

AVEIR™ VR  
Leadless Pacemaker

SETTING THE PACE  
FOR WHAT'S TO COME



Abbott

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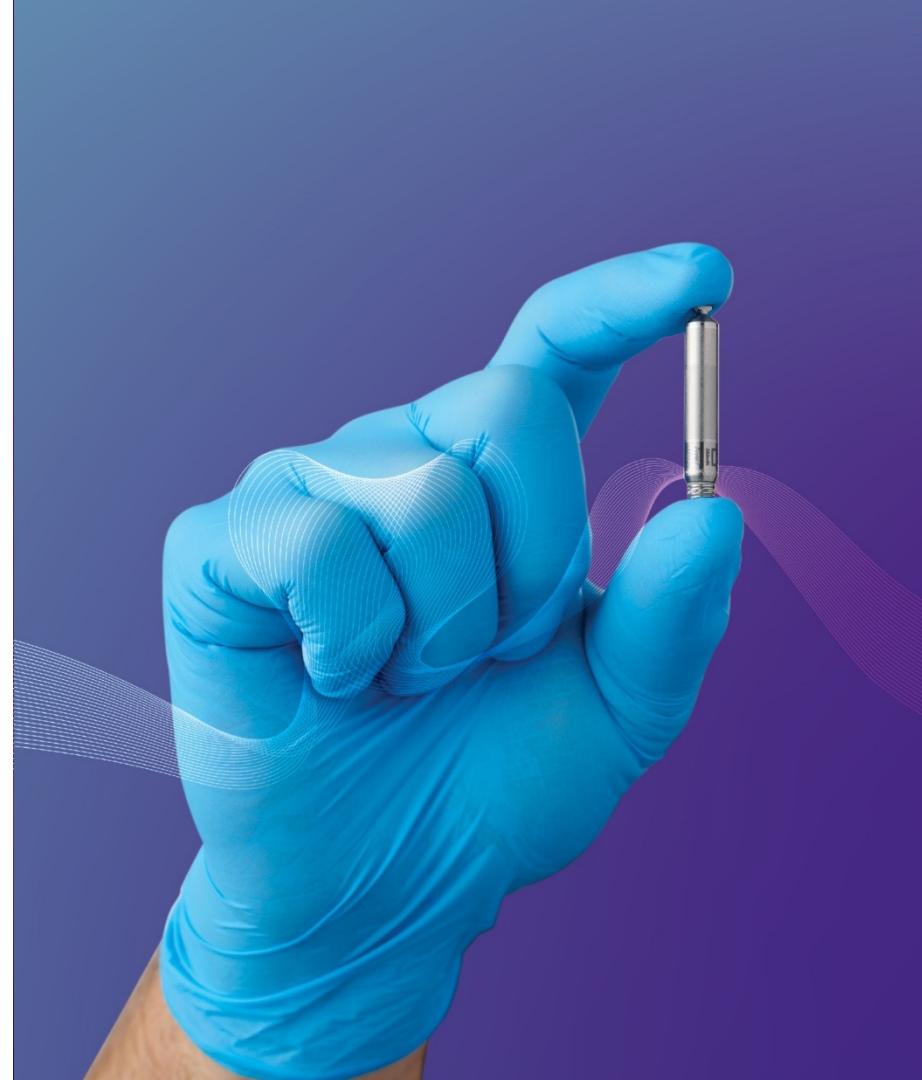
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REFERENCES



# LEADLESS PACEMAKER CLINICAL HISTORY

# TRADITIONAL TRANSVENOUS PACEMAKER SYSTEM

## MAJOR CLASS I INDICATIONS FOR PACING

- Sick Sinus Syndrome / Sinus Node Dysfunction
- 3<sup>rd</sup> degree, advanced 2<sup>nd</sup> degree AV block
- Chronic bifascicular block
- Neuro-cardiogenic syncope / hypersensitive carotid sinus syndrome
- Tachycardia Prevention
- Symptomatic Bradycardia Post Cardiac Transplantation

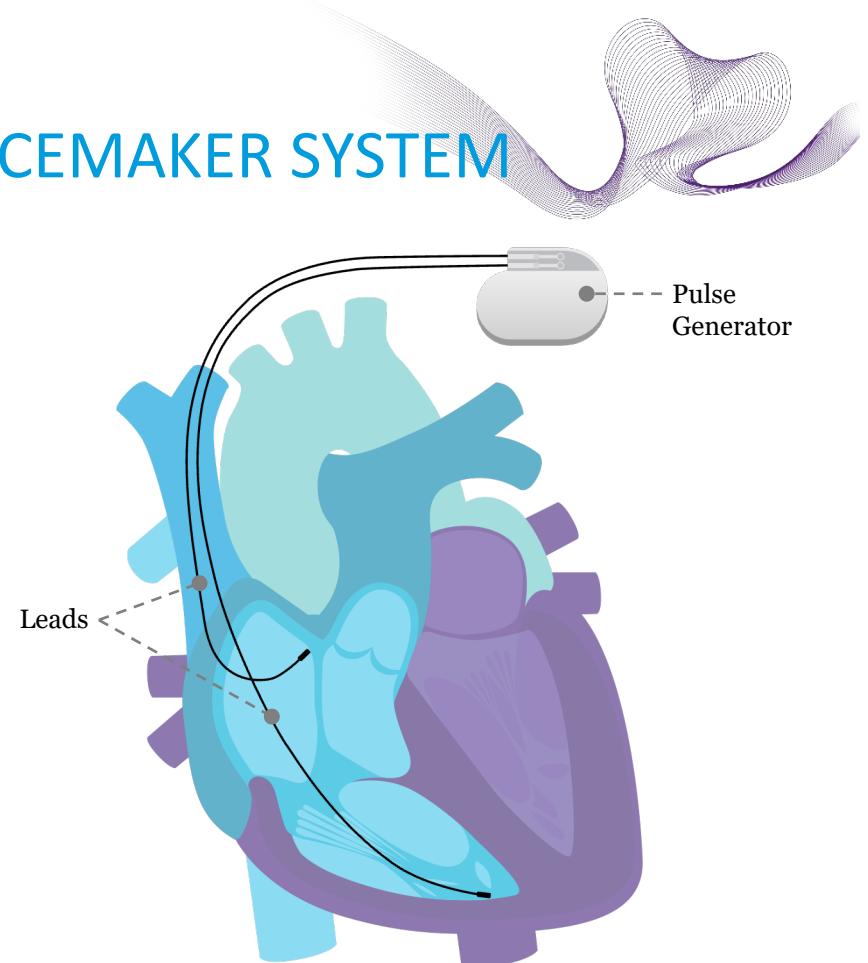
## PACEMAKER COMPONENTS

### Pulse Generator

- Houses battery and electronics

### Leads

- One or two leads (to RA/RV) (*i.e., Single-Chamber vs. Dual Chamber Pacing*)
- Senses heart's electrical activity
- Sends electrical impulses to heart when pacing is required, enabling contraction



