

16SOFTTG CANNULAS WITH FEMALE THREAD GRIP CONNECTOR
PREMATURE, NEONATAL, INFANT

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

DEVICE MANUFACTURING SPECIFICATIONS	
Reference Number	16SOFTTG-PRE, 16SOFTTG-NEO, 16SOFTTG-INF
Manufacturer	SunMed LLC/Salter Labs
Classification – US	Class I Medical Device
FDA Product Code	CAT – Nasal Oxygen Cannula
Classification – EU	Class IIa
CE Mark/Notified Body	CE 2797/BSI Group
Authorized Representative	Mt Promedt Consulting GmbH
Classification – Canada	Class 2
EMDN Code	R03010203, Air/Oxygen Nasal Cannula
GMDN Code	35201 Nasal Cannulas
UMDNS Code	12799, Cannulae, Nasal Oxygen
Made In	Mexico
Usage	Disposable, Single Patient Multiple Use
Sterile	No
Packaging	Individually Packaged, 50/Case
Shelf Life	5 Years

USER SPECIFICATIONS

Patient Population	Approximate Age	Approximate Weight	Space Between Prongs	Prong Length
Premature	≤ 28 Weeks GA	≤ 1400 g	.22"	0.3" ± 0.025
Neonatal	28 - 36 Weeks GA	1400 g to 2.5 kg	.26"	0.3" ± 0.025
Infant	Full Term to 6 Months	2.5 kg to 4.0 kg	.3"	0.325" ± 0.025

Description: Over-the-ear style infant cannula with soft headset tubing and nasal prongs. Includes oxygen supply tubing with a female thread grip connector.

Intended Purpose: A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils at flows from ≤ 3 LPM.

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

Duration of Use: Discard and replace nasal cannula every 30 days or sooner if the cannula becomes soiled or damaged.

Contraindications: No known.

Part Number	UOM	GTIN
16SOFTTG-PRE-7	Each	00607411952593
16SOFTTG-PRE-7-50	Case	10607411952590
16SOFTTG-NEO-7	Each	00607411959615
16SOFTTG-NEO-7-50	Case	10607411959612
16SOFTTG-INF-7	Each	00607411952647
16SOFTTG-INF-7-50	Case	10607411952644



DEVICE SPECIFICATIONS

Description	Specification
O ₂ Supply Tubing	Clear, 3-Channel Safety
O ₂ Supply Length	7' (2.1 m)
O ₂ Flow Rate	0 LPM to 3 LPM
Tubing End Connector	Female DISS Thread Grip
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C

DEVICE MATERIAL

Component	Material
Nasal Face Piece	Plastisol, Reddish Tint
O ₂ Tubing	Polyvinyl Chloride, 3-Channel
Headset Tubing	Soft Durometer Polyvinyl Chloride, 3-Channel
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 (GMP's) as listed in 21 C.F.R. (U.S. code of Federal Regulations).