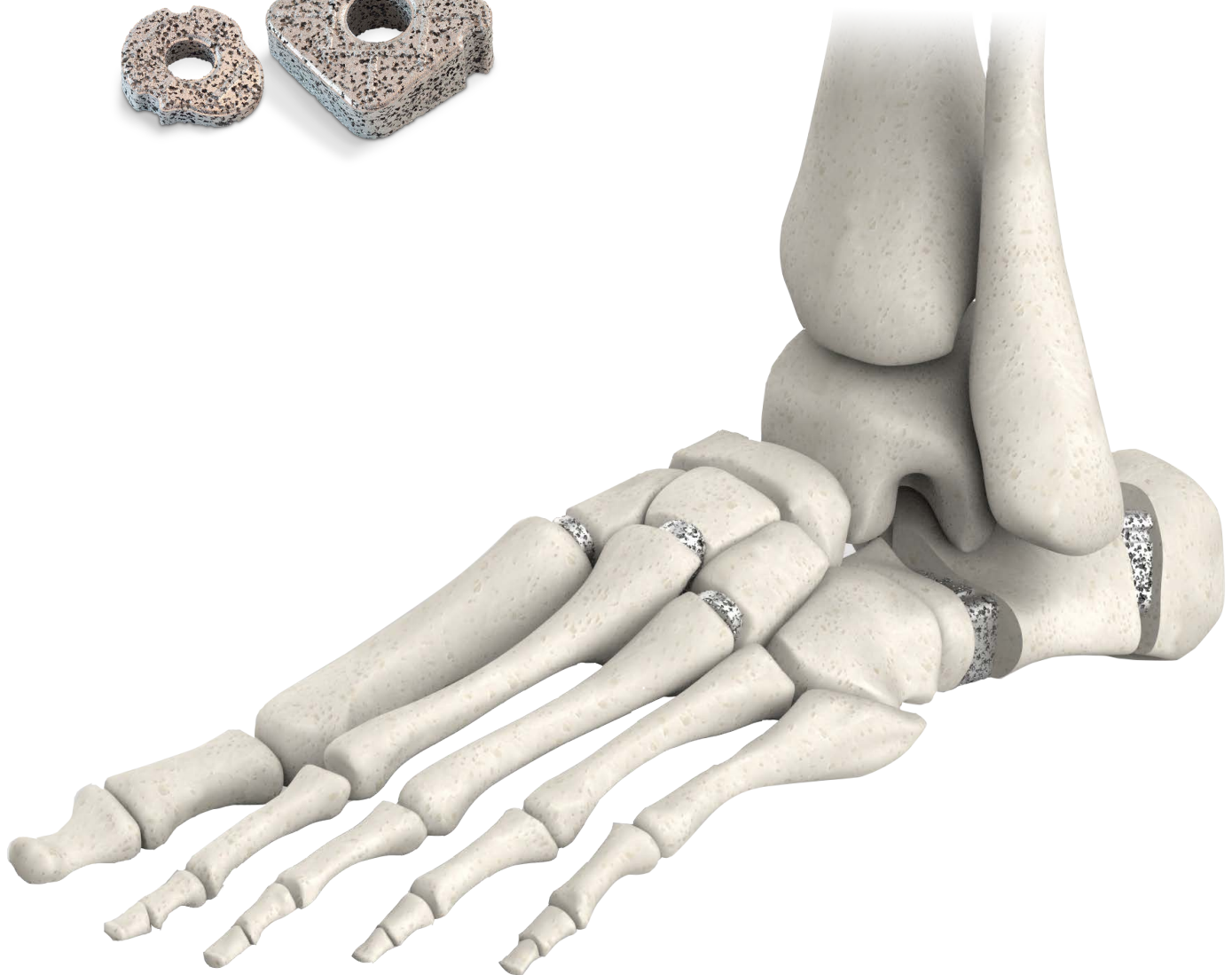


# Implantable wedges for correction of foot deformities

**OsteoSinter® EVANS and COTTON wedges**



## General description

OsteoSinter® EVANS and COTTON wedges are porous 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).

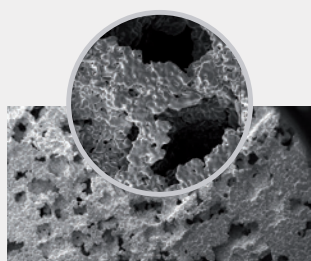
The implant is intended to be used with the associated instrument kit (made of Polyamide grade 12) in a surgical setting by a medical professional (traumatologist). The product is presented unitarily packed in blister and sterilized with gamma radiation.



### Trabecular bone mimicry



Trabecular bone<sup>(1)</sup>



OsteoSinter® material<sup>(2)</sup>

The **OsteoSinter® material<sup>(3)</sup>** is biocompatible **CP Titanium** manufactured by means of Powder Metallurgy technology.

A special design of the manufacturing process allows to obtain a product with interconnected porosity (62-66%)<sup>(4)</sup> in volume), favoring osteointegration of the surrounding bones.

The result is a **material that mimics the structure and characteristics of human bone**, specially the apparent elastic modulus and the porosity shape.

<sup>(1)</sup> AME19-C015

<sup>(2)</sup> p00100\_osteosinter porosity

<sup>(3)</sup> Patented material

<sup>(4)</sup> p00100\_te\_medical device



## 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:

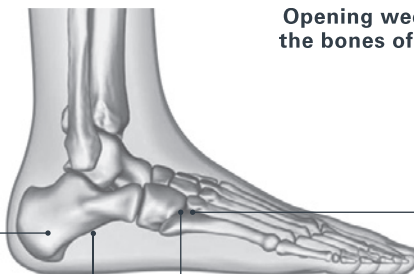
- Opening wedge osteotomies of the bones of the foot (including osteotomies for Hallux Valgus).
- Opening wedge of medial cuneiform or Cotton osteotomies.
- Lateral column lengthening (Evans lengthening osteotomy or Calcaneal Z osteotomy).
- Metatarsal/Cuneiform arthrodesis.

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.



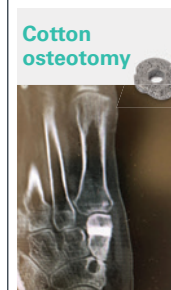
Courtesy of Dr. Rodrigo Diaz Fernandez



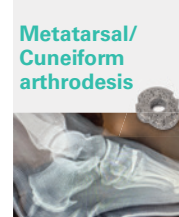
**Opening wedge osteotomies of the bones of the foot (including Hallux Valgus)**



p00100\_4.1.25-1



p00100\_4.1.25-1



## Contraindications

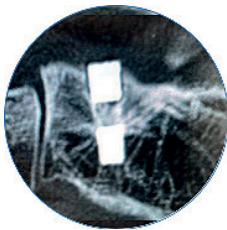
- Infection.
- Physiologically or psychologically inadequate patient (conditions that tend to limit the patient's ability or willingness to restrict activities or follow post-operative care instructions).
- Inadequate skin, bone or neurovascular conditions, which may delay healing.
- Growing patients 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.

Please consult IFU for further information

## Benefits



### Osteointegration

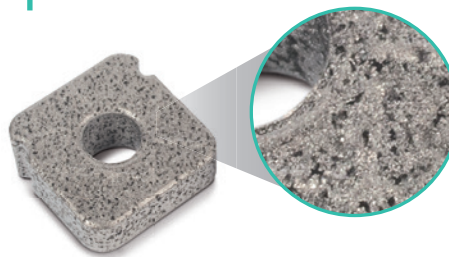


p00100\_4.1.25-1

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



### Primary fixation



The porous structure of the material and the relief shape of the surfaces provide primary fixation to the bone.



### Mechanical properties

The OsteoSinter® material exhibits an **elastic mechanical behavior very similar to the human bone**.

