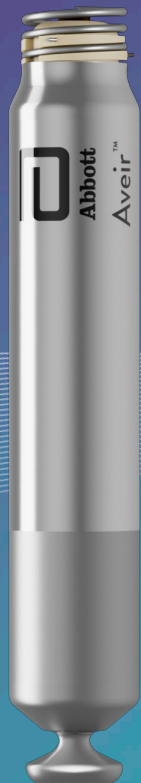


AVEIR™ VR
Leadless Pacemaker

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 retrieval³
- 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

*AVEIR DR dual chamber leadless pacemaker system is commercially approved for use only in the USA market at this time.

The AVEIR AR and DR systems are currently under review and pending CE mark.



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 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}

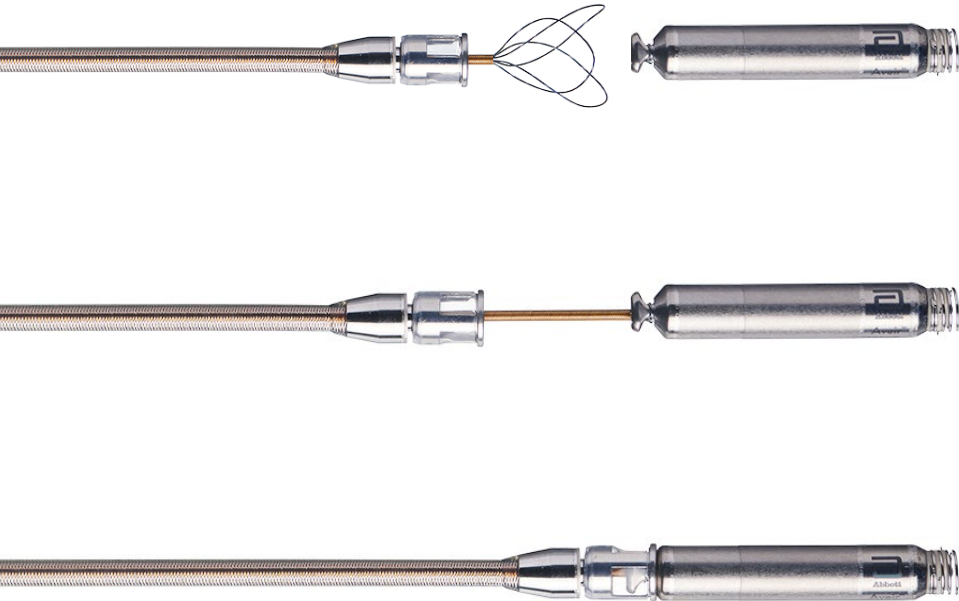
LONG-TERM RETRIEVAL



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



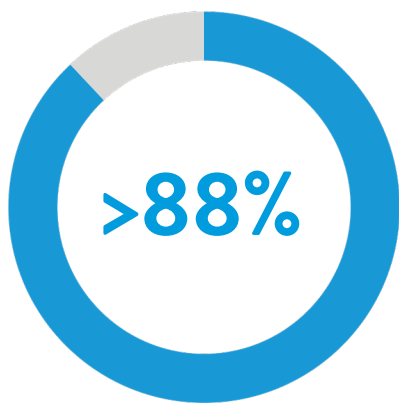
TRI-LOOP SNARE RETRIEVAL MECHANISM





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 an

OVERALL LONG-TERM RETRIEVAL SUCCESS RATE

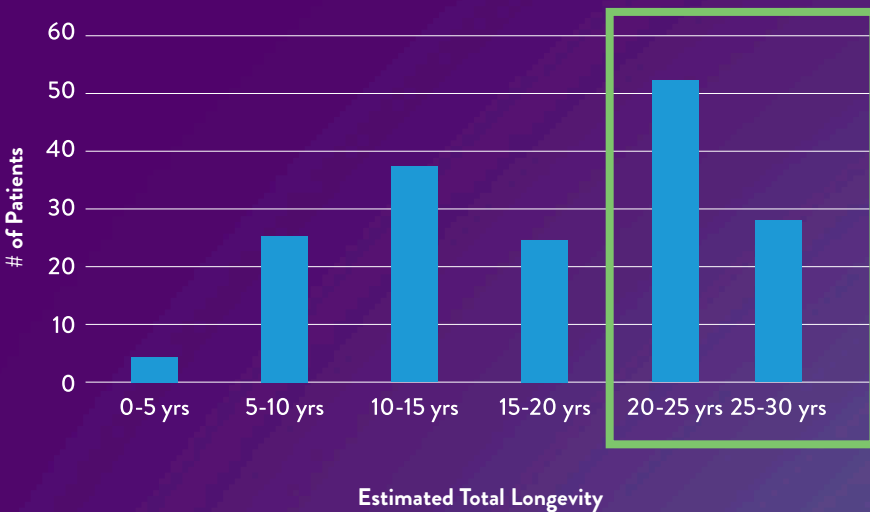
above 88% with helix fixation with up to 9 years of retrieval experience. AVEIR VR LP is designed for long-term retrieval. Limited data is available for the AVEIR VR LP.³

LONG LASTING



Increased projected battery longevity over current available leadless pacemakers^{4,5} opens the door to more patients.

