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Acumed Implants in the MR Environment

Table of Contents

Introduction

Magnetic Resonance Imaging (MRI) is one of many imaging modalities used by radiologists to diagnose and treat various conditions within the body. MRI is often favored for its detail and clarity when imaging soft tissues, and doing so without delivering the ionizing radiation inherent with X-ray and CT. Because of the strong, static magnetic field, and varying magnetic and electric fields during scanning, the safety of patients in the MR environment is of great importance to the healthcare professionals who perform these procedures.

Safety concerns arise when a patient has orthopaedic implants manufactured from metal or carbon fiber, or when external fixation devices are in place, because of the potential for movement or heating of the devices in the MR environment. In some cases, safety concerns may be greater due to the type, location, or configuration of the implant or the presence of multiple implants in close proximity to one another. Consequently, the use of MRI technology may not always be possible.

Purpose

This document will communicate MRI safety information regarding Acumed implants in the MR environment. While we cannot make specific MR claims for all of our implants at this time, Acumed will present the results of our testing in this document as additional information becomes available. When allowed by regulatory authorities, Acumed will use one of the internationally recognized ASTM symbols in our implant labeling.

Implant Materials

Acumed implants are commonly manufactured from commercial pure (CP) titanium (Ti) and titanium alloys, such as Ti-6Al-4V ELI. A recent FDA article[1] states:

"...[Test} results indicate that for alloys Ti-6Al-7Nb, CP titanium Grades 1 through 4, Ti-6Al-4V ELI, Ti-15Mo, Biodur 108, and Co-28Cr-6Mo ..., magnetically induced force is less than the device weight in any current clinical 1.5, 3.0, and 7.0-T MR system."

Accordingly, many Acumed devices do not pose significant risk for magnetically induced force or torque. Refer to the device label and Instructions for Use to determine the implant material.

Terminology

ASTM International is an international standards organization that has published the following voluntary consensus standards for the testing and labeling of devices that may be used in MRI:

- F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants
- F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
- F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

ASTM F2503 defines the three classifications for products used in MRI as MR Safe, MR Conditional, and MR Unsafe. Products in these classifications may be labeled with the following symbols:

MR Safe

MR Safe is an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic. The MR Safe icon consists of the letters “MR” surrounded by a green square.

MR Conditional

MR Conditional is an item with demonstrated safety in the MR environment within defined conditions. At minimum, the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields must be disclosed. Additional conditions may be required. The MR Conditional icon consists of the letters “MR” within a yellow equilateral triangle with a thick black band around the perimeter.

MR Unsafe

MR Unsafe is an item that poses unacceptable risks to the patient, medical staff, or other persons within the MR environment. The MR Unsafe marking consists of the letters “MR” surrounded by a red circle with a diagonal red bar across the letters extending from the upper left quadrant to the lower right quadrant of the circle and oriented at 45° from the horizontal.

The symbols may appear in black and white when not practical to print in the standard colors.

Warnings & Precautions

Unless explicitly stated in this document, Acumed devices have not been tested for heating, migration, or image artifact in the magnetic resonance (MR) environment and the safety of these devices in the MR environment is unknown. Scanning a patient with untested implants may result in patient injury.

Patients with implants should seek a medical opinion before entering the MR environment.

For Devices That Have Been Tested

Warning

- Failure to follow the specific MR conditions may result in injury to the patient.
- Unconscious patients or those insensitive to heat or pain may not inform the technologist that the implant is being affected by the MR environment.
- Long scanning time or higher specific absorption rate (SAR) increases the risk of heating. Pause the scan periodically and solicit feedback from the patient.
- Unknown and untested implant configurations or the addition of implants from other manufacturers may increase the risks of heating and image artifact.

Caution

- Local transmit coils are not recommended for use on the area with implants as their effects have not been tested.
- Maximize the distance from the implant to the image area to minimize any potential artifact, when possible.
- Maximize the distance between the implant and sides of the bore, coils, and conductors to minimize the risk of heating, when possible.
- The implants have not been assessed for compatibility with MRI systems above 3 Tesla.

Important

- An increase in ventilation through the bore may help to lessen the increase in body temperature during scanning and reduce the effects of implant heating.
- Nonclinical testing does not account for the variations in MRI systems, pulse sequences, multi-channel RF coils, and local transmit coils that might be used. Some MRI systems have image artifact reduction sequences if imaging near a device is necessary.
- The use of low field MRI systems (less than 1 T) can mitigate risks for patients with implants by lowering the frequency and SAR.

IFU and Surgical Technique

Acumed offers Instructions for Use (IFU) and Surgical Techniques to promote the safe and effective use of our systems. Visit **www.acumed.net** for the most current versions.

Important: IFUs and Surgical Techniques may contain important safety information. They are intended for the Operating Surgeon and supporting Healthcare Professionals.

Anatomic Radial Head System, Anatomic Radial Head Solutions, Anatomic Radial Head Solutions 2

Implants that have been tested

TR-HXXXL-S	Head, Left, 20, 22, 24, 26, and 28 mm
TR-HXXXR-S	Head, Right 20, 22, 24, 26, and 28 mm
5001-02XXL-S	ARH Solutions Head, Left, 20, 22, 24, 26, and 28 mm
5001-02XXR-S	ARH Solutions Head, Right 20, 22, 24, 26, and 28 mm
5001-05XXL-S	ARH Solutions 2 Head, Left, 18, 20, 22, 24, 26, and 28 mm
5001-05XXR-S	ARH Solutions 2 Head, Right, 18, 20, 22, 24, 26, and 28 mm
TR-SXX0X-S	Stems, 6mm to 12 mm diameter by 1 mm increments 0 mm to 8.0 mm collar height by 2 mm increments
50-0XXX-S	ARH Partial Grit Blast Stems, 6 mm to 12 mm diameter by 1 mm increments 0 mm to 8.0 mm collar height by 2 mm increments
TR-SLXX-S	Morse Taper Long Stem, 6 mm to 12 mm diameter range by 1 mm increments

Conditions for safe scanning in the MRI

A patient with the head and stem implants of the Anatomic Radial Head System, Anatomic Radial Head Solutions, and Anatomic Radial Head Solutions 2 may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Nominal value(s) of Static Magnetic Field	3.0 T
Maximum Spatial Field Gradient	19 T/m (1900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coilHead RF transmit-receive coil
Maximum Whole-Body SAR at 1.5 T and 3.0 T	2.0 W/kg
Limits on Scan Duration 1.5 T	2.0 W/kg whole-body average SAR for fifteen (15) minutes of continuous RF (a sequence or back to back series/scan without breaks)
Limits on Scan Duration 3.0 T	2.0 W/kg whole-body average SAR for twelve (12) minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 71 mm

If information about a specific parameter is not included, there are no conditions associated with that parameter.

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Reference

1. Woods T, Delfino J, Rajan S. Assessment of magnetically induced displacement force and torque on metal alloys used in medical devices. *J Test Eval 49.* Published online July 3, 2019. https://doi.org/10.1520/JTE20190096.