References
2. National Cancer Institute April 2009. Us estimated complete prevalence including counts by age on 1/1/2006. Based on population

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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.45
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.\(^6\)

**Pacemaker Cohort** (n = 27,580)
% of patients with traditional pacemaker receiving an MRI annually

**Non-Pacemaker Cohort** (n = 27,580)
% of patients receiving an MRI annually

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

**MRI Rate Following Implant of Full SureScan System**
Post-Approval Study (n = 2,637)

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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.\(^6\)

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).\(^7\)

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* Patient cohorts were matched so both represent a group of patients with the same
  1) Gender, 2) Age, 3) Major comorbidities.
INTRODUCING ADVISA MRI™

Now two generations ahead in pacemakers approved for MRI
- Most advanced pacing technology
- Only pacing technology FDA-approved for full body MRI use
- Designed and tested for cardiac MRI
- Proven reduction of progression to permanent AF

NO COMPROMISES

Most Advanced Pacing Technology

<table>
<thead>
<tr>
<th>Feature</th>
<th>Adapta™</th>
<th>Revo MRI11</th>
<th>Advisa MRI12</th>
</tr>
</thead>
<tbody>
<tr>
<td>SureScan Technology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full body MRI access with no position</td>
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<td>●</td>
<td>●</td>
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<tr>
<td>restrictions</td>
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<tr>
<td>MVP*</td>
<td>●</td>
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<td>●</td>
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<tr>
<td>Reducing unecessary ventricular pacing</td>
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<tr>
<td>has been shown to reduce the risk of AF</td>
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<tr>
<td>16</td>
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<tr>
<td>MVP has been shown to reduce</td>
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<tr>
<td>unnecessary ventricular pacing</td>
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<tr>
<td>Complete Capture Management*</td>
<td>●</td>
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<tr>
<td>proven to extend longevity of the device</td>
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<tr>
<td>by up to one year</td>
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<td>18</td>
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<tr>
<td>Higher Upper Tracking Rates</td>
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<tr>
<td>provide pacing support at higher heart</td>
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<td>rates for active and younger patients</td>
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<tr>
<td>Rate Drop Response</td>
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<tr>
<td>may reduce the frequency of syncopal</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>episodes19,20</td>
<td></td>
<td></td>
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<tr>
<td>Programmable Polarity</td>
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<td>●</td>
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<tr>
<td>may reduce the likelihood for lead</td>
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<tr>
<td>modification post-implant</td>
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<tr>
<td>AF Diagnostics</td>
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<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Atrial ATP – including Reactive ATP</td>
<td>●</td>
<td>●</td>
<td>●</td>
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<tr>
<td>EGM Storage/Maximum Number of Episodes</td>
<td>48 sec/8</td>
<td>17 min/55</td>
<td>23 min/&gt; 100</td>
</tr>
<tr>
<td>Patient-Activated EGM Viewer</td>
<td>●</td>
<td></td>
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</tr>
</tbody>
</table>

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.
SUPPORTED BY EXTENSIVE EVIDENCE AND EXPERIENCE

- Industry proprietary computer model evaluated more than 2 million scenarios
- Over 3,300 patients studied in three prospective clinical studies
- 20.2% of SureScan MRI pacemaker patients are estimated to undergo an MRI within 24 months post-implant in the US

Advisa MRI Clinical Trial

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

![Graph showing change in atrial pacing capture threshold (V)]

- MRI (n = 141)
- Control (n = 75)

![Graph showing change in ventricular pacing capture threshold (V)]

- MRI (n = 149)
- Control (n = 80)
FULL BODY MRI ACCESS
NO POSITIONING RESTRICTIONS FOR MR SCANS

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

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

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

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\textsuperscript{13-16}

- MVP\textsuperscript{*} has been shown to reduce unnecessary ventricular pacing\textsuperscript{7}

- Appropriate initiation of anticoagulants can reduce the risk of AF-related strokes by up to 80\%\textsuperscript{26}

- Medtronic pacing devices have less than 5\% false positive rates for AF detection.\textsuperscript{27,28} 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\textsuperscript*} Network. Cardiac Compass\textsuperscript*} 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{9}

Atrial Reactive ATP + Atrial intervention + MVP = 61\% relative reduction in permanent AF\textsuperscript{9}

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{9}
- 52\% reduction in AF-related hospitalizations and ER visits\textsuperscript{9}

Risk of Permanent Atrial Fibrillation\textsuperscript{9}

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

CLINICALLY PROVEN TO BETTER DETECT AND TREAT AF
Excluding – 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 AF⁹
• 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.

**Risk of Persistent AF⁹ (episodes longer than 7 days)**

<table>
<thead>
<tr>
<th>Observation Period (month)</th>
<th>0.00</th>
<th>0.10</th>
<th>0.20</th>
<th>0.30</th>
<th>0.40</th>
<th>0.50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control DDDR vs aATP + Atrial Intervention + MVP (ATP success ≤ 43%)</td>
<td>34%</td>
<td>28%</td>
<td>15%</td>
<td>12%</td>
<td>8%</td>
<td>5%</td>
</tr>
<tr>
<td>aATP + Atrial Intervention + MVP (ATP success &gt; 43%)</td>
<td>34%</td>
<td>28%</td>
<td>15%</td>
<td>12%</td>
<td>8%</td>
<td>5%</td>
</tr>
</tbody>
</table>

**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.

**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:**
• Various degrees of AV block to maintain the atrial contribution to cardiac output
• SVT 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.

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• 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.

**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 other complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to:
• Valve damage, fibrosis, thrombosis, thrombotic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial rub, infection, myoccardial irritability, and pneumothorax. Other potential complications related to the lead may include lead dislodgment, 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, 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.