Parker Medical Trach-Vac Endotracheal Tube (PFTVPU)
Subglottic Suction Tube with Parker Flex-Tip® and ThinCuff® (Polyurethane)

DESCRIPTION

The Parker Medical Trach-Vac subglottic suction endotracheal tubes are sterile, single use devices. They are produced with a polyurethane Parker Thin-Cuff® mounted on medical grade PVC tubing. Each tube has an evacuation port and lumen in the dorsal wall of the tube, proximal to the cuff, for evacuating accumulated secretions from the subglottic space. The evacuation lumen is connected to suction tubing extending outside the tube wall and having a capped connector for attachment to an external suction device. The polyurethane cuff is high-volume, low-pressure with an attached pilot balloon and self-sealing valve. The Trach-Vac tube also has a Parker Flex-Tip® flanked by dual Murphy eyes at the distal end of the tube, a standard 15 mm connector and a radiopaque line to assist in radiographic visualization of the tube. The Parker Medical Trach-Vac tube has depth marks that indicate the distance to the distal tip of the tube; and bold black marks proximal to the cuff, for reference in determining the position of the tube tip and cuff in the trachea after they pass through the vocal cords.

INDICATIONS

The Parker Medical Trach-Vac endotracheal tubes are indicated for nasal or oral intubation of the trachea for anesthesia and airway management, including mechanical ventilation and suctioning of accumulated subglottic secretions in the trachea.

CONTRAINDICATIONS

As with any endotracheal tube, use of the Parker Thin-Cuff® endotracheal tube in procedures that will involve the use of a laser beam or electrosurgical active electrode in the immediate area of the device is contraindicated. Contact of the endotracheal tube with a LASER beam or electrosurgical active electrode, especially in the presence of oxygen or nitrous oxide enriched mixtures could result in rapid combustion of the endotracheal tube with harmful thermal effects and with emission of corrosive and toxic products, including hydrochloric acid (HCl).
It has been reported by Hirshman and Smith that mixtures of nitrous oxide and oxygen support combustion about the same as pure oxygen, and that in addition to ignition by direct contact with the beam, the interior of the tube can also be ignited by contact with flaming tissue in close proximity to the tip of the tube. (Hirshman C.A. and Smith J.: Indirect Ignition of the Endotracheal Tube during Carbon Dioxide Laser Surgery. Arch Otolaryngol Vol. 106:639-641, 1980).

WARNINGS

- Each tube's cuff, pilot balloon and valve should be tested by inflation prior to use.
- Do not overinflate the cuff. Ordinarily, the cuff pressure should not exceed 25 cm H_2O. Over inflation can result in tracheal damage, rupture of the cuff with subsequent deflation or cuff distortion which may lead to airway blockage.
- Deflate the cuff prior to repositioning the tube. Movement of the tube with the cuff inflated could result in patient injury. This can also cause cuff damage.
- Various bony anatomical structures (e.g., teeth, turbinates) within the airway or any intubation tools with sharp surfaces might jeopardize cuff integrity. Damage to the cuff during insertion will subject the patient to the risk of extubation and the need for re-intubation.
- If the cuff is damaged, the tube should not be used. Keep tubing straight and free of kinks.
- It is essential to verify that the tube position remains correct after intubation, especially when a patient's position or the tube placement is altered. Any malposition of the tube should be corrected immediately.
- If extreme flexion of the head (chin-to-chest), movement of the patient (e.g. to a lateral or prone position), or tube compression is anticipated after intubation, the use of a reinforced tracheal tube should be considered.
- Syringes, three-way stopcocks or other devices should not be left inserted in the inflation valve for an extended period of time. The resulting stress could crack the valve housing and cause the cuff to deflate.
- Excessive amounts of lubricant can dry on the inner surface of the tracheal tube resulting in either a lubricant plug or a clear film that partially or totally blocks the airway.
- Diffusion of a nitrous oxide mixture, oxygen or air may either increase or decrease cuff volume and pressure. Nitrous oxide may diffuse through the material of the Salter Thin-Cuff® endotracheal cuff at a higher rate than a standard PVC cuff. When using nitrous oxide mixtures, the care giver should frequently monitor cuff volume and pressure and make inflation adjustments as necessary. The use of a cuff pressure gauge is advised to verify appropriate inflation pressure.

