# Guidelines for the Management of Patients with Coronary Artery Stents Referred for MRI Examinations*

**Frank G. Shellock, Ph.D., FACR, FISMRM**
**Adjunct Clinical Professor of Radiology and Medicine**
**Keck School of Medicine, University of Southern California**
www.MRIsafety.com

In the clinical magnetic resonance imaging (MRI) setting, there is often misunderstanding associated with the management of patients with coronary artery stents, including confusion regarding stents labeled “MRI Safe" or "MRI Compatible” (i.e., due to labeling applied prior to the change in terminology, 2005) or “MR Conditional”, the timing of performing MRI following stent placement, and regarding what MRI limitations may exist (e.g., those related to the acceptable static magnetic field strength, maximum spatial gradient magnetic field, whole body averaged specific absorption rate or SAR, and other conditions)(1-3, 24). This may result in restricted access to MRI for certain patients, particularly those with coronary artery stents for which there is unknown labeling information.

The previous belief that it may be necessary for patients to wait six weeks or longer after implantation of certain coronary artery stents to allow for endothelialization or other mechanism to prevent migration has been refuted because there are no known coronary artery stents made from ferromagnetic materials (4-24).

By following the pertinent MRI labeling information (i.e., presented in the *Instructions for Use*, Product Manual, Patient Identification Card, etc.), patients with coronary artery stents have safely undergone MRI examinations, including those performed using MR systems operating at 3-Tesla (3-24). Notably, there has never been an adverse event reported in association with performing MRI in patients with these implants.

The standard policy that MRI labeling information is required before allowing the use of MRI in patients with coronary artery stents limits access to this important diagnostic imaging modality for those patients for which labeling information is unavailable. Taking into account the peer-reviewed literature and other related information (3-25), it is acceptable to perform MRI examinations in patients with all coronary artery stents by following specific guidelines developed by considering the primary safety concerns (i.e., magnetic field-related force, torque, and RF-induced heating) for these implants.

**Guidelines.** A patient with a with coronary artery stent (e.g., drug-eluting or bare metal version), including when there are two or more stents or two or more overlapping stents, may undergo MRI using the following guidelines:

- 3-Tesla or less
- No restriction on the direction of the static magnetic field
- No restriction on the value of the spatial gradient magnetic field

- For a coronary artery stent located *inside* of the area of the transmitted RF energy, use a whole-body averaged specific absorption rate (SAR) of 2-W/kg (i.e., operating the MR system in the Normal Operating Mode)

- For a coronary artery stent located entirely *outside* of the area of the transmitted RF energy, a whole-body averaged specific absorption rate (SAR) of 4-W/kg (i.e., operating the MR system in the First Level Controlled Operating Mode) may be used

- Maximum imaging time, 15 minutes per pulse sequence, multiple pulse sequences are allowed

***Important Note:** The *"Guidelines for the Management of Patients with Coronary Artery Stents Referred for MRI Examinations"* should only be implemented for use after the careful review by the supervising radiologist or other physician responsible for the MRI facility and with the adoption of the information as a written policy.

**Important Note:** Any deviation from the above MRI conditions requires prior approval by the Radiologist or supervising physician.

**Important Note:** These guidelines must be reviewed on an annual basis to confirm that no new coronary artery stent has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe.

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# Guidelines for the Management of Patients with Passive, Internal Orthopedic Implants Referred for MRI Examinations*

**Frank G. Shellock, Ph.D., FACR, FISMRM**
**Adjunct Clinical Professor of Radiology and Medicine**
**Keck School of Medicine, University of Southern California**
**www.MRIsafety.com**

Passive, internal orthopedic implants are defined as medical devices that are entirely implanted in patients, that have no active electronic components or power source. These passive, internal orthopedic implants include disc replacement implants, interspinous spacers, meshes, nails, pins, plates, rods, staples, screws, wires, cranial closure or fixation systems, sternal closure devices, and total or partial joint replacement implants used for the hips, knees, shoulders, elbows, and other joints.

