

Instructions for use

2023-03-15

Curera® Positioning

Curera® Rectangular Pillow

Curera® Positioning Roll

Curera® Back Support Pillow

Curera® Neck Pillow

Curera® Multi Pillow

Curera® Torso Support Pillow

Curera® Abduction Pillow

Curera® Curved Pillow

Curera® Triangle Pillow

Curera® Support Wedge

Curera® S-Shaped Pillow

Curera® Ear Pillow

Curera® leg/knee separator

Optimal Hygienic Pillow

Optimal Sens pillow

Molly Heel protection



Instructions for use item number: 95-001105



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WARNINGS AND SAFETY PRECAUTIONS

Read all instructions before use or repair

WARNING! To minimize the risk of fire, personal injury, and equipment/property damage, adhere to the following instructions:

1. The product must only be used for its intended purpose as described in this manual. The product may not be combined, fitted, or repaired with other parts, accessories, or spare parts other than those described in this manual or other documentation published by Care of Sweden.
2. Do not use in the vicinity of or in contact with naked flames or hot surfaces, such as fires, burning cigarettes or hot lamps. Although the product has undergone fire testing, it may become damaged if it comes into contact with fire sources.
3. Position and use the product in a manner that prevents it from being crushed or damaged. Pay particular attention where bed rails are used. Avoid injury caused by sharp objects that may affect the hygiene cover's function.
4. The hygiene cover does not allow liquid or air to penetrate but is vapour permeable (vapour is wicked away). Make sure that the patient is positioned correctly to avoid the risk of suffocation.
5. Avoid using other fully covering plastic protectors in combination with the hygiene cover, since this may affect vapour permeability.

1 Introduction



Always read the instructions for use prior to use.

1.1 General information

The product is a medical device with CE marking in accordance with MDR (EU) 2017/745. According to this regulation the manufacturer is required to report all accidents or incidents involving the products. All information involving accidents or incidents relating to our products, shall be reported immediately to Care of Sweden.

1.2 Intended purpose

The positioning pillows are intended to be used for positioning, prevention of pressure ulcers/pressure injuries and as an aid to relieve pressure ulcers/pressure injuries (PU/PI).

1.3 Intended user

The positioning pillows are intended to be used by all kind of patients.

1.4 Intended use environment

The positioning pillows are intended to be used in all kinds of healthcare environments, including home care.

1.5 Indications

For patients with an increased risk of pressure ulcers/pressure injuries (PU/PI).

1.6 Contraindications

There are no known contraindications. They must be used in a manner that prevent hyperextension, spasticity, and contractures.

1.7 Clinical benefit

The clinical benefit for the products included in this instruction for use are:

- Pressure redistribution
- Comfort
- Safety
- Easy handling

2 Operation

When unpacking, check that no parts are damaged. If any damage is found, contact Care of Sweden or your local distributor before using the product.

2.1 Operation Molly Heel Protector

- 1 Place the heel protection on the leg. Always use a gauze bandage between the product and the skin.
- 2 Wait 15-20 minutes until the foam has adjusted to the patient's leg.
- 3 Check the distance between the heel and the mattress, it should be approximately 2 cm. If the distance is too big, a smaller size should be used. If the distance is too small, a larger size should be used.

Note:

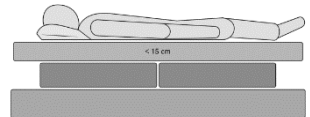
- When the patient lies on the side, the product should be rotated so that the opening is facing the mattress, in order for the height to be correct.
- When using the product for preventing crossing of the legs, the product should be placed on the healthy leg.

2.2 Operation Curera Support Wedge

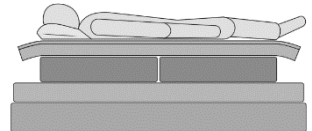
The support wedge may be placed in different ways.

Below are three different examples:

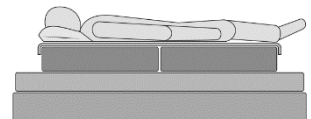
With a mattress up to 15 cm height two support wedges could be placed under the mattress.



If a mattress overlay is used two support wedges could be placed between the overlay and the mattress.



If a replacement mattress is over 15 cm in height two support wedges could be placed between the sheet and the mattress.



2.3 Operation Curera Positioning Pillows

The following operation apply to these pillows:

Curera® Rectangular Pillow
Curera® Positioning Roll
Curera® Back Support Pillow
Curera® Neck Pillow
Curera® Multi Pillow
Curera® Torso Support Pillow
Curera® Abduction Pillow
Curera® Curved Pillow
Curera® Triangle Pillow
Curera® S-Shaped Pillow
Curera® Ear Pillow
Curera® leg/knee separator
Optimal Hygienic Pillow
Optimal Sens pillow

When using these products, positioning can be determined based on diagnosis. It is recommended to change position regularly. Time intervals must be determined by attending personnel based on diagnosis, condition and general health. For greater patient comfort, it is recommended to not use a hygiene cover directly against the skin.

3 Product description

The products meet the applicable requirements of the following standards: SS 876 00 01, SS 876 00 04, SS 876 00 02, SS-EN-ISO 14971, SS-EN ISO 10993-1, SS-EN ISO 12952-1.

3.1 Curera® Leg/knee separator

The leg separator is used to keep legs apart. It is made of sturdy foam with a degree of elasticity to provide support for the patient.

Foam core: Vulcanised rubber

Cover: Polyester

3.2 Optimal Hygienic pillow

The Optimal Hygienic Pillow is a pillow with good quality and comfort.

