

Labeling for P010031/S232

The labeling for this submission is extensive and includes:

- A Clinical Manual with a Clinical Studies Summary Section
- Patient Labeling

There are ten (10) Cardiac Resynchronization Therapy – Defibrillators (CRT-D) systems included in this supplement:

Concerto Model C154DWK
Concerta II Model D274TRK
Consulta Models D224TRK and D204TRM
Maximo II Models D284TRK and D264TRM
Protecta Models D334TRG and D334TRM
Protecta XT Models D314TRG and D314TRM

Each of these CRT-D models has a clinical-type manual and an identical section that contains the clinical study summary. There is one (1) common Patient Labeling that is applicable to all ten (10) CRT-D models.

Instead of posting virtually identical physician labeling for each of the ten (10) CRT-D systems listed above, a representative example of the labeling from two (2) systems are posted.

Posted are 1) the Concerta Implant and Reference Manuals, 2) the Consulta Clinical Manual (which is virtually identical to the Clinical Manual of the Concerta II, Maximo II, Protecta, and Protecta XT labeling), and 3) the Clinical Summary (which is identical for all ten (10) systems).

Please contact Medtronic or view their website for copies of any specific labeling.



Medtronic

CONCERTO[®] C154DWK

Dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy (VVE/DDE-DDDR), atrial and ventricular therapies, OptiVol[®] Fluid Monitoring, and Conexus[®] Telemetry

Implant Manual

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

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ATP During Charging, Active Can, Capture Management, Cardiac Compass, CareAlert, ChargeSaver, Concerto, Conexus, EnTrust, Flashback, GEM, GEM DR, InCheck, InSync, InSync ICD, InSync II Marquis, InSync III Marquis, InSync Marquis, Marker Channel, Marquis, Medtronic, Medtronic CareAlert, OptiVol, PR Logic, Paceart, Quick Look, Reactive ATP, SessionSync, T-Shock

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1 Description

The Medtronic Model C154DWK Concerto dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT-D), including sequential biventricular pacing, is an implantable medical device that automatically detects and treats episodes of ventricular fibrillation (VF), ventricular tachycardia (VT), fast ventricular tachycardia (FVT), and bradyarrhythmia. The device also detects and treats atrial tachyarrhythmia (AT) episodes¹.

The Model C154DWK Concerto CRT-D, along with pacing leads and defibrillation leads, constitutes the implantable portion of the device system.

Programmer, software, and magnet – Use the appropriate Medtronic programmer, software, and magnet to program this device. Programmers from other manufacturers are not compatible with Medtronic devices but will not damage Medtronic devices.

Network connectivity and data exchange – The system supports network connectivity and the exchange of data between the Medtronic Carelink 2090 programmer and the Medtronic Paceart data management system using the SessionSync feature.

The system supports the use of the Medtronic 2290 Analyzer, which allows you to have a device session and an analyzer session running at the same time, quickly switch from one to the other without having to end or restart sessions, and export data from the analyzer to the device software application.

The system supports Remote View, which allows you to use a personal computer in your office or elsewhere to view the screen displays from a Medtronic Carelink programmer in a clinic, hospital, or other location.

Conexus wireless telemetry – Conexus wireless telemetry is designed to provide clinicians and patients with an easier and more efficient implant, follow-up, and monitoring experience. The system uses radio frequency (RF) telemetry for wireless communication between the implanted device and programmer in the hospital or clinic, and between the implanted device and the patient's monitor. This eliminates the need to have a programming head over the implanted device for the duration of a programming or monitoring session.

During a wireless telemetry session, all other programmers are locked out from communicating or initiating a session with your patient's implanted device, maintaining patient safety and privacy. Similarly, other patients with implanted devices are locked out from any communication or programming occurring during your patient's session.

Conexus Activator – The Medtronic Model 27901 Conexus Activator can be used by clinicians to turn on Conexus wireless telemetry for implanted devices that support wireless telemetry.

Model 2696 InCheck Patient Assistant – The patient can use the Model 2696 InCheck Patient Assistant to perform the following tasks:

- Verify whether the implanted device has detected a suspected atrial tachyarrhythmia.
- Initiate recording of cardiac event data in the device memory.
- Request delivery of atrial cardioversion therapy (if the device is programmed to allow patient-activated cardioversion).

Note: Patient-activated cardioversion is only delivered if the implanted device is currently detecting an AT/AF episode.

Contents of sterile package – The package contains one implantable cardioverter defibrillator, one torque wrench, and one DF-1 pin plug.

About this manual – This document is primarily an implant manual. Regular patient follow-up sessions should be scheduled after implant. Follow-up procedures such as monitoring battery measurements and confirming therapy parameters are described in the product documentation that is included with the software that supports this device. To obtain additional copies of product documentation, contact a Medtronic representative.

¹ AT therapies are available with appropriate software. Contact your Medtronic representative.

2 Indications and usage

The Concerto CRT-D system is 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 who remain symptomatic despite optimal medical therapy, 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 $\leq 35\%$ and a prolonged QRS duration.
- Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction $\leq 30\%$, and NYHA Functional Class II.

The system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive (PMOP) are indicated for the suppression of atrial tachyarrhythmias in implantable cardioverter defibrillator (ICD)-indicated patients with atrial septal lead placement and an ICD indication.

3 Contraindications

The Concerto CRT-D system is contraindicated for 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.

The device is contraindicated for patients who have a unipolar pacemaker implanted.

The device is contraindicated for patients with incessant VT or VF.

The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

4 Warnings and precautions

4.1 General

Anti-coagulation – Use of the device should not change the application of established anti-coagulation protocols.

Avoiding shock during handling – Disable tachyarrhythmia detection during implant, explant, or postmortem procedures. The device can deliver a high-voltage shock if the defibrillation terminals are touched.

Electrical isolation during implant – Do not allow the patient to have contact with grounded equipment that might produce electrical current leakage during implant. Electrical current leakage may induce arrhythmias that may result in the patient's death.

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use whenever arrhythmias are possible or intentionally induced during device testing, implant procedures, or post-implant testing.

Lead compatibility – Do not use another manufacturer's leads without demonstrated compatibility with Medtronic devices. If a lead is not compatible with a Medtronic device, the result may be undersensing of cardiac activity, failure to deliver necessary therapy, or a leaking or intermittent electrical connection.

Occurrence of stroke – Following an ischemic or cerebrovascular accident, disable atrial cardioversion therapies until the patient has stabilized.

4.2 Handling and storage instructions

Follow these guidelines when handling or storing the device.

4.2.1 Device handling

Checking and opening the package – Before opening the sterile package tray, visually check for any signs of damage that might invalidate the sterility of the package contents. Refer to the sterile package opening instructions found inside the product box.

If the package is damaged – The device packaging consists of an outer tray and inner tray. Do not use the device or accessories if the outer packaging tray is wet, punctured, opened, or damaged. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment. This device is for single use only and is not intended to be resterilized.

Device temperature – Allow the device to reach room temperature before it is programmed or implanted. Device temperature above or below room temperature may affect initial device function.

Dropped device – Do not implant the device if it has been dropped on a hard surface from a height of 30 cm (12 in) or more after it is removed from its packaging.

“Use by” date – Do not implant the device after the “Use by” date because the battery longevity could be reduced. Resterilizing a device does not extend the “Use by” date.

For single use only – Do not resterilize and reimplant an explanted device that has been contaminated by contact with body fluids.

4.2.2 Device storage

Avoid magnets – To avoid damaging the device, store the device in a clean area away from magnets, kits containing magnets, and any sources of electromagnetic interference.

Temperature limits – Store and transport the package between $-18\text{ }^{\circ}\text{C}$ and $+55\text{ }^{\circ}\text{C}$ ($0\text{ }^{\circ}\text{F}$ and $131\text{ }^{\circ}\text{F}$). Electrical reset may occur at temperatures below $-18\text{ }^{\circ}\text{C}$ ($0\text{ }^{\circ}\text{F}$). Device longevity may decrease and performance may be affected at temperatures above $+55\text{ }^{\circ}\text{C}$ ($131\text{ }^{\circ}\text{F}$).

4.3 Explant and disposal

Consider the following information related to device explant and disposal:

- Interrogate the device and disable tachyarrhythmia detection before explanting, cleaning, or shipping the device. This prevents the device from delivering unwanted shocks.
- Explant the implantable device postmortem. In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; please check the local regulations. In addition, if subjected to incineration or cremation temperatures, the device may explode.
- Medtronic implantable devices are intended for single use only. Do not resterilize and reimplant explanted devices.
- Please use the Tachyarrhythmia Product Information Report to return explanted devices to Medtronic for analysis and disposal.

4.4 Lead evaluation and lead connection

Lead connection – Consider the following information when connecting the lead and device:

- Cap abandoned leads to avoid transmitting electrical signals.
- Plug any unused lead ports to protect the device.
- Verify lead connections. Loose lead connections may result in inappropriate sensing and failure to deliver arrhythmia therapy.

Lead Impedance – Consider the following information about lead impedance when evaluating the lead system.

- Ensure that the defibrillation lead impedance is greater than 20 Ω . An impedance of less than 20 Ω may damage the device or prevent delivery of high-voltage therapy.
- Before taking electrical or defibrillation efficacy measurements, move objects made from conductive materials, such as guide wires, away from all electrodes. Metal objects, such as guide wires, can short a device and lead, causing electrical current to bypass the heart and possibly damage the device and lead.
- If the LV pacing impedance for pacing LVtip to RVcoil is greater than 2500 Ω and the V. Defib (HVB) impedance is greater than 200 Ω , then use LV EGM (LVtip to Can) to assess the integrity of the LV lead.
- Refer to the lead technical manuals for specific instructions and precautions about lead handling.

Patch leads – Do not fold, alter, or remove any portion of a patch lead. Doing so may compromise electrode function or longevity.

4.5 Device operation

Accessories – Use this device only with accessories, parts subject to wear, and disposable items that have been tested to technical standards and found safe by an approved testing agency.

Battery depletion – Carefully monitor battery longevity. Battery depletion will eventually cause the device to stop functioning. Cardioversion and defibrillation are high-energy therapies that shorten battery longevity. An excessive number of charging cycles will also shorten battery longevity.

Charge Circuit Timeout or Charge Circuit Inactive – Contact a Medtronic representative and replace the device immediately if the programmer displays a Charge Circuit Timeout or Charge Circuit Inactive message. If this message is displayed, high-voltage therapies are not available for the patient.

Concurrent pacemaker use – If a pacemaker is used concurrently with the ICD, verify that the ICD does not sense the pacemaker output pulses because this can affect the detection of tachyarrhythmias by the ICD. Program the pacemaker to deliver pacing pulses at intervals longer than the ICD tachyarrhythmia detection intervals.

End of Service (EOS) indicator – Replace the device immediately if the programmer displays an EOS indicator. The device may not perform adequately after the EOS indicator appears.

Follow-up testing – Consider this information when performing follow-up testing of the device.

- Keep external defibrillation equipment nearby for immediate use in case the patient requires external rescue.
- Changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia postoperatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during the implantation procedure is no assurance that conversion will occur postoperatively.

Higher than programmed energy – The device may deliver a therapy of higher than programmed energy if it was previously charged to a higher energy and that charge remains on the capacitors.

Magnets – Positioning a magnet over the device suspends detection and treatment but does not alter bradycardia therapy. The programming head contains a magnet that can suspend detection. However, detection is not suspended if conventional telemetry between the device and programmer is established.

Pacemaker-dependent patients – Always program Ventricular Safety Pacing to On for pacemaker-dependent patients. Ventricular Safety Pacing prevents ventricular asystole due to inappropriate inhibition of ventricular pacing caused by oversensing.

Programmers – Use only Medtronic programmers and application software to communicate with the device. Programmers and software from other manufacturers are not compatible with Medtronic devices.

Patient safety during a wireless telemetry session – Make sure that you have selected the appropriate patient before proceeding with a wireless patient session. Maintain visual contact with the patient for the duration of the session. If you select the wrong patient and continue with the session, you may inadvertently program the patient's device to the wrong settings.

Rate control – Decisions regarding rate controls should not be based on the ability of the device to prevent atrial arrhythmias.

4.6 Medical therapy hazards

Computed tomographic x-ray (CT scan) – If the patient undergoes a CT scan procedure and the device is not directly in the CT scan x-ray beam, the device is not affected. If the device is directly in the CT scan x-ray beam, oversensing may occur for the duration of the time in the beam.

Disable the tachycardia detection function. This measure prevents false detection. After completing the CT scan, enable the tachy detection function.

If the duration of the time in the beam is longer than 4 s, take appropriate measures for the patient, such as enabling an asynchronous mode for pacemaker-dependent patients or enabling a nonpacing mode for nonpacemaker-dependent patients. These measures prevent false inhibition and false tracking. After completing the CT scan, restore the desired parameters.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Electrosurgical cautery – Electrosurgical cautery may induce ventricular arrhythmias and fibrillation or may cause device malfunction or damage. If electrosurgical cautery cannot be avoided, observe the following precautions to minimize complications:

- Keep temporary pacing and defibrillation equipment available.
- Program the device to an asynchronous pacing mode for pacemaker-dependent patients.
- Suspend tachyarrhythmia detection using a magnet, or disable detection using the programmer. Do not enable tachyarrhythmia detection until the electrosurgical cautery procedure is complete.
- Use a bipolar electrocautery system if possible. If unipolar cautery is used, position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm (6 in) away from the device and lead system.
- Avoid direct contact of the cautery equipment with the implanted device or leads.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.

External defibrillation – External defibrillation may damage the implanted device. External defibrillation may also temporarily or permanently elevate pacing thresholds or temporarily or permanently damage the myocardium at the electrode tissue interface. Current flow through the device and lead may be minimized by following these precautions:

- Use the lowest clinically appropriate defibrillation energy.
- Position the defibrillation patches or paddles a minimum of 15 cm (6 in) away from the device.
- Position the defibrillation patches or paddles perpendicular to the device and lead system.

If an external defibrillation is delivered within 15 cm (6 in) of the device, contact a Medtronic representative.

High-energy radiation – Diagnostic x-ray and fluoroscopic radiation should not affect the device; however, high-energy radiation sources such as cobalt 60 or gamma radiation should not be directed at the device. If a patient requires radiation therapy in the vicinity of the device, place lead shielding over the implant site as a precaution against radiation damage. Contact Medtronic Technical Services for information on high-energy therapeutic radiation exposure. See back cover for contact information.

Lithotripsy – Lithotripsy may permanently damage the device if the device is at the focal point of the lithotripter beam. If lithotripsy must be performed, take the following precautions:

- Keep the focal point of the lithotripter beam a minimum of 2.5 cm (1 in) away from the implanted device.
- Disable tachyarrhythmia detection for the duration of the lithotripsy procedure.
- Program the device to an asynchronous pacing mode for pacemaker-dependent patients.

Magnetic resonance imaging (MRI) – Do not use magnetic resonance imaging (MRI) on patients who have an implanted device. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias. MRI may also cause damage to the device.

Medical treatment influencing device operation – The electrophysiological characteristics of a patient's heart can change over time, especially if the patient's medications have changed. As a result of the changes, programmed therapies may become ineffective and possibly dangerous to the patient.

Radio frequency (RF) ablation – An RF ablation procedure may cause device malfunction or damage. Radio frequency ablation risks may be minimized by observing the following precautions:

- Keep temporary pacing and defibrillation equipment available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm (6 in) away from the device and lead system.
- Suspend tachyarrhythmia detection using a magnet, or disable detection using the programmer. Do not enable tachyarrhythmia detection until the RF procedure is complete.
- Program the device to an asynchronous pacing mode for pacemaker-dependent patients.

Susceptibility to radiotherapy – Exposing the device to direct or scattered neutrons may cause reset of the device, errors in diagnostic data, or loss of diagnostic data. To help prevent device reset due to neutron exposure, deliver radiotherapy treatment using photon beam energies less than or equal to 10 MV. Electron beam treatments are not a problem. Using a lead shield during radiotherapy does not protect the device from the effects of the neutrons. Immediately after radiotherapy treatment, Medtronic suggests interrogating the device. In some devices, an alarm in the device sounds when a reset occurs. A device reset requires device parameters to be reprogrammed.

Therapeutic ultrasound – Do not expose the device to therapeutic ultrasound. Therapeutic ultrasound may permanently damage the device.

4.7 Home and occupational environments

Cellular phones – This device contains a filter that prevents most cellular phone transmissions from interacting with device operation. To further minimize the possibility of interaction, observe these cautions:

- Maintain a minimum separation of 15 cm (6 in) between the device and the cellular phone, even if the cellular phone is not on.
- Maintain a minimum separation of 30 cm (12 in) between the device and any antenna transmitting above 3 W.
- Hold the cellular phone to the ear farthest from the device.

This device has been tested using the ANSI/AAMI PC-69 standard to ensure compatibility with cellular phones and other hand-held transmitters with similar power. These transmission technologies represent the majority of cellular telephones used worldwide. The circuitry of this device, when operating under nominal conditions, has been designed to eliminate any significant effects from cellular telephones.

Electromagnetic interference (EMI) – Instruct patients to avoid devices that generate strong EMI. Electromagnetic interference may result in delivery of unneeded therapy. Electromagnetic interference may also cause device malfunction or damage. The patient should move away from the EMI source or turn off the source because this usually allows the device to return to its normal mode of operation. EMI may be emitted from these sources:

- high-voltage power lines
- communication equipment such as microwave transmitters, linear power amplifiers, or high-powered amateur transmitters
- commercial electrical equipment such as arc welders, induction furnaces, or resistance welders

Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. There are reports of temporary disturbances caused by electric hand tools or electric razors used directly over the implant site.

Electronic article surveillance (EAS) – Electronic article surveillance equipment, such as retail theft prevention systems, may interact with devices and result in inappropriate therapy delivery. Advise patients to walk directly through an EAS system and not remain near an EAS system longer than necessary.

Static magnetic fields – Patients should avoid equipment or situations where they would be exposed to static magnetic fields greater than 10 gauss or 1 mT. Static magnetic fields may suspend arrhythmia detection. Sources of static magnetic fields include, but are not limited to, stereo speakers, bingo wands, extractor wands, magnetic badges, or magnetic therapy products.

5 Potential adverse events

Potential adverse events associated with the use of transvenous leads and pacing systems include (but are not limited to) the following (listed in alphabetical order):

- Acceleration of arrhythmias (caused by ICD)
- Air embolism
- Bleeding
- Body rejection phenomena including local tissue reaction
- Cardiac dissection
- Cardiac perforation
- Cardiac tamponade
- Chronic nerve damage
- Coronary sinus dissection
- Death
- Endocarditis
- Erosion
- Erosion through the skin
- Excessive fibrotic tissue growth
- Extrusion
- Fibrillation or other arrhythmias
- Fluid accumulation
- Formation of hematomas or cysts
- Heart block
- Heart wall or vein wall rupture
- Hematoma/seroma
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration/dislodgement
- Muscle and/or nerve stimulation
- Myocardial damage
- Myocardial irritability
- Myopotential sensing
- Pericardial effusion
- Pericardial rub
- Pneumothorax
- Potential mortality due to inability to defibrillate or pace
- Rejection phenomena (local tissue reaction, fibrotic tissue formation, device migration)
- Shunting current or insulating myocardium during defibrillation
- Threshold elevation
- Thromboemboli
- Thrombolytic and air embolism
- Thrombosis

- Transvenous lead-related thrombosis
- Valve damage (particularly in fragile hearts)
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management could develop psychological intolerance to an ICD system that might include the following conditions:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking (phantom shock)

6 Adverse events and clinical trial data

Information regarding clinical studies and adverse events related to this device is available at www.medtronic.com/manuals. To view, download, print, or order the following clinical studies from the Medtronic website, perform the following steps:

1. Navigate your web browser to <http://www.medtronic.com/manuals>.
2. Select the hyperlink that corresponds to your location.
3. Select the Search field on the left side of the screen and type "C154DWK".
4. Click [Search]. All technical literature for this device is listed.

The following clinical studies are related to this device:

Concerto AT clinical study – This clinical study evaluated the safety of the Concerto system and the efficacy of atrial shock therapy in patients with a current indication for Cardiac Resynchronization Therapy (CRT) and an Implantable Cardioverter Defibrillator (ICD). It provides support for atrial cardioversion therapy in the Concerto Model C154DWK devices.

EnTrust clinical study – This clinical study, which evaluated the safety and clinical performance of the EnTrust ICD system, provides support for the Concerto Model C154DWK devices.

EnTrust tachyarrhythmia detection performance vs. GEM DR tachyarrhythmia detection performance – This retrospective evaluation of the EnTrust detection algorithm was performed on spontaneous rhythms recorded in patients implanted with the GEM DR ICD. It provided support for the modifications made to the PR Logic Sinus Tachycardia criterion in the EnTrust devices. These modifications also apply to the Concerto Model C154DWK devices.

FAST study – This clinical study, which evaluated the OptiVol Fluid Monitoring feature in InSync Marquis devices to corroborate the MIDHeFT clinical data, provides support for the OptiVol Fluid Monitoring feature in Concerto Model C154DWK devices.

GEM DR clinical studies – This clinical study, which evaluated the appropriateness of dual chamber sensing and tachyarrhythmia detection during induced and simulated cardiac arrhythmias in GEM DR devices, provides support for the Concerto Model C154DWK devices.

InSync ICD clinical study – This clinical study, which evaluated the safety and efficacy of cardiac resynchronization therapy (CRT) in patients who are indicated for an ICD, provides support for CRT pacing in Concerto Model C154DWK devices.

InSync Marquis clinical study – This clinical study assessed the safety of the InSync Marquis dual chamber, rate responsive ICD with CRT Therapy, and confirmed appropriate VT/VF detection and biventricular capture over the range of heart rates achieved during exercise. It provides support for the Concerto Model C154DWK devices.

InSync III Marquis clinical study – This clinical study, which evaluated the safety and efficacy of sequential biventricular CRT pacing and the Conducted AF Response feature in the InSync III Marquis devices, provides support for CRT pacing and Conducted AF Response in Concerto Model C154DWK devices.

Left Ventricular Capture Management Software Download Clinical Trial (LVCM) – This clinical study, which evaluated the accuracy of the Left Ventricular Capture Management feature in modified InSync II Marquis devices, provides support for the Left Ventricular Capture Management feature in Concerto Model C154DWK devices.

Medtronic Impedance Diagnostics in Heart Failure Trial (MIDHeFT) – This clinical study, which demonstrated the use of intrathoracic impedance as a surrogate measure of fluid status in patients with heart failure, provides support for the OptiVol Fluid Monitoring feature in Concerto Model C154DWK devices.

Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction (REVERSE) and Resynchronization/Defibrillation for Ambulatory Heart Failure Trial (RAFT) – These clinical studies, which evaluated cardiac resynchronization therapy in mildly (REVERSE and RAFT) symptomatic and moderately symptomatic (RAFT) heart failure patients, provide support for Concerto Model C154DWK devices in these patients.

7 Implant procedure

Warnings:

- Do not permit the patient to contact grounded equipment that could produce hazardous leakage current during implantation. Resulting arrhythmia induction could result in the patient's death.
- The device is intended for implant in the pectoral region with Medtronic transvenous defibrillation leads. Implantation of the device outside of the pectoral region, or the use of an epicardial defibrillation lead instead of an RVcoil (HVB) may adversely affect the results of the OptiVol fluid measurements. No claims of safety and efficacy can be made with regard to other acutely or chronically implanted lead systems that are not manufactured by Medtronic.

Caution: Lead coils and Active Can electrodes in contact during a high-voltage therapy may cause electrical current to bypass the heart, possibly damaging the device and leads. While the device is connected to the leads, verify that therapeutic electrodes, stylets, or guide wires are not touching or connected by an accessory low impedance conductive pathway. Move objects made from conductive materials (for example, an implanted guide wire) well away from all electrodes before delivering a high voltage shock.

Proper surgical procedures and sterile techniques are the responsibility of the physician. The following procedures are provided for information only. Each physician must apply the information in these procedures according to professional medical training and experience.

The implant procedure includes the following steps:

- Program the device before implant.
- Verify lead and connector compatibility.
- Position the leads.
- Test the lead system.
- Connect the leads to the device.
- Test defibrillation thresholds.
- Position and secure the device.
- Program the device.

For information about replacing a previously implanted device, see Section 7.9, "Replace a device", page 20.

7.1 Program the device before implant

Caution: Do not implant the device after the "Use by" date. Battery longevity may be reduced.



Medtronic

CONCERTO[®] C154DWK

Dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy (VVE/DDE-DDDR), atrial and ventricular therapies, OptiVol[®] Fluid Monitoring, and Conexus[®] Telemetry

Reference Manual

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

CONCERTO® C154DWK

Reference Manual

A guide to the operation and programming of the Model C154DWK Concerto dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy, OptiVol® Fluid Monitoring, and Conexus™ Telemetry

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ATP During Charging, Active Can, Capture Management, Cardiac Compass, CareAlert, CareLink, ChargeSaver, Checklist, Concerto, Conexus, Flashback, InCheck, Intrinsic, Marker Channel, Medtronic, Medtronic CareAlert, Medtronic CareLink, OptiVol, PR Logic, Paceart, Quick Look, QuickLink, Reactive ATP, SessionSync, Switchback, T-Shock

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Introduction

About this manual

This manual describes the operation and intended use of the Concerto Model C154DWK system.

Concerto Model C154DWK devices provide atrial and ventricular tachyarrhythmia detection and therapy, a full range of dual chamber bradycardia pacing modes and associated features, and cardiac resynchronization therapy.

Programmer hardware and screen images

The screen image examples in this manual were taken from the Medtronic CareLink Model 2090 programmer with Conexus Telemetry.

The information provided in this manual about using the programmer assumes the Medtronic CareLink Model 2090 Programmer with Conexus Telemetry is used. For information about using the Medtronic CareLink Model 2090 Programmer without Conexus Telemetry, see the *Medtronic CareLink Model 2090 Programmer Instruction Manual*.

Manual conventions

Throughout this document, the word “device” refers to the implanted Concerto device.

The \diamond symbol in parameter tables indicates the Medtronic nominal value for that parameter.

On-screen buttons are shown with the name of the button surrounded by brackets: [Button Name].

Nomenclature for product battery life terms

This manual uses a nomenclature for certain terms related to product battery life as defined in CENELEC pacemaker standard EN 45502-2-1:2003. This standard applies to Active Implantable Medical Devices (AIMD) intended to treat bradyarrhythmias. This standard was approved and published in December 2003.

Medtronic has adopted this nomenclature to comply with the CENELEC standard and in anticipation of the nomenclature becoming an international standard. The nomenclature defined in EN 45502-2-1:2003 replaces previously used terms related to product battery life.

The nomenclature defined in EN 45502-2-1:2003, and the terms this nomenclature replaces, are presented in the following table:

Nomenclature in EN 45502-2-1: 2003		Previously used nomenclature	
BOS	Beginning of Service	BOL	Beginning of Life
EOS	End of Service	EOL	End of Life
RRT	Recommended Replacement Time	ERI	Elective Replacement Indicator
PSP	Prolonged Service Period	Post-ERI conditions	
Projected service life		Longevity	

Additional literature

Before implanting the device, it is strongly recommended that you take the following actions:

- Refer to the product literature packaged with the device for information about prescribing the device.
- Thoroughly read the technical manuals for the leads used with the device.
- Discuss the procedure and the device with the patient and any other interested parties, and provide them with any patient information packaged with the device.

Technical support

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products.

In addition, Medtronic maintains a professional staff of consultants to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise.

For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

Customer education

Medtronic invites physicians to attend an educational seminar on the device. The course describes indications for use, system functions, implant procedures, and patient management.

References

The primary reference for background information is Zacouto FI, Guize LJ. Fundamentals of Orthorhythmic Pacing. In: Luderitz B, ed. *Cardiac Pacing Diagnostic and Therapeutic Tools*. New York: Springer-Verlag; 1976: 212-218.

See these additional references for more background information:

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- Singer I, Ed. *Implantable Cardioverter-Defibrillator*. Armonk, NY: Futura Publishing Co. 1994.
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- Stadler RW, Gunderson BD, Gillberg JM. An Adaptive Interval-Based Algorithm for Withholding ICD Therapy During Sinus Tachycardia. *Pace*. 2003; 26:1189–1201.

Notice

This software is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Medtronic makes no representation as to the accuracy or completeness of the data input into the software. Medtronic SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULTS FROM THE USE OF THE INFORMATION PROVIDED IN THE SOFTWARE.

Part I

Quick overview

1 Quick reference

1.1 Physical characteristics

Table 1. Device physical characteristics

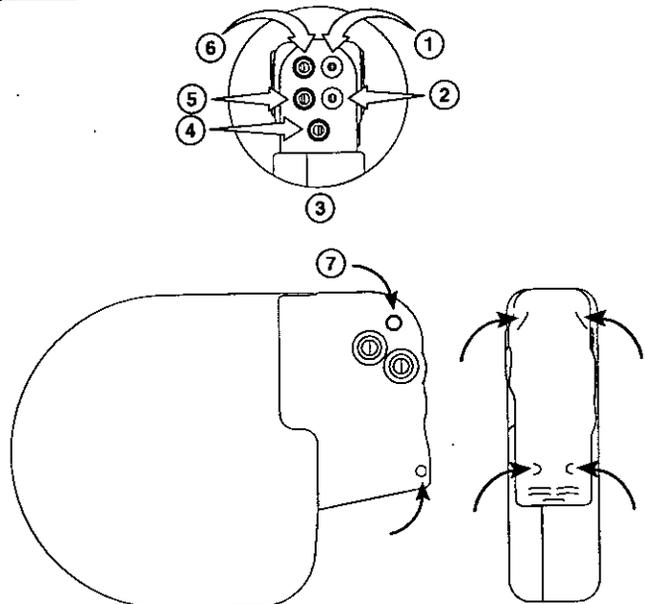
Volume ^a	38 cm ³
Mass	68 g
H x W x D ^b	69 mm x 51 mm x 15 mm
Surface area of device can	59 cm ²
Radiopaque ID	PVR
Materials in contact with human tissue ^c	Titanium, polyurethane, silicone rubber
Battery	Lithium silver vanadium oxide hybrid

^a Volume with connector holes unplugged.

^b Grommets may protrude slightly beyond the can surface.

^c These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Figure 1. Connector and suture holes



- 1 DF-1 connector port, SVC (HVX)
- 2 DF-1 connector port, RV (HVB)
- 3 Device Active Can electrode, Can (HVA)
- 4 IS-1 connector port, LV
- 5 IS-1 connector port, RV
- 6 IS-1 connector port, A
- 7 Suture holes

1.2 Replacement indicators

Battery voltage and messages about replacement status appear on the programmer display and on printed reports. The Recommended Replacement Time (RRT) and the End of Service (EOS) conditions are listed in Table 2.

Table 2. Replacement indicators

Recommended Replacement Time (RRT)	≤ 2.62 V on 3 consecutive daily automatic measurements
End of Service (EOS)	3 months after RRT

RRT date – The Quick Look and Battery and Lead Measurements screens display the date when the battery reached RRT.

EOS indication – If the programmer indicates that the device is at EOS, replace the device immediately.

Prolonged Service Period (PSP) conditions – The Prolonged Service Period (PSP) is the time between the Recommended Replacement Time (RRT) and End of Service (EOS). EOS device status is defined as 3 months following an RRT indication assuming the following PSP conditions: 100% DDD pacing at 60 bpm; 3 V atrial and RV pacing amplitude; 4 V LV pacing amplitude; 0.4 ms; 500 Ω pacing load; and 6 full-energy charges. EOS may be indicated before the end of 3 months if the device exceeds these conditions.

1.3 Projected service life

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified.

The projected service life estimates assume the default automatic capacitor formation setting. As a guideline, each full energy charge decreases projected service life by approximately 27 days. Table 3 displays device projected service life in years with pacing outputs programmed to the specified amplitude and 0.4 ms pulse width, 100% biventricular pacing, specified percentage of atrial pacing at 60 bpm and the remainder at 70 bpm atrial tracking.

The service life of the device is affected by how certain features are programmed, such as pre-arrhythmia EGM storage. For more information, see Section 4.12, “Optimizing device longevity”, page 53.

Table 3. Projected service life

Pacing	Maximum energy charging frequency ^a	500 Ω pacing impedance ^d		900 Ω pacing impedance ^d	
		2.5 V ^b	3.0 V ^c	2.5 V ^b	3.0 V ^c
DDD, 0%	Semiannual	5.5 (6.5)	4.6 (5.4)	6.1 (7.4)	5.5 (6.5)
	Quarterly	5.0 (5.9)	4.3 (4.9)	5.6 (6.6)	5.0 (5.9)
DDD, 15%	Semiannual	5.4 (6.4)	4.6 (5.3)	6.1 (7.4)	5.4 (6.5)
	Quarterly	5.0 (5.8)	4.3 (4.9)	5.5 (6.6)	5.0 (5.9)
DDD, 50%	Semiannual	5.3 (6.3)	4.5 (5.2)	6.0 (7.3)	5.4 (6.4)
	Quarterly	4.9 (5.7)	4.2 (4.8)	5.5 (6.5)	5.0 (5.8)
DDD, 100%	Semiannual	5.2 (6.1)	4.4 (5.1)	5.9 (7.1)	5.3 (6.3)
	Quarterly	4.8 (5.6)	4.1 (4.7)	5.4 (6.4)	4.9 (5.7)

^a Maximum energy charging frequency may include full-energy therapy shocks or capacitor formations. Additional full-energy charges due to therapy shocks, device testing, or capacitor formation reduces longevity by approximately 27 days (0.07 year).

^b Amplitudes: when A/RV is 2.5 V, LV is 3.0 V.

^c Amplitudes: when A/RV is 3.0 V, LV is 4.0 V.

^d The first data values provided assume that Pre-arrhythmia EGM storage is programmed to On Continuous for the life of the device, which is both the Shipped and nominal value for that parameter. The data values provided in parentheses assume that Pre-arrhythmia EGM storage is programmed to Off for the life of the device, which lengthens projected service life by 18% or 2.1 months per year.

1.4 Magnet application

When a magnet is placed near the device, the device responds as shown in Table 4. When the magnet is removed, the device returns to its programmed operations.

Note: When a monitor alert condition has occurred, a magnet placed near the device will cause the device to emit a high/low dual tone regardless of how the device alert is programmed.

Table 4. Effects of magnet application on the device

Pacing mode	As programmed
Pacing rate and interval	As programmed ^a
Tachyarrhythmia detection	Suspended ^b
Medtronic CareAlert audible tones (10 s or less) ^c	With programmable alerts enabled: <ul style="list-style-type: none"> • Continuous tone (test) • On/off intermittent tone (seek follow-up) • High/low dual tone (urgent follow-up) With programmable alerts disabled: <ul style="list-style-type: none"> • No tone • High/low dual tone (urgent follow-up)

^aRate Response adjustments are suspended while a Medtronic CareAlert tone sounds.

^bDuring a wireless communication session, tachyarrhythmia detection remains suspended if a magnet (or the programming head) is placed over the device. During a conventional telemetry session, tachyarrhythmia detection is suspended when the programming head or a magnet is placed over the device, but detection resumes if telemetry between the device and programmer is established.

^cPlacing a magnet near the device suspends all device tones until 6 hours after device implant initialization.

1.5 Typical charge times

The most recent capacitor charge time appears on the programmer display and on printed reports. You can evaluate charge time using the Charge/Dump test (see Table 5).

Table 5. Typical full energy charge times with fully-formed capacitors

At Beginning of Service (BOS)	8.2 s
At Recommended Replacement Time (RRT)	9.9 s

1.6 High-voltage therapy energy

The stored energy of the device is derived from the peak capacitor voltage and is always greater than the energy delivered by the device. Table 6 compares the programmed energy levels delivered by the device to the energy levels stored in the capacitors before delivery.

Table 6. Programmed (delivered) and stored energy levels^a

Energy (J)			Energy (J)		
Programmed/ Delivered ^a	Stored ^a	Charge Time (s) ^b	Programmed/ Delivered ^a	Stored ^a	Charge Time (s) ^b
35	39	8.2	9	10.5	2.1
32	37	7.5	8	9.3	1.9
30	34	7.0	7	8.2	1.6
28	32	6.6	6	7.1	1.4
26	30	6.1	5	5.9	1.2
25	29	5.9	4	4.8	0.9
24	27	5.6	3	3.6	0.7
22	25	5.2	2	2.4	0.5
20	23	4.7	1.8	2.2	0.4
18	21	4.2	1.6	2.0	0.4
16	19	3.7	1.4	1.7	0.3
15	17	3.5	1.2	1.5	0.3
14	16	3.3	1.0	1.2	0.2
13	15	3.0	0.8	1.0	0.2
12	14	2.8	0.6	0.8	0.1
11	13	2.6	0.4	0.5	0.1
10	12	2.3			

^a Delivered energy values are based on measurements at the connector block during high-voltage therapies into a 75 Ω load. Stored energy values indicate the energy on the capacitor at the end of charging.

^b Typical charge time at Beginning of Service (BOS) with fully-formed capacitors, rounded to the nearest tenth of a second.

1.7 Stored data and diagnostics

Table 7. Arrhythmia episode data storage

Episode data type	
Treated VT/VF episode log entries	100 entries
Treated VT/VF episode EGM, markers, and intervals	9.25 min
Monitored VT episode log entries	15 entries
Monitored VT episode EGM, markers, and intervals	45 s
Non-sustained VT episode log entries	15 entries
Non-sustained VT episode EGM, markers, and intervals	30 s
Treated AT/AF episode log entries	100 entries
Treated AT/AF episode EGM, markers, and intervals	3.75 min
Monitored AT/AF episode log entries	50 entries

Table 7. Arrhythmia episode data storage (continued)

Episode data type	
Monitored AT/AF episode EGM, markers, and intervals	1.0 min
SVT episode log entries	25 entries
SVT episode EGM, markers, and intervals	1.25 min
Ventricular sensing episode log entries, markers, and intervals	8 entries
Patient activated episode log entries	50 entries
Flashback memory interval data before each of the following events:	2000 events (includes both A- and V-events)
<ul style="list-style-type: none"> • Interrogation • Latest VF episode • Latest VT episode 	
Flashback memory interval data before the latest AT/AF episode	2000 events (includes both A- and V-events)

Table 8. VT/VF episode counters

Counter data type	
Counts of each VT/VF episode type	<ul style="list-style-type: none"> • VF • FVT • VT • VT Monitor • VT-NS • Runs of PVCs • Single PVCs • Runs of VRS paces • Single VRS paces
Counts of each SVT episode type (VT/VF therapy withheld)	<ul style="list-style-type: none"> • AF/Afl • Sinus Tach • Other 1:1 SVTs • V. Stability • Onset

Table 9. VT/VF therapy counters

Counter data type	
VT/VF therapy summary counters	<ul style="list-style-type: none"> • ATP-terminated episodes • Shock-terminated episodes • Total VT/VF shocks • Aborted charges
VT/VF therapy efficacy counters	<p>For VF Rx1–Rx6 and ATP during/before charging:</p> <ul style="list-style-type: none"> • Delivered therapy counts • Successful therapy counts <p>For FVT Rx1–Rx6:</p> <ul style="list-style-type: none"> • Delivered therapy counts • Successful therapy counts • Counts of episodes accelerated to VF <p>For VT Rx1–Rx6:</p> <ul style="list-style-type: none"> • Delivered therapy counts • Successful therapy counts • Counts of episodes accelerated by 60 ms or to FVT or VF

Table 10. AT/AF episode counters

Counter data type	
AT/AF summary data	<ul style="list-style-type: none"> • Percent of time in AT/AF • Average time in AT/AF per day • Percentage of AT/AF episodes terminated by ATP
Average number per day of each AT/AF episode type	<ul style="list-style-type: none"> • Monitored AT/AF • Treated AT/AF • Non-sustained AT
Percent of time in each kind of pacing	<ul style="list-style-type: none"> • Atrial pacing • Atrial intervention pacing
Number of AT/AF episodes, presented in different groupings	<ul style="list-style-type: none"> • Grouped by duration^a • Grouped by start time^a

^aThis counter includes any instance when the device identifies AT/AF Onset. Therefore, the total number of episodes in this counter may exceed the number of detected AT/AF episodes recorded by the device.

Table 11. AT/AF therapy counters**Counter data type**

Number of AT/AF episodes treated and the percentage terminated, presented in different groupings	<ul style="list-style-type: none"> • Grouped by detection zone and therapy • Grouped by atrial cycle length
Counts of different AT/AF therapy types	<ul style="list-style-type: none"> • Delivered ATP sequences • Aborted ATP sequences • Delivered automatic atrial CV shocks • Automatic atrial CV shocks that failed to terminate the episode • Delivered patient-activated shocks • Patient-activated shocks that failed to terminate the episode

Table 12. Battery and lead measurement data

- Battery voltage
- Last capacitor formation
- Last charge
- Lead impedance:
 - A. pacing
 - RV pacing
 - LV pacing
 - RV defib
 - SVC defib (if used)
- R-wave amplitude
- P-wave amplitude
- Last high-voltage therapy
- Sensing integrity counter
- Atrial Lead Position Check results

Table 13. Lead performance trend data

14 days of daily measurements, 80 weeks of weekly minimum and maximum measurements, highest value, lowest value, value at implant, and latest value.

Lead impedance measurements:

- A. Pacing
- RV pacing
- LV pacing
- RV defibrillation
- SVC defibrillation (if used)

Sensing amplitude measurements:

- P-wave

Threshold measurements:

- LV capture threshold

Table 14. Cardiac Compass trend data

Printed report showing up to 14 months of measurement trends and summary data.

