VIA® Graft

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).

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VIA Graft is a bone allograft that consists of a bone particulate component and a cell component. The bone particulate component is derived from mineralized and demineralized bone particulates.

VIA Graft has been processed using aseptic techniques. The bone particulate component of the allograft has been treated with an antimicrobial solution (containing Gentamicin and either Vancomycin or Bacitracin), hydrogen peroxide and hydrochloric acid solutions. The bone particulate component has been lyophilized and aseptically packaged in a tear pouch within a peel pouch configuration. The bone particulate component has been sterilized using electron beam radiation.

The cell component has been treated with an antimicrobial solution (containing Gentamicin and either Vancomycin or Bacitracin) and frozen with a 100% polyampholyte-based cryoprotectant. The cell component has been aseptically packaged in a tear pouch within a peel pouch configuration.

All the respective components of VIA Graft have been packaged in one single outer container.

INTENDED USE

VIA Graft is intended for use as a bone void filler.

CONTRAINDICATIONS

VIA Graft is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, Bacitracin, hydrochloric acid, hydrogen peroxide or polyampholytes.

DONOR ELIGIBILITY

VIA Graft was recovered from qualified donors 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 donors have been screened and tested for communicable disease risks and other exclusionary medical conditions. The results of these donor screenings 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 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 have been found to be nonreactive or negative:

Cytomegalovirus*
CMV Ab (IgG & IgM)
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*
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 CMV or 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).

Epstein Barr Virus
EBV Ab (IgG & IgM)
Toxoplasma gondii
Toxoplasma Ab (IgG & IgM)
Trypanosoma cruzi
T. cruzi Ab (IgG & IgM)
Zika Virus
Zika Ab (IgM) and RT-PCR

WARNINGS

The donors of VIA Graft have 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). VIA Graft was processed using aseptic techniques and microbiologically tested. The bone particulate component 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 RE-FREEZE the allograft by any method.

FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY.

DO NOT 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

VIA Graft was processed and packaged using aseptic techniques and 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.

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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

VIA Graft must be stored at -65°C or colder. 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 CONTAINER SEAL HAS BEEN COMPROMISED, the allograft must be reconstituted and used within 4 hours of thawing, if appropriate, or otherwise discarded.

THE CHEVRON PEEL POUCHES ARE NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

OUTERMOST PACKAGE IS A PROTECTIVE COVERING FOR THE PRODUCT COMPONENTS(S).

ONLY CONTENTS OF INDIVIDUAL PRODUCT COMPONENT(S) should be presented to the operative field.

Step 1: Prepare a sterile saline or sterile water bath for thawing of the cell vial.

Step 2: Remove the chevron peel pouch containing the cell vial from the outer container.

Step 3: Utilizing aseptic technique, peel open the chevron peel pouch containing the cell vial from the chevron end and present the inner pouch containing the cell vial to the operative field.

Step 4: Remove the cell vial from the inner pouch using standard aseptic technique.

Step 5: Place the vial containing the frozen cell solution in the bath for 3-5 minutes, or until the contents of the cell vial have completely thawed.

Step 6: While the cell vial is thawing, remove the chevron peel pouch containing the bone particulate jar and spatula.

Step 7: Utilizing aseptic technique, peel open the chevron peel pouch from the chevron end and present the inner pouch containing the bone particulate jar and spatula to the operative field.

Step 8: Remove the bone particulate jar and spatula from the inner pouch using standard aseptic technique.

Step 9: Remove the liner from the inside of the bone particulate jar and add sterile saline directly to the bone particulate jar. Refer to **Table 1** for specific volumes of saline for each size:

Table 1 –Formulation Guide

Size	1 cc	2.5 cc	5 cc	10 cc
Saline Volume per Jar	0.6 mL	1.5 mL	3 mL	6 mL

Step 10: Using the spatula, mix the saline and bone particulate thoroughly.

Step 11: After the contents of the cell vial have completely thawed, carefully invert the cell vial several times.

Step 12: Pour the contents of the thawed cell vial directly into the jar containing the bone particulate/saline mixture.

Step 13: Using the spatula, mix the contents of the cell vial and the bone particulate/saline thoroughly.

Step 14: The jar containing the prepared allograft should be capped until ready for use and must be implanted within 4 hours from time of initial cell thaw.

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 VIA Graft or other complaints must be promptly reported to Vivex Biologics, Inc. at (888) 684-7783.

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

VIVEX BIOLOGICS

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