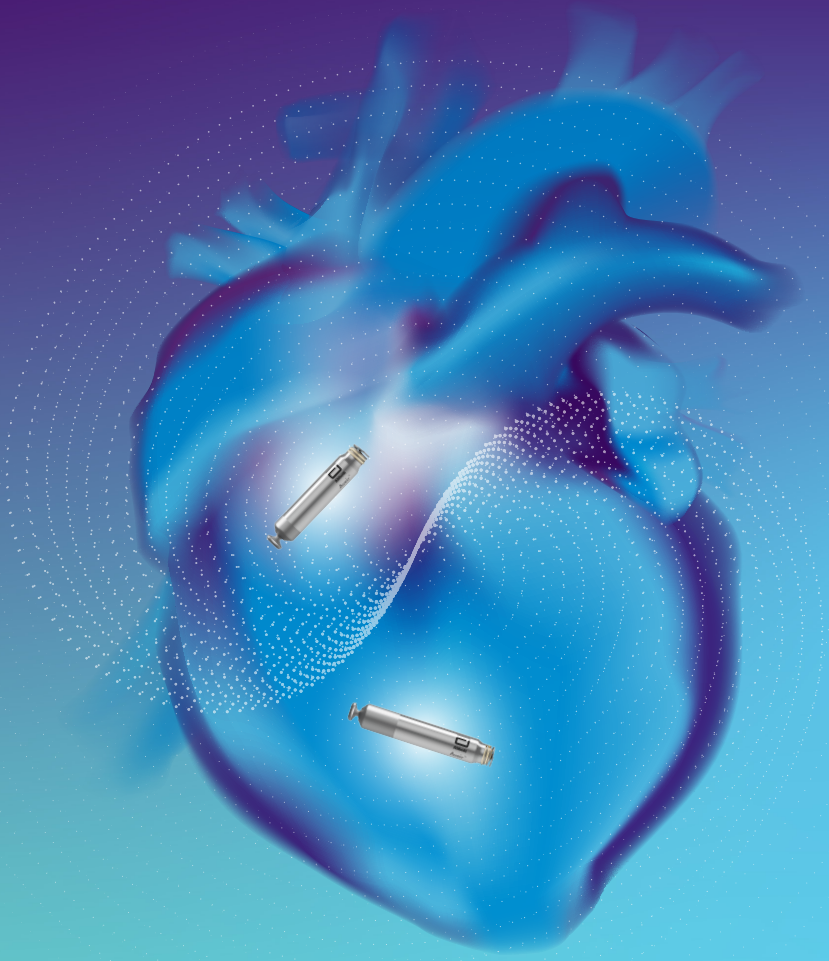
Abbott

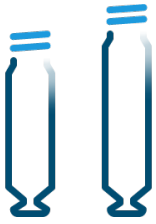
AVEIR™ DR DUAL CHAMBER
LEADLESS PACEMAKER SYSTEM



SETTING THE PACE WITH **DUAL CHAMBER LEADLESS PACING**

INTRODUCING THE WORLD'S FIRST **DUAL CHAMBER LEADLESS PACEMAKER SYSTEM**

The AVEIR™ DR Leadless Pacemaker (LP) System is a first-of-its kind, dual chamber leadless pacing system featuring:



TWO DISTINCT DEVICES

Each specifically designed for the right atrium or right ventricle.

IN BOTH CHAMBERS

Sensing and pacing in both the right atrial and right ventricular chambers.

FOR ATRIOVENTRICULAR (AV) SYNCHRONY

Made possible through proprietary implant-to-implant (i2i™) communication.

WITH AAI(R), VVI(R), AAI(R)+VVI, AND DDD(R) OPTIONS

Match your patients' pacing needs and upgrade over time as those needs change.

ELECTRICAL MAPPING PRIOR TO FIXATION

Reduces the number of repositioning attempts to find your optimal implant site.

LONG-TERM RETRIEVAL[2]

No hardware is left behind to provide options for future patient needs or therapies.

THE LEADLESS ADVANTAGE

All the clinical benefits of traditional dual chamber pacemakers without associated lead and pocket-related complications including infection, lead fracture, insulation problems, skin erosion, keloid formation and no visible scarring or movement restrictions.

