

LIFE WITH A PACEMAKER



Medtronic

TOGETHER, HELPING YOU LEAD A FULLER LIFE.

If you or someone you love has been diagnosed with a slow heartbeat (bradycardia), this brochure can help you understand your heart condition and treatment options. This brochure provides basic information about a slow heartbeat and pacemakers, including what to expect before and after you have a pacemaker implanted.

Ask your doctor about your unique medical condition and therapy management.



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 **75 gallons of blood every hour**. With bradycardia, the heart beats fewer than **60 times per minute**. At that rate, the heart is not able to pump enough oxygen-rich blood to the body during normal activity or exercise. As a result, this may cause dizziness, fatigue, or shortness of breath, or fainting spells.

What causes bradycardia?

Bradycardia can occur for several reasons. Some common causes of bradycardia include:

- Congenital heart disease (condition you were born with)
- Certain illnesses or heart medications
- Natural aging process
- Scar tissue from a heart attack
- Sick sinus syndrome, also called sinus node dysfunction (the heart's natural pacemaker is not working correctly)
- Heart block (the electrical impulse that travels from the upper to the lower chamber of the heart is irregular or blocked)

Symptoms of bradycardia

When your heart beats too slowly, you may experience various symptoms. These symptoms help your doctor assess the severity of your heart condition and determine the appropriate treatment for you.

- Dizziness and fainting
- Chronic lack of energy
- Shortness of breath

RESTORING REGULAR HEART RHYTHM WITH PACING

Diagnosing bradycardia

Only your 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 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
- External loop recorder
- Insertable cardiac monitor
- Tilt table test
- Electrophysiology study (EP study)

Treating bradycardia

How bradycardia is treated depends on what's causing it. Bradycardia can be caused by an underactive thyroid (hypothyroidism), an electrolyte imbalance, or medicines you may be taking for certain conditions. Treating these problems with new medicines, or adjusting the doses of the medicines you are currently taking, may restore a normal heartbeat.

If treating these problems medically doesn't work, or if damage to the heart's electrical system causes your heart to beat too slowly, then you may be prescribed a pacemaker.

What is a pacemaker?

When people refer to a pacemaker, they are actually discussing a pacing system, which includes the pacemaker and leads.

- A traditional **pacemaker** is a small device that is implanted under the skin, typically just below the collarbone. The device delivers therapies to treat irregular, interrupted, or slow heartbeats.
- **Leads** are thin, soft, insulated wires about the size of a spaghetti noodle. The leads carry the electrical impulse from the pacemaker to your heart and relays information about the heart's natural activity back to your pacemaker.



Pacemaker and Leads
(actual size)

RESTORING REGULAR HEART RHYTHM WITH PACING

(cont'd.)

What is the Micra™ transcatheter pacing system?

Micra TPS is a pacing capsule that is 93% smaller than traditional pacemakers. It is the size of a large vitamin capsule, and has a battery that lasts as long as a traditional pacemaker.^{1,2} Unlike a standard pacemaker, it is implanted into the heart through a vein in your leg and does not require a lead. The Micra pacing capsule'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.



ACTUAL SIZE



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

Ron,
Medtronic Micra TPS
Patient

IS MICRA TPS FOR EVERY PATIENT?

The Micra pacing capsule is intended for patients who need a single chamber (also known as a ventricular pacemaker, or VVIR) pacemaker. Talk to your doctor about the benefits and risks of Micra TPS.



Traditional pacemaker and lead

Micra pacing
capsule

Vitamin

HOW DOES A PACE MAKER **WORK?**

A pacemaker is designed to mimic the heart's natural pacemaker, the sinus node. 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 is interrupted. This electrical impulse starts a heartbeat.

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.

MRI **ACCESS**

Traditionally, most pacemakers are not considered safe in an MRI environment because the MRI could change the settings, temporarily affect the normal operation of, or potentially damage the pacemaker.

Take comfort in knowing that Medtronic has pacemaker systems FDA approved for use in the MRI environment. These pacemaker systems have a unique design, developed so that under specific conditions, patients may safely undergo MRI scans.

Talk to your doctor about the pacemaker options available to you, including a device that may allow you access to an MRI in the future.



