Memo on The Safety of MRI Scanning of Coronary Artery Stents

Developed by Tobias Gilk, Gilk Radiology Consultants

for

OneBeacon

PROFESSIONAL INSURANCE®

The problem: Many coronary artery stents have (a) no manufacturer guidance, or (b) outdated manufacturer guidance, or (c) overly-conservative manufacturer guidance with respect to scanning MRI patients.

The resolution: This memo seeks to lay out the risks (physical and legal), and provide the framework for clinical providers to make informed decisions with respect to providing MR imaging to patients with implanted coronary artery stents.

Working Information: Labeling / Instructions for Use (IFU) for MRI scanning of coronary artery stents (CAS) frequently gives the appearance that patients with these implants can not be safely scanned via MRI, an appearance that is not supported by reported adverse interactions between these stents and MRI devices. In fact, there are ways to identify means of scanning within the labeled conditions for many MRI scanners, and means of scanning beyond the labeled conditions that have no known negative outcomes.
What follows is a summarized breakdown of hazard and knowledge domains that radiologists, specifically MR medical directors, and MR technologists should familiarize themselves with. These knowledge domains are essential to be able to effectively evaluate the safety of coronary artery stents (and are many of the fundamentals to evaluate the safety of many other implants) with respect to MR patient imaging.

While the manner in which hazards are grouped and described within this document are not sequential in the order in which a care provider will have to respond to them in a patient care situation, it is recommended that this memo be used in concert with the decision support diagram, which does order the considerations in a patient care sequence.

What follows is a distilled summary of risks / considerations. Should the reader wish for expanded information on the topics herein (particularly detail on MR scanner information and vendor documentation), s/he is directed to the white paper on this same topic.

I. Know Coronary Artery Stent Device Labeling


“MR Conditional” testing / labeling criteria introduced in 2005 to indicate that an item / device is safe to be used near an MRI scanner (when device-specific limitations are observed).

Coronary artery stents with an original date of manufacture prior to 2005, that are identified as “MR Safe”, should be considered “MR Conditional”. No known CAS has received the contemporary (post-2005) “MR Safe” designation. As such, all CASs should be understood to have conditions associated with MR imaging.

Contemporary ASTM F-2503 MRI Safety Testing / Labeling Criteria:
Historic limitations of Testing / Labeling With Respect to Magnetic Spatial Gradient (MSG):

The testing methodology for “MR Conditional” labeling has been test the object and identify the object as having either passed or failed the criterion test. For example, the test for magnetic deflection is to suspend the object from a string and observe the angle of deflection at the location of greatest attractive force for a given MRI scanner. If the angle of deflection was less than 45-degrees, the force of the magnetic attraction (under those conditions) was less than the gravitational force exerted on the object. It has been conservatively presumed that magnetic force less than static gravitational force represents no meaningful risk to a patient.

Since the labeled information for the MR Conditional designation has been largely specific to individual scanners used for device testing (predominantly GE), sites utilizing other manufacturers’ systems have experienced difficulty and confusion in clearing “MR Conditional” implant / device patients.

Contemporary Extrapolated Deflection Thresholds:

Because of identified difficulties with “MR Conditional” labels identifying unique test conditions that frequently were not transferrable between different MRI system manufacturers, formats, and field strengths, the FDA now recognizes new ASTM criteria for mathematical extrapolation of deflection angle results to the 45-degree threshold. While the vast majority of implants and devices with “MR Conditional” labeling still have threshold values of 720 gauss/cm (or less), a small – but growing – number of implants are listing extrapolated magnetic field allowances that may be thousands, or even tens-of-thousands of gauss/cm.
Common CAS Material Properties:

Coronary artery stents are available in a variety of configurations and material compositions. They may be bare wire. They may be wire coated with a drug-eluting material. They may also be sheathed.

Be aware that metals identified as “stainless steel” are not sufficiently well described that we can understand their safety in a magnetic field. Some stainless steel alloys are powerfully ferromagnetic (strongly attracted to magnetic fields), while others exhibit almost no magnetic attraction. Simply knowing that a material is “stainless steel”, or “surgical steel”, tells us nothing of value with regard to assessing the device’s magnetic properties.

