Medtronic

Medtronic SureScan™ Pacing, ICD, and CRT (CRT-D and CRT-P) Systems

Cardiology order form

Patient name: _____

DOB: _____

1. Your patient has an MRI ordered. Please confirm that your patient has a Medtronic SureScan pacing/ICD/CRT system, with SureScan lead(s), that meets the specified conditions for use. (Only CRT systems may have a 6725 pin plug used in the atrial port as part of an MR Conditional system.)

☐ YES, my patient has a complete Medtronic SureScan pacing/ICD/CRT system with no lead extenders, lead adaptors, or abandoned leads.

☐ NO, my patient does not have a complete SureScan IPG/ICD/CRT-D system.

A complete SureScan pacing system is required for use in the MR environment. Any other combination may result in a hazard to the patient during an MRI scan.

2. Please confirm that CareLink SmartSync™ MRI Access app should be used for this patient. MRI Access will automatically determine the appropriate mode and rate. (All Medtronic MR Conditional devices are supported EXCEPT Revo™ MRI and Attesta™ MRI. In addition, patients programmed to unipolar pacing or those with an IPG/ICD/CRT + Reveal LINQ™ are not supported by MRI Access.)

☐ YES, please proceed with using MRI Access before and after the MRI scan. **Skip** question 3.

☐ NO, MRI Access cannot be used with this patient. Continue to question 3.

3. Before the scan, your patient's IPG/ICD/CRT will be placed in a SureScan mode. How would you like your patient's device to be programmed? Please select a pacing rate to avoid competitive pacing. (Note that post-scan, device programming will be restored to original settings.)

☐ DOO pacing rate: _____ bpm ☐ AOO pacing rate: _____ bpm

☐ VOO pacing rate: _____ bpm ☐ ODO or OVO (no pacing support)

Cardiology clinician signature: _____

Cardiology clinician name: _____

Date: _____

To look up Medtronic device MR Conditionality, visit **medtronichub.com/mriverify.** Please note, access to patient search feature needs to be granted by Medtronic. Talk to your Medtronic representative for assistance in account setup.

Please note: Patients programmed to unipolar pacing, those with impedances below or above a specified range, or devices that have reached RRT, ERI, or EOS will experience a lockout that does not allow SureScan to be programmed On.

CareLink SmartSync™ MRI Access Application Brief Statement

Indications (or Intended Use) The CareLink SmartSync™ MRI Access Application (MRI app) is intended for use by a trained healthcare professional or Medtronic representative in a clinical or hospital environment to prepare a compatible Medtronic MR conditional implanted cardiac device for an MRI scan and to return the device to pre-scan settings after the MRI scan is complete. The MRI app is installed on a compatible tablet and communicates with the Medtronic Model 24967 Patient Connector to interrogate the implanted device, perform device checks, and engage the automatic algorithms that program the appropriate device parameters prior to and after the MRI scan.

Contraindications There are no known contraindications for the use of the MRI app.

Warnings and Precautions The MRI app does not screen patients or replace the patient screening process. A complete SureScan™ system is required for use in the MR environment. The tablet used with the MRI app and the Model 24967 Patient Connector are MR Unsafe and cannot be used in Zone 4 (magnet room), as defined by the American College of Radiology. See the CareLink SmartSync™ MRI Access Application Help, CareLink SmartSync™ MRI Access Application SureScan Labeling Supplement, and 24967 Patient Connector Technical Manual for detailed information regarding the procedure, indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events. Refer to the MRI Technical Manual for the implanted device for information on MRI warnings and precautions and potential adverse events. The MRI app turns on and turns off MRI SureScan mode. When MRI SureScan mode is turned on or turned off, the patient's implanted device must meet all the labeling conditions defined in the MRI Technical Manual. See the Device Manual for the implanted device 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.

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

Medtronic Model 24967 Patient Connector:

Indications The patient connector is intended to be used with Medtronic apps to interrogate, analyze, and/or program implantable Medtronic devices. The patient connector uses Bluetooth® technology to transmit that data to a Medtronic app for further processing. The patient connector is intended to be used by trained healthcare professionals or Medtronic representatives in a clinical or hospital environment.

