RECOMMENDATIONS

1. Ensure that packaging is intact.
2. Verify the dates on which the device was sterilized and the expiration date.
3. Store the product in a dry, well-ventilated area protected from solar rays.
4. Carry out subsequent care in accordance with institutional/professional criteria.
5. This product must not be resterilized or reused since doing so may damage the product and/or constitute a risk to the patient's health.

STERILE EO Sterilized using ethylene oxide.

Reprocessing is prohibited.

PACKAGING

Blister with sterilized paper covering 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. However, all possible contraindications, precautions, and warnings are described in this document. No adverse reactions have been observed in the use of 100% silicone products.

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GMI GABISA MEDICAL INTERNATIONAL

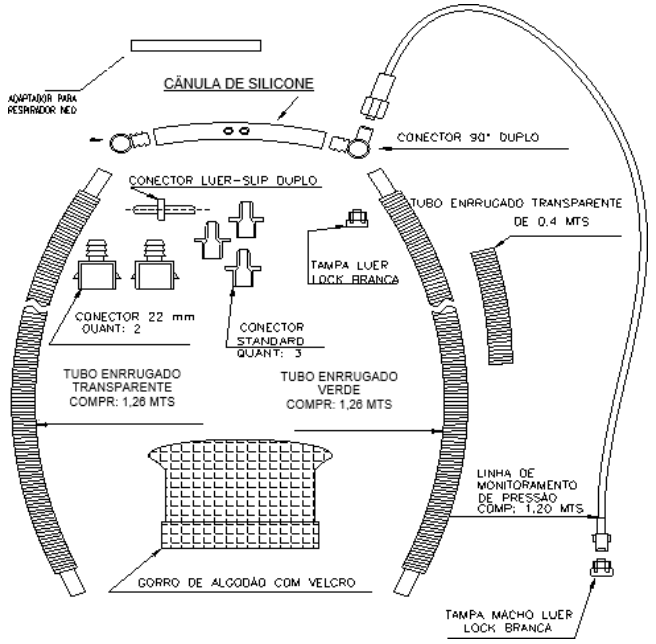
REF 233

GMI NASAL
C.P.A.P.

INTRODUCTION:

Complete neonatal nasal C.P.A.P system (dimensions presented in table below):

Accessories for exclusive use with product
1 100% silicone nasal cannula with anatomical design
2 120 cm corrugated tubes for respiratory pathways.
1 40 cm corrugated tube for humidifiers
1 pressure monitoring line
1 extra soft cotton head cap with adjustable straps in order to stabilize corrugated tubes
1 Silicone adapter for neonatal respirator
2 90º connections for inhalation/exhalation pathways
2 22 mm connections
3 Standard 10 mm connections



PRODUCT DESIGN

The nasal cannula's dimensions and respective product codes are presented in the following table.

Code	FR	Cannula e diameter (mm)	Separation between cannulae (mm)	Cannulae length (mm)	Recommendations according to patient weight	Head cap size
233-00	08	2.9	3.39	8.5	Less than 1000 g	S
233-01	10	3.30	3.00	8.8	Between 1000 g and 1500 g	S
233-02	12	4.15	2.19	10.00	Between 1500 g and 2000 g	M

PRODUCT DESCRIPTION AND COMPOSITION

The **GMI NASAL C.P.A.P.** is a modern device that includes all of the elements needed for connection to respiratory support. The unit's main element is a 100% silicone nasal cannula that can be adjusted to the patient's specific anatomical characteristics. This cannula is connected to two outputs, one for inspiration and the other for expiration through means of the accessories described above.

PURPOSE

The **GMI NASAL C.P.A.P (Continuous Positive Airway Pressure)** is used in neonatology and pediatrics to provide respiratory support to patients with breathing difficulties.
It allows a permanent airflow to be maintained, ensuring that respiratory airways are kept open, thereby providing increased oxygen distribution in alveoli.
Intended for use in patients with moderate breathing difficulties or premature patients with pulmonary immaturity, atelectasis, suffering from periods of apnea, and results indicating bradycardia.

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. This professional must carry out monitoring during application of the product as well as throughout patient treatment;
3 The **GMI NASAL C.P.A.P** must be used in accordance with the institution's standardized procedures;
4. Place patient in decubitis elevated to 30º;
5. Connect monitors for heart rate and oxygen saturation;
6. Connect monitoring line to the device and mechanical ventilator when necessary;
7. Adjust oxygen flow and pressure to indicated levels;
9. Place the nasal cannula onto the upper lip in a manner which accommodates the patient's anatomical characteristics;
10. Fasten tubes in head cap;
11. Check for perinasal release of air or air exiting from the system.

12. Assess and record the patient's general characteristics.
13. Ensure that the patient is comfortable.
14. Consistently monitor airway pressure.

CONTRAINDICATIONS
Patients with apnea associated to cardiac alterations; facial deformations.

PRECAUTIONS
1. Disposable, single use product.
2. Do not use the product is its packaging has been tampered with, otherwise sterilization cannot be guaranteed;
3. Do not resterilize the product;
4. Do not use after the expiration date;
5. The sterility of this product is guaranteed if the packaging is intact and properly sealed. Packaging preserving the product's original condition of sterility must only be opened in order to carry out the insertion procedure.
6. Special care must be taken when using cutting instruments since they may cut or damage the product's external surface;
7. All products must be used under the direct supervision of a qualified health care professional. This professional must carry out monitoring while the device is being used, as well as throughout the patient's treatment.
8. The product must be used in accordance with the practices defined by the institution;
9. Consistently monitor airway pressure;
10. 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;
11. Monitor the patient's vital signs and respiratory patterns (heart rate (fc), peripheral oxygen saturation (SPO2), and respiratory rate);
12. Consistently monitor pressure and fraction of inspired oxygen (FiO_2);
13. Continuously assess color of skin and abdominal tension;
14. Adhere to all medical recommendations and institutional protocols;
15. Carry out frequent verifications of the permeability of nasal tubing;
16. Contraindicated for patients with apnea associated to cardiac anomalies and facial deformations;
17. Do not use this product in patients using endotracheal tubes or other respiratory devices;
18. Do not use creams or gels during aspiration; use physiological solution to moisten nostrils during initial cannula insertion, if necessary.

WARNINGS
Exposure to high concentrations of oxygen for prolonged periods of time will result in adverse effects. Excessive airway pressure may cause pneumothorax. Accumulation of air in the gastric cavity may cause secondary aspiration of vomit. Special care must be taken at pressure points in order to avoid damage including injury to the nasal septum.