arthrosurface®
#STAYACTIVE

28 Forge Parkway
Franklin, MA 02038

TISSUE PACKAGE INSERT
SpeedSpiral™
Rolled Allograft Tissue

QC-605-F-85 V 1.0

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).

Tissue labeled as STERILE R 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.

INDICATIONS AND HOMOLOGOUS USE

The **CMC Allograft** is a dermal plug intended to be used for supplemental support and reinforcement of the flexor carpi radialis tendon and other structures of the capsuloligamentous complex; and as such, functions as a dense, strong and flexible connective tissue layer.

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 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.

CONTRAINDICATIONS, SIDE-EFFECTS AND HAZARDS

Use of **SpeedSpiral™** in patients exhibiting autoimmune connective tissue disease is not recommended.

Use of **SpeedSpiral™** in patients with sensitivity to any of the following antibiotics: polymyxin B, bacitracin, amphotericin B and gentamicin sulfate.

Trace amounts of isopropyl alcohol, phosphate buffered saline, and peracetic acid, EDTA, ethanol, and sodium chloride may be present and caution should be exercised if the patient is allergic to any of these agents.

A relative contraindication would include the presence of infection in the host bed where the allograft is implanted. Limitations of allografts may include uncertainty regarding incorporation and/or resorption which may be due to the difference in histocompatibility factors between the donor and recipient. Bacterial infection at the site of implantation may occur. This complication may not be apparent for long periods of time (6-24 months) after transplantation. Transmissions of infectious disease may occur despite rigorous donor selection and testing.

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.

STORAGE

FREEZE-DRIED tissue must be stored at ambient temperature.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Inherent uncertainties exist in medical and social histories and lab testing which may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation:

- Transmission of disease of unknown etiology;
- Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi;
- Immune rejection of implanted HCT/P; or
- Loss of function and/or integrity of implanted HCT/P due to resorption, fragmentation, and/or disintegration.

Any adverse outcomes potentially related to this tissue allograft must be promptly reported to Arthrosurface, Inc.

TISSUE TRACKING

Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Complete the Allograft Tracking Form on the back of this 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 of the tissue dispensing service, tissue distribution intermediary, and/or ender-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

Arthrosurface and Community Tissue Services make no claims concerning the biological or biomechanical properties of the provided tissue. Arthrosurface and 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.

Processed and Eligibility Determined by:
Community Tissue Services
Center for Tissue, Innovation and Research
Manufacturing and Distribution Center
2900 College Drive
Kettering, Ohio 45420
800-684-7783

Distributed by:
Arthrosurface
28 Forge Parkway
Franklin, MA 02038
(508) 520-3003
www.arthrosurface.com

Please contact Arthrosurface at
(508) 520-3003 should you require further information.

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How to return this form	
Email	tissueusage@patienttracking.care
Fax	937-222-2538

Allograft Tracking Form

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

Date of Surgery: _____

Patient's Medical Record Number or Date of Birth: _____

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.

Place peel-off label for up to 4 allografts or write tissue ID# in the spaces provided.
One patient, one procedure per tracking form.

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

If any questions, problems, or adverse reactions occur,
contact 1-800-684-7783 or 1-937-222-0228.