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Zenith Flex® AAA Endovascular Graft MR Information

The MR safety and compatibility of the Zenith AAA Endovascular Graft (a previous version of the device) has been evaluated through bench testing in MRI systems with static fields of ≤ 1.5 Tesla, gradient magnetic fields of ≤ 20 Tesla/second and whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of imaging. The Zenith AAA Endovascular Graft was found to exhibit significant deflection and torque of the stainless steel metallic component of the endovascular graft and therefore did not meet standard "MR Safe" bench test criteria.

Adverse events have not been reported clinically in patients who have undergone MRI. However, sufficient data are not available to demonstrate MRI safety and there may be potential risks (e.g., device migration, vessel damage) that could be associated with forces applied to the metallic components of the Zenith AAA Endovascular Graft. Therefore, a careful assessment of these potential risks and the potential benefits to the patient should be completed prior to use of MR imaging. In addition, the facility for MRI should be appropriately selected to allow for prompt intervention if necessary.

The Zenith AAA Endovascular Graft may affect the image quality (image artifact) depending on the pulse sequence that is used for MR imaging.