CAM 360™
AmnioGraft

U.S. Patent No. 9,682,160; 9,931,423

Product Insert

Description

CAM 360 AmnioGraft™ is a cryopreserved human amniotic membrane product. **CAM 360 AmnioGraft** is aseptically processed, cell devitalized and terminally sterilized via gamma irradiation with a Sterility Assurance Level (SAL) of 10^{-6}. **CAM 360 AmnioGraft** is manufactured, using the SteriTek® preservation process, from donated human birth tissue according to Current Good Tissue Practice (CGTP) and Current Good Manufacturing Practice (CGMP) regulations established by the U.S. Food and Drug Administration (FDA). **CAM 360 AmnioGraft** is stored in saline (0.9% w/v NaCl) and is delivered on a non-implantable, gridded backing for easier handling and application. **CAM 360 AmnioGraft** is for single use only in one patient by a qualified medical professional.

Product Use

- On the ocular surface, **CAM 360 AmnioGraft** exerts anti-inflammatory, anti-scarring and anti-angiogenic actions to promote wound healing, and supports epithelial adhesion and differentiation.

Precautions

- Do not use **CAM 360 AmnioGraft** if the packaging is damaged – Contact BioTissue immediately if there is any abnormality observed (e.g., labeling, packaging, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- Once the outer foil pouch is opened, **CAM 360 AmnioGraft** shall either be transplanted promptly or otherwise discarded.
- Do not re-sterilize or autoclave the product before use.
- Do not use toothed-forceps to grip the backing paper.

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 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.

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.

Upon receipt, remove the product from the shipper and store accordingly until use.

Location & Temperature	Use After Receipt
-20°C → 25°C (-4°F → 77°F)	Within the expiration date printed on product packaging (shelf-life is 1 year from date of manufacture)

Instructions

1. If frozen, allow **CAM 360 AmnioGraft** to sit at controlled room temperature (20°C to 25°C) in its original unopened packaging for at least 5 minutes.
2. Open the outer foil peel pouch and present the clear inner pouch to the sterile field using aseptic techniques.
3. Open the clear inner peel pouch to retrieve **CAM 360 AmnioGraft**.
4. Separate **CAM 360 AmnioGraft** from gridded backing.
5. Place the tissue on ocular surface.
6. Discard the gridded paper backing.

To discourage tissue displacement following transplantation, a contact lens may be used to self-retain **CAM 360 AmnioGraft** on the ocular surface.
Alternatively, **CAM 360 AmnioGraft** may also be affixed to the ocular surface using aseptic technique with different sutures and/or tissue adhesives.

CAM 360™ AmnioGraft

Donor Eligibility and Summary of Records

- This tissue was procured from a donor determined to be eligible based on the results of donor screening and testing. Donor eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, has been performed and documented by BioTissue Holdings 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 BioTissue products is available upon request.

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 product tracking labels to the DRI and mail to BioTissue. 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 BioTissue at (888) 296-8858.
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 CAM 360 AmnioGraft to BioTissue.**

For Adverse Events, notify via:
Website: www.biotissue.com/complaints
Phone: (888) 296-8858
Fax: (305) 675-3262
Email: Customerfeedback@biotissue.com

Scan Code

BioTissue®

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