AMES MEDICAL

OsteoSinter®
EVANS and COTTON wedges and related accessories

Surgical technique

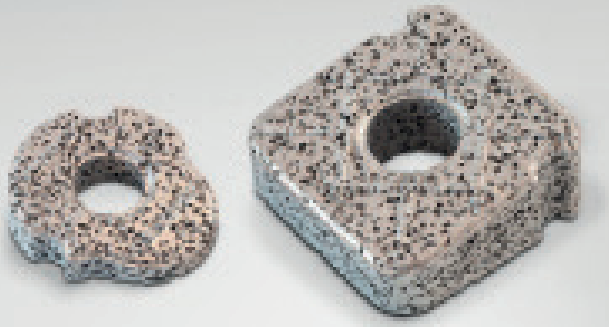


Table of Contents

01 Introduction

OsteoSinter® EVANS and COTTON wedges design rationale

OsteoSinter® EVANS and COTTON wedges are 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.

As the implant is highly porous, it induces 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.

01 Introduction

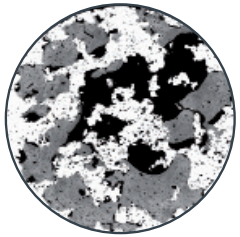
Benefits of OsteoSinter® EVANS and COTTON wedges

STRENGTH maintained throughout the remodelling process.

Pure titanium with **62-66% POROSITY.**

High primary **FIXATION** provided by the relief of the wedges.

RAPID OSTEOINTEGRATION.



After 4 weeks

57%

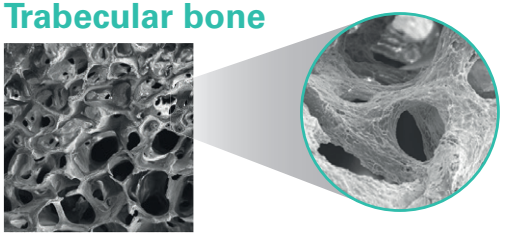
colonization

15 sterile implant size configurations, which **SHORTEN THE OPERATION TIME** vs. non-configured allografts.

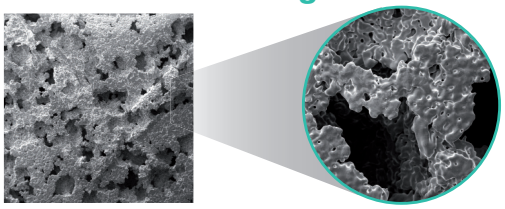
SINGLE-USE related accessories.

TRABECULAR BONE MIMICRY offered by stochasticity in wedge pore distribution.

Trabecular bone



OsteoSinter® wedge



01 Introduction

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 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 intended to be used with ancillary fixations.

