

**EMBLEM™** S-ICD System

*Protection without touching your heart*

Patient Brochure



## 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.<sup>1</sup> 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 totally subcutaneous implantable defibrillator, called the EMBLEM™ S-ICD. The EMBLEM S-ICD is a device that sits just under your skin. It constantly monitors your heart—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 the EMBLEM 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.

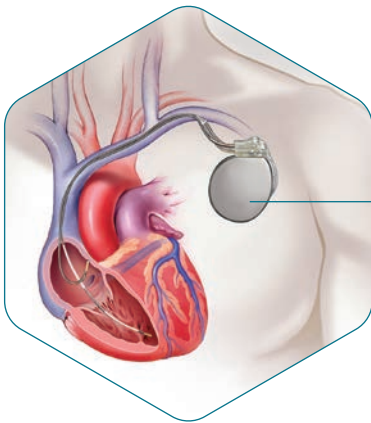
Factors such as high blood pressure or heart disease increase the risk for SCA. It's not uncommon for a person to have a heart problem and not be aware of it until after SCA has occurred.

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

## You HAVE OPTIONS

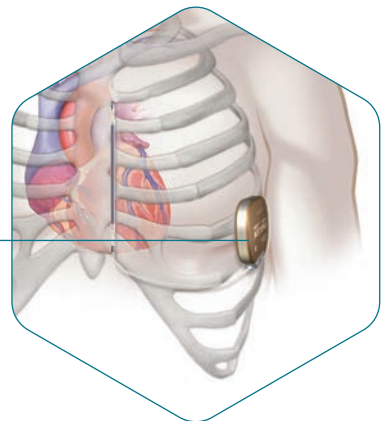
An implantable cardioverter defibrillator, commonly known as an ICD, is a device designed to administer lifesaving therapy in the event of SCA. When the ICD senses a dangerously high heart rate, it will send an electrical pulse to your heart to reset your heart's normal rhythm and allow your heart to 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 completely subcutaneous EMBLEM™ S-ICD, which does not touch the heart. 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.*

*The EMBLEM S-ICD also delivers lifesaving defibrillation therapy whenever it is needed. Unlike a transvenous ICD device, the EMBLEM S-ICD—pulse generator and electrode—is implanted just under the skin. EMBLEM S-ICD 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™ S-ICD represents a major breakthrough in defibrillation therapy and provides an important new option if you are at risk of SCA.

## ACCURATE DEFIBRILLATION THERAPY

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

## NOTHING IN YOUR HEART

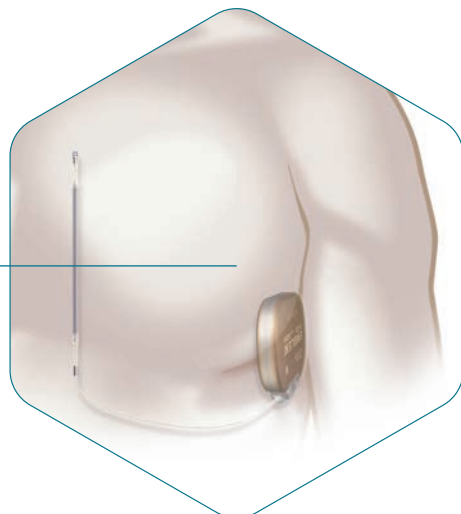
The EMBLEM S-ICD is the only implantable defibrillator that does not require electrical wires in your heart.

The EMBLEM S-ICD 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 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.

*The EMBLEM S-ICD is implanted just under your skin and provides protection from SCA.*



# 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*

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



# PREPARING *for the* IMPLANT PROCEDURE

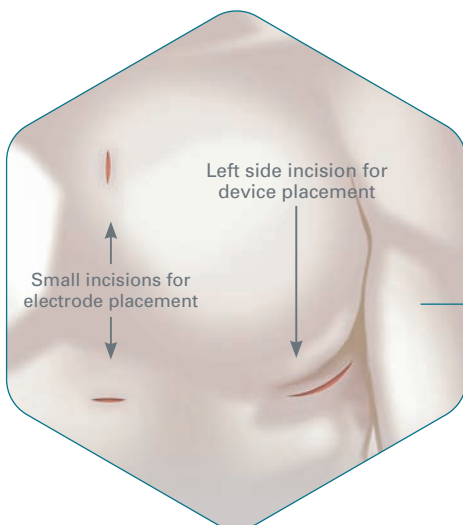
Your doctor will provide you with complete information to help you prepare for your procedure and recovery.

