



embrace freedom



Cardiac Resynchronization Therapy
Implantable Cardioverter Defibrillator

Patient booklet



SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

embrace freedom

Embrace Freedom is a clear expression of what we do and have been doing at Sorin Group for over 50 years. It is about improving the quality of life for patients around the world, through the daily effort and commitment we put into our work.

We work closely with physicians and their staffs to develop practical and meaningful health care treatment solutions. We are proud of our heritage and our breakthroughs. For example, we designed the first dual chamber defibrillator, implanted world wide.

The opportunity we have to help our patients Embrace Freedom is our driving force and what we do every day.

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1. Introduction

1.1. What is a CRT/ICD?

An implantable cardioverter defibrillator (ICD) with Cardiac Resynchronization Therapy (CRT) is a lifesaving device that is implanted in the upper chest area. It has a pacemaker and a defibrillator in it. It is about the size of a pager or a small child's palm. It is prescribed and implanted by a physician.

CRT is a therapy that consists of sending timely electrical pulses to the lower chambers of the heart. This allows the heart to beat in a more coordinated and synchronized manner, thus to beat more effectively.

An ICD automatically detects abnormal fast heart rhythms that may occur, and treats them by discharging an electric shock or rapid pacing to restore the normal rhythm.

A CRT/ICD is a device that combines these two types of therapies.

1.2. Why did my doctor recommend that I receive a CRT/ICD ?

Your doctor has recommended that you have a CRT/ICD implanted because:

1. Your heart failure condition is associated with uncoordinated ventricular contractions.

A CRT/ICD is able to restore a coordinated contraction of your heart. By this action a CRT/ICD can improve the performance of the heart and improve symptoms associated with heart failure, such as breathlessness and lack of energy. Research has shown that many patients experience an overall improvement of their quality of life and increase in their capacity to perform day-to-day activities after the implant of a CRT/ICD.

2. Your heart condition exposes you to a risk of developing a dangerously rapid, heart rhythm. These abnormal rhythms can lead to cardiac arrest, a life threatening

event. Cardiac arrests require the help of doctors or emergency medical personnel in order to provide a shock (defibrillation) to restore the heart's normal rhythm. Cardiac arrest rarely gives any warning. Emergency medical personnel are often not immediately available. A CRT/ICD automatically provides the emergency therapy required to restore normal rhythm.

1.3. Are there alternative treatments?

ALTERNATIVE TREATMENTS FOR HEART FAILURE

After lifestyle and dietary changes as advised by your physician, the first line therapy for management of heart failure is most often medications.

Cardiac Resynchronization Therapy (CRT) pacemakers are available for the treatment of patients with moderate to severe heart failure. Cardiac Resynchronization Therapy pacemakers do not have the ability to treat abnormal fast rhythm (VT and VF) with rapid pacing or a defibrillation shock.

There are other non-pharmacological means of treating heart failure that may be discussed and advised by your physician. These may include surgical techniques to correct contributing factors such as a heart valve repair or replacement, temporary implant of a device to help the left ventricle pump better called a left ventricular assistance device, or heart transplantation.

ALTERNATIVE TREATMENTS FOR LIFE-THREATENING ARRHYTHMIAS

A number of conditions, such as coronary heart disease or a previous heart attack, can put people at risk of life-threatening arrhythmias (abnormal heart rhythms). In some patients, the risk of arrhythmias can be completely eliminated or significantly reduced when the cause is treated (for example, by surgery or medication).

However for many patients, consideration of other procedures is not an option or the medications are not tolerated or effective enough. The protection given by an ICD or

CRT/ICD as determined by your physician may be the best treatment choice in managing your life-threatening arrhythmias.

CONCLUSION

A CRT/ICD may treat your heart failure condition and provide the best protection against the risk of death from life threatening arrhythmias and cardiac arrest.

1.4. Who should not receive a CRT/ICD?

CRT/ICD indications are based on medical research and your physician will determine whether or not you are indicated to receive this therapy.

Indications for consideration for patients with:

- Moderate to severe heart failure*, when symptoms can not be managed by drugs or dietary regimen alone.
- A reduced heart pumping strength. A measure called “ejection fraction” should be found less than or equal to 35%.
- Uncoordinated ventricular contractions.

This can be observed through an abnormal finding on an electrocardiogram or EKG (QRS duration above 120ms), and/or during an echocardiography.

Heart failure patients that match the following description may not be indicated for CRT/ICD therapy as determined by their physician:

- Patients with mild heart failure, whose symptoms are well controlled by drugs
- Patients whose heart failure is not associated with disorganized ventricular contractions

***Moderate to severe heart failure can be defined by:**

- Significant or severe limitation in day-to-day activities due to heart failure symptoms (even very gentle activity)
- Symptoms experienced in all situations even at rest.

Heart failure symptoms severity is generally referred to as the New York Heart Association class. Moderate to severe heart failure corresponds to class III or IV.

2. The heart and its rhythms

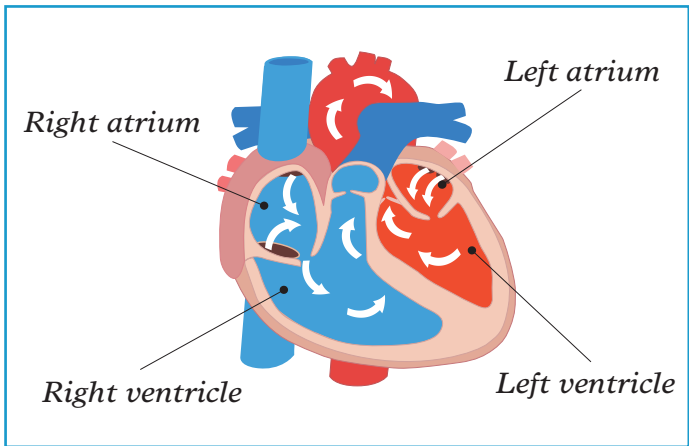
2.1. Parts of the heart

The heart is a pump that consists of four chambers separated by a wall and four valves. The two top chambers are called atria. They act like reservoirs. They collect and hold the blood until it can be moved to the main pumping chambers, the ventricles. The contraction of the atria and of the ventricles, in a coordinated sequence, make your heart pump blood to supply oxygen to your body.

