



Cardiovascular

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DATE: 21-May-2009
TO: Medical Healthcare Professionals
FROM: Boston Scientific
SUBJECT: Magnetic Resonance Imaging and Intracoronary Stents

Per your request for additional information about the safety of performing MRI following the placement of a TAXUS® Liberté® Atom™ Stent, please see the excerpt of Section 6.9 from the *Directions for Use* regarding the safety of performing MRI following the placement of a Boston Scientific Stent.

TAXUS Liberté Atom Paclitaxel-Eluting Coronary Stent System Monorail® and Over the Wire Coronary Stent Delivery System

Section 6.9 Magnetic Resonance Imaging (MRI)

Through non-clinical testing, the TAXUS® Liberté® Stent has been shown to be MR Conditional (poses no known hazards under specified conditions). The conditions are as follows:

- Field strengths of 3 Tesla or less.
- A maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg or less for a total active MR scan time (with RF exposure) of 15 minutes or less.
- Maximum Spatial Field Gradient of 70 mT/cm or less.
- A rate of change of magnetic field (dB/dt) of 60 T/s or less.

The TAXUS Liberté Stent should not migrate in this MRI environment. MR imaging within these conditions may be performed immediately following the implantation of the stent. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions.

Boston Scientific conducted tests using both single stents and overlapped stents. The maximum temperature rise was less than 2.0 degrees Celsius in all cases. The effect of heating in an MRI environment for stents with simulated fractures has been tested and found to be similar to single stents. In vivo, local SAR depends on MR field strength and may be different than the estimated whole body averaged SAR, due to body composition, stent position within the imaging field, and scanner used, thereby affecting the actual temperature rise.

MR imaging quality may be compromised if the area of interest is in exactly the same area or relatively close to the position of the stent.

To receive a complete copy of the DFU, please visit www.bostonscientific.com.