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MEMORANDUM

1023 Cherry Road
Memphis, TN 38117

Date: 12/22/2015

To: File

From: Dirk Scholvin

Re: Safety Information for Magnetic Resonance Imaging (MRI) Interactions with Wright Medical Technology Implants

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In patients requiring Magnetic Resonance Imaging as a diagnostic procedure, it is imperative that magnetic field interactions with any medical implants that the patient may have are well understood. Orthopedic implant materials can be placed in three categories:

a) Ferromagnetic materials such as martensitic steels are never safe to use in an MRI environment, due to extremely high attractive forces of the strong static magnetic field of the MRI.
b) Metallic materials that are paramagnetic such as austenitic steels can be subject to both weak magnetically induced forces as well as radio frequency (RF) induced heating. RF heating effects are dependent on both the implant design and its orientation relative to the MRI environment.
c) Non conducting materials such as most polymers and ceramics will not experience magnetically induced forces or RF heating. Implants consisting solely of these materials are safe to use in any MRI environment.

In addition to the above risks, medical implants may impact the imaging quality of the MRI at the site of the implant and in its direct vicinity. Dense materials such as metals are radiopaque. Typically, the resulting image artifacts do not extend past the implant-tissue interface.
Wright Medical manufactures orthopedic implants from titanium and titanium alloy (ASTM F67 and ASTM F136), cobalt chromium alloy (ASTM F75, ASTN F799 or ASTM F1537), stainless steels (ASTM F138, ASTM F139 and ASTM F2229) as well as several non-conductive polymers and ceramics. None of these materials are ferromagnetic and the non-conducting polymers and ceramics will experience neither magnetically induced forces nor magnetically induced heating. The metal alloys used in implants that Wright Medical manufactures are all paramagnetic and therefore are expected to experience no measurable or significant forces in either 1.5 or 3 Tesla MRI equipment. In a study conducted by Wright Medical on the Inbone® and Infinity® total ankle systems (including CoCr, titanium alloy and polyethylene components), implants were tested per ASTM F2052-6, ASTM F2119-7 and ASTM F2182-11a. No measurable forces acted on the implants[1] at either 1.5 or 3T. In the worst case configuration, a whole body averaged SAR of 2.9 W/kg led to a maximum local temperature rise of 5.3°C[1]. This amount of localized heating is considered minimal and at levels that pose no risk to the patient, which is consistent with the vast majority of orthopedic implants on the market today[2]. With the exception of external fixation devices, implants made from the materials that Wright Medical

uses are generally listed as safe or conditional for use in a 1.5 to3T MRI environment[2]. It is not impossible that a metallic implant of a certain geometry could cause temperature rises leading to discomfort or minor injury, but based on testing performed to date and case studies reported in the literature, it is highly unlikely.
In summary, all of the implants manufactured and marketed by Wright Medical are produced from either non-conductive materials or paramagnetic metals and do not present any risk of strong magnetic attraction in the MRI environment. The primary concern with metallic Wright Medical implants that have not been tested and approved for MRI safety labeling is localized heating. Based on published literature there is a relatively high risk of excessive heating in external fixation devices. It is unlikely but not impossible that other implants with a high aspect ratio (length to thickness) could lead to potentially harmful temperature rises if their long axis is oriented in parallel to the central axis of the MRI.

The statements made in this memo are applicable to all implants that Wright manufactures and distributes to date. Specific implants are listed in Appendix A.

1) Wright Medical internal document: "MRI Safety Evaluation of the Inbone® and Infinity® Total Ankle System"
2) Shellock, Frank G. "Reference Manual for Resonance Safety, Implants and Devices L: 2012 Edition", Page 568-582

12/23/15

Dirk Scholvin, Mgr, Materials Research

Appendix A – The statements made in this memo apply to all Wright implants. This includes the following:

- DART/FIRE® Small Screw System
- DARCO® BOW® Plate II
- DARCO® UPS Plate 2.7
- DARCO® MP™ Joint Fusion Plate
- DARCO® TOM Plate
- DARCO® Locking Screw 2.7
- DARCO® Standard Screw 2.7
- DARCO® LPS Plate
- DARCO® Plantar Lapidus Plate
- DARCO® PIA Plate
- DARCO® DPS Plate
- DARCO® AFP Plate
- DARCO® UPS Plate 3.5
- DARCO® RPS Plate
- DARCO® CPS Plate
- DARCO® Locking Screw 3.5
- DARCO® Standard Screw 3.5
- DARCO® Headless Compression Screw 7.0
- DARCO® Headless Compression Screw 4.3
- Washers
- CHARLOTTE® Compression Staple
- DARCO® Compression Screw 3.2
- CHARLOTTE® Snap-Off Screw
- CHARLOTTE® CLAW® Compression Plate 2.7
- CLAW® II Compression Plate 2-Hole
- CLAW® II Compression Plate 4-Hole
- CLAW® II Compression Plate 3-Hole T-Plate
- CLAW® II Compression Plate 4-Hole T-Plate
- CLAW® II Series
- CLAW® II U-Plate
- CLAW® II Screws