Safety Information

The information on this page is limited by the terms of our disclaimer. Please Read!

Coils, Filters, and Stents

Various types of intravascular and other types of coils, stents, and filters have been evaluated for safety with MR systems. Several of these demonstrated magnetic field interactions in association with scanners. Fortunately, the devices that exhibit positive magnetic field interactions typically become incorporated securely into the vessel wall primarily due to tissue ingrowth within approximately six to eight weeks after implantation. Therefore, it is unlikely that any of these implants would become moved or dislodged as a result of exposure to static magnetic fields of MR systems operating at 1.5-Tesla or less.

Other similar devices made from nonferromagnetic materials, such as the LGM IVC filter (Vena Tech) used for caval interruption or the Wallstent biliary endoprosthesis [Schneider (USA), Inc.] used for treatment of biliary obstruction, are considered to be safe for patients undergoing MR procedures. Notably, it is unnecessary to wait any period of time after surgery to perform an MR procedure in a patient with a metallic implant that is made from a nonferromagnetic material (see Guidelines for the Management of the Post-Operative Patient Referred for a Magnetic Resonance Procedure). In fact, there are various published reports in the peer-reviewed literature that describe placement of vascular stents using MR-guidance, even with high-field-strength (1.5-Tesla) MR systems.

The Guglielmi detachable coil (GDC) used for endovascular embolization, was evaluated for MR-safety. Importantly, because of the coiled-shape of the GDC, potential heating during MR imaging was suspected. Therefore, a study was performed using ex vivo testing techniques to determine the MR-safety of the Guglielmi detachable coil with respect to magnetic field interactions, heating, and artifacts. The results indicated that there were no magnetic field interactions, the temperature increase was minimal during extreme MR imaging conditions, and the artifacts involved a mild signal void relative to the size and shape of the GDC. Subsequently, more than 100 patients with GDCs underwent MR imaging without incident. Other embolization coils made from Nitinol, platinum, or platinum and iridium have been evaluated and found to be safe for patients undergoing MR procedures.

Patients with the specific coils, stents, and filters indicated in The List have had procedures using MR systems operating at static magnetic field strengths of 1.5-Tesla or less without reported injuries or other problems. Nevertheless, an MR procedure should not be performed if there is any possibility that the coil, stent, or filter is not positioned properly or firmly in place. Additionally, it should be duly noted that not all stents are safe for patients undergoing MR procedures, particularly since, to date, not all stents have undergone MR safety testing (see information for Zenith AAA Endovascular Graft below).

A study by Taal et al. supports the fact that not all stents are safe for patients undergoing MR procedures. This investigation was performed to evaluate potential problems for four different types of stents: the Ultraflex (titanium alloy), the covered Wallstent (Nitinol), the Gianturco stent (Cook), and the modified Gianturco stent (Song) - the last two being made of stainless steel.
Taal et al. reported "an appreciable attraction force and torque" found for both types of Gianturco stents. In particular, "the Gianturco (Cook) stent pulled toward the head with a force of 7 g...however, it is uncertain whether this is a potential risk for dislodgment." In consideration of these results the investigators advised, "...specific information on the type of stent is necessary before a magnetic resonance imaging examination is planned."

Zenith AAA Endovascular Graft
The MR safety and compatibility of the Zenith AAA Endovascular Graft (Cook Incorporated, Bloomington, IN) has been evaluated through bench testing in MRI systems with static fields of ≤ 1.5 Tesla, gradient magnetic fields of ≤ 20 Tesla/second and whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of imaging. The Zenith AAA Endovascular Graft was found to exhibit significant deflection and torque of the stainless steel metallic component of the endovascular graft and therefore did not meet standard 'MR Safe' bench test criteria.

Adverse events have not been reported clinically in patients who have undergone MRI. However, sufficient data are not available to demonstrate MRI safety and there may be potential risks (e.g., device migration, vessel damage) that could be associated with forces applied to the metallic components of the Zenith AAA Endovascular Graft. Therefore, a careful assessment of these potential risks and the potential benefits to the patient should be completed prior to use of MR imaging. In addition, the facility for MRI should be appropriately selected to allow for prompt intervention if necessary.

The Zenith AAA Endovascular Graft may affect image quality (image artifact) depending on the pulse sequence that is used for MR imaging.

Recently, Hiramoto et al. conducted a study to assess the effects of MRI on stainless-steel Z-stent-based abdominal aortic prostheses. Twenty-two patients underwent 1.5-Tesla MRI for various applications including brain, neck, abdomen, pelvis, and spine. No patient experienced any symptoms of abdominal or back pain during or after the MRI. Comparison of the pre- and post-MRI computed tomography scans (available in 15 of 17 patients) and abdominal radiographs showed no change in stent-graft structure, position, or function in any of these patients and no increase in abdominal aortic aneurysm diameter in any patient at an average of 899 days after MRI. Therefore, the authors concluded, MRI has no discernible effect on the structure, position, or function of stainless-steel Z-stent-based abdominal aortic prostheses. This information should be considered relative to the use of MRI in a patient with the Zenith AAA Endovascular Stent Graft.

MR Safety at 3-Tesla and Coils, Stents, and Filters
Several different coils, stents, and filters have been evaluated at 3-Tesla. Of these implants, two displayed magnetic field interactions that exceeded the ASTM guideline for MR safety (i.e., the deflection angles were greater than 45 degrees). However, similar to other coils, stents, and filters tissue ingrowth may be sufficient to prevent these implants from posing a substantial risk to a patient or individual in the 3-Tesla MR environment. Thus, these issues warrant further study.

