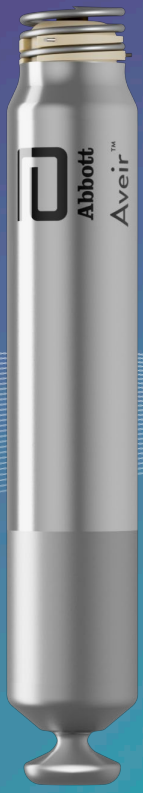
AVEIR™ VR
Leadless Pacemaker

SETTING THE PACE
FOR WHAT'S TO COME

LONG-TERM RETRIEVAL. LONG LASTING.
MAPPING PRIOR TO FIXATION.



Abbott

ADVANCING TODAY'S TECHNOLOGY WITH A **VIEW TO TOMORROW**

Leadless pacemakers (LP) have revolutionized care for heart patients. With no visible or physical reminder of a pacemaker under the skin and fewer post-implant activity restrictions,[1,2] your patients can continue living their lives to the fullest.

AVEIR™ VR Leadless Pacemaker (LP) is the next evolution in leadless technology that has been designed for

- long-term retrieval[3]
- an extended battery life[4,5]
- mapping prior to fixation for optimal device location[4,6]
- providing an upgradeable platform to later support a dual chamber pacing system when patient therapy need evolves.

At just 38.0 mm, the AVEIR VR LP has three times less volume than a standard AAA battery.

Actual size

LONG-TERM RETRIEVAL

AVEIR™ VR Leadless Pacemaker is designed for long-term retrieval. Limited data is available for AVEIR VR LP. The AVEIR VR LP's predicate device has an overall long-term retrieval success rate of more than 88% with helix fixation with up to 9 years of retrieval experience.[3]

LONG LASTING

The average battery longevity among Leadless II phase 2 IDE patients at 1 year follow-up is estimated to be 17.6 years. 48% of the study patients have an estimated battery longevity of over 20 years.[6]

MAPPING PRIOR TO FIXATION

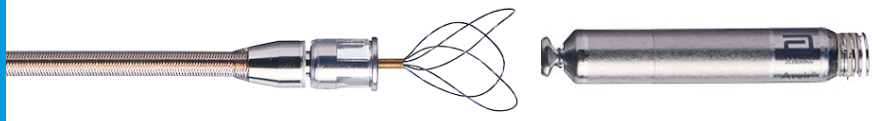
Mapping capability is designed to help reduce the number of repositioning attempts.[4,6]

**ISO standard settings: VVIR, 60bpm, 2.5V @0.4 ms, 600 Ω, 100% pacing

LONG-TERM **RETRIEVAL**

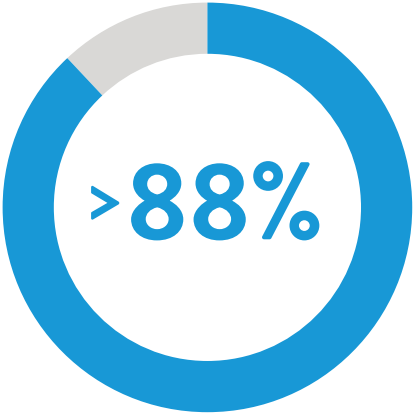
AVEIR™ VR Leadless Pacemaker's helical fixation is designed for long-term retrieval.[3]

TRI-LOOP SNARE RETRIEVAL MECHANISM



ACTIVE FIXATION HELIX

AVEIR™ VR Leadless Pacemaker's active fixation helix uses a screw-in mechanism to enable both implantation and long-term retrieval of the LP.[4]



