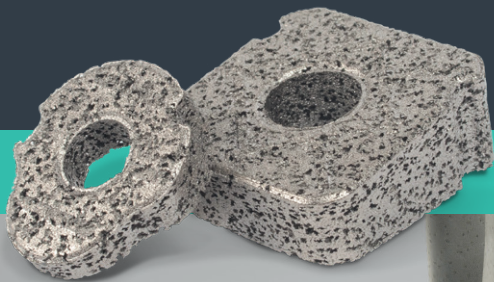


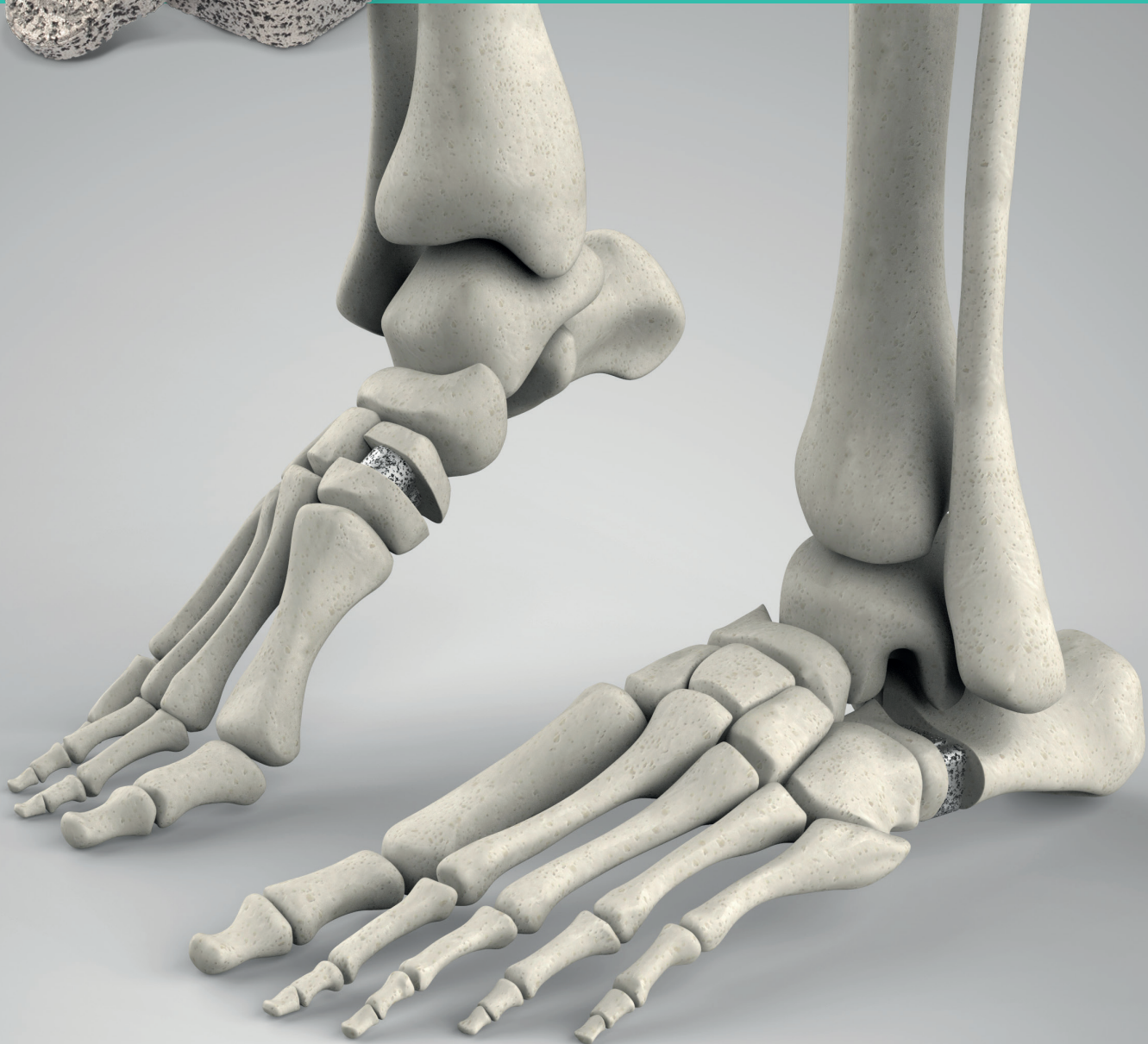
Single-use OsteoSinter®
EVANS and COTTON
instrument kit

