MRI Information

Zenith Flex® AAA Endovascular Graft

(excerpted from IFU)

MRI Information
Non-clinical testing has demonstrated that the Zenith AAA Endovascular Graft is MR Conditional. A patient with this endovascular graft can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 3.0 Tesla or less.
- Highest spatial magnetic gradient field of 720 gauss/cm

Non-clinical evaluation was conducted in a 3 Tesla MR system (General Electric Excite) with a maximum spatial magnetic gradient field of 720 gauss/cm as measured with a gaussmeter in the position of the static magnetic field pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

MRI-Related Heating

1.5 Tesla Systems:

- Static magnetic field of 1.5 Tesla
- Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per scanning sequence)

In non-clinical testing, the Zenith AAA Endovascular Graft produced a temperature rise of less than or equal to 1.4°C at a MR system reported whole-body-averaged specific absorption rate (SAR) of 2.8 W/kg for 15 minutes of MR scanning in a 1.5 Tesla Magnetom, Siemens Medical Magnetom, Numaris/4 Software, Version Syngo MR 2002B DHHS MR Scanner. The maximum whole-body-averaged specific absorption rate (SAR) was 2.8 W/kg, which corresponds to a calorimetry measured value of 1.5 W/kg.
3.0 Tesla Systems:

- Static magnetic field of 3.0 Tesla
- Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per scanning sequence)

In non-clinical testing, the Zenith AAA Endovascular Graft produced a temperature rise of less than or equal to 1.9°C at a MR system reported whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3.0 Tesla Excite, GE Electric Healthcare, G3.0-052B Software, MR Scanner. The maximum whole-body-averaged specific absorption rate (SAR) was 3.0 W/kg, which corresponds to a calorimetry measured value of 2.8 W/kg.

Image Artifact

The image artifact extends throughout the anatomical region containing the device, obscuring the view of immediately adjacent anatomical structures within approximately 20 cm of the device, as well as the entire device and its lumen, when scanned in nonclinical testing using the sequence: Fast spin echo, in a 3.0 Tesla, Excite, GE Electric Healthcare, with G3.0-052B Software, MR system with body radiofrequency coil.

For all scanners, the image artifact dissipates as the distance from the device to the area of interest increases. MR scans of the head and neck and lower extremities may be obtained without image artifact. Image artifact may be present in scans of the abdominal region and upper extremities, depending on distance from the device to the area of interest.

Clinical information is available for seventeen patients who received MRI scans after stent-graft implantation. There have been no reported adverse events or device problems in any of these patients as a result of having received an MRI. Additionally, there have been well over 100,000 Zenith AAA Endovascular Grafts implanted worldwide, in which there have been no reported adverse events or device problems as a result of MRI.

Cook recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation. The MedicAlert Foundation can be contacted in the following manners:

Mail: MedicAlert Foundation International
2323 Colorado Avenue
Turlock, CA 95382

Phone: 888.633.4298 (toll free)
209.668.3333 from outside the U.S.

Fax: 209.669.2450

Web: [www.medicalert.org](http://www.medicalert.org)
Cook Celect Vena Cava Filter

Nonclinical testing has demonstrated that the Cook Celect Vena Cava Filter is **MR Conditional** according to ASTM F2503. A patient with a Cook Celect Vena Cava Filter can be scanned safely under the following conditions:

- Static magnetic field of 1.5 tesla or 3.0 tesla
- Maximum spatial magnetic gradient of 1,600 gauss/cm (16.0 T/m) or less
- Normal operating mode
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning or less (i.e., per scanning sequence)

**Static Magnetic Field**
The static magnetic field for comparison to the above limits is the static magnetic field that is pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

**MRI-Related Heating**

**1.5 Tesla Temperature Rise**
In nonclinical testing, the Cook Celect Vena Cava Filter produced a maximum temperature change of 3.7 °C during 15 minutes of MRI (i.e., for one scanning sequence) performed in a 1.5 tesla MR system (1.5 tesla/64 MHz, Siemens Magnetom Avanto®, Numaris/4 syngo® MR B17) at an MR system-reported whole-body-averaged SAR of 2.05 W/kg (associated with a calorimetry-measured whole-body-averaged value of 1.75 W/kg).

**3.0 Tesla Temperature Rise**
In nonclinical testing, the Cook Celect Vena Cava Filter produced a maximum temperature change of 4.2 °C during 15 minutes of MRI (i.e., for one scanning sequence) performed in a 3.0 tesla MR system (3.0 tesla/128 MHz, Siemens Magnetom Trio®, A Tim System, Numaris/4 syngo MR B17) at an MR system-reported whole-body-averaged SAR of 2.08 W/kg (associated with a calorimetry-measured whole-body-averaged value of 1.71 W/kg).

