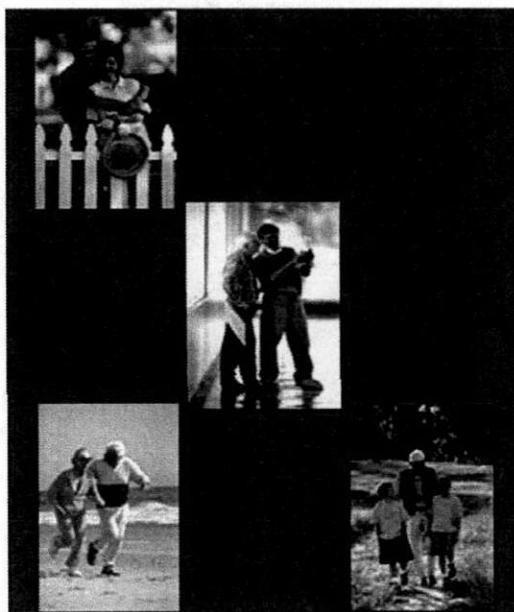


# A Patient Guide

*Living with your S-ICD® System*



**Rx Only**

*The minimally invasive S-ICD® System*

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## ABOUT THIS GUIDE



**This patient guide provides information on:**

- *Glossary of terms*
- *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.*

## GLOSSARY OF TERMS

### **Arrhythmia**

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

### **Atrium (plural: atria)**

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

### **Bradycardia**

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

### **Cardiac arrest**

See *sudden cardiac arrest (SCA)*.

### **Defibrillation**

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

### **Defibrillator**

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

### **Device**

See *pulse generator*.

### **Ejection fraction**

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

### **Electrode**

An insulated wire that is implanted under the skin and connected to the device. The electrode senses your heartbeat and delivers pacing pulses and/or shocks from the device to the heart.

### **Electromagnetic field**

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

### **Electromagnetic interference (EMI)**

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

### **Fibrillation**

See *ventricular fibrillation*.

### **Heart attack**

See *myocardial infarction (MI)*.

### **Heart rhythm**

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

### **Implantable Cardioverter Defibrillator (ICD) system**

A device (also called a pulse generator) and leads. An ICD system is implanted to monitor your heart rhythm and help treat dangerously fast or slow arrhythmias.

**Myocardial infarction (MI)**

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

**Programmer**

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

**Pulse generator**

Also called a device. The pulse generator is the part of the ICD system that contains the electronics and the battery; it is implanted under the skin on the left side of the chest.

**Radio frequency (RF) wireless communication**

Technology that allows the device to exchange information with a programmer by communicating over radio signals.

**Sinoatrial (SA) node**

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

**Sternum**

(Breast Bone) Bone located in the center of the chest which connects the ribs.

**Subcutaneous**

Just beneath the skin.

**Sudden cardiac arrest (SCA)**

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

**Sudden cardiac death (SCD)**

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

**Wireless communication**

Technology that allows a device to exchange information with a programmer wirelessly. See also *radio frequency (RF) wireless communication*.

**Ventricle**

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

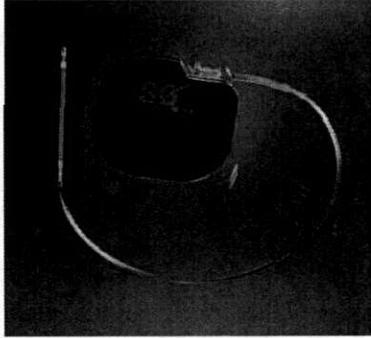
**Ventricular fibrillation (VF)**

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

**Ventricular tachycardia (VT)**

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

## 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.

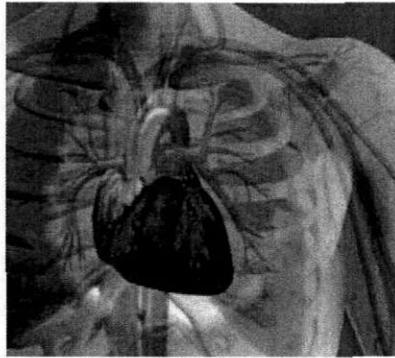
Your physician may have prescribed this device for you for one of the following reasons:

- 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

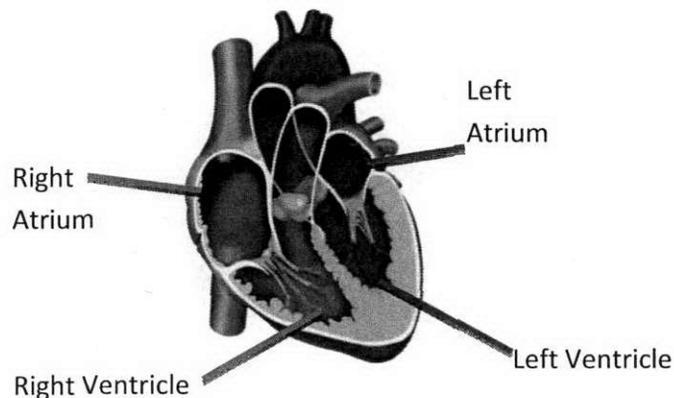


### UNDERSTANDING YOUR HEART

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.

If this rapid heartbeat continues, you may feel skipped beats or dizziness. You could eventually become unconscious, and your heart might stop beating (cardiac arrest).

### 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:

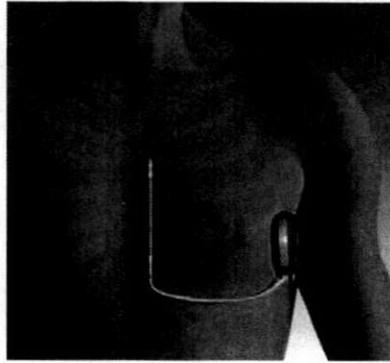
- Heart Attack: Occurs when there is a complete or sudden loss of oxygen-rich blood flow to the heart muscle due to a blocked or narrowed coronary artery. Due to the lack of an oxygen-rich blood supply, a portion of the heart muscle is injured.
- Heart Failure: A condition in which the heart cannot pump 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.

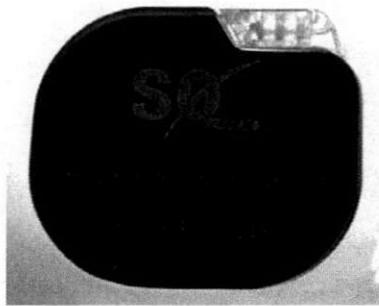
## WHAT IS THE MINIMALLY INVASIVE S-ICD SYSTEM?



### 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



**Figure 2:** 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.

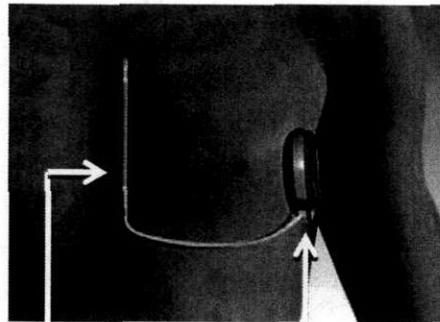
Various settings and parameters for the pulse generator are programmable through wireless communication with an external programmer. Your physician can program various settings in your pulse generator to accommodate your particular cardiac condition. When the pulse generator detects an abnormally rapid 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.

The pulse generator and electrode materials that come in contact with the body have been tested for biocompatibility. The pulse generator and electrode are composed of titanium and other metals. Allergic reactions are uncommon, but you should discuss any known allergies to metals with your physicians.



Electrode Left of Breastbone    Pulse Generator Connection  
- Left Side of rib cage

**Figure 3:** Subcutaneous Electrode Placement

#### Benefits and Risks of Having an S-ICD System

Your physician has decided that you should receive an implantable defibrillator (ICD) because you have an increased risk of sudden cardiac death due to ventricular rhythm disturbances. In particular, your physician believes you may benefit from the S-ICD System. The S-ICD System avoids some complications associated with transvenous leads by providing therapy without a lead(s) placed inside your heart. Additionally, the S-ICD System does not require the use of x-ray radiation during the implant procedure.

As with all ICD systems, there are risks associated with the S-ICD System. Although infrequent, some of the risks that may be encountered during the implant procedure include the following:

- Formation of a blood clot
- Damage to adjacent structures (tendons, muscles, nerves)
- Dangerous arrhythmias
- Heart attack
- Stroke
- Death

After the system is implanted, other infrequent risks may occur, including:

- Infection
- Erosion of the skin near your device
- Electrode and device may move out of place
- Delivery of a shock or pacing therapy when it is not needed (inappropriate therapy)
- Inability to detect or appropriately treat your heart rhythms due to electromagnetic interference or malfunction
- Difficulty coping with having an implanted device

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

## 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. Because of the lateral location of the pulse generator, females may have to consider undergarments and clothing that do not cause discomfort in the vicinity of the pulse generator pocket.

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

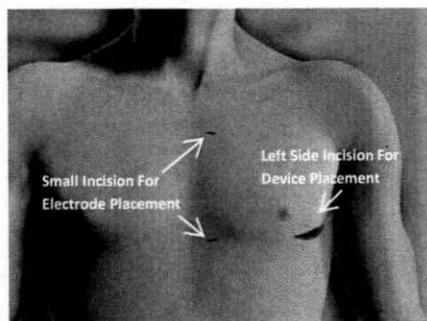
1. An incision is made on the left side of the chest, next to the rib cage.
2. A pocket, or pouch, is formed under the skin for the placement of the pulse generator.
3. Two small incisions are made to the left of the breastbone allowing placement of the subcutaneous electrode under the skin.
4. The subcutaneous electrode is connected to the pulse generator.
5. Your physician will then test your ICD system. During this test, your physician will start an arrhythmia in your heart. The device will recognize the rhythm and give a shock therapy. During this testing you will be sedated to minimize any discomfort.
6. Testing and adjustments are accomplished by the Q-TECH Programmer.
7. Once the incisions are closed, the procedure is complete.

### 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.



**Figure 4:** Implant Procedure

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

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

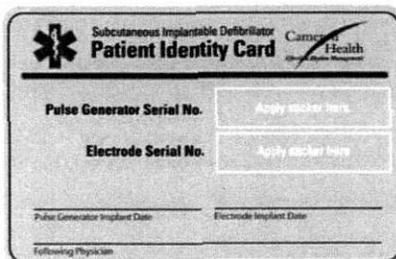


Figure 5: Patient Identity Card

- 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.

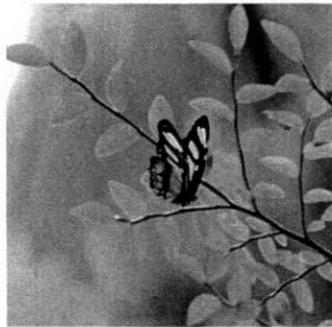
It is important to follow your physician's instructions as well as these recommendations:

- Your physician will arrange a follow-up plan with you to check your device and overall health on a regular basis. It is important that you attend your scheduled in-office follow-up visits to assure that the S-ICD System is working properly, so that the battery can be checked and that the programmed settings are appropriate.
- Ask your physician if you have any questions about or notice anything unusual with your device.
- Take the medications prescribed for you as instructed by your physician.
- Carry your medication list with you at all times.

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. Your physician or nurse can demonstrate these beeping tones so you will recognize them. Even though the system has this warning system, you should always follow your physician's instructions for regular follow-up visits.

You may have difficulty coping with having an implanted device. Some patients find it helpful to contact or join a local ICD support group. Your physician or nurse can help you locate one in your area. You can also search for ICD support groups on the internet for more information.

## ENVIRONMENTAL SAFETY WARNINGS AND PRECAUTIONS



### Electromagnetic Interference (EMI)

An electromagnetic field is created when using electrical and magnetic devices. Most of the electrical and magnetic devices you encounter create weak electromagnetic fields. Your S-ICD System is designed to protect itself from these electromagnetic fields and proper operation of your S-ICD System will not be affected when you are around the electrical and magnetic devices that create such fields.

Some electrical and magnetic devices, however, emit strong electromagnetic or radio frequency fields, which can temporarily affect the function of the S-ICD System. This form of interference is called electromagnetic interference (EMI). Typically, normal S-ICD System function resumes when you move away from the electrical and magnetic devices creating the EMI. It is important for you to be aware of what electrical and magnetic devices are likely to interfere with your S-ICD System's normal function. The following paragraphs help you identify the EMI safety of particular appliances, tools and activities.

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

#### Items that are safe under normal use:

- Air purifiers
- Blenders
- CD/DVD players
- Clothes washing machines and dryers
- Electric blankets
- Electric can openers
- Electric invisible fences
- Electric toothbrushes
- Fax/copy machines
- Hair dryers
- Heating pads
- Hot tubs/whirlpool baths

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

- Laser tag games
- Microwave ovens
- Ovens (electric, convection, and gas)
- Pagers

- Patient alert devices
- Personal computers
- Personal digital assistants (PDAs)

**NOTE:** PDAs that also function as cell phones should be kept at least 6 inches (15 cm) away from your device. Refer to section Cellular Phones.

