

## **FDA Approves BIOTRONIK's Ilesto 7 ICD/CRT-D Series**

The Associated Press

LAKE OSWEGO, Ore.--(BUSINESS WIRE)--May 7, 2013--BIOTRONIK, a leading manufacturer of cardiovascular medical technology, announced that the Food and Drug Administration (FDA) granted approval for its Ilesto 7 implantable cardioverter-defibrillator/cardiac resynchronization therapy defibrillator (ICD/CRT-D) series. The Ilesto devices exemplify the principled engineering for which BIOTRONIK is known. The devices are smaller, thinner and lighter without compromising clinical capabilities.

"BIOTRONIK lives up to its reputation for excellence in design and manufacturing with the introduction of the Ilesto family, and the new Ilesto DX device. Physicians depend on complete and timely information, and Ilesto DX with BIOTRONIK Home Monitoring ® certainly delivers. With this device, physicians can receive atrial information to ensure diagnostic accuracy and identify previously undetected atrial fibrillation. They also receive peace of mind that there is less risk of complications due to the single lead," said Paul Woodstock, executive vice president of sales and marketing at BIOTRONIK, Inc., USA. "Ilesto's smaller footprint will be more comfortable as well, which may present a win-win solution for patients and physicians alike." BIOTRONIK's DX platform, which combines the benefits of both single- and dual-chamber ICDs, provides atrial information to aid in diagnostic accuracy while reducing the risk of complications associated with an additional atrial lead. 1 It also enables early detection of atrial arrhythmia with BIOTRONIK Home Monitoring ®.

"In order to meet unprecedented demand for this novel category of device, the Ilesto DX version will be the first ICD we launch within this series," said Woodstock. "In a world driven by benefits and risks, single-lead DX systems deliver on both counts. The ability to provide comprehensive atrial diagnostics while reducing potential complications associated with additional leads represents an unrivaled cutting-edge technological advancement." BIOTRONIK DX Systems continue to give physicians the ability to remotely follow their patients' clinical and device statuses daily - anytime, anywhere in the world via the BIOTRONIK Home Monitoring ® system. The cellular-based system is the most user-friendly patient monitoring system capable of combining early detection of clinically relevant events with increased workflow efficiency. The system also allows for secure data sharing amongst multiple care teams, a critical capability as practices and hospitals push to improve patient outcomes. The clear differentiators for the BIOTRONIK Home Monitoring ® system are one-step setup, daily transmissions requiring no patient interaction and true mobility at no additional cost. These advantages clearly put the BIOTRONIK Home Monitoring ® system in a class by itself. The result is very high patient compliance, which is essential for these systems to provide meaningful clinical value.

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“BIOTRONIK is receiving attention from all the right people and for all the right reasons because we continue to grow in spite of very challenging market conditions. We’re fully engaged; investing and innovating in cardiac rhythm management (CRM) as well as launching new products and investing in clinical research,” said Rex Richmond, vice president of marketing and communications at BIOTRONIK, Inc., USA. “Relentless dedication to engineering excellence affords us the ability to deliver technology that helps physicians heal patients. BIOTRONIK is the only privately held company in the CRM space, which frees it from decisions influenced by ever-changing analyst and shareholder value demands. This, in turn, enables us to focus on long-term planning and to deliver innovations that really meet the needs of physicians and patients alike.” The Ilesto 7 series is now approved and currently available in most international markets, including the EU and Japan. In C.E. markets, the Ilesto 7 series is the second generation of BIOTRONIK’s ProMRI® technology, which enables patients access to potentially life-saving MR scans.\* BIOTRONIK’s Ilesto 7 series, DX System, Home Monitoring and ProMRI ® will be showcased at BIOTRONIK’s booth (#929) at Heart Rhythm 2013, the Heart Rhythm Society’s 34th Annual Scientific Sessions.

### **About BIOTRONIK SE & Co. KG**

As one of the world’s leading manufacturers of cardiovascular medical devices, BIOTRONIK is headquartered in Berlin, Germany, and represented in over 100 countries by its global workforce of more than 5,600 employees. Several million heart patients around the world have received BIOTRONIK implants, designed to save and improve the quality of their lives. Since its development of the first German pacemaker in 1963, BIOTRONIK has launched several innovations into the market—including remote monitoring with BIOTRONIK Home Monitoring ® in 2000 and the world’s first implantable cardioverter-defibrillators and implantable heart failure therapy devices with ProMRI ® technology\*, approved for MR scanning, in 2012. This year BIOTRONIK is celebrating its 50 th anniversary.

### **About ProMRI ®**

ProMRI ® is an innovative technology that gives patients access to magnetic resonance (MR) scanning after receiving an implant. The technology is now integrated into BIOTRONIK’s complete line of pacemakers, ICDs and leads—representing the industry’s broadest portfolio of cardiac devices approved for MR scanning.\* \*ProMRI ® is approved in the C.E. market and is not currently approved in the U.S.

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