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Technique Guide®

SpiralUp™ TCL System

Shaped Allograft for the Talocalcaneal (TCL) Joint

The **SpiralUp™ TCL System** is a pre-rolled, decellularized, freeze-dried, gamma sterilized human dermal allograft tissue intended to be used in supplementing the talocalcaneal ligament and as such, functions as a dense, strong and flexible connective tissue layer.

- Pre-Rolled in a Cylindrical Shape
- Sterile, Decellularized and Freeze-Dried (No Rehydration Necessary)
- Available in 3 Diameters: 7mm, 9mm, 11mm
- Sterile, Single-Use Delivery Instruments

SpiralUP™

Indications and Homologous Use

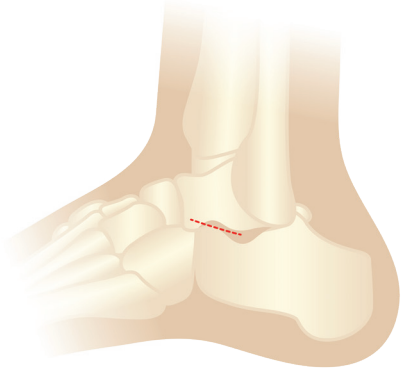
The **SpiralUp™ TCL Allograft** is a dermal plug intended to be used in supplementing the talocalcaneal ligament and as such, functions as a dense, strong and flexible connective tissue layer.

Sterility

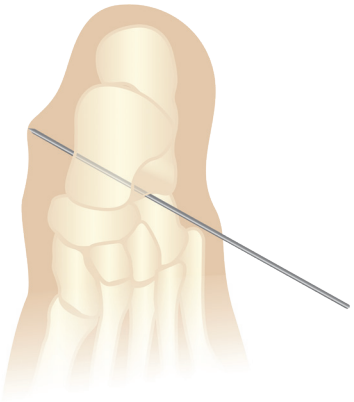
The **SpiralUp™ TCL Allograft** tissue labeled as STERILE R has been sterilized to a SAL of 10^{-6} (Sterility Assurance Level). Tissue labeled as STERILE R or irradiated has been Gamma Irradiated with Cobalt 60.

Surgical Technique

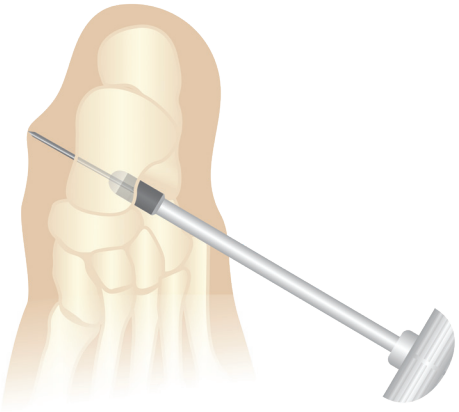
Delivery of the The SpiralUp™ TCL Allograft



1. **Exposure:** Create an incision (2-3 cm) along the relaxed skin tension lines slightly proximal to the anterior process of the calcaneus and over the center of the sinus tarsi. Taking care to protect the underlying neurovascular structures, perform blunt dissection of the subcutaneous soft tissues using curved scissors or hemostat to separate the fibers. Remove fibro-fatty plug to gain entry into the sinus tarsi. Using a rongeur or rasp, gently abrade the sinus tarsi margin and adjacent ligaments to facilitate **SpiralUp™ TCL Allograft** adhesion.

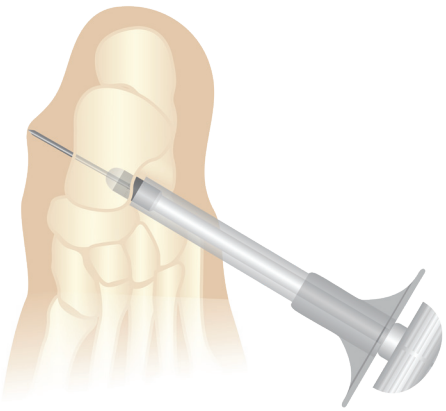


2. **Guide Pin:** Insert the 1.3 mm **Guide Pin** into the sinus tarsi in a lateral-distal to a medial-proximal orientation until tenting of the skin is observed on the medial aspect of the foot. Take care to ensure that the posterior tibial tendon is located superior to the skin tent created by the **Guide Pin**. Do not force **Guide Pin** through the skin.



