

Medtronic

Implantable Cardioverter-Defibrillators (ICDs)

Overview

Implantable cardioverter-defibrillators (ICDs) have been saving lives for more than 30 years by delivering a lifesaving shock or painless pacing to stop life-threatening fast or irregular heartbeats.

- Irregular heartbeats, also known as ventricular arrhythmias, can lead to sudden cardiac death, a condition that kills approximately 350,000 people each year in the United States.¹
- An estimated 650,000 Americans and nearly 1 million patients worldwide have an ICD or cardiac resynchronization therapy-defibrillator (CRT-D) to protect against dangerously erratic heartbeats.²

What Defibrillators Do

- ICDs administer electrical shocks or painless pacing therapy to stop ventricular fibrillation (VF) – a lethal condition in which the heart quivers chaotically and pumps little or no blood.
- ICDs also stop ventricular tachycardia (VT), and other less problematic arrhythmias.
- ICDs collect information physicians can use to program the device to the exact needs of the patient.

Effectiveness

- ICDs are proven to be 98 percent effective in treating dangerous ventricular arrhythmias that can lead to sudden cardiac arrest.^{3,4}
- Medtronic estimates more than 70,000 lives have been saved by implantable defibrillators over the past five years.⁵

Implantation and Testing

- Implantation of an ICD takes only about one hour, and sometimes can be done on an outpatient basis.
- Implantation is minimally invasive surgery. A physician injects local anesthesia and makes an incision about four inches long in the upper chest. The ICD is inserted and the leads are maneuvered through a vein into the heart.
- The physician programs the ICD and tests it before closing the incision.

Modern ICDs Are Highly Sophisticated

- They are designed to ensure that impulses are delivered only when needed.
- Today's devices often deliver pain-free rhythm-regulating therapy without the patient being aware of it.

Who Might Benefit from an ICD?⁶

- People who have intermittent ventricular tachycardia (VT), in which the heart beats suddenly and speeds up to dangerous levels without warning.
- People who have survived an episode of sudden cardiac arrest.
- People who have survived a myocardial infarction (heart attack) and have impaired pumping function in the lower chambers (ventricles).

Underserved Patient Populations

- African-Americans are twice as likely to die as a result of sudden cardiac arrest compared to caucasians⁷ and are significantly less likely to receive an ICD.⁸
- Less than 10 percent of elderly patients who survive a heart attack receive an ICD, despite a clear mortality benefit.⁹
- Women with ischemic cardiomyopathy have been found to be 65 percent less likely to receive an ICD compared with men.¹⁰

How Long Do ICDs last?

- ICDs will effectively guard against sudden cardiac arrest for up to approximately eight to 11 years, depending on the model of the device and the individual patient use.

¹Roger 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(22):e1002]. *Circulation*. January 3, 2012;125(1):e2-e220.

² Medtronic data on file. 2010.

³ Zipes, DP, Roberts, D. for the Pacemaker-Cardioverter-Defibrillator investigators. Results of the International Study of the Implantable Pacemaker Cardioverter-Defibrillator: A Comparison of Epicardial and Endocardial Lead Systems. *Circulation*. 1995;92:59-65.

⁴ Volosin et. al. "Virtual ICD: A Model to Evaluate Shock Reduction Strategies." *Heart Rhythm*. Vol. 7, N. 5, May supplement 2010. (PO3-125).

⁵ Medtronic data on file. 2010.

⁶ Epstein, A, DiMarco, J, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. *J. Hrthm*. June 2008; 5 (6): e1-e62.

⁷ Kyndaron Reinier et al. *Circulation*. 2015;132:380-387

⁸ Thomas KL, et al. Racial disparity in the utilization of implantable-cardioverter defibrillators among patients with prior myocardial infarction and an ejection fraction of $\leq 35\%$ *Am J Cardiol*. 2007;100:924

⁹ Pokorney SD, Miller AL, Chen AY, et al. Implantable Cardioverter-Defibrillator Use Among Medicare Patients With Low Ejection Fraction After Acute Myocardial Infarction. *JAMA*. 2015;313(24):2433-2440. doi:10.1001/jama.2015.6409

¹⁰ A.J. Gauri, A. Davis, T. Hong, M.C. Burke, B.P. Knight "Disparities in the use of primary prevention and defibrillator therapy among blacks and women" *Am J Med*, 119 (2006), pp. 167.e17-167.e21

Brief Statement

Medtronic ICDs and CRT-ICDs

Medtronic Implantable Cardioverter Defibrillators (ICDs) are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Medtronic Cardiac Resynchronization Therapy (CRT) ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration.

Contraindications

Medtronic ICDs and CRT-ICDs are contraindicated in patients whose ventricular tachyarrhythmias may have transient or reversible causes, patients with incessant VT or VF, or patients who have a unipolar pacemaker. Medtronic ICDs are also contraindicated for patients whose primary disorder is bradyarrhythmia.

Warnings and Precautions

Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Additionally, for CRT-ICDs, certain programming and device operations may not provide cardiac resynchronization.

Potential Complications

Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, acceleration of ventricular tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com.

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