Brief Statement
Medtronic ICDs

Indications
Medtronic implantable cardioverter defibrillators (ICDs) are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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

Warnings/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.

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 manual 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.**

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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Policy & Practice

Medtronic Sued on ICD Leads

Within a day of Medtronic Inc.'s announcement that it was recalling Sprint Fidelis leads for implantable cardioverter defibrillators, a group of plaintiffs attorneys had filed suit in federal courts in Minneapolis and Puerto Rico on behalf of two patients. But the suit is seeking class action certification and relief for an estimated 100,000 patients. The filing alleges that Medtronic gave false assurances of safety and failed to properly warn physicians, among other claims. The defects in the leads were evident as early as the spring of 2007, according to the filing, which also said that as of July 2007, the Food and Drug Administration had received 1,000 adverse event reports on the Sprint Fidelis leads. More suits are being filed in Florida and California federal courts and in Minnesota state court, although those will be on behalf of individual plaintiffs only, said Hunter J. Shkolnik of Rheingold, Valet, Rheingold, Shkolnik & McCartney LLP in New York, whose firm is one of seven that are party to the initial federal cases against Medtronic. The seven firms—already representing plaintiffs in ICD-related suits—had been investigating reports of faulty leads for 6 months, Mr. Shkolnik said in an interview. Their filings were ready to go before the recall was announced, he said. Medtronic estimates that as many as 280,000 patients have had a Sprint Fidelis lead implanted since its 2004 approval. It has been used with ICDs made by Medtronic, St. Jude Medical Inc., Boston Scientific Corp., and Guidant Corp. (now a division of Boston Scientific). In response to the suits, a company spokesman said that Medtronic had conducted a "very substantial quality evaluation of the product." And, he added, "no matter how responsibly a manufacturer acts in the course of a product field action, litigation is likely to be filed."

Framingham Data Opened

The National Institutes of Health are opening up the database from the Framingham Heart Study. The Framingham information is the first to be made available freely to researchers worldwide through the National Heart, Lung, and Blood Institute–funded SHARe database. The database is designed to help researchers make a quicker connection between genetics and disease. "As one of the most comprehensive studies ever undertaken, the Framingham Heart Study will play a vital role in laying the foundation for this vast dataset to help researchers link genes and disease," said Dr. Elizabeth G. Nabel, NHLBI director, in a statement. The Framingham study began in 1948 and contains data on 9,300 participants over three generations. It includes deidentified clinical and demographic data and results from testing for 550,000 genetic variations, or single nucleotide polymorphisms (SNPs). SHARe (SNP Health Association Resource) will continue to receive new information from Framingham as it is accumulated, and it will also incorporate data from other large studies, according to the NHLBI. Researchers can access SHARe at http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?id=phs000007.

No Cholesterol Tests for 36 Million

About 36 million Americans have never had their cholesterol tested, according to the Agency for Healthcare Research and Quality. Not surprisingly, the uninsured are most likely not to have had a cholesterol check. About one-third of those without insurance aged 20-64 years have never checked their lipid levels. That drops to 22% for people with public insurance and 16% for those with private insurance. The young are least likely to have had a cholesterol check; about 40% of those aged 20-34 years had never had a test, compared with only 2% of those older than age 65. The data come from AHRQ's Medical Expenditure Panel Survey for 2005.

Wal-Mart Expands $4 Generics

Wal-Mart has added 24 medications to its growing list of generic prescription drug products that patients can receive for $4 for a 30-day supply. The prescriptions can be filled at 4,005 Wal-Mart, Sam's Club, and Neighborhood Market pharmacies in the United States. Among the 24 new medications are carvedilol, timolol, and terbinafine. The company also expanded its reproductive drugs offerings. Wal-Mart claims that since its $4 generic program began in the fall of 2006, customers have saved $613 million. The generics represent 40% of all prescriptions filled in the last year. Because of state laws, some of the drugs cost more than $4 in California, Colorado, Hawaii, Minnesota, Montana, Pennsylvania, Tennessee, Wisconsin, and Wyoming.

Chronic Disease: $1 Trillion a Year

Seven chronic diseases—cancer, diabetes, hypertension, stroke, heart disease, pulmonary conditions, and mental illness—have a total impact on the economy of $1.3 trillion annually, including $1.1 trillion in lost productivity, according to a study by the Milken Institute. That figure could be nearly $6 trillion by midcentury, the report said. "By investing in good health, we can add billions of dollars in economic growth in the coming decades," said Ross C. DeVol, the institute's director of regional economics and principal author of the report. He noted that much of this cost was avoidable. "With moderate improvements in prevention and early intervention, such as reducing the rate of obesity, the savings to the economy would be enormous." West Virginia, Tennessee, Arkansas, Kentucky, and Mississippi have the highest rates of chronic disease. Utah, Alaska, Colorado, New Mexico, and Arizona have the lowest.

—Alicia Ault