

To whom it may concern

Valence, 25th of April 2016

AMPLITUDE's reference ATH 16 001

Implants and safety in the Magnetic Resonance (MRI) environment

As a legal manufacturer and in order to validate our implant's compatibility in Magnetic Resonance (MRI) environment, Amplitude has conducted tests according to the appropriate standards.

As per ASTM F2503-13 standard requirements the MRI information for each of the Amplitude products is provided in the corresponding Instruction For Use (IFU). The MRI information provided below is an excerpt from the latest versions to date of the referenced IFUs.

Total Hip Prosthesis system (THP) NO101/T IFU:

Security in magnetic resonance environment (MRI):

Nonclinical testing demonstrated that the devices are compatible with MRI when used with the configurations specified below:

- Static magnetic field of 1.5T or 3T
- Maximum spatial gradient field of 1500 Gauss/cm
- Normal operating mode only
- Maximum MR system reported whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning

Heating:

Maximum measured temperature rise with 1.5T MRI is 13.7°C for 15mn of scanning with a WB-SAR measured by calorimetry of 3.1 W/kg (1.5-T/64MHz, GE Signa system, HDxt, software 15.0_M4_0910.a). For a 3T MRI, maximum heating is 5.7°C for 15mn of scanning with a measured WB-SAR of 2.1 W/kg (3.0-T/128MHz, GE Signa system, HDxt, software hd23.0_v01).

Image Artifacts: MR image quality may be compromised around the position of the implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

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Primary or Revision Total Knee Prosthesis (TKP) NO109/M IFU:

Security in magnetic resonance environment (MRI):

Nonclinical testing demonstrated that the devices are compatible with MRI when used with the configurations specified below:

- Static magnetic field of 1.5T or 3T
- Maximum spatial gradient field of 1500 Gauss/cm
- Normal operating mode only
- Maximum MR system reported whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning.

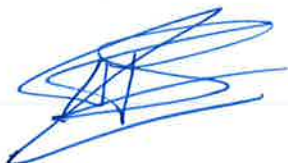
Heating:

Maximum measured temperature rise with 1.5T MRI is 8.6°C for 15mn of scanning with a WB-SAR measured by calorimetry of 3.27 W/kg (1.5-T/64MHz, GE Signa system, HDxt, software hd23.0_v02). For a 3T MRI, maximum heating is 9.9°C for 15mn of scanning with a measured WB-SAR of 2.39 W/kg (3.0-T/128MHz, GE Signa system, HDxt, software hd23.0_v02).

Image Artifacts: MR image quality may be compromised around the position of the implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

As a conclusion, AMPLITUDE's hip and knee prosthesis have no risk for patient safety with 1.5 T and 3T MR system.

The only risk is a misinterpretation of MR image by a physician due to possible artifacts. Moreover, the radiologist has the possibility to modify the sequence to reduce artifacts. So, these prostheses are MR conditional



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