

MRI Safety

ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System

Below is an excerpt of Section 6.9 from the *Directions for Use* detailing the safety of performing MRI following the placement of an ION Stent.

Section 6.9 Magnetic Resonance Imaging (MRI)

The ION Stent has been shown to be MR Conditional (poses no known hazards under specified conditions) through non-clinical testing of single and overlapped configurations up to 74 mm in overall length. The conditions are as follows:

- Field strengths of 1.5 and 3 Tesla
- Static magnetic field gradient < 9 T/m (extrapolated)
- Normal operational mode (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 ION 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 A30. RF power was applied for 15 minutes and the measured conductivity of the phantom material was about 0.3 S/m. The phantom average SAR was calculated using calorimetry to be 2.2 W/kg. The maximal in-vitro temperature rise was calculated as 2.6°C for a measured stent length of 74 mm with the whole-body SAR scaled to 2.0 W/kg. The calculations did not include the cooling effects due to blood flow.

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 10.6.2.0, 2006-03-10 whole body coil MR scanner. RF power was applied for 15 minutes and the measured conductivity of the phantom material was about 0.3 S/m. The phantom average SAR was calculated using calorimetry to be 2.1 W/kg. The maximal in-vitro temperature rise was calculated as 2.6°C for a measured stent length of 74 mm with the whole-body SAR scaled to 2.0 W/kg. The calculations did not include the cooling effects due to blood flow.

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.

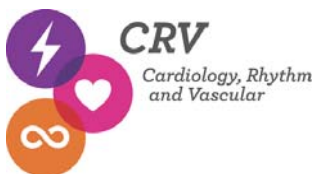
Image Artifact Information

The calculated image artifact extends approximately 7 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 5 mm beyond the perimeter of the diameter and 6 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 2.5.3.0 2007-09-28 MR system with a transmit/receive head coil.

For more information, contact your local sales representative or call patient services at 877.829.8741.

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