

Instructions for use

2020-08-24

CuroCell® AREA Zone

Hybrid mattress

Instructions for use item number: 95-001222



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WARNINGS AND SAFETY PRECAUTIONS

Read all instructions prior to use

WARNING!

- 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. NOTE: 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 user 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.

1. Introduction



Always read the user instructions for use prior to use.

1.1 General information

This CuroCell® mattress is a medical device in accordance to Medical Device Regulation (2017/745). According to statutory regulations made by the authorities regarding medical devices, the manufacturer is required to report all accidents or incidents involving their products. We would be very grateful for all information involving accidents or incidents relating to our products, by reporting them immediately to us, here at Care of Sweden. The system has been tested and approved according to the following standards: SS-EN ISO 12182, SS-EN ISO 14971, SS-EN ISO 10993, EN 597-1, EN 597-2, EN 14126.

Unprevented/untreated pressure ulcers/pressure injuries can very quickly deteriorate resulting in higher risk of complications, pain and suffering for the user.

1.2 Intended use

The CuroCell® hybrid mattresses can be used for prevention and as an aid in the treatment of pressure ulcers/pressure injuries (PU/PI).

1.3 Indications

For users with pressure ulcers/pressure injuries (PU/PI) up to and including category 3. As well as for users in risk of PU/PI.

1.4 Contraindications

There are no known contraindications.

1.5 User application

CuroCell® AREA Zone can be used in all kinds of healthcare environments and is a full replacement mattress to be used for users up to and including 230 kg.

We recommend that position changes are made regularly. The time interval must be evaluated by the responsible personnel, depending on the patient's status, diagnosis and general condition.

NOTE!

- When used together with positioning pillows, read the pillow instructions for use carefully for correct positioning of the user.
- If you are using this product with an evacuation sheet, it is the user's responsibility to ensure that it is safe to use for evacuation.
- Be careful when using bed rails or other protection on the bed so that the mattress does not become crushed or damaged.
- 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.
- 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) European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline.* Emily Haesler (Ed). EPUAP/NPIAP/PPPIA: 2019

1.3 Evacuation instructions

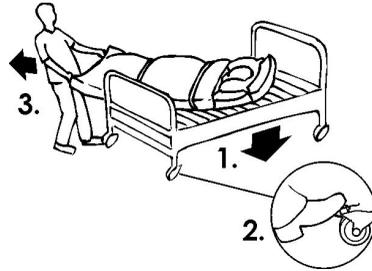
Evac is a mattress cover with a built-in function for evacuation of bed-bound users. In case of fire or other emergency, there is no time to think about what to do next. Therefore, it is very important that the safety equipment, as well as the evacuation procedures, are well planned and known in advance.

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 user 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.

WARNING!

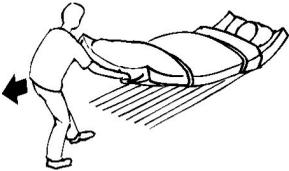
Person to perform an evacuation needs to have the necessary training. Always check the equipment, cover and mattress before commencing, to make sure an evacuation can be carried out safely. It is the user's responsibility to ensure that it is safe to use for evacuation.

Evacuation instructions



Down from the bed

- Inform the user about what will happen.
- Lower and lock the bed in position.
- Disconnect the tubes from the pump.
- Pull out and fasten the velcro straps.
- Use the outer handles at the foot end of the mattress and turn the mattress out from the bed.
- Slowly pull the user down on to the floor.

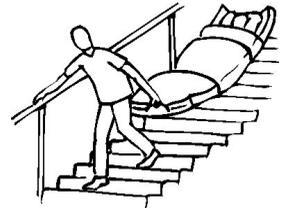


On an even surface

- Pull on the outer handles at the foot end of the mattress.
- Working position should be a little bit leaning back.

Down the stairs

- Walk backwards until the main part of the mattress has slide pass the top stair.
- Turn the back to the user and look in the moving direction.
- Hold one hand on the stair handle and pull with the other hand on the middle handle of the mattress.
- Walk down the stairs. It is important to maintain speed, without running.



Training/practise

To bear in mind when training.

Pulling down from the bed:

- The user in the bed should not be at the very top of the mattress. There could be a risk of hitting the head in the bed when pulling down.

Pulling in the stairs:

- Start with pulling an empty mattress down the stairs, in order to practice the technique.

