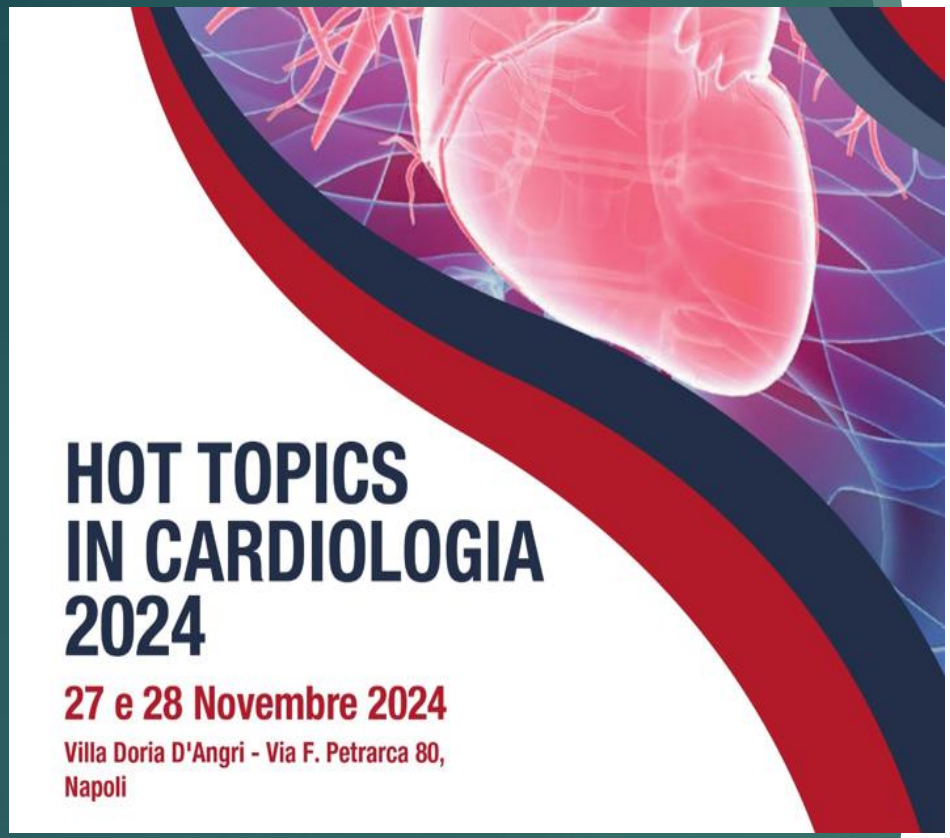


NUOVE TECNICHE D'IMPIANTO DEI PACEMAKER "LEADLESS"

RELATORE: DOTT. GIANLUCA MANZO
RESPONSABILE EP LAB
P.O. UMBERTO I NOCERA

L'evoluzione del pacing cardiaco è un lungo viaggio iniziato nel 1958.

External Pacemaker

1958

Implantable Pacemaker

1960

Rate Responsive Pacemaker

1986

1989

Dual-chamber Rate Response

1995

Microprocessor + Mode Switching

2001

Cardiac Resynchronization Therapy

2004

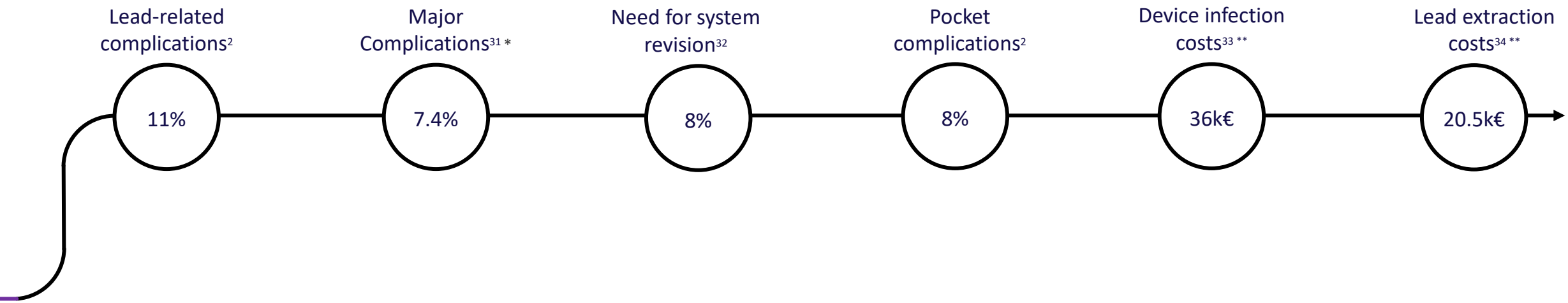
Full Automaticity Pacemaker

2011

MRI-conditional Pacemaker

Micra Leadless Pacemakers

Nonostante i progressi tecnologici compiuti in questi 60+ anni non siamo riusciti ad eliminare importanti complicanze legate ai sistemi transvenosi.



*Major complication was defined as events resulting in death, permanent loss of device function, hospitalization, prolongation of hospitalization by at least 48h or System revision.
** 1GBP = 1.17€

I pacemaker Leadless eliminano le complicanze associate alla presenza dei cateteri e della tasca.[8]

Significant complication reduction

Streamlined implant procedure

- 63% ↓ — Major complications (1-year)[4]
- 41% ↓ — Reinterventions (3-years)[6]
- 32% ↓ — Chronic complications (3-years)[6]
- >99% — Implant success rate[4,7]
- 26 min — Median procedure time[4]

Redefined patient experience

A pacemaker you don’t see every day

Fewer post-implant activity restrictions

Storia della Stimolazione Leadless

Micra VR

Introduced the first leadless pacemaker to the EU market

Micra AV

Leadless pacing with AV synchrony reimagined

Micra AV2 + VR2

Delivering meaningful improvements to Micra

Micra FIH

Micra IDE

Micra PAR

MARVEL2

Micra VR CED

2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024

Nanostim FIH

EU implants **suspended** due to battery failure

Global implants **suspended** due to battery failure

STJ acquired by ABT

Leadless II

Aveir DR i2i

Nanostim LP

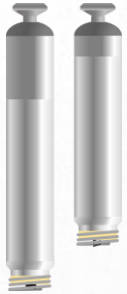
Awarded CE Mark

Aveir VR LP

CE mark in 2023

*Aveir DR LP**

CE mark in 2024



* Aveir DR is pending CE mark

LINEE GUIDA ATTUALI

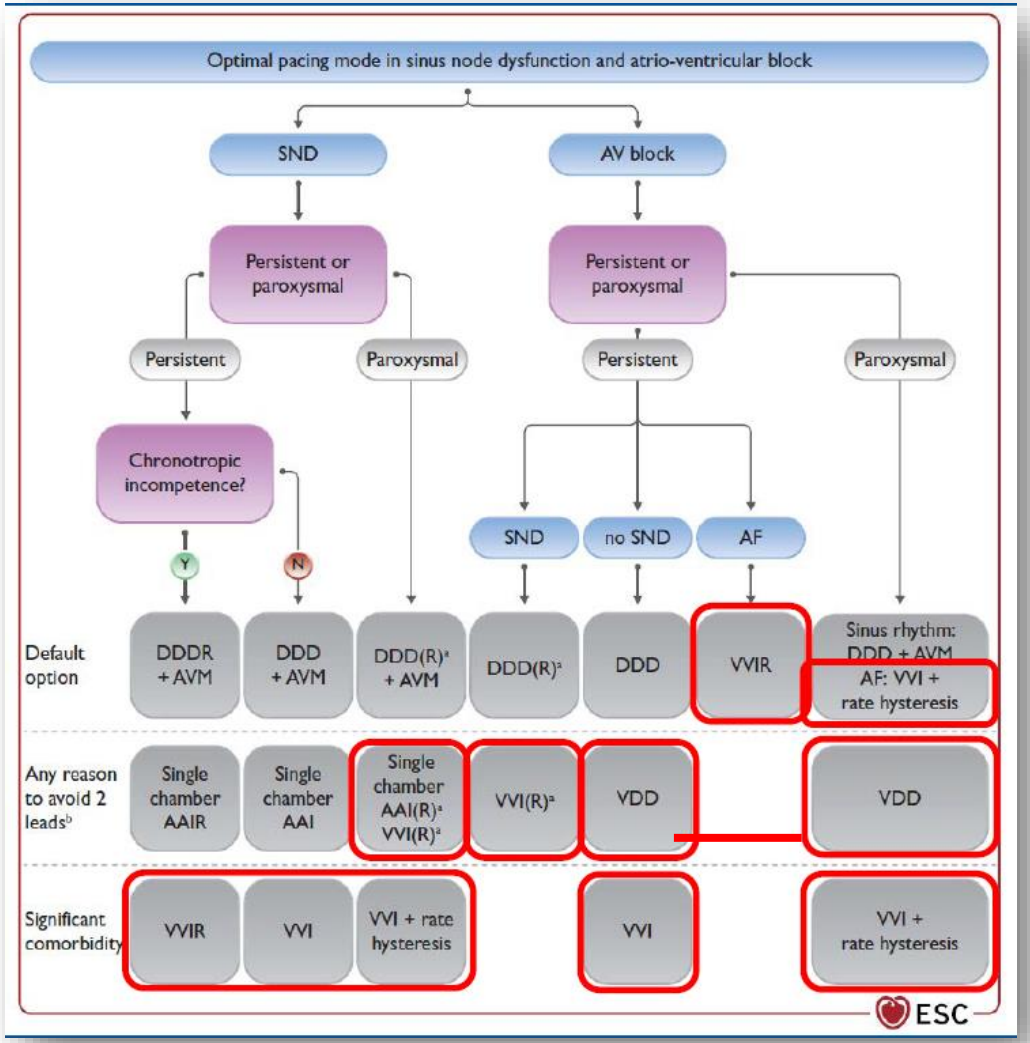
ESC European Society of Cardiology
European Heart Journal (2021) **42**, 3427–3520
doi:10.1093/eurheartj/ehab364

ESC GUIDELINES

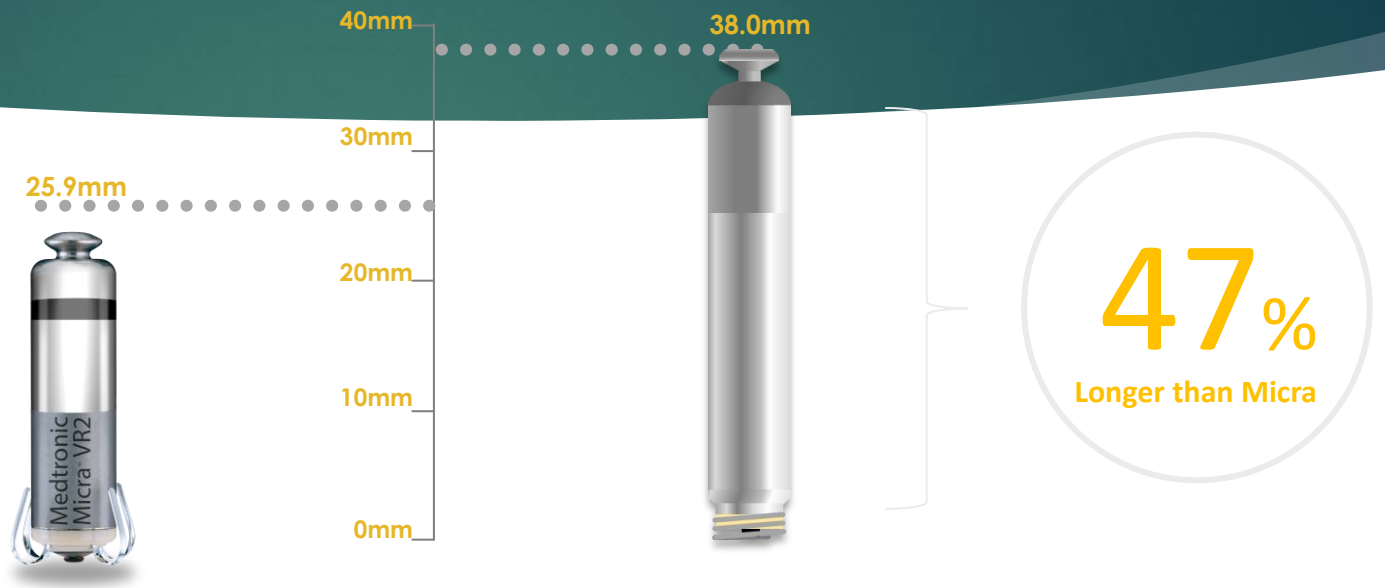
2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC)

Recommendations	Class[a]	Level[b]
Leadless pacemakers should be considered as an alternative to transvenous pacemakers when no upper extremity venous access exists or when risk of device pocket infection is particularly high, such as previous infection and patients on haemodialysis.[45,47–50,450]	IIa	B
Leadless pacemakers may be considered as an alternative to standard single-lead ventricular pacing, taking into consideration life expectancy and using shared decision-making.[45,47–50]	IIb	C



Differenti dimensioni



Micra LP

- Length: 25.9mm
- Volume: 0.8cc
- Diameter: 6.7mm
- Introducer outer diameter: 27Fr
- Introducer inner diameter: 23Fr

Aveir LP

- Length: 38.0mm
- Volume: 1.1cc
- Diameter: 6.5mm
- Introducer outer diameter: 27Fr
- Introducer inner diameter: 25Fr

[1] Leick, A. Micra vs Aveir and Transvenous Pacemaker Size Comparison*. March 2023. Medtronic data on file.

