INSTRUCTIONS FOR USE
OsteoSinter® EVANS and COTTON wedges and related accessories
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Instructions For Use intended only for the US market.
Federal Law Restricts These Devices to Sale By Or On The Order Of A Physician.

For the attention of the surgeon performing the operation

IMPORTANT MEDICAL INFORMATION
AMES Medical
OsteoSinter® EVANS and COTTON wedges and related accessories

℞ only

DEVICE DESCRIPTION:
OsteoSinter® EVANS and COTTON wedges are Titanium implants used to correct adult acquired flatfoot deformities, specifically for stage II posterior tibial tendon dysfunction. **The wedges are intended to be used as** an implant for an **Evans procedure (for lateral column lengthening) or Cotton (improve the inclination of the first radius and avoid overloading the external column)**. These wedges allow control of the amount of lengthening or declination of the osteotomies. As the implant is highly porous, it induces the osteointegration of the surrounding bones through the interconnected porous parts which allow the implant to be firmly affixed unless unexpected infection or bone damage occurs.
The implant is intended to be used with the associated instrument kit in a surgical setting by a medical professional (traumatologist).

Quantity: 1

INDICATIONS:
OsteoSinter® EVANS and COTTON wedges are intended to be used for internal bone fixation of bone fractures, fusions, or osteotomies in the foot. Specific Indications include:

- Opening wedge osteotomies of the bones of the foot (including osteotomies for Hallux Valgus).
- Opening wedge of Medial Cuneiform or Cotton osteotomies.
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy).
- Metatarsal/Cuneiform arthrodesis.

OsteoSinter® EVANS and COTTON wedges are indicated for use with ancillary bone fixation.
OsteoSinter® EVANS and COTTON wedges are not indicated for use in the spine.

PATIENT SELECTION:
Patient selection factors to be considered include:

- Good condition of the patient.
- Good neurovascular status.
- Adequate skin coverage.
- Possibility of a functional musculotendinous system.

- Adequate bone stock to receive the implant.
- Full patient skeletal maturity.
- Co-operative patient; ability and willingness of the patient to follow post-operative care instructions until healing is complete.

CONTRAINDICATIONS:
- Infection.
- Physiologically or psychologically inadequate patient (conditions that tend to limit the patient's ability or willingness to restrict activities or follow post-operative care instructions).
- Inadequate skin, bone or neurovascular conditions, which may delay healing.
- Growing patients with open epiphyses.
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to device implantation.
- Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

WARNINGS AND PRECAUTIONS:
Following the instructions for use provided can minimise the potential for complications or adverse reactions with any implant. It is the surgeon's responsibility to consider the clinical and medical status of each patient and be knowledgeable about all aspects of the implant procedure and potential complications that may occur.

Specialised instruments are designed for OsteoSinter® EVANS and COTTON wedges (Single-use OsteoSinter® EVANS and COTTON instrument kit) to assist the implantation of the wedge(s). The use of instrument components from any other systems can result in an inaccurate fit, incorrect sizing, excessive wear and device failure. All instrument components must be removed prior to closing the surgical site. Do not implant.

OsteoSinter® EVANS and COTTON wedges devices cannot be expected to replace normal healthy bone, particularly in the presence of non-union, delayed union, or incomplete healing. Therefore, it is important that immobilisation (use of external support, braces, etc.) of the fracture site be maintained until firm bony union is established (confirmed by clinical and radiographic examinations). Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight and obesity can cause premature failure of the implant by loosening, fracture, dislocation, subluxation and/or wear.

The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant and related instruments.
The main goal of surgery with this implant is to establish bone fusion. Implants are subject to repeated stress in use, which can result in fatigue fracture. Abnormal or excessive force may lead to delayed union, non-union, or failure of the implant. Abnormal force loading and subsequent wear may be caused by:
- Uncorrected instability
- Wrong size implant
- Inadequate soft tissue support
- Implant mispositioning
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity

Loads produced by weight bearing and activity may dictate the service life of the implant. IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.
The surgical technique should be followed. Deviations from the surgical technique may result in early loosening/failure of the device, or other adverse events. Clinical outcome may be affected by implant positioning. Proper placement of the implant should take into consideration individual patient anatomy as well as the surgeon's preference. The surgical technique sets forth guidelines for placement of the device.
Proper fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device. Some **preventive measures** to consider to minimise the potential for complications are:
- Follow guidelines for indications and contraindications provided. Failure to use this device in accordance with the directions for use may result in device failure, render the device unsuitable for its intended use, or compromise the procedure.
- Identify prior pathology.

