Foot and Ankle

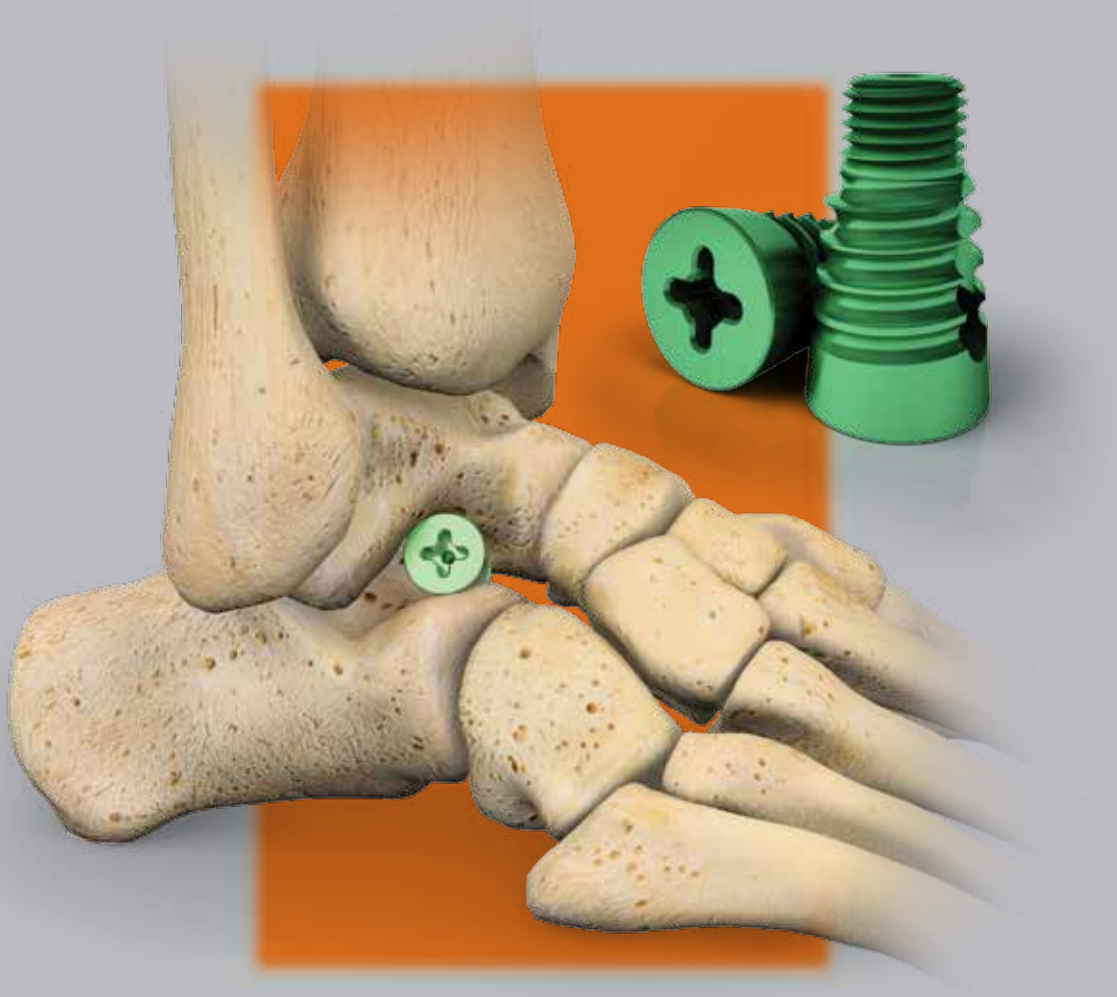
stryker®

SubFix™

Subtalar Arthroereisis Implant

Operative Technique

Foot & Ankle



This publication sets forth detailed recommended procedures for using Stryker devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments whenand as required.

A workshop training is recommended prior to performing your first surgery.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000).

Multi-component instruments must be disassembled for cleaning.

Please refer to the corresponding assembly/ disassembly instructions.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

See package insert (Instruction for Use)[IFU V15068, IFU V15069] for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

Contents

Indications, Precautions & Contraindications

Indications

The SubFix Arthroereisis Implant is intended to treat the hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus blocking excessive pronation and the resulting sequela.

