Inception

OPERATION MANUAL



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Inception Operation Manual

Thank you for choosing Inception.

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In the event of a serious incident or injury, contact Customer Support.		
Symbols Glossary		
Manufacturer M Date of manu	ifacture [Î] Consult instructions for use	
Please Note		
Supplier: These instructions 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 BodiLink®, COMFORT-TEK®, ROHO®, and STRETCH-AIR®.

GlideWear[™] is a registered trademark of MIPS.

Zytel[®] is a registered trademark of DuPont.

Product information is changed as needed; current product information is available at permobil.com.

The Comfort Companies, LLC is a part of Permobil Seating and Positioning.

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Intended Use

The Comfort Inception Cushion (Inception) is a custom-made, ready-to-use, wheelchair seating surface that is constructed as prescribed to meet the needs of a specific user in a specific wheelchair. The Inception must be properly sized and configured to the individual and must be used with a compatible cover.

The STRETCH-AIR Cover is a fluid-resistant textile enclosure intended to protect the cushion from solid debris or liquids.

The COMFORT-TEK Cover is a fluid-resistant textile enclosure intended to protect the cushion from solid debris or liquids.

The Incontinence Liner is a fluid-resistant textile enclosure intended to be used with a STRETCH-AIR Cover or COMFORT-TEK Cover to further protect the cushion from liquids.

A clinician who is experienced in seating and positioning, along with a full risk assessment and program of care, should determine whether the product is appropriate for the individual's particular seating 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 seating and mobility equipment and therapeutic interventions. A clinician who is experienced in seating and positioning 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

\land warnings:

- DO NOT REUSE. This cushion is designed to be uniquely shaped to its user. DO NOT use this cushion for another individual.
- Follow all instructions and safety information provided with the product and provided by the manufacturer of the wheelchair or other accessories.
- DO NOT use the components of this product separately. Assemble and use this product only as instructed in this manual.
- Immediately consult qualified personnel if there are any signs of user discomfort or fear associated with using the product.
- Before long-term use of the product, and for the first few weeks, the user should sit for shorter, introductory periods of time, and ONLY under supervision. During introductory sitting, the skin should be carefully monitored, while the user adjusts to the new shape and positioning.
- 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 needs to 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 healthcare professional.

- The cushion must always be used with a compatible cover.
- DO NOT place obstructions between the individual and the cushion. The cushion, the air insert, and the cover MUST be compatible sizes and MUST be used as directed in this manual. Except for the compatible covers listed in "Product Specifications" in this manual, placement of any items between the individual and the cushion: 1) may reduce or eliminate the benefits of the cushion, increasing the risk to skin or to other soft tissue, and 2) may cause the individual to become unstable and vulnerable to falling.
- DO NOT use the cushion on top of, or in conjunction with, any other products or materials, except as indicated in this manual. Using noncompatible products or materials, whether inside or outside the cover: 1) may reduce or eliminate the benefits of the cushion, increasing the risk to skin or to other soft tissue, and 2) may cause the individual to become unstable and vulnerable to falling.
- If you are unable to perform any tasks described in this manual, seek assistance by contacting a clinician, equipment provider, distributor, or Customer Support.

Important Safety Information, continued

WARNINGS, continued:

- DO NOT use the cushion or any components as a water flotation device (e.g. a Life Preserver). It will NOT support you in water.
- DO NOT modify the cushion or components. Doing so will void the warranty and may lead to personal injury or alter the effectiveness of the cushion by increasing the risk factors for skin breakdown and/or instability.
- Periodically, check the cover and components for damage and wear, and replace if necessary. See "Troubleshooting."
- 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.
- A warnings motor vehicle transportation:
- Failure to pay attention to these warnings could result in severe injury to the individual in the wheelchair or to others.
- The Inception has not been tested for use in a motor vehicle.
- Transfer out of the wheelchair installed with the Inception and into a manufacturer-installed vehicle seat, and use the vehicle's crash-tested occupant restraint system.
- If the Inception has been involved in an accident during transport, see the "Maintenance" section in this manual.