- Portable space heaters
- Radios (AM and FM)
- Remote controls (TV, garage door, stereo, camera/video equipment)
- Stoves (electric or gas)
- Televisions
- TV or radio towers (safe outside of restricted areas)
- Tanning beds
- Vacuum cleaners
- VCRs
- Video games

#### **ENVIRONMENTAL WARNINGS AND PRECAUTIONS**

READ AND FOLLOW ALL WARNINGS AND PRECAUTIONS DISCUSSED IN THIS SECTION. FAILURE TO HEED THE WARNINGS AND PRECAUTIONS MAY RESULT IN INAPPROPRIATE SHOCK THERAPY OR FAILURE TO DELIVER SHOCK THERAPY. AS A GENERAL RULE, IF YOU ARE OPERATING ANY ELECTRICAL OR BATTERY POWERED EQUIPMENT AND YOU RECEIVE A SHOCK, YOU SHOULD STOP OPERATING THE EQUIPMENT. IN ADDITION, IF YOUR DEVICE STARTS BEEPING, YOU MAY BE IN THE PRESENCE OF A STRONG MAGNETIC FIELD AND YOU SHOULD MOVE AWAY FROM THE POTENTIAL MAGNETIC SOURCE UNTIL YOUR DEVICE STOPS BEEPING. TEMPORARY BEEPING MAY ALSO BE AN INDICATION THAT YOUR DEVICE HAS DETECTED A MALFUNCTION. IF YOU HEAR YOUR DEVICE BEEPING, CONTACT YOUR PHYSICIAN IMMEDIATELY. 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, try to avoid:

- Strong magnets such as auto wrecking yards and industry
- Industrial power generators
- Large TV/Radio transmitting towers
- Power plants and high voltage power lines

#### **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.

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

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

- Cordless (household) telephones
- Electric razors
- Hand-held massagers
- Portable MP3 and multimedia players (such as iPods®) that do not also function as a cellular phone.

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

**Items that should remain at least 6 inches (15 cm) away from your device, but are otherwise safe to use:**

- Cellular phones, including PDAs and portable MP3 players with integrated cellular phones  
**NOTE:** For more information about cellular phones, see section on "Cellular phones".
- Devices transmitting Bluetooth® or Wi-Fi signals (cellular phones, wireless Internet routers, headphones and earbuds, etc.)
- Magnetic wands used in the game of Bingo

**Items that should remain at least 12 inches (30 cm) away from your device, but are otherwise safe to use:**

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

**Items that should remain at least 24 inches (60 cm) away from your device, but are otherwise safe to use:**

- Magnetic wands used in airport screening, government buildings, security systems in shopping malls, etc.
- Arc and resistance welders
- Home power generators
- Antennas used to operate a CB, ham radio, or other radio transmitter
- Running motors and alternators, especially those found in vehicles  
**NOTE:** Avoid leaning over running motors and alternators of a running vehicle. Alternators create large magnetic fields that can affect your device. However, the distance required to drive or ride in a vehicle is safe.

**Items that should not be used:**

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

If you have questions about the EMI safety of a particular appliance, tool or activity, please call Cameron Health Customer Services at 1 (877) 742-3411.

**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

### **Cellular phones**

If you use a cellular phone or a cordless phone, it is best to keep the phone more than 15 centimeters or 6 inches from your S-ICD System. It is further recommended that your cellular phone be carried on the opposite side of the implanted S-ICD System. When talking on the cellular phone, hold the cellular phone on the opposite side of the body away from the implantation site. The cellular 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 cellular phones.

### **Anti-theft 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:

- 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 without stopping.
- Do not lean against or linger near these systems. If you suspect interaction between your device and a theft detection system could occur, just move away from the system to decrease the interference.
- Most home security systems will not affect the proper function of your device.

### **Airport Security**

Your device contains metal parts that may set off airport security metal detector alarms. The security archway will not harm your device. Tell security personnel that you have an implanted medical device and show them your Medical Device Identification card.

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

If you have questions about airport security, call your physician or Cameron Health Customer Service at 1 (877) 742-3411.

## FREQUENTLY ASKED QUESTIONS



### FREQUENTLY ASKED QUESTIONS

How do I know my device is working properly?

Regular follow-up visits are required to assess your S-ICD System. Therefore, it is important to follow your physician's instructions regarding regular follow-up visits.

How do I know if increased heart rate will result in a shock, for instance from exercise?

Your heart rate will generally increase when you exercise. Your physician can program the S-ICD System to deliver therapy only when your heart exceeds a certain rate. While inappropriate shocks may occur, there are special features in the S-ICD System that are designed to tell the difference between high rates due to vigorous exercise and those due to an arrhythmia that needs therapy.

Is pacing available in the S-ICD System?

Pacing used to treat slow heart rates (Bradycardia) is only available following shock therapy. Following shock therapy, the heart may slow down or be interrupted for a brief period. The pacing following shock therapy is used for temporary support until your own heart rate returns to normal.

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 five years. There are factors that could affect battery life including your heart condition and the amount of therapy you receive. Your device will regularly check its own battery. At every follow-up visit, the physician or nurse will also check to see how much energy is remaining in the battery. When the battery's energy level decreases to a certain point, the device will begin to beep and will need to be replaced.

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, including during sexual intimacy, they may feel a harmless tingling sensation that lasts for an instant.

Will I be able to engage in sexual intimacy?

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

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. For some patients, discomfort or pain near the pulse generator or electrode may last for several weeks. In rare situations, surgical repositioning may be required to resolve discomfort.

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. Most S-ICD System patients who previously drove can resume driving. There are no physical driving impediments attributable to the S-ICD System. Furthermore, protection afforded by the S-ICD System helps make driving safe of lethal arrhythmia symptoms. Receiving a shock during driving is usually uncommon.

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 whom to speak with or contact when traveling. If you are traveling overseas, you may also contact Cameron Health Customer Service for the location of hospitals that implant and provide follow-up support for the S-ICD System.

Can I use a cellular phone?

If you use a cellular phone or a cordless phone, it is best to keep the phone more than 15 centimeters or 6 inches from your S-ICD System. It is further recommended that your cellular phone be carried on the opposite side of the implanted S-ICD System. When talking on the cellular phone, hold the cellular phone on the opposite side of the body away from the implantation site. The cellular 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 cellular phones.

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**SQ-RX® PULSE GENERATOR  
A COMPONENT OF THE S-ICD® SYSTEM  
USER'S MANUAL  
MODEL 1010**



**Rx only**

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The SQ-RX® Pulse Generator is part of the S-ICD® system, and this product alone, or in combination with other components of the S-ICD® System, is covered by at least the following US Patents:

6,721,597	7,039,459	7,330,757	7,623,920
6,754,528	7,065,407	7,376,458	7,769,457
6,865,417	7,069,080	7,444,182	7,877,139
6,927,721	7,149,575	7,623,913	7,991,459
6,952,608	7,248,921	7,623,916	7,996,082

as well as pending patent applications.

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### **Description**

The SQ-RX Pulse Generator (the "device") is a component of the Cameron Health S-ICD System, which is prescribed for patients when cardiac arrhythmia management is warranted. Implanted with the Q-TRAK Subcutaneous Electrode (the "electrode"), the device detects cardiac activity and provides defibrillation therapy.

### **Indications for Use**

The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

### **Contraindications**

Unipolar pacemakers are contraindicated for use with the S-ICD System.

### **Warnings and Cautions**

Before using the S-ICD System, read and follow all warnings and cautions provided in this manual.

The S-ICD System contains sterile products for single use only. Do not resterilize. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique.

All Cameron Health implantable components are designed for use with the Cameron Health S-ICD System only. Connection of any S-ICD System components to any other ICD system will result in failure to deliver life saving defibrillation therapy.

### **General**

- External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.
- Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response. Refer to the S-ICD System Magnet Model 4520 section.
- Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.
- The S-ICD System has not been evaluated for pediatric use.
- The S-ICD System does not provide long-term bradycardia pacing or Cardiac Resynchronization Therapy (CRT).

## **SQ-RX PULSE GENERATOR: GENERAL DESCRIPTION**

---

### ***SQ-RX Pulse Generator Packaging***

The device has been sterilized with ethylene oxide gas and is packaged in a sterile container that is suitable for use in the operating field. Store in a clean, dry area. Each package contains the following:

- One SQ-RX Pulse Generator Model 1010
- One Bi-Directional Torque Wrench
- One SQ-RX Pulse Generator Model 1010 User's Manual

Before opening any package, visually inspect the sterile packaging to ensure the contents are not contaminated or been previously used. Do not use if any of the following conditions exist:

- Tears or punctures are noted in the packaging
- "Use By" date has expired
- Evidence of damage exists
- Sterile package has been dropped from a height greater than 24 inches (61 centimeters)

Return the product to Cameron Health if any of these conditions exist. Contact your local Cameron Health representative or Customer Service Department for instructions and return packaging.

### ***Storage and Handling***

- Store the S-ICD System components in a clean, dry area away from magnets or any other electromagnetic interference source that could cause damage to the device.
- Do not expose the S-ICD System to temperatures outside the recommended storage temperatures indicated on the device package.
- Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Impairment to the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient.

### ***Implant and Programming***

- Use only the electrode insertion tool to tunnel.
- Suture only those areas indicated in the implant procedure.
- Do not place a suture directly on the electrode body.
- Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Dislodgement and/or migration of the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient.
- Use only the Q-TECH Programmer (the "programmer") and appropriate software for communicating with and programming the device.
- Verify the device is in Shelf mode or Therapy Off to prevent the delivery of unwanted shocks to the patient or the person handling the device during the implant procedure.

### ***Explanting the System***

- To avoid inadvertent shock discharges, program the device to Therapy Off during Device explantation or post mortem procedures.
- Remove the device from a deceased patient prior to cremation. The device battery may explode when exposed to extreme temperatures.

### ***Use of Other Medical Therapies/Diagnostic Procedures***

- External defibrillation or cardioversion may damage the S-ICD System. Avoid placing the defibrillation paddles directly over the device or electrode.
- Cardio Pulmonary Resuscitation (CPR) may temporarily interfere with sensing and may cause delay of therapy.
- Do not expose a patient with an implanted S-ICD System to diathermy. The interaction of diathermy therapy with an implanted SQ-RX Pulse Generator can damage the SQ-RX Pulse Generator and cause patient injury.
- Do not expose the patient to MRI scanning. MRI scanning can damage the SQ-RX Pulse Generator and cause patient injury.
- Electrical interference or "noise" from sources such as electrosurgical and monitoring equipment can interfere with the communication between the programmer and the SQ-RX Pulse Generator or cause inappropriate therapy. If interference occurs, move the programmer away from the source of the interference.
- Ionizing radiation therapy, such as radioactive cobalt, linear accelerators, and betatrons, may adversely affect the S-ICD System operation. Therapeutic ionizing radiation may not be immediately detected; however, it can damage the electronic components of the SQ-RX Pulse Generator. To minimize the risks of ionizing radiation:
  - Shield the SQ-RX Pulse Generator with a radiation-resistant material, regardless of the distance between the SQ-RX Pulse Generator and the radiation beam.
  - Do not project the radiation port directly at the SQ-RX Pulse Generator.
  - Evaluate the S-ICD System operation after each radiation treatment.
- Lithotripsy and other therapeutic forms of ultrasound may damage the SQ-RX Pulse Generator. If required, avoid direct flow of the pulse waves near the site of the implanted device.
- Use caution during ablation procedures. Program the S-ICD System to Therapy Off. Keep the current path (electrode tip to ground) as far away as possible from the implanted SQ-RX Pulse Generator and electrode.

### ***Electromagnetic Interference (EMI) Outside of the Hospital Environment***

Exposure to Electromagnetic Interference (EMI) or Static Magnetic Field sources may suspend tachyarrhythmia detection and cause temporary inhibition of therapy delivery. EMI may also trigger delivery of a shock in the absence of a tachyarrhythmia. Automatic sensing and detection of tachyarrhythmias will resume when the patient moves away from the EMI or static magnetic field source.

To minimize the risk, advise patients to avoid sources of EMI or static magnetic fields having strengths >10 gauss or 1 mTesla.

- Sources of EMI include, but are not limited to:
  - High-voltage power lines
  - Arc welding equipment
  - Electrical smelting furnaces
  - Large radio-frequency transmitters (such as radar)
  - Alternators on running engines in automobiles
  - Communications equipment (such as high-power radio transmitters)
- Sources of strong static magnetic fields may include the following:
  - Industrial transformers and motors
  - Large stereo speakers
  - Magnetic wands, such as those used for airport security

Patients should seek medical guidance from their physician before entering an area where a posted sign prohibits patients with an implantable cardioverter defibrillator or pacemaker.

### ***Potential Adverse Events***

Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following:

- Acceleration/induction of atrial or ventricular arrhythmia
- Adverse reaction to induction testing
- Allergic/adverse reaction to system or medication
- Bleeding
- Conductor fracture
- Cyst formation
- Death
- Delayed therapy delivery
- Discomfort or prolonged healing of incision
- Electrode deformation and/or breakage
- Electrode insulation failure
- Erosion/extrusion
- Failure to deliver therapy
- Fever
- Hematoma
- Hemothorax
- Improper electrode connection to the device
- Inability to communicate with the device
- Inability to defibrillate or pace
- Inappropriate post-shock pacing
- Inappropriate shock delivery
- Infection
- Keloid formation
- Migration or dislodgement
- Muscle stimulation
- Nerve damage
- Pneumothorax
- Post-shock/post-pace discomfort
- Premature battery depletion
- Random component failures
- Stroke
- Subcutaneous emphysema
- Surgical revision or replacement of the system
- Syncope
- Tissue redness, irritation, numbness or necrosis

If any adverse events occur, invasive corrective action and/or S-ICD System modification or removal may be required.

Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following:

- Depression
- Fear of shocks
- Phantom shocks

### **S-ICD System Clinical Investigation**

The S-ICD System Clinical Investigation was a single-arm, prospective, non-randomized, multicenter clinical study conducted in patients age 18 or older who had an existing transvenous ICD, or who met guideline indications for ICD therapy, and had an appropriate pre-operative ECG. Patients with documented spontaneous and frequently recurring ventricular tachycardia (VT) that was reliably terminated with anti-tachycardia pacing were excluded unless they were not a candidate for a transvenous ICD system. The study was conducted at 33 participating centers (28 centers in the United States, 2 centers in The Netherlands, 2 centers in New Zealand and 1 center in The United Kingdom). A total of 330 patients were enrolled in the study, 321 underwent an implant procedure and 314 were implanted with the S-ICD System. The mean follow-up duration for all patients implanted was 330 days with a range of 17 to 715 days. Cumulative time of follow-up for all implanted patients was 3,410 months.

### **Methods**

Clinical data were collected at the time of enrollment, implant, hospital discharge, follow-up visits, during system revisions, and upon notification of clinical events, study exit, or protocol deviations. All patients were scheduled to return for follow-up examinations after the implant procedure and predischarge follow-up at 30, 90 and 180 days post implant, and semi-annually thereafter. Data were collected via case report forms and programmer printouts. All centers followed the same Clinical Investigational Plan and methods to collect data.

### **Primary Objectives**

The primary objectives of the study were:

- To confirm safety of the S-ICD System by demonstrating that the S-ICD System complication-free rate at 180 days post-implant meets or exceeds the performance goal of 79% with at least 95% confidence.
- To confirm effectiveness of the S-ICD System by demonstrating that the induced VF conversion rate meets or exceeds the performance goal of 88% with at least 95% confidence.

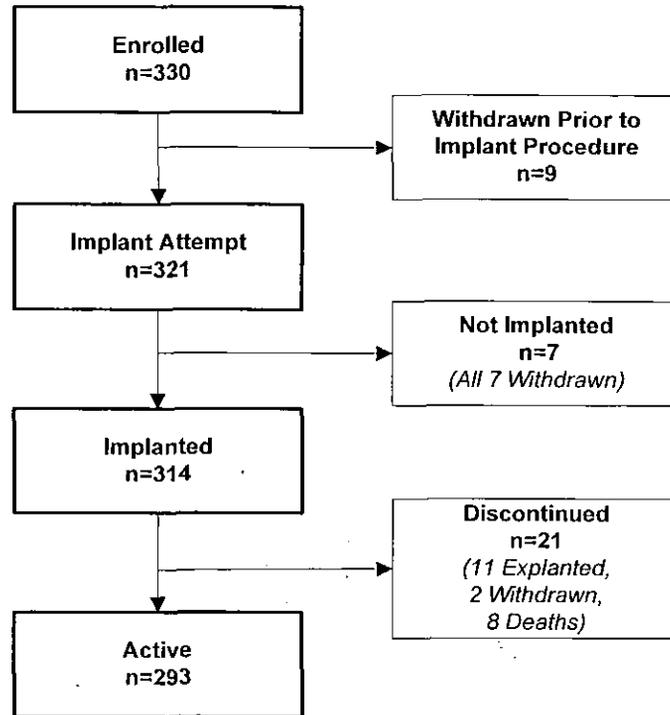
### **Additional Objectives**

Additional objectives of the study were:

- To observe the continued chronic performance of the S-ICD System during appropriate device-detected episodes of VT or VF.
- To observe the continued chronic performance of the S-ICD System during induced episodes of VT or VF at least 150 days post-implant.

**Accountability of PMA Cohort**

Of 330 patients enrolled in PMA study, 321 underwent an implant procedure, of whom 314 were implanted with the S-ICD System. There were 293 patients still active at the time of database lock on February 14, 2012. The mean follow-up duration for all patients implanted was 330 days with a range of 17 to 715 days. Cumulative time of follow-up for all implanted patients was 3,410 months. The disposition of all study participants is summarized in Figure 1 below:



**Figure 1:** Summary of Patient Status as of 14 February, 2012

The primary safety endpoint analysis cohort includes all patients who underwent an implant attempt for the S-ICD System (N=321). The primary effectiveness endpoint cohort includes all patients undergoing an implant attempt with complete acute induced VF conversion tests (N=304). A total of 17 patients did not undergo (N=1) or complete (N=16) acute induced VF conversion testing, seven of which were ultimately not implanted.

**SQ-RX PULSE GENERATOR: GENERAL DESCRIPTION**

**Study Population Demographics and Baseline Parameters**

The demographics of the study population are typical for an ICD study performed in the US. Cardiovascular history included congestive heart failure (61.4%), hypertension (58.3%), and myocardial infarction (41.4%). Secondary prevention ICD indications represented 20.6% of the population. Subject demographics (Table 1), baseline characteristics (Table 2) and ICD Indications (Table 3) are described below.

**Table 1: Subject demographics**

<b>Demographic</b>	<b>Statistic/Category</b>	<b>N=321</b>
<b>Age (years)</b>	Mean ± SD (Median) Range	51.9 ± 15.5 (53.8 ) 18.5-85.2
<b>Gender (n, %)</b>	Male	238 (74.1)
	Female	83 (25.9)
<b>Race (n, %)</b>	White or Caucasian	208 (64.8)
	Black or African American	76 (23.7)
	Hispanic or Latino	23 (7.2)
	Asian	6 (1.9)
	Asian Indian	3 (0.9)
	Maori	3 (0.9)
	Pacific Islander	2 (0.6)
<b>Height (cm)</b>	Mean ± SD (Median) Range	174.3 ± 10.2 (175.0 ) 142.2-200.7
<b>Weight (kg)</b>	Mean ± SD (Median) Range	90.5 ± 25.2 (86.6 ) 42.6-230.9
<b>BMI</b>	Mean ± SD (Median) Range	29.7 ± 7.2 (29.0 ) 15.2-69.0

**SQ-RX PULSE GENERATOR: GENERAL DESCRIPTION**

**Table 2: Baseline Characteristics**

<b>Attribute</b>	<b>Statistic/Category</b>	<b>N=321</b>
<b>Creatinine (mg/dL)</b>	Mean ± SD (Median) Range	1.1 ± 0.4 (1.0) 0.3-3.7
<b>Ejection Fraction (%) (n=299)</b>	Mean ± SD (Median) Range	36.1 ± 15.9 (31.0) 10.0-82.0
<b>NYHA Classification at Enrollment (n, %)</b>	I: No Physical Limitations	68 (21.2)
	II: Slight Physical Limitations	146 (45.5)
	III: Marked Physical Limitations	55 (17.1)
	IV: Total Physical Limitations	1 (0.3)
	Unknown/Not Assessed	51 (15.9)
<b>Co-morbidities History (n, %)</b>	Atrial Fibrillation	49 (15.3)
	COPD	27 (8.4)
	Cancer	31 (9.7)
	Congestive Heart Failure	197 (61.4)
	Diabetes	90 (28.0)
	Hypertension	187 (58.3)
	Myocardial Infarction	133 (41.4)
	Stroke	18 (5.6)
	Valve Disease	42 (13.1)
<b>Cardiac Surgical History (n, %)</b>	Ablation	16 (5.0)
	CABG	48 (15.0)
	Defibrillator	43 (13.4)
	Pacemaker	4 (1.2)
	Percutaneous Revascularization	92 (28.7)
	Valve Surgery	18 (5.6)

## SQ-RX PULSE GENERATOR: GENERAL DESCRIPTION

**Table 3: Indications According to ACC/AHA/HRS Guidelines**

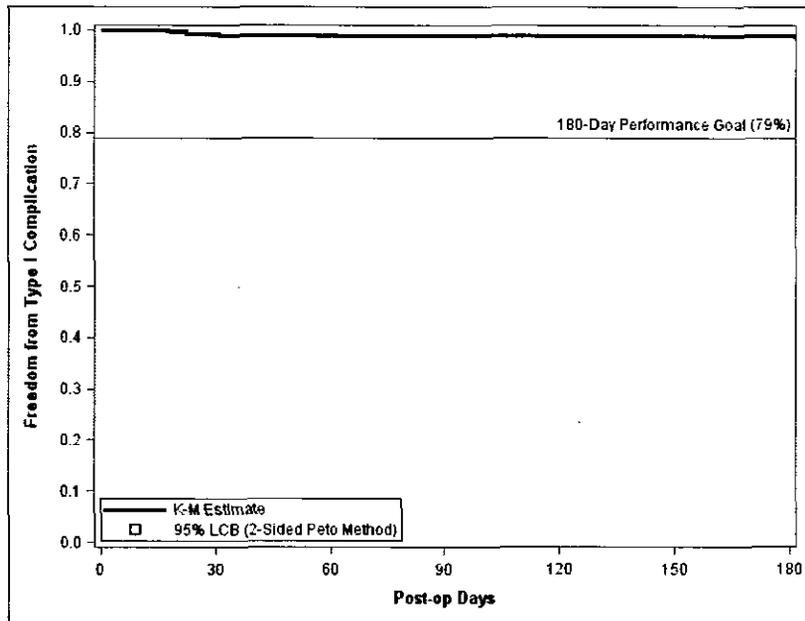
Indication Details	N=321 Patients n (%)
Left ventricular ejection fraction (LVEF) less than 35% due to prior MI who are at least 40 days post-MI and are in NYHA functional Class II or III	88 (27.4)
Non-ischemic DCM and an LVEF less than or equal to 35% and is in NYHA functional Class II or III	76 (23.7)
Survivor of cardiac arrest due to VF or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes	40 (12.5)
Hypertrophic Cardiomyopathy with risk for SCD	28 (8.7)
Structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable	15 (4.7)
Left Ventricular (LV) dysfunction due to prior MI and is at least 40 days post-MI, has an LVEF less than 30%, and is in NYHA functional Class I	13 (4.0)
Cardiomyopathy with risk for SCD	13 (4.0)
Long-QT syndrome with risk of SCD	12 (3.7)
Brugada syndrome with risk for SCD	10 (3.1)
Syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study	7 (2.2)
Familial cardiomyopathy associated with SCD	6 (1.9)
Cardiac sarcoidosis or Chagas disease	4 (1.2)
Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) with risk for SCD	3 (0.9)
Nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study	2 (0.6)
LV noncompaction	1 (0.3)
Catecholaminergic polymorphic VT	1 (0.3)
Sustained VT and normal or near-normal ventricular function	1 (0.3)
Symptomatic ventricular arrhythmia	1 (0.3)

**Safety and Effectiveness Results**

**Safety Results**

The 180-day Type I complication-free rate was assessed in all patients with an attempted S-ICD System implant (N=321) for the primary safety endpoint. A Type I complication was defined as any clinical event caused by the S-ICD System that required invasive intervention.

The Type I complication-free rate at 180 days was 99.0% with a lower 95% confidence bound of 97.9%. These results meet the primary safety endpoint performance goal of 79% and demonstrate the safety of the S-ICD System. Details of the Kaplan-Meier analysis are shown in Figure 2 and Table 4.



**Figure 2: Primary Safety Endpoint Kaplan-Meier Analysis**

**Table 4: Kaplan-Meier Estimates for Primary Safety Endpoint**

Statistic	Start of Interval (Days from Implant)				
	0	30	90	180	360
Number Remaining at Risk	319	311	308	<b>274</b>	119
Cumulative Patients Censored	2	8	10	<b>44</b>	194
Cumulative Patients with Events	0	2	3	<b>3</b>	8
KM Estimate of Patients Free from Event (%)	100	99.4	99.0	<b>99.0</b>	96.6
95% Lower Confidence Bound	100	98.5	98.0	<b>97.9</b>	93.5

## SQ-RX PULSE GENERATOR: GENERAL DESCRIPTION

### ***Clinical Events***

A *Clinical Event* is defined as any untoward medical occurrence in a patient. An *Observation* is a clinical event that does not result in invasive intervention and a *Complication* is a clinical event that results in invasive intervention. All clinical events were classified by type based on the cause of the clinical event, according to the following definitions:

- Type I: Caused by the S-ICD System
- Type II: Caused by the S-ICD System user's manual or labeling of the S-ICD System
- Type III: Not caused by the S-ICD System, but would not have occurred in the absence of the implanted S-ICD System
- Type IV: Caused by a change in the patient's condition

Table 5 summarizes all 211 clinical events reported from 139 patients, followed by a full listing of all Type I, II and III clinical events in Table 6, Table 7 and Table 8, respectively.

**Table 5: Clinical Event Summary by Type and Observation/Complication**  
All patients with an implant attempt (N=321)

Clinical Event	Complications		Observations		Total	
	Events	Patients (%)	Events	Patients (%)	Events	Patients (%)
<u>Type I</u>	12 <sup>1</sup>	11 (3.4)	35	30 (9.3)	47	3 (12.1)
<u>Type II</u>	4	4 (1.2)	0	0 (0.0)	4	4 (1.2)
<u>Type III</u>	25	24 (7.5)	83	71 (22.1)	108	88 (27.4)
<u>Type IV</u>	16	15 (4.7)	36	33 (10.3)	52	44 (13.7)
<b>All Clinical Events</b>	<b>57</b>	<b>48 (15.0)</b>	<b>154</b>	<b>116 (36.1)</b>	<b>211</b>	<b>139 (43.3)</b>

<sup>1</sup> Of note, there were a total of 12 Type I Complications, eight (8) of which occurred within 180-days of implant and are shown in the primary safety Kaplan-Meier analysis (Figure 2). The remaining four (4) events occurred after 360 days post-implant.

