

TRINITY  GUARDION



# Bed Barrier Instructions for Use



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## Overview

### Introduction

This document provides instructions for use of the Trinity Guardion Bed Barrier. Read and understand the Safety Information before using the Barrier.

The Bed Barrier covers the top and sides of the bed mattress, extending below the mattress to cover the bed deck.

The Barrier is replaced after each patient use and whenever a clean patient surface is needed. The Barrier is laundered between each use.

### Indications for Use

The Bed Barriers are covers for compatible bed decks and mattresses that provide a protective physical barrier between the equipment and patient. The device is intended to prevent soiling of bed decks and mattresses, helping to reduce contamination during use.

Soteria Bed Barriers are classified as level 4 per AAMI Standard PB70: Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for use in Healthcare Facilities.

The Soteria Bed Barriers are suitable for use with adult patients.

There are not any contraindications for Soteria Bed Barriers.

### Safety Information



**WARNING** Barrier may harbor infectious microorganisms after patient use. Replace with a laundered Barrier prior to use by another patient.



**WARNING** Barrier may harbor infectious microorganisms after patient use. Treat as a contaminated item when handling.



**WARNING** Barrier may harbor infectious microorganisms after patient use. Do not let the grey patient-side of Barrier touch the mattress or adjacent surfaces when removing the Barrier.



**WARNING** An improperly installed Barrier may prevent access to critical bed functions. Make sure the Barrier is properly installed.



**WARNING** An improperly installed Barrier may prevent correct operation of bed siderails. Make sure the Barrier is properly installed and all attachments complete.



**WARNING** Laundered Barrier may be contaminated by improper handling during unpacking and installation. Handle the Barrier so the grey patient side does not contact other surfaces.



**WARNING** Sharp objects can damage the Barrier and degrade impermeability to fluids. Prevent the Barrier from touching sharp objects and edges.

### General Product Information

See [Appendix A](#) – General Product Information.

## Barrier Identification

Always use the correct Barrier model. There are several ways to identify the correct Barrier for a specific bed and mattress.

### Edge-Ribbon Color

Barriers may be identified by the color of the ribbon on the bottom edge. A list of Barrier models and edge-ribbon colors can be found at <https://trinityguardion.com/model-number-list/>

### Laundry Package Label

The laundry package label indicates the Barrier edge color, and the applicable bed and mattress.



### Barrier ID Label

A label on the foot end of the Barrier identifies the applicable bed and mattress. The bar code includes the model and serial number of the Barrier. An RFID tag is located under the bar code to permit RF scanning.



### **Barrier Models**

A list of Barrier models can be found at <https://trinityguardion.com/model-number-list/>

## **Preparation for First Use**

### **Spacer for Mattress Vent**

Some mattresses with microclimate management systems require one-time installation of a Spacer in the mattress vent before use of the Barrier. The Spacer prevents the mattress vent from being restricted when the Barrier is in place. The vent spacers are provided by Trinity Guardion.

### **Bed Clips**

Some beds require one-time installation of adhesive clips that attach to the bed frame or bed deck before use of the Barrier. The clips are used for attachment of the Barrier. Bed clips are provided by Trinity Guardion.

### **First Laundering**

Barriers must be laundered prior to first use. Only use a Barrier taken directly from a sealed and labeled bag from the laundry.

## **Use of Barrier**

### **Storage & Handling - Laundered Barrier**

Laundered Barriers are stored in a designated clean storage area.

- Ensure the storage area provides protection against temperature and humidity extremes, dust, moisture, and insects.
- Store so the packaging is not compromised (e.g. opened, torn, punctured).
- Shelf life depends on the quality of storage conditions, transport conditions, amount of handling, and other events that may compromise package integrity.
- Inspect the package before use for loss of integrity (e.g., torn, wet, punctured). Do not use the Barrier if the package is compromised.
- If the package is compromised (e.g., torn, wet, or punctured), place the Barrier with used Barriers to be laundered.

Clean gloves should always be used when handling laundered Barriers.

### **Storage & Handling - Used Barrier**

Always use gloves when handling used Barriers.

