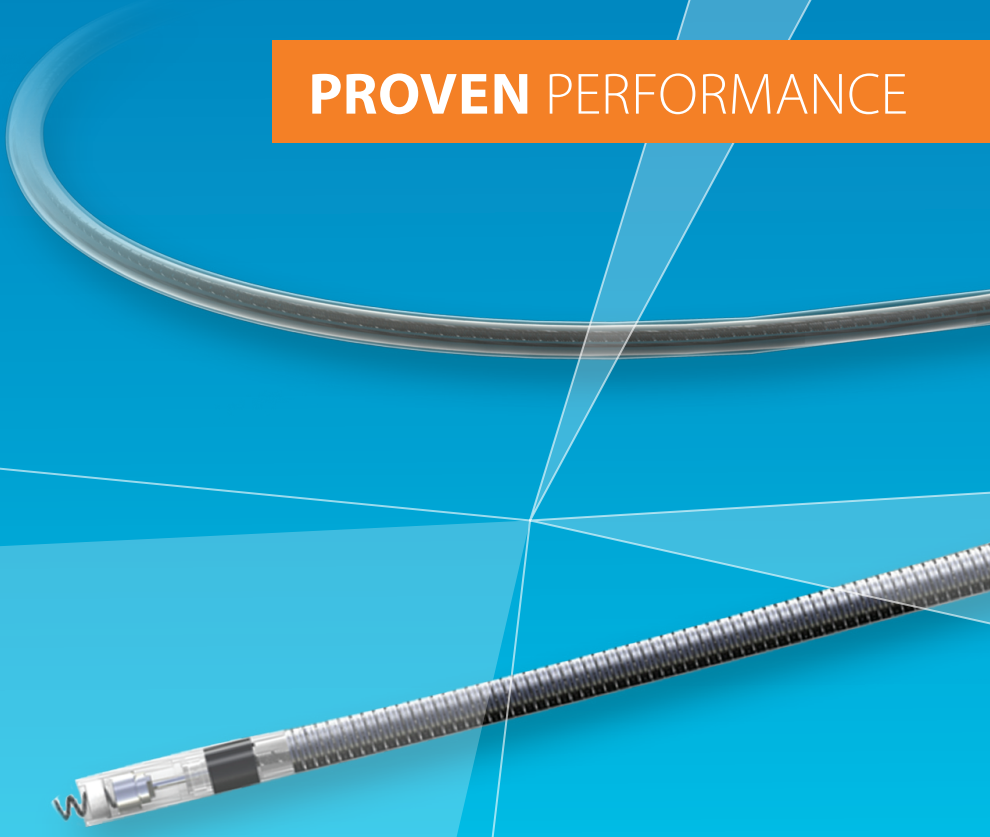
Medtronic

Sprint Quattro Secure S®

MODEL 6935M

Single Coil Active Fixation DF4 Defibrillation Lead

PROVEN PERFORMANCE



Specifications	Sprint Quattro Secure S Model 6935M
Polarity	Single coil, tripolar, true bipolar
Fixation	Helix, active fixation
Standard lengths	49, 55, 62, 72, 97 cm
Materials	
Primary insulation	Silicone
Redundant insulation	ETFE (cables) and PTFE (coil)
Overlay	Isoglide polyurethane
Steroid type	Dexamethasone acetate, (685 µg) and dexamethasone sodium phosphate (59 µg)
Electrodes	
RV coil	Platinum alloy-clad tantalum
Pace/sense	Platinized platinum alloy
Diameters	
Lead body	8.6 Fr (2.8 mm)
Defibrillation electrodes	8.6 Fr (2.8 mm)
Lead Introducer (recommended sizes)	
Without guide wire	9 Fr
With guide wire	11 Fr
Electrodes	
Defibrillation, RV coil	
Length	5.7 cm
Surface area	614 mm^2
Ring, surface area	25.2 mm^2
Helix, surface area	5.7 mm^2
Spacing	8 mm tip-ring 12 mm tip-RV electrode

