SpeedSpiral™

Rolled Allograft Tissue System
Instructions for Use - CMC

Description

The SpeedSpiral™ Rolled Allograft Tissue System consists of a pre-rolled, decellularized, freeze-dried and gamma sterilized human dermal allograft tissue, and single-use, packaged, sterile and disposable instruments consisting of trial sizers, delivery tools and suture passing pins that are used to facilitate sizing and placement of the allograft.

Indications for 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.

Materials

Allograft:	Human Dermal Tissue Allograft
Surgical Instruments:	Medical Grade Stainless Steel, Nitinol and/or High-Temperature Plastics

Refer to the SpeedSpiral™ Rolled Allograft Tissue Package Insert for description of:

- **Tissue processing**
- **Indications and Homologous Use**
- **Warnings and Precautions**
- **Contraindications, Side-Effects and Hazards**
- **Tissue Preparation**
- **Storage**
- **Complications and Possible Adverse Events**
- **Tissue Tracking**

Additional Warnings, Precautions & Possible Complications

- Proper surgical techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the instruments and techniques for each patient based on his or her own medical training and expertise. Every patient is different and patient results may vary. The operating surgeon or physician should discuss general risks and potential complications associated with this and any surgical procedure with the patient prior to patient consent.
- The SpeedSpiral™ instruments are furnished as tools to facilitate sizing and placement of the SpeedSpiral™ allograft. Excessive force applied to the instruments may cause them to deform or fracture.
- The SpeedSpiral™ Rolled Allograft Tissue System's allograft and instruments are designed for single patient use only and are not intended to undergo or withstand any form of alterations, such as disassembly, cleaning or re-sterilization, after single patient use. Reuse can compromise device performance and patient safety.
- Inspect components prior to use for damage during shipment or storage. Verify that components are within expiry date on package label. Expired product should not be used.
- Accepted practices in post-operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post-operative instructions and activity restrictions.
- General risks and complications may include, but are not limited to: infection, allergic reaction, dislocation or poor integration of the allograft, bleeding, injury to nerves, post-operative pain or incomplete resolution of pre-operative symptoms.

Sterility

The SpeedSpiral™ Rolled Allograft Tissue System's instrument components are sterilized by exposure to gamma radiation. Do not resterilize any instrument components. Do not use if packaging is opened or damaged. Do not use if beyond expiration date as indicated on the package label. For Single Use Only.

Caution

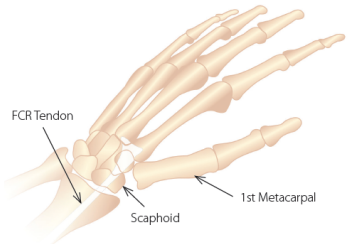
Federal Law (USA) restricts this device to sale by or on the order of a physician.

Surgical Procedure

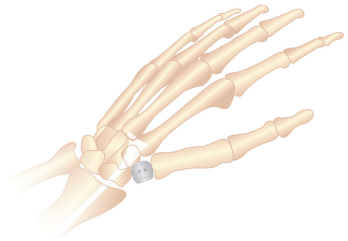
As the manufacturer of this system, Arthrosurface, Inc. does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

It is the surgeon's responsibility to be familiar with the allograft and instruments of this system. The basic technique steps describing the use of the SpeedSpiral™ instruments for accurate placement of the SpeedSpiral™ allograft for the CMC indication are provided below:

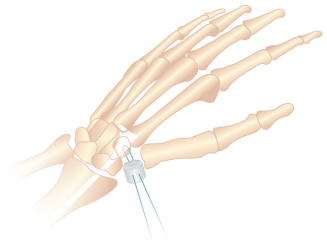
1. **Exposure:** 3-4 cm longitudinal incision over the trapezium, from the base of the first metacarpal to the radial styloid. Note the dorsal radial nerves and radial artery branches. Alternatively, a volar based Wagner approach may be used. Retract the Extensor Pollicis Brevis (EPB) tendon and continue exposing the trapeziometacarpal joint by capsular dissection. Resect all or part of the trapezium as necessary, leaving the articular surface of the metacarpal bone intact. Remove osteophytes on the metacarpal base. Care should be taken to protect the flexor carpi radialis (FCR) tendon and capsular flaps.



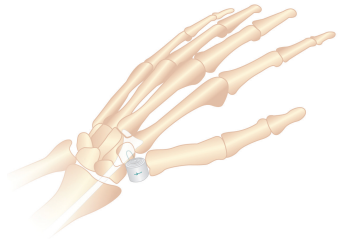
2. **Sizing:** With thumb traction applied, determine the size of the implant using the CMC Graft Sizer. Determine graft orientation that most closely corresponds to the patient's joint space.



3. **Delivery:** Deliver the SpeedSpiral™ CMC allograft into position between the base of the first metacarpal and the scaphoid to augment the stabiilty of the CMC Joint. The SpeedSpiral™ CMC allograft may be trimmed as necessary for optimal fit. If additional implant stabilization is required, a 2-0 or 3-0 non-absorbable suture can be passed through the allograft and the FCR tendon, or an appropriately sized suture anchor can be placed in the base of the index metacarpal.



4. **Closure:** Close capsular repair using absorbable sutures. Irrigate the wound with saline solution and release the tourniquet. Confirm hemostasis and complete the closure using standard techniques.



5. **Post-op:** Immobilize the thumb in a short arm thumb spica splint with the thumb interphalangeal (IP) joint free. Removal sutures 7-12 days post-operatively. Immobilize the thumb in a spica cast with the thumb IP joint free for an additional 3-4 weeks. Following cast removal at 4-6 weeks post-operatively, hand therapy is initiated as needed. At 6-8 weeks, strengthening exercises can begin as necessary.

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This product is covered by U.S. Patent No. 9,943,414 and other patents pending.

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