Orios® Moldable Plus Bone Matrix

DONATED HUMAN TISSUE

RESTRICTED TO USE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PROVIDER (physician, dentist, podiatrist, optometrist, nurse practitioner or physician assistant). NOT INTENDED FOR VETERINARY USE.

80-396 Rev. 04

DESCRIPTION

Orios® Moldable Plus Bone Matrix (Orios Moldable Plus) is a bone allograft that consists of a bone particulate component, a bone gel component, and a cell component. The bone particulate and bone gel components are derived from mineralized and demineralized bone particulates.

The bone particulate component is lyophilized and provided sterile. The cell component is preserved with a 100% polyampholyte-based cryoprotectant. Each component of Orios Moldable Plus is aseptically processed and packaged in an inner tear pouch within an outer peel pouch. The individual components of Orios Moldable Plus are packaged together, and sealed in an outermost peel pouch.

INTENDED USE

Orios Moldable Plus is intended for use for the repair, replacement, or reconstruction of osseous defects.

CONTRAINDICATIONS

Orios Moldable Plus 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

The tissue that comprises Orios Moldable Plus 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 have 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 of Vivex Biologics, Inc., and the donors have been deemed suitable for transplantation.

Communicable disease testing has been performed on each donor 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 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)
Syphilis*
Rapid Plasma Reagin (RPR) Screen
T. pallidum IgG

*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.

Additional tests for other communicable diseases, such as: Cytomegalovirus, Epstein Barr, HTLV I/II, Toxoplasma gondii, T-Cruzi, West Nile Virus, or Zika Virus may have been performed. The results of all additional communicable disease tests have been evaluated by the Medical Director and have been found acceptable according.

WARNINGS

The donors of the allograft are screened and tested for relevant communicable diseases and disease agents, and the tissue is microbiologically tested. The allograft 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 and prior to implantation, trace amounts of Gentamicin, Vancomycin, hydrogen peroxide, hydrochloric acid, and phosphate buffer solution may remain. The cell component is preserved with a polyampholyte-based reagent, which is not rinsed prior to use. The bone particulate component is terminally sterilized by a validated electron beam irradiation process in accordance with ANSI/AAMI/ISO 11137. Although 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. As with all allogenic materials, Orios Moldable Plus may transmit infectious agents; however, the risk is greatly reduced by the use of strict donor screening criteria, laboratory testing, and aseptic processing.

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.

DO NOT USE ALLOGRAFT IF EXPIRED.

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)
- Fever

STORAGE

Orios Moldable Plus 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 Moldable Plus is processed and packaged using aseptic techniques. The allograft must be handled in an aseptic manner to prevent contamination.

Do not use the allograft if the pouch integrity has been compromised.

Once the allograft container seal has been compromised, the allograft should be reconstituted and transplanted within 4 hours of thawing, if appropriate, or otherwise appropriately 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 and bone gel jar.

Step 2: Remove the peel pouch containing the bone gel jar 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 bone gel jar from the chevron end and present the inner pouch containing the bone gel jar to the operative field.

Step 4: Remove the bone gel jar from the inner pouch using standard aseptic technique.

Step 5: Place the bone gel jar in the bath until the contents of the bone gel jar have completely thawed.

Step 6: While the bone gel jar is thawing, remove the peel pouch containing the cell vial from the outermost pouch and inspect the pouch for any holes, tears, or incomplete seals.

Step 7: Using aseptic technique, open the peel pouch containing the cell vial from the chevron end and present the inner pouch containing the cell vial to the operative field.

Step 8: Remove the cell vial from the inner pouch using standard aseptic technique.

Step 9: 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 10: While the cell vial and bone gel jar are 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 11: Using aseptic technique, open the peel pouch from the chevron end and present the inner pouch containing the bone particulate jar and spatula to the operative field.

Step 12: Remove the bone particulate jar and spatula from the inner pouch using standard aseptic technique.

Step 13: Open the bone particulate jar and remove the liner. Add sterile saline directly to the bone particulate jar. Refer to **Table 1** for specific volumes of saline for each size:

Size	2.5 cc	5 cc	10 cc	15cc
Saline Volume per Vial	0.5 mL	1 mL	2 mL	3 mL

Table 1 – Formulation Guide

Step 14: Using the spatula, mix the saline and bone particulate thoroughly.

Step 15: After the contents of the cell vial have completely thawed, carefully invert the cell vial several times.

Step 16: Open the cell vial and pour the contents directly into the jar containing the bone particulate/saline mixture.

Step 17: Using the spatula, mix the contents of the cell vial and bone particulate/saline thoroughly.

Step 18: Once the contents of the bone gel jar have thawed completely, remove the bone gel jar from the bath.

Step 19: Open the jar and place the bone gel on the palm of the sterilely gloved hand.

Step 20: Using the spatula, press and spread the bone gel into the hand repeatedly until a smooth and homogenous paste consistency is obtained.

Step 21: Transfer the mixture of bone particulate/saline/cells onto the bone gel in the hand.

Step 22: Mix the bone particulate/saline/cells/bone gel mixture thoroughly until all components are incorporated and a uniform consistency is obtained.

Step 23: The prepared allograft should be placed back into the jar and capped until ready for use and should be transplanted within 4 hours from time of initial cell thaw.

RECIPIENT INFORMATION

Recipient records must be maintained for the purpose of traceability. It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain recipient records for the purpose of tracing tissue post-transplantation and 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 recipient 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 healthcare providers 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 infection; and makes no representations or warranties concerning the biological properties or biomechanical properties of the allograft.

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