HKCC ASC 2020

Leadless cardiac pacing for patients with atrioventricular block

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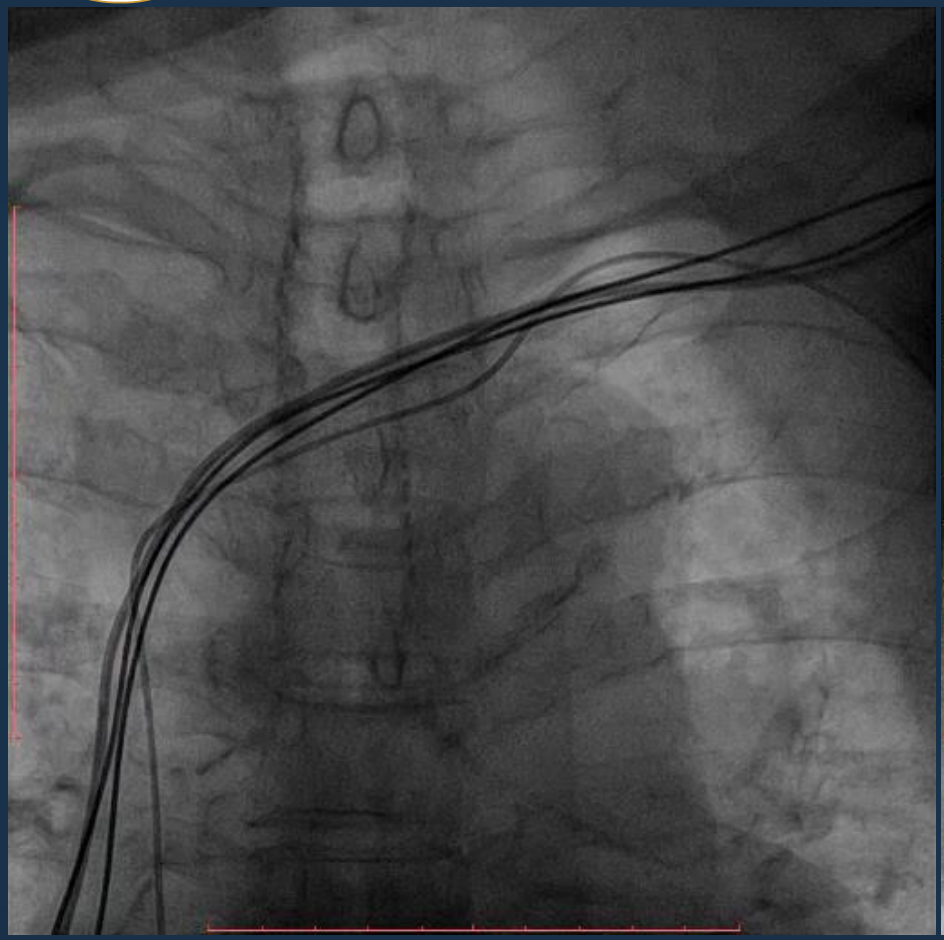
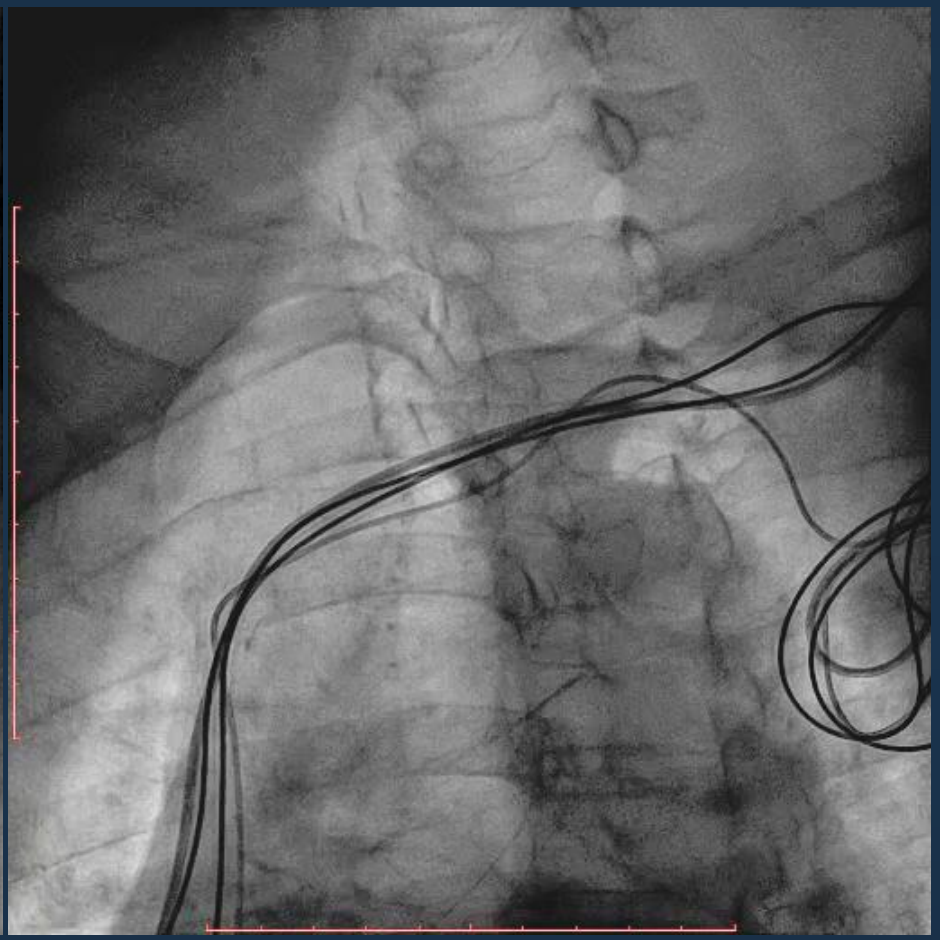
Disclosure

- None.

