

The S-ICD[®] System

The protection you need - without touching your heart



LISTEN TO YOUR HEART



Patient information



HOPE FOR SUDDEN CARDIAC ARREST

It's impossible to predict when sudden cardiac arrest might strike. Called a "silent killer," there are often few warning signs and over 95% of sufferers die before they ever reach the hospital.¹ But, an implantable defibrillator is a treatment option that can protect you.

If you are at risk of sudden cardiac arrest, your physician may recommend a totally subcutaneous implantable defibrillator, called the S-ICD[®] System. The S-ICD[®] System is a new device that sits just under your skin—constantly monitoring your heart—ready to deliver treatment if sudden cardiac arrest strikes.

This brochure provides information about how an implantable defibrillator can offer the protection you need from sudden cardiac arrest and explains how the S-ICD[®] System can provide this protection without placing a wire in your heart.

WHAT IS SUDDEN CARDIAC ARREST?

Arrhythmia, an irregular or abnormal heartbeat, results from a problem with the electrical system of your heart. In some cases, this may cause your heart rate to dangerously increase, called ventricular tachycardia or VT. If the VT becomes very fast, unstable, and irregular, it may be much more serious, which is called ventricular fibrillation or VF. With VF, the heart quivers rapidly and cannot pump blood throughout the body. This is called sudden cardiac arrest.

Sudden cardiac arrest is a very serious heart condition, and if not treated within minutes, can lead to death. Only an electrical shock administered to the heart can reset the heart's rhythm and restore normal blood flow throughout the body.

YOU HAVE OPTIONS

An implantable defibrillator, commonly known as an ICD, is a device designed to administer lifesaving therapy in the event of sudden cardiac arrest. When the ICD senses a dangerously high heart rate, it will send an electrical pulse to your heart to reset your heart's normal rhythm and allow your heart to resume pumping blood through your body—this is known as defibrillation. ICDs have been used for decades and have prolonged hundreds of thousands of lives.

There are two types of ICDs being implanted today: 1) traditional transvenous ICDs and 2) the S-ICD[®] System. Both types of ICDs administer defibrillation therapy. However, the S-ICD[®] System avoids the potential for short- and long-term complications associated with placing an electrical wire in your heart.



Traditional ICDs administer shocks through one or more electrical wires. Using x-ray imaging, the electrical wires are fed through your veins, into the heart, and across the heart valve. Once in place, the wires are attached to the heart wall.



Similar to traditional ICDs, the S-ICD[®] System also provides lifesaving defibrillation therapy whenever it is needed. In contrast, the S-ICD[®] System is implanted just under the skin with no wires implanted in the heart.

Ask your physician if the S-ICD[®] System is the right choice to protect you from sudden cardiac arrest.





DEFIBRILLATION WHEN YOU NEED IT

The design of the S-ICD[®] System represents a major breakthrough in ICD therapy and provides an important new option if you are at risk of sudden cardiac arrest.

