Staebel OptiCell SMART
User Manual

Thank you for choosing OptiCell.

We aim to ensure you are satisfied with your mattress in terms of both performance and durability. We therefore kindly ask you to spend a few minutes reading through these user instructions to ensure you can take the best possible care of your mattress.

If you have any questions that are not answered in these user instructions, please contact us at Staebel. You will find our contact details on the back page of these user instructions.

CE MARKING

The OptiCell Air Mattress system CE marked according to Medical Device Regulation MDR (EU) 2017/745 class 1. The CE marking means that OptiCell has the manufacturer's responsibility to ensure that this product meets the essential requirements of relevant European legislation. This includes the provision oftechnical documentation and assurance which is maintained for at least ten years after the product is placed on the market.

QUALITY ASSURANCE

Our quality assurance 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 Injurys, to reduce healthcare related infections and to improve fire safety within healthcare environments.

SAFETY INFORMATION

Please read the following information before using your OptiCell air mattress!

- The product should only be used in accordance with these user instructions.
- This product must not be combined, assembled or repaired with any parts, accessories or spare parts other than those described in these user instructions or other documentation from Staebel.
- Ensure the mattress is not squashed or damaged in storage.
- Avoid sharp objects close to the mattress.
- Avoid physical impact with other objects.
- OptiCell is fire tested to standard SS 876 00 01, EN 597-1 & 2.
- The customer is responsible for performing a fire risk assessment and using the right products accordingly. Please contact us if you have any questions.
- To avoid the risk of damage, these products should not come in contact with heat sources or fire, such as lit cigarettes, hot lights or similar.
- Check that you use the right mattress size for the bed in question and the correct model for the particular patient.
- Connect the product to the nearest wall socket, to ensure the shortest length of cable as possible along the floor.
- Comply with electrical safety standards.
- Always check the electrical cable before use and do not use if the cable is damaged or cracked.

THE PRODUCT MUST NOT BE USED BY

- 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

GENERAL INFORMATION ABOUT OPTICELL SMART

The OptiCell SMART has been designed as an aid in the prevention and treatment of pressure sore care up to and including bedsore category 4 depending on the mattress. Mattresses are available in a choice of models, please see summary under Intended use on page 7.

The mattresses are intended to be used with a sheet between the patient's skin and the surface of the mattress. The OpticCell Smart can be used in the following environments, defined in standard IEC 60601-2-52

- Application environment 1 (emergency care).
- Application environment 2 (short-term care in hospital or other healthcare establishments).
- Application environment 3 (long-term care in healthcare establishments).
- Application area 4 (care in home environment).
- Application area 5 (outpatient care or treatment).

In accordance with the NPUAP/EPUAP Directive, checking the condition of the patient regularly is recommended.

Commissioning

These user instructions contain information for general use, maintenance and improved safety. It is important to read these user instructions before using the product.

These user instructions should be made available to care providers who should also be informed about the risks that can arise when using electrical equipment. Product training can be provided on request.

Before using the product for the first time or when it is taken out of storage:

- Check the condition of the electrical system and that it complies with applicable safety standards.
- Connect the product to the mains power supply.
- The wall socket should be accessible to enable the mattress to be disconnected if necessary.
- Ensure that all product functions are in full working order.
- Check that the product and care environment are in a good state of hygiene.
- Check that the product is securely positioned in the operating environment.
- After the mattress has been inflated and the patient has been positioned on the mattress, a hand test should be performed (see page 11)

If the mattress is used with other medical devices, the user is liable for ensuring safety and compliance requirements are satisfied.

THE OPTITEX® COVER

OptiTex® is a bi-stretch hygiene layer whose structure boosts the pressure relieving properties of the mattress. The OptiTex™ cover has an integrated, waterproof cable holder that reduces the risk of any spread of bacteria, keeps the cable out of the way, and also protects the air hoses.

The top and bottom sides of the cover are made of PU material. The entire cover (both top and bottom sides) can be cleaned with disinfectant agents and is also machine washable at max 95o C and can be tumble dried. Cells and hoses can be detached from the cover easily and rinsed clean with warm water (max 70o C) or cleaned with a disinfectant agent.

- The Low Air Loss function allows air to be released from the cells and is also waterproof. This, together with the elasticated outer surface, helps reduce the risk of skin maceration and other complications for users.
- Drip protection waterproof zip on four sides. All seams are welded to reduce the risk of liquid penetration.
- The underside has anti-glide protection with four fixing strips.
- The cover has four handles for ease of moving.

