

47SOFT-F-PED O₂/EtCO₂ Divided Nasal Sampling Cannula – Pediatric

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

O ₂ /EtCO ₂ Divided Nasal Sampling Cannula, Female Luer, Adaptor	
Reference Number	47SOFT-F-PED-7-0-25
Manufacturer	SunMed LLC/Salter Labs
FDA	Class II K151421
Product Code	CCK Analyzer, Gas Carbon-Dioxide, Gaseous-Phase
CE Mark / Notified Body	2797 / BSI Group
Device Classification – EU	Class I, Rule 2 EU MDR 2017/745 Annex VIII
EMDN code	R9099, Respiratory and Anesthesia Devices, Other Z120306, Vital Signs Monitoring Instrument
GMDN Code	36306, Carbon Dioxide Nasal Cannula
UMDNS Code	11838, Gas Sampling Unit
Made In	Mexico
Oxygen Delivery	Yes
CO ₂ Sampling	Yes
Patient Population	Pediatric
Usage	Disposable, Single Patient Use
Sterile	No
Packaging	Individually packaged, 25/case
Shelf life	3 years

Device Description: Over-the-ear style nasal cannula with a divided face piece and soft 3-Channel headset tubing. Supplemental oxygen is delivered to one nostril, while sampling patients exhaled gases from the other nostril. Packing includes an oxygen adaptor, 22 mm x 6 mm.

Intended use: The O₂ Delivery / CO₂ Sampling Nasal Cannula is intended to be used with spontaneous breathing patients who require simultaneous low flow oxygen delivery and exhaled gas sampling.

Patient population: For use with non-intubated adult patients.

Area of use: Locations where procedures are performed where the patient requires monitoring of exhaled gases e.g. procedural sedation, lower GI procedures, EMS, or surgical cases. Used in hospital, sub-acute, and pre-hospital settings.

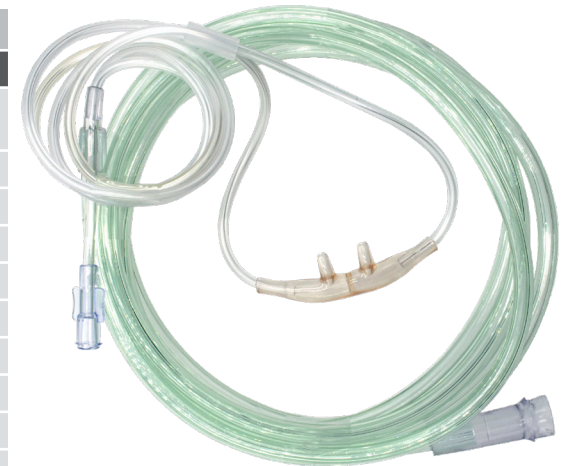
Contraindications: No known.

Benefits: 1) Improves oxygen saturation 2) Notifies clinicians of change in patient's ventilatory status 3) Improves accuracy of EtCO₂ value while delivering oxygen. 4) Soft headset tubing improves patient comfort.

Device Specifications	
Description	Specification
CO ₂ Sampling Line Internal Diameter	0.075" (1.91 mm)
CO ₂ Sampling Line Length	2" (0.5 m)
CO ₂ Line End Connectors	Female Luer Style
CO ₂ Sampling Rate	≤ 0.5 LPM
O ₂ Supply Tubing	7' (2.1 m)
O ₂ Tubing Diameter	3/16"
O ₂ Flow Rate	≤ 6 LPM
O ₂ End Connector	Trumpet, Push-On
Adaptor	22 mm ID / 6 mm OD
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C

Product Material	
Part Description	Material
Nasal Face Piece	Plastisol
Soft Headset Tubing	Soft Durometer Polyvinyl Chloride, 3-Channel
Oxygen Tubing	Polyvinyl Chloride
Oxygen End Connector	Polyvinyl Chloride
CO ₂ Tubing	Polyvinyl Chloride
CO ₂ Connector	Acrylonitrile Butadiene Styrene
Bolo	Low Density Polyethylene

Part Number	UOM	GTIN
47SOFT-F-PED-7-0	Each	00607411946721
47SOFT-F-PED-7-0-25	Case	10607411946728



Latex: SunMed® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge latex does not contact components or finished goods 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. SunMed 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).

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