All patients on optimal medical therapy and meaningful survival of greater than 1 year is expected.

Primary Prevention of SCD

**Ischemic Patient**

- MI → ≥ 40 days Post MI → LVEF ≤ 30% NYHA Class: I
- MI → ≥ 90 days postrevascularization → LVEF ≤ 35% NYHA Class: II - III
- MI → NSVT → LVEF ≤ 40% → Inducible sustained VT/VF at EPS → ICD Indicated CLASS I, LEVEL OF EVIDENCE A

**Non-ischemic Patient**

- MI → LVEF ≤ 35% NYHA Class: II - III → ICD Indicated CLASS I, LEVEL OF EVIDENCE B-R

**Ischemic Patient**

- MI → NSVT → LVEF ≤ 40% → Inducible sustained VT/VF at EPS → ICD Indicated CLASS I, LEVEL OF EVIDENCE B-R

Secondary Prevention of SCD

- Survivor of SCA due to VT/VF or experience hemodynamically unstable VT (LOE: B-R) or stable VT* (LOE: B-NR) → ICD Indicated CLASS I, LEVEL OF EVIDENCE B-R AND B-NR
- Ischemic Patient → Unexplained syncope who have inducible sustained monomorphic VT at EPS → ICD Indicated CLASS I, LEVEL OF EVIDENCE B-NR

*not due to reversible causes.
Evera MRI™ and Visia AF™ MRI System

The Evera MRI and Visia AF MRI SureScan™ DF-1 and DF4 system are MRI Conditional and, as such, are designed to allow patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. The Visia AF MRI SureScan systems also automatically detect and record the occurrence of atrial fibrillation (AF) for diagnostic purposes.

Indications for Use

The SureScan defibrillation systems are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. In addition, the Evera MRI dual chamber devices are indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. Notes: • The ICD features of the device functions the same as other approved Medtronic market-release ICDs. The following notes are applicable based on the features available in the specific Evera MRI model. • The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias. • The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating atrial tachycardia (AT) was found to be 17%, and in terminating device classified atrial fibrillation (AF) was found to be 16.8%, in the VTIAT patient population studied. • The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 11.7%, and in terminating device classified atrial fibrillation (AF) was found to be 18.2% in the AF-only patient population studied.

A complete SureScan defibrillation system is required for use in the MR environment, which is an Evera MRI SureScan ICD device with a SureScan defibrillation lead in the right ventricle and if using a dual chamber ICD, a SureScan atrial pacing lead. When a single coil SureScan defibrillation lead is used, a Medtronic DF-1 pin plug must be secured in the SVC port to make a complete SureScan DF-1 system. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan.

Contraindications

The Evera MRI SureScan system is contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis. The device is contraindicated for patients who have a unipolar pacemaker implanted. The device is contraindicated for patients with incessant VT or VF. For dual chamber devices, the device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF. For single chamber devices, the device is contraindicated for patients whose primary disorder is atrial tachyarrhythmia.

Warnings and Precautions

Changes in 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 transsthoracic defibrillation paddles directly over the device. Patients and their implanted systems must be screened to meet the following requirements for MRI: no implanted lead extenders, lead adaptors, or abandoned leads; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; a SureScan defibrillation system implanted in the left or right pectoral region; pacing capture thresholds of ≤ 2.0 V at a pulse width of 0.4 ms; no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is programmed to On.

Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5 T or 3T MRI system for hydrogen proton imaging, maximum spatial gradient ≤ 20 T/m, and maximum gradient slew rate performance per axis ≤ 200 T/m/s. 1.5T scanners must be operated in Normal Operating Mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg, head SAR ≤ 3.2 W/kg). 3T scanners must be operated in First Level Controlled Operating Mode or Normal Operating Mode. B1+RMS must be ≤ 2.8 μT when the isocenter (center of the bore) is inferior to the C7 vertebra. Scans can be performed without B1+RMS restriction when the isocenter is at or superior to the C7 vertebra. Continuous patient monitoring is required while MRI SureScan is programmed to On. While MRI SureScan is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. In addition, if the device is programmed to an asynchronous pacing mode, arrhythmia risk may be increased.

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. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block. The SureScan defibrillation systems have been designed to minimize potential complications in the MRI environment. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or MR-induced stimulation on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

See the Evera MRI or Visia AF MRI SureScan Technical Manuals before performing an MRI Scan and 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 the Medtronic website at www.medtronic.com or www.mrisurescan.com.

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

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