

AVEIR™ VR
Leadless Pacemaker

**SETTING THE PACE
FOR WHAT'S TO COME**



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LEADLESS PACEMAKER CLINICAL HISTORY



TRADITIONAL TRANSVENOUS PACEMAKER SYSTEM

MAJOR CLASS I INDICATIONS FOR PACING

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

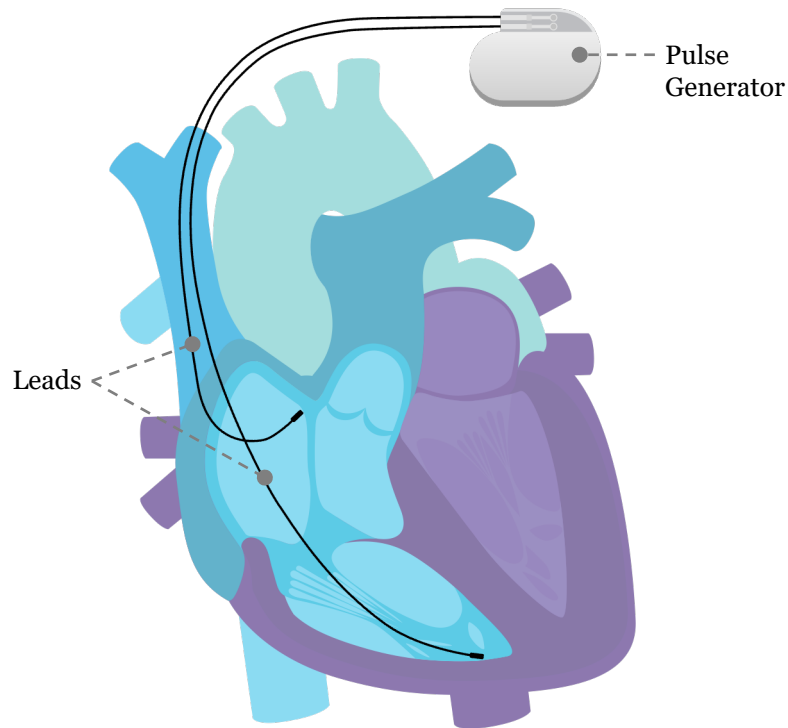
PACEMAKER COMPONENTS

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.^{1,2}

New Patient Experience

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

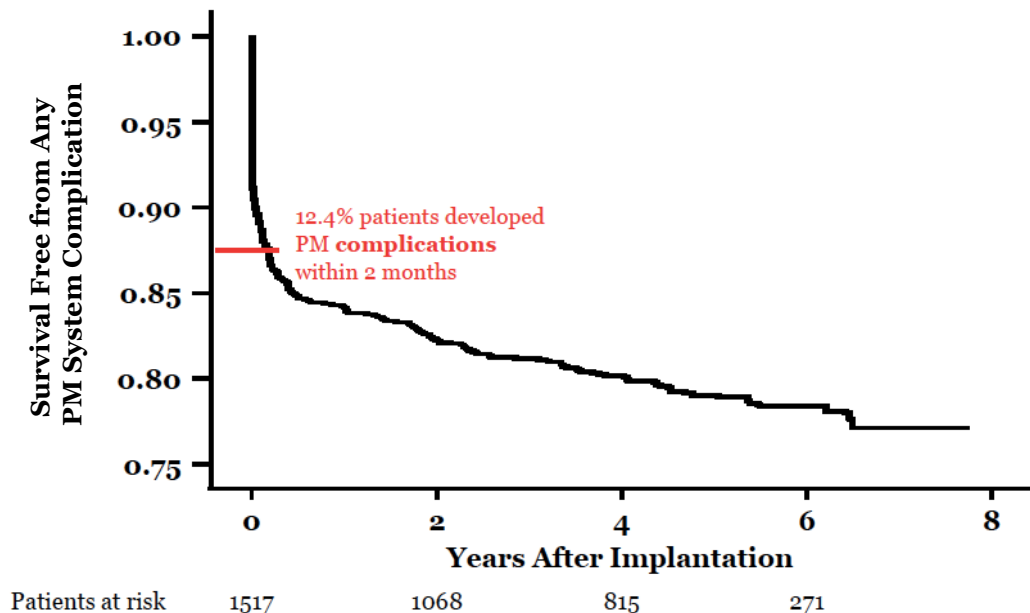
Eliminate surgical pocket-related complications – 4.75%¹

- Infection
- Hematoma
- Erosion
- Cosmetic concerns

Eliminate Lead-related Complications – 5.5%¹

- Fractures
- Insulation breaches
- Venous thrombosis and obstruction

WHY DEVELOP A LEADLESS PACEMAKER?



