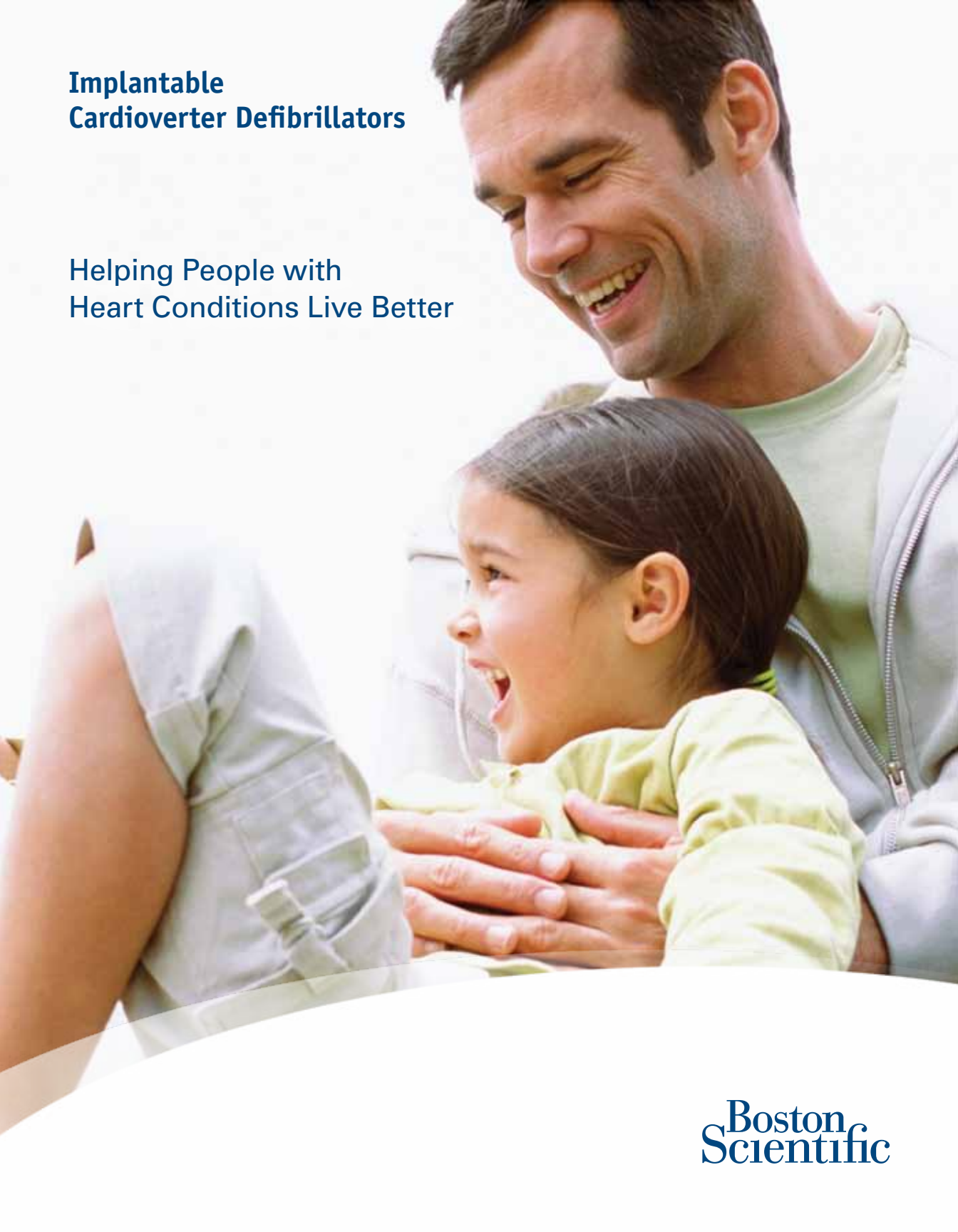


# Implantable Cardioverter Defibrillators

Helping People with  
Heart Conditions Live Better



**Boston  
Scientific**

Your doctor or nurse has given you this information because your doctor believes an implantable cardioverter defibrillator (ICD) may be right for you. The decision to have an ICD is one that you need to think carefully about. You most likely have a lot of questions.

In this brochure, we'll answer some of those questions. We'll also share stories from other people who have faced the same decision. Our goal is to provide information that can help you make a decision that is right for you.

