Core Devices
Pacemakers (PM)
Implantable Cardioverter-Defibrillators (ICD)
Cardiac Resynchronization Therapy (CRT) devices
OptiVol® Fluid Status Monitoring

FREQUENTLY ASKED QUESTIONS
MONITORING

SEPTEMBER 2016
For monitoring questions related to Reveal LINQ™ ICM, please refer to our dedicated FAQ guide for this product.
INTRODUCTION

An implantable Pacemaker (PM) helps control abnormal heart rhythms, such as a slow heart rate. An implantable cardioverter-defibrillator (ICD) is implanted to treat tachyarrhythmias. A CRT device synchronizes the rhythm of the right and left ventricles.

This guide is intended to answer frequently asked questions regarding coding, coverage and payment for PMs, ICDs, and CRT devices and related procedures/services. This document is to be used as a guideline only.

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MONITORING

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These coding suggestions do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third party payers as to the correct form of billing or the amount that will be paid to providers of service.

For comprehensive coding references and recorded WebEx sessions, please visit the following websites:
Medtronic Reimbursement website: www.Medtronic.com/crdmrereimbursement
Medtronic Academy: www.medtronicacademy.com
Q1.M: What CPT® codes are used to report monitoring of pacemakers and implantable defibrillator devices?

A1.M: The Rhythm related monitoring codes for Pacemakers (PMs) and Implantable Defibrillator (ICD) devices are included in the tables below. See the Heart Failure section for monitoring codes applicable to physiologic data elements (non-rhythm related).

Monitoring for Pacemakers

<table>
<thead>
<tr>
<th>CPT® CODE</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>93279</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system</td>
</tr>
<tr>
<td>93280</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead pacemaker system</td>
</tr>
<tr>
<td>93281</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead pacemaker system</td>
</tr>
<tr>
<td>93288</td>
<td>Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system</td>
</tr>
<tr>
<td>93294</td>
<td>Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>93296</td>
<td>Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results</td>
</tr>
</tbody>
</table>
### Monitoring for Implantable Defibrillators

<table>
<thead>
<tr>
<th>CPT® CODE</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td><strong>Transvenous Leads</strong></td>
<td></td>
</tr>
<tr>
<td>93282</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system</td>
</tr>
<tr>
<td>93283</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead transvenous implantable defibrillator system</td>
</tr>
<tr>
<td>93284</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system</td>
</tr>
<tr>
<td>93289</td>
<td>Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements</td>
</tr>
<tr>
<td>92395</td>
<td>Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead implantable defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>93296</td>
<td>Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results</td>
</tr>
<tr>
<td><strong>Subcutaneous Leads</strong></td>
<td></td>
</tr>
<tr>
<td>93260</td>
<td>Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system</td>
</tr>
<tr>
<td>93261</td>
<td>Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system</td>
</tr>
</tbody>
</table>
CORE DEVICES continued

Q2.M: For Medicare patients, what is the coinsurance responsibility for implantable pacemaker (PM) or defibrillator (ICD) device monitoring?

A2.M: The Medicare beneficiary is responsible for a 20% coinsurance payment for hospital outpatient (this may include services performed in the Emergency Department) and Physician office device monitoring, for both the technical and professional services. For inpatient hospital monitoring, the beneficiary is responsible for the coinsurance on the professional component only.²

Q3.M: If a patient receives a pacemaker (PM) or defibrillator (ICD) that stores atrial fibrillation (AF) patient data, and is transmitting this data remotely to the physician office or hospital outpatient department for review, may separate codes be billed specifically for the AF monitoring?

A3.M: No, pacemaker (PM) or defibrillator (ICD) remote monitoring codes (93294 for PM or 93295 for ICD, and 93296) are billed to identify receipt of transmissions, review and interpreting this rhythm data from a PM or ICD.¹

Q4.M: When should the peri-procedural CPT® codes 93286 for a pacemaker (PM), or 93287 for a defibrillator (ICD) be billed? How should they be billed?

