

Instructions for use

2025-11-06

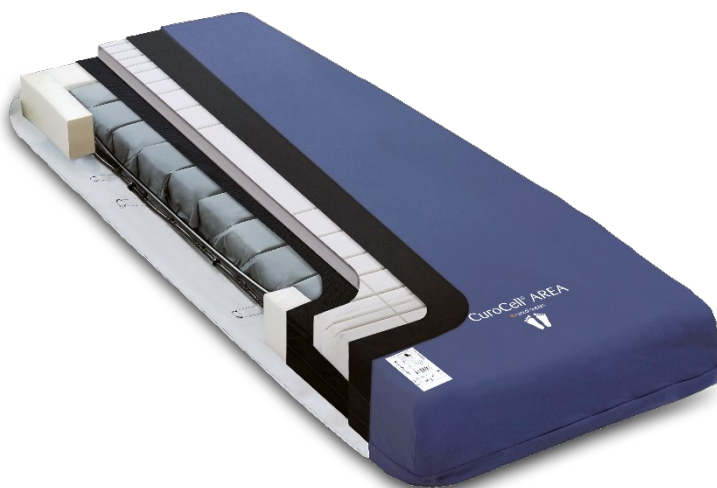
CuroCell® AREA Zone

Hybrid mattress

Instructions for use item number: 95-001222



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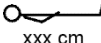




Read the instructions carefully before use.
All user instructions and safety instructions must be followed.











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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		
Symbols for product information - Mattress			
XXXX-XX-XX	Year-Month-Day		Foot placement
	Patient information – pressure ulcer category		Recommended patient weight
	Counteracts shear		Do not rotate
	Heel function		Do not turn around
	Place on top of existing mattress		Place on top of the bed
	Do not place directly on bed		Do not place on top of another mattress
	Minimum length		The mattress should be used with the patient lying lengthways
	Size of mattress		

Symbols for cleaning, reconditioning and recycling

	Machine wash at 95 °C		Drip dry
	Tumble dry		Do not iron
	Wipe clean		Do not dry clean
	Chlorine		Do not tumble dry
	Do not machine wash		Recycling

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, assembled or repaired with other parts, accessories or spare parts other than those described in this manual or other documentation from Care of Sweden.
- The mattress is protected by a hygiene cover; avoid using multiple hygiene covers as this can affect the vapor permeability of the mattress.
- If the cover is supplied with handles on the long sides, these handles are only to be used for lifting and moving the mattress itself. All other use will be your own responsibility and is not covered by the product warranty.



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 fire sources/hot surfaces, such as fire, burning cigarettes or hot lamps. Although the product has undergone fire testing, it could become damaged if it comes into contact with fire sources.
- Position and use the product in a manner that prevents it from becoming trapped or damaged. Be particularly aware of trapping damage when using bed rails.
- The hygiene cover does not allow liquid or air to penetrate but is vapor permeable. Make sure that the patient is positioned correctly to avoid the risk of suffocation.
- Prevent damage to the hygiene cover from sharp objects.
- Follow the operations and maintenance instructions carefully in order to prevent bodily injuries, as well as damage to the product or other equipment.

3 Introduction

CuroCell® AREA Zone is a mattress that combines the comfort of foam with the pressure-relieving properties of air.



For safety reasons you shall carefully read the recommendations and instructions in these instructions for use before installing and 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 CuroCell® hybrid mattresses can be used for prevention and as an aid in the treatment of pressure ulcers/pressure injuries (PU/PI).

3.3 Indications

Suitable for a wide range of patients with increased risk for pressure ulcers/injuries, including those with superficial ulcers, up to and including category III (in association with an individualized plan of care).

3.4 Intended patient population

The patient weight is up to 230 kg.

3.5 Intended user

The mattress is intended to be used by all kinds of patients, including lay persons.



The mattress is unsuitable for X-ray examinations because of the risk of blurred images or artefacts that may lead to diagnostic error.

