

# ***Listen to Your Heart***

The S-ICD™ System

The protection you need —  
without touching your heart





## Protection from sudden cardiac arrest

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

If you are at risk of sudden cardiac arrest, your doctor 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. It constantly monitors 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 inside your heart.

### ***What Is Sudden Cardiac Arrest?***

*Arrhythmia*, an irregular or abnormal heartbeat, results from a problem with the electrical system of your heart. Some arrhythmias that originate in the heart's lower chambers (the ventricles) may be life-threatening. You may have heard your doctor talk about two types:

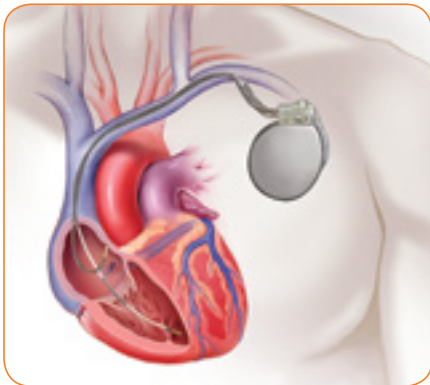
- **Ventricular tachycardia (VT)** is a fast heart rhythm that occurs in one ventricle of your heart. It is like an electrical short circuit that makes the heart beat at rates between 150 – 200 beats per minute.
- **Ventricular fibrillation (VF)** is an abnormally fast and chaotic rhythm that makes the heart beat more than 200 – 300 beats per minute. With VF, the heart quivers rapidly and cannot pump blood throughout the body. This can lead to 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***

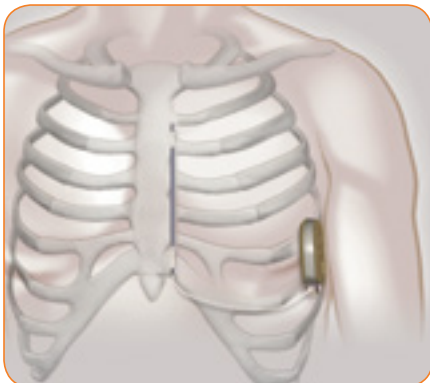
An implantable defibrillator, commonly known as an ICD, is a device designed to administer lifesaving therapy in the event of sudden cardiac arrest. When the ICD senses a dangerously high heart rate, it will send an electrical pulse to your heart to reset your heart's normal rhythm and allow your heart 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) transvenous (through the vein) ICD systems and 2) the completely subcutaneous S-ICD™ System. Both types of ICDs sense when the heart rate is dangerously fast and can deliver a shock to the heart to stop the abnormal rhythm and restore a normal heartbeat.



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*Transvenous ICDs deliver lifesaving defibrillation therapy 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.*



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*The S-ICD System also delivers lifesaving defibrillation therapy whenever it is needed. The S-ICD System — pulse generator and electrode — is implanted just under the skin. There is nothing in or on the heart.*



## Defibrillation when you need it

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

### ***Accurate Defibrillation Therapy***

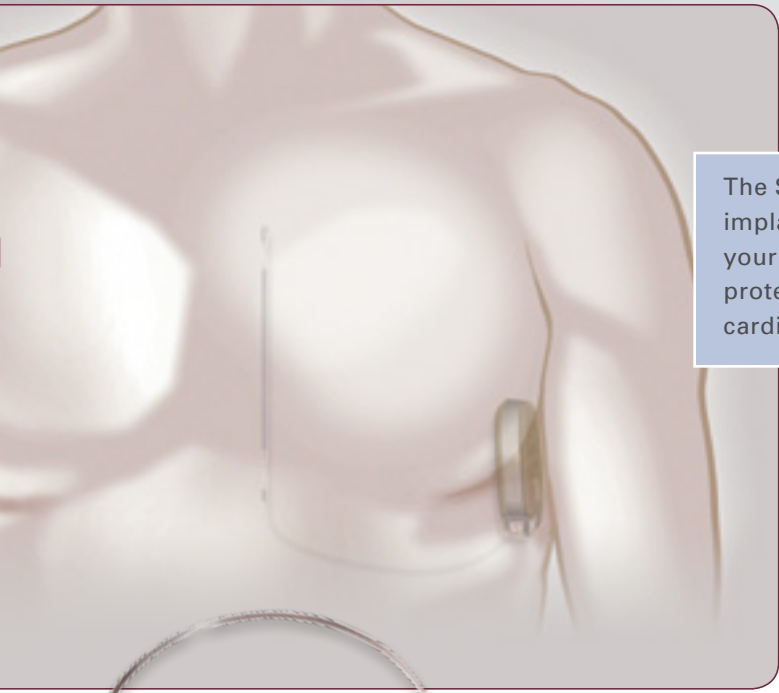
Just as your doctor places wires on your chest to monitor your heart during an electrocardiogram or ECG, the S-ICD System similarly monitors your heart with a wire just under the skin. The S-ICD System uses this ECG-like signal to monitor your heart for abnormal rhythms that indicate sudden cardiac arrest. 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 therapy.<sup>2</sup>

