



LIFE WITH AN IMPLANTABLE DEFIBRILLATOR (ICD)*

Medtronic

* Implantable Cardioverter Defibrillator (ICD)

TOGETHER, 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 brochure can help you understand the heart condition and treatment options. This brochure provides 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.



Tommy
ICD Recipient

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 ($EF \leq 35\%$), 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 include²:

- 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

Know Your EF

EF—or Ejection Fraction—is the percentage of blood that is pumped out of your heart with each heartbeat. Your doctor uses your EF number to determine how well your heart is pumping. It can change over time, so it is important for you and your doctor to check your EF number regularly.

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.

Chart of typical EF ranges²:

50–75%
Heart's
pumping
ability is
NORMAL

36–49%
Heart's
pumping
ability is
**BELOW
NORMAL**

35% & Below
Heart's
pumping
ability is
LOW

People with a low EF—35% or below—are at an increased risk for SCA.³

Quick Stats:

350,000

lives claimed by SCA
in the United States

—> **1 every 90 seconds**⁴

5%

survival rate

without defibrillation³

95%

survival rate

with an ICD⁵

TREATING SCA THROUGH DEFIBRILLATION

The most effective way to treat SCA is through defibrillation.⁶ Defibrillation involves delivering an electrical shock to your heart to restore a normal heartbeat. If not treated immediately, SCA can be fatal. Approximately 95% of people who experience an out-of-hospital cardiac arrest event and are not treated by defibrillation will die.⁴

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.

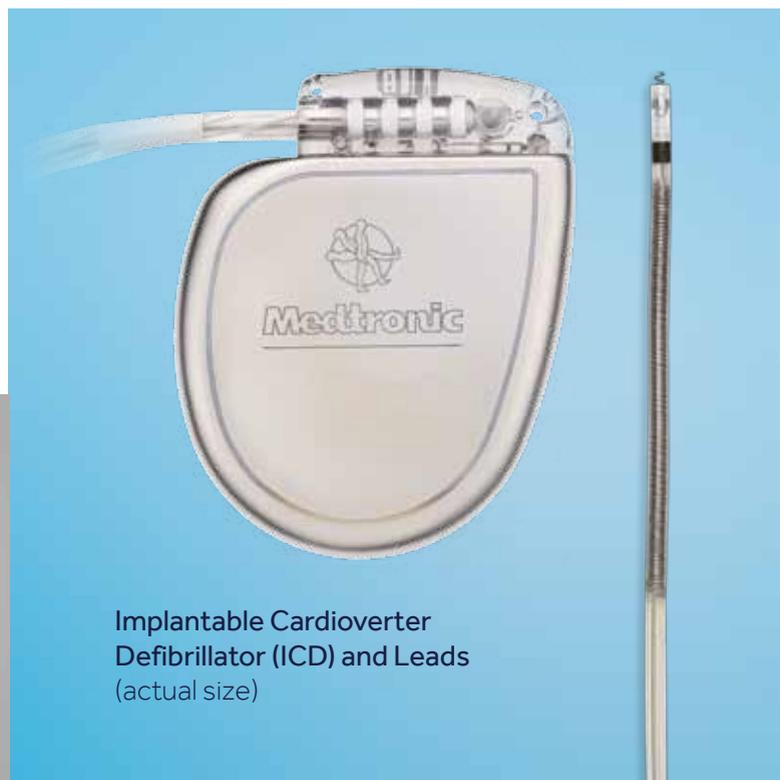
Automated
external
defibrillator,
or AED



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.



Implantable Cardioverter
Defibrillator (ICD) and Leads
(actual size)

WHY DO I NEED AN IMPLANTABLE DEFIBRILLATOR (ICD)?

If the doctor has suggested that you need an ICD, you may have experienced or may be at risk of experiencing abnormal heart rhythms (arrhythmias) called ventricular tachycardia or ventricular fibrillation. These life-threatening rhythms can cause sudden cardiac arrest (SCA), which results in death if not immediately treated.

