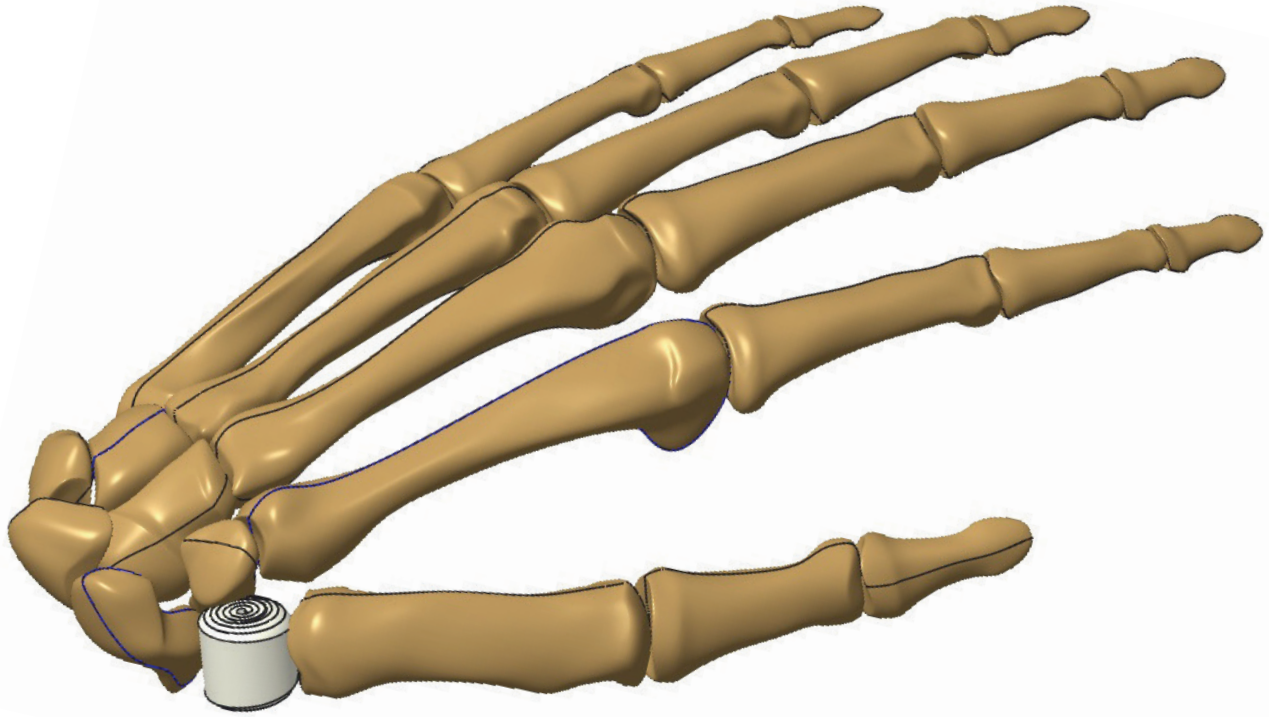
arthrosurface®

Technique Guide

SpeedSpiral™ CMC System



Shaped Allograft for Thumb CMC Joint

The **SpeedSpiral™ CMC System** utilizes a shaped allograft implant to treat thumb CMC joint pain and/or instability. It is designed to augment the FCR tendon and/or the capsuloligamentous structures at the thumb while also minimizing OR time. The SpeedSpiral™ implant shape minimizes the risk of metacarpal subsidence that is common to other autograft only procedures.

- Pre-Formed in a Cylindrical Shape
- Avoids Thumb Shortening
- Sterile, Decellularized and Freeze-Dried (No Rehydration Necessary)
- Available in 3 sizes: 13x13mm, 15x15mm & 17x15mm
- Sterile, Single-Use Delivery Instruments

SpeedSpiral™

Indications and Homologous Use

The **SpeedSpiral™ CMC Implant** is a shaped allograft 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.

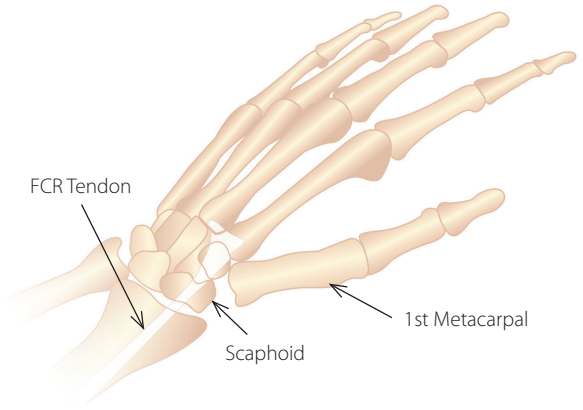
Sterility

The **SpeedSpiral™ CMC Implant** tissue labeled as STERILE R has been sterilized to an SAL of 10^{-6} (Sterility Assurance Level) using Gamma Irradiation.