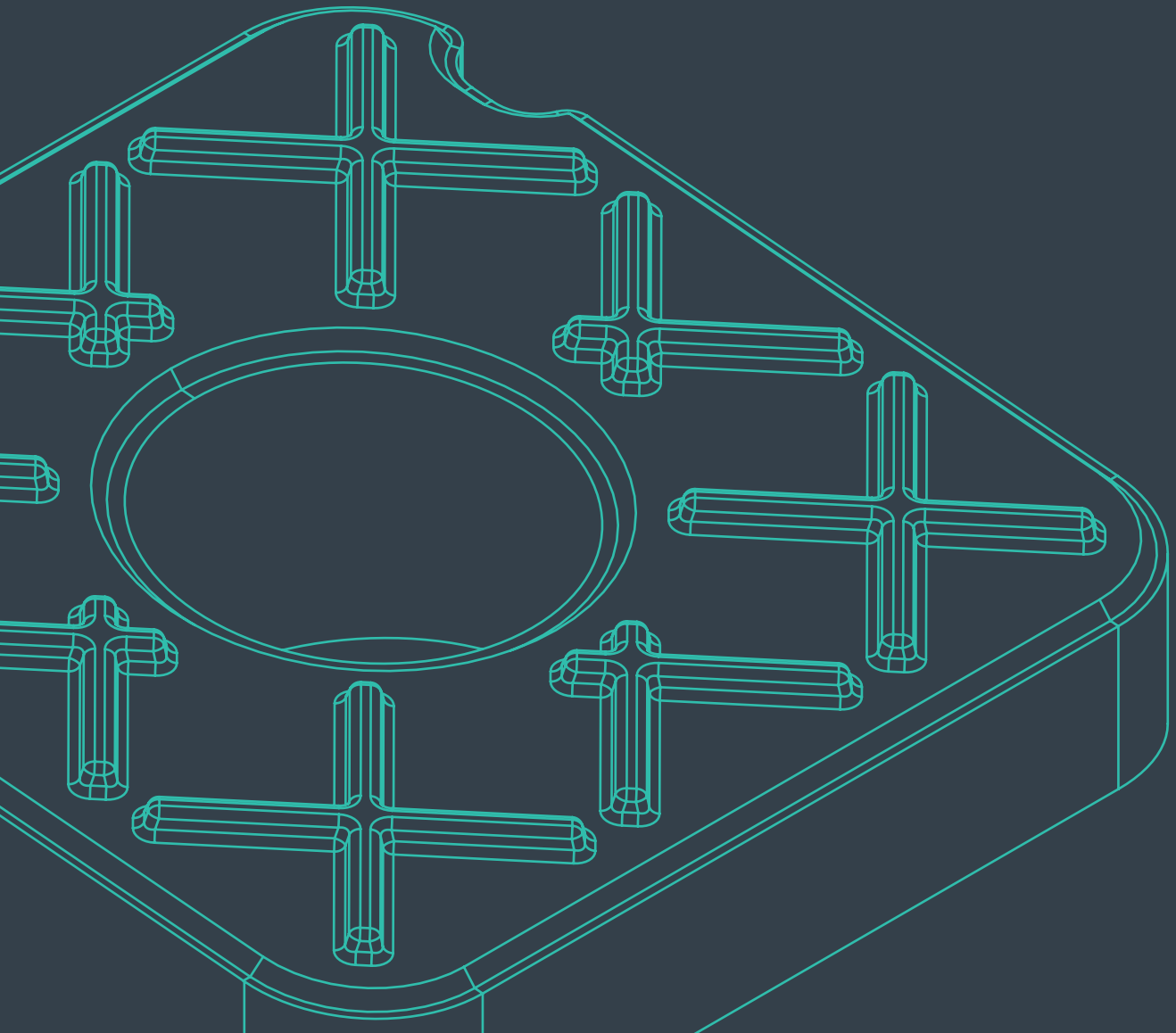
OsteoSinter® EVANS and COTTON wedges are not intended for use in the spine.

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.

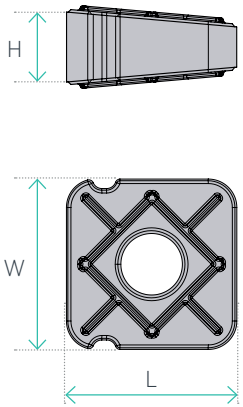
As the manufacturer of this device, AMES MEDICAL PROSTHETIC SOLUTIONS, S.A.U. does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

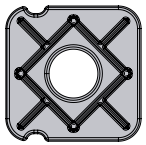
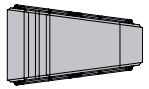
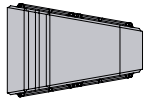
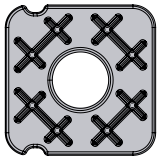
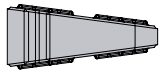
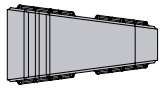
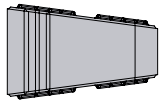
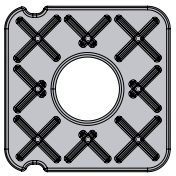
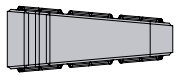
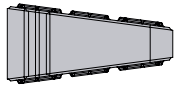
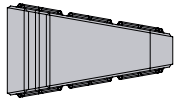
02 Surgical guide to OsteoSinter® EVANS wedges



Sizing

Table 1



Footprint options	Name	Width (mm) [W]	Length (mm) [L]	Height (mm) [H]	Height options	Reference
 18 × 18 mm	**OsteoSinter® EVANS wedge** 18W × 18L × 8H	18	18	8		P00200
	OsteoSinter® EVANS wedge 18W × 18L × 10H	18	18	10		P00201
	OsteoSinter® EVANS wedge 18W × 18L × 12H	18	18	12		P00202
 20 × 20 mm	**OsteoSinter® EVANS wedge** 20W × 20L × 8H	20	20	8		P00203
	OsteoSinter® EVANS wedge 20W × 20L × 10H	20	20	10		P00204
	OsteoSinter® EVANS wedge 20W × 20L × 12H	20	20	12		P00205
 22 × 22 mm	**OsteoSinter® EVANS wedge** 22W × 22L × 8H	22	22	8		P00206
	OsteoSinter® EVANS wedge 22W × 22L × 10H	22	22	10		P00207
	OsteoSinter® EVANS wedge 22W × 22L × 12H	22	22	12		P00208

