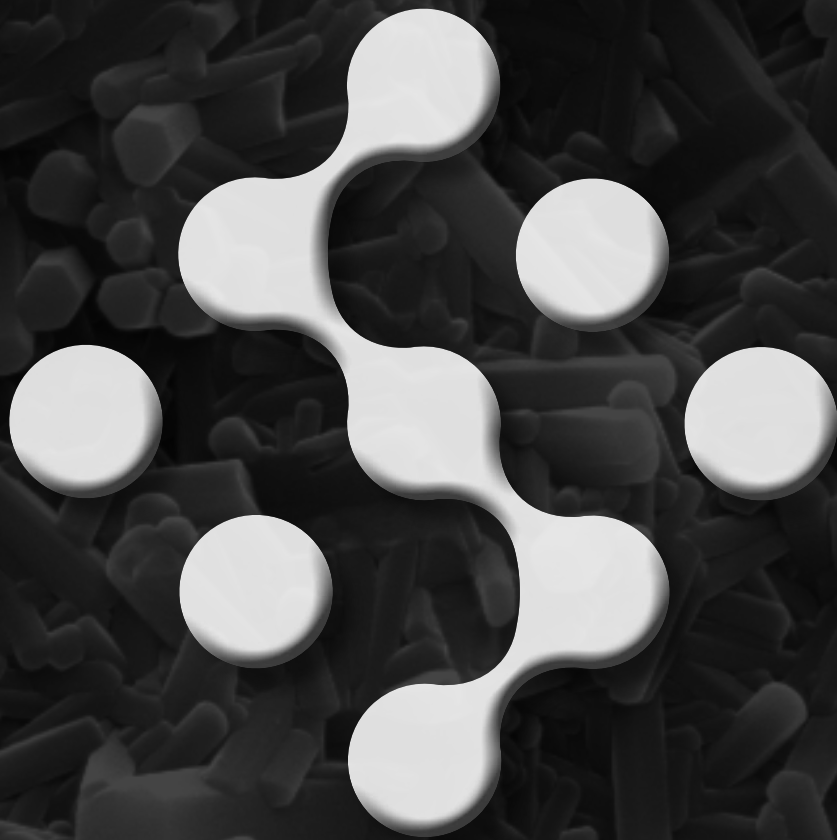


Subtalar Wedge

SINAPTIC® OSTEOTOMY WEDGE SYSTEM

SUBTALAR DISTRACTION ARTHRODESIS WEDGE

SURGICAL TECHNIQUE



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For further product information or to arrange a product demonstration, please contact your local SINTX representative or call Customer Service toll-free in the U.S. at (855) 839-3500 or email cs@sintx.com. You can also visit www.sintx.com.

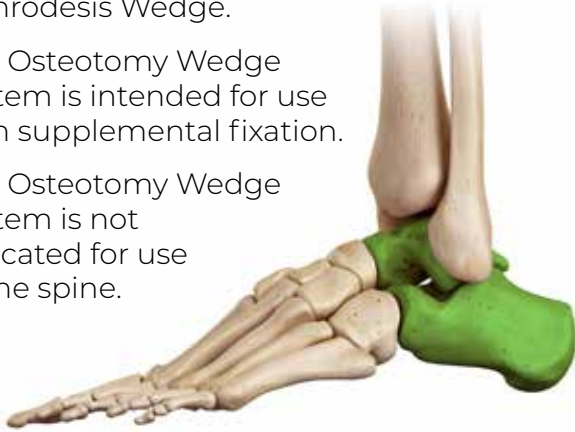


Indications

The SiNAPTIC Osteotomy Wedge System is intended to be used for internal bone fixation for fractures or osteotomies in the ankle and foot, such as Subtalar Distraction Arthrodesis Wedge.

The Osteotomy Wedge System is intended for use with supplemental fixation.

The Osteotomy Wedge System is not indicated for use in the spine.



For a full list of indications, see the product specific IFU.

