

ROHO®

SOFFLEX® 2 Mattress Overlay

Operation Manual



permobil

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Warning

Indicates that not following the specified procedure could lead to potentially hazardous conditions resulting in serious injury.

Caution

Indicates that not following the specified procedure could lead to potentially hazardous conditions resulting in minor to moderate injury or damage to the equipment or other property.

Incident Reporting

In the event of a serious incident or injury, contact Customer Support.

Symbols Glossary

Manufacturer



Fits



Serial number



This side is closest to the head of the mattress.



Date of manufacture



Model number



Fall Risk



This side is closest to the foot of the mattress.



Consult instructions for use



Quantity



Suffocation Risk



Bottom of mattress overlay.



Medical Device



Size



Entrapment Risk



Weight limit

Please Note

Supplier: This manual must be given to the user of this product.

Operator (Individual or Caregiver): Before using this product, read the instructions and save for future reference.

Products may be covered by one or more U.S. and foreign patents and trademarks, including ROHO®, SOFFLEX® and shape fitting technology®. Zytel® is a registered trademark of DuPont.

The following products are featured in this operation manual:

ROHO SOFFLEX 2 Mattress Overlay System or Section

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Intended Use

The ROHO SOFFLEX 2 Mattress Overlay System (SOFFLEX 2) is a non-powered, air-filled, adjustable, zoned, reactive, full support surface that is intended to conform to an individual's shape to provide skin/soft tissue and deep tissue injury protection and an environment to facilitate wound healing. The SOFFLEX 2 must be used on top of a standard hospital, nursing home, home care or consumer mattress. There is a weight limit of 330 pounds (150 kg) when properly sized to the bed mattress, and areas of the individual that require skin/soft tissue protection must be supported by SOFFLEX 2.

Compatibility: The SOFFLEX 2 should not be used with the ROHO Leveling Pad or the ROHO Mattress Overlay Foam Insert Pad.

An experienced clinician should determine whether the product is appropriate for the individual's particular equipment needs. The product's intended use statement alone should not be relied upon to make that determination.

The medical products featured in this document are intended to be only one part of an overall care regimen that includes all therapeutic equipment and interventions. An experienced clinician should identify this care regimen after evaluating the individual's physical needs and overall medical condition.

A clinician should also evaluate for visual, reading, and cognitive impairment to determine the need for caregiver assistance or the need for other assistive technology, such as large-print instructions, to ensure proper product use.

Important Safety Information

Warnings:

- The product should be set up by the equipment provider or clinician.
- While the product is in use, continue to follow all clinician recommendations for skin protection, including any schedule for regularly repositioning the individual.
- The support surface products featured in this manual will function without side rails; however, side rails may be necessary for some individuals. The decision whether to use side rails should be made by the individual's clinician and/or healthcare provider. If side rails are necessary for an individual, the following points should be considered by the individual in conjunction with his/her clinician or healthcare provider to reduce the risk of falling or entrapment.
 - If it has been determined that side rails are clinically indicated for an individual, knowledgeable and properly trained caregivers should identify and minimize any risks of entrapment in side rails.
 - If it has been determined that side rails are NOT clinically indicated for an individual, knowledgeable and properly trained caregivers should identify and minimize any risks of falling out of bed.
 - Whether side rails are used or not used, knowledgeable and properly trained caregivers should assess the need for devices or aids that will reduce the risk of falling out of bed or entrapment in side rails.
- The overlay MUST be correctly sized to the bed mattress and to the individual.
 - If the overlay is NOT correctly sized to the bed mattress and the individual, the product's benefits may be reduced or eliminated, increasing risk to skin and other soft tissue.
 - If a bed mattress is too wide, the straps provided to secure the SOFFLEX 2 to the bed mattress may not fit as intended. If straps are not used as instructed for the SOFFLEX 2, the product may slip or slide, and the individual may be vulnerable to falling.
- Skin/soft tissue breakdown can occur due to a number of factors, which vary by individual. Check skin frequently, at least once a day. Redness, bruising, or darker areas (when compared to normal skin) may indicate superficial or deep tissue injury and should be addressed. If there is any discoloration to skin/soft tissue, STOP USE immediately. If the discoloration does not disappear within 30 minutes after disuse, immediately consult a clinician.
- The cushioning products featured in this operation manual may introduce radiopacities and are therefore NOT recommended for use with x-rays. Radiopacities may interfere with diagnoses or surgical procedures that require radiographic images.