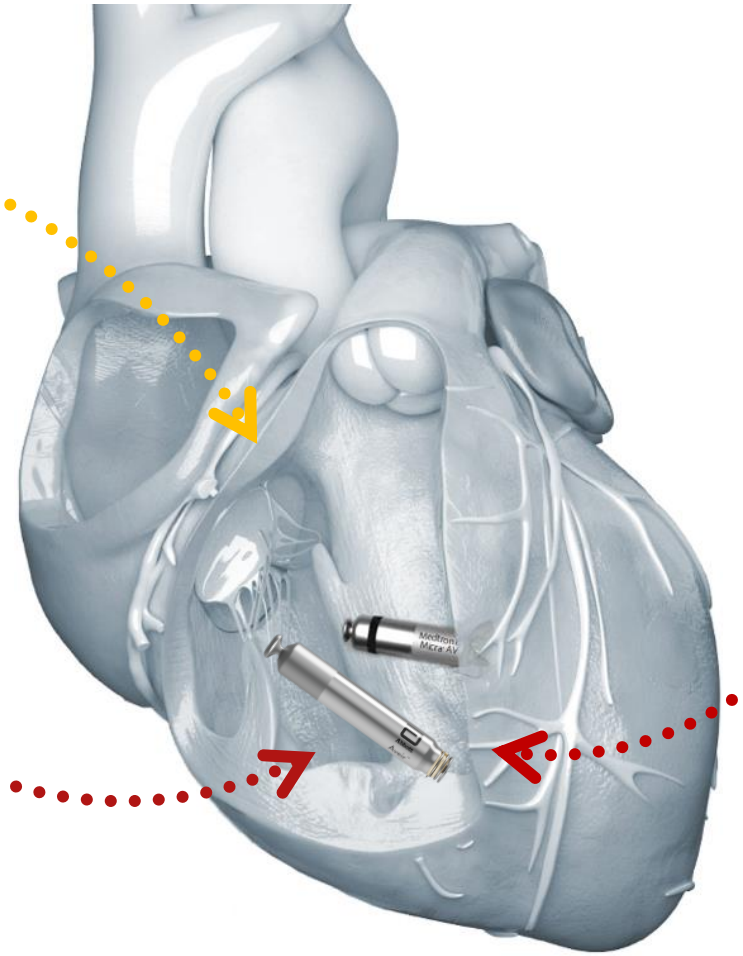
** Volume comparison based on Micra and Aveir IFU labeling*

Differenti dimensioni

Influenza la posizione d'impianto

Micra's short length accommodates recommended[1] mid-septal placement[2]

Long device may complicate navigation across tricuspid valve[3]

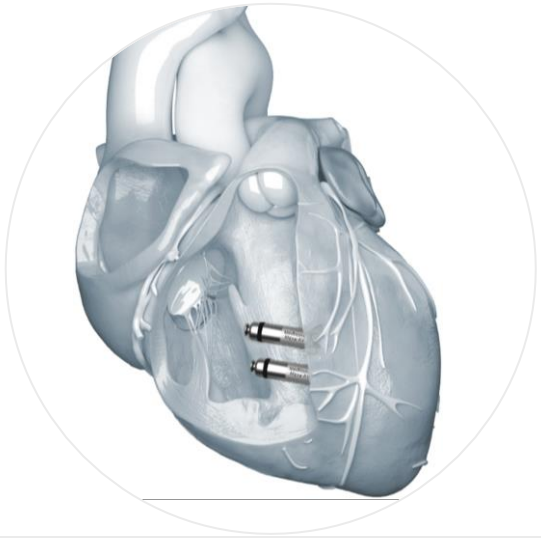


Aveir LP is intended for apical-septal placement due to increased length[3]

- [1] Piccini JP, et al. Development and validation of a risk score for predicting pericardial effusion in patients undergoing leadless pacemaker implantation: experience with the Micra transcatheter pacemaker. EP Europace. 2022;24(7):1119-1126.
- [2] Hai JJ, Fang J, Tam CC, et al. Safety and feasibility of a midseptal implantation technique of a leadless pacemaker. Heart Rhythm. June 2019;16(6):896-902
- [3] Ip JE. Advanced helix-fixation leadless cardiac pacemaker implantation techniques to improve success and reduce complications. J Cardiovasc Electrophysiol. 2023;1-9. doi:10.1111/jce.15918

Differenti dimensioni

Influenza la gestione a fine vita del device



Micra's size is **optimized** for permanent placement & multiple implants with limited interaction[1*]

Both devices are designed with capability for retrieval

Permanent placement **is recommended** for Aveir LP if unable to be retrieved[2]

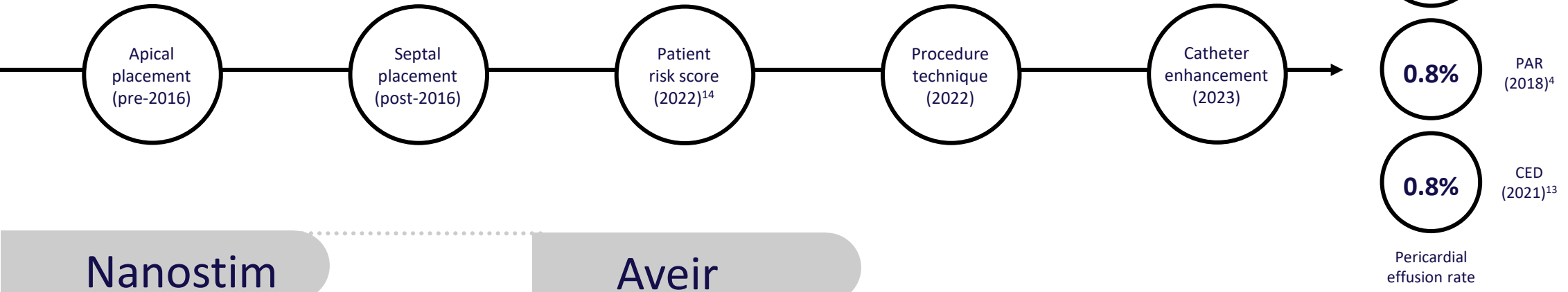
*In preclinical study

[1] Omdahl P, Eggen MD, Bonner MD, Iaizzo PA, Wika K. Right ventricular anatomy can accommodate multiple Micra transcatheter pacemakers. Pacing Clin Electrophysiol. 2016;39:393-397 Aveir

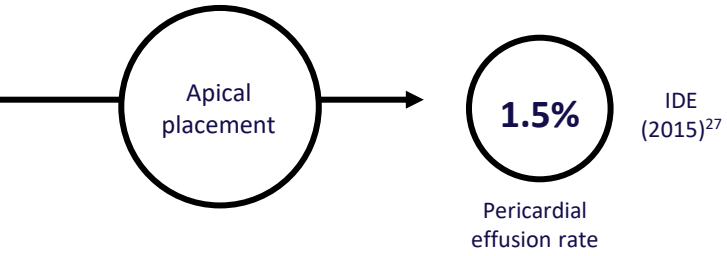
[2] Leadless Pacemaker Model LSP112V Instructions for Use. Abbott. 2022.

Micra can be placed on the septum because of its size, **away from the apex**, a known risk factor.[14]

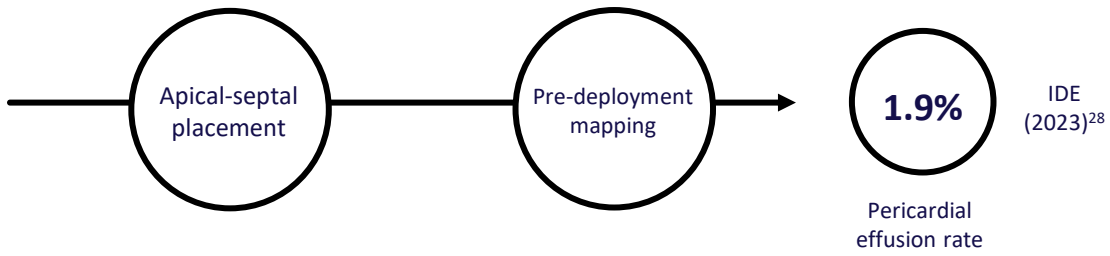
Micra

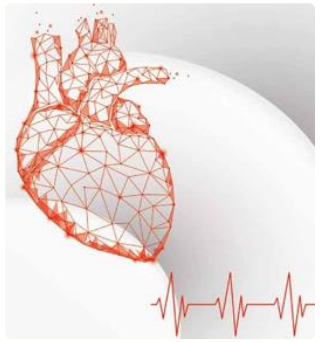


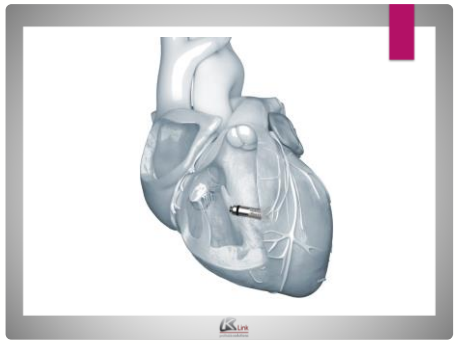
Nanostim



Aveir







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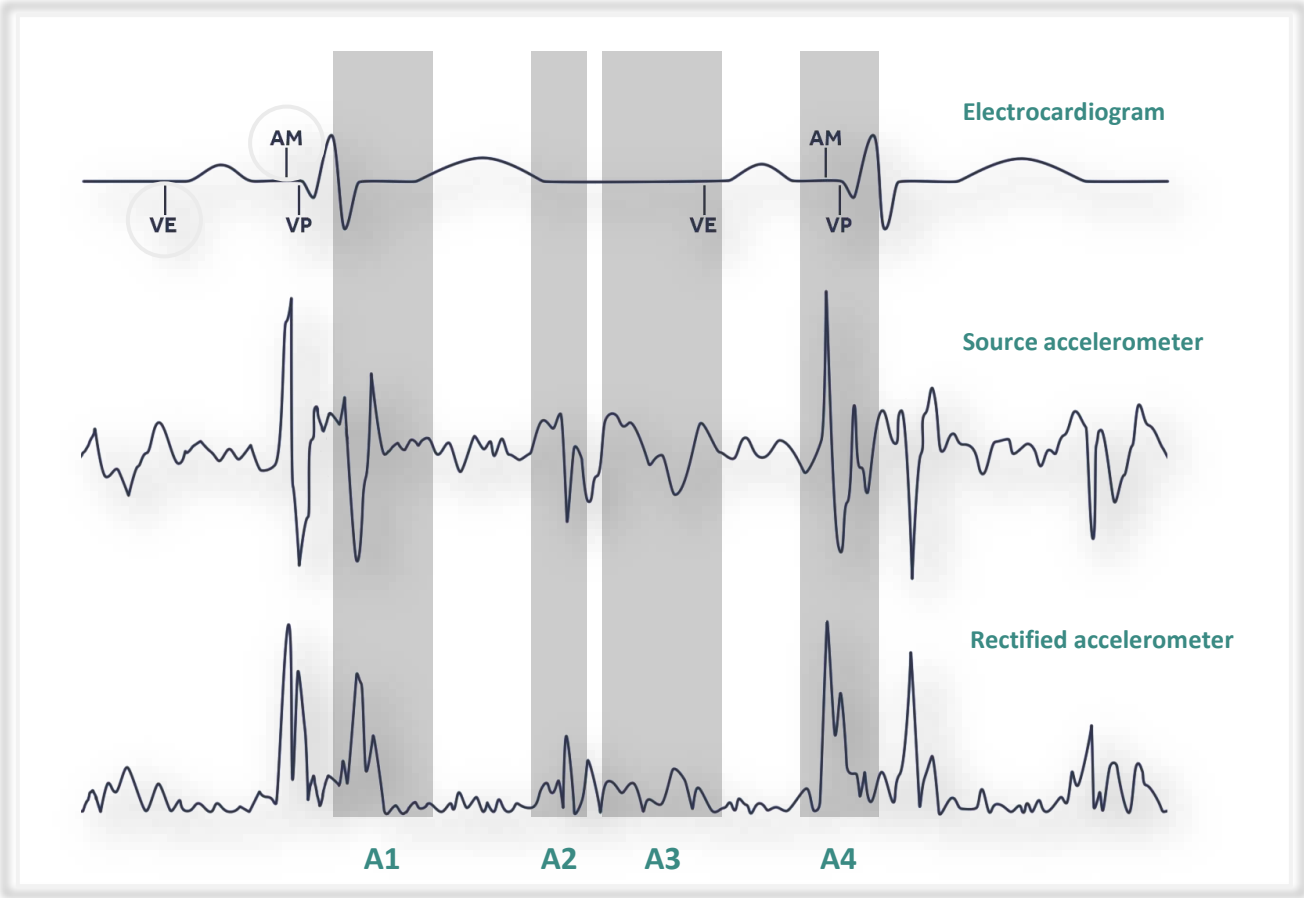
MICRA AV

