

Arthrex Amnion™ Matrix Thin and Cord



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).*

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The Arthrex Amnion Matrix (a product family consisting of Arthrex Amnion Matrix Thin amnion patch and Arthrex Amnion Matrix Cord amnion patch) is a semi-transparent, collagenous membrane allograft obtained with consent from healthy mothers during cesarean section delivery. The Arthrex Amnion Matrix Thin patch is derived from the amnion layer of the fetal membranes. The Arthrex Amnion Matrix Cord patch is derived from the umbilical cord.

The Arthrex Amnion Matrix Thin patch and Arthrex Amnion Matrix Cord patch have been processed using aseptic techniques and dehydrated. The allograft has been aseptically packaged in a tear pouch within a peel pouch configuration, and secured in an outer container.

INTENDED USE

Arthrex Amnion Matrix Thin and Arthrex Amnion Matrix Cord are both intended for use as a soft tissue barrier or wound covering.

CONTRAINDICATIONS

Arthrex Amnion Matrix Thin and Arthrex Amnion Matrix Cord have no known contraindications.

DONOR ELIGIBILITY

The Arthrex Amnion Matrix was recovered from a qualified donor 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. The donor has been screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the donor screening and testing has been reviewed by the Medical Director (or licensed physician designee) of UMTB Biomedical, Inc. and the donor has been deemed suitable for transplantation.

Communicable disease testing was 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 were 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 Lymphotropic 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 suitable for 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 suitable for 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 donor of the Arthrex Amnion Matrix has been 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 Arthrex Amnion Matrix was processed using aseptic techniques and microbiologically tested. 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 STERILIZE the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide or other chemical sterilants may render the allograft unfit for use.

PRECAUTIONS

The Arthrex Amnion Matrix was processed and packaged using aseptic techniques and 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 Arthrex Amnion Matrix 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 and 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 ARTHREX AMNION MATRIX 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 Arthrex Amnion Matrix Thin prior to use. Arthrex Amnion Matrix Cord can be rehydrated if necessary 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.

ARTHREX AMNION MATRIX ORIENTATION

The epithelial layer of the Arthrex Amnion Matrix is facing upwards when one of the following three (3) scenarios is true:

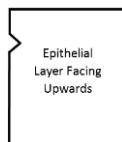


Figure 1.

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

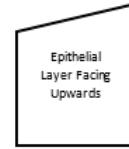


Figure 2.

2. An **angular cut** is on the top left corner of the graft as shown in Figure 2.
3. 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 Arthrex Amnion Matrix should be promptly reported to UMTB Biomedical, Inc. at (888) 684-7783. Any other complaints should be promptly reported to Arthrex, Inc. at (800) 934-4404.

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 Arthrex, Inc. prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.



Marketed By:

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Manufactured and Distributed By:

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