

**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 in this brochure.

**Implantable Devices**

**Important Safety Information**

**Pacemakers**

A pacemaker system is designed to monitor and treat your heart rhythm problems, greatly reducing the risks associated with them. These devices are sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields. With all medical procedures there are risks associated. In regard to an implanted pacemaker, the risks include but are not limited to inappropriate heart rate response to exercise, lead moves out of place, loss of stimulation capability, allergic reaction, fluid underneath the skin, and infection. In rare cases device failure or death can occur. Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of this system. To obtain a copy of the device Patient Handbook for more detailed device safety information, go to [www.bostonscientific.com](http://www.bostonscientific.com), or you can request a copy by calling 1-866-484-3268 or writing to Boston Scientific, 4100 Hamline Ave. N., St. Paul, MN 55112. 92481216 (Rev. A)

**Device Quality and Reliability**

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

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CRM-130106-AE

1 MOND, H. G. and PROCLEMER, A. (2011), The 11th World Survey of Cardiac Pacing and Implantable Cardioverter-Defibrillators: Calendar Year 2009-A World Society of Arrhythmia's Project. *Pacing and Clinical Electrophysiology*, 34: 1013-1027.



**Pacemakers**  
Helping People with Heart Conditions Live Better



You have been given this information because your doctor believes an implantable pacemaker may be right for you. The decision to have a pacemaker implanted is one you need to think carefully about. You most likely have a lot of questions.

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

Many patients find it helpful for their family and friends to learn about pacemakers as well. We encourage you to share this information with those who care about you. Please talk with your doctor to discuss your own medical history and ask any questions you have after reading this brochure.

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# Understanding Pacemaker Technology

In most people, the heart beats 60 to 100 times per minute when at rest. One of the most common reasons people need a pacemaker is when their heartbeat is abnormally slow. This can be due to many causes. When the heart beats too slowly, the body does not get enough blood and oxygen for it to function properly. A pacemaker is an implanted device that can help restore your heart rate to a more normal level so you feel better and can resume normal daily activities. Following are some answers to questions you may have about how your heart functions and about pacemakers. For additional information, we encourage you to talk to your doctor and review the resources listed on page 20.

## How does electricity work in my heart?

To understand how a pacemaker works, it's helpful to understand how electricity in your heart works. When your heart beats, it pumps blood to and from all parts of your body. In order for your heart to beat, it needs electricity that your body naturally produces. When this electricity travels across the heart muscle, it causes it to contract or beat.

Normally, the electrical signal that tells your heart to beat comes from a small area in the upper right chamber, or right atrium, of your heart. This area is called the sino-atrial node, or SA node.

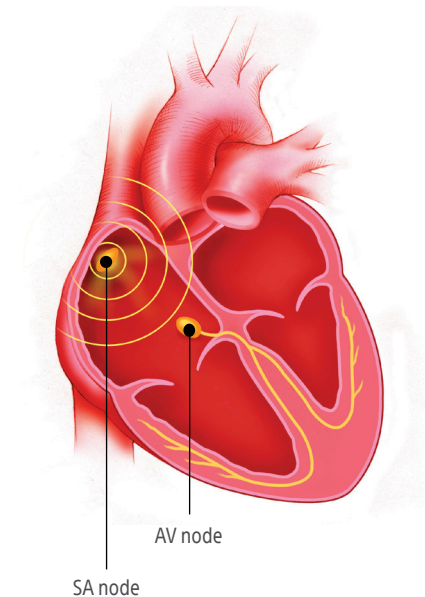
The SA node sends out natural pacemaker electrical signals through the heart's "relay station"—the atrioventricular (AV) node—and then through the ventricles, or lower chambers. These signals cause your heart muscle to beat—or contract. This produces a heartbeat, which pumps blood out of your heart to the rest of your body. This rhythmic pumping of blood is what you feel when you take your pulse.

The SA node is your heart's natural pacemaker. It automatically increases your heart rate in response to your body's needs—for example, during exercise, when more blood flow to your body is needed.

## What is bradycardia?

Sometimes the heart beats too slow—less than 60 beats per minute. This is called bradycardia. It can occur when the SA node does not work properly, or if there is a condition called heart block. Heart block exists when there is a problem with the electrical pathway between the upper chambers of the heart (atria) and the lower chambers of the heart (ventricles). The natural pacemaker signals sent out by the SA node may be delayed or blocked and may not reach the ventricles.

