Aveir™

Leadless Pacemaker

Patient Manual

Abbott

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Pat. http://www.abbott.com/patents

Contents

Your Contact and Device Information

Have your doctor or nurse complete the information on these pages before you leave the hospital.

Physician Name
Phone Number
Address
Hospital Name
Phone Number
Address
Device Model Name
Device Model Number
Serial Number
Date Implanted
Description

Introducing the Aveir™ leadless pacemaker

A pacemaker is a small implanted device that detects slow heart rate (bradycardia) and sends electrical pulses to the heart when necessary to cause the heart to beat at a normal rate. A pacemaker can improve your quality of life and possibly prolong it.

The Abbott Medical Aveir™ leadless pacemaker has these advantages over a traditional pacemaker:

- **Leaves no scar on the chest.** It is implanted through a vein in the groin and guided up to the heart. (With a traditional pacemaker, a 2 to 3-inch incision is made in the skin on the upper chest below the collarbone where the device will be imbedded.)
- **Requires no leads.** It is specially designed so that no electrical wires (called leads) are needed. (With a traditional pacemaker, at least one lead connects the device to the heart.)

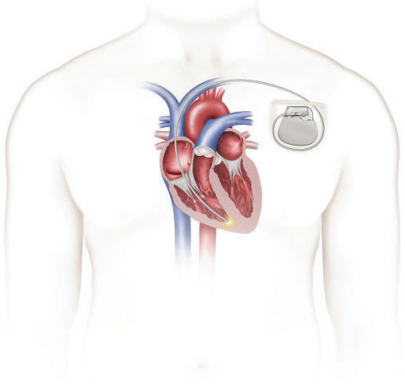
- **Stays out of sight.** It is implanted inside the heart, leaving no trace of it on the outside of the body.

The leadless pacemaker is cylindrical in shape and is about one-third the size of an AAA battery and one-tenth the size of a traditional pacemaker. Despite its small size, the leadless pacemaker can be expected to last for many years.

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 a slow or irregular heartbeat, your doctor may recommend a pacemaker to correct it.

Figure 1. Traditional Pacemaker



Since 1958, doctors have been implanting pacemakers, which require a 2- to 3-inch skin incision on the upper chest where a pacemaker is permanently placed under the skin. The doctor then feeds thin wires (called leads) through a vein to connect the pacemaker to the heart. When a slow heartbeat is detected, these leads deliver electrical pulses to the heart, causing it to contract and beat at a normal rate.

What are the complications associated with traditional pacemakers?

The rate of complications with pacemakers is low. Complications that occur typically happen in the area where the pacemaker is placed or, in the case of a traditional pacemaker, with the leads that are connected to the pacemaker.

- Area where the device is implanted may become infected.
- Leads may move out of place or get damaged, also causing complications.

While rare, complications can have a serious impact on a person's quality of life and be expensive to address.

Even without complications, some people have complained about the noticeable scar and being able to see the pacemaker under the skin. In addition, research has shown that as many as 6 out of 10 people experience reduced shoulder movement due to the implanted pacemaker.

How is the Aveir™ leadless pacemaker different?

With the Aveir™ leadless pacemaker, risks associated with these complications are reduced because the pacemaker does not have leads and does not require the doctor to create a surgical incision to place the device.

What are the risks associated with the Aveir™ leadless pacemaker?

A small number of people may develop complications from the implant procedure or the leadless pacemaker.

Complications due to the implant procedure

These can include infection; a reaction to a drug used during the procedure; 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 leadless pacemaker does carry potential risks,

such as bruising at the insertion site, infection, bleeding, reaction to the anesthesia or the contrast dye used to visualize the heart chamber, and death.

Complications related to the pacemaker

Similar to a traditional pacemaker and on rare occasions, the leadless pacemaker may not work properly because it is being affected by outside sources of electromagnetic energy. It is also possible for the leadless pacemaker to move from its original position in the heart, and that would impact the pacemaker's ability to regulate your heartbeat. This complication would require another procedure to remove the leadless pacemaker and implant a new one.

