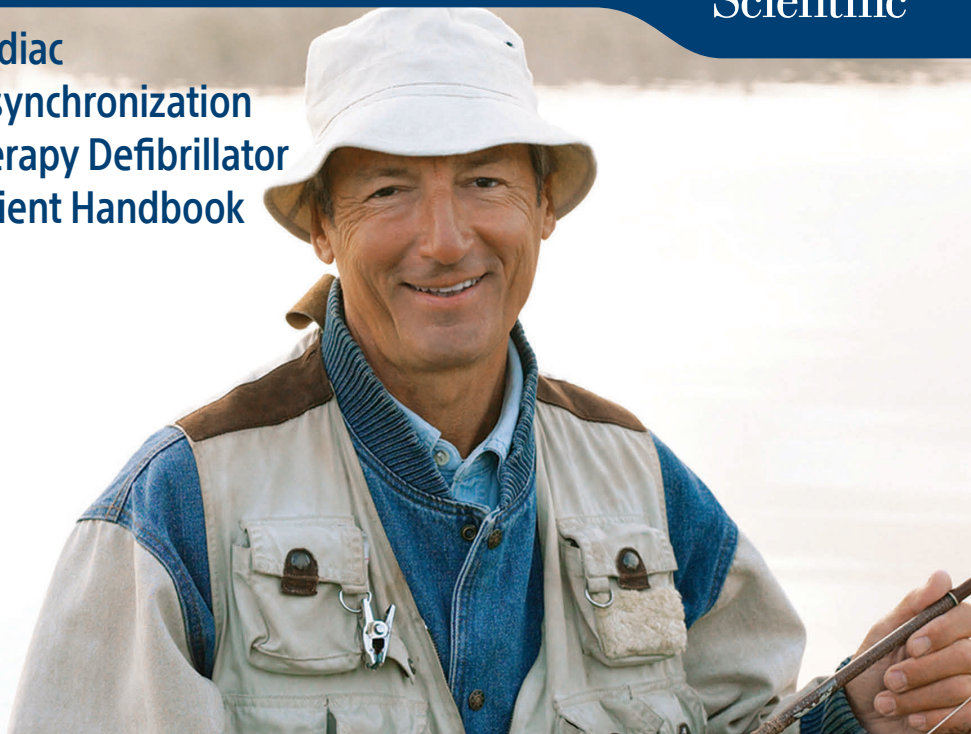


Cardiac
Resynchronization
Therapy Defibrillator
Patient Handbook





Your CRT-D system information

Have your doctor or nurse complete these forms before you go home from the hospital.

CRT-D Model Number: _____

CRT-D Serial Number: _____

CRT-D Features: RF telemetry LATITUDE™

Implant Date: _____

Lead Model/Serial Numbers: _____

Your medical contact information

Electrophysiologist Name/Phone Number:

Cardiologist Name/Phone Number:

Hospital Name/Address/Phone Number:

Medications (list): _____

By Mail:

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

By Telephone:

Worldwide: 651.582.4000
Medical Professionals: 1.800.CARDIAC (227.3422)
Patients and Families: 1.866.484.3268

On the Internet:

www.bostonscientific.com
www.bostonscientific.com/patientlabeling

Table of contents

Introduction	1
When is this device used?, 3	
How reliable is this device?, 4	
Glossary	5
Your heart's natural pacemaker	21
Heart failure, 23	
Heart failure, arrhythmias, and your device, 25	
Ventricular tachycardia, 28	
Ventricular fibrillation, 29	
Bradycardia, 31	
Sudden cardiac arrest	35
Risk factors, 35	

Identifying your SCA risk, 36

Your CRT-D system39

The device, 39

The leads, 40

Implanting your CRT-D system.42

Implant risks, 45

After your implant 49

Medications, 51

Activities and exercise, 51

Your CRT-D system information, 52

Your identification card, 52

Living with your CRT-D 54

Preparing for CRT-D shock therapy, 56

- How therapy feels, 59
- Special considerations, 62
- Replacing your system, 71

Important safety information.....74

- Operating household appliances and tools, 75
- Theft detection and security systems, 84
- Airport security, 86
- Cellular phones, 88
- Dental and medical procedures, 89

Summary..... 96

Visit us on the Internet 98

Notes and questions 99

Symbols on Packaging	101
Index	102

The following are trademarks of Boston Scientific or its affiliates: ZIP, LATITUDE

Introduction

Your doctor has determined that you have a form of heart failure—a medical condition in which your heart muscle is unable to pump enough blood to meet your body's needs. To treat your condition, your doctor has recommended an implantable cardioverter defibrillator (ICD) system with heart failure therapy.

Your doctor may also call this ICD system a cardiac resynchronization therapy defibrillator (CRT-D) system. A CRT-D system is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated with them. It is also designed to help your heart pump more effectively to meet your body's need for blood flow.

This handbook will tell you how a CRT-D system treats heart rhythms that are too fast and/or too slow. It will discuss activities you can begin and those you should avoid after your surgery. It will talk about some of the changes that may occur in your life. It will also answer many questions patients typically have. If you have questions about what you read in this handbook, ask your doctor or nurse. They are your best resource for information.

The glossary is located at the front of the handbook. It defines many of the words you will see in the upcoming pages, as well as those you may hear from your doctors and nurses.

When is this device used?

Your doctor has decided that you should receive a defibrillator with heart failure therapy because you have an increased risk of sudden cardiac death due to ventricular rhythm disturbances. Sudden cardiac death is a result of sudden cardiac arrest, which occurs when electrical problems in the heart cause a dangerously fast and irregular heart rhythm. Heart failure is a condition in which the heart cannot pump enough blood to meet your body's needs. Patients whose heart failure is not treated with drug therapy should not receive this device. Also, you may or may not have heart failure symptoms despite drug therapy. If you have any questions about when this device is used, ask your doctor.

How reliable is this device?

It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. Refer to Boston Scientific's *CRM Product Performance Report* on www.bostonscientific.com for more information about device performance, including the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products. Talk with your doctor about this product performance data, and the risks and benefits associated with the implantation of this system.

Glossary

Adaptive rate

The ability of a device to increase or decrease its pacing rate in response to bodily needs, activity, or exercise.

Antitachycardia pacing (ATP)

A series of small, rapid, low-energy pacing pulses delivered to the heart to slow a rapid heartbeat to its normal rhythm.

Arrhythmia

An abnormal heartbeat that is too fast, too slow, or irregular.

Asynchrony

A condition in which the heart fails to maintain a normal timing sequence between atrial and ventricular contractions.

Atrioventricular (AV) node

A cluster of cells located in the wall between the right and left atrium, just above the ventricles. This part of the heart's electrical pathway helps carry signals from the atria to the ventricles.

Atrioventricular (AV) synchrony

The normal timing sequence for an atrial contraction followed, after a fraction of a second, by a ventricular contraction.

Atrium (plural: atria)

One of the two upper chambers of the heart—specifically, the right atrium and left atrium. The atria collect blood as it comes into the heart and pump blood into the lower chambers (ventricles).

Bradycardia

An abnormally slow heartbeat, typically fewer than 60 beats per minute.

Cardiac arrest

See *sudden cardiac arrest (SCA)*.

