



**Abbott**

# AVEIR™ LEADLESS PACEMAKER SYSTEM MEDICARE FACILITY CODING & PAYMENT REPORT

Hospital              National

Physician Locale:    National

Prepared On:        Jan 22, 2026

## TERMS AND CONDITIONS

Estimates shown are for illustrative purposes only. This content is not intended for any other purpose. Estimates may be based upon several sources, included but not limited to: primary sources, scientific literature, commercially available data sets, data/inputs provided by the customer, and various external sources.

It should be noted that there are usually differences between modelling estimates and actual results. Abbott does not take responsibility for any such discrepancies. There is no guarantee of any potential economic outcome, including payment, cost savings, or procedure volume. Estimates are modelled using the Medicare Prospective Payment System fee schedule.

Certain Maryland hospitals paid under Maryland Waiver provisions using All Patients Refined Diagnosis Related Groups (APR-DRG) are excluded from payment under the Inpatient Prospective Payment System (IPPS). Providers using any other Medicare payment system are also excluded from this model.

Abbott may not provide Vermont Health Care Providers with any item of value at no-charge unless it is listed in the Vermont statute. Vermont does not list reimbursement or technical support services as items that may be provided. Abbott considers basic coding, coverage and reimbursement information related to procedures involving Abbott products to be “educational items” that are permissible under the Vermont statute. This reimbursement lookup is considered an educational item that is permissible under the Vermont statute.

This information is expressly not to be distributed to third parties. A provider may only receive their own information. Provider data may not be shared to other entities.



HOSPITAL INPATIENT

HOSPITAL OUTPATIENT

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IMPORTANT SAFETY INFORMATION

## AVEIR™ LEADLESS PACEMAKER SYSTEM

**Hospital Inpatient** 000000 - National

PROCEDURE	ICD-10 PCS CODE	TYPICAL MS-DRG ASSIGNMENT	MEDICARE LOCAL RATE	MEDICARE NATIONAL RATE
<b>INSERTION</b>		228 (w/MCC) Or 229 (w/o MCC)	\$36,001	\$36,001
AVEIR™ VR de novo insertion	02HK3NZ			
AVEIR™ AR/AVEIR™ AR2 de novo insertion	02H63NZ			
AVEIR™ DR de novo insertion	X2H63V9 + X2HK3V9			
<b>UPGRADE TO DUAL CHAMBER LP SYSTEM</b>				
AVEIR™ AR/AVEIR™ AR2 Insertion (existing AVEIR™ VR)	X2H63V9	Or 229	\$22,918	\$22,918
AVEIR™ VR Insertion (existing AVEIR™ AR/AVEIR™ AR2)	02HK3NZ			
<b>REMOVAL &amp; REVISION</b>				
Leadless Pacemaker Removal	02PA3NZ			
Leadless Pacemaker Revision	02WA3NZ			

Effective Dates: October 1, 2025 - September 30, 2026



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## AVEIR™ VR de novo

**Hospital Outpatient** 000000 - National

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE LOCAL RATE	MEDICARE NATIONAL RATE
<b>IMPLANT/REPLACEMENT</b>					
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed.	J1	5224	\$19,679	\$19,679
<b>REMOVAL WITHOUT LEADLESS REPLACEMENT</b>					
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed.	J1	5183	\$3,226	\$3,226
<b>PACEMAKER DEVICE PROGRAMMING- IN PERSON</b>					
93279	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system or leadless pacemaker system in one cardiac chamber	Q1	5741	\$38	\$38
<b>PACEMAKER DEVICE INTERROGATION- IN PERSON</b>					
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	Q1	5741	\$38	\$38
<b>PERI-PROCEDURE DEVICE PROGRAMMING; PACEMAKER</b>					
93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system, or leadless pacemaker system	N	NA	NA	NA

J1: Hospital Part B services paid through a comprehensive APC

N: Items and Services Packaged into APC Rates

Q1: STV-Packaged Codes

NA: Medicare has not established a payment amount for this code. Check with your local Medicare Administrative Contractor (MAC) to verify the payment amount.

