11 YEARS PROVEN PERFORMANCE

Sprint Quattro™
Defibrillation Leads
We made intentional choices and took proactive steps — from lead design to active product monitoring — to ensure reliability of the Sprint Quattro™-lead family.

**SPRINT QUATTRO™ MODEL 6947 HAS 11 YEARS OF PROVEN PERFORMANCE**

**1**

**BACKED BY A LIFETIME WARRANTY**

**2**

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**Why RPA alone isn’t enough:**

Only a portion of leads make it back to the manufacturer for analysis when no longer in use. Some remain in the body and others are discarded. Returned Product Analysis underestimates lead failure rates, which is why it is not sufficient to estimate survival. **Active lead monitoring is the best estimate for actual lead survival.**

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**PROVEN PERFORMANCE.**

**PROVEN RELIABLE.**

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**PROVEN BY ACTIVE MONITORING.**
Pair Sprint Quattro Secure™ with a Medtronic SureScan™ cardiac device today; provide access to MRI scans tomorrow.

Patients with a Sprint Quattro™ MRI SureScan™ lead, coupled with a Medtronic SureScan™ cardiac device, are now able to safely undergo an MRI scan when MR conditions for use are met.

A complete SureScan™ system is required for use in the MR environment, which includes a Medtronic SureScan™ device connected to Medtronic SureScan™ leads.

- DF4 Models: 6947M or 6935M
- Lead Lengths: 55, 62 cm
- DF-1 Models: 6947 or 6935
- Lead Lengths: 58, 65 cm

Sprint Quattro™ leads have true bipolar pacing and sensing.

**True Bipolar Sensing**
- Senses between the lead tip and ring
- May reduce oversensing due to smaller sensing area

**Integrated Bipolar Sensing**
- Senses between the lead tip and the RV coil
- May cause potential oversensing due to larger sensing area
Insulation
All silicone is not the same

Many types of silicone were tested and one high performance silicone was purposefully selected for the demands of the Quattro ICD leads in vivo.

High Performance Silicone
- Used to avoid externalization (creep), abrasion, and crush

ETFE Coating
- Provides a necessary barrier between the cables and the silicone

55D Polyurethane
- The muscular area of the pocket can put high stresses on a lead
- A relatively stiff polyurethane (55D) covers the proximal length to protect against lead crush, lead-to-lead and lead-to-can abrasion

80A Polyurethane
- In the intercardiac space, forces are less but there is a greater need for flexibility to accommodate the movement of the heart
- A softer, more supple polyurethane (80A) is used as an overlay between the coils

Asymmetrical Design Advantage
- High-voltage defibrillation cable conductor
- Compression lumens
- Low-voltage ring electrode cable conductor
- Low-voltage helix electrode coil conductor

Compared to a symmetrical lead design, offsetting the coil and cable offers several advantages:
- Promotes reduced tip pressure and lead body flexibility
- Allows for greater insulation thickness between conductors to help reduce the risk of insulation failure
- Facilitates increased lead strength allowing room for two cables (1 cable for Model 6935M) with a 7 x 7 configuration (1 x 19 cable configuration for Model 6944)
- Designed to reduce stresses on the conductors in a crush situation, allowing for individual compression lumens to help reduce the risk of failure
Lead Monitoring Algorithms

Lead Integrity Alert (LIA)
Monitors the lead at all times to provide advance warning for lead fracture and extends the VF detection time.

Lead Noise Discrimination and Alert (LNDA)
Identifies oversensing due to noise artifacts, provides ability to withhold therapy and notifies clinician to potential lead noise.

Exclusive Medtronic Features

Tip seal
- designed to reduce fluid ingress and facilitate reinsertion of a stylet

Solid tip housing
- protects internal mechanisms from damage

Conductor cable to anode crimp joint
- is a reliable connection

Tensi-Lock™ cable
- design secures the tip assembly and provides greater lead strength, which may aid in the lead extraction

Isoglide™ overlay
- produces an isodiametric lead body facilitating lead passage durability and lead-to-lead interaction

Blue lead pin (DF4 models)
- provides additional visual confirmation during lead insertion into DF4 header device

Silicone backfilled defibrillation electrode
- reduces tissue growth

Redundant high-voltage connector
- in both RV and SVC defibrillation electrodes ensure uniform current distribution

DESIGNED FOR RELIABILITY.

WITH SMARTSHOCK™ TECHNOLOGY, WE’VE MADE THE WHOLE ICD SYSTEM SMARTER.
Quality measures during manufacturing ensure you’re consistently getting a quality product.

OVER 1 MILLION SPRINT QUATTRO™ LEADS HAVE BEEN IMPLANTED WORLDWIDE.

The Sprint Quattro™ lead is manufactured in Medtronic’s facility in Villalba, Puerto Rico.

Components are inspected and certified. The workforce is trained and certified every 6 months.

Medtronic’s systems, policies, and procedures limit the variability of products that are built by human beings.
Medtronic SureScan™ ICD and CRT-D

Medtronic SureScan ICD and CRT-D systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. When programmed to On, the Medtronic SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete transvenous SureScan system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. 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 ICD or CRT-D 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.

Indications
SureScan ICD systems are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. In addition, the 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.

SureScan CRT-D systems are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the classifications detailed in the specific device manuals. New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II. NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤ 50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post implant. Some CRT-D systems are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

Contraindications
SureScan defibrillation ICD and CRT-D systems are contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes, or patients with incessant VT or VF. For dual chamber and CRT-D 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 trans-thoracic defibrillation paddles directly over the device. Additionally, for CRT-D devices, certain programming and device operations may not provide cardiac resynchronization. Use of the device should not change the application of established anticoagulation protocols.

Patients and their implanted SureScan ICD and CRT-D systems must be screened to meet the following requirements for MRI: No lead extenders, lead adaptors, or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; and the system must be implanted in the left or right pectoral region. For pacemaker-dependent patients, it is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms. A higher pacing capture threshold may indicate an issue with the implanted lead. 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 on. It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks).

MR Scanning Conditions: Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T 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+unc must be ≤ 2.8 μT when the isocenter (center of the bore) is inferior to the C7 vertebra. Scans can be performed without B1+ restriction when the isocenter is at or superior to the C7 vertebra.

For SureScan defibrillation and CRT-D systems, continuous patient monitoring is required while MRI SureScan is programmed to On. Do not scan a patient without first programming MRI SureScan to On and do not leave the device in the MRI environment after the scan is complete. 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, device migration, infection, or erosion through the skin. Potential complications associated with cardiac rhythm devices include muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibration, thrombosis, thrombotic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial rub, infection, myocardial irritability, and pneumothorax. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block. 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 appropriate product MRI SureScan Technical Manual before performing an MRI Scan and see the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, 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.