



# ELECTRA

4-5 DÉCEMBRE 2025

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pratiques de rythmologie  
& de stimulation cardiaque

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## *Le futur de la CRT « All leadless CRT »*

*Pascal Defaye  
Décembre 2025*



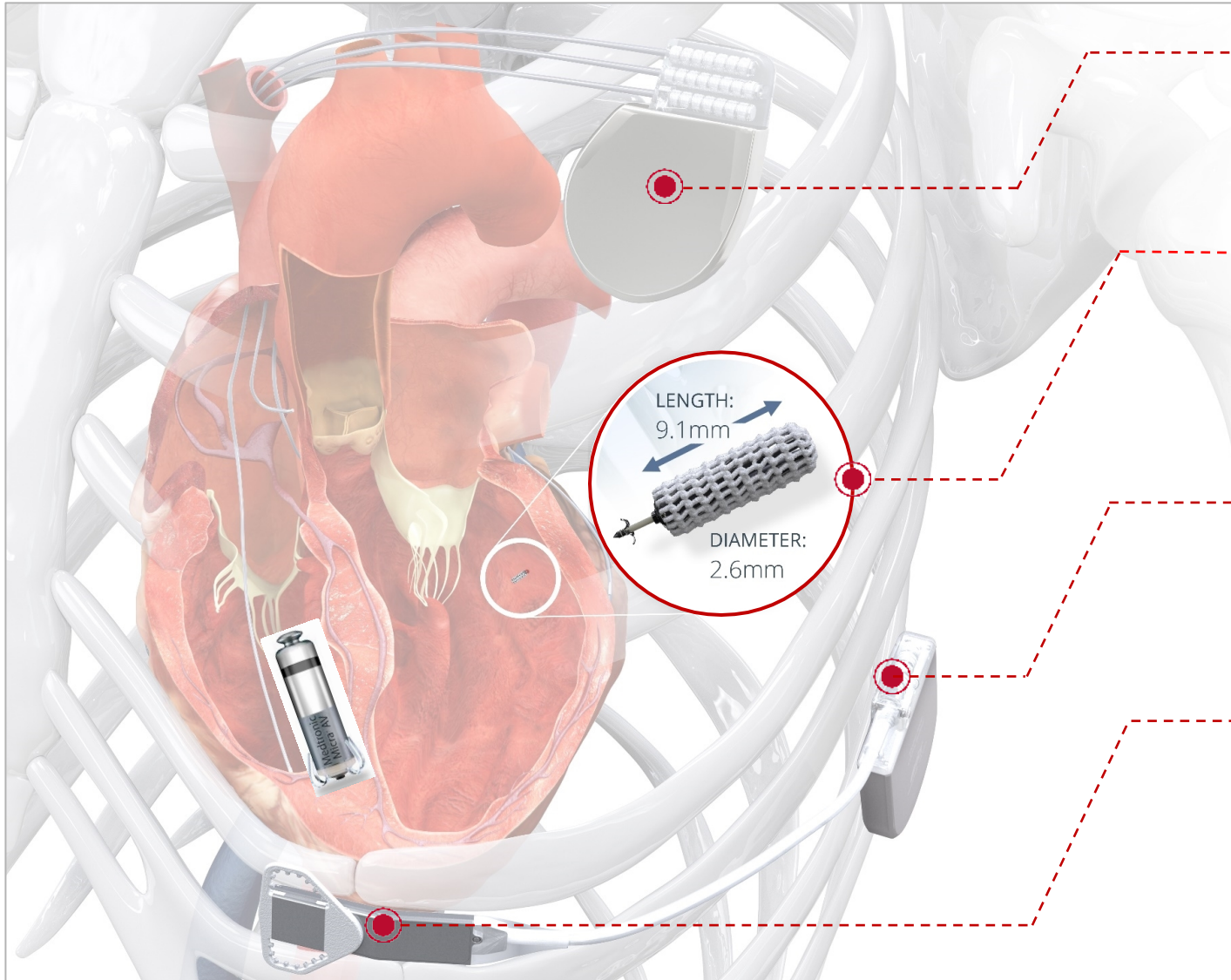
# Leadless Pacemakers

- The use of leadless pacemakers continues to expand.
- 1/3 of all pacemakers/University Hospital Grenoble Alpes (180/550 PM)
- 2022 : first implantation of Aveir DR leadless PM  
2024 : commercial launch Europe and US  
➔ usefulness of “All leadless CRT”
- Possibility of association between :
  - Micra VR/ Micra AV
  - Aveir VR/DR /Aveir AR??with **WISE-CRT**
- These patients will also develop pacing induced heart failure and require upgrade to CRT



Abbott  
Aveir DR

# The WiSE CRT System – system components



## CO-IMPLANT DEVICE

Leadless pacemaker VVI or DDD (Micra/ Micra AV/ Aveir VVI or DDD)

## RECEIVER ELECTRODE

Implanted on the endocardium, the Receiver Electrode converts ultrasound energy into electrical energy to pace the left ventricle.

## BATTERY

Implanted subcutaneously on the left mid axillary line, powers the Transmitter.

## TRANSMITTER

Phased array ultrasound transmitter is implanted sub-muscular over a cardiac echo window. Synchronizes with an RV pacing pulse to transmit ultrasound energy to the Receiver Electrode to provide Bi-V endocardial pacing.

# How it Works

1

## DETECT

Transmitter **detects** the RV pacing pulse from the co-implant device.

2

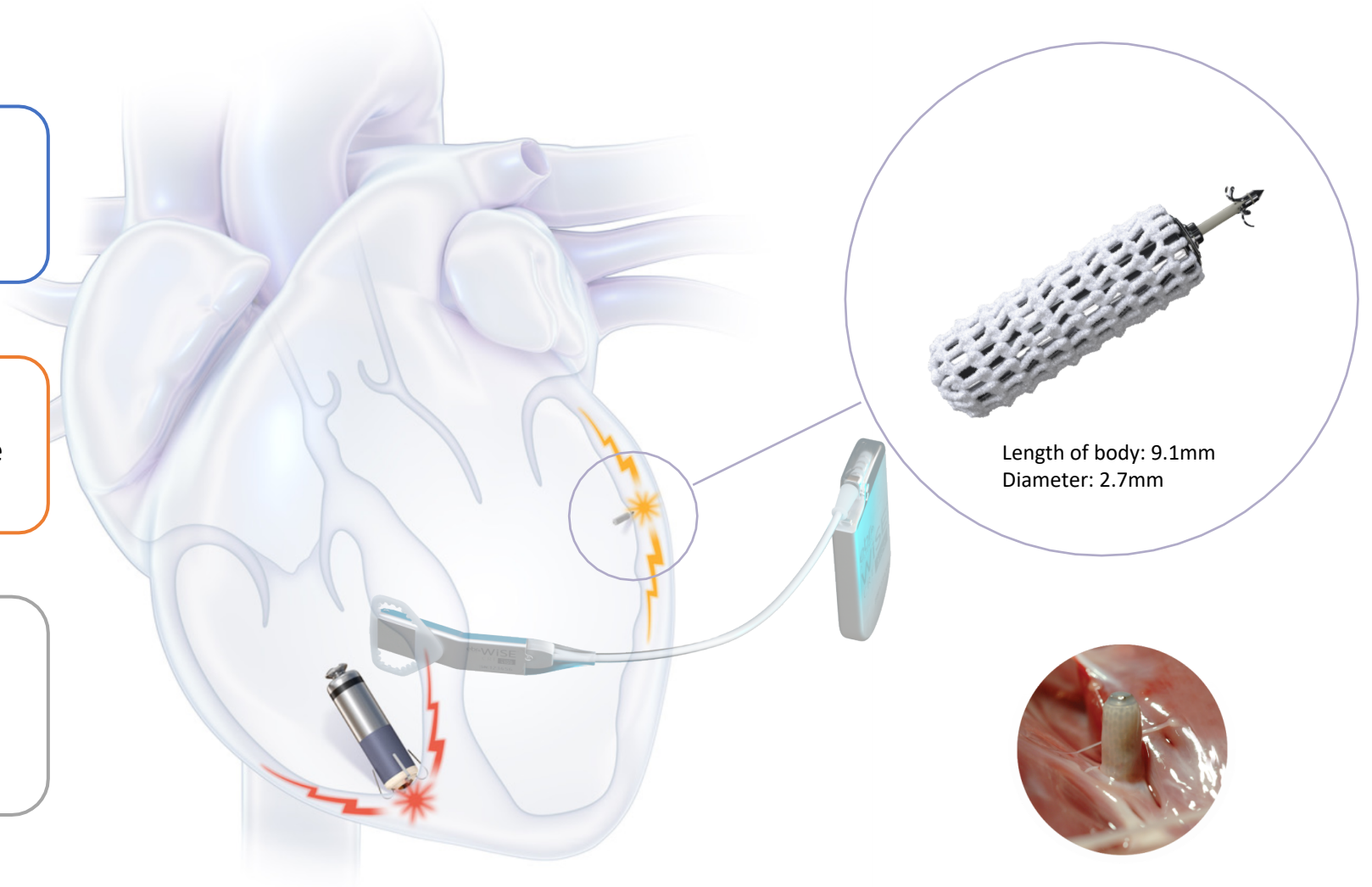
## TRANSMIT

Transmitter **transmits** ultrasound energy to the Electrode.

3

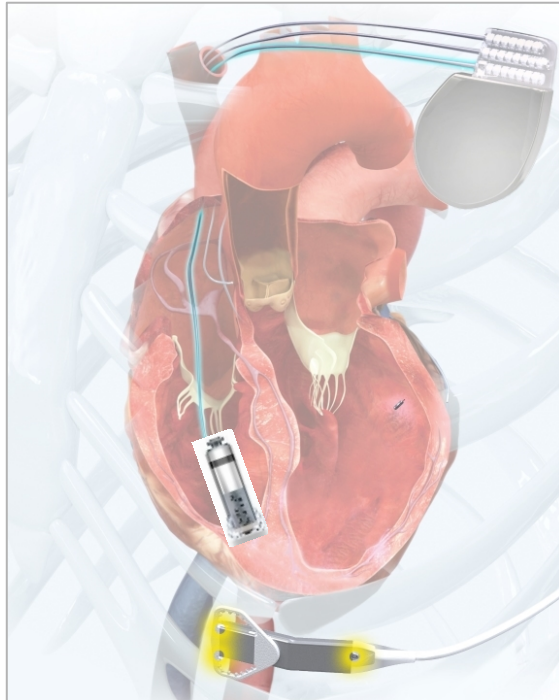
## PACE

The Electrode converts ultrasound energy into an electrical **pacing** pulse causing the heart to beat synchronously.

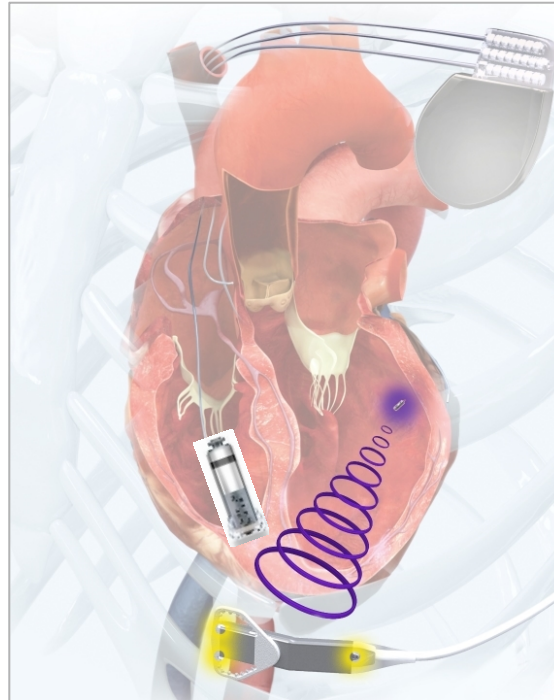


# *The WiSE CRT System – how it works*

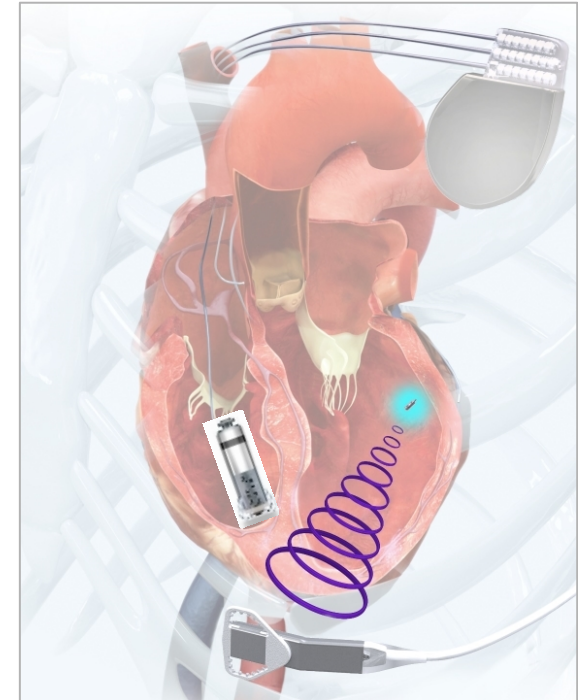
**1) RV pacing stimulus of the leadless PM detected**