It is possible to make determinations on a coronary artery stent's magnetic safety based on an informed assessment of the device’s components.

II. Know MRI System Indications

Magnetic Spatial Gradient System Information

It is essential for the effective evaluation of the safety of scanning patients with CASs that providers obtain the most up-to-date information for each of their MRI systems. If this is not in the operators manuals for each system, contact the MRI manufacturer and request the most recent information on the magnetic spatial gradient available for each system.

Understanding MSG Maps / Tabular Data

Magnetic spatial gradient values tend to be greatest close to the surfaces of the MRI scanner, and further from the area at the center of the scanner where the imaging occurs. For bore-format magnets, the area of greatest MSG tends to be near the mouth of the bore, either just inside the opening along the side walls, or just outside of the opening on the face of the scanner.

The distribution of the magnetic fields is largely symmetrical. This means that the location of greatest MSG is not simply a single point, but a ring, radially symmetrical about the centerline of the MRI. It also means that whatever is true at one end of a bore-format magnet, is equally true at the other end of the MRI scanner.

Understanding the Physical Bounds of Label-Exceeding Volumes

Once an MRI provider has an understanding of their MRI system’s MSG distribution, it is a simple step to identify the bounds beyond which an implant or device’s magnetic spatial gradient tolerances are exceeded. Let’s assume we have a patient with an implant with the frequently-occurring 720 g/cm condition on the “MR Conditional” labeling, and the MRI provider is
assessing whether or not this implant might be scanned within the conditions on a Siemens Espree.

Below is a coronal MSG map of the Siemens Espree (modified by the author to show the whole magnet, and added a silhouette for scale reference), in which we have highlighted the area that would exceed the labeled limitations of the implant in question. Note that while the system maximum for the Espree greatly exceeds the labeled conditions for our implant, the actual volume of space that would exceed the conditions is quite small.

Understanding RF Deposition

It is important to note that while magnetic spatial gradient is frequently the most confusing and confounding element to providing MR scans for patients with “MR Conditional” implants and devices, it is not the only limiting element.

Radiofrequency energy (RF) is an essential part of MR imaging. RF energy used in MR scanning is naturally converted to diffused heat in the patient’s body. However, if there is an electrical conductor in the MRI scanner with the patient, including electrically conductive elements within the body of the patient, there are conditions under which those elements can heat, sometimes dangerously.
One of the key elements for dangerous RF heating is the physical length of the electrical conductor. Unlike stents that may be used in other vessels throughout the body, coronary artery stents are fairly uniform in size and shape. No single coronary artery stent known to the author at the time of this memo is of a length at which there is a serious concern about RF-induced heating.

Often, CAS patients have multiple serial or overlapping stents placed. While individual stents, or even two or three serially-positioned or overlapping stents, should not present unusual heating risks, if the length of a sequence of CASs exceeds 7.5 cm, there may begin to be heating risks at 3.0 Tesla, and if the length of a sequence of CASs exceeds 10 cm, there may begin to be heating risks at 1.5 Tesla (although CASs, in patent arteries, represent one of the best models for perfusion heat-dissipation). Even if the CASs are not touching, a patient’s own tissues act as electrical conductors and may help complete a coherent circuit among the CASs.

Depending on CAS particulars, and the MRI scanner being utilized, it may be entirely possible to scan patients in whom there are chains of CASs of greater than 7.5 cm at 3.0 T (or 10 cm at 1.5 T). It is advisable that MRI providers retain the special skills of a credentialed MR Safety Expert (MRSE) to assist with technical evaluation of ambiguous or complicated conditions.

Understanding ‘Scan Time’ as Applied to MR Conditional Labeled Criteria

Unless explicitly stated otherwise, when an “MR Conditional” label indicates something along the lines of “maximum scan time of 15 minutes of continuous scanning at 1.5T and at 3T,” the time allotment is per sequence, and does NOT represent the total amount of time to which the MR examination is limited.

