

Guidelines for Managing Patients with Heart Valve Prostheses and Annuloplasty Rings With Unknown Labeling Information Referred for MRI Procedures

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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 valve implants used in association with minimally invasive procedures] and annuloplasty rings (1-20).

MRI labeling information exists for many heart valve prostheses and annuloplasty rings. By following the pertinent MRI labeling information (i.e., presented in the Instructions for Use, Patient Identification Card, etc.), patients with heart valve prostheses and annuloplasty rings have safely undergone MRI examinations, including those performed at 1.5- and 3-Tesla (15, 20, 22). Notably, there has never been an adverse event reported in association with performing MRI in patients with these particular implants.

Unfortunately, the standard policy that MRI labeling information is required before allowing the use of MRI in a 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. However, in consideration of the relevant peer-reviewed literature and other related documents (1-22), it is acceptable and safe to perform MRI examinations in all patients with heart valve prostheses and annuloplasty rings by following specific guidelines developed by taking into consideration possible safety concerns (i.e., magnetic field interactions and MRI-related heating) for these implants.

Notably, by adhering to these admittedly conservative MRI conditions, all patients with heart valves and annuloplasty rings can benefit from the diagnostic imaging information provided by one of the most important noninvasive imaging modalities.

Guidelines. The following guidelines apply to using MRI in all patients with heart valve prostheses and annuloplasty rings, including those that have unknown labeling information:

(1) Patients with all commercially available heart valve prostheses and annuloplasty rings can be scanned at 1.5-Tesla/64-MHz or 3-T/128-MHz, regardless of the value of the spatial gradient magnetic field.

(2) Patients with all commercially available heart valve prostheses and annuloplasty rings can undergo MRI immediately after placement of these implants.

(3) The MRI examination must be performed using the following parameters:

- 1.5-Tesla or 3-Tesla, only
- Whole body averaged specific absorption rate (SAR) of 2-W/kg, operating in the Normal Operating Mode for the MR system
- Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient are allowed)

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

Important Note: These guidelines must be reviewed on an annual basis to confirm that no new 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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