



# 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<sup>1</sup>

## 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:

### SICK SINUS SYNDROME

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.

## TRADITIONAL PACEMAKERS



Approximate Dimensions:  
47 mm high / 50 mm wide / 6 mm thick

- 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 A small incision is made near the collarbone to allow physicians to access the blood vessel and later place the pacemaker.
- 3 Insulated wires, called leads, will be threaded through the blood vessel and placed in your heart. They will be connected to your pacemaker. This is usually the most time-consuming part of the procedure.
- 4 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.
- 5 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.\*

## LEADLESS PACEMAKERS (LP)



Approximate dimensions:  
38 mm high / 6.6 mm wide

- 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 A catheter that contains the LP is passed through a small incision in the groin and threaded into the heart using a minimally invasive procedure.
- 3 The LP is then secured into the interior wall muscle of your heart, tested and programmed to each patient's unique needs.
- 4 Unlike traditional pacemakers, leadless pacemakers reside entirely in the heart. That means there are no leads, no chest incisions and no permanent pocket under the skin.

\*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 or the possibility of using a leadless pacemaker that do not require any incision in the chest and no permanent pocket under the skin.



## 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 for traditional pacemakers and a minimally invasive surgery for leadless pacemakers, 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. You can also review information available at [cardiovascular.abbott.com/pacemakers](https://www.cardiovascular.abbott.com/pacemakers).

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 or skin electrodes. 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.



\*Remote monitoring is currently not available for AVEIR VR Leadless Pacemakers.

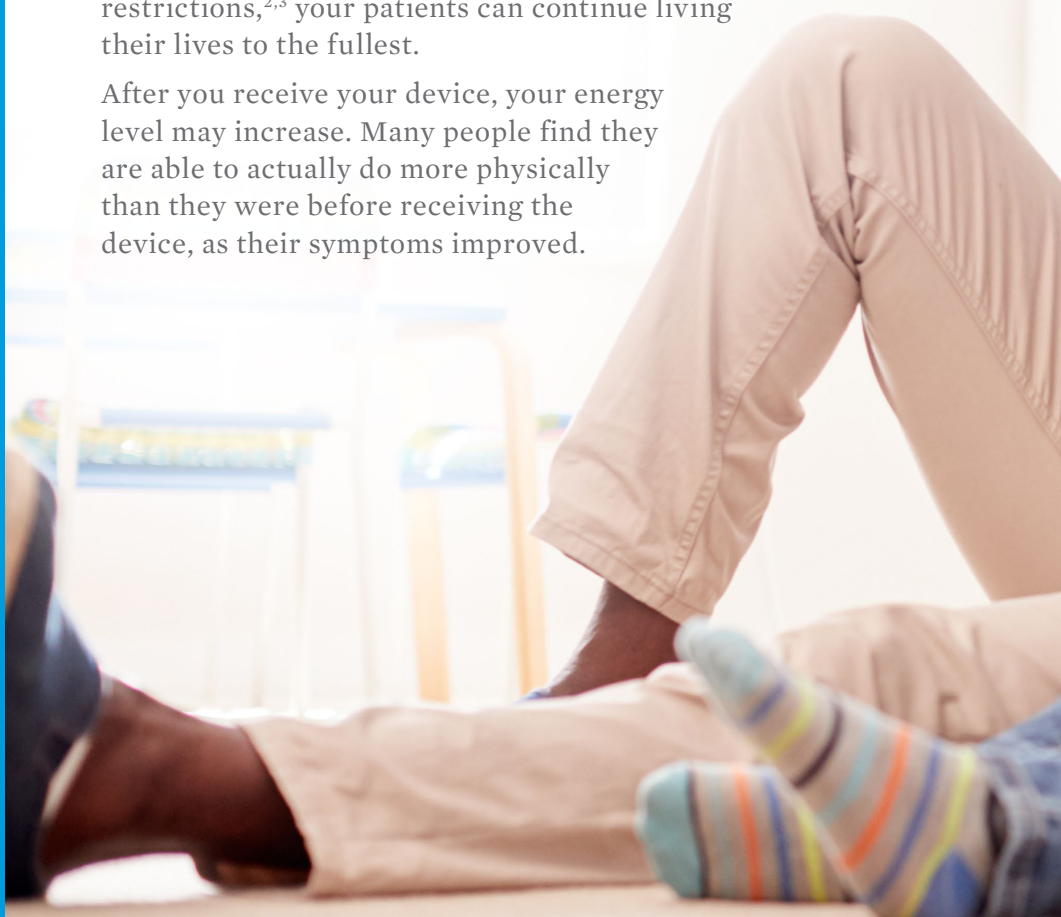
## THE PATH TO YOUR BEST POSSIBLE LIFE

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. For traditional pacemakers, 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 for traditional pacemakers, 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.