Single-use OsteoSinter® EVANS instrument kit

Reference P00401

Table 2

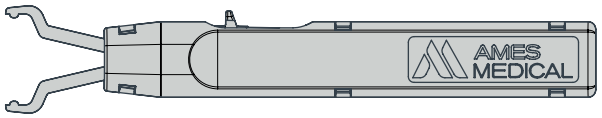
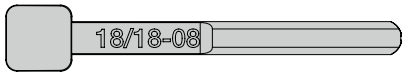
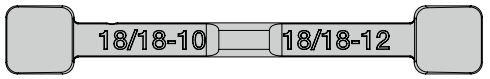
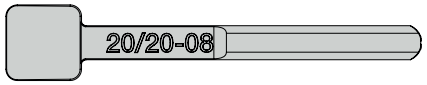
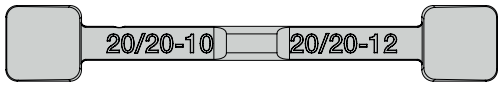
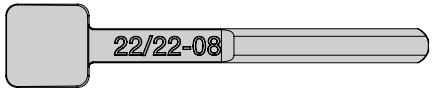
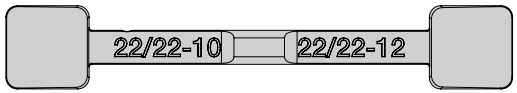
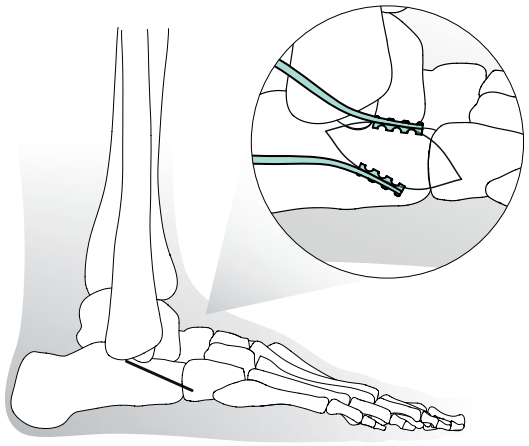
Design	Name	Reference
	**EVANS tweezer**	P00402
	**EVANS impactor**	P00412

Table 3

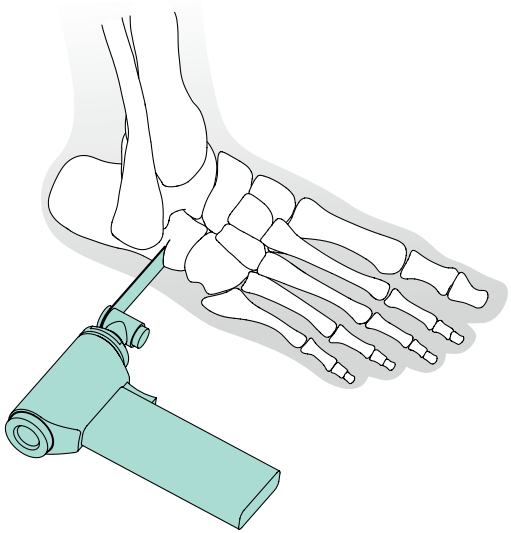
Design	Name	Footprint (width × length in mm)	Height (mm)	Reference
	**EVANS wedge 18 × 18 × 8 sizer**	18 × 18	8	P00406
	**EVANS wedge 18 × 18 × 10/12 sizer**	18 × 18	10 12	P00407
	**EVANS wedge 20 × 20 × 8 sizer**	20 × 20	8	P00408
	**EVANS wedge 20 × 20 × 10/12 sizer**	20 × 20	10 12	P00409
	**EVANS wedge 22 × 22 × 8 sizer**	22 × 22	8	P00410
	**EVANS wedge 22 × 22 × 10/12 sizer**	22 × 22	10 12	P00411

