

Cardia Ultrasept Closure Device

MRI Summary Statement



MR Conditional*

The Ultrasept was determined to be MR-conditional.*

Non-clinical testing demonstrated that the Ultrasept is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- 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 Ultrasept produced the following temperature rise during MRI performed for 15-min. of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.6°C

Therefore, the MRI-related heating experiments for the Ultrasept 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 Ultrasept. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e. as seen on the gradient echo pulse sequence) extends approximately 10-mm relative to the size and shape of the Ultrasept.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,710-mm ²	506-mm ²	2,132-mm ²	837-mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

***MR Conditional**—An item that has been demonstrated to pose no known hazards in a *specified* MR environment with specified conditions of use. Field conditions should be enumerated on the product, its packaging or in the enclosed literature. Additional conditions, including specific configurations of the item, may be required.