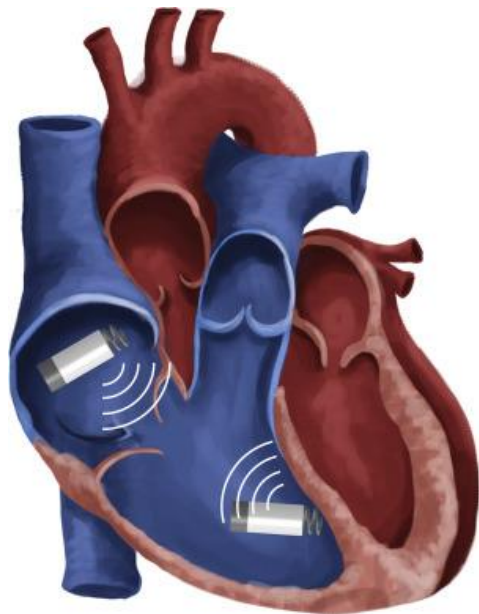


DUAL CHAMBER LEADLESS PACEMAKERS

Present & Future



RHYTHM

19 Mai 2022

DR Nicolas CLEMENTY
CHU Tours (FR)

DISCLOSURES

Dr Nicolas CLEMENTY has received **consulting fees** from:

Abbott

Biotronik

Boston Sci

Medtronic

Microport



Micra Transcatheter Pacing System

1st Generation: VR

Micra TPS (Medtronic)

Battery

Longevity $\cong$ 12 years

(VVIR, 50% pacing, 1V@0,24ms)

Modes

- Pacing mode: VVI(R)
- Bipolar sensing
- Compatible MRI 3T (full body)
- Capture Management™
- Accelerometer (3-axis)

However...

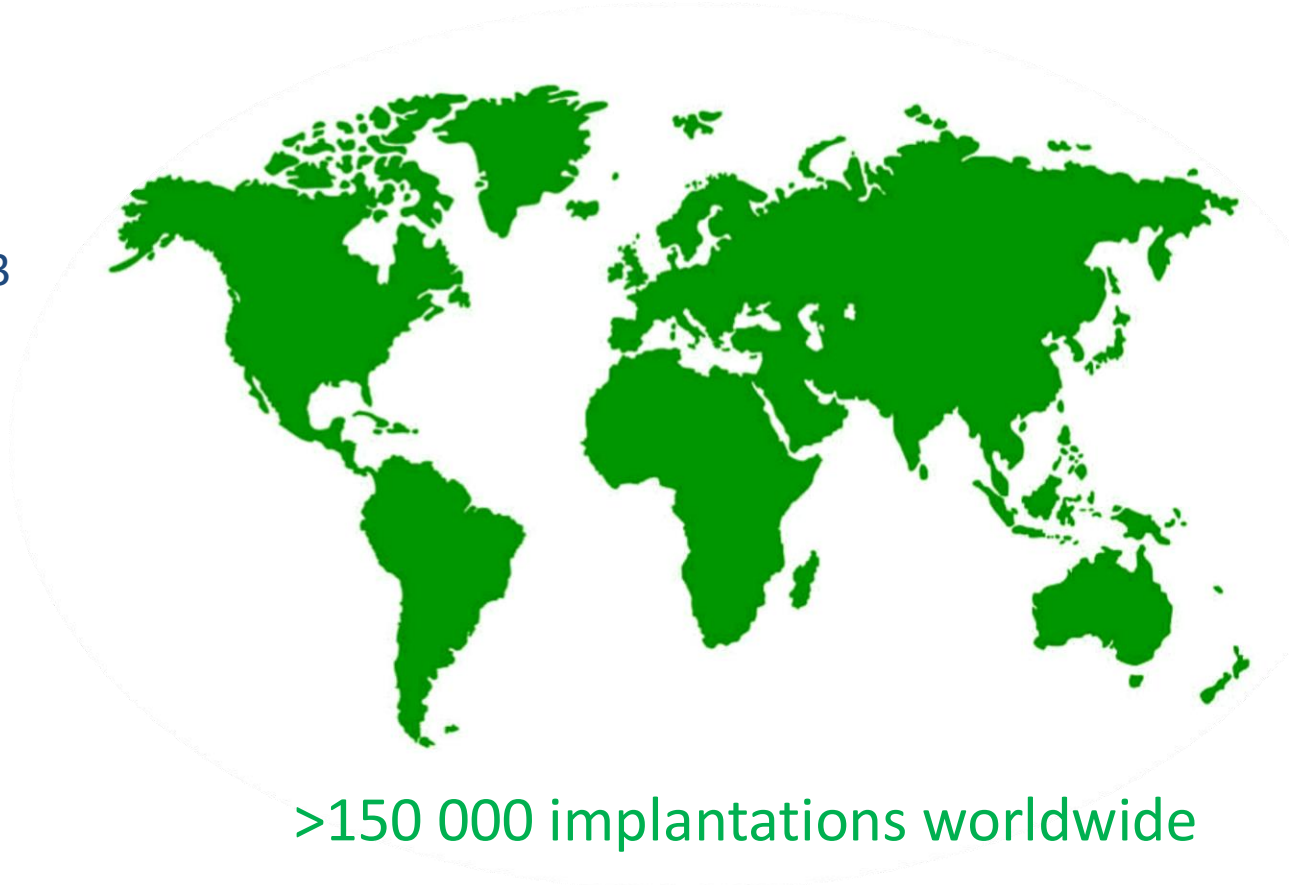
- No arrhythmic event memory
- No magnet mode
- No *trigger* (T) mode



