Hoffmann II MRI
Wallchart for Radiologists

Hoffmann II MRI
Hoffmann II Compact MRI
MRI Color Code Information
The MRI components have been tested according to ASTM Standards F2052, F2182, and F2213.

The color coding scheme illustrated below must be followed to ensure correct MRI usage.

The Hoffmann® II MRI System is designed for MRI use up to 3.0 Tesla. To ensure patient safety during MRI procedures and to distinguish the system from the standard Non-MRI Hoffmann® II System, the Hoffmann® II MRI is color-coded in GREEN.

MRI rods are YELLOW.

All MRI clamps, couplings, and tubes have GOLD headed bolts.

All MRI components are marked with “MRI”.

The Hoffmann® II MRI System can only be guaranteed for MRI use when using Stryker’s Apex® Pins to build a frame.
It has been shown by specific MRI tests that the Hoffmann® II MRI External Fixation System may be used for patients undergoing MRI procedures using up to 3.0 Tesla MR systems if certain specific conditions are followed.

Two commonly used frames have been tested for MRI use at 1.5 and 3.0 Tesla. The results are as follows:

<table>
<thead>
<tr>
<th>MR System</th>
<th>B&lt;sub&gt;max&lt;/sub&gt;</th>
<th>T&lt;sub&gt;max&lt;/sub&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5 Tesla</td>
<td>31.4 mT/cm</td>
<td>2.65°C at 2.0W/kg at a whole body average SAR for MR imaging time of 6 minutes</td>
</tr>
<tr>
<td>3.0 Tesla</td>
<td>70 mT/cm</td>
<td>2.34°C at 0.5W/kg at a whole body average SAR for MR imaging time of 6 minutes</td>
</tr>
</tbody>
</table>

In this testing, each of the frames shown above produced a temperature rise not greater than 3°C for a maximum MR imaging time of 6 minutes. Tests have been performed using MR systems from different suppliers. Please note that the Specific Absorption Rate (SAR) may be reported differently, e.g. as whole body averaged SAR or as partial SAR by the software depending on the MR system used.

Note: These tests have been performed in areas where the greatest temperature increase is expected with commonly used frames. Due to the versatility of the system, an unlimited number of frames can be built which makes it impossible to test each and every construct.

Based on the test results, the Hoffmann® II MRI may be used in MRI procedures under the specified conditions. There are factors that can influence these results like the number of pins used in the clamps and the number of open and closed loops in the frame. Therefore, it is recommended that each frame be evaluated by a radiologist or MR scientist before the MRI procedure to ensure patient safety. Since different frame configurations and frame sizes might lead to higher temperature increases, Stryker recommends for patient’s safety to minimize SAR settings as much as possible.

None of the components should move or migrate in the 1.5 or 3.0-Tesla MRI environments.

Non-clinical testing has not been performed to rule out the possibility of component movement or migration at static magnetic field strengths higher than 3.0 Tesla or maximum spatial gradients higher than 70.0 mT/cm.

MR image quality may be compromised if the area of interest is in the exact same area as or relatively close to the position of the frame or its individual components.

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1 Test Data on File at Stryker Trauma AG
**Technical Details - Hoffmann® II Compact™ MRI**

The MRI components have been tested according to ASTM Standards F2052, F2182, and F2213.

The color coding scheme illustrated below must be followed to ensure correct MRI usage.

<table>
<thead>
<tr>
<th>Hoffmann® II Compact™ MRI</th>
<th>Standard Hoffmann® II Compact™ (Non MRI Safe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI posts have a GOLD tip.</td>
<td>These products are ferromagnetic and/or conductive; therefore, they are not MRI Safe.</td>
</tr>
<tr>
<td>MRI rods are YELLOW.</td>
<td>These standard rods come in carbon and stainless steel. Do not mix them with the MRI System since they are not MRI Safe.</td>
</tr>
</tbody>
</table>

The Hoffmann® II Compact™ MRI is also designed for MRI use up to 3.0 Tesla. To ensure patient safety during MRI procedures and to distinguish the system from the standard Non-MRI Hoffmann® II Compact™ System, the Hoffmann® II Compact™ MRI is color-coded in ORANGE.

All MRI components are marked with “MRI”.

MRI rods are YELLOW.

The Hoffmann® II Compact™ MRI can only be guaranteed for MRI use when using Apex® Pins to build a frame.
It has been shown by specific MRI tests that the Hoffmann® II Compact™ MRI External Fixation System may be used for patients undergoing MRI procedures using up to 3.0 Tesla MR systems if certain specific conditions are followed.

Two standard wrist frames have been tested at 1.5 and 3.0 Tesla. The results are as follows:

### 3.0 Tesla MR System

- $B_{\text{max}}$: 70 mT/cm
- $\Delta T_{\text{max}}$: 1.55°C at 0.5W/kg at a whole body average SAR for MR imaging time of 6 minutes

In this testing, each of the frames shown above produced a temperature rise of less than 3°C for a maximum MR imaging time of 6 minutes. Tests have been performed using MR systems from different suppliers. Please note that the monitored Specific Absorption Rate (SAR) refers to the whole body averaged SAR or to the partial SAR depending on the software that is used.

**Note:**
These tests have been performed in areas where the greatest temperature increase is expected with commonly used frames. Due to the versatility of the system, an unlimited number of frames can be built which makes it impossible to test each and every construct.

Based on the test results, the Hoffmann® II Compact™ MRI may be used in MRI procedures under the specified conditions. There are factors that can influence these results like the number of pins used in the clamps and the number of open and closed loops in the frame. Therefore, it is recommended that each frame be evaluated by a radiologist or MR scientist before the MRI procedure to ensure patient safety. Since different frame configurations and frame sizes might lead to higher temperature increases, Stryker recommends for patient’s safety to minimize SAR settings as much as possible.

None of the components should move or migrate in the 1.5 or 3.0-Tesla MRI environments. Non-clinical testing has not been performed to rule out the possibility of component movement or migration at static magnetic field strengths higher than 3.0 Tesla or maximum spatial gradients higher than 70.0 mT/cm.

MR image quality may be compromised if the area of interest is in the exact same area as or relatively close to the position of the frame or its individual components.

1 Test Data on File at Stryker Trauma AG
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