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

UNMATCHED FEATURE SUITE

Extended Longevity

Mean longevity projections based on CareLink™ patient data*

8.3 YEARS
Claria MRI™ Quad and Amplia MRI™ Quad CRT-Ds†[1]
Mean longevity projection based on real-world programming of U.S. national CareLink network patients. January 2019.

10.1 YEARS
Cobalt HF Quad CRT-Ds[2]
Mean longevity projection based on median CareLink settings in the Cobalt manual.

10.5 YEARS
Evera MRI™ XT and Evera MRI™ S Dual Chamber ICDs[3]
Mean longevity projection based on real-world programming of U.S. national CareLink network patients. January 2019.

11.9 YEARS
Cobalt Dual Chamber ICDs[4]
Mean longevity projection based on median CareLink settings in the Cobalt manual.

12.0 YEARS
Visia AF MRI™ Single Chamber ICDs[5]
Mean longevity projection based on real-world programming of U.S. national CareLink network patients. January 2019.

13.6 YEARS
Cobalt Single Chamber ICDs[6]
Mean longevity projection based on median CareLink settings in the Cobalt manual.

*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]

MAXIMUM PROGRAMMED ENERGY
40 J

MAXIMUM DELIVERED ENERGY**
40 J

MAXIMUM STORED ENERGY††
47 J

**Energy delivered at connector block into a 50 Ω ± 1% load.

††Energy stored at charge end on capacitor.

UNMATCHED FEATURE SUITE

PhysioCurve Design

PhysioCurve showed a 30% reduction in overall skin pressure compared to noncontoured devices.[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[8]

SmartShock™ 2.0 Technology

Lowest inappropriate shock rate.*[9]

SmartShock 2.0 includes six exclusive algorithms that discriminate true lethal arrhythmias from other arrhythmic and nonarrhythmic events.†[10]

1.5%
Inappropriate shock rate in dual and triple chamber patients at one year[9]

2.5%
Inappropriate shock rate in single chamber patients at one year[9]

*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.
†PR Logic™ 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 mortality†[12]

REDUCTION IN HOSPITALIZATIONS

59%

Reduction in a patient's odds of 30-day HF readmission with AdaptivCRT[13]

*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).

UNMATCHED FEATURE SUITE

Exclusive Algorithms to Manage AF

DETECT

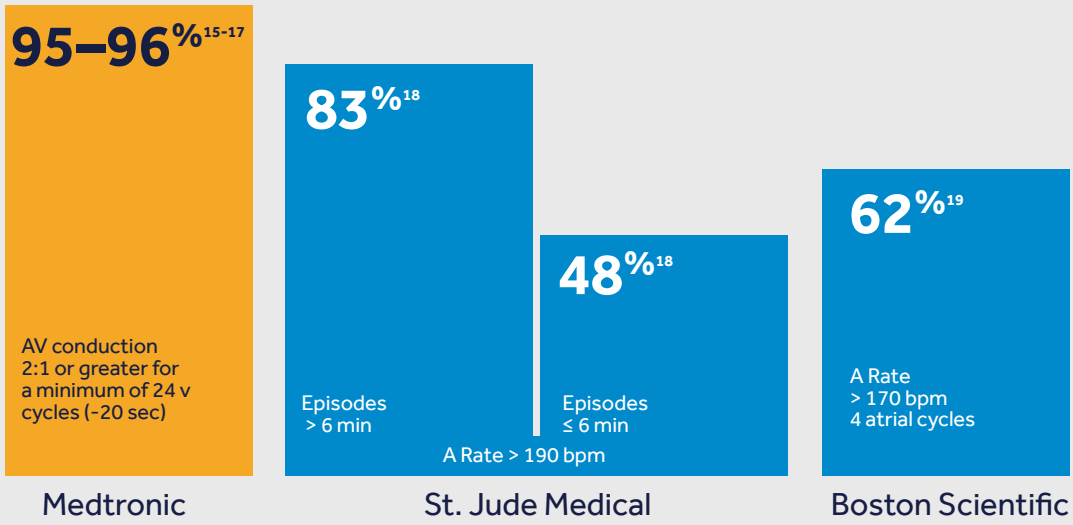
Single Chamber

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).*†[14-17]

AF Episode Detection Accuracy (PPV)*†[14]



*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

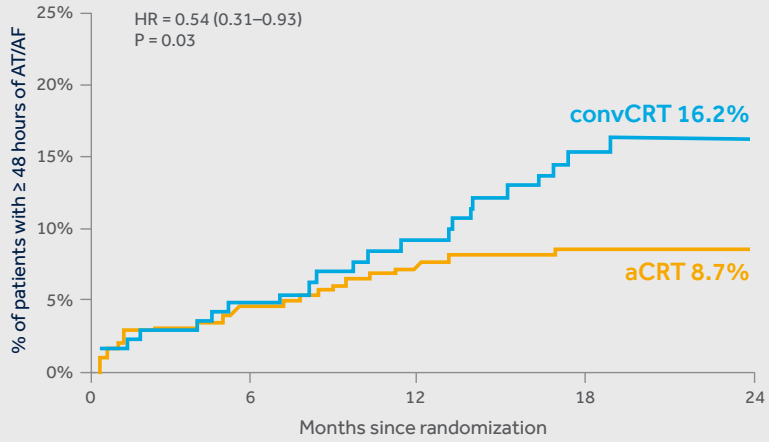
REDUCE

CRT-D

46% reduction in AF risk with AdaptivCRT Algorithm*[20]

