Abbott

# WHAT TO EXPECT WITH YOUR PACEMAKER

# WHEN A DOCTOR SAYS YOUR HEART COULD BENEFIT FROM A PACEMAKER:

It's a good time to learn more about these medical devices which are designed to help pace your heart rhythm.

Since the first successful implant over 70 years ago, millions of people around the world have benefited from having a pacemaker.

# 1,250,000

Estimated number of pacemakers implanted worldwide each year.[1]

## WHEN A PACEMAKER MAKES SENSE

The heart is powered by a complex, natural electrical system that helps it maintain a healthy rhythm, while pumping blood throughout the body.

For some people, however, the heart's electrical signals can become blocked or irregular, causing it to beat too slowly, a condition known as bradycardia. There are two common causes of bradycardia:

### SINUS NODE DYSFUNCTION

Sinus Node Dysfunction, or sometimes referred to as Sick Sinus Syndrome, is when the natural pacemaker within your heart is not working properly.

### HEART BLOCK

Heart Block occurs when the upper chambers (atria) and lower chambers (ventricles) of your heart are not beating in sync.

Symptoms can cause problems if ignored and can lead to more serious problems including: fatigue, lightheadedness, shortness of breath, chest pains and premature tiring during physical activity.

This is where a pacemaker can make a difference.

# WHAT IS A PACEMAKER?

## HEART RATE MANAGER

A pacemaker is a small, battery-powered device that "listens" to your heart. If it's beating properly, the pacemaker does nothing. But when your heart is beating too slowly, the pacemaker sends electrical pulses to get your heart rhythm within your normal range.

**A pacemaker's electrical pulses are very tiny and most people do not feel them.**

## INFORMATION INSIGHTS

At the same time the device is helping your heart maintain its rhythm, it is also storing information about your heart. This information can be viewed by your doctor to help make sure your device is optimally programmed to meet your specific therapy needs.

# RECEIVING YOUR DEVICE

As with all medical procedures, talk with your doctor beforehand to review any special instructions, which may include eating and drinking limitations. Implanting your pacemaker usually takes one to two hours. Never forget that your doctor is your best source of information about your procedure. Be sure to consult with your doctor before your procedure and discuss any concerns you might have afterwards, including risks.

## Although implant procedures vary depending on the individual person, typical implant procedures include the following steps:

1 You will be given medicine to help with discomfort and relaxation. You will still be aware of your surroundings and be able to hear and talk with your doctor.

2 Insulated wires, called leads, will be placed in your heart and will be connected to your pacemaker. This is usually the most time-consuming part of the procedure.

3 While the leads are being placed, the doctor will test them to make sure they are in the best position to deliver electrical pulses to the heart when needed.

4 Your doctor will then connect the leads to the pacemaker, set the pacemaker in place – just under the skin, usually near the collarbone – and close the incision.*


**Approximate Dimensions:**

47 mm high x 50 mm wide x 6 mm thick

*Actual Size (size varies by device)*

**If you are concerned about having a small scar or bump in this location after the incision heals, ask your doctor before surgery about the possibility of placing the device where it will be less noticeable to others.*

# WHAT TO EXPECT IN YOUR RECOVERY

The typical hospital stay after receiving a pacemaker is only a few days.

This is a good time to discuss with your doctor any symptoms you may experience, especially soreness or tenderness around the incision. If you are already home when you notice redness or soreness around your incision area, call your doctor immediately — do not wait for your next appointment.

Implanting a pacemaker is considered minor surgery, but a small number of people 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.

Your doctor is your best source of information about complications as well as other information about your procedure and your device.

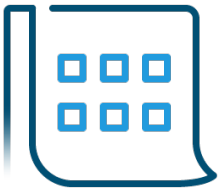
Your doctor will discuss with you all the precautions you should follow.

Be sure to ask your doctor if you have any questions. Also, read any literature that comes with your device, paying close attention to items labeled as ‘warning’ or ‘important’ as these contain important safety information.

# FOLLOW-UP: AN IMPORTANT PART OF THE JOURNEY

After your surgery, you will likely be asked to visit the doctor several times. During these important visits, your doctor will confirm your device is working properly. If minor adjustments to your device are needed, they can be made painlessly by your clinic using technology that communicates directly with your pacemaker and updates program settings for optimal care.

If changes are made to your pacemaker at the time of your visit, a follow-up appointment may be needed.



**It is very important to keep your follow-up appointment schedule with your doctor.**

**Remote monitoring does not take the place of in-person appointments.**

# STAYING CLOSE, EVEN FROM A DISTANCE

Some pacemakers use wireless remote monitoring and others require a wand. Remote monitoring sends device information to your clinic. These details may include device battery status, your heart rhythm information or an irregularity in heart rhythm that your doctor is specifically monitoring. In order for remote monitoring to work, your transmitter should be connected and plugged in near your bed.

When properly connected, the transmitter will collect information from your pacemaker at night while you sleep and send it to your doctor as scheduled.

# THE PATH TO YOUR BEST POSSIBLE LIFE

After surgery you will need to take it easy for a while. Your doctor will let you know when it is safe to resume activities. It is important that you avoid bumping or hitting the area around your implant, because you may damage the device or leads.

Contact sports may be off-limits. Also, if you participate in an activity that affects your chest or arm – swimming or golf, for example – you might want to discuss this with your doctor before receiving your device. It may affect what device is selected and where and how it is implanted.

After you receive your device, your energy level may increase. Many people find they are able to actually do more physically than they were before receiving the device, as their symptoms improved.

