LEGACY MEDICAL CONSULTANTS

IMPAX

Dual Layer Amniotic Tissue Allograft

Product description: Read this entire package insert carefully prior to use.

Single patient use only, on a single visit.

Restricted to sale by or on the order of a health professional**.** Only qualified licensed professionals should transport/transplant this donated human tissue.

This allograft is manufactured by BioXtek, LLC and distributed by Legacy Medical Consultants using a proprietary minimally manipulated system. This allograft is restricted to homologous use.

Product Use

IMPAX Membrane is a sterile, by e-beam irradiation, and dehydrated amniotic membrane allograft derived from donated human placental tissue. The epithelial basement membrane and intact extracellular matrix of this tissue graft confer a natural scaffold that provides a protective cover from the surrounding environment and a favorable microenvironment for skin repair.

The **IMPAX Membrane** graft is intended to remain on the recipient and is absorbed in the wound bed. The graft is anchored based on the health professional's choice of fixation including staples or sutures in surgical procedures, when medically necessary.

Storage and Expiration

Do not re-sterilize or freeze. Store **IMPAX Membrane** optimally in a clean environment at ambient temperature (15-30ºC or 55-86ºF) up until the expiration as labeled on the product and package label.

The expiration is a MM/YYYY format, where the expiration is extended through the last day of the month.

General Instructions

IMPAX Membrane can be used as a wound cover to protect damaged soft tissue from the surrounding environment, in acute and chronic wounds.

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties. Health professional experience and knowledge are key to proper application and usage. If unsure as to appropriate application, do not use until fully informed as to protocol and technique from an experienced user.

For use on a single visit/surgery/episode for a single patient, product cannot be shared. Do not use if:

a. Past expiration date specified on the product label.

b. If the allograft or packaging is damaged.

c. If there are discrepancies in label information.

Note: Photograph and document, all packages with flaws in the sterile barrier or lacking allograft or wrong size or wrong labeling.

Outer packaging **is not sterile**. If used in a surgical environment, only put the innermost envelope onto the surgical field.

Instructions:

1. The outer peel pouch packaging is opened using sterile technique. Maintain a distance of at least 12" from the sterile, surgical field. Position the package in both of your hands by grasping one edge of the peel-pouch in each hand. Slowly pull the sides of the peel-pouch away from each other until the package is open just past the top corners of the seal. Once the edges are separated, they must remain separated. Continue to separate the edges of the peel pouch while your lower hand moves downward, and your upper hand moves upward. The motion used is similar to that of a turning windmill. As the remainder of the package is opened completely, the sterile item is transferred onto the sterile field.
2. To prevent contamination of the allograft, use sterile technique for preparation and application / implantation.
3. To prepare the wound:
   a. Debridement of the wound, remove any and all necrotic tissue to healthy tissue level utilizing health professionals preferred method.
   b. Wash wound with health professionals preferred wound wash.
   c. Wash wound with sterile saline or equivalent.
   d. Gently dry the wound sterile gauze or equivalent.
   e. Apply the placental allograft to the wound, the applied membrane can be cut to size when necessary.
   f. Cover wound with non-stick type dressing.
   g. If there is significant drainage an alginate can be applied.
   h. Cover wound with comfortably applied dressing avoid over tightening/ compressing or restricting blood flow.
   i. Revaluate wound between 10-14 days.
4. Using the QR code printed on the product label, fill out the Tissue Tracking Record (even if the allograft is discarded) and submit using the online portal. This information is kept confidential and used only for HCT/P tracking.
5. Use standard practices for handling and disposal of human tissue.
6. Follow your patient and inform Legacy Medical Consultants of any adverse events, concerns, complaints, or questions immediately.

Donor Screening and Testing

The donated human placental tissue was recovered by a non-profit birth tissue procurement agency, after informed consent and screening for healthy mothers scheduled for elective Caesarian and Vaginal deliveries. The donor consents to the collection of this tissue, provided that its collection does not cause any harm to their infants. The donor's blood was tested for relevant communicable diseases in a laboratory certified under the Clinical Laboratory Improvement Amendments of the 1988 (CLIA) and 42 CFR Part 493, or equivalent, and registered with the FDA for donor testing.

IMPAX Membrane is prepared from a donor determined to be eligible based on the results of screening and testing. **It is the responsibility of BioXtek's Medical Director to determine donor eligibility**. The following test criteria were met for this donor:

Required donor testing: *All results must be reported negative or non-reactive to allow release.*	**Donor Screening*:** *The following risk factors are screened and are evaluated on a case-by-case basis by the Medical Director.*
HIV-1/ HIV-2 + Group O Antibodies	CMV Ab (IgG & IgM)
Hepatitis C Virus Antibodies	Epstein Barr EBV Ab (IgG & IgM)
Hepatitis B Surface Antigen	Toxoplasma gondii Ab (IgG & IgM)
Hepatitis B Core Antibodies	Trypanosoma cruzi Ab (IgG & IgM)
HIV 1&2 /HBV/HCV-NAT	Creutzfeldt-Jakob (CJD)
Syphilis	Mycobacterium tuberculosis

Additional donor testing may be required:

- Human T-Cell lymphotropic Virus I/II Antibodies
- WNV-NAT
- Borrellia burgdorferi (Lyme)

* The donor screening, in addition to blood analysis, may be completed via social and medical questions. A licensed health professional has reviewed the results of testing and determined the donor has met all eligibility requirements. The health professional utilized available relevant medical records which may have included, but was not limited to: Donor risk assessment interview, medical/hospital records, donor physical assessment, infectious disease test results, radiology/pathology, and other records if available and pertinent. Recipient records must be maintained for tracing tissue post-transplant per Joint Commission and FDA requirements.

