AMNIOGRAFT®

U.S. Patent No. 6,152,142 and 6,326,019

Product Insert

Description:

AmnioGraft® is a cryopreserved human amniotic membrane product classified as a 361 'Human Cells, Tissues, and Cellular and Tissue-based Product' (HCT/P). AmnioGraft is aseptically processed from tissue 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 suitable 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 & auto-immune diseases and for other exposures or social habits, has been determined and documented by TissueTech, 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 screened 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.
- AmnioGraft 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 suitable 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:

- AmnioGraft is the only amniotic membrane tissue graft designated by the FDA as a 361 (HCT/P) meeting both the minimal manipulation and homologous use criteria for ocular wound repair and healing. On the ocular surface, AmnioGraft reduces pain, exerts anti-inflammatory, anti-scarring and anti-angiogencic actions to promote wound healing, and supports epithelial adhesion and differentiation.
- AmnioGraft is for single use only in one patient by a medical professional.

Precautions:

- Do not use AmnioGraft 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.
- AmnioGraft 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, AmnioGraft 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 or Amphotericin B.
- 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.

After receipt, store AmnioGraft accordingly until time of use:

Location & Temperature	Use After Receipt
Unopened insulated shipping container	Within the expiration date printed on outer shipping box
-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 AmnioGraft 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 and retrieve AmnioGraft.
- Place the tissue on the surgical area to deliver the therapeutic actions of AmnioGraft.

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 AmnioGraft to Bio-Tissue.

Complete the following section. Notify via:

Phone: (888) 296-8858 or (305) 412-4430
Fax: (305) 412-4429
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: _____

_____

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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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Health Canada CTO Registration #: 100041

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