**SQ-RX PULSE GENERATOR: GENERAL DESCRIPTION**

**Table 6: Type I Clinical Events**

All patients with an implant attempt (N=321)

Clinical Event	Complications		Observations		Total	
	Events	Patients (%)	Events	Patients (%)	Events	Patients (%)
Discomfort	3	3 (0.9)	8	7 (2.2)	11	11 (3.4)
Inability to Communicate with the Device	2	2 (0.6)	0	0 (0.0)	2	2 (0.6)
Inappropriate Shock: Oversensing	5	5 (1.6)	25	21 (6.5)	30	25 (7.8)
Numbness at Device Site	0	0 (0.0)	1	1 (0.3)	1	1 (0.3)
Premature Battery Depletion	2	2 (0.6)	0	0 (0.0)	2	2 (0.6)
Subcutaneous Emphysema	0	0 (0.0)	1	1 (0.3)	1	1 (0.3)
<b>All Type I Clinical Events</b>	<b>12</b>	<b>11 (3.4)</b>	<b>35</b>	<b>30 (9.3)</b>	<b>47</b>	<b>39 (12.1)</b>

**Table 7: Type II Clinical Events**

All patients with an implant attempt (N=321)

Clinical Event	Complications		Observations		Total	
	Events	Patients (%)	Events	Patients (%)	Events	Patients (%)
Electrode Movement	2	2 (0.6)	0	0 (0.0)	2	2 (0.6)
Inappropriate Electrode Connection to the Device	1	1 (0.3)	0	0 (0.0)	1	1 (0.3)
Sub-optimal Electrode Position	1	1 (0.3)	0	0 (0.0)	1	1 (0.3)
<b>All Type II Clinical Events</b>	<b>4</b>	<b>4 (1.2)</b>	<b>0</b>	<b>0 (0.0)</b>	<b>4</b>	<b>4 (1.2)</b>

**SQ-RX PULSE GENERATOR: GENERAL DESCRIPTION**

**Table 8: Type III Clinical Events**

All patients with an implant attempt (N=321)

Clinical Event	Complications		Observations		Total	
	Events	Patients (%)	Events	Patients (%)	Events	Patients (%)
Acute Hypoxic Respiratory Failure	0	0 (0.0)	1	1 (0.3)	1	1 (0.3)
Adverse Reaction to Medication	3	3 (0.9)	5	5 (1.6)	8	8 (2.5)
Atrial Fibrillation / Flutter	0	0 (0.0)	14	14 (4.4)	14	14 (4.4)
Bleeding	0	0 (0.0)	1	1 (0.3)	1	1 (0.3)
Discomfort	1	1 (0.3)	12	12 (3.7)	13	12 (3.7)
Electrode Movement	1	1 (0.3)	0	0 (0.0)	1	1 (0.3)
Fever	0	0 (0.0)	3	3 (0.9)	3	3 (0.9)
Hematoma	1	1 (0.3)	5	4 (1.2)	6	5 (1.6)
Inadequate/Prolonged Healing of Incision Site	3	3 (0.9)	2	2 (0.6)	5	5 (1.6)
Inappropriate Shock: SVT Above Discrimination Zone (Normal Device Function)	4	4 (1.2)	17	14 (4.4)	21	16 (5.0)
Incision/Superficial Infection	1	1 (0.3)	13	13 (4.0)	14	14 (4.4)
Keloid	1	1 (0.3)	0	0 (0.0)	1	1 (0.3)
Local Tissue Reaction	0	0 (0.0)	1	1 (0.3)	1	1 (0.3)
Numbness at Device Site	0	0 (0.0)	1	1 (0.3)	1	1 (0.3)
PG Movement/Revision	1	1 (0.3)	0	0 (0.0)	1	1 (0.3)
Phantom Shock	0	0 (0.0)	5	3 (0.9)	5	3 (0.9)
Redness/Irritation	0	0 (0.0)	2	2 (0.6)	2	2 (0.6)
Stroke	0	0 (0.0)	1	1 (0.3)	1	1 (0.3)
Sub-optimal PG and Electrode Position	3	3 (0.9)	0	0 (0.0)	3	3 (0.9)
Sub-optimal Pulse Generator Position	1	1 (0.3)	0	0 (0.0)	1	1 (0.3)
Suspected Worsening of Ischemia	1	1 (0.3)	0	0 (0.0)	1	1 (0.3)
System Infection	4	4 (1.2)	0	0 (0.0)	4	4 (1.2)
<b>All Type III Clinical Events</b>	<b>25</b>	<b>24 (7.5)</b>	<b>83</b>	<b>71 (22.1)</b>	<b>108</b>	<b>88 (27.4)</b>

**Device Explants**

Eleven (11) patients exited the study after the S-ICD System was removed for: system infection (4), oversensing (2), pre-mature battery depletion (1), transvenous device implanted to provide overdrive pacing for ventricular arrhythmia trigger suppression (1), elective explant due to the development of an indication for biventricular pacing (1), elective explant due to development of high defibrillation threshold (1), and elective due to patient request (1).

**Patient Deaths**

Eight (8) deaths occurred in the study. None of the deaths were conclusively identified to be associated with the device or procedure.

**Effectiveness Results**

The effectiveness of the S-ICD System was assessed by the proportion of patients with successful acute (induced) VF conversion in all patients with an attempted S-ICD System implant (N=320).<sup>2</sup> A successful VF conversion test required two consecutive VF conversions at 65 J from four induction attempts within a given shock polarity.

Of the 320 patients who underwent acute VF conversion testing, 16 patients<sup>3</sup> yielded non-evaluable results due to incomplete protocol testing. Of the 304 evaluable results, the S-ICD System acute VF conversion success rate was 100% with a lower 95% confidence bound of 98.8% (Table 9). These results met the primary safety endpoint performance goal of 88% and demonstrate the effectiveness of the S-ICD System.

**Table 9: Effectiveness Endpoint Result - Acute VF Conversion Rate**  
Patients undergoing acute VF conversion testing (N=320)

Non-evaluable Results	Evaluable Results		Estimate (%)	95% Clopper-Pearson Interval (%)
	Successful	Failure		
16	304	0	100.0	(98.8-100.0)

Of the 16 non-evaluable patients, 11 were associated with at least one failed conversion attempt at 65 J and, due to physician discretion, did not exhaust all of the protocol defined induction attempts in both shock polarities. A sensitivity analysis was performed to impute these patients as failures despite incomplete testing, resulting in an imputed VF conversion success rate of 96.5%.

<sup>2</sup> One (1) patient did not undergo testing at the discretion of the investigator.

<sup>3</sup> Seven (7) patients with non-evaluable tests were not implanted and 9 patients were implanted.

## SQ-RX PULSE GENERATOR: GENERAL DESCRIPTION

### ***Spontaneous Episodes***

A total of 119 spontaneous VT/VF episodes in 21 patients were treated by the S-ICD System through February 14, 2012. A VT/VF episode refers to a device-declared episode in which device rate/discrimination criteria were met in response to a ventricular tachyarrhythmia and therapy was delivered. A single episode may contain up to 5 shocks. The episode ends when the rolling average of the rate falls below the lowest programmed rate zone for 24 consecutive intervals.

For analysis, episodes were sub-divided into two classes: 1) *discrete episodes* that were temporally independent (<3 within 24 hours); and, 2) *VT/VF storms* that comprise 3 or more treated VT/VF episodes within 24 hours in the same patient. Of the 38 discrete device episodes, 35 (92.1%) were converted with the first shock and 37 (97.4%) were converted by any shock (Table 10). One episode terminated spontaneously after an unsuccessful first shock (MVT). Four (4) VT/VF storms from 2 patients resulted in 81 total device episodes, 40 of which were VF and stored in S-ICD System memory with the remaining 41 episodes not stored due to memory capacity limitations. Three (3) storms were ultimately converted by the S-ICD System and 1 was ultimately converted with an external defibrillation shock (Table 11).

**Table 10: Conversion Effectiveness of Discrete Device Episodes (non-Storm)**  
Patients with discrete episodes (N=16); Discrete device episodes (N=28)

<b>Rhythm</b>	<b>Patients</b>	<b>Device Episodes</b>	<b>Episode Converted by 1<sup>st</sup> Shock (%)</b>	<b>Episode Converted by Any Shock (%)</b>
MVT	13	22	21 (95.5)	21 (95.5)
PVT/VF	11	16	14 (87.5)	16 (100.0)
<b>Total</b>	<b>21</b>	<b>38</b>	<b>35 (92.1)</b>	<b>37 (97.4)</b>

**Table 11: Conversion of VT/VF Storms**  
Patients with VT/VF Storms (N=2), Storm events (N=4), Stored Device episodes (N=40)

<b>Patients</b>	<b>VT/VF Storms</b>	<b>Device Episodes</b>	<b>Final Storm Conversion Method (%)</b>
2	4	40	<b>S-ICD: 3 (75)</b>
			External: 1 (25)
			Spontaneous Conversion: 0 (0)

### ***Chronic Conversion Substudy***

The chronic performance of the S-ICD System was assessed by the proportion of patients with successful conversion of induced VT/VF  $\geq 150$  days post-implant in all implanted patients who provided informed consent for this testing (N=78). Three (3) patients were excluded from the analysis because they met the pre-specified definition of a non-evaluable test (did not complete testing in the opposite polarity after a failed 65J shock, as required by the protocol). All three were converted with a subsequent 80J S-ICD System shock.

The rate of successful conversion by a sub-maximal (65J) S-ICD System shock was 72/75 (96.0%). All 3/75 (4.0%) patients who failed to convert with a sub-maximal (65J) S-ICD System shock in either polarity were successfully converted with a subsequent higher-energy S-ICD System shock.

### **Subgroup Analyses**

Stepwise logistic regression models (backward elimination with a threshold p-value of 0.20) were used to evaluate basic demographic characteristics (age, gender, African American race) and baseline device programming (dual zone programming at hospital discharge) for statistical associations between with following safety-related outcomes:

- All Inappropriate shocks (n=41)
- Inappropriate shocks for oversensing (n=25)
- Inappropriate shocks for SVT (n=16)
- Discomfort (n=22)
- System and Superficial/Incision Infection (n=18)
- Type I-III Complications (n=35)

#### ***Age***

Age was a significant predictor for inappropriate shocks. Patient who experience inappropriate shocks were younger with a mean age of 47 compared to a mean age of 53 for patients who did not received any inappropriate shocks.

#### ***Gender***

Female gender was significantly associated with a higher risk for device or procedure related discomfort. Although the numbers are very small, it is notable that the inframammary crease was cited in 2 cases of female discomfort and the interface between the device site and the patient's bra was cited in another case.

#### ***Race***

African American race was not associated with device or procedure related complications.

#### ***Dual Zone Programming at Discharge***

Dual zone programming at the time of hospital discharge was associated with significantly fewer inappropriate shocks than those programmed with a single zone. There was a 70% relative reduction of incidence for inappropriate shocks due to SVT with heart rates in the Shock only zone and a 56% relative reduction of incidence for inappropriate shocks due to oversensing, when compare to single zone programming.

### **Conclusion**

The purpose of the S-ICD System Clinical Investigation was to evaluate the safety, effectiveness and chronic performance of the S-ICD System. There were 330 patients enrolled in the study and 321 underwent an implant procedure. The 314 patients implanted with the S-ICD System generated 3,410 months of patient data.

The data demonstrate that the S-ICD System operates appropriately per design for the S-ICD System's intended uses and as described in the S-ICD System's labeling. All objectives of the S-ICD System Clinical Investigation were met demonstrating safety and effectiveness of the S-ICD System.

### Patient Screening

The patient screening tool (Figure 3) is a customized measurement tool made of transparent plastic printed with colored profiles. The profiles are designed to ensure appropriate device performance by identifying signal characteristics that may lead to unsatisfactory detection outcomes for a patient before implant. The patient screening process is completed in three steps: (1) Collecting the surface ECG, (2) Evaluating the surface ECG and (3) Determining an acceptable sense vector.

The patient screening tool can be obtained from any Cameron Health representative or by calling the Customer Service Department.

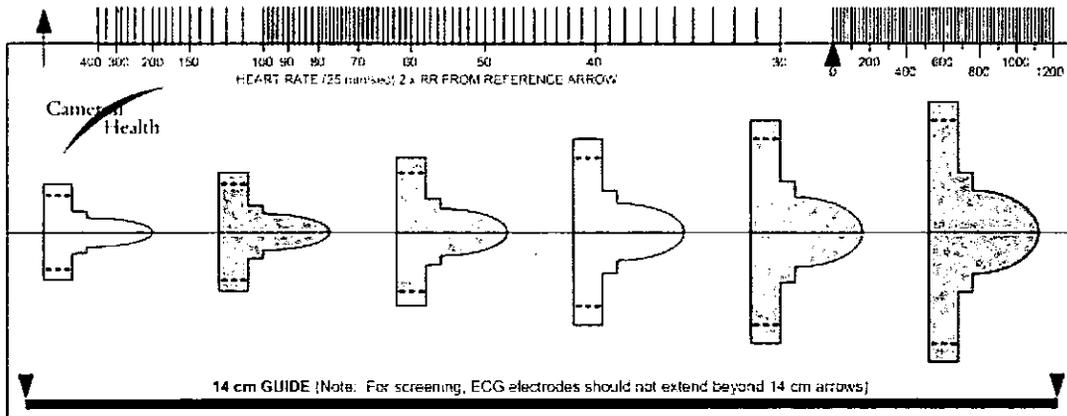


Figure 3: Patient Screening Tool

### Collecting the Surface ECG

1. In order to perform the patient screening process, a surface equivalent of the subcutaneous sensing vectors must be obtained. It is important to collect the surface ECG in the location that represents the intended position of the implanted S-ICD System. When placing the S-ICD System in the typical implant location, the surface ECG electrode should be positioned as described below (Figure 4). If a non-standard S-ICD System electrode or pulse generator placement is desired, the surface ECG electrode locations should be modified accordingly.
  - **ECG Electrode LL** should be placed in a lateral location, at the 5th intercostal space along the mid-axillary line to represent the intended location of the implanted pulse generator.
  - **ECG Electrode LA** should be placed 1 cm left lateral of the xiphoid midline to represent the intended location of the proximal sensing node of the implanted electrode.
  - **ECG Electrode RA** should be placed 14 cm superior to the ECG Electrode LA, to represent the intended position of the distal sensing tip of the implanted electrode. A 14 cm guide is located at the bottom of the transparent screening tool.



