



Product Insert

Description

Clarix 100 is a cryopreserved human amniotic membrane product. **Clarix 100** is aseptically processed and cell devitalized. **Clarix 100** is manufactured, using the CryoTek® cryopreservation process, from donated human birth tissue according to Current Good Tissue Practice (CGTP) and Current Good Manufacturing Practice (CGMP) regulations established by the U.S. Food & Drug Administration (FDA). **Clarix 100** is stored in a solution of 1:1, v/v Dulbecco's Modified Eagle Medium (DMEM)/Glycerol containing 1.25 µg/ml Amphotericin B. **Clarix 100** is delivered on a non-implantable, gridded paper backing for easier handling and application. **Clarix 100** is for single use only in one patient by a qualified medical professional.

Product Use

- **Clarix 100** is intended for homologous use as a protective barrier from the surrounding environment for acute and chronic wounds.

Contraindications

- **Clarix 100** should not be used on wounds that are actively infected.

Precautions

- Do not use **Clarix 100** if the packaging is damaged – Immediately report if there is any abnormality observed (e.g., labeling, packaging, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- **Clarix 100** exposed to controlled room temperature (20°C to 25°C, 68°F to 77°F) for up to 6 hours may be returned to cold temperature storage in accordance with the Storage section as long as the packaging remains unopened and intact.
- Once the outer foil pouch is opened, **Clarix 100** shall either be transplanted or otherwise discarded.
- Do not sterilize or autoclave the product before use.

Warnings

- Do not use on patients with a history of drug reactions to Amphotericin B, Glycerol, and/or DMEM.
- As with the use of any human tissue, the possibility of infectious agent transmission cannot be completely eliminated although all screening and microbial testing results for this donor were satisfactory for transplantation.
- It is imperative that the graft is stored properly until use. For proper storage instructions, refer to the Storage section.

Storage

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

Upon receipt, ensure the validated time on the shipper has not expired. Remove the product and store accordingly until use.

Location & Temperature	Use After Receipt
-80°C → 4°C (-112°F → 39.2°F) Example: ultra-low temperature freezer, standard freezer, or standard refrigerator	Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)

Instructions

1. If frozen, allow **Clarix 100** to sit at controlled room temperature (20°C to 25°C) in its original unopened packaging for at least 5 minutes.
2. Open the outer foil peel pouch and present the clear inner pouch to the sterile field using aseptic techniques.
3. Open the clear inner peel pouch to retrieve **Clarix 100**.
4. Gently peel the **Clarix 100** from the gridded paper backing.
5. The product may be rinsed in sterile saline, water or balanced salt solution prior to application.
6. Secure **Clarix 100** onto the wound bed.
7. Discard the gridded paper backing.

Place UDI Label Here
For Canadian Shipments Only

See Reverse



Donor Eligibility and Summary of Records

- This tissue was procured from a donor determined to be eligible based on the results of donor screening and testing. Donor eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, has been performed and documented by BioTissue Holdings Inc.
- A blood specimen, drawn within $\pm$ 7 days of donation, has undergone serological testing by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). The donor has been tested for the following infectious diseases and results were non-reactive:

— HIV-1 & HIV-2 Antibody	— Hepatitis B Virus (HBV, DNA-NAT)
— HIV-1 (RNA-NAT)	— Hepatitis C Antibody (HCVAb)
— Hepatitis B Surface Antigen (HBsAg)	— Hepatitis C Virus (HCV, RNA-NAT)
— Hepatitis B Core Antibody (HBcAb)	— Syphilis (RPR)
	— HTLV I & II Antibody (HTLV I/II Ab)
	— West Nile Virus (WNV, RNA-NAT)

- This tissue has been deemed eligible for transplantation based on acceptable screening, serological and microbial test results.
- Microbial testing of final product has also been performed to ensure no growth of aerobic, anaerobic or fungal cultures.
- A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls is available upon request.

Recipient Records

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain records for the purpose of tracing tissue post-transplantation. The transplanting entity should document the disposition (transplanted or discarded) on the Donor and Recipient Information Card (DRI), attach one of the provided product tracking labels to the DRI and mail to the manufacturer. Attach the remaining labels in patient and hospital records.

Customer Feedback

Report any customer feedback, including complaint, error or accident notification promptly to BioStem at:

Phone: +1 (954)-380-8342 ext. 4

Email: quality@biostemtech.com

Adverse Events

The FDA requires that information be supplied to the product manufacturer for mandatory reporting of adverse events. Possible significant adverse events include, but are not limited to microbial infection and transmission of viral disease. **The doctor is responsible for immediately reporting any adverse event potentially attributable to the use of Clarix 100 to BioStem.**

For Adverse Events and/or Complaints, notify via:

Phone: +1 (954)-380-8342 ext. 4

Email: quality@biostemtech.com



Manufactured and Distributed by BioTissue Holdings Inc.
for BioStem Technologies Inc.

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