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

smith&nephew

Supporting healthcare professionals for over 150 years

Summary

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

- **Static magnetic field of 1.5 T and 3.0 T**
- **Maximum spatial field gradient of 4'100 G/cm (41 T/m)**
- **Maximum MR system reported whole body averaged specific absorption rate (SAR) of**
  1.0 W/kg at 1.5 T
  0.6 W/kg at 3.0 T

Under the scan conditions defined above the Smith & Nephew knee systems are expected to produce a temperature rise of max. 4.0°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 126mm from the knee system when imaged with a spin echo or gradient echo pulse sequence and a 3.0 T MRI system.

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 has 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 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

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 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

Largest artifacts of	Spin Echo		Gradient Echo	
	1.5 T	3 T	1.5 T	3 T
Test object length	44.5 mm	53.1 mm	88.1 mm	95.5 mm
Test object width	107.3 mm	67.6 mm	99.3 mm	113.2 mm

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

RT-PLUS◇ and RT-PLUS Modular Knee Systems

Largest artifacts of	Spin Echo		Gradient Echo	
	1.5 T	3 T	1.5 T	3 T
Test object length	83.5 mm	40.7 mm	88.7 mm	52.6 mm
Test object width	119.1 mm	71.1 mm	121.8 mm	125.4 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 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.

Notes

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

Manufacturer
Smith & Nephew Orthopaedics AG
Theilerstrasse 1A
6300 Zug
Switzerland

www.smith-nephew.com

08558-en V4 (2184) 11/24

Supporting healthcare professionals for over 150 years