

## **Boston Scientific INGENIO Family of Pacemakers Receives CE Mark Approval for use in MRI Scans**

First European Implants of INGENIO™ MRI Pacemaker with New Image Ready™ Technology Performed This Week

Boston Scientific Corporation (NYSE: BSX) has received CE Mark approval for use of its INGENIO™ and ADVANTIO™ pacemakers in patients in need of a magnetic resonance imaging (MRI) scan. Now equipped with new Image Ready™ technology, the first European implants of the INGENIO MRI pacemaker are being performed in the United Kingdom by Dr. John Bayliss, Consultant Cardiologist at Watford General Hospital, London, in Italy by Prof. Massimo Santini, Director of Cardiology Department, San Filippo Neri, Roma, and in Germany by Dr. Joern Schmitt, Oberarzt der Justus-Liebig Universitätsklinik Gießen.

Pacemakers are designed to treat bradycardia, a condition in which the heart beats too slowly, depriving the body of sufficient oxygen. Many patients with pacemakers are restricted from undergoing MRI procedures as magnets may interfere with pacemaker functionality, or cause heating of the lead. With Image Ready technology, INGENIO MRI pacemakers, in combination with FINELINETM II leads, allow patients to undergo MRI procedures as needed.

"A significant number of patients with pacemakers may be affected by other conditions, which often require MRI scanning," said Prof. Santini. "The ability for these patients to undergo detection of other conditions is an important advancement in improving overall patient health and outcomes."

FINELINE II pacing leads are backward MRI compatible and therefore replacement of the lead is not required when implanting the new INGENIO MRI or ADVANTIO MRI pacemakers. More than one million FINELINE II leads have to date been implanted worldwide.

The INGENIO and ADVANTIO pacemakers were first approved in Europe in April 2012. Featuring RightRate™ pacing technology, the devices are designed to treat chronotropic incompetence, a form of bradycardia in which the heart is unable to regulate its rate appropriately in response to physical activity. Chronotropic incompetence affects up to 42 percent of pacemaker patients.

"The ability to use the INGENIO platform during MRI procedures is a significant advancement to our family of bradycardia devices," said Michael Onuscheck, senior vice president and president of Europe, Middle East and Africa at Boston Scientific. "This progression in the use of the INGENIO family of pacemakers represents another step in our commitment to expanding our pacing capabilities and improving the lives of patients."

The INGENIO family of pacemakers is compatible with the new LATITUDE™ NXT Remote Patient Management system, which enables physicians to conduct remote follow-ups 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. LATITUDE NXT is also compatible with the wireless weight scale and blood pressure monitor from Boston Scientific. Physicians can choose to remotely monitor a series of relevant health status indicators including weight and blood pressure, as well as respiratory and sleep apnea trending. Centers across Europe are currently enrolling patients in the LATITUDE NXT program.

### **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](http://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 product launches and launch cadence, clinical trials and impact of data, 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.

<sup>1</sup>Survival probability is comprised of all RELIANCE and RELIANCE G models combined as one population. Data source and data cut off is based on the BSC Q2 2012 Product Performance report. Data and calculations on file.

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