



Pacemaker
Therapy

**Boston
Scientific**

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Approved

1121452 B



Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Approved

1121452 B

Your pacemaker system information

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

Pacemaker Model Number: _____

Pacemaker Serial Number: _____

Implant Date: _____

Lead Model/Serial Numbers: _____

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Your medical contact information

Electrophysiologist Name/Phone Number:

Cardiologist Name/Phone Number:

Hospital Name/Address/Phone Number:

Medications (list): _____

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

By Mail:

Boston Scientific
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798

By Phone:

Patients and families: 1.866.484.3268
Medical professionals: 1.800.CARDIAC (227.3422)
Worldwide: 1.651.582.4000

On the Internet:

www.lifebeatonline.com

Medical Records:

1.800.PATDATA (1.800.728.3282)
7 a.m.–7 p.m. (Central Time), Monday–Friday
email: medical.records@bsci.com

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Approved

1121452 B

Table of contents

Introduction	1
When is this device used?,	2
When is this device not used?,	3
How reliable is this device?,	3
Glossary	5
Your heart's natural pacemaker	15
Bradycardia,	17
Your pacemaker system	21
The device,	21

Boston Scientific Confidential. Unauthorized use is prohibited.
LIT APPROVAL - Brady Patient Handbook US

Types of pacemakers, 23
The leads, 25

Implanting your pacemaker system 26
Implant risks, 30

After your implant 35
Medications, 37
Activities and exercise, 38
Your pacemaker system information, 38
Your identification card, 39

Living with your pacemaker system 41
Special considerations, 42
What you should know about your
pacemaker's battery, 47

Replacing your system, 48

Important safety information 52

- Operating household appliances and tools, 53
- Theft detection and security systems, 62
- Airport security, 64
- Cellular phones, 65
- Dental and medical procedures, 67

Summary 74

Visit us on the Internet 76

Notes and questions 77

Index 79

Boston Scientific Confidential. Unauthorized use is prohibited.
LIT APPROVAL - Brady Patient Handbook US



Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Approved

1121452 B

Introduction

Your doctor has recommended a pacemaker system to treat your slow heart rhythm. As a person with a slow heart rhythm, you may experience symptoms that can affect your quality of life. A pacemaker is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated with them.

This handbook will tell you how a pacemaker system treats heart rhythms that are too slow. It will discuss activities you can begin and those you should avoid after your surgery. It will talk about some of the changes that may occur in your life. It will also answer many

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

The glossary is located at the front of the handbook. It defines many of the words you will see in the upcoming pages, as well as those you may hear from your doctors and nurses.

When is this device used?

Your doctor has decided that you should receive a pacemaker system to treat and monitor your slow heart rhythm. If you have any questions about when this device is used, ask your doctor.

When is this device not used?

Patients who have additional medical conditions that may not allow the pacemaker to function appropriately should not receive a device. If you have any questions about when this device is not used, ask your doctor.

How reliable is this device?

It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. Refer to Boston Scientific's *CRM Product Performance Report* on www.bostonscientific.com for more information about device performance, including

the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products. Talk with your doctor about this product performance data, and the risks and benefits associated with the implantation of this system.

Glossary

Adaptive rate

The ability of a device to increase or decrease its pacing rate in response to bodily needs, activity, or exercise.

Asynchrony

A condition in which the heart fails to maintain a normal timing sequence between atrial and ventricular contractions.

Atrioventricular (AV) node

A cluster of cells located in the wall between the right and left atrium, just above the ventricles. This

part of the heart's electrical pathway helps carry signals from the atria to the ventricles.

Atrioventricular (AV) synchrony

The normal timing sequence for an atrial contraction followed, after a fraction of a second, by a ventricular contraction.

Atrium (plural: atria)

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

Bradycardia

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

Catheter

A thin, flexible tube or wire inserted into the body for a variety of purposes. Catheters are inserted into the heart during an electrophysiology (EP) test to monitor your heart's electrical activity. Hollow catheters are also used to carry a lead through a blood vessel. See also *electrophysiology (EP) test or study*.

Device

See pulse generator.

ECG/EKG (electrocardiogram)

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

Electromagnetic field

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

Electromagnetic interference (EMI)

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

Electrophysiology (EP) test or study

A test in which catheters (thin, flexible tubes or wires) are inserted into your heart to identify and measure the type of electrical signals in your heart. The test

results can help your doctor identify the origins of your abnormal heart rhythms, determine how well medications work, and decide what treatment is best for your condition.

Heart attack

See *myocardial infarction (MI)*.

Heart block

A condition in which the electrical signals of your heart's natural pacemaker (SA node) are delayed or do not reach the ventricles.

Heart rhythm

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

Lead (pronounced “leed”)

An insulated wire that is implanted in the heart and connected to the device. The lead senses your heartbeat and delivers pacing pulses from the device to the heart. The leads are usually passed into your heart through a vein.

