

Instructions for use

ekaFlex-S-Mattress



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SCOPE OF DELIVERY

- The scope of delivery includes:
- Mattress
- Cover
- Instructions for use
- Outer packaging

Please check the scope of delivery immediately to ensure that it is complete.

INTENDED USE

The ekaFlex-S mattress is used for pressure ulcer prevention and treatment.

TARGET PATIENT GROUP

The ekaflex-S mattress is suitable for patients of all ages and can be supplied in lengths and widths to fit the respective nursing bed. The mattress is suitable for patients weighing between 50 kg and 140 kg.

INDICATION / CONTRAINDICATION

The ekaFlex-S mattress is suitable and recommended

- for existing pressure ulcers (up to and including III according to EPUAP)
- for persons with a medium to high risk of pressure ulcers (according to Branden)
- for persons who must remain in a lying position due to disability or illness
- The product cannot be used in cases of known foam or plastic allergies.

EKAFLEX-S FOAM

The ekaFlex-S mattress offers outstanding comfort thanks to its two-layer construction. The lying surface features 5 cm thick viscoelastic foam (ekaFlex-S foam). A 7 cm thick cold foam increases the support and enables optimal positioning. ekaFlex-S foam is a temperature-responsive, viscoelastic PU foam with an open cell structure. These properties result in a unique, pressure-relieving product that offers you optimal comfort.

Where the body puts pressure on the ekaFlex-S foam, it reacts by distributing the pressure evenly across the entire contact surface. The pressure-relieving properties of ekaFlex-S foam significantly reduce the risk of pressure ulcers.

After being subjected to pressure, ekaFlex-S foam returns to its original shape after a certain temperature-dependent standard delay due to its viscoelasticity. ekaFlex-S foam reacts to body heat and thus adapts optimally to the shape of the body even at low temperatures.

COVERS

INCONTINENCE COVER

The bi-elastic moisture protection cover of the ekaFlex-S mattress is a special incontinence cover. It is fully elastic on both sides and adapts to the contours of the user's body.

In addition, the cover is particularly soft, skin-friendly and bacteria-proof thanks to our bi-elastic material. The bi-elastic moisture protection cover promotes a healthy sleeping environment and offers the foam special moisture protection.

The cover is made of elastic, breathable polyester with a PU coating. This fabric is impermeable to liquids, but allows the foam material to breath.

For daily cleaning, we recommend wiping the incontinence cover with mild soapy water and disinfecting it using a commercially available wipe disinfectant.

The incontinence cover can be machine washed at 95°C. It must be washed inside out with the zip open. Hang to dry. Liquid, moisture, excrement and exudate stains must be removed immediately.

The cover is also suitable for dry cleaning and can be autoclaved at 134°C/7 min.

JERSEY STRETCH COVER

ekamed products are also available with a jersey stretch cover. The jersey stretch cover is made of 100% polyester. The cover is easy to remove and can be machine washed without any problems, provided the washing instructions on the label are followed. The jersey stretch cover must be washed inside out with the zip closed.

APPLICATION

- The ekaFlex-S mattress has a height of 12 cm. Check whether the nursing or hospital bed has been approved by the bed manufacturer for a mattress of this height. The free side rail height (distance between the top of the mattress and the top edge of the side rail) must be at least 22 cm. If the free side rail height is less than this, you must use a side rail extension. In this case, please contact your bed manufacturer!
- Remove the existing mattress from the patient's bed and place the ekaFlex-S mattress with cover in the bed. Make sure that the words 'Liegefläche' (lying surface) are facing upwards.
- For beds with adjustable lying surfaces that comply with DIN EN 60601-2-52, the ekaFlex-S mattress adapts to the adjustable lying surface. It can be used without restriction.
- If damage to the cover or foam is visible, the mattress should no longer be used. If the cover is damaged, it can be replaced with a new cover.
If the mattress shows signs of indentation, it should no longer be used.
- The formation of hollows can be minimised by rotating the mattress (180° horizontally). We recommend rotating it once a month. This will increase the period of use of the mattress.
- From time to time, the mattress should be placed on its side with the zip facing upwards and the zip opened for ventilation.
- In the event of heavy wetting or perspiration, place a bed protector on the mattress and ventilate the mattress more frequently to allow it to dry.
- Ensure that air can circulate underneath the mattress. It is recommended that the bed has a slatted frame or a grid frame, for example.
- Stains caused by liquids, moisture, excrement and exudate must be removed immediately.

SAFETY INSTRUCTIONS

- Do not clean ekamed products with steam cleaners or high-pressure cleaners. Only use the cleaning methods described in the 'Cleaning' section.
- The free side rail height (distance between the top of the mattress and the top edge of the side rail) must be at least 22 cm.

