

Boston Scientific WallFlex® Enteral Stents Shown To Be Safe and Effective in Three Clinical Registries

NATICK, Mass., Feb. 7, 2012 [PRNewswire](#)/ -- Boston Scientific Corporation (NYSE: BSX) welcomes positive results from three studies of the WallFlex® Enteral Stent Systems, a family of self-expanding metal stents (SEMS) used to alleviate obstructive symptoms caused by cancers of the gastrointestinal tract. The studies, published in peer-reviewed medical journals, determined the WallFlex Stents to be safe and effective for the treatment of malignant colorectal and gastroduodenal obstruction.

The first publication appeared in the October 2011 issue of *Gastrointestinal Endoscopy*, and reported the short-term safety and effectiveness of the Boston Scientific WallFlex Enteral Colonic Stent for relieving malignant colorectal obstruction. This 447-patient study represents the largest prospective, multi-center series to date of colonic SEMS placement in both palliative and bridge-to-surgery settings. The WallFlex Enteral Colonic Stent was determined to be safe and effective for treatment of malignant colorectal obstruction with a clinical success rate of 90.5 percent. The authors determined that SEMS allowed most bridge-to-surgery patients to have an elective surgical procedure without a colostomy and most incurable patients to receive minimally invasive palliation instead of surgery.

"Based on results from this study, physicians should consider SEMS as a first-line treatment option for patients with malignant colorectal obstruction," said Soren Meisner, M.D., Bispebjerg Hospital, Copenhagen, Denmark and principal author of the study. "SEMS provide patients with a less-invasive alternative to surgery and may also improve quality of life."

The second publication, appearing in the December 2011 issue of *The American Journal of Gastroenterology*, reports on 182 patients from the WallFlex Colonic Stent registries who received a WallFlex Colonic Stent as a bridge to surgery. Findings show rates of 97.8 percent procedural success and 94 percent clinical success, prompting the authors to conclude that the WallFlex Colonic Stent is both safe and effective as a bridge-to-surgery treatment in patients with acute malignant obstruction.

Third, results from the international, multi-center WallFlex Duodenal Stent registry were published in the January 2012 issue of *Digestive and Liver Disease*. The largest prospective study of its kind assessed the treatment of malignant gastroduodenal obstruction in 202 patients. Results confirmed the safety and effectiveness of the WallFlex Enteral Duodenal Stent, which demonstrated procedural and clinical success rates of 98 and 91 percent respectively. The authors concluded that adoption of duodenal stenting could result in this minimally invasive procedure becoming standard of care when managing inoperable patients with advanced cancer experiencing gastric outlet obstruction.

"Boston Scientific is focused on conducting research that has the potential to expand treatment options and improve patient care. Our Endoscopy group has invested millions of dollars over the past five years to conduct clinical trials involving nearly 1,400 patients at more than 110 medical centers in 21 countries," said David Pierce, President of the Endoscopy Division at Boston Scientific. "We are honored to partner with worldwide experts in gastrointestinal endoscopy to design and conduct trials with high standards of quality and scientific rigor."

About WallFlex® Enteral Stents

The WallFlex Enteral Stents are part of an advanced stenting system for the treatment of malignant colonic and duodenal obstruction. The braided structure provides flexibility to adapt to various anatomies while maintaining integrity of the lumen.

Design features such as flared and looped ends reduce the risk of stent migration, while a variety of product lengths and sizes offer options for improved obstruction relief. For more information on the WallFlex System, visit the Boston Scientific Endoscopy Channel at www.youtube.com/bostonscientificendo.

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.

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 and research and development plans, clinical studies, 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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