Tissue ID Number:

Place Sticker Here

Amnio-Maxx® Dual Layer Amnion Patch

PRODUCT DESCRIPTION

The **Amnio-Maxx Dual Layer Amnion Patch** is an allograft derived from donated human birth tissue. The **Amnio-Maxx Dual Layer Amnion Patch** is supplied dry.

The **Amnio-Maxx Dual Layer Amnion Patch** is intended to serve as a barrier and provide protective coverage from the surrounding environment for acute and chronic wounds. **Amnio-Maxx Dual Layer Amnion Patch** may be applied from the onset of the wound and for the duration of the wound, weekly or at the discretion of the health care practitioner.

The **Amnio-Maxx Dual Layer Amnion Patch** is processed using aseptic techniques, treated with a saline solution and dehydrated. The allograft is aseptically packaged in a peel pouch within a dual peel tray configuration. The allograft has been sterilized using radiation in accordance with ANSI/AAMI/ISO 11137 and secured in an outer container.

"DONATED HUMAN TISSUE": Human tissue for transplantation shall not be offered, distributed, or dispensed for Veterinary Use.

STORAGE CONDITIONS

Specified storage is 15-30°C (59-86°F) until use.

INSTRUCTIONS FOR IMPLANTATION OF ALLOGRAFT

1) Remove carton from storage.
2) Open carton and remove the outer tray containing the product. The outer pouch is not sterile and should not be placed directly onto the sterile field.
3) Peel open the outer tray and remove the inner tray using aseptic technique. The inner tray is sterile and may be placed onto the sterile field.
4) Open the inner tray using aseptic technique, peel the tray open, and aseptically remove the package containing the allograft. Always use sterile gloves or sterile forceps when handling the allograft.
5) **Amnio-Maxx Dual Layer Amnion Patch:**
    - Using sterile scissors, cut open the package.
    - Apply **Amnio-Maxx Dual Layer Amnion Patch** to the area of interest.
    - **Amnio-Maxx Dual Layer Amnion Patch** may be sutured, glued or placed into position without attachment.
6) After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.
7) Once container seal has been compromised, the allograft shall either be transplanted, if appropriate, or discarded.

DONOR SCREENING AND TESTING

Prior to processing, the donor's medical and social history were screened for conditions and disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures at Pinnacle Transplant Technologies, LLC (PTT). All policies and procedures for donor screening, serologic and microbiologic testing meet current Standards established by the Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB).

Contraindications for allograft donation include but are not limited to presence of identified infectious disease, neurological degenerative disease, disease of unknown etiology, and exposure to toxic substances. Donor blood sample is taken prior to or at the time of tissue recovery and tested for relevant communicable disease agents in accordance with Federal Regulations.

Communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments (CLIA) and 42 CFR Part 493, or that has equivalent requirements as determined by the Centers for Medicare and Medicaid Services. Names and addresses of testing laboratories, interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records are kept on file at PTT and are available to the end-user upon request, except as prohibited by law. Donor blood samples taken prior to or at the time of recovery were tested and found negative/nonreactive using FDA licensed tests for, at minimum:

- HBsAg: Hepatitis B Surface Antigen
- HBcAb: Hepatitis B Core Antibody
- HCVAb: Hepatitis C Antibody
- HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody
- HCV NAT: Hepatitis C Virus
- HIV NAT: Human Immunodeficiency Virus
- HBV NAT: Hepatitis B Virus
- RPR/STS or Equivalent: Syphilis
- HTLV I/II: Human T-Cell Lymphotropic Virus
- WNV: West Nile Virus

Based on screening and testing results, this donated human tissue product has been deemed suitable for transplant by the Medical Director and Quality Assurance.

PROCESSING AND STERILITY

Donor tissue is recovered using the safest recovery techniques and sterile equipment to minimize bioburden contamination. Allografts are procured via a network of qualified and trained recovery partners, using a stringent screening and recovery protocol, in a highly controlled processing environment, minimizing risk of disease transmission. All tissues are processed aseptically and sterilized using Gamma irradiation. Do not re-sterilize.

ADVERSE REACTIONS

Health professionals should discuss possible adverse reactions prior to product use. General risks and complications arising from application of **Amnio-Maxx Dual Layer Amnion Patch** include but are not limited to infection, bleeding, swelling, redness, and injury to nerves and other soft tissue. Complications may occur with allograft use, including but not limited to:

- Transmission of disease of unknown etiology
- Transmission of unknown infectious agents including but not limited to, HIV, Hepatitis, syphilis and bacteria
- Graft-versus-host immune rejection or other allergic reactions

Any adverse outcomes potentially related to product use must be promptly reported to Royal Wound-X at (201) 488-1549.

WARNINGS AND PRECAUTIONS

Amnio-Maxx Dual Layer Amnion Patch must not be transplanted under the following conditions:

- If mishandling has caused possible damage or contamination
- If the allograft is past its expiration date printed on the product carton
- If any of the allograft elements, packaging, labels and/or barcodes are missing, damaged, illegible or defaced
- If the allograft has not been stored according to specifications set forth in this insert

Notify Royal Wound-X immediately at (201) 488-1549 if any of these conditions exist or are suspected.

HCT/P TRACKING

FDA 21 CFR 1271.290, Regulation of Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps) requires that documentation regarding tissue disposition enabling tracking from donor to the consignee and/or final disposition be maintained. Joint Commission standard QC.5.310.7 requires that "the organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities." To comply with these requirements, a Tissue Tracking/Transplant Record (TTR) and pre-printed labels are provided with each product allograft. Record the patient information, the transplant facility name and address, allograft tissue information (using enclosed stickers) and comments regarding tissue use on the TTR. Return the completed TTR and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, a completed TTR with the allograft identification information and reason for discard shall be returned as well.

RETURN POLICY

Royal Wound-X, may accept return of **Amnio-Maxx Dual Layer Amnion Patch** allografts for credit or exchange if the incorrect product was shipped or product was received in a damaged state. Royal Wound-X reserves the right to reject a return if any of the conditions are not met.

1. For damaged items and incorrect shipments, Royal Wound-X may replace the product with the appropriate product or issue a credit.
2. A Return Material Authorization (RMA) number must be obtained from Royal Wound-X no later than 24 hours from receipt for damaged product or incorrect shipments.
3. Original product packaging must be intact and unopened.
4. Responsibility for facilitating shipping arrangements must be assumed by the returning facility unless the allograft is damaged or defective. Returning facility must complete, sign and return the RMA Form stating that all required criteria have been met.
5. Credit cannot be issued if the RMA Form has not been completed by the returning facility and received by Royal Wound-X.

   If you experience a problem with your product, notify Royal Wound-X immediately for an RMA number at (201) 488-1549.

LABEL AND PACKAGE SYMBOL DEFINITIONS

	Do not reuse; single patient use only
SN	Serial number (Tissue ID number)
STERILE **R**	Sterile by Gamma Irradiation
	Expiration Date (MM/DD/YYYY)

Disclaimer: It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant. Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Royal Wound-X, Inc. is not liable for any damages, whether direct or indirect, special, incidental or consequential, resulting from improper use of this allograft. These Instructions For Use are specific, and Royal Wound-X disclaims all responsibility associated with the mishandling, inappropriate storage, misuse, and off-label use of the product included with this insert.

PROCESSED AND ELIGIBILITY DETERMINED BY

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DISTRIBUTED BY

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ROYAL WOUND-X