

Pro3™ Flowable Ambient



STERILE | R

Sterilized by Irradiation

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).*

**80-338 Rev. 02
P01-IFU-0008 Rev B**

Pro3 Flowable Ambient (Pro3-FA) is derived from donated human birth tissue and fluid. Birth tissue is obtained with consent from cesarean section delivery. Pro3-FA is processed using aseptic techniques and stored under ambient temperature conditions. The allograft is packaged in a sterile vial and sealed in packaging consisting of 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

Pro3-FA is intended to provide cushioning within joint capsules when a physician concludes that such function is medically indicated.

CONTRAINDICATIONS

Pro3-FA has no known contraindications.

DONOR ELIGIBILITY

Pro3-FA 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 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 has been 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 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 Lymphotropic Virus I/II*

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

Syphilis**

Rapid Plasma Reagin (RPR) Screen

T. Pallidum IgG 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 are cleared for transplantation 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, are 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 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 Pro3-FA 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). Pro3-FA was 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.

DO NOT FREEZE the allograft by any method.

FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY

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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.

PRECAUTIONS

Pro3-FA was processed and packaged using aseptic techniques and terminally sterilized. The allograft must be handled in an aseptic manner to prevent contamination.

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

Pro3-FA 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

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

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

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

It is not necessary to dilute the allograft prior to implantation.

Step 1: Remove the pouch containing the allograft from the outer container.

Step 2: Utilizing aseptic technique, peel open the outer peel pouch from the chevron end and present the inner pouch that contains the sterile vial containing the allograft to the operative field.

Step 3: Locate the tear notch on the pouch and tear open, removing the vial containing the allograft.

Step 4: Carefully invert the vial containing the allograft several times.

Step 5: Draw the allograft out of the vial with a sterile 30G or larger needle into a syringe.

Step 6: Apply the allograft using a 30G or larger needle into and around the targeted area.

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 Pro3-FA 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® prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.



Distributed by:

Paragon 28®, Inc.
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