CRANIOFIX and CRANIOFIX2 Systems

MRI SAFETY INFORMATION

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:

<table>
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<tr>
<th>First Level Controlled Operating Mode, scaled to whole body averaged SAR of 4-W/kg. highest temperature change.</th>
<th>1.5 Tesla</th>
<th>3 Tesla</th>
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<tr>
<td></td>
<td>+2.6°C</td>
<td>+2.8°C</td>
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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).