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Office: BEROMED GMBH HOSPITAL PRODUCTS · Kronenstrasse 19 · 10117 Berlin · Germany

Summary essential technical data - *BEROTUBE* Sterile endotracheal tube (reinforced) for Single Use

Manufacturer: Beromed GmbH Hospital Products
Kronenstraße 19
10117 Berlin
GERMANY

Product: Tracheal tube (endotracheal)

Brand: *BEROTUBE*

UMDNS code: 14-085

Risk Class: IIa according to Annex IX, rule 5 of Council Directive 93/42/EEC,
amended by Council Directive 2007/47/EC

Conformity assessment procedure: according to Annex V of Council Directive 93/42/EEC,
amended by Council Directive 2007/47/EC

Notified Body: TUEV Süd Product Service GmbH
Ridlerstraße 65
80339 Munich, Germany
Identification no 0123

Brief description of the product

A tracheal tube is used in general anaesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into the patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs.

The endotracheal tube is regarded as the most reliable available method for protecting a patient's airway.

Reinforced endotracheal tubes are characterized through their special kinking resistance thanks to a metal spring safely embedded in the tubus wall. The spring also facilitates radiographical control of the tubus' correct position.

BEROTUBE reinforced endotracheal tubes are available with and without cuff. The high volume low pressure cuff provides an effective and gentle low pressure seal.

The product is intended for short-term use.

BEROTUBE is sterile and pyrogen-free.

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| Registered Office: | Berlin |
| Managing Director: | Jörg Bartz |
| Commercial Registry: | Berlin-Charlottenburg HRB 65718 |
| VAT-No. | DE 812 404 118 |



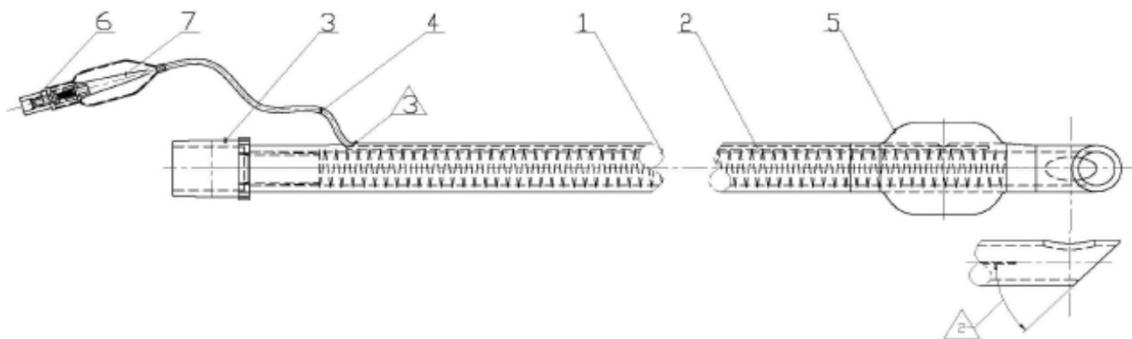
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Drawing and Material specifications::

A. Reinforced endotracheal tube with cuff

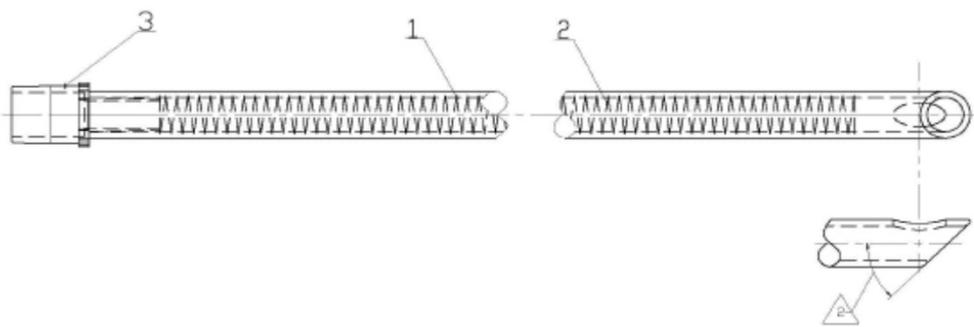


△ Angle of bevel: 45± 10°

| Component | Material |
|------------------|-----------------------------------------------|
| 1 Main Tube | Polyvinylchloride (PVC) |
| 2 Spring | stainless steel 302 |
| 3 Connector | Polypropylene (PP) |
| 4 Inflating tube | Polyvinylchloride (PVC) |
| 5 Cuff | Polyvinylchloride (PVC) |
| 6 Valve | PVC/ Stainless Steel / PP / ABS / Silicone |
| 7 Balloon | Polyvinylchloride (PVC) |

plasticizer: DOP (DEHP)