Myocardial infarction (MI)

Also called a heart attack. A myocardial infarction occurs when an artery that supplies blood to the heart becomes blocked. As a result, blood does not

reach some parts of the heart, and some of the heart tissue dies. Symptoms of a myocardial infarction may include shortness of breath, nausea, fatigue, and/or pain in the chest, arm, or neck.

Pacemaker system

A pulse generator (also called a device) and leads. A pacemaker system is implanted to monitor your heart rhythm and treat dangerously slow rhythms.

Pectoral

The area above the breast and below the collarbone. This is a common area for a device implant.

Programmer

Microcomputer-based equipment that is used to communicate with the device. The programmer is

used during testing and follow-up exams to gather and display information from the device. The doctor or technician also uses the programmer to adjust the device so that it senses and treats your slow heart rate.

Pulse generator

Also called a device. The pulse generator is the part of the pacemaker system that contains the electronics and battery; it is implanted under the skin in the pectoral (or, in some cases, abdominal) area. See also *pectoral*.

Sinoatrial (SA) node

The heart's natural pacemaker. The SA node is a small group of specialized cells in the upper right chamber of the heart (right atrium) that normally generates an

electrical signal. This signal runs through the heart and causes the heart to beat.

Ventricle

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

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Approved

1121452 B

Your heart's natural pacemaker

Your heart works as both a mechanical pump and an electrical organ. It is able to beat because it produces electrical signals. These signals travel through the electrical pathways of your heart (Figure 1), causing the muscle contraction that pumps blood throughout your body.

Normally these signals come from a small area in your heart called the sinoatrial (SA) node. This area is located in the upper right chamber, or right atrium. When the SA node signals reach the two upper chambers of the heart (the atria), they contract at

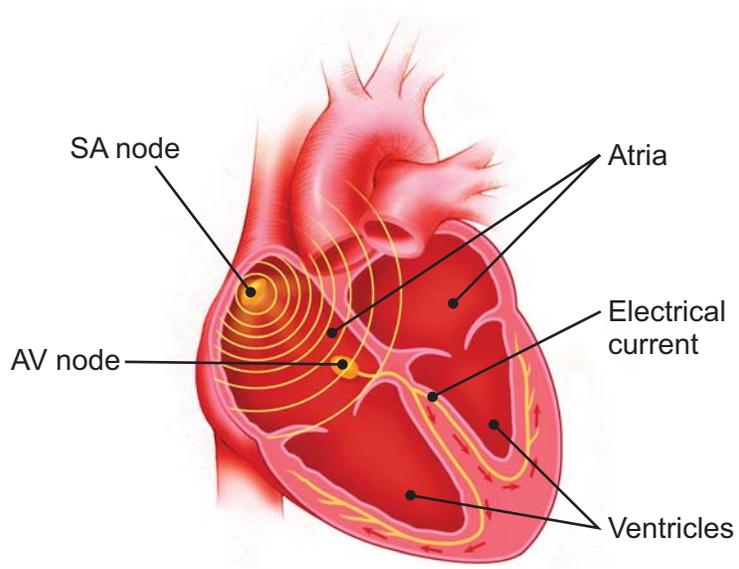


Figure 1. The heart and its electrical pathways.

the same time. The atrial contraction fills the two lower chambers (the ventricles) with blood (Figure 2). As the electrical signal travels through the ventricles, it causes them to contract, which pumps blood out to your body. The contraction of the heart muscle (ventricles) is what you feel as a heartbeat. After a brief rest, the cycle begins again.

Bradycardia

Sometimes the heart beats too slowly. This can be caused by the SA node not working properly or by a condition called heart block (Figure 3). Heart block exists when there is a problem with the electrical pathway between the atria and the ventricles. The

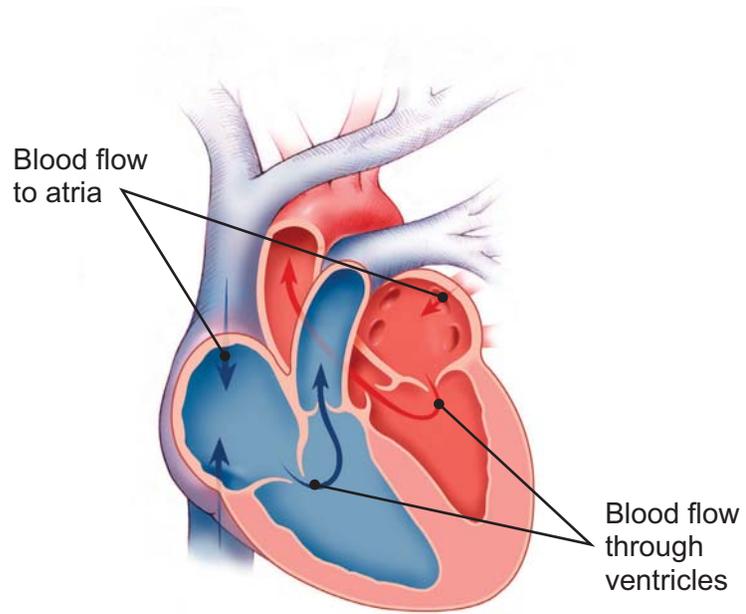


Figure 2. The heart and its blood flow.

