PRODUCT DATA SHEET



Tracoe Speaking Valves – REF 650-TO

Tracoe Phon Assist I - Speaking valve with two infinitely adjustable side openings

Product Description

Speech is our most important means of communication, so losing one's voice after going through a tracheostomy highly affects the patient's life. Tracoe Phon Assist I speaking valve has infinitely adjustable airway resistance and offers therapeutic options, e.g. for weaning from ventilation, stimulation of the oropharyngeal region, and to produce voice.



General Information	
Product line	Speaking Valves
Legal manufacturer	Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm
Country of origin	Germany
Handling	STERUZE (11)
Shelf life	5 years, as from date of production
Maximum useful life	6 months

Material Specifications	
Material Flap	Silicone
Material housing	PP
Biocompatibility	EN ISO 10993-1
RHT STER,LE EO	

Packaging	
Packaging unit	1 piece
Weight	7 g
Dimensions (W x H x L)	144 x 40 x 80 mm
Material outer packaging:	Cardboard box
Material sterile packaging:	Sterile bag with medical paper and transparent heatsealable PET/PP foil

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Dimensions	
Height	38 mm
Diameter (incl. Oxygen support port) (machine end connector patient end)	26 mm (34 mm) / 15 mm

Certification	
Product classification acc. MDR	Is
CE Marking	((
GMDN	36071
Quality system certified to	EN ISO 13485
FDA registration	Clearance Number K043160 / D020866



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