Your heart is normally slightly larger than your clenched fist. Your heart is capable of beating over 100,000 times a day (at a rate of about 70 beats per minute). In one day it pumps more than 1,760 gallons (8,000 liters) of blood through approximately 11,800 miles (19,000 km) of circulatory system.

THE HEART AND ITS RHYTHMS

The right atrium collects “used” blood from all over your body. The right ventricle pumps the “used” blood to both lungs. The left atrium collects the newly oxygenated blood from your lungs. The left ventricle pumps the oxygen-rich blood back to feed the heart muscle itself and to the rest of your body.



2.2. Heart Failure

Heart failure is a progressive condition affecting patients whose heart cannot pump

enough blood to meet the needs of their body. Unlike other common cardiac disorders, such as heart attacks (myocardial infarctions or MI) or arrhythmias (abnormally fast or slow, or irregular cardiac activity), the heart does not suddenly lose its function, but, usually, weakens gradually over a period of time.

In early stages of heart failure, the heart and the vascular system (veins, arteries and capillaries) might compensate for the weakening of pumping activity, producing only mild to moderate symptoms.

Over time, this burden causes the heart to enlarge and heart muscles to weaken further, limiting the amount of blood that can be pumped throughout the body.

The contraction of the heart muscle can become disorganized, with different parts of the heart contracting at different times, thus reducing pump efficiency. A vicious cycle begins and symptoms worsen when the body cannot adjust to small additional burdens, such as light exercise. At this stage

other organs become involved, with fluid accumulating in the lungs, feet and legs, and even the abdomen.

The causes of heart failure are multiple and can be present many years before symptoms develop. Damage to the heart muscle by a heart attack is a common starting point.

Other chronic conditions, such as high blood pressure, heart valve disease, diabetes, arterial disease, lung disease and familial causes are the main contributors.

2.3. Rhythm disturbances

NORMAL RHYTHM

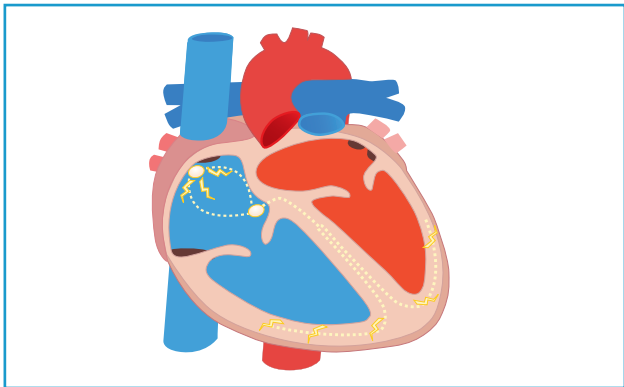
The normal rhythm is called sinus rhythm. Your own natural pacemaker, the sino-atrial (SA) node, is located in the right atrium.

Every second or less, this pacemaker fires, and an electrical signal spreads through the right and left atria, then continues down to the ventricles.

The normal rhythm of your heart can be disturbed in a number of ways.

THE HEART AND ITS RHYTHMS

An example of normal rhythm.



The electrical signal originates in the upper right atrium, propagates to the atria and reaches the ventricles. Both the right and left ventricles are activated at the same time. In response, the atria and ventricles can contract in a coordinated manner, to make the heart pump effectively.

BRADYCARDIA (SLOW HEART RHYTHM)

Your heart normally beats between 60 and 80 times a minute. A rate lower than 60 beats per minute is normal only if you are

resting, asleep, or very physically fit. A heart rate below 60 beats per minute is called bradycardia.

An abnormally slow heart rate or a very long pause between beats can cause tiredness, dizziness, and blackouts. When bradycardia is diagnosed in isolation, this condition is normally treated with a pacemaker. A CRT/ICD is also able to treat bradycardia, should this condition occur in conjunction with the CRT/ICD indication.

TACHYARRHYTHMIAS

(abnormal fast heart rhythms)

If your heart rate is over 100 beats per minute this is called tachycardia. There are normal and abnormal fast heart rhythms. Exercise, mental or emotional stress, and some illnesses can cause your heart rate to rise normally, above 100 beats per minute.

When your heart rate is too fast, however, or occurs without cause, or is too fast and irregular, it is called a tachyarrhythmia.

The different types of tachyarrhythmia

include Ventricular Tachycardia (VT) and Ventricular Fibrillation (VF), and are described below.

VENTRICULAR TACHYCARDIA (VT)

VT is an abnormal rapid heart rate that originates in the ventricles. The heart pumps less blood with each beat because there isn't enough time for the chambers to refill with blood between beats. This causes symptoms such as dizziness, lightheadedness, near fainting symptoms, fainting, and loss of consciousness. For most patients, VT is dangerous if not treated.

VENTRICULAR FIBRILLATION (VF)

In VF, the heart beats very fast and irregularly. This is due to chaotic electrical activity of the ventricles. Little or no blood is pumped. Your brain, heart and the rest of your body are quickly starved of oxygen.

