

Pacemakers

Helping People with
Heart Conditions Live Better

**Boston
Scientific**

What's Inside?

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. If you have more questions after reading this brochure, please talk with your doctor.

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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 18.

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.

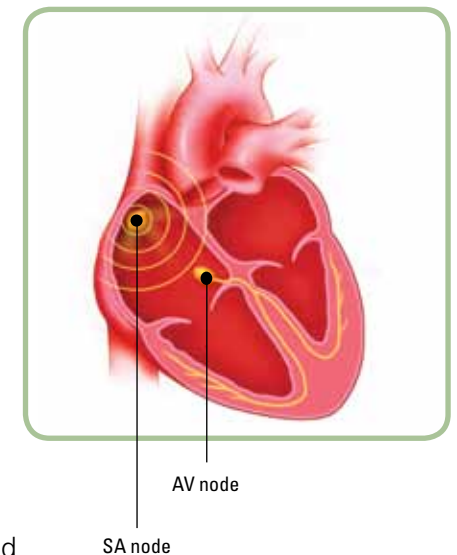
The SA node sends out natural pacemaker electrical signals through the heart's "relay station"—the atrioventricular (AV) node—and then through the ventricles, or lower chambers. These signals cause your heart muscle to beat—or contract. This produces a heartbeat, which pumps blood out of your heart to 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 slowly—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.





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 "read" 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 being energetic 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: Some 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.



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 electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues, including heart tissue and nerves.
- The device might be prevented from pacing due to electromagnetic interference (see additional information on page 13).

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 19.

Are pacemakers reliable?

Pacemakers are reliable. More than 3 million people worldwide have received a pacemaker.¹ Every year, pacemakers help millions of people live longer.

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.

Do insurance and Medicare cover a pacemaker?

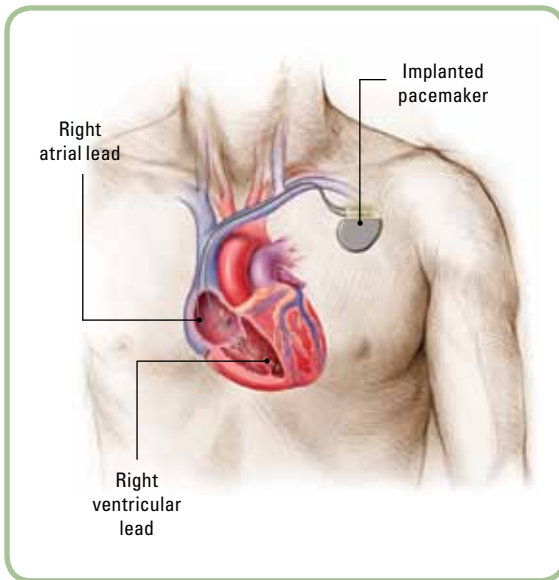
Most health insurance companies view a pacemaker as medically necessary for appropriately selected patients. If your doctor has determined that a pacemaker is right for you, your insurance will usually pay. Be sure to provide your doctor's office with your insurance information. Ask your doctor's office 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. 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.

Following 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 check out the online resources listed on page 18 in this brochure.



How big is a pacemaker and where is it implanted?

