MICROCUFF® ADULT ENDOTRACHEAL TUBE (EU MDR)

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

DEVICE MANUFACTURING SPECIFICATIONS	
Product Family	Microcuff Adult Endotracheal Tube
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	Adult
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.

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® ADULT 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-Recieve 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 and 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
				Min	Max	
35210A	5.0 ± 0.15 mm	6.9 ± 0.15 mm	18.1	10 mm	14 mm	245 ± 5.0 mm
35211A	5.5 ± 0.15 mm	7.5 ± 0.15 mm	18.1	10 mm	14 mm	275 ± 5.0 mm
35212A	6.0 ± 0.2 mm	8.2 ± 0.15 mm	20.5	11.8 mm	18 mm	285 ± 5.0 mm
35213A	6.5 ± 0.2 mm	8.8 ± 0.2 mm	20.5	11.8 mm	18 mm	295 ± 5.0 mm
35214A	7.0 ± 0.2 mm	9.6 ± 0.2 mm	26.5	18 mm	22 mm	305 ± 5.0 mm
35215A	7.5 ± 0.2 mm	10.2 ± 0.2 mm	26.5	18 mm	22 mm	315 ± 5.0 mm
35216A	8.0 ± 0.2 mm	10.9 ± 0.2 mm	30.6	18 mm	22 mm	325 ± 5.0 mm
35217A	8.5 ± 0.2 mm	11.5 ± 0.2 mm	30.6	18 mm	22 mm	325 ± 5.0 mm
35218A	9.0 ± 0.2 mm	12.1 ± 0.2 mm	30.8	18 mm	22 mm	325 ± 5.0 mm
35220A	10.0 ± 0.2 mm	13.6 ± 0.2 mm	30.8	18 mm	22 mm	325 ± 5.0 mm

Part Number	Description	Each GTIN	Box GTIN	Case GTIN
35210A	Adult, 5.0 mm, Endotracheal Tube	06925816613869	16925816613866	26925816613863
35211A	Adult, 5.5 mm, Endotracheal Tube	06925816613876	16925816613873	26925816613870
35212A	Adult, 6.0 mm, Endotracheal Tube	06925816613883	16925816613880	26925816613887
35213A	Adult, 6.5 mm, Endotracheal Tube	06925816613890	16925816613897	26925816613894
35214A	Adult, 7.0 mm, Endotracheal Tube	06925816613906	16925816613903	26925816613900
35215A	Adult, 7.5 mm, Endotracheal Tube	06925816613913	16925816613910	26925816613917
35216A	Adult, 8.0 mm, Endotracheal Tube	06925816613920	16925816613927	26925816613924
35217A	Adult, 8.5 mm, Endotracheal Tube	06925816613937	16925816613934	26925816613931
35218A	Adult, 9.0 mm, Endotracheal Tube	06925816613944	16925816613941	26925816613948
35220A	Adult, 10.0 mm, Endotracheal Tube	06925816613951	16925816613958	26925816613955

TDS-20539-C1 Rev1