

Aurora EV-ICD™ MRI SureScan™

Extravascular Implantable Cardioverter
Defibrillator

Patient Manual



Medtronic

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Aurora EV-ICD, CareLink, Medtronic, Medtronic CareAlert, Medtronic CareLink, SureScan

Information about you and your device

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 _____
Name/address/phone _____

Your heart device information

Type or model of heart device _____

Serial # _____

Lead 1 model _____

Serial # _____

Date of implant _____

Hospital where implanted _____

How to contact Medtronic

If you are experiencing health concerns or symptoms, contact your physician or health care professional.

Contact us by phone

Our Patient Services group can answer any questions or concerns about your heart device. To speak with a Patient Services Specialist, call 1-800-551-5544. Our staff is available Monday through Friday from 7:00 AM to 6:00 PM (Central Time).

Contact us online

For up-to-date information about your heart device, visit www.medtronic.com.

To submit questions, suggestions, or requests, use the online form at <http://www.medtronic.com/us-en/about/contact-us.html>.

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 heart device ID card” on page 86.

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1

Introduction

This manual is for people who are about to have or already have a type of **heart device** called an **implantable cardioverter defibrillator (ICD)**. This manual describes your heart device and its therapies. It also explains the implant procedure and what you can expect afterward. Encourage your family and caregivers to review this manual.

If you have questions about your heart device that are not covered in this manual, or you want more information about your heart device, contact Medtronic Patient Services (see page 5). You can also visit www.AsktheICD.com for general questions.

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

For Spanish translations of the patient manual, contact Medtronic Patient Services (see page 5). Or go to www.medtronic.com to view or download English and Spanish patient manuals.

Words in **bold** are defined in the glossary starting on page 105.



2

Frequently asked questions

New patients often have the same concerns about their heart devices. Here are some of the questions new patients often ask.

Why do I need this heart device?

An implantable cardioverter defibrillator (ICD) is designed to relieve heart disease symptoms for most patients. This heart device does not prevent or cure your heart condition.

Heart medications and surgical procedures may be prescribed instead of, or in addition to, an ICD. Based on your health condition, your doctor has determined that a heart device may help to improve your symptoms.

Although your heart device is not a cure, it does help to protect you from heart rhythms that can weaken or even endanger your health. Many patients say that this heart device gives them and their families a sense of security. See “Caring for yourself” on page 97 for guidance on dealing with anxiety and other concerns.

Is it safe for me to have an MRI scan?

A **magnetic resonance imaging (MRI)** scan is a type of diagnostic that creates an internal view of the body.

The energy fields present during an MRI scan may harm a traditional heart device, which could endanger a patient's health. However, your SureScan heart device was designed to reduce these risks to a very low level so that you can safely undergo MRI scans under specified conditions.

You can have an MRI scan if you meet the eligibility requirements that Medtronic provides to your heart doctor. For example, your heart device system must consist only of a Medtronic SureScan heart device and SureScan **lead**. Your heart device ID card lists your heart device and lead models.

Before you receive an MRI scan, your doctor will verify that you are eligible and that your heart device system is functioning properly. Your doctor will then turn on the SureScan feature. This feature disables the ability of your heart device to deliver a **therapy shock** so that you may safely have an MRI scan.

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

After the MRI scan, your doctor will turn off the SureScan feature. Your heart device is again able to deliver a therapy shock, if needed.

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. A concern about driving is that you might faint if your heart starts to beat dangerously fast. Many people with a heart device can resume driving if their doctor approves and if allowed by the laws and insurance regulations in their state. For more information, see “Driving a car” on page 59. If you have concerns, talk with your doctor.

Will I be able to travel?

Most people who have a heart device can travel without taking special precautions if they follow their doctor’s instructions.

Wherever you travel, your heart device monitors your heart and provides therapy whenever it is needed. You can travel knowing that support for your heart device is available around the world. Your doctor may also be able to check your heart device remotely.

It is unlikely that your heart device will trigger the security gates at airports or other secure buildings. If it does, present your heart device ID card. If

a handheld screening wand is used, ask the security operator not to hold it over your heart device or wave the wand back and forth over your heart device. See “Security systems” on page 78 for more information.

A heart device travel card is available with instructions in several languages for safe security scanning. The card is especially useful for international travel. See page 88 for more information about the heart device travel card and how to request one.

Can I walk through antitheft systems found in public places?

Yes, simply walk through the antitheft system at a normal pace. In some cases, the systems located in stores, libraries, and other places may temporarily interfere with your heart device if you stop 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). However, mobile phones may cause electrical interference with your heart device when the phone is turned on and held too close to your heart device. Also, some accessories for mobile phones contain magnets, such as cases with magnetic clasps.

To avoid interference between mobile phones or accessories and your heart device, keep them at least 6 inches (15 centimeters) away from your heart device. When using a mobile phone, hold it to the ear that is farthest away from your heart device. Also, do not carry a mobile phone close to your heart device, such as in a shirt pocket.

For more information about using mobile phones and other wireless communication devices, see “Avoiding interference from electrical items or magnets” on page 62.

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 heart device” on page 57 for information about electrical items and any restrictions or cautions you should know about.

Will my heart device need to be replaced?

Yes. Because your heart device operates using a battery sealed inside the device, the entire heart device will need to be replaced when battery power falls to a low level. The heart device battery typically lasts about 9-12 years. How long your battery lasts depends on several factors. Some of these factors include the type of heart device you have, the nature of your heart condition, and how often your heart device provides therapy to your heart.

The battery power is checked at each follow-up appointment. Your doctor or nurse will let you know when you need to have your heart device replaced.

How often will my doctor need to check my heart device?

When you go home after your implant procedure, your doctor will periodically check your heart device. These follow-up appointments can be performed at your clinic. Or, if your doctor prescribes **remote monitoring**, you can send your heart device information directly to your doctor or clinic. For more information about follow-up services, see “Follow-up care” on page 89.

How do I know if my heart device battery is still working?

The strength of your heart device battery is checked during your follow-up appointments, either in the clinic or through built-in device monitoring. **Medtronic CareAlert monitoring** is a safety feature built into your heart device that can be set up by your doctor. It alerts you with a beeping tone when the battery power for your heart device is getting low. Because the battery is sealed inside your heart device and cannot be recharged, your heart device will need to be replaced when the battery power is low. For more information, see “Replacement of your heart device” on page 94.

What if my heart device is making a beeping tone?

Your heart device may make a beeping tone if your doctor has enabled Medtronic CareAlert monitoring. The beeping tone lets you know that something needs attention from your doctor. For example, the device can make a beeping tone when the number of therapies you have received has increased or when the battery power of your heart device is low.

If your heart device detects one of these conditions, it makes a beeping tone for up to 30 seconds, at least once a day. The alert continues until your doctor or nurse checks your heart device. The beeping tone is designed to get your attention, not to alarm you. If you hear beeping tones from your heart device, call your doctor for instructions.

What if my heart device is making a steady tone?

Your heart device may make a steady tone if you are close to a strong magnetic field, such as the field in a store's anti-theft system. This tone warns you to move away from the magnetic field. For more information, see "What you need to know about electromagnetic compatibility (EMC)" on page 59.

Will my device deliver a therapy shock during normal activity?

A therapy shock during normal activity is unlikely. Your heart device is designed to respond to abnormal **heart rates** and rhythm patterns. Normal exercise or physical activity should not trigger your heart device to deliver a therapy shock. If a therapy shock happens, stop the activity and notify your doctor. Your doctor may change the settings of your heart device to prevent therapy shocks during your normal activities.

What is sudden cardiac arrest?

Sudden cardiac arrest occurs when the heart's electrical system malfunctions and the heart beats dangerously fast and irregularly. The ventricles may flutter or quiver, causing the heart to stop beating. The symptoms of sudden cardiac arrest are immediate and dramatic and can include a loss of consciousness, sudden collapse, and the lack of a pulse.

Sudden cardiac arrest is not the same as a **heart attack**. A heart attack happens when a blood vessel in the heart suddenly becomes blocked. The most common symptoms are chest pain or discomfort and shortness of breath.

Can others feel a therapy shock if they are touching me?

If you receive a therapy shock, anyone touching you may feel the shock as a muscle spasm or a tingle, although it is unlikely. A therapy shock can be startling, but it will not hurt a person touching you.

What if I receive a therapy shock?

Ask your doctor or nurse what you should do if your heart device delivers a therapy shock. Your doctor or nurse should give you specific instructions about when to contact your doctor if you have received a therapy shock.

In general, follow these steps if you feel the symptoms of a rapid heart rhythm or if you receive a therapy shock:

1. Stay calm and move to where you can lie down or sit comfortably.
2. Have someone stay with you until you feel better.
3. If you receive more than one therapy shock or if you remain unconscious for more than 1 minute, have a companion call 911 for an ambulance.

If you remain unconscious and you have no pulse, a companion trained in **cardiopulmonary resuscitation (CPR)** should begin CPR immediately. When your heart starts beating again, your companion should stop CPR.

Note: Anyone touching you during a therapy shock might feel your muscles contract slightly. They also might see you jump with a sudden start. A therapy shock will not harm a person touching you.

4. If you do not feel well after the shock, have someone call your doctor and take you to the hospital emergency room.
5. Follow your doctor's or nurse's directions after receiving a shock. The doctor or nurse may ask the following questions:
 - What were you doing right before the shock?
 - What symptoms did you notice before the shock?
 - How did you feel right after the shock?
 - How are you feeling right now?

Can I have sexual relations?

Most people resume sexual activity, based on their doctor's instructions. Physical activity is not likely to cause your heart device to deliver a shock. But if a shock does happen during intercourse, stop and notify your doctor just as you would if it happened during exercise. The shock will not hurt your partner. Your partner may feel a tingle or a slight muscle spasm, but nothing more.

How are my heart device and data secured?

