White Paper on The Safety of MRI Scanning of Coronary Artery Stents

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The problem: Many coronary artery stents have (a) no manufacturer guidance, or (b) outdated manufacturer guidance, or (c) overly-conservative manufacturer guidance with respect to scanning MRI patients.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 white paper 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.
I. Know Coronary Artery Stent Device Labeling


The FDA recognizes testing and labeling criteria for MRI safety as developed by the ASTM International (formerly the American Society for Testing and Materials). Prior to 2005, ASTM criteria labeled devices that were safe for use (within device-specific limitations) in proximity to the MRI scanner as “MR Safe”. Because of misperceptions about the term “Safe”, and the mistaken belief that devices labeled as “MR Safe” didn’t have restrictions on their use (and accidents that resulted from these misperceptions), ASTM revised their criteria in 2005. From 2005, onward, the meaning of “MR Safe” was changed to mean what some had presumed it to mean, safe without restrictions, and a new term, “MR Conditional” was introduced 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:

Contemporary ASTM labeling of MR safety of implants and devices uses the ASTM F-2503 standard. This standard tests a device’s safety in the MRI environment against three principal criteria: magnetic attraction / rotation, electrical interaction, and radiofrequency absorption. The results of the tests on these criteria result in labeling of the device as either “MR Unsafe”, “MR Conditional”, or “MR Safe”. The overwhelming majority of all implants and devices tested and labeled with the contemporary ASTM criteria are labeled “MR Conditional”

<table>
<thead>
<tr>
<th>MR safe</th>
<th>The device or implant is completely nonmagnetic, nonelectrically conductive, and nonradiofrequency reactive, therefore eliminating all the primary potential risks during MRI scanning</th>
</tr>
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<tbody>
<tr>
<td>MR conditional</td>
<td>The device or implant may contain magnetic, electrically conductive, or radiofrequency-reactive components that are safe for operation in proximity to the MRI, provided the conditions for safe operation are defined and observed (both for the MR scanner and the device itself)</td>
</tr>
<tr>
<td>MR unsafe</td>
<td>Objects that are significantly ferromagnetic and pose a clear and direct threat to persons and equipment within the magnet room</td>
</tr>
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</table>
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 (Indicated by the white arrow in the illustration). If the angle of deflection was less than 45-degrees, then 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.

One of the difficulties with this methodology, however, has been that the location where the test is conducted presents a magnetic field of a value less than the maximum for the MRI system, and some MRI manufacturers had been resistant to release any information other than the system maximum values for the magnetic field for their MRI systems (location indicated by the black arrow in the illustration). If a device was tested at a magnetic field value of 720 gauss/cm (a measure of the ‘steepness’ of a magnetic field), but the MRI manufacturer only published the system maximum value for that same scanner (760 gauss/cm), clinical providers found themselves in the ironic position of not feeling as though they could safely scan an implant patient on the exact type of MRI scanner that was used to demonstrate the safety of MRI scanning of that implant.
Further frustrating the use of the labeled information has been the fact that other MRI scanners (of different field strengths, construction, or format) have different magnetic spatial gradient values, some of which are appreciably greater than those most frequently used for testing. Since the labeled information for the MR Conditional designation has been largely specific to individual scanners (predominantly GE), sites utilizing other manufacturers' systems have experienced difficulty and confusion in clearing “MR Conditional” implant / device patients.

Manufacturer / Testing Body Deflection Angle Data:

Since device manufacturers were only obligated to identify whether their device passed the criteria for “MR Conditional” labeling, they have almost never included information within their “MR Conditional” conditions, or the device’s IFU, that describe how much (or how little) the device deflected. If we knew, for example, that a tested device deflected only 2-degrees, for example, at a test condition of 720 gauss/cm, MRI providers would have a high degree of confidence in the safety of scanning a patient with that same implanted device at a worst-case condition of 760 gauss/cm, knowing that there were orders-of-magnitude margins of safety between the 2-degree deflection and the 45-degree ‘equal to gravitational force’ threshold.

