

[54] T-SHAPED TRACHEAL STENT

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[58] Field of Search 128/1 R, 303 R, 351

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[57] ABSTRACT

A T-shaped stent for use following surgical reconstruction of the cervical trachea and surgical correction of tracheal and subglottic stenosis. The stent comprises a tubular intraluminal portion and a tubular tracheotomy portion connected thereto between its ends and provided with a removable plug. The tubular portions are of a resiliently yieldable stock enabling the ends of the intraluminal portion to be folded together or against the tracheotomy portion for insertion and removal through a tracheotomy orifice. The intraluminal portion provides internal support for the repaired part of the trachea and the cross sectional area of the tracheotomy portion increases at its junction with the intraluminal portion to an axial extent such that external tapering surfaces are provided for entry into the posterior end of the orifice to provide molding support for and overcorrecting the inferior margin of adjacent portions of the anterior tracheal wall.

2 Claims, 7 Drawing Figures

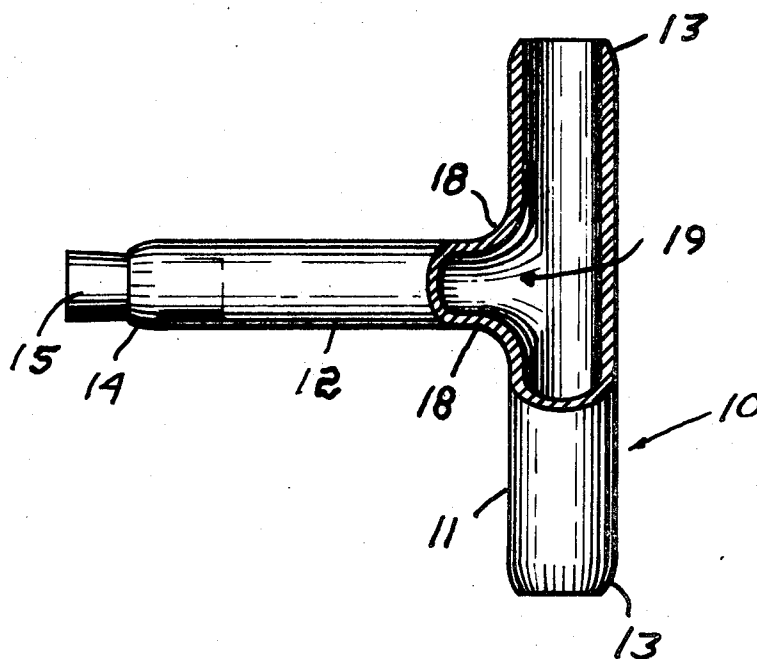


FIG. 1

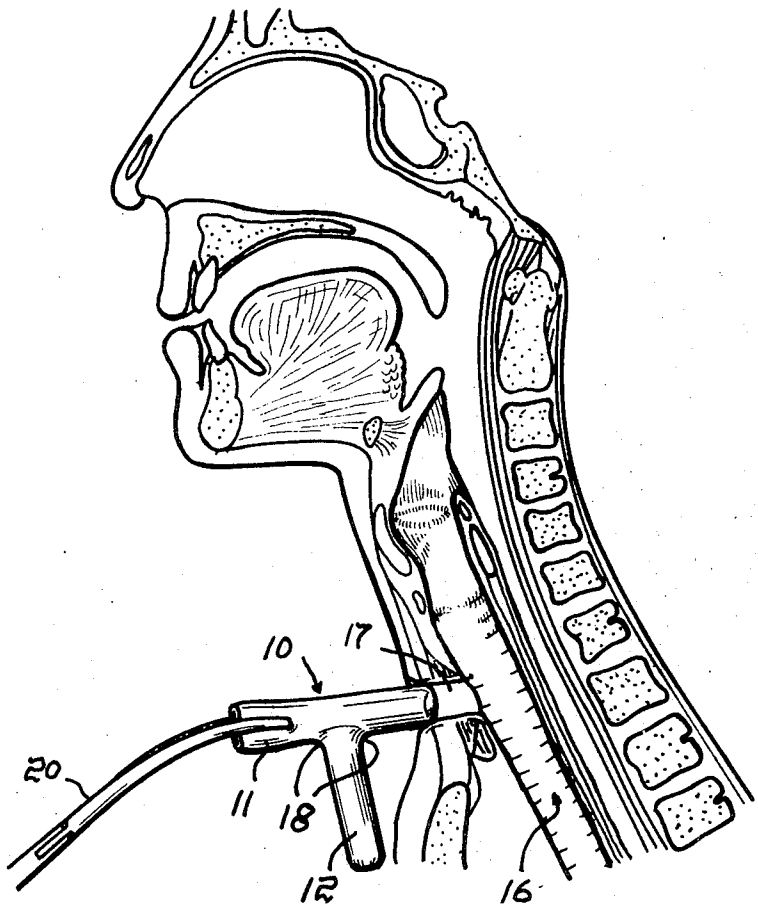
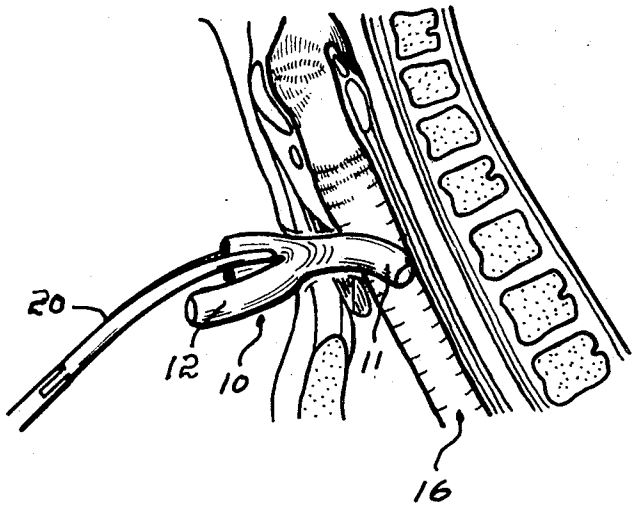


FIG. 2



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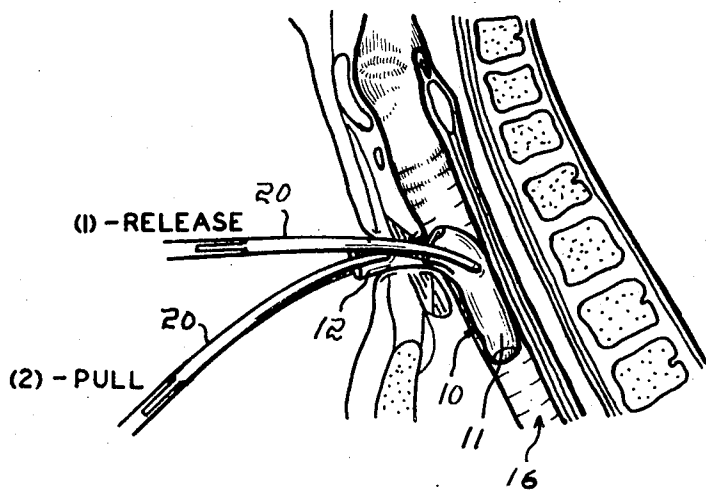


