



USER GUIDE

OptiCell Soft

Constant low air pressure overlay mattress



Järven Health Care

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Thank you for choosing the OptiCell Soft constant low air pressure overlay mattress from Järven Health Care.

Our goal is for you to be satisfied with the mattress in terms of both function and service life. Therefore, please take a few minutes to read through this guide to understand the best way to manage and care for your mattress.

If you have any questions that are not answered here, please contact us at Järven Health Care. You can find our contact information at the back of this guide.

SYMBOLS USED THROUGHOUT THIS GUIDE



Important note:

All instructions denoted by this symbol must be observed. It highlights information and guidelines that are important to the user.



Risk of damage to mattress:

Important information denoted by this symbol must be observed in order not to damage the mattress or other material.

CE MARKING

Järven Health Care hygiene mattresses are CE marked according to Medical Device Directive 93/42/EEC Class 1 (Medicintekniskt Direktiv 93/42/EEG). The CE marking signifies that OptiCell AB has the manufacturer's responsibility to ensure that this product meets the essential requirements of relevant European legislation. This includes the provision of technical documentation and assurance which is maintained for at least five years after the product is placed on the market..



QUALITY

Our quality standards and customer focus goals are realised by responding to the needs and expectations of our customers. We believe in building long-term relationships through collaboration and trust.

Continuous improvement in our products and services is the basis of our ability to satisfy both current and future customers. Our approach includes the development of evaluation methods and standards that offer the customer a guaranteed quality in terms of comfort, function, durability and price.

Through our team of skilled and dedicated employees, we are focused on supporting education, development and innovation within the healthcare profession. Our goals are to facilitate high quality care aimed at preventing pressure ulcers, to reduce healthcare related infections and to improve fire safety within healthcare environments.

SAFETY INSTRUCTIONS

Read the following information before using your OptiCell Soft mattress!



- **The product should only be used in accordance with this user guide.**
- The product should not be assembled, combined or repaired with any parts or accessories other than those described in this guide or in other documentation from Järven Health Care.
- Ensure that the mattress does not become misshapen or damaged during storage.
- Avoid sharp objects near the mattress so that the surface does not get damaged.
- Avoid severe physical impact from other objects.
- The mattress is fire safety tested according to standards **SS 8760001, EN 597-1** and **EN 597-2**. It is the customer's responsibility to make a fire risk assessment of the intended usage environment and then use the right product. Please contact us if you have any questions.
- In order to avoid damage, the mattress should not come into contact with heat sources or fire, such as burning cigarettes, heat lamps or the like.
- Make sure that you use the correct mattress size for the bed and the appropriate model for the patient.
- Connect the product to the nearest situated power outlet in order to reduce the amount of power cable lying across the floor.
- Follow appropriate electrical safety standards.

THE PRODUCT MUST NOT BE USED FOR:

- Patients with unstable spinal fractures. For other unstable fractures, a medical examination is required to determine if it is appropriate to use the product.
- Patients with abnormal anatomies.
- Patients undergoing cervical traction or leg traction.

PRODUCT INFORMATION

OPTICELL SOFT AIR MATTRESS SYSTEM

The product is designed to help prevent pressure ulcers from Categories 1-2 (low risk to medium risk) for patients within the weight range 25-250 kg.

The product is intended for use with a sheet between the patient's skin and the mattress surface.

The mattress can be used within the following environments, defined by IEC 60601-2-52:

- Operating environment 1 (*emergency care*).
- Operating environment 2 (*short-term care in hospitals or other healthcare facilities*).
- Operating environment 3 (*long-term care in healthcare facilities*).
- Operating environment 4 (*care in the home environment*).
- Operating environment 5 (*outpatient care*).

In accordance with directives from the European and the US National Pressure Ulcer Advisory Panels (EPUAP and NPUAP), it is recommended that each patient's condition be checked regularly.

PREPARATION

This user guide contains information for general use, maintenance and improved safety.

It is very important to read this guide carefully before using the product. Care personnel must be given access to this user guide and also be informed of the risks that may arise when using electrical equipment. Training on the product can be provided on request.

