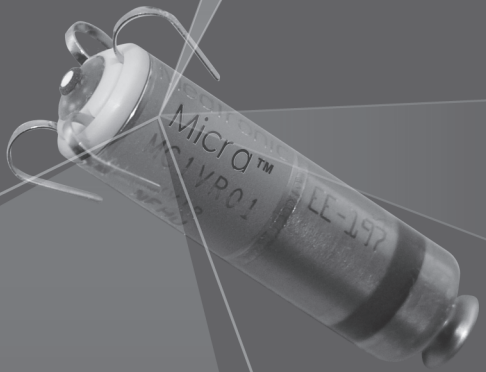
Medtronic

MR
MR Conditional

Micra™ Transcatheter Pacemaker

Patient Manual



Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

We are *there* when you need us.

Contents

Information about you and your pacemaker

Your personal information

Your name _____

Your doctor's name _____

Specialty _____ Phone _____

Your doctor's name _____

Specialty _____ Phone _____

Your medications _____

_____

_____

_____

_____

_____

_____

Emergency contact information

Name/address/phone _____

_____

Name/address/phone _____

_____

Your pacemaker information

Type of pacemaker _____

Serial # _____

Date of implant _____

Hospital where implanted _____

_____

_____

How to contact Medtronic

Contact us by phone

Our experienced Patient Services group is available to answer any questions or concerns you may have about your heart device. To speak directly with a Patient Services Specialist, call 1-800-551-5544. Our staff is available Monday through Friday from 8:00 AM to 5:00 PM (Central Time).

Contact us online

Medtronic is dedicated to providing you with the most up-to-date information available about your Medtronic heart device. Website information is available 24 hours a day.

- Medtronic website: www.medtronic.com
- Patient Services website: www.medtronic.com/rhythms

If you would like to submit questions, suggestions, or requests to us online, you can use the online form provided at www.medtronic.com/corporate/contact.jsp.

Contact us by mail or fax

Medtronic Inc.
Patient Services Department
Mail Stop MVS 14
8200 Coral Sea Street NE
Mounds View, MN 55112
Fax: (763) 367-5809

Contacting Medtronic about your ID Card

To update information on your ID card or if you have questions about your ID card, see “Your pacemaker ID card” on page 62.

Medtronic Warranty

For complete warranty information, call Medtronic Patient Services at 1-800-551-5544. Our staff is available Monday through Friday from 8:00 AM to 5:00 PM (Central Time)

1 Why read this manual?

Your doctors should be your first source of information about your heart condition and your general health.

This manual is for people who are about to have or already have a Medtronic Micra transcatheter pacemaker. This manual explains what the pacemaker is, what pacing therapies it provides, how it is implanted, and what you can expect after you have your pacemaker. It is a good idea to encourage your family and caregivers to read this manual.

Words that appear in **bold** are defined in the glossary starting on page 89.

Frequently asked questions

New patients often have the same initial concerns about their pacemakers. Here are some of the questions that new patients frequently ask.

? Why do I need this pacemaker?

Based on your individual health condition, your doctor has determined that the treatment provided by this pacemaker may help to improve your symptoms. Although this pacemaker does not prevent or cure your underlying heart rhythm condition, it does help to protect you from heart rhythms that can weaken or even endanger your health. Having a pacemaker should also improve your quality of life. Many patients say that a pacemaker gives them and their families a sense of security.

The most common medical condition that needs a pacemaker is **bradycardia**. Bradycardia is an abnormally low **heart rate** that is less than 60 beats per minute during normal activities of daily living. A pacemaker stimulates or increases the heart rate to a level that meets the demands of everyday living.

? Who should not receive this pacemaker (contraindications)?

Patients with previously implanted medical devices or certain health conditions may not be eligible to receive this pacemaker. Consult your doctor to determine whether or not this pacemaker is right for you.

? 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. You can undergo an MRI scan as long as you meet the patient eligibility requirements that Medtronic provides to your heart doctor. Your pacemaker ID card specifies your implanted device model.

Unlike earlier generations of pacemakers, your Micra pacemaker was designed, tested and approved to be used safely with MRI scanners. The electromagnetic fields present during MRI scans have the potential to cause hazardous effects on pacemakers, which can result in cardiac tissue heating, inappropriate pacing, and dangerous arrhythmias. Due to the unique design of this pacemaker, these risks are reduced to a very low level so that under specified conditions, patients may safely undergo MRI scans.

Prior to receiving an MRI scan, your doctor will verify that you meet the patient eligibility requirements, verify that your pacemaker is

functioning properly, and ensure that the SureScan feature is programmed to “On”.

During the MRI procedure, you are monitored continuously to ensure your safety.

If you have questions about your eligibility to receive an MRI scan, contact your doctor or nurse. If any of your doctors have questions, they should contact a Medtronic representative or Medtronic Technical Services.

? Will I be able to drive?

Whether you will be able to drive depends on your individual heart condition. Many people with pacemakers are able to resume driving if their doctors approve and if allowed by the laws and insurance regulations in their states. For more information, see “Driving a car” on page 41. If you have concerns, talk with your doctor.

? Will I be able to travel?

Most people who have pacemakers can travel without taking special precautions if they follow their doctor's instructions. Wherever you travel, your pacemaker continues to monitor your heart and provide therapy when it is needed.

It is unlikely that your pacemaker will trigger the security gates at airports or other secure buildings. If it does, present your pacemaker ID card. If a handheld screening wand is used, ask the security operator not to hold it over your pacemaker and not to wave the wand back and forth over your pacemaker. See "Security systems" on page 51 for more information.

A multilanguage pacemaker travel card is available that gives instructions in several languages for safe security scanning; the card is especially useful for international travel. See page 64 for more information about the multilanguage pacemaker travel card.

If you have any other travel-related questions, consult the Medtronic travel website at www.medtronic.com/traveling.

? Can I walk through antitheft systems found in public places?

Yes, simply walk through the antitheft system at a normal pace. Under some circumstances, the systems located in stores, libraries, and other places may temporarily interfere with your pacemaker if you stop or linger near this equipment. The interference stops when you move away from the equipment.

? Can I use a mobile phone?

Yes, you can use mobile phones, including cellular phones and other wireless phones. For more information about using mobile phones and other wireless communication devices, see “General guidelines for avoiding interference from electrical items or magnets” on page 44.

? Can I use a microwave oven and other electrical items?

Yes, you can use a microwave oven as well as major appliances, electric blankets, and heating pads. See “Living life with your pacemaker” on

page 39 for information about electrical items and any restrictions or cautions you should know about.

? Will my pacemaker need to be replaced?

Yes. Because your pacemaker operates using a battery sealed inside the pacemaker, you will need to get a new pacemaker when battery power falls to a low level. Battery power is affected by many factors, including the nature of your heart condition. Although battery life may vary, the estimated average longevity for this pacemaker is 12 years after it is implanted, based on device settings observed in the Micra clinical trial[1].

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

[1] Reynolds D, Duray GZ, Omar R, et al. A leadless intracardiac transcatheter pacing system. N Engl J Med. DOI: 10.1056/NEJMoa1511643

? How often will my doctor need to check my pacemaker?

The first follow-up appointment is typically scheduled about 1 month after your implant procedure. Additional follow-up appointments are scheduled every 3-6 months, depending on your doctor's normal practice and your medical condition. These follow-up appointments can be performed at your clinic. For more information about follow-up services, see "Follow-up care" on page 71.

? How do I know if my pacemaker battery is still working?

The strength of your pacemaker battery is checked during your follow-up appointments. Because the battery is sealed inside your pacemaker and cannot be recharged, you will need a new pacemaker when the battery power is low. For more information about pacemaker replacement, see "Pacemaker replacement" on page 74.

