Brief Statement

Additional Device Information

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

Risks associated with pacemaker system implant include, but are not limited to, infection at the surgical site and/or sensitivity to the device material, failure to deliver therapy when it is needed, or receiving extra therapy when it is not needed. After receiving an implantable pacemaker system, you will have limitations with magnetic and electromagnetic radiation, electric or gas-powered appliances, and tools with which you are allowed to be in contact.

A complete Revo MRI™ SureScan® pacing system, including a Revo MRI SureScan pacemaker and two CapSureFix MRI® SureScan leads is required for use in the MRI environment. Any other pacing system combination may result in a hazard to the patient during an MRI scan. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing.

This treatment is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary.

The Medtronic CareLink® Monitor is a prescription device indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. This product is not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician.

The CareLink® Service is prescribed by your physician. This service is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this service, results may vary. For further information, please call the Medtronic toll-free number at 1 (800) 551-5544 (Monday-Friday, 7:00 a.m. to 6:00 p.m., Central time) or see the Medtronic website at www.medtronic.com.
What is bradycardia?
Bradycardia is a condition in which the heart beats too slowly. A healthy heart beats 60 to 100 times per minute, pumping about 75 gallons of blood every hour. When you have bradycardia, the heart beats fewer than 60 times per minute. At that rate, the heart is not able to pump enough oxygen-rich blood to the body during normal activity or exercise. As a result, you might feel dizzy, tired, or short of breath or have fainting spells.

What causes bradycardia?
Bradycardia can occur for several reasons. Some common causes of bradycardia include:
• Congenital heart disease (condition you were born with)
• Certain illnesses or heart medications
• Natural aging process
• Scar tissue from a heart attack
• Sick sinus syndrome, also called sinus node dysfunction (the heart’s natural pacemaker is not working correctly)
• Heart block (the electrical impulse that travels from the upper to the lower chamber of the heart is irregular or blocked)

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

• Dizziness and fainting
• Chronic lack of energy
• Shortness of breath
Diagnosing bradycardia
Only your doctor can determine if you have bradycardia and, if so, how far it has progressed. To rule out or confirm the diagnosis of bradycardia, one or several diagnostic tests may be ordered, depending on the suspected heart rhythm problem. These may include:
• Electrocardiogram (ECG)
• Exercise, ECG, or stress test (measures your heart rhythm while you’re engaged in a physical activity)
• Holter or event monitor
• External loop recorder
• Insertable cardiac monitor
• Tilt table test
• Electrophysiology study (EP study)

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

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

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

• A pacemaker is a small device that is implanted under the skin, typically just below the collarbone. The device delivers therapies to treat irregular, interrupted, or slow heartbeats.

• Leads are thin, soft, insulated wires about the size of a spaghetti noodle. The leads carry the electrical impulse from the pacemaker to your heart and relay information about the heart’s natural activity back to your pacemaker.

How does a pacemaker work?
A pacemaker is designed to mimic the heart’s natural pacemaker, the sinus node. The pacemaker has two main purposes – pacing and sensing.

Pacing: A pacemaker will send an electrical impulse to the heart through a pacing lead when the heart’s own rhythm is too slow or interrupted. This electrical impulse starts a heartbeat.

Sensing: A pacemaker will also “sense” (monitor) the heart’s natural electrical activity. When the pacemaker senses a natural heartbeat, it will not deliver a pacing pulse.
Currently, most pacemakers are not considered safe in an MRI environment because the MRI could change the settings, temporarily affect the normal operation of, or potentially damage the pacemaker.

Medtronic has a pacemaker system* which is FDA approved for use in the MRI environment. This pacemaker system has a unique design, developed so that under specific conditions, patients may safely undergo MRI scans.

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

* The Revo MRI™ SureScan® pacing system is MR Conditional designed to allow patients to undergo MRI under the specified conditions for use. A complete system, consisting of a Medtronic Revo MRI SureScan IPG implanted with two CapSureFix MRI® SureScan leads, is required for use in the MRI environment.
Getting a pacemaker implanted

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

The general steps for implanting a pacemaker include:

• A small incision, approximately two to four inches long, will be made in your upper chest area, just below your collarbone

• One or two leads will be guided through a vein into your heart, and the leads will be connected to the pacemaker

• Pacemaker settings will be programmed, and the device will be tested to ensure it is working properly to meet your medical needs

• The pacemaker will be inserted beneath your skin, and the incision in your chest will be closed

Follow-up care and monitoring

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

• Monitor the battery status of the pacemaker

• Check the leads to determine how they are working with the pacemaker and your heart

• Review your pacemaker settings to ensure they are programmed appropriately to your medical needs

• Make programming adjustments to your pacemaker

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

This remote monitoring can replace some visits, but not all. Your doctor may still need to perform a physical examination to adjust your pacemaker settings or medications.

Remote monitoring via the Medtronic CareLink® Network

The CareLink® Network allows you to send information stored in your implanted pacemaker to your clinic, as instructed by your doctor, using a portable home monitor connected to a telephone landline or the Medtronic M-Link® Cellular Accessory.* Your pacemaker information is then transmitted to a secure Internet website where your clinic can access and review information about how your heart and pacemaker are working. The CareLink Network provides the same pacemaker information to your doctor that an in-clinic office visit provides.

* For more information about the M-Link® Cellular Accessory, please call 1 (877) 609-6698.

Not all devices are available on the CareLink Network.
Living with a pacemaker

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

Frequently asked questions

Can I use a cell phone?
Yes. When talking on a cell phone keep the phone’s antenna six inches away from your pacemaker, and use the phone on the ear opposite your pacemaker. We also recommend you avoid placing the cell phone in a pocket near your pacemaker.

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

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

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

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

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

Educational services for patients

Medtronic Patient Services
If you have a Medtronic cardiac device and want to learn more or have questions about living with an implanted pacemaker, please contact Medtronic Patient Services at 1 (800) 551-5544, ext. 41835. Our Patient Services Specialists are available to assist you, Monday-Friday from 7 a.m. to 6 p.m. Central time.

Medtronic.com
The Medtronic website includes in-depth information on heart conditions and treatment options for patients and their caregivers. Our interactive website allows you to take assessments, view video, read patient stories, and link to other resources. Visit us online at www.medtronic.com.