**2) Location pulses find WiSE Electrode**



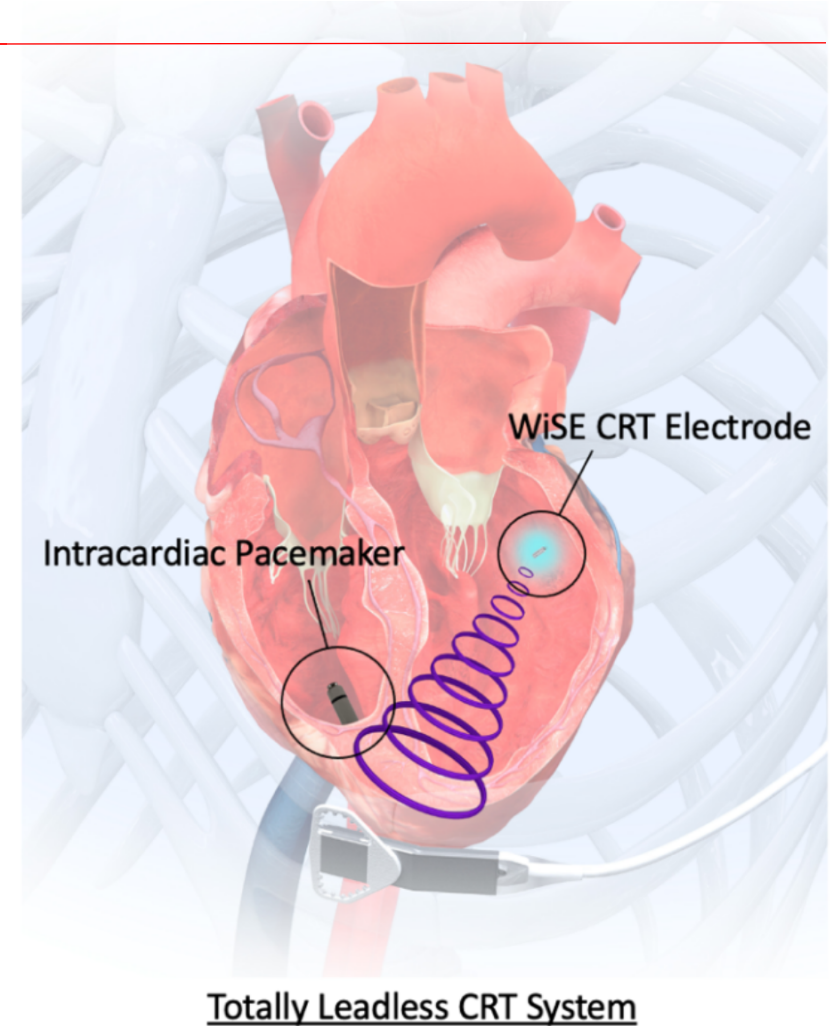
**3) Ultrasound pulse converted to electrical energy**



***...all within 2-5 msec***

# Totally leadless CRT

***The WiSE CRT System is the only means to upgrade an existing leadless pacemaker to CRT, without replacing it with a conventional lead-based system***



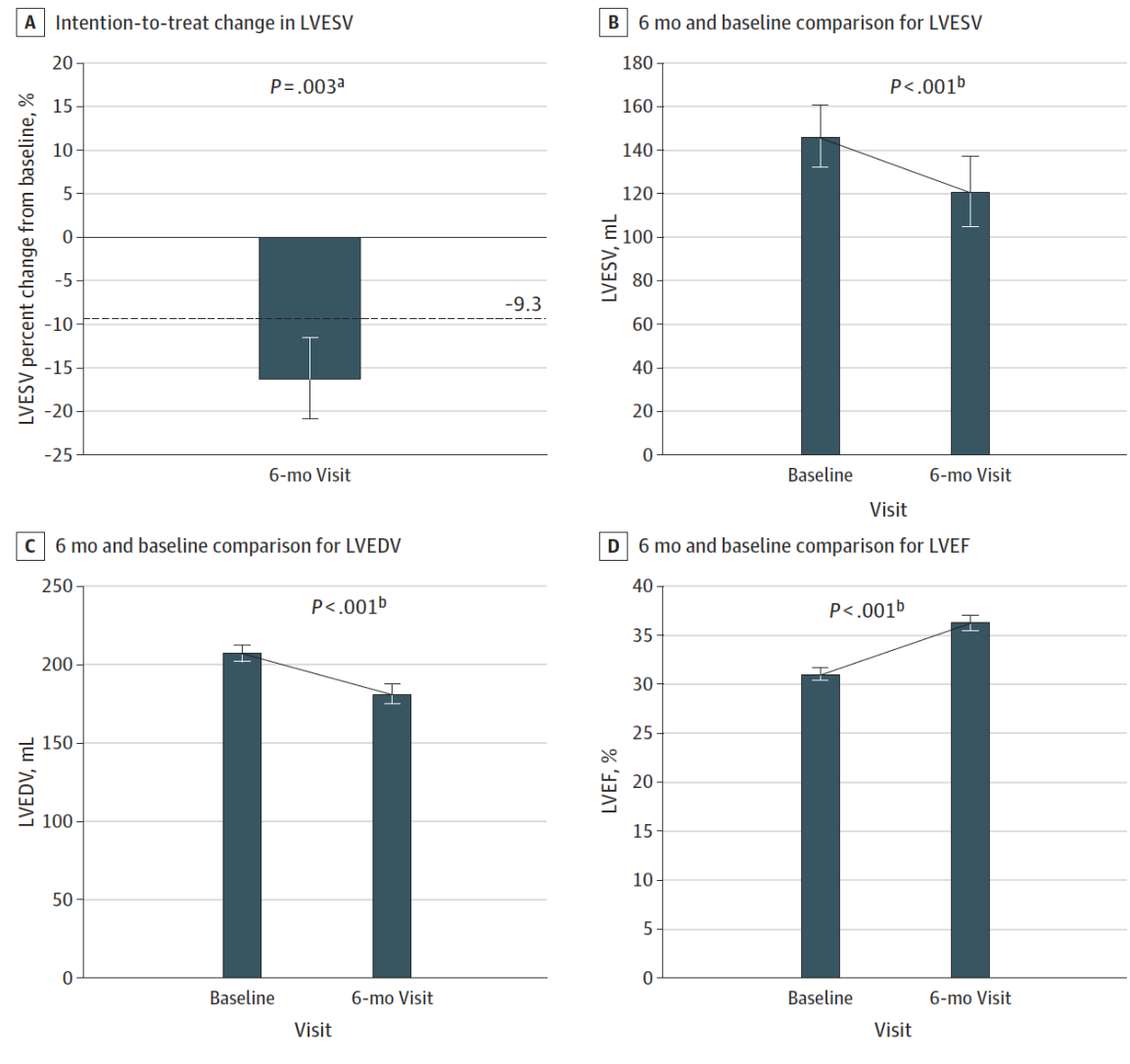
# Leadless Ultrasound-Based Cardiac Resynchronization System in Heart Failure

Jagmeet P. Singh, MD, DPhil; Christopher A. Rinaldi, MBBS; Prashanthan Sanders, MBBS, PhD; Spencer H. Kubo, MD; Simon James, MD; Imran K. Niazi, MD; Timothy Betts, MBChB; Christian Butter, MD; Toshimasa Okabe, MD; Ryan Cunnane, MD; Emad Aziz, MD; Mauro Biffi, MD; Amir Zaidi, MD; Jeffrey Alison, MD; Pascal Defaye, MD, FEHRA; Angelo Aurrichio, MD, PhD; Michael R. Gold, MD, PhD; JoAnn Lindenfeld, MD; Tyson Rogers, MS; Mary Norine Walsh, MD; for the SOLVE-CRT Investigators

**Table 2. Summary of Type I Complications**

Type I complications <sup>a</sup>	No. of patients (%) [No. of events]
Type I	35 (19.1) [43]
Study device system event	12 (6.6) [12]
Electrode not anchored	7 (3.8)
No biventricular capture	3 (1.6)
Transmitter revision	1 (0.5)
Ventricular tachycardia	1 (0.5)
Vascular event	5 (2.7) [5]
Groin hematoma	2 (1.1)
Ischemic leg	1 (0.5)
Retroperitoneal bleed	2 (1.1)
Stroke and other thromboembolic events (eg, TIA)	3 (1.6) [3]
Cardiac perforation	7 (3.8) [7]
Surgically repaired	4 (2.2) [4]
Pericardiocentesis	3 (1.6) [3]
Pocket events	12 (6.6) [15]
Hematoma, conservative treatment	3 (1.6)
Hematoma requiring transfusion	1 (0.5)
Infection	4 (2.2)
Transmitter revision, uneventful	1 (0.5)
Transmitter revision, pneumothorax	1 (0.5)
Battery revision due to erosion	2 (1.1)
Other (anemia postoperative)	1 (0.5) [1]

**Figure 3. Percent Change in Left Ventricular End Systolic Volume (LVESV) at 6 Months vs Performance Goal and LVESV, Left Ventricular End Diastolic Volume (LVEDV), and Left Ventricular Ejection Fraction (LVEF) Baseline vs 6-Month Follow-Up**



# Previous Clinical Experience with Totally Leadless CRT

## Leadless Cardiac Resynchronization Therapy Implantation:

Experience at Naples Community Hospital (NCH) Healthcare System

The WiSE CRT System provides leadless, LV endocardial pacing for patients who would benefit from CRT.

Interview by Jodie Elrod

## Successful implementation of a totally leadless biventricular pacing approach



Moritoshi Funasako, MD, PhD,\* Petr Neuzil, MD, PhD,\* Libor Dujka, MD,\* Jan Petru, MD,\* Lucie Sediva, MD, PhD,\* Jaroslav Simon, MD,\* Tobias Hauser, MSc,† Jiri Baroch, MSc,\* Vivek Y. Reddy, MD\*‡

From the \*Cardiology Department, Na Homolce Hospital, Prague, Czech Republic, †EBR Systems Inc, Sunnyvale, California, and ‡The Helmsley Electrophysiology Center, Mount Sinai School of Medicine, New York, New York.

JACC: CLINICAL ELECTROPHYSIOLOGY  
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### IMAGES IN ELECTROPHYSIOLOGY

## Completely Leadless Cardiac Resynchronization Defibrillator System



Baldeep S. Sidhu, BM,<sup>a,b</sup> Justin Gould, MBBS, PhD,<sup>a,b</sup> Bradley Porter, MBChB, PhD,<sup>a,b</sup> Mark Elliott, MBBS,<sup>a,b</sup> Vishal Mehta, MBBS,<sup>a,b</sup> Steven Niederer, DPM,<sup>a</sup> Christopher A. Rinaldi, MD<sup>a,b</sup>

ESC European Society of Cardiology  
Europace (2020) 00, 1–8  
doi:10.1093/europace/ea342

CLINICAL RESEARCH

## European experience with a first totally leadless cardiac resynchronization therapy pacemaker system

Adrien Carabelli<sup>1</sup>, Mariem Jabeur<sup>1</sup>, Peggy Jacq<sup>1</sup>, Christopher Aldo Rinaldi<sup>2</sup>, Christophe Leclercq<sup>3</sup>, Giovanni Rovaris<sup>4</sup>, Martin Arnold<sup>5</sup>, Sandrine Venier<sup>1</sup>, Petr Neuzil<sup>6</sup>, and Pascal Defaye<sup>1\*</sup>

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DOI: 10.1111/jace.13750

PACE WILEY

### CASE REPORT

## First-in-man fully leadless transvenous CRT-P with a transeptal implant of WiSE-CRT<sup>®</sup> system and Micra<sup>®</sup> PM

Elisabetta Montemerlo MD<sup>1</sup> | Mattia Pozzi MD | Sergio De Ceglia MD | Francesca Santini MD | Elena Piazzi MD | Giovanni Rovaris MD

Cardiology and Electrophysiology Unit, San Gerardo Hospital, Monza, Italy

**Abstract**  
We describe the world's first fully leadless cardiac resynchronization therapy pacemaker implant with transeptal approach, in a patient with pacemaker dependency, atrial fibrillation, ischemic hypokinetic cardiomyopathy, and a history of pocket infections. After lead extraction, we implanted a Micra Transcatheter Pacing System<sup>®</sup> (Medtronic, Minneapolis, MN, USA) as the sole right ventricular pacemaker, and the WiSECRT system (EBR Systems, Sunnyvale, CA, USA) to provide biventricular pacing. We performed the WiSECRT implant procedure using the transeptal approach given the presence of a prosthetic aortic mechanical valve, achieving satisfactory periprocedural results.