Expansion

Micra TPS (Medtronic)

- Project start: 2006
- 1st Human: December 2013
- G1 CE mark: April 2015
- G2 CE mark: May 2020

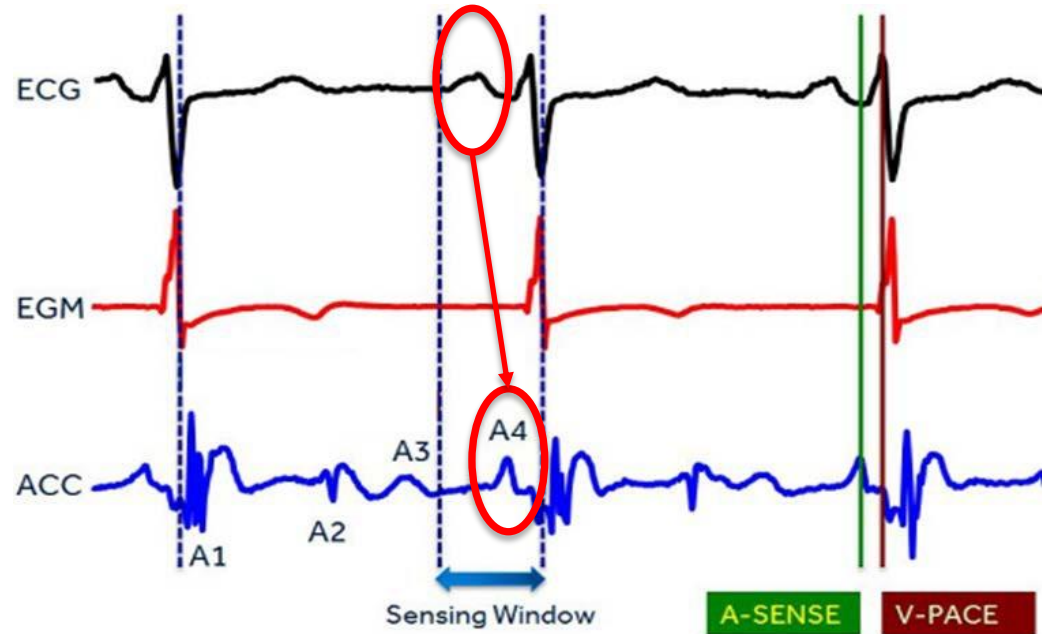
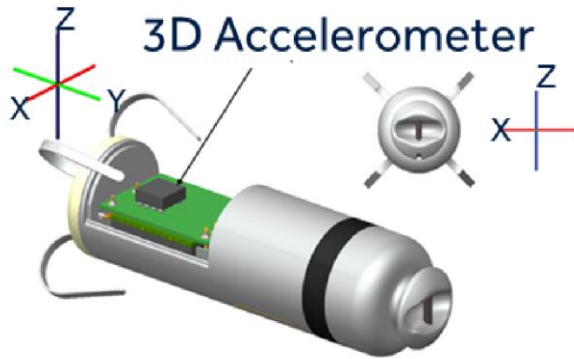


>150 000 implantations worldwide

Micra Transcatheter Pacing System

2nd Generation: AV

Micra AV



- **A1** – Isovolumic contraction and AV valves closure
- **A2** – Aortic/pulmonic valves closure
- **A3** – Passive ventricular filling (« E-wave »)
- **A4** – Atrial contraction – Active ventricular filling (« A-wave »)

Micra Transcatheter Pacing System

2nd Generation: AV

Micra Studies

> 17 000 patients

Premarket studies

Safety/efficacy of Micra VR and AV
>1,300 global enrollments in the IDE¹, Continued Access², China Study³ and AV development⁴ studies



Micra VR PAR⁵

Surveillance registry to demonstrate real-world safety and performance
>1800 patients globally
Follow-up ongoing

