Boston Scientific

Boston Scientific Receives FDA 510(k) Clearance for the Rhythmia™ Mapping System

NATICK, Mass., July 24, 2013 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the Rhythmia™ Mapping System, a next-generation 3D mapping and navigation solution for use in cardiac catheter ablations and other electrophysiology (EP) procedures to diagnose or treat a variety of conditions in which the heart beats abnormally.

Cardiac mapping has become a standard tool for the diagnosis and treatment of arrhythmias. Current mapping systems require a manual, labor intensive process to create maps, making tradeoffs between accuracy and speed. Current systems also offer limited indication of therapy success. The Rhythmia Mapping System is designed to intelligently automate map creation, increasing the speed and improving the density of mapping compared to existing systems. The system also features vMap™, a validation map, which is designed to enable electrophysiologists, for the first time, to rapidly confirm the endpoints of the ablation treatment.

"I believe the Rhythmia Mapping System will become the new gold standard for mapping and navigation," said Warren Jackman, M.D, professor of Medicine, University of Oklahoma Health Sciences Center. "Rhythmia delivers maps of exceptional clarity because it captures thousands versus hundreds of data points. The magic of Rhythmia is continuous mapping. The intelligence built into the system virtually eliminates the need for manual annotation, which is expected to facilitate the diagnosis, treatment and final verification of arrhythmias."

Boston Scientific is offering the Rhythmia Mapping System with the company's 64-electrode IntellaMap Orion™ High Resolution Mapping Catheter, which has also received FDA 510(k) clearance.

"We are committed to developing technologies that surround electrophysiologists with innovative solutions designed to meaningfully improve patient outcomes and increase operational efficiencies," said Pete Sommerness, general manager, Electrophysiology, Boston Scientific. "Extending the reach of the Rhythmia Mapping System to electrophysiologists in the U.S. marks another significant milestone in our journey to redefine cardiac arrhythmia ablation management. We believe this clearance will help Boston Scientific achieve scale and scope to better serve the rapidly growing global EP market."

The Rhythmia Mapping System received CE Mark approval in May of 2013.

Images of the Rhythmia Mapping System and IntellaMap Orion High Resolution Mapping Catheter are available for download here.

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 business plans, markets for our products and our position in those markets, new product launches, regulatory approvals, clinical trials, 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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