AV synchrony reimagined

- Micra AV accelerometer signals explained



Micra AV's accelerometer detects mechanical atrial activity and uses this information to deliver AV synchronous ventricular pacing.

Ventricular end (VE) marker
End of the A1–A3 ventricular-event signals

Atrial mechanical (AM) marker
Marker that indicates the device detected the atrial mechanical contraction or A4

A1 Start of ventricular systole, mitral and tricuspid valves close

A2 End of ventricular systole, aortic and pulmonic valves close

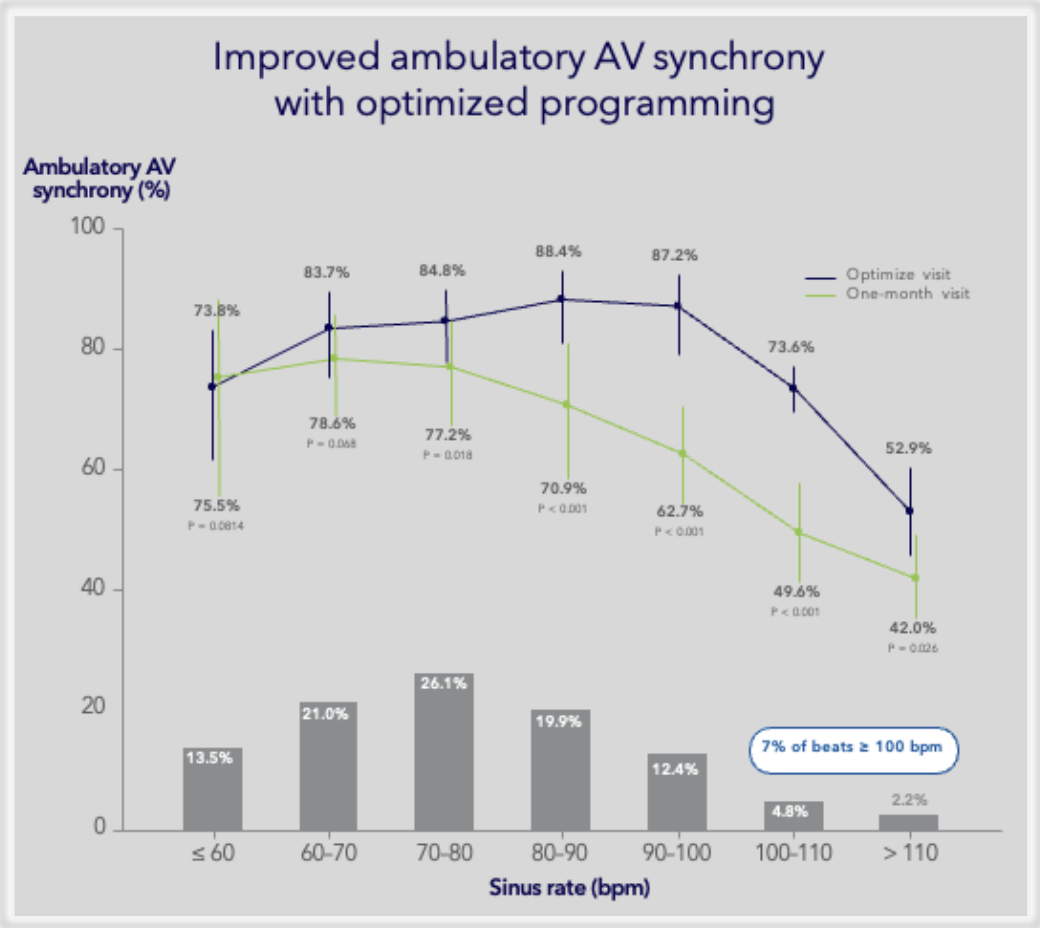
A3 Diastole, passive blood flow from A to V, corresponds to E-wave on Doppler echo

A4 Atrial systole, blood pushed into ventricles,100ms electromechanical delay, corresponds to A-wave on Doppler echo

A7 Occurs when the A3 and A4 signals fuse: passive and active filling of the ventricles occurs simultaneously, resulting in a larger amplitude signal.

AV synchrony reimagined

- AccelAV study recommendations[19]

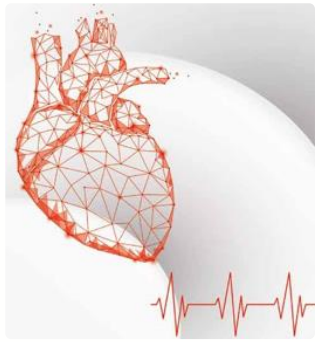


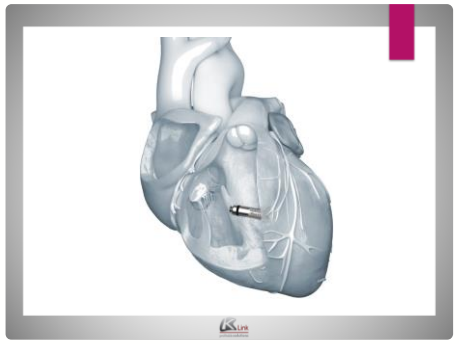
1. Program the auto A3 threshold feature to "Off" and program a fixed A3 threshold to a value approximately 1.0 m/s2 greater than the amplitude of an isolated A3 signal.

2. Ensure the A3 window end is programmed to a value just longer than the end of the accelerometer A3 signal (i.e. confirm the A3 window end was not shorter than the A3 signal).

3. Review the A4 threshold and maintain the auto A4 threshold = "On", except in cases with highly variable and very low A4 signals.

4. Turn the tracking check feature "Off" and review the PVAB, PVARP, and upper tracking rate parameters to enable tracking at the highest at the highest possible sinus rate without substantial risk of oversensing the A2 or A3 signal.





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JUGULAR APPROACH

Micra via Jugular

Only Leadless PM approved for jugular approach

95 Published Cases over past 4 years + growing

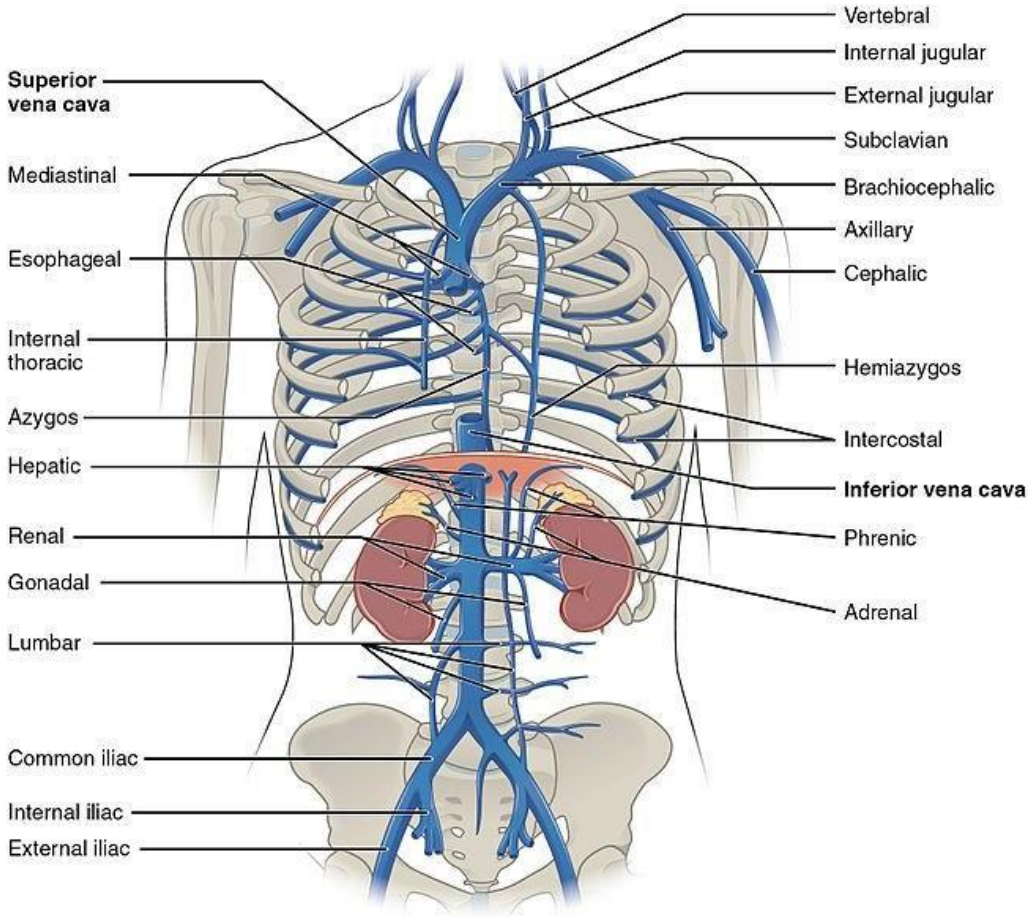
- >500 successful Jugular Micra implants in Europe
- > 80 successful Jugular Micra implant in Italy

