AmchoPlast™ ™

DEHYDRATED, HUMAN AMNION/CHORION MEMBRANE ALLOGRAFT

Package Insert (Instructions for Use)

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 COLLECTED FROM
A DONOR WITH WRITTEN CONSENT.

PROCESSING AND PACKAGING
PERFORMED UNDER ASEPTIC CONDITIONS.

TERMINAL STERILIZATION PERFORMED
USING GAMMA IRRADIATION.

PASSES USP <71> STERILITY TEST.
DO NOT RESTERILIZE

DESCRIPTION

AmchoPlast is a sterile minimally manipulated dehydrated human amnion, intermediate layer, 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 gamma sterilized to achieve a sterility assurance level (SAL) of 1×10^{-6}. AmchoPlast is packaged as a sterile product in sealed, single-use pouches.

INDICATION FOR USE

AmchoPlast 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 dosage and application of AmchoPlast are determined by the treating physician based on individual patient factors and the specific condition being treated.

DONOR SCREENING AND TESTING

AmchoPlast 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.

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 established by the American Association of Tissue Banks and 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
- HTLV I/II antibody
- HIV (NAT)
- HBV (NAT)
- HCV (NAT)
- Malaria
- Syphilis
- WNV (NAT)

CONTRAINDICATIONS

AmchoPlast 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 AmchoPlast Allograft preparation steps as mentioned below using aseptic technique.

AmchoPlast is aseptically packaged in primary and secondary tear-pouches and tertiary outer cover to ensure allograft integrity.

THE INNER POUCH IS CONSIDERED STERILE. USE CAUTION WHEN OPENING.

Step 1 : Remove the allograft from the outer packaging.
Step 2 : Inspect the pouch packaging. DO NOT USE if the packaging is damaged, if elements are missing or appear to have been tampered with, if the labeling is illegible, or if the expiration date occurs in the past.
Step 3 : Utilizing aseptic technique, peel open the outer pouch and place the inner pouch to the sterile field.
Step 4 : Wait to open the inner pouch until ready to place the graft. Locate the tear notch on the pouch, and tear open.
Step 5 : Using sterile non-toothed forceps, remove the graft and place it directly at the surgical or wound site. Allograft can be trimmed with a sterile sharp scissor in its dry state if there is a requirement.
Step 6 : Apply AmchoPlast on the wound gently with sterile forceps and spread the membrane to maximize the contact with the wound surface. If needed, prior to application, the membrane can be hydrated with sterile saline solution. When necessary secure using the physician's choice of fixation.
Note: Allografts are human tissue products and appearance may vary between donors. Variations in color, 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. AmchoPlast 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.
Please contact your local sales representative, authorized distributor, or at 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 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

AmchoPlast 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 and then packed in a pre-printed tertiary pack.

- 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:

AmchoPlast is available in multiple sizes, ranging from 14mm disc to 18mm disc, and 2cmx2cm to 20cmx20cm based on the size of the wound.

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:

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www.cellutionbiologics.com

USFDA Facility Registration No. : 3031041395

CB/IFU/ACP V2 03/25

Manufactured by:

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Chennai, 600127, Tamil Nadu

USFDA Facility Registration No. FEI: 3007953176

AATB Accredited Member #00323

DISCLOSURE
Cellution Biologics Inc. 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 Inc.

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