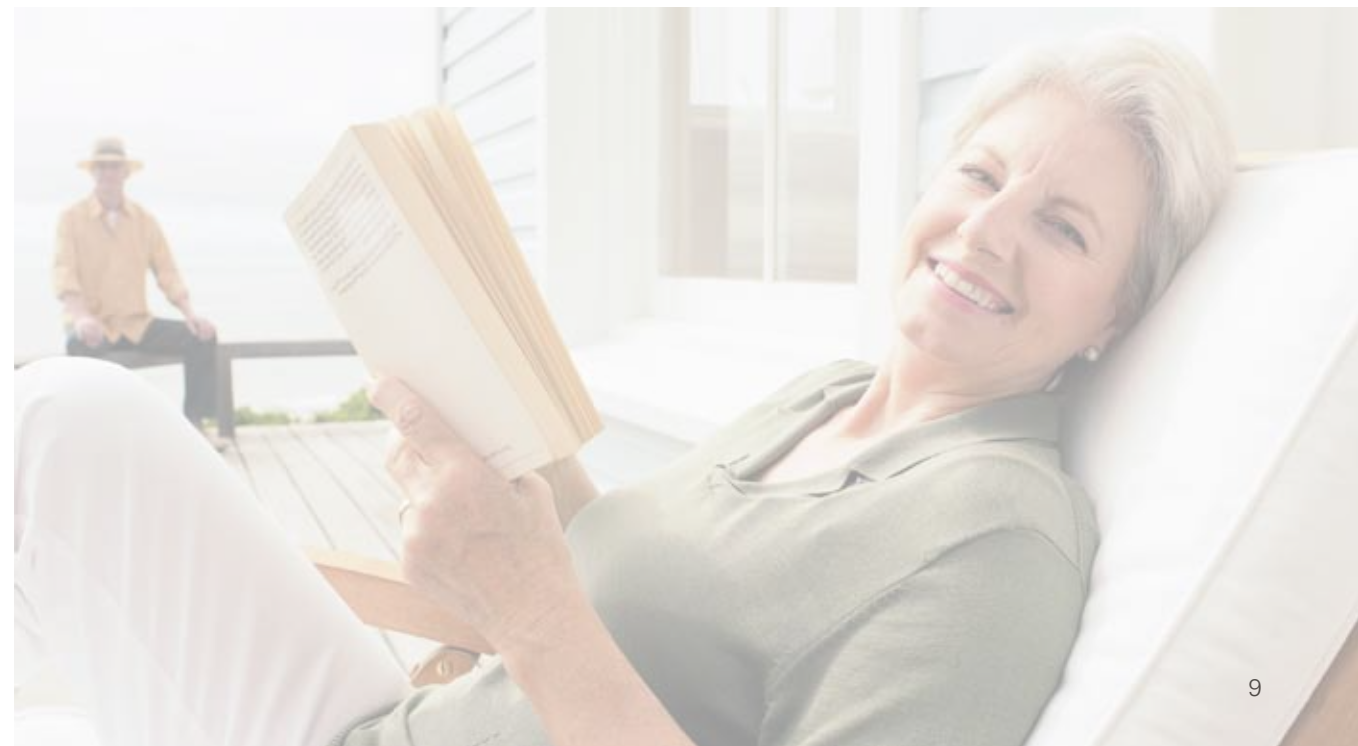
Today's pacemakers are amazingly small. The average pacemaker is about the size of a 50-cent piece, and about three times as thick. Doctors usually implant a pacemaker in the chest, just under the skin near the collarbone. The lead(s) will be positioned in the right side of your heart (see illustration). Your doctor will discuss with you which side of your chest the pacemaker will be implanted.

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 19.

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.



Living with a Pacemaker

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 18.

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 5) 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 when the battery's energy is used up—usually several years after your implant. With regular followup, 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 telephone 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 Boston Scientific's 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.lifebeatonline.com.



Meet Patrick R.

For Pat R. from Mountain View, Calif., his pacemaker has been nothing short of “a life changer.” Within weeks of having his first pacemaker implanted, he went from being bedridden, unable to work and confined to his home to playing tennis. Before the pacemaker, “I was absolutely ‘cooked,” Pat explained.

Pat’s journey to a pacemaker began in 1968, when he was just 32 years old. He suddenly began experiencing atrial fibrillation, a common heart condition in which there is an abnormally fast and chaotic heart rate in the heart’s upper chambers (atria). After simply “living with” the condition for many years, Pat finally went on medication in 1984.

By the time he was 55, however, medications could no longer control his condition. “It was a runaway train. I was in a constant state of flutter and fibrillation at about 180-plus beats a minute. I was also developing congestive heart failure.”

At the recommendation of a friend at Stanford University, Pat went to see his cardiologist about an AV node ablation

procedure. His cardiologist determined that he needed the procedure, which is used when the heart rate affects of atrial fibrillation cannot be stopped. Since the ablation alters the entire AV node (which relays the heart’s electrical signals), a pacemaker is needed after the surgery to regulate the heart’s rhythm.

After the ablation and surgery to implant the pacemaker, Pat said his doctor wanted him to walk down to the end of the hall. “I wanted to RUN down there because I had a new life. I am serious—I had a new life. You just do not lead a normal life with your heart beating 180 beats a minute.”

Enjoying an active lifestyle

After the surgery, with his doctor’s approval Pat started playing tennis within weeks. “I ended up playing competitive tennis. I could play about 2-1/2 to 3 hours of singles full blast, but I also had deteriorated a lot because I hadn’t exercised a lot, so I had to build my body up. My wife Sue and I also played club tennis. We played mixed doubles and it was terrific.”

Although the pacemaker enabled him to enjoy a very active lifestyle, Pat noticed that when he and Sue would walk their dogs, he struggled to walk up a hill—particularly a steep hill. It was also difficult to ride a bike, again especially uphill.

