

Instructions for use

2023-03-15

CuroCell® AREA Zone

Hybrid mattress

Instructions for use item number: 95-001222



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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, assembled or repaired with other parts, accessories or spare parts other than those described in this manual or other documentation from Care of Sweden.
2. The mattress is protected by a hygiene cover; avoid using multiple hygiene covers as this can affect the vapor permeability of the mattress.
3. 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.
4. 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.
5. Always make sure the mattress has the right size.
6. The hygiene cover does not allow liquid or air to penetrate, but is vapour permeable. Make sure that the patient is positioned correctly to avoid the risk of suffocation.
7. Prevent damage to the hygiene cover from sharp objects.
8. 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 at your own responsibility and is not covered by the product warranty.
9. Follow the operations and maintenance instructions carefully in order to prevent bodily injuries, as well as damages to the product or other equipment.
10. This mattress is unsuitable for use during x-ray examinations because of the risk of blurred images or artefacts that may lead to diagnostic errors.

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 mattress is intended to be used for prevention and as an aid in the treatment of pressure ulcers/pressure injuries (PU/PI).

1.3 Intended user

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

1.4 Intended user environment

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

1.5 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 individualised plan of care). The patient weight is up to 230 kg.

1.6 Contraindication

There are no known contraindications.

1.7 Clinical benefit

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

- Safety
- Comfort
- Pressure redistribution
- Easy to handle

Note!

- When used together with positioning pillows, read the pillow instructions for use carefully for correct positioning of the patient.
- If you are using this product with an evacuation sheet, it is the patient's 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.

2 Assembly and installation

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.

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 using it.

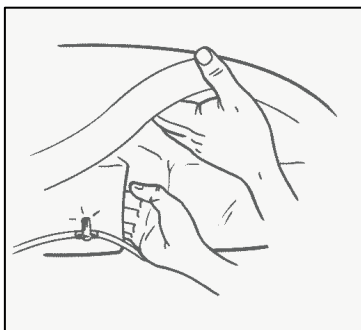
Note!

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

3 Operation

3.1 Hand check (function control)

The hand check is used to ensure that the mattress is working properly. This must be performed regularly; we recommend once per shift, or every eight hours. Open the cover and insert your hand between the air cells directly underneath the patient's pelvic region, use a vertical hand. There should be a clearance of 2-3 fingers between mattress base and the patient.



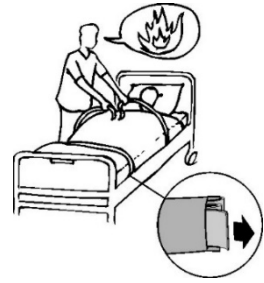
3.2 Operations Evac Cover

This section will only explain how to use the Evac cover. Refer to 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.

Operation 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.



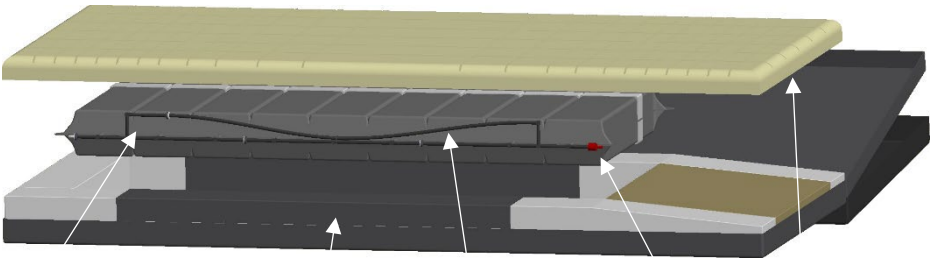
Note!

- If the velcro straps are not used, there is a risk of the patient sliding/rolling down from the mattress.
- Pulling at the foot end reduces the strain on the puller, meaning faster and safer evacuation is possible.
- 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.

4 Product description

Care of Sweden reserves the right to modify the product specification at any time.

The mattress is a combination of foam and air that operates without electricity.



1. Label "Head end" 2. Foam core 3. Tubing system 4. Air cells 5. Foam top part

4.1 Standards

The system has been tested and approved according to following standards where applicable demands are fulfilled: SS-EN ISO 20342, SS-EN ISO 14971, SS-EN ISO 10993, EN 597-1, EN 597-2.

5 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.

5.1 Cleaning and disinfection

MATTRESS COVER

Wipe off



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.

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.

5.2 Reconditioning

Cleaning of mattress

1. Clean all external surfaces of the mattress according to section 5.1 Cleaning and disinfection - Inner cover and Mattress cover - Wipe off. Ensure that all areas are free of dirt residues.
2. If the mattress is heavily soiled, it is recommended that the mattress is taken apart and cleaned, follow the instructions below according to points 3-5.
3. Remove the covers.
4. Wipe off the cells and tubing with a cleaning agent according to local instructions and the instructions for use of the cleaning and disinfecting agent.
5. 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 4.

Disinfection of mattress

1. Disinfect all external surfaces of the mattress with disinfectant according to section 5.1 Cleaning and disinfection - Inner cover and Mattress cover - Wipe off. 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.
4. If the mattress is heavily soiled, it is recommended that the mattress is taken apart and

disinfected, follow the instructions below according to points 5-8.

5. Remove the covers.

6. Wipe the cells and tubes with a disinfectant.

7. Allow the disinfectant to work according to the instructions from the agent's manufacturer.

8. 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 section 4.

Note!

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

6 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).

7 Maintenance

Service and maintenance must always be performed by Care of Sweden or one of its authorized technicians. Only use spare parts approved by Care of Sweden.

8 Troubleshooting

If the problems keep occurring, please contact Care of Sweden or your local distributor.






















Problem	Solution
The patient is "bottoming out"	Open covers and check cells and tubing Check again through hand check (see 3.1)

9 Marking and Symbol key












9.1 Marking

The mattress is labelled with product name, production date, item number, size, care and wash instructions, EAN-bar code, as well as space for own labelling. The product also displays which side is up/down and head/foot.

9.2 Symbol Key

Symbols to convey medical device information			
	CE-marked in accordance with Medical Device Regulation (EU) 2017/745		Manufacturer
	Medical Device		UDI
	Distributor		
Symbols for traceability and product information			
	Item number		Type BF
	IP class (Enclosure class)		Class II Equipment (double insulated). Indicated on the power supply.
Symbols for user information			
	Recommended patient weight	XXXX-XX-XX	Year-month-day
	Counteracts shear force		User information - category
	Placed directly on the bed base		User information - category
	Foot placement		Do not rotate
	Heel function		Do not turn around
	The mattress should be used with the patient lying lengthways		Read the instructions for use
	Read the instructions for use		

Symbols for cleaning and recycling

	Machine wash at 95 °C		Do not iron
	Do not machine wash		Chlorine
	Wipe clean		Tumble dry
	Do not dry clean		Do not tumble dry
	Drip dry		Do not dispose of with household waste
	Recycling		

10 Other information

10.1 Recommended lifetime of the product

The estimated lifetime of this product is 5 years.

10.2 Disassembly and recycling

The mattress is recyclable as combustible waste.

10.3 Returns

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



Manufactured by



Care of Sweden

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