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

Incidence of Primary End Point[20]
(≥ 48 consecutive hours of AT/AF)



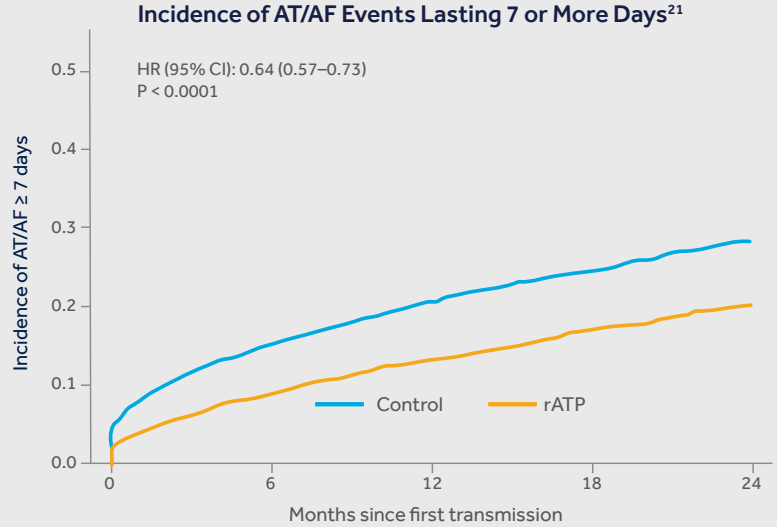
Number	160	141	126	109	33
Remaining	312	280	260	241	83

Dual Chamber and CRT-D

36% relative reduction in AT/AF episodes ≥ 7 days with Reactive ATP™ Algorithm†[21]

†Compared to matched control group.

Incidence of AT/AF Events Lasting 7 or More Days[21]



Control	4,016	2,527	1,740	1,203	845
rATP	4,016	2,578	1,763	1,160	748

REIMAGINED CONNECTIVITY

BlueSync Technology

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

Tablet-based CareLink SmartSync™ device manager

Cobalt ICDs and CRT-Ds

MyCareLink Heart™ mobile app or MyCareLink Relay™ Home Communicator

CareLink network

Supported by the Get Connected service

Security Measures[2,4,6]

BlueSync Technology

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]

77%
Bedside Monitor

94.6%
MyCareLink Heart

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.

STREAMLINED WORKFLOWS

Additional CareAlerts

Tachyarrhythmia Status:

- Monitored VT
- Weekly ATP delivered
- Daily VT/VF episodes

Bradyarrhythmia Status:

- Right ventricular pacing > 40%
- High capture thresholds

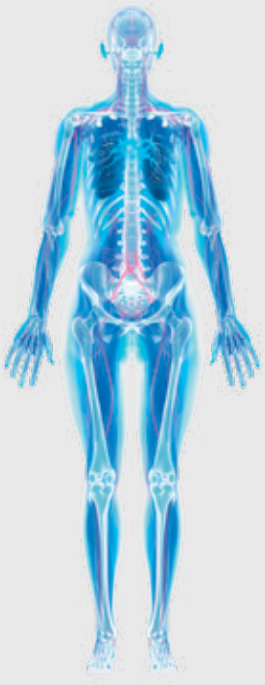
Heart Failure Status:

- 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.†
- 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]



*When MR conditions for use are met.
†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, Amplia 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™ and Evera MRI™ S DR SureScan™ Mean Projected Service Life based on U.S. CareLink™ transmission data as of January 2019; UC201802366 EN.

[4] Medtronic Cobalt™ DR MRI SureScan™ Model DDPB3D4 device manual.

[5] Medtronic Visia AF™ VR SureScan™ Mean Projected Service Life based on U.S. CareLink™ transmission data as of January 2019; UC201802366 EN.

[6] Medtronic Cobalt™ VR ICD MRI SureScan™ Model DVPB3D4 device manual.

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

[8] Lulic T. March 26, 2013. Medtronic data on file.

[9] Auricchio A, Schloss EJ, Kurita T, et al. Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results. *Heart Rhythm*. May 2015;12(5):926-936.

[10] Volosin KJ, Exner DV, Wathen MS, Sherfesee L, Scinicariello AP, Gillberg JM. Combining shock reduction strategies to enhance ICD therapy: a role for computer modeling. *J Cardiovasc Electrophysiol*. March 2011;22(3):280-289.

[11] Birnie D, Lemke B, Aonuma K, et al. Clinical outcomes with synchronized left ventricular pacing: analysis of the adaptive CRT trial. *Heart Rhythm*. September 2013;10(9):1368-1374.