Your heart device has built-in safeguards that protect your heart device and your device data. In addition, the therapies provided by your heart device can only be programmed by your doctor or nurse during an office visit.



3

Your heart has a natural rhythm

This chapter describes the anatomy of the heart and some common types of abnormal heart rhythm conditions. To understand how your heart device works, you need to know how the heart functions and how abnormal heart rhythms can affect the heart.

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

This chapter includes the following topics:

- The anatomy of the heart (see page 27)
- Electrical conduction in the heart (see page 30)
- How abnormal heart rhythms affect the heart (see page 32)

The anatomy of the heart

The heart is a fist-sized pump that circulates blood throughout the body. Arteries carry blood with oxygen and nutrients to all parts of the body. Veins carry blood depleted of oxygen and nutrients back to the heart and the lungs.

The heart is a large, hollow muscle divided into four chambers. The two upper chambers are the right **atrium** and the left atrium. Atria, the plural of atrium, refers to both the right atrium and the left atrium.

The lower chambers of the heart are the right **ventricle** and the left ventricle. The **septum** is the muscled wall dividing the right and left sides of the heart.

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

Each chamber 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 one direction. What we hear as a heartbeat is actually the opening and closing of the valves.

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. See Figure 1.

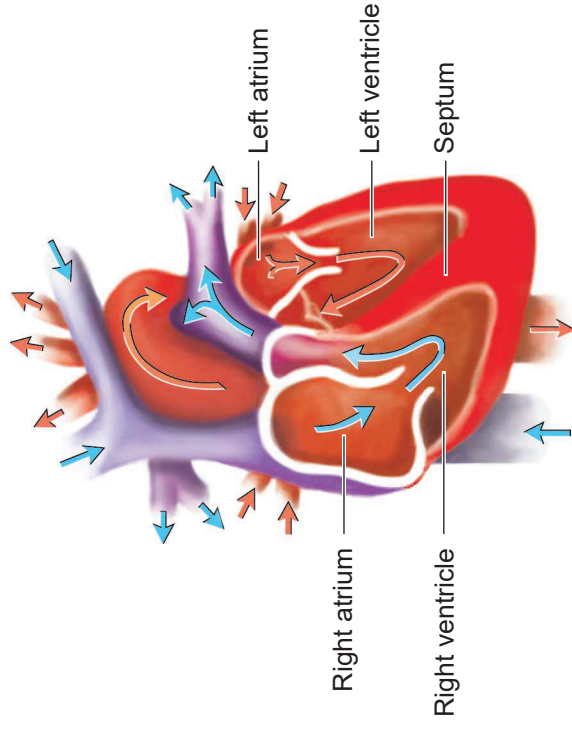


Figure 1. Four chambers of the heart contract in a controlled sequence to circulate blood throughout the body.

Electrical conduction in the heart

Electrical impulses cause the cells of the heart to contract and relax. The **sinoatrial node** (or SA node) generates these impulses. The SA node is found on the upper inside wall of the right atrium.

When the SA node releases an electrical impulse, the impulse travels across the top of the atria and down through the atria. The atria contract from the top down, pushing blood into the ventricles. When the electrical impulse reaches the lower wall of the atria, it stimulates the **atrioventricular node** (or AV node). 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 thread-like paths into the ventricles.

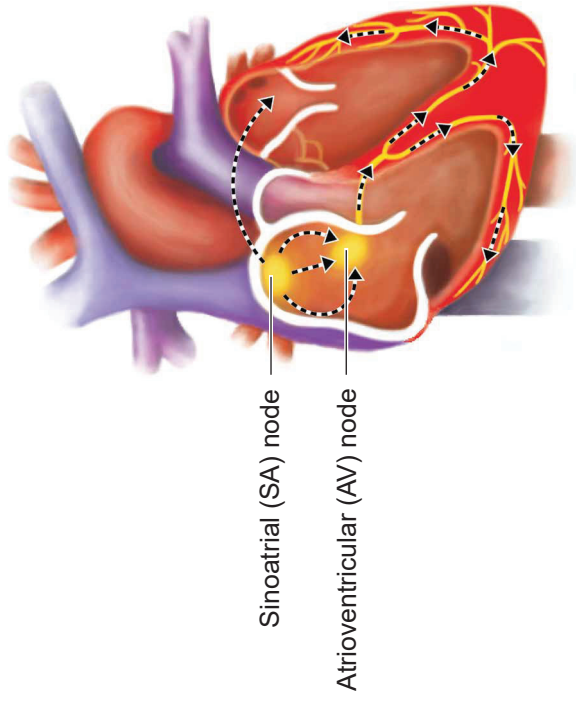


Figure 2. The electrical impulses that cause the heart to contract start at the SA node and move through the atria to the AV node. The AV node controls when the impulse is released to travel through the ventricles.

The AV node controls how quickly the impulse travels through the rest of the heart. The proper coordination between the contracting chambers of the heart maintains adequate blood flow between the heart and the rest of the body.

The electrical impulse then travels to the bottom of the ventricles. The impulse sweeps across the surface of the ventricles from the bottom up, causing the ventricles to contract from the bottom up. This action pushes the blood out of the valves into 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 brain and the **autonomic nervous system** control how fast the chambers of the heart contract. For example, if you start to jog instead of walk, your body's demand for blood increases. Your heart automatically contracts faster when you are active to supply more blood to your body.

How abnormal heart rhythms affect the heart

Disease, defect, or injury can cause the heart's conduction system to become unreliable. The areas that control heart rhythm can malfunction, causing slow, fast, erratic, or uncoordinated heart rhythms. These abnormal heart rhythms affect the amount of blood supplied to the body. The effects

of abnormal heart rhythms can range from severe fatigue to sudden cardiac arrest.

When the heart is not beating normally, the problem may be one of these common heart rhythm conditions:

- **Tachyarrhythmia** – when the heart beats too fast
- **Bradycardia** – when the heart beats too slowly

These conditions can be treated with medications or by implanting a heart device. Sometimes they are treated with both.

Your heart device can treat the following heart conditions:

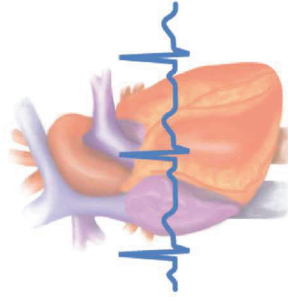
- Tachyarrhythmia
- Bradycardia

Tachyarrhythmia – When the heart beats too fast

Tachyarrhythmia is a heart rate that is faster than the rate needed to supply the body with oxygen. It is caused by a problem in the heart's electrical system. Overly sensitive cells in the heart release electrical impulses faster than the normal heart rate. Sometimes just a few cells are responsible for starting an abnormally fast heart rhythm.

A normal heart at rest beats between 60 and 100 beats per minute. Exercise or stress can cause the heart to beat faster, but this increase is a normal response to the body's need for more blood. During a tachyarrhythmia, the heart beats at more than 100 beats per minute. It can beat as fast as 400 beats per minute.

Normal heart rate
72 beats per minute (bpm)



Tachyarrhythmia heart rate
144 beats per minute (bpm)

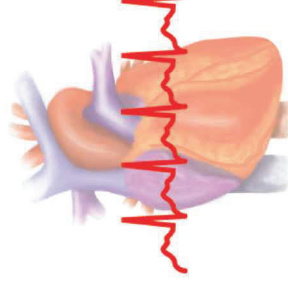


Figure 3. A normal heart rate compared to a tachyarrhythmia rate

Causes of tachyarrhythmias

Tachyarrhythmias can start in the atria or the ventricles. Causes of tachyarrhythmias include the following:

- High blood pressure (hypertension)
- Coronary artery disease
- Heart valve disease
- Heart failure
- Tumors
- Infections
- Thyroid disease
- Certain lung diseases
- **Electrolyte imbalance**
- Alcohol or drug abuse

Types of tachyarrhythmias

Atrial flutter and **atrial fibrillation (AF)** are tachyarrhythmias that start in the atria. Ask your doctor if your heart device treats **atrial tachyarrhythmias**.

Ventricular tachyarrhythmias start in the ventricles. They are called **ventricular tachycardia (VT)** and **ventricular fibrillation (VF)**. Because the ventricles pump blood to the body, both conditions can lead to a quick depletion of oxygen-rich blood to the body, a life-threatening condition.

Ventricular tachycardia is a heart rhythm that is regular but very fast. This condition causes the heart to beat too fast to pump blood effectively.

Ventricular fibrillation is a tachyarrhythmia that has become unstable and irregular. Ventricular fibrillation causes the heart muscles to quiver uselessly, instead of pumping blood.

During ventricular fibrillation the body is quickly starved of oxygen. The person usually passes out within a few seconds. Ventricular fibrillation is always life-threatening.

Symptoms of tachyarrhythmia include the following:

- Shortness of breath
- Dizziness
- Sudden weakness
- Fluttering or pounding in the chest
- Light-headedness

- Fainting

Bradycardia – When the heart beats too slowly

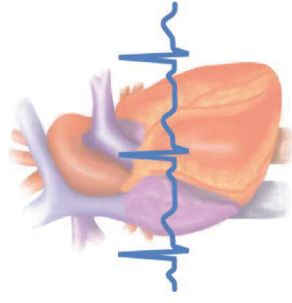
Bradycardia is a slower than normal heart rate, usually less than 60 beats per minute. The heart cannot pump enough blood to the body to support daily activities or mild exercise.

Bradycardia can be caused by the delayed release of electrical impulses from the SA node. It can also appear when the normal pathway for electrical impulses is interrupted (**heart block**). Hereditary defects, certain illnesses, some cardiac drugs, or a heart attack can cause bradycardia. It can also appear as part of the aging process.

