

Instructions for use

2025-11-12

Curera® Consil
Curera® Contur
Curera® Contur EX
Curera® Contur Child
Curera® Concept
Curera® Concept EX
Curera® Concept Latus
Curera® Tremix
Curera® Seat cushion
CuroCell® S.A.C.
Levelling plate
Curera seat cushions

Instructions for use item number: 97-001003


























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

Table of content

1	Symbol key	3
2	Warnings- and safety precautions	4
3	Introduction	5
3.1	<i>General information</i>	5
3.2	<i>Intended purpose</i>	5
3.3	<i>Indications</i>	5
3.4	<i>Intended patient population</i>	5
3.5	<i>Intended user</i>	5
3.6	<i>User qualification</i>	5
3.7	<i>Intended use environment</i>	5
3.7.1	Optimum environmental conditions	5
3.8	<i>Contraindications</i>	5
3.9	<i>Clinical benefit</i>	5
4	Assembly and installation	6
4.1	<i>Curera® Consil, Curera® Contur, Curera® Contur EX, Curera® Contur Child, Curera® Consept, Curera® Consept EX, Curera® Consept Latus, Curera® Tremix</i>	6
4.2	<i>Curera® seat cushion</i>	6
4.3	<i>CuroCell® S.A.C.</i>	7
4.4	<i>Using levelling plate without an anti-slip</i>	7
4.5	<i>Using levelling plate with an anti-slip</i>	7
5	Product description	8
5.1	<i>Curera® Consil</i>	8
5.2	<i>Curera® Contur</i>	8
5.3	<i>Curera® Contur EX</i>	9
5.4	<i>Curera® Consept</i>	9
5.5	<i>Curera® Consept EX</i>	9
5.6	<i>Curera® Consept Latus</i>	10
5.7	<i>Curera® Tremix</i>	10
5.8	<i>Curera® Contur Child</i>	11
5.9	<i>Curera® Seat Cushion</i>	11
5.10	<i>CuroCell® S.A.C.</i>	11

5.11	<i>Levelling plate (accessory)</i>	11
6	Reuse and cleaning	12
6.1	<i>Cleaning and disinfection</i>	12
6.1.1	Cushions Curera® Contur, Curera® Concept, Curera® Concept Latus, Curera® Tremix, Curera®, Curera® Contur Child, CuroCell® S.A.C	12
6.1.2	Cushions Curera® Consil, Curera® Seat cushion, Curera® Contur EX, Curera® Concept EX.	12
6.1.3	Levelling plate (accessory)	13
6.1.4	Covers Standard Cover, Deluxe Cover, Hood Cover	13
6.1.5	Cover Hygienic Cover	13
7	Maintenance	14
7.1	<i>Between patients</i>	14
8	Storage	14
9	Standards	14
10	Other information	14
10.1	<i>Technical lifetime</i>	14
10.2	<i>Warranty</i>	14
10.3	<i>Disassembly and recycling</i>	14
10.4	<i>Return</i>	14

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 – Seat cushion			
XXXX-XX-XX	Year-Month-Day		Recommended patient weight
	Patient information – pressure ulcer category		
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		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 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.
- The product must be placed and used so that it does not become trapped or damaged.



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

- 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.
- 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.
- 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.
- Always check that the cushion is of the correct size.
- Before use, check the cushion to ensure that it is not damaged.
- Avoid damaging the hygiene cover using sharp objects.
- Extended periods of sitting increase the risk of DVT (deep-vein thrombosis).
- Regularly check the skin for redness. If redness occurs, stop using the cushion immediately and contact your prescriber.
- 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 levelling plate is available as an accessory.
- Cushions must always be used with a cover.
- Check to ensure that the cover fits the cushion well - it must always be a good fit.

3 Introduction

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



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 products are medical devices 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

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

3.3 Indications

For patients having difficulty maintaining a stable seated position.

3.4 Intended patient population

Recommended maximum patient weight for each seat cushion is described under section 5.

