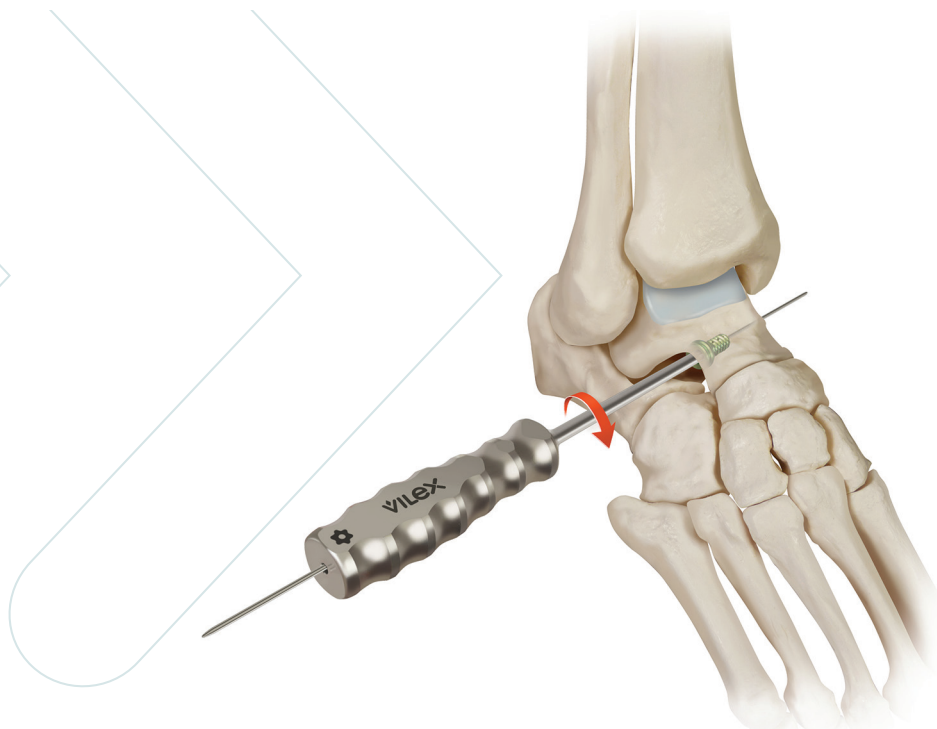


Talex™

SUBTALAR STABILIZATION SYSTEM



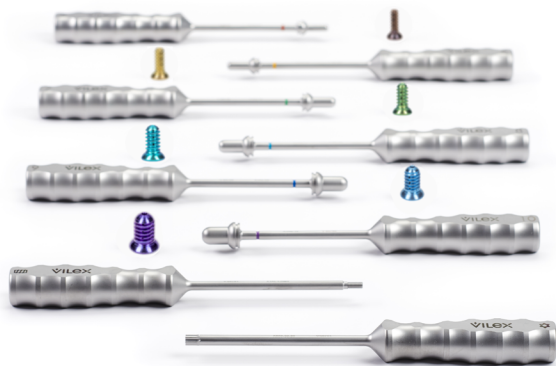
VILEX

Talex™

SUBTALAR STABILIZATION SYSTEM

Design Rationale

The Talex™ Subtalar Stabilization System is the latest advancement in the evolution of subtalar implants. The implants are engineered to more closely match the anatomy of the sinus tarsi. Talex™ implants are designed with a smooth, toroid-shaped head to realign the rotational axis of talar motion, and a stem for medial anchoring in the canalis tarsi. The hexalobe drive mechanism offers enhanced driver engagement with the implant, improving driving force and reducing potential for stripping of the implant. The head is also custom cut to reduce the lateral weight of the implant, providing a neutral, more even weight distribution of the implant.



The drive system combined with Grippex™ thread technology offers greater control and improved bite, potentially reducing the incidence of rotational backout after implantation. Talex™ implants are designed with axial cut channels and cross holes on the medial stem to facilitate ingrowth which may decrease the chance of implant migration. The Talex™ Subtalar Stabilization System offers improved ease of use and surgeon comfort. The ergonomically designed instrumentation includes color coded trial sizers that match the bright colors of the implants. Trial sizers accurately correspond to the implant sizes. The completely cannulated system offers precise positioning of the implant and the inclusion of the patented reverse thread removal tool provides an option for repositioning or removing the implant with greater ease.