Symptoms of bradycardia include the following:

- Dizziness
- Shortness of breath
- Extreme fatigue
- Fainting spells

Normal heart rate
72 beats per minute (bpm)



Bradycardia heart rate
45 beats per minute (bpm)

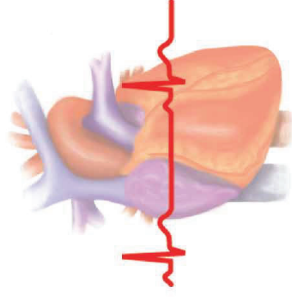


Figure 4. A normal heart rate compared to a bradycardia rate

4

About your heart device

Your doctor has prescribed an implantable cardioverter defibrillator (ICD) to treat your heart disease symptoms. This heart device does not prevent or cure your heart rhythm condition, but it can improve the quality of your life.

This chapter includes these topics:

- What is an ICD? (see page 40)
- What does my heart device do? (see page 43)
- What types of therapies does my heart device provide? (see page 43)
- What do the therapies feel like? (see page 46)
- What is Medtronic CareAlert monitoring? (see page 47)
- How does my heart device communicate wirelessly? (see page 50)

If you have questions that are not answered in this manual, ask your doctor or nurse to contact Medtronic Patient Services (see page 5).

What is an ICD?

Your heart device is designed to monitor your heart rate and deliver immediate treatment when necessary for any irregular heart rhythms, including sudden cardiac arrest.

The ICD provides these therapies: post-shock **pacing**, temporary pacing for slow heart rhythm, anti-tachycardia pacing, pause prevention pacing therapy, and **defibrillation**. For details about these therapies, see “What types of therapies does my heart device provide?” on page 43.

Your heart device

Your heart device has an outer case, a battery, a small computer, and a connector block. All electronic parts are sealed inside a metal case, sometimes called a “can,” made of titanium.

Inside your heart device is a miniature computer that is powered by a lithium battery. The energy from the battery is transformed into tiny electrical pulses. These tiny pulses stimulate the heart. The computer controls the timing and the intensity of the electrical pulses delivered to the heart. The plastic connector block, placed on top of the metal case, connects the heart device to the lead.

Implanted lead

A lead is an insulated wire that relays electrical signals from your heart to your device to monitor your heart. A lead also delivers therapies from the device to your heart. When your heart device is implanted, your doctor places one end of your lead under your sternum. Your doctor then connects the other end of the lead to your heart device.

Leads are extremely flexible and strong. They can withstand the body's twisting and bending.

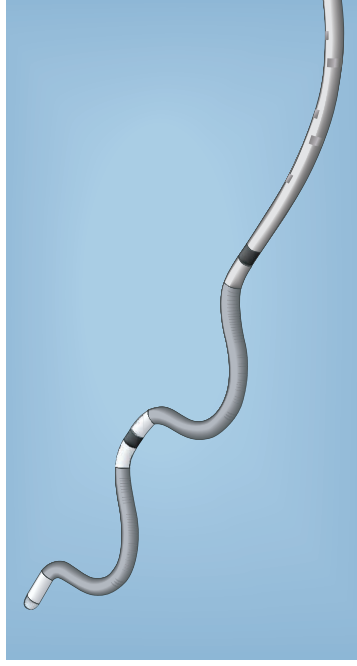


Figure 5. Example of a lead

With Aurora EV-ICD, a lead is placed under the sternum outside the heart (see Figure 6). Your doctor will determine the best way to deliver the type of therapy needed to help relieve your heart disease symptoms.

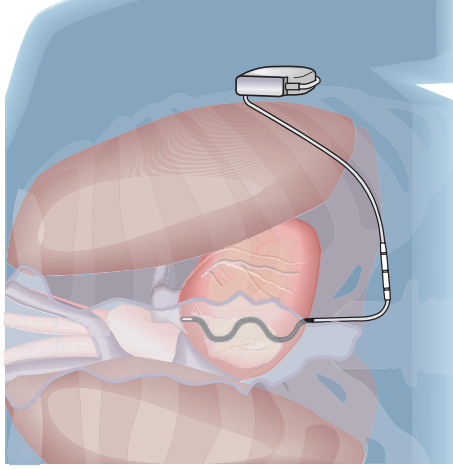


Figure 6. The lead is attached to your heart device.

What does my heart device do?

Your heart device has two main functions. It continuously monitors your heart rhythm and it delivers therapies. If your heartbeat is too fast or irregular, your heart device delivers pulses of electricity directly to your heart through the implanted lead. This therapy helps your heart to beat in a regular rhythm. Your heart device can deliver different therapies, depending on the type of abnormal heart rhythm it detects.

What types of therapies does my heart device provide?

Your heart device can detect irregular rhythms and automatically deliver the most appropriate therapy when it is needed. Your heart device provides the following therapies:

- **Antitachycardia pacing (ATP)** therapy for a fast or irregular heart rhythm
- **Defibrillation therapy** for a fast or irregular heart rhythm
- **Post-shock pacing therapy** to help the heart resume a normal rhythm
- **Pause prevention pacing therapy** when your heart device detects a slow heart rhythm, the device will provide a short series of electrical pulses that will return your heart to a regular rhythm.

Therapies for an irregular heart rhythm

Antitachycardia pacing (ATP) therapy

During antitachycardia pacing therapy, the heart device releases several short bursts of pacing pulses. Then it pauses to check for a normal heartbeat. If the heart rhythm is still irregular, the device can repeat therapy.

If the therapy restores a normal rhythm, the heart device does not deliver more treatment. If the heart rate is still too fast or irregular, the heart device delivers defibrillation therapy.

Defibrillation therapy

If your heart device detects a fast and unstable heart rhythm, it delivers a therapy shock to your heart. This therapy is called defibrillation. It is like the treatment provided by an **external defibrillator**, which uses paddles on the outside of the body to shock the heart. However, your heart device delivers much less electricity because the therapy is applied directly to the heart through the lead.

Your heart device responds automatically with life-saving defibrillation during the first crucial seconds of a fast heart rhythm. This response is important because an emergency team may be minutes away or unavailable.

The therapy shock usually stops the abnormal electrical impulses that are causing your heart to beat too fast. After each therapy shock, your heart device monitors your heart for a normal rhythm. If the rhythm is still too fast, it delivers another therapy shock.

When a normal heart rhythm is restored, the device delivers no more therapy.

For more information, see “What if I receive a therapy shock?” on page 23.

Post-shock pacing therapy

After your heart device delivers a therapy shock, if needed it can then deliver a steady pattern of small electrical pulses to your heart to encourage a regular heartbeat. The delivery of these pulses is called pacing your heart. Pacing therapy ensures that your heart resumes a heart rhythm that supports your body’s needs.

Pause prevention pacing therapy

When your heart device detects a slow heart rhythm, the device will provide a short series of electrical pulses that will return your heart to a regular rhythm.

What do the therapies feel like?

Although experiences vary from person to person, people have reported the following sensations during therapy:

Antitachycardia pacing (ATP) – This therapy does not last long. People may feel the extravascular pacing therapy and have described it as feeling like a “tapping sensation under their sternum” or very brief electrical stimulation pulses. When you feel this sensation, it is an indication that your heart is beating at a rapid rate and your device is attempting to end the arrhythmia.

Defibrillation – Some people lose consciousness because of a rapid heartbeat, and they are not aware they received a therapy shock. Others who are awake during a therapy shock describe it as a “kick in the chest.” The shock startles them, but the feeling passes quickly. Some find it fleeting but still distressing. Others find the therapy shock a reassuring reminder that their heart device is protecting them from sudden cardiac arrest.

Pause prevention pacing therapy – People may feel the extravascular pacing therapy and have described it as feeling like a “tapping sensation under their sternum” or a slowly repeating series of electrical stimulation pulses. When you feel this sensation, it is an indication that your heart is

beating too slowly and your device is attempting to restore normal heart rhythm.

Post-shock pacing therapy – People may feel the extravascular pacing therapy and have stated it feels like a “tapping sensation under their sternum.” The feeling is an indication the device is delivering pacing therapy.

What is Medtronic CareAlert monitoring?

Using the Medtronic CareAlert monitoring feature, your doctor can program your heart device to monitor itself, your lead, and your heart for changes that require attention.

Your heart device can be programmed to make a beeping tone when something has happened that your doctor needs to be aware of. If you hear a beeping tone, contact your doctor. Your doctor can discuss with you what has happened.

Where available, your doctor can also program your heart device to send heart information automatically through a wireless device to your clinic without having your heart device beep. Your doctor will explain the type of wireless device that will be used to send your heart information.

Ask your doctor if the Medtronic CareAlert monitoring feature is turned on and which conditions are being monitored. Ask whether there is likely to be a beeping tone. Answers to these questions will help you understand the purpose of Medtronic CareAlert monitoring and how your doctor has programmed the device to meet your needs.

Conditions that Medtronic CareAlert monitoring can detect

When your heart device is implanted or during a routine follow-up appointment, your doctor can set Medtronic CareAlert monitoring to alert you about the following situations:

- The status of your heart device battery
- The status of your lead
- The number of therapies detected

Your heart device can also monitor changes in your heart rhythm that your doctor wants to be aware of. If your heart device detects one of these conditions, it will make a beeping tone for up to 30 seconds, at least once a day. Call your doctor if your heart device starts to make a beeping tone.

Checking your Medtronic CareAlert status

Your doctor may give you a **patient magnet** to check your Medtronic CareAlert status. To check if the Medtronic CareAlert monitoring feature has triggered an alert, place your patient magnet over your heart device.

- If an alert has occurred, your heart device makes a beeping tone.
- If no alert has occurred, your heart device makes a steady tone.

Cautions:

- **Never carry, store, or leave the patient magnet over your heart device. Your heart device cannot treat a tachyarrhythmia (fast heart rhythm) while the magnet is placed over it.**
- **The patient magnet is a special magnet and should be used only as directed by your doctor. Other magnets should never be placed over or held close to your heart device. For more information, see “Avoiding interference from electrical or magnetic items” on page 62.**

Your nurse or doctor can explain how to use the patient magnet and what to do if an alert occurs.

