# Leadless Pacemaker: Current data and stage of development

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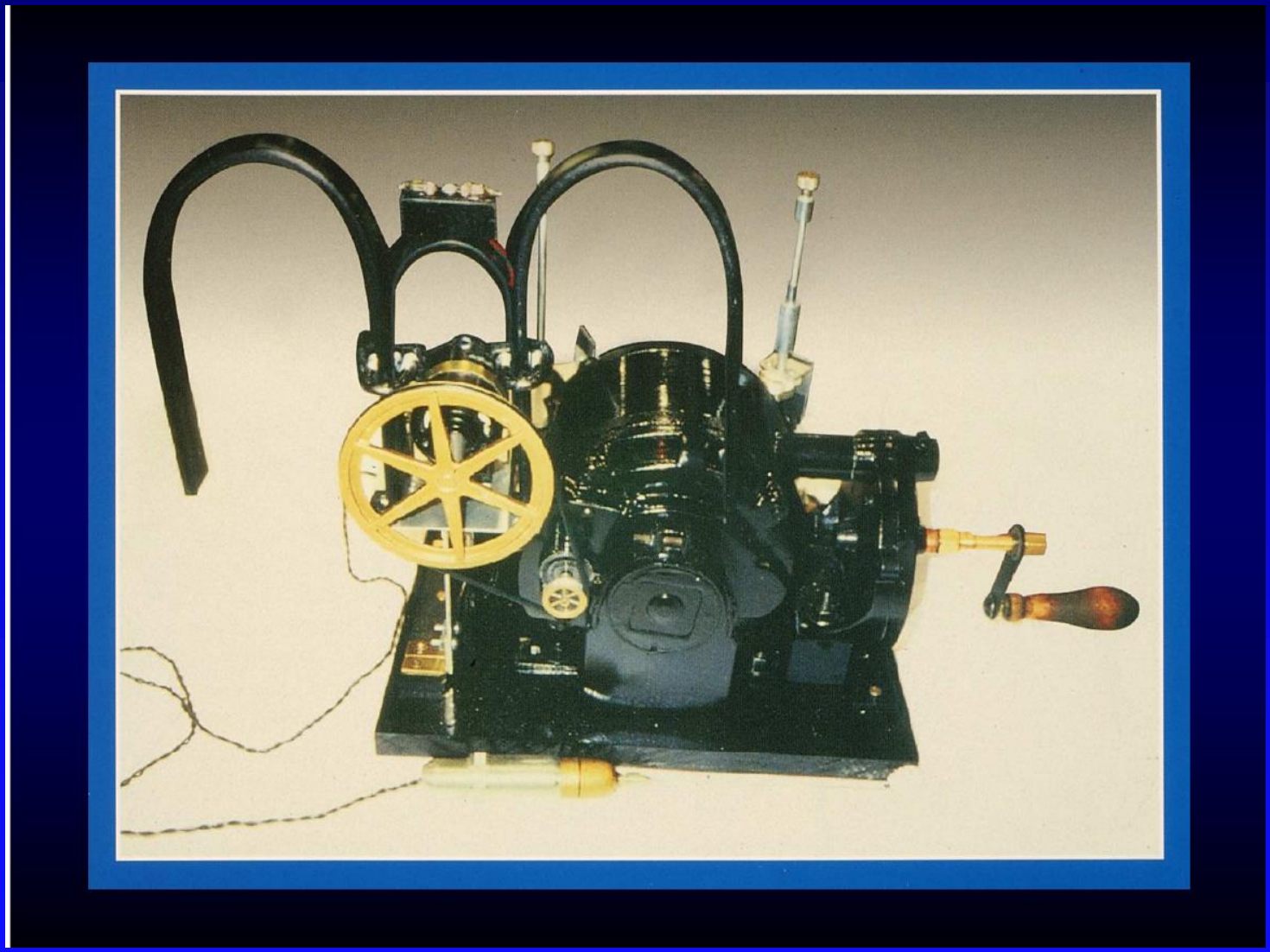
# Disclosure

