# PRODUCT DATA SHEET



## Tracoe Vario Extract - REF 470-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.



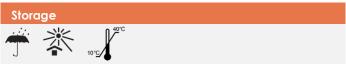
#### Scope of Supply

- Obturator
- Adjustable neck strap
- Product info card with two detachable labels

General Information	
Product line	Vario Extract
Legal manufacturer	TRACOE medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm, Germany
Country of origin	Germany
Colour Coding	REF 470-P
Handling	THE LAW TO THE
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				
RHT STER.LE EO					



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

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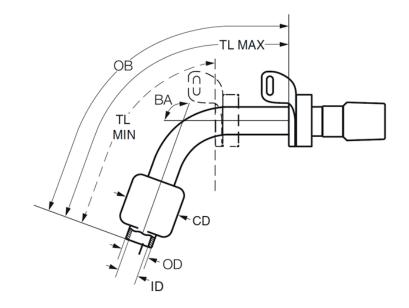


Product Range									
Size	Order Number	ID	OD	TL (TL Min-TL Max)	ОВ	BA	CD	Gross weight	Global Trade Item Number
		mm	mm	mm	mm	Θ°	mm	g	
08	REF 470-08-P	8.0	11.2	63.0 - 83.0	97	100	28.0	231	04035324017089
09	REF 470-09-P	9.0	12.3	64.0 - 91.0	106	100	30.0	234	04035324017096

### 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 ОВ Length along outer bend

ВА Bending angle Cuff diameter CD





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