WORLD’S SMALLEST, LONGEST-LASTING WIRELESS, MRI PACEMAKER*

Assurity MRI™ Pacemaker | Tendril MRI™ Lead
Assurity MRI™ Pacemaker

SJM MRI Activator™ Handheld Device

Tendril MRI™ Lead
**COMPARABLE LEAD PERFORMANCE: PROVEN RELIABILITY**

<table>
<thead>
<tr>
<th></th>
<th>TENDRIL MRI™ LEAD†</th>
<th>TENDRIL™ STS LEAD‡</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WORLDWIDE SALES</strong></td>
<td>214,689 leads</td>
<td>1,100,386 leads</td>
</tr>
<tr>
<td><strong>WORLDWIDE MALFUNCTION RATES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abrasion</td>
<td>0.005%</td>
<td>0.041%</td>
</tr>
<tr>
<td>Fracture</td>
<td>0.007%</td>
<td>0.004%</td>
</tr>
<tr>
<td><strong>WORLDWIDE CUSTOMER COMPLAINT RATES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dislodgement</td>
<td>0.083%</td>
<td>0.204%</td>
</tr>
<tr>
<td>Perforation</td>
<td>0.019%</td>
<td>0.022%</td>
</tr>
</tbody>
</table>
Clinical Evidence

- Demonstrated to reduce distal heating
- Allows 1.5T MRI scans
- Clinical use since 2011

Worldwide Acceptance
with over 200,000 leads implanted in last six years.
ELIMINATE PACEMAKER MRI REPROGRAMMING

May reduce the time, effort, space and patient inconvenience associated with pre/post MRI scan reprogramming.

SJM MRI ACTIVATOR™ HANDHELD DEVICE

MRI Ready pacemakers work with the SJM MRI Activator™ device, which triggers pre-established MRI appropriate settings.

Easy to use or acceptable according to 99% of U.S. clinical trial respondents.⁴
**MRI PATIENT WORKFLOW TRADITIONAL PROCESS**

1. **Patient needs an MRI scan**
2. **Patient goes to cardiology center or physician goes to MRI clinic**
3. **Device is programmed to temporary MRI settings**
4. **Patient has MRI scan**
5. **Patient goes to cardiology center or physician goes to MRI clinic**
6. **Device reprogrammed back to pre MRI scan settings**
7. **Patient goes home**

**MRI PATIENT WORKFLOW SJM MRI ACTIVATOR™ DEVICE**

1. **Patient needs an MRI scan**
2. **Patient goes to cardiology center for device check**
3. **Patient has MRI scan**
4. **Patient goes home**
MRI READY PACEMAKERS WORK WITH THE MERLIN™ PCS, ALLOWING THE PROGRAMMING OF MRI SETTINGS.
MERLIN.NET™ PCN INCLUDES CUSTOMIZED ALERTS FOR PATIENT SAFETY THAT NOTIFIES PHYSICIAN IF DEVICE SETTINGS HAVE NOT BEEN RESET.
MANAGING RISK FOR DEVICE PATIENTS

Patients who are at risk benefit from early detection.

**EXAMPLE: ASYMPOTOMATIC ATRIAL FIBRILLATION AND STROKE RISK**

- **2.5x**
  - Increased Stroke Risk
  - for pacemaker patients with device detected asymptomatic atrial tachyarrhythmias (AT/AF) \( p = 0.007 \)^4

- **35%**
  - of pacemaker patients have asymptomatic AT/AF^4

- **AT/AF EPISODES AS SHORT AS 6 MINUTES**
  - in duration increase the risk of stroke^4

- **35 DAYS**
  - = Median Time to first detection of asymptomatic AT/AF by pacemakers^4

**WIRELESS DEVICES** enable early detection of AT/AF to reduce patient risk of stroke.
ENHANCING PATIENT COMFORT

- Pacemaker patients frequently complain of device discomfort
- Female patients more concerned with cosmesis

ASSURITY MRI™ PACEMAKER IS...

- Smallest RF pacemaker in the world*
- 15% thinner than competitive pacemakers5
- 20% lighter than conventional SJM™ pacemakers6

SMALLER DEVICES

with a unique organic shape and outstanding longevity, means fewer potential complications7,8 and greater patient comfort.
SMALLER SIZE

**ASSURITY MRI™ PACEMAKER**
(47 mm x 50 mm x 6 mm)

10.4 cc  
6 mm

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**MEDTRONIC ADVISA MRI™ DR PACEMAKER**
(45 mm x 51 mm x 8 mm) - no RF

12.7 cc  
7.5 mm

**BIOTRONIK ELUNA™ PACEMAKER**
(53 mm x 44.5 mm x 6.5 mm)

12.0 cc  
6.5 mm

**BOSTON SCIENTIFIC ACCOLADE™ MRI DR PACEMAKER**
(44.5 mm x 50.2 mm x 7.5 mm)

13.7 cc  
7.5 mm

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**ASSURITY MRI™ PACEMAKER** The world’s smallest, longest-lasting wireless MRI pacemaker*
**LONGER-LASTING**

**ASSURITY MRI™ PACEMAKER**

**vs.**

**MEDTRONIC ADVISA MRI™ DR PACEMAKER**

A,V = 2.5 V @ 0.4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON.

