

16SOFT Adult Nasal Cannula with Ribbed Connector

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

Salter-Style® 16SOFT Adult Nasal Cannula		
Reference Number	16SOFT-2-50	16SOFT-4-50
	16SOFT-7-50	16SOFT-14-50
	16SOFT-25-50	
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 EC Directive 93/42/EEC Annex IX	
CE Mark/ 93/42 Notified Body Number	CE 2797 / Mt Promedt Consulting GmbH	
GMDN Code	35201 Nasal Cannulas	
UMDNS Code	12700, Cannulae, Nasal Oxygen	
Usage	Disposable, Single Patient Multiple Use	
Sterile	No	
Patient Population	Adult	
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.

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 Supply Tubing	2' (0.6 m), 4' (1.2 m), 7' (2.1 m), 14' (4.2 m), 25' (7.6 m) Clear, 3-Channel Safety Tubing
Oxygen flow rate	0 LPM to 6 LPM
Tubing End Connector	Universal, Push-On, Ribbed Connector
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	Polyvinylchloride, 3-Channel
Headset tubing	Soft durometer, Polyvinylchloride, 3-Channel
Tubing end connector	Polyvinylchloride
Bolo	Low Density Polyethylene

Part Number	UOM	Tube Length	GTIN
16SOFT-2	Each	2' (0.6 m)	607411918032
16SOFT-2-50	Case	2' (0.6 m)	10607411918039
16SOFT-4	Each	4' (1.2 m)	607411915833
16SOFT-4-50	Case	4' (1.2 m)	10607411915830
16SOFT-7	Each	7' (2.1 m)	607411915772
16SOFT-7-50	Case	7' (2.1 m)	10607411915779
16SOFT-14	Each	14' (4.2 m)	607411915840
16SOFT-14-50	Case	14' (4.2 m)	10607411915847
16SOFT-25	Each	25' (7.6 m)	607411915857
16SOFT-25-50	Case	25' (7.6 m)	10607411915854



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).

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