



TISSUE PACKAGE INSERT

QC-605-F-93 V 1.0

MEDLINEUNITE bone products consist of cancellous bone and may be used in a variety of orthopedic, neurosurgical, and reconstructive procedures.

MEDLINEUNITE is supplied in cancellous chips.

DESCRIPTION

DONATED HUMAN TISSUE. Tissue grafts are recovered from deceased human donors. All tissue is recovered, processed, stored and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB). Donor has been determined to be eligible by a Community Tissue Services Medical Director at 349 S. Main St., Dayton, OH 45402 based on the results of screening and testing. Screening includes a review of medical and social history, hospital records, infectious disease screening, autopsy report (if performed), and physical exam. Donors are tested and found negative (acceptable) for anti-HIV 1/2, HBsAg, anti-HBc, anti-HCV, HIV NAT, HBV NAT, HCV NAT and syphilis. U.S. Food and Drug Administration (FDA) licensed test kits are used when available. Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation.

Communicable disease testing was performed by a laboratory registered with 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, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

Aseptically processed musculoskeletal allografts are manufactured in a cleanroom environment, following rigorous quality assurance standards. Tissue labeled as **STERILE R** has been sterilized to an SAL of 10^{-6} (Sterility Assurance Level). Tissue labeled as **STERILE R** or irradiated has been Gamma Irradiated with Cobalt 60. Tissue has been processed with Bacitracin and/or Polymyxin B and traces may remain. Demineralized tissue has also been processed with HCl, alcohol, sodium phosphate (monobasic and dibasic) and traces may remain.

WARNINGS AND PRECAUTIONS

1. Intended for use in one patient, on a single occasion only.
2. Do not use if package integrity has been compromised. Once the user breaks the container seal, the tissue grafts must be transplanted or discarded.
3. Tissue may not be sterilized or re-sterilized.
4. This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrists.
5. Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents or diseases of unknown etiology. Infectious agents can include, but are not limited to, viruses, bacteria and fungi. Other complications can include, Immune rejection of the implanted HCT/P or loss of function and/or integrity of the implanted HCT/P due to resorption, fragmentation, and/or disintegration. However, the risk is greatly reduced by using the processing treatments shown to be capable of reducing this risk as well as the use of strict donor screening and validated processing methods.
6. Adverse outcomes potentially attributable to this tissue must be reported promptly to Medline Industries, Inc.
7. Do not use if the expiration date has been exceeded.
8. Do not use if the tissue has not been stored in accordance with the storage instructions specified in this insert.

TISSUE PREPARATION

FREEZE-DRIED TISSUE

1. Inspect for package integrity and expiration date prior to opening.
2. Tissue in peel packages: peel outer package down and aseptically deliver inner package to the sterile field or sterile team member.
3. Remove tissue from inner package and place in sterile basin and cover with normal saline or isotonic solution of choice. Antibiotics of choice may be added.
4. **IMPORTANT!** Crushed bone and soft tissue should be reconstituted for 30 to 45 minutes. Weight bearing grafts (tri-cortical blocks, segments, struts, dowels, etc.) should be reconstituted about 1 hour. Grafts that are to be manipulated by drilling or cutting may require a longer period of reconstitution time. Final determination of allograft reconstitution should be made by the physician prior to use.
5. Tissue should be used as soon as possible after reconstitution. If tissue is to be stored for longer than 2 hours after reconstitution, it should be refrigerated at 1 to 10°C in an aseptic container for no longer than 24 hours.
6. **IMPORTANT!** Peel away and remove all internal packaging materials from the graft (i.e. gauze or mesh) prior to implantation.

STORAGE

FREEZE-DRIED tissue must be stored at ambient temperature or colder.

Tissue may not be stored at liquid nitrogen (LN₂) vapor phase or LN₂ liquid temperatures. It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

TISSUE TRACKING

Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Complete the Allograft Tracking Form on the back of this form and return to Community Tissue Services. Federal Regulations (21 CFR 1271.290(b)) and Joint Commission Standards (TS.03.02.01, EP 7) require proper tracking of this tissue. It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

Medline Industries and Community Tissue Services make no claims concerning the biological or biomechanical properties of the provided tissue. Community Tissue Services disclaims all liability and responsibility for any misuse of tissue provided for clinical application.

Community Tissue Services is accredited by the American Association of Tissue Banks. Community Tissue Services – Center for Tissue, Innovation and Research is ISO 13485 certified. Health Canada Registration: 100076.

Please contact Medline Industries at 1-800-MEDLINE should you require further information.

Processed by:

Community Tissue Services
2900 College Drive
Kettering, Ohio 45420
800-684-7783

Distributed by:

Medline Industries, Inc.
Three Lakes Dr.
Northfield, IL. 60093
1-800-MEDLINE



How to return this form	
Email	tissueusage@patienttracking.care
Fax	937-222-2538

Allograft Tracking Form

FDA Regulations and Joint Commission Standards require tissue tracking systems in all hospitals using allograft tissue for transplantation. In order to comply with these requirements, please complete ALL fields on this form.

Date of Surgery: _____

Patient's Medical Record Number or Date of Birth: _____

Community Tissue Services does not consider the information requested on this form to be protected health information (PHI), as defined under the HIPAA regulations. Information considered to be PHI by the originator should not be released to Community Tissue Services.

**Place peel-off label for up to 4 allografts or write tissue ID# in the spaces provided.
One patient, one procedure per tracking form.**

Allograft Tissue ID# _____ Place Peel-Off Label Here

Allograft Tissue ID# _____ Place Peel-Off Label Here

Allograft Tissue ID# _____ Place Peel-Off Label Here

Allograft Tissue ID# _____ Place Peel-Off Label Here

**If any questions, problems, or adverse reactions occur,
contact 1-800-684-7783 at 1-937-222-0228.**