While deflection angle data is not typically found on “MR Conditional” labels, device manufacturers are free to share this information upon request.

It is recommended that providers contact device manufacturers to request deflection angle test results if they have questions about the MRI safety of a
specific implant / device that has been tested and labeled as “MR Conditional”

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 (see https://www.bostonscientific.com/content/dam/bostonscientific/endo/portfolio-group/resolution-clip/resolutionclip_resources_MRpatientcard.pdf for example of a non-CAS implant with an extrapolated rating). These extrapolated values are not necessarily identified as extrapolations. If you have any question about the validity of an unusually high number for static magnetic field conditions, understand that it may very well be an extrapolated value. If you still have questions or concerns, contact the device manufacturer for specific information on their testing / labeling methodology.

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.

304 is an austenitic stainless steel alloy that is very weakly magnetic in its raw state (http://en.wikipedia.org/wiki/Stainless_steel). However, processing 304 (heating it, cutting it, pressing it, forming it, etc…) can turn a non-ferromagnetic material into a strongly ferromagnetic material. Unless very strict manufacturing processes are followed to reduce the degradation of the material during manufacturing, a product made of 304 stainless steel may be significantly ferromagnetic. No inferences should be made about the magnetic ‘safety’ of a device made of 304 stainless steel if the manufacturer
can not guarantee that the manufacturing process preserved the non-magnetic nature of the raw state.

316L is a superaustenitic stainless steel alloy that has very weak ferromagnetic properties ([http://en.wikipedia.org/wiki/Stainless_steel](http://en.wikipedia.org/wiki/Stainless_steel)). It is one of the most commonly used metal alloys for implants and devices both because of its very low reactivity within the body, and also because, unlike 304 stainless steel, 316L becomes ferromagnetic very reluctantly, even with significant working. Implants / devices made wholly from 316L stainless steels can be presumed to have negligible magnetic risks.

Nitinol is a special alloy of equal parts of nickel and titanium ([http://en.wikipedia.org/wiki/Nickel_titanium](http://en.wikipedia.org/wiki/Nickel_titanium)). The unique crystalline structure of this alloy completely negates the strong magnetic properties of the nickel component, making the alloy non-magnetic. Implants / devices made wholly from Nitinol can be presumed to have negligible magnetic risks.

These magnetic properties of common alloys are provided because even when CAS manufacturers do not have their devices tested / labeled for MRI safety, they do frequently identify the materials of construction. With the appropriate information, a provider can make an informed decision about ferromagnetic risks based on the material composition of the device.

II. Know MRI System Indications

Magnetic Spatial Gradient System Information

At the time of the authoring of this white paper, all US vendors of MRI systems now provide significantly more information about their magnetic fields than just the system maximum for the magnetic spatial gradient (MSG). However, the documentation provided with MRI systems sold in prior years may not have included this detail. Even those MRI manufacturers who previously were reluctant to share this information are now making the information available, even for ‘legacy’ MRI systems.

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.

What follows are illustrations from MRI manufacturers that demonstrate the different ways in which magnetic spatial gradient information may be portrayed.

**Spatial gradient of the static magnetic field $B_0$**

The rise of the magnetic field as a function of the distance to the magnet is expressed by the spatial gradient of $B_0$. The following figures show lines with the same gradient in T/m. The magnetic attraction force on a magnetically saturated ferromagnetic object is proportional to this quantity.

Please note: Sometimes this quantity is expressed in G/cm (1 T/m = 100 G/cm).

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The above illustration is taken from the operators manual for a Siemens Espree 1.5 Tesla MRI scanner. Siemens illustrates the distribution of their spatial gradient values by showing one-quarter sectional view through the MRI scanner. It is up to the end-user to imagine the isogradient lines rotated around the central Z axis, and mirror the image (in this case) from right to left to understand the distribution of the magnetic spatial gradient lines near the backside of the MRI scanner.

Many MRI providers find it much more ‘user friendly’ to ‘unfold’ the image, and create a full illustration of the magnetic spatial gradient lines around the full scanner. The following is a standard axial quarter diagram from Siemens for their Espree magnet that has been ‘unfolded,’ and includes a silhouette as a scale reference.