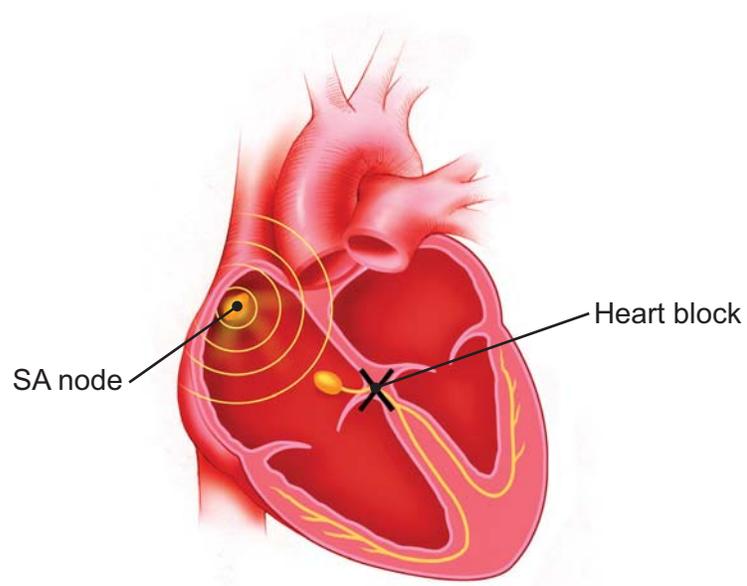


Figure 3. An example of heart block.

natural pacemaker signals sent out by the SA node could be delayed or 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. If you have bradycardia, you may feel tired or dizzy, or you may faint.

Your pacemaker system

Your pacemaker system is designed to monitor and treat your heart rhythm. The system consists of a pulse generator (also called a device), which is typically implanted in your chest, and one or more leads, which are implanted in your heart and connected to the device.

The device

The device contains a small computer. It runs on a battery that is safely sealed within its case. The device continuously monitors your heart rhythm and

delivers electrical energy (as programmed by your physician) to pace your heart during a slow rhythm.

As the device monitors your heart rhythm, it can also store information about your heart. Your doctor can review this information using a special computer called a programmer. The programmer communicates with the device from outside your body through a wand that is placed over your skin. With the programmer, your doctor can better evaluate the programmed therapy for your heart rhythm and adjust the settings if necessary.

Types of pacemakers

There are two different types of pacemakers: single-chamber and dual-chamber. Both of these pacemakers continuously monitor your heart rate and send out pacing signals when necessary. It is important to discuss with your doctor which kind of pacemaker is right for you.

Single-chamber pacemakers

A single-chamber pacemaker has one lead to monitor signals from and deliver pacing pulses to one chamber of your heart (either the right atrium or right ventricle). This type of pacemaker is often selected for a person whose SA node sends out signals too slowly.

Dual-chamber pacemakers

A dual-chamber pacemaker has two leads. One lead is placed in the right atrium, and the other lead is placed in the right ventricle. Because there are leads in two chambers, the pacemaker can monitor signals from and deliver pacing impulses to either or both of these heart chambers.

A dual-chamber pacemaker may be selected for many different reasons. For some people, the SA node's signals are too slow and the electrical pathway to the ventricles is partly or completely blocked. A dual-chamber pacemaker can help treat both problems. For other people, the timing of the atrial and ventricular

contractions is uncoordinated (asynchronous). A dual-chamber pacemaker can restore a normal timing sequence (also called AV synchrony).

The leads

A lead is an insulated wire implanted in your heart and connected to the device. A lead carries the heart signal to the device. It then carries energy from the device back to the heart to coordinate your heart rhythm.

Implanting your pacemaker system

A pacemaker system is implanted during a surgical procedure. To keep you as comfortable as possible, you will be sedated for this surgery. During the procedure, your doctor will insert the lead into a vein, usually through a small incision near your collarbone. The doctor will then pass the lead through the vein into your heart (in either the right atrium or the right ventricle), where the tip of the lead will rest directly against your heart's inner wall (Figure 4).

