1 DEVICES:

Facts and Basics

Living with Devices

Living with Shocks

Implant Procedures

How a Device Works

Purpose of an ICD

The primary purpose of your ICD (implantable cardioverter defibrillator) is to restore your heart to normal rhythm when it beats too fast (tachyarrhythmia). It restores that rhythm by delivering therapies your physician has programmed into the device. These therapies begin mildly and become progressively stronger, as needed.

The Parts of Your ICD System

An ICD system consists of three parts: an ICD and a lead, which are implanted in your body, and a programmer, an external computer at your clinic or doctor's office.

ICD

The ICD itself is actually a tiny computer, plus a battery, contained in a small titanium metal case about two and three quarters inches by two inches, and only about half an inch thick. The device weighs about three ounces. Implanted in your body, it continually monitors your heart, watching for any rapid, slow or irregular heart rhythm. When it detects one, it delivers an electrical therapy to return your heart to a more normal rhythm. It also has a large memory that stores important information that your doctor retrieves during follow-up visits.

Leads

Leads, the second part of your implanted ICD system, serve two purposes: they carry information signals from your heart to the ICD, sensing and monitoring your heart's natural electrical activity. And when necessary, they carry electrical impulses to the heart.

Programmer

An external programmer is used to "talk" to your ICD. Located in your doctor's office or clinic, the programmer is used by your doctor or nurse to program the ICD to detect and properly treat your rapid heart rhythm. During follow-up visits, the programmer is used to retrieve many useful facts stored in the ICD's memory.

Your ICD Can Deliver Three Types of Therapy

Antitachycardia pacing. If your heart begins to beat too fast (typically more than 140 beats per minute) the ICD is programmed to deliver small, rapid pacing signals (these are low-energy pulses that attempt to override the fast rhythm and restore a normal heart rate). If the normal rhythm is restored, no further treatment is delivered.

What it feels like:* Most patients do not feel these impulses. A few do and describe the impulses as painless.

Cardioversion. If antitachycardia pacing does not stop the rapid heart rhythm, the ICD can deliver stronger impulses, from low to high energy as needed.

What it feels like:* Patients often describe this shock as "a thump on the chest" and associate it with mild discomfort.

Defibrillation. When a tachyarrhythmia becomes unstable and irregular, it is called ventricular fibrillation (VF). In that case, the ICD will send a high-energy shock to your heart. This is designed to interrupt the rapid heart rhythm so a more normal rhythm can be restored.

What it feels like:* Some people lose consciousness when their hearts go into VF, so they are not aware of receiving this shock. Those who are awake describe it as "a kick in the chest." They say it startles them, but passes very quickly. It can also be reassuring because you know your ICD is restoring your heart's rhythm, as it was programmed to do.

**Each person's experience is unique, so we can only describe general feelings.*

Other Features Your Device May Have

Slow heart rate detection. Your ICD may also be able to detect a very slow heart rate (bradycardia). If that happens, it will pace your heart with small pulses of electricity until it maintains a normal rate.

Rate responsive pacing. Many ICDs have this feature, which automatically adjusts your pacing rate to match your level of physical activity, such as walking, exercising, or gardening. When you slow down, the rate decreases.

Unique system monitoring. To increase your peace of mind, your ICD may have our PatientAlert™ system monitoring. Available only on Medtronic ICDs, this system provides a sound to notify you when your ICD may require evaluation by your doctor for certain conditions. Please note: Because every patient and his or her condition is unique, this feature may or may not be turned on by your physician. The next time you go for a follow-up exam or speak to your doctor, you may want to ask about this.

History of an ICD

ICD History

Over time, Medtronic implantable cardioverter defibrillators have been made smaller, more powerful, and full of features that make it easier to live a full and active life.

For more than 15 years, defibrillation systems have allowed people with tachyarrhythmias to live longer, better lives. While antiarrhythmic drugs may prevent the occurrence of arrhythmias in some patients, ICDs and external defibrillators are the only therapy that can terminate an existing arrhythmia once it has started.

Clinical Study Results

Recently, results of several large clinical trials comparing drugs and ICDs have shown an advantage in favor of ICD therapy for improving patient survival. As a result, many physicians are recommending ICDs as a first choice for certain patients with ventricular arrhythmias. Aside from the therapy delivered by an ICD (shock therapy and pacing therapy), there should be few side effects.

Market Leader

Medtronic is the market leader in this area. As we develop new products, we are looking for ways to:

- Treat more diseases of the heart
- Treat heart diseases more effectively
- Collect more data about the heart
- Reduce the device size and weight
- Make the battery last longer

Since the introduction of implantable ICDs in 1989, our ICDs have become packed with enhanced features and benefits. Yet they have also become significantly smaller – less than one-fifth their original size overall and about one-half their original thickness. And they weigh only about one-fourth as much.

Modern ICDs

Current ICDs are about the size of a pager and are implanted in the upper chest in a relatively simple surgical procedure that lasts about an hour. Previous systems needed to be implanted in the abdomen and used leads that attached to the outside of your heart (epicardium) rather than inside your heart (transvenous). The early surgical procedures were more invasive, as the lead had to be sewn to the outside of the heart, which took more time.

