

## MRI Safety

### Promus ELITE™ Everolimus-Eluting Platinum Chromium Coronary Stent System

Below is an excerpt of Section 6.8 from the *Directions for Use* detailing the safety of performing MRI following the placement of a Promus ELITE™ Stent.

#### 6.8 Magnetic Resonance Imaging (MRI)

Through non-clinical testing, the Promus ELITE Stent has been shown to be MR Conditional (poses no known hazards under specified conditions.) The conditions are as follows:

- Field strengths of 3 Tesla or less with
- Static magnetic field gradient < 14 T/m (extrapolated)
- Product of static magnetic field and static magnetic field gradient < 25 T<sup>2</sup>/m (extrapolated)
- A calculated rate of change of magnetic field (dB/dt) of 60 T/s or less
- A maximum whole body averaged specific absorption rate (SAR) of lower than 2.0 W/kg for a total active MR scan time (with RF exposure) of 15 minutes or less

The Promus ELITE Stent should not migrate in this MRI environment. MR imaging within these conditions may be performed immediately following the implantation of the stent. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions.

#### 3.0 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 123 MHz in a 3.0 Tesla Magnetom Trio™, Siemens Medical Solutions MR system, software version Numaris/4, syngo™ MR A30A. The stents were in a location and orientation in the phantom that produced the worst case Radio Frequency (RF) heating. RF power was applied for 15 minutes and the measured conductivity of the phantom material was about 0.50 S/m. The phantom average SAR calculated using calorimetry was 2.3 W/kg. The maximal in-vitro temperature rise was calculated as 2.6°C when the local SAR was scaled to 2.0 W/kg for a measured overlapped stent length of 74 mm. Other stent lengths exhibited a lower temperature rise. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded to the following maximal in vivo rises: for landmarks at the chest level, the calculated temperature rise was 2.6°C with a calculated uncertainty upper bound temperature of 4.7°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

#### 1.5 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 64 MHz in a 1.5 Tesla Intera™ Philips Medical Systems, software version Release 12.6.1.3, 2010-12-02 whole body coil MR scanner. The stents were in a location and orientation in the phantom that produced the worst case RF heating. RF power was applied for 15 minutes and the measured conductivity of the phantom material was about 0.51 S/m. The phantom average SAR calculated using calorimetry was 2.1 W/kg. The maximal in-vitro temperature rise was calculated as 2.6°C when the local SAR was scaled to 2.0 W/kg for a measured single stent length of 39 mm. Other stent lengths exhibited a lower temperature rise. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded to the following maximal in vivo rises: for landmarks at the chest level, the calculated temperature rise was 2.6°C with an uncertainty upper bound temperature of 4.8°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.

The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

In vivo, local SAR depends on MR Field strength and may be different than the estimated whole body averaged SAR, due to body composition, stent position within the imaging field, and scanner used, thereby affecting the actual temperature rise. No tests have been performed on possible nerve or other tissue stimulation possible to be activated by strong gradient magnetic fields and resulting induced voltages.

#### Image Artifact Information

The calculated image artifact extends approximately 8 mm from the perimeter of the device diameter and 5 mm beyond each end of the length of the stent when scanned in non-clinical testing using a Spin Echo sequence. With a Gradient Echo sequence the calculated image artifact extends 7 mm beyond the perimeter of the diameter and 7 mm beyond each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla Intera (Achieva Upgrade), Philips Medical Solutions, software version Release 2.6.3.5 2009-10-12 MR system with a transmit/receive head coil. This testing was completed using ASTM F2119-07 test method.

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

For more information, contact your local sales representative.