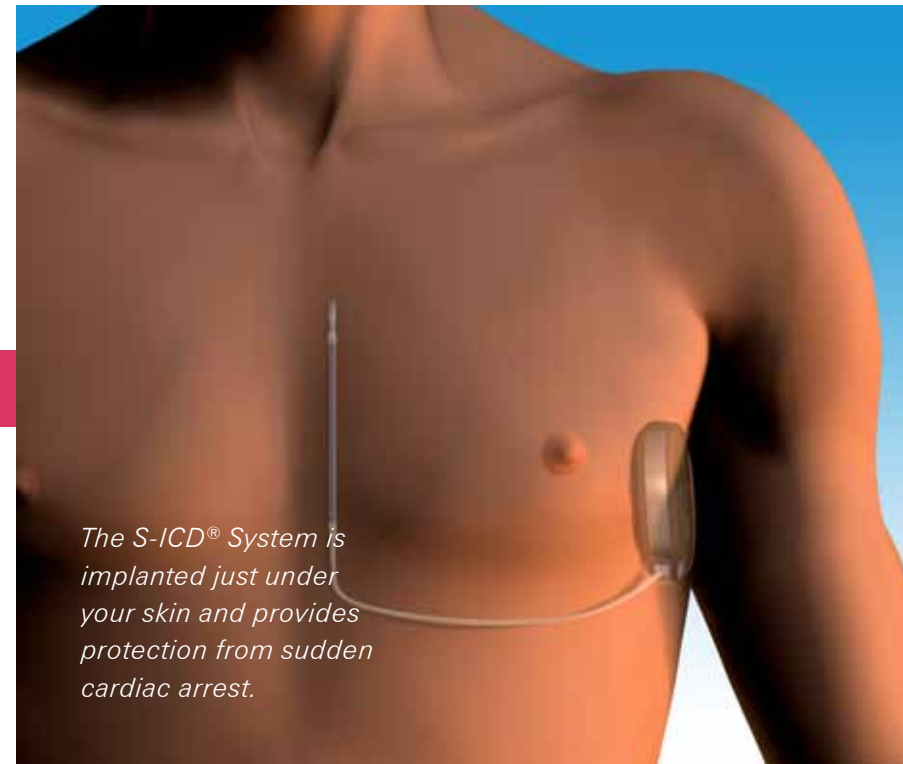
ACCURATE DEFIBRILLATION THERAPY

Just as your physician places wires on your chest to monitor your heart during an electrocardiogram or ECG, the S-ICD[®] System similarly monitors your heart with a wire just under the skin. Only the S-ICD[®] System uses this ECG-like signal to monitor your heart for abnormal rhythms that indicate sudden cardiac arrest. The S-ICD[®] System is designed to accurately treat sudden cardiac arrest when you need it, and it may also reduce the likelihood of receiving unnecessary shocks.

NOTHING IN YOUR HEART

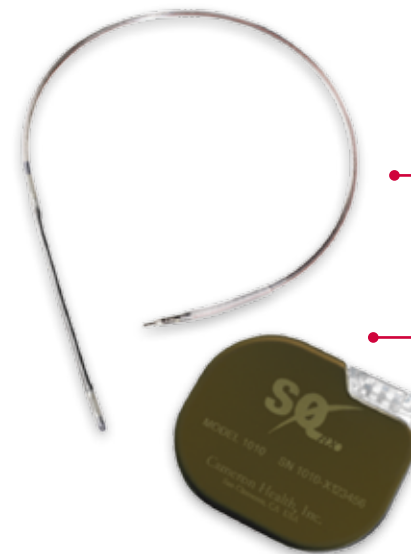
The S-ICD[®] System is the only implantable defibrillator that does not require electrical wires in your heart.

The S-ICD[®] System is implanted using a completely subcutaneous procedure that leaves the heart and blood vessels untouched and intact. By placing the electrode just under the skin, the S-ICD[®] System eliminates potentially serious short- and long-term risks associated with placing electrical wires inside your heart or blood vessels. When sudden cardiac arrest is detected, the electrode delivers a shock to the heart similar to external defibrillator paddles used by paramedics. Even without directly touching the heart, the shock can reset the heart's normal rhythm.



The S-ICD[®] System is implanted just under your skin and provides protection from sudden cardiac arrest.

ADVANCED DESIGN FOR COMPLETELY SUBCUTANEOUS DEFIBRILLATION THERAPY



Electrode

An insulated wire that senses the heart's electrical signals and transmits data to the pulse generator.

Pulse generator

A sophisticated, battery-powered, electronic device that monitors the heart's rhythms. The pulse generator additionally sends an electrical shock through the electrode when dangerously fast heart rhythms are detected.