AVEIR™ VR
Leadless Pacemaker

FOLLOWPACE STUDY HIGHLIGHTS¹

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

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PRODUCT OVERVIEW

An abstract graphic composed of numerous thin, white, overlapping lines that form a complex, flowing, and somewhat symmetrical shape. It resembles a stylized heart or a series of concentric, wavy loops. The graphic is positioned on the right side of the slide, extending from the middle towards the bottom right corner.

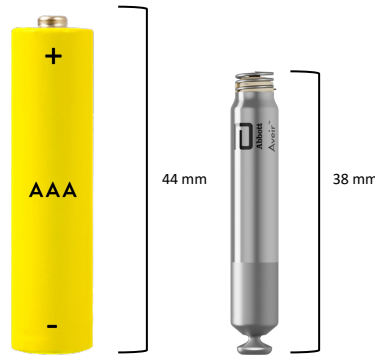
ADVANCING TODAY'S TECHNOLOGY WITH A VIEW TO TOMORROW

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,^{1, 2} 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 retrieval³
- an extended battery life^{4, 5}
- mapping prior to fixation for optimal device location^{4, 6}
- 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.



Actual Size

*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.³

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.⁶

MAPPING PRIOR TO FIXATION



Mapping capability is designed to help reduce the number of repositioning attempts.^{4, 6}

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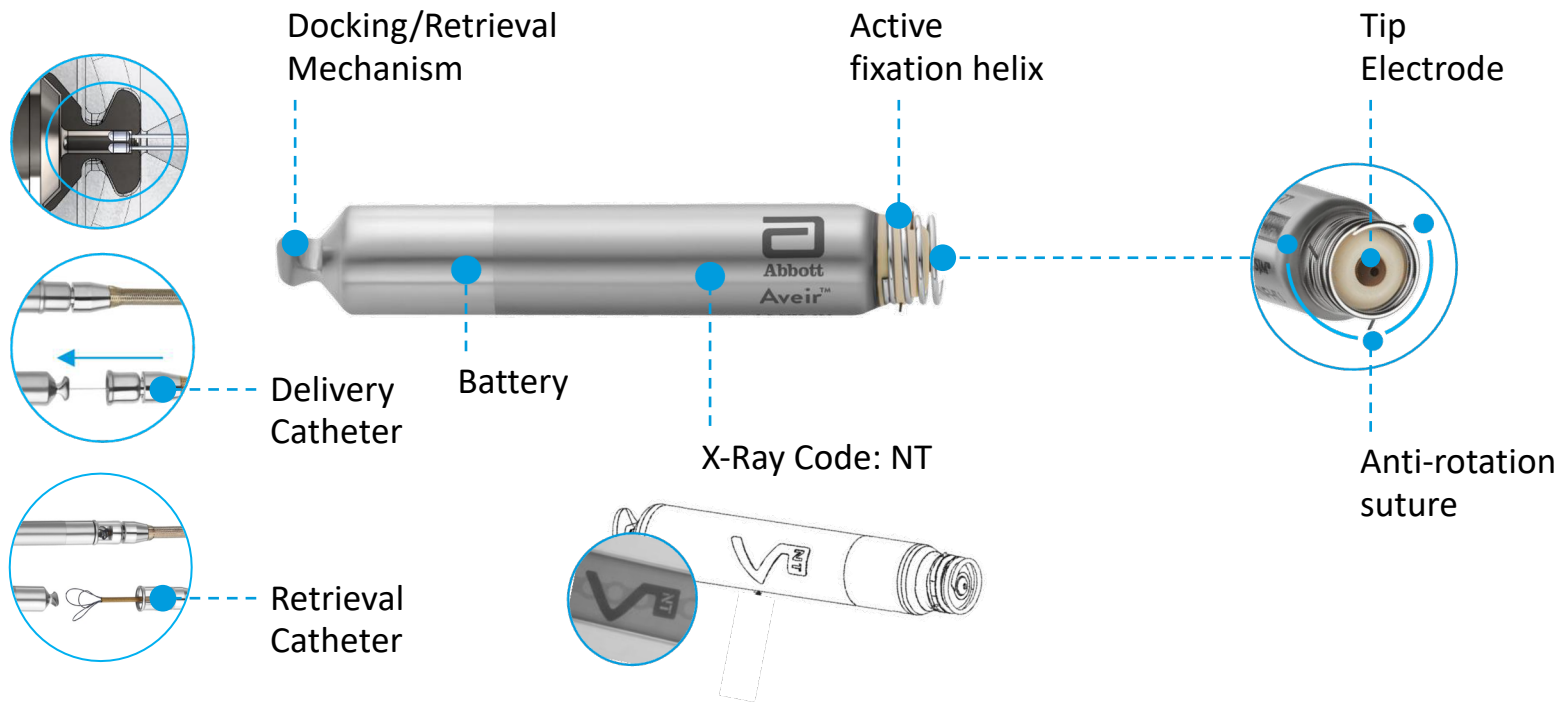
AVEIR™ VR LEADLESS PACEMAKER