If your doctor decides your heart condition requires a dual-chamber system, an additional lead will be

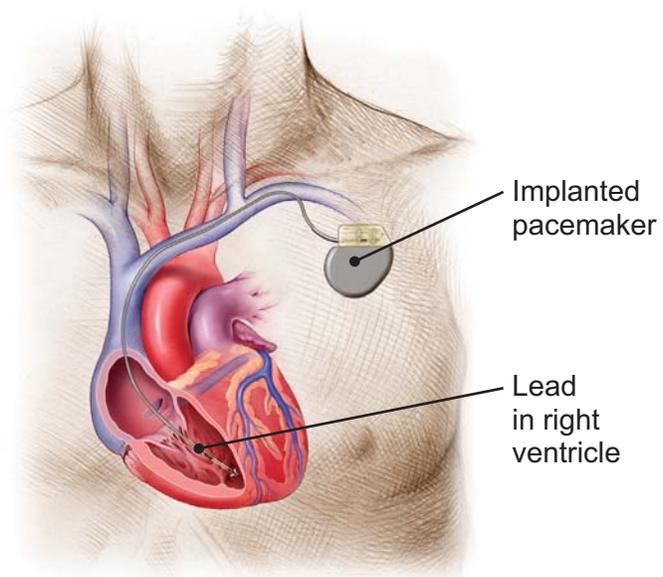


Figure 4. An implanted single-chamber pacemaker system.

implanted. One lead will be positioned in the atrial chamber of your heart and the other will be positioned in the ventricular chamber (Figure 5).

After the leads are positioned, they will be tested to make sure they clearly sense your heart signal and can adequately pace your heart. After this testing, the device will be connected to the leads and placed in position (usually below the collarbone, just beneath the skin).

Your doctor will then test your pacemaker system to make sure it can appropriately monitor and treat your heart rhythm.

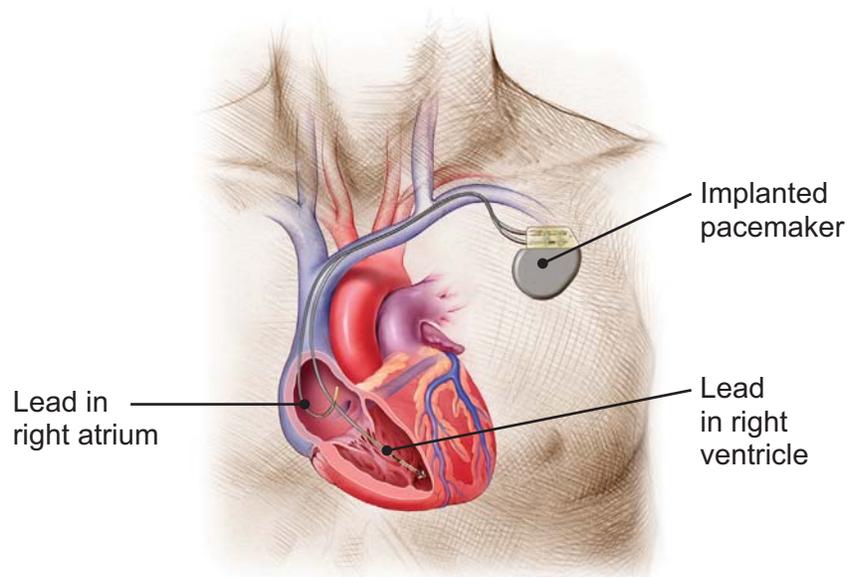


Figure 5. An implanted dual-chamber pacemaker system.

After your doctor has finished testing your system, the incision will be closed. You may experience some discomfort from the incision as you recover from the surgery. You should be able to return to normal activities soon after the procedure.

Implant risks

As with any surgical procedure, it is important to understand that, while complications do not happen very often, there are risks associated with the implantation of a device or lead. You should talk with your doctor about these risks, including those listed below.

Some of the risks encountered during the implant procedure include, but are not limited to, the following:

- Bleeding
- Formation of a blood clot
- Damage to adjacent structures (tendons, muscles, nerves)
- Puncture of a lung or vein
- Damage to the heart (perforation or tissue damage)
- Dangerous arrhythmias
- Heart attack
- Stroke
- Death

Some of the risks encountered after the system is implanted may include, but are not limited to, the following:

- You may develop an infection.
- You may experience erosion of the skin near your device.
- The device may move from the original implant site.
- 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.

- You may have difficulty coping with having an implanted device.
- The device might be prevented from pacing due to electromagnetic interference (see “Important safety information” on page 52).
- You may receive pacing therapy when it is not needed (unnecessary therapy).
- 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. See “How reliable is this device?” on page 3.

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.

After your implant

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

- Report any redness, swelling, or drainage from your incisions.
- Avoid lifting heavy objects until instructed by your doctor.

- Walk, exercise, and bathe according to your doctor's instructions.
- Do not wear tight clothing that could irritate the skin over your device.
- Contact your doctor if you develop a fever that does not go away in two or three days.
- Ask your doctor any questions you may have about your pacemaker system, heart rhythm, or medication.
- Avoid rubbing your device or the surrounding chest area.
- If directed by your doctor, limit arm movements that could affect your lead system.