### ***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. The electrode is just under the skin. 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***

#### ***Subcutaneous 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*

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Ask your doctor if the S-ICD System is the right choice to protect you from sudden cardiac arrest.



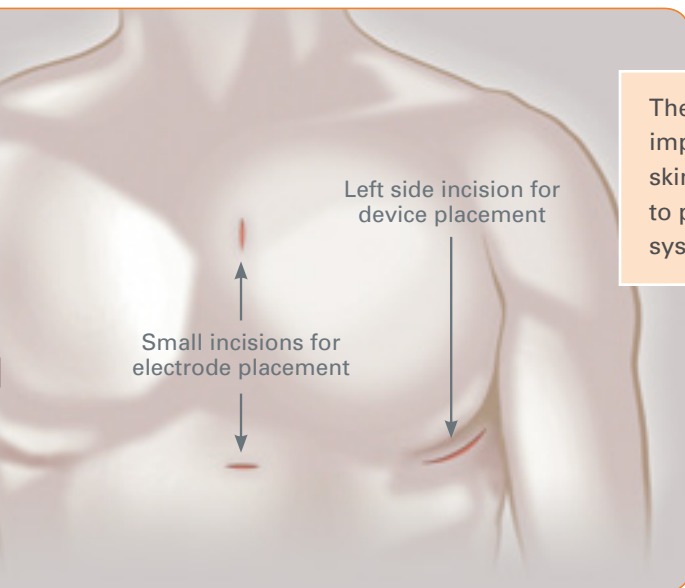


Preparing for the implant procedure

***Implantation of the S-ICD™ System typically takes about 1 hour. Your doctor will provide you with complete information to help you prepare for your procedure and recovery.***

### ***What to Expect During the Procedure***

- Depending on your doctor'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 doctor will close the incisions to complete the procedure.



Left side incision for  
device placement

Small incisions for  
electrode placement

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 doctor will provide a complete set of instructions for you to follow immediately after your procedure. Always consult your doctor 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 Doctor***

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

If you receive a shock, be sure to notify your doctor. 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; however, you should make sure to discuss all potential risks with your physician. 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 doctor will give you a complete set of instructions. Be sure to read all of the literature that comes with your S-ICD System.



# S-ICD System

## 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. People who survive an SCA episode have a high chance of having another one in the next few years.

### **How often does the S-ICD System deliver therapy?**

Therapy delivery varies for each patient and depends on your specific heart condition. For each sudden cardiac arrest episode, a single therapy shock will be delivered to restore the heart's normal 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 several 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 doctor will let you know when the S-ICD System needs to be replaced.

### **Is a shock from the S-ICD System painful?**

With both transvenous and subcutaneous ICDs, 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, it is over in an instant. 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 become used to it after 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).

\* For a complete list of risks associated with the S-ICD System refer to the patient handbook that comes with the device.

## 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 differ from transvenous ICDs?

With a transvenous 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 S-ICD System does not require electrical wires in the heart and is designed to reduce rare complications associated with the implantation of transvenous ICD electrical wires.

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

The S-ICD System implantation, like every surgical procedure, does carry risks, including infection and bleeding. Your doctor is the best source of information about the risks of having the S-ICD System. Be sure to talk with your doctor about all your questions and concerns.\*

## Will I be able to drive?

Your ability to drive with your heart condition depends on your state's or country's ICD driving laws and your specific symptoms. Your doctor will advise you if, and when, you may drive after your S-ICD System has been implanted.