FIG. 3

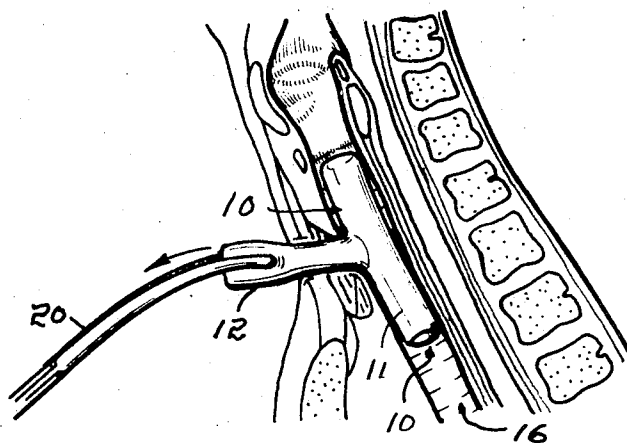


FIG. 4

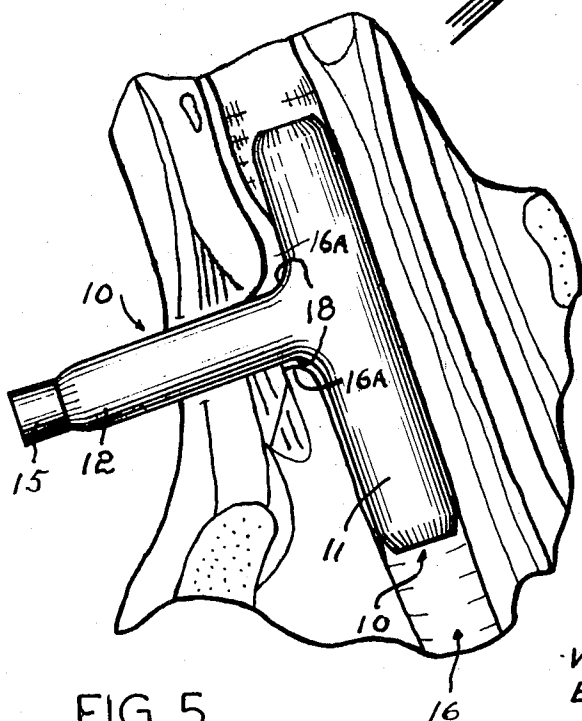


FIG. 5

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FIG. 6

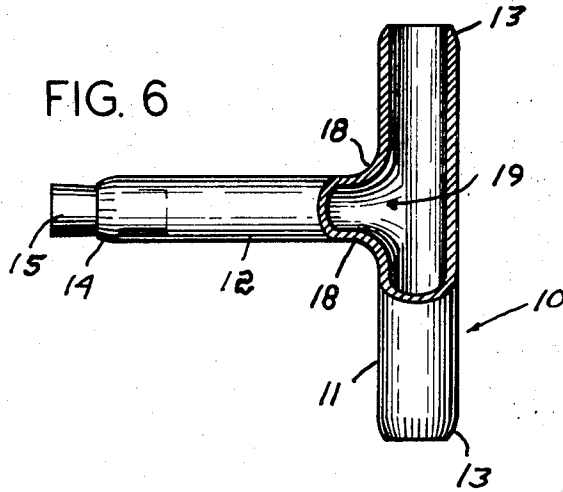
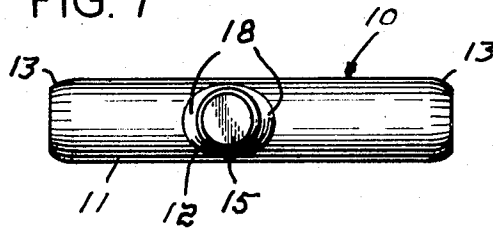


FIG. 7



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T-SHAPED TRACHEAL STENT

The present invention relates to T-shaped tracheal stents and a scar tissue controlling method for use following surgical reconstruction of the cervical portion of the trachea and surgical correction of tracheal and subglottic stenosis.

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We developed a T-shaped stent for insertion into the trachea in the zone where it was reconstructed or corrected, the stent consisting of an intraluminal tube and a tracheotomy tube joined thereto between its ends. Both tubes were of a soft flexible material, silicone rubber in practice, that had sufficient resiliency to enable the stent to be readily deformed by folding one of its intraluminal portions against the tracheotomy portion or with both intraluminal portions folded together for entry or removal through the tracheotomy and also to conform, when inserted, to normal contours of the trachea and yet provide good support therefor.