A4.M: Peri-procedural services should be reported when PM or ICD system device settings are evaluated to determine if adjustments to these settings are needed for a patient prior to and/or after a surgery, procedure, or test. Both the pre-testing and post-testing, if performed, may be submitted for payment. The professional component for services performed in the hospital is billed with a -26 modifier. The applicable additional modifier -76 or -77 would also be billed for the second evaluation. These modifiers are defined as:

Modifier 76: Repeat procedure or service by same physician or other qualified health care professional¹
Modifier 77: Repeat procedure by another physician or other qualified health care professional¹

The technical component for these services is packaged. See table below for CPT® code 93286 and 93287 descriptions.¹

Peri-procedural CPT® codes¹

<table>
<thead>
<tr>
<th>CPT® CODE</th>
<th>DESCRIPTION</th>
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<tr>
<td>93286</td>
<td>Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system</td>
</tr>
<tr>
<td>93287</td>
<td>Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system</td>
</tr>
</tbody>
</table>

September 2016 | References listed on page 12
**Q5.M:** The Pacemaker National Coverage Determination (NCD) was revised for pacemaker (PM) implants in 2013. Was the pacemaker device evaluation NCD also revised?

**A5.M:** No. The PM device evaluation NCD (20.8.1 and 20.8.1.1) is still in effect, even though monitoring methods have changed, for example, with the addition of remote monitoring. Some Medicare Administrative Contractors (MACs) have incorporated the NCD into Local policies and do warn that the total frequency of all types of evaluations will be taken into consideration for medical necessity. The PM device evaluation NCD speaks to routine monitoring, and thus increased monitoring due to symptoms and issues may be acceptable to bill as long as there is documented medical necessity. The local MAC will determine coverage.³

**Q6.M:** There are some practices who continue to use Transtelephonic (TTM) codes for monitoring pacemakers (PM). The NCD for Pacemaker evaluations suggests the frequency of these TTM evaluations. May the TTM code be billed every time these TTM services are performed?

**A6.M:** No. TTM monitoring is billed using an episode of care code which includes all TTM monitoring in a 90 day period.¹

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**90 Day Monitoring Period**

**Q7.M:** All of the defibrillator and pacemaker implant codes have a 90 day global surgical period. Will the physician practice be allowed to bill for monitoring during this global surgical period?

**A7.M:** Yes. Medicare classifies device monitoring services as diagnostic tests, and diagnostic tests are not included in the global surgical period.⁴

**Q8.M:** Is there a way to separately bill for a CareLink Alert during a 90 remote monitoring period?

**A8.M:** No. When remote monitoring services are performed, there will be only one payment for the 90 day episode regardless of the number of times that the data is transmitted and reviewed.¹

**Q9.M:** What is the minimum number of days that a patient with an implantable pacemaker or defibrillator needs be enrolled in a remote monitoring period during the 90 day period in order for the service to be billable?

**A9.M:** The patient must be in the 90 day remote monitoring program period for at least 30 days or the CPT® codes 93294-93296 are not billable.¹

**Q10.M:** If the automatic (remote) transmission from a pacemaker (PM) or defibrillator (ICD) is received and the Physician or Non-Physician Practitioner (NPP), such as a Nurse Practitioner (NP) or Physician Assistant (PA), does not review this information for a few days, what date of service (DOS) should be submitted on the claim?

**A10.M:** There is no current guidance from Medicare (CMS) regarding what date of service should be used when billing remote services. However, some local Medicare Administrative Contractors (MACs) have provided guidance. The local MAC should be contacted for the specific contractor policy. The practice is encouraged to develop a consistent method of billing to ensure that each episode of care has a period of 90 days before it is billed.¹
**CORE DEVICES** continued

**Q11.M:** If the patient receives an in person interrogation of their implanted pacemaker (PM) or defibrillator (ICD) (CPT® codes 93288 (PM) or 93289 (ICD) and this service is provided during a 90 day remote monitoring period for the implantable device, how does that affect billing?

