

Date: April 20, 2016

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## **BIOTRONIK ICD Lead Data from Long-Term Registries Published by Journal of Cardiovascular Electrophysiology**

BERLIN, Germany, April 20, 2016 — **BIOTRONIK**, a leader in cardio- and endovascular medical technology, today announced the publication of positive long-term data on the reliability of its Linox and Linox<sup>smart</sup> implantable cardioverter defibrillator (ICD) leads. The company is strongly committed to evidence-based medicine and evaluating the long-term performance of its implantable cardiac devices and leads. As part of a continuous effort to assess and monitor the real world performance of its leads, BIOTRONIK is conducting the multicenter, prospective, non-randomized, observational GALAXY and CELESTIAL registries. During the course of the two trials, a total of 3,933 LINOX ICD leads have been implanted in 3,840 patients at 146 US study centers.

"The results of this large scale, prospective analysis should provide assurance to both implanting physicians and their patients that the magnitude of scientific evidence shows these leads to be safe and reliable," commented lead author Dr. Eric Good, formerly with University of Michigan Cardiology, US. "Their 'real-world' performance and survival rates are similar to other well-performing leads reported in the literature."

The ongoing observational GALAXY and CELESTIAL registries collect lead safety and reliability data for five years post-implantation, with all protocol-defined procedural and system-related adverse events recorded at each follow-up. The estimated cumulative survival probability for Linox leads at five years is 96.3 percent, while for Linox<sup>smart</sup> leads at four years, it is 96.6 percent, both well within industry standards for safety and reliability. Long-term data on the Linox and Linox<sup>smart</sup> ICD leads from the ongoing GALAXY and CELESTIAL registries is now available from the [Journal of Cardiovascular Electrophysiology](#).

"The scale and thoroughness of the GALAXY and CELESTIAL registries demonstrate BIOTRONIK's deep commitment to evaluating our ICD leads' long-term durability, a product of an intensive design process followed by extremely rigorous testing," commented Manuel Ortega, Senior Vice President at BIOTRONIK. "As good is never enough for us, we constantly strive to further refine our products' reliability, performance, and usability. Our philosophy has always been incremental improvement with a strong focus on durability and

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performance. That's what our engineers in Germany, Switzerland, and the US are constantly working hard to achieve."

**Clinical Trials Registration Information:** ClinicalTrials.gov  
NCT00836589 and NCT00810264

## **About BIOTRONIK**

A global leader in cardio- and endovascular medical technology, BIOTRONIK is headquartered in Berlin, Germany, and represented in over 100 countries. Several million patients have received BIOTRONIK implants designed to save and improve the quality of their lives, or have been treated with BIOTRONIK coronary and peripheral vascular intervention products. Since its development of the first German pacemaker in 1963, BIOTRONIK has engineered many innovations, including BIOTRONIK Home Monitoring<sup>®</sup>; Pulsar\*, the world's first 4 F compatible stent for treating long lesions; Orsiro\*, the industry's first hybrid drug-eluting stent; and the world's first implantable cardioverter defibrillators and heart failure therapy devices with ProMRI<sup>®</sup> technology.

\* Investigational device: Limited by United States law to investigational use.

**For more information, visit:** [www.biotronik.com](http://www.biotronik.com)

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