

MEDICAL DEVICE DESCRIPTION – The Phoenix Sinus Tarsi Stent is a non-pyrogenic type IIB extraosseous talotarsal stabilization (EOTTS) device used in the treatment of talotarsal joint instability per Graham Et al. EOTTS classification system. The system consists of implants of various sizes and an instrumentation set. The implants, provided sterile for single use only, are packaged separately from the instrument set. The instrument set is provided non-sterile and is re-usable. The instrument set contains a driver, a positioning sleeve, guidewires, and trial sizers. Only the implant remains in the patient.

INDICATIONS – 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.

IMPLANT MATERIAL – This stent is made of titanium alloy (Ti-6Al-4V ELI, ASTM F-136).

CONTRAINDICATIONS – 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:

- Failure of previous conservative treatment options in correcting deformity and achieving pain relief.
- Adequacy of bone stock to support implant components.
- Patient age 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.

INTENDED USER – The Phoenix Sinus Tarsi Stent System is intended to be used by a licensed orthopedic or podiatric surgeon only.

WARNINGS & 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 canal 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 instability 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.
- 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 stent, 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 implant from the packaging.
- Inspect the stent for any physical defects and return any stent(s) that exhibit surface or configuration damage.
- These stents are intended to be fitted and installed with the associated instruments; use of instruments from other systems may result in improper stent selection, fitting, and placement, which could result in implant failure or poor clinical outcome.

MR. SAFETY INFORMATION – These stents have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of these stents in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

POTENTIAL ADVERSE EVENTS/ SIDE-EFFECTS – The following potential adverse effects associated with the use of this device may include:

- Prolonged pain, edema, soreness, numbness, redness, stiffness, discomfort, and walking difficulty
- Infection
- Lack of relief/correction
- Synovitis/capsulitis/bursitis
- Loosening, migration or displacement of the stent within the sinus tarsi
- Scarring from the incision
- Intolerance to the stent
- Decrease in bone density surrounding the stent due to stress shielding
- Foreign body reaction
- Need for revision surgery or removal

These potential risks should be discussed pre-operatively with the patient prior to the procedure. There may be other adverse effects that can occur with any surgical procedure. These potential risks should be discussed pre-operatively with the patient prior to the procedure. The surgeon should discuss general risks and potential complications associated with this and any surgical procedure with the patient prior to patient consent (e.g., pain, swelling, redness, soreness, implant-related issues, etc.).

INSERTION TECHNIQUE

STEP ONE: 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.

STEP TWO: 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 mm). Open the tips of the scissors to blunt dissect the fascial covering of the sinus tarsi.

STEP THREE: Sinus Tarsi Decompression and Insertions of Guide Wire

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 canal portions of the sinus tarsi.

Pre-measured 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.

STEP FOUR: 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.

STEP FIVE: Phoenix 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.

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.

STEP SIX: 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.

Phoenix Stent REMOVAL TECHNIQUE

STEP ONE: Skin Incision

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.

STEP TWO: Blunt Dissection

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 mm).

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

STEP THREE: Phoenix Stent Removal

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.

If permanent removal, only resuture the skin, do not attempt to reappropriate the deeper tissues, this is unnecessary.

Insert stent removal forceps into the space, grasp the stent, rotate it 360 degrees, and remove it. Repeat trial sizing and stent placement for a revision procedure as described above or simply close the skin for a permanent removal.

LIMITED WARRANTY – Astra OrthoMed, Inc. warrants that this device meets the manufacturer’s specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the device prior to implantation. Astra OrthoMed, Inc. does not warrant the outcome of the surgical procedure

Astra OrthoMed, Inc.
7842 Hickory Flat Hwy
Woodstock, Georgia, USA 30188
+1 ###-###-####
Made in USA
www.phoenix-sts.com

Any serious incident in relation to the device should be reported to Astra OrthoMed, Inc. and the competent authorities.

Glossary Of Symbols used on the Shelf Box Package Label and / or Instructions for Use

	Batch code		Use-by date
	Catalog number		Date of manufacture
	Do not re-use		Manufacturer
	Do not re-sterilize		Double sterile barrier system
	Caution		Sterilized using irradiation
	Prescription use only		Do not use if package is damaged
	Medical device		Unique device identifier
	Serial number		Non-sterile
	Consult instructions for use		Non-Pyrogenic