# THE LEADLESS ADVANTAGE



Patients treated with a traditional pacing system experience a complication attributed to the pocket or leads.<sup>1,2</sup>

## New Patient Experience

- No chest scar or bump
- No visible or physical reminder of a pacemaker under the skin
- No arm movement restrictions

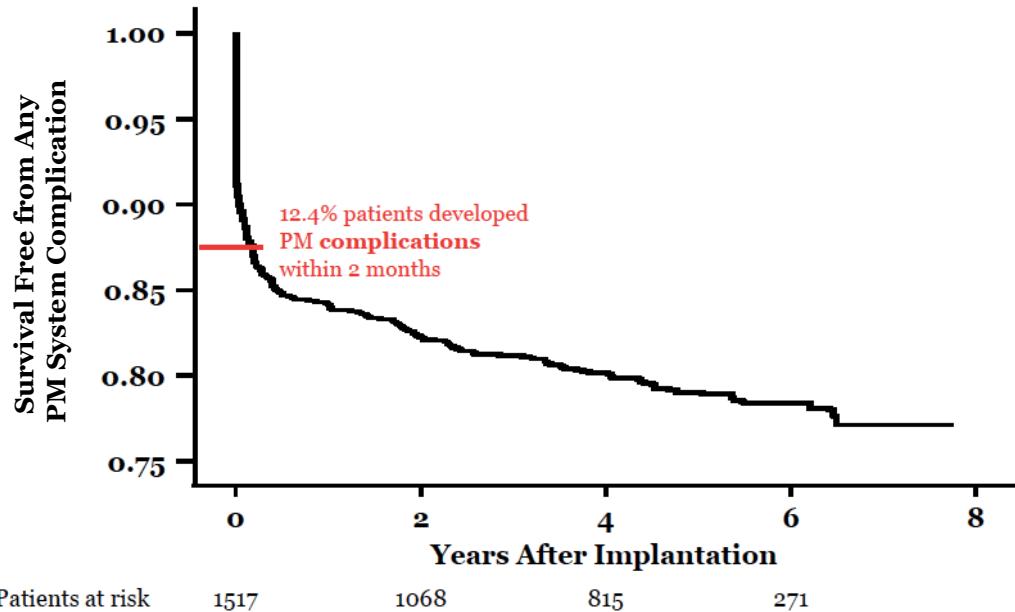
## Eliminate surgical pocket-related complications – 4.75%<sup>1</sup>

- Infection
- Hematoma
- Erosion
- Cosmetic concerns

## Eliminate Lead-related Complications – 5.5%<sup>1</sup>

- Fractures
- Insulation breaches
- Venous thrombosis and obstruction

# WHY DEVELOP A LEADLESS PACEMAKER?



# FOLLOWPACE STUDY HIGHLIGHTS<sup>1</sup>

**1517** patients follow-up for a mean of **5.8y**

## COMPLICATIONS

Acute: **10-15%**

Chronic: **9-10%**

Note: Includes both single- and dual-chamber pacemakers

# PRODUCT OVERVIEW

**AVEIR™ VR**  
Leadless Pacemaker

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# ADVANCING TODAY'S TECHNOLOGY WITH A VIEW TO TOMORROW

Leadless pacemakers (LP) have revolutionized care for heart patients. With no visible or physical reminder of a pacemaker under the skin and fewer post-implant activity restrictions,<sup>1, 2</sup> your patients can continue living their lives to the fullest.

AVEIR™ VR Leadless Pacemaker (LP) is the next evolution in leadless technology that has been designed for

- long-term retrieval<sup>3</sup>
- an extended battery life<sup>4, 5</sup>
- mapping prior to fixation for optimal device location<sup>4, 6</sup>
- providing an upgradeable platform to later support a dual chamber pacing system when patient therapy need evolves\*

**At just 38.0 mm, the AVEIR VR LP has three times less volume than a standard AAA battery.**



**AVEIR™ VR**  
Leadless Pacemaker

\*AVEIR DR dual chamber leadless pacemaker system is commercially approved for use only in the USA market at this time. The AVEIR AR and DR systems are currently under review and pending CE mark.

## LONG-TERM RETRIEVAL



AVEIR™ VR Leadless Pacemaker is designed for long-term retrieval. Limited data is available for AVEIR VR LP. The AVEIR VR LP's predicate device has an overall long-term retrieval success rate of 88% with helix fixation with up to 9 years of retrieval experience.<sup>3</sup>

## LONG LASTING



The average battery longevity among Leadless II phase 2 IDE patients at 1 year follow-up is estimated to be 17.6 years.

48% of the study patients have an estimated battery longevity of over 20 years.<sup>6</sup>

## MAPPING PRIOR TO FIXATION



Mapping capability is designed to help reduce the number of repositioning attempts.<sup>4, 6</sup>

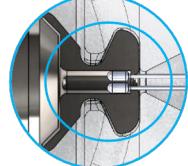
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# AVEIR™ VR LEADLESS PACEMAKER

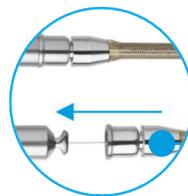
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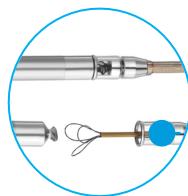
# AVEIR™ VR LP | COMPONENTS



Docking/Retrieval Mechanism



Delivery Catheter

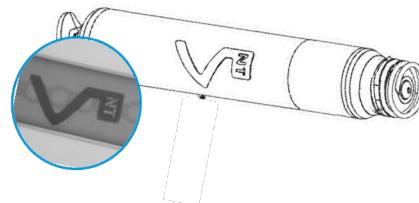


Retrieval Catheter



Battery

X-Ray Code: NT



Active fixation helix



Tip Electrode

Anti-rotation suture

# THE DOCKING BUTTON

The **proximal end** of the device has a fixed docking button that enables delivery and retrieval of the leadless pacemaker



