

AMNIOGRAFT®

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

Product Insert

Description: **AmnioGraft®** is a human amniotic membrane product classified as a 'human tissue and cell-based product' (HCT/P). The cell activity in the tissue has been inactivated to eliminate the possibility of graft rejection while retaining the natural biologic properties. **AmnioGraft®** is stored in a validated medium made of Dulbecco's Modified Eagle Medium/Glycerol (1:1) containing Ciprofloxacin and Amphotericin B.

Indications:

- **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®** reduces pain, acts as an anti-scarring, anti-inflammatory, and anti-angiogenic agent, and supports epithelial adhesion and differentiation.
- **AmnioGraft®** is for single use only.

Precautions:

- Do not use **AmnioGraft®** if the packaging is damaged - Contact Bio-Tissue immediately if there is any abnormality observed in any area (e.g. labeling, packaging, shipping, missing information, etc).
- 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:

- 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 were satisfactory for this donor.
- It is imperative that the graft is stored properly until use.

Instructions:

- Allow **AmnioGraft®** to thaw at room temperature in its original unopened packaging for at least 5-10 minutes.
- Open the outer foil peel pouch and aseptically present the inner clear pouch to the sterile field.
- Open the inner clear peel pouch and retrieve **AmnioGraft®**. If tissue backing has detached, use a dry Weck-Cel to determine the 'sticky' stromal side.
- Place the tissue on the surgical area to act as a covering or to deliver the therapeutic actions **AmnioGraft®**.
- After transplantation, complete the Donor and Recipient Information Form and return to Bio-Tissue immediately. If the tissue is discarded, please record this on the Donor and Recipient Information Form.

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.

Also see **Handling & Storage Instructions** and **Certificate of Analysis** provided with each shipment