

Instructions for use

2023-03-16

Curera® Seat Cushions

Curera® Consil

Curera® Contur

Curera® Contur EX

Curera® Plantur

Curera® Concept

Curera® Concept EX

Curera® Concept Latus

Curera® Hemi

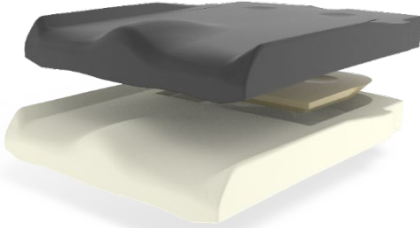
Curera® Tremix

Curera® Contur Children

Curera® Seat cushion

CuroCell® S.A.C.

Levelling plate



Instructions for use item number: 97-001003



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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 instructions for use. The product may not be combined, fitted or repaired with other parts, accessories or spare parts other than those described in this instructions for use or other documentation published by Care of Sweden.
2. If the cushion is protected by a hygiene cover, avoid combining it with other fully covering plastic protectors. The cover's vapour permeability may be affected.
3. DO NOT USE in the vicinity of or in contact with naked flames/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 naked flames.
4. The product must be placed and used so that it does not become trapped or damaged.
5. If the cushion has been exposed to high temperatures, e.g. if it has been stored in direct sunlight, you must check that it is not too hot to sit on prior to use.
6. Always check that the cushion is of the correct size.
7. Before use, check the cushion to ensure that it is not damaged.
8. Avoid damaging the hygiene cover using sharp objects.
9. Extended periods of sitting increase the risk of DVT (deep-vein thrombosis).
10. Regularly check the skin for redness. If redness occurs, stop using the cushion immediately and contact your prescriber.
11. The cushion is designed to be used in a wheelchair or a chair with back and arm supports. When using in a wheelchair with a suspension kit, a balancing plate is available as an accessory.
12. Cushions must always be used with a cover.
13. Check to ensure that the cover fits the cushion well - it must always be a good fit.

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

Curera® seat cushions are intended to be used for positioning, as an aid for prevention of pressure ulcers/pressure injuries (PU/PI).

1.3 Intended user

Curera® seat cushions are intended to be used by all kind of patients, including lay persons.

1.4 Intended user environment

Curera® seat cushions are designed to be used in wheelchairs and on furniture, for pressure redistribution and positioning, in all kinds of healthcare environments, including home care.

1.5 Indications

For patients having difficulty maintaining a stable seated position.

1.6 Contraindications

There are no known contraindications.

1.7 Clinical benefit

The clinical benefit for Curera Seat cushions included in these instructions for use are:

- Pressure redistribution
- Safety
- Comfort
- Easy to handle

2 Operation

All of the cushions in these instructions for use may be used for wheelchairs with rigid seat base or adjustable seat base.

The following operation apply to these cushions:

Curera® Consil, Curera® Contur, Curera® Contur EX, Curera® Plantur, Curera® Consept, Curera® Consept EX, Curera® Consept Latus, Curera® Hemi, Curera® Tremix, Curera® Contur Children.

Operation:

1. Check that the cushion fits correctly in the cover. Follow the markings on the cover and cushion.
2. Place the cushion as indicated by the markings on the cushion in the wheelchair or armchair. Check that the cushion is the correct size for the chair seat.
3. The patient can now start using the cushion.

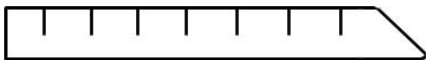
Note!

- If the cushion Curera® Tremix has been stored in a temperature below + 10°C it shall be stored at room temperature for at least 1 hour before being put into service.

The following operation apply to Curera® Seat Cushion

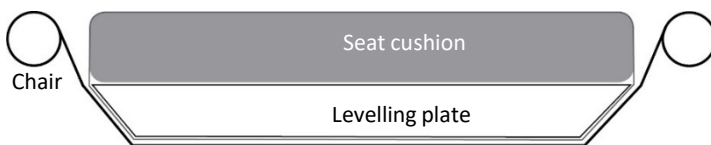
1. Check that the cushion fits correctly in the cover. Follow the markings on the cover and cushion.
2. Place the cushion in the wheelchair with the 'squares' facing upwards (feel with your hand) and the bevelled edge facing forwards.

