

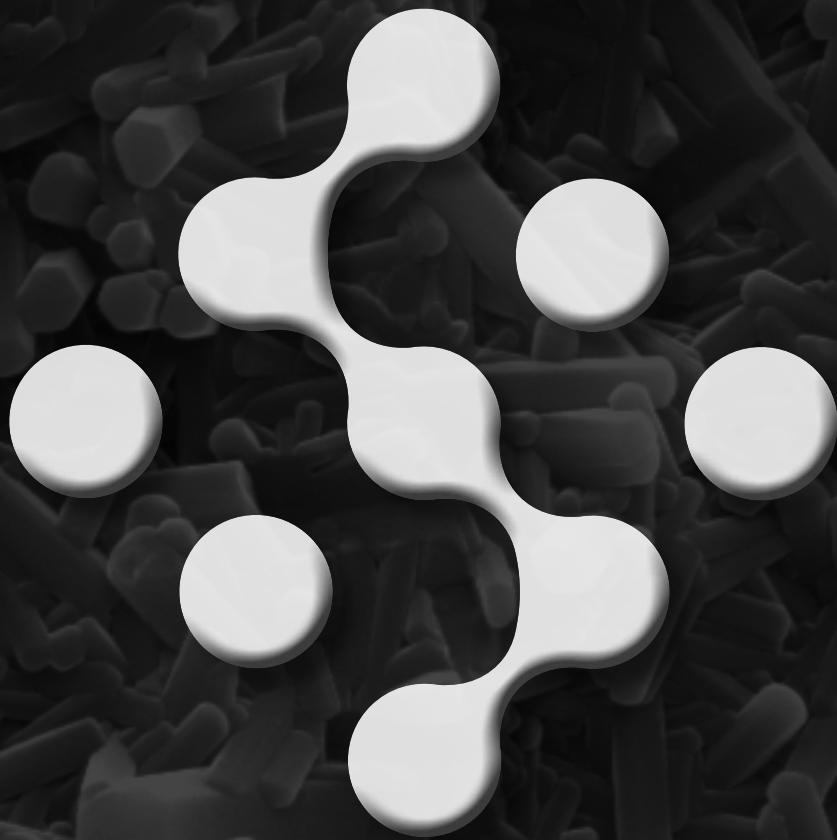


Cotton Wedge

SINAPTIC[®] OSTEOTOMY WEDGE SYSTEM

COTTON MEDIAL CUNEIFORM OPENING WEDGE

SURGICAL TECHNIQUE



Contents

Indications & Contraindications	1
Product Overview	2
Product Overview	2
Sizing Options.....	2
Implants	3
Reusable Instrumentation	3
Cotton Wedge Surgical Technique.....	4
Explant Information.....	8
Ordering Information – Implants.....	8
Cotton Wedges.....	8
Ordering Information – Instrumentation	9
Reusable Surgical Kit.....	10
Reusable Kit Components.....	10

IMPORTANT NOTE: SINTX, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. SINTX is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient. Always refer to the package insert, product label and/or product instructions prior to using any SINTX product.

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:

- Opening wedge of medial cuneiform or cotton osteotomies

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.

