TECHNICAL SUMMARY SHEET

Portex™ Polar™ Preformed Tracheal Tube Clear PVC, South Facing, Oral, Uncuffed, 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.
- All Portex tracheal tubes are packed with a 15 mm connector conforming to ISO 5356, BS EN 1782:1998+A1:2009.

Sterile unless the unit pack is opened or damaged.
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.

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 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. 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.
5. Following intubation, the tracheal tube should be properly secured to help eliminate undesirable movement.
6. Follow standard infection control procedures as specified by the Centers for Disease Control and Prevention (USA), or local equivalent.
7. The use of topical aerosol anaesthetic agents has been associated with the formation of pinholes in PVC cuffs.

Component Composition

- Tube: Clear PVC

This device contains plasticiser diethylhexylphthalate (DEHP).
This device does not contain 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

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Country of Origin

Mexico

Sterilisation Method

Ethylene oxide (EO)

Shelf Life

5 years

Labelling and Packaging

100/134/030_050			
Container Type	Length (mm)	Width (mm)	Height (mm)
Single Unit	165	105	19.5
Shelf Carton (10 Units)	143	90	170
Transit Carton (220 units)	945	290	215

100/134/055_075			
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 pack. Ten units are packaged per shelf carton. For sizes 3.0 mm to 5.0 mm, twenty-two shelf cartons are packaged per transit carton, for a total of two-hundred-twenty units. For sizes 5.5 mm to 7.5 mm, 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 blister, shelf pack and transit carton labels.

Product Specifications

Portex Polar Preformed Tracheal Tube, Clear PVC, South Facing, Oral, Uncuffed, Murphy Eye				
Product Code	ID (mm)	OD (mm)	Length (mm)	Units per Case
100/134/030	3.0	4.2	170	10
100/134/035	3.5	4.8	175	10
100/134/040	4.0	5.5	195	10
100/134/045	4.5	6.2	215	10
100/134/050	5.0	6.9	220	10
100/134/055	5.5	7.6	230	10
100/134/060	6.0	8.2	240	10
100/134/065	6.5	8.9	250	10
100/134/070	7.0	9.6	275	10
100/134/075	7.5	10.3	290	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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