



Role of Pacemaker and Implantable Defibrillator (ICD) Device Therapy

In the normal healthy heart, the upper and lower chambers contract in sequence, pumping blood through the arteries to all parts of the body and brain. A series of electrical signals generated inside the heart stimulates the contractions. A problem at the signal origin or anywhere along the electrical pathway disrupts the normal pattern and causes an irregular heartbeat – too rapid, too slow or chaotic. An abnormal heartbeat is called an arrhythmia.

Treatment for cardiac arrhythmias has come a long way in the past 15 to 20 years with the development of and advances in cardiac device therapies. The various devices available today, including pacemakers, implantable cardioverter defibrillators (ICDs), biventricular pacemakers, biventricular ICDs and combination devices, are safe and effective in treating heart rhythm problems.

Cardiac devices are tiny, electronic, battery-powered devices that are surgically implanted under the skin. Using computer technology, the devices monitor and deliver treatment to correct irregular heart rhythms when needed.

“Implanted cardiac devices help tens of thousands of people enjoy full, active lives and are the most effective technology we have for stopping life-threatening arrhythmias,” says Bruce Wilkoff, M.D., Director of Cardiac Pacing and Tachyarrhythmia Devices at Cleveland Clinic.

Device Therapy to Reduce Risk of Sudden Cardiac Arrest

Ventricular arrhythmia, a serious type of rhythm disorder that affects the heart’s lower chambers, is a leading cause of sudden cardiac arrest (SCA). During a ventricular arrhythmia, rapid, irregular contractions of the heart’s lower chambers reduce the heart’s ability to pump blood to the body and brain. Unless the heart’s normal rhythm is restored immediately with cardiopulmonary resuscitation (CPR) and defibrillation, the person experiences sudden cardiac arrest which can lead to sudden cardiac death in minutes.

Device therapy is an important treatment for patients who have an increased risk of ventricular arrhythmia and sudden cardiac arrest. Individuals who have heart disease or who have had a previous heart attack and have a low ejection fraction (see sidebar) are at the highest risk. Other risk factors include a previous episode or family history of sudden cardiac arrest, family history of sudden cardiac death, a personal or family history of certain abnormal heart rhythms, or ventricular fibrillation after a heart attack.

Sudden cardiac arrest causes an estimated 325,000 deaths in the United States each year, according to the Heart Rhythm Society. The good news is that implantable defibrillator device therapy stops sudden cardiac arrest and reduces death from all causes from 25-50%, depending on the type of heart problem.

Know Your Ejection Fraction

Ejection fraction (EF) is a key indicator for heart health. EF is the amount of blood pumped out of the left ventricle of the heart during each beat or contraction.

A healthy heart pumps a little more than half the heart’s blood volume with each beat. A normal EF is between 50 and 65. Many people with heart failure or heart disease have an EF of 50 or less. Recent scientific research shows that a reduced EF (usually less than 35%) is the single most important risk factor for sudden cardiac death.

It is important for you and your doctor to know your EF. Your EF can change, depending on your heart condition and the effectiveness of the therapies that have been prescribed for you. It is important to have a baseline EF measured at the beginning of your treatment and repeat EF measurements as needed, based on changes in your condition. Your doctor can advise you on how frequently you should have your EF checked.

Types of Devices

Although each type of cardiac device is engineered to treat specific types of heart rhythm problems, they share some common characteristics. The two main components of all implanted cardiac devices are a metal can called a generator and one or more wires called leads.

Generator: The generator houses the battery, an antenna and a tiny computer. Energy is stored in the battery until it is needed. The computer receives information from the leads to determine what rhythm is occurring, stores records of abnormal rhythms, and tells the battery when to send small electric impulses or a larger electric shock to the heart. The information in the computer is read through the antenna messages and can be adjusted to work in the best way as the patient’s needs change.

Leads: Insulated wires that send messages to the computer about the heart’s electrical activity and return impulses from the pulse generator to the heart muscle to help regulate the rhythm. Each impulse causes the heart to contract.

