





# Tissue Insert and Usage Form

SYMBOL GLOSSARY	
	Do not reuse
	Do not re-sterilize
	Sterilized using irradiation
	Consult instructions for use

QC-605-F-89 V 2.0

## 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 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 is released for transplantation with final culture results that demonstrate no bacterial growth. Tissue labeled as **STERILE R** has been sterilized to a SAL of 10<sup>-6</sup> (Sterility Assurance Level). Tissue labeled as **STERILE R** or irradiated has been Gamma Irradiated with Cobalt 60 or by electron beam sterilization. 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. Skin tissue may have been processed with Kanamycin Sulfate and/or Cephazolin and/or Gentamicin Sulfate and traces may remain. Skin has been cryopreserved with a 6-10% (v/v) glycerol solution and does remain on tissue.

## STORAGE

**FREEZE-DRIED** tissue must be stored at ambient temperature or colder.  
**FROZEN MUSCULOSKELETAL** tissue must be stored at -40°C or colder. Short term storage of up to 6 months is acceptable if tissue is maintained at -20°C to -39°C.

**SKIN** must be stored at -40°C or colder.

**TISSUE IN SALINE** must be stored at ambient temperature down to refrigerated temperature. **DO NOT FREEZE.**

Tissue may not be stored at liquid nitrogen (LN<sub>2</sub>) vapor phase or LN<sub>2</sub> 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 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. Tissue in vacuum sealed jars: peel off metal cap and wipe rubber stopper with alcohol or betadine. Using a syringe, inject sufficient saline or air to release vacuum. If vacuum is present, plunger will be drawn down. **DO NOT USE IF VACUUM IS NOT PRESENT.** Remove rubber stopper with aid of sterile forceps.
4. 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.
5. **IMPORTANT!** Bone particulates (chips and powder) and fibers should be reconstituted for a minimum of 10 minutes. Demineralized cancellous sponges and cubes should be reconstituted for a minimum of 15 minutes. 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.
6. 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.
7. **IMPORTANT!** Peel away and remove all internal packaging materials from the graft (i.e. gauze or mesh) prior to implantation.

### FROZEN TISSUE AND SKIN

1. Inspect for package integrity and expiration date prior to opening.
2. **IMPORTANT!** Double packaged graft may be sealed in a non-sterile outer cover. Remove before proceeding.
3. Peel or tear the outer package down and aseptically deliver inner package to the sterile field or sterile team member.
4. 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.
5. Tissue should remain in solution until thawed. Tissue thawing temperature should not exceed ambient or room temperature.
6. Tissue should be used as soon as possible after thawing. If tissue is to be stored for longer than 2 hours after thawing, it should be refrigerated at 1 to 10°C in an aseptic container for no longer than 24 hours.
7. **IMPORTANT!** Peel away and remove all internal packaging materials from the graft (i.e. gauze or mesh) prior to implantation.

### TISSUE IN SALINE

1. Inspect for package integrity and expiration date prior to opening.
2. Tissue is double-packed with inner package containing the tissue and normal saline solution.
3. Peel outer package down and aseptically deliver inner package to the sterile field or sterile team member.
4. 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.
5. Tissue should be used as soon as possible after opening. If tissue is to be stored for longer than 2 hours after opening, it should be refrigerated at 1 to 10°C in an aseptic container for no longer than 24 hours.

Insert continued on reverse side below usage form



## Tissue Insert and Usage Form

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

How to return this form	
Email	tissueusage@communitytissue.org
Fax	937-222-2538
Mail	Community Tissue Services Attn: Tissue Usage 2900 College Dr. Kettering, OH 45420

Patient ID or Date of Birth: \_\_\_\_\_

Date of Surgery: \_\_\_\_\_

Surgical Procedure: \_\_\_\_\_

Completed By: \_\_\_\_\_ Date: \_\_\_\_\_

Comments: \_\_\_\_\_

One patient, one procedure per usage form. Place peel-off label for up to 3 allografts or write tissue ID# in the spaces provided.

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.

Allograft Tissue ID#  _____ Place Peel-Off Label Here
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Allograft Tissue ID#  _____ Place Peel-Off Label Here
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Allograft Tissue ID#  _____ Place Peel-Off Label Here
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### Tissue Insert Continued

#### WARNINGS AND PRECAUTIONS

- Intended for use in one patient, on a single occasion only.
- Do not use if package integrity has been compromised. Once the user breaks the container seal, the tissue grafts must be transplanted or discarded.
- Tissue may not be sterilized or re-sterilized.
- This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrists.
- Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- Adverse outcomes potentially attributable to this tissue must be reported promptly to Community Tissue Services.
- Final determination of allograft preparation or reconstitution should be made by the physician prior to use.

#### TISSUE TRACKING

Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Complete the enclosed Allograft Tracking 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.

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.

Please contact Community Tissue Services at (937) 222-0228 or (800) 684-7783 should you require further information.

#### COMMUNITY TISSUE SERVICES

Main Office  
349 South Main Street  
Dayton, Ohio 45402  
800-684-7783  
(937) 222-0228

#### COMMUNITY TISSUE SERVICES - CTIR

Center for Tissue, Innovation and Research  
Manufacturing and Distribution Center  
2900 College Drive  
Kettering, Ohio 45420  
800-684-7783  
(937) 222-0228  
Fax (937) 461-4237