



HEALTHY HEART

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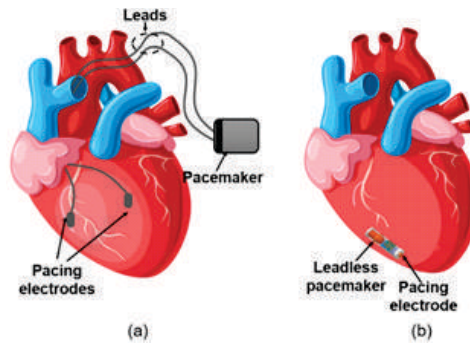
Leadless Pacemaker

A leadless pacemaker is a one-piece device a provider implants into your heart by way of a vein. Unlike with traditional pacemakers, you do not need a separate battery (Pulse Generator) under your skin or leads that go to your heart. Signals from a leadless pacemaker keep your heart beating normally.



What is a leadless pacemaker?

A leadless pacemaker is a small, one-piece device that a healthcare provider inserts into your heart to prevent slow heart rates



(Bradycardia). All the parts of a leadless pacemaker are inside one device. There's no separate battery. And it doesn't need leads (wires) because the whole device sits in your heart's right ventricle (heart chamber).

Leadless pacemakers are about 1 to 1.5 inches (3 to 4 centimeters) long. The device looks like a small metal cylinder, just a little bigger than a medicine capsule. It's smaller than an AAA battery.

How does a leadless pacemaker



work?

A healthcare provider programs and customizes your device to send small electrical impulses to your heart muscle when it needs it. A leadless pacemaker can sense your heart's own electrical signals. It can

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provide additional electrical impulses when your natural ones aren't frequent enough.

Who is suitable for a leadless pacemaker?

Pacemakers help people who have bradyarrhythmias, or slow heart rates. These are slow heart rhythms that may occur as a result of disease in your heart's conduction system.

A provider may implant a leadless pacemaker when people have:

- A need for pacing some of the time.
- Atrial fibrillation (Afib) with slow heart rates or pauses.
- Atrial fibrillation or sinus rhythm with AV block.
- Tachy-Brady syndrome (fast and slow heart rhythms).
- Bradycardia with symptoms.

Some people aren't candidates for a leadless pacemaker. Currently, the device is available only for people with certain medical conditions and a slow heart rate (bradycardia) who only need pacing in one heart chamber.

Your provider can tell you if you could receive a leadless pacemaker after reviewing your:

- Medical history.
- Heart rhythm.
- Results from non-invasive tests such as an echocardiogram (ultrasound of your heart, also called an echo).

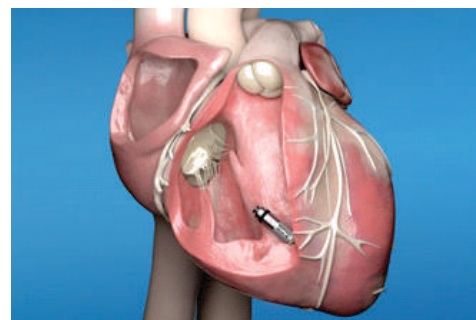
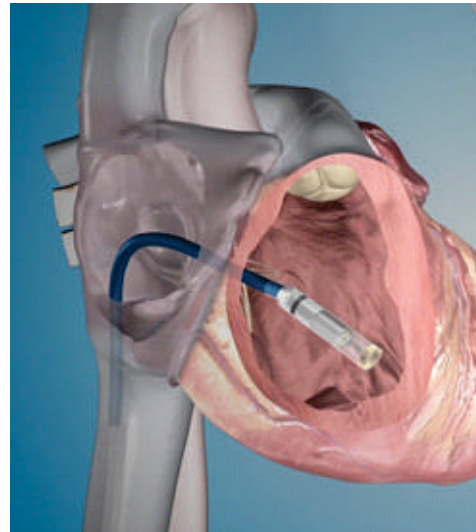
Procedure Details

How should I prepare for this procedure?

Before receiving a leadless pacemaker, you'll:

- Receive instructions from a provider about what time to stop eating or taking certain medicines

before your procedure. Don't stop taking any medicines unless your



provider tells you to do so.

