12 YEARS PROVEN PERFORMANCE

Sprint Quattro™
Defibrillation Leads
Proven by Active Monitoring

Sprint Quattro Secure™ 6947 lead shows a **95% lead survival rate at 12 years** when measured by active monitoring.¹

<table>
<thead>
<tr>
<th>Year</th>
<th>Survival Rate (%)</th>
<th># Leads</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>96.5</td>
<td>3,556</td>
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<tr>
<td>2</td>
<td>95.3</td>
<td>2,377</td>
</tr>
<tr>
<td>3</td>
<td>94.7</td>
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<td>1,946</td>
</tr>
<tr>
<td>5</td>
<td>94.0</td>
<td>1,891</td>
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<tr>
<td>6</td>
<td>93.8</td>
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<tr>
<td>7</td>
<td>93.6</td>
<td>1,577</td>
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<td>8</td>
<td>93.4</td>
<td>1,489</td>
</tr>
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<td>9</td>
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<td>1,412</td>
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<tr>
<td>10</td>
<td>93.0</td>
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<tr>
<td>11</td>
<td>92.7</td>
<td>1,260</td>
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<tr>
<td>12</td>
<td>92.5</td>
<td>1,194</td>
</tr>
</tbody>
</table>

SPRINT QUATTRO™ MODEL 6947 HAS 12 YEARS OF PROVEN PERFORMANCE¹ BACKED BY A LIFETIME WARRANTY*  

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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*This lifetime limited warranty is applicable only to Sprint Quattro leads implanted after December 1, 2008. Some restrictions apply. The limited warranty covers the performance of the lead and may include some reimbursement to patients of unreimbursed medical expenses. Consult the written Limited Warranty document for eligibility requirements and details, a copy of which is included in each product package and can be provided upon request by contacting the Medtronic Warranty team at rs.warranty@medtronic.com.
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

**Pair Sprint Quattro™ with a Medtronic MRI 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: 6946M, 6947M, 6935M
- Lead Lengths: 55, 62 cm
- DF-1 Models: 6947, 6935
- Lead Lengths: 58, 65 cm

**Tips**
- True Bipolar Sensing
- Integrated Bipolar Sensing

**Ring**
- RV Electrode
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

ETF 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

DESIGNED FOR RELIABILITY.

Purposeful design decisions were made to produce a lead that lasts.
Lead Monitoring Algorithms

Lead Integrity Alert (LIA)\textsuperscript{11-14}
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\textsuperscript{™} cable
design secures the tip assembly and provides greater lead strength,\textsuperscript{5,6} which may aid in the lead extraction\textsuperscript{7,10}

Isoglide\textsuperscript{™} overlay
produces an isodiametric lead body facilitating lead passage durability and lead-to-lead interaction\textsuperscript{15}

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

Silicone backfilled defibrillation electrode
reduces tissue growth\textsuperscript{16}

Redundant high-voltage connector
in both RV and SVC defibrillation electrodes ensure uniform current distribution\textsuperscript{17}
**OVER 1 MILLION SPRINT QUATRO™ LEADS HAVE BEEN IMPLANTED WORLDWIDE.**

The Sprint Quatro™ lead is manufactured in Medtronic's facility in Villalba, Puerto Rico.

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

The system's policies, procedures, and regulations are designed to minimize the risk of product failure or injury to patients.