Contraindications There are no known contraindications for the use of the Patient Connector.

Warnings and Precautions The Patient Connector may experience connectivity or performance issues. See the 24967 Patient Connector Technical Manual for details and troubleshooting instructions. See the 24967 Patient Connector Technical Manual before using the MRI app for detailed information regarding the indications or intended uses, 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.

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General IPG, CRT-P, ICD, and CRT-D with MRI Brief Statement

Indications

Transvenous Implantable Pulse Generators (IPGs) are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Dual chamber SureScan pacing systems are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony.

Transcatheter Implantable Pulse Generators (IPGs) are indicated for paroxysmal or permanent high-grade AV block in the presence of AF, or in the absence of AF when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy. It may also be used for symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy and for VDD pacing in patients with adequate sinus rates who may benefit from maintenance of AV synchrony.

Cardiac Resynchronization Therapy (CRT) IPGs are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have 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.

Implantable cardioverter defibrillators (ICDs) are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Some ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

CRT ICDs 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 following classifications: 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 ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

MRI SureScan IPGs, CRT IPGs, ICDs and CRT ICDs only:

Medtronic SureScan systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. When SureScan systems are programmed to On, the MRI 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. 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.

Contraindications

Transvenous IPGs and CRT-Ps are contraindicated for concomitant implantation with another bradycardia device or an implantable cardioverter defibrillator.

Transcatheter IPGs are contraindicated for patients who have the following types of medical devices implanted: an implanted device that would interfere with the implant of the Micra device, an implanted inferior vena cava filter, a mechanical tricuspid valve, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device. The device is contraindicated for patients who have the following conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤12.5 cm (4.9 in), or known intolerance to the materials listed in the Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated, or if the steroid dose from this device cannot be tolerated.

ICDs and CRT-Ds are contraindicated in patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis; patients who have a unipolar pacemaker implanted, patients with incessant ventricular tachycardia (VT) or ventricular fibrillation (VF), and patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

Warnings and Precautions Changes in a 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 under-detection, 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. For transcatheter devices when End of Service (EOS) condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads. The use of deactivated transcatheter devices in situ and an active transcatheter device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active transcatheter device, or an active transvenous pacemaker or defibrillator, next to an inactivated transcatheter device is unlikely to cause EMI or physical interaction. Currently recommended end of device life care for a transcatheter device may include the addition of a replacement device with or without explanation of the transcatheter device, which should be turned off. Additionally, for CRT-Ds and CRT-Ps, certain programming and device operations may not provide cardiac resynchronization. Also for CRT-Ps, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and/or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set. Use of the device should not change the application of established anticoagulation protocols.

MRI SureScan systems: Patients and their implanted 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. Before an MRI scan is performed on a patient implanted with the Micra device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks as defined in the device manuals.

Potential Complications Potential complications for transvenous systems 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, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for ICDs and CRT ICDs is the acceleration of ventricular tachycardia.
Potential complications for transcatheter IPGs include, but are not limited to, toxic/allergic reaction, oversensing, pacemaker syndrome, cardiac arrest, acceleration of tachycardia, necrosis, myocardial infarction and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, device embolization, hematoma, AV fistula, vessel dissection, infection, cardiac inflammation, and thrombosis.

MRI SureScan Systems: Potential MRI complications for the SureScan system include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or MRI induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse; spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan is programmed to On; potential for VT/VF induction when the patient is programmed to an asynchronous pacing mode during MRI SureScan; device heating resulting in tissue damage in the implant pocket or patient discomfort or both; or damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer. See the MRI SureScan Technical Manual before performing an MRI Scan.

See the appropriate product Device Manuals for detailed information regarding the implant procedure, indications (or intended use), contraindications, warnings, precautions, and potential complications/adverse events. See the appropriate product MRI SureScan Technical Manual before performing an MRI Scan. For further information, call Medtronic at 1 (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com or www.mrisurescan.com.

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