Boston Scientific

Boston Scientific Announces European Approval and First Implants of New Defibrillation Lead System Designed to Simplify the Surgical Process

PRNewswire
NATICK, Mass.
(NYSE:BSX)

Company's new lead system reduces implant size of the world's smallest and thinnest high-energy devices

NATICK, Mass., May 12 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today announced CE Mark and the first human implants of the Company's ENDOTAK RELIANCE® 4-SITE defibrillation lead system. Defibrillation leads are insulated wires that connect an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) to the heart and, when needed, deliver life-saving therapy.

The ENDOTAK RELIANCE 4-SITE lead system is designed to simplify the implant procedure by combining three terminals into one integrated connector, reducing the required implant area within the body. This system, combined with the new TELIGEN® ICD and COGNIS® CRT-D, is designed to comply with the forthcoming international connector standard(1). The new standard will permit product compatibility across manufacturers. The Company is working with physicians to launch the system in several phases with a focus on monitoring clinical performance through robust post-market analysis enhanced by the LATITUDE® Patient Management system(2).

"We are pleased to announce CE Mark and the first human implants of the ENDOTAK RELIANCE 4-SITE lead system," said Fred Colen, President, Boston Scientific Cardiac Rhythm Management. "This new system represents the next advance for the ENDOTAK RELIANCE lead family, which has demonstrated reliability in more than 350,000 implants worldwide."

This technology allows the world's smallest, thinnest high-energy ICDs and CRT-Ds to become even smaller. The connector reduces the volume of TELIGEN and COGNIS to 30 cc and 32 cc respectively, while maintaining a thickness of less than 10 mm.

Some models of the ENDOTAK RELIANCE 4-SITE product line feature a proprietary GORE™ covering designed to prevent tissue ingrowth into the defibrillation coils, without compromising the electrical performance of the lead. The ENDOTAK RELIANCE G model is the only defibrillation lead on the market to address tissue ingrowth using this innovative approach. Preventing tissue ingrowth assists physicians with the long-term management of device patients. Although rare, lead removal is sometimes necessary. Studies have shown that the proprietary covering helps physicians perform this procedure more easily and effectively.

The implants were performed under the leadership of the following physicians:

- Oliver Przibille, M.D., Cardioangiolisches Centrum Bethanien, Frankfurt, Germany
- Hans-Joachim Trappe, M.D., Marienhospital Herne Klinikum der Ruhr-Universitat Bochum, Herne, Germany
- Johannes Heintze, M.D., Herz und Diabeteszentrum Nordrhein-Westfalen Bad Oeynhausen, Bad Oeynhausen, Germany
- Lieselot van Erven, M.D., Leiden University Medical Center, Leiden, The Netherlands

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: 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.

(1) International Organization for Standardization (ISO) IS-4/DF-4 standard.

(2) The LATITUDE Patient Management system is not yet approved in Europe.

CONTACT: David Knutson
651-582-6572 (office)
651-260-8288 (mobile)
Media Relations
Boston Scientific Corporation

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

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

---

https://news.bostonscientific.com/news-releases?item=59143