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Tissue Insert and Usage Form

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QC-605-F-02 Ver 2

Symbol Glossary

Consult Instructions For Use		Do Not Reuse	
Use By Date		Serial Number	SN
Manufacturer		Do Not Use If Package Is Damaged	
Batch Code	LOT	Sterilized Using Irradiation	STERILE R
Catalogue Number	REF	Magnetic Resonance Safe	MR
Do Not Resterilize		Prescription Use Only	Rx Only

All symbols may not appear in labeling

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). Tissue is manufactured in a clean room environment, following rigorous quality assurance standards. Tissue has been processed using a proprietary method. Tissue labeled as STERILE R has been sterilized to a SAL of 10^{-6} (Sterility Assurance Level). Tissue labeled as STERILE R or irradiated has been Gamma (Cobalt 60) or Electron Beam terminally sterilized. The procedures executed to manufacture this graft including recovery, donor screening, testing, processing, packaging, labeling, storage, and distribution were performed in compliance with all applicable local, state, and federal regulations, including the U.S. Food and Drug Administration (FDA) regulations published at 21 CFR Part 1271, and the current edition of the American Association of Tissue Banks Standards for Tissue Banking.

SCREENING AND TESTING

Donor has been determined to be eligible by a Solvita Medical Director at 349 S Main Street Dayton, Ohio 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. 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 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 determine by the Centers for Medicare and Medicaid Services (CMS).

Non-irradiated musculoskeletal tissue is verified using microbiological testing per USP <71>, Sterility Tests and released for transplantation with final culture results that demonstrate no bacterial growth. Tissue may have been processed with one or more of the following: Kanamycin Sulfate, Cephazolin, Gentamicin Sulfate, Polymyxin or Bacitracin. Traces may remain. Skin has been cryopreserved with a 6-10% (v/v) glycerol solution and does remain on tissue. Representative skin samples have been tested and released based off of acceptable results.

Storage

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 may not be stored at liquid nitrogen (LN_2) vapor phase or LN_2 liquid temperatures.

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 Preparation

FREEZE-DRIED TISSUE AND SKIN

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. 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. For Cortical Fibers packaged in a sterile dish, grafts can be rehydrated in the dish. 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.
   - Pericardium and Fascia should be reconstituted for 5 minutes.
   - Weight bearing grafts (tri-cortical blocks, segments, struts, dowels, etc.) should be reconstituted about 1 hour.
   - Acellular Dermal Matrix should be reconstituted for 2 minutes.

   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 (e.g. gauze or mesh) prior to implantation.
8. Final determination of allograft preparation or reconstitution should be made by the physician prior to use.

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 (e.g. 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 Allograft Tissue Usage form.

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Allograft Tissue 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@solvita.org
Fax	937-222-2538
Mail	Solvita Attn: Tissue Usage 2900 College Drive Kettering, Ohio 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.

Solvita 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 Solvita.

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

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.
- Final determination of allograft preparation or reconstitution should be made by the physician prior to use.
- Adverse outcomes potentially attributable to this tissue must be reported promptly to Solvita.
- Demineralized tissue has also been processed with HCl, alcohol, sodium phosphate (monobasic and dibasic) and traces may remain.

Tissue Tracking

Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Complete the enclosed Allograft Tracking Form and return to Solvita. 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 Solvita to maintain records for the purpose of tracing the tissue post-transplant.

Solvita is accredited by the American Association of Tissue Banks. Solvita is ISO 13485 certified. Health Canada Registration: 100076.

Solvita makes no claims concerning the biological or biomechanical properties of the provided tissue. Solvita disclaims all liability and responsibility for any misuse of tissue provided for clinical application.

Please contact Solvita at 937-222-0228 or 800-684-7783 should you require further information.

Processed, Released and Distributed By:
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