

Subcutaneous ICD | S-ICD

Protection without touching the heart

Patient Brochure



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For more information and patient stories: www.s-icd.eu

PROTECTION *from* SUDDEN CARDIAC ARREST

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

If you are at risk of SCA, your doctor may recommend a subcutaneous implantable defibrillator (S-ICD). An S-ICD is a device that sits just under your skin. It constantly monitors your heart to be ready to deliver treatment if SCA strikes.

This brochure provides information about how an implantable defibrillator can offer the protection you need from SCA and explains how an S-ICD can provide this protection without placing a wire inside your heart.

WHAT *is* SUDDEN CARDIAC ARREST?

SCA is a serious and life-threatening medical emergency. During SCA, heart function stops—abruptly and without warning. This causes a rapid loss of consciousness (fainting). Without immediate treatment with defibrillation (an electric shock to the heart), brain damage and death can occur.

The definitions of SCA and heart attack are completely different. A heart attack is a "plumbing" problem caused by one or more blockages in the heart's blood vessels that prevent proper flow. A person having a heart attack is awake and breathing.

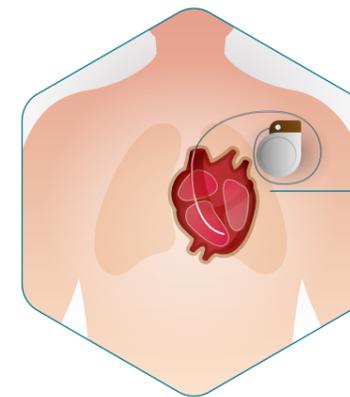
SCA is defined as an "electrical" problem, caused by an arrhythmia (irregular heartbeat) that prevents the heart from pumping blood to the brain and vital organs. A person experiencing SCA may be unconscious and not breathing.

Factors such as high blood pressure or heart disease increase the risk for SCA. It's not uncommon for a person to have a heart problem and not be aware of it until after SCA has occurred.

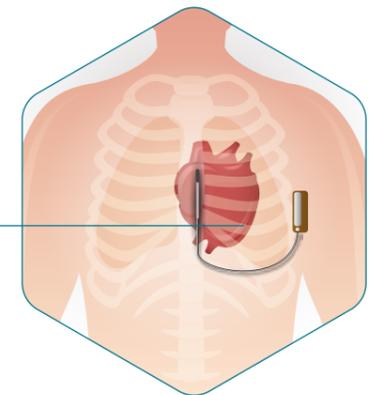
You HAVE OPTIONS

An implantable cardioverter defibrillator, commonly known as an ICD, is a device designed to administer lifesaving therapy in the event of SCA. 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 veins and into the heart) ICD systems and 2) the subcutaneous S-ICD, which does not touch the heart but sits just under your skin. 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.



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.



An S-ICD also delivers lifesaving defibrillation therapy whenever it is needed. Unlike a transvenous ICD device, an S-ICD—pulse generator and electrode—is implanted just under the skin. An S-ICD leaves the heart and blood vessels untouched and intact, minimizing the risk of certain complications.

*Watch the animation explaining Sudden Cardiac Arrest at:
www.S-ICD.eu/SCA*

*Watch the animation explaining the difference
between a Transvenous ICD and Subcutaneous ICD at:
www.S-ICD.eu/implant*

*More than 95% of sufferers die before
they ever reach the hospital.¹*

DEFIBRILLATION WHEN *you* NEED IT

ACCURATE DEFIBRILLATION THERAPY

Just as your doctor places wires on your chest to monitor your heart during an electrocardiogram or ECG, an S-ICD similarly monitors your heart with a wire just under the skin. The S-ICD uses this ECG-like signal to monitor your heart for abnormal rhythms that indicate SCA. An S-ICD is designed to accurately treat SCA when you need it.

NOTHING IN YOUR HEART

ICD therapy is a very trustworthy therapy that has prolonged hundreds of thousands of lives. ICD therapy has evolved from the more invasive abdominal ICD, which was introduced in the 1980s, to the transvenous ICD and then to the less invasive subcutaneous ICD, which was introduced in 2008.

One of the reasons for the development of the less invasive S-ICD therapy was to reduce the risk of complications associated with transvenous leads that are attached to the heart. As the subcutaneous electrode is not placed in either the veins or the heart, an S-ICD eliminates the risk of a bloodstream infection.

Another reason for the development of the S-ICD was to reduce the possibility of lead fractures (a thin and flexible lead in the heart undergoes much more mechanical stress than an insulated electrode which sits just under the skin) and therefore the need to remove or replace the lead in the heart.

When SCA 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.



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

The PROS and CONS of the S-ICD in a nutshell

PROS

The S-ICD System provides reliable protection against SCA.