These stents have been used with success in a substantial number of operations. While their use clearly promotes healing, it has been noted that after the tracheal orifice has healed, scar tissue will often be found that projects into the tracheal passage to a troublesome extent.

The principal objective of the invention is to provide a T-shaped stent possessed of the virtues of the one whose construction was just summarized and that will prevent the resulting scar tissue from being a troublesome problem. In accordance with the invention, this objective is attained by providing that the tracheotomy tube has, at its junction with the intraluminal tube, a cross sectional area that so increases towards the intraluminal tube as to provide external surfaces that taper through a predetermined axial zone thus to provide molding surfaces for entry into the posterior end of the tracheotomy to overcorrect the inferior margins of adjacent portions of the anterior tracheal wall and thereby prevent objectionable scar tissue from ultimately projecting into the tracheal passage.

A particular objective of the invention is to have such molding surfaces disposed towards the opposite ends of the intraluminal portion.

Yet another objective of the invention is to provide that the junction between the two tubular portions provides internal surfaces that are flared towards the ends of the intraluminal portions thus to facilitate the introduction of a catheter into an intraluminal portion through the tracheotomy portions if its use becomes necessary.

Another objective of the invention is to provide a method by which scar tissue at the posterior end of a tracheal orifice can be prevented from being an interference within the trachea, an objective attained by overconnecting the inferior layer of portions of the anterior tracheal wall adjacent the orifice with a molding tracheotomy support.

In the accompanying drawings, there is shown an embodiment of the invention illustrative of these and other of its objectives, novel features, and advantages. In the drawings:

FIG. 1 is a section taken vertically through the trachea illustrating the introduction of one end of the intraluminal portion of the stent into the surgically established tracheal orifice;

FIG. 2 is a like view illustrating the entered end of the stent being inserted downwardly into the trachea;

FIG. 3 is a view similar to FIG. 2 illustrating the introduction of the other end of the intraluminal portion into the trachea to extend upwardly therein;

FIG. 4 is a like view illustrating the final step in positioning the installed stent;

FIG. 5 is another like view showing the installed stent with a plug inserted in the exposed end of its tracheotomy portion;

FIG. 6 is a side elevation of a stent in accordance with the invention; and

FIG. 7 is a view of the stent as seen from the free end of the tracheotomy portion.

A T-shaped tracheal stent in accordance with the invention is generally indicated at 10 and, as may best be seen in FIGS. 6 and 7, it comprises an intraluminal portion 11 and a tubular tracheotomy portion 12 of a somewhat smaller diameter and joined to the portion 11 between the ends thereof with the lower portion slightly longer than the upper portion. The portion 11 has both of its ends inwardly curved as at 13 while the outer or free end of the tracheotomy portion 12 is inwardly curved as at 14 and is closed by a stopper or plug 15. The portions 11 and 12 are of a soft, resiliently yieldable material such as silicone rubber that is relatively inert. In practice, the wall thickness of the tubular portions 11 and 12 is in the neighborhood of 1.5 mil and their outside diameters vary as the stents are made available to meet requirements ranging from male adults to infants as the intraluminal portions must fit the trachea 16 snugly to provide support therefor. By way of example, the outside diameter of the intraluminal portion for pediatric uses is 8 mm, that for adolescents 10 mm, while the adult sizes are 12 mm, 14 mm, and 16 mm. Either end of the portion 11 may be trimmed if necessary. The stent 10, as thus far described is substantially that previously referred to as having been successfully used for some time.

