PRO3-P™ and PRO3-C™ Amniotic Membranes

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).

80-129 Rev. 04
P01-IFU-0004 RevE

The PRO3 amniotic membrane (a product family consisting of the PRO3-P amniotic placental membrane and PRO3-C amniotic umbilical cord membrane) is a semi-transparent, collagenous membrane allograft obtained with consent from healthy mothers during cesarean section delivery. The PRO3-P amniotic placental membrane is derived from the amnion layer of the fetal membranes. The PRO3-C amniotic umbilical cord membrane is derived from the umbilical cord.

The PRO3-P amniotic placental membrane and the PRO3-C amniotic umbilical cord membrane have been processed using aseptic techniques and dehydrated. The allograft has been 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 PRO3-P amniotic placental membrane and the PRO3-C amniotic umbilical cord membrane are intended for use as a soft tissue barrier or wound covering.

CONTRAINDICATIONS

The PRO3-P amniotic placental membrane and the PRO3-C amniotic umbilical cord membrane have no known contraindications.

DONOR ELIGIBILITY

The PRO3 amniotic membrane was 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 has been screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the donor screening and testing has 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 was 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 were found to be nonreactive or negative:

Human Immunodeficiency Virus (HIV)
HIV-1/2 Antibodies (HIV-1/2-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 (if performed) (HBV NAT)
Hepatitis C Virus (HCV)
HCV Antibody (HCVAb)
Nucleic Acid Test for HCV RNA (HCV NAT)
Human T Cell Lymphotrophic Virus I/II* (if performed)
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 with a reactive result for the HTLV-I/II Antibody test is suitable for use only when the result from a confirmatory assay is nonreactive.
**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 suitable for 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 is not required for these tests, however, all results are evaluated on a case-by-case basis by the Medical Director (or licensed physician designee).

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)

WARNINGS

The donor of the PRO3 amniotic membrane has been 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). The PRO3 amniotic membrane processed using aseptic techniques and microbiologically tested. The allograft has been terminally sterilized by electron beam radiation technology in accordance with ANSI/AAMIISO 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

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 sterilants may render the allograft unfit for use.

PRECAUTIONS

The PRO3 amniotic membrane was processed and packaged using aseptic techniques and sterilized. The allograft must be handled in an aseptic manner to prevent contamination.

80-129 Rev. 04
P01-IFU-0004 RevE

ADVERSE EVENTS

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, transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, hepatitis, syphilis, or microbial contaminants.

STORAGE

The PRO3 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.

ALLOGRAFT PREPARATION

USE CAUTION WHEN OPENING; THE PRO3 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.

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

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

It is not necessary to rehydrate the PRO3 amniotic membrane prior to use.

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.

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.

PRO3 AMNIOTIC MEMBRANE ORIENTATION

The epithelial layer of the PRO3 amniotic membrane is facing upwards when one of the following two (2) scenarios are true:

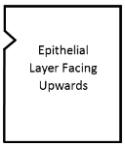

Figure 1.

1. **A triangle notch** is 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.

To facilitate identification of the epithelial layer, combinations of the above listed scenarios might be present.

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 OUTCOME AND COMPLAINT REPORTING

Adverse outcomes potentially attributable to the PRO3 amniotic membrane must be promptly reported to Vivex Biologics, Inc. at (888) 684-7783. Any other complaints must be promptly reported to Paragon 28, Inc. at (855) 786-2828.

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 Paragon 28, Inc. prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

Exclusively foot & ankle Paragon 28®

Distributed by:
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, Colorado 80112 USA
TEL: (855) 786-2828
FAX: (888) 728-1220
www.paragon28.com

Manufactured by:
Vivex Biologics, Inc.
1951 N.W. 7th Avenue, Suite 200
Miami, Florida USA 33136

PRO3-P™ and PRO3-C™ are trademarks of Paragon 28, Inc.

Copyright © 2019 Vivex Biologics, Inc. All rights reserved.

STERILE R
Sterilized by Irradiation

80-129 Rev. 04
P01-IFU-0004 RevE