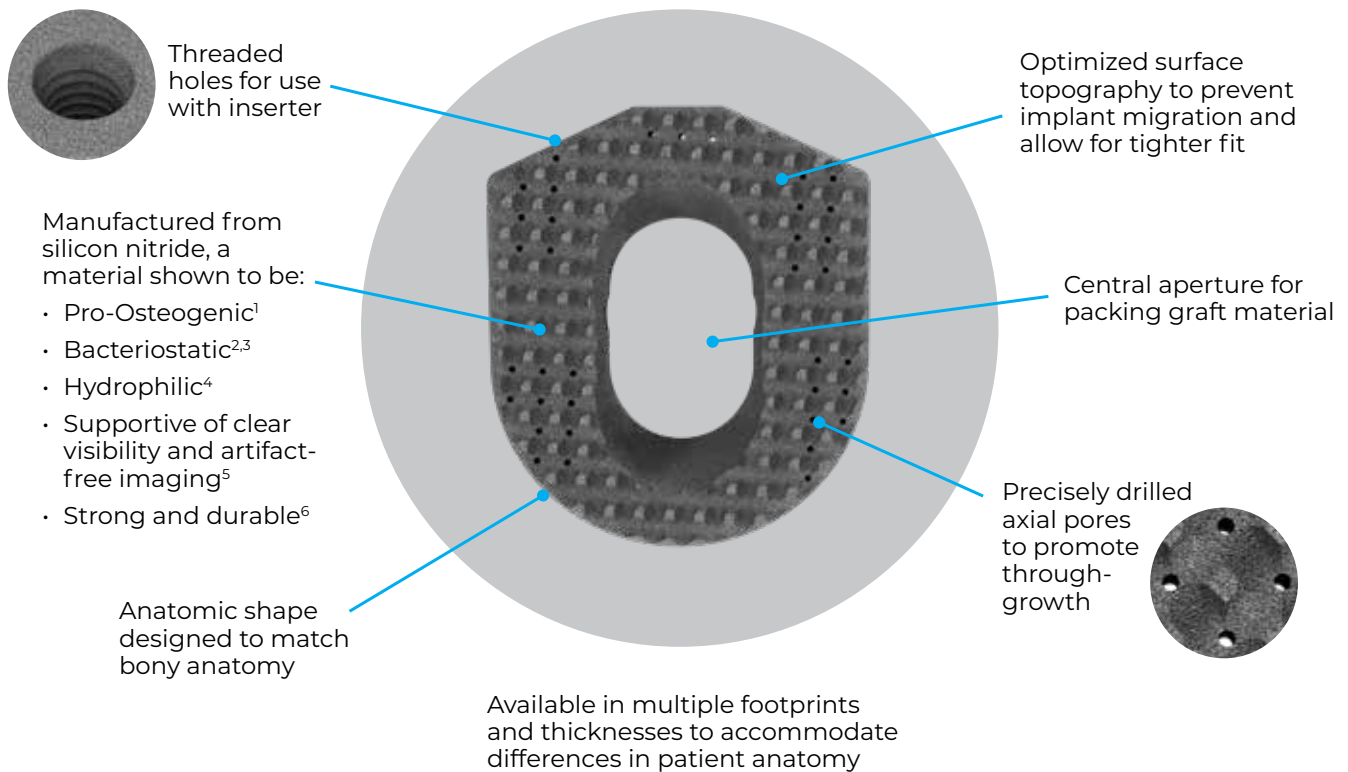
Contraindications

The wedges are contraindicated for use in cases of:

- Infection
- Physiologically or psychologically inadequate patients
- Inadequate skin, bone, or neurovascular status
- Insufficient quantity or quality of bone to permit stabilization of the osteotomy
- Conditions that restrict the patient's ability or willingness to follow post-operative instructions during the healing process.
- Irreparable tendon system
- Growing patients with open epiphyses
- Patients with high levels of activity
- Malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless additional supplemental fixation or stabilization methods are utilized
- Foreign body sensitivity – where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.

