

ARKEO™

Surgical Technique

Auxano® Wedge Fixation System

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1.) INTRODUCTION

1.1. PRODUCT DESCRIPTION

The Auxano® Wedge Fixation System (WFS) is a titanium implant that is designed to be used for internal bone fixation and angular correction of foot geometry. The implants are offered in different length x width profiles (16x11, 20x14, 18x18, 20x20, and 22x22 mm) and heights (4.50, 5.50, 6.50, 8, 10, and 12 mm) to address different anatomic locations and size variations. All implants are made from Ti-6AL-4V ELI Titanium alloy per ASTM F3001. The Auxano® Wedge Fixation System includes implants, the instruments necessary to implant them, and the tray system for transport, storage and sterilization.

1.2. INDICATIONS FOR USE

The Auxano® Wedge Fixation System is intended to be used as internal bone fixation for bone fractures or osteotomies in the ankle and foot. Specific indications include:

- Cotton (opening wedge) osteotomies of the medial cuneiform
- Evans lengthening osteotomies

The Auxano® Wedge Fixation System is indicated for use with ancillary plating fixation.

The Auxano® Wedge Fixation System is not intended for spinal use.

1.3. CONTRAINDICATIONS

- Active or suspected infection, sepsis and osteomyelitis
- Malignant primary or metastatic tumors which preclude adequate bone support
- Conditions which tend to retard bone healing, such as, blood supply limitations, previous infections, insufficient quantity & quality of bone, etc.
- Insufficient quantity or quality of bone to permit stabilization of the fusion complex
- Conditions that restrict the patient's ability or willingness to follow post-operative instructions during the healing process
- Suspected or documented foreign body sensitivity or intolerance
- Skin atrophy where there is an increased risk of wound healing problems and infection
- Immunocompromised

1.4. STERILITY

The Auxano® WFS kit is comprised of implants (single-use) and instruments (both reusable and single-use) that are supplied NON-STERILE and must be fully processed prior to clinical use. Do NOT reuse implants or single-use instruments. See the separate Processing Instructions document detailing the specific processing procedure. Processing steps include manual cleaning, inspection and steam sterilization that are detailed in the Auxano® WFS Processing Instructions. The following steam sterilization cycle has been validated with an FDA cleared sterilization wrap and steam sterilizer.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME *
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	Minimum 40 Minutes

*Outside of standard sterilization cycle timing. Requires manual cycle & process modification.



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1.5. MATERIAL SPECIFICATION

The implants in the Auxano® WFS kit are manufactured from implant grade Ti-6Al-4V Titanium Alloy (ASTM F3001). The reusable instrumentation is manufactured from biocompatible, medical grade stainless steels (ASTM F899). The single-use K-wires are made from 316L stainless steel (ASTM F138).

1.6. WARNINGS AND PRECAUTIONS

- **Single Use:** The implants of the Auxano® WFS kit are designed for single use only and must never be reused. Reuse of a device could compromise device performance and/or potentially result in infection.
- **Patient Selection:** The use of fixation hardware requires careful patient consideration for positive outcomes.
 - Mental conditions and/or behavioral traits that could compromise the following of post-operative instructions and limitations.
 - Occupation and/or activity level that could violate limitations during the healing period.
 - Health conditions or history, such as metal allergies, osteoporosis, obesity, smoking, etc., could negatively affect tissue healing.
- **Surgical Technique and Training:** Auxano® WFS implantation should be performed by experienced surgeons with specific training in the use of the Auxano® WFS. The surgeon must read and adhere to all instructions, warnings and precautions regarding the Auxano® WFS. Failure to do so could lead to serious surgical consequences and patient injury. US federal law restricts this device to sale and use by, or on the order of, a physician.
- **Internal fixation devices** such as the Auxano® WFS are intended to provide temporary structural stability until bone fusion is established. If a delayed union or nonunion occurs with the presence of load bearing, the implant could eventually break, subside, or become loose. Factors, such as correct implant size selection, patient's weight, activity level and adherence to post-operative instructions and limitations, can affect the implant's longevity. Infection can damage bone structure which may lead to implant loosening, implant fracture or bone fracture.
- **Do not use** any components of the Auxano® WFS with components of other manufacturers, unless otherwise specified in the surgical technique.
- Adjacent soft tissues should be checked to ensure that abrasive contact with the implants does not occur.
- Confirm correct implant position radiographically prior to completion of the surgical procedure.
- Removal of the Auxano® WFS implants may be warranted if deemed medically necessary to avoid possible adverse effects. Explanted or soiled implant(s) should be disposed of as medical waste according to facility procedures and required compliance regulations.
- The Auxano® WFS implants 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 Auxano® WFS implants 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. These implants have not been tested for heating or migration in the MR environment.

