

A Patient Guide

Living with your S-ICD[®] System



The minimally invasive S-ICD[®] System

Cameron
Health
Effortless Rhythm Management

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ABOUT THIS GUIDE

This patient guide provides information on:

- *Anatomy of the heart*
- *Heart rhythm*
- *The S-ICD System*
- *Implant procedure*
- *Post operative events*

Note: *Your physician will discuss any potential risks or adverse events that may be associated with your implanted S-ICD System. However, be sure to carefully read and understand all warnings and safety precautions discussed in this guide.*

INTRODUCTION TO THE S-ICD SYSTEM



INTRODUCTION TO THE S-ICD SYSTEM

Your physician has recommended a Cameron Health minimally invasive implantable defibrillator (S-ICD System). The S-ICD System is designed as a life saving measure to treat your heart rhythm abnormalities.

Your physician may have prescribed this device for you for one of the following reasons:

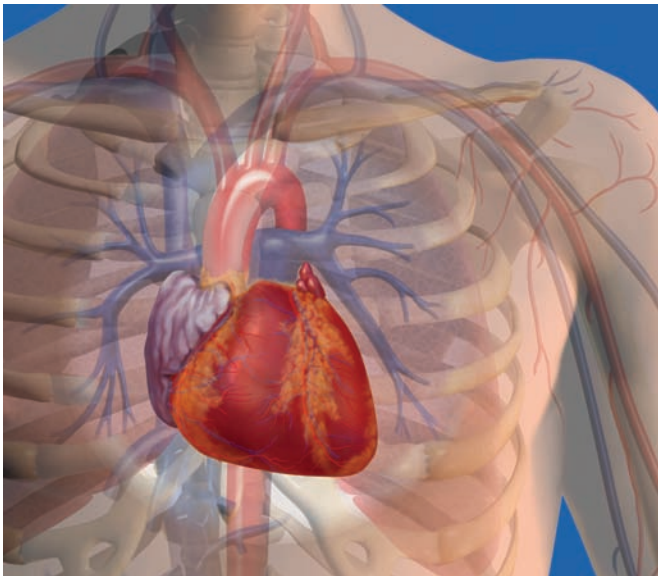
- *You have experienced an abnormally rapid heart rhythm (Ventricular Tachycardia or Ventricular Fibrillation).*
- *You are at risk of developing an abnormally rapid heart rhythm.*

These rapid heart rhythms, known as cardiac arrhythmias, may be life threatening. When a cardiac arrhythmia occurs, it interrupts the normal pumping function of the heart. This disruption of normal heart function may lead to loss of consciousness, and ultimately, be lethal.

The minimally invasive S-ICD System is a treatment for correcting an abnormally rapid heart rhythm. The S-ICD System is not a cure for the underlying cause of your cardiac arrhythmia, but rather serves as an automatic “emergency response team” in your chest.



UNDERSTANDING YOUR HEART



UNDERSTANDING YOUR HEART

This section will discuss the basic function of the normal heart and will also explain what happens when the heart develops abnormally rapid heart rhythms.

The Normal Heart

The heart is divided into four chambers: two upper chambers called the atria and two lower chambers called the ventricles (*Figure 1*). The four chambers fill with blood when the heart is at rest and then pump the blood throughout the body with each heart contraction.

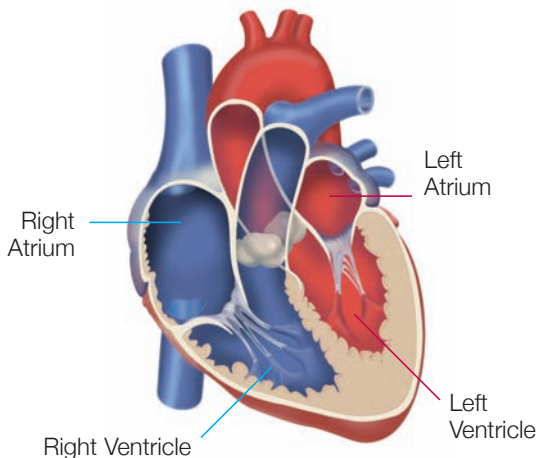


Figure 1: Chambers of the Heart

The heart has a specialized conduction system that produces electrical impulses that stimulate the heart to contract. Normally, your heart's pumping action is controlled by steady electrical signals that are produced by your heart's natural pacemaker, the sinoatrial (SA) node. Electrical signals from the SA node travel through the atria and follow an electrical pathway to the ventricle. This creates an electrical stimulation that causes the heart muscle to contract. The heart then rests and fills with blood until the next contraction occurs. This cycle occurs millions of times in a year.

