Boston Scientific

Boston Scientific Announces CE Mark For MRI Compatible Labeling For ICD And CRT-D Systems

Updated labeling allows backwards-compatibility for MRI scans for the industry's longest-lasting ICD and CRT-D systems

MARLBOROUGH, Mass., Aug. 24, 2015 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received CE Mark on magnetic resonance imaging (MRI) conditional labeling for the current family of EL (Extended Longevity) and MINI implantable cardioverter defibrillator (ICD) and the X4 cardiac resynchronization therapy defibrillator (CRT-D) systems. This revised labeling ensures that future patients and those already implanted with these systems are able to undergo MRI scans if indicated.

Patients with implantable cardiac devices have a wide variety of diagnostic imaging available to them, including x-rays and CT scans, but Boston Scientific systems had not been evaluated as MRI conditional. This new system labeling, referred to as ImageReady™ MR Conditional devices, stipulates the conditions under which the systems are considered safe for use in a MRI setting.

"While the broader imaging compatibility will be important for some patients, I still expect device longevity and the ability to mitigate risk of complications to be the most critical factors in choosing the best system for each patient," said Gianluca Botto, head of Electrophysiology and Clinical Arrhythmias at S. Anna Hospital, Como, Italy and president of Italian Association of Pacing and Arrhythmias.

"We are pleased to combine broader imaging options with our long-lasting, high-voltage portfolio, offering additional value to our exclusive EnduraLife™ battery technology for European physicians and their patients," said Joe Fitzgerald, executive vice president and president of the Rhythm Management division of Boston Scientific. "We are seeking regulatory approvals for revised labeling and updated software for these systems in major markets by 2017."

Adding ImageReady capabilities to virtually all high-voltage products currently marketed – which include AUTOGEN™, DYNAGEN™, INOGEN™ and ORIGEN™ devices – as well as ACUITY™ X4 quadripolar LV leads, INGEVITY™ and FINELINE™ II pacing leads and RELIANCE® 4-SITE™ and 4-FRONT™ defibrillator leads, gives Boston Scientific the largest portfolio of MRI-compatible products in Europe.

MRI compatibility has not received regulatory approval in all geographies. For a list of all ImageReady products visit www.bostonscientific.com/imageready.

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 35 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, regulatory approvals, and product performance and impact. 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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