During bradycardia, the chambers of the heart do not contract often enough to supply the proper amount of blood to your body. This may cause you to frequently feel tired or dizzy.



# Understanding Pacemaker Technology



## What is a pacemaker and how does it treat bradycardia or other rhythm problems?

A pacemaker system is designed to monitor and treat your slow heart rhythm. The system consists of two components:

**The pacemaker (also called a pulse generator):** The pacemaker is a small computer with several electronic circuits. These circuits control the pacemaker's functions. The pacemaker runs on a battery that is safely sealed within its case. It continuously monitors your heart rhythm and provides a small amount of electrical energy to pace your heart during a slow rhythm.

**One or two thin, insulated wires called leads (pronounced "leeds"):** Leads connect the pacemaker to your heart. They "monitor" your heart's rhythm and deliver the electrical energy from the pacemaker to your heart.

## Why would my doctor recommend a pacemaker?

Based on test results, your doctor has determined that you have a slow or irregular heart rhythm. Some people also have problems with the heart's conduction. A conduction problem means that the electrical signals that travel through the heart muscle are too slow, irregular, or are missing completely, such as in the condition known as heart block.

Having a slow or irregular heart rhythm or conduction problem may make it difficult to perform daily activities. It can also put you at high risk of serious complications that could lead to passing out or fainting or even death. Your doctor may be recommending a pacemaker for you because:

- You have episodes of a very slow heart rhythm
- You have fainting spells, accompanied by a slow or irregular heart rhythm
- Your heart rhythm makes you unable to perform daily activities such as walking up stairs, carrying groceries, etc.
- Your AV node is not working due to an ablation procedure
- You may have an inherited heart condition that causes a slow heart rhythm

A pacemaker is not for everyone. Your doctor will review your personal health condition in determining whether a pacemaker is right for you.

## How is a pacemaker evaluated?

Today's pacemakers rely on sophisticated computer technology. When your doctor implants your pacemaker, an external computer, or programmer, is used. A special wand is placed over the pacemaker 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 or health care provider will program your pacemaker so that it will best meet your individual needs.

## How does a pacemaker work and will I feel it working?

Pacemakers operate "on demand," or in other words, as needed. This means a pacemaker monitors, beat by beat, the natural rate of the heart's upper and/or lower chambers. If the natural rate tries to fall below the rate set for the pacemaker, it will send out an impulse to pace your heart, which makes your heart's chambers contract and pump blood. You will not feel these electrical impulses.

Activities such as playing sports or running demand more oxygenated blood flow to the body than sedentary activities do. Usually, your heart responds to the body's needs for more blood flow by increasing the heart rate. Sometimes, however, the heart rate is unable to increase on its own and may need to rely on the pacemaker to do this.

**Programmable Sensors:** Boston Scientific pacemakers have special features called sensors. These sensors can detect an increase in your body's motion or an increase in your breathing rate when you are more active. When the sensor detects this increase, it will adapt its pacing rate as needed. This increase in heart rate will change with your needs during everyday activities or exercise.

Your doctor or health care provider knows the activity support needs that your individual condition requires, as well as your individual heart rhythm's ability to meet those needs.

He or she will program the pacemaker sensor with both a minimum-rate pacing limit and maximum-rate pacing limit.



*Doctors and health care providers use a programmer to check a pacemaker and communicate with it.*



# Understanding Pacemaker Technology

## Are there risks to having a pacemaker?

After a pacemaker is implanted, some risks do exist. The following are some risks that can occur:

- The lead(s) may move out of place in the heart
- The lead could cause uncomfortable sensations as a result of pacing or damage to the surrounding area that might require a second intervention
- The device might be prevented from pacing due to electromagnetic interference (see additional information on page 15)

Be sure to talk with your doctor or health care provider so that you thoroughly understand both the risks and benefits associated with having a pacemaker. For more information regarding some of the potential risks, please see page 21.

## Are pacemakers reliable?

Every year, approximately 1 million pacemakers are implanted worldwide.<sup>1</sup> Depending on physician determined programmed settings, a Boston Scientific pacemaker can last an average of 10 years.

Along with other therapy your doctor has prescribed, a pacemaker may be the best choice to help protect your heart from dangerously slow rhythms. However, pacemakers 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.