Cardiac resynchronization therapy

Therapy administered by the device that coordinates the ventricles to help them contract at the same time, allowing the heart to pump more effectively.

Cardiac resynchronization therapy defibrillator (CRT-D) system

A device (also called a pulse generator) and leads. A CRT-D system is implanted to treat a condition called heart failure. It helps the heart pump more effectively to meet the body's need for blood flow by coordinating the left and right ventricular

contractions. A CRT-D system can also function as a defibrillator by delivering an electrical shock to the heart to restore an extremely rapid and sometimes irregular heart rate to a normal rhythm. See also *defibrillator* and *heart failure*.

Cardioversion

Procedure in which a fast heart rate (i.e., ventricular tachycardia) is restored to a normal rhythm with a low-to moderate-energy electrical shock that is carefully timed with your heartbeat.

Catheter

A thin, flexible tube or wire inserted into the body for a variety of purposes. Catheters are inserted into the heart during an electrophysiology (EP) test to monitor your heart's electrical activity. Hollow catheters are also used to carry a lead through a blood vessel. See also *electrophysiology (EP) test or study*.

Communicator

See *LATITUDE Communicator*.

Defibrillation

Procedure in which a fast heart rate (i.e., ventricular fibrillation, ventricular tachycardia) is restored to a normal rhythm by delivering an electrical shock.

Defibrillator

A device that delivers an electrical shock to the heart to restore an extremely rapid and sometimes irregular heart rate to a normal rhythm. A defibrillator may be an implanted medical device or external medical equipment.

Defibrillator with heart failure therapy

See *cardiac resynchronization therapy defibrillator (CRT-D) system*.

Device

See *pulse generator*.

ECG/EKG (electrocardiogram)

A graphic representation of your heart's electrical signals. The graph shows how electrical signals travel through your heart. Your doctor can tell what kind of rhythm you have by looking at the pattern of your heartbeat.

Ejection fraction

The percentage of blood ejected from the left ventricle with each heartbeat. A healthy ejection fraction is usually higher than 55%, although this can vary depending on the individual. Patients with a low ejection fraction may have an increased risk of sudden cardiac arrest. Talk with your doctor about your ejection fraction and what impact it has on your health.

Electromagnetic field

Invisible lines of force that result from electrical fields (produced by voltage) and magnetic fields (produced by current flow). Electromagnetic fields decrease in strength the farther they are from their source.

Electromagnetic interference (EMI)

Interference that occurs when an electromagnetic field interacts with an implanted device. See also *electromagnetic field*.

Electrophysiology (EP) test or study

A test in which catheters (thin, flexible tubes or wires) are inserted into your heart to identify and measure the type of electrical signals in your heart. The test results can help your doctor identify the origins of your abnormal heart rhythms, determine how well medications work, and decide what treatment is best for your condition. The test can also be used to

see how well your device operates during your abnormal heart rhythm.

Fibrillation

See *ventricular fibrillation*.

Heart attack

See *myocardial infarction (MI)*.

Heart block

A condition in which the electrical signals of your heart's natural pacemaker (SA node) are delayed or do not reach the ventricles.

Heart failure

A medical condition in which the heart muscle is unable to pump enough blood to meet the body's needs.

Heart rhythm

A series of heartbeats. You may hear your doctor refer to your rhythm as being normal or irregular. A normal heart rate typically ranges from 60 to 100 beats per minute at rest.

Implantable Cardioverter Defibrillator (ICD) system

See *defibrillator*.

Interrogation

The process whereby a computerized device (programmer or LATITUDE Communicator) uses telemetry communication signals to gather identification and status information from your device. Your doctor uses this information to evaluate how your device is performing and check for any arrhythmia episodes you may have had. See also *telemetry communication*.

LATITUDE Communicator

An in-home monitoring system that communicates with your device. The Communicator can gather and send device data to the LATITUDE Patient Management System, which your physician can then view via the Internet. Your device may or may not be configured to use the LATITUDE Patient Management System. See also *LATITUDE Patient Management System*.

LATITUDE Patient Management System

A remote monitoring system that collects important data from your device. This patient information can be viewed via the Internet, only by members of your health care support team. Your device may or may not be configured to use the LATITUDE Patient Management System. See also *LATITUDE Communicator*.

Lead (pronounced "leed")

An insulated wire that is implanted in the heart and connected to the device. The lead senses your heartbeat and delivers pacing pulses and/or shocks from the device to the heart. The leads are usually passed into your heart through a vein.

Myocardial infarction (MI)

Also called a heart attack. A myocardial infarction occurs when an artery that supplies blood to the heart becomes blocked. As a result, blood does not reach some parts of the heart, and some of the heart tissue dies. Symptoms of a myocardial infarction may include pain in the chest, arm, or neck; nausea; fatigue; and/or shortness of breath.

Pectoral

The area above the breast and below the collarbone. This is a common area for a device implant.

Programmer

Microcomputer-based equipment that is used to communicate with the device. The programmer is used during testing and follow-up exams to gather and display information from the device. The doctor or technician also uses the programmer to adjust the device so that it senses and treats your arrhythmias.

Pulse generator

Also called a device. The pulse generator is the part of the CRT-D system that contains the electronics and the battery; it is implanted under the skin in the pectoral (or, in some cases, abdominal) area. See also *pectoral*.

Radio frequency (RF) telemetry communication

Technology that allows the device to exchange information with a programmer or LATITUDE Communicator by communicating over radio signals. RF telemetry is sometimes referred to as

ZIP™ Wandless Telemetry. Your device may or may not be configured for RF telemetry communication. See also *telemetry communication*.

Sinoatrial (SA) node

The heart's natural pacemaker. The SA node is a small group of specialized cells in the upper right chamber of the heart (right atrium) that normally generates an electrical signal. This signal runs through the heart and causes the heart to beat.

Sudden cardiac arrest (SCA)

The sudden, abrupt loss of heart function (i.e., cardiac arrest) usually due to electrical problems in the heart that cause a dangerously fast and irregular heart rhythm. If untreated, SCA can lead to death (also called sudden cardiac death).

Sudden cardiac death (SCD)

Death occurring from sudden cardiac arrest. See also *sudden cardiac arrest (SCA)*.

Telemetry communication

Technology that allows a device to exchange information with a programmer or LATITUDE Communicator by using radio frequency (RF) telemetry communication.

Ventricle

One of two lower chambers of the heart. The right ventricle pumps blood to the lungs, and the left ventricle pumps oxygen-carrying blood from the lungs to the rest of the body.

Ventricular dyssynchrony

A condition in which the heart fails to maintain a normal timing sequence between the contractions of the left and right ventricles.

Ventricular fibrillation (VF)

A very fast, irregular heart rhythm caused by abnormal electrical signals starting from several areas of the ventricle. The ventricle beats so fast that it pumps very little blood to the body. A heart in VF may beat more than 300 beats per minute. Without immediate medical attention, VF can be fatal. Defibrillation is the only way to treat VF once it occurs.

Ventricular tachycardia (VT)

A fast rhythm caused by abnormal electrical signals coming from the ventricle. The rapid rate of 120 to 250 beats per minute may produce dizziness, weakness, blind spots, and eventual unconsciousness. VT may progress to ventricular fibrillation.

