OsteoVive™

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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OsteoVive™ is a bone allograft consisting of the following components: bone scaffold and cells. The bone scaffold is derived from mineralized and demineralized bone microparticulates.

OsteoVive™ bone allograft 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, hydrochloric acid, and phosphate buffer solutions and lyophilized. The bone particulate component has been aseptically packaged in a tear pouch within a peel pouch configuration and frozen.

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

The bone and cell components of OsteoVive™ have been packaged in one single outer container.

INTENDED USE

OsteoVive™ is intended for use as a bone void filler.

Human tissue for transplantation shall not be offered, distributed or dispensed for veterinarian use.

CONTRAINDICATIONS

OsteoVive™ is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, Bacitracin, hydrochloric acid, hydrogen peroxide, or phosphate buffer.

DONOR ELIGIBILITY

OsteoVive™ was recovered from a qualified donor and 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 UMTB Biomedical, Inc. and the donor has been determined to be suitable.

Communicable disease testing was performed by an FDA-registered laboratory using FDA-licensed tests 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 were 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 Lymphotrophic Virus I/II* (if performed)
HTLV-I/II (Antibody HTLV-I/II-Ab)
Syphilis**
Rapid Plasma Reagin (RPR) Screen
T. Pallidum IgG

*A donor with a reactive result for the 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).

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 OsteoVive™ 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). OsteoVive™ was processed using aseptic techniques and microbiologically tested. 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

OsteoVive™ is 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.

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

OsteoVive™ 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 and 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

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

ONCE THE TEAR POUCH SEAL HAS BEEN OPENED, the allograft must be used, or otherwise discarded.

ONCE THAWED, the allograft must be used within 2 hours.

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

Step 1: Prepare a 37 ± 2 ˚C sterile saline or sterile water bath for thawing the cell vial(s). A prepared room temperature irrigation bath can also be used.

Step 2: Open the box for the cells and retrieve the pouch containing the cell vial(s).

Step 3: Open the outer pouch and present the inner pouch containing the cell vial(s) to the operative field.

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

Step 5: Add sterile saline to the vial(s) containing the frozen cells; refer to the table below for specific amounts for each size. Place the vial(s) containing the cell solution upright in the bath until the contents of the cell vial(s) have completely thawed.

Size	1 cc	2.5 cc	5 cc	10 cc
Amount Per Vial	0.6 mL	1.5 mL	3 mL	3 mL
Number of Vials	1	1	1	2

Step 6: Open the box for the microparticulate bone and retrieve the pouch containing the microparticulate jar.

Step 7: Open the outer pouch and present the inner pouch containing the microparticulate jar to the operative field.

Step 8: Remove the microparticulate jar from the inner pouch using standard aseptic technique.

Step 9: After the contents of the cell vial(s) have completely thawed, carefully invert the cell vial(s) several times. Remove the liner from the inside of the microparticulate jar and pour the contents of the thawed cell vial(s) into the microparticulate jar.

Step 10: Mix the contents of the cell vial(s) and the microparticulate bone thoroughly.

Step 11: Cap the jar of prepared graft and allow to sit for 15 minutes.

Step 12: The allograft is now ready for use.

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 XTANT Medical 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 XTANT Medical, scan and e-mail to cs@xtantmedical.com, or fax to (406) 388-3380.

ADVERSE OUTCOME AND COMPLAINT REPORTING

Adverse outcomes potentially attributable to OsteoVive™ should be promptly reported to UMTB Biomedical, Inc. at (888) 684-7783. Any other complaints should be promptly reported to XTANT Medical at (888) 886-9354.

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

XTANT MEDICAL

BACTERIN + X-spine

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