PRODUCT DATA SHEET



Tracoe Vario Extract – REF 470

Tracheostomy tube with adjustable neck flange, low-pressure cuff, subglottic suction, scale and 15 mm connector

Product Description

Tracoe Vario is a soft, flexible tube with an adjustable neck flange. By means of a practical push-button mechanism, the flange can be moved and individually adjusted for each patient. In this way, the correct length can be achieved. A scale ensures the exact positioning of the neck flange in preparation for a tube change. The flange is then locked in place by moving the orange lever upward. Locking with a twist lock is no longer necessary. Tracoe Vario tubes are made of DEHP-free, medical grade PVC and are available with and without sprial-reinforcement. The assortment includes both standard and extra-long versions.



Scope of Supply

- Obturator
- Adjustable neck strap
- Product info card with two detachable labels

| General Information | |
|---------------------|---|
| Product line | Vario Extract |
| Legal manufacturer | Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm, Germany |
| Country of origin | Germany |
| Colour Coding | REF 470 |
| Handling | |
| Shelf life | 5 years, from date of production |
| Maximum Useful Life | 29 days, from first use |
| | |

| Packaging | |
|-----------------------------|---|
| Packaging unit | 1 piece |
| 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 |

| Material Specifications | | | | | |
|-------------------------|-------------------|--|--|--|--|
| Material Outer cannula | Polyvinylchloride | | | | |
| Material Neck Flange | Polysulfone/ TPE | | | | |
| Material Cuff | Polyvinylchloride | | | | |
| Biocompatibility | EN ISO 10993-1 | | | | |
| RHP STERLE EO | | | | | |
| Storage *** | | | | | |

| Certification | |
|---------------------------------|--------------------------|
| Product classification acc. MDR | llb |
| CE Marking | (€ 0 1 2 3 |
| GMDN | 35404 |
| Quality system certified to | EN ISO 13485 |
| FDA registration | Clearence Number K203362 |

PRODUCT DATA SHEET



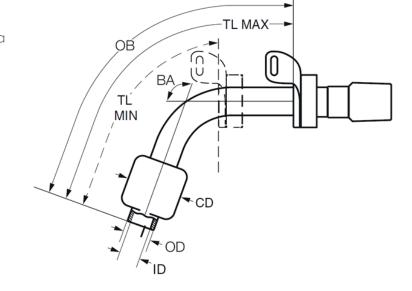
| Product Range | | | | | | | | | |
|---------------|-----------------|------|------|-----------------------|-----|-----|------|-----------------|-----------------------------|
| Size | Order Number | ID | OD | TL (TL Min-TL Max) | ОВ | BA | CD | Gross weight | Global Trade Item Number |
| | | mm | mm | mm | mm | Θ° | mm | g | |
| 07 | REF 470-07 | 7.0 | 9.7 | 55.0 – 70.0 | 86 | 100 | 23.0 | 177 | 04035324013005 |
| 08 | REF 470-08 | 8.0 | 11.2 | 63.0 - 83.0 | 97 | 100 | 28.0 | 182 | 04035324013029 |
| 09 | REF 470-09 | 9.0 | 12.3 | 64.0 - 91.0 | 106 | 100 | 30.0 | 184 | 04035324013036 |
| 10 | REF 470-10 | 10.0 | 13.7 | 64.0 – 99.0 | 120 | 100 | 32.0 | 189 | 04035324013043 |

Legend

CD

ID Inner diameter at bottom of cannula
OD Outer diameter at bottom of cannula
TL MIN Minimum length along centre line
TL MAX Maximum length along centre line
OB Length along outer bend
BA Bending angle

Cuff diameter





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

Breathing-Speaking-Living

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