

## **BIOTRONIK Ilesto 7 ICD/CRT-D Series With ProMRI(R) Technology Gains CE Approval**

The Associated Press

BIOTRONIK, the leading manufacturer of cardiovascular medical technology that is celebrating its 50th anniversary in 2013, announced today that the Ilesto 7 implantable cardioverter-defibrillator/cardiac resynchronization therapy defibrillator (ICD/CRT-D) series has received CE approval. The Ilesto 7 series includes one of the world's smallest ICDs and features ProMRI® technology, which enables access to potentially life-saving MR scans. Furthermore, Ilesto offers patients and physicians the greatest longevity available -- up to 11.5 years for the single chamber ICD and 7.5 years for the CRT-D device.

The first implantations of the Ilesto 7 second-generation ProMRI® devices are currently taking place across Europe. With its new Ilesto 7 series and existing Lumax 740 ICD/CRT-D series that was launched in the European market in April 2012, BIOTRONIK offers the world's only two ICD/CRT-D series approved for MR scanning.

Prof. Dr. Paul Erne from Lucerne Cantonal Hospital (LUKS), Lucerne, Switzerland, one of the first physicians to implant the Ilesto device, explains, "The Ilesto 7 series, as well as many other BIOTRONIK devices, boasts ProMRI® capability and BIOTRONIK's Home Monitoring® technology. With this, we have the opportunity to offer our patients the most advanced and reliable ICD and CRT-D therapy, an enhanced quality of life, and an opportunity to live as normal a life as possible."

"As patients get older and have comorbidities," Prof. Erne continues, "they often require MR scanning at some point in the future. With Ilesto 7 I can ensure that my patients will have access to the gold standard of soft tissue imaging when needed -- even with an ICD or a CRT-D."

In addition to the enhanced diagnostic potential and longevity advantages of the new Ilesto 7 series, the devices' optimized shape and the new DF4 connector provide a number of important benefits for both physicians and patients. Patients also benefit from secure remote monitoring via BIOTRONIK Home Monitoring®.

Dr. Leonardo Calò from the Polyclinic Casilino, Rome, Italy, reports, "Patients feel more comfortable post implant. They leave with peace of mind knowing that they will be constantly monitored via BIOTRONIK Home Monitoring®, that they will receive an in-office follow-up when needed, that their physicians can initiate their therapy at a very early stage, and that they will receive the right treatment. They also know that they can undergo the most advanced diagnostic procedure available today as a result of having an ICD or CRT-D with BIOTRONIK's ProMRI® technology."

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Patient safety is at the core of the Ilesto -- safety related to both the device itself and its impact on patients' lives.

"With all our innovations, patient safety comes first," says Christoph Böhmer, President International at BIOTRONIK. "Our Ilesto implants and Linx Smart leads are designed to continue our tradition of providing products with the highest reliability. Furthermore these devices bring patients a number of important safety benefits, including a reduced risk of inappropriate shocks, stroke, and other comorbidities."

The European market release of the Ilesto 7 series with ProMRI® technology and the new DF4 connectors is expected in midyear 2013.

First implanters of BIOTRONIK's Ilesto 7 series are: Leonardo Calò, MD, Polyclinic Casilino, Rome, Italy; Pascal Defaye, MD, Grenoble University Hospital (CHU), Grenoble, France; Paul Erne, Prof. MD, Lucerne Cantonal Hospital (LUKS), Lucerne, Switzerland; Juan Gabriel Martínez, MD, General de Alicante, Alicante, Spain; Martin Jan Schalijs, Prof. MD, and Lieselot van Erven, MD, Leiden University Medical Center (LUMC), Leiden, Netherlands; Tamas Szili-Torok, MD, Erasmus Medical Center, Rotterdam (EMC), Netherlands.

About BIOTRONIK SE & Co.

KGAs 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 50th anniversary.

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