1.7. POTENTIAL ADVERSE EFFECTS

In any surgical procedure, the potential for complications and adverse reactions exist. These do not include all adverse effects which can occur with surgery, but are important considerations particular to metallic internal stabilization devices. Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery.

- Nonunion or delayed union which may lead to implant breakage or subsidence
- Bending or fracture of the implant
- Loosening of the implant from insufficient fixation
- Early or late infection, both deep and superficial.
- Tissue reactions from material allergies or foreign body reaction to generated particulate
- Migration and/or subsidence of the implant
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Localized tissue reaction or pain from corrosion
- Bone loss due to stress shielding
- Intraoperative or postoperative bone fracture and/or postoperative pain
- Bone necrosis
- Soft tissue irritation from surgical trauma or prominent hardware

1.8. SURGEON TRAINING

Surgeon training on the Auxano® Wedge Fixation System is available prior to initial clinical use of the system. Training will familiarize the clinician with the Auxano® WFS implants, instruments, and procedures in order to ensure the safe and effective use of the device to maximize patient benefit. Training options include (but are not limited to) in-person training labs (cadaver or synthetic models) or in-person (or virtual) training meetings utilizing training literature or presentations. The training session duration will be proportional to the type of training and sufficient to convey understanding of system use.



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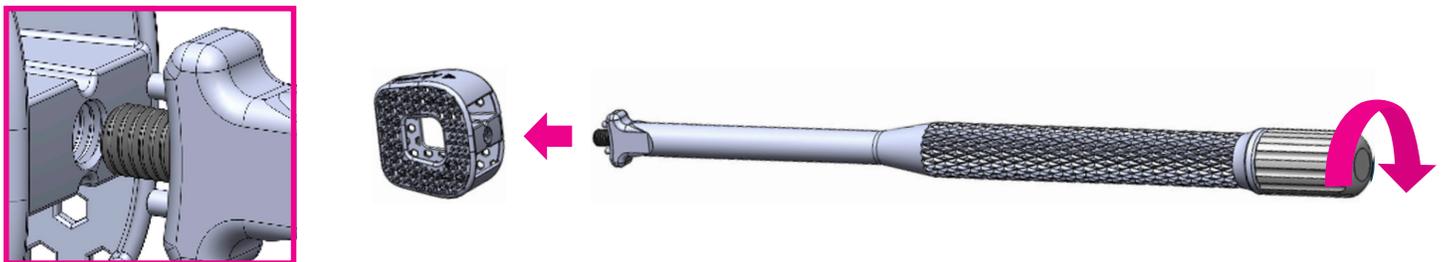
2.) SURGICAL TECHNIQUE – EVAN'S WEDGE

The purpose of this surgical technique guide is to demonstrate the general use of the Auxano® Wedge Fixation System for the Evan's osteotomy procedure. This is meant to serve as technique guidance. The surgeon must consider the needs of the patient on a case-by-case basis when making necessary deviations.

- Prepare the implantation site using standard surgical techniques. Make an incision below the sinus tarsi, extending longitudinally 20-30mm proximal to the calcaneocuboid joint.
- Dissect to the bone surface while identifying and retracting pertinent neurovascular and/or tendinous structures. The peroneal tendons and sural nerves should be retracted plantarly to expose the calcaneocuboid joint.
- Pin the calcaneocuboid (C-C) joint by inserting a k-wire if desired by the surgeon. This will secure the anterior fragment created by the ensuing osteotomy cut. Verify the location with fluoroscopy to make sure the k-wire is not placed too far posteriorly or inhibiting the osteotomy site.
- Locate the osteotomy site approximately 10-15mm proximal to the C-C joint. Perform osteotomy cut using an oscillating saw parallel to the C-C joint. Leave the distal cortex intact.
- Distract the osteotomy site to the desired correction using one of the following methods:
 1. Using the mallet, insert osteotomes into the osteotomy site in a stacked configuration.
 2. Placing a 1.6mm k-wire on each side of the osteotomy and attaching a Hintermann distractor over top of the k-wires.
- Starting with the smaller lollipop trials, place trials in the osteotomy site one at a time. Select the size that creates the appropriate amount of correction both clinically and via fluoroscopy.
 1. Note: Lower edge of trials is to the size listed. Extended region accounts for pillar height (0.5mm).
- Select the corresponding Evan's wedge implant from the appropriate caddy in the tray.
- If pre-packing bone graft into the hollow implant is desired, it can be packed at this stage with the surgeon's preferred product (prior to implantation) using the graft window, lattice fenestrations, and proximal opening. Post-packing will be limited to the back opening following implant placement.
- Assemble the inserter by placing the draw rod into the bore of the inserter handle.



