Abbott

AVEIR™ LEADLESS PACEMAKERS

Introducing the World's First Dual Chamber Leadless Pacemaker[1]

WHAT IS A **PACEMAKER?**

It's a 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 tiny electrical signals to get your heart rhythm within your normal range.

It can evaluate your heart.

While the device is assisting your heart to maintain its rhythm, it's also storing data about your heart. Your doctor can then view the data to ensure that your device is working to meet your heart's specific needs.

WHY DO I NEED **A PACEMAKER?**

If you are experiencing symptoms such as:

- Fatigue
- Lightheadedness
- Shortness of breath
- Chest pain or pressure
- Trouble with normal activities and exercise

You may have a condition called bradycardia. This is when the heart's electrical signals can become blocked or irregular, causing it to beat too slowly. A pacemaker can assist your heart to function normally and get you feeling better quickly.

THERE ARE TWO COMMON **CAUSES OF BRADYCARDIA:**

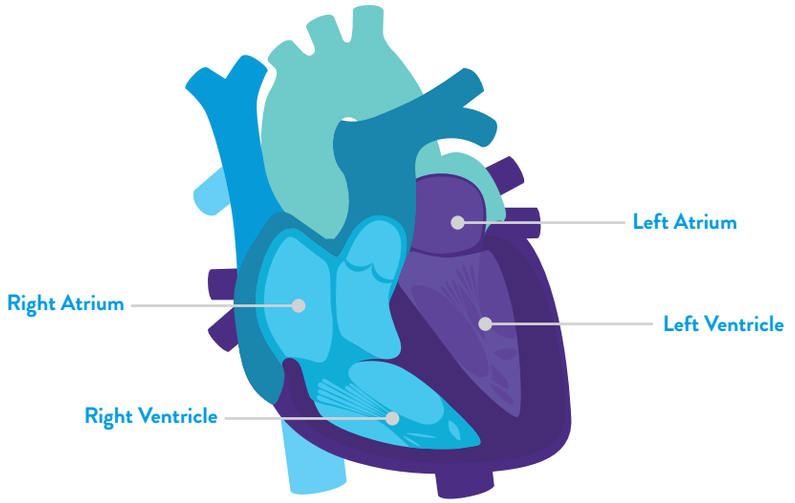
Sick Sinus Syndrome

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.

WHAT IS THE **ANATOMY OF THE HEART?**



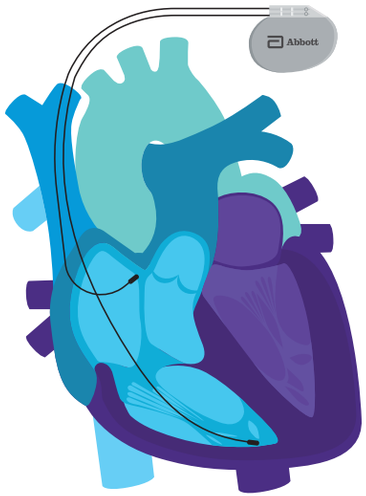
The heart has four main compartments, or "chambers." The top two chambers are called the right atrium and left atrium. The bottom two chambers are called the right ventricle and left ventricle.

WHAT ARE THE **TYPES OF PACEMAKERS?**

TRADITIONAL PACEMAKER WITH LEADS

A traditional pacemaker is implanted under the skin in the chest area and connected to leads that travel down blood vessels to the heart and attach to the heart tissue.

- Placed **in the chest** under the skin through a **surgical procedure**
- **Leads** connect the pacemaker to heart tissue to transmit the electrical therapy
- Chest scar and device bulge are **visible**
- Some **arm/shoulder mobility restrictions** will exist



Traditional Pacemaker and Leads Placement

LEADLESS PACEMAKER

A leadless pacemaker is implanted in your heart through a blood vessel in your leg. The device is 10 times smaller than a traditional pacemaker and does not require leads.

