MRI Statement for the Optima™ Coil System

MRI COMPATIBILITY

Non-clinical testing and MRI simulations were performed to evaluate the entire family (i.e., available diameters and lengths) of the Optima Coil System. Non-clinical testing demonstrated that the entire family of these embolization coils is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence).

Under the scan conditions defined, the Optima Coil System is expected to produce a maximum temperature rise of 2.0°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Optima Coil System extends approximately 5-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system. In addition, the use of an MRA pulse sequence at 3T, using an echo time of 3.5ms, generated a signal void artifact of 3 mm from the edge of the coil.