OsteoSinter®
EVANS and COTTON wedges

Porous titanium wedges used to correct adult-acquired flatfoot deformities
OsteoSinter® EVANS and COTTON wedges are porous titanium implants used to correct adult-acquired flatfoot deformities.

The wedges are intended to be used as an implant specifically designed for Evans procedures (for lateral foot column lengthening) or Cotton (improve the inclination of the first radius and avoid overloading the external column). These wedges allow very precise control of the amount of lengthening or declination of osteotomies.

OsteoSinter® EVANS and COTTON wedges are delivered with a single-use and recyclable surgical instrument kit, made of Polyamide grade 12, which contributes to a precise implantation of the product. The product is presented unitarily packed in blister and sterilized with gamma radiation.

General description

OsteoSinter® EVANS and COTTON wedges are porous titanium implants used to correct adult-acquired flatfoot deformities.

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Trabecular bone mimicry

The OsteoSinter® material is biocompatible pure Titanium manufactured by means of Powder Metallurgy technology.

A special design of the manufacturing process allows to obtain a product of high interconnected porosity (62-66% in volume), and with great stochasticity of pores distribution, favoring osteointegration of the surrounding bones.

The result is a material that mimics the structure and characteristics of human bone, especially the elastic modulus and the porosity shape, while providing good mechanical and fatigue resistance.

The manufacturing process of the OsteoSinter® material guarantees a high homogeneity of porosity and material characteristics piece by piece in large serial production.

Indications

OsteoSinter® EVANS and COTTON wedges are intended to be used for internal bone fixation for foot osteotomies such as:

- Opening wedge osteotomies of the bones of the foot (including addition 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.

Contraindications

- Infection.
- Physiologically or psychologically inadequate patient.
- Inadequate skin, bone or neurovascular conditions.
- Growing patients with open epiphyses.
- Metal allergy.
- Smoking patients.
OsteoSinter® EVANS and COTTON wedges

**Benefits**

**Rapid osteointegration**

The interconnected porosity of the OsteoSinter® material enhances the osteointegration of the surrounding bones.

After 4 weeks, the result is a very fast osteointegration, reaching 57% of bone colonization.

**Excellent mechanical properties**

The OsteoSinter® material exhibits a mechanical behavior very similar to the human bone, both in elastic modulus as in compression and fatigue resistance. It also has a high friction coefficient that ensures high primary fixation to the bone, and great wear resistance.

**High primary fixation**

The porous structure of the material and the relief shape of the surfaces provide a high primary fixation to the bone. Optional: in case of instability, reinforcement by fixing with auxiliary plates is recommended.

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**Osteointegration versus material (%)**

<table>
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<tr>
<th>Time</th>
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<th>Trabecular Metal™</th>
<th>OsseoTi®</th>
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<td>2 weeks</td>
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<td>57.0</td>
<td>41.5 - 52.9(^{[1]})</td>
<td>55.0(^{[2]})</td>
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4. Gupta G, McLain K. “Coefficient of Friction for Porous Metal Structures Against Cortical Bone”. Biomet Inc. 58 E Bell Dr., Warsaw, IN 46582. ©2013 Society For Biomaterials.
6. ADVANCE® BIOFOAM™ Cancellous Titanium™ Tibial implants_Technical Monograph.
8. Trabecular Metal™ Material Product Brochure.
Benefits

Single-use instruments

The OsteoSinter® EVANS and COTTON wedges are placed using a sterile, single-use instrument kit made of Polyamide 12 material. The single-use OsteoSinter® EVANS and COTTON instrument kits include:
- A set of sizers (one for each size and type of wedge).
- A tweezer to hold and insert the wedge.
- An impactor to seat the implant in its suitable position by tapping gently with a standard hammer (not supplied in the kit).

Reduction of healthcare costs

OsteoSinter® EVANS and COTTON wedges are offered in 15 sizes to achieve proper anatomical correction in each particular case. OsteoSinter® EVANS and COTTON wedges are metallic implants and therefore do not present reabsorption issues.

The OsteoSinter® EVANS and COTTON wedges and their single-use related accessories reduce the surgery time compared to unconfigured allografts, because:
1) They do not require prior defrosting or on-site cutting.
2) They provide greater precision.
3) They facilitate reproducibility.
### Summarized surgical technique of OsteoSinter® EVANS wedge

|--------------------------------|------------------|--------------------|--------------------------|

### Summarized surgical technique of OsteoSinter® COTTON wedge

|--------------------------------|------------------|--------------------|--------------------------|

The complete and detailed surgical technique is available in a complementary document. Please consult the website [www.ames-medical.net](http://www.ames-medical.net), or ask it to your current AMES MEDICAL contact person.
OsteoSinter® EVANS wedges

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OsteoSinter® COTTON wedges

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The OsteoSinter® EVANS and COTTON wedges have the CE Marking according to 93/42/EEC Medical Devices Directive (MDD) with certificate n." G1 104088 0001, and are Class IIb classified.

The OsteoSinter® material is protected under patent n." EP 3 122 497 B1.