AIRLIFE® CUSHION NASAL CANNULA WITH U/CONNECT-IT®

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

DEVICE MANUFACTURING SPECIFICATIONS	
Product Family	AirLife Cushion Nasal Cannula with U/Connect-It Connector or standard connector
Manufacturer	AirLife
Manufacturer Address	Salter Labs, 30 Spur Drive, El Paso, TX 79906 USA
Country of Origin/Made In	Mexico
Classification – US/510k #	Class I Medical Device
Classification – Australia	Class IIa
Classification – Canada	Class II
Classification – GHTF	Class B According to the Principles of Medical Device Classification, GHTF/SG1/N15
GMDN Code	35201 – Nasal Cannulas
UMDNS Code	12799 – Cannulae, Nasal Oxygen
UNSPS Code	42271700 – Oxygen Therapy Delivery Systems and Devices
Duration of Use	Disposable, Single Patient, Multiple-Use Discard and replace nasal cannula every 30 Days or sooner if the cannula becomes soiled or damaged.
Patient Population	Adult, Pediatric, Infant, Neonatal
Area of Use	Hospitals, Medical Clinics, Home, Surgical Centers, Skilled Nursing Facilities
Sterility	Non-Sterile
Packaging	Individually Packaged in Poly Bag, 50/Case
Shelf Life	5 years
Storage Conditions	-20°C to +50°C
Disposal Instruction	Dispose of device in accordance with local, state or national regulations. Decontaminate and dispose of all potentially biohazardous material.

Description: Over-the-ear style headset tubing with curved, non-flared nasal prongs and soft headset tubing. Includes supply tubing with a threaded, U/Connect-It® end connector, or standard ribbed connector, available in different lengths.

Intended Purpose: A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils at flow of 0 LPM to 6 LPM

Contraindications: No known contraindication.

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Nasal Prongs	Curved, Non-Flared Tip
Oxygen Supply Tubing	3-Channel, Crush Resistant Tubing
Headset Tubing	Soft, Crush Resistant Tubing
Oxygen Supply Tubing Length	Adult: 7' (2.1 m), 14' (4.3 m), 25' (97.6 m) Pediatric/Infant/Neonate: 7' (2.1 m)
Oxygen Flow Rate	Adult/Pediatric: > 0 LPM ± 6 LPM Infant/Neonate: > 0 LPM ± 3 LPM
Tubing End Connector	Universal, Oxygen DISS, Female Threaded Connector, or Standard Ribbed Connector
Operating Temperature	5°C to 40°C

DEVICE MATERIAL

COMPONENT	MATERIAL
Nasal Facepiece	Polyvinyl Chloride (PVC)
Headset Tubing	Polyvinyl Chloride (PVC)
Supply Tubing	Polyvinyl Chloride (PVC)
Connector	Polyvinyl Chloride (PVC)
Bolo	Low Density Polyethylene (LDPE)

Biocompatibility: All materials are biocompatible, meeting skin irritation and sensitization requirements. The oxygen cannulas do not contain DEHP, or natural rubber latex or BPA. The oxygen cannulas are REACH compliant and do not contain 3TG conflict minerals. The oxygen cannulas do not contain blood derivatives or materials derived from animal or human tissue.

PART	PATIENT	LENGTH	UOM	GTIN
SFT2601	Infant	7'	Each	10889483599563
			Case	20889483599560
SFT2611	Neonate	7'	Each	10889483605769
			Case	20889483605766
SFT2614U	Adult	14'	Each	10889483605790
			Case	20889483605797
SFT2625U	Adult	25'	Each	10889483605813
			Case	20889483605810
SFT2692	Pediatric	7'	Each	10889483605820
			Case	20889483605827
SFT2699	Adult	7'	Each	10889483605837
			Case	20889483605834

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