# SPECIFICATIONS

Sprint Quattro Secure S MRI™ SureScan™
6935M

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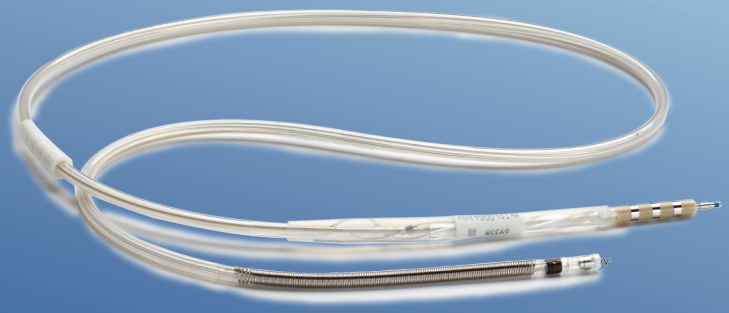
6935M



## Product specifications

| MR-conditional | |
|---|---|
| MR | Initial Implant<br>Existing Implant |

| Physical Characteristics | |
|---|---|
| Type | Single coil, tripolar |
| Fixation | Helix, active fixation |
| MR-conditional Lengths | 55, 62 cm |
| Not approved for MRI | 49, 72, 97 cm |

| Connector | |
|---|---|
| Quadripolar (three active circuits) | Four-pole inline configuration (DF4-LLHO) |

| Materials | |
|---|---|
| Conductors | MP35N coil<br>MP35N composite cables |
| Insulation | Silicone, PTFE, ETFE |
| Overlay | Isoglide Polyurethane |
| Tip electrode (pace, sense) | Platinized platinum alloy |
| Ring electrode (pace, sense) | Platinized platinum alloy |
| RV coil | Platinum-clad Tantalum |
| DF4 pin and ring | MP35N |
| Steroid type | Dexamethasone acetate and dexamethasone sodium phosphate |

| Diameters | |
|---|---|
| Lead body | 8.6 Fr (2.8 mm) |
| Tip | 8.6 Fr (2.8 mm) |
| Helix | 4.3 Fr (1.4 mm) |

- Dexamethasone acetate and dexamethasone sodium phosphate steroid-eluting
- Tripolar
- Screw-in
- Ventricular lead with RV defibrillation coil electrode

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## Lead introducer (recommended sizes)

| | |
|---|---|
| Without guide wire | 9.0 Fr (3.0 mm) |
| With guide wire | 11.0 Fr (3.7 mm) |

## Electrodes

| | |
|---|---|
| Defibrillation, RV coil | |
| Length | 57 mm |
| Surface area | 614 $mm^2$ |
| Ring, Surface area | 25.2 $mm^2$ |
| Helix, Surface area | 5.7 $mm^2$ |
| Spacing | 8 mm tip-ring<br>12 mm tip-distal RV coil |

**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 and 6947M) 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:
- For the sole use of detection and treatment of atrial arrhythmias
- In patients with tricuspid valvular disease and/or patients with mechanical tricuspid heart valves
- For patients with transient ventricular tachyarrythmias due to reversible causes (drug intoxication, electrolyte imbalance, sepsis, hypoxia) or other factors (myocardial infarction, electric shock)
- In patients for whom a single dose of 1.0 mg of dexamethasone acetate and dexamethasone sodium phosphate may be contraindicated

**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. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device. 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: A complete SureScan™ defibrillation system is required for use in the MR environment. Before performing an MRI scan, refer to the MRI Technical Manual for MRI-specific warnings and precautions. 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 1.5T 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. $B_{1+RMS}$ must be ≤ 2.8 μT when the isocenter (center of the bore) is inferior to the C7 vertebra. Scans can be performed without $B_{1+RMS}$ restriction when the isocenter is at or superior to the C7 vertebra.

**Potential Complications**
Potential complications include, but are not limited to, acceleration of ventricular tachycardia, air embolism, bleeding, body rejection phenomena which includes local tissue reaction, cardiac dissection, cardiac perforation, cardiac tamponade, chronic nerve damage, constrictive pericarditis, death, device migration, endocarditis, erosion, excessive fibrotic tissue growth, extrusion, fibrillation or other arrhythmias, fluid accumulation, formation of hematomas/seromas or cysts, heart block, heart wall or vein wall rupture, hemothorax, infection, keloid formation, lead abrasion and discontinuity, lead migration/ dislodgement, mortality due to inability to deliver therapy, muscle and/or nerve stimulation, myocardial damage, myocardial irritability, myopotential sensing, pericardial effusion, pericardial rub, pneumothorax, poor connection of the lead to the device, which may lead to oversensing, undersensing, or a loss of therapy, threshold elevation, thrombosis, thrombotic embolism, tissue necrosis, valve damage (particularly in fragile hearts), venous occlusion, venous perforation, lead insulation failure or conductor or electrode fracture.

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 heating and tissue damage resulting in loss of sensing or capture or both, 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* www.medtronic.com *or* www.mrisurescan.com.

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

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