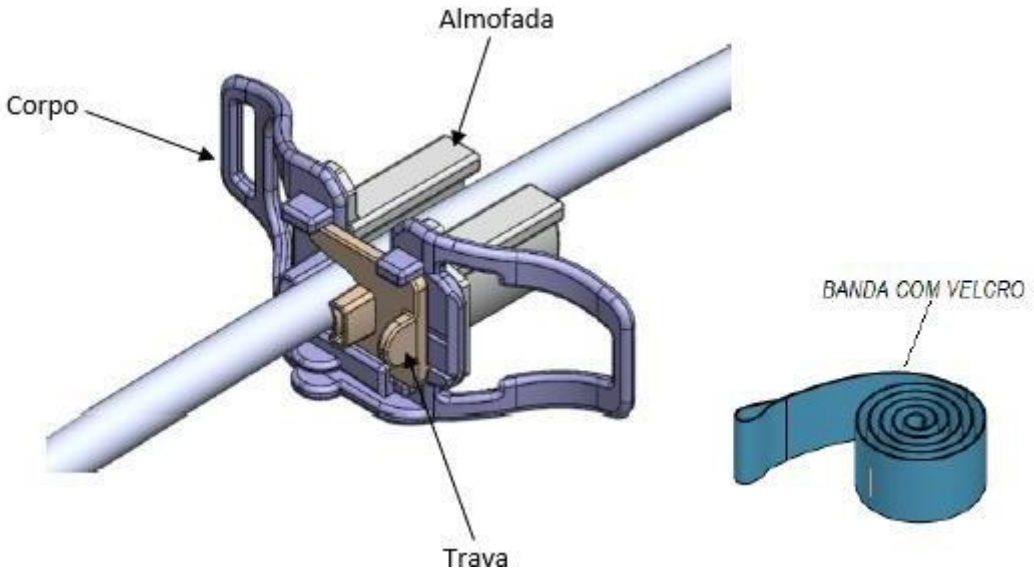
REF 551

GMI TRACHEOFIX + - ENDOTRACHEAL TUBE FASTENER PLUS

The following table presents the product codes and dimensions:

Code	Description	Body length (mm)
551.1.1	TRACHEOFIX + S - Single Unit	90
551.3.1	TRACHEOFIX + L - Single Unit	100



PRODUCT DESCRIPTION AND COMPOSITION

The **GMI ENDOTRACHEAL TUBE FASTENER PLUS** consists of a medical-grade polycarbonate fastener base (body) and locking mechanism, Velcro fabric strap and medical-grade silicone 30 Shore skin barrier pads, the measurements for length and caliber of which vary according to the product code.

INSTRUCTIONS FOR USE

The Endotracheal Tube Fastener is designed for safe fastening of endotracheal tubes in intubated patients under mechanical ventilation, reducing the risk of accidental extubation. Intended for use in adult patients.

FUNCTIONAL PRINCIPLES AND ENGAGEMENT MECHANISM

The endotracheal tube fastener provides a convenient means of keeping the oral endotracheal tube in place without the need for adhesive tape. It allows the tube to be repositioned in any direction along its guide without the necessity of removing the device.

INSTRUCTIONS FOR USE

1. Ensure that the packaging is not torn or damaged.
2. Place the Tracheofix in the area in which the endotracheal tube is inserted and slide the lock in the direction of the tube until it is well-fastened and tight.
3. Insert the fastening strap through the closure on the side of the endotracheal fastener, fasten using the Velcro, wrap the fastening strap around the patient's head and fasten on the other side of the endotracheal tube's slot, adjusting the length to ensure that the strap is not loose.
4. To remove the product, release the fastening strap.
5. Push the lock support downwards and slide the lock to the side to open. Afterwards remove the product carefully to ensure that the endotracheal tube is not removed.

WARNINGS

1. Must be stored at room temperature in a clean dry environment, away from light and excessive humidity;
2. Completely free of latex and its derivatives;
2. Always ensure that you have read the instructions for use before using the device;
3. Do not use the product if its packaging has been damaged;
4. The manufacturer recommends that the product be applied for single use only in order to ensure that the product's integrity has not been compromised and/or the patient is not affected by cross infections.

PRECAUTIONS

1. Open the device's packaging as close as possible to the moment at which it will be used;
2. Always confirm the product's expiration date and conditions of the packaging before use;
3. After use, the filter must be disposed of in an appropriate location in accordance with hospital standards and protocols.
4. Adjustment factors that are to be considered include patients with an overbite, patients without teeth or upper dentures and that therefore do not have the jaw support needed to use the ENDOTRACHEAL TUBE FASTENER and/or patients with significant lip thickness, or that use dental appliances or have significant facial swelling.
5. Once the ENDOTRACHEAL TUBE FASTENER has been positioned, continuously check the patient to ensure that both the ENDOTRACHEAL TUBE FASTENER and the endotracheal tube itself are fastened and correctly positioned.
6. To minimize the risk of injury due to pressure, inspect the patient's lips and skin every two hours or at a greater frequency if required by the patient's condition.
7. Discontinue use of the apparatus if redness or irritation of the skin occurs.

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 HANDLING, STORAGE AND TRANSPORT

1. The Tracheofix must be handled in health care units for use on patients by properly qualified medical professionals;
2. Use aseptic techniques;
3. Check the apparatus's expiration date before use;

4. Rigorously adhere to the manufacturer's recommended instructions for use;
5. Must be stored at room temperature in a clean dry environment;

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6. It must be transported in the same conditions in which it is stored, thereby guaranteeing its quality, safety, and effectiveness.

Product Not Sterilized

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