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Memorandum

Date: May 17, 2010
Subject: Magnetic Resonance Imaging (MRI) Information

Non-clinical testing¹ has demonstrated that **DePuy Mitek Metal Implants are MR Conditional**. A patient with a metallic implant can be scanned safely under the following conditions.
3.0 Tesla Systems:

- Static magnetic field of 3.0 Tesla.
- Highest spatial gradient magnetic field of 720 Gauss/cm or less.

MRI Related Heating

- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of scanning (i.e., per pulse sequence).
MRI related heating was assessed for the representative configurations of the DePuy Mitek metal implants following guidelines provided in ASTM F2182-02a. A maximum temperature change equal to or less than 2.0 °C was observed during testing (parameters listed below).

Parameters:

- Maximum MR system-reported, whole-body-averaged SAR of 2.9 W/kg
- 15-minute duration MR scanning (i.e., per pulse sequence).
- 3 Tesla MR System (EXCITE® MR Scanner, Software G3 .0-052B, General Electric Healthcare, Milwaukee, WI) using a transmit/receive RF body coil.

Artifact Information

MR Image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the DePuy Mitek metal implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Sincerely,

A handwritten signature in black ink, appearing to read "George Cakounes", written over a horizontal line.

George Cakounes
NPD Quality Manager



¹ Testing was performed by Shellock R&D Services, Inc. Reports are on file at DePuy Mitek.