**KEYWORDS**  
CRT, leadless, Micra, wireless, wise

## Feasibility of totally leadless left bundle branch area pacing via a left endocardial pacing electrode in patients with heart failure: A 3-case series



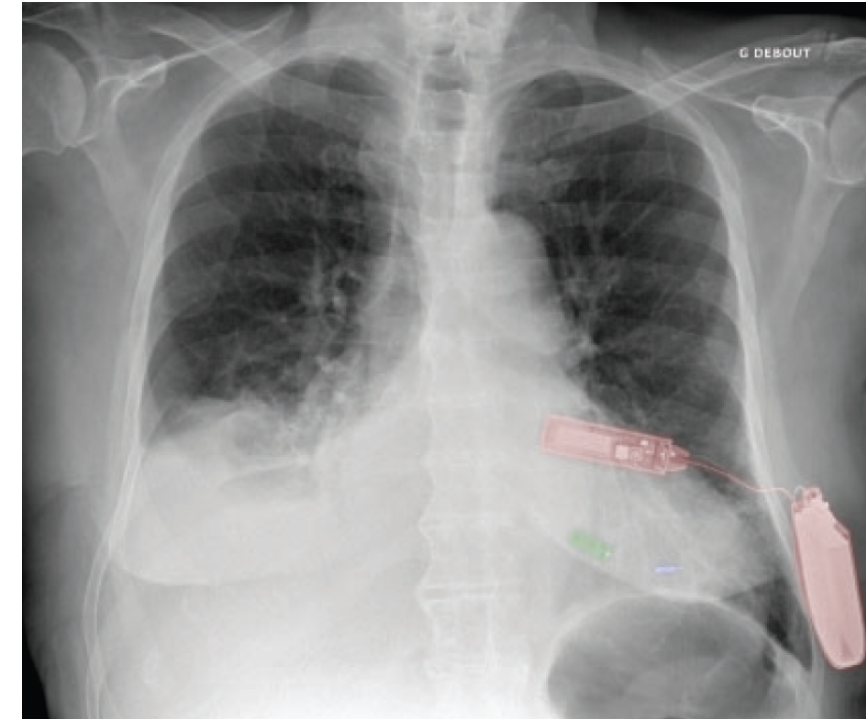
Elodie Deschamps, MD, Yann Lacombe, MSc, Sandrine Venier, MD, Adrien Carabelli, MD, Peggy Jacq, MD, Pascal Defaye, MD

(Heart Rhythm Case Reports 2025;11:1120–1125)

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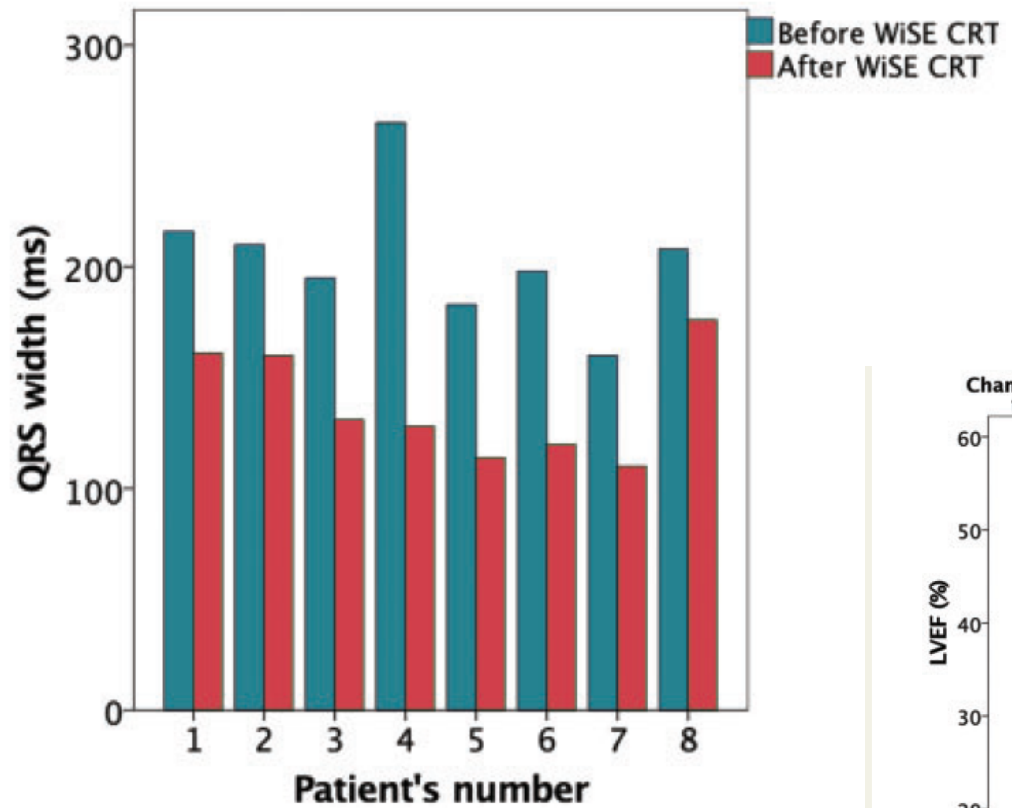
Patient no.	Site	Sex	Age	Comorbidities	Cardiomyopathy	NYHA	LVEF%	Cardiovascular meds	Pre-procedure rhythm	Indication for WiSE	Pre-procedure %RV paced	Pre-procedure paced QRS duration (mS)
1	Erlangen Germany	M	81	Aortic, mitral and tricuspid valve disease; hypertension	Ischaemic	3	20.0	Bisoprolol, ramipril, spironolactone, torasemid, atorvastatin, phenprocoumon	AF	Upgrade	100	183
2	Erlangen Germany	M	77	Mitral valve disease (mitracip); hypertension; PVD; diabetes; renal failure grade III	Non-ischaemic	3	30.0	Rivaroxaban, carvedilol, torasemid, ramipril, simvastatin, eplerenon	AF	Upgrade	50.4	195
3	Na Homolce Czech Republic	M	70	Hypertension; diabetes	Non-ischaemic	2	33.0	Metoprolol, candesartan, digoxin, eplerenon, furosemid, amlodipin, rivaroxaban	AF	Upgrade	99.7	198
4	Na Homolce Czech Republic	F	77	Hypertension; renal failure Grade I	Non-ischaemic	2	43.0	Bisoprolol, digoxin, furosemide, dabigatran, rilmenidin, spironolacton	AF	Upgrade	55	160
5	Rennes France	M	81	Hypertension, diabetes, previous MI, PVD, COPD	Ischaemic	2	26.0	Furosemide, atorvastatin, ezetimib, spironolactone, rivaroxaban	AF	Infection	100	216
6	Grenoble France	M	77	Hypertension, renal failure Grade III; diabetes	Non-ischaemic	3	20	Bisoprolol, apixaban, spironolactone, furosemid	AF	Upgrade	100	208
7	San Gerardo Italy	M	82	Mechanical aortic valve; mitral valvuoplasty; diabetes	Ischaemic	N/A	26	Furosemide, canrenone, bisoprolol, coumadin, digoxin, losartan, trinitrine	AF	Infection	100	265
8	St. Thomas UK	M	63	Previous MI; renal failure Grade III; diabetes	Ischaemic	3	27	Apixaban, atorvastatin, bumetanide, bisoprolol, eplerenone	AF	Infection	77	210



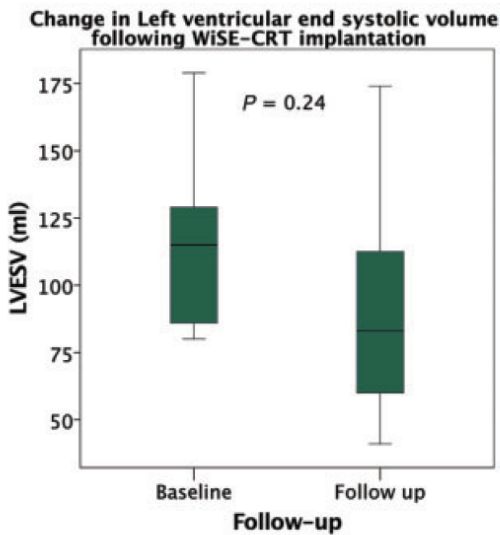
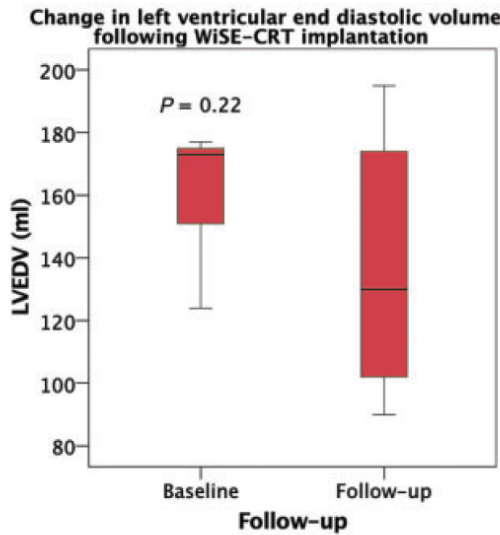
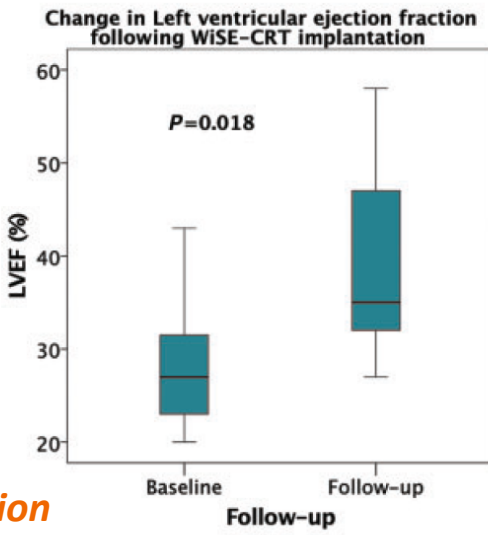
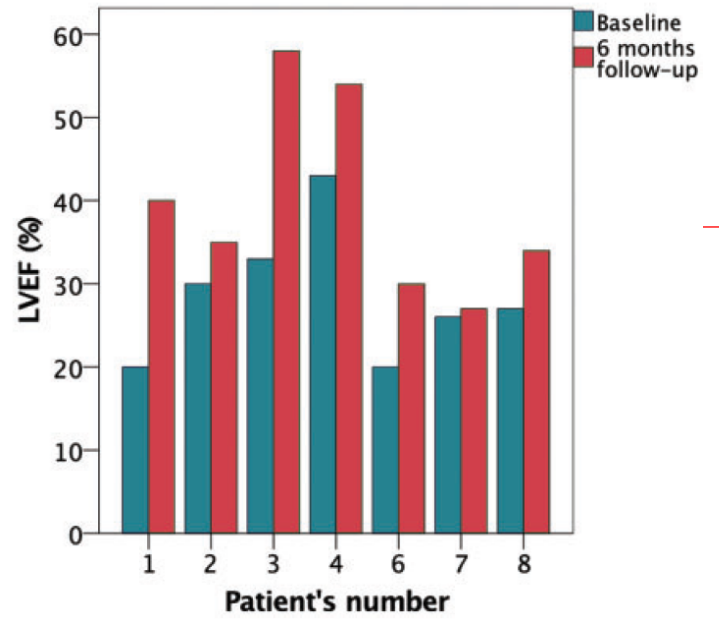
## Baseline patient characteristics

# European experience with a first totally leadless cardiac resynchronization therapy pacemaker system

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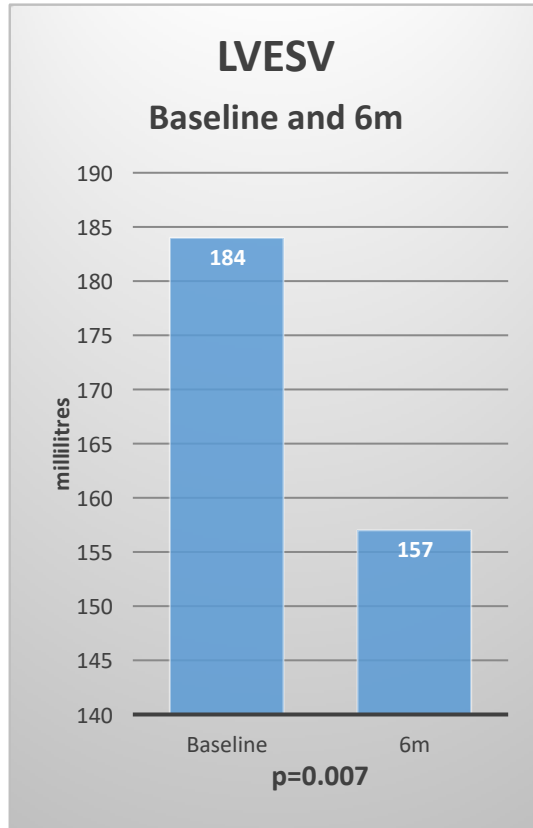