THE WORLD'S FIRST AND ONLY ATRIAL DEVICE[1]

AVEIR™ AR Atrial LP

1. Docking button
2. Outer fixation helix
3. Inner helix tip electrode

Length: 32.2 mm **Diameter:** 6.5 mm

The atrial device has an additional inner-helix that acts as an electrode for pacing and sensing while also designed to provide extra anchoring and stability in the atrium.[2]

THE VENTRICULAR DEVICE

AVEIR™ VR Ventricular LP

1. Docking button
2. Fixation helix and distal dome tip electrode *(not pictured)*

Length: 38.0 mm
Diameter: 6.5 mm

BEAT-TO-BEAT SYNCHRONY

AVEIR™ DR Leadless Pacemaker System is capable of pacing and sensing in both chambers through the combination of an atrial leadless pacemaker (AVEIR™ AR LP) and a ventricular leadless pacemaker (AVEIR™ VR LP).

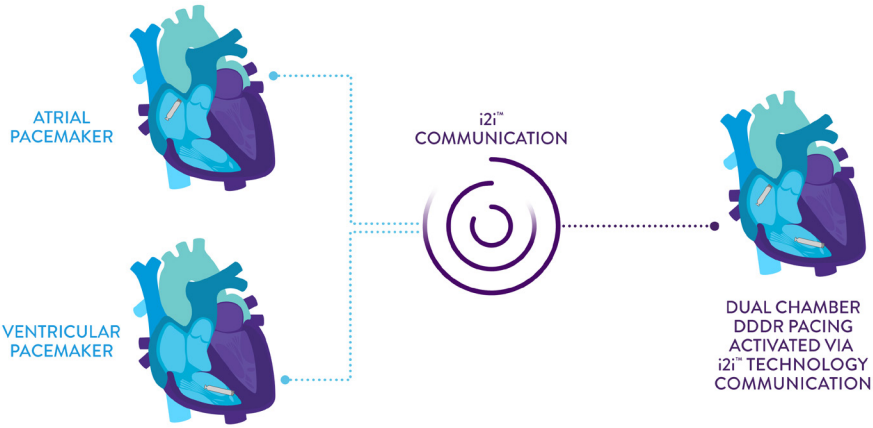
Dual chamber, leadless synchronous pacing between the atrium and the ventricle is made possible with industry-first, proprietary implant-to-implant (i2i™) communication technology capable of providing true DDD(R) pacing for continuous, atrioventricular (AV) synchrony, regardless of patient posture.[3,4]

Mean AV synchrony observed for multiple postures and gaits

(including sitting, supine, left lateral recumbent, right lateral recumbent, standing, normal walking and fast walking).[3]

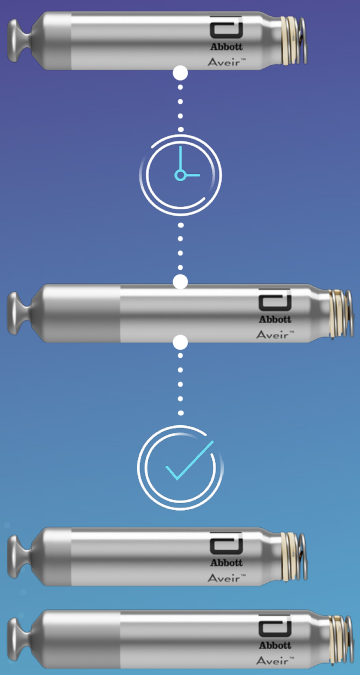
i2i™ TECHNOLOGY

To support the dual chamber therapy, each implant communicates beat-to-beat with a paired, co-implanted device. This novel technology employs low-energy, subthreshold pulses between implanted devices using the conductive nature of the body's blood pool and myocardial tissue. These high frequency pulses of data are delivered concurrently with each locally paced or sensed event without impact on pacing or intrinsic sensing.



UPGRADEABLE SYSTEM[4]

Patient therapy can be tailored by implanting an atrial or ventricular device alone, or both combined for dual chamber support. The option to upgrade over time allows you to meet your patient's needs today and adapt to common disease progression later.



START WITH THE ATRIAL DEVICE

Treat sinus node dysfunction today.

