

Information for MRI Professionals

Magnetic Resonance Imaging (MRI) Information

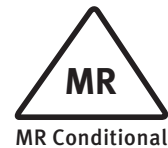
For the Ponto Bone Anchored Hearing System

The sound processor MUST be removed if the patient needs to undergo Magnetic Resonance Imaging (MRI). The implant and the abutment can remain in place.

Non-clinical testing has demonstrated the Ponto implant system is MR Conditional.

It can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm
- Maximum whole body averaged specific absorption rate of 4 W/kg for 15 minutes of scanning in the first level controlled mode



In non-clinical testing, the Ponto implant system produced a temperature rise of less than 2.2°C at a maximum whole body average specific absorption rate SAR of 4 W/kg, as assessed by calorimetry for 15 minutes of MRI scanning in a (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI scanner.

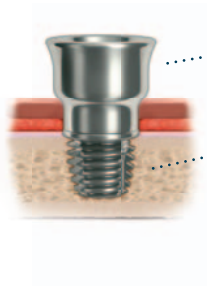
Image Artifact

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. The maximum artifact size extends approximately 10 mm relative to the size and shape of the implant.

Components of the Implant system:



Ponto sound processor



Ponto titanium abutment

Ponto titanium implant



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