INSTRUCTIONS FOR USE

DESCRIPTION

DONATED HUMAN TISSUE.

Tissue grafts consisting of cortical and cancellous bone that is fully mineralized or has been partially demineralized 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). The 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 I/II, HBsAg, anti-HBc, anti-HCV, HIV NAT, HCV NAT, HBV 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 allografts are manufactured in a controlled clean room environment, following rigorous quality assurance standards. The sterility of the final product is tested using microbiological verification testing per USP <71>, Sterility Tests. Tissue has been processed with Gentamicin, Vancomycin, and Amphotericin 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 or dentists.
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.
6. Any adverse outcomes potentially attributable to this tissue must be reported promptly to Zimmer Biomet/Biomet 3i, LLC.

STORAGE

Freeze-dried tissue must be stored at ambient temperature or colder. 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.

TISSUE PREPARATION

FREEZE-DRIED TISSUE

1. Inspect for package integrity and expiration date prior to opening.
2. Peel outer package from the chevron end and aseptically deliver the container to the sterile field or sterile team member.
3. Secure the container in the upright position and ensure that the bone particulate is settled in the base of the container.
4. Unscrew the lid and place it in the upright position on the sterile field. Remove the liner from the container and discard.
5. Aspirate about 1 cc of normal saline (or isotonic solution of choice) into a syringe and gently dispense the solution into the container until the particulate tissue is moist and the desired consistency is attained. Antibiotics of choice may be added.
6. **IMPORTANT!** Particulate tissue must be reconstituted for a minimum of 5 minutes. Final determination of allograft reconstitution time should be made by the physician prior to use.
7. 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. Do not freeze.
8. **IMPORTANT!** Peel away and remove all internal packaging materials from the graft (i.e. gauze, liner, or mesh) prior to implantation.

Processed By:

Community Tissue Services
2900 College Drive
Kettering, OH 45420

Community Tissue Services makes 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.

ZIMMER BIOMET

Marketed By:

Biomet 3i, LLC
4555 Riverside Drive
Palm Beach Gardens, FL 33410
561-776-6700

Imported and Marketed in Canada by:

Zimmer Biomet Dental Canada, Inc.
2323 Argentia Road
Mississauga, ON L5N 5N3
CTO: C100086

ZIMMER BIOMET

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 this form and email or fax to the number at the top.

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 8 allografts or write tissue ID# in the spaces provided. One patient, one procedure per tracking form. Additionally, for end users in Canada also include the expiration date adjacent to the tissue ID per CTO regulations 31.3 and 31.20 if peel-off label is not used.

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
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 561-776-6700.