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

Medications

Your pacemaker system is designed to help treat your heart condition. However, you may need to

continue taking certain medications as well. It is important that you follow your doctor's instructions regarding any medications.

Activities and exercise

Your doctor will help you decide what level of activity is best for you. He or she can help answer your questions about lifestyle changes, travel, exercise, work, hobbies, and resuming sexual intimacy.

Your pacemaker system information

Have your doctor or nurse complete the "Your pacemaker system information" form at the front of this handbook before you go home from the hospital.

Your identification card

Whether you are going away for the weekend or running a quick errand, carry your Medical Device Identification Card with you. In an emergency, the card will alert medical and security personnel that you have an implanted device.

You will be given a temporary Medical Device Identification Card when you receive your device. Boston Scientific will mail you a permanent Medical Device Identification Card about six to eight weeks after your implant.

Your Medical Device Identification Card contains your name, your doctor's name and phone number, and the model numbers of your device and leads.

If you move or select a new doctor, please call Boston Scientific Medical Records at 1.800.728.3282 to update your records. When you notify us of a change, we will send you a new identification card reflecting the change.

Living with your pacemaker system

It is important to follow your doctor's instructions and keep your scheduled follow-up appointments. You should also do the following:

- Ask your doctor if you have any questions about or notice anything unusual with your device.
- Take the medications prescribed for you as instructed by your doctor.
- Carry your identification card and medication list with you at all times.

- Tell your family doctor, dentist, and emergency personnel that you have a pacemaker.

Special considerations

Your doctor might ask you to avoid activities where the risk of unconsciousness could endanger you or others. These activities might include driving, swimming or boating alone, or climbing a ladder.

Driving

Driving laws and symptoms caused by your heart rhythm are often the deciding factors in whether

you will be allowed to drive. Your doctor will advise you about what is best for your safety and the safety of others.

When to call your doctor

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

- Have a heart rate that drops below the minimum rate set for your pacemaker.
- Have symptoms of an abnormal heart rhythm and have been instructed to call.
- Notice any swelling, redness, or drainage from your incisions.

- Develop a fever that does not go away in two or three days.
- Have questions about your device, heart rhythm, or medications.
- Plan to travel or move away. Work with your doctor to develop a follow-up plan while you are away.
- Notice anything unusual or unexpected, such as new symptoms or symptoms like the ones you had before you received your device.

Remember that your pacemaker is designed to monitor and treat your slow heart rate. It can be a great source of reassurance for you and your friends and family.

Follow-up visits

Your doctor will schedule regular follow-up visits. It is important that you attend these visits, even if you are feeling well. Your pacemaker has many programmable features; follow-up visits will help your doctor program your pacemaker to best meet your individual needs.

During your visit, the doctor or nurse will use a programmer to check your device. The programmer is a special external computer that can communicate with your device in two ways:

1. By using radio frequency (RF) telemetry communication, if you have an RF-enabled device.

2. By using wanded telemetry communication. In this case, the doctor or nurse will place a wand over your skin near your device.

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

What you should know about your pacemaker's battery

A battery, safely sealed inside your device, provides the energy needed to monitor your heart rhythm and pace your heart. Just like any other type of battery, the battery in your device will be used up over time. Since the battery is permanently sealed within your device, it cannot be replaced when its energy is depleted. Instead, your entire device will need to be replaced (see "Replacing your system" on page 48). How long your pacemaker's battery lasts depends upon the settings your doctor programs and how much therapy you receive.

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

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

Replacing your system

Eventually, the energy in your device's battery will decrease to a point where your device will need to be replaced (see "What you should know about your pacemaker's battery" on page 47). Your doctor will

monitor your device's battery levels and determine when to replace your device.

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

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

Should a lead need to be replaced, your doctor will insert a new lead into a vein, similar to how the

original lead was implanted. See “Implanting your pacemaker system” on page 26.

Your doctor will then connect the leads to your new device. Finally, he or she will test your new system to make sure it is working properly.

After the testing is complete, the pocket of skin will be closed. You may experience some discomfort from the incision as you recover from the surgery. You should be able to return to normal activities soon after the procedure.

Risks

Risks encountered during a device and/or lead replacement procedure are similar to the risks of the initial implant, such as infection, tissue damage, and bleeding. See “Implant risks” on page 30.

Be sure to talk with your doctor about the potential risks when making decisions about replacing your system.

Important safety information

Your device has built-in features that protect it from interference produced by most electrical equipment. Most of the things you handle or work around on a daily basis are not going to affect your device. However, your device is sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields.

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

with your physician. He or she may ask you to contact Boston Scientific Patient Services.

Operating household appliances and tools

Use the following guidelines for safe interaction with many common tools, appliances, and activities.