? Can I have sexual relations?

People often have questions about resuming sexual relations after receiving a pacemaker. Most people resume sexual activity, based on their doctor's guidance. You and your partner should be able to enjoy all the benefits of intimacy.

2 About your pacemaker

Your doctor has prescribed a Medtronic Micra transcatheter pacemaker to relieve your symptoms of heart rhythm disturbances. Although this pacemaker does not prevent or cure your underlying heart rhythm condition, it may improve the quality of your life.

This chapter should answer many of your questions about your pacemaker, including the following questions:

- What is a pacemaker?
- What is a transcatheter pacemaker, and how is it different from other pacemakers?
- What are the components of my pacemaker?
- How does a pacemaker work?
- What is a **pacing therapy**, and what does it feel like?
- What types of therapy can my pacemaker provide?

If you have questions that are not answered in this manual, ask your doctor or nurse.

What is a pacemaker?

A pacemaker is an implanted medical device that stimulates the heart muscle with timed pulses of electricity (called pacing therapy or simply therapy). These small amounts of electricity cause the heart to contract, mimicking a naturally occurring heart rhythm.

A pacemaker relieves symptoms of heart rhythm disturbances by restoring normal heart rates. If the heart is beating too slowly (called **bradycardia**), a pacemaker responds with therapy to restore a normal heart rate.

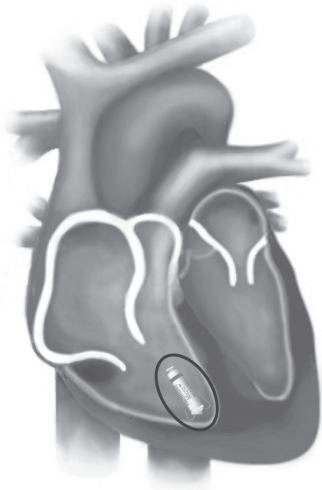
A normal heart rate provides your body with the proper amount of blood circulation. This stops the fatigue, dizziness, and shortness of breath caused by your heart beating too slowly. It also improves your breathing comfort during normal activities.

Although a pacemaker relieves symptoms for most patients, it does not prevent or cure heart disease or prevent **heart attacks**.

What is a transcatheter pacemaker, and how is it different from other pacemakers?

A traditional pacemaker is implanted in the chest and connected to leads that are inserted into the heart. Unlike a traditional pacemaker, a transcatheter pacemaker has no leads and is implanted directly into the right ventricle of the heart (see Figure 1). The Micra pacemaker is about one inch long and about one quarter of an inch wide. It is called a transcatheter pacemaker because it is attached to a catheter delivery system. This system is used to carry and position the pacemaker in the correct location in the heart. The pacemaker is implanted through an incision, generally in the groin area of the leg. After the pacemaker is implanted, the catheter delivery system is removed.

Figure 1. Transcatheter pacemaker in the right ventricle of the heart

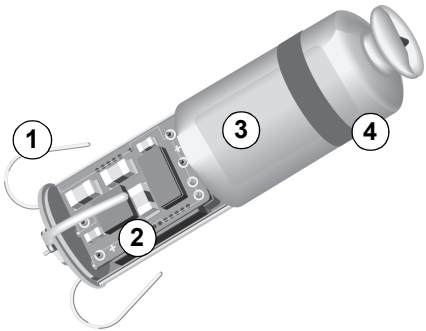


What are the components of my pacemaker?

Your pacemaker contains a very small computer that is powered by a tiny lithium battery. All electronic components are sealed inside a

titanium metal case. Tines attached to the outer case help position and hold the pacemaker in place. See Figure 2.

Figure 2. Pacemaker components



1. Tines
2. Computer
3. Battery (in titanium case)
4. Titanium case

- **Tines.** The flexible tines hold or fix the pacemaker to the heart.
- **Computer.** The computer controls the timing and intensity of the electrical impulses delivered to the heart that stimulate the heart to beat.

- **Battery.** The pacemaker is powered by a small, sealed lithium battery.
- **Titanium case.** The battery and computer are sealed inside a metal case that is sometimes called a "can".

How does a pacemaker work?

When the heart's own rhythm is interrupted, irregular, or too slow, the pacemaker sends an electrical impulse to the heart. This pacing pulse starts a heartbeat. The pacemaker also monitors (or senses) the heart's natural electrical activity. This is called **sensing**. The pacemaker does not deliver a pacing pulse when it senses a natural heartbeat.

What is a pacing therapy, and what does it feel like?

If your heart's rhythm becomes too slow, your pacemaker delivers a steady pattern of small electrical pulses to your heart to encourage a regular heartbeat. This is called **pacing** your heart. The pacing therapy provided by your pacemaker makes sure that your heart maintains a heart rhythm that supports your body's needs.

Most people do not feel pacing therapies when they are delivered. The few that report feeling this type of therapy describe it as painless.

What types of therapy can my pacemaker provide?

Your doctor has set up your pacemaker to deliver the most effective types of therapy for your specific heart rhythm condition. Your pacemaker provides fixed rate therapy and **rate-responsive therapy**.

Fixed rate therapy

Fixed rate therapy paces the heart at a steady rate that does not increase during activities, such as exercise, or decrease when you are resting.

Rate-responsive therapy

A normal heart rhythm slows down or speeds up many times during the day. Your heart beats slower while you are resting or sleeping. It beats faster in response to exercise or excitement. Your heart rate changes to supply the blood your body needs during your changing levels of activity.

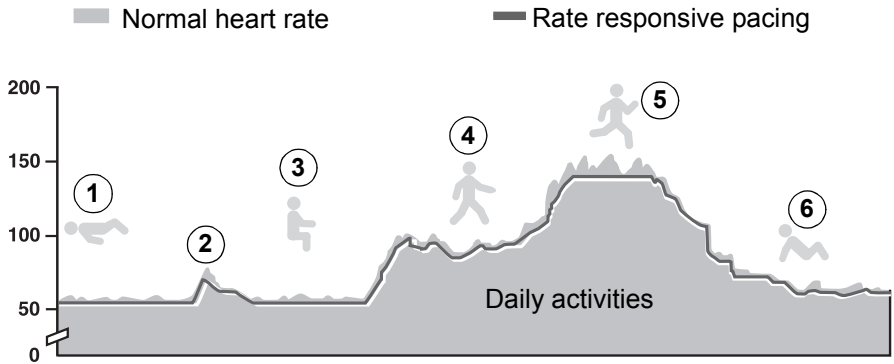
When your heart cannot adjust its rate to meet the needs of your body, rate-responsive therapy or pacing is needed. This type of pacing varies its rate depending on your level of activity. A **rate-responsive pacemaker** uses one or more special sensors to monitor changes in your

body. The pacemaker uses this information to increase or decrease your heart rate.

Patients who have rate-responsive pacing report feelings of well-being and the ability to resume active and satisfying lifestyles. Variations in pacing rate allow you to perform your everyday activities with ease. If you are walking, exercising, or gardening, the pacemaker automatically adjusts your heart rate to match your level of activity. When you slow down, rest, or sleep, the rate decreases.

You do not need to engage in strenuous activity to benefit from a rate-responsive pacemaker. The simple act of walking may require a rate of more than 100 beats per minute, as shown in Figure 3.

Figure 3. Rate-responsive pacing adjusts the pacing rate according to the needs of your body.



1. Sleeping
2. Wake-up
3. Sitting
4. Walking
5. Running
6. Resting

3 Your implant procedure and recovery

Being told you need a pacemaker can be upsetting, but knowing what to expect about your implant procedure can help reduce your concern. The implant procedure does not require open heart surgery. You will be given medication to make you sleepy and comfortable. Typically you will also be given local anesthesia at the access site.

