Pacemaker patients are more likely to need an MRI

86% of pacemaker patients are at least 65 years old and have multiple comorbidities for which MRI may be needed.1-4

The Prevalence of Common Comorbidities Increases Rapidly Over Age 652-4

Stroke is a leading cause of death and the leading cause of permanent disability in the United States.4,5
Historically, pacemaker patients are being denied access to MRI\(^6\)

0.32% of traditional pacemaker patients get an MRI annually versus 15% of non-pacemaker patients.\(^6\)

Now SureScan\(^\circledast\) patients are getting MRI scans

20% of patients with SureScan devices are estimated to undergo an MRI at 24 months post-implant.\(^7\)

Stroke patients with a pacemaker are not getting optimal diagnostic imaging

49% of non-pacemaker patients undergo an MRI within 3 days of stroke or TIA diagnostic vs. 0.34% of patients with a traditional pacemaker.\(^5\)

Of those patients receiving a scan, 47% had no previous MRI and/or CT scan prior to implantation of the SureScan pacing system (preliminary results of the SureScan post-approval study).\(^7\)
**ADISSA SR MRI™ SURESCAN**

Extending the SureScan family to patients indicated for single chamber pacing

*35% Greater Longevity*  
versus Adapta® SR®

Also included in the SureScan family are the Advisa DR MRI® and Revo DR MRI Pacemakers and the 5076 MRI and 5086MRI Pacing Leads.

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**MOST ADVANCED PACING TECHNOLOGY**

### Dual Chamber

<table>
<thead>
<tr>
<th>Feature</th>
<th>Adapta® DR MRI ADDR01</th>
<th>Advisa SR MRI A2DR01</th>
</tr>
</thead>
<tbody>
<tr>
<td>SureScan Technology</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>On Screen Cardiac Compass® and Rate Histograms</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Complete Capture Management™</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>High Upper Tracking Rates</td>
<td>210 bpm</td>
<td>210 bpm</td>
</tr>
<tr>
<td>Upper Sensor Rate</td>
<td>180 bpm</td>
<td>175 bpm</td>
</tr>
<tr>
<td>Rate Drop Response</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Programmable Polarity</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>AF Diagnostics</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Atrial Reactive ATP®</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>MVP®</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>EGM Storage/Maximum # of Episodes</td>
<td>48 sec/8</td>
<td>23 min/&gt; 100</td>
</tr>
<tr>
<td>Patient-Activated EGM Viewer</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Longevity*</td>
<td>9.0 years</td>
<td>8.7 years</td>
</tr>
</tbody>
</table>

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### Single Chamber

<table>
<thead>
<tr>
<th>Feature</th>
<th>Adapta® SR ADR01</th>
<th>Advisa SR MRI A3SR01</th>
</tr>
</thead>
<tbody>
<tr>
<td>SureScan Technology</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>On Screen Cardiac Compass® and Rate Histograms</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ventricular Capture Management®</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Upper Sensor rate</td>
<td>180 bpm</td>
<td>175 bpm</td>
</tr>
<tr>
<td>Programmable Polarity</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>EGM Storage/Maximum # of Episodes</td>
<td>48 sec/8</td>
<td>9 min/&gt; 30**</td>
</tr>
<tr>
<td>Patient-Activated EGM Viewer</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Longevity*</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>VVIR, 100% pacing, 2.5 V, 60 ppm, 0.4 ms, 500 ohms; VHR only, not AAIR.</em></td>
<td>8.7 years</td>
<td>11.7 years</td>
</tr>
</tbody>
</table>

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*The service life projections are based on the following assumption: VVIR, 100% pacing, 2.5 V, 60 ppm, 0.4 ms, 500 ohms. VVIR only, not AAIR.

**Includes 2 additional minutes of patient-activated episodes viewable only on the CareLink® Network.*
SUPPORTED BY EXTENSIVE EVIDENCE AND EXPERIENCE

- Industry proprietary computer model evaluated more than 2 million scenarios\(^\text{18}\)
- Over 3,600 patients studied in four prospective clinical studies\(^\text{19,20}\)
- 20.2\% of SureScan MRI pacemaker patients are estimated to undergo an MRI within 24 months post-implant in the US\(^7\)

Advisa DR MRI Clinical Trial\(^\text{19}\)
Advisa MRI SureScan system is safe and effective in the MRI environment
- Prospective, randomized, controlled, multi-center/263 patients
- Designed to confirm safety, effectiveness, and image quality for MR scans of chest area with no isocenter positioning restrictions

Results – Safety and Effectiveness
- No MRI-related complications
- No difference in pacing capture threshold changes between the MRI and control groups

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\* This study was conducted with the C1-T12 MRI scan exclusion zone in place.
The Importance of Cardiac MRI

- Cardiac MRI (CMR) is emerging as one of the fastest growing new fields of broad MR application.
- CMR can now be used for morphological and functional evaluation of the heart with good reliability and high spatial and temporal resolution.
- Cardiac MRI is employed mainly for assessing ischemic heart disease in a single examination, serving as a true comprehensive cardiac study.

