

SEPTAL-H™ GENTLE CANNULA STABILIZATION

LATEX FREE | DISPOSABLE | SINGLE PATIENT MULTIPLE USE | NON-STERILE | DEHP FREE | PVC FREE

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Septal-H
Company	AirLife
Manufacturer	Westmed 5580 S. Nogales Highway Tucson, Arizona 85706 USA
Country of Origin/Made In	U.S.A.
Classification - US/510k #	Class I
Classification - EU	Class I, Rule 1
CE Mark/Notification Body	CE
EU Authorized Representative	MT Promedt Consulting GmbH
EMDN Code	V028099 Neonatal and Pediatric Devices - Other Accessories
GMDN Code	64491, Medical/Surgical Interventional Tube/Cable Securement Strap
UMDNS Code	13-858, Supports/Accessories
Usage	Single Patient, Multiple Use
Patient Population	Infant, Pediatrics
Sterility	Non-Sterile
Packaging	Individually Packaged 80/Case
Shelf Life	5 Years
Disposal Instruction	Safely dispose in accordance with local, state, or national regulations
Duration of Use	> 24 Hours to 30 Days



DEVICE MATERIAL

COMPONENT	MATERIAL
Tape-Base	Hydrocolloid
Hooks	Polypropylene
Loops	Polyester
Packaging (Each)	Polybag
Packaging (Container)	Plastic Clamshell Box
Packaging (Case)	Cardboard Box

Description: A securement device used to support nasal breathing tubes. Non-sterile, disposable, and for single patient use. It functions as a device for tube support.

Intended Purpose: The Septal H is intended for use as a fixation device for nasal cannulas on infants.

Indication for Use: Indicated for use to protect newborn skin during treatment with a nasal breathing tube.

Area of Use: This device is intended to be used by medical staff within a pediatric or neonatal setting.

Contraindications: None-known.

PART	DESCRIPTION	PATIENT SIZE	UOM	GTIN
CP-5400	Septal-H Premie Size	Up to 500 Grams	Container (20)	00709078013119
			Case (80)	10709078013116
CP-5410	Septal-H Neonatal Size	500-1200 Grams	Container (20)	00709078013126
			Case (80)	10709078013123
CP-5500	Septal-H Infant Size	1200-2500 Grams	Container (20)	00709078013133
			Case (80)	10709078013130
CP-5510	Septal-H Pediatric Size	> 2500 Grams	Container (20)	00709078013140
			Case (80)	10709078013147