Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508.650.8000
www.bostonscientific.com

Magnetic Resonance Imaging (MRI) Safety for Boston Scientific Peripheral Stents

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The provided MRI information is intended as reference for post-implantation of a Boston Scientific stent. If a stent has not been implanted, please reference the complete Directions For Use for full prescribing information.

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1. Express® LD Iliac Premounted Stent System

Warning

The Express LD Iliac Stent may cause image artifacts with MRI scans due to distortion of the magnetic field.

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION :
Non-clinical testing has demonstrated the Express LD Stent in single and overlapped conditions is MR Conditional. It can be scanned safely, immediately after placement of this implant, under the following conditions:
• Static magnetic field of 1.5 Tesla or 3.0 Tesla.
• Spatial gradient field of 700 Gauss/cm or less.
• Normal operating mode of the MR system and use of whole body transmit coils only.
• Maximum whole-body-averaged specific absorption rate (WBA-SAR) of 2 Watts/kilogram, (W/kg), for 15 minutes of scanning for patient landmarks above the umbilicus (patient navel).
• Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.
The Express LD Stent 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 stent 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 testing was according to ASTM

F2182 and 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 conductivity of the phantom material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was 1.8 W/kg. The maximal in-vitro temperature rise was 4.0 °C when the local SAR was scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower temperature rise. Fractured stents exhibited similar heating. 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 landmarks above the umbilicus the calculated temperature rise was 5.2 °C with an uncertainty upper bound temperature of 6.6 °C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.
- For landmarks below the umbilicus the calculated temperature rise was 4.1 °C with an uncertainty upper bound temperature of 5.2 °C for a whole body average SAR value of 1.0 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 10.6.2.0, 2006-03-10 whole body coil MR scanner. The testing was performed according to ASTM F2182 and 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 conductivity of the phantom material was about 0.3 S/m. The phantom average SAR calculated using calorimetry was 2.1 W/kg. The maximal in-vitro temperature rise was 2.2 °C when the local SAR was scaled to 2 W/kg for a stent length of 101 mm. Other stent lengths exhibited a lower temperature rise. Fractured stents exhibited similar heating. 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 above the umbilicus, the calculated temperature rise was 3.2 °C with an uncertainty upper bound temperature of 4.1 °C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.

• For landmarks below the umbilicus the calculated temperature rise was 3.2 °C with an uncertainty upper bound temperature of 4.1 °C for a whole body average SAR value of 1.0 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 flood in the lumen of the stent and blood perfusion in the tissue outside the stent.

Image Artifact Information:

The image artifact extends approximately 7 mm from the perimeter of the device diameter and 6 mm beyond each end of the length of the stent when scanned in nonclinical testing using a Spin Echo sequence. With a Gradient Echo sequence the image artifact extends 13 mm beyond the perimeter of the diameter and 12 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. It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

2. Express® SD Renal Premounted Stent System

Precaution

The Express SD Renal Stent has been shown to be MR safe at field strength of 3 Tesla (T) or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging. The Express SD Renal Stent should not migrate in this MR environment. MR imaging at 3 T or less may be performed immediately following the implantation of the Express SD Renal Stent.

In this testing, the stent experienced a maximum temperature rise of 0.96 ºC at a maximum whole body averaged SAR of 2.0 W/kg for 15 minutes of MR imaging. The temperature rise was observed to be similar for a stent with a fractured strut. The maximum temperature rise observed for two overlapping Express SD stents was 1.15 ºC (5 mm overlap at the ends). MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

This stent has not been evaluated to determine if it is safe in MRI systems with field strengths greater than 3T.