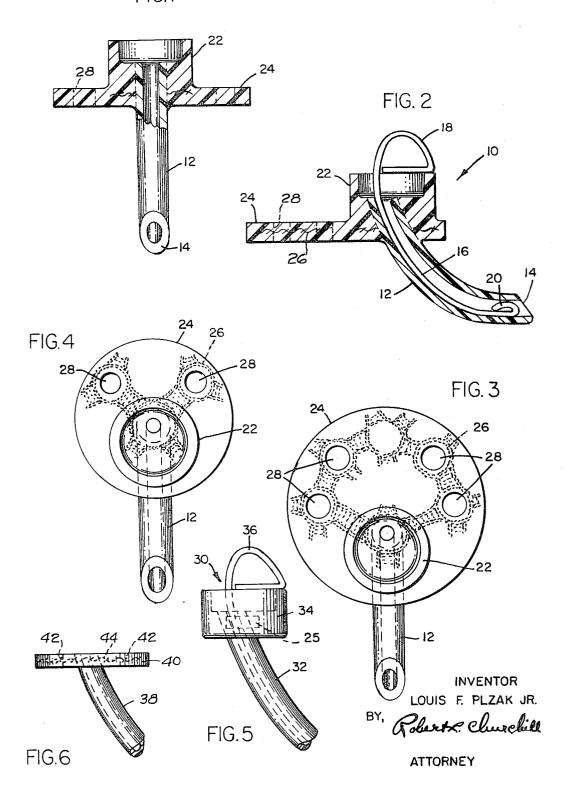
L. F. PLZAK, JR

SURGICAL TUBE

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FIG.I



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3,395,711 SURGICAL TUBE Louis F. Plzak, Jr., 1 Glen Brook Road, Wellesley, Mass. 02181 Filed May 26, 1965, Ser. No. 458,856 5 Claims. (Cl. 128—351)

ABSTRACT OF THE DISCLOSURE

A relatively soft and flexible surgical tube having a 10 flange portion, an adapter for connection to respiratory equipment and a wire obdurator removably received in the tube to assist in introducing the relatively soft and flexible tube into the trachea.

This invention relates generally to surgical tubing and more particularly to tracheostomy and endotracheal tubes.

The invention has for an object to provide a novel and improved surgical tube characterized by being com- 20 posed of a soft, flexible non-rigid material capable of conforming readily to the shape of the patient's tracheal contour and to contour changes due to different postures of the patient.

Another object of the present invention is to provide a 25 novel and improved surgical tube of the character specified which is further characterized by novel means for facilitating insertion of the relatively soft flexible tube.

The invention has for another object to provide a novel and improved surgical tube of the character specified 30 which is further characterized by being composed of a biologically inert material whereby to reduce to a minimum stimulation of mucous secretions effected by the

Another object of the invention is to provide a novel 35 and improved surgical tube, such as a tracheostomy tube or an endotracheal tube, of the character specified having an adapter at its proximal end particularly adapted for connection to conventional respiratory assistance equipment.

A still further object of the invention is to provide a novel and improved surgical tube, such as a tracheostomy tube, having a flange at its proximal end adapted for superior fitting to the neck of the patient.

With these general objects in view and such others as 45 may hereinafter appear, the invention consists in the surgical tube as hereinafter described and particularly defined in the claims at the end of this specification.

In the drawings illustrating the preferred embodiment of the invention:

FIG. 1 is a front elevation in cross section of a tracheostomy tube embodying the present invention;

FIG. 2 is a cross sectional view of the same in side elevation;

FIG. 3 is a plan view of the tracheostomy tube shown 55 in FIG. 2;

FIG. 4 is a view similar to FIG. 3 showing a modified form of the present tube;

FIG. 5 is a side elevation of a modified form of the present tube adapted for use as an endotracheal tube; and 60 FIG. 6 is a side elevation of a further modified form of

the present invention.

In general, the present invention relates to a novel surgical tube, such as a tracheostomy tube or an endotracheal tube. The invention is herein illustrated as embodied in a 65 tracheostomy tube for use when it is necessary to provide an artificial airway into the trachea through a surgically created opening in the anterior aspect of the trachea. This necessity may arise in conditions of respiratory insufficiency in which it is desirable to decrease the amount of 70 "respiratory dead space"; to better control and assist the respiratory effort of the patient; to permit tracheal-bron2

chial cleansing; and to by-pass areas of upper airway ob-

The prior tracheostomy tubes now in use consist of rigid matched inner and outer tubes with a flange on either side of the outer tube to which a tape or strap is attached and then tied around the neck. These rigid tubes are constructed of relatively reactive materials, such as silver or rigid plastic material of predetermined and set curvature. The reactive materials cause irritation of adjacent tracheal mucosa which in turn promotes increased mucous secretions tending to obstruct the airway. This necessitates the presence of an inner tube which can be frequently removed for cleansing purposes. The rigidity of such prior tubes does not allow for individual variations in the contour of the trachea or changes in the contour with changes in the patient's posture. Also, such prior tube materials do not lend themselves to be readily shortened by the physician as may be necessary to prevent a long tube from obstructing one or another of the mainstem bronchi, nor do they permit the tubes to be fenestrated by the physician. The use of a double tube results in a relatively narrow internal diameter in relationship to the outside diameter, but the greater the relative internal diameter, the greater the safety of the tube as occlusion of the lumen by mucous is less likely.

