



ALLOGRAFT INSTRUCTIONS FOR USE AND INFORMATION

Contents

This package contains Human Cellular and Tissue Based Product (HCT/P) as defined in US FDA 21 CFR Part 1271.

Description

ACMShield™ Soft Tissue Barrier is a sterile human placental membrane allograft, composed of amnion and chorion, and processed by DCIDS Tissue Bank from donated amniotic-derived human tissue. DCIDS Tissue Bank is a full service not-for-profit tissue bank accredited by AATB and registered with FDA.

Intended Use

ACMShield is a human placental membrane allograft intended for use as a protective barrier in surgical applications.

CAUTION: This product is restricted to sale by or on the order of a physician or properly licensed practitioner.

Donor Screening for Tissue Procurement

An appropriate blood sample from the donor is tested for relevant communicable diseases by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on live human specimens under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 using, when available, FDA approved test kits. This tissue was tested for and had negative or non-reactive results for the following:

- Human Immunodeficiency Virus (HIV) 1 & 2 Antibodies
- HIV/HCV/HBV Nucleic Acid Test (NAT)
- Hepatitis B (HBV) Surface Antigen (HBsAg)
- Hepatitis B (HBV) Core Total Antibodies
- Hepatitis C Virus (HCV) Antibody
- Syphilis
- Human T-Cell Lymphotropic Virus (HTLV) Type 1 & 2 Antibodies
- West Nile Virus (WNV) Nucleic Acid Test (NAT)

Additional tests for other communicable diseases, such as T. Cruzi, Cytomegalovirus and Epstein Barr Virus may have been performed. The results of all additional communicable disease tests have been evaluated by the Medical Director and have been found acceptable according to regulations, standards and DCIDS Tissue Bank policies and procedures.

These test results, as well as, a donor risk assessment questionnaire, donor physical examination and other available relevant donor records have been evaluated and deemed eligible for transplant by a Medical Director. Donor eligibility determination was performed by DCIDS Tissue Bank.

Processing

Technical Quality Assurance standards are rigorously maintained by DCIDS Tissue Bank. Tissue is processed aseptically in a controlled, ultra-clean environment. Final product is terminally sterilized using a validated gamma irradiation process. These terminally sterilized

tissues are labeled as sterile on the product label.

Contraindications

- Active or latent infection in or around the surgical implantation site.
- Sensitivity or allergies to any of the processing agents or antibiotics listed under the Warnings & Precautions section of this document.
- Use in immune compromised patients.

Warnings & Precautions

As with all allogeneic materials, it is not possible to provide an absolute guarantee that no infectious disease will be transmitted. However, this risk is greatly reduced by using processing treatments shown to be capable of reducing this risk as well as the use of strict donor screening criteria, laboratory testing, aseptic processing and terminal gamma irradiation of final product.

- **Single patient, single use only.**
- **Do not sterilize or re-sterilize.**
- Return all compromised or flawed packaging to **Checkpoint Surgical, Inc.**
- Do not use if:
 - The packaging integrity has been violated, opened, or damaged, or if mishandling has caused possible damage or contamination.
 - Any seal is broken or compromised.
 - The expiration date has been exceeded, as indicated by the product label.
 - The tissue has not been stored according to the recommended storage conditions.
- This tissue was processed using some or all the following agents: DMEM, CHAPS Detergent – (3-((3-cholamidopropyl) dimethylammonio)-1-propanesulfonate), Gentamicin, and Vancomycin. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the medications and chemicals may remain. Use of antibiotics should be discussed with the patient to discern patient status regarding antibiotic sensitivity.
- Prior to clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the product.

Complications and Possible Adverse Effects

Inherent uncertainty exists in medical and social histories and lab testing which may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation:

- Transmission of diseases of unknown etiology;
- Transmission of known infectious agents including, but not limited to, viruses, bacteria and fungi;
- Immune rejection of implanted HCT/P; or

- Loss of function and/or integrity of implanted HCT/P due to resorption, fragmentation, and/or disintegration.

Report any adverse outcomes to Checkpoint Surgical, Inc. and DCIDS Tissue Bank immediately.

Tissue Preparation and Use

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

Non-Sterile Team Member

1. Visually inspect packaging to ensure that it is intact and that its integrity has not been compromised. If the packaging is damaged, the enclosed graft may be contaminated and should not be used.
2. Peel open outer heat-sealed package and pass the inner envelope packing onto the sterile field using aseptic technique.

Sterile Team Member

1. Visually inspect the envelope to ensure that it is intact and that its integrity has not been compromised. If the packaging is damaged, the enclosed graft may be contaminated and should not be used.
2. If no damage is detected, open the inner envelope and remove the graft. The graft may be immediately implanted, then rehydrated with sterile solution after implantation.
3. Any unused portion of the graft should be discarded per institutional protocol.

HCT/P Tracking

Checkpoint Surgical, Inc. is required by 21 CFR 1271 to maintain documentation about the disposition of each tissue to enable tracking from the donor to the consignee or final disposition. Joint Commission standards require that “the organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities.”

To comply with these requirements, Checkpoint Surgical, Inc. provides an *Allograft Tracking Record* and preprinted labels with every graft. Record the patient information, the transplantation facility name and address, the allograft tissue identification information (using stickers) and comments regarding tissue on the *Allograft Tracking Record*. Return the completed form to Checkpoint Surgical, Inc. and retain a copy in the patient medical record. Even if

the tissue has been discarded for any reason, the *Allograft Tracking Record* completed with the allograft identification information and reason for discard needs to be returned to Checkpoint Surgical, Inc.

Storage and Handling

It is the responsibility of the user facility and user clinician to maintain allograft tissue in appropriate storage conditions prior to transplant. All dehydrated allografts must be maintained at ambient temperature (15°C to 30°C) prior to use. **DO NOT FREEZE.**

Return Policy

Please contact Customer Service at 877.478.9106 for information regarding the Checkpoint Surgical, Inc. Tissue Return Policy.

Disclaimer

DCIDS Tissue Bank and Checkpoint Surgical, Inc. make no claims concerning the biologic or biomechanical properties of allograft tissue. All tissue has been collected, processed, stored, and distributed according to nationally recognized standards and in compliance with applicable U.S. Food and Drug Administration requirements. Although efforts have been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. Adverse outcomes potentially attributable to the tissue must be reported immediately to DCIDS Tissue Bank and Checkpoint Surgical, Inc.

Donor Assessment, Tissue Processing, Release for Distribution by:

DCIDS Tissue Bank
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Nashville, TN 37228
(800) 216-0319
Website: <http://tissuebank.dcids.org>

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