

## **NOVATECH® GSS™**

### **MRI Information**



The NOVATECH® GSS™ is **MR Conditional**

Non-clinical testing demonstrated that the NOVATECH® GSS™ Stent 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 36,000-Gauss/cm (extrapolated) 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 of operation for the MR system

### **MRI-Related Heating**

In non-clinical testing, the NOVATECH® GSS™ Stent produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in a 3-Tesla MR system (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI):

|                                                         |          |
|---------------------------------------------------------|----------|
| MR system reported, whole body averaged SAR             | 2.9-W/kg |
| Calorimetry measured values, whole body averaged SAR    | 2.7-W/kg |
| Highest temperature change                              | 1.7°C    |
| Temperature scaled to whole body averaged SAR of 4-W/kg | 2.3°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 NOVATECH® GSS™ Stent. 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 NOVATECH® GSS™ Stent.

|                   |                    |                    |                     |                     |
|-------------------|--------------------|--------------------|---------------------|---------------------|
| Pulse Sequence    | T1-SE              | T1-SE              | GRE                 | GRE                 |
| Signal Void Size  | 57-mm <sup>2</sup> | 41-mm <sup>2</sup> | 155-mm <sup>2</sup> | 176-mm <sup>2</sup> |
| Plane Orientation | Parallel           | Perpendicular      | Parallel            | Perpendicular       |