Top



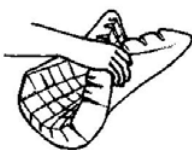
Front

3. The cushion is primarily intended for use on a flat seat. If it is a suspended seat with a drop (h) greater than about 25 mm, we recommend using a levelling plate.



Note!

- Attach and detach the cover as shown in the pictures below to minimize the risk of ripping it.



The following operation apply to CuroCell® S.A.C

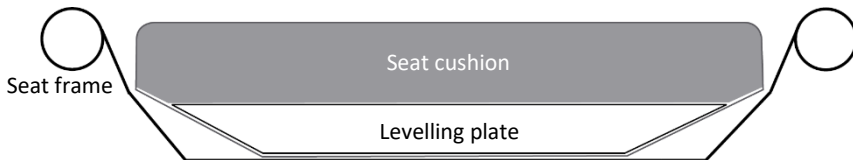
1. Check that the cushion is properly inflated. Roll the cushion from one side, it should be possible to roll the cushion to the second row of holes.
2. Place the cushion on the intended seat.
3. Perform a hand check to make sure that the cushion works properly. Do this by placing your hand between the base and the cushion to check the patient does not sit through the cushion.

Note!

- When using this cushion in a wheelchair with a suspension kit, a levelling plate might be necessary.

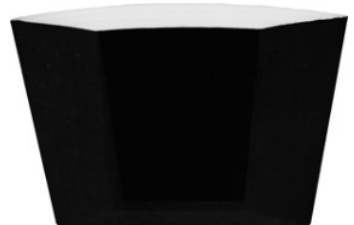
If you are using a Levelling Plate without an anti-slip:

Place the plate inside the cover, under the cushion, with the rounded rear edge facing backwards and the bevelled underside facing down against the underside of the cover. The plate is also labelled as to how it should be placed.



If you are using a Levelling Plate with an anti-slip:

Place the plate under the wheelchair cushion with the anti-slip material facing downwards.



3 Product description

The recommended patient weight of the cushions differs depending on the size of the cushion. For information about the product, contact Care of Sweden or your local distributor.

3.1 Curera® Consil

A pressure redistributing and anatomically shaped seat cushion.

Material in cushion: Polyurethane foam

Height: 5 cm

Covers that fit: Standard cover, Hygienic cover, Hood cover, Onyx cover, Onyx+ cover

3.2 Curera® Contur

A pressure redistributing seat cushion, constructed from an anatomically moulded polyurethane foam base with viscose elastic foam on the underside. The cushion is liquid proof.

Material in cushion: Polyurethane foam, viscose elastic foam, vulcanised rubber

Height: 5 cm

Covers that fit: Standard cover, Hygienic cover, Onyx cover, Onyx+ cover

3.3 Curera® Contur EX

A pressure redistributing cushion, constructed from an anatomically moulded polyurethane foam base with viscose elastic foam on the underside.

Material in cushion: Polyurethane foam, elastic foam

Height: 5 cm

Covers that fit: Standard cover, Hygienic cover

3.4 Curera® Plantur

A pressure redistributing seat cushion, constructed from anatomically moulded polyurethane foam with a flat top side and a viscose elastic foam insert in the underside. The cushion is liquid proof.

Material in cushion: Polyurethane foam, viscose elastic foam, vulcanised rubber

Height: 5 cm

Covers that fit: Standard cover, Hygienic cover, Onyx cover, Onyx+ cover

3.5 Curera® Consept

A pressure redistributing seat cushion, constructed from an anatomically moulded polyurethane foam base with viscose elastic foam insert on the top side. The cushion is liquid proof.

Material in cushion: Polyurethane foam, viscose elastic foam, vulcanised rubber

Height: 5 cm

Covers that fit: Standard cover, Hygienic cover, Onyx cover, Onyx+ cover

3.6 Curera® Concept EX

A pressure redistributing cushion, constructed from an anatomically moulded polyurethane foam base with viscose elastic foam the top side.

Material in cushion: Polyurethane foam, elastic foam

Height: 5 cm

Covers that fit: Standard cover, Hygienic cover

3.7 Curera® Concept Latus

A pressure redistributing seat cushion designed for heavier patients. It is constructed from an anatomically moulded polyurethane foam base with a viscose elastic foam insert from the top side. The cushion is liquid proof.

