INSTRUCTIONS FOR USE
Disco Subtalar Implant System

TRILLIANT SURGICAL

900-01-005 Rev O
March 2019

Description
The Disco Subtalar Implant is a one-piece titanium alloy implant comprised of diameters of 7mm to 12mm intended for the treatment of hyperpronation. System instrumentation includes trials, guide pins, probe, insertion tool, removal tool, and cannulated driver handle. The implants and guide wires are intended for single use only.

Implant Materials
All implants are made from Titanium Alloy (ASTM-F136, ASTM-F3001). The instrumentation is made from medical grades of titanium, stainless steel, anodized aluminum, and plastic.

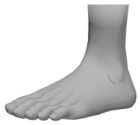
Indications
The Disco subtalar implant is indicated for the use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is intended to block the forward, downward, and medial displacement of the talus, thus allowing normal subtalar joint motion but limiting excessive pronation.

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.

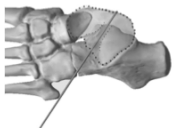
Warnings
1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant 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 ensure 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. The Disco Subtalar Implant System should be used in a sterile environment.

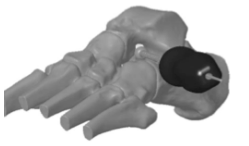
Instructions for Use, Disco Subtalar Implant System



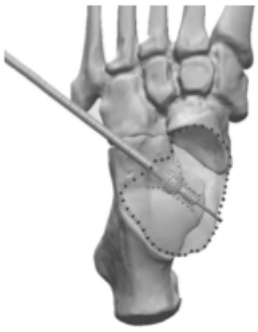
1. Make a 2-3cm incision on the lateral aspect of the foot over the sinus tarsi along the relaxed skin tension lines. Avoid the intermediate dorsal cutaneous nerves that should course superior to the incision, and sural nerve that should course inferior to the incision.
2. Identify the deep fascia and 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 rotating clockwise. Once implant has been advanced 3-4 full turns into the canalis tarsi, remove the guide pin and fully seat the implant until it does not advance any further. Final placement should match the predetermined length noted with the depth measurement from the trial until clinical correction is noted. Intra-operative imaging in the AP and lateral view should be used to verify final implant placement. The trailing edge of the implant should sit +/- 2mm from the neck of the talus.
6. Once final placement of the implant has been achieved, asses 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. For validated cleaning instructions, please reference document 900-06-015, Twist Subtalar Implant System and Disco Subtalar Implant System Cleaning and Sterilization Protocol.

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:

Sterilization Method	Pre-Vacuum Steam	Gravity Steam
Condition	Wrapped*	Wrapped*
Temperature	270°F (132°C)	270°F (132°C)
Time	4 minutes	15 minutes
Dry Time	Recommended 50 minutes**	Recommended 50 minutes**

* The system shall be packaged for sterilization by double wrapping in standard central supply wrap (i.e. Bio-Shield® Sterilization Wrap).
** Trilliant Surgical has validated the recommended sterilization cycle and dry time for trays. The dry time varies due to load configuration, wrapping method, and material.

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.

MRI Safety Information
The Disco Subtalar Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Disco Subtalar Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Symbols Glossary

Symbol	Description	Designation Number, ISO 15223-1:2016
REF	Catalog Number	5.1.5
LOT	Batch Code	5.1.6
	Do not use if package is damaged	5.2.8
	Do not reuse	5.4.2
	Non-Sterile	5.2.7
	Device only to be sold on or by the order of a physician	N/A*
	Manufacturer	5.1.1
	Caution	5.4.4
	Consult instructions for use	5.4.3

*Symbol allowed under 21 CFR 801. The above symbols are outlined in ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements. Note: QTY is an abbreviation of "QUANTITY".

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

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