MRI Safety Information & Parameters for Smith & Nephew Orthopaedics AG Knee Implants
Summary

All knee implants of Smith & Nephew Orthopaedics AG are considered MR conditional and can be scanned safely if the following criteria are met.

TC-PLUS Knee Systems (1)
- static magnetic field of 1.5 or 3 T, with
- spatial gradient field of 95 T/m (value extrapolated) or less
- spatial gradient field product of 178 T²/m (value extrapolated) or less
- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of
  < 0.5 W/kg at 1.5 Tesla (local SAR < 2.1 W/kg)
  < 0.2 W/kg at 3 Tesla (local SAR < 1.6 W/kg)
for 15 minutes of continuous MR scanning
(15 minutes duration given due to recommendations in ASTM F2182)
A temperature increase limit of 2°C was used for extrapolation of “estimated WBA SAR” and “recommended local SAR” based on in vitro test results.

RT-PLUS and RT-PLUS Modular Knee Systems (2)
- static magnetic field of 1.5 or 3 T, with
- spatial gradient field of 41 T/m (value extrapolated) or less
- spatial gradient field product of 99 T²/m (value extrapolated) or less
- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of
  < 0.2 W/kg at 1.5 Tesla (local SAR < 0.9 W/kg)
  < 0.1 W/kg at 3 Tesla (local SAR < 1.0 W/kg)
for 15 minutes of continuous MR scanning
(15 minutes duration given due to recommendations in ASTM F2182)
A temperature increase limit of 2°C was used for extrapolation of “estimated WBA SAR” and “recommended local SAR” based on in vitro test results.
Background

Magnetic resonance imaging (MRI) is an imaging technique used in medical settings to produce high quality images of the inside of the human body. MRI is based on the principles of nuclear magnetic resonance, a spectroscopic technique to obtain microscopic chemical and physical information about molecules (3).

MRI can be used as a powerful diagnostic tool for disease and injury detection throughout the body. In orthopaedics, MRI is a source of accurate information about the structure of the joints, soft tissues as well as bones.

Patients with metallic implants can experience adverse effects from the electromagnetic field or radio frequency pulses used for MRI e.g. excessive MRI-related heating.

The definitions of MR safety (ASTM F2503) are the following:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR Safe</td>
<td>An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic and nonmagnetic.</td>
</tr>
<tr>
<td>MR Conditional</td>
<td>An item with demonstrated safety in the MR environment within defined conditions.</td>
</tr>
<tr>
<td>MR Unsafe</td>
<td>An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.</td>
</tr>
</tbody>
</table>

Tested products

A knee system contains at least a femoral component, a tibial component and a tibial insert. Some knee systems contain additional components.

All knee implant components from Smith & Nephew Orthopaedics AG were considered for the tests.

The defined worst case combinations were non-clinically tested for radio frequency heating (RF heating) in a MR environment according to ASTM F2182. Before testing mechanically, a computer simulation defined the worst case systems for RF heating.

Furthermore, the implants were non-clinically tested for magnetically induced displacement force (ASTM F2052) and torque (ASTM F2213) and image artifacts (ASTM F2119).

Field strengths of 1.5 T and 3 T were taken into consideration for the tests.
Results

Non-clinical testing has demonstrated that all knee implants of Smith & Nephew Orthopaedics AG are MR conditional. The conditions for MR scanning of Smith & Nephew Orthopaedics AG knee implants are listed in the summary above.

MR conditional Smith & Nephew Orthopaedics AG knee implants may cause image artifacts.

MR image artifacts may distort the visualisation of the area surrounding the implant surface as follows.

**TC-PLUS Knee Systems (1)**

<table>
<thead>
<tr>
<th>Largest artifacts of</th>
<th>Spin Echo</th>
<th>Gradient Echo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.5 T</td>
<td>3 T</td>
</tr>
<tr>
<td>Test object length</td>
<td>44.5 mm</td>
<td>53.1 mm</td>
</tr>
<tr>
<td>Test object width</td>
<td>107.3 mm</td>
<td>67.6 mm</td>
</tr>
</tbody>
</table>

(object long axis parallel to the main magnetic field $B_0$)

**RT-PLUS and RT-PLUS Modular Knee Systems (2)**

<table>
<thead>
<tr>
<th>Largest artifacts of</th>
<th>Spin Echo</th>
<th>Gradient Echo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.5 T</td>
<td>3 T</td>
</tr>
<tr>
<td>Test object length</td>
<td>83.5 mm</td>
<td>40.7 mm</td>
</tr>
<tr>
<td>Test object width</td>
<td>119.05 mm</td>
<td>71.1 mm</td>
</tr>
</tbody>
</table>

(object long axis parallel to the main magnetic field $B_0$)

The width was measured in direction of the worst artifact across the centre of the test object. The length was measured parallel to the test object long axis. The given values represent the artifact extension from the surface of each side of the implant. For example, when imaged with a spin echo pulse sequence and a 1.5 T MRI system, the image artifact caused by the TC-Plus Knee System extends approximately 44.5 mm from the implant in the direction of its long axis.
SAR values should be kept as low as possible in order to minimize any risk for the patient. Before each individual MR scan it might be necessary to discuss the situation with regard to patient benefit, consulting medical experts and MR physicists.

Smith & Nephew Orthopaedics AG

This safety information applies to TC-PLUS and RT-PLUS product groups.