Guidance for Industry and FDA Staff

Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

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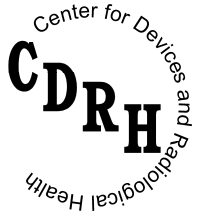

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Solid and Fluid Mechanics
Office of Science & Engineering Laboratories

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance addresses testing and labeling of passive implants for safety and compatibility in the magnetic resonance (MR) environment. In preparing a premarket approval application (PMA), Investigational Device Exemption (IDE), and premarket notification (510(k)) submission, this guidance document applies to MR devices that serve their function without the supply of electronic power. Active implants or devices that are not implants do not fall within the scope of this guidance. The information in this guidance supplements the Agency's related publications on PMA's, IDE's, and 510(k)s and is not intended to describe or substitute the information otherwise required in the following premarket submissions:

- **Premarket Approval Application (PMA) Information**

For general information about PMA applications, refer to 21 CFR 814 or "**Application Methods**," at http://www.fda.gov/cdrh/devadvice/pma/app_methods.html.

- **Investigational Device Exemption (IDE) Information**

For general IDE information, refer to 21 CFR Part 812 or to the "**Introduction IDE Overview**," at http://www.fda.gov/cdrh/devadvice/ide/index.shtml.

- **Premarket Notification (510(k)) Information**

For general information on 510(k), refer to 21 CFR 807.87, the guidance entitled "**Format for Traditional and Abbreviated 510(k)s**" and "**Premarket Notification 510(k)**" in the (Center for Devices and Radiological Health) **CDRH Device Advice** at http://www.fda.gov/cdrh/devadvice/314.html.

A manufacturer who intends to market a passive implant must conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the act).

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. MR Testing

The main issues affecting the safety and compatibility of passive implants in the MR environment concern magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts. The MR static field induces displacement forces and torques on magnetic materials. Patients have been killed by the projectile effect on devices and by the rotations produced by magnetically induced force and torque.[1] RF heating in the body is created by currents induced by the RF excitation pulses applied during MR scanning. Patients have been severely burned as a result during an MR scan.[2] The presence of an implant may produce an image artifact that may appear as a void region or as a geometric distortion of the true image. If the image artifact is near the area of interest, the artifact may make the MR scan uninformative or may lead to an inaccurate clinical diagnosis, potentially resulting in inappropriate medical action.

We recommend that you provide the nonclinical testing described below in your PMA, IDE or 510(k) to establish the safety and compatibility of your passive implant in the MR environment. Testing should encompass the range of sizes of the device you intend to market. If you do not test all sizes of the device you intend to market, we recommend you test a size or combination of sizes that represent the worst-case scenario for each test.

We recommend you explain the rationale for determining why the size(s) you selected represent the worst-case scenario for each test.

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[1] Woods, T.O. "MRI Safety" in Wiley Encyclopedia of Biomedical Engineering (Metin Akay, ed.) Hoboken: John Wiley & Sons, Inc., 2006, pp. 2360-2371.
[2] Ibid.

We suggest you present data in a clear tabular or graphical form. We also recommend you describe all testing protocols. Each protocol description should include:

- test objective
- equipment used
- acceptance criteria
- rationale for test conditions
- rationale for the acceptance criteria
- number of devices tested
- description of devices tested, including device size
- description of any differences between test sample and final product, and justification for why differences would not impact the applicability of the test to the final product
- results (summarized and raw form).

Terminology

Terminology for defining the safety of items in the MR environment is provided in ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. We recognize implementing new terminology may be challenging, but FDA believes this new terminology will help reduce the possibility of injuries involving passive implants related to MRI (Magnetic Resonance Imaging). We recommend using the terminology MR Safe, MR Conditional, and MR Unsafe, defined in ASTM F2503. If you label your device as "MR Safe," your submission should include a scientific rationale or the testing described below. If you label your device as "MR Conditional," your submission should include the testing described below. If you label your device as "MR Unsafe," your submission should include a scientific rationale or the testing described below.

MR Safe based on scientific rationale

A scientifically based rationale rather than test data may be sufficient to support identifying an implant as "MR Safe," for example, a nonconducting or a nonmagnetic item, such as a plastic Petri dish, poses no known hazards in all MR environments.

If you intend to use a scientific rationale to support identifying your device as "MR Safe," we recommend that you provide a scientific rationale that addresses the following issues.

- magnetically induced displacement force
- magnetically induced torque
- heating of your device by RF (radio frequency) fields.

MR Unsafe based on scientific rationale

A scientifically based rationale rather than test data, may be sufficient to support identifying an item as "MR Unsafe."

If you intend to use a scientific rationale to support identifying your device as "MR Unsafe," we recommend that you provide a scientific rationale to address:

- magnetically induced displacement force
- magnetically induced torque
- heating of your device by RF (radio frequency) fields.

