

Boston Scientific

Boston Scientific Announces FDA Clearance and CE Mark for WallFlex® Fully Covered Esophageal Stent

PRNewswire
NATICK, Mass. and LONDON
(NYSE:BSX)

NATICK, Mass. and LONDON, Nov. 20 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) and CE Mark approval to market its WallFlex® Fully Covered Esophageal Stent for the treatment of malignant esophageal strictures (obstructions) caused by tumors in patients with resectable or non-resectable esophageal cancer.

(Photo: <http://www.newscom.com/cgi-bin/prnh/20091120/NE13563>)

The WallFlex® Partially Covered Esophageal Stent was cleared by the FDA and received CE Mark in 2008. Both stents -- along with the complete WallFlex Stent family of self-expanding metal stents (SEMS) -- will be available for hands-on demonstration at the GASTRO 2009 conference, which is being held November 21-25 in London.

"The low profile delivery system (18.5 Fr) of the WallFlex Esophageal Stents has allowed me to traverse tight strictures, facilitating stent placement within malignancies that, in the past, needed to be pre-dilated," said Drew Schembre, M.D., Chief of Gastroenterology at Virginia Mason Medical Center in Seattle, Washington. "Moreover, the fully covered option may be a viable choice for patients with operable esophageal cancer who are undergoing chemotherapy and radiation treatment in preparation for surgery."

Patients with obstructions due to esophageal cancer may have difficulty swallowing, resulting in severely limited quality of life. Complete blockages of the esophagus can prevent liquid consumption. The WallFlex Esophageal Stent allows physicians to re-establish patency (openness) of the esophagus, enabling resumption of oral intake.

The WallFlex Fully and Partially Covered Stents employ a proprietary Permalume® silicone covering designed to prevent tumor ingrowth, seal concurrent esophageal fistulas and help reduce food impaction. The stents' progressive-step, flared ends are designed to reduce the risk of migration and may assist in anchoring the fully covered stent within the esophageal lumen. The multiple wire-braided construction is engineered to allow the stent to adjust to forces within the esophagus such as peristalsis (involuntary contractions) and strictures. In addition, the WallFlex Fully Covered Stent may be reconstrained up to 75 percent deployment.

"The availability of the complete line of WallFlex Fully and Partially Covered Esophageal Stents represents a tremendous milestone for Boston Scientific," said Michael Phalen, President, Boston Scientific Endoscopy. "This advanced line of esophageal stents is designed to improve the quality of life for the thousands of patients suffering from esophageal cancer. We are pleased that our entire WallFlex Stent family -- biliary, enteral and now esophageal -- is available in the U.S., Europe and other strategic international markets. This underscores our mission to meet the high expectations of our customers and deliver a complete range of innovative treatment options to diagnose, palliate and treat patients with diseases of the gastrointestinal tract."

Symposium at GASTRO 2009

Boston Scientific will host a symposium titled "Esophageal Stenting: Changing Algorithms, Changing Outcomes" on Tuesday, November 24 at 7:00 a.m. at GASTRO 2009 in London. The event will be moderated by Professor Horst Neuhaus of Evangelisches Krankenhaus in Dusseldorf, Germany. Panelists and topics include Dr. Marc Giovannini, Institut Paoli-Calmettes in Marseille, France, who will discuss advancing treatment options; Professor Jacques Deviere, Erasme Hospital in Brussels, Belgium, who will address benign conditions and expanding the role of stents; and Professor Peter Siersema, University

Medical Center Utrecht in The Netherlands who will discuss minimizing reintervention rates in stenting.

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: www.bostonscientific.com.

About Boston Scientific Endoscopy

Boston Scientific Endoscopy develops innovative technology for less invasive, more efficient gastrointestinal procedures.

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, our product performance, regulatory approval of our products, competitive offerings, our growth strategy, 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 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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