Allograft Tissue Information and Preparation Package Insert

Read Before Using

- **This Allograft Unit is Derived from Donated Human Tissue.**
- **This Allograft is Intended for Use in One Patient, on a Single Occasion Only.**
- **Caution: Federal (USA) law restricts this tissue to sale by or on the order of a physician or hospital.**
- **Human tissue for transplantation shall not be offered, distributed or dispensed for veterinary use.**
- **All tissue has been recovered, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (AATB), the US FDA regulations and the Health Canada CTO Regulations and associated Standards (when applicable).**

Contents

This package contains Donated Human Tissue Allografts as defined in US FDA 21 CFR Part 1271

Description

OsteoVive® Plus is a human tissue allograft consisting of cancellous bone combined demineralized bone fibers and demineralized cortical bone powder cryopreserved with a 0% DMSO cryopreservation solution with an osmolality of 300 – 380 mOsm/Kg H_20 under Drug Master File 29073. This graft was prepared from tissue procured from a deceased donor, determined to be eligible based on the result of donor screening and testing, using aseptic surgical techniques. This graft was processed by Xtant Medical and may contain traces of the processing reagents: cryoprotectant, physiological buffers, acids, alcohols, surfactants, hydrogen peroxide, PVP-Iodine, Citric Acid, Sodium Citrate, Glucose, Gentamicin Sulfate, Vancomycin HCl, and Amphotericin B.

Indications and Usage

Human Musculoskeletal allograft may be used in several orthopedic, reconstructive, and dental applications. Allograft bone may be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or it may be used as a standalone bone graft. Surgeons using these allografts should possess the training and skills necessary for use. A US flag on the packaging of the graft indicates the graft is only approved for distribution and use in the United States of America.

Donor Eligibility

Donor eligibility (screening and testing) is performed in accordance with US FDA regulations, and AATB Standards. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation.

Donor eligibility determination is conducted by a licensed Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request. Donor eligibility was determined by the following establishment:

Xtant® Medical
664 Cruiser Lane
Belgrade, MT 59714
(888)886-9354

Donor Serological Testing

Communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493. The testing was conducted using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens where applicable. The records of this testing are maintained at Xtant Medical. The following required testing was performed and found to be negative or non-reactive;

- HBsAg (Hepatitis B Surface Antigen)
- HBcAb (Hepatitis B Core Total Antibody)
- HBV-NAT (Hepatitis B Nucleic Acid Test)
- HCV (Hepatitis C Antibody)
- HIV 1/2-Ab (Antibody to Human Immunodeficiency Virus Types 1 and 2)
- Syphilis
- HIV-1 NAT (HIV-1 Nucleic Acid Test)
- HCV NAT (HCV Nucleic Acid Test).

Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I and II (HTLV I & II) may have been performed at the time of donor screening and were found to be acceptable for transplantation. A list of additional communicable disease test(s) performed will be provided upon request.

Processing

Technical Quality Assurance standards are rigorously maintained by Xtant medical. Processing is performed in a controlled, ISO Class 5 environment. All tissue is recovered and processed using aseptic techniques and each lot is evaluated according to aseptic control requirements set under an aseptic process validation. No aseptic tissue is released for transplantation unless the final culture results support no bacterial growth.

Quality Control Testing

Representative product from each lot is sacrificed for destructive microbiological verification testing per USP <71> Sterility tests. The results must show “No Growth” after 14 days incubation in growth promoting media.

Warnings/Contraindications

- Do not use if active or latent infection is present in or around the surgical implantation site.
- Do not use if patient has sensitivity or allergies to any of the processing agents listed above.
- Do not use in immune compromised patients.

The following precautions must be taken with this allograft:

- Single patient, single use only.
- Do not sterilize or re-sterilize.
- Do not use if packaging has been compromised. Return all allografts with compromised packaging to Xtant Medical.
- Do not use if the expiration date has been exceeded.
- Use of this tissue is limited to specific health professionals (e.g. physicians, dentists, and/or podiatrists)
- Do not use if the tissue has not been stored in accordance with the storage instructions specified in this insert.

Side Effects and Hazards

Despite the extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of an infectious disease through the use of this graft is still possible. Bacterial infection at the graft site may occur.

Any Transmission of disease that is suspected to be caused by the graft or any other adverse outcome potentially attributed to this graft must be reported to Xtant Medical.

Tissue Tracking

This graft is packaged in sterile, single-patient-use containers, with unique graft serial number, expiration date, product code, size, and additional information listed on the package label.

The Hospital must maintain records so that possible infections or other adverse reactions associated with this graft can be linked back to the original source. It is the responsibility of the user surgeon to complete recipient records for the purpose of tracking tissue post-transplant. Complete the enclosed Transplant Utilization Record in detail and return as indicated. If the graft is not used for any reason after opening, complete the enclosed Transplant Utilization Record in detail, noting the method of disposal, and return as indicated. Copies of this information should be retained by the transplant facility

Storage

It is the responsibility of the Tissue Dispensing Service and/or end-user clinician or facility to maintain this product in appropriate storage conditions prior to transplantation.

> **Frozen** Tissue – Store at temperature of -65 ºC or colder.

It is the responsibility of the end user to document the maintenance of the HCT/P at these required storage conditions.

General Instructions for Use

Always use aseptic technique when handling the graft. Do not use this allograft if: 1) Any of the package or product elements appears to be missing, tampered with or damaged; 2) The product label or identifying bar code is severely damaged, illegible or missing, or 3) The expiration date shown on the package label has passed. Once a package seal has been opened, the tissue shall be either transplanted, if appropriate, or otherwise discarded. Discard all unused portions of the graft.

Instructions for Use

OsteoVive Plus

1. OsteoVive Plus packaging consists of the following a) Dust Cover; b) Outer Pouch[1]; c) Inner pouch[1]; and d) Sealed Jar[1] or Syringe[1].
2. Remove the dust cover.
3. Examine the outer pouch for integrity. Do not use if there is evidence that the outer pouch is damaged or sterility has been compromised, or if the identifying bar code is severely damaged, illegible, or missing. Confirm that the expiration date shown on the included label has not passed.
4. Open the outer pouch using aseptic technique.
5. Introduce the sterile contents onto the sterile field.
6. Transfer the graft into a basin containing room temperature thawing solution such as sterile water or sterile saline.
7. Allow graft to thaw.
8. Warning: Do not use water/saline at a temperature greater than 39°C (102.2°F).
9. Once thawed, the tissue is ready for use and should be implanted within 4 hours.
10. Remove the sealed jar or syringe and twist off jar lid or syringe cap.
11. Remove graft from jar or push on plunger to extrude graft for use.
12. Note: It is not necessary to decant and discard excess preservation solution. The graft can be used as supplied.
13. Apply and use the OsteoVive Plus as per established surgical technique and surgeon's preference.

Note: Once the inner pouch containing OsteoVive Plus has been opened, the allograft must be transplanted during that surgical procedure or discarded.

[1] : *The outer pouch, inner pouch, and jar/syringe are sterilized prior to final packaging.*

Disclaimer

Xtant Medical makes no claims concerning the biological or biomechanical properties of allograft issue. All tissue has been collected, processed, stored, and distributed according to nationally recognized standards an in compliance with applicable U.S. Food and Drug Administration requirements. Although efforts have been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. **Adverse outcome potentially attributed to the tissue must be reported to Xtant Medical immediately.**

RETURNS

If for any reason tissue must be returned, a return authorization is required from Xtant Medical prior to shipping.

Manufactured and provided for distribution by Xtant Medical.

Xtant Medical
664 Cruiser Lane
Belgrade, MT 59714
888-886-9354