Manufacturing an ICD

Carefully Controlled Process

Manufacturing implantable cardioverter defibrillators (ICDs) is a carefully controlled process. It is based on scientific research and thorough product design, using input from both physicians and patients. This process ensures that all ICDs will have the dependability you count on.

Developing New Products

As we develop new products, we are always looking to make them better than those currently available. For instance, we are looking for ways to:

- Treat more diseases of the heart
- Treat heart diseases more effectively
- Collect more data about the heart
- Reduce the device size and weight
- Make the battery last longer

The Manufacturing Process

Manufacturing takes place in a very clean environment, a "cleanroom," which prevents foreign particles from entering the inner workings of the ICD. Product assemblers build and test each ICD. Computer-controlled processes play an important role in the assembly and testing as well.

All parts of the ICD are tested before assembly, then again after assembly. After the ICD has been sealed in its metal case, the completed device is tested. Once the testing is complete, the ICD is sterilized and packaged, ready to be implanted in a person.

Clinical Studies and Regulatory Reviews

Once a new ICD has been proven effective in the lab, a clinical study may be conducted if needed or required by the U.S. Food and Drug Administration. Medtronic sets up a controlled study administered by selected doctors. These doctors choose patients who have volunteered to be treated by the new ICD.

Following procedures that are monitored carefully by government agencies like the U.S. Food and Drug Administration, the doctors work closely with their patients to gather information about the new ICD. We will offer this ICD as a new product only after it has been proven safe and effective in these clinical studies and it has received government approval.

ICDs and Daily Life

Driving

Since most people are not allowed to drive right after receiving an implantable cardioverter defibrillator (ICD), you should discuss with your doctor when, and if, you can safely drive a car, boat, or other vehicle.

The decision generally is based on your recovery, medical conditions, and state laws. If your heart beats too fast or if the defibrillator delivers a shock, you may feel dizzy or even pass out, which could result in a hazardous situation.

Your state's laws or your doctor may ask you to give up driving for a certain length of time in order to assess your response to your defibrillator therapies. Your doctor will carefully review these responses and also will evaluate the results of your electrophysiology (EP) tests, your medications, and other variables.

State laws and insurance guidelines also may affect this decision. Be sure to research the guidelines for your state and insurance company, and then talk them over with your doctor. He or she may need to inform these agencies of the risks to yourself and the public if you resume driving.

Although many ICD wearers are able to resume driving privileges, if your doctor advises you to stop driving, you should do so for your safety and that of others. Also, your insurance coverage may be affected if you do not follow your doctor's advice.

If your driving has been restricted, be sure to review your situation with your doctor periodically. Your medical condition may change, possibly allowing your driving privileges to resume.

Remember to:

- Investigate your state laws and insurance guidelines regarding driving with your heart condition and its treatment
- Follow your doctor's advice and comply with your state's laws

What Should I Do if I Can't Drive?

There are options to consider if you have been advised not to drive:

- Investigate public transportation like buses, taxis, trains, and subways
- Consider walking or biking for short trips
- Share transportation with family, friends, neighbors, or work associates
- Shop over the Internet or by phone

Give yourself some time to get used to your defibrillator. Most people find that the benefits of defibrillator therapies and the assurance they provide during normal daily activity outweigh any restrictions they may impose.

Intimacy

After your incision is healed, you and your partner should be able to enjoy all the benefits of intimacy in its various forms, including hugging, kissing, cuddling, and sexual intercourse.

You may be concerned that your defibrillator will deliver a shock during intimacy. To reduce the chances of this happening, your defibrillator is programmed to an "upper rate limit" that allows your heart rate to rise to a certain limit, determined by your doctor. Your device will deliver a shock only when your heart rate surpasses this limit.

For example, if your defibrillator is set at an upper rate limit of 150 beats per minute, it will deliver therapy to your heart when it beats faster than 150 beats per minute.

It is possible that intimacy and other activities could raise your heart rate so that your defibrillator delivers a shock, but this is a rare occurrence. If it happens, notify your doctor or nurse. Studies show that the normal heart range during intimacy is between 90 and 144 beats per minute. There may be treatment options such as:

- Reprogramming your defibrillator to a higher upper rate limit
- Drug therapy to slow down the heart rate during exercise

If your defibrillator delivers a shock during intimacy, it will not harm you or your partner. However, your partner may be startled by the shock or muscle spasm. And, you will feel the discomfort normally associated with shock therapy.

If you are looking for more information, contact Medtronic Patient Services at 1 (800) 551-5544, or call your physician or clinic.

Going Shopping

Theft-detection systems used in stores and libraries can sense the metal in your defibrillator and set off a store's alarm. It also may be possible, under certain circumstances, for these systems to create electromagnetic interference and affect the operation of your defibrillator.

This interaction could prevent your defibrillator from delivering the right therapies, or it may cause your defibrillator to deliver inappropriate therapies when you are close to a system.

It is unlikely that an anti-theft system will have a significant effect on your device. Simply walk at a normal pace through the detectors. Any interference will end as soon as you finish walking through or move away from the equipment.