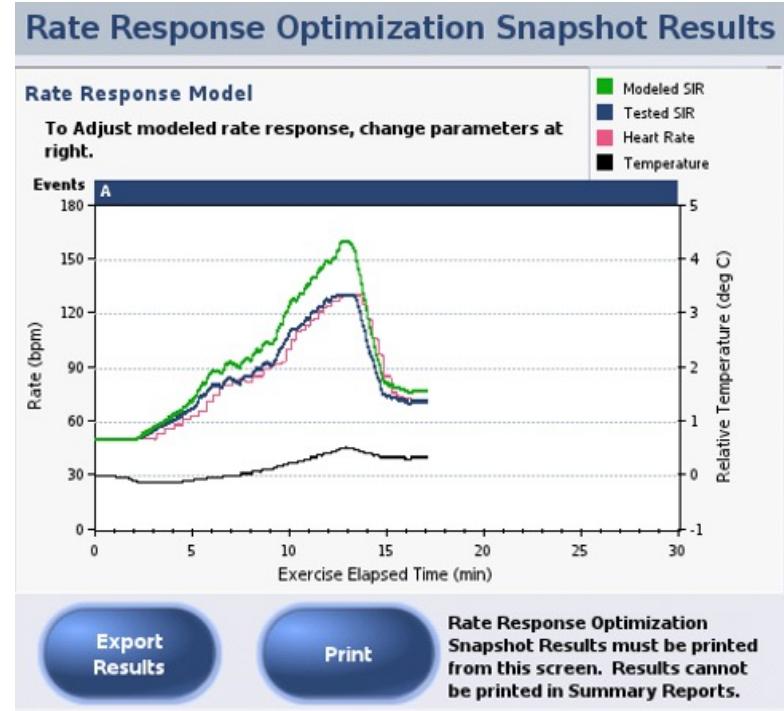
Tethers from the **Delivery Catheter** seat into the shaft in the docking button



The snare of the **Retrieval Catheter** catches the docking button to allow removal of a previously implanted device

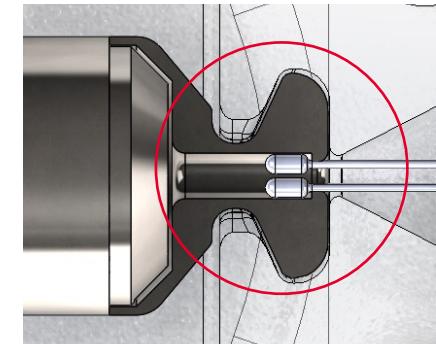
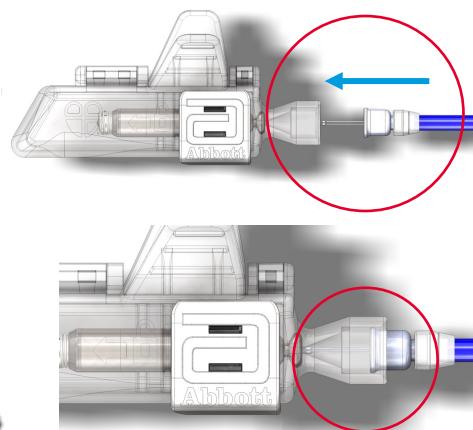
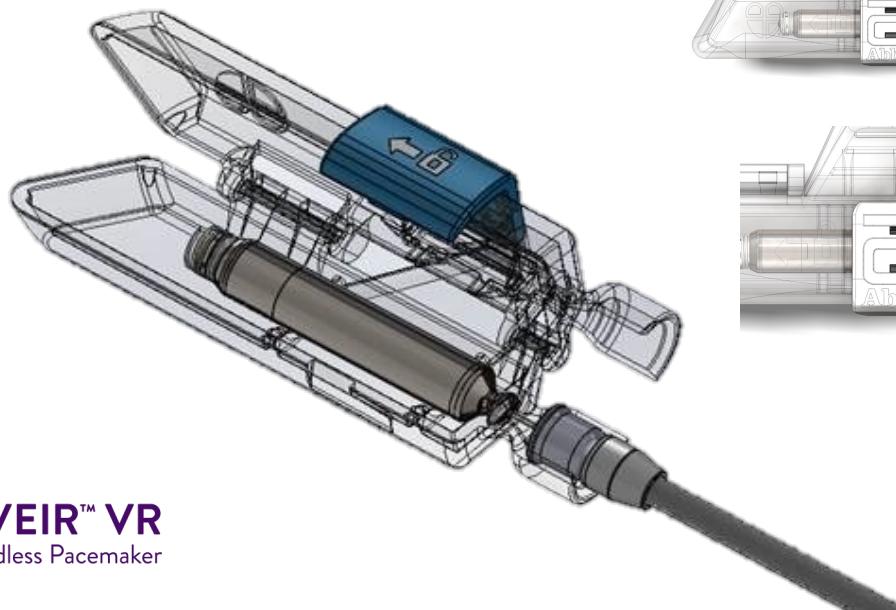
# RATE-RESPONSIVE pacing

- The AVEIR™ VR Leadless Pacemaker uses a temperature-based sensor to modulate rate-responsive pacing
- A semi-conductor in the nosecone of the device detects changes in central venous temperature that accompany the onset of exercise
- Real-time modeling of different parameters for patient-specific optimization



# AVEIR™ VR LP | LOADING TOOL

THE AVEIR™ LP IS PACKAGED SEPARATELY FROM THE AVEIR™ DELIVERY CATHETER:



