



EMBLEM™ MRI

S-ICD System

Protection without touching your heart

**Boston
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Protection from Sudden Cardiac Death

It's impossible to predict when Sudden Cardiac Death (SCD) might strike. Called a "silent killer," there are often few warning signs. SCD is the largest cause of natural death in the United States, causing 325,000 adult deaths in the U.S. each year.¹ But, an implantable cardioverter-defibrillator (ICD) is a treatment option that can protect you.

If you are at risk of SCD, your doctor may recommend a totally subcutaneous implantable cardioverter-defibrillator (S-ICD), called the EMBLEM™ MRI S-ICD System. The S-ICD system sits beneath the surface of the skin and is hidden between two muscle layers outside your rib cage and is easily concealable under clothing. It constantly monitors your heart rhythm and is ready to deliver therapy (an electric shock) if a life-threatening arrhythmia arises.

This brochure provides information about how an ICD can protect you from SCD and explains how the S-ICD System can provide this protection while remaining completely outside the heart—offering double protection—protection from SCD and protection from the higher risks and complications of having an electrical wire called a lead, inside the heart.

What is Sudden Cardiac Arrest?

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 SCD 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 to the heart muscle. 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.

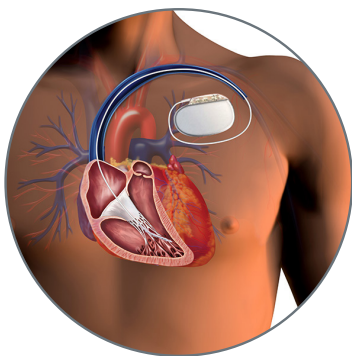
Sudden Cardiac Death is the largest cause of natural death in the United States, causing 325,000 adult deaths in the U.S. each year.¹

You Have Options

An implantable cardioverter-defibrillator, commonly known as an ICD, is a device designed to administer lifesaving therapy in the event of a life-threatening heart rhythm. When the ICD senses this dangerous heart rhythm, it will send an electrical shock to your heart to reset your heart to its normal rhythm and allow it 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.

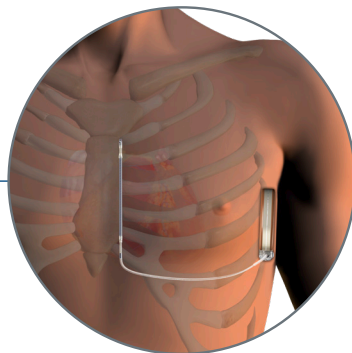
There are two types of approved ICDs being implanted today: 1) transvenous (through the veins and into the heart) TV-ICD system and 2) the completely subcutaneous (placed under the skin) S-ICD system, which does not touch the heart. Both types of ICDs sense when the heart rate is dangerously fast or irregular and can deliver a shock to the heart to stop the abnormal rhythm and restore a normal heartbeat.

The S-ICD system has been designed to reduce the risk of serious infection and other complications associated with leads placed in the heart. The S-ICD system has over fifteen years of clinical data. Data from a large head-to-head clinical trial showed that TV-ICD patients have twice as many infections requiring device removal and four times as many complications with the system leads compared to S-ICD patients.² S-ICD system implantation, like every surgical procedure, does carry risks. Such risks include infection and bleeding. After the surgery, you will likely feel discomfort, which should decrease over time. Make sure to discuss all potential risks with your doctor.



TV-ICDs deliver lifesaving defibrillation therapy through one or more leads. Using x-ray imaging, the leads are fed through your veins, into the heart, and across a heart valve. Once in place, the leads are attached to the inside of the heart wall.

The EMBLEM™ MRI S-ICD System also delivers lifesaving defibrillation therapy whenever it is needed. Unlike a TV-ICD device, the S-ICD system—pulse generator and electrode—is implanted just under the skin. The S-ICD system leaves the heart and blood vessels untouched and intact, minimizing the risk of certain complications.



Defibrillation When you Need It

The design of the EMBLEM™ MRI S-ICD System provides an additional option for those at risk of SCD without requiring a lead in the heart.

Delivering 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 an insulated wire (electrode) just under the skin. The S-ICD system uses this ECG-like signal to monitor your heart for abnormal rhythms that indicate SCA. The S-ICD system is designed to detect life-threatening heart rhythms when it happens and provide defibrillation therapy when you need it.

Nothing in Your Heart

The EMBLEM MRI S-ICD System is the only FDA approved implantable defibrillator that does not require leads in your heart.

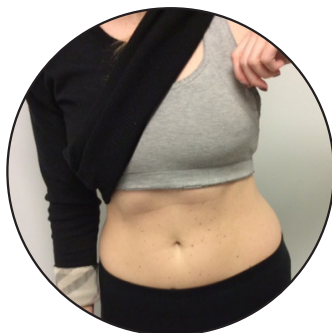
The S-ICD System is implanted using a completely subcutaneous procedure that leaves the heart and blood vessels untouched and intact. The electrode is just under the skin.