Follow these general precautions:

- Be aware of theft detectors. They are usually found in retail stores and libraries
- Walk at a "normal" walking speed; do not linger near the theft detection equipment
- If an alarm sounds – meaning the system detected the metal case of your ICD – simply present your defibrillator identification card to store or library personnel

If you experience dizziness, fast heartbeats (palpitations), or an extra shock caused by interference from any equipment, simply move away from the source and your defibrillator will immediately resume normal operation.

If you are looking for more information, visit Ask Patient Services, contact Medtronic Patient Services at 1 (800) 551-5544, or call your physician or clinic.

Using Cell Phones

Recent studies have indicated there may be a potential interaction between cell phones and defibrillator operation due to the radio frequency signal or the magnet within the phone. This interaction could prevent your defibrillator from delivering the right therapies, or it may cause your defibrillator to deliver inappropriate therapies when the phone is too close to your implant site.

Any interference encountered with cell phones is temporary. Simply move the phone away from your defibrillator to allow it to function normally again.

A few general guidelines will safeguard the proper operation of your defibrillator near cell phones:

- Keep the phone at least six inches (15 cm) from your defibrillator site; for phones transmitting above three watts, keep at least 12 inches (30 cm) between the cell phone and your defibrillator site. Contact your phone's manufacturer to check the wattage
- Hold the phone to the ear opposite the side your defibrillator is implanted
- Do not carry the phone in a pocket or on a belt that is within six inches of your defibrillator
- If you experience dizziness, fast heartbeats (palpitations), or an extra shock caused by interference from a cell phone, simply move the phone further away from your defibrillator and it will immediately resume normal operation. **Note:** It is safe to use ordinary cordless phones and standard desk and wall phones commonly used in the home or office.

Fixing the Car

Precautions are always needed if you work on any gasoline-powered equipment. First, turn off the engine before repairing or adjusting a car engine or other gasoline-powered equipment.

Do not touch:

- the coil,
- distributor, or
- spark plug cables of a running engine.

What Should I Wear?

If your defibrillator is implanted near your collarbone, you may see a small bulge under your skin. Choosing slightly looser clothing may help you feel more comfortable.

Suspenders and bra straps may rub against the defibrillator implant site, but they will not affect defibrillator operation. Padded seat belt protectors are also available from auto supply stores or home health aid outlets. These protectors can make you much more comfortable when driving or riding in a car.

If your defibrillator is implanted in the abdominal area, loose slacks, skirts, and belts are recommended. Some patients have felt suspenders work well, for belts may rub on the implant site

If you are looking for more information, visit Ask Patient Services, contact Medtronic Patient Services at 1 (800) 551-5544, or call your physician or clinic.

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ICDs and Work

In the Office

Your implanted defibrillator has built-in features that protect it from most electromagnetic interference created by common office equipment.

It's alright to use:

- Personal computers
- Laptop computers
- Larger, mainframe computers
- Computer back-up devices
- Modems
- Laser, dot-matrix, and ink jet printers
- Electric typewriters
- Facsimile (FAX) machines
- Copying machines
- Scanners

With all appliances or tools, follow a few precautions:

- Ensure that any electrical equipment you use is in good working order and properly grounded to prevent shock
- Keep hand-held appliances at least six inches from your implant site
- Avoid using appliances that could harm you if you become dizzy or receive a therapeutic shock from your defibrillator

If you are looking for more information, visit Ask Patient Services, contact Medtronic Patient Services at 1 (800) 551-5544, or call your physician or clinic.

Possible Sources of Interference

Some equipment in your daily environment or medical or dental procedures could affect your defibrillator. If you experience dizziness or a feeling of rapid or irregular heartbeats (palpitations), or an extra shock caused by interference from equipment, simply move farther away from the item. Your defibrillator will immediately return to working normally.

Around Industrial Equipment

Heavy electrical or industrial equipment often creates high electromagnetic interference and can interfere with the proper functioning of your implanted defibrillator.

Check with your doctor before working with the following equipment for the first time after you have received an ICD:

- Electric arc welding equipment
- Dielectric heaters, used in industry to bend plastic
- Induction furnaces such as kilns
- Electric steel furnaces used in factories
- Large generators and electric motors

In general, avoid:

- Carrying or holding large magnets or magnetic materials near your defibrillator site
- Large magnets used in some stereo speakers
- Touching the antenna of an operating citizen band (CB) or ham radio or other radio transmitters
- Motorized radio frequency equipment

If you experience dizziness, fast heartbeats (palpitations), or an extra shock caused by interference from any equipment, simply move away from the source and your defibrillator will immediately resume normal operation.

Around Transmission and Power Lines

Large television or radio transmitting towers **are** likely to interfere with the operation of your defibrillator.

Transmission power lines that carry more than 100,000 volts will also create interference. Avoid the following, especially if they are labeled "restricted access":

- Broadcasting antennas of AM, FM, short wave radio, and television stations
- Power plants, large generators, transmission lines, and transmission buildings
- Walking underneath large transmission towers. Transmission power lines transmit power to local power plants and usually have tall supporting towers with large electrical insulators.
- Distribution power lines supply power to homes and businesses. Alone, distribution power lines usually do not affect a defibrillator's operation. However, when both distribution and transmission power lines are found next to each other, they can affect how your defibrillator works.