**Figure 4:** Typical placement of surface ECG electrodes for patient screening

2. Using a standard ECG machine, record 10 – 20 seconds of ECG using Leads I, II and III with a sweep speed of 25 mm/sec and ECG gain between 5 – 20 mm/mV (use the largest ECG gain that does not result in clipping).

**Note:** It is important to establish a stable baseline when collecting the surface ECG. If a wandering baseline is noted, ensure that the appropriate ground electrodes from the ECG machine are attached to the patient. To yield an acceptable signal for testing, the gain may be adjusted for each ECG lead independently.
3. Record ECG signals in at least two postures: (1) Supine and (2) Standing. Other postures may be collected including: Seated, Left Lateral, Right Lateral, and Prone.

**Note:** If the S-ICD System is to be implanted with a concomitant pacemaker, all ventricular morphologies (paced and intrinsic, if normal conduction is expected) should be collected

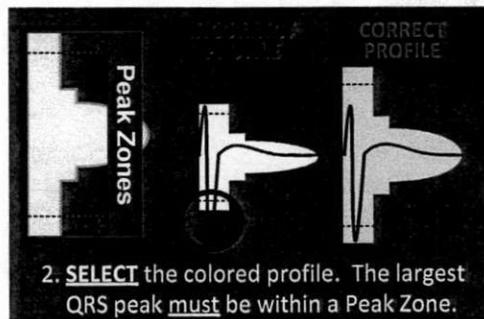
**Evaluating the Surface ECG**

Each surface ECG should be evaluated by analyzing at least 10 seconds of QRS complexes. If multiple morphologies are noted (e.g., bigeminy, pacing, etc.), all morphologies should be tested as described below before the vector is deemed acceptable.

Each QRS complex is evaluated as follows:

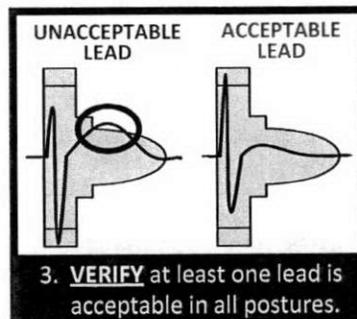
1. **Select** the colored profile from the Patient Screening Tool that best matches the amplitude of the QRS (Figure 5). For biphasic signals, the larger peak should be used to determine the appropriate colored profile. The QRS peak must fall within the window bounded by the dotted line and the peak of the colored profile.

**Note:** ECG gains > 20 mm/mV are not permitted. If, when printed at the maximum 20 mm/mV gain, the QRS peak does not reach the minimum boundary (dotted line) of the smallest colored profile, that QRS complex is deemed unacceptable.



**Figure 5:** Selecting the colored profile

2. **Align** the left edge of the selected colored profile with the onset of the QRS complex. The horizontal line on the colored profile should be used as a guide for isoelectric baseline alignment.
3. **Evaluate** the QRS complex. If the entire QRS complex and trailing T-wave are contained within the colored profile, the QRS is deemed acceptable. If any portion of the QRS complex or trailing T-wave extends outside of the colored profile, the QRS is deemed unacceptable (Figure 6).



**Figure 6:** Evaluating the QRS complex

4. **Repeat** the above steps with all QRS complexes collected with all surface ECG leads in all collected postures.

### ***Determining an Acceptable Sense Vector***

Each collected surface ECG lead represents a sense vector of the S-ICD System. Evaluate each surface ECG lead independently for acceptability. A surface ECG lead (sense vector) should be deemed acceptable only if all of the following conditions are met:

- All tested QRS complexes and morphologies from the surface ECG lead (sense vector) must pass the QRS evaluation.
- The morphology of the intrinsic/paced QRS complex is stable across postures. No significant change to the QRS complex is noted as a result of postural changes.
- The surface ECG lead (sense vector) must be deemed acceptable in all tested postures.

A patient is considered suitable for implant of the S-ICD System if at least one surface ECG lead (sense vector) is acceptable for all tested postures.

**Note:** *Special circumstances may present in which the physician elects to proceed with the implantation of the S-ICD System despite failing the screening process. In this case, careful attention should be applied to the device setup process of the S-ICD System as the risk of poor sensing and/or inappropriate shock is increased.*

### General

The S-ICD System is designed for ease of use and simplicity of patient management. The arrhythmia detection system employs up to two rate zones, and the device has a single automatic response to a detected ventricular tachyarrhythmia – a nonprogrammable, maximum-energy, biphasic shock of 80 J. The device has a number of automatic functions designed to reduce the amount of time required for implantation, initial programming and patient follow-up.

### Modes of Operation

The device has three modes of operation:

- Shelf
- Therapy On
- Therapy Off

#### *Shelf Mode*

The Shelf mode is a low power consumption state intended for storage only. When communication is initiated between the device and the programmer, a full-energy capacitor reformation is performed and the device is prepared for set-up. Once the device is taken out of Shelf mode, it cannot be reprogrammed back into Shelf mode.

#### *Therapy On Mode*

The Therapy On mode is the primary operating mode of the device, allowing automatic detection of and response to ventricular tachyarrhythmias. All device features are active.

**Note:** *The device must be programmed out of Shelf mode before being programmed to Therapy On.*

#### *Therapy Off Mode*

The Therapy Off mode disables automatic therapy delivery and enables manual control of shock delivery. Programmable parameters may be viewed and adjusted via the programmer. Also, the subcutaneous electrogram (S-ECG) may be displayed or printed.

The device automatically defaults to Therapy Off when taken out of Shelf mode.

**Note:** *Manual and rescue shock therapy are available only after the initial Setup process is complete. Refer to the Q-TECH Programmer User's Manual for details.*

### Sensing Configuration and Gain Selection

During the Automatic Setup process, the device automatically selects an optimal sensing vector based on an analysis of cardiac signal amplitude and signal-to-noise ratio. This analysis is performed on the three available vectors:

- **Primary:** Sensing from the proximal electrode ring on the electrode to the active surface of the device.
- **Secondary:** Sensing from the distal sensing electrode ring on the electrode to the active surface of the device.
- **Alternate:** Sensing from the distal sensing electrode ring to the proximal sensing electrode ring on the electrode.

The sensing vector can also be selected manually. The Q-TECH Programmer User's Manual provides instructions for sensing vector selection.

The device automatically selects an appropriate gain setting during the Automatic Setup process. The gain can also be manually selected, as further explained in the Q-TECH Programmer User's Manual. There are two gain settings:

- **1x Gain ( $\pm 4$  mV):** Selected when the signal amplitude is clipped at the 2x gain setting.
- **2x Gain ( $\pm 2$  mV):** Selected when the signal amplitude is not clipped at this setting.

### Sensing and Tachyarrhythmia Detection

The device is designed to prevent inappropriate therapy delivery as a result of noise sensing or multiple counting of individual cardiac cycles. This is accomplished by an automatic analysis of sensed signals, which includes event detection, certification and decision phases.

#### *Detection Phase*

During the Detection Phase, the device uses a detection threshold to identify sensed events. The detection threshold is automatically adjusted continuously using amplitudes of recently detected electrical events. In addition, detection parameters are modified to increase sensitivity when rapid rates are detected. Events detected during the Detection Phase are passed on to the Certification Phase.

#### *Certification Phase*

The Certification Phase examines the detections and classifies them as certified cardiac events or as suspect events. Certified events are used to ensure that an accurate heart rate is passed to the Decision Phase. A suspect event can be one whose pattern and/or timing indicates the signal is caused by noise, such as a muscle artifact or some other extraneous signal. Events are also marked as suspect if they appear to derive from double or triple detections of single cardiac events. The device is designed to identify and correct multiple detections of wide QRS complexes and/or erroneous detections of a T-wave.

#### *Decision Phase*

The Decision Phase examines all certified events and continuously calculates a running four R-to-R interval average (4 RR average). The 4 RR average is used throughout the analysis as an indicator of the heart rate.

**Therapy Zones**

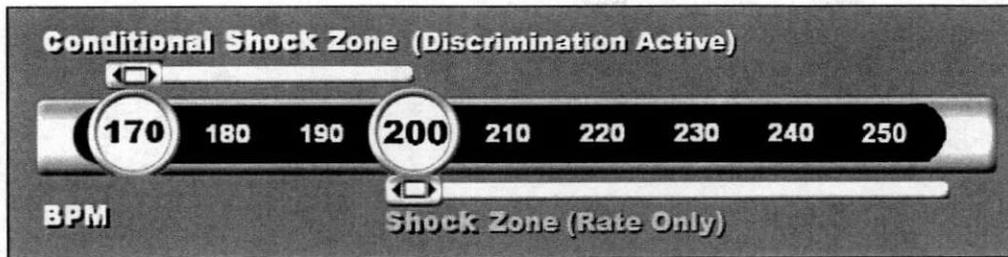
The device allows the selection of rate thresholds that define a Shock Zone and an optional Conditional Shock Zone. In the Shock Zone, rate is the only criterion used to determine if a rhythm will be treated with a shock. The Conditional Shock Zone has additional discriminators used to determine if a shock is warranted to treat an arrhythmia.

The Shock Zone is programmable from 170 – 250 bpm in increments of 10 bpm. The Conditional Shock Zone must be lower than the Shock Zone, with a range of 170 – 240 bpm in increments of 10 bpm.

**Note:** To ensure proper detection of VF, program the Shock Zone or Conditional Shock Zone to 200 bpm or less.

**Note:** The IDE Study demonstrated a significant reduction in inappropriate therapy with the activation of the Conditional Shock Zone prior to hospital discharge (see S-ICD System Clinical Investigation, page 9).

Graphically, the use of a Shock Zone and Conditional Shock Zone is shown below (Figure 7):



**Figure 7:** Shock Zone Rate Detection Diagram

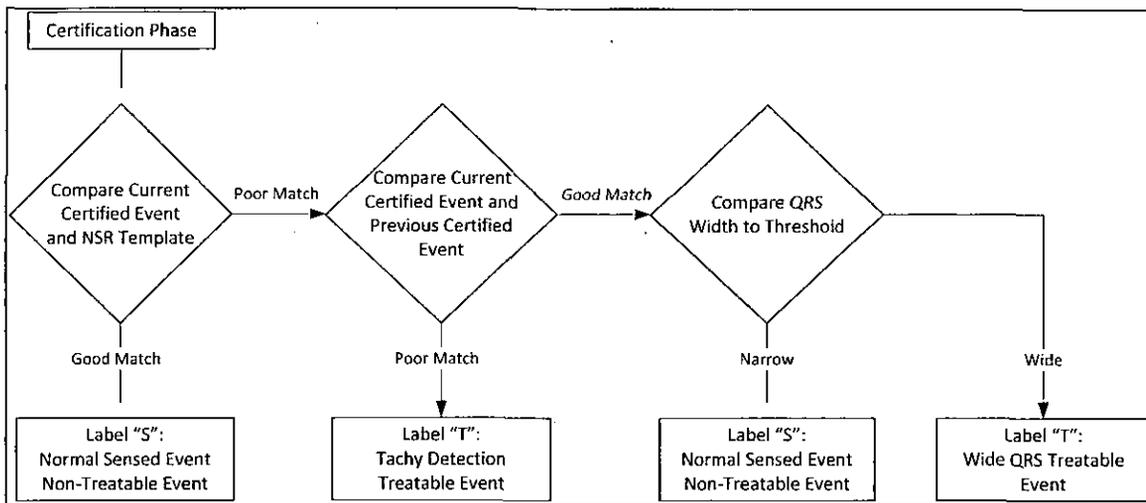
The device declares a Tachycardia when the 4RR average enters either therapy zone.

Once a Tachycardia is declared, the 4RR average must become longer (in ms) than the lowest rate zone, plus 40 ms for 24 cycles for the device to consider the episode to have ended. In the Shock Zone, treatable arrhythmias are determined by rate alone.

**Analysis in the Conditional Shock Zone**

In contrast, rate and morphology are analyzed in the Conditional Shock Zone. The Conditional Shock Zone is designed to discriminate between treatable and other high-rate events such as atrial fibrillation, sinus tachycardia and other supraventricular tachycardias.

A normal sinus rhythm template (NSR Template) is formed during device initialization. This NSR template is used during analysis in the Conditional Shock Zone to identify treatable arrhythmias. In addition to morphology comparison with the NSR template, other morphologic analysis is used to identify polymorphic rhythms. Morphology and QRS width are used to identify monomorphic arrhythmias such as ventricular tachycardia. If the Conditional Shock Zone is enabled, then an arrhythmia is found to be treatable according to the decision tree shown below (Figure 8):



**Figure 8:** Decision tree for determining treatable arrhythmias in the Conditional Shock Zone

For some patients, a NSR Template may not be formed during device initialization as a result of variability in their cardiac signal at resting heart rates. For such patients, the device uses beat-to-beat morphology and QRS width analysis for arrhythmia discrimination.

