

A Patient  
**EDUCATION  
HANDBOOK**  
**ON LEADLESS PACING**



ST. JUDE MEDICAL

# YOUR LEADLESS 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).
- 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, 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 operated household appliances, such as microwave ovens.
- Pacemakers can help people to enjoy longer, more productive, happier and healthier lives.

## INTRODUCING THE NANOSTIM™ LEADLESS PACEMAKER

A standard pacemaker is a small device that is placed in a patient's chest with leads to the heart that send electrical pulses to help the heart beat at a normal rate. Pacemakers can improve a patient's quality of life and possibly prolong it.

St. Jude Medical, the maker of the world's first pacemaker, is also the first to invent a leadless device, called the Nanostim™ leadless pacemaker. Unlike a standard pacemaker, the Nanostim leadless pacemaker:

- 1 Leaves no scar on the chest** – it is implanted through a small incision at the top of your leg and guided up a vein to your heart. With a standard pacemaker a 2-3 inch incision is made in the upper chest wall.
- 2 Requires no leads** – it is specially designed so that it is not necessary to feed wires (called “leads”) through a vein and into the heart. With a standard pacemaker, at least one lead connects the device to the heart.
- 3 Stays out of sight** – it is implanted inside the heart, leaving no trace of it on the body surface.



**The Nanostim leadless pacemaker** is cylindrical in shape, about one-fourth the size of a AAA battery and one-tenth the size of a standard pacemaker. It will detect if the heart beat is too slow and will send an electric pulse to prompt the heart to beat normally. Despite its small size, the pacemaker battery life is equivalent to that of standard pacemakers and can last at least 10 years for most patients. Otherwise, it performs just like a standard pacemaker does.

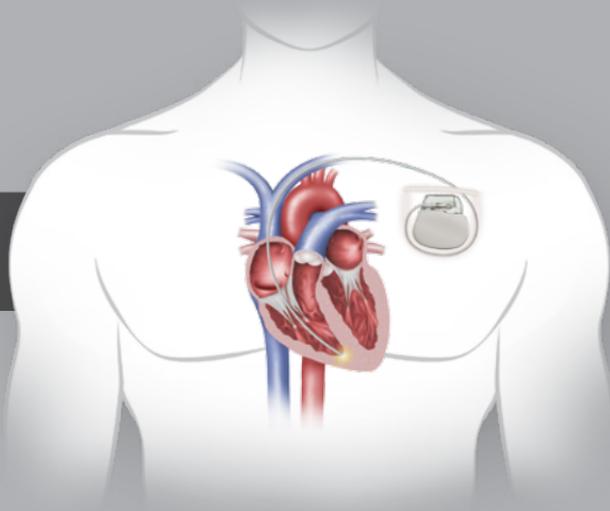
## WHAT ARE PACEMAKERS?

A normal, healthy heart automatically regulates its own heart rate. Unfortunately, some hearts beat too slowly or in an irregular pattern. If you are diagnosed with these problems, your doctor may recommend a pacemaker to correct it. Since the first fully implanted pacemaker in 1958, millions of 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.

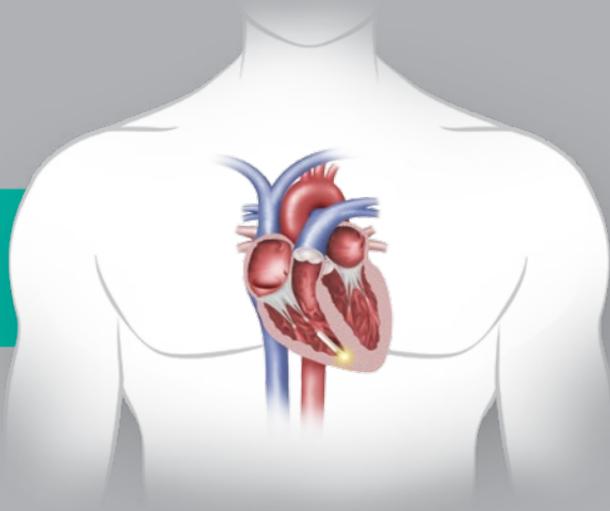
## HOW DOES A PACEMAKER WORK?