Warnings:

- DO NOT use the product as a water flotation device (e.g., a Life Preserver). It will NOT support you in water.
- If you are unable to perform any tasks described in this manual, seek assistance by contacting your clinician, equipment provider, distributor, or Customer Support.
- DO NOT expose the product to high heat, open flames or hot ashes. Testing or certification claims, including for flammability, may no longer apply to this device when it is combined with other products or materials. Check testing and certification claims for all products used in combination with this device.
- DO NOT use the product as a transfer surface. DO NOT reposition the product while it is in use.
- The mattress overlay surface will acclimate to the surrounding temperature. Take appropriate precautions, especially when the overlay will contact unprotected skin.
- The SOFFLEX 2 should not be used by infants or other individuals who are at risk of suffocation.

Cautions:

- Periodically, check the cover and components for damage and replace if necessary.
- DO NOT use a pump, cover or repair kit other than those compatible with the product.
- Changes in altitude may require adjustment to the product.
- Keep the product away from sharp objects.
- If a product has been in temperatures less than 32°F / 0°C and exhibits unusual stiffness, allow the product to warm to room temperature, then open air valve(s). Roll and unroll the product until the material is soft and pliable again. Repeat Hand Check/Adjustment instructions before using.
- DO NOT use any valve or air cell as a handle for carrying or pulling the product. Grasp the product by the base or the outside edges.

Important Notes:

- An unoccupied product may appear to be underinflated (not enough air) even if it has been inflated and correctly adjusted for a specific individual. This is because the individual's body mass is not pushing down on the air cells.
- CPR may be performed without deflating the product. A cardiac board is not necessary.

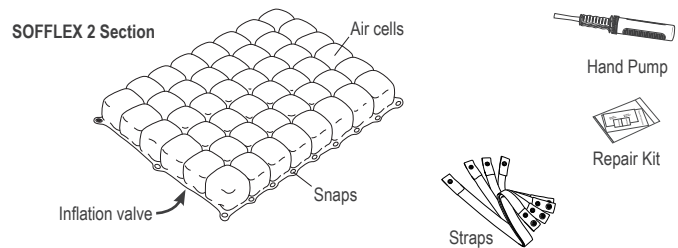
Parts Detail

Package contents: overlay sections or system, straps, dual action hand pump, repair kit, operation manual, limited warranty supplement, product registration card

The SOFFLEX 2 Mattress Overlay System, which includes three SOFFLEX 2 Sections that snap together, may also include a Reusable Overlay Cover or Overlay Enclosure Cover. Refer to the instructions provided with the cover.

To order replacement parts, contact the product provider or Customer Support.

Note: An inflation valve is located on the bottom of each SOFFLEX 2 section.



Placing and Securing the Overlay

⚠ Warnings:

- Risk of falling: The SOFFLEX 2 must be securely attached to the bed mattress, either with the provided straps or with the Overlay Enclosure Cover straps.
- Risk of falling: Any overlay section or system MUST NOT hang over the edges of the bed mattress.

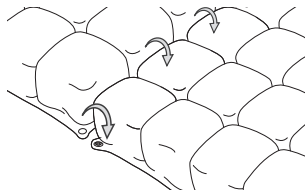
- 1 Remove all bed linens from the bed mattress. A support pad or a fitted sheet may remain on the bed mattress. Make sure the bed mattress is in a flat position.

STOP HERE if you are using the zipped Overlay Enclosure Cover. See the instructions provided with the Overlay Enclosure Cover; then, continue with the instructions to inflate and adjust the overlay.

- 2 Place and Secure the Overlay to the bed mattress:

a. Place the Overlay:

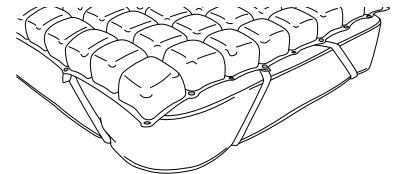
Align the overlay sections on the bed mattress, air cells facing up, and snap them together.



b. Secure the Overlay to the bed mattress with the provided straps:

Note: If you are using the Overlay Enclosure Cover, skip this step.