# AVEIR™ INTRODUCER DELIVERY AND RETRIEVAL CATHETER

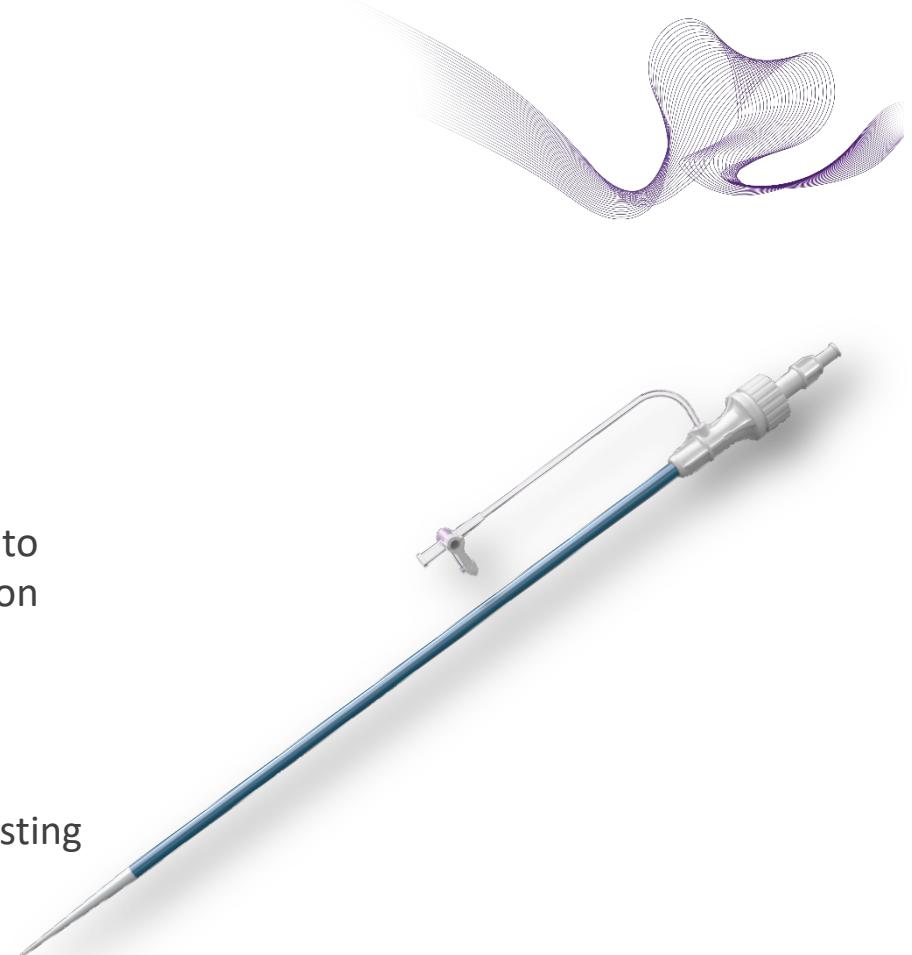


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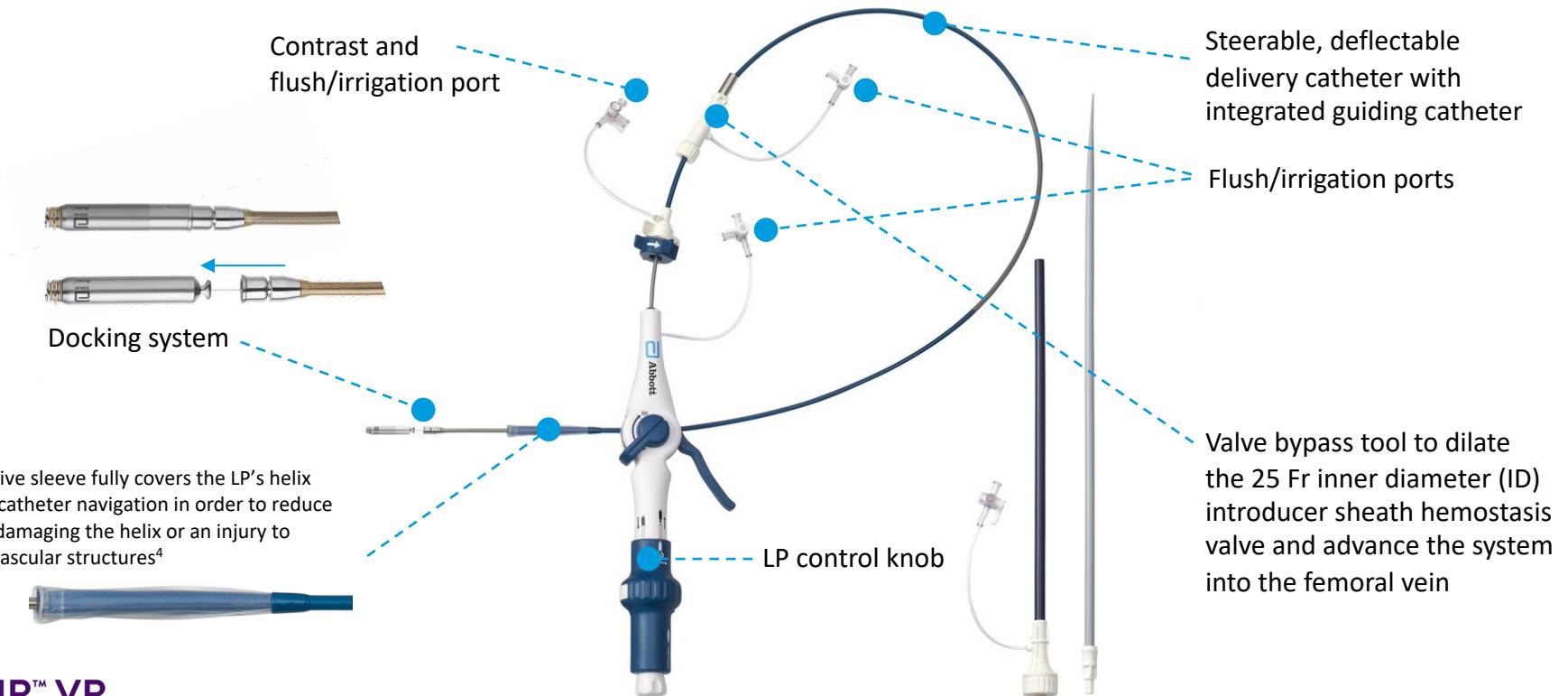
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# AVEIR™ VR LP | INTRODUCER

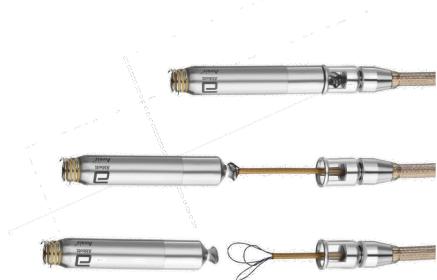
- 25 F Introducer, use with both the delivery and retrieval catheters
- 30cm and 50cm length options
- Valve bypass tool from delivery catheter locks into the Introducer for smoother catheter introduction through the hemostasis valve
- Note: Physicians are encouraged to use their existing protocol for sizing up access