- The cushion surface will acclimate to the surrounding temperature. Take appropriate precautions, especially when the cushion will contact unprotected skin.
- Keep small components out of the reach of children and any individuals who have a tendency to place inedible objects in their mouths. Swallowing or inhalation may lead to serious injury or death. IMMEDIATELY seek emergency medical assistance.

- Keep the product away from sharp objects.
- DO NOT use the air insert inflation valve as a handle for carrying or pulling the cushion. Carry the cushion by the cushion base or by the carrying handle on the cover. Use of any other components to carry or pull the cushion may damage the product.

Parts Detail and Product Specifications

Package contents: Inception, operation manual

Optional package contents:

ROHO Air Insert (includes a hand pump and repair kit) Covering options: COMFORT-TEK Cover or STRETCH-AIR Cover (available with GlideWear); Incontinence Liner (to be used with a cover)

Rigid Insert (removable version) See the instructions in this manual. Standard Anti-Thrust Growth Kit (CD-AT-STND-GROWTH-KIT); See the instructions below.

Materials: (This is a made-to-order product. Materials will vary.)

Inception: urethane foam

Rigid Insert: ABS plastic

ROHO Air Insert: neoprene rubber (made without latex) and Zytel inflation valve

Covering(s): Refer to product labels for material content and for compliance to flammability requirements.

Compatible products and accessories:

 \square IMPORTANT! Follow the instructions included with these items.

ATI (Adjustable Technology Insert) Removable Solid Seat Pan BodiLink Lateral Pelvic Thigh Support (LPTS) Bodilink Medial Knee Thigh Support (MKTS)

Expected lifetime of Inception: 5 Years

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

Standard Anti-Thrust Growth Kit

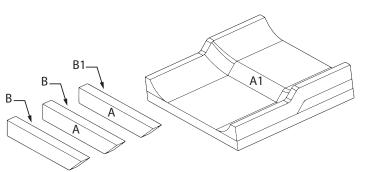
WARNING: The Inception may have been ordered to include a Standard Anti-Thrust Growth Kit (CD-AT-STND-GROWTH-KIT), which is foam pieces that can be removed and replaced as prescribed. The foam pieces must be correctly aligned and secured in the cushion. Skewed, loose, or other incorrect placement of the foam pieces may reduce or eliminate the benefits of the cushion, increasing the risk to skin or to other soft tissue.

A = loop fastener strip

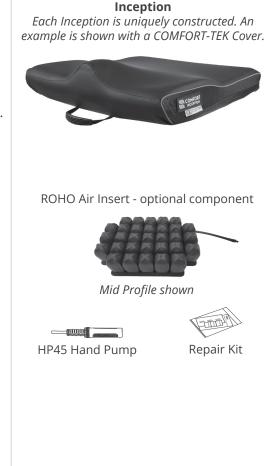
B = hook fastener strip

Removal or Replacement: Have the user transfer off the cushion. Remove the covering(s) and air insert (if included). Lift the upper foam layers to remove or replace the Growth Kit foam pieces as prescribed. Lower the foam layers and replace all other components, following the instructions in this manual.

When replacing Growth Kit foam pieces: First, align and secure the hook fastener strip (B1) on a foam piece to the loop fastener strip (A1) on the cushion. Then, align and secure additional foam pieces, as prescribed.



The image is an example only. Each Inception is uniquely constructed. The mid and top foam layers that are adhered to the front part of the cushion are not shown.



Inception Placement

A WARNINGS:

- The cushion must be used with compatible covering(s).
- DO NOT use the Incontinence Liner alone; it must be used with a cover.
- Inspect the cover and the foam for damage, and replace if necessary.
- When possible, use hook and loop fasteners to further secure the cushion to the seating surface. Hook fasteners are available upon request.
- **1** Place the cushion inside the covering(s). See the cover installation instructions.
- **2** Place the cushion on the seat.

WARNING: If the ROHO Air Insert is included with the cushion, follow the air insert setup instructions in this manual **before transferring to the cushion**.

