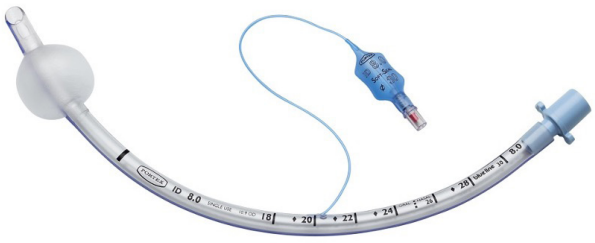
TECHNICAL SUMMARY SHEET

Portex™ Tracheal Tube, Clear PVC, Murphy Eye, Oral/Nasal, Profile™ SOFT-SEAL™ (Low Pressure/High Volume) Cuff



Device Classification

GMDN: 46967
Classification: Class IIa

Device Description

A range of sterile, single-use tracheal tubes for oral or nasal intubation intended for airway management. Manufactured from clear polyvinyl chloride (PVC), incorporating the following features:

- Thermosensitive materials with sufficient initial rigidity for intubation which then conforms to the individual patient's respiratory tract at body temperature ensuring minimum trauma
- Radiopaque Blue Line™ to confirm correct tube placement by X-ray
- Smooth Murphy eye
- As a reference during intubation, the tracheal tubes have depth marks in centimeters, which indicate the distance to distal tip.
- Packed with a 15 mm connector conforming to ISO 5356 and ISO 7228

Product is sterile unless the unit pack is opened or damaged.

Indications

Portex tracheal tubes are intended for oral and/or nasal intubation for airway management.

As per Instructions for Use

1. The integrity of the cuff and inflation system should be checked prior to insertion.
2. Firmly insert the 15 mm connector provided into the tracheal tube.
3. Intubate the patient orally or nasally following currently accepted medical techniques. The intubation depth mark may be used as a guide for correct placement of the tube.
4. Inflate the cuff with the minimum amount of air to provide an effective seal.

Contraindications

There are no known contraindications for this device.

Precautions

1. The security of all breathing system connectors should be checked when the breathing circuit is established and frequently thereafter.
2. Patients should be adequately humidified to minimise encrustation of the tracheal tube lumen and prevent tracheal mucosal damage.
3. The patency of the tracheal tube lumen must be assured by regular suctioning. Check routinely and replace as required to maintain a patent airway. Maximum recommended period of use is 30 days.
4. Cuff pressure and volume should be monitored and adjusted routinely.
5. Devices used in/or during inflation of the cuff must be clean and free from all foreign matter. The inflation device must be removed from the inflation valve immediately after use.
6. Guard against cuff damage by avoiding contact with sharp edges. If cuff is damaged, patient should be reintubated and the damaged tube discarded.
7. The inflation line valve may interfere with magnetic resonance imaging (MRI) picture clarity. Ensure the valve is positioned away from the area being scanned.
8. Repositioning and movement of the in situ tracheal tube, while the cuff is inflated, should be avoided.
9. In the event that unusual positioning of the head or neck is to be required following intubation, use of a reinforced tube should be considered to avoid the potential for kinking.
10. Following intubation, the tracheal tube should be properly secured to help eliminate undesirable movement
11. Follow standard infection control procedures as specified by the Centers for Disease Control and Prevention (USA), or local equivalent.

Component Composition

- Tracheal tube: Clear PVC
- Radiopaque Blue Line: Comprised of a barium sulfate (BaSO4)
- 15 mm connector: Polypropylene
- Inflation line and pilot balloon: PVC
- Profile SOFT-SEAL cuff: PVC
- One-way luer-check valve: PVC with polyester, nitrile, and stainless-steel elements

This device does not contain latex.

This device is not manufactured using derivatives of tissues or cells of animal origin.

Legal Manufacturer Name and Address

ICU Medical, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442 USA

Country of Origin

Mexico

Sterilisation Method

Ethylene oxide

Shelf Life

5 years

Labelling and Packaging

Container type	Length (mm)	Width (mm)	Height (mm)
Single unit	317	135	24.5
Shelf carton (20 units)	195	156	320
Transit carton (120 units)	494	399	328

One (1) tracheal tube unit is packaged per each individual in a form-fill-seal unit pack. Twenty (20) units are packed per shelf carton, and six (6) shelf cartons are packed per transit carton. The label is printed with product specific information. Product is sterile, nontoxic and non-pyrogenic unless package is open, wet, or damaged. Discard if open, wet, or damaged.

Storage

Store in a dry and clean area.

Product Specifications

Tracheal Tube, Clear PVC, Murphy Eye, Blue Line, Profile Soft-Seal (Low Pressure, High Volume)					
Item Number	I.D. (mm)	O.D. (mm)	Length (mm)	Cuff Ø	Units per Case
100/199/050	5.0	6.9	250	17	20
100/199/055	5.5	7.6	280	17	20
100/199/060	6.0	8.2	290	23	20
100/199/065	6.5	8.9	300	23	20
100/199/070	7.0	9.6	310	30	20
100/199/075	7.5	10.3	320	30	20
100/199/080	8.0	10.9	330	30	20
100/199/085	8.5	11.6	330	30	20
100/199/090	9.0	12.3	330	30	20
100/199/095	9.5	13.0	330	30	20
100/199/100	10.0	13.7	330	34	20

For more information, visit www.icumed.com or call +44 (0)845 850 0445

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The product complies with current legislation and has the corresponding CE marking (2797). For additional information, warnings and/or safety precautions, refer to the manufacturer's Instructions for Use.