Usually you will stay in the hospital overnight and go home the next day. Your doctor will give you instructions on caring for your incision as well as any limitations you may have.

This chapter covers information about the following topics:

- The implant procedure
- Potential risks after the implant procedure
- Recovering after your implant procedure
- When to call your doctor
- Follow-up appointments

The implant procedure

The procedure for implanting the pacemaker uses a catheter with a navigation handle called a delivery system. The delivery system holds the pacemaker and allows the doctor to move the pacemaker into the correct position and place it in the right ventricle of the heart. The implant procedure generally takes 1 hour or less.

How the procedure is done

1. Your doctor inserts the catheter delivery system into your vein through a small incision at the access site, typically in the groin area of your leg.
2. The doctor uses the delivery system to move the pacemaker into the right ventricle of your heart.
3. Once the delivery system is in the correct position, the doctor fixes the pacemaker into the muscle of your heart using the tines on the pacemaker.
4. The doctor uses a small external programmer to test and program your pacemaker.
5. The doctor then removes the delivery system through the access site.

6. The doctor or other medical professional closes the incision at the access site, completing the procedure.

Potential risks after the implant procedure

Your doctor and Medtronic have attempted to minimize the risks associated with implanting this pacemaker. However, as with any surgery, there are potential risks.

The following potential risks are associated with implanting your pacemaker:

- tearing of the blood vessel where the catheter was inserted
- bleeding from the site where the catheter was inserted
- pain, swelling, or bruising at the site where the catheter was inserted
- infection
- perforation of the heart chamber
- blood clots
- heart attack
- stroke

Recovering after your implant procedure

After your pacemaker is implanted, your doctor may order tests such as an **electrocardiogram (ECG)**, blood tests, or x-rays to confirm the location of your pacemaker. The operating settings of your pacemaker may also be checked again to make sure that your pacemaker is providing the best treatment for your heart condition.

As you recover, follow your doctor's suggestions about resuming normal activities. Here are general recommendations for the first few weeks after your implant procedure:

- Call your doctor immediately if any swelling, warmth, or drainage appears around the incision or if you develop a fever.
- Use care when exercising and bathing, according to your doctor's directions.
- Avoid tight clothing that may irritate your incision.
- Avoid lifting more than 10 to 15 pounds (5 to 7 kilograms).
- Avoid pushing or pulling heavy objects.

- Tell your doctors and your dentist that you have a pacemaker. They may choose to prescribe antibiotics for you to take before and after surgery or dental work to prevent infection.

When to call your doctor or nurse

Contact your doctor or nurse if you experience any of the following situations:

- You notice swelling, warmth, or drainage around your incision, or if you develop a fever while your incision is healing.
- You notice new, unexplained heart symptoms, or you are experiencing the same symptoms you experienced before receiving your pacemaker.
- You have heart rhythm symptoms that last longer than 3 minutes (or any length of time specified by your doctor). These symptoms can include extreme fatigue, racing heart, pounding heart, and feeling faint or dizzy.

Follow-up appointments

Your doctor or nurse will work with you to schedule follow-up care appointments. For more information about these appointments, read Chapter 7, “Follow-up care” on page 71

4 Living life with your pacemaker

Many people resume their normal daily activities after full recovery from their implant procedure. However, there may be certain situations that your doctor will ask you to avoid. Your doctor will provide the most important guidance for your particular condition.

This chapter has important information about the following topics:

- Food and medications (see page 40)
- Recommendations about your physical activity (see page 40)
- What you need to know about electromagnetic compatibility (EMC) (see page 42)
- Precautions about medical procedures (see page 55)

Food and medications

Your doctor may instruct you to eat or avoid eating certain foods. Your doctor may also prescribe medications that will treat your heart condition. Talk with your doctor to get specific information about food and medications.

Recommendations about your physical activity

Upon the advice of your doctor, you can gradually return to your normal lifestyle and to activities such as these:

- pursuing hobbies or recreational activities
- returning to your job
- resuming strenuous activity
- resuming sexual activity
- traveling

Your doctor might ask you to avoid situations where a few seconds of unconsciousness could be dangerous to you or others. These situations may include driving, swimming or boating alone, or climbing a ladder.

Recreation and activities

Ask your doctor if there are any activities that you should avoid after your implant procedure. Your doctor may suggest that you limit your physical activity, which could include the following restrictions:

- no heavy lifting
- limited walking
- no climbing stairs or ladders

If you have additional questions about any recreational activities you normally pursue, contact your doctor or nurse.

Driving a car

Discuss with your doctor whether you can safely drive a car or other vehicle. You may be able to resume driving, depending on local laws and insurance regulations and on your medical condition. Your doctor will decide what is best for your safety and the safety of others.

There are no special restrictions for hybrid cars. You can drive and ride in hybrid cars just as you would in non-hybrid cars.

What you need to know about electromagnetic compatibility (EMC)

Everything that uses electricity produces an **electromagnetic energy field**. This energy field surrounds the electrical item while it is connected to a source of electricity (even a battery source). The energy field is strongest near the item and weakens with distance from the item.

The relationship between these energy fields and your pacemaker is called **electromagnetic compatibility (EMC)**. Most electromagnetic energy fields are small and weak and do not affect your pacemaker. Electrical items that generate strong electromagnetic energy fields may not be compatible with your pacemaker.

Safeguards are built into your pacemaker to shield it from strong electromagnetic energy fields. For example:

- The metal case of your pacemaker acts as a shield against electromagnetic energy fields.
- Electronic filters are built into your pacemaker that help your pacemaker distinguish between external electromagnetic energy fields and the internal electrical pulses of your natural heartbeat.

You can avoid potential electromagnetic interference by keeping your pacemaker a minimum distance away from the electrical item. See the following pages for more information, including the recommended safe distances for certain types of electrical items.

? How could electromagnetic energy fields affect my pacemaker?

High electromagnetic energy fields could affect how your pacemaker senses your heart rhythm. Because your pacemaker is designed to sense the electrical activity of your heart, it may also sense a strong electromagnetic energy field outside your body.

If your pacemaker is exposed to a strong electromagnetic energy field, it may not detect an abnormal heart rhythm or it may deliver a pacing therapy when your heart does not need it. Any effects of electromagnetic energy fields on your pacemaker are temporary and will stop when you move away from the source of the electromagnetic energy field.

? What about static electricity or shocks from household outlets?

Static electricity shocks will not damage your pacemaker. A momentary shock from a household electrical outlet (110/220 volts) is unlikely to damage your pacemaker, depending on how long you stay in contact with the outlet.

? What items are safe, and what kind of precautions do I need to take?

Most electrical items are safe for you to use. However, you should keep some items that produce a stronger electrical field a minimum distance away from your pacemaker. This minimum distance can range from 6 to 12 inches (15 to 30 centimeters) or more, depending on the type of item. Refer to the information beginning on page 46 for recommended safe distances.

General guidelines for avoiding interference from electrical items or magnets

The following pages provide tips on how to avoid any possible temporary effects of electromagnetic energy fields on your pacemaker. If

you have questions about electromagnetic energy fields or the safe use of a specific item that is not listed in this chapter, consult with your doctor or nurse.

Area restrictions

Before entering an area where signs are posted prohibiting persons with an implanted cardiac device, such as a pacemaker or implantable cardioverter defibrillator (ICD), consult with your doctor.

Symptoms of electromagnetic interference (EMI)

If you become dizzy or feel rapid or irregular heartbeats while using an electrical item, release whatever you are touching or move away from the item. The pacemaker should immediately return to normal operation. If symptoms do not improve when you move away from the item, consult with your doctor.

Proper grounding of electrical items

To avoid interference from electrical current that may leak from improperly grounded electrical items and pass through the body, observe the following precautions:

- Make sure that all electrical items are properly wired and grounded.
- Make sure that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

Household and hobby items with motors and other items that cause electromagnetic interference (EMI)

Household and hobby items that have motors or magnets or that generate electromagnetic energy fields could interfere with your pacemaker. Keep your pacemaker at least 6 inches (15 centimeters) away from the following items:

- Handheld kitchen appliances, such as electric mixers
- Sewing machines and sergers
- Personal care items, such as corded handheld hair dryers, corded electric shavers, electric or ultrasonic toothbrushes (base charger), or electric massagers

The following household and hobby items require special precautions:

- **Boat motors –** Keep your pacemaker at least 12 inches (30 centimeters) away from electric trolling motors or gasoline-powered boat motors.
- **Electronic body fat scale –** Using this type of scale is not recommended for pacemaker patients because it passes electricity through the body and can interfere with the pacemaker.
- **Electronic pet fences or invisible fences –** Keep your pacemaker at least 12 inches (30 centimeters) away from the buried wire and the indoor antenna of electronic pet fences or invisible fences.
- **Home-use electric kilns –** Keep your pacemaker at least 24 inches (60 centimeters) away from home-use electric kilns.
- **Induction cook tops –** An induction cook top uses an alternating magnetic field to generate heat. Keep your pacemaker at least 24 inches (60 centimeters) away from the heating zone when the induction cook top is turned on.
- **Portable electric generators up to 20 kilowatts –** Keep your pacemaker at least 12 inches (30 centimeters) away from portable electric generators.

- **UPS (uninterruptable power source) up to 200 amperes –** Keep your pacemaker at least 12 inches (30 centimeters) away from a UPS. If the UPS is operating by battery source, keep your pacemaker at least 18 inches (45 centimeters) away.

Home power tools

Most home power tools should not affect pacemakers. Consider the following common-sense guidelines:

- Keep all equipment in good working order to avoid electrical shock.
- Be certain that plug-in tools are properly grounded or double insulated. Using a ground fault interrupter outlet is a good safety measure (this inexpensive device prevents a sustained electrical shock).

Some home power tools could affect pacemaker operation. Consider the following guidelines to reduce the possibility of interference:

- **Electric yard and handheld power tools (plug-in and cordless) –** Keep your pacemaker at least 6 inches (15 centimeters) away from such tools.

- **Soldering guns and demagnetizers –** Keep your pacemaker at least 12 inches (30 centimeters) away from these tools.
- **Gasoline-powered tools and gasoline-powered yard equipment –** Keep your pacemaker at least 12 inches (30 centimeters) away from components of the ignition system. Turn off the motor before making adjustments.
- **Car engine repair –** Turn off car engines before making any adjustments. When the engine is running, keep your pacemaker at least 12 inches (30 centimeters) away from components of the ignition system.

Industrial equipment

After recovering from implant surgery, you likely will be able to return to work, to school, or to your daily routine. However, if you will be using or working near high-voltage equipment, sources of high electric current, magnetic fields, or other EMI sources that may affect pacemaker operation, consult with your doctor. You may need to avoid using, or working near, the following types of industrial equipment:

- Electric furnaces used in the manufacturing of steel

- Induction heating equipment and induction furnaces, such as kilns
- Industrial magnets or large magnets, such as those used in surface grinding or electromagnetic cranes
- Dielectric heaters used in industry to heat plastic and dry glue in furniture manufacturing
- Electric arc and resistance welding equipment
- Broadcasting antennas of AM, FM, shortwave radio, and TV stations
- Microwave transmitters. Note that microwave ovens are unlikely to affect pacemakers.
- Power plants, large generators, and transmission lines. Note that lower voltage distribution lines for homes and businesses are unlikely to affect pacemakers.

Radio transmitters

Determining a safe distance between the antenna of a radio transmitter and a pacemaker depends on many factors such as transmitter power, frequency, and the antenna type. If the transmitter power is high or if the antenna cannot be directed away from your pacemaker, you may need

to stay farther away from the antenna. Refer to the following guidelines for different types of radio transmitters:

- **Two-way radio transmitter (less than 3 watts) –** These low-power devices present low risk to your pacemaker.
- **Portable transmitter (3 to 15 watts) –** Keep your pacemaker at least 12 inches (30 centimeters) away from the antenna.
- **Commercial and government vehicle-mounted radio transmitters (15 to 30 watts) –** Keep your pacemaker at least 24 inches (60 centimeters) away from the antenna.
- **Other transmitters (125 to 250 watts) –** Keep your pacemaker at least 9 feet (2.75 meters) away from the antenna.

For transmission power levels higher than 250 watts, contact a Medtronic representative for more information.

Security systems

When passing through security systems, follow these precautions:

- **Electronic antitheft systems, such as in a store or a library, and point-of-entry control systems, such as gates or readers that include radio frequency identification equipment –** These systems should

not affect your pacemaker, but as a precaution, do not linger near or lean against such systems. Simply walk through these systems at a normal pace. If you are near an electronic antitheft or entry control system and experience symptoms, promptly move away from the equipment. After you move away from the equipment, the pacemaker resumes its previous state of operation.

- **Airport, courthouse, and jail security systems –** Given the short duration of security screening, it is unlikely that metal detectors (walk-through archways and handheld wands) and full body imaging scanners (also called millimeter wave scanners and three-dimensional imaging scanners) in airports, courthouses, and jails will affect your pacemaker. When encountering these security systems, follow these guidelines:
  - Always carry your pacemaker ID card. If your pacemaker sets off a metal detector or security system, show your ID card to the security operator.
  - Minimize the risk of temporary interference with your pacemaker while going through the security screening process by not 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 or wave it back and forth over your pacemaker.
- If you have concerns about security screening methods, show your cardiac device ID card to the security operator, request alternative screening, and then follow the security operator's instructions.

Examples of items that have low or no risk of interfering with your pacemaker

Patients frequently have questions about the items in the following list. These items have low or no risk of temporarily interfering with your pacemaker. If you have questions about items not listed in this manual, contact your doctor or nurse.

Kitchen items – Microwave ovens; electric, gas, or convection ovens; toasters; blenders; electric can openers; food processors; or cordless electric knives

Personal care items – Salon hair dryers, cordless shavers, electric blankets; or heating pads

Communication devices – Handheld cellular, mobile, home or public telephones; two-way pagers, two-way walkie-talkies (less than 3 watts); personal digital assistants (PDAs); smartphones; and mobile email devices

Home office items – Desktop, laptop, notebook, or tablet computers; network routers; home-use copiers, printers, scanners, or fax machines

Home electronics items – AM and FM radios; cassette tape recorders; CD players; camcorders; video recorders (VCR); MP3 players; televisions; video game systems; stereos; DVD players; wireless headsets; remote controls for entertainment systems; or radio-controlled toys

Items that contain magnets – Magnetic mattress pads or pillows; bingo wands; mechanic's extractor wands; magnetic bracelets; magnetic clasps; magnetic chair pads; or stereo speakers

Miscellaneous items – Laundry and cleaning items, such as clothes irons, vacuum cleaners, or electric brooms; pagers that only receive messages; remote controls for garage doors; remote keyless entry or car starter devices; or portable space heaters

Precautions about medical procedures

Caution: Before you undergo any medical procedure, tell the health care professional, such as the doctor or nurse, that you have an implanted pacemaker.

- The health care professional may need to speak with your heart doctor before performing the procedure. Showing them your heart device ID card may be helpful.
- Some procedures may potentially affect the function of your pacemaker, and such procedures may require precautionary measures to prevent or minimize impact on your pacemaker.

Talk with your health care professional to weigh any potential risk against the benefits of the medical procedure. See the following pages for more information.

