

MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing demonstrated that the SEAL[™] Embolization Device <u>implant only</u> is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined above, the SEAL[™] Implant is expected to produce a maximum temperature rise of +1.4° C after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the SEAL[™] Implant extends approximately 5 mm from the implant when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system.

MR Angiography

MR angiography may not be diagnostic due to the extent of the image artifact and alternate vascular imaging is recommended. The SEAL[™] Implant will create a signal loss depending on the pulse sequence parameters on a magnetic resonance angiography (MRA) exam, which may impact the diagnostic quality of the procedure. Therefore, an alternative imaging procedure may be needed, such as digital subtraction angiography (DSA).

MR Unsafe 🕅

For devices that will not be implanted: The Pusher Delivery System (non-implant) of the SEAL[™] Embolization System and the SEAL[™] Detachment Handle (non-implant) were not evaluated for magnetic resonance (MR) safety. They are classified as MR Unsafe.