Exclusively foot & ankle Paragon 28®

STERILE | R

MUSCULOSKELETAL ALLOGRAFT TISSUE 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: Restricted to use by a Qualified Physician, Podiatrist or Dentist.**
- **This Allograft may not be Sterilized or Re-Sterilized by the End User.**

Description

This graft was prepared from tissue procured from a cadaver donor using aseptic surgical techniques. This graft was processed by Xtant 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 can be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or it can be used by itself as a bone graft. Dermal grafts may be used for replacement of damaged or inadequate integumental tissue.

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 Screening and Testing

The donor from whom this allograft was derived has been tested and found negative for the following tests:
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), and HCV NAT (HCV Nucleic Acid Test).

Additional RCDAD Donor Screening Test Attached in this Space.

If additional donor screening tests for RCDADs are not listed in this space there were none performed.

The donor was also tested for HTLV I/II (Human T lymphotrophic Virus Types I and II) and the results were found to be acceptable. Note: HTLV I/II testing is not currently a required test. If a donor was NOT tested for HTLV I/II the donor will be listed as a USA-only donor.

Additional donor screening tests may have been performed on the donor. If additional tests for Human Immunodeficiency Virus, Hepatitis B, Hepatitis C, or Syphilis were performed the results were reviewed and found to be **NEGATIVE**. Additional tests for other communicable diseases, such as West Nile Virus, T. Cruzi, Cytomegalovirus and Epstein Barr 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 Xtant policies and procedures. If additional screening tests were performed for relevant communicable disease agents and diseases (RCDADs) as defined by the US FDA, they will be listed along with results in the adjacent box labeled “Additional RCDAD Donor Screening Tests Attached In This Space”.

The communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing using FDA-licensed tests when available 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 donor was selected based on results of the donor screening tests, review of the donor’s medical history, social history, external exam and relevant medical records available at the time of recovery which may include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor eligibility. Such records have been evaluated by Xtant’s Medical Director and are sufficient to indicate that donor eligibility criteria in place at the time of procurement have been met. This tissue is eligible for transplantation.

The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the eligibility of this human tissue are on file at Xtant and are available upon request. The criteria used for donor selection are in accordance with current policies and procedures approved by Xtant. Policies and procedures for donor screening, serologic and microbiologic testing meet current standards established by the American Association of Tissue Banks and FDA Regulations and Guidance Documents.

Contraindications / Precautions

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 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. Any other complaints must be promptly reported to Paragon 28, Inc. at (855)-786-2828.

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. 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; 3) The expiration date shown on the package label has passed; or 4) Frozen allograft has not been stored according to storage temperature requirements or the allograft has been prematurely thawed. 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.

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

Opening Instructions:
1. Peal 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).

Lyophilized (Freeze Dried) Tissue:
1. Reconstitute tissue in sterile fluid at room temperature (normal saline, water for irrigation, or Lactated Ringer's) or antibiotic solution of physician's preference. Some product comes in a jar or syringe, remove and discard cap prior to use. The graft may be reconstituted in the jar or syringe or removed to a separate basin on the operative field

   Note: If reconstitution takes place prior to the start of the case, 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. Each allograft should be reconstituted individually.
2. Add sufficient sterile reconstitution fluid to the jar, syringe, or basin to cover the graft. Ensure the graft remains submerged during reconstitution. Rinse the allograft thoroughly with sterile solution prior to transplant.
3. For syringes, push on the plunger to extrude reconstituted graft.

Reconstitution Times Recommendation for Sterile Lyophilized Tissue	
Type of Allograft	**Room Temp Fluid**
BEAST™ Osteobiologic products	5 to 30 Minutes or until desired malleability is achieved

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

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

Donor Eligibility Assessment and Processed by:

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

Distributed by:

Paragon 28
14445 Grasslands Drive
Englewood, CO 80112
888-728-1888