Filling: Polyester/ball fiber.

Cover: Polyurethane-coated polyester

3.3 Optimal Sens pillow

The Optimal Sens is an anatomically shaped sleeping pillow designed in accordance with ergonomic principles to support the head and neck.

Filling: Viscose elastic memory foam

Cover: Polyurethane-coated polyester

3.4 Curera® Support Wedge

The support wedge may be used in different ways depending on the mattress used, see section 2.2 for more information.

Foam core: 100 % cold foam

Cover: Polyurethane-coated polyester

3.5 Molly Heel protection

The product has a core of visco-elastic foam and a hygiene cover. The cover is liquid resistant yet vapour permeable and is removable and washable.

Foam core: 100% visco-elastic foam (so called memory foam)

Cover: Polyurethane covered polyester

3.6 Curera® Positioning pillows

Curera® Positioning Roll, Curera® Rectangular Pillow, Curera® Multi Pillow, Curera® Neck Pillow, Curera® Backrest Pillow, Curera® Torso Support Pillow, Curera® Triangle Pillow, Curera® Curved Pillow, Curera® Abduction Pillow, Curera® Ear pillow, Curera® S-Shaped Pillow

Filling: 50 % foam, 50 % polyester fibres

Cover: Polyurethane covered polyester

4 Reuse and cleaning

The product is reusable. Before using the product again for a new patient, it is recommended to clean the product. Always follow local instructions and the instructions for use of the cleaning and disinfecting agent. Consult your hygiene manager or Care of Sweden for help and instructions in case of uncertainty.

4.1 Inner pillow

Curera® Rectangular Pillow, Curera® Positioning Roll, Curera® Back Support Pillow, Curera® Neck Pillow, Curera® Multi Pillow, Curera® Torso Support Pillow, Curera® Abduction Pillow, Curera® Curved Pillow, Curera® Triangle Pillow, Curera® S-Shaped Pillow, Curera® Ear Pillow:



Prevent over-drying when using a tumble dryer/drying cabinet. For faster drying, run the spin cycle 3-4 times.

4.2 Pillows

Optimal hygienic pillow and Optimal Sens pillow:



The hygiene cover completely encloses and protects the core so that it is rarely necessary to clean it. If cleaning is needed, clean the soiled area with a mild detergent (such as washing-up liquid) and water (spray it with a shower head, for example).

Carefully squeeze the water out. Do not wring or roll the foam core to extract water. Let the core dry in a warm, ventilated area (not in direct sunlight). The core must be completely dry before it is used again. Use an alcohol-based disinfectant if required.

4.3 Foam core

Molly heel protector, Curera® Support Wedge



Clean the affected area with a mild cleaning solution for this purpose: primarily use solvent-free soap with a neutral pH value. If necessary, a disinfectant and/or cleaning agent can be used such as: alcohol with or without surfactants or oxidizing solutions such as: chlorine and/or hydrogen peroxide, concentration 1000 ppm/0,1%. In exceptional cases, a maximum concentration of 10,000 ppm/1% can be used.

Press out the water carefully. Let the foam core dry in a warm, ventilated area, without direct exposure of sunlight. The foam core needs to be completely dry before it is used again.

Leg/knee separator



Clean the leg separator with a mild detergent (e.g. washing-up liquid) and water or with a disinfectant/cleaner intended for this purpose.

Let it dry in a warm, ventilated area (not in direct sunlight). It must be completely dry before it is used again.

4.4 Covers



Primarily use solvent-free soap with a neutral pH value. For a daily basis cleaning, a disinfectant and/or cleaning agent can be used such as: alcohol with/without surfactants or oxidizing solutions such as: chlorine and/or hydrogen peroxide, concentration 1000ppm/0,1%. In exceptional cases, a concentration of a maximum of 10,000ppm/1% can be used, then consider that high concentrations can shorten the life of the coating.

Excrement and blood stains must be removed as soon as possible using cold water. Carefully follow local instructions and the instructions for the detergent.



Cotton cover (accessory)



Note:

- Check the hygiene cover each time the product is cleaned. If damaged, it must be replaced or repaired.

5 Storage

Store at a dry area at room temperature. The product must be stored where it will not be subjected to knocks, impacts et cetera. Avoid exposing the product to direct sunlight.

6 Maintenance

The product requires no servicing or maintenance other than cleaning as described in this instructions for use.






7 Marking and symbol key

7.1 Marking


The product is labelled with its date of manufacture, item number, size, care and maintenance advice, EAN number.

7.2 Symbol key



Symbols to convey medical device information

	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
	UDI		Medical Device
	Distributor		













Symbols for traceability and product information

	Item number		
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Symbols for user information

	Read the instructions for use		Read the instructions for use
XXXX-XX-XX	Year-month-day		

Symbols for cleaning and recycling

	Machine wash at 95 °C		Machine wash at 70 °C
	Do not wash with water		Chlorine
	Wipe clean		Tumble dry
	Do not dry clean		Do not tumble dry
	Drip dry		Do not iron
	Recycling		Iron with medium temperature (max 150°C)

8 Other information

8.1 Recommended lifetime of the product

The estimated lifetime of this product is 2 years.

8.2 Disassembly and recycling

The product is completely recyclable and must be sorted as 'combustible waste'. No disassembly is necessary.

8.3 Returns

Contact Care of Sweden or your local distributor before returning the product.



Manufactured by



care of sweden

SUPPORTING LIFE

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