtue of valve spring 35. 38, 39. In this manner, the expiring air is required to pass up the trachea and out through the oral and nasal chambers. In so passing, the air effects the normal biological function of purging mucus and other foreign matter from the trachea e.g., by coughing.

Of course when the patient's malady is such that the normal biological function cannot be performed, such as occurs when the larynx is so markedly obstructed as to prevent the egress of air from the trachea into the oral pharynx, the valve means 31 can be removed. In this manner, the free and unobstructed ingress and egress of air is effected through the trachea with the tube 10 and the functionally occluded larynx will be by passed. If the obstruction is of a permanent nature, valve cap 31 will be replaced with a threaded foraminous cap (not shown), which can be substantially identical to valve cap 31, with only membrane 33 and holder 34 being omitted.

The occlusion of the larynx is disadvantageous, the patient obtains immediate relief by removing valve cap 31 from tube 11 whereupon the free passage of air is immediately obtained.

In inserting tracheotomy tube 10 into the patient as shown in FIG. 6, valve cap 31 and inner cannula 27 will now be removed and obturator 41 inserted into outer cannula 11 whereupon the proximal end 12 of the cannula 11 and contoured face 44 of obturator lead portion 43 cause to form a continuous smooth surface which can easily be slid through the tracheotomy to position the anterior flange 17 within the trachea 47. Obturator 41 is, as indicated, prevented from extending too far through cannula 11 by the engagement of the annular distal end surface 13 of the cannula by detent 45.

When cannula 11 has been inserted as indicated, wing members 20, 21 will engage the surface of the patient's neck 70 and obturator 41 is removed from the cannula. Then, if desired, securing means 49 is comfortably wrapped around the rear of the patient's neck and attached to wing members 20, 21, in openings 22, 23. If it is desired to use inner cannula 27, it is readily slid telescopically into the outer cannula 11 until distal flange 29 engages on the annular distal end surface 13 of the cannula 11. Then valve cap 31 is screwed into place until seat means 40 engages distal flange 29 thereby locking inner cannula 27 against outer cannula 11 and effectively preventing air leakage from between the cannulas. The primary reason for using the inner cannula 27 is to facilitate cleaning.

When it is not desired to employ the inner cannula 27 or to remove it for cleaning, valve cap 31 is screwed directly onto cannula 11. In both instances, the operation of tube 10 is as described.

Thus, embodiments have been herein described for both patients who are and those who are not capable of exhaling from the trachea. Regardless, the novel concept of stabilizing the tracheotomy tube is equally applicable to both. Likewise, the stabilizing structure is the same when the tube is connected serially to an artificial larynx.

The term "tracheotomy tube" as used herein defines the surgical appliance employed in the performance of a tracheotomy which permits the patient to breathe and which is sometimes called a "tracheotomy tube" and a "tracheal tube."

From the foregoing it becomes apparent that a new and improved tracheotomy tube has been described which completely fulfills all of the asforesaid objectives to a remarkably unexpected extent and which greatly advances the art of surgical appliances.

It is of course understood that such modifications, alterations and applications as may readily occur to one skilled in the art when confronted with this disclosure are intended within the spirit of the present invention especially as it is defined by the scope of the claims appended hereto.

Thus, having now particularly described and ascertained the nature of my said invention and the manner in which it is to be performed, I declare that what I claim is:

1. A surgical appliance for a patient comprising in combination: first and second axially extending tubular members, each of said members having a distal end and a proximal end, said first member having a first and a second annular flange integrally formed therewith adjacent said proximal end in spaced axial relationship to each other, said first and second flange coacting with a portion of said second member to define a groove substantially equal in width to the thickness of the patient's tracheal wall and adapted to receive and contain living trachea tissue therein, said first flange defining an annular surface adapted to engage an internal surface of the patient's trachea and coacting with said annular surface of said first flange to laterally contain the patient's trachea therebetween, said first member having radially extending securing means disposed adjacent said distal end thereof defining a surface adapted to engage an external surface of the patient's neck, said second member being telescopically inserted in said first member without said proximal end thereof penetrating the plane of said proximal end of said first member; and one-way inflation valve means detachably secured to said first member with sufficient force to prevent the unintentional removal therefrom and coacting therewith to secure said second member in a fixed position relative thereto while permitting the inere of air to and preventing the egress of air from said patient.

2. A surgical appliance for human patients according to claim 1 in which said valve means comprises a cap member having a foraminous upper surface, a continuous side wall, an axially slideable diaphragm, and means supporting said diaphragm to said upper surface permitting to axial movement of said diaphragm relative thereto into and out of sealing engagement with said foraminous upper surface.

3. A surgical appliance according to claim 1 in which
said second member has an annular flange extending radially therefrom at the distal end thereof and engages said distal end of said first member to limit the axial movement of said second member into said first member.

4. A surgical appliance according to claim 1 in which said securing means comprises oppositely extending wing portions disposed adjacent said distal end and connectable by a neck band to anchor said portions relative to said patient.

5. A surgical appliance for human patients comprising in combination a first axially extending hollow member having a proximal end, a distal end, first and second radially extending non-rotating flanges formed integrally therewith adjacent said proximal end in spaced relationship to each other and defining therebetween a groove for receiving and containing trachea tissue therein, and radially extending securing means adjacent said distal end for engaging the patient's neck, and a second axially extending hollow member telescopically disposed within said first-mentioned hollow member and having at said distal end thereof a radially extending flange which when in engagement with the distal end of said first-mentioned member prevents the proximal end thereof from penetrating the plane of the proximal end of said first-mentioned member; and one-way inhalation valve means detachably secured to said first-mentioned member with sufficient force to prevent the unintentional removal therefrom and locking said second member relative to said first-mentioned member while coacting with said second member to effect the ingress of air to the patient’s trachea while preventing the egress of air therefrom.

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