Micra VR regional studies⁶

Acute performance registries to demonstrate real-world safety and performance
~1500 patients across Europe, Japan, Asia Pacific, and China Enrolling, ongoing

AccelAV⁷

Single arm, interventional study to characterize AV synchrony with Micra AV
~150 patients across US and Asia Pacific

Micra AV PAR⁸

Observational, post-approval study focused on safety, major complications, and quality of life
~750 patients across US, Europe, and Asia Pacific
3 year follow-up ongoing

Micra VR and AV CED^{9,10}

US CMS Claims database
>12,000 patients, focused on complications and survival rate
Enrolling, ongoing

¹Reynolds D, et al. *N Engl J Med*. 2016;374:533-41. ²ClinicalTrials.gov ID: NCT02488681; ³Chen K, et al. *Int J Heart Rhythm*. 2021;6:47-53. ⁴Chinitz L, et al. *Heart Rhythm*. 2018;15:1363-73. ⁵El-Chami, et al. *Heart Rhythm*. 2018;15:1800-1807. ⁶Garweg C, et al. *Europace*. 2021;23S3:euab116-389. ⁷ClinicalTrials.gov ID: NCT04245345. ⁸ClinicalTrials.gov ID: NCT0425318. ⁹El-Chami MF, et al. *Eur Heart J*. 2021;43:1207-15. ¹⁰ClinicalTrials.gov ID: NCT04235491

Micra Transcatheter Pacing System

2nd Generation: AV

Micra AV PAR Interim Analysis (N=519)

POPULATION

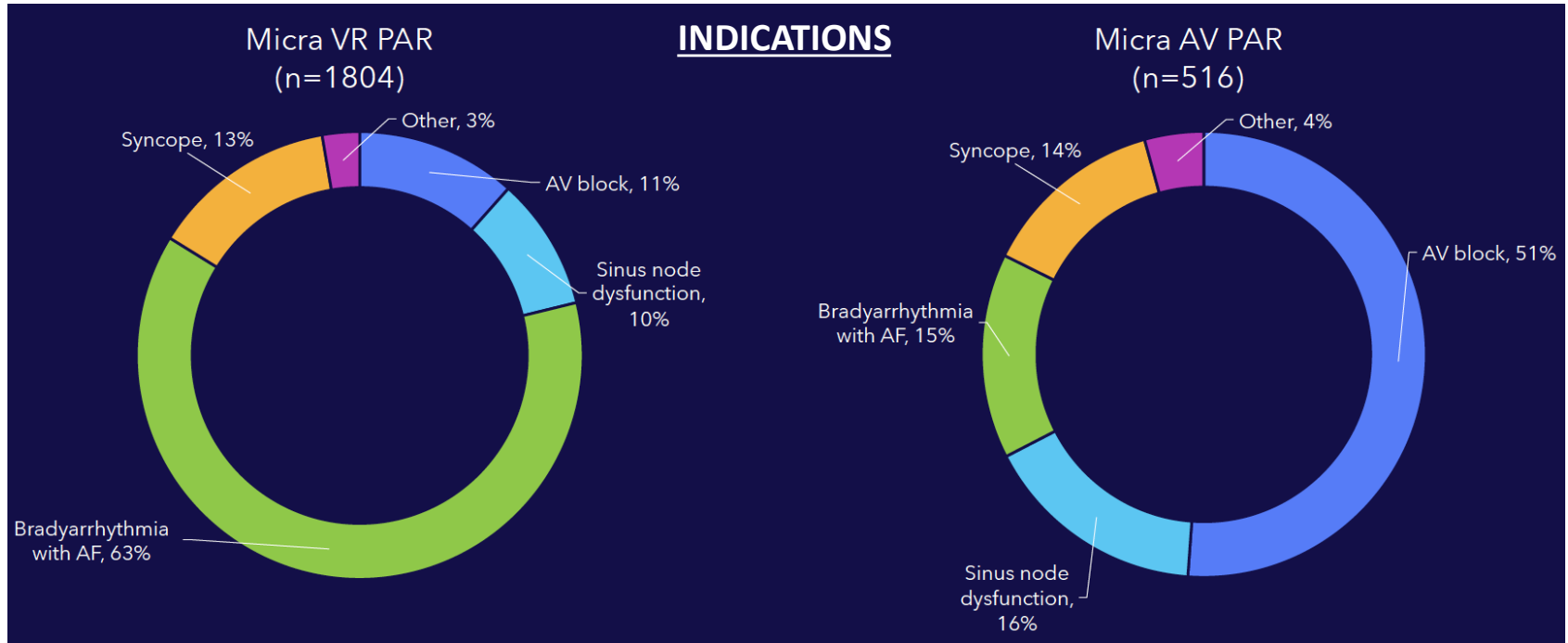
	Micra VR PAR (N=1811)	Micra AV PAR (N=519)	P-value
Age (years)	75.6 ± 15.1	74.4 ± 15.1	0.07
Female	703 (38.8%)	217 (41.8%)	0.22
Persistent/permanent AF	1016 (56.1%)	37 (7.1%)	<0.001
CHF	280 (15.5%)	75 (14.5%)	0.63
COPD	177 (9.8%)	43 (8.3%)	0.35
CAD	398 (22.0%)	121 (23.3%)	0.55
HTN	1175 (64.9%)	357 (68.8%)	0.10
Diabetes	480 (26.5%)	164 (31.6%)	0.026
TV-PPM precluded	433 (23.9%)	164 (31.8%)	<0.001



