

## Tracoe Vario – REF 450-P

Tracheostomy tube spiral-reinforced with minimally traumatic insertion system, adjustable neck flange, low-pressure cuff, 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 spiral-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   |
| Legal manufacturer                   | Tracoe Medical GmbH<br>Reichelsheimer Str. 1/3 55268<br>Nieder-Olm, Germany |
| Country of origin                    | Germany   |
| Colour Coding                        | <b>REF 450-P</b>  |
| 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 piece   |
| Weight                      | See Table   |
| Dimensions (W x H x L)      | 271 x 47 x 113 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    |
|                         |                   |

| Storage |  |
|---------|--|
|         |  |

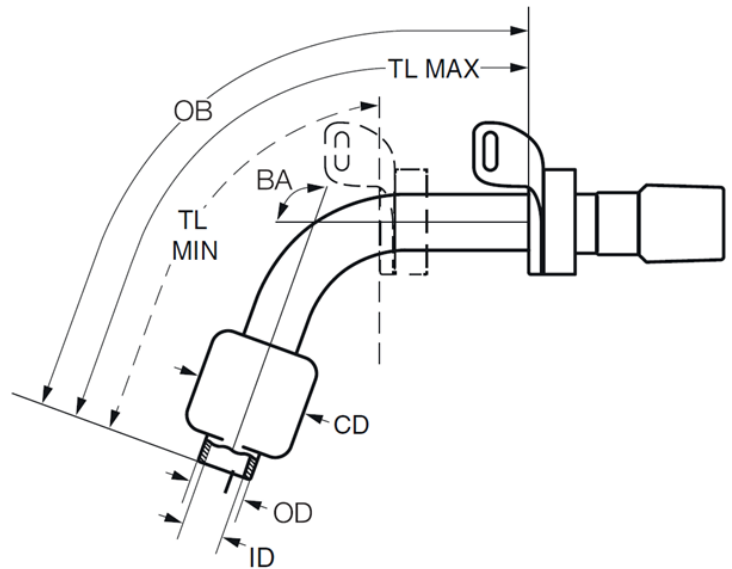
| Certification                   |                          |
|---------------------------------|--------------------------|
| Product classification acc. MDR | IIb                      |
| CE Marking                      |                          |
| GMDN                            | 47657                    |
| Quality system certified to     | EN ISO 13485             |
| FDA registration                | Clearance Number K203362 |

## Product Range

| Size | Order Number | ID  | OD   | TL<br>(TL Min-TL Max) | OB  | BA  | CD   | Gross weight | Global Trade Item Number |
|------|--------------|-----|------|-----------------------|-----|-----|------|--------------|--------------------------|
|      |              | mm  | mm   | mm                    | mm  | e°  | mm   | g            |                          |
| 07   | REF 450-07   | 7.0 | 9.7  | 53.0 – 68.0           | 86  | 100 | 23.0 | 193          | 04035324012282           |
| 08   | REF 450-08   | 8.0 | 11.2 | 64.0 – 84.0           | 97  | 100 | 28.0 | 197          | 04035324012299           |
| 09   | REF 450-09   | 9.0 | 12.3 | 66.0 – 93.0           | 106 | 100 | 30.0 | 200          | 04035324012305           |

## Legend

- 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
- CD Cuff diameter



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