AVEIR™ AR
Atrial Leadless Pacemaker

MULTI-CENTER REAL-WORLD EXPERIENCE WITH THE FIRST ATRIAL LEADLESS PACEMAKER SYSTEM

CYRUS HADADI MD

ASSOCIATE DIRECTOR OF ARRHYTHMIA RESEARCH

MEDSTAR HEART & VASCULAR INSTITUTE

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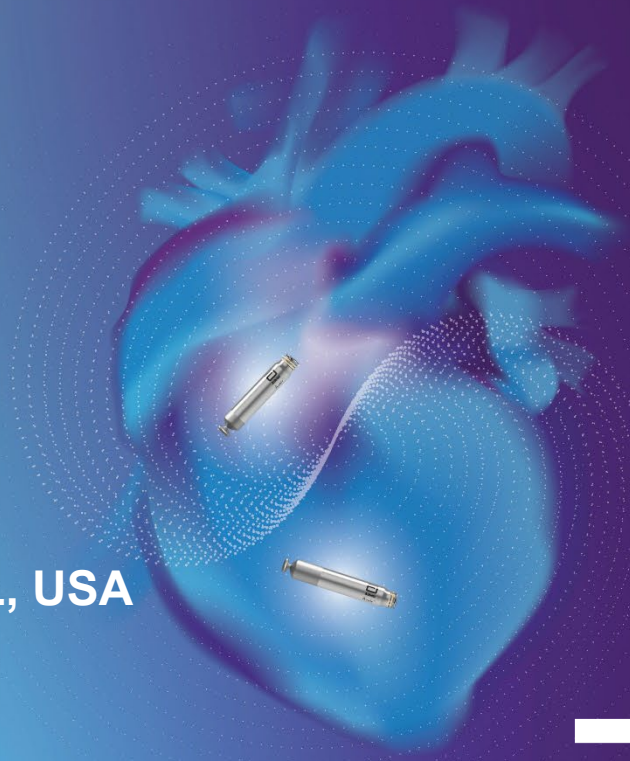

On behalf of:

Devi Nair MD, FACC, FHRS[1];
Ken W. Lee MD, FACC[2]

1. St. Bernards Medical Center & Arrhythmia Research Group, Jonesboro, AR, USA
2. Health First Medical Group, Melbourne, FL, USA

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Disclaimers

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Disclosures

- I have served on the advisory board, served as a consultant, or received honoraria, research grants, or support from Abbott

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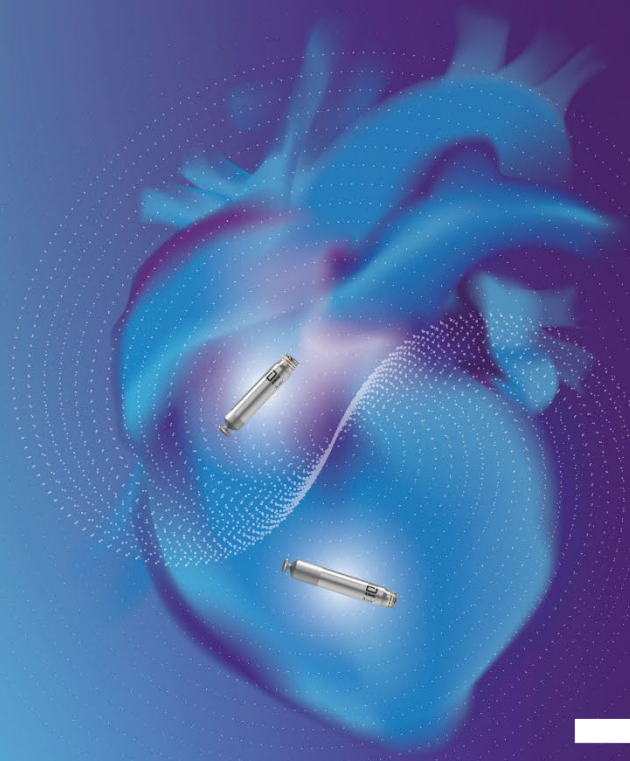
THE AVEIR AR LEADLESS PACEMAKER



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Introduction to AVEIR AR Leadless Pacemaker

- The AVEIR AR Leadless Pacemaker (Abbott) is a new single-chamber leadless pacemaker (LP) designed specifically for the right atrium
- The initial commercial implant experience with this atrial LP alone continues to be described and evaluated

Takeaways from the AVEIR DR IDE

- 63.3% of patients had sick sinus syndrome (SSS)
- 98.3% implant success
- 1.7% dislodgements
- 0.7% pericardial effusion (compared to 1.5% AVEIR VR LP)

Knops RE, Reddy VY, Ip JE, et al. A Dual-Chamber Leadless Pacemaker. New England Journal of Medicine. 2023 May 20.

Introduction to AVEIR AR Leadless Pacemaker

- A single chamber only atrial pacemaker?
- Before the AVEIR AR LP I had never implanted one
- Have *you* ever implanted one?