- Stabilise collapsed deformities.
- Bone graft pre-existing cysts.
- Use a properly sized implant. Correct selection of the implant is extremely important. The potential for success is increased by selecting the proper implant size and design. The patient's anatomy and indication will determine the size of the wedge to be used. The size and shape of the human bones present limiting restrictions on the size and strength of implants. Avoid overcorrection because it could cause stiffness, lateral column overload and excessive plantar flexion.
- Do not reuse this device. This is a single use device. Reuse of this product may result in infection or other systemic complications that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particle release and should be discarded.
- Do not resterilise this device. The device is delivered sterile. This implant has been sterilised by gamma radiation and is sterile in the unopened, undamaged package. If either the implant or the package appears damaged, is beyond the sterility expiry date, or if sterility is questioned for any reason, the implant should not be used. Resterilisation could lead to mishandling and surface damage that could result in implant fracture and/or particulate debris.
- Do not use implants or instruments after their expiry date.
- Avoid K-wires and sutures through the implant.
- Avoid flawing implant surfaces to minimise the potential for early fatigue failure. Correct handling of implants is extremely important. Do not modify implants. Notches or scratches put in the implants during the course of surgery may contribute to breakage.
- The ancillary fixation should be manufactured in titanium to reduce the likelihood of galvanic corrosion. Implant materials are subject to corrosion. Implanting metals subjects them to constant changing environments of salts, acids and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may promote the fracture of implants. Every effort should be made to use compatible metals when mating components.

If complications develop, possible **corrective procedures** include:

- Implant removal
- Bone grafting of cysts
- Replacement of the implant
- Removal of the implant with fusion of the joint

Clinical results depend on the 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 the patient prior to surgery. The patient is to be made aware and warned of general surgical risks and possible adverse effects. The patient must be warned that non-compliance with post-operative instructions may increase the risk of device failure: could lead to breakage of the implant or fracture or osteotomy non-union requiring revision surgery to remove the device. The patient is to be advised of the need for regular post-operative follow-up examinations as long as the implant remains implanted. Surgeons must balance many considerations to achieve the best result in individual patients.

Recommendations regarding device fragments:

- Use medical devices in accordance with their labelled indications and instructions for use, especially during insertion and removal.
- Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices immediately upon removal from the patient for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with AMES MEDICAL PROSTHETIC SOLUTIONS, S.A.U.'s analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a The material composition of the fragment (if known);
    b The size of the fragment (if known);
    c The location of the fragment;
    d The potential mechanisms for injury, e.g., migration, infection.

The benefits derived from implant surgery may not meet the patient's expectations or may decrease with time, necessitating revision surgery to replace the implant or carry out alternative procedures.

Revision surgery with implants is common. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure.

ADVERSE EVENTS:
In any surgical procedure, there is potential for complications. 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.
- Bone resorption or over-production.
- Allergic reaction to implant material.
- Untoward histological responses possibly involving macrophages and/or fibroblasts.
- Migration of wear debris possibly resulting in a bodily response.
- Unwanted soft tissue damage and/or articular surface damage due to incorrect wedge placement.
- Embolism.

If any serious incident occurred in relation to the device, it should be reported to the manufacturer and the competent authority.

SURGICAL TECHNIQUE:

Step 1. Incision and retraction

OsteoSinter® EVANS wedges: In a slightly lateralized supine position, surgical access is made under the sinus tarsi and the incision is extended distally to the calcaneus-cuboid joint (approximately 3 cm proximal). The peroneal tendons along with the sural nerves are carefully retracted so that the lateral calcaneal and calcaneocuboid joint are exposed.

OsteoSinter® COTTON wedges: In supine decubitus, surgical access is executed by a longitudinal incision centred on the medial cuneiform. Retract the extensor hallucis longus and dissect soft tissues down to the surface of the medial cuneiform. The medial and lateral cortices should be visualized.

