



BACKGROUND

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MEDTRONIC'S IMPLANTABLE DEFIBRILLATORS

What Defibrillators Do

An implantable cardioverter-defibrillator (ICD) has been called “an emergency room in the chest.” When first introduced in the mid-1980s, ICDs did almost exactly what the emergency squad does when it treats a victim of the Sudden Death Syndrome or Sudden Cardiac Arrest. It administered intense electrical shocks to stop ventricular fibrillation -- a lethal condition in which the heart quivers rapidly and pumps little or no blood. If successful, the shock stopped the heart and allowed it to quickly resume a normal rhythm.

Today, ICDs do much more and have been proven to be 99 percent effective in treating dangerous ventricular arrhythmias. Modern defibrillators, such as the Medtronic Marquis® family of ICDs or the high-output Maximo™ ICD, continuously monitor the electrical conduction system of the heart, watching for dangerous acceleration patterns and delivering electrical therapy when needed that may range from a steady impulse much like a cardiac pacemaker's to a full, life-saving shock. This is called tiered therapy. Dangerous patterns may indicate ventricular fibrillation (VF), ventricular tachycardia (VT) or less problematic supraventricular tachycardias that arise in the upper chamber of the heart. At the same time, ICDs now collect information for the physician to use in programming the device to the exact needs of the patient. Devices such as the Medtronic Gem® III AT ICD is designed to also monitor electrical activity in the upper heart (atrium) and deliver therapies there to interrupt accelerating heartbeats and restore a more natural rhythm.

Implantation and Testing

Implantation of a modern defibrillator is much simpler than it used to be and the procedure takes only about one hour. The electrical leads of the modern device are maneuvered through the vascular system into position in the atria and ventricles. First, the physician injects local anesthesia and makes an incision about 4 inches long in the pectoral area to access the cephalic or subclavian veins. Through a small incision in a vein, he or she maneuvers the leads into position in the heart. The defibrillator is connected to the leads and slipped into the “pocket” -- through the incision. Next the device is carefully programmed by the physician, who sends signals from an external device called a Medtronic CareLink™ programmer. Now the device is ready to be tested. Using its capabilities, the device induces a rapid heartbeat, pauses, then treats it with electrical impulses. If all goes well, the physician simply checks everything again and closes the incision. The device is ready to do its job.

Modern ICDs Are Highly Sophisticated

The Medtronic Marquis® family of defibrillators is designed to make major advancements in patient therapy, bringing higher levels of confidence and comfort. They are designed to ensure that impulses are delivered when needed, but not when they are unnecessary. New, sophisticated programs, embedded in the device circuitry, identify precisely where errant heart rhythms are originating and deliver the right therapy to the right place to correct those rhythms -- often without the patient being aware of it. The device can carefully discriminate between relatively benign atrial arrhythmias and problematic ventricular episodes so shocks are withheld when not needed. Also, both devices continuously monitor their own performance and alert the patient if he or she should check with the physician.

Who Might Benefit from an ICD?

One large group of potential patients has intermittent ventricular tachycardia (VT), in which the heartbeat suddenly and without warning speeds up to dangerous rates. Persons in another group, who may also have VT, have survived an episode of Sudden Cardiac Death -- an emergency squad got there in time to successfully treat their ventricular fibrillation, a lethal rapid heart condition. It is estimated that there are about 300,000 new patients each year in these two groups who could benefit from ICD therapy. A third important group is patients who have survived a myocardial infarction (heart attack) and have impaired pumping function in the ventricles. An article about a recent clinical study published in the New England Journal of Medicine showed that ICD patients had a 31 percent reduction in mortality over those who didn't receive an ICD, and that an additional 300,000 patients in this group could benefit from ICD therapy.

Interestingly, some of these patients may also have bradycardia in which the heart sometimes beats too slowly. The Marquis family devices can treat that, too, with rate responsive therapy that is automatically adjusted to meet the needs of the patient's circulatory system. This pacing therapy can be delivered to upper or lower chamber of the heart, or both and is fully programmable by the physician to ensure that only appropriate therapy is delivered.

How long do Medtronic devices last?

Marquis family devices are designed to last longer than any other currently marketed implantable defibrillators. If they deliver constant pacing and about four shocks a year, they are expected to serve for up to seven years before replacement. However, the device would last longer if it has less work to do, such as delivering fewer shocks per year. The Maximo ICD has a longevity of between 8-10 years, depending on the model and use.

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