**A11.M:** When an in person and remote interrogation of the same device during the same 90 day monitoring period is performed, the in person interrogation should not be billed. Only the remote service is billable (CPT® codes 93294 (PM) or 93295 (ICD), and 93296).

**Q12.M:** If the patient receives an in person programming evaluation of their implanted pacemaker or defibrillator (CPT® codes 93279-93281 (PM) or 93282-93284 (ICD); depending on the number of active leads, and this service is during a 90 day remote monitoring period for the implanted pacemaker or defibrillator, how does that affect billing?

**A12.M:** When an in person programming evaluation is performed during the remote 90 day episode, the programming evaluation does not impact the 90 day monitoring period, and may be separately billed.

**HEART FAILURE**

**Q13.M:** What CPT® code should be reported for a heart failure (HF) patient when the physician reviews the heart failure parameters from the patient’s defibrillator?

**A13.M:** If the implanted defibrillator stores at least one physiologic data element (non-rhythm related), such as intrathoracic impedance (OptiVol® Monitoring) to assist with HF monitoring, and the patient is in person, then CPT® code 93290 is appropriate. If the patient is transmitting remotely, then the Implantable Cardiovascular Monitor (ICM) CPT® codes may be reported. See table below.

### Implantable Cardiovascular Monitor (ICM) CPT® Codes

<table>
<thead>
<tr>
<th>CPT® CODE</th>
<th>DESCRIPTION</th>
</tr>
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<tbody>
<tr>
<td>93290</td>
<td>Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors</td>
</tr>
<tr>
<td>93297</td>
<td>Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional</td>
</tr>
<tr>
<td>93299</td>
<td>Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results</td>
</tr>
</tbody>
</table>
HEART FAILURE continued

Q14.M: What is the appropriate coding if the rhythm pacemaker (PM) or defibrillator (ICD) remote monitoring is running concurrently with the HF management remote monitoring (ICM), and the same practice or physician or hospital outpatient clinic is reporting the remote monitoring for both rhythm and physiological (OptiVol® Monitoring) ICM monitoring?

A14.M: The Practice intends to bill for both the 30 day ICM OptiVol® monitoring period and the 90 day rhythm monitoring period for the CRTD with the same date of service, as they are provided concurrently. For the ICM OptiVol® monitoring, the claim would include the professional component only (93297), as the technical component has been captured with the technical rhythm code (93296). Both codes are billable. However, if the date of service for the ICM and the rhythm monitoring episode is the same, both technical components may NOT be billed. The professional reviews may be billed, provided there is a separate report for the professional component of the ICM and for the PM or ICD rhythm monitoring.¹

Example: The codes reported would be: 93295 and 93296 for the rhythm technical and professional service, and 93297 for the OptiVol® Monitoring professional service. If this Physician continues to monitor (download, review, interpret) the ICM data based on medical necessity, 31 days later (or as directed by the local Medicare contractor), both ICM codes (93297 and 93299) may be reported.

Q15.M: The remote technical component (TC) for Medtronic’s OptiVol® Monitoring feature (CPT® code 93299) is contractor priced. How does that affect payment?

A15.M: Contractor priced means that the reimbursement for the service is determined by the local Medicare Administrative Contractor (MAC) for office based services. These rates vary greatly throughout the country depending on the MAC. For Medicare hospital outpatient (OP) services, there is an identified APC payment for CPT® code 93299.⁵,⁶

Q16.M: Why are there no RVUs (Relative Value Units) for the technical component CPT® 93299?

A16.M: Medicare (CMS) does not assign RVUs for services that are contractor priced.⁶
ALL DEVICES

Supervision

Q17.M: What type of supervision does Medicare (CMS) require when performing device monitoring services?

