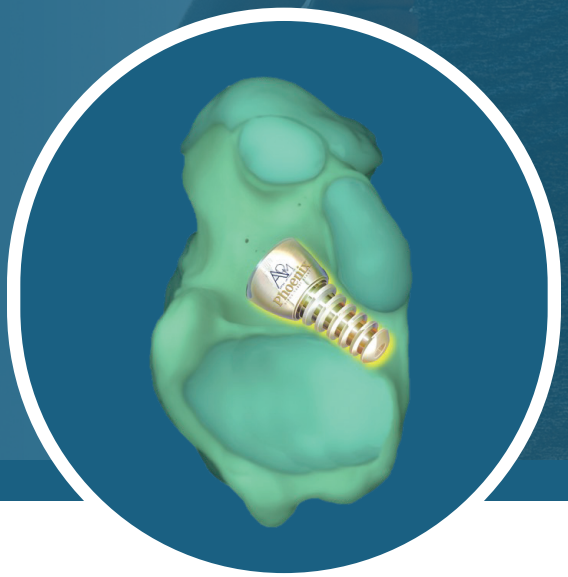

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SINUS TARSI STENT

The Next Evolution of EOTTS

Surgical Technique

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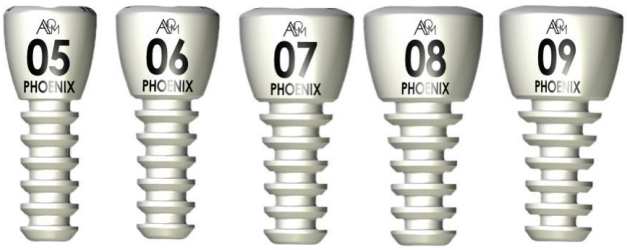
SINUS TARSI STENT

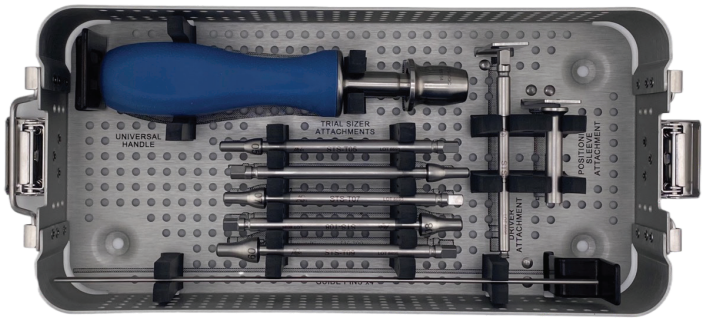
Medical Device and System Description

Implantable Stabilization Devices



The Phoenix Sinus Tarsi Stent System consists of implantable stabilization devices, of various sizes, and an instrumentation set. The stents are provided sterile for single use only, packaged separately from the instrument set, which is non-sterile and reusable.

Instrument Set



The instrument set contains a universal handle, driver, positioning driver sleeve, guidewires, and trial sizers. Only the stent remains in the patient.

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Indications for Use

Phoenix Sinus Tarsi Stent is an implant stabilization device used in the treatment of talotarsal joint instability in adult and pediatric patients four years of age and older. The stent is designed to stabilize the talus to prevent excessive anterior, and/or medial, and/or plantarflexion of the talus, while allowing normal talotarsal joint motion.

Contraindictations

The device should not be used in patients with the following conditions:

- Local active infection
- Allergic reaction to titanium
- Severe talar or calcaneal bone demineralization, poor bone stock
- Rigid or semi-rigid deformity
- Children three years old and younger
- Vascular compromised patient

Target Patient Population

Patient selection factors to be considered include:

- Adequacy of bone stock to support implant components.
- Patient age indicative of children four years and older.
- Functionality and/or stability of patient's musculotendinous system.
- Patient overall well-being, including the ability and willingness to follow pre and post-operative treatment regimen.

Implant Material

The Phoenix Sinus Tarsi Stent is made of titanium alloy (Ti-6Al-4V ELI).