Micra Transcatheter Pacing System

2nd Generation: AV

Micra AV PAR Interim Analysis (N=519)



Micra Transcatheter Pacing System

2nd Generation: AV

Micra AV PAR Interim Analysis (N=519)

REVISIONS

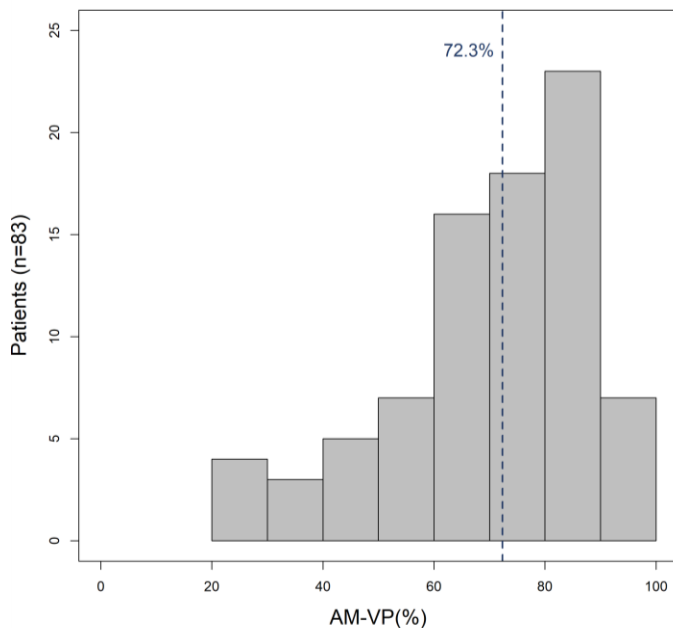
N	Days post-implant	Micra Retrieved	PM syndrome	New device	Prior device	History of infection
1	66	N	N	CRT-P	N	Y
2	113	Y	Y	Dual-chamber TV-PPM	N	N
3	133	N	Y	CRT-P	CRT-P	Y
4	154	Y	N	Single-chamber TV-PPM	Transvenous pacemaker	Y

Micra Transcatheter Pacing System

2nd Generation: AV

Micra AV PAR Interim Analysis (N=519)

