OsteoFactor Pro Allogeneic Proteins

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

OsteoFactor® Pro is a human tissue allograft. 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: physiological buffers, acids, alcohols, surfactants, hydrogen peroxide, PVP-Iodine, and Gentamicin Sulfate. Tissue is first disinfected and then terminally sterilized via gamma irradiation.

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

AlloSource®
6278 South Troy Circle
Centennial, CO 80111
(800)557-3587

STERILE R Sterilized using gamma irradiation

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.

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 in the description.
- 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.

Lyophilized Tissue – (Freeze-Dried Tissue) Store at room temperature (0°C - 37°C).

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

OsteoFactor Pro

Remove pouch from box.

1. Peel open the outer pouch using aseptic technique to access the inner pouch (primary sterile barrier).
2. Cut the inner pouch (primary sterile barrier) to open and access the vial.
3. Remove only the cap from vial and inject sterile water OR sterile saline with a needle and syringe through the rubber stopper.

Note: Refer to the following table for reconstitution volume:

OsteoFactor Pro Size	Suggested Reconstitution Volume
Small	1cc
Medium	2.5cc
Large	5cc
XLarge	10cc

Note: Additional solution may be added to remove any remaining product.

4. Vigorously agitate and invert the vial to ensure adequate mixing.
5. Remove the metal ring by pulling up and out; then remove the rubber stopper, if required.
6. Uniformly distribute reconstituted liquid onto a scaffold.

Disclaimer

Xtant Medical makes no claims concerning the biological or biomechanical properties of allograft tissue. All tissue has been collected, processed, stored, and distributed according to nationally recognized standards and 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