Medtronic News

Medtronic Receives CE Mark for Cobalt™ and Crome™ Portfolio of BlueSync™-Enabled Implantable Defibrillators, Cardiac Resynchronization Therapy-Defibrillators

Next Generation Technology Includes Features that Automatically Adjust to Patient Needs, and Offers Physicians Heart Failure Diagnostic Insights

DUBLIN, Jan. 30, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced it has received CE (*Conformité Européenne*) Mark for its Cobalt™ and Crome™ portfolio of implantable cardioverter-defibrillators (ICD) and cardiac resynchronization therapy-defibrillators (CRT-D). ICDs monitor heart rhythms and deliver therapy to correct heart rates that are too fast and can lead to sudden cardiac arrest. CRT-Ds, a treatment option for some individuals with heart failure, send small electrical impulses to the lower chambers of the heart to help them beat in more synchronized patterns and reduce patient symptoms.

“Cobalt and Crome heart devices deliver the opportunity of a personalized approach to defibrillator therapy, demonstrating how far we have come in this field,” said Klaus Witte, M.D., of the School of Medicine, University of Leeds, United Kingdom. “Moreover, these devices offer seamless patient care through their ability to transmit device and patient data via smartphone or tablet.”

With the launch of the Cobalt and Crome platform, Medtronic also is making TriageHF™ technology available. This techology assesses patients’ heart failure risk through a simplified, integrated, automatic tool that identifies patient status changes that may lead to worsening heart failure and hospitalization. TriageHF stratifies patients into three risk categories (high, medium or low) by evaluating factors such as heart rate variability, atrial fibrillation and fluid status. The TriageHF assessment tool is compatible with all Medtronic ICDs and CRT-Ds with the Medtronic OptiVol™ fluid status monitoring feature, including those currently implanted in patients.

This newest generation of implantable heart devices also includes several “smart” features:

- Intrinsic ATP™ (iATP), available on Cobalt XT ICDs and CRT-Ds, is the only automated algorithm that adapts to a patient’s irregular heart rhythms and attempts to reset them with painless pacing therapy, possibly avoiding the need for shocks. This ventricular anti-tachycardia pacing (ATP) provides individualized therapy in real-time and is paired with Medtronic-exclusive SmartShock™ 2.0 shock-reduction technology. The devices also feature improved longevity and energy output.
- This is the first Medtronic ICD and CRT-D portfolio to offer connected health with BlueSync™ Technology, which enables the implanted devices to communicate with the tablet-based CareLink SmartSync™ Device Manager for physicians, and the MyCareLink Heart™ mobile app for patients.
- The new CRT-Ds also include the EffectivCRT™ algorithm and the AdaptivCRT™ algorithm, which adjusts therapy according to minute-by-minute evaluations of each patient’s heart rhythm. AdaptivCRT has been shown to increase patients’ response to CRT1; reduce unnecessary right ventricular pacing1,2; reduce the likelihood of 30-day heart failure hospital readmissions3; and reduce the risk of atrial fibrillation.4 In addition, AdaptivCRT is associated with improved patient survival.5

“The Cobalt and Crome devices demonstrate our commitment to enhancing device connectivity and personalized patient care,” said Rob Kowal, M.D., Ph.D., chief medical officer of the Cardiac Rhythm and Heart Failure division, which is part of the Cardiac and Vascular Group at Medtronic. “These advancements will help physicians respond to patients’ individual needs through informed clinical decision making, potentially improving the outcomes of patients around the world.”

The Medtronic portfolio of therapies, diagnostic tools and services for patients suffering from heart failure includes ICD and CRT devices, including MR-conditional ICDs, CRT-Ds and CRT-pacemakers; mechanical circulatory support therapy for advanced heart failure patients; and heart failure diagnostics.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative

medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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1 Birnie D, et al. Heart Rhythm. 2013;10:1368-1374.
2 Martin DO, et al. Heart Rhythm. 2012;9:1807-1814.
3 Starling RC, et al. JACC Heart Fail. 2015;3:565-572.
4 Birnie D, et al. Heart Rhythm. 2017;14:1820-1825.
5 Singh JP, et al. Improved Survival With Dynamic Optimization Of CRT Pacing Using AdaptivCRT Algorithm: Analysis Of Real-world Patient Data. Presented at HRS 2018 (Abstract B-AB37 -06).

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https://news.medtronic.com/2020-01-30Medtronic-Receives-CE-Mark-for-Cobalt-TM-and-Crome-TM-Portfolio-of-BlueSync-TM-Enabled-Implantable-Defibrillators-Cardiac-Resynchronization-Therapy-Defibrillators