HEALTH ECONOMICS & REIMBURSEMENT

AVEIR™ LEADLESS PACEMAKER CODING GUIDE

FOR VENTRICULAR, ATRIAL, AND DUAL CHAMBER

Hospital Inpatient

Effective October 1, 2026 to September 30, 2027

Hospital Outpatient, Physician

Effective January 1, 2026 to December 31, 2026

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OVERVIEW

This content is intended to provide reference material related to general guidelines for reimbursement when used consistently with the product's labeling. This content includes information regarding coverage, coding and reimbursement.

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AVEIR VR de novo insertion

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AVEIR™ AR/AVEIR™ AR2 Atrial LP System

AVEIR AR/AVEIR™ AR2 de novo insertion

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AVEIR™ DR Dual Chamber LP System

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NATIONAL MEDICARE PAYMENT RATES

The payment rates shown are the National Average Medicare payment rates for all sites of service.

REIMBURSEMENT SUPPORT

REIMBURSEMENT HOTLINE

Abbott offers a reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement assistance is provided subject to the disclaimers set forth in this guide.

8 a.m. to 5 p.m. Central Time, Monday – Friday

Call (855) 569-6430

Email reimbursementhelp@abbott.com

This content and supporting documents are available at: www.cardiovascular.abbott/us/en/hcp/reimbursement

REIMBURSEMENT FIELD TEAM

To contact a reimbursement specialist for coverage, coding or payment questions, scan the QR code or send an email to LeadlessReimbursement@abbott.com.

PATIENT THERAPY ACCESS TEAM

Abbott has a team of patient therapy access specialists to assist with prior authorization questions. Email aveir_pta@abbott.com

MEDICARE COVERAGE

LEADLESS PACEMAKER THERAPY

The Leadless Pacemaker must be used in accordance with FDA-approved label for the device. It is the responsibility of the physician to determine whether the procedure meets the criteria for coverage and for confirming use in accordance with approved labeling. It is the responsibility of the physician to diagnose and treat the patient and to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure claims are accurate, complete, and supported by documentation in the patient's medical record.

The Leadless Pacemaker System is approved by CMS under a claims analysis study that will passively collect and analyze real world data to demonstrate the role of the therapy in patients that need a pacemaker. View National Coverage Determination (NCD): Leadless Pacemakers (20.8.4) for more information: www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=370

MEDICARE CLAIM FORM INSTRUCTIONS

The AVEIR™ leadless pacemaker system is provided under a CMS-approved Coverage with Evidence Development (CED) study. As outlined in the CMS Manual, Transmittal 2955, it is mandatory that the national clinical trial number be reported on the professional and institutional claims for all AVEIR™ procedures billed for Traditional Medicare and Medicare Advantage beneficiaries.

CLAIMS IDENTIFYING INFORMATION TO SIGNIFY PATIENT IS PARTICIPATING IN A STUDY	PROFESSIONAL CLAIM FORM (CMS 1500-837P)	INSTITUTIONAL CLAIM FORM (UB-04-837i)
National Clinical Trial (NCT) Number	VR: 05336877 (For paper claims, report: CT05336877) AR: 06100770 (For paper claims, report: CT06100770) DR (including upgrades): 05932602 (For paper claims, report: CT05932602)	VR: 05336877 AR: 06100770 DR (including upgrades): 05932602
Condition Code	Not reported on Physician Claim	30 qualifying clinical trial
Secondary Diagnosis Code	Z00.6 (Encounter for examination for normal comparison and control in clinical research program)	Z00.6 (Encounter for examination for normal comparison and control in clinical research program)
Q0 (zero) Modifier	Q0 (Investigational clinical service provided in a clinical research study that is an approved clinical research study)	Q0 (Investigational clinical service provided in a clinical research study that is an approved clinical research study) Q0 modifier applies to outpatient claims only
Value codes	Not applicable	D4 (“code”) and NCT number (“amount”)

MEDICARE ADVANTAGE COVERAGE

Medicare Advantage plans must cover AVEIR™ Leadless Pacemaker systems consistent with the NCD.

- Medicare Advantage plans may not impose more restrictive coverage criteria than detailed in the NCD.
- Medicare Advantage plans may use prior authorization/pre-certification to ensure compliance with the NCD.

Please reach out directly to Medicare Advantage plan administrators to understand any specific prior authorization/pre-certification requirements that may apply.

COMMERCIAL PAYERS COVERAGE

- There is coverage available, subject to commercial payer policy.
- Commercial payers should be consulted in advance of the procedure to verify terms and conditions of coverage.
- Please check with the payer regarding appropriate coding and payment information.

Please consult the commercial payer directly to ensure complete understanding of any relevant coverage policies and billing requirements.