Property	Material	
	OsteoSinter® [1, 2, 3]	Trabecular bone [2, 4, 5, 6]
Elastic modulus (GPa)	2.8	0.01 - 3
Compressive yield strength (MPa)	31	0.1 - 30
Friction coefficient	1.22	0.44 - 0.63
Compressive fatigue limit	5 M cycles at > 11.3 MPa w/o failure	-

Representative values

[1] P00100\_compressive properties osteosinter.

[2] proy180093.

[3] proy220128.

[4] ADVANCE® BIOFOAM™ Cancellous Titanium Tibial implants\_Technical Monograph.

[5] Morgan EF, Unnikrisnan GU, Hussein AI. **Bone Mechanical Properties in Healthy and Diseased States**. Annu Rev Biomed Eng. 2018 Jun 4;20:119-143. doi: 10.1146/annurev-bioeng-062117-121139. PMID: 29865872; PMCID: PMC6053074.

[6] Shirazi-Adl A1, Dammak M, Paiement G. **Experimental determination of friction characteristics at the trabecular bone/porous-coated metal interface in cementless implants**. J Biomed Mater Res. 1993 Feb;27(2):167-75.



### 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).
- **Tweezers** to hold and insert the wedge.
- **An impactor** to seat the wedge in its implanted position by tapping gently with a standard hammer (not supplied in the kit).

*The surgical technique is available in the Instructions For Use.*



#### Sizers

- Sizers replicate the shape of the wedges to select patient's correction prior to final implant selection.
- Size identification on the sizer.

#### Tweezers

- Allow the user to grab the implant and place it into the osteotomy site.



### Reduction of healthcare costs

OsteoSinter® EVANS and COTTON wedges are titanium implants and therefore **do not present reabsorption issues**.

The OsteoSinter® EVANS and COTTON wedges and related accessories **reduce the surgery time** compared to unconfigured allografts, because:

• **Simplify pre-operative handling.**

• **Direct placement, without carving or on-site adjustment.**

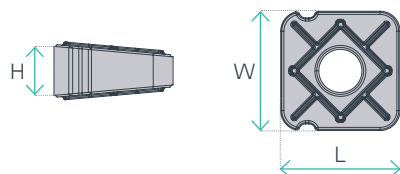
• **OsteoSinter® EVANS and COTTON wedges and related accessories are provided sterile.**



## Sizes

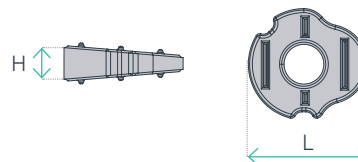
OsteoSinter® EVANS and COTTON wedges are provided in **18 sizes** to achieve proper anatomical correction in each particular case.

### OsteoSinter® EVANS wedges



Width (mm) [W]	Length (mm) [L]	Height (mm) [H]
18	18	6
		8
		10
		12
20	20	6
		8
		10
		12
22	22	6
		8
		10
		12

### OsteoSinter® COTTON wedges



Length (mm) [L]	Height (mm) [H]
15	4,5
	5,5
	6,5
20	4,5
	5,5
	6,5

**RECOMMENDATION:** It is recommended to carefully read the Instructions for Use (IFU) that accompany the product.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.



Manufacturer  
AMES Medical Prosthetic Solutions, S.A.U.  
Ctra. Laureà Miró, 388  
08980 Sant Feliu de Llobregat, Barcelona (Spain)  
[www.ames-medical.net](http://www.ames-medical.net)



Distributor  
BioPro, Inc  
2929 Lapeer Road  
Port Huron, MI 48060 USA  
[www.bioproimplants.com](http://www.bioproimplants.com)

This surgical technique is available in the Instruction for Use.

AMES MEDICAL is certified for the production and sale of medical devices according to EN ISO 13485 standard.

AMES MEDICAL has the Manufacturing License n.º 7549-PS granted by the AEMPS (Agencia Española de Medicamentos y Productos Sanitarios).

The OsteoSinter® EVANS and COTTON wedges and related accessories have the CE Marking under Regulation (EU) 2017/745 (MDR).

Medical devices with Food and Drug Administration clearance under K240461.

