MR-CONDITIONAL CARDIAC DEVICE SUMMARY CHART

- The chart below contains all Medtronic cardiac devices FDA approved for MRI scans under specific conditions for use.
- If a model number and/or lead length is not listed, then it is not FDA approved for the MR environment.

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THERAPY	PRODUCT	MODEL NUMBER	MR CONDITIONAL	MR SYSTEM	SURESCAN™ LEADS
PACEMAKERS	Micra™ AV	MC1AVR1	Yes	Horizontal cylindrical bore magnet 1.5T or 3T	Not Applicable
	Micra™ VR*	MC1VR01			
	Azure™	W1DR01, W1SR01, W3DR01, W3SR01	Yes — if complete system is implanted with a SureScan pacemaker and SureScan lead(s)		1.5T or 3T pacing leads: 3830: 59, 69, 74 cm 4076: 35, 45, 52, 58, 65,85 cm 4074: 52, 58 cm 4574: 45, 53 cm 5086MRI: 45, 52, 58 cm 5076: 35, 45, 52, 58, 65, 85 cm
	Advisa MRI™	A2DR01, A3SR01			
	Attesta™	ATDR01, ATDRS1, ATDRL1, ATSR01			
	Sphera™	SPSR01, SPDR01, SPDRL1			
	Astra™	X1SR01, X3SR01, X1DR01, X3DR01			
	Revo MRI™†	RVDR01		Horizontal cylindrical bore magnet 1.5T	
CARDIAC DEFIBRILLATORS	Cobalt™ XT	DVPA2D1,** DVPA2D4, DDPA2D1,** DDPA2D4	Yes — if complete system is implanted with a SureScan ICD and SureScan lead(s)	Horizontal cylindrical bore magnet 1.5T or 3T	1.5T or 3T defibrillation leads: DF4: 6947M, 6946M, 6935M Lengths: 55, 62 cm DF-1: 6947, 6935 Lengths: 58, 65 cm See above for pacing leads.
	Cobalt™	DVPB3D1,** DVPB3D4, DDPB3D1,** DDPB3D4			
	Crome™	DVPC3D4, DVPC3D1,** DDPC3D4, DDPC3D1**			
	Primo MRI™	DDMD3D1,** DDMD3D4, DVMD3D1,** DVMD3D4			
	Visia AF MRI™	DVFB1D1,** DVFB1D4			
	Visia AF MRI™ S	DVFC3D1,** DVFC3D4			
	Evera MRI™ XT	DDMB1D4, DVMB1D4, DDMB1D1,** DVMB1D1**			
	Evera MRI™ S	DDMC3D4, DDMC3D1,** DVMC3D1,** DVMC3D4			
	Mirro MRI™	DVME3D1,** DVME3D4, DDME3D1,** DDME3D4			
CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS	Cobalt™ XT HF Quad CRT-D	DTPA2Q1,** DTPA2QQ	Yes — if complete system is implanted with a SureScan CRT-D and SureScan lead(s) or the Model 6725 atrial pin plug	Horizontal cylindrical bore magnet 1.5T or 3T	1.5T or 3T CRT leads: 4196, 4296,4396 Lengths: 78, 88 cm 4298, 4398, 4598, 4798 Lengths: 78, 88 cm See above for defibrillation and pacing leads.
	Cobalt™ XT HF CRT-D	DTPA2D4, DTPA2D1**			
	Cobalt™ HF Quad CRT-D	DTPB2Q1,** DTPB2QQ			
	Cobalt™ HF CRT-D	DTPB2D1,** DTPB2D4			
	Crome™ HF Quad CRT-D	DTPC2Q1,** DTPC2QQ			
	Crome™ HF CRT-D	DTPC2D1,** DTPC2D4			
	Claria MRI™ Quad CRT-D	DTMA1QQ, DTMA1Q1**			
	Claria MRI™ CRT-D	DTMA1D4, DTMA1D1**			
	Amplia MRI™ Quad CRT-D	DTMB1QQ, DTMB1Q1**			
	Amplia MRI™ CRT-D	DTMB1D4, DTMB1D1**			
	Compia MRI™ Quad CRT-D	DTMC1QQ			
	Compia MRI™ CRT-D	DTMC1D1**			
CARDIAC RESYNCHRONIZATION THERAPY PACEMAKERS	Percepta™ Quad CRT-P	W4TR01	Yes — if complete system is implanted with a SureScan CRT-P and SureScan lead(s) or the Model 6725 atrial pin plug	Horizontal cylindrical bore magnet 1.5T or 3T	1.5T or 3T CRT leads: 4196, 4296, 4396 Lengths: 78, 88 cm 4298, 4398, 4598, 4798 Lengths: 78, 88 cm See above for pacing leads.
	Percepta™ CRT-P	W1TR01			
	Serena™ Quad CRT-P	W4TR02			
	Serena™ CRT-P	W1TR02			
	Solara™ Quad CRT-P	W4TR03			
	Solara™ CRT-P	W1TR03			