Many patients find it helpful for their family and friends to learn about the ICD as well. We encourage you to share this information with those who care about you. If you have more questions after reading this brochure, please talk with your doctor.

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# Understanding ICD Technology

*Irregular heart rhythms are called arrhythmias. Some can be life-threatening. So imagine if you had the help of a device designed to monitor your heart all the time—a device that sensed every single heartbeat and responded to save your life if your heart started beating dangerously fast. That's exactly what an ICD does.*

*An ICD has the ability to improve your health—and may improve your life. Following are some answers to questions you may have about arrhythmias and ICDs. For additional information, we encourage you to talk to your doctor and visit the online resources listed on page 20.*



## What are ventricular tachycardia and ventricular fibrillation?

Arrhythmias result from a problem in your heart's electrical system. Some arrhythmias that originate in the heart's lower chambers (the ventricles) may be life-threatening. You may have heard your doctor talk about two types: ventricular tachycardia and ventricular fibrillation.

- **Ventricular tachycardia (VT):** Tachycardia is an abnormally fast heartbeat, or heart rhythm. When tachycardia occurs in the ventricles, it is called ventricular tachycardia. VT causes the heart to beat more than 100 times per minute, rather than the normal rate of 60 to 100 times per minute.

As a result, your body and brain may not get enough oxygen and nutrients to function properly. You may experience symptoms such as shortness of breath, fatigue, chest pain or pressure, dizziness or fainting, or a feeling that your heart is racing. Sometimes VT stops on its own after a few seconds, and there are no lasting effects. Other times it continues. It can even progress into a faster, chaotic arrhythmia called ventricular fibrillation.

- **Ventricular fibrillation (VF):** Fibrillation is an abnormally fast *and* chaotic heart rhythm. When fibrillation occurs in the heart's ventricles, it is called ventricular fibrillation. VF causes the heart to beat more than 200 to 300 times per minute. VF is also a chaotic rhythm. That means the heart's ventricles try to contract so fast that they quiver rather than beat. The heart rate is so fast that your heart does not have time to pump enough blood to your brain and body tissue.

VF is the most dangerous type of arrhythmia. It often strikes without warning. Within seconds after VF begins, a person can lose consciousness. If the person doesn't receive immediate treatment from a defibrillator, sudden cardiac arrest and sudden cardiac death can occur within just a few minutes.

These types of arrhythmias occur in individuals of all ages, from young children to the elderly. Studies have shown that VT often occurs in patients who have had damage from a heart attack, cardiac surgery, or other conditions. Some people with inherited heart defects also experience VT. Sometimes VT affects individuals with no history of a heart condition.

## What is an ICD and how does it treat ventricular tachycardia and ventricular fibrillation?

An ICD system consists of two components—the pulse generator, or device, and one or two thin, insulated wires called leads. Leads carry electrical signals between the heart and the pulse generator.

An ICD treats abnormally fast ventricular heart rhythms by delivering tiny amounts of electrical energy (anti-tachycardia pacing) to the heart. This energy slows the heart down to a more normal rhythm. If the device senses a heart rate that is dangerously fast, it delivers a shock to the heart. This shock (defibrillation) stops the abnormal rhythm. Without this lifesaving therapy, the dangerously rapid rhythm could lead to sudden cardiac arrest. And that could lead to sudden cardiac death within minutes.

## How serious is the risk of sudden cardiac death?

The risk of sudden cardiac death is something to take very seriously.

- Sudden death due to cardiac arrest affects 330,000 people each year in the United States (meaning that almost 1,000 die from it each day). Sudden cardiac death kills more people each year than AIDS, breast cancer, and lung cancer combined.<sup>1</sup>
- ICDs have been shown to effectively stop 95% or more of dangerously fast heart rhythms.<sup>2</sup>
- Patients who do not receive an ICD for life-threatening arrhythmias are at high risk for sudden cardiac death.<sup>3</sup> According to the American Heart Association, approximately 95% of sudden cardiac death victims die before reaching the hospital.<sup>1</sup>

## Did you know?

**Sudden cardiac arrest is not the same as a heart attack.** Sudden cardiac arrest occurs when electrical problems in the heart cause a dangerously fast heart rate. Sudden cardiac arrest can lead to sudden cardiac death. A heart attack is different. It results from heart muscle damage from blood flow blockage, rather than an electrical problem.