If you're at risk for sudden cardiac arrest, an ICD is the best treatment option available. 98% of people survive a lethal arrhythmia when treated with defibrillation.⁷ Only 5% of people survive SCA without defibrillation.³

HOW DOES AN ICD 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.

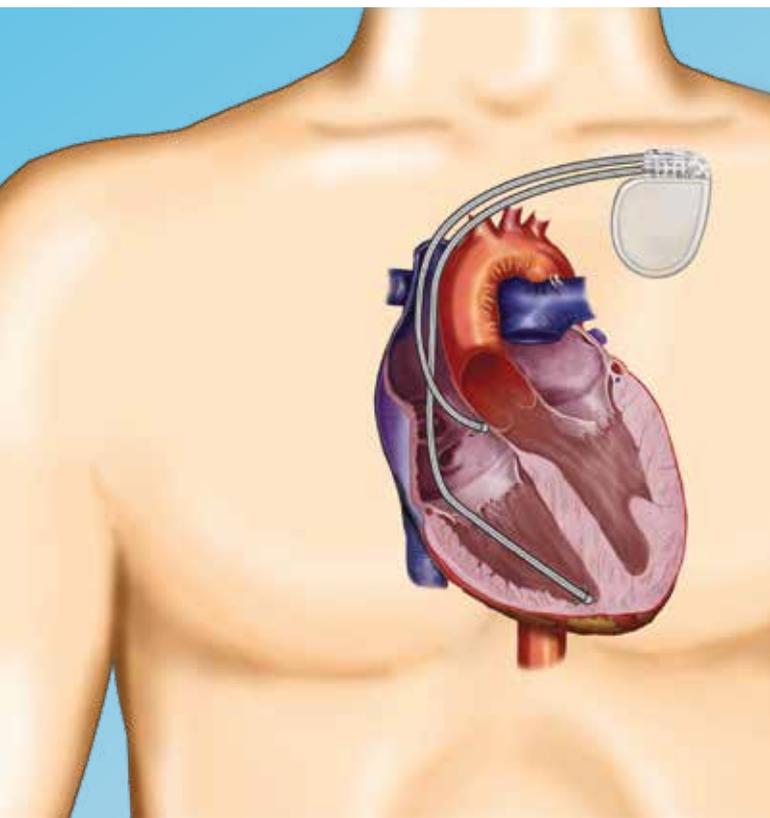
Your doctor will program the ICD to deliver the most effective therapies for your specific heart condition.

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.

General steps of an implant procedure:

- 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

MyCareLink™
Patient Monitor
(uses cellular technology)



We understand it is important to stay connected to your care team from the comfort of your home or wherever you're traveling; remote monitoring allows for this flexibility.*

Improved outcomes

Today, hundreds of thousands of patients are remotely monitored. Patients with implanted heart devices who are remotely monitored:

- Spend less time and effort traveling to their clinic for a check-up⁸
- Enjoy a greater sense of security and peace of mind^{9,10}
- Benefit from earlier detection of issues and spend less time at the hospital¹¹
- Have an improved quality of life¹²
- See an improved survival rate (ICD and CRT patients)¹³

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.

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.

* 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.

COMMON QUESTIONS

Can I use a cell phone?

Yes, mobile devices are safe to use as long as you maintain proper distance between them and your ICD. When using a cell phone, tablet computer or other mobile device, keep the device six inches from your ICD as it could create interference. We also recommend using your phone on the ear opposite your ICD and to avoid placing the cell phone in a pocket near your ICD.

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?

Even though most electromagnetic fields in the home environment will rarely affect the function of an ICD, it is recommended you keep any item containing magnets six inches away from your implantable defibrillator.



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

Can I get an MRI (magnetic resonance imaging)?

Most ICDs are not considered safe in the MRI environment because the MRI could change the settings, temporarily affect the operation of, or potentially damage the device. However, Medtronic has ICD systems that are FDA approved for use in the MRI environment. The ICD system has a unique design, developed so that under specific conditions, patients may safely undergo MRI scans.

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

Will I be able to travel?

