AMNIOGRAFT® ST

SteriTek®

Product Insert

US Patents # 9,931,423 and 9,682,160

Description:

AmnioGraft *ST* is a sterile, human amniotic membrane product classified as a 361 'Human Cells, Tissues, and Cellular and Tissue-based Product' (HCT/P). The tissue is processed in compliance with Current Good Tissue Practices (CGTP) and Current Good Manufacturing Practices (CGMP) from donated human birth tissue. The tissue is stored in saline (0.9% w/v NaCl) and terminally sterilized by gamma irradiation with a Sterility Assurance Level (SAL) of 10^{-6}.

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 & 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 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.
- A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls for Bio-Tissue products is available upon request.

Indications:

- **AmnioGraft *ST*** is the only amniotic membrane tissue allograft that is designated by the US Food & Drug Administration (FDA) as a 361 (HCT/P) meeting both the homologous use and minimal manipulation criteria for ocular wound repair and healing. On the ocular surface, the amniotic membrane tissue reduces pain, acts as an anti-scarring, anti-inflammatory, and anti-angiogenic agent, and supports epithelial adhesion and differentiation.
- **AmnioGraft *ST*** is for single use only, in one patient, by an ophthalmologist.

Precautions:

- Do not use **AmnioGraft *ST*** 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.). Refer to the Customer Feedback section for reporting.
- Once the outer foil pouch is opened, **Amniograft *ST*** shall either be transplanted or otherwise discarded.
- Do not re-sterilize the product. Do not autoclave before use.

Warnings:

- 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 tissue 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.

After receipt, store product as follows until time of use:

Location & Temperature	Use After Receipt
Controlled Room Temperature 20°C → 25°C	Until the expiration date printed on outer product packaging (shelf-life is 2 years from date of manufacture)

Instructions:

- Open outer foil pouch to retrieve inner pouch. Then, open inner pouch to retrieve **AmnioGraft *ST*.** Apply or deliver the tissue with a sterile surgical tool.
- It is imperative that the tissue is stored properly until use.
- After transplantation, complete the Donor and Recipient Information (DRI) Card and return to Bio-Tissue, Inc.

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 associated with HCT/Ps. 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 *ST*** 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: _____

_____

_____

HCCTO# 100041
FEI# 3009809074

biotissue®

Manufactured for Bio-Tissue, Inc. by TissueTech, Inc.
8305 NW 27th St, Suite 101, Doral, FL 33122 USA