Clinical Considerations

May provide alternative approach if femoral access issues

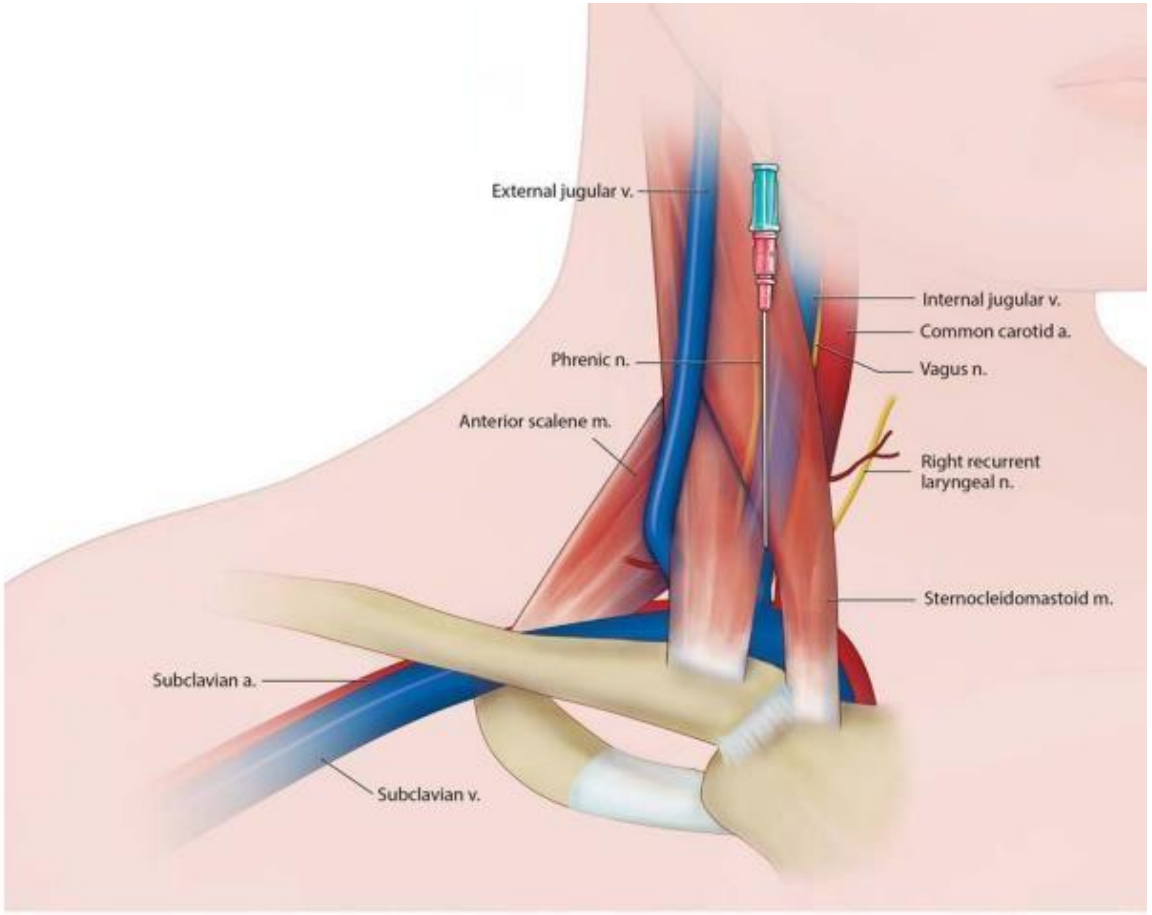
May assist ease in small / large anatomies

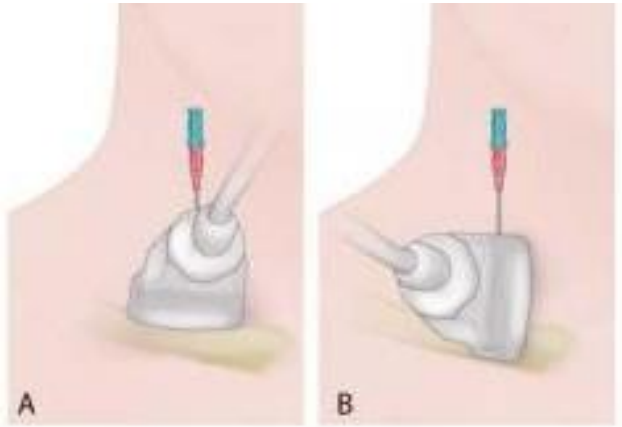
Anatomia del sistema venoso superiore e inferiore



Superior vena cava	Inferior vena cava
• Short	• Long
• Diameter 18-22 mm	• Diameter 27-36 mm
• Located in the anterior right superior mediastinum	• Located in the posterior mediastinum

Vessel anatomy of the neck



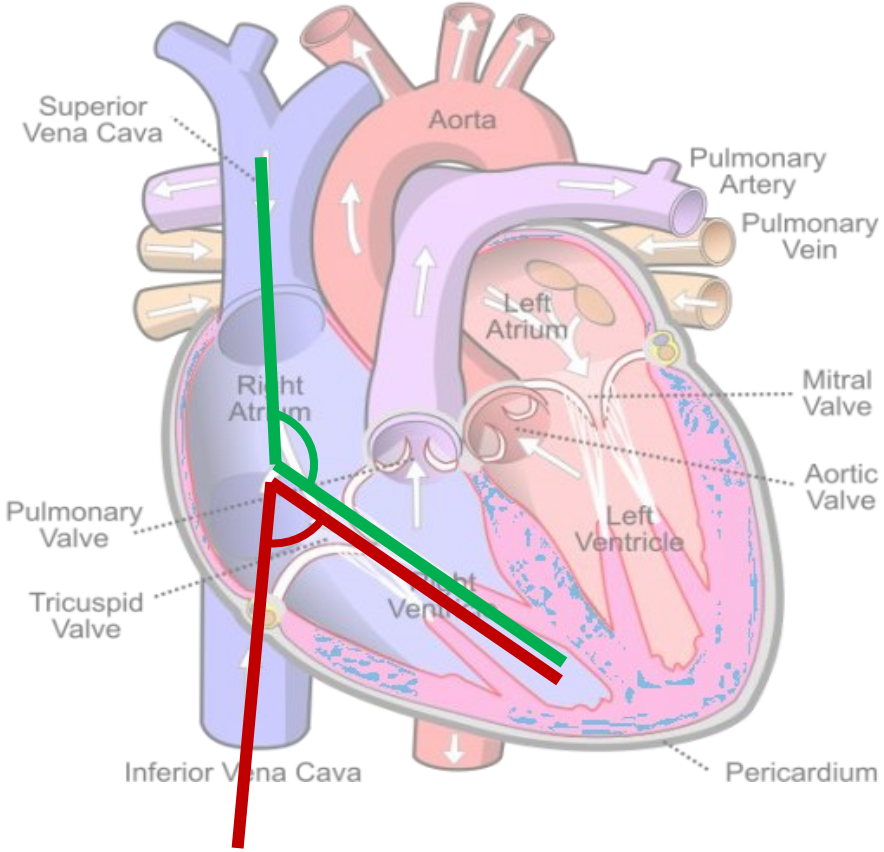


Hoffman et al. *Clinical Anatomy* 2017; 30: 237-250

IMPLANT PROCEDURE VIDEO

Perché l’approccio da Giugulare può risultare più semplice?

Miglior angolo tra la vena Cava e la Tricuspide



- Easier access into the right ventricle
- Easier access to the right ventricular septum
- BUT: Potentially more direct push to the tip of the delivery catheter

P.O. UMBERTO I NOCERA

EP LAB

OUR LEADLESS EXPERIENCE

DAL 2019 AD OGGI

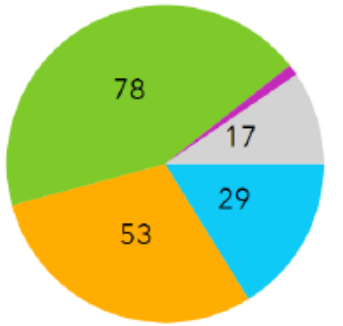
OUR LEADLESS PACEMAKER EXPERIENCE

FEMORAL APPROACH

PM Indication at implant

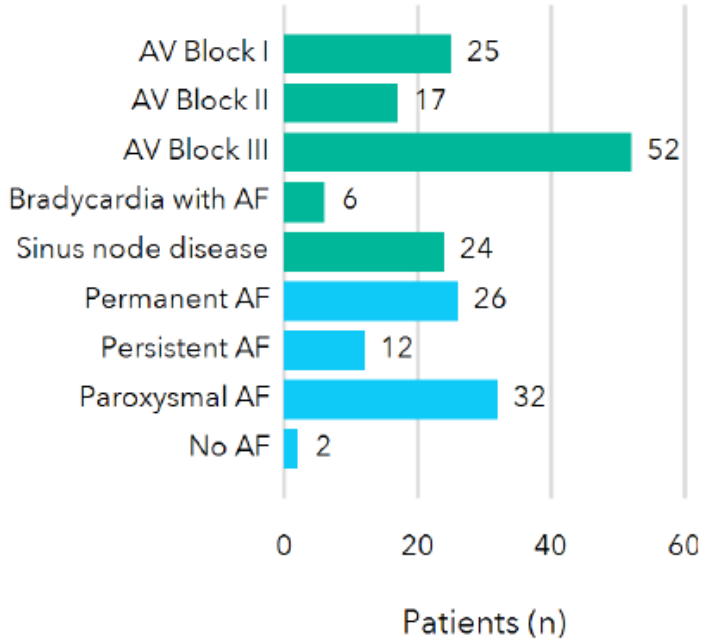
TPS as first implant: 179

TPS as system modification: 0

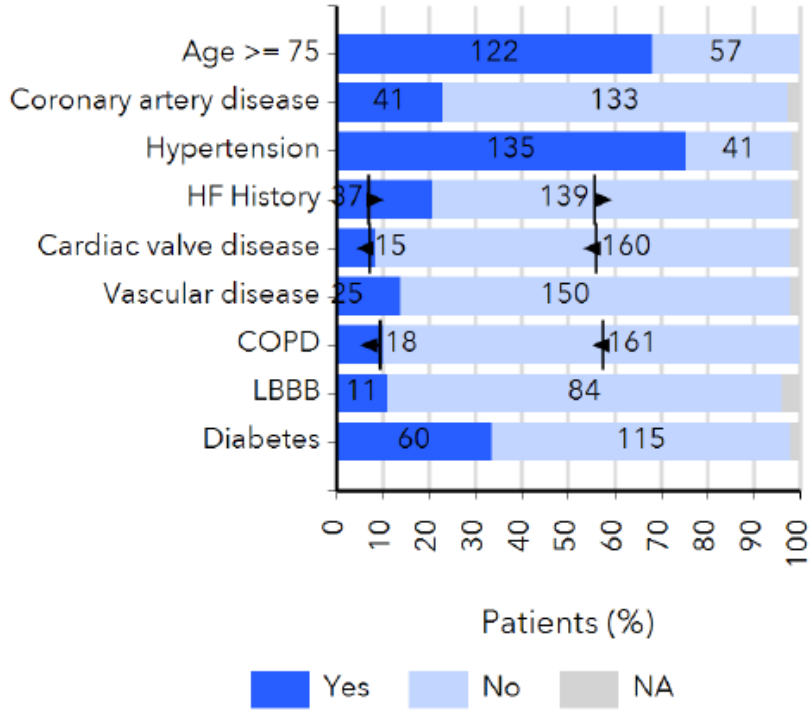


Sinus Node Dysfunction
AV block
Syncope
HF in a patient indicated to CRT
Other indication

Conduction system & AF



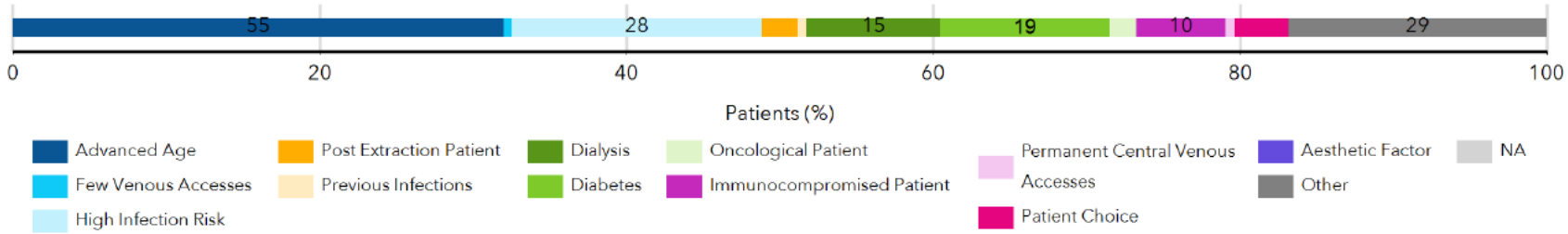
Risk factors



OUR LEADLESS PACEMAKER EXPERIENCE

FEMORAL APPROACH

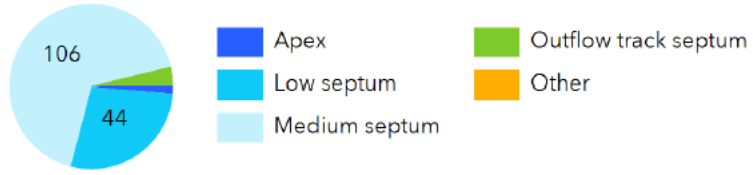
Why was chosen a TPS device



IMPLANT INFORMATION

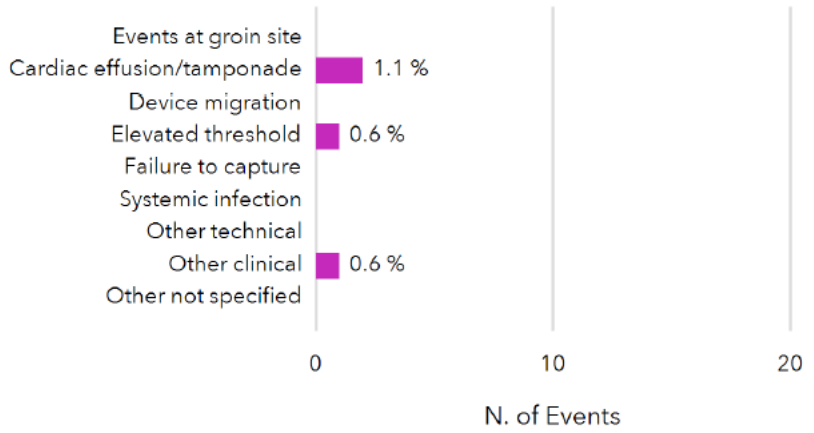
	Pts with data	Median	Q1 - Q3
Procedure time (min)	177	25	19 - 45
Fluorosopy time (min)	177	5	3 - 7
N. of TPS deployments	177	1	1 - 1
N. of tines fixed	177	3	2 - 3