III. Know Your Patient

What Specific Implant(s) Does S/He Have?

The aim of MR imaging patients with medical implants should always be to obtain manufacturer, device, model, variant (as applicable), and date of implantation, for every implanted medical device within the patient. With this information, clearing the patient for an MR exam is substantially more direct than without it.

However, we recognize that medical records are often incomplete or fragmented, and patients are not reliable medical historians with the specific details that would provide us the quantity and quality of information desired to make these clinical decisions.
Where, Anatomically, is The Implant?

Because of the magnetic spatial gradient distribution of differing MR devices, the position of an implant within the body of the patient, and the patient’s position within the MRI scanner, are vital to establishing what magnetic spatial gradient an implanted device is likely to be exposed to.

Where Will This Anatomy Traverse / Reside For The MRI Scan?

It is important to note that there are areas near the face of bore-format MRI scanners where there are MSG values that are higher than within the bore. As such, it is insufficient to think of only where the patient will be during the imaging study. One must also consider the patient’s movement, from sitting on the table, to being positioned outside the bore, to the travel into the imaging position, and then the reverse.

Generally speaking, the areas outside the bore of the MRI that present MSG values that may exceed specific “MR Conditional” conditions are unlikely volumes for patient movement. It remains important, however, to understand where these volumes are and, as appropriate, provide instruction to patients about where they should (and shouldn’t) move before, during, and after the MRI exam.

Confounding Factor: Multiple Discreet Coronary Artery Stents

As described in the section on Understanding RF Deposition, there are particular risks associated with multiple, in-line coronary artery stents. When several coronary artery stents are placed proximal to one another within the same vessel, the functional length should be considered to be the full length of the series of stents. When this length approaches / exceeds 7.5 cm, the risks of RF heating increase at 3.0 T (10 cm at 1.5 T). In these instances, the tissues between the stents may act as conductors, connecting a ‘train’ of discreet CASs.

As the space between the stents increases, so too does the electrical resistance to a coherent circuit encompassing each of the stents. In light of this, two 1 cm stents with 5.5 cm of tissue between them would be fundamentally lower risk of thermal injury than would six 1 cm stents, with a 0.3 cm gap between each stent. While in both situations, the total length is 7.5 cm, the thermal risks are not likely comparable.

Confounding Factor: Multiple Overlapping Coronary Artery Stents

When multiple coronary artery stents overlap, there should be no question with regard to their continuous electrical conductivity. Again, 7.5 cm should be viewed as the length beyond which thermal risks may become significant at 3.0 T (10 cm at 1.5 T).
Magnet System Selection Based on (Confounding) Factors

For MRI providers who have multiple MR scanners from which to choose, the selection of a specific magnet system may be made either to assure compliance with “MR Conditional” conditions, or to minimize risk factors for patients for whom a conclusive identification of each CAS has not been made. MRI scanners may be selected based on levels of control over resonant heating lengths, RF deposition, system static magnetic field strength, availability of localized transmit coils, or system magnetic spatial gradient.

Anatomy Being Imaged And Effect on Risk

Specifically with regard to RF heating risks, the further an implant is from the volume being imaged, the lower the RF energy deposition. Depending on your MRI system, anatomy only 30 cm from isocenter may be receiving 1% or less of the designed RF energy deposition. What this likely means is that an MRI scan of a normal-height adult’s ankle would deposit virtually no RF energy on the heart (and coronary artery stents therein).

Like magnetic spatial gradient data, RF dropoff data specific to each scanner is also vital information available from your MR system vendor that should be understood by MR technologists and radiologists.

IV. Risk : Benefit Assessment

Patient Indication for MRI Exam

In all cases, the appropriateness of an MR examination should be established prior to imaging. When a patient has an inconclusively identified coronary artery stent (or several), the importance of appropriateness of the exam is magnified.

