Magnetic Resonance Imaging (MRI) Safety for
Boston Scientific Products

Table of Contents

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 September 20, 2016. Please refer to device DFU for updates prior to use.

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

Magnetic Resonance Imaging (MRI)

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.

Image Artifact Information
The calculated 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 non-clinical testing using a Spin Echo sequence. With a Gradient Echo sequence the calculated image artifact extends 11 mm beyond the perimeter of the diameter and 13 mm beyond each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla Achieva, Philips Medical Systems MR system, software version 2.6.3.3 2009-04-25 with a transmit/receive head coil. This testing was completed using ASTM F2119-07 test method.

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.

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

Transhepatic Biliary.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated that WALLSTENT™ Transhepatic Biliary is MR Conditional for single and overlapping lengths up to 94 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:
• Static magnetic field of 1.5 Tesla or 3.0 Tesla
• Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤2 W/kg

RF Heating

Under the scan conditions defined above, WALLSTENT Transhepatic Biliary is expected to produce a maximum in-vivo temperature rise of 0.64°C after 15 minutes of continuous scanning.

Image Artifact

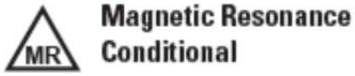
In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

TracheoBronchial.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION



Non-clinical testing has demonstrated that WALLSTENT Tracheobronchial is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:
• Static magnetic field of 1.5 Tesla or 3.0 Tesla
• Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤2 W/kg

RF Heating

Under the scan conditions defined above, WALLSTENT™ Tracheobronchial is expected to produce a maximum in-vivo temperature rise of 3.51°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

TIPS

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Non-clinical testing has demonstrated that WALLSTENT TIPS is MR Conditional for single and overlapping lengths up to 94 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:
• Static magnetic field of 1.5 Tesla or 3.0 Tesla
• Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤2 W/kg

RF Heating

Under the scan conditions defined above, WALLSTENT TIPS is expected to produce a maximum in-vivo temperature rise of 0.64°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

Venous

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated that WALLSTENT™ Venous is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

• Static magnetic field of 1.5 Tesla or 3.0 Tesla

• Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less Gauss/cm) or less

• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤1 W/kg for patient landmarks above the umbilicus (patient navel) and ≤2 W/kg (Normal Operating Mode) for patient landmarks below the umbilicus

RF Heating

Under the scan conditions defined above, WALLSTENT Venous is expected to produce a maximum in-vivo temperature rise of 3.1°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

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

Magnetic Resonance Imaging (MRI) Compatibility

The WALLGRAFT Endoprosthesis was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

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^{o}C
- Highest temperature change, two overlapped stents ≤1.55^{o}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^{o}C (for a single stent) and ≤1.55^{o}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 and Biliary Monorail Premounted Stent Systems*

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Magnetic Resonance Conditional
Non-clinical testing has demonstrated that the Express SD Stent is MR Conditional for single and overlapping lengths up to 32 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 (19 T/m) or less.
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Express SD Stent is expected to produce a maximum temperature rise of less than 2.0 ^{o}C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends approximately 11.4 mm from the Express SD Stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact 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.

5. *Express® LD Iliac Premounted Stent System*

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Magnetic Resonance Conditional
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.

6. *Express® LD Biliary Premounted Stent System*

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

Magnetic Resonance Conditional

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.

7. *Carotid WALLSTENT® Endoprosthesis*

MAGNETIC RESONANCE (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated the Carotid WALLSTENT System is MR Conditional for single and overlapping lengths up to a total length of 64 mm. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla using a quadrature body coil only
- Maximum spatial gradient field of <2500 gauss/cm (<25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg for patient landmarks above the umbilicus (patient navel) and 2 W/kg (Normal Operating Mode) for patient landmarks below the umbilicus

MR imaging within these conditions may be performed immediately following the implantation of the stent.

Under the scan conditions defined above, the Carotid WALLSTENT System is expected to produce a maximum temperature rise of 4.5^{o}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 4 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 image artifact extends 10 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 2.5.3.0 2007-09-28 MR system with a transmit/receive head coil.

Recommendations
It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

8. 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 155 mm and overlapping stents up to 155 mmm 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-SAR 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 155 mm produced a maximum temperature rise of 4.4^{o}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^{o}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^{o}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 1.25 mm from the perimeter of the device diameter and 2 mm 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.

9. 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 T^2/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.

Image Artifact Information
The maximum image artifact extends approximately 10 mm from the perimeter of the device diameter and 2 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 image artifact extends 10 mm beyond the perimeter of the diameter and 2 mm beyond each end of the length with both sequences partially shielding the lumen in a 3.0 Tesla Siemens Magnetom Trio®, Siemens Medical Solutions, software version Numaris/4 Syngo® MR A30, COEM VD20F, Syngo VE31G, N4 VA30A_LATEST with a transmit/receive head coil.

10. 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.

11. 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).

12. 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.

13. Innova™ Vascular Self-Expanding Stent System

MAGNETIC RESONANCE (MRI) SAFETY INFORMATION
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.