

**AVEIR™ VR**  
Leadless Pacemaker

# SETTING THE PACE FOR WHAT'S TO COME

CHRONIC 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,<sup>1,2</sup> your patients can continue living their lives to the fullest.

Aveir™ Leadless Pacemaker (LP) is the next evolution in leadless technology that has been designed for chronic retrieval,<sup>3</sup> to have an extended battery life,<sup>4,5</sup> fewer lead-related complications compared to transvenous pacemakers<sup>1,2</sup> and to provide an expandable platform to later support a dual chamber pacing system, upon regulatory approval.\*

**At just 38.0 mm, the Aveir VR LP is smaller than a standard AAA battery.**



\*ASIC chip designed to provide an expandable platform to later support a dual chamber pacing system once approved by the U.S. Food and Drug Administration (FDA).



## CHRONIC RETRIEVAL

Aveir Leadless Pacemaker is designed for chronic retrieval. Limited data is available for Aveir LP. The Aveir LP's predicate device has chronic retrieval success rate >80% with helix fixation through 7 years regardless of implant duration.<sup>3</sup>



## LONG LASTING

Battery is projected to offer up to twice the longevity of current VR leadless pacemakers based on ISO standard settings<sup>4,5\*\*</sup>



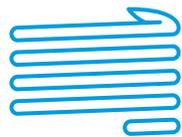
## MAPPING PRIOR TO FIXATION

Mapping capability is designed to help reduce the number of repositioning attempts<sup>4,6</sup>

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

# CHRONIC RETRIEVAL

Leadless pacemaker's helical fixation is designed for chronic retrieval.<sup>3</sup>



RETRIEVAL

## TRI-LOOP SNARE RE-DOCKING MECHANISM



The tri-loop snare enables retrieval of the LP.

## ACTIVE FIXATION HELIX

Aveir LP active fixation helix uses a screw-in mechanism to enable both implantation and chronic retrieval of the LP.<sup>4</sup>



The Aveir™ LP's predicate device has a

## CHRONIC RETRIEVAL SUCCESS RATE

above 80% with helix fixation through 7 years regardless of implant duration.<sup>3</sup> Aveir LP is designed for chronic retrieval. Limited data is available for Aveir LP.

# LONG LASTING

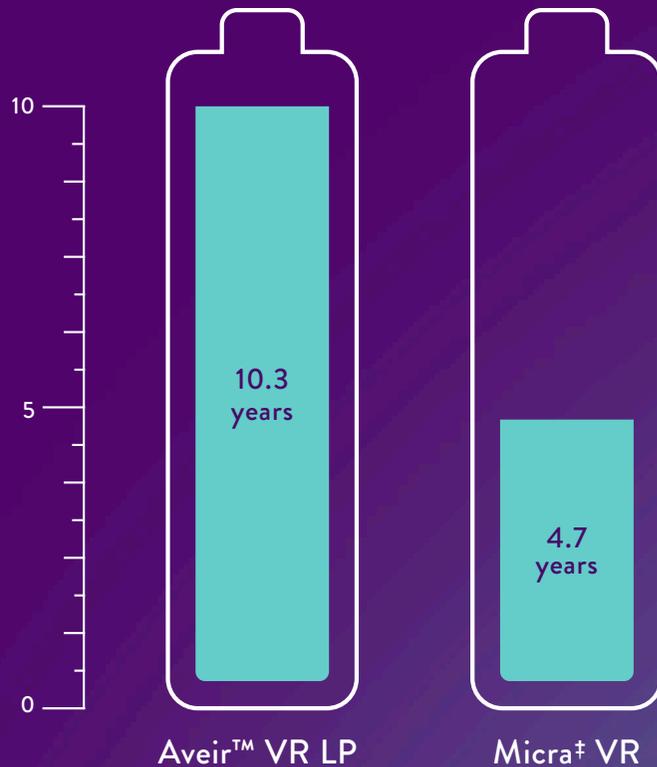


Increased projected battery longevity over current available leadless pacemaker<sup>4,5\*\*</sup> opens the door to more patients.

## Up to TWICE THE PROJECTED LONGEVITY

of current VR leadless pacemaker based on ISO standard settings<sup>4,5\*\*</sup>

PROJECTED YEARS OF BATTERY LIFE<sup>4,5\*\*</sup>



BATTERY CAPACITY

243  
mAh

120  
mAh

Aveir™ VR LP

Micra† VR

Aveir™ VR LP has more than double the battery capacity of current leadless pacemakers (243 mAh<sup>4</sup> vs 120 mAh<sup>5</sup>)

\*\*Battery longevity estimates based on projections derived from published technical specifications and the ISO standard settings<sup>4,5</sup>

ISO Standard settings: 4.7 yrs Micra † / 10.3 yrs Aveir VR LP: VVIR 60 bpm, 2.5V @0.4 ms, 600 Ω, 100% pacing