**Medical Device ID**  
Implanted Cardiac Rhythm Patient

**Patient:** Dave Johnson  
**Physician:** JOE D ANDERSON MD  
**Patient Telephone:** (555) 555-5555

MFG	Product	Model/Serial	Implant DT
Guidant	AICD	1851 00909	09-OCT-2006
Guidant	Lead	0125 909910	09-OCT-2006
Guidant	Lead	497-01 887766	09-OCT-2006
Guidant	Lead	82-0002-8001 00599SK	09-OCT-2006
Guidant	Accessory	6831 123456	09-OCT-2006
Oscor	Lead	PY485BV	09-OCT-2006

**Management Patient**  
Instructions or emergency

**For Security Personnel**  
MAGNETIC SECURITY  
WANDS MAY AFFECT  
DEVICE FUNCTION.  
DO NOT HOLD  
WAND OVER DEVICE.

**For Patients**  
1.866.484.3268 (USA) – 1.651.582.4000  
Outside USA: 001.651.582.4000  
**For Medical Personnel**  
1.800.227.3422 – 651.582.4000  
[www.bostonscientific.com](http://www.bostonscientific.com)  
[www.lifebeatonline.com](http://www.lifebeatonline.com)

If your name, mailing address, or physician changes, please call Medical Records:  
1.866.484.3268, 7 AM – 7 PM Central Time, Monday – Friday CRM-64301-AA

## Can I travel?

The S-ICD System does not prevent you from traveling. However, the S-ICD System is currently not available in all countries worldwide. Your doctor may give you guidance on whom to speak with or contact when traveling. Check with your doctor 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, such as running motors and large magnets. Most medical equipment will not interfere with the S-ICD System, but be sure to inform the health care professional that you have an implanted medical device. Talk with your doctor for a complete list of precautions for your S-ICD System.

# Meet Matt

*“Matt has a long family history of people dying fairly young with unknown heart problems. Since Matt received his device, four more members of the family have received the S-ICD™ System.”*



*“Just having the security blanket  
means the world for me and my family.”*

### **How was your heart condition diagnosed?**

“One day last year, my mom called me and said, “Sit down and don’t worry.”

“My dad learned that his deceased sister had been diagnosed with a prolonged QT interval in her heart rhythm. He was tested, and he was also diagnosed with for Long QT Syndrome.

“Within the month, I had a blood test and it showed that I had both LQTS and Factor V Leiden, a blood clotting issue also common to my Dad’s side of the family.”

“When we found out Matt had Long QT,” his dad, Jim, said, “I was thinking about all the relatives we buried at very young ages, and it scared me!”

“Once we learned that my tests were positive,” said Matt, “we immediately started checking the web, talking with cardiologists, looking for a solution.”

### **How did you decide on the S-ICD System?**

“The cardiologist said I needed the implanted defibrillator to manage my high risk of sudden cardiac death. They also gave me the great option of the S-ICD System, an implanted device that didn’t go into the veins, which could cause me to have a blood clot issue with my Factor V Leiden.”

### **How did you feel after your device was implanted?**

“The recovery process wasn’t too bad at all. I was able to take two weeks off of work. There was a little pain and discomfort from the swelling of the stitches on my side, but not too bad overall.”

### **How are you feeling now?**

“The S-ICD System hasn’t affected my life in any major way. The device is just there for me. I still do visual merchandising. I set up the store, take down displays, especially working on the window displays.

“I know the S-ICD System definitely has impacted my family. Going through the surgery and having the S-ICD device brought ease of mind to my mom, especially. Just having the security blanket means the world for me and my family.”



# Meet Lisa

*“When I was 9 years old, I was playing outside with my brother, Adam, and he actually laid down and didn’t wake back up. At that time, we didn’t know what happened. But he passed away.”*



*"I look forward to my kids growing up.  
I look forward to living life again,  
like getting a good night's sleep."*

### **How was your heart condition diagnosed?**

"In 2005, I was diagnosed with the same heart condition my brother had died from and caused my dad to receive a heart transplant. I knew I needed a defibrillator and had a traditional ICD implanted."

