F&P Optiflow™ Filtered Nasal Interface with CO_2 Sampling

REF AA031J S/M/L

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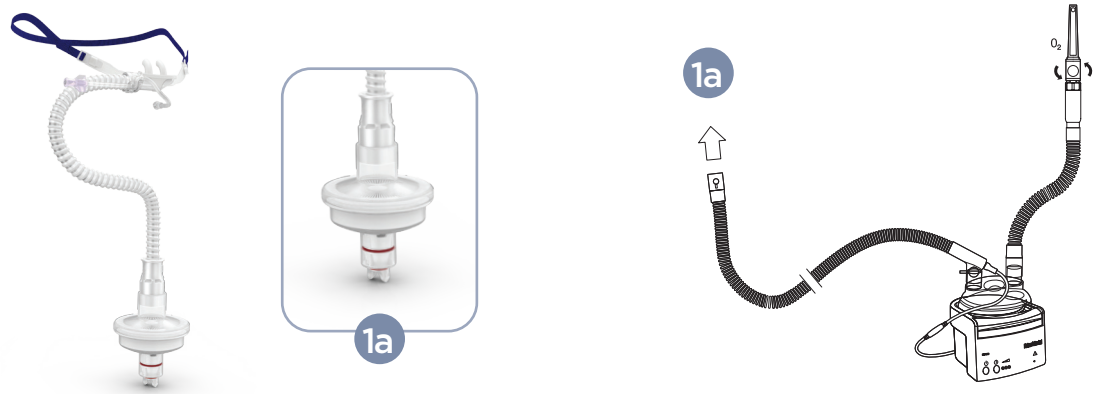

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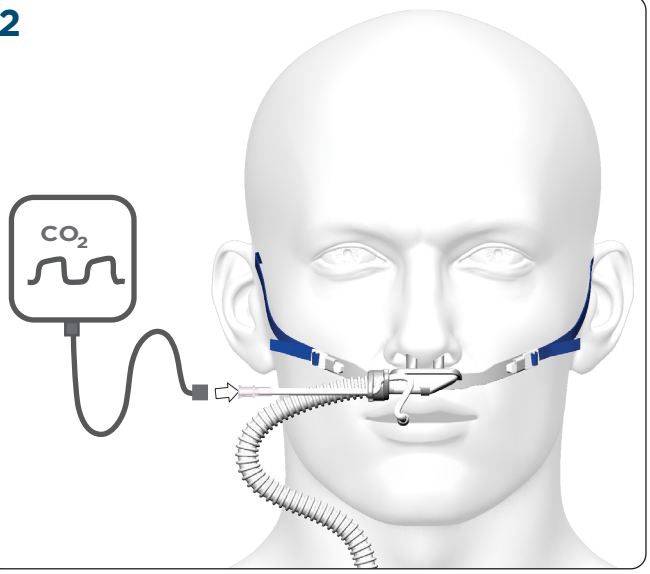

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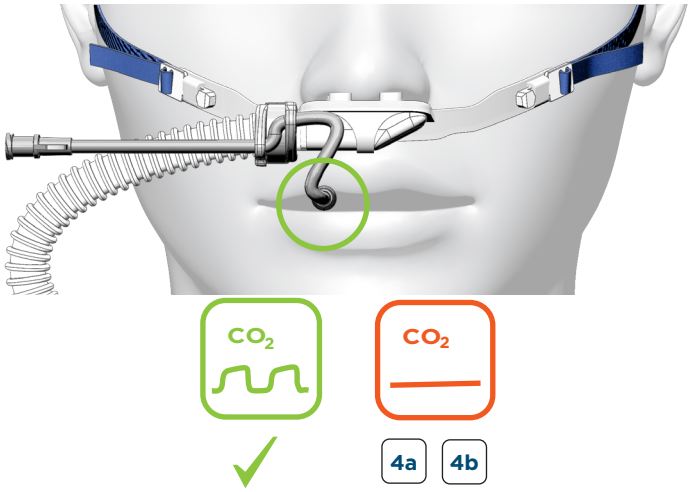