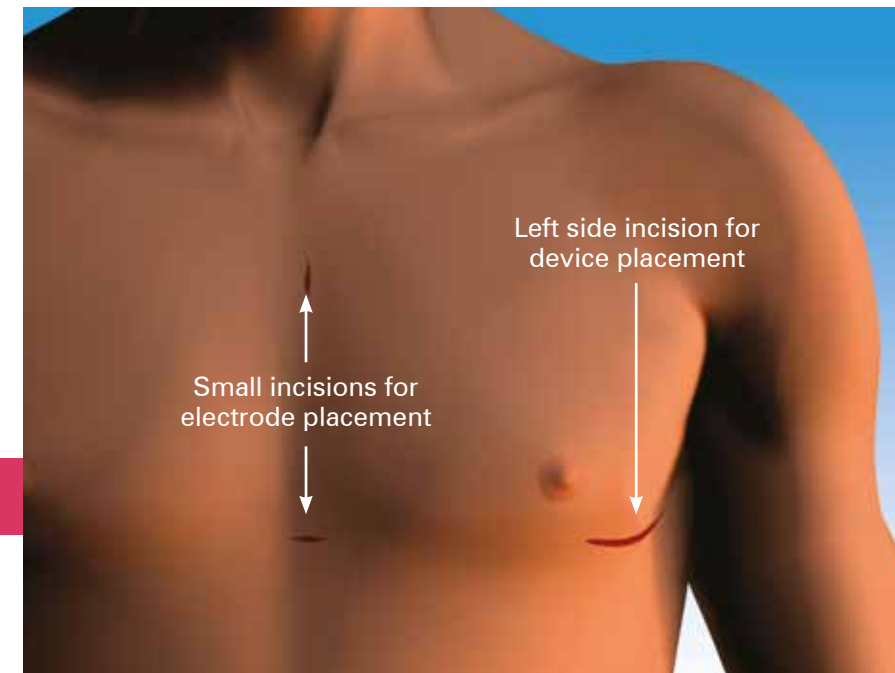


PREPARING FOR THE IMPLANT PROCEDURE

Implantation of the S-ICD® System typically takes about one hour. Your physician will provide you with complete information to help you prepare for your procedure and recovery.

WHAT TO EXPECT DURING THE PROCEDURE

- Depending on your physician's and hospital's practice, general or local anesthesia will be administered to make you comfortable during the procedure.
- Next, a small incision is made on the left side of the chest, next to the rib cage.
- A pocket or pouch is formed under the skin, where the S-ICD® System pulse generator will be placed.
- Two small incisions will be made slightly to the left of the breastbone to allow the electrode to be placed under the skin.
- The electrode is then attached to the S-ICD® System pulse generator.
- Using a separate programmer that looks much like a laptop, the S-ICD® System will be tested and the settings adjusted to work best for your heart.
- Finally, the physician will close the incisions to complete the procedure.



The S-ICD® System is implanted just under the skin, using three incisions to place and secure the system components.



LIVING WITH THE S-ICD[®] SYSTEM

After recovering from the procedure, you should be able to continue to enjoy travel or exercise to improve the health of your heart. With the added protection against sudden cardiac arrest, the S-ICD[®] System will give you peace of mind to live your life to the fullest, do the things you enjoy, and spend valuable time with the ones you love.

LEAVING THE HOSPITAL

It is difficult to determine recovery time because every patient is different. In most cases, you should be allowed to go home shortly after the procedure.

Your physician will provide a complete set of instructions for you to follow immediately following your procedure. Always consult your physician for specific information. You will also receive a patient identification card, allowing you to alert medical and security professionals that you have an implanted medical device.

CHECKING IN WITH YOUR PHYSICIAN

Your physician will prescribe a follow-up schedule of regular visits to check your S-ICD[®] System. During these routine visits, your physician may adjust the settings of the S-ICD[®] System using a wireless programmer.

If you receive a shock, be sure to notify your physician. While the shock may be uncomfortable and startling, it means that the S-ICD[®] System may have detected a dangerously fast heart rhythm and delivered the defibrillation therapy you needed to reset your heart's electrical system.

RISKS OF ICD THERAPY

The S-ICD[®] System has been designed to reduce risk of serious infection and other complications associated with electrical wires placed in the heart. However, the S-ICD[®] System implantation, like every surgical procedure, does carry risks. Such risks include infection and bleeding. After the surgery, it is likely that you will feel discomfort, which should decrease over time.