### **What symptoms led up to a change in your therapy?**

"Everything seemed okay in the beginning, but then I began to experience difficult symptoms. I had swelling in my neck and face and the veins on the side of my neck would bulge out. I couldn't sleep lying down on my back, but had to sleep propped up. I eventually ended up in the emergency room and had some tests. At that point, my cardiologist described something called Superior Vena Cava syndrome."

The Superior Vena Cava is a large vein that collects blood from the head and arms and delivers it back to the right atrium of the heart. When the entire SVC vein is compressed, there can be swelling of the face and arms. At that point, there is nothing to do but remove the ICD lead.

"Through talking with friends and looking online, I heard about a new device where the leads were not placed in your vein, but on the outside of the ribs."

### **How did you feel about having an S-ICD™ System?**

"I was thrilled, I was excited to have an alternative to protect me from sudden cardiac arrest, but I didn't have to be concerned as I had previously. I am about two years out with the S-ICD System, I am back to doing the things I want to do. We spend time at the beach, hiking, and surfing. These are things I had given up when I had complications from the previous system."

### **How are you feeling now?**

"I look forward to my kids growing up. I look forward to living life again, like getting a good night's sleep."

## Important Safety Information to Discuss with Your Doctor

An implantable defibrillator can protect you from the effects of sudden cardiac arrest by reviving your heart rhythm. But it is not for everyone, including people with certain steroid allergies. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. The device is available by prescription only. Individual results may vary. As outlined below, there are risks during the device implant procedure, following the implant, and during and following a replacement procedure. Complications do not happen often. However, it is important that you talk with your doctor about potential risks.

### When your doctor implants your S-ICD™ System, the potential procedure risks include, but are not limited to:

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

### About Device Monitoring and Replacement

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

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

For information about Boston Scientific device performance, refer to the Product Performance Report on [www.bostonscientific.com](http://www.bostonscientific.com).

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

### Monitoring the battery

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

### Monitoring system performance

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

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

Replacement involves some risks. It is important for you and your doctor to consider these risks when making a decision about device replacement. For more information on risks, please see the patient handbook that comes with the device.

**Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.**

### Important Patient Information for the S-ICD™ System

An implantable cardioverter defibrillator is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated with them. There are risks associated with this device including, but not limited to, allergic reactions, bleeding, death, fever, infection, kidney failure, need for surgical replacement, nerve damage, stroke and tissue damage. Electrical or magnetic fields can affect the device. In some cases, the device may not respond to irregular heartbeats or may deliver inappropriate shocks and in rare cases severe complications or device failures can occur. Your physician should discuss all potential benefits and risks with you and describe the appropriate medical care.

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### Reference:

1. American Heart Association. "Long-term Treatment for Cardiac Arrest." Available at [www.heart.org](http://www.heart.org). Accessed 04/30/14.
2. Bardy GH, Smith WM, Hood MA, Crozier IG, Melton IC, et al. An Entirely Subcutaneous Implantable Cardioverter-Defibrillator. *N Engl J Med* 2010; 363:36-44.

This material is intended for general educational purposes only. Use of these products is expressly limited to individuals skilled in cardiac rhythm management procedures. Boston Scientific does not practice medicine or provide medical services. This brochure is not intended to replace the literature accompanying the S-ICD System. Please review the appropriate literature accompanying the components of the S-ICD System for a complete listing of warnings and precautions.

### After your doctor implants your S-ICD System, you may experience certain complications. These may include, but are not limited to:

- You may develop an infection.
- You may experience erosion of the skin near the device.
- You may experience discomfort or prolonged healing of incision
- The electrode or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues.
- The device may move from the original implant site (migration).
- You may not feel or function the same psychologically.
- The device may deliver inappropriate therapy (shocks or pacing).
- The device might not be able to detect or appropriately treat your heart rhythms.
- The device may exhibit malfunctions that may result in lost or compromised ability to deliver therapy.

### When your S-ICD System is replaced, the potential risks may be similar to, or even greater than, those of your original S-ICD System implant. Additional risks from these replacement procedures may include:

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

It is important for you and your doctor to consider these potential risks when making a decision about device replacement.

**Boston  
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Advancing science for life™

### Rhythm Management

300 Boston Scientific Way  
Marlborough, MA 01752-1234  
[www.bostonscientific.com](http://www.bostonscientific.com)

### Medical Professionals:

1.800.CARDIAC (227.3422)

### Patients and Families:

1.866.484.3268

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