*Individual changes in QRS width from baseline to WiSE-CRT implantation*

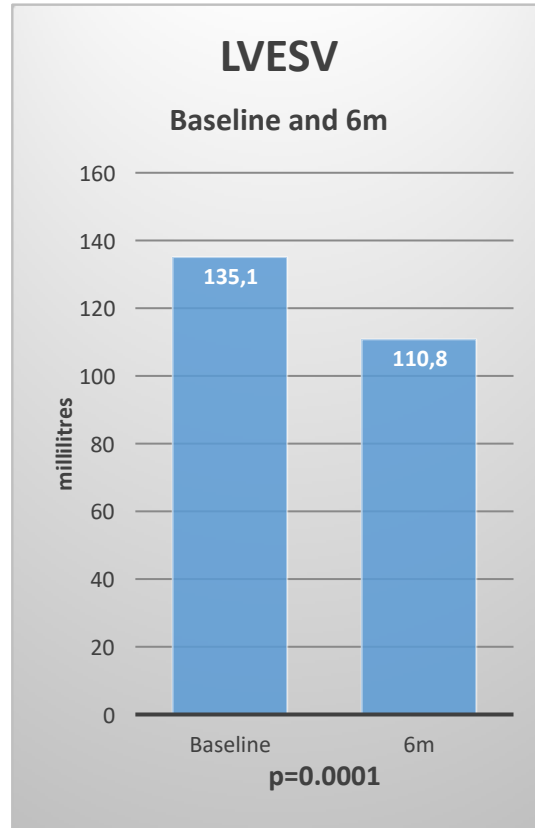


# WiSE Clinical Results

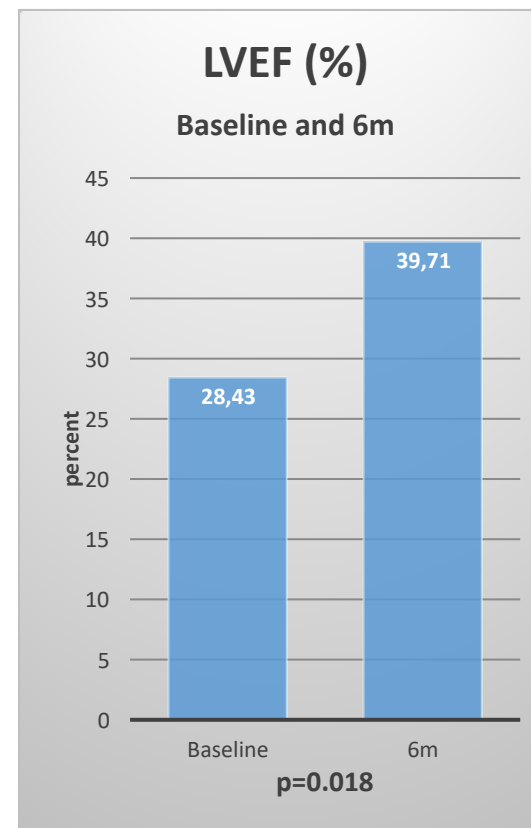
## SELECT-LV<sup>1</sup>



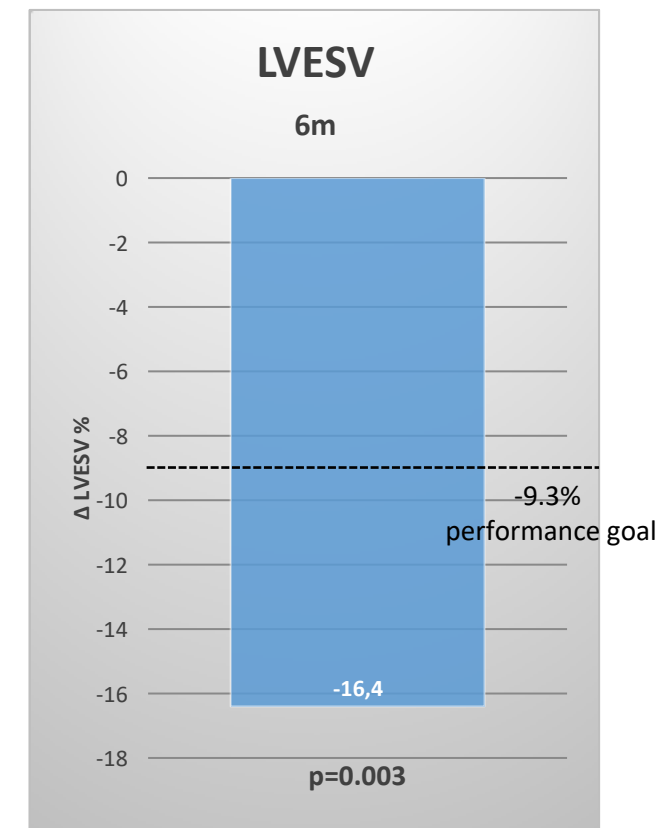
## EU REGISTRY<sup>2</sup>



## TOTALLY LEADLESS CRT<sup>3</sup>



## SOLVE-CRT<sup>4</sup>



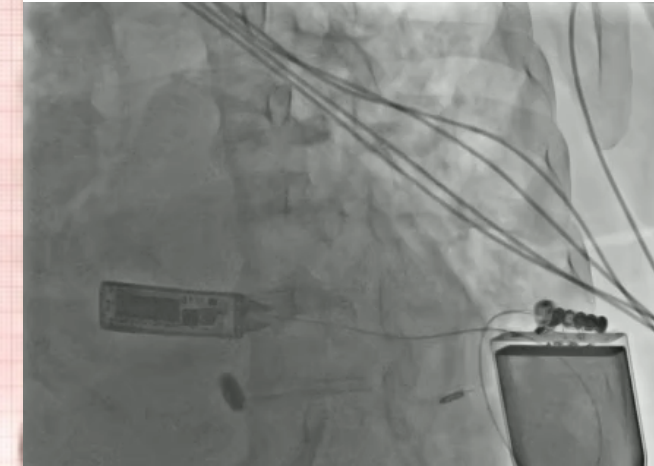
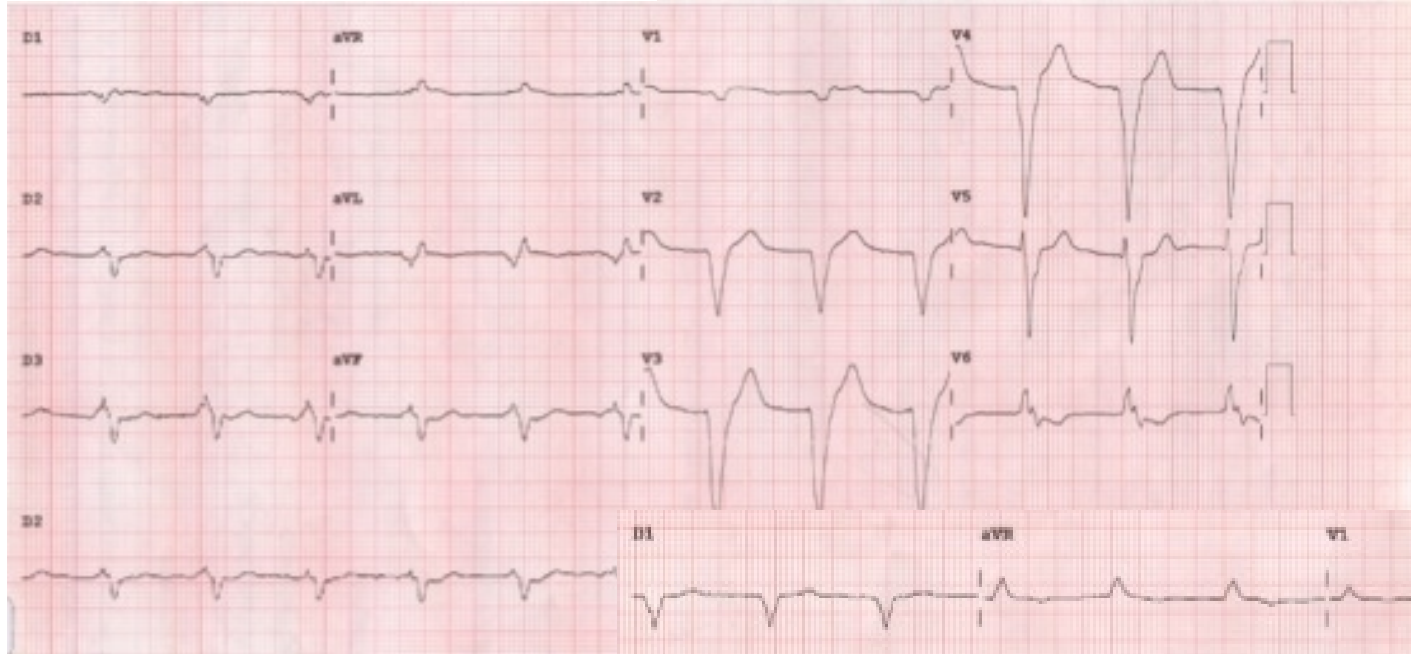
1. Reddy VY, et al., J Am Coll Cardiol, 2017. 69(17)
2. Sieniewicz BJ, et al., Heart Rhythm, 2020. 17(8)
3. Carabelli A, Defaye P et al., Europace, 2021. 23(5)
4. Singh JP, et al., JAMA Cardiol, 2024. 9(10)

# Feasibility of totally leadless left bundle branch area pacing via a left endocardial pacing electrode in patients with heart failure: A 3-case series

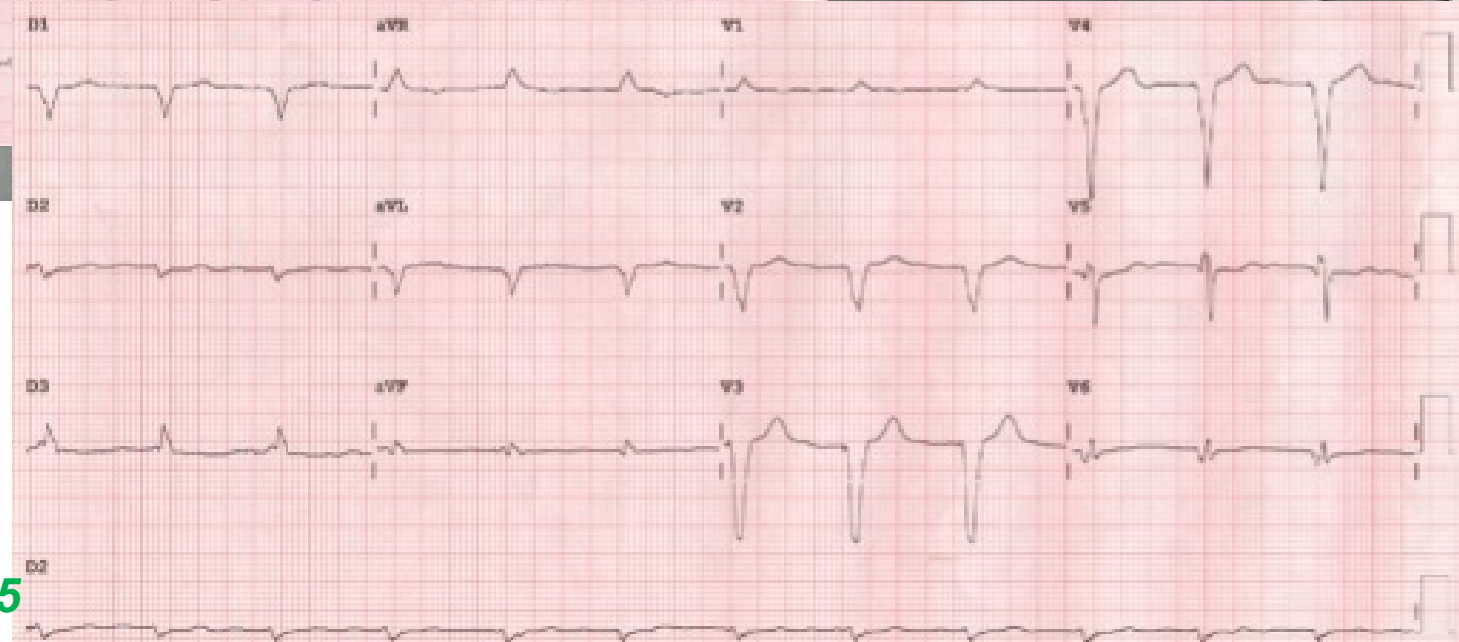
Elodie Deschamps, MD, Yann Lacombe, MSc, Sandrine Venier, MD, Adrien Carabelli, MD, Peggy Jacon, MD, Pascal Defaye, MD

Mr Lh...

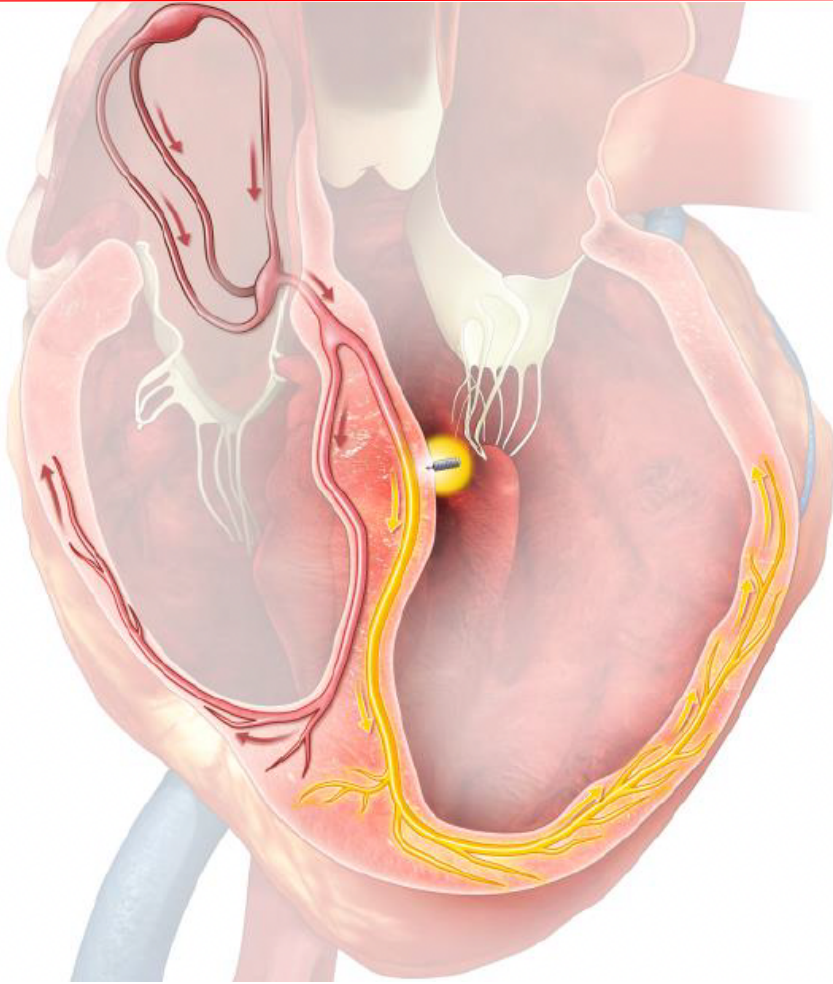
**1st patient/2019**  
**WISE CRT : lateral Wall LV**  
**Retrograde aortic approach**



***“All leadless”***



# *Leadless left bundle branch pacing*

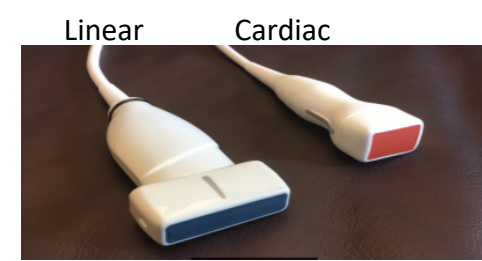


## ***Potential advantages :***

- ***Physiologic pacing***
- ***Low pacing threshold***
- ***No need to deep penetration into interventricular septum***
- ***Negligible damage to conductive tissue***
- ***Low risk of endocarditis***

