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

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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. All information contained in this document is current as of August 6, 2015. Please refer to device DFU for updates prior to use.

1. WALLSTENT™ Iliac Endoprosthesis with Unistep™ Plus Delivery System

Through non-clinical testing, the WALLSTENT™ RP Endoprosthesis stent has been shown to be MR conditional (poses no known hazards under specified conditions). It can be scanned safely in single and overlapped configurations up to 120 mm in length under the following conditions:
- Field strengths of 3 Tesla and 1.5 Tesla with
- Static magnetic field gradient < 19 T/m, (1900 Gauss/cm) (extrapolated)
- 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 WALLSTENT RP Endoprosthesis 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.

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.

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, COEM VD20F, syngo VE31G, N4 VA30A_LATEST. Predicted in-vivo heating produced a calculated maximal temperature rise of 3.5°C for a whole body average SAR value of 2.0 W/kg. The reported temperatures are conservative as they do not take into account the cooling effects of perfusion or 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 MR system, software version 10.6.2.5 2006-03-10 whole body coil MR scanner. Predicted in-vivo heating produced a calculated maximal temperature rise of 6.5°C for a whole body average SAR value of 2.0 W/kg. The reported temperatures are conservative as they do not take into account the cooling effects of perfusion or blood flow.

2. **WALLSTENT™ RP Endoprosthesis (Transhepatic Biliary; Tracheobronchial; TIPS; Venous)**

MRI Safe: The WALLSTENT™ Endoprosthesis and ™ Endoprosthesis have shown no deflection or torque in the area of maximum spatial gradient (450 gauss centimeter) of a 1.5 tesla MRI system under conditions that produced a Specific Absorption Rate (SAR) of 1.3 W/Kg. Imaging artifacts affect the region of interest at the location of the device (artifact ratio 0.8 to 7.0), while areas away from the device appear unaffected by their presence.

3. **WALLGRAFT™ Endoprosthesis with Unistep™ Plus Delivery System**

Magnetic Resonance Imaging (MRI) Compatibility

Magnetic Fields
Non-clinical testing demonstrated that the WALLGRAFT Endoprosthesis is MR Condition. 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 72mT/cm or less

**MRI-Related Heating**
In non-clinical testing, the WALLGRAFT Endoprosthesis produced the following temperature rise during MRI performed for a maximum of 15 minutes in the 3-Tesla (3-Tesla/128-MHz, Excita, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR system:
- Highest temperature change, single stent ≤1.18°C
- Highest temperature change, two overlapped stents ≤1.55°C

Therefore, the MRI-related heating experiments for the WALLGRAFT Endoprosthesis at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SASR of 2.0-W/kg indicated that the greatest amount of heating that occurred in association with these specific conditions was ≤1.18°C (for a single stent) and ≤1.55°C (for two overlapped stents).

The effect of heating for stents with fractured struts is not known.

**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 WALLGRAFT Endoprosthesis. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

4. **Express® SD Renal Monorail Premounted Stent System**

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 2.0W/kg for 15 minutes of MR imaging. The Express SD Renal Stent should not migrate in this MR environment. MR imaging at 3T 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°C at a maximum whole body averaged SAR of 2.0W/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°C (5mm 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.
5. **Express® Biliary SD Stent System**

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 2.0W/kg for 15 minutes of MR imaging. The Express SD Renal Stent should not migrate in this MR environment. MR imaging at 3T 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°C at a maximum whole body averaged SAR of 2.0W/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°C (5mm 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.

6. **Express® LD Iliac Over-the-Wire Premounted Stent System**

**MAGNETIC RESONANCE IMAGING (MRI) INFORMATION**

**Magnetic Resonance Conditional MR**

Non-clinical testing has demonstrated that the Express LD Stent is MR Conditional for single and overlapping lengths up to 101 mm. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla.
- Maximum spatial gradient magnetic field of 1900 Gauss/cm or less.
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) for landmarks above the umbilicus and 1 W/kg for landmarks below the umbilicus.

