CAPSUREFIX NOVUS MRI™ SURESCAN®

5076 MRI Lead Specifications

MR-Conditional

MR	Initial Implant Existing Implant

Physical Characteristics

Polarity	Bipolar
Shape	Straight
Chamber	Atrium/Ventricle
Fixation	Helical Screw-Extendable/Retractable
MR-Conditional Lengths	35, 45, 52, 58, 65, 85 cm
Contraindicated for MRI*	110 cm
Connector	IS-1 BI

Materials

Inner/Outer Insulation	Silicone (MED-4719)
Conductor	MP35N
Distal Electrode	Platinized Helix
Ring Electrode	Connector pin: Platinized Connector ring: Stainless Steel

Diameter

Body	2.0 mm (6 Fr)
Helix	O.D. 1.17 mm
Ring Electrode	2.0 mm

Recommended introducer Size

Without Guide Wire	7 Fr
With Guide Wire	9 Fr

Electrode Surface Area

Helix	4.2 mm^2
Ring	22 mm^2

Other Characteristics

Steroid	DXAC (Dexamethasone Acetate) 1.0 mg maximum
Helix Length	1.8 mm
Tip-to-Ring Spacing	10 mm
Conductor Resistance	58 cm
Unipolar	33 Ω
Bipolar	61 Ω
Serial Prefix	PJN

Stylets

Inserted	Gray Straight
Packaged	(1) Blue J (1) Gray J (1) Blue Straight (1) Gray Straight (1) White J

* Lead length is contraindicated because it was not tested in the MR environment.

Brief Statement: SureScan® Pacing Systems

Medtronic SureScan pacing systems are MR Conditional and as such are designed to allow patients to undergo MRI under the specified conditions for use. A complete SureScan pacing system, which consists of an MRI SureScan device with two SureScan leads, is required for use in the MRI environment. Consult the device manuals to ensure all system components are MR Conditional.

Indications

Medtronic SureScan pacing systems are indicated for the following:

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity
- Accepted patient conditions warranting chronic cardiac pacing include:
  - Symptomatic paroxysmal or permanent second or third-degree AV block
  - Symptomatic bilateral bundle branch block
  - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders
  - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

Note: The Advisa MRI™ pacing system includes the following additional indication:

- Vasovagal syndromes or hypersensitive carotid sinus syndromes

The systems are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output
- VVI intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm

Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.

Contraindications

Medtronic SureScan pacing systems are contraindicated for:

- Concomitant implantation with another bradycardia device
- Concomitant implantation with an implantable cardioverter defibrillator

There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician.

- Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate
- Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter
- Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms
- Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance
- ATP therapy is contraindicated in patients with an accessory antegrade pathway

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 transthoracic defibrillation paddles directly over the device. Use of the device should not change the application of established anticoagulation protocols.

Patients and their implanted systems must be screened to meet the MRI Conditions of Use. Do not scan patients who do not have a complete Medtronic SureScan pacing system consisting of a SureScan device and two SureScan leads; patients who have broken, abandoned or intermittent leads; or patients who have a lead impedance value of $< 200\ \Omega$ or $> 1{,}500\ \Omega$. Do not scan patients with a SureScan pacing system implanted in sites other than the left or right pectoral region.

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 arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibrillation, 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. The SureScan 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 device manuals before performing an MRI Scan for detailed information regarding the implant procedure, indications, MRI conditions of use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Medtronic at 1 (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com.

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

www.medtronic.com

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for
physicians and medical professionals)

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