Position



EARLY SAFETY (Events: 4 | Pts involved: 4 (2.2 %))

Periprocedural event type (within 30 days since implant)



OUR LEADLESS PACEMAKER EXPERIENCE

FEMORAL APPROACH

frontiers in Cardiovascular Medicine

ORIGINAL RESEARCH
published: 14 January 2022
doi: 10.3389/fcvm.2021.781335

Single-Chamber Leadless Cardiac Pacemaker in Patients Without Atrial Fibrillation: Findings From Campania Leadless Registry

Vincenzo Russo[1], Antonello D'Andrea[2], Stefano De Vivo[3], Anna Rago[3], Gianluca Manzo[2], Antonio Bocchetti[1], Andrea Antonio Papa[3], Valerio Giordano[2], Ernesto Ammendola[3], Berardo Sarubbi[3], Paolo Golino[1], Antonio D'Onofrio[3] and Gerardo Nigro[1]*

[1] Cardiology Unit, Department of Medical Translational Sciences, University of Campania "Luigi Vanvitelli", Naples, Italy, [2] Department of Cardiology, Umberto I Hospital, Nocera Inferiore, Salerno, Italy, [3] Department of Cardiology, Monaldi Hospital, Naples, Italy

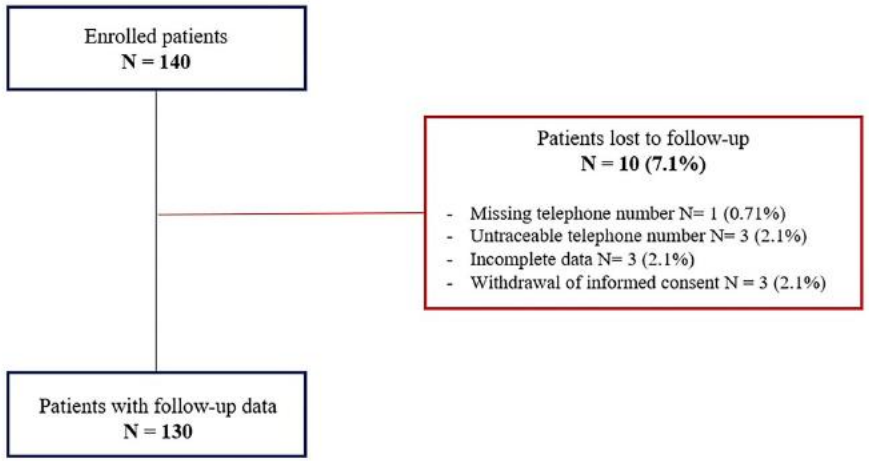


FIGURE 1 | Study of the flowchart.

TABLE 4 | Electrical parameters and clinical events at follow-up.

	Overall population *n: 130*	AF group *n: 61*	No AF group *n: 69*	*P*
Electrical parameters				
R wave amplitude, mV	13.75 ± 5.04	11.8 ± 5.2	10.9 ± 4.8	*0.32*
Ventricular threshold, V	1.2 ± 0.4	0.53 ± 0.45	0.55 ± 0.37	*0.79*
Ventricular impedance, Ohm	716.9 ± 187.4	707.9 ± 168	711 ± 187	*0.92*
Ventricular pacing (%)	40 ± 29	31 ± 16	52 ± 36	*0.002*
Clinical events				
Syncope, *n* (%)	5 (3.8)	2 (3.3)	3 (4.3)	*0.71*
Cardiac hospitalization, *n* (%)	7 (5.4)	3 (4.9)	4 (5.8)	*0.82*
All-cause death, *n* (%)	10 (7.7)	5 (8.2)	5 (7.2)	*0.83*

OUR LEADLESS PACEMAKER EXPERIENCE

FEMORAL APPROACH

CONFIDENTIAL INFORMATION

Outcomes of Micra Leadless Pacemaker Implants in Centers With and Without Cardiac Surgery

Short Title: Leadless Outcomes in non surgical centers

Gianluca Manzo[1], Gabriele Giannola[2], Gerardo Nigro[3], Giulio Zucchelli[4], Antonino Nicosia[5], Pietro Palmisano[6], Luca Bontempi[7], Miguel Viscusi[8], Mattia Liccardo[9], Marcello Piacenti[10], Giuseppe Coppola[11], Mario Volpicelli[12], Giovanni Morani[13], Sem Briongos[14], Saverio Iacopino[15]

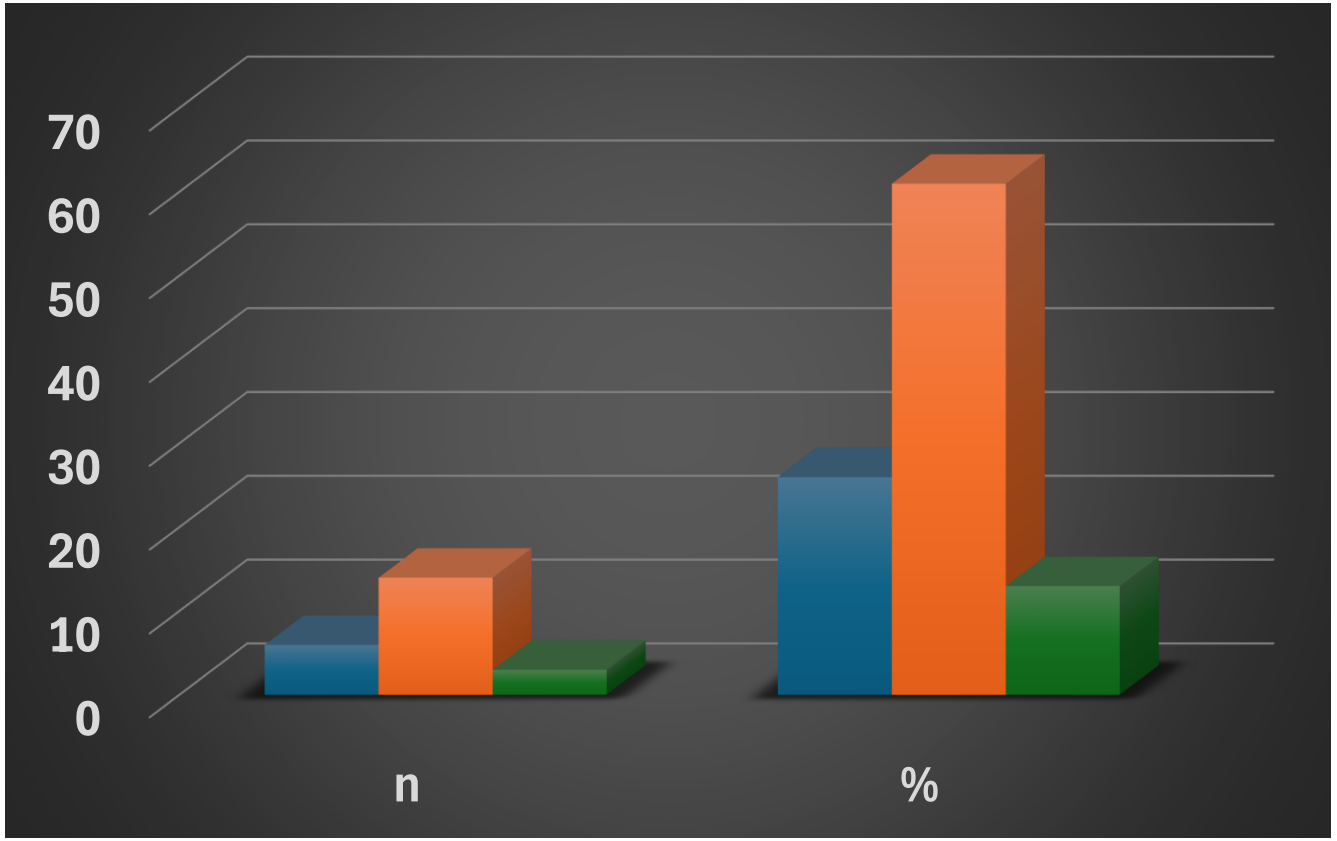
Table 3. Acute procedural complication of the overall patient population and stratified by the two study groups: patients treated in centers with cardiac surgery facilities versus those treated in centers without cardiac surgery

Event	TOTAL (N = 1899)	No CS Group (N = 874)	CS Group (N = 1025)	p-value
At least one acute periprocedural event	**0.6% (12/1899)**	**0.8% (7/874)**	**0.5% (5/1025)**	**0.391**
Septal Perforation	0.1% (1/1899)	0.1% (1/874)	0% (0/1025)	0.279
Pericardial effusion	0.1% (2/1899)	0.2% (2/874)	0% (0/1025)	0.125
Pericardial separation	0.1% (1/1899)	0.1% (1/874)	0% (0/1025)	0.279
Cardiac tamponade	0.1% (1/1899)	0% (0/874)	0.1% (1/1025)	0.356
Femoral Pseudoaneurysm	0.1% (1/1899)	0% (0/874)	0.1% (1/1025)	0.356
Femoral AV fistula	0.1% (2/1899)	0.2% (2/874)	.% (./1025)	0.125
Failure to capture due to High threshold	0.1% (1/1899)	0% (0/874)	0.1% (1/1025)	0.356
Elevated threshold	0.1% (2/1899)	0.1% (1/874)	0.1% (1/1025)	0.910
Device migration	0.1% (1/1899)	0% (0/874)	0.1% (1/1025)	0.356

OUR LEADLESS PACEMAKER EXPERIENCE

JUGULAR APPROACH

Implant Position	n	%
RVOT	6	26
RV mid - septum	14	61
RV apical - septum	3	13

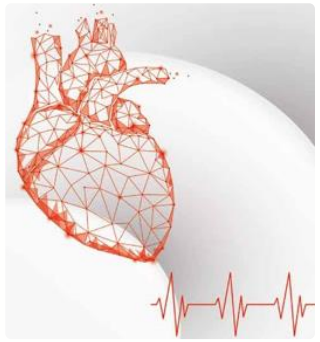


PRIMO CENTRO IN ITALIA

Implant Position	n	%
RVOT	6	26
RV mid - septum	14	61
RV apical - septum	3	13

OUR LEADLESS PACEMAKER EXPERIENCE

JUGULAR APPROACH



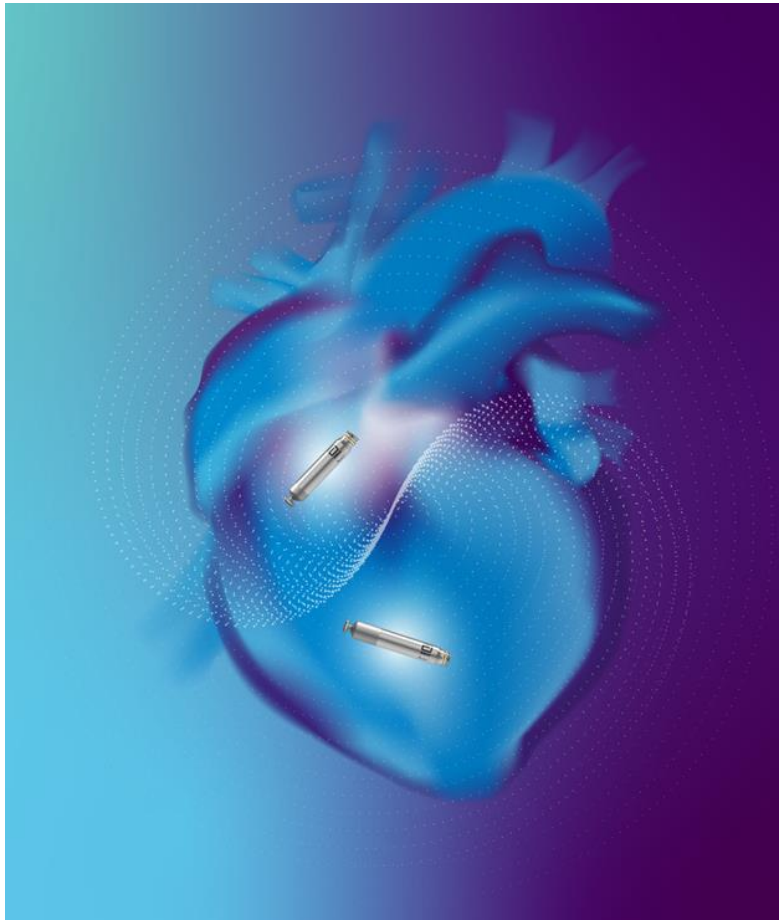
Never Stop Evolving

AVEIR DR

Introducing The World's First Leadless Dual Chamber Pacemaker System[1,2]

