JRF ORTHO

PACKAGE INSERT

QC-605-F-98 Ver 2

Description

DONATED HUMAN TISSUE
JRF Ortho Presutured Tendons are comprised of a human cadaveric tendon preassembled with the Arthrex® FiberWire® Suture Family. The device may include Achilles, patellar, anterior tibialis, posterior tibialis, peroneus longus, semitendinosus, quadriceps and gracilis tendons. The suture is comprised of nonabsorbable sutures made of Ultra High Molecular Weight Polyethylene (UHMWPE), or a polyblend of UHMWPE and polyester. Constructs labeled as STERILE-R have been terminally sterilized to a Sterility Assurance Level (SAL) of 10^{-6} by exposure up to 17.5kGy of gamma irradiation with Cobalt 60 under low temperature conditions.

Refer to the Arthrex eDFU portal at https://edfu.arthrex.com/ARX/en/products?keycode=DFU-0222-EO and enter the Arthrex suture part number or scan the QR code below.

JRF Ortho Graft	Order Code	Arthrex Suture Part #
GraftLink® XL Tendon	GRX-001	AR-7210, AR-7246, AR-7200, AR-7202
PilotGraft BTB Tendon	PSP-101, PSP-091, PSP-111	AR-7234
SpeedGraft® QuadLink™	SPQ-001	AR-7201, AR-7264, AR-7266
SpeedGraft® Tendon	SPD-001	AR-7234, AR-7234T
SpeedGraft® Achilles Tendon	PSA-101	AR-7234, AR-7233
VersaGraft® Tendon	VRG-001	AR-7234
VersaGraft® 3.5 Tendon	VRG-351	AR-7253

Indications for Use

JRF Ortho Presutured Tendons, which include SpeedGraft® QuadLink™, SpeedGraft® Tendon, GraftLink® Tendon, GraftLink® XL Tendon, VersaGraft® Tendon, VersaGraft® 3.5 Tendon, PilotGraft BTB Tendon, and SpeedGraft® Achilles Tendon are intended for use as a construct in soft tissue approximation and or ligation. JRF Ortho Presutured Tendons are for single patient use only.

Contraindications

JRF Ortho Presutured Tendons should not be used in cases of known or suspected infection at the intended surgical site.

Adverse Effects

Possible adverse effects of using JRF Ortho Presutured Tendons include, but are not limited to:

- Infection of soft tissue and/or bone(osteomyelitis); fever; deformity of the bone at the site.
- Incomplete bone growth, delayed union or non-union or fracture of newly formed bone.
- Disease transmission and undesirable immune response.

Adverse outcomes potentially attributable to the tissue must be promptly reported to JRF Ortho at 877-255-6727 and Solvita at 800-684-7783.

Warnings

- CAUTION: Federal (US) law restricts this device to sale, distribution or use by or on the order of a physician or other qualified healthcare specialist.
- Intended for use in one patient, on a single occasion only.
- This tissue is intended for use by qualified healthcare specialists, such as physicians.
- Do not use if package integrity has been compromised. Once a container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.
- Do not sterilize or re-sterilize.
- Do not allow to thaw prior to use.
- Tissue has been processed with Bacitracin, Gentamicin and/ or Polymyxin B and traces may remain.
- Although this tissue has been tested and screened for pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- Use caution in the following circumstances:
  - Severe vascular or neurological disease
  - Fever; uncontrolled diabetes; pregnancy
  - Renal-compromised patients
  - Osteomyelitis at the surgical site
  - Sepsis in or around the surgical site
  - Inability to cooperate with and/ or comprehend post-operative instructions

MRI Safety Information

Magnetic Resonance (MR) Safe. The Arthrex® sutures used for JRF Ortho Presutured Tendons are MR safe.

Storage

JRF Ortho Presutured Tendons must be stored at -40°C or colder, for long term storage. 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.

Packaging and Labeling

JRF Ortho Presutured Tendons are aseptically packaged in a sterile peel pouch. The constructs are terminally sterilized to an SAL of 10^{-6}.
JRF Ortho Presutured Tendons must not be used if:

- The integrity of packaging has been compromised.
- The label and/or bar code on the packaging is damaged or illegible.
- The expiration date shown on the packaging label has passed.

Instructions for Use

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.

Donor Screening and Testing

Tissue grafts are recovered from deceased human donors. 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 American Association of Tissue Banks Standards for Tissue Banking. The 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 for HIV 1/2 Antibody, Hepatitis B Surface Antigen, Anti-Hepatitis B Core Antibody, Anti-Hepatitis C Virus Antibody, HIV-1 NAT, HBV NAT, HCV NAT, and syphilis. Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation.

Test kits licensed by the FDA are used when available. Communicable disease testing is performed by a laboratory registered with the U.S. Food and Drug Administration to perform tissue 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).

Viral Clearance and Inactivation

Tissue has been processed using a patented bone and soft tissue cleaning technology. In addition to risk reduction through the process of donor screening and infectious disease testing, this tissue undergoes a thorough disinfection process. This treatment provides a 9-20 log reduction in microorganisms and a 2.2-12.4 log viral reduction. Presutured tendons are terminally sterilized in its final packaging to an SAL of 10^{-6}.

Patient Record

Recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue posttransplantation. It is the responsibility of the end-user to provide this information, which enables JRF Ortho & Solvita to maintain records for the purpose of tracing the tissue posttransplant. Complete the enclosed. Transplantation Record & Feedback Form online at: JRFORTHO.org/trff.

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.

SpeedGraft, GraftLink, and VersaGraft are registered trademarks of Arthrex, Inc.

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

Processed to JRF Ortho specifications by:

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Fax 937-461-4237

Distributed by:

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877-255-6727

Symbol Glossary

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

All symbols may not appear in labeling