- **3** Before sitting on the cushion, check the orientation: Make sure that the handle is in the front and the zipper is in the back.
- **4** The user should sit on the cushion, in their usual sitting position. Make sure that the cushion is properly sized to the individual.

Cushion with Cover: Orientation



Handle in Front

(I) WARNING - If using the ATI or Rigid Insert (removable version): The ATI or the Rigid Insert must be placed beneath the cushion (and beneath the Incontinence Liner, if using) and inside the cover. If using the ATI, refer to the instructions provided with the ATI for placement and adjustment.

Coverings - Installation and Removal

⚠ WARNINGS:

- Risk of falling: The bottom of the Incontinence Liner is slippery; DO NOT use the Incontinence Liner without a cover.
- If using the Incontinence Liner, place the cushion into the Incontinence Liner first, before installing the cover.
- The cover and the Incontinence Liner must be correctly oriented on the cushion. See "Troubleshooting" for orientation guidance. If needed, seek assistance by contacting a clinician, equipment provider, distributor, or Customer Support.

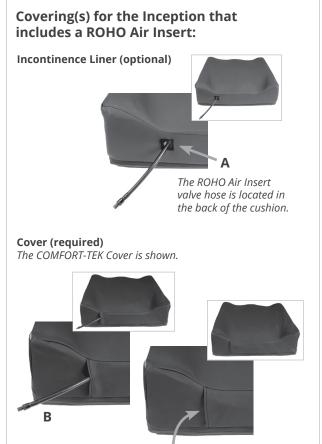
Install the Incontinence Liner <u>first</u>, if using: Open the zipper. Place the cushion into the Incontinence Liner. Close the zipper. **Install the Cover:** Open the zipper. Place the cushion into the cover. Close the zipper.

Removal of Covering(s): Open the zipper of the cover (and the Incontinence Liner, if using). Remove the covering(s) from the cushion.

If using the ROHO Air Insert:

For easy access to the inflation valve, there is an opening in the back of the Incontinence Liner (A) and in the back of the cover (B). During installation of covering(s), place the valve hose through the opening(s), and then tuck the valve hose into the fabric panel (C).

When removing the covering(s), gently pull the inflation valve hose through the opening in the cover (and the opening in the Incontinence Liner, if using).



С

Rigid Insert (Removable Version)

WARNINGS:

- Follow these instructions for the correct placement of the Rigid Insert. Place the Rigid Insert inside the cover and beneath the cushion. Placing the Rigid Insert outside the cover will interfere with the cover's non-skid bottom.
- Make sure the Rigid Insert is correctly oriented so it matches the shape of the cushion bottom. Request assistance if needed.

Removal: Have the user transfer off the cushion. Unzip the cover. Remove the Rigid Insert.

Replacement:

- 1. Have the user transfer off the cushion. Unzip the cover. Place the Rigid Insert inside the cover and beneath the cushion.
- 2. If using the Incontinence Liner, place the Rigid Insert beneath (not inside) the Incontinence Liner.
- 3.Confirm all cushion components are correctly placed. Close the zipper.
- 4.If using a ROHO Air Insert, follow the air insert setup instructions.

ROHO Air Insert Placement and Removal

Placement:

- 1 Line up the hook and loop fastener strips and refer to directional labels to correctly place the air insert on the cushion. Press to attach securely.
- **2** Insert the inflation tubing through the hole, located in the back of the cushion.
- **3** Check inflation. If adjustment is needed, follow the air insert setup instructions.
- **4** Place the covering(s) on the cushion. See "Coverings Installation and Removal" in this manual.

Removal:

- **1** Remove the covering(s) from the cushion. See "Coverings Installation and Removal" in this manual.
- **2** Gently pull the inflation tubing through the hole, located in the back of the cushion.
- **3** Remove the air insert from the cushion.

ROHO Air Insert Setup

Important Safety Information

Note: If a ROHO Air Insert is included with the product, read these warnings and follow the instructions on the next page.