**Image Artifacts**
MR image quality may be compromised if the area to be scanned is within approximately 21 mm of the position of the Cook Celect Vena Cava Filter. This 21 mm range is based on nonclinical testing with T1-weighted spin-echo and gradient-echo pulse sequences in a 3.0 tesla MR system (Excite, GE Healthcare). If you need to scan an area within 21 mm of the filter, you may have to optimize MR imaging parameters to compensate for the presence of this metallic filter.

**For U.S. Patients Only**
Cook recommends that the patient register these MR conditions with the MedicAlert Foundation. The MR conditions disclosed in this document are taken from the product IFU. The contact information for the MedicAlert Foundation is below:
Cook Medical adheres to the F2503-08 standard of MR (magnetic resonance) terminology adopted by the American Society for Testing and Materials (ASTM). This practice of marking medical devices came about in an effort to clarify the terminology, provide a uniform system for marking and, more important, because misuse of old terminology could result in serious injuries for patients and other individuals. This new system references the MR environment where testing took place, which includes field strength, spatial gradients, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields and specific absorption rate (SAR).

Taking these conditions into consideration, three new categories of MR marking exist: MR Safe, MR Conditional, and MR Unsafe. In this system, “safe” and “unsafe” are the two extremes. “Conditional” is in the middle and characterizes the behavior of a medical device under specific conditions in the MR environment as determined by testing. In addition to the new terms, the ASTM International document introduced corresponding icons consistent with international standards for colors and shapes of safety signs. The icons are intended for use on items that may be brought into or near the MR environment as well as in product labeling. The new terminology and icon structure is intended to help clarify matters related to biomedical implants and devices to ensure the safe use of MRI technology.

**MR Safe**—An item that poses no known hazards in all MR environments. MR Safe items include nonconducting, nonmetallic, nonmagnetic items such as plastic, silicone and glass. An item may be determined to be MR Safe on the basis of scientific rationale rather than test data.

**MR Conditional**—An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions should be enumerated on the product, its packaging or in the enclosed literature. Additional conditions, including specific
configurations of the item, may be required.

**MR Unsafe**—An item that is known to pose hazards in all MR environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors.

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Nonclinical testing has demonstrated that the Zilver Self-Expanding Stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3 tesla or less
- Spatial gradient field of 720 gauss/cm or less
- Whole-body averaged specific absorption rate (SAR) of 1.5 W/kg (for a single stent at 1.5 tesla) and 3 W/kg (for a single stent at 3 tesla and a pair of overlapping stents at 1.5 and 3 tesla) for 20 minutes (for a single stent at 1.5 tesla) and 15 minutes of scanning (for a single stent at 3 tesla and a pair of overlapping stents at 1.5 and 3 tesla), respectively.
In nonclinical testing, the Zilver Self-Expanding Stent produced maximum temperature rises of 0.1, 3.8, 0.8, and 0.1 degrees C (for a single stent at 1.5 tesla, a pair of overlapping stents at 1.5 tesla, a single stent at 3 tesla, and a pair of overlapping stents at 3 tesla, respectively) at whole-body averaged specific absorption rates (SAR) of 1.5 W/kg (for a single stent at 1.5 tesla) and 3 W/kg (for a single stent at 3 tesla and a pair of overlapping stents at 1.5 and 3 tesla) for 20 minutes (for a single stent at 1.5 tesla) and 15 minutes (for a single stent at 3 tesla and a pair of overlapping stents at 1.5 and 3 tesla) of MR scanning in a 1.5 tesla/64 MHz GE Healthcare MR scanner, a 1.5 tesla Magnetom Siemens Medical Solutions MR Scanner (to evaluate a pair of overlapping stents), and a 3 tesla Excite GE Healthcare MR scanner.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Zilver Self-Expanding Stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

Heating in the MRI environment for stents with fractured struts is not known.

**Embolization Coils - Stainless Steel**

For patients implanted with stainless steel coils, recent testing shows that these coils are MR Conditional.

Nonclinical testing has demonstrated that the standard embolization coil (Stainless Steel) is MR Conditional according to ASTM F2503. A patient with this coil may be scanned safely anytime after placement under the following conditions.