How does my heart device communicate wirelessly?

Your heart device uses wireless technology to connect and communicate with other Medtronic equipment. Medtronic designs and manufactures its products to be as safe and secure as possible, yet accessible for the patients and doctors who depend on these products. For more information about Medtronic's security efforts, go to www.medtronic.com/security.

5

Your implant procedure and recovery

Being told you need a heart device can be upsetting, but knowing what to expect 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, but the surgery is typically performed using general anesthesia.

You usually will stay in the hospital overnight and go home the next day with instructions on caring for your incision. For a short time after surgery, your doctor may want you to limit how much you move the arm that is closest to your implant site.

This chapter includes these topics:

- The implant procedure (see page 52)
- Potential risks after the implant procedure (see page 53)
- Recovering after your implant procedure (see page 54)
- Follow-up appointments (see page 56)

The implant procedure

The implant procedure includes these steps:

1. Making the incision and inserting the lead
2. Testing the lead
3. Implanting the heart device and closing the incision

Making the incision and inserting the lead

Your doctor makes a small incision just below the tip of your sternum. The doctor uses a tool to make space for the lead under your sternum and inserts the lead into that space. The lead is shaped like the letter “E” in cursive and the curves help keep it in place next to your heart. The part of the lead under the sternum delivers therapies to the right ventricle.

Testing the lead

After placing the lead next to your heart, your doctor tests the lead to make sure it can accurately monitor your heart rate and deliver therapies.

Implanting the heart device and closing the incision

After testing the lead, your doctor attaches the lead to your heart device. The doctor makes an incision under your left armpit for the device. Your doctor uses a tool to place the end of your lead under your skin and pull

it to the incision under your armpit where the lead is attached to the heart device. Your doctor then implants the heart device under your skin and closes the incision.

Before you leave the operating room, your doctor may check the heart device by starting a rapid heart rhythm and allowing the heart device to correct it. Your doctor will give you medication to let you sleep while this check is performed.

Potential risks after the implant procedure

Your doctor and Medtronic have tried to reduce the risks associated with implanting a heart device. However, as with any kind of surgery, there are potential risks.

The following risks are associated with implanting a heart device:

- Pain, swelling, or bruising around the implant site
- Bleeding
- Infection
- Blood clots
- Punctures of the heart muscle, vein, or lung space
- Heart attack

- Stroke

Talk with your doctor about these risks and other possible risks of this surgical procedure.

After surgery there are also possible risks. You might need to go back to the hospital for another surgery to adjust your lead or your heart device. These situations could require further surgery:

- The heart device moves from its original location.
- The skin over the heart device wears away.
- Changes in your heart rhythm require changes to the **lead system**.
- Changes to the lead system prevent the heart device from detecting your heart rhythm or delivering therapies.

Recovering after your implant procedure

After your implant procedure, your doctor may order tests such as an **electrocardiogram (ECG)**, blood tests, or x-rays. Your doctor may also recheck your device settings to make sure your heart device is providing the best treatment for your heart condition.

As you recover, follow your doctor's suggestions about resuming normal activities. Expect your recovery to be gradual. It is normal to see a slight bulge under your skin where the heart device is implanted.

Here are general recommendations for the first few weeks after your surgery:

- Call your doctor immediately if any swelling, warmth, or drainage appears around your 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.
- Limit arm movements as directed by your doctor.
- Avoid lifting more than 10 to 15 pounds (5 to 7 kilograms).
- Avoid excessive twisting of your torso.
- Avoid pushing or pulling heavy objects.

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

Follow-up appointments

Your doctor or nurse will work with you to schedule follow-up appointments. For more information about these appointments, read Chapter 8, “Follow-up care” on page 89.

6

Living life with your heart device

Many people go back to their normal activities after they recover from implant procedure. Your doctor is the best source of information about how to manage your life with your heart device.

This chapter includes these topics:

- Food and medications (see page 57)
- Your physical activity (see page 58)
- What you need to know about electromagnetic compatibility (see page 59)
- Precautions about medical procedures (see page 80)

Food and medications

Your doctor may instruct you to eat or avoid eating certain foods. For information about food, talk with your doctor.

Your doctor may prescribe medications that will treat your heart condition. Please talk with your doctor about medications.

Your physical activity

Depending on your doctor's recommendations, you can gradually return to your normal activities such as these:

- Hobbies and recreational activities
- Your job
- Strenuous physical activities
- Sexual activity
- Travel

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

Recreation and activities

Avoid rough physical contact that could cause you to fall or to hit your implant site. You could damage your heart device, or your lead could detach from your heart device during rough contact.

If you plan to scuba dive, discuss your heart condition with your doctor. Recommendations about scuba diving vary, depending on many factors. If you have other questions about recreational activities, talk to your doctor or nurse.

Driving a car

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

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 heart device is called **electromagnetic compatibility (EMC)**. Most energy fields are weak and do not affect your heart device. Electrical items that generate strong energy fields may not be compatible with your heart device.

Because your heart device is designed to sense the electrical activity of your heart, it may also sense a strong energy field outside your body. If that happens, it might not detect an abnormal heart rhythm, or it may deliver a therapy shock when your heart does not need it.

Several safeguards are built into your heart device to shield it from strong energy fields. For example, the metal case of your heart device acts as a shield against these energy fields. Also, your heart device has electronic filters that distinguish between external energy fields and the internal electrical pulses of your own heartbeat.

Any effects of energy fields on your heart device are temporary. These effects will stop when you move away from the source of the energy field. Your heart device can emit a steady tone if you are getting close to a magnetic field. This tone is warning you to move away from the magnet or to move the magnet away from your heart device.

You can avoid interference by keeping your heart device a minimum distance away from the electrical item. See page 62 to page 79 for recommended safe distances.

What do I do if I think that an electrical item is affecting my heart device?

If you feel dizzy, feel rapid or irregular heartbeats, or receive a shock while using an electrical item, release whatever you are touching and move away from the item. Your heart device should immediately return to its normal operation. If your symptoms do not improve when you move away from the item, talk to your doctor.

What about static electricity or shocks from household outlets?

Static electricity shocks will not damage your heart device. A “momentary” shock from an electrical outlet (110/220 volts) is unlikely to damage your heart device.

What items are safe and what kind of precautions should I take?

Most electrical items are safe for you to use. However, you should keep some items away from your heart device. See page 62 to page 79 for recommended safe distances. If you have questions, contact Medtronic Patient Services (see page 5). Also, before entering an area where signs are posted prohibiting persons with an implanted heart device such as a **pacemaker** or a **defibrillator**, talk to your doctor.

Proper grounding of electrical items

To avoid interference from improperly grounded electrical items, take these 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.

Avoiding interference from electrical or magnetic items

Caution: Items that have motors or magnets or that generate electromagnetic energy fields could interfere with your heart device. Move away from the interference source or turn off the source if you feel any dizziness or heart palpitations.

Household and recreational items

Table 1. Household and recreational items

Item	Keep this far from your heart device
Battery charger for household batteries	No restriction

Table 1. Household and recreational items

Item	Keep this far from your heart device
Beach comb / metal detector, from detector head	24 inches (60 centimeters)
Bed, adjustable	No restriction
Bingo wand	6 inches (15 centimeters)
Casino slot machine	No restriction
Clothes iron	No restriction
Curling iron / hair straightener	No restriction
Digital weight scale	No restriction
Disney MagicBand reader	6 inches (15 centimeters)
Disney MagicBand wristband	No restriction
Electrical transformer box, residential	12 inches (30 centimeters)
Exercise bike, wheel magnet	6 inches (15 centimeters)
Garage door opener, remote control	No restriction
Guitar, electric	No restriction
Guitar speakers, electric	6 inches (15 centimeters)
Hair dryer, handheld	6 inches (15 centimeters)
Hair dryer, hooded salon	No restriction

Table 1. Household and recreational items

Item	Keep this far from your heart device
Hair shaver / trimmer, battery powered	No restriction
Hair shaver / trimmer, corded	6 inches (15 centimeters)
Heart rate monitor, chest band	No restriction
Heating blanket or heated mattress pad	No restriction
Heating pad	No restriction
Home security system, from transmitter	6 inches (15 centimeters)
Hot tub (must be properly grounded)	No restriction
House arrest anklet	No restriction
House arrest bracelet	6 inches (15 centimeters)
Induction cooktop	24 inches (60 centimeters)
Jewelry clasp, magnetic	6 inches (15 centimeters)
Kiln, 115 to 120 volts alternating current	No restriction
Kitchen appliances (electric handheld)	6 inches (15 centimeters)

Table 1. Household and recreational items

Item	Keep this far from your heart device
Kitchen appliances (large): dishwasher, microwave oven, refrigerator, stove	No restriction Notes: <ul style="list-style-type: none"> • Keep your heart device at least 6 inches (15 centimeters) away from the magnetic closure strip of a refrigerator. • Keep your heart device at least 24 inches (60 centimeters) away from a stove with an induction cooktop.
Kitchen appliances (small): blender, food processor, can opener, toaster	No restriction
Laser tag, from magnet or transmitter in some vests	6 inches (15 centimeters)
Magnets	6 inches (15 centimeters)

Table 1. Household and recreational items

Item	Keep this far from your heart device
Massager, handheld	6 inches (15 centimeters)
Medical alert necklace or pendant	No restriction
Model cars, airplanes, video drones (remote controlled), from controller antenna	6 inches (15 centimeters)
Pet shock collar for electric pet fence, including remote control and base with antenna	6 inches (15 centimeters)
Residential power line	No restriction
Sauna, electric	No restriction
Sewing machine or serger, from motor	6 inches (15 centimeters)
Smart meter (used by utility companies)	6 inches (15 centimeters)
Smart scale that measures body mass index (BMI)	Not recommended
Swimming pool (must be properly grounded)	No restriction
Tanning bed	No restriction

Table 1. Household and recreational items

Item	Keep this far from your heart device
Tattoo machine	6 inches (15 centimeters)
Toothbrush, electric, from charging base	6 inches (15 centimeters)
Toy trains, electric, from transformer and rails	6 inches (15 centimeters)
Treadmill, from electric motor	6 inches (15 centimeters)
Ultrasonic pest control device	6 inches (15 centimeters)
Vacuum cleaner, from motor	6 inches (15 centimeters)

Communications and electronics

Caution: Do not carry a wireless device in a pocket over your heart device or in a shoulder bag near your heart device.