## 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.

### THE 6-STEP PROCEDURE IS DESCRIBED IN MORE DETAIL BELOW:

- 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 EMBLEM™ S-ICD pulse generator will be inserted.
- 3 Two small incisions are typically 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 EMBLEM S-ICD pulse generator.
- 5 Once the EMBLEM S-ICD has been implanted, most doctors will test the device.  
You will be asleep during this part of the procedure, during which the doctor induces an arrhythmia (irregular heartbeat) and the EMBLEM S-ICD is 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.



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



## LIVING *with the* EMBLEM™ S-ICD

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 SCA, the EMBLEM S-ICD 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 EMBLEM 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.



# LATITUDE™ NXT REMOTE PATIENT MANAGEMENT

Your doctor may prescribe the LATITUDE NXT Patient Management System to work with your implanted device between scheduled visits.

The LATITUDE NXT Patient Management System is an in-home monitoring system that gives your healthcare team access to information from your implanted device.

The LATITUDE Communicator checks your implanted device in the convenience of your home and sends information to a secure website that your healthcare team can view.

## CHECKING *in with* YOUR DOCTOR

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

If your EMBLEM 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 EMBLEM S-ICD 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 EMBLEM S-ICD has been designed to reduce risk of serious infection and other complications associated with electrical wires placed in the heart. However, the EMBLEM 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 EMBLEM 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 EMBLEM S-ICD.

# EMBLEM™ S-ICD: *Frequently Asked Questions*

## **Why do I need the EMBLEM S-ICD if I have already experienced an SCA?**

Although you have already experienced an SCA, 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 the EMBLEM 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 the EMBLEM 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 the EMBLEM 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 EMBLEM S-ICD will continue to monitor your heart and deliver additional shocks if needed.

## **How long will the EMBLEM S-ICD last?**

The battery in the EMBLEM 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 EMBLEM S-ICD needs to be replaced.

## **What are the risks associated with implanting the device?**

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

## **Will I be able to feel the implanted EMBLEM S-ICD?**

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

## **Is a shock from the EMBLEM 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 EMBLEM S-ICD is monitoring and responding to dangerous heart rhythm irregularities.

\* For a complete list of risks associated with the EMBLEM 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 EMBLEM™ S-ICD has been implanted.

## Will my EMBLEM S-ICD affect my ability to participate in physical activities such as running, skiing, and sexual intimacy?

Generally, the EMBLEM 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 EMBLEM S-ICD does not prevent you from traveling. However, the EMBLEM 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.

## 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 EMBLEM S-ICD know the difference between that and an arrhythmia?

With highly advanced technology, the EMBLEM 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 EMBLEM 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, or 6 inches, from the EMBLEM S-ICD. Being too close to electronic or strong electromagnetic devices may cause interference with the EMBLEM S-ICD, such as running motors and large magnets. Most medical equipment will not interfere with the EMBLEM 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 EMBLEM S-ICD.

Medical Device ID		Boston Scientific	
Implanted Cardiac Rhythm Patient			
Patient: Dave Johnson			
Physician: JOE D ANDERSON MD			
Patient Telephone: (658) 555-5555			
MFG	Product	Model/Serial	Implant DT
Guidant	AICD	1851 03609	09-OCT-2006
Guidant	Lead	0125-908910	09-OCT-2006
Guidant	Lead	425741 887766	09-OCT-2006
Guidant	Lead	82-0002-86D1 0059SK	09-OCT-2006
Guidant	Accessory	8631 123456	09-OCT-2006
Oscor	Lead	PY48SBV	09-OCT-2006
		In USA – 1.851.582.4000	
		Outside USA: (01)651.582.4000	
MAGNETIC SECURITY WANDS MAY AFFECT DEVICE FUNCTION. DO NOT HOLD WAND OVER DEVICE.		For Medical Personnel 1.800.227.3422 – 651.582.4000 www.bostonscientific.com www.lifebeatonline.com	
If your name, mailing address, or physician changes, please call Medical Records: 1.800.484.3268, 7 AM – 7 PM Central Time, Monday – Friday CR6-44301-AA			

## 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 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

Lisa received her S-ICD™ System in 2013. The device has protected her from three life-threatening arrhythmias. Embracing life in full stride as a lawyer, traveler, wife, sister, and friend, Lisa is also an impassioned S-ICD advocate and supports other people at risk of sudden cardiac arrest. Connect with her on Facebook at Living with the S-ICD.



*My device has saved my life three times, now.*





## **HOW DID YOU FEEL WHEN YOU WERE FIRST DIAGNOSED?**

"I was always active as a kid. I did sports in high school. I ran track, I did cheerleading."