A pacemaker is typically used for cardiac rhythm disorders involving a too-slow heart rate (bradycardia) or because electrical impulses get delayed on their way through the heart. The pacemaker “listens” to the heart. When the heart's own electrical system sends a signal and the heart beats, the pacemaker waits and does nothing. When the heart's system misses a signal, the pacemaker sends a signal to replace it. 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.

Standard  
Pacemaker



Nanostim™  
Leadless  
Pacemaker



## 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:

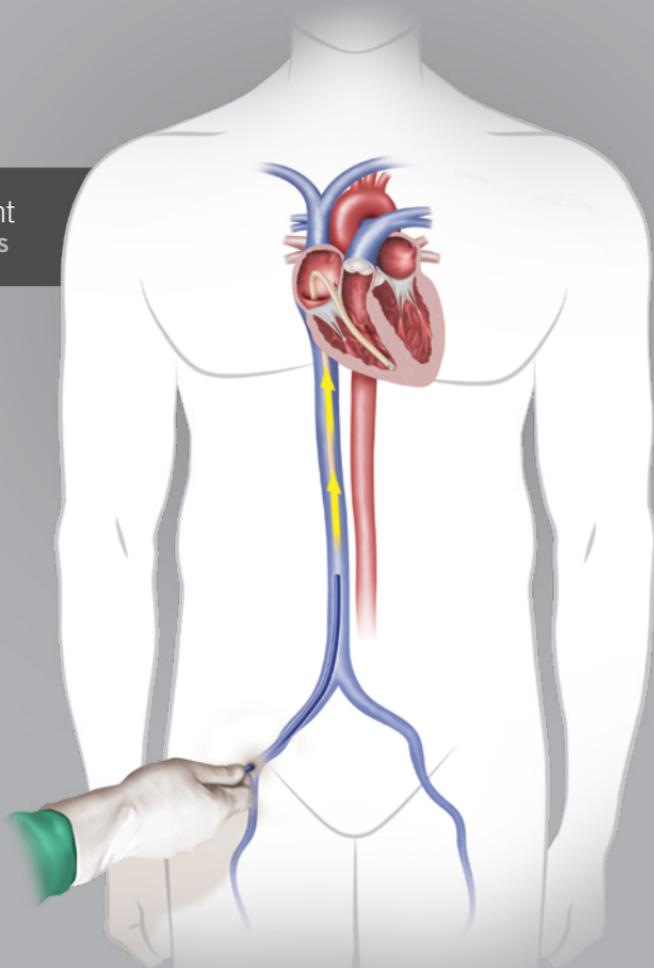
- 1 **Sick Sinus Syndrome**, which is a disease of the sinoatrial (SA) node, the heart's natural pacemaker, and
- 2 **Atrioventricular block**, which occurs when the upper chambers (atria) and lower chambers (ventricles) are not coordinated, also commonly called heart block. These diseases can cause 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, most often causing fatigue and lightheadedness and sometimes fainting.



## **HOW IS A PACEMAKER IMPLANTED?**

Usually, the procedure for an implanted cardiac device is not done under general anesthesia. Instead conscious sedation is used. 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 made.

Implant  
Process



## HOW IS THE NANOSTIM LEADLESS PACEMAKER IMPLANTED?

Most of the time, it will take about 20 to 45 minutes to implant the Nanostim™ leadless pacemaker.<sup>1</sup> Here are the four steps involved:

- 1 A small incision** is made at the top of your leg on the groin to gently pass the implant tool and the leadless pacemaker. The implant tool will then guide the leadless pacemaker up through the femoral vein to enter the heart.
- 2 Once inside the heart**, your doctor will carefully attach the leadless pacemaker near the bottom of the right ventricle.
- 3 The doctor will wirelessly connect** your leadless pacemaker with a computer program to see if it is in a good place to deliver the electrical pulse when you need it. The doctor also will use the computer to program the device settings to your needs.
- 4 When done**, the implant tool will be removed and the leadless pacemaker will be permanently implanted in your heart. The incision in your groin will be closed.