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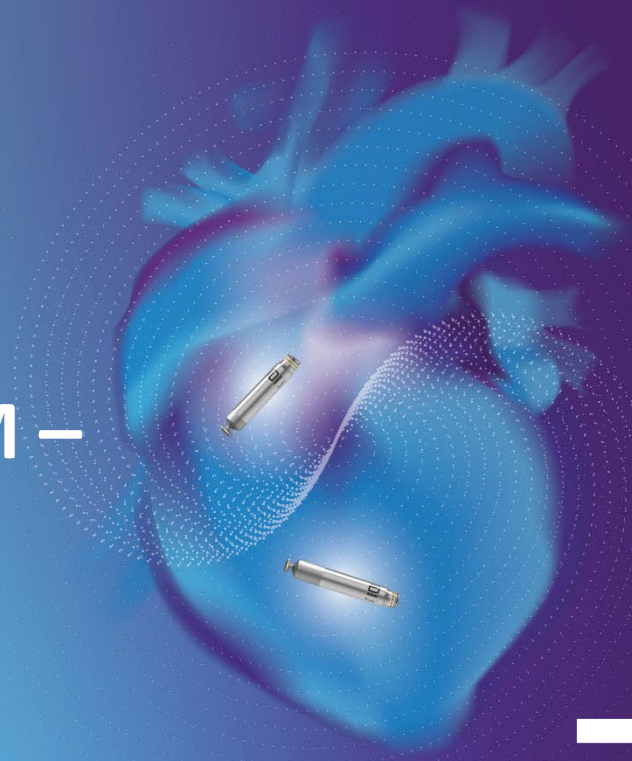
DAWN OF A NEW PARADIGM – LEADLESS AAI(R) PACING



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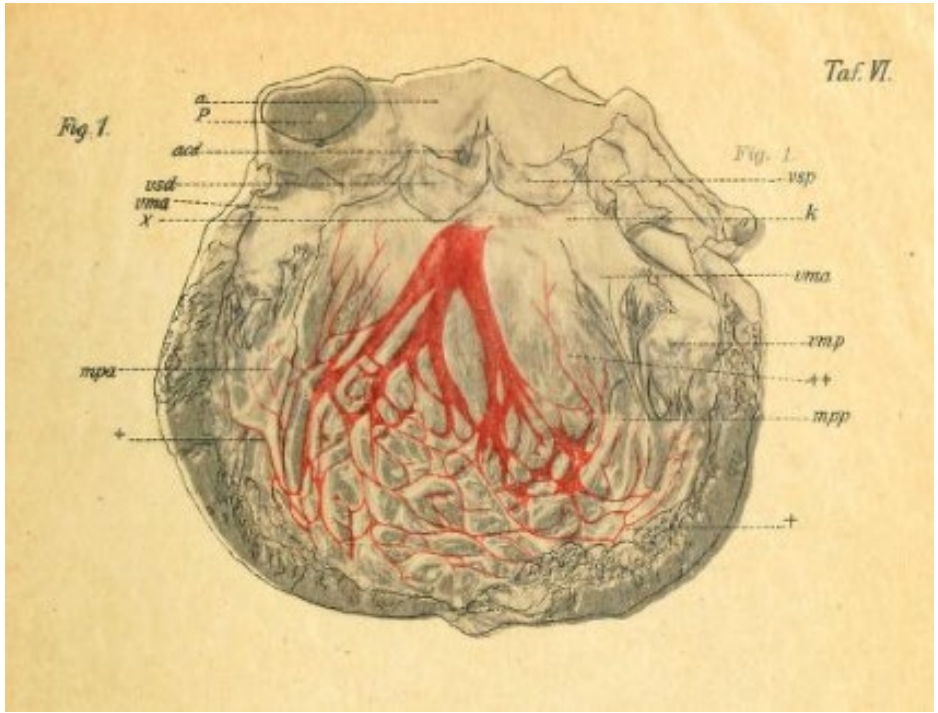
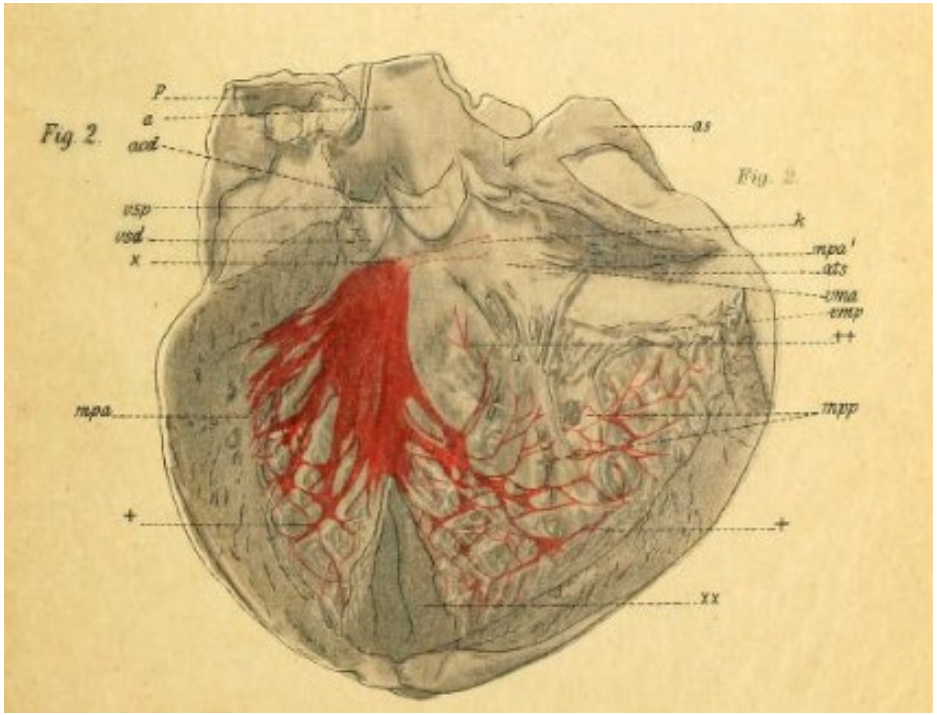
Dr. Sunao Tawara

- A Japanese-trained dermatologist, Dr. Tawara came to Germany as doctoral student under the mentorship of Dr. Ludwig Aschoff
- His 1906 monograph Das Reizleitungssystem des Säugetierherzens (The Conduction System of the Mammalian Heart) first described the conduction system of the heart

Dr. Sunao Tawara





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Dr. Sunao Tawara

- Tawara described the specialized cardiomyocytes that span the heart from atrium to AV node, bundle of His and His-Purkinje system, allowing for rapid impulse conduction
- We know from almost 70 years of experience with clinical permanent pacemakers and from the AVEIR DR IDE that most patients have sick sinus syndrome and preserved His-Purkinje conduction
- Why wouldn’t you implant an atrial only device?