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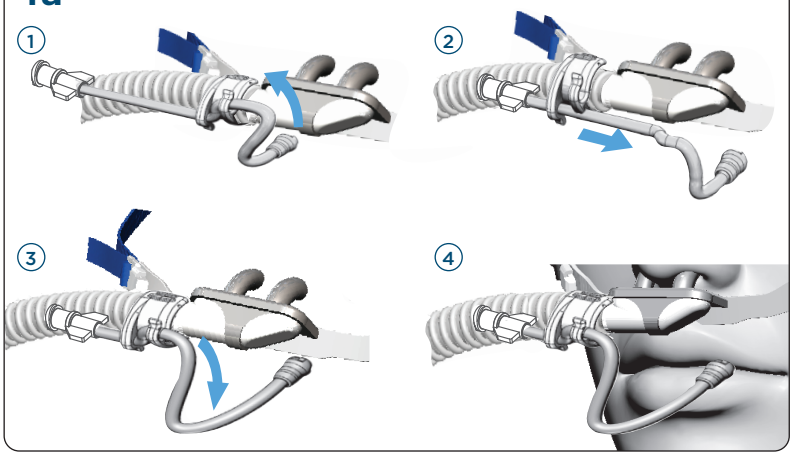

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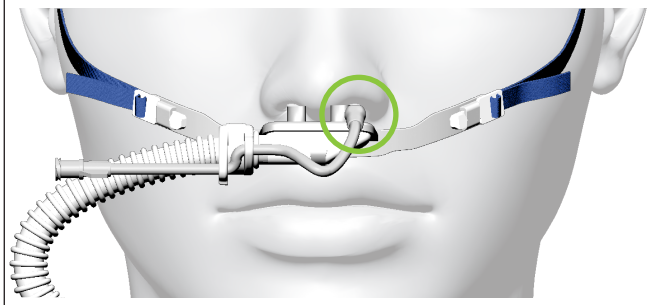

Rx only

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English (en)

F&P Optiflow™ Filtered Nasal Interface with CO_2 Sampling AA031J S/M/L (Small / Medium / Large)

Indications for Use

This product is a single-patient-use device that delivers respiratory gases to adult patients in hospitals.

This product is indicated for the delivery of Nasal High Flow (NHF) and Low Flow Oxygen to spontaneously breathing patients by appropriately qualified healthcare professionals.

Qualitative carbon dioxide sampling can be used at nasal cannula flow rates from 5 to 50 L/min in operating and procedure rooms.

This product can be used for pre-oxygenation and short-term supplemental oxygenation (up to 10 minutes) during intubation in operating rooms under the direction of a physician anesthesiologist.

This product is not indicated for apneic ventilation.

⚠ Contraindications

The following are contraindicated for this product. Failure to comply can lead to serious injury or death.

- Do not use this product with electrosurgery or electrocautery devices on the head or neck. Refer to the FIRE DANGER information.
- Do not use where Continuous Positive Airway Pressure (CPAP) is contraindicated (e.g. pneumothorax, bullous lung disease, craniofacial trauma or surgery, airway foreign body, unstable hemodynamics).
- Do not use where nasal interfaces are contraindicated (e.g. nasal obstruction, nasal trauma).
- Do not administer inhalants, anesthetic gases or vapors through this product.
- Do not use an anesthesia mask while this product is in use. Attempting to seal the mask over the product may result in excessive delivered pressure.

⚠ FIRE DANGER

This product is an open oxygen delivery system. Open oxygen delivery can increase the risk of a surgical fire occurring, causing serious injury or death. Extreme care must be taken. The following is advised.

- **Contraindication:** Do not use this product with electrosurgery or electrocautery devices on the head or neck.
- **Warning:** Do not use this product where ignition sources and fuel are present. Use with ignition sources and fuel present completes the fire triangle, increasing the risk of fire. The following steps should be taken to reduce the risk of a surgical fire occurring:
  - Evaluate the oxygen needs of each individual patient and use the minimum supplementation required. Oxygen titration with a gas mixer should be considered.
  - Ensure the use of this product is communicated to all operating room personnel when conducting the procedure's fire risk assessment.
  - Ensure gas flow from the product is not in or near the surgical field AND the surgical site is free of all potential fuel sources, including alcohol skin preparation, gauze, sponges and drapes BEFORE potential ignition sources, such as electrosurgery, electrocautery or laser devices are used.
  - Ensure the room is adequately ventilated as oxygen may accumulate over time.
  - Ensure gas flow from the product does not pool under drapes.
  - Follow the instructions for use of all surgical devices, including electrosurgery, electrocautery and laser devices, regarding oxygen delivery.

