

# Aveir™

Leadless Pacemaker

# Patient Manual



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# Contents

Introducing the Aveir™ leadless pacemaker. . . . .	1
What are pacemakers?. . . . .	2
What are the complications associated with traditional pacemakers?. . . . .	4
How is the Aveir™ leadless pacemaker different?. . . . .	5
What are the risks associated with a leadless pacemaker?. . . . .	5
How is the Aveir™ leadless pacemaker implanted?. . . . .	7
What can be expected after the implant procedure?. . . . .	9
Day of the implant. . . . .	9
Duration of the hospitalization. . . . .	10
Your patient identification card. . . . .	10
Following up with the doctor. . . . .	12
Operating lifetime of the leadless pacemaker. . . . .	13
Replacing your leadless pacemaker. . . . .	13
What are the precautions for living with a leadless pacemaker?. . . . .	14
Who should I tell about my leadless pacemaker?. . . . .	14
What about security checkpoints, electronic article surveillance (EAS) systems, or metal detectors?. . . . .	15
Will a cellular phone or portable electronic device interfere with my pacemaker?. . . . .	16
What precautions should I take with electrical equipment?. . . . .	17
What other precautions should I take?. . . . .	18
MRI safety information. . . . .	18
Product Materials. . . . .	19
Clinical Data Summary . . . . .	20

Symbols.....	21
Glossary.....	23

# Introducing the Aveir™ leadless pacemaker

A pacemaker is a small implanted device that detects slow heart rate 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 small incision at the top of the leg and guided up a vein to the heart. (With a traditional pacemaker, a 2 to 3-inch incision is made in the skin near the heart.)
- **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 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.

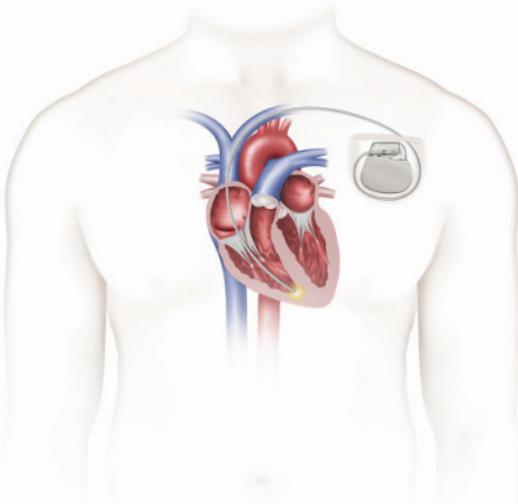
The leadless pacemaker is cylindrical in shape and is about one-third the size of an AAA battery and one-tenth the size of a traditional pacemaker. Despite its small size, the leadless pacemaker can be expected to last 15 years.

## **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

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Since 1958, doctors have been implanting pacemakers, which requires a 2 to 3-inch chest incision 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, 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 a 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, and/or reaction to the anesthesia or the contrast dye used to visualize the heart chamber.

## **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:

- 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?**

Most of the time, it will take about 20 to 45 minutes to implant the Aveir™ leadless pacemaker. These are the steps involved:

1. For most people, the procedure is done under local anesthetic. You will be given some medicine to calm you and numbing medicine for your upper leg.
2. A small incision will be 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.
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 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.

The following figures illustrate difference in the implant location of the leadless pacemaker compared with a traditional pacemaker.

Figure 2. Traditional pacemaker implant

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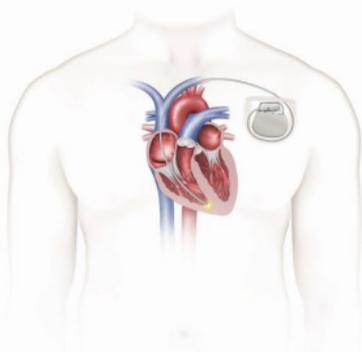
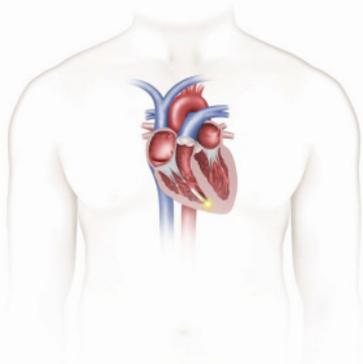


Figure 3. Aveir™ Leadless pacemaker implant

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## 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.

