

Tracheal & Thoracic T-Tubes

Patents Applied

Single use only

These instructions are for professional reference prior to surgical procedures and should be read carefully before using the products.

Postoperative Nursing Manual and Home Care Instructions are also included. If the product were to be re-used, there would be a risk of cross contamination.

Description and Function

Hood Tracheal and Thoracic T-Tubes enable surgical management of tracheal and subglottic stenosis and the reconstruction of cervical and thoracic trachea. These patented products are designed to maintain patency of the tracheal airway and to provide respiration through the larynx. They allow normal humidification and phonation, and provide support in the management of acute tracheal injury. The T-Tubes, made of implant-grade silicone material, will not harden and are non-reactive and non-irritating to ensure patient comfort. The prostheses are also available in implant-grade radiopaque silicone. **Hood Radiopaque T-Tubes** meet all the indications for use as referred to in the description and function of Tracheal and Thoracic T-Tubes.

Tracheal T-Tubes, with standard and long limbs, serve as both a tracheostomy tube and a tracheal stent. **Thoracic T-Tubes** are designed with extra-long limbs to bypass and stent a tracheal stenosis between the thoracic inlet and the carina.

The extraluminal limb of the **Pediatric T-Tube** has an enlarged tip. This allows for easier handling of the plug, improved visualization, and maintenance by medical personnel. The T-Tube plug, which is inserted in the external, horizontal limb and secured by a slight twist, is held in place by friction. The plug stays in place in order to allow for normal respiration and phonation.

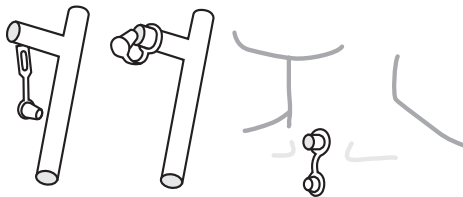
Hood Tracheal T-Tubes are designed with the stopper plug attached to the extraluminal limb to ensure the most secure placement and offer extra convenience in daily cleaning, maintenance, and training. Initially, the single-piece construction eliminates misplacement of plugs while medical personnel and patients develop routine breathing and maintenance.

The Ring Flanged Plug can be detached and threaded over the extraluminal limb to fit snugly against the patient's tracheostoma, adding long-term security by reducing excessive movement of the T-Tube. The smooth extraluminal stem provides comfort for a wide range of patients, thin and obese, and eliminates complications in cases of edema.

The intraluminal portion of the tube is sufficiently dense and thick to support reconstituted or stenotic trachea, and sufficiently soft to preclude injury to mucosa or supporting structure of the trachea.

The portion of the tube which projects from the tracheostomy orifice is smaller in diameter than the intraluminal portion, with a substantial internal radius and outside diameter at the junction. The internal radius aids in the insertion of a catheter for suctioning and cleaning, while the outside diameter provides molding support for the reconstructed trachea. The external portion of the tube can be tilted to insert suction catheters inferiorly or superiorly.

The flexible, non-irritating material causes little tissue reaction and prevents hardening of the T-Tube even after prolonged contact with body temperatures and secretions. Ends are tapered so asynchronous motion in between the tube and tracheal mucosa will not cause injury. Mucus and crusts do not readily adhere to its rounded surfaces when the side arm is kept plugged.



Indications

The T-Tube serves as both a tracheal stent and tracheostomy tube, and can be used under the following circumstances:

- In tracheal stenosis, when the cervical or thoracic airway cannot be repaired, or as a substitute for the cervical trachea when it cannot be reconstituted or reconstructed.
- As a support following reconstituted or reconstructed cervical trachea.
- Prior to reconstruction to maintain an adequate airway while waiting for inflammation to subside.
- As a palliative measure for patients with unresectable carcinoma of the trachea.
- When there is not enough trachea left to repair because of prior surgery.
- With segmental resection and anastomosis.
- When the patient is medically not a candidate for surgery.

Contraindications

The T-Tube cannot be used to prevent aspiration or used as a conduit for positive ventilation.

It should be predetermined if the proximal limb will rest on the vocal cords.

Sterilization

Preferred Sterilization Procedure

Follow Instructions Carefully

The following sterilization procedures have been applicable to other Hood silicone devices and may be applied to the Tracheal & Thoracic T-Tubes.

All Hood products should not be removed from the package until immediately prior to sterilization since the material will attract dust particles to its surface. Products should be thoroughly rinsed before sterilization.

CAUTION: Products are for single patient use only and should not be resterilized.

Pre-sterilization instructions:

1. Remove product from package. Rinse using sterile water and pat dry with a sterile towel.
2. When sterilizing any T-Tube, unplug stopper before cleaning and sterilizing.