Range 0 to 9 years
(mean 3.1 ± 1.8 years)
n=241

The AVEIR™ VR Leadless Pacemaker's predicate device has a

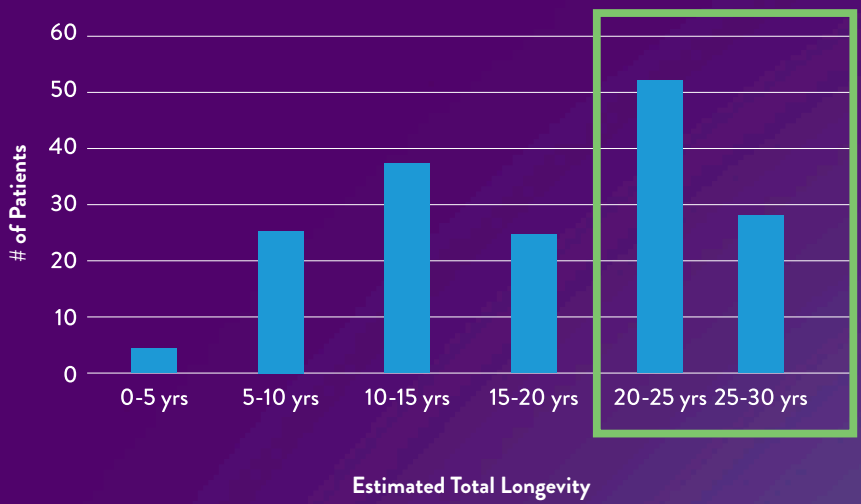
OVERALL LONG-TERM RETRIEVAL SUCCESS RATE

above 88% with helix fixation with up to 9 years of retrieval experience. AVEIR VR LP is designed for long-term retrieval. Limited data is available for the AVEIR VR LP.[3]

LONG LASTING

Increased projected battery longevity over current available leadless pacemakers[4,5]** opens the door to more patients.

Mean ± SD: 17.6±6.6 years
95% CI: 16.6 to 18.6 years



- The average battery longevity among Leadless II phase 2 IDE patients at 1 year follow-up is estimated to be 17.6 years.
- 48% of the study patients have an estimated battery longevity of over 20 years.

***Battery longevity estimates based on projections derived from published technical specifications and the ISO standard settings[4,5]*

LONG LASTING

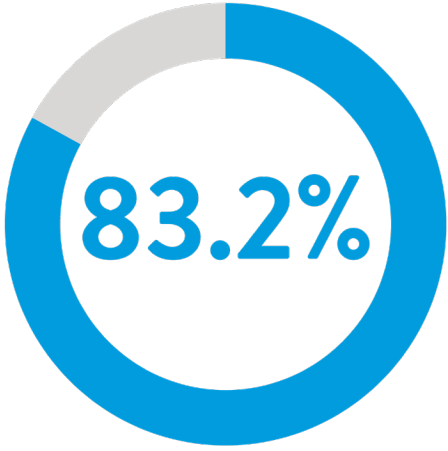
Up to

TWICE THE BATTERY CAPACITY

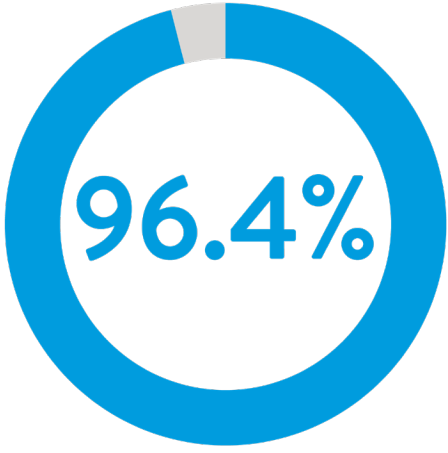
of current VR leadless pacemakers[4,5]

MAPPING PRIOR TO FIXATION

AVEIR™ VR Leadless Pacemaker mapping capability is designed to help reduce the number of repositioning attempts.[4,6]

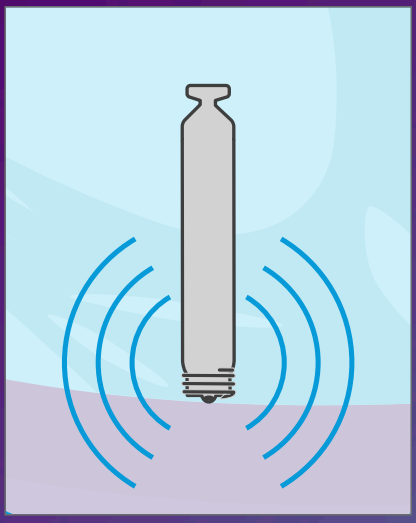


83.2% of patients had successful implants with no repositioning attempts[6]



