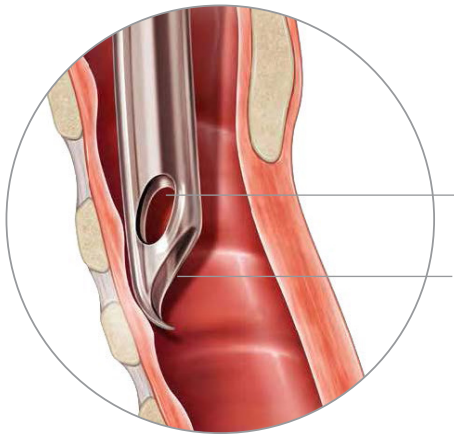
TRACH-VAC™ SUBGLOTTIC SUCTION ENDOTRACHEAL TUBE WITH FLEX-TIP®

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE | DEHP FREE



Dual Murphy Eyes aid in collateral gas flow

Tapered and centered Flex-Tip glides safely along airway anatomy

Subglottic suction port affixes to continuous or intermittent suction devices

Atraumatic Flex-Tip

Subglottic suction port inside the tube

Available with durable PVC Cuff or Ultra-thin Polyurethane Cuff

FLEX-TIP®
Endotracheal Tube Tip

STANDARD
Endotracheal Tube Tip

INSTRUCTIONS FOR USE

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.

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.
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 using 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.

WARNING: Always read instructions for use on product packaging prior to use on of these devices.

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