Medtronic

Micra™
transcatheter pacing systems

Out of sight.
Out of mind.

Meet Micra

Out of sight. Out of mind.

Micra™ is the world's smallest pacemaker[1] – leaving no bump under the skin, no chest scar, and requiring no lead. Micra is completely self-contained within the heart and provides the therapy needed without a visible or physical reminder of a medical device.

Actual size

What is bradycardia?

Bradycardia is a condition in which the heart beats too slowly. A healthy heart beats 60 to 100 times per minute, pumping about 284 liters of blood every hour. When you have bradycardia, the heart beats fewer than 60 times per minute. At that rate, the heart may not be able to pump enough oxygen-rich blood to the body during activity or exercise. As a result, you might feel dizzy, tired, short of breath, or have fainting spells.

Diagnosing bradycardia

Only a doctor can determine if you have bradycardia and, if so, how far it has progressed. To rule out or confirm the diagnosis of bradycardia, one or several diagnostic tests may be ordered, depending on the suspected heart rhythm problem.

These tests may include:

- Electrocardiogram (ECG)
- Exercise ECG, or stress test (measures your heart rhythm while you're engaged in a physical activity)
- Holter or event monitor
- Insertable cardiac monitor
- External loop recorder
- Tilt table test
- Electrophysiology study (EP Study)

Treating bradycardia

Treatment strategies vary, depending on your bradycardia causes and symptoms. Your doctor might prescribe new medications, or adjust the doses of medications you are currently taking to restore your normal heart rate. If this fails to restore your normal heartbeat, a pacemaker can regulate your heart's rhythm.

A pacemaker is designed to mimic the heart's natural rhythm. By sending an impulse when the heart's rhythm is slow or interrupted, it effectively regulates the heart rate automatically, freeing you to enjoy your regular activities.

How do pacemakers work?

A pacemaker is designed to mimic the heart's natural rhythm when there are disturbances, such as pauses, in the natural rhythm. The pacemaker has two main purposes – pacing and sensing.

- **Pacing:** A pacemaker will send an electrical impulse to the heart when the heart's own rhythm is too slow or interrupted.
- **Sensing:** A pacemaker will also "sense" (monitor) the heart's natural electrical activity. When the pacemaker senses a natural heartbeat, it will not deliver a pacing pulse.

Traditional pacing system

Most pacemakers require a device (about the size of a tea bag) to be surgically implanted under your skin in the upper chest. The system also requires a lead or leads to be guided through the vein into the heart. The lead carries electrical signals from the pacemaker to your heart to help it beat regularly.

Micra transcatheter pacing systems

Micra is 93% smaller than traditional pacemakers.[2] It is comparable to the size of a large vitamin capsule, and has a battery that typically lasts between 8 and 13 years.[3,4] Unlike a standard pacemaker, it is implanted into the heart through a vein in your leg and does not require a lead. Micra's miniaturized size and minimally invasive approach leaves no visible sign of a medical device under the skin. This can mean fewer post-implant activity restrictions and no obstructions to shoulder movement.

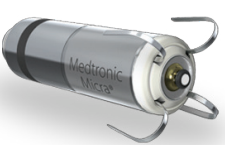
Is Micra for every patient?

Micra is intended for patients with specific pacing needs. Talk to your doctor about the benefits and risks of Micra.

93%

smaller than traditional pacemakers.[2]

Traditional single-chamber pacemaker and lead†



Micra†

Vitamin†

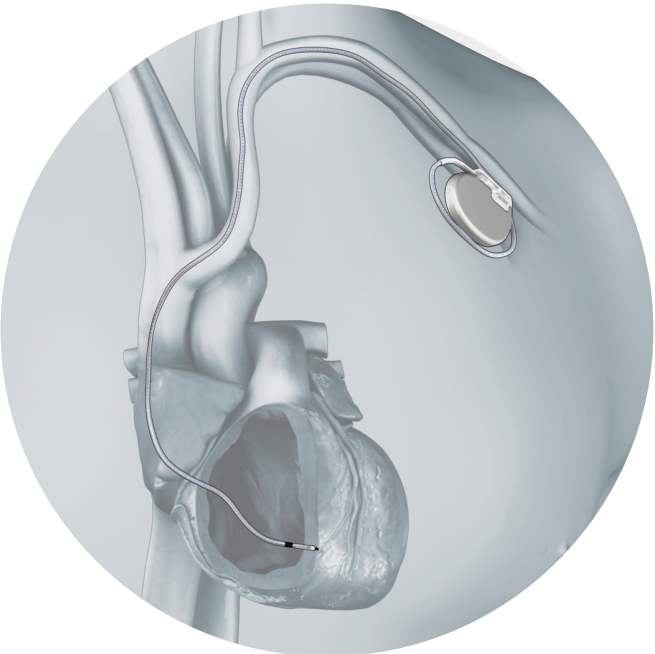
†Actual size.

"I know it's there, but it's not there."

Ron,
Medtronic Micra patient

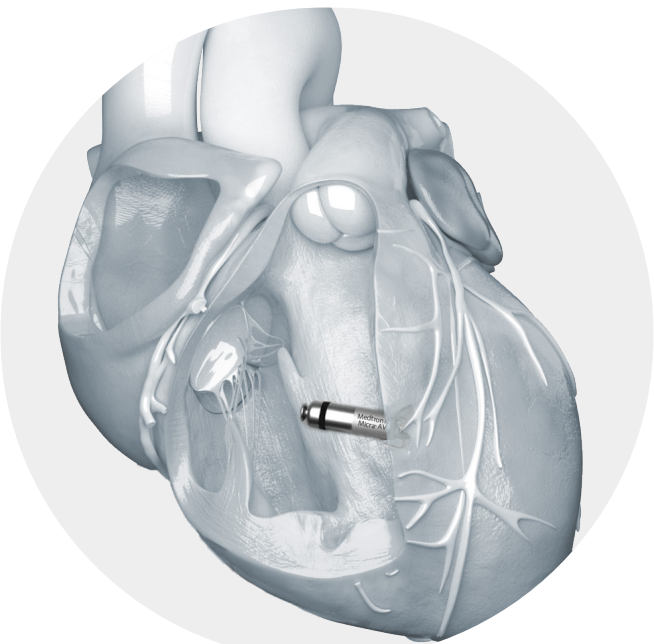
How is a traditional pacemaker system implanted?

- A small incision, approximately 5 cm long, is made in the upper chest
- A lead(s) (thin insulated wire, like a spaghetti noodle) is guided through the vein into the heart
- Your doctor connects the lead to the pacemaker and programs the device
- The pacemaker is then inserted beneath the skin
- Your doctor tests the pacemaker to ensure it is working properly
- The incision is then closed



How is Micra implanted?[5]

- Your doctor will insert a straw-like catheter system into a vein, typically near the upper thigh area of your leg
- The catheter system moves Micra into the right ventricle of the heart
- Micra is placed against the heart wall and secured with flexible tines (see image at the far right below)
- Your doctor tests Micra to ensure it is working properly
- The catheter system is then removed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Micra AV

Frequently asked questions

Many people with a pacemaker like Micra resume their normal daily activities after recovering from the implant procedure. There may be certain situations your doctor will ask you to avoid. Discuss your activity and lifestyle goals with your doctor and develop a plan that works best for you.

Visit MRISureScan.com for questions about MRI scanning eligibility or about the scanning process. Heart doctors with questions should contact a Medtronic representative or Medtronic Technical Services.

Is it safe for me to have an MRI scan?

A magnetic resonance imaging (MRI) scan is a type of medical imaging that uses magnetic fields to create an internal view of the body, which doctors use for diagnostic purposes. Micra was designed, tested, and approved to be used safely with MRI scanners. You can undergo an MRI scan as long as patient eligibility requirements are met. Please consult your heart doctor about these eligibility requirements.

Can I go through airport security?