The SubFix Arthroereisis Implants are intended for single use only.

Contraindications

- Acute or chronic infections, local or systemic
- Surgical procedures other than those mentioned in the indications section
- Do not use on patients allergic to the components of the product or having known allergies
- Poor or insufficient bone stock
- The presence of any clinical or functional abnormalities that would preclude the potential of achieving a good result for the patient
- Other conditions that may place the patient at risk (physiologically)

Precautions

Stryker systems have not been evaluated for safety and compatibility in Magnetic Resonance (MR) environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

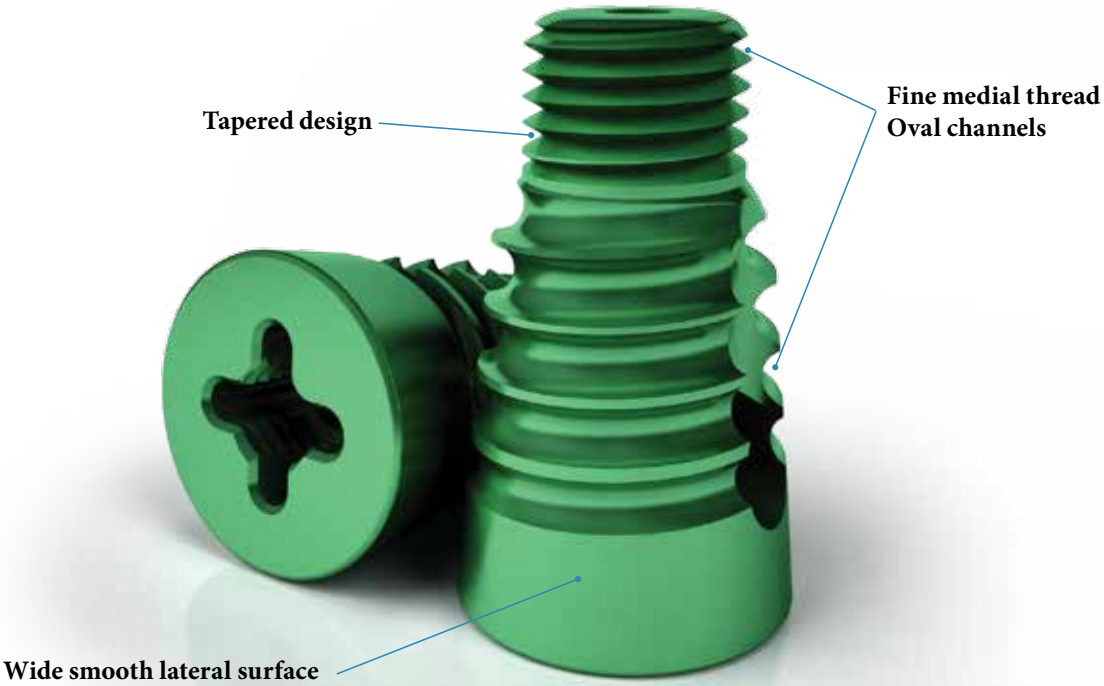
Never perform intramuscular injection next to the implant, detailed information is included in the instructions for use being attached to every implant.

See package insert for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

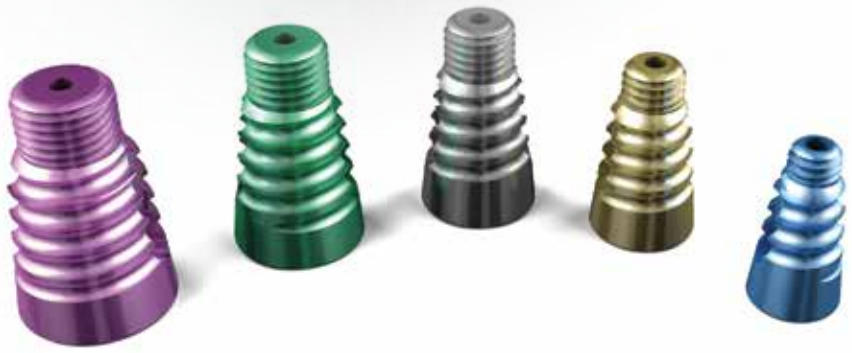
Implant Overview

SubFix Arthroereisis Implant addresses the hindfoot component of a broad spectrum of flexible pes plano valgus deformities such as the hypermobile flatfoot to Stage II posterior tibial tendon dysfunction.

Manufactured from medical grade titanium, the SubFix Arthroereisis Implant features a conical shape that is finely threaded medially and tapers into a wider smooth lateral surface.



The SubFix Arthroereisis implant is available in a spectrum of sizes ranging from 6.5mm to 11.5mm, with color coded SubFix Trials.



SIZE	11.5mm	10mm	9mm	8mm	6.5mm
REF	SUT0115	SUT0100	SUT0090	SUT0080	SUT0065

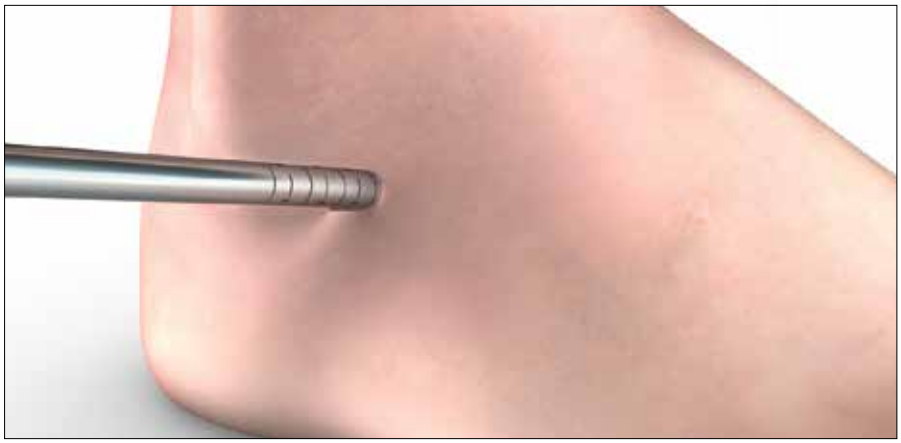
Instrumentation Overview

Insertion Driver

Instrumentation includes the Insertion Driver (XTV009001) with stab and grab implant handling.

Markings

Trials (XFA008065 to XFA008115) and Insertion Driver (XTV009001) laser markings allow final implant depth insertion, after X-Ray verification.



Removal Driver

In particular cases where removal may be required. A reverse threaded Removal Driver (XEX001001) is included in the set. Before using the Removal Driver (XEX001001) try to loosen the implant with the Insertion Driver (XTV009001). In a second step insert the Removal Driver and turn it in a counterclockwise motion to engage the reverse threads inside the SubFix Arthroereisis implant. Continue until implant is removed.

Guidewire - Rounded Tips

Chrome Cobalt Guidewire (XBR001001).

Operative Technique

Incision

Create a 1-3cm incision within the relaxed skin tension lines overlying the sinus tarsi which can be identified with direct palpation, or approximately 1cm inferior and 1.5cm anterior to the tip of the lateral malleolus.

Note:

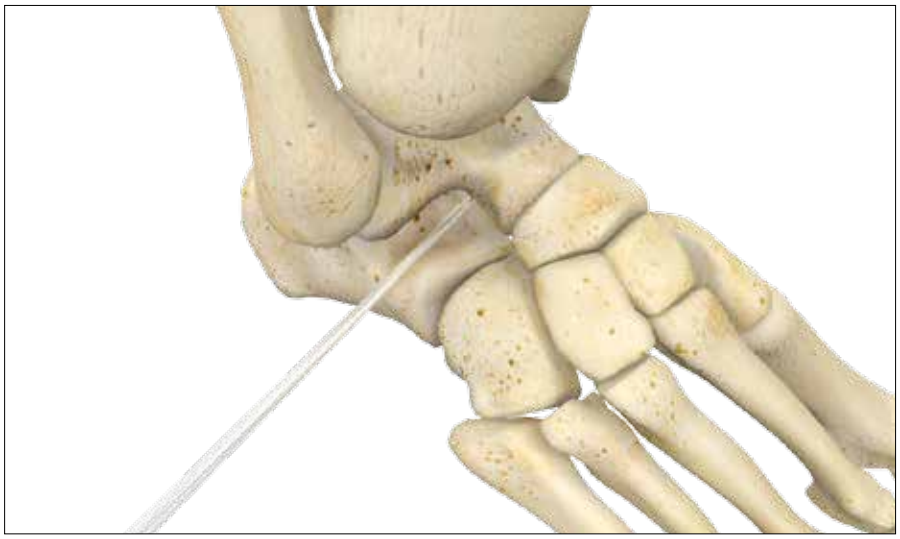
Open the deep fascia with a blunt ringed instrument (i.e. hemostat) once the skin is incised, and penetrate into the sinus tarsi. You should avoid the intermediate dorsal cutaneous nerve and peroneal tendons. If they are encountered, they should be retracted as needed. Make a linear incision into the retinaculum, to expose the lateral sinus tarsi.

