

## Porous titanium wedges used to correct adult-acquired flatfoot deformities



### Indications



#### Foot osteotomies that require addition wedges:

- 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.



Product with CE Marking according to 93/42/EEC Medical Devices Directive (MDD) with certificate n° G1 104088 0001

### Specifications

Commercial name <b>OsteoSinter® EVANS and COTTON wedges</b>	Service life <b>15 years minimum (single use)</b>
Material <b>Porous titanium OsteoSinter® under patent EU2476065B1, based on CPTi (Commercial Pure Titanium)</b>	Sterilization method <b>Gamma radiation</b>
Manufacturing technology <b>Powder metallurgy</b>	Packaging dimensions <b>130W × 105L × 30H (mm) (OsteoSinter® EVANS) 130W × 105L × 30H (mm) (OsteoSinter® COTTON)</b>
Device classification <b>Class IIb according to Annex IX, Rule 8, 93/42/CEE</b>	Packaging weight <b>60 g (OsteoSinter® EVANS) 57 g (OsteoSinter® COTTON)</b>
NANDO classification <b>MD 0203 – Non-active functional implants</b>	Storage conditions <b>Must be stored in a clean and dry environment, protected from sunlight and extremes temperature</b>
GMDN code <b>61617 - Metallic osteotomy fusion cage, sterile</b>	Device-specific applying harmonized standards <b>ISO 14630, ISO 14602, ISO 10993</b>

### Related accessories

#### Single-use OsteoSinter® EVANS and COTTON instrument kit

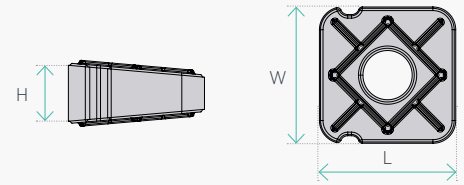
- **It will be employed** in conjunction with the common instrumentation of a standard orthopedic surgery, for both Evans and Cotton osteotomies.
- **It includes:**
  - Set of sizes (one for each size and type).
  - Tweezer to hold and insert the wedge.
  - Impactor to seat the implant in its implanted position tapping gently with a hammer.


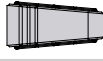
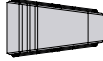
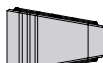

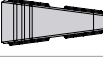
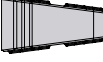


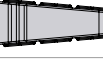
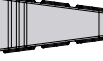

Commercial name <b>Single-use OsteoSinter® EVANS and COTTON instrument kit</b>	Sterilization method <b>Gamma radiation</b>
Material <b>Polyamide grade 12</b>	Packaging dimensions <b>255W × 350L × 45H (mm) (OsteoSinter® EVANS) 255W × 350L × 45H (mm) (OsteoSinter® COTTON)</b>
Manufacturing technology <b>Plastic injection molding</b>	Packaging weight <b>370 g (OsteoSinter® EVANS) 305 g (OsteoSinter® COTTON)</b>
Device classification <b>Class IIa according to Annex IX, Rule 6, 93/42/CEE</b>	Storage conditions <b>Must be stored in a clean and dry environment, protected from sunlight and extremes temperature</b>
NANDO classification <b>MD 0106 – Non-active instruments</b>	Device-specific applying harmonized standards <b>ISO 16061, ISO 10993</b>
Service life <b>Single use: 1 surgical intervention</b>	



## OsteoSinter® EVANS wedges

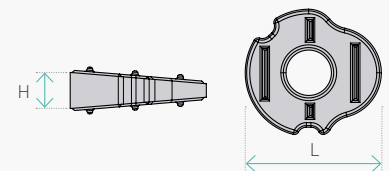
9 sizes (3 different surface dimensions and 3 thicknesses for each one)





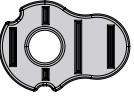





Footprint options	Name	Width (mm) [W]	Length (mm) [L]	Height (mm) [H]	Height options	Reference
 18 × 18 mm	<b>OsteoSinter® EVANS wedge</b> 18W × 18L × 8H	18	18	8		P00200
	<b>OsteoSinter® EVANS wedge</b> 18W × 18L × 10H	18	18	10		P00201
	<b>OsteoSinter® EVANS wedge</b> 18W × 18L × 12H	18	18	12		P00202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

## OsteoSinter® COTTON wedges

6 sizes (2 different surface dimensions and 3 thicknesses for each one)



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