

MICROCUFF® PEDIATRIC ORAL-NASAL MAGILL ENDOTRACHEAL TUBE (EU MDR)

DISPOSABLE | SINGLE-USE | STERILE | DEHP FREE | LATEX FREE | MR CONDITIONAL

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Pediatric Oral-Nasal Endotracheal Tube, Magill
Manufacturer (Legal)	Well Lead Medical, LTD (Manufactured for AirLife)
Manufacturer Address	C-4 Jinhu Industrial Estate Hualong 511434 Panyu, Guangzhou People Republic of China
Made In	China
Classification – US	Class II
FDA Product Code	BTR – Tube, Tracheal (w/wo Connector)
Classification – Australia	Class IIb
Classification – Canada	Class II, Rule 2
Classification – European Union	Class IIa, Rule 5
CE Mark	CE 0123
EU Authorized Representative	Shanghai International Holding Corp
EMDN Code	R0103 – Endotracheal Tubes R010302 – Endotracheal Tubes with Cuff R01030201 – Endotracheal Tubes with Cuff, Not Reinforced
GMDN Code	46967 – Basic Endotracheal Tube, Single-Use
UMDNS Code	14085 – Tubes, Tracheal Tube
UNSPSC Code	42271903 – Endotracheal Tubes
Duration of Use	Single Use, should not be used for more than 28 days
Patient Population	Neonatal, Infant, Pediatric
Environment of Use	Hospitals, Surgery, Surgical Centers, Pre-Hospital
Sterility	Sterile, Ethylene Oxide (ETO), Tyvek Pouch
Packaging	Individually Packaged, 10/Box, 10/Case
Shelf Life	2 Years
Storage Conditions	Store in cool dry place, protect from moisture and excessive heat, avoid exposure to ultraviolet, sunlight and fluorescent light, store in a manner to prevent crushing
Disposal Instruction	Safely discard the used tracheal tube per your facility policy

Description: An endotracheal tube is a hollow cylinder inserted orally or nasally into the trachea to provide an unobstructed airway to convey gases and vapors to and from the lungs during anesthesia, resuscitation, or other conditions where a patient is not properly ventilated. Radio-opaque; Short, cylindrical cuff placed near the tracheal tube tip; anatomically based intubation depth mark; four precision bands for tube placement. Disposable, single patient, single-use.

Intended Purpose: The endotracheal tube is inserted into the trachea through the nose or mouth and is indicated for facilitating positive pressure ventilation and maintaining upper airway patency.

Contraindications: The use of endotracheal tubes in procedures which will involve the use of a laser beam or electrosurgical active electrode in the immediate area of the device is contraindicated. Contact of the endotracheal tube with a laser beam or electrosurgical active electrode, especially in the presence of oxygen-enriched mixtures could result in rapid combustion of the endotracheal tube with harmful thermal effects and with emission of corrosive and toxic products, including hydrochloric acid (HCl).



DEVICE MATERIAL

Component	Material
Main Tube	Polyvinyl Chloride (PVC)
Cuff	Polyurethane (PU)
Opaque Line	Polyvinyl Chloride (PVC)
Inflation Line	Polyvinyl Chloride (PVC)
Pilot Ballon	Polyvinyl Chloride (PVC)
Valve	Polyvinyl Chloride (PVC), Polypropylene (PP), Silicone, Stainless Steel (SS), Acrylonitrile, Butadiene and Styrene (ABS)
Connector	Polypropylene (PPH)

Biocompatibility Evaluation: Per EN ISO 18562-1:2020, the endotracheal tubes are part of the gas pathway.

The endotracheal tubes do not contain DEHP, natural rubber latex or BPA.

The endotracheal tubes are REACH compliant and do not contain 3TG conflict minerals

The endotracheal tubes do not contain blood derivatives or materials derived from animal or human tissue.

MICROCUFF® PEDIATRIC ORAL-NASAL MAGILL ENDOTRACHEAL TUBE (EU MDR)

MR Safety: Non-clinical testing demonstrated that Microcuff is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

MR INFORMATION	
Nominal Value(s) of Static Magnetic Field	1.5 T or 3 T
Maximum Spatial Field Gradient (T/m and Gauss/cm)	14 T/m (1400 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole Body Transmit Coil, Head RF Transmit-Receive Coil
Maximum Whole Body SAR (W/kg)	2.0 W/kg (Normal Operating Mode)
Maximum Head SAR (W/kg)	3.2 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 57 mm

If information about a specific parameter is not included, there are no conditions associated with that parameter

DEVICE SPECIFICATIONS

Part	Specification
ET Tube Adaptor	15 mm O.D.
Cuff	High-Volume, Low Pressure

Part Number	I.D.	O.D.	Cuff ± 10%	Trachea Diameter		Length	Recommended Age and Weight
				Min	Max		
35111A	3.0 ± 0.15 mm	4.2 ± 0.15 mm	10.3	6 mm	8.1 mm	170 ± 5.0 mm	≥ 3 kg < 8 m
35112A	3.5 ± 0.15 mm	4.9 ± 0.15 mm	12.3	6 mm	8.1 mm	185 ± 5.0 mm	8 mo to < 2 yrs
35113A	4.0 ± 0.15 mm	5.5 ± 0.15 mm	12.3	6 mm	8.1 mm	205 ± 5.0 mm	2 to < 4 yrs
35114A	4.5 ± 0.15 mm	6.2 ± 0.15 mm	13.8	8.1 mm	10 mm	225 ± 5.0 mm	4 to < 6 yrs
35115A	5.0 ± 0.15 mm	6.7 ± 0.15 mm	13.9	8.1 mm	10 mm	245 ± 5.0 mm	6 to < 8 yrs
35116A	5.5 ± 0.15 mm	7.3 ± 0.15 mm	16.5	8.1 mm	10 mm	275 ± 5.0 mm	8 to < 10 yrs
35117A	6.0 ± 0.2 mm	8.0 ± 0.15 mm	16.5	10 mm	11.8 mm	285 ± 5.0 mm	10 to < 12 yrs
35118A	6.5 ± 0.2 mm	8.7 ± 0.2 mm	20.3	10 mm	11.8 mm	295 ± 5.0 mm	12 to < 14 yrs
35119A	7.0 ± 0.2 mm	9.3 ± 0.2 mm	20.3	10 mm	11.8 mm	305 ± 5.0 mm	14 to < 16 yrs

Part Number	Description	Each GTIN	Box GTIN	Case GTIN
35111A	Pediatric, 3.0 Endotracheal Tube, Magill	06925816613685	16925816613682	26925816613689
35112A	Pediatric, 3.5 Endotracheal Tube, Magill	06925816613692	16925816613699	26925816613696
35113A	Pediatric, 4.0 Endotracheal Tube, Magill	06925816613708	16925816613705	26925816613702
35114A	Pediatric, 4.5 Endotracheal Tube, Magill	06925816613715	16925816613712	26925816613719
35115A	Pediatric, 5.0 Endotracheal Tube, Magill	06925816613722	16925816613729	26925816613726
35116A	Pediatric, 5.5 Endotracheal Tube, Magill	06925816613739	16925816613736	26925816613733
35117A	Pediatric, 6.0 Endotracheal Tube, Magill	06925816613746	16925816613743	26925816613740
35118A	Pediatric, 6.5 Endotracheal Tube, Magill	06925816613753	16925816613750	26925816613757
35119A	Pediatric, 7.0 Endotracheal Tube, Magill	06925816613760	16925816613767	26925816613764