Boston Scientific

FDA Approves Boston Scientific's Apex™ PTCA Dilatation Catheter

New design provides more options for treating patients with complex lesions

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NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., Nov. 10 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has received approval from the U.S. Food and Drug Administration to market its Apex™ PTCA(1) Dilatation Catheter. The Apex Catheter is a high-performance pre-dilatation balloon catheter developed specifically to address physicians' needs in treating the most challenging atherosclerotic lesions. It is available for distribution in both Monorail® and Over-The-Wire (OTW) catheter platforms.

The Apex Catheter represents the next generation of dilatation catheter technology, utilizing a new Bi-Segment™ inner shaft for improved pushability and flexibility. Additionally, it has a redesigned tip with the same low profile as the Maverick® PTCA Dilatation Catheter for excellent turning and wire tracking.

It is available in a wide array of balloon diameters from 1.5mm up to 5.0mm, with balloon lengths ranging from 8mm up to 40mm (for select diameters). Both the Apex Monorail and OTW catheters are available in two different 1.5mm designs -- "Apex Push Catheter" and "Apex Flex Catheter." The Apex Push Catheter is designed to enhance pushability for tight lesions, while the Apex Flex Catheter is designed to enhance trackability for tortuous arteries. The two 1.5mm Apex Catheter designs enable physicians to select the appropriate catheter based on the clinical situation.

"A much greater number of 'complex' lesions could be more readily crossed and dilated if more advanced, next-generation, catheter technology were available," said James Hermiller, M.D., Director of the Interventional Fellowship at St. Vincent Heart Center of Indiana in Indianapolis. "I believe the Apex Catheter represents a next generation of catheter technology."

"The Apex Catheter is a reflection of Boston Scientific's commitment to providing physicians with the most complete set of high-performance cardiovascular devices possible," said Hank Kucheman, Senior Vice President and Group President, Cardiovascular. "As an established market leader, we listened to physicians' requests for improvements to existing balloon catheters, and responded with the advanced technology found in the Apex Catheter."

The Apex Catheter builds on Boston Scientific's reputation for developing market-leading balloon catheters. Boston Scientific makes the number one selling pre- and post-dilatation catheters (Maverick® and Quantum™ Maverick®) in the U.S. market today.

The Apex Catheter is the latest technological development by Boston Scientific intended to improve the management of patients with coronary atherosclerosis undergoing percutaneous coronary intervention (PCI). Boston Scientific furthers PCI optimization through a broad range of devices, including ultrasound imaging to assess lesions and balloon catheters and drug-eluting stents to reopen blocked arteries. This broad portfolio of devices supports physicians' efforts to achieve safe and effective outcomes for their patients.

PTCA dilatation catheters are used in coronary angioplasty and stenting procedures to open arteries blocked by atherosclerosis, which if left untreated can cause heart attack and stroke. Coronary artery disease represents the leading cause of death in the United States, accounting for more than 870,000 deaths each year.(2)

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: http://www.bostonscientific.com/.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of 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 clinical trials, product performance, competitive offerings, procedural volume, overall market size and our market position. 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 thereafter. 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.

(1) Per Percutaneous Transluminal Coronary Angioplasty

(2) Source: http://www.americanheart.org/downloadable/heart/1166712318459HS_StatsInsideTex t.pdf (Due to length of URL, please copy and paste into browser).

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