

A black and white photograph of a person running on a dirt path, seen from behind. The person is in mid-stride, with their right leg forward and arms pumping. The background shows a dirt road leading into a field of tall grass under a cloudy sky. A thin orange line with a small circle at the end points from the text 'Shoulder Implants' to the runner's right shoulder.

Shoulder Implants

**MRI Safety Information & Parameters  
for Smith & Nephew Orthopaedics AG  
Shoulder Implants**

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## Summary

All shoulder 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 41 T/m (value extrapolated) or less
- spatial gradient field product of 107 T<sup>2</sup>/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 < 0.8 W/kg)
  - < 0.2 W/kg at 3 Tesla (local SAR < 1.4 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 (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.

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.

## Tested products

A shoulder system comprises several components, for example a standard shoulder system comprises a stem, a body, an inclination set, a humeral head, and a glenoid. The material composition might vary for each component, depending on combination options.

All shoulder 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.

Tests for magnetically induced displacement force (ASTM F2052) and torque (ASTM F2213) and image artefacts (ASTM F2119) were not performed for the shoulder implants. A rationale related to the hip implants provides evidence for safe scanning (1).

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

1 TR0051-6 Marking Draft Shoulder Systems  
2 The Basics of MRI © 1996-2013 J.P. Hornak

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## 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 shoulder implants from Smith & Nephew Orthopaedics AG are MR conditional. The conditions for MR scanning of Smith & Nephew Orthopaedics AG shoulder implants are listed in the summary above.

MR Conditional Smith & Nephew Orthopaedics AG shoulder implants may cause image artifacts.

MR image artifacts may distort the visualisation of the area surrounding the implant as follows (1).

Largest artifacts of	Spin Echo		Gradient Echo	
	1.5 T	3 T	1.5 T	3 T
Test object length	71.8 mm	97.4 mm	87.0 mm	67.5 mm
Test object width	104.0 mm	119.7 mm	117.7 mm	119.1 mm

(object long axis parallel to the main magnetic field B<sub>0</sub>)

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

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# Notes

A series of horizontal dotted lines for taking notes.





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:

PROMOS Primary

PROMOS Reverse

PROMOS Resurfacing

**Manufacturer**

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