If you experience dizziness, fast heartbeats (palpitations), or an extra shock caused by interference from any equipment, simply move away from the source and your defibrillator will immediately resume normal operation.

Medical and Dental Procedures

Medical Procedures

Always tell medical personnel that you have an implanted defibrillator before undergoing any medical procedure.

The degree of interference that a medical procedure may cause can be grouped into four categories:

1. Not likely to cause interference
2. Can be minimized if equipment is not placed directly over the defibrillator
3. Interference is likely but may be minimized by your doctor
4. Interference is likely and the procedure should be avoided

Procedures that are the least likely to cause interference with your defibrillator include:

- Diagnostic x-rays, including chest x-rays, computerized axial tomography (CT or CAT) scans, and mammograms. If your implant is in the upper chest area, x-ray equipment for mammograms can be adjusted to exert less pressure. **Note: If you need a CT or CAT scan, the detection feature of your ICD may need to be turned off.**
- Fluoroscopy – an examination that uses an instrument consisting of an x-ray machine and a fluorescent screen to view the internal organs of the body

The following procedures may be performed if the equipment is not placed directly over the implant site:

- Ultrasound for diagnostic purposes, including bone density tests
- Ultrasound for therapeutic purposes; the transducer head should be kept at least ten inches away from the defibrillator

Have your doctors consult with one another regarding ways to minimize interference before having the following procedures performed:

- External defibrillation (strong electrical shocks to the heart); paddles should not be placed directly over the implanted defibrillator
- Transcutaneous electrical nerve stimulation (TENS), which uses strong electrical current to reduce chronic pain
- Electrolysis (for removal of unwanted hair)
- Electrocautery (stops bleeding during surgery)
- Lithotripsy (crushing of stones using sound waves, usually performed in the gall bladder or urinary tract)
- Radiation therapy (often used for cancer treatment)

The following procedures are likely to cause interference and should be avoided:

- Magnetic resonance imaging (MRI). Even when the MRI scanner is turned off, a strong magnetic field surrounds it, which has the potential to interfere with your defibrillator. When you are in or near an MRI room, your defibrillator may be affected;
- Diathermy (heat treatment using electricity). Therapeutic diathermy can cause fibrillation, burning of the heart tissue and irreversible damage to the ICD due to induced currents.

Dental Procedures

Always tell dental personnel that you have an implanted defibrillator before undergoing any dental procedures.

Most dental equipment and procedures are unlikely to cause interference with your defibrillator. These include:

- Dental drills
- Ultrasonic probes to clean teeth
- Dental x-rays

Have your doctors consult with one another regarding ways to minimize interference before having the following procedures performed:

- Electrocautery during dental procedures (stops bleeding during surgery)
- Diathermy (heat treatment using electricity). Therapeutic diathermy can cause fibrillation, burning of the heart tissue, and irreversible damage to the ICD due to induced currents.

If you experience dizziness, fast heartbeats (palpitations), or an extra shock caused by interference from any medical or dental equipment, tell the attending professional immediately. Your defibrillator will resume normal operation after the procedure is stopped.

Travel and Leisure

General Travel

Once you have recovered from surgery, you should be able to travel with your implanted defibrillator. Most people with defibrillators feel more secure when traveling because they know their device will deliver the appropriate therapy if they need it.

Before planning the first trip you take after your implant, you may want to check with your doctor or nurse. They will help you with precautions, give you instructions on what to do in case of emergencies, and, for extended travel, give you your ICD's program settings in writing so you have them handy if you need them during your travels.

Follow these general recommendations when you travel:

- Find the names of hospitals or heart centers in the area you will be visiting in case you have questions or have an emergency.
- Carry your defibrillator identification card. To order or update your card, click here.
- Wear your medical jewelry. If you don't have a piece of medical identification, you may order one online at American Medical Identifications, www.americanmedical-id.com.
- Plan for emergencies (for example, what should you do if your device shocks you repeatedly, or if you don't feel well in general).
- Ask your doctor for an emergency care sheet that includes your defibrillator settings. This sheet will help other medical professionals care for you in an emergency.
- Ask your doctor for names of doctors and heart centers in the area you will be visiting in case you have questions or have an emergency.
- If you are traveling outside of the country, ask your doctor about international heart centers. Or call a major medical institution when you arrive to see where you should go in case of emergencies. Consider getting a free six-language defibrillator identification card from Medtronic Patient Services. Contact Medtronic Patient Services at 1 (800) 551-5544 to order a six-language card.
- If there are no heart centers at your destination, call other emergency services in the area to find out who can provide care for defibrillator patients
- Tell your traveling companions about your implanted defibrillator. Tell them what to expect and what to do if your defibrillator delivers a shock, or if you pass out.
- Check out the special considerations that apply to traveling by air, traveling by car, and extended travel

Travel by Air

Most people with implantable defibrillators can travel by air unless restricted by their underlying medical condition. You may want to get your doctor's guidelines for the very first flight you take after receiving your ICD.

Also, check out the special needs that apply to general travel and extended travel. Want to find a heart rhythm physician at your destination? Use the NASPE (North American Society of Pacing and Electrophysiology) Find a Physician website.