3.5 Intended user

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

3.6 User qualification

Training is not mandatory to use the seat cushions.

3.7 Intended use 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.

3.7.1 Optimum environmental conditions

The seat cushions are intended to be used indoors at room temperature.

3.8 Contraindications

There are no known contraindications.

3.9 Clinical benefit

The clinical benefit for Curera® seat cushions included in this instructions for use are:

- Pressure redistribution
- Safety
- Comfort
- 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.

4.1 Curera® Consil, Curera® Contur, Curera® Contur EX, Curera® Contur Child, Curera® Consept, Curera® Consept EX, Curera® Consept Latus, Curera® Tremix

Make the cushion ready to use by following these steps:

1. Check that the cushions fit correctly in the cover. Follow the marking on the cover and cushions.
2. Place the cushions 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.

4.2 Curera® seat cushion

Make the cushion ready to use by following these steps:

1. Check that the cushion fits correctly in the cover. Follow the markings on the cover and cushions.

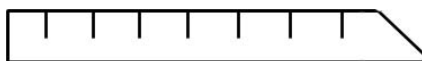


Attach and detach the cover as shown in the illustration below to minimize the risk of ripping the cover.



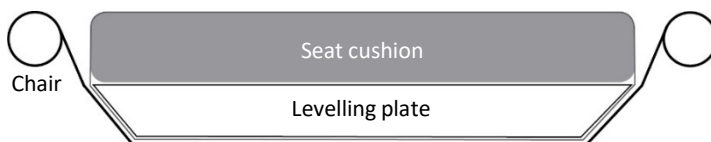
2. Place the cushion in the wheelchair with the squares facing upwards (feel with your hand) and the bevelled edge facing forwards. See the illustration to the right.

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.



4. The patient can now start using the cushion.

4.3 CuroCell® S.A.C.

Make the cushion ready to use by following these steps:

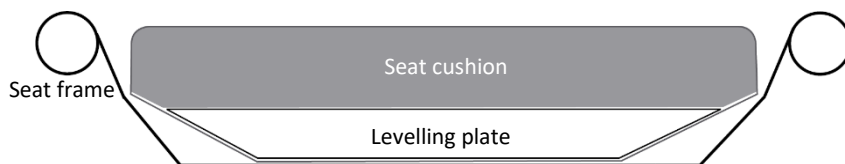
1. Check that the cushion is properly inflated. To check this, start rolling the cushions from one side, it should be possible to roll the cushion to the second row of holes.
2. Place the cushion in the intended seat.
3. Place the patient on the cushion.
4. Perform a hand check to make sure that the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



When using CuroCell® S.A.C. in a wheelchair with a suspension kit, a levelling plate might be necessary.

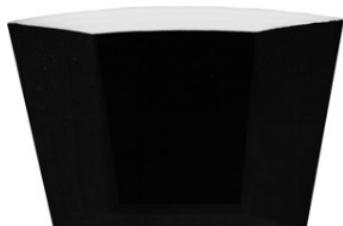
4.4 Using levelling plate without an anti-slip

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.



4.5 Using levelling plate with an anti-slip

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



5 Product description

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

5.1 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

Recommended max patient weight in kg:

Width (cm)							
Depth (cm)	35	37	40	42	45	47	50
35	70						
40	70	90	90	125	135	135	150
45		90	90	125	135	150	150
50					135	150	150

5.2 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

Recommended max patient weight in kg:

Width (cm)										
Depth (cm)	30	33	35	38	40	42	45	47	50	52
30	125	125								
35	125	125	125		125					
40	125	125	125	125	125	125	135	135	150	150
42					125	125	135	135	150	
45			125	125	125	125	135	150	150	150
47					125	125	135			
50				125	125	125	135		150	150
55									150	

5.3 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

Recommended max patient weight in kg:

Width (cm)							
Depth (cm)	35	37	40	42	45	47	50
35	125		125				
40	125	125	125	125	135	135	150
45	125	125	125	125	135	150	150
50		100	125	125	135		150

