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Magnetic Resonance Imaging-related safety information for Sugita Aneurysm Clips

We conducted non-clinical testing and identified Sugita Aneurysm Clips for permanent occlusion as "MR Conditional" device defined in ASTM F2503-13.

The non-clinical testing demonstrated a patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 1,000-Gauss/cm (10-T/m) for Sugita Aneurysm Clips (Elgiloy)
Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m) for Sugita Titanium Clips
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the Sugita Aneurysm Clips for permanent occlusion are expected to produce a maximum temperature rise of 2.4°C for Sugita Aneurysm Clips (Elgiloy), 2.2°C for Sugita Titanium Clips after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Sugita Aneurysm Clips for permanent occlusion extends approximately 25-mm from Sugita Aneurysm Clips (Elgiloy), 5-mm from Sugita Titanium Clips when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Signature: _____



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