XTANT MEDICAL

MUSCULOSKELETAL ALLOGRAFT TISSUE PACKAGE INSERT

⇉⇊ Sterilized using gamma irradiation

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.**
- **This Allograft may not be Re-Sterilized.**
- **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).**

Description

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 Gentamicin, Polymyxin B Sulfate, Amphotericin B, Cefazolin, PVP-Iodine, alcohol and surfactants. Tissue is first disinfected and then terminally sterilized via gamma irradiation.

Indications and Usage

Human Musculoskeletal allograft may be used in a number of 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. 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, AATB Standards, and Health Canada CTO regulations. 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 one of the following establishments:

Xtant® Medical	AlloSource®
664 Cruiser Lane	6278 South Troy Circle
Belgrade, MT 59714	Centennial, CO 80111
(888)886-9354	(800)557-3587

The establishment responsible for donor eligibility can be identified via the donor number located on the product label. The first character, “A” or “B” corresponds to AlloSource or Xtant Medical respectively.

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

The allograft should not be used if the expiration date has been surpassed, the container in which the product is stored is damaged, the container is not labeled, or the product has not been stored at the recommended temperature. Caution should be exercised if the patient is allergic to any of the antibiotics or chemicals listed in processing and testing. The presence of infection at the transplantation site is a contraindication for the use of this allograft. Xtant Medical makes no claims concerning the biologic or biomechanical properties of this allograft tissue.

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 and the unique graft serial number, expiration date, product code, size, and additional information are 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.
Frozen Tissue – Store at temperature of -40 ºC or colder.
Pre-Hydrated Tissue – Store at room temperature.

Note: If the allograft is to be stored at temperatures between -20 ºC and -39 ºC, the tissue may only be stored for up to six months (storage time may not exceed the original expiration date documented on the tissue label). If the tissue is not implanted by the end of the 6 months, it must be discarded.

General Instructions for Use

Always use aseptic technique when handling the graft. 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.

Note: If the graft is thawed prior to the start of the procedure, it is recommended that the tissue be refrigerated at temperatures between 1 °C and 10 °C in an aseptic container for no longer than 24 hours.

Opening Instructions:

1. Peel open the outer pouch using aseptic technique.
2. Introduce the sterile contents onto the sterile field.
3. Follow preparation steps below for specific graft type (Lyophilized, Frozen, or Pre-Hydrated).

Frozen Grafts:

Frozen grafts are shipped on dry ice and must be maintained at the recommended temperature until ready for use. Before use, the allograft must be thawed using aseptic practices and utilized as soon as possible following thawing. The allograft must not be refrozen after thawing.

Do Not Microwave

1. Place the tissue into a basin on the operative field and, if desired, add sufficient sterile reconstitution fluid to cover the graft. Reference the table below for Thaw Time Recommendations.

Thaw Time Recommendations for Sterile FROZEN Tissue			
Type of Allograft	**Room Air**	**Warm Saline (37 °C)**	**Room Temp Saline**
Sports Medicine Allografts	30 Minutes	5 Minutes	10 Minutes

2. Place the thawed graft into a separate sterile basin for a series of baths to remove any potential residual traces of reagents used in processing the graft (3 baths for 5 minutes is the recommended practice), discarding the rinse solution between baths.

Lyophilized (Freeze Dried) Tissue:

1. Remove tissue from the sterile package and place into a basin. For products that come in a jar, remove and discard the lid.
2. Add sufficient sterile, room temperature fluid to cover the graft, ensuring the graft remains submerged during reconstitution. Normal saline, water for irrigation, Lactated Ringers or an antibiotic solution of the physician's preference may be utilized.

Reconstitution Times Recommendation for Sterile Lyophilized Tissue	
Type of Allograft	**Room Temp Fluid**
OsteoSponge®	5 to 30 Minutes or until desired malleability is achieved
OsteoWrap®	5 to 30 Minutes or until desired malleability is achieved
3Demin® Cortical Fibers, Boats and Strips	5 to 30 Minutes or until desired malleability is achieved
Lyophilized Soft Tissue Allografts	30 Minutes
Mineralized Bone Allografts	60 Minutes

OsteoSponge®, OsteoWrap® and 3Demin®

Due to biologic variability the reconstitution time for each graft will vary. Within a single graft some parts may rehydrate sooner than others.

OsteoWrap®

Larger sizes of OsteoWrap may feature a small, natural foramen (opening) as a result of its anatomical origin.

Pre-Hydrated Tissue:

Pre-hydrated grafts are packaged in pre-hydration fluid and stored at room temperature until ready for use. Pre-hydrated grafts are ready for immediate use and should be used as soon as possible after opening. Per surgeon's preference, tissue may be soaked or rinsed in sterile fluid prior to implantation.

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

Processed and provided for distribution by Xtant Medical.

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

Health Canada
CTO Registration
Certificate Number
100170