

Reference: Current MTF policies and procedures in compliance with current FDA, AATB and other regulatory requirements.

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Definitions of Label Symbols



See IFU



Do Not Reuse

Processed by:

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Transplant
Foundation

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All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

CAUTION: Restricted to use by a physician, dentist and/or podiatrist. Please note: Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.

MTF tissue forms and products are protected by one or more issued or licensed United States patents. A list of patents on available tissues and related technologies may be found on the MTF web site www.mtf.org.

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CTO: 100024

READ BEFORE USING

Dry Amniotic Membrane

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY. Aseptically Processed. Passes USP <71> Sterility Tests. Not Terminally Sterilized. Do Not Sterilize.

THIS TISSUE WAS COLLECTED FROM A DONOR WITH DOCUMENTED PERMISSION FOR COLLECTION AND DONATION. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS.

DESCRIPTION

Dry Amniotic Membrane is minimally processed human allograft which retains the structural properties of the extracellular matrix. The resulting dehydrated allograft serves as a wound covering.

INDICATIONS FOR USE

Dry Amniotic Membrane is an allograft membrane covering for interior or exterior wounds including use as a covering for the surgical site.

ADVERSE EFFECTS

Possible adverse effects of using human tissues include but are not limited to:

- Infection of soft tissue and/or bone (osteomyelitis)
- Fever
- Disease transmission and undesirable immune response

Within the United States: Adverse outcomes attributable to the tissue must be promptly reported to MTF. Outside of the United States: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.

CONTRAINDICATIONS

The presence of severe vascular compromise, active or latent infection, or uncontrolled infection at the wound site may compromise the usefulness of the tissue.

CAUTIONS

Do not sterilize. No known sensitizing agents are present in this tissue. NOTE: No antibiotics were used during the processing of this tissue.

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and Testing). Transmission of infectious diseases such as HIV or hepatitis, as well as a theoretical risk of the Creutzfeldt-Jakob (CJD) agent, may occur in spite of careful donor selection and serological testing.

ALLOGRAFT INFORMATION

Dry Amniotic Membrane is dehydrated. During tissue processing and packaging, this allograft was tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests. **Do not subject allograft to additional sterilization procedures.**

Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials.

INSTRUCTIONS FOR USE

Dry Amniotic Membrane is packaged in a sterilized foil pouch that is designed to be passed directly into the sterile field.

1. Peel back the outer Tyvek Package and pass the inner foil pouch to the sterile field.
2. Remove the tissue from the inner pouch using sterile gloves/forceps.
3. Apply Dry Amniotic Membrane directly to the patient site. If required the membrane may be hydrated with sterile saline or sterile water.

NOTE: Remove the tissue from the innermost pouch using sterile gloves/forceps. Once the foil pouch is opened, tissue should be used promptly. Innermost pouch alone is not intended for storage of tissue, as it may not provide an adequate moisture or sterile barrier.

NOTE: The tissue must be implanted or discarded within 24 hours of opening the tissue container provided the allograft tissue is maintained in an aseptic environment.

Implantation

The Dry Amniotic Membrane is packaged ready for application in the surgical site. It may be aseptically trimmed, with scissors or scalpel, to fit the dimensions of the application site.

Orientation

There is no specific orientation required for Dry Amniotic Membrane.

DONOR SCREENING & TESTING

Prior to donation, the donor's medical/social history is screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by the MTF Medical Board of Trustees.

Donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and registered with the FDA for:

- Hepatitis B surface antigen
- Hepatitis B core antibody
- Hepatitis C antibody
- HBV (NAT)
- HIV-1/2 antibody
- Syphilis
- HIV -1 (NAT)
- HCV (NAT)

All infectious disease tests were negative. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, consent, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, and information obtained from any source or records which may pertain to

donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening, serologic and microbiologic testing meet or exceed current standards established by the American Association of Tissue Banks.

PACKAGING & LABELING

Dry Amniotic Membrane is aseptically packaged in a sterilized hermetically sealed foil pouch. The foil pouch containing the allograft is inside a sealed sterilized Tyvek pouch. The Tyvek pouch is sealed, labeled and then placed inside an envelope.

This allograft must not be used under any of the following circumstances:

- If the container seal is damaged or not intact or has any physical damage;
- If the container label or identifying bar code is severely damaged, not legible or is missing; or
- If the expiration date shown on the container label has passed.

Once a container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

STORAGE

Dry Amniotic Membrane should be stored at ambient temperature. Do not refrigerate or freeze. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant.

PATIENT RECORD

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. A TissueTrace® Tracking Form and peel-off stickers have been included with each package of tissue. Please record the patient ID, name and address of the transplant facility, allograft tissue information (using the peel-off stickers), and comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively a system for electronic submission may be used and sent to MTFTTC@Sceris.com. **Within the United States:** Once completed, the bottom page of the form should be returned to MTF using the self-addressed mailer. Copies of this information should be retained by the transplant facility for future reference. **Outside of the United States:** Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained by the hospital for future reference.