AV SYNCHRONY



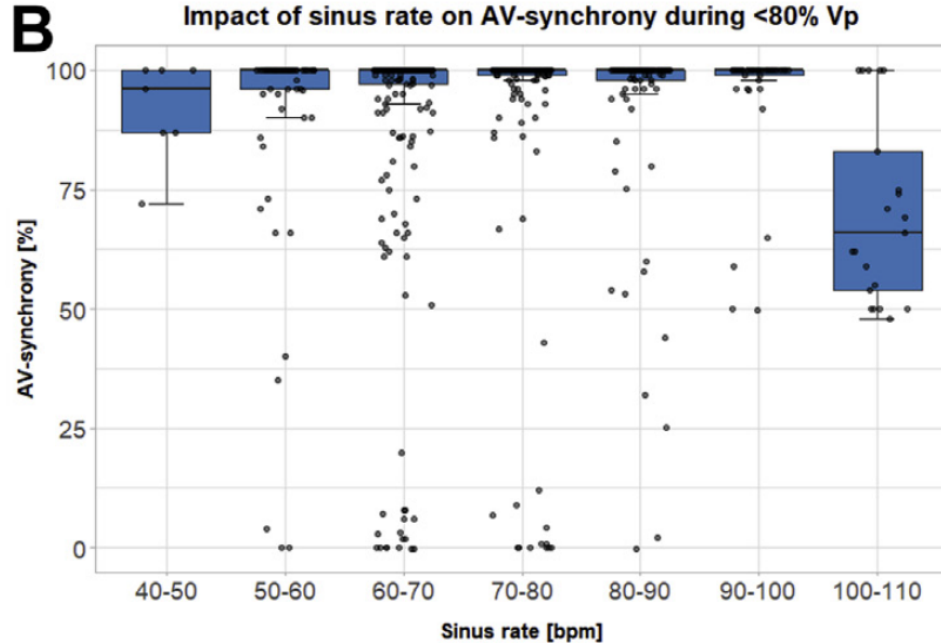
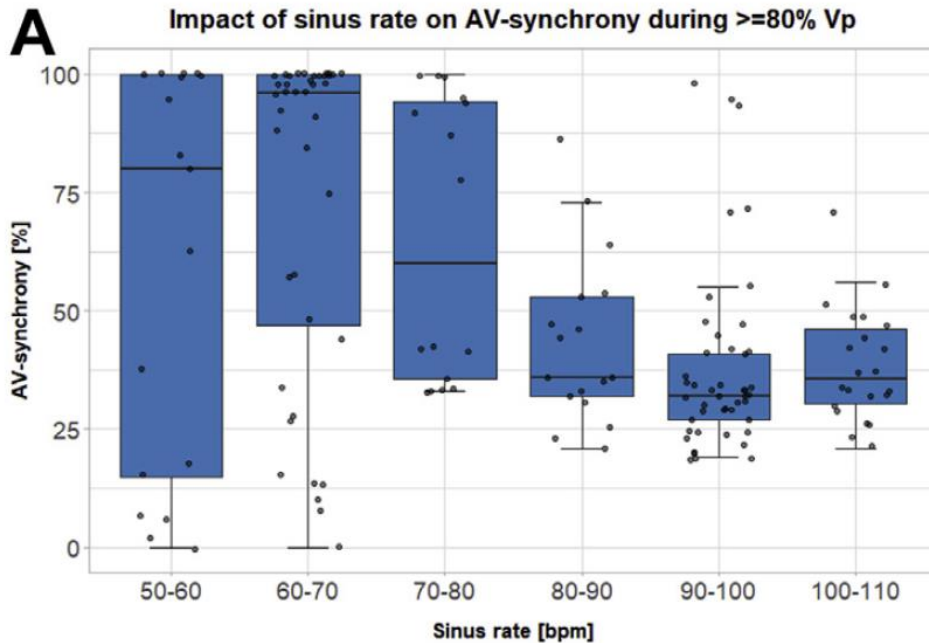
Patients with >90% Vp

AM-VP (%)	N (%)
0% - 25%	1 (1.2%)
25% - 50%	11 (13.3%)
50% - 75%	32 (38.6%)
75% - 90%	32 (38.6%)
>90%	7 (8.4%)

