Orios Bone Matrix® Bone Matrix

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). NOT INTENDED FOR VETERINARY USE.

80-375 Rev. 02

DESCRIPTION

Orios Bone Matrix Bone Matrix 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.

The bone particulate component is lyophilized and provided sterile. The cell component is frozen with a 100% polyampholyte-based cryoprotectant. Each component of Orios Bone Matrix is aseptically processed and packaged in an inner tear pouch within an outer peel pouch. The individual components of Orios Bone Matrix are packaged together and sealed in an outermost peel pouch to ensure allograft integrity.

INTENDED USE

Orios Bone Matrix is intended for use as a bone void filler.

CONTRAINDICATIONS

Orios Bone Matrix is contraindicated in patients with known sensitivities or allergies to any of the agents listed below in the Warnings section and in patients who have an active systemic infection or any disorder that would create an unacceptable risk of post-operative complications.

DONOR ELIGIBILITY

Orios Bone Matrix is 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 are 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 is 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 Plus O Antibodies (HIV-1/2 Plus O 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 (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
West Nile Virus (WNV)***
Nucleic Acid Test for WNV RNA (WNV NAT)
Zika Virus***
Zika Ab (IgM)
Nucleic Acid Test for Zika RNA (Zika NAT)

*A donor with a reactive result for the CMV or HTLV-I/II Antibody test is 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, is cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.
***These tests are only required for a cell donor.

Screening tests for exposure to other viruses or parasites such as those listed below may have been completed. A negative/nonreactive result may not be required for these tests; however, all results are evaluated on a case-by-case basis by the Medical Director (or licensed physician designee) of VIVEX Biologics.

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

WARNINGS

The donors of Orios Bone Matrix are screened and tested for relevant communicable diseases and disease agents, and the tissue is microbiologically tested. Orios Bone Matrix is processed using aseptic techniques and may be exposed to Gentamicin, Vancomycin, hydrogen peroxide, hydrochloric acid, and phosphate buffer solution. Although the tissue is rinsed using sterile water or sterile saline during the manufacturing process, trace amounts may remain. The cell component is cryopreserved in a polyampholyte-based cryoprotectant, which is not rinsed prior to use. The bone particulate component is terminally sterilized by electron beam irradiation, validated 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. Orios Bone Matrix may transmit infectious agents.

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 sterilant may render the allograft unfit for use.

ADVERSE EVENTS AND REACTIONS

Possible adverse events may include:

- Immunologic response (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)
- Transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, syphilis, or microbial contaminants
- Infection of soft tissue and/or bone (osteomyelitis)
- Incomplete bone growth, delayed union or nonunion
- Fever

STORAGE

Orios Bone Matrix 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.

PRECAUTIONS

Orios Bone Matrix is processed and packaged using aseptic techniques and must be handled in an aseptic manner to prevent contamination.

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 transplanted within 4 hours of thawing, if appropriate, or otherwise discarded.

The outermost peel pouch is a protective covering for the product component(s) and is not sterile. The component-specific peel pouches are also not sterile. These pouches should not be placed on an operative field. Only the inner tear pouches should be presented to the operative field.

ALLOGRAFT PREPARATION

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

Step 2: Remove the peel pouch containing the cell vial from the outermost pouch and inspect the pouch for any holes, tears, or incomplete seals.

Step 3: Using aseptic technique, open the peel pouch containing the cell vial from the chevron end and present the sterile 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 peel pouch containing the bone particulate jar and spatula from the outermost pouch and inspect the pouch for any holes, tears, or incomplete seals.

Step 7: Using aseptic technique, open the peel pouch from the chevron end and present the sterile 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:

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

Table 1 –Formulation Guide

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 clinician to provide VIVEX Biologics 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, scan and e-mail to turs@VIVEX.com, or fax to (888) 630-4321.

ADVERSE REACTION OUTCOME AND COMPLAINT REPORTING

Adverse reaction outcomes potentially attributable to the allograft must be promptly reported to VIVEX Biologics at (888) 684-7783. Any other complaints must be promptly reported to Spinal Elements at (760) 607-0121.

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 Spinal Elements prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

The product manufacturer warrants that the allograft will conform to the specifications set forth herein provided that the allograft is handled, stored, and implanted by health care professionals according to the requirements set forth herein or as provided by it in writing. The product manufacturer makes no other warranties regarding the allograft; specifically disclaims any implied or statutory warranties, including any warranty against disease transmission; and makes no representations or warranties concerning the biological properties or biomechanical properties of the allograft.

Distributed by:
Spinal Elements
3115 Melrose Drive, Suite 200
Carlsbad, California 92010, USA
P: (760) 607-0121|www.spinalelements.com

Manufactured by:
VIVEX Biologics, Inc.
2430 NW 116th Street
Miami, Florida 33167 USA
P: (888) 684-7783 F: (305) 356-0900