- Static magnetic field of 3.0 tesla or less
- Maximum spatial magnetic gradient of 1,600 gauss/cm or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg normal operating mode for 15 minutes of scanning or less (i.e., per scanning sequence)

**Static Magnetic Field**
The static magnetic field for comparison to the above limits is the static magnetic field that is pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

**MRI-Related Heating**
In nonclinical testing, the standard embolization coil (stainless steel) produced a maximum temperature rise of 1.8 °C during 15 minutes of MR imaging (i.e., for one scanning sequence) performed in a MR 3 tesla system (General Electric Excite, Software 14X.M5) at an MR system reported whole-body-averaged SAR of 2.9 W/kg (associated with a calorimetry measured whole-body-averaged value of 2.7 W/kg).
**Image Artifact**

MR image quality may be compromised if the area of interest is within approximately 75 mm of the position of the standard embolization coil (stainless steel) as found during nonclinical testing using T1-weighted, spin echo and gradient echo pulse sequence in a 3.0 tesla MR system (Excite, General Electric Healthcare, Milwaukee, WI). Therefore, it may be necessary to optimize MR imaging parameters for the presence of this coil.

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- **Mail:** MedicAlert Foundation
  International
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  Turlock, CA 95382
- **Phone:** 888.633.4298 (toll free)
  209.668.3333 from outside the U.S.

**Gianturco-Roehm Bird’s Nest® Vena Cava Filter**

Nonclinical testing has demonstrated that the Gianturco-Roehm Bird’s Nest Vena Cava Filter is MR Conditional. According to the article “MR Imaging of the Bird’s Nest Filter” by Alyssa T. Watanabe, “No complication or symptomatic filter displacement was encountered as a result of MR imaging performed at 1.5 T.” The article also states that the filters created significant local artifact distortion on MR images; however, diagnostic images of the pelvis, spine and brain may still be obtained.

MRI diagnostic procedures should be postponed for six weeks following filter implantation to ensure device incorporation into the vessel wall.

**Formula 418® Balloon Expandable Biliary Stent**

Nonclinical testing has demonstrated that the Formula biliary stent is MR Conditional. A patient with this stent may undergo MRI immediately after placement under the following conditions:

- Static magnetic field of 3.0 tesla or less
- Maximum spatial gradient magnetic field of 720 gauss/cm
- Maximum MR system reported whole-body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning
In nonclinical testing, the Formula biliary stent produced a temperature rise of less than 1°C at an MR-system-reported maximum whole-body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 tesla system (Excite, Software G3.0-052B, GE Healthcare).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Formula biliary stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant. The effect of heating in the MRI environment for overlapping stents or stents with fractured struts is unknown.

» **Günther Tulip™ Vena Cava Filter**

Nonclinical testing has demonstrated that the Günther Tulip Vena Cava Filter is **MR Conditional** according to ASTM F2503. A patient with a Günther Tulip Vena Cava Filter can be scanned safely under the following conditions:

- Static magnetic field of 1.5 tesla or 3.0 tesla
- Maximum spatial magnetic gradient of 1,600 gauss/cm (16.0 T/m) or less
- Normal operating mode
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning or less (i.e., per scanning sequence)

**Static Magnetic Field**
The static magnetic field for comparison to the above limits is the static magnetic field that is pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

**MRI-Related Heating**

1.5 Tesla Temperature Rise
In nonclinical testing, the Günther Tulip Vena Cava Filter produced a maximum temperature change of 3.8 °C during 15 minutes of MRI (i.e., for one scanning sequence) performed in a 1.5 tesla MR system (1.5 tesla/64 MHz, Siemens Magnetom Avanto®, Numaris/4 syngo® MR B17) at an MR system-reported, whole-body-averaged SAR of 2.05 W/kg (associated with a calorimetry-measured whole-body-averaged value of 1.75 W/kg).

3.0 Tesla Temperature Rise
In nonclinical testing, the Günther Tulip Vena Cava Filter produced a maximum temperature change of 5.2 °C during 15 minutes of MRI (i.e., for one scanning sequence) performed in a 3.0 tesla MR system (3.0 tesla/128 MHz, Siemens Magnetom Trio®, A Tim System, Numaris/4 syngo MR B17) at an MR system-reported whole-body-averaged SAR of 2.08 W/kg (associated with a calorimetry-measured
whole-body-averaged value of 1.71 W/kg).

**Image Artifacts**
MR image quality may be compromised if the area to be scanned is within approximately 21 mm of the position of the Günther Tulip Vena Cava Filter. This 21 mm range is based on nonclinical testing with T1-weighted spin-echo and gradient-echo pulse sequences in a 3.0 tesla MR system (Excite, GE Healthcare). If you need to scan an area within 21 mm of the filter, you may have to optimize MR imaging parameters to compensate for the presence of this metallic filter.