A17.M: Device monitoring services are diagnostic tests. The Medicare Physician Fee Schedule defines the type of supervision required for a diagnostic test, which is listed in the table below.6

Supervision Definitions6

<table>
<thead>
<tr>
<th>SERVICE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>In person programming or interrogation</td>
<td>Direct supervision by a physician (the physician must be in the suite/office when the test is being performed)</td>
</tr>
<tr>
<td>Remote monitoring</td>
<td>General supervision, which means there must be physician oversight of the monitoring program</td>
</tr>
</tbody>
</table>

Q18.M: May a Non-Physician Practitioner (NPP) such as a Nurse Practitioner (NP) serve as a supervisor for in person monitoring services?

A18.M: No. Medicare (CMS) diagnostic testing rules state that the supervisor must be a Physician. If a NPP performs the service, the NPP may bill the service with his/her own billing number, provided State licensure allows it. The NPP may NOT supervise a technician, nurse, or other office staff for in person monitoring services.4

Q19.M: Rather than should the submitted claim include the billing number of the physician who was the supervisor in the office when the monitoring service was performed?

A19.M: No, under Medicare (CMS) diagnostic testing rules, the physician who reads the report may bill for the service. The practice should keep a schedule to document the physician supervisor for the date of service when the in person monitoring was performed. This is different than the incident-to rules that govern how to report evaluation and management services.2
ALL DEVICES  continued

Professional and Technical Components

Q20.M: If the industry representative provides the technical component of an in person service, how does the Practice bill for the service?

A20.M: It is recommended that the Practice bill only the professional component by using modifier -26 on the professional claim form.7

Q21.M: How does a hospital clinic or a provider-based office bill for device monitoring?

A21.M: The table below outlines how a hospital (Inpatient, Outpatient, Emergency Department, or clinic), or a provider based clinic may bill for monitoring.1

Example: Billing for Device Monitoring (Hospital or Provider-Based Clinic) 1

<table>
<thead>
<tr>
<th>SERVICE</th>
<th>MODIFIER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
</table>
| In person  programming or interrogation | -26      | • The physician or non-physician practitioner (NPP) bills the professional component of the service  
                                 |           | • The professional claim (billing the professional component) includes the appropriate place of service (POS) code on the claim |
| Remote monitoring              | NA       | • The hospital or provider-based practice bills the CPT® code for the professional component on a professional claim with the appropriate POS |
| Remote monitoring              | NA       | • The hospital or provider-based practice bills the CPT® code for the professional component on a professional claim with the appropriate POS |
|                                | NA       | • The hospital bills the CPT® code for the technical component (TC) of the outpatient service |

Q22.M: Who bills the professional component if the technical component is provided by a commercial company such as an Independent Diagnostic Testing Facility (IDTF)?

A22.M: If the technical component of the claim for remote monitoring is provided by an IDTF, the physician or Non-Physician Practitioner (NPP) bills the professional component of the service only, with place of service Office (POS 11).8

Q23.M: The remote technical component (TC) for Medtronic’s OptiVol® Monitoring feature (CPT® code 93299) is contractor priced. How does that affect payment?

A23.M: Contractor priced means that the reimbursement for the service is determined by the local Medicare Administrative Contractor (MAC) for office based services. These rates vary greatly throughout the country depending on the MAC. For Medicare hospital outpatient (OP) services, there is an identified payment for CPT® code 93299.5,6
CONNECTED CARE

**Q24.M:** How does a hospital bill for Carelink Express™ (CLE) services?

**A24.M:** There is no applicable CPT® code to describe the CLE technical component that would be billed by the hospital, and thus it is not billable. ¹

**Q25.M:** Hospitals want to bill the MyCarelink (MCL) monitor as Durable Medical Equipment. Is that possible?

**A25.M:** The MCL monitor does not meet the definition for durable medical equipment and may not be billed as such. Furthermore, there is specific instruction from Medicare (CMS) that states the implant procedure includes a monitoring device (packaged to the implant). Therefore, the MCL monitor is not billable to Medicare as a separate line item. ⁹

