Boston Scientific

EMBLEM™ S-ICD System
Patient Handbook


Outdated version.
Version obsolète. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úrelt útgáfa. Notið ekki.
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Zastaralá verzia. Nepoužívať.
Različica. Ne uporabite.
Använd

Your EMBLEM S-ICD System information

Have your doctor or nurse complete these forms before you go home from the hospital.

S-ICD Model Number: _____

S-ICD Serial Number: _____

Implant Date: _____

Subcutaneous Electrode Model Number: _____

Subcutaneous Electrode Serial Number: _____

Your medical contact information

Cardiologist Name/Phone Number:

_____

Electrophysiologist Name/Phone Number:

_____

Hospital Name/Address/Phone Number:

_____

_____

Medications (list): _____

_____

_____

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Introduction to the EMBLEM S-ICD System

Your physician has recommended a Boston Scientific minimally invasive implantable defibrillator (EMBLEM S-ICD System). The EMBLEM S-ICD System is designed as a life saving measure to treat your heart rhythm abnormalities.

Your physician may have prescribed this device for you for one of the following reasons:

- You have experienced an abnormally rapid heart rhythm (Ventricular Tachycardia or Ventricular Fibrillation)
- You are at risk of developing an abnormally rapid heart rhythm.

These rapid heart rhythms, known as cardiac arrhythmias, may be life threatening. When a cardiac arrhythmia occurs, it interrupts the normal pumping function of the heart. This disruption of normal heart function may lead to loss of consciousness, and ultimately, be lethal.

The minimally invasive S-ICD System is a treatment for correcting an abnormally rapid heart rhythm. The S-ICD System is not a cure for the underlying cause of your cardiac arrhythmia, but rather provides defibrillation (shock) therapy to restore your heart to its normal rhythm.

About this guide

This patient handbook provides information on:

- *Glossary of terms*
- *Anatomy of the heart*
- *Heart rhythm*
- *The S-ICD System*
- *Implant procedure*
- *Post operative events*

Note: *Your physician will discuss any potential risks or adverse events that may be associated with your implanted S-ICD System. However, be sure to carefully read and understand all warnings and safety precautions discussed in this guide.*

The Glossary on page 6 defines many of the words you will see in the upcoming pages, as well as those you may hear from your doctors and nurses.

If you have questions about what you read in this handbook, ask your doctor or nurse. They are your best resource for information.

When is this device used?

Your doctor has decided that you should receive a defibrillator because you have an increased risk of sudden cardiac death due to ventricular rhythm disturbances, and you do not have other types of arrhythmias that would be more appropriately treated with a pacemaker or other type of implanted device. Sudden cardiac death is a result of sudden cardiac arrest, which occurs when electrical problems in the heart cause an abrupt loss of heart function. If you have any questions about when this device is used, ask your doctor.

When is this device not used?

Patients who have other implanted devices delivering unipolar stimulation or using certain impedance-based features should not receive this device. If you have any questions about when this device is not used, ask your doctor.

How reliable is this device?

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. Talk with your doctor about this product performance data, and the risks and benefits associated with the implantation of this system.

Glossary

Antitachycardia pacing (ATP)

A series of small, rapid, low-energy pacing pulses delivered to the heart to slow a rapid heartbeat to its normal rhythm.

Arrhythmia

An abnormal heartbeat that is too fast, too slow, or irregular.

Atrium (plural: atria)

One of the two upper chambers of the heart—specifically, the right atrium and left atrium. The atria collect blood as it comes into the heart and pump blood into the lower chambers (ventricles).

Bradycardia

An abnormally slow heartbeat, typically fewer than 60 beats per minute.

Cardiac arrest

See *Sudden cardiac arrest (SCA)*.

Communicator

See *LATITUDE Communicator*.

Defibrillation

Procedure in which a fast heart rate (i.e., ventricular fibrillation, ventricular tachycardia) is restored to a normal rhythm by delivering an electrical shock.

Defibrillator

A device that delivers an electrical shock to the heart to restore an extremely rapid and sometimes irregular heart rate to a normal rhythm. A defibrillator may be an implanted medical device or external medical equipment.

Device

See *Pulse generator*.

ECG/EKG (electrocardiogram)

A graphic representation of your heart's electrical signals. The graph shows how electrical signals travel through your heart. Your doctor can tell what kind of rhythm you have by looking at the pattern of your heartbeat.

Echocardiogram

A test used to measure your heart's pumping function (ejection fraction).

Ejection fraction

The percentage of blood ejected from the left ventricle with each heartbeat. A healthy ejection fraction is usually higher than 55%, although this can vary depending on the individual. Patients with a low ejection fraction may have an increased risk of sudden cardiac arrest.

Electromagnetic field

Invisible lines of force that result from electrical fields (produced by voltage) and magnetic fields (produced by current flow). Electromagnetic fields decrease in strength the farther they are from their source.

Electromagnetic interference (EMI)

Interference that occurs when an electromagnetic field interacts with an implanted device. See also *Electromagnetic field*.

Electrophysiology (EP) test or study

A test in which catheters (thin, flexible tubes or wires) are inserted into your heart to identify and measure the type of electrical signals in your heart. The test results can help your doctor identify the origins of your abnormal heart rhythms, determine how well medications work, and decide what treatment is best for your condition. The test can also be used to see how well your device operates during your abnormal heart rhythm.

Fibrillation

See *Ventricular fibrillation (VF)*.

Heart attack

See *Myocardial infarction (MI)*.

Heart rhythm

A series of heartbeats. You may hear your doctor refer to your rhythm as being normal or irregular. A normal heart rate typically ranges from 60 to 100 beats per minute at rest.

Holter monitor

An external monitor worn for an extended period that records your heart's electrical activity.

Implantable Cardioverter Defibrillator (ICD) system

An ICD system is implanted to monitor your heart rhythm and help treat dangerously fast arrhythmias. There are two types of ICD systems:

- Transvenous ICD systems include a pulse generator and leads. The leads are inserted into your blood vessels and directly contact the heart tissue.
- Subcutaneous ICD systems include a pulse generator and a subcutaneous electrode. The subcutaneous electrode is inserted just under the skin of your chest and does not directly contact the heart tissue.

Interrogation

The process whereby a computerized device (programmer or LATITUDE Communicator) uses telemetry communication signals to gather identification and status information from your device. Your doctor uses this information to evaluate how your device is performing and check for any arrhythmia episodes you may have had.