- When training with a person on the mattress, a string or rope can be fasten in the handles at the head end. Another person can then walk behind the mattress and help out if problems should occur.
- It is advisable to practice in the same stairs where an evacuation can be necessary.

General:

- The main purpose of the training is not to reach high speed, but to learn the correct technique.

Training covers

- Because of the heavy strain on the equipment when evacuating, always check the seams and handles at the end of training. We recommend that equipment used for training is marked with “Training equipment” and is only used for this purpose.

Explanations

- If the velcro straps are not used, there is a risk of the user sliding/rolling down from the mattress.
- Pulling at the foot end reduces the strain on the puller, which means faster and safer evacuation is possible.
- Pulling in the stairs is the most difficult part of the evacuation and should be practiced extra carefully.
- The arms of the user shall be inside of the velcro straps. This way reduces the risk of the user grabbing hold to something out of fear.

NOTE!

When using wider mattresses, make sure that the evacuation routes are clear (size of doors etc.). Responsible personnel have to ensure that the evacuation can be performed safely. To ensure proper function of the Evac cover, it is important to regularly check the quality of the mattress. Check for damages that could cause problems when evacuating.

Action plan for Pressure ulcers/pressure injuries

For the best possible results when using these products, we recommend a structured and planned approach. Examples that can be applied to the use of our products can be found in the ‘Action plan for pressure ulcers’ guidelines.

Mattress guide

This guide provides guidance to personnel and prescribers when choosing a mattress from Care of Sweden. CuroCell® AREA Zone is a mattress in function group B. This information can be found on our website www.careofsweden.com or ordered from Customer Services (see contact information on the final page).

2. Product description

Because of its unique construction combining foam and air, this mattress provides high user comfort, as well as a solution for pressure care without the need for external pump or electricity. The system uses user weight and movements to distribute the internal air reservoir amongst the cells, in order to always maintain low surface pressure.

The CuroCell® AREA Zone is produced in high quality materials for function and durability. Foam part in two layers. Zone profiled top part.

All mattresses have a sloped heel section for protection of heels.

Available sizes are (width, length and height) 80/85/90/105/120 x 200/210 x 18 cm. For request of other sizes please contact Care of Sweden or your local distributor.

2.1 Description covers

CuroCell® AREA Zone is delivered with hygiene cover Steel/Duro. It is easy to handle and maintain, and conforms to the stringent requirements in respect of cleaning and hygiene. The cover is vapor permeable, which reduces risk of skin maceration. An inner cover protects foam and cells.

Cover Steel/Duro is a two-part cover with welded seams and a protected zipper. Has functional handles for transportation of the mattress. Colour: blue.

An inner cover is also included.

Cover Steel/Evac

Cover with welded seams and a protected zipper on all sides, divisible (top and bottom part). Functional handles for evacuation, moving and transport. Colour: blue/black.

Cover Stone/Duro

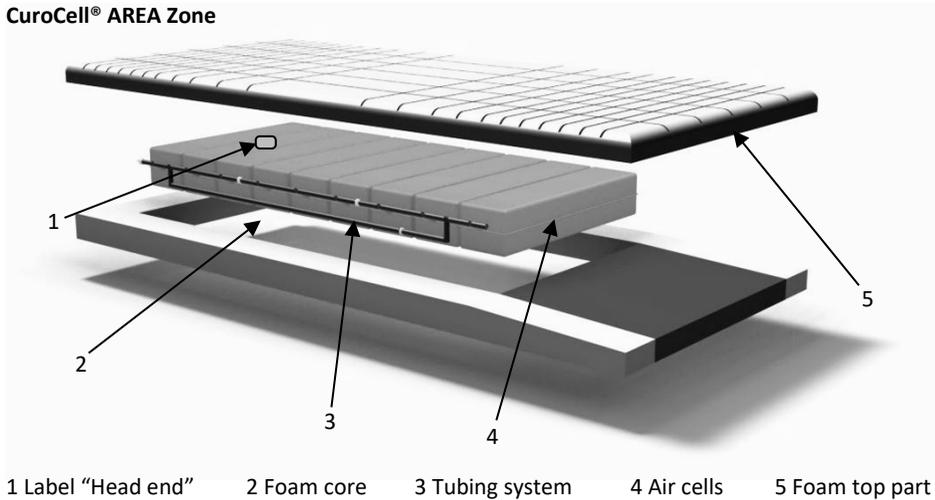
Crib 5 cover with welded seams and a protected zipper on all sides, divisible (top and bottom part). Colour grey/blue.

