



TTC INTUITIVE DEPTH BOUGIE™

INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION

The TTC Intuitive Depth Bougie™ is a 15 French, 70 cm long introducer. It has a rounded-tip with centimeter markings as well as color zonal markings to facilitate placement and use. The distal end of the introducer is angled with a rounded tip that can be passed with visualization into the trachea.

INTENDED USE

The TTC Intuitive Depth Bougie™ is intended to facilitate endotracheal intubation with Grades I or II Cormack-Lehane classifications (i.e. with a full or partial view of the glottis). The TTC Intuitive Depth Bougie™ has been designed for placement of a single lumen endotracheal tube whose inner diameter is 6 mm or larger.

Each TTC Intuitive Depth Bougie™ is intended for up to 1 minute of continuous use.

CONTRAINDICATIONS

- Not intended for use with Grade III or Grade IV Cormack-Lehane laryngoscopy classifications (i.e. the entrance to the trachea cannot be visualized).
- Do not use if unable to place a laryngoscope into patient's airway.
- Not intended for use in pediatric patients.
- Not intended for adults with abnormal lower airway anatomy.
- Not intended for use if unable to visualize the color-depth-zone system throughout the procedure.

- Do not use with double-lumen endotracheal or endobronchial tubes.

NOTES

- The product is intended for use by clinicians trained and experienced in airway management.
- If intubation cannot be completed, the ET tube and the introducer should be removed.
- Examine the patient's anatomy to help determine the optimal placement for the TTC Intuitive Depth Bougie™. Ensure the introducer is in the clinician-preferred location relative to the carina by referencing its centimeter markings or color-zoned-tip.

POTENTIAL COMPLICATIONS

- Trauma to the lungs, bronchial injury, or pneumothorax.
- Injury to the epiglottis and glottis, perforation of the sinus pyriformis, bronchus, or trachea.
- Bronchospasm.
- Unintended endobronchial intubation.
- Esophageal intubation.
- Introduction of foreign material into the lungs.

INSTRUCTIONS FOR USE

1. Lubricate an appropriately sized single lumen endotracheal tube and the introducer.
2. Using a laryngoscope, advance the tip of the introducer into the trachea. If resistance is encountered, do not force the introducer.

NOTE: During introduction you may feel the tracheal rings.

3. Insert the device into the trachea until the green zone of the color-depth-zone system is at the entrance to the trachea.
4. Place an endotracheal tube on the back of the introducer
5. While maintaining the green zone of the color-depth-zone system at the vocal cords, pass tube over introducer into the trachea.
6. While leaving ET tube in place, remove introducer.











NOTE: Examine the introducer for any missing material; if foreign material is suspected in the lungs, take appropriate action.

7. Remove laryngoscope.
8. Inflate the cuff of the ET tube (if present).
9. Ventilate patient.
10. Confirm proper placement of the endotracheal tube using standard methods (e.g. capnography, breath sounds, chest x-ray, visualization of entry into the trachea).

HOW SUPPLIED

Supplied sterilized by gamma radiation in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from the package, inspect the product to ensure no damage has occurred.

SYMBOLS

	Manufacturer		Do not re-use
	Catalogue number		Consult instructions for use
	Batch code		Sterilized using irradiation
	Date of manufacture		European Authorized Representative
	Use-by-date		Caution



MANUFACTURER

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