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

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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 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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