Back to the Future

- In 1994 in *The Lancet*, Andersen et al. performed a prospective RCT in 225 consecutive patients (63% women; mean age 76 years) with SSS randomized to atrial (n = 110) or ventricular (n = 115) pacing and followed for mean 3.3 years
- Atrial pacing was associated with lower frequencies of atrial fibrillation, thromboembolic complications, and low risk of atrioventricular block (AVB)

Back to the Future

- AVB occurred in 2 patients in the atrial group
- In a 1997 follow-up, AVB occurred in 4 patients in the atrial group **(0.6% annual risk)**

DANPACE

- In 2010 in *European Heart Journal*, the DANPACE investigators performed a prospective RCT in 1,415 patients (65% women; mean age 73 years) with SSS and no clinical AVB randomized to AAI(R) (n = 707) or DDDR (n = 709) pacing and followed up for mean 5.4 years

- Patients randomized to AAI(R) who demonstrated AVB when atrial paced at 100 bpm crossed over to DDDR arm

DANPACE

- In the AAI(R) group, 585 patients (83%) never had a ventricular lead
- In the remaining 122 patients (17%), a ventricular lead was implanted either at the original operation if they failed the atrial pacing test or at some point during follow-up

DANPACE

- There was **no difference** in all-cause mortality between the AAI(R) pacing and DDDR pacing arms (29.6% vs. 27.3%, 95% CI 0.88–1.29, p = 0.53)
- Paroxysmal AF was observed more frequently in the AAI(R) group (28.4% vs. 23.0%, p = 0.024), as were pacemaker reoperations (22.1% vs. 11.9%, p < 0.001)
- Findings supported the use of dual-chamber pacemakers

DANPACE FOLLOW-UP

- In 2013 in *EuroPace*, a follow-up cohort study within DANPACE further characterized indications and risk for DDDR upgrade in the AAI(R) group, as well as complications after upgrade
- A total of 66 patients out of 660 underwent DDDR upgrade after a mean of 1.8 years **(1.7% annual risk)**

DANPACE FOLLOW-UP

Table 1 Baseline characteristics of patients randomized to AAIR pacing in DANPACE (n = 707)

	Without upgrade (n = 641)	With upgrade (n = 66)	P value
Female gender, n (%)	437 (68)	35 (53)	0.01
Age, years (mean ± SD)	74 (11)	70 (12)	0.01
Prior history of atrial fibrillation, n (%)	280 (44)	23 (35)	0.17
Left atrial diameter in mm, mean ± SD	39 (6)	40 (6)	0.19
Medication at randomization, n (%)			
Sotalol	39 (6)	4 (6)	0.99
β-Blocking agent	147 (23)	12 (18)	0.38
Calcium-channel blocker	124 (19)	13 (20)	0.95
Digoxin	63 (10)	10 (15)	0.18
Amiodarone	21 (3)	4 (6)	0.24
Class 1 antiarrhythmics	13 (2)	1 (2)	0.78
Left anterior or left posterior			
Fascicular block, n (%)	18 (3)	1 (2)	0.54
PQ-interval, ms			
0–160	207 (34)	20 (33)	
161–180	152 (25)	13 (219	
181–200	184 (30)	17 (28)	
201–	65 (11)	11 (18)	0.38
Stim-Q100, ms			
0–220	275 (56)	22 (48)	
221–	215 (44)	24 (52)	0.28

AAIR, single lead atrial pacing; SD, standard deviation; Stim-Q100, atrial stimulus-Q interval at atrial pacing rates of 100 b.p.m.
Data were incomplete for the following parameters: left atrial diameter (n = 506); PQ-interval (n = 669); Stim-Q100 (n = 536).

Table 4 Predictors for system upgrade in the AAIR group in DANPACE (n = 707)

	Risk, %	cOR	aOR[b] (95% CI)	P value
Gender				
Female[a]	7.4	1.0		
Male	13.2	1.9	1.7 (1.0–2.8)	0.06
Age, years[c]	–	1.0	0.98 (0.6–1.0)	0.04
Prior history of atrial fibrillation				
No[a]	10.6	1.0		
Yes	7.6	0.7	0.8 (0.4–1.3)	0.31
Left atrial diameter				
≤40 mm[a]	8.1	1.0		
>40 mm	13.3	1.7	1.9 (1.0–3.8)	0.04
Left anterior or left posterior fascicular block				
No[a]	9.5	1.0		
Yes	5.3	0.5	0.6 (0.1–4.3)	0.57
PQ-interval, ms				
0–160[a]	8.8	1.0		
161–180	7.9	0.9	0.9 (0.4–1.9)	0.82
181–200	8.5	1.0	1.1 (0.5–2.1)	0.89
201–	14.5	1.8	2.1 (0.9–4.7)	0.07
Stim-Q100, ms				
0–220[a]	7.4	1.0		
221–	10.0	1.4	1.7 (0.9–3.1)	0.11

AAIR, single lead atrial pacing; aOR, adjusted odds ratio; CI, confidence interval; cOR, crude odds ratio Stim-Q100, atrial stimulus-Q interval at atrial pacing rates of 100 b.p.m.
[a]Reference group.
[b]Adjusted for age and gender.
[c]aOR for each 1-year increase in age.

