Living with Your Implantable Defibrillator (ICD)*

Brief Statement

Additional Device Information

An implantable cardioverter defibrillator (ICD) system delivers therapies to treat patients with heart rhythm disorders or who are at significant risk of developing heart rhythm disorders. An ICD is placed inside your body and works automatically. Risks associated with an ICD 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 ICD 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.

Treatment with an ICD system is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary. For further information, please call the Medtronic toll-free number at 1 (800) 551-5544, x41835 (8:00 a.m. to 5:00 p.m., Monday–Friday, Central time) or see the Medtronic website at www.medtronic.com.

Medtronic MyCareLink® Patient Monitor, Medtronic CareLink® Monitor and Medtronic CareLink™ Patient Information Site

The Medtronic MyCareLink Patient Monitor and the CareLink® Monitor are prescription devices indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manuals. The CareLink Patient Information Site is intended to provide patients, their friends/family and caregivers messages regarding transmission status of patient device diagnostic data to the CareLink Network. Transmissions to the CareLink Network sent via cellular connectivity are subject to cellular service availability. The monitor must be on and in range of the patient device diagnostic data to the CareLink Network. Transmissions to the CareLink Network sent via cellular connectivity are subject to cellular service availability. The monitor must be on and in range of the patient device diagnostic data to the CareLink Network. Transmissions to the CareLink Network sent via cellular connectivity are subject to cellular service availability.


www.medtronic.com

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 314-4000
Fax: (763) 314-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

Patient Services
Medtronic, Inc.
8200 Coral Sea St. NE
MVS14
Mounds View, MN 55112

Patient toll-free line:
1 (800) 551-5544
Fax: (763) 367-5809
8:00 am to 5:00 pm CT Mon.-Fri.
Helping you lead a fuller life.

If you or someone you love has been diagnosed with a fast heartbeat (tachycardia), has had a heart attack, or has heart failure, this booklet can help you understand the heart condition and treatment options. It is designed to provide you with basic information about sudden cardiac arrest (SCA) and implantable defibrillators, including what to expect before and after you have an implantable defibrillator implanted. Ask your doctor about your unique medical condition and therapy management.

What is tachycardia?

Tachycardia is a condition where the heart beats too fast. A healthy heart beats 60 to 100 times per minute, pumping about 75 gallons of blood every hour. Exercise, stress, or fear can cause the heart to beat faster, but this is a normal response. With tachycardia, the heart beats at more than 100 beats per minute and can beat as fast as 400 beats per minute for no specific reason. At this rate the heart is not able to pump blood effectively to the body and brain.

There are different types of fast heart rhythms that can occur in either the upper chambers (atria) or lower chambers (ventricles) of the heart.

• Atrial flutter and atrial fibrillation start in the upper chambers of the heart
• Ventricular tachycardia and ventricular fibrillation start in the lower chambers of the heart

What is sudden cardiac arrest?

Sudden Cardiac Arrest (SCA) is an electrical problem with the heart that triggers a dangerously fast heart rhythm (ventricular fibrillation). The rapid, irregular heart rhythm causes the heart to quiver rather than contract or pump. When the heart stops pumping blood, oxygen cannot reach the body and brain. If not treated immediately, SCA can be fatal.

One of the nation’s top killers, sudden cardiac arrest, claims more lives than breast cancer, AIDS, or lung cancer.¹
Heart attack and SCA: What are the differences?

Sudden cardiac arrest is not the same as a heart attack, although the two are often confused.

Heart Attack –
A circulation or plumbing problem

Cause
Blockage in a vessel that supplies blood to the heart muscle, which may permanently damage part of the heart

Risk factors
High cholesterol, high blood pressure, obesity, smoking, family history of a heart attack, diabetes

Symptoms
May be accompanied by pressure in the chest, pain radiating to the arm, shortness of breath, sweating, nausea

Sudden Cardiac Arrest (SCA) –
An electrical problem

Cause
Electrical malfunction of the heart that results in no blood flow to the body and brain

Risk factors
Previous heart attack, heart failure, abnormal heart rhythm, low ejection fraction (EF ≤ 35%), family history of SCA

Symptoms
Generally no symptoms, may experience racing heartbeat, lightheadedness, dizziness, fainting

Who is at risk of sudden cardiac arrest?

Generally, sudden cardiac arrest strikes without warning. People who are at a higher risk for SCA include:

- Those who have had a heart attack
- Heart failure patients
- Survivors of a previous SCA or those who have a family member who has had an SCA event
- People with a low ejection fraction

EF number: a number you should know
EF stands for “ejection fraction.” It is the percentage of blood that is pumped out of the heart with each heartbeat. Your doctor determines how well your heart is pumping based on your EF number.

Your EF number can change over time. It is important for you and your doctor to check your EF regularly.

