



# Posey Cufflator™ 8199 Application Instructions



## Rx ONLY

**DESCRIPTION OF PRODUCT:** Endotracheal Tube Inflator and Manometer

**INTENDED USE:** The Cuff Pressure Gauge is used to adjust and control the cuff pressure of high-volume low-pressure cuffs of tracheal tubes.

**CONTRAINDICATIONS:** None

### Instructions

#### Functional Check:

- Before use, the control inflator needs to be checked as follows:
  - Close connecting piece with the finger (Fig. 1).
  - Inflate with inflation bulb to 40 cm H<sub>2</sub>O; value must be constant for 2-3 seconds. If the pressure drops, contact TIDI customer service.
  - Connect the connecting tubing to the luer connection of the already tested Cuff Pressure Gauge. Seal the end of the connecting tubing with your finger. Inflate to 40 cm H<sub>2</sub>O using the inflation bulb. The value must remain constant for 2 - 3 seconds. If the pressure drops, the connecting tubing is leaking and must be replaced.



#### Application Instructions:

- To properly seal:
    - Connect the Posey Cufflator to the cuff inflation line, and inflate the cuff to ensure minimal leak technique (refer to the tracheal tube IFU for proper inflation pressure levels). This will ensure that the cuff is in close contact with the tracheal wall.
- CAUTION** NOTE: The Posey Cufflator is designed only for use with air-filled cuffs. Use with saline-filled cuffs will cause damage to the unit and void the product warranty.
- Immediately release air by pressing the red release button (Fig. 2) until the lowest safe cuff pressure level is reached.
  - Intra-cuff pressure should be maintained to reduce the occurrence of microaspiration, decreasing the incidence of mucosal ischemia and subsequent stenosis.
    - Defer to the tracheal tube IFU for proper inflation pressure levels. Follow all your hospital policies and procedures that are compliant with USA CMS guidelines and state laws or other governing agencies outside the USA.
- The extension tube may be used if constant monitoring of intra-cuff pressure is desired. Connect the extension tube to the cuff inflation line and to the Posey Cufflator. Use the hook on the back of the Posey Cufflator to hang it on the headboard of the bed. The Posey Cufflator will now monitor the intra-cuff pressure continuously and can be inflated or deflated as required.

**CAUTION** When using the connecting tubing, the system must always be disconnected at the control valve of the cuff to prevent the cuff pressure from dropping without control.

- The Posey Cufflator is calibrated in cm of water pressure (H<sub>2</sub>O). The conversion rate is 1 mm of mercury (Hg) equals 1.36 cm water (H<sub>2</sub>O).
- The accuracy of measurements is ± 2 cm H<sub>2</sub>O for the entire range.

### Cleaning

After every use the Cufflator must be disinfected. Wipe the surface thoroughly with commercially available alcohol based disinfectants or QACs (quaternary ammonium compounds). After disinfecting, inspect the product for visible contamination. If necessary, repeat disinfection step. After disinfection, check the functionality of the product (see "Functional check"). The Posey Cufflator face should be cleaned with a glass cleaner only.

#### CAUTION

- Do not submerge the Posey Cufflator
- Do not sterilize the Posey Cufflator



### Posey Cufflator™

**REF** 8199 - Cufflator, complete with extension tube

### Storage and Handling

- Protect from heat and store in a dry place.
- Keep away from sunlight and light sources.
- Store and transport in the original packaging.

### Disposal

The Cuff Pressure Gauge and connecting tubing must be disposed of in accordance with the applicable local or facility guidelines.

### Warranty (Limited)

Posey warrants to the original purchaser that the Posey Cufflator is free of defects in materials and workmanship for a period of one (1) year from date of first use. If the product is found to be defective in workmanship or materials, Posey will replace it with an equivalent product at no charge, other than certain transportation charges. This warranty does not cover damage caused by accident, water immersion, misuse, abuse, improper care, alteration or exposure to heat.

### WARNING:

- Do not use with saline.
  - If the Posey Cufflator is used out of calibration, it may lead to incorrect readings.
  - NEVER alter or repair this product. ALWAYS inspect before each use. DO NOT use damaged products. doing so may result in serious injury or death. Dispose of damage products per facility policy for BIOHAZARDUS material.
  - The Posey Cufflator is a mechanical device. It may fail to work if subjected to severe shock, such as being dropped or immersed in liquid. To reduce the risk of an inaccurate reading (either high or low), inspect the Posey Cufflator each time before putting into use. Do not use if the needle is not on zero when not connected.
- The connecting tubing is intended for single use and must not be reused and/or reprocessed. Reprocessing influences the function of the connecting tubing. Any reuse entails a potential infection hazard.

#### CAUTION

- Federal law (USA) restricts this device to sale by or on order of a physician.
- This product must only be used by medically trained personnel.



The product is latex free.