

Boston Scientific

Boston Scientific Announces FDA Approval of New Family of Advanced Pacemakers

PRNewswire-FirstCall
NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., May 8 [PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration (FDA) approval of its ALTRUA™ family of pacemakers. ALTRUA is Boston Scientific's most advanced pacemaker and delivers enhanced therapies while maintaining its small size and battery longevity. It is the first Boston Scientific-branded pacemaker 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.

"FDA approval of Boston Scientific's ALTRUA family of pacemakers -- especially following the European approval of ALTRUA we announced yesterday -- further demonstrates the significant progress we have made rebuilding our CRM organization and reinvigorating our product pipeline," said Fred Colen, Executive Vice President, Operations and Technology, Cardiac Rhythm Management. "Pacemakers are the most implanted device in the cardiac rhythm management industry and we look forward to making the ALTRUA family broadly available to physicians and their patients."

The ALTRUA pacemaker provides physicians with diagnostic and therapeutic capabilities that enable them to tailor the therapy to meet specific patient requirements:

- Multiple Atrial Ventricular (AV) Delay programming options: These options are designed to reduce unnecessary right ventricular (RV) pacing, without dropping ventricular beats, a key distinction from other competitive RV pacing algorithms. The ALTRUA 60 series also includes an enhanced AV search hysteresis feature, now with an extendable AV delay out to 400 milliseconds, providing physicians with additional flexibility to tailor device programming for unique patient needs.
- Stored Onset Electrograms (EGM): This feature provides diagnostic information about the patient's heart rhythm before the onset of an arrhythmia, enabling physicians to more easily and effectively troubleshoot patient arrhythmias. Boston Scientific's proprietary design enables continuous onset EGM monitoring without reducing battery longevity, a key difference from most competitive pacemakers.
- Minute Ventilation (MV) Blended Sensor: This proprietary technology treats a condition called Chronotropic Incompetence (CI), which is the inability of the heart to regulate its rate appropriately in response to physical activity and emotional stress. Boston Scientific's MV Blended Sensor is the only sensor that has been shown to restore Chronotropic Competence, enabling a patient's heart rate to function appropriately in different situations such as carrying groceries or climbing stairs. This feature is only available in the ALTRUA 60 and 40 series.

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: <http://www.bostonscientific.com/>.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of 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 product performance, regulatory approval of our products, new product launches, competitive offerings, our growth strategy, and our market position. 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 thereafter. 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.

CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Paul Donovan, Media Relations, +1-508-650-8541 (office), +1-508-667-5165 (mobile), or Larry Neumann, Investor Relations, +1-508-650-8696 (office), both of Boston Scientific Corporation

Web site: <http://www.bostonscientific.com/>

<https://stage.mediaroom.com/bostonscientific/fda-approval-new-advanced-pacemakers>