It is unlikely that your Medtronic ICD 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 ICD while going through the security screening process, 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 ICD. 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.

MRI SCAN ACCESS

Traditionally, most ICDs 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 ICD.

Take comfort in knowing that Medtronic has ICD systems which are FDA approved for use in the MRI environment. The ICD system has a unique design developed so that under specific conditions, patients may safely undergo MRI scans.

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

EDUCATIONAL RESOURCES

Life with an ICD

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

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

In-depth information on heart conditions and treatment options for patients and their caregivers is provided on this website. Explore the website and take assessments, view video, read patient stories and link to other resources. Visit www.medtronic.com.



References

- ¹ Rosamond W, Flegal K, Furie K, et al. Heart disease and stroke statistics – 2008 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. January 29, 2008;117(4):e25-146.
- ² American Heart Association. Statistical fact sheet. Sudden death from cardiac arrest. www.americanheart.org.
- ³ Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities [corrections appear at *J Am Coll Cardiol*. April 21, 2009; 53(16):1473. *J Am Coll Cardiol*. January 6, 2009;53(1):147]. *J Am Coll Cardiol*. May 27, 2008;51(21):e1-62.
- ⁴ Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics - 2012 update: a report from the American Heart Association. [published correction appears in *Circulation*. 2012;125:e1002]. *Circulation*. January 3, 2012;125(1):e2-e220.
- ⁵ Himmrich E, Liebrich A, Michel U, et al. [Is ICD-programming for double intraoperative defibrillation threshold energy safe and effective during long-time follow-up? Results of a prospective randomized multicenter study (Low-Energy Endotak Trial--LEET)]. *Z Kardiol*. February 1999;88(2):103-112. (Article in German).
- ⁶ Zipes DP, Roberts D. Results of the international study of the implantable pacemaker cardioverter-defibrillator. A comparison of epicardial and endocardial lead systems. The Pacemaker-Cardioverter-Defibrillator Investigators. *Circulation*. July 1, 1995;92(1):59-65.
- ⁷ Glikson M, Friedman PA. The implantable cardioverter defibrillator. *Lancet*. April 7, 2001;357(9262):1107-1117.
- ⁸ Crossley G, Boyle A, Berman BJ, et al. Patient and caregiver burden following implantable cardioverter defibrillators. *Heart Rhythm*. May 2008;5(5):S259.
- ⁹ CareLink Network New Remote Monitor Qualitative Study. Medtronic Data on File. February 2013.
- ¹⁰ Cronin EM, Ching E, Varma N, Martin D, Wilkoff B, Lindsay B. Remote monitoring of cardiovascular devices: A time and activity analysis. *Heart Rhythm*. December 2012;9(12):1947-1951.
- ¹¹ Crossley GH, Boyle A, Vitense H, Chang Y, Mead RH, and the CONNECT Investigators. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts. *J Am Coll Cardiol*. March 8, 2011;57(10):1181-1189.
- ¹² Landolina M, Perego GB, Lunati M, et al. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. *Circulation*. June 19, 2012;125(24):2985-2992.
- ¹³ Saxon LA, Hayes DL, Gilliam FR, et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: The ALTITUDE survival study. *Circulation*. December 7, 2010; 122(23):2359-2367.

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 device in order to wirelessly receive data from your implanted device. Web browsers currently supported by the CareLink Patient Information Site are: Microsoft® Internet Explorer for Windows Version 8.x and Version 9.x, Mozilla Firefox® for Windows Version 13.x, Google Chrome™ for Windows Version 20.x. CareLink Patient Information Site availability may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area.

These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician.

The Medtronic CareLink Service is prescribed by your physician. This service is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this service, results may vary. For further information, please call CareLink Patient Services at 1 (800) 929-4043 (8:00 a.m. to 5:00 p.m., Monday–Friday, Central time) or see the Medtronic website at www.medtronic.com.

Patient Services

Medtronic
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.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Toll-free: 1 (800) 328-2518
(24-hour technical support for
physicians and medical professionals)

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