**Q26.M:** What dates of service should be used for remote monitoring services?

**A26.M:** Remote monitoring is paid based on an episode of care. That episode is described as a period of 90 days for implantable pacemakers (PM) and defibrillators (ICDs), and a period of 30 days for Implantable Cardiovascular Monitors (ICM) and Implantable Loop Recorders (ILR). The episode is not billed until after the 90 or 30 days is completed, and the date of service should reflect the episode, not an individual professional review of a transmission. Providers need to check with local Medicare contractors (MACs) or private payers to establish what date of service is required.¹

**Q27.M:** Medicare (CMS) is promoting Telehealth to help with patient access to care. Is remote monitoring using CareLink eligible to be billed to Medicare as a Telehealth service?

**A27.M:** No. Medicare (CMS) Telehealth services are restricted to Telehealth codes approved by Medicare (CMS), and the remote monitoring codes are not included in this listing as covered Telehealth services. Telehealth also includes various rules regarding location and technical set-up that need to be met even when service codes are included on the Telehealth approved list. ¹⁰
REFERENCES

1 AMA 2016 CPT Professional Codebook


6 The National Medicare Physician Fee Schedule Relative Value file is at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html


10 The list of Medicare approved Telehealth Services is available at: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html

These coding suggestions do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third party payers as to the correct form of billing or the amount that will be paid to providers of service.

CRHF Economics and Health Policy
Reimbursement website: www.Medtronic.com/CRDMreimbursement
Email: rs.healthcareeconomics@Medtronic.com
Coding Hotline: 1-866-877-4102
BRIEF STATEMENT: CRT IPGS AND CRT ICDs

**Indications:** Cardiac Resynchronization Therapy (CRT) IPGs are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post implant. Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity. Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications.

CRT ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction < 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration > 130 ms, left ventricular ejection fraction < 30%, and NYHA Functional Class II. NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤ 50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post implant. Some CRT ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The RV Lead Integrity Alert (LIA) feature is intended primarily for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead (Models 6949, 6948, 6931, and 6930, based on performance data. The RV LIA feature may not perform as well with a St. Jude Riata/Durata lead or a Boston Scientific Endotak lead as it does when used with a Medtronic Sprint Fidelis lead. This is because different lead designs may have different failure signatures and conditions that may or may not be detected early by the RV LIA feature.

**Contraindications:** CRT IPGs are contraindicated for concomitant implant with another bradycardia device and concomitant implant with an implantable cardioverter-defibrillator. There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient’s age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. Antitachycardia pacing (ATP) therapy is contraindicated in patients with an accessory antegrade pathway. CRT ICDs are contraindicated in patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis; patients who have a unipolar pacemaker implanted, patients with incessant ventricular tachycardia (VT) or ventricular fibrillation (VF), and patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.
Warnings/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. Additionally, for CRT ICDs and CRT IPGs, certain programming and device operations may not provide cardiac resynchronization. Also for CRT IPGs, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and/or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set. Use of the device should not change the application of established anticoagulation protocols.

Potential complications: Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for CRT ICDs is the acceleration of ventricular tachycardia.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic’s website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.
The Medtronic MyCareLink Patient Monitor and the Medtronic CareLink Network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to internet connectivity and access, and service availability. The MyCareLink Patient Monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

**Brief Statement:** Medtronic MyCareLink™ Patient Monitor, Medtronic CareLink™ Network and CareLink™ Mobile Application.

**Intended Use:** The Medtronic MyCareLink Patient Monitor and CareLink Network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. The CareLink Mobile Application is intended to provide current CareLink Network customers access to CareLink Network data via a mobile device for their convenience. The CareLink Mobile Application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. CareLink Network availability and mobile device accessibility may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the internet is required and subject to coverage availability. Standard text message rates apply.

**Contraindications:** There are no known contraindications.

**Warnings and Precautions:** The MyCareLink Patient Monitor must only be used for interrogating compatible Medtronic implantable devices.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 929-4043 and/or consult Medtronic’s website at www.medtronic.com.

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