PRO3™-C AND PRO3™-P AMNIOTIC MEMBRANES

DISTRIBUTED BY:
PARAGON 28, INC.
4B INVERNESS CT. E, STE 280
ENGLEWOOD, CO USA 80112
TEL: (888) 728-1888 | FAX: (888) 728-1220
www.paragon28.com

PROCESSED BY:
UMTB BIOMEDICAL INC.
1951 N.W. 7th AVENUE, SUITE 200
MIAMI, FLORIDA USA 33136
TEL: (888) 684-7783 | FAX: (305) 356-0900
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QUALITY ASSURANCE STATEMENT AND PREPARATION FOR USE INSTRUCTIONS

80-039 02 06/2015

The enclosed tissue is for single patient use only. There is no charge for the tissue. Accompanying charges cover excision and processing expenses.

The enclosed donated human-tissue allograft distributed by Paragon 28, Inc. and processed by UMTB Biomedical, Inc. is for use by, on order for, a licensed physician. The tissue was recovered and processed aseptically, following rigorous and technical quality assurance standards, in a controlled environment. The donor and donor tissue have been subjected to extensive biological and medical screening to guard against the possibility of recipient exposure to, or transmission of, infectious processes such as HIV, Hepatitis, or exclusionary medical conditions. These screening procedures are performed in accordance with standards, regulations, statutes and/or directives of the American Association of Tissue Banks (AATB)[1], the U.S. Food and Drug Administration (FDA)[2], State Licensing Agencies[3,4,5,6,7], the European Union[9], and Health Canada[10]. Additional infectious disease testing and screening in excess of the requirements by the AATB and FDA may have been completed. Data has been reviewed by a Medical Director or Associate Medical Director (licensed physician) of UMTB Biomedical, Inc. and the allograft has been deemed suitable for transplantation.

DESCRIPTION

The Pro3™-P Amniotic Placental Membrane and Pro3™-C Amniotic Umbilical Cord Membrane are semi-transparent collagenous membranes obtained with consent from healthy mothers during cesarean section delivery. The Pro3™-P membrane is derived from the amnion layer of the fetal membranes. The Pro3™-C patch is derived from the umbilical cord. Pro3™-P and Pro3™-C are processed by UMTB Biomedical, Inc. and distributed by Paragon 28, Inc.

APPLICATIONS FOR USE

This tissue is restricted to homologous use as a soft tissue barrier or wound covering. This tissue is for single patient use only, and is restricted to use by a licensed physician.

DONOR SCREENING & TESTING

1. A qualified donor blood sample was tested using test kits licensed (if available) for donor screening by a laboratory certified/registered to perform such testing in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and FDA. All required **infectious disease tests** listed below were found to be **nonreactive or negative**.

TEST	SYMBOL
-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 applicable)	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 applicable)	
HTLV-I/II Antibody	HTLV-I/II-Ab*
-Syphilis – Rapid Plasma Reagin Screen	RPR**
or	
T. Pallidum IgG	T. pallidum IgG

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

**Tissues from 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, are cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

2. Non-required screening tests for exposure to other viruses or parasites such as those listed below may have been completed on the donor by other agencies involved in the donation process. A negative/nonreactive result is not required for these tests; however, all donors are evaluated on a case-by-case basis by the Medical Director or Associate Medical Director.

-Cytomegalovirus	CMV Ab (IgG & IgM)	-Toxoplasma gondii	Toxoplasma Ab (IgG & IgM)
-Epstein Barr Virus	EBV Ab (IgG & IgM)	-Trypanosoma cruzi	T. cruzi Ab (IgG & IgM)

3. The accompanying allograft has been subjected to **microbiologic studies** at each phase of development: recovery, processing, and final packaging.
4. There are no known contraindications.

Although all efforts have been made to ensure the safety of the allograft, current technologies may not preclude the transmission of all diseases. As with any surgical procedure, the potential for infection exists.

Any adverse outcomes potentially attributable to the tissue must be reported immediately to UMTB Biomedical, Inc. at the telephone number indicated above.