B. Reinforced endotracheal tube without cuff



△ Angle of bevel: 45± 10°

| Component | Material |
|-------------|-------------------------|
| 1 Main Tube | Polyvinylchloride (PVC) |
| 2 Spring | stainless steel 302 |
| 3 Connector | Polypropylene (PP) |

plasticizer: DOP (DEHP)

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Features:

For both nasal and oral intubation
Atraumatic soft rounded beveled tip
Highly resistant against kinking
High-volume low-pressure cuff provides
an effective low pressure seal
Soft rounded Murphy eye
Accurate depth marks
Standard connector
Radio-opaque line provided

Sterilization:

by Ethylene Oxide (EO)

Latex:

BEROTUBE reinforced endotracheal tube is latex-free

Shelflife:

5 years from the date of manufacture
dates of manufacture and expiry are printed on the individual package

Storage:

Store in a dry, cool and dark place

Precautions for use:

The operators should be professionally trained medical staff.

Check the integrity of the individual package before use. Do not use
if the package is damaged.

For single use only. To be used immediately when individual package is opened.

Discard after single use to avoid risk of infection.

Use within the validity period.

Do not use if the patient is known to develop an allergic reaction
to any of the material the product consists of.

Do not re-sterilize.

Do not re-use. Re-use of single-use devices creates a potential risk of patient or user.
It may lead to contamination and/or impairment of functional capability. Contamination
and/or limited functionality of the device may lead to injury, illness or death of the patient.

Plasticizer DOP (DEHP):

Animal experiments have shown DEHP to be potentially toxic to reproduction.
Given the current state of scientific knowledge, a risk (in case of long-term use) especially
for premature male babies cannot be completely excluded. As a precaution, the application
of medical products containing DEHP should be restricted to short-term use for pregnant
women, breastfeeding mothers, infants, and children.

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Packing data:

| | pieces per | dimensions (m) |
|---------------------------------------------|------------|-------------------------------------------------------------------------------|
| Individual packing (blister package) | 1 | until size 4.5: 0,27 x 0,1 from size 5.0: 0,343 x 0,149 |
| Inner box | 10 | until size 4.5: 0,275 x 0,105 x 0,080 from size 5.0: 0,35 x 0,155 x 0,090 |
| Export carton | 100 | until size 4.5: 0,420 x 0,290 x 0,230 from size 5.0: 0,459 x 0,370 x 0,340 |

Variants:

BEROTUBE, reinforced endotracheal tube, Murphy type

| Uncuffed | | | | |
|------------|-----------------------------------|---------------------------------|---------|---------------------------------|
| Article no | Size (inner diameter (mm)) ± 0.15 | Size (outer diameter (mm) ± 0,3 | CH / FR | Length of main tube (mm) ± 5 mm |
| B262415 | 3,0 | 5.3 | 12 | 175 |
| B262422 | 3,5 | 5.8 | 14 | 195 |
| B262439 | 4,0 | 6.3 | 16 | 215 |
| B262446 | 4,5 | 6.8 | 18 | 240 |
| B262453 | 5,0 | 7.3 | 20 | 256 |
| B262460 | 5,5 | 7.8 | 22 | 286 |
| B262965 | 6,0 | 8.4 | 24 | 295 |
| Article no | Size (inner diameter (mm)) ± 0.2 | Size (outer diameter (mm) ± 0,3 | CH / FR | Length of main tube (mm) ± 5 mm |
| B262972 | 6,5 | 9.0 | 26 | 301 |
| B262989 | 7,0 | 9.6 | 28 | 315 |
| Cuffed | | | | |
| Article no | Size (inner diameter (mm)) ± 0.15 | Size (outer diameter (mm) ± 0,3 | CH / FR | Length of main tube (mm) ± 5 mm |
| B262477 | 3,0 | 5.3 | 12 | 175 |
| B262484 | 3,5 | 5.8 | 14 | 195 |
| B262491 | 4,0 | 6.3 | 16 | 215 |
| B262507 | 4,5 | 6.8 | 18 | 240 |
| B262514 | 5,0 | 7.3 | 20 | 256 |
| B262521 | 5,5 | 7.8 | 22 | 286 |
| B262538 | 6,0 | 8.4 | 24 | 295 |
| Article no | Size (inner diameter (mm)) ± 0.2 | Size (outer diameter (mm) ± 0,3 | CH / FR | Length of main tube (mm) ± 5 mm |
| B262545 | 6,5 | 9.0 | 26 | 301 |
| B262552 | 7,0 | 9.6 | 28 | 315 |
| B262569 | 7,5 | 10.2 | 30 | 325 |
| B262576 | 8,0 | 10.8 | 32 | 337 |
| B262583 | 8,5 | 11.3 | 34 | 337 |
| B262590 | 9,0 | 11.9 | 36 | 337 |
| B263344 | 9,5 | 12.4 | 38 | 337 |
| B263351 | 10,0 | 13.6 | 40 | 337 |

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