- Annotations of interrogations, programming, and remote sessions
- VT and VF episodes per day
- High-voltage therapies delivered per day
- Ventricular rate during VT or VF
- Episodes of non-sustained tachycardia per day
- Heart rate variability
- Total daily time in AF or AT
- Ventricular rate during AF or AT
- Percent pacing per day
- Patient activity
- Average day and night ventricular heart rate
- Thoracic impedance
- Accumulated differences between the daily and reference thoracic impedance (OptiVol fluid index)

Table 15. Rate Histograms report**Data type**

Graphs displaying the percent of time in each rate range for the listed conditions:

- Atrial pacing and atrial sensing^a
- Ventricular pacing and ventricular sensing
- Ventricular pacing and ventricular sensing during AT/AF

Percent of time for each event type:^b

- AS-VS events
- AS-VP events
- AP-VS events
- AP-VP events

Percent of all ventricular events delivered by the VSR feature

^aIf more than 2% of atrial sensed events are identified as far-field R-waves, the general percentage range (either "2% to 5%" or "> 5%") is reported above the atrial rate histogram.

^bIf the programmed pacing mode during the reporting period was a dual chamber mode, the report displays the AS-VS, AS-VP, AP-VS, and AP-VP event sequence data. If a single chamber mode was programmed, the report displays the percent of time spent pacing and sensing.

Table 16. Medtronic CareAlert event data

Log of events that triggered Medtronic CareAlert notifications. Each log entry includes the following information:

- Date when the event first occurred (since the last interrogation)
- Description of event that triggered the Medtronic CareAlert notification
- Programmed threshold for the Medtronic CareAlert notification, if applicable

2 The Concerto system

2.1 System overview

The Concerto dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT-D), including sequential biventricular pacing, is an implantable medical device that automatically detects and treats episodes of ventricular fibrillation (VF), ventricular tachycardia (VT), fast ventricular tachycardia (FVT), and bradyarrhythmia. The device also detects and treats atrial tachyarrhythmia (AT) episodes¹.

Each Concerto system includes 5 major components: the implanted device, the leads connecting the device to the patient's heart, the Medtronic programmer with Concerto application software installed, the Conexus Activator, and the Medtronic CareLink Monitor. The system uses Conexus wireless telemetry for communication between the device and programmer and between the device and patient's monitor.

2.1.1 Implanted device

The device senses the electrical activity of the patient's heart using the sensing electrodes of the implanted atrial and right ventricular leads. It then analyzes the heart rhythm based on selectable sensing and detection parameters. The device provides the following functions:

- simultaneous or sequential biventricular pacing for cardiac resynchronization
- automatic detection and treatment of ventricular tachyarrhythmias (ventricular fibrillation, ventricular tachycardia, and fast ventricular tachycardia) with defibrillation, cardioversion, and antitachycardia pacing therapies
- single or dual chamber pacing for patients requiring rate support
- diagnostics and monitors that evaluate the system and assist in patient care
- automatic detection and treatment of atrial tachyarrhythmias (AT/AF and Fast AT/AF) with cardioversion, and antitachycardia pacing therapies

¹ AT therapies are available with appropriate software. Contact your Medtronic representative.

2.1.2 Leads

The device can be used with transvenous or epicardial defibrillation leads. The lead system should consist of bipolar or paired unipolar² pacing/sensing leads in the right atrium and right ventricle of the heart, a pacing lead for the left ventricle, and 1 or 2 high-voltage cardioversion/defibrillation electrodes. In addition to the lead system, the Active Can feature enables the device to act as one of the high-voltage electrodes. The device delivers pacing and cardiac resynchronization therapy via the atrial (A), right ventricular (RV), and left ventricular (LV) leads. The device senses using the atrial and RV leads. Cardioversion/defibrillation therapy is delivered with 2 lead-based high-voltage electrodes, or with the Active Can electrode and 1 or 2 lead-based high-voltage electrodes.

Note: OptiVol fluid monitoring may be adversely affected by the use of an epicardial defibrillation lead instead of an RVcoil (HVB) lead.

2.1.3 Programmer and software

The Medtronic programmer and Concerto application software allow you to perform the following tasks:

- configure the detection, therapy, and bradycardia features for your patient
- perform electrophysiological studies and system tests
- monitor, display, or print patient cardiac activity information
- view patient and device diagnostic data

The Concerto devices and application software are compatible with the following programmer systems:

- Medtronic CareLink Model 2090 programmer with Conexus Telemetry
- Medtronic CareLink Model 2090 programmer with a Model 2067 or 2067L programming head

2.1.4 Network connectivity and data exchange

The system supports network connectivity and the exchange of data between the Medtronic Carelink 2090 programmer and the Medtronic Paceart data management system using the SessionSync feature.

The system supports the use of the Medtronic 2290 Analyzer, which allows you to have a device session and an analyzer session running at the same time, quickly switch from one to the other without having to end or restart sessions, and export data from the analyzer to the device software application.

² With an appropriate unipolar to bipolar adapter kit.

The system supports Remote View, which allows you to use a personal computer in your office or elsewhere to view the screen displays from a Medtronic Carelink programmer in a clinic, hospital, or other location.

2.1.5 Conexus wireless telemetry

Conexus wireless telemetry is designed to provide clinicians and patients with an easier and more efficient implant, follow-up, and monitoring experience. The system uses radio frequency (RF) telemetry for wireless communication between the implanted device and programmer in the hospital or clinic, and between the implanted device and the patient's monitor. This eliminates the need to have a programming head over the implanted device for the duration of a programming or monitoring session.

2.1.6 Conexus Activator

The Medtronic Model 27901 Conexus Activator can be used by clinicians to turn on Conexus wireless telemetry for implanted devices that support wireless telemetry.

2.1.7 Monitor

The patient's monitor remotely interrogates device parameter settings, episode data, device status data, and patient data from the patient's device. When a patient receives their monitor, they must perform a manual interrogation session to initialize their monitor to their device. This initialization ensures that the patient's device and the patient's monitor will only be able to transmit information between one another.

2.1.8 Patient assistant

Patients can use the Model 2696 InCheck Patient Assistant to perform the following functions:

- Verify whether the implanted device has detected a suspected atrial tachyarrhythmia.
- Initiate recording of cardiac event data in the device memory.
- Request delivery of atrial cardioversion therapy (if the device is programmed to allow patient-activated cardioversion).

Note: Patient-activated cardioversion is only delivered if the implanted device is currently detecting an AT/AF episode.

2.1.9 Cardiac resynchronization

To improve cardiac output in patients with ventricular dyssynchrony, the device provides biventricular pacing. The device paces either the right ventricle or both ventricles as programmed, unless pacing is inhibited by a sensed event in the RV.

- Ventricular pacing sequence, V-V pace delay and LV pacing vector are programmable.
- Optional CRT features promote sustained resynchronization pacing that could be interrupted during episodes of accelerated AV conduction, atrial rate excursions, PVCs, or atrial arrhythmia.
- Pacing amplitudes and pulse widths are selected independently for each ventricle.

2.1.10 Detecting ventricular tachyarrhythmias

The device monitors the cardiac rhythm for short ventricular intervals that may indicate the presence of VF, VT, or FVT.

You can program the device to distinguish between true ventricular arrhythmias and rapidly conducted supraventricular tachycardia (SVT) and to withhold therapy for SVT.

The device also has the ability to detect double tachycardias (unrelated ventricular arrhythmias occurring simultaneously with SVTs) so that therapy is not withheld for a ventricular arrhythmia in the presence of an SVT.

2.1.11 Treating ventricular tachyarrhythmias

The device treats detected VF episodes by delivering a biphasic defibrillation shock. If the VF episode persists, up to 5 more individually programmed defibrillation shocks can be delivered.

You also have the option of delivering 1 sequence of ATP therapy before or during charging for a VF therapy. This option can prevent delivery of painful shocks for episodes that are detected as VF but can be terminated by pacing therapy.

The device treats detected VT episodes by delivering either a Ramp, Ramp+, or Burst antitachycardia pacing therapy or a biphasic cardioversion shock synchronized to a ventricular depolarization. If the VT episode persists, up to 5 more individually programmed VT therapies can be delivered.

The device treats detected FVT episodes by delivering either a Ramp, Ramp+, or Burst antitachycardia pacing therapy or a biphasic cardioversion shock synchronized to a ventricular depolarization. If the FVT episode persists, up to 5 more individually programmed FVT therapies can be delivered.

2.1.12 Detecting atrial tachyarrhythmias

If there is no ventricular episode in progress, the device applies the AT/AF detection algorithm, which detects AT/AF episodes by examining the atrial rate and the relationship between atrial and ventricular events. The device can detect AT/AF episodes, and respond to detected AT/AF episodes with programmed atrial tachyarrhythmia therapies. The device also provides an additional detection zone for Fast AT/AF episodes. This second zone allows the device to treat a second, faster atrial tachyarrhythmia with a separately programmable set of therapies.

2.1.13 Treating atrial tachyarrhythmias

The device treats detected AT/AF episodes by delivering Burst+, Ramp or 50 Hz Burst antitachycardia pacing therapy or by delivering an atrial cardioversion. Each sustained AT/AF episode can be treated with up to 5 automatic therapies per detection zone: 3 antitachycardia pacing therapies and 2 atrial cardioversion therapies. Patient-activated cardioversion is also available to treat AT/AF episodes.

2.1.14 Treating bradycardia

The device provides rate responsive pacing to treat bradycardia. An internal accelerometer senses the patient's physical activity, allowing the device to increase and decrease the pacing rate in response to changes in the level of activity. The device provides dual chamber pacing and single chamber pacing modes.

2.1.15 Monitoring for real-time and stored data

The device and programmer provide real-time information on detection and therapy parameters and status during a patient session. The device also provides accumulated data on device operation, including stored electrograms, detected and treated tachyarrhythmia episodes, bradycardia interventions, and the efficacy of therapy. The Cardiac Compass report provides up to 14 months of clinically significant data, including arrhythmia episodes, shocks delivered, physical activity, heart rate, bradycardia pacing activities, and thoracic fluid trends. The Rate Histograms report shows the percent of time that cardiac events occurred at different heart rates. This report also shows the distribution of ventricular heart rates during AT/AF episodes.

All of this information can be printed and retained in the patient's file or saved in electronic format on a floppy diskette.

2.1.16 Conducting electrophysiologic tests

You can use the system to conduct non-invasive electrophysiologic studies, including manual delivery of therapies, to manage an induced or spontaneous tachyarrhythmia.

2.1.17 Alerting the patient to system events

You can use the programmable Medtronic CareAlert monitoring feature to notify the patient with audible tones if certain conditions occur that are related to the leads, battery, charge time, and therapies. The patient can then respond based on your prescribed instructions. The patient's monitor can then notify the patient or a family member of certain event conditions.

2.2 Indications and usage

The Concerto CRT-D system is 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 who remain symptomatic despite optimal medical therapy, 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 $\leq 35\%$ and a prolonged QRS duration.
- Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction $\leq 30\%$, and NYHA Functional Class II.

The system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive (PMOP) are indicated for the suppression of atrial tachyarrhythmias in implantable cardioverter defibrillator (ICD)-indicated patients with atrial septal lead placement and an ICD indication.

2.3 Contraindications

The Concerto CRT-D system is contraindicated for 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.

The device is contraindicated for patients who have a unipolar pacemaker implanted.

The device is contraindicated for patients with incessant VT or VF.

The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

2.4 Patient screening

Before implant, patients should undergo a complete cardiac evaluation, including electrophysiologic testing. Also, electrophysiologic evaluation and testing of the safety and efficacy of the proposed tachyarrhythmia therapies are recommended during and after device implant.

Other optional screening procedures could include exercise stress testing to determine the patient's maximum sinus rate, and cardiac catheterization to determine if there is a need for concomitant surgery, medical therapy, or both.



Medtronic

CONSULTA[®] CRT-D D224TRK

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)

Complete Capture Management[™] Diagnostic (ACM, RVCM, LVCM), Detailed EGM[™] Viewer, OptiVol[®] Fluid Status Monitoring, ATP During Charging[™] Feature, TherapyGuide[™] Feature, and Conexus[®] Wireless Telemetry

Clinician Manual

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

CONSULTA[®] CRT-D D224TRK

Clinician Manual

A guide to the operation and programming of the Model D224TRK Consulta CRT-D digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)

The following list includes trademarks or registered trademarks of Medtronic in the United States and possibly in other countries. All other trademarks are the property of their respective owners.

ATP During Charging, Active Can, Capture Management, Cardiac Compass, CareAlert, CareLink, ChargeSaver, Checklist, Concerto, Conexus, Consulta, EnPulse, EnTrust, Flashback, GEM, GEM DR, InCheck, InSync, InSync ICD, InSync II Marquis, InSync III Marquis, InSync Marquis, Kappa, Marker Channel, Marquis, Medtronic, Medtronic AT500, Medtronic CareAlert, Medtronic CareLink, OptiVol, PR Logic, Paceart, Quick Look, Reactive ATP, SessionSync, SureScan, Switchback, T-Shock, TherapyGuide

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1 System overview

1.1 Introduction

1.1.1 About this manual

This manual describes the operation and intended use of the Consulta CRT-D Model D224TRK system.

1.1.1.1 Manual conventions

Throughout this manual, the word “device” refers to the implanted Consulta CRT-D device.

The symbol \diamond in parameter tables indicates the Medtronic nominal value for that parameter.

The programmer screen image examples in this manual were produced using a Medtronic CareLink Model 2090 Programmer. These screen images are provided for reference only and may not match the final software.

The names of on-screen buttons are shown within brackets: [Button Name].

Programming instructions in this manual are often represented by a programming block, which describes the path through the application software to specific screens or parameters. The following conventions are used in programming blocks:

- The “⇒” symbol precedes the screen text you can select to navigate to a new screen.
- The “▷” symbol precedes the name of a parameter you can program for a feature.
- When a navigation step refers to a field on the screen that is labeled with both a row title and a column title, the “|” character is used to divide the separate titles. Parameter values, however, do not use this convention.
- When a particular value for a parameter must be selected to make the remaining parameters or navigation possible, that value appears within <brackets>.

Here is an example of a programming block using these conventions:

Select Params icon

- ⇒ Screen text to select...
- ⇒ Screen field Row Title | Column Title...
 - ▷ Parameter Name <Required Value>
 - ▷ Parameter Name
 - ▷ Parameter Name

Except in the Warnings, Precautions, and Potential Adverse Events section of this manual, Medtronic uses an empty triangle symbol next to cautions and a black triangle with an exclamation point symbol next to warnings.

1.1.1.2 Nomenclature for product battery life terms

This manual uses a nomenclature for certain terms related to product battery life as defined in CENELEC pacemaker standard EN 45502-2-1:2003. This standard applies to Active Implantable Medical Devices (AIMD) intended to treat bradyarrhythmias. This standard was approved and published in December 2003.

Medtronic has adopted this nomenclature to comply with the CENELEC standard and in anticipation of the nomenclature becoming an international standard. The nomenclature defined in EN 45502-2-1:2003 replaces previously used terms related to product battery life.

The nomenclature defined in EN 45502-2-1:2003, and the terms this nomenclature replaces, are presented in the following table:

Nomenclature in EN 45502-2-1: 2003		Previously used nomenclature	
BOS	Beginning of Service	BOL	Beginning of Life
EOS	End of Service	EOL	End of Life
RRT	Recommended Replacement Time	ERI	Elective Replacement Indicator
PSP	Prolonged Service Period	Post-ERI conditions	
Projected service life		Longevity projections	

1.1.2 Product literature

Before implanting the device, it is strongly recommended that you take the following actions:

- Read the product literature provided for information about prescribing, implanting, and using the device, and for conducting a patient follow-up session.
- Thoroughly read the technical manuals for the leads used with the device. Also read the technical manuals for other system components.
- Discuss the device and implant procedure with the patient and any other interested parties, and provide them with any patient information materials packaged with the device.

1.1.3 Technical support

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products.

In addition, Medtronic maintains a professional staff of consultants to provide technical consultation to product users.

For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

1.1.4 Customer education

Medtronic invites physicians to attend an educational seminar on the device. The course describes indications for use, system functions, implant procedures, and patient management.

1.1.5 References

The primary reference for background information is Zacouto FI, Guize LJ. Fundamentals of Orthorhythmic Pacing. In: Luderitz B, Ed. *Cardiac Pacing Diagnostic and Therapeutic Tools*. New York: Springer-Verlag; 1976: 212-218.

See these additional references for more background information:

- Estes M, Manolis AS, Wang P, Eds. *Implantable Cardioverter-Defibrillators*. New York, NY: Marcel Dekker, Inc. 1994.
- Kroll MW, Lehmann MH, Eds. *Implantable Cardioverter-Defibrillator Therapy: The Engineering-Clinical Interface*. Norwell, MA: Kluwer Academic Publishers 1996.
- Singer I, Ed. *Implantable Cardioverter-Defibrillator*. Armonk, NY: Futura Publishing Co. 1994.
- Singer I, Barold SS, Camm AJ, Eds. *Nonpharmacological Therapy of Arrhythmias for the 21st Century: The State of the Art*. Armonk, NY: Futura Publishing Co. 1998.
- Stadler RW, Gunderson BD, Gillberg JM. An Adaptive Interval-Based Algorithm for Withholding ICD Therapy During Sinus Tachycardia. *Pace*. 2003; 26:1189-1201.

1.1.6 FCC declaration of conformity

The transmitter covered by this manual has been certified under FCC ID:LF5MICSIMPLANT2. This transmitter is authorized by rule under the Medical Implant Communications Service (47 C.F.R. Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation.

This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

1.1.7 Explanation of symbols

This list of symbols applies to various products. Refer to the package labels to see which symbols apply to this product.

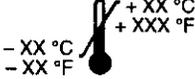
Table 1. Explanation of symbols on package labeling

Symbol	Explanation
	
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.
	The use of this device might be subject to individual country licensing regimes in Europe.
	This symbol means that the device fully complies with the Australian Communications and Media Authority (ACMA) and the New Zealand Ministry of Economic Development Radio Spectrum Management standards for radio communications products.
	Radio compliance. This symbol means that telecommunications and radio communications regulations in your country may apply to this product. Please go to www.medtronic.com/radio for specific compliance information related to telecommunications and radio standards for this product in your country.

Table 1. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	MR Conditional. The SureScan pacing system is safe for use in the MRI environment when used according to the instructions in the SureScan technical manual. Note: Not all devices are MR Conditional.
	Caution
	Open here
	Do not use if package is damaged
	Do not reuse
	Sterilized using ethylene oxide
	Consult instructions for use
	For US audiences only
	Date of manufacture
	Manufacturer
	Authorized representative in the European community
	Use by
	Lot number

Table 1. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Reorder number
	Serial number
	Temperature limitation
	Adaptive
	Package contents
	IPG device
	Coated (IPG device)
	ICD device
	Coated (ICD device)
	Cardiac resynchronization therapy (CRT) device
	Coated (CRT device)
	Product documentation
	Torque wrench

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Table 1. Explanation of symbols on package labeling (continued)

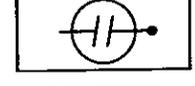
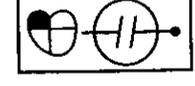
Symbol	Explanation
	Accessories
	Amplitude/pulse width
	Atrial amplitude/pulse width
	RV amplitude/pulse width
	LV amplitude/pulse width
	Upper tracking rate/lower rate
	Rate
	Lower rate
	Sensitivity
	Sensed A-V interval
	A-V interval (paced/sensed)
	Refractory period
	Atrial refractory period

Table 1. Explanation of symbols on package labeling (continued)

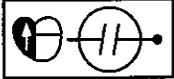
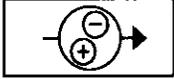
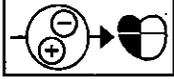
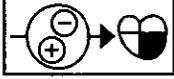
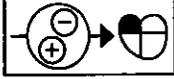
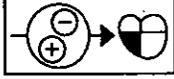
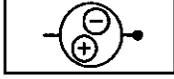
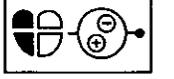
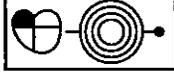
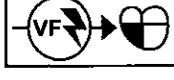
Symbol	Explanation
	Ventricular refractory period
	(PVARP) Post Ventricular Atrial Refractory Period
	Polarity
	Pacing polarity (single chamber)
	Pacing polarity (dual chamber)
	LV Pace polarity
	Atrial Pace polarity
	RV Pace polarity
	Sensing polarity (single chamber)
	Sensing polarity (dual chamber)
	Atrial sensitivity
	Ventricular sensitivity
	VF therapies (del/sto)

Table 1. Explanation of symbols on package labeling (continued)

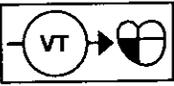
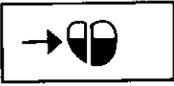
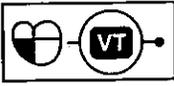
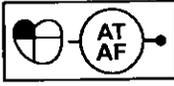
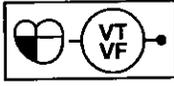
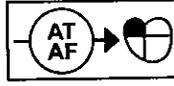
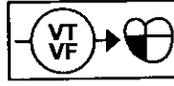
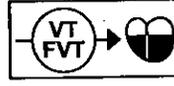
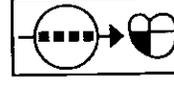
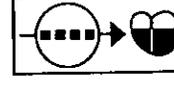
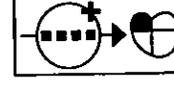
Symbol	Explanation
	VT therapies
	V pacing/V-V pace delay
	VT monitor
	AT/AF detection
	VT, VF detection
	VT, FVT, VF detection
	AT/AF therapies
	VT, VF therapies
	VT, FVT therapies (CRT)
	AT/AF intervention
	Burst
	Burst (CRT)
	Burst+

Table 1. Explanation of symbols on package labeling (continued)

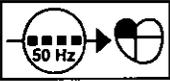
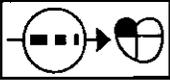
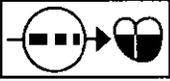
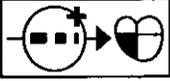
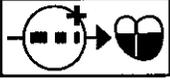
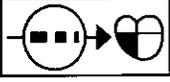
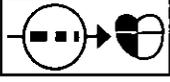
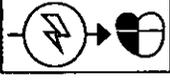
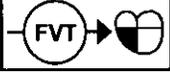
Symbol	Explanation
	50 Hz Burst
	A ramp
	Ramp (CRT)
	Ramp+
	Ramp+ (CRT)
	V ramp
	AV ramp
	Defibrillation
	V cardioversion
	AV cardioversion
	FVT therapies
	Mode Switch
	Magnet Rate

Table 1. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Dangerous voltage
	Active Can

1.1.8 Notice

Software is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Medtronic makes no representation as to the accuracy or completeness of the data input into the software. Medtronic SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULT FROM THE USE OF THE INFORMATION PROVIDED IN THE SOFTWARE.

1.2 System description

The Medtronic Model D224TRK Consulta CRT-D dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT-D) is a multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber rate-responsive bradycardia pacing, sequential biventricular pacing, ventricular tachyarrhythmia therapies, and atrial tachyarrhythmia therapies.

The device senses the electrical activity of the patient's heart using the electrodes of the implanted atrial and right ventricular leads. It then analyzes the heart rhythm based on selectable detection parameters.

The device automatically detects ventricular tachyarrhythmias (VT/VF) and provides treatment with defibrillation, cardioversion, and antitachycardia pacing therapies. The device also automatically detects atrial tachyarrhythmias (AT/AF) and provides treatment with cardioversion and antitachycardia pacing therapies. Simultaneous or sequential biventricular pacing is used to provide patients with cardiac resynchronization therapy. The device responds to bradyarrhythmias by providing bradycardia pacing therapies.

The device also provides diagnostic and monitoring information that assists with system evaluation and patient care.

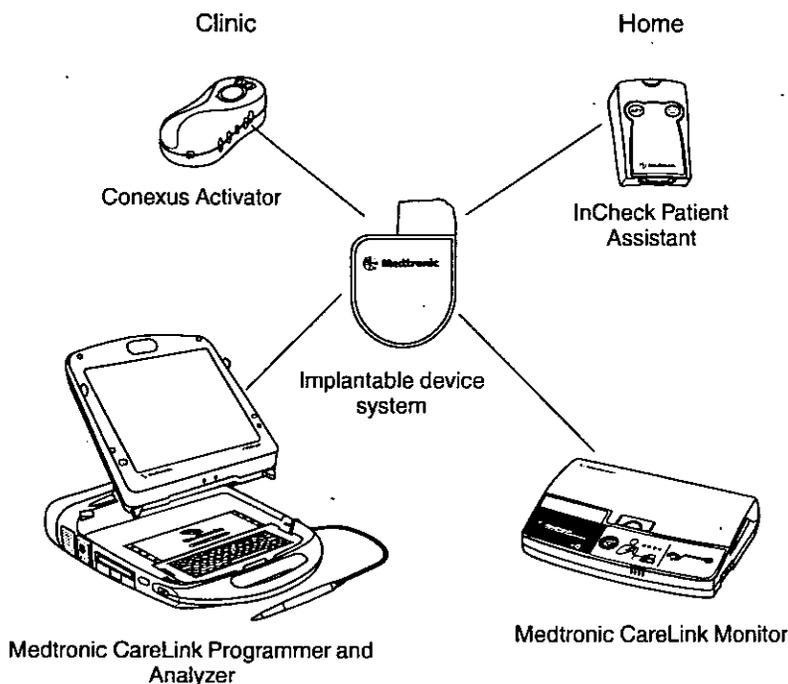
Leads – The lead system used with this device must provide pacing to the left ventricle (LV), sensing, pacing, and cardioversion/defibrillation therapies to the right ventricle (RV),

and sensing and pacing to the atrium (A). Do not use any lead with this device without first verifying lead and connector compatibility.

For information about selecting and implanting leads for this device, refer to Section 5.2, "Selecting and implanting the leads", page 100.

Implantable device system – The Model D224TRK Consulta CRT-D along with pacing leads and defibrillation leads constitute the implantable portion of the device system. The following figure shows the major components that communicate with the implantable device system.

Figure 1. System components



Programmers and software – The Medtronic CareLink Model 2090 Programmer and software are used to program this device. The Medtronic CareLink Model 2090 Programmer with Conexus wireless telemetry is designed to provide clinicians and patients with an easy and efficient implant, follow-up, and monitoring experience. Conexus wireless telemetry eliminates the need to have a programming head placed over the implanted device for the duration of a programming or monitoring session. The system uses radio frequency (RF) telemetry for wireless communication between the implanted device and programmer in the hospital or clinic. Conexus telemetry operates within the Medical Implant Communications

Service (MICS) Band, which is the only band designated for implantable medical devices. Using the MICS Band prevents interference with home electronics such as microwaves, cell phones, and baby monitors.

To turn on Conexus telemetry in an implanted device, you must use the Conexus Activator or the programming head. If you do not use the Conexus Activator or if you are using a programmer with nonwireless telemetry, you will need to use the programming head to both initiate and conduct communications with the device in the clinic.

During a wireless telemetry session, all other programmers are prevented from communicating or initiating a session with the patient's implanted device, maintaining patient safety and privacy. Similarly, other patients with implanted devices are not affected by any communication or programming occurring during the patient's session.

Programmers from other manufacturers are not compatible with Medtronic devices but will not damage Medtronic devices.

Model 27901 Conexus Activator – The Medtronic Model 27901 Conexus Activator allows you to turn on Conexus wireless telemetry for implanted devices that support wireless telemetry. The Conexus Activator is used in conjunction with the Medtronic CareLink Model 2090 Programmer with Conexus telemetry in the hospital or clinic.

Model 2290 Analyzer – The system supports the use of the Medtronic CareLink Model 2290 Analyzer, an accessory of the Medtronic CareLink programmer. The system allows you to have a device session and an analyzer session running at the same time, to quickly switch from one to the other without having to end or restart sessions, and to send data from the analyzer to the programmer.

Remote View – The system supports Remote View, which allows you to use your personal computer to view the screen displays from a Medtronic CareLink programmer that may be in a clinic, hospital or other location. You need to install and configure the Remote View software on your personal computer before you are able to view a programming session. Installation and configuration instructions are provided with the software. Refer to the programmer reference guide for information about using Remote View.

Model 2490C Medtronic CareLink Monitor – Patients use the Model 2490C monitor to automatically gather information from their implanted device and communicate the information to their physician. The monitor communicates wirelessly with the patient's device and transmits the information over a home telephone line at times scheduled by the clinic. Typically, these transmissions are scheduled while the patient is asleep. The monitor can also send device alerts to the clinic outside of the scheduled transmission times, if the device has been programmed to do so. The patient does not need to interact with the monitor other than performing the initial setup procedure. Refer to the monitor literature for connection and usage information.

Model 2696 InCheck Patient Assistant – Patients can use the Model 2696 InCheck Patient Assistant to perform the following tasks:

- Initiate recording of cardiac event data in the device memory. Cardiac event data can be viewed either on the programmer or using CareLink. In addition, when the InCheck Patient Assistant is activated, the EGM signals of the programmed EGM sources and markers are stored in the device and are available for review using CareLink. The CareLink monitor transmits the EGM data and markers from the patient's device to the CareLink Network. You can identify patients who have new, not previously viewed patient-activated episodes and then proceed to view their EGM data using the Detailed EGM Viewer on CareLink.
- Verify whether the implanted device has detected a suspected atrial tachyarrhythmia.
- Request delivery of atrial cardioversion therapy (if the device is programmed to allow patient-activated cardioversion).

Note: Patient-activated cardioversion is delivered only if the implanted device is currently detecting an AT/AF episode and the physician has programmed the device to allow patient-activated cardioversion.

Contents of sterile package – The package contains one implantable cardioverter defibrillator, one torque wrench, and one DF-1 pin plug.

1.3 Indications and usage

The Consulta CRT-D system is 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 who remain symptomatic despite optimal medical therapy, 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 $\leq 35\%$ and a prolonged QRS duration.
- Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction $\leq 30\%$, and NYHA Functional Class II.

The system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive (PMOP) are indicated for the suppression of atrial tachyarrhythmias in implantable cardioverter defibrillator (ICD)-indicated patients with atrial septal lead placement and an ICD indication.

1.4 Contraindications

The Consulta CRT-D system is contraindicated for 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.

The device is contraindicated for patients who have a unipolar pacemaker implanted.

The device is contraindicated for patients with incessant VT or VF.

The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

2 Warnings, precautions, and potential adverse events

2.1 General warnings and precautions

Anti-coagulation – Use of the device should not change the application of established anti-coagulation protocols.

Avoiding shock during handling – Disable tachyarrhythmia detection during implant, explant, or postmortem procedures. The device can deliver a high-voltage shock if the defibrillation terminals are touched.

Electrical isolation during implant – Do not allow the patient to have contact with grounded electrical equipment that might produce electrical current leakage during implant. Electrical current leakage may induce tachyarrhythmias that may result in the patient's death.

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use whenever tachyarrhythmias are possible or intentionally induced during device testing, implant procedures, or post-implant testing.

Lead compatibility – Do not use another manufacturer's leads without demonstrated compatibility with Medtronic devices. If a lead is not compatible with a Medtronic device, the result may be undersensing of cardiac activity, failure to deliver necessary therapy, or a leaking or intermittent electrical connection.

Occurrence of stroke – Following an ischemic or cerebrovascular accident, disable atrial cardioversion therapies until the patient has stabilized.

2.2 Explant and disposal

Consider the following information related to device explant and disposal:

- Interrogate the device and disable tachyarrhythmia detection before explanting, cleaning, or shipping the device. This prevents the device from delivering unwanted shocks.
- Explant the implantable device postmortem. In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; please check the local regulations. In addition, if subjected to incineration or cremation temperatures, the device may explode.

- Medtronic implantable devices are intended for single use only. Do not resterilize and reimplant explanted devices.
- Please use the Tachyarrhythmia Product Information Report to return explanted devices to Medtronic for analysis and disposal.

2.3 Handling and storage instructions

Carefully observe these guidelines when handling or storing the device.

2.3.1 Device handling

Checking and opening the package – Before opening the sterile package tray, visually check for any signs of damage that might invalidate the sterility of the package contents.

If the package is damaged – The device packaging consists of an outer tray and inner tray. Do not use the device or accessories if the outer packaging tray is wet, punctured, opened, or damaged. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment. This device is for single use only and is not intended to be resterilized.

Device temperature – Allow the device to reach room temperature before it is programmed or implanted. Device temperature above or below room temperature may affect initial device function.

Dropped device – Do not implant the device if it has been dropped on a hard surface from a height of 30 cm (12 in) or more after it is removed from its packaging.

“Use by” date – Do not implant the device after the “Use by” date because the battery longevity could be reduced.

For single use only – Do not resterilize and reimplant an explanted device.

2.3.2 Device storage

Avoid magnets – To avoid damaging the device, store the device in a clean area away from magnets, kits containing magnets, and any sources of electromagnetic interference.

Temperature limits – Store and transport the package between $-18\text{ }^{\circ}\text{C}$ and $+55\text{ }^{\circ}\text{C}$ ($0\text{ }^{\circ}\text{F}$ and $131\text{ }^{\circ}\text{F}$). Electrical reset may occur at temperatures below $-18\text{ }^{\circ}\text{C}$ ($0\text{ }^{\circ}\text{F}$). Device longevity may decrease and performance may be affected at temperatures above $+55\text{ }^{\circ}\text{C}$ ($131\text{ }^{\circ}\text{F}$).

2.4 Lead evaluation and lead connection

Refer to the lead technical manuals for specific instructions and precautions about lead handling.

Hex wrench – Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew. Other torque wrenches, (for example a blue-handled or right-angled hex wrench) have torque capabilities greater than the lead connector can tolerate.

Lead connection – Consider the following information when connecting the lead and the device:

- Cap abandoned leads to avoid transmitting electrical signals.
- Plug any unused lead ports to protect the device.
- Verify lead connections. Loose lead connections may result in inappropriate sensing and failure to deliver arrhythmia therapy.

Lead Impedance – Consider the following information about lead impedance when evaluating the lead system:

- Ensure that the defibrillation lead impedance is greater than 20 Ω . An impedance of less than 20 Ω may damage the device or prevent delivery of high-voltage therapy.
- Before taking electrical or defibrillation efficacy measurements, move objects made from conductive materials, such as guide wires, away from all electrodes. Metal objects, such as guide wires, can short circuit a device and lead, causing electrical current to bypass the heart and possibly damage the device and lead.
- If the LV pacing impedance for pacing LVtip to RVcoil is greater than 3000 Ω and the V. Defib (HVB) impedance is greater than 200 Ω , then use LV EGM (LVtip to Can) to assess the integrity of the LV lead.

Patch leads – Do not fold, alter, or remove any portion of a patch lead. Doing so may compromise electrode function or longevity.

2.5 Device operation

Accessories – Use this device only with accessories, parts subject to wear, and disposable items that have been tested to technical standards and found safe by an approved testing agency.

Atrial Capture Management – Atrial Capture Management does not adjust atrial outputs to values greater than 5.0 V or 1.0 ms. If the patient needs atrial pacing output greater than 5.0 V or 1.0 ms, manually program the atrial amplitude and pulse width. If a lead dislodges partially or completely, Atrial Capture Management may not prevent loss of capture.

Battery depletion – Carefully monitor battery longevity. Battery depletion eventually causes the device to stop functioning. Cardioversion and defibrillation are high-energy therapies that shorten battery longevity. An excessive number of charging cycles also shortens battery longevity.

Charge Circuit Timeout or Charge Circuit Inactive – Contact a Medtronic representative and replace the device immediately if the programmer displays a Charge Circuit Timeout or Charge Circuit Inactive message. If this message is displayed, high-voltage therapies are not available for the patient.

Concurrent pacemaker use – If a separate pacemaker is used concurrently with the ICD, verify that the ICD does not sense the pacemaker output pulses because this can affect the detection of tachyarrhythmias by the ICD. Program the pacemaker to deliver pacing pulses at intervals longer than the ICD tachyarrhythmia detection intervals.

Device status indicators – If any of the device status indicators (for example, Electrical Reset) are displayed on the programmer after interrogating the device, inform a Medtronic representative immediately. If these device status indicators are displayed, therapies may not be available to the patient.

Electrical reset – Electrical reset can be caused by exposure to temperatures below -18°C (0°F) or strong electromagnetic fields. Advise patients to avoid strong electromagnetic fields. Observe temperature storage limits to avoid exposure of the device to cold temperatures. If a partial reset occurs, pacing resumes in the programmed mode with many of the programmed settings retained. If a full reset occurs, the device operates in VVI mode at 65 bpm. Electrical reset is indicated by a programmer warning message that is displayed immediately upon interrogation. To restore the device to its previous operation, it must be reprogrammed. Inform a Medtronic representative if your patient's device has reset.

End of Service (EOS) indicator – Replace the device immediately if the programmer displays an EOS indicator. The device may soon lose the ability to pace, sense, and deliver therapy adequately.

Follow-up testing – Consider the following information when performing follow-up testing of the device:

- Keep external defibrillation equipment nearby for immediate use. Potentially harmful spontaneous or induced tachyarrhythmias may occur during device testing.
- Changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), preventing the device from terminating the patient's tachyarrhythmias postoperatively. Successful termination of ventricular fibrillation or ventricular tachycardia during the implant procedure is no assurance that tachyarrhythmias can be terminated postoperatively.

Higher than programmed energy – The device may deliver a therapy of higher than programmed energy if it was previously charged to a higher energy and that charge remains on the capacitors.

Magnets – Positioning a magnet over the device suspends tachyarrhythmia detection, but does not alter bradycardia therapy. If you place a programming head over the device during a wireless telemetry session, the magnet in the programming head always suspends tachyarrhythmia detection. If you place a programming head over the device and establish a nonwireless telemetry session, tachyarrhythmia detection is not suspended.

Pacing and sensing safety margins – Lead maturation may cause sensing amplitudes to decrease and pacing thresholds to increase, which can cause undersensing or a loss of capture. Provide an adequate safety margin when selecting values for pacing amplitude, pacing pulse width, and sensitivity parameters.

Patient safety during a wireless telemetry session – Make sure that you have selected the appropriate patient before proceeding with a wireless patient session. Maintain visual contact with the patient for the duration of the session. If you select the wrong patient and continue with the session, you may inadvertently program the patient's device to the wrong settings.

Phrenic nerve stimulation – Phrenic nerve stimulation may occur as a result of left ventricular pacing at higher amplitudes. Although this is not life threatening, it is recommended that you test for phrenic nerve stimulation at various pacing amplitude settings with the patient in various positions. If phrenic nerve stimulation occurs with the patient, determine the minimum pacing threshold for phrenic nerve stimulation and program the pacing amplitude to a value that minimizes stimulation but provides an adequate pacing safety margin. If LV Capture Management is used, set the LV Maximum Adapted Amplitude to a value that minimizes phrenic nerve stimulation but provides an adequate pacing safety margin. Carefully consider the relative risks of phrenic nerve stimulation versus loss of capture before programming lower pacing amplitudes for the patient.

Pacemaker-mediated tachycardia (PMT) intervention – Even with the PMT Intervention feature programmed on, PMTs may still require clinical intervention such as device reprogramming, drug therapy, or lead evaluation.

Programmers – Use only Medtronic programmers and application software to communicate with the device. Programmers and software from other manufacturers are not compatible with Medtronic devices.

Rate control – Decisions regarding rate controls should not be based on the ability of the device to prevent atrial arrhythmias.

Rate-responsive modes – Do not program rate-responsive modes for patients who cannot tolerate rates above the programmed Lower Rate. Rate-responsive modes may cause discomfort for those patients.

RV Capture Management – RV Capture Management does not program right ventricular outputs to values greater than 5.0 V or 1.0 ms. If the patient needs right ventricular pacing output greater than 5.0 V or 1.0 ms, manually program right ventricular amplitude and pulse width. If a lead dislodges partially or completely, RV Capture Management may not prevent loss of capture.

Shipping values – Do not use shipping values or nominal values for pacing amplitude and sensitivity without verifying that the values provide adequate safety margins for the patient.

Single chamber atrial modes – Do not program single chamber atrial modes for patients with impaired AV nodal conduction. Ventricular pacing does not occur in these modes.

Slow retrograde conduction and PMT – Slow retrograde conduction may induce pacemaker-mediated tachycardia (PMT) when the VA conduction time is greater than 400 ms. Programming PMT Intervention can only help prevent PMT when the VA conduction time is less than 400 ms.

Testing for cross-stimulation – When atrial ATP therapy is enabled, conduct regular testing at the programmed atrial ATP output settings to ensure that ventricular capture does not occur. This is particularly important when the lead is placed in the inferior atrium.

Twiddler's syndrome – Twiddler's syndrome, the tendency of some patients to manipulate their device after implant, may cause the pacing rate to increase temporarily if the device is programmed to a rate-responsive mode.

2.5.1 Pacemaker-dependent patients

Ventricular Safety Pacing – Always program Ventricular Safety Pacing (VSP) to On for pacemaker-dependent patients. Ventricular Safety Pacing prevents ventricular asystole due to inappropriate inhibition of ventricular pacing caused by oversensing in the ventricle.

ODO pacing mode – Pacing is disabled under ODO pacing mode. Do not program the ODO mode for pacemaker-dependent patients. Instead, use the Underlying Rhythm Test to provide a brief period without pacing support.

Underlying Rhythm Test – Use caution when using the Underlying Rhythm Test to inhibit pacing. The patient is without pacing support when pacing is inhibited.

2.6 Medical therapy hazards

Computed tomographic x-ray (CT scan) – If the patient undergoes a CT scan procedure and the device is not directly in the CT scan beam, the device is not affected.

