SpiralUP™

Rolled Dermal Allograft System
Instructions for Use - TCL

Description

The SpiralUp™ TCL Rolled Allograft Tissue System consists of a pre-rolled, decellularized, freeze-dried, gamma sterilized human dermal allograft tissue, and single-use, packaged, sterile and disposable instruments. Instruments consist of trial sizers, delivery tools and guide pin that are used to facilitate sizing and placement of the allograft.

Indications for 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.

Materials

Allograft:

Human Dermal Tissue Allograft

Surgical Instruments:

Medical Grade Stainless Steel, and
High-Temperature Plastics

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

- Tissue Processing
- Indications and homologous use
- Warnings and Precautions
- Contraindications, Side-Effects and Hazards
- Storage
- Complications and Possible Adverse Events
- Tissue Tracking

Additional Warnings, Precautions & Possible Complications

1. 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.
2. The SpiralUp™ TCL instruments are furnished as tools to facilitate sizing and placement of the SpiralUp™ TCL allograft. Excessive force applied to the instruments may cause them to deform or fracture.
3. The SpiralUp™ TCL 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.
4. 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.
5. Accepted practices in postoperative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to postoperative instructions and activity restrictions.
6. 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, postoperative pain or incomplete resolution of pre-operative symptoms.

Sterility

The SpiralUp™ TCL 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

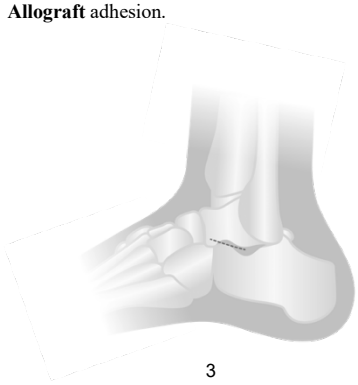
United States Federal Law restricts this device to sale by or on the order of a physician.

Surgical Procedure

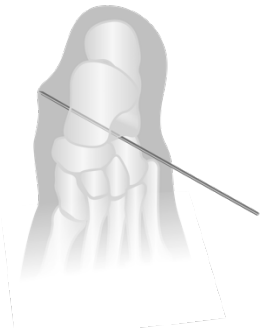
As the manufacturer of this system, Arthrosurface, Inc. does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

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 SpiralUp™ TCL instruments for accurate placement of the SpiralUp™ TCL Allograft are provided below:

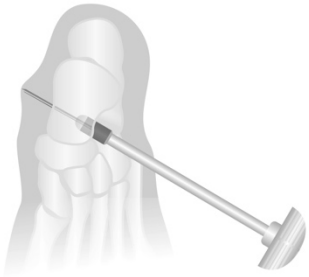
1. **Exposure:** Create an incision (2-3 cm) along the relaxed skin tension lines slightly proximal to the anterior process of the calcaneus and over the center of the sinus tarsi. Taking care to protect the underlying neurovascular structures, perform blunt dissection of the subcutaneous soft tissues 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.



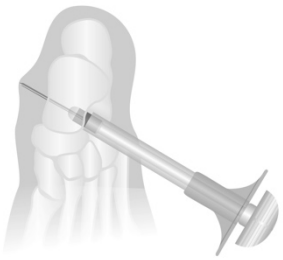
2. **Guide Pin:** Insert the 1.3 mm guide pin into the sinus tarsi in a lateral-distal to a medial-proximal orientation until tenting of the skin is observed on the medial aspect of the foot. Take care to ensure that the posterior tibial tendon is located superior to the skin tent created by the **Guide 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.



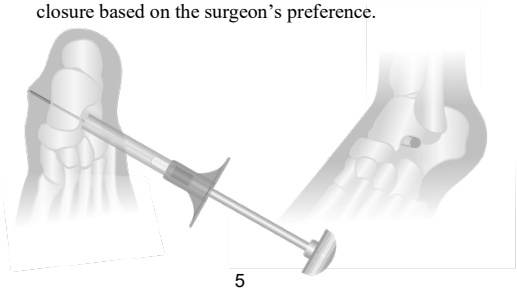
4. **Delivery Cannula:** Remove the **Sizing Trial**, leaving the **Guide Pin** in place. Insert the **Sizing Trial** into the **Delivery Cannula** to facilitate positioning of the **Delivery Cannula**. Remove the **Sizing Trial**.



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.



Manufacturer

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Gamma Irradiated

R_xONLY

Single-Use Only. Do Not Re-Sterilize

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