Surgical technique



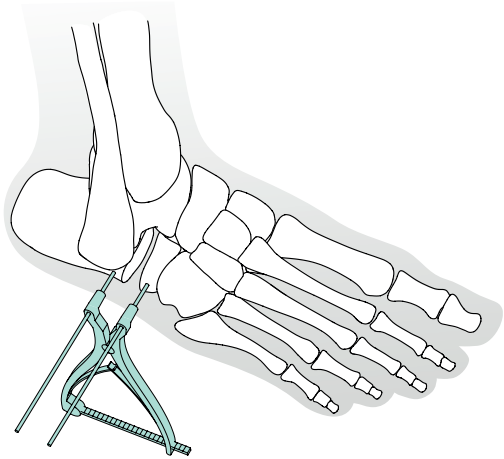
Step 1. Incision and retraction

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.



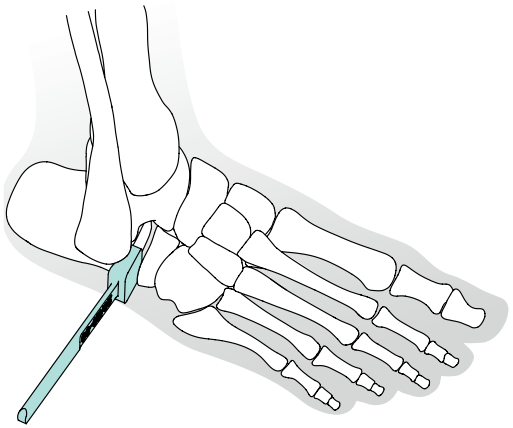
Step 2. Osteotomy

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.



Step 3. Distraction

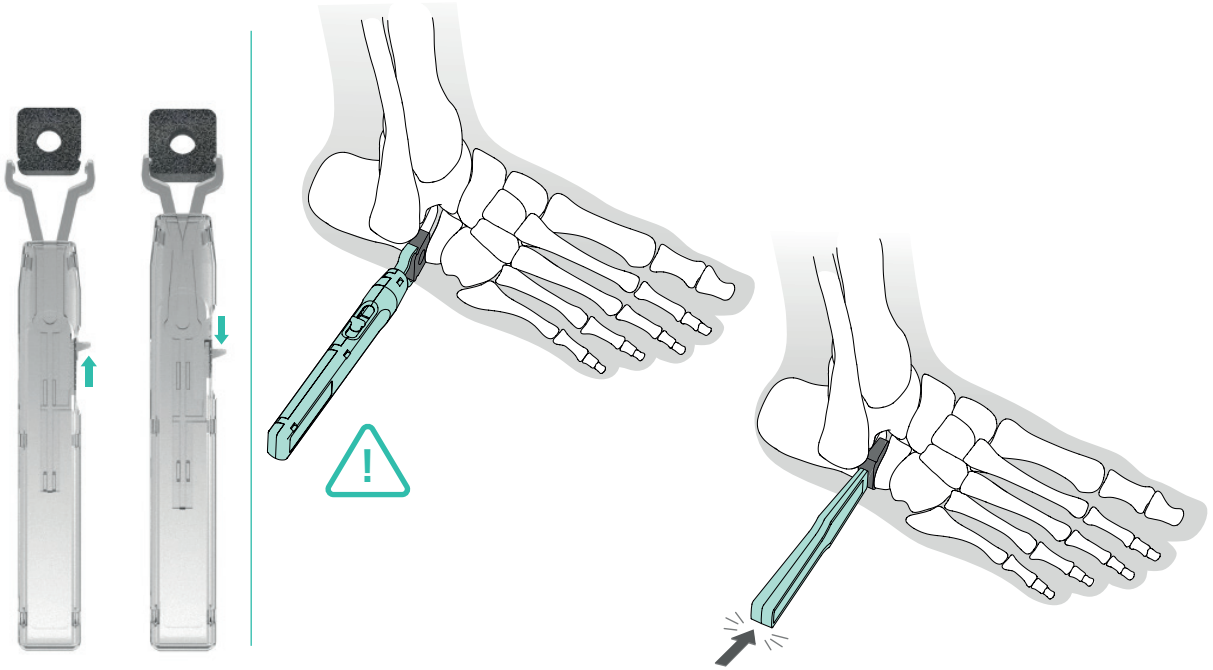
A pin-style distractor, with pin placement on either side of the osteotomy, is installed to provide controlled distraction and unobstructed access to the osteotomy site. A provisional K-wire may be placed across the calcaneal-cuboid joint to prevent subluxation of the joint during distraction.