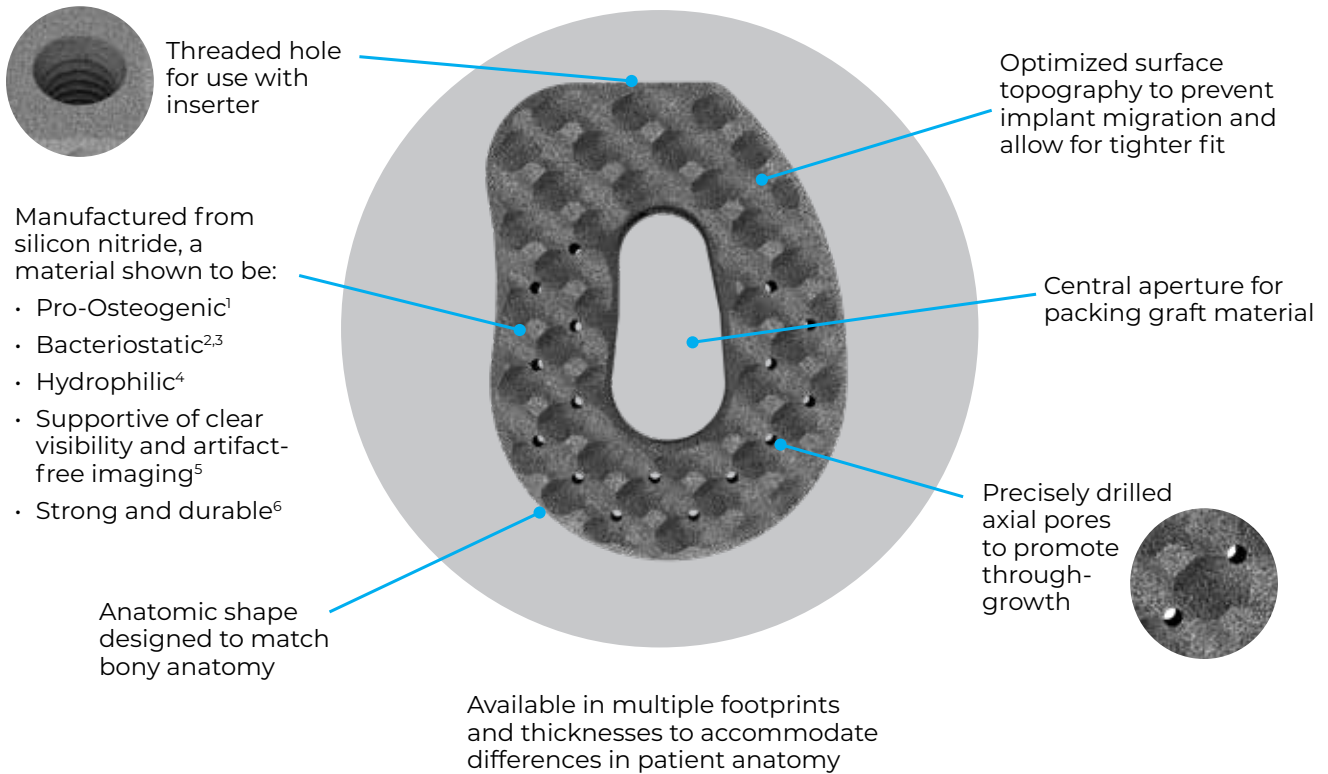
Contraindications

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.

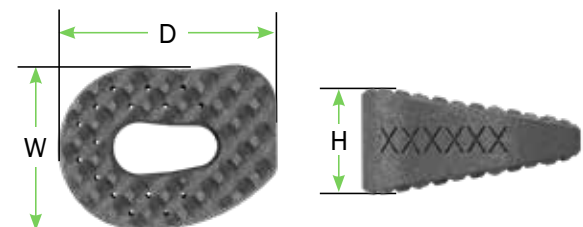
Product Overview

The SiNAPTIC Cotton Osteotomy Wedge is designed for internal bone fixation for fractures or osteotomies in the foot and ankle. The Cotton Wedges are for plantar flexion opening wedge osteotomies of the medial cuneiform. Manufactured from silicon nitride, a variety of footprint sizes and thicknesses are provided to accommodate differences in patient anatomy.



Sizing Options

WIDTH (MM)	DEPTH (MM)	HEIGHT* (MM)
12mm	16mm	5mm, 6mm, 7mm, 8mm, 10mm, 12mm
14mm	18mm	5mm, 6mm, 7mm, 8mm, 10mm, 12mm



Implants

The SiNAPTIC Cotton 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

Cotton 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 to facilitate placement within the medial cuneiform osteotomy
- Designed to support accurate seating depth and reproducible alignment
- Three Inserters are provided to allow for more efficient procedures



Cotton Wedge Surgical Technique

1. Make an incision to expose the medial cuneiform.

Make a 2-3 cm incision dorsally over the body of the medial cuneiform.

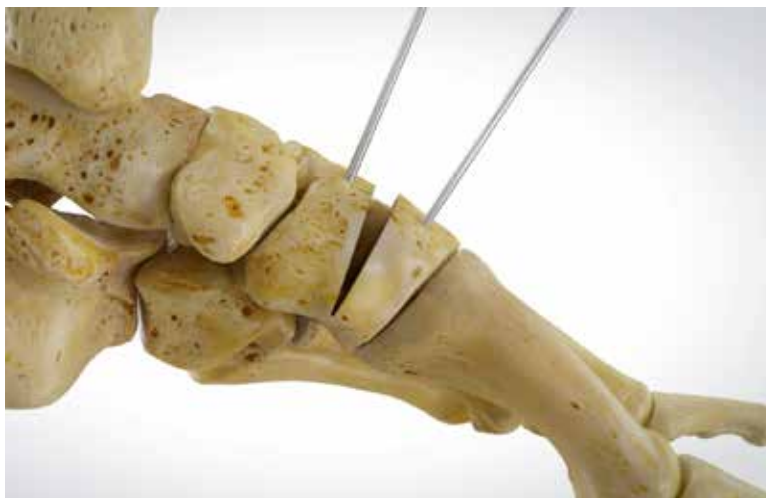
Use blunt dissection to expose the first metatarsal cuneiform and navicular medial cuneiform joints, taking care to retract both the extensor hallucis longus and tibialis anterior tendons.