CAUTIONS

- This product cannot be adequately cleaned or sterilized by the user in order to facilitate safe reuse and is therefore intended for single use only. Attempts to clean or sterilize these devices may result in bio incompatibility, infection, or product failure risks to the patient.
- Use Minimal Occluding Volume or Minimum leak techniques in conjunction with an intra-cuff pressure-measuring device to select the sealing pressure. Continuously monitor the cuff pressure and investigate any deviation from the selected seal pressure. Correct deviations immediately.
- The use of Lidocaine Topical Aerosol has been associated with the formation of pinholes in PVC cuffs. Exercise expert clinical judgment when using this substance. A Lidocaine hydrochloride solution has been reported not to have this effect.
- Inflation of the cuff by "feel" alone or by using a measured amount of air is not recommended, since compliance is an unreliable guide during inflation. Intracuff pressure should be closely monitored with a pressure measuring device. The pilot balloon is only intended to indicate the presence of pressure or vacuum in the cuff and is not intended to provide an indication of pressure level.
- Non-standard dimensioning of some connectors on ventilatory or anesthesia equipment may make secure mating with the tracheal tube 15 mm connector difficult. Use only with equipment having standard 15 mm connectors.
- Use of lubricating jelly to ease connector reinsertion is not recommended, as it may contribute to accidental disconnections.
- Avoid exposure of the tubes to elevated temperatures or ultraviolet light during storage.
- The 15 mm connector is seated so that it can be removed with effort if pre-cutting the tube is desired. Follow the DIRECTIONS FOR USE to evaluate the tube and connector for suitability if pre-cutting is considered. Always assure that the connector is firmly seated in both the tracheal tube and the breathing circuit to prevent disconnection during use.
- Follow the manufacturer's instructions if lubricating jellies are used with the tracheal tube. Excessive amounts of lubricating jellies can dry on the inner surface of the tracheal tube resulting in a lubricant plug or a clear film that partially or totally blocks the airway.
- Connect the subglottic suction line to a dedicated subglottic suction regulator. Use a separate regulator for oral and endotracheal tube suctioning.

ADVERSE REACTIONS

The following adverse reactions have been reported to be associated with the use of cuffed endotracheal tubes during the intubation procedure, during the intubation period or subsequent extubation. The order of listing does not indicate frequency or severity. Reported adverse reactions include: abrasion of the arytenoid cartilage vocal process; cartilage necrosis; cicatrix formation: consequences of failure to ventilate, including death; damage to the perichondrium; development of dense or diffuse fibrosis invading the entire glottic area; emphysema; endobronchial aspiration: endobronchial intubation (hypoxemia); endotracheobronchial aspiration; epistaxis; esophageal intubation (stomach distension): excoriated membranes of the pharynx: eye trauma: fibrin deposition: formation of subglottic web: fracture-luxation of cervical column (spinal injury); fragmentation of cartilage; glottic edema (supraglottic, subglottic, retroarytenoidal); granuloma of the inner arytenoid area; infections (laryngitis, sinusitis, abscess, respiratory tract infection); inflammation: intermittent aphonia and recurrent sore throat; laryngeal fibrosis: laryngeal granulomas and polyps; laryngeal obstruction; laryngeal stenosis; laryngeal ulcers; laryngotracheal membranes and webs: membranous glottic congestion: membranous tracheobronchitis: mild edema of the epiglottis: mucosa! sloughing: paresis of the hypoglossal and/or lingual nerves; perforation of esophagus: perforation of the trachea; Pneumothorax; replacement of the tracheal wall with scar tissue; respiratory obstruction; retrobulbar hemorrhage; retropharyngeal abscess; retropharyngeal dissection; rupture of the trachea; sore throat; dysphagia; stricture of nostril; stridor; subglottic annular cicatricia1 stenosis; submucosal hemorrhage: sub mucous puncture of the larynx; superficial epithelial abrasion; swallowed tube; synechia of the vocal cords; teeth trauma: tissue bums: tracheal bleeding; tracheal stenosis; trauma to lips, tongue, pharynx, nose, trachea, glottis, palate, tonsil, etc.; traumatic lesions of the larynx and trachea; ulcerations exposing cartilaginous rings and minor erosions at cuff site; ulceration of the lips, mouth, pharynx; ulcers of the arytenoids; vocal cord congestion; vocal cord paralysis and vocal cord ulcerations.

DIRECTIONS FOR USE

1. Inspect the package for any sterile seal damage. Do not use if the pouch is damaged or altered.
   Replace with a fresh unit.
2. Remove the sterile Trach-Vac tube from its protective package using aseptic technique.
3. Test the cuff, pilot balloon and valve for integrity by inflation prior to use. Insert a Luer tip syringe into the cuff inflation valve housing and inject enough air to fully inflate the cuff.
4. After the inflation test, completely evacuate the air from the cuff, pilot balloon and valve.
5. Before intubating, lubricate the external surface of the flexible tip and the cuff of the tracheal tube with a sterile water soluble surgical lubricant.
6. If shortening of the endotracheal tube by cutting is desired, evaluate the tube for pre-cutting suitability prior to intubation. Tubes with 15 mm connectors that cannot be removed with reasonable manipulation are not suitable for cutting. Cut the tube at a slight angle to facilitate reinsertion of the 15 mm connector into the tube. Always assure that the connector is firmly seated in both the tracheal tube and the breathing circuit to prevent disconnection during use.
7. In situations where it is deemed appropriate to cut the tube, the user is cautioned that anatomical variations, conditions of use or other factors may result in an endotracheal tube that is too short for a given patient. Expert clinical judgment should be used in selecting the appropriate tube size and precut length for each patient.
8. Follow currently accepted medical techniques for intubation, with consideration given to the specific Warnings and Cautions stated in this product insert. Verify that the endotracheal tube has been placed in the trachea and not inadvertently in the esophagus or mainstem bronchus.