Patients usually pass out within a few seconds. VF almost never stops on its own, and is therefore fatal unless the normal rhythm is restored with an electric shock to

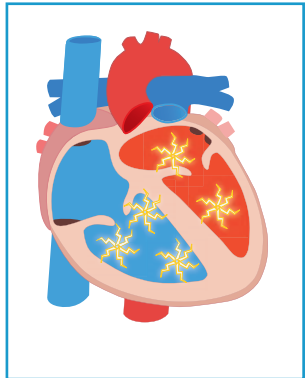
THE HEART AND ITS RHYTHMS

“reset” the heart (defibrillation).

Defibrillation can be given by doctors or emergency medical personnel using paddles held to the chest (external defibrillation), or automatically by a CRT/ICD.

VT and VF have a number of causes, the most common of which is scarring of the heart due to a previous heart attack. Cardiac enlargement as a result of heart failure is also an important cause.

An example of ventricular fibrillation. The electrical signal is not following the normal pathway. Instead, multiple pacemakers are firing at the same time. The heart can not contract properly, making the pump inefficient until a normal rhythm is restored.



3. Description of the CRT/ICD

Your CRT/ICD treats heart failure by continuously helping your heart to beat with more strength. It can also automatically recognize and stop abnormal heart rhythms, VT and VF.

3.1. Parts of the device

PULSE GENERATOR

The pulse generator is a sealed titanium metal container about the size of a matchbox that contains electronic circuits, a memory and a battery.

By sending electrical pulses to both the right and left ventricles, the pulse generator helps the heart to beat more efficiently.

The pulse generator constantly checks your heart's natural electrical signals. If it detects an abnormal heart rhythm, it will convert it to a normal rhythm.

LEADS

The pulse generator is connected to the

heart by three leads (insulated wires) that are threaded into the heart through veins, making their implantation a simple procedure. These leads allow the CRT/ICD to monitor your heart's rhythm, and deliver therapies (electrical pulses or shock) to your heart.

PROGRAMMER

The programmer is a kind of computer, kept in the hospital or your doctor's office. It can communicate with the pulse generator by means of a wand that is held over the skin covering your pulse generator. It is used to test your CRT/ICD, program the treatments that your doctor wishes the CRT/ICD to use, and read the information stored in the memory between office visits.

3.2. How a CRT/ICD works

CARDIAC RESYNCHRONIZATION THERAPY

The normal contractions of the heart chambers (atria and ventricles) are precisely timed (or synchronized), and

follow a strictly defined sequence. When this synchronization becomes disrupted, the amount of blood pumped with each beat is reduced, which is a cause of heart failure. A Cardiac Resynchronization Therapy (CRT) device paces the heart (using the same small electrical impulses as a standard pacemaker) both in the right and the left ventricles in order to resynchronize their contraction and attempt to increase the cardiac output. This therapy is also referred to as “Biventricular pacing”.

In order to function properly, pacing leads (wires) must be placed in the right atrium, the right ventricle, and inside a cardiac vein to pace the left ventricle. All the leads can be implanted through the veins, without having to open the chest.

TACHYARRHYTHMIA THERAPIES

Your CRT/ICD constantly checks your heart’s electrical activity. It can tell whether the heart rhythm is normal, too slow, or too fast. If the rhythm is abnormal, an electrical

treatment will automatically be given to your heart.

The kind of treatment will depend on the settings your doctor chooses. Your doctor will tell you which therapy he or she has programmed into your CRT/ICD.

VF can be an immediate life-threatening situation. The CRT/ICD is designed to deliver a shock in order to restore the heart's normal rhythm. This is called defibrillation. Your CRT/ICD can also deliver other types of therapy to treat abnormal heart rhythms, Anti-tachycardia pacing, and Anti-bradycardia pacing.

DEFIBRILLATION

If your CRT/ICD detects VF, it delivers a high-energy shock. This is called defibrillation. Because the shock is given directly to the heart, the strength required is only about 1/10th of that given when doctors or emergency medical personnel place paddles on the chest. The total time from the start of VF to the shock itself is usually around 10

seconds. This is the amount of time it takes for the CRT/ICD to accumulate energy in the pulse generator so that a big shock can be given. Fainting from the VF is not uncommon during the time it is charging.

ANTI-TACHYCARDIA PACING

When VT is detected, the CRT/ICD checks if the rhythm should be treated. If the doctor has programmed this treatment, the CRT/ICD gives a short burst of small, rapid electrical pulses to interrupt the arrhythmia. This is called Anti-Tachycardia pacing. You may not even feel these pulses.

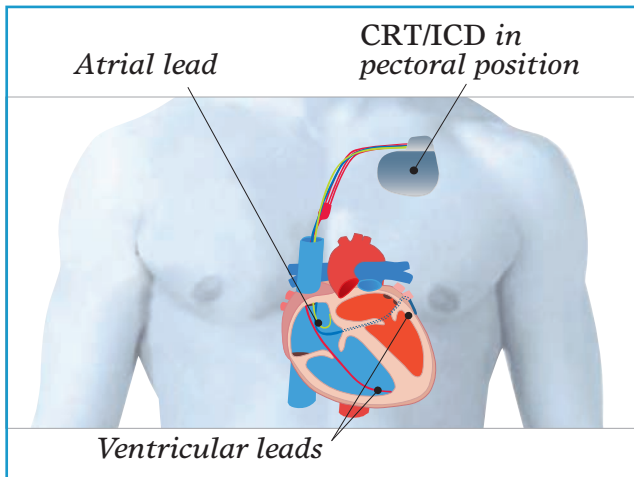
ANTI-BRADYCARDIA PACING

Your CRT/ICD can act as a pacemaker, to prevent your heart from beating too slowly. CRT/ICDs can sense and pace the atria and the ventricles to ensure a proper heart rate.

