



Instructions for use

2025-11-10

Curera positioning 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® Support Wedge
- Curera® S-Shaped Pillow
- Curera® Ear Pillow
- Curera® leg/knee separator
- Optimal Hygienic Pillow
- Molly Heel protection

Instructions for use item number: 95-001105



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Read the instructions carefully before use.
All user instructions and safety instructions must be followed.

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












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1 Symbol key

Symbols to convey medical device information			
	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
	Medical device		Distributor
	Unique device identifier		Date of manufacture
	Warning		Caution
	Catalogue number		Batch code
	Serial number		Read the instructions for use
	Consult instructions for use	XXXX-XX-XX	Year-Month-Day
Symbols for cleaning, reconditioning and recycling			
	Machine wash at 95 °C		Machine wash at 70 °C
	Machine wash at 60 °C		Do not machine wash
	Drip dry		Do not tumble dry
	Tumble dry		Do not iron
	Iron with medium temperature (max 150°C)		Do not dry clean
	Wipe clean		Recycling
	Chlorine		

2 Warnings- and safety precautions



The following points contain important information about using the product.

- The instructions in this document shall always be followed.
- The instructions for use shall always be kept together with the product.
- It is recommended to always use the original packaging to store and transport the product.
- 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.



Adhere to the following points to minimize risk for fire, personal injury, equipment- or property damage.

- 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.
- 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.
- 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.
- Avoid using other fully covering plastic protectors in combination with the hygiene cover, since this may affect vapour permeability.

3 Introduction

This instructions for use contain information about sixteen different products. Read the label of your product carefully to understand which product you are using.



For safety reasons you shall carefully read the recommendations and instructions in these instructions for use before using the product.

3.1 General information

The system 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.

3.2 Intended purpose

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

3.3 Indications

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

3.4 Intended user

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

3.5 User qualification

Training is not mandatory to use the positioning pillows.

3.6 Intended use environment

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

3.6.1 Optimum environmental conditions

The positioning pillows are intended to be used indoors at room temperature.

3.7 Contraindications

There are no contraindications.

3.8 Clinical benefit

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

- Pressure redistribution
- Comfort
- Safety
- Easy handling

4 Operation Molly Heel Protector

When the product is unpacked, check that no parts are damaged. If damage is found, contact Care of Sweden or your local distributor before using the product. Do not use sharp objects when unpacking as it might damage the product.

How to use 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.



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.



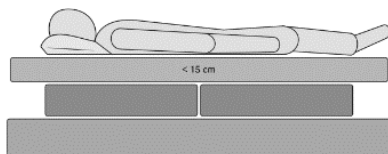
When using the product for preventing crossing of the legs, the product should be placed on the healthy leg.

5 Operation Curera Support Wedge

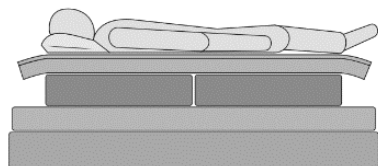
When the product is unpacked, check that no parts are damaged. If damage is found, contact Care of Sweden or your local distributor before using the product. Do not use sharp objects when unpacking as it might damage the product.

The support wedge may be placed in different ways. Below are three different examples:

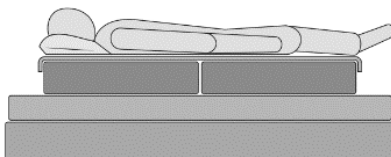
With a mattress up to 15 cm height two support wedges could be placed under the mattress.



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.



6 Operation Curera Positioning Pillows

When the product is unpacked, check that no parts are damaged. If damage is found, contact Care of Sweden or your local distributor before using the product. Do not use sharp objects when unpacking as it might damage the product.

The following text applies to these Positioning 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

How to use the pillows above:

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 not to use a hygiene cover directly against the skin.

7 Product description

Read the label of your product carefully to understand which product you are using.

7.1 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.

Materials the user comes in contact with:

- Vulcanized rubber (foam core)
- Polyester (hygiene cover)

7.2 Optimal Hygienic pillow

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

Materials the user comes in contact with:

- Polyester/ball fiber (filling)
- Polyurethane coated polyester

7.3 Curera® Support Wedge

The support wedge may be used in different ways depending on the mattress used, see section 5 for more information.

Materials the user comes in contact with:

- 100% cold foam
- Polyurethane coated polyester

7.4 Molly Heel Protection

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

Materials the user comes in contact with:

- 100% visco-elastic foam (so called memory foam)
- Polyurethane coated polyester

7.5 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.

Materials the user comes in contact with:

- 50% foam, 50% polyester fibres
- Polyurethane coated polyester

8 Reuse and cleaning

The product is reusable. Before reusing, it is important to follow the instructions below for cleaning, disinfection, and reconditioning. Disinfection is recommended between patients according to the instructions below.



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.



Check the hygiene cover each time the product is cleaned. Damaged parts must be repaired or replaced.

8.1 Cleaning and disinfection

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 tumbling dryer/drying cabinet. For faster drying, run the spin cycle 3-4 times.

PILLOWS

Optimal Hygienic 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).

Optimal hygiene pillow can be washed in machine at 70 degrees.

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.

FOAM CORE

Molly Heel Protector, Curera® Support Wedge:

Information on detergent	
Primarily	Solvent-free soap with a neutral pH-value.
If necessary	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 1000 ppm (0,1%).
Exceptional cases	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 10 000 ppm (1%).

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.

COVERS

Information on detergent	
Primarily	Solvent-free soap with a neutral pH-value.
If necessary	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 1000 ppm (0,1%).
Exceptional cases	Disinfectant, such as alcohol with or without surfactants or oxidizing solutions. For example, chlorine or hydrogen peroxide. Concentration: 10 000 ppm (1%). 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.

For mechanical cleaning:



COTTON COVER (accessory)



9 Maintenance

9.1 General

The product needs no other service or maintenance than cleaning as described in section 8.

10 Storage

Store in 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.

10.1 Standards

The products are tested and approved according to the following European standards, where applicable requirements are met.

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		

11 Other information

11.1 Technical lifetime

The technical lifetime of the product is 2 years when used under normal conditions.

11.2 Warranty

The product warranty covers manufacturing defects and is valid from the date the product is shipped with intent of usage, either directly from Care of Sweden or through one of Care of Sweden's designated distributors. The product warranty does not cover normal wear and tear, issues resulting from improper use, or damage caused by non-compliance with usage instructions. Any intentional damage, such as modifications, disassembly, or unauthorized repairs, voids the warranty. Contact Care of Sweden or your distributor for more information.

11.3 Disassembly and recycling



The products shall not be disposed of with household waste.



If the product is, or could be, contaminated the product must be handled according to the healthcare provider's or local authority's procedures for contaminated waste.

11.4 Return

Contact Care of Sweden or your distributor before the product is returned.

11.5 Customer responsibilities

The safety of the product and of the operator cannot be guaranteed if the following conditions are not satisfied:

- Always use a cover, never keep sharp objects nearby the positioning pillow.
- Operators should be familiar with the procedures, prohibitions and warning described in this manual, in addition with safety regulations applicable.

Manufactured by



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