

Boston Scientific Announces FDA Approval Of Innovative New Defibrillators And Heart Failure Devices

NATICK, Mass., April 15, 2014 /[PRNewswire](#)/ -- Boston Scientific Corporation (NYSE: BSX) has received FDA approval for its latest generation of defibrillators and heart failure devices designed to advance patient care. The newly approved devices include the DYNAGEN™ MINI and INOGEN™ MINI ICDs, as well as the DYNAGEN™ X4 and INOGEN™ X4 CRT-Ds.

The X4 line of quadripolar CRT-Ds offers 70 percent more pacing options to address high capture thresholds and phrenic nerve stimulation effectively, along with the largest battery capacity in the industry. These newly approved devices continue the Boston Scientific history of industry-leading projected longevity and a six-year CRT-D warranty.

Extending the Boston Scientific portfolio of defibrillators, the ICDs in the MINI family are the world's smallest and thinnest devices and are designed for patient comfort. The small dimensions of the MINI ICD are up to 20 percent smaller by volume and up to 24 percent thinner than competitive devices from other manufacturers.^[i]

"The tiny size of the MINI ICD provides a real benefit to some patients, in particular those with a smaller frame," said Prof. Dr. Hans-Joachim Trappe from University Marien Hospital Herne, Hospital of Ruhr-University, Bochum, Germany. "The MINI ICD not only improves patient comfort, but also provides these patients with innovative technology to help treat life-threatening arrhythmias of the heart."

"With these new devices and our current line of long-lasting ICDs and CRT-Ds, including the world's only subcutaneous ICD, we believe we offer the very best range of options for patients at risk of sudden cardiac arrest with or without the need for cardiac resynchronization therapy," said Joe Fitzgerald, executive vice president and president for the Rhythm Management division of Boston Scientific. "Our devices simply offer more options to improve outcomes, reduce complications and lower the costs of treating patients."

ICDs and CRT-Ds are designed to treat patients suffering from heart failure and/or to provide protection to patients at risk of sudden cardiac death. Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's need for blood and oxygen.^[ii] Sudden cardiac death (SCD) is a sudden, unexpected death caused by loss of heart function and is a leading cause of death. Nearly 400,000 out-of-hospital cardiac arrests occur annually in the United States.^[iii]

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, new product launches and launch cadence, regulatory approvals, clinical trials, product performance and impact, battery longevity, 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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[i] Based upon relevant Clinician Manuals; Boston Scientific MINI VR ICDs: 26.5cc volume and 9.9mm thickness. Medtronic Evera VR ICD: 33cc volume and 13mm thickness.

[ii] American Heart Association:
http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/About-Heart-Failure_UCM_002044_Article.jsp; content was last reviewed on 08/20/2012.

[iii] American Heart Association:
http://www.heart.org/HEARTORG/Conditions/More/MyHeartandStrokeNews/Heart-Attack-or-Sudden-Cardiac-Arrest-How-Are-They-Different_UCM_440804_Article.jsp; content was last updated on 5/14/2013.

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