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AVEIR™ VR LP | COMPONENTS



THE DOCKING BUTTON

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



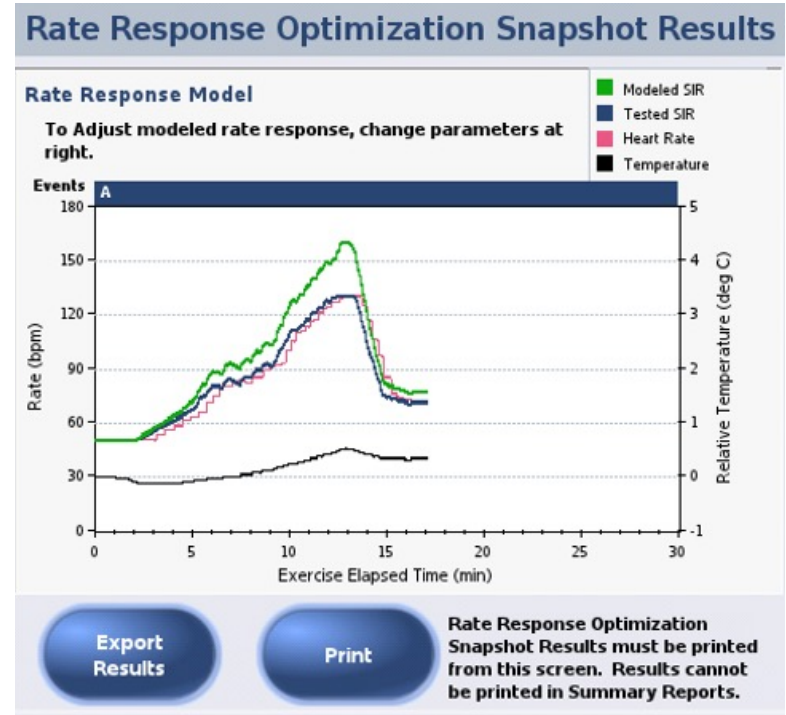
Tethers from the **Delivery Catheter** seat into the shaft in the docking button



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

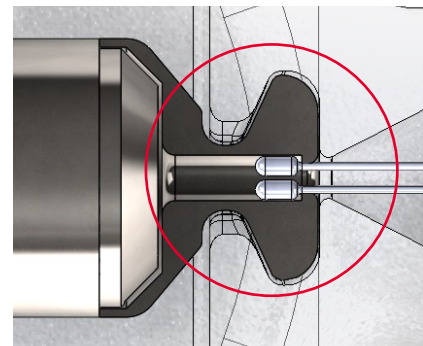
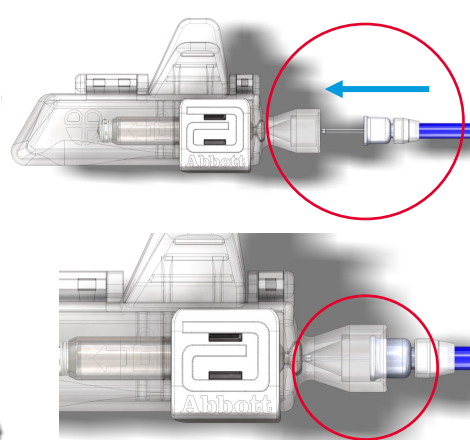
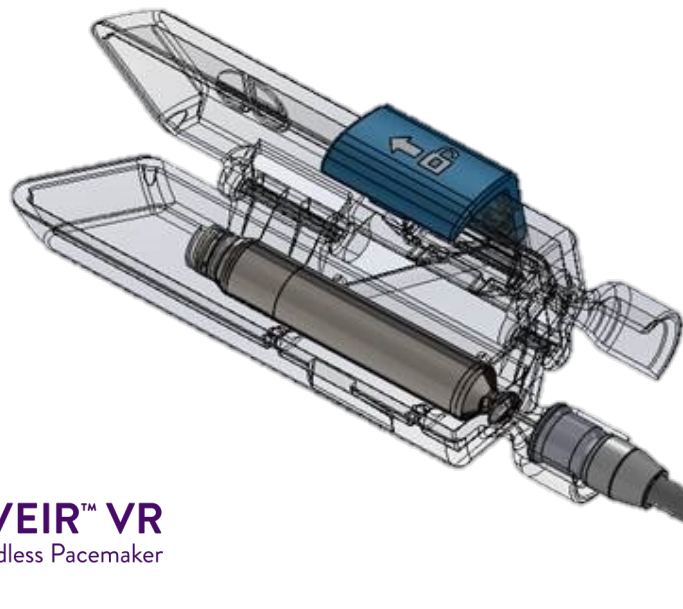
RATE-RESPONSIVE pacing

