

CRANIOFIX and CRANIOFIX2 Systems

MRI SAFETY INFORMATION



MR Conditional

Non-clinical testing demonstrated that the CRANIOFIX2 System is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 3,000 Gauss/cm or less
- First Level Controlled Operating Mode, with a maximum whole-body averaged SAR of 4-W/kg

MRI-Related Heating

In non-clinical testing, the **CRANIOFIX2** System produced the following temperature rises during MRI performed for 15 min 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 Activeshielded, 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.

For MRI Safety Information, including artifact information, Warnings and Precautions see product [IFU SOP-AIC-5000564 \(TA011200\)](#).