OsteoSinter® EVANS and COTTON wedges

Porous titanium wedges used to correct
adult-acquired flatfoot deformities



HUMAN



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 (according to Bluman classification)



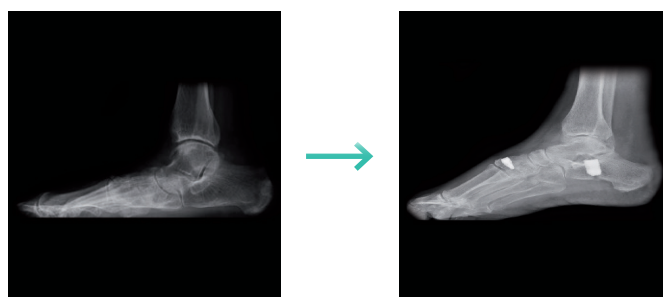
The wedges are intended to be used as an implant specifically designed for Evans procedures (for lateral foot column lengthening) or Cotton (improve the inclination of the first radius and avoid overloading the external column). These wedges allow very precise control of the amount of lengthening or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

Pre-Post EVANS

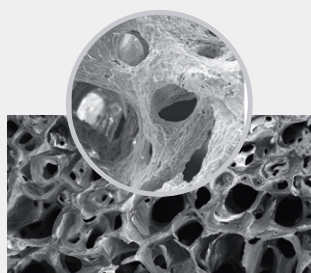


Pre-Post COTTON

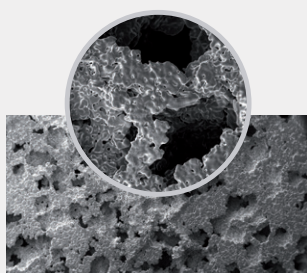


Trabecular bone mimicry

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



Trabecular bone



OsteoSinter® material

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.



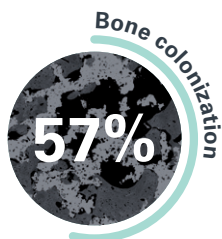
Contraindications

- Infection.
- Physiologically or psychologically inadequate patient.
- Inadequate skin, bone or neurovascular conditions.
- Growing patients with open epiphyses.
- Metal allergy.
- Smoking patients.

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.

Time	Osteointegration versus material (%)			
	OsteoSinter®	Trabecular Metal™	OsseoTi®	Biofoam®
2 weeks	-	13.3 ^[1]	16.0 ^[2]	-
3 weeks	-	23.0 ^[1]	-	45.0 ^[3]
4 weeks	57.0	41.5 - 52.9 ^[1]	55.0 ^[2]	-

[1] Bobyn, et al. "Characteristics of Bone Ingrowth and Interface Mechanics of a New Porous Tantalum Biomaterial." The Journal of Bone and Joint Surgeries (Br) 81-B (1999): 907-913.

[2] Regenerex Porous Titanium construct. Biomet Form BOI0316.0 REV101508. 2008.

[3] Biofoam Technical Monograph MIO23-109. Wright Medical. 2009.

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**.

Property	Material					
	OsteoSinter®	Trabecular bone ^[6, 9, 10]	Trabecular Metal™ ^[8]	OsseoTi® ^[4, 5]	Biofoam® ^[6]	Biosync® ^[7]
Elastic modulus (GPa)	2.5 - 3.5	2.0	3.2	1.6	2.7	3.2
Compressive yield strength (MPa)	40 - 45	10 - 30	76	-	86	-
Compressive fatigue limit	5 M cycles at > 18 MPa without failure	-	-	-	-	10 M cycles at > 10 MPa without failure
Friction coefficient	1.22	0.44 - 0.63	0.88	1.33	0.58	1.07
Abrasion (% of weight loss at 1.000 N)	0.34	-	-	-	13.0	0.20

[4] Gupta G, McLain K. "Coefficient of Friction for Porous Metal Structures Against Cortical Bone". Biomet Inc. 56 E Bell Dr., Warsaw, IN 46582. ©2013 Society For Biomaterials.