In accordance with the invention, the cross sectional area of the tracheotomy tube 12 is increased to have a cross sectional area greater than that of the tracheotomy orifice through an appreciable axial zone where it joins the intraluminal tube 11 to provide tapering surfaces for entry into the posterior end of the tracheotomy orifice 17 and provide molding support therefor. As shown in the drawings, the increased cross sectional area is such that the molding surfaces are in the form of shoulders 18, each disposed toward an end of the intraluminal portion 11, the molding shoulders being for use in overcorrecting the inferior margin of the anterior tracheal wall adjacent the tracheotomy orifice 17. In practice, the shoulders are arcuate with the radius varying with the diameter of the intraluminal portion in the neighborhood of five thirty-seconds of an inch with the 12 mm intraluminal tube. This construction provides another advantageous feature since it results in the junction between the tubes being in the form of a mouth 19, see FIG. 6, flared towards the ends of the intraluminal portion 11 to enable catheter insertion to be more easily effected than is the case with a substantially right angular junction.

Such a stent is installed through the tracheotomy orifice 17 following surgical reconstruction of the cervical portion of the trachea 16 or correction of tracheal and subglottic stenosis. Reference is made to FIGS. 1 - 4 to show the manner in which the stent 10 is installed.

A stent 10 is selected for use having the diameter of its intraluminal portion 11 such as to provide a supporting fit for the patient's trachea when inserted therein. As shown in FIG. 1, the end of the stent portion 11 that is to extend upwardly in the trachea is gripped by forceps 20 by which the other end may be entered into and pushed through the tracheotomy orifice 17 and downwardly into the trachea 16. As will be apparent from FIG. 2, the inwardly curved end 13 facilitates such entry.

In FIG. 3, it will be noted that as the forceps-held end of the portion 11 is forced through the tracheotomy orifice, the stent collapses at the junction of the portions 11 and 12. The stent portion 11 is then released and the outer end of the tubular portion 12 is then gripped by the forceps with an outward pull moving the intraluminal portion into a position supporting the cervical portion of the trachea and the shoulders 18 into molding contact with the posterior end of the tracheotomy to overcorrect the inferior margin 16A of the reconstructed or reconstituted anterior tracheal wall, see FIG. 5, thus to prevent any resulting scar tissue from projecting into the trachea when the tracheotomy has healed. By way of example, anterior tracheal stenosis is a collapse or buckling in of the anterior tracheal wall requiring surgery to enable the tracheal rings to be repositioned or the anterior wall supported by the sternohyoid muscles. In either case, scar tissue is present that must be removed and a stent in accordance with the invention prevents recurrence of scar tissue formation and thus prevents recurrent stenosis.

We claim:

1. A T-shaped stent for insertion through a tracheotomy orifice into a trachea following surgical reconstruction of the cervical portion thereof, and surgical correction of tracheal and subglottic stenosis, said stent comprising an intraluminal tubular portion open at both ends and whose outside diameter is such as to provide a snugly fitting internal support for the reconstructed or corrected part of the trachea, and an integral tracheotomy tubular portion of a diameter less than that of the intraluminal portion and disposed at an angle thereto intermediate the ends thereof and in communication with the interior of said intraluminal portion, and said tracheotomy portion being of a length to project outwardly through a tracheotomy orifice after the disposition of the intraluminal portion within a trachea through said orifice, the junction of the two portions being ovate with its long axis lengthwise of the intraluminal portion and providing external flared shoulders lengthwise of both portions and of substantial axial such as to provide, when the stent is in place, molding surfaces for entry into the interior end of the tracheotomy orifice in molding support of the margin of adjacent margins of the tracheal wall and operable to overcorrect said margins thereby to avoid the protrusion of any resulting scar tissue into the trachea, said stent being of resiliently yieldable stock enabling one end of the intraluminal portion to be folded against the tracheotomy portion or both ends thereof to be folded together for insertion and removal through said orifice, and means releasably closing the exposed end of the tracheotomy portion.

2. The T-shaped stent of claim 1 in which the external molding surfaces of the tracheotomy portion are arcuate with their radius varying with the diameter of the intraluminal portion.

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