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CAUTION : FEDERAL LAW (USA) RESTRICTS CARDIAC ARRHYTHMIA MANAGEMENT DEVICES TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.

Brief Summary: Please review the appropriate literature accompanying the device for a complete listing of warnings and precautions.

This pamphlet is for general information only and is not intended to replace the literature accompanying the device.

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LIVING WITH YOUR PACEMAKER



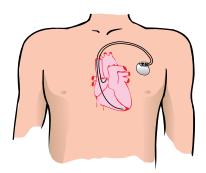
Your Pacemaker-At a Glance

- Your heart is a muscle about the size of your fist and has a complex electrical system.
 It generates its own electricity, which causes it to contract and relax in the proper timing sequence, pumping blood to the body.
- For the heart to work correctly, the chambers must beat in a coordinated manner at a resting heart rate between 60 and 100 beats per minute.
- Electrical signals can become blocked or irregular, causing the heart to beat too quickly (tachycardia) or too slowly (bradycardia).
- Pacemakers are miniaturized computers about the size of a couple of stacked silver dollars. They are usually implanted just underneath the skin in the chest area.
- A pacemaker monitors the heart's rate (how fast it beats) and rhythm (the pattern in which it beats) and provides electrical stimulation when the heart does not beat or beats too slowly.
- To provide support, the pacemaker sends a tiny electrical pulse down a wire or wires into your heart, stimulating the heart to beat.
- The pacemaker also stores information about your heart, which can be retrieved by your doctor. This helps your doctor to program the settings of the pacemaker to provide you with the best therapy for your needs.
- Pacemakers cannot be damaged by properly operating household appliances, such as microwave ovens.
- Pacemakers can help people to enjoy longer, more productive, happier and healthier lives.

Frequently Asked Questions

Living with your pacemaker.

Since the first fully implanted pacemaker in October of 1958, more than 2 million people have benefited from pacemaker therapy. A pacemaker monitors the heart's rate (how fast it beats) and rhythm (the pattern in which it beats), and it provides electrical stimulation when the heart does not beat or beats too slowly. Pacemakers can help to reduce symptoms of dizziness and fatigue brought on by a slow heart rhythm, helping patients to enjoy a better quality of life.



Why do I need a pacemaker?

The heart has a complex electrical system. It actually generates its own electricity, which causes it to contract and relax in the proper timing sequence, so that it can pump blood to the body. Electrical signals can become blocked or irregular, causing the heart to beat too quickly (tachycardia) or too slowly (bradycardia). For the heart to work correctly, the chambers must beat in a coordinated

manner at a resting heart rate between 60 and 100 beats per minute. There are two common causes of bradycardia: sick sinus syndrome, which is a disease of the sinoatrial (SA) node. the heart's natural pacemaker and heart block, which occurs when the upper chambers (atria) and lower chambers (ventricles) are not coordinated, resulting in atrioventricular (AV) block (also commonly called heart block). These diseases can cause the heart to beat too slowly, either occasionally or all the time. In both cases, the heart might not pump enough blood to meet the body's needs. As the heart rate declines, there might not be sufficient blood flow to the brain, causing lightheadedness and (sometimes) fainting.

How does a pacemaker work?

Pacemakers are actually miniaturized (about the size of a couple of stacked silver dollars), battery-powered computers that are usually implanted just underneath the skin in the chest area. To provide electrical support, the device sends a tiny electrical pulse down a wire, called a lead, into your heart, which stimulates the heart to beat. These impulses are very tiny, and most people do not feel them at all.



While the device is helping your heart to maintain its rhythm, it is also storing a lot of information about your heart. This information



can be retrieved by your doctor, and it helps him or her to program your device in a way that provides you with the best therapy for your condition.

Are there different kinds of pacemakers for different activity levels?

Today's pacemakers have the capability for their settings to be adjusted by your physician in order to provide appropriate support for a wide range of lifestyles and activities. If you enjoy walking, playing golf, swimming or participating in most other activities, you need not worry. Your doctor can help provide you with a device that meets both your medical and lifestyle needs

How is a pacemaker implanted?

