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October 17, 2011

To whom it may concern:

In order to characterize the response of DePuy Spine implants to simulated hospital MRI conditions, worst case representatives for the following DePuy Spine product lines;

Product Brand	Material
Expedium™ Spine System	*Titanium*
Expedium™ SFX™ Cross Connector System	*Titanium*
Concorde™ Bullet Spinal System	*Carbon-fiber reinforced polymer PEEK Optima*

were assembled into typical constructs and tested under two power level modalities, 1.5 Tesla and 3.0 Tesla. Implants were tested within the bore of the MR system at locations determined to create the greatest MR effect for translational attraction, torque and heating. Per ASTM F2503-08, the implants are determined to be MR Conditional *(demonstrated to pose no known hazards in a specified MR environment with specified conditions of use)* at 1.5 and at 3.0 Tesla.

Typical implant constructs have been in-vitro tested and found to be safe at the following parameters; Static magnetic field of 3-Tesla or less, Maximum spatial gradient magnetic field of 720-Gauss/cm. MRI

DePuy Spine, Inc., 325 Paramount Drive, Raynham, MA, USA 02767-0350
(508) 880-8100 Fax: (508) 828-3797

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testing regimen of 15 min (i.e., per pulse sequence), SAR of 2.5W/kg or less in 1.5-Tesla (1.5T/64Mhz, Magnetom, Siemans Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS) and 3-Tesla (3T/128MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR systems or equivalent. MR image quality will be compromised in the vicinity of the implant, optimization of MR imaging parameters may be necessary to compensate for the presence of the implant, and some localized tissues will be obscured by the implant image artifact.

Sincerely,

J. Riley Hawkins
Principal Engineer
DePuy Spine, Inc.

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