

Boston Scientific

Boston Scientific Announces Results for Large Clinical Trial Studying Dual-Chamber Pacing in Implantable Cardioverter Defibrillators

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NATICK, Mass., May 20 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today reported that the INTRINSIC RV investigative team presented results of a clinical trial designed to study unnecessary pacing in recipients of an implantable cardioverter defibrillator (ICD). The trial, Inhibition of Unnecessary Right Ventricular Pacing with AV Search Hysteresis in ICDs (INTRINSIC RV), was designed to advance our understanding of a proprietary feature that minimizes unnecessary right ventricular pacing in patients who received the Company's market-released dual-chamber ICD. A dual-chamber ICD can pace and/or sense in the upper and lower chambers of the heart. The results were announced at the Heart Rhythm Society (HRS) annual meeting in Boston.

INTRINSIC RV is a multi-center, randomized trial enrolling more than 1,500 patients at 108 centers in the United States, Germany, Italy and Australia. 988 patients with mild and moderate pacing requirements were randomized to either atrial support pacing (DDDR+AVSH) or ventricular only (VVI) pacing groups. The trial utilized the Company's exclusive AV Search Hysteresis (AVSH) feature, which has been incorporated in all the Company's dual-chamber ICDs since June 2000. The technology prevents right ventricular pacing if the heart's natural rhythm is detected and was launched by the Company's Cardiac Rhythm Management group, formerly part of Guidant. Boston Scientific acquired Guidant on April 21.

Brian Olshansky, M.D., Director of Cardiac Electrophysiology at the University of Iowa Hospitals and co-principal investigator of INTRINSIC RV reported:

* The benefits of dual-chamber pacing (DDDR+AVSH) were seen in a majority of patients. This study showed that patients in the dual-chamber arm performed as well as patients programmed to VVI. (p<0.001, non-inferiority primary endpoint)

* While the trial was not designed to test for superiority, investigators noted that patients randomized to dual-chamber pacing with the AVSH feature tended to have a lower risk of combined all-cause mortality and heart failure hospitalizations compared to those randomized to the single chamber pacing (VVI) arm.

"This trial highlights the importance of evidence-based medicine to further the understanding of advanced-feature medical devices, because INTRINSIC RV actually refutes the notion that dual-chamber ICD programming poses an inherent safety risk," said Dr. Olshansky. "In fact, by using AV Search Hysteresis, outcomes with dual-chamber programming performed as well as, if not better, than single-chamber programming."

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/>.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with new product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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