Speakers fee, Advisory Board, Travel Support

- Biotronik
- Biosense
- Boston Scientific
- Medtronic
- Abbott
- Zoll

# First external PM (1932) Albert S. Hyman



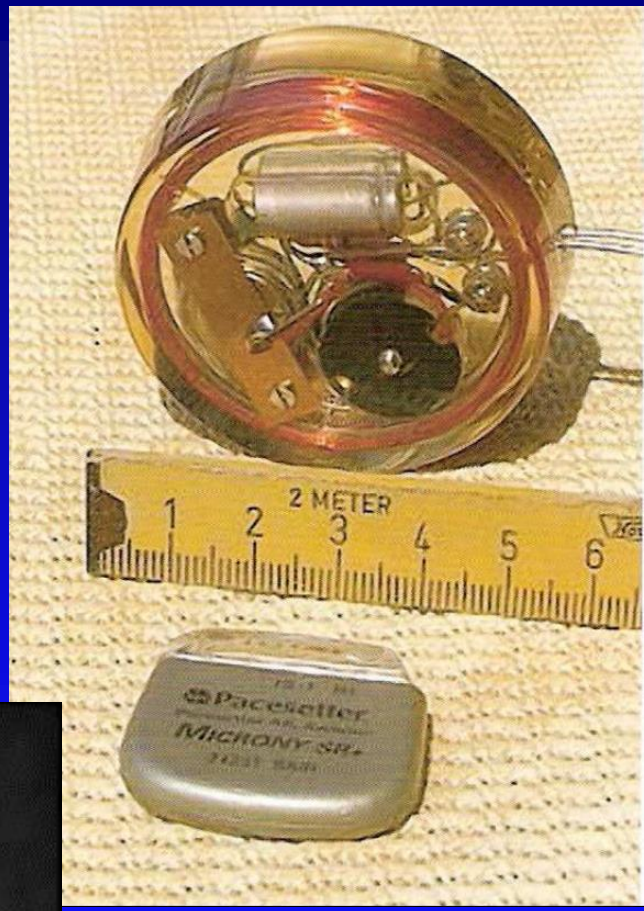
- Transthoracic stinged stimulation needle
- Induction of current using a crank hurdle

# Transvenous external PM (1958) - S. Furman

First Patient with an external transvenous PM system.
The stimulation catheter was left 13 weeks

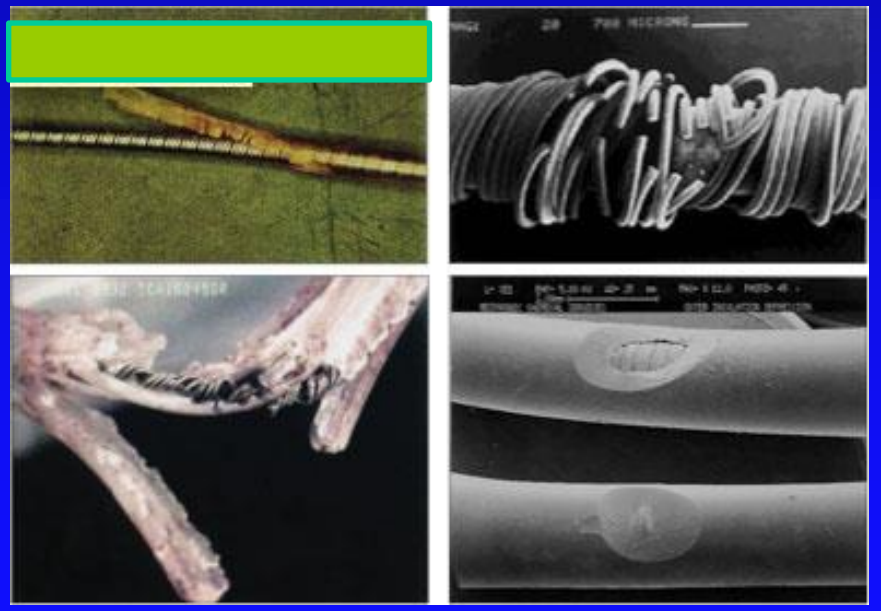
# 8th October 1958
# first implanted pacemaker

**Arne Larsson**
and his first PM



# PM-Pocket and Electrodes

- Pockets
  - Patient discomfort
  - Hematomas
  - Infections
  - Cosmestic concerns
- Leads
  - Mechanical failures
  - Infections
  - Extractions
  - Mobility restrictions
  - Incompatible w/ MRI



