

Statement

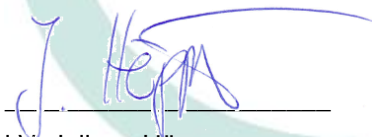
An external magnetic field can have different effects on an implant in the body. A strong electromagnetic field, as it is the case with MRI, can heat the materials used, which can eventually damage the tissue surrounding the endoprosthesis by hyperthermia. Additionally, implants can loosen due to its movement within the magnetic fields, which is particularly the case when ferromagnetic materials are used. However, this is rarely observed with well-integrated endoprostheses.

implantcast has not investigated the effects of MRI fields on its implants and MRI examinations of implants with large surfaces and with a statistically significant number are not available. Available literature indicates that the metals and their alloys used for the implants of implantcast are either paramagnetic or slightly ferromagnetic, such as TiAl6V4 acc. to ISO 5832-3, TiAl6Nb7 acc. to ISO 5832-11, commercially pure Titanium (cpTi) acc. to ISO 5832-2 or CoCrMo acc. to ISO 5832-4. All materials are standard materials for orthopedic implants and are recommended for use by ISO 21534 *“Non-active surgical implants - Joint replacement implants - Particular requirements”*.

Sommer et al.¹ describe, that in studies with MRI systems using a magnetic flux density of 1,5 T the aforementioned metals can be regarded as “safe”.

Since implantcast components have not been evaluated for safety and compatibility in the MR environment no respective claims or clearances are made in the respective IFU's.

implantcast

A handwritten signature in blue ink, appearing to read 'J. Höppner', written over a horizontal line.

i.V. Juliane Höppner

Team Leader Regulatory Affairs

¹ Sommer T., Maintz D., Schmiedel A., Hackenbroch M., Hofer U., Urbach H., Pavlidis C., Träger F., Schild H., Höher M.: Hochfeld-Magnetresonanztomographie: Magnetische Anziehungs- und Rotationskräfte auf metallische Implantate bei 3,0 T. Fortschr Röntgenstr 2004; 176: 731-738 © Georg Thieme Verlag Stuttgart · New York, DOI 10.1055/s-2004-812754.