

Zenith Flex[®] AAA MRI Safety and Compatibility

Non-clinical testing has demonstrated that the Zenith AAA Endovascular Graft 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 AAA Endovascular Graft produced a temperature rise of less than or equal to 1.4 °C at a maximum whole body averaged specific absorption rate (SAR) of 2.8 W/kg, as assessed by calorimetry 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
- 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 AAA Endovascular Graft produced a temperature rise of less than or equal to 1.9 °C at a maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg, as assessed by calorimetry 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.

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 50,000 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 US

Fax: 209-669-2450

Web: www.medicalert.org