Be sure to identify yourself as a defibrillator patient to the airport security person. Show your defibrillator identification card.

If you are traveling internationally, you may want to carry an additional card that states "I have an implanted heart ICD that may set off your metal detection device," in English and five other languages. Order this six-language card via email by clicking Ask Patient Services.

Security systems (both the walk-through archway and hand-held wands) are metal detectors. These systems are likely to sense the defibrillator's metal case and set off the system's alarm.

It is unlikely that the walk-through archway will affect defibrillator operation. Simply walk through it at a normal pace. However, hand-held wands, with their strong magnets, have the potential to affect the normal operation of your defibrillator. Ask for a hand search instead.

Travel by Car

Most people with implanted defibrillators can easily take a road trip, whether by car, bus, or train. As with any travel, check with your doctor first before planning a day-long road trip. And, remember to follow general travel tips and recommendations for extended travel.
Whether or not you are allowed to drive depends on your condition and the laws in your area and at your destination. Discuss these issues with your doctor before your trip.

These general travel recommendations are a good idea for anyone taking to the road:

- Ensure your car is in good working order
- Plan ahead. Know where you are going and what weather conditions will be.
- Wear loose, comfortable clothing. For your comfort, consider extra padding if your seat belt rubs on your defibrillator site.
- Plan frequent stops to rest and stretch muscles.
- Don't over-do. Stop before excessive fatigue sets in, and never drive when sleepy.
- Consider subscribing to a roadside assistance program and carrying a cell phone in case of emergencies
- If you are feeling dizzy or your heart is racing, pull off to the side of the road and rest until you feel normal. If you continue to feel poorly, you may want to call 911.

If you are looking for more information, contact Medtronic Patient Services at 1 (800) 551-5544 or call your physician or clinic.

Hobbies

You should be able to resume normal activities and hobbies after you've recovered from the implant surgery. Knowing that your defibrillator will provide the right therapy if a dangerous heart rhythm occurs will likely enhance your joy in returning to favorite activities.

Always ask your doctor before resuming any hobby or activity. He or she may even recommend avoiding certain activities, depending on your condition and how you react to your defibrillator therapies.

In general, you should be able to participate in the following pastimes:

- Walking
- Gardening
- Cooking
- Playing an electric guitar or keyboard
- Model trains
- Electronic casino games
- Video arcade games
- Amusement park rides
- Hot tub or sauna activities

Some hobbies, however, require special precautions:

- Stereo equipment: Large stereo speakers have strong magnets inside. Do not lift or carry these speakers close to your defibrillator;
- CB radios, ham radios, walkie-talkies, remote control toys: These items require special precautions.

If you experience dizziness, fast heartbeats (palpitations), or an extra shock caused by interference from any equipment, simply move away from the source and your defibrillator will immediately resume normal operation.

If you are looking for more information, contact Medtronic Patient Services at 1 (800) 551-5544 or call your physician or clinic.

Hobbies Using Radio Transmitters

The antennas of citizen band (CB) radios, ham radios, walkie-talkies, and those used on controls for remote control toys can produce interference with defibrillator operation. Keep a safe distance between your defibrillator and the antenna. The required distance, however, depends on factors such as transmitter power, frequency, and type of antenna.

The table below lists general guidelines for distances to maintain between your defibrillator and antenna. Longer distances may be needed if the power level of your equipment is higher than those shown or if the antenna is highly directional.

Radio Transmitter for CB, Ham or Other Device	Power Level	Keep This Distance Between the Antenna and Your Defibrillator
Portable	3 watts	1 foot
Car	25 watts	3 feet
Home	200 watts	10 feet

If you are looking for more information, contact Medtronic Patient Services at 1 (800) 551-5544 or call your physician or clinic.

Possible Sources of Interference

Some equipment in your daily environment or medical or dental procedures could affect your defibrillator.

If you experience dizziness, fast heartbeats (palpitations), or an extra shock caused by interference from any equipment, simply move away from the source and your defibrillator will immediately resume normal operation.

Sports

While you should talk to your doctor before getting involved in recreational sporting activities again, you should be able to enjoy most recreational sports, including:

- Golfing
- Swimming
- Fishing
- Boating
- Canoeing
- Biking
- Bowling
- Hiking and walking
- Hunting (make sure the rifle butt rests on the side opposite your implant site if you have an upper chest implant)

An ICD is designed to deliver therapy if it senses fast rhythms. Therefore, consult with your doctor regarding your underlying medical condition and your defibrillator settings before engaging in more strenuous sports such as:

- Racquetball
- Tennis
- Jogging

Also, use your good judgment and avoid rough physical contact sports that involve jarring or falling, including:

- Football
- Baseball
- Soccer
- Basketball
- Downhill skiing
- Cross country skiing
- Water skiing
- Snow boarding
- Ice skating
- In-line skating

Avoid activities that could jeopardize your safety (e.g., rock climbing, camping in remote areas, boating alone, swimming alone).

If you experience dizziness, fast heartbeats (palpitations), or other unusual symptoms, stop the activity immediately and call your doctor as soon as you can.

If you are looking for more information, contact Medtronic Patient Services at 1 (800) 551-5544 or call your physician or clinic.

