



Cardiac Resynchronization Therapy Devices

Helping People with Heart Conditions Live Better



Your doctor or nurse has given you this information because your doctor believes a cardiac resynchronization therapy (CRT) device may be right for you. The decision to have a CRT device is one that you need to think carefully about. You most likely have a lot of questions.

In this brochure, we will try to answer some of those questions. We'll also share stories from other people who have faced the same decision. Our goal is to provide information that can help you make a decision that is right for you.

Many patients find it helpful for their family and friends to learn about the CRT device as well. We encourage you to share this information with those who care about you. Please talk with your doctor to discuss your own medical history and ask any questions you have after reading this brochure.

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Heart failure is a common and serious medical condition. About 6.2 million adults in the United States have heart failure. Each year doctors diagnose about 1 million new cases of heart failure.¹

Heart failure develops gradually over time in a damaged heartsometimes over years. The heart simply cannot pump enough blood and oxygen to meet your body's needs. Without enough blood, important organs like your brain and kidneys cannot function properly.

So, imagine if you had a device designed to help your heart pump more efficiently—a device that helped you feel better and helped you resume a more normal life. That's exactly what a CRT device does.

Following are some answers to questions you may have about CRT devices. For additional information, we encourage you to talk to your doctor and check out the online resources listed on page 22.

How does a CRT device treat heart failure?

All people with heart failure have one thing in common. Their hearts do not pump as well as they should, so blood does not circulate as well as it should. Your body needs that blood to live and work.

In a healthy heart, both ventricles (lower part of the heart) pump or beat at exactly the same time in a coordinated way. It's like making a fist—all of the fingers squeeze in unison. But for many people with heart failure, the ventricles do not pump at the same time. For these people, the pumping is uncoordinated. It's like making a fist just one finger at a time.

A CRT system consists of two componentsthe pulse generator, or device, and three thin, insulated wires called leads. A CRT device delivers tiny amounts of electrical energy to the heart through these leads. This helps restore the normal timing of the heartbeats, causing both ventricles to pump together again. CRT helps both sides of your heart work together again in a coordinated way. It's like a fist closing normally again.

What types of CRT devices are there?

There are two types of CRT devices. One is a special kind of pacemaker. It's called a cardiac resynchronization therapy pacemaker (CRT-P) or "biventricular pacemaker." The other is the same device, but it also includes a built-in implantable cardioverter defibrillator (ICD). This type is called a cardiac resynchronization therapy defibrillator (CRT-D).

What does a CRT-P device do?

While functioning like a normal pacemaker to treat slow heart rhythms, a CRT-P device also delivers small electrical impulses to the left and right ventricles to help them contract at the same time. This will help your heart pump more efficiently.







The two upper chambers in your heart are called the atria. The two lower chambers are called ventricles. A CRT device monitors or senses the rate of your heartbeat in the right side of your heart. Based on what it senses, the CRT device delivers electrical impulses to your ventricles to help coordinate the heart's contractions.

What does a CRT-D device do?

A CRT-D device is a special device for heart failure patients who are also at high risk for sudden cardiac death.

While functioning like a normal pacemaker to treat slow heart rhythms, a CRT-D device also delivers small electrical impulses to the left and right ventricles to help them contract at the same time. This will help your heart pump more efficiently.

A CRT-D device can also treat dangerously fast heart rhythms (arrhythmias) that can lead to sudden cardiac arrest. If the device senses heartbeats that are dangerously fast, it delivers a shock to the heart. This shock (defibrillation) stops the abnormal rhythm. Without this life-saving therapy, the dangerously rapid rhythm could lead to death in just minutes.

DID YOU KNOW?

Sudden cardiac arrest is not the same as a heart attack. Sudden cardiac arrest occurs when electrical problems in the heart cause a dangerously fast heart rate. Sudden cardiac arrest can lead to sudden cardiac death. A heart attack is different. It results from heart muscle damage from blood flow blockage, rather than an electrical problem.

- Sudden death due to cardiac arrest affects about 1 of every 7.5 people each year in the United States²
- ICDs have been shown to effectively stop 95% or more of dangerously fast heart rhythms³
- Patients who do not receive an ICD for life-threatening arrhythmias are at high risk for sudden cardiac death²
- A report from the American Heart Association indicates that earlier intervention in cases of sudden cardiac arrest increases chances of survival and better quality of life²

Why would your doctor recommend a CRT device?