Usually, surgery for an implanted cardiac device is not done under full anesthesia. It is generally implanted under what doctors call "conscious sedation." You will be given medication to help you relax, but you will still be aware of your surroundings and able to hear and even talk with the medical team as the procedure is being conducted. Numbing medication will be given where the incision is to be made. While the local anesthetic will block sharp pain, you may still feel some pressure while the device is being implanted.

What happens during surgery to implant a pacemaker?

The doctor will first make a small cut in the upper chest and locate a vein. A small puncture is made in the vein, and the leads, long flexible wires, will be guided down the vein to the heart. The surgical team monitors the placement of the lead using a large overhead monitor called a fluoroscope. This is a kind of moving x-ray picture. The leads must be placed in exactly the right spot for best results, so this is often the most time-consuming part of the operation. Once that is done, the doctor will test the leads to make sure that they are in the best position to deliver energy to the heart.

After the leads are in place, your doctor might ask you to go through some simple maneuvers, such as taking a deep breath or coughing vigorously, to help assess the stability of the lead. Then, he or she will make a "pocket" by separating the skin and underlying tissue from the muscle beneath the tissue. After the pulse generator is connected to the leads, it is placed in that pocket.

Once the device is in place, the doctor will sew up the incision. Many people just notice a small scar and a small bump after the incision heals. However, in people who are very small or thin, the device might stick out more. If you are worried about how this might look, talk to your doctor. In some cases, the device can be located somewhere that will be less noticeable.

The length of the surgery depends on what kind of device you are getting, as well as your specific anatomy and the time it takes to locate a good position for the lead. Implanting a pacemaker can take a number of hours.

What risks are associated with having a pacemaker?

Implanting a pacemaker is considered minor surgery, but a small number of patients will develop complications because of the implant procedure. They may include infection, a reaction to a drug used during surgery or to the device itself and blood loss or damage to a blood vessel, the heart wall or other organs. These complications can usually be corrected or cured, but may require a repeat operation or a longer than normal hospital stay. After the surgery, you will feel some discomfort, and you will be tired. As you recover, you will feel better. However, some patients continue to feel some discomfort where the pacemaker is implanted. Speak to your doctor if this occurs.

Your doctor will discuss with you all the precautions you should follow. Also, read completely any literature that came with your device, and pay close attention to sentences that are labeled with the word "warning" or "important." Those sentences contain important safety information. Finally, remember these are man-made devices. It is important to monitor the device regularly with follow-up visits as often as your doctor recommends.

What happens after the surgery?

Right after the surgery, you will be taken to a recovery room. You may experience some tenderness at the implant site for a while. You may stay in the hospital several hours or several days. You should discuss the specifics of your case with your physician.

In the period after surgery, follow all of your physician's instructions carefully. Above all, be sure to report any redness, soreness or tenderness around the implant site. If you are already back home when you notice redness

or soreness around your scar, call your doctor immediately—do not wait for your next appointment.

How long will it take me to recover?

It is difficult to be specific about your recovery because every patient is different. Follow your doctor's instructions carefully. Your activities will be restricted for a period following surgery. Your doctor is your best source of advice on the subject of resuming your normal activities.

How often do I need to see my doctor once I have a device?

You will be asked to see your doctor regularly for routine checkups.

Immediately after your surgery, you will probably be asked to visit the doctor several times. These are all very important visits, and they allow your physician to be sure your device is working properly. Sometimes minor adjustments are required, which can be done painlessly in the doctor's office using a tabletop computer called a programmer. Your doctor will also want to check the incision to see how it is healing.



After that, your physician will want to see you for regular follow-up visits. He or she will advise you how often you should be evaluated because it varies by patient and condition.

What happens during a follow-up appointment?

The follow-up is completely painless and usually takes less than half an hour. During this time, the doctor or nurse will put a wand over the spot where the device is implanted. The wand is about the size and shape of a television remote control device.

For some devices, a wand is not used; the information is sent wirelessly. The device tells the programmer about the battery status, performs other system checks and can report on your heart's rhythms since your last follow-up.