EXPECTED USEFUL LIFE
Under normal conditions and normal maintenance, our OptiCell systems have an expected useful life of 5 years.

FIRE SAFETY
OptiCell 4 PRO V2 pressure air mattresses are tested and approved in accordance with SS 876 00 01, EN 597-1 and EN 597-2.

INTENDED USE
The OptiCell SMART is an alternating and pressure relieving air mattress system that has been designed as an aid for the prevention and treatment of pressure sores up to and including bedsore category 4.

OptiCell SMART - mattress configuration
The combination of pump and mattress gives the system a unique set of functions. The aim is to reduce the learning curve for using these systems and ultimately give staff greater self-confidence. See summary below for information on each mattress and its properties.

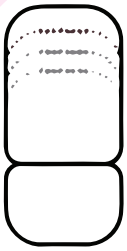
SERIES N NYLON CELLS	THICKNESS	LAX LOAD	CELL TYPE *	MATTRESS TYPE **
SMART N5	130 mm	200 kg	Single Cell	Bed
SMART N7	180 mm	230 kg	Single Cell	Combi
SMART N8	200 mm	250 kg	Cell-on-Cell	Replacement

SERIES T TPU CELLS	THICKNESS	LAX LOAD	CELL TYPE *	MATTRESS TYPE **
SMART T5	130 mm	200 kg	Single Cell	Bed
SMART T7	180 mm	230 kg	Single Cell	Combi

SERIES N TPU CELLS	THICKNESS	LAX LOAD	CELL TYPE *	MATTRESS TYPE **
SMART R6	150 mm	210 kg	Cell-on-Cell	Replacement
SMART R7	180 mm	230 kg	Cell-on-Cell	Replacement
SMART R8	200 mm	250 kg	Cell-on-Cell	Replacement
SMART R10	250 mm	350 kg	Cell-on-Cell	Replacement

*** Single cell Mattress consists of several individual cells.** Cell-on-Cell The mattress consists of several individual cells where each cell has two air compartments.
**** Bed The bed mattress is to be used in combination with a separate foam mattress underneath.** The Combi Mattress has a built-in foam core (5 cm) under the air cells and is placed directly on the bed base. A replacement mattress consists of Cell-on-Cell air cells and is placed directly on the bed base.

SINGLE CELL
The cell consists of an alternating air chamber



CELL-ON-CELL
The cell consists of two air chambers where the upper one is an alternating cell. The lower air chamber is designed to prevent the patient “lying through”.

FEATURES, OPTICELL SMART

OptiCell SMART air mattress systems are designed to enable individual cells to be disconnected simply while a patient is lying on the mattress. The mattresses have three different types of cells with different functions.

- Main cells - Continuously inflated air cells used primarily under the head.
- Standard cells - dual chamber cells where some chambers are continuously inflated and others have alternating air pressure.
- Ventilation cells - act like standard cells, but with ventilation holes that blow small amounts of air upwards into the cover. This is to create air circulation that helps keep the top of the cover dry and reduce the risk of damage.

By connecting in an additional ventilating cell, an airier feeling can be created if the user says the cover feels hot in a certain area.

Individual cells can be disconnected simply by:

- Removing the air hose from the cell concerned by pressing the button on the air hose connector.
- Disconnecting both buttons on both sides of the cell.

AIR HOSES FROM THE PUMP.

The OptiCell SMART has a connector with three hoses from the pump to the mattress.
The intermediate hose (red), is used to inflate the main cells under the patient's head and to inflate the lower cell chambers in the other cells. This is to ensure there is always air in the mattress irrespective of the pump setting or if the pump were to stop working (power outage or similar).
The two other hoses supply either alternating or static pressure to the standard and ventilation cells.
See section "Air hose connection" (page 10) for further information.

THE DIFFERENT PUMP SETTINGS.

By changing the settings, the mattress can be used in either static or alternating pressure mode with different degrees of air pressure. See Overview Pump, page 15.

BEFORE USE

Delivery & Unpacking

OptiCell SMART mattresses are delivered rolled up in cardboard. Do not use a knife to open the packaging to avoid any risk of damaging the product. First check that the product is not damaged. In the event of transport damage, see page 17.