Tested and Approved for Cardiac MRI

SureScan devices do not reduce diagnostic quality of Cardiac MRI (CMR) imaging.

Advisa DR MRI Clinical Study – CMR Image Quality Evaluation

Left ventricular (LV) and right ventricular (RV) cine long-axis

The Advisa DR MRI clinical study showed that 95 to 98% of cardiac MRI images are of diagnostic quality.

40% of all MRIs are performed in the torso area. Now, SureScan patients can easily undergo these MRI scans without any positioning restrictions.
Reducing unnecessary ventricular pacing has been shown to reduce the risk of AF by 80%.

- MVP has been shown to reduce unnecessary ventricular pacing.

Appropriate initiation of anticoagulants can reduce the risk of AF-related strokes by up to 80%.

- MVP has been shown to reduce unnecessary ventricular pacing.

Medtronic pacing devices have less than 5% false positive rates for AF detection. Therefore, clinicians can feel confident taking clinical action based on device reported AF without the need for intensive review of individual episodes.

Exclusive Atrial Reactive ATP + Atrial intervention + MVP is clinically proven to reduce permanent AF by 61% compared to standard dual chamber pacing.

Atrial Reactive ATP + Atrial intervention + MVP = 61% relative reduction in permanent AF

MINERVA Study

Objective
- To demonstrate benefit of Atrial ATP + Atrial intervention + MVP in delaying AF disease progression compared to standard dual chamber pacing

Study Design
- Randomized, prospective, international study
- Bradyarrhythmia patients with no history of permanent AF or third-degree AV block

Results
- Compared to the Control DDDR patients at 2 years, Atrial ATP + Atrial intervention + MVP patients experienced:
  - 61% relative reduction in permanent AF
  - 52% reduction in AF-related hospitalizations and ER visits

Risk of Permanent Atrial Fibrillation

Log Rank p-value comparing
- Control DDDR
- Atrial ATP + Atrial Intervention + MVP

61% relative reduction
Exclusive – Reactive Atrial ATP

Offers more opportunities to restore and maintain sinus rhythm

- In some patients, AT/AF episodes tend to change in pattern and rate. A patient’s AF may at one point transition back to AT or to atrial flutter, and then change once again into AF.

- Changes in a rhythm’s regularity and/or cycle length present new opportunities for ATP to be successful in terminating the arrhythmia

- Reactive ATP continuously monitors and allows for multiple deliveries of programmed ATP therapies for longer atrial episodes if the arrhythmia shifts in rate or regularity

In the MINERVA study, increased ATP efficacy is associated with lower risk of persistent AF

- This points to the second generation Atrial Reactive ATP’s ability to disrupt AT/AF episodes as the likely driver of the results seen in MINERVA

Brief Statement: Advisa DR MRI™ and Advisa SR MRI™ SureScan® Pacing Systems

The Advisa DR MRI and Advisa SR MRI SureScan pacing systems are MR Conditional, and as such designed to allow patients to undergo MRI under the specified conditions for use. A complete SureScan pacing system, which consists of an approved combination (see http://www.misurescan.com/ ) MRI SureScan device with SureScan lead(s), is required for use in the MRI environment. Consult the device manuals to ensure all system components are MR Conditional.

Indications: The Advisa DR MRI SureScan Model A2DR01 and Advisa SR MRI SureScan Model A3SR01 IPGs are indicated for use as a system. A complete SureScan pacing system, including an Advisa MRI SureScan IPG and SureScan lead(s), are required for use in the MRI environment.

The Advisa DR MRI and Advisa SR MRI SureScan 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

The Advisa DR MRI device is 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
- Vasovagal or vasopressor-related sinus pauses
- Bradyarrhythmia-tachyarrhythmia syndrome
- Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications

Contraindications: The Advisa DR MRI and Advisa SR MRI SureScan 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 implantation 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 thoracic 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 following requirements:
- no lead extenders, lead adaptors or abandoned leads
- no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history
- a SureScan pacing system that has been implanted for a minimum of 6 weeks
- a SureScan pacing system implanted in the left or right pectoral region
- pace polarity parameters set to Bipolar for programming MRI SureScan to On
- pacing capture thresholds of ≤ 2.0 volts (V) at a pulse width of 0.4 milliseconds (ms)
- a lead impedance value of ≥ 200 ohms (Ω) and ≤ 1500 Ω
- a SureScan system implanted in the left or right pectoral region
- pacing capture thresholds of ≤ 2.0 volts (V) at a pulse width of 0.4 milliseconds (ms)
- a lead impedance value of ≥ 200 ohms (Ω) and ≤ 1500 Ω
- 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 on

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, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hemotoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to, failure mode, insulation failure, 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) 228-2518 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.