Memo

To: Whomever It May Concern

Date: Tuesday, May 26, 2015

Re: MRI Exposure Labeling

Discussion:

Arthrex has validated its implantable products and tested their compatibility to MRI Exposure. The MRI validation was completed using Shellock R&D Services, Inc. in compliance with ASTM F 2052-06e1, Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment. The validation results summarized in Table 1 conclude compatibility within a magnetic resonance environment. Additional information regarding such testing may be referenced in the full reports. All materials tested have been deemed appropriate for MRI exposure of 3-Tesla or less with no adverse effects to the patient.

Results:

Table 1: Arthrex MRI Labeling Chart

Material	Device Used	MRI Labeling
Cobalt Chrome CoCr per ASTM F75	AR-503-PSLF iBalance Femoral Knee Implant	MR Conditional
Biocomposite PLLA/bTCP – AMS-0100-14	AR-5035TC 35MM Biocomposite Interference Screw	MR Safe
PEEK-Optima LT1 per ASTM F2026	AR-5035P-12 35MM PEEK Interference Screw	MR Safe
Bioabsorbable PLLA per AMS-0100-03/04	AR-1351LBT 3.0MM Bioabsorbable Transfix	MR Safe
316L – Stainless Steel Per ASTM F138	AR-8840C -55 55MM Low Profile Cannulated Screw	MR Conditional
Titanium 6AL-4VELI per ASTM F136	AR-8944CL-L Low Profile MTP Plate	MR Conditional
Titanium Alloy 6AL-4VELI per ASTM F136	AR-8967-18120 Low Profile Screw	MR Conditional
Ti6Al4V per ASTM F136, F620, and coating per F1580	AR-705-1500 Tapered Hip Stem	MR Conditional
Carbon Fiber PEEK with Tantalum Fibers, made from Endolign CFP	AR-14503R Distal Radius Plate	MR Conditional
Carbon Fiber PEEK with Tantalum Fibers, made from IcoTec CFP	AR-13401L HTO Plate	MR Conditional

For any questions or concerns please contact Arthrex Customer Service (800) 934-4404