# MAPPING PRIOR TO FIXATION

Aveir™ VR LP mapping capability is designed to help reduce the number of repositioning attempts.<sup>4,6</sup>



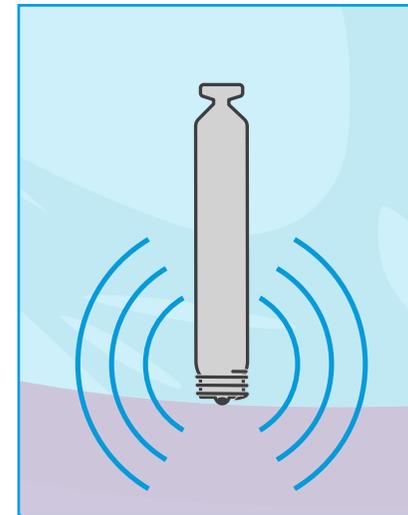
## Aveir VR LP



83.2% of patients had successful implants with no repositioning attempts<sup>6</sup>

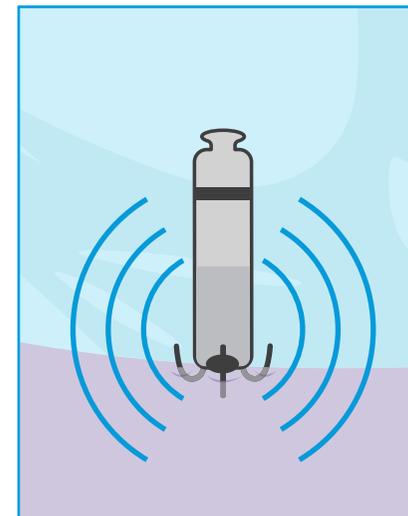


96.4% of patients had successful implants in 1 or less repositioning attempts<sup>6</sup>



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.<sup>4,6</sup>
- Aveir VR LP is engaged with a rotational motion into the endocardium.<sup>4</sup>



Micra+ VR

- Micra+ VR requires LP deployment before taking initial electrical readings.<sup>5</sup>
- Micra+ VR is inserted with a forward tip pressure against endocardium.<sup>5</sup>

# 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 LP, 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<sup>4,7</sup>
- Hydrophilic coating on introducer sheath and a choice of 30cm and 50cm lengths<sup>8</sup>
- 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<sup>4,7</sup>



## DUAL-CHAMBER SYSTEM EXPANDABILITY

The software for Aveir VR LP was designed for expandability to a dual chamber system to be introduced to the Aveir VR system via software updates in the future, upon regulatory approval.<sup>4\*</sup>



## 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\*\*\*



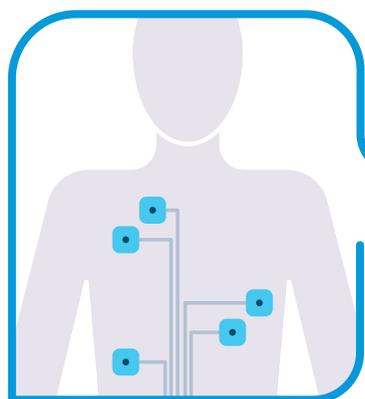
MAGNET (TESLA)	1.5T AND 3T
SCAN TYPE	FULL-BODY
SCANNER MODE	FIRST LEVEL CONTROLLED OPERATING MODE OR NORMAL OPERATING MODE

\* ASIC chip designed to provide an expandable platform to later support a dual chamber pacing system once approved

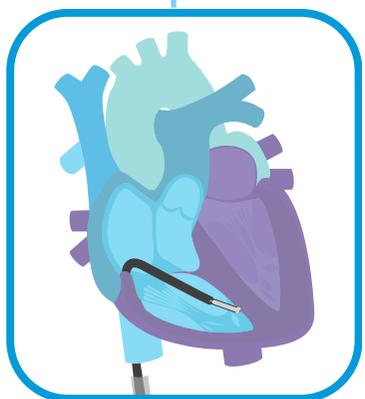
\*\*\*For additional information about specific MR Conditional details, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the MRI-Ready Leadless System Manual at [medical.abbott/manuals](http://medical.abbott/manuals) or check our MRI Ready resources at [cardiovascular.abbott/mrready](http://cardiovascular.abbott/mrready)

# WORKFLOW<sup>4</sup>

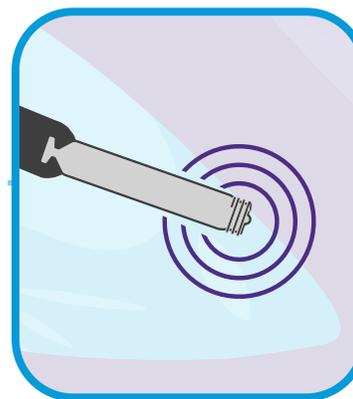
Using the power of leadless technology, the Aveir™ VR LP is implanted in the heart through a minimally invasive catheter procedure.



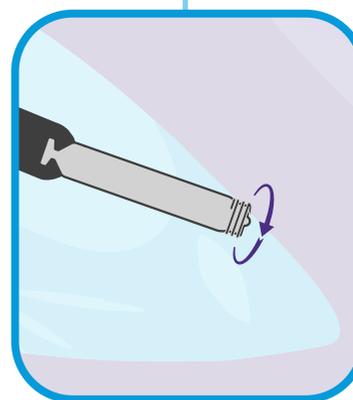
**1**  
**CONNECT** patient's skin electrodes to Merlin Programmer™ via Aveir™ Link Module



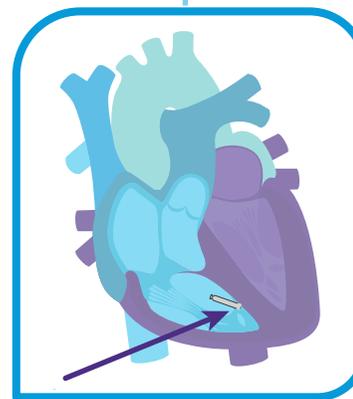
**2**  
**INSERT** LP via ergonomic catheter for minimally invasive procedure, ensuring helix is fully covered during catheter navigation



**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 LP 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:10.1080/20009666.2020.1786901
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. Chronic Retrievability with a Leadless Pacemaker: A Worldwide Nanostim Experience out of 7y. Presented at: HRS 2021; Jul 28-31, 2021; Boston, MA.
4. Aveir™ VR Leadless Pacemaker and Delivery Catheter IFU. ARTEN600175956
5. Micra‡ VR IFU M991010A001 REV. B
6. Reddy, VY et al. Primary Results on Safety and Efficacy from the LEADLESS II-Phase 2 Worldwide Clinical Trial, *JACC: Clinical Electrophysiology*, 2021, ISSN 2405-500X, <https://doi.org/10.1016/j.jacep.2021.11.002>.
7. Aveir™ Retrieval Catheter IFU. ARTMT600174816
8. Aveir™ Introducer IFU. ARTEN600174817

## Rx Only

**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).

™ indicates a trademark of the Abbott group of companies.

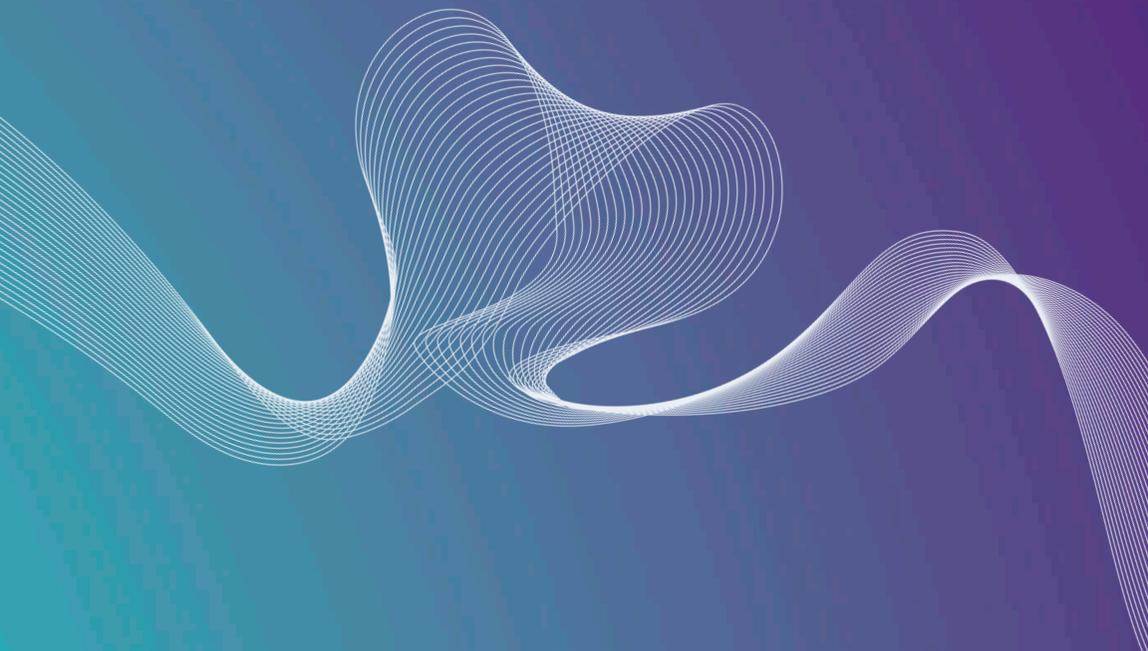
‡ Indicates a third-party trademark, which is property of its respective owner.

# AVEIR™ VR

Leadless Pacemaker



Contact your Abbott Sales Representative or visit [cardiovascular.abbott/AveirVR](https://cardiovascular.abbott/AveirVR)



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