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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® Express® Atom™ Stent, please refer to the *Directions for Use* regarding the safety of performing MRI following the placement of a Boston Scientific Stent.

**TAXUS® Express²™ and TAXUS® Express²™ Atom Paclitaxel-Eluting Coronary Stent System Monorail® and Over the Wire Coronary Stent Delivery System**

## Section 5.9 Magnetic Resonance Imaging (MRI)

Through non-clinical testing, the TAXUS Express Stent has been shown to be MRI safe at field strengths of 3 Tesla or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MRI. The TAXUS Express Stent should not migrate in this MRI environment. MRI at 3T or less may be performed immediately following the implantation of the TAXUS Express Stent. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3 Tesla.

In this testing, the stent produced a maximum temperature rise of 0.65 degrees C at a maximum whole body averaged SAR of 2.0 W/kg for 15 minutes of MRI. The effect of heating in the MRI environment was similar for overlapping bare metal stents (2 to 5 mm overlap at the ends), made of the same stainless steel material and having the same stent design. The effect of heating in the MRI environment on stents with fractured struts is not known. The temperature rise of 0.65 degrees C for 15 minutes is calculated to result in an increase in cumulative drug release of 0.001% of the total dose. MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

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


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