Magnetic Resonance Imaging (MRI)
PALMAZ-SCHATZ® Balloon-Expandable Stent Systems

The Cordis PALMAZ-SCHATZ® Mini Crown Balloon-Expandable Stent with DYNASTY™ Over the Wire Delivery System is indicated for improving coronary luminal diameter in treatment of abrupt or threatened closure in patients with failed interventional therapy in lesions (25 mm) with reference diameters of 2.25 to 3.25 mm.¹

Long-term outcome (beyond 1 month) for this permanent implant is unknown at present.¹

The PALMAZ-SCHATZ® CROWN balloon-expandable Stent with POWERGRIP Over-the-Wire delivery system is indicated for use in patients eligible for balloon angioplasty with symptomatic ischemic heart disease due to de novo and restenotic native coronary artery lesions (length <25 mm) with a reference vessel diameter in the range of 3–4 mm. Long-term outcome (beyond one year) for this permanent implant is unknown at present.²

You specifically asked for information relevant to magnetic resonance imaging (MRI) after the implantation of the PALMAZ-SCHATZ® Balloon-Expandable Stent Systems.

INSTRUCTIONS FOR USE
The following information is provided in the PALMAZ-SCHATZ® Balloon-Expandable Stent Systems Instructions For Use:

Do not perform a magnetic resonance imaging (MRI) scan on a patient after stent implantation until the stent has completely endothelialized (8 weeks) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field.¹ ³

ADDITIONAL INFORMATION
Porto et al conducted a retrospective study of in-hospital and 9-month outcome data to evaluate the safety of MRI performed in a 1.5 Tesla magnet 1-3 days after bare-metal stent (BMS) and drug-eluting stent (DES) implantation. Forty-nine patients underwent cardiovascular MRI imaging. Fifteen of these patients received DES; paclitaxel (n=14) and sirolimus (n=1), and 34 patients received BMS. The average number of stents placed per patient was 2.2 +/- 1.1. Of note, no acute thrombosis was recorded and at 9-month clinical follow-up, 2 patients from the BMS group (4%) developed an adverse event. The authors concluded that it is safe to perform an MRI within 1-3 days after BMS and DES implantation.³

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Rev. 2.1
3 Tesla / 128 MHz MR scanner (Signa HDx 3T, General Electric Healthcare, software version 4\[LX\]MR).²

ADDITIONAL INFORMATION
Differences exist when comparing FDA mandated testing for device MRI compatibility and MR system values for a particular machine. Medical device companies report on testing that involves measuring a deflection angle; therefore, this is not the actual Gauss of the machine that was used in testing. MR machine manufacturers document spatial gradient magnetic fields at a location closer to the magnet of the MRI machine. Also, during most testing environments, the manufacturers of the MRI machine remove covers and/or the shroud from the scanner which allows access to stronger static magnetic fields and spatial gradient magnetic fields, and therefore, values are typically higher than would be realized in a patient setting.³

We appreciate your interest in the CYPHER® Stent. If you require further information or would like to obtain the current Instructions For Use, please feel free to contact Cordis Medical Information at 1-800-781-0282 or visit www.cordislabeling.com.

References:
1. CYPHER® Sirolimus-eluting Coronary Stent current Instructions For Use.