Agenda

- Current experience with leadless pacemaker
- Need of AV synchrony
- MARVEL Algorithm
- Patient selection and limitations





Real World Experience

Objective

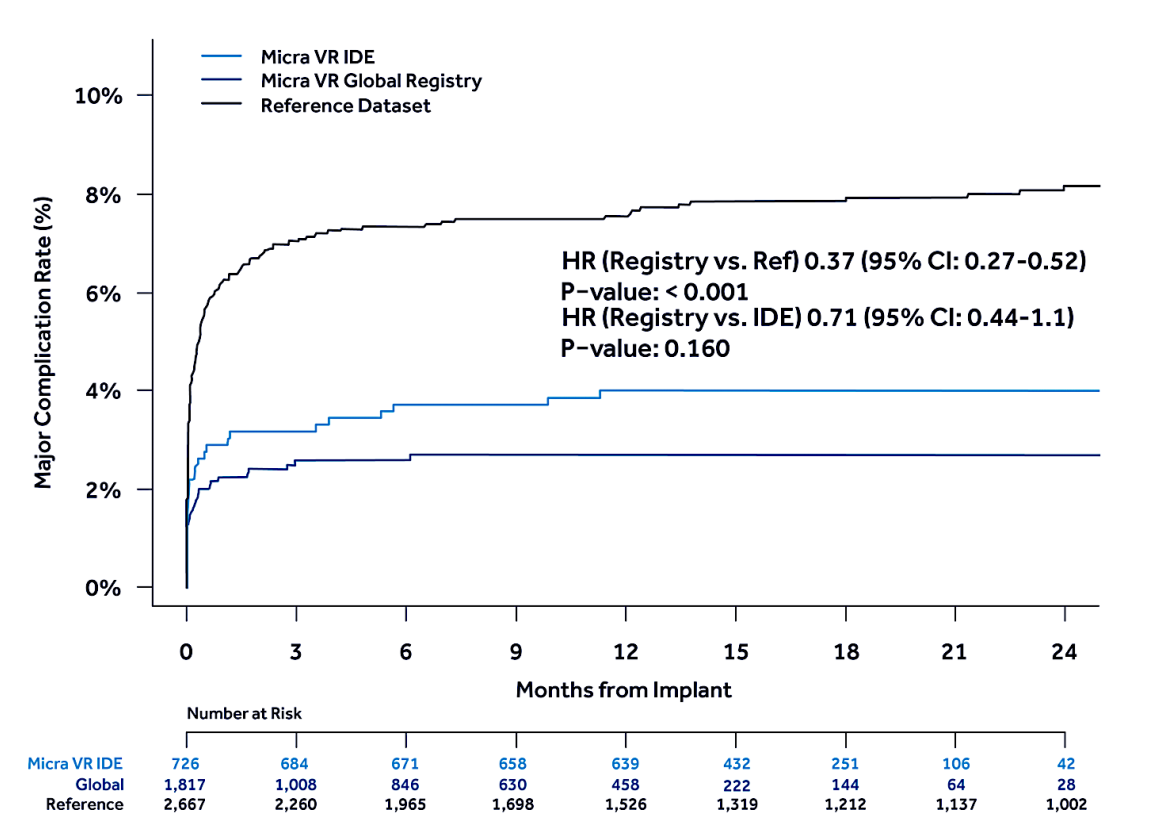
To report updated performance of the Micra transcatheter pacemaker from a worldwide registry and compare it with the IDE study and a transvenous historical control

Analysis Design

System- or procedure-related complications through 12 months were compared for 1,801 successfully implanted Micra patients in clinical setting, versus 726 Micra IDE patients and 2,667 patients with transvenous pacemakers

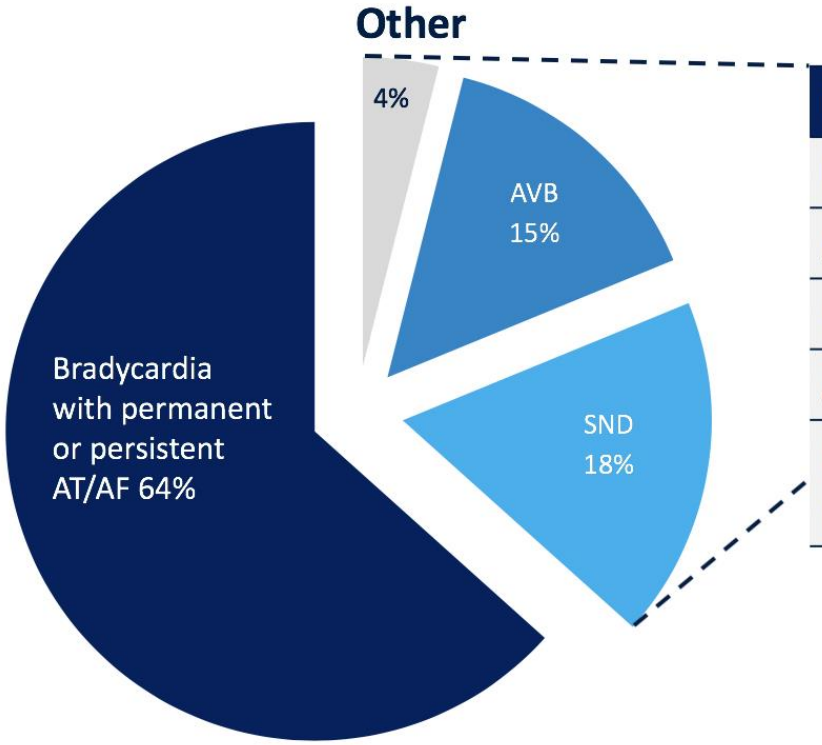
Results

A 63% reduction in major complications compared with transvenous system



El-Chami MF, et al. Heart Rhythm. December 2018;15(12):1800-1807.