![Author’s ‘Unfolded’ MSG Diagram of Siemens Espree](image)

Because of the radial symmetry of the magnetic field, other MRI manufacturers present their magnetic spatial gradient information in the form of cylinder maps. Imagine a series of nested cylinders of space, like invisible nesting Russian dolls, within the bore of the MRI scanner.
Philips portrays their magnetic spatial gradient information using the cylinder model. Their information gives the ‘worst case’ MSG value to which a patient could potentially be exposed within each cylindrical volume.

### Philips MSG Diagram and Tabular Data

Philips’ system combines an illustration of the concentric rings of space, with a table that states the maximum MSG in both standard units, Tesla/meter (T/m) and gauss / centimeter (g/cm). Philips’ table provides the data for all of their bore-format magnets in a single table.
At the present time, GE provides their MSG data only in tabular format.

<table>
<thead>
<tr>
<th>Field magnet</th>
<th>Item</th>
<th>On patient Z axis</th>
<th>on 20 cm Diameter Cylinder surface</th>
<th>on 30cm Diameter Cylinder surface</th>
<th>on 40cm Diameter Cylinder surface</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Peak R,Z (m,ms)</td>
<td>Peak R,Z (m,ms)</td>
<td>Peak R,Z (m,ms)</td>
<td>Peak R,Z (m,ms)</td>
</tr>
<tr>
<td>3.0T 3TLC</td>
<td>Bo (T)</td>
<td>3.0</td>
<td>[0.000,0.250]</td>
<td>[0.100,0.358]</td>
<td>[0.150,0.460]</td>
</tr>
<tr>
<td></td>
<td>Gradient (T/m)</td>
<td>5.1</td>
<td>[0.000,0.880]</td>
<td>[0.100,0.880]</td>
<td>[0.150,0.880]</td>
</tr>
<tr>
<td></td>
<td>BxG (T2/m)</td>
<td>10.6</td>
<td>[0.000,0.790]</td>
<td>[0.100,0.785]</td>
<td>[0.150,0.785]</td>
</tr>
</tbody>
</table>

**GE Tabular Magnetic Field Data**

The middle (shaded) row contains the Magnetic Spatial Gradient Data for the particular magnet identified in the leftmost cell of the table.

In addition to cylindrical / bore-format MRI systems, which are the most common type, there are a variety of other configurations. The only other we will identify in this white paper is the high-field open (HFO) MRI. HFO systems are characterized by having two thick disk-shaped magnets, one that the patient lays on, and the other that is suspended above them on columns rising up from the lower disk. The format can result in MSG values that may be significantly higher than bore-format magnets, even when the bore-format systems have a higher rated static field strength (Tesla).
HFO magnet systems typically represent their MSG values in a format similar to the Philips cylinder maps, except that instead of being cylindrical, the volumes frequently used for HFO maps are slab-like. Reverting to analogies, whereas bore-format magnets may use Russian doll shapes for their MSG maps, high-field open magnets use a stack of pancakes.

![Figure 3.8 Panorama: Maximum levels of |grad|B|](image)

**Philips HFO Panorama ‘Slab’ MSG Table**

Irrespective of what manufacturer, field strength, or format of magnet is being used, the ability to assess the safety of providing MRI imaging for patients with CASs depends on having and understanding the information specific to each and every MRI system at a provider’s disposal. Different models may have significantly different MSG maps, and it is essential that providers have the information particular to each magnet.

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.
The Siemens Espree is a wide-bore (70 cm) MRI scanner. The system maximum MSG for this magnet is approximately 15 Tesla/meter, or 1,500 gauss/cm. If all we evaluated was the system maximum, we would believe it to be vastly beyond the labeled conditions to scan an implant with an “MR Conditional” label of 720 g/cm on a scanner that has an MSG of 1,500. If we failed to identify the extents of the exceeding volume for this scanner, we would fail to recognize that – for the vast majority of cases – compliant patients with the implant or device in question would likely be able to undergo MRI exam without exceeding the “MR Conditional” condition for magnetic spatial gradient.