Normal resting heart rates are usually in the range of 60 to 100 beats per minute. However, your heart rate may increase or decrease outside this range depending on activity levels. Generally, the heart rate will increase during exercise and decrease during sleep.

When the Heart Beats Too Fast

An abnormal condition exists when your heart rate increases significantly in the absence of exercise or emotional stress. This is known as a tachycardia. Not all tachycardias cause serious problems. Some tachycardias may cause discomfort, but are not life threatening; whereas other tachycardias may be very serious and life threatening.

Tachycardias are also associated with injury to the heart muscle, which can occur with coronary artery disease. Coronary artery disease may cause a myocardial infarction (commonly referred to as a heart attack), which may



damage the heart muscle. Tachycardias may also result from other diseases or certain genetic defects that weaken the heart muscle.

Ventricular Tachycardia

A tachycardia that originates in the lower chamber of the heart, or ventricle, is known as Ventricular Tachycardia (**VT**). When ventricular tachycardia is very fast, unstable and irregular, it may become ventricular fibrillation.

Ventricular Fibrillation

Ventricular Fibrillation (**VF**) causes the heart to quiver which prevents the heart from pumping blood to your body. If you are experiencing VF, you may become unconscious within a few seconds. Death is almost certain unless an electrical shock is delivered to the heart to restore the heart back to a normal rhythm.

Why do I need a minimally invasive S-ICD System?

Your physician has recommended implantation of a minimally invasive S-ICD System because you are at risk for VT or VF. Some heart disorders that are associated with risks of developing VT or VF are listed below:

- *Heart Attack: Occurs when there is a complete or sudden loss of oxygen-rich blood flow to the heart muscle due to a blocked or narrowed coronary artery. Due to the lack of an oxygen-rich blood supply, a portion of the heart muscle is injured.*
- *Heart Failure: A condition in which the heart cannot pump enough blood to the body or other organs.*
- *Cardiomyopathy: A disease process that causes the heart to become abnormally large, thickened or stiffened. As a result, the heart muscle weakens, decreasing the heart's ability to pump blood efficiently to the body.*
- *Primary Rhythm Disorder: An abnormality within the conduction system in the heart.*



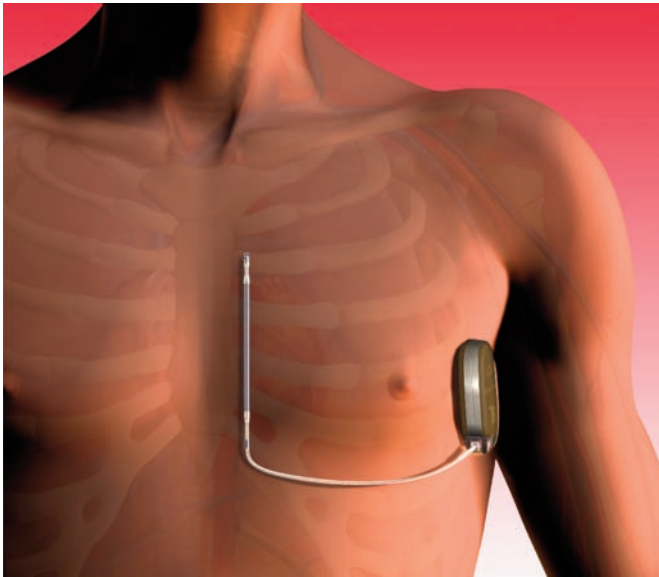


Am I at risk for developing a Ventricular Tachycardia or Ventricular Fibrillation?

When a portion of the heart muscle is injured or the heart is abnormally enlarged, the heart is not able to pump blood efficiently to the body. Measurements may be made to assess the condition of your heart. One such measurement is known as ejection fraction (**EF**). EF measures how much blood is pumped out to the body with each heart beat, or contraction.

Medical studies have determined that patients who have a low EF measurement are particularly at risk for developing ventricular tachycardias or ventricular fibrillation.

WHAT IS THE MINIMALLY INVASIVE S-ICD SYSTEM?





The implantable components of the minimally invasive **S-ICD** System are implanted beneath the surface of the skin outside the rib cage.

S-ICD System Components



Pulse Generator

The pulse generator (*Figure 2*) is a battery powered, computer-controlled device encased in metal. The pulse generator is implanted on the left side of the chest wall.

