Magnetic Resonance Imaging (MRI) Safety Information for UOC Implants

Magnetic Resonance Imaging (MRI) is a commonly accepted and widely used diagnostic medical procedure. UOC has performed testing according to ASTM standards to identify the level of safety of UOC implants in the MR environment.
The MR environment includes the static magnetic field (1.5 & 3.0 Tesla most common), the spatial gradient of the static magnetic field, and the radio frequency (RF) field (1.5-T/64MHz & 3.0-T/128Mhz). Each of these fields interacts with implants in different ways, producing medical device concerns. These concerns include: magnetic field interactions (including magnetically induced displacement and torque) on the implant, MR induced image artifacts, and RF induced currents resulting in heating.

1. Magnetic Field Interactions

UOC metallic implants may include the following non-ferromagnetic materials: Titanium Alloys (Ti-6Al-4V), Titanium, and Cobalt Chrome Molybdenum (CoCrMo). The non-ferromagnetic components preformed the test pointed out that magnetic field interactions (including magnetically induced displacement and torque) were acceptable.

2. Imaging Artifacts

Using the MR scanner may cause imaging artifacts, however these artifacts do not compromise patient safety. Thus, imaging artifacts are not considered a performance risk. Testing was carried out to characterize these artifacts and determine to what extent these artifacts will affect image quality.
Surgeons should warn patients with metallic implants of the potential risks of undergoing a MRI scan. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, implant damage or malfunction, or other undesirable effects.

3. RF-Induced Heating Interactions

The interaction between RF field of the MR and metallic component's geometry caused a concern of inducing heating. In particular, elongated features can form a resonance antenna, resulting in internal heating. UOC implants were evaluated to determine the extent of induced heating and temperature rises were found to be acceptable.

Precautions: The above mentioned test relies on nonclinical testing however the actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:
- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- It is suggested that patients with impaired thermoregulation or temperature sensation should be excluded form MR scanning procedures.
- Typically, under a low field strength is a preferable condition in the presence of conductive implants and reduce the specific absorption rate (SAR) as low as possible.
- In order to further decrease the temperature increased in the body, choosing the ventilation system may be a method.

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Metallic Hip Implants

Information for the use of MRI procedures pertains to MRI systems under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) and 3.0-Tesla (3.0T)
- Maximum Spatial gradient field of 5,100-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/Kg (Normal Operating Mode) for 15 minutes

Torque and Displacement according to ASTM F2213 and ASTM F2052
Testing of a worst case scenario indicated no known risks of magnetically induced displacement force or torque. The maximum deflection angle was measured to be 5° or less in the 3.0T MRI System.

Image Artifacts according to ASTM F2119
In non-clinical testing of a worst case scenario, the image artifact caused by the device extends approximately 91.1mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

MR Heating according to ASTM F2182
Non-clinical testing of a worst case scenario was performed and yielded the following:
1.5T MR system
64 MHz, Intera, Software: Release 12.6.1.4 2012-05-22, Quadrature body integrated transmit-receive coil, Philips Medical Systems (PMS), Best, The Netherlands. Horizontal static magnetic field, actively shielded.

- A temperature rise of 12.4°C or less was measured at a whole-body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of continuous scanning.

3.0T MR system
128MHz, Magnetom Trio, Software: Numaris/4 syngo MR B17, Whole body transmit-receive coil, Siemens Medical Solutions, Erlangen, Germany. Horizontal static magnetic field, actively shielded

- A temperature rise of 9.6°C or less was measured at a whole-body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of continuous scanning.

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