Press Release

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BIOTRONIK Becomes First Manufacturer of Single- and Dual-Chamber Pacemakers and ICDs Approved for Use in 3 Tesla MRI Scans Worldwide

BERLIN, Germany, July 28, 2015 – BIOTRONIK, the world's leader in ProMRI® cardiac devices, has announced CE approval of 3 tesla (T) MRI scanning with exclusion zone for its two latest generations of pacemakers.* BIOTRONIK is now the only company offering both implantable cardioverter-defibrillators (ICDs) and pacemakers approved for 3 T scans.

Roughly between 20-30 percent of all MRI scanners installed worldwide are 3 T. However, sales of these are growing three times faster than those of 1.5 T scanners.[1]

"The benefits of 3 T MRI scanners are clear," commented Dr. Maurizio Lunati, Niguarda Hospital, Milan, Italy. "3 T scanners offer superior image quality, as well as a shorter scan time compared to a 1.5 T machine. Patients with ProMRI devices enabling 3 T scans benefit from a shorter time spent in the sometimes uncomfortable MRI machine, while doctors benefit from clearer images to diagnose conditions. Reduced scan times can improve clinical workflow, granting more patients access to this vital diagnostic tool."

To help physicians keep track of which ProMRI devices and leads are approved in their own region, new functions have been added to the ProMRI Systems Check website at www.promricheck.com. ProMRI System Check allows physicians to verify whether a patient's individual BIOTRONIK device and lead combination is MR conditional, and under which scanning conditions. It is now available in five languages: English, French, German, Italian and Spanish.

"Along with the development of tools like the ProMRI System Check website, our continued effort to gain MRI approval for all our devices and leads demonstrates BIOTRONIK's commitment to serving patients and physicians. As 3 T MRI scanners become more and more prevalent, it is essential that device patients are able to access them," stated Manuel Ortega, Senior Vice President of BIOTRONIK. "Through innovation and diligence we have developed the world's largest portfolio of ProMRI devices. We are pleased to expand our existing portfolio of approved ICDs and pacemakers by gaining CE approval for 3 T MRI scanning for the latest pacemaker generations."

About ProMRI
BIOTRONIK ProMRI technology enables patients with a pacemaker, implantable defibrillator or Cardiac Monitor to undergo MRI scans. BIOTRONIK has the broadest portfolio of cardiac devices approved for use in the MR environment on the market, and is the only company to allow heart failure patients with CRT devices to take advantage of MRI. ProMRI technology grants cardiac device patients access to 1.5 T or 3.0 T MRI scans, allowing physicians to select the best choice for an optimal diagnostic outcome. For more details, please go to www.promricheck.com.

About BIOTRONIK
One of the world's leading manufacturers of cardio- and endovascular 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 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®; the world's first 4 F-compatible 200 mm peripheral stent; Orsiro, the industry's first hybrid drug-eluting stent; and the world's first implantable cardioverter-defibrillators and heart failure therapy devices with ProMRI® technology.

References:
[1] Global Data 2011: Magnetic Resonance Imaging (MRI) Systems - *Global Pipeline Analysis, Opportunity Assessment and Market Forecasts to 2016.*

For more information, visit: www.biotronik.com

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[*] For all regions in line with CE regulations, all single- and dual-chamber ProMRI models of Eluna 8, Epyra 8/6 Etrinsa 8/6 and Evia, Entovis, Estella, Ecuro are now approved for 3 T MRI scanning with an exclusion zone. All Setrox, Solia, Siello and Safio leads in combination with these devices, are approved for 3 T MRI scanning under certain conditions. The dual-chamber system of Siello/Solia JT 45 is also 3 T approved.