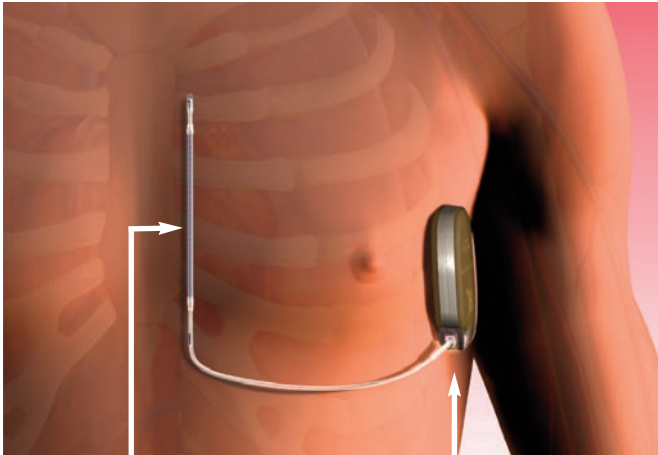
Figure 2: Pulse Generator

Various settings and parameters for the pulse generator are programmable through wireless communication with an external programmer. Your physician can program various settings in your pulse generator to accommodate your particular cardiac condition. When the pulse generator detects an abnormally rapid heart rhythm, a shock is delivered to restore the heart back to its normal rhythm. This shock therapy is called defibrillation. The S-ICD System will record and store these abnormally rapid heart rhythms. Your physician may retrieve the saved information during your routine scheduled follow-up visits. This can be accomplished via a wireless external programmer called the Q-TECH Programmer.

Subcutaneous Electrode

The subcutaneous electrode comprises a partially coated (insulated) wire that is surgically implanted above and to the left of the breastbone (sternum). The subcutaneous electrode is connected to the pulse generator (*Figure 3*).

The S-ICD System uses the electrode to sense electrical signals in the heart. When necessary, the S-ICD System delivers a shock to restore the heart back to normal rhythm.



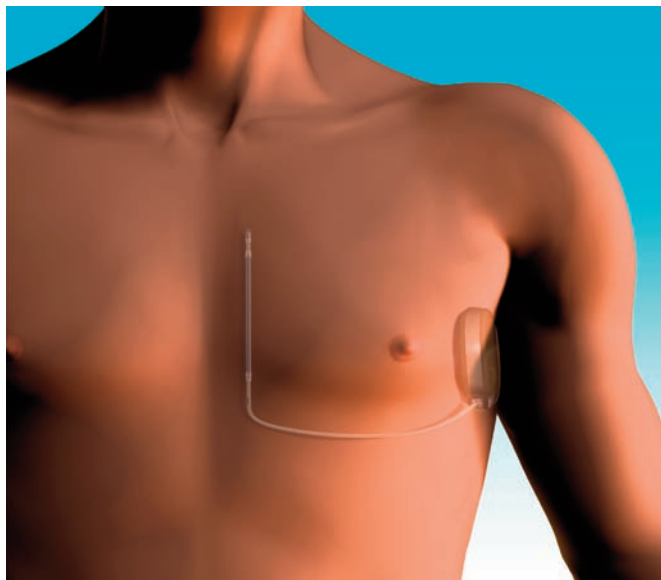
Electrode Left of Breastbone

Pulse Generator Connection
- Left Side of rib cage

Figure 3: Subcutaneous Electrode Placement



UNDERSTANDING THE IMPLANT PROCEDURE



UNDERSTANDING THE IMPLANT PROCEDURE

Depending on the hospital and physician practice, local or general anesthesia is administered to make you comfortable during the implant procedure. The duration of the implant procedure will vary depending on the type of anesthesia.

The following section outlines the basic steps of the implant procedure (*Figure 4*):



- 1. An incision is made on the left side of the chest, next to the rib cage.*
- 2. A pocket, or pouch, is formed under the skin for the placement of the pulse generator.*
- 3. Two small incisions are made to the left of the breastbone allowing placement of the subcutaneous electrode under the skin.*
- 4. The subcutaneous electrode is connected to the pulse generator.*
- 5. Testing and adjustments are accomplished by the Q-TECH Programmer.*
- 6. Once the incisions are closed, the procedure is complete.*

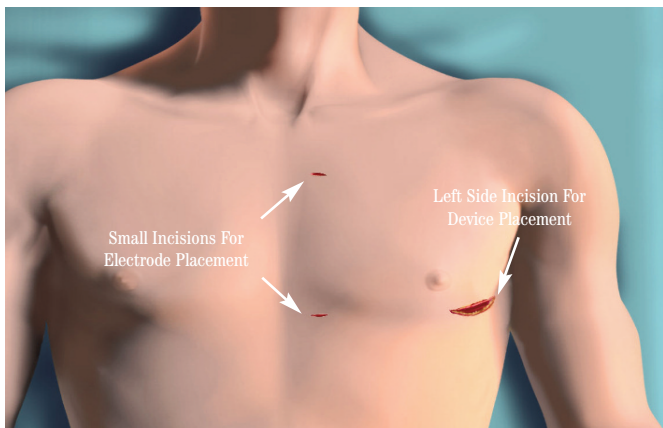


Figure 4: Implant Procedure

Discharge from the Hospital

Recovery from your S-ICD System implant procedure should not prevent you from returning to an active lifestyle. Follow your physician's post-operative instructions.