- Attach the inserter to the selected implant by aligning the inserter's securement pins to the notches on the implant attachment site and then threading the draw rod into the implant.

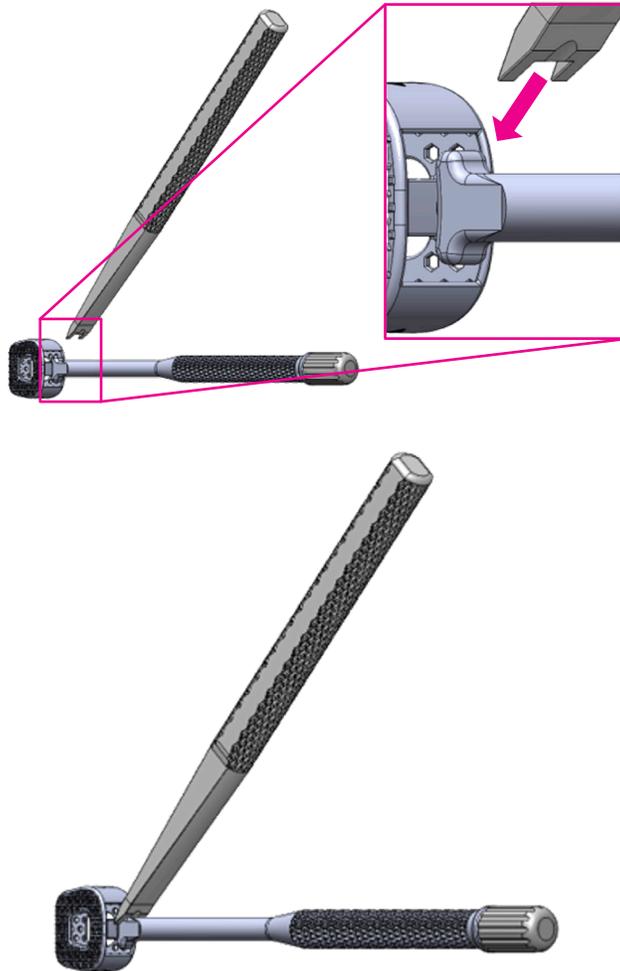


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- Using the mallet on the inserter, drive implant into the osteotomy site. The implant position can be further adjusted by engaging the impactor with the head of the inserter and tapping the back of the impactor.



- Once the implant is in the surgeon's preferred position, disengage the inserter by unthreading counterclockwise.
- If utilized, remove k-wire pinning the anterior fragment.
- Confirm the correct placement of the implant visually and using fluoroscopy.
 1. Ensure the distal cortex is not compromised.
 2. Check that there is uniform contact between the implant and osteotomy faces.
 3. Ensure implant is recessed to prevent soft tissue irritation.
 4. Confirm implant will not interfere with motion of the talus.
- Post-packing bone graft can be done through the proximal window using the surgeon's preferred product.
- Ancillary fixation is required with use of the Auxano® WFS. Refer to the specific surgical technique guide of the ancillary fixation. The ancillary fixation should not directly contact the Auxano® WFS implant. Verify final placement using fluoroscopy.

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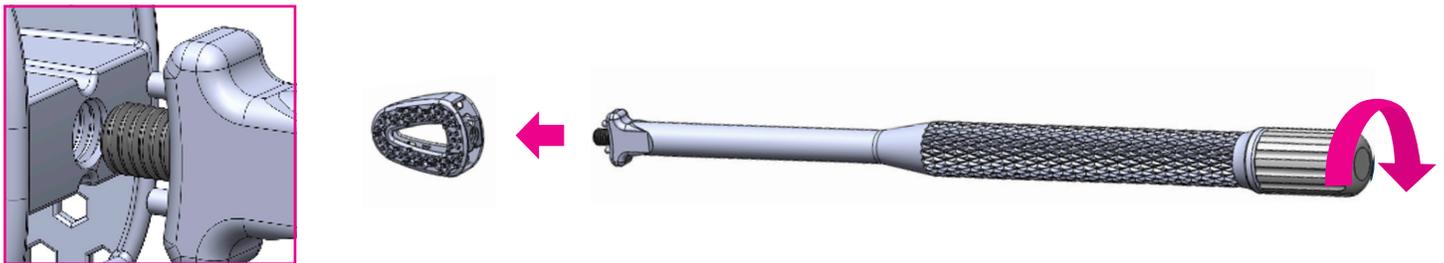
3.) SURGICAL TECHNIQUE – COTTON WEDGE

