16SOFT™ NASAL CANNULA WITH RIBBED CONNECTOR – ADULT

DISPOSABLE | SINGLE PATIENT MULTIPLE USE | LATEX FREE | DEHP FREE | BPA FREE

DEVICE MANUFACTURING SPECIFICATIONS	
Product Family	Salter Labs Soft Nasal Cannulas
Company	AirLife
Legal Manufacturer and Address	Salter Labs 30 Spur Drive El Paso, TX 79906 USA
Country of Origin/Made In	Mexico
Classification – US/510k #	Class I Medical Device
FDA Product Code	CAT – Nasal Oxygen Cannula
Classification – Canada	Class 2
Classification – IMDRF (GHFT)	Class A
Classification – EU	Class IIa
CE Mark/Notification Body	CE 2797/BSI Group
EU Authorized Representative	Mt Promedt Consulting GmbH
EMDN Code	R0301020301 -Oxygen Therapy Standard Nasal Cannulas (Goggles)
GMDN Code	35201, Nasal Oxygen Cannula, Basic
UNSPSC Code	42271709, Medical Nasal Cannula
Duration of Use	Discard and replace nasal cannula every 30 days or sooner if the cannula becomes soiled or damaged
Patient Population	Premature, Neonatal, Infant, Toddler, Pediatric, and Adult
Area of Use	Hospitals, Medical Clinics, Home, Surgical Centers, Skilled Nursing Facilities
Packaging Material	Individually Packaged, 50/Case
Shelf Life	5 Years

Description: An over-the-ear nasal cannula featuring soft, flexible headset tubing and nasal prongs for comfortable, secure fit. Includes oxygen supply tubing and a variety of end connectors.

Intended Purpose: The nasal cannula is a two-pronged device used to administer oxygen to a patient through both nostrils. Depending on the cannula style flow rates will vary from > 0 LPM to ≤ 15 LPM.

Contraindiction(s): None known

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Supply Tubing	Clear, 3-Channel Safety
High Flow Supply Tubing	Green, 3-Channel Safety
Supply Tubing Length	2" (0.05 m), 1' (0.3 m), 4' (1.2 m), 7' (2.1 m), 14' (4.2 m), 25' (7.6 m)
O_2 Flow Rate	0 LPM to 15 LPM
Headset Tubing	3-Channel
Tubing End Connector	Ribbed, Female DISS Thread Grip, Barb, 2' Tube
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C

POPULATION	APPROXIMATE AGE	WEIGHT	BETWEEN PRONGS	PRONG LENGTH
Premature	≤ 28 Weeks GA	≤ 1400 g	0.22"	0.3" ± 0.025
Neonatal	28 - 36 Weeks GA	1400 g to 2.5 kg	0.26"	0.3" ± 0.025
Infant	Full Term - 6 Months	2.5 kg to 4.0 kg	0.3"	0.325" ± 0.025
Toddler	3 Months - 12 Months	4.0 kg to 10.0 kg	0.26"	0.325" ± 0.025



DEVICE MATERIAL

COMPONENT	MATERIAL
Nasal Face Piece	Polyvinyl Chloride (PVC) Plastisol-Reddish Tint
Headset Tubing	Soft Durometer Polyvinyl Chloride (PVC)
Bolo	Low Density Polyethylene (LDPE)
Tubing End Connector	Polyvinyl Chloride (PVC)
Supply Tubing (Smooth Bore)	Polyvinyl Chloride (PVC)
Supply Tubing (3-Channel)	Polyvinyl Chloride (PVC)
WYE Connector	Polyvinyl Chloride (PVC)

Biocompatibility Evaluation: Utilized the EN ISO 10993-1:2020 and EN ISO 18562-1:2020 guidelines within a risk management process and in compliance with the European Union Medical Device Regulation of 2017 (EU MDR) and the U.S. Food and Drug Administration (FDA). The subject devices are not made of natural rubber latex. The selected materials are not formulated with DEHP or BPA. These devices do not contain blood derivatives or materials derived from animal or human tissues.

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PART	SIZE	FLOW RATE	CONNECTOR	LENGTH	EACH GTIN	CASE GTIN
16SOFT-B-0-50	Adult	0 LPM to 6 LPM	Barbed	N/A	00607411917288	10607411917285
16SOFT-0-50	Adult	0 LPM to 6 LPM	Rigid Tube	2"	00607411916014	10607411916011
16SOFT-1-50	Adult	0 LPM to 6 LPM	Ribbed	1' (0.31 m)	00607411919930	10607411919937
16SOFT-4-50	Adult	0 LPM to 6 LPM	Ribbed	4' (1.2 m)	00607411915833	10607411915830
16SOFT-7-50	Adult	0 LPM to 6 LPM	Ribbed	7' (2.1 m)	00607411915772	10607411915779
16SOFT-14-50	Adult	0 LPM to 6 LPM	Ribbed	14' (4.2 m)	00607411915840	10607411915847
16SOFT-25-25	Adult	0 LPM to 6 LPM	Ribbed	25' (7.6 m)	00607411915857	10607411915854
16SOFTTG-7-50	Adult	0 LPM to 6 LPM	Thread Grip	7' (2.1 m)	00607411102288	10607411110228
16SOFTTG-14-50	Adult	0 LPM to 6 LPM	Thread Grip	14' (4.2 m)	00607411102301	10607411102308
16SOFTTG-25-25	Adult	0 LPM to 6 LPM	Thread Grip	25' (7.6 m)	00607411102318	10607411102315
16SOFT-PED-4-50	Pediatric	0 LPM to 6 LPM	Ribbed	4' (1.2 m)	00607411918476	10607411918473
16SOFT-PED-7-50	Pediatric	0 LPM to 6 LPM	Ribbed	7' (2.1 m)	00607411918483	10607411918480
16SOFTTG-PED-7-50	Pediatric	0 LPM to 6 LPM	Thread Grip	7' (2.1 m)	00607411102370	10607411102377
16SOFTTG-INF-7-50	Infant	0 LPM to 3 LPM	Thread Grip	7' (2.1 m)	00607411952647	10607411952644
16SOFT-HF-7-25	Adult	0 LPM to 15 LPM	Ribbed	7' (2.1 m)	00607411915786	10607411918466
16SOFT-HF-14-25	Adult	0 LPM to 15 LPM	Ribbed	14' (4.2 m)	00607411915864	10607411915861
16SOFT-HF-25-10	Adult	0LPM to 15 LPM	Ribbed	25' (7.6 m)	00607411915871	10607411915878
16SOFTTG-HF-7-25	Adult	0 LPM to 15 LPM	Thread Grip	7' (2.1 m)	00607411102394	10607411102391
16SOFTTG-HF-14-25	Adult	0 LPM to 15 LPM	Thread Grip	14' (4.2 m)	00607411102400	10607411102407
16SOFTTG-HF-25-10	Adult	0LPM to 15 LPM	Thread Grip	25' (7.6 m)	00607411915871	10607411915878
16SOFT-PRE-7-50	Premature	0 LPM to 3 LPM	Ribbed	7' (2.1 m)	00607411952613	10607411952616
16SOFT-NEO-7-50	Neonatal	0 LPM to 3 LPM	Ribbed	7' (2.1 m)	00607411952623	10607411952620
16SOFT-INF-7-50	Infant	0 LPM to 3 LPM	Ribbed	7' (2.1 m)	00607411952609	10607411952606
16SOFT-TOD-7-50	Toddler	0 LPM to 3 LPM	Ribbed	7' (2.1 m)	00607411952630	10607411952637

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