

TRINITY  GUARDION



Neonatal Mattress Barrier Instructions for Use



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Overview

Introduction

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

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 Neonatal Mattress Barrier is a cover for compatible incubator and warmer mattresses that provides a protective physical barrier between the mattress and patient. The device is intended to prevent soiling of mattresses, helping to reduce contamination during use.

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

The Neonatal Barriers are suitable for use with pediatric and neonatal patients, including pre-term infants in enclosed environments.

There are not any contraindications for Soteria Neonatal Mattress 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 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 two ways to identify the correct Barrier for a specific incubator or warmer.

Laundry Package Label

The package label indicates the applicable incubator or warmer model.



Example of Package Label

Barrier ID Label

A label on the bottom of the Barrier identifies the applicable incubator or warmer.



Example of Barrier ID Label

Barrier Models

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

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.

Only use a Barrier taken directly from a sealed and labeled bag from the laundry.

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 a designated storage location close to the incubator or warmer, such as under the mattress or in a nearby cabinet or drawer.

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.

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

In the NICU, replace the Barrier during same-patient use:

- When the bedding is replaced.
- When the incubator or warmer is exchanged or terminally cleaned.
- When the bedding is soiled if patient risk/benefit is appropriate.
- Before a patient procedure if patient risk/benefit is appropriate.

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 Mattress

1. Put on gloves for personal protection.
2. Retrieve Used Barrier Bag from designated storage location or laundered barrier package and open bag.
3. Remove mattress bedding.
4. Pull the Barrier around and off edges of mattress. Do not let grey side contact other surfaces.
5. Place used Barrier in Used Barrier Bag. Do not discard Barrier.
6. Place Bag with Barrier in designated location.
7. Wipe mattress with a baby wipe or chemical free water wipe. Mattress may also be wiped with a disinfectant approved for use by the mattress manufacturer. Allow to dry.

Laundered Barrier Placement on Mattress

1. Whenever possible, place the Barrier on the mattress just before patient use.
2. Put on gloves to protect the Barrier.
3. Retrieve laundered Barrier from designated storage location and open package.
4. Remove the Used Barrier Bag and place in the designated storage location.
5. Pull the Barrier around and over the edges of mattress. Do not let grey side contact other surfaces.
6. Reposition the mattress as needed and ensure the Barrier is lying flat on the mattress.
7. Place bedding over Barrier.

Removal from Service

Never discard a Barrier. Trinity Guardion is responsible for disposition and permanent removal of Barriers from service.

Barriers are removed from service after 105 laundry cycles. Laundry cycles are tracked by Trinity Guardion during transfers.

Barriers are removed from service 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 105 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 105 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 75 launderings, then your prorated share of the replacement cost will be \$357.14 ($75 / 105 \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 105 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

BENEFITS	1. Reduces time required to manually clean and disinfect the mattress. 2. Provides an extremely clean patient surface. See Reprocessing Validation below. 3. Permits removal of pathogenic microbes from the facility with the soiled Barrier. 4. Provides repeatable and reliable reprocessing by an automated laundry process. 5. Eliminates skin issues caused by residual disinfectant. 6. Prevents patient fluids from reaching the mattress. 7. Protects the mattress from damage and prolongs life. 8. Eliminates need for frequent mattress inspections - inspected between each use.
FABRIC	Patient-side – polyurethane polymer coating. Under-side – knit nylon fabric. • Fabric does not create x-ray ghosting. • Does not cause dermal sensitization (per ISO 10993-10). • Does not irritate skin (per ISO 10993-10). • Does not emit harmful VOC's (per ISO 18562-3) • High stretch fabric minimizes hammocking and reduces skin pressure.
DESIGN	Pocketed design fully encapsulates the top and sides of the mattress (patent pending). Variations available to fit any pediatric mattress.
CONSTRUCTION	Sealed seams are welded and tested to withstand fluid penetration.
LAUNDERING	Tested to 105 launderings in front-load washer/extractors using a rigorous laundry process, including alkaline detergent, chlorine bleach, 160-degree water, and a pH neutral rinse.
REPROCESSING VALIDATION	• >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>. • >99.9999% reduction by wash-off of <i>Mycobacterium terrae</i>. • >99.9999% reduction by wash-off of <i>Clostridium difficile</i> spores.
PRODUCT TRACKING	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.
COUNTRY OF ORIGIN	Trinity Guardion Neonatal Mattress Barriers are made in the USA.