

TO WHOM IT MAY CONCERN

Statement concerning MRI safety of Mathys implants

Bettlach, March 19th, 2009

a) Ferromagnetic objects:

Ferromagnetic objects can develop strong magnetic forces in a magnetic field and therefore might represent a risk for the patient.

Mathys hip, knee and shoulder implants are made of Titanium, Titanium alloys and CoCrMo alloys as well as stainless steel. All these materials contain hardly any ferromagnetic material.

Therefore, there is no risk for the patient.

b) Formation of artefacts:

It is generally known that stainless steel produces artefacts during an MRI-examination. The exact place of examination relatively to the bone and the implant is crucial for a better or worse imaging quality.

c) Heating of implants:

MRI examination might lead to heating of some materials. However, several studies have shown that heating of implants is nearly unmeasurable.



Guri-Grit Liebezeit
Head of Regulatory Affairs

To our customers

Bettlach, 19.08.09

Statement Regarding Routine MRI Examination of Patients with Orthopedic Hip, Knee, Shoulder or Finger Joint Replacements

Mathys AG Bettlach and independent research institutes examined and evaluated possible risks and side effects during a routine MRI examination, for patients who carry orthopedic joint replacements. For the manufacture of joint prostheses, Mathys AG Bettlach exclusively employs materials, which are considered to be MRI-safe, due to in-vitro tests and under the following conditions:

- static magnetic field strength ≤ 3 Tesla
- dynamic electromagnetic gradient field ≤ 720 Gauss/cm
- SAR (whole-body-averaged specific absorption rate) during 15 min ≤ 3 W/kg

Should you experience any MRI protocol deviations from the above, please contact us for further clarifications.

Mathys AG Bettlach



Gerald Barth
Director Marketing and Development