MRI Safety Information and Parameters for Smith & Nephew Orthopaedics AG Hip Implants

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Summary

All hip implants of Smith & Nephew Orthopaedics AG are considered MR conditional and the following criteria must be met:

- **Static magnetic field of 1.5 T or 3.0 T**
- **Maximum spatial field gradient of 1'400 G/cm (14 T/m)**
- **Maximum MR system reported whole body averaged specific absorption rate (SAR) of**
  0.3 W/kg at 1.5 T
  0.2 W/kg at 3.0 T

Under the scan conditions defined above the Smith & Nephew hip systems are expected to produce a maximum temperature rise of less than 2.0°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 120mm from the hip system when imaged with a spin echo or gradient echo pulse sequence and a 3.0 T MRI system.

The table below provides an overview of MR conditional device combinations. Combinations of devices within the same box can be scanned safely.

Femoral Stems	Femoral Heads	Acetabular Cups	Accessories
POLARSTEM®[1] SL-PLUS®[1] SLR-PLUS®[1] SL-PLUS® MIA[1] SYNERGY®[2] ECHELON®[2] REDAPT®[2] SPECTRON®[2] CPCS[2] ANTHOLOGY®[2] SMF®[2] CONQUEST®[2] NANOS®[3]	OXINIUM®[2] CoCr[1,2] Stainless Steel[1,2] BIOLOX® Forte[1,2] BIOLOX® Delta[1,2] BIOLOX® Option[1] TANDEM® Bipolar[2] TANDEM® Unipolar[2] Bipolar Prosthesis[1] Fracture Head[1]	POLARCUP®[1] HI[1] REDAPT[2] R3®[2] REFLECTION®[2] CONTOUR®[2]	Titanium Modular Head Sleeve for CoCr/OXINIUM heads[2] ACCORD® Cable System[2]
POLARSTEM[1] SL-PLUS[1] SLR-PLUS[1] SL-PLUS MIA[1] ADR[1] CPS-PLUS[1] CS-PLUS[1] CSL-PLUS®[1] Geradschaft-PLUS[1] IPA[1] MODULAR-PLUS®[1] SBG[1]	OXINIUM[2] CoCr[1,2] Stainless Steel[1,2] BIOLOX® Forte[1,2] BIOLOX® Delta[1,2] BIOLOX® Option[1] Bipolar Prosthesis[1] Fracture Head[1]	POLARCUP[1] BICON-PLUS®[1] EP-FIT PLUS®[1] HI[1] MPF[1]	

Manufacturer:
1. Smith & Nephew Orthopaedics AG, Baar, Switzerland

For the following two Manufacturers, the instructions for use of these devices may allow additional combinations or different scanning parameters not covered here. However, the stricter scanning parameters should always be followed.

2. Smith & Nephew, Inc., Memphis, USA
3. OHST Medizintechnik AG, Rathenow, Germany

Important: This table does not represent information about what devices combinations can be safely implanted. Please, refer to the instructions for use of the respective product.

Caution: Combinations with other devices, which are not approved by Smith & Nephew, have not been evaluated for safety and compatibility in the MR environment. These combinations have not been tested for heating, migration, or image artefact in the MR environment. The safety of such a combination in the MR environment is unknown. Scanning a patient who has a combination with other devices may result in patient injury. Therefore, a combination with implants which are not approved by Smith & Nephew has to be declared as MR unsafe.

Smith & Nephew sales representatives can be contacted for further information.

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.

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 including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields

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

Tested products

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

All hip implant components from Smith & Nephew Orthopaedics AG and compatible hip implants were considered as part of 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 3.0 T were taken into consideration for the tests.

Results

General notice: The whole body or head averaged (WBA) 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.

Largest artifacts of	Spin Echo		Gradient Echo	
	1.5 T	3.0 T	1.5 T	3.0 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_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 Hip System extends approximately 71.8 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.

This safety information applies to the following product groups and compatible hip implants:

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
BIOLOX® OPTION

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