Patient selection



Reasons for selecting VVIR
Infrequent pacing expected
Advanced age
Sedentary lifestyle
Anatomical limitations
Comorbidities increasing complication risk
Compromised venous access
Need to preserve veins for hemodialysis
Thrombosis
History of infection
Cancer
Other†

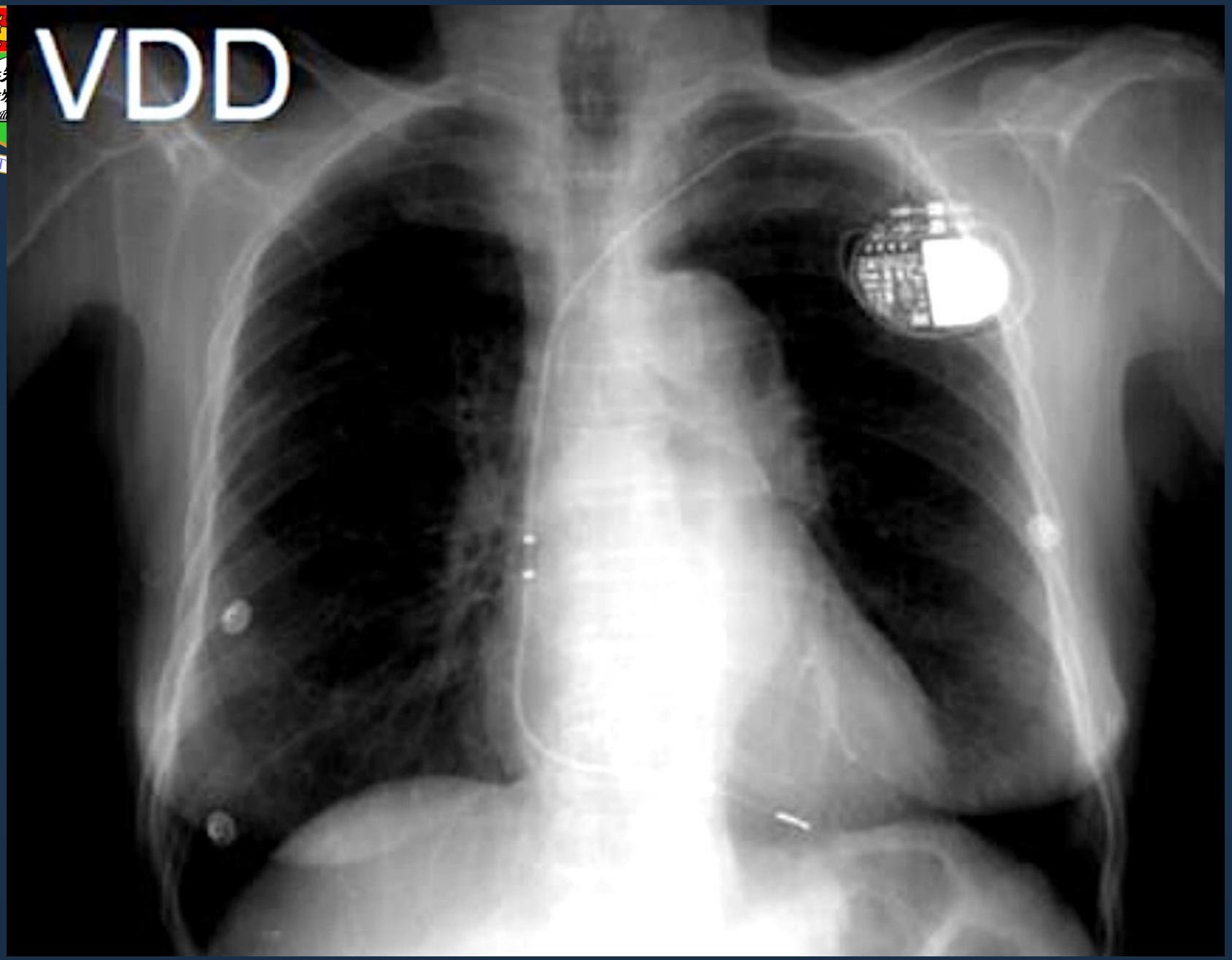
Reynolds D, et al. N Engl J Med. February 11, 2016;374(6):533-541

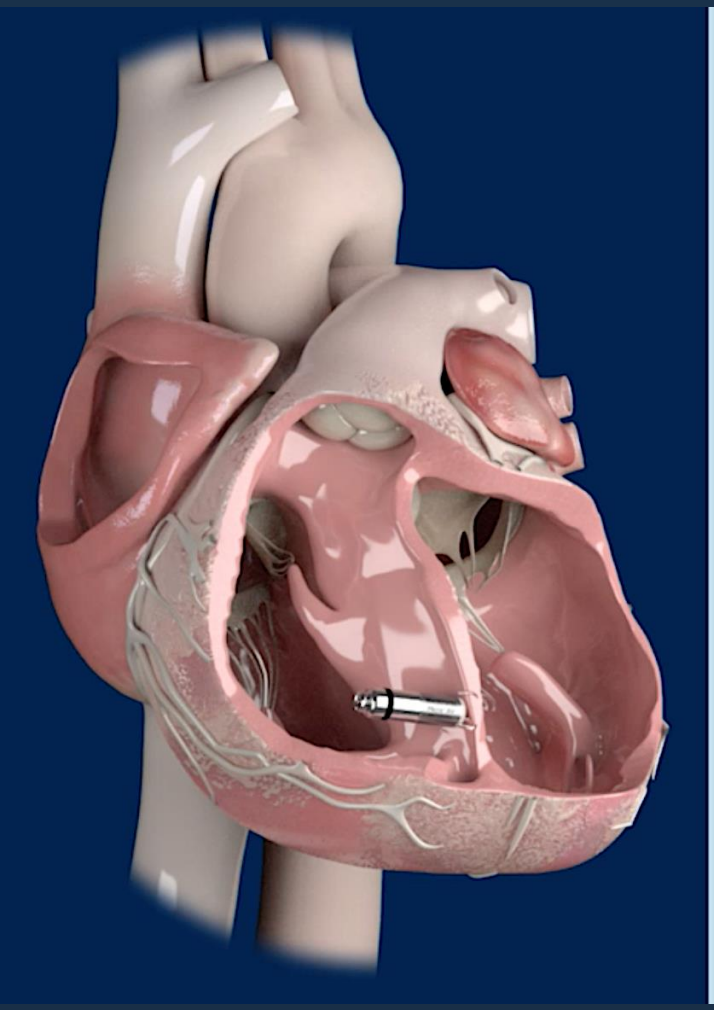
Importance of AV synchrony

- Contraction contributes >20% cardiac output
- Pacemaker syndrome
- Atrial fibrillation (18-47% vs. 0-17%)
- Heart failure
- Quality of life