# Leadless Pacing

## The Micra Transcatheter Pacing System

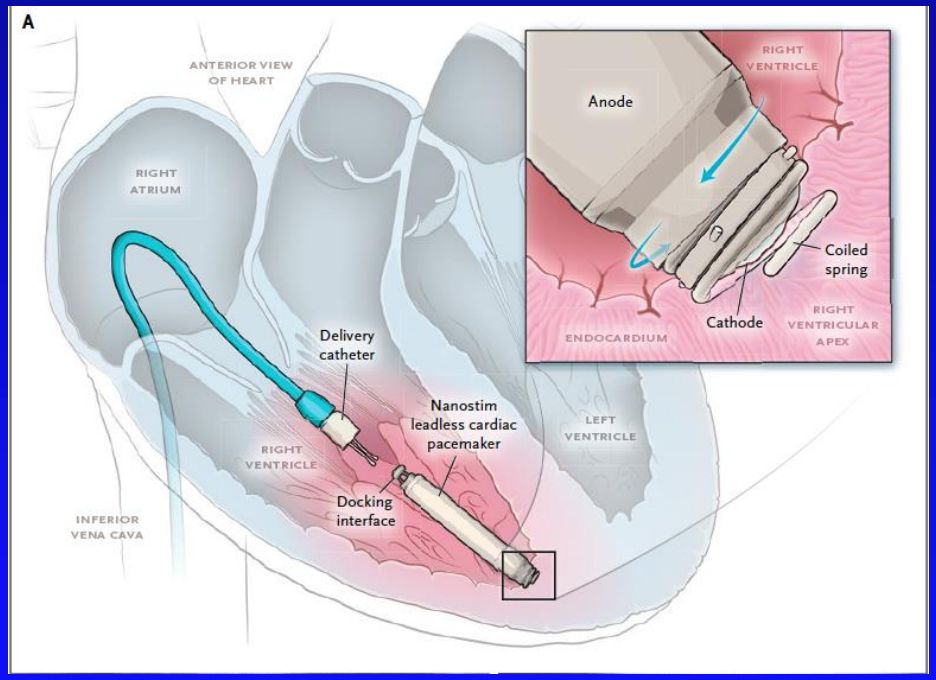
## Nanostim leadless cardiac pacemaker

## Boston Scientific ATP-enabled leadless pacemaker



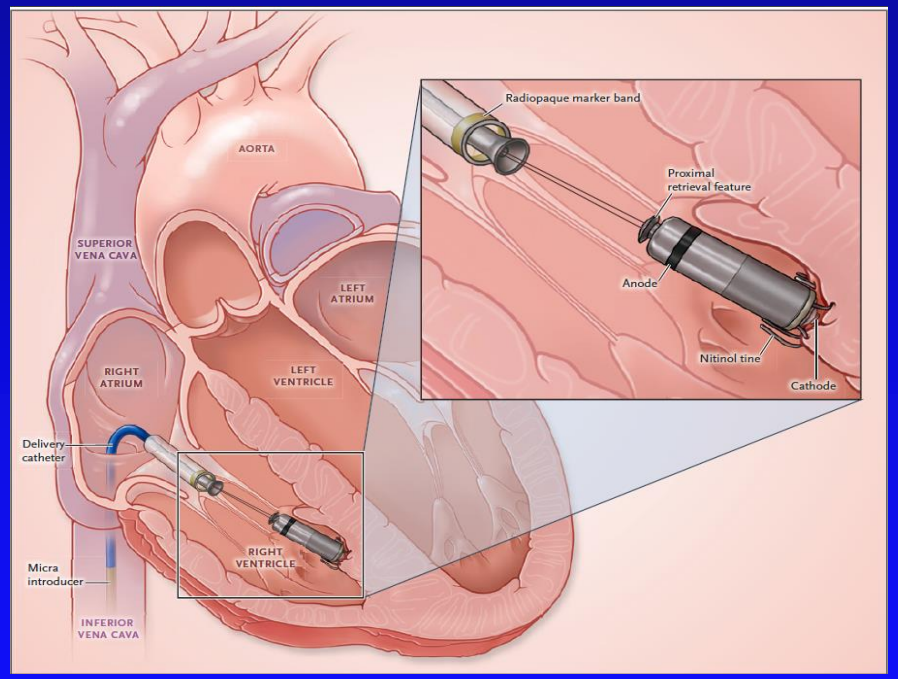
# Leadless Pacemakers

## Nanostim Leadless PM




Reddy et al. NEJM 2015

## Micra Leadless PM




Reynolds et al. NEJM 2016

# Summary of Nanostim LCP and Micra TPS investigational device exemption (IDE) trials

| Variables | Trials | |
|---|---|---|
| | Leadless II-LCP (n=526) | Micra-TPS (n=725) |
| Implant Success | 95.8% | 99.2% |
| Thresholds @ Implant (V@ms) | 0.82 @ 0.4 | 0.63 @ 0.24 |
| Threshold @ 6 Months (V@ms) | 0.53 @ 0.4 | 0.54 V @ 0.24 |
| Complication Rates (6 months) | 6.5% | 4% |
| Pericardial Effusion | 1.5% | 1.6% |
| Groin Complication | 1.2% | 0.7% |
| Device Dislodgement | 1.1% | 0% |

