

Dear Physician,

As of 2011, the Food and Drug Administration has cleared the following data relating to the MRI compatibility of Boston Scientific's line of pushable and detachable platinum peripheral embolization coils.

MAGNETIC RESONANCE IMAGING (MRI)

Non-clinical testing has demonstrated that the detachable Interlock™ Fibered IDC™ Occlusion System, the detachable IDC™ Interlocking Detachable Coil, and the pushable VortX™ -18, VortX Diamond -18, Straight -18, Figure 8 – 18, Multiloop – 18, Complex Helical – 18, VortX – 35 and 2D Helical – 35 Fibered Platinum Coils, are **MR Conditional**. These coils can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Static magnetic field gradient < 25 T/m
- Product of static magnetic field and static magnetic field gradient < 50 T²/m (extrapolated)
- Normal operating mode of the MR system with a maximum whole body averaged specific absorption rate of 2 W/kg and use of transmit/receive head coil and/or whole body transmit coils.

The detachable Interlock™ Fibered IDC™ Occlusion System, the detachable IDC™ Interlocking Detachable Coil, and the pushable VortX™ -18, VortX Diamond -18, Straight -18, Figure 8 – 18, Multiloop – 18, Complex Helical – 18, VortX – 35 and 2D Helical – 35 Fibered Platinum Coils should not migrate in this MRI environment. Non-clinical testing at field strengths other than 1.5 Tesla or 3 Tesla has not been performed to evaluate coil migration or heating.

3.0 Tesla Temperature Information

Non-clinical testing of RF-induced heating was performed at 128 MHz in a 3.0 Tesla Magnetom Trio, Siemens Medical Solutions MR system, software version Numaris/4, syngo MR A30. The coils tested 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 with the conductivity of the phantom material about 0.24 S/m. The phantom average SAR calculated using calorimetry was 3.3 W/kg. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded the following maximal in vivo rises:

- For vessels in the body the calculated temperature rise was 2.8°C with an uncertainty upper bound temperature of 3.8°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 around the coil and blood perfusion in the tissue outside the coil.

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. The coils tested were in a location and orientation in the phantom that produced the worst case RF heating. RF power was applied for 15 minutes with the conductivity of the phantom material about 0.26 S/cm. The phantom average SAR calculated using calorimetry was 3.6 W/kg. Predicted in-vivo heating based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI yielded the following maximal in vivo rises:

- For vessels in the body the calculated temperature rise was 5.2°C with an uncertainty upper bound temperature of 7.1°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 around the coil and blood perfusion in the tissue outside the coil.

Image Artifact Information

MR image at 1.5 and 3 Tesla may be performed immediately following the implantation of the detachable Interlock™ Fibered IDC™ Occlusion System, the detachable IDC™ Interlocking Detachable Coil, and the pushable VortX™ -18, VortX Diamond -18, Straight -18, Figure 8 – 18, Multiloop – 18, Complex Helical – 18, VortX – 35 and 2D Helical – 35 Fibered Platinum Coils. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the coil. MR image artifact has been evaluated at 1.5 and 3.0 Tesla only.

The image artifact extended as much as 8 mm from the metal of the device when scanned in non-clinical testing using a Spin Echo sequence. With a Gradient Echo sequence, the image artifact extended as much as 10 mm beyond the metal of the device. Image tests were made in a 3.0 Siemens Magnetom Trio, software version Numaris/4. This testing was completed using the ASTM F2119-07 test method.

In the event that you have any questions regarding the above information, please feel free to contact your local Boston Scientific Sales Representative, or Boston Scientific customer service at +1-888-272-1001.

Kind Regards,

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