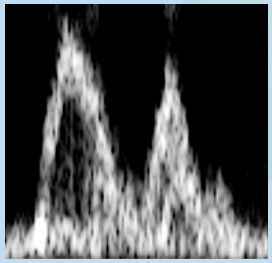
AV Synchronous Pacing Using a Ventricular Leadless Pacemaker: Primary Results from the MARVEL 2 Study

Larry A. Chinitz, MD; Surinder Kaur Khelae, MBBS; Christophe Garweg, MD; Joseph Yat Sun Chan, MD; Philippe Ritter, MD; Jens Brock Johansen, MD, PhD; Venkata Sagi, MD; Laurence M. Epstein, MD; Jonathan P. Piccini, MD, MHS; Mario Pascual, MD; Lluis Mont, MD, PhD; Todd J. Sheldon, MS; Vincent Splett, MS; Kurt Stromberg, MS; Nicole Wood, BS; Clemens Steinwender, MD

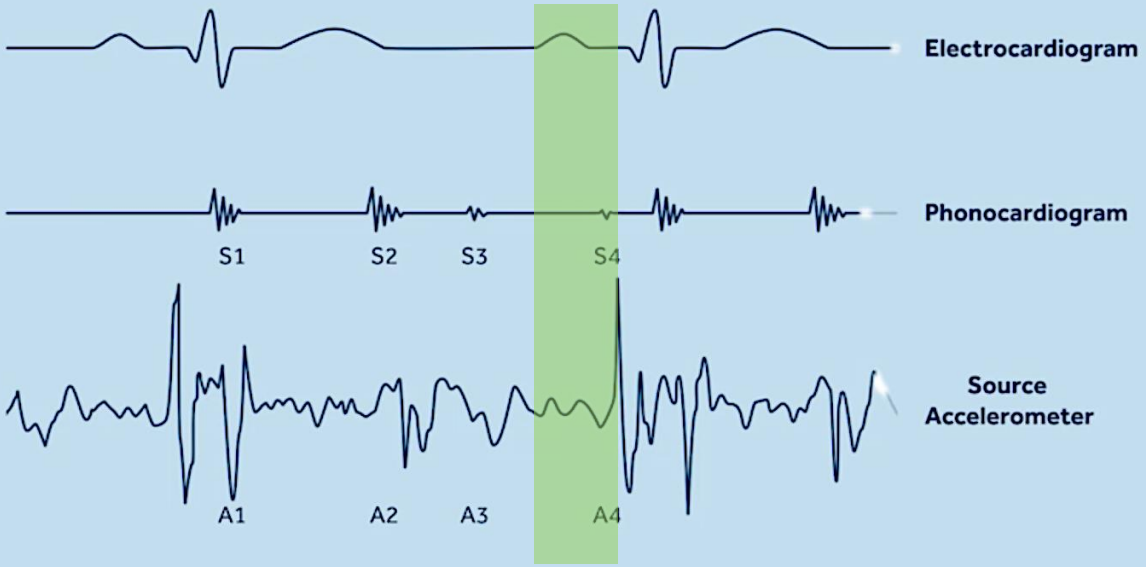

VDD

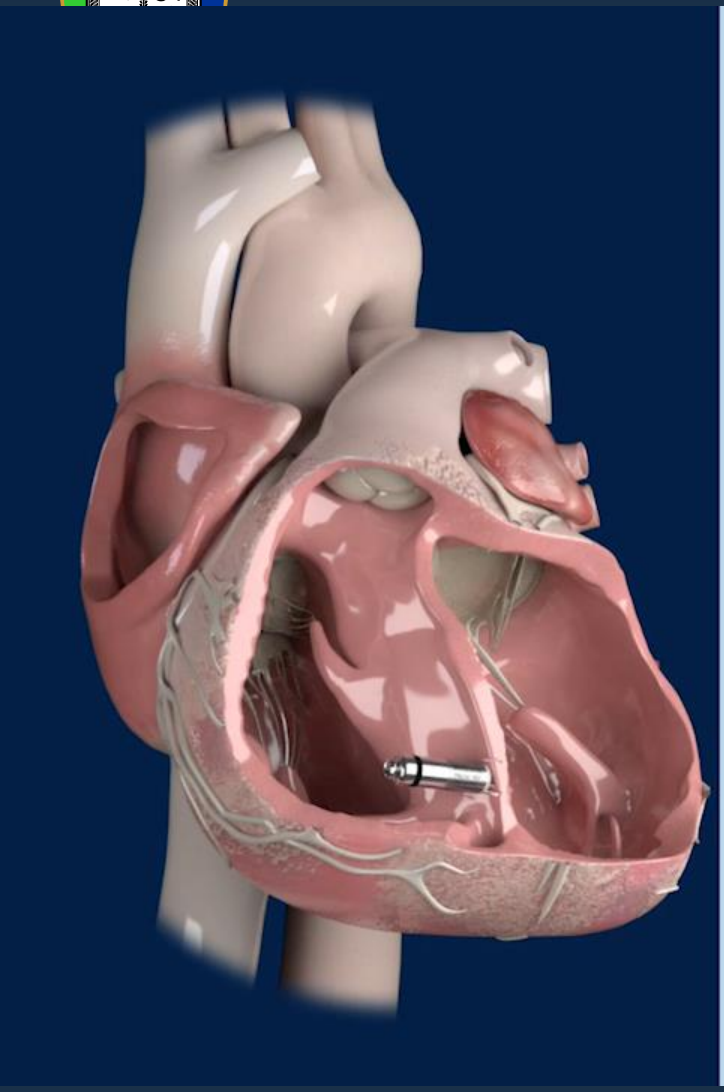


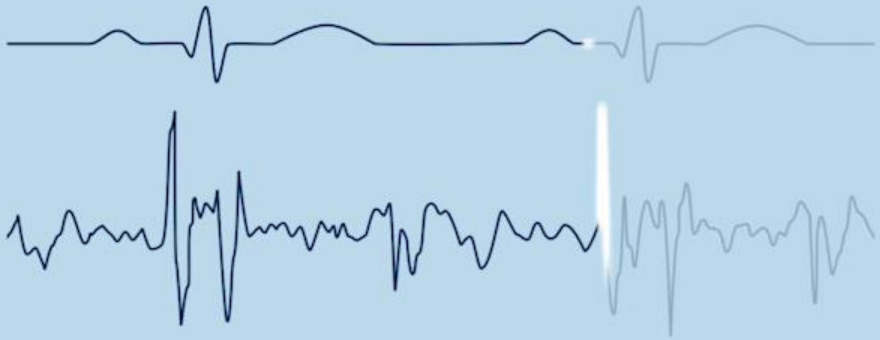
The **Micra 3-Axis Accelerometer** is used for:



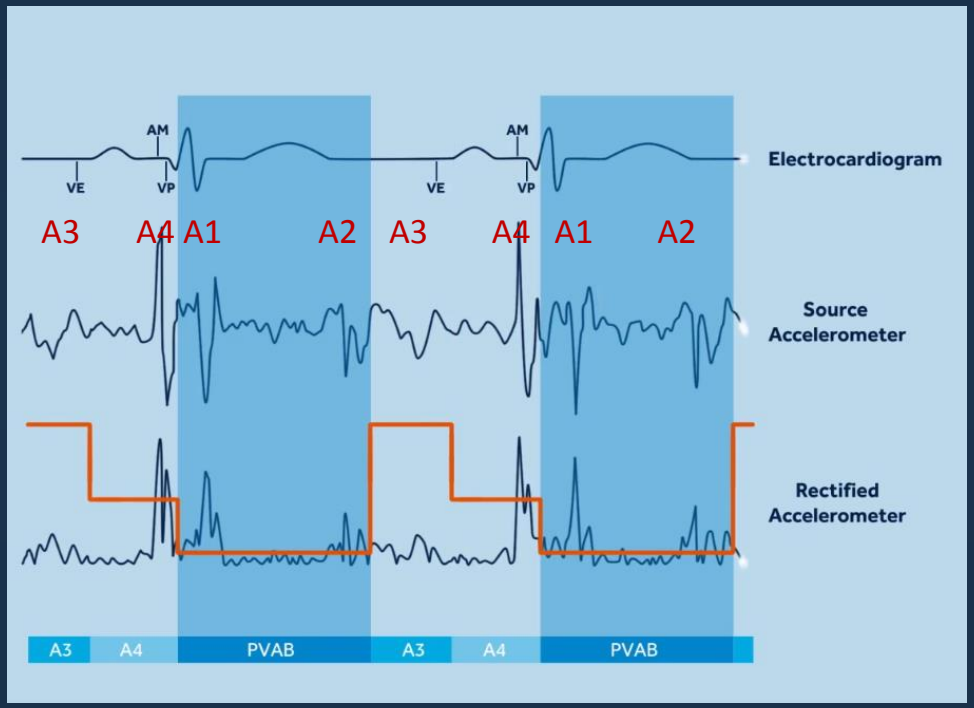
Vector 1 = X Direction
Vector 2 = Y Direction
Vector 3 = Z Direction






Electrocardiogram
Source
Accelerometer

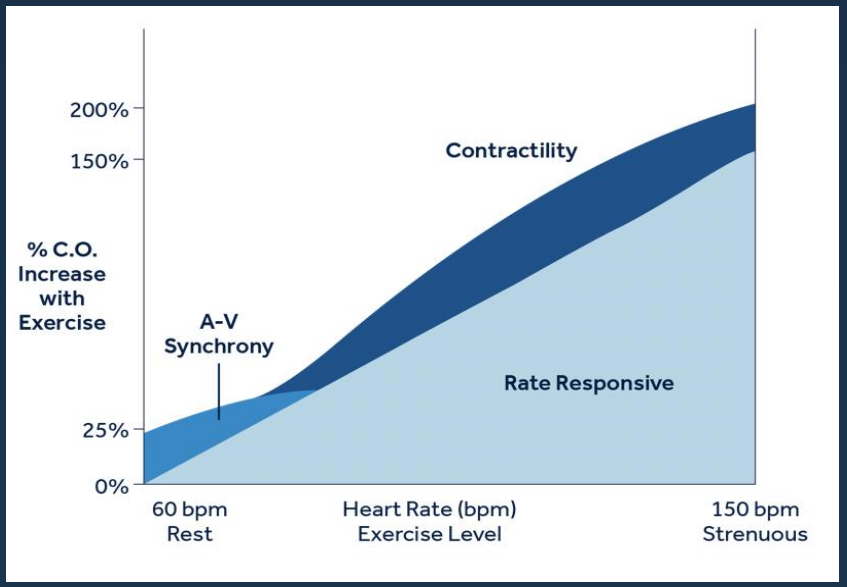
MARVEL 2 Algorithm

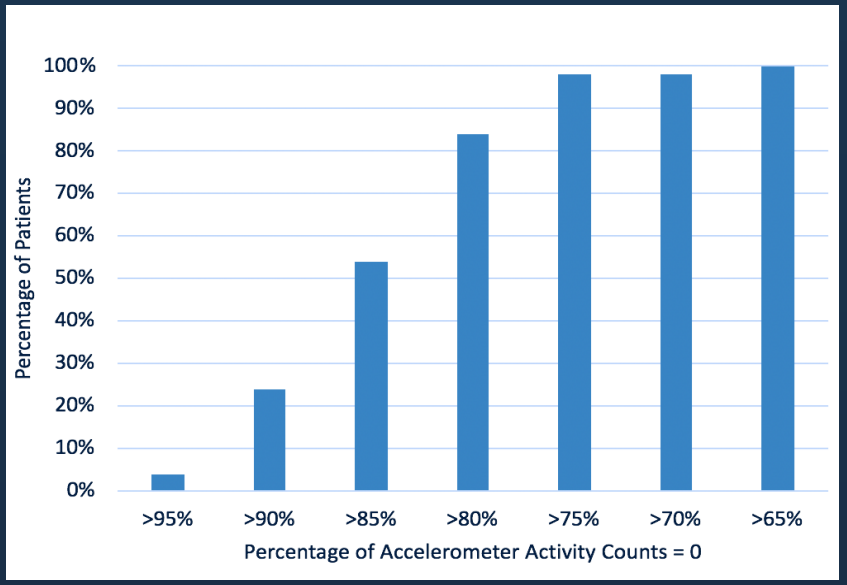


- Sense / pace QRS that marks A1
- PVAB 500-550ms to blank A1 and A2
- Algorithm automatically sets which accelerometer vector to use for detection; A3 threshold; A3 end; A4 threshold
- Mode-switch to VVI-40 for patients with intact AV conduction
- Mode-switch to VVIR during periods of high activity
- When A4 falls into PVAB during resting tachycardia, AM-VP delay will be progressively decreased to avoid sudden drop in pacing rate

AV synchrony during exercise matters?

