

DECLARATION

OF COMPATIBILITY WITH MAGNETIC RESONANCE IMAGING (MRI) OF IMPLANTS MANUFACTURED BY CHM AND MADE OF: TITANIUM, TITANIUM ALLOYS AND COBALT ALLOYS

GENERAL INFORMATION

Due to the fact that over the years several generations of devices for magnetic resonance studies have been produced by different manufacturers, one should be absolutely familiar with the contraindications and warnings established by MRI manufacturer, on which the study is to be performed.

MR imaging may be interfered if the area of interest is in the exact same area or relatively close to the position of the implant.

The MRI procedure should not be performed if tissue integrity in the implantation site and fixation stability of the implant are questionable.

Detailed information regarding MRI compatibility with specific implants is presented in the product Instructions for Use.

MRI COMPATIBILITY OF IMPLANTS

For implants made of implantable titanium (in accordance with ISO 5832-2/ASTM F67), titanium alloys (in accordance with ISO 5832-3/ASTM F136, ISO 5832-11/ASTM F1295) and cobalt alloys (in accordance with ISO 5832-12/ASTM 1537) there are no general contraindications against carrying out the magnetic resonance imaging studies.

Titanium and its alloys, and cobalt alloys are widely used as materials for long-term orthopedic implants. Due to their non-ferromagnetic properties, implants made of those alloys are recognized as MR *Conditional 8*¹.

Numerous, non-clinical studies² carried out for different types of implants made of: titanium, titanium alloys, cobalt alloys confirmed that these materials are safe and compatible with MRI procedures.

Approved by:

Zbigniew Murawski

08.03.2021


R&D Director

ChM

ChM sp. z o.o.

DYREKTOR DS. | Zbigniew
BADAŃ I ROZWOJU | Murawski

¹ Terminology defined by the American Society for Testing and Materials (ASTM) and utilized by FDA refers to MR conditional as an item that has been demonstrated to pose no known hazards in specified MRI conditions of use. In particular it means that a patient with device determined to be MR conditional 8 can be scanned safely under the following conditions:

- static magnetic field of 1.5-Tesla and 3-Tesla, only,
- maximum spatial gradient magnetic field of 720-Gauss/cm or less,
- maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2W/kg for 15 minutes of scanning.

Devices tested under these conditions produced temperature rise of less than or equal to 3 Celsius degrees..

² F. G. Shellock. Reference Manual for Magnetic Resonance Safety, Implants, and Devices. 2015 edition, p. 367-369, 413-422, 617-635.