



- Maximum spatial gradient magnetic field of 3,000 Gauss / cm or less
- First Operating Level Controlled Operating Mode, whole body averaged SAR of 4-W / kg for 15 minutes of scanning (i.e., per pulse sequence)

### MRI-Related Heating

In non-clinical testing, the CranioFix®2 System produced the following temperature rises during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in 1.5-Tesla / 64 MHz (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris / 4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3-Tesla (3-Tesla / 128 MHz, Excite, HDx, Software 14X, M5, General Electric Healthcare, Milwaukee, WI).

MR Systems:

	1.5-Tesla	3-Tesla
First Level Controlled Operating Mode, scaled to whole body averaged SAR of 4-W / kg, highest temperature change	+2.6°C	+2.8°C

These temperature changes will not pose a hazard to a human subject under the conditions indicated above.

### Artifact Information:

The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5 mm relative to the size and shape of this implant.

## MRI SAFETY INFORMATION

 MR Conditional

### The CranioFix®2 Titanium Clamps are MR Conditional.

Non-clinical testing demonstrated that the CranioFix®2 System is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less



MR Conditional Pictorial is for reference only.

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