	Technical data sheet	att.no.6 pt.1 subpt.1.1
	TD-40	Revision 3
	REINFORCED ENDOTRACHEAL TUBE CUFFED WITH PRELOADED STYLET	date: 2021-05-31 change of day: 2024-07-08

MEDICAL DEVICE DATA:			
CATALOGUE NUMBER	RIMZP-30, RIMZP-35, RIMZP-40, RIMZP-45, RIMZP-50, RIMZP-55, RIMZP-60, RIMZP-65, RIMZP-70, RIMZP-75, RIMZP-80, RIMZP-85, RIMZP-90, RIMZP-95, RIMZP-100		
MANUFACTURER	ZARYS International Group sp. z o.o. sp. k., Poland		
CLASSIFICATION	Ila	RULE	5
METHOD OF STERILIZATION	Ethylene oxide	CODE OF GENERIC DEVICE GROUP ACCORDING TO GMDN	46569
PERFORMANCE CHARACTERISTICS	<p>Device introduced through the nose or mouth into the trachea in order to:</p> <ul style="list-style-type: none"> - ensuring airway patency - performing artificial ventilation - preventing pulmonary aspiration of gastric contents and enabling its aspiration - administering medicines in cases of sudden cardiac arrest (alternative route) <p>Tube is used for intubation during surgical procedures requiring atypical position of the patient e.g. with bent or craned head (orthopaedic, neurosurgical, ENT procedures). Reinforcement used along the entire length of the tube prevents complete closure of the lumen in case of tube bending</p> <p>Endotracheal tube is inserted using a laryngoscope</p>		
CURRENT TECHNICAL STANDARDS ARE APPLICABLE TO THE DEVICE	<p>EN ISO 5356-1 Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets</p> <p>EN ISO 5361 Anaesthetic and respiratory equipment - Tracheal tubes and connectors</p> <p>EN ISO 15001 Anaesthetic and respiratory equipment -- Compatibility with oxygen</p>		

TECHNICAL DATA:	
RAW MATERIALS	<ul style="list-style-type: none"> ▪ tube – medical PVC ▪ reinforcement of the tube – SS (stainless steel) ▪ radiopaque line – BaSO₄ (barium sulphate) ▪ cuff – medical PVC ▪ inflation tube – medical PVC ▪ pilot balloon – medical PVC ▪ one-way valve – PVC + steel ▪ connector – PP (polypropylene) ▪ overprint/ink - Marastar SR ▪ intubation stylet – aluminium + PVC
COLOUR	<ul style="list-style-type: none"> ▪ tube – transparent ▪ reinforcement of the tube – natural steel ▪ radiopaque line – blue ▪ cuff – transparent ▪ inflation tube – blue ▪ pilot balloon – blue transparent ▪ one-way valve – transparent + white ▪ connector – blue ▪ overprint/ink – black ▪ intubation stylet - white
FEATURES	<ul style="list-style-type: none"> ▪ made of flexible PVC, ensuring high flexibility of the tube ▪ reinforcement molded into the body along the entire length of the tube ▪ radiopaque line over the entire tube length ▪ distal end with lateral Murphy's eye ▪ with an intubation stylet



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- tube size marked in 4 places (on the connector, on the pilot balloon and in two places on the tube body)
- double depth marker to control the position of the tube
- graduated every 1 cm
- low-pressure, high-volume cuff
- pilot balloon with LOT and size indication
- valve for inflating and deflating the cuff
- indissociable connector with an outer diameter of 15 mm
- latex-free
- contains phthalates
- single-use
- EO sterilized
- packaging: 1 pc./TYVEK-foil
- shelf life – 5 years

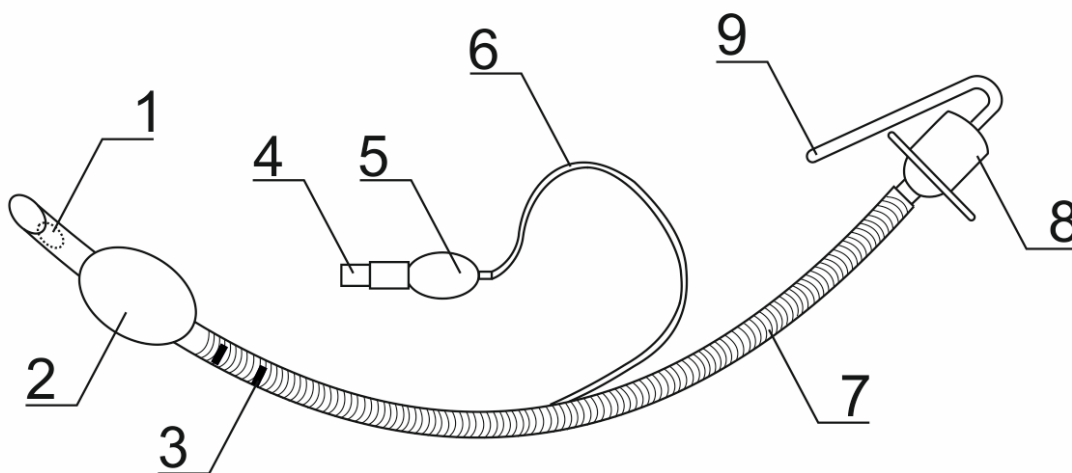
VARIABLES

n/a

SIZE

I.D. [mm]: 3.0; 3.5; 4.0; 4.5; 5.0; 5.5; 6.0; 6.5; 7.0; 7.5; 8.0; 8.5; 9.0; 9.5; 10.0