## PACEMAKER EFFECTS ON MEDICATION AND DIET

Usually, having a pacemaker does not replace medication. They work together. But your doctor may change the amount or type of medication you take. Also, depending on your overall heath, your doctor may recommend changes to your diet.

## WHEN A PACEMAKER BATTERY RUNS LOW

Most pacemaker batteries last six to twelve years, depending on the device and how often it delivers therapy to the heart. Since the pacemaker itself is sealed, when the battery gets too low to deliver therapy to your heart, it must be replaced. Typically, this surgery does not last as long as your original implant procedure because your new device will simply be plugged into the leads that have already been placed in your heart. Your doctor will discuss a replacement pacemaker with you when it is needed.

## WONDERING ABOUT CERTAIN ACTIVITIES?

If you have any questions or concerns about an activity you would like to do, talk with your doctor. The next page offers some guidance on common activities many people ask about after receiving their pacemaker.

# LIVING WITH YOUR PACEMAKER

| SITUATION | INSIGHTS |
|---|---|
| **HOME APPLIANCES AND OFFICE EQUIPMENT**<br>(microwave ovens, blenders, toasters, electric knives, electric blankets, stoves, garage door openers, computers, tablets) | No known risks. |
| **MEDICAL EQUIPMENT**<br>(x-rays, diagnostic ultrasound, CT scans, mammography, fluoroscopy, Magnetic Resonance Imaging) | Before any procedure, talk with your healthcare provider to let them know you have a pacemaker. This includes any dental procedure.<br>Some pacemaker systems are MR Conditional, meaning it can be safe to have a MRI under specific conditions. Your doctor will need to confirm if your pacemaker is one of them.<br>Avoid electrical nerve and muscle stimulators (i.e. TENS units). |
| **ELECTROMAGNETIC INTERFERENCES (EMI)**<br>(electrical appliances in poor conditions or not grounded correctly, industrial generators, arc welders, specific medical equipment, magnets, large heaters, radio transmitters) | If you become lightheaded or feel palpitations (rapid, irregular heartbeat), your device may be experiencing electromagnetic interference. If you are near electrical equipment or magnets, simply turn off the equipment or walk away.<br>The pacemaker should resume normal operation. |
| **USING A CELL PHONE** | May interfere with pacemaker operation. Minimize risk by avoiding carrying the phone in a breast pocket over the pacemaker. Hold the phone to the ear farthest from the pacemaker.<br>Abbott has special filters in their pacemakers to reduce the possibility of cell phone interference. |
| **USING AN MP3/ MULTIMEDIA PLAYER** | No known risks. |
| **GOING TO THE HOSPITAL** | Medical equipment may interfere with the function of a pacemaker.<br>Tell hospital personnel you have a pacemaker before you undergo any procedure.<br>Do not enter areas that have a “No Pacer” sign posted. |
| **DRIVING AN AUTOMOBILE** | Having a pacemaker implanted should not affect your ability to drive, but it is best to discuss this with your doctor before you begin driving again. |
| **TRAVELING** | With some extra planning, you can travel to most locations.<br>Airport security systems are generally not a concern, but be sure to show your patient ID card before entering airport security areas.<br>Carry your physician’s name and number with you. |

# FOR MORE INFORMATION,
# **PLEASE CONSULT WITH YOUR PHYSICIAN.**


**REFERENCES**

1. Raatikainen M.J.P., Arnar D.O., Merkely B., Nielsen J.C., Hindricks G., Heidbuchel H., Camm J.A. Decade of Information on the Use of Cardiac Implantable Electronic Devices and Interventional Electrophysiological Procedures in the European Society of Cardiology Countries: 2017 Report from the European Heart Rhythm Association. EP Europace. 2017;19:ii1–ii90. doi: 10.1093/europace/eux258.


**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.

**Indications/Intended Use:** Implantation is indicated in one or more of the following permanent conditions, or any combination of these symptoms: syncope, presyncope, fatigue, disorientation. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for those patients exhibiting: sick sinus syndrome; chronic, symptomatic second-degree and third-degree AV block; recurrent Adams-Stokes syndrome; symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with significant bradycardia and: normal sinus rhythm with only rare episodes of AV block or sinus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression™ algorithm stimulation is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

**Contraindications:** Implanted cardioverter-defibrillator (ICD). Dual-chamber pulse generators are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-adaptive pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression™ algorithm stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-chamber pacing, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-chamber atrial pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

**Potential Adverse Events:** The following are potential complications associated with the use of any pacing system: air embolism; body rejection phenomena; cardiac tamponade or perforation; hematoma, bleeding hematoma, seroma; formation of fibrotic tissue, local tissue reaction; inability to interrogate or program a device due to programmer or device malfunction; infection; erosion; interruption of desired device pulse generator function due to electrical interference, either electromyogenic or electromagnetic; lead malfunction due to conductor fracture or insulation degradation; loss of capture or sensing due to lead dislodgement or reaction at the electrode/tissue interface; loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation); loss of normal device function due to battery failure or component malfunction; pacemaker migration or pocket erosion; pectoral muscle or diaphragmatic stimulation; phrenic nerve stimulation; pneumothorax/hemothorax; device migration and pocket erosion; endocarditis; excessive bleeding; induced atrial or ventricular arrhythmias; myocardial irritability; pericardial effusion; pericardial rub; pulmonary edema; rise in threshold and exit block; valve damage; death.

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