SiNAPTIC® Osteotomy Wedge System
Instructions for Use (IFU)

1) DEVICE DESCRIPTION

The SiNAPTIC Osteotomy Wedge System is a set of implantable wedge-shaped devices for use in osteotomies of the small bones of the foot and ankle. The wedges are manufactured from medical grade Silicon Nitride. The wedges are offered in a variety of footprints and heights to accommodate varying patient anatomies. The wedges are intended to be used with supplemental fixation.

All implants are provided with instrumentation to assist in the implantation of the devices. The system includes trials, inserters and tamps to facilitate the placement and positioning of the wedges. Additionally, for some of the implants, optional guides are provided to help ensure proper positioning of ancillary screw fixation

2) IMPLANT MATERIALS

The SiNAPTIC Osteotomy Wedge System implants are manufactured from a medical grade of Silicon Nitride (Si_3N_4).

3) INDICATIONS FOR USE

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 osteotomies of the bones of the foot, including osteotomies for Hallux Valgus
- Opening wedge of the medial cuneiform or Cotton osteotomies.
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z-Osteotomy)
- Metatarsal Cuneiform osteotomies
- Nonunion of arthrodesis of the Midfoot including Metatarsal Cuneiform osteotomies (TMT or Lapidus)
- Hindfoot osteotomies such as Ankle fusion and Subtalar fusion

The SiNAPTIC Osteotomy Wedge System MTP Wedges are intended to be used for internal fixation of metatarsal bones that have been surgically prepared (osteotomy) for correction of deformity.

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

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

4) DIRECTIONS FOR USE

Utilizing the provided trials and inserter handles, determine the appropriately sized wedge for the anatomic location and indication. Thread the inserter to the selected implant, taking care not to overtighten the inserter as it may result in damage to the implant. Using the inserter, insert the implant into the desired location. Confirm the correct placement of the wedge. If the wedge is not in the desired location, the implant may be repositioned using the inserter or provided tamp. Remove the inserter and complete the procedure. Detailed surgical techniques for using the instruments are available.

Note: The inserter sleeves, k-wire guide arms, and k-wire sleeves are single-use only. All other instruments are offered in reusable and single-use versions.

A surgical technique is available which outlines the basic procedure for device implantation and the use of specialized surgical instrumentation. It is the responsibility of the surgeon to be familiar with the procedure before using these products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

5) 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.

6) WARNINGS AND PRECAUTIONS

Caution: U.S. federal law restricts this device to sale by or on the order of a physician

Read all the instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.

WARNINGS

- The implants are provided sterile and are for ONE TIME USE ONLY. If the implant or the package appear damaged the implant should not be used. DO NOT reuse as this may damage or compromise the performance of the device and may expose patient to risk of transmitting infectious diseases. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage or contamination that could result in implant failure and should be discarded.
- Preoperative and operative procedures, including knowledge of surgical techniques, good reduction and proper selection and placement of the implants are important considerations in the successful utilization of these devices
- Correct sizing of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implants. The patient's anatomy and indication will determine the size of the implant to be used. The size and shape of the human bones presents limiting restrictions on the size and strength of implants
- In evaluating patients for orthopedic appliance application, the patient's weight, occupation, activity level and any degenerative diseases are of extreme importance to the eventual success of the procedure. These conditions must be evaluated as part of preoperative planning. Conditions of senility, mental illness, alcoholism, tobacco or drug abuse must also be taken into consideration.
- It is important that immobilization of the osteotomy site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established to reduce the likelihood of delayed or non- union of the fracture or osteotomy site. Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to the healing of the fracture. Due to normal fatigue, these stresses can cause eventual bending or breakage of the device.
- Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant or osteotomy nonunion requiring revision surgery to remove the device. The risk of device failure may increase due to patient-related factors including activity level, weight, or noncompliance due to psychological condition.
- The use of wedges provides the physician a means of correction. These implants are intended as a guide to normal healing and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or non-unions in the presence of load bearing or weight bearing might eventually cause the implant to break due to fatigue. All surgical implants are subject to repeated stress in use which can result in fatigue.
- Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bone union, the patient must be warned that breakage of the device may occur as a result of the weight bearing or muscle activity. An active patient or a debilitated or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.

