Community Tissue Services®
www.communitytissue.org

2900 College Drive
Kettering, OH 45420
1-800-684-7783

TISSUE PACKAGE INSERT

DESCRIPTON

DONATED HUMAN TISSUE. Tissue grafts are retrieved from deceased human donors. All tissue is retrieved, 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, 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 has been performed by a laboratory registered with the FDA and certified under CLIA or equivalent requirements.

Tissue labeled as STERILE R has been sterilized to an SAL of 10^{-6} (Sterility Assuance Level). Tissue labeled as STERILE R or irradiated has been Gamma Irradiated with Cobalt 60. Tissue has been processed with Bacitracin and/or Polymyxin B and traces may remain. Tissue labeled as Allowash® has been processed using Allowash®, a patented bone and soft tissue cleaning technology under license from LifeNet Health.[1] Some devices may be presutured with FiberWire®[2] suture from the Arthrex FiberWire® Suture Family.

Please refer to the Arthrex FiberWire® Suture Family package insert for information regarding the sutures.

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. Do not remove the FiberWire® from tendon allografts that were constructed with FiberWire® suture.
6. Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
7. Adverse outcomes potentially attributable to this tissue must be reported promptly to Community Tissue Services.
8, Refer to the FiberWire® Suture Family package insert for additional FiberWire® precautions.

STORAGE

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 (LN2) vapor phase or LN2 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 TRACKING

Complete the enclosed Allograft Tracking Form and mail 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.

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.
8. **IMPORTANT!** Do not remove the FiberWire® from tendon allografts that were constructed with FiberWire® suture.

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 13485:2003 certified. Health Canada Registration: 100076.

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

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Commitment. Technology. Safety.

COMMUNITY TISSUE SERVICES
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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
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1. Allowash® is a registered trademark of LifeNet Health. Products and processes may be covered by one or more of the following U.S. patents: 6,024,735, 5,977,032, 5,977,034, 5,820,581, 5,797,871, and 5,556,379. Community Tissue Services licenses the Allowash® Service from LifeNet Health, Virginia Beach, VA

2. FiberWire® is a registered trademark of Arthrex, Inc. Naples, FL. Arthrex FiberWire® are covered by U.S. PATENT NOS. 6,716,234; 7,029,490; 7,147,651 and 7,326,222 and PATENTS PENDING.

Applies To:	**Dayton Distribution; Marketing; Lot Processing; QRA (Tissue)**
Review/Approval Requirements:	**QC Supervisor; QRA Manager**

REVISION TRACKING

Rev #	Explanation of Changes *(include what changed including reason, when applicable)*	Change Initiated By	Implementation Date
Rev 00	New IFU for Arthrex – see CO130075	T. Adamson/ D. Meade	7-12-13