Before using the product for the first time, or when it is retrieved from a storage location:

- Check the condition of the electrical system and its compliance with applicable safety standards.
- Connect the product to the mains power supply.
- The power outlet used should be easily accessible so that the product can be disconnected if necessary.
- Ensure that all of the product's functions are in good working order.
- Ensure that the product and the care environment are in good hygienic condition.
- Check that the product is positioned in a safe manner in the care environment.

If the mattress is used with other medical devices, it is the user's responsibility to meet all relevant safety and compliance requirements.

THE HYGIENE COVER

OptiCell Soft comes with a durable water resistant bi-elastic hygiene cover which contributes to the mattress's pressure relieving properties.

The cover is made of a polyurethane (PU) material. The entire cover can be cleaned with disinfectants or machine washed at maximum 95° C and tumble dried.

The cell mat and air hose can easily be removed from the cover and rinsed clean with disinfectants or with warm water at maximum 70° C.

There is a zip on three sides, covered by a protective flap.

APPLICATIONS

The OptiCell Soft is a constant low air pressure overlay mattress that is placed on top of a foam mattress (for example, one of Järven's standard mattresses). It aids the prevention of pressure ulcers up to and including Category 2.

OptiCell Soft has a height of 10 cm and comes with a durable cover and a CPR valve for emergency situations.

The supplied OC-10 pump provides constant low air pressure only. It can be adjusted manually to adapt to the patient's weight.

FIRE PROTECTION

The OptiCell Soft mattress is tested and approved according to **SS 8760001**, **EN 597-1** and **EN 597-2**.

SYSTEM FEATURES

OptiCell Soft is designed to make it easy to adjust the air pressure based on the patient's weight and preferences.

OptiCell Soft provides a constant low air pressure which is adjusted by setting the dial on the pump. The pump indicates a scale in **kg** (corresponding to the patient's weight) which provides an initial guideline for the carer when the patient is lying down.

When the patient is in a sitting position, turn the dial to increase the pressure level by one weight setting on the pump indicator scale. For patients over 200 kg, set the pump at maximum pressure (250 kg) when in a sitting position.

The mattress can be used immediately after delivery and unpacking. Inflating the mattress takes about 15 minutes and should be done before the patient is placed on the mattress.

AIR HOSE PUMP CONNECTION

The OptiCell Soft air mattress is connected to the pump by a cable comprised of two air hoses. The pump has two air outlets that easily connect to the air hose cable.

Connecting the air hose to the pump:

To connect or disconnect the air hose, push in the clip on the connector. This action releases the hook that holds the connector in place.

To minimise the risk of air leakage during hose connection, check:

- That the hook and clip are intact and not damaged.
- That the black o-rings on the connector's two air hoses are not cracked or missing.
- That no debris has entered the connector causing a bad connection or blocking the air hoses.

USE OF PRODUCT

RECEIVING AND UNPACKING

The OptiCell Soft air mattress is delivered rolled up in cardboard. Use of knives should be avoided when unpacking and handling due to risk of damage.

An OptiCell air mattress system contains:

- 1 pump, with power cable
- 1 mattress, with air hoses cable, CPR valve and water resistant bi-elastic cover

Check that the product is not damaged. In the event of transport damage, see page 14.

The mattress can be set in place and made ready for use immediately.

PLEASE NOTE:

- The air pump should not be used in humid areas nor should it be left outdoors in damp weather conditions. If the pump is exposed to water, avoid handling it until it has dried.
- Take care when handling the pump, power cable and air hose. Air hoses can be pinched and damaged by bed rails etc.
- The mattress's comfort and function change depending on the its air pressure in relation to the patient's weight. Keep in mind that a tall patient can weigh the same as a short patient, but may need a different pressure. This must always be carefully observed for each patient.
- The biggest risk for the patient is to "bottom out" on the mattress. The basic rule is that the part of the body to be unburdened must not be subject to pressure. If the patient "bottoms out", the objective of the mattress is lost. A hand check test should be performed when the patient is positioned on the mattress. Ensure that one hand can be inserted between the OptiCell Soft air mattress and the underlying foam mattress.
The important conclusion of the check is that there is space between the patient and the bed base.
- The patient should not be positioned with their respiratory system turned towards the mattress.

