

47SOFT-FTG O₂/EtCO₂ Divided Nasal Sampling Cannula with Salter Eyes, Adult

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

| O ₂ /EtCO ₂ Divided Nasal Sampling Cannula, Female Luer, Adaptor | | |
|--|---|---------------------|
| Reference Number | 47SOFT-FTG-7-7-25 | 47SOFT-FTG-10-10-25 |
| 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 | Adult | |
| 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. The prongs have two small holes to enable uninterrupted monitoring should the prong become blocked or occluded. 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.

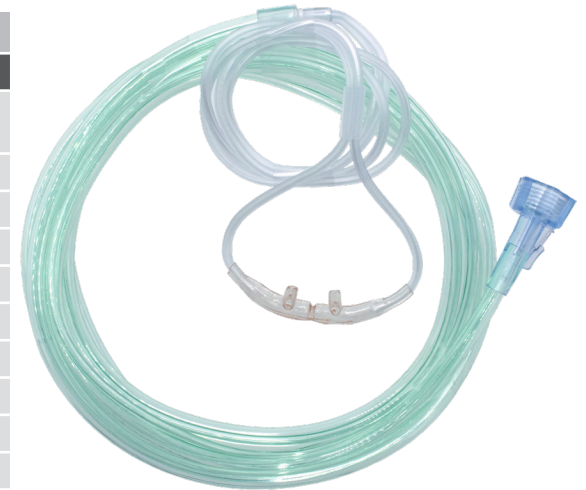
Contraindications: No known.

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 | 7' (2.1 m), 10' (3.0 m) |
| CO ₂ Line End Connectors | Female Luer Style |
| CO ₂ Sampling Rate | ≤ 0.5 LPM |
| O ₂ Supply Tubing | 7' (2.1 m), 14' (4.2 m) |
| O ₂ Tubing Diameter | 3/16" |
| O ₂ Flow Rate | ≤ 6 LPM |
| O ₂ End Connector | Thread Grip, O ₂ DISS |
| 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-7-7 | Each | 00607411946745 |
| 47SOFT-F-7-7-25 | Case | 10607411947152 |
| 47SOFT-F-10-10 | Each | 00607411401312 |
| 47SOFT-F-10-10-25 | Case | 10607411945400 |



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).

TDS-10070 Rev 1