An OptiCell SMART air mattress system contains

- 1 X pump
- 1 X power cable (6 meters) to pump
- 1 X mattress, with air hoses and CPR valve plus OptiTex ™ cover.

The OptiCell can be installed and used immediately.

To Think About

- **The air pump should not be used in humid areas,** nor left outdoors in damp weather conditions. Avoid handling the pump if it has been exposed to damp, until it has dried.
- **Handle the pump, air hoses and power connection with care.** Air hoses can be squashed and damaged by the bed frame etc.
- **The comfort and performance of the mattress** will change in relation to the air pressure in the mattress and the weight of the patient. Bear in mind that a tall user can weigh as much as a short person but will need different pressure. This must always be carefully checked for each user.
- **It is important to make sure that the mattress isn't bottoming out**.
  If the user bottoms out, the mattress will not work properly.
  See page 16 for information on how to conduct a "bottoming-out"-test.
- **The user must not be positioned such that their respiratory airways are turned towards the mattress.**

It is important that no sharp objects come in contact with the mattress.
Avoid knives, keyrings or other objects that could cut or puncture the mattress if they come in contact with it.

Storage

OptiCell pressure air systems should be stored at room temperature in a dry space. We recommend the mattress is stored rolled up in our practical transport bag (accessory). The mattress should be handled with care in storage to avoid risk of damage.
Avoid exposing the mattress to direct sunlight for an extended period.

HANDLING

The mattress can be inflated and used immediately on delivery. It takes around 15 minutes to inflate the mattress and this should be done without a patient lying on the mattress.

Automatic Setting

When you start the pump, it is set to automatically adjust the air pressure to the weight, height, location, movement and position of the user in the bed. The pump is preset to comfort mode "0" and a 10-minute cycle time. This means it is simple to start using the mattress. Both comfort mode and the cycle time can be adjusted via the pump control panel, (see page 12).

Static Mode

In certain cases it is better to keep the air pressure of the mattress static, e.g. in care situations or if alternating pressure disturbs the patient. The mattress is simply switched to static position via the pump control panel. (see page 12).
NOTE THAT the correct therapeutic effect is achieved in alternating mode. Static air pressure (constant low pressure) should only be used when this is necessary.

Low Pressure Alarm

If the mattress pressure becomes too low, the Leaking light will come on and a sound alarm will start. Start by pressing the Mute button (position H on page 12) to mute the alarm. Then check the following points to find the cause.

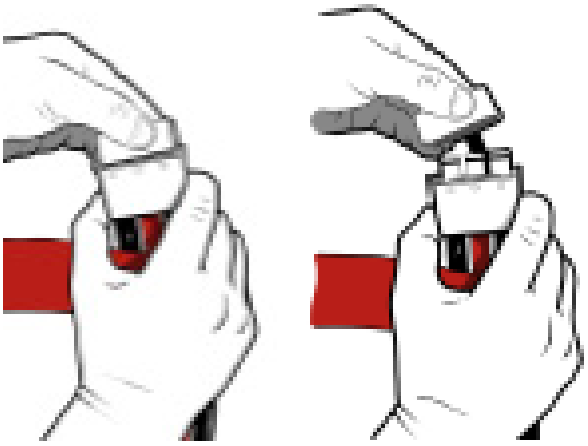
- Check that the air hoses are correctly connected to the pump. Also check that the rubber seals around the plug are not missing, incorrectly positioned or badly worn.
  Make sure that there is no leaks between the air cells and the air hoses.
- Check that the CPR valve is properly connected.

If no fault / leakage can be detected, the mattress should be replaced, contact Staebel for further advice. Contact information can be found on the last page of the user instructions. Check all air cells for leaks. This is easiest when the pump is set to care mode (See page 12).