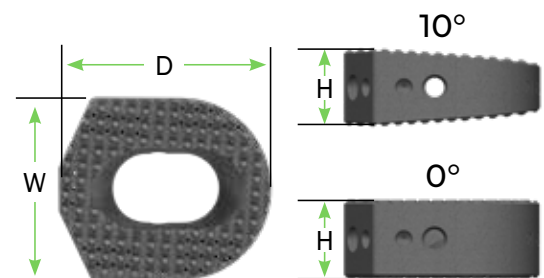
Product Overview

The SiNAPTIC Subtalar Wedge is designed for internal bone fixation for fractures or osteotomies in the foot and ankle. The Subtalar Wedge is intended to address subtalar arthrosis, calcaneal fracture neglect, and malunion. Manufactured from silicon nitride, a variety of footprint sizes and thicknesses are provided to accommodate differences in patient anatomy. The wedge portfolio is designed to provide options for valgus, neutral, and varus corrections. All wedges can be inserted from a lateral or posterolateral approach.



Sizing Options

WIDTH (MM)	DEPTH (MM)	HEIGHT* (MM)	VARUS/ VALGUS CORRECTION
19mm	25mm	8mm, 10mm, 12mm, 14mm, 16mm	0°/10°
23mm	25mm	8mm, 10mm, 12mm, 14mm, 16mm	0°/10°



*Height of Subtalar Wedges are in 2mm increments.

Implants

The SiNAPTIC Subtalar Wedge System is designed to interface with a threaded inserter to allow for accurate placement. Once the implant is definitively positioned, simply unscrew the inserter to release. The inserters are included in the instrumentation kits and interface with the implants, trials, and tamp tip.



Reusable Instrumentation

Subtalar Wedges are available with reusable trials and inserters. The instrument kit includes inserters and trials corresponding to implant sizes in a reusable tray. The trials are threaded onto the end of the inserter and used to determine the footprint and height of implant which will provide the desired correction.

Sizing Trials

- Designed to allow intraoperative assessment of correction prior to definitive wedge placement
- Quick exchange between trial sizes to help identify optimal anatomic fit and deformity correction
- Stable seating within the osteotomy site to evaluate alignment
- Geometry matched to the definitive silicon nitride wedge for accurate fit evaluation
- Available in incremental sizes to support precise gap assessment



Inserter

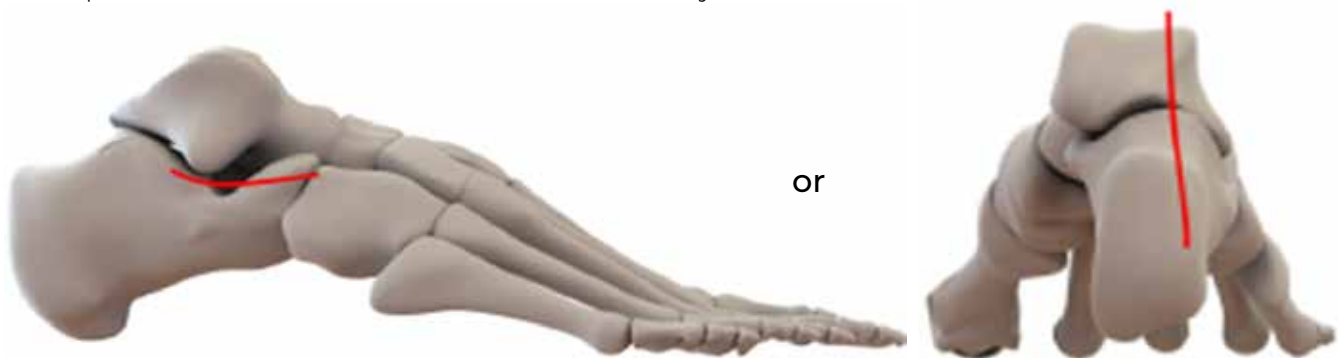
- Positive engagement interface designed to maintain implant stability during advancement
- Instrument geometry aligned with medial column anatomy to support planned correction
- Low-profile tip designed for controlled placement within the Subtalar osteotomy
- Designed to support accurate seating depth and reproducible alignment
- Three Inserters are provided to allow for more efficient procedures



Subtalar Wedge Surgical Technique

1. Surgical approach.

Plan an incision that will allow the addressing of any calcaneal deformity, removal of any hardware present, correcting of any calcaneal malunion and lateral wall exostosis, and access to the subtalar joint for distraction arthrodesis. Common incisions include those made along the curve of the peroneals, sinus tarsi, or an extensile lateral incision. Release the calcaneofibular ligaments laterally and mobilize the peroneal tendons and sural nerve. Identify and safeguard the flexor hallucis longus tendon, as it protects the neurovascular bundle. Release the talocalcaneal interosseous ligament to allow for improved mobilization and distraction of the joint.



