

Arthrex Amnion™ Viscous Amniotic Fluid



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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Arthrex Amnion™ Viscous is a versatile and manageable amniotic fluid product that is derived from donated human birth tissue and fluid. Birth tissue is obtained with consent from healthy mothers during cesarean section delivery. Arthrex Amnion™ Viscous has been processed using aseptic techniques, and frozen. The allograft is aseptically packaged in a tear pouch within a chevron peel pouch configuration and secured in an outer container.

INTENDED USE

Arthrex Amnion™ Viscous is intended for use as an additive for applications associated with soft-tissue procedures.

CONTRAINDICATIONS

Arthrex Amnion Viscous has no known contraindications.

DONOR ELIGIBILITY

The Arthrex Amnion™ Viscous 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 in accordance with 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. 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™ Viscous 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™ Viscous 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 RE-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™ Viscous was processed and packaged using aseptic techniques and must be handled in an aseptic manner to prevent contamination.

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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™ Viscous must be transferred to a monitored freezer which maintains the temperature at -20°C or colder for short-term storage (less than 6 months) or -40°C or colder for long-term storage (until expiration date on graft). 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

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

ONCE THE ALLOGRAFT CONTAINER SEAL HAS BEEN OPENED, the allograft shall be transplanted, or otherwise discarded.

ONCE THAWED, the allograft must be used within 2 hours.

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

It is not necessary to dilute the allograft prior to implantation.

Step 1. Remove container from either the freezer or the dry ice shipping carton. Open and remove the pouch from the container.

Step 2. Outside of the operative field, from the chevron end, peel open the pouch and remove the inner pouch that contains the cryovial containing the allograft.

Step 3. Open the inner pouch and remove the cryovial containing the Arthrex Amnion™ Viscous using standard aseptic technique.

Step 4. Thaw the cryovial in hand prior to taking the cap off. Allow allograft to thaw completely prior to implantation.

Step 5. Draw the allograft out of the cryovial with a sterile 30g or larger needle into a syringe. The allograft may then be implanted directly, or may be mixed with an equal amount of any one of the following diluents prior to implantation.

- 1% preservative free plain Lidocaine or Marcaine
- Normal Saline
- Platelet Rich Plasma (PRP)
- Bone Marrow Aspirate
- Patient's Blood

Step 6. Apply the allograft or mixed allograft using a 30g or larger needle into and around the targeted area.

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™ Viscous 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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