Table 2. Communications and electronics

Item	Keep this far from your heart device
Activity band or wearable fitness monitor (if it contains a magnet)	6 inches (15 centimeters)
Amateur radio, ham radio, marine radio, or 2-way portable radio (walkie-talkie), less than 3 watts, from antenna	6 inches (15 centimeters)
Amateur radio, ham radio, or 2-way portable radio, 3 to 15 watts, from antenna and base station	12 inches (30 centimeters)
Amateur radio, ham radio, or 2-way portable radio, 15 to 30 watts, from antenna and base station	24 inches (60 centimeters)
2-way portable radio, 30 to 50 watts, from antenna	3 feet (1 meter)
2-way portable radio, 50 to 125 watts, from antenna	6 feet (2 meters)

Table 2. Communications and electronics

Item	Keep this far from your heart device
Amateur radio, ham radio, marine radio, or 2-way portable radio, 125 to 250 watts, from antenna	9 feet (3 meters) Note: For transmitters with power levels higher than 250 watts, avoid restricted areas that contain the antenna.
Amateur or ham radio, 250 to 500 watts	12 feet (4 meters)
Amateur or ham radio, 500 to 1,000 watts	20 feet (6 meters)
Amateur or ham radio, 1,000 to 2,000 watts	30 feet (9 meters)
Badge (name tag) with magnetic clasp	6 inches (15 centimeters)
Badge (security) with externally activated electronic circuit	6 inches (15 centimeters)
Barcode scanner	No restriction
Bluetooth technology	No restriction
CB (citizens band) radio, greater than or equal to 3 watts, from antenna	6 inches (15 centimeters)
CD / DVD / DVR player, without speakers	No restriction

Table 2. Communications and electronics

Item	Keep this far from your heart device
CD / DVD / DVR player, with speakers	6 inches (15 centimeters)
Cellular adaptor for laptop computer	6 inches (15 centimeters)
Cellular tower	9 feet (3 meters)
Commercial broadcast tower, 125 to 250 watts	9 feet (3 meters)
Computer keyboard, wireless	6 inches (15 centimeters)
Computer (personal, laptop, or tablet)	6 inches (15 centimeters)
Copy machine	No restriction
Cordless microphone, from transmitter	6 inches (15 centimeters)
Cordless telephone, from antenna and base station	6 inches (15 centimeters)
Digital music player (for example, iPod)	No restriction
eReader	6 inches (15 centimeters)
Fax machine	No restriction
Gaming console and controllers	6 inches (15 centimeters)
GPS (global positioning system)	No restriction
Headphones / earbuds, from magnets	6 inches (15 centimeters)

Table 2. Communications and electronics

Item	Keep this far from your heart device
Magnetic cover for phones or tablets	6 inches (15 centimeters)
Marine radio, less than 3 watts, from antenna	6 inches (15 centimeters)
Marine radio, 3 to 15 watts, from antenna	12 inches (30 centimeters)
Marine radio, 20 to 25 watts, from antenna	24 inches (60 centimeters)
Mobile phones (including cell phones and smartphones)	6 inches (15 centimeters) Note: Keep mobile phone accessories containing magnets (such as cases with magnetic clasps) at least 6 inches (15 centimeters) away from your heart device.
Network router	6 inches (15 centimeters)
Pager, receiver only	No restriction
Pager, 2-way, less than or equal to 3 watts, from antenna	6 inches (15 centimeters)

Table 2. Communications and electronics

Item	Keep this far from your heart device
Pager, 2-way, 3 to 15 watts, from antenna	12 inches (30 centimeters)
Printer, office	No restriction
Radio, AM/FM	No restriction
Radio transmitters, vehicle-mounted, 15 to 30 watts, from antenna	24 inches (60 centimeters)
Radiofrequency (RF) wireless charger	6 inches (15 centimeters)
Remote control for CD or DVD player, television, etc.	No restriction
Remote keyless entry and remote car starter key fob	6 inches (15 centimeters)
Satellite dish, receiving	6 inches (15 centimeters)
Satellite dish, 2-way receiving	24 inches (60 centimeters)
Security badge wall scanner	6 inches (15 centimeters)
Smart watch	6 inches (15 centimeters)
Stereo speakers, from magnet	6 inches (15 centimeters)
Television	No restriction

Table 2. Communications and electronics

Item	Keep this far from your heart device
Television audio headset, from transmitter near television	6 inches (15 centimeters)
Transmitter, portable, 3 to 15 watts, from antenna	12 inches (30 centimeters)
Walkie-talkie, less than 3 watts, from antenna	6 inches (15 centimeters)
Wi-Fi modem or transmitter / receiver	6 inches (15 centimeters)

Tools and industrial equipment

Table 3. Tools and industrial equipment

Item	Keep this far from your heart device
Bench-mounted or free-standing tools with motors less than or equal to 400 horsepower	24 inches (60 centimeters)
Cattle prod / stock prod, from electrodes	12 inches (30 centimeters)

Table 3. Tools and industrial equipment

Item	Keep this far from your heart device
Degausser / demagnetizer	12 inches (30 centimeters)
Generator, electric portable, up to 20 kilowatts	12 inches (30 centimeters)
GPS (global positioning system) survey equipment	24 inches (60 centimeters)
Laser level, battery operated	No restriction
Lawn and garden implements and gas-powered engines, from spark plugs (for example, backpack leaf blower)	12 inches (30 centimeters)
Soldering gun	12 inches (30 centimeters)
Soldering iron	No restriction
Stud finder	No restriction
Tools, battery-powered	6 inches (15 centimeters)
Tools, handheld electric, from motor	6 inches (15 centimeters)
Tools, small electric, from motor	6 inches (15 centimeters)

Table 3. Tools and industrial equipment

Item	Keep this far from your heart device
UPS (uninterruptible power source) – commercial power failure back-up system, up to 200 amperes	12 inches (30 centimeters)

Industrial equipment that may require special precautions

After you recover from implant procedure, you will likely return to your daily routine. However, if you use or work near energy sources that could affect the operation of your heart device, talk to your doctor or contact Medtronic Patient Services (see page 5). You may need to avoid 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, such as those used in surface grinding and electromagnetic cranes
- Dielectric heaters used 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 heart devices.
- Power plants, large generators, and transmission lines. Note that lower voltage distribution lines for homes and businesses are unlikely to affect heart devices.

Vehicles and related items

Keep your heart device at least 12 inches (30 centimeters) away from an engine that is running or that has its ignition switch turned on. Before repairing an engine, turn it off.

Table 4. Vehicles and related items

Item	Keep this far from your heart device
Boat motor	12 inches (30 centimeters)
Car battery charger for gas engines	12 inches (30 centimeters)
Car battery charger (or charging station) for electric cars	12 inches (30 centimeters)
Car, electric / hybrid	No restriction

Table 4. Vehicles and related items

Item	Keep this far from your heart device
Car, truck, motorcycle, or other vehicle powered by gasoline	12 inches (30 centimeters)
Diesel engine	No restriction
Extractor wand, for car mechanics	6 inches (15 centimeters)
Forklift, battery powered, from battery	24 inches (60 centimeters)
Forklift fueled by gas, propane, or natural gas	12 inches (30 centimeters)
Golf cart, electric	No restriction Note: Keep your heart device at least 6 inches (15 centimeters) away from the battery.
Jet ski	12 inches (30 centimeters)
Jumper cables, during use	24 inches (60 centimeters)
Motorcycle vest, heated	No restriction
OnStar Technology, from antenna	6 inches (15 centimeters)

Table 4. Vehicles and related items

Item	Keep this far from your heart device
Personal scooter or electric grocery cart, from battery	6 inches (15 centimeters)

Security systems

Home security systems – It is unlikely that your device will be affected by home security systems. However, if the home security system uses wireless transmitters, keep the transmitters at least 6 inches (15 centimeters) away from your heart device.

Electronic antitheft systems, such as in a store or a library, and point-of-entry control systems, such as gates or readers that include radiofrequency identification equipment – These systems should not affect your heart device. However, 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 such a system and experience symptoms, promptly move away from the system. After you move away, the heart device resumes its previous state of operation.

Airport, courthouse, and jail security systems – It is unlikely that security systems will affect your heart device. These systems include metal detectors (walk-through archways and handheld wands) and full-body imaging scanners in airports, courthouses, and jails. When encountering these security systems, follow these guidelines:

- Always carry your heart device ID card. This card is helpful if your heart device sets off a metal detector or a security system.
- Minimize the risk of interference by not touching metal surfaces around screening equipment.
- Do not stop 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 heart device.
- If you have concerns about security screening methods, show your heart device ID card to the security operator. Then request alternative screening and follow the security operator's instructions.

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 heart device.

- The health care professional may need to speak with your heart doctor before performing the procedure. Showing the health care professional your heart device ID card may be helpful.
- Some procedures might affect the function of your heart device. Such procedures require precautions to prevent or minimize their impact on your heart device.

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. Refer to the glossary for definitions of medical procedures and other terms that appear in **bold**.

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 5 lists the procedure that is not recommended for someone with your heart device.

