

K960450

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**SMDA Summary**

***This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.***

**Product:** Hebeler Safe-T-Tube

**Description:** The Hebeler Safe-T-Tube is a tracheal T-Tube with a molded internal balloon designed to be inflated for intermittent closure of the upper intraluminal limb. During anesthesia or ventilation, the balloon is inflated, closing the upper end of the Safe-T-Tube. Inflation of the internal balloon creates a closed system between the tracheotomy and lungs. Following anesthesia or ventilation, the balloon is deflated and the upper limb becomes open for upper respiratory access.

The Hebeler Safe-T-Tube is designed to maintain an adequate airway as well as to provide support in the stenotic trachea which has been reconstituted or reconstructed. The exclusive design of ridges and grooves along the extraluminal limb of the tube allows a ring washer to be attached, significantly reducing the possibility of accidental posterior displacement. All Hebeler Safe-T-Tubes are supplied as a set which includes the tube, ring washers and a plug.

**Indication For Use:** To be used as a tracheostomy tube for the following indications:

1. Provide a secondary airway;
2. Acute tracheal or laryngeal injuries;
3. A need to support intrathoracic tracheal stenosis;
4. A need to support a reconstituted trachea;
5. A need to support a reconstructed trachea;
6. Tracheal stenosis when the cervical or thoracic trachea cannot be repaired; and
7. Segmental resection and anastomosis.

**Predicate Device:** Montgomery Safe-T-Tube, manufactured and marketed by Boston Medical Products, Inc.

**Testing:** Finished device sample passed cytotoxicity testing and were determined to be non-reactive and non-cytotoxic based on Elution Test, USP 23.

Submitted by: Stuart K. Montgomery, PRESIDENT  
Stuart K. Montgomery, President

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