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

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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.

References

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