2. Prepare the joint.

Correct any bony malunion (i.e.- varus) or nonunion at this time. Remove any large exostosis, which is posterior and superior to the calcaneal tuberosity or lateral calcaneal wall. Realign and stabilize any bony malalignment prior to preparing the joint for fusion. Distract the subtalar joint and remove the remaining cartilage on either side of the posterior facet. Prepare the subchondral bone for fusion by cracking or scaling and drilling the bone surfaces for better surface integration in the fusion. When preparing the joints, pay attention to create a flat surface on the calcaneus and talus to ensure the appropriate bone-implant apposition.



3. Determine the correct implant size and shape with the implant trial(s).

Trial selection depends on the thickness, width, and depth of the osteotomy site, the preparation technique, and the patient's anatomy. Based on the preoperative imaging and surgical technique, choose a trial of the appropriate size, thread the desired trial head onto inserter shaft, tightening with two fingers, and carefully insert it into the osteotomy site. Sequentially trial until desired correction is achieved.

Using fluoroscopy verify the correct sizing of the trial (footprint, thickness, and angle), ensure that the selected trial is congruent to the osteotomy site, and visually assess that the correction is adequate, paying particular attention to the coronal plane alignment. Remove the trial and select the corresponding Subtalar Wedge.

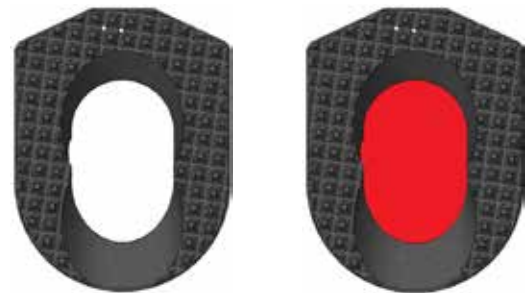
NOTE: At this time, ensure that the skin incision will close without tension after the correction and joint distraction.

NOTE: If using the posterolateral insertion, the inserter will be at an approximate angle of 25 degrees to the center plane of the foot. Pulling the inserter into closer alignment with the center plane of the foot will rotate the implant and severely alter the trajectory of fixation screws if the wire guides are used.

PRECAUTION: The inserter should not be used as a lever arm to provide lateral movement to the trial or implant in the osteotomy. This puts undue strain on the threaded joint between the trial or implant and the inserter.

4. Prepare the implant, including packing with bone graft material, if desired.

If desired, the interior of the wedge may be packed with bone graft material.



Before Placing Graft

After Placing Graft

5. Place the implant on the inserter handle.

Attach the wedge to the inserter by threading the inserter's tip into the corresponding threaded hole on the wedge. Thread the implant onto the inserter until some resistance is felt and the implant is held flush against the inserter and securely in place.



PRECAUTION: Take caution to not overtighten when threading the implant onto the inserter as overtightening could result in failure to disengage the implant after insertion.

6. Orient the implant and inserter in the correct alignment and carefully insert the implant into the distracted segment.

Carefully insert the implant into the osteotomy site. If necessary, use light impaction to advance the implant until it is flush with bone. If a pin-based distractor or laminar spreader was used to maintain access to the osteotomy site, remove it now.