- 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:



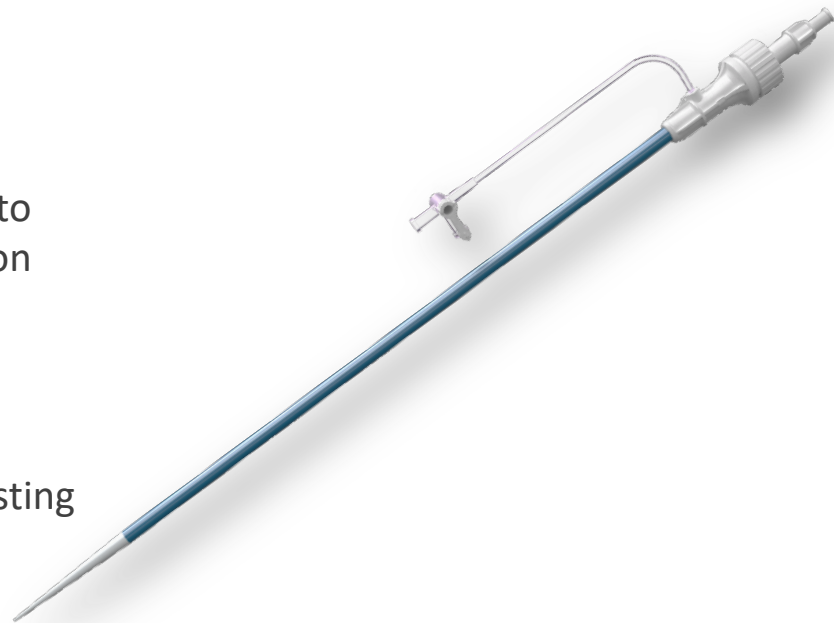
AVEIR™ INTRODUCER DELIVERY AND RETRIEVAL CATHETER

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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