Effective Dates: January 1, 2026 - December 31, 2026





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## AVEIR™ AR/AVEIR™ AR2 de novo

**Hospital Outpatient** 000000 - National

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE LOCAL RATE	MEDICARE NATIONAL RATE
<b>INSERTION</b>					
0823T	Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	J1	5224	\$19,679	\$19,679
<b>REMOVAL</b>					
0824T	Transcatheter removal of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography), when performed	J1	5183	\$3,226	\$3,226
<b>REMOVAL &amp; REPLACEMENT</b>					
0825T	Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	J1	5224	\$19,679	\$19,679
<b>PROGRAMMING DEVICE EVALUATION</b>					
0826T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, leadless pacemaker system in single-cardiac chamber	Q1	5741	\$38	\$38
<b>INTERROGATION</b>					
93288	Interrogation device evaluation (in person) with analysis, review and report by physician or other qualified healthcare professional, includes connection, recording, and connection per patient encounter; single, dual or multiple lead pacemaker system, or leadless pacemaker system	Q1	5741	\$38	\$38

Effective Dates: January 1, 2026 - December 31, 2026

J1: Hospital Part B services paid through a comprehensive APC

Q1: STV-Packaged Codes





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## AVEIR™ DR de novo & Upgrades to DR

**Hospital Outpatient** 000000 - National

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE LOCAL RATE	MEDICARE NATIONAL RATE
<b>INSERTION</b>					
0795T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, (right atrial and right ventricular components)	J1	5224	\$19,679	\$19,679
<b>UPGRADE TO DUAL CHAMBER LP SYSTEM</b>					
0796T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual chamber leadless pacemaker system)	J1	5224	\$19,679	\$19,679
0797T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, right ventricular pacemaker component (when part of a dual chamber leadless pacemaker system)	J1	5224	\$19,679	\$19,679
<b>REMOVAL</b>					
0798T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	J1	5183	\$3,226	\$3,226
0799T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial component)	J1	5183	\$3,226	\$3,226
0800T	Transcatheter removal of permanent dual chamber leadless pacemaker (right ventricular component)	J1	5183	\$3,226	\$3,226
<b>REMOVAL AND REPLACEMENT</b>					
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	J1	5224	\$19,679	\$19,679
0802T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial component)	J1	5224	\$19,679	\$19,679
0803T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right ventricular component)	J1	5224	\$19,679	\$19,679

Effective Dates: January 1, 2026 - December 31, 2026

**J1:** Hospital Part B services paid through a comprehensive APC





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## AVEIR™ DR de novo & Upgrades to DR

**Hospital Outpatient** 000000 - National

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE LOCAL RATE	MEDICARE NATIONAL RATE
<strong>PROGRAMMING AND DEVICE EVALUATION</strong>					
0804T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review, and report by physician or other qualified healthcare professional; leadless pacemaker system in dual cardiac chambers	Q1	5741	\$38	\$38
<strong>INTERROGATION</strong>					
93288	Interrogation device evaluation (in person) with analysis, review and report by physician or other qualified healthcare professional, includes connection, recording, and connection per patient encounter; single, dual or multiple lead pacemaker system, or leadless pacemaker system	Q1	5741	\$38	\$38

Effective Dates: January 1, 2026 - December 31, 2026

Q1: STV-Packaged Codes



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## AVEIR™ DR de novo MEDICARE ADDITIONAL PAYMENT

Medicare provides a pathway for additional device reimbursement when certain new medical technologies are used for eligible cases on Medicare beneficiaries in the hospital inpatient and outpatient settings. The new technology add-on payment (NTAP) and transitional pass-through (TPT) payment are two types of add-on payments. The purpose of NTAP and TPT payments is to ensure Medicare beneficiaries' access to technologies that are too new to be well represented in the data CMS uses to set rates under Medicare's Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS), respectively. In other words, NTAP and TPT payments are intended to minimize cost and payment barriers that would otherwise inhibit the adoption of new, outcome-improving technologies for Medicare beneficiaries. A criterion for both NTAP and TPT applications is that the new medical technology represents a substantial clinical improvement over current therapy options. In both cases, CMS determined the AVEIR™ DR Dual Chamber Leadless Pacemaker (LP) System met this criterion.



## Hospital Inpatient – New Technology Add-On Payment (NTAP)

The NTAP reimburses procedures performed in the hospital inpatient setting for costs related to their use of eligible new technologies in addition to the prospective diagnosis related group (MS-DRG) payment. The NTAP amount is the lesser of 65 percent of the cost of the new medical technology or 65 percent of the amount by which the costs of the case exceed the standard MS-DRG payment.

NTAP only applies to AVEIR™ DR de novo and AR/AR2 upgrade (with existing VR) cases for Traditional Medicare patients in the hospital inpatient setting.

