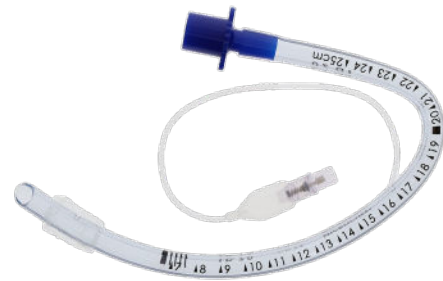


MICROCUFF® PEDIATRIC ORAL CURVED (EU MDR)

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

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Microcuff Pediatric Oral Curved Endotracheal Tube
Manufacturer (Legal)	Well Lead Medical, LTD (Manufactured for AirLife)
Manufacturer Address	C-4 Jinhu Industrial Estate Hualong 511434 Panyu, Guagzhou 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	Ethylene Oxide (ETO), Tyvek Pouch
Packaging	Individually Packaged, 10/Box, 10/Cases
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, and store in a manner to prevent crushing
Disposal Instruction	Safely discard the used tracheal tube per your facility policy



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.

Description: The endotracheal tube has a preformed bend in the tube facing toward the patient’s chest (south-facing). Radio-opaque; short, cylindrical cuff placed near the tracheal tube tip; anatomically based intubation depth mark; four precision bands for tube placement.

Intended Purpose: The endotracheal tube is inserted into the trachea through the nose or the 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).

MICROCUFF® PEDIATRIC ORAL CURVED (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

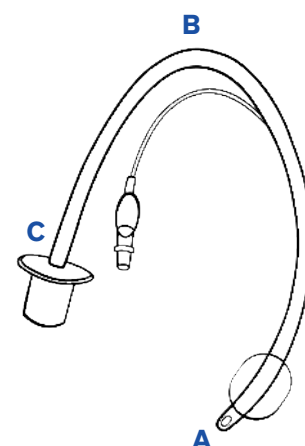
If information about a specific parameter is not included, there are no conditions associated with that parameter

DEVICE SPECIFICATIONS

Part	Specification
ET Tube Adapter	15 mm O.D. Complies with ISO 5356
Cuff	High-Volume, Low Pressure

Part Number	I.D.	O.D.	Cuff ± 10%	Trachea Diameter		Length	Recommended Age and Weight
				Min	Max		
35161A	3.0 ± 0.15 mm	4.2 ± 0.15 mm	10.3	6 mm	8.1 mm	105*/155** mm	≥ 3 kg < 8 m
35162A	3.5 ± 0.15 mm	4.9 ± 0.15 mm	12.3	6 mm	8.1 mm	120*/175** mm	8 m to < 2 yrs
35163A	4.0 ± 0.15 mm	5.5 ± 0.15 mm	12.3	6 mm	8.1 mm	130*/195** mm	2 to < 4 yrs
35164A	4.5 ± 0.15 mm	6.2 ± 0.15 mm	13.8	8.1 mm	10 mm	150*/215** mm	4 to < 6 yrs
35165A	5.0 ± 0.15 mm	6.7 ± 0.15 mm	13.9	8.1 mm	10 mm	155*/220** mm	6 to < 8 yrs
35166A	5.5 ± 0.15 mm	7.3 ± 0.15 mm	16.5	8.1 mm	10 mm	165*/230** mm	8 to < 10 yrs
35167A	6.0 ± 0.15 mm	8.0 ± 0.15 mm	16.5	10 mm	11.8 mm	180*/250** mm	10 to < 12 yrs
35168A	6.5 ± 0.2 mm	8.7 ± 0.2 mm	20.3	10 mm	11.8 mm	190*/260** mm	12 to < 14 yrs
35169A	7.0 ± 0.2 mm	9.3 ± 0.2 mm	20.3	10 mm	11.8 mm	200*/285** mm	14 to < 16 yrs

*length from A to B, ** length from A to C



Part Number	Description	Each GTIN	Box GTIN	Case GTIN
35161A	Pediatric, 3.0 mm Oral Curved Endotracheal Tube	06925816613777	16925816613774	26925816613771
35162A	Pediatric, 3.5 mm Oral Curved Endotracheal Tube	06925816613784	16925816613781	26925816613788
35163A	Pediatric, 4.0 mm Oral Curved Endotracheal Tube	06925816613791	16925816613798	26925816613795
35164A	Pediatric, 4.5 mm Oral Curved Endotracheal Tube	06925816613807	16925816613804	26925816613801
35165A	Pediatric, 5.0 mm Oral Curved Endotracheal Tube	06925816613814	16925816613811	26925816613818
35166A	Pediatric, 5.5 mm Oral Curved Endotracheal Tube	06925816613821	16925816613828	26925816613825
35167A	Pediatric, 6.0 mm Oral Curved Endotracheal Tube	06925816613838	16925816613835	26925816613832
35168A	Pediatric, 6.5 mm Oral Curved Endotracheal Tube	06925816613845	16925816613842	26925816613849
35169A	Pediatric, 7.0 mm Oral Curved Endotracheal Tube	06925816613852	16925816613859	26925816613856