Less invasive: the S-ICD System leaves your heart and blood vessels untouched and intact.

Avoidance of typical complications, such as infections in your bloodstream and the need to remove or replace the leads in the heart.

Less physical limitations: although the size of the S-ICD can is larger than a transvenous ICD can, the S-ICD should not limit your (arm) movements because it is not implanted under the collarbone.

The S-ICD System can be implanted using only anatomical landmarks, thereby reducing the need for fluoroscopy (and thus your exposure to radiation).

CONS

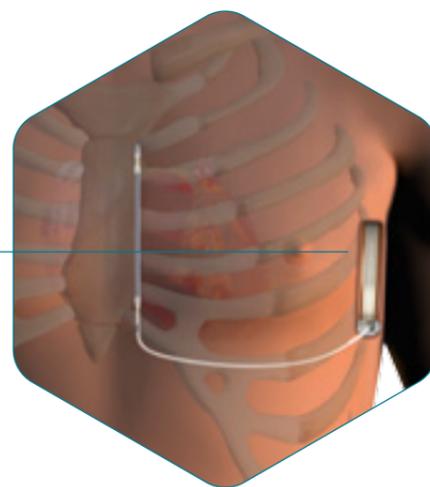
As with any surgical procedure, implanting the S-ICD System does carry potential risks, such as wound infection and bleeding.

No pacing: patients who have a slow heart rate or spontaneous, frequently recurring Monomorphic Ventricular Tachycardia (MVT) that is reliably treated with Antitachycardia Pacing (ATP), are more likely to benefit from a transvenous ICD with a pacing function.

The S-ICD System does not provide Cardiac Resynchronisation Therapy (CRT).

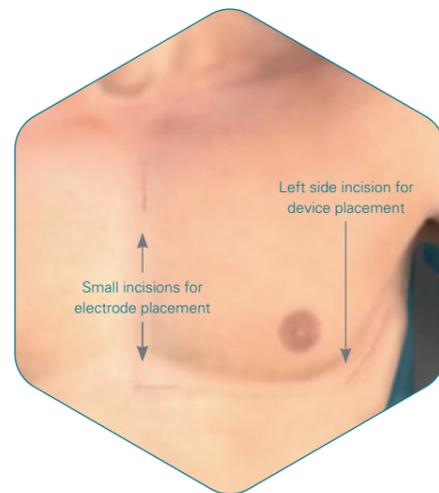
Some people feel discomfort when sleeping on their left side or wearing their usual bra.

The pulse generator and lead of the S-ICD are implanted just under your skin and provides protection from SCA.



CAN I CHOOSE WHICH TYPE OF DEVICE I WANT TO HAVE FITTED AND CAN I MAKE THIS CHOICE MYSELF?

Unless you have had an ICD/S-ICD implanted during emergency surgery, you may be able to choose which type of device you want to have fitted. However, it is important that you make this choice together with your doctor. Your doctor can advise which device is best suited to you and provide you with the expert advice you need to make an informed choice. You are the person who will be living with the device so it is important that it fits your body, your condition and your lifestyle.



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

Watch the video on how the S-ICD will be implanted on www.S-ICD.eu/implant

PREPARING *for the* IMPLANT PROCEDURE

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.

- 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, where the S-ICD pulse generator will be inserted.
- 3 Two small incisions are made slightly to the left of the breastbone to allow the electrode to be placed under the skin.
- 4 The electrode is then attached to the S-ICD pulse generator.
- 5 Once the S-ICD has been implanted, most doctors will test the device by inducing an arrhythmia (irregular heartbeat). The S-ICD is then allowed to detect and stop your abnormal heart rhythm automatically. Some settings will be adjusted to work best for your heart using a separate programmer tablet.
- 6 Finally, your doctor will close the incisions to complete the procedure.



*Visit www.s-icd.eu
and download the discussion guide to help you
ask the right questions to your doctor.*

LIVING *with an* S-ICD

Having a defibrillator implanted can be experienced as a life-changing event, as it is there to protect you from Sudden Cardiac Arrest. This might have a physical and emotional impact, to which every person can react differently.

Generally, having an S-ICD fitted will have little impact on your daily life. Most people can resume their normal daily activities. You should be able to continue to enjoy travel or exercise and live your life based on your physician's instructions.



REMOTE PATIENT MANAGEMENT

Your doctor may prescribe a Remote Patient Monitoring system to work with your implanted device between scheduled visits.

This is an in-home monitoring system that gives your healthcare team access to information from your implanted device.

This monitoring system checks your implanted device in the convenience of your home and sends information to a secure website that your healthcare team can view.