Snap the ends of the strap to the overlay; then stretch a strap around each corner of the bed mattress.



- 3 Continue with the instructions provided in this manual for covering, inflating, and adjusting the overlay.

Cover Guide

⚠ Warning: Placing too many linens between the individual and the product will reduce its effectiveness.

Before the individual transfers to the overlay, place any needed covering on top of the overlay. If you are using the Reusable Overlay Cover or the Overlay Enclosure Cover, refer also to the instructions provided with the cover.

If needed, ONLY the following items may be placed on top of the mattress overlay and ROHO Cover (Reusable Overlay Cover or the Overlay Enclosure Cover):

One (1) flat or contoured sheet, arranged loosely • One (1) incontinent pad • One (1) draw sheet, for moving and transferring

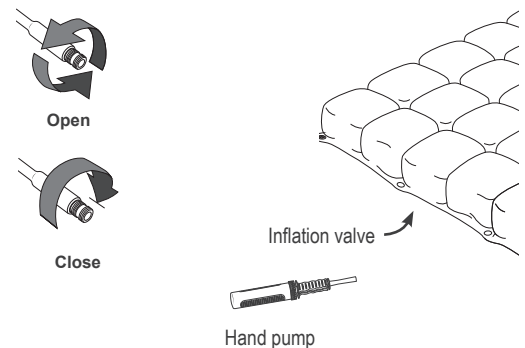
Inflating the Overlay

⚠ Warning: All sections of the product MUST be inflated and adjusted to ensure proper immersion and to provide skin/soft tissue protection to the individual, including their areas of risk (for example, head, shoulder blades, tailbone, hip bones, heels).

- 1 Slide the hand pump nozzle over the inflation valve. Open the inflation valve. Inflate until the section arches slightly or until all of the air cells feel firm.

Note: To open, turn the inflation valve at least one full rotation.

- 2 Close the inflation valve until it comes to a stop. Remove the hand pump. Make sure the inflation valve is closed.
- 3 Repeat for all sections, and then follow the instructions to adjust the overlay.



Adjusting the Overlay

⚠ Warnings:

- DO NOT use a product that is underinflated or overinflated, because 1) the product benefits will be reduced or eliminated, resulting in an increased risk to skin and other soft tissue, and 2) the individual may become unstable and vulnerable to falling. Carefully follow the instructions for inflation and adjustment. If the product does not appear to be holding air, or if you are not able to inflate or deflate the product, see "Troubleshooting". Immediately contact your equipment provider, distributor, or Customer Support if the problem persists.
- All sections of the product MUST be inflated and adjusted to ensure proper immersion and to provide skin/soft tissue protection to the individual, including their areas of risk (for example, head, shoulder blades, tailbone, hip bones, heels).
- After setting up the product the first time, perform a Hand Check frequently, at least once a day.
- A Hand Check MUST be performed EVERY TIME the individual transfers onto the product. If the individual transfers off and then back onto the product, a Hand Check MUST be performed to ensure the product is correctly adjusted and will continue to provide protection.

Transfer

⚠ Warning: Before the individual transfers onto the overlay: 1) Risk of falling: Make sure the straps are securely snapped to the overlay. 2) Make sure that all sections of the overlay are aligned and snapped together. If the sections are not snapped together, the individual could be exposed to areas that do not provide sufficient skin/soft tissue protection.

- 1 Before the individual transfers onto the overlay, confirm the following:
 - The overlay and the bed mattress are in a flat position.
 - All sections are inflated, aligned and snapped together. The provided straps are securely snapped to the overlay and installed on the bed mattress; or, if using the Overlay Enclosure Cover, the straps are securely attached to the bed mattress. See "Placing and Securing the Overlay".
 - Any needed coverings are in place on the overlay. See the "Cover Guide".
- 2 The individual should transfer onto the overlay. The individual should be in their usual position (lying on their back, their side, or other usual position).

Hand Check

- 3 Perform a Hand Check to ensure that all sections, have the correct amount of air.

