Non-clinical testing has demonstrated that the device is “MR Conditional”. A patient with this device can be scanned safely immediately after placement under the following conditions:

**Static Magnetic Field**
- Static Magnetic Field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 3,000 Gauss/cm or less

**MRI-Related Heating**
In non-clinical testing, the device produced a temperature rise of up to 1.9°C during MRI performed for 15 minutes 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.

Therefore, the MRI-related heating experiments for the device at 3 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged specific absorption rate (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 1.9°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 device (within 4 – 40 cm², depending on port size and materials). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.