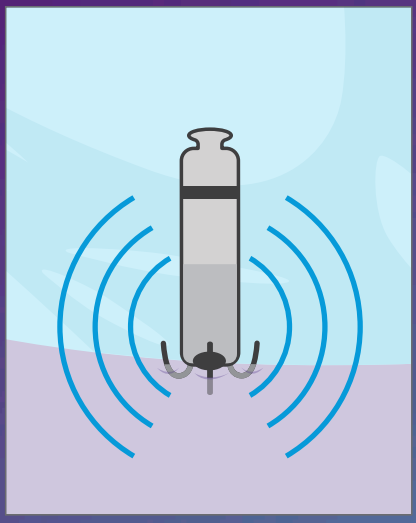
96.4% of patients had successful implants in 1 or less repositioning attempts[6]

AVEIR™ VR LP



- Aveir VR LP can measure R-waves, impedance and an initial capture threshold before fixation by simply touching the LP's tip electrode to the endocardial tissue.[4,6]
- Aveir VR LP is engaged with a rotational motion into the endocardium.[4]

Micra‡ VR



- Micra‡ VR requires LP deployment before taking initial electrical readings.[5]
- Micra‡ VR is inserted with a forward tip pressure against endocardium.[5]

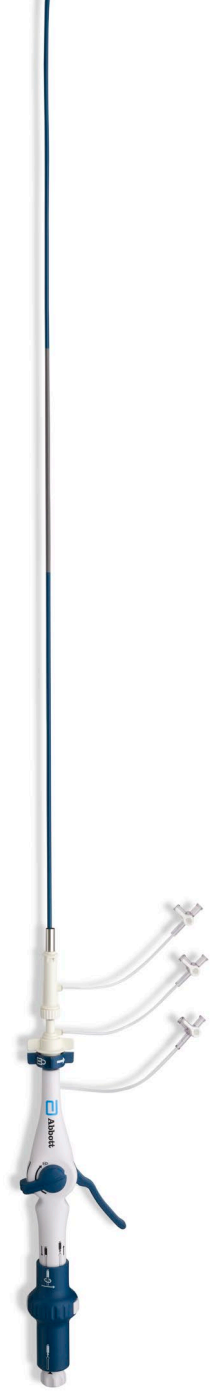
LIFE-CHANGING **INNOVATION**

At Abbott, we adapt quickly to changes in the world around us, harnessing leading-edge science and technology to deliver the best possible solutions for some of the world's most important health challenges.

Our medical devices, like the AVEIR™ VR Leadless Pacemaker, use the most advanced technologies to keep hearts beating more regularly.

AVEIR DELIVERY AND RETRIEVAL CATHETERS

- Designed for ergonomic, single operator use
- Steerable delivery catheter with deflection mechanism[4,7]
- Hydrophilic coating on introducer sheath and a choice of 30cm and 50cm lengths[8]
- Protective sleeve fully covers the LP's helix during catheter navigation in order to reduce risk of damaging the helix or an injury to cardiovascular structures[4,7]



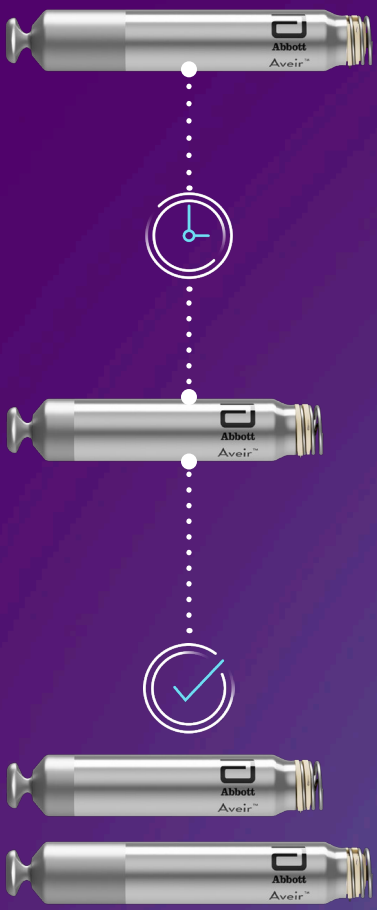
Delivery Catheter

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

Retrieval Catheter
Tri-Loop Snare

UPGRADABLE 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.