When used along with medications, a CRT device can change the course of heart failure in its earliest stages even before you feel symptoms. Not everyone with heart failure will benefit from a CRT device. Some people may not need a CRT device if they respond favorably to other treatments, such as lifestyle changes and medication. Your doctor will review your personal health condition in determining whether a CRT-P or a CRT-D may be right for you.

In general, patients who are good candidates for a CRT device are those with:

- Moderate to severe heart failure symptoms (for example, difficulty breathing or extreme tiredness), despite other therapy
- A weakened and enlarged heart
- An electrical problem that causes uncoordinated pumping of the ventricles
- Heart failure with left bundle branch block; even though they have no symptoms (NYHA Class I) or mild symptoms (NYHA Class II) they are a high risk for a heart failure event/hospitalization or bad heart rhythm

What are the benefits of a CRT device?

Heart failure is a chronic, progressive disease. Early use of CRT therapy can help keep you alive longer and out of the hospital for heart failure. If you have been experiencing symptoms, a CRT device has the ability to improve your health—and may improve your life. A CRT device does not *cure* heart failure. But many people who receive a CRT device notice that they feel better. They experience relief from their symptoms, such as shortness of breath. They also have more energy to participate in everyday activities.

For more information about heart failure, talk with your doctor and visit www.bostonscientific.com/patients

Are there risks to having a CRT device?

After a CRT device is implanted, some risks do exist. Although uncommon, the following are some risks that can occur:

- The leads may move out of place in the heart
- The leads or electrical impulses may irritate or damage the surrounding tissues, including heart tissue and nerves
- The CRT device might not be able to detect or appropriately treat your heart rhythms

Be sure to talk with your doctor so that you thoroughly understand both the risks and benefits associated with having a CRT device. For more information regarding some of the potential risks, please see page 22.

Do you still need medication with a CRT device?

Even with a CRT device, medications remain important. Your doctor will determine the best therapy for you, which often includes both medication and a CRT device. However, your doctor may reduce or change your medications once you have a CRT device. It is very important that you follow your doctor's instructions regarding any medications.

How is a CRT device checked?

Today's CRT devices rely on sophisticated technology. When your doctor implants your CRT device, a programmer is used. A programmer is a custom designed computerbased system used to communicate with your device. A special communication wand is placed over the CRT device which initiates communication with the programmer. After communication is initiated, the device and programmer then relay information wirelessly.

Your doctor will program your CRT device to deliver the right type of therapy for your heart condition. After your implant, your doctor or nurse will use the programmer regularly to evaluate your device and make any changes if needed. The programmer reads all of the information stored in the CRT device. Additionally, your doctor may be able to monitor your CRT device remotely, while you are at home, with the LATITUDE[™] Patient Management System. See page 14 for details.



Doctors and nurses use a programmer to check a CRT device and communicate with it.

What types of therapy does a CRT device deliver, and do you feel the therapy?

Your CRT device will deliver therapy based on what your doctor programs it to do.

Heart failure and pacing therapy: When a CRT device delivers heart failure and pacing therapy, it uses low-energy electrical impulses to help your heart pump more efficiently and speed up your heartbeat if it is too slow. If you have a heart rate that is regular but fast, the CRT device can use low-energy electrical impluses to return your heart to its normal rhythm. Most people do not feel these therapies.

Defibrillation therapy: When a CRT-D device shocks the heart in order to slow down a fast heartbeat, it uses higher energy. This gives a feeling that some people describe as a "kick in the chest." Some patients are unconscious when the shock is delivered and don't remember the shock at all. The shock comes quickly and lasts only a second.

Are CRT devices reliable? Does research support their use?

CRT devices are reliable. Every year, CRT devices help hundreds of thousands of people feel better and live better. However, devices are not perfect and may exhibit problems. For more information about device reliability and effectiveness, please see the back cover of this brochure, and talk with your doctor. The COMPANION study, sponsored by Boston Scientific, is the largest research study of people with CRT devices. It found that people treated with a CRT-D device and medication lived longer than those treated with medications only. It also found that people who received a CRT-D device had fewer symptoms and reported a better quality of life.⁵

The MADIT-CRT study results show that early intervention with CRT-D therapy can help keep you alive longer and out of the hospital for heart failure events. Heart failure is a progressive disease with no cure. In its earliest stages, you may not feel very sick. However, as the disease progresses, your chances of spending time in the hospital increases.⁶

Does insurance cover a CRT device?