He learned that his 1990s-era pacemaker did not yet have the technology to sense the subtle physical, muscular activity exerted when going *up* a hill. However, if he were to walk *down* a hill where his legs were pounding the pavement a little bit more, the pacemaker would be able to sense more measurable physical muscular activity.

Sophisticated technology made the difference

In 2002, Pat’s friend at Stanford shared with him some information about new pacemakers with more sophisticated sensor technology. Since his pacemaker batteries were wearing down, Pat went in for replacement surgery. They used his existing leads and gave him a new pacemaker with advanced sensor technology. It would do a better job of adjusting his heart rate while going uphill or doing other activities by sensing the associated increase in his breathing.

Two days after receiving the new pacemaker, Pat walked up a very steep hill in Saratoga. “As you increase your breathing, it is kind of like an automatic transmission in a car. I just went right up that hill like I was driving an old ‘88 Olds. I am not a mountain climber or a rock guy or anything like that, but this new device is just another facilitator of being able to lead a more full life. For me the pacemaker has just made all the difference in the world.”

Note: Individual symptoms, situations, results, and circumstances may vary. Please consult your doctor 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



Meet Sharon S.

Most people in their thirties feel as if they are too young to have a heart condition, and they certainly don't expect to need an implanted cardiac device. Sharon S. had a pacemaker implanted in 2004. By age 35, Sharon was usually so tired that she had to spend much of her time on the couch. She no longer played with her three sons or attended their baseball games. She had also given up the creative outlets she loved: drawing, painting, and writing.

Then doctors discovered that Sharon had a heart condition called bradycardia, and she received a pacemaker. With a pacemaker, she found that she again had the energy for her family, her job, her writing, and her artwork. "I felt like I did when I was 18," said Sharon. "I was just revitalized."

Before getting her pacemaker, Sharon noticed her health changing in profound ways.

"I began noticing that I was often tired, light-headed, dizzy, and out of breath. Over the years it got worse. Eventually I started fainting, too. I'd have to sit and rest on the

edge of the bed for 20 minutes in-between tasks. Or else I would pick just one thing to do during the day, and I'd save all my energy for that."

It was when Sharon and her family moved to a different city that her new doctor referred her to a cardiologist. "He had me wear a Holter monitor, and he diagnosed profound bradycardia. My heart rate was very slow, sometimes down to 32 beats per minute. [Note: A normal heart rate is 60-100 beats per minute.] He also found that my heart sometimes paused for up to 3 seconds while I slept at night."

Sharon's doctor recommended a pacemaker. "Even with all I had been through, I was reluctant to have the implant. I think I was just in denial. But my nurse said it would make a big difference."

"I felt like I did when I was 18, I was just revitalized."

Living with a pacemaker

"I noticed a change immediately. In fact, I was astonished at how much better I felt in the hospital. I really didn't know how sick I was until after getting the pacemaker, when I felt well again.

"For a while the pacemaker felt heavy, but that feeling went away in a matter of days. The pacemaker helped me feel incredibly revitalized. I felt like jumping, running—everything I couldn't do before. I was so excited. I have a lot more energy for my kids, my husband, my job, and everything else. I'm an elected official, the town recorder. Plus I'm on the library board. I'm now swimming again and riding bikes with the kids."

Sharon has also launched a new art career. An art major in college, she always loved drawing and painting, but for years she didn't have the energy to pick up a pencil. "Returning to art has been absolutely great. I sell my artwork online, I sell in a shop downtown, and I recently had an art exhibit in a nearby city. I also started teaching private art lessons, and I volunteer in art class at my sons' school.

"I used to work as a newspaper reporter, and now I've also returned to writing. One thing I really enjoy is writing a blog [an online journal]. So I've really been making up for lost time."

Note: Individual symptoms, situations, results, and circumstances may vary. Please consult your doctor 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

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

lifebeatonline.com	mayoclinic.com
bostonscientific.com	hrspatients.org
americanheart.org	heart.healthcentersonline.com

LifeBeatSM Online Newsletter

Every issue includes articles about the road to recovery, cardiac news and interviews with patients. To subscribe, visit lifebeatonline.com.



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 allergies. Patients who have additional medical conditions that may not allow the pacemaker to function appropriately should not receive a device. 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 delivery 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.

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 experiences, 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

On an individual basis, your doctor or nurse will regularly monitor how your device is working. This includes 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. 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 19 in this brochure.

Footnotes:

¹ www.mayoclinic.com/health/pacemakers/HQ01165. Accessed November 19, 2007.

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Delivering what's next.™

Cardiac Rhythm Management

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