

## Tracoe Vario XL – REF 461-P

Tracheostomy tube 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 XL
Legal manufacturer	Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm, Germany
Country of origin	Germany
Colour Coding	REF 461-P XL
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)	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
   	

Storage	
  	

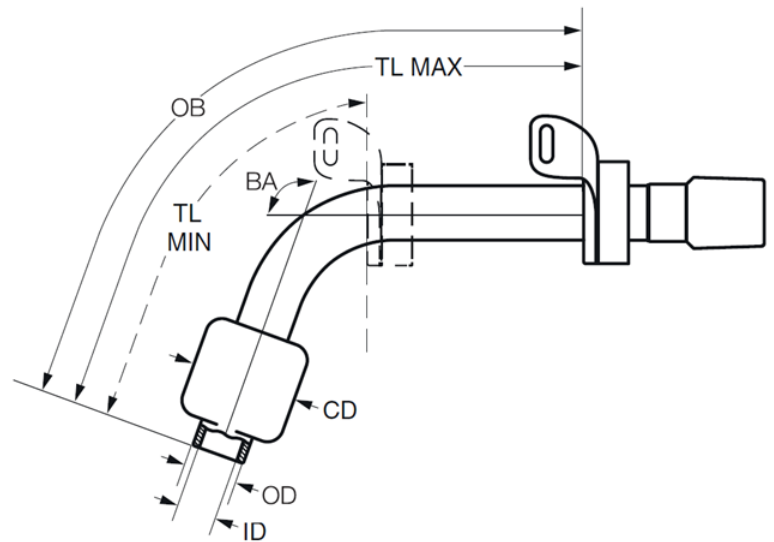
Certification	
Product classification acc. MDR	IIb
CE Marking	 0 1 2 3
GMDN	35404
Quality system certified to	EN ISO 13485
FDA registration	Clearance Number K203362

## Product Range

Size	Order Number	ID	OD	TL (TL Min-TL Max)	OB	BA	CD	Gross weight	Global Trade Item Number
		mm	mm	mm	mm	°	mm	g	
07	REF 461-07	7	9.7	64.5 – 97.5	110	100	23	237	04035324019298
08	REF 461-08	8	11.2	73.5 – 113.5	128	100	28	243	04035324019304
09	REF 461-09	9	12.3	78.0 – 123.0	134	100	30	245	04035324019328

## 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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Breathing-Speaking-Living

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