

Boston Scientific Receives CE Mark Approval For The Rhythmia™ Mapping System

NATICK, Mass., May 10, 2013 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) has received CE Mark approval 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 treat a variety of conditions in which the heart beats abnormally. Some of those conditions include atrial flutter, atrial fibrillation and ventricular tachycardia. Boston Scientific is offering the Rhythmia Mapping System with the company's 64 electrode IntellaMap Orion™ Mapping Catheter, which has also received CE Mark approval. The combination, part of the 2012 Rhythmia Medical acquisition, is designed to provide electrophysiologists with accurate, high-resolution electro-anatomical maps.

"In a pair of independent clinical studies, we repeatedly showed that the Rhythmia Mapping System can rapidly generate and display high density electro-anatomical maps that allowed clinicians to effectively diagnose and treat even the most complex patients," said Hiroshi Nakagawa, M.D., PhD, professor of Medicine, director, Clinical Catheter Ablation Program, University of Oklahoma Health Sciences Center, and one of the principle investigators in the studies. "The IntellaMap Orion Catheter has a sophisticated 64 electrode design and unique deployable basket that provided a high degree of maneuverability."

Mapping and navigation systems have become a standard tool for physicians performing catheter ablations, and current systems demand tradeoffs between accuracy and speed. A more accurate, high resolution image may improve a physician's ability to select the appropriate site to ablate, improving procedural efficacy. Similarly, increasing the speed at which a mapping system can provide a high resolution map may significantly reduce procedure time. The Rhythmia Mapping System is designed to increase speed and improve density of mapping compared to existing systems, potentially offering significant benefit to patients, physicians and health care systems.

"We believe the Rhythmia Mapping System can become a leader in EP mapping with unparalleled speed, clarity and simplicity which should enable electrophysiologists to perform procedures with great efficiency and precision," said Pete Sommerness, general manager, Electrophysiology, Boston Scientific. "Bringing the Rhythmia system to our electrophysiology customers is a major step toward realizing our vision to redefine ablation technology."

In the United States, the Rhythmia Mapping System is an investigational device and not available for sale.

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, clinical trials, product performance and its importance, 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.

CONTACT:
Steven Campanini

508-652-5740 (office)
Global Media Relations
Boston Scientific Corporation
media@bsci.com

Michael Campbell
508-650-8023 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

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