## Does insurance and Medicare cover a pacemaker?

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

Over the years, advances in medical technology have made the surgery to implant a pacemaker much simpler. After surgery, you may be in the hospital for a day or two. Several centers will send you home the same day thanks to remote monitoring technology. This allows the doctors and health care providers to watch and record your heart rhythm.

When your doctor determines you are ready, you will be allowed to return home. On the following page are some answers to questions you may have about receiving a pacemaker 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.

## Are there risks to the procedure?

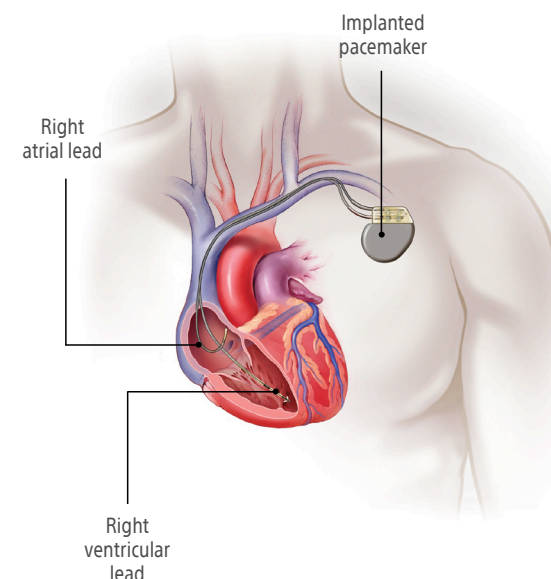
As with any surgical procedure, it is important to understand that there are risks associated with the implantation of a pacemaker and/or lead(s). Some risks encountered during the implant procedure may include infection, tissue damage, bleeding, and an irregular heart rhythm. Complications do not happen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

## What is recovery like?

Full recovery from surgery can take a few days to a few months. While you recover, your doctor or health care provider may ask you to avoid strenuous activity (especially lifting and other activities that use your upper body). This gives the lead(s) time to firmly attach to your heart tissue and allows the incision where the device was implanted time to heal.

## How big is a pacemaker and where is it implanted?

The average pacemaker is about the size of a half-dollar coin, and about three times as thick. Doctors usually implant a pacemaker in the chest, just under the skin near the collarbone. The lead(s) will be positioned in the right side of your heart (see illustration). Your doctor will discuss with you which side of your chest the pacemaker will be implanted.





Having a pacemaker allows you to live your life knowing that your device will treat your slow heart rhythm as your doctor has prescribed and programmed. For many people, their lifestyles are no different once they have a pacemaker. They are able to work and enjoy hobbies, sexual activity, and travel. A pacemaker will help you enjoy as active and productive a lifestyle as your overall health permits. *(Individual results may vary.)* Following are some answers to questions you may have about daily living with a pacemaker. 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 a pacemaker?

Most people feel reassured knowing that a pacemaker may help them to feel better—or in extreme cases—to save their life. However, having a pacemaker 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 pacemaker will likely grow.

It's also important to remember that everyone is different about how private they are. 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 does a doctor monitor your heart when you have a pacemaker?

Your doctor will want to check your device and your overall health on a regular basis. It is important that you attend all scheduled follow-up visits—even if you are feeling well.

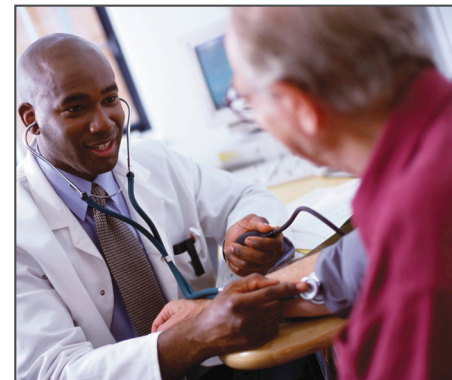
At follow-up visits in the doctor's office or hospital, the programmer (described on page 7) will be used to make sure your device is working properly to provide the best treatment for your heart rhythm. If your pacemaker needs any programming adjustments, your doctor or health care provider will use the programmer and wand to make changes. This is done outside the body and does not require surgery.

Your doctor or health care provider will also check the amount of energy left in your pacemaker's battery. The battery cannot be recharged or separated from the pacemaker. This means the pacemaker will need to be replaced before the battery's energy is used up—

usually several years after your implant. With regular follow-up, you and your doctor or health care provider will know ahead of time when your pacemaker will need to be replaced.