*The two upper chambers in your heart are called the atria. The two lower chambers are called ventricles. An ICD monitors or senses the rate of your heartbeat in the right side of your heart. Based on what it senses, the ICD device delivers electrical impulses to your ventricles to restore a normal heart rhythm.*

### **Why would my doctor recommend an ICD?**

Based on your test results, your doctor may have determined that you might experience irregular heart rhythms. You may be at risk for sudden cardiac death.

#### **Even if you are taking medication, you can still have irregular heart rhythms.**

Your doctor may be recommending an ICD for you because you have:

- Had at least one documented episode of a dangerous ventricular arrhythmia
- Previously passed out because of an arrhythmia
- A recurring fast heart rhythm that puts you at risk for sudden cardiac death
- A fast heart rhythm that cannot be controlled with medication
- Severe side effects from your medication
- A fast heart rhythm that cannot be cured by surgery
- Survived a heart attack and have a low ejection fraction, which is a measurement of how well your heart is pumping
- An inherited heart defect that causes a fast heart rhythm

An ICD is not for everyone. Your doctor will review your personal health condition in determining whether an ICD is right for you.

## Why would my doctor recommend an ICD if I have survived a heart attack?

You might feel fine right now and wonder why you need an ICD. However, depending on the severity of your heart attack, you may be at increased risk for sudden cardiac death. Damage to your heart muscle from your heart attack may affect your heart's ability to pump properly.

- After a heart attack, your doctor will test how well your heart is pumping. A simple test called an echocardiogram can measure the amount of blood your heart pumps with each heartbeat. This measurement is called an ejection fraction (EF). People with healthy hearts have an EF of 50% or greater.
- If you have survived a heart attack and also have a low EF, you may be at risk for sudden cardiac death. An ICD can prevent sudden cardiac death by detecting and treating any fast, dangerous heart rhythms that you may experience in the future.
- Guidelines from the American College of Cardiology and the American Heart Association recommend an ICD for heart attack survivors who have an ejection fraction of  $\leq 30\%$ .



In 2005, the American College of Cardiology and the American Heart Association revised their guidelines for treating patients with certain heart conditions. Device therapy received the highest level recommendation for patients who meet certain criteria. Your doctor may follow these guidelines in determining whether you are a good candidate for an ICD. Along with any medication your doctor has prescribed, an ICD is the standard of care for many patients to help treat dangerously fast arrhythmias and protect against sudden cardiac death.

*Doctors and nurses use a programmer to check an ICD and to communicate with it.*



## How is an ICD evaluated?

Today's ICDs rely on sophisticated computer technology. When your doctor implants your ICD, a programmer is used. A special wand is placed over the ICD device implant site. Like a TV remote, the special wand sends radio wave signals to the programmer to download information from your device.

Your doctor will program your ICD to deliver the right type of therapy for your heart condition. After your implant, your doctor or nurse will use the programmer regularly to evaluate your device and make any changes if needed. The programmer reads all of the information stored in the ICD.

## What types of therapy does an ICD deliver and will I feel the therapy?

An ICD can use one or more types of energy to help your heart beat normally again. They include:

- **Bradycardia pacing therapy:** ICDs have the ability to treat a slow heart rate, a condition called bradycardia. When an ICD treats an abnormally slow heart rate, you generally don't feel anything because it uses low energy to pace the heart.
- **Antitachycardia pacing (ATP):** If your rhythm is regular but fast, the ICD can deliver a series of small, rapid electrical pacing pulses. These pulses interrupt the arrhythmia and return your heart to its normal rhythm. You generally don't feel anything because ATP uses low energy to pace the heart.
- **Defibrillation:** For arrhythmias that are very fast, the ICD may use a high-energy shock to stop the arrhythmia. Then your heart can return to its normal rhythm. This type of therapy uses higher energy, so you may feel the shock. The feeling varies from person to person. It can even be different for the same patient at different times.

Some patients have described the shock therapy as a small thump in the chest. Others describe the feeling as a kick in the chest. Some patients are unconscious when the shock is delivered and don't remember the shock at all. The shock comes quickly and lasts only a second.

## Are there risks to having an ICD?

After an ICD is implanted, some risks do exist, including:

- The leads may move out of place in the heart.
- The leads or electrical impulses may irritate or damage the surrounding tissues, including heart tissue and nerves.
- The ICD might not be able to detect or appropriately treat your heart rhythms.

Be sure to talk with your doctor so that you thoroughly understand both the risks and benefits associated with having an ICD. For more information regarding some of the potential risks, please see page 21 in this brochure.

