

To whom it may concern:

## Biomet UK Implants and Safety in the Magnetic Resonance (MRI) Environment

Biomet UK implants are manufactured from non-ferromagnetic materials such as 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 performed a Magnetic Resonance Imaging (MRI) safety check on various representative implants manufactured from these materials. Each of the representative implants was tested for: (1) magnetically induced displacement force as per ASTM F2052; (2) magnetically induced torque as per ASTM F2213; (3) magnetically induced heating as per ASTM F2182 and image artefacts as per ASTM F2119.

The results of this study indicate that implants manufactured from these materials may be safely used in the MRI environment and each of the implants tested may be considered as "MRI Conditional" as per ASTM F2503. "MRI Conditional" is defined as an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use (ASTM F2503, 3.1.9). The specified conditions of use are:

- \* Static magnetic field of 3 Tesla, or less.
- \* Spatial gradient field of 720 Gauss/cm, or less.

\* Maximum MRI system reported whole-body-averaged specific absorption rate (SAR) of 3W/kg for 15 minutes of scanning.

These test results indicate that Biomet implants manufactured from the materials listed above may be considered safe for use in the MRI environment. However, Biomet UK Limited assumes no responsibility for their use in the MRI environment. Biomet UK Limited recommends that medical professionals and the MRI equipment manufacturer be consulted for implant compatibility before use.

Comments regarding Biomet UK Limited implants should be directed to:

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For and on behalf of  
 Biomet UK Limited



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