INDICATIONS FOR USE

The Talex™ Subtalar Stabilization System is indicated for use on patients with flat foot or a pronated subtalar joint.

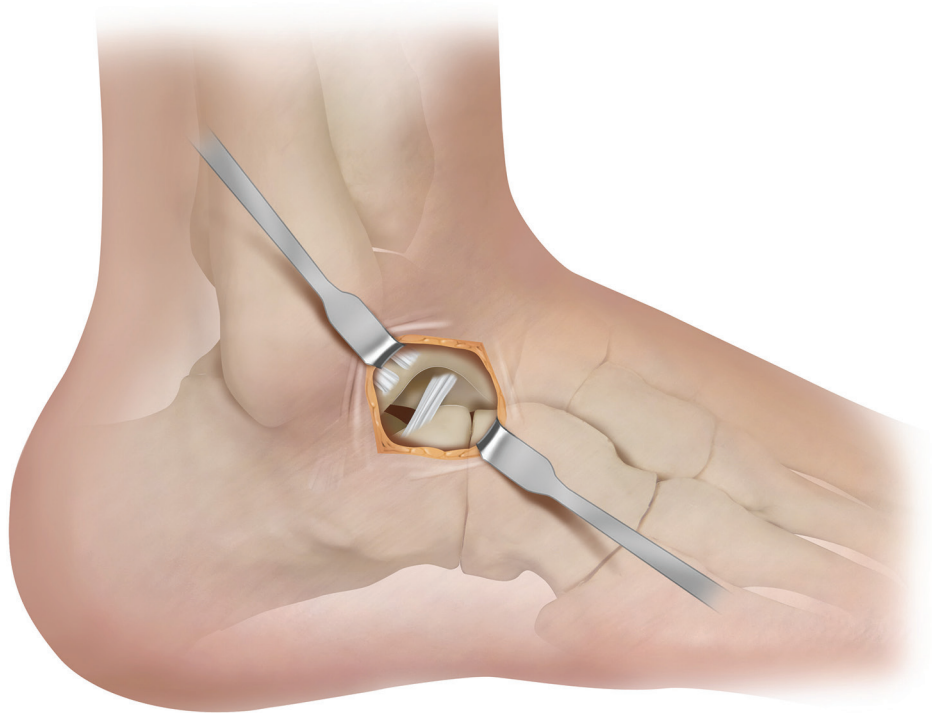
1 Surgically expose the joint

Locate the central depression of the sinus tarsi on the lateral surface of the foot. Create a 1 – 2.5 cm incision directly over the center of the sinus and dissect the fascia to allow access to the talocalcaneal (subtalar) space.



SURGICAL TIP

To minimize post-op discomfort, the surgeon may inject several ccs of a long-acting local anesthetic, with or without a steroid to minimize post-operative swelling.



2 Place the guide wire

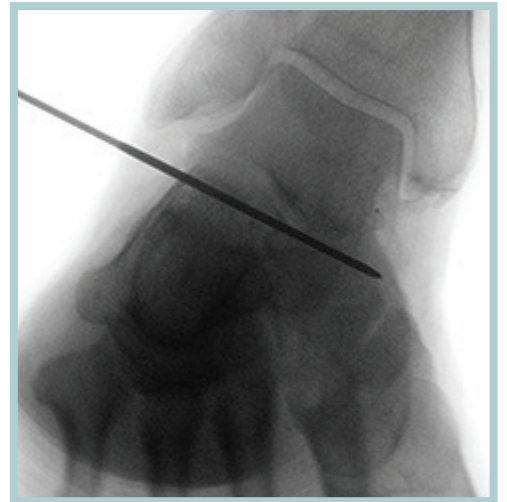
Insert the double-sided blunt guide wire into the sinus tarsi and through the canalis tarsi lateral-to-medial until the wire tents against the skin on the medial side of the foot inferior to the medial malleolus, ensuring that the canal has been fully traversed. If desired this step may be combined with the subsequent step by utilizing the smallest trial sizer (Size 5) as a probe to dilate the canal, easing the guide wire insertion.



