THE FUTURE IS HERE

Meet Cobalt™ ICDs and CRT-Ds

Medtronic
THE FUTURE IS HERE

UNMATCHED FEATURE SUITE

- Extended longevity and higher output, while maintaining exclusive PhysioCurve™ size and shape
- Exclusive technology to reduce shocks
- Exclusive algorithms to optimize CRT
- Exclusive algorithms to manage atrial fibrillation (AF)

REIMAGINED CONNECTIVITY

BlueSync™ technology that enables tablet-based programming and app-based remote monitoring

STREAMLINED WORKFLOWS

Manage alerts of clinically relevant events with additional CareAlert™ notifications

Meet Cobalt™ ICDs and CRT-Ds
Extended Longevity
Mean longevity projections based on CareLink™ patient data*

<table>
<thead>
<tr>
<th>Model</th>
<th>Mean Longevity</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>Claria MRI™ Quad</td>
<td>8.3 YEARS</td>
<td>Mean longevity projection based on real-world programming of U.S. national CareLink network patients. January 2019.</td>
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<tr>
<td>Claria MRI™ Quad and</td>
<td></td>
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<tr>
<td>Amplia MRI™ Quad CRT-Ds</td>
<td>10.1 YEARS</td>
<td>Mean longevity projection based on median CareLink settings in the Cobalt manual.</td>
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<tr>
<td>Evera MRI™ XT and</td>
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<tr>
<td>Evera MRI™ S Dual Chamber ICDs</td>
<td>10.5 YESRS</td>
<td>Mean longevity projection based on median CareLink settings in the Cobalt manual.</td>
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<tr>
<td>Cobalt Dual Chamber ICDs</td>
<td>11.9 YEARS</td>
<td>Mean longevity projection based on median CareLink settings in the Cobalt manual.</td>
</tr>
<tr>
<td>Visia AF MRI™ Single Chamber ICDs</td>
<td>12.0 YEARS</td>
<td>Mean longevity projection based on median CareLink settings in the Cobalt manual.</td>
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</tbody>
</table>

*These values should not be interpreted as precise numbers. Individual patient results may vary based on their specific programming and experience.
†With AdaptivCRT™ programmed to BiV and LV.

Option for 40 J Energy Delivery on All Shocks (including first shock)²,4,6

<table>
<thead>
<tr>
<th>Maximum Programmed Energy</th>
<th>40 J</th>
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<tr>
<td>Maximum Delivered Energy</td>
<td>40 J</td>
</tr>
<tr>
<td>Maximum Stored Energy</td>
<td>47 J</td>
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</tbody>
</table>

**Energy delivered at connector block into a 50 Ω ± 1% load.
††Energy stored at charge end on capacitor.
PhysioCurve Design

PhysioCurve showed a 30% reduction in overall skin pressure compared to noncontoured devices.\textsuperscript{7}

- Tapered at the head and bottom of device to reduce skin pressure and promote patient comfort
- Smaller footprint for a smaller incision
- Designed with lead wrap in mind — landing area to minimize additional stresses on the lead\textsuperscript{8}

SmartShock\textsuperscript{TM} 2.0 Technology

**Lowest inappropriate shock rate.**\textsuperscript{*9}

SmartShock 2.0 includes six exclusive algorithms that discriminate true lethal arrhythmias from other arrhythmic and nonarrhythmic events.\textsuperscript{10}

1.5% Inappropriate shock rate in dual and triple chamber patients at one year\textsuperscript{9}

2.5% Inappropriate shock rate in single chamber patients at one year\textsuperscript{9}

\textsuperscript{*}A controlled, head-to-head study evaluating the comparative performance of device algorithms has not been done. Comparison of inappropriate shock rates based on survey of published literature.

\textsuperscript{*}PR Logic\textsuperscript{™} does not apply to VR devices.
Exclusive Algorithms to Optimize CRT Delivery

**AdaptivCRT™** Algorithm adapts to patients’ changing needs by optimizing CRT pacing minute-to-minute.

**IMPROVEMENT IN CRT RESPONSE**

12%

Improvement in CRT patient response with AdaptivCRT*11

**RELATIVE REDUCTION IN MORTALITY**

29%

AdaptivCRT is associated with a 29% relative reduction in mortality112

**REDUCTION IN HOSPITALIZATIONS**

59%

Reduction in a patient’s odds of 30-day HF readmission with AdaptivCRT13

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*Comparing AdaptivCRT to echo-optimized BIV pacing in patients with normal AV conduction, percentage of patients improved in Packer clinical composite score (CCS) at 6-month follow-up. CCS is a composite measure of mortality, HF hospitalizations, and symptomatic changes.

†Patients who received AdaptivCRT were associated with a 29% relative reduction in all-cause mortality vs. conventional CRT (after adjusting for other potential risk factors including age, gender, LVEF, NYHA class, QRS duration, AF, CAD, hypertension, AV block, and LBBB).
Exclusive Algorithms to Manage AF

**DETECT**

### Single Chamber

TruAF™ Detection Algorithm can detect AF in single chamber ICD patients using a traditional lead.

