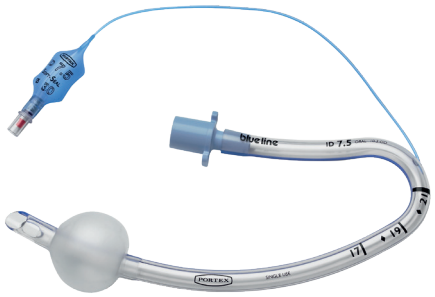
TECHNICAL SUMMARY SHEET

Portex™ Tracheal Tube

Polar™ Preformed, Clear PVC, South Facing, Oral, Profile™ SOFT-SEAL™ (Low Pressure/High Volume) Cuff, Murphy Eye



Device Classification

GMDN: 46967
Classification: Class IIa

Device Description

A range of sterile, single-use preformed tracheal tubes for oral use manufactured from clear polyvinyl chloride (PVC) incorporating the following features:

- Anatomically shaped design with a preformed curve at the point where the tube emerges from the patient's mouth or nose with radiopaque Blue Line™ to confirm correct tube placement by X-ray.
- Packed with a 15 mm connector conforming to ISO 5356 and ISO 7228.
- The intubation depth mark on the tube indicating position at the teeth or nares is for guidance only. The depth of insertion of the tube is therefore subject to clinical judgement.

Sterile unless the unit pack is opened or damaged.

Indications

Portex Polar preformed tracheal tubes are intended for airway management during surgical procedures involving the head, neck or mouth where it would be advantageous to remove all connections from the operative field.

Contraindications

There are no known contraindications.

Precautions

1. The security of all breathing system connections 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 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.
12. The use of topical aerosol anaesthetic agents has been associated with the formation of pinholes in PVC cuffs.

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Component Composition

- Tracheal tube: Clear PVC
- Radiopaque Blue Line: Barium sulphate (BaS04) strip
- 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 contains plasticiser diethylhexylphthalate (DEHP).
This device is not made with natural rubber 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 (EO)

Shelf Life

5 years

Labelling and Packaging

Container Type	Length (mm)	Width (mm)	Height (mm)
Single Unit	240	140	19.5
Shelf Carton (10 units)	246	90	286
Transit Carton (100 units)	494	399	365

One unit is packaged per blister packet. Ten units are packaged per shelf pack. Ten shelf cartons are packaged per transit carton, for a total of one-hundred units. Product is single use, sterile and latex-free. Discard if open, wet or damaged. Product should be kept out of direct sunlight.

The lot number, manufacturing date and expiration date are located on the single-unit, shelf pack and transit carton labels.

Product Specifications

Portex Tracheal Tube, Polar Preformed, Clear PVC, South Facing, Oral, Profile SOFT-SEAL (Low Pressure/High Volume) Cuff, Murphy Eye					
Item Number	I.D. (mm)	O.D. (mm)	Length (mm)	Cuff Ø (mm)	Units per Case
100/136/050	5.0	6.9	240	17	10
100/136/055	5.5	7.6	252	17	10
100/136/060	6.0	8.2	265	23	10
100/136/065	6.5	8.9	280	23	10
100/136/070	7.0	9.6	300	30	10
100/136/075	7.5	10.3	315	30	10
100/136/080	8.0	10.9	330	30	10
100/136/085	8.5	11.6	345	30	10
100/136/090	9.0	12.3	360	30	10

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.

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