AmchoMatrix™

STERILE DEHYDRATED HUMAN AMNION - CHORION MEMBRANE ALLOGRAFT

Package Insert (Instructions for Use)

CAUTION
FOR SINGLE PATIENT USE ONLY.

FOR SINGLE USE ONLY.

TO BE USED BY & ON ORDER OF REGISTERED PHYSICIAN.

IMPORTANT NOTICE TO END-USER
Please record the tracking label (provided along with the tissue) in your records and in the patient's file.

THIS ALLOGRAFT WAS COLLECTED FROM A DONOR WITH WRITTEN CONSENT.

PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS.

TERMINAL STERILIZATION WAS PERFORMED USING GAMMA IRRADIATION.

PASSES USP <71> STERILITY TEST.
DO NOT RESTERILIZE

DESCRIPTION

AmchoMatrix is a sterile minimally manipulated dehydrated human amnion, and chorion membrane allograft. The allograft is derived from human placental tissue collected from consenting donors. This dehydrated allograft is processed aseptically and is terminally sterilized and achieves a sterility assurance level (SAL) of 1×10^{-6} utilizing gamma irradiation.

INDICATION FOR USE

AmchoMatrix is restricted to homologous use. It acts as a barrier and provide a protective coverage from the surrounding environment for acute and chronic wounds such as partial and full thickness wounds, pressure sores/ ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (e.g., donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

DOSAGE

The quantity and size of product used will vary based upon wound size and physician recommendation. Application of AmchoMatrix is recommended weekly for up to 12 weeks or until the wound is closed.

DONOR SCREENING AND TESTING

AmchoMatrix is manufactured from “DONATED HUMAN TISSUE”. All tissue recovered meets stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease. Serologic and microbiologic testing meet or exceed current standards established by the American Association of Tissue Banks and international laws and regulations as required.

The Medical Director has assessed the results of infectious disease testing, consent documentation, the donor's current medical history interview and behavior risk assessment, physical examination, and relevant medical records, including past medical history, laboratory tests, and other pertinent information regarding donor suitability. Based on this evaluation, it has been determined that the donor meets the criteria for suitability in accordance with the current standards at the time of

procurement. The criteria used for donor screening adhere to FDA regulations outlined in 21 CFR Part 1271 on Human Cells, Tissues, and Cellular and Tissue-Based Products, where applicable as well as relevant international laws and regulations. The donor's blood samples are screened negative/non-reactive for the following infectious diseases:

- HIV-1/2 antibody
- Hepatitis B surface antigen
- Hepatitis B core antibody (Total)
- Hepatitis C antibody
- HIV (NAT)
- HBV (NAT)
- HCV (NAT)
- Malaria
- Syphilis
- WNV (NAT)

CONTRAINDICATIONS

AmchoMatrix should not be used with known hypersensitivity to ofloxacin, vancomycin, and amphotericin B. It should not be used on (1) areas with active or latent infection and/or (2) a patient with a disorder that would create an unacceptable risk of post-operative complications.

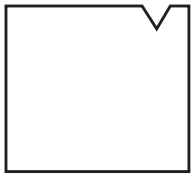
RECOMMENDED INSTRUCTIONS FOR USE

These recommendations are designed only to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Prior to use, carefully follow the AmchoMatrix Allograft preparation steps as mentioned below using aseptic technique.

Step 1 : Wound bed preparation Cleanse the wound bed gently with saline solution and then perform the debridement using a sterile instrument.
Step 2 : Choosing the right size Measure the wound and choose the appropriate size of AmchoMatrix.

Step 3 : Unpacking and applying AmchoMatrix on the wound bed, cut the outer pouch carefully and then open the inner foil pouch that contains AmchoMatrix. Remove the tissue from the inner pouch using sterile forceps. AmchoMatrix may be cut with sharp scissors to the size required. Use AmchoMatrix promptly after opening the inner sterile pouch.



Step 4 : Ensuring a proper product orientation
To ensure the appropriate orientation of AmchoMatrix. The notch in the allograft's top right corner can be used to determine the orientation side. The side that faces down is the chorion, whereas the upper side is amnion.

Step 5 : Applying the membrane Apply AmchoMatrix on the wound gently with sterile forceps and spread the membrane to maximize the contact with the wound bed. If needed, roll a moistened sterile cotton swab in sterile saline solution to ensure there are no air bubbles beneath the graft. A few drops of sterile saline can be sprinkled on top of the allograft to hydrate the tissue. Secure AmchoMatrix using the physician’s choice of fixation, as required.

Step 6 : Wound dressing post-application A non-adherent absorbent secondary dressing can be used to manage wounds with higher levels of exudate. A super absorbent dressing, which can lead to faster drying of the dressing, is not recommended. For dry wounds, apply a hydrogel as a secondary dressing. Dispose of excess or unused allograft and all other packaging in contact with the allograft in accordance with the recognized procedures for discarding regulated medical waste materials.

Step 7 : Re-application of AmchoMatrix It is recommended that AmchoMatrix allografts are applied on a weekly basis until epithelialization is achieved. However, clinician discretion should be used based on patient and wound condition/progress.