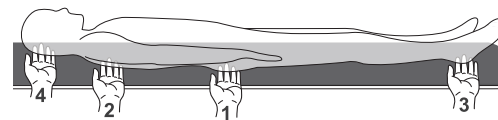
Hand Check Method:

- a. Position your hand between the overlay and the individual and feel for the lowest bony prominence.
- b. Keeping your hand in place, open the inflation valve, and remove air until you can barely move your fingertips.
- c. Close the inflation valve.

Note: The recommended distance from the base is 1 in. - 1½ in. (2.5 cm to 4 cm).

REPEAT THE HAND CHECK FOR ALL SECTIONS.

- 4 If you are using the Overlay Enclosure Cover, zip the cover closed.

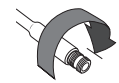


Hand Check Method - Notes:

- » The overlay is shown with a cover.
- » The numbers on the "hands" show a sequence for adjusting the overlay sections. This is only a suggestion. The adjustment sequence may vary for each individual.
- » The supine position shown is for illustration purposes only. The individual should be in their usual position.



Open



Close

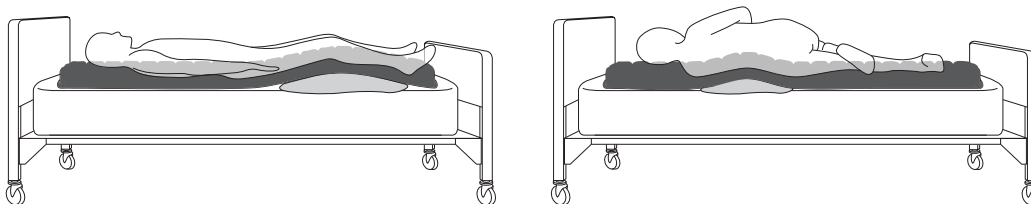
⚠ IMPORTANT! If the individual transfers off the overlay and then back onto the overlay, perform all of the steps above in "Transfer" and "Hand Check" to ensure that the overlay will continue to perform as intended.

Pillow Positioning

⚠ Warnings:

- DO NOT place a pillow between the individual and the overlay. Doing so will reduce the effectiveness of the overlay.
- To ensure proper immersion and to provide skin/soft tissue protection to the individual, ALWAYS repeat the Hand Check Method after any pillow placement.

Instructions: Pillow positioning may be prescribed by a clinician. If a pillow is used for positioning, the pillow MUST be placed under the mattress overlay, not between the individual and the overlay.



Examples of positioning with a pillow.

Troubleshooting

For additional assistance, contact the equipment provider, distributor, or Customer Support.

The product is not holding air.	Inflate the product. Confirm that the inflation valve(s) are completely closed. Inspect the inflation valves and hoses for damage. Look for holes in the product. <ul style="list-style-type: none"> - If very small holes or no holes are visible, follow the instructions in the Repair Kit provided with the product. - For inflation valve or hose damage, or for large holes or leaks in the product, see the Limited Warranty supplement, or contact Customer Support.
Not able to inflate or deflate the product.	<ul style="list-style-type: none"> - Make sure the inflation valve is open. - Inspect the inflation valves and hoses for damage.
The product is uncomfortable or unstable.	<ul style="list-style-type: none"> - Make sure the product is not underinflated or overinflated. Refer to adjustment instructions in this manual. - Make sure the air cells are facing the individual. - Make sure the product is the correct size for the individual and the bed. <p>If the cushion still feels uncomfortable or unstable after checking all of the above, immediately consult the prescribing healthcare professional.</p>
The product slides on the bed.	<ul style="list-style-type: none"> - Make sure that sections are snapped together. - Make sure the product is not on a slippery surface. - If using the Overlay Enclosure Cover, make sure the straps are secure. - If using the SOFFLEX 2 without the Overlay Enclosure Cover: make sure you use the provided straps to securely attach the overlay to the bed mattress.
The product appears to be uninflated	An unoccupied product may appear to be underinflated (not enough air) even if it has been inflated and correctly adjusted for a specific individual. This is because the individual's body mass is not pushing down on the air cells.
A component is damaged.	Contact Customer Support for a replacement.