Most health insurance companies, including Medicare, view a CRT device as medically necessary for appropriately selected patients. If your doctor has determined that a CRT device is right for you, your insurance will usually pay. Be sure to provide your doctor's office with your insurance information. Ask your doctor's office to verify your coverage before scheduling your implant procedure.

Preparing for a CRT Device Implant



Over the years, advances in medical technology have made the surgery to implant a CRT device much simpler. It can take about 2 to 4 hours. After surgery, you may be in the hospital for a day or two. This allows the doctors and nurses to watch and record your heart rhythm. When your doctor determines you are ready, you will be allowed to return home.

Following are some answers to questions you may have about receiving a CRT device implant. For more detailed information on the surgery, we encourage you to talk to your doctor and visit the online resources listed on page 22.

Are there risks to the procedure?

As with any surgical procedure, it is important to understand that there are risks associated with the implantation of a CRT device or lead(s). Some risks encountered during the implant procedure may include infection, tissue damage, bleeding, and an irregular heart rhythm. Complications do not happen very often. However, it is important that you talk with your doctor about the risks of having a CRT device implanted, as well as the benefits. For more information regarding some of the potential risks, please see page 23.

How big is a CRT device and where is it implanted?

Today's CRT devices are amazingly small. The average device is about the size of a small bar of soap. It measures about 2 x 2 inches (5 x 5 centimeters) and about 0.5 inches (11 millimeters) thick. It weighs about 1 to 3 ounces (28 to 85 grams).

Typically, a CRT device is implanted just under the skin in your chest, near your collarbone. The leads are placed in the right atrium, the right ventricle and on the surface of the left ventricle (see illustration). Your doctor will discuss with you which side of your chest the device will be implanted.

What is recovery like?

Full recovery from surgery can take from several days or weeks to a few months. While you recover, your doctor may ask you to avoid strenuous activity (especially lifting and other activities that use your upper body). Doing so helps ensure that any leads have time to firmly attach to your heart tissue. After that, you'll have the added assurance that your CRT device is helping your heart work better and treating your heart rhythms.



The median longevity of the CRT-D device battery is about 9.5 years with a typical range from 8 to 11 years.⁷ Your doctor or nurse will regularly check to see how much energy is remaining in your device's battery. He or she will recommend replacement when the remaining battery energy drops to a certain level.

Many people who receive a CRT device report fewer symptoms, more energy, and a higher quality of life after the device implant. It allows you to live your life knowing that your device is helping your heart beat more efficiently. Your device also will treat irregular heart rhythms as your doctor has prescribed and programmed.

With a device, you are able to work and enjoy hobbies, sexual activity, and travel. A CRT device will help you enjoy as active and productive a lifestyle as your overall health permits. Following are some answers to questions you may have about daily living with a CRT device. Your doctor can answer other questions and advise you on the appropriate level of activity for you. For additional information, visit the online resources listed on page 22.

How do most people feel emotionally after receiving a CRT device?

Having a CRT device can be a major turning point in your life. Afterward, you may feel sad or worried. It's an event that may change your thoughts and feelings about your health. Some people may feel vulnerable at first because they depend on an implanted device.

As you return to daily life, your level of confidence and comfort with the CRT device will likely grow. As you can see from the patient stories we've included in the back of this brochure, many people feel much better than they did before. (Individual results may vary.)

It's also important to remember that everyone is different about how private they are. How much you share with others is up to you. Sometimes it's perfectly healthy not to talk about your heart condition. But if you are anxious, scared or depressed, you might want to talk to a therapist or find a support group.

In 2012, the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) and Heart Rhythm Society (HRS) updated their guidelines for treating heart failure patients. Device therapy received the highest level recommendation for patients who meet certain criteria. Your doctor may follow these guidelines in determining whether you are a good candidate for a CRT device. Along with any medication your doctor has prescribed, a CRT device is the standard of care for many patients to help treat heart failure and protect against sudden cardiac death.



How does a doctor monitor your heart when you have a CRT device?

Your doctor will want to check your CRT device and overall health on a regular basis. Your follow-up plan will include visits to your doctor's office. It's important to attend these visits, even if you are feeling well. In the clinic, your doctor or nurse will use the programmer to ensure your CRT device is working properly to best treat your heart condition.