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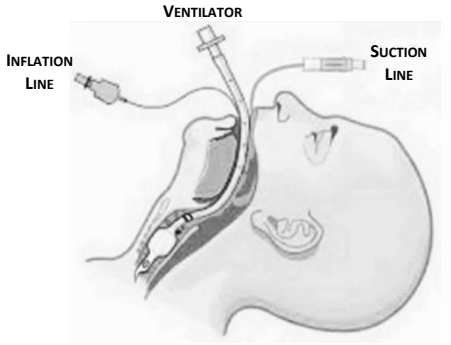
9. If a stylet is used, reshape the stylet to the configuration which best facilitates intubation. Be sure the stylet can be easily removed from the endotracheal tube prior to intubation. The stylet tip must not extend beyond the patient end of the endotracheal tube. Do not abrade the plastic sheath of the stylet on the sharp edges of the 15 mm connector during insertion or removal from the tracheal tube. If the stylet sheath is torn, cut, or lacerated while reshaping the stylet, do not use for intubation as a damaged sheath presents an increased hazard of separation during withdrawal of the stylet.
10. Once the patient is intubated, connect a syringe filled with air to the check valve housing and inflate the cuff only enough to provide an effective seal at the desired lung inflation pressure.
11. Use Minimal Occluding Volume, Minimum Leak techniques, and monitoring of cuff pressure to reduce the occurrence of many of the adverse reactions associated with cuffed tracheal tubes.
12. Remove the syringe from the valve housing after cuff inflation. Leaving the syringe attached will keep the valve open, permitting the cuff to deflate.
13. Verify that the cuff inflation system is not leaking. Integrity of the system should be checked frequently and periodically during the intubation period. Any deviation from the selected seal pressure should be investigated and corrected immediately.
14. Connect the Trach-Vac to the breathing circuit and secure in the patient's airway following currently accepted medical techniques.
15. Connect the subglottic suction line to the suction receptacle tubing. Set the subglottic suction regulator to either continuous or Off/intermittent mode.
16. The suction Lumen should be checked periodically for patency. If blockage of the suction lumen or port is suspected, the lumen may be cleared by using a syringe to administer a bolus of 3–5 cc of air into the suction port.
17. Suction secretions above the cuff using the minimum suction pressure required to effectively remove the secretions. Continuous suction at 20 mm Hg may be used. Intermittent suctioning u sing practices similar to standard suctioning through endotracheal tubes may also be used. Typically, these practices include suction at 100-150 mm Hg for 10-15 seconds. Alternative methods for suctioning the subglottic space are described in Smolders K, et al. Chest: 2002; 121:858-862 and Mahul Ph, et al. Intensive Care Medicine. 1992:18:20-25.
18. Deflate the cuff prior to extubation by inserting a syringe into the valve and removing the gas mixture until a definite vacuum is noted in the syringe and the pilot balloon collapses.
19. Suction oral secretions and then extubate the patient following standard medical techniques.
20. Discard the endotracheal tube using accepted medical standards for disposal of biomedical waste.

INSTALLATION INSTRUCTIONS

After the patient is intubated, connect the Trach-Vac as shown.
Connect the 15 mm connector to the ventilator breathing circuit and the barbed suction connector to a suction source to ensure the removal of all accumulated subglottic fluids.



Note: The following performance parameters were collected using a bench test that is intended to provide a comparison of the sealing characteristics of tracheal tube cuffs only in a laboratory setting and not configured or intended to predict performance in a clinical setting.

Trach-Vac Endotracheal Tubes Tracheal Tube Cuff Performance by Tracheal Tube Size, Cuff Pressure 27 hPa (cm H_2O) (per ISO 5361 method)						
	Minimum Trachea Diameter			**Maximum** Trachea Diameter		
Trach-Vac Tube ID (mm)	Trachea Diameter (mm)	Leakage Rate Range (ml/h)		Trachea Diameter (mm)	Leakage Rate Range (ml/h)	
		50th Percentile	90th Percentile		50th Percentile	90th Percentile
6.0	14.5	0	0	19.0	0	0
6.5	16.9	0	0	22.8	0	0
7.0	17.2	0	0	22.8	0	0
7.5	18.6	0	0	24.7	0	0
8.0	18.9	0	0	24.7	0	0
8.5	21.3	0	0	28.5	0	0
9.0	21.6	0	0	28.5	0	0

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