**Charge Confirmation**

The device must charge the internal capacitors before shock delivery. Confirmation of the ongoing presence of a tachyarrhythmia requires monitoring a moving window of the 24 most recent intervals defined by certified events. Charge confirmation employs an X (treatable interval) out of Y (total intervals in the window) strategy to accomplish this. If 18 of the 24 most recent intervals are found to be treatable, the device begins to analyze rhythm persistence. Persistence analysis requires the X out of Y condition be maintained or exceeded for at least two consecutive intervals; however, this value may be increased as a result of Smart Charge, as explained below.

Capacitor charging is initiated when the following three conditions are met:

1. X of Y criterion is satisfied.
2. Persistence requirement is satisfied.
3. The last two certified intervals are in the treatable zone.

### Therapy Delivery

Rhythm analysis continues throughout the capacitor charging process. Therapy delivery is aborted if the 4 RR average interval becomes longer (in ms) than the lowest rate zone plus 40 ms for 24 intervals. When this occurs, an untreated episode is declared and a Smart Charge extension is incremented, as explained below.

Capacitor charging continues until the capacitor has reached its target voltage, at which time reconfirmation is performed. Reconfirmation is used to ensure that the treatable rhythm did not spontaneously terminate during the charging cycle. Reconfirmation requires the last three consecutive detected intervals (regardless of whether the intervals are certified or suspect) to be faster than the lowest therapy zone. If non-treatable events are detected during or after the charging sequence, reconfirmation is automatically extended, one interval at a time, up to a maximum of 24 intervals.

Reconfirmation is always performed and shock delivery is non-committed until reconfirmation is complete. Once the criteria for reconfirmation is met, the shock is delivered.

### Smart Charge

Smart Charge is a feature that automatically increases the Persistence requirement by three intervals each time an untreated episode is declared, up to a maximum of five extensions. Thus, after an untreated episode, the requirement to start capacitor charging becomes more stringent. The Smart Charge extension value can be reset to its nominal value (zero extensions) using the programmer. The Smart Charge feature cannot be disabled, though it is not used for the second and later shocks that occur during any given episode.

### Redetection

A blanking period is enabled following delivery of a high-voltage shock. After delivery of the first shock, up to four additional shocks will be delivered if the episode does not terminate. Rhythm analysis for delivering shocks 2 – 5 generally follows the detection steps described above, with the following exceptions:

1. Following the first shock delivery, the X/Y criterion is modified to require 14 treatable intervals in the last 24 (14/24), rather than 18.
2. The Persistence Factor is always set to two intervals (i.e., not modified by the Smart Charge feature).

### Shock Waveform and Polarity

The shock waveform is biphasic, with a fixed tilt of 50%. The shock is delivered synchronously unless a 1000 ms time out expires without an event being detected for synchronization, at which time the shock is delivered in an asynchronous manner.

The device is designed to automatically select the appropriate polarity for therapy. Both standard and reversed polarity shocks are available. If a shock fails to convert the arrhythmia and subsequent shocks are required, polarity is automatically reversed for each successive shock. The polarity of the successful shock is then retained as the starting polarity for future episodes. Polarity can also be selected during the Induction and Manual Shock process to facilitate device-based testing.

### **Post-Shock Bradycardia Pacing Therapy**

The device provides optional post-shock, on-demand bradycardia pacing therapy. When enabled via the programmer, bradycardia pacing occurs at a non-programmable rate of 50 bpm for up to 30 seconds. The pacing output is fixed at 200 mA, and uses a 15 ms biphasic waveform.

Pacing is inhibited if the intrinsic rate is greater than 50 bpm. In addition, post-shock pacing is terminated if a tachyarrhythmia is detected or a magnet is placed over the device during the post-shock pacing period.

### **Manual and Rescue Shock Delivery**

Upon programmer command, the device can deliver manual and rescue shocks. Manual shocks are programmable from 10 to 80 J delivered energy in 5 J steps. Rescue shocks are non-programmable, delivering the maximum output of 80 J.

**Note:** *The Rescue Shock will not be inhibited with magnet application. Refer to the S-ICD System Magnet Model 4520 section for complete information.*

### **Additional Features of the S-ICD System**

This section presents descriptions of several additional features available in the S-ICD System.

#### ***Auto Capacitor Reformation***

The device automatically performs a full-energy (80 J) capacitor reformation when taken out of Shelf mode and every four months until the device reaches End of Life (EOL). The energy output and reformation time interval are non-programmable. The Auto Capacitor Reformation interval is reset after any 80 J capacitor charge is delivered or aborted.

#### ***Internal Warning System – Beeper Control***

The device has an internal warning system (beeper) that emits an audible tone to alert the patient to certain device conditions that require prompt consultation with the physician. These conditions include:

- Elective Replacement (ERI) and End of Life (EOL) indicators
- Electrode impedance out of range
- Prolonged charge times
- Failed Device Integrity Check
- Irregular battery depletion

This internal warning system is automatically activated at time of implant. Once triggered, the beeper sounds for 16 seconds every nine hours until the trigger condition has been resolved. If the triggering condition reoccurs, then the tones will once again alert the patient to consult the physician. The beeper can be disabled via the programmer once ERI is reached.

**Note:** *The beeper may be activated by applying a magnet over the device to elicit the beeping tones. Patients should be educated to contact their physician immediately whenever the beeper is heard.*

#### ***Arrhythmia Induction***

The device facilitates testing by providing the capability to induce a ventricular tachyarrhythmia. Via the programmer, the implanted system can deliver a 200 mA output at a frequency of 50 Hz. The maximum length of stimulation is 10 seconds.

**Note:** *Induction requires that the device be programmed to Therapy On.*

### **System Diagnostics**

The S-ICD System automatically performs a diagnostic check at scheduled intervals.

#### ***Electrode Impedance***

Electrode impedance is measured each time a shock is delivered. In addition, a lead electrode integrity test is performed once a week. The shock impedance values are stored and displayed in the episode data and summary report.

**Note:** *If the device is taken out of Shelf mode, but not implanted, the internal warning system will be activated due to the weekly automatic measurements of impedance. Device beeping due to this mechanism is normal behavior.*

#### ***Device Integrity Check***

The Device Integrity Check is automatically performed daily by the implanted system, and also each time the programmer links to an implanted device. This test scans for any unusual conditions in the device and, if any are detected, the system provides a notification either via the device's internal warning system or on the programmer screen.

#### ***Battery Performance Monitoring System***

The device automatically monitors battery status to provide notice of impending battery depletion. Two indicators are provided via messages on the programmer, each activated by declining battery voltage. ERI and EOL are also signaled by activation of the device's beeper.

- **Elective Replacement Indicator (ERI):** When the ERI is detected, the device will provide therapy for at least three months, if no more than six maximum energy charges/shocks occur. The patient should be scheduled for replacement of the device.
- **End of Life (EOL):** When the EOL indicator is detected, the device should be replaced immediately. Therapy may not be available when EOL is declared.

**Storing and Analyzing Data**

The device stores S-ECGs for up to 24 treated and 20 untreated tachyarrhythmia episodes. The number of treated episodes, untreated episodes, and the therapy shocks delivered since the last follow-up procedure and initial implant are recorded and stored. Through wireless communication with the programmer, the stored data is retrieved for analysis and report printouts.

**Note:** Episodes that occur during communication with the programmer will not be stored.

**Note:** SVT episodes with heart rates lower than and within the Conditional Shock zone are not stored.

**Treated Episodes**

Up to 128 seconds of S-ECG data is stored for each treated episode:

- **First Shock:** 44 seconds prior to capacitor charging, up to 24 seconds prior to shock delivery and up to 12 seconds of post-shock S-ECG.
- **Subsequent Shocks:** A minimum of 6 seconds of pre-shock and up to 6 seconds post-shock S-ECG.

**Untreated Episodes**

For untreated episodes, 44 seconds of pre-episode and up to 24 seconds of episode S-ECG are stored. A return to normal sinus rhythm during an untreated episode halts S-ECG storage.

**Captured S-ECG**

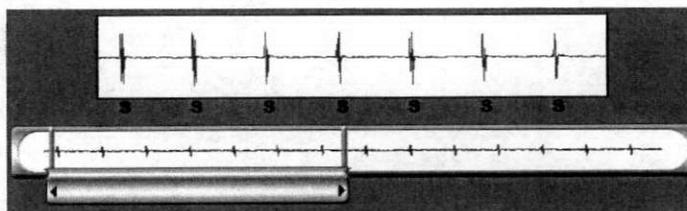
The S-ECG can be captured in real time on rhythm strips when the device is actively linked via wireless telemetry to the programmer. Up to five 12-second recordings of S-ECG can be stored.

**S-ECG Rhythm Strip Markers**

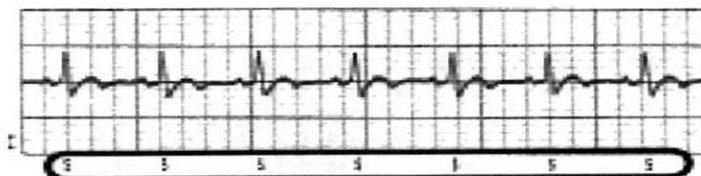
The system provides S-ECG annotations (Table 12) to identify specific events during a recorded episode. Sample annotations are shown for the programmer display (Figure 9) and the printed report (Figure 10).

**Table 12:** S-ECG Rhythm Strip Markers

Description	Marker	Display Screen	Printed Reports
Charging	C	X	✓
Sensed Beat	S	✓	✓
Noisy Beat	N	✓	✓
Paced Beat	P	✓	✓
Tachy Detection	T	✓	✓
Discard Beat	•	✓	✓
Shock		✓	✓
Return to NSR		X	✓



**Figure 9:** Programmer Display Markers



**Figure 10:** Printed Report Markers

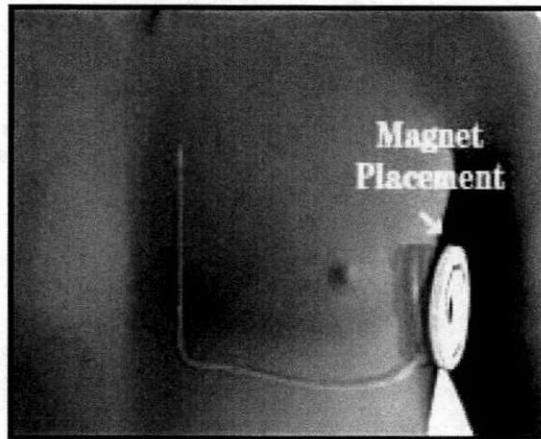
### **Patient Data**

The device can store the following patient data, which can be retrieved and updated through the programmer:

- Patient's name
- Physician's name and contact information
- Device and electrode identification information (model and serial numbers) and implant date
- Patient Notes (displayed upon connection to the device)

### **S-ICD System Magnet Model 4520**

The Cameron Health Magnet (the "magnet") is a nonsterile accessory used to inhibit the delivery of therapy from the device. Apply the magnet flat against the skin directly over the implanted SQ-RX device for a minimum of one (1) second (Figure 11) to suspend arrhythmia detection. Removal of the magnet will return the device to normal operation. If the magnet is applied during an episode, the episode will not be stored in the device memory.



**Figure 11:** Magnet Model 4520

Other behaviors of magnet application:

- Inhibit shock therapy delivery
- Terminate post-shock pacing therapy
- Prohibit arrhythmia induction testing
- Activate the device's beeper with each detected QRS complex for 60 seconds

**Note:** *A programmer commanded Rescue Shock can override the use of the magnet as long as the magnet was in place prior to the initiation of the programming command. If the magnet is applied after the initial command, the Rescue Shock will be terminated.*

**Note:** *Magnet application does not affect wireless communication between the device and the programmer.*

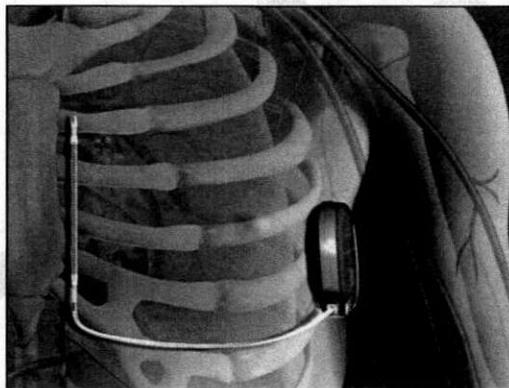
### **Implanting the S-ICD System**

This section presents the information necessary for implanting and testing the S-ICD System, including:

- Implanting the SQ-RX Pulse Generator (the "device")
- Implanting the Q-TRAK Subcutaneous Electrode (the "electrode") using the Q-GUIDE Subcutaneous Electrode Insertion Tool (the "EIT")
- Setting up and testing the device using the Q-TECH Programmer (the "programmer"). Refer to the Q-TECH Programmer User's Manual for additional information.

The S-ICD System is designed to be positioned using anatomical landmarks. However, it is recommended to review a pre-implant chest x-ray in order to confirm that a patient does not have notably atypical anatomy (e.g. dextrocardia). Additionally, it is not recommended to deviate from the implant instructions to accommodate for physical body size or habitus, unless a pre-implant chest x-ray has been reviewed.

