INFINITY | SINGLE LAYER, MEDIUM THICKNESS, AND MAXIMUM THICKNESS AMNION PATCHES

STERILE R
Sterilized by Irradiation

DONATED HUMAN TISSUE

RESTRICTED TO USE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PROFESSIONAL (physician, dentist, podiatrist, optometrist, nurse practitioner or physician assistant).

80-294 01 08/2017
IFU-810-00(R1)

DESCRIPTION

The Infinity | Amnion Patches (a product family consisting of Single Layer amnion patch, Medium Thickness amnion patch, and Maximum Thickness amnion patch) is a semi-transparent, collagenous membrane allograft obtained with consent from healthy mothers during cesarean section delivery. The Single Layer amnion patch is derived from the amnion layer of the fetal membranes. The Medium Thickness amnion patch is derived from the umbilical cord. The Maximum Thickness amnion patch is derived from placental tissue.

The Single Layer amnion patch and Medium Thickness amnion patch are processed using aseptic techniques and dehydrated. The allograft is aseptically packaged in a tear pouch within a peel pouch configuration. The allograft has been exposed to electron beam radiation at a dosage range of 15-22 kGy.

The Maximum Thickness amnion patch is processed using aseptic techniques, treated with an antimicrobial solution (containing Gentamicin and either Vancomycin or Bacitracin), and dehydrated. The allograft is aseptically packaged in a tear pouch within a peel pouch configuration. The allograft has been exposed to electron beam radiation at a dosage range of 15-22 kGy.

INTENDED USE

The Amnion Patches are intended for use as a soft tissue barrier or wound covering.

CONTRAINDICATIONS

The Single Layer and Maximum Thickness amnion patches have no known contraindications.

The Maximum Thickness amnion patch is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, or Bacitracin.

DONOR ELIGIBILITY

The Amnion Patch is recovered from qualified donors and processed using aseptic techniques in accordance with federal, state, and/or international regulations and to the standards of the American Association of Tissue Banks. Each donor is screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the donor screening and testing have been reviewed by the Medical Director (or licensed physician designee) of UMTB Biomedical, Inc. and the donors have been deemed suitable for transplantation.

Communicable disease testing is performed by an FDA-registered laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Results from the following infectious disease tests have been found to be nonreactive or negative:

Human Immunodeficiency Virus (HIV)
HIV-1/2 Antibodies (HIV-1/2-Ab)
Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)
Hepatitis B Virus (HBV)
HBV Surface Antigen (HBsAg)
HBV Core Antibody (IgG & IgM) (HBcAb)
Nucleic Acid Test for HBV DNA (if performed) (HBV NAT)
Hepatitis C Virus (HCV)
HCV Antibody (HCVAb)
Nucleic Acid Test for HCV RNA (HCV NAT)
Human T Cell Lymphotrophic Virus I/II* (if performed)
HTLV-I/II (Antibody HTLV-I/II-Ab)
Syphilis**
Rapid Plasma Reagin (RPR) Screen
T. Pallidum IgG

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

Screening tests for exposure to other viruses or parasites such as those listed below may have been completed. A negative/nonreactive result is not required for these tests, however, all results are evaluated on a case-by-case basis by the Medical Director (or licensed physician designee).

Cytomegalovirus
CMV Ab (IgG & IgM)
Epstein Barr Virus
EBV Ab (IgG & IgM)
Toxoplasma gondii
Toxoplasma Ab (IgG & IgM)
Trypanosoma cruzi
T. cruzi Ab (IgG & IgM)

WARNINGS

The donors of the Amnion Patch are screened and tested for relevant communicable diseases and disease agents in compliance with the FDA regulations, relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). The Amnion Patch is processed using aseptic techniques and microbiologically tested. The allograft has been terminally sterilized by electron beam radiation technology in accordance with ANSI/AAMI/ISO 11137. Although all efforts have been made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination.

DO NOT FREEZE the allograft by any method.

FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY

DO NOT RE-STERILIZE the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide, or other chemical sterilant may render the allograft unfit for use.

PRECAUTIONS

The Amnion Patch is processed and packaged using aseptic techniques and sterilized. The allograft must be handled in an aseptic manner to prevent contamination.

ADVERSE EVENTS

Allogeneic cells or tissues can induce an immunologic response in the recipient. The possibility that a patient may develop alloantibodies should be considered for any patient who might be a future recipient of allograft tissue or cells.

Possible adverse events may include: immunologic response, transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, hepatitis, syphilis, or microbial contaminants.

STORAGE

The Amnion Patch must be stored at ambient temperature (2°C to 30°C). It is the responsibility of the Tissue Dispensing Service, Tissue distribution Intermediary, and/or End-User clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly.

Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

ALLOGRAFT PREPARATION

USE CAUTION WHEN OPENING, THE AMNION PATCH IS A SEMI-TRANSPARENT MEMBRANE.

ONCE OPENED, the allograft must be used within 24 hours, or otherwise discarded.

DO NOT USE THE ALLOGRAFT if the pouch integrity has been compromised.

THE OUTERMOST POUCH IS NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

It is not necessary to rehydrate the Amnion Patch prior to use.

Step 1: Remove the pouch containing the allograft from the box packaging.

Step 2: Inspect the pouch packaging.

Step 3: Utilizing aseptic technique, peel open the outer peel pouch from the chevron end and present the inner pouch to the operative field, when required.

Step 4: Wait to open the inner pouch until ready to place the allograft. Locate the tear notch on the pouch and tear open.

Step 5: Grasp the allograft and place it directly on the surgical or wound site.

AMNION PATCH ORIENTATION

The epithelial layer of the Amnion Patch is facing upwards when one of the following two (2) scenarios is true:

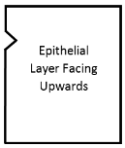

Figure 1.

1. **A triangle notch** is on the upper left hand corner of the graft as shown in Figure 1.

2. **The orientation indicator sticker** located on the tissue pouch is facing upwards.

To facilitate identification of the epithelial layer, combinations of the above listed scenarios might be present.

RECIPIENT INFORMATION

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide UMTB Biomedical, Inc. with information pertaining to the traceability of the allograft used. For this purpose, the postage paid Tissue Utilization Report (TUR) card is provided with the allograft. Once the allograft is used, peel off the small product labels provided on the product packaging and affix on the TUR card and applicable patient records. Complete the TUR card and mail to UMTB Biomedical, Inc., scan and e-mail to turs@umtb.com, or fax to (888) 630-4321.

ADVERSE OUTCOME AND COMPLAINT REPORTING

Adverse outcomes potentially attributable to the Amnion Patch or other complaints should be promptly reported to UMTB Biomedical, Inc. at (888) 684-7783.

RETURNED GOODS POLICY

Due to the delicate biological nature of a processed allograft, it cannot be returned for credit. If for any reason the allograft must be returned, a return authorization is required from UMTB Biomedical, Inc. prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

INFINITY BIOLOGICS

Distributed by:
Infinity Biologics, Inc.
P.O. Box 3323
Spartanburg, SC 29304
TEL: (877) 299-2772
www.infinitybiologics.com

Manufactured by:
UMTB Biomedical, Inc.
1951 N.W. 7th Avenue, Suite 200
Miami, Florida 33136

STERILE R
Sterilized by Irradiation