LATITUDE Communicator

An in-home monitoring system that communicates with your device. The Communicator can gather and send device data to the LATITUDE Patient Management System, which your physician can then view via the Internet. Your device may or may not be configured to use the LATITUDE Patient Management System. See also *LATITUDE Patient Management System*.

LATITUDE Patient Management System

A remote monitoring system that collects important data from your device. This patient information can be viewed via the Internet, only by members of your health care support team. Your device may or may not be configured to use the LATITUDE Patient Management System. See also *LATITUDE Communicator*.

Myocardial infarction (MI)

Also called a heart attack. A myocardial infarction occurs when an artery that supplies blood to the heart becomes blocked. As a result, blood does not reach some parts of the heart, and some of the heart tissue dies. Symptoms of a myocardial infarction may include shortness of breath, nausea, fatigue, and/or pain in the chest, arm, or neck.

Programmer

Microcomputer-based equipment that is used to communicate with the device. The programmer is used during testing and follow-up exams to gather and display information from the device. The doctor or technician also uses the programmer to adjust the device so that it senses and treats your arrhythmias.

Pulse generator

Also called a device. The pulse generator is the part of the S-ICD system that contains the electronics and the battery.

Radio frequency (RF) wireless communication

Technology that allows the device to exchange information with a programmer or LATITUDE Communicator by communicating over radio signals.

Sinoatrial (SA) node

The heart's natural pacemaker. The SA node is a small group of specialized cells in the upper right chamber of the heart (right atrium) that normally generates an electrical signal. This signal runs through the heart and causes the heart to beat.

Sternum

(Breast bone) Bone located in the center of the chest which connects the ribs.

Subcutaneous

Just beneath the skin

Subcutaneous electrode

An insulated wire that is implanted under the skin and connected to the device. The subcutaneous electrode senses your heartbeat and delivers pacing pulses and/or shocks from the device to the heart.

Sudden cardiac arrest (SCA)

The sudden, abrupt loss of heart function (i.e., cardiac arrest) due to electrical problems in the heart. If untreated, SCA can lead to death (also called sudden cardiac death).

Sudden cardiac death (SCD)

Death occurring from sudden cardiac arrest. See also *Sudden cardiac arrest (SCA)*.

Supraventricular tachycardia (SVT)

A fast heart rhythm caused by signals coming from a specific area above the ventricles, usually in the atria. A heart with SVT may beat over 150 beats per minute, which may produce palpitations and fluttering in the chest.

Telemetry communication

Technology that allows a device to exchange information with a programmer or LATITUDE Communicator by using radio frequency (RF) telemetry communication.

Ventricle

One of two lower chambers of the heart. The right ventricle pumps blood to the lungs, and the left ventricle pumps oxygen-carrying blood from the lungs to the rest of the body.

Ventricular fibrillation (VF)

A very fast, irregular heart rhythm caused by abnormal electrical signals starting from several areas of the ventricle. In VF, the ventricle beats so fast that it pumps very little blood to the body. A heart in VF may beat more than 300 beats per minute. Without immediate medical

attention, VF can be fatal. Defibrillation is the only way to treat VF once it occurs.

Ventricular tachycardia (VT)

A fast rhythm caused by abnormal electrical signals coming from the ventricle. The rapid rate of 120 to 250 beats per minute may produce dizziness, weakness, and eventual unconsciousness. VT may progress to ventricular fibrillation.

Wireless communication

Technology that allows a device to exchange information with a programmer wirelessly. See also *Radio frequency (RF) wireless communication*.

Understanding your heart

This section will discuss the basic function of the normal heart and will also explain what happens when the heart develops abnormally rapid heart rhythms.

The normal heart

The heart is divided into four chambers: two upper chambers called the atria and two lower chambers called the ventricles. The four chambers fill with blood when the heart is at rest and then pump the blood throughout the body with each heart contraction (Figure 1 on page 17).

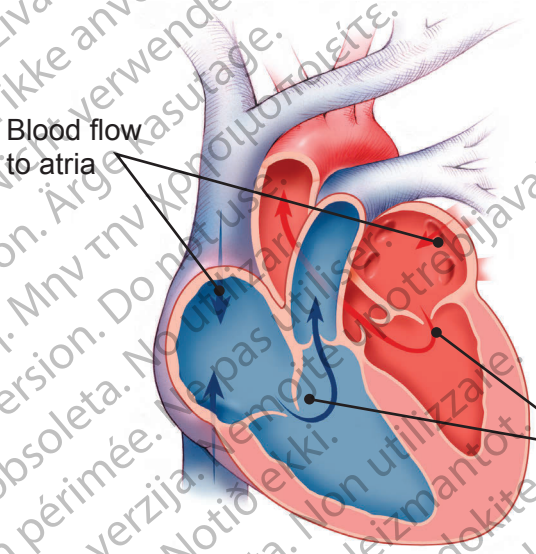

Figure 1. The heart and its blood flow.

The heart has a specialized conduction system that produces electrical impulses that stimulate the heart to contract (Figure 2 on page 18). Normally, your heart's pumping action is controlled by steady electrical signals that are produced by your heart's natural pacemaker, the sinoatrial (SA) node. Electrical signals from the SA node

travel through the atria and follow an electrical pathway to the ventricle. This creates an electrical stimulation that causes the heart muscle to contract. The heart then rests and fills with blood until the next contraction occurs. This cycle occurs millions of times in a year.

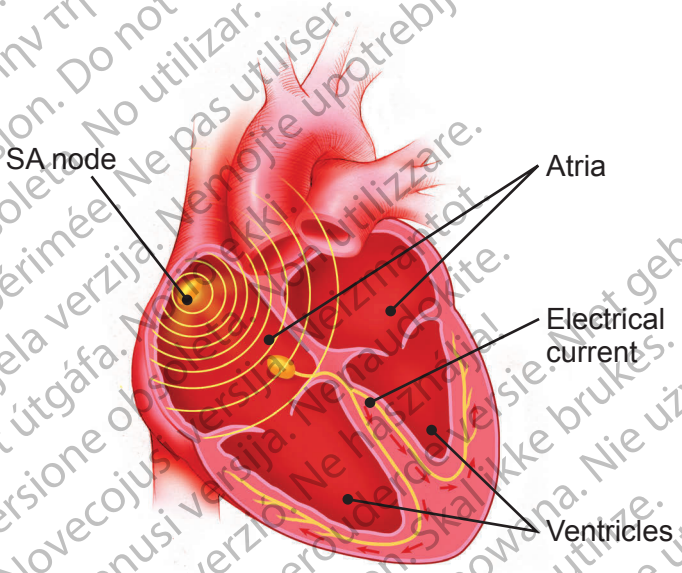

Figure 2. The heart and its electrical pathways.