Contrast and
flush/irrigation port

Steerable, deflectable
delivery catheter with
integrated guiding catheter

Flush/irrigation ports

Docking system

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 structures⁴

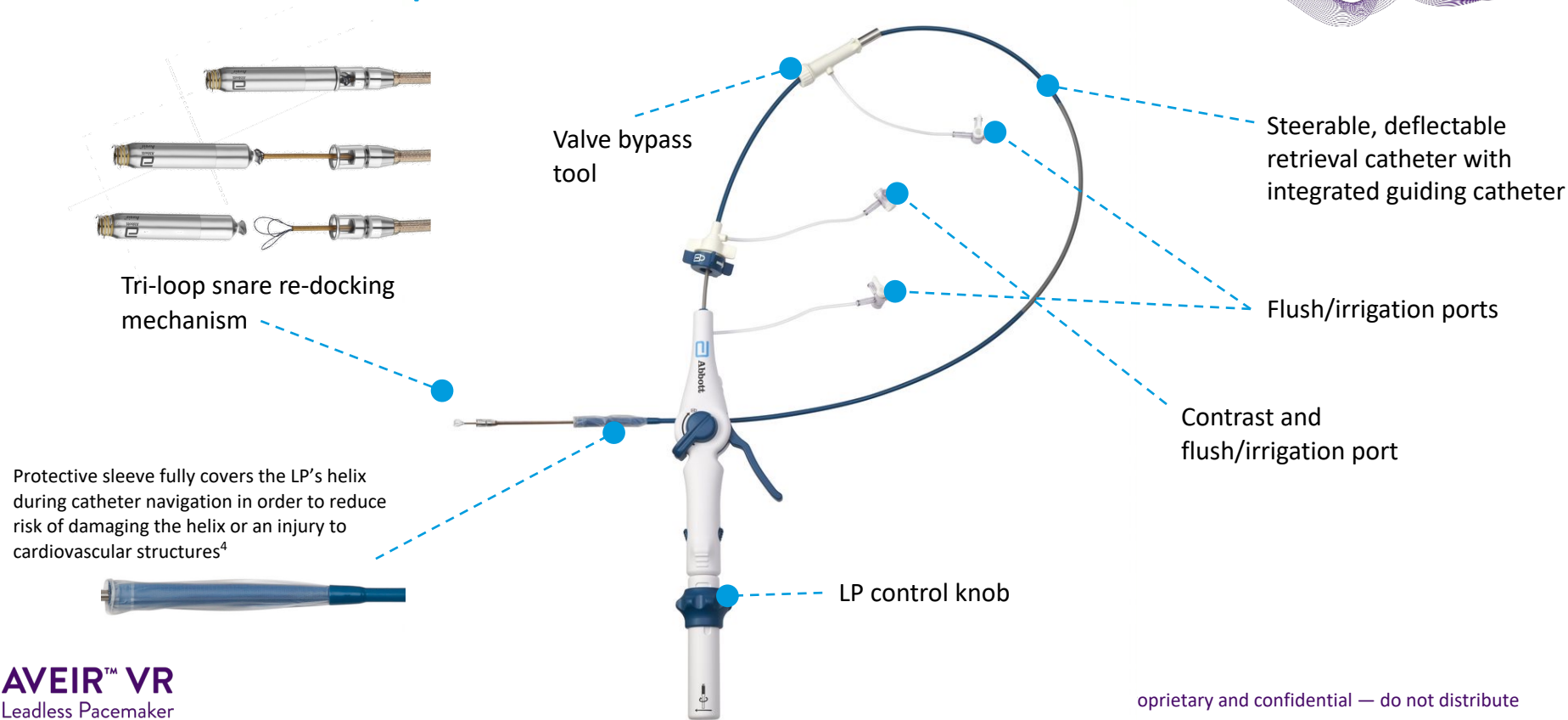
LP control knob

Valve bypass tool to dilate
the 25 Fr inner diameter (ID)
introducer sheath hemostasis
valve and advance the system
into the femoral vein

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AVEIR™ VR LP | RETRIEVAL SYSTEM

