Provenda® 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.

80-387 Rev. 02

DESCRIPTION

Provenda Amniotic Membrane (Provenda) is a semi-transparent, collagenous membrane obtained with consent from healthy mothers during childbirth. Provenda is derived from placental tissue.

Provenda is processed using aseptic techniques and dehydrated. The allograft is aseptically packaged in a tear pouch within a peel pouch and provided sterile.

INTENDED USE

Provenda is intended for use as a soft tissue barrier or wound covering.

CONTRAINDICATIONS

Provenda is contraindicated in patients with known sensitivities or allergies to any of the agents listed below in the Warnings section. Provenda should not be used in areas with severe vascular compromise or with active or latent infection or in a patient with a disorder that would create an unacceptable risk of post-operative complications.

DONOR ELIGIBILITY

Provenda 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. The 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 donor has 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)
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 (or licensed physician designee) of VIVEX Biologics.

Cytomegalovirus**
CMV Ab (IgG & IgM)
Epstein Barr Virus
EBV Ab (IgG & IgM)
Human T Cell Lymphotropic Virus I/II**
HTLV-I/II (Antibody HTLV-I/II-Ab)
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)

**A donor with a reactive result for the CMV or HTLV-I/II Antibody test is cleared for transplantation use only when the result from a confirmatory assay is nonreactive.

WARNINGS

The donor of Provenda Amniotic Membrane is screened and tested for relevant communicable diseases and disease agents, and the tissue is microbiologically tested. Provenda may be exposed to Gentamicin and Vancomycin. Although the tissue is rinsed using sterile water during the manufacturing process, trace amounts may remain. Provenda is processed using aseptic techniques and is terminally sterilized by electron beam irradiation validated 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. Provenda 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

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

Provenda 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

Provenda 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, as Provenda is a semi-transparent membrane.

Once the allograft container seal has been compromised, the allograft must be transplanted, 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 Provenda prior to use.

ALLOGRAFT PREPARATION

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

Step 2: Inspect the pouch for any holes, tears, or incomplete seals.

Step 3: Using aseptic technique, open the outer peel pouch from the chevron end and present the sterile 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 using caution, as Provenda is a semi-transparent membrane.

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

ALLOGRAFT ORIENTATION

The epithelial layer of the allograft is facing upwards when one of the following two (2) scenarios are true:

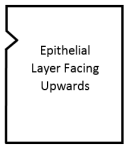

Figure 1.

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 clinician to provide VIVEX Biologics 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, scan and e-mail to turs@VIVEX.com, or fax to (888) 630-4321.

ADVERSE REACTION OUTCOME AND COMPLAINT REPORTING

Adverse reaction outcomes potentially attributable to the allograft must be promptly reported to VIVEX Biologics at (888) 684-7783. Any other complaints must be promptly reported to Spinal Elements at (760) 607-0121.

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 Spinal Elements prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

The product manufacturer warrants that the allograft will conform to the specifications set forth herein provided that the allograft is handled, stored, and implanted by health care professionals according to the requirements set forth herein or as provided by it in writing. The product manufacturer makes no other warranties regarding the allograft; specifically disclaims any implied or statutory warranties, including any warranty against disease transmission; and makes no representations or warranties concerning the biological properties or biomechanical properties of the allograft.

SPINAL elements

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