ADD VENTRICULAR PACING LATER

Treat those same patients by adding a ventricular device if heart block develops later to provide DDD(R) or AAI(R)+VVI therapy.

ACHIEVE DUAL CHAMBER PACING

Now you have options to adapt to patient needs over time.

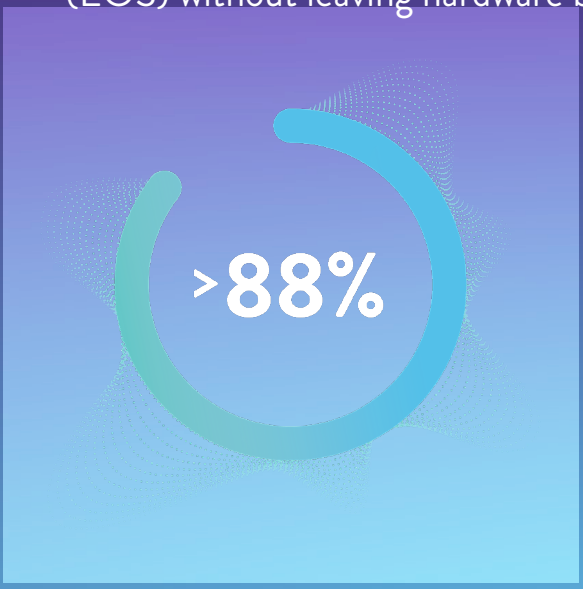
AAI(R)+VVI Pacing Mode Available†

Tailored for sinus node dysfunction patients, each leadless pacemaker provides independent single-chamber pacing and sensing. With beat-to-beat communications turned off, it offers increased battery longevities and backup ventricular pacing.

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

LONG-TERM RETRIEVAL[2]

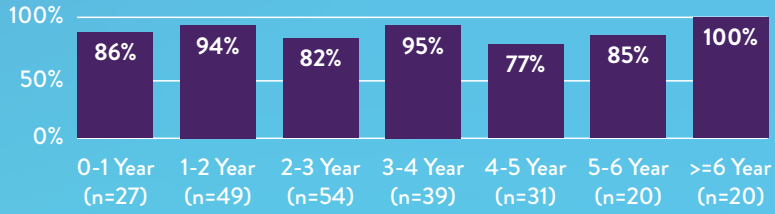
This allows for the replacement of the atrial or ventricular device at end of service (EOS) without leaving hardware behind.



The AVEIR™ VR ventricular leadless pacemaker predecessor has a **long-term retrieval success rate above 88%** with helix fixation through 9 years regardless of implant duration.[2]

The custom designed retrieval catheter provides added confidence and is supported by a step-by-step retrieval protocol.[5] AVEIR™ devices have an active fixation design that uses a screw-in mechanism to enable both implantation and long-term retrieval of the atrial and ventricular devices.[4]

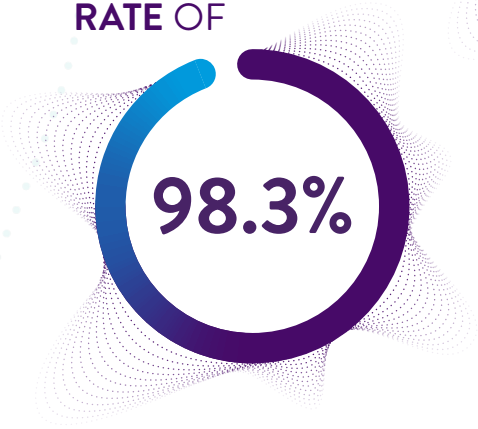
RETRIEVAL SUCCESS BY IMPLANT DURATION[2]

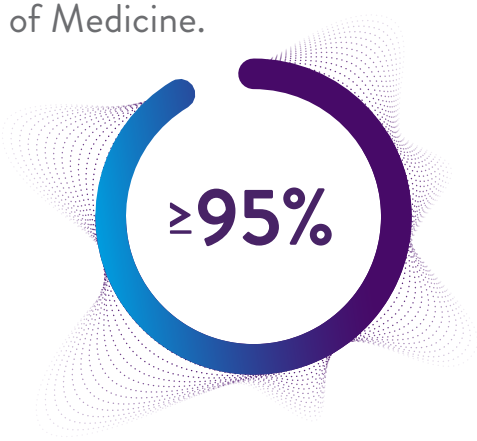


PROVEN CLINICAL OUTCOME[3]

The following safety and efficacy results were observed at the three-month follow-up of the AVEIR™ DR i2i™ IDE study as cited in the New England Journal of Medicine.