Warranty

This tissue allograft processed and packaged for surgical implantation, is unique and does not constitute a product under liability laws. No implied warranties of merchantability or fitness for a specific purpose are applicable. No implied warranties exist as to defects in allograft product, which cannot be detected, removed, or prevented by reasonable use of available scientific procedures or techniques. Furthermore, all warranties are disclaimed, whether expressed or implied by operation of law or otherwise including all implied warranties of merchantability or fitness for a particular purpose.

Processing

Donor tissue is recovered using the safest techniques and sterile instruments to minimize any bioburden contamination. The donor tissue is procured via a network of qualified and trained recovery partners, using the most stringent screening and recovery protocols in a controlled environment, minimizing and limiting the risks of disease transmission at every step of the process.

All allografts are processed using aseptic technique. This allograft was processed in a classified, controlled environment from a single donor. Process controls and precautions were taken to ensure no introduction of any contamination, cross-contamination, and accidental exposure of HCT/Ps to communicable diseases.

Terminal sterilization was conducted via a validated electron beam process to an SAL of 10^{-6}. The allograft was released for transplantation based on the Medical Director's donor eligibility determination and Quality Assurance review of manufacturing records and lot release criteria.

This product is STERILE, only the inner packaging and allograft product are STERILE.

Packaging and Labeling

Dry, placental human amniotic membrane tissue is aseptically packaged and sealed in a double peel pouch. The peel pouch containing the allograft is inside a sealed sterilized peel pouch. The peel pouches are sealed, labeled, and then placed inside a white mailer envelope.

The peel pouch containing the allograft is affixed with a product label, that comes with six (6) pre-printed piggyback labels to be used as patient labels, if needed. The white mailer envelope is affixed with a package label.

This allograft must not be used under any of the following circumstances:

- If the container seal is damaged or not intact or has any physical damage;
- If the container label or identifying bar code is severely damaged, not legible or is missing; or
- If the expiration date shown on the product / package label has passed.

Once a container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

HCT/P Tracking

Per 21 CFR 1271.290, enable tracking from the donor to the consignee or final disposition must be maintained. The consignee is responsible for documenting disposition of the tissue while it is in their possession and providing tracking to the next destination or final disposition. Joint Commission standard QC.5.310.7 or equivalent regulations requires that "the organization that receives tissue provide 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 Record (TTR) is provided using the QR code listed on the product label. Fill out the required fields and submit electronically on the website portal. Or print out the TTR, use a provided patient label, and return the completed TTR to BioXtek using the address found at the end of this document. 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 must be completed and returned to BioXtek.

Warnings

Same and similar potential medical conditions, surgical conditions, or complications that apply to any surgical procedure may occur during or following implantation or application of this allograft. The health professional or surgeon is responsible for informing patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue allograft, the potential for transmission of infectious agents may exist.

Precautions and Contraindications

Prior to use, the surgeon must become familiar with the allograft and the surgical procedure. The allograft should be used with considerable caution in surgical sites where an active or latent infection is present, in necrotic sites, uncontrolled infection site, or in sites with poor perfusion / severe vascular compromise. This may compromise the usefulness of the tissue. Appropriate placement of the allograft is critical for successful outcomes.

The implant should NOT be used under high tension or pressure. It is **NOT** recommended for use in the spinal canal, disc, or epidural space.

Customer Returns and Concerns

Returns are not accepted. If a product discrepancy is discovered, take photographs to document any damage, defects, or deficiencies, send to BioXtek via email ASAP. Call number below to report the issue to the Quality Assurance department.

Disclaimer: It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplant in appropriate storage containers and temperatures. Recipient records must be maintained for tracing tissue post-transplantation. BioXtek will not be liable for any damages, whether direct or indirect, special, incidental, or consequential, resulting from improper use of this allograft. The instructions for use are specific, and BioXtek waives all responsibility associated with mishandling, inappropriately storing, and/or not taking proper precautions with the allograft tissue included with this insert.

Relevant Symbols

℞	To be used with prescription only
STERILE R	Sterilized using irradiation
SN	Serial number (unique identification code, consisting of lot number – unit number)
REF	Catalog number / Product Code
	Expiration date

Contact

Questions or concerns contact: Please contact Legacy Medical immediately at (817) 961-1288.

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LEGACY MEDICAL CONSULTANTS

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