- Placed in the heart using a **small tube** (aka catheter) **through the groin**
- Attached to **the heart tissue**
- **No leads** required
- No chest incision or pocket means **no visible scarring or bulge**
- There are **no arm mobility restrictions**, allowing normal activities to resume sooner

Leadless Pacemaker Placement

AVEIR™ LEADLESS PACEMAKERS

AVEIR leadless pacemakers represent a groundbreaking innovation that offer both single chamber and the world's first dual chamber support. This pioneering technology operates discreetly within your heart, providing the necessary assistance you need without a chest incision or pacemaker placement under your skin.

At just 38.0 mm, the AVEIR VR LP has three times less volume than a standard AAA battery.

AVEIR AR
Leadless Pacemaker

AVEIR VR
Leadless Pacemaker

AVEIR leadless pacemakers are unique as they are the only leadless pacemaker system that can be implanted in either the right atrium (single chamber), right ventricle (single chamber), or both (dual chamber), depending on your needs.[1] And, in cases where your doctor recommends a dual chamber system, patented implant-to-implant (i2i™) technology allows the devices to "talk" to each other, keeping your heart chambers in sync.[2]

Atrial Device

Ventricular Device

Atrial and Ventricular Devices together for Dual Chamber Support

WHY AN **AVEIR™ LEADLESS PACEMAKER?**

You can now choose an AVEIR leadless pacemaker for any condition requiring a pacemaker, with these benefits:[3,4]

- **NO VISIBLE SCAR** or bulge on your chest.
- **NO CONSTANT REMINDER THAT YOU HAVE A PACEMAKER**, as it's placed inside the heart.
- **NO RISK OF LEAD OR POCKET COMPLICATIONS** associated with traditional pacemaker systems.
- **NO ARM MOVEMENT RESTRICTIONS** unlike a traditional pacemaker.
- **MINIMALLY INVASIVE PROCEDURE** for implant, removal, and replacement, if needed.

WHAT ARE THE STEPS IN THE **MINIMALLY INVASIVE PROCEDURE?**

Once you and your doctor have decided that an AVEIR™ pacemaker is right for you, the procedure takes place in a hospital setting.

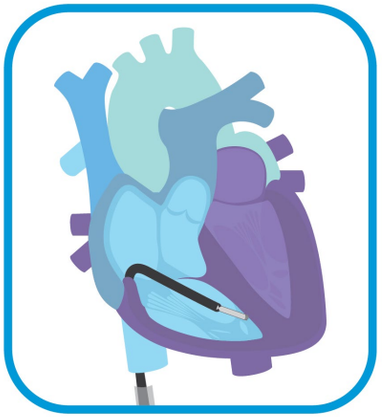


Diagram of AVEIR Ventricular Leadless Pacemaker implantation

1

The implant procedure can consist of one or two leadless pacemakers, each delivered into the targeted chamber(s) of your heart through a catheter, or tube, inserted through the groin.

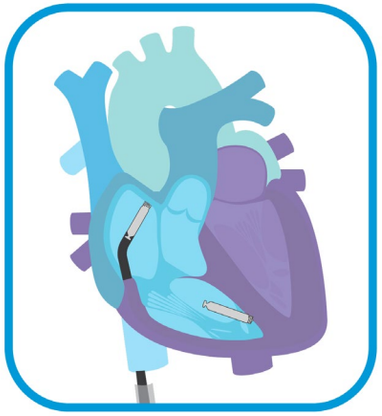


Diagram of AVEIR Dual Chamber Leadless Pacemaker Placement

2

Once delivered, one or two leadless pacemakers are attached to the interior wall muscle of your heart.

