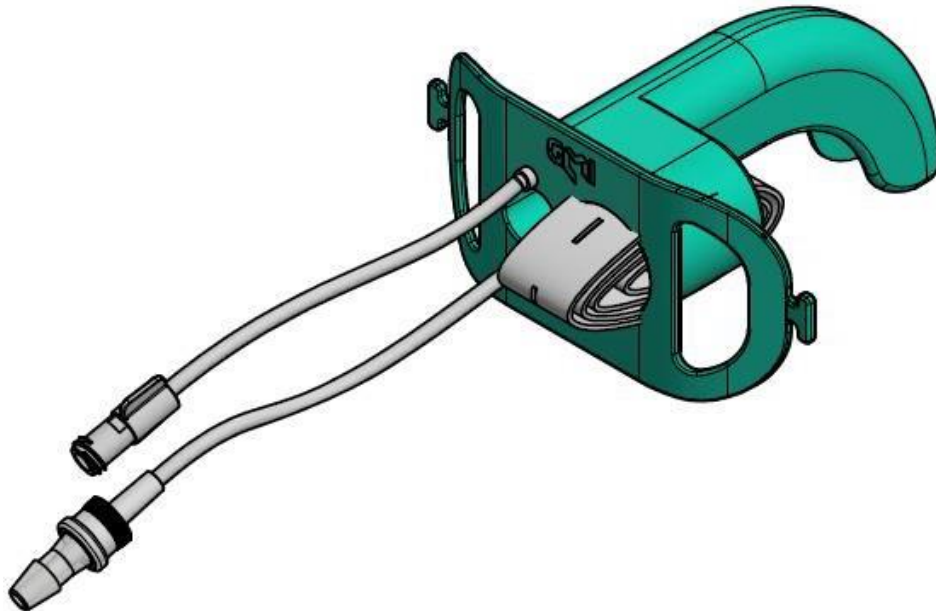


GMI OROPHAR DOUBLE LUMEN OROPHARYNGEAL CANNULA

Product Specifications:

Product Codes:

540.5.90 OROPHAR 90 MM
540.5.100 OROPHAR 100 MM



Recommended Use

The OROPHAR DOUBLE LUMEN OROPHARYNGEAL CANNULA is designed to maintain patency of airways while carrying out endoscopic procedures. This product may be used in deep sedation with spontaneous ventilation or invasive positive pressure ventilation.

It is recommended for use in anesthetic procedures such as airway endoscopies, fiberoptic bronchoscopy, endoscopy of the digestive tract, transesophageal echocardiography, and endoscopic retrograde cholangiopancreatography (ERCP).



Facilitates the insertion of endoscopic probes, protecting them from damage to the fiberoptics caused by the mouthpiece.

Functional Principles and Engagement Mechanism

The OROPHAR DOUBLE LUMEN OROPHARYNGEAL CANNULA offers protection and prevents the tongue from abutting the posterior pharynx.

Instructions for Use

1) Endoscopy of digestive tract

Position the elastic neck strap before sedating patients, leaving the two ends free.

The cannula can be inserted once the sedation process has been initiated (loss of palpebral/corneal reflex).

Use one hand to open the patient's mouth and lower the tongue using the pointer finger or thumb, or a tongue compressor.

The device must be centered on the patient's upper lip, and the mouthpiece protector must be positioned between the incisors (upper and lower).

Attach the elastic neck strap to the cannula and adjust the pressure until the cannula is secure. For greater comfort and safety, adjust the strips on both sides. Do not overtighten the straps.

Once the elastic strap has been fastened, the CO₂ measuring device and oxygen catheter must be connected.

O₂, oxygen flowmeter adjusted to 2 to 4 liters/min.

CO₂, connected to capnograph, or gas analyzer in order for CO₂ readings

to be taken. Introduce the probe into the rounded orifice (A)

2) Airway endoscopy (flexible fiberoptic bronchoscopy – access in cases in which difficulty is encountered in endotracheal intubation).

Position the elastic neck strap before sedating patients, leaving the two ends free.

The cannula can be inserted once the sedation process has been initiated (loss of palpebral/corneal reflex).

Use one hand to open the patient's mouth and lower the tongue using the pointer finger or thumb, or a tongue compressor.



The device must be centered on the patient's upper lip, and the mouthpiece protector must be positioned between the incisors (upper and lower).

Attach the elastic neck strap to the cannula and adjust the pressure until the cannula is secure. For greater comfort and safety, adjust the straps on both sides. Do not overtighten the straps.

Once the elastic strap has been fastened, the CO₂ measuring device and oxygen catheter must be connected.

O₂, oxygen flowmeter adjusted to 2 to 4 liters/min.

CO₂, connected to capnograph, or gas analyzer in order for CO₂ readings

to be taken. Introduce the probe into the squared orifice (B)

Routine care

Ensure that the cannula is properly positioned taking observing gas readings through means of capnography and arterial oximetry, as well as clinical parameters such as unobstructed breathing and thoracic expansion.

Removing the cannula

Once the endoscopic probe has been removed, release the cannula's elastic strap, inspect opening of the mouth for signs of dental trauma or damage to lips.

Conditions for Handling

1. Must be handled by a fully qualified medical professional;
2. Use recommended aseptic techniques in accordance with institutional protocols established by the health unit;
3. Check the apparatus's expiration date and the condition of packaging before use;
4. Rigorously adhere to the manufacturer's recommended instructions for use.

Warnings

The OROPHAR DOUBLE LUMEN OROPHARYNGEAL CANNULA was assessed for use on adult populations. This product is not designed to be used with pediatric patients.

Adjustment factors that are to be considered including patients with an overbite, loose or soft teeth, tumors in the oral cavity, and restricted opening of the mouth.

The manufacturer recommends that this product be applied for single use only.



Contraindications

There are no contraindications for this product provided that it is used in accordance with the instructions for use.

Adverse Effects

There are no adverse effects associated with the use of this product provided that it is used in accordance with the instructions for use.

Conditions for Storage and Transport

The product must be stored at room temperature in a clean dry environment, away from light and excessive humidity.



Product Not Sterilized

Technician Responsible - Dr. Josimra dos Santos Almeida Possidonio - CRF-

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