Product Insert

Description

AmnioGraft is a cryopreserved human amniotic membrane product. **AmnioGraft** is aseptically processed and cell devitalized. **AmnioGraft** 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). **AmnioGraft** is stored in a solution of 1:1, v/v Dulbecco's Modified Eagle Medium (DMEM)/Glycerol containing 20 µg/ml Ciprofloxacin and 1.25 µg/ml Amphotericin B. **AmnioGraft** is delivered on a non-implantable, gridded paper backing for easier handling and application. **AmnioGraft** is for single use only in one patient by a qualified medical professional.

Product Use

- On the ocular surface, **AmnioGraft** exerts anti-inflammatory, anti-scarring and anti-angiogenic actions to promote wound healing, and supports epithelial adhesion and differentiation.

Precautions

- Do not use **AmnioGraft** if the packaging is damaged – Contact BioTissue immediately if there is any abnormality observed (e.g., labeling, packaging, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- **AmnioGraft** 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, **AmnioGraft** shall either be transplanted or otherwise discarded.
- Do not sterilize or autoclave the product before use.
- Do not use toothed forceps to grip the backing paper.

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.

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 **AmnioGraft** 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 **AmnioGraft**.
4. Use non-toothed forceps to grip the paper backing with gridded side facing up and use 0.12 toothed forceps to separate the tissue from the backing paper.
5. The product may be rinsed in sterile saline, water or balanced salt solution prior to application.
6. Place the tissue on the surgical area.
7. Discard the gridded paper backing.

Place UDI Label Here
For Canadian Shipments Only

See Reverse

AmnioGraft®

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 ± 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)

- 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 for BioTissue products 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 BioTissue. 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 BioTissue at (888) 296-8858.
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 AmnioGraft to BioTissue.**

For Adverse Events, notify via:
Website: www.biotissue.com/complaints
Phone: (888) 296-8858
Fax: (305) 675-3262
Email: Customerfeedback@biotissue.com

Scan Code

BioTissue®

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