## STEP 1 : Acoustic Window screening

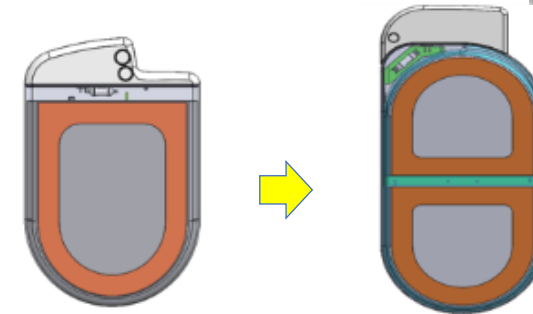
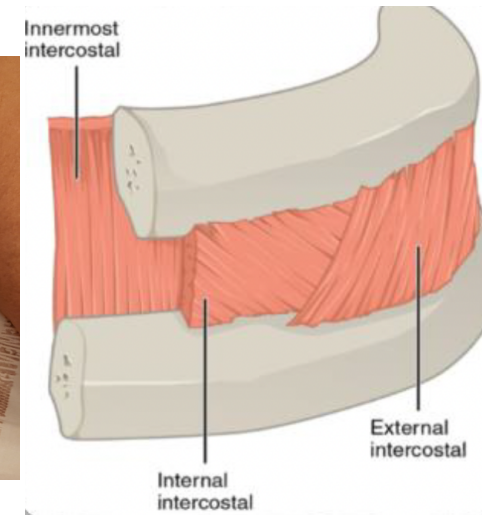
- Distance from transmitter to electrode: less than 10 cm
- Transmission angle less than 30 degrees for optimal transmission



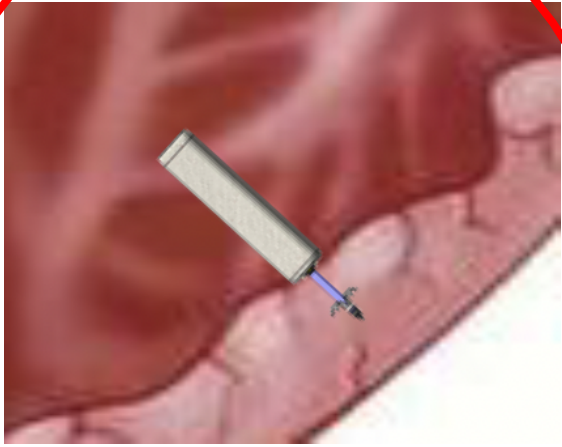
## STEP 2 : Submuscular implantation of the ultrasound transmitter



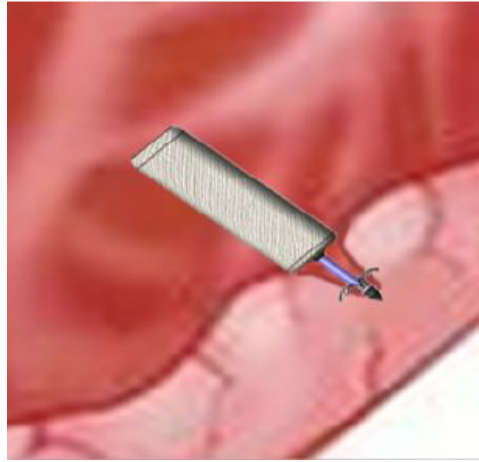
2d generation transmitter



2d generation battery (>4,5 y.)