Normal resting heart rates are usually in the range of 60 to 100 beats per minute. However, your heart rate may increase or decrease outside this range depending on activity levels. Generally, the heart rate will increase during exercise and decrease during sleep.

When the heart beats too fast

An abnormal condition exists when your heart rate increases significantly in the absence of exercise or emotional stress. This is known as a tachycardia. Not all tachycardias cause serious problems. Some tachycardias may cause discomfort, but are not life threatening; whereas other tachycardias may be very serious and life threatening.

Tachycardias are also associated with injury to the heart muscle, which can occur with coronary artery disease. Coronary artery disease may cause a myocardial infarction (commonly referred to as a heart attack), which may damage the heart muscle. Tachycardias may also result from other diseases or certain genetic defects that weaken the heart muscle.

If this rapid heartbeat continues, you may feel skipped beats or dizziness. You could eventually become unconscious, and your heart might stop beating (cardiac arrest).

Ventricular tachycardia

One type of arrhythmia you may experience is ventricular tachycardia (VT). With this type of arrhythmia, your heart's electrical signals may come from one of the ventricles instead of the SA node (Figure 3 on page 21). The electrical signal does not pass through the heart normally and causes a fast, sometimes irregular heartbeat. As your heart beats faster, it pumps less blood to your body. If this rapid heartbeat continues, you may feel skipped beats or dizziness. You could eventually become unconscious, and your heart might stop beating (cardiac arrest).

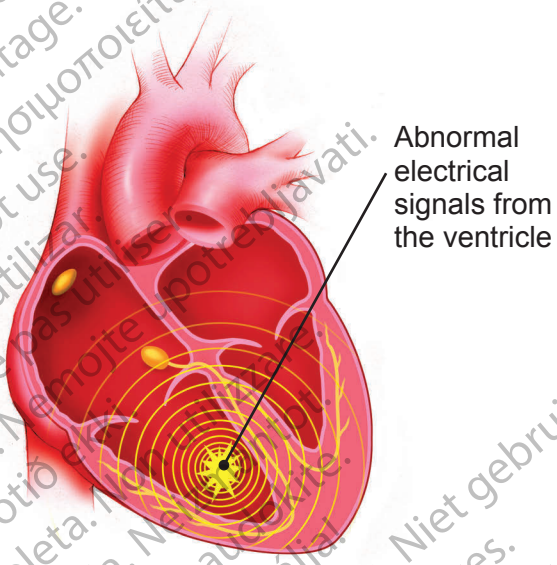

Figure 3. An example of ventricular tachycardia.

VT can sometimes be treated with medication. In other cases, an external defibrillator—such as those used by paramedics—or an ICD may be used to stop the abnormal signals and return your heart to a more normal rhythm.

Ventricular fibrillation

Another type of arrhythmia is ventricular fibrillation (VF). With this arrhythmia, irregular electrical signals come from several spots in the ventricles (Figure 4 on page 22). This causes a rapid heart rate. In some cases, the heart will beat more than 300 beats per minute.

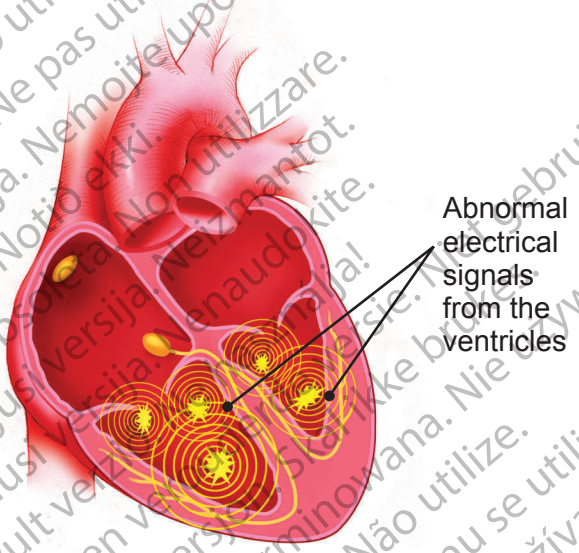

Figure 4. An example of ventricular fibrillation.

When you experience VF, very little blood is pumped from your heart to the rest of your body. When your heart is in VF, you will become unconscious very quickly. Like ventricular tachycardia, VF can be treated with a defibrillator. The defibrillator produces an electrical shock that passes through the heart. The shock stops the abnormal signals and allows the SA node to return the heart to a more normal rhythm.

If an episode of VT or VF continues without medical treatment, your heart cannot supply enough oxygen-carrying blood to your brain and body tissues. Without oxygen, your brain and body tissues cannot function normally, which could be fatal.

Why do I need a minimally invasive S-ICD System?

Your physician has recommended implantation of a minimally invasive S-ICD System because you are at risk

for VT or VF. Some heart disorders that are associated with risks of developing VT or VF are listed below:

- Heart Attack: Occurs when there is a complete or sudden loss of oxygen-rich blood flow to the heart muscle due to a blocked or narrowed coronary artery. Due to the lack of an oxygen-rich blood supply, a portion of the heart muscle is injured.
- Heart Failure: A condition in which the heart cannot pump enough blood to the body or other organs.
- Cardiomyopathy: A disease process that causes the heart to become abnormally large, thickened or stiffened. As a result, the heart muscle weakens, decreasing the heart's ability to pump blood efficiently to the body.
- Primary Rhythm Disorder: An abnormality within the conduction system in the heart.

Am I at risk for developing a ventricular tachycardia or ventricular fibrillation?

When a portion of the heart muscle is injured or the heart is abnormally enlarged, the heart is not able to pump blood efficiently to the body. Measurements may be made to assess the condition of your heart. One such measurement is known as ejection fraction (EF). EF measures how much blood is pumped out to the body with each heart beat, or contraction.

Medical studies have determined that patients who have a low EF measurement are particularly at risk for developing ventricular tachycardias or ventricular fibrillation.

Sudden cardiac arrest

A cardiac arrhythmia such as ventricular fibrillation may lead to sudden cardiac arrest. The result of sudden cardiac arrest is that the heart fails to pump blood to the body. Because the heart does not pump enough blood throughout the body, most people tend to lose consciousness suddenly. If SCA is not treated, it can lead to sudden cardiac death (SCD). The only way to stop ventricular fibrillation is to deliver an electrical shock with a defibrillator.