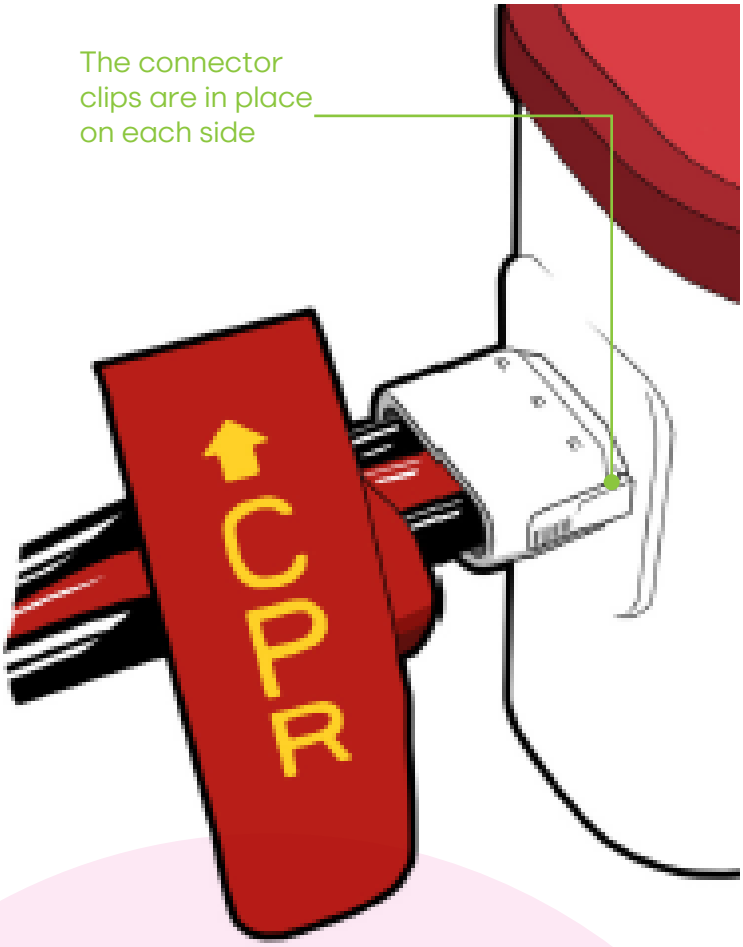
AIR HOSE CONNECTION

Connect the air hoses to the pump
To connect or disconnect the air hoses to/from the pump and to remove the protective cover on the air connector, press in the clips on both sides of the connector. This releases the catches that hold the connector in place.

To minimise the risk of air leaks at the connector, check:
- That the two catches are not damaged and still retain their resilience.
- That the black O-rings on the three air tubes at the connector are not cracked, missing or worn.
- That no debris is blocking the air tube or preventing a good seal.



The air hoses are connected simply by hand. No special tools required.



OVERVIEW - PUMP OC55

Inflating the mattress normally takes approx. 15 minutes. When the light comes on, the mattress is ready to use.

1. Dynamic mode, select to set the pump to dynamic (alternating) mode.
2. Static mode, select to set the pump to static mode.
3. Nursing mode, provides maximum static pressure to facilitate nursing care times. The mattress automatically returns to the previous settings after 30 minutes.
4. The buttons on the panel are locked to prevent unauthorised adjustment of pump operation. To unlock the panel, hold this button in for 5 seconds.
5. Adjust comfort mode, there are five comfort modes to choose from. The patient experience of the mattress is affected by the comfort mode chosen.
6. Select the cycle time for switching in minutes.
7. Silence alarm, press to silence possible alarm signals. The “ ” light comes on when the air pressure in the mattress is low. Check for leaks. The “ “ light comes on in the event of a power failure. See page 22 - What to do if the alarm sounds.

SPECIFICATIONS

Pump OC20 V2	Specifications
Size	280 x 110 x 205 mm
Weight	3.4 kg
Pressure Range	20 ~ 70 mm Hg
Cycle Time	10, 15, 20 or 30 minutes

System	Specifications
Classification	Electrical Classification: Class II; IP Rating 21 (IP21); No AP/APG; Type BF**
Applied Part	Mattress
Power Rating	AC 220-240 alt. 110-240 universal power supply - 50 Hz 1A, 17W
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, IP21

For spare parts and accessories please contact your distributor or Staebel. See back page for contact details.

CARE - INSPECTION & TROUBLESHOOTING

Inspection of your Mattress

An inspection plan ought to be established for the mattress to ensure your pressure air mattress stays in good condition and lasts as long as possible. If you would like help with this, please contact us at Staebel. See back page of the user instructions for contact details.

Inspection of your Mattress and Pump

- Check the electric cable and plug for any damage or abnormal wear.
- Check the cover for any damage or abnormal wear.
- Check the mattress cells are correctly connected to the air hoses.
- Start the pump and check the air flow from the pump (with air hose disconnected). The air flow should alternate between the upper and lower hole (of three) each cycle time. The hose from the middle hole is switched off.
- Check the air hoses for any damage or abnormal wear.
- Check the air hose connection. See page 8.