Wanded telemetry communication

Technology that allows a device to exchange information with a programmer or LATITUDE Communicator through a wand that is placed over the skin near the device. See also *telemetry communication*.

ZIP™ Wandless Telemetry

See *radio frequency (RF) telemetry communication*.

Your heart's natural pacemaker

Your heart works as both a mechanical pump and an electrical organ. It is able to beat because it produces electrical signals. These signals travel through the electrical pathways of your heart (Figure 1), causing the muscle contraction that pumps blood throughout your body.

Normally these signals come from a small area in your heart called the sinoatrial (SA) node. This area is located in the upper right chamber, or right atrium. When the SA node signals the two upper chambers of the heart (the atria), they contract at the same time. The atrial contraction fills the two lower chambers (the ventricles) with blood (Figure 2). As the electrical signal travels through the ventricles, it causes them to contract, which pumps

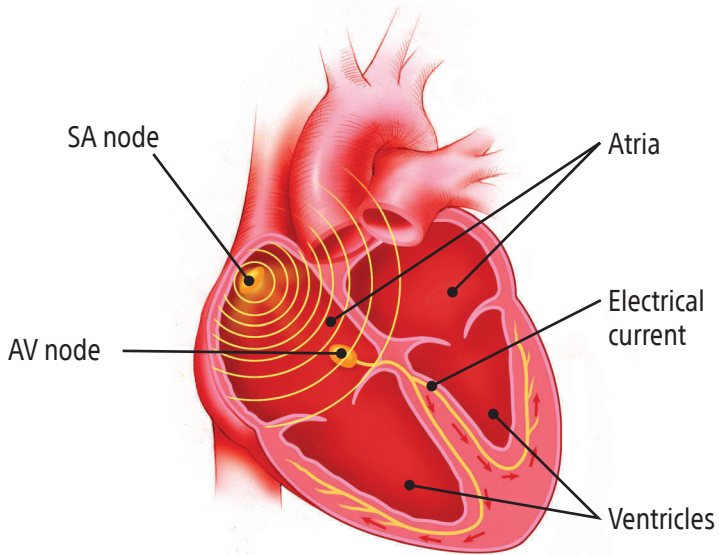


Figure 1. The heart and its electrical pathways.

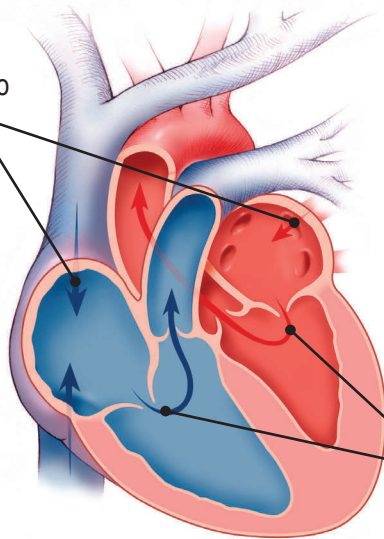
blood out to your body. The contraction of the heart muscle (ventricles) is what you feel as a heartbeat. After a brief rest, the cycle begins again.

Heart failure

The heart may begin to fail for a variety of reasons. One reason may be a result of muscular damage from a heart attack. The heart can also be weakened from prolonged periods of pumping against high blood pressure in the arteries.

Over time, the heart muscle weakens and becomes enlarged (Figure 3). The ventricles are unable to contract with the same strength or coordination as before. As a result, the flow of blood and oxygen to the body is poor.

Blood flow to
atria



Blood flow
through
ventricles

Figure 2. The heart and its blood flow.

This failure of the heart to pump efficiently and meet the body's need for blood and oxygen is known as heart failure. When you have heart failure, you may feel short of breath, tired, or light-headed, or you may faint. Medications are often used to treat heart failure and its symptoms. However, some people may also need a CRT-D system to help the heart beat more efficiently again.

Heart failure, arrhythmias, and your device

People with heart failure may also experience abnormal, irregular heartbeats called arrhythmias. An arrhythmia occurs when something goes wrong in the heart's electrical system. If the

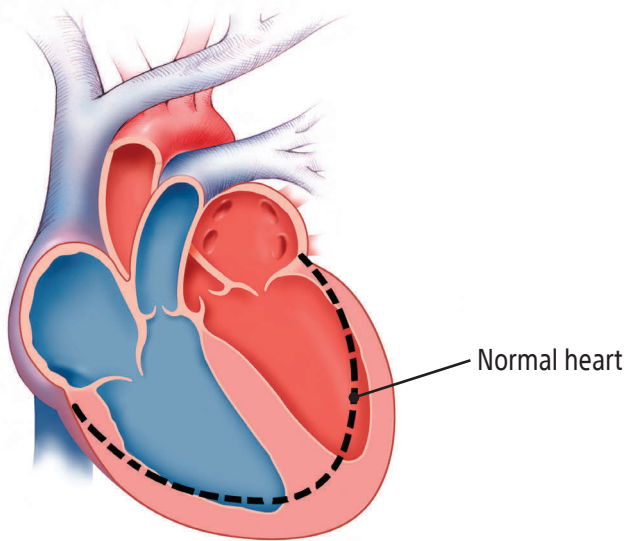


Figure 3. An example of an enlarged heart due to heart failure.

arrhythmia continues, it may prevent the heart from pumping enough blood throughout your body.

What your device does

Your device is designed to monitor and treat certain rhythm problems and greatly reduce the risks associated with them.

Several types of arrhythmias are described in the following paragraphs. Ask your doctor which of these arrhythmias you may experience, and consider recording this information in the “Notes and questions” space on page 99.

Ventricular tachycardia

One type of arrhythmia you may experience is ventricular tachycardia (VT). With this type of arrhythmia, your heart's electrical signals may come from one of the ventricles instead of the SA node (Figure 4). The electrical signal does not pass through the heart normally and causes a fast, sometimes irregular heartbeat. As your heart beats faster, it pumps less blood to your body. If this rapid heartbeat continues, you may feel skipped beats or dizziness.

You could eventually become unconscious, and your heart might stop beating (cardiac arrest).

VT can sometimes be treated with medication. In other cases, an external defibrillator—such as those used by paramedics—or

a CRT-D system may be used to stop the abnormal signals and return your heart to a more normal rhythm.

Ventricular fibrillation

Another type of arrhythmia is ventricular fibrillation (VF). With this arrhythmia, irregular electrical signals come from several spots in the ventricles (Figure 5). This causes a rapid heart rate. In some cases, the heart will beat more than 300 beats per minute.