Sprint Quattro Secure S®: Single Coil Active Fixation DF4 Defibrillation Lead
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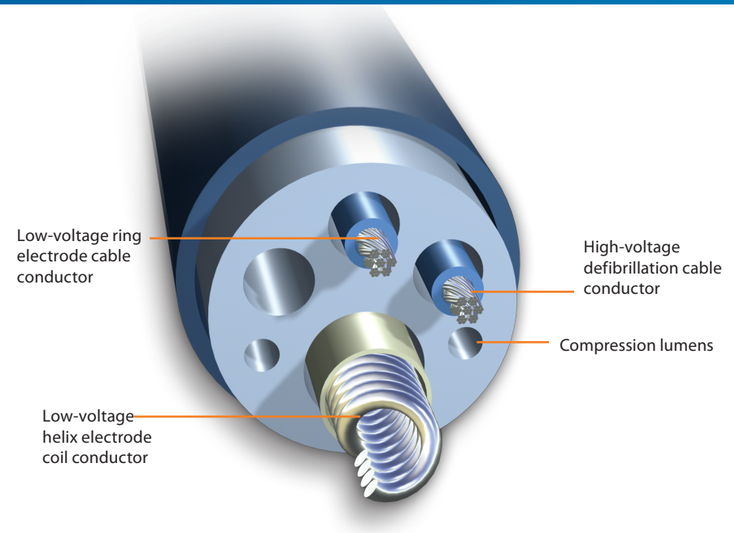
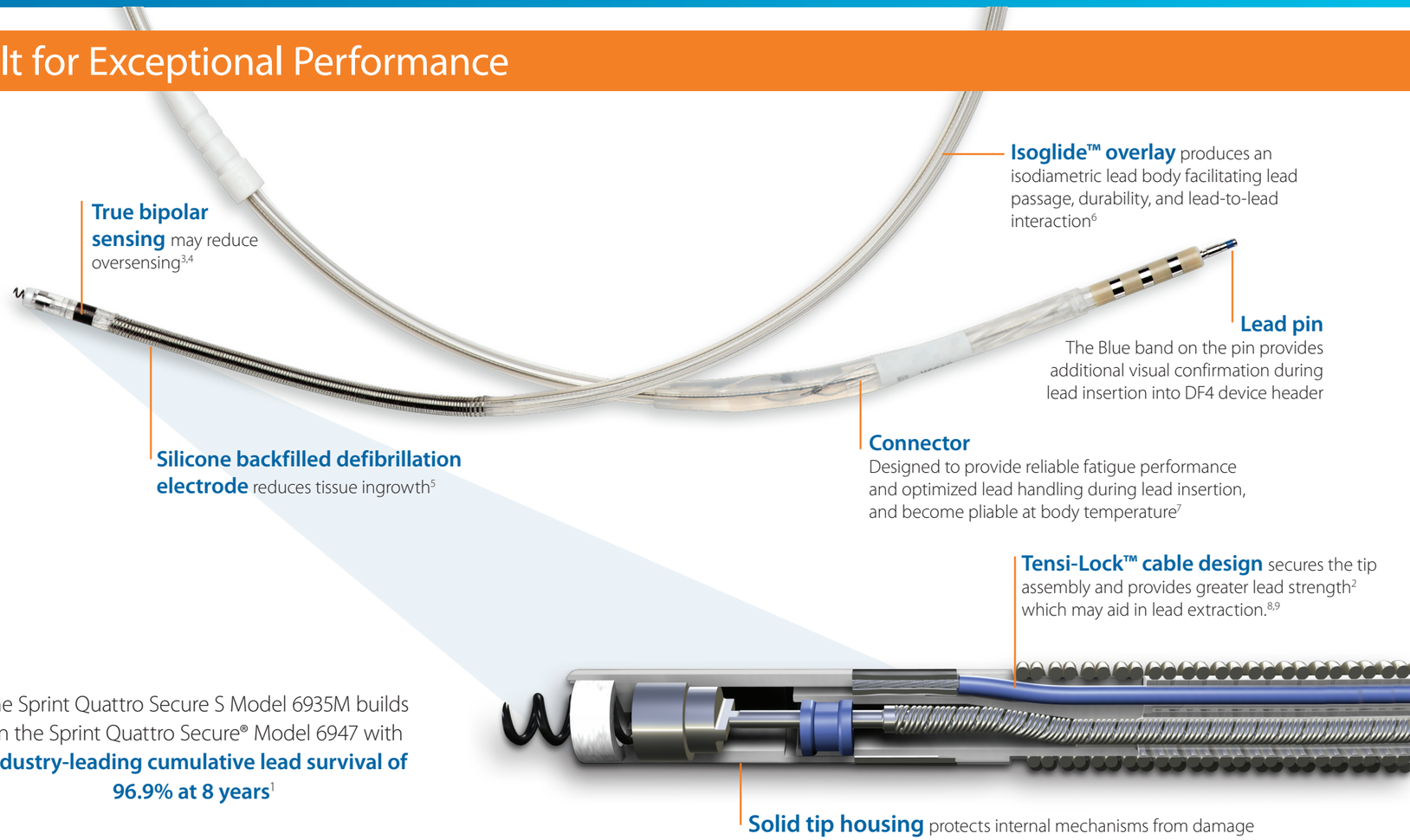