The doctor can also alter certain settings on your device to adjust your therapy, if needed. For these reasons, it is very important that you keep your follow-up schedule with your doctor.

How will my doctor change the batteries in my device?

Implantable devices are powered by special batteries that are made to last a long time. These batteries do not suddenly wear out, like flashlight batteries, but they give plenty of warning that they are reaching end of service.

Your doctor will monitor the battery as part of your regular device check-up. Most device batteries last five to ten years although it depends on the device and how often it sends electrical impulses to the heart.

When the device indicates a low battery, your physician will arrange for a replacement. Implantable devices are sealed shut, so the batteries are not replaceable. Instead, your doctor will implant a new device. Typically, this surgery does not last as long as your original device implant because your new device will simply be plugged into the leads that have already been placed in your heart.

Will a pacemaker change my life?

The truth is that your life could be longer, more productive, happier and healthier. After surgery, you will need to take it easy for a while. Be sure to carefully follow all of your doctor's instructions. But pretty soon, you should be able to do all the things you used to do—even more.

Do I have to stay away from things like microwaves, magnets or strobe lights?

Implantable devices cannot be damaged by using properly operating household appliances, such as microwave ovens, electric blankets and most power tools. Using electric arc welders or working on automobile ignition systems also will not damage pacemakers; however, there is a possibility that they may briefly interfere with proper pacemaker operation. Some medical equipment also may interfere with the function of the pacemaker. If you become lightheaded or feel palpitations (rapid, irregular heartbeats), you should simply turn off the electrical equipment or walk away from it, and the implanted device should resume normal operation.

If using problematic equipment is something that you cannot avoid, your doctor can tell you what to do. You might also contact the device manufacturer for guidance. Most manufacturers have engineers who can

determine if the electrical field generated by the equipment can interfere with the pacemaker.

What if I am going into a hospital or clinic?

Tell the hospital personnel that you have a pacemaker before you undergo any medical procedure, such as electrosurgery, electrocautery, external defibrillation, lithotripsy or radiation therapy, or a dental procedure or test. Do not enter areas that have a "no pacer" symbol posted.

Do not undergo any diathermy procedure, even if your pacemaker has been turned off. It could cause damage to the tissue around the implanted electrodes or permanent damage to the pacemaker.

Can I use a cell phone?

Cellular phones, which send electromagnetic signals, can interfere with proper device operation. However, simple precautions—such as not carrying the phone in a breast pocket over the pacemaker and holding it to the ear that is farthest from the pacemaker—minimize the risk. St. Jude Medical has put special filters in their pacemakers to prevent cell phone interference.

Will an iPod® music player or other portable multimedia player interfere with my pacemaker?

There is no indication that compact multimedia players, such as iPod products or MP3 players, interfere with the normal function of a St. Jude Medical pacemaker. Some limited data suggests that during device evaluation in the hospital or in a clinic, use of one of these players within approximately 12 inches of the implanted pacemaker and programmer wand could disrupt the communication between the programmer and the pacemaker. Again, this interference is only observed when the multimedia player is within 12 inches of the implanted pacemaker and the programmer's telemetry wand. This causes a distortion on the programmer screen, but it has absolutely no effect on the implanted pacemaker or ICD. You should simply turn off the multimedia player during a follow-up session, or move it and any earphone wiring more than 12 inches from the programmer wand, to avoid this interference.

Though there is no data that carrying a multimedia player device affects a pacemaker's ability to deliver therapy, it is nonetheless recommended that, if you carry the player in your breast pocket, you do so on the opposite side from your implanted pacemaker.

Why do I need an identification card?

As a device patient, you should wear medical jewelry, such as a bracelet, that alerts people to the presence of your device. You should also be sure to tell other physicians, dentists and healthcare professionals that you have an implanted device to help control your heart rhythm. Some manufacturers will send you an

PATIENT:	BIII JONES		
	MODEL NUMBER	SERIAL NUMBER	IMPLANT DATE
PACEMAKER	2222	444444	19/JUN/2009
A	4444	A555555	19/JUN/2009
V	66666	B7777777	19/JUN/2009



identification card that you should carry in your wallet. If you do not receive a card in the mail, ask your doctor what information you should carry in your wallet to identify yourself as having an implanted device.