When you experience VF, very little blood is pumped from your heart to the rest of your body. When your heart is in VF, you will become unconscious very quickly. Like ventricular tachycardia, VF can be treated with a defibrillator. The defibrillator produces an electrical shock that passes through the heart. The shock stops

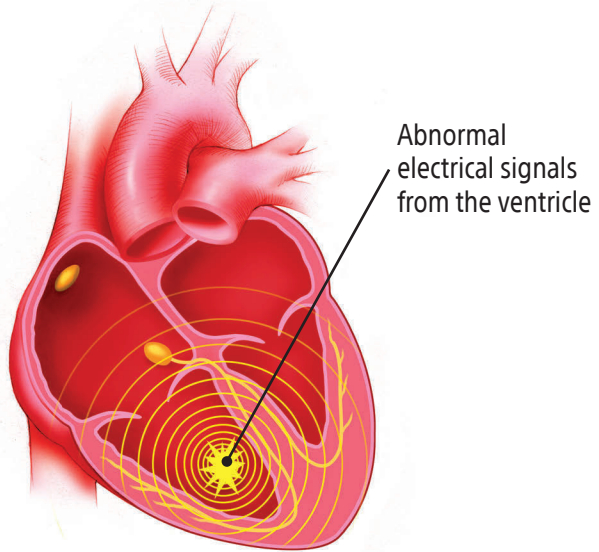


Figure 4. An example of ventricular tachycardia.

the abnormal signals and allows the SA node to return the heart to a more normal rhythm.

If an episode of VT or VF continues without medical treatment, your heart cannot supply enough oxygen-carrying blood to your brain and body tissues. Without oxygen, your brain and body tissues cannot function normally, which could be fatal.

Bradycardia

Sometimes the heart beats too slowly. This can be caused by the SA node not working properly or by a condition called heart block (Figure 6). Heart block exists when there is a problem with the electrical pathway between the atria and the ventricles. The natural pacemaker signals sent out by the SA node could be delayed or may not reach the ventricles.

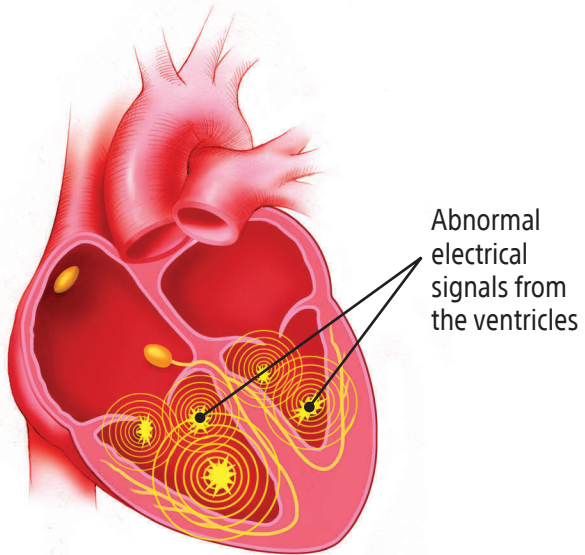


Figure 5. An example of ventricular fibrillation.

During bradycardia, the chambers of the heart do not contract often enough to supply the proper amount of blood to your body. If you have bradycardia, you may feel tired or dizzy, or you may faint.

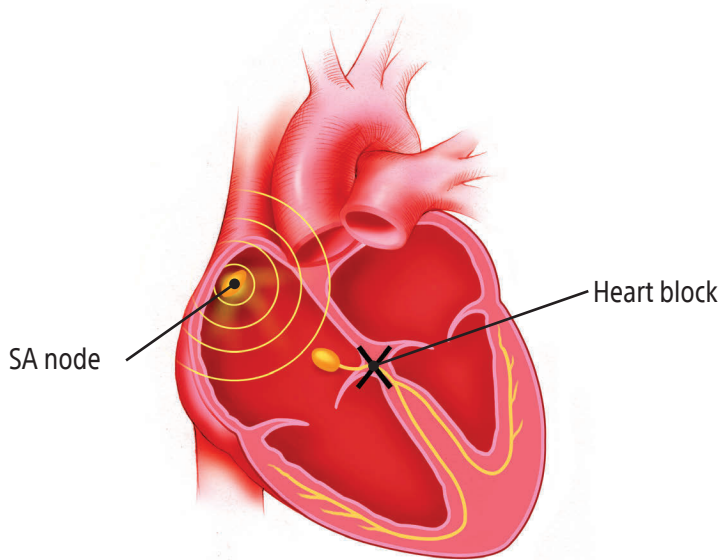


Figure 6. An example of heart block.

Sudden cardiac arrest

If you have had a heart attack, you may also be at risk for sudden cardiac arrest (SCA). Sudden cardiac arrest occurs when the heart beats very fast and irregularly as a result of abnormal electrical signals (VF), causing it to pump very little blood to the body. Because the heart does not pump enough blood throughout the body, most people tend to lose consciousness suddenly. If SCA is not treated, it can lead to sudden cardiac death (SCD). The only way to stop this type of arrhythmia is to deliver an electrical shock with a defibrillator.

Risk factors

Most people do not have obvious symptoms of SCA, so it is important to be aware of possible risk factors:

- Previous heart attack
- Impaired pumping function of the heart muscle
- Rapid, abnormal heart rhythms coming from the ventricles
- A family history of SCA or SCD

Early identification of your SCA risk is the key to prevention. If you are at risk, it is important to talk to your doctor.

Identifying your SCA risk

Your doctor may perform one or more of the following tests to assess your risk for SCA.

Echocardiogram: An echocardiogram is a test that measures your heart's ejection fraction. The ejection fraction determines your heart's pumping function. During this test, ultrasound waves are used to provide a moving image of your heart. Based upon the results of this test, your doctor will determine if further testing is needed.

Holter monitoring: A Holter monitor is an external monitor that is worn for an extended period. The monitor records your heart's electrical activity, including any arrhythmias you experience. Your doctor analyzes the recording to determine if you experience any abnormal rhythms.

Electrophysiology (EP) testing: An EP test identifies and measures the type of electrical signals in your heart. During this test, your doctor will insert catheters (thin, flexible tubes or wires)

into your heart. The catheters record electrical signals within your heart. Your doctor can also use the catheters to stimulate your heart to see if you could develop an arrhythmia. This test can help your doctor recognize if you have an abnormal heart rhythm and identify its origins. It will also determine how well certain medications or an implanted device would work to treat your heart rhythm. Your doctor can then decide what treatment is best for your condition.

Your CRT-D system

Your CRT-D system is designed to monitor and treat your heart arrhythmias. The system consists of a pulse generator (also called a device), which is typically implanted in your chest, and three leads, which are implanted in your heart and connected to the device.

The device

The device is a small computer. It runs on a battery that is safely sealed within its case. The device continuously monitors your heart rhythm and delivers electrical energy (as programmed by your physician) to your heart when it senses an arrhythmia. The device can act as a pacemaker, cardioverter, or defibrillator.

For more information about these types of therapies, see “How therapy feels” on page 59.

As the device monitors your heart rhythm, it can also store information about your heart. Your doctor can review this information using a special computer called a programmer. The programmer communicates with the device from outside your body (see “Patient follow-up options” on page 66). With the programmer, your doctor can better evaluate the programmed therapy for your heart rhythm and adjust the settings if necessary.

The leads

A lead is an insulated wire implanted in your heart and connected to the device. The lead carries the heart signal to the

device. It then carries energy from the device back to the heart to coordinate your heart rhythm.

Implanting your CRT-D system

A CRT-D system is implanted during a surgical procedure. To keep you as comfortable as possible, you will be sedated for this surgery. During the procedure, your doctor will insert two leads into a vein, usually through a small incision near your collarbone. The doctor will then pass these leads through the vein into your heart (one in the right atrium and the other in the right ventricle), where the tips of the leads will rest directly against your heart's inner wall. A third lead will also be inserted into a vein near your collarbone, and placed within a coronary vein, which lies on the outside surface of your heart's left ventricle (Figure 7).