Do not discard used Barriers, even if damaged. Place the used Barrier in a Used Barrier Bag immediately after removal from the mattress.

A Used Barrier Bag is included in each laundered Barrier package and should be stored in under the mattress.

Do not mix used Barriers with other soiled linens. Used Barriers are taken to the designated soiled linen room and placed in a special Trinity Guardion container.

### **General Use**

Barrier does not require any special care or cleaning during use. A soiled Barrier may be replaced with a laundered Barrier if needed during patient care.

Barrier may be cleaned during a patient stay by wiping with a pH neutral cleaner in accordance with the manufacturer's instructions for use. To maintain warranty, residual cleaner must be fully rinsed from the Barrier with water.

Always replace the Barrier with a freshly laundered Barrier between patients.

Do not let sharp objects contact the Barrier. If damage occurs during use, including nicks, holes, or tears in the fabric, replace the Barrier immediately. Put the Barrier in a Used Barrier Bag and place it in the designated location for used Barriers.

### **Used Barrier Removal from Bed**

Videos showing how to properly remove Barriers from a bed can be found at <https://trinityguardion.com/training-videos/>

1. Put on gloves for personal protection.



2. Confirm bed brake is on and bed deck is flat.



3. Remove footboard from bed.



4. Remove soiled linens following standard procedures.



5. Detach the Barrier from the bed frame at each “Attach Below” label on the Barrier.



6. Pull the Barrier off of the head-end of the bed deck and mattress. **Do not allow the soiled grey patient side of the Barrier to contact the mattress.**



7. Pull the Barrier off of the foot-end of the bed deck and mattress. **Do not allow the soiled grey patient side of the Barrier to contact the mattress.**



8. Fold the Barrier inward to a manageable size and place in a Used Barrier Bag. Place the Bag in the designated location for laundry pick-up. **Do not discard the Barrier.**



9. Clean the exposed areas of the mattress and bed deck with a suitable cleaner. Allow the mattress to dry and be sure the rest of the bed has been disinfected before installing a laundered Barrier.



### **Laundered Barrier Placement on Bed**

Videos showing how to properly place laundered Barriers on a bed can be found at <https://trinityguardion.com/resources/training-videos/>

1. Put on new gloves to protect the Barrier.



2. Retrieve laundered Barrier from designated storage location. Select the correct Barrier for the bed. See the "Barrier Identification" section for details. Open package.



3. Lay the Barrier on one end of the bed, unroll, and unfold. **Do not allow the grey patient side of the Barrier contact other surfaces.**



4. Find the head or foot end label and orient the Barrier correctly on the bed.



5. If the mattress has a footboard-mounted air system, disconnect the hose from the air system and pull the hose through the opening in the corner of the Barrier.

6. Place the foot-end corners around the foot-end of the mattress, taking care to tuck the bottom edge of the Barrier under the mattress.



7. Stretch the Barrier over the head-end corners of the mattress, taking care to tuck under the mattress and around the head-end of the bed deck.



8. Place the bottom edge of the Barrier so it covers the bed deck, taking care to align any openings for IV poles, CPR levers, line managers, and drainage bag holders. The fit and placement vary for different bed models. Examples are shown below



*Note: Pictures show typical fitments, which may be different depending on bed model.*

9. Attach the Barrier to the bed frame at each “Attach Below” label on the Barrier. The number and type of clips vary for different bed models. Examples are shown below.



*Note: Pictures show typical attachment points, which may be different depending on bed model.*

10. Confirm that:

- Barrier is lying flat on the mattress
- Exposed portions of the bed deck are covered
- All attachment points are connected.
- Barrier is not damaged. If any damage is observed, remove the Barrier, and return to the laundry facility for replacement.

11. Place linens and footboard on the bed.



**Removal from Service**

Never discard a Barrier. The laundry facility returns damaged Barriers to Trinity Guardion for disposition of Barriers and permanent removal of Barriers from service if required.

Barriers are removed from service after 150 laundry cycles.

Barriers are removed from service by Trinity Guardion if damaged beyond repair. Barriers are inspected for damage after each laundering. Backlighting is used during inspection to highlight pinholes.

