

DESCRIPTION OF PRODUCT: Respiratory therapy – Endotracheal tube inflator and manometer

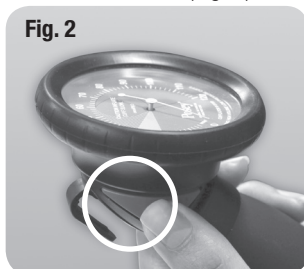
Rx ONLY

Instructions for Use

- The Posey Cufflator should only be used on tracheal tubes with high-volume, low-pressure cuffs. **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.
- Before use, the control inflator needs to be checked as follows:
 - Close connecting piece with the finger (Fig. 1).
 - Inflate with inflation bulb to 120 cm H₂O; value must be constant for 2-3 seconds. If the pressure drops, the device needs repair by the Posey Company.
 - Inspect the unit and check the cuff for leaks prior to use. Prior to intubation or extubation, withdraw all the air from the cuff with a syringe and close the inflation line.
- To properly seal:
 - Connect the patient to the ventilator.
 - Connect the Posey Cufflator to the cuff inflation line, and inflate the cuff to a pressure in the range of 60-90 cm H₂O. This will ensure that the cuff is in close contact with the tracheal wall.
 - 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 at a minimum of 20-25 cm H₂O to reduce the occurrence of microaspiration¹ and a maximum of 34 cm H₂O to decrease the incidence of mucosal ischemia and subsequent stenosis.²
- 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.
- The accuracy of the Posey Cufflator may be verified by connecting it to a mercury sphygmomanometer. **Note:** The Posey Cufflator is calibrated in cm of water pressure (H₂O). The conversion rate is 1 mm of mercury (Hg) equals 1.36 cm water (H₂O). For example, the Posey Cufflator will read 20 cm H₂O when the mercury sphygmomanometer reads 14.7 mmHg.
- The accuracy of measurements is ± 2 cm H₂O for the entire range.

WARNING Do not use with saline.

WARNING If the Posey Cufflator is used out of calibration, it may lead to incorrect readings.



Cufflator

REF 8199 Cufflator, complete with extension tube

Cleaning Instructions

Wipe the surface thoroughly with an alcohol-based disinfectant. Do not submerge the Posey Cufflator, and do not autoclave. The Posey Cufflator face should be cleaned with a glass cleaner only.

Storage

- This device is designed for use in normal indoor environments.
- This device may be stored in ambient warehouse temperatures at normal humidity levels. Avoid excess moisture or high humidity that may damage product materials.

Disposal

WARNING Dispose of per facility policy for BIOHAZARDOUS material. Be sure to follow all laws that apply.

Service/Repair

The Posey Cufflator should be calibrated annually. If measurements fall outside of the range, or if the Cufflator needle does not indicate a reading of zero when nothing is connected, or if the unit is ever dropped, calibration is recommended.

Cufflator 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 repair or 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. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

WARNING Never open the Posey Cufflator body. If the Posey Cufflator body is opened, any damages that result will not be covered under warranty.

Obtaining Warranty Service

Service under this warranty is available by contacting the Posey Customer Service hotline (1.800.447.6739 or 1.626.443.3143) for a return authorization, and by sending the product to Posey in clean condition, freight pre-paid, and with a dated proof of purchase.

WARNING 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.

CAUTION Federal law (USA) restricts this device to sale by or on order of a physician.

¹ Elpern EH. Pulmonary aspiration in hospitalized adults. *Nutr Clin Pract.* 1997;12(1):5-13.

² Hill BB, Zweng TN, Maley RH et. al. Percutaneous dilational tracheostomy: report of 356 cases. *J Trauma.* 1996;40:238-245.

For additional information see Stauffer, J.L. Complications of endotracheal intubation and tracheotomy. *Respir Care.* 1999;44(7):828-844.