XTANT MEDICAL

BACTERIN + X-spine

MUSCULOSKELETAL ALLOGRAFT
TISSUE PACKAGE INSERT

STERILE	R

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 Bacterin 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), 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).

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.

This donor may have been tested for HBV-NAT (Hepatitis B Nucleic Acid Test); if the donor was tested the results were found to be nonreactive. Note: HBV-NAT is not currently a required 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.

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 Bacterin 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".

Donor screening tests are performed by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and registered with the FDA to perform donor testing using FDA-licensed tests when available.

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 suitability. Such records have been evaluated by Bacterin'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 suitable 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 suitability of this human tissue are on file at Bacterin and are available upon request. The criteria used for donor selection are in accordance with current policies and procedures approved by Bacterin. Policies and procedures for donor screening, serologic and microbiologic testing meet current standards established by the American Association of Tissue Banks, current US Public Health Services Recommendations 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. Bacterin 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 Bacterin.

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 ambient room temperature or cooler. Do not freeze.
Frozen Tissue – Store at temperatures of -40 ºC to -80 °C. Do not store in liquid nitrogen.

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 appear 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. If any of the conditions exist or are suspected, this graft should not be used. 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.

Preparation of 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 technique. The allograft must not be refrozen after thawing. Each allograft should be thawed individually. The tissue should be used as soon as possible after it is thawed.

Do Not Microwave.

Directions for Frozen Grafts:

1. Utilizing aseptic technique, the non-sterile team member should peel open the outer peel pouch and deliver the middle peel pouch and inner sealed pouch to the sterile field or sterile team member.
2. The sterile team member should examine the peel pack to ensure it is intact. Graft should not be used if damage is noted.
3. Peel open the middle peel pouch, open the inner sealed pouch and remove the graft. The sterile graft is then placed into a separate basin on the operative field and sufficient sterile reconstitution fluid is added to cover the graft. Reference the table below* for Thaw Time Recommendations.
4. Place the thawed graft in a separate sterile basin for a series of baths (3 baths for 5 minutes is the recommended practice), discarding the rinse solution between baths. The purpose of this step is to remove any potential residual traces of reagents used in processing the graft.
5. Once the pouch seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.
6. Discard any unused portion.

* Thaw Time Recommendations for Sterile FROZEN Tissue			
Type of Allograft	**Room Air**	**Warm Saline (37 °C)**	**Room Temp Saline**
hMatrix ADM	45 Minutes	15 Minutes	20 Minutes
Sports Medicine Allografts	30 Minutes	5 Minutes	10 Minutes

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.

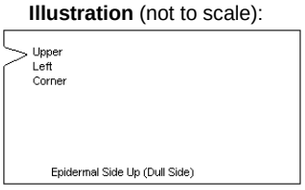
hMatrix ADM

If any hair is visible, remove before implantation using aseptic technique.

Orientation

The graft will have a small notch cut into the upper left corner of the graft (see illustration). When this notch is oriented in the upper left corner as pictured below, the graft will be in proper orientation for placement. The basement membrane (dull side) of the tissue will be up and the reticular side (shiny side) will be down. The reticular side should be placed against the most vascular tissue.

Illustration (not to scale):



Preparation of Lyophilized (Freeze-Dried) Grafts:

Reconstitute tissue in sterile fluid at room temperature (normal saline, water for irrigation, or Lactated Ringer's) or antibiotic solution of physician's preference. 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.

Directions for Sterile Freeze-Dried Tissues in Peel Packs, Jars, or Syringes:

1. Utilizing aseptic technique, the non-sterile team member should peel open the outer peel pouch and deliver the middle pouch and inner sealed pouch to the sterile field or sterile team member.
2. The sterile team member should examine the pouches to ensure they are intact. Graft should not be used if damage is noted.
3. Peel open the middle peel pouch, open the inner sealed pouch and remove the graft.
   a. Some grafts are packaged inside jars or syringes that are sealed inside the inner pouch.
   b. Once the jar or syringe is removed from the inner pouch, twist off jar lid or syringe cap.
   c. The graft may be reconstituted in the jar or syringe or removed to a separate basin on the operative field.
4. Add sufficient sterile reconstitution fluid to the jar, syringe, or basin to cover the graft. Ensure the graft remains submerged during reconstitution. Please refer to reconstitution times* for grafts. Rinse the allograft thoroughly with sterile solution prior to transplant.
5. For syringes, push on the plunger to extrude reconstituted graft.
6. Once the pouch seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.
7. Discard any unused portion.

* Reconstitution Times Recommendation for Sterile Lyophilized Tissue	
Type of Allograft	**Room Temp Fluid**
OsteoSponge® products	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.

Returns

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

Manufactured and provided for distribution by Bacterin.

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

Health Canada
CTO Registration
Certificate Number
100170