GETTING A PACEMAKER IMPLANTED

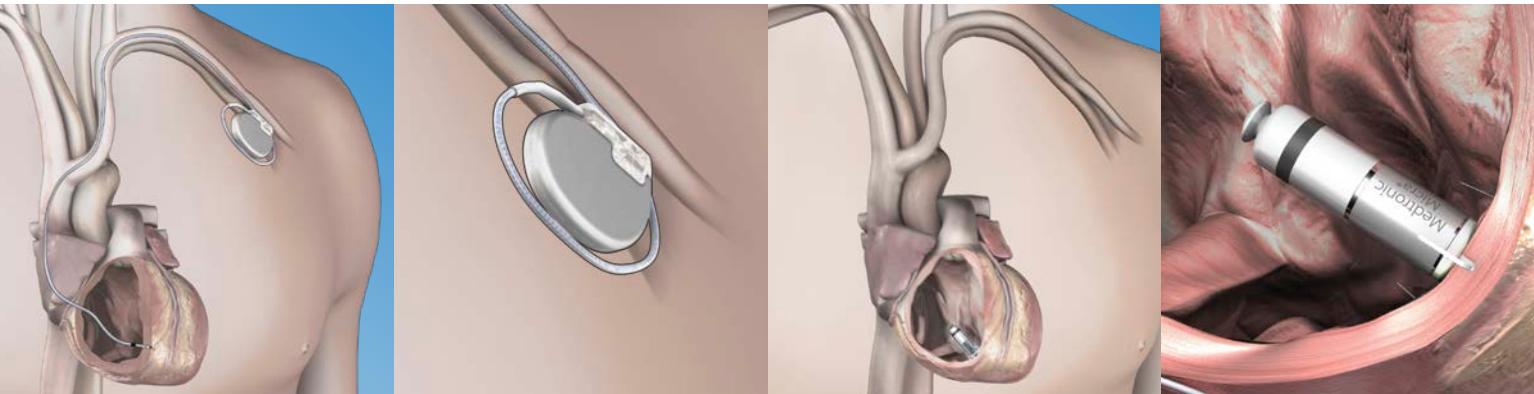
The procedure to implant a pacemaker does not require open heart surgery, and most people go home within 24 hours. Before the surgery, medication may be given to make you sleepy and comfortable. Generally, the procedure is performed under local anesthesia.

How is a traditional pacemaker system implanted?

- A small incision, approximately 5 cm long, is made in the upper chest.
- A lead (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 the Micra transcatheter pacing system implanted?

- 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 the Micra TPS into the right ventricle of the heart.
- The Micra pacing capsule is placed against the heart wall and secured with flexible tines (see image at the far right below).
- Your doctor tests the Micra TPS to ensure it is working properly.
- The catheter system is then removed.



FOLLOW-UP CARE & **REMOTE MONITORING**

Follow-up appointments enable the pacemaker to be thoroughly checked. During these checkups, your doctor may:

- Monitor the battery status of the pacemaker
- Check the leads to determine how they are working with the pacemaker and your heart
- Review your pacemaker settings to ensure they are programmed appropriately to your medical needs
- Make programming adjustments to your pacemaker

In addition to these checkups with your doctor, your clinic or practice may choose to have your pacemaker checked through remote monitoring.*

Today millions of people all over the world benefit from remote monitoring of their heart devices. Remote monitoring of your Medtronic heart device allows you to send device information to your doctor or clinic through a small monitor. Your clinic can review this information on the secure CareLink™ network and take appropriate action.

Medtronic patient monitors are easy to use and offer convenient connection options — Wi-Fi, Internet connection, or cellular signal — depending on your specific monitor.

To find out if remote monitoring is right for you, please talk to your doctor.

*CareLink compatibility: currently not available for Micra transcatheter pacing system

PATIENT **TESTIMONIALS**



"With remote monitoring, you're more connected with your clinic. It's easy. It's reliable. It's just a great tool and a great asset to your medical care — and making sure you're connected with your doctor."

Robbie
(Medtronic employee
and pacemaker
patient)



"Why wouldn't you do something like this (remote monitoring)? It's convenient. It's accurate. It's not intrusive."

Doug
(ICD patient)

COMMON QUESTIONS

Can I use a mobile phone?

Yes, you can use mobile phones (including cellular phones and smartphones); however, proximity requirements between your mobile phone and your pacemaker vary based on your type of pacemaker. Your pacemaker ID card will indicate if you have a "SureScan" device.

For SureScan™ Devices

Some accessories for mobile phones contain magnets, such as cases with magnetic clasps. To avoid interference between these accessories and your pacemaker, keep them at least 6 inches (15 centimeters) away from your pacemaker. Do not carry a mobile phone with one of these accessories in a pocket over your pacemaker or in a shoulder bag near your pacemaker.

For Non-SureScan Devices

Mobile phones may cause electrical interference with your pacemaker when the phone is turned on and held too close to your pacemaker. Any effect is temporary, and simply moving the phone away will return the pacemaker to its previous state of operation. To avoid any possible interference between mobile phones and your pacemaker, keep all mobile phones at least 6 inches (15 centimeters) away from your pacemaker. When using a mobile phone, hold it to the ear that is farthest away from your pacemaker. Also, do not carry a mobile phone close to your pacemaker, such as in a shirt pocket (or a pants pocket if your pacemaker is implanted in your abdomen).