The chart below contains Medtronic cardiac devices FDA cleared for MRI scans under specific conditions for use.

INSERTABLE CARDIAC MONITORS	Reveal LINQ™	LNQ11	Yes	Horizontal cylindrical bore magnet 1.5T or 3T	Not Applicable
	Reveal™ XT†	9529	Yes	Closed bore, cylindrical magnet 1.5T or 3T	

MR To obtain the MR Conditions for Use, go to **manuals.medtronic.com/manuals/mri** or **medtronic.com/us-en/healthcare-professionals/mri-resources/implantable-cardiac-devices.html**

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*The single chamber Micra Transcatheter Pacing System is being described herein as Micra VR in order to distinguish it from the dual chamber (VDD) Micra AV product. When information in this document relates to both Micra AV and VR, "Micra Transcatheter Pacing Systems" is used to represent the portfolio of devices.
†Product is no longer marketed in the United States.
**When a single coil SureScan defibrillation lead is used, a Medtronic DF-1 pin plug must be secured in the SVC port to make a complete SureScan DF-1 defibrillation system.

Brief Statement
Medtronic SureScan™ Portfolio for 1.5T and 3T MR-conditional Use

Indications
The SureScan MRI transvenous pacing systems 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.

The SureScan MRI defibrillation systems are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. In addition, the dual chamber devices are indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias.

The SureScan MRI CRT-D systems 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. Claria MRI™/Amplia MRI™ only: Some CRT-D system are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

The SureScan CRT-P Systems 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. Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity. Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications.

Micra™ Model MC1VR01 is indicated for patients with symptomatic paroxysmal or permanent high-grade AV block in the presence of AF. Along with Micra AV Model MC1AVR1, it is also indicated in the absence of AF as an alternative to dual chamber pacing, or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia/sinus pauses) when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy.

The Reveal LINQ™ Insertable Cardiac Monitor (ICM) is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated for patients with clinical syndromes or situations at increased risk of cardiac arrhythmias, or patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia.

MR Conditions of Use
Medtronic SureScan systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. Micra, Reveal LINQ, and transvenous SureScan system patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. When programmed to On, products with 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
The SureScan transvenous pacing and CRT-P systems are contraindicated for concomitant implantation with another bradycardia device or an implantable cardioverter defibrillator.

Micra IPG is 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 in the judgment of the implanting physician, 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 or 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 pre-medicated.

SureScan defibrillation and CRT-D systems are contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes, or patients with incessant VT or VF. For dual chamber and CRT-D devices, the device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF. For single chamber devices, the device is contraindicated for patients whose primary disorder is atrial tachyarrhythmia.

Reveal LINQ: There are no known contraindications for the implant of the Reveal LINQ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

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. Additionally, for CRT-D devices, certain programming and device operations may not provide cardiac resynchronization. Use of the device should not change the application of established anticoagulation protocols.

SureScan transvenous 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. Micra devices can't be scanned if any abandoned leads are present.

Potential Adverse Events
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 muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, 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. Other potential complications related to Micra are access site hematoma, AV fistulae, and vessel spasm, 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 MR-induced stimulation on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse. Potential complications of the Reveal LINQ device include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

See the appropriate product MRI SureScan Technical Manual before performing an MRI Scan and see the device manuals 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 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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