HOSPITAL INPATIENT[1]

Effective October 1, 2026 to September 30, 2027

AVEIR™ VR Ventricular LP System	AVEIR™ AR/AVEIR™ AR2 Atrial LP System	AVEIR™ DR Dual Chamber LP System (Includes Upgrades)

AVEIR™ LEADLESS PACEMAKER

AVEIR™ Leadless Pacemaker procedures are assigned MS-DRG 228/229: Other Cardiothoracic Procedures. The rates in the table below are the Medicare national average reimbursement rates. For hospital specific rates, please contact your local Abbott representative.

PROCEDURE	ICD-10-PCS CODE	DESCRIPTION	TYPICAL MS-DRG	MEDICARE RATE
INSERTION				
VR de novo insertion	02HK3NZ	Insertion of Intracardiac Pacemaker into Right Ventricle, Percutaneous Approach	228* (w/MCC) OR 229** (w/o MCC)	$36,694 / $25,421
AR/AR2 de novo insertion	02H63NZ	Insertion of Intracardiac Pacemaker into Right Atrium, Percutaneous Approach		
DR de novo insertion	X2H63V9	Insertion of Dual-Chamber Intracardiac Pacemaker into Right Atrium, Percutaneous Approach, New Technology Group 9		
	X2HK3V9	Insertion of Dual-Chamber Intracardiac Pacemaker into Right Ventricle, Percutaneous Approach, New Technology Group 9		
UPGRADE TO DUAL CHAMBER LP SYSTEM				
AR/AR2 insertion (existing VR)	X2H63V9	Insertion of Dual Chamber Intracardiac Pacemaker into Right Atrium, Percutaneous Approach, New Technology Group 9		
VR insertion (existing AR)	02HK3NZ	Insertion of Intracardiac Pacemaker into Right Ventricle, Percutaneous Approach		
REMOVAL & REVISION				
Leadless Pacemaker Removal	02PA3NZ	Removal of Intracardiac Pacemaker from Heart, Percutaneous Approach		
Leadless Pacemaker Revision	02WA3NZ	Revision of Intracardiac Pacemaker in Heart, Percutaneous Approach		

*MS-DRG 228: Other cardiothoracic procedures with MCC (Major complications and comorbidities)
**MS-DRG 229: Other cardiothoracic procedures without MCC (Major complications and comorbidities)

Disclaimer: This is not an all-inclusive list of possible MS-DRGs. MS-DRG assignment is based on many factors including documented patient conditions, as well as services rendered during an inpatient admission.

NEW TECHNOLOGY ADD-ON PAYMENT (NTAP)

NTAP effective October 1, 2023 to September 30, 2026 and applies only to AVEIR™ DR de novo and AR upgrade (with existing VR) cases for Traditional Medicare patients in the hospital inpatient setting.[15]

- The NTAP provides incremental payment in addition to the applicable Medicare Severity Diagnosis Related Group (MS-DRG) Payment for qualified technologies.
- The NTAP amount is the lesser of the NTAP maximum payment OR 65% of the amount by which the case costs exceed the assigned MS-DRG payment.
- DR de novo NTAP maximum payment $15,600.
- AR Upgrade (existing VR) NTAP maximum payment $10,725.

Contact LeadlessReimbursement@abbott.com to request sample calculations.

HOSPITAL OUTPATIENT[2] & PHYSICIAN[3]

Effective January 1, 2026 to December 31, 2026

AVEIR™ VR Ventricular LP System | AVEIR™ AR/AVEIR™ AR2 Atrial LP System | AVEIR™ DR Dual Chamber LP System (Includes Upgrades)

AVEIR™ VR DE NOVO

CPT‡ CODE	DESCRIPTION	HOSPITAL OUTPATIENT SI	HOSPITAL OUTPATIENT APC	HOSPITAL OUTPATIENT MEDICARE RATE	PHYSICIAN WORK RVU	PHYSICIAN FACILITY	PHYSICIAN OFFICE
INSERTION/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	$19,679	7.61	$420	NA
REMOVAL							
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	8.38	$447	NA
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	$38	0.63	$31*	$67
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	$38	0.42	$20*	$55

J1 = Hospital Part B services paid through a comprehensive APC
Q1 = STV-Packaged Codes
* Facility rates shown with an * reflect payment when modifier 26 is used (i.e., payment only for the professional component)

See Important Safety Information referenced within on page 12-13

HOSPITAL OUTPATIENT[2,5] & PHYSICIAN[3]

Effective January 1, 2026 to December 31, 2026

AVEIR™ VR Ventricular LP System | **AVEIR™ AR/AVEIR™ AR2 Atrial LP System** | AVEIR™ DR Dual Chamber LP System (Includes Upgrades)

