Empliq™
Dermal

INSTRUCTIONS FOR USE

DESCRIPTION

Empliq™ Hydrated Acellular Dermal Matrix produced from donated human skin and processed to remove epidermal and dermal cells while preserving the extracellular dermal matrix. It provides a structural dermal matrix for the repair and replacement of damaged or inadequate integumentary tissue, and for the reinforcement or supplemental support of soft tissue defects. Each allograft is intended for homologous use in one single patient on a single occasion by a licensed physician.

REGULATORY CLASSIFICATION

Empliq™ is processed and distributed in accordance with U.S. Food and Drug Administration (FDA) requirements for Human Cell, Tissue, and Cellular and Tissue-based Products (HCT/P) (21CFR Part 1271), Industry Standards and State regulations.

INDICATIONS FOR USE

Empliq™ is intended for homologous use in the replacement of damaged or inadequate integumental tissue or the repair, reinforcement, or supplemental support of soft tissue defects. **This allograft is intended for single patient use only.**

Human tissue shall not be offered or dispensed for veterinary use.

SUMMARY OF DONOR SUITABILITY AND ELIGIBILITY

Donated human tissue for transplantation is specifically granted in a document of gift/authorization or in a record of informed consent. After obtaining authorization, the donor tissue collection is performed in an aseptic manner by appropriately licensed tissue establishments.
Donor eligibility is evaluated in accordance with FDA requirements, Industry Standards, and applicable State guidelines. Tissue donors are evaluated for risk behaviors and relevant communicable diseases. Donor screening includes a review of their medical and social history, a physical assessment, serological screening, and tissue collection microbiology.

Each donor is tested and shown to be negative or nonreactive for the following:

HIV-1/HIV-2 Antibody	Negative/Non-Reactive
Hepatitis B Surface Antigen	Negative/Non-Reactive
Hepatitis C Antibody	Negative/Non-Reactive
Hepatitis B Core Antibody Total (Total IgG and IgM)	Negative/Non-Reactive
Human T-Cell Lymphotropic Virus Type I/II Antibody (HTLV I/II) - For International Distribution	Negative/Non-Reactive
Syphilis Rapid Plasma Reagin (RPR) or Treponemal Specific Assay	Negative/Non-Reactive
HIV-1/HCV/HBV Ultrio Nucleic Acid Test (NAT)	Negative/Non-Reactive

This testing is performed by a laboratory registered with the FDA to perform donor testing and certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493 or has met equivalent requirements determined by the Centers for Medicare and Medicaid Services (CMS). Test kits used are approved by the FDA.

J4 Biologics Medical Director reviews donor records and determines tissue suitability for transplantation. All donor testing and medical release records are maintained by J4 Biologics.

PROCESSING

Empliq™ is processed by J4 Biologics in a controlled environment using methods to prevent contamination and cross contamination. Proprietary physiological buffers, surfactants, and alcohol are used during processing, and the final product may contain trace amounts of these processing agents. Following sizing and packaging, the final product is sterilized using gamma irradiation.

Empliq™ tissue will naturally vary in color from white, off-white to pale yellow. Localized areas of discoloration are normal.

CONTRAINDICATIONS

It is the responsibility of the licensed practitioner to determine contraindications for the use of this allograft.

WARNINGS

Careful donor screening, laboratory testing and tissue processing have been utilized to minimize the risk of transmission of communicable diseases to the patient. As with any processed human donor tissue, this allograft cannot be guaranteed to be free of all pathogens.

The contents of the package are sterile. Do not reuse or re-sterilize the product.

PACKAGING AND LABELING

Each allograft is packaged in a heat-sealed poly-Tyvek pouch and assigned Tissue ID.

The seal provides a sterile barrier and if the innermost pouch shows evidence of being opened, or damaged, or otherwise compromised, **do not use this allograft.**

The package label includes graft details such as Tissue ID, size, expiration date and product code.

STORAGE

Maintain allograft in a clean, dry environment and stored at ambient temperature 15°C- 30°C.
No refrigeration is necessary.

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.

EXPIRATION

It is the responsibility of the end-user to maintain this allograft in the appropriate storage conditions prior to transplant and to ensure the allograft has not exceeded its expiry date at the time of implantation.

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INSTRUCTIONS FOR USE

PREPARATION OF ALLOGRAFT

Examine packaging and ensure it is intact.

Step 1: Open the outer pouch and deliver the sterile inner peel pouch containing the allograft tissue to a sterile field.

Step 2: Open the inner peel pouch and deliver the allograft tissue to a sterile field.

Step 3: Carefully remove the allograft for tissue placement at the treatment site.

Step 4: At the discretion of the healthcare provider the allograft tissue may be hydrated with sterile saline prior to placement.

NOTE: Once graft has been opened, it must be used or discarded.

If for any reason the package is opened and the allograft has not been used, it should be disposed of properly. Product that cannot be used because it is defective or does not meet specifications should be returned to J4 Biologics by following appropriate return procedures described below. Document the reason for the non-use of the allograft, indicate the disposition of the tissue on the Tissue Transplantation Record (TTR) and return the card to J4 Biologics.

ORIENTATION

Empliq™ has two distinct sides, a dermal side and a basement membrane side. The dermal side absorbs blood. The basement membrane side repels blood. When applied as an implant, the dermal side should be placed against the vascular tissue.

To determine the deep dermal side of the implant from the basement membrane side, add a drop of blood to each side of the implant and rinse with sterile saline solution. The dermal side will have a bloody appearance. Where the basement membrane will remain pink.

RETURNS

If the allograft must be returned for any reason, a return authorization must be obtained from J4 Biologics prior to shipping the allograft. It is the responsibility of the health care institution returning the allograft to adequately package and label the allograft for return.

TISSUE TRANSPLANTATION RECORD (TTR)

Recipient records must be maintained for the purpose of tracking the allograft following transplantation. Record the Tissue ID in your records and in the patient's medical record. It is recommended that the following information be recorded in the patient's medical record and the TTR card should be returned to J4 Biologics.

- Description of Tissue
- Tissue ID
- Expiration Date
- Description of Procedure
- Date and Time of Procedure
- Surgeon or Doctor Name
- Any other pertinent information

POTENTIAL COMPLICATIONS

All allografts have the potential to elicit hypersensitivity, allergic reactions, or other immune responses. Any adverse outcomes potentially attributed to this allograft must be promptly reported to J4 Biologics at 210-251-4337.

Possible complications can occur with any surgical procedure including, but not limited to pain, infection, hematoma and/or immune rejection of the introduced tissue. Disease screening methods are thorough but limited, therefore certain diseases may not be detected.

The following complications of tissue transplantation may occur:

a) Transmission of diseases of unknown etiology.
b) Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi.

Conditions that could potentially inhibit integration of Empliq™ Hydrated Acellular Dermal Matrix include, but are not limited to the following:

a. Fever
b. Uncontrolled diabetes
c. Pregnancy
d. Low vascularity of the surrounding tissue
e. Local or systemic infection
f. Mechanical trauma
g. Poor nutrition or poor general health
h. Dehiscence and/or necrosis due to poor revascularization.
i. Inability to cooperate with and/or comprehend post operative instructions.
j. Infected or nonvascular surgical sites

DISPOSAL

Allograft disposal shall be in accordance with local, state, and federal regulations for human tissue.

INFORMATION

For additional information, or to report adverse reactions, contact J4 Biologics at 210-251-4337.

MANUFACTURED FOR:
ReNerve Ltd.
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Phone: (612) 293-8673

PROCESSING AND DONOR ELIGIBILITY DETERMINED BY:

J4 Biologics
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(210) 251-4337