3.3. Implantation procedure

The operation to implant a CRT/ICD is usually performed under heavy sedation or occasionally general anesthesia. Your doctor will discuss this with you. The pulse generator will most commonly be implanted in your chest. Your doctor will first make an incision in the skin. Your doctor will then make a “pocket”, either under the skin or under the muscle, in which to place the pulse generator. The three leads are then passed through a vein and positioned in chambers of your heart.

The position is checked by x-ray, and the leads are tested to ensure that they are in good contact with the heart. The leads are connected to the pulse generator, which is then placed in the pocket. Before the incision is closed, your doctor will perform different tests to check the proper connection of your CRT/ICD system.



3.4. At hospital discharge

Your doctor will tell you whether you have skin stitches which dissolve in time, or whether the stitches will need to be removed later in an office visit. The wound and the pocket under the skin will be rather sore for a few days.

Always follow your doctor's directions while you recover and begin to resume normal activities. Some suggestions that will help in

your recovery:

- Bathe, exercise, and walk according to your doctor's instructions.
- Don't lift anything heavy (more than 10 or 15 pounds) until your doctor gives the OK.
- Limit arm movements that could affect the leads, if your doctor has instructed you to.
- Don't wear tight clothing that may irritate the skin over the pulse generator.
- Avoid any activity or contact sport that could result in a blow to your implant. These include, but are not limited to, karate, football, tennis, golf, or placing a shotgun or rifle against the side of the chest your device is implanted.

Be sure to tell all your doctors, dentists or any emergency personnel that you have an implant.

WARNING: Tell your doctor immediately if there is redness, swelling, warmth, or drainage from your incisions. This may indicate an infection which could be serious.

Contact your doctor if your arm becomes swollen or if pain persists after the initial healing of your incision, or if you develop a fever that does not go away in two or three days. Pain can also indicate the need to contact your physician as soon as possible.

3.5. Follow-up visits

After implant, it is normal that you continue to see your regular physician, cardiologist, and heart failure specialist for overall management of your condition and to follow-up on the functioning of your CRT/ICD. Your doctor will use the programmer to “talk” with the CRT/ICD.

He/she will:

- Check that the leads are working well,
- Check that Cardiac Resynchronization Therapy is delivered correctly,
- Check the battery to see how much energy is left, and
- Find out if the CRT/ICD has treated any arrhythmias.

Your doctor will also ask you which drugs you are taking and check if there are any interactions with your CRT/ICD.

He or she will also check to see if your heart condition has changed since your last visit. Depending upon your condition and the information retrieved from the CRT/ICD, your doctor may wish to “fine-tune” some of the CRT/ICD’s settings. Your doctor will use the programmer to make any of these changes. Your doctor will give you a schedule to follow for these follow-up visits.

3.6. Unit replacement

The batteries in your CRT/ICD should last for a number of years. They wear down very gradually and predictably. Several months before the batteries are expected to run down, your doctor will tell you that your pulse generator must be replaced. In an operation much like the original implant, your scar will be opened and the old pulse generator removed (it is a sealed unit, so the batteries cannot be replaced separately). The leads

will also be tested. They are then connected to a new pulse generator and then the pocket is closed.

Occasionally, leads need to be replaced. Lead replacement procedures can be more complex procedures, similar to the initial implant procedure. Ask your doctor for more information.

4. Warnings and precautions

- ☞ WARNING:** Tell your doctor immediately if there is redness, swelling, warmth, or drainage from your incisions. This may indicate an infection which could be serious. Contact your doctor if your arm becomes swollen or if pain persists after the initial healing of your incision, or if you develop a fever that does not go away in two or three days. Pain can also indicate the need to contact your physician as soon as possible.
- ☞ WARNING:** Follow all warnings concerning pacemaker patients, such as those in airports, near high voltage sources, and near extremely strong magnets. These types of equipment may interfere with your CRT/ICD and temporarily prevent a normal functioning.
- ☞ WARNING:** Always walk briskly through security gates in stores, libraries, and

airports. Security detectors may cause temporary interference with your CRT/ICD and prevent a normal functioning.

- ☞ **WARNING:** Avoid activities likely to cause a blow to the skin over the CRT/ICD. This would not normally damage the device, but could injure the tissues lying over it.
- ☞ **WARNING:** Magnetic resonance imaging (MRI) is not recommended for any patient with a CRT/ICD under any conditions. Because the equipment uses such powerful magnets, avoid even entering any room with MRI equipment - no matter what the reason. The circuits of your CRT/ICD could be permanently damaged or the programmed setting changed.
- ☞ **WARNING:** Make sure others know that they should dial the emergency number immediately if you remain unconscious for more than one minute after a shock

treatment.

☞ **WARNING:** Make sure others know that they should call your doctor if you don't feel well after shock treatment, even if you regain consciousness. Give them your doctor's phone number ahead of time.

Other Warnings and Precautions are listed in some specific sections of this document. Please refer to these sections whenever you are seeking information.


5. Living with your CRT/ICD


5.1. Your CRT/ICD identification card

You will be given a card when you leave the hospital. Always carry your CRT/ICD identification card with you when you go out, even for a quick errand. Your card has important information about your CRT/ICD and leads, and your doctor's name and phone number.

It also has important information for emergency medical personnel, if treatment is necessary. If you move, change your phone number, or change doctors, tell your doctor you need a new CRT/ICD identification card. Or, you can contact ELA Medical Inc Patient/Device Tracking directly (see “User Assistance Information” section at the end of this booklet).