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SINUS TARSI STENT

Warnings and Precautions

- The surgeon should be familiar with the recommended surgical procedure for this implant.
- An extremely critical part of the surgery is cutting of the talocalcaneal ligament deep in the canalis portion of the sinus tarsi.
- It is especially important to select the correct size of the implant to achieve the best possible correction.
- Over- or under-correction of talotarsal joint motion and incorrect placement of the stent may result in adverse conditions long-term.
- The package should be inspected for damage. If there is a question of sterility, another stent should be used.
- The expiration date should be checked; if expired, the stent should not be used.
- If the stent appears defective, it should not be used.
- This stent should NOT be re-sterilized or reused.
- Reuse or re-sterilization may result in inadequate cleaning/sterilization of the device, which could result in patient infection.
- The stents should be stored in their protected sterilized packages until use.
- Use relevant sterile techniques when removing the stent from the packaging.
- Inspect the stent for any physical defects and return any implant(s) that exhibit surface or configuration damage.
- These stents are intended to be sized and placed with the associated instruments; use of instruments from other systems may result in improper stent selection, and placement, which could result in device failure or poor clinical outcome.

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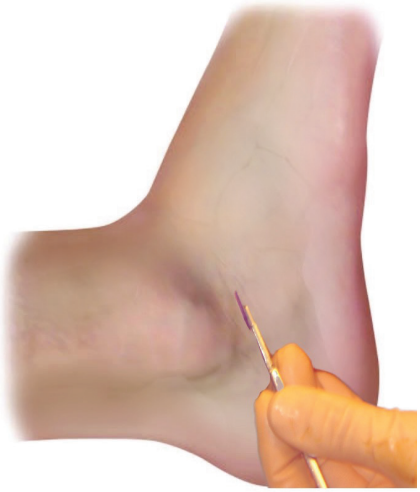
SINUS TARSI STENT

1 | Skin Incision

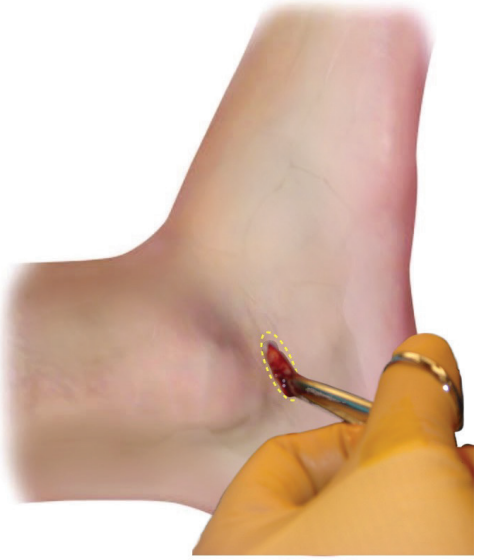


Utilizing a #15 blade, make a lateral skin incision, approximately a 1.5 to 2.0 cm within the skin lines centered over the sinus tarsi.

Surgical Tip:

To minimize post-procedure discomfort, the surgeon may inject 8 to 10 ccs of a long-acting local anesthetic, with or without a short- to mid-acting steroid to minimize post-operative swelling. A tourniquet in not necessary for this procedure.

2 | Blunt Dissection



Utilizing 4 ½ inch curved Steven's tenotomy scissors, puncture through the dermis into the superficial fascia with the tips closed (approximately 3 to 5 mms).

Open the tips of the scissors to blunt dissect the fascial covering of the sinus tarsi.

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SINUS TARSI STENT

3 | Sinus Tarsi Decompression

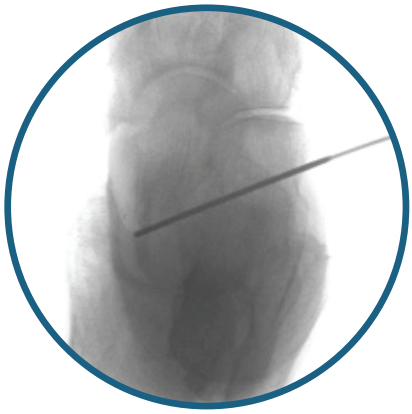
A critical step in this procedure is to make sure to decompress the soft tissues within the sinus tarsi. This allows proper placement of the trial sizer(s) and the cut ends of the tissue will heal around the notched portion of the stent.

Advance the curved Steven's tenotomy scissors deeper into the sinus tarsi space with a cutting action. Remember the oblique orientation of the sinus tarsi. Open and close the blades to cut the mid-substance of the ligaments within both the lateral sinus and deeper medial canalis portions of the sinus tarsi.