Europace (2013) 15, 1166–1173 doi:10.1093/europace/eut039

DANPACE FOLLOW-UP

Table 2 Indication for system upgrade in the AAIR group in DANPACE ($n = 66$)

	Total number	Symptom			Mode changed to
		Syncope	Other symptoms[a]	Asymptomatic	
Class I indication for system upgrade					
Third degree AV block	19	10	7	2	DDDR
Second degree AV block type 2[b]	12	2	6	4	DDDR
Second degree AV block type 1	6	2	4	0	DDDR
Atrial fibrillation with bradycardia	17	7	9	1	DDDR
Chronic heart failure and BBB	1	0	1	0	CRT-P
Ventricular tachyarrhythmias	3	2	1	0	ICD
Others[c]	1	1	0	0	VVIR
No class I indication for system upgrade[d]	7	4	3	0	DDDR

AAIR, single lead atrial pacing; AV, atrioventricular; BBB, bundle branch block; CRT-P, cardiac resynchronization therapy pacemaker; DDDR, dual-chamber pacing; ICD, implantable cardioverter-defibrillator; VVIR, single lead ventricular pacing.

[a]Dizzy spells, dyspnoea, or angina.

[b]All types of second degree AV block other than Wenckebach type (second degree AV block type 1).

[c]Malfunctioning atrial lead (exit block) with failure to gain atrial capture during reoperation.

[d]See *Table 3* for details.

Europace (2013) 15, 1166–1173 doi:10.1093/europace/eut039

DANPACE FOLLOW-UP

- **11 patients (16.7%)** experienced major complication after DDDR upgrade
- **3 patients** additionally experienced minor hematoma
- No fatalities due to complications
- The risk of complications was markedly higher after DDDR upgrade than after first implantation

DANPACE FOLLOW-UP

- There did not appear to be any significant risk for the development of cardiomyopathy with atrial-only pacing
- Only **1 patient** out of 660 AAI(R) pacemakers met indications for CRT!
- The follow-up DANPACE II study in 2023 did not explicitly evaluate for this, but there was **no difference** in all-cause mortality with minimization of atrial pacing
- The drivers for risk in DANPACE were atrial fibrillation, reoperation to upgrade to DDDR, and the complications of reoperation

DANPACE FOLLOW-UP

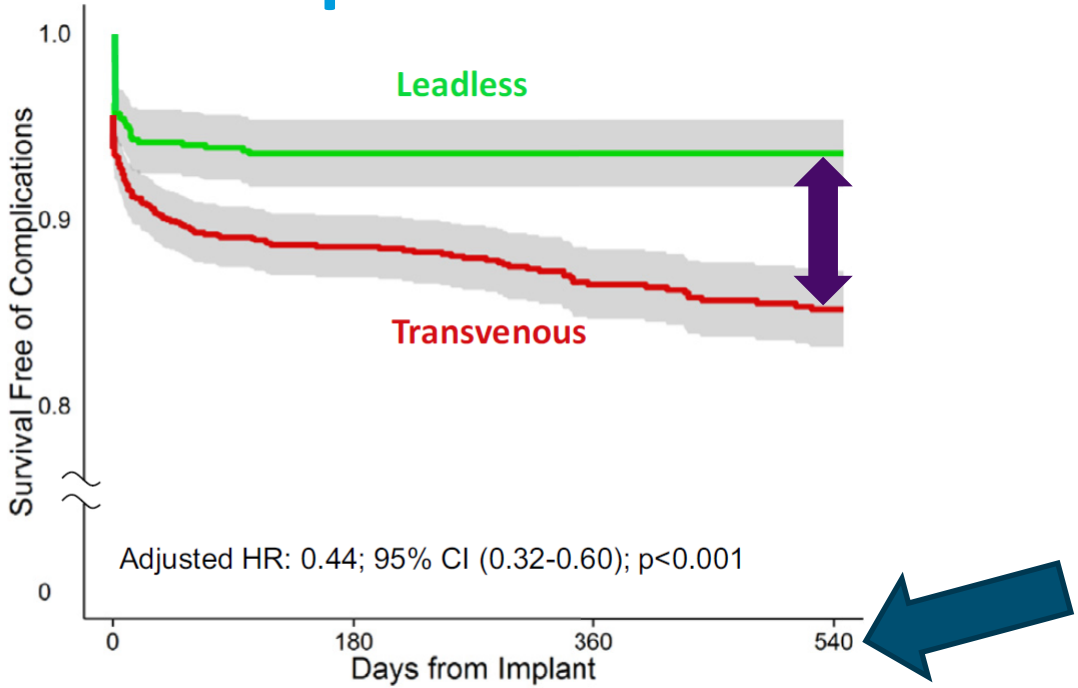
Table 5 Major complications after system upgrade in the AAIR group in DANPACE (*n* = 11)

Gender	Age at upgrade, years	Primary mode	Mode changed to	Class I indication for upgrade	Complication	Time to complication, days
Male	87	AAIR	DDDR	No	Myocardial perforation requiring cardiac surgery with thoracotomy, and reoperation with repositioning of the RV lead	2
Female	85	AAIR	DDDR	No	Reoperation because of RV lead dislodgement	
Male	71	AAIR	DDDR	No	System extraction because of systemic infection	
Female	79	AAIR	DDDR	Yes	Pneumothorax treated with a chest tube Pocket revision because of skin necrosis	
Female	85	AAIR	DDDR	Yes	Pneumothorax treated with a chest tube	
Female	76	AAIR	DDDR	Yes	Very large haematoma prolonging hospital stay fo 3 days	
Male	71	AAIR	DDDR	Yes	Reoperation because of RV lead dislodgement	
Male	69	AAIR	DDDR	Yes	Deep venous thrombosis in the arm and neck treated with anticoagulation	
Male	60	AAIR	DDDR	Yes	Reoperation because of RV lead dislodgement Reoperation because of RV lead dislodgement Pocket revision because of pain Reoperation because of RV and RA lead dislodgement Wound infection treated with antibiotics for 2 months System extraction because of pocket infection	
Female	66	AAIR	DDDR	Yes	Pocket revision because of pain	
Male	68	AAIR	ICD	Yes	Reoperation because of RA lead dislodgement	45

AAIR, single lead atrial pacing; DDDR, dual-chamber pacing; RA, right atrial; RV, right ventricular.

