PRODUCT DATA SHEET



Tracoe Vario XL – REF 461

Tracheostomy tube spiral-reinforced, with 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 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 XL
Legal manufacturer	Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm, Germany
Country of origin	Germany
Colour Coding	REF 461 XL
Handling	STERNIZE (11) MR
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				
RHIT NATES STERLE EO					
Storage					
* * 10°C					

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

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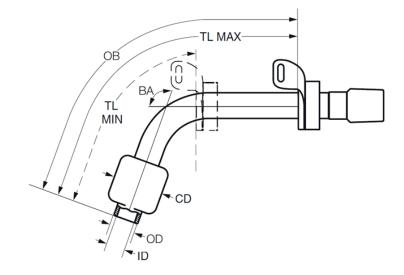


Product Range									
Size	Order Number	ID	OD	TL (TL Min-TL Max)	ОВ	BA	CD	Gross weight	Global Trade Item Number
		mm	mm	mm	mm	Θ°	mm	g	
07	REF 461-07	7.0	9.7	64.5 – 97.5	110	100	23.0	206	04035324018970
08	REF 461-08	8.0	11.2	73.5 – 113.5	128	100	28.0	211	04035324018987
09	REF 461-09	9.0	12.3	78.0 – 123.0	134	100	30.0	213	04035324018994
10	REF 461-10	10.0	13.7	84.5 – 129.5	146	100	32.0	217	04035324019007

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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