It is important to monitor the device regularly with follow-up visits as often as your doctor recommends.

Contact your doctor if you notice any of the following or have concerns about your device:

- You feel tired, short of breath, or you feel your heart rate is changing
- The insertion site is red, hot, swollen, more painful, or beginning to drain fluid

- Symptoms you had before receiving the pacemaker return

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

How is the Aveir™ leadless pacemaker implanted?

Depending on your heart condition and diagnosis, your doctor may prescribe therapy using either a single leadless pacemaker or a dual-chamber leadless pacemaker system.

- A single leadless pacemaker is implanted into the right atrium or right ventricle of the heart to provide pacing therapy.
- A dual-chamber leadless pacemaker system uses two leadless pacemakers. One pacemaker is implanted in the right ventricle and the other pacemaker is implanted in the right atrium. In a dual-chamber system, the two leadless pacemakers communicate wirelessly to send messages between the two heart chambers and work jointly to provide synchronized pacing. Both pacemakers may

be implanted at the same time, or a second pacemaker may be implanted at a later time in order to function together with an existing leadless pacemaker as a dual-chamber system.

The following figures illustrate the implant locations of a single leadless pacemaker in the right ventricle compared with a dual-chamber leadless pacemaker system with one leadless pacemaker implanted in the right ventricle and a second leadless pacemaker implanted in the right atrium.

Figure 2. Aveir™ leadless pacemaker single-chamber implant

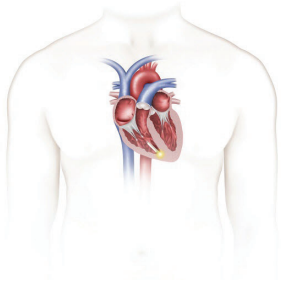
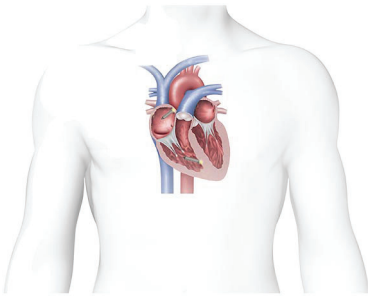


Figure 3. Aveir™ leadless pacemaker dual-chamber system



The Implant Procedure

Most of the time, it will take about 30 to 60 minutes for the implant procedure. These are the typical steps involved:

1. For most people, the procedure is done using a local anesthetic. You will be given some medicine to calm you and numbing medicine for your upper leg.
2. Your doctor will guide the implant tool and the leadless pacemaker through a vein in your leg to reach your heart.
3. Once inside the heart, your doctor will carefully attach the leadless pacemaker near the bottom of the right ventricle. Your

doctor will use fluoroscopy (a type of X-ray) as a guide.

4. The doctor will wirelessly connect to your leadless pacemaker using a computer programmer to confirm if it is in a good place to deliver the therapy when you need it. The doctor will also use the computer to program the device settings to your needs.
5. When this procedure is complete, the implant tool will be removed, and the leadless pacemaker will remain implanted in your heart.
6. If you are receiving a dual-chamber system, your doctor will guide the second leadless pacemaker with an implant tool through the same vein in your leg to reach your heart and attach it in the right atrium. Once both leadless pacemakers are implanted in their proper positions and are communicating with each other, the doctor will complete the programming for the system.

What can be expected after the implant procedure?

Here is what you can expect after your implant procedure.

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 time can vary; however, most patients should be able to go home the day following their procedure.

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

Following up with the doctor

You will be asked to see the doctor that performed your leadless pacemaker implant approximately 2 weeks after the procedure to

check that you are recovering well and that your pacemaker is working properly. The doctor may make some minor adjustments to your pacemaker with a programmer or computer. These adjustments do not require intervention, are completely painless, and only take a few minutes.

