To whom it may concern.

**MRI Safety Information for the Nit-Occlud® PDA device**


Non-clinical testing demonstrated that the Nit-Occlud® PDA coil 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
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- The maximum whole-body averaged specific absorption rate (SAR) shall be limited to 2.0 W/kg (normal operating mode only) for 15 minutes of scanning.

**MRI-Related Heating**

In non-clinical testing, the Nit-Occlud® PDA coil produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla/128-MHz, Excite, HDX, Software 14X.MS, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.6°C.

Therefore, the MRI-related heating experiments for the Nit-Occlud® PDA coil at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

**Artifact Information**

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Nit-Occlud® PDA coil. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. In non-clinical testing for different imaging sequences, the artifacts presented as signal voids of the following sizes:
<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>369 mm²</td>
<td>118 mm²</td>
<td>647 mm²</td>
<td>739 mm²</td>
</tr>
<tr>
<td>Plane Orientation</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

Kindest Regards,

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[Signature]

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