In accordance with one feature of the present invention the present surgical tube comprises a non-reactive, transparent material, such as a silicone rubber, which is characterized by being biologically inert and which is sufficiently soft and flexible to conform to the contour of any trachea. The inert properties of silicone rubber reduce to a minimum the promotion of mucous secretions in the trachea so that the inner tube formerly used to remove such secretions is eliminated entirely in the present tracheostomy tube. The relative softness of the silicone rubber tubing also avoids traumatic injury during insertion thereof and also prevents damage due to pressure against the tracheal wall by the tube which might otherwise occur with the prior tubes because of individual differences in tracheal contour or contour changes due to posture changes. This feature is extremely important when the tube is inserted in the trachea of an infant where the trachea is delicate and readily perforated by rigid tubes.

Prior to the present invention it has been necessary to employ a rigid or semirigid material having a set curvature in the construction of such surgical tubes so that the tube could be better controlled and moved into position. For this reason, it has not been considered practical to employ a relatively soft, flexible and limp material, such as silicone rubber, for surgical tubing. In accordance with another feature of the present invention, I provide a rigid obdurator or stiff wire introducer which may be inserted into the opening of the relatively soft, flexible tube to permit the tube to be easily inserted whereupon the introducer may be withdrawn.

In accordance with another feature of the present invention, the proximal end of the tube is provided with a cup-shaped silicone rubber adapter molded integrally with the tube and which is of a size such as to facilitate connection to existing respiratory assistance equipment. The present tracheostomy tube is also provided with a circular silicone rubber flange molded integrally therewith and to the adapter, the flange being reinforced with nylon mesh molded therein to prevent tearing. The flange is also provided with openings through which a strap or tape may be threaded for tying around the neck. The inert nature of the flange also makes possible direct suturing of the flange through the nylon mesh to the neck in the cases of infants to insure against inadvertent removal of the tube from the trachea.

Other advantages of the present silicone rubber surgical tube are that it is light in weight; sturdily constructed;

and capable of being sterilized by heat, gas or any of the conventional sterilizing solutions. The present tube may also be easily cut to the desired length by the surgeon at the time of its insertion.

Referring now to the drawings, 10 represents a tracheostomy tube embodying my invention, the tube being composed of a biologically inert material, such as silicone rubber, and which comprises a relatively soft non-rigid transparent flexible material. The tube 12 may be made of any convenient length and in practice may be cut off to the required length by the surgeon. The distal end 14 of the tube is cut at an angle, as shown, and the edges are rounded and smoothed to facilitate insertion.

As illustrated in FIG. 2, because of the limp and nonrigid nature of the silicone rubber material, a rigid wire 15 obdurator or introducer 16 having a set curvature is extended into the tube to enable the tube to be easily inserted into the trachea. The outer end 18 of the wire is looped or otherwise bent to provide a stop to limit the extension of the wire into the tube, and the inner end of 20 the wire terminates within the distal end of the tube. The inner end of the wire is also bent upon itself as indicated at 20 to prevent piercing of the tube. After insertion of the tube, the wire introducer 16 may be withdrawn to enable the tube to conform to the contour of 25 the individual trachea.

As illustrated herein, the proximal end of the tracheostomy tube 10 is provided with a cup-shaped adapter 22 molded integrally with the end of the tube. The adapter 22 is also composed of silicone rubber material and is 30 conveniently made with a 15-millimeter outside diameter to fit standard respiratory assistance equipment. The inside diameter of the adapter is constructed so as to provide a smooth surface for easy cleansing and so as to minimize "dead space."

As herein shown, the present tube is also provided with a circular flange 24 molded integrally with the tube. The flange is also composed of silicone rubber material and is herein shown as molded integrally with the adapter 22 and the tube. In order to reinforce the flange to prevent 40 tearing thereof, a nylon mesh or lace material 26 is molded into the flange as shown. The flange 24 is also provided with two or more openings 28 through which a tape or strap, not shown, may be threaded for tying the tube to the neck. The inert nature of the flange also makes pos- 45 sible direct suturing of the flange to the neck. It will be observed that the openings 28 through which the straps may be threaded or tied are located remote from the opening in the neck, that is, the tie is made above the tube fixation into the trachea rather than in horizontal alignment therewith so as to enable superior fitting to the neck.

It will be understood that the flange 24 and the tube 12 may vary in size. One size of flange as shown in FIG. 3 being molded around the holes, as shown, and also around the end of the tube 12 molded within the adapter 22. A smaller size flange shown in FIG. 4 is provided with two openings with the nylon mesh also molded around the openings and around the end of the tube. In practice, the 60 tube size may be imprinted on the adapter or on the flange as indicated at 25 in FIG. 5. It will be noted that the tube 12 is molded into the bottom of the adapter 22 at a slight angle relative to the base of the adapter of the flange to conform generally to the angle at which the tube is intro- 65 duced into the trachea through the neck.