Micra Transcatheter Pacing System

2nd Generation: AV

AV SYNCHRONY

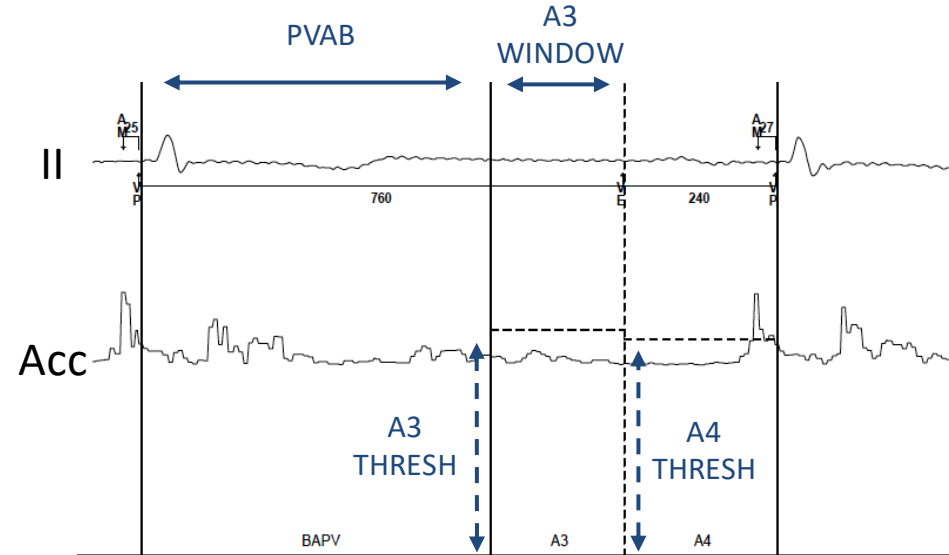


Micra Transcatheter Pacing System

2nd Generation: AV

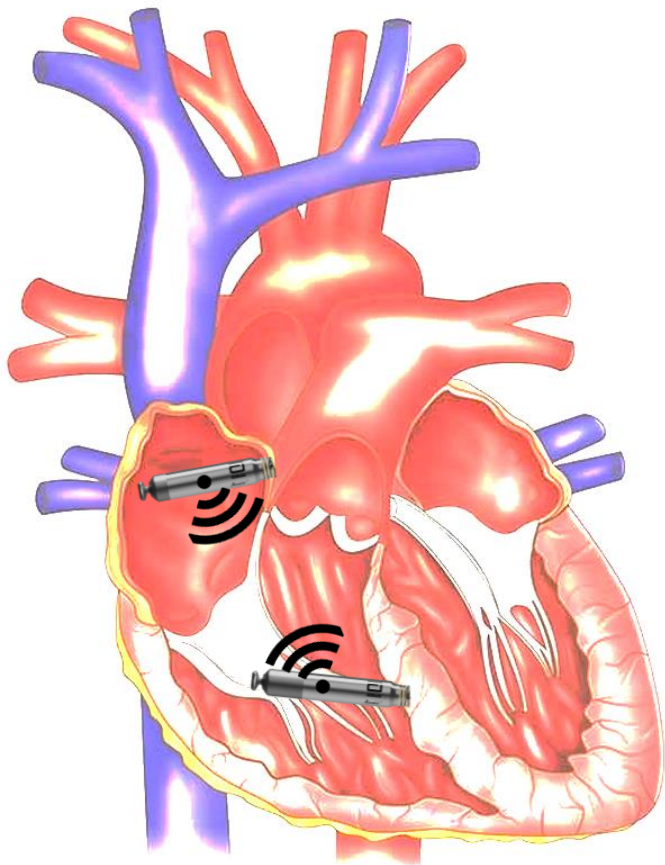
AV Synchrony Optimization +++

A3 Window End >> 700-800 ms
Auto A3 threshold >> OFF
Tracking Check >> OFF



Abbott Aveir DR

- Aveir VR: FDA approval April 2022
- Aveir DR: 1st implantation February 2022
- Aveir DR i2 Study ongoing...



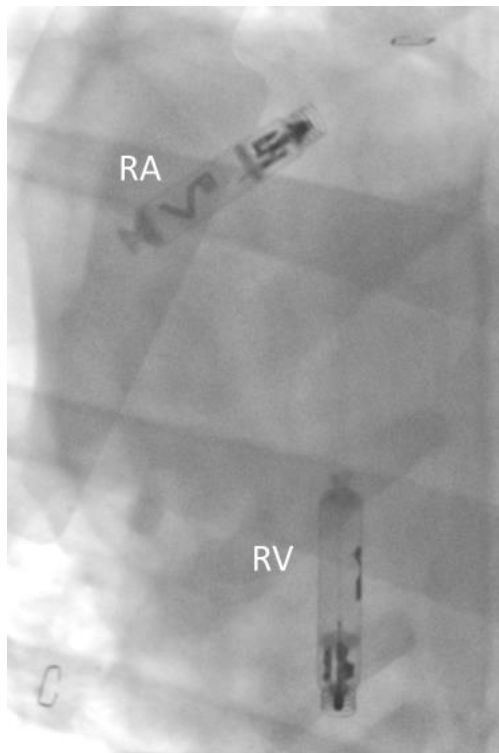
RA: 32.3mm (1.27in)



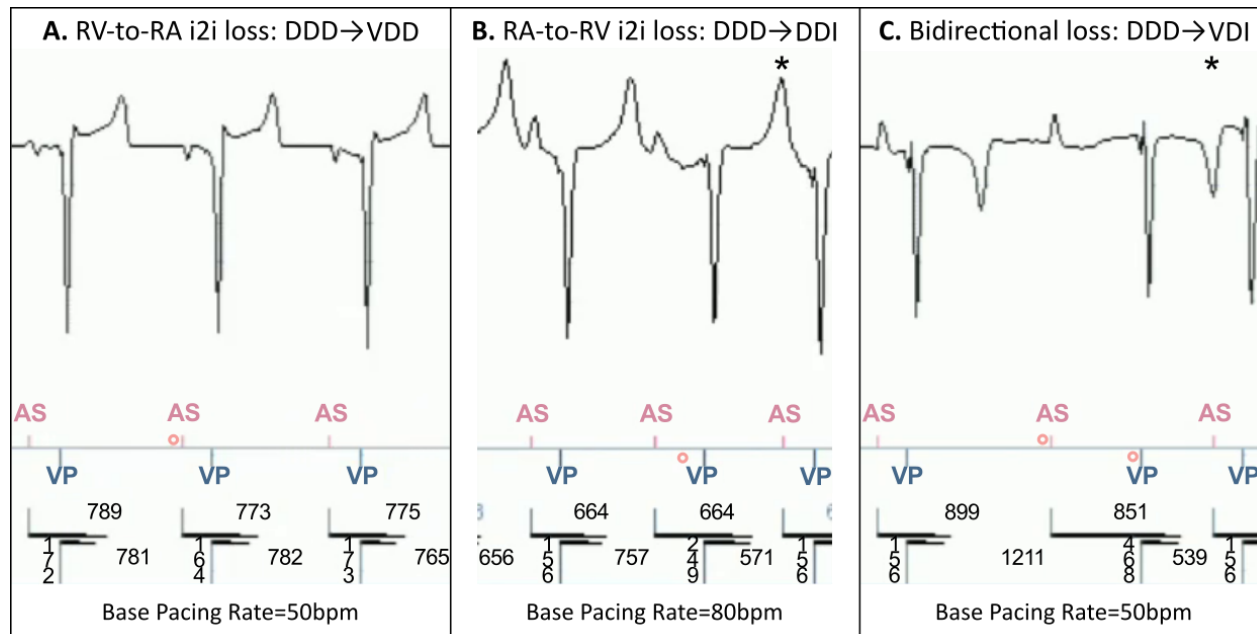
RV: 38.0mm (1.50in)