Note to the user and/or patient:

All serious incidents related to the product must be reported to Ekamed GmbH and the competent authority of the Member State in which the user and/or patient is located!

TRANSPORT AND STORAGE

The following must be observed when transporting or storing ekamed products:

- Our ekaFlex-S mattresses are delivered in a cardboard box ready for immediate use.
- Our ekaFlex-S mattresses can be rolled up for transport or storage. The lying surface must always face outwards, as otherwise material damage may occur.
- Always use a suitable cardboard box for storage and shipping.

CLEANING

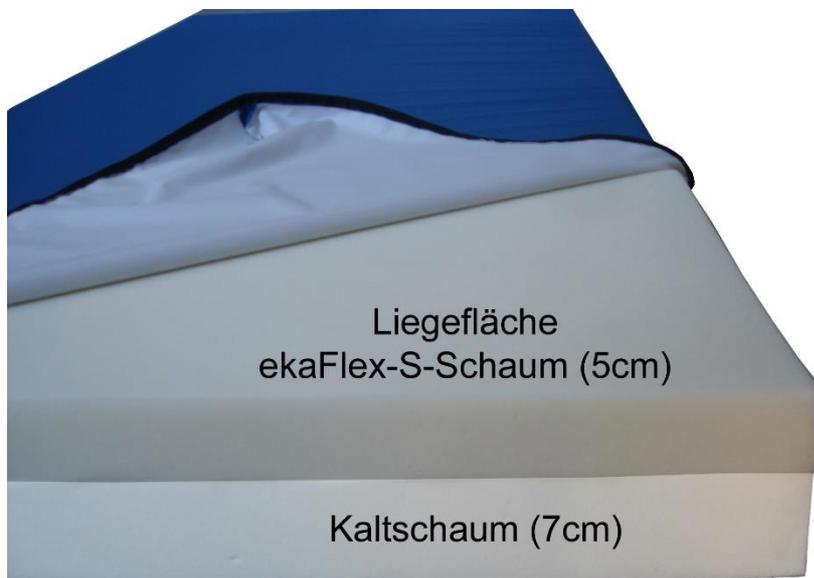
The ekaFlex-S mattress can be cleaned/wiped with mild household cleaning agents (e.g., dish soap) and disinfected with commercially available disinfectants. A list of approved disinfectants can be requested from Ekamed GmbH&Co.KG.

The ekaFlex-S foam must not be washed, i.e., completely soaked, as this may impair the material properties. The foam can also be cleaned with a suitable cleaning agent/disinfectant for PU foams.

Sterilization in an autoclave is not recommended.

For cleaning recommendations for the cover, please refer to the description in the chapter on covers on page 5 of these instructions for use.

The cover can be opened and removed using the zipper. When putting on the cover, please ensure that the label "lying surface" appears on the narrow (viscoelastic) foam layer. Otherwise, the effectiveness of the ekaFlex-S mattress will be reduced.



DISCLOSURE

The ekaFlex-S mattress is not recommended for reuse for hygienic reasons.

However, if it is used for another patient, proper hygienic preparation (cleaning and disinfection) must be ensured.

DISPOSAL

At the end of its service life, you can have the ekaFlex-S mattress disposed of by a regional waste disposal company.

Before disposal, disinfection must be carried out to minimize the risk of germ transmission

TECHNICAL DATA

Dimensions (LxWxH): 200 cm x 90 cm x 12 cm

Weight: 13 kg

Density of ekaFlex-S foam (5 cm): 48 kg/m³

Compression hardness of ekaFlex-S foam (5 cm): 3.5 kPa

Density of cold foam HR: 41 kg/m³

Compression hardness of cold foam HR: 4.7 kPa

Incontinence cover: PU-laminated PES fabric

Patient weight: 50 - 140 kg

Cover:

Flame behavior

UK-BS 7175 Crib 5

Antibacterial properties

BC-100 ULTRA-FRESH,

Active substance: 3-iodopropynylbutylcarbamate (CAS No. 55406-53-6)

PURE TAG HEIQ

Complies with the following standards:

Biocompatibility ISO 10.993-10 : 2010

Cytotoxicity ISO 10.993-5 : 2009

Ökotex100 Class 1 (Valid certificate available)

CE MARKING

This ekamed product, the “ekaFlex-S mattress,” bears the CE mark for medical devices (Class I). The product and the associated technical documentation comply with the high requirements of the MDR (Medical Device Regulation - Regulation (EU) 2017/745 on medical devices).

WARRANTY

We provide a 2-year warranty on the entire mattress when used and cleaned properly.

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