



Laryngectomy

Tubes and Accessories



Manufacturer:
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INTENDED USE:

A Laryngectomy tube is intended for use in the establishment of an alternate airway due to obstruction of the upper airway, where the larynx has been surgically removed.

Device Description:

Premier Laryngectomy tubes are made of Stainless steel to exacting standards with precise tolerances. The tube consists of three parts such as Outer Cannula, Inner Cannula and Pilot (Obturator), which varies in size, degree of curvature and length. Accessory set could include small (1-6) or large (7-10) size tracheal tube brushes for gentle and thorough cleaning of the device.

Contraindications:

Laryngectomy tubes and accessories should not be used under following conditions

- High Ventilatory/positive end-expiratory pressure (PEEP) requirements.
- History of neck surgery and throat cancer.
- Active infection or cellulitis at the laryngectomy stoma site.

WARNINGS:

- When bathing or taking a shower, keep water out of the tube. Do not swim.
- Avoid powders, aerosol sprays, dust, smoke and lint from facial tissues.
- Do not use over-the-counter antihistamines (cold medications), which dry secretions and the airway.
- Avoid fumes from cleaning solutions such as ammonia or bleach.
- Properly train the patient about the device usage and cleaning procedure.
- Stainless Steel tubes are not MRI compatible.

PRECAUTIONS:

- Do not use if the package is damaged/broken, prior to use.
- Prior to first and subsequent use, inspect the device for breaks, cracks and malfunction in Swivel or Hub lock mechanism.
- Replace the device, if any cracks or fractures are noticed.
- Laryngectomy tubes are not provided sterile, Sterilize prior to use.
- Use surgical gloves and proper Personal Protective Equipment (PPE) when handling the sterile laryngectomy tube and its accessories.
- Patient's airway should be cleared by suctioning prior to laryngectomy procedure.
- Laryngectomy tube must be removed from stoma before cleaning. Do not clean while the tube is in stoma. A second complete sterile laryngectomy tube set of the same size should be readily available.

Equipment and setup

Laryngectomy Care kit

- Suction device and appropriate sized suction catheters.
- Two equal lengths of cotton ties (approximately 40cm) or
- Velcro ties (for patients older than 6 years).

Materials: Laryngectomy tube set:

Components	Materials
Inner cannula with swivel or hub lock	304 Stainless Steel (ASTM A269) & 303 Stainless Steel (ASTM A582)
Outer cannula with neck plate	304 Stainless Steel (ASTM A269) & 303 Stainless Steel (ASTM A582)
Obturator (Pilot)	304 Stainless Steel (ASTM A269), 303 Stainless Steel (ASTM A582), 360 BRASS (ASTM B-16) & NICKEL PLATED (ASTM B689)

Directions for Use:

1. Collect and set up all the supplies and equipment.
2. Wash your hands with soap and water before doing any laryngectomy stoma care.
3. Position the patient supine with pillow under shoulders to extend neck, which allows you to see laryngectomy site easily.
4. Patients return from operation theatre with stay sutures (nylon sutures) inserted on either side of the tracheal opening (stoma). The stay sutures should be taped to the chest wall and labeled as "left" and "right".
5. Examine around the stoma for signs of skin breakdown, irritation or infection.
6. Select appropriate size laryngectomy tube based on the patient surgical and anatomical requirements.
7. Insert laryngectomy tie/Velcro strap through slit in the neck plate of the outer cannula.
8. Ensure that Pilot (Obturator) and Inner Cannula properly fit the Outer Cannula.
9. Lubricate the tip of the Obturator and Outer Cannula with normal saline solution or water-soluble lubricant. Place the Obturator in the Outer Cannula.
10. Pulling the stay sutures up and out will apply traction to the stoma opening to assist with insertion of the tube.
11. Insert the sterile laryngectomy tube into stoma. During insertion, the obturator should be held securely inside the Outer Cannula.
12. After Insertion of the tube, immediately remove the Obturator.
13. Securely knot the tie/Velcro strap around neck.
14. Now insert the Inner Cannula into Outer Cannula and lock (Swivel or Hub lock) in place.
15. Ensure that the Obturator and tracheal tube brush is readily available to the patient.
16. Ensure that patient is able to breathe easily without any complications.

Cleaning & Sterilization Prior to Patient's initial Use

Cleaning:

- Place new Outer cannula, Inner cannula and Obturator (Pilot) in a clean container filled with warm water and mild dishwashing soap (one tablespoon per quart of water).
- Allow parts to soak in a soapy water for one (1) hour.
- Use appropriate size tracheal tube brush to thoroughly clean inside and outside of:
 - Inner Cannula
 - Outer Cannula
 - Obturator (Pilot)
- Completely rinse all the laryngectomy tube parts with sterile water and boil for 30 minutes.
- Place all of the laryngectomy tube parts on a clean dry cloth or paper towel and let them dry completely.
- Store all parts in a clean dry closed container. Follow recommended sterilization instructions.
- Do not soak, wash or expose tubes to peroxide, enzyme cleaners or sodium hydroxide. These chemical agents may cause damage to the tubes.

Sterilization:

- Laryngectomy tube can be sterilized by autoclave.
- Autoclave process carried out at temperature 273°F (134°C) for 5 minutes, 30 minutes of dry time.
- Dry heat sterilization not recommended.

Reprocessing

Entire Laryngectomy tube at Health-care facility:

- Collect all the supplies and remove laryngectomy tube from stoma
- Place all the dirty laryngectomy tube parts and strap in a clean container filled with warm water and mild dishwashing soap (one tablespoon per quart of water).
- Allow parts to soak in a soapy water for one (1) hour. This will soften and loosen the mucus.
- Use appropriate size tracheal tube brush to remove all the secretions thoroughly inside and outside of:
 - Inner Cannula
 - Outer Cannula
 - Obturator (Pilot)
- Completely rinse all the laryngectomy tube parts with sterile water and boil for 30 minutes.
- Place all of the laryngectomy tube parts on a clean dry cloth or paper towel and let them dry completely. Have an extra Laryngectomy tube ready for use while the newly cleaned tube dries.
- Store all parts in a clean dry closed container. Follow recommended sterilization instructions.

Cleaning Inner Cannula at Home:







- Wash your hands.
- Unlock the Inner cannula while holding the neck plate securely. Note: Health-care provider should train the patient to easily engage and disengage Inner cannula locking (swivel or hub lock) with neck plate.
- Place inner cannula in a clean container filled with warm water and mild dishwashing soap until the mucus softened.
- Use appropriate size tracheal tube brush to remove all the secretions thoroughly inside and outside of Inner cannula.
- Rinse the tube with sterile water and boil for 30 minutes.
- Place the inner cannula on clean dry cloth or paper towel and let it dry completely. Have an extra Laryngectomy tube ready for use while the newly cleaned tube dries.
- Store the tube in clean dry closed container.

Storage:

- Always store the laryngectomy tube in original protective packaging, prior to first usage.
- Do not expose metal tubes to temperatures above 400°F (204.4°C).

Shelf Life: Laryngectomy tubes made of Stainless steel have indefinite shelf life.

For Further Information: Please visit premiermedicalco.com

Symbols	Symbol Meaning
	Manufacturer
	Batch number
	Caution: See instructions for use
Rx ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Non-Sterile
	Storage Temperature Range
	Single Patient, Multiple use