Risk factors

Most people do not have obvious symptoms of SCA, so it is important to be aware of possible risk factors:

- Previous heart attack
- Impaired pumping function of the heart muscle
- Rapid, abnormal heart rhythms coming from the ventricles
- A family history of SCA or SCD

Early identification of your SCA risk is the key to prevention. If you are at risk, it is important to talk to your doctor.

Identifying your SCA risk

Your doctor may perform one or more of the following tests to assess your risk for SCA.

Echocardiogram: An echocardiogram is a test that measures your heart's ejection fraction. The ejection fraction determines your heart's pumping function. During this test, ultrasound waves are used to provide a moving image of your heart. Based upon the results of this test, your doctor will determine if further testing is needed.

Holter monitoring: A Holter monitor is an external monitor that is worn for an extended period. The monitor records your heart's electrical activity, including any arrhythmias you experience. Your doctor analyzes the recording to determine if you experience any abnormal rhythms.

Electrophysiology (EP) testing: An EP test identifies and measures the type of electrical signals in your heart. During this test, your doctor will insert catheters (thin, flexible tubes or wires) into your heart. The catheters record electrical signals within your heart. Your doctor can also use the catheters to stimulate your heart to see if you could develop an arrhythmia. This test can help your doctor recognize if you have an abnormal heart rhythm and identify its origins. It will also determine how well certain medications or an implanted device would work to treat your heart rhythm. Your doctor can then decide what treatment is best for your condition.

The implantable components of the minimally invasive EMBLEM S-ICD System are implanted beneath the surface of the skin outside the rib cage.

EMBLEM S-ICD System components

Pulse generator

The pulse generator is a battery powered, computer controlled device encased in metal. The pulse generator is typically implanted on the left side of the chest wall.

Various settings and parameters for the pulse generator are programmable through wireless communication with an external programmer. Your physician can program various settings in your pulse generator to accommodate your particular cardiac condition. When the pulse generator detects an abnormally rapid heart rhythm, a shock is delivered to restore the heart back to its normal rhythm. This shock therapy is called defibrillation. The S-ICD System will record and store these abnormally rapid heart rhythms.

Your physician may retrieve the saved information during your routine scheduled follow-up visits. This can be accomplished via a wireless external programmer.

Subcutaneous electrode

The subcutaneous electrode comprises a partially coated (insulated) wire that is surgically implanted just under the skin, parallel to the breastbone (sternum). The subcutaneous electrode is connected to the pulse generator (Figure 5 on page 30).

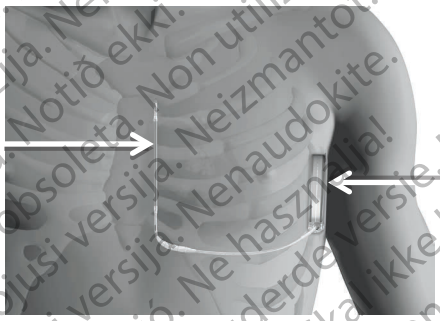

Figure 5. Subcutaneous electrode placement

The S-ICD System uses the electrode to sense electrical signals in the heart. When necessary, the S-ICD System delivers a shock to restore the heart back to normal rhythm.

Materials

The pulse generator and electrode materials that come in contact with the body have been tested for bio-compatibility. The pulse generator and electrode are composed of titanium and other metals (Table 1 on page 32). Allergic reactions are uncommon, but you should discuss any known allergies to metals with your physicians.

Table 1. Patient-contacting Materials

Material	% of Total Exposed Surface Area
Pulse Generator (Models A209, A219)	
Cured epoxy	14%
Titanium (with titanium nitride coating)	86%
Electrode (Model 3501)	
Polycarbonate polyurethane	40%
Metal alloy (MP35N®[1,2])	35%
Silicone	25%

[1] MP35N is a registered trademark of SPS Technologies, Inc.

[2] This material contains cobalt. Based on animal studies, the European Commission has classified cobalt as a substance that may:

- cause cancer, or
- interfere with normal reproduction.

However, research shows that metal alloys containing cobalt used in medical devices do not cause an increased risk of these effects. Talk with your doctor if you have questions about your device.

Understanding the implant procedure

Depending on the hospital and physician practice, local or general anesthesia is administered to make you comfortable during the implant procedure. The duration of the implant procedure will vary depending on the type of anesthesia. Because of the lateral location of the pulse generator, females may have to consider undergarments and clothing that do not cause discomfort in the vicinity of the pulse generator pocket.

The following section outlines one of several surgical approaches that can be used to appropriately implant and position the S-ICD System (Figure 6 on page 34). Your doctor will determine the optimal implant method and location for your S-ICD System depending on your physical anatomy and lifestyle considerations.

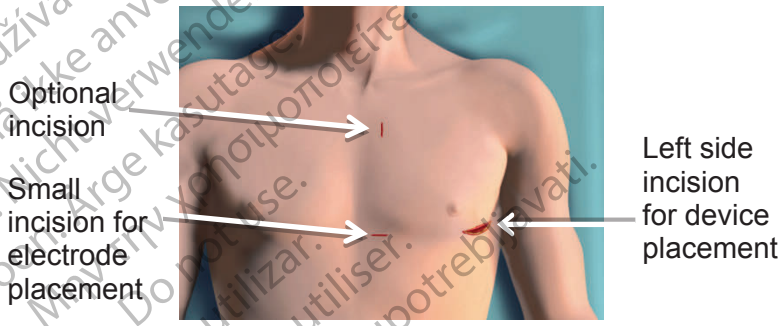

Figure 6. Implant procedure.

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 for the placement of the pulse generator.
3. Either one or two small incisions are made close to the breastbone allowing placement of the subcutaneous electrode under the skin.
4. The subcutaneous electrode is connected to the pulse generator.
5. Your physician will then test your S-ICD system. During this test, your physician will start an

arrhythmia in your heart. The device will recognize the rhythm and give a therapeutic shock. During this testing you will be sedated to minimize any discomfort.

6. Testing and adjustments are accomplished by the S-ICD System Programmer.
7. Once the incisions are closed, the procedure is complete.

Discharge from the hospital

Recovery from your S-ICD System implant procedure should not prevent you from returning to an active lifestyle. Follow your physician's post-operative instructions.