Storage, Transport, Disposal and Recycling

Storage and Transport: Clean and disinfect the product. Open the inflation valve(s). Deflate the product (detach any product sections). Place in a container that protects the product from moisture, contaminants and damage. After storing or transporting, inspect the product to ensure it was not damaged (see "Troubleshooting"), and follow instructions to prepare the product for use..

Disposal: The components of the products in this manual are associated with no known environmental hazards when properly used and when disposed of in accordance with all local/regional regulations. At the end of its useful life, treat as healthcare waste and dispose of according to local healthcare-waste guidelines. Incineration must be performed by a qualified, licensed waste management facility.

Recycling: Contact a local recycling agency to determine recycling options for the product.

Limited Warranty

Limited Warranty Term from the date the product was originally purchased: SOFFLEX 2: 18 months; The warranty does not apply to punctures, tears, burns, or misuse. See also the Limited Warranty supplement provided with the product, or contact Customer Support.

Product Specifications

All measurements are approximate.

Contact Customer Support about available sizes.

SOFFLEX 2 Section

Width x Length x Height : 36 x 27½ x 3½ in. (91.5 x 70 x 9 cm)

Weight: 2¼ lb. (1 kg)

SOFFLEX 2 System (3 Sections)

Width x Length x Height: 36 x 81¼ x 3½ in. (91.5 x 207.5 x 9 cm)

Weight: 6½ lb. (2.9 kg)

1 in. = 2.54cm = 25.4mm

Materials:

Cover materials - Refer to the care label on the cover.

Mattress overlay materials - polyether polyurethane; Zytel inflation valves; polyester/spandex straps

Covers and Accessories Compatible with SOFFLEX 2:

Reusable Overlay Cover • Overlay Enclosure Cover

Not available in all markets. Contact Customer Support.

Product expected lifetime: 5 years

Cleaning and Disinfecting

⚠ Warnings:

- Inspect the product for damage and replace if necessary.
- DO NOT allow water or cleaning solution to enter the product. Make sure the inflation valves are closed.
- DO NOT machine wash or sanitize or machine dry overlay products.
- Cleaning and disinfecting are separate processes. Cleaning must precede disinfection. Before use by a different individual: clean, disinfect, and check the product for proper functioning.
- Clean the product regularly and when it becomes soiled.
- Follow all manufacturer bleach container and germicidal disinfectant safety guidelines.
- Note about sterilization: High temperatures accelerate aging and will damage the product assembly. The products featured in this manual are not packaged in a sterile condition, nor are they intended or required to be sterilized prior to use. If institution protocol demands sterilization: First, follow the cleaning and disinfecting instructions; then, open the inflation valves and use the lowest possible sterilizing temperature, but not to exceed 70°C (158°F), for the shortest time possible. DO NOT autoclave.

⚠ Cautions:

- Use of the following may cause damage to the product: abrasives (steel wool, scouring pads); caustic, automatic dishwasher detergents; cleaning products that contain petroleum or organic solvents, including acetone, toluene, Methyl Ethyl Ketone (MEK), naphtha, dry cleaning fluid, adhesive remover; oil-based lotions, lanolin, ozone gas; ultraviolet light cleaning methods.
- DO NOT expose to direct sunlight.
- Rinse thoroughly. Detergent residue may cause air cells to stick together.

Recommendation: When washing by hand, use room-temperature water.

Note: Deflated air cells may be easier to thoroughly clean. To deflate the air cells: with the inflation valve(s) open, roll up and/or compress the cushion, and then completely close the inflation valve(s).






To Clean Overlay Section(s): Remove all linens and straps. Close valves. Unsnap overlay sections. Place each overlay section in a large sink. Hand wash, using mild liquid hand soap, hand dishwashing liquid, laundry detergent, or a multipurpose detergent (follow the product label instructions). Gently scrub all product surfaces, using a soft plastic bristle brush, a sponge or a cloth. Rinse with clean water. Air dry.



To Disinfect the Overlay: Follow the cleaning instructions, using 1 part household liquid bleach per 9 parts water. Keep the product wet with the bleach solution for 10 minutes. Rinse thoroughly with clean water. Air dry.



Care Symbols

 Hand wash.	 Line dry in the shade.	 Bleach (1 part bleach: 9 parts water).
 Do not tumble dry.	 Do not machine wash.	