Step 2. Osteotomy

OsteoSinter® EVANS wedges: Depending on the surgeon's preference, the calcaneus osteotomy can be placed approximately 1 cm from the calcaneus-cuboid joint and proximal under the sinus tarsi, following the anterior edge of the posterior subastragaline joint over the Gissane angle, according to the technique described by Hintermann. The osteotomy is made with an oscillating saw, and the cut is finished with an osteotome.

OsteoSinter® COTTON wedges: Perform a transverse osteotomy on the dorsal surface of the medial cuneiform close to the centre of bone towards the deep plantar cortex. The osteotomy may be opened using an osteotomy distractor. The pin-style distractor is optional and used according to the surgeon's preference. The osteotomy is made with an oscillating saw, and the cut is finished with an osteotome.

Step 3. Distraction

A pin-style distractor, with pin placement on either side of the osteotomy, is installed to provide controlled distraction and unobstructed access to the osteotomy site.

OsteoSinter® EVANS wedges: A provisional K-wire may be placed across the calcaneal-cuboid joint to prevent subluxation of the joint during distraction.

Step 4. Implant selection

The osteotomy diastasis is performed, clinically assessing the degree of correction required. At this time, the sizers (from the Single-use OsteoSinter® EVANS instrument kit or Single-use OsteoSinter® COTTON instrument kit, according to the wedge type) are used at the distracted osteotomy site until

the footprint is congruent to the dimensions of the osteotomy surface. Once this has been achieved and assessed both clinically and fluoroscopically, the optimal implant size can be selected.

Step 5. Implantation

Open the tweezer clamps (from the Single-use OsteoSinter® EVANS instrument kit or Single-use OsteoSinter® COTTON instrument kit, according to the wedge type) by sliding the tab forward and place the clamps on the implant notches. Then, close the clamps by moving the tab backwards in order to hold the implant. If the use of an autograft or allograft is desired, the material should be placed into the centre of the cavity of the implant prior to implantation. Place the assembly at the osteotomy site and remove the tweezer. Do not impact the tweezer to place the implant. Carefully impact the implant until it is fully seated using the impactor (from the Single-use OsteoSinter® EVANS instrument kit or Single-use OsteoSinter® COTTON instrument kit, according to the wedge type) and a mallet.

Step 6. Fixation

The ancillary fixation should be manufactured in titanium to reduce the likelihood of galvanic corrosion. After confirmatory AP and lateral x-rays, the incision is closed in layers of soft tissue using the surgeon's preferred technique. An appropriate post-operative protocol should be followed according to the surgeon's preference.

Removal (if needed)

Remove the ancillary plate using the same plate-specific instrumentation used to implant the plate following the manufacturer's instructions. In case the implant is loosened and without integration, the extraction will be performed by means of the same positioning tweezers, pulling the wedge from its position using this instrument or other general instruments to grasp and pull the implant. In case of osseointegration of the implant, a saw or an osteotome can be used to cut along the surface of the wedge to free the wedge from the bone. If necessary, another spacer implant or autograft or allograft can be used to fill the gap.

MRI Safety Information:
The OsteoSinter® wedge has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of OsteoSinter® wedge 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.

HANDLING AND STERILISATION:
The implants and related accessories are provided sterile. Do not resterilise. The device has been sterilised by gamma radiation and is sterile in the unopened, undamaged package. Implants and related accessories in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If either the implant or the package appears damaged, is beyond the sterility expiry date, or if sterility is questioned for any reason, the implant should not be used. Resterilisation could lead to mishandling and surface damage that could result in implant fracture and/or particulate debris. The implants and related accessories should be opened using an aseptic OR technique. The implants should only be opened after the correct size has been determined.

Do not reuse this device. This is a single use device. Reuse of this product may result in infection or other systemic complications that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect function of the device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particle release and should be discarded. After use, the device may be a potential biohazard.

STORAGE CONDITIONS:
All implants and related accessories must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature and should not be used after the expiry date.

	Sterilized using irradiation		Do not use if package is damaged and consult instructions for use
	Do not re-use		Keep dry
	Do not resterilize		Keep away from sunlight
	Use-by date		Batch code
	Catalogue number		Manufacturer
	Date of manufacture		Prescription device
	Unique Device Identifier		Consult electronic instructions for use. Instructions for use are available in an electronic format at www.ames-medical.net/ifus
	Medical device		Single sterile barrier system with protective packaging inside

The relevant contents of these Instructions for Use were reviewed by the U.S. Food and Drug Administration under K240461.