3.6 User qualification

Training is not mandatory to use the mattress. Lay persons are qualified to operate the mattress.

3.7 Intended use environment

The mattress is intended to be used in all kinds of healthcare environments, including home care.

3.7.1 Optimum environmental conditions

The product is intended to be used indoors in room temperature.

3.8 Contraindications

There are no known contraindications.

3.9 Clinical benefit

Care of Sweden's clinical benefits and claims for CuroCell® hybrid mattresses consist of

- Safety
- Comfort
- Pressure redistribution
- Easy to handle

4 Assembly and installation

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 operator should follow and check the below information before use.

How to start using the mattress:

1. Put the mattress on the bed frame and adjust the cover if necessary.
2. Leave the mattress on the bed for a few minutes before placing the patient on the mattress.



It is recommended to make the bed with a bed sheet.



Always make sure the mattress is the right size.

5 Operation CuroCell® AREA Zone



When used together with positioning pillows, read the pillow instructions for use carefully for the correct positioning of the patient.



If you are using this product with an evacuation sheet, it is the users responsibility to ensure that it is safe to use for evacuation.



The mattress must not be lifted with a person lying on it or used for any other type of transport other than a possible evacuation using an evacuation sheet.

5.1 Function control

A function control is performed to ensure that the mattress is working properly. The recommendation is to perform a function control once per work shift.

Inspect the mattress by feeling for the bed base through the mattress. Use both hands, placing one hand on top of the other, and press firmly into the mattress. Start at the foot end of the mattress and methodically check the entire mattress this way. The mattress should provide resistance, and the bed base should not be felt through the mattress. It is normal for the middle of the mattress to offer slightly less resistance.

5.2 How to use the Evac cover

This section will only explain how to use the Evac cover. Follow your local evacuation routines to perform the whole evacuation safely.

Evac cover is a mattress cover with a built-in function for evacuation of bed-bound patients. The Evac cover is equipped with three handles on the head and foot end. On the sides, there are handles with velcro straps. These straps are to be used to fixate the patient to the mattress before commencing the evacuation. The straps are folded in the protective pockets on the side of the mattress with the ends sticking out to ensure that they are easy to pull out.

How to use the Evac cover:

1. Pull out and fasten the Velcro straps so that the mattress forms a tube around the patient.
2. Use the outer handles at the foot end of the mattress and turn the mattress out from the bed.
3. Slowly pull the patient down on the floor.
4. Pull on the outer handles at the foot end of the mattress.
5. The patient may now be moved, refer to local evacuation routines. Pulling at the foot end reduces the strain on the puller, meaning faster and safer evacuation is possible.



If the Velcro straps are not used, there is a risk of the patient sliding/rolling down from the mattress.