## **Warranty**

This Limited Warranty (“Warranty”) covers the Trinity Guardion Barrier (“Barrier”) purchased (or leased) from Trinity Guardion, Inc (“Trinity”) and the obligations of Trinity and your warranty remedies are limited to the terms set forth below.

### **Warranty**

Trinity warrants to the original purchaser (or lessee) that the Barrier, when properly installed, used, handled and laundered in accordance with the Instructions for Use – Barrier and the Laundry Manual provided with the Barrier, will be free from all material defects in workmanship and materials that affect the performance of the Barrier, subject to the limitations described in this Warranty. Trinity undertakes no responsibility for the quality of the Barrier except as otherwise provided in this Warranty. This Warranty is Trinity’s sole obligation and your exclusive remedy for the Barrier if it does not conform as warranted in this Warranty. There are no warranties that extend beyond the description on the face hereof.

### **Warranty Period; Prorated Coverage**

For a period commencing on the delivery date of the Barrier to you (“Delivery Date”) and expiring upon 150 launderings of the Barrier, Trinity will, at its sole option, replace the Barrier if it does not conform to the Warranty, as verified by Trinity, provided you follow the procedures specified in the Warranty Claim Procedure section. Trinity’s replacement of the Barrier will be charged to you at a prorated cost that will be determined by applying the ratio of the number of launderings since the Delivery Date over 150 launderings, multiplied by the original purchase price you paid for the Barrier. By way of illustration only, if the Barrier purchase price is \$500.00 and the Barrier is replaced under this Warranty after 100 launderings, then your prorated share of the replacement cost will be \$333.33 ( $100 / 150 \times \$500.00$ ). If a Barrier is discovered to be nonconforming to the Warranty prior to its use or first laundering, as verified by Trinity, then Trinity will at its sole option, replace the Barrier at no cost to you, provided you follow the procedures specified in the Warranty Claim Procedure section and notify Trinity in writing no later than 5 business days after the Delivery Date of the Barrier to you. The replacement cost does not include the cost of any taxes applicable to the replaced Barrier.

### **Exclusions from Warranty; Warranty Void**

Any failure of the Barrier to conform as warranted due in whole or in part to the following items is not covered by this Warranty: (a) negligent or improper use, misuse, neglect or maintenance of the Barrier; (b) force majeure (for example, but not limited to: vandalism, storms, water damage, fire, etc.) and other influences of outside elements; (c) damage due to transportation when not carried out by or on behalf of Trinity; (d) unauthorized interventions, repair attempts, alterations, or modifications to the Barrier; (e) use outside specified environmental conditions for the Barrier; (f) noncompliance with the Instructions for Use – Barrier or the Laundry Manual provided with the Barrier; or (g) a Barrier that is laundered in excess of 150 launderings. The occurrence of any of the matters listed in (a), (d), (e), (f), or (g) above will void the Warranty.

### **Warranty Claim Procedure**

If the Barrier fails to conform as warranted, you must promptly notify Trinity in writing within the Warranty Period. Your notice must provide information relevant to the nonconformity, as detailed as possible. After receipt of the claim, Trinity will decide whether the Barrier will be shipped to Trinity for inspection. If the Barrier is to be shipped to Trinity, you will ship the Barrier to Trinity in Batesville, Indiana, transportation charges prepaid. If the nonconforming Barrier is covered by the Warranty, Trinity will reimburse you for such transportation charges. Trinity will replace the covered nonconforming Barrier (at the cost determined in accordance with the Warranty Period; Prorated Coverage section) and will deliver the replacement Barrier to the freight forwarder and ship to you FOB your delivery address. The Warranty Period for the replaced Barrier will not be extended due to the replacement of the nonconforming Barrier but will instead be the remaining number of launderings left on the Warranty Period for the Barrier that was replaced.