Guidewire Insertion

Insert the 1.9mm CoCr Guidewire (XBR001001) into the sinus tarsi until tenting is seen on the medial aspect of the foot, the wire should be superior to the sustentaculum tali and inferior to the tip of the medial malleolus.

Note:

Intra-operative fluoroscan imaging is used to ensure proper placement of the Guidewire.



Operative Technique

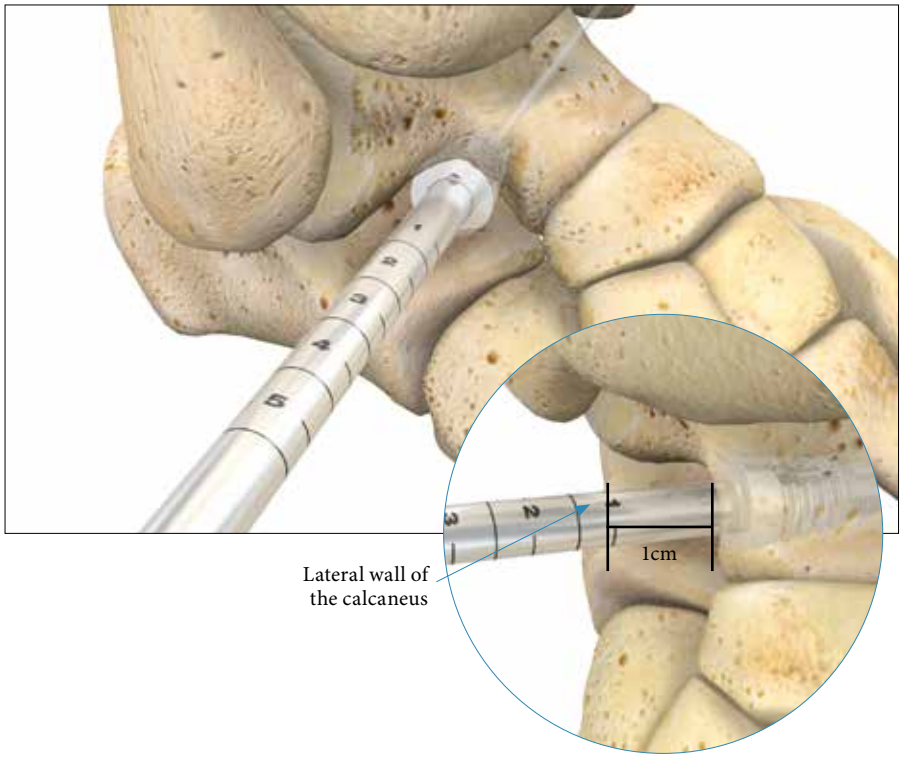
Trial

Select and deliver over the Guidewire the right size of the implant necessary to achieve normal hindfoot motion.

Start with the smaller sized Trial, insert over the Guidewire until the implant is 1cm from the lateral wall of the calcaneus or until the leading edge of the implant is past the talar neck midline bisection. Check for excessive subtalar pronation. Increase the size of the Trial as needed for the desired effect. You should avoid over sizing the Trial: this could dilate the sinus tarsi and delay proper seating of the correct sized implant. If this does occur you may consider prolonged period of non weight-bearing.

Evaluate the positioning via X-Ray (both anterior/posterior and lateral) and reference it via the markings on the Trial handle.

If the implant is inserted too far medially there is a chance of medial dislocation of the implant; inserting an implant too large will inhibit normal pronation.