Cover Stone/Evac

Crib 5 cover with welded seams and a protected zipper on all sides, divisible (top and bottom part). Functional handles for evacuation, moving and transport. Colour grey/black.

2.2 Description mattress

CuroCell® AREA Zone



3. Instruction for use

3.1 Unpacking the mattress

The mattress is packed in a box.

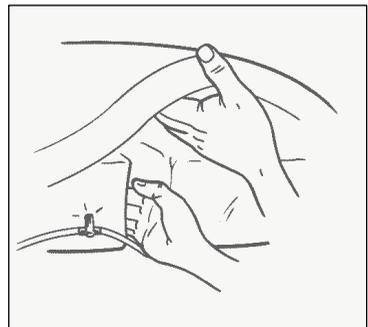
1. Start with making sure that the package is not damaged. When opening the box and any other protective material, avoid using a knife since this could damage the mattress and cover.
2. Put the mattress on the bed frame and correct the cover if necessary.
3. After a few minutes the product is ready to be used.

3.2 Hand check

Hand check is used to ensure that the function of the mattress is correct. This should be done regularly.

Open the cover and insert your hand between the air cells directly underneath the user's pelvic region, use a vertical hand. There should be a clearance of 2-3 fingers between mattress base and the user. If not, you need to check cells and tubing.

If the problem is not resolved, please contact Care of Sweden or your local distributor.



4. Reuse, cleaning and reconditioning

The product is reusable. When reusing, it is important to follow the instructions below for cleaning and reconditioning. Before using the product again for a new user, it is recommended to clean the mattress in accordance with the instructions below. Consult your hygiene manager or Care of Sweden for help and instructions if you are unsure.

Cleaning and reconditioning should otherwise be performed as required.

NOTE!

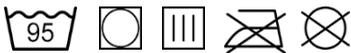
Check the hygiene cover each time the product is cleaned. If damaged, it must be replaced or repaired.

4.1 Covers

MATTRESS COVER



Covers can be wiped off with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or chlorine max 1 %. Excrements and blood spots must be removed immediately with cold water. Carefully follow local instructions and usage instructions for the cleaner.

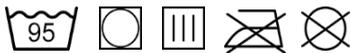


Multi-layer covers should be divided before washing. Wash with similar colours.



Chlorine and phenol-based cleaners could have a negative impact on the PU surface and should be avoided. If chlorine is used, we recommend a mixture of max. 1 %.

INNER COVER



Clean the affected area with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or chlorine max 1 %.

4.2 Foam core



Clean the affected area with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70%, oxidating solutions or chlorine max 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.

4.3 Air cells

1. Remove the covers. See instructions in chapter 4.1 for cleaning covers.
2. Carefully remove the air cells from the foam core. Remove the cell holder from the cells.
3. Place the air cells and the tubes on a clean area which is suitable for washing.
4. Wipe off the cells, all tubes with a mild cleaning solution for this purpose such as: alcohol with or without tensides, Isopropanol 70 %, oxidating solutions or chlorine max 1 %.

5. Replace the cells into the cell holder. Place the air cells back into the foam core. Check that all the tubes and connectors are secure and tight, before closing the cover.
6. Wipe off work surfaces with alcohol-based disinfectant/cleaner intended for this purpose.

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.

5. 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).

6. Troubleshooting

Problem	Solution
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The user is bottoming out	Open covers and check cells and tubing. Check again through Hand check (see chapter 3.2).
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If your questions are not answered by information above, please contact Care of Sweden or your local distributor.

7. Technical description

7.1 Technical specification

MATTRESS	SPECIFICATION
Model	CuroCell® AREA Zone
Dimension (WxLxH)	80/85/90/105/120 x 200/210 x 18 cm
Weight	16 kg (90x200x18 cm)

NOTE: The manufacturer retains the right to modify the product specification at any time.

7.2 Labelling

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.