### NTAP Payment Example (does not represent any known hospital)

DESCRIPTION		CALCULATION	
	Hospital Charges (entire hospital stay, including device)	A	
	Hospital Inpatient Charge Ratio (published by Medicare; hospital specific)	B	
NTAP ELIGIBILITY	Total Hospital Case Cost	C	A X B
	Hospital Specific Reimbursement MS-DRG 228 or 229	D	228 or 229
	Hospital Case Cost Minus MS-DRG Payment (hospital case cost must exceed MS-DRG payment)	E	C - D
NTAP PAYMENT	65% of Hospital Case Cost Minus MS-DRG Payment	F	E X .65
	65% of New Medical Technology (set by Medicare during NTAP application process)	G	
	NTAP Payment Amount	H	Lesser of F and G
TOTAL REIMBURSEMENT	NTAP Payment + MS-DRG 228 or 229		D+H



## Hospital Outpatient – Transitional Pass-Through (TPT) Payment

The TPT payment reimburses hospitals for costs related to their use of eligible new technologies in the outpatient setting in addition to the prospective ambulatory payment classification (APC) payment. The amount of the TPT payment is the hospital's charge for the device adjusted to the actual cost for the device minus the device related portion of APC. The TPT payment amount varies depending on, among other things, the amount a hospital charges for the AVEIR™ DR System and the hospital's cost-to-charge (CCR) ratio.

TPT only applies to AVEIR™ DR de novo cases for Traditional Medicare patients in the hospital outpatient setting.

### TPT Payment Example (does not represent any known hospital)

	DESCRIPTION	CALCULATION	
Transitional Pass-Through (TPT) Payment	Hospital Charge for AVEIR™ DR Dual Chamber LP	A	
	Implantable Device Cost to Charge Ratio (Published by Medicare; varies for each specific hospital)	B	
	Hospital Cost for AVEIR™ DR Dual Chamber LP	C	A X B
	Device Related Portion of APC 5224 (offset) (Published by Medicare)	D	\$11,354
	Transitional Pass-Through Payment	E	C - D
APC Payment	Medicare Reimbursement APC 5224 (hospital specific)	F	
<b>TOTAL REIMBURSEMENT</b>	<b>TPT Payment Amount + Procedure Payment</b>		<b>E + F</b>



## AVEIR™ VR de novo

### HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
AVEIR™ VR insertion (de novo)	
C1786	Pacemaker, single-chamber rate responsive (implantable)
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser
C1894	Leadless Delivery Catheter

### ICD-10-CM (International Classification of Diseases, Tenth Revision, Clinical Modification) Diagnosis Codes

Diagnosis codes are used by both hospitals and physicians to document the indication for the procedure. For Cardiac Pacemaker, Implantable Cardioverter Defibrillator (ICD) and Implantable/Insertable Cardiac Monitors (ICM) patients, there are many possible diagnosis code scenarios and a wide variety of possible combinations. The possible scenarios and combinations are too numerous to capture in this document. The customer should check with their local carriers or intermediaries and should consult with legal counsel or a financial, coding or reimbursement specialist for coding, reimbursement or billing questions related to ICD-10-CM diagnosis codes. Diagnosis is the sole responsibility of the physician and reimbursement support provided is not intended to affect the physician's independent clinical judgment.

### Commercial (Private) Payers

Coverage for leadless pacemakers varies by payer policy.

We encourage providers to contact non-Medicare payers to confirm coverage prior to performing the procedure.



## AVEIR™ AR/AVEIR™ AR2 de novo

### HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
AVEIR™ AR/AVEIR™ AR2 Insertion (de novo)	
C1786	Pacemaker, single-chamber rate responsive (implantable)
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser
C1894	Leadless Delivery Catheter

### ICD-10-CM (International Classification of Diseases, Tenth Revision, Clinical Modification) Diagnosis Codes

Diagnosis codes are used by both hospitals and physicians to document the indication for the procedure. For Cardiac Pacemaker, Implantable Cardioverter Defibrillator (ICD) and Implantable/Insertable Cardiac Monitors (ICM) patients, there are many possible diagnosis code scenarios and a wide variety of possible combinations. The possible scenarios and combinations are too numerous to capture in this document. The customer should check with their local carriers or intermediaries and should consult with legal counsel or a financial, coding or reimbursement specialist for coding, reimbursement or billing questions related to ICD-10-CM diagnosis codes. Diagnosis is the sole responsibility of the physician and reimbursement support provided is not intended to affect the physician's independent clinical judgment.

### Commercial (Private) Payers

Coverage for leadless pacemakers varies by payer policy.

We encourage providers to contact non-Medicare payers to confirm coverage prior to performing the procedure.



