

## Tracoe Twist Plus – REF 311

### Tracheostomy tube with low pressure cuff

#### Product Description

The Tracoe Twist Plus 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
- Perforated obturator
- Neck strap



#### General Information

|                     |                                                                                     |
|---------------------|-------------------------------------------------------------------------------------|
| Product line        | Twist Plus                                                                          |
| Legal manufacturer  | Tracoe Medical GmbH<br>Reichelsheimer Str. 1/3 55268<br>Nieder-Olm, Germany         |
| Country of origin   | Germany                                                                             |
| Colour Coding       | REF 311<br>++                                                                       |
| Handling            |  |
| Shelf life          | 5 years, from date of production                                                    |
| Maximum Useful Life | 29 days, from first use                                                             |

#### Material Specifications

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

#### Storage



#### Packaging

|                             |                                                                         |
|-----------------------------|-------------------------------------------------------------------------|
| Packaging unit              | 1 unit                                                                  |
| Weight                      | See Table                                                               |
| Dimensions (W x H x L)      | 210 x 113 x 50 mm                                                       |
| Material outer packaging:   | Cardboard box                                                           |
| Material sterile packaging: | Sterile bag with medical paper and transparent heatsealable PET/PP foil |

#### Certification

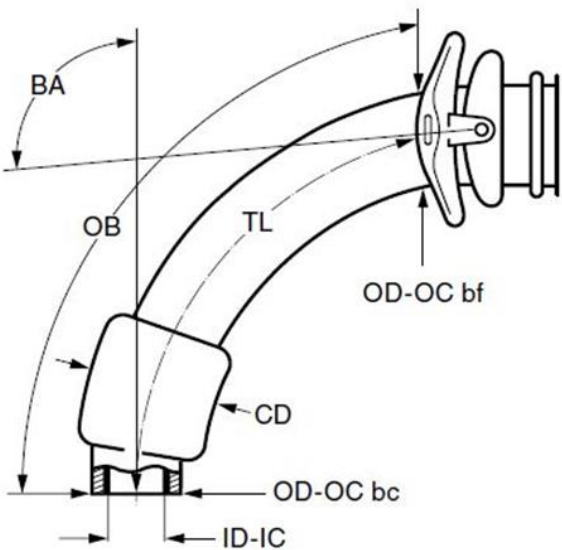
|                                 |                                                                                       |
|---------------------------------|---------------------------------------------------------------------------------------|
| Product classification acc. MDR | IIb                                                                                   |
| CE Marking                      |  |
| GMDN                            | 35404                                                                                 |
| Quality system certified to     | EN ISO 13485                                                                          |
| FDA registration                | Clearance Number K961449                                                              |

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  | θ°  | mm | g            |                          |
| 07   | REF 311-07   | 7,0   | 9,8      | 10,1     | 85 | 91  | 100 | 26 | 112          | 4035324017942            |
| 08   | REF 311-08   | 8,0   | 10,8     | 11,1     | 88 | 95  | 100 | 28 | 113          | 4035324017959            |
| 09   | REF 311-09   | 9,0   | 11,8     | 12,1     | 90 | 99  | 100 | 30 | 114          | 4035324017966            |
| 10   | REF 312-10   | 10,0  | 12,8     | 13,1     | 92 | 102 | 100 | 32 | 115          | 4035324017973            |

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



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