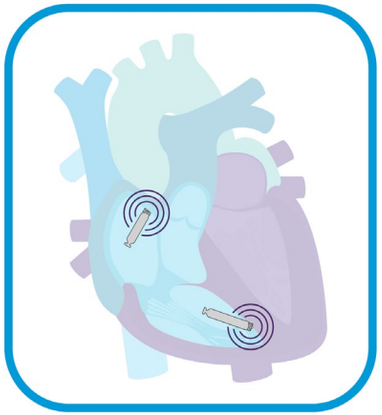


Diagram of devices pairing via i2i technology

3

If a dual chamber system is recommended, your doctor will pair the devices via i2i™ technology and then check your pacemaker system to ensure it is working properly. The catheter will be removed, and the AVEIR™ leadless pacemaker(s) will remain securely implanted in your heart.

FOLLOWING UP **WITH YOUR DOCTOR**

You will most likely be asked to see your doctor approximately two weeks after the procedure to check that you are recovering well and that your pacemaker is working properly. Your doctor may make some minor adjustments to your pacemaker with a programmer or computer. These adjustments do not require intervention and only take a few minutes.

FAQs

CAN I GO THROUGH AIRPORT SECURITY?

Yes, you can go through airport security as both AVEIR™ atrial and ventricular leadless pacemakers are shielded against this equipment. Please carry your device identification card with you at all times.

WHAT ABOUT CELL PHONE USE?

Cell phones 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.

WHAT ABOUT HOUSEHOLD DEVICES?

Standard household devices, such as microwave ovens, blenders, toasters, electric knives, televisions, electric blankets, stoves, garage door openers, computers, and tablets, may be used. Also, common household appliances, such as washing machines, vacuum cleaners, dishwashers, blenders, and microwaves, are fine to use with AVEIR™ leadless pacemakers.

Caution should be used around induction cooktops, as well as devices with strong electromagnetic fields. Consult manufacturers of induction cooktops.

WHAT IF I NEED AN MRI?

The AVEIR family of leadless pacemakers is MRI ready and safe for you to use in an MRI scanner after being programmed to MRI mode.

Note that not all MRI clinics are trained on working with medical devices so be sure to check with your physician on the correct MRI clinic.

WHAT ABOUT GOING TO THE HOSPITAL?

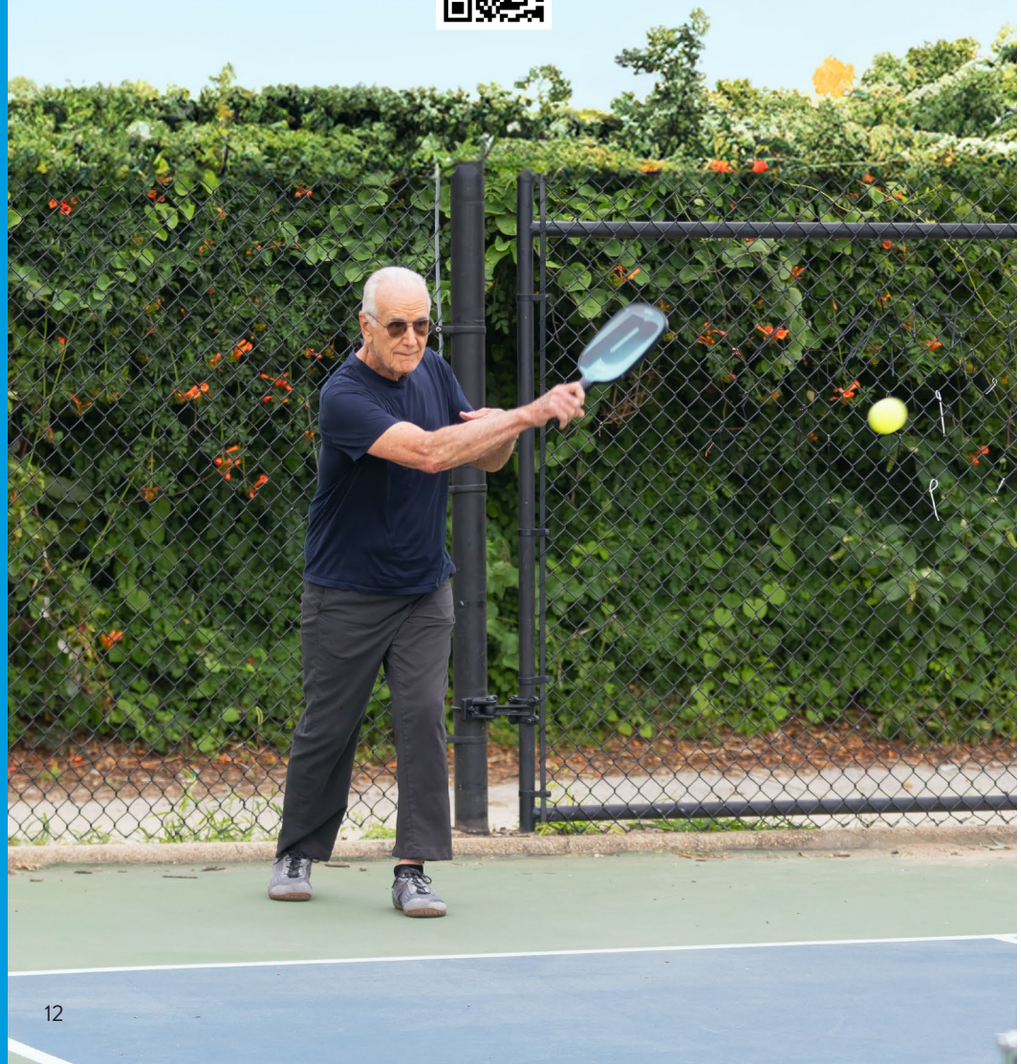
Medical equipment may interfere with the function of a pacemaker. Tell hospital personnel you have a pacemaker before you undergo any procedure. Do not enter areas that have a “No Pacer” sign posted.