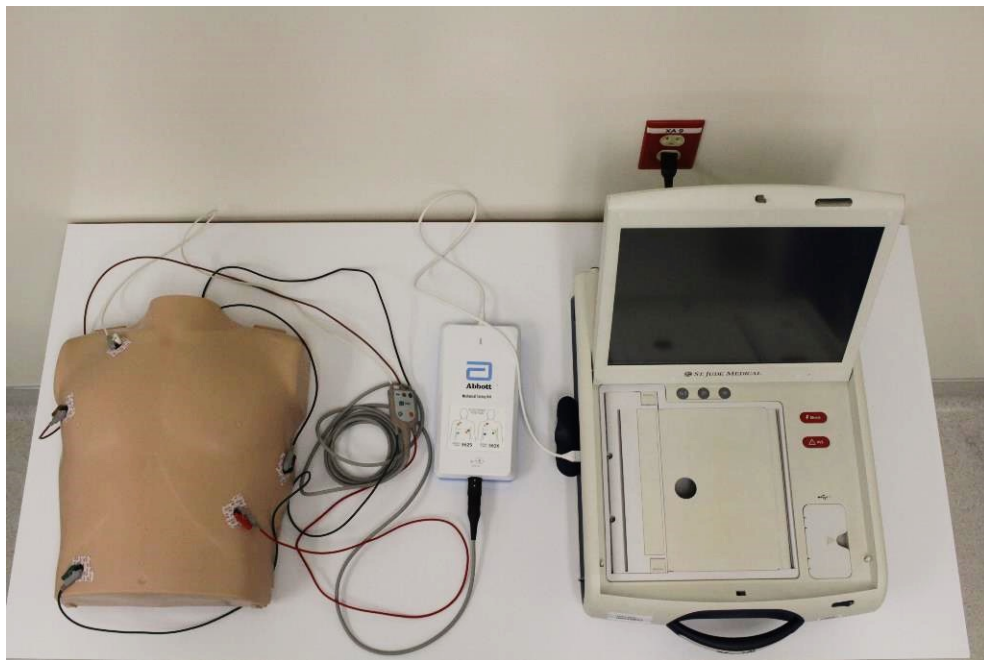


AVEIR™ LINK MODULE AND CONNECTIVITY





CONDUCTED Communication



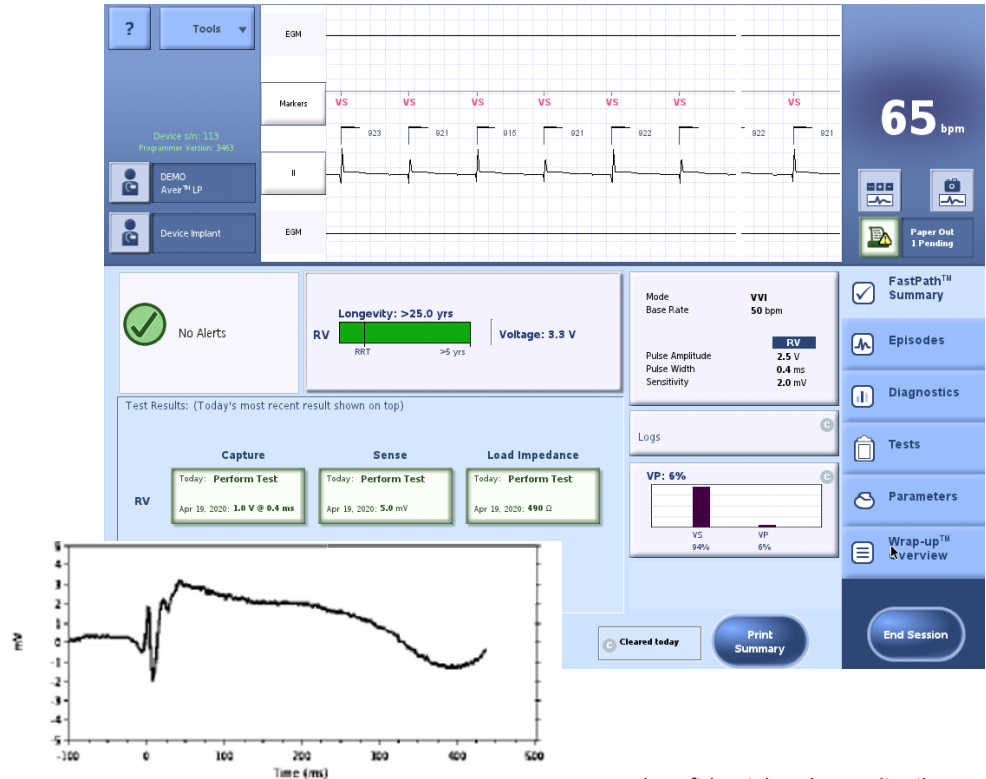
- Data is encoded in high-frequency pulses between the leadless pacemaker and surface electrodes placed on the patient
- Significantly reduces battery drain compared to other commonly used forms of communication

PROGRAMMER Interface

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

New features such as¹:

- 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



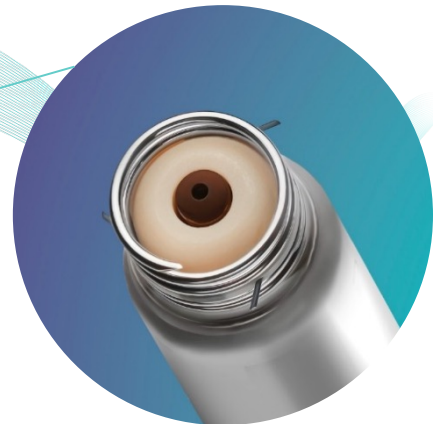
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LONG-TERM RETRIEVAL

