

To	Memo to File
From	Conceptus Clinical Research & Regulatory Affairs Department
Re	Magnetic Resonance Imaging safety with Essure Micro-inserts in place

MEMO

MRI Information

The Essure Micro-insert was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

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, Milwaukee, 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

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	173-mm ²	53-mm ²	621 -mm ²	277-mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular