

# **ABBOTT AVEIR™ DR**

## **DUAL-CHAMBER LEADLESS PACEMAKER**

March 7, 2023

## PACEMAKER THERAPY

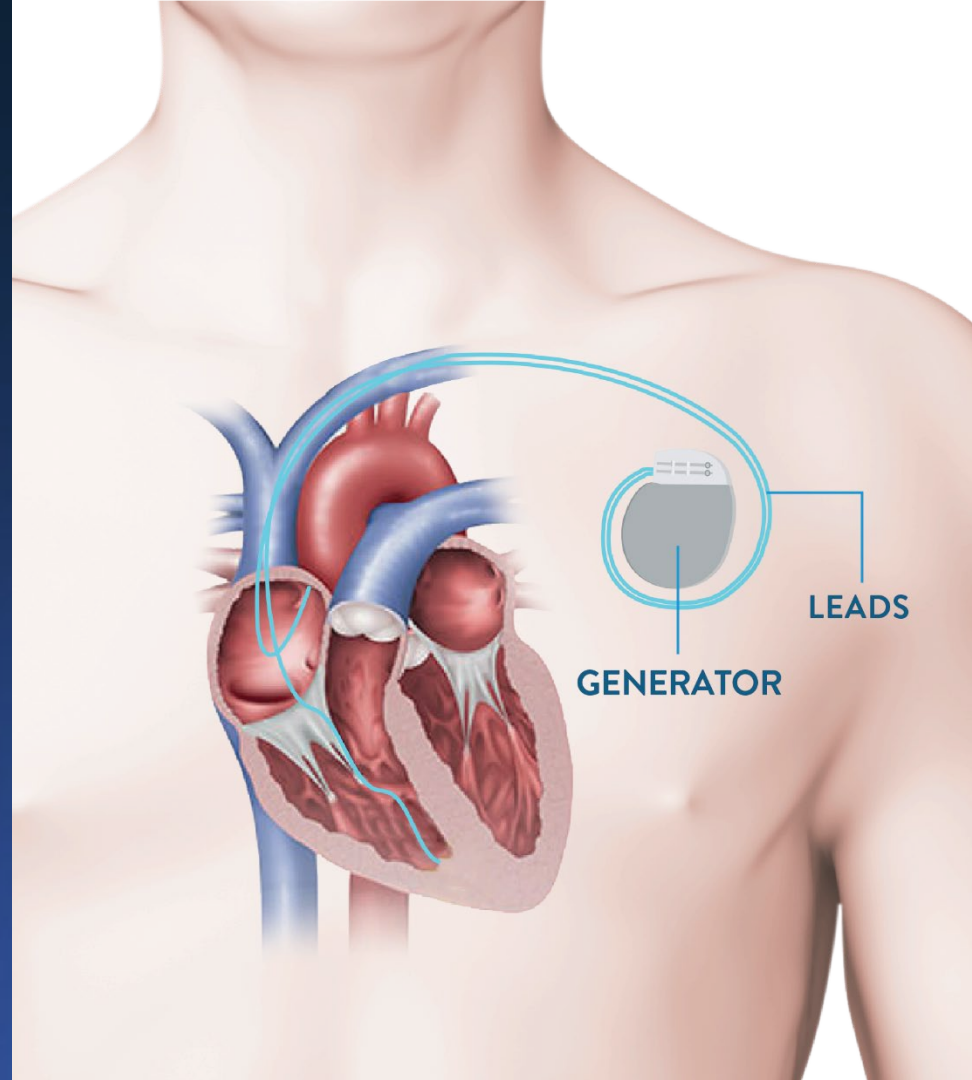
# Device Overview

### WHAT IS A PACEMAKER?

- A programmable, battery-powered implantable medical device that sends electrical pulses to the heart whenever it detects a slow heartbeat or no heartbeat at all

### WHAT DOES IT TYPICALLY INCLUDE?

- Pulse Generator (also called a can or battery) placed surgically under collar bone
- Leads (also called electrodes), positioned in various heart chambers, including right ventricle (RV) and right atrium (RA)