MR Safety at 3-Tesla and Coronary Artery Stents
Patients with coronary artery disease are often treated by percutaneous transluminal coronary angioplasty (PTCA). Re-narrowing at the angioplasty site, or restenosis, occurs in as many as 50% of patients following PTCA. Therefore, after coronary artery intervention, either a bare metal or drug eluting stent is placed in an effort to prevent restenosis. There is considerable attention focused on the use of drug eluting stents to prevent coronary artery restenosis that tends to occur in a substantial number of patients following stenting with “bare” devices. Studies have reported that drug eluting stents reduce the incidence of target vessel failure compared to uncoated metallic stents. As such, drug eluting stents are now used on a widespread basis (upwards of 80%) in patients with coronary artery disease.
Recently, MR safety information has been obtained for several bare wire and drug eluting coronary stents, which have been reported to be safe for patients undergoing MR procedures at 3-Tesla or less (i.e., based on assessments of magnetic field interactions and MRI-related heating). These coronary artery stents include, the following:

**Endeavor Drug Eluting Coronary Artery Stent (Medtronic Vascular) -**
Through non-clinical testing, the Endeavor stent has been shown to be MRI safe at field strengths of 3 Tesla or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MRI. The Endeavor stent should not migrate in this MRI environment. MRI at 3-T or less may be performed immediately following the implantation of the Endeavor stent. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3-Tesla.

In this testing, the stent produced a maximum temperature rise of 0.5 degrees C at a maximum whole body averaged SAR of 2.0 W/kg for 15 minutes of MRI.

MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

**TAXUS Express Paclitaxel-Eluting Coronary Stent (Boston Scientific Corporation) -**
Through non-clinical testing, the TAXUS Express stent has been shown to be MRI safe at field strengths of 3 Tesla or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MRI. The TAXUS Express stent should not migrate in this MRI environment. MRI at 3-T or less may be performed immediately following the implantation of the TAXUS Express stent. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3-Tesla.

In this testing, the stent produced a maximum temperature rise of 0.65 degrees C at a maximum whole body averaged SAR of 2.0 W/kg for 15 minutes of MRI. The effect of heating in the MRI environment was similar for overlapping bare metal stents (2 to 5-mm overlap at the ends), made of the same stainless steel material and having the same stent design. The effect of heating in the MRI environment on stents with fractured struts is not known. The temperature rise of 0.65 degrees C for 15 minutes is calculated to result in an increase in cumulative drug release of 0.001% of the total dose.

MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

**Liberté Coronary Artery Stent (bare metal coronary artery stent, Boston Scientific Corporation) -**
The Liberté Stent has been shown to be MR safe at field strengths of 3 Tesla (T) or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging. The Liberté Stent should not migrate in this MR environment. MR imaging at 3-T or less may be performed immediately following the implantation of the Liberté Stent.

In this testing, the stent experienced a maximum temperature rise of 0.65 degrees C at a maximum whole body averaged SAR of 2 W/kg for 15 minutes of MR imaging. The temperature rise was observed to be similar for comparable bare metal overlapping stents (2 to 5-mm overlap at the ends). Heating has not been determined for fractured struts.

MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

This stent has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 3 T.

**TAXUS Liberté Paclitaxel-Eluting Coronary Stent (Boston Scientific Corporation) -**
Through non-clinical testing, the TAXUS Liberté stent has been
shown to be MRI safe at field strengths of 3 Tesla or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MRI. The TAXUS Liberté stent should not migrate in this MRI environment. MRI at 3T or less may be performed immediately following the implantation of the TAXUS Liberté stent. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3 Tesla.

In this testing, the stent produced a maximum temperature rise of 0.65 degrees C at a maximum whole body averaged SAR of 2.0 W/kg for 15 minutes of MRI. The effect of heating in the MRI environment was similar for overlapping bare metal stents (2 to 5-mm overlap at the ends), made of the same stainless steel material and having the same stent design. The effect of heating in the MRI environment on stents with fractured struts is not known. The temperature rise of 0.65 degrees C for 15 minutes is calculated to result in an increase in cumulative drug release of 0.001% of the total dose.

MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

(Note: “TAXUS” is the trademark name on the drug coating, and refers to the drug eluting coating addition to the bare metal stent. As such, when there is the addition of the drug eluting coating, it will be referred to as the TAXUS and then the specific name of the stent. For example, TAXUS Express stent. The bare metal stent does not contain the TAXUS prefix.)

**CYPHER Sirolimus-eluting Coronary Stent (Cordis Corporation/Johnson and Johnson)** - Through non-clinical testing, single and two overlapping CYPHER Stents have been shown to be MRI safe at field strengths of 3 Tesla or less, and a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of MRI. Single and two overlapping CYPHER Stents should not migrate in this MRI environment. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3-Tesla.

In this testing, single CYPHER Stents up to 33-mm in length produced a temperature rise of less than 1 degree C, and two overlapped 33-mm length CYPHER Stents produced a temperature rise of less than 2 degrees C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of MRI. The effect of heating in the MRI environment for stents with fractured struts is not known. The effect of heating in the MRI environment on the drug or polymer coating is not known.

MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

(Note: This statement applies to all currently marketed CYPHER Stents in the United States.)

**Contact the respective manufacturer to obtain the latest information for drug eluting stents.**

**Coils, Filters, and Stents References**


(c) 2001 by Shellock R & D Services, Inc. and Frank G. Shellock, Ph.D. All Rights Reserved. All copyrights and pertinent trademarks are owned by Shellock R & D Services, Inc. and Frank G. Shellock, Ph.D. No part of the MRIsafety.com web site may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, physical, electronic or otherwise, without the prior written permission of Shellock R & D Services, Inc. or Frank G. Shellock, Ph.D.

Request for permission to reproduce any information contained on the MRIsafety.com web site should be addressed to: frank.shellock@gte.net

Be sure to read our disclaimer.