3. **Sizing:** Insert **Sizing Trial** over the **Guide Pin** and into the sinus tarsi. Utilizing x-ray or fluoroscopy, visualize the talar navicular congruity. Select the appropriate diameter of **Sizing Trial (7mm, 9mm, 11mm)** to maximize talar navicular congruity for desired outcome.

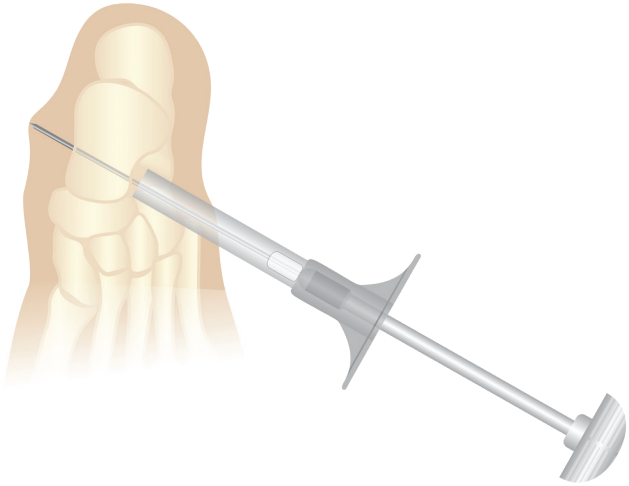
4. **Delivery Cannula:** Remove the **Sizing Trial**, leaving the **Guide Pin** in place. Insert the **Sizing Trial** into the **Delivery Cannula** to facilitate positioning of the **Delivery Cannula**. Remove the **Sizing Trial**.

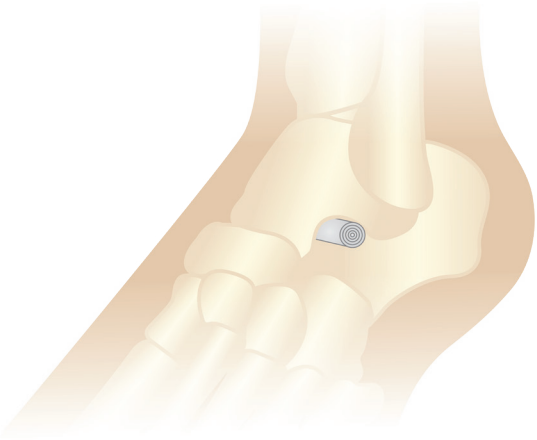


5. **Allograft:** Insert the corresponding size of the **SpiralUp™ TCL Allograft** over the **Guide Pin** and into the **Delivery Cannula**. Deliver the **SpiralUp™ TCL Allograft** using the **Sizing Trial** to advance the **SpiralUp™ TCL Allograft** into final position.

   Note: **SpiralUp™ TCL Allograft** should not extend past the lateral margin of the calcaneus. Trim **SpiralUp™ TCL Allograft** if necessary.

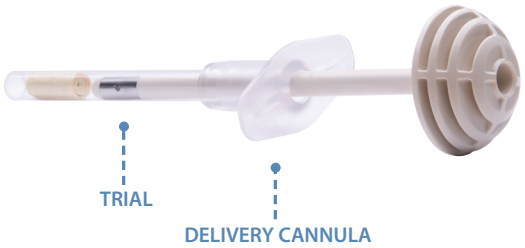
6. Remove all instruments and discard appropriately. Evaluate the foot utilizing x-ray or fluoroscopy to ensure that the talar head is congruous on the navicular with foot loaded. The incision can now be closed with deep sutures combined with a subcutaneous or skin closure based on the surgeon's preference.





SpiralUp™ TCL System

INSTRUMENTATION:



IMPLANT:

System Catalog

Instrumentation Systems (Disposable)	
9ST9-0100	Sizing Trial Kit, SpiralUp TCL

SpiralUp TCL Allografts	
9ST0-0007	SpiralUp TCL Allograft, Ø7mm
9ST0-0009	SpiralUp TCL Allograft, Ø9mm
9ST0-0011	SpiralUp TCL Allograft, Ø11mm

SpiralUP™

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 **SpiralUp™** in patients exhibiting autoimmune connective tissue disease is not recommended.

Use of **SpiralUp™** in patients with sensitivity to any of the following antibiotics: polymyxin B, bacitracin, amphotericin B and gentamicin sulfate is not recommended.

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 **SpiralUp™** TCL Instructions for use for additional information.
The TCL 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.