

## The Boston Scientific Epic™ Stent Continues to Demonstrate Positive Clinical Outcomes for Patients with Iliac Artery Disease

NATICK, Mass., Oct. 23, 2012 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) reports twelve-month clinical endpoint data from the ORION trial, which demonstrated robust safety and effectiveness outcomes for the Epic™ Self-Expanding Nitinol Stent System in patients with obstructed iliac arteries. Results were presented today by Daniel Clair, M.D., FACS, principal investigator of the ORION trial and chairman of the Department of Vascular Surgery at The Cleveland Clinic Foundation, at the 24th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

"Following the recent presentation of our nine-month data, the 12-month ORION data continue to show very strong clinical outcomes," said Dr. Clair. "The performance of the Epic Stent in challenging iliac artery lesions and the long-term demonstration of both safety and efficacy of the Epic Stent is another example of our ability to offer patients a durable treatment option for iliac artery disease."

The prospective, single-arm ORION trial enrolled 125 patients at 28 sites in the United States. The trial previously met its primary endpoint of major adverse events (MAE) at nine months with a rate of 3.4 percent for the Epic Stent compared to a pre-specified performance goal. Major adverse events are defined as death within 30 days, myocardial infarction (MI, or heart attack) occurring during hospitalization, target vessel revascularization (TVR) through nine months and amputation of the treated limb through nine months. The MAE rate at 12 months was 5.4 percent, with all MAEs related to TVR. No amputations were reported through the 12-month period. The positive data support the Boston Scientific goal of delivering products designed to reduce the need for reinterventions and help lower overall healthcare costs.

Duplex ultrasound, which measures blood flow through arteries and veins, showed a primary patency (level of un-obstruction) of 94.4 percent, indicating the vast majority of treated lesions remained open through the 12-month follow-up period.

Furthermore, outcomes for very complex (TASC C/D) lesions were similar to those reported for less complex (TASC A/B) lesions. Patients experienced significant clinical improvement from baseline to twelve months based on feedback from validated questionnaires evaluating walking distance, speed and stair climbing.

"The positive 12-month data from the ORION trial complement our early launch success and market share gains," said Jeff Mirviss, president of Peripheral Interventions at Boston Scientific. "The Epic Stent has been very well-received by physicians across the country. They appreciate the radial force of the stent, which helps allow the artery to stay open, and the flexibility in its design, which helps in deliverability. Our ability to provide a total iliac solution, with the market-leading Express LD Stent and our expansive balloon catheter portfolio, allows Boston Scientific to offer a complete line of advanced solutions to physicians and patients."

### About Epic and the ORION Trial

The Epic Stent is a self-expanding nitinol stent designed to sustain vessel patency, while providing enhanced visibility and accuracy during placement. It employs an innovative Tandem Architecture™, which is engineered to provide excellent stent flexibility while maintaining predictable radial force characteristics across a variety of stent sizes. The Epic Stent is compatible with 6F sheaths, and the stent delivery system is compatible with 0.035 inch guidewires.

The ORION clinical data was used to support application for U.S. Food and Drug Administration approval of the Epic Stent System.

The Epic Nitinol Stent System received CE Mark approval and was launched in Europe and other international markets in 2009. It was launched in the United States in May of 2012.

### About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. For more information, please visit: [www.bostonscientific.com](http://www.bostonscientific.com).

### Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans, clinical trials and outcomes, our technology, product performance and importance, and competitive offerings. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business

strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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