1610 Premature Nasal Cannula with Trumpet Connector

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

Salter-Style® 1600 Premature Nasal Cannula

Reference Number	1610-7-50
Manufacturer	SunMed LLC/Salter Labs
FDA Classification	Class I Medical Device
FDA Product Code	CAT – Nasal Oxygen Cannula
Canadian MDR	Class II, Conformity Assessment Route: Medical Device License
Classifications – EU	Class IIa, Rule 2 , MDR 2017/745, Annex VIII
CE Mark/Notified Body	CE2797 / BSI Group
EMDN Code	R03010203, Air/Oxygen Nasal Cannula
GMDN Code	35201 Nasal Cannulas
UMDNS Code	12799, Cannulae, Nasal Oxygen
Usage	Disposable, Single Patient Multiple Use
Sterile	No
Patient Population	Premature
Approximate Weight	≤ 1400 g
Approximate Age	≤ 28 Weeks GA
Packaging	Individually Packaged, 50/case

Intended use: Over-the-ear style nasal cannula for delivery of supplemental oxygen to nares of a spontaneously breathing patient.

Area of use: Hospitals, medical clinics, home, surgical centers, skilled nursing facilities, NICU.

Duration of use: Discard and replace nasal cannula every 14 days or sooner if the cannula becomes soiled or damaged.

Contraindications: No known.

Caution: Keep tubing straight and free of kinks. Do not sterilize.

Warning:

- If patient develops infection, skin irritation or material sensitization consult physician.
- Patient may become hypoxic if oxygen flow is interrupted.
- Position tubing to avoid strangulation or tripping hazard.
- Do not place anything on oxygen tubing that may obstruct flow.
- Use oxygen product as prescribed.
- When using oxygen, do use open flame or heat source.

Device Specifications

Description	Specification
Oxygen Tubing Length	7' (2.1 m)
Oxygen Flow Rate	0 LPM to 3 LPM
Tubing End Connector	Universal Trumpet, Push-On
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C

Product Material

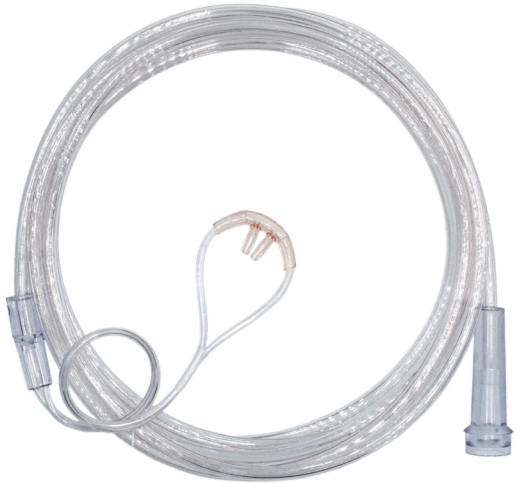
Part Description	Material
Nasal Face Piece	Plastisol, Reddish Tint
Oxygen Tubing	Polyvinyl Chloride, 3-Channel
Headset Tubing	Polyvinyl Chloride, Smooth Bore
Tubing End Connector	Polyvinyl Chloride
Bolo	Low Density Polyethylene

Latex: Salter Labs® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge, latex does not come in contact with 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.

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 (GMPs) as listed in 21 C.F.R. (U.S. Code of Federal Regulations).



Part Number	UOM	GTIN/UDI
1610-7	Each	607411100611
1610-7-50	Case	20607411100615

TDS-10146 Rev 1

SunMed®