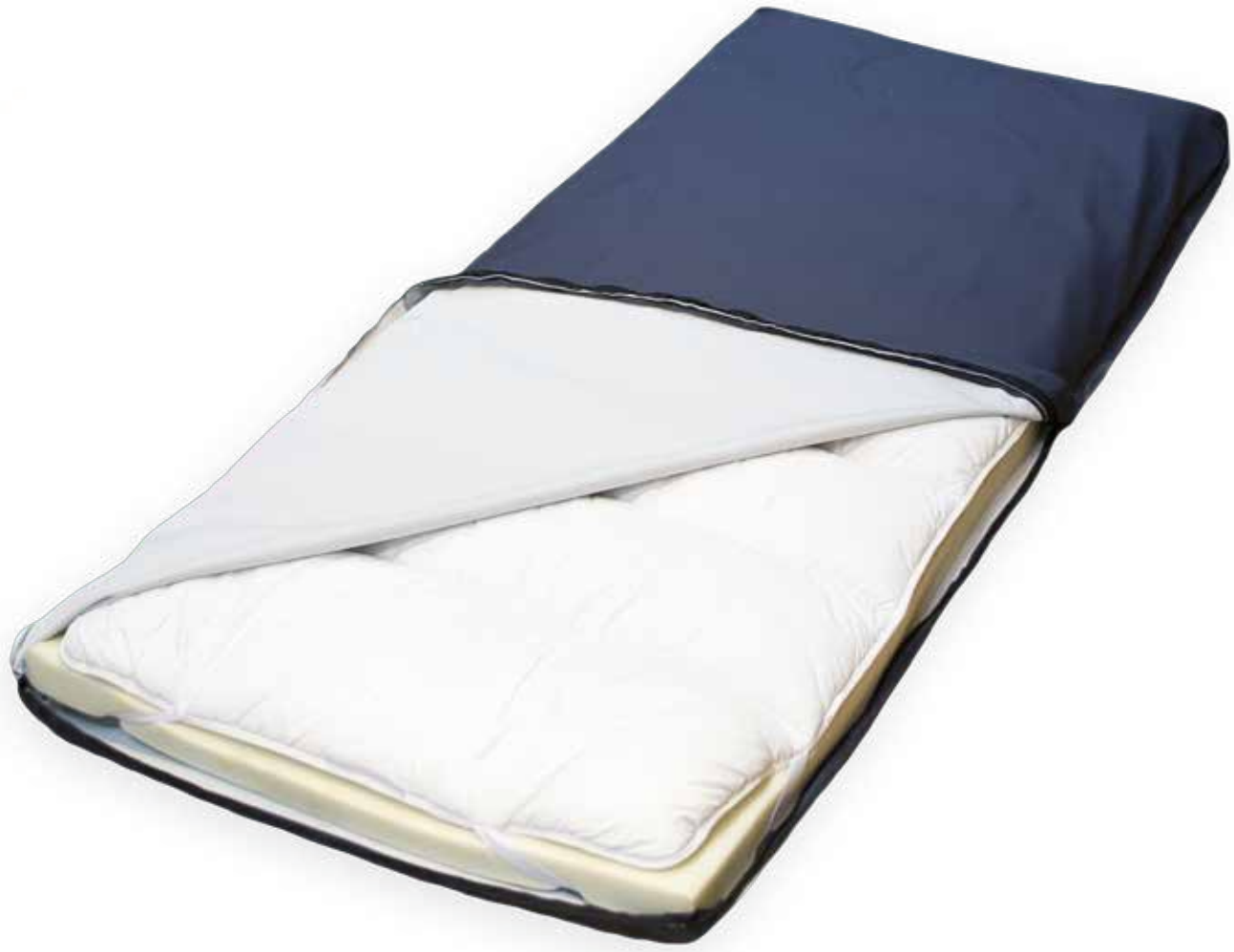
User manual

Anti-Decubitus overlay



Designation	**Elatex Combi**
Item no.	994003

novacare

With the novacare® Elatex Combi you have acquired a high quality care hollow fiber overlay for the treatment of decubitus and decubitus prophylaxis.

A good decision.
Your novacare – Team

Please read the following user instructions carefully and observe the warning information before using the system.

1. The overlay / application area

The novacare® Elatex Combi is a care overlay for the treatment and prophylaxis of decubitus. It is intended for use in household, nursing and clinical areas. It can be used in standard beds, although it is best suited for use in hospital or care beds. Use in beds with adjustable sleeping surfaces is also possible.
The novacare Elatex Combi is an anti decubitus overlay made of silicoized hollow polyester fibers and an Elatex foam combined to an overlay. The choice of materials and the type of construction meet the requirements for an anti-decubitus overlay in terms of functionality, medical efficacy and patient safetyness.

2. Indication / contraindication

Indication:
Treatment and prophylaxis of pressure sores / decubitus. The system should be used in accordance with the care plan of the nursing staff. Observe the national decubitus standard. (see Braden Scale)

Contraindication:
The overlay should not be used with allergies to the cover. In the case of patients who exceed the specified weight limits, an alternative system from the novacare® range should be selected.

3. Description of function, design and material

The hollow fiber product line was developed especially for the treatment and prophylaxis of pressure sores in home care.