- A positive chronotropic response provides 75% of the increment in cardiac output during exercise
- Only 8% of this increment was attributed to AV synchrony, and the rest was due to increase in HR
- 95% of patients with dual chamber pacemaker are inactive >75% of the time





Buckingham TA, et al. *Prog Cardiovasc Dis*. 1992;34:347-366.
Benditt DG, et al. *Ann Intern Med*. 1987;107:714-724.
Karloff I. *Acta Med Scand*. 1975;197:195-206.
Fananapazir L, et al. *Pacing Clin Electrophysiol*. 1983;6:601-608.
Sheldon T. Bradycardia Patient Activity Analysis. December 2019. Medtronic Data on File.

MARVEL 2 Study

- MARVEL 2 algorithm downloaded into existing Micra™ devices*
  - 75 patients enrolled & completed study procedures at 12 centers in Europe, the U.S., Malaysia, and Hong Kong
  - Continuous ECG monitoring at rest post-transplant
- Primary Efficacy Objective: Demonstrate increased AV Synchrony with MARVEL 2 (VDD pacing) vs. VVI-50 in patients with complete heart block and normal sinus rhythm (≥ 70% AV synchrony)
- Primary Safety Objective: Freedom from pauses and inappropriate tracking >100 bpm
- Secondary Objective: Demonstrate higher LVOT VTI in VDD vs. VVI

*For investigational use only. Algorithm was downloaded for up to 5 hours.

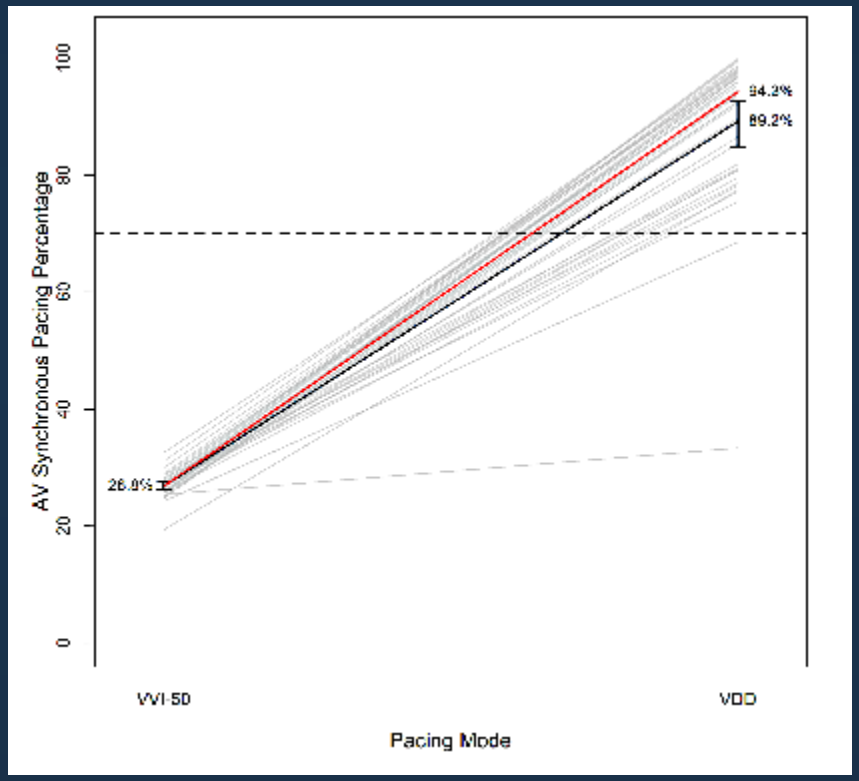
NCT number: NCT03752151

Baseline Demographics

	Downloaded MARVEL 2 Software (n = 75)	Evaluable for Primary Efficacy Objective (n =
Age (years)	77.5 ± 11.8	76.7 ± 12.9
Time since implant	13.8 ± 14.6 Range: 0-62.1	14.6 ± 16.6 Range: 0-62.1
Female	30 (40%)	22 (55%)
Hypertension	52 (69%)	28 (70%)
Paroxysmal AF	14 (19%)	3 (8%)
Diabetes	13 (17%)	6 (15%)
CAD	23 (31%)	8 (20%)
COPD	7 (9%)	4 (10%)

*Patients with complete heart block and normal sinus rhythm

Algorithm Performance vs. VVI at Rest



Primary Efficacy Objective:

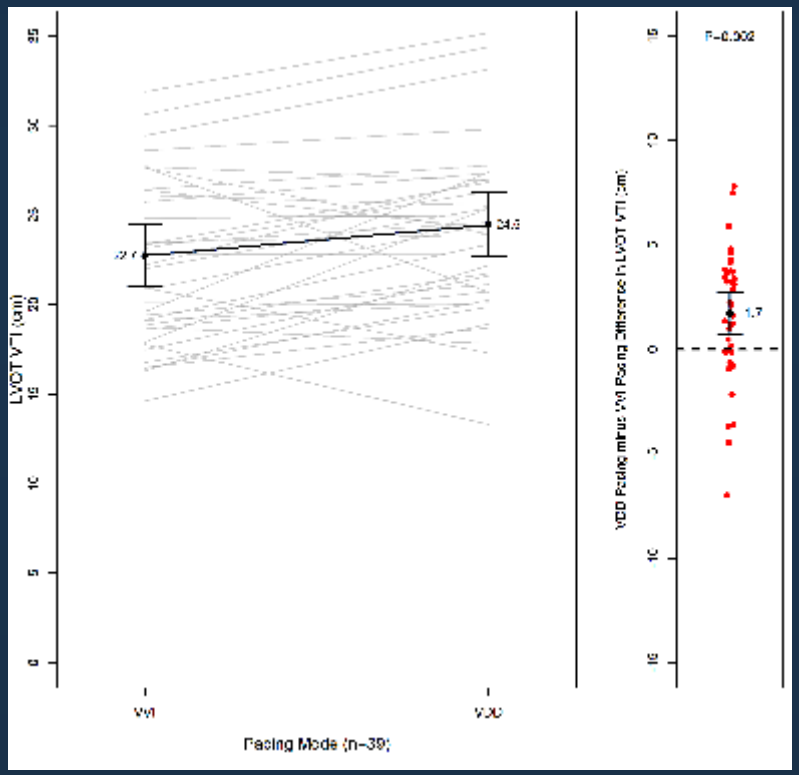
- The % of patients with ≥ 70% AV synchrony was significantly greater with VDD pacing vs. VVI-50 pacing **(95% vs. 0%, P < 0.001)**
- Median AV synchrony during VDD vs. VVI-50 was **26.8% vs. 94.3%**
- AV synchrony remained > 70% during postural maneuvers

MARVEL 2 Safety

Primary Safety Objective:

- **No pauses observed**
- **No oversensing-induced tachycardia observed**
- Six adverse events collected, none related to the investigational algorithm
- No adverse events reported due to lack of synchrony

Improved Stroke Volume



Secondary Objective:

- LVOT VTI increased **by 1.7 cm (8.8%, 95% CI: 0.7-2.7 cm, P = 0.002)** during VDD pacing

Mode Switching and Automaticity

- **Appropriate rate-related mode-switch**
  - The pacing mode remained in VVI-40 during periods of intrinsic AV conduction and appropriately switched to VDD during AV block
- **Appropriate activity-related mode switch**
  - Appropriate pacing support during hallwalk exercise
- **Efficient sensing algorithm**
  - The automatic algorithm was effective in choosing and adjusting most detection parameters throughout the study

Limitations

- Acute download study of research algorithm
- Current Micra™ VVIR device unable to efficiently process accelerometer signal for AV synchrony long-term
- Performance over time has yet to be evaluated

Patient selection

Patients with the following conditions should be considered for a dual-chamber transvenous pacing system:

- *Sinus node dysfunction*
- *Frequent premature atrial or ventricular contractions*
- *Symptoms during loss of AV synchrony*
- *High sinus rates requiring atrial tracking*
- *Weak atrial contraction*

Conclusions

- Accelerometer-based atrial sensing with a novel, automated, enhanced algorithm significantly improves AV synchrony in patients with AV block and a single chamber leadless pacemaker implanted in the right ventricle
- AV conduction and activity mode switches performed as intended
- No adverse events reported due to lack of synchrony

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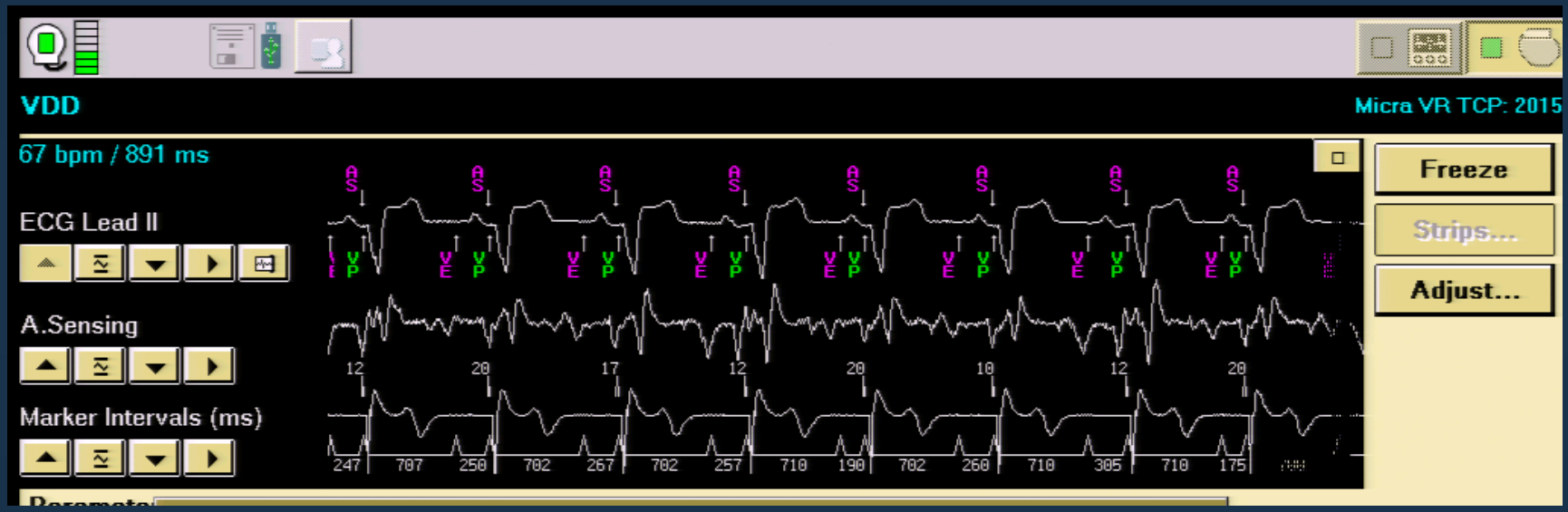
MARVEL 2 in AV block patients



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Potential benefit of leadless pacing

Redefined Patient Experience

- No chest scar
- No bump
- No visible or physical reminder of a pacemaker under the skin
- Fewer post-implant activity restrictions

Eliminated Pocket-related Complications[11]

- Infection
- Hematoma
- Erosion

Eliminated Lead-related Complications[11]

- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation

~1 in 8 patients treated with a traditional pacing system experience a complication attributed to the pocket or leads.[11]

Lead- and pocket-related complications can be costly to the hospital and patient.[10]

Cantillon DJ, et al. JACC Clin Electrophysiol. November 2017;3(11):1296-1305.
Udo EO, et al. Heart Rhythm. May 2012;9(5):728-735.