Pulse Generator Replacement

When the battery supply of your pulse generator becomes low or depleted, the pulse generator will need to be replaced. An incision is made along the previous scar and the old pulse generator is exchanged for a new one.

LIVING WITH YOUR S-ICD SYSTEM



LIVING WITH YOUR S-ICD SYSTEM

Patient Responsibilities

This section provides an outline of what you should know about your S-ICD System and returning to your daily activities post-surgery.

- *A Patient Identity card (ID) (Figure 5) will be issued to you prior to your discharge from the hospital. Carry this ID card with you at all times. The card will alert medical and security personnel that you have an implanted medical device.*

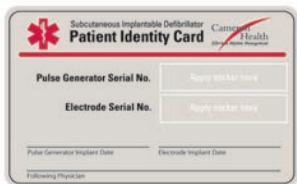


Figure 5: Patient Identity Card

- *Notify your physician if the card is lost.*

Note: *Always show your ID card when visiting a new doctor or dentist, or when passing through airport security.*



- *If you receive a shock while conscious, it may be uncomfortable and startling. Try to remain calm. Receiving a shock at some point in time is an expected event. Be secure in knowing that the S-ICD System has done its job. Follow the instructions that your physician has given you. Be sure to notify your physician whenever a shock occurs. To help your physician, note the following details:*
- *What were you doing when you received the shock?*
- *What was the date and time when you received the shock?*
- *How did you feel before and after receiving the shock? For example, were you dizzy or short of breath?*

To ensure that your S-ICD System continues to function properly, maintain the follow-up visit schedule that is prescribed by your physician. Check with your physician to determine the frequency of these visits.

As a safety feature, the S-ICD System has a built-in self monitoring function that checks the circuitry of the pulse generator. If you should hear beeping tones coming from your pulse generator, contact your physician. The beeping indicates that your S-ICD System requires immediate follow-up by your physician.

ENVIRONMENTAL SAFETY PRECAUTIONS



S-ICD SYSTEM WARNINGS AND CAUTIONS

READ AND FOLLOW ALL WARNINGS AND CAUTIONS DISCUSSED IN THIS SECTION. TALK TO YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS OR CONCERNS REGARDING THIS INFORMATION.

Warnings

Certain electrical or magnetic fields may interfere with the S-ICD System's function. To minimize the possibility of any interference, maintain a 12 inch/30 centimeter distance between the implanted S-ICD System and:

- *Strong magnets*
- *Magnetic wands used in airport screening, government buildings, security systems in shopping malls, etc.*
- *Industrial equipment: motors, arc and resistance welders, power generators*

Try to avoid:

- *Large TV/Radio transmitting towers*
- *Power plants*
- *Antennas used to operate a CB, ham radio, or other radio transmitter*



ENVIRONMENTAL SAFETY PRECAUTIONS

This section presents the environmental safety precautions for which you must be aware. Be sure to carefully read and understand each of these precautions. If you still have questions or concerns regarding these precautions, please contact your physician or Cameron Health.

Electro-Magnetic Interference (EMI)

An electromagnetic field is created when using electrical and mechanical devices. Most of the equipment with which you have daily contact gives off weak electromagnetic fields; they will not affect the proper operation of your S-ICD System. Some devices emit strong electromagnetic or radio frequency fields, which can temporarily affect the function of your S-ICD System. This form of interference is called Electro-Magnetic Interference or EMI. Typically, normal device function resumes when you move away from the EMI source.

Your S-ICD System is designed to protect itself from most of the daily types of interference. It is important for you to be aware of which EMI sources are likely to interfere with your S-ICD's normal system function.



Medical Procedures

Inform your physician, nurse, dentist or dental assistant that you have an implanted S-ICD System before any medical or dental procedure.