Your doctor may also recommend follow-up checks using a remote monitoring system. Your doctor or health care provider will explain how to use such a system if it is recommended for you.

Your doctor may also give you instructions about taking your own pulse each day, about exercise and about any other conditions for which you are seen. Be sure to tell any health care provider you see—including your dentist or chiropractor—that you have a pacemaker.



It is important that you attend all scheduled follow-up visits—even if you are feeling well.

## Does a pacemaker affect driving privileges?

Whether or not you are able to drive once you have a pacemaker will depend on your specific symptoms and the driving laws where you live. Generally, having a pacemaker does not prohibit you from driving, although you may be asked to wait during the early stage of recovery. Be sure to ask your doctor or health care provider about any restrictions you may have.

## What about sexual intimacy?

Many people are concerned about sexual intimacy. For most people with a pacemaker, 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 at the hospital to become familiar with how your heart rate increases. This will help him or her program your pacemaker settings.

## Can I still travel with a pacemaker?

Patients with a pacemaker can feel confident and safe when traveling. The Medical Device ID card that you receive with your device helps you 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. Walking through a metal detector will not harm your pacemaker. Airport security wands could temporarily affect the device. If security personnel use a handheld wand, ask them to do the search quickly and not to hold the wand over the device. You can also request a hand search if you prefer.

If you receive a pacemaker from Boston Scientific, a listing is available of medical facilities worldwide that have treated patients with these products. The listing is available by calling the Boston Scientific Patient Services department at 1-866-484-3268.

## Is there a risk of interference from household appliances with a pacemaker?

Under normal use, it is safe for someone with a pacemaker to use most household items. This includes hair dryers, heating pads, electric razors, remote controls, vacuums, microwaves, TVs, radios, computers, and many other appliances and items. But people with a

pacemaker do need to be aware that it 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 not used. Your doctor or health care provider 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. The information can also be found online at [www.bostonscientific.com/patients](http://www.bostonscientific.com/patients).

## Am I able to have an MRI scan?

Some pacemaker patients need to have MRI scans to diagnose their health conditions and determine proper treatment. MRI (Magnetic Resonance Imaging) is a diagnostic tool that uses different types of magnetics and electromagnetic fields to image soft tissue in the body. Many pacing systems are not appropriate for use during an MRI scan or near MRI scanners. You may be eligible to have an MRI scan if you are implanted with an MR-Conditional Pacing System (pacemaker and lead wires designed to work in the MRI environment) and meet the conditions of use. Your heart doctor or health care provider will work with you to determine if you and your pacing system can undergo an MRI scan.





## Meet Julie E.

Some people who have a heart condition become resigned to the idea that they may not be able to do all the things they want to do. Not Julia E. from North Carolina. Julia's journey began as a high school student with a pacemaker who wanted to run track and eventually the Boston Marathon. Julia shares her story about how the pacemaker device made a dramatic difference in her daily life.

### What symptoms led up to your needing pacemaker therapy?

"I was born with a 2-centimeter hole in my heart. All my life I had to sit on the sideline because I had a sick heart. When I was 17, I started having seizures from epilepsy. I was told not to drive and prescribed medication. It was a pretty scary time in my life. I just wanted to be normal like my friends.

"I went to my cardiologist and had several tests. My heart rate was down to 28 beats per minute. They told me they could fix my heart rate with a device called a pacemaker."

### How did you decide on the pacemaker device?

"I had never heard of this device before. When I learned more, it seemed a device for someone 60-years-old like my dad, not a teenager like me.

"But, I knew that this condition was not going to beat me. With a pacemaker, I could do the things I wanted to do."

### How did you feel after your first pacemaker device was implanted?

"With my first pacemaker, I was able to challenge everything I had done before. I swam, ran track, and competed with my friends. But, I really wanted to run marathons. The technology of the pacemaker at the time was not able to help me do that.

Julia's first pacemaker had a motion sensor called an accelerometer.

"I would be working harder and harder and be exhausted. I would be short of breath if I really pushed myself. When I was really active, my heart rate was erratic. I was pushing the limits of the technology available at the time."

### What did you find out about your second pacemaker device?

"When it was time for my second pacemaker, the Boston Scientific pacemaker had the technology to help my heart rate match the work I was doing."