TECHNICAL DRAWING



DESCRIPTION OF PARTS OF THE PRODUCT AND ITS FUNCTION

1. lateral Murphy eye – alternative route for the breathing mixture in case of closure of the distal opening e.g. by adhesion to the tracheal wall
2. cuff – serves to seal the tube after placement in the airway, allows the tube to remain in the desired position
3. depth markers – facilitates verification of the position of the tube in the airway
4. valve – enables inflation of the cuff and retention of air in the control balloon, as well as its deflation
5. pilot balloon – allows control of the degree of filling of the cuff seal
6. inflation tube – tube transporting air to the sealing cuff
7. tube – transports the respiratory mixture to/from the lungs; has imprints: size indication, purpose, scaling, a radiopaque line on the entire length and molded-in reinforcement. Reinforcement along the entire length of the tube prevents complete closure of the lumen if the tube is bent



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8. connector – allows the tube to be connected to other medical devices intended to support ventilation
9. stylet - allows to give the endotracheal tube the right curvature

DETAILED
DIMENSIONS
/ SPECIFICATION

REF	SIZE	TUBE			CUFF	INFLATION TUBE	STYLET	CONNECTOR	
		OUTER DIAMETER O.D. (mm) / TOLERANCE	INNER DIAMETER I.D. (mm) / TOLERANCE	LENGTH (mm)	DIAMETER (mm)	LENGTH (mm)	SIZE - LENGTH (mm)	OUTER DIAMETER (mm)	LENGTH (mm)
RIMZP-30	3.0	4,7 ± 0,15	3,0 ± 0,15	165 ± 2	11	210	6FR - 310mm	15	39
RIMZP-35	3.5	5,5 ± 0,15	3,5 ± 0,15	185 ± 2	11	210	6FR - 310mm	15	39
RIMZP-40	4.0	6,0 ± 0,15	4,0 ± 0,15	210 ± 2	11	210	6FR - 310mm	15	39
RIMZP-45	4.5	6,7 ± 0,15	4,5 ± 0,15	225 ± 2	11	210	10FR - 410mm	15	39
RIMZP-50	5.0	7,3 ± 0,15	5,0 ± 0,15	245 ± 2	13	210	10FR - 410mm	15	39
RIMZP-55	5.5	8,0 ± 0,15	5,5 ± 0,15	275 ± 2	13	210	10FR - 410mm	15	39
RIMZP-60	6.0	8,7 ± 0,15	6,0 ± 0,15	285 ± 2	17	210	10FR - 410mm	15	39
RIMZP-65	6.5	9,3 ± 0,20	6,5 ± 0,20	295 ± 2	17	210	10FR - 410mm	15	39
RIMZP-70	7.0	10,0 ± 0,20	7,0 ± 0,20	310 ± 2	21	210	14FR - 410mm	15	39
RIMZP-75	7.5	10,5 ± 0,20	7,5 ± 0,20	315 ± 2	21	210	14FR - 410mm	15	39
RIMZP-80	8.0	11,0 ± 0,20	8,0 ± 0,20	330 ± 2	21	210	14FR - 410mm	15	39
RIMZP-85	8.5	11,6 ± 0,20	8,5 ± 0,20	330 ± 2	24	210	14FR - 410mm	15	39
RIMZP-90	9.0	12,0 ± 0,20	9,0 ± 0,20	330 ± 2	24	210	14FR - 410mm	15	39
RIMZP-95	9.5	12,7 ± 0,20	9,5 ± 0,20	330 ± 2	24	210	14FR - 410mm	15	39
RIMZP-100	10.0	13,3 ± 0,20	10,0 ± 0,20	330 ± 2	27	210	14FR - 410mm	15	39

PACKAGING

	number of pieces	packaging material	packaging dimensions
individual packaging	1 pc.	Foil-TYVEK	460 x 80 mm
intermediate packaging	10 x 1 pc.	cardboard	460 x 85 x 95 mm
bulk packaging	10 x 10 pcs	corrugated cardboard	460 x 200 x 490 mm

STORAGE
CONDITIONStemperature:
humidity:5°C - 40°C
30% - 80%