# AVEIR™ VR LP | DELIVERY SYSTEM



# AVEIR™ VR LP | RETRIEVAL SYSTEM

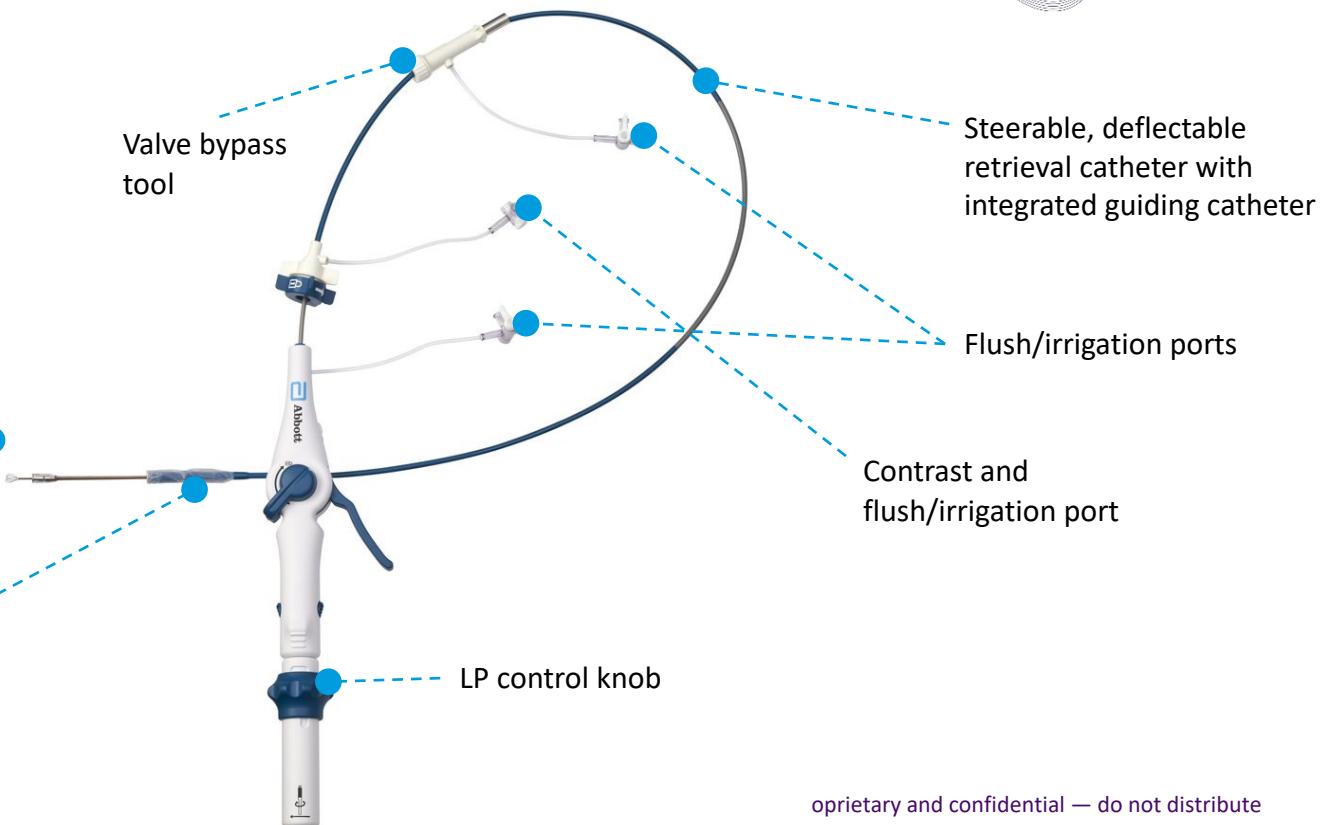


Tri-loop snare re-docking mechanism

Protective sleeve fully covers the LP's helix during catheter navigation in order to reduce risk of damaging the helix or an injury to cardiovascular structures<sup>4</sup>



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Valve bypass tool

Steerable, deflectable retrieval catheter with integrated guiding catheter

Flush/irrigation ports

Contrast and flush/irrigation port

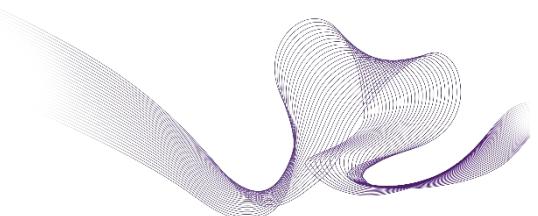
LP control knob

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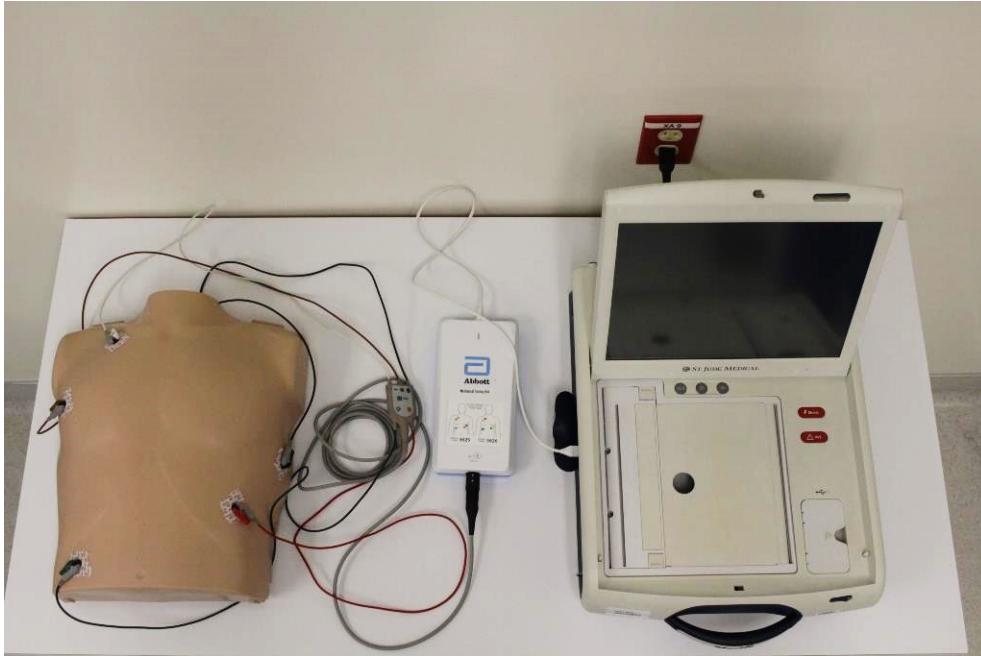
# AVEIR™ LINK MODULE AND CONNECTIVITY