If the device is directly in the CT scan beam, oversensing may occur for the duration of time the device is in the beam. If the device will be in the beam for more than 4 s, take the following precautions to minimize complications:

- Suspend tachyarrhythmia detection using a magnet, or disable tachyarrhythmia detection using the programmer. After the CT scan is complete, remove the magnet or use the programmer to enable tachyarrhythmia detection.
- If appropriate for the patient, program the pacing mode to minimize the effects of oversensing on pacing (for example, false inhibition). For pacemaker-dependent patients, program the device to an asynchronous pacing mode. After the CT scan is complete, program the pacing mode to its original setting.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Electrosurgical cautery – Electrosurgical cautery may induce ventricular tachyarrhythmias and fibrillation or may cause device malfunction. If electrosurgical cautery cannot be avoided, take the following precautions to minimize complications:

- Keep temporary pacing and defibrillation equipment available.
- For pacemaker-dependent patients, program the device to an asynchronous pacing mode. After the electrosurgical cautery procedure is complete, program the pacing mode to its original setting.
- Suspend tachyarrhythmia detection using a magnet, or disable tachyarrhythmia detection using the programmer. After the electrosurgical cautery procedure is complete, remove the magnet or use the programmer to enable tachyarrhythmia detection.
- Use a bipolar electrocautery system if possible. If unipolar cautery is used, position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm (6 in) away from the device and lead system.
- Avoid direct contact of the cautery equipment with the implanted device or leads. Direct contact may damage the device or leads.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.

External defibrillation – External defibrillation may damage the implanted device. External defibrillation may also temporarily or permanently elevate pacing thresholds or temporarily

or permanently damage the myocardium at the electrode tissue interface. Current flow through the device and lead may be minimized by taking the following precautions:

- Use the lowest clinically appropriate defibrillation energy.
- Position the defibrillation patches or paddles a minimum of 15 cm (6 in) away from the device.
- Position the defibrillation patches or paddles perpendicular to the device and lead system.

If an external defibrillation is delivered within 15 cm (6 in) of the device, contact a Medtronic representative.

Lithotripsy – Lithotripsy may permanently damage the device if the device is at the focal point of the lithotripter beam. If lithotripsy must be performed, take the following precautions:

- Disable tachyarrhythmia detection using the programmer. After the lithotripsy procedure is complete, enable tachyarrhythmia detection.
- For pacemaker-dependent patients, program the device to an asynchronous pacing mode. After the lithotripsy procedure is complete, program the pacing mode to its original setting.
- Keep the focal point of the lithotripter beam a minimum of 2.5 cm (1 in) away from the implanted device.

Magnetic resonance imaging (MRI) – Do not use magnetic resonance imaging (MRI) on patients who have this device implanted. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias. MRI may also cause damage to the device.

Medical treatment influencing device operation – The electrophysiological characteristics of a patient's heart can change over time, especially if the patient's medications have changed. As a result of the changes, programmed therapies may become ineffective and possibly dangerous to the patient. Conduct regular follow-up appointments to monitor the appropriateness of programmed therapies.

Radio frequency (RF) ablation – An RF ablation procedure may cause device malfunction or damage. Radio frequency ablation risks may be minimized by taking the following precautions:

- Keep temporary pacing and defibrillation equipment available.
- Program the pacing mode to minimize the effects of oversensing on pacing (for example, false tracking or false inhibition). For pacemaker-dependent patients, program the device to an asynchronous pacing mode. For patients who are not pacemaker-dependent, program the device to a nonpacing mode. After the ablation procedure is complete, program the pacing mode to its original setting.

- Suspend tachyarrhythmia detection using a magnet, or disable tachyarrhythmia detection using the programmer. After the ablation procedure is complete, remove the magnet or use the programmer to enable tachyarrhythmia detection.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm (6 in) away from the device and lead system.

Radiotherapy and oversensing – If the patient undergoes radiotherapy, the device may inappropriately sense direct or scattered radiation as cardiac activity for the duration of the procedure. Take the following precautions to minimize complications:

- Suspend tachyarrhythmia detection using a magnet, or disable tachyarrhythmia detection using the programmer. After the radiotherapy procedure is complete, remove the magnet or use the programmer to enable tachyarrhythmia detection.
- For pacemaker-dependent patients, program the device to an asynchronous pacing mode. After the radiotherapy procedure is complete, program the pacing mode to its original setting.

Radiotherapy and device damage – Do not expose the device to high doses of direct or scattered radiation. An accumulated dose of radiation to the device circuits above 5 Gy may damage the device; however, the damage may not be immediately apparent. Damage may present in various ways including increased current drain leading to shortened device life or a shift in sensing performance.

If a patient requires radiation therapy, from any source, do not expose the device to radiation exceeding an accumulated dose of 5 Gy. Use appropriate shielding or other measures to limit device exposure. The accumulated dose from diagnostic x-ray, CT scan, or fluoroscopic equipment is normally not sufficient to cause damage to the device. Consider the accumulated dose to the device from previous exposures for patients undergoing multiple radiation treatments.

Radiotherapy and device operational errors – Exposing the device to direct or scattered neutrons may cause electrical reset of the device, errors in device functionality, errors in diagnostic data, or loss of diagnostic data. To help reduce the chance of electrical reset due to neutron exposure, deliver radiotherapy treatment using photon beam energies less than or equal to 10 MV. The use of conventional x-ray shielding during radiotherapy does not protect the device from the effects of the neutrons. If photon beam energies exceed 10 MV, Medtronic recommends interrogating the device immediately after radiotherapy treatment. An electrical reset requires reprogramming of device parameters. Electron beam treatments do not cause electrical reset of the device.

Therapeutic ultrasound – Do not expose the device to therapeutic ultrasound. Therapeutic ultrasound may permanently damage the device.

2.7 Home and occupational environments

Cellular telephones – This device contains a filter that prevents most cellular telephone transmissions from interacting with device operation. To further minimize the possibility of interaction, instruct patients to:

- Maintain a minimum separation of 15 cm (6 in) between the device and the cellular telephone, even if the cellular telephone is not on.
- Maintain a minimum separation of 30 cm (12 in) between the device and any antenna transmitting above 3 W.
- Hold the cellular telephone to the ear farthest from the device.

This device has been tested using the EN 45502-2-2:2008 and ANSI/AAMI PC-69:2007 standards to ensure compatibility with cellular telephones and other hand-held transmitters with similar power. These transmission technologies represent the majority of cellular telephones used worldwide. The circuitry of this device, when operating under nominal conditions, has been designed to eliminate any significant effects from cellular telephones.

Electromagnetic interference (EMI) – Instruct patients to avoid devices that generate strong EMI. Electromagnetic interference may result in delivery of unneeded therapy. Electromagnetic interference may also cause device malfunction or damage. The patient should move away from the EMI source or turn off the source because this usually allows the device to return to its normal mode of operation. EMI may be emitted from the following sources:

- high-voltage power lines
- communication equipment such as microwave transmitters, linear power amplifiers, or high-powered amateur transmitters
- commercial electrical equipment such as arc welders, induction furnaces, or resistance welders

Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. There are reports of temporary disturbances caused by electric hand tools or electric razors used directly over the implant site.

Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity to its minimum (most sensitive) setting of 0.15 mV.

Electronic article surveillance (EAS) – Electronic article surveillance equipment, such as retail theft prevention systems, may interact with devices and result in inappropriate therapy delivery. Advise patients to walk directly through an EAS system and not remain near an EAS system longer than necessary.

Static magnetic fields – Patients should avoid equipment or situations where they would be exposed to static magnetic fields greater than 10 gauss or 1 mT. Static magnetic fields

may suspend tachyarrhythmia detection. Sources of static magnetic fields include, but are not limited to, stereo speakers, bingo wands, extractor wands, magnetic badges, or magnetic therapy products.

2.8 Potential adverse events

Potential adverse events associated with the use of transvenous leads and pacing systems include, but are not limited to, the following events (listed in alphabetical order):

- acceleration of tachyarrhythmias (caused by device)
- air embolism
- bleeding
- body rejection phenomena including local tissue reaction
- cardiac dissection
- cardiac perforation
- cardiac tamponade
- chronic nerve damage
- death
- endocarditis
- erosion
- erosion through the skin
- excessive fibrotic tissue growth
- extrusion
- fibrillation or other arrhythmias
- fluid accumulation
- formation of hematomas or cysts
- heart block
- heart wall or vein wall rupture
- hematoma/seroma
- infection
- keloid formation
- lead abrasion and discontinuity
- lead migration/dislodgment
- myocardial damage
- muscle stimulation, nerve stimulation, or both
- myopotential sensing
- myocardial irritability
- pericardial rub
- pericardial effusion
- potential mortality due to inability to deliver therapy
- pneumothorax
- rejection phenomena (local tissue reaction, fibrotic tissue formation, device migration)
- threshold elevation
- thromboemboli
- thrombolytic and air embolism
- thrombosis
- transvenous lead-related thrombosis
- valve damage (particularly in fragile hearts)
- venous occlusion
- venous or cardiac perforation

An additional potential adverse event associated with the use of transvenous left ventricular pacing leads is coronary sinus dissection.

Additional potential adverse events associated with the use of ICD systems include, but are not limited to, the following events:

- inappropriate shocks
- potential mortality due to inability to defibrillate
- shunting current or insulating myocardium during defibrillation

Patients susceptible to frequent shocks despite medical management could develop psychological intolerance to an ICD system that might include the following conditions:

- dependency
- depression
- fear of premature battery depletion
- fear of shocking while conscious
- fear that shocking capability may be lost
- imagined shocking (phantom shock)

3 Clinical data

3.1 Adverse events and clinical trial data

Information regarding clinical studies and adverse events related to this device is available at www.medtronic.com/manuals. To view, download, print, or order the following clinical studies from the Medtronic website, perform the following steps:

1. Navigate your web browser to <http://www.medtronic.com/manuals>.
2. Select the hyperlink that corresponds to your location.
3. Select the Search field on the left side of the screen and type "D224TRK".
4. Click [Search]. All technical literature for this device is listed.

The following clinical studies are related to this device:

Atrial Capture Management (ACM) study – This clinical study, which evaluated the Atrial Capture Management feature in EnPulse pacemakers, provides support for the Atrial Capture Management feature in Consulta CRT-D Model D224TRK devices.

Atrial Septal Pacing Efficacy Trial (ASPECT) – This clinical study, which evaluated the safety and efficacy of the Medtronic AT500 DDDR Pacing System devices, provides support for the atrial intervention pacing therapies.

Atrial Therapy Efficacy and Safety Trial (ATTEST) – This clinical study, which evaluated the safety and efficacy of the Medtronic AT500 DDDR Pacing System devices, provides support for the Consulta CRT-D Model D224TRK devices.

Concerto AT clinical study – This clinical study evaluated the safety of the Concerto system and the efficacy of atrial shock therapy in patients with a current indication for Cardiac Resynchronization Therapy (CRT) and an Implantable Cardioverter Defibrillator (ICD). It provides support for atrial cardioversion therapy in the Consulta CRT-D Model D224TRK devices.

EnTrust clinical study – This clinical study, which evaluated the safety and clinical performance of the EnTrust ICD system, provides support for the Consulta CRT-D Model D224TRK devices.

EnTrust tachyarrhythmia detection performance vs. GEM DR tachyarrhythmia detection performance – This retrospective evaluation of the EnTrust detection algorithm was performed on spontaneous rhythms recorded in patients implanted with the GEM DR ICD. It provided support for the modifications made to the PR Logic Sinus Tachycardia criterion in the EnTrust devices. These modifications also apply to the Consulta CRT-D Model D224TRK devices.

FAST study – This clinical study, which evaluated the OptiVol Fluid Monitoring feature in InSync Marquis devices to corroborate the MIDHeFT clinical data, provides support for the OptiVol Fluid Monitoring feature in Consulta CRT-D Model D224TRK devices.

GEM DR clinical studies – This clinical study, which evaluated the appropriateness of dual chamber sensing and tachyarrhythmia detection during induced and simulated cardiac arrhythmias in GEM DR devices, provides support for the Consulta CRT-D Model D224TRK devices.

InSync ICD clinical study – This clinical study, which evaluated the safety and efficacy of cardiac resynchronization therapy (CRT) in patients who are indicated for an ICD, provides support for CRT pacing in Consulta CRT-D Model D224TRK devices.

InSync Marquis clinical study – This clinical study assessed the safety of the InSync Marquis dual chamber, rate responsive ICD with CRT Therapy, and confirmed appropriate VT/VF detection and biventricular capture over the range of heart rates achieved during exercise. It provides support for the Consulta CRT-D Model D224TRK devices.

InSync III Marquis clinical study – This clinical study, which evaluated the safety and efficacy of sequential biventricular CRT pacing and the Conducted AF Response feature in the InSync III Marquis devices, provides support for CRT pacing and Conducted AF Response in Consulta CRT-D Model D224TRK devices.

Kappa 700 clinical study – This study, which evaluated the safety and clinical performance of the Kappa 700 pacemakers, provides support for the Right Ventricular Capture Management feature and other bradycardia pacing features.

Left Ventricular Capture Management Software Download Clinical Trial (LVCM) – This clinical study, which evaluated the accuracy of the Left Ventricular Capture Management feature in modified InSync II Marquis devices, provides support for the Left Ventricular Capture Management feature in Consulta CRT-D Model D224TRK devices.

Medtronic Impedance Diagnostics in Heart Failure Trial (MIDHeFT) – This clinical study, which demonstrated the use of intrathoracic impedance as a surrogate measure of fluid status in patients with heart failure, provides support for the OptiVol Fluid Monitoring feature in Consulta CRT-D Model D224TRK devices.

Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction (REVERSE) and Resynchronization/Defibrillation for Ambulatory Heart Failure Trial (RAFT) – These clinical studies, which evaluated cardiac resynchronization therapy in mildly (REVERSE) and moderately symptomatic (RAFT) heart failure patients, provide support for Consulta CRT-D Model D224TRK devices in these patients.



Medtronic

REVERSE and RAFT CLINICAL STUDIES

Summary of Clinical Results

Clinical Study

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

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Summary of Clinical Results

The Medtronic-sponsored “Resynchronization reVERses Remodeling in Systolic left vEntricular dysfunction” (REVERSE) Clinical Study, and the University of Ottawa Heart Institute-sponsored “Resynchronization / defibrillation for Ambulatory heart Failure Trial” (RAFT), evaluated the safety and effectiveness of cardiac resynchronization therapy (CRT) in subjects with mild to moderate heart failure, reduced left ventricular ejection fraction (LVEF), and a prolonged QRS duration. The results from these studies, both of which utilized Medtronic devices, provide support for the expanded indication for use of Medtronic CRT-D devices in heart failure patients who remain symptomatic despite optimal medical therapy, and meet the following criteria:

- NYHA Class II
- Left bundle branch block (LBBB)
- QRS duration ≥ 130 ms
- Left ventricular ejection fraction (LVEF) $\leq 30\%$

Demonstration of the clinical effectiveness for expanding the indication for use for Medtronic CRT-D systems to this milder heart failure population is based on a subset of post-hoc results from the two studies. Determination of criteria for the expanded indication population was based on inclusion criteria common to both studies, and further narrowed to LBBB patients with QRS ≥ 130 ms as a stronger benefit was observed in these subgroups. A comparison of study designs is provided below in Table 1.

Table 1: REVERSE and RAFT Comparison of Study Designs

	REVERSE	RAFT
Study Design	Randomized CRT-D or CRT-P vs. no CRT Double-blinded	Randomized CRT-D vs. ICD Double-blinded
Implant	Implanted with CRT-D or CRT-P device prior to randomization. Control group (CRT OFF) did not have CRT functionality turned on.	Randomized prior to implant, then implanted with CRT-D or ICD.
Randomization Ratio	2:1 CRT ON : CRT OFF	1:1 CRT-D : ICD
Size	n=610 U.S., Europe, Canada	n=1798 Canada, Western Europe, Turkey, Australia
Duration	12 months (U.S. and Canada) 24 months (Europe only) At these time points, all subjects had CRT turned on and were followed for a total of 5 years.	Minimum 18 months Average follow-up 40 months Subjects stayed in their randomized arm throughout the study.
NYHA Class	I or II (ACC/AHA Stage C)	II or III

	REVERSE	RAFT
LVEF	$\leq 40\%$	$\leq 30\%$
QRS Duration	$\geq 120\text{ms}$	$\geq 120\text{ms}$
Primary Endpoint	HF Clinical Composite (proportion worsened)	Total mortality and heart failure hospitalization

The following sections provide an overview of the REVERSE study and results and the RAFT study and results. Where appropriate, results for the expanded indication population are provided following the full cohort results.

I. REVERSE Study

A. Study Scope, Design and Methods

The REVERSE study was a prospective, randomized, double-blind, multi-center global study conducted in the United States, Canada and Europe. It was designed to determine whether biventricular pacing in conjunction with optimal medical therapy (OMT) limited the progression of heart failure in subject clinical status as compared to OMT alone in subjects with asymptomatic or mild heart failure (New York Heart Association (NYHA) Functional Class I and II, Stage C), ventricular dyssynchrony (QRS ≥ 120 ms), and reduced systolic left ventricular ejection fraction (LVEF $\leq 40\%$).

Enrolled subjects were implanted with a Medtronic CRT-P or CRT-D system (depending on ICD indication), and following successful implant were randomized in a 2:1 fashion to one of two study arms: biventricular pacing in conjunction with optimal medical therapy (CRT ON) or optimal medical therapy alone (CRT OFF).

In the U.S. and Canada, subjects were unblinded at 12 months and continued to be seen annually through 5 years of follow-up. European subjects were unblinded at 24 months and were seen annually thereafter until 5 years. It was recommended that all subjects have CRT programmed on at the conclusion of the blinded follow-up.

B. Subject Selection

Subjects were considered enrolled upon signing the study informed consent document. Subjects of both genders who satisfied all inclusion and did not meet any exclusion criteria were eligible for this clinical study.

Inclusion Criteria

- Subject has signed and dated study informed consent.
- Subject is able to receive a pectoral implant.
- Subject is NYHA Functional Class I or II with current American College of Cardiology/ American Heart Association (ACC/AHA) Stage C classification¹ as confirmed by the documented consensus of two qualified individuals within 30 days prior to enrollment or during the baseline assessment. Stage C classification includes subjects who have current or prior symptoms of heart failure associated with underlying structural heart disease. Qualified individuals must include at least one cardiologist and another physician or a heart failure clinician/ nurse. A minimum of one classifying individual must be recorded on the Blinding Log. If the two qualified individuals assessing the NYHA Functional classification do not reach a consensus, the subject is not eligible.
- Subject has ventricular dyssynchrony by QRS duration ≥ 120 ms (at Baseline or within the 30 days prior to enrollment).
- Subject has a history of a left ventricular ejection fraction $\leq 40\%$, which is confirmed at the baseline echo.
- Subject has a history of a left ventricular end diastolic diameter (LVEDD) ≥ 55 mm or the equivalent value via LVEDD Index (i.e., LVEDDi ≥ 2.8 cm/m²), which is confirmed at the baseline echo.^{2,3}

- Subject is on a stable optimal medical regimen, which minimally includes an Angiotensin Converting Enzyme- Inhibitor (ACE-I) or Angiotensin Receptor Blockers (ARB) at therapeutic dose for 30 days prior to enrollment, if tolerated, and a beta blocker (BB) that is approved and indicated for HF within the geography for 90 days prior to enrollment, if tolerated, with a stable dosage for 30 days prior to enrollment. If the subject is intolerant of ACE-I or BB, documented evidence must be available. If anti-aldosterone therapy is needed in the NYHA Functional Class II subjects, it must be initiated and optimized prior to enrollment. Eplerenone requires dosage stability for 30 days prior to enrollment. Diuretics may be used as necessary to keep the subject euvolemic. Therapeutic equivalence for ACE-I substitutions is allowed within the enrollment stability timelines.
- Subject is expected to remain available for follow-up visits.
- Subject is willing and able to comply with the Clinical Investigation Plan.
- Subjects who will be implanted with a CRT/ICD system will have an indication for an ICD as defined by the associated geography current at the time of enrollment.^{4,5,6,7}

Exclusion Criteria

- Subject requires permanent cardiac pacing.
- Subject has been classified as NYHA Functional Class III or IV in the 90 days prior to enrollment.
- Subject is ≤ 18 years of age, or the subject is under a higher minimum age that is required as defined by local law.
- Subject has experienced decompensation of heart failure requiring hospitalization for the treatment of heart failure within the 90 days prior to enrollment.
- Subject has experienced unstable angina, acute MI, CABG or PTCA within the 90 days prior to enrollment.
- Subject has chronic (permanent) or persistent atrial arrhythmias. Chronic (permanent) atrial arrhythmias are defined as cases of long-standing atrial fibrillation (e.g., greater than 1 year) in which cardioversion has not been indicated or attempted. Persistent atrial arrhythmias are defined as recurrent atrial fibrillation (i.e., 2 episodes or more) that does not self-terminate.⁸
- Subject has had cardioversion for atrial fibrillation or paroxysmal atrial fibrillation event within the past 30 days.
- Subject is enrolled in a concurrent study, with the exception of a study-manager approved study that is strictly observational in nature and does not confound the results of this study (e.g. registries).
- Subject has a life expectancy of less than 12 months.
- Women who are pregnant or women of childbearing potential who are not on a reliable form of birth control. Women of childbearing potential are required to have a negative pregnancy test within the seven (7) days prior to device implant.
- Subjects with a CRT, pacemaker, ICD or CRT/ICD device implanted previously or currently, except in cases where previously implanted non-CRT ICD device lifetime counters indicate the device is 95% free of ventricular and atrial pacing. If the ICD device or the subject records cannot provide this data, the subject is not eligible.
- Subject has a mechanical right heart valve.
- Primary valvular disease and indication for valve repair or replacement.
- Subject has had a heart transplant.

- Subject has significant renal dysfunction, as manifested by serum creatinine level > 3.0 mg/dl. Note: documentation of serum creatinine within the 30 days prior to enrollment or at baseline will be required.
- Subject has significant hepatic dysfunction, as evidenced by a hepatic function panel (serum) > 3 times upper limit of normal. Note: documentation of hepatic function panel (serum) within the 30 days prior to enrollment or at baseline will be required.
- Chronic or treatment resistant severe anemia (hemoglobin \leq 10.0 g/dL). Note: documentation of hemoglobin within the 30 days prior to enrollment or at baseline will be required.
- Subject is on continuous or intermittent (i.e., more than two infusions per week) intravenous inotropic drug therapy.

C. Results

The first REVERSE subject was enrolled on September 3, 2004. A total of 684 subjects signed an informed consent form at 73 clinical study centers. Enrollment was completed on September 11, 2006. There were 36 subjects who were exited prior to completion of the baseline visit. Of the remaining 648 subjects, six were exited prior to an implant attempt, 21 were not successfully implanted with a CRT system, and 621 were successfully implanted. Of the 621 successfully implanted, 11 (1.8%) were not randomized. This left 610 subjects randomized: 419 to CRT ON and 191 to CRT OFF.

The results presented in this clinical summary manual are based on REVERSE subject data included in the June 14, 2010 database freeze for the U.S. pre-market approval submission to FDA.

Subject Demographics

Baseline demographic data for the 610 randomized subjects are provided below in Table 2.

Table 2: REVERSE Baseline Demographics – Full Cohort

Subject Characteristic	CRT OFF (n= 191)	CRT ON (n= 419)
Male	80% (152)	78% (327)
Age (years)	61.8 \pm 11.6	62.9 \pm 10.6
Ethnicity		
Black	3% (6)	7% (28)
American Indian	0% (0)	<1% (1)
Asian	1% (2)	<1% (1)
White	86% (164)	83% (346)
Hispanic	1% (2)	2% (8)
Hawaiian	0% (0)	<1% (1)
Other	1% (2)	0% (0)
Not specified	8% (15)	8% (34)
LVEF (%)	26.4 \pm 7.1	26.8 \pm 7.0
LVEDD (mm)	67.4 \pm 8.9	66.7 \pm 8.9
QRS Duration (ms)	154 \pm 24	153 \pm 21

Subject Characteristic	CRT OFF (n= 191)	CRT ON (n= 419)
QRS Morphology Type		
RBBB	10% (20)	9% (37)
LBBB	59% (59)	61% (256)
IVCD	30% (58)	29% (123)
Ischemic	51% (97)	56% (236)
Device		
CRT-D	85% (163)	82% (345)
CRT-P	15% (28)	18% (74)
NYHA Classification		
Class I	17% (32)	18% (75)
Class II	83% (159)	82% (344)
Beta blocker	94% (179)	96% (401)
ACE-I/ARB	97% (186)	96% (404)
Diuretic	77% (148)	81% (339)

Baseline demographics for the expanded indication population from REVERSE, which comprise 29% of REVERSE full cohort, are presented in Table 3.

Table 3: REVERSE Baseline Demographics - Expanded Indication Population

Subject Characteristic	CRT OFF (n= 60)	CRT ON (n= 119)
Male	73% (44)	76% (91)
Age (years)	58.7 ± 12.1	62.9 ± 11.6
Ethnicity		
Black	3% (2)	8% (9)
American Indian	0% (0)	0% (0)
Asian	2% (1)	0% (0)
White	80% (48)	76% (90)
Hispanic	2% (1)	4% (5)
Hawaiian	0% (0)	0% (0)
Other	0% (0)	0% (0)
Not specified	13% (8)	13% (15)
LVEF (%)	22.8 ± 5.6	22.7 ± 5.1
LVEDD	70.3 ± 9.8	68.5 ± 9.2
QRS duration (ms)	168 ± 19	165 ± 19
QRS Morphology Type		
RBBB	0% (0)	0% (0)
LBBB	100% (60)	100% (119)
IVCD	0% (0)	0% (0)
Ischemic	32% (19)	45% (53)

Subject Characteristic	CRT OFF (n= 60)	CRT ON (n= 119)
Device		
CRT-D	100% (60)	100% (119)
CRT-P	0% (0)	0% (0)
NYHA Classification		
Class I	0% (0)	0% (0)
Class II	100% (60)	100% (119)
Beta blocker	93% (56)	97% (116)
ACE-I/ARB	97% (58)	97% (116)
Diuretic	78% (47)	81% (96)

Primary Objective

The primary objective in the REVERSE study was to compare the HF Clinical Composite Response⁹ between subjects in the CRT OFF and CRT ON groups. The Clinical Composite Response (CCR) utilizes clinically meaningful endpoints including mortality, hospitalizations for heart failure, crossover, NYHA Functional Class and the Patient Global Assessment, to categorize subjects as improved, unchanged, or worsened. REVERSE evaluated the proportion of subjects in each randomization group that were characterized as “worsened” according to the CCR at 12 months as compared to baseline.

Subjects were classified as “worsened”, “improved”, or “unchanged” according to the following definitions:

Worsened - Subject dies; is hospitalized due to or associated with worsening heart failure; permanently discontinues double-blind treatment due to or associated with worsening heart failure, treatment failure or lack of/insufficient therapeutic response; permanently discontinues double-blind treatment due to withdrawal of consent or other administrative reason and has worsening heart failure at the time of study discontinuation; demonstrates worsening in NYHA Class at last observation carried forward (LOCF) or moderate-marked worsening in patient global assessment at LOCF.

Improved - Subject has not worsened (as defined above), and demonstrates improvement in NYHA Class at LOCF and/or moderate-marked improvement in patient global assessment at LOCF.

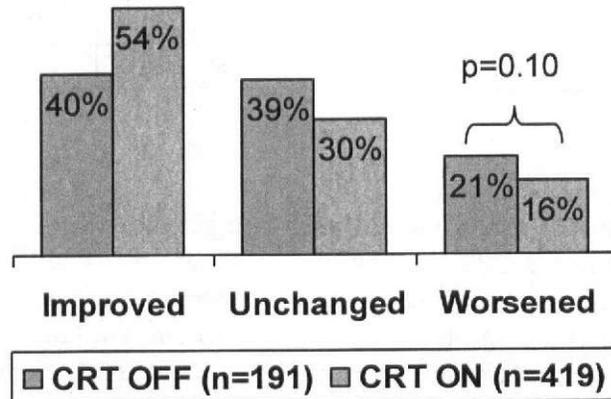
Unchanged - Subject is neither improved nor worsened.

A Clinical Composite Response was assessed at 12 months for all 610 randomized subjects. The Clinical Investigation Plan pre-specified that a comparison would be made between the two groups based on the percentage of subjects with a worsened response. Results of this analysis showed that in the full cohort, 21% of the CRT OFF group subjects worsened vs. 16% of the CRT ON group subjects. Although CRT ON resulted in a more favorable response, it did not achieve statistical significance at 12 months (p=0.10).

The Clinical Composite Response was further analyzed in a post-hoc analysis by looking at the distribution of responses, a method described by Milton Packer in his original paper on the Clinical Composite Response endpoint⁹ and utilized in prior CRT and drug trials.^{1,2,10} When the

12-month results are analyzed using this method as shown in Figure 1, a difference in the distribution of the CCR between CRT OFF and CRT ON is observed, with more CRT ON subjects improving and less CRT ON subjects worsening.

Figure 1: REVERSE Clinical Composite Response Distribution of Responses Analysis at 12 Months – Full Cohort (post-hoc analysis)



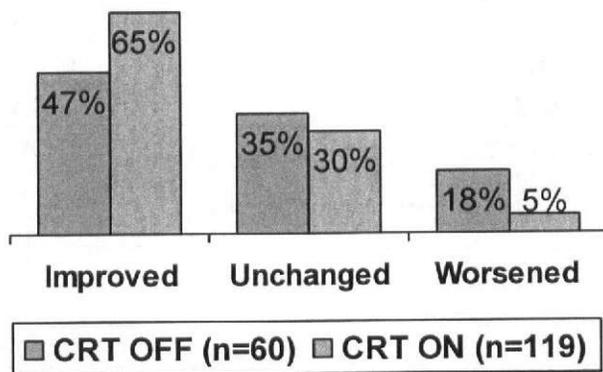
Additional details on the Clinical Composite Response results at 12 months for the full cohort are provided in Table 4. Note that a subject is only indicated in the sub-category in the highest row which was met (e.g., a subject who died and had a HF-hospitalization is only listed in the “Death” row). The total percentage of subjects improving their NYHA class can be found by adding the number improving both patient global assessment and NYHA class and those improving just NYHA class.

Table 4: Detailed Clinical Composite Response at 12 Months – Full Cohort (post hoc analysis)

Clinical Composite Response	CRT OFF (n=191)	CRT ON (n=419)
WORSENERD	41 (21%)	67 (16%)
Death	3 (2%)	9 (2%)
Hospitalized for worsening HF	14 (7%)	14 (3%)
Crossover due to worsening HF	5 (3%)	1 (<1%)
Moderately or Markedly Worse Patient Global Assessment and Worsened NYHA	0 (0%)	2 (<1%)
Worsened NYHA	18 (9%)	38 (9%)
Moderately or Markedly Worse Patient Global Assessment	1 (1%)	3 (1%)
IMPROVED	76 (40%)	228 (54%)
Moderately or Markedly Improved Patient Global Assessment and Improved NYHA	11 (6%)	69 (16%)
Improved NYHA	28 (15%)	59 (14%)
Moderately or Markedly Improved Patient Global Assessment Only	37 (19%)	100 (24%)
UNCHANGED	74 (39%)	124 (30%)

The primary endpoint was also analyzed for the expanded indication population. As shown in Figure 2, 18% of subjects in the CRT OFF group had a worsened CCR vs. 5% of the subjects in the CRT ON group. Additionally, as with the full cohort, a difference in the distribution of the CCR between CRT OFF and CRT ON is observed, with more CRT ON subjects improving and less CRT ON subjects worsening.

Figure 2: REVERSE Clinical Composite Response 12-month Results – Expanded Indication Population

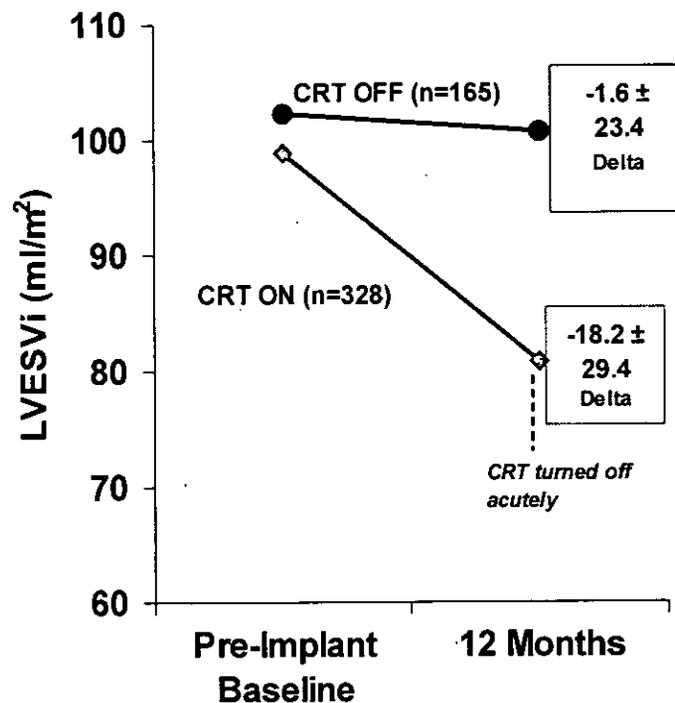


Key Secondary Objective

Left ventricular end systolic volume index (LVESVi) was a prospectively powered secondary endpoint in the REVERSE study. The change in LVESVi from baseline to 12 months was compared between the CRT OFF and CRT ON groups. While LVESVi was a pre-specified analysis, the primary endpoint of the study was not met.

Cardiac resynchronization therapy was programmed off for all subjects while the 12-month echo was performed in order to eliminate the potential acute effects of CRT on the LVESVi measurement. The CRT OFF subjects averaged a 1.6 ml/m² reduction in LVESVi over 12 months while the CRT ON subjects averaged an 18.2 ml/m² reduction Figure 3.

Figure 3: REVERSE LVESVi (ml/m²): Baseline vs. 12 Months (CRT programmed off) – Full Cohort



Additional Analyses

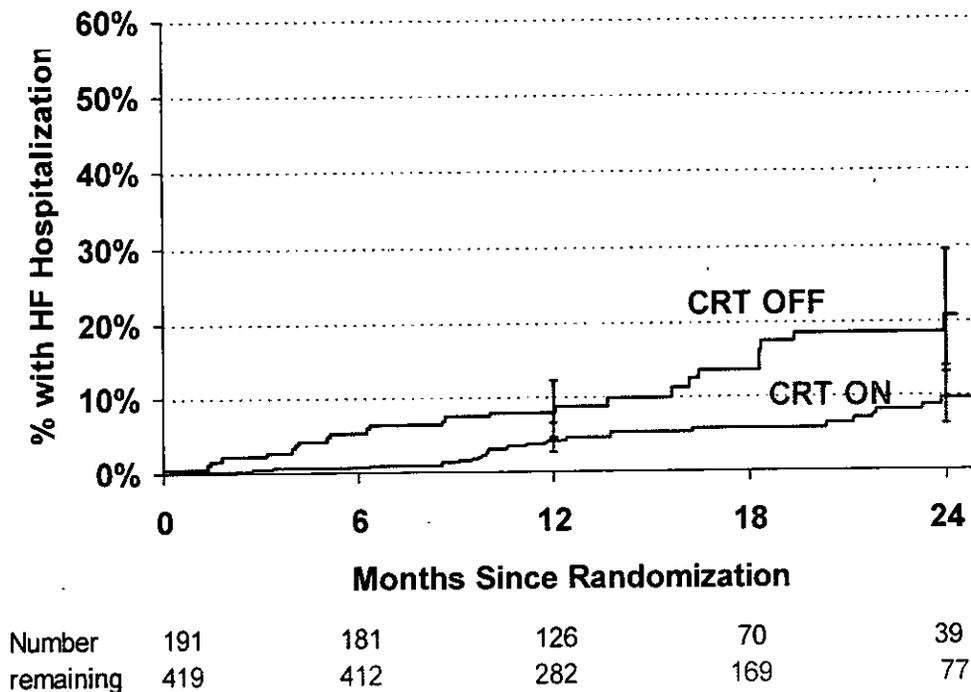
Time to First Heart Failure Hospitalization (post-hoc analysis)

Time to first heart failure (HF) hospitalization was compared between the CRT OFF and CRT ON groups as part of the secondary healthcare utilization objective. An HF hospitalization was defined as an overnight hospital admission, where the admission date and discharge date are different, and the Adverse Event Advisory Committee (AEAC) adjudicated the event as heart failure related.

Figure 4 shows the time to the first HF hospitalization for all randomized subjects. At 12 months, the rate in the CRT OFF group was 7.9%, compared to the rate in the CRT ON group of 4.2%. At 24 months, the rates were 20.5% in the CRT OFF group and 9.5% in the CRT ON group.

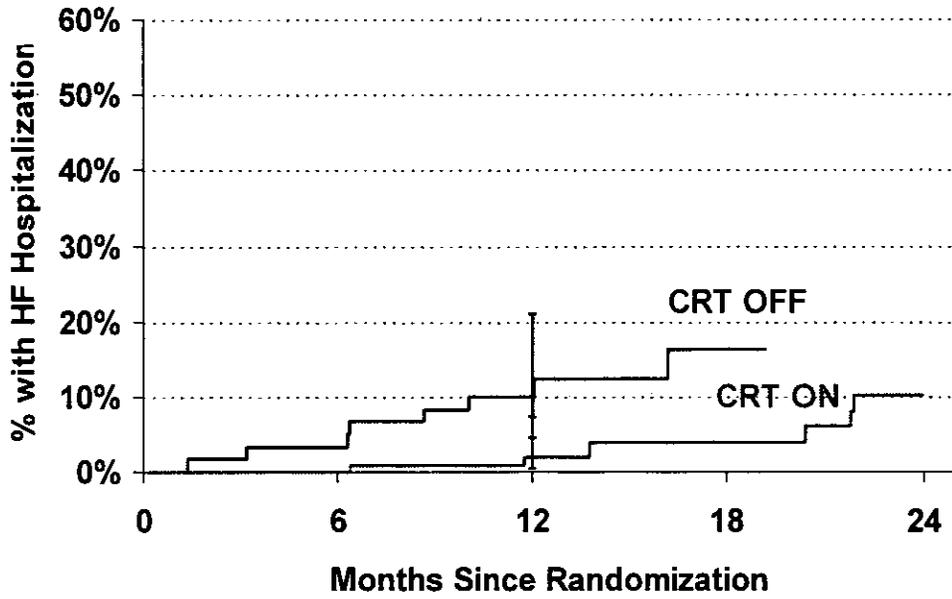
For Figure 4 through Figure 7, note that U.S. and Canadian subjects were unblinded at 12 months, while European subjects were unblinded at 24 months. The poolability analysis of US and OUS patients showed differences in baseline characteristics and results. Therefore, the results at 24 months might not be applicable to U.S. patients.

Figure 4: REVERSE Time to First HF Hospitalization – Full Cohort (post-hoc analysis)



Time to first HF hospitalization was also analyzed for the expanded indication population as shown in Figure 5.

Figure 5: REVERSE Time to First HF Hospitalization – Expanded Indication Population (post-hoc analysis)



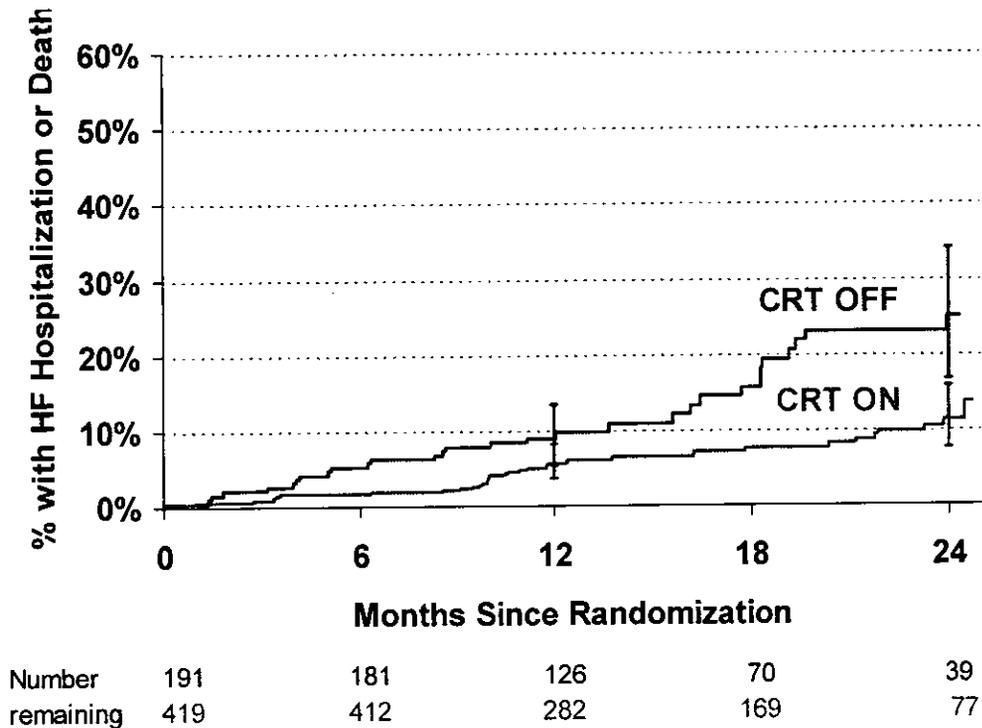
Number	60	58	39	21	11
remaining	119	117	82	46	19

Time to First Heart Failure Hospitalization or All-cause Death (post-hoc analysis)

The composite endpoint of HF hospitalization or all-cause death is a common endpoint in heart failure studies. Although not pre-specified in REVERSE, an analysis of this endpoint was performed to align with recent CRT trials, including RAFT.

