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
BioDOptix® is a human amnion membrane allograft provided in prescribed geometric configurations. BioDOptix is dehydrated during processing and should be visibly 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 T Racing Record and a Trace Record.

Contents / How Supplied
The results of donor testing for the tissue contained in this product to aid in the tracking and tissue post-transplant per The Joint Commission and FDA requirements. The allograft ID number must be recorded in the operative record. Please complete and return the enclosed Tracing Record card following the use of the product.

Recipient records, which include tissue numbers, are contained in this package to aid in the tracking process.

General Usage
BioDOptix is intended for use as a wound covering. This product is an allograft tissue intended for homologous use as a protective barrier covering during the repair of soft tissue wounds at the direction of a physician.

Precautions
1. BioDOptix 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, BioDOptix should not be in used 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

Advise Reactions
An Adverse Reaction is defined by the FDA as any noxious or unintended response for which there is a reasonable possibility that the HCT/P caused the reaction. This includes, but is not limited to, the transmission of communicable diseases or infectious agents such as viruses, bacteria or fungi, or allergic reaction. Adverse reactions should be reported immediately to Integra LifeSciences Customer Service Department at 1-609-275-0500.

Tissue Distribution
BioDOptix is distributed by Integra LifeSciences Sales, LLC.

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Introduction
BioDlogics, LLC, is registered with the Food and Drug Administration (FDA) as a manufacturer, and Integra LifeSciences Sales, LLC, as the distributor of human cells, tissue, and cellular and tissue-based products (HCT/P).

Donor Selection
The Medical Director of BioDlogics, LLC 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 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 nonreactive:
   - Antibodies to the human immunodeficiency virus type 1and type 2 (anti-HIV-1 and anti-HIV-2)
   - HIV-1/Hepatitis B/Hepatitis C by Transcription Mediated Amplification
   - Hepatitis B surface antigen (HBsAg)
   - 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
   - West Nile Virus using WNV NAT test

All infectious disease tests were performed by laboratories registered with the FDA to perform laboratory testing. All laboratories performing these tests are certified 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 propagated 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’s 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.

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Recommended Instructions for Use of BioDOptix

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. Open carton or box containing BioDOptix and remove the foil pouch.
2. Peel open the foil pouch and remove the inner Tyvek pouch using aseptic technique.

Note:
-The inner Tyvek pouch and its contents are sterile and may be placed directly into the sterile field.
3. Peel the inner Tyvek pouch open and place the implant into the sterile field.

Note:
-Care must be taken in transferring/removing the graft from the package as it is lightweight and may be easily displaced.
- The BioDOptix graft is translucent and will look off-white or yellowish.
- It is important to note that the drier the surface to be covered with the graft, the easier the application.
4. Place the graft at the desired location.

Return Policy
All return orders of BioDOptix require a Return Authorization (RA) number before product may be returned for credit. Please contact the Integra LifeSciences Customer Service Team for more information. All products 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.

PRODUCT INFORMATION DISCLOSURE
INTEGRA HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

WARNINGS

- Do not re-sterilize
- Do not re-use
- Sterilized using irradiation
- Do not use if package is damaged
- Use-by date

Store at room temperature.

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, Eligibility Determined, and Processed by:
BioDlogics, LLC
7740A Trinity Road, Suite 107
Cordova, TN 38018
Tel: 901-417-7868

Distributed by:
Integra LifeSciences Sales, LLC
1100 Campus Road
Princeton, NJ 08540
1-609-275-0500

For more information or to place an order, please contact:
USA 800–654–2873 • 888–980–7742 Fax
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