While living with your S-ICD[®] System, there are certain precautions that you should follow. Your physician will give you a complete set of instructions. Be sure to read all of the literature that comes with your Cameron Health S-ICD[®] System.

Traditional ICDs and the S-ICD[®] System are designed to ensure that lifesaving defibrillation therapy is delivered whenever it is needed. There is a small risk that the ICD may not deliver therapy when you need it, or that it will deliver therapy when you do not need it. This risk applies to traditional ICDs and the S-ICD[®] System alike. Ask your physician about the risks and benefits of ICD therapy prior to receiving any ICD.



FREQUENTLY ASKED QUESTIONS

Why do I need the S-ICD® System if I have already experienced sudden cardiac arrest?

Although you have already experienced a sudden cardiac arrest, you are still at risk for having another episode. The American Heart Association reports that 95% of those who had sudden cardiac arrest without an ICD die before reaching the hospital.¹

How often does the S-ICD® System deliver therapy?

Therapy delivery varies for each patient and is dependent on your specific heart condition. For each instance of sudden cardiac arrest, a single therapeutic shock will be delivered to restore the heart's natural rhythm. After a shock is delivered, the S-ICD® System will continue to monitor your heart and deliver an additional shock if needed.

How long will the system last?

The battery in the S-ICD® System can typically last many years and will be capable of protecting you from multiple episodes of sudden cardiac arrest. There are factors that could affect battery life including your heart condition and the number of therapies you receive. Your physician will let you know when the S-ICD® System needs to be replaced.

Is a shock from the S-ICD® System painful?

People have reported a wide range of experiences as a result of receiving a shock, from a mild thump to a kick in the chest. While the shock may be painful, this means your S-ICD® System is monitoring and responding to dangerous heart rhythm irregularities.

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

Many people are aware of their implanted S-ICD® System, but quickly become used to it over a short period of time.

Can I participate in physical activities such as running, skiing, and sexual intimacy?

Generally, the S-ICD® System is compatible with an active lifestyle. After your recovery, your doctor will advise you on when you can get back to your regular activities.

If my heart is beating faster while exercising, how does the S-ICD® System know the difference?

With highly advanced technology, the S-ICD® System is designed to detect the difference between increased heart rates due to exercise and dangerously fast heart rhythms due to ventricular fibrillation (VF).

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

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

How does the S-ICD® System compare to traditional ICDs?

With a traditional ICD device, electrical wires are fed through your veins, into the heart, and across the heart valve. Once the wires are in place, they are attached to the heart wall. The subcutaneous placement of the Cameron Health S-ICD® System does not require electrical wires in the heart and was designed to reduce complications associated with the implantation of traditional ICD electrical wires.

What are the risks associated with the S-ICD® System?

The S-ICD® System has been designed to reduce risk of serious infection and other complications associated with traditional ICD electrical wires. However, the S-ICD® System implantation, like every surgical procedure, does carry risks, including infection and bleeding. Your physician is the best source of information about the risks of having the S-ICD® System. Be sure to talk with your physician about all your questions and concerns.

Will I be able to drive?

This depends on your state's or country's ICD driving laws and your specific symptoms. Your physician will advise you if, and when, you may drive after your S-ICD® System has been implanted.

Can I travel?

The S-ICD® System does not prevent you from traveling. However, the Cameron Health S-ICD® is currently not available in all countries worldwide. Your physician may give you guidance on whom to speak with or contact when traveling. Check with your physician about guidelines regarding any travel restrictions. Be sure to carry your patient identification card while traveling.

Will my S-ICD® System interfere with mobile phones and other electronic devices?

You will be able to use typical household items, such as microwave ovens, electric blankets, power tools, MP3 players, and automobile ignition systems. Cell phones should be kept at least 15 centimeters, or 6 inches from the S-ICD® System. Strong electromagnetic devices may cause interference with the S-ICD® System. Most medical equipment will not interfere with the S-ICD® System, but be sure to inform the healthcare professional that you have an implanted medical device. Talk with your physician for a complete list of precautions for your S-ICD® System.