Items that are safe under normal use:

- Air purifiers
- Blenders
- CD/DVD Players
- Clothes washing machines and dryers

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

NOTE: *Consult with your doctor before using a hot tub. Your medical condition may not permit this activity; however, it will not harm your device.*

- Laser tag games
- Microwave ovens
- Ovens (electric, convection, or gas)
- Pagers
- Patient alert devices
- Personal computers
- Personal digital assistants (PDAs)

NOTE: PDAs that also function as cell phones should be kept at least 6 inches away from your device. See "Cellular phones" on page 65.

- Portable space heaters

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

Warnings and precautions

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

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

- Cordless (household) telephones
- Electric razors
- Hand-held massagers

- Portable MP3 and multimedia players (such as iPods®) that do not also function as a cellular phone (see “Cellular phones” on page 65)
***NOTE:** While portable MP3 players themselves should not interfere with your device, the headphones or earbuds should be stored at least 6 inches (15 cm) away from your device, and you should avoid draping the headphones around your neck.*

iPod is a registered trademark of Apple Inc.

Items that should remain at least 6 inches (15 cm) away from your device:

- Cellular phones, including PDAs and portable MP3 players with integrated cellular phones

NOTE: For more information on cellular phones, see “Cellular phones” on page 65.

- Devices transmitting Bluetooth® or Wi-Fi signals (cellular phones, wireless Internet routers, etc.)

- Headphones and earbuds

NOTE: It is safe to use headphones and earbuds, but you should refrain from draping them around your neck and from storing them in a breast or other shirt pocket that places them within 6 inches (15 cm) of your device.

Bluetooth is a registered trademark of Bluetooth SIG, Inc.

- Magnetic wands used in the game of Bingo

Items that should remain at least 12 inches (30 cm) away from your device:

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

- Snowblowers
- Stereo speakers

Items that should remain at least 24 inches (60 cm) away from your device:

- Arc welders
- CB and police radio antennas
- Running motors and alternators, especially those found in vehicles

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

Items that should not be used:

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

If you have questions about the EMI safety of a particular appliance, tool, or activity, please call Boston Scientific Patient Services at 1.866.484.3268.

Theft detection and security systems

Electronic antitheft systems and security gates or tag readers that include radio frequency identification

(RFID) equipment (often found in store and library doorways, and in point-of-entry access control systems) should not cause you any worry if you follow these guidelines:

- Walk through theft detection and security systems at a normal pace.
- Do not lean against or linger near these systems.
- If you are near an electronic antitheft, security, or entry control system and suspect interaction (experience symptoms) with your device from one of these systems, promptly move away from equipment nearby and inform your doctor.

Your Boston Scientific implantable device is unlikely to set off the alarm from an electronic antitheft or security system.

Airport security

Your device contains metal parts that may set off airport security metal detector alarms. The security archway will not harm your device. Tell security personnel that you have an implanted device and show them your Medical Device Identification Card.

Airport security wands could temporarily affect your device. If possible, ask to be hand-searched instead of

being searched with a handheld wand. If a wand must be used, inform the security personnel that you have an implanted device. Tell the security personnel not to hold the wand over your device and to perform the search quickly.

If you have questions about airport security, call your doctor or Boston Scientific Patient Services at 1.866.484.3268.

Cellular phones

Keep your cellular phone at least 6 inches (15 cm) away from your device. Your cellular phone is a source of EMI and could affect your device's operation. This interaction is temporary, and moving the phone away

from your device will return it to proper function.
To reduce the chance of interaction, follow these precautions:

- Maintain a distance of at least 6 inches (15 cm) between the cellular phone and your device. If the phone transmits more than 3 watts, increase the distance to 12 inches (30 cm).
- Hold the cellular phone to your ear on the opposite side of your body from your device.
- Do not carry a cellular phone in a breast pocket or on a belt if that places the phone within 6 inches (15 cm) of your device.

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

Dental and medical procedures

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

- **Magnetic resonance imaging (MRI):** This is a diagnostic test that uses a strong electromagnetic

field. Some pacemaker systems have been engineered to allow the patient to undergo MRI scans under specific conditions. Talk to your physician about the capabilities of your device and leads. If your system is not one of those eligible to be scanned, or if the required conditions are not met, MRI scans can severely damage your pacemaker system or injure you and should not be performed. Your physician must always confirm that both you and your pacing system are eligible and ready for an MRI scan in order for you to undergo this procedure.

Hospitals keep MRI equipment in rooms marked with signs that indicate magnets are inside. Do not

go inside these rooms unless your physician has confirmed that your pacing system is eligible and you meet the requirements for an MRI scan.

- **Diathermy:** This uses an electrical field to apply heat to tissues in the body and could damage your device or injure you. Diathermy should not be performed.
- **Electrocautery:** This is used during surgical procedures to stop vessels from bleeding. If electrocautery must be used, talk with your heart doctor and the doctor performing the medical procedure.