After the first follow-up visit with your doctor, you will be asked to come back at a minimum every 6 months or more frequently. During these visits, the doctor will confirm your leadless pacemaker is operating properly with the information retrieved from the programmer or computer that communicates with your pacemaker.

Operating lifetime of the leadless pacemaker

The longevity of the pacemaker battery depends on your therapy settings, medical condition, and other factors. The battery will not stop working suddenly; it will gradually run down over a period of months and allow more than enough time to schedule a replacement. Your doctor will check the battery at each follow-up visit. When the pacemaker battery

energy becomes low, the pacemaker will need to be replaced with a new one to continue therapy.

Your patient identification card

Your doctor will give you a patient identification card to carry with you that will let emergency medical personnel know about your leadless pacemaker.

Your patient identification card should be included with the information your doctor provides when you leave the hospital. Your doctor will complete the card and give it to you.

This card does the following things:

- Identifies you as having an implanted medical device and its location in the body
- Identifies the name and model of your implanted system
- Helps you pass through security systems like those in airports
- Provides information that allows your doctor to be contacted in an emergency

The following figures illustrate a sample patient identification card.

Figure 4. Patient identification card (front side)

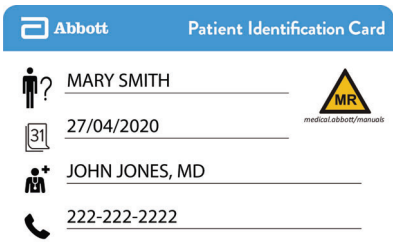
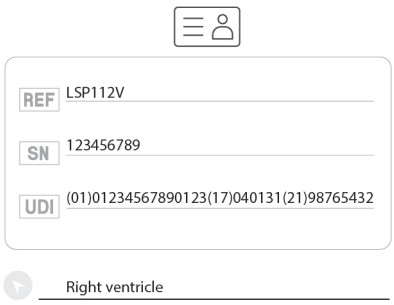


Figure 5. Patient identification card (inner section)



See Symbols for explanations of the symbols that appear on the card.

If you have questions about your card or need to request a replacement card, contact your doctor.

Replacing your leadless pacemaker

When it is time to replace your leadless pacemaker, your doctor will advise you on whether your pacemaker can be safely removed or if it should be left in place and a second device added.

What are the precautions for living with a leadless pacemaker?

As a person living with an implanted leadless pacemaker, it is recommended that you follow these safety precautions.

If you have any other questions, talk with your doctor since your doctor knows the details about your case.

Who should I tell about my leadless pacemaker?

The decision to tell others that you have a pacemaker is yours, in most instances. Always tell healthcare professionals about your leadless pacemaker, including dentists, physical therapists, nursing staff and other healthcare

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.

What about security checkpoints, electronic article surveillance (EAS) systems, or metal detectors?

There is very little metal in the leadless pacemaker, so most detectors will not sense it. However, it is possible that a very sensitive detector might detect the pacemaker.

If you must pass through security checkpoints, EAS systems, or metal detectors, pass through at a normal pace and do not pause within the detector. If you do not feel comfortable going through the system, show your patient identification card to the security personnel, who are trained how to check people with pacemakers.

EAS systems, like the ones used at entrances, exits, or checkout counters are also sources of electromagnetic interference (EMI). When you enter or leave a place with a security system,

walk through the entrance or exit at a normal pace.

Will a cellular phone interfere with my pacemaker?

Cellular phones, which send electromagnetic signals, should not interfere with proper operation of your leadless pacemaker. You can minimize the possibility of interference by taking simple precautions, such as not carrying the phone in a breast pocket or other location if they are over the pacemaker. Some accessories for cellular phones may contain magnets, such as cases with magnetic clasps.

Avoid interference between cellular phones or smart watches and the leadless pacemaker by keeping them at least 6 inches (15 centimeters) away from the chest.

Portable electronic devices may contain a magnet or magnetic material, or may emit RF signals that can interfere with the leadless pacemaker.