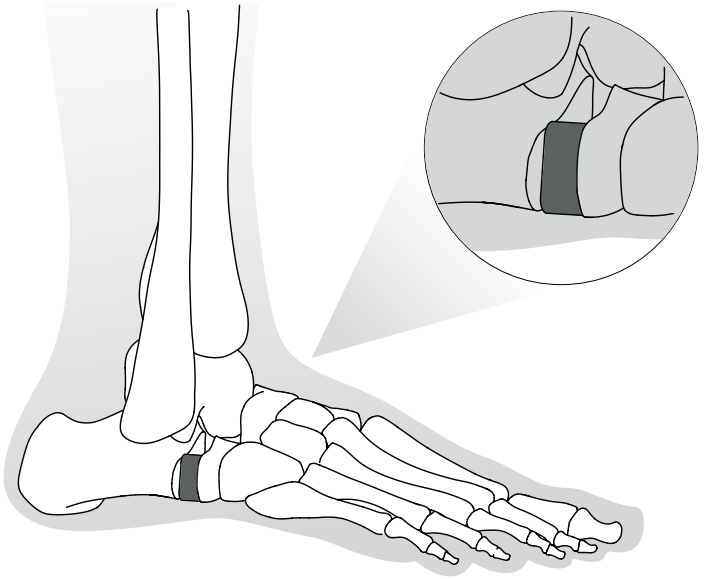


Step 4. Implant selection

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 are used at the distracted osteotomy site until the footprint is congruent to the dimensions of the osteotomy surface. Refer to Table 3 for sizer dimensions. Once this has been achieved and assessed both clinically and fluoroscopically, the optimal implant size can be selected from Table 1.

Surgical technique





Step 5. Implantation

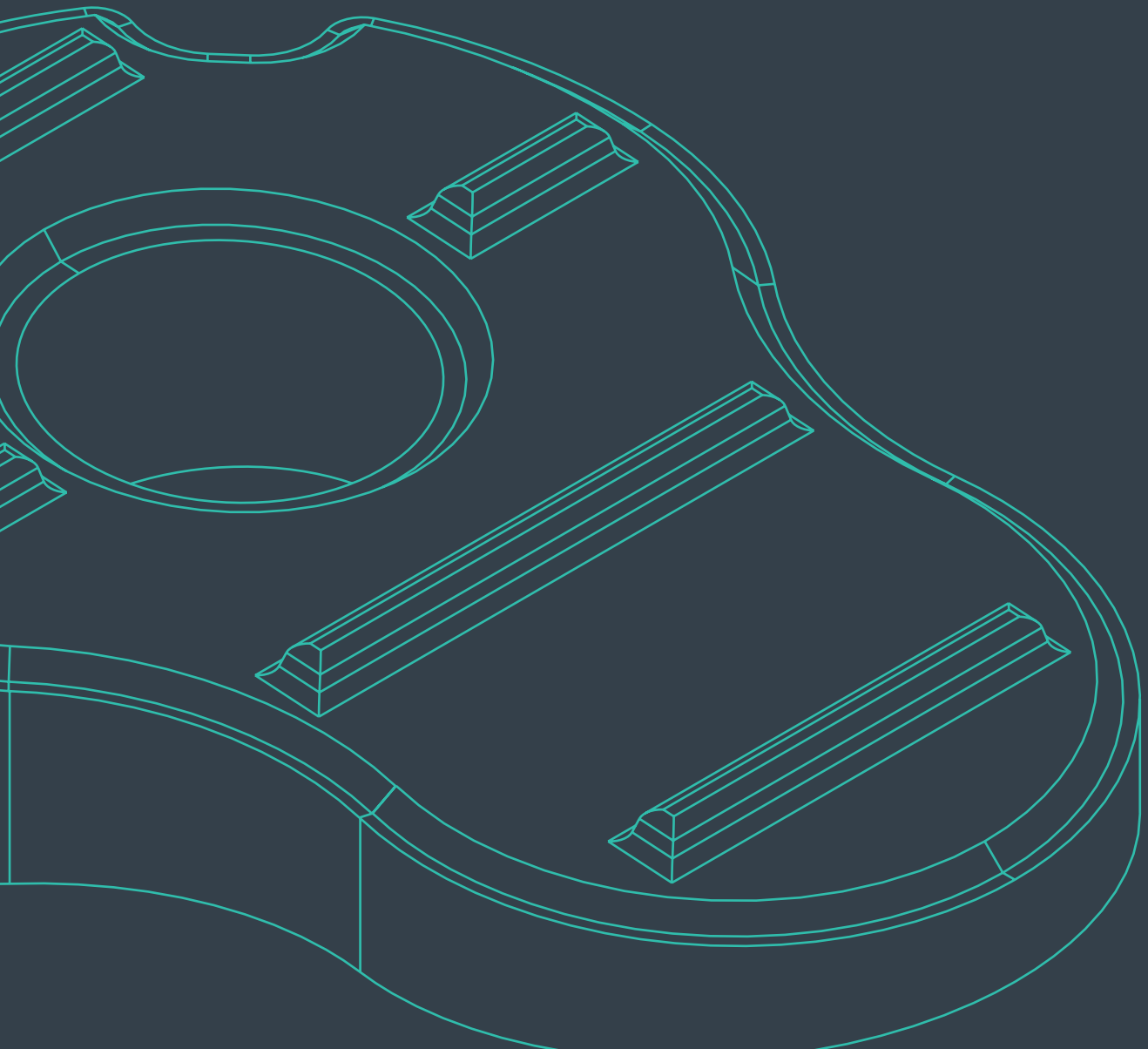
Open the EVANS tweezer clamps by sliding the tab forward and place the clamps on the implant notches. Then, close the clamps by moving the tab backwards in order to hold the implant. If the use of an autograft or allograft is desired, the material should be placed into the centre of the cavity of the implant prior to implantation. Place the assembly at the osteotomy site and remove the tweezer.

