

Tracoe Twist – REF 301-P

Tracheostomy tube with minimally traumatic inserter and low pressure cuff

Product Description

The Tracoe Twist tracheostomy tubes are used as ventilation and therapy tubes with inner cannulas in hospitals, rehabilitation, and community settings. A special feature is the curved neck flange that moves in both the vertical and horizontal axes, following the movements of the patient's head. The thin tube walls of inner and outer cannulas allow for a good inside - outside diameter ratio. Tracoe Twist and Twist Plus tracheostomy tubes are made of polyurethane (PU). The low-pressure cuff is made of medical grade PVC.



Scope of Supply

- 2 inner cannulas with 15 mm connector
- Reinsertion tube
- Lubricating gel
- Perforated obturator
- Neck strap

General Information

| | |
|--------------------------------------|---|
| Product line | Twist |
| Legal manufacturer | Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm, Germany |
| Country of origin | Germany |
| Colour Coding | REF 301-P |
| Handling | |
| Shelf life | 5 years, from date of production |
| Maximum Useful Life | 29 days, from first use |
| Maximum Useful Life Insertion System | single-use disposable product |

Packaging

| | |
|-----------------------------|---|
| Packaging unit | 1 unit |
| Weight | See Table |
| Dimensions (W x H x L) | 271 x 47 x 113 |
| Material outer packaging: | Cardboard box |
| Material sterile packaging: | Sterile bag with medical paper and transparent heatsealable PET/PP foil |

Material Specifications

| | |
|------------------------|-------------------|
| Material Outer cannula | Polyurethane |
| Material Neck Flange | Polycarbonate |
| Material Cuff | Polyvinylchloride |
| Biocompatibility | EN ISO 10993-1 |



Storage



Certification

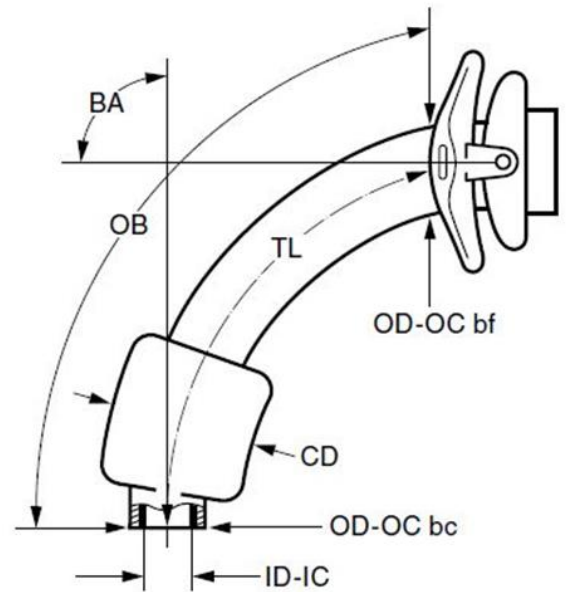
| | |
|---------------------------------|--------------|
| Product classification acc. MDR | IIb |
| CE Marking | |
| GMDN | 35404 |
| Quality system certified to | EN ISO 13485 |
| FDA registration | n. A. |

Product Range

| Size | Order Number | ID-IC | OD-OC bc | OD-OC bf | TL | OB | BA | CD | Gross Weight | Global Trade Item Number |
|------|--------------|-------|----------|----------|------|------|----|------|--------------|--------------------------|
| | | mm | mm | mm | mm | mm | ° | mm | g | |
| 07 | REF 301-07-P | 7,0 | 10,4 | 12,0 | 74,0 | 80,5 | 95 | 26,0 | 227 | 4035324015153 |
| 08 | REF 301-08-P | 8,0 | 11,4 | 12,7 | 76,0 | 83,0 | 90 | 28,0 | 229 | 4035324015160 |
| 09 | REF 301-09-P | 9,0 | 12,5 | 14,2 | 78,0 | 88,5 | 90 | 30,0 | 233 | 4035324015177 |

Legend

- ID-IC** Inside diameter at bottom of inner cannula
- OD-OC bc** Outside diameter at bottom of outer cannula
- OD-OC bf** Outside diameter of outer cannula behind the flange
- TL** Length along centre line from start of neck flange to bottom of tube
- OB** Length along outer bend from start of neck flange to bottom of tube
- BA** Bending angle
- CD** Cuff diameter



Tracoe Medical GmbH
 Reichelsheimer Str. 1 / 3
 55268 Nieder-Olm
 Germany

Atos Medical AB
 Hyllie Boulevard 17
 215 32 Malmö
 Sweden
www.atosmedical.com