Some medical or diagnostic procedures that may cause interference with the S-ICD System include:

- *Diathermy*
- *Lithotripsy*
- *Transcutaneous Electrical Nerve Stimulator (TENS)*
- *Radiation Therapy*
- *Surgical and Dental Procedures*
- *Magnetic Resonance Imaging (MRI)*
- *Electrolysis*





Household Appliances and Common Tools

The S-ICD System allows you to safely operate most household appliances, office equipment and common tools that are properly grounded and in good repair. These include the following:

- *Microwave ovens and toasters*
- *Blenders, electric can openers, electric knives*
- *Televisions, VCRs, remote controls, video games, CD players, AM/FM radios*
- *Personal computers, fax machines, copiers/printers, electric typewriters*
- *Garage door openers*
- *Electric blankets and heating pads*
- *Washers, dryers, electric range ovens*
- *Hair dryers, electric shavers, electric toothbrushes*
- *Most transmitters for radio-controlled devices, such as toys*
- *Spark-ignited internal combustion engines, such as lawn mowers, leaf blowers, automobiles*
- *Machine shop tools, such as table saws and drills*

Maintain a 6 inch/15 centimeter distance between the implanted S-ICD System and:

- *Magnets used in large stereo speakers, magnetic badges, hand-held massagers*

Mobile Phones

If you use a mobile phone or a cordless phone, it is best to keep the phone more than 15 centimeters or 6 inches from your S-ICD System. Distances less than those recommended may affect the normal operation of the S-ICD System. It is further recommended that your mobile phone be carried on the opposite side of the implanted S-ICD System. When talking on the mobile phone, hold the mobile phone on the opposite side of the body away from the implantation site. The mobile phone may affect the therapy functions of the S-ICD System. Consult your physician if you have specific questions about the S-ICD System and the potential interaction with mobile phones.



Security Systems

Typically, anti-theft and security detection systems have minimal effect on the S-ICD System. However, there are a few notes to remember when in the presence of these devices:

- *The security archway that is located in airports and government buildings will not harm your S-ICD System, but the security system may detect the metal case included in the S-ICD System and set off the alarm. If this happens, present your Cameron Health ID card to the security personnel and request a hand search.*
- *Anti-theft systems or Electronic Article Surveillance systems are frequently found at the entrances and exits of stores, banks, libraries, etc. Although unlikely, these systems could interact with your S-ICD System. To minimize this interaction, pass through these systems at a normal pace. Do not stop in close proximity of the detection system.*
- *Home security systems will not affect the proper function of your device.*

FREQUENTLY ASKED QUESTIONS





FREQUENTLY ASKED QUESTIONS

How often does the S-ICD System deliver therapy?

Therapy delivery varies for each patient and may be dependent upon your specific heart condition.

How long will the battery last?

The battery in the S-ICD System can typically last many years. There are factors that could affect battery life including your heart condition and the amount of therapy you receive. Your physician will let you know when the energy level decreases in the device battery.

What will it feel like if I receive a shock?

Patients vary in their descriptions of experiencing a shock. These descriptions range from a “mild thump” to a “swift kick” in the chest. Most patients are reassured in knowing that a rapid heart rhythm was treated with the shock and they can resume their normal daily routine. Follow your physician’s instructions if you receive a shock.

What happens if someone is touching me when I receive a shock?

If you receive a shock while engaging in physical contact with another individual, they may feel a harmless tingling sensation that lasts for an instant.

Will I be able to feel the implanted S-ICD System?

Most people are aware of the implanted S-ICD System, but become accustomed to it quickly.

What should I do if my device is beeping?

Make note of what you were doing then contact your physician.

Can I exercise?

The S-ICD System itself does not prevent you from exercising. Follow your physician's instructions on the amount and type of exercise you are permitted to do after implantation of the S-ICD System.

When can I resume driving?

Your physician will advise you if, and when, you may drive after your S-ICD System has been implanted. This decision is based upon your specific heart condition. The driving laws for patients who have implantable defibrillation devices vary from state to state and country to country.

Can I travel?

The S-ICD System does not prevent you from traveling. Check with your physician about guidelines regarding any travel restrictions. Your physician may give you guidance on who to speak with or contact when traveling.

Can I use a mobile phone?

If you use a mobile phone or a cordless phone, it is best to keep the phone more than 15 centimeters or 6 inches from your S-ICD System. Distances less than those recommended may affect the normal operation of the S-ICD System. It is further recommended that your mobile phone be carried on the opposite side of the implanted S-ICD System. When talking on the mobile phone, hold the mobile phone on the opposite side of the body away from the implantation site. The mobile phone may affect the therapy functions of the S-ICD System. Consult your physician if you have specific questions about the S-ICD System and the potential interaction with mobile phones.





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