Type of Device	Condition Treated	How it Works
Pacemaker	Pacemakers are used to treat abnormally slow heartbeats (bradycardia).	A pacemaker monitors the heart by reading signals sent back to the pulse generator through a lead connected to the ventricle or atrium (the heart's upper chamber). When it detects too slow a heart rate, the generator delivers tiny amounts of electrical energy that pace the heart to beat at a normal rate.
Implantable Cardioverter Defibrillator (ICD)	ICDs are used to treat ventricular arrhythmias that lead to sudden cardiac death.	An ICD stops fast rhythms by delivering low amounts of electrical energy to the heart. When the device senses a dangerously fast arrhythmia, it delivers a high-energy shock called defibrillation.
Biventricular Pacemaker (also called cardiac resynchronization therapy or CRT)	A CRT device is used to treat the uncoordinated beating (dyssynchrony) of the heart's ventricles.	A CRT device sends tiny amounts of electrical energy to both of the ventricles. The energy causes the ventricles to contract at the same time to improve cardiac function.
Biventricular ICD	A biventricular ICD is used to treat people with heart failure who are at higher risk of sudden cardiac death.	Depending on the specific rhythm problems being treated, some people may receive a combination CRT plus an ICD.

Safety of Cardiac Devices

You may have heard stories in the news recently that contained conflicting information about the safety of cardiac devices. Although implantable cardiac devices are complex, Dr. Wilkoff stresses, “they are manufactured to very high reliability standards.”

The U.S. Food and Drug Administration has issued safety advisories on certain devices over the years, most recently on some ICD models. The most recent advisories were prompted by data indicating that some ICD models have a design flaw that can potentially cause them to malfunction. Pacemakers also have had safety advisories issued in the past related to problems with the leads that transmit heart rhythm information to the device's computer. A safety advisory does not mean that every device will malfunction. **“Most device malfunctions are not harmful to the patient,” Dr. Wilkoff says.**

Device problems often are related to the software that runs the device and can be fixed by reprogramming. This is a simple, non-invasive procedure performed in your doctor's office or at the hospital's outpatient clinic that involves downloading new software to the device.

In ICDs, device malfunction may prevent generation of the electrical pulse necessary to correct a ventricular arrhythmia. This may be caused by an electrical malfunction of the lead wire or its insulation. Other, non-life-threatening pulse generator malfunctions can occur and may require that the device be replaced. These types of malfunctions are very rare, occurring in only about 2% of cases.

“Although sometimes the device does need to be removed and replaced, in the vast majority of patients, this is not the best answer,” Dr. Wilkoff says. This is because the risks associated with device removal, such as infection, heart failure or hematoma can be as great

as or greater than the risks of device malfunction.

Talk To Your Doctor

If you have a device that is listed in a safety advisory, start by talking to your doctor about treatment risks, benefits and alternatives.

Questions to ask include:

- **What is the actual risk of the device failing?**
- **What are the potential consequences for you personally in the event of a malfunction?**
- **What are the risks you would face if the device needed to be replaced?**
- **What alternatives are there to replacing the device?**

Other Points to Remember:

- Your doctor will tell you how often to have your device checked.
- Keep your follow-up appointments with your heart rhythm specialist. During a device check, the doctor will determine if your device detected or treated any abnormal heart rhythms since your last visit and will check the battery.
- You will also need to see a cardiologist at least once a year.
- Contact your doctor immediately if you feel a shock from your device or if you hear beeping sounds coming from it.

“While a safety advisory may alert us to the need for certain precautions and more frequent follow-ups, at Cleveland Clinic we continue to have confidence in the overall safety and effectiveness of these devices,” Dr. Wilkoff says.

This information is educational and does not serve to endorse any person, product or company. Information provided by the Cleveland Clinic is not intended to replace the medical advice of your doctor or health care provider. Please consult your health care provider for advice about a specific medical condition.