MRI Safety
Promus ELITE™ Everolimus-Eluting Platinum Chromium Coronary Stent System

Below is an excerpt of Section 6.12 from the Directions for Use detailing the safety of performing MRI following the placement of a Promus ELITE™ Stent.

6.12 Magnetic Resonance Imaging (MRI) Safety Information:
Non-clinical testing has demonstrated that the Promus ELITE Stent is MR Conditional for single and overlapped conditions up to 74 mm. A patient with this device can be safely scanned in a Magnetic Resonance system meeting the following conditions:

- Static magnetic field of 3.0 and 1.5 Tesla only
- Maximum spatial gradient magnetic field of 2200 gauss/cm (22 T/m)
- Product of static magnetic field and static magnetic field gradient < 25 T²/m (extrapolated)
- Maximum Magnetic Resonance system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Promus ELITE Stent is expected to produce a maximum temperature rise of 2.6°C after 15 minutes of continuous scanning.

Non-clinical testing has demonstrated that the image artifact caused by the device extends approximately 8 mm from the Stent when imaged with a spin echo pulse sequence and a 3.0 Tesla MRI system. The artifact does not obscure the device lumen.

Medical Registration
It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

For more information, contact your local sales representative or call the Boston Scientific Customer Service Center at 888-272-1001.

View the full DFU>>