[5] <https://www.zimmerbiomet.com/medical-professionals/common/our-science/osseoti-porous-metal.html>

[6] ADVANCE® BIOFOAM™ Cancellous Titanium Tibial implants_Technical Monograph.

[7] Mechanical Characteristics of OsteoSync™Ti: 2007-001-41 REV A.

[8] Trabecular Metal™ Material Product Brochure.

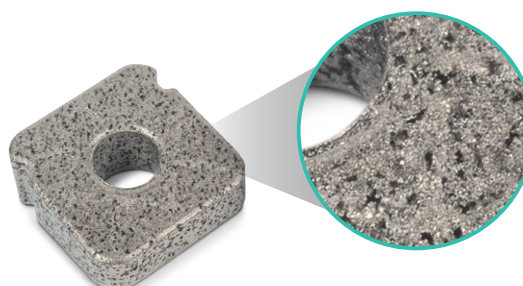
[9] Bobyn, J. D., Stackpool, G. J., Hacking, S. A., Tanzer, M., & Krygier, J. J. (1999). Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial. The Journal of Bone and Joint Surgery. British Volume, 81-B(5), 907-914.

[10] 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.

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: it is possible to reinforce the fixation with auxiliary plates, at the discretion of the surgeon.



Benefits

Reduction of healthcare costs

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:

- They do not require prior defrosting.
- Direct placement, without carving or on-site adjustment.
- They provide greater precision.
- They facilitate reproducibility.
- No sterilization or instrument treatment is required.
- They do not need a fixing plate.

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).



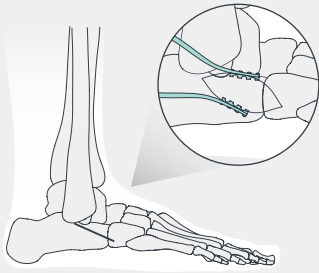
Single-use OsteoSinter® EVANS instruments



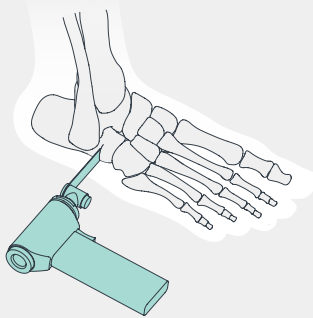
Single-use OsteoSinter® COTTON instruments

Summarized surgical technique of OsteoSinter® EVANS wedge

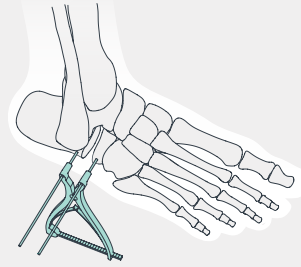
Step 1. Incision and retraction



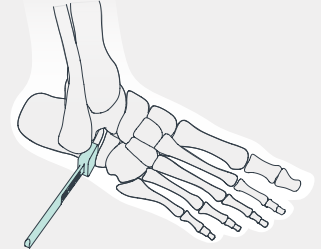
Step 2. Osteotomy



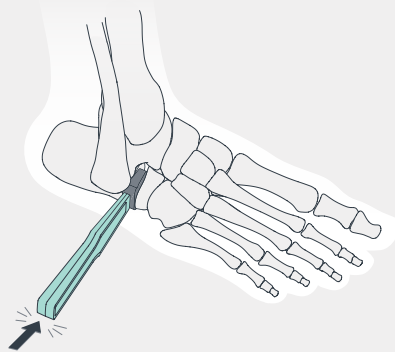
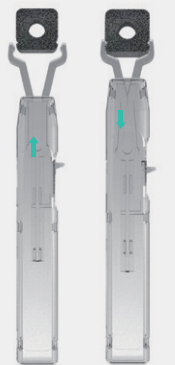
Step 3. Distraction