What to Do if You Receive a Shock

Your clinic will give you specific, detailed instructions on what to do if you experience a shock from your defibrillator.

The clinic's recommendations are based on:
- Your clinic's defibrillator follow-up guidelines
- Your medical history
- The length of time you've had the device
- How you feel after receiving a shock

Every clinic has its own procedures for helping you after a shock, but most follow these general rules:
- You may receive one shock and feel fine afterward. Your clinic may tell you to call them, but that it is not necessary for you to visit right away. During your next follow-up visit, clinic staff will interrogate the defibrillator to see what your heart was doing when the therapy was delivered.
- There may be times you receive a shock, but don't feel well afterward. When you contact clinic staff, they may ask you to come in that day, schedule an appointment for you, or tell you to go to an emergency room for an evaluation.
- You are experiencing multiple shocks in a short time period. Someone experiencing multiple arrhythmias and receiving many shocks is usually treated as a medical emergency. Depending on the time of day, your doctor or clinic may recommend that you go directly to the clinic or an emergency room.

When you visit the clinic or emergency room following a shock, you will receive a physical exam and diagnostic tests may be conducted. Your defibrillator may also be interrogated to see what your heart was doing and why a shock was delivered at that time.

Multiple Arrhythmias or "Electrical Storms"

Note: If you are experiencing multiple shocks from your defibrillator – sometimes called "electrical storms" – always call 911 or follow other instructions from your clinic.

About 60% of the people who receive a defibrillator will experience at least one episode of ventricular tachycardia or fibrillation within the first two years following their implant. These arrhythmias are stopped by an appropriate shock from the defibrillator.

Some patients, however, experience repeated episodes of ventricular tachycardia or fibrillation that cause the device to deliver multiple shocks in a short period of time. This condition – called an "arrhythmic or electrical storm" – occurs in about 20% of people with defibrillators.

Receiving more than two to three shocks in any 24-hour period leads to the need for urgent therapy in most people. One study of electrical storms found the median number of "arrhythmic episodes" (ventricular tachycardias or fibrillation) was 17 within a single 24-hour period; so the range of multiple arrhythmias can vary greatly from person to person.

Multiple arrhythmias may occur at any time: right after the defibrillator has been implanted, four to six months after implant, or even years after implant.

Management of Multiple Arrhythmias or Electrical Storms

Note: If you are experiencing multiple shocks from your defibrillator – sometimes called "electrical storms"– always call 911 or follow other instructions from your clinic.

Someone experiencing multiple arrhythmias and receiving many shocks is usually treated as a medical emergency. Depending on the time of day, your doctor or clinic may recommend that you go directly to an emergency room.

Once at the ER or your clinic, the physician may do a number of things to stop the multiple arrhythmias and determine their cause.

They may first stabilize you by:

- Sedating you appropriately so you are more comfortable
- Turning off the defibrillator and placing you on monitoring equipment
- Administering medications, such as beta-blockers or amiodarone, which work to suppress the arrhythmias

Once you have been stabilized, your doctors will look for the cause of your multiple arrhythmias and seek to treat them appropriately.

Questions Your Doctor May Ask You

To determine the cause of multiple arrhythmias, your doctor may ask you a number of questions:

- Do you feel palpitations? Are they regular or irregular?
- Were you short of breath or did you have chest pain?
- Did you feel dizzy or faint?
- Have there been any changes to your medications?
- Was your defibrillator reprogrammed recently?
- What were you doing when the defibrillator shocked you?
- How many shocks have you received in the past 24 hours?
- Do you have other diseases, such as congestive heart failure, coronary artery disease, or high blood pressure?

The more you or your family and friends can tell the doctor, the better able he or she will be to help you.

Causes of Electrical Storms

Electrical storms may be caused by a number of conditions, the most common of which are:

- Lack of oxygen in the heart muscle (myocardial ischemia) which can lead to a heart attack (myocardial infarction)
- A deficiency of potassium in the blood, a condition called hypokalemia
- Acute congestive heart failure, a condition in which the heart can't pump enough blood to the rest of the body due to a variety of factors

Once the cause of the multiple arrhythmias has been determined, your physician may:

- Start you on new heart medications or change your current medications
- Reprogram your defibrillator
- Decide if you need a procedure such as a coronary artery revascularization (bypass surgery or angioplasty) or ablation, which uses radio frequency or heat to destroy the heart cells causing the arrhythmias

Implanting an ICD

What to Expect

Part of the anxiety associated with any surgery comes from not knowing what to expect. This section provides an overview of the general procedure for implanting the ICD as well as what to expect after your surgery.

To implant the ICD and leads, your doctor will first decide what type of surgery is needed. This decision will be based on your body size and shape, whether you have already had chest surgery, and what method is safest for you.

Most of the time, ICDs are implanted in a simple surgical procedure, with an incision made in the upper part of t he chest. Local anesthesia is frequently used, and the surgery is often an outpatient procedure.

Occasionally, a patient who requires other surgery, such as a coronary bypass, will have the device implanted during that procedure. In these cases, general anesthesia is used, and the device is usually implanted on the left side of the abdomen.