Benefits and risks of having an S-ICD System

Your physician has decided that you should receive an implantable defibrillator (ICD) because you have an increased risk of sudden cardiac death due to ventricular rhythm disturbances. In particular, your physician believes

you may benefit from the S-ICD System. The S-ICD System avoids some complications associated with transvenous leads by providing therapy without a lead(s) placed inside your heart. Additionally, the S-ICD System does not require the use of x-ray radiation during the implant procedure.

As with all ICD systems, there are risks associated with the S-ICD System. Although infrequent, 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
- Death

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

Be sure to talk with your physician so that you thoroughly understand all of the risks and benefits associated with the implantation of this system.

Report any serious incident that occurs in relation to your device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country.

For customers in Australia, report any serious incident that occurs in relation to your device to Boston Scientific and to the Therapeutic Goods Administration (https://www.tga.gov.au).

After your implant

As you recover from your implant surgery, you will find that your device may allow you to return to an active lifestyle. It is important that you become actively involved in your recovery by following your doctor's instructions, including:

- Report any redness, swelling, or drainage from your incisions.
- Avoid lifting heavy objects as instructed by your doctor.
- Walk, exercise, and bathe according to your doctor's instructions.
- Do not wear tight clothing that could irritate the skin over your device.
- Contact your doctor if you develop a fever that does not go away in two or three days.
- Ask your doctor any questions you may have about your device, heart rhythm, or medication.
- Avoid rubbing your device or the surrounding area.

- Avoid rough contact that could result in blows to your implant sites.
- Tell your other doctors, dentists, and emergency personnel that you have an implanted device and show them your Implant Card.
- Contact your doctor if you notice anything unusual or unexpected, such as new symptoms or symptoms like the ones you experienced before you received your device.

Medications

Your device is designed to help treat your heart condition. However, you may need to continue taking certain medications as well. It is important that you follow your doctor's instructions regarding any medications.

Activities and exercise

Your doctor will help you decide what level of activity is best for you. He or she can help answer your questions

about lifestyle changes, travel, exercise, work, hobbies, and sexual intimacy.

Your S-ICD System information

Have your doctor or nurse complete the “Your EMBLEM S-ICD system information” form at the front of this handbook before you go home from the hospital.

Patient responsibilities

This section provides an outline of what you should know about your S-ICD System and returning to your daily activities postsurgery.

Preparing for S-ICD shock therapy

While the device's monitoring of your heart won't cause any noticeable sensations, shock therapy for an arrhythmia may be very noticeable. It is important that you know what to expect.

Before you experience symptoms or receive a shock, discuss with your doctor or nurse a plan for contacting your doctor and, if necessary, emergency personnel. Use the forms in this handbook to write down important telephone numbers and information about your current medications. It might be helpful to keep this information near your phone.

If you have symptoms of a fast heart rate, it is likely that your device will deliver therapy within a few seconds. Try to remain calm, and find a place to sit or lie down.

The sensation from receiving therapy should only last a moment.

It is possible, however, that you may require additional medical attention. Be sure to talk with your doctor about what you should do, and consider the following suggestions:

1. If possible, have someone who is prepared to perform cardiopulmonary resuscitation (CPR)—should you need it—stay with you through the event.
2. Make sure a friend or family member knows to phone your local emergency response system if you remain unconscious.
3. If you are conscious but do not feel well after a shock, have someone call your doctor.
4. If you feel fine after a shock and no more symptoms appear, it may not be necessary to seek medical help immediately. However, follow your doctor's instructions for when to call his or her office. For example, if a shock occurs at night, your doctor may tell you to call

him or her the next morning. Someone at the doctor's office will ask you questions such as:

- What were you doing right before the shock?
- What symptoms did you notice before the shock?
- At what time did the shock occur?
- How did you feel right after the shock?

5. It is possible that you could feel symptoms of an arrhythmia but not receive therapy. This depends on the programmed settings of your device. For example, an arrhythmia may cause symptoms, but it may not be fast enough for your device to deliver therapy. In any case, if your symptoms are severe or continue for more than a minute or so, you should seek immediate medical attention.

Special considerations

Your doctor might ask you to avoid activities where the risk of unconsciousness could endanger you or others. These

activities might include driving, swimming or boating alone, or climbing a ladder.

When to call your doctor

Your doctor will provide guidelines for when you should contact him or her. In general, phone your doctor if you:

- Receive any arrhythmia therapy from your device and have been instructed to call.
- Have symptoms of an abnormal heart rhythm and have been instructed to call.
- Notice any swelling, redness, or drainage from your incisions.
- Develop a fever that does not go away in two or three days.
- Have questions about your device, heart rhythm, or medications.
- Plan to travel or move away. Work with your doctor to develop a follow-up plan while you are away.

- Hear any beeping sounds from your device. This indicates that your device needs to be checked immediately. See “What should you do if your device starts to beep?” on page 48.
- Notice anything unusual or unexpected, such as new symptoms or symptoms like the ones you had before you received your device.

Remember that your device is designed to monitor and treat your life-threatening arrhythmias. It can be a great source of reassurance for you and your friends and family.

Follow-up visits

To ensure that your S-ICD System continues to function properly, maintain the follow-up visit schedule that is prescribed by your physician. Check with your physician to determine the frequency of these visits. Your physician will arrange a follow-up plan with you to check your device and overall health on a regular basis. It is important that you attend your scheduled in-office follow-up visits, even if you are feeling well.

A typical follow-up visit takes about 20 minutes. During your visit, your doctor or nurse will use the programmer to interrogate, or check, your device. They will review your device's memory to evaluate its performance since your last visit and check for any arrhythmia episodes you may have had. If necessary, they will adjust your device's programmed settings. They will also check the battery to see how much energy is left.

It is important to follow your physician's instructions as well as these recommendations:

- Follow-up visits are typically every 3-6 months.
- Ask your physician if you have any questions about or notice anything unusual with your device.
- Take the medications prescribed for you as instructed by your physician.
- Carry your medication list with you at all times.

Remote follow-up sessions

Your physician may want you to use the LATITUDE Patient Management System. When using the LATITUDE Patient

Management System, you will receive a home monitoring unit called a Communicator. The Communicator is used to interrogate your device on a regular schedule that is set by your physician. The Communicator then sends the data gathered from your device to the LATITUDE Patient Management secure database. Your doctor can then access this database using an Internet-enabled personal computer.

While use of the Communicator does not eliminate the need for in-office visits that may be scheduled by your physician, it can minimize the number of them. The Communicator cannot reprogram or change any functions of your device. Your physician can only do this using a programmer during an office visit.

