

INSTRUCTIONS FOR USE

Twist Subtalar Implant System



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Description

The Twist 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 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.

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 Twist Subtalar Implant System should be used in a sterile environment.

Instructions for Use, Twist 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, which should course inferior to the incision.
2. Identify the deep fascia and bluntly dissect allowing entrance into the lateral sinus tarsi.



3. Insert the guide pin into the sinus tarsi from lateral to medial until tenting is noted anterior and slightly inferior to the medial malleolus.
4. Introduce the cannulated probe over the guide pin and into the sinus tarsi with a gentle twisting motion to slightly dilate the tarsal canal.
5. Remove the cannulated probe and leave the guide pin in place.



6. Choose the appropriate trial based on the size and anatomy of the patient. 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 from lateral to medial until the leading edge of the trial is 1/3 to half way across the subtalar joint. The leading edge of the trial should not cross the longitudinal bisection of the talus and the trailing edge of the implant should be more than 5mm medial to the lateral wall of the calcaneus. 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.



7. Place the equivalent size implant onto the insertion tool and introduce over the guide pin and thread into the joint with a clockwise rotation to the predetermined length noted from 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 leading edge of the implant should be 1/3 to half way across the subtalar joint and the leading edge of the implant should not cross the longitudinal bisection of the talus while the trailing edge should be more than 5mm medial to the lateral wall of the calcaneus.
8. 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.
9. Remove the insertion tool and the guide pin.
10. 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 Twist 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 Twist 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
	Catalog Number	5.1.5
	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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