Mean \pm SD: 17.6 \pm 6.6 years⁶
95% CI: 16.6 to 18.6 years⁶



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



Up to
**TWICE THE
BATTERY
CAPACITY**

of current VR
leadless pacemakers^{4,5}

BATTERY
CAPACITY

**243
mAh**

AVEIR™ VR LP

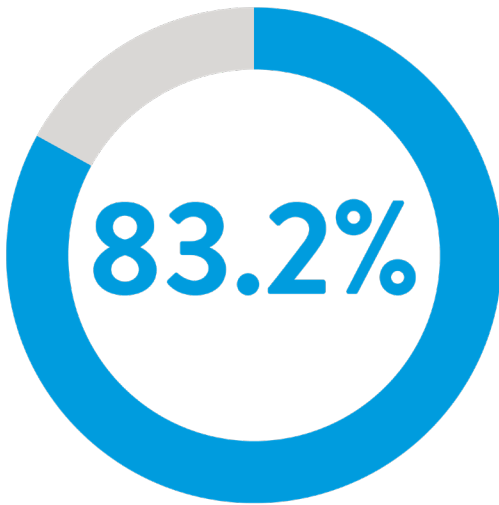
**120
mAh**

Competition

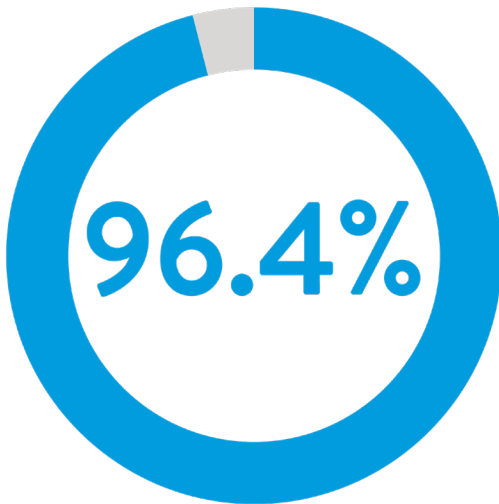
MAPPING PRIOR TO FIXATION



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

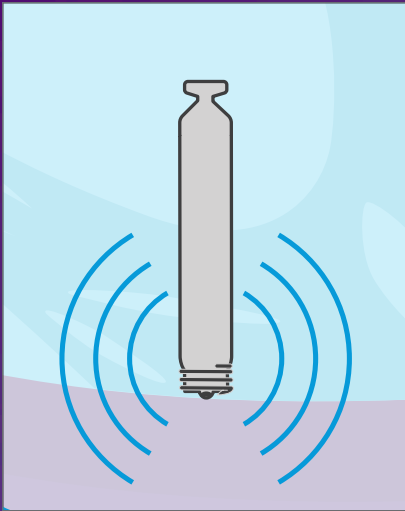


83.2% of patients had successful implants with no repositioning attempts⁷



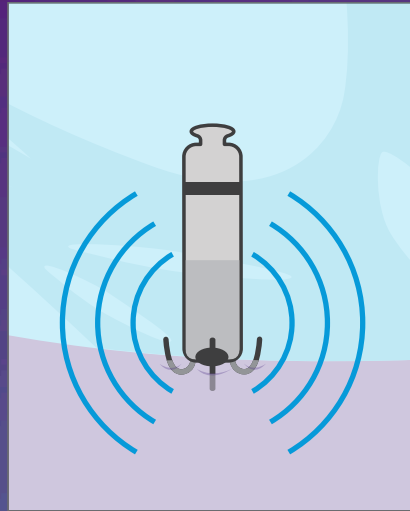
96.4% of patients had successful implants in 1 or less repositioning attempts⁷

AVEIR™ VR LP



- AVEIR VR LP can measure R-waves, impedance, Current of Injury 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 catheters with deflection mechanism^{4,8}
- Hydrophilic coating on introducer sheath and a choice of 30cm and 50cm lengths⁹
- 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^{4,8}





DUAL-CHAMBER SYSTEM UPGRADABILITY

Should new pacing indications present, the software for AVEIR VR LP is designed to pair with AVEIR AR Atrial LP, allowing the devices to upgrade to an AVEIR DR Dual Chamber Leadless Pacemaker System.*



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

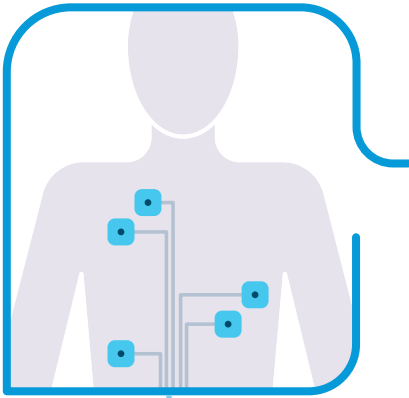
*AVEIR AR Atrial leadless pacemaker system and AVEIR DR dual chamber leadless pacemaker system are commercially approved for use only in the USA market at this time.

The AVEIR AR and DR systems are currently under review and pending CE mark.

**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/mrireedy

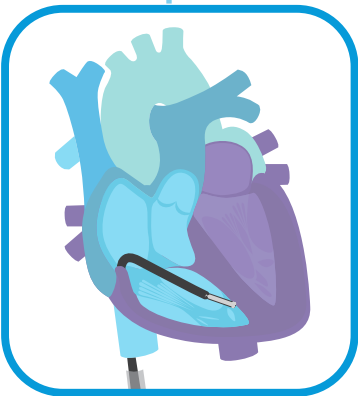
WORKFLOW⁴

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



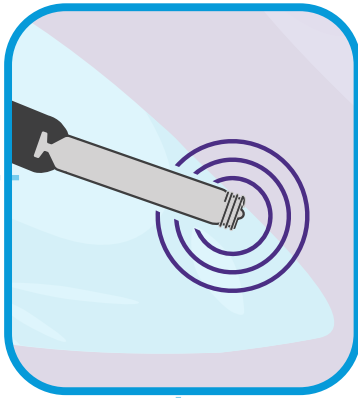
1

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



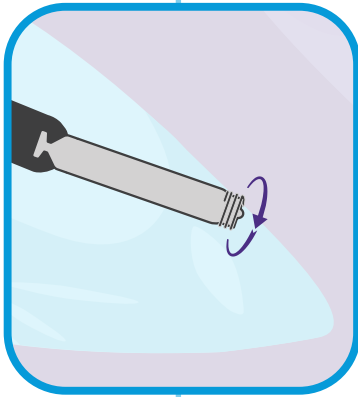
2

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



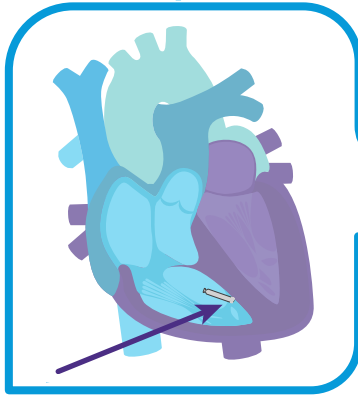
3

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.

ABOUT ABBOTT

When people are at their healthiest, they have the potential to live not just longer, but better. This simple truth inspired the creation of AVEIR™ VR Leadless Pacemaker and has been Abbott's guiding principle for more than 130 years.

Every day, Abbott harnesses leading-edge science and technology to deliver the best possible solutions for some of the world's most important health challenges. Through our nutrition products, diagnostics solutions, branded generic medicines and medical devices, we've helped people live fuller, healthier lives.



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:10.1080/2009666.2020.1786901
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™ VR Leadless Pacemaker and Delivery Catheter IFU. ARTEN600175956, ARTEN600175957
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. Reddy, VY et al. Primary Results on Safety and Efficacy from the LEADLESS II-Phase 2 Worldwide Clinical Trial, *JACC: Clinical Electrophysiology*, 2021, ISSN2405-500X, <https://doi.org/10.1016/j.jacep.2021.11.002>
8. AVEIR™ Retrieval Catheter IFU. ARTMT600174816
9. 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 patients with significant bradycardia and:

- Normal sinus rhythm with rare episodes of A-V block or sinus arrest
- Chronic atrial fibrillation
- Severe physical disability

Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

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. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy to the target patient population.

The AVEIR™ Delivery Catheter system 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 Product Materials section in 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 chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Valve damage and/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, 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 pacing and/or sensing due to dislodgement or mechanical malfunction of the LP (non-battery related), Loss of capture or sensing due to embolization or fibrotic tissue response at the electrode, Increased capture threshold, Inappropriate sensor response, 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, Helix distortion), 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 hypotension, dyspnea, respiratory failure, syncope, 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.



Contact your Abbott Sales Representative for more
information about **AVEIR™ VR Leadless Pacemaker**.

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