Note: Allografts are human tissue products and appearance may vary between donors. Variations in color (tan to light brown), opacity, and thickness are normal due to the nature of human tissue.

RECIPIENT TRACKING

The authorized medical professional is required to maintain tissue recipient records to trace the tissue post-transplantation. The responsible entity should use provided peel-off tracking labels on the patient record and enclosed Tissue Utilization Card. The card must be completed and mailed to the distributors. The authorized medical professional shall be solely responsible for determining the adequacy and appropriateness of the allograft for all uses to which the user shall apply the allograft. Copies of this information should be retained by the transplant facility for future reference.

WARNINGS AND PRECAUTIONS

1. Do not resterilize, keep away from sunlight, do not use if package is damaged and consult instructions for use, keep dry, keep out of reach of children. Do not re-use. Contains biological material of human origin.
2. Caution should be used when treating patients with a known sensitivity to ofloxacin, vancomycin, and amphotericin antibiotics. Expert opinion is required before use on babies and pregnant women.
3. The graft is intended for single-patient use only.
4. 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. As with any allograft, complications at the graft site may occur post operatively that are not readily apparent. These include, but are not limited to:

- Transmission of communicable diseases, including those of unknown etiology
- Transmission of infectious agents such as viruses, bacteria and fungi
- Immune rejection of, or allergic reaction to, implanted HCT/Ps

5. Discard all damaged, mishandled or potentially contaminated tissue.
6. This product has not been tested in combination with other products.
7. AmchoMatrix shall not be offered, distributed or dispensed for veterinary use.

COMPLAINTS, ADVERSE EVENTS, AND RETURNS:

As with any procedure the possibility of infection exists. Proprietary processing and validated sterilization methods are employed to eliminate potential deleterious components of the allograft. However with biological implants, the possibility of rejection still exists.

Complaints or adverse events, including the suspected transmission of diseases attributable to this allograft, should be reported immediately to Cellution Biologics.

Please contact your local sales representative, authorized distributor, or customerservice@cellutionbiologics.com for information on returns. All products being returned must be in original unopened container, packaging, original label and in resalable condition.

STORAGE REQUIREMENTS

Store in a clean and dry environment at ambient room temperature. DO NOT FREEZE.

The distributor, intermediary and/or end-user clinician or facility is responsible for storing product under appropriate conditions prior to further distribution or implantation.

SHELF LIFE

Refer package label for expiration date.

PACKAGING & HANDLING

AmchoMatrix is aseptically packaged in a sterilized hermetically sealed aluminum-PVC foil pouch. The aluminum-PVC foil pouch containing allograft is additionally packed in another aluminum-aluminum foil pouch. The foil pouch is sealed, labeled and then packed in a pre-printed envelope.

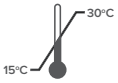
- Please inspect the integrity of the package upon receipt. If the package and contents appear defective or damaged in any way, immediately contact the distributor.

- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and national laws and regulations.
- Discard all damaged, mishandled or potentially contaminated tissue.

AVAILABLE SIZES:

AmchoMatrix is available in different size variants (14mm disc, 18mm disc, 2x2cm², 2x3cm², 2x4cm², 3x3cm², 3x5cm², 4x4cm², 4x6cm², 4x7cm², 4x8cm², 5x5cm², 6x8cm², 6x12cm², 7x7cm², 10x10cm², 10x20cm², and 20x20cm²,) to suit multiple wound sizes.

DEFINITIONS OF LABEL SYMBOLS

 Consult instructions for use	 Do not resterilize	 Do not re-use	 Caution
Rx only Prescription Use Only	 Expiration Date	LOT Lot Number	SN Serial Number
 Do not Use If package is damaged	 Storage Temperature Limits	STERILE R Sterilized Using Irradiation	REF Catalogue Number
 Manufacturer			

FOR MORE INFORMATION OR TO PLACE AN ORDER, PLEASE CONTACT

Distributed by:

CELLUTION BIOLOGICS

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www.cellutionbiologics.com

CB/IFU/ACM V2 08/24

Donor Eligibility Determination, Processed and Manufactured by:

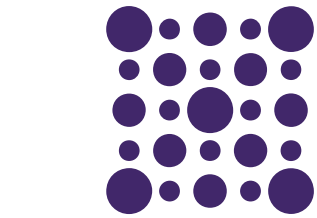
LifeCell International Pvt. Ltd.
Chennai, Tamil Nadu - 600127, India.

USFDA Facility Registration No. FEI: 3007953176

AATB Accredited Member #00323

DISCLOSURE

Cellution Biologics makes no claims concerning the biological properties of allograft tissue. All tissue has been collected, processed, stored, and distributed in compliance with the AATB, FDA regulations governing HCT/Ps. Although every effort has been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. Due to the inherent variability of allograft tissue, biological and biomechanical properties cannot be guaranteed by Cellution Biologics. Cellution Biologics excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Cellution Biologics shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Cellution Biologics neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products.



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