In some cases, a patient may need to have the third lead placed on the heart's surface through an incision on the side of the chest

instead of through a vein. Your doctor will discuss whether this type of chest surgery is an alternative for you.

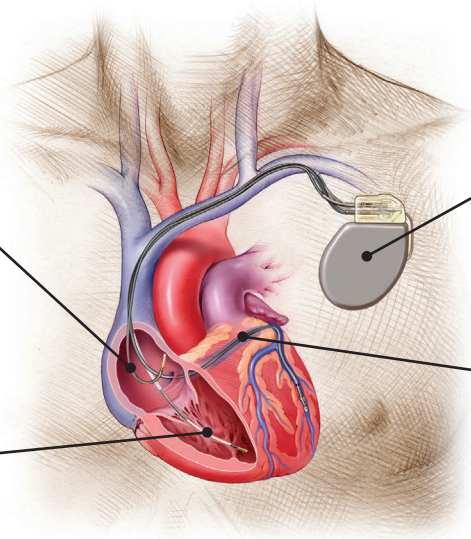
After the leads are positioned, they will be tested to make sure they clearly sense your heart signal and can adequately pace your heart. After this testing, the device will be connected to the leads and placed in position (usually below the collarbone, just beneath the skin).

Your doctor will then test your CRT-D system. During this test, your doctor will start an arrhythmia in your heart. The device will recognize the rhythm and give the programmed treatment.

After your doctor has finished testing your system, the incision will be closed. You may experience some discomfort from the

Lead
in right
atrium

Lead
in right
ventricle



Implanted
CRT-D

Lead within
coronary
sinus vein

Figure 7. An implanted CRT-D system.

incision as you recover from the surgery. You should be able to return to normal activities soon after the procedure.

Implant risks

As with any surgical procedure, it is important to understand that, while complications do not happen very often, there are risks associated with the implantation of a device or lead. You should talk with your doctor about these risks, including those listed below.

Some of the risks encountered during the implant procedure include, but are not limited to, the following:

- Bleeding
- Formation of a blood clot

- Damage to adjacent structures (tendons, muscles, nerves)
- Puncture of a lung or vein
- Damage to the heart (perforation or tissue damage)
- Dangerous arrhythmias
- Kidney failure
- Heart attack
- Stroke
- Death

Some of the risks encountered after the system is implanted may include, but are not limited to, the following:

- You may develop an infection.

- You may experience erosion of the skin near your device.
- The lead(s) may move out of place in the heart.
- The electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues, including heart tissue and nerves.
- The device may move from the original implant site.
- You may have difficulty coping with having an implanted device.
- The device might be prevented from shocking or pacing due to electromagnetic interference (see “Important safety information” on page 74).

- You may receive a shock or pacing therapy when it is not needed (unnecessary therapy).
- The device might not be able to detect or appropriately treat your heart rhythms.
- The device may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. See “How reliable is this device?” on page 4.

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of this system.

After your Implant

As you recover from your implant surgery, you will find that your device may allow you to return to an active lifestyle. It is important that you become actively involved in your recovery by following your doctor's instructions, including:

- Report any redness, swelling, or drainage from your incisions.
- Avoid lifting heavy objects as instructed by your doctor.
- Walk, exercise, and bathe according to your doctor's instructions.
- Do not wear tight clothing that could irritate the skin over your device.

- Contact your doctor if you develop a fever that does not go away in two or three days.
- Ask your doctor any questions you may have about your device, heart rhythm, or medication.
- Avoid rubbing your device or the surrounding chest area.
- If directed by your doctor, limit arm movements that could affect your lead system.
- Avoid rough contact that could result in blows to your implant site.
- Tell your other doctors, dentists, and emergency personnel that you have an implanted device and show them your Medical Device Identification card.

- Contact your doctor if you notice anything unusual or unexpected, such as new symptoms or symptoms like the ones you experienced before you received your device.

Medications

Your device is designed to help treat your heart condition. However, you may need to continue taking certain medications as well. It is important that you follow your doctor's instructions regarding any medications.

Activities and exercise

Your doctor will help you decide what level of activity is best for you. He or she can help answer your questions about lifestyle changes, travel, exercise, work, hobbies, and sexual intimacy.

Your CRT-D system information

Have your doctor or nurse complete the “Your CRT-D system information” form at the front of this handbook before you go home from the hospital.

Your identification card

Whether you are going away for the weekend or running a quick errand, carry your Medical Device Identification card with you. In an emergency, the card will alert medical and security personnel that you have an implanted device.

You will be given a temporary Medical Device Identification card when you receive your device. Boston Scientific will mail you a

permanent Medical Device Identification card about six to eight weeks after your implant.

Your Medical Device Identification card contains your name, your doctor's name and phone number, and the model numbers of your device and leads.

Updating your identification card

If you move or select a new doctor, please call Boston Scientific Medical Records at 1.800.728.3282 to update your records. When you notify us of a change, we will send you a new identification card reflecting the change.

Living with your CRT-D

It is important to follow your doctor's instructions as well as these recommendations:

- Your doctor will arrange a follow-up plan with you to check your device and overall health on a regular basis. It is important that you attend your scheduled in-office follow-up visits, even if you are enrolled in the LATITUDE Patient Management System. LATITUDE does not eliminate the need for in-office visits, although it can minimize the number of them. For more information about the LATITUDE Patient Management System, see "Patient follow-up options" on page 66.

- If you are enrolled in the LATITUDE Patient Management System, use your LATITUDE Communicator as directed by your doctor or clinician.
- Ask your doctor if you have any questions about or notice anything unusual with your device.
- Take the medications prescribed for you as instructed by your doctor.
- Carry your identification card and medication list with you at all times.
- Tell your family doctor, dentist, and emergency personnel that you have an implanted device.

Preparing for CRT-D shock therapy

While the device's monitoring of your heart won't cause any noticeable sensations, shock therapy for an arrhythmia may be very noticeable. It is important that you know what to expect.

Before you experience symptoms or receive a shock, discuss with your doctor or nurse a plan for contacting your doctor and, if necessary, emergency personnel. Use the forms in this handbook to write down important telephone numbers and information about your current medications. It might be helpful to keep this information near your phone.

If you have symptoms of a fast heart rate, it is likely that your device will deliver therapy within a few seconds. Try to remain

calm, and find a place to sit or lie down. The sensation from receiving therapy should only last a moment.

It is possible, however, that you may require additional medical attention. Be sure to talk with your doctor about what you should do, and consider the following suggestions:

1. If possible, have someone who is prepared to perform cardiopulmonary resuscitation (CPR)—should you need it—stay with you through the event.
2. Make sure a friend or family member knows to phone your local emergency response system if you remain unconscious.
3. If you are conscious but do not feel well after a shock, have someone call your doctor.