Chart of typical EF ranges:

<table>
<thead>
<tr>
<th>EF Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>50–75%</td>
<td>Heart’s pumping ability is NORMAL</td>
</tr>
<tr>
<td>36–49%</td>
<td>Heart’s pumping ability is BELOW NORMAL</td>
</tr>
<tr>
<td>35% &amp; Below</td>
<td>Heart’s pumping ability is LOW</td>
</tr>
</tbody>
</table>

People with a low EF – 35% or below – are at an increased risk for SCA.

How is EF measured?
The most common way to measure EF is with an echocardiogram. This test is usually performed in a doctor’s office or hospital’s diagnostic area.
Treating SCA through defibrillation

The most effective way to treat SCA is through defibrillation. Defibrillation involves delivering an electrical shock to your heart to restore a normal heartbeat. To survive an SCA event you must receive defibrillation within ten minutes. Only about 5% of people survive SCA, because defibrillation was not delivered within this critical time frame.

There are two primary forms of defibrillation:

- **An automated external defibrillator**, or AED, is a portable device that measures the heart’s electrical activity. It is used by emergency response teams or the general public to shock the heart.

- **An implantable defibrillator**, or ICD, is a device that is implanted under the skin. The implantable defibrillator delivers therapies to treat fast, irregular rhythms.

What is an implantable defibrillator?

When people refer to an implantable defibrillator, they are actually discussing the system – the defibrillator and the leads.

- A **defibrillator** continuously monitors the heart and automatically delivers therapies to correct fast heart rhythms

- **Leads** are thin, soft insulated wires about the size of a spaghetti noodle. The leads carry the electrical impulse from the defibrillator to your heart and relay information about the heart’s natural activity back to the implantable defibrillator.
How does an implantable defibrillator work?

An implantable defibrillator is designed to monitor your heart rhythm 24 hours a day. If your heart is beating too fast or irregularly, the device will first send small painless electrical signals to correct your heart rate. If the fast heart rate continues, the defibrillator will deliver a shock to restore your heart to a normal rate. The implantable defibrillator can also treat slow heart rhythms by sending electrical pulses to the heart to correct it.

Your doctor will program the ICD to deliver the most effective therapies for your specific heart condition.

Getting a defibrillator implanted

The procedure to implant a defibrillator 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 of an implant procedure 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 implantable defibrillator
- The defibrillator settings will be programmed, and the device will be tested to ensure it is working properly to meet your medical needs
- The defibrillator will be inserted beneath your skin, and the incision in your chest will be closed
Remote monitoring of your heart device

Remote monitoring allows you to stay connected to your care team from the comfort of your home or wherever you’re traveling.*

Improved outcomes

Today, hundreds of thousands of patients are remotely monitored. It’s been shown that those patients with implanted heart devices who are remotely monitored:

• Spend less time and effort traveling to their clinic for a check-up⁵
• Enjoy a greater sense of security and peace of mind⁶,⁷
• Benefit from earlier detection of issues and spend less time at the hospital⁸
• Have an improved quality of life⁹
• See an improved survival rate (ICD and CRT patients)¹⁰

How remote monitoring works

A small monitor is used to send information from your implanted heart device to your clinic. Information is sent automatically when scheduled by your doctor, usually while you sleep. Your implanted heart device is also able to send a Medtronic CareAlert® Notification to your doctor when certain conditions are met, such as when it detects an irregular heartbeat.** Once received, your clinic can review your information on the secure CareLink®

Website and take appropriate action.

Remote monitoring is prescribed by your doctor. It provides easy access to information that allows your doctor to:

• Manage your heart condition
• Monitor your implanted heart device
• Obtain information from your implanted heart device on an as-needed basis

Medtronic patient monitors are easy to use, easy to transport, and connect using either cellular technology or an analog telephone line.

MyCareLink® Patient Monitor
(uses cellular technology)

CareLink® Patient Home Monitor
(uses an analog telephone line)

* Cellular connectivity is dependent on cellular availability.
** CareAlert® Notifications are designated by your clinic. Data availability and alert notifications are subject to Internet connectivity/access and service availability. The CareLink Home Monitor must be on and in range of the device. Alert notifications are not to be used as the sole basis for making decisions about patient medical care.
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 implantable defibrillator, and use the phone on the ear opposite your implantable defibrillator. We also recommend you avoid placing the cell phone in a pocket near your implantable defibrillator.

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 handheld massagers can temporarily affect the operation of your implantable defibrillator. Therefore, it is recommended you keep items containing magnets at least six inches away from your implantable defibrillator. 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 implantable defibrillator 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 implantable defibrillator 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 implantable defibrillator and not to wave it back and forth over your implantable defibrillator. 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 implantable defibrillator, please contact Medtronic Patient Services at 1 (800) 551-5544, ext. 41835. Our Patient Services Specialists are available to assist you, Monday-Friday from 8 a.m. to 5 p.m. Central time.

Medtronic.com
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.

Living with an implanted defibrillator

Many people with an implanted defibrillator 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.

AsktheICD.com
At AsktheICD.com you can start an anything-goes Q&A about living with an Implantable Cardioverter Defibrillator.