AVEIR™ AR/AVEIR™ AR2 DE NOVO

CPT‡ CODE	DESCRIPTION	HOSPITAL OUTPATIENT			PHYSICIAN		
		SI	APC	MEDICARE RATE	WORK RVU[6]	FACILITY	OFFICE
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	$19,679	C	C	NA
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	$3,226	C	C	NA
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	$19,679	C	C	NA
PROGRAMMING – IN PERSON							
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	C	C	C
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	$38	0.42	$20*	$55

Category III CPT‡ codes, or T-codes, are temporary codes assigned to emerging technologies. T-codes do not have established RVUs or reimbursement rates and are contractor-priced. The AVEIR™ AR and AVEIR™ DR Leadless Pacemaker procedures have T-codes. Check your local payer contracts and policies to verify appropriate conditions of coverage and payment.

Contact LeadlessReimbursement@abbott.com to request Physician Coding Guides, including instructions for Category III CPT‡ codes.

J1 = Hospital Part B services paid through a comprehensive APC
Q1 = STV-Packaged Codes
C = Contractor-priced code. Contractors establish RVUs and payment amounts for these services
* Facility rates shown with an * reflect payment when modifier 26 is used (i.e., payment only for the professional component)

See Important Safety Information referenced within on page 12-13

HOSPITAL OUTPATIENT[2,5] & PHYSICIAN[3]

Effective January 1, 2026 to December 31, 2026

AVEIR™ VR Ventricular LP System | AVEIR™ AR/AVEIR™ AR2 Atrial LP System | **AVEIR™ DR Dual Chamber LP System (Includes Upgrades)**

AVEIR™ DR DE NOVO & UPGRADES TO DR

CPT‡ CODE	DESCRIPTION	HOSPITAL OUTPATIENT SI	HOSPITAL OUTPATIENT APC	HOSPITAL OUTPATIENT MEDICARE RATE	PHYSICIAN WORK RVU[6]	PHYSICIAN FACILITY	PHYSICIAN OFFICE
INSERTION							
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	J1	5224	$19,679	C	C	NA
UPGRADE TO DUAL CHAMBER LP SYSTEM							
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; 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	C	C	NA
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	J1	5224	$19,679	C	C	NA
REMOVAL							
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	J1	5183	$3,226	C	C	NA
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component	J1	5183	$3,226	C	C	NA
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	J1	5183	$3,226	C	C	NA
REMOVAL & REPLACEMENT							
0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)	J1	5224	$19,679	C	C	NA
0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component	J1	5224	$19,679	C	C	NA
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	J1	5224	$19,679	C	C	NA

Category III CPT‡ codes, or T-codes, are temporary codes assigned to emerging technologies. T-codes do not have established RVUs or reimbursement rates and are contractor-priced. The AVEIR™ AR and AVEIR™ DR Leadless Pacemaker procedures have T-codes. Check your local payer contracts and policies to verify appropriate conditions of coverage and payment.

Contact LeadlessReimbursement@abbott.com to request Physician Coding Guides, including instructions for Category III CPT‡ codes.

J1 = Hospital Part B services paid through a comprehensive APC
* Facility rates shown with an * reflect payment when modifier 26 is used (i.e., payment only for the professional component)

See Important Safety Information referenced within on page 12-13

HOSPITAL OUTPATIENT[2,5] & PHYSICIAN[3]

Effective January 1, 2026 to December 31, 2026

AVEIR™ VR Ventricular LP System	AVEIR™ AR/AVEIR™ AR2 Atrial LP System	**AVEIR™ DR Dual Chamber LP System (Includes Upgrades)**

AVEIR™ DR DE NOVO & UPGRADES TO DR

CPT‡ CODE	DESCRIPTION	HOSPITAL OUTPATIENT			PHYSICIAN		
		SI	APC	MEDICARE RATE	WORK RVU[6]	FACILITY	OFFICE
PROGRAMMING – IN PERSON							
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	C	C	C
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	$38	0.42	$20*	$55

Category III CPT‡ codes, or T-codes, are temporary codes assigned to emerging technologies. T-codes do not have established RVUs or reimbursement rates and are contractor-priced. The AVEIR™ AR and AVEIR™ DR Leadless Pacemaker procedures have T-codes. Check your local payer contracts and policies to verify appropriate conditions of coverage and payment.

Contact LeadlessReimbursement@abbott.com to request Physician Coding Guides, including instructions for Category III CPT‡ codes.

Q1 = STV-Packaged Codes
* Reflect payment when modifier 26 is used (i.e., payment only for the professional component)

See Important Safety Information referenced within on page 12-13

HOSPITAL OUTPATIENT[2]

Effective January 1, 2026 to December 31, 2026

TRANSITIONAL PASS THROUGH PAYMENT (TPT) ADD-ON PAYMENT*

Effective July 1, 2024 to June 30, 2027, Medicare approved Transitional Pass-Through (TPT) payment when the AVEIR™ DR Dual Chamber LP System is utilized in eligible procedures in the hospital outpatient setting.[14]

- 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 AVEIR DR Dual Chamber LP System adjusted to the actual cost for the AVEIR DR Dual Chamber LP System 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 for implantable medical devices.