For more information visit www.bostonscientific.eu/latitude

CHECKING *in with* YOUR DOCTOR

Your doctor will schedule regular visits with you to see how you are doing and to check your S-ICD. During these routine check-ups, your doctor may adjust the settings of your S-ICD using a wireless programmer.

If your S-ICD delivers therapy (an electric shock), you should notify your doctor. Some people experience the therapy as painful or uncomfortable. While it may be startling, it means that the defibrillator may have detected a dangerously fast heart rhythm and delivered the defibrillation therapy you needed to reset your heart's electrical system.

YOUR *Recovery* PROCESS

Because every S-ICD patient is different, it's hard to say with certainty what your recovery time will be. In general, you should be able to return home the day after your implant procedure. Full recovery from the procedure normally takes about 4 to 6 weeks.

Your doctor will provide you with a complete set of instructions for you to follow once your procedure is completed. Always consult your doctor for specific information or to ask any additional questions you might have. You'll also receive a patient identification card, which alerts medical and security professionals that you have an implanted medical device.

RISKS *of* ICD THERAPY

An S-ICD has been designed to reduce risk of serious infection and other complications associated with electrical wires placed in the heart. However, the S-ICD 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. Make sure to discuss all potential risks with your physician.

While living with your S-ICD, 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.

Frequently Asked Questions

WHY DO I NEED AN S-ICD IF I HAVE ALREADY EXPERIENCED SCA?

Although you have already experienced 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 DOES AN S-ICD 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 an S-ICD does not require electrical wires in the heart and is designed to reduce complications associated with the implantation of transvenous ICD electrical wires.

HOW OFTEN DOES AN S-ICD DELIVER THERAPY?

Therapy delivery varies for each patient and depends on your specific heart condition. For each SCA episode, a therapy shock will be delivered to restore the heart's normal rhythm. After a shock is delivered, the S-ICD will continue to monitor your heart and deliver additional shocks if needed.

HOW LONG WILL THE S-ICD LAST?

The battery in the S-ICD is projected to last

between 6-8 years and is 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 needs to be replaced.

WHAT ARE THE RISKS ASSOCIATED WITH IMPLANTING THE DEVICE?

The S-ICD 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. Be sure to talk with your doctor about all your questions and concerns.*

WILL I BE ABLE TO FEEL THE IMPLANTED S-ICD?

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

IS A SHOCK FROM AN S-ICD 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 defibrillator is monitoring and responding to dangerous heart rhythm irregularities.

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

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 has been implanted.

WILL THE S-ICD AFFECT MY ABILITY TO PARTICIPATE IN PHYSICAL ACTIVITIES SUCH AS RUNNING, SKIING, AND SEXUAL INTIMACY?

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

WILL I BE ABLE TO TRAVEL?

The S-ICD does not prevent you from traveling. However, the S-ICD 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. On www.s-icd.eu you can find a locator map showing all hospitals worldwide that have experience with implanting and following-up on S-ICDs.

WHAT HAPPENS IF SOMEONE IS TOUCHING ME WHEN I RECEIVE AN ELECTRIC SHOCK?

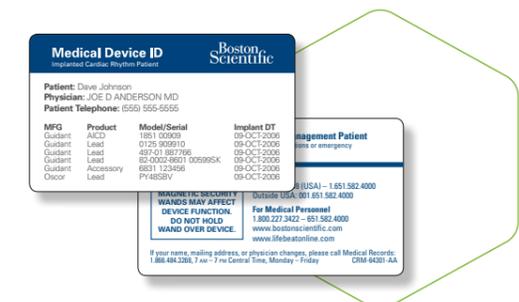
If you receive a shock while in contact with another individual, they may feel a harmless tingling sensation that lasts for an instant.

IF MY HEART IS BEATING FASTER WHILE EXERCISING, HOW DOES THE S-ICD KNOW THE DIFFERENCE BETWEEN THAT AND AN ARRHYTHMIA?