DUAL CHAMBER PROCEDURE **SUCCESS RATE** OF





Mean AV synchrony observed for multiple postures and gaits

(including sitting, supine, left lateral recumbent, right lateral recumbent, standing, normal walking and fast walking).[3]

90.3%

of patients were **FREE FROM DEVICE** or procedural related **COMPLICATIONS.**

90.2%

of patients met the atrial device's **ELECTRICAL PERFORMANCE ENDPOINT** (pacing capture threshold, p-wave amplitude).

ELECTRICAL MAPPING PRIOR TO FIXATION[4]

Designed to help reduce the number of repositioning attempts in the atrium and ventricle, AVEIR™ Leadless Pacemakers can assess current of injury via Commanded EGM, initial pacing capture thresholds, sensing amplitudes, and impedance in both atrial and ventricular chambers.[3,4]

of patients had successful **VENTRICULAR IMPLANTS WITH 1 OR LESS REPOSITIONING ATTEMPTS.**[3]

of patients had successful **ATRIAL IMPLANTS WITH 1 OR LESS REPOSITIONING ATTEMPTS.**[3]

DELIVERY & RETRIEVAL CATHETERS[4,5]

Designed for ergonomic, single operator use.

Steerable catheters with deflection mechanism.

Hydrophilic coating on introducer sheath and a choice of 30 cm and 50 cm lengths.[6]

Protective sleeve fully covers the LP's helix during catheter navigation to reduce risk of damaging the helix or an injury to cardiovascular structures.

AVEIR™ Delivery Catheter Handle

AVEIR™ Retrieval Catheter Handle

Delivery Catheter

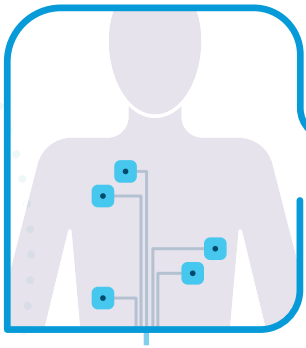
Misaligning and aligning the ends of the tethers allows for the loading and release of the pacemaker.

Retrieval Catheter Tri-Loop Snare

WORKFLOW[4]

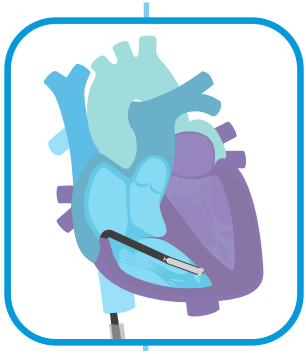
The AVEIR™ DR Dual Chamber Leadless Pacemaker System implant procedure.

Scan to view the single chamber implant procedure workflow.



1

PREP the patient's skin and apply EKG electrodes. Connect to the Merlin™ Programmer via the EKG cable and AVEIR Link Module.

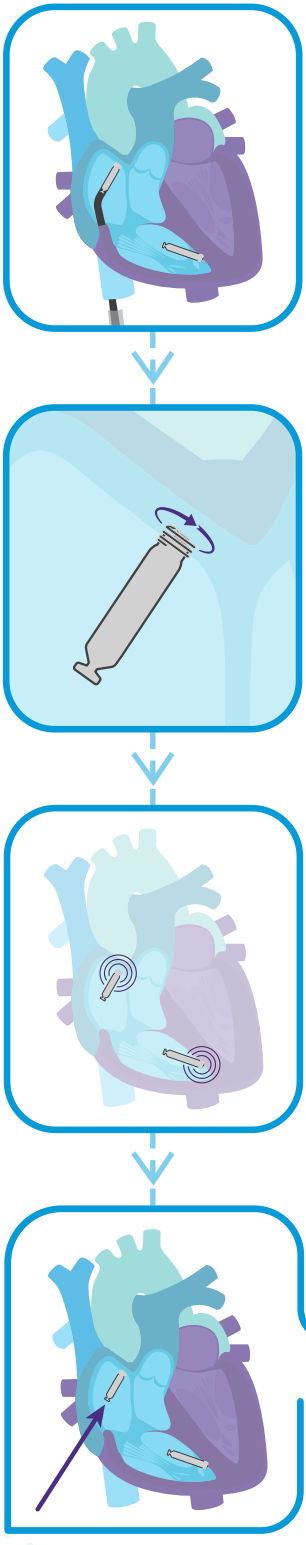


2

After gaining femoral vein access and visualizing the heart's anatomy and size via imaging, **INSERT** delivery catheter with attached ventricular leadless pacemaker. Navigate to right ventricle and map for ideal implant site

