

Boston Scientific Announces FDA Approval of Innova™ Vascular Self-Expanding Stent System

U.S. Launch Underway for Therapy Designed to Treat Peripheral Artery Disease

MARLBOROUGH, Mass., Aug. 19, 2015 /[PRNewswire](#)/ -- Boston Scientific Corporation (NYSE: BSX) has received Food and Drug Administration (FDA) approval for the Innova™ Vascular Self-Expanding Stent System, an advanced treatment option for patients with narrowing or blockages in the superficial femoral artery (SFA) or proximal popliteal artery (PPA). This can cause peripheral artery disease (PAD), a circulatory disorder that results from a build-up of plaque in one or more of the arteries, most often in the legs. PAD of the lower extremities can lead to painful ulcers, infections, or amputation of the toes or feet. The company has commenced a full commercial launch of the Innova Stent System in the U.S.

"It is gratifying to be able to offer this minimally invasive therapy to improve the quality of life in those patients who suffer from PAD," said Richard Powell, M.D., section chief, Department of Vascular Surgery, Dartmouth Hitchcock Medical Center, Lebanon, N.H., professor of Surgery and Radiology at the Geisel School of Medicine, and global principal investigator of the SuperNOVA trial, evaluating the safety and effectiveness of the Innova Stent System. "The SFA and proximal popliteal arteries present a challenging environment for stents. The flexibility, radial strength and fracture resistance of the Innova Stent are designed specifically for this anatomy."

The Innova stent platform consists of a Nitinol self-expanding bare metal stent with an advanced delivery system, and is available in a range of sizes, including diameters from 5 mm to 8 mm and lengths of 20 mm to 200 mm. It features a hybrid cell architecture with open-cells along the stent body and closed cells at each end for uniform and accurate deployment. This stent platform serves as the foundation for the new Eluvia™ Drug-Eluting Vascular Stent, designed specifically for the SFA. The Innova Stent System was designed with an intuitive triaxial delivery system for precise, predictable stent placement and uniform deployment.

"The Innova delivery system allowed me to place the stent smoothly and accurately," said Jaafer Golzar, M.D., interventional cardiologist, Advocate Christ Medical Center, Oak Lawn, Ill., and the first to use the Innova Stent System in a clinical procedure following FDA approval. "The first step to achieving an optimal outcome is accurate placement, and then stent properties like radial strength and flexibility come into play." Dr. Golzar is also a clinical assistant professor, University of Illinois at Chicago and director of Limb Salvage & Endovascular Intervention, Advocate Trinity Hospital, Chicago.

"This is an important therapy for a disease that can have life-changing consequences, including limb amputation," said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. "The Innova and the Eluvia Stent Systems together demonstrate our commitment to improving health outcomes in the treatment of a disease affecting more than 200 million people worldwide."

Get more [information about the Innova Stent System](#). [View or download an image](#) of the Innova Stent System. The Innova Stent System received CE Mark approval in May 2012. The Eluvia Stent System is pending CE Mark and is not available for use or sale in the U.S.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on [Twitter](#) and

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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 regulatory approvals, new product launches, clinical trials and impact of data and product performance and impact. 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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