STORAGE

The OptiCell Soft air mattress system should be stored in the dry and at room temperature.

We recommend that the mattress be kept rolled up in one of our optional transport bags. The mattress should not be treated carelessly when stored, as it risks being damaged.

Avoid exposing the mattress to direct sunlight for prolonged periods.





It is important that no sharp objects come in contact with the mattress.

To prevent damage to the mattress avoid knives, keys and other objects with a cutting or puncturing ability from coming into contact with the mattress.

INSPECTION AND TROUBLESHOOTING

INSPECTION OF YOUR OPTICELL SOFT AIR MATTRESS SYSTEM

An inspection plan should be established in order for your air mattress to function and last for as long as possible. Please contact us if you would like assistance with this. Järven Health Care's contact details can be found on the back cover of this guide.

INSPECTION OF THE MATTRESS AND PUMP

- Check the electrical cord and plug for signs of damage or abnormal wear.
- Check the mattress for signs of damage or abnormal wear.
- Check that the mattress is correctly connected to the air hose cable.
- Start the pump and examine the air flow from the pump (with the air hose cable disconnected). There should be air flowing from both holes.
- Check the air hoses for signs of damage or abnormal wear.
- Check the air hose connector (see page 7).

INSPECTION OF THE MATTRESS COVER

Regularly check the cover for visible signs of damage or wear, such as tears, cracks, holes, stains or discolouration. Check all sides including the underside.

TROUBLESHOOTING

The pump does not work or does not start:

- Make sure the electrical plug is properly inserted, then turn on the pump's power switch.
- If the power indicator is off, there may be a problem with the electrical socket. Test another power outlet.
- If the power indicator is on but the pump does not work, contact Järven Healthcare.

The mattress does not inflate properly (pressure too low):

- Set the pressure to maximum, check if the air hoses are pinched anywhere or if there is air leakage from any cell. Check that the CPR valve is closed.

CLEANING

CLEANING THE PUMP

To clean the pump, use a damp cloth and mild detergent on the pump housing and the power cable.

CLEANING THE MATTRESS COVER

The cover is made of a polyurethane (PU) material on both top and bottom. The entire cover (both upper and lower parts) can be cleaned with disinfectants. Use alcohol-based disinfectants.

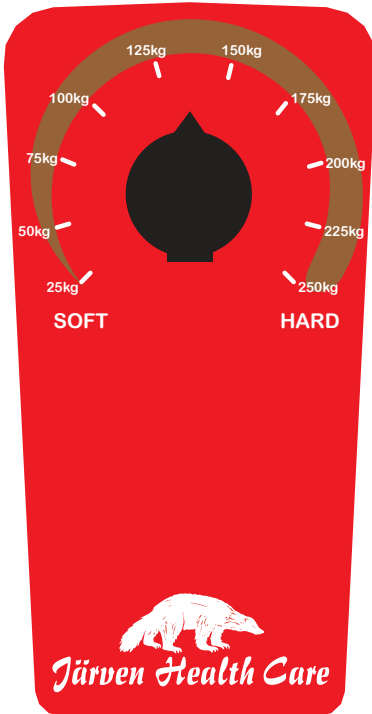
The cover can be machine washed at a maximum of 95° C and tumble dried.

Healthcare textiles (mattress coverings, bedding, etc.) can be contaminated by pathogenic microorganisms. These should be washed at a minimum of 70° C for at least 10 minutes with unscented detergent, according to standard ***“BS-EN 14065: 2016 Textiles – Laundry Processed Textiles - Biocontamination Control System”***.

CLEANING THE CELLS AND AIR HOSES

The cell mat can be cleaned using a damp cloth and mild detergent. The air hoses can also be wiped with a damp cloth and mild detergent.

PUMP OVERVIEW – OC-10



The power switch is located on the right-hand side of the pump.

Press **"On/Off"** to start or stop the pump.

