



Tracheostomy

Tubes and Accessories



Manufacturer:
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INTENDED USE:

Tracheostomy tube is intended for use in the tracheal opening (Stoma) to facilitate mechanical ventilation and proper airway management for patients experiencing airway obstruction. Device indicated for use in patients with acute or chronic upper airway obstruction, major head or neck trauma management, reduce pulmonary aspiration risk and to facilitate non-invasive weaning from mechanical ventilation.

Device Description:

Premier Tracheostomy tubes are made of Stainless steel or Nylon 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. Accessories include Decannulation Stoppers and tracheal tube brushes. Modifications include 15mm adaptors for Jackson Improved and Air-Lon tubes, and fenestrations.

Contraindications:

Tracheostomy 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 tracheostomy site.
- Injury to the nerve that moves the vocal cords (recurrent laryngeal nerve).

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.
- Tracheostomy tubes are not provided sterile, Sterilize prior to use.
- Use surgical gloves and proper Personal Protective Equipment (PPE) when handling the sterile tracheostomy tube and its accessories.
- Patient's airway should be cleared by coughing or suctioning prior to tracheostomy procedure.
- Tracheostomy tube must be removed from stoma before cleaning. Do not clean while the tube is in stoma. A second complete sterile tracheostomy tube set of the same size should be readily available.
- Rx only, Prescription Device.

Equipment and setup

Tracheostomy 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: Tracheostomy tube set:

Components	Materials
Inner cannula with swivel or hub lock	Nylon (Air-Lon®) (ASTM F2726), 304 Stainless Steel (ASTM A269) & 303 Stainless Steel (ASTM A582)
Outer cannula with neck plate	Nylon (Air-Lon®) (ASTM F2726), 304 Stainless Steel (ASTM A269) & 303 Stainless Steel (ASTM A582).
Obturator (Pilot)	Nylon (Air-Lon®) (ASTM F2726), 304 Stainless Steel (ASTM A269), 303 Stainless Steel (ASTM A582), 3 60 BRASS (ASTM B-16) & NICKEL PLATED (ASTM B689)

Directions for Use:

- Collect and set up all the supplies and equipment.
- Wash your hands with soap and water before doing any tracheostomy care.
- Position the patient supine with pillow under shoulders to extend neck, which allows you to see tracheostomy site easily.
- 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".
- Examine around the stoma for signs of skin breakdown, irritation or infection.
- Select appropriate size Tracheostomy tube based on the patient surgical and anatomical requirements.
- Insert tracheostomy tie/Velcro strap through slit in the neck plate of the outer cannula.
- Ensure that Pilot (Obturator) and Inner Cannula properly fit the Outer Cannula.
- Lubricate the tip of the Obturator and Outer Cannula with normal saline solution or water-soluble lubricant. Place the Obturator in the Outer Cannula.
- Pulling the stay sutures up and out will apply traction to the stoma opening to assist with insertion of the tube.
- Insert the sterile tracheostomy tube into stoma. During insertion, the obturator should be held securely inside the Outer Cannula.
- After Insertion of the tube, immediately remove the Obturator.
- Securely knot the tie/Velcro strap around neck.
- Now insert the Inner Cannula into Outer Cannula and lock (Swivel or Hub lock) in place.
- Ensure that the Obturator and tracheal brush is readily available to the patient.
- 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 tracheostomy tube parts with sterile water and boil for 30 minutes.
- Place all of the tracheostomy 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:

- Tracheostomy 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 Tracheostomy tube at Health-care facility:

- Collect all the supplies and remove Tracheostomy tube from stoma
- Place all the dirty tracheostomy 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 tracheostomy tube parts with sterile water and boil for 30 minutes.
- Place all of the tracheostomy tube parts on a clean dry cloth or paper towel and let them dry completely. Have an extra Tracheostomy 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 Tracheostomy tube ready for use while the newly cleaned tube dries.
- Store the tube in clean dry closed container.

Storage:







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

Shelf Life: Tracheostomy tubes made of Stainless steel or Nylon have indefinite shelf life.

DECANNULATION:

- Decannulation stoppers are available in two sizes.
 - Half (½") Decannulation Stopper
 - Full Decannulation Stopper
- Size of the Decannulation stopper selected should match with size of the Tracheostomy tube.
- If a Decannulation stopper used during the procedure, secure the strings of the Decannulation stopper to tracheostomy tube tie/Velcro strap.
- The physician may begin the decannulation procedure with a half (½") Decannulation Stopper.
- Assess the patient carefully for signs of respiratory difficulty and continue to observe at frequent intervals.
- If the patient does not show respiratory distress, the physician may begin the decannulation procedure with full Decannulation Stopper.
- Following Decannulation, a Tracheostomy tube of appropriate size should be readily available for reinsertion if the patient develops respiratory distress.

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