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Blue Line Ultra® Paediatric Tracheostomy Tube

Technical Summary Sheet

DEVICE CLASSIFICATION

GMDN: 35404

EU: Class IIb

Australia: Class IIb

Canada: Class II

DESCRIPTION AND PRODUCT CODES

The Blue Line Ultra® paediatric tracheostomy tube with cotton tape incorporates the following features:

- Thermosensitive material with sufficient initial rigidity intubation that conforms to the individual patient's upper respiratory tract at body temperature
- Anatomically shaped design with radio-opaque blue line to confirm correct tube placement by X-ray
- 15 mm connector allows attachment of humidification device and/or ventilation equipment
- Disconnection of tracheostomy tubes from breathing system may be facilitated with use of a disconnection wedge
- Maximum recommended period of use is 29 days
- Do not re-sterilize the Blue Line Ultra® paediatric tracheostomy tube by any method
- Designed and provided as sterile, single-use, DO NOT REUSE

Patient Category	Intended delivered Tidal Volume (Vt)
Adult	Vt ≥ 300 mL
Paediatric	50 mL <Vt <300 mL
Neonatal	Vt ≤ 50 mL

PRODUCT RANGE:

Product code	Tube I.D. (mm)	Tube O.D. (mm)	Length (mm)
101/506/030	3.0	4.2	35.8
101/506/035	3.5	4.9	39.3
101/506/040	4.0	5.5	42.7
101/506/045	4.5	6.2	46.2
101/506/050	5.0	6.9	49.7

INDICATIONS

Blue Line Ultra® paediatric tracheostomy tubes are indicated for airway maintenance of tracheostomised patients.

CONTRAINDICATION

- Do not use a decannulation cap with the above products because it may be difficult to remove in a critical or emergency situation, potentially resulting in obstruction of the patients airway.

WARNINGS

1. Avoid application of excessive rotational or linear forces on the tube during and after attachment of the breathing system to the tracheostomy tube connector, to prevent accidental disconnection or occlusion.
2. Secure all breathing systems connectors and check the breathing circuit is established and verify frequently thereafter.
3. Avoid contact with electro-surgery electrodes or laser surgery beams because PVC material will produce toxic fumes in air or ignite in an enriched oxygen environment (e.g. anaesthesia).
4. Guard against contact of tube with sharp edges to avoid tracheostomy tube damage.
5. Ensure the sterile lubricating jelly does not occlude the lumen of the tube, preventing ventilization of the patient.

PRECAUTIONS:

1. Must change tracheostomy tubes regularly to suit individual patient's needs. Maximum recommended period of use is 29 days.
2. Adequately humidify air delivered to patients to minimize mucus encrustation of the tracheostomy tube lumen.
3. The Blue Line Ultra® paediatric device is suitable for use with flammable anaesthetic agents/gases.
4. If tracheostomy tubes are used outside the hospital, the patient must be instructed by a healthcare professional in the safe use and handling of the product. Contact Smiths Medical Customer Service for *A Handbook for the Home Care of Your Child with a Tracheostomy.*

COMPONENT COMPOSITION

This device is not made with plasticizer Diethylhexylphthalate (DEHP). This device in not made with natural rubber latex. The tracheostomy tube, flange and blue connector are manufactured from Polyvinyl Chloride (PVC).

The blue line (stripe) is made from Polyvinyl Chloride (PVC) and radio-opaque material barium-sulphate.

The bezel (white connector) is manufactured from Acetal.

PRODUCT COMPONENTS

The product package consists of a paediatric tracheostomy tube and cotton tape (neck strap). The tube is manufactured with a flange, blue line and a 15 mm connector. The flange has eyelet like openings for the cotton tape to be used to secure the tube to the patient's neck. The blue line is radio-opaque material for x-ray use. The 15 mm connector is for attachment to standard healthcare anaesthesia equipment for humidification and/or ventilation.

MANUFACTURING SITE NAME AND ADDRESS

Smiths Healthcare Manufacturing S.A. de C.V.
Ave Calidad No. 4,
Parque Industrial Internacional Tijuana
Tijuana, B.C. 22425, Mexico

COUNTRY OF ORIGIN

Mexico

ANIMAL ORIGIN

No animal origin

STERILISATION

The Blue Line Ultra® paediatric tracheostomy tube device is Ethylene Oxide (EO) sterilised and provided to the end user in a sterile package. The device remains sterile as long as the package integrity had not been compromised and/or the "use by date" not exceeded. The "use by date" and integrity of the outer tray/lid should be verified prior to use; if the "use by date" has expired or packaging is compromised, the tube must not be used. The Blue Line Ultra® paediatric tracheostomy tube must not be re-sterilised by the end user.

SHELF-LIFE

A 2-year expiration date is assigned to the product as long as the packaging is undamaged and unopened, based initially on accelerated aging stability studies followed by real time aging.

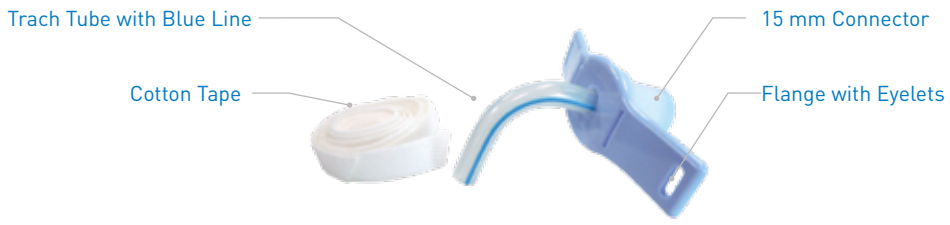
LABELLING AND PACKAGING

One (1) tracheostomy tube unit is packaged in a form-fill seal cavity with a coated 1073B Tyvek® lid and then placed inside a shelf carton. The Tyvek® lid is printed with product specific information. Product is sterile, non-toxic and non-pyrogenic unless package is open, wet, or damaged. Discard if open, wet, or damaged. Ten (10) units are packed per shelf carton and ten (10) shelf cartons are packed per transit carton. The lot number, manufacturing date, and expiration date are located on the unit pack, shelf carton and transit carton labels.

PACKAGING DIMENSIONS:

Container Type	Length	Width	Height
Shelf carton box (10 units)	150 mm	100 mm	220 mm
Transit carton (100 units)	310 mm	229 mm	522 mm

PRODUCT IMAGE:



PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

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