AmnioRepair®

THIS PRODUCT IS MANUFACTURED FROM DONATED PLACENTAL TISSUE, RECOVERED FROM A SINGLE DONOR WITH DOCUMENTED INFORMED CONSENT. THE TISSUE IS COLLECTED AND SUPPLIED FROM U.S. TISSUE BANKS ONLY. THE RECOVERY, PROCESSING AND PACKAGING WAS PERFORMED USING ASEPTIC TECHNIQUES.

DESCRIPTION AND INDICATION FOR USE

AmnioRepair® is a lyophilized placental membrane allograft that is aseptically processed to preserve the native extracellular matrix and endogenous proteins. AmnioRepair® is indicated for use as a biological barrier or wound cover. AmnioRepair® is a Human Cellular and Tissue Based Product (HCT/P) per 21 CFR Part 1271. Each allograft is restricted to homologous use for use in procedures on a single occasion by a licensed physician or surgeon.

DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

AmnioRepair® was prepared using tissue from a donor determined by the Medical Director of Aziyo or physician designee to be eligible for donation based on the results of screening and testing. Donors are screened for high risk behavior and contraindications to transplant through medical/social history interview, review of medical records, physical assessment, and review of post mortem-examination results (when applicable). Tissue from this donor has passed bacteriological testing by a CLIA Certified Laboratory. Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS) and found to be negative or non- reactive for a minimum of:

- HIV type 1 and 2 antibody (HIV-1 & 2 Ab)
- HIV type 1 nucleic acid test using PCR and/or TMA format (HIV-1 NAT)
- Hepatitis B virus (HBsAg and HBV NAT)
- Hepatitis B core antibody total (HBcAb IgG/IgM or total)
- Hepatitis C virus (HCV Ab and HCV NAT)
- Syphilis by rapid plasma reagin (RPR) or other serological tests
- West Nile Virus (WNV NAT)

Additional tests, including Human T-lymphotropic virus I/II, may have been performed at the time of screening, and results were found acceptable for transplantation. Any additional test(s) performed can be provided upon request. Donor eligibility determination was made by Aziyo Biologics in compliance with U.S. FDA regulations (21 CFR 1270 and 1271) and American Association of Tissue Banks® (AATB®) Standards. The Medical Director determined final eligibility and acceptability for transplantation after review of donor screening and testing records.

WARNINGS AND PRECAUTIONS

Potential adverse effects that may result from placement of AmnioRepair® include but are not limited to wound or systemic infection, seroma, dehiscence, hypersensitivity, allergic or other immune response, sloughing or failure of the graft and disease transmission.

AmnioRepair® is processed using sodium chloride solution, povidone iodine, Dulbecco's phosphate buffered saline, sodium chloride irrigation solution, anticoagulant acid citrate dextrose-formula A, glycerol, mannitol and trehalose and trace amounts of these solutions may be present in the product.

TRANSPORTATION, STORAGE AND HANDLING

AmnioRepair® is supplied ready to use and must be stored in its original packaging between at 1°C to 36°C (33.8°F to 96.8°F) until ready for use. It is the responsibility of the transplant facility or clinician to maintain the allograft intended for transplantation in the appropriate recommended storage conditions prior to transplant.

HOW SUPPLIED

AmnioRepair® is enclosed inside a sterile inner pouch, which is then enclosed in a secondary outer pouch. The outer pouch is contained in a labeled box. Allograft size is indicated on the package label.

STERILITY CONTROL

AmnioRepair® allografts have been processed under aseptic conditions to prevent contamination and cross contamination of the product. Destructive microbiological testing per USP <71> *Sterility Tests* is performed on samples from each lot and must show "No Growth" after a 14-day incubation in growth promoting media.

PRECAUTIONS

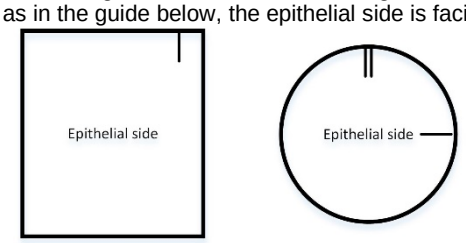
Inspect the integrity of the package upon receipt and before use. Do not use AmnioRepair® under the following conditions:

- The pouch in which the allograft is stored is damaged or the label has been damaged or defaced.
- The allograft expiration date has passed.
- Recommended storage conditions have not been maintained.

INSTRUCTIONS FOR USE

It is important to utilize aseptic techniques when unpacking the allograft.

1. Examine the labeling and outer peel pouch. Do not use if there is evidence that the integrity of the outer pouch has been compromised.
2. Aseptically present the inner pouch onto a sterile field.
3. Don sterile surgical gloves and remove the contents from the inner pouch.
4. When packaged without backing material the allograft can be used immediately after removal from the pouch.
5. **Orientation:** AmnioRepair® has 2 distinct sides: an epithelial side and a stromal side. The epithelial side is smooth while the stromal side is dull. In addition, the graft has 1 to 3 orientation guide slits that when positioned as in the guide below, the epithelial side is facing upward.



Sheet
1 slit

Disc
3 slits

6. Using sterile forceps, apply the graft directly onto the prepared wound bed with the stromal side directly against the wound bed. Trim excess graft as necessary. The graft should absorb moisture directly from the wound bed, however, a few drops of sterile saline may be added to the graft after it has been applied to the wound if there are areas that are not rehydrated.
7. Cover the treated wound with a non-adherent dressing followed by saline moistened gauze to fill but not pack the wound. Continue dressing.
8. AmnioRepair® is intended for single use and should not be repackaged or sterilized.

TRACEABILITY

The physician is responsible for updating the recipient records to ensure traceability to the donor. As a convenience, an Allograft Tracking Form is provided to be completed at the time of use. A completed original is to be retained in the patient record and the copy sent back to Zimmer Biomet Irvine. If the entire graft was discarded, return the Allograft Tracking Form with the reason for discard.

ADVERSE REACTION

The physician must promptly report any adverse outcomes potentially attributable to AmnioRepair® to Zimmer Biomet at 800-348-9500.

Distributed by:
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