## Are ICDs reliable? Does research support their use?

ICDs are reliable. Nearly 600,000 people worldwide have received a defibrillator.<sup>4</sup> Every year, ICDs help hundreds of thousands of people live longer.

Along with any medication your doctor has prescribed, an ICD may be the best choice to help protect your heart from dangerous heart rhythms. However, devices are not perfect and may exhibit problems. For more information about device reliability and effectiveness, please see the back cover of this brochure, and talk with your doctor.

Several research studies have shown the benefits of an ICD:

- The MADIT II study showed that an ICD can decrease the risk of death for heart attack survivors. It compared people who were treated with both an ICD and medication to people treated with only medication.<sup>5</sup>
- The SCD-HeFT study of heart failure patients compared therapy with medications and therapy with both medications and an ICD. Patients who had an ICD in addition to medication had a 23% lower risk of death.<sup>6</sup>



### **Do insurance and Medicare cover an ICD?**

Most health insurance companies view an ICD as medically necessary for appropriately selected patients. If your doctor has determined that an ICD is right for you, your insurance will usually pay.

Based in part on the findings from research studies, the agency that oversees Medicare made a decision in 2005 to pay for an ICD for many people who have not first had a heart attack, arrhythmias, or proven risk of arrhythmias. It made this decision to help more people live longer.

Be sure to provide your doctor's office with your insurance information. Ask your doctor's office to verify your coverage before scheduling your implant procedure.

# Preparing for an ICD Implant

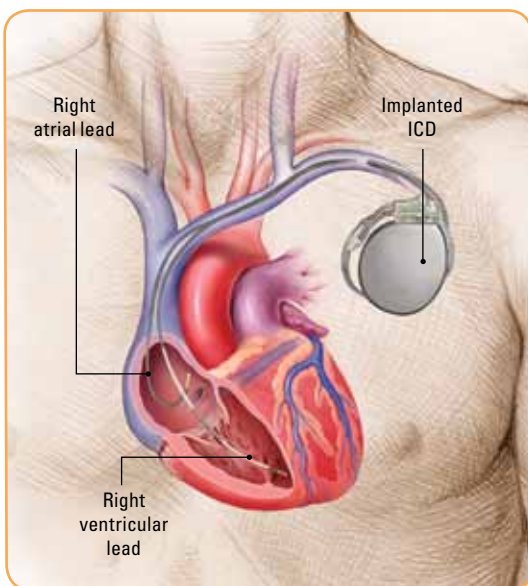
*Over the years, advances in medical technology have made the surgery to implant an ICD much simpler. Today, the implant takes about 1 hour. After surgery, you may be in the hospital for a day or two. This allows the doctors and nurses to watch and record your heart rhythm. When your doctor determines you are ready, you will be able to return home.*

*Below are some answers to questions you may have about receiving an ICD implant. For more detailed information on the surgery, we encourage you to talk to your doctor and visit the online resources listed on page 20.*

## How big is an ICD and where is it implanted?

Today's ICDs are amazingly small. The average device is about the size of a small bar of soap. It measures about 2 x 2 inches (5 x 5 centimeters) and less than 0.5 inches (11 millimeters) thick. It weighs about 1 to 3 ounces (28 to 85 grams).

Doctors will usually implant your ICD in your chest. Typically, an ICD is implanted just under the skin near your collarbone. One lead will be positioned in the atrial chamber of your heart and the other will be positioned in the ventricular chamber (see illustration). Your doctor will discuss with you in which side of your chest the device will be implanted.



### **Are there risks to the procedure?**

As with any surgical procedure, it is important to understand that there are risks associated with the implantation of an ICD and/or lead(s). Some risks encountered during the implant procedure may include infection, tissue damage, bleeding, and an irregular heart rhythm. Complications do not happen very often. However, it is important that you talk with your doctor about the risks of having an ICD implanted, as well as the benefits. For more information regarding some of the potential risks, see page 21.

### **What is recovery like?**

Full recovery from surgery can take from several days or weeks to a few months. While you recover, your doctor may ask you to avoid strenuous activity (especially lifting and other activities that use your upper body). Doing so helps ensure that any leads have time to firmly attach to your heart tissue. After that, you'll have the added assurance that your ICD is treating your heart rhythms.