Table 5. Medical procedure that is not recommended

<p>Warning: People with an implanted heart device and accompanying lead should not receive the following medical procedure. This procedure can result in serious injury and damage to your heart device or lead:</p> <p>Diathermy, microwave or shortwave</p>

Medical procedures that require some precautions

If health care professionals take certain precautions to avoid serious injury, damage to your heart device, and device malfunction, the medical procedures listed in Table 6 can be safely performed.

If your health care professionals have any concerns about the precautions that should be taken, they should contact a Medtronic representative or Medtronic Technical Services.

Your heart doctor should make sure that your heart device is operating correctly after the procedure is completed.

Table 6 lists procedures that require some precautions.

Table 6. Medical procedures that require some precautions

<p>Warning: People with an implanted heart device and accompanying lead can safely receive the following medical procedures if their health care professionals take certain precautions when performing them. If the precautions are not taken, the following procedures can result in serious injury, damage to your heart device or lead, device malfunction, or a temporary change to the way your heart device functions. If you have questions about these procedures, talk to your heart doctor.</p> <p>Ablation (specifically, microwave ablation and radiofrequency ablation)</p> <p>Computerized axial tomography (CT or CAT) scan</p> <p>Diathermy, ultrasonic</p> <p>Electrolysis</p> <p>Electrosurgery and other procedures that use an electric probe to control bleeding, cut tissue, or remove tissue</p> <p>External defibrillation and elective cardioversion</p> <p>Hyperbaric Oxygen Therapy (HBOT)</p> <p>Lithotripsy</p>
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Table 6. Medical procedures that require some precautions

MRI (magnetic resonance imaging) scans For information on MRI scan precautions, see “Is it safe for me to have an MRI scan?” on page 16. Caution: If your doctor provided you with a patient magnet, patient assistant (handheld recorder), or home communicator, do not take them into a room where an MRI scan is performed. They are unsafe for an MRI environment.
Therapeutic ultrasound
Transcutaneous Electrical Nerve Stimulation (TENS), including neuromuscular electrical stimulation (NMES) Note: A TENS device is not recommended for in-home use because it can affect the function of your heart device. If your doctor decides that you need a TENS device, your doctor should contact a Medtronic representative for more information.
Transurethral needle ablation and transurethral microwave therapy

Acceptable medical procedures

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

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

Table 7 lists some of the acceptable medical procedures.

Table 7. Examples of acceptable medical procedures

Colonoscopy
Continuous positive airway pressure (CPAP) machine
Dental procedures that use dental drills or ultrasonic probes to clean teeth, and dental x-rays
Note: Keep your heart device at least 6 inches (15 centimeters) away from magnets, such as magnets found in the pillow headrests in a dental office.
Diagnostic radiology , such as x-rays and mammograms
Note: For precautions on CT scans, see Table 6 on page 82.
Diagnostic ultrasound , such as an echocardiogram
Laser surgery

7 Registering your heart device

Registering your heart device makes sure that your medical information is on file. Medtronic uses this information to notify your doctor of any changes affecting your heart device.

The Food and Drug Administration (FDA) requires medical device companies to register their devices implanted in the United States. The information must be accurate and current. It is always kept confidential.

This chapter includes the following topics:

- Heart device registration (see page 85)
- Your heart device ID card (see page 86)
- Medtronic heart device travel card (see page 88)

Heart device registration

In the United States and its territories, your doctor, nurse, or Medtronic representative completes the registration for your heart device when the device is implanted. The data is then sent to Medtronic.

The registration includes this information:

- Your name and contact information
- Your heart device model and serial number
- Date of implant
- The name and phone number of the doctor providing your follow-up care

Your temporary and permanent heart device ID cards also include this information.

Your heart device ID card

While you are in the hospital, you will receive a temporary heart device ID card. Your permanent card will be mailed to you in the next six weeks. If you have not received your card within six weeks of your implant procedure, contact Medtronic Patient Services (see page 5).

Keep your heart device ID card with you all the time

Your ID card could be useful during your follow-up appointments, when you see other doctors or your dentist, and when you travel. The information on the card could be essential in a medical emergency.

If you have a medical emergency and you do not have your ID card with you, your doctor or nurse can call Medtronic for information about your heart device. Or they can call the medical records department of the hospital where your heart device was implanted.

The card states that your heart device is “**MR Conditional**.” This label means you can have an MRI scan if certain conditions are met and your doctor follows the guidelines from Medtronic. (For more information, see “Is it safe for me to have an MRI scan?” on page 16). If any of your doctors want you to have an MRI scan, show your ID card to that doctor. The card advises the doctor to contact your attending heart doctor.

Requesting a new ID card or updating personal information

If you lose your heart device ID card or you need to update your personal information, such as your name or your address, contact Medtronic Patient Services (see page 5). Or update your information online at www.medtronic.com/iccard. Also, notify Medtronic if you no longer live in the United States.

If you change your doctor

If you change your heart doctor or if your doctor's contact information changes, notify Medtronic Patient Services. Or update your ID card online at www.medtronic.com/idcard.

Medtronic heart device travel card

A Medtronic heart device travel card is also available. This card states that you have an implanted heart device. The card tells security personnel how to properly scan your device with a handheld scanner.

You can use this card, along with your heart device ID card, when you pass through security gates at airports and other secured buildings. The travel card is especially useful when traveling internationally.

To request a Medtronic heart device travel card, contact Medtronic Patient Services (see page 5).

8

Follow-up care

Before you leave the hospital, your doctor will tell you when to schedule a follow-up appointment. At this appointment, the doctor ensures that your heart device settings are working well for you. Checking your heart device is painless. No surgery is involved. The appointment takes about as much time as a regular doctor's visit.

Your doctor may also use remote monitoring to keep track of how your heart device is working if it is available in your region. For more information, see "Remote monitoring" on page 91.

This chapter includes these topics:

- Follow-up appointments (see page 90)
- When to call your doctor or nurse (see page 93)
- Replacement of your heart device (see page 94)

Follow-up appointments

During a follow-up appointment, the doctor or nurse completes the following tasks:

- Assesses your general medical condition
- Checks how well your heart device is working, including battery power and your implanted lead
- Reviews the information saved by your heart device
- Adjusts your heart device settings, if needed
- Reviews your current medications and answers your questions

Your doctor will tell you how often your heart device should be checked. Your first follow-up appointment is usually within the first 3 months after your heart device is implanted.

Depending on your doctor's advice and your medical condition, additional follow-up appointments may be scheduled every 3 to 6 months.

As your heart device gets close to its replacement time, you usually have more appointments.

Remote monitoring

Where available, your doctor can also monitor your heart device using the **Medtronic CareLink Network**. The network supports most Medtronic heart devices and can be prescribed by your doctor. With remote monitoring, your heart device information is sent automatically through a wireless device to your clinic. You can send follow-up information about your heart device to your doctor from your home, from your work, or while you are traveling. The information you send is available for your clinic's review within minutes.

If the information sent to your doctor indicates that you need to be seen in person, your doctor or your clinic will contact you to set up an appointment. The doctor may need to adjust your heart device settings or your medications.

Will remote monitoring replace all clinic visits?

Remote monitoring is not meant to replace all clinic visits. If you feel that you need to see your doctor, do not hesitate to contact your clinic. You may need to visit a clinic to have your heart device settings adjusted.

Sometimes your doctor or nurse may ask you to transmit your heart device information before you come to the clinic.

Is there a cost for using the Medtronic CareLink Network?

The cost for using the Medtronic CareLink Network is about the same as a co-payment for a clinic visit. For more information, talk with your health care provider.

Medtronic programmer

The Medtronic programmer is a specialized computer designed to work specifically with your Medtronic heart device. Your doctor or nurse uses the programmer during the implant procedure to initially set up and change the heart device settings. Using radio waves to “read” your heart device, the programmer displays information that is collected and stored in your heart device.

Your doctor or nurse uses the Medtronic programmer during every follow-up appointment to make sure that your heart device is operating correctly and to check for any changes in your heart rhythm condition.

Reviewing information saved by your heart device

During a follow-up appointment in the clinic or hospital, your doctor or nurse will use the Medtronic programmer to read data collected by your heart device or to change the operating settings of your heart device.

Your heart device collects and saves the following information:

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Follow-up care

- ECG recordings of any unusual heart rhythms
- A list of any therapies you have received
- The status of the heart device battery
- The status of your implanted leads

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

When to call your doctor or nurse

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

- Swelling, warmth, or drainage around your incision.
- A fever while your incision is healing.
- New heart symptoms or the same heart symptoms you had before receiving your heart device.
- Heart symptoms that last longer than 3 minutes (or any length of time specified by your doctor), such as extreme fatigue, racing heart, pounding heart, or feeling faint or dizzy.
- Beeping tones coming from your heart device. For more information, see “What is Medtronic CareAlert monitoring?” on page 47.

- A shock from your heart device (if your doctor has told you to call). For more information, see “What if I receive a therapy shock?” on page 23.

Replacement of your heart device

Your heart device is powered by a lithium battery. This battery is sealed inside the titanium case of your heart device. Eventually, when the battery power is low, your heart device will need to be replaced. The average battery lasts about 9-12 years. How long the battery lasts depends on several factors, including how often your heart device provides therapy to your heart.

Replacing your heart device is typically easier and quicker than your first implant procedure. Your doctor makes an incision, removes your current heart device, and checks the lead.

Your implanted lead can be used with your new heart device if the lead is still in good condition. If not, your doctor will implant a new lead.

The doctor connects the lead to the new heart device. Then the doctor tests the heart device and implants it, usually in the same place as your current heart device. The doctor closes the incision and programs the features of your new heart device.

Medtronic Warranty

For complete warranty information, contact Medtronic Patient Services (see page 5).



9 Caring for yourself

Caring for yourself is an important part of your recovery. It is normal to feel a little nervous about how your heart device will affect your life. Your emotions may range from upbeat and positive to worry and distress. Give yourself and your family a few months to adjust to your life with a heart device.