4. If you feel fine after a shock and no more symptoms appear, it may not be necessary to seek medical help immediately. However, follow your doctor's instructions for when to call his or her office. For example, if a shock occurs at night, your doctor may tell you to call him or her the next morning. Someone at the doctor's office will ask you questions such as:
- What were you doing right before the shock?
 - What symptoms did you notice before the shock?
 - At what time did the shock occur?
 - How did you feel right after the shock?
5. It is possible that you could feel symptoms of an arrhythmia but not receive therapy. This depends on the programmed

settings of your device. For example, an arrhythmia may cause symptoms, but it may not be fast enough for your device to deliver therapy. In any case, if your symptoms are severe or continue for more than a minute or so, you should seek immediate medical attention.

How therapy feels

Your device is designed to always monitor your heart rhythm. If it senses an arrhythmia, it will deliver therapy to your heart. Remember that your doctor has programmed your device to meet your individual needs. The type of therapy you receive and when you receive it is based upon those programmed settings.

Antitachycardia pacing (ATP): If your arrhythmia is fast but regular, your device can deliver a series of small, rapid pacing

pulses to interrupt the arrhythmia and return your heart to its normal rhythm. You may not feel the pacing therapy, or you may have a feeling of fluttering in your chest. Most patients who receive this pacing therapy say it is painless.

Cardioversion: If your arrhythmia is very fast but regular, your device can deliver a low- to moderate-energy shock to stop the arrhythmia and return your heart to its normal rhythm. Many patients say cardioversion is mildly uncomfortable, like a thump on the chest. This sensation will only last for a moment.

Defibrillation: If your arrhythmia is very irregular and fast, your device can deliver a high-energy shock to stop the arrhythmia and return your heart to its normal rhythm. Many patients faint or become unconscious shortly after a very fast VT or VF rhythm begins. As a result, many patients do not feel these high-energy

shocks. Some describe the sudden but brief shock as a “kick in the chest.” This sensation will only last for a moment. While many find the shock reassuring, other patients may be upset for a short time after the shock is delivered.

Cardiac resynchronization therapy (CRT): To help treat heart failure, your device monitors your heart’s signals and coordinates the right and left ventricles to help them contract at the same time. The electrical signals used for heart failure therapy are of very low energy. Patients do not typically feel this type of therapy.

Bradycardia pacing: If your heart signals are too slow, your device can pace your heart. It sends signals to your upper and/or lower chambers, telling them to contract more frequently to meet your body’s needs. This can help maintain your heart rate until

your body's natural pacemaker is able to take control. Patients do not typically feel the electrical pulses used to pace the heart.

Special considerations

Your doctor might ask you to avoid activities where the risk of unconsciousness could endanger you or others. These activities might include driving, swimming or boating alone, or climbing a ladder.

Driving

Driving laws and symptoms caused by your arrhythmia are often the deciding factors in whether you will be allowed to drive. Your doctor will advise you about what is best for your safety and the safety of others.

Sexual intimacy

For most patients, sexual intimacy is not a medical risk. The natural heart rate increase that occurs during sex is the same as the heart rate increase when you exercise. Exercise testing at the hospital will help your doctor program your device settings so you should not get a shock during sex. If you receive a shock during sex, your partner may feel a tingling sensation. The shock is not harmful to your partner. Be sure to let your doctor know if you receive a shock during sex so he or she can consider reprogramming your device.

When to call your doctor

Your doctor will provide guidelines for when you should contact him or her. In general, phone your doctor if you:

- Receive any arrhythmia therapy from your device and have been instructed to call.
- Have symptoms of an abnormal heart rhythm and have been instructed to call.
- Notice any swelling, redness, or drainage from your incisions.
- Develop a fever that does not go away in two or three days.
- Have questions about your device, heart rhythm, or medications.
- Plan to travel or move away. Work with your doctor to develop a follow-up plan while you are away.

- Hear any beeping sounds from your device. This indicates that your device needs to be checked immediately. See “What should you do if your device starts to beep?” on page 70.
- Notice anything unusual or unexpected, such as new symptoms or symptoms like the ones you had before you received your device.

Remember that your device is designed to monitor and treat your life-threatening arrhythmias. It can be a great source of reassurance for you and your friends and family.

Patient follow-up options

Your doctor will schedule regular follow-up sessions to check your device and monitor your condition. There are two follow-up options: in-office visits and remote follow-up sessions.

In-office follow-up visits

Your doctor will schedule regular in-office follow-up visits. It is important that you attend these visits, even if you are feeling well.

During your visit, the doctor or nurse will use a programmer to check your device. The programmer is a special external computer that can communicate with your device in two ways:

1. By using radio frequency (RF) telemetry communication, if you have an RF-enabled device.
2. By using wand telemetry communication. In this case, the doctor or nurse will place a wand over your skin near your device.

A typical follow-up visit takes about 20 minutes. During your visit, your doctor or nurse will use the programmer to interrogate, or check, your device. They will review your device's memory to evaluate its performance since your last visit and check for any arrhythmia episodes you may have had. If necessary, they will adjust your device's programmed settings. They will also check the battery to see how much energy is left.

Remote follow-up sessions

Your doctor may want you to use the LATITUDE Patient Management System. When using the LATITUDE Patient Management System, you will receive a home monitoring unit called a Communicator. The Communicator is used to interrogate your device on a regular schedule that is set by your physician. The Communicator then sends the data gathered from your device to the LATITUDE Patient Management secure database. Your doctor can then access this database using an Internet-enabled personal computer.

While use of the Communicator does not eliminate the need for in-office visits that may be scheduled by your physician, it can minimize the number of them. The Communicator cannot

reprogram or change any functions of your device. Your physician can only do this using a programmer during an office visit.

What you should know about your device's battery

A battery, safely sealed inside your device, provides the energy needed to monitor your heart rhythm, pace your heart, or deliver electrical therapy. Just like any other type of battery, the battery in your device will be used up over time. Since the battery is permanently sealed within your device, it cannot be replaced when its energy is depleted. Instead, your entire device will need to be replaced (see "Replacing your system" on page 71). How long your device's battery lasts depends upon the settings your doctor programs and how much therapy you receive.

How will you know if your device's battery is running down?

Device batteries have very predictable behavior over time. Your device will regularly check its own battery. At every follow-up visit, the doctor or nurse will also check to see how much energy is remaining in the battery. When the battery's energy level decreases to a certain point, your device will need to be replaced.

Your doctor can turn on a feature that will cause your device to beep when replacement time is near. See "What should you do if your device starts to beep?" on page 70.

What should you do if your device starts to beep?

Under certain conditions, your device will beep 16 times every 6 hours. Call your doctor immediately any time you hear beeping

tones from your device. Your doctor or nurse can demonstrate these beeping tones so you'll recognize them.

Replacing your system

Eventually, the energy in your device's battery will decrease to a point where your device will need to be replaced (see "What you should know about your device's battery" on page 69). Your doctor will monitor your device's battery levels and determine when to replace your device.

To replace your device, your doctor will surgically open the pocket of skin where your device is located. He or she will disconnect your old device from your leads and then check to make sure your leads work properly with your new device.

In rare instances, your leads may not work properly with your new device, and your doctor may need to replace the leads. Your doctor will determine if your leads should be replaced.

Should a lead need to be replaced, your doctor will insert a new lead into a vein, similar to how the original lead was implanted. See “Implanting your CRT-D system” on page 42.