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# CONDUCTED Communication



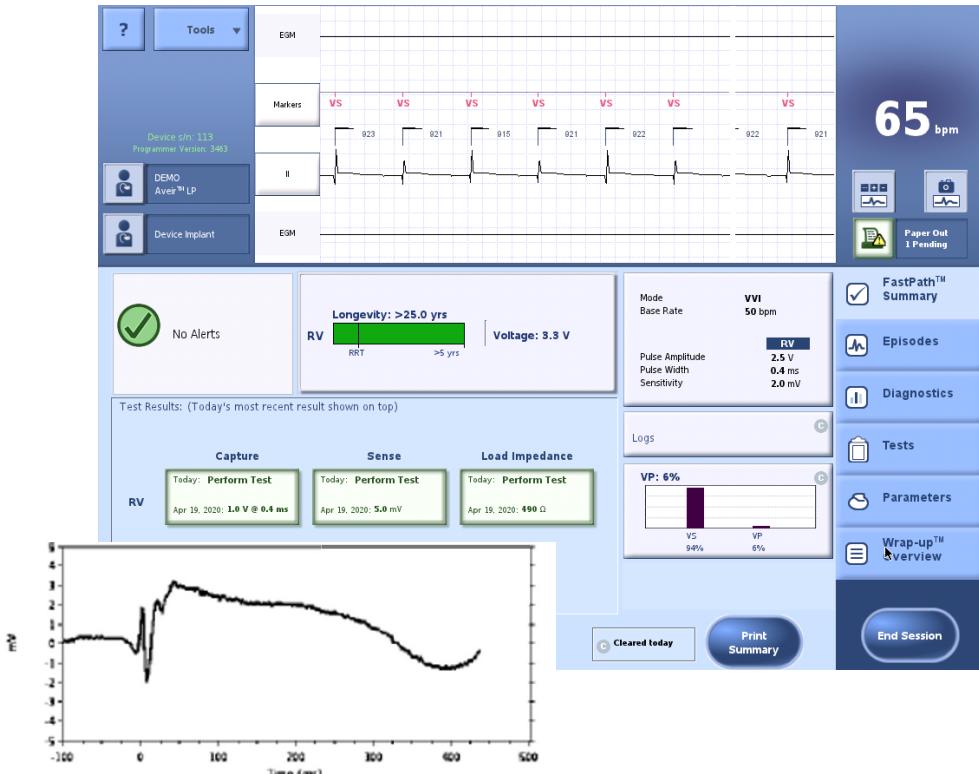
- Data is encoded in high-frequency pulses between the leadless pacemaker and surface electrodes placed on the patient
- Significantly reduces battery drain compared to other commonly used forms of communication

# PROGRAMMER Interface

Programmer interface is very similar to Abbott's traditional CRM devices

New features such as<sup>1</sup>:

- Commanded EGM (for current of injury) prior to fixation
- Rate Response Optimization to evaluate ideal sensor parameters for each patient



# AVEIR™ VR LEADLESS PACEMAKER DATA

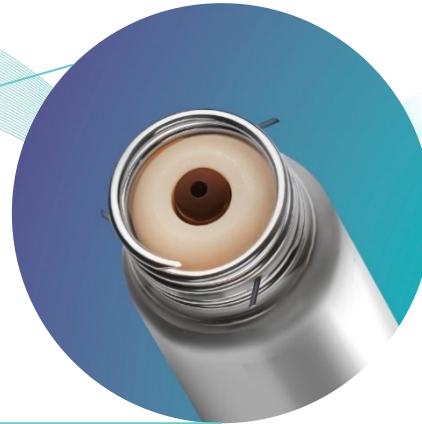
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# LONG-TERM RETRIEVAL

AVEIR™ VR Leadless Pacemaker's helical fixation is designed for long-term retrieval.<sup>3</sup>

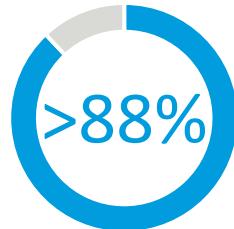


## TRI-LOOP SNARE RE-DOCKING MECHANISM



## ACTIVE FIXATION HELIX

AVEIR™ VR Leadless Pacemaker's active fixation helix uses a screw-in mechanism to enable both implantation and long-term retrieval of the LP.<sup>4</sup>



Range 0 to 9 years  
(mean  $3.1 \pm 1.8$  years)  
n=241

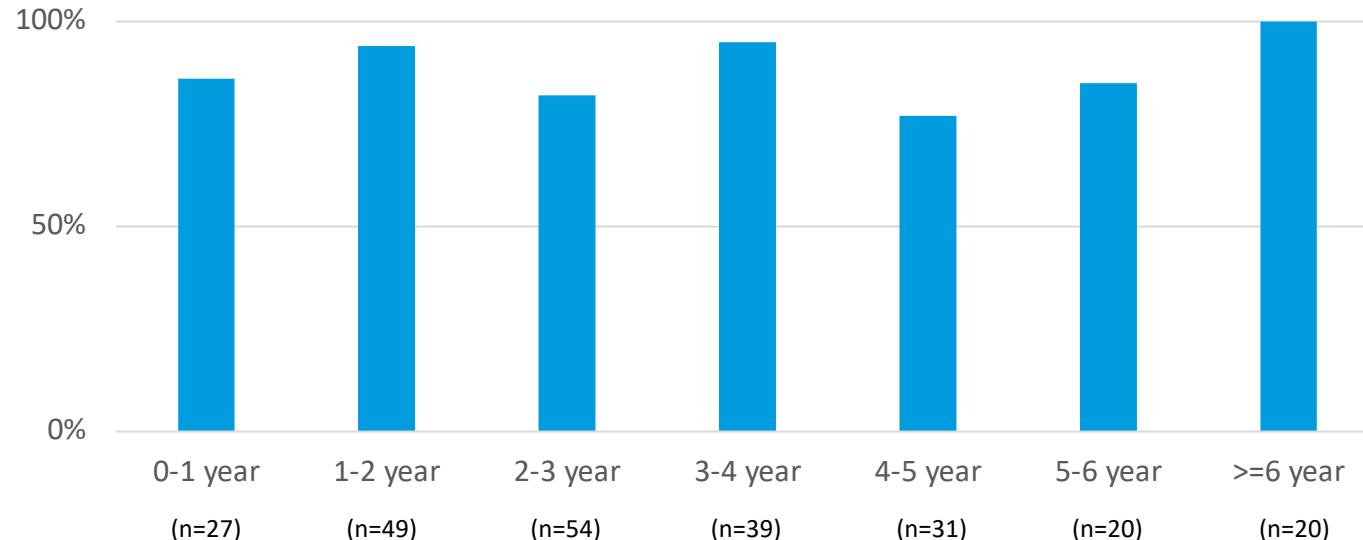
The AVEIR™ VR Leadless Pacemaker's predicate device has a

## OVERALL LONG-TERM RETRIEVAL SUCCESS RATE

above 88% with helix fixation with up to 9 years of retrieval experience. AVEIR VR LP is designed for long-term retrieval. Limited data is available for the AVEIR VR LP.<sup>3</sup>



## Retrieval success rates remained high, regardless of implant duration<sup>1</sup>



\* Limited data is available for AVEIR leadless pacemakers

<sup>1</sup> Reddy, VY, et al. Worldwide Experience with Leadless Pacemaker Retrievals: A Worldwide Nanostim Experience out of 9y. Presented at: APHRS 2022; Nov 18-20, 2022; Singapore.



