

AMNIOGUARD® ST

SteriTek™

Product Insert

DESCRIPTION:

AmnioGuard ST is a sterile, human placental tissue allograft 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) from donated human tissue after determination of donor eligibility and placenta suitability. Processing retains the key biological characteristics of the tissue. The tissue is innately hydrated with saline (0.9% w/v saline) and terminally sterilized by gamma irradiation with a Sterility Assurance Level (SAL) of 10^{-6} .

INDICATIONS:

- **AmnioGuard ST** is intended for use when durable tensile strength is indicated.
- When **AmnioGuard ST** is used for tectonic support (e.g. protection of a Glaucoma Drainage Device tube), it serves to strengthen the cornea, conjunctiva, tenon or sclera because of its thickness and tensile strength.
- The tissue allograft is for single use only in one patient by a licensed physician.

PRECAUTIONS:

- Do not use **AmnioGuard 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.).
- Once the outer foil pouch is opened, the tissue should be used as soon as possible.
- 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.

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 **AmnioGuard 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 transplanting entity 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 (DRI) Card, 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.

DONOR ELIGIBILITY AND SUMMARY OF RECORDS

Donated human tissue used to manufacture this product is procured and processed according to Good Tissue Practices (GTP) and Good Manufacturing Practices (GMP) regulations established by the US Food & Drug Administration (FDA).

Placental tissues are recovered aseptically from donors via elective Cesarean Section delivery under full informed consent. Donors are screened for infectious, malignant, neurological, and auto-immune diseases, other exposures, and social habits. Suitability is determined by reviewing medical records and history of possible transmissible diseases, physical examination, and screening by serological blood tests. Donor specimens are serologically tested ±7 days from donation by an independent lab, registered with 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), and must be found non-reactive using FDA licensed test kits for the following tests:

- HIV-1 & HIV-2 Antibody
 - HIV-1 (RNA-NAT)
 - Hepatitis B Surface Antigen (HBsAg)
 - Hepatitis B Core Antibody (HBcAb)
 - Hepatitis B (HBV,DNA-NAT)
 - Hepatitis C Antibody (HCVAb)
 - Hepatitis C Virus (HCV, RNA-NAT)
 - Syphilis (RPR)
 - HTLV I & II Antibody (HTLV I/II Ab)
- Only tissue from donors with acceptable screening, serological and microbial test results are released for transplantation.
 - A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls for Bio-Tissue products is available upon request.

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 reporting any adverse event potentially attributable to the use of the amniotic membrane to Bio-Tissue, Inc immediately.**

Complete the following section and FAX to (305) 412-4429 or CALL Adverse Event Reporting at (305) 412-4430 or (888) 296-8858.

Serial Number: _____

Expiration Date: _____

Doctor Name: _____

Facility Name: _____

Surgery Date: ____/____/____

Surgical Diagnosis/Procedure: _____

Site of Use: _____

Point of Contact's Name: _____

Point of Contact's Phone Number: (____) _____

| TYPE OF ADVERSE EVENT | CHECK ONE |
|--|--|
| <input type="checkbox"/> Microbial Infection | <input type="checkbox"/> Probably Product Related |
| <input type="checkbox"/> Transmission of Viral Disease | <input type="checkbox"/> Probably NOT Product Related |
| <input type="checkbox"/> Other | |

Date Adverse Event was reported: ____/____/____

Describe the Adverse Event: _____

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Manufactured for Bio-Tissue, Inc. by TissueTech, Inc.
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