"I had been running for about six years. During my training, I was struggling with peeling off some weight. So my husband, who is a personal trainer, said to me that I should go check my thyroid. And I was eventually diagnosed with arrhythmogenic right ventricular dysplasia cardiomyopathy."

"I was absolutely devastated."

## **HOW DID YOU DECIDE ON THE S-ICD™ SYSTEM?**

"So I was immediately told that I needed to get a defibrillator."

"I felt like I lost my purpose in life. I'd thought I had everything in place. We were trying to start a family, we were running, we were having fun...I felt like the wheels came off."

## **HOW DID YOU FEEL AFTER YOUR DEVICE WAS IMPLANTED?**

"My device has saved my life three times, now."

"Having cardiomyopathy, no one sees a physical change in you. It can be a very lonely place, because you're feeling sick and you know that you're not well, but people tell you that you look well. When you tell people you're sick sometimes they look at you like, "You're not really that sick," and a lot of what you suffer is silent."

"And I've found that also sharing what I'm going through helps answer questions for individuals who have never been through a shock—who are just living in fear of being shocked."

## **HOW ARE YOU FEELING NOW?**

"One afternoon, I decided I was going to start my own Facebook Group page, called Living with the S-ICD. It's really therapeutic to be there with people who are going through the same things as you are."

"I used to be a planner; I had five, ten, fifteen years where I wanted to be, but now I take every day as it comes and try to have a positive outlook. You're still gonna get up, you still gotta get out the door, you still gotta go about your daily life."

"I'd rather take the glass half full any day over the glass half empty."

## *Meet* **TODD**

Todd received his S-ICD™ System 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™ SYSTEM?

“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.”



*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.*



Learn more about EMBLEM™ S-ICD at [sicdsystem.com](https://www.sicdsystem.com)

### 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 EMBLEM S-ICD, 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.**

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. J) EMBLEM S-ICD®, SQ-RX® and Q-TRAK® are registered trademarks of Cameron Health, Inc. Q-TECH™, Q-GUIDE™ and INSIGHT™ are trademarks of Cameron Health, Inc.

### Important Patient Information for the EMBLEM S-ICD

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.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. J) EMBLEM S-ICD®, SQ-RX® and Q-TRAK® are registered trademarks of Cameron Health, Inc. Q-TECH™, Q-GUIDE™ and INSIGHT™ are trademarks of Cameron Health, Inc.

### LATITUDE™ (NXT) Patient Management System from Boston Scientific Important Safety Information

LATITUDE™ NXT Patient Management is a remote monitoring system that gives your health care provider access to your implanted device data. The LATITUDE Patient Management system is not intended to assist with medical emergencies. If you are not feeling well, call your physician or 911. The Communicator does not provide continuous monitoring. Your Communicator is designed to be used only in the United States, Canada, and Puerto Rico.

The Communicator is designed to operate on standard telephone lines like those found in most homes. The Communicator may work on other telephone systems, such as Digital Subscriber Line (DSL) and Voice Over IP (VoIP) Internet systems, if those systems provide an analog interface for connecting the Communicator.

The Communicator is designed to work only with the implanted device of the patient for whom it was prescribed. It will not work with other patients' implanted devices and should be used only as authorized by the prescribing physician. The Communicator is not for use with any pulse generator other than a Boston Scientific device. Ask your physician if you have questions about any risks with using the Communicator or your implanted device.

It is very important that the Communicator remain plugged into the power outlet. Your communicator should remain connected to a telephone line, unless you are subscribed to the LATITUDE Cellular Data Plan. Some household appliances and other sources of electromagnetic energy could interfere with the communication between your Communicator and your implanted device. You should be at least 36 inches (3 ft.) away from televisions, VCRs, DVD players, personal computers, and other electronic equipment, when you are using the Communicator. It is recommended that the customer install a surge arrester in the electrical outlet to which the Communicator is connected.

Rx only (Rev.C)

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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. National Heart, Lung, and Blood Institute – What is Sudden Cardiac Arrest? Available at: [http://www.nhlbi.nih.gov/health/dci/Diseases/scda/scda\\_whats.html](http://www.nhlbi.nih.gov/health/dci/Diseases/scda/scda_whats.html). Accessed June 7, 2014.
3. 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 EMBLEM S-ICD. Please review the appropriate literature accompanying the components of the EMBLEM S-ICD for a complete listing of warnings and precautions.

### After your doctor implants your EMBLEM S-ICD, 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 EMBLEM S-ICD is replaced, the potential risks may be similar to, or even greater than, those of your original EMBLEM S-ICD 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.



### Rhythm Management

4100 Hamline Avenue North  
St. Paul, MN 55112-5798

[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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