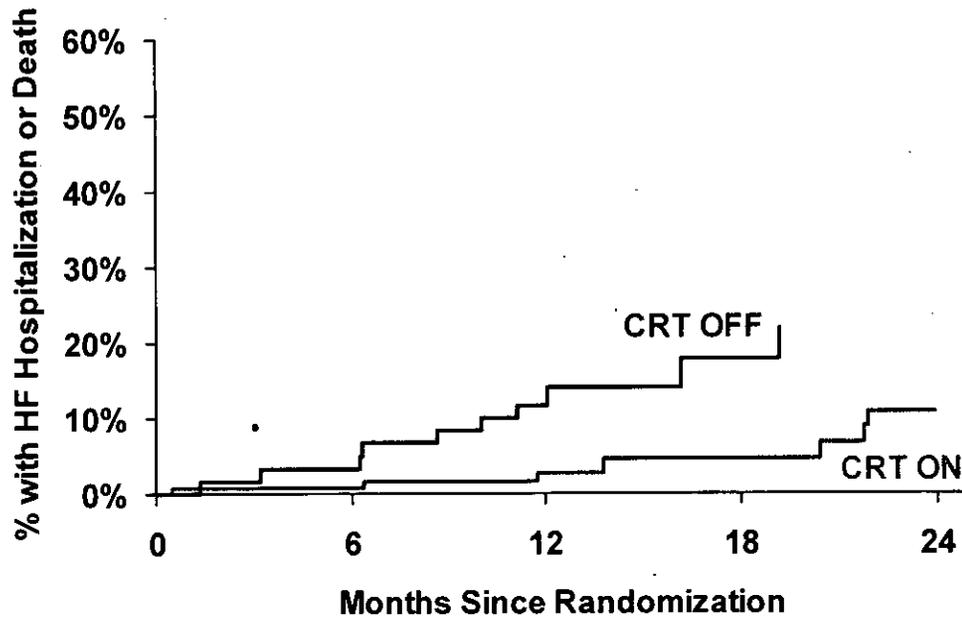
Figure 6 is a Kaplan-Meier analysis of time to first HF hospitalization or all-cause death for the REVERSE full cohort. At 12 months, the rate in the CRT OFF group was 8.9% and the rate in the CRT ON group was 5.6%. At 24 months, the rates were 25.0% in the CRT OFF group and 11.3% in the CRT ON group.

Figure 6: REVERSE Time to First HF Hospitalization or All-cause Death – Full Cohort (post-hoc analysis)



Time to first HF hospitalization or all-cause death was also analyzed for the expanded indication population as shown in Figure 7.

Figure 7: REVERSE Time to First HF Hospitalization or All-cause Death - Expanded Indication Population (post-hoc analysis)



Number	60	58	39	21	11
remaining	119	117	82	46	19

Subject Survival

An additional secondary endpoint was to characterize subject survival in each treatment arm. Due to the low number of deaths occurring during the randomized period, the results of this analysis were not clinically meaningful and are therefore not included in this clinical summary.

Subgroup Analyses

Subgroup analyses on ischemic/non-ischemic subjects, U.S./non-U.S. subjects, and ICD/non-ICD subjects were pre-specified to be performed for the primary endpoint and prospectively powered secondary endpoint.

Subgroup analyses performed for CCR worsened and time to first HF hospitalization or all-cause death are summarized below in Figure 8 and Figure 10. Lines represent 95% confidence intervals, which should be interpreted with the understanding that no subgroup was powered to see a difference between CRT OFF and CRT ON. In addition, post-hoc subgroup analyses of QRS duration evaluated as a continuous variable, along with categorical analysis in groups of 10 ms (120-129, 130-139, etc.) are presented in Figure 9 and Figure 11.

Figure 8: REVERSE Clinical Composite Response Worsened Subgroup Analysis – Full Cohort (post-hoc analysis)

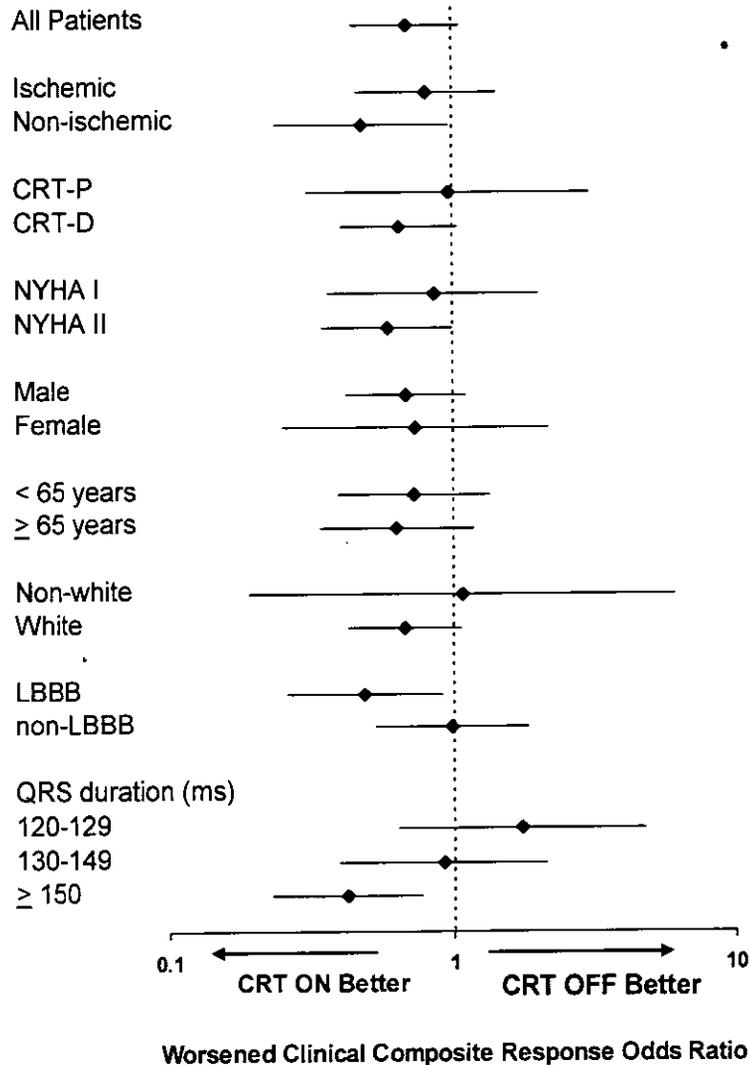


Figure 9: REVERSE Clinical Composite Response Worsened Subgroup Analysis: QRS Duration Odds Ratio – Full Cohort (post-hoc analysis)

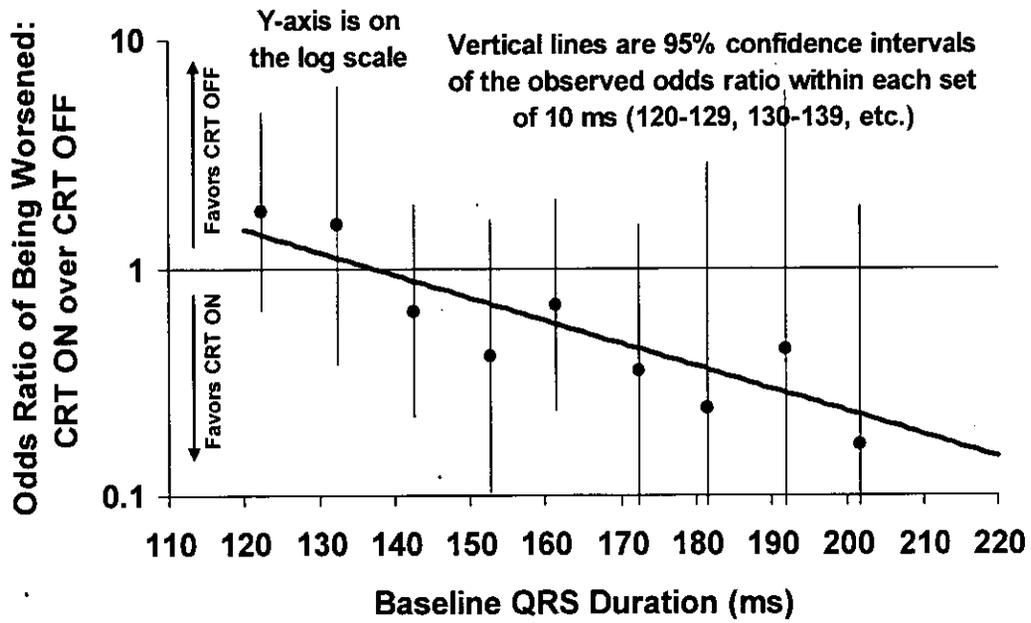


Figure 10: REVERSE Time to First HF Hospitalization or All-cause Death Subgroup Analysis – Full Cohort (post-hoc analysis)

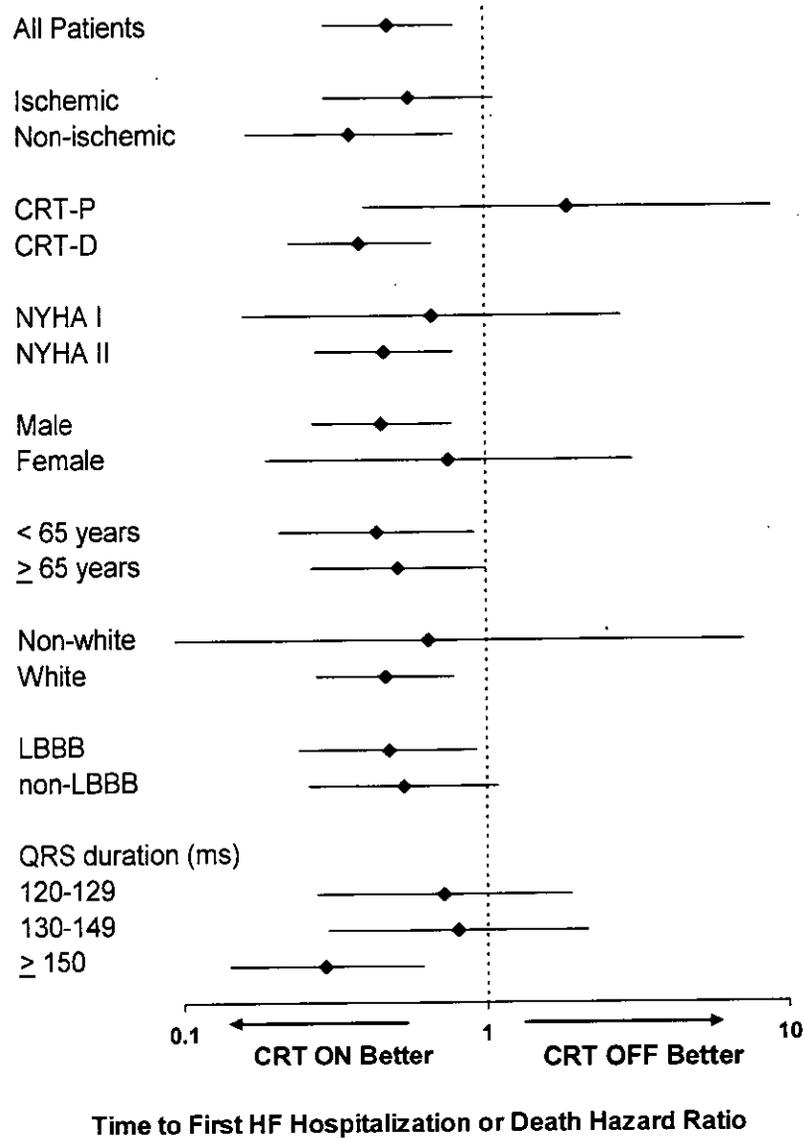
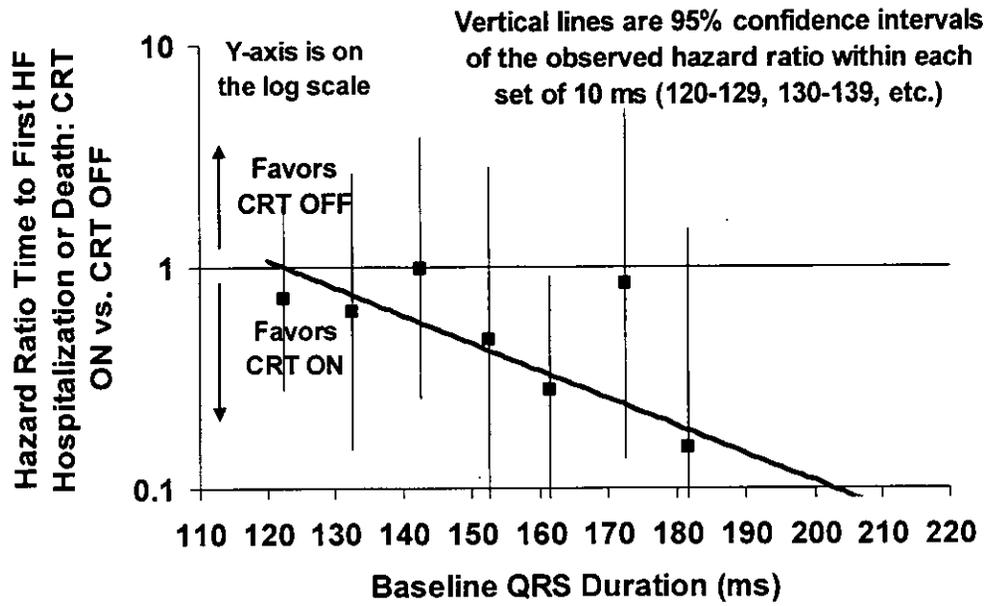
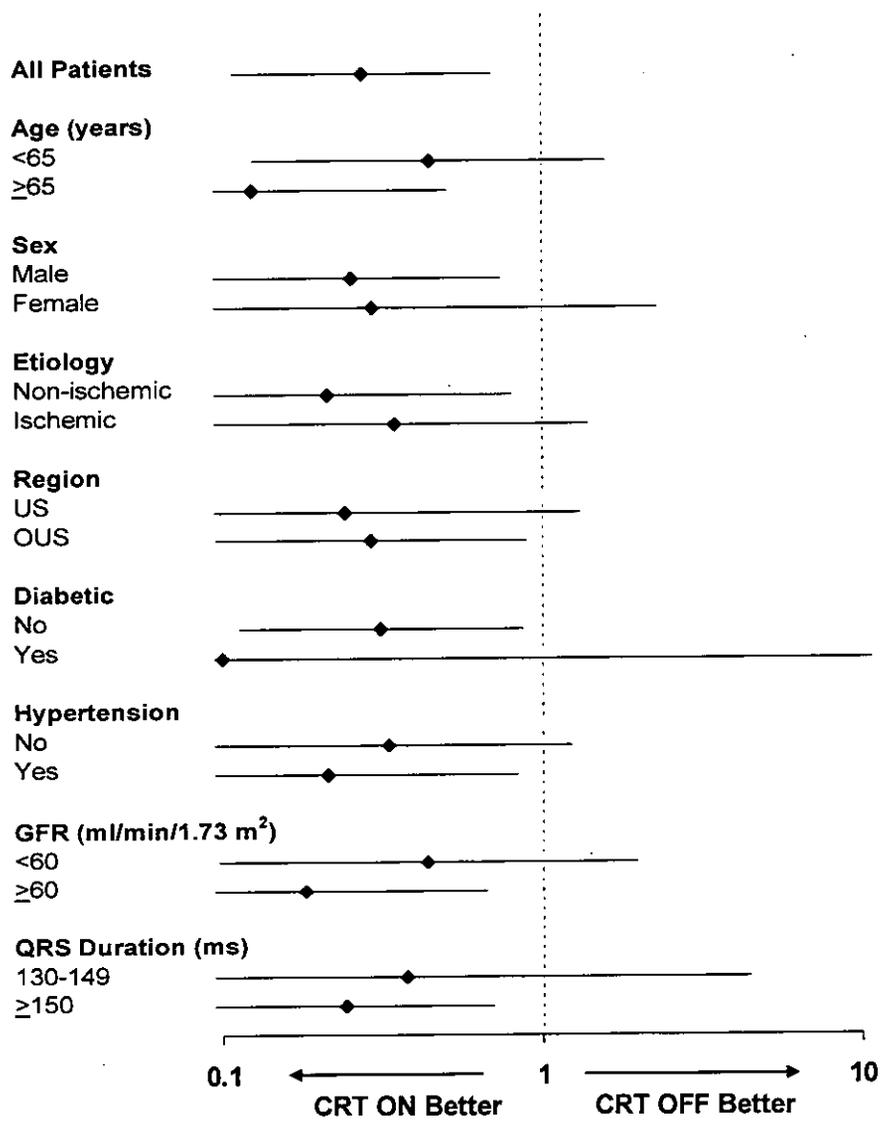


Figure 11: REVERSE Time to First HF Hospitalization or All-cause Death Subgroup Analysis: QRS Duration Odds Ratio – Full Cohort (post-hoc analysis)



Additionally, a subgroup analysis for time to first HF hospitalization or death was performed for the expanded indication population as summarized in Figure 12. Lines represent 95% confidence intervals, which should be interpreted with the understanding that no subgroup was powered to see a difference between CRT OFF and CRT ON.

Figure 12: REVERSE Time to First HF Hospitalization or All-cause Death Subgroup Analysis – Expanded Indication Population (post-hoc analysis)



Time to First HF Hospitalization or All-cause Death Hazard Ratio

Gender Analysis

Per FDA request, additional subgroup analyses were performed by gender. In REVERSE, both men and women demonstrated improvement with CRT ON over CRT OFF in both the full cohort and the expanded indication population. There was no significant difference in results for the primary endpoint, the Clinical Composite Response.

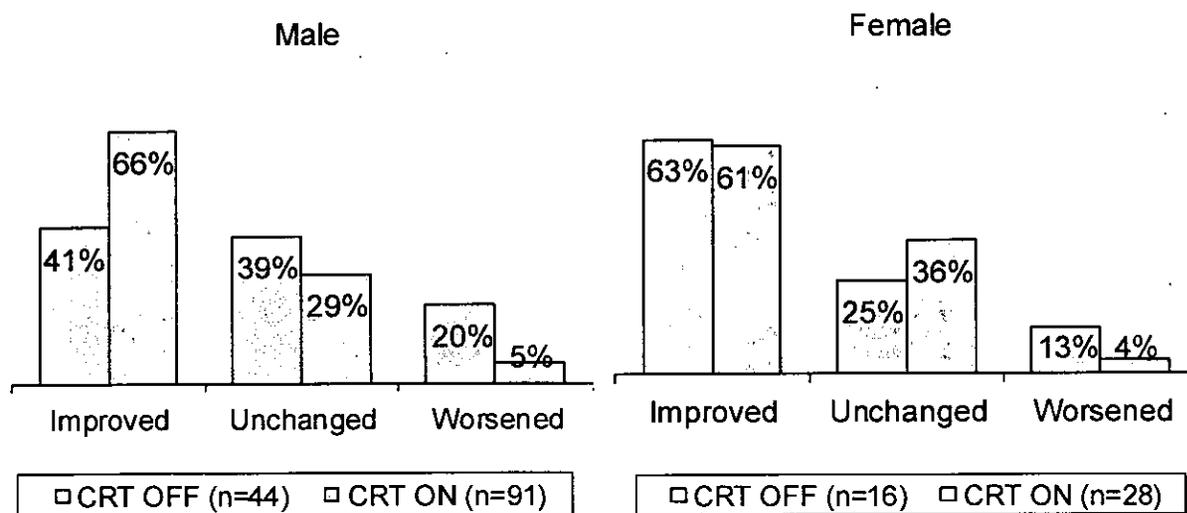
The proportion of female subjects enrolled in the REVERSE study is lower than the gender-specific incidence or prevalence of heart failure in this patient population, however similar to what has been observed in other trials of CRT.¹¹ In the REVERSE full cohort, 79% of subjects were male and 21% were female, and in the REVERSE expanded indication population, 75% were male and 25% were female.

Analyses by gender for the REVERSE expanded indication population are presented below for the primary CCR percent worsened endpoint and key secondary LVESVi endpoint. P-values comparing male and female results are from the interaction term of logistic regression (Clinical Composite Score) or linear regression (LVESVi) models. Terms fit in the models were randomization, gender, and their interaction.

Primary Endpoint

The primary endpoint results by gender for the expanded indication population are presented in Figure 13. There is no evidence of differences in worsened Clinical Composite Response between males and females ($p=0.92$).

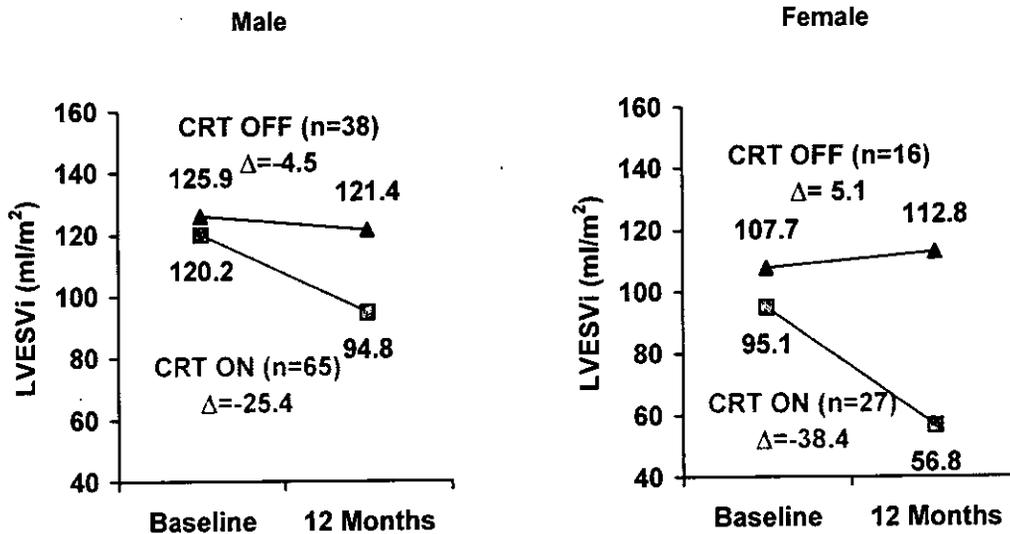
Figure 13: REVERSE Clinical Composite Response at 12 Months by Gender - Expanded Indication Population



Key Secondary Endpoint

Change in left ventricular end systolic volume indexed (LVESVi) from baseline to 12 months was a secondary endpoint in REVERSE. Figure 14 shows the results for males and females in the expanded indication population. Though both improved their LVESVi with CRT, females showed more of an improvement than males ($p=0.05$).

Figure 14: REVERSE LVESVi Change at 12 Months by Gender - Expanded Indication Population



D. Adverse Events Summary

All adverse events, except unavoidable adverse events, were collected and documented during the blinded portion of the study. After unblinding (12 months for U.S. and Canada and 24 months for Europe), only cardiovascular, pulmonary, device-related, and system-related adverse events were collected. All adverse events were reviewed and classified by a blinded Adverse Event Advisory Committee (AEAC).

All events were classified as either complications or observations. The following definitions were used:

Complication: An adverse event that results in invasive intervention, or the termination of significant device function regardless of other treatments. Intravenous (IV) and intramuscular (IM) drug therapies are considered invasive treatment.

Observation: Any adverse event that is not a complication.

There were 660 implant attempts in a total of 642 subjects. This included 621 successful implants and 39 unsuccessful implant attempts (16 subjects had two or more attempts). A total of 608 adverse events were classified as procedure, system, or therapy-related at the time of the data cut-off, as listed in Table 5, which is sorted in descending order based on the total number of events.

Table 5: REVERSE Procedure, System, or Therapy-related Adverse Events – Full Cohort

Event Description	Complications		Observations		Total	
	# Events	# Subjects	# Events	# Subjects	# Events	# Subjects
Inappropriate device stimulation of tissue	17	16 (2.6%)	69	58 (9.3%)	86	69 (11.1%)
Medical device change	71	70 (11.3%)	0	0 (0.0%)	71	70 (11.3%)
LV lead dislodgement	47	44 (7.1%)	1	1 (0.2%)	48	44 (7.1%)
Device lead damage	43	42 (6.8%)	1	1 (0.2%)	44	43 (6.9%)
Implant site hematoma	5	5 (0.8%)	15	15 (2.4%)	20	20 (3.2%)
Coronary sinus dissection	2	2 (0.3%)	17	17 (2.7%)	19	19 (3.1%)
RV lead dislodgement	18	17 (2.7%)	0	0 (0.0%)	18	17 (2.7%)
RA lead dislodgement	16	15 (2.4%)	2	2 (0.3%)	18	16 (2.6%)
Implant site infection	5	4 (0.6%)	11	11 (1.8%)	16	15 (2.4%)
Atrial fibrillation	9	9 (1.4%)	5	5 (0.8%)	14	14 (2.3%)
Implant site pain	0	0 (0.0%)	14	14 (2.3%)	14	14 (2.3%)
Inappropriate device therapy	6	6 (1.0%)	7	7 (1.1%)	13	13 (2.1%)
Failure to capture	11	10 (1.6%)	1	1 (0.2%)	12	11 (1.8%)
Pericardial effusion	5	5 (0.8%)	4	4 (0.6%)	9	9 (1.4%)
Hypotension	6	6 (1.0%)	2	2 (0.3%)	8	8 (1.3%)
Pleural effusion	0	0 (0.0%)	8	8 (1.3%)	8	8 (1.3%)
Pneumothorax	5	4 (0.6%)	2	2 (0.3%)	7	6 (1.0%)
Oversensing	2	2 (0.3%)	5	5 (0.8%)	7	7 (1.1%)
Atrioventricular block third degree	1	1 (0.2%)	5	5 (0.8%)	6	6 (1.0%)
Cardiac failure acute	4	4 (0.6%)	1	1 (0.2%)	5	5 (0.8%)
Atrial flutter	4	4 (0.6%)	1	1 (0.2%)	5	5 (0.8%)
Atrioventricular block complete	3	3 (0.5%)	2	2 (0.3%)	5	4 (0.6%)
Electrical reset of device	1	1 (0.2%)	4	4 (0.6%)	5	5 (0.8%)
Cardiac failure chronic	1	1 (0.2%)	4	4 (0.6%)	5	5 (0.8%)
Adverse drug reaction	3	3 (0.5%)	1	1 (0.2%)	4	4 (0.6%)
Defibrillation threshold increased	3	3 (0.5%)	1	1 (0.2%)	4	4 (0.6%)
Arrhythmia supraventricular	1	1 (0.2%)	3	2 (0.3%)	4	3 (0.5%)

Event Description	Complications		Observations		Total	
	# Events	# Subjects	# Events	# Subjects	# Events	# Subjects
Elevated pacing threshold	1	1 (0.2%)	3	3 (0.5%)	4	4 (0.6%)
Edema peripheral	0	0 (0.0%)	4	4 (0.6%)	4	4 (0.6%)
Shoulder pain	0	0 (0.0%)	4	4 (0.6%)	4	4 (0.6%)
Subclavian vein thrombosis	3	3 (0.5%)	0	0 (0.0%)	3	3 (0.5%)
Sudden cardiac death	3	3 (0.5%)	0	0 (0.0%)	3	3 (0.5%)
Renal failure	3	3 (0.5%)	0	0 (0.0%)	3	3 (0.5%)
Cardiac tamponade	3	3 (0.5%)	0	0 (0.0%)	3	3 (0.5%)
Cardiac perforation	3	3 (0.5%)	0	0 (0.0%)	3	3 (0.5%)
Syncope vasovagal	2	2 (0.3%)	1	1 (0.2%)	3	3 (0.5%)
Ventricular tachycardia	2	2 (0.3%)	1	1 (0.2%)	3	3 (0.5%)
Drug hypersensitivity	1	1 (0.2%)	2	2 (0.3%)	3	3 (0.5%)
Device electrical finding	1	1 (0.2%)	2	2 (0.3%)	3	3 (0.5%)
Suture related complication	0	0 (0.0%)	3	3 (0.5%)	3	3 (0.5%)
Impaired healing	0	0 (0.0%)	3	3 (0.5%)	3	3 (0.5%)
Atelectasis	0	0 (0.0%)	3	3 (0.5%)	3	3 (0.5%)
Muscle spasms	0	0 (0.0%)	3	3 (0.5%)	3	3 (0.5%)
Medical device discomfort	0	0 (0.0%)	3	3 (0.5%)	3	3 (0.5%)
Implant site erosion	2	2 (0.3%)	0	0 (0.0%)	2	2 (0.3%)
Ventricular fibrillation	2	2 (0.3%)	0	0 (0.0%)	2	2 (0.3%)
Implant site irritation	2	1 (0.2%)	0	0 (0.0%)	2	1 (0.2%)
Endocarditis	2	2 (0.3%)	0	0 (0.0%)	2	2 (0.3%)
Acute pulmonary edema	2	2 (0.3%)	0	0 (0.0%)	2	2 (0.3%)
Device migration	1	1 (0.2%)	1	1 (0.2%)	2	2 (0.3%)
Decreased RV Sensing	1	1 (0.2%)	1	1 (0.2%)	2	2 (0.3%)
Pyrexia	1	1 (0.2%)	1	1 (0.2%)	2	2 (0.3%)
Pneumonia	1	1 (0.2%)	1	1 (0.2%)	2	2 (0.3%)
Pericarditis	1	1 (0.2%)	1	1 (0.2%)	2	1 (0.2%)
Deep vein thrombosis	1	1 (0.2%)	1	1 (0.2%)	2	2 (0.3%)
Dyspnea	0	0 (0.0%)	2	2 (0.3%)	2	2 (0.3%)
Wheezing	0	0 (0.0%)	2	2 (0.3%)	2	2 (0.3%)
Bradycardia	0	0 (0.0%)	2	2 (0.3%)	2	2 (0.3%)

Event Description	Complications		Observations		Total	
	# Events	# Subjects	# Events	# Subjects	# Events	# Subjects
Implant site haemorrhage	0	0 (0.0%)	2	2 (0.3%)	2	2 (0.3%)
Supraventricular tachycardia	0	0 (0.0%)	2	2 (0.3%)	2	2 (0.3%)
Anxiety	0	0 (0.0%)	2	2 (0.3%)	2	2 (0.3%)
Pain in extremity	0	0 (0.0%)	2	2 (0.3%)	2	2 (0.3%)
Iodine allergy	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Intracardiac thrombus	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Influenza	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Cardiac arrest	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Vertigo CNS origin	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Implant site inflammation	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Vascular pseudoaneurysm	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Twiddler's syndrome	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Death	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Hematoma evacuation	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Contrast media reaction	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Gastrointestinal hemorrhage	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Phantom shock	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Muscle strain	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Electromechanical dissociation	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Medical device complication	1	1 (0.2%)	0	0 (0.0%)	1	1 (0.2%)
Keloid scar	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Inappropriate device signal detection	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Implant site swelling	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Implant site rash	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Ventricular asystole	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Urinary retention postoperative	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Undersensing	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Thermal burn	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)

Event Description	Complications		Observations		Total	
	# Events	# Subjects	# Events	# Subjects	# Events	# Subjects
Tachycardia	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Implant site edema	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Body temperature increased	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Implant site cellulitis	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Hypoxia	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Puncture of periosteum	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Blood creatinine increased	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Pleuritic pain	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Fatigue	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Chest wall pain	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Periarthritis	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Extrasystoles	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Oxygen saturation decreased	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Chest pain	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Enteritis	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Non-cardiac chest pain	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Myalgia	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Musculoskeletal pain	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Limb discomfort	0	0 (0.0%)	1	1 (0.2%)	1	1 (0.2%)
Total	343	230 (37.0%)	265	196 (31.6%)	608	338 (54.4%)

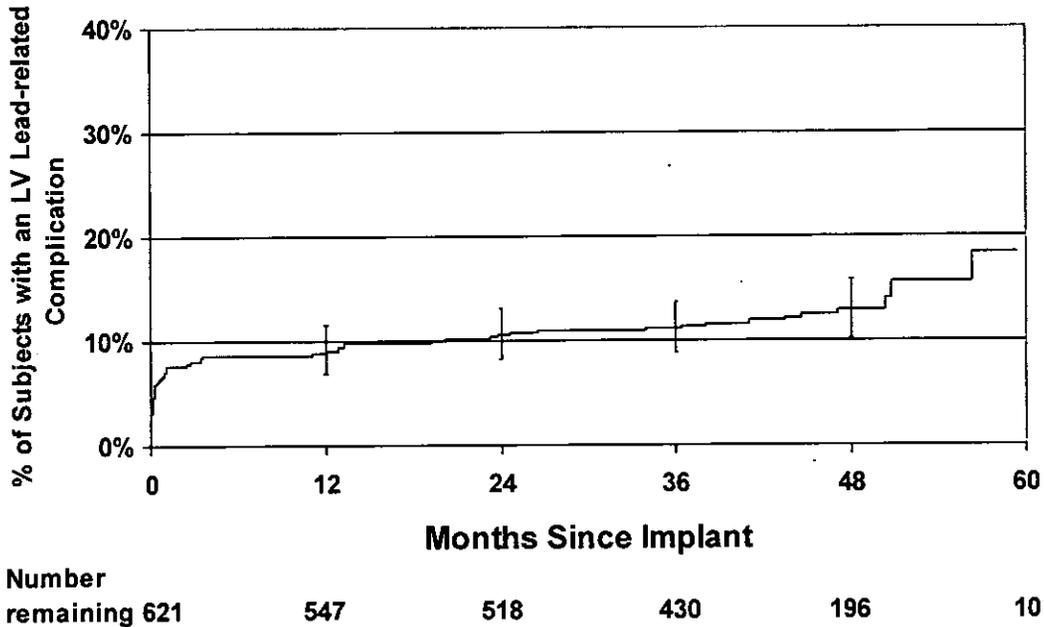
All subjects in the trial received a CRT-P or CRT-D device, depending on whether they were indicated for an ICD. Since the majority of REVERSE subjects were already indicated for an ICD⁴ at the time of enrollment (83%), the incremental risk for these subjects was the implantation of the LV lead and potential subsequent complications. All subjects in the trial received an LV lead, however the LV pacing feature was not activated for subjects in the CRT OFF group until the end of their randomization period (12 months in the U.S. and Canada, and 24 months in Europe).

Among the 621 subjects that were successfully implanted with the CRT system, 77 had a total of 92 LV lead-related complications after their successful implant. The two most common LV lead-related complications, accounting for 70% of these types of events, were LV lead dislodgement and diaphragmatic stimulation.

A Kaplan-Meier curve for the time to the first LV lead-related complication post-implant is shown in Figure 15 (all implanted subjects are included from their time of implant regardless of

randomization). The majority of these events occurred within 3 months post-implant, at which time the LV lead complication rate was 8.1% (95% confidence interval: 6.1-10.4%). At 12 months, the LV lead-related complication rate was 9.1% (95% confidence interval: 7.0-11.5%). At 24 months, the LV lead-related complication rate was 10.6% (95% confidence interval: 8.3-13.2%). At 48 months, the rate was 12.8% (95% confidence interval: 10.2-15.8%).

Figure 15: REVERSE Time to First Post-implant LV Lead-related Complication



E. Death Summary

During the randomized period, 19 deaths occurred in the study: 7 in the CRT OFF group (3.7%), and 12 in the CRT ON group (2.9%). All deaths were adjudicated by the Adverse Event Advisory Committee. Per the Clinical Investigation Plan, if insufficient information was available to classify a death as sudden cardiac, non-sudden cardiac, or non-cardiac, the death was classified as unknown.

The most common cause of death during the randomized period was progressive heart failure (4 of 19 deaths). At least 8 of the 19 (42.1%) deaths were from non-cardiac causes.

Death information for all randomized subjects who died prior to their 12-month follow-up (U.S. and Canada) or their 24-month follow-up (Europe) is summarized in Table 6.

Table 6: REVERSE Cause of Death Summary – Full Cohort

	CRT OFF (n=191)	CRT ON (n=419)	Total (n=610)
Non-cardiac	3 (43%)	5 (42%)	8 (42%)
Sudden cardiac	2 (29%)	4 (33%)	6 (32%)
Non-sudden cardiac, HF related	1 (14%)	3 (25%)	4 (21%)
Unknown	1 (14%)	0 (0%)	1 (5%)
Total	7 (100%)	12 (100%)	19 (100%)

F. REVERSE Study Conclusion

The purpose of the REVERSE study was to assess whether cardiac resynchronization therapy (CRT) in conjunction with optimal medical therapy (OMT) limited the progression of heart failure in subject clinical status as compared to OMT alone in subjects with asymptomatic or mild heart failure (NYHA Class I and II, Stage C), ventricular dyssynchrony (QRS \geq 120 ms), and reduced systolic left ventricular ejection fraction (LVEF \leq 40%).

The primary endpoint in REVERSE, which was to compare the Clinical Composite Response (CCR) percent worsened between subjects in the CRT OFF and CRT ON groups, was not met at the 12-month time point ($p=0.10$) for the full cohort. However, when the CCR is analyzed post-hoc using the conventional distribution of responses method, a difference in the distribution of the CCR between CRT OFF and CRT ON is observed in both the full cohort and expanded indication population, with more CRT ON subjects improving and less CRT ON subjects worsening.

For the prospectively powered secondary endpoint in REVERSE, cardiac resynchronization therapy was associated with a significant reduction in heart size as measured by LVESVi. In the full cohort, the CRT OFF subjects averaged a 1.6 ml/m² reduction in LVESVi over 12 months while the CRT ON subjects averaged an 18.2 ml/m² reduction.

Time to first HF hospitalization was compared (post hoc) between the CRT OFF and CRT ON groups as part of the secondary healthcare utilization objective. A reduction in HF hospitalizations was observed with active CRT.

In addition, a post-hoc analysis of the composite endpoint of time to first heart failure hospitalization or all-cause death was performed for the REVERSE full cohort to align with other CRT trials, including RAFT. In both the full cohort and expanded indication population in REVERSE, cardiac resynchronization therapy was associated with a reduction in the risk of heart failure hospitalization or all-cause death during the randomized period.

Most subjects in REVERSE (83%) received a CRT-D system. The incremental risk for these ICD-indicated subjects is associated with the implantation the LV lead and potential subsequent complications. In the REVERSE full cohort, the LV lead complication rate was 9.1% at 12 months post-implant. The majority of these events occurred within 3 months post-implant, at which time the rate was 8.1%.

II. RAFT Study

A. Study Scope, Design and Methods

The RAFT study was a prospective, randomized, double-blind, multi-center, global post-market clinical study conducted in Canada, Europe, Turkey and Australia. The study was designed to determine whether biventricular pacing with an ICD (CRT-D) plus optimal medical therapy (OMT) reduces total mortality and heart failure hospitalizations as compared to ICD plus OMT, in subjects with mild to moderate heart failure (New York Heart Association (NYHA) Functional Class II and III), ventricular dyssynchrony (intrinsic QRS ≥ 120 ms), and reduced systolic left ventricular ejection fraction (LVEF $\leq 30\%$).

Enrolled subjects were randomized in a 1:1 fashion to either CRT-D or ICD arms. All subjects received commercially available Medtronic devices and commercially available leads. Subjects were followed for a minimum of 18 months and remained blinded for the duration of the study.

Initially, RAFT allowed enrollment of both NYHA Class II and III subjects. In 2005, the CARE-HF trial results were published,¹² which showed that patients with NYHA Class III or IV, reduced LVEF and ventricular dyssynchrony had significant morbidity and mortality benefits associated with CRT. This led to published guidelines (ACC/AHA; HFSA; Canadian Cardiovascular Society/ESC) recommending CRT pacing for that patient population.^{1,13,14} Because of this, the RAFT study design was updated to enroll only NYHA Class II subjects thereafter. The NYHA Class III patients already enrolled continued to be followed for the duration of the trial.

B. Subject Selection

Subjects were considered enrolled subsequent to signing the study informed consent document and the site contacting the RAFT Coordinating Center for randomization assignment. Subjects of both genders who satisfied all inclusion and did not meet any exclusion criteria were eligible for this clinical study.

Inclusion Criteria

- NYHA Class II or III¹
- LVEF $\leq 30\%$ by MUGA/catheterization OR LVEF $\leq 30\%$ and LV end diastolic dimension ≥ 60 mm (by echocardiogram) within 6 months prior to randomization
- Intrinsic QRS duration ≥ 120 ms OR paced QRS measurement ≥ 200 ms
- ICD indication for primary or secondary prevention¹⁵
- Optimal heart failure pharmacological therapy (defined later in this section)
- Normal sinus rhythm OR chronic persistent atrial tachyarrhythmia with resting ventricular heart rate ≤ 60 bpm and 6-minute hall walk ventricular heart rate of ≤ 90 bpm OR chronic persistent atrial tachyarrhythmia with resting ventricular heart rate > 60 bpm and 6-minute hall walk ventricular heart rate of > 90 bpm and booked for atrioventricular junction ablation

¹ This was changed in protocol version 4, dated February 28, 2006 to only allow NYHA Class II patients to be enrolled moving forward.