SURGICAL TIPS

The head should be $\pm 2-3$ mms from the neck of the talus.

If you are unsure, increase trial size until it locks the joint, then use the next size down.

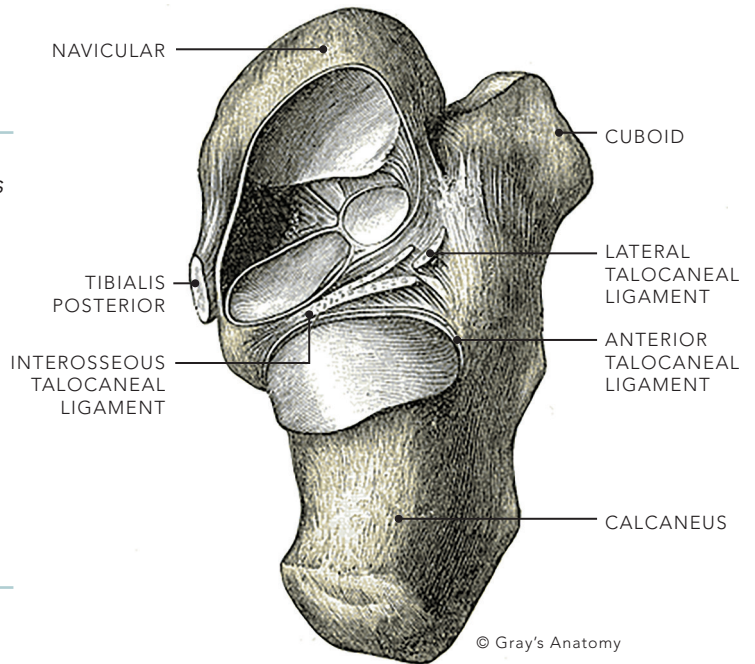


INSTRUMENTATION USED

- K300-20 Double-sided Blunt Wire
- XTAL-05 Talex Trial Sizer, 5mm
- XTAL-07 Talex Trial Sizer, 7mm

3 Determination of appropriate size

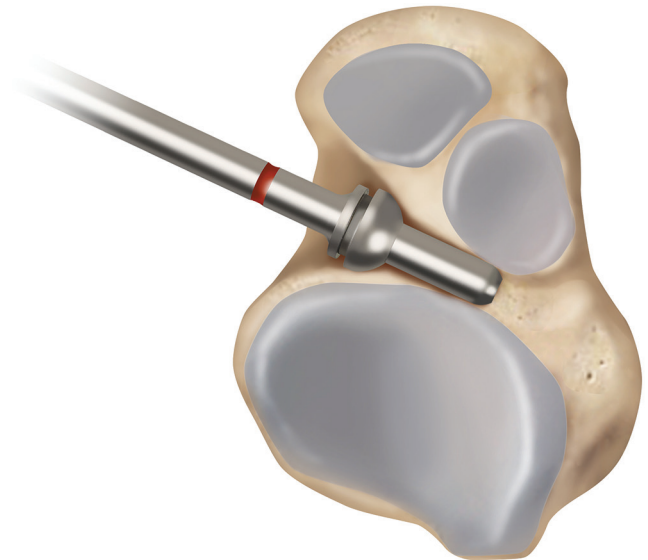
NOTE: *It is recommended that the interosseous ligament be surgically excised from the canalis tarsi prior to the determination of the correct size. An intact interosseous ligament can interfere with correct sizing of the subtalar implant and increase the forces acting along the axis of the implant (increasing backout incidence).*



Perform the initial trial as follows:

TRIAL PLACEMENT

Place the smallest trial instrument (Size 5) over the lateral end of the guide wire. Advance the trial through the sinus tarsi and deep into the canalis tarsi until the head of the implant stops against the talocalcaneal bone surfaces.