Medical procedures that are not recommended

Some medical procedures should not be performed on anyone with a heart device. Talk to your health care professionals about finding alternatives to these procedures. Your doctor may decide to contact your heart doctor or Medtronic Technical Services for more information.

Table 1 lists procedures that are not recommended for someone with your pacemaker.

Table 1. Medical procedures that are not recommended

Warning: People with metal implants such as an implanted heart device should not receive the following medical procedure:

Diathermy treatment (high frequency, short wave, or microwave) – Treatment that involves the therapeutic heating of body tissues. Diathermy treatments may result in serious injury or permanent damage to your pacemaker.

Medical procedures that require some precautions

If health care professionals take certain precautions to avoid serious injury, damage to your pacemaker, and device malfunction, the medical procedures listed in Table 2 can be safely performed.

If you or your doctor have any concerns about the precautions that should be taken, your doctor should contact a Medtronic representative or Medtronic Technical Services.

The doctor should make sure that your pacemaker is operating correctly after completing the procedure.

Table 2 lists procedures that require some precautions.

Table 2. Medical procedures that require some precautions

Ablation (specifically microwave ablation and radio frequency ablation) – Procedure in which radio frequency or microwave energy is used to destroy cells by creating heat. Ablation can result in serious injury, damage to your pacemaker, or device malfunction.
Computed axial tomography (CT or CAT) scan – Computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image. This procedure can affect the function of your pacemaker.
Electrolysis – Permanent removal of hair by using an electrified needle (AC or DC) that is inserted into the hair follicle. Electrolysis can affect the function of your pacemaker.
Electrosurgery – Process in which an electric probe is used to control bleeding, to cut tissue, or to remove unwanted tissue. Electrosurgery can result in serious injury, damage to your pacemaker, or device malfunction.

Table 2. Medical procedures that require some precautions (continued)

External defibrillation and **elective cardioversion –** Therapies that deliver an electrical shock to the heart to convert an abnormal heart rhythm to a normal rhythm. These therapies can affect the function of your pacemaker.

Hyperbaric Oxygen Therapy (HBOT) – The medical use of oxygen at a higher than atmospheric pressure. HBOT can damage your pacemaker.

Lithotripsy – Medical procedure that uses electrically produced shock waves to break up kidney or gallbladder stones. Lithotripsy can damage your pacemaker.

Magnetic resonance imaging (MRI) – For information on MRI scan precautions, see "Is it safe for me to have an MRI scan?" on page 15.

MR Conditional symbol – Your pacemaker has been shown to pose no known hazards in a specified MR environment with specified conditions of use. Your heart doctor will have information about the environment and conditions.

Radiotherapy (including high-energy radiation therapy) – Cancer treatment that uses radiation to control cell growth. Radiotherapy can damage your pacemaker or affect the function of your pacemaker.

Table 2. Medical procedures that require some precautions (continued)

Stereotaxis – Catheter navigation platform that allows clinicians to steer catheter-based diagnostic and therapeutic devices throughout the body by means of magnetic navigation. Stereotaxis can affect the function of your pacemaker.

Therapeutic ultrasound – The use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Therapeutic ultrasound can result in permanent damage to your pacemaker.

Transcutaneous electrical nerve stimulation (TENS), including neuromuscular electrical stimulation (NMES) – Pain control technique that uses electrical impulses passed through the skin to stimulate nerves.

A TENS device is not recommended for in-home use because it can affect the function of your pacemaker. If use of a TENS device is determined to be medically necessary, your doctor should contact a Medtronic representative for more information.

Transmitting loop for digital hearing aid – Using a transmitting loop can affect the function of your pacemaker.

Transurethral needle ablation – Surgical technique in which precisely focused radio frequency energy is used to destroy prostate tissue. This treatment can affect the function of your pacemaker.

Acceptable medical procedures

Many medical procedures will not affect your pacemaker. However, the equipment used for the procedure must be used correctly and must be properly maintained.

Tell your doctors and dentist that you have an implanted pacemaker before beginning any medical or dental procedure.

Table 3 lists some of the acceptable medical procedures.

Table 3. Examples of acceptable medical procedures

Capsule endoscopy and **pH capsule procedures –** Procedure in which a capsule containing a tiny camera is swallowed by the patient to take pictures of the patient's digestive tract. These procedures are acceptable.
Dental procedures that use dental drills or ultrasonic probes to clean teeth are acceptable. Dental x-rays are also acceptable.
Diagnostic radiology, such as x-rays and mammograms, are acceptable. For precautions on CT scans, see page 57.
Diagnostic ultrasound, such as an echocardiogram, is acceptable.

5 Registering your pacemaker

Registering your pacemaker is important. Registration ensures that medical information related to your pacemaker is on file and that Medtronic can notify your doctor with any relevant device information if necessary.

The Food and Drug Administration (FDA) requires that medical device companies keep track of their devices implanted in the United States. The registration information must be accurate and current. This information is always kept confidential.

This chapter has important information about the following topics:

- Pacemaker registration form
- Your pacemaker identification (ID) card
- Medtronic pacemaker travel card

Pacemaker registration form

In the United States and its territories, the pacemaker registration form is completed by your doctor, nurse, or Medtronic representative at the time of your implant. This form is then sent to Medtronic.

The form includes this information:

- your name and contact information
- pacemaker model and serial number
- date of implant
- your follow-up care doctor's name and phone number

This same information is included on your temporary and permanent pacemaker ID cards.

Your pacemaker ID card

While in the hospital, you will receive a temporary pacemaker ID card. Your permanent card will be mailed to you within 6 weeks of your implant. If you have not received your card within 6 weeks of your implant procedure, contact Medtronic Patient Registration Services at 1-800-551-5544.

Carry your pacemaker ID card with you at all times

Your pacemaker ID card is especially helpful during your follow-up appointments, when seeing other doctors or your dentist, and when traveling. It could be essential in case of a medical emergency.

If you do not have your pacemaker ID card with you during a medical situation, your doctor or nurse can call Medtronic or the medical records department of the hospital where your pacemaker was implanted to request information about your pacemaker.

To request a new ID card or update your personal information

If you lose your pacemaker ID card or need to update your personal information, such as your name or address, contact Medtronic Patient Registration Services at 1-800-551-5544 or update your information online at www.medtronic.com/idcard. Also, notify Medtronic if you no longer reside in the United States.

If you change your doctor

If you change your heart doctor or if the contact information for your doctor changes, notify Medtronic Patient Registration Services by calling

1-800-551-5544 or by updating your ID card information online at www.medtronic.com/idcard.

Medtronic pacemaker travel card

A special Medtronic pacemaker travel card is also available from Medtronic. This multilanguage card identifies you as having an implanted pacemaker and has instructions for security personnel on how to properly scan your pacemaker with a handheld scanner.

You can use this card, along with your pacemaker ID card, when you pass through security gates at airports and other secured buildings such as some libraries and government buildings. The card is especially useful when traveling internationally.

You can request the Medtronic pacemaker travel card by calling Medtronic Patient Registration Services at 1-800-551-5544 or at www.medtronic.com/rhythms.

6 Caring for yourself

Caring for yourself is one of the most important parts of your follow-up care. Talk with your family, caregivers, and friends about how you are feeling, and share the information in this manual with them so that they can help you return to your normal activities.

Give yourself a few months to adjust to living with your pacemaker. Most people report that they have a wide range of emotions after receiving a pacemaker. It is natural and normal to feel a little cautious and nervous about how your pacemaker will affect your life.

With time, your confidence will return as you get back to your normal activities. Addressing your concerns and having a positive attitude toward your pacemaker and the therapies it provides can enhance the quality of your life over the long term.

Shaping a positive attitude about life with your heart device

Remind yourself of the benefits – Remind yourself that your heart device protects you from the serious consequences of irregular heartbeats.

Block negative thinking – Catch yourself if you are imagining the worst-case scenarios. Remind yourself that most patients feel overwhelmingly positive about having their heart device.

Discuss concerns – Make a list and discuss any worries you might have about your condition or heart device with your doctor and with your loved ones. Develop a plan about how to cope with your concerns.

Explore the unknown – Learn about your medical condition and your heart device from your doctor, nurse, library, device manufacturer, and Internet websites. Often learning about your heart device helps reduce anxiety.

Plan your quality of life – The goal of your ongoing care is to achieve the best quality of life possible. Take an inventory of the activities that are most important to you and discuss plans to return to those activities with your doctor.

Provided by: Dr. Sam Sears of East Carolina University and Dr. Wayne Sotile of Wake Forest University. Both health psychologists are experts who work extensively with heart device patients and provide educational information on www.medtronic.com.

Dealing with anxiety and getting the support you need

After receiving a pacemaker, many people report a positive change with feelings of relief, comfort, and well-being. Yet, experiencing feelings of anger, fear, and guilt are also natural and expected. You may want to talk with your doctor or nurse about anything that is causing you to worry.

? What is one common source of stress for pacemaker patients and families?

A common worry pertains to the pacemaker performance. Medtronic medical pacemakers are extremely reliable, and most patients feel that their quality of life improves after the implant because the pacemaker can effectively relieve the troubling symptoms. Yet, at times, you may worry about whether the pacemaker will work when needed. Follow-up appointments help monitor the performance of your pacemaker and give you an opportunity to ask questions.

? What are some other ways to relieve stress and get answers to my questions?

It often helps to talk with other people who have pacemakers and ask them how they have adjusted to them. Ask your doctor or nurse if there is a support group for pacemaker patients at your clinic or a nearby hospital.

In addition, Medtronic websites provide information you may find helpful:

- For patient brochures, patient manuals, frequently asked questions, and other patient resources go to www.medtronic.com/rhythms.
- For in-depth information on heart conditions and various heart devices used to treat heart conditions, such as pacemakers and defibrillators, go to www.medtronic.com.

Medical care

- Follow your doctor's instructions about diet, medications, and physical activity.

- Attend all pacemaker follow-up appointments and other general health checkups.
- Before any medical or dental treatments, tell your doctors, dentists, and other health care professionals that you have an implanted pacemaker.

Planning for an emergency

Because you have a pacemaker, it is important to be prepared in case of any emergency. Talk to your doctor or nurse about planning for emergencies. They may suggest that you develop a plan with your family and friends that includes the following points:

- Carry your pacemaker ID card in an easy-to-find place, such as a wallet.
- Carry a list of medications and dosages.
- Keep emergency phone numbers in an easy-to-find place.
- Inform significant coworkers, traveling companions, and so on, that you have a pacemaker.
- When traveling by air, inform airline security personnel that you have a pacemaker.

You may also want to post information that you want to have readily available near your phone.

What your family and friends should know

Your family and friends can be a big support for you during your hospital stay and after you get home. Encourage them to learn about your pacemaker and about how they can continue to support you.

If your family or caregivers have any questions or concerns, have them call your doctor or nurse.

Some friends and family members may want to receive training in **cardiopulmonary resuscitation (CPR)**. They may also want to attend support group meetings with you.

7 Follow-up care

As you transition into life with your new pacemaker, questions and concerns will arise. This chapter contains information on follow-up care, including what to expect in follow-up appointments, how to schedule appointments, how your pacemaker will be monitored, and when to replace your pacemaker.

Follow-up appointments

Before you leave the hospital, your doctor will tell you when you need to schedule a follow-up appointment.

Follow-up appointments are important to make sure that your pacemaker settings are working well for you. No surgery is required, and the procedure is painless. The appointment usually takes the same amount of time as a regular doctor's appointment.

During follow-up appointments, your doctor or nurse will complete the following tasks:

- Assess your general medical condition.
- Check the operation of your pacemaker. This includes checking the battery power.
- Review the information saved by your pacemaker.
- Adjust your pacemaker settings, if necessary, to provide the best treatment for your heart condition.

Your doctor or nurse can also review your current medications with you and can answer any questions you may have.

Your doctor will tell you how often your heart device should be checked. Your first follow-up appointment is usually scheduled for 1 month after your pacemaker is implanted. Depending on your doctor's normal practice and your medical condition, additional follow-up appointments are scheduled every 3-6 months. More frequent appointments are usually scheduled as your heart device nears its expected replacement time. You may need additional visits. For more information, see "When to call your doctor or nurse" on page 37.

More frequent appointments are usually scheduled as your pacemaker nears its expected replacement time.

Medtronic programmer

A Medtronic programmer is a specialized computer designed to work specifically with your Medtronic pacemaker. Using radio waves to "read" your pacemaker, the programmer displays information that is collected and stored in your pacemaker.

Your doctor or nurse uses the programmer during the implant procedure to set up and change the pacemaker settings initially and during every follow-up appointment to make sure that your pacemaker is operating correctly.

Reviewing information saved by your pacemaker

During a follow-up appointment in the clinic or hospital, your doctor or nurse uses the programmer to read data collected by your pacemaker or to change the operating settings of your pacemaker.

Your pacemaker collects and saves the following information:

- the status of the pacemaker battery
- diagnostic information about how the pacemaker is performing

Based on this information and a review of your medications, your doctor may adjust the settings of your pacemaker to fit your individual needs.

Pacemaker replacement

Your pacemaker is powered by a lithium battery, which is sealed inside the titanium case of your pacemaker. Eventually, when the battery power is low, you will need a new pacemaker. How long your battery lasts depends on several factors, including the nature of your heart condition. Although battery life may vary, the estimated average longevity for this pacemaker is 12 years after it is implanted, based on device settings observed in the Micra clinical trial[1].

[1] Reynolds D, Duray GZ, Omar R, et al. A leadless intracardiac transcatheter pacing system. N Engl J Med. DOI: 10.1056/NEJMoa1511643

8 Your heart has a natural rhythm

To help you understand how your pacemaker works, it is helpful to understand how the heart functions and how abnormal heart rhythms can affect the heart. This chapter describes the anatomy of the heart and one common type of abnormal heart rhythm conditions.

For details about your health and individual heart condition, always talk to your doctor.

The anatomy of the heart

The heart is a fist-sized organ that acts as a pump to circulate blood through the body. Arteries are the blood vessels that carry blood with oxygen and nutrients to all parts of the body. Veins are the blood vessels that carry blood depleted of oxygen and nutrients back to the heart and lungs.

The heart is actually a large hollow muscle divided into four chambers. The two upper chambers are referred to as the right **atrium** and the left

atrium. The term **atria**, the plural of atrium, refers to both the right and the left atrium.

The lower chambers of the heart are called the **ventricles** and are referred to as the right ventricle and the left ventricle. The muscled wall dividing the right and left sides of your heart is called the septum.

The right atrium draws in blood from your body and pumps it into the right ventricle. The right ventricle then pumps the blood into the lungs to be **reoxygenated**. The left atrium draws in oxygen-rich blood from the lungs and pumps it into the left ventricle. The left ventricle then pumps the blood out to the rest of your body.

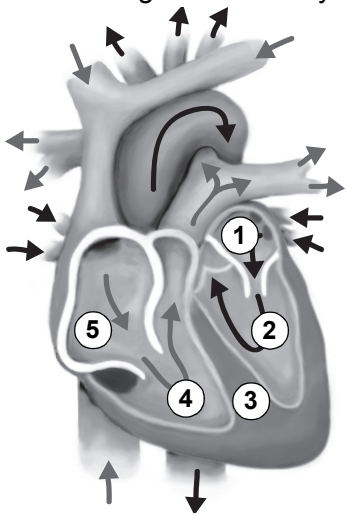
Each chamber of the heart contracts by squeezing its muscles together. Each contraction pushes blood from one chamber to the next chamber or out into the body. Heart valves regulate the flow of blood between each chamber and keep the blood flowing in only one direction. It is the actual opening and closing of the valves that creates what we hear as a heartbeat.

After each chamber contracts completely, pushing out most of the blood, it relaxes and fills with more blood again. In a healthy heart, each

chamber contracts in a coordinated effort with the other chambers of the heart.

The atria contract first, filling the ventricles with blood. When the ventricles are filled, they both contract at the same time, moving the blood into the lungs and the rest of the body, as illustrated in Figure 4 on page 80.

Figure 4. Four chambers of the heart contracting in a controlled sequence to circulate blood throughout the body



1. Left atrium
2. Left ventricle
3. Septum
4. Right ventricle
5. Right atrium

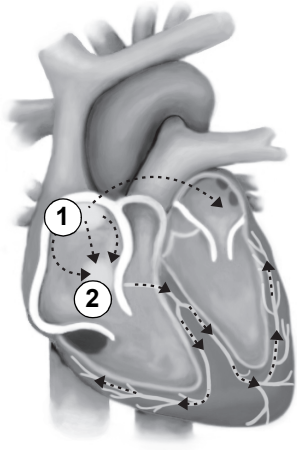
Electrical conduction in the heart

The muscle cells of the heart, just like all the muscle cells throughout your body, contract and relax in response to electrical impulses. The electrical impulses that cause your heart muscle to contract are generated by the heart's natural pacemaker, called the **sinoatrial node** (or **SA node**).

The SA node is located on the upper inside wall of the right atrium. These natural electrical impulses move through the muscle of your heart in tiny thread-like paths, from the top of the atria to the bottom of the ventricles, and then up the ventricles' outer walls.

After the SA node releases an electrical impulse, the impulse travels across the top of the right atrium and the left atrium. The impulse then travels down through both atria. As the atria are stimulated, they contract from the top down, pushing blood into the ventricles. When the electrical impulse reaches the lower wall of the atria, the **atrioventricular node** (or **AV node**) is stimulated. The AV node delays the impulses just long enough for the atria to finish pushing blood into the ventricles. Then it passes the impulse along organized pathways into the ventricles.

Figure 5. The electrical impulses that cause the heart to contract start at the SA node and move through the atria to the AV node. The AV node controls when the impulse is released to travel through the ventricles.



1. Sinoatrial (SA) node
2. Atrioventricular (AV) node

The AV node controls how quickly the impulse travels through the rest of the heart. This controlled impulse release helps coordinate when each chamber contracts. Without this control, the heart would not pump blood very productively. The coordination between the contracting chambers of the heart is very important for maintaining adequate blood flow between your heart and the rest of your body.

The electrical impulse passes down to the bottom of the ventricles. From here, the pulse sweeps across the surface of the right and left ventricles from the bottom up, causing the ventricles to contract in the same bottom-up direction. This action pushes the blood out of the valves at the top of the ventricles to the lungs (from the right ventricle) and to the rest of the body (from the left ventricle).

The heart is very sensitive to the body's needs

The rate at which the chambers of the heart contract is controlled by your brain and your **autonomic nervous system**.

If, for example, you start to jog instead of walk, your body's demand for blood increases. When you are active, your heart automatically contracts faster to increase the amount of blood supplied to your body.

How abnormal heart rhythms affect the heart

There are many reasons why a heart might not beat normally. Whether due to disease, defect, or injury, the heart's conduction system can become unreliable. The areas of the heart that control the heart rhythm can malfunction, causing slow, fast, erratic, or uncoordinated heart rhythms. Any of these abnormal heart rhythms can affect the amount of blood supplied to the body.

The effects of abnormal heart rhythms can range from severe fatigue to **sudden cardiac arrest (SCA)**.

If the heart is not beating normally because of a problem with its conduction system, then the problem may be bradycardia, a common abnormal heart rhythm condition.

This condition can be treated with medications or by implanting a pacemaker. Sometimes it is treated with both methods. The Micra pacemaker is capable of treating bradycardia. Consult your doctor to determine whether or not the Micra pacemaker is right for you.

Bradycardia

Bradycardia is a slow or irregular heart rhythm, usually less than 60 beats per minute. When the heart rate is this slow, not enough oxygen-rich blood is pumped to the body to support daily activities or mild exercise.

Bradycardia can be caused by the delayed release of electrical impulses from the SA node or when the normal pathway for electrical impulses in the heart is interrupted (heart block).

Symptoms of bradycardia include the following:

- dizziness
- shortness of breath
- extreme fatigue
- fainting spells

Some causes of bradycardia include the following:

- hereditary defects
- certain illnesses
- some cardiac drugs
- the aging process
- a heart attack
- an unknown cause

Figure 6. A normal heart rate compared to a bradycardia rate

1. Normal heart rate – 72 beats per minute (bpm)
2. Brady heart rate – 45 beats per minute (bpm)

Sinoatrial (SA) node disease

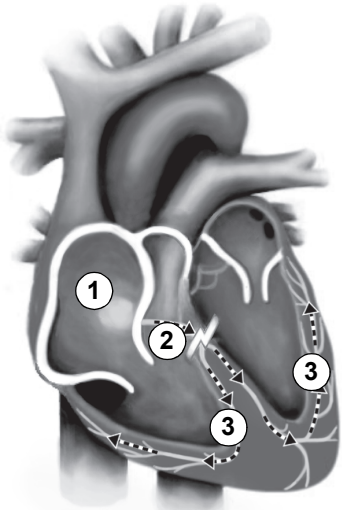
Rhythm disorders of the SA node are described as "sick sinus syndrome". Sometimes the SA node, your heart's natural pacemaker, cannot begin a heartbeat or cannot increase the heart rate. When this happens, other tissues in the heart often take over the job of the SA node.

However, the other tissue often cannot maintain a consistent heart rate. Or the other tissue may create a rate that is too slow or too fast for normal activities. A pacemaker can solve this problem by taking over the job of the SA node.

Heart block

The electrical signal from the SA node must pass through the AV node. The signal then continues through the conduction pathways of the ventricles. At or below the AV node, the electrical signal may become slow or irregular. The signal may even stop. This is called heart block because the electrical impulse is blocked from moving from the atria to the ventricles. Heart block is described as first, second, or third degree. How slow the heart rate becomes depends on the degree of heart block. A pacemaker can take over for an impaired AV node and restore normal heart functioning. For an illustration of how heart block interrupts the electrical signals to the ventricles, see Figure 7.

Figure 7. Electrical signal to the ventricles is blocked or interrupted



1. AV node
2. Blocked or interrupted signal
3. Conduction pathways

Glossary

The words that appear in this section are found in **bold** throughout this manual.

atrium (plural = atria) – The two upper chambers of the heart are referred to as the right atrium and the left atrium. The term "atria" is the plural of "atrium," and refers to both the right and the left atrium.

autonomic nervous system – The autonomic nervous system regulates internal body processes that require no conscious effort, such as heart rate and blood pressure. This system is made up of the sympathetic and parasympathetic systems. These systems work together; for example, the sympathetic division increases pulse, blood pressure, and breathing rates, and the parasympathetic system decreases each of them.

bradycardia – Heart condition in which the heart beats less than 60 beats a minute (the heart beats too slowly).

cardiopulmonary resuscitation (CPR) – Life-saving procedure that includes the timed external compression of the chest wall to stimulate blood flow, alternating with mouth-to-mouth breathing to provide oxygen.