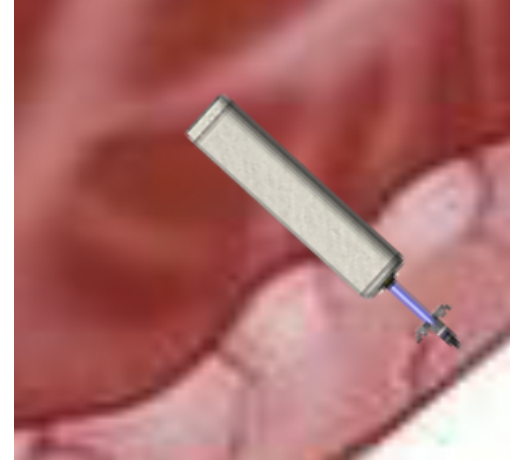
**Ideal electrode anchor**



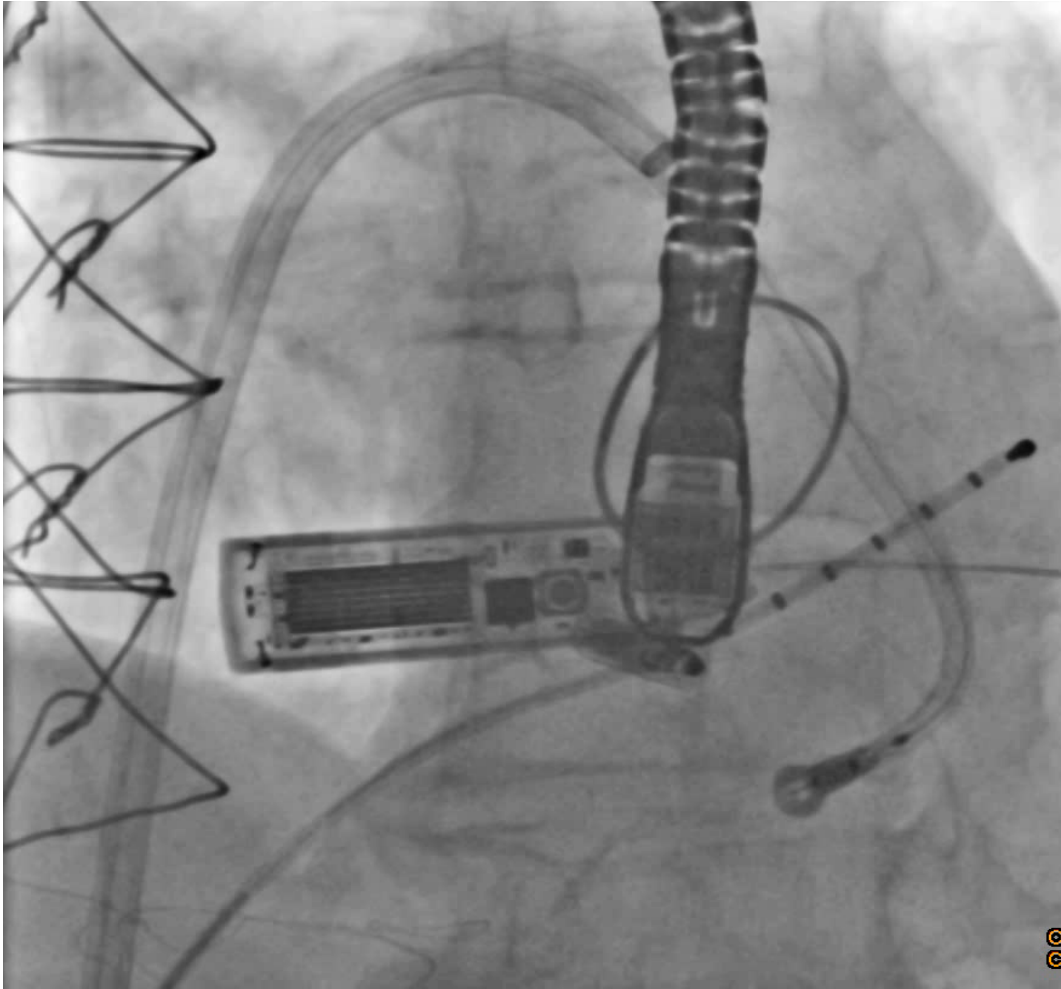
**Tenting**



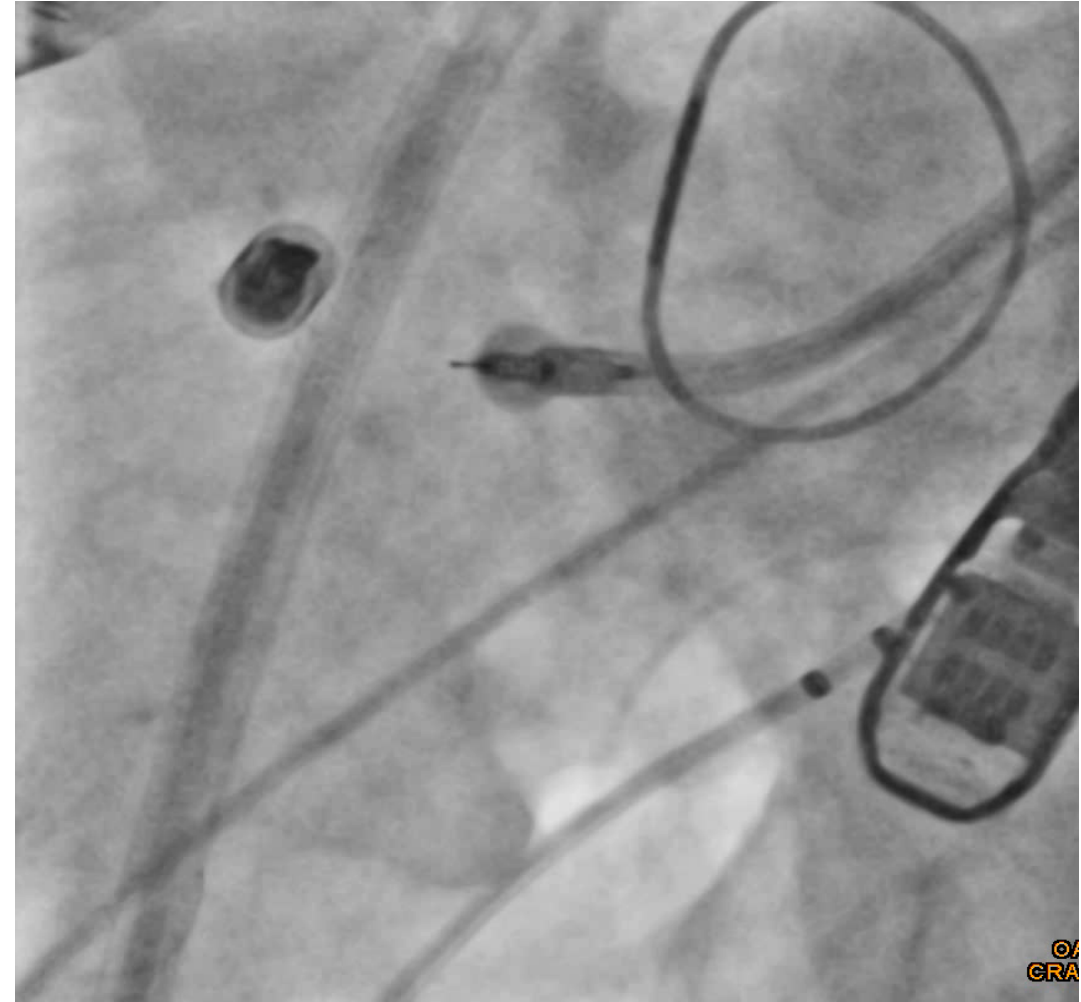
**Shallow angle**



**Too deep**



*First : mapping  
with Biosense blue curve D*

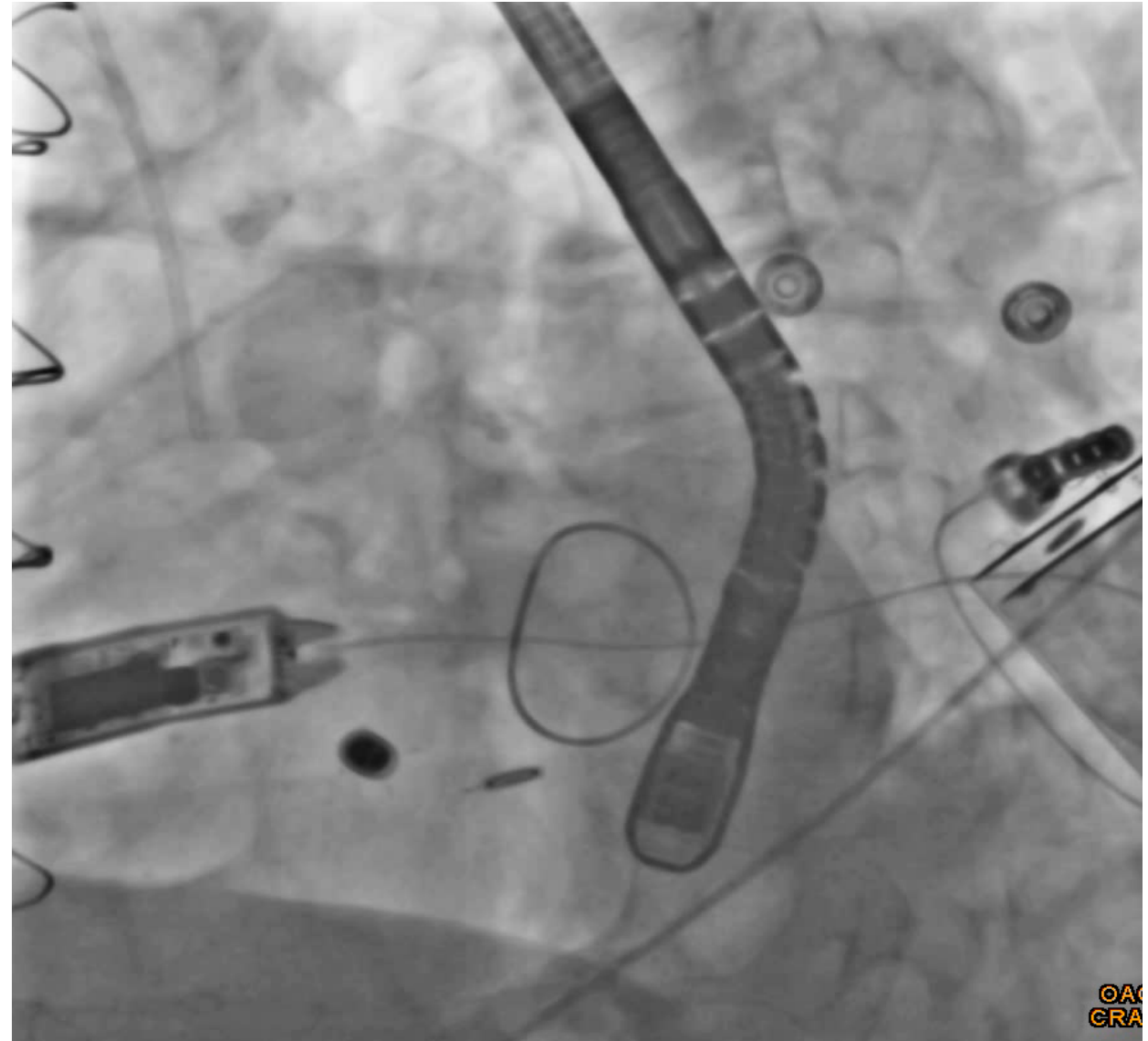


*Patient 11 : indication of upgrade after Micra LPM*

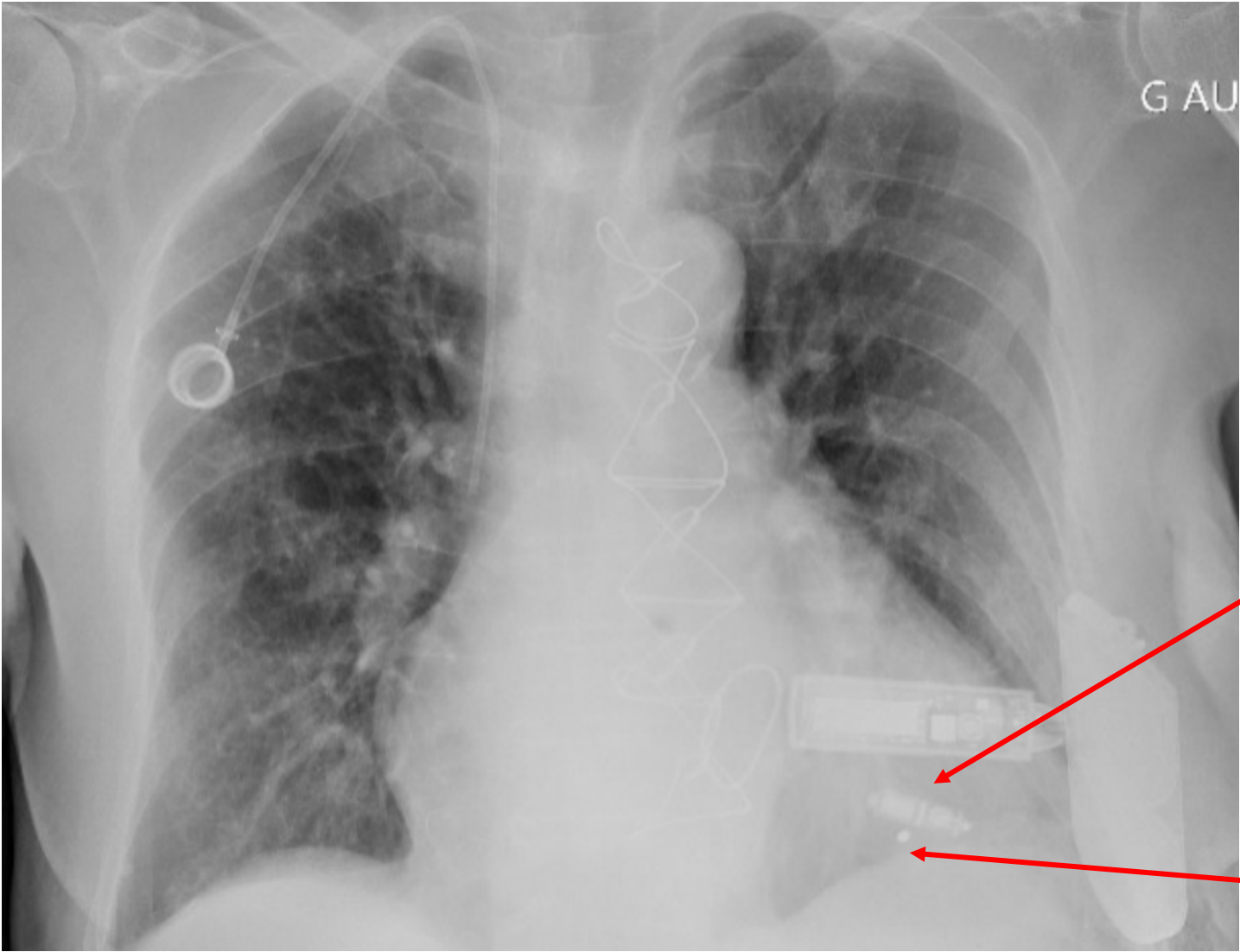
# Feasibility of totally leadless left bundle branch area pacing via a left endocardial pacing electrode in patients with heart failure: A 3-case series

Elodie Deschamps, MD, Yann Lacombe, MSc, Sandrine Venier, MD, Adrien Carabelli, MD, Peggy Jacon, MD, Pascal Defaye, MD

*Heart Rhythm Case Reports 2025;11:1120–1125*



06/04/2022 / Wyse CRT implantation/ transeptal approach



D1

aVR

V1

V4

D2

aVL

V2

V5

D3

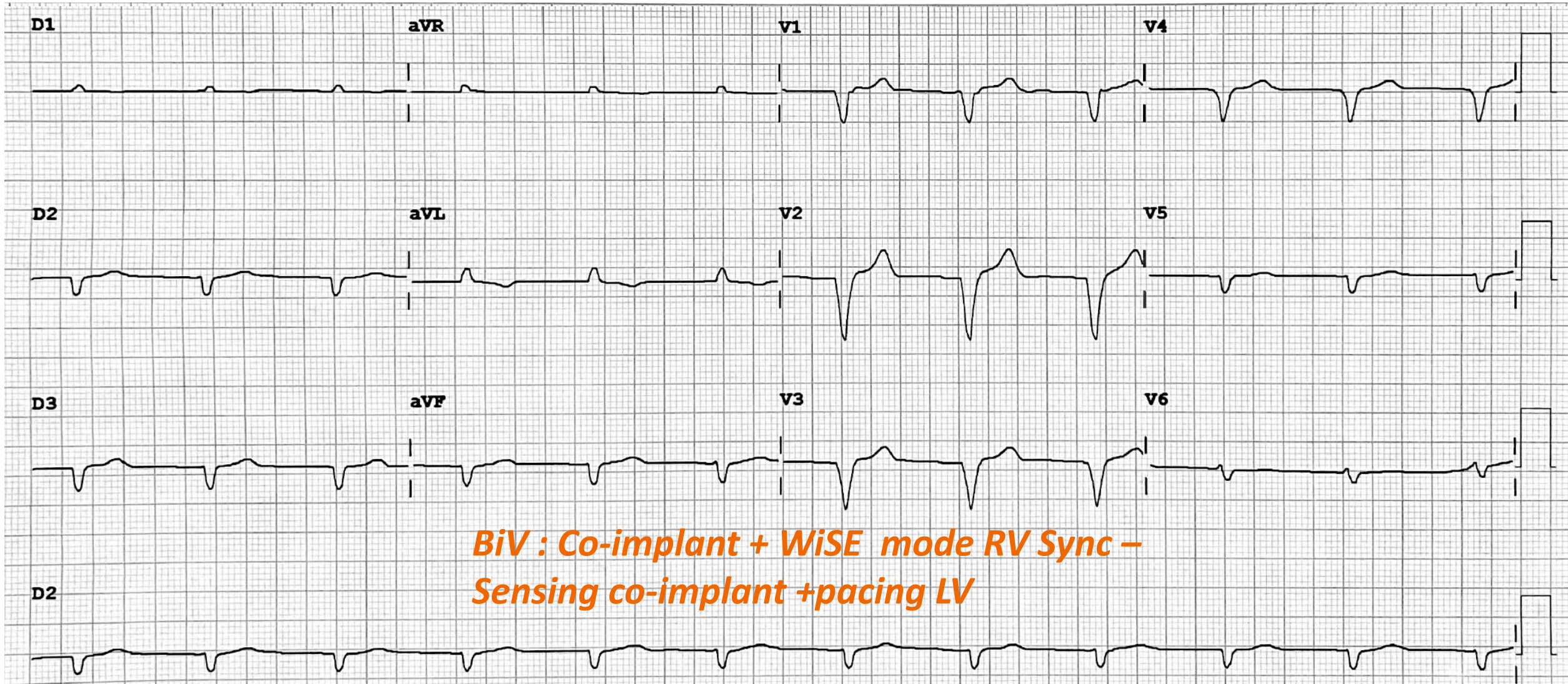
aVF

V3

V6

D2

***BiV : Co-implant + WiSE mode RV Sync –  
Sensing co-implant + pacing LV***



# 14 patients implanted

- Age: 69 ± 16.5 years
- Sex: 12 male & 2 female
- Cardiomyopathy: 9 non-ischaemic
- NYHA Class: 2.5 ± 0.4
- LVEF: 31.1 ± 8.8%
- AF: 10 permanent/4 sinus
- QRS Duration: 196 ± 33ms

## *Indication for Totally Leadless CRT*

- Infection of conventional CRT system = 5
- Upgrade of chronic Micra = 5
- De Novo implant = 3
- Failed CRT System = 1

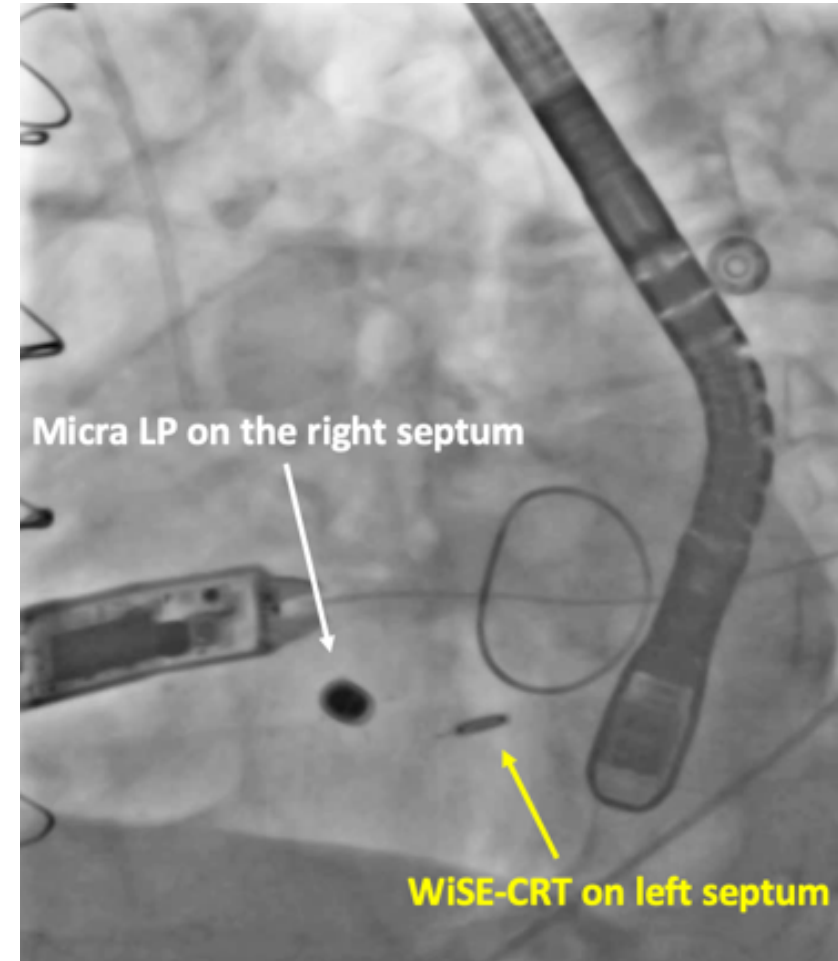
## **Implanted in one or two stage approach**

- One stage: WiSE Battery & Transmitter, followed by WiSE Electrode in same procedure
- Two stage: WiSE Battery & Transmitter, WiSE Electrode implanted following day

***Next patient : next week ...December 2025***

# Results – Technical Success

- **Success implant** in all 14 patients:
  - **4 x Micra AV**
  - **10 x Micra VR**
- **All WiSE-CRT devices were able to detect the Micra pacing output and deliver synchronous LV endocardial pacing, resulting in successful CRT.**
- **No unforeseen device - device interactions were observed.**
  - **One acute complication**  
premature detachment of an unanchored WiSE Electrode. Another Electrode was safely implanted without clinical sequelae.