### Dual Chamber and CRT-D

Highest published AF episode detection accuracy (PPV). *

**AF Episode Detection Accuracy (PPV)**

- **Medtronic**: 95–96% *15-17*
- **St. Jude Medical**: 83% *18*
- **Boston Scientific**: 48% *18*
  - AV conduction 2:1 or greater for a minimum of 24 v cycles (~20 sec)
  - Episodes > 6 min
  - A Rate > 190 bpm
- **Boston Scientific**: 62% *19*
  - A Rate > 170 bpm
  - 4 atrial cycles

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* A controlled, head-to-head study evaluating the comparative performance of device algorithms has not been done. AF detection accuracy rates determined from independent clinical trials are presented for reference.
* Detection accuracy is compared using PPV, which is the percentage of all AT/AF episodes detected by the individual device detection algorithm that were adjudicated as true AT/AF.
Exclusive Algorithms to Manage AF

REDUCE

**CRT-D**

46% reduction in AF risk with AdaptivCRT Algorithm*

*Most of the reduction in AF occurred in subgroups with prolonged AV conduction at baseline and with significant left atrial reverse remodeling.

**Dual Chamber and CRT-D**

36% relative reduction in AT/AF episodes ≥ 7 days with Reactive ATP™ Algorithm†

†Compared to matched control group.
REIMAGINED CONNECTIVITY

BlueSync Technology
Cobalt ICDs and CRT-Ds with BlueSync technology enable secure, wireless communication.

Security Measures

BlueSync technology security was designed to protect the device, patient data, and connectivity.

Device Protection
- BlueSync devices do not accept programming from unauthorized sources.
- BlueSync devices are not connected to internet. Devices do not have an IP address, unlike other connected consumer products.

Data Privacy
End-to-end encryption
Data are encrypted in BlueSync technology using NIST* government standard for security before it is transmitted to the CareLink network.

Please go to medtronic.com/security for up-to-date security information.

*NIST: National Institute of Standards and Technology.
Increase Patient Adherence, Save Lives

Cardiac device patients who are not adherent with remote monitor transmissions will miss out on the following benefits:

- **50%** potential increase in survival rate of patients\(^{22-24}\)
- **35%** potential reduction in ER visits\(^{25,26}\)
- **18%** potential reduction in length of hospital stay\(^{27}\)

MyCareLink Heart results in **94.6%** patient adherence to transmission schedule compared to **77%** patient adherence for bedside monitors.\(^{28}\)

Alternative Monitoring Option

**MyCareLink Relay Home Communicator**

A Bluetooth home communicator offers your patients an alternative option for easy and reliable monitoring.
- No manual pairing required
- Requires little to no user interaction

For patients who prefer not to use a smartphone.

MyCareLink Relay must be plugged in and patients must be within communication range for successful transmissions. Requires Wi-Fi or cellular connection.
Additional CareAlerts

**Tachyarrhythmia Status:**
- Monitored VT
- Weekly ATP delivered
- Daily VT/VF episodes

**Bradyarrhythmia Status:**
- Right ventricular pacing > 40%
- High capture thresholds

**Heart Failure Status:**
- Ventricular pacing < 90%
- OptiVol™ 2.0 Fluid Status Monitoring (CRT-D)

Built for MRI

*With Cobalt MRI, patients have access to 1.5T and 3T full body scanning*[^2,^4,^6]  
- Our SureScan™ devices and leads work in any combination.[^1]  
- Scanning conditions are simple: no MRI exclusion zone, no patient height restriction, no MRI duration restriction.[^2,^4,^6]  
- BiV pacing now available in MRI SureScan mode.[^2]

[^1]: When MR conditions for use are met.  
[^2]: For a complete list of approved device and lead combinations, please visit mrisurescan.com.
Meet Cobalt ICDs and CRT-Ds

References

1 Medtronic Compia MRI™ CRT-D, Ampla MRI™ CRT-D, and Claria MRI™ CRT-D Mean Projected Service Life based on U.S. CareLink™ transmission data as of January 2019; UC201802366 EN.
2 Medtronic Cobalt™ HF Quad CRT-D MRI SureScan™ Model DTPB2QQ device manual.
3 Medtronic Evera MRI™ XT DR SureScan™ Mean Projected Service Life based on U.S. CareLink™ transmission data as of January 2019; UC201802366 EN.
4 Medtronic Cobalt™ VRICDMRISureScan™ Model DVPB3D4 device manual.
5 Medtronic Visia AF™ VRSureScan™ Mean Projected Service Life based on U.S. CareLink™ transmission data as of January 2019; UC201802366 EN.
6 Medtronic Cobalt™ VRICDMRISureScan™ Model DVPB3D4 device manual.
The Cobalt and Crome HF CRT-D MRI SureScan systems are indicated for use in patients who are at significant risk of developing atrial and/or life-threatening ventricular arrhythmias and who have heart failure with ventricular arrhythmias. Heart failure patients must have experienced one or more of the following conditions:

- NYHA Functional Class III or IV patients who remain symptomatic despite stable, optimal medical therapy and have LVEF ≤ 35% and a prolonged QRS duration
- NYHA Functional Class I patients who have left bundle branch block (LBBB) with a QRS duration > 130 ms and a left ventricular ejection fraction ≤ 30%
- NYHA Functional Class II, I, or III who are on stable, optimal medical therapy (if indicated) and have LVEF ≤ 50%, atrioventricular block (AV block), and are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing.