PRECAUTIONS

- Correct selection of implants is extremely important. The potential for success is increased by selecting the proper implant size, shape, and design. The patient's anatomy and indication will determine the size of the wedge to be used.
- No partial weight-bearing or non-weight-bearing device can be expected to withstand the unsupported stresses of full weight bearing. Until the bony union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at fracture site and delay healing.
- The Osteotomy Wedge System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the system 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.
- When inserting the implant, care should be taken to avoid using excessive impaction force to prevent damage to the implant or surrounding tissue.
- While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, devices should be removed once their service as an aid to healing is accomplished, particularly in younger more active patients.

7) POSSIBLE ADVERSE EVENTS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Loss of anatomic position with nonunion or malunion with rotation or angulation
- Bone resorption or over-production
- Allergic reaction to the implant material
- Untoward histological responses possibly involving macrophages and/or fibroblasts

8) STERILITY

Implants

Implants are provided sterile in an unopened, undamaged package. If either the implant or the package appears damaged, if the package is beyond the sterility expiration date, or if sterility is questioned for any reason, the implant should not be used

Instruments

Instruments provided in both sterile and non-sterile options.

Sterile instruments are provided in an unopened, undamaged package. If either the instrument or the package appears damaged, is beyond the sterility expiration date, or if sterility is questioned for any reason, the instrument should not be used.

Non-sterile instruments are provided clean but NOT sterile. Instruments must be sterilized prior to use. Instruments are intended to be sterilized with steam sterilization. The following moist heat sterilization cycle, which results in a SAL of 10^{-6}, was validated for use in accordance with applicable standards, including ANSI/AAMI ST79

Configuration	Wrapped in FDA cleared sterilization wrap
Sterilizer	Pre-Vacuum
Cycle	Four (4) minutes at 270°F (132°C)
Dry Time	Forty Five (45) minutes

Sterilization cycles beyond the prescribed parameters must be validated independently by the facility. Each facility's process parameters should be validated for the type of sterilization equipment and product load configuration.

9) REUSABLE INSTRUMENT CLEANING

All reusable instruments must be thoroughly cleaned, inspected, and sterilized between uses. Clean instruments as quickly as possible after each use. It is important not to allow blood or debris to dry on the instruments

- Completely disassemble instruments, as appropriate.
- Fully immerse the instruments in enzymatic detergent prepared according to the detergent manufacturer's recommendations for a minimum of 20 minutes.
- Thoroughly brush the instruments using a soft-bristled brush, assuring all hard-to-reach areas and cannulas are accessed and all visible soil has been removed.
- Rinse instruments in lukewarm tap water for a minimum of 3 minutes until all detergent residues are removed. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
- Fully immerse instruments in enzymatic detergent prepared according to the detergent manufacturer's and placed in a sonication unit. Sonicate for 10 minutes at 45-60 kHz.
- Rinse instrument with lukewarm purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
- Repeat sonication and rinse steps above.
- Dry the instruments using a clean, soft, non-absorbing cloth.
- Visually inspect the instruments to confirm there is no visible soil remaining on the instruments. If there is any remaining contaminants or soil on the device, repeat the cleaning process.
- Return dry instruments to the sterilization tray.
- Instruments MUST be sterilized prior to use.

10) STORAGE

Store sterile packaged instruments in an area that provides protection from dust, moisture, insects, vermin and temperature/humidity extremes.

11) DISPOSAL

Upon removal of implant(s), dispose of as a biohazard material.

12) SYMBOLS GLOSSARY

STERILE R	Sterilized using irradiation	UDI	Unique device identifier
	Double sterile barrier system	REF	Model or Part Number
	Single sterile barrier system	LOT	LOT or Batch Code
NON STERILE	Non-sterile		Date of Manufacture
	Single Use Do not re-use		Manufacturer
	Do not use if package is damaged and consult instructions for use		Use by Date
	Consult instructions for use	Rx Only	Caution: USA Federal Law restricts this device to sale by or on the order of a physician
	Caution		

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