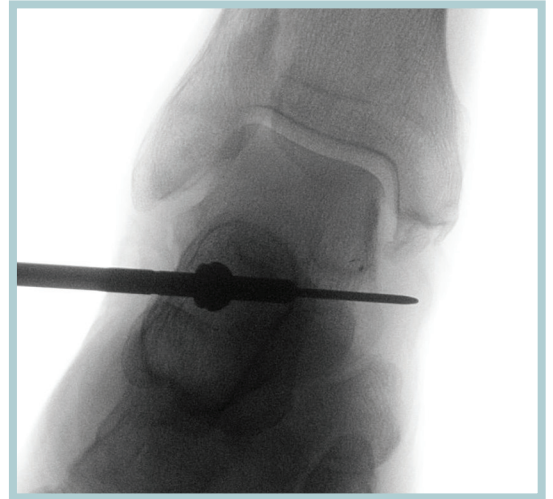
INSTRUMENTATION USED

- XTAL-05 Tallex Trial Sizer, 5mm

*Step 3, continued***MOTION ASSESSMENT**

Assess the subtalar joint through a complete range of motion, ensuring no impingement is present and the level of correction is adequate: the correct size will allow approximately three degrees of eversion motion within the joint.

Repeat the above process using subsequent larger size trial instruments until the correct size is determined. Use multi-planar fluoroscopy to verify that the end of the trial instrument is seated correctly in the subtalar joint, providing an accurate representation of the implant behavior within the joint. The narrow portion of the trial tip should be fully within the canalis tarsi and the toroidal head of the trial should be against the talocalcaneal bone surfaces at the entrance to the canal.

**SURGICAL TIPS**

When the tip of the sizer meets with initial resistance at the entrance to the canalis tarsi, angle the sizer posteriorly. This will allow the tip of the implant to enter the canalis tarsi.

Ensure proper placement under fluoroscopy. The tapered portion should abut the entrance to the canalis tarsi.

INSTRUMENTATION USED

- XTAL-05 through 10 Talex Trial Sizer, 5mm - 10mm

4 Implantation

Remove the correctly-sized trial instrument and place the corresponding implant onto the lateral end of the guide wire – the instruments and implants are linked through color coding for easy recognition.

Install the implant into the subtalar joint using the driver instrument over the guide wire as follows:

INTRODUCING THE IMPLANT

Use firm linear pressure to advance the implant along the wire to the entrance of the canalis tarsi (until the threaded region of the implant's shaft makes contact with the canal).

ADVANCING THE IMPLANT

Turn the driver clockwise while applying firm linear pressure to advance the implant shaft deep into the canal using the shaft threading.

FULLY SEATING THE IMPLANT

Increased resistance will be felt when the toroidal head of the implant makes contact with the talus or calcaneus at the canal entrance – at this point the implant is fully implanted.

