Cordis Corporation
430 Route 22 East, Bridgewater, NJ 08807
p (908) 541 4100

Mailing Address:
P.O. Box 6008, Bridgewater, NJ 08807-0008

Cordis

Magnetic Resonance Imaging (MRI)
CYPHER® Sirolimus-eluting Coronary Stent

The CYPHER® Stent is indicated for improving coronary luminal diameter in patients with symptomatic ischemic disease due to discrete *de novo* lesions of length ≤30 mm in native coronary arteries with a reference vessel diameter of ≥2.25 mm to ≤3.5 mm.[1]

You specifically asked for information relevant to magnetic resonance imaging (MRI) after the deployment of the CYPHER® Stent.

Current MRI information is listed below.

Non-clinical testing has demonstrated that the CYPHER Stent®, in single and in overlapped configurations with a minimum overlap of 2 mm, is MR-conditional. These stents can be scanned safely, immediately post implantation, under the following conditions:[2]

- Static magnetic field of 1.5 or 3 Tesla.
- Spatial gradient field of 1350 Gauss/cm or less.
- Maximum whole-body-averaged specific absorption rate (WB-SAR) of 2.0 W/kg for 15 minutes of scanning (i.e.- per pulse sequence)
- Normal operating mode of the MR system

MRI-Related Heating

In non-clinical testing using computer modeling, a single CYPHER Stent® up to 33 mm in length or in overlapped configurations up to 64 mm in length produced an estimated *in-vivo* temperature rise of less than 5.3.°C at a WBSAR of 2.0 W/kg for 15 minutes of MR scanning (i.e.- per pulse sequence) in a 3 Tesla / 128 MHz MR Scanner (Signa HDx 3T,General Electric Healthcare, software version 4\LX\MR) and in a 1.5 Tesla / 64 MHz stand alone body coil (Signa coil, General Electric Healthcare). The effect of heating in the MRI environment for stents with fractured struts is not known.[2]

Artifacts

The image artifact completely obscures the device lumen and extends approximately 3 mm to 15 mm from the outside of device for either spin echo or gradient echo images taken either parallel or perpendicular to the static magnetic field when scanned in non-clinical testing in a

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Data specific to the safety of the PALMAZ-SCHATZ® Balloon-Expandable Stent Systems in MRI field strengths in excess of 1.5 Tesla are not currently available. However, the CYPHER® Sirolimus-eluting Coronary Stent, built on the same 316L stainless steel platform as the PALMAZ-SCHATZ® Balloon-Expandable Stent Systems, has been shown through non-clinical testing to be safe at field strengths of 1.5 Tesla and 3 Tesla. No waiting time is required post-implantation. Citations for the CYPHER® Sirolimus-eluting Coronary Stent are included for your review.[4]

We appreciate your interest in the PALMAZ-SCHATZ® Balloon-Expandable Stent Systems. If you require further information, please feel free to contact Health Care Systems at 1-800-327-7714 (option 2).

References:

1. PALMAZ-SCHATZ® Mini Crown Balloon-Expandable Stent with DYNASTY™ Over the Wire Delivery System Instructions For Use.

2. PALMAZ-SCHATZ® CROWN Balloon-Expandable Stent with POWERGRIP Over-the-Wire Delivery System Instructions For Use.

3. Porto I, Selvanayagam J, Asbar V, et al. Safety of Magnetic Resonance Imaging One to Three Days After Bare Metal and Drug-Eluting Stent Implantation. *Am J of Cardiol. 2005;96:366-368.*

4. CYPHER® Sirolimus-eluting Coronary Stent on RAPTOR™ Over-the-Wire Delivery System and CYPHER® Sirolimus-eluting Coronary Stent on RAPTORRAIL® Rapid Exchange Delivery System Instructions For Use.