Surgical Tip:

Remember to have the angle portion of the scissors aimed posteriorly so they will enter the canalis portion of the sinus tarsi.

4 | Guide Pin Insertion



Premeasured guide pins are available to assist in the accurate placement of the trial sizers and the final placement of the stent. Insert the guide pin through the incision and aim at the posterior aspect of the medial malleolus.

If it seems difficult to insert the guide pin into the sinus tarsi, then it is possible that either the direction of insertion is incorrect or that there is inadequate transection of the interosseous ligament. The guide pin should be removed and the Steven's tenotomy scissors should be reinserted and cut any remaining fibers then finally reinsert the guide pin.

Surgical Tip:

Remember the orientation of the sinus is from anteriolateral distal to posteriomedial proximal.

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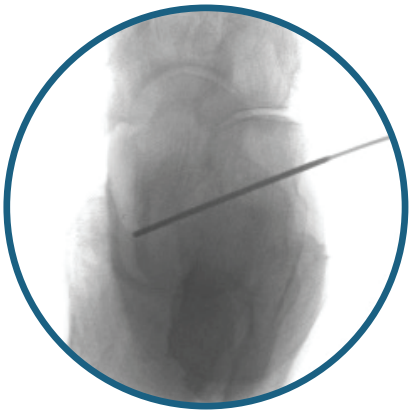
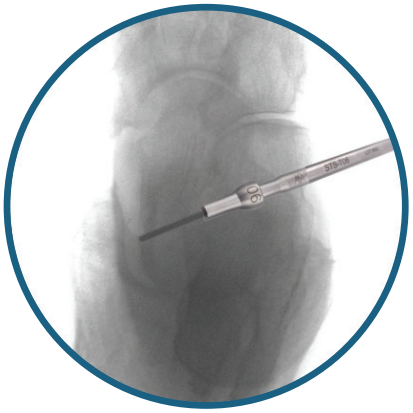
5 | Trial Sizing





Utilize the trial sizers to determine the appropriate stent size required to maintain the desired correction while still allowing the normal amount of talotarsal motion.

Select the specific size of the trial sizer and attached it on the universal driver.

Place the sizer into the sinus tarsi ensuring, via fluoroscopic or radiographic imaging, that the lateral end of the sizer is deeper than the lateral neck of the talus. Perform talotarsal joint range of motion.

Repeat the trial sizing & range of motion test using a larger or small trial sizer until you achieve the normal amount of talotarsal motion (identifying proper stent size).

When the desired range of motion is achieved, the trial sizer is removed from the sinus tarsi. Remove the trial sizer from the driver.

Surgical Tip:

If there appears to be a similar degree of correction between two sizes, it is preferred to use the smaller size.

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SINUS TARSI STENT

6 | Phoenix Sinus Tarsi Stent Placement

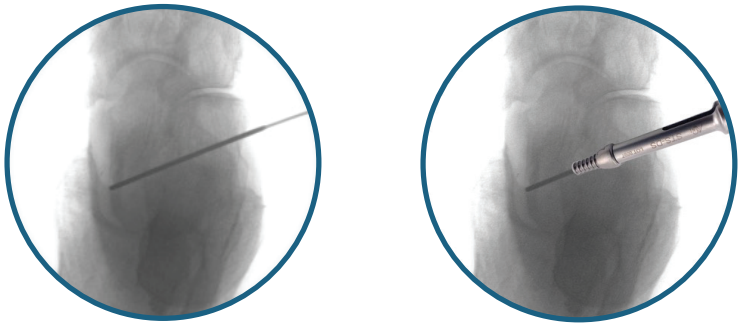
Attach the driver to the universal handle and then place the driver sleeve over the driver so that the prongs are toward the tip of the driver.

Have an authorized team member remove the pre-sterilized Phoenix stent from the shelf box after double-checking the size ensuring that the packaging is not damaged and check the expiration date is still valid, utilizing sterile technique.

