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

---

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 11, 2014.

This document supersedes Establishing Safety and Compatibility of Passive Implants in Magnetic Resonance (MR) Environment, August 21, 2008.

For questions about this document, contact Terry O. Woods, Ph.D. at 301-796-2503 or by email at terry.woods@fda.hhs.gov, or the Office of Science & Engineering Laboratories at 301-796-2530.

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

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

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments 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.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number (1685) to identify the guidance you are requesting.

Table of Contents

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

---

Guidance for Industry and Food and Drug Administration Staff

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.

I. 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 passive implants, i.e., implanted 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.

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 guidance means that something is suggested or recommended, but not required.

II. 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 static magnetic field of the MR system 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 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 non-clinical testing (see Section III.C) and appropriate MR safety labeling (see Section IV) 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. Please note that the worst-case for magnetically induced force and torque may not be the worst-case for RF heating.

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).

[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.

III. MR Safety Terminology

Terminology for defining the safety of items in the MR environment is provided in ASTM F2503-13, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment." We recommend using the terminology MR Safe, MR Conditional, and MR Unsafe, defined in ASTM F2503-13. 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.

A. 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, an electrically nonconductive or a nonmagnetic item, such as a small polymer screw, 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
- RF-induced heating of tissue around your device.

B. 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
- RF-induced heating of tissue around your device.

C. 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 non-clinical testing methods described in the standards below or equivalent methods.

- Magnetically Induced Displacement Force
  ASTM F2052-14, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

- Magnetically Induced Torque
  ASTM F2213-06 (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

- Heating by RF Fields
  ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

- Image Artifact
  ASTM F2119-07 (Reapproved 2013), 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 Conditional in a 1.5T scanner may not be safe to scan in an MR system with a higher or lower field strength. The amount of RF heating depends on the geometry of the device (e.g., the conductive length) as well as the characteristics of the MR system and the selected scan conditions. To achieve worst-case heating conditions in the phantom, you should place the implant in the phantom at the area of worst case local specific absorption rate (SAR). This local SAR should be quantified and compared to the maximum local SAR that can be achieved in a patient undergoing an MRI scan. You should report the field conditions under which your device was tested. Anatomical positioning of the implant in the phantom does not reliably predict RF-induced heating in the patient.

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.

Note that the current recognized versions of standards referenced in this guidance can be found in the CDRH Recognized Consensus Standards database[3].

IV. Labeling for the MR Environment

We recommend you consider using the MR terminology in ASTM F2503-13, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. See **Section II. MR Testing** for information describing the process to determine the appropriate MR safety terminology for your device. Your device labeling should include MR safety labeling using one of the following four options:

A. MR Safe

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

> The <*device name*> is MR Safe.

B. MR Unsafe

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

> The <*device name*> is MR Unsafe.

C. MR Conditional

Labeling for MR Conditional devices should be included in a section headed "MRI Safety Information" that is included in the table of contents. The labeling should indicate the device was tested under non-clinical conditions and list the conditions under which the device can be safely scanned, for example:

MRI Safety Information

Non-clinical testing has demonstrated the <*device name*> is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of <*specific field strength(s)*> T

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

- Maximum spatial field gradient of *<maximum for which device is safe>* gauss/cm (*<maximum for which device is safe>*T/m)

- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of *<2 W/kg (Normal Operating Mode)>* or *<4 W/kg (First Level Controlled Operating Mode)>*

- *<Any additional instructions or information essential to safe use in the MR environment that can be described briefly.* Additional instructions may include positional requirements (e.g. device must remain outside the scanner bore) or restrictions on coil type (e.g. head transmit/receive coil only; quadrature body coil only). If this information can be kept brief, place here. For more complicated instructions or information, list the additional conditions below the image artifact information as shown in the examples indicated by * below.>

Under the scan conditions defined above, the *<device name>* is expected to produce a maximum temperature rise of less than *<specific value>*ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately *<specific value>* mm from the *<device name>* when imaged with a *<gradient echo* or *spin echo>* pulse sequence and a *<specific field strength)>* T MRI system.

Additional instructions or information essential to safe use in the MR environment that require more than a few words to describe should be placed here.
*For example: Provide a paragraph giving any positional requirements.
*For example: Provide a paragraph giving any restrictions on coil type.

Example for a device called “star implant”

MRI Safety Information

Non-clinical testing has demonstrated the star implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T

- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)

- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the star implant is expected to produce a maximum temperature rise of less than 2º C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 2 mm from the star implant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

D. Safety in MRI Not Evaluated

For devices that have historically not provided any information about MRI safety, the following labeling may be used in certain circumstances. If used, this information should be included in a section headed "MRI Safety Information" that is included in the table of contents. We recommend you provide a rationale as to why this labeling is appropriate for your device.

> The <*device name*> has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of <*device name*> in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The above labeling option is NOT appropriate if:

- there are any known adverse effects or adverse events due to exposure to the MR environment for the device or device type, or
- the device or device type has typically been labeled as MR Conditional or MR Unsafe (for example, including but not limited to cardiovascular stents, intracranial aneurysm clips, endovascular grafts, and transprostatic tissue retractors), or
- this is a new device type, or
- the device contains ferromagnetic materials.

If you are uncertain whether your device can be labeled "Safety in MRI Not Evaluated", we recommend that you submit a pre-submission to obtain feedback prior to submission of a regulatory submission.