Your doctor will then connect the leads to your new device. Finally, he or she will test your new system to make sure it is working properly.

After the testing is complete, the pocket of skin will be closed. You may experience some discomfort from the incision as you recover from the surgery. You should be able to return to normal activities soon after the procedure.

Risks

Risks encountered during a device and/or lead replacement procedure are similar to the risks of the initial implant, such as infection, tissue damage, and bleeding. See “Implant risks” on page 45.

Be sure to talk with your doctor about the potential risks when making decisions about replacing your system.

Important safety information

Your device has built-in features that protect it from interference produced by most electrical equipment. Most of the things you handle or work around on a daily basis are not going to affect your device. However, your device is sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields.

If your employment requires you to be close to large industrial generators or sources of radar, you may need special consideration before returning to work. If your work takes place in such an environment, please talk with your physician.

Operating household appliances and tools

Use the following guidelines for safe interaction with many common tools, appliances, and activities.

Items that are safe under normal use:

- Air purifiers
- Blenders
- CD/DVD players
- Clothes washing machines and dryers
- Electric blankets
- Electric can openers

- Electric invisible fences

- Electric toothbrushes

- Fax/copy machines

- Hair dryers

- Heating pads

- Hot tubs/whirlpool baths

NOTE: Consult with your doctor before using a hot tub. Your medical condition may not permit this activity; however, it will not harm your device.

- Laser tag games

- Microwave ovens

- Ovens (electric, convection, and gas)

- Pagers
- Patient alert devices
- Personal computers
- Personal digital assistants (PDAs)
NOTE: PDAs that also function as cell phones should be kept at least 6 inches (15 cm) away from your device. See "Cellular phones" on page 88.
- Portable space heaters
- Radios (AM and FM)
- Remote controls (TV, garage door, stereo, camera/video equipment)
- Stoves (electric or gas)

- Televisions
- TV or radio towers (safe outside of restricted areas)
- Tanning beds
- Vacuum cleaners
- VCRs
- Video games

Warnings and precautions

If you use any of the following items, it is important that you keep them the recommended distance away from your device to avoid interaction.

Items that should not be placed directly over your device, but are otherwise safe to use:

- Cordless (household) telephones
- Electric razors
- Hand-held massagers
- Portable MP3 and multimedia players (such as an iPod®) that do not also function as a cellular phone (see “Cellular phones” on page 88)

NOTE: *While portable MP3 players themselves should not interfere with your device, the headphones or earbuds should be stored at least 6 inches (15 cm) away from your device, and you should avoid draping the headphones around your neck.*

iPod is a trademark of Apple Inc.

Items that should remain at least 6 inches (15 cm) away from your device:

- Cellular phones, including PDAs and portable MP3 players with integrated cellular phones

NOTE: For more information about cellular phones, see “Cellular phones” on page 88.

- Devices transmitting Bluetooth® or Wi-Fi signals (cellular phones, wireless Internet routers, etc.)

The Bluetooth word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by Boston Scientific Corporation is under license. Other trademarks and trade names are those of their respective owners.

- Headphones and earbuds

NOTE: It is safe to use headphones and earbuds, but you should refrain from draping them around your neck and from storing them in a breast or other shirt pocket that places them within 6 inches (15 cm) of your device.

- Magnetic wands used in the game of Bingo
- Purses, attaché bags, backpacks, bracelets, and electronic device cases/holders with magnetic closures/snaps; respiratory masks (e.g., CPAP masks) with magnetic straps; and clothing with built-in magnets

Items that should remain at least 12 inches (30 cm) away from your device:

- Battery-powered cordless power tools
- Chain saws
- Corded drills and power tools
- Home power generators
- Lawn mowers
- Leaf blowers
- Remote controls with antennas
- Shop tools (drills, table saws, etc.)
- Slot machines

- Snow blowers
- Stereo speakers

Items that should remain at least 24 inches (60 cm) away from your device:

- Arc welders
- CB and police radio antennas
- Running motors and alternators, especially those found in vehicles

NOTE: *Avoid leaning over running motors and alternators of a running vehicle. Alternators create large magnetic fields that can affect your device. However, the distance required to drive or ride in a vehicle is safe.*

Items that should not be used:

- Body-fat measuring scales
- Jackhammers
- Magnetic mattresses and chairs
- Stun guns

If you have questions about the EMI safety of a particular appliance, tool, or activity, please call Boston Scientific Patient Services at 1.866.484.3268.

Theft detection and security systems

Electronic antitheft systems (including tag deactivation) and security gates or tag readers that include radio frequency

identification (RFID) equipment (often found in store and library doorways, at checkout counters, and in point-of-entry access control systems) should not cause you any worry if you follow these guidelines:

- Walk through theft detection and security systems at a normal pace.
- Do not lean against or linger near these systems.
- Do not lean against checkout counter-mounted or handheld tag deactivation systems.
- Avoid lingering near entrance and exit doorways, as some theft detection systems may be hidden in the walls or the floor in these areas.

- If you are near an electronic antitheft, security, or entry control system and suspect interaction (experience symptoms) with your device from one of these systems, promptly move away from equipment nearby and inform your doctor.
- Most home security systems are unlikely to affect the proper function of your implanted system.

Your Boston Scientific implantable device is unlikely to set off the alarm from an electronic antitheft or security system.

Airport security

Your device contains metal parts that may set off airport security metal detector alarms. The security archway will not harm your

device. Tell security personnel that you have an implanted device and show them your Medical Device Identification card.

Airport security wands could temporarily affect your device or turn it off if the wand is held over it for a period of time (about 30 seconds). If possible, ask to be hand-searched instead of being searched with a handheld wand. If a wand must be used, inform the security personnel that you have an implanted device. Tell the security personnel not to hold the wand over your device and to perform the search quickly.

If you have questions about airport security, call your doctor or Boston Scientific Patient Services at 1.866.484.3268.

Cellular phones

Keep your cellular phone at least 6 inches (15 cm) away from your device. Your cellular phone is a source of EMI and could affect your device's operation. This interaction is temporary, and moving the phone away from your device will return it to proper function. To reduce the chance of interaction, follow these precautions:

- Maintain a distance of at least 6 inches (15 cm) between the cellular phone and your device. If the phone transmits more than 3 watts, increase the distance to 12 inches (30 cm).
- Hold the cellular phone to your ear on the opposite side of your body from your device.

- Do not carry a cellular phone in a breast pocket or on a belt if that places the phone within 6 inches (15 cm) of your device.

These precautions apply only to cellular phones, not to household cordless phones. However, you should avoid placing your household cordless phone receiver directly over your device.

Dental and medical procedures

Some medical procedures could damage or otherwise affect your device. Be sure to always tell your dentist and physicians that you have an implanted device so that they can take the necessary precautions. Be especially careful with the following procedures:

- **Magnetic Resonance Imaging (MRI):** This is a diagnostic test that uses a strong electromagnetic field. Some defibrillation systems have been evaluated to allow the patient to undergo MRI scans under specific conditions. Talk to your physician about the capabilities of your defibrillation system. If your system is not one of those eligible to be scanned, or if the required conditions are not met, MRI scans can severely damage your device and should not be performed. Hospitals keep MRI equipment in rooms marked with signs that indicate magnets are inside. Do not go inside these rooms unless your physician has confirmed that your defibrillation system is eligible and you meet the requirements for an MRI scan.