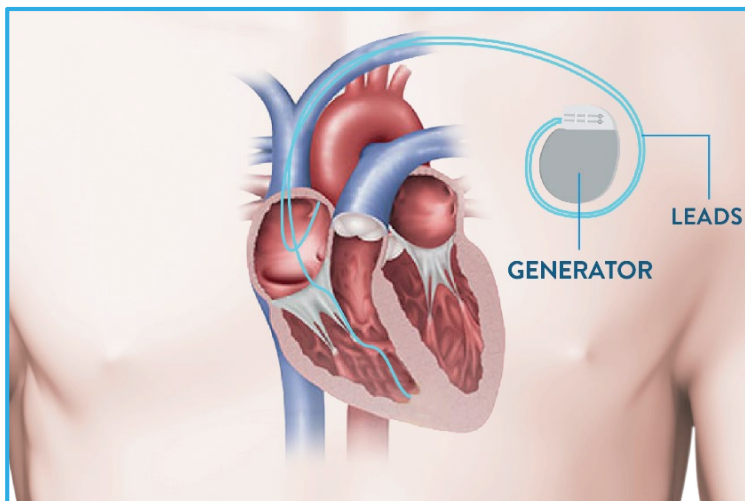


## LEADLESS TECHNOLOGY OVERVIEW

# Pursuing Separate ICD-10-PCS Code as Leadless Pacemakers Have Different Insertion Procedures

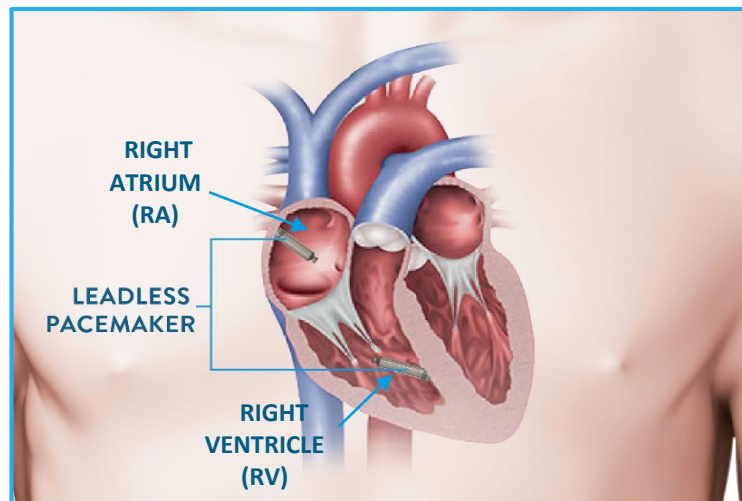
### TRANSVENOUS PACEMAKER

Subcutaneous generator and lead(s)

