

AMNIOGUARD®

U.S. Patent No. 6,326,019 and Patent Pending

Product Insert

Description:

AmnioGuard® is a cryopreserved human amniotic membrane and umbilical cord product classified as a 361 'Human Cells, Tissues, and Cellular and Tissue-based Products' (HCT/P). AmnioGuard is aseptically processed from tissues obtained from donated human tissue (placentas) according to current Good Tissue Practices (cGTP) and Good Manufacturing Practices (cGMP) regulations established by the US Food & Drug Administration (FDA).

Donor Eligibility and Summary of Records:

- This tissue was procured from a donor determined to be eligible based on the results of screening and testing. HCT/P donor eligibility and placenta suitability, which is based on the results of donor screening at delivery for infectious, malignant, neurological & autoimmune diseases and for other exposures or social habits, has been determined and documented by TissueTech, 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
 - HIV-1 (RNA-NAT)
 - Hepatitis B Surface Antigen (HBsAg)
 - Hepatitis B Core Antibody (HBcAb)
 - Hepatitis B Virus (HBV, DNA-NAT)
 - Hepatitis C Antibody (HCVAb)
 - Hepatitis C Virus (HCV, RNA-NAT)
 - Syphilis (RPR)
 - HTLV I & II Antibody (HTLV I/II Ab)
 - West Nile Virus (WNV, RNA-NAT)
- Microbial testing has also been performed on the final product to ensure no growth of aerobic, anaerobic or fungal cultures.
- The cell activity in the tissue has been inactivated using our CryoTek® cryopreservation process to reduce the possibility of graft rejection, while retaining the natural biologic properties.
- AmnioGuard is stored in a medium of Dulbecco's Modified Eagle Medium/Glycerol (1:1) containing 20 µg/ml Ciprofloxacin and 1.25 µg/ml Amphotericin B.
- This tissue has been deemed eligible for transplantation based on acceptable screening, serological and microbial test results.
- A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls for Bio-Tissue, Inc. products is available upon request.

Indications:

- AmnioGuard is a thicker cryopreserved amniotic membrane/umbilical cord tissue intended for use when durable tensile strength is indicated.
- When AmnioGuard is used for tectonic support (e.g. protection of a Glaucoma Drainage Device tube), it serves to strengthen the cornea, conjunctiva, tenon or sclera because of its thickness and tensile strength.
- AmnioGuard is for single use only in one patient by an ophthalmologist.

Precautions:

- Do not use AmnioGuard if the packaging is damaged - contact Bio-Tissue immediately if there is any abnormality observed (e.g. labeling, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- AmnioGuard exposed to controlled room temperature (20°C to 25°C) 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, AmnioGuard 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 Ciprofloxacin, 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.

Place UDI Label Here
For Canadian Shipments Only

See Reverse

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:

- If frozen, allow AmnioGuard to sit at controlled room temperature (20°C to 25°C) in its original unopened packaging for at least 5 minutes.
- Open the outer foil peel pouch and present the clear inner pouch to the sterile field using aseptic techniques.
- Open the clear inner peel pouch to retrieve AmnioGuard.
- Place the tissue on the surgical area to deliver the therapeutic actions of AmnioGuard.

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 allograft tracking labels to the DRI and mail to Bio-Tissue, Inc. Attach the remaining labels in patient and hospital records.

Customer Feedback:

Within the United States: Report any customer feedback, including complaint, error or accident notification promptly to Bio-Tissue at (888) 296-8858 or (305) 412-4430.

Outside of the United States: Report feedback to your local tissue provider.

Adverse Events:

The FDA requires that information be supplied to the product manufacturer for mandatory reporting of adverse events. Possible significant adverse events include microbial infection and transmission of viral disease. The doctor is responsible for immediately reporting any adverse event potentially attributable to the use of AmnioGuard to Bio-Tissue.

For Adverse Events, complete the following section. Notify via:

Phone: (888) 296-8858 or (305) 412-4430

Fax: (305) 675-3262

Email: Customerfeedback@biotissue.com

Serial Number: _____

Expiration Date: ____/____/____

Doctor Name: _____

Facility Name: _____

Transplant Date: ____/____/____

Diagnosis/Procedure: _____

Site of Use: _____

Point of Contact's Name: _____

Point of Contact's Phone Number: ____/____/____

Date Adverse Event was Reported: _____

Type of Adverse Event: Microbial Infection Transmission of Viral Disease Other

Describe the Adverse Event: _____

La version française de cette notice est disponible à www.biotissue.com.
Puede conseguir la versión en español de este prospecto del producto en www.biotissue.com.

Manufactured for Bio-Tissue, Inc. by
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