When a life-threatening heart rhythm is detected, the S-ICD system 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 to its normal rhythm.

Excellent Cosmetic Outcomes

Your EMBLEM MRI S-ICD will be placed under the skin on your left side and is hidden underneath your arm. This location is different from that of traditional ICDs and provides excellent cosmetic outcomes.



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

Advanced Design for Completely Subcutaneous Defibrillation Therapy



Subcutaneous Electrode

An insulated wire that enables the S-ICD to sense the electrical signals.



Pulse Generator

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



LATITUDE™ NXT Remote Patient Management System

A secure remote monitoring system that collects data from your implanted device and sends this data to your healthcare provider. This system also provides you with information about device battery life and your next scheduled remote follow-up.

Ask your doctor if the EMBLEM™ MRI S-ICD System is an option to protect you from sudden cardiac arrest.

Living with the EMBLEM™ MRI S-ICD

After recovering from the procedure, you should be able to continue to enjoy travel or exercise to improve your heart's health. With the added protection against SCD, 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.



Your Recovery Process

Because every 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 of, or the day after, your S-ICD system 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.

How does the S-ICD system differ from transvenous ICDs?

With a transvenous ICD device, leads are fed through your veins, into the heart, and across a heart valve. Once the leads are in place, they are attached to the inside of the heart wall. The S-ICD system leaves the heart and vasculature untouched, which results in fewer lead complications as well as fewer complications overall.²

How long will the battery last?

The battery in the S-ICD system is projected to last close to 9 years* and can protect 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.

Can my device undergo MRI scans?

Yes, when the conditions of use are met, you can receive an MRI scan with your S-ICD system. Always discuss the need for an MRI scan and your eligibility with your doctor before scheduling an MRI scan.

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 time.

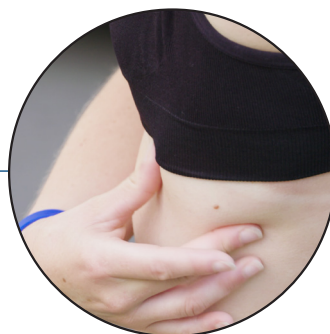
Your EMBLEM MRI S-ICD System is designed to not limit range of motion and most patients are able to resume normal daily activity shortly after the procedure.

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. Being too close to electronic or strong electromagnetic devices may cause interference with the S-ICD system, such as running motors and large magnets. Talk with your doctor for a complete list of precautions for your S-ICD system.

Will I be able to travel?

The S-ICD system does not prevent you from traveling. However, the S-ICD system is currently not available in all countries. Your doctor may guide you 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.



Checking in with Your Doctor

Your doctor will schedule regular visits to see how you are doing and to check your EMBLEM™ MRI S-ICD system. During these routine check-ups, your doctor may adjust the settings of your S-ICD System.

If your S-ICD system 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 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.



There are resources for you to help make this decision. EMBLEM™ MRI S-ICD System information, FAQ, and patient testimonials are available at sicsystem.com

*Longevity projections and the associated energy consumptions is based on analysis of >2900 EMBLEM patients followed on LATITUDE, Mar 2020.

Reference:

1. What are sudden cardiac arrest and sudden cardiac death. "Sudden Cardiac Death (Sudden Cardiac Arrest)." Available at: myclevelandclinic.org. Accessed 12/20/20.
2. Knops R. et al., A Randomized Trial of Subcutaneous versus Transvenous Defibrillator Therapy: The PRAETORIAN Trial. Heart Rhythm Society Late-Breaking Clinical Trials LBCT-01 2020.

S-ICD™ System

Important Safety Information

An implantable cardioverter defibrillator is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated with them. These devices are sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields. As with all ICD systems, there are risks associated with the S-ICD System. 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); injury to or pain in upper extremity including clavicle, shoulder, and arm; dangerous arrhythmias; stroke. 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; fainting (syncope); delivery of a shock or therapy when it is not needed (unnecessary therapy); inability to detect or appropriately treat your heart rhythms due to electromagnetic interference or malfunction; difficulty coping with having an implanted device; bleeding or formation of a blood clot (hematoma); pain and discomfort; injury to or pain in upper extremity including clavicle, shoulder, and arm; allergic reaction; need for surgical replacement. You may experience some discomfort from the incision as you recover from the surgery. In rare cases severe complications can occur, such as device failures or death. Your physician should discuss all potential benefits and risks with you and describe the appropriate medical care. Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.

Device Quality and Reliability

It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. Refer to Boston Scientific's CRM product performance report on www.bostonscientific.com for more information about device performance, including the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products. Also, it is important that you talk with your doctor about the risks and benefits associated with the implantation of a device. 92481216 (Rev B)

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Cardiology

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