



Grace Medical

AN INNOVIA MEDICAL COMPANY

INSTRUCTIONS FOR USE

EPIPATCH

HUMAN AMNIOTIC MEMBRANE ALLOGRAFT

READ BEFORE USING DONATED HUMAN TISSUE

Product Description

EpiPatch is an allograft derived from voluntarily donated human amniotic membrane. The tissue is recovered, processed, stored, and distributed in accordance with applicable regulations of the U.S. Food and Drug Administration (FDA) under 21 CFR Part 1271 and, where applicable, Health Canada's Cells, Tissues and Organs for Transplantation (CTO) Regulations.

EpiPatch® is supplied in single-use configurations and is intended for use by qualified healthcare professionals. Human tissue for transplantation shall not be offered, distributed, or dispensed for veterinary use.

Intended Use / Indications

EpiPatch is intended for use by qualified healthcare professionals as a protective barrier, consistent with the native support and protective properties of amniotic membrane, during surgical procedures and at the discretion of the treating physician.

Preparation for Use

EpiPatch is supplied in a dry form and is intended to be applied directly to the surgical site using aseptic technique. Reconstitution occurs naturally upon contact with bodily fluids, including blood, at the implantation site. No pre-hydration or soaking is required prior to use. Once the package seal has been broken, the allograft should be used promptly or discarded. Do not re-sterilize or reuse the tissue.

Contraindications

Use of this allograft may be contraindicated, at the discretion of the treating physician, in patients with active infection at the implantation site, known sensitivity to processing reagents, or conditions that would contraindicate implantation of human tissue.

Warnings and Precautions

This allograft is intended for single patient use only and must not be reused or re-sterilized. Do not use the allograft if the package seal is damaged, missing, or compromised, or if the product label or identifying information is missing or illegible. Despite donor screening and testing, transmission of infectious disease cannot be eliminated. Aseptic technique must be used during handling and implantation.

Trace amounts of processing agents may be present. Caution should be exercised in patients with known sensitivities to these substances. Any unused tissue and all packaging that has come into contact with the tissue should be disposed of in accordance with procedures for regulated medical waste.

Donor Screening and Testing

Donor eligibility determination was performed based on medical and social history, physical assessment, and communicable disease testing in accordance with FDA regulations under 21 CFR Part 1271. Communicable disease testing was conducted using FDA-licensed, approved, or cleared assays by FDA-registered and CLIA-certified laboratories.

Storage and Handling

EpiPatch® must be stored according to the conditions specified on the product label. The allograft must not be used beyond the labeled expiration date. If storage conditions or packaging integrity have been compromised at any time prior to use, the allograft should be discarded.

Possible Adverse Reactions

Possible adverse reactions associated with the use of human tissue include infection, inflammatory response, immune response, or disease transmission.

Adverse Event Reporting

Within the United States, adverse reactions or suspected disease transmission attributable to this allograft should be reported to the commercial distributor listed on the product label. Outside the United States, adverse events should be reported to the local representative.

Traceability

Each allograft is identified by a unique tissue identification number. Recipient records must be maintained to support tissue traceability, recall capability, and adverse event investigation in accordance with FDA regulations and Joint Commission requirements.

Responsible Parties

Donor eligibility determination and tissue processing were performed by an FDA-registered tissue establishment in compliance with 21 CFR Part 1271. The processing establishment is identifiable through the unique tissue identification information provided on the product label.

This allograft is stored, maintained, and shipped by BioMed ENT, Inc., an FDA-registered tissue establishment.

BioMed ENT, Inc.
757 North Water Street, Suite 300
Milwaukee, Wisconsin 53202

Commercial distribution, order processing, and customer support are provided by Grace Medical, Inc.

Grace Medical, Inc.
8500 Wolf Lake Drive, Suite 110
Memphis, Tennessee 38133

Tissue Utilization Record

Federal regulations and accreditation standards require traceability for all human tissue allografts. A completed Tissue Traceability and Utilization Record must be maintained by the healthcare facility and returned to BioMed ENT after implantation or discarded in order to support compliance with 21 CFR Part 1271 and Joint Commission requirements.