🖄 WARNINGS:

- An Incontinent Liner, when ordered with a ROHO Air Insert, has a small valve-access opening that will reduce the liner's fluid-resistance.
- The air insert MUST be correctly installed in the cushion.
- DO NOT use an under-inflated or over-inflated air insert 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 hand check.
- After setting up the air insert for the first time, check inflation frequently, at least once a day. Follow the hand check instructions in this manual.
- If the air insert does not appear to be holding air, or if you are not able to inflate or deflate the air insert, see "Troubleshooting". Immediately contact the equipment provider or Customer Support if the problem persists.
- The air insert surfaces will acclimate to the surrounding temperature. Take appropriate precautions, especially when the air cells will contact unprotected skin.

- Periodically, check the air insert for damage and wear, and replace if necessary.
- DO NOT use a pump, cover or repair kit other than those compatible with the product.
- DO NOT allow the air insert to come into contact with oil-based lotions or lanolin. They may degrade the material.
- Prolonged exposure to ozone may degrade materials used in the air insert, affect performance, and void the warranty
- Changes in altitude may require adjustment to the air insert.
- DO NOT expose the air insert to temperatures above 70°C (158°F), which may accelerate aging and cause product damage.
- If the air insert has been in temperatures lower than 32°F (0°C) and exhibits unusual stiffness, allow to warm to room temperature.

ROHO Air Insert Setup, continued

IMPORTANT! Before following these instructions, read the safety information on the previous page. See also "ROHO Air Insert Placement and Removal" in this manual.

1 Inflate the air insert:

Suggestion: transfer off the air insert before inflating.

- a. Locate the inflation valve in the back of the cover, as shown.
- b. Slide the hand pump nozzle over the inflation valve. Open the inflation valve, at least one full rotation.
- c. Inflate until all of the air cells feel firm.
- d. Close the inflation valve completely. Remove the hand pump. Make sure the inflation valve is closed.
- e. Tuck the valve hose into the fabric panel.

Note: To open, turn the inflation valve at least one full rotation. The inflation valve will spin freely when open.

2 Transfer - Warnings:

- Before the user transfers to the cushion, make sure the air insert and the cover are correctly positioned on the foam base.
- Before performing a Hand Check, the user must transfer to the cushion in their usual sitting position.

3 Perform a Hand Check:

During a Hand Check, you will use the width of the fingers to see if the air cells are properly inflated*. When the air cells are properly inflated, the user is both immersed in the air cells and supported by the air cells.

- a. Slide your hand between the air cells and the user, and feel for the user's lowest bony prominences**.
- b. Refer to the Hand Check Guide below to adjust the air insert.
- * The recommended distance between the lowest bony prominence and the seating surface is ½ 1 in. (1.5 2.5 cm).

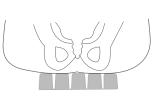
**Suggestion: To help locate the bony prominences while performing a hand check, lift and lower the leg.

Hand Check Guide

Place a hand beneath the lowest bony prominences (ITs) and make sure there is at least ½ in. (1.5 cm) of air.

If the air cells are not properly inflated, add or remove a small amount of air. Repeat until the air cells are properly inflated.





Overinflated



Close

Open

Proper Inflation ½ - 1 in. (1.5 - 2.5 cm)

IMPORTANT - NO VALVE ACCESS: If the air insert requires adding or removing air, but the type of wheelchair does not allow access to the inflation valve, the user should transfer off the cushion; add or remove a small amount of air, as required; then the user should transfer back to the cushion. Repeat until the air cells are properly inflated.

Cleaning and Disinfecting

MARNINGS:

- Follow all manufacturer bleach container and germicidal disinfectant safety guidelines.
- Cleaning and disinfecting are separate processes. Cleaning must precede disinfection. If the product becomes soiled: clean, disinfect, and check the product for proper functioning.
- Clean the product regularly and when it becomes soiled.

Covers

- Before cleaning and disinfecting, remove the covering(s) from the cushion. Remove any hook fastener pieces from the bottom of the cover.
- Frequent heat drying and bleaching will cause fabric to break down. Air drying and cleaning without bleach are recommended, whenever possible, to help extend the life of the cover.