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

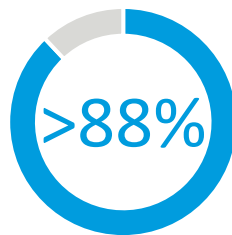


TRI-LOOP SNARE RE-DOCKING MECHANISM



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.⁴



Range 0 to 9 years
(mean 3.1 ± 1.8 years)
n=241

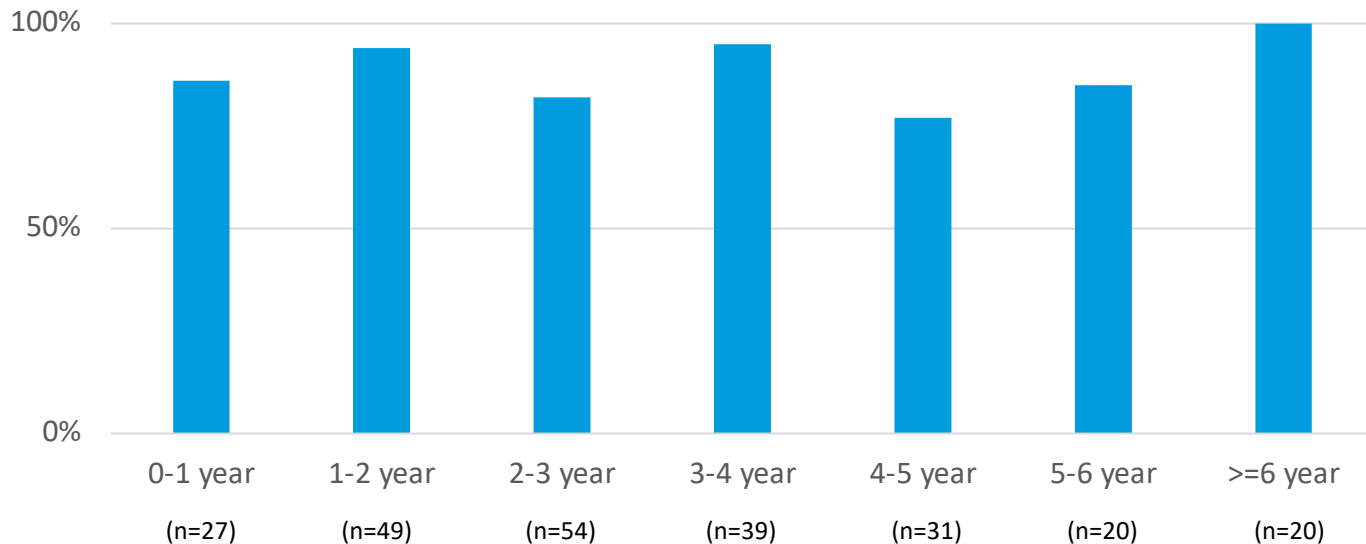
The AVEIR™ VR Leadless Pacemaker's predicate device has a

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.³



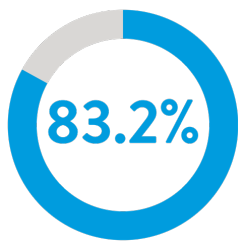
Retrieval success rates remained high, regardless of implant duration¹



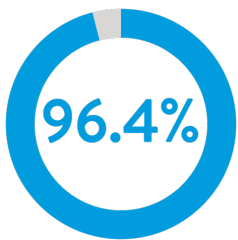


MAPPING PRIOR TO FIXATION

AVEIR™ VR Leadless Pacemaker mapping capability is designed to help reduce the number of repositioning attempts.^{4,6}



83.2% of patients had successful implants with no repositioning attempts⁶



96.4% of patients had successful implants in 1 or less repositioning attempts⁶

AVEIR™ VR
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AVEIR™ VR LP



- 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.^{4,6}
- AVEIR VR LP is engaged with a rotational motion into the endocardium.⁴

MICRA⁺ VR

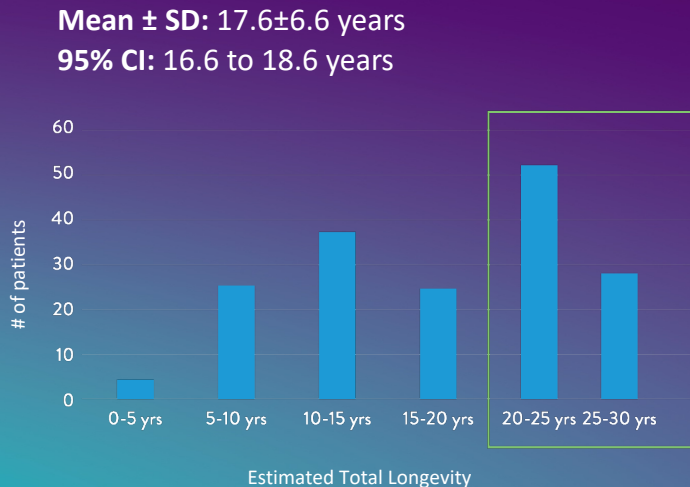


- Micra⁺ VR requires LP deployment before taking initial electrical readings.⁵
- Micra⁺ VR is inserted with a forward tip pressure against endocardium.⁵



LONG LASTING

Increased projected battery longevity over current available leadless pacemaker^{4,5} opens the door to more patients.



- 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.

Up to

TWICE THE BATTERY CAPACITY

of current VR
leadless pacemakers^{4,5}

BATTERY
CAPACITY

243
mAh

AVEIR™ VR LP

120
mAh

Competition

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^{4,7}
- Hydrophilic coating on introducer sheath and a choice of 30cm and 50cm lengths⁸
- 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^{4,7}



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

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*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.

