

OSSDSIGN® Cranial MR CONSIDERATIONS

BACKGROUND

Magnetic Resonance (MR) is a common medical imaging method during which a patient is placed in a strong magnetic field. It is being used for diagnostic as well as medical follow-up and has applications in many medical areas.

MR has a very good safety record with more than 50 million scans performed worldwide every year, and the most frequently reported complications are related to external objects accidentally being drawn into the magnetic field. However, MR can constitute a safety risk to patients with certain implant devices. Within the magnetic field, these devices can potentially move, experience force and torque effects and generate heat due to conductivity.

OSSDSIGN CRANIAL PSI

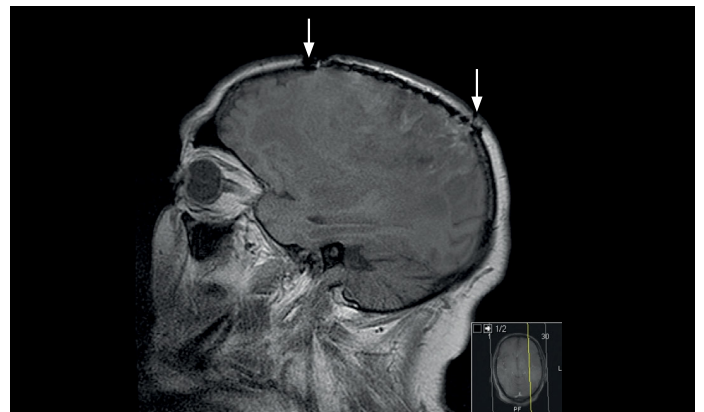
OSSDSIGN Cranial PSI is partially made from titanium, a material that is non-magnetic but may heat when subject to a strong magnetic field. Non-clinical testing and in-vivo electromagnetic stimulations demonstrate that OSSDSIGN Cranial PSI is MR Conditional. A patient with this device can be scanned safely in an MR system after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla or 3 Tesla
- Maximum spatial gradient of 3000 Gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) and head average SAR of <3.2 W/kg (Normal Operating Mode).
- Body coil only, do not use head transmit/receive coil.
- Quadrature transmit coils only.

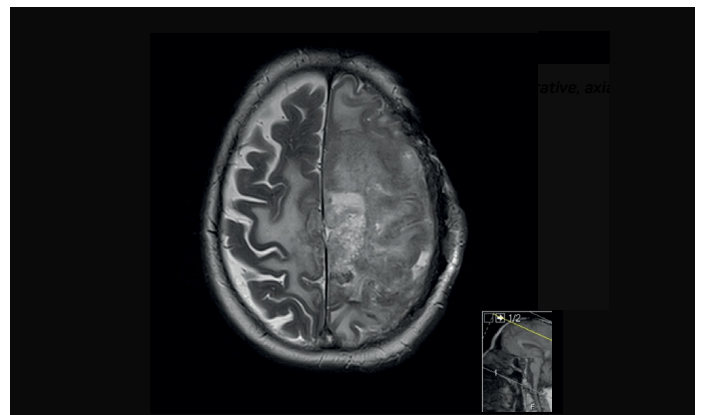
Under the scan conditions defined above, OSSDSIGN Cranial PSI is expected to produce a maximum temperature rise of 2°C after 15 minutes of continuous scanning.

ARTIFACT INFORMATION

In non-clinical testing, the image artifact caused by OSSDSIGN Cranial PSI extends approximately 7 mm from the implant when imaged using a gradient echo pulse sequence and a 3 Tesla MR system.



MRI postoperative, sagittal. Arrows indicate OSSDSIGN Cranial implant border.



MRI postoperative, axial middle.

Always read the Instructions for Use which accompany the product for indications, contraindications, warnings and precautions.