When can I resume physical activities?

Your doctor will let you know when it is safe for you to resume activities. It is important that you avoid bumping or hitting the area around your implant, so contact sports, like football, may not be a good idea because you might damage the device or leads. Your energy level may increase after you receive your device, and many people find they are able to do more physically than they were before because their symptoms have improved.

Can I participate in strenuous activities like hiking, skiing or jogging?

It is always best to discuss your plans with your doctor. He or she can advise you as to your limits or signs that you might be engaging in activities that are too strenuous. If you participate in a particular activity that affects your chest or arm (shooting or archery, for example), you might want to discuss this with your doctor before receiving your device. It may affect how the device is selected and where and how it is implanted.

Is it safe to engage in sexual activity?

Other than a brief stay in the hospital and a short recovery period, receiving an implantable device typically does not have any adverse effect on a patient's sex life. It is important, though, to follow your doctor's advice as to when to resume any physical activity.

Will I be able to drive?

Talk to your doctor about driving. Having a pacemaker implanted should not affect your ability to drive, but it is best to discuss driving with your physician before you resume driving.

Can I travel?

Your physician is your best resource for the answer to this question. Many pacemaker patients, however, find that with some extra planning and care, they can enjoy touring to many locations. If traveling by car or RV, it is wise to plan your route carefully and give a copy of your itinerary to a loved one, just in case you have difficulties on the road.

Will airport security interfere with my device?

Though many patients worry about airport security systems, there is really no need for concern. It is true that airport security has been tightened, but this does not place an added burden on you in terms of your implanted device. The best thing to do when you reach airport security is to walk through the metal detector at a normal pace. If the alarm sounds (it may or may not), it only means that the system detected the metal in your device. Simply show your identification card. Ask for a hand pat-down search. Security personnel may perform a search with a handheld wand. If so,

it is important to tell them that the search should be done quickly and that they should avoid holding the wand over your implanted device for more than a second.

What else should I know about traveling with an implantable device?

Remember that, while traveling, it is important to carry with you important medical information, such as medication names and dosages, your physician's name and phone number and how to care for you in an emergency.

You should also ask your physician for a copy of the final printout from the programmer associated with the testing results and settings at the most recent evaluation. If you are going to a Spanish, French or German speaking country, your physician might also be able to give you a printout in the language of the country you will visit. (Printouts in Italian, Japanese and Chinese may also be available for some devices.)

Carry with you enough medications, and have a supply in your carry-on luggage and your suitcase when traveling by train or plane. Lastly, alert any travel personnel to special dietary needs you might have, and exercise good eating habits while on the road.

Will I still need to take medication after I have a pacemaker?

This is a question for your doctor. Usually, having an implantable device does not replace medication. Instead, medication and implantable devices work together. But your doctor may change your dosage.

Will I have any diet restrictions?

For overall heart health, doctors recommend following a diet that is low in sodium, fat and sugar and high in fiber and carbohydrates.

I am feeling better physically, but sometimes I feel worried or sad. Is there anything I can do?

Health is not just physical. Many patients experience stressful feelings after a device has been implanted. There are many coping strategies, including focusing on vibrant activities, staying close to loved ones and getting enough rest. Living with a cardiac issue can be disconcerting. But an implantable device is designed to offer you some comfort. It is there to back you up. If you are experiencing feelings of anxiety or depression, discuss this with your physician.

Many hospitals have patient support groups that meet regularly to learn about device therapy, heart disease and so on. It is not unusual for patients—particularly right after surgery—to be nervous or apprehensive about the device. These groups can offer insight and support as you become used to your new lifestyle. They will also help you meet other patients. Ask your doctor about local patient support groups.

Important Information

Implantable device manuf	facture	r:		
Device make and model number:				
Implanting physician:				
Implanting physician phone number:				
Implantation date:				
Hospital where implant was performed:				
Attending physician:				
Attending physician phone number:				
Medications:				
Name		Dosage		
Travel checklist:				
Patient ID card				
Printout of device settings	8			
Medications				

My additional notes and questions:

