Summary

All hip implants of Smith & Nephew Orthopaedics AG are considered MR conditional and can be scanned safely if the following criteria are met (1).

- static magnetic field of 1.5 or 3 T, with
- spatial gradient field of 14 T/m (value extrapolated) or less
- spatial gradient field product of 39 T^2/m (value extrapolated) or less
- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of
  - < 0.3 W/kg at 1.5 T (local SAR < 0.9 W/kg)
  - < 0.2 W/kg at 3 T (local SAR < 1.3 W/kg)

(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.

In combination with a Polarcup™ the following restrictions apply additionally to the general criteria mentioned for hip implants:

- spatial gradient field of 9.3 T/m (value extrapolated) and less
- spatial gradient field product of 18.9 T^2/m (value extrapolated) and less
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 (2).

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.

Tested products

A hip system contains a stem, a ball head, a cup and an insert. The material composition might vary for each component, depending on combination options.

All hip 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.

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

MR Safe is 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.

MR Conditional is an item with demonstrated safety in the MR environment within defined conditions.

MR Unsafe is an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

2 The Basics of MRI © 1996-2013 J.P. Hornak
Results

General notice: The whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR generally displayed by the scanner’s software.

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

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

MR image artifacts may distort the visualisation of the area surrounding the implant as follows [1].

<table>
<thead>
<tr>
<th>Largest artifacts of</th>
<th>Spin Echo 1.5 T</th>
<th>Spin Echo 3 T</th>
<th>Gradient Echo 1.5 T</th>
<th>Gradient Echo 3 T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test object length</td>
<td>71.8 mm</td>
<td>97.4 mm</td>
<td>87.0 mm</td>
<td>67.5 mm</td>
</tr>
<tr>
<td>Test object width</td>
<td>104.0 mm</td>
<td>119.7 mm</td>
<td>117.7 mm</td>
<td>119.1 mm</td>
</tr>
</tbody>
</table>

[object long axis parallel to the main magnetic field B0]

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 Hip System extends approximately 71.8 mm from the implant in the direction of its long axis.

[1 TR0411210-9a Marking Draft Hip Implant System]
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 the following product groups:

- ADR
- BICON-PLUS
- Ceramic Ball Heads and Metal Ball Heads
- CPS-PLUS
- CS-PLUS and CSL-PLUS
- EP-FIT PLUS
- Fracture Head and Bipolar Prosthesis
- Geradschaft-PLUS
- HI
- IPA
- MODULAR-PLUS
- MPF
- POLARCUP
- POLARSTEM
- SBG
- SL-PLUS, SLR-PLUS and SL-PLUS MIA

Manufacturer
Smith & Nephew Orthopaedics AG
Oberneuhofstrasse 10d
6340 Baar
Switzerland

www.smith-nephew.com

©2017 Smith & Nephew.