PRODUCT DATA SHEET



Tracoe Vario XL Extract – REF 471

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 XL Extract
Legal manufacturer	Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm, Germany
Country of origin	Germany
Colour Coding	REF 471 XL
Handling	STENDEZE (11) AR
Shelf life	5 years, from date of production
Maximum Useful Life	29 days, from first use

1 piece
See Table
210 x 113 x 50 mm
Cardboard box
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					
RHT STERLE EO						
Storage						
★						

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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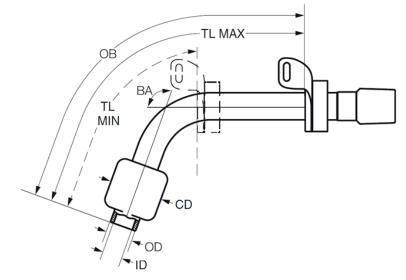


Product Range									
Size	Order Number	ID	OD	TL (TL Min-TL Max)	ОВ	BA	CD	Gross weight	Global Trade Item Number
		mm	mm	mm	mm	Θ°	mm	g	
07	REF 471-07	7.0	9.7	60.0 - 93.0	110	100	23.0	190	04035324019021
08	REF 471-08	8.0	12.3	73.0 – 113.0	128	100	28.0	196	04035324019038
09	REF 471-09	9.0	13.7	73.5 – 118.5	134	100	30.0	197	04035324019045
10	REF 471-10	10.0	14.8	80.0 – 125.0	146	100	32.0	202	04035324019052

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





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