# MAPPING PRIOR TO FIXATION

AVEIR™ VR Leadless Pacemaker mapping capability is designed to help reduce the number of repositioning attempts.<sup>4,6</sup>



**83.2%** of patients had successful implants with no repositioning attempts<sup>6</sup>



**96.4%** of patients had successful implants in 1 or less repositioning attempts<sup>6</sup>

**AVEIR™ VR**  
Leadless Pacemaker

AVEIR™ VR LP



MICRA‡ VR



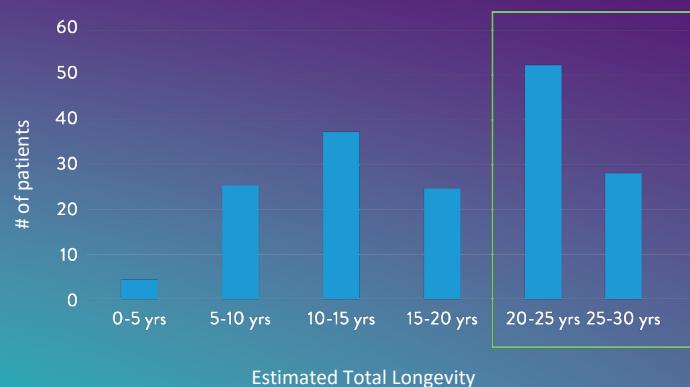
- AVEIR VR LP can measure R-waves, impedance and an initial capture threshold before fixation by simply touching the LP's tip electrode to the endocardial tissue.<sup>4,6</sup>
- AVEIR VR LP is engaged with a rotational motion into the endocardium.<sup>4</sup>
- Micra‡ VR requires LP deployment before taking initial electrical readings.<sup>5</sup>
- Micra‡ VR is inserted with a forward tip pressure against endocardium.<sup>5</sup>



# LONG LASTING

Increased projected battery longevity over current available leadless pacemaker<sup>4,5</sup> opens the door to more patients.

**Mean  $\pm$  SD:**  $17.6 \pm 6.6$  years  
**95% CI:** 16.6 to 18.6 years



Up to  
**TWICE THE  
BATTERY CAPACITY**  
of current VR  
leadless pacemakers<sup>4,5</sup>

BATTERY  
CAPACITY

**243  
mAh**

**120  
mAh**

AVEIR™ VR LP

Competition

- The average battery longevity among Leadless II phase 2 IDE patients at 1 year follow-up is estimated to be 17.6 years.
- 48% of the study patients have an estimated battery longevity of over 20 years.

# LIFE-CHANGING INNOVATION

At Abbott, we adapt quickly to changes in the world around us, harnessing leading-edge science and technology to deliver the best possible solutions for some of the world's most important health challenges.

Our medical devices, like the AVEIR™ VR Leadless Pacemaker, use the most advanced technologies to keep hearts beating more regularly.

## AVEIR DELIVERY AND RETRIEVAL CATHETERS

- Designed for ergonomic, single operator use
- Steerable delivery catheter with deflection mechanism<sup>4,7</sup>
- Hydrophilic coating on introducer sheath and a choice of 30cm and 50cm lengths<sup>8</sup>
- Protective sleeve fully covers the LP's helix during catheter navigation in order to reduce risk of damaging the helix or an injury to cardiovascular structures<sup>4,7</sup>



## DUAL-CHAMBER SYSTEM UPGRADABILITY

Should new pacing indications present, the software for AVEIR VR Ventricular LP is designed to pair with AVEIR AR Atrial LP, allowing the devices to upgrade to an AVEIR DR Dual Chamber Leadless Pacemaker System.\*



## ENABLING SAFE MRI SCANS



### AVEIR is 1.5T and 3T MR Conditional

AVEIR VR LP is MR Conditional for full body scans using a 1.5T or 3T field strength MRI scanner.

#### AVEIR VR LP MR CONDITIONAL FEATURES\*\*\*



MAGNET (TESLA)	1.5T AND 3T
SCAN TYPE	FULL-BODY
SCANNER MODE	FIRST LEVEL CONTROLLED OPERATING MODE OR NORMAL OPERATING MODE

**AVEIR™ VR**  
Leadless Pacemaker

\*AVEIR AR Atrial leadless pacemaker system and AVEIR DR dual chamber leadless pacemaker system are commercially approved for use only in the USA market at this time. The AVEIR AR and DR systems are currently under review and pending CE mark.

\*\*For additional information about specific MR Conditional details, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the MRI-Ready Leadless System Manual at [medical.abbott/manuals](http://medical.abbott/manuals) or check our MRI Ready resources at [cardiovascular.abbott/mriready](http://cardiovascular.abbott/mriready)

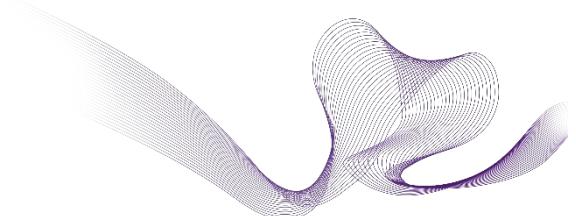
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# COMPETITIVE COMPARISON

AVEIR™ VR  
Leadless Pacemaker

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# COMPETITIVE COMPARISON<sup>4,5</sup>



Attribute	MDT Micra‡ VR: MC1VR01	ABT AVEIR™ VR LP: LSP112V
Length (mm); Volume (cc); Weight (g); Outer Diameter (Fr)	25.9 mm; 0.8 cc; 1.75 g; 20.1 Fr	38.0 mm; 1.1 cc; 2.4 g; 19.8 Fr
Introducer (OD)	27 Fr	27 Fr
Mean Battery Capacity	120 mAh	243 mAh
Projected Longevity based on ISO standard settings*	4.7 years	10.3 years
Fixation Mechanism	4x Nitinol FlexFix™ Tines	Active Fixation Helix
MRI Labeling	MRI SureScan 1.5T and 3T	1.5T and 3T
Rate Response	3-axis accelerometer sensor Individually selectable with one vector used	Temperature-based
Mapping Prior to Fixation	No	Yes
Designed for chronic retrieval	No	Yes