With today's innovative technology, you may not have to visit your doctor's office as often as patients did in the past. If you receive a CRT device from Boston Scientific, you may be able to use an automatic, in-home device monitoring system. The LATITUDE[™] Patient Management system allows your doctor to check certain types of CRT devices remotely you do not have to leave the comfort of your home.

Your doctor can get important data from your CRT device—such as whether it delivered high-energy therapy or how much energy is left in the battery. If your CRT device delivered a therapy, its computer memory will store information about what your heart was doing before, during and after the arrhythmia. You can even measure your weight and blood pressure at home and have the measurements sent automatically to your doctor. The system can check your CRT device as often as every day and notify your doctor if necessary (for example, if the battery power is low). This is useful information for your doctor in making your treatment decisions.



An in-home device monitoring system provides a convenient way for doctors to monitor your device.



Your doctor will provide guidelines for when you should contact him or her between visits.



Can you still travel with a CRT device?

Patients with a CRT device can feel confident and safe when traveling. The Medical Device ID card that you receive with your device helps you alert medical and security personnel that you have an implanted CRT device.

It's important to carry your card when you have a device because the device does contain metal parts that may set off airport security metal detector alarms. Airport security wands could also temporarily affect the device. Security personnel should perform a hand search instead of using a handheld wand. If a wand must be used, you can ask security personnel to do the search quickly and not to hold the wand over the device.

If you receive a CRT device from Boston Scientific, a listing is available of medical facilities worldwide that have treated patients with Boston Scientific products. The listing is available online at www.bostonscientific.com/patients or by calling Boston Scientific's Patient Services department at 1-866-484-3268.

Does a CRT-D device affect driving privileges?

Whether you are able to drive once you have a CRT-D device will depend on your specific symptoms (like passing out prior to the implant) and the driving laws where you live. Generally, having a CRT-D device does not prohibit you from driving, although you may be asked to wait during the early stage of recovery. In some cases, restrictions are necessary. That's because a few seconds of unconsciousness could be dangerous to both you and others. Your doctor or nurse will discuss any restrictions with you.

What about sexual intimacy?

For most people with a CRT-D device, sexual intimacy is not a medical risk. This is because the natural heart rate increase that occurs during sex is the same as the heart rate increase when you exercise. Your doctor may perform exercise tests to become familiar with how your heart rate increases. This will help him or her program the CRT-D device system settings.

Is there a risk of interference from household appliances with the CRT device?

Your device has built-in features that protect it from electromagnetic interference (EMI) produced by most electrical equipment. Under normal use, it is safe for someone with a CRT to use most household items. This includes kitchen counter-top appliances, convection ovens, electric blankets, heating pads, home security systems, microwave ovens, electric and gas ovens, TV (television), TV remotes —infrared (standard), and vacuum cleaners.

Cellular phones or devices that have integrated cellular phones should be kept at least 6 inches (15 cm) away from your implanted device.

Certain tools and household items should be used with caution or avoided. Your doctor can answer questions about a specific appliance, tool, or piece of equipment. Specific guideline information is also available from Boston Scientific Patient Services at 1-866-484-3268 and online at www.bostonscientific.com/emiguide and www.bostonscientific.com/patients.

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Additional resources are available at www.bostonscientific.com/latitudetravel



Melanie G lives in Hanover, Virginia with her husband, Tom. She received her heart failure device after the birth of her daughter, Grace. Melanie shares her story about how CRT-D therapy made a dramatic difference in her daily life.

How was your heart condition diagnosed?

Meet Melanie G.

"When I was 15, I was a high school freshman and cheerleader, but my passion was dance. I was training for an audition with the NYC Ballet Company when I developed a pain in my back and down my left leg. I was diagnosed with a tumor growing through my pelvis. In order to save my life, my left leg and pelvis were amputated.

"Immediately after having chemotherapy, I was diagnosed with cardiomyopathy.

"At age 36, I discovered I was pregnant! In addition to the risk of carrying the baby to term due to my surgery, 12 weeks into the pregnancy I was in congestive heart failure."

What heart failure symptoms did you have?

"I used to sing for weddings and in church. When I was in heart failure, I couldn't do a lot of that because I would simply run out of air. When you combine not being able to breathe well with nerves, it makes it very difficult to breathe at all.

"After Grace was born, I couldn't do every day things, be a wife, or take care of an infant. I needed care 24 hours a day. My husband and mother took shifts taking care of me and Grace. I would go down stairs in the morning, and up again at night. That was all I could do. When I needed to move, they had to help me."

