



AVEIR™ LEADLESS PACEMAKERS (LPs) IMPLANT STEPS



1. LAB PREPARATION AND VENOUS ACCESS

- Lab prepared with appropriate equipment and patient connected to the Merlin™ 3650 PCS Programmer and Link module.
- Gain access, dilate per standard of care, then prepare AVEIR™ Introducer
 - Prep AVEIR Introducer: Flush and wipe introducer and dilator; Lock dilator to introducer.
- Perform pigtail angiogram to assess RA and RV anatomy and pre-plan implant zones.
- Advance AVEIR Introducer to RA/IVC junction over super stiff J-tip guidewire; Remove dilator and guidewire, aspirate, flush, connect Line A (1 drip/sec).

2. PREPARE DELIVERY CATHETER

- Load LP: Ensure AVEIR Delivery Catheter is in short-tether mode, misalign tethers, insert into loading tool funnel (ensure snap-fit clicks in), re-align tethers, remove loading tool (Keep LP elevated, taking care to protect the helix).
- Retract LP Control Knob until audible click to dock, cover helix with protective sleeve, lock hub lock and perform deflection test.
- Connect all remaining driplines (B=Bypass Tool, C=Contrast, D= Delivery handle) and flush catheter.
- Advance Valve Bypass Tool (VBT) over the protective sleeve.



RV in loading tool



RA LP in loading tool

3. INTRODUCE LP AND ESTABLISH CONNECTIVITY

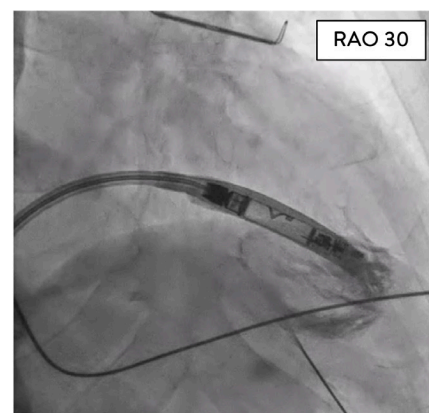
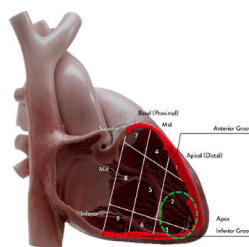
- Lock VBT into introducer and advance catheter to appropriate gray marker band for introducer length.
- Retract the introducer, typically 2 device lengths from the RA/IVC junction.
- Retract protective sleeve, establish and confirm communication with the programmer.
- Program LP as desired and recover with the protective sleeve.

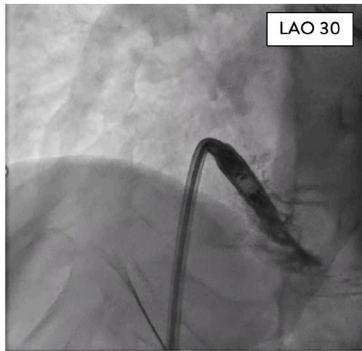
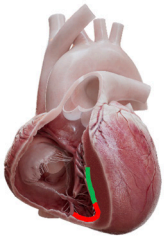


4. CHAMBER NAVIGATION (RV AND RAA)

Right Ventricle (RV) Navigation

- **Crossing the Tricuspid Valve:** In RAO 30, initiate deflection low at the RA/IVC junction (may need some CCW rotation). Advance the catheter across the tricuspid valve into the RV mid-septal region. Apply deflection brake to maintain curve.
- **Angiographic Assessment:** Cine and inject contrast/saline mix in RAO and LAO views to visualize anatomy. Adjust catheter position as needed using deflection, rotation, and advancement/retraction to avoid the tricuspid valve, intraventricular-septal groove, apex and free wall.

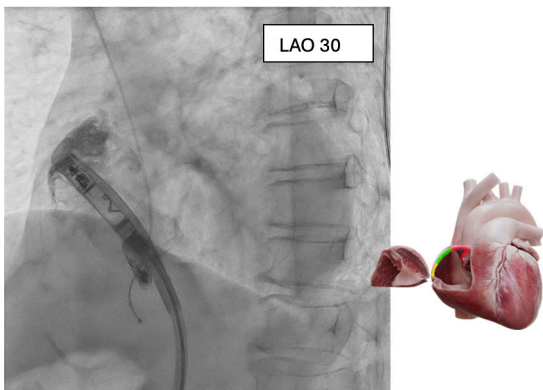
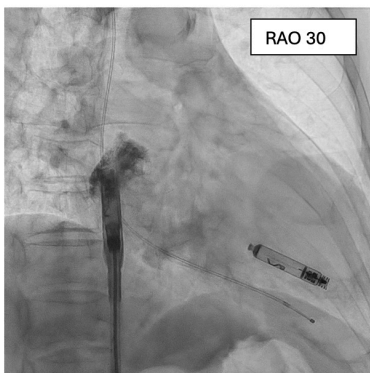




- **Tissue Engagement:** Under fluoro, note movement of the distal section of the delivery catheter with the cardiac cycle. Retract the protective sleeve fully and lock the hub lock to expose the helix and confirm stable contact in target location.

Right Atrial Appendage (RAA) Navigation

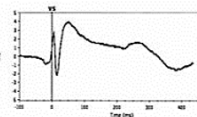
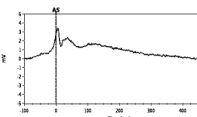
- **Positioning in RAO 30:** Begin with slight counterclockwise (CCW) rotation and slight deflection at the RA/IVC junction. Advance the catheter toward the base of the RAA using pigtail angiogram as a roadmap. Stop if “windshield wiper” motion or if billowing of the protective sleeve is observed.
- **Angiographic Assessment:** Inject contrast/saline mix in RAO 30 and LAO 30 views to visualize the appendage anatomy. Identify the target implant zone and avoid deep appendage



- **Tissue Engagement:** Advance the catheter in target location until the protective sleeve shows slight billowing, indicating contact. Retract the sleeve fully and lock the hub lock in place to expose the helix and confirm the LP remains stable under fluoroscopy.

5. MAP AND FIXATE

- Remove brake and deflection and assess catheter motion. Assess electricals:

Target Pre-Fixation Electricals ¹		
	Ventricular LP	Atrial LP
CEGM		
Impedance	350-700 Ω	$\geq 250 \Omega$
Sensing	≥ 5 mV	≥ 1 mV
Threshold	≤ 2.0 V @ 0.4 ms	≤ 3.0 V @ 0.4 ms

- Fixate LP: Cine chevron location for reference. Rotate the control knob clockwise 1.5 turns, pausing at 1 turn to ensure smooth torque transfer.
- Confirm and monitor slow and stable torque transmission via fluoro.

6. TETHER AND TEST

Right Ventricular LP

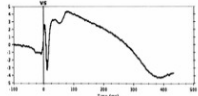
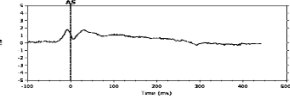
- Following fixation, proceed to **short tether mode** at the black line, ensuring no resistance is met
- Deflection test – Utilizing deflection with brake, deflect the catheter until the LP button moves 30-45°.
- Ensure helix is stable, no chevron rotation and LP movement is similar before and after test.
- Confirm electricals (CEGM, impedance, sensing, threshold).

Right Atrial LP

- Following fixation, proceed to **long tether mode**, ensuring no resistance is met.
- Tension test – Retract catheter until the atrial LP motion is dampened for 2-3 cardiac cycles then advance the catheter to return the slack.
- Ensure helix is stable, no chevron rotation and LP movement is similar before and after test.
- Confirm electricals (CEGM, impedance, sensing, threshold).



Tether Mode Hand Position

Target Post-Fixation Electricals		
	Ventricular LP	Atrial LP
CEGM		
Impedance	Usually $\uparrow$ $\leq 1500 \Omega$	Either stable or slight $\uparrow$ 250-500 Ω
Sensing	Likely $\downarrow$ Then $\uparrow$ ≥ 5 mV	Likely $\downarrow$ Then $\uparrow$ ≥ 1 mV
Threshold	Likely $\uparrow$ Then $\downarrow$ ≤ 1.25 V @ 0.4ms	Very reactive, will $\uparrow$ Then $\downarrow$ ≤ 3.0 V @ 0.4ms

1. Neuzil, P., Hubbard, C., Doshi, R. N., Reddy, V. Y., Canby, R., Defaye, P., Exner, D. V., Shoda, M., Bongiorno, M. G., Hindricks, G., Callahan, T., Sundaram, S., Bruhns, K. P., Booth, D. F., Knops, R. E., & Ip, J. E. (2024). Implantation techniques for a helix-fixation dual-chamber leadless pacemaker. *Heart rhythm*, 21(12), 2552–2562. <https://doi.org/10.1016/j.hrthm.2024.09.053>

7. PAIR (IF DR SYSTEM) AND FINAL TEST

- Pair RA and RV LPs; assess i2i communication (signal strength and % throughput).
- Retest electricals before release.
- If needed, unpair, redock and reposition based on comprehensive assessment.

8. RELEASE AND REMOVE SYSTEM

- Retract catheter to remove slack on the tethers and ensure coaxial in both views.
- Brace LP control knob, pull out and rotate release knob counterclockwise to release LP.
- Retract catheter into protective sleeve and VBT; remove system safely.
- Confirm final electricals, final programming, and complete closure.



Hand Position for Release

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.

Important Safety Information (USA):

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 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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