ECG or EKG – ECG (EKG) is an abbreviation for "electrocardiogram." An electrocardiogram is a test that measures the electrical activity of a person's heart.

electrocardiogram – See **ECG.**

electromagnetic compatibility (EMC) – Fields of energy around certain types of equipment that use electricity and magnets may interfere with the normal operation of other electronic devices, such as an implanted pacemaker. These energy fields created around electrical items can be strong or weak. The closer to the item you are, the stronger the energy field. Electromagnetic compatibility means that the electrical energy field generated by an electrical item is compatible with other electrically sensitive items, such as an implanted pacemaker.

electromagnetic energy field – Force that certain types of equipment that use electricity and magnets exert on objects in their vicinity.

EMC – See **electromagnetic compatibility.**

external defibrillator – Emergency personnel use either manual external defibrillator equipment or a handheld automated external defibrillator (AED) to deliver defibrillation therapy shocks to treat.

external defibrillation – Use of an **external defibrillator.**

heart attack (myocardial infarction) – When some of the heart's blood supply is reduced or cut off, causing the heart muscle (myocardium) to die because it is deprived of its oxygen supply.

heart block – Type of heart problem where the electrical impulses traveling from the upper chambers to the lower chambers of the heart are slowed (first degree heart block), irregular (second degree heart block), or blocked (third degree heart block).

heart device – An active, implantable medical device, such as a pacemaker, that treats abnormal heart rhythms (arrhythmias). Types of arrhythmias that can be treated include bradycardia, when the heart beats too slowly, or tachycardia, when the heart beats too fast. See also **pacemaker.**

heart rate – The number of contractions of the cardiac ventricles per unit of time (such as beats per minute).

magnetic resonance imaging (MRI) – See **MRI.**

MRI – Type of medical imaging that uses magnetic fields to create an internal view of the body.

pacemaker – An implanted medical device that restores your heart rate to a more normal rhythm by stimulating the heart with precisely timed pulses of electricity. These very small amounts of electricity cause the heart to contract (push blood out), mimicking a naturally occurring heart rate.

pacing, pacing therapy – Type of therapy provided by an implanted pacemaker or defibrillator to treat a slow heart rate. Pacing consists of small electrical pulses delivered to the heart to speed up a person's heart rate.

rate-responsive pacemaker – Type of pacemaker with one or more special sensors. These sensors recognize changes in the body, such as movement of the body or respiration rate (breathing), and change the rate of electrical pulses generated by the pacemaker to achieve a faster heart rhythm for that period of time.

rate-responsive therapy – Type of pacing in which the pacing rate varies to meet the body's changing needs.

reoxygenated – To add oxygen back into the blood cells.

sensing – The ability of a pacemaker to detect an electrically conducted signal produced by the heart. The pacemaker determines (or senses) whether the heart is beating normally; if it is not, the pacemaker can deliver the required pacing therapy.

sinoatrial node (SA node) – The heart's natural pacemaker located in the right atrium. Electrical impulses originate here and travel through the heart, causing it to beat. Also called the sinus node. See also **atrium.**

sudden cardiac arrest (SCA) – Also called "cardiac arrest." Failure of the heart to pump blood through the body. If left untreated, it will lead to death within minutes.

ultrasound – Medical imaging technique that uses sound waves to create an internal image of the body.

ventricles – The two lower chambers of the heart. These are called the left and the right ventricles.

Index

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Our mission is to help improve your life.

At Medtronic, we're proud of our reputation as the worldwide leader in medical technology. In fact, we've been collaborating with physicians around the world to develop devices to treat heart disease for over 50 years.

Every 3 seconds, somewhere in the world, a person's life is saved or improved by a Medtronic product or therapy. Physicians have prescribed Medtronic pacemakers to thousands of patients worldwide.

Remember, too, that we never stop working on ways to help people lead fuller, longer, healthier lives. We hope we can improve yours.

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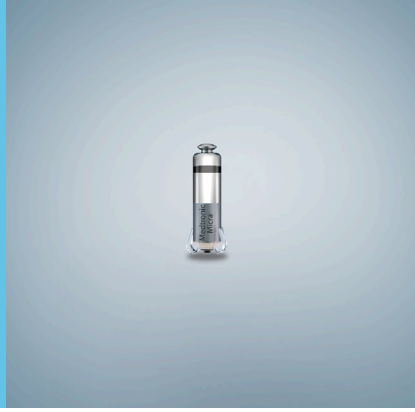
2016-03-11

Medtronic

M951401A001

PATIENT
CLINICAL SUMMARY

Micra™
Transcatheter Pacing System



This is a brief overview of information related to your pacemaker, which is further discussed in the patient manual at manuals.medtronic.com.

WHEN IS IT USED?

(Indications for Use)
Pacemakers are used to treat bradycardia (slow or irregular heart rhythms). The Micra pacemaker can send electrical pulses when the heart is beating too slowly and can adjust your heart rate based on your physical activity level. The Micra is implanted inside the heart and does not require any pacing leads. A traditional pacemaker would require a lead to be inserted into your heart from the pacemaker in your chest (see picture below).

WHAT WILL IT ACCOMPLISH?

A clinical study of patients needing this device was performed in 719 implanted patients with average follow-up of each patient of 4.4 months (ranging from 0-14 months) to learn about the basic benefits and risks.

Benefits:
Micra provides the same benefits as a traditional pacemaker to increase the heart rate and help relieve the symptoms of bradycardia. The Micra clinical study showed additional benefits include:

- Eliminates scar on the chest
- Eliminates bulge on the chest
- Able to resume regular activities after implant (no activity restrictions to prevent dislodging of traditional pacemaker leads)
- No upper chest implant complications (a punctured lung which may require a tube to be inserted into the chest to re-inflate the lung, a blood clot in the subclavian vein)
- No pacing lead complications (lead moving from original place in the heart, lead breaking, lead infections, lead not being connected to the device the right way)

Risks:
The Micra clinical study showed risks of the Micra pacemaker were unncommon. Risks with Micra include some of the same risks as traditional pacemakers, such as:

- Puncture of your heart muscle, which can lead to bleeding into the lining of your heart and may require emergency medical care (16/1,000 patients may experience a major type of this risk based on what is currently known from the Micra clinical study). Traditional systems typically see 11/1,000 patients for these types of events.
- An abnormal blood clot which can float in the bloodstream and cause complications by going to the lungs, the leg, or the brain

New risks of Micra can include:

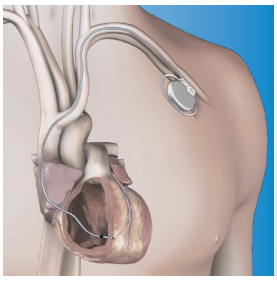
- Groin complications where the catheter is inserted, such as bleeding or collecting blood on the outside of a vessel wall
- Currently, Medtronic suggests Micra be turned off when the battery ends. It is not yet known if Micra can or should be removed as scar tissue forms around the device over time.
- If more than one Micra is placed in the heart, there could be new risks that are currently not known

WHEN SHOULD IT NOT BE USED?

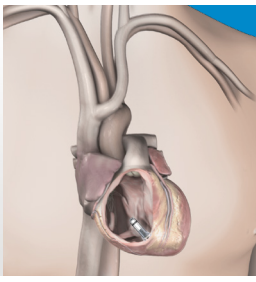
Your doctor will determine if the Micra should not be used for your condition. Micra should not be used if you already have a pacemaker providing active therapy, or if your body size cannot support implant requirements, or if you are allergic to the pacemaker's materials or medications for the implant.

ADDITIONAL INFORMATION

Refer to Medtronic.com for complete details on the Micra and the patient brochure.



Traditional Pacemaker



Micra

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