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A. H. RATHJEN

3,499,450

PEDIATRIC SIZE TRACHEAL TUBE

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2 Sheets-Sheet 1



Fig. 1

INVENTOR

ARTHUR H. RATHJEN

BY *Howard W. Korman*

ATTORNEY

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A. H. RATHJEN

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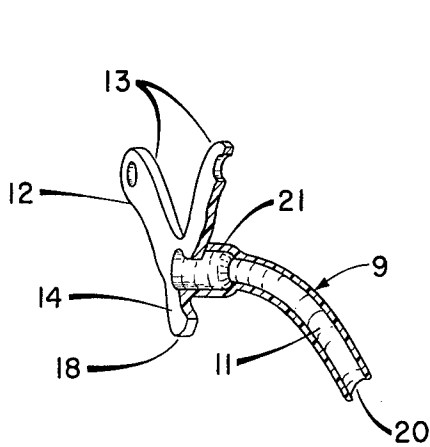


Fig. 2

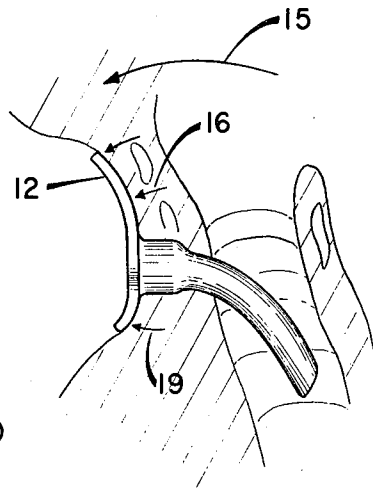


Fig. 4

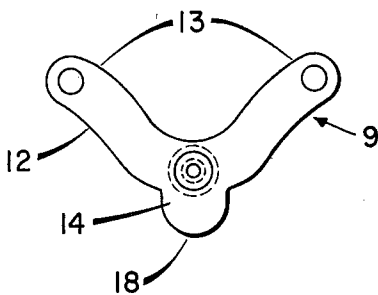
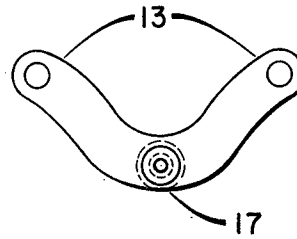


Fig. 3



PRIOR ART

Fig. 5

INVENTOR

ARTHUR H. RATHJEN

BY *Howard W. Hermann*
ATTORNEY

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PEDIATRIC SIZE TRACHEAL TUBE

Arthur H. Rathjen, Midland, Mich., assignor to Dow Corning Corporation, Midland, Mich., a corporation of Michigan

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5 Claims

ABSTRACT OF THE DISCLOSURE

An improved tracheostomy tube of the size suitable for use in infants. The tube is preferably made of radiopaque silicone rubber and includes a transversely extending flexible flange at its proximal end. The flange has upwardly extending arms suitable for securing the tube to the infant's neck and a downwardly extending tongue, or tracheotomy incision shield, suitable for holding the tube in the trachea of the infant regardless of the position or forward movement of the infant's head and for providing an inferior contact edge of the tube at a point away from the wound site on the neck of the infant.

BACKGROUND OF THE INVENTION

The present invention relates to the field of surgical appliances, and more particularly, to tracheal tubes, and the like, suitable for use in infants, and constitutes an improvement over the tube described by Aberdeen at pages 900-902 of the Proceedings of the Royal Society of Medicine, November 1965, vol. 58, No. 11.

The nose and throat sometimes are impaired in their normal respiratory functions. In such situations various techniques for cleaning the airways may be tried, e.g. aspiration and sedation or physiotherapy. When such techniques fail to clear the airways, it is quite common to perform a tracheostomy on the patient. That is, an incision is made in the patient's throat and a tracheal tube is inserted through the incision and into the trachea. This procedure allows air to pass into the trachea by bypassing the nose and throat in the respiratory process. Tracheal tubes and their uses in tracheostomies are well known for adult patients. Yet, while this surgical procedure is now commonly used on adult patients, serious problems are still met when it is needed and used on infant patients.

It is common for infants suffering from diseases such as congenital heart disease, esophageal atresia, diaphragmatic hernia, and congenital emphysema to need a tracheostomy for lung drainage or respiratory efficiency. Of the serious problems arising following a tracheostomy in an infant, two of them are directly related to the various tracheal tubes that previously have been used for this purpose. The first problem concerns the irritation, edema, tissue granulation and general trauma which the infant experiences at the cutaneous or external wound site as the result of contact with the tube. This problem is caused by the heretofore used tubes which are generally made of silver or plastic and are therefore rigid, heavy, and of a predetermined curvature, all of which causes the infant great discomfort and tissue irritation.

