

CONFORMITY DECLARATION CE MEDICAL DEVICES AND MRI DECLARATION

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform European Medical Devices Directive - 93/42/EEC - Medical Devices Annex II rule 8

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|---------------------------------------|---|
| Manufacturer: | Episcan Srl Via Custoza, 10 20811 Cesano Maderno MB Italy |
| Orthopaedics Medical devices: | Bone Implants |
| Risk class: | <input checked="" type="checkbox"/> IIb |
| Certification CE: | Certificate n. 0068/QCO-DM/049-2018 |
| Notify Body: | 0068 MTIC InterCert S.r.l. - Via Moscova, 11 - 20017 Rho MI – Italy |
| Raw Material | |
| Screws titanium: | Titanium alloy Ti6Al4V in according ISO.5832.3 /ASTM F136 |
| Malleolar plates : | Titanium alloy Ti6Al4V in according ISO.5832.3 /ASTM F136 |
| Calcaneal Displacement Plates: | Titanium alloy Ti6Al4V in according ISO.5832.3 /ASTM F136 |
| Others Plates: | Pure Titanium Ti2 or Ti4 in according ISO.5832.2 /ASTM F67 |

MRI Compatibility

All Episcan implants are made in Titanium (Ti2 or Ti4 or Ti6Al4V) which is known to be non-magnetic and biocompatible for this reason, patients on which it was implanted a screws or plates can be subjected to MRI exams.

Studies indicated that MRI procedure hasn't effects on Titanium Medical Orthopedic implant devices up to 3 Tesla.

Patient should note that there are several different manufacturers and generations of MRI equipment available, and Episcan Medical cannot make claims regarding compatibility of Episcan Medical implants with any specific MRI unit. It is recommended that the patient contact the surgeons or the manufacturer of the MRI devices to discuss the compatibility of Episcan Medical implants with the MRI equipment before undergoing any test.

Following metals and implants have non-ferromagnetic behavior:

- ⇒ Forefoot Surgery System 2,7mm
- ⇒ Universal Plate 2,7mm
- ⇒ Open-Wedge (OWP) Plate 2,7mm
- ⇒ Tarsal Plate 2,7mm
- ⇒ MPJ Plate 2,7mm
- ⇒ Cotton Plate 2,7mm
- ⇒ Revision Plate 2,7mm
- ⇒ Plantar Lapidus Plate 2,7mm
- ⇒ Compression Cortical Screw 2,7mm

- ⇒ Locked Cortical Screw 2,7mm
- ⇒ Rearfoot Surgery System 3,5mm
- ⇒ Lapidus Plate 3,5mm
- ⇒ Interposition Plate 3,5mm
- ⇒ Universal Plate 3,5mm
- ⇒ Multihole Plate 3,5mm
- ⇒ USG Plate 3,5mm
- ⇒ H Plate 3,5mm
- ⇒ Evans Plate 3,5mm
- ⇒ Calcaneus Plate 3,5mm
- ⇒ Calcaneal Displacement Plate 3,5mm
- ⇒ Diabetic Foot Plate 3,5mm
- ⇒ Malleolar Plate 3,5mm
- ⇒ Compression Cortical Screw 3,5mm
- ⇒ Locked Cortical Screw 3,5mm
- ⇒ Double Threaded Cannulated Screw 2,5/3,2mm
- ⇒ Double Threaded Cannulated Screw 3,0/3,9mm
- ⇒ Double Threaded Cannulated Screw 3,5/4,5mm
- ⇒ Double Threaded Cannulated Screw 4,7/6,0mm
- ⇒ Double Threaded Cannulated Screw 6,0/7,5mm
- ⇒ Cannulated Cortical Screw 1,8/2,3/2,7/3,0/3,5/4,5mm
- ⇒ Washers for Cannulated Cortical Screws 1,8/2,3/2,7/3,0/3,5/4,5mm
- ⇒ Cannulated Cancellous Screw 4,0/6,5/7,3mm

We remain at your disposal for any additional information you may require.

Cesano Maderno, 24/01/2019



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