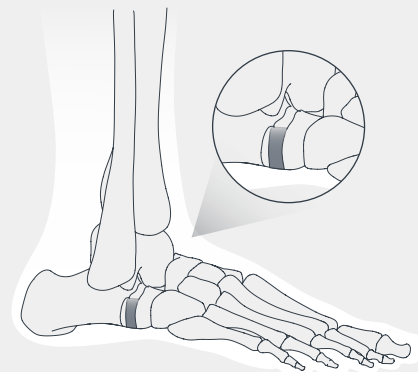
Step 4. Implant selection



Step 5. Implantation

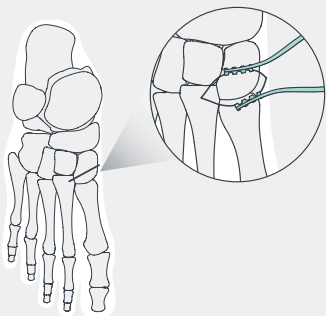


FINAL POSITION

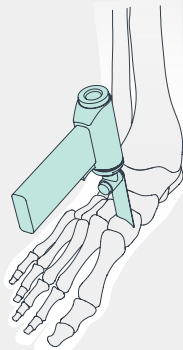


Summarized surgical technique of OsteoSinter® COTTON wedge

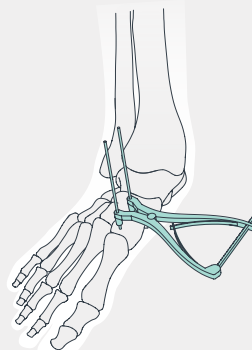
Step 1. Incision and retraction



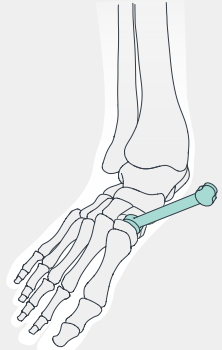
Step 2. Osteotomy



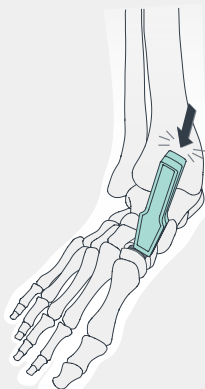
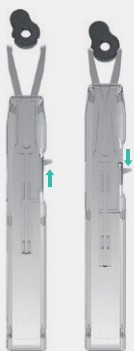
Step 3. Distraction



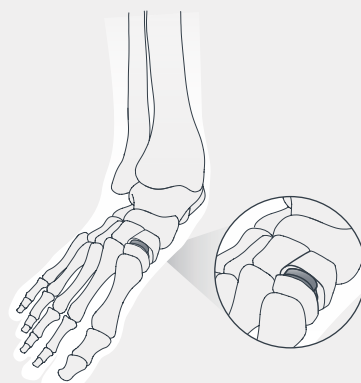
Step 4. Implant selection



Step 5. Implantation



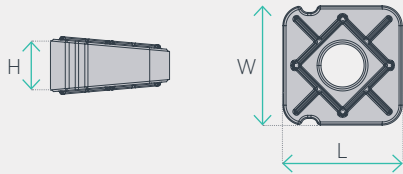
FINAL POSITION



Sizes

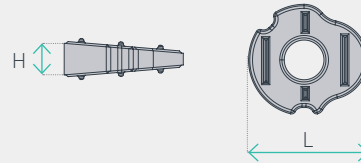
OsteoSinter® EVANS and COTTON wedges are offered in **15 sizes** to achieve proper anatomical correction in each particular case.

OsteoSinter® EVANS wedges



Width (mm) [W]	Length (mm) [L]	Height (mm) [H]	Reference
18	18	8	P00200
18	18	10	P00201
18	18	12	P00202
20	20	8	P00203
20	20	10	P00204
20	20	12	P00205
22	22	8	P00206
22	22	10	P00207
22	22	12	P00208

OsteoSinter® COTTON wedges



Width (mm) [L]	Length (mm) [H]	Reference
15	4.5	P00300
15	5.5	P00301
15	6.5	P00302
20	4.5	P00303
20	5.5	P00304
20	6.5	P00305




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AMES MEDICAL is certified for the production and sale of medical devices according to EN ISO 13485:2016 standard with certificate n.º Q5 104088 0002.

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

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

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