FIXATE ventricular leadless pacemaker, go into tether mode to assess electrical measurements release, and then withdraw the delivery catheter.

For a more detailed workflow, refer to the AVEIR™ DR Instructions For Use (IFU) or contact your Abbott Sales Representative for training.



3

Load the atrial leadless pacemaker onto a new delivery catheter, **INSERT** and navigate to right atrium and map for ideal implant site.

4

FIXATE atrial leadless pacemaker, go into tether mode to assess electrical measurements, finalize atrial device.

5

PAIR devices via i2i™ technology, assess i2i™ communication between the two pacemakers, and program dual chamber or an appropriate mode.

6

RELEASE atrial device, remove delivery catheter and close access.

ENABLING SAFE MRI SCANS

AVEIR™ Leadless Pacemakers are MR Conditional for full body scans using a 1.5T or 3T field strength MRI scanner.

AVEIR LP MR CONDITIONAL FEATURES*	
MAGNET (TESLA)	1.5T AND 3T
SCAN TYPE	FULL-BODY
SCANNER MODE	FIRST LEVEL CONTROLLED OPERATING MODE OR NORMAL OPERATING MODE

MODEL NUMBERS

MODEL NUMBER	DESCRIPTION	GTIN**
LSP201A	AVEIR™ Leadless Pacemaker (Right Atrial)	05415067040701
LSP202V	AVEIR™ Leadless Pacemaker (Right Ventricular)	05415067040725
LSCD201	AVEIR™ Delivery Catheter	05415067038487
LSCR111	AVEIR™ Retrieval Catheter	05415067034496
LSN25501	AVEIR™ Introducer - 50 cm	05415067034847
LSN25301	AVEIR™ Introducer - 30 cm	05415067034823

** For additional information about specific MR Conditional details, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the MRI-Ready Leadless Systems Manual at medical.abbott/manuals or check our MRI-Ready resources at cardiovascular.abbott/mriready*

*** the leading "Os" are required for GINs*

REFERENCES:

1. AVEIR™ DR FDA Approval.
2. Reddy, VY, et al. Worldwide Experience with Leadless Pacemaker Retrievals: A Worldwide Nanostim Experience out of 9y. Presented at: APHRS 2022; Nov 18-20, 2022; Singapore.
3. Knops, Reinoud E., et al. "A Dual-Chamber Leadless Pacemaker." New England Journal of Medicine (2023). DOI: 10.1056/NEJMoa2300080
4. AVEIR™ Leadless Pacemakers and Delivery Catheter IFU, ARTEN600284235.
5. AVEIR™ Retrieval Catheter IFU. ARTMT600174816.
6. AVEIR™ Introducer IFU. ARTEN600174817.

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.

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, disorientation, 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.

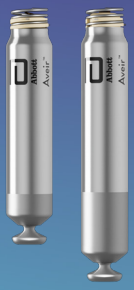
Adverse Events: Potential complications associated with the use of the AVEIR™ Leadless Pacemaker system are the same as with the use of single or dual chamber pacemakers with active fixation pacing leads including, but not limited to: cardiac perforation; cardiac tamponade; pericardial effusion; pericarditis; endocarditis; valve damage or regurgitation; heart failure; pneumothorax/hemothorax; 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 electromyogenic 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.

POWERING HEARTS BEAT TO BEAT

Partnering with you to personalize care from diagnosis through treatment and ongoing management.

AVEIR™ DR
DUAL CHAMBER LEADLESS PACEMAKER SYSTEM.

ONLY FROM ABBOTT.



Contact your Abbott Sales Representative or visit **Cardiovascular.Abbott/AVEIRDR**

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