The second problem concerns the displacement of the tracheal tube out of the trachea of the infant. It is well known in the field of pediatrics, that unlike an adult, or even an adolescent child, an infant does not have a fully developed neck. Consequently, the head of an infant is positioned closely to its shoulder line and the incision made during the tracheostomy necessarily is located at a point near the base of the infant's neck.

A cord attached to the flange on the proximal end of a tube at the base of the infant's neck cannot be secured properly to the neck of the infant, since the diameter and

shape of its neck change with any head movement, thereby allowing the cord to slip freely to the base of the infant's neck. Thus, in order to properly secure the tube to the neck of the infant, the tubes heretofore used provide a pair of arms extending upwardly from the proximal end of the tube, to a height near the middle of the infant's neck, through which a cord can be tied around the infant's neck in a nearly horizontal plane. However, it is now well known to pediatric surgeons, that even tubes having these arms can be improperly secured to the infant's neck.

If the cord securing the tracheal tube is tied while the neck of the infant is extended in a normal straight position, two things can happen when the neck flexes into a more natural and comfortable position. Firstly, the trachea will sink forward, together with the tracheal tube, when the head of the infant moves forward. Thus, since the tube arms are secured to a small surface portion of the neck, while the inferior edge is not secured, the distal end of the tube may be dislodged from the lumen of the trachea by the forward movement of the infant's head. Secondly, since the cord is tied while the infant's neck is extended, the cord will become loose when the neck is flexed, because the diameter of the neck is reduced. Thus, the proximal end of the tube is pressed into the external wound site on the neck of the infant as the tube slides freely in and out of the lumen of the infant's trachea.

When the tube is in fact displaced, the distal tip of the tube frequently buries itself in the soft tissue of the infant's neck. Further, since the tube is not in place to hold open the incision, the soft tissues of the neck and the edges of the tracheal incision are sucked together on inspiration, thereby preventing air from entering the trachea, which is the major reason for performing the tracheostomy.

SUMMARY OF THE INVENTION

The primary object of the present invention, therefore, is to provide an improved pediatric size tracheal tube device which will be free from the aforementioned and other disadvantages of prior devices of this type.

More particularly, it is an object of the present invention to provide a pediatric size tracheal tube device which will cause a minimum of inflammation, skin irritation and discomfort to the infant, but which is inexpensively manufactured, and easily inserted.

Another object is to provide an improved pediatric size tracheal tube device which allows freedom of motion of the infant's head and neck without allowing the tube to become removed or dislodged from the trachea of the infant.

Still another object is to provide an improved pediatric size tracheal tube device which is both inert to the human body and radiopaque.

In accordance with these and other objects, there is provided by the present invention a pediatric size tracheal tube device made of silicone rubber which is preferably radiopaque. Silicone rubber is inert to the human body and being radiopaque allows the position of the tube in the neck to be checked by X-ray. Further, X-rays are absorbed by the radiopaque tube, thereby enabling the tube to be left in the trachea of the infant without fear of X-ray scattering or radiation burns when radiation therapy is needed. Also, the tube by the nature of silicone rubber is so flexible that any one shape will bend to fit a number of different curvatures. Thus, when the tube is in place in the trachea of the infant, the head and neck of the infant are virtually unrestricted, or unharmed by any unrestricted movements of the infant's head and neck.

Since silicone rubber is soft and relatively inexpensive, the distal end of the tube may be manufactured at any

suitable length, then cut to a desired length before insertion and the excess discarded. Accordingly, doctors and hospitals only need to stock one length of the tubes.

Finally, provision is made for a flexible flange at the proximal end of the tube providing upwardly extending arms for securing the tube to the infant's neck and a downwardly extending tongue, or tracheotomy incision shield, for holding the tube in the trachea of the infant regardless of the position or forward movement of the infant's head. That tongue further provides the tube with an inferior contact edge which is at a point away from the wound site on the neck of the infant. Further, the arms and the tongue are capable of flexing independently of each other, thereby allowing the flange to adapt and conform to the surface of the infant's neck without distortion of the flange.

