

PTCL Flex-Tip Cuffed Endotracheal Tube – Magill Style

SINGLE PATIENT USE | DISPOSABLE | LATEX FREE

Device Manufacturing Specifications	
Reference	H-PTCL, I-PTCL
Manufacturer	By Well Lead Medical, LTD for SunMed LLC/Salter Labs
Made in	China
Classification – US	Class II, K984528
FDA Product Code	BTR
Registration #	868.5730
Classification – CA	Class 2
Classifications – EU	Class IIa
CE Mark/Notified Body	0123
EC Rep	Shanghai International Holding Corp
GMDN Code	46967, Basic Endotracheal Tube, Single Use
UMDNS Code	14085 Tubes, Tracheal Tube
EMDN Code	R0103, Endotracheal Tubes R010302, Endotracheal Tubes, with Cuff R01030201, Endotracheal Tubes, with Cuff, Not Reinforced
Sterile	Ethylene Oxide, Tyvek Pouch
Patient Population	Neonates, Pediatric, and Adults
Packaging	Individually Packaged, 10/Box, 100/Case
Shelf Life	5 Years

Description: The Flex-Tip ThinCuff endotracheal tubes (ETT) are made with a high-volume, low-pressure PVC cuff mounted on DEHP-free tubing. The ETTs are available in a variety of sizes with a tip-to-tip radiopaque line, and a distal flex tip with no Murphy eyes (Magill style). The ThinCuff ETT has depth marks which indicate the distance to the distal tip of the tube. Bold black lines above the cuff provide a reference for determining the position the tube and cuff after the tube passes through the vocal cord.

Intended Use: Endotracheal tubes, cuffed or uncuffed, are indicated for airway management by nasal or oral intubation of the trachea.

Environment of Use: Endotracheal tubes are used wherever an intubation is preformed- in the operating and recovery rooms, intensive care units, delivery rooms, emergency rooms, catheterization labs, acute care floors and pre-hospital emergencies. Intubations usually occur in controlled, well-light environment, but emergent intubations could occur outside, varying lighting conditions and in less favorable conditions.

Product Specifications	
Part Description	Specification
ET Tube Adaptor	15 mm O.D.
Cuff	High-Volume, Low Pressure
Tube Style	Magill
Magill	< 55°C

Product Material		
Part Description	Material	Patient/User Contact
Main Tube	Polyvinyl Chloride	Yes – Mucosal Membrane
Cuff – PU	Polyurethane	Yes – Mucosal Membrane
Opaque Line	Polyvinyl Chloride	Yes – Mucosal Membrane
Inflation Line	Polyvinyl Chloride	Yes – Intact skin
Connector	Polypropylene	Yes – Intact skin
Pilot Balloon	Polyvinyl Chloride	Yes – Intact skin
Valve End Cap	Polyvinyl Chloride	Yes – Intact skin
Valve Core	Silicone	No
Valve Spring	Stainless Steel	No

Device Material: Endotracheal tubes do not contain any medical substance, tissue, blood, or other human or animal products. They are not radioactive.

Latex: SunMed® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge, latex does not contact components or finished goods during the manufacturing process.

Phthalates: Material does not contains DEHP.

Mercury-Lead: The selected materials do not contain lead or mercury.

Biocompatible: Per device classification in ISO 10993. SunMed manufactures product from medical grade materials in compliance with Good Manufacturing Practices (GMPs) as listed in 21 C.F.R. (U.S. Code of Federal Regulations).

The ETT is sterilized by ETO in accordance with ENISO11135-1, the index of the biological compatibility conforms to ENISO10993-1.



PTCL Flex-Tip Cuffed Endotracheal Tube

Part Number	Tube Size	I.D ± 0.15 mm	O.D ± 0.15 mm	Cuff ± 0.15 mm	Length
PTCL-30	3.0	3.0 mm	4.3 mm	10 mm	120 mm
PTCL-35	3.5	3.5 mm	5.0 mm	12 mm	130 mm
PTCL-40	4.0	4.0 mm	5.6 mm	12 mm	140 mm
PTCL-45	4.5	4.5 mm	6.2 mm	14 mm	150 mm
PTCL-50	5.0	5.0 mm	6.9 mm	14 mm	160 mm
PTCL-55	5.5	5.5 mm	7.5 mm	16 mm	170 mm
PTCL-60	6.0	6.0 mm	8.2 mm	16 mm	190 mm
PTCL-65	6.5	6.5 mm	8.8 mm	20 mm	210 mm
PTCL-70	7.0	7.0 mm	9.6 mm	20 mm	230 mm



North American Part Number	International Part Number	UOM	GTIN	UOM	GTIN	UOM	GTIN
H-PTCL-30	I-PTCL-30	Each	10749065161307	Box	30749065161301	Case	50749065161305
H-PTCL-35	I-PTCL-35	Each	10749065161352	Box	30749065161356	Case	50749065161350
H-PTCL-40	I-PTCL-40	Each	10749065161406	Box	30749065161400	Case	50749065161404
H-PTCL-45	I-PTCL-45	Each	10749065161451	Box	30749065161455	Case	50749065161459
H-PTCL-50	I-PTCL-50	Each	10749065161505	Box	30749065161509	Case	50749065161503
H-PTCL-55	I-PTCL-55	Each	10749065161550	Box	30749065161554	Case	50749065161558
H-PTCL-60	I-PTCL-60	Each	10749065161604	Box	30749065161608	Case	50749065161602
H-PTCL-65	I-PTCL-65	Each	10749065161659	Box	30749065161653	Case	50749065161657
H-PTCL-70	I-PTCL-70	Each	10749065161703	Box	30749065161707	Case	50749065161701

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