

1016-1017 EAR WRAPS

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

DEVICE MANUFACTURING SPECIFICATIONS	
Reference Number	1016 (Cannula), 1017 (Mask Strap)
Manufacturer	AirLife
Manufacturer Address	Salter Labs, 60 Spur Road, El Paso, TX 79906
Country of Origin/Made In	Mexico
Classification – US/510k #	Class I, Exempt
FDA Product Code	KGX Medical Adhesive Tapes and Bandages
Classification – Canada	Class I
Classification – EU	Class I, Annex VIII, Rule 1
CE Mark	CE
EU Authorized Representative	Mt Promedt Consulting GmbH
EMDN Code	M030302, Protection System
GMDN Code	44990, Skin-Cover Adhesive Strip
UMDNS Code	10028, Adhesive Strips, Hypoallergenic
UNSPSC Code	42271709 Medical Nasal Cannula
Usage	Disposable, Single Patient Multiple Use
Patient Population	Pediatric, Adult
Area of Use	Hospitals, Pre-Hospital, Home, Surgical Centers, Skilled Nursing Facilities, Medical Clinics
Sterility	Non-Sterile
Packaging	Individually Packaged, 50 Pairs/Case (1016) and 25 Pairs/Case (1017)
Shelf Life	5 Years
Disposal Instruction	Used or damaged products must be disposed according to applicable national and international legal directives.

Description: Soft, light gray, closed cell foam tubes designed to cover the cannula headset tubing (1016) or the mask's elastic strap (1017) that fits around the ears.

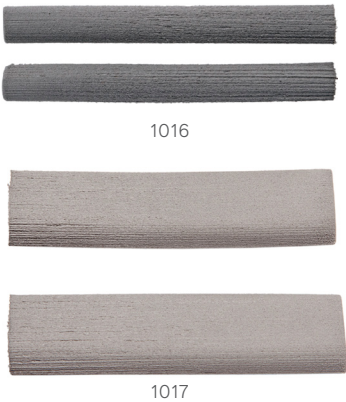
Intended Purpose: Soft, closed-cell foam tube accessories designed to prevent ear chafing when used with cannulas and masks.

Compatibility:

- 1016 – Compatible with oxygen cannula with standard headset tubing. Do not use with soft headset tubing.
- 1017 – Compatible with Salter Labs® oxygen and aerosol masks with a flat elastic strap.

Contraindications: No known contraindications.

PART	UOM	GTIN
1016-0	Each	00607411001048
1016-0-50	Case	10607411001045
1017-0	Each	00607411891717
1017-0-25	Case	10607411891714



TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Cannula Ear Wraps (1016)	3" Length
Mask Ear Wraps (1017)	3" Length
Operating Temperature	+5°C (41°F) to +40°C (104°F)
Storage Temperature	-20°C (-4°F) to +50°C (122°F)

DEVICE MATERIAL

COMPONENT	MATERIAL
E-Z Wrap	Low Density Polyethylene Foam, Gray

Biocompatibility: The device is biocompatible, meeting cytotoxicity requirements, skin irritation and sensitization requirements per ISO 10993.

The device does not contain natural rubber latex, DEHP or BPA.

The device is REACH compliant and do not contain 3TG conflict minerals.

The device does not contain blood derivatives or materials derived from animal or human tissue.