# Results – Clinical Success

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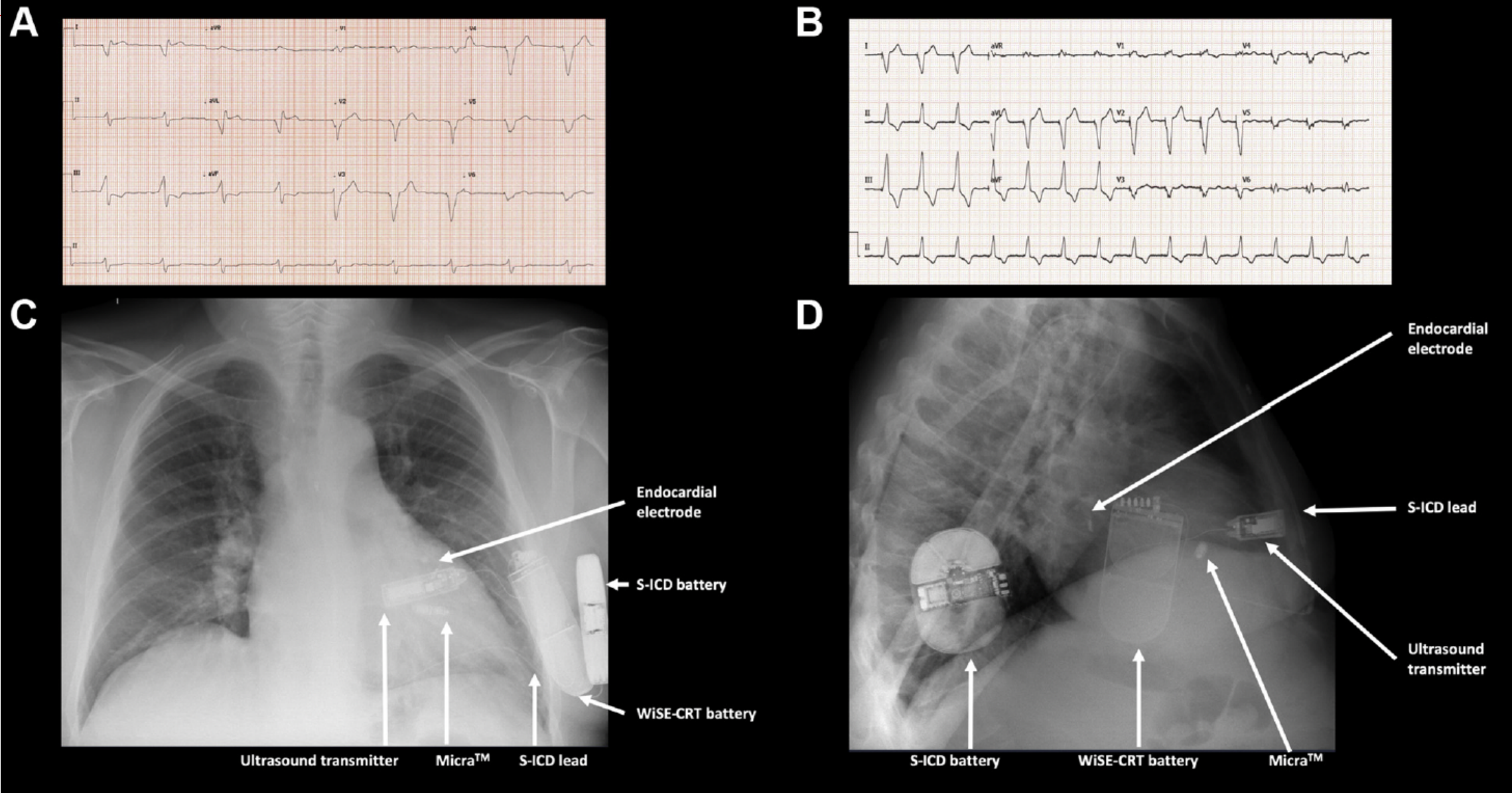
## Follow-up 6 months

- **Significant increase in ejection fraction:**
  - $31.1 \pm 8.8\%$  vs  $40.1 \pm 12.3\%$ ,  $P=0.02$
- **Significant decrease in QRS Duration:**
  - $196 \pm 33\text{ms}$  vs  $130 \pm 31\text{ms}$ ,  $P<0.001$
- **Trend toward improvement in NYHA class:**
  - $2.5 \pm 0.5$  vs  $2 \pm 0.9$ ,  $P=0.11$

# Completely Leadless Cardiac Resynchronization Defibrillator System

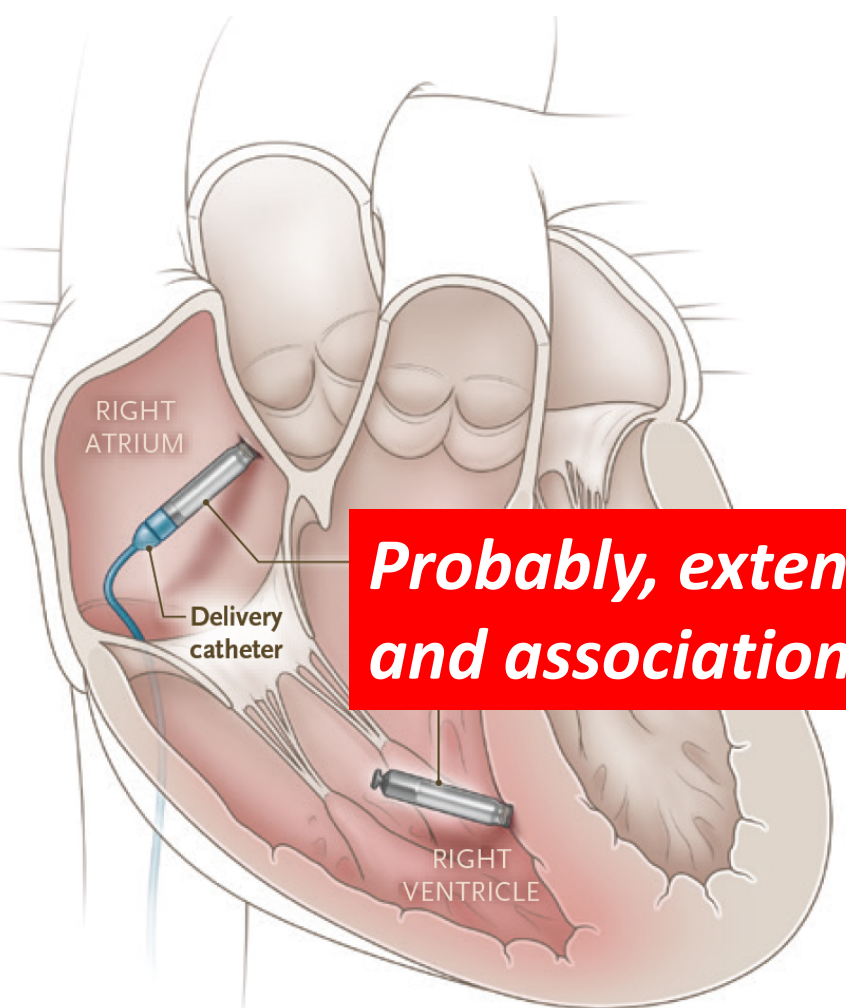
JACC EP 2020

Baldeep S. Sidhu, BM,<sup>a,b</sup> Justin Gould, MBBS, PhD,<sup>a,b</sup> Bradley Porter, MChB, PhD,<sup>a,b</sup> Mark Elliott, MBBS,<sup>a,b</sup> Vishal Mehta, MBBS,<sup>a,b</sup> Steven Niederer, DPM,<sup>a</sup> Christopher A. Rinaldi, MD<sup>a,b</sup>

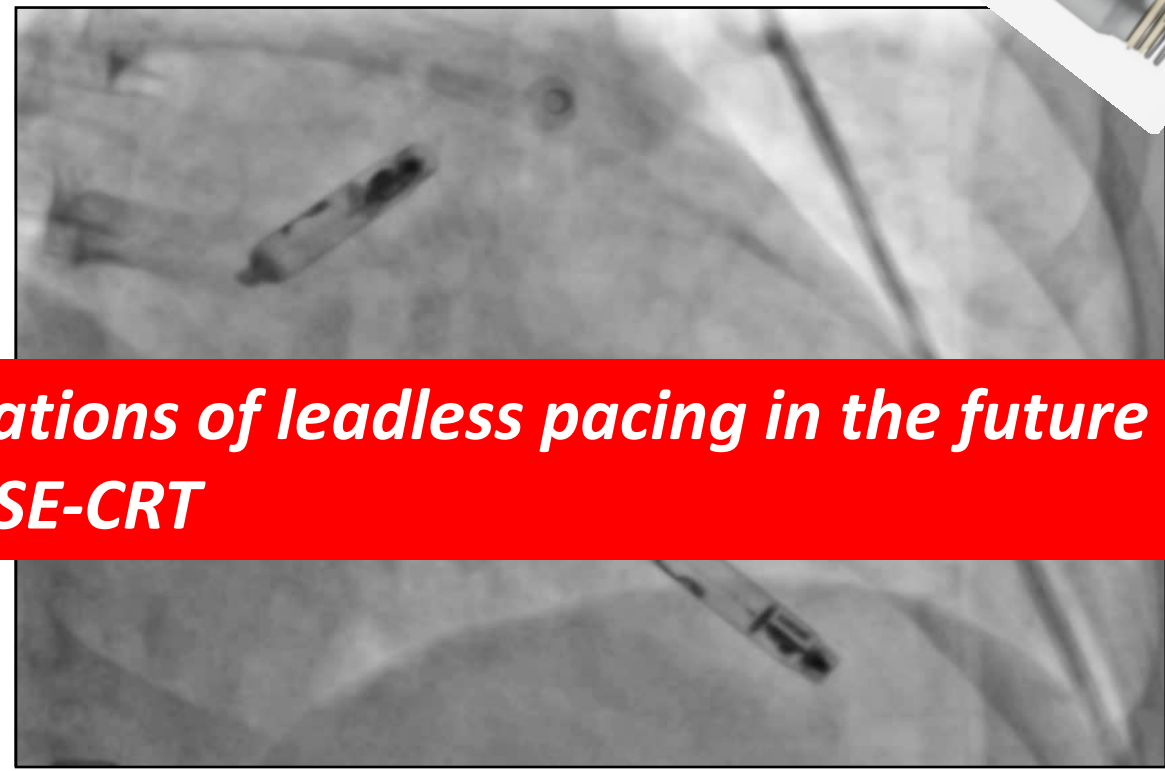


# A Dual-Chamber Leadless Pacemaker

Reinoud E. Knops, M.D., Ph.D., Vivek Y. Reddy, M.D., James E. Ip, M.D.,  
Rahul Doshi, M.D., Derek V. Exner, M.D., M.P.H., Pascal Defaye, M.D.,  
Robert Canby, M.D., Maria Grazia Bongiorno, M.D., Morio Shoda, M.D.,  
Gerhard Hindricks, M.D., Petr Neuzil, M.D., Mayer Rashtian, M.D.,  
Karel T.N. Breeman, M.D., Jordan R. Nevo, M.S., Leonard Ganz, M.D.,  
Chris Hubbard, M.B.A., and Daniel J. Cantillon, M.D.,  
for the Aveir DR i2i Study Investigators\*