- **Electrolysis and Thermolysis:** These are dermatology or hair removal procedures that pass electrical current into the skin. Talk with your heart doctor before having any electrolysis or thermolysis treatment.
- **External defibrillation:** This is a procedure, typically used in medical emergencies, that uses external equipment to deliver an electrical shock to your heart to restore a rapid and irregular heart rate to a normal rhythm. External defibrillation can affect your device, but can still be performed if necessary. If you receive external defibrillation, be sure to contact your physician as soon as possible

following the emergency to verify that your device is functioning properly.

- **Lithotripsy:** This is a medical procedure that is used to break up stones in the urinary tract (e.g., kidney stones). Lithotripsy can damage your device if certain precautions are not taken. Talk with your heart doctor as well as the doctor performing the procedure about what can be done to protect your device.
- **Therapeutic radiation treatment for cancer:** This procedure can affect your device and will require special precautions. If you should need radiation treatment, talk with your heart doctor as well as the doctor performing the medical procedure.

- **Transcutaneous Electrical Nerve Stimulation**

(TENS) unit: This is a device prescribed by physicians or chiropractors for control of chronic pain. A TENS unit can affect your device and will require special precautions. If you must use a TENS unit, talk with your heart doctor.

Most medical and dental procedures will not affect your device. Some examples include:

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

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

- EKG machines
- CT scans

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

If you have questions about a specific appliance, tool, medical procedure, or piece of equipment, please talk with your doctor or call Boston Scientific Patient Services at 1.866.484.3268.

Summary

It is natural for you to feel anxious or nervous about receiving a pacemaker. Remember that your pacemaker system can be a great source of reassurance for you and your friends and family.

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

The information presented in this handbook is intended to help you understand more about your heart condition

and your device. If you have questions about what you have read, be sure to ask your doctor or nurse. They are your best resource for information about your particular needs or situation.

Visit us on the Internet

Boston Scientific's patient-focused website, *LifeBeat Online*, offers a variety of information of interest to people with cardiac devices, including cardiac news, health tips, patient stories, frequently asked questions about living with your implanted device, and links to additional resources. You can also subscribe to have the free newsletter delivered to your email address.

www.lifebeatonline.com

Notes and questions

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

Index

A

Activities, 38, 42
Airport security, 64
Atria, 15

B

Battery, 47
end of life, 47, 48
Bluetooth, 59
Boating, 42

Bradycardia, 17

C

Calling your doctor, 43
Catheter, 7
Cellular phones, 59, 65
Cordless phones, 57, 67
CT scans, 72

D

Dental equipment, 71
Dental procedures, 67
Dermatology procedures, 69
Device, 21
 dual-chamber, 24
 implanting, 26
 reliability, 3
 replacing, 48
 single-chamber, 23
Diathermy, 68
Driving, 42

E

EKG machines, 72
Electrocautery, 68
Electrolysis, 69
Electromagnetic interference (EMI), 52
Electronics
 precautions, 52
Electrophysiology, 8
Exercise, 38
External defibrillation, 69

F

Follow-up visits, 45

G

Glossary, 5

H

Hair removal procedures, 69

Heart block, 17

Heart function, 15

Household appliances
precautions, 53

I

Identification card, 39

Implanting the system, 26
recovery, 35

risks, 30

iPods, 58

L

Ladders, 42

Leads, 25
implanting, 26
replacing, 49

Lithotripsy, 70

Living with your device, 41
ID card, 39

M

Mammograms, 71

Medical procedures, 67
Medications, 37
MP3 and multimedia
players, 58
MRI, 67

P

Pacemaker system, 21
 device, 21
 dual-chamber, 24
 implanting, 26
 leads, 25
 reliability, 3
 replacing, 48
 risks, 30

single-chamber, 23
Precautions, 52
 airport security, 64
 cellular phones, 59, 65
 dental procedures, 67
 diathermy, 68
 electrocautery, 68
 electrolysis, 69
 external defibrillation, 69
 household
 appliances, 53
 lithotripsy, 70
 medical procedures, 67
 MRI, 67
 radiation treatment, 70
 TENS unit, 71

theft detection and security systems, 62
thermolysis, 69
tools, 53
Programmer, 22,45
Pulse generator, *see* Device

R

Radar, 52
Radiation treatment, 70
Radio frequency (RF) telemetry, 45
Recovery, 35
Reliability, 3

Replacing the system, 48
risks, 51

Risks, *see* Precautions
electromagnetic interference, 52
implant procedure, 31
post-implant, 32
replacement procedure, 51

S

Safety, *see* Precautions
Security systems, 62
Sinoatrial (SA) node, 15
Swimming, 42

T

Telemetry communication
 radio frequency (RF), 45
 wanded, 46

TENS units, 71

Theft detection and security
systems, 62

Thermolysis, 69

Tools
 precautions, 53

Traveling, 38,44
 airport security, 64

U

Ultrasound, 71

V

Ventricles, 17

W

Wanded telemetry, 46

Warnings, *see* Precautions

X

X-rays, 71

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Approved

1121452 B



Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Approved

1121452 B

Boston Scientific

Advancing science for life™

Boston Scientific

4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA
Tel: 651.582.4000

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

www.bostonscientific.com

© 2014 Boston Scientific Corporation
or its affiliates. All rights reserved.