Standard gravity sterilizer:

1. Follow pre-sterilization instructions, above.
2. 30 minutes at 121°C –132°C at 100kPa.

It is not recommended that the T-Tubes be resterilized. The product may be stored, in the product box, indefinitely until surgery is scheduled and it becomes necessary to sterilize the device.

NOTE: Additional attention is necessary in the maintenance of small diameter T-Tubes. Correct placement and internal cleanliness should be closely monitored.

Operative Procedure

Insertion and Removal

Management of complex laryngeal, tracheal, and laryngotracheal stenosis has been extensively described in medical reports. Whether placed by external (open intraoperative) or by endoscopic techniques, the T-Tube has been effectively utilized in many of these problems. It is important to note that when handling or inserting a T-Tube do not use any sharp edged instruments.

Although not usually emphasized, the placement maintenance and removal or replacement of the T-Tube can be time consuming and difficult. The intraoperative placement at the conclusion of resection reanastomosis is achieved by careful positioning of the T-Tube to support the freshly reconstructed site; the horizontal arm is ideally placed away from the anastomosis (to minimize risk of healing delay).

The properly placed T-Tube can be left in place for 29 days to allow for healing and stabilization of the repair. T-Tube maintenance is essential to prevent the accumulation of secretions which can **accrete**, **desiccate**, and produce **lumen obstruction**.

Removal of the T-Tube is best performed under anesthesia so that:

1. The airway patency can be evaluated endoscopically.
2. Undue patient discomfort and risk are avoided.
3. Granulations, sutures and other impediments can be removed.

The actual length of time that the device is left in place will depend upon the surgeon's judgement. Removal after a maximum of 29 days is recommended.

Endoscopic Placement of T-Tube

The endoscopic placement of the T-Tube can be time consuming and difficult. Ideally, the T-Tube section should consider the lumen caliber and desirable length to provide serviceable airway through the stenotic segment(s). **The correct T-Tube diameter should be determined so as to allow for little or no horizontal movement.** In cases of subglottic stenosis the T-Tube is preferably trimmed so that it does not extend above the free border of the vocal cords.

The tube is accurately tailored to suit the precise dimensional requirements. The placement of the T-Tube is preceded by dilation using the Brass Jackson dilators (**Fig. 1**). On the basis of the largest dilators passed, a series of rubber (Tucker) esophageal dilators is serially connected. These dilators or a section of umbilical tape¹ (**Fig. 2**) is introduced through the tracheostoma and passed retrograde through the larynx (**Fig. 3**), grasped through the laryngoscope, and drawn out through the mouth (**Fig. 4**).

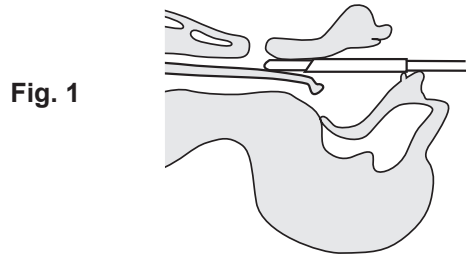


Fig. 1

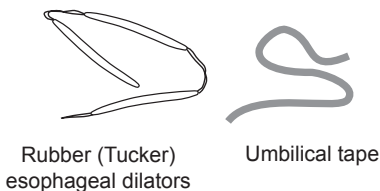


Fig. 2

Rubber (Tucker)
esophageal dilators

Umbilical tape

Fig. 3

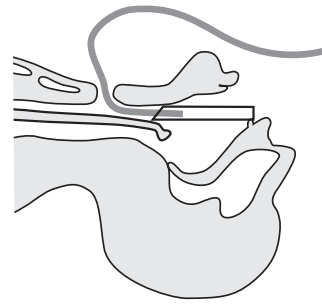


Fig. 4

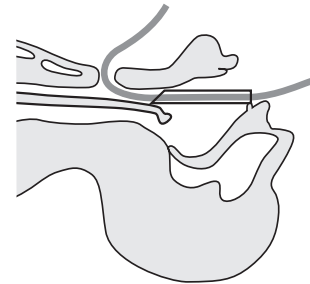
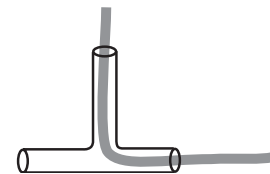


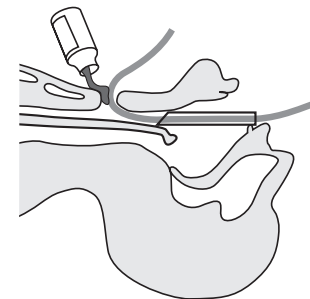
Fig. 5



The T-Tube is correctly oriented, snugly fitted over the final dilator, if the dilators are used, and the trailing end of the dilators or tape is brought out through the horizontal arm of the T-Tube (**Fig. 5**).

