

MRI safety information

Instructions for use THM61157



MR Conditional

Non-clinical tests and MRI simulations have been conducted for the assessment of the Thommen Medical implant system. The non-clinical tests showed that Thommen Medical products are conditionally MRI safe (MR conditional). Patients with a dental implant and screwed-on abutment from the Thommen Medical implant system can be scanned safely in an MRI system under the following conditions:

General criteria

It is recommended to take out any removable restorations before an MRI scan. The patient's tongue must be kept as far away from the teeth as possible during the MRI scan.

- Static magnetic field strength: 1.5 or 3 T (Tesla)
- Cylindrical bore
- Horizontal magnetic field (B0)

Maximum spatial field gradient

- 1.5 T: 61.07 T/m (6107 Gauss/cm)
- 3 T: 30.54 T/m (3054 Gauss/cm)

High frequency (HF) and radio frequency (RF) field exposure:

- RF excitation: Circularly polarized (CP) or multichannel-2 (MC-2)
- RF transmitter coil: A whole body transmitter coil or any local transmitter coil can be used, apart from head coils
- HF receiver coil type: Any receiver coil can be used
- Maximum permitted whole-body average specific absorption rate (SAR): In normal operating mode 2 W/kg
- Scan duration and wait time: Maximum 1 hour of continuous scanning.

HF heating

Under the specified conditions, the maximum increase in temperature in a dental implant with a screwed-on abutment from Thommen Medical after 15 minutes continuous scan duration:

- at 3 T: less than 3.7°C
- at 1.5 T: less than 3.3°C

Image artifacts in the 1.5 T system

Under the specified conditions, image artifacts can be caused by dental implants with a screwed-on abutment from Thommen Medical. Image artifacts occur around the dental implant construction in a radius of approximately 30 mm due to the use of a gradient echo sequence. Image artifacts in a radius of about 26 mm are to be observed with a spin-echo pulse sequence.

Disclaimer

Because of the great variety of commercially available MRI devices, Thommen Medical can make no predictions about the safety or behavior of implants and components in any specific MRI system. Furthermore, Thommen Medical cannot accept any responsibility for the composition and behavior of products made by other manufacturers (including crowns, bridges, bars, prostheses, etc.). Products, which have not been manufactured by Thommen Medical, may contain materials which are not compatible with an MRI imaging procedure.



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