Brady

356429-010 EN US 2014-08

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - Brady Patient Handbook US

Approved

1121452 B

Your ImageReady™ MR Conditional Pacing System and MRI Scans

Overview

Magnetic Resonance Imaging (MRI) is a diagnostic test that uses a powerful magnet and radio waves to produce images of the human body. Most pacing systems are not appropriate for use during an MRI scan or near MRI scanners. However, some pacemaker patients need to have MRI scans to diagnose their health conditions and determine proper treatment. Boston Scientific has developed a pacing system that can be scanned when certain conditions are met. This includes programming the pacemaker to special settings for MRI.

You **MAY** be eligible to have an MRI scan if you are implanted with the Boston Scientific ImageReady MR Conditional pacing system (pacemaker and lead wires designed to work in the MRI environment). Your heart doctor or healthcare provider will work with you to determine if you and your pacing system can undergo an MRI scan.

Make sure you and your physician(s) are comfortable with the risks and benefits of having an MRI scan.

Common Questions

To be eligible for an MRI scan, you must have the right pacing system implanted. This includes the pacemaker and the lead wires. The clinic performing the scan must use an MRI machine that meets the technical requirements of the ImageReady pacing system.

Common questions include:

1. Am I able to have an MRI scan?
 - If a healthcare provider recommends an MRI scan, talk to your heart doctor before scheduling your MRI scan.
 - Your heart doctor will check you and your ImageReady pacing system to determine if you are eligible for an MRI scan.
 - Even if your pacing system is eligible, you may have other implanted devices or metal in your body that may prevent you from having an MRI scan.

- You must be physically capable of having an MRI scan. This means that you can lay flat during the scan, and tolerate how the pacemaker functions during the scan.
- Your implanted pacemaker and lead wires are listed on your current medical device ID card. You should keep this card with you at all times, and take it with you to the MRI facility.
- Always check with your heart doctor or a healthcare provider if you have questions before or after the MRI scan.

2. What can I expect during an MRI scan?

- Before the scan, your ImageReady pacing system will be programmed to the MRI settings. These settings are necessary for you to receive an MRI scan. While your pacing system is programmed to these settings, your heart rate may be different from what you are accustomed to.
- Your heart function will be monitored during the scan.
- Your ImageReady pacing system may stay in the new MRI settings for a limited time. If so, you or your caregiver may be notified of the duration of time your device will remain in the MRI settings. The MRI scan needs to be completed before that time expires.
- You may see signs at the MRI facility that warn you not to enter if you have a pacemaker. These signs apply to pacing systems that are not eligible, programmed, and cleared to have an MRI scan. Always check with a healthcare provider if you have questions.
- During the MRI scan, you may experience the following:
 - Loud noises are part of a normal MRI scan; the noises are not coming from your pacemaker.
 - You might feel slight movement or vibration of the pacemaker, or a warm sensation from the pacemaker.

3. What happens after the scan?

- After the scan, follow the directions provided by your heart doctor or healthcare provider.
- Your implanted ImageReady pacing system may be checked to ensure it is working normally. The pacing system may be programmed out of the MRI settings, or it may return to your normal pacing settings automatically after a specific period of time set by your doctor.
- If you experience any new symptoms after the scan, contact your heart doctor or healthcare provider.
- If you need additional MRI scans, you and your pacing system must be checked for eligibility for a scan each time. If your implanted pacing system has changed, for example a new pacemaker or lead wires, or if aspects of your health have changed, it is possible that you are no longer eligible for an MRI scan.

ImageReady is a trademark of Boston Scientific or its affiliates.

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - INGENIO₂ MRI PATIENT GUIDE US

Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - INGENIQ₃ MRI PATIENT GUIDE US

Approved

1117667 B

Boston Scientific

Boston Scientific
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA
Tel: 651.582.4000

Medical Professionals:
1.800.CARDIAC (227.3422)

Patients and Families:
1.866.484.3268

www.bostonscientific.com

© 2014 Boston Scientific Corporation or its affiliates.
All rights reserved.

359260-001 EN US 2014-07



Boston Scientific Confidential. Unauthorized use is prohibited.

LIT APPROVAL - INGENIQ MRI PATIENT GUIDE US