

ACTISHIELD™ and ACTISHIELD™CF

ALLOGRAFT TISSUE INFORMATION AND PREPARATION INSTRUCTIONS

CONTENTS

This package contains a human tissue allograft [Human Cellular and Tissue Based Product (HCT/P)] for transplantation regulated by US Food and Drug Administration under 21 CFR Part 1271. In addition to this product insert, the following items should be included in the product package:

- One (1) Outer Box
- One (1) Double Peel-Pouch (containing the graft)
- One (1) Allograft Tracking Record
- One (1) Set of Supplemental Labels for Patient Documentation

CAUTION: U.S. Federal law restricts this tissue to use by or on the order of a physician.

PRODUCT DESCRIPTION

ACTISHIELD™/ACTISHIELD™CF is a sterile, human tissue allograft, derived from allogeneic dehydrated and decellularized human amniotic membrane, intended for homologous use as a wound covering.

HANDLING

ACTISHIELD™/ACTISHIELD™CF is packaged in a double peel-pouch and outer box. The inner peel-pouch and tissue are terminally sterilized via irradiation, and may be placed directly onto the sterile field.

- ACTISHIELD™/ACTISHIELD™CF is for single patient, one time use only.
- Once opened, the graft must be used within one (1) hour.
- Product use must be recorded (see HCT/P TRACKING section).

STORAGE

It is the responsibility of the Tissue Dispensing Service and/or the end user to maintain the graft in its original packaging and at ambient temperature (50-86°F / 10-30°C) until ready for use.

RECOMMENDED INSTRUCTIONS FOR USE

NOTE: These recommendations are designed only to serve as general guidelines. They are not intended to supersede any institutional protocols or professional clinical judgment concerning patient care.

PREPARATION

1. Open carton or box containing ACTISHIELD™/ACTISHIELD™CF and remove the peel-pack.
2. Using aseptic technique, peel open the outer pouch and present the inner peel-pouch onto the sterile field. (ACTISHIELD™/ACTISHIELD™CF is the translucent sheet inside the inner pouch.)

NOTE: The inner peel-pouch and product are sterile.

3. Peel open the inner pouch over a sterile basin to expose the graft.

APPLICATION

4. Using dry, sterile forceps, apply the graft over the intended site. Achieve full contact.
TIP: It is important to note that the drier the surface to be covered with the graft, the easier the application.
5. If desired, graft may be hydrated prior to application with sterile saline, for tight or hard to reach areas.

NOTE: Once the package is opened, the graft should be used within one (1) hour or disposed of appropriately.

HCT/P TRACKING

IMPORTANT NOTICE TO END-USER: Recipient records must be maintained for the purpose of tracking tissue post-transplant per The Joint Commission and FDA requirements. The allograft ID number must be recorded in the operative record. The *Graft Tracking Record* must be completed and returned to Human Regenerative Technologies, LLC. Supplemental labels, which indicate the Tissue ID Number, are contained in this package to aid in the tracking process.

RECOVERY

Tissue recovery is performed using aseptic technique. At the time of recovery, medical records are collected and reviewed as part of donor eligibility.

DONOR SCREENING

The DONATED HUMAN TISSUE has been determined to be eligible for transplantation by a licensed physician, Medical Director of the Tissue Bank.

Review of donor records to include the medical history and risk behavior assessment, medical records and recent physical examination indicate that the donor is free from risk factors for and clinical evidence of infection due to relevant communicable diseases and other exclusionary disease conditions.

Additionally, testing of a qualified blood sample indicates that the donor is **negative** or **nonreactive** for the following communicable disease markers:

- Human Immunodeficiency Virus (HIV)
HIV-1/2 Antibodies
Nucleic Acid Test for HIV-1 RNA
- Hepatitis B Virus (HBV)
HBV Surface Antigen
HBV Core Antibody (Total)
Nucleic Acid Test for HBV RNA
- Hepatitis C Virus (HCV)
HCV Antibody
Nucleic Acid Test for HCV RNA
- Human T Cell Lymphotropic Virus I/II
HTLV-I/II Antibody
- Syphilis
Rapid Plasma Reagin Screen*, or
Treponemal Specific Test

*Tissues from a donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as RPR test, or with a reactive result from the non-treponemal screening assay, are cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

The following non-required screening test for exposure to other viruses listed below may have been performed on the donor. A negative / nonreactive result is not required for these tests; however, all donors are evaluated on a case-by-case basis by the Medical Director.

- Cytomegalovirus – CMV Antibody (Total)

All laboratories performing these tests are registered with FDA and certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or equivalent requirements. Test kits used are approved and cleared (for screening blood specimens collected from living donors) by the FDA.

A copy of the medical records can be obtained upon request.

PROCESSING

The HCT/Ps are processed in a controlled environment using methods designed to prevent contamination of the tissues. Tissues are exposed to antibiotics at an initial processing step and subsequently subjected to multiple rinse steps using sterile saline. Final products are sized and packaged according to approved specifications and procedures and are terminally sterilized using E-Beam irradiation technology in accordance with ANSI/AAMI/ISO 11137.

PRECAUTIONS

1. In order to reduce the risk of complications, ACTISHIELD™/ACTISHIELD™CF should not be implanted in the presence of active infection.
2. Although the tissue has been rinsed several times with sterile saline during processing, antibiotic residuals such as amphotericin, penicillin, streptomycin and neomycin may remain in the tissue.

ADVERSE REACTIONS

No adverse clinical reactions to this product have been reported. Adverse reactions or outcomes that potentially involve the use of ACTISHIELD™/ACTISHIELD™CF must be reported immediately to Human Regenerative Technologies, LLC.

NOTE: Human Regenerative Technologies, LLC (HRT) make no claims concerning the biological properties of tissue allograft. All tissues have been collected, processed, stored, and distributed in compliance with FDA regulations governing HCT/P's. Although every effort has been made to ensure the safety of the allograft, current technologies may not preclude the transmission of disease.

WARNINGS
Do not re-sterilize. Dispose all open and unused portions of the product.
Do not use if the package integrity has been violated, opened or damaged, or if mishandling has caused possible damage or contamination. Do not use if seal is broken or compromised.
Store at ambient temperature, and keep away from excessive heat. DO NOT FREEZE.
Once the expiration date on the label has been reached, the allograft must be disposed with other medical waste.
Each allograft is intended for single patient use, on a single occasion only.
Use is limited to specific qualified 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.

Distributed by:

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Donor Suitability Determined by:

Human Regenerative Technologies, LLC

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