PRO3™-F AMNIOTIC FLUID ALLOGRAFT

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
www.umtb.com

QUALITY ASSURANCE STATEMENT AND PREPARATION FOR USE INSTRUCTIONS

80-076 02 12/2015

The enclosed allograft 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, or 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 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

Pro3™-F is a versatile and manageable Amniotic Fluid Allograft product that is derived from donated human birth tissue and fluid. Amniotic fluid and membrane are obtained with consent from healthy mothers during cesarean section delivery.

APPLICATIONS FOR USE

This tissue is restricted to homologous use as an additive for surgical applications associated with soft tissue procedures. This allograft 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.

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

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

There have been no reported adverse reactions associated with Pro3™-F Amniotic Fluid Allograft, however general risks and complications may include, but are not limited to infection, bleeding, injury to nerves, etc. Complications may occur with tissue transplantation and surgeons should discuss the following possible adverse events with their patients (transmission of disease of unknown etiology, transmission of unknown infectious agents including, but not limited to, HIV, Hepatitis, syphilis and bacteria, and immune rejection of HCT/P).

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

STORAGE REQUIREMENTS AND PREPARATION FOR USE OF PRO3™-F AMNIOTIC FLUID ALLOGRAFT

The allograft has been frozen, sealed in its packaging container, and must be stored frozen at -80ºC ± 15ºC. 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 dilute the allograft prior to implantation.

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

The allograft is aseptically packaged in a single peel pouch and secured in a box to ensure allograft integrity.

Step 1. Remove carton from either the freezer or the dry ice shipping container. Open and remove the allograft 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. Remove vial from inner pouch. Thaw vial in hand prior to taking the cap off. Allow product to thaw completely prior to implantation.

Step 5. Draw the allograft out of the vial with a sterile 30g or larger needle. The allograft may then be implanted directly, or may be mixed with an equal amount of any one of the following diluents prior to implantation.

- 1% plain preservation free Lidocaine
- Normal Saline
- Platelet rich plasma
- Bone marrow aspirate
- Patient's blood

Step 6. Apply the allograft or mixed allograft using a 30g or larger needle into and around the area requiring the allograft.

Step 7. After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

TISSUE TRACKING INSTRUCTIONS

It is the responsibility of the end-user or the clinician to provide UMTB Biomedical, Inc. with information pertaining to the traceability of the implanted tissues. For this purpose, the 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 and e-mail to 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. Returns will not be accepted.

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)**

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
www.umtb.com

80-076 02 12/2015
P01-IFU-0005 RevA

PRO3™-F AMNIOTIC FLUID ALLOGRAFT

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
www.vivex.com

QUALITY ASSURANCE STATEMENT AND PREPARATION FOR USE INSTRUCTIONS

80-122 01 01/2016

The enclosed allograft 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, or on order for, a licensed physician. The tissue was recovered and processed aseptically, following rigorous technical and quality assurance standards, in a controlled environment. The donor and donor tissue have been subjected to 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. 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

Pro3™-F is a versatile and manageable Amniotic Fluid Allograft product that is derived from donated human birth tissue and fluid. Amniotic fluid and membrane are obtained with consent from healthy mothers during cesarean section delivery.

APPLICATIONS FOR USE

This tissue is restricted to homologous use as an additive for surgical applications associated with soft tissue procedures. This allograft 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 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicaid and Medicare Services (CMS). 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.

-Cytomegaliovirus	CMV Ab (IgG & IgM)
-Epstein Barr Virus	EBV Ab (IgG & IgM)
-Toxoplasma gondii	Toxoplasma 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: pre-processing and final packaging.
4. There are no known contraindications.

There have been no reported adverse reactions associated with Pro3™-F Amniotic Fluid Allograft, however general risks and complications may include, but are not limited to infection, bleeding, injury to nerves, etc. Complications may occur with tissue transplantation and surgeons should discuss the following possible adverse events with their patients (transmission of disease of unknown etiology, transmission of unknown infectious agents including, but not limited to HIV, Hepatitis, syphilis and bacteria, and immune rejection of HCT/P).

Any adverse outcomes potentially attributable to the tissue must be reported immediately to UMTB Biomedical, Inc. at the TEL (888) 684-7783.

OVER

STORAGE REQUIREMENTS AND PREPARATION FOR USE OF PRO3™-F AMNIOTIC FLUID ALLOGRAFT

The allograft has been frozen, sealed in its packaging container, and must be stored frozen at -80ºC ± 15ºC. 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 dilute the allograft prior to implantation.

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

The allograft is aseptically packaged in a single peel pouch and secured in a box to ensure allograft integrity.

Step 1. Remove carton from either the freezer or the dry ice shipping container. Open and remove the allograft 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. Outside of the sterile field, from the chevron end, peel open the pouch and present the inner pouch containing the cryovial to the sterile field.

Step 4. Open the inner pouch and remove the cryovial containing the Amniotic Fluid Allograft using standard sterile technique.

Step 5. Thaw vial in hand prior to taking the cap off. Allow product to thaw completely prior to implantation.

Step 6. Draw the allograft out of the vial with a sterile 30g or larger needle. The allograft may then be implanted directly, or may be mixed with an equal amount of any one of the following diluents prior to implantation.

- 1% plain preservation free Lidocaine
- Normal Saline
- Platelet rich plasma
- Bone marrow aspirate
- Patient's blood

Step 7. Apply the allograft or mixed allograft using a 30g or larger needle into and around the area requiring the allograft.

Step 8. After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state, and federal regulations.

TISSUE TRACKING INSTRUCTIONS

It is the responsibility of the end-user or the clinician to provide UMTB Biomedical, Inc. with information pertaining to the traceability of the implanted tissue. For this purpose, the 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 and e-mail to 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. Returns will not be accepted.

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
www.vivex.com

80-122 01 01/2016
P01-IFU-0005 RevB