Exclusion Criteria

- Intravenous inotropic agent in the last four days
- Patients with a life expectancy of less than one year from non-cardiac cause
- Expected to undergo cardiac transplantation within one year (status I)
- Patients with an acute coronary syndrome including MI² can be included if the patient has had a previous MI with LV dysfunction (LVEF \leq 30%)
- In-hospital patients who have acute cardiac or non-cardiac illness that requires intensive care
- Uncorrected or uncorrectable primary valvular disease.
- Restrictive, hypertrophic or reversible form of cardiomyopathy
- Severe primary pulmonary disease such as cor pulmonale
- Tricuspid prosthetic valve
- Patients with an existing ICD (patients with an existing pacemaker may be included if the patients satisfies all other inclusion/exclusion criteria)
- Coronary revascularization (coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI)) < 1 month if previously determined LVEF > 30% (patients with a more recent revascularization can be included if a previous determined LVEF was \leq 30%)
- Patients included in other clinical trial that will affect the objectives of this study
- History of noncompliance of medical therapy
- Unable or unwilling to provide informed consent

All subjects were required to receive optimal medical therapy for 6 weeks prior to enrollment. This was defined to be:

- ACE Inhibitor / ARB: All patients were to receive ACE inhibitor whenever possible, limited by symptomatic hypotension, renal dysfunction, cough, allergic reaction, or significant other side effect. A target dosage of enalapril 10 – 20 mg bid (or equivalent ACE inhibitor and dosage) was recommended. For patients unable to tolerate ACE inhibitor, an ARB or a hydralazine/nitrate combination was expected.
- Beta-blocker: All patients were to receive a beta-blocker whenever possible, limited by symptomatic bradycardia, allergic reaction, or significant side effect. A target dosage of metoprolol 75 mg BID, carvedilol 25 mg BID, or bisoprolol 10 mg OD was recommended unless limited by symptomatic bradycardia or hypotension, pulmonary wheeze, allergic reaction, or significant other side effect.
- Digoxin: Digoxin was allowed at the discretion of the treating physician.
- Nitrates: Any formulation of nitrates could be used for heart failure symptom control.
- Diuretic: Diuretics could be added or reduced according to patient's symptoms.
- Amiodarone: Amiodarone was allowed for the treatment of symptomatic atrial arrhythmias. Amiodarone was not to be started for asymptomatic or minimally symptomatic PVC or non-sustained VT.

² Definition of MI (myocardial infarction) requires 2 of 3 following criteria: (1) symptoms of chest pain; (2) cardiac enzymes elevation TNT or TNI or CKMB>1.5X; (3) ECG changes.

- Other anti-arrhythmic medications: Amiodarone was expected to be the drug of choice if anti-arrhythmic drug is necessary. In the event that a patient required an anti-arrhythmic drug and was intolerant to or had significant side effects from amiodarone, another anti-arrhythmic drug could be chosen at the discretion of the treating physician.
- Anti-coagulant: Anticoagulants could be prescribed as clinically indicated.

Heart failure medication was allowed to be adjusted post-randomization during the study as indicated with the intention to provide optimal medical care for each patient. Up-titration of heart failure medications, especially beta-blockers and ACE inhibitors, was encouraged as this trial tested optimal therapy including device support for drug dosing. It was understood that drug imbalance would occur, but the result of the trial would be more applicable to the reality of heart failure patient care. Down-titration of heart failure medication was discouraged.

Amiodarone was allowed to be used for symptomatic ventricular arrhythmias developed after a subject's enrollment into the study, or frequent ICD shocks due to atrial or ventricular arrhythmias.

C. Results

The first RAFT subject was enrolled on January 13, 2003. A total of 1798 subjects signed an informed consent form at 34 clinical study centers. Enrollment was completed on February 27, 2009. Nine hundred and four (904) subjects were randomized to the ICD arm, and 894 were randomized to the CRT-D arm. There were 11 subjects that did not have a device implanted, although these subjects continued to be followed. The 1798 randomized subjects were followed for a mean of 40 ± 20 months.

The results included in this clinical summary include RAFT subject data that occurred on or before September 15, 2010. Updates to the database were allowed until the final database freeze, which was utilized for the REVERSE PMA submission, on November 12, 2010. Following the database freeze, adverse events continued to be adjudicated and an updated data set was provided to the FDA. The final adjudicated data is presented in the adverse events section of this clinical summary manual.

Subject Demographics

Baseline demographic data for the 1798 randomized subjects are provided in Table 7 below.

Table 7: RAFT Baseline Demographics – Full Cohort

Subject Characteristic	ICD (n= 904)	CRT-D (n= 894)
Male	81% (732)	85% (758)
Age (years)	66.2 ± 9.4	66.1 ± 9.3
LVEF (%)	22.6 ± 5.1	22.6 ± 5.4
QRS Duration (ms)	158 ± 24	157 ± 24

Subject Characteristic	ICD (n= 904)	CRT-D (n= 894)
QRS Morphology Type		
RBBB	10% (93)	8% (68)
LBBB	71% (643)	73% (652)
NIVCD	11% (101)	12% (106)
Ventricular paced	7% (67)	8% (68)
Ischemic	65% (587)	69% (614)
Diabetes	34.6% (313)	32.8% (293)
Hypertension	397 (43.9%)	402 (45.0%)
NYHA Classification		
Class II	81% (730)	79% (708)
Class III	19% (174)	21% (186)
Beta blocker	89% (805)	90% (808)
ACE-I/ARB	97% (878)	96% (859)
Diuretic	756 (84%)	85% (757)

Baseline demographics for the expanded indication population from RAFT, which comprise 47% of the RAFT full cohort, are presented in Table 8.

Table 8: RAFT Baseline Demographics - Expanded Indication Population

Subject Characteristic	ICD (n= 425)	CRT-D (n= 425)
Male	80% (338)	83% (354)
Age (years)	64.8 ± 9.1	65.0 ± 9.6
LVEF (%)	22.6 ± 5.2	22.4 ± 5.3
QRS duration (ms)	166 ± 22	164 ± 22
QRS Morphology Type		
RBBB	0% (0)	0% (0)
LBBB	100% (425)	100% (425)
NIVCD	0% (0)	0% (0)
Ventricular paced	0% (0)	0% (0)
Ischemic	56% (238)	62% (262)
Diabetes	32% (135)	30% (129)
Hypertension	44% (185)	47% (198)
NYHA Classification		
Class II	100% (425)	100% (425)
Class III	0% (0)	0% (0)
Beta blocker	90% (384)	93% (394)
ACE-I/ARB	98% (415)	96% (407)
Diuretics	81% (344)	81% (346)

Primary Objective

The primary objective of the RAFT study was to compare time to first heart failure (HF) hospitalization or all-cause death between the ICD and CRT-D groups. An HF hospitalization was defined as an admission to a healthcare facility lasting more than 24 hours with symptoms of congestive heart failure and subsequent treatment for heart failure that was adjudicated by the Event Committee as heart failure exacerbation.

The primary endpoint for the study was time to first HF hospitalization or all-cause death. All hospitalizations greater than 24 hours were adjudicated by the blinded Adjudication Committee to be either heart failure related or not heart failure related. The time to the first HF hospitalization or all-cause death for all randomized subjects is shown in Figure 16. The primary outcome occurred in 364 of 904 subjects (40.3%) in the ICD group and 297 of 894 subjects (33.2%) in the CRT-D group. The hazard ratio was 0.75 in favor of CRT-D, which was statistically significant (p adjusted for interim analysis=0.014). At 5 years, the observed rates were 51.3% in the ICD group and 42.4% in the CRT-D group.

Figure 16: RAFT Time to First HF Hospitalization or All-cause Death – Full Cohort

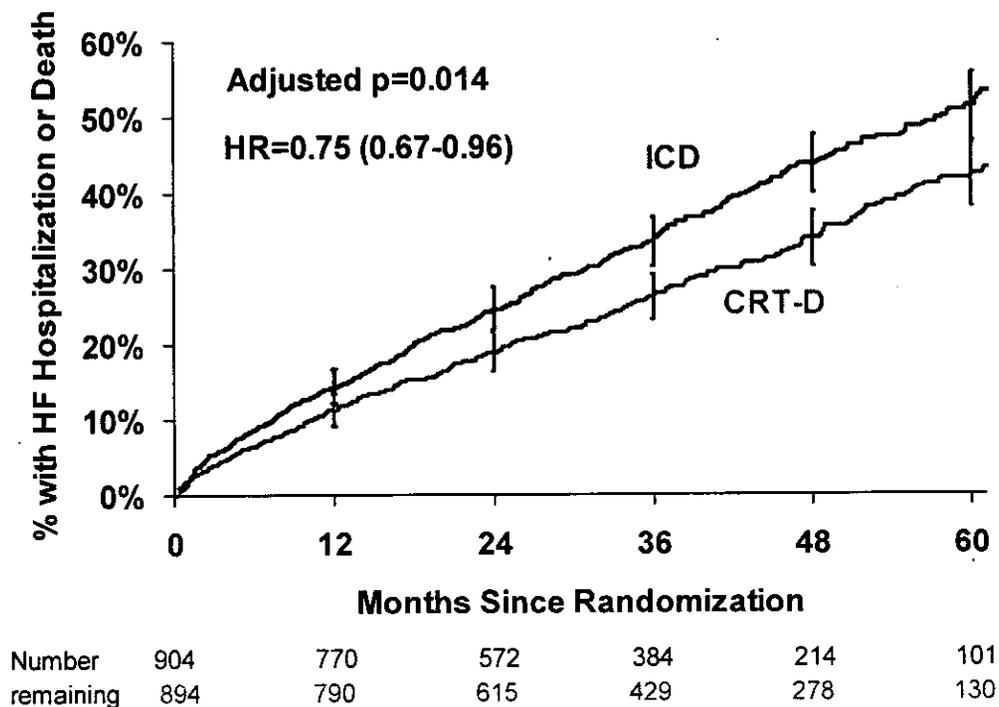
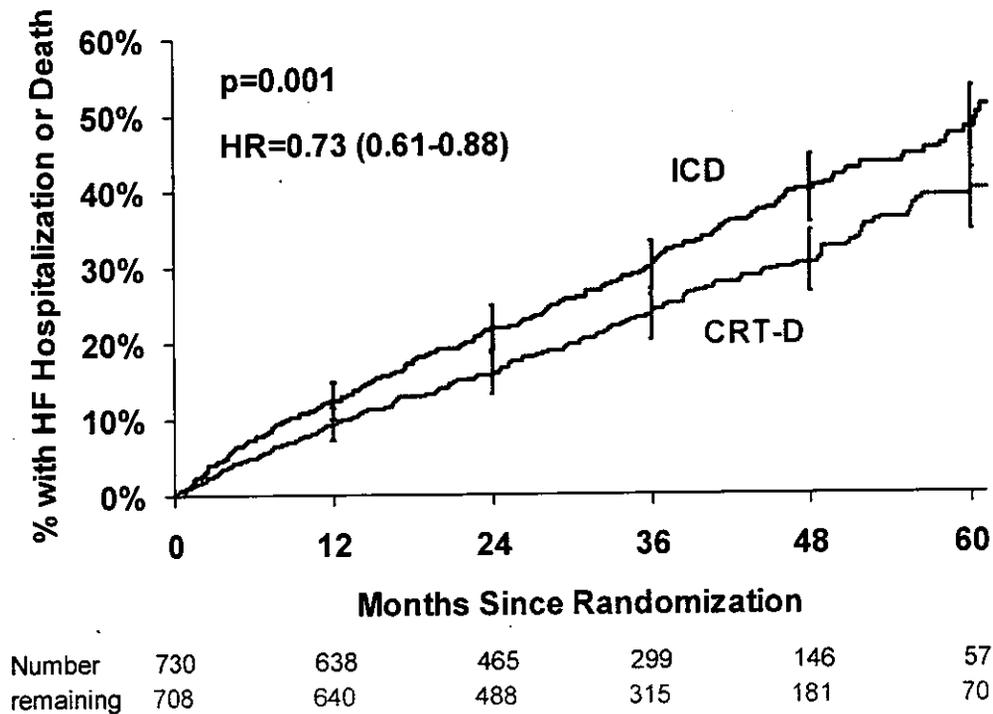


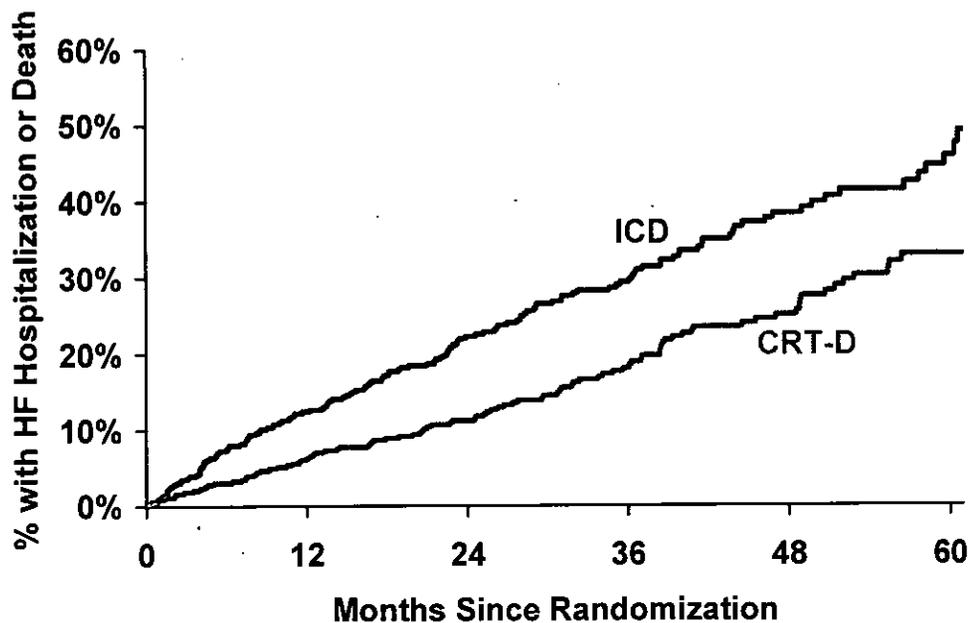
Figure 17 shows the time to the first HF hospitalization or all-cause death for the pre-specified NYHA Class II subgroup. The primary outcome for the NYHA Class II subjects occurred in 253 of 730 subjects (34.7%) in the ICD group and 193 of 708 (27.3%) in the CRT-D group. The hazard ratio was 0.73 in favor of CRT-D, which was statistically significant ($p=0.001$). At 5 years, the rates were 48.1% in the ICD group and 40.0% in the CRT-D group.

Figure 17: RAFT Time to First Heart Failure Hospitalization or All-cause Death - NYHA Class II Cohort



The primary endpoint was also analyzed for the expanded indication population (Figure 18). There was an observed 42% reduction in this endpoint with CRT-D. The estimated rate of HF hospitalization or all-cause death 4 years post-implant is 38.4% in the ICD group and 25.1% in the CRT-D group.

Figure 18: RAFT Time to First HF Hospitalization or All-cause Death – Expanded Indication Population



Number	425	372	269	176	89	35
remaining	425	399	312	207	122	47

Secondary Objectives

Total Mortality

A secondary objective for the study was to compare time to all-cause death between the ICD and CRT-D groups.

Figure 19 shows the time to all-cause death for all randomized subjects. During the study, 236 of 904 (26.1%) ICD subjects died, and 186 of 894 (20.8%) CRT-D subjects died. The hazard ratio was 0.75 in favor of CRT-D, which was statistically significant ($p=0.003$). At 5 years, the mortality rates were 34.6% in the ICD group and 28.6% in the CRT-D group.

Figure 19: RAFT Mortality – Full Cohort

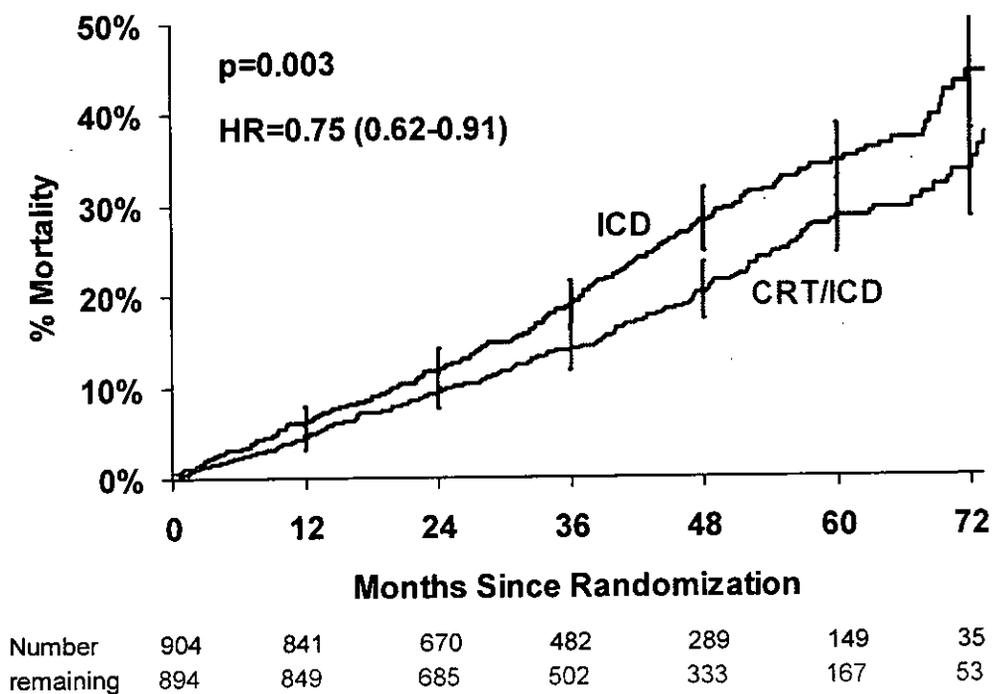
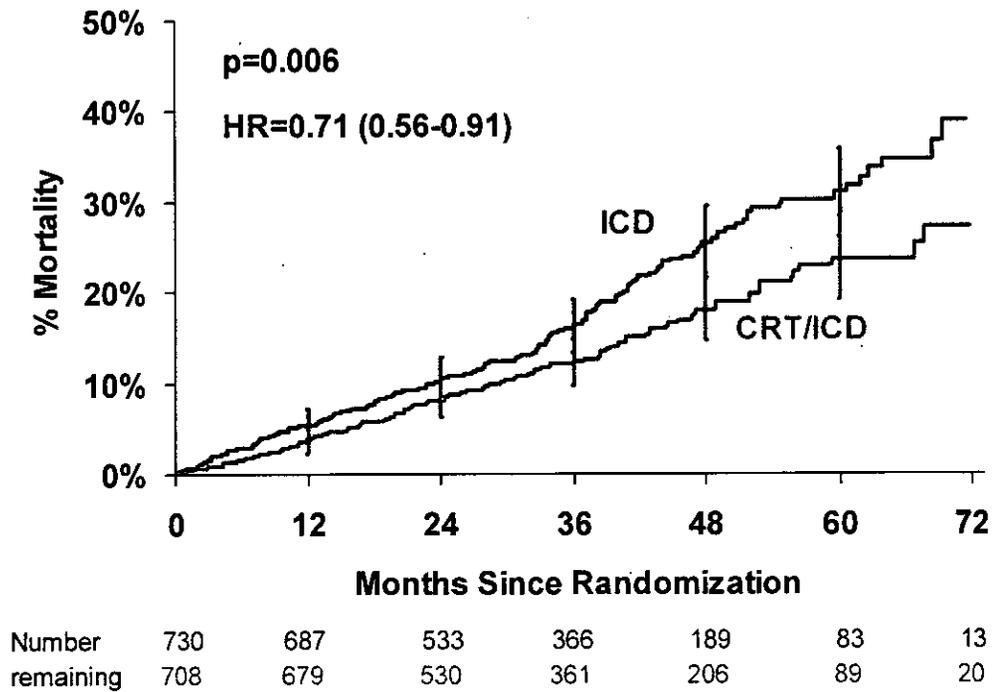


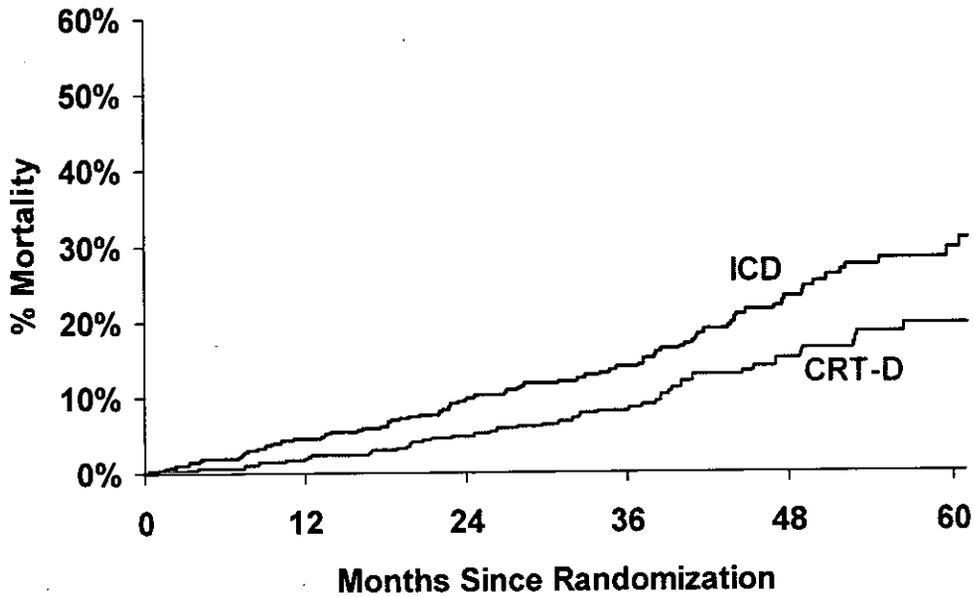
Figure 20 shows the time to all-cause death for the pre-specified NYHA Class II subgroup. Of the 730 NYHA Class II subjects in the ICD group, 154 (21.1%) of them died, while in the CRT-D group, 110 of 708 (15.5%) died. The hazard ratio was 0.71 in favor of CRT-D. These differences were statistically significant ($p=0.006$). At 5 years, the mortality rates were 31.0% in the NYHA Class II ICD group, and 23.7% in the NYHA Class II CRT-D group.

Figure 20: RAFT Mortality - NYHA Class II Cohort



Total mortality was also analyzed for the expanded indication population (Figure 21). There was an observed 42% reduction in death with CRT-D. The estimated mortality rate 4 years post-implant is 23.2% in the ICD group and 14.9% in the CRT-D group.

Figure 21: RAFT Mortality - Expanded Indication Population



Number	425	405	315	224	117	52
remaining	425	418	333	232	135	55

Time to First Heart Failure Hospitalization

An additional secondary objective for the study was to compare time to first HF hospitalization between the ICD and CRT-D groups.

The time to first HF hospitalization for all randomized subjects is shown in as shown in Figure 22. In the full cohort, 410 subjects were hospitalized for HF at least once (22.8%) over the course of the study. Hospitalization for HF occurred in 236 of 904 subjects (26.1%) in the ICD group and 174 of 894 (19.5%) in the CRT-D group. The hazard ratio was 0.68 in favor of CRT-D ($p < 0.0001$). At 5 years, the HF hospitalization rates were 36.6% in the ICD group and 26.8% in the CRT-D group.

Figure 22: RAFT Time to First HF Hospitalization – Full Cohort

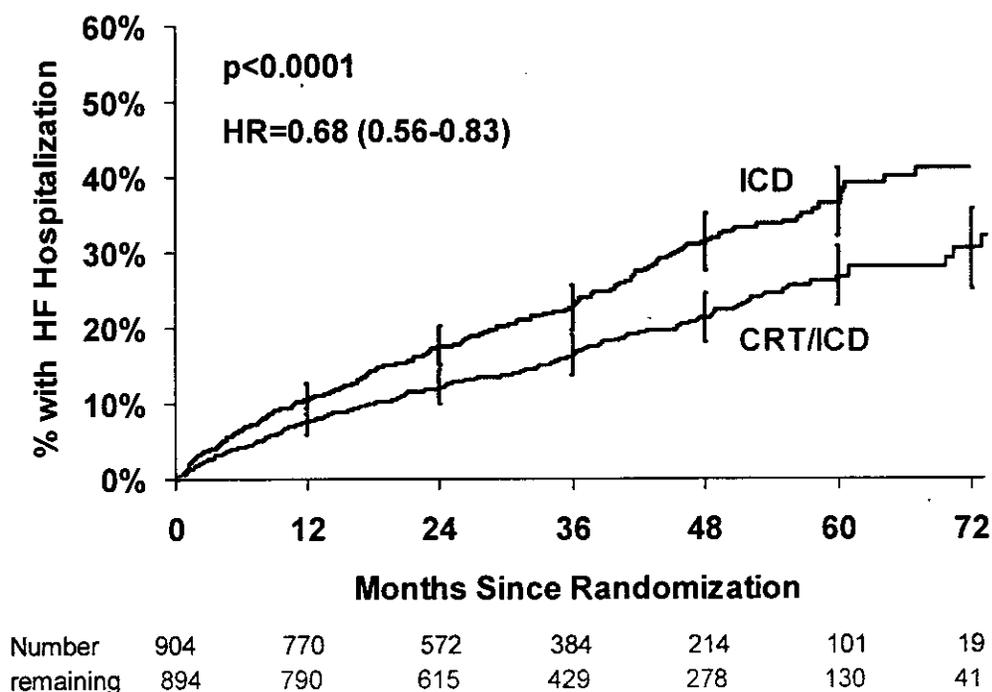
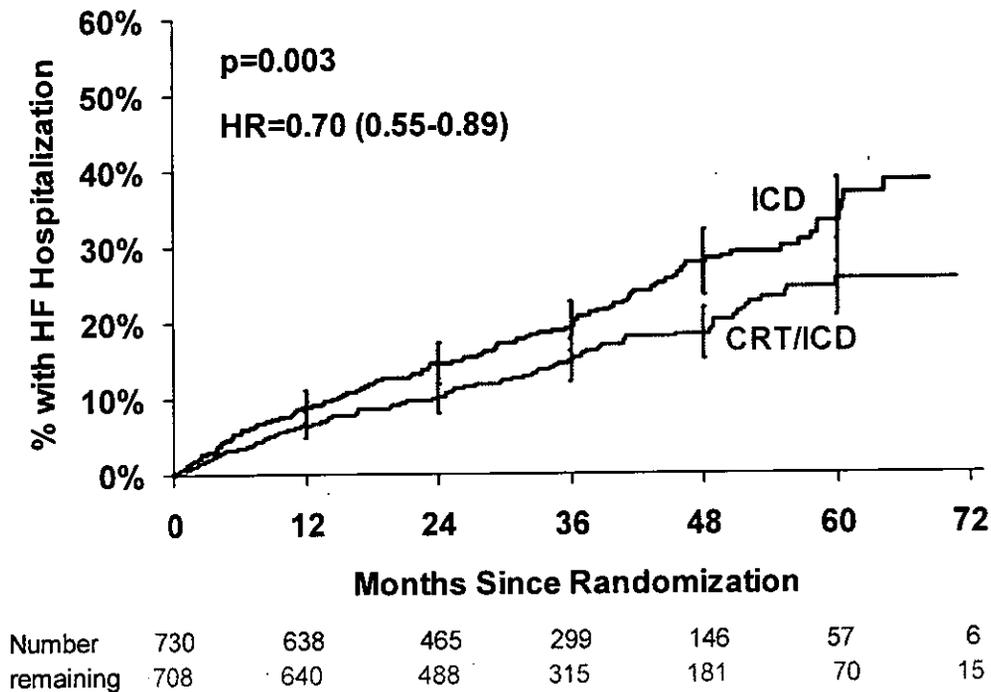


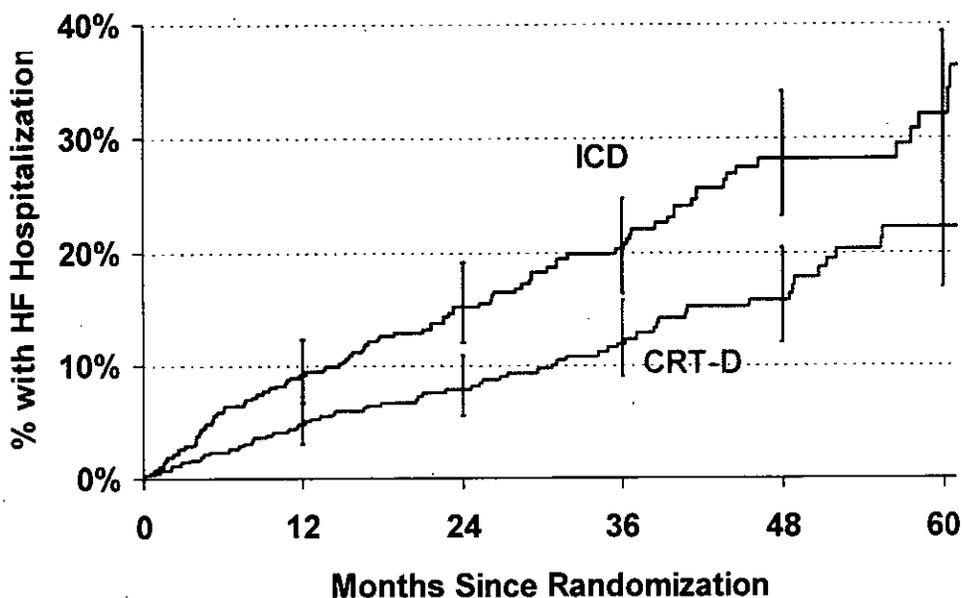
Figure 23 shows the time to first HF hospitalization for the pre-specified NYHA Class II subgroup. Of the 1438 NYHA Class II subjects, 274 experienced at least one HF hospitalization (19.1%). Hospitalization for HF occurred in 159 of 730 subjects (21.8%) in the ICD group and 115 of 708 (16.2%) in the CRT-D group. The hazard ratio was 0.70 in favor of CRT-D ($p=0.003$). At 5 years, the HF hospitalization rates were 33.3% in the NYHA Class II ICD group and 25.7% in the NYHA Class II CRT-D group.

Figure 23: RAFT Time to First HF Hospitalization - NYHA Class II Cohort



The time to first HF hospitalization was also analyzed for the expanded indication population (Figure 24). As with the full and NYHA Class II cohorts, a reduction in the risk of HF hospitalization was observed with CRT-D.

Figure 24: RAFT Time to First HF Hospitalization – Expanded Indication Population (post-hoc analysis)



Number	425	372	269	176	89	35
remaining	425	399	312	207	122	47

Subgroup Analyses

Analyses were performed for the following subgroups: age, gender, underlying heart disease type, QRS duration, LVEF, QRS morphology, atrial rhythm, diabetes, hypertension, and estimated glomerular filtration rate (eGFR).

Subgroup analyses performed for the RAFT NYHA Class II cohort for time to first HF hospitalization or all-cause death and total mortality are summarized below in Figure 25 and Figure 27. Lines represent 95% confidence intervals, which should be interpreted with the understanding that no subgroup was powered to see a difference between ICD and CRT-D. In addition, post-hoc subgroup analyses of QRS duration evaluated as a continuous variable, along with categorical analysis in groups of 10 ms (120-129, 130-139, etc.) are presented in Figure 26 and Figure 28.

Figure 25: RAFT Time to First HF Hospitalization or All-cause Death Subgroup Analysis - NYHA Class II Cohort (post-hoc analysis)

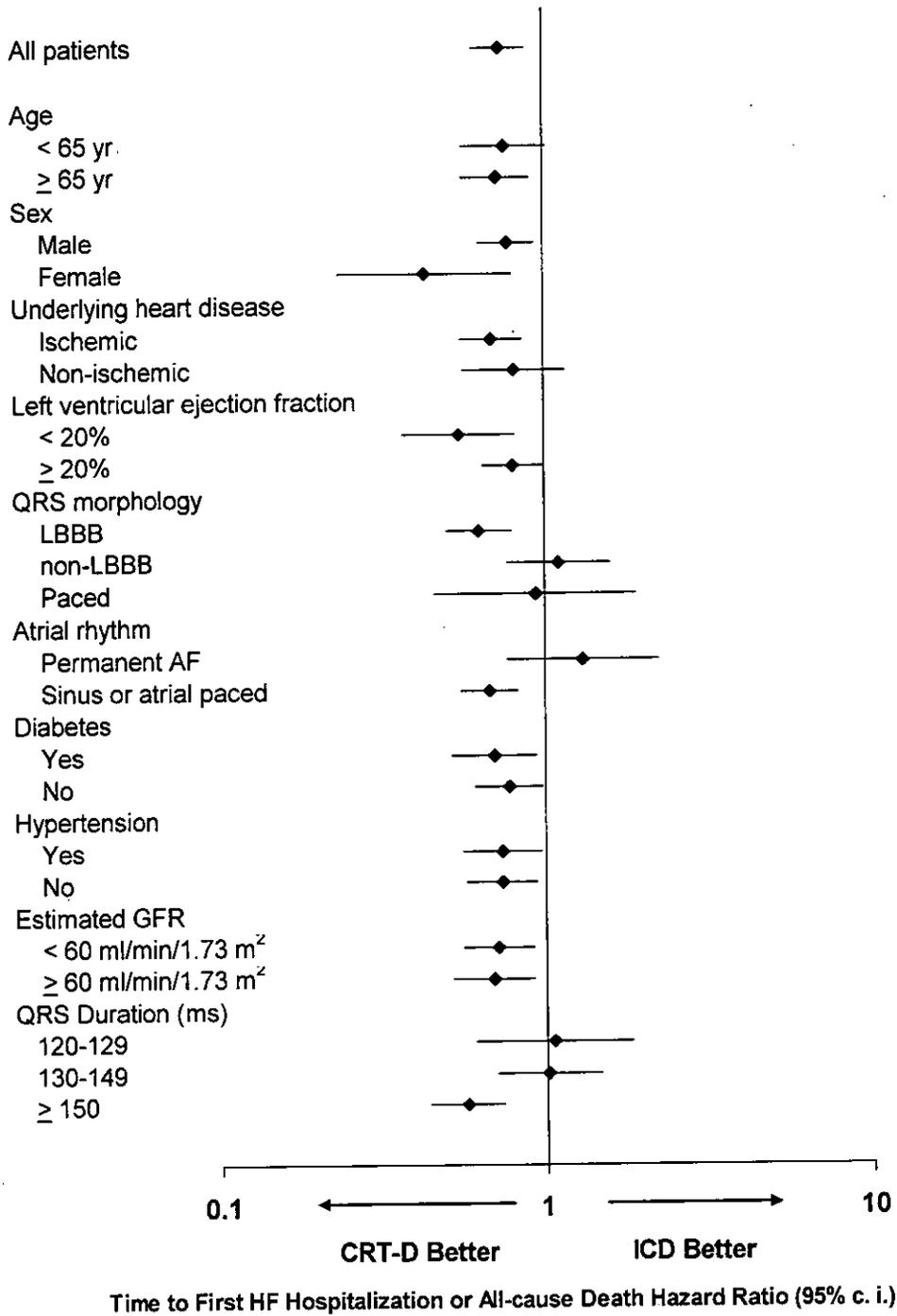


Figure 26: RAFT Time to First HF Hospitalization or All-cause Death: QRS Duration Odds Ratio - NYHA Class II Cohort (post-hoc analysis)

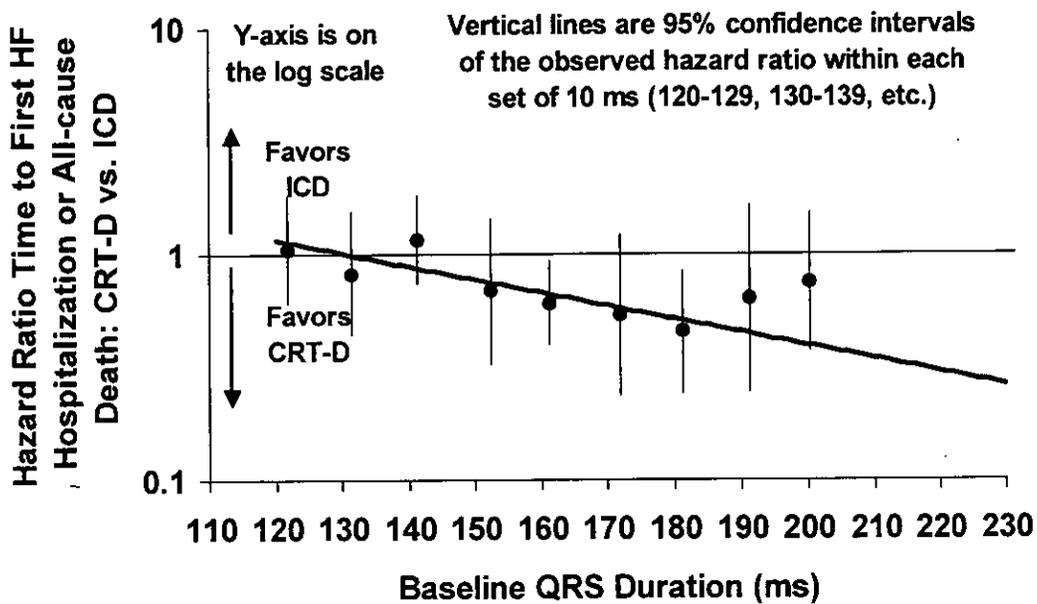


Figure 27: RAFT Mortality Subgroup Analysis - NYHA Class II Cohort (post-hoc analysis)