## **WHAT CAN BE EXPECTED AFTER THE NANOSTIM™ LEADLESS PACEMAKER IMPLANT?**

### **DAY OF THE IMPLANT**

After the leadless pacemaker procedure, you will be taken to a recovery room or a telemetry unit, which is a special monitoring facility. Although you may feel some pain or tenderness in the groin area, your recovery should be relatively smooth.

### **DURATION OF THE HOSPITALIZATION**

Hospitalization may vary, however, most patients should be able to go home the day following their procedure.

When you go home, you should follow all of your physician's instructions carefully.

### **FOLLOWING-UP WITH THE DOCTOR**

You will be asked to see the doctor that performed the pacemaker implant at one or two weeks after surgery to ensure your recovery is going well and the pacemaker is performing as expected. The doctor may make some minor adjustments to your pacemaker with a programmer or computer. This adjustment is completely painless and takes a few minutes.

After the first follow-up visit with your doctor, you will be asked to come back at a minimum of every six months. During these visits, the doctor will confirm your leadless pacemaker is operating properly with the information retrieved from the computer program that communicates with your pacemaker.

## **HOW DOES MY NANOSTIM™ LEADLESS PACEMAKER KNOW WHEN TO PULSE?**

The Nanostim™ leadless pacemaker can sense the heart's rhythm. The Nanostim leadless pacemaker can be programmed to either send out a pulse or to wait for the heart to beat on its own. Once this pacemaker is inside your body, its settings can be adjusted. Doctors and clinicians “talk” to it with a programmer. This is a computer that sends signals through the body to the Nanostim leadless pacemaker through the surface ECG electrodes. The procedure is painless. The programmer also displays information the pacemaker has collected about the heart.

## **WILL I FEEL THE NANOSTIM LEADLESS PACEMAKER WHEN IT'S IN MY HEART?**

This pacemaker will probably not be noticeable to you. You should start to feel better, have more energy and be less fatigued. Other symptoms, such as dizziness, are likely to improve as well. Talk to your doctor if your symptoms do not improve in the first weeks and months after having your pacemaker implanted.

## **WHAT DOES A PULSE FROM MY PACEMAKER FEEL LIKE?**

Most people can't feel the pulse from the Nanostim leadless pacemaker at all. The electrical pulse is very small. If you do feel a pulse, your doctor or clinician may change the settings to make you more comfortable.

## **WHAT ARE THE COMPLICATIONS ASSOCIATED WITH LEADLESS PACEMAKERS?**

When a standard pacemaker has a complication, it is usually related to the pocket that holds the pacemaker or the leads. With the Nanostim™ leadless pacemaker, risks associated with these complications are reduced because the device does not have leads and does not require the doctor to create a surgical incision to place the device. A small number of patients may develop complications from the implant procedure or pacemaker.

### **COMPLICATIONS DUE TO THE IMPLANT PROCEDURE**

These can include infection, a reaction to a drug used during surgery, blood loss, or damage to a blood vessel, the heart wall or other organ. These complications can usually be corrected, but may require a longer hospital stay or another surgical procedure.

As with any surgical procedure, implanting the Nanostim™ leadless pacemaker does carry potential risks, such as bruising at the insertion site, infection, bleeding, and/or reaction to the anesthesia or the contrast dye used to visualize the advancement of the device in the veins and its position in the heart.

