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Cardiac Rhythm Management

BIOTRONIK Launches the World's Smallest 3T Full-Body MR Conditional ICD and CRT-D Devices on the European Market

The Acticor and Rivacor Families Feature an Ultraslim BIOshape as well as Extended Battery Life and Warranty

BERLIN, Germany, March 11, 2019 – **BIOTRONIK** today announced the European market release of the world's smallest ICD and CRT-D devices that are approved for 3 Tesla (3T) full-body MRI scans.¹

Devices in the **Acticor** and **Rivacor** families are only 10 mm slim, with a smooth and elliptical BIOshape that facilitates the insertion procedure. "The slenderness and smoother shape of the new devices play a key role in easing the insertion procedure and improving how the device looks after implantation," reported Dr. Iain Matthews, Northumbria Healthcare, UK, following his first implantations of the devices. More than 90% of implanting physicians rated "patient comfort" as "better" or even "much better" in comparison with previous models during post-market observation.²

Besides their body-friendly shape, Acticor and Rivacor devices feature an extended battery life, with up to 15 years for ICDs³ and nine years for CRT-Ds⁴. Increased device longevity is designed to lower the need for device replacements, resulting in reduced risks⁵, less distress for patients, and fewer procedure costs. The new range of devices are also supported by a fully warranty of 10 years for ICDs and six years for CRT-Ds.

With **BIOTRONIK Home Monitoring**[®], cardiovascular data from an Acticor or Rivacor device can be transmitted to the physician on a daily basis with programmable alerts about relevant changes in patient health and device status. The IN-TIME randomized controlled trial has demonstrated more than 60% reduction in all-cause mortality when CRT-Ds are used with BIOTRONIK Home Monitoring.⁶ In ICDs, Home Monitoring has been clinically proven to help physicians detect atrial fibrillation earlier⁷, as well as reduce the number of inappropriate shocks by 90% and related hospitalization rates by 73%⁸. BIOTRONIK Home Monitoring's new QuickCheck feature gives access to patient data typically within three to four minutes.⁹

The typical non-response rate of 30-40% of all patients is a major problem in cardiac resynchronization therapy (CRT).^{10,11} To counter this, Acticor and Rivacor CRT-Ds feature CRT AutoAdapt to fit

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patients' individual pacing needs and provide continuous CRT adaptation – automatically adjusting to changes sensed in a patient's condition every minute. Auto LV VectorOpt further helps to evaluate clinically relevant pacing parameters, with automatic threshold measurements across 20 vectors¹² in less than 2.5 minutes¹³ and rapid direct programming.

All Acticor and Rivacor devices feature **ProMRI**, giving patients full access to high-resolution 3T MRI without any exclusion zone. With sensor-based MRI AutoDetect technology, once activated for a programmable window of up to 14 days, the devices can automatically recognize an MR environment and switch in and out of MRI mode as required. This ensures that patients receive optimal therapy, with tachycardia therapy suspension limited to the duration of the MRI scan, as well as fewer in-office visits required for device programming. Acticor and Rivacor devices also feature **DX technology**, enabling complete atrial diagnostics without an atrial lead.

"The Acticor and Rivacor families embody BIOTRONIK's dedication to quality and innovation that saves and improves patients' lives," said Dr. Alexander Uhl, Senior Vice President Corporate Marketing at BIOTRONIK. "With a full range of functionality in a small and slim device, we want to equip physicians to provide optimal therapy to tachycardia and heart failure patients without compromising on device longevity or patient safety and comfort."

References:

- ¹ As part of an MR conditional system.
- ² Post-Market observation; final-report, March 1, 2019. Data on file.
- ³ Acticor/Rivacor VR-T Standard conditions. 15.4 years @ 40 ppm; 0% pacing @ 2.5V/0.4ms; 500 Ohms; 2 max. energy shock/year. Data on file.
- ⁴ Acticor/Rivacor HF-T QP, 9.3 years @ 60 ppm; RA 15%, RV/LV 100% pacing, RA/RV/LV @ 2.5 V/0.4 ms; 500 Ohms, 2 max. energy shocks/year. Data on file.
- ⁵ Polyzos KA et al. *Europace*. 2015, 17(5).
- ⁶ Hindricks G et al. *The Lancet*. 2014, 384(9943).
- ⁷ Varma N et al. *Circulation*. 2010, 122(4).
- ⁸ Guedon-Moreau L et al. *J Cardiovasc Electrophysiol*. 2014, 25(7).
- ⁹ Performance analysis. Data on file.
- ¹⁰ Daubert C et al. *Eur Heart J*. 2017, 38(19).
- ¹¹ Auricchio A et al. *J Am Coll Cardiol*. 2008, 51(15).
- ¹² QP models only.
- ¹³ Post-Market observation; final report, March 1, 2019. Data on file.

About BIOTRONIK

BIOTRONIK is a leading medical device company that has been developing trusted and innovative cardiovascular and endovascular solutions for more than 50 years. Driven by a purpose to perfectly match technology with the human body, BIOTRONIK innovations deliver care that saves and improves the lives of millions diagnosed with heart and blood vessel diseases every year. BIOTRONIK is headquartered in Berlin, Germany, and represented in over 100 countries.

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Press Release



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