## **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 to help determine if you can safely have an MRI scan
- 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)

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The image shows the front side of a patient identification card. At the top, there is a blue header with the Abbott logo on the left and the text "Patient Identification Card" on the right. Below the header, there are four rows of information, each with an icon on the left and a text field on the right. The first row has a person icon with a question mark and the text "MARY SMITH". The second row has a calendar icon and the text "27/04/2020". The third row has a person icon with a plus sign and the text "JOHN JONES, MD". The fourth row has a telephone icon and the text "222-222-2222". To the right of the text fields, there is a yellow triangular warning icon with the letters "MR" inside, and below it, the text "medical.abbott/manuals".

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Figure 5. Patient identification card (inner section)

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The image shows the inner section of a patient identification card. At the top, there is a square icon containing a menu symbol (three horizontal lines) and a person icon. Below this icon is a rounded rectangular box containing three rows of information. Each row has a label in a small box on the left and a text field on the right. The first row has the label "REF" and the text "LSP112V". The second row has the label "SN" and the text "123456789". The third row has the label "UDI" and the text "(01)01234567890123(17)040131(21)98765432". Below the rounded box, there is a circular icon with a right-pointing arrow and the text "Right ventricle".

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See Symbols (page 21) 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.

## **Following up with the doctor**

You will be asked to see the doctor that performed your leadless pacemaker implant at 1 or 2 weeks after the procedure to check that you are recovering well and how your pacemaker is working. 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 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 leadless pacemaker operates using a battery and has an estimated operating life of 15 years. 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 allowing 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.

## **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 or portable electronic device 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 pacemaker.

**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 18).

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.

## Product Materials

The following product materials are intended to come into contact with blood or tissue:

- 35N LT‡
- Dexamethasone sodium phosphate (DSP)
- MP35N‡
- Nylon
- Parylene
- Polyether Ether Ketone (PEEK)
- Silicone elastomer

- Silicone medical adhesive Type A
- Silicone rubber
- Titanium Grade 2
- Titanium nitride-coated platinum/iridium alloy

NOTE: Cobalt is present as part of a cobalt alloy in the Aveir™ leadless pacemaker. Scientific information shows that medical devices made with metal alloys containing cobalt do not cause an increased risk of cancer or problems with reproduction.

## Clinical Data Summary

A summary of the safety and clinical performance (SSCP) for this device is available at <https://ec.europa.eu/tools/eudamed>. Search for your device using the UDI provided on your patient ID card. This is the SSCP location after the launch of the European Database on Medical Devices/Eudamed.

# Symbols

These symbols may be found on your patient identification card.

Symbol	Description
 medical.abott/manuals	Follow instructions for use on this website
<b>UDI</b>	Unique Device Identifier
<b>REF</b>	Catalog number
<b>SN</b>	Serial number
<b>MD</b>	Medical Device
<b>Leadless Pacemaker</b>	Leadless Pacemaker
	Magnetic Resonance (MR) Conditional, device with demonstrated safety in an MRI environment within the defined conditions
	Patient identification card label
	Location of implant

<b>Symbol</b>	<b>Description</b>
	Patient identification
	Implant date
	Healthcare center or physician
	Physician telephone
	Manufacturer
	Importer

# Glossary

## **Anesthetic**

A substance that produces numbness or sleep.

## **Arrhythmia**

An abnormal heartbeat.

## **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.

## **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) that has been demonstrated to pose no known hazards 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 body.









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2023-05  
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