

AmnioFix™

Human Amniotic Membrane

Allograft Information / Directions for Use



SURGICAL BIOLOGICS

A MiMedx Group Company

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AmnioFix® Specifications

Human amniotic membrane is a unique, thin, collagenous membrane derived from the submucosa of the placenta, the area in which the human fetus grows and develops within the mother's uterus. Human amniotic membrane consists of collagen layers including: (1) basement membrane; (2) stromal matrix.

AmnioFix allografts are processed, dehydrated, sterilized human amniotic membrane tissue grafts. Each allograft is packed in a double peel-pouch packaging configuration. AmnioFix allografts are thin, opaque and extremely lightweight.

Recovery & Quality Control

All tissue recovered meets stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease. AmnioFix allografts are procured and processed according to standards established by the American Association of Tissue Banks (AATB) and the United States Food & Drug Administration (FDA). All tissues are recovered under full informed consent of the donors (represented by the mothers of the newborn children). The donors have consented to transfer of the allografts to third parties. A thorough medical and social history of the donor is also obtained, including detailed family history. The donor is screened for:

HIV-1&2 Antibody	Serologic Test for Syphilis	Hepatitis B Surface Antigen
HIV Type 1 Nucleic Acid Test (NAT)	CMV Total Antibody	Hepatitis C Antibody
HTLV-1&2 Antibody	Hepatitis B Core Antibody	Hepatitis C Virus Nucleic Acid Test (NAT)

All tests results are reviewed prior to the release of the tissue. Only tissue from donors with acceptable test results, according to the standards of Surgical Biologics, as well as the standards of all state and federal regulatory bodies, are released.

The infectious disease test results, together with the consent documents, donor medical history and behavior risk assessment according to current public health services guidelines, physical assessment, available relevant medical records, as well as information from other sources or records which may pertain to donor suitability, along with tissue procurement test results, have been evaluated and are sufficient to indicate that the donor suitability criteria current at this time of tissue recovery have been met.

The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of this allograft are on file and available upon request.

This allograft has been determined to be suitable for transplantation.

Allograft Processing/Preservation/Sterilization

AmnioFix allografts are processed and sterilized based upon strict, quality-controlled protocols. Each allograft is thoroughly cleaned using a process that leaves no deleterious residue. An additional assurance of safety is achieved by terminally sterilizing each allograft. Based upon validations, each graft has been effectively sterilized without causing adverse effects to the biomechanical properties of the collagen. AmnioFix allografts are processed with Streptomycin Sulfate and Gentamicin Sulfate.

Contraindications

AmnioFix should not be implanted into: (1) areas with active or latent infection; and/or (2) into a patient with a disorder that would create an unacceptable risk of post-operative complications.

Preparation, Reconstitution and Surgical Use

Prior to surgery, carefully follow the AmnioFix allograft preparation steps below using aseptic technique:

1. The outer peel is NOT considered sterile. The inner pouch, which contains the allograft, is considered sterile (unless the pouches are damaged or compromised).
2. Carefully open the peelable corner of the outer pouch and present the inner pouch onto the sterile field. Ensure that the inner pouch does not come in contact with any portions of non-sterile surface of the outer pouch.
3. In the sterile field, SLOWLY peel a corner of the inner peel pouch and allow the surgeon to grasp the allograft with fingers or non-toothed, sterile forceps. PLEASE TAKE GREAT CARE WHEN REMOVING THE ALLOGRAFT FROM THE INTERNAL POUCH. THE ALLOGRAFT IS THIN AND EXTREMELY LIGHTWEIGHT.
4. In its dry state and prior to hydration, the surgeon may cut the allograft with sharp scissors to the appropriate and approximate size required.
5. The allograft should then be placed on the surgical site, using the orientation of the embossment lettering as a guide. Proper orientation of the allograft can be noted when the embossment nomenclature reads correctly from left to right. The orientation of the allograft at the surgical site will vary based on the surgical indication.
6. The allograft can then be hydrated while on the surgical site with sterile saline solution. Simply apply several drops of sterile solution to the allograft at one to two minute intervals for a period of 5 to 10 minutes. During and following hydration, the embossment on the allograft will begin to fade. It may take several minutes for the embossment to completely fade.
7. Following the recommended hydration period, the surgeon should monitor the effect of hydration by visual inspection and while manipulating the allograft. Some allografts may take slightly longer to hydrate.
8. Absorbable, non-absorbable suture material and/or tissue adhesives can be used to fixate AmnioFix allografts to the surgical site.

Precautions/Warnings

- AmnioFix allografts remain suitable for transplantation in an unopened, undamaged package.
- Please inspect the integrity of the package upon receipt. If package and contents appear defective or damaged in any way, immediately contact the distributor.
- This allograft is intended for single-patient use only, performed by physician or surgeon. Discard all unused material.
- Strict donor screening and laboratory testing, along with dedicated processing and sterilization methods, are employed to reduce the risk of any disease transmission. However, as with all biological implants, an absolute guarantee of tissue safety is not possible. This allograft has the potential to transmit infectious disease to the recipient.
- The reaction of the body to any biological implant is not completely understood.
- Discard all damaged, mishandled or potentially contaminated tissue.
- DO NOT RE-STERILIZE.

Adverse Effects & Reporting

- As with any surgical procedure, the possibility of infection exists.
- Dedicated processing and sterilization methods are employed to eliminate deleterious properties of the allograft. However, as with all biological implants, the possibility of rejection exists.
- Any adverse reactions, including the suspected transmission of disease attributable to this allograft, should be immediately reported to Surgical Biologics.

Recommended Storage

AmnioFix allografts should be stored in a clean, dry environment at controlled room temperature of 0° C to 38° C (32° to 100° F).

Recipient Tracking

The F.D.A requires that recipient records be maintained for the purpose of tracking the allograft following surgical transplantation. The surgeon or operating staff member must complete the enclosed Allograft Utilization Record, attach a peel-off, allograft-tracking label provided, and mail to the distributor (postage-paid). Please use the remaining peel-off, allograft-tracking labels for patient and hospital records.

Caution: Federal law (U.S.A.) restricts this unit to sale by or on the order of a physician.

Surgical Biologics and its affiliates supply the allograft without any express or implied warranties. All statements or description are informational only and not made or given as a warranty of the allograft in any way. Surgical Biologics and its affiliates make no guarantee whatsoever concerning the biological or biomechanical properties of the allograft. The user shall be solely responsible for determining the adequacy and appropriateness of the allograft for any and all uses to which the user shall apply the allograft.

Processed with Purion Technology



Processed by:



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