The skin at the tracheostoma is lubricated with a water soluble jelly (**Fig. 6**) to facilitate passage.

Fig. 6



Steady traction through the upper dilators advances the tube until the trailing (lower) end is properly positioned in the distal trachea (**Fig. 7**).

Fig. 7

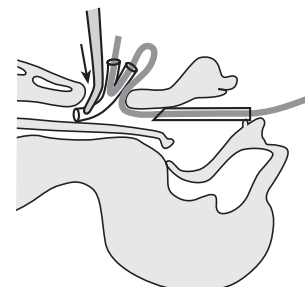
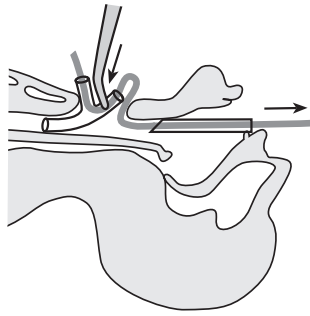


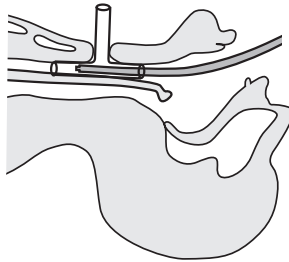
Fig. 8



The dilator is disengaged (**Fig. 8**) and the T-Tube position checked for accurate level of placement. Umbilical tape (manufactured by DeRoyal) could also be used to position the tube as illustrated in Figures 3, 4, 5, 6, 7, and 8.

An endoscopic examination verifies that the T-Tube is correctly positioned without buckling and the patient is permitted to awaken (**Fig. 9**). Improper length of the T-Tube is preferably corrected as soon as recognized.

Fig. 9



The use of the Brass Jackson dilators has been ideal in that the stenotic segments are atraumatically dilated and the T-Tube drawn into the stenotic segment for support. Umbilical tape has been adapted in more recent procedures.

The horizontal arm is plugged and the patient's airway status evaluated. When a larger size T-Tube is desirable, the endoscopic procedure is repeated after several weeks and the larger caliber T-Tube inserted. When the final lumen size has been achieved, the patient is evaluated for final T-Tube removal which is performed under anesthesia to permit the endoscopic evaluation. **Before removing the T-Tube, suction completely and confirm that there is no evidence of excess deposits on the interior of the T-Tube.**

Postoperative Management

Refer to the Postoperative Nursing Manual and Home Care Instructions provided.

Tracheal T-Tubes with Stoma Rings

The Hood T-Tubes with stoma rings enable surgical management of tracheal and subglottic stenosis with the added feature of stoma rings on the horizontal limb. These rings provide additional support to minimize the instance of stent migration.

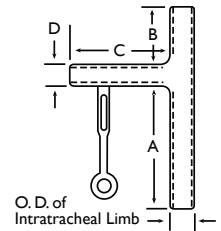
The devices are designed to maintain patency of the tracheal airway and to provide respiration through the larynx. They allow normal humidification and phonation, and provide support in the management of the acute tracheal injury. The T-Tubes, made of implant-grade silicone material, will not harden and are non-reactive and non-irritating to ensure patient comfort. The devices are also available in implant-grade radiopaque silicone. Hood Radiopaque T-Tubes meet all the indications of use as referred to in the description and function of Tracheal and Thoracic T-Tubes. Tracheal T-Tubes, with standard and long limbs, serve as both a tracheostomy tube and tracheal stent.

Ordering Information

Shaded areas indicate pediatric sizes.

Refer to this drawing to determine size.

Size = O.D.(mm) of intratracheal limb



Long Tracheal T-Tubes*

Code No.	O.D. Size	A	B	C	D
LT-506-S	6	34	7	48	5
LT-507-S	7	40	8	48	6
LT-508-S	8	58	12	39	6.5
LT-509-S	9	63	14	43	8
LT-510-S	10	63	17	50	8
LT-511-S	11	62	17	55	9
LT-512-S	12	72	20	59	11
LT-513-S	13	72	20	68	11
LT-514-S	14	72	23	66	11
LT-516-S	16	81	24	70	12
LT-518-S	18	81	24	55	14

*Also available in Radiopaque (RLT-XX-S)

Thoracic T-Tubes*

(extra-long tubes with free standing plug)

These tubes are designed to be cut to desired lengths but care must be taken to trim and smooth the cut edges. Custom-cut lengths are available upon request.

Code No.	O.D. Size	A	B	C	D
ELT-06-S	6	40	30	48	5
ELT-07-S	7	40	30	48	6
ELT-08-S	8	60	49	40	6.5
ELT-10-S	10	68	48	41	8
ELT-12-S	12	98	39	64	11
ELT-14-S	14	97	48	74	11

*Also available in Radiopaque sizes (ELT-08-S through ELT-14-S ONLY)

Pediatric & Standard Tracheal T-Tubes*

Code No.	O.D. Size	A	B	C	D
ST-506-S	6	10	6	48	5
ST-507-S	7	13	9	48	6
ST-508-S	8	16	12	36	6
ST-509-S	9	19	15	40	8
ST-510-S	10	23	17	44	8
ST-511-S	11	27	20	50	9
ST-512-S	12	31	21	55	11
ST-513-S	13	31	22	60	11
ST-514-S	14	32	23	64	11
ST-515-S	15	34	24	64	11
ST-516-S	16	31	23	63	12

*Also available in Radiopaque (RST-XX-S)

Ringed T-Tubes

Extra plugs available upon request.

Code No.	O.D. Size	A	B	C	D
RTR-11-S	11	93	39	60	10
RTR-12-S	12	93	39	60	11
RTR-13-S	13	93	39	60	11
RTR-14-S	14	93	39	60	12
RTR-15-S	15	93	39	60	11

Angled Stem T-Tubes

Code No.	O.D. Size	A	B	C	D
AST-10-S	10	23	20	38	8.0
AST-12-S	12	32	26	50	9.5
AST-14-S	14	34	32	57	11.0

Angled Stem T-Tubes/Rings

Code No.	O.D. Size	A	B	C	D
ASTR-08-S	8	42	45	45	8.0
ASTR-10-S	10	39	39	52	8.5
ASTR-12-S	12	42	42	49	11.0
ASTR-14-S	14	47	47	51	12.0

Reducing Diameter T-Tube

Code No.	O.D. Size	A	B	C	D
HTT-11-8-S	11	38	27	53	11
HTT-12-10-S	12	43	60	53	11
HTT-13-10-S	13	31	39	52	13
HTT-14-12-S	14	25	12	49	14
HTT-16-12-S	16	15	11	49	16

Reducing Diameter T-Tubes with Rings

Code No.	O.D. Size	A	B	C	D
HTTR-10-8-S	10	78	78	70	8
HTTR-13-10-S	13	78	78	70	11

These tubes are designed to be cut to desired lengths but care must be taken to trim and smooth the cut edges. Custom-cut lengths and angles are available upon request.

Ordering Information for Additional Plugs

Tracheal T-Tube Code No:	Plug Size Code No:
ASTR-08	PL-08
ASTR-10 & AST-10	PL-9-10
ASTR-12 & AST-12	PL-12-14
AST-14	PL-12-14
ASTR-14	PL-16
ELT, LT, ST, RST and RLT-6 & 7mm OD	PL-4.5-7
ELT, LT, ST, RST, RLT-8mm OD	PL-08
ELT, LT, ST-9mm & 10mm OD	PL-9-10
ELT, LT, ST-12,13 & 14mm OD	PL-12-14
LT, ST, RLT-16mm OD	PL-16
LT-518 & RLT-18-S	PL-18
HTT-11-8 & HTT-12-10-S	PL-12-14
HTT-13-10 & HTT-14-12-S	PL-18
HTT-16-12	Special Plug
HTTR-10-8	PL-08
HTTR-13-10	PL-12-14
RTR-11,12,13 & 15	PL-12-14
RTR-14	PL-16

These products are available with

Ultra-smooth^{Plus}

Ultra-smooth Plus[®] surface treatment is a proprietary technology that modifies the surface properties of silicone. Ultra-smooth Plus[®] treated silicone is thromboresistant, resistant to biofilm germination, bacterial and fungal growth, and has less surface friction.

Quality Management System-
ISO 13485: 2016



Latex Free



Single Use Only
DO NOT RESTERILIZE

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Professional References:

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- Grillo, H.C., Zanini, P., Michaelassi, F.
Complications of Tracheal Reconstruction, Journal Thoracic and Cardiovascular Surgery, Vol. 91, No. 3 pp. 322-328, March 1986.
- Montgomery, W. W.
Surgery of the Upper Respiratory System, Vol. 11, 2nd ed., Lea and Febiger Philadelphia, 1989.

Footnotes:

- Ernst, Armin MD., St. Elizabeth's Medical Center, Brighton, MA, Wahidi, Momen MD., Duke University, Durham, NC.

CAUTION: Federal Law restricts this device to sale by or on the order of the physician.

Further information may be obtained and orders can be placed by calling (800)942-5227 or through our 24-hour fax (781)826-3899.



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