Abbot Aveir DR

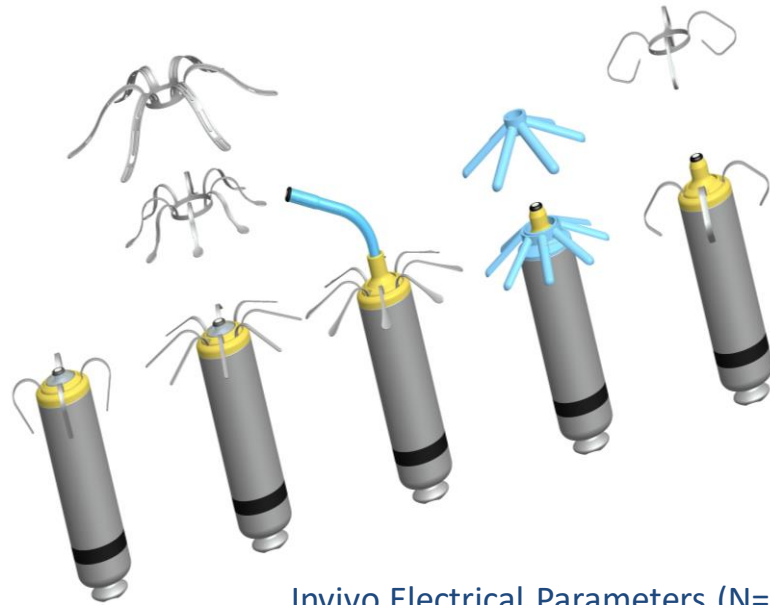


bidirectional beat-by-beat i2i communication >> ~99% AV synchrony

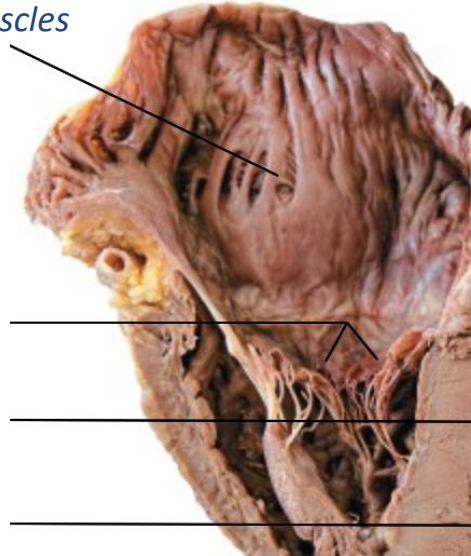


Micra DR ?

Micra AR

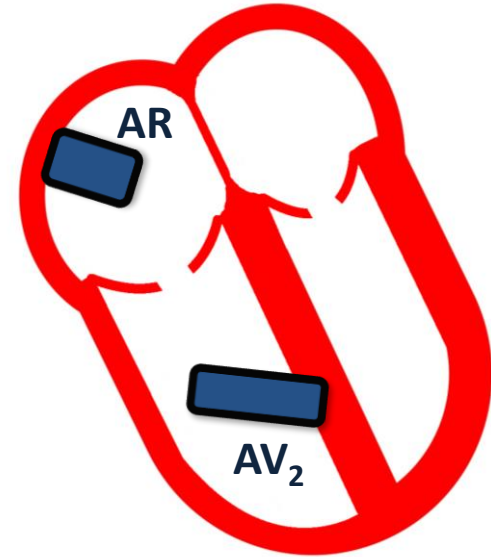


*pectinate
muscles*



Invivo Electrical Parameters (N=13)