- The AVEIR™ DR System features

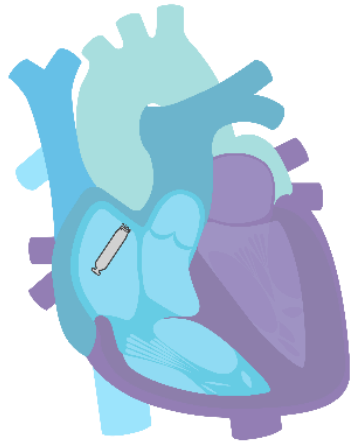
- Two distinct devices
- Sensing and pacing in both the right atrial and right ventricular chambers
- AV synchrony (AVS) made possible through proprietary implant-to-implant (i2i™) communication
- Upgradeable to match your patient's pacing needs today and over time as those needs change



AVEIR™ Leadless Pacemakers can Provide Therapy for all Common Pacemaker Indications[1,2,3]

INDICATIONS FOR USE

AVEIR AR ATRIAL PACEMAKER

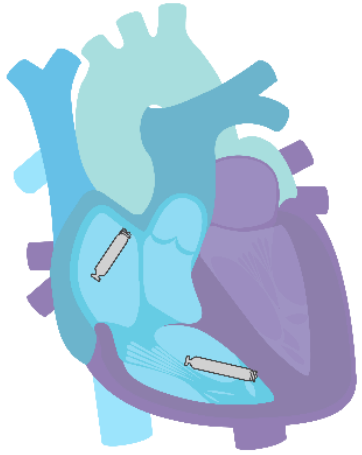


- Sinus node dysfunction and normal AV and intraventricular conduction systems

AVEIR VR VENTRICULAR PACEMAKER

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

AVEIR DR DUAL CHAMBER PACEMAKER SYSTEM



- Sick sinus syndrome
- Chronic, symptomatic 2nd- and 3rd-degree AV block
- Symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out

[1] AVEIR Leadless Pacemakers and Delivery Catheter IFU. ARTEN600307044.
[2] Micra‡ VR2 MC2VR01 IFU
[3] Micra‡ AV2 MC2AVR1 IFU

The World's FIRST and ONLY Atrial Leadless Pacemaker[1]

AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER SYSTEM

AVEIR™ AR Atrial LP

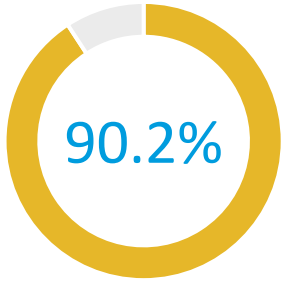
1. Docking button
2. Outer fixation helix
3. Inner helix tip electrode

Length: 32.2 mm **Diameter:** 6.5 mm (19.5 F)

Dual Helix Design for Atrial Therapy

- 1.63 mm inactive outer helix provides primary fixation
- Recessed, inner helix acts as the pacing electrode and provides additional fixation and electrical stability
- Recommended implant site: base of the right atrial appendage

Electrical Performance at 3 Months



Patients with acceptable atrial device pacing capture threshold (≤ 3 V at 0.4 ms) and sensing amplitude (≥ 1 mV)[3]

- 95.2% success rate with modified sensing criteria (≥ 0.5 mV)[4]

[1] AVEIR DR FDA approval and CE Mark Approval.
[2] AVEIR Leadless Pacemakers and Delivery Catheter IFU. ARTEN600307044.
[3] Knops, Reinoud E., et al. "A Dual-Chamber Leadless Pacemaker." New England Journal of Medicine (2023). DOI: 10.1056/NEJMoa2300080
[4] Cantillon, Daniel, et al. (2023, May 19-21). Percutaneous implantation of a dual chamber leadless cardiac pacemaker system with bidirectional communication for atrioventricular synchrony. [Conference presentation]. Heart Rhythm Society 2023, New Orleans, USA.

Ventricular Device

AVEIR™ DR DUAL CHAMBER LEADLESS PACEMAKER SYSTEM

AVEIR™ VR Ventricular LP

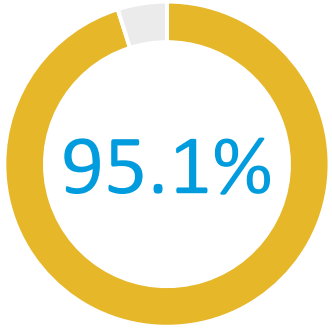
1. Docking button
2. Fixation helix
3. Distal dome tip electrode

Length: 38.0 mm **Diameter:** 6.5 mm (19.5 F)

Single Helix Design for Ventricular Therapy

- 1.63 mm electrically inactive outer helix provides primary fixation
- Electrical mapping prior to fixation
- Recommended RV implant site: low to mid-septum

Ventricular Device Performance from the LEADLESS II-Phase 2 Study at 1 Year



Patients with acceptable ventricular device pacing capture threshold and sensing amplitude[2]

[1] AVEIR Leadless Pacemakers and Delivery Catheter IFU. ARTEN600307044.

[2] 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.2023.01.031.

Trasmissione I2I

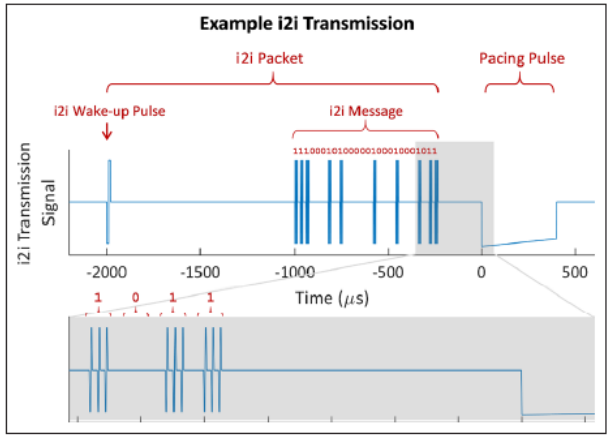


Figure 1. Example implant-to-implant transmission signal before pacing pulse delivery.
Transmission packet includes implant-to-implant (i2i) wake-up pulse preceding the i2i message (**top**). The i2i message is encoded as a binary signal using a series of pulse triplets (close-up, **bottom**).

Table. Automatic Safeguard Modes to Mitigate Loss of i2i Communication

Programmed mode	Automatic safeguard mode		
	RA-to-RV I2I loss	RV-to-RA I2I loss	Bidirectional I2I loss
DDD	*DDI*	*VDD*	*VDI*
DDI	*DDI*	*VDI*	*VDI*
VDD	*VDI*	*VDD*	*VDI*
DOO	*DOO*	*VOO*	*VOO*

i2i indicates implant-to-implant; RA, right atrium; and RV, right ventricle.

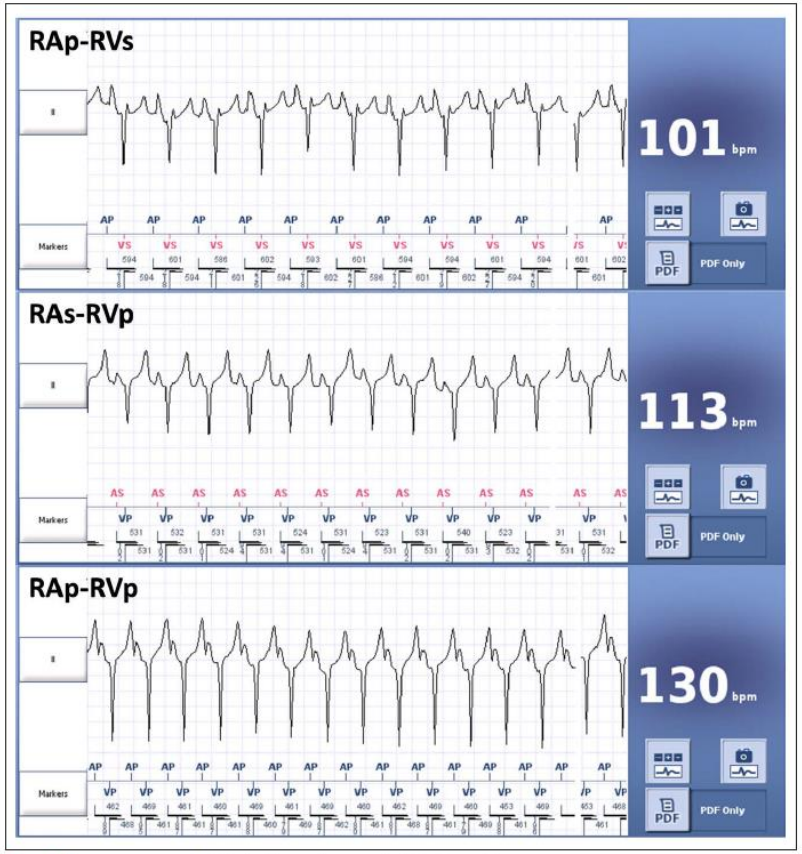
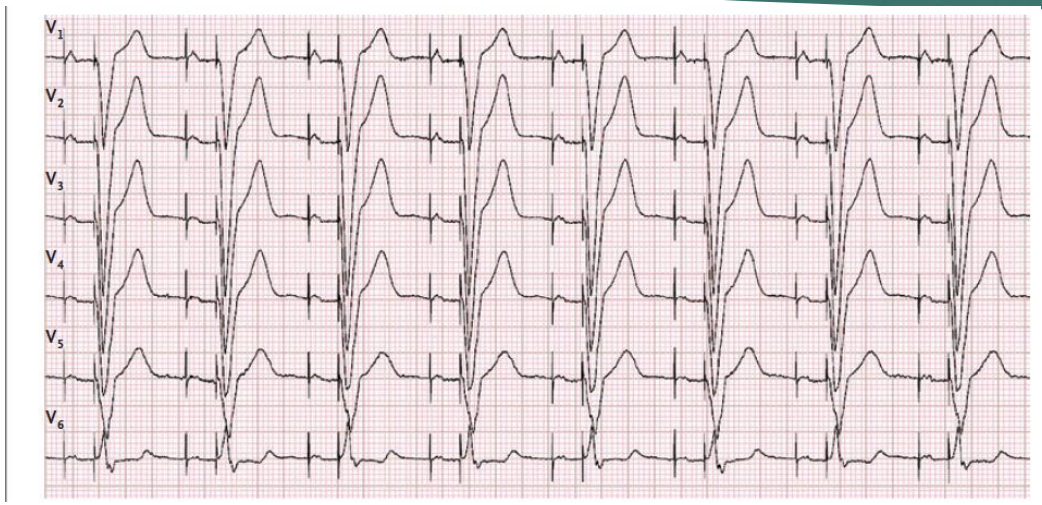
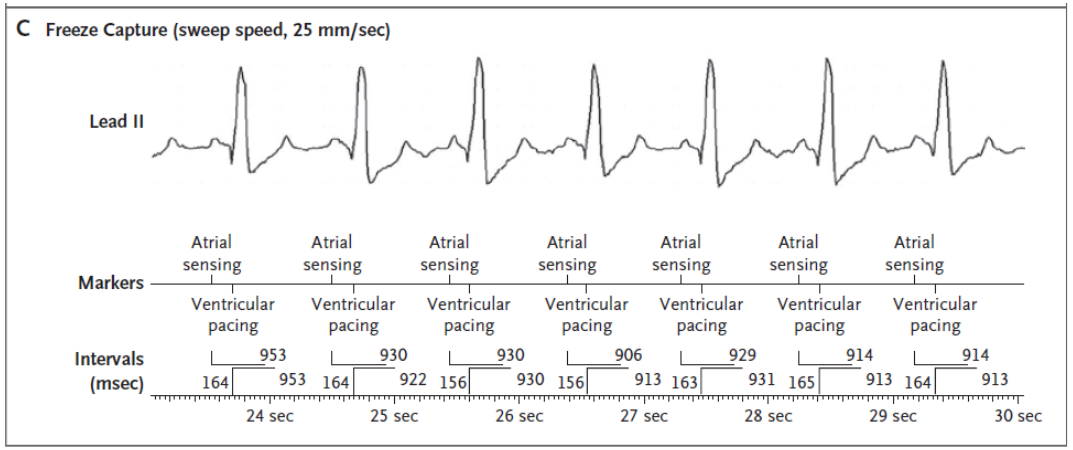
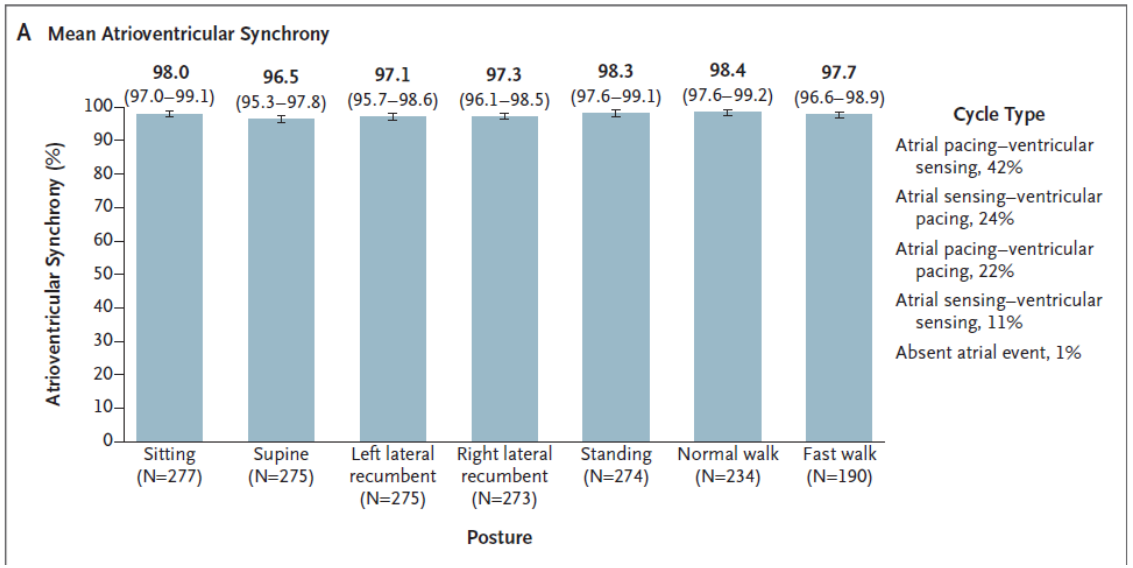


