GIMA
PROFESSIONAL MEDICAL PRODUCTS

ENGLISH

# *SILICONE HOLLOW FIBER CUSHIONS*

**WARNINGS**
Before performing any operation, visually check the integrity of the device. If the product shows any anomalies, immediately contact the point of sale where the purchase was made. Erregi sas assumes no responsibility for the improper use of the device. In the event of a serious incident related to the use of the device, please report the incident to the manufacturer and the competent authority of the member state where the user and/or patient is located.

**DESCRIPTION**
Cushions for the prevention of pressure ulcers, made of cotton with hollow siliconized fiber padding. Some devices are equipped with fastening systems using Velcro closures. High resilience and excellent breathability allow for effective prevention of pressure ulcer formation.

**INTENDED USE**
Pressure ulcer prevention for adult patients aimed at reducing pressure peaks, minimizing shear and friction forces, and promoting air circulation.

**INDICATIONS AND PRECAUTIONS FOR USE**
Medical device indicated for the prevention of pressure ulcers, to be used following clinical evaluation by a specialist physician. Place the cushion on the wheelchair seat, ensuring that the Velcro fastenings, where present, are positioned toward the backrest. Then secure the cushion to a rigid part of the wheelchair frame using the Velcro fastenings. Although the device is intended for the prevention of pressure ulcers, it cannot control all the factors that contribute to their development.
It is recommended to regularly monitor the affected area, frequently reposition the patient, and pay particular attention to hygiene. For this purpose, it is advisable to consult protocols and guidelines for the prevention of pressure ulcers. Always use the device while wearing a protective garment. This device is not fire-resistant.

**CONTRAINDICATIONS**
No contraindications have been detected, except in cases of proven sensitivity to the component materials.

**COMPOSITION**
COVER: Cotton
FILLING: Siliconized hollow fiber

**WASHING INSTRUCTIONS**

| | | | |
|---|---|---|---|
|  |  |  |  |
| WASH AT MAX 40°C | DO NOT BLEACH | DO NOT IRON | DO NOT TUMBLEDRY |
|  | USE ANY SOLVENT EXCEPT TETRACHLORETHYLENE | | |

*The manufacturer is not responsible for any changes in the technical specifications of the device in case of non-compliance with the washing instructions.*

**DISINFECTION**
Use products for medical-surgical use.

**STORAGE**
Store in a place protected from light, heat, and moisture.

**DISPOSAL**
Dispose of the device in accordance with the applicable environmental protection regulations and separate waste collection.

| | | | |
|---|---|---|---|
|  | Product code |  | Medical Device |
|  | Lot number |  | Manufacturer |
|  | Medical Device compliant with Regulation (EU) 2017/745 |  | Consult instructions for use |
|  | Keep away from sunlight |  | Keep in a cool, dry place |
|  | Date of manufacture |  | Not made with natural rubber latex |
|  | Authorized Representative in Switzerland |  | Distributed by |
|  | Unique Device Identifier | | |

**DO NOT remove the label from the Medical Device, as it allows tracing the supplied product (Manufacturer, UDI, batch number, product code).**

**GIMA WARRANTY TERMS**
The Gima 12-month standard B2B warranty applies.

**Gima 28549 - 28550 - 28551 - 28552**

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