Disco Subtalar Implant
Instructions for Use

900-01-005, Rev C

Description
The Trilliant Surgical Ltd subtalar implant is a one-piece titanium alloy implant comprised of diameters of 7mm to 12mm intended for the treatment of hyperpronation. The instrumentation includes trials, guide pins, insertion tool, removal tool, and cannulated driver handle

Implant Materials
All implants are made from Titanium Alloy (ASTM F-136). The instrumentation is made from medical grades of titanium, stainless steel, anodized aluminum, and plastic.

Indications
The Trilliant Surgical subtalar implant is indicated for the use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is intended to block the forward, downward, and medial displacement of the talus, thus allowing normal subtalar joint motion but limiting excessive pronation.

The Trilliant Surgical subtalar implants are intended for single use only.

Contraindications
Use of the Trilliant Surgical subtalar implant is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; in patients with superstructural alignment deformities; in patients with previous subtalar joint infection or tumor; in patients with inadequate bonestock; or in patients with certain metabolic diseases.

Warnings
1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
3. Instruments, guide wires and implants are to be treated as sharps.

Maintaining Device Effectiveness
1. The surgeon should have specific training; experience and thorough familiarity with the use of implant devices.
2. The surgeon should familiarize him/her self with the surgical technique.
3. The Trilliant Surgical subtalar implants are not intended to endure excessive abnormal functional stresses.
4. All Trilliant Surgical subtalar implants and instrumentation may be required for each surgery. Failure to use dedicated, unique Trilliant Surgical instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
5. Carefully inspect the Trilliant Surgical implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments that are faulty, damaged, or suspect should not be used. They should be replaced or sent to Trilliant Surgical for disposition and repair.
6. Trilliant Surgical recommends the use of Trilliant Surgical products in a sterile environment.

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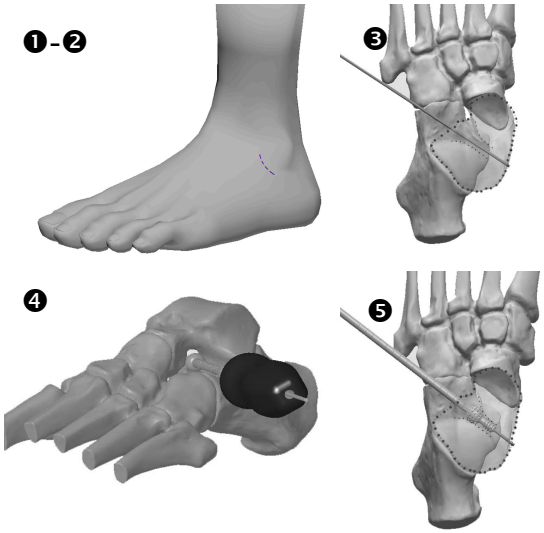

1. Make a 2-3cm incision on the lateral aspect of the foot over the sinus tarsi along the relaxed skin tension lines. Avoid the intermediate dorsal cutaneous nerves that should course superior to the incision, and sural nerve that should course inferior to the incision.
2. Identify the deep fascia and bluntly dissect allowing entrance into the lateral sinus tarsi. If the surgeon chooses to release the interosseous talocalcaneal ligament, certain care should be taken to avoid any arteries, veins, or nerves that supply the area.
3. Insert the guide pin into the sinus tarsi from anterior lateral to posterior medial until tenting is noted slightly posterior to the medial malleolus.
4. Choose the appropriate trial based on the size and anatomy of the patient. It is recommended to start with the smallest trial and increase trial sizing until the desired correction is achieved. The use of intra-operative AP and lateral view imaging is recommended to evaluate the placement of the trial. Introduce the selected cannulated trial over the guide pin into the sinus tarsi and canalis tarsi from anterior lateral to posterior medial until the trial will not advance anymore. The appropriate trial size should limit abnormal calcaneal eversion and will allow approximately 2-4 degrees of subtalar joint eversion. Once the appropriate size trial is determined, make note of the depth measurement on the calibrated section of the trial at the skin line and remove the trial from the joint while leaving the guide pin in place.
5. Place the equivalent size implant onto the insertion tool and introduce over the guide pin and thread into the joint with a clockwise rotation. Once the implant has been advanced 3-4 full turns into the canalis tarsi, remove the guide pin and then fully seat the implant until it does not advance any further. Final placement should match the predetermined length noted with the depth measurement determined from the trial until clinical correction is noted. The use of intra-operative imaging in the AP and lateral view should be used to verify the final placement of the implant. The trailing edge of the implant should sit +/- 2mm from the neck of the talus.

6. Once the final placement of the implant has been achieved, assess the range of motion of the subtalar joint. A significant reduction of excess subtalar joint pronation should now be appreciated.
7. Irrigate then close the deep tissue, fascia, subcutaneous tissue, and skin layers. Place the foot in a mild compressive dressing.

Post-operative Care
Assuming no adjunctive procedures were performed, a protective, weight bearing, below the knee walking cast or boot for 2-4 weeks is used. A gradual return to limited activity in 4-6 weeks is permitted as tolerated.

Implant Removal
In the event the implant needs to be removed, the threaded removal tool is inserted into the proximal end of the implant and turned in a counter-clockwise motion to engage the reverse threads in the cannulation of the implant to back out and remove the implant.

Cleaning

Non-sterile products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization. Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents. Trilliant Surgical recommends the following cleaning and sterilization instructions for Instrumentation:

1. Clean all instruments thoroughly using mild detergent, soft brush and warm water. Ensure that dried blood, bone particulate and other deposits are removed from the instruments and sterilization tray.
2. Thoroughly rinse all instruments and the sterilization tray with clean water.
3. Arrange all the instruments in the sterilization tray and insure that the lid is in place and properly closed.
4. Steam autoclave per the following sterilization instructions.

Packaging and Sterility

NON-STERILE PRODUCT

The Trilliant Surgical Subtalar implant system (Instruments and implants) can be packaged non-sterile and therefore must be sterilized prior to surgical use. Use of the sterilizer shall comply with the manufacturer's user instructions. The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures. Non-sterile devices are sterilizable by steam sterilization (autoclaving). The following parameters should be followed.

Pre-Vacuum Steam Sterilization:	Gravity Steam Sterilization:
Condition: Wrapped	Condition: Wrapped
Temperature: 270· F (132· C)	Temperature: 270· F (132· C)
Time: 4 minutes	Time: 15 minutes

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.
Do not attempt a surgical procedure with faulty, damaged or suspect Trilliant Surgical instruments or implants.
Inspect all components preoperatively to assure utility.

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Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

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