TECHNICAL SUMMARY SHEET

Portex™ Tracheal Tube, Siliconised 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 for airway management. Manufactured from siliconised 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™ line to confirm correct tube placement by X-ray
- 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.

Contraindications

There are no contraindications for this product.

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 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.

icumedical
human connections

Component Composition

- Tracheal tube: siliconised PVC
- Radiopaque Blue Line: barium sulfate ($BaSO_4$) strip
- 15 mm connector: polypropylene

This device does not contain natural rubber latex.
This device is not manufactured using derivatives of tissues or cells of animal origin.
This device contains plasticiser diethylhexylphthalate (DEHP).

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

100/111/020 to 100/111/045			
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

100/111/050 to 100/111/090			
Container Type	Length (mm)	Width (mm)	Height (mm)
Single unit	350	140	22
Shelf carton (10 units)	199	82	365
Transit carton (100 units)	494	399	365

One (1) tracheal tube unit is packaged per each individual in a form-fill seal unit pack. Ten (10) units are packaged per shelf carton. Ten (10) shelf cartons are packaged per transit carton.
The lot number, manufacturing date and expiration date are located on the single, shelf and transit labels. Discard if open, wet or damaged. Product should be kept out of direct sunlight.

Product Specifications

Tracheal Tube, Siliconised PVC, Oral/Nasal, Uncuffed				
Item Number	I.D. (mm)	O.D. (mm)	Length (mm)	Units per Case
100/111/020	2.0	3.0	140	10
100/111/025	2.5	3.5	150	10
100/111/030	3.0	4.2	170	10
100/111/035	3.5	4.8	190	10
100/111/040	4.0	5.5	210	10
100/111/045	4.5	6.2	230	10
100/111/050	5.0	6.9	250	10
100/111/055	5.5	7.6	280	10
100/111/060	6.0	8.2	290	10
100/111/065	6.5	8.9	300	10
100/111/070	7.0	9.6	310	10
100/111/075	7.5	10.3	320	10
100/111/080	8.0	10.9	330	10
100/111/085	8.5	11.6	330	10
100/111/090	9.0	12.3	330	10

The product complies with current legislation and has the corresponding CE marking (CE2797).
For additional information, warnings and/or safety precautions, refer to the manufacturer's Instructions for Use.

icumedical
human connections

 |

+44 (0)845 850 0445 | www.icumed.com