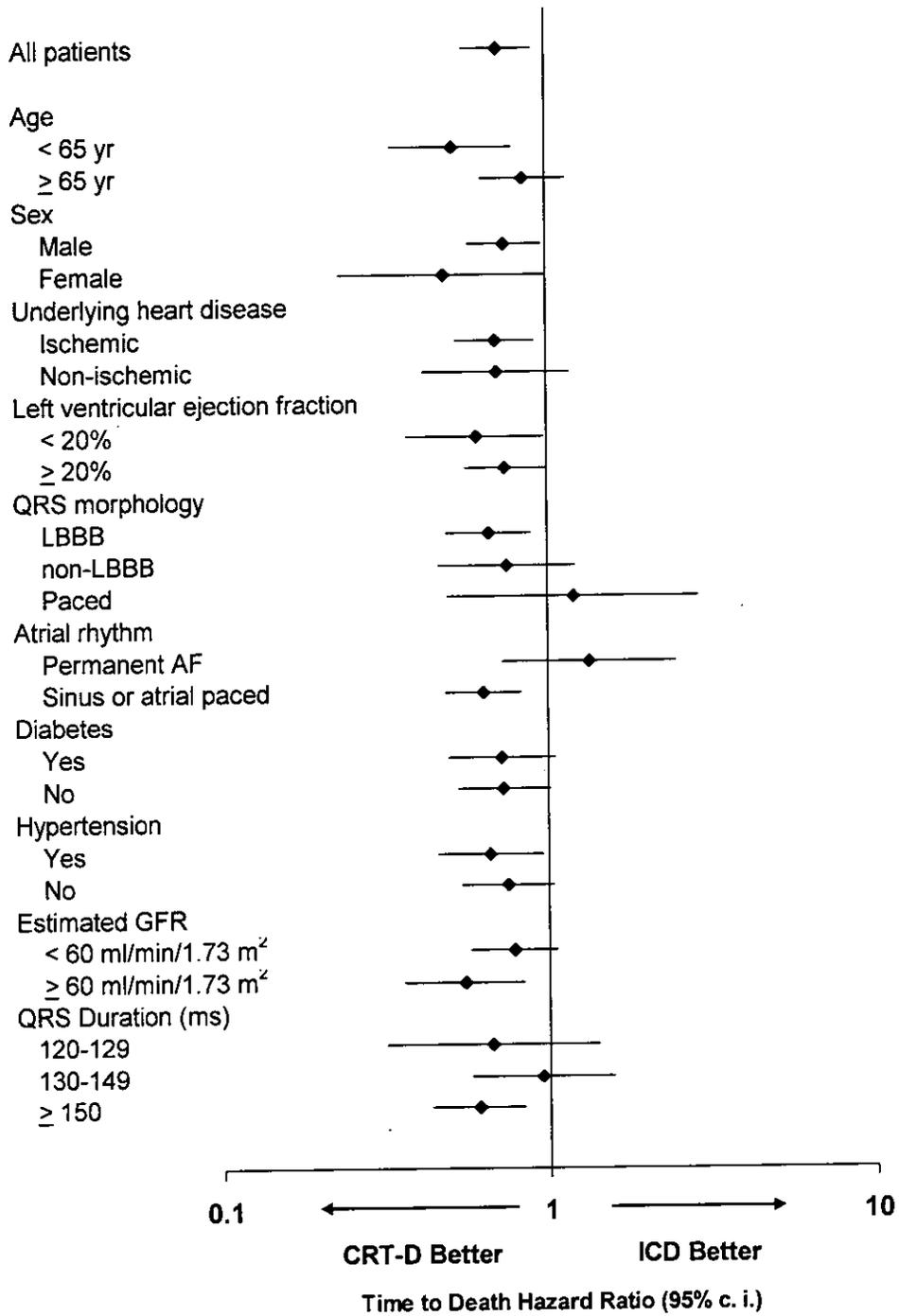
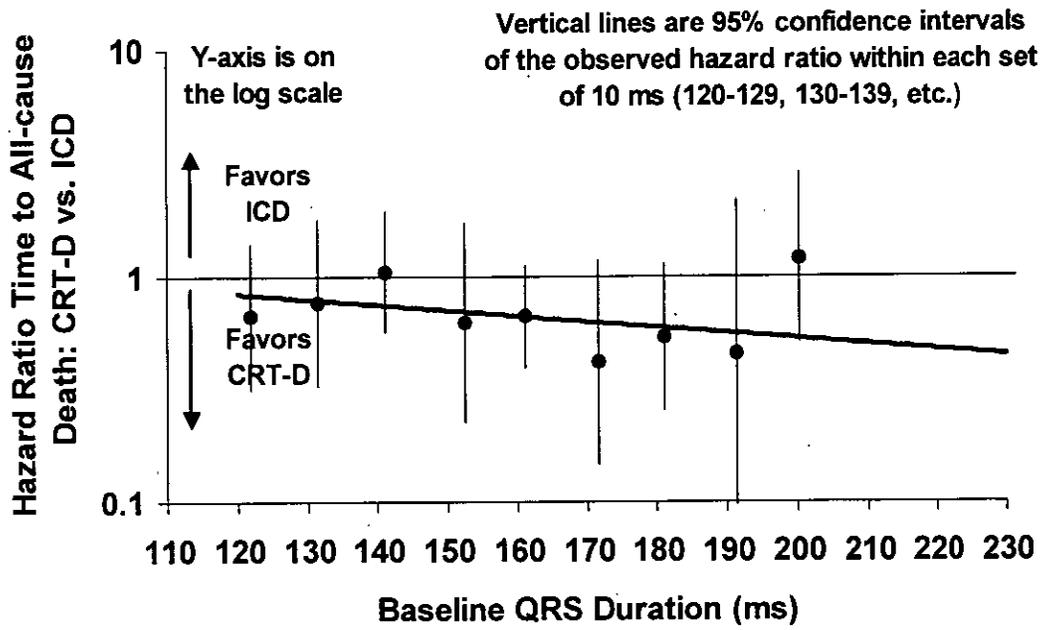
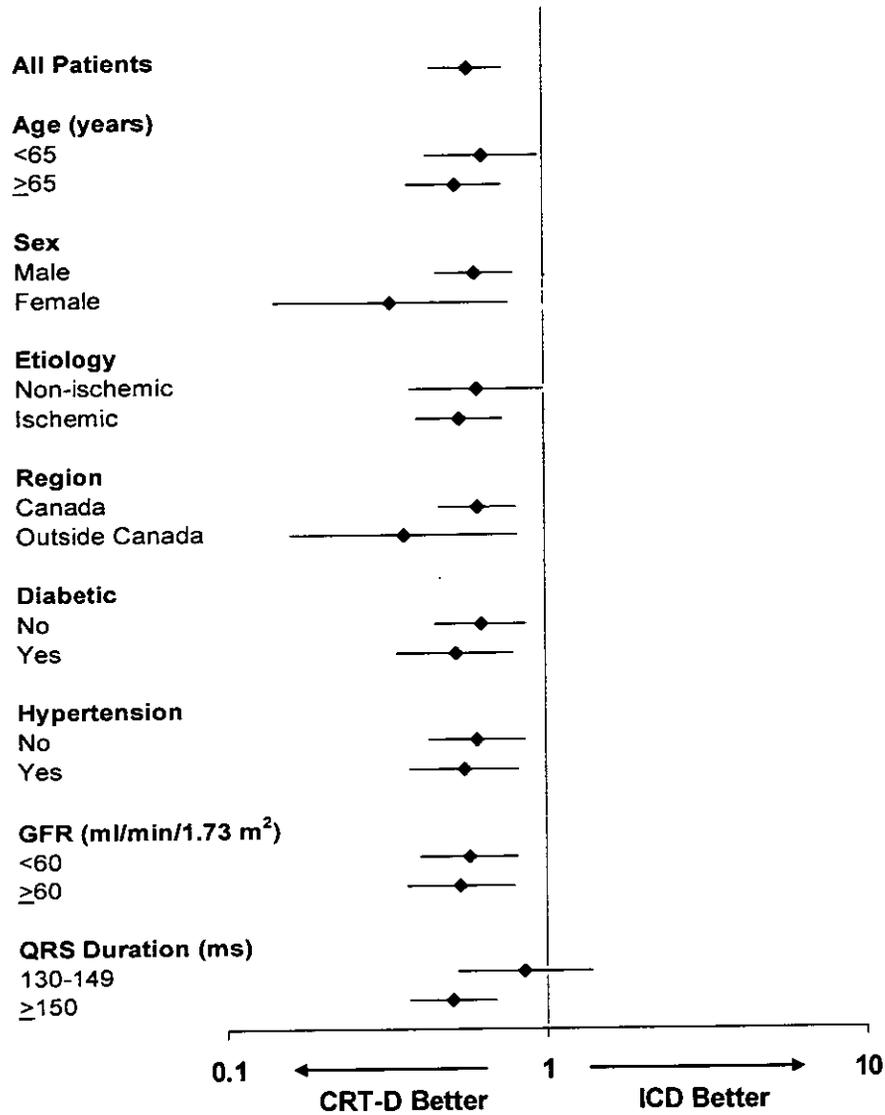


Figure 28: RAFT Mortality: QRS Duration Odds Ratio - NYHA Class II Cohort (post-hoc analysis)



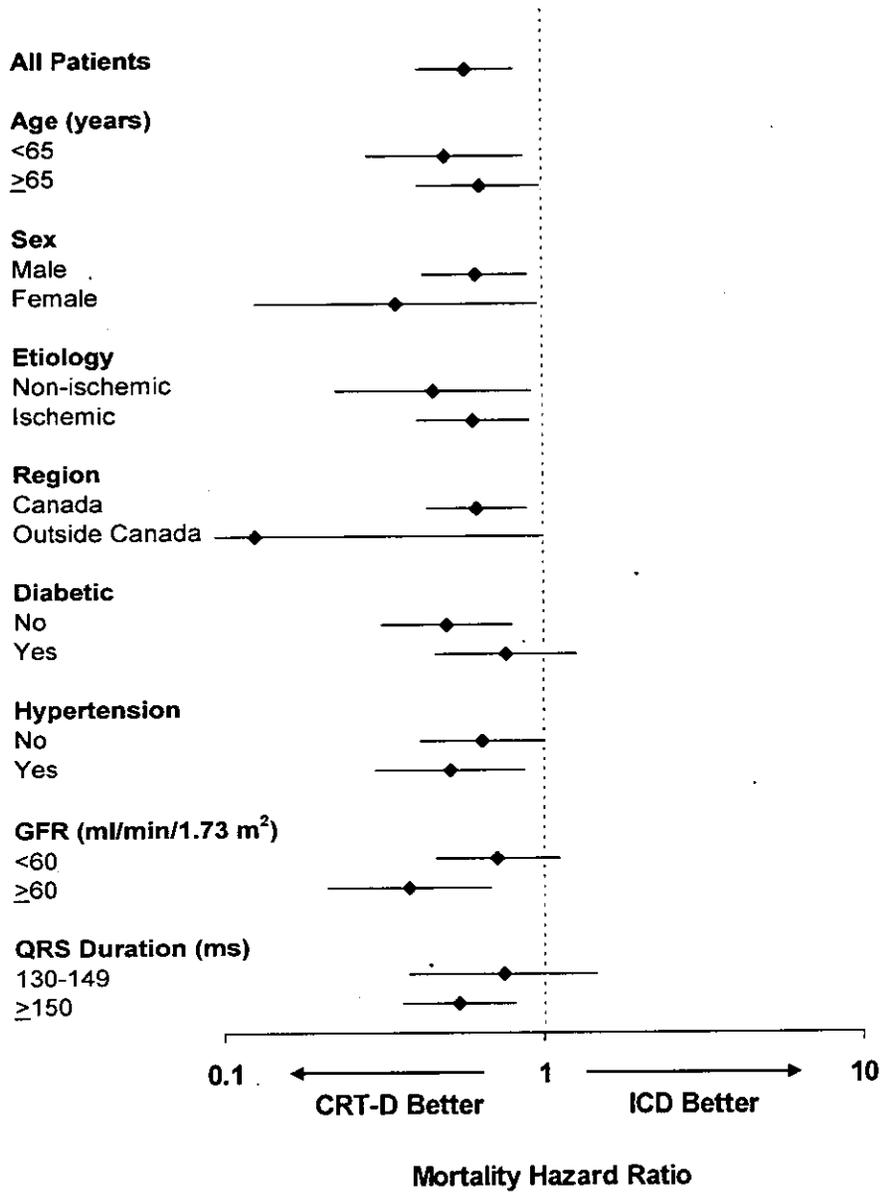
Subgroup analyses for time to first HF hospitalization or death as well as for total mortality were also performed for the expanded indication population, as summarized in Figure 29 and Figure 30. Lines represent 95% confidence intervals, which should be interpreted with the understanding that no subgroup was powered to see a difference between ICD and CRT-D.

Figure 29: RAFT Time to First HF Hospitalization or All-cause Death Subgroup Analysis - Expanded Indication Population (post-hoc analysis)



Time to First HF Hospitalization or All-cause Death Hazard Ratio

Figure 30: RAFT Mortality Subgroup Analysis - Expanded Indication Population (post-hoc analysis)



Gender Analysis

Per FDA request, additional subgroup analyses were performed by gender. In RAFT, both men and women demonstrated improvement with CRT-D over ICD. There was no significant difference in results for the primary endpoint, time to first heart failure hospitalization or all-cause death.

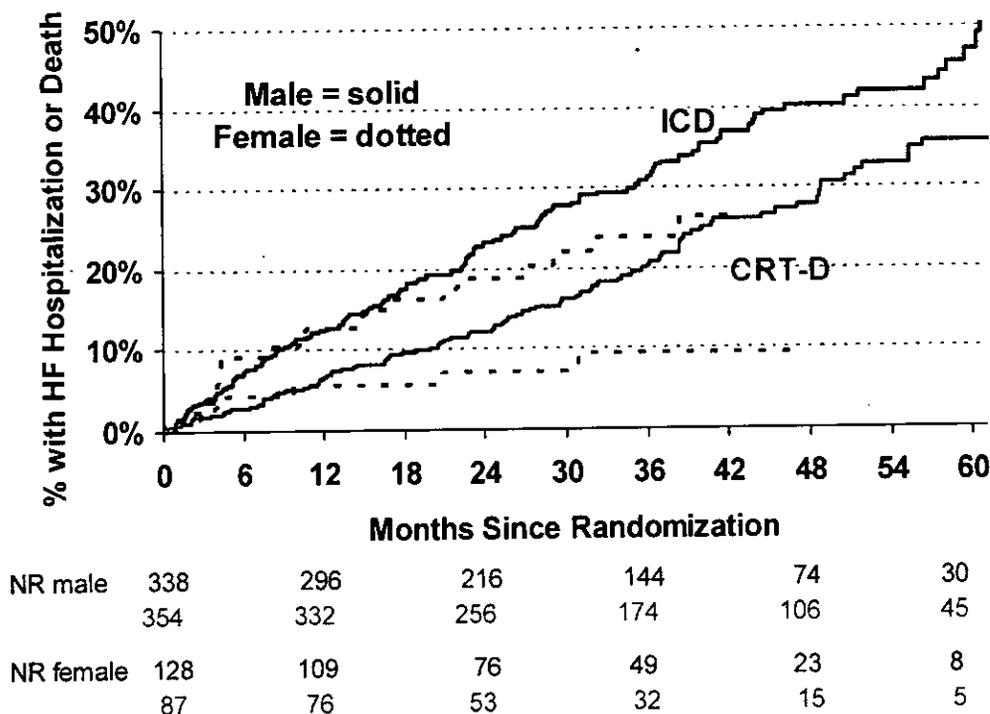
The proportion of female subjects enrolled in RAFT is lower than the gender-specific incidence or prevalence of heart failure in this patient population, however similar to what has been observed in other trials of CRT.¹¹ In the RAFT NYHA Class II cohort, 84% of subjects were male and 16% were female, and in the expanded indication population, 81% were male and 19% were female.

Analyses by gender for the RAFT expanded indication population are presented below for the primary endpoint of time to first HF hospitalization or all-cause death, and for the secondary endpoint of mortality. P-values comparing male and female results are from the interaction term of Cox proportional hazards models. Terms fit in the models were randomization, gender, and their interaction.

Primary Endpoint

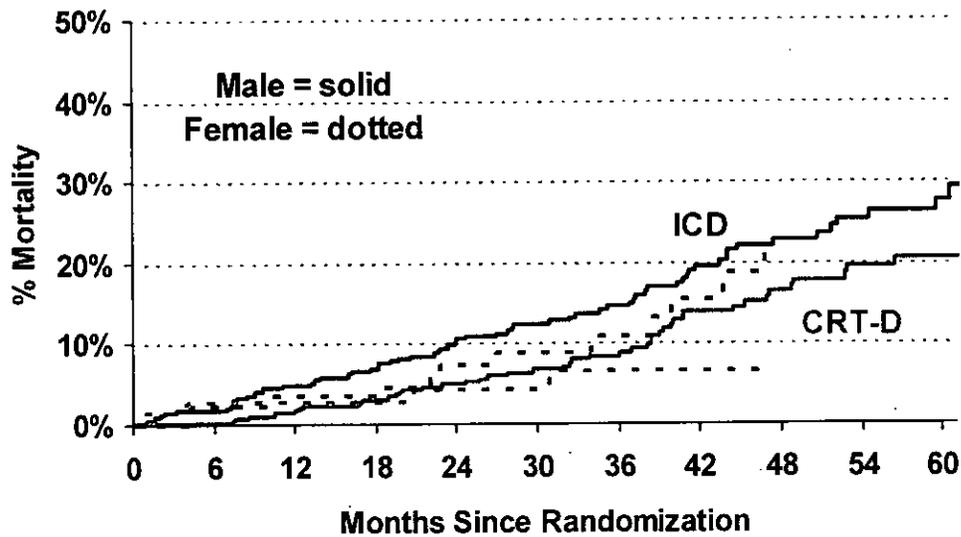
The primary endpoint results by gender for the expanded indication population are presented in Figure 31. There is no evidence of differences in CRT-D vs. ICD results between males and females ($p=0.16$). Both males and females showed improvement with CRT-D. Males had a hazard ratio of 0.61 (39% reduction in HF hospitalization or death), while females had a 0.33 hazard ratio.

Figure 31: RAFT Time to First HF Hospitalization or All-cause Death by Gender - Expanded Indication Population



Mortality results for the expanded indication population by gender can be seen in Figure 32. There is no evidence of differences in CRT-D vs. ICD results between males and females ($p=0.33$). Both males and females showed improvement with CRT-D. Males had a hazard ratio of 0.62 (38% reduction in mortality), while females had a 0.35 hazard ratio.

Figure 32: RAFT Mortality by Gender - Expanded Indication Population



NR male	338	321	253	183	99	47
	354	349	276	198	118	53
NR female	87	84	62	41	18	5
	71	69	57	34	17	2

D. Adverse Events Summary

Procedure and system-related complications were collected at implant and each follow-up visit for the RAFT study. These complications were reviewed at DSMB meetings to ensure subject safety and adjudicated by a blinded Event Committee. No specific objective was pre-specified surrounding adverse events.

A summary of all procedure or system-related complications occurring in the study is presented in Table 9, which is sorted in descending order based on the total number of events. Of the 1798 randomized subjects, 1787 had an attempted device implant and accrued 5974 years of follow-up (ICD: $n=899$, 2923 years; CRT-D: $n=888$, 3051 years). During the study, 894 procedure or system-related complications were reported in 583 subjects.

In the ICD group, 24.9% of the subjects had at least one procedure or system-related complication during the study, and 40.4% of the subjects in the CRT-D group reported at least one. Much of the difference was due to expected battery depletion and subsequent device replacement in the CRT-D group. In the first 30 days post implant, 6.0% of the subjects in the ICD group had a procedure or system-related complication, compared to 11.7% of the subjects in the CRT-D group.

Table 9: RAFT Procedure or System-related Complications

Key Term	All subjects n = 1787		ICD group n = 899		CRT-D group n = 888	
	Years of follow-up = 5974.0	# AEs # AEs within 30 days of implant	Years of follow-up = 2922.9	# AEs # AEs within 30 days of implant	Years of follow-up = 3051.1	# AEs # AEs within 30 days of implant
Expected battery depletion leading to PG change	219 (120, 5.7%)	0 (0, 0%)	28 (28, 3.1%)	0 (0, 0%)	191 (188, 21.2%)	0 (0, 0%)
Lead dislodgement – intervention	190 (160, 9.0%)	81 (77, 4.3%)	56 (49, 5.5%)	22 (21, 2.3%)	134 (111, 12.5%)	59 (56, 6.3%)
Upgrade to CRT-D	102 (102, 5.7%)	1 (1, 0.1%)	101 (101, 11.2%)	1 (1, 0.1%)*	1 (1, 0.1%)*	0 (0, 0%)
Prophylactic lead replacement	61 (61, 3.4%)	1 (1, 0.1%)	27 (27, 3.0%)	0 (0, 0%)	34 (34, 3.8%)	1 (1, 0.1%)
Lead fracture	55 (53, 3.0%)	0 (0, 0%)	16 (16, 1.8%)	0 (0, 0%)	39 (37, 4.2%)	0 (0, 0%)
Pocket infection – intervention	45 (42, 2.4%)	8 (8, 0.4%)	18 (18, 2.0%)	4 (4, 0.4%)	27 (24, 2.7%)	4 (4, 0.5%)
Sensing/pacing issues	45 (43, 2.4%)	3 (3, 0.2%)	15 (15, 1.7%)	0 (0, 0%)	30 (28, 3.2%)	3 (3, 0.3%)
Premature battery depletion	43 (43, 2.4%)	0 (0, 0%)	16 (16, 1.8%)	0 (0, 0%)	27 (27, 3.0%)	0 (0, 0%)
Prophylactic pulse generator replacement	30 (30, 1.7%)	0 (0, 0%)	7 (7, 0.8%)	0 (0, 0%)	23 (23, 2.6%)	0 (0, 0%)
Pocket hematoma- intervention	25 (25, 1.4%)	20 (20, 1.1%)	11 (11, 1.2%)	9 (9, 1.0%)	14 (14, 1.6%)	11 (11, 1.2%)
Hemo/pneumothorax- intervention	20 (20, 1.1%)	18 (18, 1.0%)	8 (8, 0.9%)	8 (8, 0.9%)	12 (12, 1.4%)	10 (10, 1.1%)
CS dissection	14 (14, 0.8%)	13 (13, 0.7%)	1 (1, 0.1%)	0 (0, 0%)	13 (13, 1.5%)	13 (13, 1.5%)
Other - increase hospitalization	12 (12, 0.7%)	9 (9, 0.5%)	7 (7, 0.8%)	7 (7, 0.8%)	5 (5, 0.6%)	2 (2, 0.2%)
Loose set screw	11 (11, 0.6%)	6 (6, 0.3%)	6 (6, 0.7%)	3 (3, 0.3%)	5 (5, 0.6%)	3 (3, 0.3%)
Device pocket problems requiring revision	10 (10, 0.6%)	0 (0, 0%)	4 (4, 0.4%)	0 (0, 0%)	6 (6, 0.7%)	0 (0, 0%)
HF exacerbation - intervention IV meds and increase hospitalization	7 (7, 0.4%)	7 (7, 0.4%)	3 (3, 0.3%)	3 (3, 0.3%)	4 (4, 0.5%)	4 (4, 0.5%)
Cardiac perforation/pericarditis/tamponade – intervention	5 (5, 0.3%)	3 (3, 0.2%)	2 (2, 0.2%)	0 (0, 0%)	3 (3, 0.3%)	3 (3, 0.3%)
Total	894 (583, 32.6%)	170 (158, 8.8%)	326 (224, 24.9%)	57 (54, 6.0%)	568 (359, 40.4%)	113 (104, 11.7%)

* Subject 19007 had CRT-D explanted due to perforation of the right lung. A St. Jude CRT-D was subsequently implanted.

A Kaplan-Meier curve for the time to first procedure or system-related complication is shown in Figure 33. In the initial few months, the CRT-D group has a higher rate of procedure or system-related complications, but after about 3 months, the rate of these complications is similar between the ICD and CRT-D groups, as indicated by the similar slope of the curves. As expected, at about 48 months, the curve rises more rapidly in the CRT-D group due to subjects with a CRT-D device reaching end of battery life sooner than the subjects originally implanted with an ICD.

At 30 days, the procedure or system-related complication rate was 6.0% in the ICD group and 11.7% in the CRT-D group. At 12 months, the rate was 11.9% in the ICD group and 17.5% in the CRT-D group, and at 24 months the rate was 15.4% in the ICD group and 21.8% in the CRT-D group.

Figure 33: RAFT Time to First Procedure or System-related Complication

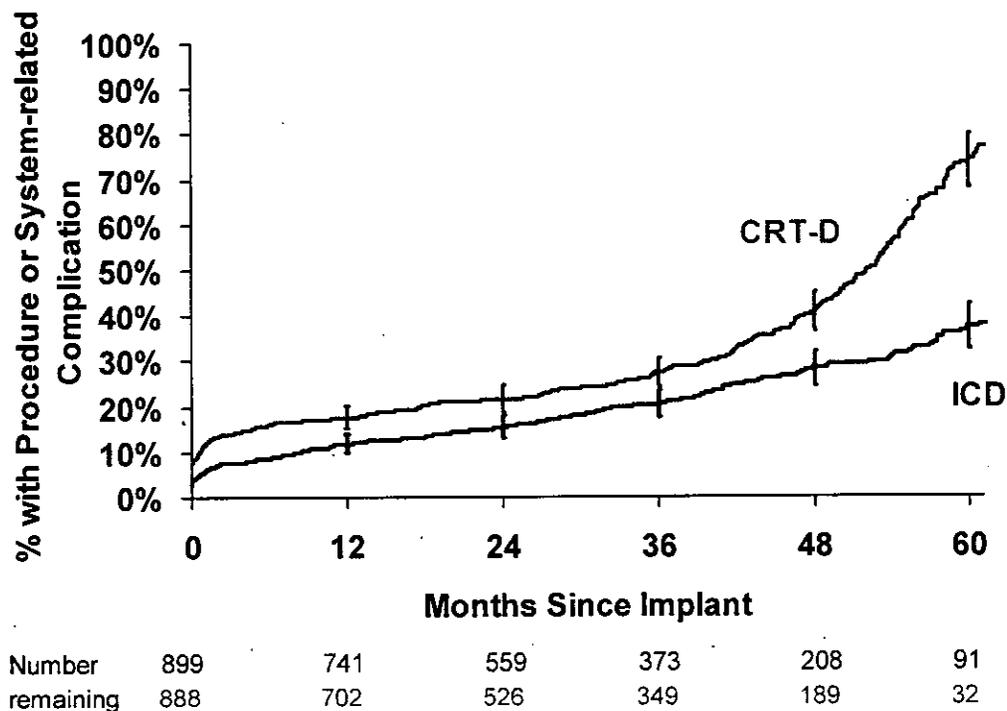
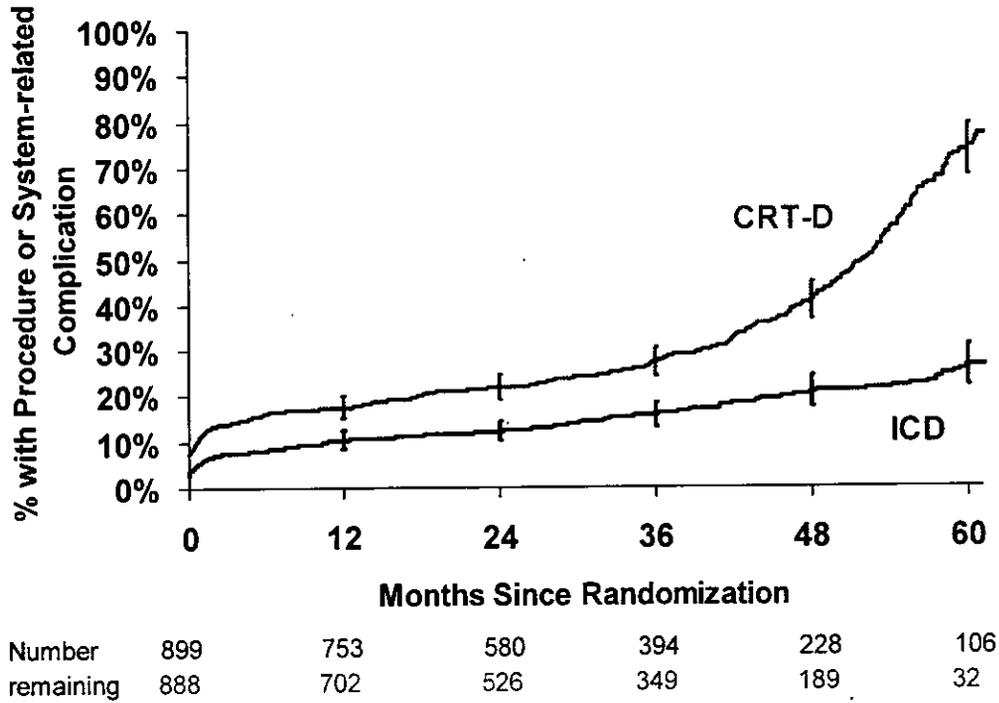


Figure 34 shows time to first procedure or system-related complication, but with CRT upgrades removed in the ICD arm. As anticipated, the number of complications in the ICD group is reduced.

Figure 34: RAFT – Time to First Procedure or System-related Complication (excluding CRT-D upgrades in ICD group)



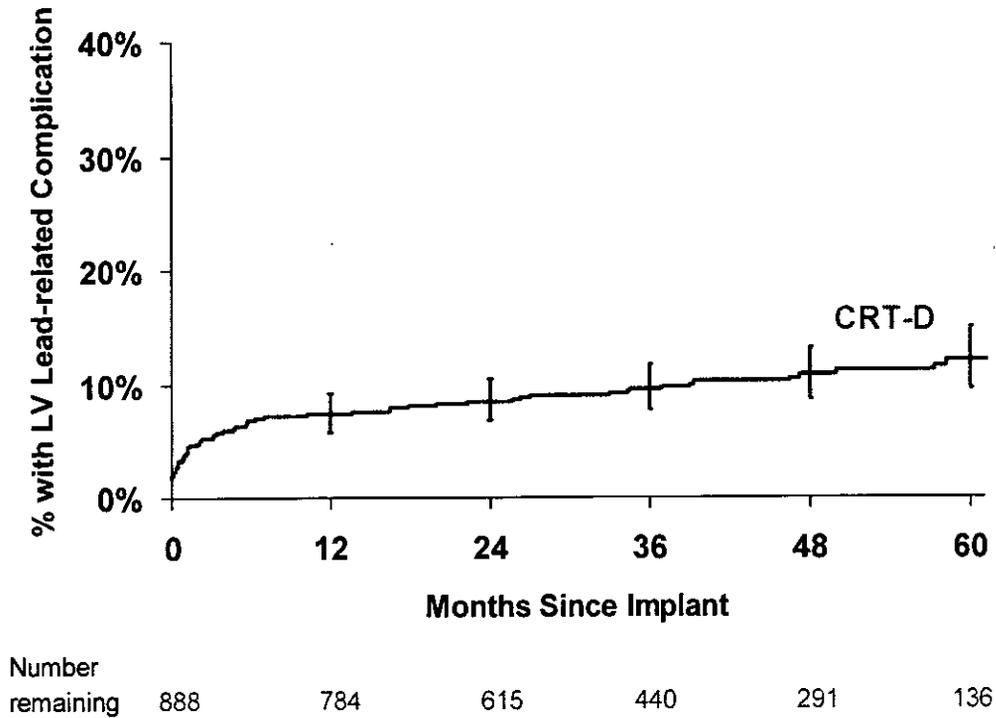
As all subjects in the RAFT study were indicated for an ICD, the incremental risk between the CRT-D group and the ICD group was the LV lead. There were 106 LV lead-related complications reported in the CRT-D group during the study as summarized in Table 10.

Table 10: RAFT LV Lead-related Complications

Number of Events (Number of Subjects, % of Subjects with an Attempted Implant)		
Key Term	CRT-D group	
	# AEs	# AEs within 30 days of implant
Lead dislodgement - intervention	83 (72, 8.1%)	34 (31, 3.5%)
Sensing/pacing issues	15 (14, 1.6%)	3 (3, 0.3%)
Lead fracture	3 (2, 0.2%)	0 (0, 0%)
Prophylactic lead replacement	3 (3, 0.3%)	0 (0, 0%)
Loose set screw	2 (2, 0.2%)	1 (1, 0.1%)
Total	106 (90, 10.1%)	38 (34, 3.8%)

A Kaplan-Meier curve for the time to the first LV lead-related complication is shown in Figure 35. At 12 months, the LV lead-related complication rate in the CRT-D group was 7.4%. At 24 months, the rate in the CRT-D group was 9.6%. At 48 months, the rate was 10.8%.

Figure 35: RAFT Time to First LV Lead-related Complication



E. Death Summary

Table 11 provides a summary of all deaths occurring during the course of the study.

Table 11: RAFT Cause of Death Summary

	ICD (n=904)	CRT-D (n=894)	Total (n=1798)
Non-cardiovascular	70 (30%)	54 (29%)	124 (29%)
Unexpected death presumed to be cardiovascular disease, occurring within 24 hrs of the onset of symptoms without confirmation of cardiovascular cause, and without clinical or post mortem evidence of etiology	25 (11%)	20 (11%)	45 (11%)
Myocardial Infarction: Death within 7 days of the onset of documented MI	4 (2%)	3 (2%)	7 (2%)
Congestive Heart Failure: Death due to clinical, radiological or post-mortem evidence of CHF, without clinical or postmortem evidence of other cause, such as ischemia, infection, dysrhythmia	95 (40%)	81 (44%)	176 (42%)
Post cardiovascular intervention: Death associated with the intervention: within 30 days of cardiovascular surgery, or within 7 days of cardiac catheterization/angioplasty	1 (<1%)	0 (0%)	1 (<1%)

	ICD (n=904)	CRT-D (n=894)	Total (n=1798)
Documented Arrhythmia: Death due to brady or tachyarrhythmias, not induced by an acute ischemic event	24 (10%)	23 (12%)	47 (11%)
Stroke: Death due to stroke occurring within 7 days of the signs and symptoms of stroke	13 (6%)	4 (2%)	17 (4%)
Other cardiovascular diseases: Death due to other vascular diseases such as pulmonary embolism, aortic aneurysm, etc.	0 (0%)	1 (1%)	1 (<1%)
Presumed cardiovascular death: Suspicion of CV death that does not fulfill other criteria	4 (2%)	0 (0%)	4 (1%)
Total	236 (100%)	186 (100%)	422 (100%)

F. RAFT Study Conclusion

The RAFT study was designed to determine whether CRT-D plus optimal medical therapy (OMT) reduces total mortality and HF hospitalizations as compared to ICD plus OMT in subjects with mild to moderate HF (NYHA Class II and III), ventricular dyssynchrony (QRS ≥ 120 ms), and reduced systolic left ventricular ejection fraction (LVEF $\leq 30\%$).

The primary outcome of time to first heart failure hospitalization or all-cause death was met for both the full cohort and the pre-specified NYHA Class II subgroup. The hazard ratio for the NYHA Class II subgroup was 0.73 in favor of CRT-D, which was statistically significant ($p=0.001$). In a post-hoc analysis, the expanded indication population also demonstrated a reduction in the risk of HF hospitalization or all-cause death with CRT-D.

Total mortality was analyzed as a secondary objective for the RAFT study. A statistically significant reduction in mortality with CRT-D was observed in both the full cohort and pre-specified NYHA Class II subgroup. For the pre-specified subgroup analysis of NYHA Class II subjects, the hazard ratio was 0.71 in favor of CRT-D ($p=0.006$). In a post-hoc analysis, the expanded indication population also observed a reduction in mortality with CRT-D.

Time to first HF hospitalization was also analyzed as a secondary endpoint in the study. For the pre-specified subgroup analysis of NYHA Class II subjects, the hazard ratio was 0.70 in favor of CRT-D ($p=0.003$). The expanded indication population also observed a reduction in the risk of HF hospitalization with CRT-D (post-hoc).

IV. Overall Conclusions

The REVERSE and RAFT studies assessed the effects of cardiac resynchronization therapy in mildly symptomatic heart failure patients. There were some differences in subject inclusion criteria and primary endpoints, but the core group of subjects studied had NYHA Class II heart failure symptoms, a prolonged QRS duration and decreased left ventricular ejection fraction.

Determination of criteria for the expanded indication population was based on inclusion criteria common to both studies, and further narrowed to LBBB patients with QRS \geq 130 ms as a stronger benefit was observed in these subgroups.

In both REVERSE and RAFT, CRT effectively reduced HF hospitalization or all-cause mortality in the expanded indication population. REVERSE was not powered for this endpoint, but nonetheless demonstrated a reduction in risk of first HF hospitalization or all-cause death. CRT-D reduced HF hospitalization or all-cause mortality by an observed 73% in the REVERSE expanded indication population. In the RAFT study, an overall 42% reduction in HF hospitalization or all-cause mortality was observed with CRT-D in the comparable expanded indication population.

In addition, RAFT demonstrated an overall 42% mortality risk reduction in the expanded indication population.

Adequate safety of the therapy was also demonstrated in both studies. The incremental risk for these ICD-indicated patients is the implantation of the LV lead and potential subsequent complications. In the REVERSE full cohort, the LV lead complication rate was 9.1% at 12 months post-implant. The RAFT full cohort had a similar rate of 7.4% at 12 months post-implant.

In conclusion, the totality of the REVERSE and RAFT data provide reasonable assurance of safety, efficacy, and an acceptable risk/benefit ratio to support the use of Medtronic CRT-D devices in patients with NYHA Functional Class II heart failure symptoms despite optimal medical therapy, with a left bundle branch block, QRS \geq 130 ms, and LVEF \leq 30%.

Of note, some analyses in this report were not pre-specified in the statistical analysis plan of the study and are therefore considered post-hoc. P-values are not presented with the data in these cases to emphasize that caution should be used in interpreting them. Table 12 provides a summary of post-hoc statistics to assist with interpretation of these analyses.

Table 12: Post-hoc Statistics

Analysis	Page Number	p-value	Hazard Ratio (95% c.i.)
REVERSE CCR distribution – full cohort	10	p=0.004	--
REVERSE CCR percent worsened - expanded indication population	12	p=0.004	--
REVERSE CCR distribution - expanded indication population	12	p=0.007	--
REVERSE time to first HF hospitalization – full cohort	14	p=0.003	0.45 (0.26-0.77)

Analysis	Page Number	p-value	Hazard Ratio (95% c.i.)
REVERSE time to first HF hospitalization – expanded indication population	15	p=0.009	0.28 (0.10-0.78)
REVERSE time to first HF hospitalization or all-cause death – full cohort	16	p=0.004	0.49 (0.30-0.80)
REVERSE time to first HF hospitalization or all-cause death - expanded indication population	17	p=0.004	0.27 (0.11-0.70)
RAFT time to first HF hospitalization or all-cause death - expanded indication population	37	p<0.0001	0.58 (0.45-0.75)
RAFT mortality - expanded indication population	40	p=0.002	0.58 (0.41-0.82)
RAFT time to first HF hospitalization – expanded indication population	43	p=0.0003	0.56 (0.40-0.77)

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Heart Failure Pacemaker
with Defibrillation
Patient Manual



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

We are *there* when you need us.

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How to contact Medtronic

Contact us by phone

Our experienced Patient Services group is available to answer any questions or concerns you may have about your heart device. To speak directly with a Patient Services Specialist, call 1-800-551-5544. Our staff is available Monday through Friday from 7:00 AM to 6:00 PM (Central Time).

Contact us online

Medtronic is dedicated to providing you with the most up-to-date information available about your Medtronic heart device. Website information is available 24 hours a day.

- Medtronic website: www.medtronic.com
- Patient Services website: www.medtronic.com/rhythms
- Heart Help website: www.HeartHelp.com

Contact us by mail or fax

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1 Why read this manual?

Your doctor or doctors should be your first source of information about your heart condition and your general health.

This manual is for people who are about to have or already have a heart failure pacemaker with defibrillation (also called cardiac resynchronization therapy with defibrillation, heart failure heart device, biventricular heart device, and three-lead heart device). This manual explains what the heart device is, how it is implanted, what it feels like when you receive therapy from the heart device, and what you can expect after you have your heart device. It's a good idea to encourage your family and caregivers to review this manual.

For your convenience, words that appear in **bold** are defined in the glossary at the end of this manual.

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determined that the treatment provided by a heart device may help to improve your symptoms.

Although your heart device is not a cure, it does help to protect you from heart rhythms that can weaken or even endanger your health. Many patients say that this heart device gives them and their families a sense of security. See "Caring for yourself" on page 129 for guidance on dealing with anxiety and other concerns.

? Will I be able to drive?

Whether you will be able to drive or not depends on your individual heart condition. The concern about driving is that you might faint if your heart starts to beat dangerously fast. Many people with a heart failure pacemaker with defibrillation are able to resume driving if their doctor approves and if allowed by the laws and insurance regulations in their state. For more information, see "Driving a car" on page 30. If you have concerns, talk with your doctor.

If you have questions that are not covered in this manual or you want more information about your heart device, contact Medtronic Patient Services at 1-800-551-5544.

Frequently asked questions

New patients often have the same initial concerns about their heart devices. Here are some of the questions new patients frequently ask.

? Why do I need this heart device?

A heart failure pacemaker with defibrillation is designed to relieve heart failure symptoms for most patients. It improves the heart's ability to pump blood and oxygen to the body. Although this heart device does not prevent or cure your underlying heart rhythm condition, it should improve your quality of life and help you get back to doing things that you haven't been able to do for a while.

Heart medications and surgical procedures may be prescribed instead of, or in addition to, a heart failure pacemaker with defibrillation. Based on your individual health condition, your doctor has

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Why read this manual?

? Will I be able to travel?

Most people who have a heart device can travel without taking special precautions if they follow their doctor's instructions.

Wherever you travel, your heart device will monitor your heart and provide therapy whenever it is needed. You can travel knowing that resources for your device are available in 120 countries (see the back cover of this manual for information on contacting Medtronic headquarters located worldwide). When you travel, your doctor may also be able to check your heart device remotely with the **Medtronic CareLink Service** (see page 120 for more information).

It is unlikely that your heart device will trigger the security gates at airports or other secure buildings. If it does, present your heart device ID card. If a handheld screening wand is used, ask the security operator not to hold it over your heart device and not to wave the wand back and forth over your heart device. See "EMC and security systems" on page 53 for more information.

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Why read this manual?

A multilingual heart device travel card is available that provides instructions in several languages for safe security scanning; the card is especially useful for international travel. See page 115 for more information about the multilingual heart device travel card.

If you have any other travel-related questions, contact Medtronic Patient Services or consult the Medtronic travel website at www.medtronic.com/traveling.

? Can I walk through antitheft systems found in public places?
Yes, simply walk through the antitheft system at a normal pace. Under some circumstances, the systems located in stores, libraries, and other places may temporarily interfere with your heart device if you stop or linger near this equipment. The interference stops when you move away from the equipment.

? Can I use a microwave oven and other electrical items?
Yes, you can use a microwave oven as well as major appliances, electric blankets, and heating pads. See "Living life with your heart device" on page 27 for information about electrical items and any restrictions or cautions you should know about.

? Will my heart device need to be replaced?
Yes. Because your heart device operates using a battery sealed inside the heart device, the entire heart device will need to be replaced when battery power falls to a low level. Battery power is affected by many factors, including how often your heart device provides therapy to your heart. The average heart device battery lasts 4 to 7 years after it is implanted.

The battery power is checked at each heart device follow-up appointment. Your doctor or nurse will let you know when you need to have your heart device replaced.

? Can I use a mobile phone?

Yes, you can use mobile phones (including cellular phones and other wireless phones). However, mobile phones may cause electrical interference with your heart device when the phone is turned on and held too close to your heart device. Any effect is temporary, and simply moving the phone away will return the heart device to its previous state of operation.

To avoid any possible interference between mobile phones and your heart device, keep all mobile phones at least 6 inches (15 centimeters) away from your heart device. When using a mobile phone, hold it to the ear that is farthest away from your heart device. Also, do not carry a mobile phone close to your heart device, such as in a shirt pocket (or in a pants pocket if your heart device is implanted in your abdomen). For more information about using mobile phones and other wireless communication devices, see page 34.

? How often will my doctor need to check my heart device?

When you go home after your implant surgery, your doctor will periodically check your heart device. These follow-up appointments can be performed at your clinic, or if your clinic subscribes to the Medtronic CareLink Service, you can send your heart device information directly to your doctor or clinic from home. For more information about follow-up services, see "Follow-up care" on page 117.

? How do I know if my heart device battery is still working?

The strength of your heart device battery is checked during your follow-up appointments, either in the clinic or through built-in device monitoring. Medtronic CareAlert monitoring is a safety feature built into your heart device that can be set up by your doctor to alert you with a beeping sound when the heart device battery power is getting low. For more information about the Medtronic CareAlert monitoring feature, see "What is Medtronic CareAlert monitoring?" on page 98. Because the battery is sealed inside your heart device and cannot be

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recharge your heart device will need to be replaced when the battery power is low. For more information about heart device replacement, see "Heart device replacement" on page 126.

? What if my heart device is making a beeping sound?

Your heart device may make a beeping sound if the Medtronic CareAlert monitoring feature is turned on. Your doctor can have your heart device alert you with a beeping sound under certain conditions, such as the following conditions:

- The number of therapies you have received has increased.
- The battery power of your heart device is low.

The beeping tone will sound for approximately 10 seconds and will repeat periodically. Some alerts sound at the same time every day. The alerts will continue until your heart device is checked by your doctor or nurse. Do not be alarmed by the beeping. This alert feature is designed to get your attention. If you hear beeping tones from your heart device, call your doctor for instructions. For more information

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about the Medtronic CareAlert monitoring feature, see "What is Medtronic CareAlert monitoring?" on page 98.