**On average, an ICD lasts 4 to 8 years. Your doctor or nurse will regularly check to see how much energy is remaining in your device's battery. He or she will recommend replacement when the remaining battery energy drops to a certain level.**

# Living with an ICD

*Having an ICD allows you to live your life knowing that your device will treat irregular heart rhythms as your doctor has prescribed and programmed.*

*For many people, their lifestyles are no different once they have an ICD. They are able to work and enjoy hobbies, sexual activity, and travel. An ICD will help you enjoy as active and productive a lifestyle as your overall health permits (individual results may vary).*

*The following section provides answers to some questions you may have about daily living with an ICD. Your doctor can answer other questions and advise you on the appropriate level of activity for you. For additional information, visit the online resources listed on page 20.*



## **How do most people feel emotionally after receiving an ICD?**

Having an ICD can be a major turning point in your life. Afterward, you may feel sad or worried. It's an event that may change your thoughts and feelings about your health. Some people may feel vulnerable at first because they depend on an implanted device.

As you return to daily life, your level of confidence and comfort with the ICD will likely grow. As you can see from the patient stories in the back of this brochure, many people feel reassured knowing that a device may help to save their life.

It's also important to remember that everyone is different about their privacy. How much you share with others is up to you. Sometimes it's perfectly healthy not to talk about your heart condition. But if you are anxious, scared, or depressed, you might want to talk to a therapist or find a support group.

## **How will a doctor monitor my heart when I have an ICD?**

Your doctor will want to check your ICD and overall health on a regular basis. It's important to attend your doctor visits, even if you are feeling well. In the clinic, your doctor or nurse will use the programmer to read all of the information stored in your ICD. This information includes whether your ICD delivered high-energy therapy. If it delivered a therapy, the ICD's computer memory will store information about what your heart was doing before, during, and after the arrhythmia. The programmer also indicates how much energy is left in the battery. Based on this information, your doctor can help ensure your ICD is working properly to best treat your heart condition.

Your device may be checked at the clinic and at your home using an in-home (remote) monitoring system. If your doctor wants to monitor your device from your home, a portable communications device can transmit device and health information through your regular phone line to a secure web site that only your health care support team can access.

Your doctor will provide guidelines for when you should contact him or her between visits.

## **Does an ICD affect driving privileges?**

Whether you are able to drive once you have an ICD will depend on your specific symptoms (like passing out prior to the implant) and the driving laws where you live. Generally, having an ICD does not prohibit you from driving, although you may be asked to wait during the early stage of recovery. In some cases, restrictions are necessary. That's because a few seconds of unconsciousness could be dangerous to both you and others. Your doctor or nurse will discuss any restrictions with you.

## **What about sexual intimacy?**

For most people with an ICD, sexual intimacy is not a medical risk. This is because the natural heart rate increase that occurs during sex is the same as the heart rate increase when you exercise. Your doctor may perform exercise tests to become familiar with how your heart rate increases. This will help him or her program the ICD system settings.

## **Can I still travel with an ICD?**

Patients with an ICD can feel confident and safe when traveling. The Medical Device ID card that you receive with your device helps alert medical and security personnel that you have an implanted device.

It's important to carry your card when you have a device, because the device does contain metal parts that may set off airport security metal detector alarms. Airport security wands could also temporarily affect the device. Security personnel should perform a hand search instead of using a handheld wand. If a wand must be used, you can ask security personnel to do the search quickly and not to hold the wand over the device.

If you receive a device from Boston Scientific, a listing is available of medical facilities worldwide that have treated patients with Guidant/Boston Scientific products. The listing is available online at [www.lifebeatonline.com](http://www.lifebeatonline.com) or by calling Boston Scientific's Patient Services department at 1.866.484.3268.

## **Is there a risk of interference from household appliances with an ICD?**

Under normal use, it is safe for someone with an ICD to use most household items. This includes hair dryers, heating pads, electric razors, remote controls, vacuums, microwaves, TVs, radios, computers, lawn mowers, and many other appliances and tools. But people with an ICD do need to be aware that the device can be affected by electromagnetic interference (EMI). EMI is caused by strong electrical or magnetic fields.

Certain tools and household items should be used with caution or avoided. Your doctor can answer questions about a specific appliance, tool, or piece of equipment. Specific guideline information is also available from Boston Scientific Patient Services at 1.866.484.3268 and online at [www.lifebeatonline.com](http://www.lifebeatonline.com).





## Meet Bob B.

For a man in his mid-seventies, Bob B. of Malaga, New Jersey, has some pretty amazing moves: he can do handstands, cartwheels, and the splits.