N.B.: Do not impact the tweezer to place the implant.
Carefully impact the implant until it is fully seated using the EVANS impactor and a mallet.

FINAL POSITION

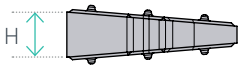
After confirmatory AP and lateral x-rays, the incision is closed in layers of soft tissue using the surgeon's preferred technique. An appropriate post-operative protocol should be followed according to the surgeon's preference.
OPTIONAL: Though OsteoSinter® EVANS wedges provide high primary fixation, the insertion of a surface plate over the wedge is a choice of the surgeon. The ancillary fixation should be manufactured in titanium to reduce the likelihood of galvanic corrosion.

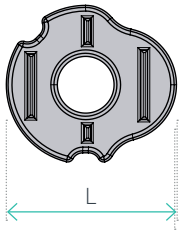
03 Surgical guide to OsteoSinter® COTTON wedges

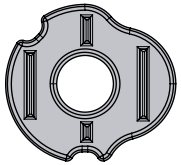
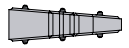
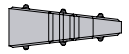
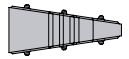
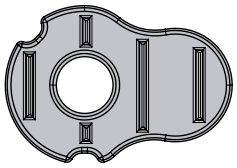
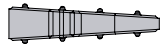
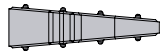
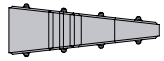


Sizing

Table 4





Footprint options	Name	Length (mm) [L]	Height (mm) [H]	Height options	Reference
 15 mm	**OsteoSinter® COTTON wedge** 15L × 4.5H	15	4.5		P00300
	OsteoSinter® COTTON wedge 15L × 5.5H	15	5.5		P00301
	OsteoSinter® COTTON wedge 15L × 6.5H	15	6.5		P00302
 20 mm	**OsteoSinter® COTTON wedge** 20L × 4.5H	20	4.5		P00303
	OsteoSinter® COTTON wedge 20L × 5.5H	20	5.5		P00304
	OsteoSinter® COTTON wedge 20L × 6.5H	20	6.5		P00305