2. Perform an osteotomy and distract to allow for access into the site.

Make a transverse osteotomy on the dorsal surface of the medial cuneiform to avoid articular injury. Leave the plantar cortex intact to provide stability to the osteotomy while also aiding in the correction of a plantar deformity.

A pin based distractor or laminar spreader may provide controlled distraction of the osteotomy. Once access is secured, distract the osteotomy to your desired correction. The trials may be used to hold distraction of the anatomy intraoperatively.



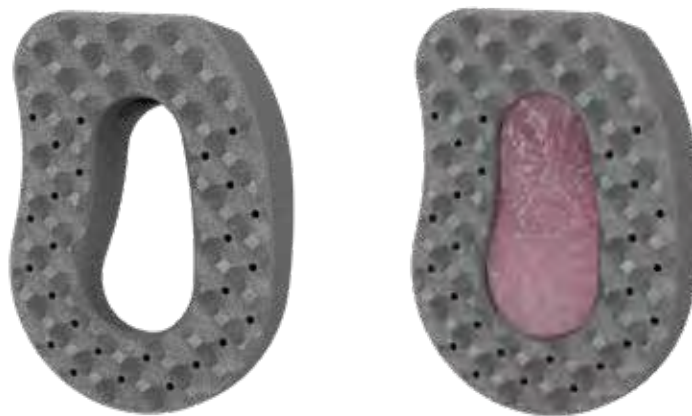
3. Determine the correct implant size and shape with the implant trial(s).

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. Verify correct sizing via fluoroscopy and select the implant that corresponds to the footprint and thickness determined using the implant trial(s).

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.

NOTE: When using fluoroscopy, the inserter may be left connected to the trial or implant since it is radiolucent.

8. Remove the inserter and inspect implant.

Unscrew inserter from the wedge. Inspect the wedge to ensure there is congruent contact with bone along its surface.



9. Implant fixation.

SiNAPTIC Osteotomy Wedges are intended for use with supplemental fixation such as plating fixation, screws or staples.

The fixation selected should be based on the surgeon's preference.





10. Complete surgical procedure as required.

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 Cotton Wedge. Remove this with corresponding instrumentation (screw, plate, or staple removal instrumentation). Use the Cotton 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

Cotton Wedge – Implants

IMPLANT	PART #	DESCRIPTION	WIDTH	DEPTH	HEIGHT
	S-111-121605	Cotton Wedge Implant	12mm	16mm	5mm
	S-111-121606				6mm
	S-111-121607				7mm
	S-111-121608				8mm
	S-111-121610				10mm
	S-111-121612				12mm
	S-111-141805	Cotton Wedge Implant	14mm	18mm	5mm
	S-111-141806				6mm
	S-111-141807				7mm
	S-111-141808				8mm
	S-111-141810				10mm
	S-111-141812				12mm

Cotton Wedge – Reusable Surgical Kit

KIT / TRAY COMPONENTS	PART #	DESCRIPTION
  <i>115-15-1000</i>	100-15-1000	Universal Reusable Tray Assembly
	100-15-1000-1	Universal Reusable Tray, Base
	100-15-1000-2	Universal Reusable Tray, Lid
	115-15-1000	Cotton Reusable Surgical Caddy, Kit
	115-15-1000-1	Cotton Reusable Surgical Caddy, Caddy
	115-15-1000-2	Cotton Reusable Surgical Caddy, Lid