Journal Pre-proof

Atrioventricular synchronous pacing using a leadless ventricular pacemaker: Results from the MARVEL 2 study

Clemens Steinwender, MD, Surinder Kaur Khelae, MD, Christophe Garweg, MD, Joseph Yat Sun Chan, MD, Philippe Ritter, MD, Jens Brock Johansen, MD, PhD, Venkata Sagi, MD, Laurence M. Epstein, MD, Jonathan P. Piccini, MD, MHS, Mario Pascual, MD, Lluis Mont, MD, Todd Sheldon, MS, Vincent Splett, MS, Kurt Stromberg, MS, Nicole Wood, BS, Larry Chinitz, MD

INDICATIONS FOR USE

Micra™ AV Transcatheter Pacing System

Micra AV Model MC1AVR1 is indicated for use in patients who have experienced one or more of the following conditions:

- Paroxysmal or permanent high-grade AV block in the presence of AF
- Paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy
- Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy

INDICATIONS FOR USE

Micra™ AV Transcatheter Pacing System

(Indications for Use continued):

The device is also indicated for VDD pacing in patients with adequate sinus rates who may benefit from maintenance of AV synchrony.

The Micra AV device provides AV synchronous ventricular pacing similar to a transvenous VDD system. The implanted device depends on the appropriate sensing of atrial mechanical signals to achieve AV synchrony. The level of AV synchrony may vary in individual patients and may not be predictable prior to implant.

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

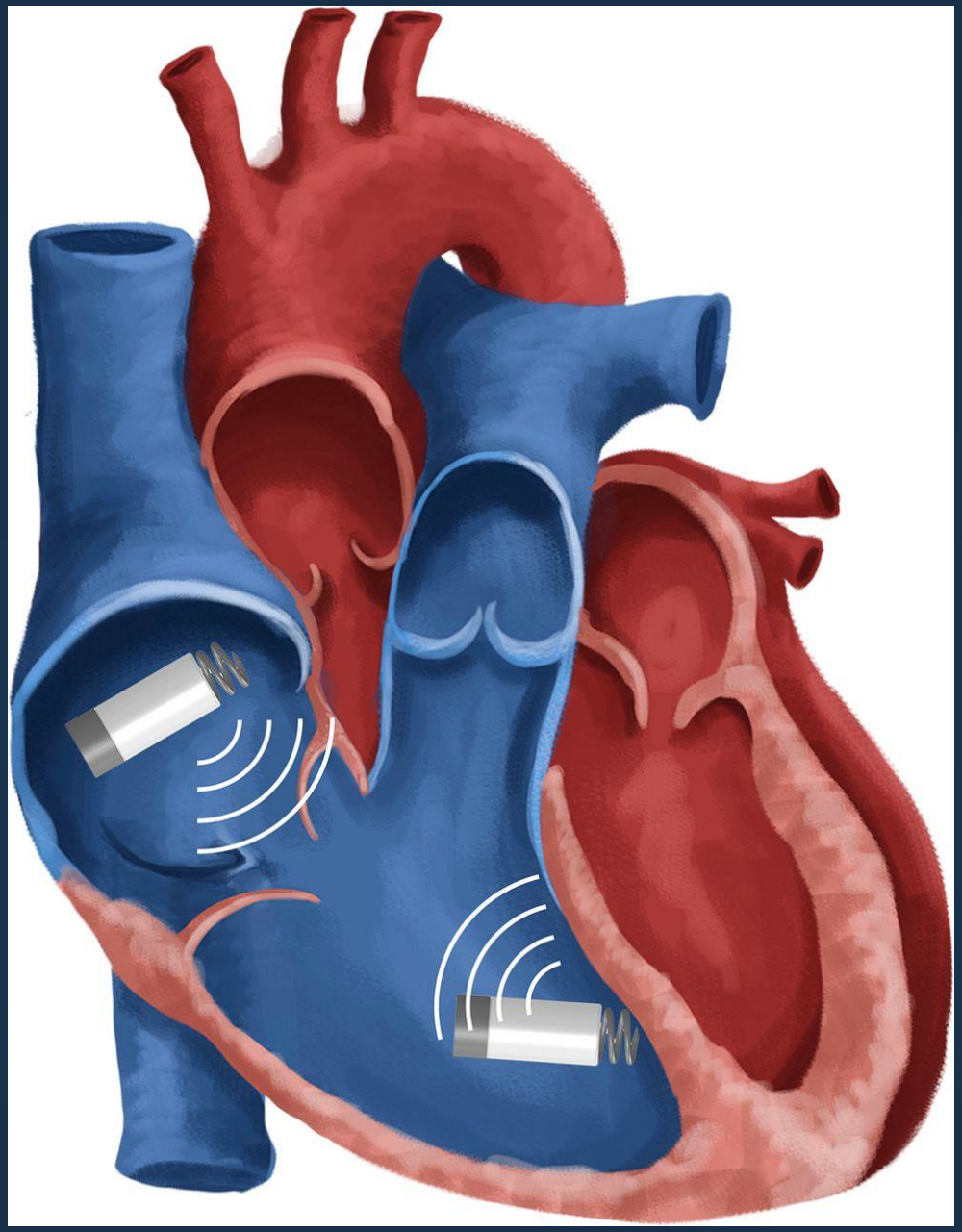
The device is designed to be used only in the right ventricle.

PRE-IMPLANT CONSIDERATIONS

Micra™ AV Transcatheter Pacing System

Pre-Implant Considerations

The Micra AV device is **intended to provide AV synchrony at rest and VVIR pacing during periods of high patient activity**. Synchronous ventricular pacing using sensing of atrial mechanical contraction may not provide continuous AV synchrony. Device-mediated AV synchrony can vary depending on patient condition and activity levels, and it can be limited at high sinus rates. During periods of intermittent AV synchrony, the device will provide ventricular pacing support with increased potential for pacing rate variability.



Bereuter L, et al. JACC Vol 3, Issue 6, December 2018. DOI:10.1016/j.jacbts.2018.07.009.