Single-use OsteoSinter® COTTON instrument kit

Reference P00413

Table 5

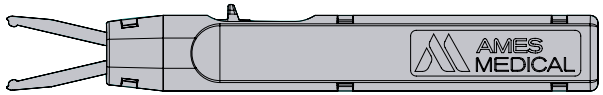
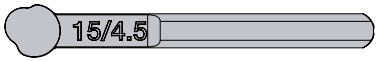
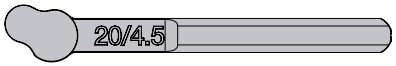
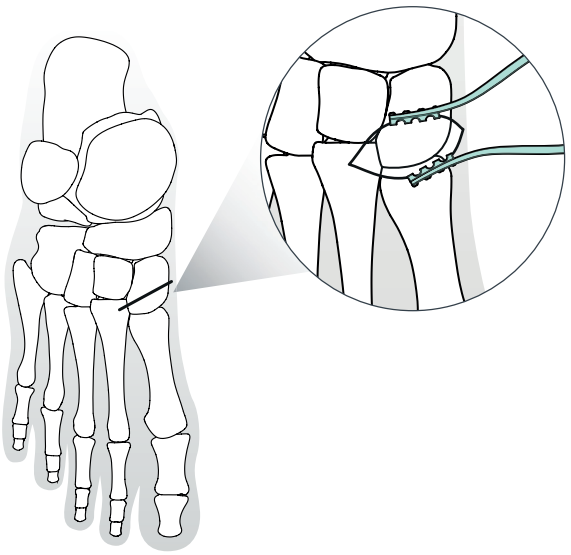
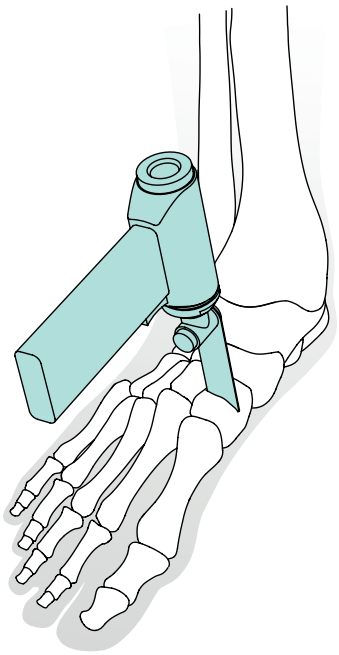
Design	Name	Reference
	**COTTON tweezer**	P00414
	**COTTON impactor**	P00422

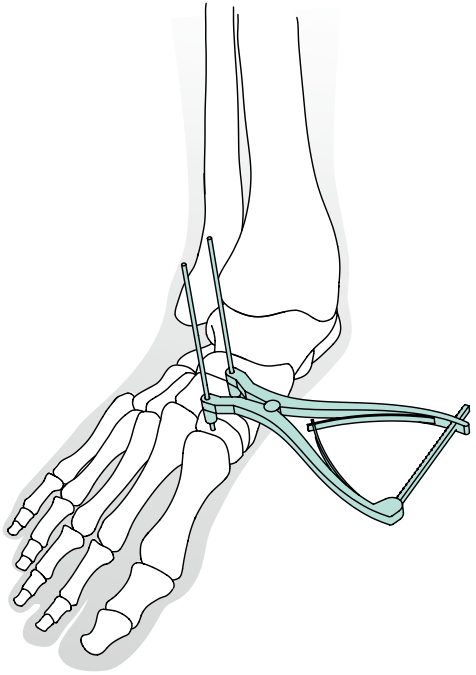
Table 6

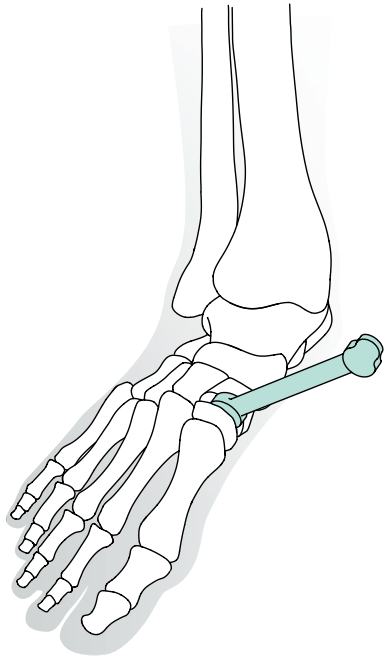
Design	Name	Footprint (depth in mm)	Thickness (mm)	Reference
	**COTTON wedge 15 × 4.5 sizer**	15	4.5	P00418
	**COTTON wedge 15 × 5.5/6.5 sizer**	15	5.5 6.5	P00419
	**COTTON wedge 20 × 4.5 sizer**	20	4.5	P00420
	**COTTON wedge 20 × 5.5/6.5 sizer**	20	5.5 6.5	P00421

Surgical technique









Step 1.
Incision and retraction

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

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.