As you get back to your normal activities, your confidence will increase. Facing your concerns and having a positive attitude about your heart device can enhance the quality of your life over time. Talk with family members, caregivers, and friends about how you are feeling. Share the information in this manual with them.

This chapter includes these topics:

- Dealing with anxiety and getting support (see page 98)
- Medical care (see page 101)
- Planning for an emergency (see page 101)
- What your family and friends should know (see page 102)

Dealing with anxiety and getting support

Often people report feeling relieved after having a heart device implanted. They report a positive change in their sense of well-being. But feeling angry, fearful, and guilty is also natural and expected. Talk with your doctor or nurse about anything that is causing you to worry.

What is a common source of stress for heart device patients and families?

Patients sometimes worry that their heart devices will not work when needed. Most patients feel that their quality of life improves after the implant. Yet at times they still worry about the performance of the device. Keep your follow-up appointments and follow your transmission schedule (if you are using remote monitoring). Reviewing the performance of your heart device with your doctor will reassure you that your device is working well. During these appointments you can also ask any questions that are troubling you.

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

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

Also, the Medtronic website has useful information. For brochures, patient manuals, frequently asked questions, and in-depth information on heart conditions and heart devices, go to www.medtronic.com.

Shaping a positive attitude about living with a 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 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 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.

Medical care

To get the most out of your medical care, follow these guidelines:

- Follow your doctor's instructions about diet, medications, and physical activity.
- Attend all heart device follow-up appointments and other general health checkups.
- If your doctor prescribes remote monitoring, follow your remote transmission schedule. If needed, you can reschedule your transmission appointment by contacting your doctor's office. For more information, see "Remote monitoring" on page 91.
- Before any medical or dental treatments, tell your doctors, dentists, and other health care professionals that you have an implanted heart device.

Planning for an emergency

Because you have a heart device, it is important to be prepared for 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 heart device 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.
- Talk with your doctor and know what to do if you receive a therapy shock.
- Inform significant coworkers, traveling companions, and others that you have an implanted heart device.
- When traveling by air, inform airline security personnel that you have an implanted heart device.

Post important information that you want to have readily available, and share it with your family members or caregivers.

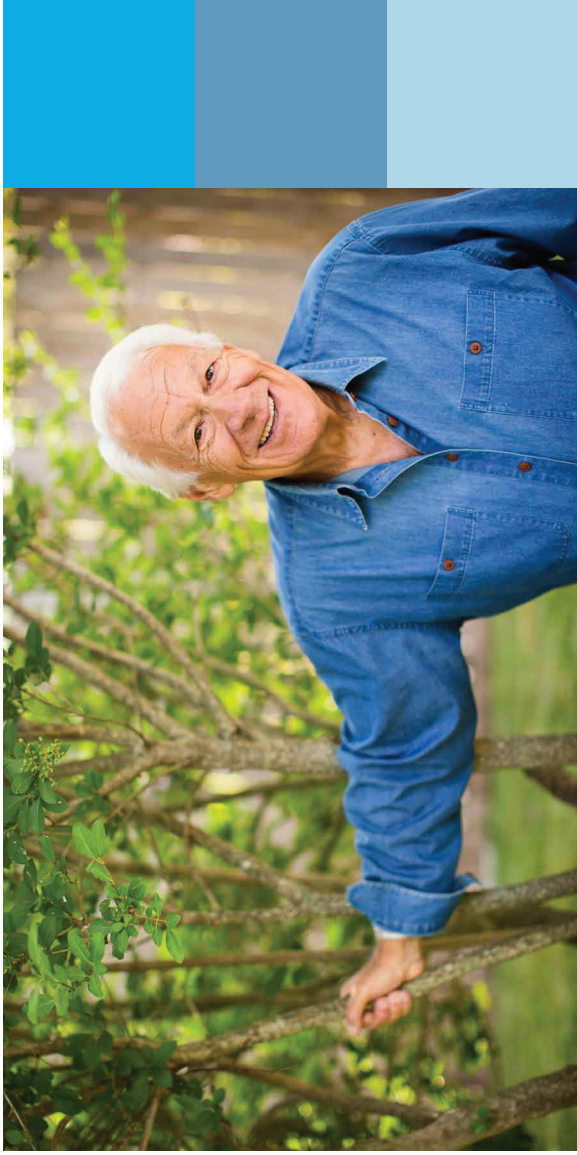
What your family and friends should know

Support from your family and friends can be important for you during your hospital stay and after you get home. Encourage them to learn about your heart device and how they can 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.

For information on what you should do if your heart device delivers a shock therapy, see “What if I receive a therapy shock?” on page 23.



Glossary

The words that appear in this section are found in **bold** throughout this manual. It may be helpful to familiarize yourself with them.

ablation – A surgical technique in which radiofrequency (RF) or microwave energy is used to destroy cells by creating heat.

antitachycardia pacing (ATP) – Small, rapid pacing pulses delivered by a heart device to treat an abnormally fast heartbeat.

atrial fibrillation (AF) – A heart rhythm that causes the atria to quiver in one place rather than contract.

atrial flutter – An atrial heart rhythm that is regular but very fast.

atrial tachyarrhythmias – Abnormally fast heart rhythms that start in the atria. Atrial flutter and atrial fibrillation (AF) are atrial tachyarrhythmias.

atrioventricular node (AV node) – An area of cardiac muscle fibers located in the middle of the heart. Electrical signals from the sinoatrial (SA) node travel through the AV node before moving to the rest of the heart.

The AV node helps keep the upper and lower heart chambers beating in a balanced rhythm.

atrium (atria) – The two upper chambers of the heart are called 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.

bradycardia – A type of heart condition in which the heart beats slowly (less than 60 beats per minute).

cardiopulmonary resuscitation (CPR) – A life-saving procedure that includes the timed external compression of the chest wall (to stimulate blood flow) and may include mouth-to-mouth breathing to provide oxygen.

CareAlert monitoring – See **Medtronic CareAlert monitoring**.

CareLink Network – See **Medtronic CareLink Network**.

colonoscopy – a procedure used to diagnose colon and bowel disease.

computerized axial tomography (CT or CAT) scan – A computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image.

continuous positive airway pressure (CPAP) machine – A machine with a mask that keeps the airway open in patients with sleep apnea.

defibrillation – A type of therapy provided by a heart device or external electronic equipment to treat a fast, life-threatening heart rhythm. Defibrillation therapy involves delivering a high-energy therapy shock to the heart.

defibrillator – An external or implanted heart device used to deliver defibrillation therapy to the heart.

device manager – A piece of Medtronic equipment used by your doctor, nurse, or trained technician to check your heart device settings, retrieve information stored by your heart device, and adjust your heart device settings if necessary.

diagnostic radiology – Imaging techniques, such as x-rays and mammograms, that use a radiation beam to produce images used for diagnostic purposes.

diagnostic ultrasound – An imaging technique used to visualize muscles and internal organs, their size, structures, and any pathological lesions.

diathermy treatment – A treatment involving therapeutic heating of body tissues.

elective cardioversion – A procedure that delivers an electrical shock to the heart to convert an irregular or fast heart rhythm to a normal heart rhythm.

electrocardiogram (ECG) – A test that measures the electrical activity of a person's heart.

electrolysis – The permanent removal of hair by using an electrified needle that is inserted into the hair follicle.

electrolyte imbalance – Electrolytes are nutrients needed for bodily function. An electrolyte imbalance is an abnormal level of electrolytes in the body.

electromagnetic compatibility (EMC) – The ability of an electrical item to operate without interfering with an electrically sensitive device such as a heart device.

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

electrosurgery – A process in which an electric probe is used to control bleeding, to cut tissue, or to remove unwanted tissue.

EMC – See electromagnetic compatibility.

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

external defibrillator – A device that sends an electric shock to the heart to restore a normal heart rhythm in the event of sudden cardiac arrest or atrial or ventricular fibrillation.

fibrillation – See **ventricular fibrillation (VF)**, **atrial fibrillation (AF)**.

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

heart block – A 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 implantable cardiac device, such as a pacemaker or implantable cardioverter defibrillator, that treats abnormal heart rhythms.

heart failure (congestive heart failure) – A condition in which the heart cannot pump enough blood to meet the needs of the body. Symptoms may include shortness of breath and tiredness from daily activities.

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

home communicator – A piece of Medtronic equipment that is used with the Medtronic CareLink Network to send your heart device information to your doctor or clinic.

hyperbaric oxygen therapy (HBOT) – The medical use of oxygen at a higher than atmospheric pressure.

implantable cardioverter defibrillator (ICD) – A heart device that is used to treat abnormal, fast ventricular heart rhythms.

laser surgery – a procedure that uses a laser to remove diseased tissues or treat bleeding blood vessels.

lead, lead system – An insulated wire that connects to a heart device, carries the electrical impulse from the heart device to the heart, and relays information from the heart's natural activity back to the heart device.

lithotripsy – A medical technique that uses electrically produced shock waves to break up kidney and gallbladder stones.

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

Medtronic CareAlert monitoring – A feature provided by most Medtronic heart devices, which activates an alert when certain conditions occur. A tone sounds at the same time every day until the heart device is reset by your doctor or nurse.

Medtronic CareLink Network – The remote monitoring service for people with Medtronic heart devices. This service allows your heart device follow-up information to be sent to your doctor or clinic while you are at home, at work, or traveling.

microwave ablation – A surgical technique where microwaves are used to destroy cells by creating heat.

MR Conditional – A term applied to a device, such as your heart device, to indicate that it has been shown to pose no known hazards in a specified MR environment with specified conditions of use. If you are being considered for an MRI scan, your heart doctor will have information about the environment and conditions.

MRI (magnetic resonance imaging) – A type of medical imaging that uses magnetic fields to create an internal view of the body.

neuromuscular electrical stimulation (NMES) – A pain control technique that uses electrical impulses passed through the skin to stimulate nerves.

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.

pacing – A type of therapy provided by a heart device (pacemaker or defibrillator) to treat a slow heart rate. Pacing consists of small electrical impulses delivered to the heart to speed up a person's heart rate.

patient magnet – A blue-coated, ring-shaped magnet used with certain Medtronic heart devices to test the Medtronic CareAlert monitoring feature or to test for certain heart device operating conditions programmed by your doctor.

pause prevention pacing therapy – A type of therapy provided by the heart device when it detects a “pause” in heart beats or a slowed heart rhythm. The device provides a regular series of small electrical impulses to return the heart to a regular rhythm.

post-shock pacing – A type of therapy provided by a heart device to help the heart return to a normal rhythm after receiving a therapy shock. It consists of small electrical impulses delivered to the heart.

radiofrequency ablation – A procedure used with heart patients, in which painless radio waves are used to destroy cells by creating heat, thereby stopping the extra electrical pulses that caused the abnormal heartbeats.

remote monitoring – A feature that allows your heart device information to be sent to your doctor or clinic while you are at home, at work, or traveling.

reoxygenated – To add oxygen back into the blood cells.

septum – The muscled wall dividing the right and left sides of the heart.

sinoatrial (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 – Also called “cardiac arrest.” Failure of the heart to pump blood through the body. If left untreated, it will lead to death within minutes.

tachyarrhythmia – A fast or irregular heart rhythm, usually more than 100 beats per minute and as many as 400 beats per minute. See also **tachycardia**.

tachycardia – An abnormally fast heart rhythm, usually between 100 to 250 beats per minute. See also **tachyarrhythmia**.

therapeutic ultrasound – The use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body.

therapy shock – See **defibrillation**.

transcutaneous electrical nerve stimulation (TENS) – A pain control technique that uses electrical impulses passed through the skin to stimulate nerves.

transurethral microwave therapy – A surgical technique in which microwave energy is used to destroy prostate tissue.

transurethral needle ablation – A surgical technique in which radiofrequency energy is used to destroy prostate tissue.

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

ventricular fibrillation (VF) – A very fast, chaotic heart rhythm that starts in the ventricles. During VF, the heart quivers instead of contracting. If left untreated, VF is fatal.

ventricular tachyarrhythmia – Abnormally fast heart rhythms that start in the ventricles. Ventricular fibrillation (VF) and ventricular tachycardia (VT) are ventricular tachyarrhythmias.

ventricular tachycardia (VT) – A rapid heart rate that starts in the ventricles. During VT, the heart does not have time to fill with enough blood between heartbeats to supply the entire body with sufficient blood. VT may cause dizziness and light-headedness.

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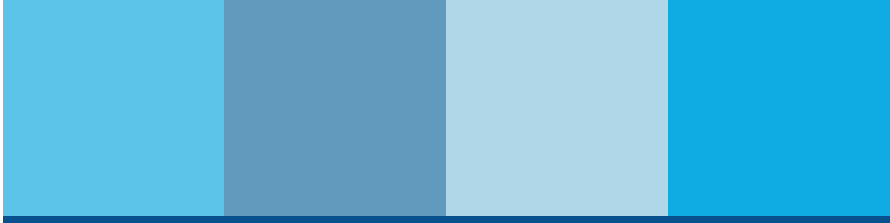
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Medtronic has partnered with physicians to develop devices to treat heart disease since the 1950s. We continually strive to create new solutions to help our patients live longer, healthier lives.

Working with patients and physicians around the world, we are taking health care Further, Together.



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M00024C001 A
2020-04-08



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Radio Regulatory Compliance Information

For devices supporting wireless telemetry

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

FCC Compliance Information (FCC ID: LF5MICSIMPLANT4):

The following provision applies to the low frequency communications system in the device: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The following provision applies to the UHF communications system in the device: This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

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Technical manuals
www.medtronic.com/manuals



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2020-03-13

Medtronic

NOTE TO IMPLANTING FACILITY:

PLEASE PROVIDE A COPY OF THIS WARRANTY TO THE PATIENT AND PLACE A COPY IN THE PATIENT'S CHART

Limited warranty and general warning

Implantable Cardioverter Defibrillator limited warranty

A. This Limited Warranty¹ provides, for a period of six (6) years commencing with the date of the implant (the "Implantation Date"), the following assurances to and for the benefit of the patient ("Patient") who is implanted with a Medtronic Implantable Cardioverter Defibrillator (hereafter referred to as "Device") packaged with this Warranty:

- (1) Should the Device function in a manner inconsistent with its intended operation and performance due to the quality of materials or workmanship, and should such event occur within the three (3) year period commencing on the Implantation Date, Medtronic will, at its option, either:
 - a) Issue a credit to the purchaser of a Medtronic device to be used as a replacement of the Device (the "Replacement"), equal to the lesser of the net price paid by: (i) the original implanting facility, for the original Device (the "Original Purchase Price"), or (ii) the purchaser of the Replacement (the "Purchaser"), for the Replacement (the "Actual Purchase Price"); or
 - b) Without charge, provide to the Purchaser a Replacement for use in the Patient that is functionally comparable to the Device.
- (2) Should the Device function in a manner inconsistent with its intended operation and performance due to the quality of materials or workmanship, and should such event occur after

¹ This Limited Warranty is provided by Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432-5604. It applies only to the United States. Areas outside the United States should contact their Medtronic representative for exact terms of the Limited Warranty.

three (3) years but prior to six (6) years from the Implantation Date, Medtronic will provide the Purchaser with a credit against the purchase of the Replacement, in an amount equal to one-half (1/2) of the lesser of the Original Purchase Price or the Actual Purchase Price, reduced on a pro rata basis (at the rate of 1/24th per month) over this three (3) year period.

In addition, Medtronic may, for the benefit of the Patient and at its option, pay up to Two Thousand Five Hundred Dollars (\$2,500) of reasonable uninsured medical expenses associated with the replacement of the Device with the Replacement.

- (3) THIS LIMITED WARRANTY IS NOT A REPRESENTATION THAT THE BATTERY OF THIS DEVICE WILL LAST THE ENTIRE SIX (6) YEAR WARRANTY PERIOD. Although battery cell depletion will occur with time and is not considered to be caused by the quality of materials or workmanship, the remedies set forth in Subsections A(1) and A(2) will apply to a Device that must be replaced during the warranty period due to battery depletion on account of its failure to perform as warranted. The Device batteries have a specified capacity that may deplete at different rates depending on Device settings and requirements for pacing, cardioversion, defibrillation or other Device functions.

B. To qualify for this Limited Warranty, all of these conditions must be met:

- (1) The Device must be implanted on or before its "Use By" or "Use Before" date in conjunction with Medtronic leads or leads of equal quality and comparable electrical characteristics.
- (2) The Device must be used in accordance with the labeling and not altered or subjected to misuse, reuse, abuse, accident, or improper handling.
- (3) All Device registration materials must be completed and returned to Medtronic within thirty (30) days of the Implantation Date.
- (4) Replaced Devices must be returned to Medtronic at the address listed below within thirty (30) days of explantation. By returning the Device and seeking a remedy under this warranty, the Patient agrees that the Device shall be the property of Medtronic.
- (5) Replaced Devices must be accompanied by a written statement from the Purchaser indicating that the Device is being returned

to Medtronic to determine whether a warranty credit is due under the warranty, and that the Purchaser will credit the Patient's account in the full amount of any credit received pursuant to this warranty and will adjust the Patient's bill to account for the full value of any free product or uninsured medical expenses paid under this warranty. Additional warranty information is available at www.medtronic.com/manuals.

The remedies provided hereunder are offered for the benefit of the Patient when conditions specified in this Limited Warranty are met. The determination that a component of the Device is not as warranted shall be made by Medtronic after its tests and inspections.

PATIENTS SHOULD ENSURE THAT THEIR HEALTH CARE PROVIDERS HAVE COMPLIED WITH THESE CONDITIONS IN ORDER TO ENSURE THE AVAILABILITY OF THIS LIMITED WARRANTY.

C. This Limited Warranty is limited to its express terms. In particular:

- (1) THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, AND FITNESS FOR A PARTICULAR USE. THE REMEDIES PROVIDED UNDER THIS LIMITED WARRANTY ARE THE PATIENT'S EXCLUSIVE REMEDIES. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE. NO SUCH EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN SUBSECTIONS A(1), A(2), AND A(3). THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON. Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, MALFUNCTION, OR FAILURE OF THE DEVICE TO FUNCTION IN A MANNER CONSISTENT WITH ITS INTENDED OPERATION AND PERFORMANCE

DUE TO THE QUALITY OF MATERIALS AND WORKMANSHIP, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE. These remedies will not be deemed to have failed of their essential purpose so long as Medtronic is willing and able to provide them to the Patient.

- (2) This Limited Warranty is made only to the Patient in whom the Device was originally implanted.
- (3) The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the Patient specific legal rights. The Patient may also have other rights, which vary from state to state.
- (4) No person has any authority to bind Medtronic to any representation, condition, or warranty with respect to the Device that deviates in any respect from this Limited Warranty.
- (5) THIS LIMITED WARRANTY IS NOT APPLICABLE TO LEADS OR ACCESSORIES USED WITH THE DEVICE.

General Warning

Medtronic devices are implanted in the extremely hostile environment of the human body. This environment places severe limitations on the design and function of the device and lead. These limitations unavoidably reduce the potential performance and longevity of the device and the lead despite the exercise of due care in design, component selection, manufacture, and testing prior to sale. Reference is hereby made to published data on predictable failure rates of the device and the lead and their implantation, which have either been furnished by Medtronic to physicians or are otherwise available to physicians.

Medtronic

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2021-02-09



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