Leadless pacemakers (LP) have revolutionized care for heart patients. With no visible or physical reminder of a pacemaker under the skin and fewer post-implant activity restrictions,<sup>2,3</sup> your patients can continue living their lives to the fullest.

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 health, 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. For traditional pacemakers, 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. For leadless pacemakers, the procedure requires a new device implant with a similar procedure as your original implant procedure. Some leadless pacemakers will allow for chronic retrieval before a new device is implanted. 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

### Home appliances and office equipment

(microwave ovens, blenders, toasters, electric knives, televisions, electric blankets, stoves, garage door openers, computers, tablets)

## INSIGHTS

No known risks.

### Medical equipment

(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.

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.

Avoid electrical nerve and muscle stimulators (i.e. TENS units).

### Electromagnetic interferences (EMI)

(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. 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.

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.

Tell hospital personnel you have a pacemaker before you undergo any procedure.

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.

Airport security systems are generally not a concern, but be sure to show your patient ID card before entering airport security areas.

Carry your physician’s name and number with you.



To learn more,  
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:iii-ii90. doi: 10.1093/europace/eux258.
2. Sattar et al. Complications of leadless vs conventional (lead) artificial pacemakers - a retrospective review. Journal of community hospital internal medicine perspectives vol. 10, 4 328-333. 2 Aug. 2020, doi:10.1080/20009666.2020.1786901
3. Reddy VY, Cantillon DJ, John IP. San Francisco, CA: 6 May 2016. A comparative study of acute and mid-term complications of leadless vs transvenous pacemakers. Late-Breaking Clinical Trials II. Presented at Heart Rhythm Society 2016; pp. 02-04. Abstract LBCT.

## 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:** The AVEIR™ Leadless Pacemaker system is indicated for patients with significant bradycardia and:

- Normal sinus rhythm with rare episodes of A-V block or sinus arrest
- Chronic atrial fibrillation
- Severe physical disability

Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

**Intended Use:** The AVEIR™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy to the target patient population.

The AVEIR™ Delivery Catheter system is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

**Contraindications:** Use of the AVEIR™ Leadless Pacemaker is contraindicated in these cases:

Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.

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.

Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor-driven rates.

Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.

Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in Product Materials section in IFU) contained in the device and a thorough history of allergies must be discussed.

**Adverse Events:** Potential complications associated with the use of the AVEIR™ Leadless Pacemaker system are the same as with the use of single chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Valve damage and/or regurgitation, Heart failure, Pneumothorax/hemothorax, Cardiac arrhythmias, Diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation, Palpitations, Hypotension, Syncope, Cerebrovascular accident, Infection, Hypersensitivity reaction to device materials, medications, or direct toxic effect of contrast media on kidney function, Pacemaker syndrome, Inability to interrogate or program the LP due to programmer or LP malfunction, Intermittent or complete loss of pacing and/or sensing due to dislodgement or mechanical malfunction of the LP (non-battery related), Loss of capture or sensing due to embolization or fibrotic tissue response at the electrode, Increased capture threshold, Inappropriate sensor response, Interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic, Battery malfunction/ premature battery depletion, Device-related complications (Premature deployment, Device dislodgement/embolization of foreign material, Helix distortion), Death.

As with any percutaneous catheterization procedure, potential complications include, but are not limited to: Vascular access complications (such as perforation, dissection, puncture, groin pain), Bleeding or hematoma, Thrombus formation, Thromboembolism, Air embolism, Local and systemic infection, Peripheral nerve damage, General surgery risks and complications from comorbidities (such as hypotension, dyspnea, respiratory failure, syncope, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death).

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