What should you do if your device starts to beep?

As a safety feature, the S-ICD System has a built-in self-monitoring function that checks the circuitry of the pulse generator. If you should hear beeping tones coming from your pulse generator, contact your physician. The beeping

indicates that your S-ICD System requires immediate follow-up by your physician. Your physician or nurse can demonstrate these beeping tones so you will recognize them. Even though the system has this warning system, you should always follow your physician's instructions for regular follow-up visits.

What you should know about your device's battery

A battery, safely sealed inside your device, provides the energy needed to monitor your heart rhythm, pace your heart, or deliver electrical therapy. Just like any other type of battery, the battery in your device will be used up over time. Since the battery is permanently sealed within your device, it cannot be replaced when its energy is depleted. Instead, your entire device will need to be replaced (see "Replacing your system" on page 50). How long your device's battery lasts depends upon the settings your doctor programs and how much therapy you receive.

How will you know if your device's battery is running down?

Device batteries have very predictable behavior over time. Your device will regularly check its own battery. At every follow-up visit, the doctor or nurse will also check to see how much energy is remaining in the battery. When the battery's energy level decreases to a certain point, your device will need to be replaced.

You may hear the device beeping when replacement time is near. See "What should you do if your device starts to beep?" on page 48.

Replacing your system

Eventually, the energy in your device's battery will decrease to a point where your device will need to be replaced (see "What you should know about your device's battery" on page 49). Your doctor will monitor your device's battery levels and determine when to replace your device.

To replace your device, your doctor will surgically open the pocket of skin where your device is located. He or she will disconnect your old device from your subcutaneous electrode and then check to make sure your subcutaneous electrode works properly with your new device.

In rare instances, your subcutaneous electrode may not work properly with your new device, and your doctor may need to replace the subcutaneous electrode. Your doctor will determine if your subcutaneous electrode should be replaced.

Should a subcutaneous electrode need to be replaced, your doctor will insert a new subcutaneous electrode under the skin, similar to how the original subcutaneous electrode was implanted. See “Implanting your EMBLEM S-ICD System” on page 33.

Your doctor will then connect the subcutaneous electrode to your new device. Finally, he or she will test your new system to make sure it is working properly. After the testing is complete, the pocket of skin will be closed. You may experience some discomfort from the incision as you

recover from the surgery. You should be able to return to normal activities soon after the procedure.

Risks

Risks encountered during a device and/or subcutaneous electrode replacement procedure are similar to the risks of the initial implant, such as infection, tissue damage, and bleeding. See “Benefits and risks of having an S-ICD System” on page 35. Be sure to talk with your doctor about the potential risks when making decisions about replacing your system.

Questions you may have about living with your EMBLEM S-ICD System

How do I know my device is working properly?

Regular follow-up visits are required to assess your S-ICD System. Therefore, it is important to follow your physician’s instructions regarding regular follow-up visits.

How do I know if increased heart rate will result in a shock, for instance from exercise?

Your heart rate will generally increase when you exercise. Your physician can program the S-ICD System to deliver therapy only when your heart exceeds a certain rate. While inappropriate shocks may occur, there are special features in the S-ICD System that are designed to tell the difference between high rates due to vigorous exercise and those due to an arrhythmia that needs therapy. Your physician can explain how your device is programmed and which heart rates could result in a shock.

Is pacing available in the S-ICD System?

Pacing used to treat slow heart rates (Bradycardia) is only available following shock therapy. Following shock therapy, the heart may slow down or be interrupted for a brief period. The pacing following shock therapy is used for temporary support until your own heart rate returns to normal.

How often does the S-ICD System deliver therapy?

Therapy delivery varies for each patient and may be dependent upon your specific heart condition.

How long will the pulse generator last?

The lifetime of the pulse generator is based on the battery. The battery in the pulse generator will typically last seven years. There are factors that could affect battery life including your heart condition and the amount of therapy you receive. Your device will regularly check its own battery. At every follow-up visit, the physician or nurse will also check to see how much energy is remaining in the battery. When the battery's energy level decreases to a certain point, the device may begin to beep and will need to be replaced.

How long will the subcutaneous electrode last?

The lifetime of the electrode is based on design and testing. The electrode will typically last a minimum of 10 years. Your doctor will monitor the long-term performance of your implanted electrode and will determine if and when the electrode may need to be replaced.

What will it feel like if I receive a shock?

Patients vary in their descriptions of experiencing a shock. These descriptions range from a “mild thump” to a “swift kick” in the chest. Most patients are reassured in knowing that a rapid heart rhythm was treated with the shock and they can resume their normal daily routine. Follow your physician’s instructions if you receive a shock.

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

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

Will I be able to engage in sexual intimacy?

For most patients, sexual intimacy is not a medical risk. The natural heart rate increase that occurs during sex is the same as the heart rate increase when you exercise.

Exercise testing at the hospital will help your physician program your device settings so you should not get a shock during sex. If you receive a shock during sex, your partner may feel a tingling sensation. The shock is not harmful to your partner. Be sure to let your physician know if you receive a shock during sex so he or she can consider reprogramming your device.

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

Most people are aware of the implanted S-ICD System, but become accustomed to it quickly. For some patients, discomfort or pain near the pulse generator or electrode may last for several weeks. In rare situations, surgical repositioning may be required to resolve discomfort.

What should I do if my device is beeping?

Make note of what you were doing then contact your physician.

Can I exercise?

The S-ICD System itself does not prevent you from exercising. Follow your physician's instructions on the

amount and type of exercise you are permitted to do after implantation of the S-ICD System.

When can I resume driving?

Your physician will advise you if, and when, you may drive after your S-ICD System has been implanted. This decision is based upon your specific heart condition. The driving laws for patients who have implantable defibrillation devices vary from state to state and country to country. Most S-ICD System patients who previously drove can resume driving. There are no physical driving impediments attributable to the S-ICD System. Furthermore, protection afforded by the S-ICD System helps make driving safe of lethal arrhythmia symptoms. Receiving a shock during driving is usually uncommon.

Can I travel?

The S-ICD System does not prevent you from traveling. Check with your physician about any travel-related considerations for before, during or after your trip. Your physician may give you guidance on whom to speak with or contact when traveling. If you are traveling overseas,

you may also contact Boston Scientific for the location of hospitals that implant and provide follow-up support for the S-ICD System.

Can I use a cellular phone?