Most orthopedic implants are made of weakly or nonferromagnetic materials including commercially pure titanium, titanium alloy, cobalt-based alloys, tantalum, magnesium-based alloys, austenitic stainless steel (commonly, 316 stainless steel), niobium (Nb), titanium (Ti), and zirconium (Zr)(Nb-Ti-Zr) alloys (1). For orthopedic implants made of ferromagnetic material, *in situ* counter-forces (i.e., the implants are retained in positions by various means of fixation) will prevent movement or dislodgement of the device (2, 4).

While there is a theoretical risk of MRI-related excessive heating of certain passive, internal orthopedic implants such as internal fixation systems used for the spine, to date, there has been no evidence of substantial heating occurring in a patient, nor a report of a patient burn associated with these implants related to the clinical use of MRI examinations. Notably, there has never been an adverse event reported in association with performing MRI in patients with passive, internal orthopedic implants.

Taking into account the peer-reviewed literature and other related information, it is acceptable to perform MRI examinations in patients with all passive, internal orthopedic implants by following specific guidelines developed by considering the primary safety concerns (i.e., magnetic field-elated force, torque, and RF-induced heating) for these implants.

**Guidelines:** A patient with a passive, internal orthopedic implant may undergo MRI using the following guidelines:

- 3-Tesla or less
- No restriction on the direction of the static magnetic field
- For a passive, internal orthopedic implant located *inside* of the area of the transmitted RF energy, use a whole-body averaged specific absorption rate (SAR) of 2-W/kg (i.e., operating the MR system in the Normal Operating Mode)
- For a passive, internal orthopedic implant located entirely *outside* of the area of the transmitted RF energy, a whole-body averaged specific absorption rate (SAR) of 4-W/kg

(i.e., operating the MR system in the First Level Controlled Operating Mode) may be used

- Maximum imaging time, 15 minutes per pulse sequence, multiple pulse sequences are allowed

**Exclusions:** Orthopedic implants that are excluded from these guidelines include external fixation systems, external cervical fixation systems (e.g., halo vests), traction devices, magnetically-controlled or programmable implants (e.g., PRECISE System, MAGEC System), bone fusion stimulation systems, prosthetic limbs, and prostheses with microprocessors.

***Important Note:** The "*Guidelines for the Management of Patients with Internal, Passive Orthopedic Implants Referred for MRI Examinations*" should only be implemented for use after careful review by the supervising radiologist or other physician responsible for the MRI facility and with the adoption of the information as a written policy.

**Important Note:** Any deviation from the above MRI conditions requires prior approval by the supervising physician.

**Important Note:** These guidelines must be reviewed on an annual basis to confirm that no passive, internal orthopedic implant has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe.

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# Guidelines for the Management of Patients with Vascular Access Ports Referred for MRI Examinations*

**Frank G. Shellock, Ph.D., FACR, FISMRM**
**Adjunct Clinical Professor of Radiology and Medicine**
**Keck School of Medicine, University of Southern California**
**www.MRIsafety.com**

In the clinical magnetic resonance imaging (MRI) setting, it is often necessary to manage patients with vascular access ports (1-6). MRI labeling information exists for numerous vascular access ports. By following the labeling information (i.e., presented in the *Instructions for Use*, Product Manual, Patient Identification Card, etc.), patients with vascular access ports have safely undergone MRI examinations, including those performed using MR systems operating at 3-Tesla (1-6). Notably, there has never been an adverse event reported in association with performing MRI exams in patients with these implants.

The standard policy that MRI labeling information is required before allowing the use of MRI in patients with vascular access ports limits access to this important diagnostic imaging modality for those patients for which labeling information is unavailable. Taking into account the peer-reviewed literature and other related information (1-6), it is acceptable to perform MRI examinations in patients with all vascular access ports by following specific guidelines developed by considering the primary safety concerns (i.e., magnetic field-related force, torque, and RF-induced heating) for these implants.

