

## **Magnetic Resonance Imaging (MRI) Safety Information for Biotek Implants**

Magnetic Resonance Imaging (MRI) is a commonly accepted and widely used diagnostic medical procedure. It is often safe to perform MRI on an individual that has an orthopaedic implant device. The main issues affecting the safety of passive implants (medical devices that serve their function without the supply of power) in the MR environment involve magnetically induced displacement force and torque and radio frequency (RF) induced heating. The MR static field induces displacement forces and torques on ferromagnetic materials. However, both ferromagnetic and non-ferromagnetic metallic devices of certain geometries may experience heating caused by interactions with the RF field. Of secondary concern is the possibility of image artefacts that can compromise image quality.

### **Implant Movement**

Biotek metallic implants are manufactured using one or more of the following non-ferromagnetic materials: commercially pure titanium (CP Titanium), Ti-6Al-4V alloy, Co-Cr alloys (ASTM F75), and implant grade stainless steels: 316L. Testing has revealed that although each metallic material exhibits a small but measurable magnetic attraction in the 1.5 Tesla and 3.0 Tesla environments, the maximum magnetic force exerted on a device (stainless steel) is less than 25% of the force exerted on the device due to gravity. None of the metallic materials exhibit any torque movement in 1.5 Tesla and 3.0 Tesla MR environments. Therefore, no movement or deflection of Biotek devices manufactured from the aforementioned metallic materials is expected in 1.5 Tesla and 3.0 Tesla MR environments.

The polymer (plastic) materials used in the manufacture of some Biotek implants are non-metallic and non-ferromagnetic and pose no risk of movement or deflection due to exposure to the MR environment.

### **Implant Heating**

In regards to RF induced heating, one recent publication states “.....to date, there has been no report of a patient being seriously injured as a result of excessive heat that developed in a "passive" metallic implant or device. However, heating is potentially problematic for implants that have an elongated shape or those that form a conducting loop of a certain diameter.”

Patients should note that there are several different manufacturers and generations of MRI systems available, and Biotek cannot make any claims regarding the safety of Biotek implants and devices with any specific MR system.

If more information is needed, please contact BIOTEK Customer Service Department.