

Boston Scientific

Boston Scientific Announces FDA Approval and First U.S. Implant of New Devices To Treat Bradycardia

NATICK, Mass., May 7, 2012 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) announces U.S. Food and Drug Administration (FDA) approval and market launch of its INGENIO™ and ADVANTIO™ pacemakers and INVIVE™ cardiac resynchronization therapy pacemakers (CRT-P). The first implant of the INGENIO pacemaker in the U.S. was performed on May 3 by Bruce L. Wilkoff, M.D., Director of Cardiac Pacing and Tachyarrhythmia Devices at the Cleveland Clinic.

To access the multi-media press release, click on the following link: <http://www.multivu.com/mnr/43512-boston-scientific-fda-approval-ingenio-advantio-invive-pacemakers>.

(Photo: <http://photos.prnewswire.com/prnh/20120507/MM92795>)

Pacemakers are designed to treat bradycardia, a condition in which the heart beats too slowly – usually less than 60 beats per minute – depriving the body of sufficient oxygen. The INGENIO and ADVANTIO pacemakers feature RightRate™ pacing technology designed to treat chronotropic incompetence (CI). CI is the inability of the heart to regulate its rate appropriately in response to physical activity, which may cause patients to feel tired or short of breath during daily activities such as walking or climbing stairs. RightRate employs Boston Scientific's minute ventilation (MV) sensor, the only sensor clinically proven to restore chronotropic competence, and adds programming options to promote ease of use and in-clinic time savings.

"Matching the patient's need to increase their heart rate with their precise activities is the main goal of cardiac pacing," said Dr. Wilkoff, who also serves as the President of the Heart Rhythm Society, and has authored numerous articles on chronotropic response and rate adaptive pacing. "Achieving that match depends on having the right tools such as an MV sensor and intelligent programming."

In addition to RightRate, the INGENIO pacemaker offers Respiratory Rate Trend (RRT), an exclusive feature that monitors respiration – a key vital sign. The INVIVE CRT-P offers RRT as part of HF Perspectiv™ – a comprehensive suite of heart failure diagnostics designed to provide health care professionals with additional information to guide treatment decisions.

"We are very pleased to receive FDA approval for these advanced devices, and excited about the potential they bring to our bradycardia business. With these products, Boston Scientific embarks on a new era in pacing technology," said Joe Fitzgerald, senior vice president and president of the Boston Scientific Cardiac Rhythm Management group. "The company's significant investments in the INGENIO platform have been focused on long-term innovation in pacing technologies, and are expected to support a comprehensive series of launches over the next several years to expand our pacing capabilities and help improve patient outcomes."

The INGENIO, ADVANTIO and INVIVE devices are designed for use with Boston Scientific's new LATITUDE™ NXT Remote Patient Management system, which is currently under review by the FDA, and will enable physicians to conduct remote follow-ups of these device patients to monitor specific pacemaker information and heart health status. The system is designed to detect clinical events between scheduled visits and send relevant data directly to a secure physician-accessible website via landline or cellular-based telephone technology using AT&T's wireless network, under an agreement between Boston Scientific and AT&T.

In April, the company announced CE Mark approval and European market launch of the INGENIO and ADVANTIO pacemakers and INVIVE CRT-P.

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 product launches and launch cadence, regulatory approvals, development and commercialization of enhanced technologies, product performance and effects, clinical outcomes, our business plans 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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