If it is believed that there is a reasonable opportunity to obtain missing implant information with additional time, and there is no adverse risk to the patient of a delay in the MR examination, a supervising physician should make the determination about whether or not to postpone the exam in hopes of obtaining missing implant information.

Managing CAS Risk: Magnetic Attraction

For most contemporary clinical MRI scanners, there is no adjusting the magnetic field’s reach or intensity. Similarly, there is no simple and risk-free way to turn the MRI scanner’s magnetic field off. In the event that magnetic attractive forces are a significant concern for a CAS patient, the MRI options are to image them on a magnet with lower magnetic field strength / lower magnetic spatial gradient, or to not image them via MRI.
Managing CAS Risk: RF Energy

As described in the section on the Anatomy Being Imaged and Effect On Risk, RF energy deposition may be mitigated, or even practically eliminated, by distance from the anatomy being imaged. Another means of reducing RF deposition on the coronary artery stent(s) within a patient is to use transmit / receive coils when imaging peripheral anatomy.

By using a transmitting anatomy-specific coil, instead of the body coil for RF transmission, only the anatomy within / under the coil receives the full RF energy. When standard receive-only coils are used for imaging, the RF transmission emanates from the body coil located behind the surfaces of the patient bore, and deposits RF energies within all the anatomy in the central part of the MRI scanner.

Informed Consent

Should a supervising radiologist feel that real / significant potential risks to the patient remain, despite efforts to identify risk factors and mitigate those factors within the radiologist’s control, and that the prospective benefit to the patient warrants the exam, it is advised (and may be a legal obligation) for the physician to obtain the patient’s informed consent to proceed with a non-emergent MR exam.

V. Disclaimer

The purpose of this memo is to provide the practitioner with objective information about the risks associated with MR imaging of FDA-approved coronary artery stents. This guidance does not apply to any other implant or device. This guidance represents the state of the art at the time it was drafted and no warranty is expressed or implied about this guidance at periods subsequent to its issue, or under conditions not expressly covered.

The guidance in this memo is technical in nature, and should not be interpreted to indicate or direct the legal practice of medicine. This memo’s sole intent is to provide technical information to the medical practitioner such that s/he may have the benefit of this information when making the decision to recommend or authorize clinical MRI care.

If the reader has questions or concerns regarding any of the guidance in this white paper, or does not understand the underpinnings of any of the guidance herein, the reader is directed to seek clarification from a MRSC™ credentialed MRMD, MRSO, or MRSE, or other expert MR safety resource. It is essential that any medical practitioner understand the basis for (and consequences of) MR safety decisions regarding coronary artery stents (or any other implants), particularly when guidance may diverge from existing practices.
VI. Summary

It is possible to safely provide MRI examinations of many patients with coronary artery stents, in such a way as to comply with MR Conditional restrictions with enhanced understanding of those conditions and the specific operation of the provider’s MRI scanner. Similarly, it may be possible to also provide MRI examinations of patients with coronary artery stents without known manufacturer conditions, or scans that may exceed manufacturer conditions, without adverse effect.

By utilizing this information, it may be possible to provide MRI scanning to patients who previously were thought ineligible for MRI exams, simultaneously improving patient care options and increasing the utilization of the MRI scanner.

It is strongly recommended that MRI providers encourage MRI safety specific knowledge and credentialing of technologists, radiologists, and medical physicists charged with responsibility for MRI safety. Providers are encouraged to explore credentialing through the American Board of Magnetic Resonance Safety (ABMRS).

This publication is provided for general informational purposes only and does not constitute legal, risk management, or other advice. Readers should consult their own counsel or other advisors for such advice. OneBeacon Professional Insurance, Inc. (OBPI) and OneBeacon Insurance (OBI) assume no responsibility or liability for the discovery or elimination of risks that possibly could cause accidents, injuries, or damages. Compliance with any strategies or opportunities for improvement provided in this publication does not assure elimination of risks or the satisfaction of requirements of applicable law. OBPI and OBI shall not be responsible for any damages resulting from any error, omission, inaccuracy, or misstatement contained in this publication.