Julia's second pacemaker had a blended sensor from Boston Scientific, which includes both an accelerometer motion sensor and a physiologic sensor called minute ventilation.

### How are you feeling now?

I completed a marathon without the blended sensor and a marathon with it. I can tell the difference. The new pacemaker allows me to stay at a steady state and gradually get my heart rate up to the level I need for the work I am doing.

"With pacemaker therapy, I am able to live the life I want. I am active in my community, working full-time, and training for upcoming events. I teach cycle classes at the YMCA twice a week."

### What's next for you as a pacemaker patient?

"I have completed more than 15 marathons, a half-ironman, and 40-mile ultra-marathon. I am very proud to have qualified for the Boston Marathon three times. I proudly wear the name "Boston Scientific" and tell people that I am a heart patient. At the event in 2010, I was approached by another pacemaker patient. He could not believe I was running a marathon. I knew that I wanted to finish each race to show other heart patients what is possible."

*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 Ric Y.

Ric Y. is from Nashville, Tennessee. After his first heart attack, Ric had two speeds, slow and stop. That changed with his pacemaker, which provided important support later when he had a second heart attack. Ric shares his story about how pacemaker therapy and coronary stents made a dramatic difference in his daily life.

### How was your heart condition diagnosed?

"One evening while watching Sunday night football, I passed out. My wife, Ruth, was there and woke me. I am a diabetic so she checked my blood sugar, then my pulse. We went right to the hospital. My heart rate went as low as 20-beats-per-minute.

"When we arrived at the emergency room, I was rushed right into the heart catheterization lab. I was having a heart attack! They cleared a 100% blockage in my right coronary artery. I was good to go two days later."

### What symptoms did you have?

"After my first heart attack, my pulse did not come back. My heart rate was running 36, 38, or 40 beats per minute. I was in heart block after the heart attack. Given a little time, we expected it to return to a normal rate. But up until December, it still hadn't come back. After doing some research and talking to my cardiologist, we decided to put in a Boston Scientific pacemaker."

### How did you feel after your pacemaker device was implanted?

"The difference was like night and day after the pacemaker was implanted. It was like having the Energizer Bunny™ back on board, all charged up, and raring to go! My heart rate was no lower than 60. Less than two weeks after the pacemaker was implanted, I was able get back to square dancing.

"As we got closer to the anniversary of my first heart attack, we thought that everything was going fine. This time, I woke up from sleep. I had pain in my arm and jaw, and felt like an elephant sat on my chest. When I got to the emergency room that night, I saw that my pulse never got below 60. The pacemaker helped keep me stable and allowed the doctors to observe me overnight. They determined that I had the blockage on the left coronary artery and needed stenting. I requested that Boston Scientific products be used. Two days later and I was good to go again.

"Ruth told me that we would not be making this an annual event."

### How are you feeling now?

"I have a second chance in life, and I want to take advantage of it everyday. I live for my family and friends, and for the opportunity to help people. Without the devices I have in me, all of that would not be here. I don't take anything for granted.

"I am vertical, above ground, and still looking at the green side of the grass. That is where I want to stay."

*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?

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

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

[www.heart.org](http://www.heart.org)

[www.mayoclinic.org](http://www.mayoclinic.org)

[www.hrsonline.org/patient-resources](http://www.hrsonline.org/patient-resources)

## Important Safety Information to Discuss with Your Doctor

A pacemaker system can monitor and treat your heart rhythm by delivering electrical energy to pace your heart when it senses a slow rhythm. But it is not for everyone, including patients with certain steroid and metal allergies. In some cases, the device may not respond to your heart rhythm. In rare cases severe complications or device failures can occur. Electrical or magnetic fields can affect the device. Only your doctor knows what is right for you. This 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. It is important that you talk with your doctor about potential risks.

### When your doctor implants your pacemaker, the potential 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)
- Damage to the heart (perforation or tissue damage)
- Puncturing of the heart or a vein on the outside of the heart (tamponade)
- Dangerous arrhythmias (abnormal heart rhythms)
- Kidney failure [if a contrast medium (dye) is used during implant]
- Heart attack
- Stroke
- Death

**After your doctor implants your pacemaker, 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 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 pacing therapy

### When your device or leads are replaced, the potential risks may be similar to, or even greater than, those of your original pacemaker 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.

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