Medtronic

Cobalt™ And Crome™ Implantable Cardioverter-Defibrillators (ICDs) and Cardiac Resynchronization Therapy-Defibrillators (CRT-Ds)

The Medtronic Cobalt™ and Crome™ portfolio of implantable cardioverter-defibrillators (ICD) and cardiac resynchronization therapy-defibrillators (CRT-D) features enhanced connectivity and remote patient monitoring.

In 2020, Medtronic received U.S. Food and Drug Administration (FDA) approval for the Cobalt and Crome portfolio. The latest generation of ICDs and CRT-Ds uses smart technology and new built-in alerts, allowing physicians to better respond to individual patient needs.

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.

The Cobalt and Crome portfolio's advanced technology automatically adjusts to patient needs. The portfolio offers several remote monitoring features that allow clinicians to manage patients and receive alerts through app-based and automatic monitoring technologies. In the current COVID-19 environment, these devices are able to transmit device and patient data via smartphones and/or tablets, reducing the need for in-office visits.

Remote and Automatic Monitoring Technologies

- **App-Based Technology:** 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.
- **TriageHF™ Heart Failure Risk Status:** TriageHF technology 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.
- **CareAlerts:** Clinicians can elect to receive a TriageHF™ CareAlert – via text, email, or voicemail, in addition to a CareLink display observation – when a patient's heart failure risk status indicates a high risk.
- **Intrinsic ATP™ (iATP):** Available on Cobalt XT ICDs and Cobalt XT CRT-Ds, iATP is the only automated algorithm that adapts to a patient's irregularly fast 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.

Additional Medtronic-Exclusive Features

These new products also incorporate existing Medtronic-exclusive features, including MRI SureScan™ technology, PhysioCurve™ design, and the AdaptiveCRT™ and EffectivCRT™ algorithms:

- **MRI SureScan** allows for MRI scans via 1.5 or 3 Tesla scanners on any part of the body without positioning restrictions.
- The **PhysioCurve** design features a contoured shape with thin, smooth edges that better fits inside the body, ultimately enhancing patient comfort[1] by reducing overall skin pressure.[2]
- **AdaptivCRT** is the only CRT algorithm with published evidence showing a reduction in heart failure hospitalizations.[3] Additionally, it has been shown to increase patients' response to CRT;[4] reduces unnecessary right ventricular pacing;[5] and reduces the risk of atrial fibrillation.[6] In addition, AdaptivCRT is associated with improved patient survival.[7]
- **The EffectivCRT Diagnostic** automatically determines the effectiveness of each left ventricular pace, and the EffectivCRT During AF™ algorithm automatically adjusts pacing rates during AF, without adversely affecting the average heart rate.

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[1] Ceelen KK, et al. J Biomech. 2008;41:3399-3404

[2] Flo D, et al. IS4/DF4 Device Shape Analysis. January 2013. Medtronic data on file

[3] Starling RC, et al. JACC Heart Fail. 2015;3:565-572.

[4] Birnie D, et al. Heart Rhythm. 2013;10:1368-1374.

[5] Martin DO, et al. Heart Rhythm. 2012;9:1807-1814.

[6] Birnie D, et al. Heart Rhythm. 2017;14:1820-1825.

[7] Singh JP, et al. Improved Survival With Dynamic Optimization Of CRT Pacing Using AdaptivCRT Algorithm: Analysis Of Real-world Patient