If you use a cellular phone or a cordless phone, it is best to keep the phone more than 15 centimeters or 6 inches from your S-ICD System. It is further recommended that your cellular phone be carried on the opposite side of the implanted S-ICD System. When talking on the cellular phone, hold the cellular phone on the opposite side of the body away from the implantation site. The cellular phone may affect the therapy functions of the S-ICD System. Consult your physician if you have specific questions about the S-ICD System and the potential interaction with cellular phones.

Electromagnetic interference

An electromagnetic field is created when using electrical and magnetic devices. Most of the electrical and magnetic devices you encounter create weak electromagnetic fields. Your S-ICD System is designed to protect itself from these electromagnetic fields and proper operation of your S-ICD System will not be affected when you are around the electrical and magnetic devices that create such fields.

Some electrical and magnetic devices, however, emit strong electromagnetic or radio frequency fields, which can temporarily affect the function of the S-ICD System. This form of interference is called electromagnetic interference (EMI). Typically, normal S-ICD System function resumes when you move away from the electrical and magnetic devices creating the EMI. It is important for you to be aware of what electrical and magnetic devices are likely to interfere with your S-ICD System's normal function. The following paragraphs help you identify the EMI safety of particular appliances, tools and activities. If your

employment requires you to be close to large industrial generators or sources of radar you may need special consideration before returning to work. If your work takes place in such an environment, please talk with your physician.

Household appliances and common tools

The S-ICD System allows you to safely operate most household appliances, office equipment and common tools that are properly grounded and in good repair. Use the following guidelines for safe interaction with many common tools, appliances, and activities.

Items that are safe under normal use:

- Air purifiers
- Blenders
- CD/DVD players
- Clothes washing machines and dryers
- Electric blankets
- Electric can openers

- Electric invisible fences
- Electric toothbrushes
- Fax/copy machines
- Hair dryers
- Heating pads
- Hot tubs/whirlpool baths

  NOTE: *Consult with your doctor before using a hot tub. Your medical condition may not permit this activity; however, it will not harm your device.*
- Laser tag games
- Microwave ovens
- Ovens (electric, convection, and gas)
- Pagers
- Patient alert devices
- Personal computers
- Personal digital assistants (PDAs)

  NOTE: *PDAs that also function as cell phones should be kept at least 6 inches (15 cm) away from your implanted system. Refer to "Cellular phones" on page 70.*

- Portable space heaters
- Radios (AM and FM)
- Remote controls (TV, garage door, stereo, camera/ video equipment)
- Stoves (electric or gas)
- Televisions
- TV or radio towers (safe outside of restricted areas)
- Tanning beds
- Vacuum cleaners
- VCRs
- Video games

Warnings and precautions

Read and follow all warnings and precautions discussed in this section. Failure to heed the warnings and precautions may result in inappropriate shock therapy or failure to deliver shock therapy. As a general rule, if you are operating any electrical or battery powered equipment and you receive a shock, you should stop operating the

equipment. In addition, if your device starts beeping, you may be in the presence of a strong magnetic field and you should move away from the potential magnetic source until your device stops beeping. Temporary beeping may also be an indication that your device has detected a malfunction. If you hear your device beeping, contact your physician immediately. Talk to your physician if you have any questions or concerns regarding this information.

Warnings

Certain electrical or magnetic fields may interfere with the S-ICD System's function. To minimize the possibility of any interference, try to avoid:

- Strong magnets such as auto wrecking yards and industry
- Industrial power generators
- Large TV/Radio transmitting towers
- Power plants and high voltage power lines
- Occupational exposure to power systems for European trains operating at 16.6 Hz

Environmental safety precautions

This section presents the environmental safety precautions for which you must be aware. Be sure to carefully read and understand each of these precautions. If you still have questions or concerns regarding these precautions, please contact your physician.

If you use any of the following items, it is important that you keep them the recommended distance away from your implanted system to avoid interaction.

Items that should not be placed directly over your implanted system, but are otherwise safe to use:

- Cordless (household) telephones
- Electric razors
- Hand-held massagers
- Portable MP3 and multimedia players (such as iPod™) that do not also function as a cellular phone (see “Cellular phones” on page 70).

iPod is a trademark or registered trademark of Apple Inc.

NOTE: *While portable MP3 players themselves should not interfere with your implanted system, the headphones or earbuds should be stored at least 6 inches (15 cm) away from your implanted system, and you should avoid draping the headphones around your neck.*

Items that should remain at least 6 inches (15 cm) away from your implanted system, but are otherwise safe to use:

- Cellular phones, including PDAs and portable MP3 players with integrated cellular phones
  NOTE: *For more information about cellular phones, refer to* *on "Cellular phones" on page 70.*
- Devices transmitting Bluetooth™ or Wi-Fi signals (cellular phones, wireless Internet routers, etc.)
- Headphones and earbuds
  NOTE: *It is safe to use headphones and earbuds, but you should refrain from storing them in a breast or other shirt pocket that places them within 6 inches (15 cm) of your implanted system.*
- Magnetic wands used in the game of Bingo

- Purses, attaché bags, backpacks, bracelets, and electronic device cases/holders with magnetic closures/snaps; respiratory masks (e.g., CPAP masks) with magnetic straps; and clothing with built-in magnets

Items that should remain at least 12 inches (30 cm) away from your implanted system, but are otherwise safe to use:

- Battery-powered cordless power tools
- Chain saws
- Corded drills and power tools
- Home power generators
- Lawn mowers
- Leaf blowers
- Remote controls with antennas
- Shop tools (drills, table saws, etc.)
- Slot machines
- Snow blowers

- Stereo speakers

Items that should remain at least 24 inches (60 cm) away from your implanted system, but are otherwise safe to use:

- Arc and resistance welders
- Police radio antennas and antennas used to operate a CB, ham radio or other radio transmitter
- Running motors and alternators, especially those found in vehicles

  NOTE: *Avoid leaning over running motors and alternators of a running vehicle. Alternators create large magnetic fields that can affect your implanted system. However, the distance required to drive or ride in a vehicle is safe.*

Items that should not be used:

- Body-fat measuring scales
- Jackhammers
- Magnetic mattresses and chairs
- Stun guns

If you have questions about the EMI safety of a particular appliance, tool, or activity, please call your physician.

