

Orios XT[®]

Viable Allogenic 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.

80-607 Rev. 03

DESCRIPTION

Orios XT[®] is a cryopreserved viable bone allograft consisting of cancellous chips and demineralized bone fibers. Orios XT is aseptically processed and packaged in a syringe in an inner tear pouch within an outer peel pouch and secured in an outermost peel pouch. The allograft is frozen with a 100% polyampholyte-based cryoprotectant.

INTENDED USE

Orios XT is intended for use as a bone void filler.

CONTRAINDICATIONS

Orios XT 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 XT is 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 of Vivex Biologics, Inc., and the donor has 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 to regulations, standards, and Vivex Biologics policies and procedures.

WARNINGS

The donor of the allograft is 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, hydrochloric acid, and phosphate buffer solution. Although the tissue is rinsed using sterile water or sterile saline during the manufacturing process, trace amounts of Gentamicin, Vancomycin, hydrochloric acid, and phosphate buffer solution may remain. Orios XT is preserved with a polyampholyte-based reagent, which is not rinsed prior to use. 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 XT may transmit infectious agents; however, this 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 XT 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 XT 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 two outermost peel pouches are not sterile and should not be placed on an operative field. Only the inner tear pouch should be presented to the operative field.

80-607 Rev. 03

ALLOGRAFT PREPARATION

Step 1: Prepare an ambient sterile saline bath for thawing of the allograft.

Step 2: Remove the pouch containing the allograft by peeling the chevron end of the outermost peel pouch. Inspect all pouches for any holes, tears, or incomplete seals. Using aseptic technique, peel open the outer peel pouch from the chevron end and present the inner tear pouch to the operative field.

Step 3: Locate the tear notch on the inner pouch and tear open. Remove the syringe with product from the inner pouch and confirm the syringe cap is securely locked.

Step 4: Place the syringe in the ambient sterile bath for 10-15 minutes, ensuring the contents are submerged.

Step 5: After the allograft has completely thawed, remove the syringe end cap completely and apply slight pressure to the plunger to extrude the allograft.

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.

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

Orios XT® is a Registered Trademark® of Spinal Elements.