Europace (2013) 15, 1166–1173 doi:10.1093/europace/eut039

Acute and Chronic Complications LP vs. TVP



Number at risk				
Leadless	718	516	285	82
Transvenous	1436	939	665	486

Heart Rhythm (2018) 15(7), 1023–1030 doi:10.1016/j.hrthm.2018.04.022

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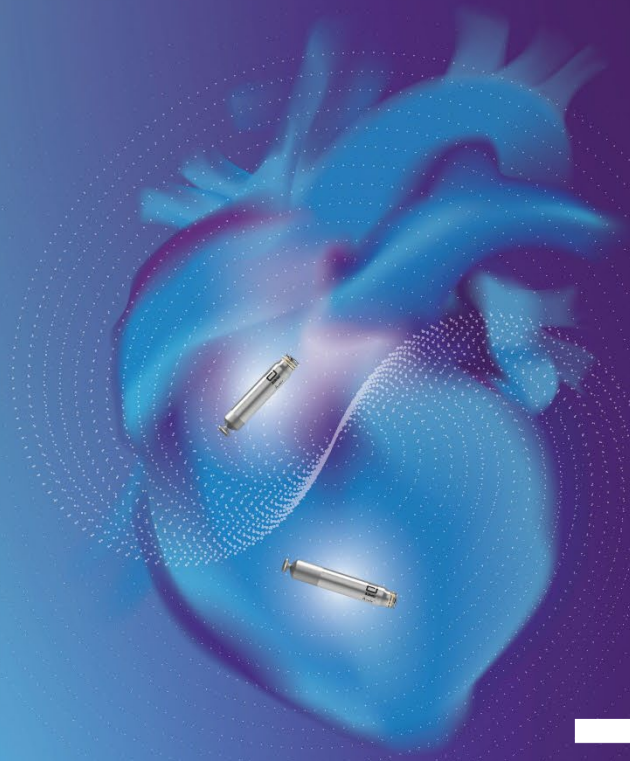
METHODS



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Methods

- Patients implanted with a de novo AVEIR AR LP device for Sinus Node Dysfunction in the USA after commercial release were consecutively included
- Procedural characteristics were evaluated
- Electrical parameters were measured during pre-fixation mapping, post-fixation tether mode, after LP release, and prior to patient discharge
- Any acute procedure- or device-related complications within 30 days were collected

Implant Procedure

- My practice is to use a modified DANPACE criteria
- Check the baseline HV interval
- Pace the high right atrium at 600 msec and 500 msec cycle length
- Baseline HV <70 msec w/o inducible 2° AVB → AVEIR AR LP only

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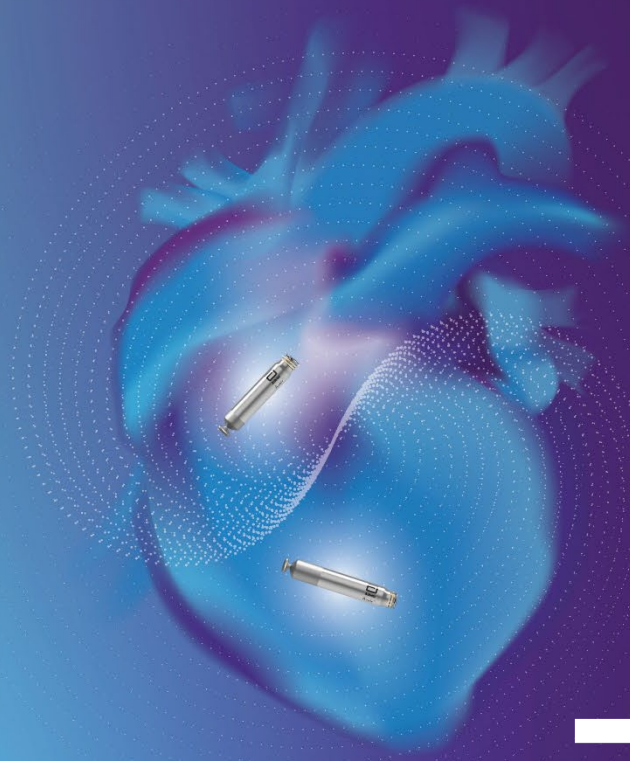
RESULTS



