References
9. Advisa DR MRI™ SureScan A2DR01, ADVISA SR MRI™ SureScan A3SR01 Clinician Manual.
22. Data from 2010 MarketScan® Commercial and Medicare databases, as presented at Tuven Health Analytics, Inc. were used to characterize non-pacemaker and pacemaker cohorts and utilization or radiology services. Cohorts were matched based on age, gender, and co-morbidities.
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
Now patients with SureScan® devices are getting MRI scans

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

Historically, pacemaker patients are being denied access to MRI

0.32% of traditional pacemaker patients get an MRI annually versus 15% of non-pacemaker patients.

 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.

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).
Extending the SureScan family to patients indicated for single chamber pacing

Advisa SR MRI™+
SURESCAN
WITH 5086MRI

Also included in the SureScan family are the Advisa DR MRI and Revo DR MRI SureScan pacemakers.

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MOST ADVANCED PACING TECHNOLOGY

**Dual Chamber**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Advisa® DR MRI® ADDR01</th>
<th>Advisa DR MRI™+ A2DR01</th>
</tr>
</thead>
<tbody>
<tr>
<td>SureScan Technology</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Full body MRI access with no position restrictions</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>Proven to extend longevity of the device by up to one year‡</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>High Upper Tracking Rates</td>
<td>210 bpm</td>
<td>210 bpm</td>
</tr>
<tr>
<td>Provide pacing support at higher heart rates for active and younger patients</td>
<td></td>
<td>✓</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>May reduce the frequency of syncopal episodes§</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Programmable Polarity</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>May reduce the likelihood for lead modification post-implant</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>AF Diagnostics</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Atrial Reaction ATP®</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>MVP®</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Reducing unnecessary ventricular pacing has been shown to reduce the risk of AF® MVP has been shown to reduce unnecessary ventricular pacing</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 (DDD, 100% pacing, 2.5 V, 60 ppm, 500 ohms)</td>
<td>9.0 years</td>
<td>8.7 years</td>
</tr>
</tbody>
</table>

**Single Chamber**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Advisa SR® ADSR01</th>
<th>Advisa SR MRI™+ A3SR01</th>
</tr>
</thead>
<tbody>
<tr>
<td>SureScan Technology</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Full body MRI access with no position restrictions</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>Provides confidence in your patients’ safety with automatic threshold measurements and adjustments</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>May reduce the likelihood for lead modification post-implant</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>8.7 years</td>
<td>11.7 years</td>
</tr>
</tbody>
</table>

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† Advisa SR MRI is only approved for use with the 5086MRI lead.
‡ 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\(^\text{7}\)

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

\(^\text{18}\) This study was conducted with the C1-T12 MRI scan exclusion zone in place.
FULL BODY MRI ACCESS
NO POSITIONING RESTRICTIONS FOR MR SCANS

40% of all MRIs are performed in the torso area. Now, SureScan patients can easily undergo these MRI scans without any positioning restrictions.22

Tested and Approved for Cardiac MRI
SureScan devices do not reduce diagnostic quality of Cardiac MRI (CMR) imaging23

The Advisa DR MRI clinical study showed that 95 to 98% of cardiac MRI images are of diagnostic quality.23

The Importance of Cardiac MRI
• Cardiac MRI (CMR) is emerging as one of the fastest growing new fields of broad MR application24
• CMR can now be used for morphological and functional evaluation of the heart with good reliability and high spatial and temporal resolution24
• Cardiac MRI is employed mainly for assessing ischemic heart disease in a single examination, serving as a true comprehensive cardiac study24
CLINICALLY PROVEN
TO BETTER DETECT AND TREAT AF
ADVISA DUAL CHAMBER PACEMAKER

Reducing unnecessary ventricular pacing has been shown to reduce the risk of AF.\textsuperscript{25,26} It has been shown to reduce unnecessary ventricular pacing.\textsuperscript{17}

Appropriate initiation of anticoagulants can reduce the risk of AF-related strokes by up to 80%.\textsuperscript{29} Medtronic pacing devices have less than 5% false positive rates for AF detection.\textsuperscript{15,30} Therefore, clinicians can feel confident taking clinical action based on device reported AF without the need for intensive review of individual episodes.

23 minutes of high quality EGM storage visible through the CareLink Network. Cardiac Compass report provides AT/AF burden information.

49% of patients with a stroke or TIA diagnosis receive an MRI within 3 days.\textsuperscript{6}

Exclusive Atrial Reactive ATP + Atrial intervention + MVP is clinically proven to reduce permanent AF by 61% compared to standard dual chamber pacing.\textsuperscript{31}

Atrial Reactive ATP + Atrial intervention + MVP = 61% relative reduction in permanent AF\textsuperscript{31}

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\textsuperscript{31}
- 52% reduction in AF-related hospitalizations and ER visits\textsuperscript{31}

Risk of Permanent Atrial Fibrillation\textsuperscript{31}

\begin{center}
\textbf{Log Rank p-value comparing}
\end{center}

- Control DDDR
- Atrial ATP + Atrial Intervention + MVP
Clinically Proven to better detect and treat AF

- 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 A3DR01 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
  - Bradyarrhythmia or tachyarrhythmia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
- Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with persistent AF.
- ATP therapy 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 all 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 transcutaneous 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.
- Pacemaker polarity set to Bipolar for programming MRI SureScan to ON.
- Pacing capture thresholds ≤ 2.0 volts (V) at a pulse width of 0.4 milliseconds (ms).
- Lead impedance value ≤ 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, 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.

* The ATP studied in the MINERVA trial is available in our Advisa MRI and Revo MRI® dual chamber pacemakers.