**Guidelines.** A patient with a vascular access port may undergo MRI using the following guidelines:

- 3-Tesla or less
- No restriction on the direction of the static magnetic field
- No restriction on the value of the spatial gradient magnetic field
- For a vascular access port located *inside* of the area of the transmitted RF energy, use a whole-body averaged specific absorption rate (SAR) of 2-W/kg (i.e., operating the MR system in the Normal Operating Mode)
- For a vascular access port located entirely *outside* of the area of the transmitted RF energy, a whole-body averaged specific absorption rate (SAR) of 4-W/kg (i.e., operating the MR system in the First Level Controlled Operating Mode) may be used
- Maximum imaging time, 15 minutes per pulse sequence, multiple sequences pulse are allowed

***Important Note:** The *"Guidelines for the Management of Patients with Vascular Access Ports Referred for MRI Examinations"* should only be implemented for use after careful review by the supervising radiologist or other physician responsible for the MRI facility and with the adoption of the information as a written policy.

**Important Note:** Any deviation from the above MRI conditions requires prior approval by the supervising physician.

**Important Note:** These guidelines must be reviewed on an annual basis to confirm that no new vascular access port has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe.

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# Guidelines for the Management of Patients with Vascular Stents Referred for MRI Examinations*

**Frank G. Shellock, Ph.D., FACR, FISMRM**
**Adjunct Clinical Professor of Radiology and Medicine**
**Keck School of Medicine, University of Southern California**
www.MRIsafety.com

A vascular stent is an expandable tube-shaped device used to support and maintain blood flow through a narrowed or blocked blood vessel. Vascular stents may be bare metal, drug-eluting, or covered. Stent grafts used for the vascular system incorporate fabrics, such as Dacron, polytetrafluoroethylene (PTFE), or Gortex, that are deployed within a vessel to reinforce or replace damaged tissue. These implants include carotid artery stents, coronary artery stents, aortic aneurysm stent grafts, peripheral vascular stents, intracranial diverting stents or flow-diverting stents, and similar stents intended for use in the vascular system.

MRI labeling information exists for numerous vascular stents. By following the pertinent MRI labeling information (i.e., presented in the *Instructions for Use*, Product Manual, Patient Identification Card, etc.), patients with vascular stents have safely undergone MRI examinations, including those performed using MR systems operating at 3-Tesla. Notably, there has never been an adverse event reported in association with performing MRI in patients with these implants.

The standard policy that MRI labeling information is required before allowing the use of MRI in patients with vascular stents limits access to this important diagnostic imaging modality for those patients for which labeling information is unavailable. Taking into account the peer-reviewed literature and other related information (1-10), it is acceptable to perform MRI examinations in patients with all vascular stents by following specific guidelines developed by considering the primary safety concerns (i.e., magnetic field-related force, torque, and RF-induced heating) for these implants.

**Guidelines.** A patient with a with vascular stent, including when there are two or more stents or two or more overlapping stents, may undergo MRI using the following guidelines:

- 3-Tesla or less
- No restriction on the direction of the static magnetic field
- No restriction on the value of the spatial gradient magnetic field
- For a vascular stent located *inside* of the area of the transmitted RF energy, use a whole-body averaged specific absorption rate (SAR) of 2-W/kg (i.e., operating the MR system in the Normal Operating Mode)
- For a vascular stent located entirely *outside* of the area of the transmitted RF energy, a whole-body averaged specific absorption rate (SAR) of 4-W/kg (i.e.,

operating the MR system in the First Level Controlled Operating Mode) may be used

- Maximum imaging time, 15 minutes per pulse sequence, multiple pulse sequences are allowed

***Important Note:** The *"Guidelines for the Management of Patients with Vascular Stents Referred for MRI Examinations"* should only be implemented for use after the careful review by the supervising radiologist or other physician responsible for the MRI facility and with the adoption of the information as a written policy.

**Important Note:** Any deviation from the above MRI conditions requires prior approval by the Radiologist or supervising physician.