As a teacher of educational gymnastics to children ages 3 to 18, he combines his lifelong love of working with kids with a relatively more recent passion for fitness. And thanks to diligent monitoring of his heart after undergoing surgery a few years ago, he's still able to do the work he loves.

While teaching gymnastics in 1998, Bob had persistent abdominal pain that sent him to a doctor. An electrocardiogram showed that he had just had a heart attack, even though "I had none of the traditional symptoms of a heart attack, just abdominal pain," he explained. It was then determined that he needed to undergo angioplasty to treat a blocked coronary artery.

In the hospital the next night, a nurse came running to tell him that he had a very serious, irregular heart rate. "Once again, I didn't really feel anything, so I was extremely lucky to be in a hospital and on a heart monitor when it

happened. When I saw the doctor and was presented with my options, the decision to get the device wasn't difficult at all. If I had elected not to get it, I could have died anytime. Also, the medication I'm on is no guarantee that I couldn't end up in a dangerous, fast heart rhythm again.

"My doctor recommended a combination pacemaker and defibrillator. The defibrillator has never gone off, but I think of it as a guardian angel that protects me from a potentially lethal heart rhythm. My pacemaker works when I need it. It monitors my heart and then delivers pacing pulses if my heart rate becomes abnormal.

"I had no problem at all getting used to my unit. At first I had a little trouble lifting my arm and shoulder, but I worked on the pulleys and soon regained full motion in both arms, which is very important for gymnastics, of course.

"My fitness conversion came relatively late in life," continued Bob. "I was 50 when I attended a wellness conference and became certified as a YMCA physical fitness specialist. It turned my life around. When I was young I wasn't athletic at all. It always bothered me, and I didn't have a good self-image because of it."

*“The defibrillator has never gone off, but I think of it as a guardian angel that protects me from a potentially lethal heart rhythm.”*

Bob then took a course in educational gymnastics and was sold on it from the start. Unlike competitive gymnastics, educational gymnastics stresses the development of individual skills and setting personal goals. He eventually opened his own gymnastics school, and “here I am, 20 years later, still teaching.”

Although their four children are grown, Bob and his wife, Elsa, enjoy regular visits from the kids and three grandsons. “Our family lives nearby, so our house is Grand Central Station,” said Bob. “I love it that way. I’d miss them if they weren’t around.”

Bob is now on his third ICD. His first ICD lasted about 5 years. In 2004, he was involved in a serious car accident, and the impact from the crash caused his second device to shift in his chest. Although the device could be surgically repositioned, Bob’s doctor recommended replacing the device. As long as Bob needed to undergo surgery, he suggested replacing the 2-year-old device with a new one so that Bob wouldn’t need surgery again for another 4

to 6 years. In 2005, with his doctor’s blessing, Bob even trained for and participated in a polar swimming event with his students in 28-degree weather. “It felt great, and my ICD didn’t bother me at all. I forget it’s there,” said Bob.

“My situation is unusual, because I had a good quality of life right up to getting my device. Little did I know how dangerous my condition was. This came as a complete surprise. Now that I have a device, I feel like I’ve come to respect life more. I’ve been given another chance, and I can enjoy things more fully because of it. It really helps you to learn to live each day and make the most of it. You take inventory of your blessings.”

*Note: Individual symptoms, situations, results, and circumstances may vary. Please consult your physician or qualified health provider regarding your condition and appropriate medical treatment. Your doctor will help decide what activities and activity level are right for you. The information provided is not intended to be used for medical diagnosis or treatment or as a substitute for professional medical advice.*



## Meet April R.

It isn't uncommon for sleep-deprived mothers of young children to become somewhat forgetful. But April R. has no memory whatsoever of a couple of winter months in 1990. Her son, Skyler, was almost 2 years old at the time.

April had a sudden cardiac death episode one morning after getting out of bed to answer the phone. "We were visiting relatives in Utah, and my mother-in-law found me passed out. While she called 911, I stopped breathing. Emergency Medical Services arrived and defibrillated me with external paddles after I'd stopped breathing for 4 minutes.

"My mother-in-law rode along when the ambulance took me to the hospital. She didn't want her son to think that I had died without a loved one nearby. My husband was in Arizona on business at the time."

April was resuscitated with external defibrillator paddles two times in the hospital. She then lapsed into a coma for 2 days.