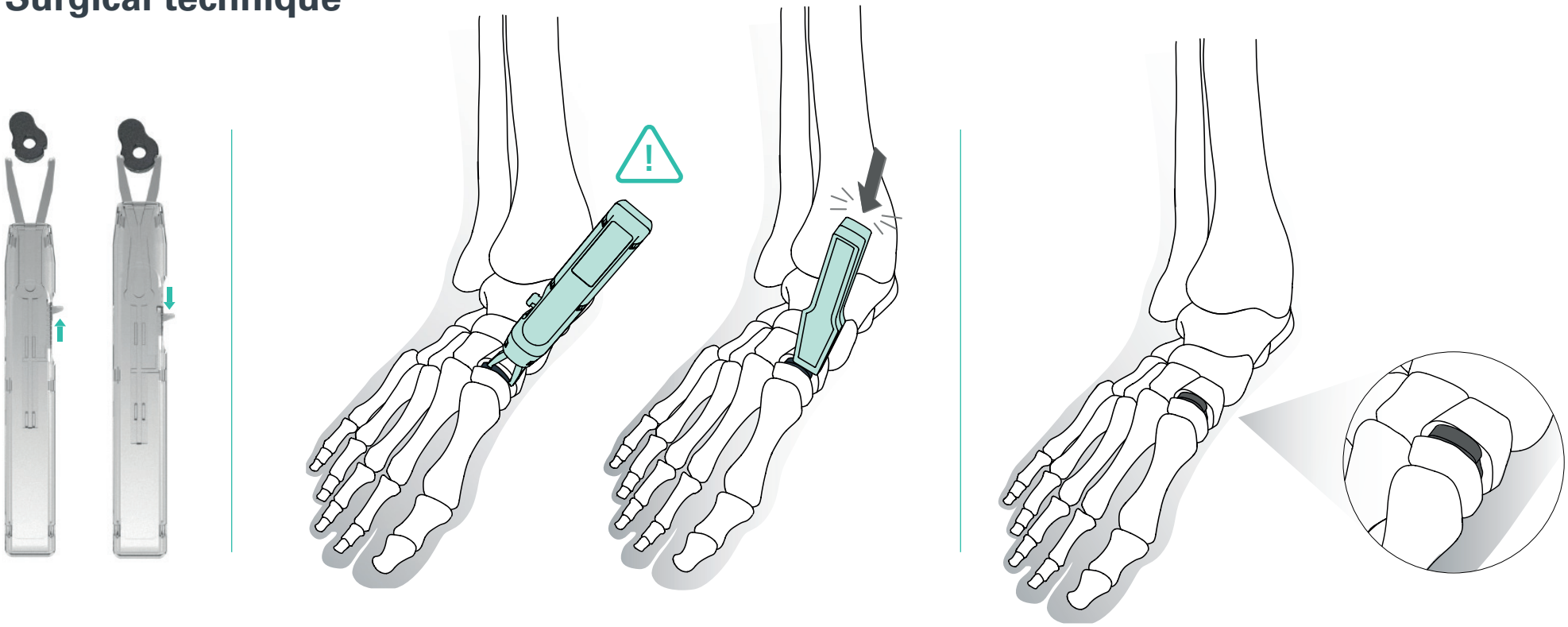
Step 3.
Distraction

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.

Step 4.
Implant selection

The osteotomy diastasis is performed and the degree of correction required is clinically assessed. At this time, the sizers from the Single-use OsteoSinter® COTTON instrument kit are used at the distracted osteotomy site until the footprint is congruent to the dimensions of the osteotomy surface. Refer to Table 6 for sizer dimensions. Once this has been achieved and assessed both clinically and fluoroscopically, the optimal implant size can be selected (see Table 4).

Surgical technique



Step 5. Implantation

Open the COTTON tweezer clamps 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 implant cavity prior to implantation. Place the assembly at the osteotomy site and remove the tweezer.

N.B.: Do not impact the tweezer to place the implant.
Carefully impact the implant until it is fully seated using the COTTON impactor and a mallet.

FINAL POSITION

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.
OPTIONAL: Though OsteoSinter® COTTON wedges provide high primary fixation, the insertion of a surface plate over the wedge is a choice of the surgeon. The ancillary fixation should be manufactured in titanium to reduce the likelihood of galvanic corrosion.

AMES MEDICAL

AMES MEDICAL PROSTHETIC SOLUTIONS, S.A.U.
Ctra. Laureà Miró, 388. 08980 Sant Feliu de Llobregat,
Barcelona (Spain)

CE 0123

www.ames-medical.net