5.4 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

Recommended max patient weight in kg:

Width (cm)							
Depth (cm)	35	37	40	42	45	47	50
35	70	70	105				
40	70	105	115	135	135	135	150
42			115	135	135	135	150
45	70	105	115	135	135	150	150
50	70	105	115	135	135	150	150
55							150

5.5 Curera® Consept EX

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

Material in cushion: Polyurethane foam, elastic foam

Height: 5 cm

Covers that fit: Standard cover, Hygienic cover

Recommended max patient weight in kg:

Width (cm)							
Depth (cm)	35	37	40	42	45	47	50
35	70						
40	70	105	115	130	130	130	150
42			115	130	130	130	150
45	70	105	115	130	130	150	150
50	70	105	115	130	130	150	150

5.6 Curera® Consept 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

Recommended max patient weight in kg:

Width (cm)					
Depth (cm)	50	52	55	57	60
40		250	250	250	270
42	250				
45	250	250	250		270
47					270
50	250	250	250	270	270
55	250		250	270	270

5.7 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

Recommended max patient weight in kg:

Width (cm)									
Depth (cm)	35	37	40	42	45	47	50	52	55
35	70								
40	70	105	115	130	130	130	150	150	160
45		105	115	130	130	150	150	150	160
50			115	130	130	150	150	150	160

5.8 Curera® Contur Child

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

Recommended max patient weight in kg:

Width (cm)						
Depth (cm)	25	27	30	32	33	35
25	40	40	60	60		60
27	40	40				
30	40	60	60		60	60
32						60
35	40		60	60	60	60
40			60		60	60

5.9 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

Recommended max patient weight: 120 kg

5.10 CuroCell® S.A.C.

A static, redistributing seat cushion of air.

Material: Polyurethane

Covers that fit: Hygienic cover

Recommended max patient weight: 160 kg

5.11 Levelling plate (accessory)

The levelling plate is used to level the seat surface in wheelchairs with a hammock seat. It is intended to be used with seat cushions with a flat bottom.

The levelling plate is available in two versions; one without anti-slip that can be placed inside the cover under the cushion, with the rounded back edge facing back and the beveled underside facing down towards the underside of the cover. The other has anti-slip and can be placed directly in the wheelchair, under the wheelchair cushion, to fill the gap between the cushion and the hammock seat.

6 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 cover and cushion each time the product is cleaned. Damaged covers should be repaired or replaced.

6.1 Cleaning and disinfection

6.1.1 Cushions Curera® Contur, Curera® Concept, Curera® Concept Latus, Curera® Tremix, Curera®, Curera® Contur Child, CuroCell® S.A.C

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%).

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

6.1.2 Cushions Curera® Consil, Curera® Seat cushion, Curera® Contur EX, Curera® Concept EX

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. Do not wring or roll the cushion to extract water. Let the foam core dry in a warm, ventilated area without direct exposure to sunlight. The foam core needs to be completely dry before it is used again.

6.1.3 Levelling plate (accessory)



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%.

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

6.1.4 Covers Standard Cover, Deluxe Cover, Hood Cover



The cover must be completely dry before being refitted.

6.1.5 Cover Hygienic 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%).

Machine wash:



7 Maintenance

7.1 Between patients

Before using the product again for a new patient, it is recommended to clean the product as described in section 6.

8 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.

9 Standards

The seat cushions are tested and approved according to the following European standards, where applicable requirements are met: SS-EN 1021-1, SS-EN 1021-2.

10 Other information

10.1 Technical lifetime

The technical lifetime of the product is 2 years, except for CuroCell® S.A.C., when used under normal conditions.

The estimated lifetime for CuroCell® S.A.C. is 1 year when used under normal conditions.

10.2 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.

10.3 Disassembly and recycling

The cushions shall be sorted as combustible waste. No disassembly is necessary.



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.

10.4 Return

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

Manufactured by



Contact:

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