What happens during this procedure?

A healthcare provider will:

- Numb an area in your groin with a local anesthetic (pain-relieving medication).
- Make a very small incision in your groin.
- Insert a long, thin tube called a catheter into your femoral vein through the incision.
- Use an X-ray machine to guide the catheter to your heart.
- Place the leadless pacemaker into position inside your right ventricle and secure it there. They attach it to your heart muscle by screwing it in or using the device's nickel titanium tines.

- Test the leadless pacemaker to make sure they've attached it to the ventricle wall and programmed it correctly.
- Remove the catheter. Close the incision site by applying pressure to the area.

How long does a leadless pacemaker procedure take?

The procedure takes about 30 – 60 minutes to complete. However, this can vary from person to person based on the device and your anatomy.



What happens after this procedure?

After receiving a leadless pacemaker, you'll need to:

Lie flat and keep your leg straight for two to six hours to prevent bleeding from the access site. Avoid sitting or standing.

Have a provider place a sterile dressing on your groin area to protect it from infection.

Spend the night in the hospital.

Go home after a provider checks your device and takes a chest X-ray.

Benefits of a leadless pacemaker include:

- No need for connecting leads



(wires), a separate power source or the creation of a surgical pocket on the chest to hold the power source. These are the most common causes of traditional pacemaker complications (infections or broken leads).

- No lump under the skin on the chest or leads anchored to the muscle, which can cause minor discomfort.
- No chest incision or scar from generator placement and replacements.
- A shorter procedure time than a traditional pacemaker implant procedure.
- With no wires or generator, there's no need to limit upper body activity after the implant.
- It's one piece, which is 90% smaller than a traditional pacemaker.
- It's safe to use in an MRI (magnetic resonance imaging) machine.
- It's appropriate for some people who aren't candidates for a traditional pacemaker.

Disadvantages of a leadless pacemaker include:

- It can only pace one ventricle (heart chamber).
- It can't defibrillate.
- Swelling and bleeding at the incision site (the most common possible problems after a leadless pacemaker implant). Typically, these aren't life-threatening but may lead to a longer hospital stay or slower recovery.
- Risk of heart puncture.
- Higher cost than traditional pacemakers.

More serious but rare complications

include the device moving out of place or internal bleeding, such as pericardial effusion or cardiac tamponade.

How successful are leadless pacemakers?

The implant success rate is 95% to 99%, with complication rates below 2%.

How long does a leadless pacemaker last?

The battery in a leadless pacemaker lasts about 5 to 15 years. When the battery gets too low, a provider can turn off your old pacemaker and put in a new leadless pacemaker. The pacemaker itself may last 10 years. There's enough room in your right ventricle for more than one pacemaker if they need to leave the old one there.

Can leadless pacemakers be removed?

Yes, providers can remove leadless pacemakers.

Can you have a magnetic resonance imaging (MRI) scan if you have a leadless pacemaker?

Yes, leadless pacemakers are usually safe in an MRI under certain conditions. For example, there may be a limit on the strength of the magnet in the MRI machine that's OK for you to use. A provider will check to ensure that you can have an MRI scan.

Recovery and Outlook

What is the recovery time?

You can go back to everyday activities two weeks after receiving a leadless pacemaker.

What follow-up appointments will I need?

A provider will check your leadless pacemaker:

- Within 24 hours of putting it in.

- After one month.
- Every three, six or 12 months.

They'll want to make sure you're healing well and your device is working without complications. They'll also check your device's battery charge at each visit.

When to Call the Doctor

Contact your provider if you:

- Have an infection or bleeding around your incision.
- Have swelling in your calves or ankles.
- Feel like you did before getting a pacemaker.
- Feel faint or dizzy.
- Have trouble breathing.

How long will I need a leadless pacemaker?

You'll need a leadless pacemaker for as long as you have the condition it treats.

How common is a leadless pacemaker?

Each year, more than 1 million people in the world get a pacemaker. Only about half of those who need a pacemaker are candidates for a leadless pacemaker. In the first four years after the US FDA approved leadless pacemakers, more than 50,000 people received one.

