Boston Scientific

# Improved Device Programming Reduces Inappropriate Therapy and Risk of Death for Implantable Defibrillator Patients

NATICK, Mass., Nov. 6, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) and the University of Rochester Medical Center presented positive results from the Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy (MADIT-RIT) clinical trial that demonstrated improved programming of Boston Scientific dual-chamber implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) heart devices can reduce inappropriate therapy and risk of death. MADIT-RIT is a prospective randomized three-arm trial comparing conventional programming with two alternative settings: a high-rate therapy arm and a duration-delay arm. The study was designed to determine if alternate programming could reduce the occurrence of inappropriate therapy in primary prevention patients. The results were presented at the American Heart Association Scientific Sessions 2012 in Los Angeles. The full MADIT-RIT results were published today in the *New England Journal of Medicine*.

When compared to conventional programming, significant reduction of inappropriate therapy was seen in both the high-rate and duration-delay therapy arms [79 and 76 percent, respectively ($p<0.001$ in both arms)].

In the high-rate therapy arm, there was a significant 55 percent reduction of the risk of death ($p=0.01$) compared to conventional programming. While not statistically significant, the risk of mortality was reduced in the duration-delay therapy arm by 44 percent ($p=0.06$).

"MADIT-RIT shows that improved programming can dramatically reduce inappropriate therapies and increase survival when compared to conventional device programming," said Kenneth Stein, M.D., chief medical officer of the Cardiac Rhythm Management Group at Boston Scientific. "This will have immediate clinical significance for physicians who implant and manage these devices. While previous studies have shown that ICDs are very effective in preventing sudden cardiac death, this study demonstrates that substantially more lives can be saved and many unnecessary and inappropriate therapies can be avoided with improved device programming."

Both shock therapy and anti-tachycardia pacing (ATP) therapy were evaluated in the trial. ICD and CRT-D devices constantly monitor the rate and rhythm of the heart and are designed to deliver electric shocks in response to very fast and potentially fatal heart rhythms. Shocks are highly effective in returning the heart to a normal rhythm and provide life-saving therapy to patients who develop ventricular arrhythmias. Anti-tachycardia pacing is effective in converting some types of fast heart rhythms. The devices may be programmed to deliver ATP before the shock, and if successful, a shock can be avoided.

The MADIT-RIT clinical trial was sponsored exclusively by Boston Scientific. MADIT-RIT evaluated 1,500 primary prevention patients with an ICD or CRT-D at 98 centers in 15 countries, including the U.S., Europe, Canada, Israel and Japan. The trial was conducted under the leadership of principal investigator Arthur J. Moss, M.D., professor of medicine at the University of Rochester Medical Center.

"I have been the principal investigator of a series of MADIT trials that have improved survival of high-risk heart patients during the past 20 years," said Dr. Moss. "I am pleased to report on our latest 1,500-patient MADIT study in which we have significantly improved the effectiveness of ICDs by reducing inappropriate electrical stimulation of the heart by up to nearly 80 percent while further increasing patient survival by up to 55 percent. These life-saving findings from our current study add an important new chapter in the evolution of the ICD to improve the treatment of patients with advanced heart disease."

MADIT-RIT is an important continuation of Boston Scientific's exclusive sponsorship of landmark clinical trials. More than 80 percent of U.S. patients who receive an ICD or CRT-D were first indicated for this therapy by a clinical trial sponsored by Boston Scientific or its predecessor companies. Boston Scientific estimates that 75,000 lives have been saved worldwide by implantable defibrillators over the past five years.

**About Boston Scientific**
Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

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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, clinical trials and the importance of their findings; clinical outcomes, 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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