Example of the CRT/ICD identification card:

IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR (ICD) CARD	
 SORIN GROUP <small>AT THE HEART OF MEDICAL TECHNOLOGY</small> ELA Medical, Inc. 14401 West 65th Way, Denver, CO 80004 – 3599 Tel: 877-ONE-SORIN / 877-663-7674 Fax: 866-500-6096	
PATIENT NAME: _____	
ADDRESS: _____	
PHONE: _____	

MANUFACTURED BY  SORIN GROUP	
IMPLANT DATE: _____	
MAGNET RATE: _____	
ICD	
Mode	_____
Serial	_____
LEADS	
Mfg. Mode	_____
Serial	_____
Mfg. Mode	_____
Serial	_____
Mfg. Mode	_____
Serial	_____
Mfg. Mode	_____
Serial	_____
PHYSICIAN TO NOTIFY IN EMERGENCY	
NAME: _____	
ADDRESS: _____	
PHONE: _____	

5.2. Activities and exercise

Your doctor may advise you to avoid activities where a few seconds of dizziness or unconsciousness could be dangerous to you or others. These activities might include:

- Driving a car,
- Swimming or boating alone, or
- Climbing a ladder.

Your doctor will tell you if you can start driving again. This will be determined by the laws in your state and by your medical

condition. Contact your physician if you experience any dizziness, blackouts, or loss of consciousness.

Patients with a CRT/ICD automatically lose their right to pilot an airplane because of their underlying heart condition.

Always follow your doctor's recommendations about resuming your normal daily activities. Such activities may include:

- Returning to your job,
- Resuming sexual activity,
- Travel, and
- Exercise, recreation, or other hobbies.

RETURNING TO YOUR JOB

Your CRT/ICD should not affect your ability to work, except under special circumstances. Because jobs and workplaces vary, there is no single answer. Be sure to tell your doctor if you use or must come near:

- High voltage electrical equipment,
- Strong magnets, like those used in the steel or auto scrap industry,

- Radar, or
- Other sources of strong electromagnetic interference.

Tell people at work that you have a CRT/ICD and what they should do if you receive a shock (see section 5.4).

If you have any questions about your work or workplace, ask your doctor.

SEXUAL RELATIONS

Your CRT/ICD should not interfere with sexual intimacy. If you receive a shock treatment while someone is in contact with you, they may feel it but it should not harm them.

TRAVEL

Your CRT/ICD should not prevent you from traveling. Check with your doctor for specific advice before planning any trip that would make it difficult for you to come back within one day.

Remember to:

- Take along this manual, if you or emergency medical personnel have any questions.
- Ask your doctor for the name of a doctor or heart clinic in the city, state, or country you will be visiting.

If an emergency occurs, you will be prepared to seek help.


- Always show your CRT/ICD identification card at security checkpoints, such as airports. Ask for a hand search without a hand-held screening wand. Security detectors are unlikely to cause problems if you walk through the “gate” without lingering.
- Ask your doctor to arrange a follow-up visit with a doctor in the area you will be visiting if you will be away for more than six months.

EXERCISE, RECREATION, AND OTHER HOBBIES

Exercise is good for the heart, and you are encouraged to lead an active life. You should discuss with your doctor what kind of exercise

program is best for you. A small number of sports should be avoided:

- Contact sports (such as karate or football)
- Deep sea diving
- The butt of a shotgun or rifle should not be held against the side of your chest where the CRT/ICD is implanted.

 **WARNING:** Avoid activities likely to cause a blow to the skin over the CRT/ICD. This would not normally damage the device, but could injure the tissues lying over it.

Avoid direct sun exposure to the skin over your implant. Be sure to wear at least a T-shirt or other clothing to shield this area.

The following activities will not cause problems to your CRT/ICD but may be of concern because of your medical condition. You should discuss possible heart risks with your doctor regarding:

- Snorkling, and
- Shallow scuba-diving.

5.3. When to call your doctor

Your doctor will give you instructions about when you should call him or her. In general, you may be asked to call if you:

- Receive a shock or any other therapy from your CRT/ICD
- Have symptoms of an abnormal heart rhythm.
- Notice any swelling, redness, warmth, or drainage from any incision.
- Have any questions about your CRT/ICD, heart rhythm, or medications.
- Plan to travel or move.
- Notice anything unusual, such as new, unexplained symptoms or symptoms like those you had before you received your CRT/ICD.

5.4. What to do if you receive a shock treatment

If you begin to feel symptoms of a fast heart rate, your CRT/ICD will probably deliver therapy within a few seconds.

Your physician will discuss this with you and

give you specific instructions on what to do if you receive a shock. These may include:

1. You should stay calm. Find a place to sit or lie down.

2. If possible, ask someone to stay with you throughout the event. If someone is touching you when the CRT/ICD delivers a shock, they should feel little more than a tingle, as the device is designed to focus its current on your heart, not elsewhere.

It will not harm anyone touching you. They might also feel your muscles become tense or see you “jump” slightly, as if startled.

3. Have a friend or family member phone the emergency number if you remain unconscious for more than one minute.

4. If you are conscious but do not feel well after shock therapy, have someone call your doctor immediately.

Follow your doctor’s orders. You may be told to come to the emergency room.

5. If you feel fine after therapy and symptoms

do not reappear, you may not need to seek medical help immediately.

Follow your doctor's instructions on when to call after receiving a shock. When you do call, your doctor or a nurse may ask you the following questions:


- What were you doing right before shock therapy?
- What symptoms did you notice before shock therapy?
- How did you feel right after shock therapy?