It can be unsettling to think about having a medical device in your body, but you aren't alone. Millions of people across the globe have pacemakers. But leadless pacemakers aren't a good solution for everyone; while a leadless pacemaker has advantages, a traditional pacemaker is a better option for some people. Talk with your provider about your questions and concerns



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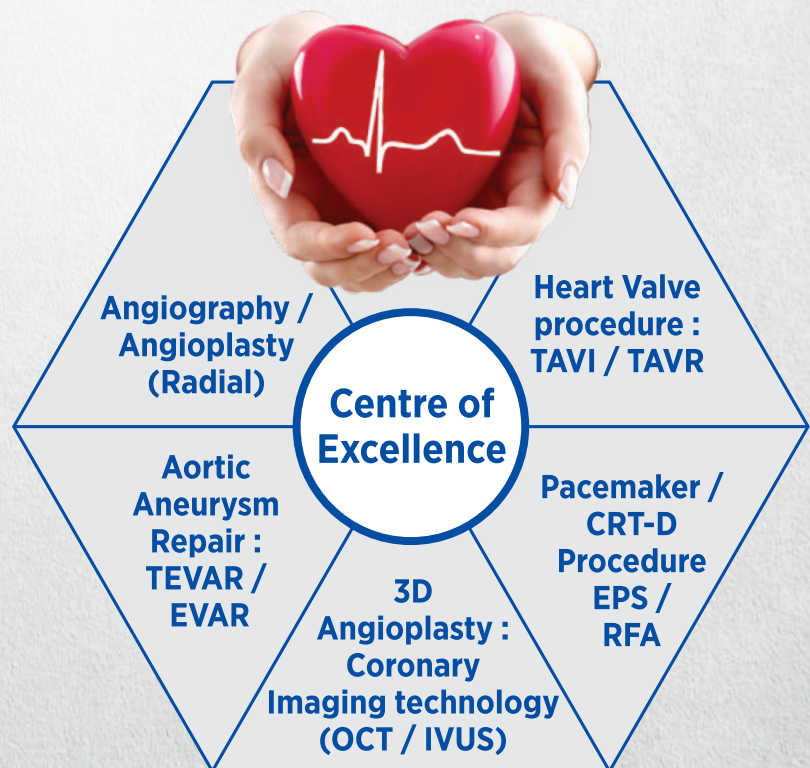
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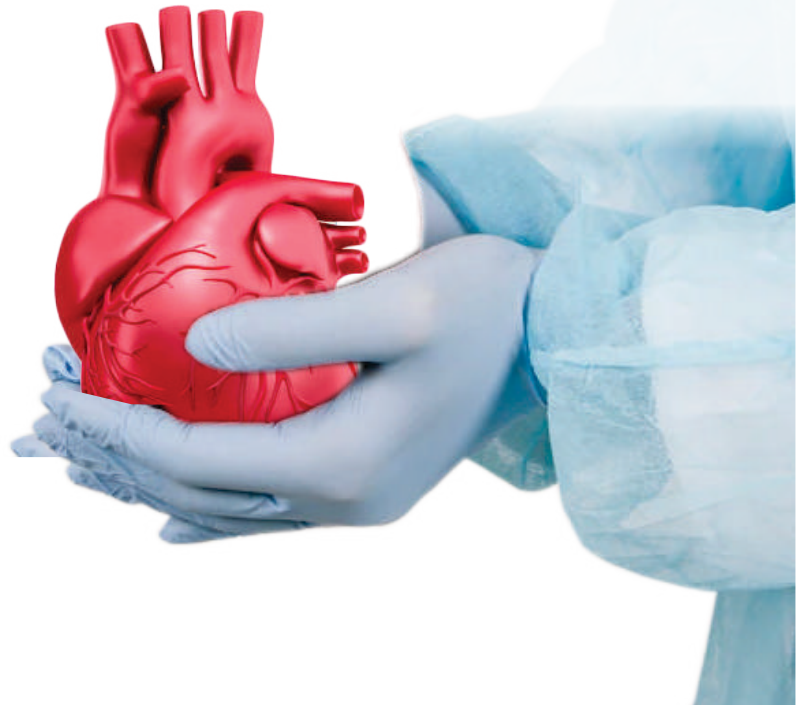
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