HOW DO AVEIR™ PACEMAKERS **CHANGE PATIENTS' LIVES?**

"I am free to go swimming. I am free to play pickleball. I am free to do whatever I want. This system has given me the assurance that I can continue to be who I am and who I want to be in my life."

— Dennis

Watch Dennis' Story **here:**



"I was back in the gym within two days!"

— Chelsey

Watch Chelsey's Story **here:**

"Since it's been inserted, I don't even know it's there."

— Jack

Watch Jack's Story **here:**

ABOUT ABBOTT

A healthy heart is essential to good health. That's why we are committed to advancing treatments for people with cardiovascular disease. Our breakthrough medical technologies help restore people's health so they can get back to living their best lives, faster.

We focus on innovative technologies that can improve the way doctors treat people with heart arrhythmias, or irregular heartbeats.

Our cardiac rhythm management devices keep the heart beating at a healthy pace with pacemakers, implantable cardiac defibrillators, and implantable cardiac monitors, all designed to get people's hearts working better sooner.

For more information, **please consult with your physician.**

REFERENCES

1. AVEIR™ DR FDA approval.
2. AVEIR™ Leadless Pacemakers and Delivery Catheter IFU. ARTEN600284235.
3. 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
4. Udo EO, Zuithoff NPA, van Hemel NM, et al. Incidence and predictors of short and long-term complications in pacemaker therapy: the FOLLOWPACE study. Heart Rhythm 2012; 9: 728-35.

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 management of one or more of the following permanent conditions: Syncope, Pre-syncope, 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 patients exhibiting: Sick sinus syndrome, Chronic, symptomatic second- 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. MR Conditional: The AVEIR Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

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 and/or right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy within the implanted chamber for the target treatment group. The LP is also intended to operate optionally with another co-implanted LP to provide dual-chamber pacing therapy. The AVEIR™ Delivery Catheter 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 the Product Materials section of the 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 or dual chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Endocarditis, Valve damage 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, contrast media, 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 capture, pacing or sensing (non-battery related), Oversensing, Increased capture threshold, Inappropriate sensor response, Corrupted, intermittent, or loss of i2i communications, 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, Inability to release/re-dock of the LP from the catheter, Helix distortion), Additional surgery or intervention, 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, dyspnea, respiratory failure, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death.

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