It is important to plan ahead with your family and friends for contacting emergency medical personnel and your doctor. The section “User Assistance Information” at the end of this manual has space for your local emergency phone numbers and information about your current medications. Keep a copy of this information next to your phone so anyone can see it easily if an emergency occurs.

6. Electromagnetic interference

Anything that uses electricity, is powered by batteries, or contains magnets has an electromagnetic field around it.

For most household appliances, these fields do not cause any problem to your CRT/ICD. This is because the field is very weak to begin with. It is also because the strength of an electromagnetic field decreases very rapidly, even with a small distance. However, a very strong electromagnetic field could interfere with your CRT/ICD; this is called electromagnetic interference (EMI).

 **WARNING:** Follow all warnings concerning pacemaker patients, such as those in airports, near high voltage sources, and near extremely strong magnets. These types of equipment may interfere with your CRT/ICD and temporarily prevent normal functioning. Strong EMI can keep your CRT/ICD from delivering the right treatment to your heart

in case of abnormal heart rhythm. It can even cause your CRT/ICD to give you an inappropriate shock. The effect usually lasts only while you are near the source of strong EMI. Move away and the normal function of your CRT/ICD will usually return once the EMI stops. In rare cases, really strong EMI can permanently damage your CRT/ICD's circuits or change the programmed settings.

6.1. Safe household appliances, tools and other equipment

Your CRT/ICD has been built to protect it from interference by most electrical appliances. The following are safe to operate if they are in good repair and properly grounded (if required):

- Microwave ovens,
- Televisions, AM/FM radios, video cameras, VCRs, and their remote controls,
- Garage door openers,
- Countertop appliances, such as toasters, blenders, food processors, electric knives, electric can openers, etc.

MAGNETIC INTERFERENCE

- Hand-held appliances, such as hair dryers, shavers, curling irons, etc.
- Major appliances, such as washers, dryers, electric stoves, refrigerators and freezers, dishwashers, etc.
- Electric blankets and heating pads,
- remote-controlled transmitters for toy cars and airplanes.
- Personal computers and printers,
- Electric typewriters, fax machines, and copy machines,
- Low-power radio transmitters, such as cordless telephones or walkie-talkies.

Also safe to use are:

- Spark-ignited internal combustion engines, such as those in lawn mowers, leaf-blowers, and automobiles (if your doctor has not restricted your right to drive),
- Battery-operated conveyances, such as golf carts or electric wheelchairs.

6.2. Equipment that may not be safe to use

CELLULAR PHONES

Digital cellular phones can cause EMI if they are very close (within 6 to 12 inches) to the CRT/ICD. The effect is temporary. To avoid interference:


- Don't carry a cellular phone in a breast pocket on the same side as the pulse generator, if it is implanted in your chest.
- Hold the cellular phone to the ear on the opposite side of your body from the pulse generator.

SECURITY DETECTORS

Security detectors used in stores and libraries are unlikely to cause problems if you walk through the “gate” without lingering. Do not stand close to the outside of the detection equipment. If you have any concern, show your CRT/ICD identification card and ask that the detector be turned off while you walk through.

The security detectors (both walk-through and handheld wands) used in airports and government buildings may cause temporary interference with your CRT/ICD.

The metal case of your pulse generator may set off security alarms. Present your CRT/ICD identification card to security personnel and ask for a hand search. It is important that security personnel understand that a search with a handheld wand should be avoided.

 **WARNING:** Always walk briskly through security gates in stores, libraries, and airports. Security detectors may cause temporary interference with your CRT/ICD and prevent normal functioning.

OTHER EQUIPMENT

The following may be sources of EMI. Keep them at least 12 inches away from your CRT/

ICD:

- Running car engines (sparks can cause EMI and some alternators contain strong magnets),
- Electric motors, if running,
- Machine shop tools, such as electric drills, circular saws, table saws, etc.
- Furnaces,
- Hot water heaters.

👉 **WARNING: Do not use body-fat monitors designed for home use. This equipment may cause temporary interference with your CRT/ICD.**

The following may be sources of strong EMI. Keep them at least 24 inches away from your CRT/ICD:

- Stereo speakers in large stereo systems, large radios
- Strong magnets,
- Industrial equipment such as power generators and arc-resistance welders,
- Battery-powered cordless tools, such as drills, screwdrivers, etc.


MAGNETIC INTERFERENCE

- Antennas used for medium power radio transmitters, such as ham or CB radio, long-distance radio, or satellite telephones,
- High-power loudspeakers (such as those found in public buildings).

The following are sources of very strong EMI.

Keep away from:

- Any radar equipment,
- Large TV or radio transmission towers,
- Power lines carrying more than 100,000 volts.

 **WARNING:** Keep away from high power equipment like power lines, radar, large TV or radio transmission towers. These equipments may cause interference with your CRT/ICD. The circuits of your CRT/ICD could be permanently damaged or the programmed setting changed.

6.3. Medical and dental procedures

Most medical and dental procedures will not interfere with your CRT/ICD. These procedures include:

- Diagnostic x-rays, such as chest, dental, CT scans, and mammography,
- Dental procedures to clean or repair teeth.

Some procedures can be carried out with proper precautions (the equipment should not be placed directly over the pulse generator):

- Transcutaneous electrical nerve stimulation (TENS).

Other medical procedures or devices produce a high level of interference that could seriously affect the function of your CRT/ICD. Be sure to discuss their risks and benefits with your doctor. These include:

- Lithotripsy (the use of shock waves to break up kidney and gall stones inside your body),
- Electrocautery (this is an electronic device used to stop bleeding during surgery),
- Diathermy (this equipment uses an electric field to apply heat to tissues, such as muscle),

MAGNETIC INTERFERENCE

- Radiation therapy,
- Therapeutic ultrasound.