TRIAL & IMPLANT COLOR CODING

5 MM

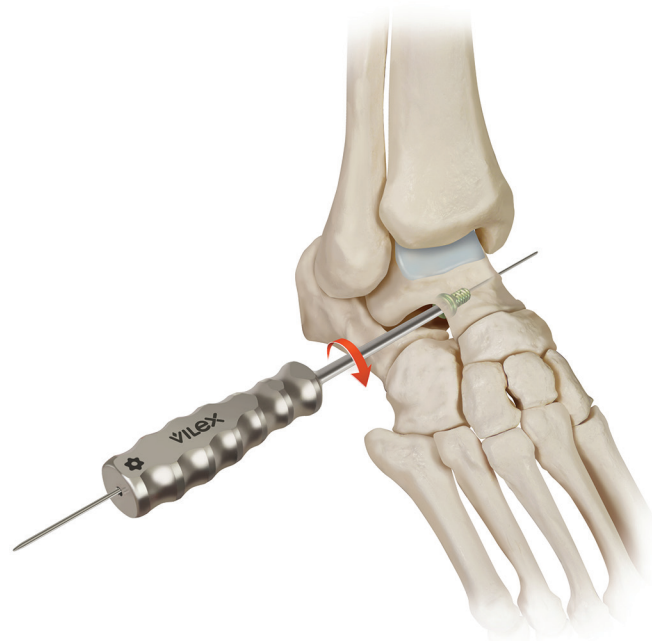
6 MM

7 MM

8 MM

9 MM

10 MM

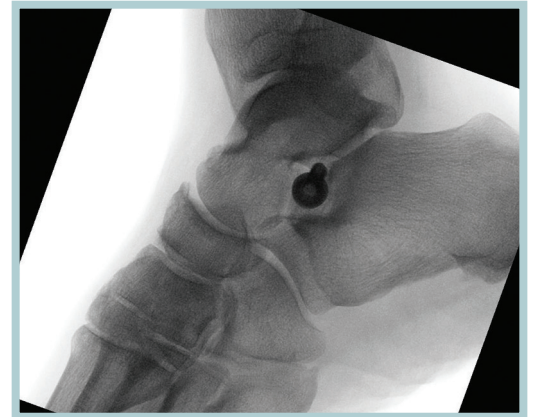
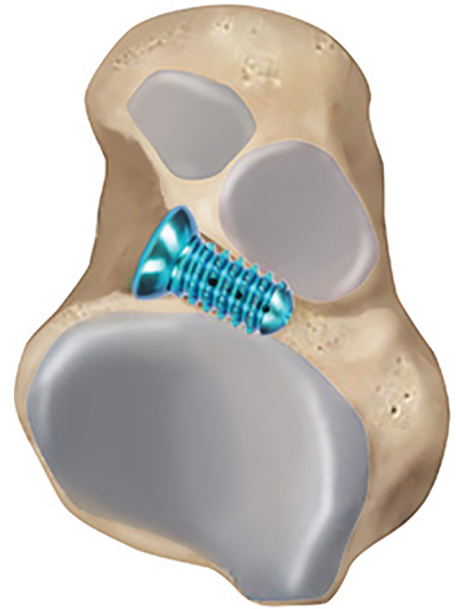


INSTRUMENTATION USED

- X500-30-20 Driver, Talex T30
- K300-20 Double-sided Blunt Wire
- Implant shown: TAL-07T, 7mm

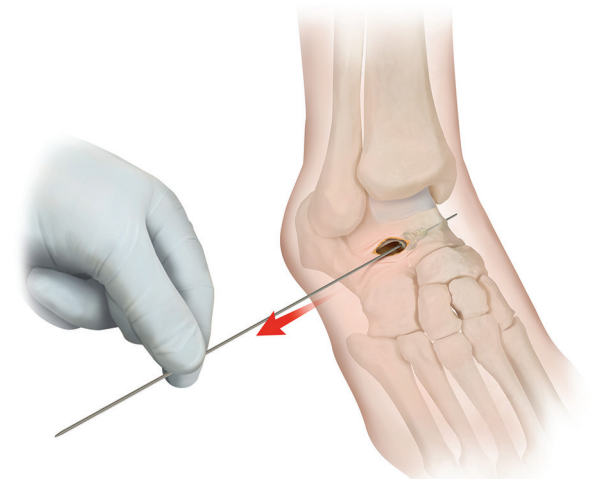
5 Ensure correct implant position

Confirm implant sizing and placement by assessing the joint range of motion and utilizing multi-planar fluoroscopy to verify that the narrow shaft of the implant is fully within the canalis tarsi and the toroidal head of the implant is against the talocalcaneal bone surfaces at the entrance to the canal. If the implant is not appropriately installed, utilize the implant removal procedure described later in this technique to reinstall the implant or repeat the sizing procedure as needed.



6 Instrument removal and final verification

Grasp the guide wire and gently apply linear pressure in the lateral direction to remove the guide wire from the surgical incision and implant. Slowly turning the wire clockwise while applying force may facilitate removal. Once the wire has been removed, perform a final verification step to ensure that the implant has remained in the correct position: re-assess joint range of motion and use multi-planar fluoroscopy to visualize the implant's relationship to the joint.



INSTRUMENTATION USED

- K300-20 Double-sided Blunt Wire
- Implant shown: TAL-07T, 7mm

7

Completion of procedure

Ensure all instrumentation is removed from the surgical incision. Irrigate the incision and joint region and perform a surgical closure of the deep and superficial tissues.

POST-OPERATIVE INSTRUCTIONS

- Bandage over surgical site.
- An anti-inflammatory and pain medication may be prescribed.
- Minimize weight bearing for the first 3-10 days.
- Casting is not generally recommended.