The Cobalt and Crome VR and DR ICD MRI SureScan systems are indicated for the automated treatment of patients who have experienced or are at significant risk of developing, atrial and/or life-threatening ventricular arrhythmias through the delivery of anti-tachycardia pacing, cardioversion, and defibrillation therapies.

**M.R.I. Conditions for Use**

Medtronic SureScan ICD and CRT-D systems are M.R.I. Conditional, and as such are designed to allow patients to undergo M.R.I. under the specified conditions for use. ICD and CRT-D SureScan system patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T M.R.I. system for hydrogen proton imaging. When programmed to On, the M.R.I. SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete SureScan defibrillation system, which is a SureScan device with appropriate SureScan leads, is required for use in the M.R.I. environment. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com/. Any other combination may result in a hazard to the patient during an M.R.I. scan.

**Contraindications**

The Cobalt and Crome VR and DR ICD, and CRT-D MRI SureScan systems are contraindicated for use in the following situations:

- If implanted with a unipolar pacemaker
- If incessant VT or VF exists
- If the primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF
- If tachyarrhythmias with transient or reversible causes exist, including the following known issues: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, and sepsis

**Warnings and Precautions**

Changes in a patient’s disease and/or medications may alter the efficacy of the device’s programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place trans thoracic defibrillation paddles directly over the device.

Patients and their implanted systems must be screened to meet the following requirements for M.R.I.: no lead extenders, lead adaptors, or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; the device must be operating within the projected service life; and the system must be implanted in the left or right pectoral region.

**Potential Adverse Events**

Potential adverse events include, but are not limited to, the following events: allergic reactions, atrial fibrillation, bradycardia, cardiac arrest, device migration, discomfort, dizziness, dyspnea, erosion, excessive fibrotic tissue growth, heart failure or loss of CRT (for CRT-D patients), hemotoma, hemorrhage, inability to deliver therapy, inappropriate shock, infection, lead migration/dislodgement, lethargy, loss of pacing, mental anguish, necrosis, nerve damage, oversensing, palpitations, seroma, syncope, tachyarrhythmia, tissue damage due to heating of the device, undersensing, and wound dehiscence.

Potential M.R.I. complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, spontaneous tachyarrhythmia, potential for VTVF induction, device heating that results in tissue damage, stimulation of the leads that results in continuous capture, VTVF, hemodynamic collapse, damage to the device or the leads, causing the system to fail or treat the patient’s condition incorrectly, and movement or vibration of the device or the leads, resulting in dislodgement.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and adverse events. See the M.R.I. SureScan Technical Manual before performing an M.R.I. Scan. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com or mrisurescan.com.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

**Medtronic Model 24970A CareLink SmartSync™ Device Manager Base and Associated Apps**

**Indications**

The base is intended to be used as part of the CareLink SmartSync Device Manager system. Clinicians use the base to analyze the electrical performance of cardiac leads during device implant or invasive troubleshooting. Clinicians use the base’s ECG connections along with the app display to view, measure, and record live cardiac waveforms. The base is intended to be used by healthcare professionals only in operating environments under direct medical supervision.

**Contraindications**

The base is not intended for use as an external pulse generator (EPG) outside of the implant procedure. In addition, the patient’s age and medical condition may dictate the lead analyses appropriate for the patient. See the CareLink SmartSync 24970A and Technical Manual and 24967 Patient Connector Technical Manual before using the CareLink SmartSync Device Manager for detailed information regarding the procedure, indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

**Medtronic Model 24967 Patient Connector and Associated Apps**

**Indications**

The patient connector is intended to be used with Medtronic apps to interrogate, analyze, and/or program implantable Medtronic devices. The patient connector uses Bluetooth® Technology to transmit that data to a Medtronic app for further processing. The patient connector is intended to be used by healthcare personnel only in a clinical or hospital environment.

**Precautions**

- Security — Maintain adequate physical security of the patient connector to prevent unauthorized use that could lead to harm to patients. Bluetooth communication in the patient connector is encrypted for security. Medtronic inductive telemetry uses short-range communication to protect patient information. If the patient connector should fail, there is no risk of patient harm. See the 24967 Patient Connector Technical Manual before using the CareLink SmartSync Device Manager for detailed information regarding the procedure, indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

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