Surface Cleaning for COMFORT-TEK Fabric Only: Spray with common household or commercial antibacterial cleansers or disinfectants. Wipe with a damp, water-only cloth after disinfecting. Let dry completely before use.

Cleaning: When possible, hand wash in warm water with mild soap, rinse thoroughly with clean water, and line dry. Let dry completely before use.

Or

Machine wash using common laundry detergent and tumble dry low.

Disinfecting: Hand wash the cover with water and bleach using 1 part household liquid bleach per 8 parts warm 40°C/104°F water. Rinse thoroughly with clean water, and line dry. Let dry completely before use.

Or

Machine wash hot using common laundry detergent and tumble dry low.

Foam Components

WARNING: Disinfectants are NOT effective on porous surfaces such as foam. DO NOT use if the foam becomes soiled or contaminated. Replace all soiled or contaminated foam or foam components.

CAUTIONS: DO NOT submerge any foam components in water. DO NOT use soap. DO NOT expose to direct sunlight.

Remove the covering(s). Wipe lightly with a damp cloth. DO NOT use soap. Air dry completely before use. Replace the covering(s) only after the foam is completely dry.

Rigid Insert and Removable Solid Seat Pan

Rigid Insert Caution: Before cleaning or disinfecting, remove the Rigid Insert from the cover. Refer to the instructions in this manual.

Cleaning: Hand wash in warm (40°C/104°F) water with soap and a sponge. Rinse with clean water and wipe dry with a clean cloth. Dry completely before use.



Disinfecting: Wipe gently with a cloth dampened with a household disinfectant. Rinse with clean, warm water. Wipe dry with a clean cloth. Dry completely before use.

Cleaning and Disinfecting, continued

ROHO Air Insert

WARNINGS:

- Cleaning and disinfecting are separate processes. Cleaning must precede disinfection. If the product becomes soiled, clean, disinfect, and check the product for proper functioning.
- DO NOT allow water or cleaning solution to enter the air insert. Make sure the inflation valve is closed.
- Remove the air insert from the cushion before cleaning or disinfecting.

CAUTIONS: Use of the following may cause damage to the air insert: 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 sunlight.

CAUTION: Rinse thoroughly. Detergent residue may cause air cells to stick together.

Cleaning: Remove the air insert from the cushion. Close the inflation valve and place in a large sink. Hand wash, using mild liquid hand soap, hand dish-washing liquid, laundry detergent, or a multipurpose detergent (follow product label instructions). Gently scrub all surfaces, using a soft plastic bristle brush, a sponge or a cloth. Rinse thoroughly with clean water. Let dry completely before use.

Disinfecting: 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. Let dry completely before use.

Car	e Symbols						
	Wipe with a damp cloth.		Hand wash.		Dry flat.	Ι	Line dry.
40C	Hand wash warm.	\odot	Tumble dry low.	<u> </u>	Bleach (1 part bleach: 8 parts water).		Dry flat in the shade.
40C	Machine wash warm, gentle.	600C	Machine wash hot, normal, at the temperature shown.	1:9	Bleach (1 part bleach: 9 parts water).		

Maintenance

WARNING: DO NOT continue to use the product if any part is damaged or is not functioning properly. Periodically, the product should be thoroughly inspected by a qualified professional or healthcare provider.

Components that show excessive wear should be replaced. For information on replacements, refer to the "Warranty" section in this manual.

Storage, Transport, Disposal and Recycling

Storage or Transport: Clean and disinfect the product. Open the inflation valve (air insert only). 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.