How did heart failure medications help your symptoms?

"We did drug therapies for almost two years, and I had maxed out on all of the available drugs. The doctor told me that I might need a pacemaker."

How did you decide on the CRT device?

"I did all kinds of research on the internet, including the Boston Scientific website (then Guidant). I wanted to read anything I could find about the therapy. My doctor fed me information as well. It really felt right.

"The day of the implant, I wanted to see what the device looked like. The company representative pulled out a demo of the heart failure device that I was going to receive. I held the box in my hand and I said, 'This is it. This is my miracle."

How did you feel after your CRT device was implanted?

"After the CRT implant, my mom was amazed. My cheeks were rosy! I felt instantly healthier. Congestive heart failure feels like you have a huge elephant sitting on your chest, and you just can't catch your breath. Within a day or two of receiving the device, I felt like that elephant had finally moved away."

How are you feeling now?

"Not only do I feel like a mother and wife, but I am back to singing. I am alive and living the life I always imagined I could have.

"My goal was to be an active mother for my daughter's life and future. Now, I have energy

to take care of Grace. We are inseparable. I can push her on the swing. We go to violin lessons, we go to gymnastics, and we love to go the pool."

Overall, how has CRT affected your life?

"The fact that these devices exist means that I won't need a heart transplant at this time, or perhaps ever.

"I think I have a responsibility to my daughter. Life isn't always easy, but we can have joy in what we do."

Note: Individual symptoms, situations, results, and circumstances may vary. Please consult your physician or qualified health provider regarding your condition and appropriate medical treatment. Your doctor will help decide what activities and activity levels are right for you. The information provided is not intended to be used for medical diagnosis or treatment or as a substitute for professional medical advice.





Meet Walen L.



For a man in his early eighties, Walen L. of Montana has some amazing moves, most notably, the Bud-Man-Pump-Boy classic fly-fishing cast. Walen shares his story about how CRT-D therapy made a dramatic difference in his daily life.

"My heart disease just snuck up on me. My loss of energy increased, but I excused it as just getting older. I had trouble moving around. I coughed a lot, and had difficulty moving my hands. This made it hard to do the things I loved, like fly fishing.

"Fishing is my life. But I found that after one or two casts, I was too tired to do it again. I just lost interest.

"I have the art of denial. For a long time, I denied that I really had a problem. I had to accept that."

How was your heart condition diagnosed?

"I went to the doctor for a Lyme's disease check. He told me that I had two silent heart attacks. When I heard that part of my heart was half dead, it was really a shock.

"The doctor told me that I had nonischemic dilated cardiomyopathy."

"My doctor determined that an implanted heart failure device would help my heart beat better."

How did heart failure medications help your symptoms?

"The medication I was on did not help my heart get better. We waited two years, and I felt worse as each year passed."

How did you decide on the CRT-D device?

"My doctor determined that an implanted heart failure device would help my heart beat better."

How did you feel after your CRT-D device was implanted?

"After the implant, I felt something right away. I felt like they had turned the clock back. I had energy again, and I didn't have the hoarseness in my voice any longer. I felt transformed."

How are you feeling now?

"Since getting this device, I feel it has brought me back 10 years. It has made it possible to do the things I like to do and fishing is one of them."

Overall, how has CRT affected your life?

"The heart failure device I have is not only a life saver, but it is a life style. It's given me an opportunity to live the life the way I want to live."

Note: Individual symptoms, situations, results, and circumstances may vary. Please consult your physician or qualified health provider regarding your condition and appropriate medical treatment. Your doctor will help decide what activities and activity levels are right for you. The information provided is not intended to be used for medical diagnosis or treatment or as a substitute for professional medical advice.

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With its life-saving technology, a CRT device can improve your life and give you and your family peace of mind. You have an important decision to make about your health. If your condition is not immediately life-threatening, you have some time to talk with your doctor and your loved ones. This brochure is just one source of information to help you as you make your decision. If you have additional concerns or questions not answered in this brochure, please talk with your doctor.