**For U.S. Patients Only**
Cook recommends that the patient register these MR conditions with the MedicAlert Foundation. The MR conditions disclosed in this document are taken from the product IFU. The contact information for the MedicAlert Foundation is below:

- **Mail:** MedicAlert Foundation International  
  2323 Colorado Avenue  
  Turlock, CA 95382
- **Phone:** 888.633.4298 (toll free)  
  209.668.3333 (outside the U.S.)
- **Fax:** 209.669.2450
- **Web:** [www.medicalert.org](http://www.medicalert.org)

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» **Hilal Embolization Microcoils™**

Hilal Embolization Microcoils are manufactured from a platinum composition that has been shown to have no ferromagnetic response. Through nonclinical testing, embolization coils manufactured of this material have been shown to be MR Conditional. A patient with one of these implants can be safely scanned immediately after placement under the following conditions:

- Static magnetic field strengths of 3.0 tesla or less
- Maximum spatial gradient field of 330 gauss/cm
- Maximum MR system whole-body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

In this testing, platinum embolization coils produced a temperature rise of greater than 0.5°C at a maximum whole-body averaged specific
absorption rate (SAR) of 2.0 W/kg for 20 minutes of MRI. The effect of heating for other conditions, multiple coils or overlapping coils is unknown.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of platinum embolization coils.

» **Cook-Swartz Doppler Flow Probe**

**WARNING–MR UNSAFE**

Do not expose patient to an MRI procedure while a Cook-Swartz Doppler Flow Probe is implanted. Substantial MRI-related heating of the Doppler flow probe may occur. Doppler flow probe must be removed prior to any MRI procedure.

» **MReye® Embolization Coils**

Through nonclinical testing, the MReye Embolization Coil has been shown to be MR Conditional. It can be scanned safely immediately after placement under the following conditions:

- Static magnetic field strengths of 3.0 tesla or less
- Maximum spatial gradient of 330 gauss/cm
- Maximum whole-body averaged specific absorption rate (SAR) of 2.0 W/kg for 20 minutes of MRI

The MReye Embolization Coil will not migrate in this MRI environment. Nonclinical testing has not been performed to rule out the possibility of device migration at static magnetic field strengths higher than 3.0 tesla and a maximum spatial gradient higher than 330 gauss/cm.

In this testing, the MReye Embolization Coil produced a temperature rise of greater than or equal to 0.6°C at a maximum whole-body averaged specific absorption rate (SAR) of 2.0 W/kg for 20 minutes of MRI. The effect of heating in the MRI environment for other conditions, multiple coils or overlapping coils is unknown.

MRI image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the MReye Embolization Coil.
» **MReye Flipper® Detachable Embolization Coils**

Through nonclinical testing, the MReye Flipper Detachable Embolization Coil Delivery System has been shown to be MR Conditional. It can be scanned safely immediately after placement under the following conditions:

- Static magnetic field strengths of 3.0 tesla or less
- Maximum spatial gradient of 330 gauss/cm
- Maximum whole-body averaged specific absorption rate (SAR) of 2.0 W/kg for 20 minutes of MRI

Embolization coils manufactured of Inconel will not migrate in this MRI environment. Nonclinical testing has not been performed to rule out the possibility of device migration at static magnetic field strengths higher than 3.0 tesla and a maximum spatial gradient higher than 330 gauss/cm.

In this testing, the MReye Flipper Embolization Coil produced a temperature rise of greater than or equal to 0.6°C at a maximum whole-body averaged specific absorption rate (SAR) of 2.0 W/kg for 20 minutes of MRI. The effect of heating in the MRI environment for other conditions, multiple coils or overlapping coils is unknown.

MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the MReye Flipper Embolization Coil.

» **MReye® Needles for Magnetic Resonance Imaging**

Cook’s interventional MReye® Needles are used for initial puncture and positioning control as well as biopsies and other interventional procedures in combination with magnetic resonance imaging.

- MReye products are created from a nonferromagnetic material that helps prevent disturbing artifacts.
- MReye needles are recommended for use with MRI scanners not exceeding 1.5 tesla.

