PRODUCT DATA SHEET



Tracoe Vario XL Extract - REF 471-P

Tracheostomy tube with minimally traumatic insertion system, 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 XL Extract				
Legal manufacturer	Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm, Germany				
Country of origin	Germany				
Colour Coding	REF 471-P XL				
Handling	STEPRIZE (11) AR				
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				

Material Outer cannula	Polyvinylchloride			
Material Neck Flange	Polysulfone/ TPE			
Material Cuff	Polyvinylchloride			
Biocompatibility	EN ISO 10993-1			
RHT STERLE EO				

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

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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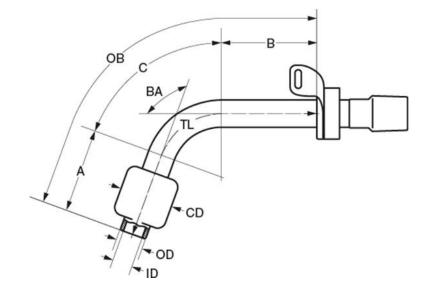


Produc	Product Range									
Size	Order Number	ID	OD	TL (TL Min-TL Max)	ОВ	BA	CD	Gross weight	Global Trade Item Number	
		mm	mm	mm	mm	Θ°	mm	g		
08	REF 471-08-P	8	11.2	73.0 – 113.0	128	100	28	235	04035324019335	
09	REF 471-09-P	9	12.3	73.5 – 118.5	134	100	30	236	04035324019342	

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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