**Important Note:** These guidelines must be reviewed on an annual basis to confirm that no new vascular stent has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe.

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# Guidelines for the Management of Patients with Heart Valve Prostheses and Annuloplasty Rings Referred for MRI Examinations*

**Frank G. Shellock, Ph.D., FACR, FISMRM**
**Adjunct Clinical Professor of Radiology and Medicine**
**Keck School of Medicine, University of Southern California**
**www.MRIsafety.com**

In the clinical magnetic resonance imaging (MRI) setting, it is often necessary to manage patients with heart valve prostheses [including *transcatheter* aortic *valve* replacements (*TAVR*), transcatheter aortic valve implantation (TAVI*)* devices, percutaneous aortic valve replacement (PAVR) implants, transcatheter heart valves (THV), as well as other similar heart valve implants used in association with minimally invasive procedures] and annuloplasty rings (1-21).

MRI labeling information exists for numerous heart valve prostheses and annuloplasty rings. By following the MRI labeling information (i.e., presented in the *Instructions for Use*, Product Manual, Patient Identification Card, etc.), patients with heart valve prostheses and annuloplasty rings have, have safely undergone MRI examinations, including those performed using MR systems operating up to 3-Tesla (5, 16, 21). Notably, there has never been an adverse event reported in association with performing MRI in patients with these implants.

The standard policy that MRI labeling information is required before allowing the use of MRI in patients with heart valve prostheses and annuloplasty rings limits access to this important diagnostic imaging modality for those patients for which labeling information is unavailable. Taking into account the peer-reviewed literature and other related information (1-21), it is acceptable to perform MRI examinations in patients with all heart valve prostheses and annuloplasty rings by following specific guidelines developed by considering the primary safety concerns (i.e., magnetic field-elated force, torque, and RF-induced heating) for these implants.

**Guidelines.** A patient with a heart valve prosthesis or an annuloplasty ring may undergo MRI using the following guidelines:

- 3-Tesla or less
- No restriction on the direction of the static magnetic field
- No restriction on the value of the spatial gradient magnetic field
- For a heart valve prosthesis or an annuloplasty ring located *inside* of the area of the transmitted RF energy, use a whole-body averaged specific absorption rate (SAR) of 2-W/kg (i.e., operating the MR system in the Normal Operating Mode)
- For a heart valve prosthesis or an annuloplasty ring located entirely *outside* of the area of the transmitted RF energy, a whole-body averaged specific absorption rate (SAR) of 4-W/kg (i.e., operating the MR system in the First Level

Controlled Operating Mode) may be used

- Maximum imaging time, 15 minutes per pulse sequence, multiple pulse sequences are allowed

***Important Note:** The *"Guidelines for the Management of Patients with Heart Valve Prostheses and Annuloplasty Rings Referred for MRI Examinations"* should only be implemented for use after the careful review by the supervising radiologist or other physician responsible for the MRI facility and with the adoption of the information as a written policy.

**Important Note:** Any deviation from the above MRI conditions requires prior approval by a supervising physician.

**Important Note:** These guidelines must be reviewed on an annual basis to confirm that no heart valve prosthesis or annuloplasty ring has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe.

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# Guidelines for the Management of the Post-Operative (Post-Op) Patient Referred for an MRI Examination

**Frank G. Shellock, Ph.D., FACR, FISMRM**
**Adjunct Clinical Professor of Radiology and Medicine**
**Keck School of Medicine, University of Southern California**
**www.MRIsafety.com**

There is often confusion regarding the issue of performing a magnetic resonance imaging (MRI) examination during the post-operative period in a patient with a metallic implant or device. Studies have supported that, if the metallic medical product is a “passive implant” (i.e., the implant serves its function without supply of electrical energy or any source of power other than that directly generated by the human body or gravity) and it is made from nonferromagnetic material, the patient may undergo an MRI exam *immediately* after implantation using an MR system operating at 3-Tesla or less. Notably, there are numerous reports that describe placement of vascular stents, coils, filters, and other metallic implants or devices using MR-guided or interventional procedures that include the use of 1.5- and 3-Tesla scanners, illustrating that patients with certain implants may immediately undergo MRI exams. Additionally, a patient or individual with a nonferromagnetic passive implant is allowed to enter the room associated with an MRI system operating at 3-Tesla or less immediately after the implantation of the medical product.