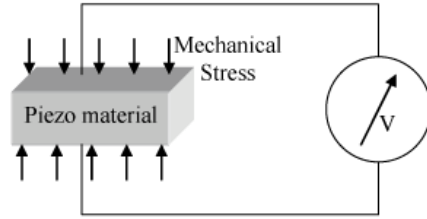
R-wave 4 mV / Threshold 0.6 V / Impedance 400 Ω



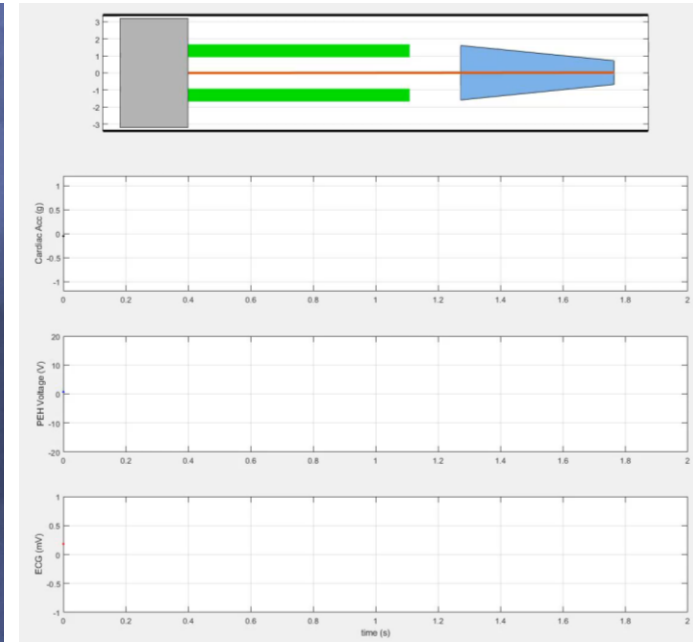
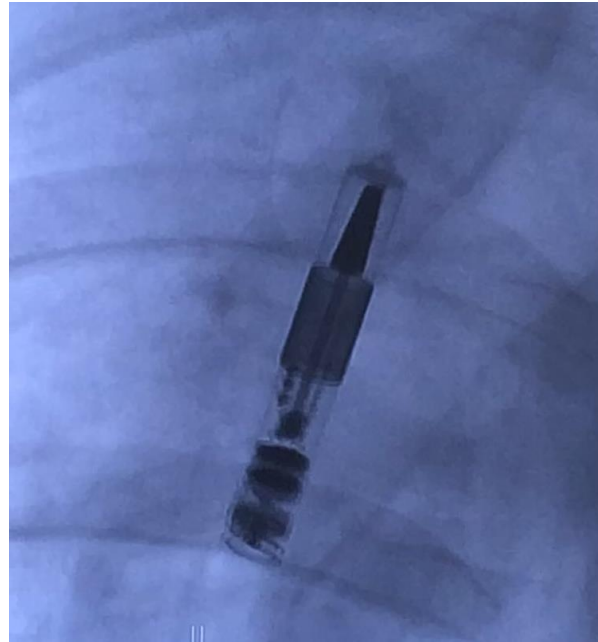
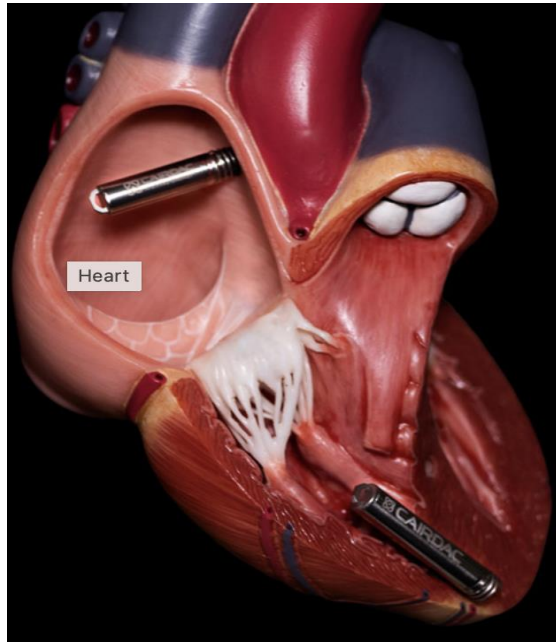
Micra AV gen2

- improved mechanical sensing
- improved detection algorithms

Self-Sustainable Leadless PM ?



kinetic energy harvesting



Conclusions

- Leadless pacing is expanding fast due to an excellent safety/efficacy profile (Micra).
- 2nd generation Micra (AV) with decent AV synchrony capability allows leadless implantation in patients with complete AV block and a sinus rhythm, with a low rate of revision for pacemaker syndrome.
- True dual-chamber leadless pacemaker (Aveir) is a reality and under evaluation...