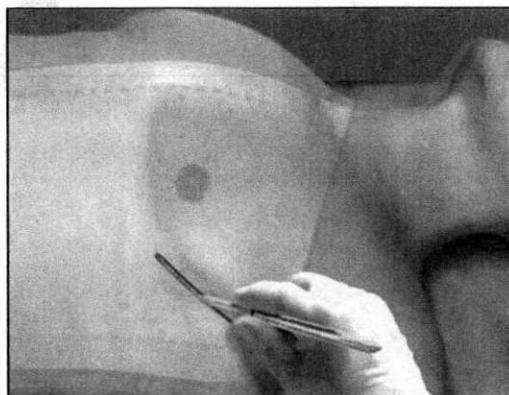
The device and electrode are typically implanted subcutaneously in the left thoracic region (Figure 12). The EIT is used to create the subcutaneous tunnels in which the electrode is inserted.



**Figure 12:** *Placement of the S-ICD System*

### **Creating the Device Pocket**

The device is implanted in the left lateral thoracic region. To create the device pocket, make an incision such that the device can be placed in the vicinity of the left 5<sup>th</sup> and 6<sup>th</sup> intercostal spaces and near the mid-axillary line (Figure 13). This can be accomplished by making an incision along the inframammary crease.

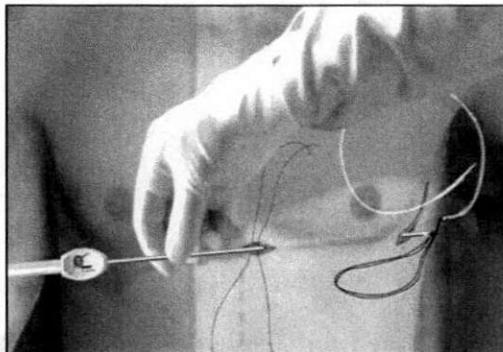


**Figure 13:** *Creating the device pocket*

***Implanting the Q-TRAK Subcutaneous Electrode***

The procedure described below is one of several surgical approaches that can be used to appropriately implant and position the electrode. Regardless of the surgical approach, the defibrillation coil must be positioned parallel to the sternum, approximately 2 cm from the sternal midline (Figure 12).

1. Make a small, 2 cm horizontal incision at the xiphoid process (xiphoid incision)  
**Note:** *If desired, in order to facilitate attachment of the suture sleeve to the fascia following electrode placement, two suture ties to the fascia can be made at the xiphoid incision prior to continuing.*
2. Insert the distal tip of the EIT at the xiphoid incision and tunnel laterally until the distal tip emerges at the device pocket.  
**Note:** *The EIT is malleable and can be curved to match the patient's anatomical profile.*
3. Using conventional suture material, tie the anchoring hole of the electrode to the EIT creating a long 15-16 cm loop (Figure 14).

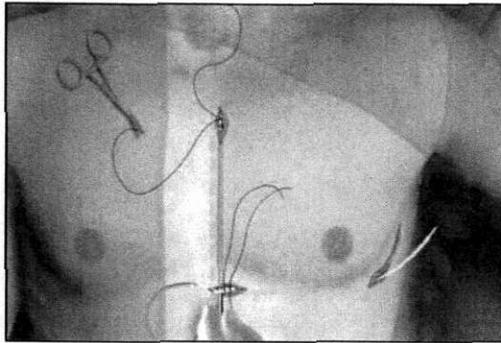


**Figure 14:** *Connecting distal end of electrode to the EIT*

4. With the electrode attached, carefully pull the EIT back through the tunnel to the xiphoid incision until the proximal sensing electrode emerges.
5. Place a suture sleeve over the electrode shaft 1 cm below the proximal sensing electrode. Using the preformed grooves, bind the suture sleeve to the electrode shaft using 2-0 silk or similar non-absorbable suture material, making sure not to cover the proximal sensing electrode. Check the suture sleeve after anchoring to assure stability by grasping the suture sleeve with fingers and try to move the electrode in either direction.  
**Note:** *Do not secure the suture sleeve and electrode to the fascia until electrode placement is complete.*
6. Make a second incision approximately 14 cm superior to the xiphoid incision (superior incision). If desired, place the exposed electrode on the skin to make this measurement. The distance between the superior and xiphoid incisions must accommodate the portion of the electrode from the distal sensing electrode to the proximal sensing electrode.

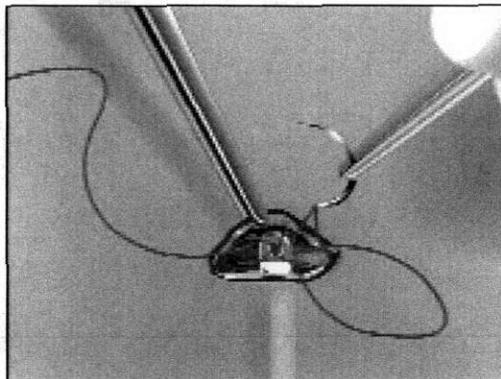
## SQ-RX PULSE GENERATOR: USING THE SQ-RX PULSE GENERATOR

7. Insert the distal tip of the EIT into the xiphoid incision and tunnel subcutaneously towards the superior incision (Figure 15).



**Figure 15:** Tunneling to superior incision

8. Once the distal tip of the EIT emerges from the superior incision, disconnect and retain the suture loop from the distal tip of the EIT. Secure the ends of the suture with a surgical clamp. Remove the EIT.
9. Using the secured suture at the superior incision, carefully pull the suture and electrode through the tunnel until the electrode's anchoring hole emerges. The electrode should be parallel to the sternal midline.
10. Cut and discard the suture material.
11. At the xiphoid incision, secure the suture sleeve with the electrode to the fascia using 2-0 silk or similar non-absorbable suture material.  
**Note:** Ensure that the suture is securely fastened to fascia by gently tugging on the suture prior to tying to the suture sleeve and electrode.
12. At the superior incision, secure the anchoring hole to the fascia using 2-0 silk or similar non-absorbable suture material (Figure 16).



**Figure 16:** Anchoring the distal electrode tip

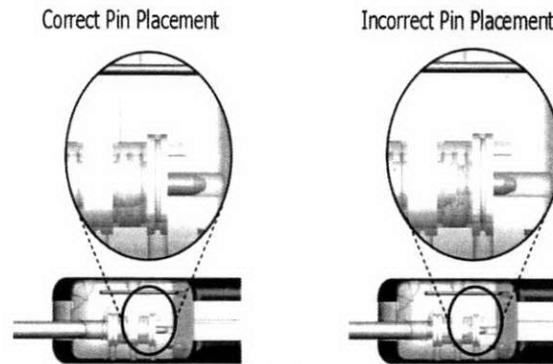
- Note:** Ensure that the suture is securely fastened to fascia by gently tugging on the suture prior to tying to the electrode anchoring hole.
13. Gently tug the electrode at the superior incision to ensure the anchoring hole is secured to the fascia.
14. To dispose of the EIT, return the used product to the original package, then dispose in a biohazard container.

### Connecting the Electrode to the Device

**Note:** Avoid allowing blood or other body fluids to enter the connector port in the device header. If blood or other body fluids inadvertently enter the connector port, flush with sterile water.

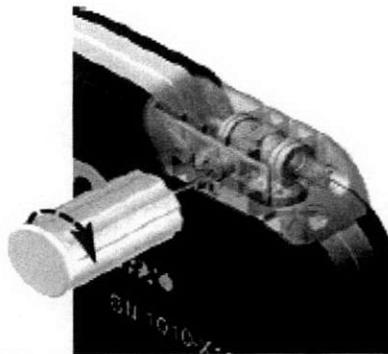
**Note:** Do not implant the device if the set screw seal plug appears to be damaged.

1. Grip the electrode close to the electrode connector pin and insert it straight into the connector port. Minimize bending or buckling of the electrode during insertion.
2. Ensure that the electrode pin is well past the innermost connector ring in the header (Figure 17). When viewed from the top of the header, the distal pin should extend past the connector ring, at least half way to the end of the electrode cavity.



**Figure 17:** Position of the electrode pin

3. Use the torque wrench to tighten the set screw in a clockwise motion (Figure 18). The torque wrench is designed to apply the proper amount of force to the set screw. Tighten the set screw until the wrench ratchet clicks.



**Figure 18:** Using torque wrench to tighten set screw

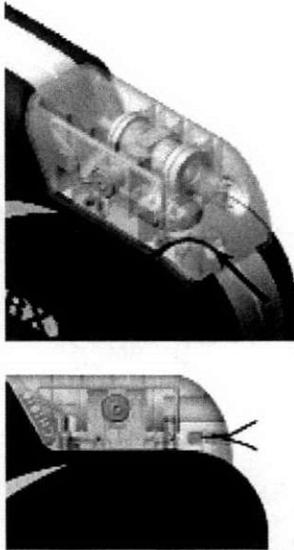
**Note:** When connecting the electrode to the device, use only the tools provided in the device tray. Failure to use the supplied tools may result in damage to the set screw. Retain the tools until all testing procedures are complete and the device is implanted.

4. Gently tug on the electrode body to confirm a secure connection.
5. Insert the device into the subcutaneous pocket, with any excess electrode placed underneath the device.

## SQ-RX PULSE GENERATOR: USING THE SQ-RX PULSE GENERATOR

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- Anchor the device to the fascia to prevent possible migration using conventional 0-silk or similar non-absorbable suture material. A suture hole is provided in the header for this purpose (Figure 19).

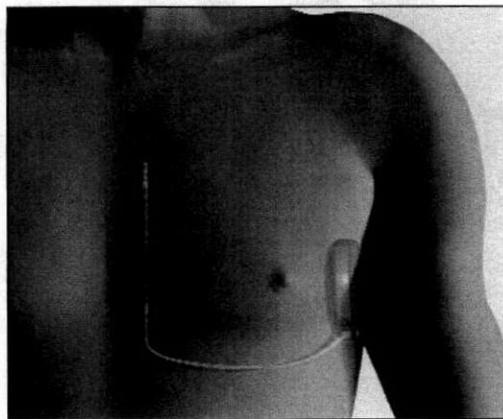


**Figure 19:** *Anchoring the device using header suture hole*

- Refer to the Q-TECH Programmer User's Manual for instructions for set-up and/or induction testing.

**Note:** *Initial set-up is recommended at implant.*

- After device set-up, close all incisions using standard suture protocol (Figure 20).



**Figure 20:** *System placement after closure of all incisions*

### Setting Up the SQ-RX Pulse Generator

A brief set-up process must be completed before the device can deliver manual or automatic therapy. This process can be performed *automatically or manually* during the implant procedure, although Automatic Set-up is recommended. During set-up, the system automatically:

- Confirms entry of the subcutaneous electrode model and serial numbers
- Measures the shock electrode impedance
- Optimizes the sense electrode configuration
- Optimizes the gain selection
- Acquires a reference NSR template

Instructions for completing this process can be found in the Q-TECH Programmer User's Manual.

### Defibrillation Testing

Once the device is implanted and Automatic Therapy is programmed On, defibrillation testing may be conducted. A 15J safety margin is recommended for defibrillation testing.

**Note:** *Defibrillation testing is recommended at implant to confirm the ability of the S-ICD System to sense and convert VF.*

If appropriate sensing or VF conversion cannot be demonstrated, consider relocating the electrode or device and retest. VF conversion testing can be conducted in either polarity. Refer to the Q-TECH Programmer User's Manual for instructions for set-up and induction testing.

### Post Implant Follow-Up Procedures

During a follow-up procedure, it is recommended that the location of the electrode be periodically verified by palpation and/or X-ray. When device communication with the programmer is established, the programmer automatically notifies the physician of any unusual conditions. Refer to the Q-TECH Programmer User's Manual for more information.

Patient management and follow-up are at the discretion of the patient's physician, but are recommended at least every 3 months to monitor the condition of the patient and evaluate device function.

### Explanting the S-ICD System

If a device explant is required, observe the following guidelines:

1. Use the programmer to ensure the device is programmed to Therapy Off.
2. Use a sterile no. 2 bi-direction torque wrench to disconnect the electrode from the device. If a directional torque wrench is not available or cannot loosen the screw, use a sterile no. 2 fixed wrench to loosen the set screw. Do not back the set screw out against the backstop. Once the set screw is freely turning the electrode can be removed.
3. Return the explanted device to Cameron Health, Inc. along with a completed Explant/Complication Reporting Form. Contact your local Cameron Health representative or Customer Service Department for instructions and return packaging.

**Federal Communications Commission (FCC) Compliance**

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150 – 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

FCC ID SDYCHI1010

**1999/5/EC Compliance (R&TTE Directive)**

The S-ICD System contains radio equipment in the frequency range 402 MHz to 405 MHz for ultra low power active medical implants. The radio equipment in the S-ICD System complies with the applicable harmonized standards and essential requirements of the R&TTE Directive.

## SQ-RX PULSE GENERATOR: ADDITIONAL INFORMATION

### Device Longevity

At the time of manufacture, the device has the capacity for over 100 full energy shocks. The average projected longevity, which accounts for the energy used during manufacture and storage, assumes the following conditions:

- 2 maximum energy shocks at implant and 6 maximum energy shocks in the final 3-month period between ERI and EOL
- Device implantation in the last month of the labeled shelf life

**Table 13: Device Longevity**

Annual Full Energy Charges	Average Projected Longevity
3 (Normal Use <sup>1</sup> )	5.4 yrs
4	5.2 yrs
5	4.9 yrs

<sup>1</sup> The median number of annual full energy charges in the IDE Study was 3.3

Full energy charges result from capacitor reformations, non-sustained episodes and delivered shocks. Increased numbers of full energy charges shorten battery longevity. Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning.