BRIEF DESCRIPTION OF THE DRAWING

Other objects and many more attendant advantages will become obvious to those skilled in the art by reading the following detailed description in connection with the accompanying drawings wherein:

FIG. 1 is a view in perspective showing the tracheal tube device of the present invention in place on the throat of an infant patient;

FIG. 2 is a view in perspective, partly in cross-section, of the device shown in FIG. 1;

FIG. 3 is an end view in elevation of the device shown in FIG. 1;

FIG. 4 is a side view in elevation showing the device shown in FIG. 1 in place in the throat of an infant patient; and

FIGURE 5 is an end view in elevation of the flange portion of a prior art device.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings wherein like reference numerals designate like or corresponding parts throughout the figures thereof, there is shown in FIG. 1, a pediatric size tracheal tube device, shown generally as 9, made of radiopaque silicone rubber material which is inserted into an incision through the patient's throat and into the trachea. The device 9 may be secured in place by means of a cord or neckband 10 connected to a flange 12, which is formed on the proximal end portion of the tube 11 of the device 9, as may be seen in greater detail in FIG. 2, and is adapted to rest against the throat of the infant patient.

As may be seen in FIG. 2, the flange 12 extends transversely from the tube 11 at its proximal end and comprises two upwardly extending arms 13 and a downwardly extending tongue 14, best seen in FIG. 3. The arms 13 are adapted to allow the device 9 to be secured to the neck of the infant patient by means of a tiecord or neckband. As has been described hereinabove, the neck of an infant is not fully developed and is very short relative to the length of its head and entire body. Consequently, the infant's head is only very slightly elevated above its shoulders and the incision into the trachea must be made at the base of the neck of the infant. In order that the cord may be tied securely around the neck of the infant, the arms 13 of the flange 12 extend upward to a height near the middle of the neck of the infant, as was previously explained.

The tongue 14 of the transverse flange 12 extends downwardly and serves to provide an inferior contact point for the device at a point away from the wound site on the neck of the infant and further serves as a means for holding the tube in the trachea of the infant regardless of the forward movements of the head and neck of the infant.

Because of the relatively short neck of the infant, any motion of the infant's head is quickly transmitted to and followed by the neck of the infant. Thus, as has been

described hereinabove, and as is illustrated in FIG. 4, when the head of the infant rotates forward as illustrated by the arrow 15, the neck also rotates forward causing a change in the diameter of the neck and a slackening of the cord or neckband 10. Such a slackening is a practical necessity, since the cord or neckband must be fastened when the neck of the infant is in a straight or normal position to avoid any possibility of choking or restricting the neck movements of the infant. This possibility is created by fastening the cord or neckband when the head of the infant is rotated forward and the tube is in place in the trachea of the infant. Because of this slackness of the cord or neckband 10, a rotational force illustrated by the arrow 16 is exerted upon the arms 13 of the device from the forward movement of the head, neck, and trachea. Consequently, the tube tends to dislodge from the trachea and rotate forwardly about the inferior contact edge of the device.

As may be seen in FIG. 5, this inferior contact edge 17 of the prior art devices is at a point very near the wound site on the neck of the infant. Accordingly, the above-mentioned rotation causes the edge 17 to be pressed into the wound site, thereby frequently causing serious skin irritation and inflammation to the neck of the infant around the inferior edge of the tube. In the device of the present invention, the inferior contact edge 18 of the tongue 14 is at a point sufficiently removed from the wound site on the neck of the infant to allow the tongue 14 to be pressed against the neck of the infant without being pressed into the wound site, and thus the serious skin irritation and inflammation caused by the prior art devices is avoided.

In the devices of the prior art, once the rotation forward of the arms 13 begins, there is no correcting or offsetting force to keep the tube in the trachea of the infant. Since an infant has neither the intellect nor the dexterity to reinsert the tube into its own trachea, once the tube is dislodged from the trachea the infant can be without air and subject to serious harm from the distal end of the tube, until a nurse comes to its rescue.

In the device of the present invention, once the rotation forward of the arms 13 begins, as is illustrated in FIG. 4 by the arrow 16, the tongue 14 of the flange 12 is forced against the neck of the infant. Likewise, an equal and opposite force is exerted on the tongue 14 by the neck. Then due to the flexibility of the silicone rubber, that opposite force, as is illustrated in FIG. 4 by the arrow 19, tends to correct or offset the force illustrated by arrow 16, thereby providing a means for securing the tracheal tube device 11 in the trachea of the infant, regardless of the position or forward movement of the infant's head.

