

Mini Whiskers®

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

Mini Whiskers® Securement Device

Reference Number	MW100-0-120
GTIN Code	10607411007313
Manufacturer	SunMed LLC/Salter Labs
Classification-USA	FDA Class 1 Medical Device
Product Code	KGX Medical Adhesive Tapes and Bandages
Classifications-EU	Class 1a EC Directive 93/42/EEC Annex IX
Classification-Canada	Class1 Canadian Medical Device Regulations
CE Mark/ 93/42 Notified Body Number	CE 2797 / Mt Promedt Consulting GmbH
GMDN Code	44990, Skin-Cover Adhesive Strip
UMDNS Code	10028, Adhesive Strips, Hypoallergenic
Usage	Disposable, Single Use
Sterile	No
Patient population	Neonates, Infant and Pediatrics
Packaging	In labeled plastic pouch that contains a precut card of 6 Mini Whiskers and 2 Velcro loop strips. A box contains 20 pouches of Mini Whiskers, and an Instructions for Use document.
Shelf life	2 Years

Description: Mini Whiskers® are designed to be placed on an infant's upper lip and cheeks allowing tubing such as a nasal cannula to be secured in position in the nares. They may also be applied below the lower lip to secure an OG tube, or anywhere on the cheek that is appropriate to secure an OG or NG tube. Mini Whiskers, in effect, suspend tubing above the skin rather than fixing it on the skin.

Indication for Use: Mini Whiskers securement device aids in the placement and securement of nasal cannulas and feeding tubes in infants less than 2000 grams.

Area of use: Mini Whiskers is for use in acute care environments, e.g. hospitals, NICU.

Duration of use: Single use up to 24 hours. Do not reapply.

Benefit: Maintains cannula position to help prevent interruption of therapy.

Contraindications: Not for use over broken skin or on patients with known sensitivity to device materials.

Caution:

- Do not use if known sensitivity to hydrocolloids.
- If skin irritation is noted, discontinue use.
- This product is disposable and is not intended for prolonged or extended use.



Warning: Mini Whiskers are not for securement of endotracheal tubes.

Disposal: Sticky Whiskers come in contact with body fluids and are classified as hazardous material. Use PPE to handle used Sticky Whiskers. Discard according to local regulations governing the handling of hazardous waste. Sticky Whisker may be safely incinerated.

Product Material

Part Description	Material
Tear Drop	Pectin Based-Hydrocolloid Adhesive on Polyurethane Film
Velcro Hook	Velcro Look, Polyethylene
Velcro Loop	Velcro Loop, Nylon Acrylic, White Colored

White Velcro Strips Device Specifications

Description	Specification
Length	1.74" (44 mm)
Width	0.25" (6 mm)
Box Weight (20 pouches)	181 g
Operating temperature	0°C to 45°C
Storage temperature	0°C to 50°C
Storage humidity	30% RH to 80% RH

Tear Drop Device Specifications

Description	Specification
Length	1.4" long (88.9 mm)
Width	0.5" (12.7 mm)
Thickness	1 mm

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 good during the manufacturing process.

Phthalates: The selected materials are Non-DEHP; DEHP was not intentionally added as part of the manufacturing process.

BPA: SunMed does not intentionally add or use material with bisphenol A (BPA) to manufacture bubble humidifiers.

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).

