

Dear Doctor,

Thank you for your inquiry regarding the use of MRI with patients wearing Essure devices. 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, P0 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

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 mrissafety@conceptus.com.

Sincerely,

Medical Affairs Department at Conceptus

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

1. Correia L, Ramos AB, Machado AI, Rosa D, Marques C. Magnetic resonance imaging and gynecological devices. *Contraception*. 2011 Nov 29. [Epub ahead of print]
2. Wittmer, M. H. F., A.O.; Brown, D.L.; Hartman, R.P.; Kawashima, A.; King, B.F. (2006). "Sonography, CT, and MRI Appearance of the Essure Microinsert Permanent Birth Control Device." *AJR Women's Imaging* **187**: 959-964.
3. Muhler M, Taupitz M: How safe is magnetic resonance imaging in patients with contraceptive implants? *Der Radiologe* 2006, 46(7):574-578.
4. Shellock, F. G. (2002). "New metallic implant used for permanent contraception in women: evaluation of MR safety." *AJR Am J Roentgenol* **178**(6): 1513-1516.