PARKER MEDICAL Flex-Tip Tracheal Tubes

Tracheal Tubes

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed practitioner.

STERILE (ETO) Unless package has been opened or damaged.

FOR SINGLE USE ONLY. DO NOT REUSE.

DESCRIPTION
Parker Medical’s Flex-Tip Tracheal Tubes have two Murphy eyes flanking a flexible distal tip and are available either plain (uncuffed) or cuffed in a variety of sizes and styles. Cuffed tracheal tubes have a Low Profile cuff or a High Volume Low Pressure cuff and an attached pilot balloon with a one-way valve. All tubes have a radiopaque line or wire, depth marks in centimeters, a standard 15mm connector, and one or two ring marks for reference in determining the position of the cuff and/or distal tip in the trachea. Meets American ASTM F1242-96 standard, except for its unique tip.

INDICATIONS AND USAGE
Flex-Tip Tracheal Tubes are designed for oral intubation of the trachea and are indicated for anesthesia or ventilator support of respiration. Expert clinical judgment should be exercised in the selection of the appropriate tracheal tube size and style for an individual patient.

CONTRAINDICATIONS
Use of Flex-Tip Tracheal Tubes in procedures which will involve the use of a LASER beam or electrosurgical active electrode in the immediate area of the device is contraindicated. Contact of the tracheal tube with such LASER beam or electrode, especially in the presence of oxygen-enriched mixtures, could result in rapid combustion of the tracheal tube with harmful thermal effects and with emission of corrosive and toxic products, including hydrochloric acid (HCl).

WARNINGS
General
- Should be considered as contaminated medical waste after use.

Cuffed Tubes
- Deflate cuff prior to repositioning the tube. Movement of the tracheal tube with cuff inflated could result in patient injury or damage to the cuff, requiring a tube change.
- Do not overinflate cuff. Overinflation can result in rupture of the cuff with subsequent deflation, or in cuff distortion which may lead to airway blockage.

CAUTIONS
General
- Do not use if package has been previously opened or damaged.
- Do not use a tracheal tube larger than that which is expected to fit easily within the glottic aperture.
- Lubricate the external surface of the flexible tip of the tube with a water soluble surgical lubricant prior to inserting the tube. Avoid placing such lubricant on the inner surface of the flexible tip or on the beveled distal opening of the tube.
- Avoid exposure to elevated temperatures and ultraviolet light during storage.
- Intubation and extubation should be performed using currently accepted medical techniques.
- Should extreme chin-to-chest flexing of the head or movement of the patient (e.g., to a lateral or a prone position) be anticipated after intubation, use of a reinforced tracheal tube to reduce the potential for kinking should be considered.
- When the patient’s position is altered after intubation, it is essential to verify that the tube position remains correct in the new patient position.
- Tubes should be securely anchored to avoid unnecessary tube movement.
- Seat the connector firmly in both the tracheal tube and the adapter on the ventilation equipment to prevent disconnection during use.
- A bite block should be used in cases where the patient may bite down and flatten the endotracheal tube.
- Non-standard dimensioning of some connectors on ventilators or anesthesia equipment may make secure mating with the 15mm connector of the tracheal tube difficult.
- Do not resterilize. Reuse of this product can result in danger to the patient.

Cuffed Tubes
- Each tube’s cuff, pilot balloon, and valve should be tested by inflation before use.
- Avoid damaging the thin-walled cuff during intubation. If the cuff is damaged, the tube should not be used.
- Inflation of cuff by “feet” or by using a measured amount of air is not recommended, since resistance is an unreliable guide during inflation.
- In selecting the sealing pressure, an intracuff pressure measuring device should be used in conjunction with Minimal Occluding Volume or Minimum Leak techniques.
- Cuff pressure should be monitored. Any deviation from the selected seal pressure should be investigated and corrected immediately.

- Diffusion of nitrous oxide mixture, oxygen, or air may either increase or decrease cuff volume and pressure. To decrease such diffusion, inflating the cuff with the same gas mixture that will contact the cuff’s external surface is recommended.
- Three-way stopcocks or other devices should not be left inserted in the inflation valve for extended periods of time. The resulting stress could crack the valve housing and allow the cuff to deflate.
- The use of Lidocaine Topical Aerosol has been associated with the formation of pinholes in PVC cuffs. (Jayasuria, K.D., and Watson, W.F., PVC Cuffs and Lidocaine-based Aerosol. Brit J Anesth 53:1368-1369, 1981). The same authors report that lidocaine hydrochloride solution does not have this effect.
- Follow the manufacturer’s application instructions when using lubricating jellies with trachea tubes. If excessive amounts of jelly dry onto the inner surface of the tracheal tube, it could result in either a lubricant plug or a clear film that partially or totally blocks the airway.

ADVERSE REACTIONS
Reported adverse reactions associated with the use of tracheal tubes are many and diverse. Standard textbooks and scientific literatures should be consulted for specific adverse reaction information.

Helpful references for more detailed discussion of tracheal tube adverse reactions include the following:

DIRECTIONS FOR USE: Useseptic technique.
Intubation and extubation should be performed following currently accepted medical techniques. Expert clinical judgment should be used in choosing the suitable tracheal tube size and style for each patient.

1. Remove sterile tracheal tube from the protective package.
2. For cuffed tubes, test integrity of cuff before intubation. Inflate cuff with a luer-tip syringe. Then completely deflate air from cuff after test inflation.
3. Ensure that 15mm connector is firmly attached to the tracheal tube.
4. Lubricate the external surface of the flexible tip of the tracheal tube with water soluble surgical lubricant before intubating.
5. Intubate patient in accordance with currently accepted medical techniques.
6. For cuffed tubes, inflate cuff with sufficient gas mixture to provide an effective seal at the desired lung inflation pressure. Use of Minimal Occluding Volume Technique can reduce occurrence of many of the adverse reactions associated with the use of cuffed tracheal tubes.
7. For cuffed tubes, remove luer-tip syringe from valve to effect closing of one-way valve.
8. For cuffed tubes, before extubation, completely deflate cuff using a luer-tip syringe until a definite vacuum is noted.
9. Extubate using currently accepted medical techniques.

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Other patents pending.

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Manufactured for:
Parker Medical
Telephone: 303-799-1990
www.parkermedical.com

Distributed by:
Portex, Inc.
Keene, NH 03431, USA
Phone: 800-258-5361
FAX: 603-352-3703