TECHNICAL SUMMARY SHEET

Portex™ Reinforced Tracheal Tube

Profile™ SOFT-SEAL™ Cuffed, Murphy Eye

Device Classification

GMDN: 46569
Classification: Class IIa

Device Description

A range of sterile, single-use reinforced tracheal tubes with a wire-reinforced (radiopaque) clear polyvinyl chloride (PVC) shaft, for airway management during anaesthesia to reduce the risk of the tube kinking when the patient's head or neck is in an extended or flexed position, for example during neuro, orthopaedic or ENT surgery.

All Portex tracheal tubes are packed with a 15 mm connector conforming to ISO 5356.

Sterile unless unit pack is opened or damaged

Indications

1. The Portex reinforced tracheal tubes with cuff are designed for oral or nasal intubation for airway management during anaesthesia. The product may be used where the patient's neck is likely to be moved or flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.
2. For oral or nasal intubation, for airway management in cases of difficult intubation where a reinforced tracheal tube may be beneficial

Contraindications

There are no known contraindications.

Precautions

1. Reinforced tracheal tubes must not be cut to length because it will expose the metal reinforcing wire, and the bonded integral 15 mm connector cannot be removed from the tube and reinserted.
2. Insertion and removal of the lubricated intubation stylet and integrity of the tube, cuff and inflation system should be checked prior to intubation.
3. The security of all breathing system connections should be checked when the circuit is established and frequently thereafter.
4. Patients should be adequately humidified to minimise encrustation of the tracheal tube lumen and prevent mucosal damage.
5. Intubation stylets and suction catheters require lubrication with a suitable sterile, water-based lubricant prior to use.
6. The patency of the tracheal tube lumen must be assured by regular suctioning. Maximum recommended period of use is 30 days.
7. Devices used in or during inflation of the cuff must be clean and free from all foreign matter and must be removed from the inflation line check valve following use.
8. Guard against cuff damage by avoiding contact with sharp edges. If cuff is damaged, patient should be reintubated and the damaged tube discarded.
9. Repositioning and movement of the in situ tracheal tube, while the cuff is inflated, should be avoided.
10. Following intubation, the tracheal tube should be properly secured to help eliminate undesirable movement.
11. The use of topical aerosol anaesthetic agents has been associated with the formation of pin holes in PVC cuffs.
12. Follow standard infection control procedures as specified by the Centers for Disease Control and Prevention (USA), or local equivalent.

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Component Composition

- Tracheal tube: Clear PVC
- Spring: Stainless steel
- 15 mm connector: Acrylic
- Profile SOFT-SEAL cuff: 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.

- MRI Compatibility: MR Unsafe

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 (100/110/050-055)	440	70	-
Single unit (100/110/060-095)	510	70	-
Shelf carton (5 units)	442	86	52
Transit carton (50 units)	445	272	184

One unit packaged per pouch. Five units packaged per shelf carton. Ten shelf cartons are packaged per transit carton, for a total of fifty 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 carton and transit carton labels.

Product Specifications

Portex Reinforced Tracheal Tube, Profile SOFT-SEAL Cuffed, Murphy Eye					
Item Number	ID (mm)	OD (mm)	Length (mm)	Cuff Ø (mm)	Units per Case
100/110/050	5.0	8.2	259	17	5
100/110/055	5.5	8.6	287	17	5
100/110/060	6.0	9.1	297	23	5
100/110/065	6.5	9.8	307	23	5
100/110/070	7.0	10.4	318	30	5
100/110/075	7.5	11.1	328	30	5
100/110/080	8.0	11.9	338	30	5
100/110/085	8.5	12.4	338	30	5
100/110/090	9.0	13.1	338	30	5
100/110/095	9.5	13.7	338	30	5

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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