The products are filled with siliconized hollow polyester fibers. In this method, highquality hollow fibers are coated with an ultrathin layer of silicone. The thus reached lubricity of the fiberfill causes a very high degree of shear force reduction.
The consistent, dense filling, which is additionally stitched to prevent slipping, allows an equal pressure distribution, thereby the contact pressure will be reduced considerably.

The product features at a glance:

- Equal pressure distribution
- easy handling and cleaning
- breathable
- reduction of shear forces

4. Area of application

The novacare® Elatex Combi is suitable for use with decubitus grade I (according to Seiler) or category I per EPUAP/NPUAP.

5. Maximum load / patient weight

The novacare® Elatex Combi is intended for a patient weight of min. 5 kg and max. 75 kg.

6. Packaging materials

Check for any damage to the product and packaging at the time of delivery. If it is intended that the overlay be transported after use, use the original packaging. Otherwise, dispose of the packaging in accordance with the national disposal regulations.

7. Safety measures prior to use

In order to avoid damage due to erroneous use, or danger for the patient or user, read the user instructions thoroughly prior to use. Observe the warning information! Use the mattress exclusively in accordance with these user instructions.
Store these user instructions in a safe place, so that the respective user can access them at all times. With a change in owner, pass the user instructions on too.
novacare® gmbh does not accept any liability for use of the overlay for any applications other than those described in these user instructions.

- The overlay must be used as intended, and must not be changed or modified.
- Be aware of changes in the skin; if necessary consult your doctor or nurse.
- In general, observe the provisions of the German Medical Devices Act and Medical Devices Operator Ordinance.

8. Safety precautions before use

Remove the overlay from the original packaging.
The foot end is marked with imprinted feet on the cover. The mattress should be positioned so, that the printed feet are visible at the foot end.
In order to protect the mattress beneath, obtain these optionally with an incontinence guard reference.

9. Warning information

- Keep sharp and pointed objects away. Do not fasten the support by unsuitable means.
- When using side rails, ensure that the prescribed minimum distance is observed. Use side rail height extensions if it is not possible to attain the minimum distance.
- When using side rails ensure the correct and smooth seating of the mattress and avoid crushing or warping.
- With renewed use, check the cover for damage.
- Observe the provisions of the German Medical Devices Act and Medical Devices Operator Ordinance.
- When used outside of Germany, observe the national regulations governing medical devices

10. Environmental conditions

Storage

Temperature:	-10 °C to +50 °C
Relative humidity:	20 % to 90 % at 30 °C – not condensing
Air pressure:	700 to 1060 hPa

Use

Temperature:	+5 °C to +40 °C
Relative humidity:	20 % to 90 % at 30 °C – not condensing
Air pressure:	700 to 1060 hPa

11. Technical data

Weight:	5,6 kg
Dimensions:	200 x 90 x 15 cm
Cover:	52% Polyester / 48% Polyurethan
Anti-Decubitus overlay:	65 % Cotton, 35 % Polyester,siliconized hollow polyester fibers
Foam layer:	33 kg/m³ , 5 cm hight, Elatex foam

12. Hygiene / Reprocessing by qualified personnel

The overlay can be cleaned in a washing machine or by a chemical/thermal process up to 60 °C with commercial detergents. After washing do spin dry. Do not drying in the tumbler! No bleaching, no ironing.

13. Disposal

The materials used in the overlay are not harmful to the environment. They can be disposed of together with domestic waste. They should preferably be taken to the official waste combustion plant responsible**.**

14. Explanation of symbols

The CE marking indicates that all standards relevant to the product and all EU directives are complied with. (see operating instructions and packaging)

Manufacturer novacare® gmbh, 67098 Bad Dürkheim, Germany (see label)

Maximum washing temperature 60 °C

Do not bleach

Do not dry

Do not iron

Professional chemical purification regular process

15. Warranty

- The warranty complies with the statutory regulations and is valid for 24 months from the date of handover.
- All warranty claims are excluded if the goods supplied by us are processed, treated or modified by another party without our approval, or with a failure to observe our user instructions.
- In the case of medical devices according to directive 93/42/EEC, the use (if applicable Medical Devices Operator Ordinance) of which is subject to reprocessing, the warranty only remains valid if the hygiene specifications of the manufacturer are observed.
- Observe the provisions of the German Medical Devices Act and Medical Devices Operator Ordinance.

16. General information

The novacare® Elatex Combi is a medical device. It is predominantly supplied by novacare gmbh to specialist medical groups (med. nurses, specialist med. dealers, operators, med. facilities, social services, etc.) or professional users.

The specialist groups and professional users include persons who, due to their medical or comparable training and qualifications, possess sufficient knowledge regarding the illness to be treated with the mattress or its avoidance, with which to enable the patient and/or non-professional users or medical laypersons to adequately use the system. The installation and adjustment of the mattress with the patient, as well as handover to and instruction of non-professional users or medical laypersons, shall be performed by the specialist medical groups.

This must take place within the framework of the standard instruction obligations, for example a description of the functions, cleaning and mode of action of the mattress, and information regarding any possible risks.

17. Scope of supply

- Overlay
- User manual

D-67098 Bad Dürkheim, Bruchstrasse 48, Tel. +49(0)6322-9565-0,
Fax +49(0)6322-9565-65, www.novacare.de