Among First Hospitals in the United States to Use Implantable Defibrillators with Advanced Technology to Reduce Inappropriate Shocks and Improve Patient Quality of Life

– Physicians at [institution] are the first in the [state] to treat patients who suffer from irregular heartbeats with the latest implantable cardiac rhythm device technology. Medtronic’s Protecta™ portfolio of implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy-defibrillators (CRT-Ds) with SmartShock™ Technology were recently approved by the U.S. Food and Drug Administration (FDA). [Institution] also began enrolling patients with Protecta in the global PainFree SST clinical trial.

The new family of implantable defibrillators is the first to feature SmartShock Technology, six Medtronic-exclusive algorithms that recognize life-threatening arrhythmias and deliver therapeutic shocks only when appropriate, therefore improving patient quality of life.¹

(Draft physician quote for consideration) “With the advanced shock reduction technology available in this new portfolio of devices, I can offer patients an option that will protect them from life-threatening arrhythmias and give them the peace-of-mind that they will not be shocked inappropriately so they can continue to lead an active, normal life,” said Dr. [name], [title].

Implantable defibrillators are designed to provide lifesaving shocks or painless pacing to stop life-threatening fast or irregular heartbeats, also known as ventricular arrhythmias, which can lead to sudden cardiac death. Sudden cardiac death kills more people each year than lung cancer, breast cancer and HIV/AIDS combined.² ³

About PainFree SST
The PainFree SST clinical trial is a global, prospective, multi-center study evaluating the impact of SmartShock technology in reducing inappropriate shocks in patients implanted with a Medtronic Protecta™ implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy-defibrillator (CRT-D) devices. Secondary objectives include safety equivalence of VF NID programming in secondary prevention patients, quality of life, healthcare utilization, syncopal events and reasons for inappropriate shocks will be analyzed. Currently being conducted at up to 150 centers in the United States, Europe, Canada, Middle East and Africa, the trial will enroll up to 2,000 patients.

About Cardiac Device Therapy
Implantable cardiac devices such as ICDs and CRT-D devices are designed to treat a variety of problems that stem from a faulty electrical system in the heart. The devices benefit patients who experience dangerously erratic heart beats, have experienced a previous heart attack or have survived sudden cardiac arrest, which puts them at risk for future life-threatening episodes.

The devices are tiny, battery-powered computers about the size of a pocket watch. They are implanted under the skin, generally on the left side of the chest near the collarbone, and connected to the heart via leads. These tiny wires are inserted into the chambers of the heart through blood vessels for two purposes—to carry information signals from the heart to the device, and to carry electrical impulses from the device to the heart. The third part of the implantable device system is a programmer, an external computer located in the doctor’s office or clinic that is used to program the heart device, as well as retrieve information from the
device about the patient’s condition and device status that will assist the doctor in treating the disorder.

**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 bradycardia.

**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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