Figure 2. Programmer screenshots illustrating synchronous dual-chamber pacing.
Electrogram signals and markers are shown for right atrial pacing (RAp)–right ventricular sensing (RVs; **top**), RA sensing (RAs)–RV pacing (RVp; **middle**), and RAp-RVp (**bottom**). Pacing rates above 60 bpm were programmed only acutely and are shown here for illustrative purposes only. As indicates atrially-sensed event; and Vp, ventricular-paced event.

Trasmissione I2I

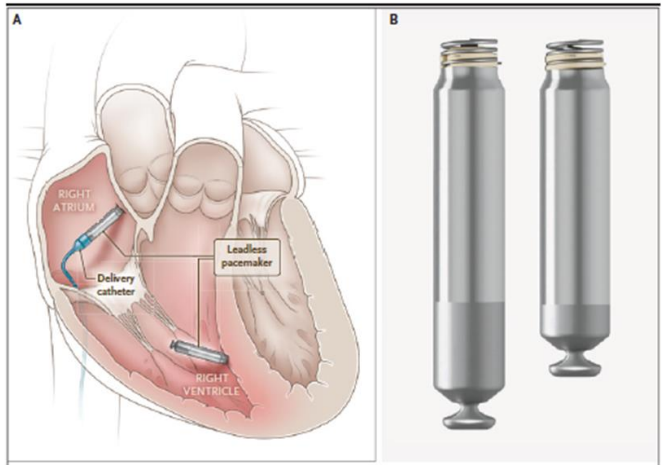






AVEIR DR

Circ Arrhythm Electrophysiol. 2023;16:e012232. DOI: 10.1161/CIRCEP.123.012232



HRS - New Orleans (16th May 2023)

Aveir DR i2i IDE study results:

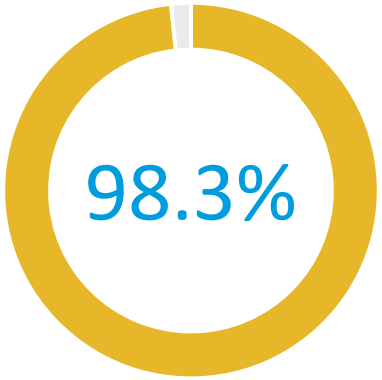
- **300** attempted implants
- **98,3%** successful implants
- Primary efficacy endpoint **90.8%**

(atrial threshold 0.82±0.70 V, and P wave amplitude was 3.58 ±1.88 mV)

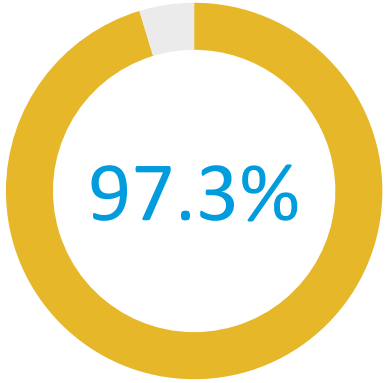
- **AV syncrony efficacy endopoint 98,2%**

AVEIR™ DR i2i™ STUDY Met Its 3-Month Safety and Efficacy Rates as Highlighted in the New England Journal of Medicine[1]

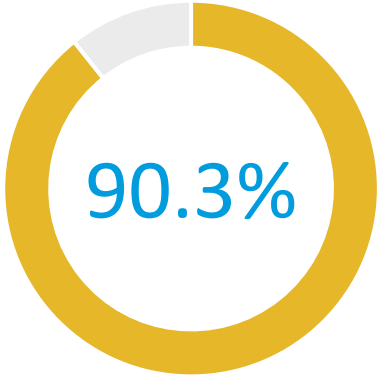
PROVEN CLINICAL EVIDENCE



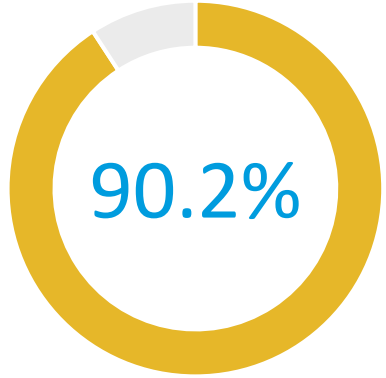
Patients with successful dual chamber procedures



Patients achieved atrioventricular synchrony (AVS) performance endpoint



Patients free from system-related complications*



Patients with acceptable atrial device pacing capture threshold and sensing amplitude

[1] Knops, Reinoud E., et al. "A Dual-Chamber Leadless Pacemaker." New England Journal of Medicine (2023). DOI: 10.1056/NEJMoa2300080

Patient Characteristics[1]

Characteristic	All Subjects (N=300)
Age (Yrs.)	
Mean	69.2 ± 13.5
Range	20-90
Sex, Female	37.7% (113/300)
BMI (kg/m^2)	28.1 ± 5.6 (300/300)
Range	15.1-49.7
Ethnicity	
Hispanic or Latino	3.3% (10/300)
Not Hispanic or Latino	67% (201/300)
Declined/Unable to Disclose	29.7% (89/300)
Race	
White / Caucasian	66.7% (200/300)
Declined or Unable to Disclose	29.7% (89/300)
Black	2% (6/300)
Asian	1.7% (5/300)
American Indian or Alaska Native	0.3% (1/300)

Characteristic	All Subjects (N=300)
Primary Pacemaker Indication	
Sinus Node Dysfunction	63.3% (190/300)
AV Block	33.3% (100/300)
3rd Degree	13.7% (41/300)
Other Conduction Disorder	1.3% (4/300)
Vasovagal (Reflex) Syncope	2% (6/300)
Prior Ablation	20% (60/300)
Tricuspid Valve Disease	
Insufficiency, Prolapse or Regurgitation	24% (72/300)
Repair or Replacement	1% (3/300)
Arrhythmia History	
Ventricular	4.3% (13/300)
Supraventricular (includes AF)	45% (135/300)
Prior Extractions	
Transvenous Lead Extraction	8% (24/300)
Leadless Pacemaker Extraction	0.7% (2/300)

[1] Knops RE, Reddy VY, Ip JE, et al. (2023, Sep 1-3). Safety and Electrical performance of the first dual-chamber leadless pacemaker at 6 months post-implant. [Conference presentation]. Asia Pacific Heart Rhythm Society 2023, Hong Kong.

Procedural Characteristics[1]

Implant Success: Two functioning leadless pacemakers implanted with established i2i™ communication

Implant Success Rate: 295/300 (98.3%)

Characteristic	Implanted Population (N=298)
Procedural time (min.)*	70.9 ± 30.5
Atrial	40.2 ± 22.6
Ventricular	24.0 ± 16.2
Total Fluoroscopic Duration (min.)	18.3 ± 10.7

Characteristic	Implanted Population (N=298)
Atrial Repositioning - % (N)	
None	75.8% (226/298)
Once	13.8% (41/298)
>1 Reposition	10.4% (31/298)
Ventricular Repositioning - % (N)	
None	86.6% (258/298)
One	11.4% (34/298)
>1	2% (6/298)
Final Atrial Placement	
Right atrial appendage (RAA) base	61.1% (182/298)
Mid to deep RAA	22.8% (68/298)
RA Lateral Wall	10.7% (32/298)
RA Posterior Wall or RA Septum	2.3% (7/298)
Other	3.0% (9/298)
Final Ventricular Placement	
RV Apical Septum	55.4% (165/298)
RV Mid Septum	33.9% (101/298)
RV Apex	7.0% (21/298)
Other	3.7% (11/298)

*First Delivery Catheter Insertion to Last Delivery Catheter Removal.

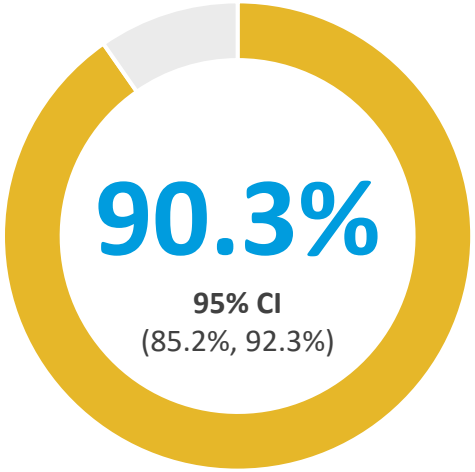
[1] Knops RE, Reddy VY, Ip JE, et al. (2023, Sep 1-3). Safety and Electrical performance of the first dual-chamber leadless pacemaker at 6 months post-implant. [Conference presentation]. Asia Pacific Heart Rhythm Society 2023, Hong Kong.

Key Complications at 3-Month Follow-Up[1]

The inclusion of arrhythmias as a safety end point increased the overall incidence of complications as compared with other studies of leadless pacemakers, which excluded arrhythmias from the end point.