Troubleshooting						
For additional assistance, contact the equipment provider or Customer Support.						
The air insert is not holding air.	Inflate the air insert. Inspect the inflation valve and hose for damage. Confirm that the inflation valve is completely closed. Look for holes in the air insert. If very small holes are visible, follow the instructions in the repair kit provided with the air insert. For inflation valve or hose damage, or for large holes or leaks in the air insert, contact Customer Support.					
Not able to inflate or deflate the air insert.	Confirm that the inflation valve is open.Inspect the inflation valve and hose for damage.					
The product is uncomfortable or unstable.	 Make sure that all components are correctly installed. See below for cushion and cover orientation. Confirm that the cushion is centered beneath the user. Confirm that the cushion is properly sized to the user and the wheelchair. If an air insert is used: Confirm that the air insert has the correct amount of air (see "ROHO Air Insert Setup"). Make sure that the air insert is correctly placed on the cushion. The air cells and the top of the cover should face up. The air insert should be centered beneath the user. After checking all of the above, allow the individual at least one hour to adjust to the air insert. 					
Not sure about orientation of the cushion and covering(s).	 Orientation Guide The covering(s) should be oriented with the zipper in the back of the cushion. If the foam is contoured on top, the contoured shape of the cushion and the covering(s) should face up. Not every Inception is contoured. Each Inception is uniquely constructed. If the cushion is uniform in shape, orient as prescribed for the user and the wheelchair. Some Inception cushions include a dark foam layer on the bottom. 					
The air insert slides on the cushion.	Make sure the air insert is correctly attached to the cushion and that the hook and loop fastener strips line up correctly (see "ROHO Air Insert Placement and Removal").					
The cushion slides on the wheelchair.	 Make sure the non-skid bottom of the cover is facing down. When possible, use hook and loop fastener strips to further secure the cushion to the seating surface. Hook fasteners are available upon request. 					
A component is damaged.	Contact Customer Support for a replacement.					

Warranty

Inception (including coverings):

This product is covered by a lifetime warranty against manufacturer defects. If a manufacturing defect should occur, discontinue use immediately; note that the product will be replaced at no cost to the buyer. Wear from regular use is not considered a manufacturing defect. Replacement parts are available by contacting the supplier, distributor, or retailer.

What is not covered? Any product that has been misused, damaged by an accident or damage from an "act of Nature" (e.g., flood, tornado, earthquake, fire, etc.). Any substitutions of the supplied accessories or modification to the product may void the warranty.

Warranty Replacement Procedure

Warranty claims should be initiated by the original purchaser, who should contact the DME supplier, distributor or retailer from whom the product was purchased, if they are available, or any authorized Permobil DME supplier, distributor or retailer.

Whenever possible, the DME supplier, distributor or retailer with a warranty issue should contact Customer Support and provide the original purchase order number, sales order number, or invoice number. Before a warranty replacement order or quote may be processed, Customer Support must issue a Return Merchandise Authorization (RMA).

ROHO Air Insert:

Limited Warranty Term: 24 months from the date the product was originally purchased. The warranty does not apply to punctures, tears, burns, or misuse.

What is covered? Defects in materials or workmanship of the product.

What is not covered? A product that has been misused, damaged by an accident, or damaged from "an act of Nature", e.g., flood, tornado, earthquake, fire. Any substitutions of supplied product accessories or modification to the product will void the warranty.

What the customer must do: Contact Customer Support. Items sent without prior authorization will not be returned to the customer.

Disclaimer and Limitation of Warranties: Any implied warranties, including the MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, are limited to the time period defined in the instructions provided with the product, and any action for a breach of such warranties or any express warranties herein must be commenced within that time. Permobil shall not be responsible for any incidental or consequential damages, whether as a result of a breach of express or implied warranties or otherwise. Some jurisdictions do not allow limitations on how long implied warranties will last and some jurisdictions do not allow the exclusion or limitation of consequential or incidental damages, so those provisions may not apply to you. While this warranty gives you specific legal rights, you may also have other rights which vary from jurisdiction to jurisdiction.

Any warranties and services are limited to products purchased from authorized Dealers in the USA or International Distributors. If you purchase a ROHO product from an unauthorized Dealer or an unauthorized International Distributor, or if you reside outside the USA and you purchase a ROHO product from anyone other than the authorized International Distributor for your country of residence, your warranty will not be valid.

Return Policy: Product must be new and unused, and prior authorization is required; contact Customer Support. May be subject to a restocking charge.

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