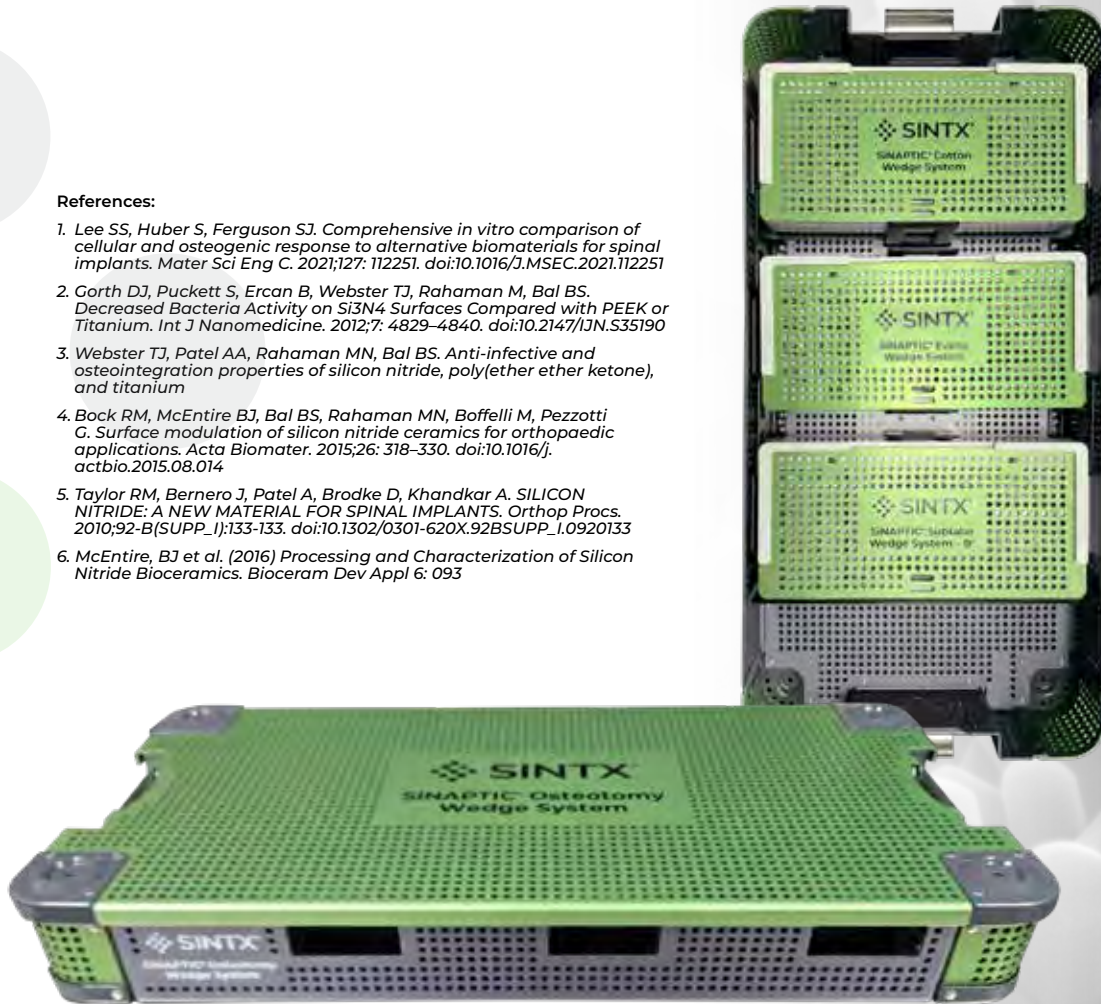
Cotton Wedge – Reusable Kit Components



INSTRUMENT	PART #	DESCRIPTION	WIDTH	DEPTH	HEIGHT
	113-25-121605	Cotton Wedge Trial	12mm	16mm	5mm
	113-25-121606				6mm
	113-25-121607				7mm
	113-25-121608				8mm
	113-25-121610				10mm
	113-25-121612				12mm
	113-25-141805	Cotton Wedge Trial	14mm	18mm	5mm
	113-25-141806				6mm
	113-25-141807				7mm
	113-25-141808				8mm
	113-25-141810				10mm
	113-25-141812				12mm
	103-15-1100	Inserter			
	103-15-1200	Tamp Tip			

References:

1. Lee SS, Huber S, Ferguson SJ. Comprehensive in vitro comparison of cellular and osteogenic response to alternative biomaterials for spinal implants. *Mater Sci Eng C*. 2021;127: 112251. doi:10.1016/J.MSEC.2021.112251
2. Gorth DJ, Puckett S, Ercan B, Webster TJ, Rahaman M, Bal BS. Decreased Bacteria Activity on Si₃N₄ Surfaces Compared with PEEK or Titanium. *Int J Nanomedicine*. 2012;7: 4829–4840. doi:10.2147/IJN.S35190
3. Webster TJ, Patel AA, Rahaman MN, Bal BS. Anti-infective and osteointegration properties of silicon nitride, poly(ether ether ketone), and titanium
4. Bock RM, McEntire BJ, Bal BS, Rahaman MN, Boffelli M, Pezzotti G. Surface modulation of silicon nitride ceramics for orthopaedic applications. *Acta Biomater*. 2015;26: 318–330. doi:10.1016/j.actbio.2015.08.014
5. Taylor RM, Bernero J, Patel A, Brodke D, Khandkar A. SILICON NITRIDE: A NEW MATERIAL FOR SPINAL IMPLANTS. *Orthop Procs*. 2010;92-B(SUPP_1):133-133. doi:10.1302/0301-620X.92BSUPP_1.0920133
6. McEntire, BJ et al. (2016) Processing and Characterization of Silicon Nitride Bioceramics. *Bioceram Dev Appl* 6: 093



1885 West 2100 South
Salt Lake City, UT 84119
Phone: 1.855.839.3500

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

© 2026 SINTX Technologies, Inc. Marks noted with ® or TM are trademarks of SINTX. All Rights Reserved.
Printed in the USA.

MKG-LE-WED-FA-COT-STG-002 REV 0