- **Diathermy:** This uses an electrical field to apply heat to tissues in the body and could damage your device or injure you. Diathermy should not be performed.
- **Electrocautery:** This is used during surgical procedures to stop vessels from bleeding. It should be used only when your device is turned off. Talk with your heart doctor and the doctor performing the medical procedure to determine who turns off your device.
- **Electrolysis and Thermolysis:** These are dermatology or hair removal procedures that pass electrical current into the skin. Talk with your heart doctor before having any electrolysis or thermolysis treatment.

- **External defibrillation:** This is a procedure, typically used in medical emergencies, that uses external equipment to deliver an electrical shock to your heart to restore a rapid and irregular heart rate to a normal rhythm. External defibrillation can affect your device, but can still be performed if necessary. If you receive external defibrillation, be sure to contact your physician as soon as possible following the emergency to verify that your device is functioning properly.
- **Lithotripsy:** This is a medical procedure that is used to break up stones in the urinary tract (e.g., kidney stones). Lithotripsy can damage your device if certain precautions are not taken. Talk with your heart doctor as well as the doctor performing the procedure about what can be done to protect your device.

- **Therapeutic radiation treatment for cancer:**

This procedure can affect your device and will require special precautions. If you should need radiation treatment, talk with your heart doctor as well as the doctor performing the medical procedure.

- **Transcutaneous Electrical Nerve Stimulation (TENS) unit:**

This is a device prescribed by physicians or chiropractors for control of chronic pain. A TENS unit can affect your device and will require special precautions. If you must use a TENS unit, talk with your heart doctor.

Most medical and dental procedures will not affect your device.

Some examples include:

- Dental drills and cleaning equipment

- Diagnostic X-rays
- Diagnostic ultrasound procedures
- Mammograms

NOTE: Mammograms will not interfere with your device. However, your device could be damaged if it gets compressed in the mammogram machine. Make sure the doctor or technician knows that you have an implanted device.

- EKG machines
- CT scans

If you need to undergo any surgical procedures, tell your dentist and/or doctor that you have an implanted device. They can contact the physician who monitors your device to find the best way to provide treatment.

If you have questions about a specific appliance, tool, medical procedure, or piece of equipment, please talk with your doctor or call Boston Scientific Patient Services at 1.866.484.3268.

Summary

It is natural for you to feel anxious or nervous about receiving a device. You have been identified by your physician as having heart failure, as well as having a significant risk of sudden cardiac death. Remember that your device can be a great source of reassurance for you and your friends and family.

Talking with other CRT-D patients is often helpful while adjusting to your new device. Ask your doctor, nurse, or Boston Scientific representative if there is a local CRT-D patient support group in your area.

The information presented in this handbook is intended to help you understand more about your heart condition and your device. If you have questions about what you have read, be

sure to ask your doctor or nurse. They are your best resource for information about your particular needs or situation.

Visit us on the Internet


Boston Scientific's website, www.bostonscientific.com, offers a variety of information of interest to people with cardiac devices, including frequently asked questions about living with your implanted device, health tips, patient stories, and links to additional resources.

www.bostonscientific.com

Notes and questions

Use this space to write down questions or additional information about your device:

Symbols on Packaging

Symbol	Definition
	Manufacturer

Index

A

Activities, 51,62

Airport security, 86

Antitachycardia pacing, 59

Arrhythmia, 25

ventricular fibrillation, 29

ventricular tachycardia, 28

Atria, 21

B

Battery, 69

beeping tones, 71,77

end of life, 70,71

Beeping tones, see Battery

Boating, 62

Bradycardia, 31

Bradycardia pacing, 61

C

Calling your doctor, 70

Cardiac resynchronization therapy, 61

Cardioversion therapy, 60

Cellular phones, 88,89

Communicator, see LATITUDE Patient Management System

Cordless phones, 79,82

CRT-D system, 39

device, 39

implanting, 42

leads, 40

reliability, 4

replacing, 71

risks, 45

CT scans, 94

D

Defibrillation therapy, 60

Dental equipment, 93

Dental procedures, 89

Device, 39

implanting, 42

reliability, 4

replacing, 71

Diathermy, 91

Driving, 62

E

Echocardiogram, 37

EKG machines, 94

Electrocautery, 91

Electrolysis and Thermolysis, 91

Electromagnetic interference
(EMI), 74

Electronics

precautions, 78

Electrophysiology (EP) test, 37

Exercise, 51

External defibrillation, 92

F

Follow-up visits, 66

G

Glossary, 5

H

Heart block, 31

Heart failure, 25

Heart function, 21

Holter monitoring, 37

Household appliances

precautions, 78

I

Identification card, 52

Implanting the system, 42

recovery, 49

risks, 45

L

Ladders, 62

LATITUDE Patient Management System, 54, 69

Communicator, 55, 68

Leads, 40

implanting, 42

replacing, 71

Lithotripsy, 92

Living with your device, 54

ID card, 52

preparing for therapy, 56

M

Mammograms, 94

Medical procedures, 89

Medications, 51

MRI, 90

P

Precautions, 78

airport security, 86

cellular phones, 80, 88

dental procedures, 89

diathermy, 91

electrocautery, 91

external defibrillation, 92

household appliances, 75

lithotripsy, 92

medical procedures, 89

MRI, 90

radiation treatment, 93

TENS units, 93

theft detection systems, 85

tools, 75

Programmer, 40,66

Pulse generator, *see* Device

R

Radiation treatment, 93

Radio frequency (RF)
telemetry, 67

Recovery, 49

Reliability, 4

Replacing the system, 71

risks, 73

Risks, *see* Precautions

*electromagnetic
interference, 74*

implant procedure, 45

post-implant, 49

replacement procedure, 73

sudden cardiac arrest, 35

S

Safety, *see* Precautions

Security systems, 84

Sexual intimacy, 63

Sinoatrial (SA) node, 21

Sudden cardiac arrest, 35

diagnosis, 36

risk factors, 35

Sudden cardiac death, see Sudden cardiac arrest

Swimming, 62

T

Telemetry communication

radio frequency (RF), 67

wanded, 67

TENS units, 93

Theft detection systems, 85

Therapy

antitachycardia pacing, 59

bradycardia pacing, 61

cardiac resynchronization therapy, 61

cardioversion, 60

defibrillation, 60

how it feels when delivered, 59

preparing for, 56

Tools

precautions, 78

Traveling, 51,64

airport security, 86

U

Ultrasound, 94

V

Ventricles, 23

Ventricular fibrillation (VF), 29

Ventricular tachycardia (VT), 28

W

Wanded telemetry, 67

Warnings, see Precautions

X

X-rays, 94

Boston Scientific

Advancing science for life™



Manufacturer:

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA
Tel: 651.582.4000

Medical Professionals:

1.800.CARDIAC (227.3422)

Patients and Families: 1.866.484.3268

www.bostonscientific.com/patientlabeling

© 2020 Boston Scientific Corporation or its
affiliates. All rights reserved.

CRT-D

51114095-001 en USA 2020-12