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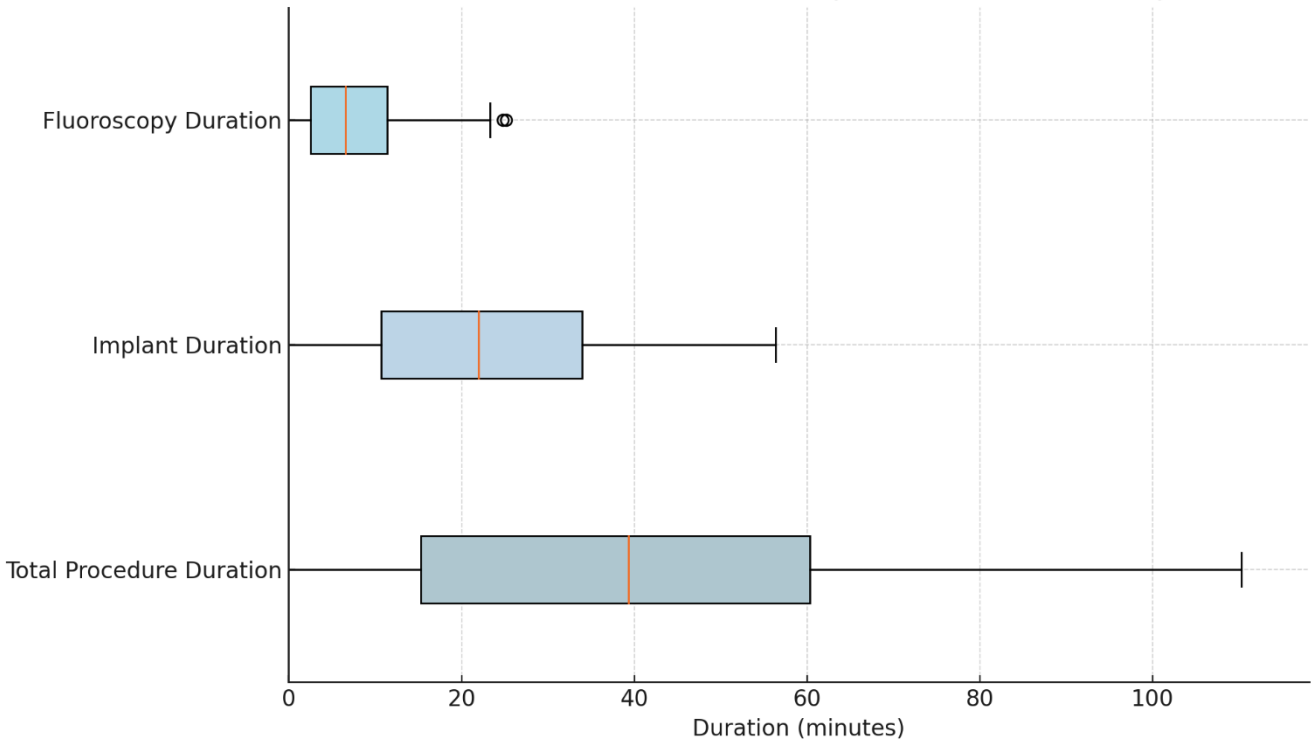
Results

- 75 patients were implanted with AVEIR AR LP per standard practice at 3 high-volume centers
- Age 72 ± 13 years; Sex 52% male
- Height 165.0 ± 13.3 cm; Weight 80.6 ± 26.6
- 92% of implants (69 patients) were de novo implants
- 8% of implants replaced an existing dual- or single-chamber transvenous device post extraction

Results

- ALPs placement predominantly in the base of the right atrial appendage (83%)
- 5 ALPs were placed at Bachman's Bundle(!)
- Implants could be performed under additional ICE guidance per SOC for individual physician
- **100% of implants were successful**

Procedural Duration



Procedural Duration – De Novo vs. Post Extract

- The total procedure duration for the 69 de novo implants, which did not include removing existing transvenous hardware, was slightly shorter at 32.3 ± 21.9 min

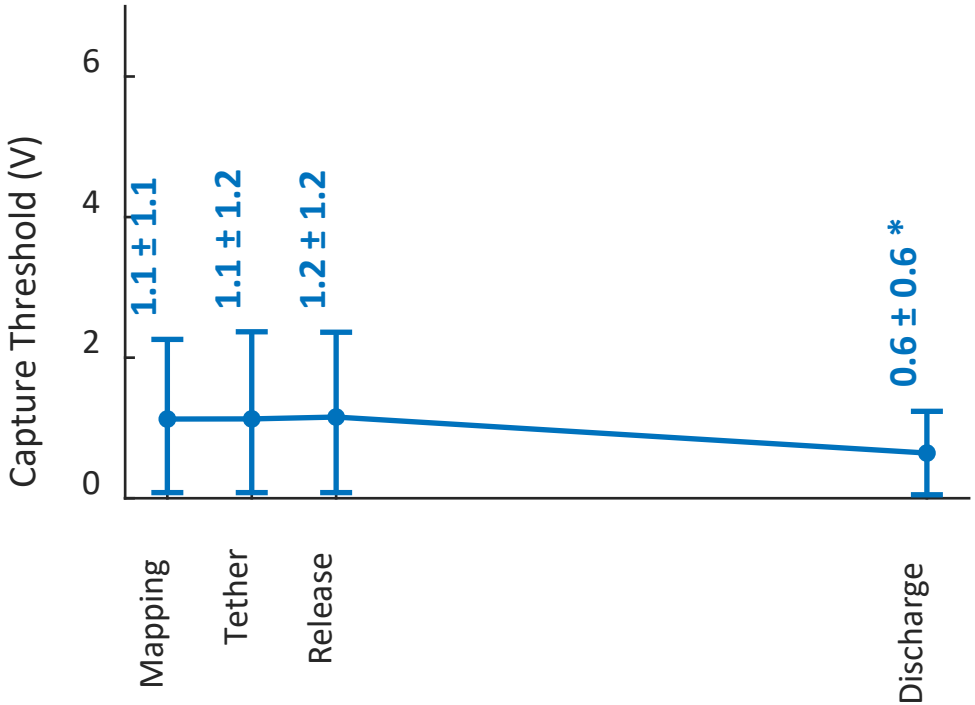
Positioning and Repositioning

- **71 patients (94.7%) required no repositioning**
- 3 LPs (4.0%) were repositioned due to inadequate electrical metrics; 1 LP (1.3%) was replaced and repositioned because the delivered LP could not be easily released from the delivery catheter