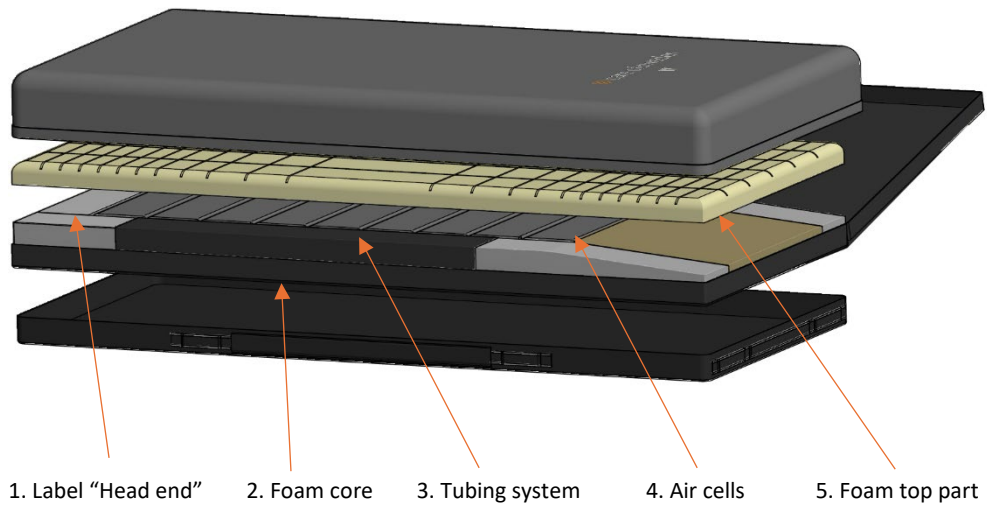


The arms of the patient shall be inside of the Velcro straps. This reduces the risk of the patient grabbing hold to something out of fear.

6 Product description


Materials the user comes in contact with:


- High resilience foam




7 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.

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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.
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Check the hygiene cover and tube connectors each time the product is cleaned. Damaged parts must be repaired or replaced.
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To ensure maintained hygiene, the mattress should not be exposed to urine or other body fluids for an extended period of time. If such an incident occurs, the mattress must be cleaned in accordance with the applicable cleaning and disinfection procedures. Failure to follow hygiene routines may result in persistent odor.

7.1 Cleaning and disinfection

MATTRESS COVER

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%). Note: Using 1% solution regularly may damage and fade the surface of the cover.


Mechanical cleaning



Covers consisting of several parts must be separated before washing.

FOAM CORE

Clean the affected area with a mild detergent (such as washing-up liquid) and water or with an alcohol-based disinfectant or cleaner intended for this purpose. Gently squeeze out any water.

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Do not wring or roll the foam core to extract the water. Let it dry in a warm, ventilated area (not in direct sunlight). The foam core must be completely dry before it is used again.

7.2 Reconditioning

Cleaning of mattress

Primarily	Clean all external surfaces of the mattress according to section 7.1 Cleaning and disinfection – Mattress cover. Ensure that all areas are free of dirt residues.
If necessary	<ol style="list-style-type: none">1. Remove the covers.2. Wipe off the cells and tubing with a cleaning agent according to local instructions and the instructions for use of the cleaning agent.3. When all parts are dry, assemble the mattress. If cells have become detached from the tubes, these must be put back according to drawing in section 6.

Disinfection of mattress

Primarily	<ol style="list-style-type: none">1. Disinfect all external surfaces of the mattress with disinfectant according to section 7.1 Cleaning and disinfection – Mattress cover. Ensure that all areas are free of dirt residue.2. Allow the disinfectant to work according to the instructions from the manufacturer of the agent.3. Let the cover dry.
If necessary	<ol style="list-style-type: none">1. Remove the covers.2. Wipe the cells and tubes with a disinfectant.3. Allow the disinfectant to work according to the instructions from the agent's manufacturer.4. When all parts are dry, assemble the mattress. If cells have become detached from the tubes, they need to be put back according to the drawing in 6.

8 Maintenance

8.1 Between patients

Before using the product again for a new patient, it is recommended to clean the product as described in section 7.

9 Troubleshooting

Problem	Solution
The patient is bottoming out	Open covers and check cells and tubing. Perform a function control, see chapter 5.1.

10 Storage

Store the mattress on a flat surface or carefully rolled/folded with the zipper closed. Always store at room temperature in a dry area. Make sure the mattress is stored where it will not be exposed to thrusts, hits or other things that can damage it. Avoid direct exposure of sunlight. If the mattress is to be stored more than 3 months, we recommend it is stored on a flat surface (not folded or rolled up).

11 Standards

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

SS-EN ISO 20342	EN 597-1
SS-EN ISO 14971	EN 597-2
SS-EN ISO 10993	

12 Other information

12.1 Technical lifetime

The technical lifetime of the product is 5 years when used under normal conditions.

12.2 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.

12.3 Disassembly and recycling

The mattress shall be sorted as combustible 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.

12.4 Return

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

12.5 Customer responsibilities

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

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

Own notes



Manufactured by



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