

Malleable Intubating Stylet

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

Device Manufacturing Specifications

Reference Number	I-STLT, H-STLT
Manufacturer	Well Lead Medical, LTD for SunMed LLC/Salter Labs
Classification – US	Class I
FDA Product Code	BSR
Classifications – EU	Class 2a Rule 5 of Annex IX, III of Council Directive 93/42/EEC (2007)
CE Mark	0123
EU Authorized Representative	Shanghai International Holding Corp
Classification – Canada	Class 2
EMDN Code	Intubating Stylet-R010380
GMDN Code	37469, Artificial Airway Stylet, Single-Use
UMDNS Code	14084 Stylets, Tracheal Tube
Made In	China
Usage	Single Patient Use, Disposable
Sterile	Ethylene Oxide, Paper Pouch
Patient Population	Pediatric, Adult
Packaging	20/Box
Shelf Life	5 Years

Description: The intubating stylet is a malleable, aluminum stylet in a PVC sheath with a blunt ends to reduce the risk of trauma if the stylet should extend beyond the tip of the tracheal tube. The intubating stylet provides a positive aid to intubation. It is intended to facilitate quick curving of tube in preparation for intubation. Allow the ET tube to be directed more easily for the difficult intubation.

Intended Purpose: Intubating stylet is intended to shape appropriate curve of endotracheal tubes prior intubation to facilitate insertion of endotracheal tubes.

Environment of Use: Intubating stylet are used in primarily in the operating and recovery rooms, intensive care units.



Device Material

Component	Material	Patient/User Contact
Sleeve	PVC	Yes – Direct
Rod	Malleable Aluminum	No

Device Material: Endotracheal tubes do not contain any medical substances or other human or animal products. They are not radioactive. The ETT is sterilized by ETO in accordance with ENISO11135-1, the index of the biological compatibility conforms to ENISO10993-1.

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

Phthalates: The selected materials do not contain DEHP.

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

Biocompatible: Per device classification in ISO 10993.

Salter Labs manufactures product from medical grade materials in compliance with Good Manufacturing Practices (GMP's) as listed in 21 C.F.R. (U.S. code of Federal Regulations).

Device Specifications

Description	Specification	
Storage Temperature	< 55°C	
Size	O.D. mm (±0.2 mm)	Length mm (±10 mm)
6 Fr	2.0	272
10 Fr	3.3	346
14 Fr	4.7	337

International	GTIN	North America	GTIN
I-STLT-6	749065813209	H-STLT-6	088948327335
I-STLT-10	749065813339	H-STLT-10	088948327333
I-STLT-14	749065813476	H-STLT-14	088948327334