

# SUNSLIP™ PVC COATED STYLET

SINGLE PATIENT USE | DISPOSABLE | LATEX FREE | STERILE

## DEVICE MANUFACTURING SPECIFICATIONS

Product Family	SunSlip Stylet
Manufacturer	Well Lead
Manufactured For	SunMed
Country of Origin/Made In	China
Classification - US	Class I
FDA Product Code	BSR - Stylet, Tracheal Tube
Classification - Canada	Class 2
GMDN Code	37469 - Artificial Airway Stylet, Single-Use
UMDNS Code	14084 - Stylets, Tracheal Tube
UNSPSC Code	42272004 - Intubation Stylets
Usage	Single Patient Use, Disposable
Patient Population	Infant, Pediatric, Adult
Sterility	Ethylene Oxide, Paper Pouch
Packaging	20/Box
Shelf Life	5 Years
Storage Conditions	There are no special storage conditions or handling requirements.
Disposal Instruction	Dispose of in accordance with national and local authority regulations.

**Description:** The SunSlip™ stylet is a malleable, aluminum stylet in a PVC coating. The stylet is inserted into the endotracheal tube (ETT) to help maintain the shape of the ETT during intubation.

**Intended Purpose:** Used for endotracheal tube intubation.

**Contraindications:** None known.

## INTERNATIONAL MALLEABLE INTUBATING STYLET

Part Number	SIZE	LENGTH (in.)	UOM	GTIN
9-0203-06	6 Fr	10"	Each	10889483033302
			Box	20889483033309
9-0203-10	10 Fr	11.5"	Each	10889483033319
			Box	20889483033316
9-0203-14	14 Fr	12.5"	Each	10889483033326
			Box	20889483033323



## DEVICE MATERIAL

Component	Material
Sleeve	Polyvinyl Chloride (PVC)
Rod	Acrylic

**Device Material:** The stylet is sterilized by ETO in accordance with ENISO11135-1, the index of the biological compatibility conforms to ENISO10993-1.

**Biocompatibility:** All materials are biocompatible, meeting skin irritation and sensitization requirements. The stylet does not contain DEHP, natural rubber latex, or BPA. This device does not incorporate medicinal products. This device does not contain blood derivatives or materials derived from animals or human tissue.