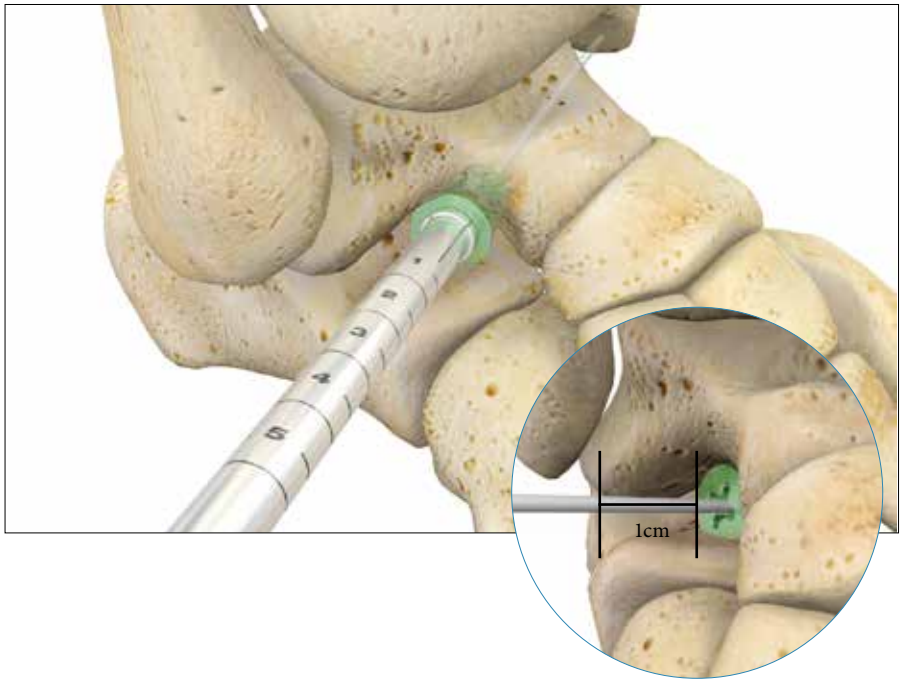


Final Implant Insertion

Following Trial implant removal, select the appropriate implant (SUT0065 to SUT0115), attach it to the Insertion Driver (XTV009001) and place it over the Guidewire. Use the Insertion Instrument to place the implant according to both the markings on the handle as well as radiographic verification.

As with Trial implant insertion, hindfoot motion and degree of deformity correction should be assessed clinically to verify adequate correction. The trailing end of the implant should be 1cm or more medial to the lateral wall of the calcaneus.

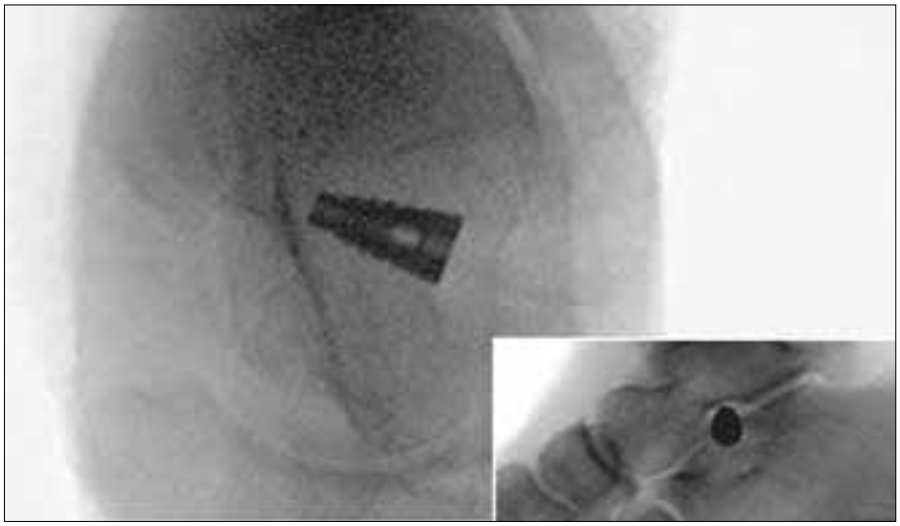
The wound should be irrigated and closed in layers according to the surgeons preference.



Operative Technique

Post-operative Protocol

Post-operative recovery is dependent on any concomitant procedures performed. Provided that the SubFix Arthroereisis Implant is performed in isolation, protected weight-bearing in a below-the-knee walking cast or boot for 2-4 weeks followed by gradual return to limited activity permitted at 4-6 weeks is most commonly performed.



Notes

Notes

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