



## Biomet® Implants in the Magnetic Resonance (MR) Environment

Biomet® implants are manufactured out of non-ferromagnetic materials such as commercially pure titanium (CP-Titanium), titanium alloy (Ti-6Al-4V), cobalt-chromium-molybdenum alloy (Co-Cr-Mo), 300 series stainless steels (316L), tantalum, ultra high molecular weight polyethylene (UHMWPE), and polyetheretherketone (PEEK).

Biomet has performed non-clinical Magnetic Resonance Imaging (MRI) studies on various representative metallic implants which are determined to be MR Conditional in accordance to ASTM F2053-08 *Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment*. MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

### MR Information

Safety information for the use of MRI procedures (i.e., imaging, angiography, functional imaging, spectroscopy, etc.) pertains to shielded MRI systems under the following specifications:

- Static magnetic field of 3-Tesla or less
- Spatial gradient field of 720-Gauss/cm or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning

The effects of MRI procedures using MR systems and conditions above these levels have not been determined.

### MR Related Heating

In non-clinical testing, the representative metallic devices produced a temperature rise of less than 2.5°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla MR system (Excite, Software G3.0-52B, General Electric Healthcare, Milwaukee, WI).

### Image Artifacts

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 these implants; imaging may not be possible due to the presence of these implants.

Comments regarding Biomet® implants can be directed to: Regulatory Compliance Department, Biomet Orthopedics, Warsaw, Indiana, USA

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