

Contents / How Supplied

This package contains Human 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

AMNIOEXCEL[®] is an amniotic membrane allograft provided in prescribed multiple geometric configurations. AMNIOEXCEL[®] is dehydrated during processing and should be dry when the package is opened. The inner peel pouch and tissue product are terminally sterilized via E-beam irradiation and may be placed directly into the sterile field. Included in the packaging along with this insert are a Tracing Record and a set of patient labels.

- AMNIOEXCEL[®] is sterile and packaged for single patient, one time use only.
- Once opened, AMNIOEXCEL[®] must be used immediately or discarded.

Introduction

BioDlogics, LLC is registered with the Food and Drug Administration (FDA) as a manufacturer and Derma Sciences, Inc. as the distributor of human cells, tissue, and cellular and tissue-based products (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

AMNIOEXCEL[®] is processed by BioDlogics, LLC in a controlled environment using methods designed to prevent contamination and cross-contamination of the products. Technical quality assurance standards are rigorously maintained. Ethanol is used during processing, and trace residuals remain on the product.

Tissue Distribution

AMNIOEXCEL[®] is distributed by Derma Sciences, Inc.

Tissue Storage

It is the responsibility of the Tissue Dispensing Service and/or end user to maintain AMNIOEXCEL[®] in its original packaging and at room temperature until ready for use.

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

AMNIOEXCEL[®] 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. AMNIOEXCEL[®] contains trace amounts of ethanol. It should not be used in patients with known sensitivity to ethanol.
2. In order to reduce the risk of complications, AMNIOEXCEL[®] should not be used in the presence of active infection.
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 AMNIOEXCEL[®] should be reported immediately to Derma Sciences, Inc. Customer Service Department at 1-800-825-4325.

Recommended Instructions for use of AMNIOEXCEL[®]

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.

AMNIOEXCEL[®] has been packaged with one piece of sterile mesh to facilitate placement of the graft if the surgeon wants to hydrate the graft before application.

DO NOT LEAVE ANY MESH IN WOUND

Preparation Instructions

1. Open carton or box containing AMNIOEXCEL[®] and remove the peel-pack.
2. Peel open the outer package and remove the inner foil pouch using aseptic technique.

Note: The inner foil pouch and its contents are sterile and may be placed directly into the sterile field.

3. Peel the inner pouch open and place the implant with the accompanying mesh into the sterile field.

Note: The AMNIOEXCEL[®] graft is translucent and will look off-white or yellowish on the mesh that is still in contact with allograft.

It is important to note that the drier the surface to be covered with the graft, the easier the application.

4. If the allograft is dry, remove it from the mesh and place it at the desired location. If the allograft has been hydrated prior to application, leave the graft on the mesh

to aid in placement. Once the graft is positioned in the desired location, grasp a corner of the allograft with forceps to hold it in place while gently peeling off the mesh.

5. It is sometimes necessary to gently “brush” or “massage” the thin membrane at the edges to smooth out wrinkles and folds that can occur during graft placement.
6. If removal and replacement are needed, re-apply the mesh for ease of manipulation.
7. After final placement, discard the mesh.
8. Anchor the allograft using the physician’s choice of fixation.

Return Policy

All return orders of AMNIOEXCEL[®] require a Return Authorization (RA) number before product may be returned for credit. Please contact the Derma Sciences, Inc. Customer Service Team for more information. All product being returned must be in original unopened packaging and in resalable condition.

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 re-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 package 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 room temperature, keep from excessive heat. **DO NOT FREEZE.**

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
800-825-4325

AMNIOEXCEL [®] Amniotic Allograft Membrane					
Order Code	Description	UPC	Order Code	Description	UPC
25012	12mm disk	809958022108	25035	3.5cm x 3.5cm	809958022504
25013	15mm disk	809958022207	25044	4cm x 4cm	809958021309
25018	18mm disk	809958022306	25055	5cm x 5cm	809958022603
25024	24mm disk	809958022405	25048	4cm x 8cm	809958021408
25015	1.5cm x 1.5cm	809958021101	25110	10cm x 10cm	809958022009
25023	2cm x 3cm	809958021200			

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