? Will my device deliver a therapy shock during normal activity?

This can happen, but it is unlikely. Your heart device is designed to respond to abnormal heart rates and rhythm patterns. Normal exercise or physical activity shouldn't trigger your heart device to deliver a therapy shock.

If this ever happens, stop the activity and notify your doctor. Your doctor may change the settings of your heart device to prevent this from happening.

? Can others feel a therapy shock if they are touching me?

Though it is very unlikely, if you receive a therapy shock, anyone touching you may feel the shock as a muscle spasm. This can be startling, but it will not hurt the person.

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Why read this manual?

? What if I receive a therapy shock?

Ask your doctor or nurse what you should do if your heart device delivers a therapy shock. Your doctor or nurse should provide you with specific instructions about when you should contact your doctor if you have received a therapy shock.

In general, follow these four steps if you feel the symptoms of a rapid heart rhythm or if you receive a therapy shock:

1. Stay calm and move to where you can lie down or sit comfortably.
2. Have someone stay with you until you feel better.

If you receive more than one therapy shock or if you remain unconscious for more than 1 minute, have a companion call 911 for an ambulance.

If you remain unconscious and you have no pulse, a companion trained in cardiopulmonary resuscitation (CPR) should begin CPR immediately. When your heart starts beating again, your companion should stop CPR.

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? Can I have sexual relations?

Most people resume sexual activity, based on their doctor's instructions. You and your partner should be able to enjoy all the benefits of intimacy.

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Why read this manual?

If you have additional questions

If you have questions that are not covered in this manual or you want more information about your heart device, contact:

Medtronic Patient Services
Monday through Friday, 7:00 AM to 6:00 PM (Central Time)

1-800-551-5544
www.medtronic.com/rhythms

If you have questions about your Medtronic heart device ID card or to update your address or other contact information, contact:

Medtronic Patient Registration Services
Monday through Friday, 7:00 AM to 7:00 PM (Central Time)

1-800-551-5544
www.medtronic.com/idcard



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Chapter 1

2 Living life with your heart device

Many people resume their normal daily activities after full recovery from surgery (see "Your implant procedure and recovery" on page 103). However, there may be certain situations that your doctor will ask you to avoid. Your doctor will provide the most important guidance for your particular condition.

This chapter has important information about the following topics:

- Food and medications (see page 28).
- Your physical activity now that you have a heart device (see page 28).
- Information and instructions about any electrical equipment that may cause interference with your heart device (see page 30).
- Precautions about certain types of medical procedures (see page 55).

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Food and medications

Your doctor may instruct you to eat or avoid eating certain foods. For information about food, talk with your doctor.

Your doctor may prescribe medications that will treat your heart condition. Please talk with your doctor about medications.

Recommendations about your physical activity

Upon the advice of your doctor, you can gradually return to your normal lifestyle and to activities such as these:

- Pursuing hobbies or recreational activities
- Returning to your job
- Resuming strenuous activity
- Resuming sexual activity
- Traveling

Your doctor might ask you to avoid situations where a few seconds of unconsciousness could be dangerous to you or others. Such situations

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Living life with your heart device

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might. Include driving, swimming or boating alone, or climbing a ladder.

Recreation and activities

Avoid rough physical contact that could cause you to fall or to hit your implant site. Your heart device can be damaged or your leads could become detached from the heart device during rough contact.

- If you use a rifle or shotgun, rest the butt on the shoulder of the side opposite from your heart device.
- In activities that use a shoulder harness, protect your heart device and leads from jolts or rough rubbing.
- If you plan to scuba dive, discuss your medical condition with your doctor. General recommendations about scuba diving vary depending on many factors. Ask your doctor to contact Medtronic Technical Services for the most up-to-date information about scuba diving recommendations.

If you have additional questions about any recreational activities you normally pursue, contact Medtronic Patient Services at 1-800-551-5544.

Chapter 2

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The relationship between these energy fields and your heart device is called **electromagnetic compatibility (EMC)**. Most electromagnetic energy fields are small and weak and do not affect your heart device. Electrical items that generate strong electromagnetic energy fields may not be compatible with your heart device.

Because your heart device is designed to sense the electrical activity of your heart, it is possible that it may sense a strong electromagnetic energy field outside your body and deliver a therapy that is not needed or withhold a therapy that is needed.

Several safeguards are built into your heart device to shield it from strong electromagnetic energy fields. For example, the metal case of your heart device acts as a shield against electromagnetic energy fields. There are also electronic filters built into your heart device that help your heart device distinguish between external electromagnetic energy fields and the internal electrical pulses of your natural heartbeat.

You can avoid potential EMC problems by keeping your heart device a minimum distance away from the electrical item. See the following

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Driving a car

Discuss with your doctor whether you can safely drive a car or other vehicle. You may be able to resume driving, depending on local laws and insurance regulations and on your medical condition. Your doctor will decide what is best for your safety and the safety of others.

Seat belts are a very important safety device and should always be worn while driving or riding in a vehicle. While you are driving or riding in a vehicle, the shoulder seat belt strap may feel uncomfortable during the first few weeks after surgery. You can place a soft towel between the seat belt strap and your implant site to cushion the area.

What you need to know about electromagnetic compatibility (EMC)

Everything that uses electricity produces an **electromagnetic energy field**. This energy field surrounds the electrical item while it is connected to a source of electricity (even a battery source). The energy field is strongest near the item and weakens with distance from the item.

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Living life with your heart device

pages for more information, including the recommended safe distances for certain types of electrical items.

? How could electromagnetic energy fields affect my heart device?

High electromagnetic energy fields could affect how your heart device senses your heart rhythm. Because your heart device is designed to sense the electrical activity of your heart, it may also sense a strong electromagnetic energy field outside your body.

If your heart device is exposed to a strong electromagnetic energy field, it may not detect an abnormal heart rhythm or it may deliver a therapy shock when your heart does not need it. Any effects of electromagnetic energy fields on your heart device are temporary and will stop when you move away from the source of the electromagnetic energy field.

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Living life with your heart device

What do I do if I think that an electrical item is affecting my heart device?

If you feel dizzy, feel rapid or irregular heartbeats, or receive a shock while using an electrical item, release whatever you are touching or move away from the item. Your heart device should immediately return to its normal operation. If you receive a therapy shock or if your symptoms do not improve when you move away from the item, you should contact your doctor.

What about static electricity or shocks from household outlets?

Static electricity shocks will not damage your heart device. A "momentary" shock from an electrical outlet (110/220 volts) is unlikely to damage your heart device, depending on how long you stay in contact with the outlet.

Proper grounding of electrical items

To protect yourself from electrical current that may leak from improperly grounded electrical items and pass through your body, follow these suggestions:

- Make sure that all electrical items are properly wired and grounded.
- Make sure that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

Wireless communication devices

Follow these guidelines when using wireless communication items:

- **Handheld cellular, mobile, or cordless telephones (wireless phones)**
Your heart device has been tested with many types of wireless telephone technologies to ensure that it will operate correctly while you are using a wireless phone. Keep the antenna of a handheld

What items are safe and what kind of precautions do I need to take?

Most electrical items are safe for you to use. However, you should keep some items that produce a stronger electrical field a minimum distance away from your heart device. This minimum distance can range from 6 to 12 inches (15 to 30 centimeters) or more, depending on the type of item. Refer to the tables starting on page 39 for recommended safe distances.

General rules for safe use of electrical items

The following pages provide tips on how to avoid any possible effects of electromagnetic energy fields on your heart device. If you have questions about EMC or the safe use of a specific item that is not listed, please call Medtronic Patient Services at 1-800-551-5544.

Your home and workplace contain a variety of electrical items. Most are safe to use, and some should be kept a minimum distance from your heart device.

wireless phone at least 6 inches (15 centimeters) away from your heart device. This is easily done by holding the phone to the ear farthest away from your implant. Don't carry the phone in a pocket over your heart device or in a shoulder bag near your heart device.

- **Two-way pagers, PDAs, or mobile mailboxes**
Handheld devices that let you send text or data messages use the same type of transmitter as a handheld wireless phone, so follow the same guidelines just described for wireless phones.
- **Wi-Fi enabled laptop computers and Bluetooth devices**
Wi-Fi enabled laptop computers and Bluetooth devices contain small transmitters. Keep them at least 6 inches (15 centimeters) away from your heart device.

Kitchen appliances

One kitchen appliance that could possibly affect your heart device is an induction cooktop. An induction cooktop uses an alternating magnetic field to generate heat. You should keep your heart device at

least 6 inches (60 centimeters) away from the heating zone when the induction cooktop is turned on.

Most glass-topped or ceramic-topped ranges use conventional heating elements beneath their flat cooking surfaces. If you can use aluminum or glass cookware on your range and the cooking area stays hot after the burner has been turned off, your stove has conventional heating elements. This type of cooktop will not affect your heart device. Call Medtronic Patient Services at 1-800-551-5544 for the latest information about kitchen appliances.

Items that contain magnets

Caution: Avoid holding magnets, or items that use magnets, close to your heart device. Magnets produce magnetic fields, which can interfere with the normal operation of your heart device.

For example, avoid using magnetic mattress pads or pillows because they cannot easily be kept away from your heart device.

Table 1: Examples of EMC with household items

Low risk	Keep heart device at least 6 inches (15 centimeters) away	Special considerations
Kitchen items: Microwave oven; electric, gas, or convection oven; toaster; blender; electric can opener; food processor; cordless electric knife.	Kitchen items: Handheld appliances such as an electric mixer.	Kitchen items: Induction cooktop — keep your heart device at least 24 inches (60 centimeters) away from the heat source when cooktop is on. For more information, see "Kitchen appliances" on page 36.

The following list provides examples of items containing magnets that can be used as long as they are kept at least 6 inches (15 centimeters) away from your heart device:

- **Other large magnets** such as a bingo wand and a mechanic's extractor wand.
- **Stereo speakers.** Do not carry or hold speakers close to your heart device. Stereo speakers have magnets inside them. Even if the power for the speakers is disconnected, you should keep speakers at least 6 inches (15 centimeters) away from your heart device.

EMC with household and hobby items

Caution: Household and hobby items that have motors, have magnets, or are capable of generating electromagnetic energy fields could interfere with your heart device. You should move away from the interference source or turn off the source if you experience any dizziness or heart palpitations.

On the following pages, Table 1 and Table 2 provide the recommended minimum distances for electrical household and hobby items.

Table 1: Examples of EMC with household items (continued)

Low risk	Keep heart device at least 6 inches (15 centimeters) away	Special considerations
Personal care items: Salon hair dryer; cordless shaver; electric blanket; heating pad.	Personal care items: Corded handheld hair dryer; corded electric shaver; electric or ultrasonic toothbrush (base charger); back massager; magnetic chair pad; magnetic bracelet or magnetic clasp.	Personal care items: Electronic body fat scale — not recommended because it passes electricity through the body.

Table 1: Examples of EMC with household items (continued)

Low risk	Keep heart device at least 6 inches (15 centimeters) away	Special considerations
<p>Communication devices: Corded home or public telephone.</p>	<p>Wireless communication devices: Wireless phones (home cordless telephone, cellular phone, or mobile phone); two-way pager; mobile mailbox.</p>	<p>Wireless communication devices: For details, see page 35.</p>
<p>Home office items: Desktop or laptop computer; home-use copier, printer, fax and scanner.</p>	<p>Home office items: Personal digital assistant (PDA); modem; Bluetooth devices; Wi-Fi enabled laptop computers and devices.</p>	

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Table 1: Examples of EMC with household items (continued)

Low risk	Keep heart device at least 6 inches (15 centimeters) away	Special considerations
<p>Home electronics items: AM and FM radio; cassette tape recorder; CD player; camcorder; video recorder (VCR); MP3 player; television; video game system; stereo; DVD player; remote control for entertainment system.</p>	<p>Home electronics items: Stereo speakers.</p>	<p>Home electronics items: UPS (uninterruptible power source) up to 200 Amps — keep at least 12 inches (30 centimeters) away; if operating by battery source, keep at least 18 inches (45 centimeters) away.</p>
<p>Miscellaneous items: Sewing machine and serger (motor). Clothes iron; vacuum cleaner; electric broom. Pager that only receives messages; remote control for garage door; portable space heater.</p>	<p>Miscellaneous items: Sewing machine and serger (motor). Clothes iron; vacuum cleaner; electric broom. Pager that only receives messages; remote control for garage door; portable space heater.</p>	<p>Miscellaneous items: Electronic pet fences/ invisible fences — keep at least 12 inches (30 centimeters) away from the buried wire and the indoor antenna.</p>

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Table 1: Examples of EMC with household items (continued)

Low risk	Keep heart device at least 6 inches (15 centimeters) away	Special considerations
<p>Miscellaneous items: Sewing machine and serger (motor). Clothes iron; vacuum cleaner; electric broom. Pager that only receives messages; remote control for garage door; portable space heater.</p>	<p>Miscellaneous items: Sewing machine and serger (motor). Clothes iron; vacuum cleaner; electric broom. Pager that only receives messages; remote control for garage door; portable space heater.</p>	<p>Miscellaneous items: Electronic pet fences/ invisible fences — keep at least 12 inches (30 centimeters) away from the buried wire and the indoor antenna.</p>

Table 1: Examples of EMC with hobby items

Keep heart device at least 6 inches (15 centimeters) away

Special considerations

- Mechanic's extractor wands (uses a magnet to pick up metal items). (60 centimeters) away.
- Bingo wands.
- Radio-controlled toys (antenna).
- Two-way walkie-talkies (less than 3 watts).
- Home-use electric kilns — Keep at least 24 inches (60 centimeters) away.
- Citizen Band (CB) radio antennas, HAM radios, amateur radios, and other radio transmitters — for distance information, see "EMC and radio transmitters" on page 51.
- "Beach comb" metal detectors — Keep the detector end at least 24 inches (60 centimeters) away.

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- If you use power machinery often, a ground-fault-interrupt outlet is a good safety measure. This inexpensive device prevents a sustained electrical shock.

The following items could affect heart device operation. Follow these guidelines to reduce any possibility of interference:

- **Gas-powered tools and gas-powered yard equipment**, such as lawn mowers/tractors, snowblowers, leaf blowers, and weed eaters: Turn off the motor before making adjustments. Keep components of the ignition system at least 12 inches (30 centimeters) away from your device when operating the machinery.
- **Car engine repair**. Turn off the engine before making any adjustments. When the engine is running, keep components of the ignition system at least 12 inches (30 centimeters) away from your device.
- **Chainsaws**. Avoid using a chainsaw.
 - You could be seriously injured if you become dizzy or lose consciousness.

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Table 2: Examples of EMC with hobby items (continued)

Keep heart device at least 6 inches (15 centimeters) away

Special considerations

- Boat motors (electrical trolling motors and gas powered motors) and portable generators (up to 20 kilowatts) — Keep at least 12 inches (30 centimeters) away.
- EMC with home power tools**
- Most home power tools should not affect your heart device. Follow these common-sense guidelines:
 - Keep all equipment in good working order to avoid electrical shock.
 - Be certain that plug-in tools are properly grounded (or double insulated).

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Living life with your heart device

- You should keep the ignition system of the chainsaw at least 12 inches (30 centimeters) away from your heart device. For most chainsaws, it is difficult to maintain this distance between the ignition system and your heart device while operating the saw.
 - The ignition system, specifically the spark plug, on some chainsaws is actually inside the hand grip area. If the insulation covering the spark plug is faulty, electrical current could pass through your body and affect your heart device.
 - The vibration of a chainsaw can affect the rate of pacing you receive from your heart device.
- **Soldering irons and demagnetizers**. Keep these tools at least 12 inches (30 centimeters) away from your device.
- **Small power tools**. Keep handheld motorized tools, such as battery-operated cordless screw drivers, at least 6 inches (15 centimeters) away from your device.
- **Electric yard tools**. Keep these tools at least 6 inches (15 centimeters) away from your device.

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Living life with your heart device

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EMC and industrial equipment

After recovering from surgery, most heart device patients can return to work or school. However, if you use or work near high-voltage equipment or sources of high electrical current, consult with your doctor. Using or working near high-voltage equipment, sources of high electrical current, or magnetic fields may affect device operation. Table 3 on page 50 provides examples of industrial equipment that you may not be able to use or work near. Contact Medtronic Patient Services at 1-800-551-5544 if you have any questions or concerns about industrial equipment.

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Table 3: Examples of industrial equipment in the workplace you may need to avoid (continued)

Microwave transmitters. Note that microwave ovens are unlikely to affect your heart device.

Power plants, large generators, and transmission lines. Note that lower voltage distribution lines for homes and businesses are unlikely to affect your heart device.

EMC and radio transmitters

Determining a safe distance between the antenna of a radio transmitter and your heart device depends on many factors such as transmitter power, frequency, and the antenna type. If the transmitter power is very high, or if the antenna cannot be specifically directed away from you, you may need to stay further away from the antenna. Table 4 on page 52 lists safe distances from various radio transmitters.

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Table 3: Examples of industrial equipment in the workplace you may need to avoid

Electric furnaces used in the manufacturing of steel.

Induction heating equipment and induction furnaces, such as kilns.

Industrial magnets or large magnets such as those used in surface grinding and electromagnetic cranes.

Dielectric heaters used in industry to heat plastic and dry glue in furniture manufacturing.

Electric arc and resistance welding equipment. For detailed information about electric arc and resistance welding, call Medtronic Patient Services at 1-800-551-5544.

Broadcasting antennas of AM, FM, shortwave radio, and TV stations.

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Living life with your heart device

Table 4: Safe distances from radio transmitters

Two-way radio transmitter (less than 3 watts): Keep at least 6 inches (15 centimeters) between the antenna and your heart device.

Portable transmitter (3-15 watts): Keep at least 12 inches (30 centimeters) between the antenna and your heart device.

Commercial and government vehicle-mounted transmitters (15-30 watts): Keep at least 24 inches (60 centimeters) between the antenna and your heart device.

HAM transmitter (125-250 watts): Keep at least 9 feet (2.75 meters) between the antenna and your heart device.

For transmission power levels higher than 250 watts, consult with Medtronic Patient Services at 1-800-551-5544.

Note regarding your heart device transmitter and FCC rules: Your heart device has a transmitter inside it that allows it to communicate with the Medtronic CareLink Programmer at your doctor's office and with your Medtronic CareLink Monitor, if your doctor ordered a

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Living life with your heart device

monitored for you. The transmitter in your heart device has been certified for its intended purposes under FCC (Federal Communications Commission) rules.

EMC and security systems

Most people with heart devices can travel without taking special precautions. However, when you pass through metal detectors (such as in an airport, courthouse, or jail), you must follow certain instructions and take certain precautions.

- **Identification (ID) card.** Always carry your heart device ID card. This card is helpful should your heart device set off a metal detector or security system.
- **Electronic antitheft systems** (such as in a store or library). Electronic antitheft systems should not affect your device. Do not linger near or lean against antitheft systems, such as those found in retail stores and libraries. Simply walk through these systems at a normal pace. If you are near an antitheft system and you feel symptoms, promptly move away from the equipment. Your heart

Precautions about medical procedures

Caution: Before you undergo any medical procedure, tell the doctor, dentist, or technician that you have an implanted heart device.

- The doctor, dentist, or technician may need to speak with your heart doctor before performing the procedure. Showing them your heart device ID card may be helpful.
 - Some procedures may potentially affect the function of your heart device, and such procedures may require precautionary measures to prevent or minimize impact on your heart device.
- Talk with your doctor to weigh any potential risk against the benefits of the medical procedure. See the following pages for more information.

device will resume its previous state of operation when you move away from the equipment.

- **Home security systems.** It is unlikely that your device will be affected by home security systems.
- **Airport, courthouse, and jail security systems.** It is unlikely that a walk-through security system will affect your heart device. However, the metal case of your device could set off a metal detector. Before entering the metal detector archway, follow these steps:
 1. Identify yourself as having an implanted heart device.
 2. Show your heart device ID card.
 3. Do not linger near or lean against metal detector archways such as those found in airports, courthouses, and jails. Simply walk through these archways at a normal pace.
 4. If a handheld screening wand (metal detector) is used, ask the security operator not to hold it over your heart device and not to wave the wand back and forth over your heart device. Alternatively, you can request a hand search.

Medical procedures that are not recommended

Some medical procedures should not be performed on anyone with a heart device. Talk to your doctors about finding alternatives to these procedures. Your doctor may decide to contact your heart doctor or Medtronic Technical Services for more information.

Table 5 lists procedures that are not recommended.

Table 5: Medical procedures that are not recommended

Warning: People with metal implants such as an implanted heart device and accompanying leads should not receive the following medical procedures:

- **Catheter microwave ablation**
This treatment can result in serious injury and damage to your heart device.
- **Diathermy treatment** (high frequency, short wave, or microwave)
This treatment can result in serious injury and damage to your heart device.

Table 6: Medical procedures that are not recommended (continued)

MRI (magnetic resonance imaging) or MRA (magnetic resonance angiography) scan

This procedure can result in serious injury and damage to your heart device.

If you are in a room where an MRI/MRA scanner is kept, the function of your heart device can be affected.

Transurethral needle ablation (TUNA)

This treatment is not recommended. Your doctor should contact Medtronic Technical Support for more information.

Medical procedures that require some precautions

Some medical procedures can be safely performed, if certain precautions are taken by your doctor to avoid potential device function problems or interference.

If you or your doctor have any concerns about these necessary precautions, your doctor should contact a Medtronic representative or Medtronic Technical Services.

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Table 6: Medical procedures that require some precautions (continued)

High-energy radiation therapy

This procedure can damage your heart device and lead, or affect the function of your heart device.

Hyperbaric Oxygen Therapy (HBOT)

This procedure can damage your heart device and lead.

Lithotripsy

This procedure can damage your heart device.

Radio frequency ablation

This procedure can affect the function of your heart device.

Therapeutic ultrasound

This procedure can result in permanent damage to your heart device.

Transcutaneous Electrical Nerve Stimulation (TENS)

Using a TENS device can affect the function of your heart device.

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The doctor should make sure that your heart device is operating correctly after completing the procedure.

Table 6 lists procedures that require some precautions.

Table 6: Medical procedures that require some precautions

Computerized axial tomography (CT or CAT) scan

This procedure can affect the function of your heart device.

Diagnostic ultrasound

This procedure can affect the function of your heart device.

Electrocautery

This procedure can affect the function of your heart device.

Electrolysis

This procedure can affect the function of your heart device.

External defibrillation and elective cardioversion

These procedures can affect the function of your heart device.

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Living life with your heart device

Table 6: Medical procedures that require some precautions (continued)

Transmitting loop for digital hearing aid

Using a transmitting loop can affect the function of your heart device.

Acceptable medical procedures

Many medical procedures will not affect your heart device. However, the equipment used for the procedure must be used correctly and must be properly maintained.

Tell your doctors and dentist you have an implanted heart device before beginning any medical or dental procedure.

Table 7 lists some of the acceptable medical procedures.

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Living life with your heart device

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Table 1 : Acceptable medical procedures

Dental procedures

Procedures that use dental drills or ultrasonic probes to clean teeth are acceptable. Dental x-rays are also acceptable.

Diagnostic x-rays, such as chest x-rays and mammograms, are acceptable.

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3 Your heart has a natural rhythm

To help you understand how your heart device works, it is helpful to understand how the heart functions and how abnormal heart rhythms can affect the heart. This chapter describes the anatomy of the heart and some of the most common types of abnormal heart rhythm conditions.

For details about your health and individual heart condition, always talk to your doctor.

The anatomy of the heart

The heart is a fist-sized organ that acts as a pump to circulate blood through the body. Arteries are the blood vessels that carry blood with oxygen and nutrients to all parts of the body. Veins are the blood vessels that carry blood depleted of oxygen and nutrients back to the heart and lungs.

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The heart is actually a large hollow muscle divided into four chambers. The two upper chambers are referred to as the **right atrium** and the **left atrium**. The term **atria**, the plural of atrium, refers to both the right and the left atrium.

The lower chambers of the heart are called the **ventricles** and are referred to as the **right ventricle** and the **left ventricle**. The muscled wall dividing the right and left sides of your heart is called the **septum**.

The right atrium draws blood in from your body and pumps it into the right ventricle. The right ventricle then pumps the blood into the lungs to be **reoxygenated**. The left atrium draws oxygen-rich blood in from the lungs and pumps it into the left ventricle. The left ventricle then pumps the blood out to the rest of your body.

Each chamber of the heart contracts by squeezing its muscles together. Each contraction pushes blood from one chamber to the next chamber or out into the body. Heart valves regulate the flow of blood between each chamber and keep the blood flowing in only one direction. It is the actual opening and closing of the valves that creates what we hear as our heartbeat.

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Your heart has a natural rhythm

After each chamber contracts completely, pushing out most of the blood, it relaxes and fills with more blood again. In a healthy heart, each chamber contracts in a coordinated effort with the other chambers of the heart.

The atria contract first, filling the ventricles with blood. When the ventricles are filled, they both contract at the same time, moving the blood into the lungs and the rest of the body, as illustrated in Figure 1 on page 66.

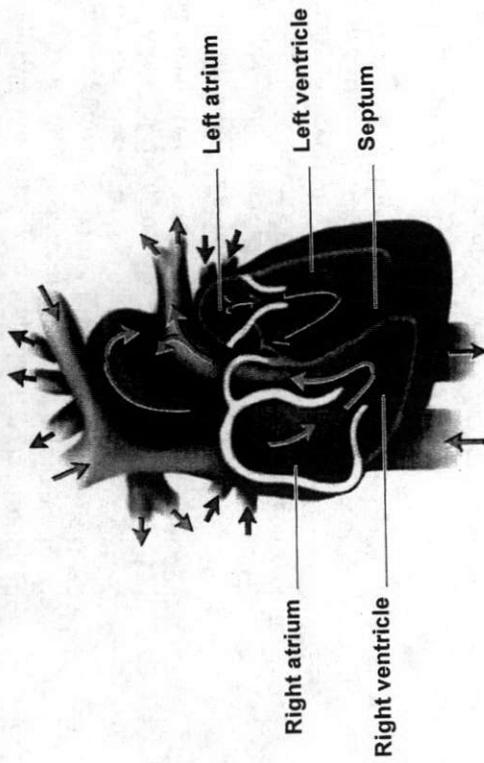


Figure 1: Four chambers of the heart contracting in a controlled sequence to circulate blood throughout the body

Electrical conduction in the heart

The muscle cells of the heart, just like all the muscle cells throughout your body, contract and relax in response to electrical impulses.

The electrical impulses that cause your heart muscle to contract are generated by the heart's natural pacemaker, called the **sinoatrial node** (or SA node). The SA node is located on the upper inside wall of the right atrium. These natural electrical impulses move through the muscle of your heart in tiny thread-like paths, from the top of the atria to the bottom of the ventricles, then up the ventricles' outer walls.

After the SA node releases an electrical impulse, the impulse travels across the top of the right atrium and the left atrium. The impulse then travels down through both atria. As the atria are stimulated, they contract from the top down, pushing blood into the ventricles. When the electrical impulse reaches the lower wall of the atria, the **atrioventricular node** (or AV node) is stimulated. The AV node delays the impulses just long enough for the atria to finish pushing blood into the ventricles, then it passes the impulse along organized pathways into the ventricles.

Your heart has a natural rhythm

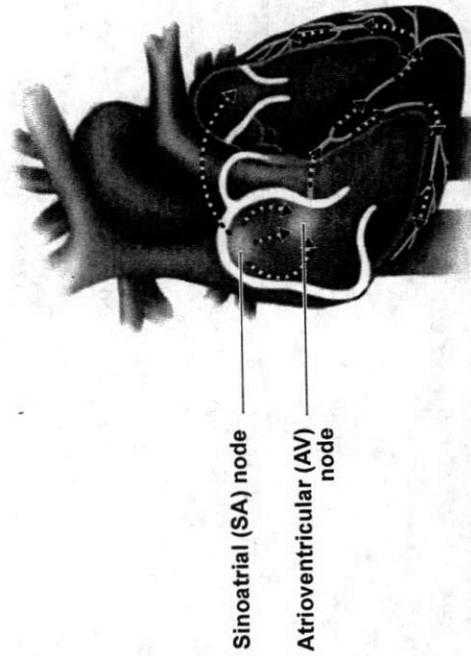


Figure 2: The electrical impulses that cause the heart to contract start at the SA node and move through the atria to the AV node. The AV node controls when the impulse is released to travel through the ventricles.

Your heart has a natural rhythm

The *r.* node controls how quickly the impulse travels through the rest of the heart. This controlled impulse release helps coordinate when each chamber contracts. Without this control, the heart would not pump blood very productively. The coordination between the contracting chambers of the heart is very important for maintaining adequate blood flow between your heart and the rest of your body.

The electrical impulse passes down to the bottom of the ventricles. From here the pulse sweeps across the surface of the right and left ventricles from the bottom up, causing the ventricles to contract in the same bottom-up direction. This action pushes the blood out of the valves at the top of the ventricles to the lungs (from the right ventricle) and to the rest of the body (from the left ventricle).

The heart is very sensitive to the body's needs

The rate at which the chambers of the heart contract is controlled by your brain and your **autonomic nervous system**.

If, for example, you start to jog instead of walk, your body's demand for blood increases. Your heart automatically contracts faster when

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Here are the three most common heart rhythm conditions:

- **Heart failure** – when the heart pumps poorly
- **Tachyarrhythmia** – when the heart beats too fast
- **Bradycardia** – when the heart beats too slowly

These conditions can be treated with medications or by implanting a heart device. Sometimes they are treated with both methods. Your heart device is capable of treating the following heart conditions:

- **Heart failure**
- **Tachyarrhythmia**
- **Bradycardia**

Heart failure – When the heart pumps poorly

The term "heart failure" (also called **congestive heart failure**) is used to describe a heart condition or collection of symptoms that indicate the heart is not pumping enough blood to meet the energy demands of the body. This term can be misleading because heart failure may sound like the heart suddenly fails or stops. Heart failure typically

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you are active in order to increase the amount of blood supp. → to your body.

How abnormal heart rhythms affect the heart

There are many reasons why a heart might not beat "normally." Whether due to disease, defect, or injury, the heart's conduction system can become unreliable. The areas of the heart that control the heart rhythm can malfunction, causing slow, fast, erratic, or uncoordinated heart rhythms. Any of these abnormal heart rhythms can affect the amount of blood supplied to the body.

The effects of abnormal heart rhythms can range from severe fatigue to **sudden cardiac arrest (SCA)**.

If the heart is not beating normally because of a problem with its conduction system, then the problem may be one of three common abnormal heart rhythm conditions.

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Your heart has a natural rhythm

develops slowly after the heart muscle is injured by a **heart attack**, coronary artery disease, untreated high blood pressure, or an abnormal heart valve. Sometimes the cause of heart failure is unknown.

Heart failure conditions can affect the heart's normal electrical conduction, causing the individual chambers of the heart to beat at the wrong time. These delays in electrical conduction are sometimes referred to as **interventricular conduction delays**. An uncoordinated heart rhythm causes strain on the heart and produces an inadequate supply of blood to the body.

If the heart rhythm is uncoordinated, or out of sync, then the amount of blood pumped by the heart decreases over time. As the amount of blood pumped to the body decreases, the heart muscle itself is not supplied with enough blood, and it becomes even weaker.

This condition can cause the heart to enlarge and fluid to build up in the heart and bloodstream, which in turn reduces the amount of blood pumped by the heart. Without treatment, this cycle of reduced blood flow and weakening heart muscle continues over time.

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Your heart has a natural rhythm

Ejection fraction

One way to measure how well the heart is pumping blood is to calculate the **ejection fraction (EF)**. The EF is the amount of blood pumped out of the heart during each beat or contraction.

In a healthy heart, 50% to 75% of the blood is pumped out during each beat. This indicates that the heart is pumping well and is able to deliver an adequate supply of blood to the body and brain. Pumping 36% to 49% of the blood is considered below normal, and less than 36% is considered low. Many people with heart failure and heart disease pump out less than 50%.

By measuring the amount of blood held in the ventricle before it contracts and then measuring again after it contracts, your doctor is able to determine how much blood is pumped out of the heart. If more blood remains in the chamber than is pumped out of the chamber, then the heart has a low ejection fraction. A low ejection fraction indicates that the heart is not pumping efficiently.

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Here are some symptoms of heart failure:

- Shortness of breath
- Cough with "frothy" sputum
- Swelling of the feet and legs
- Swollen or tender abdomen with loss of appetite
- Chronic lack of energy, feeling tired
- Increased urination at night
- Difficulty sleeping at night
- Confusion, impaired memory due to breathing problems

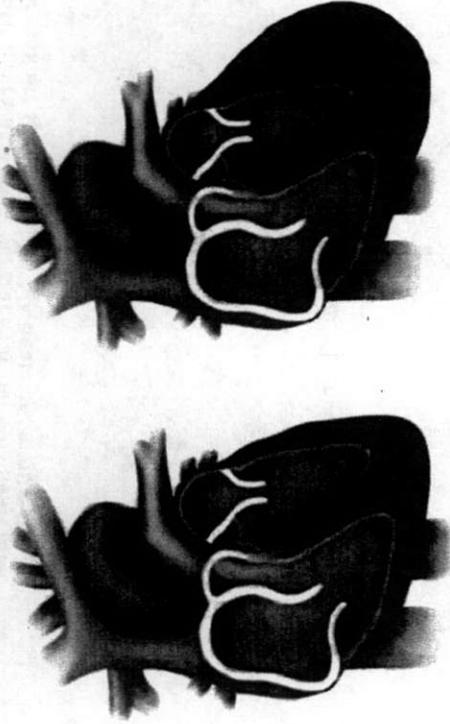
Many people don't know they have heart failure because they think that feeling tired and being short of breath is just a sign of growing older.

Here are some causes of heart failure:

- Damage to the heart from lack of blood supply to the heart muscle caused by a heart attack or coronary artery disease, infection of the heart, or toxic exposure to chemicals (which can include alcohol and drug abuse).

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Healthy heart

Enlarged heart

Figure 3: Heart failure can cause the heart to enlarge because it is working harder to pump blood to the body.

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Your heart has a natural rhythm

- Too much strain on the heart because of high blood pressure (hypertension) or heart valve problems.

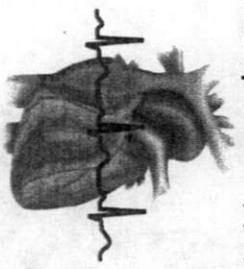
Tachyarrhythmia – When the heart beats too fast

A heart rate that is faster than what the body needs is called a **tachyarrhythmia**. A normal heart at rest beats between 60 and 100 beats per minute. Exercise or stress can cause the heart to beat faster, but this is a normal response to the body's need for more blood. During a tachyarrhythmia, the heart beats at more than 100 beats per minute and can beat as fast as 400 beats per minute, making it an ineffective pump.

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Your heart has a natural rhythm

Normal heart rate
72 beats per minute (bpm)



Tachyarrhythmia heart rate
144 beats per minute (bpm)

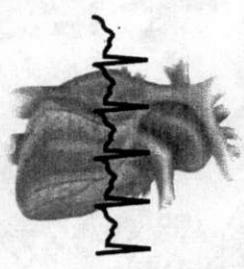


Figure 4: A normal heart rate compared to a tachyarrhythmia rate

Types of tachyarrhythmias

Tachyarrhythmias occur when overly sensitive cells in the heart release electrical impulses faster than the normal heart rate.

Sometimes just a few cells of the heart are responsible for starting an abnormally fast heart rhythm. Tachyarrhythmias can start in either the upper heart chambers (atria) or lower heart chambers (ventricles).

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During ventricular fibrillation the body is quickly starved of oxygen, and the person usually passes out within a few seconds. VF is always life threatening.

Here are some symptoms of tachyarrhythmia:

- Shortness of breath
- Fluttering or pounding in the chest
- Dizziness
- Light-headedness
- Sudden weakness
- Fainting

Here are some causes of tachyarrhythmias:

- Heart-related conditions such as high blood pressure (hypertension), poor blood supply to the heart muscle due to coronary artery disease, heart valve disease, heart failure, tumors, and infections.
- Other medical conditions such as thyroid disease, certain lung diseases, electrolyte imbalance, and alcohol or drug abuse.

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Atrial tachyarrhythmias

Atrial tachyarrhythmias start in the atria and are called **atrial flutter** or **atrial fibrillation (AF)**. Your heart device may treat atrial tachyarrhythmias. Ask your doctor if your heart device treats atrial tachyarrhythmias

Ventricular tachyarrhythmias

Ventricular tachyarrhythmias start in the ventricles and are called **ventricular tachycardia (VT)** and **ventricular fibrillation (VF)**. Because the ventricles pump blood to the body, both of these conditions can lead to a quick depletion of oxygen-rich blood to the body, a life-threatening condition.

- Ventricular tachycardia (VT) is a heart rhythm that is regular but very fast. This condition causes the heart to beat too fast to pump blood effectively.
- Ventricular fibrillation (VF) is a ventricular tachyarrhythmia that has become unstable and irregular. VF causes the heart muscles to quiver in place, without a detectable rhythm.

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Your heart has a natural rhythm

Bradycardia – When the heart beats too slowly

Bradycardia is a slow or irregular heart rhythm, usually less than 60 beats per minute. When the heart rate is this slow, not enough oxygen-rich blood is pumped to the body. With this extremely slow heart rate, the heart cannot pump enough blood to the body to support daily activities or mild exercise.

Bradycardia can be caused by the delayed release of electrical impulses from the SA node (the heart rate determining mechanism) or when the normal pathway for electrical impulses in the heart is interrupted (**heart block**).

Here are some symptoms of bradycardia:

- Dizziness
- Extreme fatigue
- Shortness of breath
- Fainting spells

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Your heart has a natural rhythm

Here are some causes of bradycardia:

- Hereditary defects
- The aging process
- Certain illnesses
- A heart attack
- Some cardiac drugs
- An unknown cause

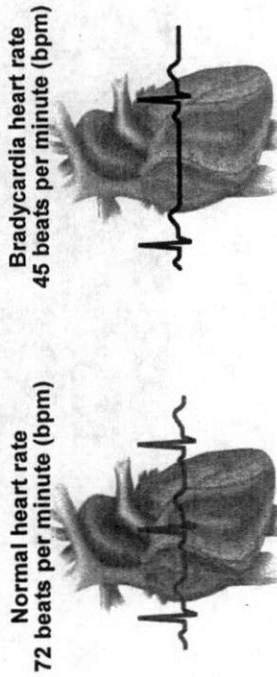


Figure 5: A normal heart rate compared to a bradycardia rate

4 About your heart device

Your doctor has prescribed a Medtronic heart failure pacemaker with defibrillation to treat your heart failure symptoms. (Your doctor may use other terms to describe this type of device, such as cardiac resynchronization therapy with defibrillation, heart failure heart device, biventricular heart device, and three-lead heart device.) A heart failure pacemaker with defibrillation can help relieve the symptoms for most patients affected by heart failure. Although this heart device does not prevent or cure your underlying heart rhythm condition, it may improve the quality of your life.

This chapter should answer many of your questions about your heart device, including the following questions:

- What is a heart failure pacemaker with defibrillation?
- What types of therapies does my heart device provide?
- What does my heart device therapy feel like?

- Are there any special features I need to know about my heart device?

If you have questions that are not answered in this manual, ask your doctor or call Medtronic Patient Services at 1-800-551-5544.

What is a heart failure pacemaker with defibrillation?

Your heart failure pacemaker with defibrillation is part of complete treatment system that includes the following components:

- An implanted heart device
- Three implanted leads
- A **Medtronic CareLink Programmer** used by your doctor to monitor and adjust the settings of your heart device

Your heart device

Your heart device contains a very small computer that is powered by a tiny lithium battery. All electronic components of your heart device are sealed inside a metal case made of titanium. Your device is

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designed to monitor your heart rate and deliver immediate treatment for any irregular heart rhythms when necessary.

The heart failure pacemaker with defibrillation provides three types of treatment or therapy for your heart: bradycardia pacing, defibrillation, and **cardiac resynchronization therapy (CRT)**. For details about these therapies, see "What types of therapies does my heart device provide?" on page 89.

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deliver the type of therapy needed to help relieve your heart failure symptoms.

Your heart device constantly monitors your heart rate using the implanted leads. If your heart device detects an irregular heart rhythm, it provides therapy to the heart by releasing an electrical pulse or multiple pulses from the tip of the lead to the heart. For descriptions of the available types of therapies, see "What types of therapies does my heart device provide?" on page 89.

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Implanted leads

A lead is soft, insulated wire that monitors your heart rate and delivers therapies to your heart when necessary. When your heart device is implanted, your doctor threads one end of the lead through a vein into your heart, then connects the other end of the lead to your heart device.

