



AMNIOTIC MEMBRANE

Donated Human Tissue

RESTRICTED TO USE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PROFESSIONAL (physician, dentist, podiatrist, optometrist, nurse practitioner or physician assistant). NOT INTENDED FOR VETERINARY USE.

80-449 Rev. 02

Description

The FuseChoice Plus Amniotic membrane is a semi-transparent, collagenous membrane allograft obtained with consent from healthy mothers during childbirth. The FuseChoice Plus Amniotic membrane is derived from placental tissue.

The FuseChoice Plus Amniotic membrane is processed using aseptic techniques, treated with an antimicrobial solution (containing Gentamicin and Vancomycin) and dehydrated. The allograft is aseptically packaged in a tear pouch within a peel pouch configuration. The allograft has been sterilized using electron beam radiation and secured in an outer container.

INTENDED USE

The FuseChoice Plus Amniotic membrane is intended for use as a soft tissue barrier or wound covering.

CONTRAINDICATIONS

The FuseChoice Plus Amniotic membrane is contraindicated in patients with known sensitivities to Gentamicin or Vancomycin.

DONOR ELIGIBILITY

FuseChoice Plus is recovered from a qualified donor and processed using aseptic techniques in accordance with federal, state, and/or international regulations and to the standards of the American Association of Tissue Banks. Each donor is screened and tested for communicable disease risks and other exclusionary medical conditions.

The results of the donor screening and testing have been reviewed by the Medical Director (or licensed physician designee) of VIVEX Biologics, Inc. and the donors have been deemed suitable for transplantation.

Communicable disease testing is performed by an FDA-registered laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Results from the following infectious disease tests have been found to be nonreactive or negative:

Human Immunodeficiency Virus (HIV)

HIV-1/2 Plus O Antibodies (HIV-1/2 Plus O Ab)
Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)

Hepatitis B Virus (HBV)

HBV Surface Antigen (HBsAg)
HBV Core Antibody (IgG & IgM) (HBcAb)
Nucleic Acid Test for HBV DNA (HBV NAT)

Hepatitis C Virus (HCV)

HCV Antibody (HCVAb)
Nucleic Acid Test for HCV RNA (HCV NAT)

Human T Cell Lymphotropic Virus I/II*

HTLV-I/II (Antibody HTLV-I/II-Ab)

Syphilis**

Rapid Plasma Reagin (RPR) Screen
T. Pallidum IgG

West Nile Virus (WNV)

Nucleic Acid Test for WNV RNA (WNV NAT)

*A donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, is cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

Screening tests for exposure to other viruses or parasites such as those listed below may have been completed. A negative/nonreactive result may not be required for these tests; however, all results are evaluated on a case-by-case basis by the Medical Director of VIVEX Biologics.

Cytomegalovirus

CMV Ab (IgG & IgM)

Epstein Barr Virus

EBV Ab (IgG & IgM)

Toxoplasma gondii

Toxoplasma Ab (IgG & IgM)

Trypanosoma cruzi

T. cruzi Ab (IgG & IgM)

Zika Virus

Zika Ab (IgM)

Nucleic Acid Test for Zika RNA (Zika NAT)

WARNINGS

The donors of FuseChoice Plus are screened and tested for relevant communicable diseases and disease agents in compliance with the FDA regulations, relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). FuseChoice Plus is processed using aseptic techniques and microbiologically tested. The allograft has been terminally sterilized by electron beam radiation technology in accordance with ANSI/AAMI/ISO 11137. Although all efforts have been made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination. FuseChoice Plus may transmit infectious agents.

DO NOT FREEZE the allograft by any method.

FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY

DO NOT RE-STERILIZE the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide, or other chemical sterilant may render the allograft unfit for use.

ADVERSE EVENTS AND REACTIONS

Allogeneic cells or tissues can induce an immunologic response in the recipient. The possibility that a patient may develop alloantibodies should be considered for any patient who might be a future recipient of allograft tissue or cells.

Possible adverse events may include:

- Immunologic response (the possibility that a patient may develop alloantibodies should be considered for any patient who might be a future recipient of allograft tissue or cells)
- Transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, syphilis, or microbial contaminants
- Infection of soft tissue and/or bone (osteomyelitis)
- Fever

STORAGE

The FuseChoice Plus Amniotic membrane must be stored at ambient temperature (2°C to 30°C). It is the responsibility of the Tissue Dispensing Service, Tissue distribution Intermediary, and/or End-User clinician to maintain the

allograft in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

PRECAUTIONS

The FuseChoice Plus Amniotic membrane is processed and packaged using aseptic techniques and terminally sterilized. The allograft must be handled in an aseptic manner to prevent contamination.

DO NOT USE THE ALLOGRAFT if the pouch integrity has been compromised.

USE CAUTION WHEN OPENING. THE FUSECHOICE PLUS AMNIOTIC MEMBRANE IS A SEMI-TRANSPARENT MEMBRANE.

ONCE THE ALLOGRAFT CONTAINER SEAL HAS BEEN COMPROMISED, the allograft shall be transplanted within 24 hours, if appropriate, or otherwise discarded.

THE OUTERMOST POUCH IS NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

It is not necessary to rehydrate the FuseChoice Plus Amniotic membrane prior to use.

ALLOGRAFT PREPARATION

Step 1: Remove the pouch containing the allograft from the box packaging.

Step 2: Inspect the pouch packaging

Step 3: Utilizing aseptic technique, peel open the outer peel pouch from the chevron end and present the inner pouch to the operative field, when required.

Step 4: Wait to open the inner pouch until ready to place the allograft. Locate the tear notch on the pouch and tear open.

Step 5: Grasp the allograft and place it directly on the surgical or wound site.

FUSECHOICE PLUS AMNIOTIC MEMBRANE ORIENTATION

The epithelial layer of the FuseChoice Plus Amniotic membrane is facing upwards when one of the following two (2) scenarios are true:

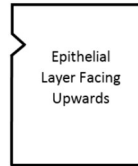


Figure 1.

1. **A triangle notch** is located on the upper left-hand corner of the graft as shown in Figure 1.
2. **The orientation indicator sticker** located on the tissue pouch is facing upwards

RECIPIENT INFORMATION:

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide VIVEX Biologics, Inc. with information pertaining to the traceability of the allograft used. For this purpose, the postage paid Tissue Utilization Report (TUR) card is provided with the allograft. Once the allograft is used, peel off the small product labels provided on the product packaging and affix on the TUR card and applicable patient records. Complete the TUR card and mail to VIVEX Biologics, Inc., scan, and e-mail to turs@VIVEX.com, or fax to (888) 630-4321.

ADVERSE REACTION AND REPORTING

Adverse reaction outcomes potentially attributable to the FuseChoice Plus Amniotic membrane or other complaints must be promptly reported to VIVEX Biologics, Inc. at (888) 684-7783.

RETURNED GOODS POLICY

Due to the delicate biological nature of a processed allograft, it cannot be returned for credit. If for any reason the allograft must be returned, a return authorization is required from CPM Medical Consultants, LLC prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

Additional Information:

Comments, questions, or concerns regarding the use of this device should be directed to the following:

Website	www.FuseMedical.Com
Email	Info@FuseMedical.Com
Phone	469-862-3030
Postal	Attn: Customer Service CPM Medical Consultants, LLC 4343 Sigma Road, Suite 500 Farmers Branch, TX 75244 www.FuseMedical.Com
Website	www.FuseMedical.Com



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CPM Medical Consultants, LLC
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Farmers Branch, TX 75244



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STERILE R

Sterilized by Irradiation