Boston Scientific

Boston Scientific Announces Expanded Indication For CRE Wireguided Balloon Dilator

NATICK, Mass., May 29, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces the U.S. Food and Drug Administration has cleared an expanded use indication for the CRE™ Wireguided Balloon Dilator for endoscopic dilation of the Sphincter of Oddi following sphincterotomy. The new indication offers physicians the ability to now perform Dilation Assisted Stone Extraction (DASE) with the CRE Wireguided Balloon Dilator. This is an alternative method for the removal of difficult stones in the biliary duct.

"Since becoming available, the DASE procedure with the CRE Wireguided Balloon has significantly changed my approach to the endoscopic removal of large common bile duct stones. It is an easy-to-use technique, and I have had great success in managing difficult stones," said Kenneth Sigman, M.D., at Birmingham Gastroenterology Associates in Birmingham, AL. "The CRE Wireguided Balloon is easy to place and is consistent and reliable for inflation size and pressure. I am very comfortable with this balloon for the DASE application as I've been using it for many years for esophageal and gastric stenosis."

The CRE Wireguided Balloon Dilator is constructed of Pebax® to provide durability and flexibility, and is designed to gradually open strictures by delivering three distinct pressure-controlled diameters in a single balloon. The rounded-shoulder design of the balloon is engineered to help facilitate endoscopic visualization or balloon endoscopy and provide greater usable balloon surface area during dilation.

"Large stone extraction with DASE is easy, procedures are completed faster, and I have achieved a high rate of complete stone clearance," said Riad Azar, M.D., Barnes Jewish Hospital, St. Louis, MO. "The technique is easy to learn, and I have taught a number of referring physicians who are now doing it successfully."

"The CRE Wireguided Balloon Dilator for the DASE procedure provides a new and alternative endoscopic therapy for the more than 60 million people worldwide affected by the presence of stones in the common bile duct," said David Pierce, president of the endoscopy division at Boston Scientific. "The CRE Wireguided Balloon Dilator is a core product in our endoscopy portfolio, and it underscores our ongoing commitment to advancing treatments that meet the needs of patients and physicians."

The CRE Wireguided Balloon Dilator is also indicated to dilate narrowed areas (or strictures) in the digestive tract.

For more information on the CRE Wireguided Balloon Dilator, visit Global Endoscopy Resources on-line at www.bostonscientific.com/endo-resources.

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.

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 new indications for our products, regulatory approvals, our business plans, markets for our products and product performance. 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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