



MRI Statement for the Barricade Coil System™

MRI COMPATIBILITY

The Barricade Coil System implant materials have been determined to be **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 **4000-Gauss/cm (40 Tesla/m) or less**
- Maximum MR system reported, whole body averaged specific absorption rate (**SAR**) of **2.9 W/kg for 15 minutes of scanning**

Under the scan conditions defined above, the Barricade Coil System is expected to produce a maximum temperature rise of 1.9° C after 15 minutes of continuous scanning.

The American Society of Testing and Materials (ASTM) has implemented the following terms to describe the safety of devices in and near MR systems²:

MR Safe: An item that poses no known hazards in all MR environments. MR safe items include non-conducting, non-magnetic items such as a plastic Petri dish

MR Conditional: An item that has been demonstrated to pose no known hazards in a specific MR environment with specific conditions of use. Field conditions that define the specific MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

MR Unsafe: An item that is known to pose hazards in all MR environments.

Non-clinical testing has demonstrated that the Barricade Coil System is MR Conditional

¹ Test data on file at Blockade Medical, LLC

² American Society for Testing and Materials (ASTM) International (www.astm.org), Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment