Memo

To: File - Arthrex Inc

From: Beau Rollins, Sterilization Engineer

Date: Tuesday, October 30th, 2012

Re: MRI Exposure Labeling

Discussion: Arthrex Inc 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 are summarized in Table 1. All materials tested are deemed acceptable for MRI exposure of 3-Tesla or less.

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-4V ELI per ASTM F136	AR-8944CL-L Low Profile MTP Plate	MR Conditional
Titanium Alloy 6AL-4V ELI 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

10-30-12

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Sterilization Engineer