It should be particularly noted that the tongue 14 is not merely a necessary inferior portion of a flange designed to prevent the tube from being totally inserted into the infant. The flanges of the prior art devices were suitable for that purpose. The tongue 14 serves at least the two separate functions just described hereinabove and should be viewed as a distinct portion of the flange having maximum width and length dimensions substantially less than the respective maximum width and length dimensions of the total flange. The tongue 14 is flexible and can be flexed independently of the remainder of the flange 12. This flexibility allows the flange to conform and adapt to the surface of the neck of the infant to a much greater degree than would be possible with an inflexible flange, or a flexible flange consisting of a large oval or variations thereof. That is, any flexing in one area of a large continuous oval-shaped flange, or a variation thereof, is transmitted to the other areas of the flange, since each such area is connected and dependent upon the other. Furthermore, since a single oval-shaped flange is normally bent in one direction to

conform to the roundness of the patient's neck, this curvature offers considerable resistance to bending in other directions caused by movement of the patient's head, thereby rendering the flange at least semirigid even though made of flexible material. Thus, such prior art flanges do not freely conform to the surface of the infant's neck and can become so distorted as to occlude the orifice of the tube at its proximal end.

Further, the flange of the present invention allows the doctor to make a visual inspection of the wound site on the infant's neck for exudations and skin irritation. A large oval-shaped flexible flange would completely hide the wound site and require removal of the tube when an inspection of the wound site was to be made.

In order to allow the pediatric size tracheal tube device 11 to be easily inserted through the external and internal incisions into the trachea, the distal end 20 of the device can be cut or formed at some acute angle to the axis or center line of the tube. Generally, an obturator is used for the insertion of a tracheal tube in adults, but because of the smallness of the trachea of an infant, a tube which can be inserted without the use of an obturator is preferred.

To allow the pediatric size tracheal tube device 11 to be easily attached to other medical devices, the flexible tube has a radial enlargement 21 at its proximal end which is adapted to receive a fitting connector. This enlargement is best seen in FIG. 2.

In one specific embodiment of the present invention, the entire pediatric size tracheal tube device was made of radiopaque silicone rubber. The outerwidth of the transverse flange was $2\frac{3}{16}$ inches at the tip of the outwardly extending arms and the height of the transverse flange from the bottom of the tongue to the tip of an arm was $1\frac{1}{4}$ inches. The horizontal distance from the front of the transverse flange to the tip of the distal end of the tube was $1\frac{3}{8}$ inches and the flexible tube had an outer diameter of 0.215 inch and an inner diameter of 0.118 inch. The radial enlargement at the proximal end of the tube had a length and diameter of $\frac{3}{8}$ of an inch. The thickness of the transverse flange was $\frac{3}{32}$ of an inch while each arm of the flange had a width of $\frac{3}{8}$ of an inch and the tongue had a diameter of $1\frac{7}{32}$ of an inch.

It will be obvious to those skilled in the art that the pediatric size tracheal tube device of the present invention could be made of other flexible materials than radiopaque silicone rubber, for example, non-radiopaque silicone rubber or polyvinylchloride. Other modifications and

variations of the above-described embodiment of the invention will also be obvious to those skilled in the art. Accordingly, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

That which is claimed is:

1. A pediatric size tracheal device comprising;
a flexible tube having a predetermined curvature therein and adapted for insertion into the trachea of an infant user through an incision in said infant's throat; and

a transversely extending flexible flange at the proximal end of said tube, which flange is adapted to bear against the skin surrounding said incision in said infant's throat, said flange having two arms extending laterally upwardly from the axis of said proximal end of said tube when the tube is in place in a patient, said arms having means for receiving a neck-band for securing said device to the neck of said infant, and a tongue extending downwardly when the tube is in place, from said proximal end of said tube for holding said flexible tube in the trachea of said infant when the head of said infant is bent forward from a normal straight position,

which arms and tongue are capable of flexing independently of each other to allow said flange to adapt and conform to the surface of said infant's neck without allowing said tube to be dislodged from the trachea of said infant.

2. A pediatric size tracheal device as described in claim 1 made of silicone rubber.

3. A pediatric size tracheal device as described in claim 2 wherein said silicone rubber is radiopaque.

4. A pediatric size tracheal device as defined in claim 1 wherein said tube has a distal end forming an acute angle with respect to the center line or axis of said tube.

5. A pediatric size tracheal device as defined in claim 1 wherein said tube has a radial enlargement at its proximal end adapted to receive a fitting connector.

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