Dear Doctor,


Non-clinical testing demonstrated that the Essure Micro-insert 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

**MRI-Related Heating**

In non-clinical testing, the Essure Micro-insert produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla/128-MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukuee, WI) MR system:

Highest temperature change +1.7°C

Therefore, the MRI-related heating experiments for the Essure Micro-insert at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 3.0-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.8-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.7°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 Essure Micro-insert. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Dimensions: Wound-down and expanded length: 4-cm
Expanded diameter: 1.5 to 2.0-mm

<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>173-mm$^2$</td>
<td>53-mm$^2$</td>
<td>621-mm$^2$</td>
<td>277-mm$^2$</td>
</tr>
<tr>
<td>Plane Orientation</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>
In an effort to provide you with information on this topic, we performed a PubMed search and a search of our internal publication database. We retrieved 4 relevant references including original articles, reviews, case reports and abstracts which we have listed in the bibliography below. In addition, information on MRI safety is available on our website, www.essuremd.com, and is available as a pingback mrisafety@conceptus.com.

Sincerely,

Medical Affairs Department at Conceptus

Associated Bibliography for Essure and MRI Safety (3/30/12)


