

Stylet – Tracheal Tube / Endotracheal Tube Introducer

Federal (USA) Law restricts this device to sale by or on the order of a physician or any other practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Intended Use:

Stylet – Tracheal Tube / Endotracheal Tube Introducers are used to assist / facilitate oral endotracheal tube intubation, where the visualisation of the glottis is inadequate. All physicians using this device should be trained and experienced in airway management techniques. Appropriate techniques for placement of an endotracheal tube should be employed.

Description / Features:

1. Controllable tip to facilitate placement through the vocal chords.
2. Centimetre markings.
3. Fluorescent flexible tip to confirm placement of catheter through vocal chords
4. Smooth tip to minimize trauma during intubation.

Contraindications:

Not to be used with a double lumen endotracheal tube
Not to be used with nasopharyngeal endotracheal tubes

Warnings/Cautions:

1. Inspect devices prior to use for damage during shipment or storage.
2. Retain original package for patient record.
3. Inspect device immediately upon removal from the patient for any signs of breakage or fragmentation.
4. Insertion of Stylet – Tracheal Tube / Endotracheal Introducers should not extend beyond the carina.
5. Do NOT use lubricants with a petrochemical base.
6. Single use only. Do not re-use.
7. Do not re-sterilize. Re-sterilization, particularly the use of rubbing alcohol (70% isopropyl) for cleaning may degrade and weaken the surface/coating of device and change the physical characteristics of the material.
8. Exposure to elevated temperatures and ultraviolet light should be avoided during storage.
9. Sterile if package is not opened or damaged. Do not use the device if package is opened or damaged.
10. The tip of the device may be damaged if there is insufficient lubrication during insertion and withdrawal.
11. If the device encounters increased resistance during insertion or withdrawal of the device, investigate the cause of the resistance before continuing. If the cause of the resistance cannot be determined and corrected, discontinue the procedure and withdraw the device.

Sizing:

Recommended use with an oral endotracheal tube of 7mm - internal diameter or larger.

Technique:

1. Apply a generous amount of water-based lubricant to the silicone tip of the Flexible Tip Stylet (Bougie) (fluorescent part).
2. Using direct or video laryngoscopy, introduce the tip of the introducer through the vocal cords.
3. The tip of the introducer can be manoeuvred by a combination of proximal or distal pressure on the tip control tabs located along the underside of the introducer and rotation of the introducer.
4. Once the vocal chords have been negotiated the tip should be advanced. Further information regarding the depth of insertion may be taken from the centimetre markings on the introducer.
5. Once satisfied with the position of the introducer, the endotracheal tube can be loaded and advanced to the desired position.
6. Maintain the endotracheal tube position whilst removing the introducer. The position of the endotracheal tube can be validated using standard clinical techniques

LOT Batch Number for the Goods **Use By / Expiry Date** **STERILIZED** Sterilized By Gamma Irradiation Keep Away from Sunlight

Date of Manufacturing **REF** Catalogue No. Keep Dry Storage Temperature Range

Manufacturer **EC** **REP** Authorized representative in European Community Consult instructions for use

Do not use if package is damaged Do not reuse **Rx Only** Prescription



GMMI SDN BHD

No.12, Persiaran Industri Rapat 2,
Perindustrian Ringan Sri Rapat,
31350 Ipoh, Perak, Malaysia.
www.gmmi-med.com

Tel: +605-3131912
Fax: +605-3131913

Registration number: GA5778520-41194