Specifications

- Product is for single-patient-use only for a maximum period of 24 hours.
- Operating flow range: 5 – 70 L/min.
  - **Caution:** Flow above 15 L/min must be humidified. Failure to humidify can cause nasal and mucosal dryness and discomfort.
  - Carbon dioxide sampling only functions within the operating flow range of 5 – 50 L/min. **Note:** Higher flow rates may dilute the qualitative trace below the minimum level of detection of the carbon dioxide analyzer.
- Use only with compatible Fisher & Paykel Healthcare (F&P) humidifiers and accessories. **Warning:** Incompatible humidifiers and accessories which are used with this product may impair the performance of this product or compromise safety (including potentially causing serious injury or death).
- Ambient operating temperature: 18 – 26 °C.
- Filtration efficiency: Viral: >99.996%, Bacterial: >99.999%.
- Filter is hydrophobic.
- This product is not intended to be sterile.
- This product was not made with natural rubber latex.

Setup Instructions

1. Connect product to compatible system.
2. Connect carbon dioxide sampling tube to carbon dioxide sampling line and analyzer. **Warning:** Luer connection for gas sampling only. Do not connect to intravenous fluids or any other device.

   Ensure the recommended water prevention system for the carbon dioxide analyzer is installed. **Note:** Failure to do so may cause condensed water, secretions and/or contaminates to impair the analyzer's performance.

   Fit product to patient.

   Ensure product is sized correctly. **Warning:** Do not create a seal in the nares as this may present a risk of barotrauma or gastric insufflation.
3. Ensure all connections are secure.

   Ensure a carbon dioxide trace is present on the carbon dioxide analyzer to confirm carbon dioxide sampling tube function and location. If a trace cannot be obtained refer to the troubleshooting instructions.

   Set flow rate and ensure gas flow is exiting the prongs.

Troubleshooting Instructions

4a. If carbon dioxide sampling tube is not long enough to reach your desired sampling location:

(1) Unwind tube from plastic clip.

(2) Pull tube to desired length.

(3) Rewind tube onto plastic clip.

(4) Bend tube to desired sampling location.

4b. If a qualitative sample cannot be obtained, bend carbon dioxide sampling tube towards patient's nose.

Operating Instructions

- During use of this product, patients may desaturate rapidly with little warning and / or their arterial carbon dioxide may increase. **Warning:** Failure to follow the practices described below and appropriately address these situations can lead to serious injury or death.
  - Use appropriate patient monitoring, including oxygen saturation and carbon dioxide monitoring.
    - For spontaneously breathing patients, this product provides a qualitative carbon dioxide trace only. Alternative monitoring methods should be used where indicated.
  - Ensure availability of appropriate measures to respond to a rapid desaturation and/or carbon dioxide increase.
  - Remove the product from the patient should an anesthesia mask based therapy be required.
  - In addition, during apnea, the following practices must also be adhered to:
    - Maintain a patent airway at all times (e.g. by applying jaw thrust).
    - Do not use product where a secure airway is indicated. This may increase the risk of pulmonary aspiration.

⚠ Warnings

- Do not occlude the patient's mouth or nose with hands or any devices. Occlusion can lead to excessive delivered pressure and cause serious injury or death.
- This product delivers oxygen. Oxygen titration with a gas mixer should be considered where hyperoxia is a concern.

⚠ Cautions

- Do not use product where quantitative exhaled gas measurements are indicated. All oxygen delivery devices modify the patient's exhaled gas composition. Exhaled gas composition measurements may be significantly altered. Alternative monitoring methods such as arterial blood gas test should be considered.
- Do not reuse product on multiple patients. Reuse may result in transmission of infectious substances, interruption to treatment, serious injury or death.
- Do not use product if damaged. Product damage may result in impaired performance.
- Do not remove the clip holding the carbon dioxide sampling tube from the product as this may damage the product or cause leaks in the system and reduce the gas supply to the patient.
- Do not soak, wash or sterilize the product. Avoid contact with chemicals, cleaning agents and hand sanitizers as this may damage the product or cause leaks in the system and reduce the gas supply/ humidity to the patient.
- Do not stretch or crush tubing, as this may occlude the gas flow or damage the tubing, resulting in impaired performance or gas leaks.
- Do not use product if packaging is not sealed or it is contaminated, as this presents a risk of infection.
- Do not use product in or near a magnetic resonance imaging (MRI) scanner.
- Dispose of product safely in accordance with standard hospital procedure. User may be exposed to respiratory tract fluids during disposal.

Notes

- Refer to the instructions for use of compatible Fisher & Paykel Healthcare humidifiers and accessories for additional warnings, cautions, contraindications, and system information.
- If a serious incident has occurred while using this product, please contact your local Fisher & Paykel Healthcare representative and Competent Authority.