



Zenith TX2 TAA Endovascular Graft MR Information

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 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 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 US

Fax: 209.669.2450

Web: www.medicalert.org