7.3 Symbol Definitions



Item number



Manufacturer

XXXX-XX-XX

Year-Month-Day



Foot placement



Read the instructions
for use



Group of function



CE marked acc.
to Device
Regulation MDR



Recycling



Not in domestic refuse,
follow recycling instructions



Recommended user weight



User information
– category



Directly on bed base



Recommended user
weight when using Evac
function



Counteract shear force



Heel function



Do not wash



Machine wash at 95 °C



<1%
Chlorine



Tumble dry



Do not tumble dry



Drip dry



Do not iron



Do not dry clean



Wipe off



Class II equipment
(Double Insulated)



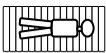
Type BF



IP-class
(Ingress Protection Rating)



Temperature range



The mattress should only
be used lying in the
lengthwise direction
on the mattress



Distributed by



Medical device



UDI

8. Spare parts

Cover Steel/Duro and Stone/Duro for CuroCell AREA Zone

Size	Top part Steel Art.no.	Top part Stone Art.no.	Bottom part Duro Art.no.
80x200 cm	CC-925511	CC-925581	CC-925011
80x210 cm	CC-925512	CC-925582	CC-925012
85x200 cm	CC-925513	CC-925583	CC-925013
85x210 cm	CC-925514	CC-925584	CC-925014
90x200 cm	CC-925515	CC-925585	CC-925015
90x210 cm	CC-925516	CC-925586	CC-925016
105x200 cm	CC-925517	CC-925587	CC-925018
120x200 cm	CC-925519	CC-925589	CC-925019
105x210 cm	CC-925518	CC-925588	CC-925030
120x210 cm	CC-925523	CC-925590	CC-925031

Art. no.	Description	Size
CC-900050	Air cell AREA, 1 pcs	63x15x12 cm

If other spare parts are needed, please contact Care of Sweden or your local distributor for further assistance.

9. Options and accessories

9.1 Options

Sturdy transport and storage bag

Art. No.	Description	Width
58-900905	Mattress bag	105-120 cm
58-900906	Mattress bag extra high	80-90 cm
58-900911	Mattress bag extra high	105-120 cm

9.2 Accessories

Cover Steel/Evac and Stone/Evac for CuroCell AREA Zone

	Top part Steel	Top part Stone	Bottom part Evac	Complete cover Steel/Evac	Complete cover Stone/Evac
Size	Art.no.	Art.no.	Art.no.	Art.no.	Art.no.
80x200 cm	CC-926110	CC-925581	461-080200	CC-925940	CC-925860
80x210 cm	CC-926111	CC-925582	461-080210	CC-925941	CC-925861
85x200 cm	CC-926112	CC-925583	461-085200	CC-925942	CC-925862
85x210 cm	CC-926113	CC-925584	461-085210	CC-925943	CC-925863
90x200 cm	CC-926114	CC-925585	461-090200	CC-925944	CC-925864
90x210 cm	CC-926115	CC-925586	461-090210	CC-925945	CC-925865
105x200 cm	CC-926116	CC-925587	461-105200	CC-925946	CC-925866
105x210 cm	CC-926117	CC-925588	461-105210	CC-925947	CC-925867
120x200 cm	CC-926118	CC-925589	461-120200	CC-925948	CC-925868
120x210 cm	CC-926119	CC-925590	461-120210	CC-925949	CC-925869

Inner cover elastic for CuroCell AREA Zone

Art. No.	Size	Art. No.	Size
CC-928250	80x200 cm	CC-928255	90x210 cm
CC-928251	80x210 cm	CC-928256	105x200 cm
CC-928252	85x200 cm	CC-928257	105x210 cm
CC-928253	85x210 cm	CC-928258	120x200 cm
CC-928254	90x200 cm	CC-928259	120x210 cm

9.3 Other accessories

To ensure the best level of comfort, we recommend use of accessories from Care of Sweden since our products are designed to work well together. Please contact Care of Sweden or your local distributor for accessories or more information on our products.

10. Warranty

10.1 Scope

This CuroCell® system is covered by a 5-year warranty for manufacturing defects. The warranty does not apply to normal wear and tear or damage due to negligence or improper handling/care.

10.2 Service and repairs

Service and maintenance must always be performed by Care of Sweden or one of its authorised technicians. Only use spare parts that have been approved by Care of Sweden. Use of non-approved spare parts invalidates the warranty.

A warranty claim must be submitted to Care of Sweden before the product is returned.

Please contact Care of Sweden or your local distributor if you have questions regarding warranty and service.

10.3 Recommended life time of the product

The estimated life time of this product is 5 years.

11. Other information

11.1 Disassembling and recycling

A used CuroCell® mattress must be taken to a recycling centre and sorted as combustible waste.

For more information contact Care of Sweden or your local distributor.



Manufactured by

 care of sweden

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