



W. L. GORE & ASSOCIATES, INC.

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MEDICAL PRODUCTS DIVISION

Dear Healthcare Professional:

As stated in the product labeling, the GORE® Septal Occluder was determined to be MR-conditional. Non-clinical testing demonstrated that the GORE® Septal Occluder 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 1.5-Tesla
- Maximum spatial gradient magnetic field of 720-Gauss / cm or less
- Maximum scanner displayed whole body averaged specific absorption rate (WB-SAR) of 3.0W / kg for 15 minutes of scanning

MRI-Related Heating

In non-clinical testing, the GORE® Septal Occluder produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla / 1 28-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 GORE® Septal Occluder 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 +1.6° 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 GORE® Septal Occluder. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

PULSE SEQUENCE	T1-SE	T1-SE	GRE	GRE
Signal Void Size	981 - mm ²	483 - mm ²	1,308 - mm ²	724 -mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Please contact me if you require further information. I can be reached at 928.864.2640 or at pzeller@wlgore.com.

Best regards,

Peter Zeller, PhD
Product Specialist