The Implant Procedure

During an ICD implant, the doctor:

- Makes an incision in the upper left-hand side of your chest. (This is the most common location. ICDs may also be implanted in the upper right-hand side of your chest or the abdominal area.)
- Inserts the leads by threading them through a vein from the ICD to the inside of your heart
- Tests the leads to ensure the best position on or in the heart
- Connects the leads to the ICD
- Tests the automatic function of the device
- Closes the incision(s)
- Programs the ICD according to the settings he or she has determined best for your particular arrhythmia

Before you leave the hospital, your doctor may test your ICD by starting a rapid heart rhythm and having the ICD correct it. This test may also let you know what the therapies might feel like.

What the Therapies, or Shocks, May Feel Like

Your ICD can deliver three types of therapy:

1. **Antitachycardia pacing.** If your heart begins to beat too fast (more than 140 beats per minute), the ICD is programmed to deliver small, rapid pacing signals (low-energy pulses in an attempt to override the fast rhythm and restore a normal heart rate). If the normal rhythm is restored, no further treatment is delivered.
   What it feels like:* Most patients do not feel these impulses. A few do and describe the impulses as painless.
2. **Cardioversion.** If antitachycardia pacing does not stop the rapid heart rhythm, the ICD can deliver stronger impulses, from low to high energy as needed.
   What it feels like:* Patients often describe this shock as "a thump on the chest" and associate it with mild discomfort.
3. **Defibrillation.** When a tachyarrhythmia becomes unstable and irregular, it is called ventricular fibrillation (VF). In that case, the ICD will send a high-energy shock to your heart. This is designed to interrupt the rapid heart rhythm so a more normal rhythm can be restored.
   What it feels like:* Some people lose consciousness when their hearts go into VF, so they are not aware of receiving this shock. Those who are awake describe it as "a kick in the chest." They say it startles them, but passes very quickly. It can also be reassuring because you know your ICD is restoring your heart's rhythm, as it was programmed to do.

**Each person's experience is unique, so we can only describe general feelings.*

Follow-Up Clinic Visits

Follow-up Care

Before being discharged from the hospital, your doctor will probably tell you when to come back, most likely within a few weeks. Remember, the doctor and follow-up nurse are available to answer specific questions you may have regarding your ICD.

In the past, follow-up visits required the patient to go to the clinic or doctor's office. Today, there are more options, include **remote monitoring** such as that offered by the Medtronic CareLink Service. This remarkable technology gives patients the ability to – at the push of a button – send their device data to their clinic from home, work or while traveling*, giving them tremendous peace of mind.

Follow-up checks are important to ensure that your ICD continues to work properly. The purpose of these visits is to assess your current medical condition and to:

- Have an electrocardiogram (ECG or EKG) taken of your heart's electrical function
- Check the ICD's functions
- Look at events that have occurred and therapies delivered since your last visit
- Determine that these were the appropriate therapies for your condition
- Verify the frequency of your follow-up checks is appropriate

Your clinic may also monitor any medications you are taking, provide psychological support, and answer any questions you may have. After studying the results of your follow-up and evaluating your condition, your doctor may adjust your medications or make changes in your ICD's settings.

It is important to keep appointments with your doctors an to follow their recommended daily care to ensure the best possible results. For a list of devices supported by Medtronic CareLink Service, go to www.medtronic.com/carelink, or to find the clinic in your area that offers it, go to www.medtronic.com/traveling.

* Medronic CareLink Service is available in the continental U.S., Alaska and Hawaii.

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Replacing an ICD

Why ICDs Are Replaced

Because your ICD runs on a battery that is sealed inside it, the ICD will eventually have to be replaced. How long the ICD lasts depends on the number and types of treatments it delivers. Generally, an ICD is designed to last five to nine years.

The replacement procedure is typically easier and quicker than the initial implant. Usually, at replacement time, your doctor will make a new incision over the old one and then remove the old ICD. He or she will then disconnect and check the leads to determine if replacement of the leads is also necessary; they may or may not be removed.

The leads are connected to the new ICD, and the ICD's function is tested. The new ICD is then inserted, and the incision is closed. Finally, the ICD's therapies are programmed.

Depending on your age and condition, the entire replacement surgery may be done on an outpatient (same-day) basis or may require an overnight stay in the hospital.

EP Study

The Electrophysiology (EP) Study

Why an electrophysiology study is recommended

Most likely, you have experienced symptoms that your doctor feels could be caused by a heart abnormality. These symptoms might include heart pounding, fluttering, lightheadedness, dizziness, faintness, shortness of breath, and/or pressure or discomfort in the chest. Another reason for the study could be if you are a survivor of cardiac arrest.

Comprehensive and thorough

There are a number of tests your doctor could use in diagnosing your abnormal heart rhythm. But an electrophysiology study (EP study) is the most comprehensive and thorough way to look at your heart's disturbance. The study evaluates the heart's electrical system and can help your doctor determine the appropriate treatment for your abnormal heart rhythm.

Preparing for the EP Study

First your doctor and nurse will review your medical history with you. They will describe the EP procedure, including any possible side effects. The procedure is normally done in a hospital or outpatient facility, in the electrophysiology (EP) or catheterization (cath) lab. Plan on arriving several hours before the test is scheduled.