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 device?

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

EDUCATIONAL RESOURCES

Will I be able to travel?

Given the short duration of security screening, it is unlikely that your Medtronic pacemaker will be affected by metal detectors (walk-through archways and hand-held wands) or full body imaging scanners (also called millimeter wave scanners and 3D imaging scanners) such as those found in airports, courthouses, and jails.

To minimize the risk of temporary interference with your pacemaker 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 hand-held wand is used, ask the security operator not to hold it over your pacemaker and not to wave it back and forth over your pacemaker. You may also request a hand search as an alternative.

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

How active can I be?

You can resume most or all activities after you recover from an implant procedure. However, there may be certain activities your doctor will ask you to avoid, like rough contact sports. Be sure to discuss your activity and lifestyle goals with your doctor to find a plan that works best for you.

Life with a Pacemaker

Many people with a pacemaker 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.

Medtronic Patient Services

If you have a Medtronic cardiac device and want to learn more or have questions about living with a pacemaker, please contact Medtronic Patient Services at 1-800-551-5544, ext. 41835. Our Patient Services Specialists are available to assist you, Monday – Friday from 8 a.m. to 5 p.m. Central Time.

Medtronic.com

General information on heart conditions and treatment options for patients and their caregivers is provided on this website. Visit medtronic.com.

References

- ¹ Nippoldt D, Whiting J. Micra Transcatheter Pacing System: Device Volume Characterization Comparison. November 2014. Medtronic Data on File.
- ² Medtronic Micra MC1VR01 Clinician Manual. November 2014.

Important Safety Information

An implantable pacemaker system relieves symptoms of heart rhythm disturbances. It does 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 or for patients who may benefit from synchronizing the pumping of the heart chambers.

Risks associated with these implantable device systems include, but are not limited to, infection at the surgical site 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 an implantable device system, you will have limitations with magnetic and electromagnetic radiation, electric or gas-powered appliances, and tools with which you are allowed to be in contact.

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.

Your physician may prescribe an MRI scan for you. 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. Unlike previous generations of heart devices, your SureScan™ heart device system was designed and tested to be used safely with MRI scanners. The electromagnetic fields present during MRI scans have the potential to cause hazardous effects on heart devices, which can result in cardiac tissue heating, inappropriate therapy, and dangerous arrhythmias. Due to the unique design of the SureScan heart device systems, these risks are reduced to a very low level so that under specified conditions, patients may safely undergo MRI scans. You can undergo an MRI scan as long as you meet the patient eligibility requirements that Medtronic provides to your heart doctor and the scan is conducted according to Medtronic directions. For example, your heart device system must consist only of a Medtronic SureScan model heart device and the appropriate number of SureScan labeled leads (visit <http://www.mrisurescan.com>). Any other combination may result in a hazard to the patient during an MRI scan.

The Revo MRI™ SureScan and Advisa MRI™ SureScan pacing systems and Micra Transcatheter Pacing System are MR Conditional. This means the system is designed to allow patients to undergo MRI when your doctor determines you meet patient eligibility requirements and the scan is conducted according to Medtronic directions.

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 1-800-551-5544 (7:00 a.m. to 6:00 p.m., Monday–Friday, Central Time) or see the Medtronic website at medtronic.com.

Medtronic MyCareLink Smart™ Monitor Reader, MyCareLink™ Patient Monitor, CareLink™ Monitor, and MyCareLink Connect™ Patient Website

The Medtronic MyCareLink Smart monitor reader, MyCareLink patient monitor, and the CareLink monitor are prescription devices indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manuals. The MyCareLink Connect patient website is intended to provide patients, their friends/family, and caregivers messages regarding transmission status of patient device diagnostic data to the CareLink network. Transmissions to the CareLink network sent via cellular or Wi-Fi connectivity are subject to cellular and/or Wi-Fi service availability. The monitor or monitor reader must be on and in range of the implanted device in order to wirelessly receive data from your implanted device. Web browsers currently supported by the MyCareLink Connect patient website are: Microsoft® Internet Explorer® for Windows® Version 8.x and Version 9.x, Mozilla Firefox® for Windows Version 13.x, Google Chrome™ for Windows Version 20.x. MyCareLink Connect patient website availability may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician.

The Medtronic CareLink service is prescribed by your physician. This service 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 service, results may vary. For further information, please call CareLink Patient Services at 1-800-929-4043 (8:00 a.m. to 5:00 p.m., Monday–Friday, Central Time) or see the Medtronic website at medtronic.com.

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Patient Services

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