ARKEO™

Instructions for Use

Auxano® Wedge Fixation System

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.

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.

CONTRAINDICATIONS:

- Active or suspected infection, sepsis and osteomyelitis.
- Malignant primary or metastasic 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.

INSTRUCTIONS FOR USE: The end-user information consists of the Instructions for Use, Surgical Technique and Processing Instructions. The operating procedure steps are described in the Surgical Technique. The steps to reprocess the set following a surgical use (or prior to initial use) are described in the Processing Instructions in order to ready the kit for introduction into a sterile, surgical environment are described in the Processing Instructions. Further copies of these documents can be requested at Auxano Medical, LLC.

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 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.

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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.
- 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 subluxation 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.

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 materials, including medical grade stainless steels (ASTM F899). The single-use K-wires are made from 316L stainless steel (ASTM F138).

PROCESSING PROCEDURE: 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.

STORAGE: Sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes in temperature and humidity.

MR SAFETY: These Auxano® WFS implants have not been evaluated for safety and compatibility in the MR environment. These implants have not been tested for heating or migration in the MR environment. The safety of the Auxano® WFS implant in the MR environment is unknown. MR scanning of a patient who has this device may result in patient injury.

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.


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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AUXANO MEDICAL

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