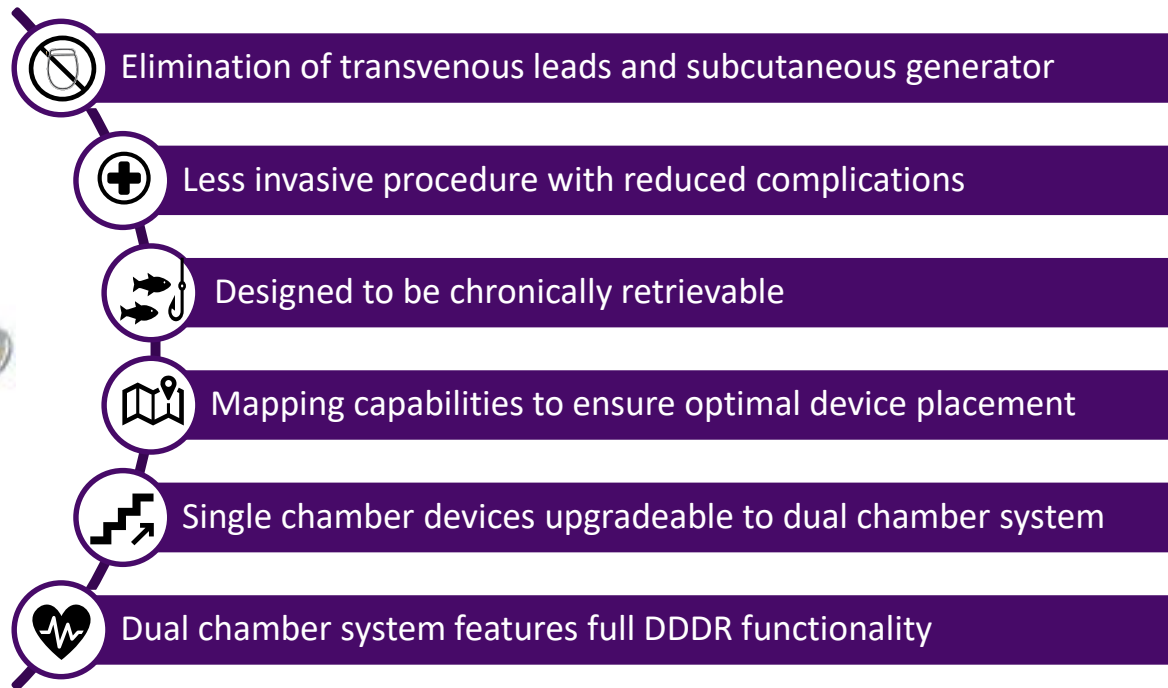


### LEADLESS PACEMAKER

Device(s) implanted directly in each chamber



# Aveir Single and Dual-Chamber Leadless Pacemakers

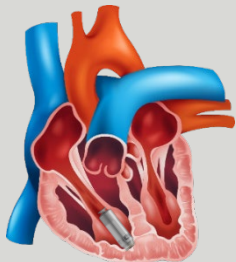


DDDR = dual chamber rate modulated mode; atrial-ventricular synchrony

# AVEIR™ is a Modular Leadless Pacemaker System

## Aveir™ VR: Right Ventricular Single-Chamber Leadless Pacemaker

- FDA approved
- Approved for CED coverage

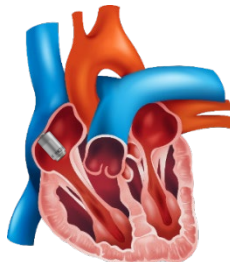


**RIGHT  
VENTRICLE**

### **Ventricular Pacing** indications:

- Significant bradycardia and normal sinus rhythm with only rare episodes of AV block or sinus arrest
- Chronic atrial fibrillation
- Severe physical disability

## Aveir™ AR: Right Atrial Single-Chamber Leadless Pacemaker

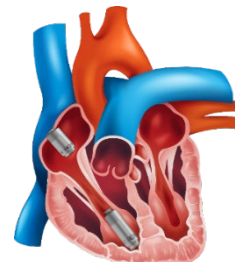


**RIGHT  
ATRIUM**

### **Atrial Pacing** indications:

- Sinus node dysfunction with normal AV and intraventricular conduction systems

## Aveir™ DR: Dual-Chamber Leadless Pacemaker



### **Dual-Chamber Pacing** indications:

- 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

Single chamber devices are upgradeable to accommodate future patient needs

# AVEIR™ Dual-Chamber Leadless Pacemaker Procedure

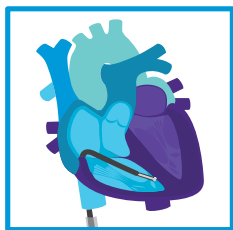
### SYSTEM OVERVIEW:

- Leadless pacemaker (LP): Battery, circuitry and electrodes combined in one device
  - Right ventricular (RV)
  - Right atrial (RA)
- Delivery catheter to place each LP
- Programmer to communicate with LP(s)

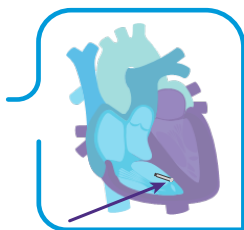
### PROCEDURAL HIGHLIGHTS:

- LP advanced through the femoral vein, directly into the target chamber with a minimally invasive approach
- Mapping can be performed to ensure accurate device placement
- **Insert, Map, Fixate, Release** steps are repeated for each separate target chamber
- Only LP device designed for chronic retrieval

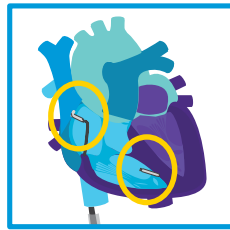
### DUAL CHAMBER LP PROCEDURE REQUIRES 2 DEVICE IMPLANTS IN SEPARATE HEART CHAMBERS



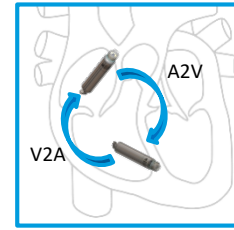
**INSERT** RV LP via delivery catheter  
**MAP** the site in RV septum



**FIXATE** LP to RV septum by rotating helix  
**RELEASE** the RV LP and withdraw delivery catheter



**REPEAT** for atrial LP  
**INSERT** RA LP via delivery catheter, **MAP** the RA site, **FIXATE** RA LP, and **RELEASE** the RA LP and withdraw delivery catheter



**PAIR** LP devices to provide AV synchronous pacing using i2i (implant to implant) communication for every heartbeat

# AVEIR™ Dual-Chamber Leadless Pacemaker Approval

FDA approval for Aveir™ DR and Aveir™ AR is anticipated by July 1, 2023.

## MEDICAL RECORD OF PROCEDURE/ TECHNOLOGY

Documentation of the Aveir™ System implant procedure will be included in the operative report

## TERMS FOR PROCEDURE/ TECHNOLOGY

- Aveir™ DR
- Aveir™ AR
- Aveir™ VR
- Dual-chamber leadless pacemaker
- Atrial leadless pacemaker
- Ventricular leadless pacemaker





**Abbott**