Below is a coronal MSG map of the Siemens Espree, 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.

Siemens Espree with 720 g/cm Volume Shaded Red
While there is a volume that is approximately 6 cm (at its deepest) ringing the opening on the face of the MRI scanner that would exceed the conditions of a 720 g/cm “MR Conditional” implant, the projection into the bore only reaches a couple of cm, and then only at the very mouth of the bore.

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.

To mitigate against this risk, “MR Conditional” devices often carry limitations on the amount of RF energy that may be used during any individual imaging sequence. Every MRI scanner has the ability to adjust / tailor the amount of RF energy used during a scan. Due to the variety of manufacturers, scanners, and scanner software releases, this white paper does not attempt to direct MRI providers as to where or how to modify the RF energy settings for your scanner, but this is critical information that MR technologists and radiologists should obtain from your MRI scanner manufacturer, if it is not already well understood. RF energy deposition limits should be observed when imaging any “MR Conditional” implant or device.

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 white paper 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.

With regard to coronary artery stents, the range and variety of known devices is relatively modest, as compared to the full panoply of implantable medical devices. This may allow for an effective risk : benefit analysis for CASs with a very small number of inputs and remaining variables.

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.

In the case of CASs, the following image demonstrates that the heart is contained within the 20 cm diameter ring. Even allowing for patient movement, with a generally cooperative patient it is highly likely that the heart (and thus, the CAS) could be kept within the 30 cm diameter ring (15
cm away from a bore wall of a 60 cm diameter bore as shown, and 20 cm away from a bore wall of a 70 cm diameter bore).

Illustration of Axial Anatomy Shown With Superimposed Cylinder Lines

With this information we could be highly confident that a CAS in a complaint patient would not come anywhere close to a 720 g/cm threshold value if, for example, this patient were being imaged on the Siemens Espree that we looked at earlier in this white paper. In fact, if the CAS remained within the center 30 cm of a Siemens Espree, it would never be exposed to a MSG of even 300 g/cm!

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, as with the Siemens Espree, 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).

Illustration of RF Energy Dropoff With Distance From Isocenter

Like magnetic spatial gradient data, RF dropoff data is also vital information available from your MR system vendor that should be understood by MR technologists and radiologists. The above illustration is unique to the Siemens Prisma MR system.

When MR imaging anatomy distant from the CAS, RF risks are minimized. Conversely, when imaging anatomy proximal to the implant, RF considerations are in full force.
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.

In an urgent / emergent situation, where there are clear and substantive risks to the patient associated with the delay of MR imaging, or of imaging on another available modality, it is the duty of the supervising physician for the MRI exam to weigh the indications for the MRI against the risks, and to manage the risks as effectively as possible to the benefit of the patient.

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.

Unlike RF energy deposition, modest distances from the imaging center of the MRI scanner will not diminish magnetic attraction forces (which are at their greatest in the same regions as the greatest Magnetic Spatial Gradient... near the entrance to the mouth of the bore).

As stated previously, risks of dislodgement of coronary artery stents from magnetic action are remote. In fact, a recent publication of one such novel event (http://circinterventions.ahajournals.org/content/6/5/e58.full) was rather resoundingly debunked in a letter just a few months later (http://circinterventions.ahajournals.org/content/7/1/128.full). Particularly if one is able to identify the materiality of the CAS in question, in many cases an appropriately educated supervising radiologist should be able to assess magnetic attraction risks associated with MR imaging a patient with this implant.
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.

As described earlier in this white paper, RF energy heating should not be presumed to be a significant risk when MR imaging of patients with one or two coronary artery stents at either 1.5 or 3.0 T, in normal operating mode. Management of RF energy risks becomes increasingly important with greater numbers of contiguous or overlapping stents. See the confounding factors, above.

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 white paper 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 white paper is technical in nature, and should not be interpreted to indicate or direct the legal practice of medicine. This white paper’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).

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