OPTION TO START WITH VENTRICULAR PACING

Treat patients for rare intermittent A-V block today.

ADD ATRIAL PACING LATER

Treat those same patients by adding an atrial device if sick sinus syndrome develops later to provide DDDR therapy.

ACHIEVE DUAL CHAMBER PACING

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

ENABLING SAFE **MRI SCANS**

AVEIR is 1.5T and 3T MR Conditional

AVEIR VR LP is MR Conditional for full body scans using a 1.5T or 3T field strength MRI scanner.

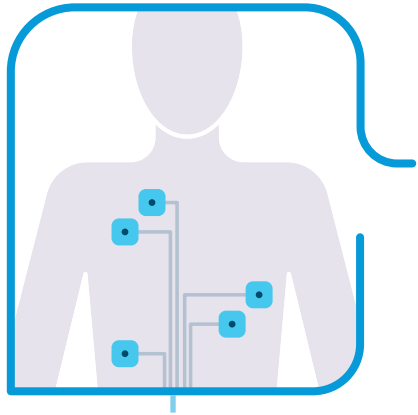
AVEIR VR LP MR CONDITIONAL FEATURES*	
Magnet (Tesla)	1.5T and 3T
Scan Type	Full-Body
Scanner Mode	First Level Controlled Operating Mode Or Normal Operating Mode

*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 System Manual at medical.abbott/manuals or check our MRI Ready resources at cardiovascular.abbott/mriready

UPGRADABLE

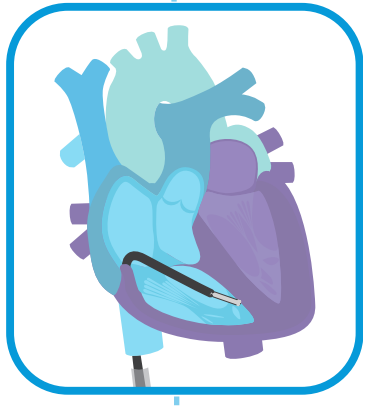
WORKFLOW[4]

Using the power of leadless technology, the AVEIR™ VR Leadless Pacemaker is implanted in the heart through a minimally invasive catheter procedure.



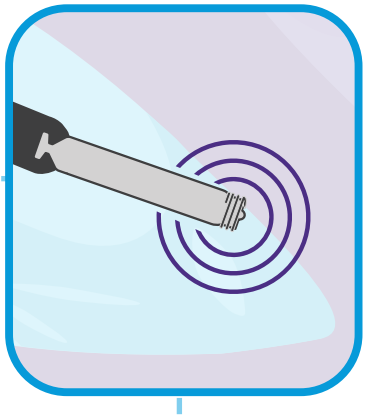
1

CONNECT patient's skin electrodes to Merlin Programmer™ via AVEIR™ Link Module.



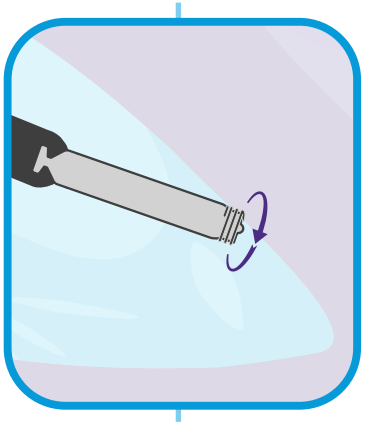
2

INSERT LP via ergonomic catheter for minimally invasive procedure, ensuring helix is fully covered during catheter navigation.



