Boston Scientific

# Boston Scientific Study Published In Gastroenterology Reports Successful Management Of Benign Biliary Strictures With Fully Covered Metal Stents

## Large, Prospective, Multi-National Study Examines Management of Benign Biliary Strictures with Fully Covered Self-Expanding Metal Stents after Extended Indwell

MARLBOROUGH, Mass., Aug. 29, 2014 /PRNewswire/ -- A Boston Scientific Corporation (NYSE: BSX) prospective, multinational study on stent removability and preliminary long term stricture resolution of benign biliary strictures has been published in the August issue of the peer-reviewed journal, Gastroenterology.

The multinational study[1] is being conducted in 11 countries and five continents, and examines removal of fully covered self-expanding metal stents (FCSEMS) after extended indwell (i.e., up to 12 months). The 187-patient study was designed to evaluate the ability to remove the Fully Covered WallFlex™ Biliary RX Stent after extended indwell and to determine treatment success of biliary obstructions resulting from benign biliary strictures.

Data highlights[1]:

- The WallFlex Biliary RX Stents were successfully removed by endoscopy from all 155 patients in whom this procedure was attempted.
- Stricture resolution without the need to restent at the time of stent removal was successful in approximately 75% of patients.
- Approximately 85% of these patients remained stricture-free after a mean follow-up of 20 months.
- The study results demonstrate that FCSEMS are an effective treatment alternative to plastic stents, and may significantly reduce the need for multiple sequential Endoscopic Retrograde Cholangiopancreatogram (ERCP) stent exchanges and the associated complications and costs.

"Boston Scientific is committed to advancing science through investment in clinical research, and improving quality of life for patients," said David Pierce, President, Endoscopy, Boston Scientific. "The results of this study reinforce that fully covered self-expanding metal stent placement has the potential to reduce the number of ERCP procedures required in the management of benign strictures."

Follow up of the patients in the study is continuing for five years to determine the long-term durability of stricture resolution after stent removal. The Fully Covered WallFlex Biliary RX Stent is the only stent that is CE Marked with a 12-month removability indication. Additionally, Boston Scientific is currently enrolling patients in another multi-center, prospective, randomized study comparing removable, self-expanding metal stents to plastic stents for the treatment of benign biliary strictures secondary to Chronic Pancreatitis[2].

WallFlex Biliary RX Stents – Fully Covered, Partially Covered and Uncovered – are available in the United States and are indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms and for use in preoperative drainage of malignant biliary strictures. WallFlex™ Biliary RX Stents are not indicated in the United States for use in benign biliary strictures. The safety and effectiveness of the stent for use in the vascular system have not been established.

WallFlex™ Biliary RX Stents are CE Marked for use in the palliative treatment of biliary strictures produced by malignant neoplasms and for treatment of benign biliary strictures.

For more information, visit Boston Scientific Endoscopy Resources online at www.bostonscientific.com/endo-resources.

**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 30 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 Facebook.

**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 products, our business plans, markets for our products, regulatory approvals, clinical trials and data, product performance and impact, 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.

**CONTACTS**

Nisha Deo
Global Media Relations
Boston Scientific Corporation
508-683-5571 (office)
Nisha.Deo@bsci.com

Susie Lisa, CFA
Investor Relations
Boston Scientific Corporation
508-683-5565 (office)
investor_relations@bsci.com

[1] https://clinicaltrials.gov/ct2/show/NCT01014390
[2] https://clinicaltrials.gov/ct2/show/NCT01543256

SOURCE Boston Scientific Corporation

---