### **LIMITATION OF LIABILITY**

EXCEPT AS EXPRESSLY STATED IN THIS WARRANTY, TRINITY MAKES NO WARRANTY, EXPRESS OR IMPLIED, REGARDING ANY MATTER WHATSOEVER. TRINITY SPECIFICALLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND ANY IMPLIED WARRANTY ARISING FROM A COURSE OF DEALING OR PERFORMANCE OR FROM USAGE OF TRADE. TO THE MAXIMUM EXTENT PERMITTED BY LAW, IN NO EVENT SHALL TRINITY BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES ARISING OUT OF THE USE OF THE BARRIER OR BREACH OF THIS WARRANTY, INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOST PROFITS, LOST REVENUE, OR LOST SAVINGS, INCURRED BY YOU OR ANY THIRD PARTY UNDER ANY LEGAL THEORY, EVEN IF TRINITY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. Some countries, districts or states do not allow the exclusion or limitation of relief, special, incidental, consequential or indirect damages, or the limitation of liability to specified amounts, so the above limitations or exclusions may not apply to you.

## Appendix A

### General Product Information

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>BENEFITS</b>                | <ol style="list-style-type: none"> <li>1. Reduces time required to manually clean and disinfect the mattress.</li> <li>2. Provides an extremely clean patient surface. See Reprocessing Validation below.</li> <li>3. Permits removal of pathogenic microbes from the facility with the soiled Barrier.</li> <li>4. Provides repeatable and reliable reprocessing by an automated laundry process.</li> <li>5. Eliminates skin issues caused by residual disinfectant.</li> <li>6. Prevents patient fluids from reaching the mattress.</li> <li>7. Protects the mattress from damage and prolongs life.</li> <li>8. Eliminates need for frequent mattress inspections - inspected between each use.</li> </ol> |
| <b>FABRIC</b>                  | <p>Patient-side – polyurethane polymer coating.<br/>Under-side – knit nylon fabric.</p> <ul style="list-style-type: none"> <li>• Fabric does not create x-ray ghosting.</li> <li>• Does not cause dermal sensitization (per ISO 10993-10).</li> <li>• Does not irritate skin (per ISO 10993-10).</li> <li>• High stretch fabric minimizes hammocking and reduces skin pressure.</li> </ul>                                                                                                                                                                                                                                                                                                                     |
| <b>DESIGN</b>                  | <p>Pocketed design encapsulates the mattress and bed deck while allowing sheets to be tucked. This patented feature ensures the Barrier remains in place during patient repositioning and lateral transfer. Barriers are designed to permit full functionality of the bed, including bed articulation, CPR release, bed deck extension, and chair positioning. Fits a wide range of mattress types, including rotation, percussion and low air-loss systems. IV poles, x-ray ports and line management systems are compatible with the Barrier.</p>                                                                                                                                                            |
| <b>CONSTRUCTION</b>            | <p>Seams are welded, sealed, and tested to withstand the laundry process. Clips are strategically placed to hold the Barrier in place.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>LAUNDERING</b>              | <p>Tested to 150 launderings in front-load washer/extractors using a rigorous laundry process, including alkaline detergent, chlorine bleach, 160-degree water, and a pH neutral rinse.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>REPROCESSING VALIDATION</b> | <ul style="list-style-type: none"> <li>• &gt;99.9999% reduction by wash-off of a mixed suspension containing <i>Escherichia coli</i>, <i>Pseudomonas aeruginosa</i>, Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA), and <i>Klebsiella pneumoniae</i>.</li> <li>• &gt;99.9999% reduction by wash-off of <i>Mycobacterium terrae</i>.</li> <li>• &gt;99.9999% reduction by wash-off of <i>Clostridium difficile</i> spores.</li> </ul>                                                                                                                                                                                                                                                               |
| <b>PRODUCT TRACKING</b>        | <p>A passive RFID tag is located under the Barrier ID label to permit RF scanning and tracking of the Barrier model and serial number. The RFID information matches the bar code information on the bar code label.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>CLINICAL RESEARCH</b>       | <p>Clinical data can be found at <a href="https://trinityguardion.com/clinical-evidence/">https://trinityguardion.com/clinical-evidence/</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>FDA CLEARANCE</b>           | <p>The Soteria Bed Barriers are 510k cleared under K201876; product code QTV.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>COUNTRY OF ORIGIN</b>       | <p>Soteria Bed Barriers are proudly made in the USA.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |