

**Product Information for the Operating Room Personnel**

*These instructions are for professional reference prior to surgery and should be read carefully.*

**Description**

INVOTEC Tracheal T-Tubes are designed for the surgical management of tracheal and subglottic stenosis and the reconstruction of cervical and thoracic trachea. The T-Tubes, made of medical grade silicone, 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.

**Indications**

The T-Tube may be used as both a tracheal stent and a tracheotomy tube and may 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 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 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.

- Caution: - This product is for single patient use only
- Federal Law restricts the sale of this device by or on the order of a physician
  - This product is shipped NON-STERILE

**Sterilization and Handling****Sterilization Techniques**

- Step 1. Remove product from package; using clean gloves, rinse T-Tube with clean water. Pat dry with lint free towel.
- Step 2. Place product in sterilization package and record proper information on sterilization label.
- Step 3. Sterilize using Steam Autoclave:  
**Steam Sterilization:** flash sterilize using steam for 3 minutes at 270 degrees F at 30 psi.

**Handling Techniques**

1. The Tracheal T-Tube should remain plugged or have a speaking valve attached when possible to help keep the trachea moist and allow normal phonation and respiration.
2. Before cleaning, remove the plug. To avoid misplacement of the plug, set aside in a clean place.
3. The Tracheal T-Tube may be suctioned 2 to 3 times per day or as directed by the physician. Tilt external portion of tube upward or downward to direct suction tip to upper or lower ends. Insert suction catheter slowly and carefully while removing mucous and secretions.
4. Clean inside and outside of external branch with cotton-tipped applicator dipped in hydrogen peroxide. Using another applicator dipped in saline solution, continue to clean until no hydrogen peroxide is left on applicator and the inside of the Tracheal T-Tube external branch is clear.
5. Twice daily, apply Betadine® solution or Aureomycin® ointment to clean skin around external portion of tube.
6. During the winter months, and if persistent crusting occurs inside the tube, constant humidity is recommended.

**Warranty**

Invotec International, Inc. warrants that the product is free from defects in material and workmanship. Invotec will replace or provide a refund for any product found to be defective so long as the product is returned according to the Returned Goods instructions in the Sales Policy. Invotec shall not be liable for any consequential loss, damage or expense directly or indirectly arising from the use of, or inability to use, this product. **THE FOREGOING WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, HOWEVER ARISING, INCLUDING MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AGAINST INFRINGEMENT OR OTHERWISE.** Invotec International neither assumes, nor authorizes any person to assume for it, any other additional liability or responsibility with respect to this product.

**Operative Procedure - Insertion and Removal**

- The Intra-operative 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 the risk of healing delay.
- A properly placed T-Tube may be left in-situ for weeks to months to allow firm healing and stabilization of the repair.
- Removal of the T-Tube is best performed under anesthesia so that the airway patency can be evaluated endoscopically, undue patient discomfort is avoided, and granulations, sutures and other impediments may be removed.
- Endoscopic placement of the T-Tube can be difficult and tedious. The correct T-Tube diameter should be determined so as to allow for little or no horizontal movement. In cases of subglottic stenosis the Tube is accurately tailored so that it does not extend above the free border of the vocal cords. The tube is preferably trimmed to suit the precise dimensional requirements.
  1. The placement of the T-Tube is preceded by dilation using the brass Jackson dilators.
  2. On the basis of the largest dilator passed, a series of rubber esophageal dilators are serially connected and introduced through the tracheostoma and passed retrograde through the larynx, grasped through the laryngoscope and drawn out through the mouth.
  3. The T-Tube is correctly orientated, snugly fit over the final dilator and the trailing end of the dilator is brought out through the horizontal arm of the T-Tube.
  4. The skin at the tracheostoma is lubricated with water soluble jelly to facilitate passage. Steady traction through the upper dilators advances the tubes until the trailing end is properly positioned in the distal trachea.
  5. The dilators are disengaged and the T-Tube position checked for accurate level placement.
  6. An endoscopic examination can verify that the T-Tube is correctly positioned without buckling and the patient is allowed to awaken. Improper length of the T-Tube is corrected as soon as recognized.
- The use of the Jackson dilators has been ideal in that the stenotic segments are atraumatically dilated and the T-Tube drawn into the stenotic segment for support. 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 larger caliber T-Tube is 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 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.**