Additional Online Resources

www.bostonscientific.com/patients

www.bostonscientific.com/emiguide

www.heart.org

www.mayoclinic.org

www.upbeat.org (Heart Rhythm Society Patient Page)

www.hfsa.org/patient

Cardiac resynchronization therapy pacemakers

(CRT-P) and defibrillators (CRT-D) are used to treat heart failure patients who have symptoms despite the best available drug therapy. These patients also have an electrical condition in which the lower chambers of the heart contract in an uncoordinated way and a mechanical condition in which the heart pumps less blood than normal. In addition, for high risk NYHA Class I and II patients with left bundle branch block (LBBB), early CRT intervention can reduce the risk of having a heart failure event or hospitalization. CRT-P and CRT-D devices are not for everyone, including people with separate implantable cardioverter-defibrillators (CRT-P only), or certain steroid allergies. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. These devices are available by prescription only. Individual results may vary. As outlined below, there are risks during the device implant procedure, following the implant, and during and following a replacement procedure. Complications do not happen often. However, it is important that you talk with your doctor about potential risks.

When your doctor implants your device, the potential procedure risks include, but are not limited to:

- Discomfort from the incision
- Dangerous arrhythmias (abnormal heart rhythms)
 Bleeding
- Kidney failure
- Formation of a blood clot (hematoma)
- Heart attack
- Damage to adjacent structures (tendons,
- Stroke muscles, nerves)
- Death
- Puncturing of a lung (pneumothorax)
- Damage to the heart
- Puncturing of the heart or a vein on the (perforation or tissue damage) outside of the heart (tamponade)

After your doctor implants your device, you may experience certain complications. These may include, but are not limited to the following:

- You may develop an infection
- You may experience erosion of the skin near the 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. This includes heart tissue and nerves
- The device may move from the original implant site (migration)
- You may not feel or function the same psychologically
- The device may deliver inappropriate therapy (shocks or pacing)
- 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

When your device or leads are replaced, the potential risks may be similar to, or even greater than, those of your original ICD implant. Additional risks from these replacement procedures may include:

- Damage to existing parts of the implanted system
- Damage to the heart
- Bleeding
- Death

It is important for you and your doctor to consider these potential risks when making a decision about device replacement. For more information on device monitoring and replacement, see the back cover of this brochure.

About Device Monitoring and Replacement

Providing reliable, high-quality implantable devices is of the utmost importance to the cardiac device industry. However, these devices are not perfect. Based on past experience, devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy.

The cardiac device industry monitors device performance to continuously improve device reliability and minimize risk to patients. The industry shares Information about device reliability and malfunctions with doctors, regulatory bodies, and the public.

For information about Boston Scientific device performance, refer to the Product Performance Report on www.bostonscientific.com.

On an individual basis, your doctor or nurse will regularly monitor how your device is working. This includes monitoring the battery and system performance.

Monitoring the battery

Like any battery, the energy in your device's battery will naturally decrease over time. Eventually, the battery energy will decrease to a point where your device will need replacement. Your doctor or nurse will monitor your device's battery levels and determine when device replacement is necessary.

Monitoring system performance

Diagnostic features provide information about how your device and the lead system are performing. Monitoring these features helps your doctor determine if the system is operating normally.

Monitoring can also help detect problems. While problems are not common, they can and have occurred in the past at low rates of occurrence. Most problems with devices and lead systems do not affect the system's ability to provide a life-saving shock when needed. However, in some instances, a problem with a device or lead may affect the system's ability to provide therapy. If this situation arises for you, your doctor may recommend replacing your device and/or leads.

Replacement involves some risks. It is important for you and your doctor to consider these risks when making a decision about device replacement. For more information on risks, please see page 22.

Implantable Devices Important Safety Information

Cardiac Resynchronization Therapy Devices

Cardiac resynchronization therapy pacemakers (CRT-P) and defibrillators (CRT-D) are designed to treat heart failure patients who may or may not have symptoms or who may have symptoms despite the best available drug therapy. They are also designed to help your heart pump more effectively and meet your body's need for blood flow. These devices are sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields. With all medical procedures there are risks associated. In regard to an implanted ICD, the risks include but are not limited to inappropriate shock, lead moves out of place, loss of stimulation capability, allergic reaction, fluid underneath the skin, and infection. In rare cases device failure or death can occur. 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. To obtain a copy of the device Patient Handbook for more detailed device safety information, go to www.bostonscientific.com, or you can request a copy by calling 1-866-484-3268 or writing to Boston Scientific, 4100 Hamline Ave. N., St. Paul, MN 55112. 92481216 (*Rev. A*)

Device Quality and Reliability

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. Also, it is important that you talk with your doctor about the risks and benefits associated with the implantation of a device. *92481216 (Rev. A)*

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