From the description thus far it will be seen that the present surgical tube and particularly a tracheostomy tube comprises an inert silicone material which is non-toxic and non-reactive in use whereby to reduce to a minimum 70 mucous secretion by the trachea. It will also be seen that the relatively soft silicone material may be easily inserted by means of a rigid wire introducer extended through the tube and that the tube will readily conform to the patient's

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removal of the wire introducer. In practice, a cap, not shown, may be provided for cooperation with the adapter for plugging the tube off when it is no longer desirable that the patient breathe through the tube, but preferable that the patient breathe through the larynx. At such time, breathing is facilitated by fenestration of the tube as it curves out of the trachea. Another advantage of the present non-reactive silicone tube is that it need not be removed if the patient undergoes radiation therapy as the inert nature of the tube causes minimal scatter of X-rays and gamma rays.

As illustrated in FIG. 5, a modified form of the present invention is adapted for use as an endotracheal tube which is passed through the mouth or nose into the trachea during surgical procedures performed under general anesthesia in order to facilitate the anesthesia and make it safer. Such a tube is frequently used as an emergency maneuver to provide an airway in cases of acute respiratory or cardiac arrest. As herein shown, the endotracheal tube, indicated generally at 30, comprises a structure similar to that above described except that it eliminates the circular flange, and the tube is made considerably longer. As illustrated, the proximal end of the tube 32 is provided with an adapter 34 molded integrally therewith, and a wire introducer 36 is arranged within the tube to facilitate intubation of the relatively limp flexible silicone tubing either orally or intranasally. It will be apparent that the endotracheal tube affords all of the advantages above ascribed to the tracheostomy tube in that it comprises a biologically inert, non-toxic and non-reactive material and that it is capable of conforming to the shape of the individual trachea.

FIG. 6 illustrates a modified form of the present surgical tube wherein the tube 38 is provided at its proximal end with a flange 40 molded integrally therewith, the adapter being eliminated. The flange may be provided with openings 42 and with the nylon mesh 44 molded within the flange and around the openings and the end of the tube to provide reinforcement of the flange.

While the preferred embodiment of the invention has been herein illustrated and described, it will be understood that the invention may be embodied in other forms within the scope of the following claims.

Having thus described the invention, what is claimed is:

- 1. A surgical tube of the character described comprising a soft, flexible non-rigid tubing for insertion within the trachea, said tubing being capable of conforming to the contour of the patient's trachea, and rigid means removably inserted within the tube to assist in introducing the tube into the trachea, said rigid means comprising a stiff wire having a predetermined curvature, the inner end of said wire being bent upon itself and spaced from the distal end of the tube when fully inserted.
- 2. A surgical tube of the character described, comprisis provided with four openings 28, the nylon mesh 26 55 ing a soft, flexible non-rigid tubing for insertion within the trachea, said tubing being capable of conforming to the contour of the patient's trachea, rigid means removably inserted within the tube to assist in introducing the tube into the trachea, said introducing means being removable after the tube is introduced, and a flange molded integrally with the tube, said flange having openings therein through which straps may be threaded, said introducing means comprising a stiff wire having a predetermined curvature, the outer end of said wire being bent to provide a stop engaged with the proximal end of said tube when the wire is in its fully inserted position, and the inner end of said wire being bent back upon itself and terminating within and spaced from the distal end of said tube when in its fully inserted position.
- 3. A surgical tube of the character described comprising a soft, flexible non-rigid tubing for insertion within the trachea and which is capable of conforming to the contour of the patient's trachea, a cup-shaped adapter molded integrally with the proximal end of the tube adapttrachea and to the changes in posture of the patient after 75 ed for connection to respiratory assistance equipment, a

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flange molded integrally with the tube and removable means for introducing the relatively soft tubing into the trachea including a rigid member removably received within the tube, said rigid member comprising a stiff wire having a predetermined curvature, the distal end of said rigid member being bent back upon itself and being spaced inwardly from the distal end of said tube when in its fully inserted position.

4. A surgical tube of the character described comprising a soft, flexible inert silicone rubber tubing for insertion within the trachea and capable of conforming to the contour of the patent's trachea, a cup-shaped adapter molded integrally with the proximal end of the tube, a flange molded integrally with the tube and with the bottom of said adapter, said flange having openings therein through which straps may be threaded for tying around the patient's neck, and a nylon mesh reinforcement molded into said flange and around said openings.

5. A surgical tube of the character described comprising a soft, flexible non-rigid tubing for insertion within the trachea and which is capable of conforming to the contour of the patient's trachea, and a flange molded integrally with the tube, said flange having openings therein through which straps may be threaded, and a nylon mesh reinforcement molded into said flange and around said openings.

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DALTON L. TRULUCK, Primary Examiner.