***Probably, extended indications of leadless pacing in the future and association with WISE-CRT***

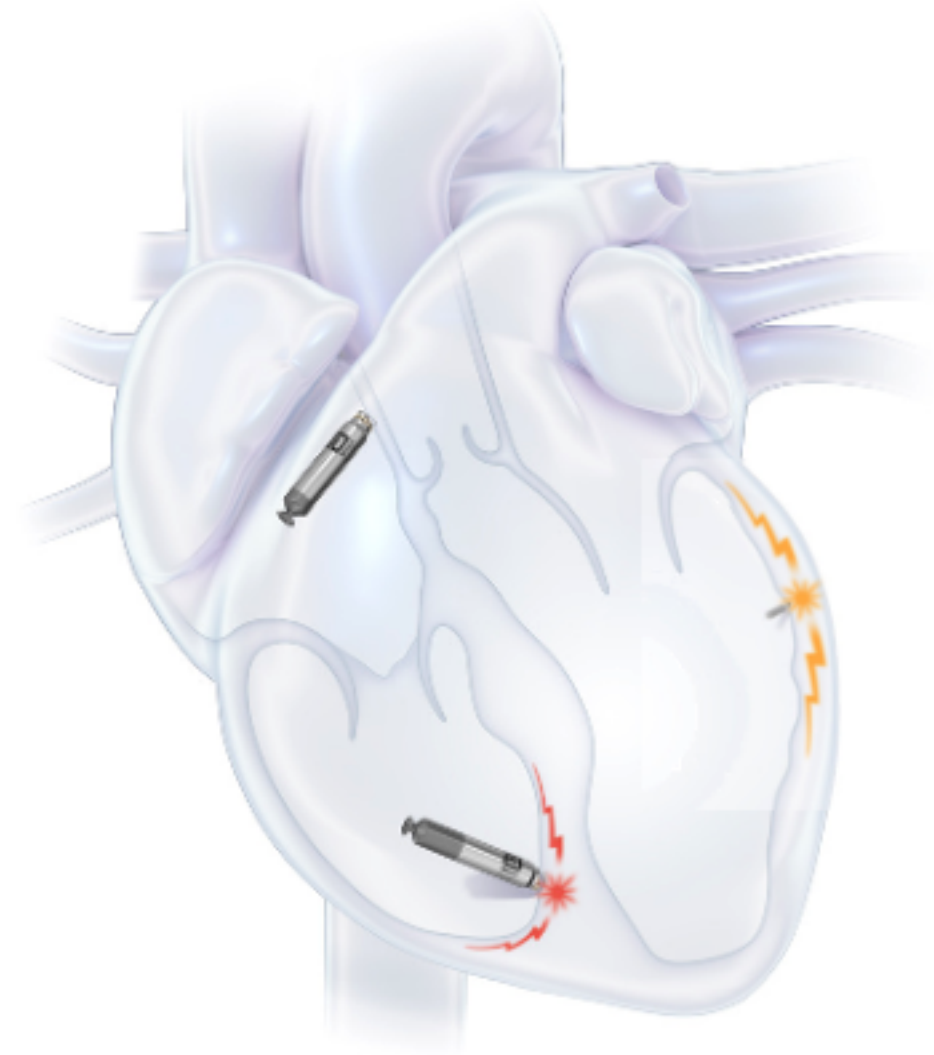


**Grenoble / April 2022**

***New Engl J of Med May 2023***

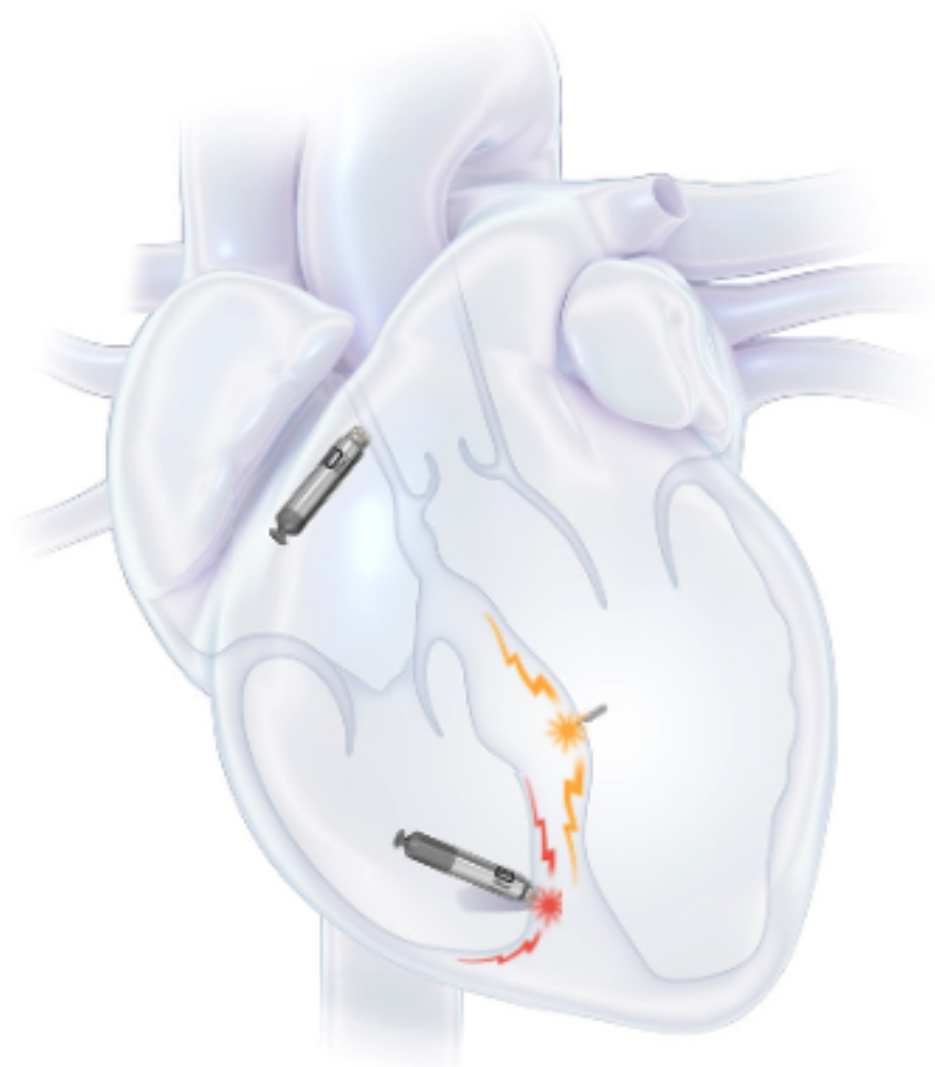
# What's Next: Totally Leadless CRT (the TLC Study)

<b>Study Name</b>	<b>TLC Study</b>
Study Design	Single arm / Prospective / Multicentre / Observational Study
Study Dates	Australia: December 2025 UK: Q1 2026
Primary Objective	Assess the safety and efficacy of the co-implantation of the WiSE CRT System with an intracardiac pacemaker to provide totally leadless CRT
Secondary Objective	Assess clinical response to totally leadless CRT. Provide analysis of different procedural approaches to de-novo co-implantation of WiSE CRT System and intracardiac pacemaker.



# *What's Next: ACCESS-CRT (the leadless conduction system pacing study)*

<b>Study Name</b>	<b>ACCESS-CRT Study</b>
<b>Study Design</b>	Single arm / Prospective / Multicentre / Observational Study
<b>Study Dates</b>	UK: Q1 2026 France & Germany: Q2 2026
<b>Primary Objective</b>	Demonstrate the feasibility / safety / outcomes of leadless conduction system pacing using WiSE CRT System
<b>Secondary Objective</b>	Assess clinical response to leadless conduction system pacing provided by WiSE CRT System at 6 months compared to baseline

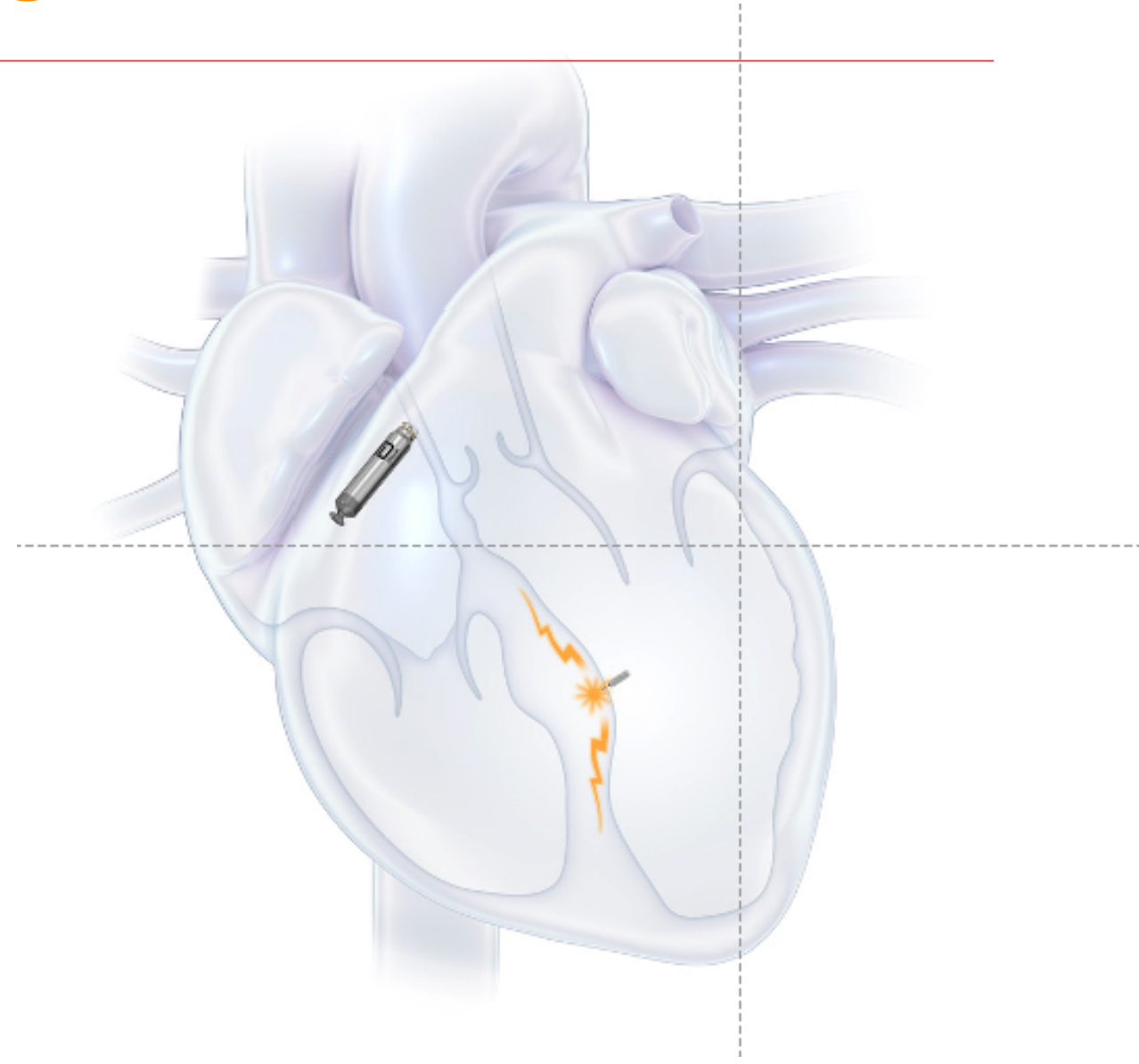


# *What's Next: Future application... Leadless Atrial Pacing + Leadless CSP*

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Concept: Pair leadless atrial pacemaker with leadless conduction system pacing

- WiSE System has ability to program a 'sync-delay'
- After detecting RA pacing, a user selected delay is programmed before pacing through WiSE Electrode

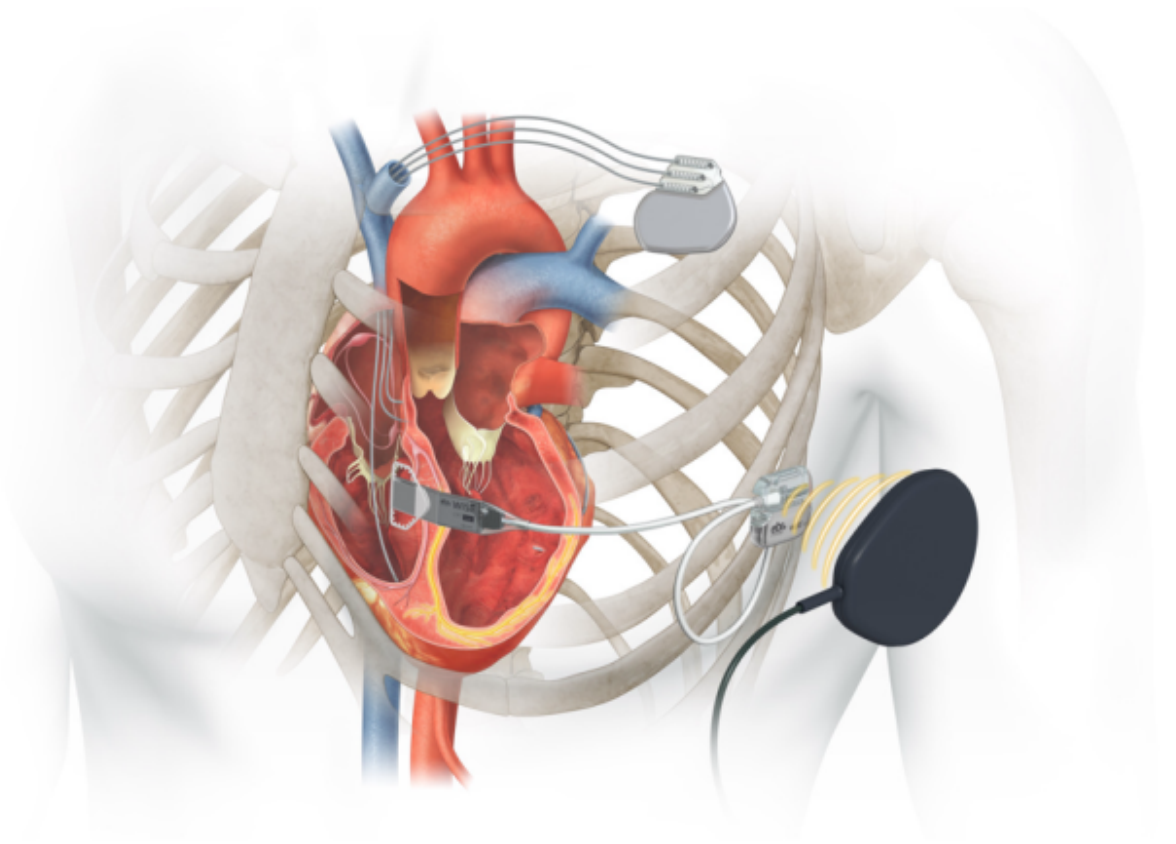


# *Product development: Rechargeable battery*

## **Patient benefits**

- Reduces need for future battery replacement surgery
- Recharge interval once per week<sup>1</sup>
- 66% reduction in size from current battery

<sup>1</sup> 95% of patients will only need to recharge once per week



*EBR's rechargeable battery will charge using a patch and external device to provide non-invasive, wireless charging*

# ***Anticipated Regulatory Approval Timelines***

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**US FDA: Q1 2025**

**Australia TGA: 2025**

**UK UKCA: 2026**

**Europe MDR: 2026**

## ***Anticipated Clinical Study Timelines***

**TLC-AU: early 2025**

**TLC-UK and EU: early 2025**

**ACCESS-EU: early-mid 2025**

**US Post Approval Study: mid 2025**

# *FDA Approval*

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- 2019: FDA granted Breakthrough Device Designation
- April 2025: FDA approval received
- April – September 2025: Pilot launch phase
  - Physicians Trained = 22
  - Implants = 12 patients treated
    - 2 implants paired with Micra
    - 2 implants paired with Aveir
- October 2025: Reimbursement schemes effective
  - New Technology Add-on Payment (NTAP – inpatients)
  - Transitory Pass-Through (TPT – outpatients)
- October 2025: Limited Market Release (LMR) begins targeting high volume and strategically important hospitals

# Conclusion : totally leadless CRT



- Achieving totally leadless CRT using a combination of a leadless pacemaker and WiSE-CRT System is **technically feasible** with good clinical outcomes.
- Further work is required to assess the efficacy and safety of this combination : **TLC study/ACCESS CRT/ Leadless atrial CRT+WISE**
- The **TLC Study** will investigate the feasibility of the implant of WiSE CRT and leadless pacemakers in de novo patient group
- Meanwhile, the WiSE-CRT System remains the only means to upgrade the expanding population of Micra VR-AV/Aveir VR-DR patients to CRT without replacing the leadless device.