OPTIONAL TECHNIQUE TIPS

Pre-surgical RFA of Sinus Tarsi

Denervation of the sinus tarsi may be performed prior to the subtalar arthroereisis procedure to minimize post-operative discomfort.

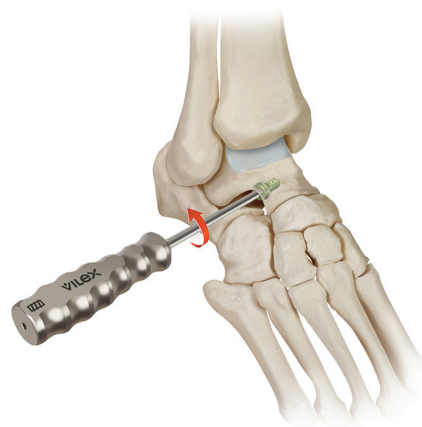
It is recommended that the subtalar arthroereisis procedure be performed unilaterally to minimize risk of displacement. Once the first foot is fully healed, the second operation may be considered (4-10 weeks generally).

This procedure may be performed in conjunction with a gastrocnemius recession when indicated.

Removal Technique

If the implant is to be removed whether as part of the initial surgical procedure or during a subsequent procedure, a dedicated removal tool has been created for this purpose. This process may be performed with or without the guide wire in place.

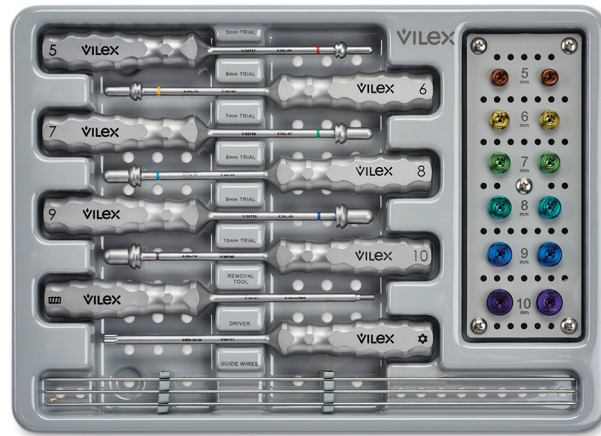
- 1 Place the removal tool over the guide wire (if present) and advance it linearly until it resides within the driver cavity of the implant body.
- 2 Turn the removal tool counter-clockwise while applying firm linear pressure to thread the removal tool into the implant (the removal tool utilizes left-handed threading). Increased resistance will be felt once the removal tool has been fully-threaded into the implant (approximately 5 turns).



- 3 Once fully-threaded, apply linear pressure laterally along the removal tool to remove the implant – turning the removal tool counter-clockwise while removing the implant may facilitate the process. Unthread the implant from the removal tool by rotating the items clockwise from one another.

INSTRUMENTATION USED

- XTAL-LHM4 Talex Removal Tool



Item Listing

VILEX P/N	DESC	CASE QTY	TYPE
TAL-05T	Talex 5mm Titanium Implant	2	Implant
TAL-06T	Talex 6mm Titanium Implant	2	Implant
TAL-07T	Talex 7mm Titanium Implant	2	Implant
TAL-08T	Talex 8mm Titanium Implant	2	Implant
TAL-09T	Talex 9mm Titanium Implant	2	Implant
TAL-10T	Talex 10mm Titanium Implant	2	Implant
XTAL-05	Talex Trial Sizer, 5mm	1	Instrument
XTAL-06	Talex Trial Sizer, 6mm	1	Instrument
XTAL-07	Talex Trial Sizer, 7mm	1	Instrument
XTAL-08	Talex Trial Sizer, 8mm	1	Instrument
XTAL-09	Talex Trial Sizer, 9mm	1	Instrument
XTAL-10	Talex Trial Sizer, 10mm	1	Instrument
K300-20	Double-sided Blunt Guide Wire	3	Instrument
X500-30-20	Driver, Talex T30	1	Instrument
XTAL-LHM4	Talex Removal Tool	1	Instrument



ADVANCE WITH US >>>

111 Moffitt Street
McMinnville, TN 37110

p: 800.521.5002
f: 866.606.4911

info@vilex.com
www.vilex.com