JRF ORTHO

**QC-605-F-40 Ver 2**

# TISSUE PACKAGE INSERT

## 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 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. 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 determine by the Centers for Medicare and Medicaid Services (CMS).

Tissue has been processed with Bacitracin, Gentamicin and/or Polymyxin B and traces may remain.

Tissue labeled STERILE R as 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.

Aseptically processed 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.

## 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.
6. Adverse outcomes potentially attributable to this tissue must be reported promptly to JRF Ortho and Solvita.

## 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 JRF Ortho and Solvita to maintain records for the purpose of tracing the tissue post-transplant.

## 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.

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

### FROZEN TISSUE

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.

JRF Ortho and Solvita make no claims concerning the biological or biomechanical properties of the provided tissue. JRF Ortho and Solvita disclaim all liability and responsibility for any misuse of tissue provided for clinical application.

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

Please contact JRF Ortho at (877) 255-6727 should you require further information.

Processed to JRF Ortho specifications by:
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**Distributed by:**

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