- Avoid carrying portable electronic devices such as e-cigarettes, or key cards, credit cards or other items with magnetic strips, in a breast pocket or near the heart.

- Avoid carrying earbuds or headphones in a breast pocket or near the heart. Do not allow earbuds or headphones to drape around the neck so they hang on the chest.

If you have further questions, contact your doctor.

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. The Aveir™ leadless pacemaker is an MR Conditional device, which means you can safely have an MRI scan, under certain conditions. See MRI Safety Information (page 20).

You should do your best to avoid electromagnetic interferences (EMI) that could be caused by electrical appliances in poor

condition or not grounded correctly, industrial generators, arc-welders, and specific medical equipment such as Transcutaneous Electrical Nerve Stimulation (TENS) units, which are electrical nerve and muscle stimulators.

What other precautions should I take?

When you have an implanted leadless pacemaker, you should avoid extremely hot or cold environments that could cause a sudden increase or decrease in body temperature because this could change the rate of therapy that the pacemaker sends to the heart.

MRI Safety Information

A Magnetic Resonance Imaging (MRI) scanner is a large machine that can create images of the soft tissues inside your body. This tool is very helpful in diagnosing many problems; but, to create the MR image the scanner must generate very strong magnetic forces that can be very dangerous to almost all implanted devices, like your pacemaker. The magnetic fields can interfere with the tiny computer in your pacemaker.

The Aveir™ leadless pacemaker, however, was specially designed to withstand the fields of most MRI scanners. Because it is an MR Conditional device, you can safely have an MRI scan under certain conditions. Before you schedule an MRI scan, ask your doctor if you are a good candidate for MRI.

Inform MRI site personnel that you have an implanted MR Conditional medical device before the MRI exam.

Symbols

These symbols may be found on your patient identification card.

Symbol	Description
UDI	Unique device identification number
REF	Catalog number
SN	Serial number
Leadless Pacemaker	Leadless Pacemaker

Symbol	Description
	Patient identification card label
	Location of implant
	Patient identification
	Implant date
	Healthcare center or physician
	Physician telephone
	Manufacturer
	Importer
	Device with demonstrated safety in the MR environment within defined conditions

Symbol	Description
	including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.

Glossary

Anesthetic
A substance that produces numbness or sleep.

Arrhythmia
An abnormal heartbeat.

Atrial
Relating to the atrium, the upper two chambers of the heart.

Atrium
One of the two upper chambers of the heart. These chambers receive blood from the body and pump it to the ventricles, the lower chambers of the heart. (Plural = Atria)

Bradycardia
A slow heart rate.

Chamber
One of the four areas in the heart that fills with blood before contracting during the heartbeat. The four chambers are: right atrium, left atrium, right ventricle, and left ventricle.

Electromagnetic Interference

Also known as EMI, this is magnetic or electrical interference from machines or devices, which can interrupt the normal operation of a leadless pacemaker.

Fluoroscopy

An imaging technique that uses X-rays to enable the internal structure and function of a patient's body to be seen by a doctor through real-time moving images.

Incision

A cut produced by a surgical instrument in order to perform surgery.

Lead

A special wire connected to a traditional pacemaker and placed in or on the heart.

Leadless Pacemaker

A small implantable device that sends electrical pulses to the heart whenever it senses that the heartbeat is too slow. A leadless pacemaker is placed directly in the heart without the need for a surgical pocket and insulation wires (called leads).

Local Anesthetic
A medication used in surgical procedures that numbs only one area of the body while the patient stays awake.

MR Conditional
A device (such as a pacemaker) with demonstrated safety in an MRI environment under specified conditions of use.

Programmer
A special computer designed to communicate with or program an implanted leadless pacemaker.

Pulse
A short output of electricity.

Veins
Blood vessels that carry blood back to the heart.

Ventricles
The two lower chambers of the heart that pump the blood out of the heart into the lungs and the body.

Ventricular
Relating to the ventricle.

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