MR Conditional, MR Safe, or MR Unsafe based on experimental data

If you identify your device as "MR Conditional," we recommend you provide experimental data as described below. You may also choose to provide experimental data to support identifying your device as "MR Safe" or "MR Unsafe." In each case, we recommend you follow the methods described in the standards below or equivalent methods.

- Magnetically Induced Displacement Force

  ASTM F2052, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

- Magnetically Induced Torque

  ASTM F2213, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

- Heating by RF Fields

  ASTM F2182, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

- Image Artifact

  ASTM F2119, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Although commercial 1.5T MR systems are currently the most common, 3T MR systems are becoming more common. A medical device that is MR Safe or MR Conditional in a 1.5T scanner may not be MR Safe or MR Conditional in an MR system with a higher or lower field strength. The amount of RF heating can vary depending on the system geometry, MR system and scan conditions, and the conductive length of the device. The critical length for a specific device during a particular MR scan cannot be calculated precisely, so we recommend you evaluate a range of lengths and conditions to determine the worst case conditions for RF induced heating. To achieve worst-case heating conditions in the phantom, you should pay attention to the local electric and magnetic field distribution near the implant inside the phantom. These fields need to be similar to the local electric and magnetic field distribution near the implant inside the patient so the heating of the implant in the phantom is comparable to the heating inside the patient. Anatomical positioning of the implant in the phantom does not reliably predict the implant heating in the patient. Therefore, we recommend you describe the field conditions and system geometry under which you tested your device and demonstrate that your test conditions are comparable to worst-case clinical conditions. Accurate assessment of the whole body averaged specific absorption rate (WB-SAR) used in your testing is critical to determining whether your testing represents reasonable worst-case heating conditions. Therefore, we recommend that you base WB-SAR assessments upon calorimetry measurements

rather than relying on the MR scanner display, which may not have adequate accuracy. See also **4. Labeling for the MR Environment**.

3. Labeling for the MR Environment

General labeling requirements for medical devices are described in 21 CFR Part 801. See CDRH **Device Advice** (http://www.fda.gov/cdrh/devadvice/33.html) for additional information. In accordance with 21 CFR 814.20(b)(10), you must submit all proposed labeling in a PMA. A 510(k) must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). An IDE must include labeling to satisfy the requirements of 21 CFR 812.5. The following suggestions may assist you in preparing labeling that satisfies the requirements of 21 CFR Part 801[3].

MR Labeling

We recommend you consider using the MR terminology in ASTM F2503, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. See **Section 3. MR Testing** for information describing the process to determine the appropriate MR safety term for your device.

MR Safe

The following statement may be used in your labeling for a MR Safe device:

> The (*insert device name)* is MR Safe.

MR Unsafe

The following statement may be used in your labeling for an MR Unsafe device:

The *(insert device name)* is MR Unsafe.

Labeling for an MR Unsafe implant should recommend that patients register their implant information with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

[3] Although final labeling is not required for 510(k) clearance, labeling is reviewed in a 510(k) and the final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

MR Conditional

Labeling for MR Conditional devices should indicate the device was tested under non-clinical conditions and list the conditions under which the device can be safely scanned, for example:

Non-clinical testing has demonstrated the *(insert device name)* is MR Conditional. It can be scanned safely under the following conditions:

- static magnetic field of ___ Tesla
- spatial gradient field of ___ Gauss/cm
- maximum whole body averaged specific absorption rate (SAR) of __W/kg for __ minutes of scanning.

In non-clinical testing, the *(insert device name)* produced a temperature rise of less than __°C at a maximum whole body averaged specific absorption rate (SAR) of ___ W/kg, as assessed by calorimetry for ___ minutes of MR scanning in a *(field strength _____)* (*model _____) (manufacturer _____) (software version _____)* MR scanner.

Image Artifact – General

We also recommend your labeling indicate the amount of image artifact and that you acquire MR images using standard sequences (e.g., as described in ASTM F2119) or an equivalent method. We recommend your labeling indicate the extent of the artifact for one or more of the sequences used in your testing. The labeling should also include information about the shape and extent of the artifact. For devices with a lumen, the labeling should indicate whether the lumen is obscured by the artifact. A dimensioned figure showing the implant in its typical implant site and the extent of the artifact in at least one plane may be included. It may be helpful to provide a separate dimensioned drawing of the implant and a figure showing the typical implant site.

Image Artifact – Special Examples

Devices with Slight (1-2mm) Artifact

The following statement may be used for a device with an image artifact that extends only slightly (1-2 mm) beyond the device:

> MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

Devices with a Lumen

For devices with a lumen, we recommend you specify whether the lumen is obscured by the artifact, for example:

The image artifact extends approximately __ mm from the device, both inside and outside the device lumen when scanned in nonclinical testing using the sequence: _____ in a (Field Strength) (Model)(Manufacturer)(software version) MR system with _____ coil.

We also recommend that the device labeling for an MR Conditional implant recommend that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.