Theft detection and security systems

Electronic antitheft systems (including tag deactivation) and security gates or tag readers that include radio frequency identification (RFID) equipment (often found in store and library doorways, at checkout counters, and in point-of-entry access control systems) should not cause you any worry if you follow these guidelines:

- Walk through theft detection and security systems at a normal pace.
- Do not lean against or linger near these systems.
- Do not lean against checkout counter-mounted or handheld tag deactivation systems.
- Avoid lingering near entrance and exit doorways, as some theft detection systems may be hidden in the walls or the floor in these areas.
- If you are near an electronic antitheft, security, or entry control system and suspect interaction

(experience symptoms) with your device from one of these systems, promptly move away from equipment nearby and inform your doctor.

- Most home security systems are unlikely to affect the proper function of your implanted system.
- Your Boston Scientific implantable device is unlikely to set off the alarm from an electronic antitheft or security system.

Airport security

Your S-ICD System contains metal parts that may set off airport security metal detector alarms. The security archway will not harm your device. Tell security personnel that you have an implanted medical device and show them your Implant Card.

Airport security wands could temporarily affect your device if the wand is held over it for a period of time (about 30 seconds). If possible, ask to be hand-searched instead of being searched with a handheld wand. If a wand must

be used, inform the security personnel that you have an implanted medical device. Tell the security personnel not to hold the wand over your device and to perform the search quickly.

If you have questions about airport security, call your physician.

Cellular phones

Keep your cellular phone at least 6 inches (15 cm) away from your implanted system. Your cellular phone is a source of EMI and could affect your implanted system's operation. This interaction is temporary, and moving the phone away from your implanted system will return it to proper function. To reduce the chance of interaction, follow these precautions:

- Maintain a distance of at least 6 inches (15 cm) between the cellular phone and your implanted system.
- Hold the cellular phone to your ear on the opposite side of your body from your implanted system.

- Do not carry a cellular phone in a pocket or on a belt if that places the phone within 6 inches (15 cm) of your implanted system.

These precautions apply only to cellular phones, not to household cordless phones. However, you should avoid placing your household cordless phone receiver directly over your implanted system.

Dental and medical procedures

Some medical procedures could damage or otherwise affect your S-ICD System. Be sure to always tell your dentist and physicians that you have an implanted device so that they can take the necessary precautions. Be especially careful with the following procedures:

- **Magnetic Resonance Imaging (MRI):** This is a diagnostic test that uses a strong electromagnetic field. Some S-ICD systems have been evaluated to allow the patient to undergo MRI scans under specific conditions. MRI scanning may result in permanent loss of Beeper volume. Talk to your physician about the capabilities of your S-ICD system. If your system

is not one of those eligible to be scanned, or if the required conditions are not met, MRI scans can severely damage your device and should not be performed. Hospitals keep MRI equipment in rooms marked with signs that indicate magnets are inside. Do not go inside these rooms unless your physician has confirmed that your S-ICD system is eligible and you meet the requirements for an MRI scan.

- **Diathermy:** This uses an electrical field to apply heat to tissues in the body and could damage your device or injure you. Diathermy should not be performed.
- **Electrocautery:** This is used during surgical procedures to stop vessels from bleeding. It should be used only when your device is turned off. Talk with your heart doctor and the doctor performing the medical procedure to determine who turns off your device.
- **External defibrillation:** This is a procedure, typically used in medical emergencies, that uses external

equipment to deliver an electrical shock to your heart to restore a rapid and irregular heart rate to a normal rhythm. External defibrillation can affect your device, but can still be performed if necessary. If you receive external defibrillation, be sure to contact your physician as soon as possible following the emergency to verify that your device is functioning properly.

- **Lithotripsy:** This is a medical procedure that is used to break up stones in the urinary tract (e.g., kidney stones). Lithotripsy can damage your device if certain precautions are not taken. Talk with your heart doctor as well as the doctor performing the procedure about what can be done to protect your device.
- **Other implanted medical devices:** Devices co-implanted with the S-ICD System (e.g., implantable neurostimulation systems, ventricular assist device, or implantable drug pumps) can result in interactions that could compromise the function of the S-ICD.

the co-implanted device, or both. If you have further questions, talk with your heart doctor.

- **Therapeutic radiation treatment for cancer:** This procedure can affect your device and will require special precautions. If you should need radiation treatment, talk with your heart doctor as well as the doctor performing the medical procedure.
- **Transcutaneous Electrical Nerve Stimulation (TENS) unit:** This is a device prescribed by physicians or chiropractors for control of chronic pain. A TENS unit can affect your device and will require special precautions. If you must use a TENS unit, talk with your heart doctor.

Most other medical and dental procedures are unlikely to affect your device. Some examples include:

- Dental drills and cleaning equipment
- Diagnostic X-rays
- Diagnostic ultrasound procedures

- Mammograms

  NOTE: *Mammograms will not interfere with your device. However, your device could be damaged if it gets compressed in the mammogram machine. Make sure the doctor or technician knows that you have an implanted device.*

- EKG machines
- CT scans

If you need to undergo any surgical procedures, tell your dentist and/or doctor that you have an implanted device. They can contact the physician who monitors your device to find the best way to provide treatment.

If you have questions about a specific appliance, tool, medical procedure, or piece of equipment, please talk with your physician.

Summary

It is natural for you to feel anxious or nervous about receiving a device. You have been identified by your physician as having a significant risk of sudden cardiac death due to your medical conditions. Remember that your device can be a great source of reassurance for you and your friends and family.

Talking with other ICD patients is often helpful while adjusting to your new device. Ask your doctor, nurse, or Boston Scientific representative if there is a local ICD patient support group in your area.

The information presented in this handbook is intended to help you understand more about your heart condition and your device. If you have questions about what you have read, be sure to ask your doctor or nurse. They are your best resource for information about your particular needs or situation.

Notes and questions

Use this space to write down questions or additional information about your device:

Symbols in Labeling

Symbol	Definition
	Manufacturer
	Authorized Representative in the European Community
	CE mark of conformity with the identification of the notified body authorizing use of the mark
	Australian Sponsor Address
	Person identification
	Date
	Health care center or doctor
	MR Conditional

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Outdated version.
Versión obsoleta. No utilizar.
Version périmée. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úrelt útgáfa. Notið ekki.
Versione obsoleta, Non utilizzare.
Novecojusi versija. Neizmantot.
Pasenusi versija. Nenaudokite.
Elavult verzió. Ne használja!
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Versiune expirată. A nu se utiliza.
Zastaralá verzia. Nepoužívať.
Različica. Ne uporabite.
Versio. Älä käytä.
Använd

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