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

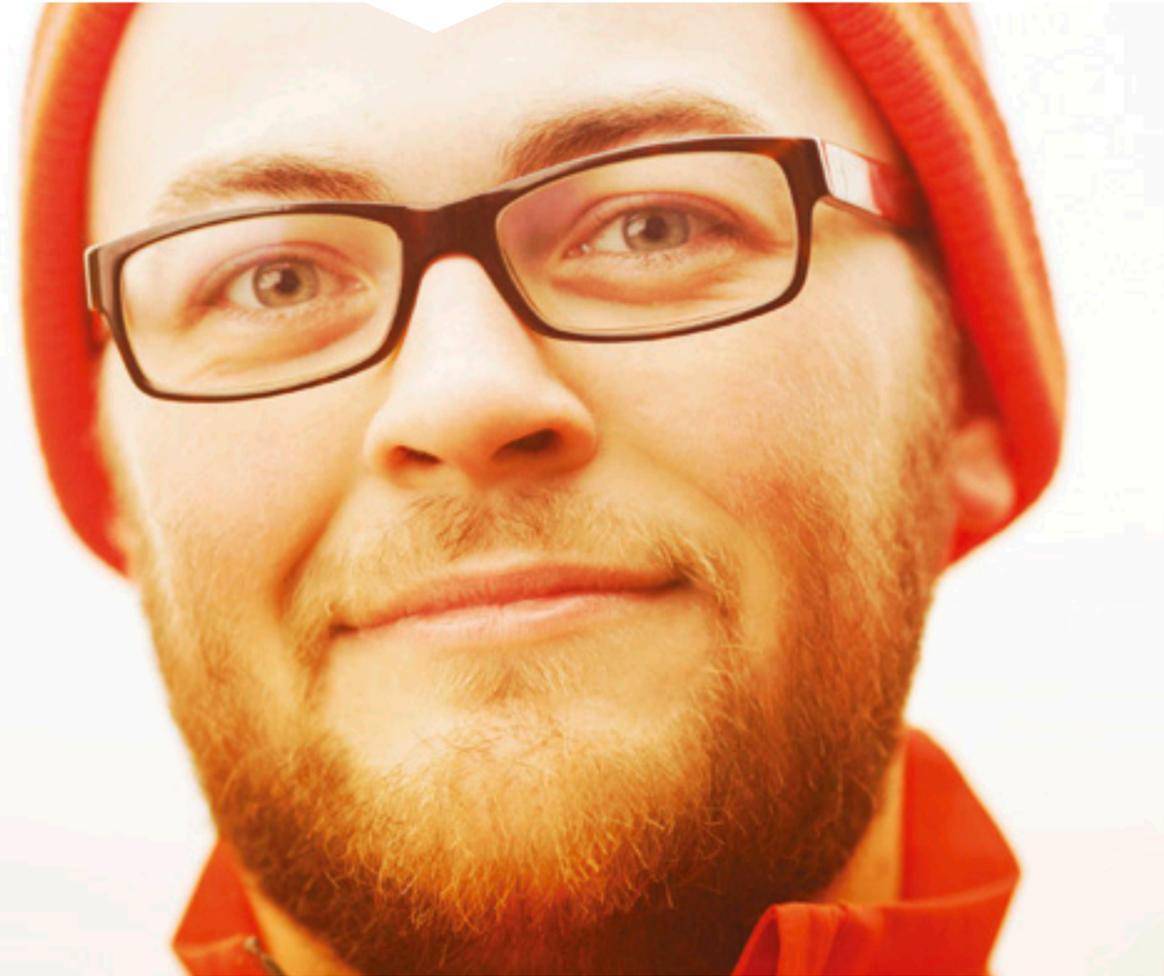
WILL MY S-ICD INTERFERE WITH MOBILE PHONES AND OTHER ELECTRONIC DEVICES?

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, from the S-ICD pulse generator. Being too close to electronic or strong electromagnetic devices may cause interference with the S-ICD, such as running motors and large magnets. Most medical equipment will not interfere with the S-ICD, but be sure to inform your health care professional that you have an implanted medical device. Talk with your doctor for a complete list of precautions for your defibrillator.



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 an S-ICD.



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 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?

"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, 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 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 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."

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

Visit www.S-ICD.eu/PatientStories for more S-ICD patient stories.



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

Meet TODD

Todd received his S-ICD in 2014. Todd has never let anything stop him from living life to the fullest—including a heart attack. An athlete, softball player, painter, father, and husband, Todd continues to embrace every day like he's training for a marathon.



HOW WAS YOUR HEART CONDITION DIAGNOSED?

"People that know me are shocked that this happened to me. Physical activity was always a part of our lives. Running, swimming, biking . . ."

"August comes along. August 19, headed out to play softball, I was having a great, great night and ran out there, and at that point my chest was starting to hurt. And I said, "We need to go. I'm not feeling right."

"So they wheeled me into the emergency room and the doctor kind of slapped me on the shoulder and said, "Well, you're having a heart attack!"

"On October 8th I got some bad news: that the lower tip of my heart was damaged, and that it probably wasn't going to come back."

HOW DID YOU DECIDE ON THE S-ICD?

"Once Dr. Pham started to explain to me what the device was, I thought we were in a pretty good spot."

Dr. Pham said, "The S-ICD is there. It's just like having an ambulance crew with you all the time. There's a guardian angel right there in his chest."

HOW DO YOU FEEL NOW?

"As my kids like to say, I'm bionic now. My life really hasn't changed. I can still do all of the things I've enjoyed doing."

"I'm still here. I'm still stompin' on the ground."

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