Under the scan conditions defined above, the Express LD Stent is expected to produce a maximum temperature rise of less than 5.2°C after 15 minutes of continuous scanning. 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 non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the Express LD Stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artefact obscures the device lumen.

**Recommendations**
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.

### 7. **Express® Biliary LD Premounted Stent System**

**MAGNETIC RESONANCE IMAGING (MRI) INFORMATION**

**Magnetic Resonance Conditional MR**
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
- Maximum spatial gradient field of 1900 Gauss/cm or less
- Normal operating mode of the MR system
- Maximum whole-body-averaged specific absorption rate (WBA-SAR) of 2 watts/kilogram, (W/kg)

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.

Under the scan conditions defined above, the Express LD Stent is expected to produce a maximum temperature rise of less than 4°C after 15 minutes of continuous scanning.

**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.
8. Carotid WALLSTENT® Endoprosthesis

Magnetic Resonance Imaging (MRI) Compatibility:
Through non-clinical testing, the Carotid WALLSTENT Monorail® Endoprosthesis (Carotid WALLSTENT Endoprosthesis), has been shown to be MRI safe at field strengths of 3.0 Tesla or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MRI exposure. In this testing, a single stent produced a temperature rise of ≤1.72°C at a maximum calculated whole body averaged SAR of 2.0 W/kg for 15 minutes of MRI. The effect of heating for stents with fractured struts is not known. The Carotid WALLSTENT Endoprosthesis should not migrate in this MRI environment. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3.0 Tesla.

MRI at 3.0-Tesla or less may be performed immediately following the implantation of the Carotid WALLSTENT Endoprosthesis. 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 stent. MR image artifact has been evaluated at 1.5 Tesla only.

9. Epic™ Vascular Self-Expanding Stent System

MAGNETIC RESONANCE IMAGING (MRI)
Non-clinical testing has demonstrated the Epic™ Stent System is MR Conditional. It can be scanned safely up to a total length of 155mm and overlapping stents up to 155mm under the following conditions:

- Static magnetic field of 3 Tesla and 1.5 Tesla.
- Spatial gradient field of 2500 Gauss/cm.
- Normal operating mode only with a maximum whole body (WB) averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of active scanning for patient landmarks above the umbilicus (patient navel).
- Maximum WB-SASR of 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.
- Use whole body transmit/receive coils only. Do not use local transmit coils. Local receive coils can be used.

MRI at 3T or 1.5T may be performed immediately following the implantation of the Epic Stent. The Epic Stent should not migrate in this MRI environment. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions.

3.0 Tesla Temperature Information:
In non-clinical testing, the Epic Stent at single lengths of 120 mm and overlapped lengths of 155mm produced a maximum temperature rise of 4.4°C at a maximum whole body
averaged of 2 W/kg, that was determined by validated calculation for 15 minutes of MR scanning in a 3 Tesla Siemens Magnetom Trio®, software version Numaris/4, Syngo® MR A30, COEM VD20F, Syngo VE31G, N4 VA30A Latest MR scanner. In this model, the reported temperatures are conservative as they do not take into account the cooling effects of perfusion and blood flow.

- For landmarks above the umbilicus the calculated temperature rise was 4.4°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 2.8°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

1.5 Tesla Temperature Information:
In non-clinical testing, the Epic Stent at single lengths of 120mm and overlapped lengths of 155mm produced a maximum temperature rise of 3.2°C at a maximum whole body averaged of 2 W/kg, that was determined by validated calculation for 15 minutes of MR scanning in a 1.5 Tesla Philips Intera®, software version Release 10.6.2.4, 2006-03-10 MR scanner. In this model, the reported temperatures are conservative as they do not take into account the cooling effects of perfusion and blood flow.