Given the short duration of security screening, it is unlikely that Micra will be affected by metal detectors (walk-through archways and handheld wands) and full body imaging scanners (also called millimeter wave scanners and 3D imaging scanners) such as those found in airports, courthouses, and jails. However, the metal case of a pacemaker could set off a metal detector.

To minimize the risk of temporary interference with Micra while going through the security screening process, avoid touching metal surfaces around any screening equipment. Do not stop or linger in a walk-through archway; simply walk through the archway at a normal pace. If a handheld wand is used, ask the security operator not to hold it over the pacemaker and not to wave it back and forth over the pacemaker. Requesting a hand search is also an alternative.

If you have concerns about these security screening methods, show your Micra ID card, request alternative screening, and then follow the instructions of the security personnel.

Can I use a mobile phone?

Yes. When talking on a mobile phone, keep the phone about 6 inches away from an implanted Micra. We also recommend avoiding placing the mobile phone in a shirt or jacket pocket of the chest.

Are household appliances safe to use?

Yes. Most household appliances are safe to use as long as they are properly maintained and in good working order. This includes microwave ovens, major appliances, electric blankets, and heating pads.

Will magnets affect my Micra?

Items that contain magnets, such as magnetic therapy products, stereo speakers, and handheld massagers can temporarily affect the operation of a pacemaker. Therefore, it is recommended to keep items containing magnets at least 6 inches away from an implanted pacemaker. We do not recommend the use of magnetic mattress pads and pillows because it is difficult to maintain a 6-inch distance when using these items.

How long will my Micra last?

A new Micra is needed when battery power falls to a low level. Battery power is affected by many factors, including the nature of the heart condition. The estimated average battery life for a Micra device is approximately 8–13 years after it is implanted[3,4]; individual patient experience may vary.

The battery power is checked at each Micra follow-up appointment. The doctor or nurse will notify you when you need a new pacemaker.

When a new device is needed, the Micra device may be either simply turned off or removed from the body before a new Micra device or traditional pacemaker system is implanted. Your doctor will determine what is best for you.[5,6]

Can I exercise? Can I go about my regular activities?

You should be able to return to your usual activities, as long as those activities do not exceed current fitness levels. Questions about specific exercises should be discussed with your physician.

Additional information can be found on our website: medtronic.ca.

References

[1] Nippoldt D, Whiting J. Micra Transcatheter Pacing System: Device Volume Characterization Comparison. November 2014. Medtronic data on file.

[2] Williams E, Whiting J. Micra Transcatheter Pacing System Size Comparison. November 2014. Medtronic data on file.

[3] Medtronic Micra™ AV MC1AVR1 Device Manual. January 2020.

[4] Pender J, Whiting J. Micra AV Battery Longevity. January 2020. Medtronic data on file.

[5] Medtronic Micra™ MC1VR01 Clinician Manual. October 2016.

[6] Reynolds D, Duray GZ, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. *N Engl J Med.* February 11, 2016;374(6):533-541.

Additional Device Information

An implantable pacemaker system relieves symptoms of heart rhythm disturbances. They do this by restoring normal heart rates. A normal heart rate provides your body with the proper amount of blood circulation. The pacemaker system is intended for patients who need rate-adaptive pacing or chronic pacing.

Risks associated with the Micra™ Transcatheter Pacing System (Micra) implant include, but are not limited to, complications at the surgical site, injury to the heart where the device is attached such as pericardial effusion (fluid around the heart) and/or sensitivity to the device material, failure to deliver therapy when it is needed, or receiving extra therapy when it is not needed. After receiving a Micra, you will have limitations with certain magnetic and electromagnetic radiation, electric or gas powered appliances, and tools with which you are allowed to be in contact.

Once implanted, removal of the Micra after it has become encapsulated may be difficult because of the development of fibrotic tissue. At such time, your physician has the option of permanently turning off the Micra, and leaving it in the heart.

This treatment is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary. For further information, please call the Medtronic toll-free number at 1-888-660-4616 (9:00 a.m. to 8:00 p.m., Monday–Friday, EST) or see the Medtronic website at www.medtronic.ca.

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