**COMPLICATIONS RELATED TO THE PACEMAKER**

Similar to a standard pacemaker, rarely, the pacemaker may not act properly because it is being affected by outside sources of electromagnetic energy. It also is possible for the pacemaker to move from its original position in the heart that would impact the pacemaker's performance from regulating your heartbeat. This complication would require another surgery to remove the pacemaker and implant a new one. 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.

**Contact your doctor if:**

- You notice you are tired, short of breath or your heart rate is changing.
- You notice the wound is red, hot, swollen, more painful or beginning to drain fluid.
- Symptoms you had before the pacemaker was implanted seem to return.

**Talk with your doctor to understand the potential risks and benefits of this therapy.**

## **OTHER QUESTIONS ABOUT LIVING WITH YOUR LEADLESS PACEMAKER**

### **SHOULD I TELL PEOPLE ABOUT MY LEADLESS PACEMAKER?**

The decision to disclose (or not) that you have a pacemaker is yours in most instances. Please always tell health care professionals about your leadless pacemaker, including dentists, physical therapists, nursing staff and other health care specialists that you see. You are encouraged to share with your family and/or caregiver(s) that you have a pacemaker so they can alert medical personnel in the event you ever need medical help and cannot speak for yourself.

**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 crucial 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 computer program 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.

## **WHAT IS A PACEMAKER IDENTIFICATION CARD?**

This card lets everyone know that you have a Nanostim™ leadless pacemaker. If you are ever in a medical emergency, this card will give emergency personnel the critical data that could save your life. Keep it with you at all times.

**WILL A CELLULAR PHONE INTERFERE WITH MY PACEMAKER?**

Studies indicate there may be potential interaction between cellular phones and pacemaker operation. The interaction is temporary, moving the phone away from the device will return it to its previous state of operation.

**WHAT PRECAUTIONS SHOULD I TAKE WITH ELECTRICAL EQUIPMENT?**

Most home appliances and office equipment in good working order are safe to use (microwave ovens, blenders, toasters, electric knives, televisions, electric blankets, stoves, garage door openers). The pacemaker will work properly with most medical equipment during x-rays, diagnostic ultrasound, CT scans, mammography, and fluoroscopy. It is also MRI conditional. You should do your best to avoid electromagnetic interferences (EMI) that could be caused by electrical appliances in poor conditions or not grounded correctly, industrial generators, arc-welders, specific medical equipment. Magnets, large heaters and radio transmitters also can cause EMI.

**CAN I GET AN MRI SCAN WITH A NANOSTIM™ LEADLESS PACEMAKER IMPLANTED?**

Yes, the Nanostim™ leadless pacemaker has been approved for use in 1.5T MRI scanners. Talk with your doctor ordering the MRI scan to ensure they know you have a Nanostim leadless pacemaker implanted.

### **WHAT IF I NEED TO VISIT A HOSPITAL OR CLINIC?**

Tell the hospital or clinic personnel that you have a Nanostim™ leadless pacemaker before you have any medical or dental procedures or tests. Do not enter areas that have a “no pacer” symbol posted.



### **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?**

Check with your doctor for your specific diet recommendations. 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.

#### **WILL I BE ABLE TO PARTICIPATE IN SPORTS AND RECREATION ACTIVITIES?**

In most cases, the Nanostim™ leadless pacemaker will not limit your fun. Before you begin any vigorous exercise or activity, talk to your doctor.

#### **WHAT IF I WANT TO KNOW MORE?**

Talk to your doctor because only he or she knows all of the details about your case.

# IMPORTANT INFORMATION

Implantable device manufacturer:

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 and dosage:

Travel checklist:

Patient ID card:

Printout of device settings:

Medications:



1. Reddy, V. Y., Exner, D. V., Cantillon, D. J., Doshi, R., Bunch, T. J., Tomassoni, G. F.,...  
Dukkipati, S. R. (2015). Percutaneous implantation of an entirely intercardiac leadless  
pacemaker. *New England Journal of Medicine*, 373, 1125-1135.

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**Rx Only**

**Brief Summary:** Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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