## AVEIR™ DR de novo & Upgrades to DR

### HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
AVEIR™ DR de novo	
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
C1605	Leadless Delivery Catheter
C1605	Leadless Delivery Catheter
C1605	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser
AVEIR™ AR/AVEIR™ AR2 Upgrade to AVEIR™ DR (existing AVEIR™ VR)	
C1786	Implantable/insertable device, not otherwise classified
C1894	Leadless Delivery Catheter
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser
AVEIR™ VR Upgrade to AVEIR™ DR (existing AVEIR™ AR/AVEIR™ AR2)	
C1786	Pacemaker, single-chamber rate responsive (implantable)
C1894	Leadless Delivery Catheter
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser

Effective July 1, 2024, a newly created Level II HCPCS Code (C1605) can be used to bill for the AVEIR™ DR Dual Chamber Leadless Pacemaker System. This code describes the actual device in the hospital outpatient setting for Medicare fee for service patients and may be billed in addition to the implant procedure codes described by Category III CPT Codes 0795T and 0801T.

### ICD-10-CM (International Classification of Diseases, Tenth Revision, Clinical Modification) Diagnosis Codes

Diagnosis codes are used by both hospitals and physicians to document the indication for the procedure. For Cardiac Pacemaker, Implantable Cardioverter Defibrillator (ICD) and Implantable/Insertable Cardiac Monitors (ICM) patients, there are many possible diagnosis code scenarios and a wide variety of possible combinations. The possible scenarios and combinations are too numerous to capture in this document. The customer should check with their local carriers or intermediaries and should consult with legal counsel or a financial, coding or reimbursement specialist for coding, reimbursement or billing questions related to ICD-10-CM diagnosis codes. Diagnosis is the sole responsibility of the physician and reimbursement support provided is not intended to affect the physician's independent clinical judgment.

### Commercial (Private) Payers

Coverage for leadless pacemakers varies by payer policy.

We encourage providers to contact non-Medicare payers to confirm coverage prior to performing the procedure.



## AVEIR™ VR Ventricular Leadless Pacemaker (LP) System

### IMPORTANT SAFETY INFORMATION

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).



## AVEIR™ AR/AVEIR™ AR2 Atrial Leadless Pacemaker (LP) System

### IMPORTANT SAFETY INFORMATION

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™ DR Dual Chamber Leadless Pacemaker (LP) System

### IMPORTANT SAFETY INFORMATION

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.



## REFERENCES

1. FY2026 IPPS Interim Final Comment Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: August 2025].  
<https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page>
2. CY2026 MPFS Final Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: November 2025].  
<https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1832-f>
3. CY2026 OPPS Final Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: November 2025].  
<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1834-fc>
4. CMS 2026 ICD-10-CM [cited: August 2025].  
<https://www.cms.gov/medicare/coding-billing/icd-10-codes#CodeFiles>
5. Leadless Pacemakers [cited: June 2022].  
<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Leadless-Pacemakers>
6. Claim Submission [cited: June 2022].  
<https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00232303>
7. AVEIR™ VR Coverage With Evidence Development Post-Approval Study (CED) [cited: June 2022]  
<https://clinicaltrials.gov/ct2/show/NCT05336877?term=NCT05336877&draw=2&rank=1>
8. AVEIR™ DR Coverage With Evidence Development Post-Approval Study (CED) [cited: November 2023]  
<https://clinicaltrials.gov/study/NCT05932602>
9. AVEIR™ AR/AVEIR™ AR2 Coverage With Evidence Development Post-Approval Study (CED) [cited: April 2024]  
<https://clinicaltrials.gov/study/NCT06100770?lead=Abbott%20Medical%20Devices&rank=5>
10. AMA CPT® Category III Codes, First Ten Years [cited: January 2024]  
<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjU6N3r65GDAxXW4TgGHbI-D2MQFnoECBMQAO&url=https%3A%2Fwww.ama-assn.org%2Fmedia%2F9291%2Fdownload&usg=AOvVaw0ZTX992B4EB2S5k76j8slK&opi=89978449>
11. AMA CPT® Category III codes long [cited: January 2024]  
<https://www.ama-assn.org/system/files/cpt-category3-codes-long-descriptors.pdf>
12. National Coverage Determination Leadless Pacemakers 20.8.4 [cited: January 2024]  
<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=370>
13. Medicare Claims Processing Manual, Chapter 32, Section 380 - Leadless Pacemakers [cited: January 2024]  
<https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c32.pdf>
14. CMS New Technology Add-on Payment [cited: April 2024]  
<https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies>
15. CMS 1500 Claim Form [cited: April 2024]  
<https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms1500.pdf>
16. CMS UB-04 Claim Form [cited: April 2024]  
<https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/downloads/cms-1450.zip>
17. Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC) [cited: May 2024]  
<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc>
18. Device Offset Code Pairs [cited: September 2024]  
<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/device-offset-code-pairs>

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