Smith & Nephew, Inc.
7135 Goodlett Farms Parkway
Cordova, TN 38016
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com

We are smith&nephew

MRI Statement

for Smith & Nephew, Inc. Hip, Knee, Shoulder and Trauma Implants

Magnetic Resonance Imaging (MRI) Safety

The main issues affecting the safety of passive implants (i.e. medical devices which serve their function without the supply of power) in the *Magnetic Resonance Imaging* (MRI) environment include *magnetically induced displacement force*, *torque* and *radio frequency (RF) induced heating*. Smith & Nephew, Inc. has undertaken efforts to design and manufacture passive implants in order to minimize the risks to patients and users when patients implanted with passive implant devices are exposed to magnetic fields such as that encountered in the MRI environment. While it is known that the magnetic resonance (MR) static field induces *displacement forces* and *torque* on materials with *ferromagnetic* properties, devices of certain geometries made from both *ferromagnetic* and *non-ferromagnetic* metallic materials may also experience *RF-induced heating* caused by interactions with the MR static field. The amount of RF heating can vary depending on device geometry, the MR system in use, scan conditions, and the conductive length of the device. Additionally, during the MR scan the critical length for a specific device cannot be calculated precisely. Of secondary concern is the potential for the implant device to create MR *image artifacts*. While image artifacts present no known risks to the patient or user their presence can compromise image quality.

Evaluations for *Displacement Force*, *Torque*, *RF Induced Heating* and *Image Artifacts*

Smith & Nephew, Inc. passive implant devices are manufactured from several different types of ***non-ferromagnetic*** metallic materials (in either an alloyed or pure form) including: *cobalt chrome*, *stainless steel*, *oxidized zirconium* (*Oxinium*) and *titanium* and from *non-metallic* polymer materials such as *ultra-high molecular weight polyethylene* (UHMWPE). Because metallic materials such as *cobalt chrome*, *stainless steel*, *oxidized zirconium* and *titanium* materials are ***non-ferromagnetic*** in nature, no magnetically induced displacement force or torque is expected as a result of their implantation in patients. Further, polymer materials do not conduct magnetic currents, thus their material characteristics negate the chance of magnetically induced displacement forces, torque and RF-induced heating.

While no specific MR safety claims are made, Smith & Nephew, Inc. has conducted MR safety testing in 1.5-Tesla (1.5T) and 3-Tesla (3T) MR systems using representative samples of actual passive implant devices in their final geometries[1]. Tested devices consisted of: 1) a titanium (Ti-6Al-4V, ASTM F1472) intramedullary nail, 2) a cobalt chrome (ASTM F75) staple, 3) a 316L stainless steel (ASTM F138) Compression Hip Screw plate and lag screw and 4) an Oxidized Zirconium (ASTM F2384) Oxinium knee femoral component.

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[1] **OR-02-12**, *Results of Magnetic Resonance Safety Tests Conducted on Smith & Nephew Products*, January 2002.

Additional MR safety testing has been conducted on a representative *total hip prosthesis* construct consisting of a titanium (Ti-6Al-4V, ASTM F1472) femoral stem, an oxidized zirconium (ASTM F2384) Oxinium femoral head and a polyethylene (UHMWPE, ASTM F648) acetabular liner in a titanium (Ti-6Al-4V, ASTM F1472) shell[2].

Results from both testing scenarios demonstrated that forces due to magnetic field interactions such as *displacement force* and *torque* were no greater than the force exerted on the device by gravity (i.e. its weight) and were acceptable per the criteria established by the applicable ASTM F2052 and F2213 standards.

Results from both testing scenarios also revealed that the peak temperature observed due to *RF-induced heating* was less than 1°C among the individual devices tested[1] and was less than 4°C for the total hip prosthesis construct tested[2]. Results from testing of the individual devices reported the maximum observed *whole body averaged Specific Absorption Rate* (*SAR*) value was 1.3 W/kg at 1.5T using a scan time of 15 minutes[1].

Results from testing of the total hip prosthesis reported the maximum observed *whole body averaged Specific Absorption Rate* value was 2.8 W/kg at 1.5T (2.3 W/kg at 3T) using a scan time of 15 minutes[2].

The ASTM F2182 standard addressing *RF-induced heating* does not establish acceptance criteria with regard to a worst case temperature. Smith & Nephew, Inc. is also unable to define an acceptable limit for *RF-induced heating* and cannot characterize the extent to which our passive implants may be affected. This is exacerbated by the fact that there is a lack of peer-reviewed literature on this subject, plus there is an absence of performance standards defining acceptable limits for *RF-induced heating*.

However, as a point of comparison, it has been reported that an average, peak exotherm temperature of 69°C was generated by plain *VersaBond Bone Cement* (with an average set time of 12 minutes) during the exothermic reaction that occurs as a result of the typical curing process for this Smith & Nephew, Inc. bone cement[3]. Thus, by comparison, a peak temperature of 4°C was observed during evaluation of the total hip prosthesis for *RF-induced heating*[2]. By comparison, this observation demonstrates a temperature rise that is less than 6% of that observed during the exothermic reaction that took place during the curing process[3].

Results from testing[1,2] identified *image artifacts*, which ranged from being relatively minor in relation to the shape and size of the actual passive implant device to those that were characterized as a concern if the MR imaging *area-of-interest* was located in or near the area where the implant was positioned. While image artifacts present no known risks to the patient or user their presence can compromise image quality.

Summary

It is also noted that there are several different manufacturers and generations of MRI systems currently in use. Smith & Nephew, Inc. is unable to define the *conditions* by which our passive implant devices

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[2] **OR-08-97**, *MRI Testing of the Synergy Hip Stem with Oxinium Femoral Head and Reflection Acetabular System*, July 2008.
[3] **OR-99-05**, *Evaluation of First Article VersaBond Bone Cement for the Exotherm Temperature, Dough Time, Set Time and Percent Porosity*, March 1999.

may be used safely in the MR environment. Therefore, Smith & Nephew, Inc. cannot make safety claims for passive implant devices or implant systems with any specific MR system.
However, to minimize the effects of *magnetic field interactions* and *RF-induced heating* as far as possible, Smith & Nephew, Inc. recommends the patient seek the advice of medical professionals prior to undergoing the MRI procedure. Care should be taken by medical professionals in determining the anatomic position of the patient's passive implant device. Depending on its position, it may be necessary to re-position the patient in a different manner within the MR static field. Smith & Nephew, Inc. also recommends that the MR technician *monitor* and *remain in close communication with the patient during the procedure.*

David Henley

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David Henley

Regulatory Affairs Project Manager
Smith & Nephew, Inc.
Advanced Surgical Devices Division

Date