The purpose of this surgical technique guide is to demonstrate the general use of the Auxano® Wedge Fixation System for the Cotton osteotomy procedure. This is meant to serve as technique guidance. The surgeon must consider the needs of the patient on a case-by-case basis when making necessary deviations.

- Prepare the implantation site using standard surgical techniques. Make an incision dorsally over the medial cuneiform.
- Retract the extensor hallucis longus and dissect the soft tissue down to the surface of the medial cuneiform.
- Perform a transverse osteotomy cut within the medial cuneiform using an oscillating saw. Leave the plantar cortex intact.
- Distract the osteotomy site to the desired correction using one of the following methods:
 1. Using the mallet, insert osteotomes into the osteotomy site in a stacked configuration.
 2. Placing a 1.6mm k-wire on each side of the osteotomy and attaching a Hintermann distractor over top of the k-wires.
- Starting with the smaller lollipop trials, place trials in the osteotomy site one at a time. Select the size that creates the appropriate amount of correction both clinically and via fluoroscopy.
 1. Note: Lower edge of trials is to the size listed. Extended region accounts for pillar height (0.5mm).
- Select the corresponding Cotton wedge implant from the appropriate caddy in the tray.
- If pre-packing bone graft into the hollow implant is desired, it can be packed at this stage with the surgeon's preferred product (prior to implantation) using the graft window, lattice fenestrations, and proximal opening. Post-packing will be limited to the back opening following implant placement.
- Assemble the inserter by placing the draw rod into the bore of the inserter handle.



- Attach the inserter to the selected implant by aligning the inserter's securement pins to the notches on the implant attachment site and then threading the draw rod into the implant.

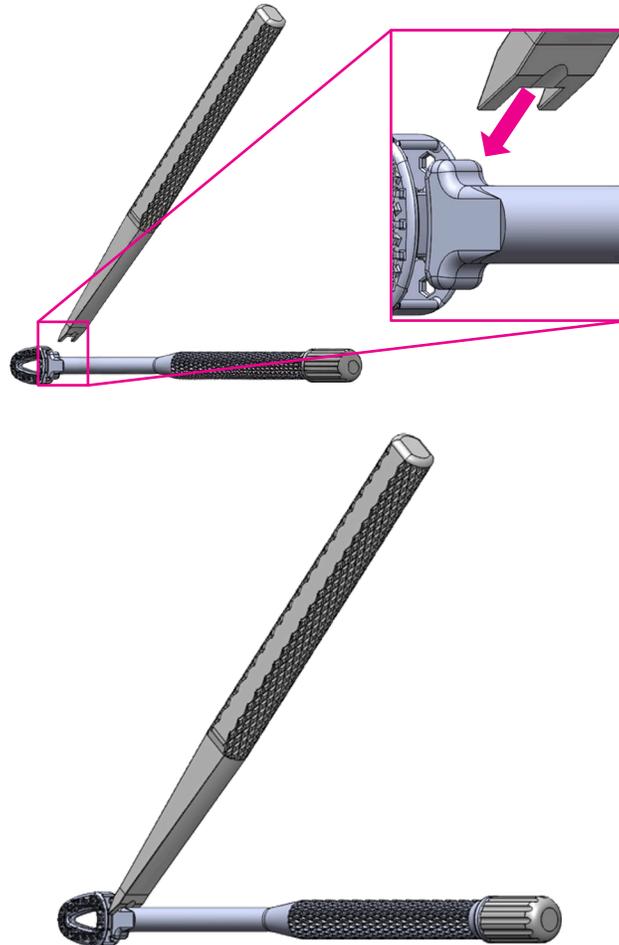


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- Using the mallet on the inserter, drive implant into the osteotomy site. The implant position can be further adjusted by engaging the impactor with the head of the inserter and tapping the back of the impactor.