- For landmarks above the umbilicus the calculated temperature rise was 3.2°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 2.7°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

Image Artifact:
The image artifact extends approximately 1.25mm from the perimeter of the device diameter and 2mm beyond each end of the length of the stent when scanned in non-clinical testing using the sequence, Spin Echo. With a Gradient Echo sequence the image artifact extends 1.25mm beyond the perimeter of the device diameter and 3mm beyond each end of the length of the stent with both sequences partially shielding the lumen in a 3.0 Tesla Siemens Medical Solutions, software version Numaris/4, Syngo MR 2004A 4VA25A MR system with a transmit/receive CP head coil. Image artifacts in a body birdcage coil are similar to the image artifacts in the transmit/receive CP head coil.

Recommendations:
It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.
10. WallFlex™ Biliary Transhepatic Stent System

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

- Field strength of 3 Tesla and 1.5 Tesla
- Static magnetic field gradient < 30 T/m
- Product of static magnetic field and static magnetic field gradient < 90 T2/m
- A rate of change of magnetic field (dB/dt) approximately 60 T/s or less along the axis of the cylindrical bore. (This criteria is met for cylindrical bore MR systems with gradient slew rate of 200 T/m/s or less.)
- Normal operating mode of the MR system and use of transmit/receive head coil and/or whole body transmit coils

The WallFlex Biliary Transhepatic stent should not migrate in this Magnetic Resonance Imaging (MRI) environment, as magnetic force and torque in the non-clinical tests was less than the values exerted by the earth’s gravity. 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. 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.

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. 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 with the conductivity of the phantom material 0.49 S/m. The phantom average SAR calculated using calorimetry was 4.2 W/kg. The maximum in-vitro temperature rise was 2.6 °C when the local SAR was scaled to 2 W/kg for a stent length of 80 mm. Other stent lengths exhibited a lower temperature rise. In vivo temperature rises were determined based on these non-clinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI. For landmarks at the chest the calculated temperature rise was 4.0 °C with an uncertainty upper bound temperature of 5.5 °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 fluid 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 with the conductivity of the phantom material about 0.49 S/m. The phantom average SAR calculated using calorimetry was 3.9 W/kg. The maximum in-vitro temperature rise was 2.8 °C when the local SAR was scaled to 2 W/kg for a stent length of 144 mm. Other stent lengths exhibited a lower temperature rise. In-vivo temperature rises were determined based on these nonclinical tests and computer simulation of the patient exposure to the electromagnetic fields in MRI. For landmarks at the chest the calculated temperature rise was 2.4 °C with an uncertainty upper bound temperature of 3.3 °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 fluid flow in the lumen of the stent and blood perfusion in the tissue outside the stent.

11. **Sentinol™ Self-Expanding Nitinol Biliary Stent System**

   **MRI Compatibility:**
   The Sentinol™ Stent is MRI safe/compatible and does not interfere with, nor is affected by, the operation of an MRI device.

12. **Titanium Greenfield™ Vena Cava Filter**

   **MRI Compatibility:**
   MRI Conditional: Lacks ferromagnetism (up to 4.7 T) and does not produce MR imaging artifact (at 0.35 T).

13. **Greenfield™ Stainless Steel Vena Cava Filter**

   **MRI Compatibility:**
   MRI Conditional: In vitro studies have demonstrated that magnetic force and torque at 0.35 T and 1.5 T cause no migration of Greenfield Stainless Steel Vena Cava Filters. Greenfield Stainless Steel Vena Cava Filters generate moderate artifact when MR imaged.

14. **Innova™ Vascular Self-Expanding Stent System**

   **Magnetic Resonance Conditional:**
A patient with this device can be scanned safely only under specific conditions. Failure to follow the conditions may result in severe injury. Non-clinical testing has demonstrated the Innova™ Stents are MR Conditional for single and overlapping lengths up to 200 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 40 Tesla/m (4,000 Gauss/cm) or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of
  - ≤2 W/kg for landmarks (i.e. center of RF coil) above the umbilicus
  - ≤1 W/kg for landmarks below the umbilicus

**RF Heating**
Under the scan conditions defined above, the Innova Stent is expected to produce a maximum in-vivo temperature rise of 4.3 °C after 15 minutes of continuous scanning.

**Image Artifact**
In non-clinical testing, the image artifact caused by the device extends approximately 12 mm from the Innova stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.