



Abbott

AVEIR™ AR2 ATRIAL LEADLESS PACEMAKER



A COMPLETE LEADLESS SOLUTION INCLUDES ATRIAL PACING

Abbott, the exclusive provider of atrial leadless pacemakers (LPs), continues to advance cardiac care with the launch of its second-generation device – AVEIR AR2 Atrial LP – delivering the proven benefits of leadless pacing to patients.

+25%

MORE BATTERY LIFE in all single/dual chamber pacing modes without increasing device size.^{1*}



10+
YEARS

OVER 10 YEARS OF PROJECTED BATTERY LIFE for SND patients (AAI(R) and AAI(R) + VVI).^{1**}

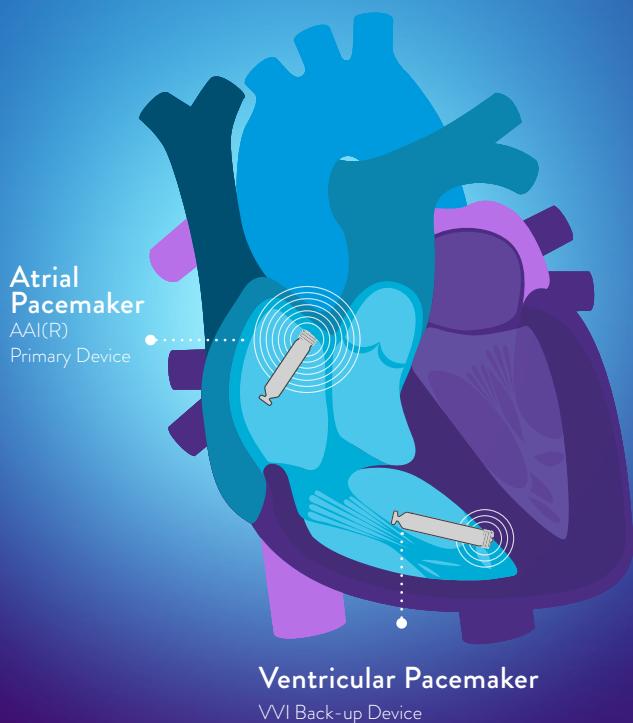
* AVEIR AR2 LP model LSP203A compared to predecessor AVEIR AR LP LSP201A: AAI(R) at 1.5 V, 300 ohms, 0.4 ms, 50 bpm, 100% atrial pacing. DDD(R) at: 1.5 V, 300 ohms, 0.4 ms, 50 bpm, 50% atrial pacing, i2i setting 4/4.

** AVEIR AR2 LP LSP203A: AAI(R) and AAI(R)+VVI at 1.5 V, 300 ohms, 0.4 ms, 50 bpm, 100% atrial pacing.

A TAILORED THERAPY OPTION FOR YOUR PACEMAKER PATIENTS

AAI(R) + VVI Pacing Mode[†], available for new and existing patients, provides increased atrial and ventricular device longevities with beat-to-beat communications turned off and offers primary atrial pacing support with ventricular back-up.¹

Mode*	Atrial Pacing	Projected Atrial Device Longevity (Years) ¹
AAI(R), AAI(R)+VVI	100%	12.4
DDD(R)**	50%	8.6



*1.5 V, 0.4 ms, 300 ohms, 50 bpm

** i2i™ setting = 4/4

[†] Note: AAI(R)+VVI mode should not be used in patients without intact AV node conduction, or with chronic atrial fibrillation or atrial flutter.

**For more information, please contact
your Abbott Sales Representative.**

References:

1. AVEIR Leadless Pacemakers and Delivery Catheter IFU. ARTEN60036108.

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Important Safety Information (USA):

Indications for Use: The AVEIR™ Leadless Pacemaker system is indicated for management of one or more of the following chronic clinical presentations: syncope, pre-syncope, fatigue, dizziness, and one or more of the indications which follow. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for 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 AV block or sinus arrest, chronic atrial fibrillation. **MR Conditional:** The AVEIR Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

Intended Use: The AVEIR™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle and the right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy within the implanted chamber for the target treatment group. The LP is also intended to operate optionally with another co-implanted LP to provide dual-chamber pacing therapy.

The AVEIR™ Delivery Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

Contraindications: Use of the AVEIR™ Leadless Pacemaker is contraindicated in these cases:

Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.

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.

Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor driven rates.

Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.

Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in the Product Materials section of the IFU) contained in the device and a thorough history of allergies must be discussed.

Adverse Events: Potential complications associated with the use of the AVEIR™ Leadless Pacemaker system are the same as with the use of single or dual chamber pacemakers with active fixation pacing leads including, but not limited to: cardiac perforation; cardiac tamponade; pericardial effusion; pericarditis; endocarditis; thrombus formation; thromboembolism; valve damage or regurgitation; heart failure; pneumothorax/ hemotorax; cardiac arrhythmias; diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation; palpitations; hypotension; syncope; cerebrovascular accident; infection; hypersensitivity reaction to device materials, contrast media, medications, or direct toxic effect of contrast media on kidney function; pacemaker syndrome; inability to interrogate or program the LP due to programmer or LP malfunction; intermittent or complete loss of capture, pacing or sensing (non-battery related); oversensing; increased capture threshold; inappropriate sensor response; corrupted, intermittent, or loss of i2i communications; interruption of desired LP function due to electrical interference, either electromagnetic or electromagnetic; battery malfunction/premature battery depletion; device-related complications (premature deployment, device dislodgement/embolization of foreign material, inability to release/re-dock of the LP from catheter, helix distortion); additional surgery or intervention; death. As with any percutaneous catheterization procedure, potential complications include, but are not limited to: vascular access complications, such as perforation, dissection, puncture, groin pain; bleeding or hematoma; thrombus formation; thromboembolism; air embolism; local and systemic infection; peripheral nerve damage; general surgery risks and complications from comorbidities; such as dyspnea, respiratory failure, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death.

[†] Indicates a trademark of the Abbott group companies.

[‡] Indicates a third-party trademark, which is property of its respective owner.

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