Abbott

Cardiac Rhythm Management

AVEIR™ LEADLESS PACEMAKER SYSTEM

MEDICARE FACILITY CODING & PAYMENT GUIDE

Effective January 1st, 2025

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TERMS AND CONDITIONS

All content herein may be based upon several sources, included but not limited to primary sources, scientific literature, commercially available data sets, customer supplied information, and external sources.
Estimates shown are for illustrative purposes only. This content is not intended for any other purpose.

It should be noted that there are usually differences between economic modelling 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. Economic outcomes are dependent on many factors and will vary.

Certain Maryland hospitals paid under Maryland Waiver provisions using All Patient Refined Diagnosis Related Group (APR-DRG) are excluded from payment under the Medicare Inpatient Prospective Payment System (IPPS).

Reimbursement Calculators should not be provided at no charge to actively licensed Healthcare Professionals (HCPs) who regularly practice in Vermont.

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AVEIR™ LEADLESS PACEMAKER SYSTEM

PROCEDURE	ICD-10 PCS CODE	TYPICAL MS-DRG ASSIGNMENT	MEDICARE NATIONAL RATE
INSERTION		228 (w/MCC) Or 229 (w/o MCC)	$35,563 / $22,168
VR de novo insertion	02HK3NZ		
AR de novo insertion	02H63NZ		
DR de novo insertion	X2H63V9 + X2HK3V9		
UPGRADE TO DUAL CHAMBER LP SYSTEM			
AR Insertion (existing VR)	X2H63V9		
VR Insertion (existing AR)	02HK3NZ		
REMOVAL & REVISION			
Leadless Pacemaker Removal	02PA3NZ		
Leadless Pacemaker Revision	02WA3NZ		

Effective Dates: October 1, 2024 - September 30, 2025

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AVEIR™ VR de novo

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	IMPLANT/REPLACEMENT			
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	$19,071
	REMOVAL WITHOUT LEADLESS REPLACEMENT			
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed.	J1	5183	$3,148
	PACEMAKER DEVICE PROGRAMMING- IN PERSON			
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	$37
	PACEMAKER DEVICE INTERROGATION- IN PERSON			
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	$37
	PERI-PROCEDURE DEVICE PROGRAMMING; PACEMAKER			
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

Effective Dates: January 1, 2025 - December 31, 2025

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.

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AVEIR™ AR de novo

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	INSERTION			
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	$19,071
	REMOVAL			
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	$3,148
	REMOVAL & REPLACEMENT			
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	$19,071
	PROGRAMMING DEVICE EVALUATION			
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	$37
	INTERROGATION			
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	$37

Effective Dates: January 1, 2025 - December 31, 2025

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

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	INSERTION			
0795T	Transcatheter insertion of a permanent dual chamber leadless pacemaker, (right atrial and right ventricular components)	J1	5224	$19,071
	UPGRADE TO DUAL CHAMBER LP SYSTEM			
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	$19,071
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	$19,071
	REMOVAL			
0798T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	J1	5183	$3,148
0799T	Transcatheter removal of permanent dual chamber leadless pacemaker (right atrial component)	J1	5183	$3,148
0800T	Transcatheter removal of permanent dual chamber leadless pacemaker (right ventricular component)	J1	5183	$3,148
	REMOVAL AND REPLACEMENT			
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial and right ventricular components)	J1	5224	$19,071
0802T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right atrial component)	J1	5224	$19,071
0803T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker (right ventricular component)	J1	5224	$19,071

Effective Dates: January 1, 2025 - December 31, 2025

J1: Hospital Part B services paid through a comprehensive APC

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AVEIR™ DR de novo & Upgrades to DR

CPT‡ CODE	DESCRIPTION	STATUS INDICATOR	APC	MEDICARE NATIONAL RATE
	PROGRAMMING AND DEVICE EVALUATION			
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	$37
	INTERROGATION			
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	$37

Effective Dates: January 1, 2025 - December 31, 2025

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.

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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 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

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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	$11,828
	Transitional Pass-Through Payment	E	C - D
APC Payment	Medicare Reimbursement APC 5224 (hospital specific)	F	
TOTAL REIMBURSEMENT	TPT Payment Amount + Procedure Payment		E + F

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AVEIR™ VR de novo

HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
	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.

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AVEIR™ AR de novo

HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
	AR 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.

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AVEIR™ DR de novo & Upgrades to DR

HCPCS Device Category C-Codes

C-CODE	DESCRIPTION
	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
	AR Upgrade to DR (existing VR)
C1889	Implantable/insertable device, not otherwise classified
C1894	Leadless Delivery Catheter
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, nonlaser
	VR Upgrade to DR (existing AR)
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.

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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).

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AVEIR™ AR 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.

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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.

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1. FY2025 IPPS Interim Final Comment Rule Home Page. U.S. Centers for Medicare and Medicaid Services. [cited: November 2024].
   https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page
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