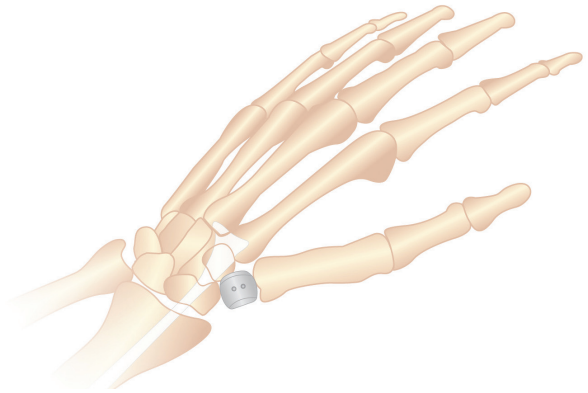
Surgical Technique

Delivery of the The SpeedSpiral™ CMC Implant

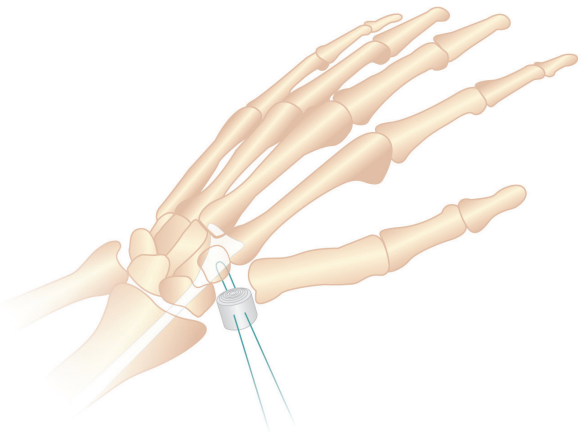
1. **Exposure:** 3-4 cm longitudinal incision over the trapezium, from the base of the first metacarpal to the radial styloid. Note the dorsal radial nerves and radial artery branches. Alternatively, a volar based Wagner approach may be used. Retract the Extensor Pollicis Brevis (EPB) tendon and continue 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.



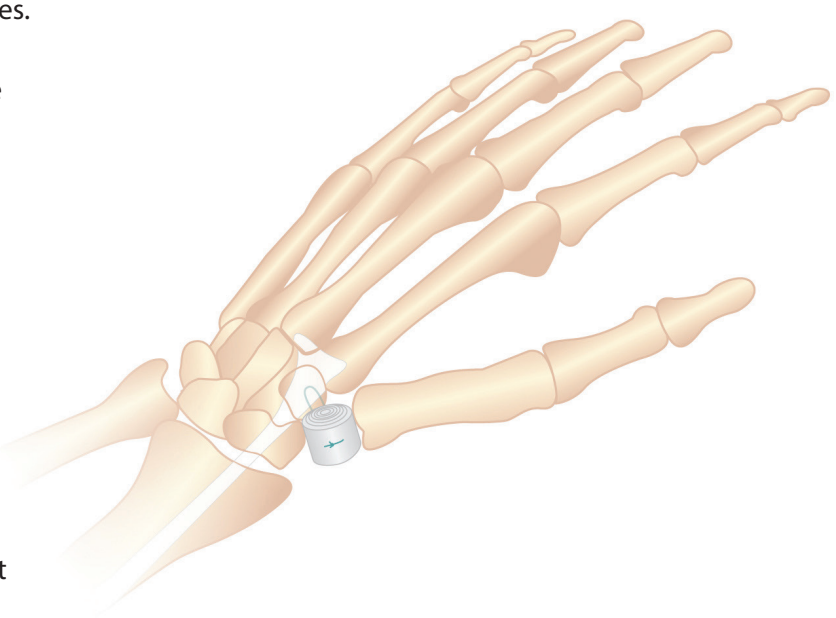
2. **Sizing:** With thumb traction applied, determine the size of the implant using the CMC Graft Sizer. Determine graft orientation that most closely corresponds to the patient's joint space.



3. **Delivery:** Deliver the SpeedSpiral™ CMC Graft into position between the base of the first metacarpal and the scaphoid to augment the stabiilty of the CMC Joint. The SpeedSpiral™ CMC Graft 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 Graft and the FCR tendon, or an appropriately sized suture anchor can be placed in the base of the index metacarpal.



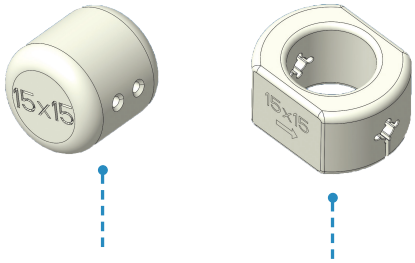
4. **Closure:** Close capsular repair using absorbable sutures. Irrigate the wound with saline solution and release the tourniquet. Confirm hemostasis and complete the closure using standard techniques.



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.

SpeedSpiral™ CMC System

INSTRUMENTATION:



TRIAL SIZER

DELIVERY TOOL

IMPLANT:

CMC SHAPED ALLOGRAFT

System Catalog

Instrumentation Systems (Disposable)	
8A07-1000	Trial Sizers
8A09-1313	Delivery Tool, 13mm
8A09-1515	Delivery Tool, 15mm
8A09-1715	Delivery Tool, 17mm

SpeedSpiral CMC Allografts	
8A00-1313	Ø13mm x L13mm
8A00-1515	Ø15mm x L15mm
8A00-1715	Ø17mm x L15mm

SpeedSpiral™

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.
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 SpiralDerm™ 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.

Storage

FREEZE-DRIED tissue must be stored at ambient temperature.

Complications & 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.

Refer to SpeedSpiral CMC System Instructions for use for additional information.
The CMC Allograft is rolled human tissue, which qualifies as an allograft under 21 CFR Part 1271 and section 361 of the Public Health Service Act.

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For more information, visit our website:
www.arthrosurface.com

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This pamphlet and information is intended for markets where regulatory approval has been granted.