OVER

STORAGE REQUIREMENTS AND PREPARATION FOR USE OF PRO3™-C AND PRO3™-P AMNIOTIC MEMBRANES

The Pro3™-C and Pro3™-P Amniotic Membranes have been dried, sealed in its packaging container, and must be stored at ambient temperature. It is the responsibility of the end-user to store tissues in appropriate storage conditions prior to further distribution or transplant, and to track expiration date accordingly. It is not necessary to reconstitute the Pro3™-C or Pro3™-P prior to implantation. *Once the package seal is broken, the allograft must be used within 24 hours.*

The allograft was processed and packaged aseptically and must be handled in an aseptic manner to prevent contamination.

DO NOT USE IF PACKAGE INTEGRITY HAS BEEN COMPROMISED.
ONCE THE USER BREAKS THE SEAL, THE GRAFT MUST BE TRANSPLANTED (if appropriate) OR DISCARDED.

PREPARATION INSTRUCTIONS FOR PRO3™-C AND PRO3™-P AMNIOTIC MEMBRANES

The Pro3™-C and Pro3™-P Amniotic Membranes are aseptically packaged in one tear-pouch and one peel pouch and secured in a box to ensure allograft integrity. THE INNER POUCH IS CONSIDERED STERILE. USE CAUTION WHEN OPENING, THE PRO3™-C AND PRO3™-P ARE SEMI-TRANSPARENT MEMBRANES.

Step 1: Remove the graft from the box packaging.

Step 2: Inspect the pouch packaging. DO NOT USE if the packaging is damaged, if elements are missing or appear to have been tampered with, if the labeling is illegible, or if the expiration date occurs in the past.

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

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

Step 5: Using sterile non-toothed forceps, grasp the Pro3™-C or Pro3™-P Amniotic Membrane and place it directly at the surgical or wound site. It is not necessary to reconstitute the graft prior to use. If placing the graft epithelial side up and stromal side down, orient the graft such that the notch is in the upper left corner.

TISSUE TRACKING INSTRUCTIONS

It is the responsibility of the end-user or the clinician to provide information pertaining to the traceability of the implanted tissue[8]. For this purpose, a postage paid *Tissue Utilization Report* (TUR) card is provided with the allograft. Once the graft is implanted, 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 UMTB Biomedical, Inc., scan to the e-mail turs@umtb.com or Fax to (888) 630-4321.

COMPLAINTS AND RETURNS

Complaints should be reported to Paragon 28, Inc. at TEL (888) 728-1888 in a timely manner. If for any reason tissue must be returned, a return authorization is required from Paragon 28 Customer Service prior to shipping. If the plastic packaging surrounding the graft has been open or compromised, returns will not be accepted. It is the responsibility of the health care institution returning the tissue to adequately package and label the tissue for return shipment.

ORDERS AND INQUIRIES

For additional information about Pro3™-C or Pro3™-P Amniotic Membrane or to place an order, contact Paragon 28 Customer Service at:

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References

1. Standards for Tissue Banking; American Association of Tissue Banks, 13th Edition, Issued February 29, 2012. **(Accredited)**
2. Code of Federal Regulations, Title 21 Part 1271 – Donor Eligibility and Good Tissue Practice (GTP) regulations for Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps), U.S. Food and Drug Administration, Final Rule, April 1, 2010. **(Registered)**
3. Florida Administrative Code Chapter 59A, Regulations of the Agency for Health Care Administration of the State of Florida, 2008. **(Certificate Issued)**
4. Part 52 of Title 10 (Health) of the Official Compliance of Codes, Rules & Regulations of the State of New York, February 24, 2007. **(Licensed)**
5. Title 10 Subtitle 50 Chapter 01 of the Official Compliance Codes, State of Maryland Department of Health and Mental Hygiene, December 1999. **(Permit Issued)**
6. Chapter 4.1 & Chapter 4.2 of the California Health and Safety Code, State of California Department of Health Services, January 2011. **(Licensed)**
7. Chapter 28 of Title 16 Health and Safety Delaware Code, February 22, 2011. (Registered)
8. Accreditation Program: Hospital Transplant Safety, The Joint Commission on Accreditation of Healthcare Organizations, 2008. **(Licensing Not Applicable)**
9. Commission Directive 2006/17/EC of 8 February 2006; Directive 2004/23/EC, Official Journal of the European Union, February 2006. **(Pending Registration)**
10. SOR/2007-118, Safety of Human Cells, Tissues and Organs for Transplantation Regulations of the Food and Drugs Act, Minister of Justice of Canada, December 2012. **(Registered)**

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Nucleic Acid Test for HIV-1 RNA	HIV-1 NAT
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