"Before I came out of the coma, they had

done the tests to determine that I wasn't brain dead. But it was still a very traumatic time for everyone but me, because I was so confused. I don't remember it. I completely lost my short-term memory."

April had no history of heart problems, and when she was transferred to Salt Lake City for tests, the doctors weren't able to make any diagnosis. "I'm thin, I exercise, and I have no family history of heart problems.

"At this point my doctor gathered my family in my hospital room to tell us about the implantable cardioverter defibrillator (ICD). He thought this would provide me with the best protection should I ever have another, similar episode. This was a long time ago now, and we had never heard of such a thing. We were all devastated."

"I was 23 years old, and the mother of a young child. My main concern was that I wouldn't be able to have more children, which was terribly important to me. But then my husband stepped in and said that we ought to go ahead with the implant, to help ensure that I would be around for the next 70 years!"

*“My husband stepped in and said that we ought to go ahead with the implant, to help ensure that I would be around for the next 70 years!”*

This all seems so long ago now, according to April. “I got a shock 7 years after my ICD was implanted. That was a reality check for me. I felt like I became a member of a different club.”

April had her initiation into this club the week before her fourth child was born. She had been asleep for about 5 minutes, when “suddenly I flew out of bed. My husband, Alan, was watching TV in bed at the time. He said I didn’t fidget or act uncomfortable in any way before this happened. I felt the shock the whole way up my chest. When my husband asked if I was sure I’d had a shock, I asked him, ‘Have you seen me move like that recently?’ After all, I was 9 months pregnant! We went to the hospital, and it turned out that everything was fine, thankfully.”

Since her daughter Savannah’s birth, April has been implanted with smaller replacement ICDs. “I had four children at this point, and I decided this was my limit. I feel so lucky to have four of the most beautiful, wonderful children. And I know that I have this defibrillator for a reason. If I hadn’t had it, I could have gone to sleep forever that night, and so would Savannah. And no one would have known until morning. I feel so lucky to have had my ICD, which saved my life.”

*Note: Individual symptoms, situations, results, and circumstances may vary. Please consult your physician or qualified health provider regarding your condition and appropriate medical treatment. Your doctor will help decide what activities and activity level are right for you. The information provided is not intended to be used for medical diagnosis or treatment or as a substitute for professional medical advice.*

# What's Next?

With its lifesaving technology, an ICD can improve your life and give you and your family peace of mind.

You have an important decision to make about your health. If your condition is not immediately life-threatening, you have some time to talk with your doctor and your loved ones. This brochure is just one source of information to help you as you make your decision. If you have additional concerns or questions not answered in this brochure, please talk with your doctor.

## Additional Online Resources

[bostonscientific.com](http://bostonscientific.com)

[lifebeatonline.com](http://lifebeatonline.com)

[americanheart.org](http://americanheart.org)

[mayoclinic.com](http://mayoclinic.com)

[hrspatients.org](http://hrspatients.org)

[heart.healthcentersonline.com](http://heart.healthcentersonline.com)



## LifeBeat<sup>SM</sup> Online Newsletter

Every issue includes articles about the road to recovery, cardiac news, and interviews with patients. To subscribe, visit [lifebeatonline.com](http://lifebeatonline.com).

## Important Safety Information to Discuss with Your Doctor

An implantable cardioverter defibrillator (ICD) 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 ICD, the potential procedure risks include, but are not limited to:**

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

### **After your doctor implants your 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.
- The lead(s) may move out of place in the heart.
- The electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues. This includes heart tissue and nerves.
- 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 device or leads are replaced, the potential risks may be similar to, or even greater than, those of your original ICD implant. Additional risks from these replacement procedures may include:**

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

It is important for you and your doctor to consider these potential risks when making a decision about device replacement. For more information on device monitoring and replacement, see the back cover of this brochure.

## 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 device and the lead system are 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 lead systems 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 lead may affect the system's ability to provide therapy. If this situation arises for you, your doctor may recommend replacing your device and/or leads.

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 page 21.



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### Cardiac Rhythm Management

Boston Scientific Corporation  
4100 Hamline Avenue North  
St. Paul, MN 55112-5798 USA  
Tel: 651.582.4000 Fax: 651.582.4166  
Medical Professionals:  
1.800.CARDIAC (227.3422)  
Patients and Families:  
1.866.484.3268

[www.bostonscientific.com](http://www.bostonscientific.com)

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CRM9-1040-0210