To see different-sized images of the needle, try these scanner parameters:

- To see an image of the needle at a ratio of 1:1, select a spin echo sequence (TR/TE 200 ms/15 ms).
- To see an image of the needle enlarged approximately 2:1, select a gradient echo sequence (TR/TE/flip angle 336 ms/15 ms/90°).
Nester® Embolization Coils

Nester Embolization Coils are manufactured from a platinum composition that has been shown to have no ferromagnetic response. Through nonclinical testing, embolization coils manufactured of this material have been shown to be MR Conditional. A patient with one of these implants can be scanned safely immediately after placement under the following conditions:

- Static magnetic field strengths of 3.0 tesla or less
- Maximum spatial gradient field of 330 gauss/cm
- Maximum MR system whole-body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

In this testing, platinum embolization coils produced a temperature rise of greater than 0.5°C at a maximum whole-body averaged specific absorption rate (SAR) of 2.0 W/kg for 20 minutes of MRI. The effect of heating for other conditions, multiple coils or overlapping coils is unknown.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of platinum embolization coils.

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Tornado® Embolization Coils

Tornado Embolization Coils are manufactured from a platinum composition that has been shown to have no ferromagnetic response. Through nonclinical testing, embolization coils manufactured of this material have been shown to be MR Conditional. A patient with one of these implants can be scanned safely immediately after placement under the following conditions:

- Static magnetic field strengths of 3.0 tesla or less
- Maximum spatial gradient field of 330 gauss/cm
- Maximum MR system whole-body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

In this testing, platinum embolization coils produced a temperature rise of greater than 0.5°C at a maximum whole-body averaged specific absorption rate (SAR) of 2.0 W/kg for 20 minutes of MRI. The effect of heating for other conditions, multiple coils or overlapping coils is unknown.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of platinum embolization coils.
Vital Port® System

Nonclinical testing demonstrated that the Vital-Port Vascular Access Ports are MR Conditional. A patient with one of these implants can be safely scanned immediately after placement under the following conditions:

- Static magnetic field of 3.0 tesla or less
- Maximum spatial gradient magnetic field of 720 gauss/cm
- Maximum MR system reported whole-body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

In nonclinical testing, the vascular access ports produced maximum temperature increases of less than or equal to 0.7°C at maximum MR system reported whole-body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 tesla MR system using a transmit/receive body coil (Excite, software G3.0-052B, GE Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the vascular access ports. Therefore, it may be necessary to optimize MR imaging parameters to compensate for the presence of one of these implants.

Zenith TX2® TAA Endovascular Graft

MRI Information
Non-clinical testing has demonstrated that the Zenith TX2 TAA Endovascular Graft with Pro-Form is MR Conditional. It can be scanned safely under the following conditions:

1.5 Tesla Systems:

- Static magnetic field of 1.5 Tesla
- Spatial gradient field of 450 Gauss/cm
- Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning.

In non-clinical testing, the Zenith TX2 TAA Endovascular Graft with Pro-Form produced a temperature rise of less than 1.4 °C at a maximum whole-body-averaged specific absorption rate (SAR) of 2.8 W/kg for 15
minutes of MR scanning in a 1.5 Tesla Magnetom, Siemens Medical Magnetom MR scanner. The maximum whole-body-averaged specific absorption rate (SAR) was 2.8 W/kg, which corresponds to a calorimetry measured value of 1.5 W/kg.

3.0 Tesla Systems:
- Static magnetic field of 3.0 Tesla
- Spatial gradient field of 720 Gauss/cm
- Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning

In non-clinical testing, the Zenith TX2 TAA Endovascular Graft with ProForm produced a temperature rise of less than 1.9 °C at a maximum whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, GE Electric Healthcare MR scanner. The maximum whole-body-averaged specific absorption rate (SAR) was 3.0 W/kg, which corresponds to a calorimetry measured value of 2.8 W/kg.

The image artifact extends throughout the anatomical region containing the device, obscuring the view of immediately adjacent anatomical structures within approximately 20 cm of the device, as well as the entire device and its lumen, when scanned in non-clinical testing using the sequence: Fast spin echo in a 3.0 Tesla, Excite, GE Electric Healthcare, with G3.0-052B software, MR system with body radiofrequency coil.

For all scanners, the image artifact dissipates as the distance from the device to the area of interest increases. MR scans of the lower extremities may be obtained without image artifact. Image artifact may be present in scans of the abdominal, upper extremity, and head and neck region, depending on distance from the device to the area of interest.

Clinical information is available on six patients who received MRI scans during the course of the clinical trial. There have been no reported adverse events or device problems in any of these patients as a result of having received an MRI. Additionally, there have been approximately 3,000 patients implanted with Zenith TAA Endovascular Grafts worldwide, in which there have been no reported adverse events or device problems as a result of MRI.

Cook recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation. The MedicAlert Foundation can be contacted in the following manners:

Mail: MedicAlert Foundation International
2323 Colorado Avenue
Turlock, CA 95382

Phone: 888.633.4298 (toll free)
209.668.3333 from outside the U.S.

Fax: 209.669.2450