[12] Singh JP, Cha YM, Lunati M, et al. Real-world behavior of CRT pacing using the AdaptivCRT algorithm on patient outcomes: Effect on mortality and atrial fibrillation incidence. *J Cardiovasc Electrophysiol*. April 2020;31(4):825-833.

[13] Starling RC, Krum H, Bril S, et al. Impact of a Novel Adaptive Optimization Algorithm on 30-Day Readmissions: Evidence From the Adaptive CRT Trial. *JACC Heart Fail*. July 2015;3(7):565-572.

[14] Sprenger M. Comparison of Manufacturer's AT/AF Detection Accuracy across Clinical Studies. January 2015. Medtronic data on file.

[15] Pürerfellner H, Gillis AM, Holbrook, Hettrick DA. Accuracy of atrial tachyarrhythmia detection in implantable devices with arrhythmia therapies. *Pacing Clin Electrophysiol*. July 2004;27(7):983-992.

[16] Ziegler PD, et al. Accuracy of Atrial Fibrillation Detection in Implantable Pacemakers. Presented at HRS 2013 (PO02-08); Denver, CO.

[17] Medtronic data on file. QADoc DSN026170, Version 2.0, "AT/AF Duration Performance Comparison."

[18] Kauffman ES, Israel CW, Nair GM, et al. Positive predictive value of device-detected atrial high-rate episodes at different rates and durations: an analysis from ASSERT. *Heart Rhythm*. August 2012;9(8):1241-1246.

[19] Nowak B, McMeekin J, Knops M, et al. Validation of dual-chamber pacemaker diagnostic data using dual-channel stored electrograms. *Pacing Clin Electrophysiol*. July 2005;28(7):620-629.

[20] Birnie D, Hudnall H, Lemke B, et al. Continuous optimization of cardiac resynchronization therapy reduces atrial fibrillation in heart failure patients: Results of the Adaptive Cardiac Resynchronization Therapy Trial. *Heart Rhythm*. December 2017;14(12):1820-1825.

[21] Crossley GH, Padeletti L, Zweibel S, Hudnall JH, Zhang Y, Boriani G. Reactive atrial-based antitachycardia pacing therapy reduces atrial tachyarrhythmias. *Pacing Clin Electrophysiol*. July 2019;42(7):970-979.

[22] Saxon LA, Hayes DL, Gilliam FR, et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. *Circulation*. December 7, 2010;122(23):2359-2367.

[23] Varma N, Piccini JP, Snell J, Fischer A, Dalal N, Mittal S. Relationship between Level of Adherence to Automatic Wireless Remote Monitoring and Survival in Pacemaker and Defibrillator Patients. *J Am Coll Cardiol*. June 23, 2015;65(24):2601-2610.

[24] Akar JG, Bao H, Jones PW, et al. Use of Remote Monitoring is Associated with Lower Risk of Adverse Outcomes Among Patients with Implanted Cardiac Defibrillators. *Circ Arrhythm Electrophysiol*. October 2015;8(5):1173-1180.

[25] Cronin EM, Ching EA, Varma N, Martin DO, Wilkoff BL, Lindsay BD. Remote monitoring of cardiovascular devices: a time and activity analysis. *Heart Rhythm*. December 2012;9(12): 1947-1951.

[26] Varma N. Rationale and design of a prospective study of the efficacy of a remote monitoring system used in implantable cardioverter defibrillator follow-up: the Lumos-T Reduces Routine Office Device Follow-Up Study (TRUST) study. *Am Heart J*. December 2007;154(6):1029-1034.

[27] Crossley GH, Boyle A, Vitense H, Chang Y, Mead RH; CONNECT Investigators. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts. *J Am Coll Cardiol*. March 8, 2011;57(10):1181-1189.

[28] Tarakji KG, Zaidi AM, Zweibel SL, et al. Performance of First in the World Pacemaker to Use Smart Device App for Remote Monitoring. Late-breaking clinical trial presented online at HRS 2020.

Brief Statements
Cobalt™/Crome™ MRI SureScan™ ICD and CRT-D Systems
Indications
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 II patients who have left bundle branch block (LBBB) with a QRS duration ≥ 130 ms and a left ventricular ejection fraction ≤ 30%
- NYHA Functional Class I, II, 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 antitachycardia pacing, cardioversion, and defibrillation therapies.
MRI Conditions for Use
Medtronic SureScan ICD and CRT-D systems are MR Conditional, and as such are designed to allow patients to undergo MRI 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 MRI system for hydrogen proton imaging. When programmed to On, the MRI 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 lead(s), is required for use in the MR 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 MRI 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 transthoracic defibrillation paddles directly over the device.
Patients and their implanted systems must be screened to meet the following requirements for MRI: 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, bradyarrhythmia, cardiac arrest, device migration, discomfort, dizziness, dyspnea, erosion, excessive fibrotic tissue growth, heart failure or loss of CRT (for CRT-D patients), hematoma, 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 MRI 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 VT/VF induction, device heating that results in tissue damage, stimulation of the leads that results in continuous capture, VT/VF, 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 MRI SureScan Technical Manual before performing an MRI 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.
Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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