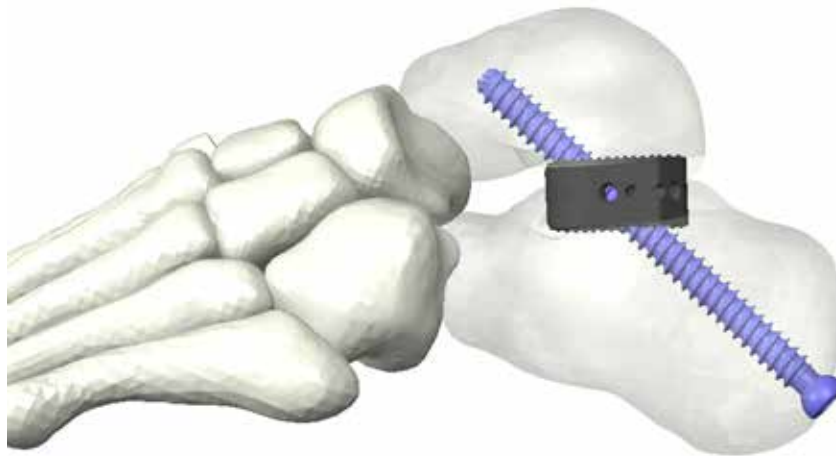
PRECAUTION: When inserting the implant, take care to avoid using excessive impaction force to prevent damage to the implant or surrounding tissue.

7. Verify implant position.

Confirm the final position of the implant via fluoroscopy.

8. Implant fixation.

SiNAPTIC Subtalar Wedges are intended for use with supplemental fixation. Once final placement is confirmed, insert a screw, or other fixation, through the calcaneus, the wedge, and into the talus to secure the wedge in place. The fixation selected should be based on the surgeon's preference. Autograft, and/or allograft bone, and/or orthobiologic can be inserted around the wedge at this time if desired.



9. Complete surgical procedure as required.

Use layers of sutures to close the incision with the surgeon's preferred technique.

Explant Information


If this implant needs to be removed due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located in this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation. Remove the additional fixation that was initially used with the Subtalar Wedge. Remove this with corresponding instrumentation (screw, plate, or staple removal instrumentation). Use Subtalar Wedge Inserter to reattach and secure to wedge. Pull or slide wedge out of osteotomy. Use distractors to distract osteotomy if wedge is tightly positioned.

Ordering Information

Subtalar Wedges - 0° and 10°

IMPLANT	PRODUCT CODE	WIDTH	DEPTH	HEIGHT	CORRECTION
	S-121-192508-0	19mm	25mm	8mm	0°
	S-121-192510-0			10mm	
	S-121-192512-0			12mm	
	S-121-192514-0			14mm	
	S-121-192516-0			16mm	
	S-121-232708-0	23mm	27mm	8mm	
	S-121-232710-0			10mm	
	S-121-232712-0			12mm	
	S-121-232714-0			14mm	
	S-121-232716-0			16mm	
	S-121-192508-10	19mm	25mm	8mm	10°
	S-121-192510-10			10mm	
	S-121-192512-10			12mm	
	S-121-192514-10			14mm	
	S-121-192516-10			16mm	
	S-121-232708-10	23mm	27mm	8mm	
	S-121-232710-10			10mm	
	S-121-232712-10			12mm	
	S-121-232714-10			14mm	
	S-121-232716-10			16mm	

Subtalar Wedge – Reusable Surgical Kit

KIT / TRAY COMPONENTS	PART #	DESCRIPTION
	100-15-1000	Universal Reusable Tray Assembly
	100-15-1000-1	Universal Reusable Tray, Base
	100-15-1000-2	Universal Reusable Tray, Lid
	125-15-1000	Subtalar – 0° Reusable Surgical Caddy, Kit
	125-15-1000-1	Subtalar – 0° Reusable Surgical Caddy, Base
	125-15-1000-2	Subtalar – 0° Reusable Surgical Caddy, Lid
	125-15-1010	Subtalar – 10° Reusable Surgical Caddy, Kit
	125-15-1010-1	Subtalar – 10° Reusable Surgical Caddy, Base
	125-15-1010-2	Subtalar – 10° Reusable Surgical Caddy, Lid

