MANUFACTURER'S STATEMENT

M-MRI-001 R01

MEDIN, a.s.

Vlachovická 619, 592 31 Nové Město na Moravě, Czech Republic

As a manufacturer of medical devices, MEDIN, a.s. issues this statement concerning magnetic resonance imaging (MRI) examinations of patients with implanted MEDIN osteosynthesis implants.

For the purposes of this statement, MEDIN osteosynthesis implants are non-active implantable medical devices intended for osteosynthesis, in particular plates, intramedullary nails, screws, wires and other implantable components of these systems.

The safety of these implants in the magnetic resonance (MR) environment is assessed as part of device risk management and clinical evaluation, using available scientific and clinical data and post-market surveillance data.

The available scientific literature reports low levels of magnetically induced displacement and heating for comparable non-active osteosynthesis implants made of implant-grade stainless steel and titanium alloys at magnetic field strengths commonly used in clinical practice. The published studies include, among other devices, plates, screws, intramedullary implants and larger osteosynthesis constructs.

The guidance document issued by the MRI Section of the Czech Radiological Society of the Czech Medical Association of J. E. Purkyně (ČLS JEP) lists osteosynthesis material that has been implanted for six weeks or more and shows no signs of loosening among implants for which MRI is generally not contraindicated. At the same time, it emphasises the need for an individual assessment of each case.

Based on the above, MEDIN, a.s. does not consider the presence of a properly fixed MEDIN osteosynthesis implant six weeks or more after implantation, with no signs of loosening, to constitute, in itself, a contraindication to magnetic resonance imaging at magnetic field strengths of up to 3 T.

The suitability of a specific MRI examination is determined by the referring physician in consultation with the MRI facility, based on the patient's clinical condition and identification of the implant.

This statement does not apply to other types of MEDIN implants manufactured in the past, in particular vascular, neurosurgical or other implants that are not orthopaedic or trauma osteosynthesis implants. If there is any uncertainty regarding the identification, material or design of a specific implant, MEDIN, a.s. must be contacted.

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