Material in cushion: Polyurethane foam, viscose elastic foam, vulcanised rubber

Height: 7 cm

Covers that fit: Standard cover, Hygienic cover

3.8 Curera® Hemi

Hemi is a specially-designed seat cushion and suitable for people who need to be able to propel themselves in their wheelchair using their legs. Three versions are available - left, right and double. The cushion is liquid proof.

Material in cushion: Polyurethane foam, viscose elastic foam, vulcanised rubber

Height: 5 cm

Covers that fit: Standard cover, Hygienic cover

3.9 Curera® Tremix

An anatomically designed seat cushion constructed in multiple layers and used to prevent pressure ulcers. The cushion is liquid proof.

Material in cushion: Polyurethane foam, viscose elastic foam, vulcanised rubber

Height: 7 cm

Covers that fit: Hygienic cover, Deluxe cover

3.10 Curera® Contur Children

A pressure redistributing seat cushion, constructed from an anatomically moulded polyurethane foam base with a viscose elastic foam insert on the top side.

Material in cushion: Polyurethane foam, viscose elastic foam, vulcanised rubber

Height: 4 cm

Covers that fit: Standard cover, Hygienic cover

3.11 Curera® Seat Cushion

A pressure redistributing seat cushion constructed with markings on the cushions which makes it easy to position.

Material in cushion: 100% flame-proof polyether foam

Height: 6 cm

Covers that fit: Hygienic cover

3.12 CuroCell® S.A.C.

A static, redistributing seat cushion of air.

Material: Polyurethane

Covers that fit: Hygienic cover

3.13 Levelling plate

A levelling plate may be used when the seat is uneven or when extra stability is needed. It can be used for all cushions included in these instructions for use, with the exception of Tremix which already has this function integrated.

There are two types of levelling plates; one without anti-slip that is to be placed inside the cover, under the cushion, with the rounded rear edge facing backwards and the bevelled underside facing down against the underside of the cover. The other plate has anti-slip and is to be placed under the cushion to fill the void between the cushion and seat.

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 Covers

Standard Cover, Deluxe Cover, Hood Cover, Onyx Cover, Onyx+ Cover



The cover must be completely dry before being refitted.

Hygienic Cover



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.

Machine wash:



4.2 Cushions

Curera® Contur, Curera® Plantur, Curera® Consept, Curera® Consept Latus, Curera® Hemi, Curera® Tremix, Curera® Contur Children, Curocell® S.A.C



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.

Let the cushion dry in a warm, ventilated area, without direct exposure of sunlight. The cushion needs to be completely dry before it is used again.

Curera® Consil, Curera® Seat Cushion, Contur EX, Consept EX



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. Don't wring or roll the cushion to extract water. 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.

Note!

- Check the cushion every time it is cleaned. If it is damaged it should be replaced.

4.3 Levelling plate (Accessory)



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

It needs to be completely dry before it is used again.

5 Storage

The cushions should be stored in a dry, room temperature area. Store the cushion so that it cannot be exposed to shocks, impacts or other mechanical influences. Avoid exposing the cushion to direct sunlight.

6 Maintenance


















The cushions require no service or maintenance other than cleaning as described in section 4.

7 Marking and symbol key

7.1 Marking

The cushion is labelled with date of manufacture, order number, item number, size, care and maintenance advice, EAN number. It is also marked showing how it must be positioned in the chair.

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		
Symbols for user information			
	Recommended user weight	XXXX-XX-XX	Year-month-day
	Read instructions for use		Read instructions for use
Symbols for cleaning and recycling			
	Machine wash at 95 °C		Chlorine
	Wipe clean		Tumble dry
	Drip dry		Do not iron
	Do not dry clean		Recycling

8 Other information

8.1 Recommended lifetime of the product

The expected lifetime for the cushions is estimated to be 2 years, except from CuroCell® S.A.C. The estimated lifetime for CuroCell® S.A.C. is estimated to be 1 year.

8.2 Standards

Most of the products included in this instructions for use fulfils the requirements in the following standards: SS-EN 1020-1 and SS-EN 1021-2.

8.3 Disassembly and recycling

The cushions are completely recyclable and must be sorted as "combustible waste". No disassembly is necessary.

8.4 Returns

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

Own notes

Own notes



Manufactured by



care of sweden

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