Inspection of the Optitex Hygiene Cover

Regularly check the cover for visible signs of damage or wear, such as rips, cracks, holes, spots or discolouring. Check all sides of the mattress (including underside).

Power cable and hose set are connected to air pump.

- With the pump switch in the off position, connect the power cable to a socket. The power socket must be within easy reach to enable the mattress to be disconnected if necessary.

Troubleshooting

The pump does not work / does not start:

- Check that the power plug is properly inserted, then turn on the pump switch.
- If the power indicator is off, there can be a problem with the power socket. Try a different power socket.
- If the power indicator is on, but the pump still does not work, contact your salesperson.

Mattress does not inflate as it should do (pressure too low):

- Turn the pressure up to maximum, check if the air hoses are kinked or if any cell is leaking. Check that the CPR valve is closed.

Poor Air Flow:

- A dirty air filter can reduce the air flow. Clean the air filter with a mild cleaning agent to keep it clean. The air filter is easy to access on the back of the pump and can be removed very easily by hand.

MAINTENANCE - CLEANING

Cleaning of the Pump
Use a damp cloth and gentle cleaning agent to clean the pump, pump housing and electric cable.

Cleaning othe cover
The top and bottom of the cover are made of PU material. If necessary, the whole cover (both the top and bottom surfaces) can be wiped clean with a disinfectant agent. Use an alcohol-based disinfectant agent.

Healthcare textiles that can harbour micro-organisms harmful to health, (mattress covers, bedding etc.) should be washed at min 70o C for at least 10 minutes with unperfumed detergent, in accordance with standard SS-EN 14065:2016 Textiles - Laundry processed textiles - Biocontamination control system.
The cover is machine washable at max 95o C.

Cleaning of Cells & Air Hose
The cells can be washed separately or in groups. Use a damp cloth and gentle detergent. Wipe the air hose with a damp cloth and gentle detergent.

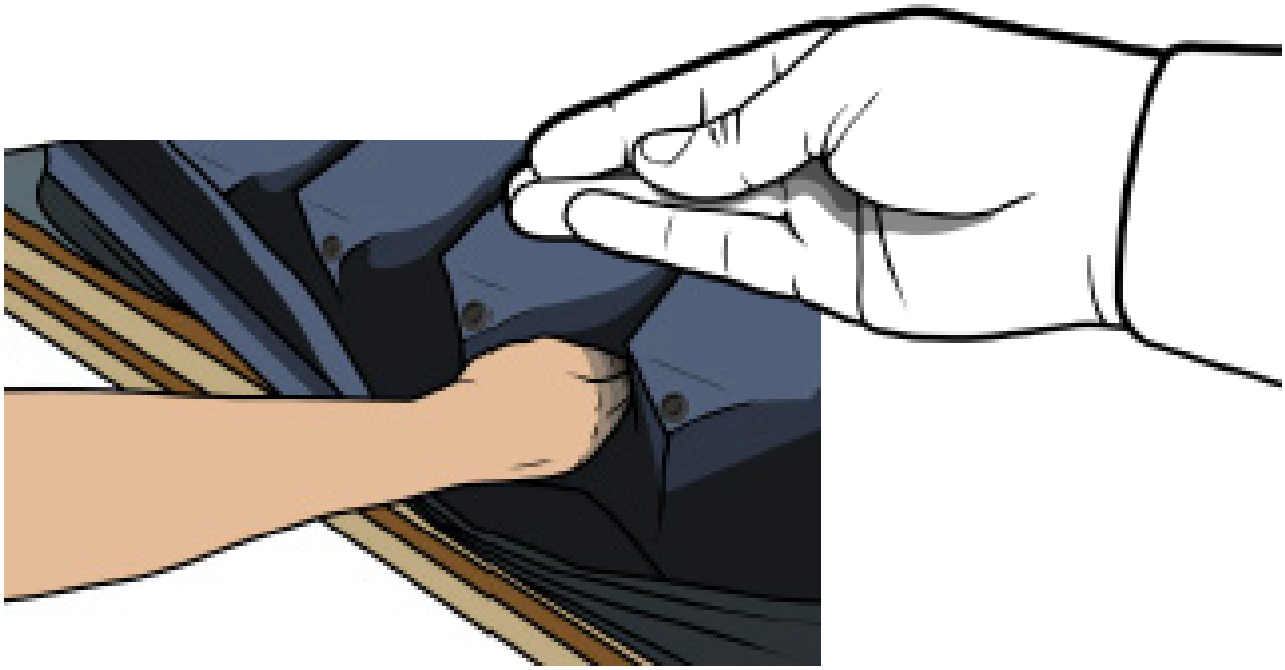
Cleaning the Air FIlter
The pump has an air filter that is easy to access via an inspection cover on the back of the pump. (See image below). Wash the filter with a gentle cleaning agent.

