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 has been performed by a laboratory registered with the FDA and certified under CLIA or equivalent requirements.

TISSUE TRACKING
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 end-user to provide this information, which enables Community Tissue Services to maintain records for the purpose of tracing the tissue post-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.

INSTRUCTIONS FOR USE
1. Intended for use in one patient, on a single occasion only ( chú).
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 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.

7. 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.

8. IMPORTANT! Peel away and remove all internal packaging materials from the graft (i.e. gauze, liner, or mesh) prior to implantation.

Tissue should be stored ambient temperature or colder. 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.

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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.
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 and email or fax to the information at the top.

Patient’s Last Name: ________________________________ First: ______________________ MI: _____

Date of Birth: ____________________ Sex: _______ Patient ID: _____________________________

Hospital: _____________________________________________________________________________

Physician: _________________________________________ Surgery Date: ______________________

Surgical Procedure:  ____________________________________________________________________

Completed By: ______________________________________ Date:______________________________

Comments:
_____________________________________________________________________________________
_____________________________________________________________________________________
_____________________________________________________________________________________

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.

If any questions, problems, or adverse reactions occur, contact 561-776-6700