

Adverse Reactions: Any adverse event potentially attributable to the use of AmnioGraft® must be reported promptly by the physician to Bio-Tissue by completing the Adverse Event Form provided with the product.

Certificate of Quality:

Product Name: **AmnioGraft®**

Good Tissue Practice (GTP) – This product was manufactured in facilities that meet FDA Good Tissue Practices (GTP) Standards.

Microbiological Testing: Microbiology testing performed by an independent CLIA certified lab showed that random samples of this product yielded no growth of anaerobic, aerobic or fungal organisms.

Donor Screening & Infectious Disease Testing: AmnioGraft® has been recovered aseptically from a donated placental membrane through elective Caesarian Section delivery. The donor was screened for infectious, malignant, neurological, and autoimmune diseases and other exposures or habits and determined to be suitable to donate membrane for human transplantation. The donor of this product was tested by an independent CLIA certified lab at the time of delivery and found to be non-reactive for HIV-1 & HIV-2 (antibodies), Hepatitis B surface antigen (HBsAg), Hepatitis B core antibody (HBcAb), Hepatitis C antibody (HCV), HTLV 1 & 2 antibodies, West Nile Virus (WNV) and syphilis (RPR) using test kits licensed by the FDA.

Contact Information:

For questions about this product, questions about donor or processing procedures or questions regarding the replacement policy, email Bio-Tissue at Info@biotissue.com or call (305) 412-4430.

Manufactured by: Bio-Tissue, Inc. 7000 SW 97th Ave, Suite 211, Miami, FL 33173

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AMNIOGRAFT®



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



BIO-TISSUE

Product Insert

(New Peelable Outer Pouch)

Description: AmnioGraft® is human amniotic membrane that has been processed using patented technologies in a validated storage medium made of Dulbecco's Modified Eagle Medium/Glycerol (1:1) containing Ciprofloxacin and Amphotericin B. AmnioGraft® has been cryopreserved to retain the natural biological properties of the membrane and no preservatives have been added. As part of the process, the tissue has been frozen at -80°C in order to kill the cells present and eliminate the possibility of graft rejection.

Indications & Usage:

- **AmnioGraft®** is the only amniotic membrane tissue (HCT/P) that is designated by the FDA as a homologous graft for ocular wound repair and healing. On the ocular surface, AmnioGraft® acts as an anti-scarring, an anti-inflammatory, and anti-angiogenic agent, and supports epithelial adhesion and differentiation.
- Each package is intended for **single use only**.

Precautions:

- Contact Bio-Tissue immediately if the packaging is damaged.
- Once the outer foil pouch is opened, AmnioGraft® should be used as soon as possible.
- Do not sterilize or re-sterilize the product. Do not autoclave before use.

Warnings:

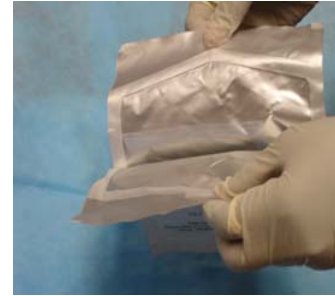
1. Do not use on patients with a history of drug reactions to Ciprofloxacin or Amphotericin B.
2. As with the use of any human tissue, although all screening and microbial testing results were satisfactory for this donor, the possibility of infectious agent transmission cannot be completely eliminated.
3. It is imperative that the graft is stored properly until transplantation.

Recommended Storage Before Use: After receipt, store AmnioGraft® as follows until time of use:

| Location & Temperature | Use After Receipt |
|--|---|
| Unopened Insulated Shipping Container | Within the expiration date printed on outer shipping box |
| Standard Refrigerator 1°C → 10°C (33.8°F → 50°F) | Within 3 months of placing in the refrigerator or until expiration date printed on outer product packaging, whichever comes first |
| Standard Freezer (home or general use) -49°C → 0°C (-56.2°F → 32°F) | Within 1 year of placing in the freezer or until expiration date printed on outer product packaging, whichever comes first |
| -80°C Freezer -85°C → -50°C (-121°F → -58°F) | Until the expiration date printed on outer <u>product packaging</u> (shelf-life is 2 years from date of manufacture) |

Instructions:

- Allow AmnioGraft® to thaw at room temperature in its original unopened product packaging for at least 5-10 minutes.
- **How to Open Peel-Pouch Package:**
 1. Open the outer foil peel pouch and aseptically present the inner clear pouch to the sterile field.
 2. Use sterile scissors to cut inner pouch at the notched edge with enough space to remove AmnioGraft®



➤ How to Use AmnioGraft®:

1. AmnioGraft® is attached to a white nitrocellulose paper with the “sticky” stromal side adherent to the paper and the basement membrane side away from the paper. (See Figure A)

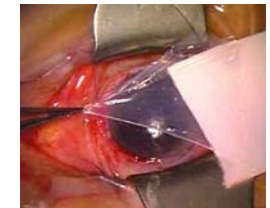


Figure A

Figure B

Figure C

2. If orientation is questionable, after detaching from the paper, use a dry Weckcel or cotton tip to check. Only the “sticky” stromal side will adhere to the Weckcel. (See Figure B)
3. The stromal side of the AmnioGraft® should be placed down onto the ocular surface for maximum wound healing. (See Figure C)
4. After transplantation, complete the Donor & Recipient (DRI) Form and return to Bio-Tissue immediately. If the tissue is discarded, please record this on the DRI form.