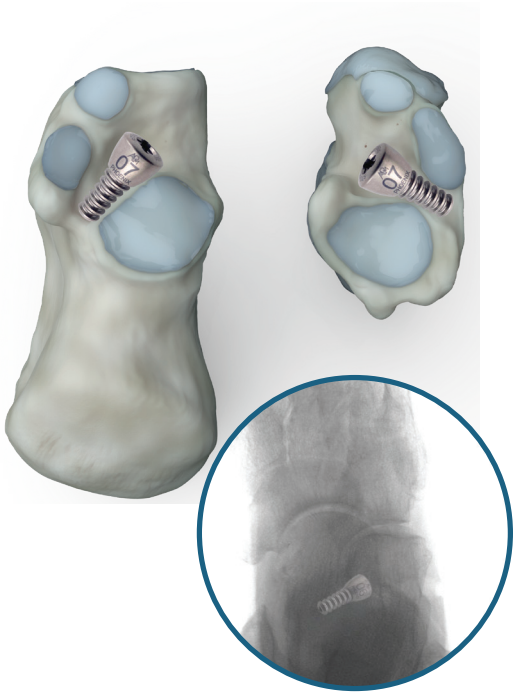
Lightly thread the Phoenix stent onto the driver.

Place the stent on the guide pin (if used) and drive the stent beneath the talus deep into the sinus tarsi to maintain the desired correction and range of motion.

Verify proper positioning of the stent with (fluoroscopic/radiographic/clinical) evaluation and talotarsal joint range of motion.



6 | Phoenix Sinus Tarsi Stent Placement Continued



Being satisfied with the final placement of the stent, advance the positioning sleeve forward, towards the tip of the driver, grasp the slotted portion with the index finger and thumb, and twist the handle counterclockwise which disengages the stent from the driver without displacing the position of the stent.

Remove all instruments from the foot. Again, check the final placement prior to closing the tissue if you suspect stent migration.

7 | Skin Closure

When satisfied with the correction achieved, the stability of the hindfoot, and the desired result, close the skin per the surgeon's choice.

Surgical Tip:

Ideally, only the skin is sutured. It is not necessary to place deeper sutures.

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SINUS TARSI STENT

Phoenix Sinus Tarsi Stent Revision or Permanent Removal

If the stent requires removal, utilize a #15 blade, make a lateral skin incision, approximately a 1.5 to 2.0 cm within the skin lines centered over the sinus tarsi.

Surgical Tip:

To minimize post-procedure discomfort, the surgeon may inject 8 to 10 ccs of a long-acting local anesthetic, with or without a short- to mid-acting steroid to minimize post-operative swelling. A tourniquet in not necessary for this procedure.

Utilize the 4 ½ inch curved Steven's tenotomy scissors, and puncture through the dermis into the superficial fascia with the tips closed (approximately 3 to 5 mms).

Open the tips of the scissors to blunt dissect the fascial covering of the sinus tarsi.

Attempt to place the guide pin within the cannula of the stent, insert the driver over the guide pin, and attempt to engage the tip of the driver into the lateral end of the stent.

Once engaged, rotate the driver several times to detach the soft tissue attachments onto the stent. And pull the stent from the sinus tarsi.

If unable to engage the driver into the lateral end of the stent, utilize implant removal forceps (not a part of the Phoenix Sinus Tarsi Stent Instrumentation), or sterile needle nose-like pliers. Place one jaw within the central canal of the stent and the opposite jaw on the periphery. Close the jaws and twist the stent more than 360 degrees in rotation to free the soft tissue attachment onto the stent. Then pull the stent laterally from the sinus tarsi.

IF A REVISION IS REQUIRED, once the stent is removed. Re-decompress with the sinus tarsi with the Steven's tenotomy scissors. Re-insert the guide pin and retrial size as per the surgical technique. Determine the desired stent size and place it within the sinus tarsi as previously described.

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SINUS TARSI STENT

Phoenix Sinus Tarsi Stents	Description	Part Number
	Size 5	STS-05
	Size 6	STS-06
	Size 7	STS-07
	Size 8	STS-08
	Size 9	STS-09

Accessory Instruments	Description	Part Number
	Universal Handle	STS-DQC
	Driver	STS-D
	Driver Sleeve	STS-DS
	Trial Sizer 5	STS-T05
	Trial Sizer 6	STS-T06
	Trial Sizer 7	STS-T07
	Trial Sizer 8	STS-T08
	Trial Sizer 9	STS-T09
	Guide Pin	STS-GP

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