Positioning and Repositioning

- Of the 4 repositioned LPs, 3 LPs were repositioned once, and 1 LP (1.3%) was repositioned twice
- LPs were ultimately placed predominantly near the base of the RA appendage (82.7%)

Electrical Parameters



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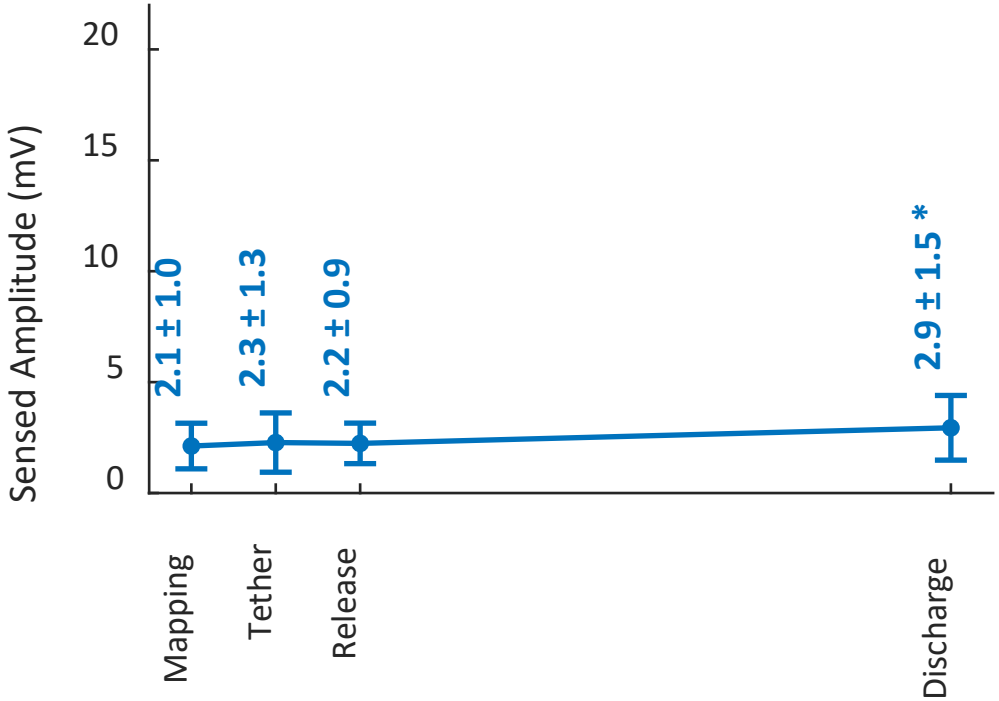
Electrical Parameters



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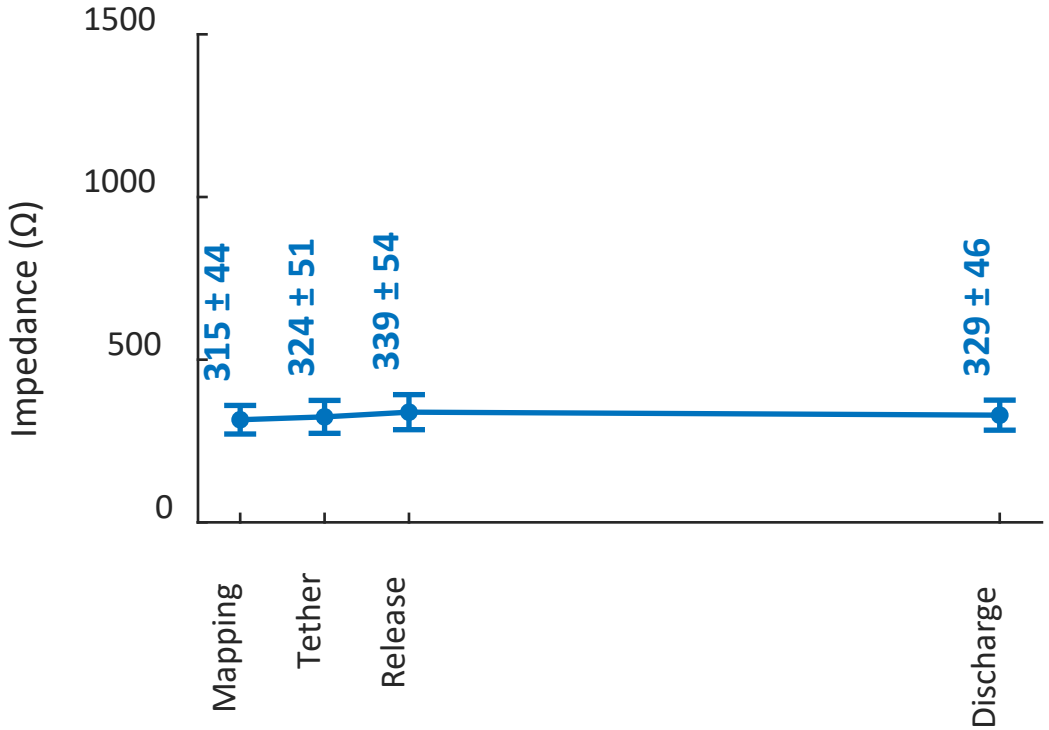
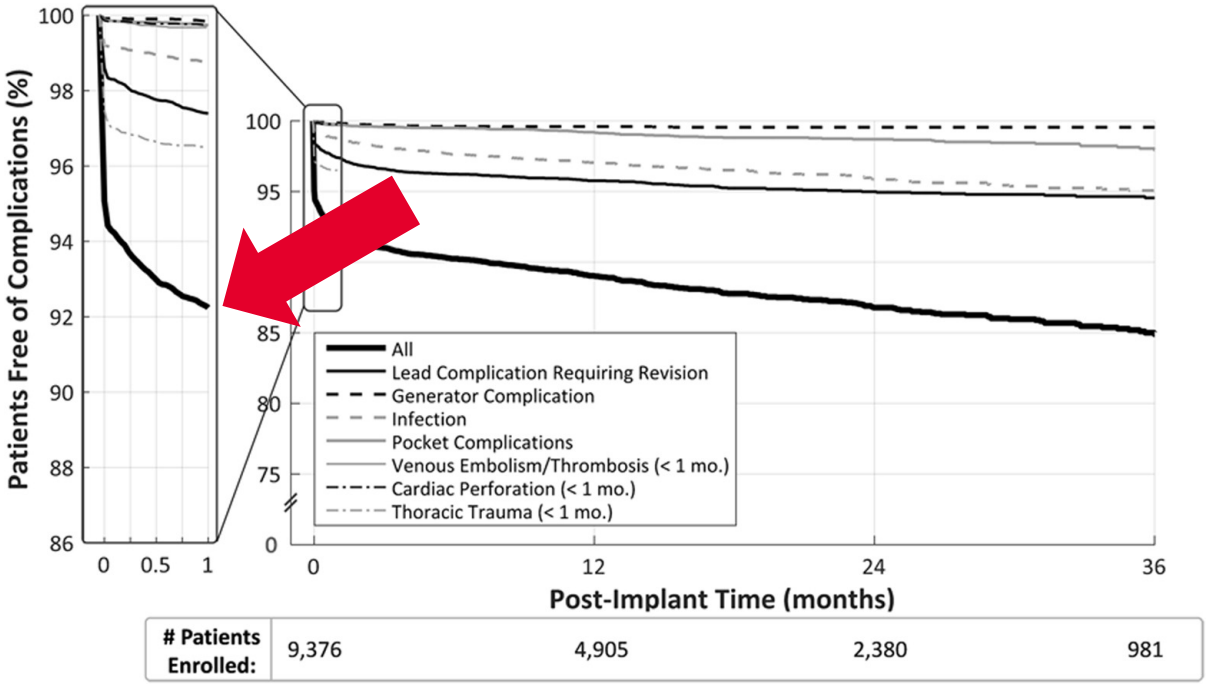


