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MRI COMPATIBILITY / SAFETY STATEMENT

This is to confirm, that below listed prosthesis are compatible with MRI use with magnetic field power up to 3 Tesla following the definition given in the 1997 FDA draft guidance document and used in ASTM F2502-02, F2213-02 and ASTM F 2182-02

Name	Material
TIFLEX staple	Titanium

Note ASTM introduced new terminology to better define the status of devices in 2008 (ASTM F 2503-08). This terminology has also been adopted by CEN in ISO 14630. The compatible category is replaced by a conditional category. This does not change the actual safety of the device. The rationale for this change is given in the appendix of ASTM F 2503-08 attached.

Thierry SOUILLAT
Product Development

Date : 4th May, 2010
Signature

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The intent of this practice is to provide needed information about the safety of items in and near MR scanners using a compact and easily recognized set of symbols and terms. The terms MR safe and MR compatible as first defined in 1997 in the FDA draft guidance document, "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems," have been used to describe the safety of devices in and near MR systems. The historical definitions are:

MR Safe	The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device that is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.
MR Compatible	The device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device that is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

However, there has been a great deal of confusion surrounding this terminology. An incorrect assumption is often made. Users often *incorrectly* assume that items labeled MR safe or MR compatible are safe or compatible for *any* MR environment. MR environments vary in terms of magnetic field strength and RF conditions. Therefore, an item tested under one set of conditions may be affected differently by the conditions in another MR environment. In addition, some devices labeled MR safe and MR compatible using the historical definitions in X1.1 have gauss line restrictions or RF pulse sequence limitations that must be adhered to in order to safely use the device in the MR environment. In short, it is impossible to definitively certify a device as MR safe or MR compatible without also specifying the conditions under which the device was tested.

X1.2 The newly proposed terms in this practice (MR Safe, MR Unsafe, and MR Conditional) are intended to clear up this confusion. The term MR Safe is redefined in this document. Under the new definition given in 3.1.10 of this practice, an item that is MR Safe poses no known hazards in any MR environment, meaning that it can be taken into and used in any MR environment without risk. An item that is MR Unsafe is known to pose hazards in all MR environments and therefore should not be allowed in any MR environment. An item that is MR Conditional has been shown to pose no hazards in a specific MR environment under the listed conditions. The MR Conditional marking is meant to emphasize to the user that there are limits on the testing that has been performed on a given item and that the marked field conditions should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. Because the term MR compatible has proved to be confusing, it is no longer supported or recommended, and the new terms MR Safe, MR Conditional, and MR Unsafe should be used as defined in this practice.

NOTE X1.1—This revised terminology has not yet been applied to all medical devices tested before the approval of Practice F 2503. Therefore, there are items that still contain the prior terminology (that is, use the old terms MR Safe and MR Compatible) in their labeling.

X1.3 Although a commercial 1.5 T MR system currently produces the conditions that are most commonly encountered, 3 T MR systems have been cleared for market and are becoming more common in clinical situations. It is important to note that an item that can be marked MR Conditional in a 1.5 T scanner may not be safe in systems with higher or lower field strength. Also, there can be major differences in the characteristics of open and cylindrical MR systems. For instance, the static field spatial gradients may be significantly higher in open systems.

X1.3.1 A brief list of potential risks and hazards that have been observed include:

(1) Magnetically induced force that acts to pull magnetic items into the bore of the MR system.

(2) Magnetically induced torque that rotates magnetic objects to align them with the MR system magnetic field (as a compass needle is aligned with the Earth's magnetic field.)

(3) Radiofrequency induced heating of objects inside the MRI bore.

(4) Device or item activation, deactivation, or damage caused by the MR system's magnetic or radiofrequency fields.

(5) False information presented on an electrically active device caused by the MR system's magnetic or radiofrequency fields.

(6) Patient nerve stimulation.

Other risks exist, and a review of the available clinical literature is recommended in determining the appropriate MR Safety marking for the device or item.

X1.4 *Recommendations for Devices and Items that can be Marked for MR Environment Use*:

X1.4.1 In general practice, items that are placed within the MR environment should be carefully evaluated prior to their placement or use within the area. The American College of Radiology recommends in its White Paper on MR Safety[3] that all portable metallic or partially metallic devices that are on or external to the patient are to be positively identified in writing as non-ferromagnetic or ferromagnetic prior to permitting them into the MR environment. Examples of such devices and items

[3] Kanal, E., Borgstede, J. P., Barkovich, A. J., et al, "American College of Radiology White Paper on MR Safety: 2004 Update and Revisions," *Am. J Roentgenol.*, 182, May 2004, pp. 1111–1114.

include fire extinguishers, oxygen tanks, intravascular guide wires, wrenches and other tools, and so forth. As a general rule the following guidelines can be used to determine which items should be marked for safety before entry into the MR environment:

(1) Any electrically operated (either AC powered or battery operated) items placed within the MR environment. These types of items generally contain magnetic materials and should be evaluated and marked accordingly.

(2) Any item or device that is known to contain metallic components or sub-components that may contain magnetic or electrically conductive materials. Be aware that some items may contain metallic components that are not obvious (for example, sandbags, pillows, batteries, certain items of clothing, and so forth). Also be aware that some non-metallic materials (for example, some carbon fiber composites) are conductive and could pose an RF heating hazard.

(3) ALL items that are intended to be placed within the MR imaging unit bore.

X1.4.2 Some items present no additional risk within the MR environment, such as most glass items, most plastics, and most wooden items (without any metallic nails or screws, or both), and may be able to be used without an MR Safe mark. However, critical judgment should be used before permitting any uncertain items into the MR environment. These items should be as carefully safety-screened for non-compatible materials as are your patients.

X1.4.3 In general, if potential injury or even delay in scanning can be avoided by having a particular device or item marked as described in this practice, marking is to be considered advisable.

X1.5 *Image Artifact*:

X1.5.1 Image artifact is not considered to be a safety issue and so is excluded in the scope of this practice. In order to provide additional information to clinicians to help them to make a decision about the appropriateness of a given MR scan for a patient with an implant or other item that is placed in the bore of the scanner during the scan (for example, an external brace or splint), a statement about image artifact produced by the item should be included in the product labeling. For devices that require patient information cards, the statement about image artifact should be included on the patient identification card. Test Method F 2119 provides a method for evaluating image artifact for passive medical implants. Other methods may be needed to assess the image artifact from other devices or items.

X1.6 The standard was revised in 2008 to include the supplementary sign for MR Conditional items.