# MICRA<sup>‡</sup> VR AND AVEIR<sup>™</sup> VR LP PROJECTED BATTERY LONGEVITY COMPARISON<sup>4,5\*</sup>

					Longevity (yrs)		Longevity (yrs)			
Pacing				PW=	Micra VR	AVEIR VR	PW=	Micra VR	AVEIR VR	AVEIR VR
Pacing %	Amplitude	Rate	Impedance		0.4 ms	0.4 ms		0.24 ms	0.2 ms	0.3 ms
0%	1.5 V	60 bpm	500 ohms		14.5	27.3		14.6	27.3	27.3
50%	1.0 V	60 bpm	500 ohms		12.5	22.6		13.3	24.4	23.4
50%	1.5 V	60 bpm	500 ohms		10.4	17.3		11.7	20.6	18.8
50%	2.0 V	60 bpm	500 ohms		8.1	15.4		9.6	19.0	17.0
100%	1.0 V	60 bpm	500 ohms		10.5	19.3		11.8	22.1	20.5
100%	1.5 V	60 bpm	500 ohms		8.0	12.7		9.6	16.5	14.3
100%	2.0 V	60 bpm	500 ohms		5.5	10.8		7.1	14.6	12.3
100%	2.5 V	60 bpm	500 ohms		4.3	9.4		5.8	13.1	10.8
100%	1.5 V	60 bpm	400 ohms		7.4	11.4		9.0	15.2	13.0
100%	1.5 V	60 bpm	600 ohms		8.4	13.8		10	17.6	15.4
100%	1.5 V	70 bpm	500 ohms		7.5	11.3		9.1	14.8	12.7
100%	1.5 V	100 bpm	500 ohms		6.4	8.4		8.0	11.3	9.6
100%	2.5 V	60 bpm	600 ohms		4.7	10.3		6.3	14.2	11.9
100%	3.5 V	60 bpm	500 ohms		2.4	5.4		3.6	8.3	6.5
100%	5.0 V	60 bpm	500 ohms		1.2	3.0		1.8	4.9	3.7

**AVEIR<sup>™</sup> VR**  
Leadless Pacemaker

\*Battery longevity estimates based on projections derived from published technical specifications and the ISO standard settings<sup>4,5</sup>  
ISO Standard settings: 5 yrs Micra / 10 yrs Aveir: VVIR 60 bpm, 2.5V @0.4 ms, 600 Ω, 100% pacing

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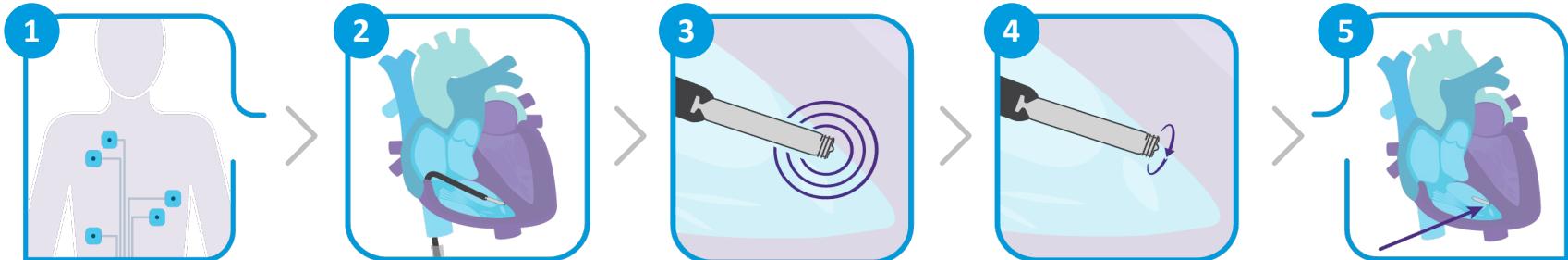
# WORKFLOW

AVEIR™ VR  
Leadless Pacemaker

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# WORKFLOW

AVEIR™ VR LP is implanted in the heart through a minimally invasive catheter procedure.



**CONNECT** patient's skin electrodes to Merlin Programmer™ via AVEIR™ Link Module

**INSERT** the LP via ergonomic catheter for minimally invasive procedure ensuring helix is fully covered during catheter navigation

**MAP** ventricular implanting location before fixation by touching endocardium with LP's tip electrode

**FIXATE** the LP to the ventricular endocardium using the screw-in mechanism

**RELEASE** the LP and withdraw delivery catheter

For a more detailed workflow, refer to the AVEIR™ VR LP Instructions For Use (IFU) or contact your Abbott Sales Representative for training.

# REFERENCES

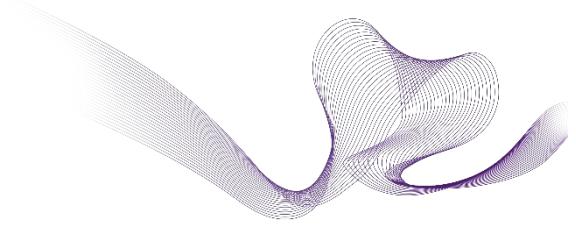
# ABOUT ABBOTT

When people are at their healthiest, they have the potential to live not just longer, but better. This simple truth inspired the creation of AVEIR™ VR LP and has been Abbott's guiding principle for more than 130 years.

Every day, Abbott harnesses leading-edge science and technology to deliver the best possible solutions for some of the world's most important health challenges. Through our nutrition products, diagnostics solutions, branded generic medicines and medical devices, we've helped people live fuller, healthier lives.

## REFERENCES

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2. Cantillon DJ, Exner DV, Badie N, et al. Complications and Health Care Costs Associated with Transvenous Cardiac Pacemakers in a Nationwide Assessment. *JACC Clin Electrophysiol.* November 2017;3(11):1296-1305.
3. Reddy, VY, et al. Worldwide Experience with Leadless Pacemaker Retrievals: A Worldwide Nanostim Experience out of 9y. Presented at APHRS 2022; Nov 18-20, 2022; Singapore.
4. AVEIR™ VR Leadless Pacemaker and Delivery Catheter IFU. ARTEN600175957
5. Micra<sup>‡</sup> VR IFU M991010A001 REV. B
6. Reddy VY, Exner D, et al. 1-Year Outcomes of a Leadless Ventricular Pacemaker: The LEADLESS II (Phase 2) Trial. *JACC : Clinical Electrophysiology* 2023, DOI: 10.1016/j.jacep.2023.01.03
7. AVEIR™ Retrieval Catheter IFU. ARTMT600174816
8. AVEIR™ Introducer IFU. ARTEN600174817



**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.

**Abbott**

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‡ Indicates a third-party trademark, which is property of its respective owner.

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MAT-2411879 v1.0 | Item approved for India and Singapore use.

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