▶ PROVEN CLINICAL EVIDENCE

Key Device or Procedure Related SADE's through 3-months post implant		
Event	N (patients)	Event Rate (%)
Cardiac Arrhythmia	**10**	**3.3%**
Atrial Fibrillation	9	3.0%
Transient Complete AV Block	1	0.3%
Intraprocedural Dislodgements	**5**	**1.7%**
Due to Inadequate Fixation	4	1.3%
Due to Mechanical Dislodgement	1	0.3%
Post-Procedural Dislodgements	**5**	**1.7%**
Urinary Retention	**3**	**1.0%**
Pericardial Effusion	**2**	**0.7%**
Percutaneous Pericardiocentesis	1	0.3%
Managed conservatively	1	0.3%

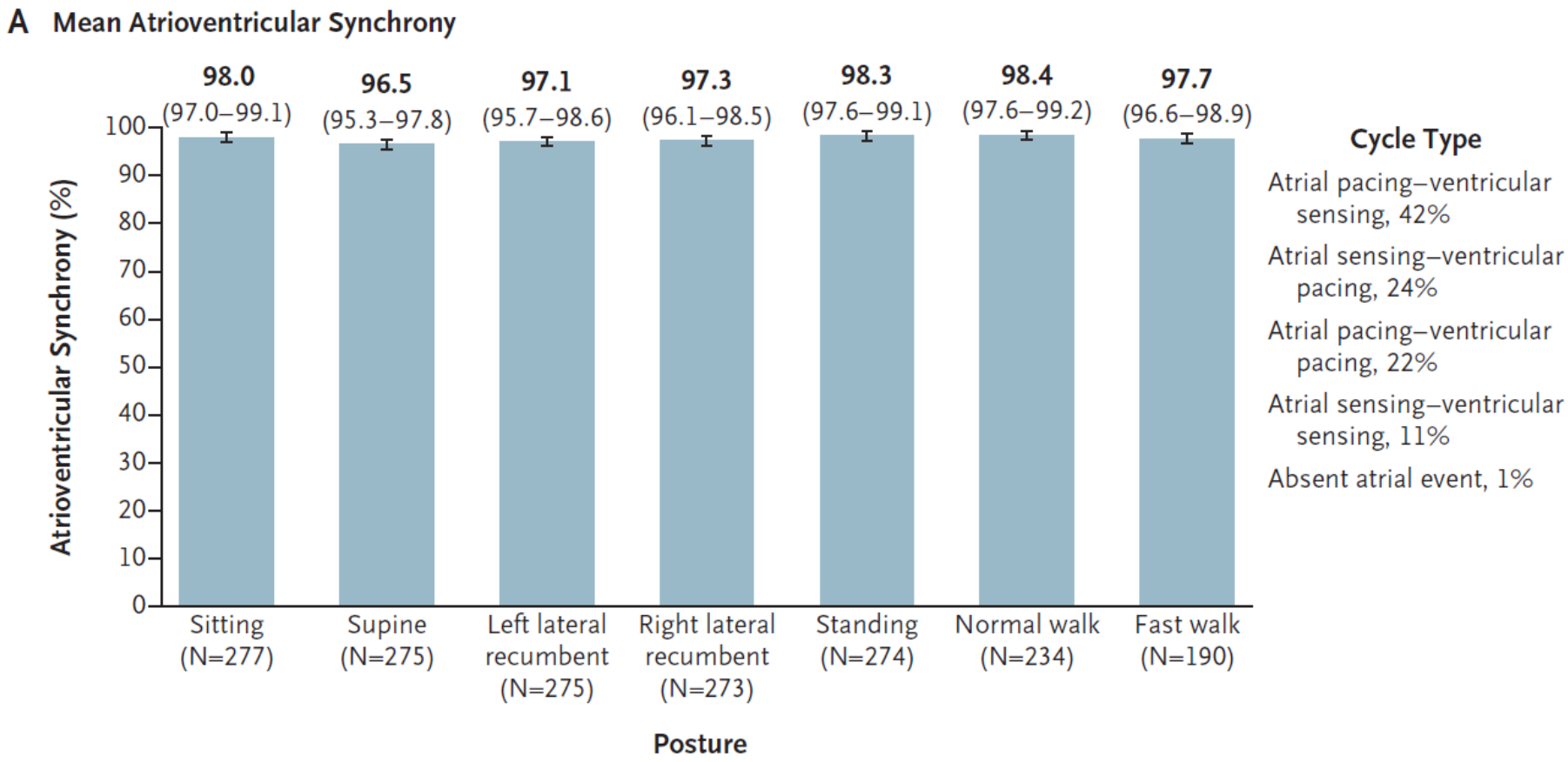


Patients free from system-related complications at 3 months

[1] Knops, Reinoud E., et al. "A Dual-Chamber Leadless Pacemaker." New England Journal of Medicine (2023). DOI: 10.1056/NEJMoa2300080

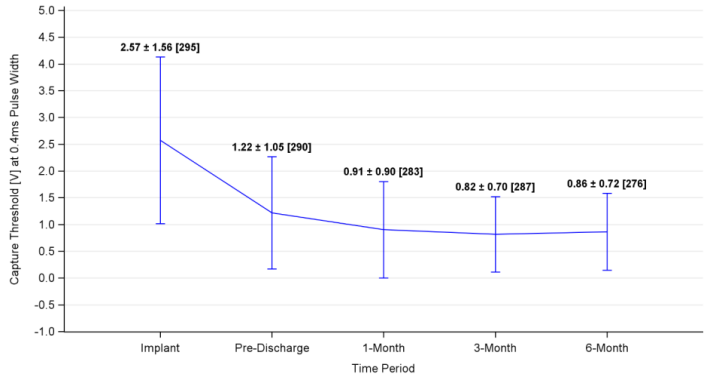
Excellent AV Synchrony Observed for Multiple Postures and Gaits at 3 Months[1]

- PROVEN CLINICAL EVIDENCE

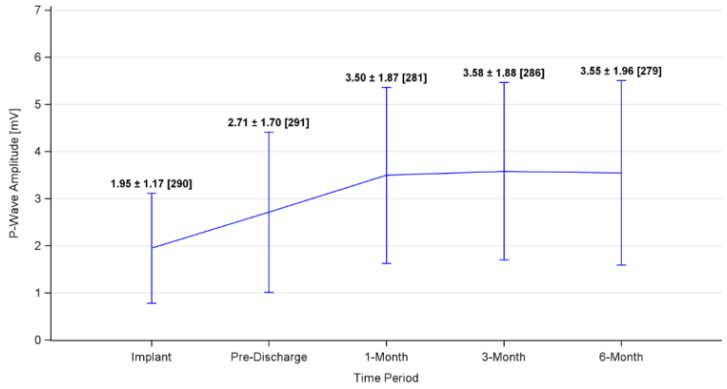


6-Month Atrial Electrical Performance[1]

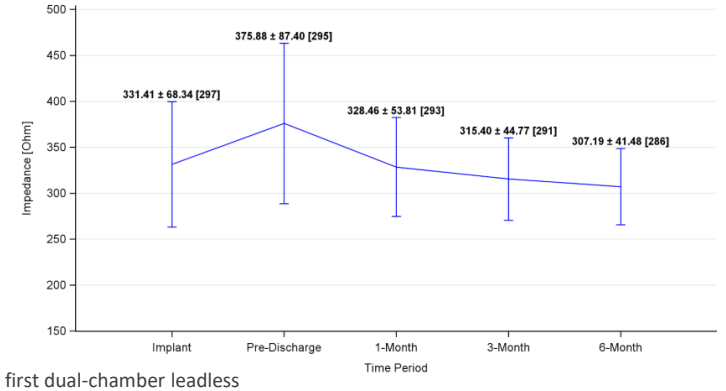
Atrial LP Capture Threshold



Atrial LP P-Wave Amplitude



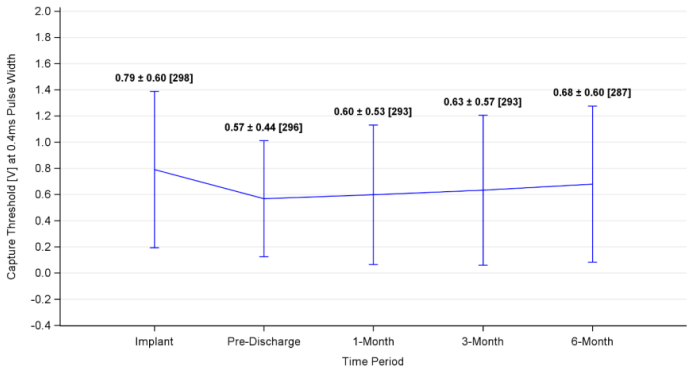
Atrial LP Impedance



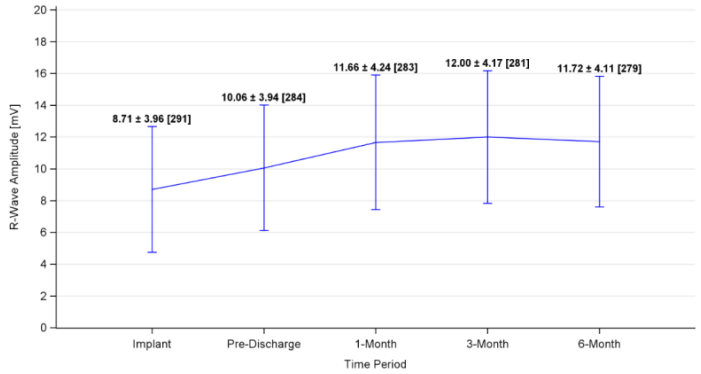
[1] Knops RE, Reddy VY, Ip JE, et al. (2023, Sep 1-3). Safety and Electrical performance of the first dual-chamber leadless pacemaker at 6 months post-implant. [Conference presentation]. Asia Pacific Heart Rhythm Society 2023, Hong Kong.

6-Month Ventricular Electrical Performance[1]

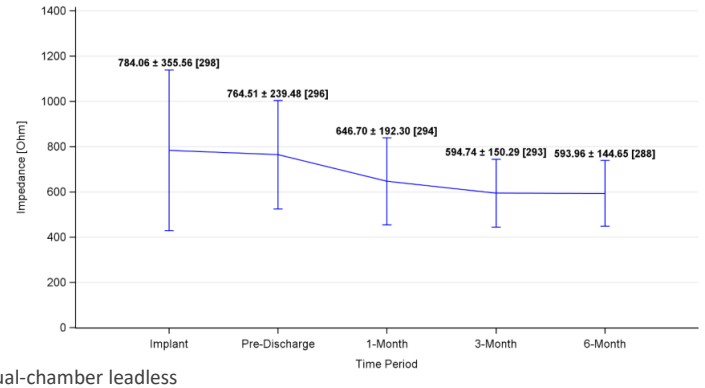
Ventricular LP Capture Threshold



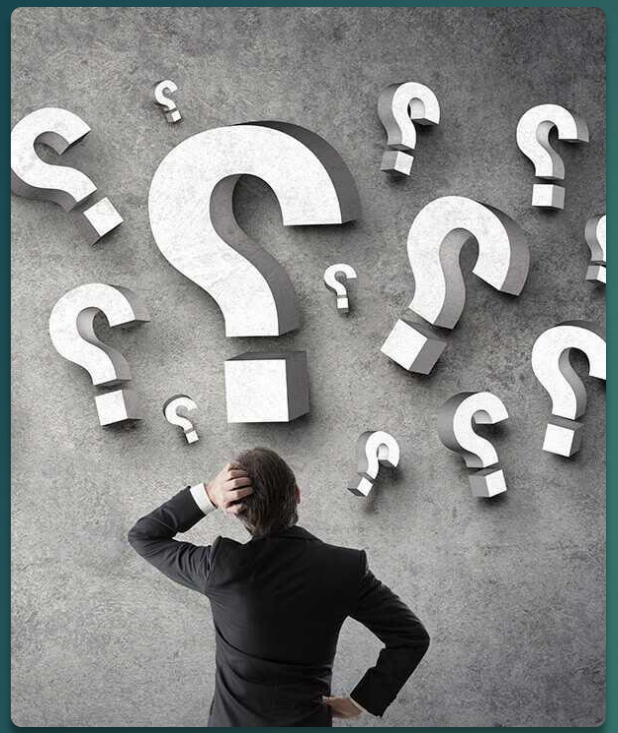
Ventricular LP R-Wave Amplitude



Ventricular LP Impedance



[1] Knops RE, Reddy VY, Ip JE, et al. (2023, Sep 1-3). Safety and Electrical performance of the first dual-chamber leadless pacemaker at 6 months post-implant. [Conference presentation]. Asia Pacific Heart Rhythm Society 2023, Hong Kong.



GRAZIE

Titolo