

For healthcare and medical media outside the U.S. and Japan

## THE BOSTON SCIENTIFIC PROMUS™ EVEROLIMUS-ELUTING CORONARY STENT SYSTEM: *Olimus made deliverable.*

The PROMUS™ Everolimus-Eluting Coronary Stent System combines the familiar Multi-Link Vision™ Stent platform with the controlled-release everolimus drug. With thin struts (.0032" or 0.08 mm) and low system profile (.042" or 1.07 mm for 3 mm diameter), the PROMUS Stent has exceptional flexibility and deliverability<sup>1</sup>. PROMUS is a private-labeled XIENCE™ V Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific.



### ***Optimal drug and polymer design***<sup>2-4</sup>

The PROMUS Stent has low drug load compared with other 'Olimus' stents. Thin, durable polymer matrix results in controlled release of the highly lipophilic everolimus drug<sup>5-7</sup>.

With this combination of Everolimus drug and Multi-Link Vision™ stent, the PROMUS stent brings efficacy where deliverability is a challenge.

### ***Early clinical experience shows strong performance***<sup>8</sup>

The U.S. pivotal SPIRIT III clinical trial results confirm early positive results of the XIENCE V (PROMUS) Stent. The primary endpoint of angiographic in-segment late loss at 8 months met its non-inferiority margin between the TAXUS™ Stent (0.28 mm) and XIENCE V (PROMUS) Stent (0.14 mm),  $p_{NI} < 0.0001$ ,  $p_{superiority} = 0.004$ .

The major clinical secondary endpoint of target vessel failure or TVF (a composite of death, myocardial infarction, and ischemia-driven target vessel revascularization) at 9 months also showed non-inferiority between the TAXUS Stent (9.0%) and the XIENCE V (PROMUS) Stent (7.2%),  $p_{NI} < 0.0001$ ,  $p_{superiority} = 0.31$ . Although not powered as an endpoint, ischemia-driven target lesion revascularization (TLR, or re-treatment rate) was comparable between the TAXUS Stent (5.0%) and the XIENCE V (PROMUS) Stent (2.6%),  $p = 0.053$ . TVR was also comparable between the TAXUS Stent (6.5%) and the XIENCE V (PROMUS) Stent (5.3%),  $p = 0.47$ .

Both the TAXUS Stent and XIENCE V (PROMUS) Stent demonstrated impressive safety results up to 9 months, with low and comparable rates of thrombosis, death, and myocardial infarction.

The XIENCE V (PROMUS) Stent has also been evaluated in the SPIRIT FIRST and SPIRIT II Trials. The SPIRIT FIRST trial met its primary endpoint of superiority to bare metal stents with an In-Stent Late Loss level of 0.10 mm. The SPIRIT II trial met its primary endpoint of non-inferiority to the TAXUS™ Stent with an In-Stent Late Loss Level of 0.11 mm.<sup>8</sup> Both the SPIRIT First and SPIRIT II trials have completed follow-up out to 2 years.<sup>9</sup>

The PROMUS Stent received CE Mark approval in October 2006 allowing Boston Scientific to distribute the stent in 27 countries of the European Economic Area. It is also available in Australia and selected countries in Asia, Latin America, Africa and Eastern Europe.

The XIENCE V (PROMUS) Stent is an investigational device in the US and not yet approved for sale. It is currently under review by the Food and Drug Administration (FDA) with an anticipated US launch in 2008.

<sup>1</sup> Testing completed by Boston Scientific Corporation. Data on file. Bench test results may not necessarily be indicative of clinical performance. Testing includes Cypher™ Stent, Cypher Select™ Stent and Endeavor™ Stent, n=6.

<sup>2</sup> PROMUS Stent, Instructions for Use (IFU).

<sup>3</sup> Cypher Stent, Instructions for Use. (IFU).

<sup>4</sup> Kandzari DE, Leon MB. J Interven Cardiol 2006;19:405–413.

<sup>5</sup> Grube E *et al.* Circulation 2004;109:2168–2171.

<sup>6</sup> Crowe A *et al.* Drug Metab Disp 1999;27:627–632.

<sup>7</sup> Crowe A, Lemaire M. Pharmaceutical Research 1998;15:1666–1672.

<sup>8</sup> SPIRIT is sponsored by Abbott. SPIRIT III Presentation, ACC 2007; Presented by Stone GW. SPIRIT FIRST in Serruys, *et al.*, Eurointervention 2005, 1:58-65, SPIRIT II in Serruys, *et al.*, Eurointervention 2006, 2 :286-294.

<sup>9</sup> SPIRIT II 2 year follow-up presentation, ACC 2008 ; Presented by Serruys P.

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