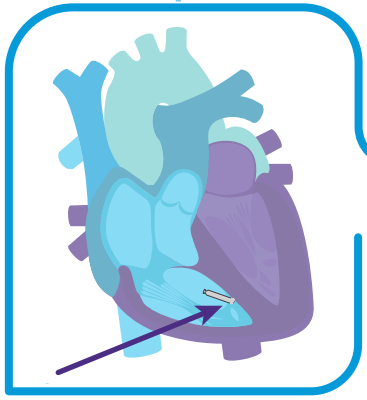
3

MAP ventricular implanting location before fixation by touching endocardium with LP's tip electrode.



4

FIXATE the LP to the ventricular endocardium using the screw-in mechanism.



5

RELEASE LP and withdraw delivery catheter.

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

POWERING HEARTS BEAT TO BEAT

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

ABOUT ABBOTT

A healthy heart is essential to good health. That's why we're committed to advancing treatments for people with cardiovascular disease. Our breakthrough medical technologies help restore people's health so they can get back to living their best lives, faster.

We focus on innovative technologies that can improve the way doctors treat people with heart arrhythmias, or irregular heartbeats.

Our cardiac rhythm management devices keep the heart beating at a healthy pace with pacemakers, implantable cardiac defibrillators and implantable cardiac monitors, all designed to get people's hearts working better, sooner.

Contact your Abbott Sales Representative or visit **cardiovascular.abbott/AVEIRVR**

ORDERING INFORMATION

Contents: AVEIR™ VR Leadless Pacemaker & AVEIR™ Delivery Catheter

MODEL NUMBER	DESCRIPTION	LENGTH (MM/INCH)	OUTER DIAMETER (MM/INCH)	WEIGHT (G)	VOLUME (CC)
LSP112V	Aveir™ VR Leadless Pacemaker	38/1.5	6.5/0.26	2.4	1.1

MODEL NUMBER	DESCRIPTION	INTRODUCER SIZE (FR) INNER DIAMETER	DEFLECTION (DEGREES)	OUTER DIAMETER OF GUIDE CATHETER BODY (MM/INCH)	EFFECTIVE LENGTH (CM/INCH)
LSCD111	Aveir™ Delivery Catheter	25	≥ 170	4.57/0.180	105/41.3

REFERENCES:

1. Sattar et al. Complications of leadless vs conventional (lead) artificial pacemakers - a retrospective review. Journal of community hospital internal medicine perspectives vol. 10,4 328-333. 2 Aug. 2020, doi:10.1080/20009666.2020.1786901

2. Reddy VY, Cantillon DJ, John IP . San Francisco, CA: 6 May 2016. A comparative study of acute and mid-term complications of leadless vs transvenous pacemakers. Late-Breaking Clinical Trials II. Presented at Heart Rhythm Society 2016; pp. 02–04. Abstract LBCT.

3. Reddy, VY, et al. Worldwide Experience with Leadless Pacemaker Retrievals at 9 years. Presented at 15th Asia Pacific Heart Rhythm Society (APHRS) Scientific Session; Nov 18-20, 2022; Singapore.

4. AVEIR™ DR Leadless Pacemaker and Delivery Catheter IFU. ARTEN600284235

5. Micra‡ VR IFU M991010A001 REV. B

6. Reddy VY, Exner D, et al. 1-Year Outcomes of a Leadless Ventricular Pacemaker: The LEADLESS II (Phase 2) Trial. JACC: Clinical Electrophysiology 2023, DOI: 10.1016/j.jacep.2023.01.031

7. AVEIR™ Retrieval Catheter IFU. ARTMT600174816

8. 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: The AVEIR™ Leadless Pacemaker system is indicated for management of one or more of the following permanent conditions: Syncope, Pre-syncope, Fatigue, Disorientation. 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, Severe physical disability. 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/or 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 the 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.

AVEIR™ VR Leadless Pacemaker

Abbott
15900 Valley View Court, Sylmar, CA 91342
Tel: +1 818 362 6822
Abbott.com

MAT-2115556 v7.0 | Item approved for US use only.

Abbott