Boston Scientific

Boston Scientific Rebuts HeartRhythm Article

NATICK, Mass., Feb. 10 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today rebutted an article published in the journal HeartRhythm. The article reported a case summary of a patient who had been implanted subcutaneously with a Cognis cardiac resynchronization therapy defibrillator. The article suggested a weakened header bond was responsible for the abnormal sensing and pacing impedance experienced by the patient.

The Company issued the following statement:

"We find it unacceptable that HeartRhythm rushed this manuscript to publication and speculated on the cause of the problem without requesting from us a detailed engineering analysis of the explanted device. Our analysis found that while the bond between the header and the case was weakened, the device functioned normally and a weakened header bond was not the cause of the abnormal sensing and pacing impedance observed in this patient.

"X-ray analysis and electrical testing verified that the header wires were neither fractured nor otherwise damaged, and the seal between the header and the case was secure with no evidence of body fluid under the header. In short, there is no mechanism to link the noise observations to a weakened header bond.

"Noise observations during the initial implant were not header-related. In fact, the authors themselves stated: 'It is possible that the initial noise observed on the RV pace/sense channel was due to an RV lead abnormality and not to the header abnormality.' None of the leads implanted in the patient were manufactured by Boston Scientific.

"Including this most recent case, only three instances of weakened header bonds have been observed in a context of more than 90,000 COGNIS and TELIGEN devices implanted subcutaneously. The overall rate of events for this device family compares very favorably to the performance of similar devices and is well within accepted performance ranges.

"We have implemented manufacturing process improvements to strengthen the header bond on these devices, allowing physicians to implant devices in either a subpectoral or subcutaneous position. We have received approval from U.S. and European regulatory authorities for the devices with the strengthened header bond and have been shipping these devices. We expect to complete the transition to these devices by next month."

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 regulatory approvals, 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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