STATIC TRACHEOSTOMY TUBE

This is a continuation of application Ser. No. 214,243, filed Dec. 8, 1980 and now U.S. Pat. No. 4,340,046.

BACKGROUND AND SUMMARY OF THE INVENTION

The invention relates to medical and surgical devices and in particular to medical and surgical devices used in conjunction with patient breathing problems. Specifically, the invention relates to tracheostomy, an operation for providing an airway for patients requiring mechanical assistance in breathing, and for conduction of anesthetic gas when the tube is placed in the trachea through the mouth or nose.

At present, the size (both calibre and length), the shape, and the overall construction of the standard tracheostomy tubes that are in use are somewhat traditional, being almost identical with that found illustrated in Mackensie's book which was published in 1880.

Initially, the tracheostomy was used almost exclusively to divert the air from an obstruction of the larynx, regardless of the cause. The tracheostomy tube was a rigid device and remains so today. With the advent of closed systems of ventilatory support used in anesthesia, an inflatable cuff was added to the device.

Recently, the tracheostomy has become critical to modern respiratory care and it is more than just an airway, it is the conduit of survival when attached to a mechanical ventilator. The effectiveness, however, is often negated by complications that are associated with the tracheostomy tubes that are in use at this time.

Among those patients requiring tracheostomy there are anatomical variations of the depth of the trachea within the neck. These differences are seen in the long neck and in the short heavy neck.

Because deviations from normal anatomical conditions are common, placing one of the currently available rigid tracheostomy tubes into a proper and a constant aligned position within the tracheal lumen becomes virtually impossible. The lack of flexibility in adjusting a tracheostomy tube to each individual trachea can require constant attention of the staff caring for these patients. Such conditions and problems can render the patentcy of the airway uncertain.

No less critical are the complications of prolonged tracheostomy. Such complications are tracheomalacia with progression to fistulae between the trachea and the esophagus, erosion of the anterior trachea and the innominate artery (often a fatal event), and later tracheal stenosis which sometimes necessitates surgical correction.

To solve the aforementioned problems and to make tracheostomy a safer modality of care, the present invention of a new tracheostomy tube has been developed. The present invention has four distinctive features. Those four distinctive features are a precision cuff fitted to each trachea, a flexible tube that will conform to any depth of the trachea within the neck, a self-locking clip that adjusts the tube securely to any neck regardless of the depth of the trachea, and a malleable but rigid obturator for ease of insertion.

The presision cuff is fitted to each trachea. The cuff of tracheostomy tubes of the prior art are not provided with this feature. Most tracheostomy tubes that are in use now and in the prior art have a soft cuff that, when inflated, assumes a fusiform shape presenting a narrow

surface in contact with the trachea mucosa. Any prolonged pressure above twenty-five torr increases the risk of tracheal necrosis.

A more or less convoluted type or fluted cuff, with constricting bands to limit distention to the specific size of each trachea, is provided by the present invention. The average tracheal lumen size in the adult male is 25 mm and in the female 23 mm, with a standard deviation of 4 mm each way.

Accurate size of each trachea is determined, before the opening is made in the trachea. This is done by placing a marker of known size on the neck and then obtaining a radiograph and measuring the film to determine the tracheal lumen size in relation to the known size of the radiographed marker. Thus, each cuff used is the precise size for each trachea as ascertained by this measurement procedure.

The advatage of the precision convoluted-like or fluted cuff is to equalize the pressure over a longer segment of the mucosa by the use of the constricting bands limiting the size in the cuff constrictions. This also insures uniform diameter and controlled expansion.

The convoluted-like or fluted cuff and the manner of assuring the precise size in relation to the patient's trachea, effects a more complete seal at a lower pressure on the tracheal mucosa. Each convolution-like roll or flute creates a seal and the plurality of seals increases the total sealing effectiveness, thus avoiding the problem of the fusiform configuration which is inherent in the single chamber cuff.

It is to be noted that the precision cuff of the present invention has been described as convolution-like or fluted on the exterior surface. Note that it is not the same as a common corrugated configuration. The plurality of adjoining adjacent circular flutes interface with each other at the sides. The flutes are somewhat like convolutions or partial toroids upon adjacent toroids, better described as being fluted. The aforementioned constriction bands each are fitted into the crease between each two adjoining and adjacent flutes.

In the prior art, some attempt has been made to change the aforementioned fusiform configuration to a convolution-like arrangement. Actually the configuration taught in the prior art is more like a corrugated configuration. The corrugated-like configuration of the prior art is not the same as the closely fluted surface of the present invention and it does not accomplish the same objective, particularly it is to be noted that no constricting bands between flutes is taught in the prior art.

Some spiral reinforcement has also been taught in the prior art, but this is not the same as the constricting circular-like bands taught in the present invention. In the present invention, when the precision cuff is inflated to a predetermined low pressure, the constricting bands limit the outside diameter to the predetermined precision fit in the trachea. There is no such predetermination or limitation in the prior art.

In the Static Tracheostomy Tube the tube design remains constant at 8 mm inside diameter and the cuff size becomes the variable in selecting the tracheostomy device to be used in a given patient. This is a unique and novel feature not provided in the prior art.

It is to be understood that the aforementioned 8 mm inside diameter for the static tracheostomy tube of this invention is the preferred embodimetn, but that it may be varied either way without departing from the scope or intent of this invention.