XCELL AMNIO MATRIX™

THIS PRODUCT IS MANUFACTURED FROM DONATED HUMAN TISSUE, RECOVERED FROM A SINGLE HUMAN DONOR WITH DOCUMENTED INFORMED CONSENT FOR DONATION AND RECOVERY. THE TISSUE IS RECOVERED AND SUPPLIED FROM U.S. TISSUE BANKS ONLY. THE RECOVERY, PROCESSING AND PACKAGING WERE PERFORMED USING ASEPTIC TECHNIQUES. THE PRODUCT IS INTENDED FOR USE IN ONE PATIENT ON A SINGLE OCCASION ONLY.

DESCRIPTION AND INDICATION FOR USE

XCELL AMNIO MATRIX™ is a lyophilized amniotic membrane allograft that is aseptically processed to preserve the native extracellular matrix and endogenous proteins that can be used as a biological barrier or wound cover. XCELL AMNIO MATRIX™ is a Human Cellular and Tissue Based Product (HCT/P) per 21 CFR Part 1271. Each allograft is restricted to homologous use for use in procedures on a single occasion by a licensed physician or surgeon.

DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

XCELL AMNIO MATRIX™ was prepared using tissue from a donor determined by the Medical Director of Aziyo or physician designee to be eligible for donation based on the results of screening and testing. Donors are screened for high risk behavior and contraindications to transplant through medical/social history interview, review of medical records and physical assessment. Tissue from this donor has passed bacteriological testing by a CLIA Certified Laboratory. Communicable disease testing was performed by a laboratory 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 found to be negative or non-reactive for a minimum of:

- HIV type 1 and 2 antibody (HIV-1 & 2 Ab)
- HIV type 1 nucleic acid test using PCR and/or TMA format (HIV-1 NAT)
- Hepatitis B virus (HBsAg and HBV NAT)
- Hepatitis B core antibody total (HBcAb IgG/IgM or total)
- Hepatitis C virus (HCV Ab and HCV NAT)
- Syphilis by rapid plasma reagin (RPR) or other serological tests
- West Nile Virus (WNV NAT)

Additional tests, including Human T-lymphotropic virus I/II, may have been performed at the time of screening, and results were found acceptable for transplantation. Any additional test(s) performed can be provided upon request. Donor eligibility determination was made by Aziyo Biologics in compliance with U.S. FDA regulations (21 CFR 1270 and 1271) and American Association of Tissue Banks® (AATB®) Standards.

WARNINGS AND PRECAUTIONS

Potential adverse effects that may result from placement of XCELL AMNIO MATRIX™ include but are not limited to wound or systemic infection, seroma, dehiscence, hypersensitivity, allergic or other immune response, sloughing or failure of the graft and disease transmission.

XCELL AMNIO MATRIX™ is processed using, povidone iodine, Dulbecco's phosphate buffered saline, anticoagulant acid citrate dextrose-formula A, glycerol, mannitol and trehalose and trace amounts of these solutions may be present in the product.

TRANSPORTATION, STORAGE AND HANDLING

XCELL AMNIO MATRIX™ is supplied ready to use and must be stored in its original packaging between at 1°C to 36°C (33.8°F to 96.8°F) until ready for use. It is the responsibility of the transplant facility or clinician to maintain the allograft intended for transplantation in the appropriate recommended storage conditions prior to transplant.

HOW SUPPLIED

XCELL AMNIO MATRIX™ lyophilized amniotic membrane is sandwiched within a sterile backing, enclosed inside a sterile inner pouch, which is then enclosed in a secondary outer pouch. The outer pouch is contained in a labeled box. Allograft size is indicated on the package label.

STERILITY CONTROL

XCELL AMNIO MATRIX™ allografts have been processed under aseptic conditions to prevent contamination and cross contamination of the product.

Destructive microbiological testing per USP <71> *Sterility Tests* is performed on samples from each lot and must show "No Growth" after a 14-day incubation in growth promoting media.

PRECAUTIONS

Inspect the integrity of the package upon receipt and before use. Do not use XCELL AMNIO MATRIX™ under the following conditions:

- The pouch in which the allograft is stored is damaged or the label has been damaged or defaced.
- The allograft expiration date has passed.
- Recommended storage conditions have not been maintained.

INSTRUCTIONS FOR USE

It is important to utilize aseptic techniques when unpacking the allograft.

1. Examine the labeling and outer peel pouch. Do not use if there is evidence that the integrity of the outer pouch has been compromised.
2. Aseptically present the inner pouch onto a sterile field.
3. Don sterile surgical gloves and remove the contents from the pouch. The allograft is sandwiched between a sterile backing that must be removed prior to use.
4. **Orientation:** XCELL AMNIO MATRIX™ has 2 distinct sides: an epithelial side and a stromal side. For orientation, the graft has a 2-3 mm vertical slit that when positioned in the upper right corner, the epithelial side is facing upward.
5. Using sterile technique, apply the graft directly onto the surgical site or wound. Trim excess graft as necessary. The graft should absorb moisture directly from the application site, however, a few drops of sterile saline may be added to the graft after it has been applied if there are areas that are not rehydrated.
6. For wounds, cover the treated wound with a non-adherent dressing followed by saline moistened gauze. For surgical sites, apply dressing as needed and close the surgical incision.
7. XCELL AMNIO MATRIX™ is intended for single use and should not be repackaged or sterilized.

TRACEABILITY

The FDA requires traceability from the donor to the recipient. The physician is responsible for completing the recipient records to ensure traceability. As a convenience, pre-printed peel-off Tissue ID Labels are included with each allograft. Using the labels, record the allograft tissue identification information in the patient medical record.

In addition, an Allograft Tracking Record is included with the allograft. In fulfilling the tissue allograft traceability requirements of the Joint Commission and the FDA, end-user establishments must facilitate tracking of each allograft to the recipient or other final disposition. In order to comply with these requirements, please complete this card and attach the applicable Tissue ID Label(s) and one Patient ID Label on the card. Return the tracking card to Precise Bioscience by Email, Fax or Mail.

ADVERSE REACTION

The physician must promptly report any adverse outcomes potentially attributable to XCELL AMNIO MATRIX™ to Precise Bioscience at (888) 248-8698.

Distributed By:

PRECISE BIOSCIENCE

Precise Bioscience
13 E First Street, Suite H
Hinsdale, IL 60521
Phone: (888) 248-8698
Fax: (888) 701-1157

Processed by:

AZIYO BIOLOGICS

Aziyo Biologics, Inc.
880 Harbour Way S, Suite 100
Phone: (800) 922-3100
Fax: (510) 307-9896

FDA Registration No. 1000100754
CTO Registration Certificate No. 100242
Accredited by the AATB.

American Association of Tissue Banks® and AATB are registered service marks of the American Association of Tissue Banks®.