User manual: Positioning aids for pressure relief and sets

BUDI: 4064551mP001X3 , 4064551mP007XF

Warning! This symbol indicates important information related to safety. Follow these instructions carefully.

To ensure safe use of this product, please read and follow these instructions before first use.

CE

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Intended use

Intended use Positioning aids for pressure relief
Pressure-relieving positioning of patients.

Consideration of the patient's anatomical conditions, quick and gentle positioning of the patient, relief for staff through easy handling.

User groups

For positioning aids for pressure relief This is a medical device that may only be used by trained professionals who have received regular training on the product. The operator and user of the medical device are responsible for providing the training. The type and indication of use is based on the current, generally accepted medical guidelines and recommendations of the relevant professional associations.

If the product is classified by the operator as a self-explanatory product for the group of intended users, this must be documented by the operator in an appropriate form (e.g. risk analysis). A general classification of the product as self-explanatory by the manufacturer is not possible, as this always depends on the intended user group.

When using the positioning aids for pressure relief, the following handling conditions must be observed in particular:

- Before each use, check for usability and functionality.
- After changes in the position of the operating table (e.g. bending), the patient must be repositioned.
- Once the patient's position has been corrected, ensure that the skin is positioned without tension.
- Repositioning intervals must be adjusted according to the patient’s previous impairments (diabetes mellitus, circulatory disorders, etc.).

The product is intended for multiple use after proper reprocessing/cleaning.
Protect from moisture and sunlight. Do not store on radiators and protect from direct sunlight.

Intended patient target group:
- Patients of all age groups to be positioned.

Use in children, pregnant or breastfeeding women:

The use of positioning aids to relieve pressure in these patient groups does not require any special precautions. The therapy recommendations of the relevant professional associations must be observed for specific treatment.

Restrictions on use / contraindications

There are no known general contraindications. Each case must be assessed individually by the user.

Products with a blue cover are not intended for use in potentially explosive areas.

Any undesirable side effects when using the product
Undesirable side effects are not to be expected when the product is used as intended.

Safety Instructions

product has no life-sustaining or life-supporting effect!
The product may only be used if it is in proper and undamaged condition.

Medical devices that can be used together with the product
The products can be combined with all approved medical devices when used as intended. (If you are unsure about the combination option, please contact the manufacturer.)

Indications of special treatment/preparation of the medical device before use

The positioning aids for pressure relief must be cleaned and disinfected before/after use on the patient.

Checking the safe and operational condition of the medical device

Immediately before using the positioning aids for pressure relief, they must be visually checked to ensure that they are in perfect condition. Damaged products must be replaced immediately.

As an immediate measure in case of suspected or obvious damage to the product, this medical device must not be used and should be replaced immediately with a new, originally packaged product.

Information on possible mutual interference during examinations and treatments
The product is permeable to X-rays and non-magnetic and can therefore be left under the patient during an X-ray examination / computer tomography / magnetic resonance imaging.
When performing magnetic resonance imaging, EEG, ECG or ultrasound examinations, artifacts may occur due to magnetic interaction and/or electromagnetic interference.

The product does not contain any metallic components. The product is not expected to interfere with MRI examinations.

Inspection & Maintenance
The product must be checked regularly for damage and functionality.
The manufacturer does not provide for any further maintenance or repair work to be carried out by the operator or user.

Repairs & Maintenance
For reasons of product liability and safety, repairs and maintenance work may only be carried out by authorized specialist companies using original spare parts. If any repairs or maintenance work need to be carried out, please contact the manufacturer.

Reusability
The product can be reused if it is still functional and the material is undamaged. Before using it again, the user must ensure that the product is in good condition. Only products that are in perfect technical and hygienic condition may be reused.
If there are signs of material wear or fatigue, the product must not be reused.

Reprocessing - Cleaning and care / disinfection *
The product can be roughly cleaned with water and a soap solution. Extreme mechanical cleaning, which can damage the surface material, should be avoided. mediplan/nerosoft covers should only be washed inside out (95°C) with neutral cleaners (must not contain softeners or bleach), the zipper must be open when washing. The foam must be removed before washing. Do not remove dirt from the cover/belt with products containing solvents, avoid using alcohol!

Do not comb out the fleece parts; any dirt on the Velcro fastener (on the operating table) can be removed using the Velcro comb (item no. 300.001). Colored materials can be washed in accordance with ISO 6330 standard - part 3A. Sufficient drying of the material is a decisive factor for the care and durability of the material. The products can be dried by hanging them up in the air or in a tumble dryer at temperatures up to 60°C. Follow the washing instructions on the product labels! Do not iron or mangle the material!

Disinfection
Disinfection of the product in the form of a surface wipe or spray disinfection is possible. Do not use strongly alkaline solutions. An overview of the approved disinfectants can be requested from mediPlac GmbH if required.

Peroxide-based disinfectants and oxidation reactions can lead to premature material aging. The materials cannot be sterilized.

If you have any questions about the applicability of specific disinfectants, please contact the manufacturer.

Reprocessing – Sterilization *

The product is not intended for sterilization.

Technical specifications / product features:

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Depending on the product, different performance characteristics (length, width, weight, strength, etc.) can be found in this product group.
The product can be used in a temperature range of -20°C - +70°C.

Storage
Store the product in a dry place, do not store it on radiators and do not expose it to direct sunlight. Protect from moisture.

Limitation of the period of use
The product is intended for a service life of 10 years from the date of manufacture. (See product labeling) Using the product after the end of the service life is considered improper use.

Information on the proper disposal of the medical device
After proper disinfection, the medical device can be disposed of. Please observe your local regulations regarding the disposal of medical waste and residual waste.

- The product packaging can be recycled.
- The metal parts can be recycled as scrap metal.
- Plastic parts can be recycled.
- Disposal must be carried out in accordance with the relevant national legal regulations.
- Please ask your city/municipal administration about local waste disposal companies.

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Warranty

The manufacturer provides a warranty for this product in accordance with statutory provisions. This covers material and processing defects. Excluded from this are wearing parts and parts/assemblies that are subject to normal wear and tear, as well as damage resulting from excessive stress, improper

use, violent damage or unauthorized modification/repair. In the event of a warranty claim, please contact the manufacturer.

Safety notice
All serious incidents related to the device must be reported immediately to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

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