

MRI Safety

Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System

Below is an excerpt of Section 6.11 from the *Directions for Use* detailing the safety of performing MRI following the placement of a Promus PREMIER Stent.

Section 6.11 Magnetic Resonance Imaging (MRI) Safety Information

Non-clinical testing has demonstrated that the Promus PREMIER Stent is MR Conditional for single and overlapped conditions up to 74mm. A patient with this device can be safely scanned in an MR system meeting the following conditions:

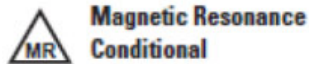
- Static magnetic field of 3.0 and 1.5 Tesla only
- Maximum spatial gradient magnetic field of 2200 gauss/cm (22 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg (Normal Operating Mode)

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

In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from the Promus PREMIER 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 Boston Scientific Patient Services at 877.829.8741.

[View the full DFU>>](#)