### Specifications

Specifications provided at 37° C ± 3° C, and assume a 75 Ohm (± 1%) load unless noted otherwise.

**Table 14: Physical Characteristics**

Component	Specification
<b>Dimensions: Height x Width x Depth</b>	78.2 mm x 65.5 mm x 15.7 mm
<b>Mass</b>	145 gm
<b>Volume</b>	69.9 cc
<b>ERI to EOL</b>	3 months therapy if no more than 6 maximum-energy charges/shocks occur
<b>Radiopaque ID in Device Header</b>	CH1010
<b>Storage and Shipping Temperature Range</b>	-18°C to +55°C (0°F to +131°F)
<b>Defibrillation/Pace/ Sense Ports</b>	Cameron Health Proprietary Tripolar Connector
<b>Pulse Generator Casing Material</b>	Hermetically Sealed Titanium, Coated With Titanium Nitride
<b>Connector Block Header</b>	Implantation Grade Polymer
<b>Battery</b>	Lithium Manganese Dioxide

**SQ-RX PULSE GENERATOR: ADDITIONAL INFORMATION**

**Table 15: Programmable Parameters**

<b>Parameter</b>	<b>Programmable Values</b>	<b>Nominal (as shipped)</b>
<b>Shock Zone</b>	170 bpm – 250 bpm (steps of 10 bpm)	200 bpm
<b>Conditional Shock Zone</b>	Off, 170 bpm – 240 bpm (If On, at least 10 bpm less than Shock Zone)	Off
<b>S-ICD System Therapy</b>	Off, Manual, Auto Therapy	Off
<b>Post-shock Pacing</b>	On, Off	Off
<b>Sensing Configuration</b>	Primary: Proximal electrode ring to device Secondary: Distal electrode ring to device Alternate: Distal electrode ring to proximal electrode ring	Primary
<b>Max Sensing Range</b>	x1 ( $\pm 4$ mV) x2 ( $\pm 2$ mV)	.x1
<b>Manual Shock</b>	10 – 80 J (in steps of 5 J)	80 J
<b>Smart Charge</b>	Resets to nominal	0 extensions
<b>Polarity</b>	Standard: Phase 1 Coil (+) Reverse: Phase 1 Coil (-)	Standard

**Table 16: Non-Programmable Parameters (Shock Therapy)**

<b>Parameter</b>	<b>Value</b>
<b>SHOCK THERAPY</b>	
<b>Delivered Energy</b>	80 J
<b>Shock Tilt (%)</b>	50%
<b>Waveform Type</b>	Biphasic
<b>Maximum Number of Shocks per episode</b>	5 shocks
<b>Charge Time to 80 J (BOL/ERI)*</b>	$\leq 10$ sec / $\leq 15$ sec **
<b>Sync Time Out</b>	1 sec
<b>Shock Sync Delay</b>	60 ms
<b>Post-Shock Blanking Period</b>	1600 ms

\* Charge time is one portion of the overall time-to-therapy

\*\* Under typical conditions

## SQ-RX PULSE GENERATOR: ADDITIONAL INFORMATION

**Table 17: Non-Programmable Parameters (Post-Shock Pacing)**

Parameter	Value
<b>POST-SHOCK PACING</b>	
Rate	50 ppm
Pacing Output	200 mA
Pulse Width (each phase)	7.6 ms
Waveform	Biphasic
Polarity (first phase)	Standard: Phase 1 Coil (+)
Mode	Inhibited Pacing
Duration	30 sec
Post-Pace Blanking Period/Refractory Period	750 ms (first pace pulse) 550 ms (subsequent pace pulses)
Runaway Protection	120 ppm

**Table 18: Non-Programmable Parameters (Detection/Rhythm Discrimination, Fibrillation Induction, Shock Electrode, Capacitor Reform Schedule)**

Parameter	Value
<b>DETECTION/RHYTHM DISCRIMINATION</b>	
X/Y for Initial Detection	18/24 intervals
X/Y for Redetection	14/24 intervals
Confirmation Before Shock	3 – 24 consecutive tachy intervals
Refractory Period	Fast 160 ms, Slow 200 ms
<b>FIBRILLATION INDUCTION</b>	
Frequency	50 Hz
Output	200 mA
Time out After Activation	10 sec
<b>CAPACITOR REFORM SCHEDULE</b>	
Automatic Capacitor Reformation Interval	Approximately 4 months*
<b>INTERNAL WARNING SYSTEM</b>	
High Impedance	> 400 Ohms
Maximum Charge Time out	44 sec

\* Reform can be delayed if capacitor was charged due to sustained/non-sustained arrhythmia in past 4 months

**SQ-RX PULSE GENERATOR: ADDITIONAL INFORMATION**

**Table 19: Episode Data Parameters**

Parameter	Value
Treated Episodes	24 stored
Untreated Episodes	20 stored
Maximum Length per S-ECG Episode	128 sec
Captured S-ECG Report	Up to 5 (12 sec each)

**Table 20: Magnet Response**

System Mode	Magnet Response
Shelf Mode	No Response
Therapy On	Arrhythmia detection and response are suspended. Beeper sounds for 60 seconds to indicate sensing is occurring.*
Therapy Off	Beeper sounds for 60 seconds to indicate sensing is occurring.*

\* Beeper Sounds – Beeper will sound for 60 seconds to indicate sensing is occurring or until the magnet is removed, whichever occurs first.

**Table 21: Stored Patient Information**

Patient Information (Stored Data)
Patient Name
Physician Name
Physician Contact Information
Device Model Number
Device Serial Number
Electrode Model Number
Electrode Serial Number
Patient Notes

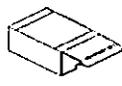
**Table 22: Model 4520 S-ICD System Magnet Specifications**

Component	Specification
Shape	Circular
Size	Approximate Diameter: 2.7 in (7.0 cm) Thickness: 0.5 in (1.3 cm)
Content	Ferrous alloys coated with epoxy
Field Strength	90 gauss minimum when measured at a distance of 1.5 in (3.8 cm) from magnet surface

**SQ-RX PULSE GENERATOR: ADDITIONAL INFORMATION**

**Definitions of Package Label Symbols**

**Table 23: Packaging Symbols: SQ-RX Pulse Generator**

Symbol	Specification	Symbol	Specification
	<b>Sterilized by Ethylene Oxide Gas</b> – Product is sterilized using ethylene oxide gas		<b>Date of Manufacture</b> – Date device was manufactured
	<b>Limitation European Community Represented</b> – Authorized representative in the EU community		<b>Use By</b> – Use by the indicated date
	<b>Part Number</b> – Component number		<b>Storage Temperature</b> – Product stored with temperature limitations
	<b>Product Packaging</b> – Used to enclose and protect product for distribution		<b>Hazardous Voltage</b> – Caution – dangerous voltage
	<b>Literature</b> – Written material included in packaging		<b>Radio</b> – Radio frequency
	<b>Serial Number</b> – Serial number of the device		<b>Instruction</b> – Consult instructions before use
	<b>Conformité Européenne</b> – Product fully complies with European Directive AIMD 90/385/EEC		<b>Open Here</b> – Symbol showing how to open the package
	<b>Non-Reusable</b> – Single use only		<b>Fragile: Handle with Care</b> – Transport and store with care
	<b>Manufacturer</b> – Place where the device is manufactured		<b>Keep Dry</b> – Ship and store in a dry place
	<b>Torque Wrench</b> – A supplementary item or accessory		<b>Product Drawing (PG)</b> – Used for visual identification of product
<b>Rx only</b>	<b>CAUTION</b> – USA Federal law restricts this device to sale by or on the order of a physician		
<b>FCC ID SDYCHI1010 – Federal Communications Commission – Identifier serial number</b>			

**Table 24: Packaging Symbols: Magnet**

Symbol	Specification	Symbol	Specification
	<b>Magnetic Field</b> – To warn of a magnetic field near the magnet		<b>Non Sterile</b> – Used to indicate magnet is not sterile
	<b>Product Drawing (Magnet)</b> – Used for visual identification of product		

### S-ICD System and Pacemaker Interaction

Interaction between the S-ICD System and a temporary or permanent pacemaker is possible and can interfere with the identification of tachyarrhythmias in several ways.

- If the pacing pulse is detected, the S-ICD System may not adjust sensitivity appropriately, fail to sense a tachyarrhythmia episode and/or not deliver therapy.
- Pacemaker sensing failure, lead dislodgment or failure to capture could result in the sensing of two asynchronous sets of signals by the S-ICD System, causing the rate measurement to be faster, and may result in delivery of unnecessary shock therapy.
- Conduction delay may cause the device to over sense the evoked QRS and T-wave resulting in unnecessary shock therapy.

Pacemakers that employ impedance checks like MV sensors and unipolar pacemakers are contraindicated for use with the S-ICD System. This includes pacemakers that revert or reset to the unipolar pacing mode.

Prior to implantation, follow the patient screening tool procedure to assure that the patient's paced S-ECG signal passes the criteria.

The following test procedure aids in determining S-ICD System and pacemaker interaction after implantation:

**Note:** *External defibrillation equipment should be available for immediate use during the implantation procedure as well as during testing and follow-up.*

**Note:** *If implanting a pacemaker with an existing S-ICD System, program the S-ICD System to Therapy Off during the implantation and initial testing of the pacemaker.*

During the testing procedure, program the pacemaker output to maximum and asynchronously pace in the pacing mode to which the pacemaker will be permanently programmed (e.g., DOO for most dual-chamber modes and VOO for single-chamber modes).

1. Complete the S-ICD System set-up procedure.
2. Observe the S-ECG for any pacing artifacts. If any pacing artifacts are present and larger in amplitude than the R-wave, use of the S-ICD System is not recommended.
3. Induce the tachyarrhythmia and observe the S-ECG markers to determine appropriate detection and delivery of therapy.
4. If inappropriate sensing is observed as a result of the device sensing the pacing artifact, reduce the pacemaker's pacing output and retest.

In addition, pacemaker operation may be affected by the S-ICD System therapy delivery. This could alter the pacemaker's programmed settings or damage the pacemaker. In this situation, most pacemakers will conduct a memory check to determine if the parameters for safe operation were affected. Further interrogation will determine if programmed pacemaker parameters are altered. Refer to the manufacturer's pacemaker manual for implantation and explantation considerations.

**Limited Warranty**

Cameron Health, Inc. warrants to Purchaser, that for a period of five (5) years or sixty (60) months commencing with the date of implantation of the SQ-RX Pulse Generator ("the Product"), should the Product fail to function in accordance with Cameron Health, Inc.'s published specifications due to a defect in materials or workmanship, Cameron Health, Inc. will, as Purchaser's sole remedy and Cameron Health, Inc.'s sole liability:

1. If within the three (3) year period, or 36 months, commencing with the date of implantation, Cameron Health, Inc. will provide a functionally comparable replacement Product at no charge.
2. If after the three (3) year period from month 37 and until five (5) years, or 60 months, commencing with the date of implantation, Cameron Health, Inc. will provide a credit to the Purchaser for a functionally comparable replacement Product in an amount equal to 50% of the original purchase price reduced on a pro rata basis over this two year period. The prorated credit amount will be calculated on a monthly basis over this twenty-four month period.

In no event will any warranty credit issued hereunder exceed the original purchase price of the Product or the purchase price of the replacement Product.

The Product is designed as a single use device and must not be resterilized. Any resterilization voids the warranty.

To qualify for this limited warranty, the following conditions must be met:

- All claims should be submitted to your Cameron Health, Inc. representative or Cameron Health, Inc.'s Customer Service Department to obtain information on how to process a claim under this limited warranty.
- The Product must be used in accordance with the labeling and not altered, subject to misuse, abuse, accident, or improper handling.
- The Product must be implanted prior to the "USE BY DATE" in conjunction with a Cameron Health, Inc. electrode.
- The Product must be returned to Cameron Health, Inc. within thirty (30) days after explant and shall be the property of Cameron Health, Inc.
- The Product must be clean and free from any bodily residue before returning.
- The replacement Product must be manufactured or distributed by Cameron Health, Inc.
- All registration materials must be completed and returned to Cameron Health, Inc. within thirty (30) days of implantation of the replacement Product.

OTHER LIMITATIONS ON THE TERM OF THIS LIMITED WARRANTY ARE PROVIDED WITH THE SALES DOCUMENTS AND ARE CONSIDERED AN INTEGRAL PART OF THIS LIMITED WARRANTY, AS ARE THE WARNINGS CONTAINED IN THE PRODUCT LABELING.

THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER EXPRESS OR IMPLIED WARRANTIES, STATEMENTS, OR REPRESENTATIONS AND UNLESS STATED HEREIN, ALL SUCH WARRANTIES, STATEMENTS OR REPRESENTATIONS INCLUDING THOSE BY ANY OTHER PERSON OR FIRM ARE VOID. CAMERON HEALTH, INC. HEREBY DISCLAIMS ALL IMPLIED WARRANTIES INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. UNDER NO CIRCUMSTANCES SHALL CAMERON HEALTH, INC. BE LIABLE FOR ANY LOSS OR DAMAGE, DIRECT, INCIDENTAL, OR CONSEQUENTIAL, INCLUDING BUT NOT LIMITED TO MEDICAL COMPLICATIONS OR DEATH, ARISING OUT OF THE USE OF, OR INABILITY TO USE, THE PRODUCT.

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