CAUTION: Always tell all medical personnel that you have a CRT/ICD. Some medical procedures or devices may cause temporary interference with your CRT/ICD and prevent normal functioning.

☞ WARNING: Magnetic resonance imaging (MRI) is not recommended for any patient with a CRT/ICD under any conditions. Because the equipment uses such powerful magnets, avoid even entering any room with MRI equipment - no matter what the reason. The circuits of your CRT/ICD could be permanently damaged or the programmed setting changed.

7. Some questions your may have about your ICD

7.1. Should I be worried about my CRT/ICD?

A CRT/ICD is meant as an aid to live a normal life, helping to overcome the symptoms of heart failure, and eliminating the constant fear of consequences of untreated cardiac arrest. For some patients, the CRT/ICD itself can become a focus of worry. Remember that it was given to you with the hope of helping you feel better and to protect you from tachyarrhythmias. CRT/ICDs are extremely reliable - they save lives every day. It is best to bring your worries into the open by discussing them with your doctor, your family, or possibly a support group.

7.2. Will I experience pain, or a big lump under the skin?

After the initial healing of the wound, the area around your CRT/ICD should be

painless. However, it is quite common for patients to remain “aware” of its presence under the skin.

In the same way, once the incision has healed, all that should be visible is a bulge under the skin, and this cannot be seen when a shirt or blouse is worn.

CAUTION: Check with your doctor if pain persists after the initial healing of your incision.

7.3. Will the CRT/ICD cure my heart disease?

Heart failure is a progressive disease. Its evolution can be influenced by appropriate treatment, but unfortunately a cure is very uncommon.

While CRT may reduce many of your symptoms and make you feel considerably better because your heart is pumping blood more efficiently, your heart failure is still present and needs to be managed carefully by your doctor. Consult your doctor before

you begin any new activities and follow his or her advice.

7.4. Will I need to take medication?

Medication is the first course of treatment for heart failure condition. Do not stop taking drugs prescribed by your heart failure doctor. The CRT/ICD does not affect the need for these medications, but it does not interfere with them either.

Even though the CRT/ICD can treat ventricular arrhythmias very successfully, it cannot prevent them from occurring. Some patients, therefore, take medication to reduce the frequency of arrhythmias and prevent the CRT/ICD from firing too often.

7.5. What will happen when the CRT/ICD “fires”?

The CRT/ICD can give a number of different treatments. Cardiac Resynchronization Therapy, as well as Anti-Bradycardia pacing, are not felt at all.

Brief awareness of a rapid heart beat may

occur right before Anti-Tachycardia pacing. Some people report a defibrillation shock as feeling like a small jolt, others like a kick in the chest. Either way, the discomfort is momentary and there are no after-effects. Of course, the arrhythmia that triggers the device may make you feel a very rapid heart beat, dizziness or even fainting. Ventricular fibrillation causes most people to black out or faint within a few seconds, so that they are not aware of the shock when it occurs.


7.6. What should I tell to my family and friends?


You should tell your family, friends, and co-workers about your CRT/ICD. They should know that if the device fires, they do not need to do anything other than to make you comfortable while you recover.

If someone is touching you when the CRT/ICD gives a shock, they should feel little more than a tingle, as the device is designed to focus its current on your heart, not elsewhere. It will

not harm anyone touching you. They might also feel your muscles become tense or see you “jump” slightly, as if startled.

Some friends and family members may want to learn cardiopulmonary resuscitation. This can be arranged through your local Red Cross chapter.

 **WARNING:** Make sure others know that they should dial the emergency number immediately if you remain unconscious for more than one minute after a shock treatment.

 **WARNING:** Make sure others know that they should call your doctor if you don't feel well after shock treatment, even if you regain consciousness. Give them your doctor's phone number ahead of time.

8. Summary

This section is a reminder of some general considerations when living with a CRT/ICD. It is not meant to replace reading the complete instructions found in this booklet.

Your doctor may have recommended that you have a cardioverter-defibrillator with cardiac resynchronization therapy implanted (CRT/ICD).

This is because your doctor believes you are at risk of developing a dangerous heart rhythm that can be treated with this device.

If you are implanted with a CRT/ICD, follow all warnings concerning pacemaker patients, such as those in airports, near high voltage sources, and near extremely strong magnets.

Your doctor has already discussed with you any precautions you need to take to protect your implant from damage. Follow these instructions very carefully.

Always follow your doctor's recommendations about resuming your normal daily activities.

These may include:

- Returning to your job,
- Returning to sexual activity,
- Travel, and
- Exercise, recreation, or other active hobbies.

Your doctor will give you instructions about when you should call him or her. In general, call your doctor if you:

- Receive a shock or any other therapy from your CRT/ICD and have been told to call,
- Have symptoms of an abnormal heart rhythm and have been told to call,
- Notice any swelling, redness, warmth, or drainage from any incision.

9. Glossary

Anti-Tachycardia pacing (ATP):

Some tachycardias can be interrupted by rapid pacing of the heart. Modern CRT/ICDs can be programmed to use Anti-Tachycardia pacing to stop an episode of ventricular tachycardia, avoiding the need for a high-energy shock.

Arrhythmia:

An abnormal heart rhythm.

Atrioventricular (AV) node:

A specialized part of the heart that is normally the only electrical connection between the atria and the ventricles.

If the AV node does not function properly, your CRT/ICD can take over by pacing the ventricles in the right rhythm with the atrium.

Atrium/Atria:

The left and right atria are the upper chambers of the heart.

