The MVP™ micro vascular plug device was determined to be MR conditional.

Non-clinical testing demonstrated that the MVP™ micro vascular plug device is 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 9,000-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence)
- First Level Controlled Operating Mode for the MR system

Patient Name: ______________________________
Date of Procedure: __________________________
Treating Physician: __________________________
Physician Phone #: __________________________
Hospital: __________________________________
Hospital Phone #: __________________________

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.
MRI-Related Heating
In non-clinical testing, the MVP™ micro vascular plug device produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.8° C

Therefore, the MRI-related heating experiments for the MVP™ micro vascular plug 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 averaged 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 +1.8° 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 MVP™ micro vascular plug device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5-mm relative to the size and shape of the MVP™ micro vascular plug device.