TPT only applies to AVEIR™ DR implant procedures described by Category III CPT‡ Codes 0795T and 0801T for Traditional Medicare patients in the hospital outpatient setting.

Contact LeadlessReimbursement@abbott.com to request sample calculations and details on required HCPCS Level II reporting. Additional resources are available at www.cardiovascular.abbott/us/en/hcp/reimbursement/crm.html.

HCPCS DEVICE CATEGORY C-CODES[4]

Effective January 1, 2026 to December 31, 2026

AVEIR™ VR Ventricular LP System	AVEIR™ AR/AVEIR™ AR2 Atrial LP System	AVEIR™ DR Dual Chamber LP System (Includes Upgrades)

LP SYSTEM	HCPCS CODE & DESCRIPTION
VR de novo	C1786 Pacemaker, Single-Chamber, Rate Responsive (implantable) C1894 Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser
AR/AR2 de novo	C1786 Pacemaker, Single-Chamber, Rate Responsive (implantable) C1894 Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser
DR de novo	C1605* Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation
AR/AR2 insertion to upgrade to a dual chamber (existing VR)	C1786 Implantable/insertable device, not otherwise classified C1894 Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser
VR insertion to upgrade to a dual chamber (existing AR/AR2)	C1786 Pacemaker, Single-Chamber, Rate Responsive (implantable) C1894 Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser

*If hospitals do not report C1605, they will not receive the TPT payment for the AVEIR™ DR Dual Chamber Leadless Pacemaker. Additionally, Medicare will not have adequate claims and cost information to determine the appropriate APC payment rate for procedures that include AVEIR™ DR Dual Chamber Leadless Pacemaker System. Contact LeadlessReimbursement@abbott.com to request components for TPT eligible procedures.

IMPORTANT SAFETY INFORMATION

AVEIR™ VR VENTRICULAR LEADLESS PACEMAKER (LP) SYSTEM

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).

See Important Safety Information referenced within on page 12-13

IMPORTANT SAFETY INFORMATION

AVEIR™ AR ATRIAL LEADLESS PACEMAKER (LP) SYSTEM & AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER (LP) SYSTEM

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, or chronic atrial fibrillation.

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 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:
- In patients with an implanted inferior vena cava filter, femoral access is contraindicated.
- In patients with an implanted superior vena cava filter, internal jugular access is contraindicated.
- Use is contraindicated in patients with a mechanical tricuspid valve because of interference between this device and the delivery system during implantation.
- In patients who are known to be hypersensitive to device material components or a single dose of 1.0 milligram of dexamethasone sodium phosphates.

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 arrhythmias; Carotid artery injury; Cardiac perforation; Cardiac tamponade; Cerebrovascular accident (CVA); Death; Diaphragmatic/phrenic nerve stimulation/extra-cardiac stimulation; endocarditis; Heart failure; Hypotension; Hypersensitivity reaction to device materials, contrast media, or medications; Infection; Pacemaker syndrome; Palpitations; Pericardial effusion; Pericarditis; Pneumothorax/Hemothorax; RV-pacing induced cardiomyopathy; Syncope; Thoracic/lymphatic duct injury; Valve damage or regurgitation. Adverse device effects include the following: Battery malfunction/ premature battery depletion; Corrupted, intermittent, or loss of i2i™ communication; Device dislodgement; Embolization of foreign material; Helix distortion; Inadequate fixation during implant with or without device migration (Intra-procedural); Inability to interrogate or program the LP due to programmer or LP malfunction; Inability to release/re-dock of the LP from catheter; Inappropriate sensor response; Increased capture threshold (Exit block, High-impedance, Threshold elevation); Intermittent or complete loss of capture, pacing or sensing (non-battery related); Interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic; Mechanical malfunction of the LP (non-battery related); Oversensing; Premature deployment; Undersensing. As with any percutaneous catheterization procedure, potential complications include, but are not limited to: Air embolism; Bleeding or hematoma; General procedural risks and complications from comorbidities, including but not limited to anesthetic complications, dyspnea, respiratory failure, syncope, pneumonia, hypertension, hypotension, cardiac failure, kidney failure due to reaction to contrast media, pain and anemia; Local and systemic infection; Peripheral nerve damage; Thrombus formation; Thromboembolism; Vascular access complications, such as arteriovenous fistula, pseudoaneurysm, perforation, dissection, puncture, venous occlusion.

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

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CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at manuals.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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