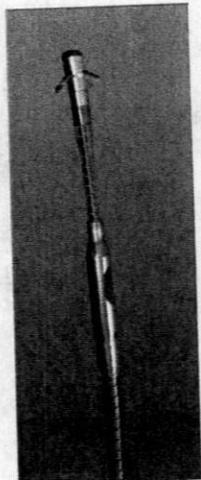


Figure 6: Example of a lead

The heart failure pacemaker with defibrillation uses three leads. One lead is placed inside the right atrium, another lead is placed inside the right ventricle, and the third lead is placed inside a vein on the outside of the left ventricle (see Figure 7 on page 88). This is the best way to

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About your heart device

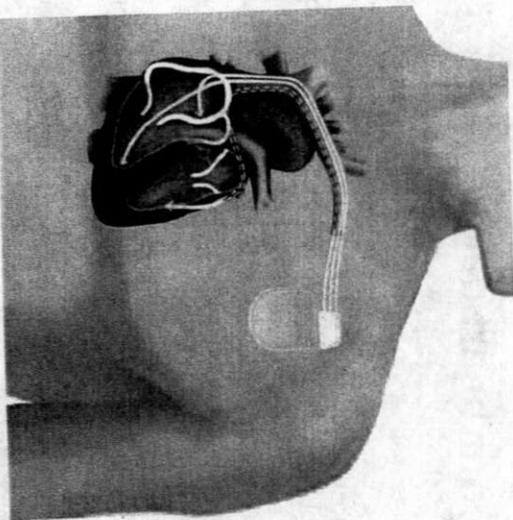


Figure 7: The leads are attached to your heart device. Leads sense your heart rate and deliver therapies to your heart when needed.

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About your heart device

What does my heart device do?

Your heart device constantly monitors your heart rhythm. If your heartbeat is too slow, too fast, or uneven, your heart device delivers pulses of electricity from the tip of the lead directly to your heart. This therapy is designed to help your heart beat in a regular rhythm. There are a few different types of therapies that your heart device can deliver. The therapy provided depends on the type of abnormal heart rhythm detected by your heart device.

What types of therapies does my heart device provide?

Your heart failure pacemaker with defibrillation can provide several types of therapies. Because your heart device is constantly monitoring the rhythm of your heart, it can detect irregular rhythms and automatically deliver the most appropriate type of therapy when it is needed.

In response to irregular heart rhythms, your heart device provides the following specialized therapies:

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Cardiac resynchronization therapy (CRT)

Cardiac resynchronization therapy can help restore a normal coordinated heart rhythm by delivering pacing therapy to both sides of the heart.

Pacing therapy consists of delivering a steady pattern of small electrical pulses to the heart muscle through the leads.

As illustrated in Figure 8 on page 92, cardiac resynchronization therapy generally first stimulates the right atrium and then both the left and right ventricles. The time between the stimulation of the right atrium and the left and right ventricles is programmed to maximize the pumping action of the heart.

These small pulses encourage the heart to beat in a regular rhythm. Because cardiac resynchronization therapy paces both the right and left ventricles, your heart device controls when each side of the heart contracts. This can help your heart maintain a normal heart rhythm.

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- Cardiac resynchronization therapy (CRT) for an uncoordinated and irregular heart rhythm
- Antitachycardia pacing (ATP), cardioversion, and defibrillation therapies for a fast or uneven heart rhythm
- Pacing therapy for a slow heart rhythm

Therapy for an uncoordinated and irregular heart rhythm

Common heart failure symptoms are a result of the heart not pumping enough blood to meet your body's needs. In a healthy heart, the upper chambers (atria) of the heart contract first, then the lower chambers (ventricles) contract. These coordinated contractions distribute blood between your lungs and heart to the rest of your body. If the contractions of the heart are not coordinated, then the body does not receive enough blood to function normally.

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About your heart device

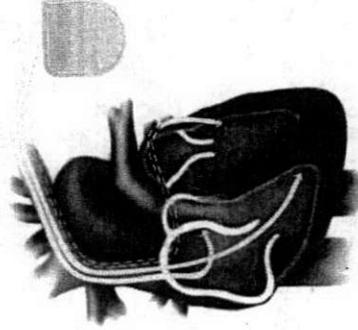


Figure 8: How CRT works

Improving the coordination of your heart rhythm helps your heart pump the amount of blood needed by your body and can help reduce the symptoms of heart failure.

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About your heart device

Therapies for a fast heart rhythm

Your heart device provides several therapies to treat a fast heart rhythm. Your doctor has set up your heart device to deliver the most effective type of therapy for your specific heart rhythm condition.

There are three kinds of therapies used to treat fast heart rhythms:

- Antitachycardia pacing (ATP)
- Cardioversion
- Defibrillation

Antitachycardia pacing (ATP) therapy

Antitachycardia pacing (ATP) is often the first type of therapy used by your heart device to treat a fast heart rhythm.

During antitachycardia pacing therapy, your heart device releases several short bursts of pacing pulses; then it pauses to check for a normal heart beat. If the heart rhythm is still irregular, the ATP therapy is repeated.

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the outside of the body over the heart. However, a much lower level of electricity is delivered by the heart device because this therapy is applied directly to the heart.

Your heart device responds automatically with life-saving defibrillation during the first crucial seconds of a tachyarrhythmia (fast heart rhythms) when an emergency team may be minutes away or not available.

The therapy shock usually stops the abnormal electrical impulses that are causing your heart to beat too fast. After each therapeutic shock, your heart device monitors your heart for a normal rhythm and delivers another therapy shock if the rhythm is still too fast.

When a normal heart rhythm is restored, no further therapy is delivered.

For information on what to do if you receive a therapy shock, see "What if I receive a therapy shock?" on page 23.

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If a normal rhythm is restored, no further treatment is delivered. If your heart rate is still too fast or uneven, your heart device delivers either cardioversion or defibrillation therapy to restore a normal heart rate.

Cardioversion therapy

Cardioversion therapy is used to treat an extremely fast but stable heart rhythm. Cardioversion therapy involves delivering a low-level shock to the heart at the same time as your natural heart beat. This therapy may increase to higher energy levels if the initial treatment is not successful.

Cardioversion therapy is typically used if an abnormally fast heart rhythm does not respond to ATP therapy.

Defibrillation therapy

If your heart device detects a very fast and unstable heart rhythm, it delivers a therapy shock to your heart. The clinical term for this therapy is defibrillation. This therapy is similar to the treatment provided by an external defibrillator, which uses paddles placed on

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About your heart device

Therapy for a slow heart rhythm

Bradycardia is a heart condition where the heart beats too slowly to provide enough blood for the body's needs. Your heart device provides pacing therapy to treat a slow heart rhythm.

Pacing therapy

If your heart's rhythm becomes too slow, your heart device delivers a steady pattern of small electrical pulses to your heart to encourage a regular heartbeat. This is called pacing your heart. Pacing therapy was one of the very first treatments available from a heart device commonly known as a **pacemaker**. The pacing therapy provided by your heart device ensures that your heart maintains a heart rhythm that supports your body's needs.

What do the therapies feel like?

The experience of receiving heart device therapies varies from person to person. The sensations people have reported feeling during the different therapies are described next.

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About your heart device

Pacing therapy – Most people do not feel pacing therapies w. , they are delivered. The few that report feeling this type of therapy describe it as painless.

What is Medtronic CareAlert monitoring?

Your heart device has the ability to monitor itself and your lead system for proper functioning. This ability is provided through the Medtronic CareAlert monitoring feature. With the Medtronic CareAlert monitoring feature, your doctor can program your heart device to monitor itself for proper functioning and to monitor your heart for changes in your heart rhythm. Your heart device may alert you to contact your doctor by emitting a beeping sound. If you hear a beeping sound, contact your doctor. Your doctor can discuss what has occurred and can further evaluate changes pertaining to the device or particular rhythms.

If you have a **Medtronic CareLink Monitor**, your doctor can also program your heart device to automatically send heart information

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About your heart device

- The number of therapies detected

Additionally, your heart device can monitor for changes in your heart rhythm that your doctor may want to be aware of. If one of these conditions is detected by your heart device, it will make a beeping sound for at least 10 seconds, at least once a day. Call your doctor if your heart device starts to make a beeping sound.

Checking your Medtronic CareAlert status

Your doctor may give you a **Patient Magnet** to check your Medtronic CareAlert status. To check if the Medtronic CareAlert monitoring feature is turned on, place your Patient Magnet over your heart device.

- If an alert has occurred, your heart device will make an alert sound.
- If no alert has occurred, your heart device will make a steady "OK" sound when a Patient Magnet is applied.

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About your heart device

Cardiac resynchronization therapy (CRT) – Since cardiac resynchronization therapy uses small pacing pulses to resynchronize the heart, most people are not aware of the therapy when it is delivered.

Antitachycardia pacing (ATP) – This therapy is often not felt at all and lasts only a short period of time. It may cause a rapid heart beat sensation, but the feeling is generally not reported as uncomfortable.

Cardioversion – This therapy is often described as "a thump on the chest" and can cause mild discomfort.

Defibrillation – Some people lose consciousness as a result of their rapid heart beat and are not aware of receiving defibrillation (or therapy shock). Others who are awake during a therapy shock describe it as a "kick in the chest." They say it startles them and that the feeling passes very quickly. Some people find the therapy shock a reassuring reminder that their heart device is protecting them from sudden cardiac arrest, while others find it fleeting but also distressing.

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through the monitor to your clinic without having your heart device beep.

Using the Medtronic CareAlert monitoring feature, your doctor chooses to monitor device function, your heart rhythm, or both. Ask your doctor if this feature is turned on and which conditions are being monitored. You should discuss whether there is likely to be a beeping sound. This will help you understand the purpose of Medtronic CareAlert monitoring and how your doctor has programmed the device to meet your needs. But remember, if your device makes a sound, you should always contact your doctor unless otherwise directed.

Conditions that Medtronic CareAlert monitoring can detect

At the time your heart device is implanted or during a routine follow-up appointment, your doctor can set Medtronic CareAlert monitoring to alert you about things such as the following:

- Heart device battery status
- The status of your leads

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Cautions:

- Never carry, store, or leave the Patient Magnet over your heart device. Your heart device cannot treat a tachyarrhythmia (fast heart rhythm) while the magnet is placed over it.
- The Patient Magnet is a special magnet and should be used only as directed by your doctor. Other magnets should never be placed over or held close to your heart device (see "Items that contain magnets" on page 37 for more information).

Your nurse or doctor will explain how to use the Patient Magnet; you can also refer to the Patient Magnet manual for additional information.

5 Your implant procedure and recovery

Being told you need a heart device can be upsetting, but knowing what to expect about your implant procedure can help reduce your concern. The implant procedure does not require open heart surgery. You will be given medication to make you sleepy and comfortable, but the surgery is typically performed using local anesthesia.

You will usually stay in the hospital overnight and go home the next day with instructions on caring for your incision. For a short time after surgery, your doctor may want you to limit how much you move the arm that is closest to your implant site.

This chapter has important information about the following topics:

- The implant procedure
- Potential risks after the implant procedure
- Recovering after your surgery and keeping follow-up appointments

The implant procedure

The implant procedure includes these general steps:

1. Making the incision and inserting the leads.
2. Testing the leads.
3. Implanting the heart device and closing the incision.

Making the incision and inserting the leads

Your doctor will make a small incision, just below your collarbone, on the left or right side of your chest. (Sometimes heart devices are implanted in the abdominal area in children or small adults.)

The doctor inserts the first two leads, one at a time, into a vein, threading each through the vein into your heart. The tip of each lead is positioned so that it touches the inside wall of your heart. This type of lead is called a **transvenous lead**. The third lead is inserted in a vein that lies on the outside of the left ventricle, where the lead tip can deliver pacing pulses to the left ventricle.

Sometimes a lead needs to be placed on the outside of the heart. This type of lead is called an **epicardial lead** or **patch lead**. If this type of lead is needed, your doctor inserts it by making a small incision between your ribs just over your heart.

In general, leads are referred to by their location in your heart:

- An atrial lead is placed in the right atria.
- A right ventricular lead is placed inside the right ventricle.
- A left ventricular lead is placed in a vein on the outside of the left ventricle.

Testing the leads

After each lead is placed in your heart, it is tested to make sure that it will operate effectively. Your doctor tests each lead to make sure that it can accurately monitor your heart rate and deliver heart rhythm therapies.

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- Bleeding
- Infection
- Blood clots
- Punctures of the heart muscle, vein, or lung space caused while implanting the leads
- Heart attack
- Stroke

Your doctor should discuss these and other potential risks of this surgical procedure with you.

After the implant procedure is finished, there is a potential risk of additional hospitalization or surgery to modify or adjust your implanted heart device. Additional hospitalization may be required under some conditions, such as these:

- Movement of the heart device from its original location or wearing away of the skin over the heart device

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Implanting the heart device and closing the incision

After testing, the leads are attached to your heart device. The heart device is then implanted under the skin. Your doctor tests the heart device and implanted leads to confirm that they are operating effectively, then closes the incision.

Before you leave the hospital, your doctor may check the heart device by starting a rapid heart rhythm and allowing the heart device to correct it. Your doctor will give you medication to let you sleep while this check is performed.

Potential risks after the implant procedure

Your doctor and Medtronic have attempted to minimize the risks associated with implanting a heart device. However, as with any kind of surgery, there are potential risks.

The following potential risks are associated with implanting a heart device:

- Pain, swelling, or bruising around the implant site

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Your implant procedure and recovery

- Changes in your heart rhythms that require adjustment or changes to the **lead system**
- Changes in the lead system that prevent the heart device from detecting the heart rhythm or delivering therapies
- Stimulation of muscles other than the heart muscle by the heart device

Recovering after your implant surgery

Some time after your heart device is implanted, your doctor may order some tests such as an ECG, blood tests, or x-rays to confirm that your leads are in the proper position inside your heart. The operating settings for your heart device may also be checked again to make sure that your heart device is providing the best treatment for your heart condition.

As you recover, follow your doctor's suggestions about resuming normal activities. Expect a gradual recovery. It is normal to see a slight bulge under your skin where the heart device is located.

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Your implant procedure and recovery

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Here are general recommendations for the first few weeks after your surgery:

- Call your doctor immediately if any swelling, warmth, or drainage appears around your incision or if you develop a fever.
- Use care when exercising and bathing, according to your doctor's directions.
- Avoid tight clothing that may irritate your incision.
- Limit arm movements as directed by your doctor.
- Avoid lifting more than 10 to 15 pounds (5 to 7 kilograms).
- Avoid excessive twisting of your torso.
- Avoid pushing or pulling heavy objects.
- When you are driving or riding in a vehicle, the shoulder seat belt strap may feel uncomfortable. You can place a soft towel between the shoulder seat belt strap and your implant site to cushion the area during the first few weeks after surgery. In any case, seat belts should be worn at all times.

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6 Registering your heart device

Registering your heart device is important. Registration ensures that medical information related to your heart device is on file and that Medtronic can notify your doctor with any relevant device information, if necessary.

The Food and Drug Administration (FDA) requires that medical device companies keep track of their devices implanted in the United States. The registration information must be accurate and current. This information is always kept confidential.

This chapter has important information about the following topics:

- Heart device registration form
- Heart device identification (ID) card
- Heart device travel card

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Tell your other doctors and your dentist that you have a heart device. They may choose to prescribe antibiotics for you to take before and after surgery or dental work to prevent infection.

Follow-up appointments

Your doctor or nurse will work with you to schedule follow-up care appointments. For more information about these appointments, read Chapter 7, "Follow-up care" on page 117.

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Your implant procedure and recovery

Heart device registration form

In the United States and its territories, the heart device registration form is completed by your doctor, nurse, or Medtronic representative at the time of your implant. This form is then sent to Medtronic.

The form includes this information:

- Your name and contact information
- Heart device model and serial number
- Date of implant
- Your follow-up care doctor's name and phone number

This same information is included on your temporary and permanent heart device ID card.

Note: Your U.S. Social Security number is a key piece of information that helps either Medtronic or your doctor locate your address if you move. If you live outside the United States, check with your doctor for the regulations in your country.

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Registering your heart device

Your heart device ID card

While in the hospital, you will receive a temporary heart device ID card. Your permanent card will be mailed to you within 6 weeks of your implant. If you have not received your card within 6 weeks of your implant surgery, contact Medtronic Patient Registration Services at 1-800-551-5544.

Carry your heart device ID card with you at all times

Your heart device ID card is especially helpful during your follow-up appointments, when seeing other doctors or your dentist, and when traveling. It could be essential in case of a medical emergency. You should carry your heart device ID card with you at all times.

If you do not have your heart device ID card with you during a medical situation, your doctor or nurse can call Medtronic (or the medical records department of the hospital where your heart device was implanted) to request information about your heart device.

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Medtronic heart device travel card

A special Medtronic heart device travel card is also available from Medtronic. This multilingual card identifies you as having an implanted heart device and provides instructions for security personnel on how to properly scan your heart device with a handheld scanner.

You can use this card, along with your heart device ID card, when you pass through security gates at airports and other secured buildings such as some libraries and government buildings. The card is especially useful when traveling internationally.

You can request the Medtronic heart device travel card by calling Medtronic Patient Registration Services at 1-800-551-5544 or from the website www.medtronic.com/rhythms.

To request a new heart device ID card or update your personal information

If you lose your heart device ID card or need to update your personal information, such as your address, ZIP code, telephone number, or heart doctor, contact Medtronic Patient Registration Services at 1-800-551-5544.

Our staff is available at the following times:

Monday through Friday, 7:00 AM to 7:00 PM (Central Time)

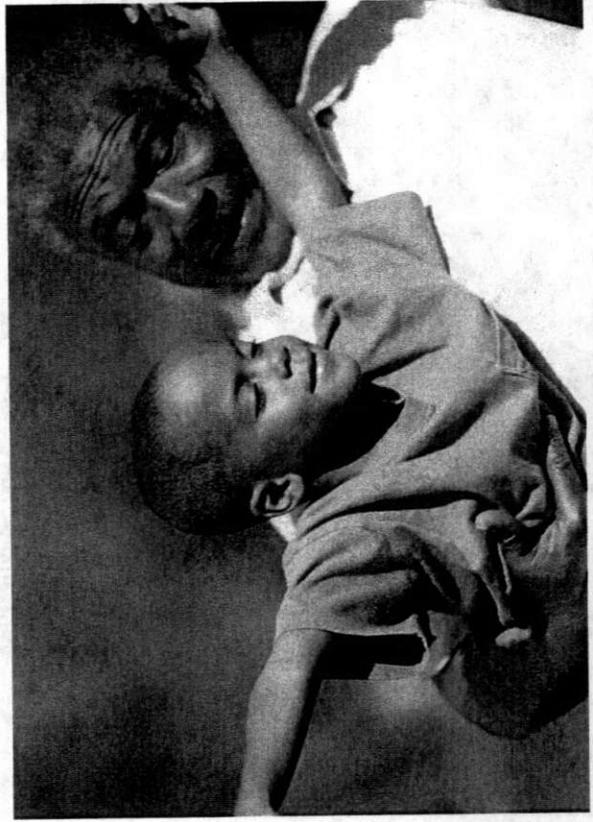
You can also update your information online at www.medtronic.com/idcard.

If you change your doctor

If you change your heart doctor, always notify Medtronic Patient Registration Services by calling 1-800-551-5544 or by updating your ID card information online at www.medtronic.com/rhythms. Also, notify Medtronic if you no longer reside in the United States.

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Registering your heart device



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7 Follow-up care

Before you leave the hospital, your doctor will tell you when you need to schedule a follow-up appointment.

Follow-up appointments are important to ensure that your heart device settings are working well for you. No surgery is required, and the procedure is painless. The appointment usually takes the same amount of time as a regular doctor's appointment.

In the past, follow-up appointments had to be done at a clinic or in your doctor's office. Today, you and your doctor have more options. Most Medtronic heart devices are supported by the Medtronic CareLink Service. This service allows you to provide your heart device follow-up information to your doctor from your own home, from work, or even while traveling within the United States.

Medtronic CareLink Service is available for use in the continental United States, Alaska, and Hawaii. For more information about the

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Depending on your doctor's normal practice and your medical condition, additional follow-up appointments are scheduled every 3 to 6 months. More frequent appointments are usually scheduled as your heart device nears its expected replacement time.

Medtronic CareLink Service, see "Remote monitoring with the Medtronic CareLink Service" on page 120.

Follow-up information

The purpose of follow-up appointments is to check or monitor the following types of information:

- Assess your general medical condition.
- Check the operation of your heart device. This includes checking the battery power and the status of your implanted leads.
- Review the information saved by your heart device.
- Adjust your heart device settings, if necessary, to provide the best treatment for your heart condition.

Your doctor or nurse will review your current medications with you and can answer any questions you have during the visit.

Your doctor will tell you how often your heart device should be checked. Your first follow-up appointment is usually scheduled for 1 month after your heart device is implanted.

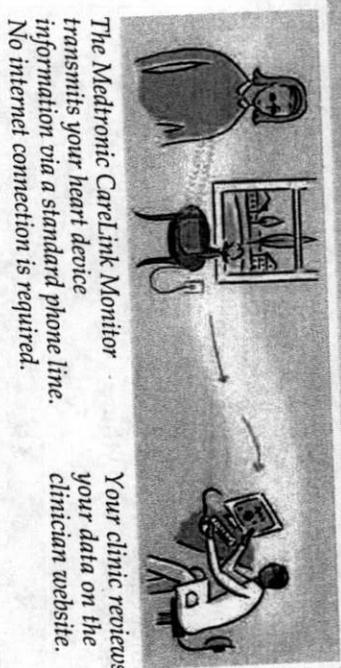
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Follow-up care

Remote monitoring with the Medtronic CareLink Service

Your clinic may offer the Medtronic CareLink Service for your heart device. The Medtronic CareLink Service allows you to send your heart device information over a standard telephone line to your clinic instead of visiting in person. The information you send is available for your doctor's review within minutes.

Medtronic CareLink Service



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Follow-up care

The Medtronic CareLink Service is convenient and provides peace of mind. One obvious advantage of using the Medtronic CareLink Service is that you will not have to leave your home for most follow-up appointments. Another benefit of this service is that it allows you to travel (within the United States) and send your heart device information from wherever you have access to a standard telephone line. The Medtronic CareLink Service cannot transmit data over a mobile phone.

If your doctor prescribes this service, Medtronic will send a Medtronic CareLink Monitor to you at your home address. The monitor comes with complete instructions and is simple for you, your family, or your care provider to use. Using wireless communication with your heart device, the monitor automatically sends follow-up information to the Medtronic CareLink Service at a time set up by you and your doctor. The monitor is easy to take with you if you plan to travel within the United States. It weighs about 1 pound (0.5 kilograms) and fits inside a suitcase or carry-on baggage.

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? Can I use the Medtronic CareLink Monitor to contact my doctor in an emergency?

No. In any emergency situation, always call 911. Unless instructed by your doctor, do not use the Medtronic CareLink Monitor to send heart device information during an emergency.

? Is there any additional cost for Medtronic CareLink Service?

Remote monitoring with the Medtronic CareLink Service is provided in the United States as a standard feature with most Medtronic heart devices. Your cost for using the Medtronic CareLink Service will be the same as a normal clinic visit co-payment. There is no cost to you for the Medtronic CareLink Monitor.

For more information about the Medtronic CareLink Service and Medtronic CareLink Monitor, talk with your doctor. You can also find information on the Medtronic website at www.medtronic.com/carelink.

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If the heart device information that is automatically sent to your doctor indicates that you should be seen in person, your doctor or clinic will contact you to set up an appointment. The doctor may need to adjust your heart device settings or adjust your medications. Your heart device settings cannot be adjusted unless you see the doctor in person.

? Will the Medtronic CareLink Service replace all clinic visits?

The Medtronic CareLink Service and Medtronic CareLink Monitor are not meant to replace all clinic visits. If you feel that you need to see your doctor, do not hesitate to contact your clinic. Sometimes, in order to determine the best course of action for you, your doctor may ask you to transmit your heart device information before coming to the clinic.

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Follow-up care

Medtronic CareLink Programmer

The Medtronic CareLink Programmer is a specialized computer designed to work specifically with your Medtronic heart device.

Your doctor or nurse uses the programmer during the implant procedure to initially set up and change the heart device settings. Using radio waves to "read" your heart device, the programmer displays information that is collected and stored in your heart device.

Your doctor or nurse uses the Medtronic CareLink Programmer during every follow-up appointment to make sure that your heart device is operating correctly and to check for any changes in your heart rhythm condition.

Reviewing information saved by your heart device

During a follow-up appointment in the clinic or hospital, your doctor or nurse will use the Medtronic CareLink Programmer to read data collected by your heart device or to change the operating settings of your heart device. Your heart device collects and saves the following information:

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Follow-up care

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- ECG recordings of any unusual heart rhythms
- A list of any therapies you have received
- The status of the heart device battery
- The status of your implanted leads

Based on this information and a review of your medications, your doctor may adjust the settings of your heart device to fit your individual needs.

When to call your doctor

Contact your doctor or nurse if you experience any of the following situations:

- You notice any swelling, warmth, or drainage around your incision or if you develop a fever while your incision is healing.
- You notice new, unexplained heart symptoms or if you experience the same heart symptoms you had before receiving your heart device.

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Replacing your heart device is typically easier and quicker than your first implant procedure. Your doctor makes an incision, removes your current heart device, and checks the leads.

Your implanted leads may be used with your new heart device if they are still in good working condition. If not, your doctor will implant new leads. At the time of heart device replacement, you should discuss lead replacement with your doctor or nurse.

The leads are connected to your new heart device, and the heart device is tested and usually implanted in the same place as your first heart device. Then the doctor closes the incision and sets the features of your new heart device.

- You have heart rhythm symptoms that last longer than 3...minutes (or any length of time specified by your doctor). These symptoms can include extreme fatigue, racing heart, pounding heart, or feeling faint or dizzy.
- You hear beeping tones coming from your heart device. For more information on the Medtronic CareAlert monitoring feature, see "What is Medtronic CareAlert monitoring?" on page 98.
- You receive a shock from your heart device and your doctor has instructed you to call. For more information, see "What if I receive a therapy shock?" on page 23.

Heart device replacement

Your heart device is powered by a lithium battery. This battery is sealed inside the titanium case of your heart device. Eventually, when the battery power is low, your heart device will need to be replaced. How long the battery lasts depends on many factors, including how often your heart device provides therapy to your heart. The average heart device battery lasts 4 to 7 years after it is implanted.

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Follow-up care

8 Caring for yourself

Caring for yourself is one of the most important parts of your follow-up care. Talk with your family and caregivers about how you are feeling, and share the information in this manual with them so that they can help you return to your normal activities.

Give yourself a few months to adjust to living with your heart device. Most people report that they have a wide range of emotions after receiving a heart device. It is natural and normal to feel a little cautious and nervous about how your heart device will affect your life. With time, your confidence will return as you get back to your normal activities and family life. Addressing your concerns and having a positive attitude toward your heart device and the therapies it provides can enhance the quality of your life over the long term (for guidance on developing a positive attitude, see page 132).

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? What are some other ways to relieve stress and get answers to my questions?

It often helps to talk with other people who have a heart device and ask them how they have adjusted to it. Ask your doctor or nurse if there is a support group for heart device patients at your clinic or a nearby hospital.

In addition, Medtronic websites provide information you may find helpful:

- *Rhythms of Life* newsletter offers information for patients about their heart devices, including patient stories and other resources. Past newsletters and additional information are available at www.medtronic.com/rhythms.
- For in-depth information on heart conditions and various heart devices used to treat heart conditions, such as pacemakers and defibrillators, see www.medtronic.com and www.hearthehelp.com.

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Chapter 8

Dealing with anxiety and getting the support you need

After receiving a heart device, many people report a positive change with feelings of relief, comfort, and well-being. Yet, experiencing feelings of anger, fear, and guilt are also natural and expected. You may want to talk with your doctor or nurse about anything that is causing you worry.

? What is one common source of stress for heart device patients and families?

A common worry pertains to the heart device performance. Medtronic medical devices are extremely reliable, and most patients feel that their quality of life improves after the implant because the device can effectively relieve the troubling symptoms. Yet, at times, you may worry about whether the device will work when needed. Follow-up appointments help monitor the performance of your device and provide you with an opportunity to ask questions. With that comes comfort and reassurance, thus reducing the anxiety.

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Caring for yourself

Shaping a positive attitude about living with a heart device

Remind yourself of the benefits – Remind yourself that your heart device protects you from the serious consequences of irregular heartbeats.

Block negative thinking – Catch yourself if you are imagining the worst-case scenarios. Remind yourself that most patients feel positive about having their heart device.

Discuss concerns – Make a list and discuss any worries you might have about your condition or heart device with your doctor and with your loved ones. Develop a plan about how to cope with your concerns.

Explore the unknown – Learn about your medical condition and your heart device from your doctor, nurse, library, device manufacturer, and Internet websites. Often learning about your heart device helps reduce anxiety.

Plan your quality of life – The goal of your ongoing care is to achieve the best quality of life possible. Take an inventory of the activities that are most important to you and discuss plans to return to those activities with your health care team.

Provided by: Dr. Sam Sears of East Carolina University and Dr. Wayne Sotile of Wake Forest University. Both health psychologists are experts who work extensively with heart device patients and provide educational information on www.medtronic.com.

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Caring for yourself

Medical care

- Follow your doctor's instructions about diet, medications, and physical activity.
- Attend all heart device follow-up appointments and other general health checkups.
- Remote monitoring may be prescribed instead of an office visit. Following your remote transmission schedule is as important as an office visit for your medical care. If necessary, you can reschedule your transmission appointment by contacting your doctor's office. For more information about remote monitoring, see "Remote monitoring with the Medtronic CareLink Service" on page 120.
- Tell any new doctor, dentist, or other health professional that you have an implanted heart device.

Planning for an emergency

Because you have a heart device, it is important to be prepared in case of any emergency. Talk to your doctor or nurse about planning for

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What your family and friends should know

Your family and friends can be a big support for you during your hospital stay and after you get home. Encourage them to learn about your heart device and about how they can continue to support you.

If your family or caregivers have any questions or concerns, have them call your doctor or nurse.

Some friends and family members may want to receive training in **cardiopulmonary resuscitation (CPR)**. They may also want to attend support group meetings with you.

For information on what you should do if your heart device delivers a shock therapy, see "What if I receive a therapy shock?" on page 23.

emergencies. They may suggest that you develop a plan with your family and friends that includes the following points:

- Carry your heart device ID card in an easy-to-find place such as a wallet.
- Carry a list of medications and dosages.
- Keep emergency phone numbers in an easy-to-find place.
- Talk with your doctor and know what to do if you receive a therapy shock.
- Inform significant coworkers, traveling companions, and so on, that you have an implanted heart device.
- When traveling by air, inform airline security personnel that you have an implanted heart device.

You may also want to post information that you want to have readily available near your phone.

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Caring for yourself



Medtronic Warranty

For complete warranty information, call Medtronic Patient Services at 1-800-551-5544. Our staff is available Monday through Friday from 7:00 AM to 6:00 PM (Central Time).

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Glossary

The words that appear in this section are found in **bold** throughout this manual. It may be helpful to familiarize yourself with them.

antitachycardia pacing (ATP) – Small, rapid pacing pulses delivered by a heart device to treat an abnormally fast heart beat.

atrial fibrillation (AF) – A heart rhythm that causes the atria to quiver in one place rather than contract.

atrial flutter – An atrial heart rhythm that is regular but very fast.

atrial tachyarrhythmias – Abnormally fast heart rhythms that start in the atria. Atrial flutter and atrial fibrillation (AF) are atrial tachyarrhythmias.

atrioventricular node (AV node) – An area of cardiac muscle fibers located in the middle of the heart. Electrical signals from the sinoatrial (SA) node travel through the AV node before moving to the rest of the heart. The AV node helps keep the upper and lower heart chambers beating in a balanced rhythm.

atrium (plural = atria) – The two upper chambers of the heart are referred to as the right atrium and the left atrium. The term "atria" is the plural of "atrium," and refers to both the right and the left atrium.

autonomic nervous system – The autonomic nervous system regulates internal body processes that require no conscious effort, such as heart rate and blood pressure. This system is made up of the sympathetic and parasympathetic systems. These systems work together; for example, the sympathetic system increases pulse, blood pressure, and breathing rates, and the parasympathetic system decreases each of them.

bradycardia – A type of heart condition in which the heart beats less than 60 beats a minute.

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Glossary

cardiac resynchronization therapy (CRT) – A therapy delivered by a heart device that provides electrical impulses to both sides of the heart. Stimulating both sides of the heart encourages the heart to beat more effectively.

cardiopulmonary resuscitation (CPR) – A life saving procedure that includes the timed external compression of the chest wall (to stimulate blood flow), and may include mouth-to-mouth breathing to provide oxygen.

cardioversion – A therapy provided by a heart device to treat an extremely fast but stable heart rhythm. Cardioversion therapy involves delivering a low-level shock to the heart at the same time as your natural heart beat. This therapy may increase to higher energy levels if the initial treatment is not successful. See also **defibrillation**.

CarAlert monitoring – See **Medtronic CarAlert monitoring**.

CarAlert Monitor – See **Medtronic CarAlert Monitor**.

CarAlert Service – See **Medtronic CarAlert Service**.

catheter microwave ablation – A surgical technique where microwaves are used to destroy cells by creating heat.

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ejection fraction (EF) – EF is the amount of blood pumped out of the heart during each beat or contraction.

electrocautery – A process in which an electric probe is used to remove unwanted tissue and to control bleeding.

electrolysis – The permanent removal of hair using an electrified needle inserted into the hair follicle.

electrolyte imbalance – Electrolytes are nutrients needed for bodily function. An electrolyte imbalance is an abnormal level of electrolytes in the body.

electromagnetic compatibility (EMC) – Fields of energy around certain types of equipment that use electricity and magnets may interfere with the normal operation of other electronic devices, such as a heart device. These energy fields created around electrical items can be strong or weak. The closer to the item you are, the stronger the energy field. Electromagnetic compatibility means that the electrical energy field generated by an electrical item is compatible with other electrically sensitive items such as a heart device.

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computerized axial tomography (CT or CAT) scan – A computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image.

congestive heart failure – See **heart failure**.

defibrillation – A type of therapy provided by a heart device or external electronic equipment to treat a fast, irregular heart rhythm. Defibrillation therapy involves delivering a high-energy therapy shock to the heart. See also **cardioversion**.

defibrillator – An external or implanted heart device used to deliver defibrillation therapy to the heart.

diagnostic ultrasound – An imaging technique used to visualize muscles and internal organs, their size, structures, and any pathological lesions.

diathermy treatment – A treatment involving the heating of various areas of the body.

EKG or ECG – ECG (EKG) is an abbreviation for "electrocardiogram." An electrocardiogram is a test that measures the electrical activity of a person's heart.

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electromagnetic energy field – A force that certain types of equipment that use electricity and magnets exert on objects in their vicinity.

epicardial lead – A pacing lead attached to the outside surface (epicardium) of the heart.

external defibrillator – Emergency personnel use either manual external defibrillator equipment or a handheld automated external defibrillator (AED) to deliver defibrillation therapy shocks to treat sudden cardiac arrest or to counteract atrial fibrillation or ventricular fibrillation. External defibrillators deliver therapy to the chest at very high energy levels.

external defibrillation – Use of an external defibrillator.

fibrillation – See **ventricular fibrillation (VF)**, **atrial fibrillation (AF)**.

heart attack (myocardial infarction) – When some of the heart's blood supply is reduced or cut off, causing the heart muscle (myocardium) to die because it is deprived of its oxygen supply.

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heart block – A type of heart problem where the electrical impulses traveling from the upper chambers to the lower chambers of the heart are slowed (first degree heart block), irregular (second degree heart block), or blocked (third degree heart block).

heart device – An active, implantable, medical device that treats abnormal heart rhythms (arrhythmias). Types of arrhythmias that can be treated include bradycardia, when the heart beats too slowly, or tachycardia, when the heart beats too fast.

heart failure (congestive heart failure) – A condition in which the heart can't pump enough blood to meet the needs of the body. Symptoms may include shortness of breath and tiredness from daily activities.

heart failure pacemaker with defibrillation – A heart device designed to relieve heart failure symptoms by improving the heart's ability to pump blood and oxygen to the body. The device combines the capabilities of a pacemaker and a defibrillator. See also **pacemaker and defibrillator**.

heart rate – The number of contractions of the cardiac ventricles per unit of time (such as beats per minute).

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magnetic resonance angiography (MRA) – See **MRA**.

Medtronic CareAlert monitoring – A feature provided by most Medtronic heart devices, which activates a beeping alert when certain conditions occur. The alert sounds at the same time every day until the heart device is reset by your doctor or nurse.

Medtronic CareLink Monitor – The monitor used with the Medtronic CareLink Service to send your heart device information to your doctor or clinic. The Medtronic CareLink Monitor plugs into a standard telephone outlet and provides you the convenience of sending follow-up information from home or while traveling within the United States.

Medtronic CareLink Programmer – A small laptop-style computer used by your doctor, nurse, or trained technician to check your heart device settings, retrieve information stored by your heart device, and adjust your heart device settings if necessary.

high-energy radiation therapy – A cancer treatment that uses radiation to control cell growth.

hyperbaric oxygen therapy (HBOT) – The medical use of oxygen at a higher than atmospheric pressure.

ICD – Abbreviation for "implantable cardioverter defibrillator," sometimes referred to as "defibrillator." An ICD is used to treat abnormal, fast ventricular heart rhythms.

interventricular conduction delays – Disturbances in the conduction of electrical signals between the ventricles, such that the ventricles do not contract at the same time.

lead, leads, lead system – A flexible wire surrounded by insulation material (urethane or silicone). The lead delivers the electrical impulse or therapy to the heart from a heart device. It also senses the electrical activity of the heart and provides this information to the heart device. See also **epicardial lead, patch lead, and transvenous lead**.

lithotripsy – A medical technique that uses electrically produced shock waves to break up kidney and gallbladder stones.

magnetic resonance imaging (MRI) – See **MRI**.

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Glossary

Medtronic CareLink Service – The remote monitoring service for people with Medtronic heart devices. Using the Medtronic CareLink Monitor allows your heart device follow-up information to be sent to your doctor or clinic while you are at home, at work, or traveling in the United States.

MRA (magnetic resonance angiography) – A test within an MRI scan that is used to examine organs and soft tissues.

MRI (magnetic resonance imaging) – A type of medical imaging that uses magnetic fields to create an internal view of the body.

pacemaker (artificial) – An implanted medical device that stimulates the heart muscle with timed pulses of electricity. These very small amounts of electricity cause the heart to contract, mimicking a naturally occurring heart rhythm.

pacemaker, natural – See **sinoatrial (SA) node**.

pacing, pacing therapy – A type of therapy provided by a heart device to treat a slow heart rhythm. Pacing consists of small electrical impulses delivered to the heart to speed up the natural heart rhythm.

patch lead – A lead that is attached to the outside of the heart muscle. See also **lead**.

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Patient Magnet – A blue-coated, ring-shaped magnet used with certain Medtronic heart devices to test the Medtronic CareAlert monitoring feature or to test for certain heart device operating conditions programmed by your doctor. When the Patient Magnet is held over your heart device, you will hear a sound. If your doctor prescribes the Patient Magnet for you, complete instructions will be provided. Not all people with a heart device will need to have a Patient Magnet.

radio frequency ablation – A surgical technique in which radio waves are used to destroy cells by creating heat.

reoxygenated – To add oxygen back into the blood cells.

septum – The muscled wall dividing the right and left sides of the heart.

sick sinus syndrome – A collection of heart rhythm disorders such as sinus bradycardia or a slow heart rate due to the slowing of the natural pacemaker of the heart, tachycardia or a fast heart rate, and bradycardia-tachycardia or an alternating slow-fast heart rate.

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transurethral needle ablation (TUNA) – A surgical technique in which precisely focused radio frequency energy is used to destroy prostate tissue.

transvenous lead – A pacing lead threaded through a vein and placed inside the heart. See also lead.

ultrasound – A medical imaging technique that uses sound waves to create an internal image of the body.

ventricle, ventricles – The two lower chambers of the heart. These are called the left and the right ventricle.

ventricular fibrillation (VF) – A very fast, chaotic heart rhythm that starts in the ventricles. During VF, the heart quivers instead of contracting. If left untreated, VF is fatal.

ventricular tachyarrhythmia – Abnormally fast heart rhythms that start in the ventricles. Ventricular fibrillation (VF) and ventricular tachycardia (VT) are ventricular tachyarrhythmias.

ventricular tachycardia (VT) – A rapid heart rate that starts in the ventricles. During VT, the heart does not have time to fill with enough blood between heart beats to supply the entire body with sufficient blood. VT may cause dizziness and light-headedness.

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sinoatrial (SA) node – The heart's natural pacemaker located in the right atrium. Electrical impulses originate here and travel through the heart, causing it to beat. Also called the sinus node. See also atrium.

sudden cardiac arrest (SCA) – Also called "cardiac arrest." Failure of the heart to pump blood through the body. If left untreated, it will lead to death within minutes.

tachyarrhythmia – A fast or irregular heart rhythm, usually more than 100 beats per minute and as many as 400 beats per minute. See also tachycardia.

tachycardia – An abnormally fast heart rhythm, usually between 100 to 250 beats per minute. See also tachyarrhythmia.

therapeutic ultrasound – The use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body.

therapy shock – See defibrillation.

transcutaneous electrical nerve stimulation (TENS) – A pain control technique that uses electrical impulses passed through the skin to stimulate nerves.

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At Medtronic, we're proud of our reputation as the worldwide leader in medical technology.

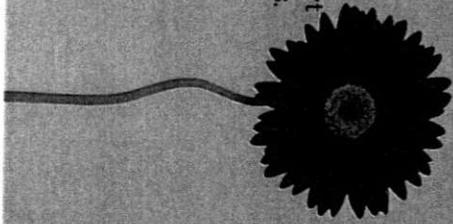
In fact, we've been collaborating with physicians around the world to develop devices to treat heart disease for over 50 years.

We were the first company in the United States to introduce a heart failure pacemaker.

Today, physicians worldwide have prescribed heart failure pacemakers for more than 120,000 patients.

We never stop working on ways to help our patients lead fuller, longer, healthier lives.

We hope we can help improve yours.



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