

## 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 T<sup>2</sup>/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 MedAlert Foundation ([www.medicalert.org](http://www.medicalert.org)) or equivalent organization.



**Magnetic Resonance  
Conditional**

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

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