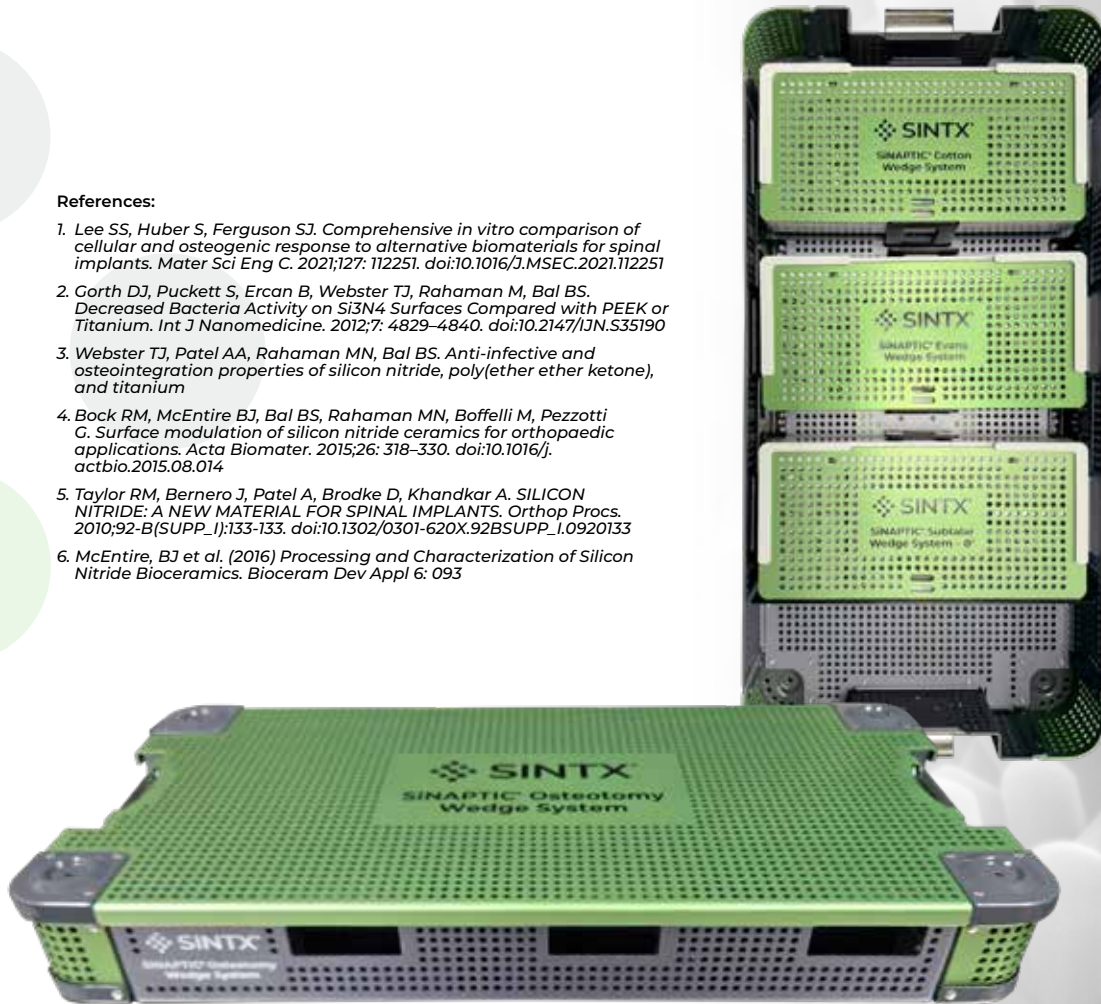
Subtalar Wedge – Reusable Kit Components



INSTRUMENT	PART #	WIDTH	DEPTH	THICKNESS	THICKNESS
	123-25-192508-0	19mm	25mm	8mm	0°
	123-25-192510-0			10mm	
	123-25-192512-0			12mm	
	123-25-192514-0			14mm	
	123-25-192516-0			16mm	
	123-25-232708-0	23mm	27mm	8mm	0°
	123-25-232710-0			10mm	
	123-25-232712-0			12mm	
	123-25-232714-0			14mm	
	123-25-232716-0			16mm	
	123-25-192508-10	19mm	25mm	8mm	10°
	123-25-192510-10			10mm	
	123-25-192512-10			12mm	
	123-25-192514-10			14mm	
	123-25-192516-10			16mm	
	123-25-232708-10	23mm	27mm	8mm	10°
	123-25-232710-10			10mm	
	123-25-232712-10			12mm	
	123-25-232714-10			14mm	
	123-25-232716-10			16mm	
	123-15-1100	Subtalar Inserter			
	103-15-1200	Tamp Tip			

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