Complications and Adverse Events

- **No complications** were observed in the first 30 days post-implant, including any device-related performance changes requiring reintervention(!)

Complications



# Patients Enrolled:	9,376	4,905	2,380	981

JACC: EP (2017) 3(11), 1296–1305 doi:10.1016/j.jacep.2017.05.007

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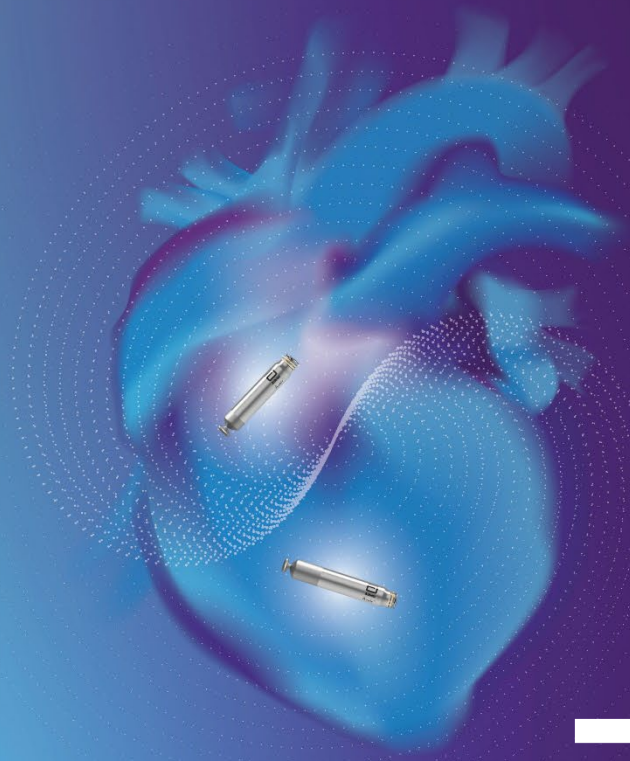
CONCLUSIONS



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The Ultimate Patient and Doctor Experience

- We’ve come a long way since DANPACE in 2011
- Atrial-only pacing offers many advantages, most importantly physiologic activation of the conduction system as described by Dr. Tawara over 100 years ago
- Atrial-only pacing fell out of favor because of the risk of development of atrial fibrillation, AVB **(0.6 – 1.7% annual risk)**, and the risk of reoperation for DDD upgrade

The Ultimate Patient and Doctor Experience

- Atrial-only pacing has never been associated with the development of cardiomyopathy!
- Our tools for atrial fibrillation management are much more sophisticated than they were in 2011
- Patients with SSS and no evidence of AVB have a very low annual risk for development of AVB, and leadless pacemakers eliminate the complications of DDDR upgrade

Real-World Experience

- The initial real-world experience of the helix-fixation, single chamber, atrial leadless pacemaker demonstrates:

1. Safe and efficient 100% implantation success
2. Clinically viable electrical metrics that continue to mature and improve until discharge
3. No acute complications

AVEIR LPs are Setting the Pace

- What pacemaker would you want for your **patients**?
- What pacemaker would you want for your **mom**?

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: 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. 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 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 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 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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15900 Valley View Court, Sylmar, CA 91342
Tel: +1 818 362 6822
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