Abbott

AVEIR™ LEADLESS PACEMAKERS OUTPERFORM TRANSVENOUS PACEMAKERS (TVP)

New Data Show Significantly Lower Complication Rates, Fewer Reinterventions, and Lower or Comparable Mortality*

Comparable or significantly lower mortality rates compared to TVP

Significantly lower rates of device-related reintervention with AVEIR LPs compared to TVP

Significantly lower rates of complications with AVEIR LPs compared to TVP

Mortality: From Respective CED Studies, Data Show AVEIR Outperforms Transvenous Pacemakers, Micra AV Has Worse Outcomes**

AVEIR LPs consistently demonstrate better or comparable mortality rates compared to TVP after risk adjustment

- **AVEIR AR: Significantly reduced** all-cause mortality rates at 3 months (2.7% vs. 5.3%, P=0.03)[1]
- **AVEIR VR: Significantly reduced** all-cause mortality rates at 12 months (17.0% vs. 18.2%, P=0.02)[2]
- **AVEIR DR: Comparable** all-cause mortality rates at 6 months[3]

Micra AV patients had significantly higher mortality rates compared to TVP despite risk adjustments

- At 30 days (adjusted 6.0% vs 3.5%; P< .0001)[4]
- At 6 months (adjusted HR 1.69; 95% CI 1.57–1.83; P< .0001)[4]
- At 2 years (adjusted HR: 1.53, 95% CI 1.44-1.62, P< 0.0001)[5]

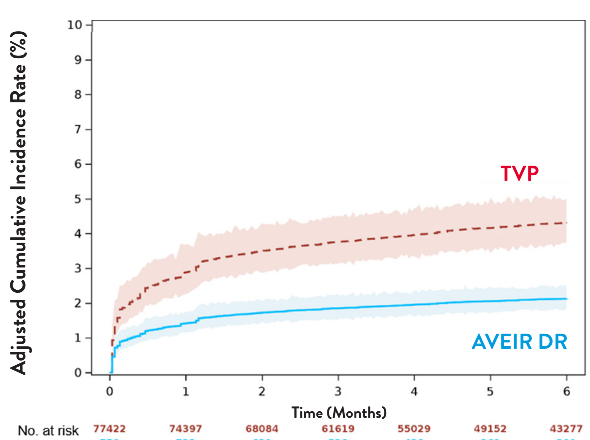
Complications and Device Reinterventions: Significantly Lower Rates with AVEIR LPs Compared to Transvenous Pacemakers

AVEIR DR[1]

Real-World Evidence (RWE) Comparison | 6-Months Outcomes (n=759 AVEIR DR, n=77,422 TVP)

- **AVEIR DR (vs. Dual-Chamber TVP):**
  - **41% lower rate** of Overall Complication (4.1% vs. 6.9%, P<0.01)
  - **52% lower rate** of Device-related Complication (2.8% vs. 5.9%, P<0.01)
  - **51% lower rate** of Device-related Reintervention (2.1% vs. 4.3%, P<0.01)

6-Month Device Reintervention Rates



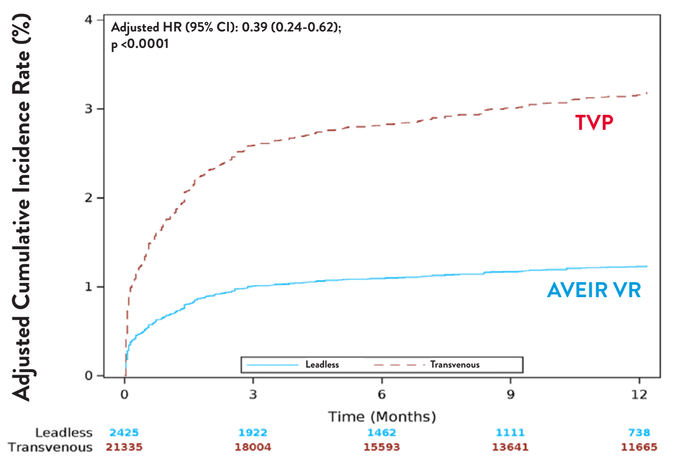
*All rates are adjusted for demographics, comorbidities, and implant encounter characteristics
**Data from separate AVEIR and Micra AV Coverage with Evidence Development (CED) studies with different patient populations. See CED studies[3,5] for full details of the study scope and limitations.

AVEIR VR[2]

Real-World Evidence (RWE) Comparison | 12-Months Outcomes (n=2,425 AVEIR VR, n=21,355 TVP)

- **AVEIR VR (vs. Single-Chamber Ventricular TVP):**
  - **30% lower rate** of Overall Complication (4.1% vs. 5.7%, P=0.02)
  - **47% lower rate** of Device-related Complication (2.8% vs. 5.2%, P=0.0002)
  - **61% lower rate** of Device-related Reintervention (1.2% vs. 3.2%, P<0.0001)

12-Month Device Reintervention Rates

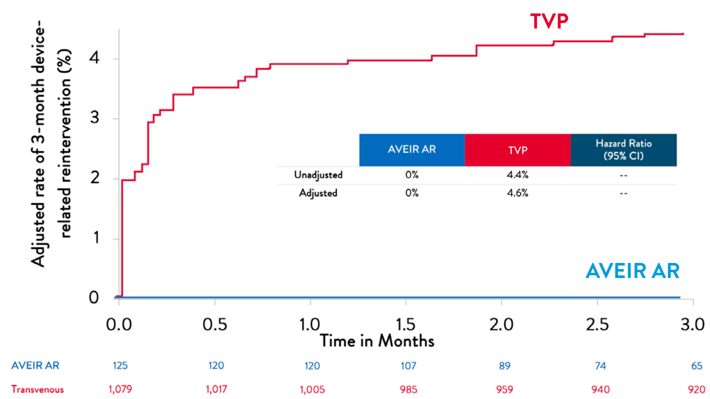


AVEIR AR[3]

Real-World Evidence (RWE) Comparison | 30 days and 3-Months Outcomes (n=125 AVEIR AR, n=1,079 TVAP)

- **AVEIR AR (vs. Single-Chamber Atrial TVP):**
  - **Lower rate** of Device-related Complications at 30 days (0.8% vs. 3.3%, P<0.01)
  - **0%** Device-related Reintervention at 3 months

3-Month Device Reintervention Rates



Learn More about AVEIR™ Leadless Pacemakers

References

1. PO-06-004 Leadless Vs. Transvenous Atrial Pacemakers: Real-world Evidence From AVEIR AR Coverage With Evidence Development Study. Nilsson, Kent R. et al. Heart Rhythm, Volume 22, Issue 4, S633. [Data obtained from final presentation]
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3. Lo M, Amin A, Kowalski M, Kroman A, Mathew D, Parikh V, Weiner S, Joseph J, Hu Y, Mortada M. Are Dual Leadless Pacemakers Safer than Transvenous Devices? Real-World Evidence from Aveir DR Coverage with Evidence Development Study. Abstract presented at: Asia Pacific Heart Rhythm Society; November 12–15, 2025; Yokohama, Japan. [Data obtained from final presentation]
4. Crossley, G. H., Longacre, C., Higuera, L., Stromberg, K., Cheng, A., Piccini, J. P., & El-Chami, M. F. (2024). Outcomes of patients implanted with an atrioventricular synchronous leadless ventricular pacemaker in the Medicare population. Heart Rhythm, 21(1), 66-73.
5. El-Chami, M. F., Higuera, L., Longacre, C., Stromberg, K., Crossley, G., & Piccini, J. P. (2024). Two-year outcomes of Micra AV leadless pacemakers in the Micra AV CED study. Europace, 26(11), euae273.

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 one or more of the following conditions: 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/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.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions, and adverse events.

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