Recommended MRI Labeling Based on ASTM F2503-20

MRI Safety Information

MR Conditional

Non-clinical testing demonstrated that the **Anastomark Coronary Artery Bypass Graft Marker, Stainless-Steel Distal** is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 1,000-Gauss/cm (10-T/m)
- 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 Anastomark Coronary Artery Bypass Graft Marker, Stainless-Steel Distal is expected to produce a maximum temperature rise of 1.5˚C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Anastomark Coronary Artery Bypass Graft Marker, Stainless-Steel Distal extends approximately 20-mm from this implant when imaged using a gradient echo pulse sequence

MRI Safety Information

MR Conditional

Non-clinical testing demonstrated that the **Anastomark Coronary Artery Bypass Graft Marker, Flexible Proximal** is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 10,000-Gauss/cm (100-T/m)
- 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 Anastomark Coronary Artery Bypass Graft Marker, Flexible Proximal is expected to produce a maximum temperature rise of 1.4˚C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Anastomark Coronary Artery Bypass Graft Marker, Flexible Proximal extends approximately 6-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.