

## Contents / How Supplied

This package contains Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) as defined by US FDA 21 CFR Part 1271.

### CAUTION:

Federal (USA) law restricts this product to sale by or on the order of a licensed physician.

The **Donated Human Tissue** has been determined eligible for transplantation by a licensed Medical Director according to the criteria listed in the Donor Selection section below.

## Product Description

AMNIOMATRIX® is a viable human, placental, liquid allograft provided cryopreserved in a vial. If the vial is open, do not use. Included in the packaging along with this insert are a Tracing Record and a set of patient labels.

- AMNIOMATRIX® is intended for single patient, one time use only.
- Once opened, AMNIOMATRIX® must be used immediately or discarded.

## Introduction

BioDlogics, LLC is registered with the Food and Drug Administration (FDA) as a processor and Derma Sciences, Inc. as the distributor of HCT/P. All donor recoveries are performed by BioRecovery, LLC, an affiliate of BioDlogics, LLC. BioRecovery, LLC is also registered with the FDA and adheres to the regulations regarding HCT/P recovery and the screening and testing of the tissue donor as verified through supplier audits.

## Donor Selection

The Medical Director of the registered recovery agency has determined that the donor of the tissue contained in this product is eligible to donate tissue for transplantation based on meeting the following criteria:

1. The results of donor screening indicated that the donor was free from risk factors for and clinical evidence of infection due to relevant communicable disease agents and diseases.
2. The results of donor testing for the

following relevant communicable disease agents are negative or non reactive:

- Antibodies to the human immunodeficiency virus type 1 and type 2 (anti-HIV-1 and anti-HIV-2)
- HIV-1/Hepatitis B/Hepatitis C by Transcription Mediated Amplification
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B total core antibody
- Antibodies to the Hepatitis C virus (anti-HCV)
- Antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II)
- Syphilis using FDA-licensed tests. If the blood sample to be used for syphilis screening is determined and documented to be unacceptable for the screening assay (e.g. hemolysis, sample testing time restriction) then an FDA-licensed treponemal-specific confirmatory assay may be performed instead (e.g. FTA-Abs).

All laboratories performing these tests are registered with the FDA to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493 or have met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

At the time of recovery, cultures of the tissue are taken and grown out for evaluation. Additionally, a donor's medical history and behavior risk assessment, incorporating U.S. Public Health Service guidelines, are obtained prior to donation. Discussions with physicians and/or the donor mother are conducted to identify circumstances that may lead to the exclusion of the donor or donated tissue. The blood sample test results, donor medical history, behavior risk assessment, physical assessment, and information from other sources or records, which may pertain to donor suitability, have been evaluated by a Medical Director. The Medical Director is a licensed physician who completes a comprehensive review of every donor record. The results are used to determine that the donor suitability criteria at the time of tissue

recovery have been met, and that the tissue is acceptable for transplantation.

The names and addresses of the testing laboratories, the interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records and all pertinent donor medical information can be quickly retrieved upon request for any allograft tissue recovered on the behalf of BioDlogics, LLC.

## Recovery

Tissue recovery is aseptically performed by BioRecovery, LLC, an FDA-registered tissue bank. At the time of recovery, medical records are collected and reviewed as part of donor eligibility.

## Processing

AMNIOMATRIX® is processed by BioDlogics, LLC, in a controlled environment under aseptic conditions using methods designed to prevent contamination and cross-contamination of the products. Technical quality assurance standards are rigorously maintained. AMNIOMATRIX® contains 10% v/v Dimethyl Sulfoxide (DMSO) as a cryoprotectant.

## Tissue Distribution

AMNIOMATRIX® is distributed by Derma Sciences, Inc.

## Tissue Storage

It is the responsibility of the Tissue Dispensing Service and/or end user to maintain AMNIOMATRIX® in its original packaging and at – 65°C or colder until ready for use. Recommended long term storage is at -80°C.

## HCT/P Tracking

**Important notice to end-user:** Recipient records must be maintained for the purpose of tracing tissue post-transplant per The Joint Commission and FDA requirements. The allograft ID number must be recorded in the operative record. The Tracing Record must be completed and returned to Derma Sciences, Inc. Patient labels which include tissue numbers are contained in this package to aid in the tracking process.

### General Usage

AMNIOMATRIX® is intended for use as a wound covering. This product is an allograft tissue intended for homologous use for the repair, reconstruction and replacement of skin at the direction of a physician.

### Precautions

1. AMNIOMATRIX® is provided in solution containing 10% v/v DMSO as a cryoprotectant. It should not be used in patients with known sensitivity to DMSO.
2. This product should not be used for intravenous or intrathecal applications.
3. Although donor tissue is evaluated and processed following strict FDA guidelines, the donor screening methods are limited and may not detect all diseases. As with any allograft, complications at the graft site may occur post operatively that are not readily apparent. These include, but are not limited to:

- Transmission of communicable diseases, including those of unknown etiology
- Transmission of infectious agents such as viruses, bacteria and fungi
- Immune rejection of, or allergic reaction to, implanted HCT/P.

### Adverse Reactions

Adverse reactions or outcomes that potentially involve the use of AMNIOMATRIX® should be reported immediately to Derma Sciences, Inc. Customer Service Department at 1-800-825-4325.

### Recommended Instructions for use of AMNIOMATRIX®

These recommendations are designed only to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

### Preparation Instructions

1. Carefully peel open the foil pouch containing the vial and aseptically transfer onto the sterile field.
2. Allow to thaw completely (approximately 10-15 minutes).
3. Once thawed, pull the AMNIOMATRIX® into a syringe and apply the allograft to the appropriate areas.

### Return Policy

Derma Sciences, Inc. accepts no returns of AMNIOMATRIX®.

**Note:** BioDlogics, LLC makes no claims concerning the biological properties of allograft tissue. All tissue has been collected, processed, stored, and distributed in compliance with the FDA regulations governing HCT/Ps. Although every effort has been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease.

## WARNINGS



Do not sterilize. Discard all open and unused portions of the product.



Once the expiration date on the label has been reached, the allograft must be discarded.



Do not use if the vial integrity has been violated, is opened or damaged, or if mishandling has caused possible damage or contamination.



Each allograft is intended for single patient use, on a single occasion only.



Not made with natural rubber latex.

**Store at -65°C or colder. Do not re-freeze once thawed!**

**Rx Only. Use is limited to specific health professionals (e.g. physicians).**

**After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.**

**Donor Procurement and Eligibility Determined by:**  
BioRecovery, LLC  
7740A Trinity Road, Suite 107  
Cordova, TN 38018  
901-417-7868

**Processed by:**  
BioDlogics, LLC  
7740A Trinity Road, Suite 107  
Cordova, TN 38018  
901-417-7868

**Distributed by:**  
Derma Sciences, Inc.  
145 Cassens Court  
St. Louis, MO 63026  
636-326-7884

AMNIOMATRIX® Amniotic Allograft Suspension		
Order Code	Description	UPC
25510	0.25ml	809958021507
25520	0.50ml	809958021606
25530	1.0ml	809958021705
25540	2.0ml	809958021804
25550	3.0ml	809958021903

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