

ATRITECH, INC.

Magnetic Resonance Imaging

MRI Information. The WATCHMAN Left Atrial Appendage Device was determined to be MR-conditional (see 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, 19428, 2005).

Non-clinical testing demonstrated that the WATCHMAN Left Atrial Appendage Device is MR Conditional. A patient with the WATCHMAN Left Atrial Appendage Device can be scanned safely, immediately after placement of this implant, under the following conditions:

Static magnetic field of 3-Tesla or less

Spatial gradient field of 720-Gauss/cm or less

MRI-Related Heating. In non-clinical testing, the WATCHMAN produced the following temperature rise during MRI performed for 15-min in a 3-Tesla MR system (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI): Highest Temperature +1.6°C

Therefore, the MRI-related heating experiments for the WATCHMAN LAA Closure Device 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 average 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 same area or relatively close to the position of the WATCHMAN Left Atrial Appendage Device. Optimization of MR imaging parameters is recommended.