HAND TEST

Check that the mattress is working with a simple hand test.
Checking the mattress is providing the correct therapeutic treatment is done via a simple hand test. This test should be done every time a mattress is used to enable any problems with the air pressure in the mattress to be detected. The test checks that the patient does not “bottom out”.

How to perform the test.
The hand test is always done with a patient on the mattress. It is important to ask the patient not to try to raise their body during the test and to lie still as usual. (It is quite common for a patient to raise their body thinking that this will make it easier for the care worker, which would give incorrect test results).

- Fold the sheet to the side and open the mattress cover to access the cells.
- Insert your hand between the cells with the patient on the mattress. (See illustration)
- Check that your hand fits between the bed base and patient.



If the hand test shows that the patient has bottomed out.
If the patient has bottomed out and that alarm has not sounded, the comfort setting needs to be raised. If the comfort setting is at max and the patient does not weigh more than the recommended max weight, the mattress and pump need to be checked by authorised personnel.

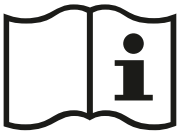
KEY TO SYMBOLS

Product code

Serial number

Batch number

States date of manufacture

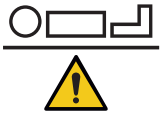


Please read the user instructions before use

The product is a medical device

This product is CE marked to MDR 2017/745

Manufacturer



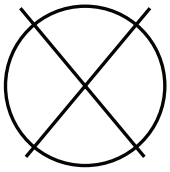
= 0-xxx kg

Maximum user weight.

Wound category the mattress is designed for.

Hand wash

Disinfect with alcohol-based agents or detergents with surfactants



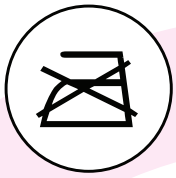
Do not spin

Do not dry clean

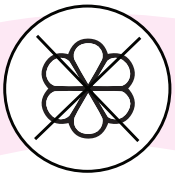
MAc temperature when washing

Do not use detergents containing chlorine

Tumble dry low



Do not iron



Fabric softener must not be used

Fire rated to SS 876 00 01 EN 597 1+2

CE MARKING

OptiCell air mattress systems are CE marked to MDR 2017/745.
This includes manufacturer liability and assurance that the product meets essential requirements and that technical documentation and assurance are stored for at least ten years.

OTHER INFORMATION

Recycling

All materials in OptiCell air mattress systems, except for certain parts in the pump, are suitable for energy recovery via combustion at waste to energy power stations. The product is PVC free.

PUMP - A used OptiCell® pump must not be dismantled, but sent to a recycling station instead. Sort as Electronic Waste.

MATTRESS - OptiCell air mattresses can be deposited at a recycling station and sorted as Combustible Waste. For more information please contact Staebel.

Product Liability

Product liability refers to the manufacturer's, importer's or seller's statutory liability for any damage caused by the product. The Product Liability Act (EU Directive 85/374 / EEC, Swedish Act SFS 1992: 18) establishes the manufacturer's, importer's or seller's statutory liability for damages for any damage caused by the product. The rules apply to physical products in the form of loose objects but also to products that are linked to other loose objects or real estate. If there is no product that has caused any form of property or personal injury, the product liability legislation is not relevant.

Expected Useful Life

Under normal conditions and normal care and maintenance, our OptiCell systems have an expected useful life of 5 years.

Product Claims & Returns

Claims must be submitted in writing to Staebel. Once a claim has been approved, the product is to be returned as advised. If the product is returned before the claim is approved, the claim will not be settled.

Transport Damage

Any damage of the product must be noted on the accompanying delivery document before accepting possession. **Please then contact your local distributor 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 Injury PREVENTION WORK

A clinical assessment of the patient's risk of developing pressure Injurys 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 Injury 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 the 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

WARRANTY: 2 Years