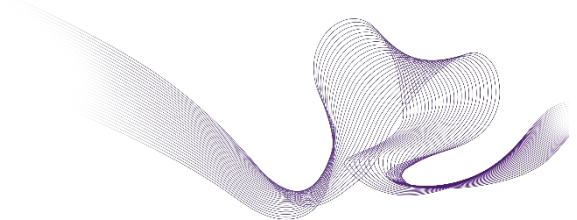
**For additional information about specific MR Conditional details, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the MRI-Ready Leadless System Manual at medical.abbott/manuals or check our MRI Ready resources at cardiovascular.abbott/mrireaddy

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COMPETITIVE COMPARISON

An abstract graphic composed of numerous thin, white, overlapping lines that form a complex, flowing, and somewhat circular shape. It resembles a stylized heart or a dynamic wave. The graphic is positioned on the right side of the slide, extending from the center towards the right edge. The background is a smooth gradient from deep purple on the left to a lighter teal on the right.

COMPETITIVE COMPARISON^{4,5}



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[‡] VR AND AVEIR[™] VR LP PROJECTED BATTERY LONGEVITY COMPARISON^{4,5*}

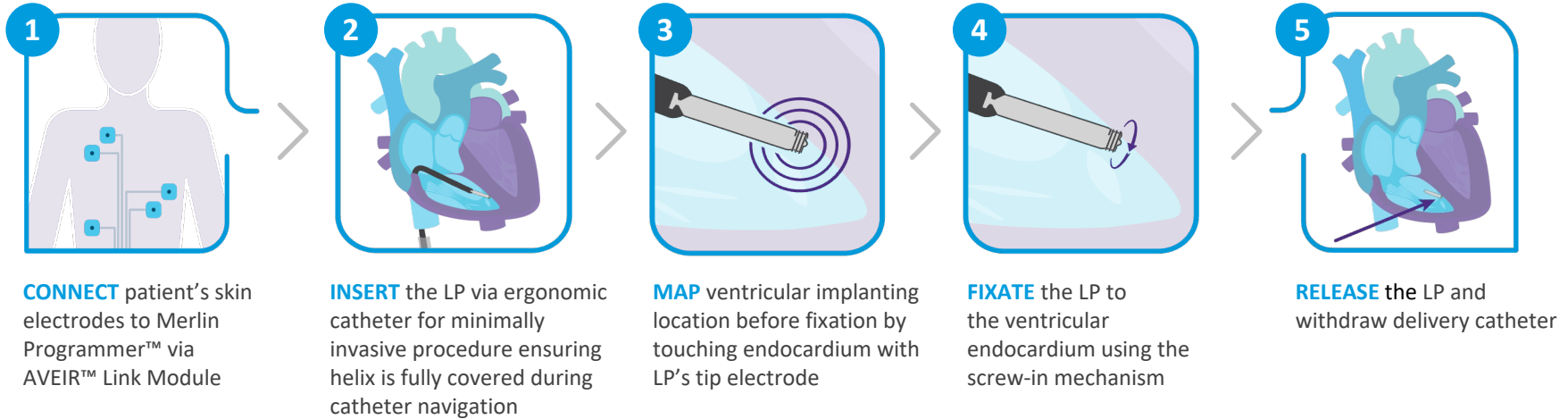
Pacing					Longevity (yrs)		PW=	Longevity (yrs)		
					Micra VR	AVEIR VR		Micra VR	AVEIR VR	AVEIR VR
Pacing %	Amplitude	Rate	Impedance	PW=	0.4 ms	0.4 ms	PW=	0.24 ms	0.2 ms	0.3 ms
0%	1.5 V	60 bpm	500 ohms		14.5	27.3		14.6	27.3	27.3
50%	1.0 V	60 bpm	500 ohms		12.5	22.6		13.3	24.4	23.4
50%	1.5 V	60 bpm	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

WORKFLOW

An abstract graphic composed of numerous thin, white, overlapping lines that form a complex, flowing, and somewhat chaotic shape. It resembles a stylized heart or a series of interconnected loops, positioned on the right side of the slide and extending towards the center.

WORKFLOW

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



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.

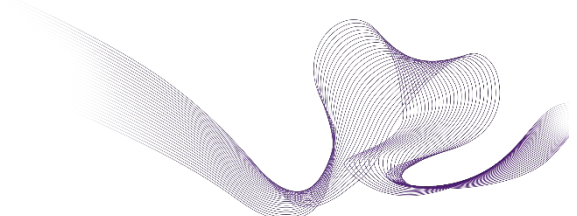
Through our nutrition products, diagnostics solutions, branded generic medicines and medical devices, we've helped people live fuller, healthier lives.

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REFERENCES

1. Udo EO, Zuithoff NP, van Hemel NM, et al. Incidence and predictors of short- and long-term complications in pacemaker therapy: the FOLLOWPACE study. *Heart Rhythm*. 2012 May;728-735.
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 Electrophysical*. 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[†] 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

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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.

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

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