Built for Exceptional Performance



Asymmetrical Design Advantage

Compared to a symmetrical lead design, offsetting the coil and cables offers several advantages[2]:

- **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 with a 7×7 configuration (49 wires per cable)
- **Designed to reduce stresses on the conductors** in a crush situation, allowing for individual compression lumens to help reduce the risk of failure

The Sprint Quattro Secure S Model 6935M builds on the Sprint Quattro Secure® Model 6947 with **industry-leading cumulative lead survival of 96.9% at 8 years**[1]

Sprint Quattro Secure S Backed by the Most Comprehensive Performance Monitoring System in the Industry[1]

References

[1] Medtronic CRDM Product Performance Report, 2012 1st Edition, Issue 66.

[2] References to support greater lead strength are:
Medtronic data on file. October 17, 2008.
Medtronic data on file. October 4, 2000.
Medtronic data on file. August 7, 1997.
Medtronic data on file. November 2, 1995.
References to Support Asymmetrical Design are:
Medtronic data on file. August 3, 2012.
Medtronic data on file. August 7, 2006.
Medtronic data on file. April 9, 2012.
Medtronic data on file. August 2007.
Medtronic data on file. August 7, 1997.

[3] Sweeney MO, Ellison KE, Shea JB, Newell JB. Provoked and spontaneous high-frequency, low-amplitude, respirophasic noise transients in patients with implantable cardioverter defibrillators. *J Cardiovasc Electrophysiol.* April 2001;12(4):402-410.

[4] Weretka S, Michaelsen J, Becker R, et al. Ventricular oversensing: a study of 101 patients implanted with dual chamber defibrillators and two different lead systems. *Pacing Clin Electrophysiol.* January 2003;26 (1 Pt 1):65-70.

[5] Wilkoff BL, Belott PH, Love CJ, et al. Improved extraction of ePTFE and medical adhesive modified defibrillation leads from the coronary sinus and great cardiac vein. *Pacing Clin Electrophysiol.* March 2005;28(3):205-211.

[6] Haqqani HM, Mond HG. The Implantable Cardioverter-Defibrillator Lead: Principles, Progress, and Promises. *Pacing Clin Electrophysiol.* October 2009;32(10);1336-1353.

[7] Medtronic data on file. January 26, 2012.

[8] Smith MC, Love CJ. Extraction of Transvenous Pacing and ICD Leads. *Pacing Clin Electrophysiol.* June 2008;31(6):736-752.

[9] Wilkoff BL, Al-Khadra AS. The Technique of Transvenous Lead Extraction. Nonpharmachological Therapy of Arrhythmias for the 21st Century: The State of the Art. Futura Publishing Co, Inc., Armonk, NY, 1998.

Brief Statement

Indications

Medtronic leads are used as part of a cardiac rhythm disease management system. Leads are intended for pacing and sensing and/or defibrillation. Defibrillation leads have application for patients for whom implantable cardioverter defibrillation is indicated.

Contraindications

Medtronic leads are contraindicated for the following:

- ventricular use in patients with tricuspid valvular disease or a tricuspid mechanical heart valve
- patients for whom a single dose of 1.0 mg of dexamethasone acetate and dexamethasone sodium phosphate may be contraindicated
- Epicardial leads should not be used on patients with a heavily infarcted or fibrotic myocardium

Warnings and Precautions

- People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive 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, or the need to reprogram or replace the device.
- Do not use magnetic resonance imaging (MRI) on patients who have this device. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias.

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.

See the 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 Medtronic's website at www.medtronic.com.

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

www.medtronic.com

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