- Once the implant is in the surgeon's preferred position, disengage the inserter by unthreading counterclockwise.
- If utilized, remove k-wire pinning the anterior fragment.
- Confirm the correct placement of the implant visually and using fluoroscopy.
 1. Ensure the distal cortex is not compromised.
 2. Check that there is uniform contact between the implant and osteotomy faces.
 3. Ensure implant is recessed to prevent soft tissue irritation.
 4. Confirm implant will not interfere with motion of the talus.
- Post-packing bone graft can be done through the proximal window using the surgeon's preferred product.
- Ancillary fixation is required with use of the Auxano® WFS. Refer to the specific surgical technique guide of the ancillary fixation. The ancillary fixation should not directly contact the Auxano® WFS implant. Verify final placement using fluoroscopy.

4.) EXPLANT INFORMATION

There are a number of instruments available for implant removal depending on how securely the implant is held within the osteotomy. If the implant is quite mobile, it can be removed using general surgical instruments, such as forceps, or by reattaching the threaded inserter. If the device is rigidly in place, the interface between implant and bone can be split with osteotomes or surgical saw. A slap hammer is available within the Auxano® WFS if further assistance is required to dislodge the implant. To use the slap hammer, securely thread the inserter into the implant and the slap hammer into the inserter draw rod. Consult the manufacturer's instructions for removal of ancillary fixation used.

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5.) Implant & Instrument Catalog

Table 1. IMPLANTS	
CATALOG NUMBER	PRODUCT NAME
02-11808	Evan's Wedge, Ti, 18x18x08
02-11810	Evan's Wedge, Ti, 18x18x10
02-11812	Evan's Wedge, Ti, 18x18x12
02-12008	Evan's Wedge, Ti, 20x20x08
02-12010	Evan's Wedge, Ti, 20x20x10
02-12012	Evan's Wedge, Ti, 20x20x12
02-12208	Evan's Wedge, Ti, 22x22x08
02-12210	Evan's Wedge, Ti, 22x22x10
02-12212	Evan's Wedge, Ti, 22x22x12
02-21645	Cotton Wedge, Ti, 16x11x4.5
02-21655	Cotton Wedge, Ti, 16x11x5.5
02-21665	Cotton Wedge, Ti, 16x11x6.5
02-22045	Cotton Wedge, Ti, 20x14x4.5
02-22055	Cotton Wedge, Ti, 20x14x5.5
02-22065	Cotton Wedge, Ti, 20x14x6.5

Table 2. INSTRUMENTS	
CATALOG NUMBER	PRODUCT NAME
02-41808	Evan's Wedge Trial, 18x18x08
02-41810	Evan's Wedge Trial, 18x18x10
02-41812	Evan's Wedge Trial, 18x18x12
02-42008	Evan's Wedge Trial, 20x20x08
02-42010	Evan's Wedge Trial, 20x20x10
02-42012	Evan's Wedge Trial, 20x20x12
02-42208	Evan's Wedge Trial, 22x22x08
02-42210	Evan's Wedge Trial, 22x22x10
02-42212	Evan's Wedge Trial, 22x22x12
02-51645	Cotton Wedge Trial, 16x11x4.5
02-51655	Cotton Wedge Trial, 16x11x5.5
02-51665	Cotton Wedge Trial, 16x11x6.5
02-52045	Cotton Wedge Trial, 20x14x4.5
02-52055	Cotton Wedge Trial, 20x14x5.5
02-52065	Cotton Wedge Trial, 20x14x6.5
02-40001	Wedge Inserter Handle
02-40002	Wedge Draw Rod Assembly
02-40003	Wedge Impactor
02-40004	Hintermann Distractor
02-40005	Mallet
02-40006	Osteotome – 6mm
02-40010	Osteotome – 10mm
02-40012	Osteotome – 12mm
02-4X164	K-Wire, 1.6x6 (Qty. 12)
02-60001	Wedge Slap Hammer Assembly

6.) DISCLAIMER

The objective of the Auxano® Wedge Fixation System Surgical Technique Guide is to illustrate the use of the Auxano® Wedge Fixation System. Numerous methods can be done for this procedure. The details described here were chosen for simplicity and display of the unique features on this device and instrumentation. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.

-  Date of Manufacture
-  Manufacturer
-  Catalog Number
-  Non-Sterile
-  Batch Code
-  Do NOT Re-use
-  Consult Instructions for Use

For product inquiries, cleaning instructions, surgical techniques, or to report any adverse event, please visit us at www.AuxanoMedical.net

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