

MR considerations

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, 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 implanted devices. These may move if they are magnetic, sustain damage from the applied fields, or heat if they incorporate electrically conducting materials.

OSSDSIGN® Cranial 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 the OSSDSIGN® Cranial PSI is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after implantation under the following conditions:

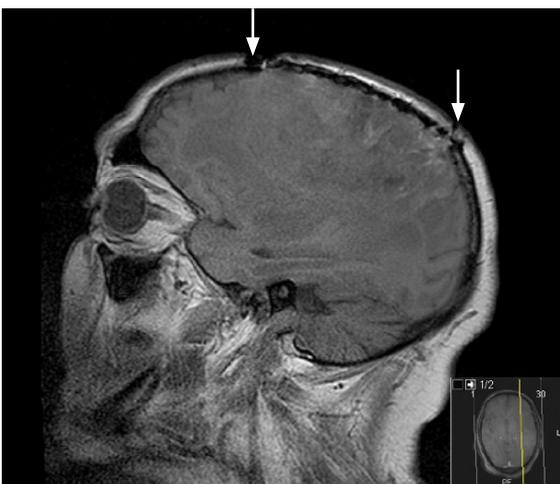
- Static magnetic field of 1.5 Tesla or 3 Tesla
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less.
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 2 W/Kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR System.

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

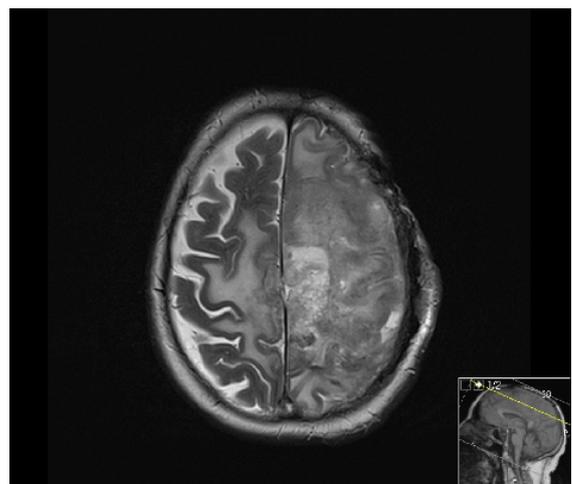
Warning: Do not use head coil at MRI procedures.

Artifact information

In non-clinical testing, the image artifact caused by the 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.