STERILE EO Sterilized using ethylene oxide.

Reprocessing is prohibited.

This product may not be resterilized or reused since doing so may damage the product and/or constitute a risk to the patient's health.

PACKAGING

Envelope pouch with ETO sterilized paper on which product characteristics and production lot are printed, as well as labeling required by respective health authorities.

DISPOSAL

All materials used must be disposed of in locations that are appropriate for potentially contaminated materials after 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. No adverse reactions have been observed in the use of 100% silicone products.

Technician Responsible - Dr. Josimara S. A. Possidonio – CRF - SP 54659 ANVISA REG.: 80423540008

GABISA MEDICAL INTERNATIONAL S.A.
Rua Tapiraí, 39 – Comp. 51/63/75 – Jardim Leocádia.
Postal Code 18085-300 Sorocaba – SP
CNPJ 08.633.431/0001-05 Tel./fax: 15 3238-4100

GMI GABISA MEDICAL INTERNATIONAL

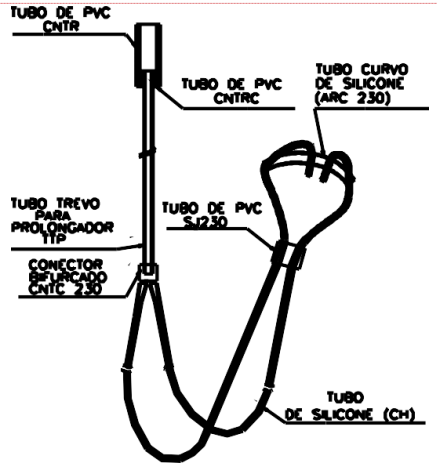
REF 230

GMI NASAL CANULA FOR OXYGEN THERAPY

INTRODUCTION

The following table presents the product's dimensions and product codes:

Code	Diameter (Fr)	Ext. Diameter (mm)	Int. Diameter (mm)	Length (mm)
230-06	06 (Neonatal)	2.30	1.40	350
230-09	09 (Pediatric)	3.30	2.00	480
230-12	12 (Adult)	4.00	2.50	500



PRODUCT DESIGN

Comentado [CK1]: CNTR PVC TUBING CNTRC PVC TUBING SILICONE CURVED TUBE (ARC 230)

STRAIGHT TUBE FOR TTP EXTENSION SJ230 PVC TUBING

BIFURCATED CNTC 230 CONNECTION

SJ230 PVC TUBING SILICONE TUBING (CH)

PRODUCT DESCRIPTION AND COMPOSITION

The **GMI NASAL CANNULA FOR OXYGEN THERAPY** consists of translucent 100% silicone tubing, with an open cylindrical-shaped distal end connecting to a silicone arc, thereby forming two oxygen injection points along a nasal arc. Tubing diameter varies according to the product code.
The proximal end of this tubing is connected using a bifurcated PVC (polyvinyl chloride) connection with PVC extension set (tubing) located at its other end with an external diameter of 6.40 mm for product codes 230-09 and 230-12 and 4.4 mm for product codes 230-06, both with a total length of 2100 mm or 7500 mm and with a cylindrical PVC connection at its end.
The part of the device that is positioned into the patient's nostrils is anatomically curved along the upper lip. The depth of the tubing inserted into the nasal can be adjusted. Patients are able to move freely when the device is securely positioned.
The extension tubing possesses an internal device that ensures that the administering of oxygen is never interrupted.

PURPOSE / RECOMMENDED USE

The **GMI NASAL CANNULA FOR OXYGEN THERAPY** is used to administer oxygen or compressed air through the upper respiratory airways in patients requiring such treatment.
It can also be used in patients with mild breathing difficulties, offering supplementary oxygen to patients with difficulty in maintaining spontaneous breathing.

INSTRUCTIONS FOR USE:

1. Open packaging while applying aseptic techniques as close as possible to the moment at which the device will be used;
2. Products must be used under the direct supervision of a qualified and fully trained health care professional.
3. Avoid applying excessive force during insertion;
4. The cannula must be inserted in accordance with the institution's standardized procedures.
5. Place the patient in the Semi-Fowler's position;
6. Adjust oxygen flow;
7. Connect the end of the extension tubing to the oxygen source (tubing has an interior design that prevents flow from being interrupted);
8. Adjust the depth of nasal tubing and place in nostrils, with anatomically curvature resting on the upper lip;
09. Adjust to the patient's face, supporting the area behind the ears and adjusting using the blue connection;
10. Ensure that the patient is comfortable.

CONTRAINDICATIONS

Patients with facial burns and/or facial deformities.

WARNINGS AND PRECAUTIONS

1- This is a disposable product intended for use on a single patient.
2- Do not resterilize the product. Single use. Reprocessing is prohibited.
3. Product must be used under the direct supervision of a qualified and fully trained health care professional.
4. The sterility of this product is guaranteed if the packaging has not been tampered with or damaged. Packaging preserving the product's original condition of sterility must only be opened in order to carry out the insertion procedure.
5. Precautions must be taken when using perforating or cutting instruments since they may damage the external surface of the product.
6. It is important to note that the techniques for use, special care taken with the product, and removal may vary in accordance with the specific circumstances of each usage;
7. Adhere to all medical recommendations and institutional standards regarding the administering of oxygen.
8. Carry out frequent verifications of the permeability of nasal tubing.
9. An oxygen concentration between 1 and 6 L / min. is suggested.
10. It is preferable the the patient be connected to a saturation monitor.
11. Excessive pressure may damage the nasal mucusa. Introducing dry oxygen for prolonged periods of time causes sequela in the nasal mucosa. Special care must be taken at pressure points in order to avoid injury (ulcers caused by pressure).
12. Do not use product after the expiration date.
13. Do not use product with patients under mechanical ventilation.
14. Product must not be used in endotracheal tubes or other respiratory devices.
15. Non-flammable product, resistant to water and solar rays.
16. Carry out subsequent care in accordance with institutional/professional criteria.
17. Product must not be resterilized since they may negatively affect the patient's health.