For a passive implant that does not state a "wait" period in the *Instructions for Use* (IFU) or product labeling, there is no need to delay the MRI examination for the patient. To date, very few passive implants indicate a wait period in the IFU or product labeling.

For patients with implants that are “weakly ferromagnetic” but rigidly fixed or otherwise anchored in the body (e.g., orthopedic implants or other similar devices), these patients may undergo MRI exams immediately after implantation of the device.

The information above specifically pertains to magnetic field-related force and torque and, thus, further consideration must be given to RF-induced heating for an implant or device.

**Special Note:** If there is concern regarding the integrity of the tissue with respect to its ability to retain the implant in place or if the implant cannot be properly identified, the patient or individual should not be exposed to the MR system.

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# Guidelines for the Management of Patients with Embolization Coils Used for Cerebral Aneurysms or Arteriovenous Malformations Referred for MRI Examinations*

**Frank G. Shellock, Ph.D., FACR, FISMRM**
**Adjunct Clinical Professor of Radiology and Medicine**
**Keck School of Medicine, University of Southern California**
**www.MRIsafety.com**

In the clinical magnetic resonance imaging (MRI) setting, it is often necessary to manage patients with embolization coils used for cerebral aneurysms or arteriovenous malformations (AVMs)(1-6). MRI labeling information exists for numerous embolization coils used for those applications. By following the MRI labeling information (i.e., presented in the *Instructions for Use*, Product Manual, Patient Identification Card, etc.), patients with embolization coils used for cerebral aneurysms or AVMs have safely undergone MRI examinations, including those performed using MR systems operating at 3-Tesla. Notably, there has never been an adverse event reported in association with performing MRI exams in patients with these implants.

The standard policy that MRI labeling information is required before allowing the use of MRI in patients with embolization coils used for cerebral aneurysms or AVMs limits access to this important diagnostic imaging modality for those patients for which labeling information is unavailable. Taking into account the peer-reviewed literature and other related information (1-7), it is acceptable to perform MRI examinations in patients with all embolization coils used for cerebral aneurysms or AVMs by following specific guidelines developed by considering the primary safety concerns (i.e., magnetic field-related force, torque, RF-induced heating) for these implants.

**Guidelines:** A patient with embolization coils used for cerebral aneurysms or AVMs may undergo MRI using the following guidelines:

- 3-Tesla or less
- No restriction on the direction of the static magnetic field
- No restriction on the value of the spatial gradient magnetic field
- For embolization coils located *inside* of the area of the transmitted RF energy, use a whole-body averaged specific absorption rate (SAR) of 2-W/kg (i.e., operating the MR system in the Normal Operating Mode)
- For embolization coils located entirely *outside* of the area of the transmitted RF energy, a whole-body averaged specific absorption rate (SAR) of 4-W/kg (i.e., operating the MR system in the First Level Controlled Operating Mode) may be used
- Maximum imaging time, 15 minutes per pulse sequence, multiple pulse sequences are allowed

***Important Note:** The "*Guidelines for the Management of Patients with Embolization Coils Used for Cerebral Aneurysms or Arteriovenous Malformations Referred for MRI Examinations*" should only be implemented for use after the careful review by the supervising radiologist or other physician responsible for the MRI facility and with the adoption of the information as a written policy.

**Important Note:** Any deviation from the above MRI conditions requires prior approval by the supervising physician.

**Important Note:** These guidelines must be reviewed on an annual basis to confirm that no embolization coil used for the treatment of a cerebral aneurysm or an AVM has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe.

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