Filling the mattress takes approximately 15 minutes.

Setting the air pressure:

The pressure can be set ranging from 25 to 250 kg.

A tall patient normally requires a lower pressure level in the mattress than a shorter patient who weighs the same amount.



When the patient is in a sitting position, turn the dial to increase the pressure level by one weight setting on the pump indicator scale. For patients over 200 kg, set the pump at maximum pressure (250 kg) when in a sitting position.

SPECIFICATIONS

Pump OC-10	Specifications
Size	25.0 x 8.5 x 12.5cm
Weight	1.4 kg
Pressure range	20 ~ 70mm Hg
Cycle time	None – static (constant low air pressure)

System	Specifications
Classification	Class II; IPXO, No AP/APG; Type BF
Applied part	Mattress
Power rating	~230V AC/50 Hz 1A, 12W
Fuse rating	250V, T 1 A
Operating environment	Temperature Use: 10° ~ 35° C Storage: -15° ~ 50° C Transport: -15° ~ 70° C Humidity Use: 20% ~ 80% without condensation Storage: 10% ~ 90% without condensation
Safety standard	CE-marked

RECYCLING



All materials in your OptiCell air mattress system, with the exception of certain parts of the pump, are energy-recoverable by incineration at designated combustion plants.

PUMP

An OptiCell pump must not be disassembled, but should be disposed at a recycling station and sorted as "Electronic waste".

MATTRESS

The OptiCell air mattress can be disposed of at a recycling station and sorted as "Combustible waste". For more information contact Järven HealthCare.

Järven Health Care takes environmental responsibility seriously.

We strive to always use materials and products with the least possible impact on the environment. We are constantly working to develop and improve production techniques. Järven Health Care is affiliated with the Swedish FTI and EI-Kretsen recycling agencies to maintain its responsibilities as a producer.

For more information on our environmental work contact Järven Health Care.

OTHER INFORMATION

PRODUCT LIABILITY

Product liability legislation (EU Directive 85/374/EEC, Swedish Law SFS 1992: 18) establishes the manufacturer's, importer's or seller's statutory liability for any damage caused by the product. The regulations apply to physical products in the form of movables, even if incorporated into another movable or into an immovable. If there is no product which has been the cause of some form of property or personal injury, then product liability legislation is not relevant.

RETURNS AND COMPLAINTS

Any complaints regarding the product must be notified in writing to Järven Health Care. The return of products must be done in accordance with our instructions.

Returning a product before a complaint case is processed will result in the case being considered closed and customer compensation will not be paid.

DAMAGE UPON DELIVERY

Any damage of the product must be noted on the accompanying delivery document before accepting possession. Then contact Customer Service at Järven Health Care (+46 660-22 28 50, healthcare@jarven.se) and provide relevant information.

NOTE! For faster processing of your case, we ask you to photograph the transport damage as thoroughly as possible before contacting Customer Service.

PRESSURE ULCER PREVENTION WORK

A clinical assessment of the patient's risk of developing pressure ulcers should be carried out. Aids to the assessment include the Norton scale, Braden scale and Risk Assessment Pressure Sore (RAPS) scale.

The assessment must be done on arrival or at the beginning of a care period, regardless of whether the patient is in a care facility or cared for in his or her own home. According to the European Pressure Ulcer Advisory Panel's (EPUAP) international guidelines, the recommendation is within 8 hours. The assessment is made to identify the specific needs of the patient regarding pressure relief and must be conducted by staff with adequate knowledge and education.

Based on the patient's assessed status, the appropriate mattress is chosen for the correct purpose and pressure relief needs.

Routinely change the patient's location and position on the mattress throughout the care period. In addition, regularly examine the patient and check their skin condition and nutritional status.

All of Järven Health Care's OptiCell mattresses have undergone pressure measurement testing according to SS 8760013 at Swerea IVF.

The results of the pressure measurement test form the basis for the classification of the pressure relief properties of the mattresses.





OPTICELL SOFT user guide.

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Järven AB reserves the right to update this guide if necessary
and/or on finding any spelling or factual errors.

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