# Boston Scientific Announces CE Mark Approval and First Use of Blazer™ Open-Irrigated Catheter in Europe

### Radiofrequency ablation catheter designed to treat a variety of arrhythmias

NATICK, Mass., May 3, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced CE Mark approval and first use in Europe of its Blazer™ Open-Irrigated Catheter, the Company's latest radiofrequency ablation (RFA) catheter designed to treat a variety of arrhythmias such as atrial fibrillation, atrial flutter, ventricular tachycardia and other supraventricular tachycardias. The product is being launched this quarter in select CE Mark countries.

The Blazer Open-Irrigated Catheter integrates Total Tip Cooling™ Design with the high-performance Blazer™ Catheter platform. Total Tip Cooling Design is intended to consistently cool the entire tip electrode during radiofrequency energy delivery. This is achieved through both internal cooling and external washing of the tip electrode, which is designed to reduce coagulum at the proximal edges of the tip.

The first European procedure using the Blazer Open-Irrigated Catheter was performed at the Hopital Cardiologique du Haut-Leveque in Bordeaux-Pessac, France, under the supervision of Prof. Michel Haissaguerre, M.D.

"The excellent cooling profile, coupled with the high performance Blazer platform, makes this catheter an important additional option for performing complex ablations," said Sebastien Knecht, M.D., Ph.D., who performed the procedure with Frederic Sacher, M.D. "The tip temperatures were lower than conventional openirrigated catheters during RF delivery, and the bidirectional catheter performed very well, accessing the pulmonary veins with dependable steering and tip stability."

Affecting more than 4.5 million Europeans, atrial fibrillation is an arrhythmia associated with a rapid rhythm in the upper chambers of the heart. Patients are most often treated with anti-arrhythmic drugs, which can often cause adverse side effects. Cardiac ablation with an RFA catheter is increasingly becoming an option for patients who cannot tolerate these medications.

"The CE Mark approval, first use and launch of the Blazer Open-Irrigated Catheter in Europe are important milestones in our continued focus on advancing cardiac ablation technology," said Hank Kucheman, Executive Vice President and President of Boston Scientific's Cardiology, Rhythm, and Vascular Group. "We are committed to expanding our European electrophysiology business and improving outcomes for patients undergoing cardiac ablation procedures."

In the U.S., the Blazer Open-Irrigated Catheter is an investigational device, limited by applicable law to investigational use only and not available for sale.

## **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: <a href="https://www.bostonscientific.com">www.bostonscientific.com</a>.

### **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 European electrophysiology business plans; new product launches and launch cadence; regulatory approvals; clinical trials; product performance 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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