# Boston Scientific Completes Clinical Trial Enrollment for Adapt<sup>™</sup> Monorail<sup>™</sup> Carotid Stent System

## European ASTI study to evaluate new nitinol stent to treat carotid artery disease

NATICK, Mass., July 12, 2011 /<u>PRNewswire</u>/ -- Boston Scientific Corporation (NYSE: BSX) has completed patient enrollment in the ASTI post-market clinical follow-up study designed to evaluate its Adapt<sup>™</sup> Monorail<sup>™</sup> Carotid Stent System in combination with its FilterWire EZ<sup>™</sup> Embolic Protection System for treatment of carotid artery disease in patients at high risk for carotid surgery. The trial began in 2010 and has reached its enrollment goal of 100 patients at 11 sites in Europe. Principal Investigator of the study is Marc Bosiers, M.D., Head of the Department of Vascular Surgery, A.Z. Sint-Blasius Hospital in Dendermonde, Belgium.

The Adapt Carotid Stent features thin struts and an innovative design engineered for flexibility in the carotid arteries. It incorporates a self-expanding, rolled nitinol sheet with patented Dynamic Tapering Technology™ designed to conform to varying carotid anatomies. This second-generation carotid stent also provides excellent visibility and has a closed-cell geometry that facilitates consistent lesion coverage. It has been sold in Europe as well as other select countries since receiving CE Mark in 2010.

"The Adapt Stent offers outstanding deliverability and scaffolding of the vessel wall, which are critical attributes for carotid stents," said Dr. Bosiers. "I look forward to seeing how the features of this new technology may be reflected in clinical outcomes from the ASTI study."

The study will examine rates of major adverse events -- defined as any death, stroke or myocardial infarction at 30 days. Additionally, it will assess rates of late ipsilateral stroke, target lesion revascularization and in-stent restenosis.

"Physician experience with the Adapt Stent has been excellent since its introduction in Europe last year," said Jeff Mirviss, President of Boston Scientific's Peripheral Interventions Division. "It provides physicians with the flexibility, deliverability and lesion coverage needed to treat narrowing in complex carotid anatomies."

In addition to its Adapt Carotid Stent, Boston Scientific markets the Carotid WALLSTENT<sup>®</sup> Monorail<sup>®</sup> Endoprosthesis, the leading carotid stent in Europe and Japan and available in all major markets worldwide. Both stents are mounted on Monorail Delivery Systems and feature closed-cell designs intended to offer increased scaffolding of the vessel wall. Both stents are also designed to be used in conjunction with the FilterWire EZ Embolic Protection System, intended to capture plaque debris released during the stenting procedure.

"The Adapt Stent is an important addition to our portfolio of leading carotid stents in Europe," said Fred Hrkac, President of Europe, Middle East and Africa at Boston Scientific. "By offering the only CE Marked, secondgeneration, closed-cell carotid stent, we plan to build on the success of the Carotid WALLSTENT and continue to provide innovative treatment options for patients with carotid artery disease."

In the U.S., the Adapt Carotid Stent System is not available for sale.

### **About Boston Scientific**

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: <a href="https://www.bostonscientific.com">www.bostonscientific.com</a>.

### **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 new product launches and launch cadence, regulatory approvals, clinical trials, product performance 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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