**Quality measures during manufacturing ensure you're consistently getting a quality product.**

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**References**

10. Eganmore CC, Gundersen BD, Studler WR, et al. Inappropriate shocks caused by St. Jude Medical. Total Sales of Sprint Quattro ICD leads may be reduced by programming more frequent atrial over-sensing and therapy to greater than 2.0 V and at 4.0 ms. A higher pacing capture threshold may be indicated in an unresponsive lead. A resynchronization algorithm at a pacing output of 5.0 V and at a pulse width of 1.2 ms in patients whose device will be programmed to an asynchronous mode when Medtronic recommends to the physician not to recommend to perform MRI scans during the lead maturation period (approximately 6 weeks).
11. MR Scanning Conditions: Patients may be scanned using a horizontal field, cylindrical bore, or open (bipole) 1.5T or 3T MRI system for high signal-to-noise imaging, maximum spatial gradient ≤ 2.8 μT, and maximum gradient slew rate performance per axis ≤ 200 T/m/s. 3T scanners must be operated in First Level Normal Operating Mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg, head SAR ≤ 3.2 W/kg). 3T scanners must be programmed to use Full Field of View Mode (FOV) ≤ 2.8 μT to prevent stimulation on leads resulting in patient discomfort or ventricular fibrillation.
12. SureScan ICD systems are indicated to provide ventricular anti-arrhythmic pacing and ventricular defibrillation for high energy power imaging, maximum spatial gradient ≤ 2.0 T/m, and maximum gradient slew rate performance per axis ≤ 20 T/m/s. 3T scanners must be operated in First Level Normal Operating Mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg, head SAR ≤ 3.2 W/kg). 3T scanners must be programmed to use First Level Normal Operating Mode. 3T must be ≤ 2.8 μT when the isocenter (center of the bore) is inferior to the C7 vertebra, ≤ 2.8 μT when it is equal to the C7 vertebra, ≤ 2.8 μT when the isocenter is superior to the C7 vertebra but inferior to the C7 vertebra, ≤ 2.8 μT when the isocenter is equal to or superior to the C7 vertebra.
13. For SureScan and CRT-D systems, continuous patient monitoring is required while MRI is performed.
14. MRI Scan and see the device manuals for detailed information regarding the MRI SureScan mode.
15. SureScan ICD and CRT-D systems are contraindicated for patients experiencing tachycardia episodes with transient or reversible causes, or patients without indication to VT or VF. For dual chamber and CRT-D devices, the device is contraindicated in patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF. For single chamber devices, the device is contraindicated to patients for whose primary disorder is atrial tachyarrhythmia.
16. AFib and atrial flutter, increased heart rate, and atrial fibrillation.
17. 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, but are not limited to, lead failure, lead dislodgement, lead breakage and lead erosion. Other potential complications such as hematoma, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve disease, fibrosis, thrombosis, thrombotic and an embolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial sac, infection, myocardial infarction, and pneumothorax. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, lead threshold elevation, or embolus. Potential/MRI complications include, but are not limited to, lead breakage and lead erosion, infection risk, lead malfunction, lead dislodgement, lead breakage and lead erosion, and other potential complications associated with device failure. See the appropriate product MRI Scan Technical Manual before performing an MRI Scan and see the device manuals for detailed information regarding the implant procedure, radiations, contraindications, earnings, 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.

Patients and their implanted SureScan ICD and CRT-D systems must be reprogrammed to meet the following requirements for MRI lead extension, lead adaptors, or abandoned leads present; no broken leads or leads with intermittent electrical contact are recommended. Lead implantation 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 using a ventricular (V)-lead pacing capture threshold is greater than 2.0 V at 4.0 ms. A higher pacing capture threshold may be indicated in an unresponsive lead. A resynchronization algorithm at a pacing output of 5.0 V and at a pulse width of 1.2 ms in patients whose device will be programmed to an asynchronous mode when Medtronic recommends to the physician not to recommend to perform MRI scans during the lead maturation period (approximately 6 weeks).
Brief Statement
Sprint Quattro™ Family of Leads

Indications
Medtronic Sprint Quattro leads are intended for pacing and sensing and/or defibrillation. Defibrillation leads have application for patients for whom implantable cardioverter defibrillation is indicated.

The Sprint Quattro MRI SureScan™ leads (which include specified lengths of Models 6935, 6935M, 6947, 6947M, and 6946M) are part of a Medtronic SureScan ICD or CRT-D system. Consult individual lead model technical manuals for more detail. A complete SureScan defibrillation or CRT-D system is required for use in the MR environment and includes a Medtronic SureScan device connected to Medtronic SureScan Leads.

Contraindications
The Sprint Quattro leads are contraindicated as described:
- Atrial use — for the sole use of detection and treatment of atrial arrhythmias.
- Ventricular use — for ventricular use in patients with tricuspid valvular disease or patients with mechanical tricuspid heart valves.
- For patients with transient ventricular tachyarrhythmias due to reversible causes (drug intoxication, electrolyte imbalance, sepsis, hypoxia or other factors (myocardial infarction, electric shock).
- Do not use in patients for whom a single dose of dexamethasone acetate and/or dexamethasone sodium acetate may be contraindicated (applies to all leads that contain these steroid configurations; see model manuals for specific dosage).

Warnings and Precautions
People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive certain forms of diathermy treatment. Diathermy treatments may result in serious injury or damage to an implanted device and lead system. Some lead models allow the use of therapeutic ultrasound; consult individual lead model technical manuals for more detail.

Do not use magnetic resonance imaging (MRI) on patients who have non-MR conditional versions/lengths of these leads implanted as part of a complete SureScan System. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias.

MRI SureScan leads only: The SureScan defibrillation system has been designed to minimize potential complications in the MRI environment. Potential MRI complications include, but are not limited to, lead electrode or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

See the MRI SureScan Technical Manual before performing an MRI Scan and Lead Technical 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 medtronic.com or mrisurescan.com.

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

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