Food and fluid intake

Your doctor will give you specific instructions regarding eating and drinking restrictions prior to the study. Don't be surprised if you are told not to eat or drink anything for six to eight hours before your procedure.

Medications

Your doctor will also give you specific instructions regarding heart rhythm medications or blood thinners that you may already be taking. You may even be asked to stop taking them. Be sure the doctor knows every medication that you are taking, even over-the-counter medications, such as aspirin.

Immediately Prior to the Study

The following preparations will take about half an hour to complete.

Medication

You may be given medication to relax you – you may even fall asleep – so be sure to tell the doctor and staff if you are allergic to any medications.

Intravenous line insertion

An intravenous (IV) line is usually started before the procedure begins. Mild sedatives, pain medication, and heart medications may be given through this line before, during, and after the procedure.

Preparation of the catheter insertion sites

The areas on the groin, arm, or neck (where the catheters are to be inserted) will be shaved and cleansed thoroughly. Tell the staff if you are allergic to any soap or tape. The areas are covered with sterile towels so it is important not to touch them. Ask a staff member for assistance if you need to change positions or move.

Monitoring heart rhythm and blood pressure

ECG patches will be attached to you so your heart rhythm can be monitored. A blood pressure cuff may also be placed on your arm which will automatically check your blood pressure. Other patches or monitors may be used as well. All of these steps are routine and are done for your safety.

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The Actual Procedure

Once preparation is complete, the actual study will begin.

Catheter insertion

A number of specially designed catheters – small flexible tubes – will be used for the study. Before they are inserted, your skin will be numbed. This may sting or slightly burn initially, but once the area is numb it should not be painful. You may feel a little pressure as the doctor works. If you do experience pain, be sure to tell the doctor or nurse.

A small incision will be made in your skin to make it easy to insert the catheters into your blood vessels. The catheters will be advanced to your heart under fluoroscopic control.

Because there are no nerves in the heart's inner lining, you should not feel the catheters themselves. You may, however, feel like your heart skips a beat as the catheters are positioned. This is normal.

Once the catheters are positioned, the EP study is performed by doing two things.

1. Recording the heart's electrical signals.

During this phase, important information about your heart's conduction system is gathered. This process records ECGs from inside your heart and compares them to an ECG from the body surface.

2. Pacing the heart.

The doctor will also pace or stimulate the heart during the study. This process may enable the doctor to reproduce the arrhythmia that has caused your symptoms. And the combination of recording and stimulating may help identify sites in your heart causing the arrhythmia.

You may feel your heart beat quickly or experience skipped beats during pacing. This again is normal and you should not be alarmed.

You may also be asked questions about how you are feeling during the study. It is important that you tell the staff as much as you can about how you feel. The doctor may ask, "Do you feel lightheaded or dizzy?" or, "Is this feeling similar to one you have had before?" Your answers are important and will help the medical staff make the best possible diagnosis.

Evaluating medications

During the study, you may be given medications to elicit symptoms or to evaluate their effect on your arrhythmia.

A Very Low-Risk Procedure

An EP study is a low-risk procedure that is considered relatively safe. As with any procedure that requires incising the skin and inserting a catheter, there is a small risk of complications. These may include bleeding at the insertion site, or less frequently, damage to blood vessels, formation of blood clots, or infection. While the vast majority of EP study patients do not experience complications, you should be aware of possible risks.

Sensations During the Study

The procedure is virtually painless. You may feel a slight pressure as the catheters are introduced. At various times, you may feel that your heart is skipping beats. You might also feel symptoms like the ones that caused you to seek treatment, e.g., heart pounding, fluttering, lightheadedness, dizziness, faintness, shortness of breath, and/or pressure or discomfort in the chest.

Medications used during the procedure may cause specific symptoms. And occasionally a shock is given to the heart to stop a fast heart rate.

Recovery and Follow-Up

When the EP study is complete, the catheters are removed. To prevent bleeding, pressure is applied to the insertion site(s) for ten to 20 minutes. You will be monitored closely and your vital signs and insertion site checked frequently.

After the procedure you may feel tired from the sedative or uncomfortable from lying still for a period of time. Be sure to let the nurses know if you have any discomfort, wetness, or swelling at the site.

Your precise recovery routine will depend on what type of blood vessel your doctor used for the procedure. Your nurse will explain what is necessary for your healing, such as the amount of time it will be necessary to stay in bed and other guidelines. Before you are dismissed, your doctor or nurse will give you specific discharge instructions and review your medications.

Your Treatment Options

Finally, your doctor will discuss the results of the EP study and describe the treatment options. These may include:

1. Medication
2. An implantable device such as an implantable cardioverter defibrillator (ICD) to help control your arrhythmia
3. Catheter ablation, which is a non-surgical, low-risk therapy that may cure your condition. Very simply, the procedure involves using a catheter to heat the appropriate area of the heart and neutralize the tissue so it is no longer capable of producing an arrhythmia.
4. Surgery

Whatever the recommended treatment, your doctor and staff will explain it in detail. Follow instructions and report any signs of side effects.

You are in partnership with your doctor and medical staff, and everyone has the same goal: to keep you as healthy as possible.

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