TECHNICAL SUMMARY SHEET

Portex™ Tracheal Tube

Ivory PVC, Oral/Nasal, Uncuffed

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 Ivory 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
- Packed with a 15 mm connector conforming to ISO 5356 and ISO 7228

Sterile unless the unit pack is opened or damaged.

Indications

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

Contra-Indications

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

- Tracheal tube: PVC Ivory
- Radiopaque Blue Line line: Barium sulphate (BaS04) strip

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.

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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

100/105/025-045			
Container Type	Length (mm)	Width (mm)	Height (mm)
Single Unit	240	105	22
Shelf Carton (10 units)	149	90	245
Transit Carton (100 units)	450	300	248

100/105/050-090			
Container Type	Length (mm)	Width (mm)	Height (mm)
Single Unit	350	140	22
Shelf Carton (10 units)	199	82	365
Transit Carton (120 units)	494	399	365

One unit is packaged per blister pack. Ten units are packaged per shelf carton. For the sizes 2.5 mm to 4.5 mm, ten shelf cartons are packaged per transit carton, for a total of one hundred units. For sizes 5.0 mm to 9.0 mm, twelve shelf packs are packaged per transit carton, for a total of one-hundred-twenty units. Product is sterile and single use, unless package is open, wet or damaged. Keep away from sunlight. Discard if open, wet or damaged. The lot number, manufacturing date and expiration date are located on each label.

Product Specifications

Portex Tracheal Tube, Ivory PVC, Oral/Nasal, Uncuffed				
Item Number	I.D. (mm)	O.D. (mm)	Length (mm)	Units per Case
100/105/025	2.5	3.7	150	10
100/105/030	3.0	4.4	170	10
100/105/035	3.5	5.1	190	10
100/105/040	4.0	5.9	210	10
100/105/045	4.5	6.6	230	10
100/105/050	5.0	7.3	250	10
100/105/055	5.5	8.0	280	10
100/105/060	6.0	8.8	290	10
100/105/065	6.5	9.5	300	10
100/105/070	7.0	10.2	310	10
100/105/075	7.5	10.9	320	10
100/105/080	8.0	11.6	330	10
100/105/085	8.5	12.4	330	10
100/105/090	9.0	13.1	330	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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