E F

8.6 yr DR

9.4 yr DR

**ASSURITY MRI™ PACEMAKER**

**vs.**

**BIOTRONIK ELUNA™ PACEMAKER**

A,V = 2.5 V @ 0.4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON.

E F

8.9 yr DR

9.4 yr DR

**ASSURITY MRI™ PACEMAKER**

**vs.**

**BOSTON SCIENTIFIC ACCOLADE™ MRI DR PACEMAKER**

A,V = 2.5 V @ 0.4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON.

E F

7.6 yr DR

9.4 yr DR

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**EXTENDED LONGEVITY**

- Reduced need for frequent replacements
- May lower risk of infection and reduce healthcare cost7,9-11
- Lower overall cost of device ownership
**INDUSTRY-LEADING DEVICE WARRANTY**

<table>
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<tr>
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<th>ST. JUDE MEDICAL ASSURITY MRI™ DEVICE</th>
<th>MEDTRONIC ADVISA MRI™ DEVICE</th>
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<th>BIOTRONIK ELUNA™ DEVICE</th>
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<tbody>
<tr>
<td><strong>SR</strong></td>
<td>10</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>DR</strong></td>
<td>8</td>
<td>5</td>
<td>DR: 5</td>
<td>DR EL: 8</td>
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<td><strong>SMALLER DEVICE</strong></td>
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<td><strong>LONGEVITY</strong></td>
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†Available outside the U.S. since 2011.
‡Available outside the U.S. since 2009.


**The SJM MRI Activator™ device is designed to enable/disable pre-programmed MRI settings quickly and easily pre- and post-scan; do not take the SJM MRI Activator device into the MRI magnet/scanner room.

Indications: Dual-Chamber Pacing (Dual-chamber pulse generators, CRT-Ps) is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular Pacing is indicated for patients with significant bradycardia and: normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. MR Conditional System: MR Conditional pacemakers are conditionally safe for use in the MRI environment when used in a complete MR conditional system and according to instructions in the MRI procedure document for the St. Jude Medical™ MR conditional system. Contraindications: Dual-Chamber Pacing (Dual-chamber pulse generators, CRT-Ps), though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction. For specific contraindications associated with individual modes, refer to the programmer’s on-screen help. Warnings: To prevent permanent damage to the device and tissue damage at the electrode/tissue interface: Electrosurgery. Do not use electrosurgical devices in the vicinity of an implanted device. If electrocautery is necessary, use a bipolar cautery or place the indifferent electrode as far from the device as possible. Lithotripsy: Do not focus a lithotripsy beam within 6 inches of the device. Program the device to Sensor Off prior to lithotripsy to prevent inappropriate increases in pacing rate. A thorough assessment of device function with special attention to the sensor should be performed following exposure to lithotripsy. Therapeutic Radiation: Do not use ionizing radiation in the vicinity of an implanted device. Radiation therapy may damage the electronic circuitry of the device. Ultrasound Treatment: Do not use therapeutic ultrasound within 6 inches of the device. Ventricular Sensing: In CRT-P, Ventricular Sensitivity should be programmed to the highest setting (lowest sensitivity) that will provide ventricular sensing with adequate sensing margin. Left ventricular lead dislodgement, to a position near the atria, can result in atrial oversensing and ventricular inhibition. Perform a thorough assessment of device function following exposure to any of the above. Backup VVI Operation: In rare instances, the device may revert to Backup VVI operation settings. These values are not programmable. When the device has reverted to Backup VVI operation, the programmer displays a pop-up message indicating that the device is operating at the Backup VVI values. Press [Continue] and follow the on-screen instructions. Elective Replacement Indicator (ERI): At ERI, the nominal life of the device is three or six months. When the device exhibits signs of ERI it should be replaced expeditiously. Patient follow-up visits should be scheduled at an appropriate frequency so that ERI can be detected well before End-of-Life (EOL). Noninvasive Programmed Stimulation (NIPS): Life-threatening ventricular tachycardia or fibrillation may occur during NIPS, therefore: (1) closely monitor the patient, and (2) make defibrillation and reusability assessment, and trained personnel, readily available during testing. Only physicians trained in tachycardia induction and reversion protocols should use NIPS. For more information on NIPS, refer to the programmer’s on-screen help. Ventricular Support Pacing during NIPS testing (Dual-chamber pulse generators, CRT-Ps) is delivered in the VOO mode. The specific indications and contraindications for VOO mode can be found on the program’s on-screen help. Precautions: For single use only. Device Communication: Communication with the device can be affected by electrical interference and strong magnetic fields. If this is a problem, turn off nearby electrical equipment or move it away from the patient and the programmer. If the problem persists, contact St. Jude Medical. Suboptimal RF Communication: For devices with RF telemetry capability, the Merlin™ PCS indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the programmer and the Merlin™ Antenna. CT Scans: CT scans, due to their increased power levels and long exposure times, have the remote possibility of interfering with implanted devices. The potential interference is transient and occurs only when the X-ray signal is present. Continuous exposure may cause a temporary sensor rate increase. In addition, there is a remote possibility for a device to intermittently oversense while the CT scanning beam is directly over the implanted device.