The right atrium pumps blood into the right

ventricle. The left atrium pumps blood into the left ventricle.

AV node (see Atrioventricular node)

Bradycardia:

A heart rate less than 60 beats per minute. This can be quite normal while at rest or sleeping, or in especially physically fit people. It may also be caused by the sinoatrial node working too slow or blockage of the electrical pathways in the heart. (See sinoatrial node)

Cardiac arrest:

During cardiac arrest the heart stops completely.

CRT (Cardiac Resynchronization Therapy):

CRT is a heart failure therapy that consists of sending timely electrical pulses to the lower chambers of the heart in order for the heart to beat in a more coordinated and synchronized manner, thus beat more effectively.

CRT/ICD:

Device that combines Cardiac Resynchronization Therapy and protection against life-threatening rhythms, by

delivering anti-tachycardia therapy or shocks, as needed.

Defibrillation:

Stopping ventricular fibrillation with an electric shock.

This can be achieved by medical personnel at the scene of a cardiac arrest, using paddles placed on the chest, or automatically by a device implanted in the chest (an ICD or CRT/ICD).

Defibrillator:

An external or implanted device that can deliver a shock to the heart. It is used to treat abnormally fast and irregular heart rhythms.

ECG/EKG:

Electrocardiogram. A printout of the electrical activity of the heart.

Electrocautery:

A procedure that uses electricity to stop bleeding during surgery.

Electromagnetic field:

This is an invisible area of energy. It is found around magnets. It also occurs when electricity is used, both around devices plugged into an outlet and those that are battery-powered.

Electromagnetic interference:

If an electromagnetic field is very strong, it can interfere with your CRT/ICD. It can prevent your CRT/ICD from giving you the right treatments or it can even cause your CRT/ICD to give you an inappropriate shock.

Fibrillation:

Rapid, irregular beating of the atrium or ventricle. (See Ventricular fibrillation).

Heart attack:

If an artery that carries blood to the heart muscle becomes blocked, the muscle is starved of oxygen. Some of your heart tissues die as a result. A previous heart attack is one of the more common causes for ventricular

arrhythmias that require treatment with an ICD or CRT/ICD. The medical term for a heart attack is a myocardial infarction.

Heart failure:

Weakness of the heart muscle. This can cause many symptoms, including breathlessness, dizziness, tiredness, and the accumulation of fluid in the lungs, abdomen, and legs.

ICD:

An implantable cardioverter defibrillator. An ICD is an implanted device that can deliver pacing for slow heart rhythms, rapid pacing (Anti-Tachycardia pacing), or a shock to the heart to treat fast abnormal heart rhythms and restore normal rhythm.

**Implantable cardioverter defibrillator
(see ICD)**

Myocardial infarction (see Heart attack)

Pacing:

Stimulation of the heart by small electrical impulses. Pacemakers are used to treat slow heart rates. ICDs and CRT/ICDs use pacing

to treat slow heart rates (bradycardia).

Programmer:

Equipment kept in your doctor's office that communicates with your CRT/ICD when you come for a checkup. The programmer can "read" a great deal of information stored in the CRT/ICD's memory. It reports the status of the battery and leads, the rhythms and rates of your heart since your last visit, and any therapies your CRT/ICD has given. The programmer can then be used to program your CRT/ICD, setting the therapies that your doctor has selected for the treatment of slow and fast heart rates.

Pulse generator:

The main part of a pacemaker, ICD or CRT Device. It is the sealed unit containing the battery, microprocessor (minicomputer), memory and electronic components. When a pacemaker, ICD or CRT device's battery is running down, the entire pulse generator is replaced.

SA node (see Sinoatrial node)

Sinoatrial (SA) node:

This is a small group of cells in the right atrium that sends electrical signals that make the heart beat.

Sudden cardiac death:

Death due to an electrical problem in the heart. It is usually caused by ventricular fibrillation or ventricular tachycardia. A CRT/ICD can greatly lower the risk of sudden cardiac death.

Tachycardia:

A heart rate usually greater than 100 beats per minute. It can be a normal response to exercise, stress, or illness.

Tachyarrhythmia:

Any disturbance of the heart's rhythm, regular or irregular, resulting in a rate over 100 beats per minute without a normal cause for tachycardia.

Ventricles:

The left and right ventricles are the main

pumping chambers of the heart. They receive blood from the left and right atria, and pump it to the body and the lungs.

Ventricular fibrillation (VF):

An arrhythmia causing an abnormally rapid and irregular beating of the ventricles. Because the heart pumps little or no blood, this arrhythmia is fatal unless a shock is given (defibrillation) to restore normal rhythm.

Ventricular tachycardia (VT):

An arrhythmia causing an abnormally rapid but regular beating of the ventricles. This can cause anything from mild symptoms of dizziness to fainting. If untreated ventricular tachycardia can lead to ventricular fibrillation.

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USER ASSISTANCE INFORMATION

(Ask your doctor or nurse to complete the information on this page before you leave the hospital.)

ELA Medical Inc Patient/Device Tracking

Toll-free number: 1-877-ONE-SORIN (1-877-663-7674)

Facsimile: 1-866-500-6096

Emergency Medical Assistance:

Name / Address / Phone Number of your cardiologist:

.....

ICD:

Type/Model Number

Date Implanted

Atrial Lead:

Type/Model Number

Date Implanted

Right Ventricular Lead:

Type/Model Number

Date Implanted

Left Ventricular Lead:

Type/Model Number

Date Implanted

Name/Address/Phone Number of Hospital:

.....

.....

Current Medications:

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Name/Phone Number of Relatives:

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