

Boston Scientific Receives FDA Approval For IntellaTip MiFi™ XP Ablation Catheter And 510(k) Clearance Of Zurpaz™ 8.5F Steerable Sheath

NATICK, Mass., Aug. 21, 2013 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) continues to expand its electrophysiology (EP) offerings with U.S. Food and Drug Administration (FDA) approval of its IntellaTip MiFi™ XP catheter and 510(k) clearance of its Zurpaz™ 8.5F steerable sheath. These products join the company's growing portfolio of next generation EP tools designed to redefine ablation technology. Catheter ablation, a procedure in which localized electrical energy is delivered into the heart tissue and is aimed at restoring the continuous normal rhythm, has become a first-line treatment approach for patients with certain kinds of irregular heartbeats.

"The IntellaTip MiFi XP is a unique high resolution catheter which provides information that allows electrophysiologists to pinpoint locations for ablation, a key element needed for success," said Tom McElderry, M.D., director of Electrophysiology, University of Alabama Hospital. "In my experience with this technology, it proved especially useful in identifying areas of interest for diagnosis and ablation. This level of high resolution electrogram is something we have never seen before and I believe it will open a whole new array of possibilities in EP."

IntellaTip MiFi XP is indicated for ablation of atrial flutter, an arrhythmia that affects nearly one million people in the United States. The catheter features sophisticated mini electrodes on the tip designed to provide information about tip location and help clinicians assess lesion maturation and differentiate viable from non-viable tissue.

"Following the recent FDA 510(k) clearance of our novel Rhythmia Mapping System, adding the IntellaTip MiFi XP to our portfolio further reinforces our commitment to redefining ablation and diagnostic tools for the EP physician—especially since the catheter is compatible with the Rhythmia system," said Pete Sommerness, general manager, Electrophysiology, Boston Scientific. "We believe that the IntellaTip MiFi XP approval, combined with the introduction of our Zurpaz steerable sheath, demonstrates how we are delivering on our promise to provide electrophysiologists with meaningful innovation and complete solutions."

The Zurpaz 8.5F steerable sheath is cleared to gain access to the heart, facilitating placement of catheters for use in a variety of procedures including treatment of atrial flutter, atrial fibrillation and ventricular tachycardia. With enhanced features, including a soft distal tip, advanced shaft construction and an intuitive ergonomic handle, Zurpaz is designed to help clinicians deliver catheters consistently and safely during electrophysiology procedures.

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 markets for our products, our business plans, regulatory approvals, 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.

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