El-Chami et al. Am J Cardiol 2017;119:145e148

# Nanostim Battery Issue

1. • Batt … avai … ctrolyte … cells

2. • Dry … (imp … ery resistance

3. • This … elec … nec … revented the … receiving … ction

*Image of inside of a returned battery showing dry/opaque white separator.*

*Image of inside of a battery showing expected wet/transparent separator.*

# Micra Post Approval Registry
## Globally Diverse Patient Population

- 1,817 patients
- > 300 implanters
- 208 centers
- 31 countries
- Followed for an average duration of 3.6 ± 4.7 months (range 0-26)

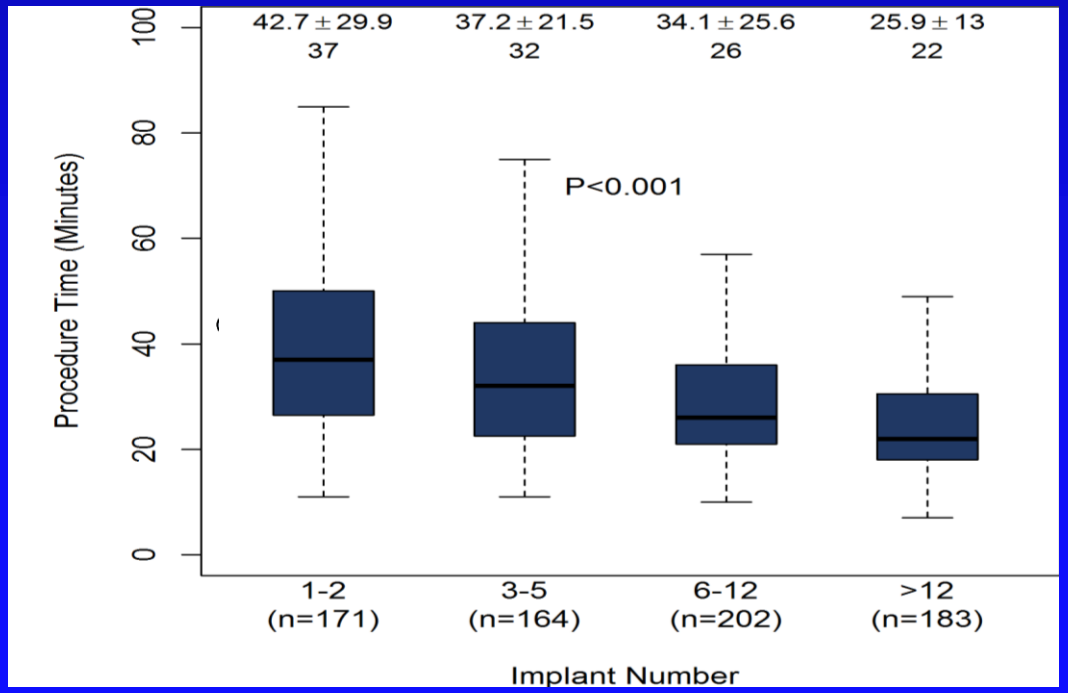
As of April 2018 data freeze

# Procedure Overview

## IDE AND REGISTRY

- **>99% implant success rate with >300 implanters**
- **Procedure times decreased by 2% from prior experience with each subsequent implant***
  - **Median implant time (introducer in/out) 28.0-32.3 min**

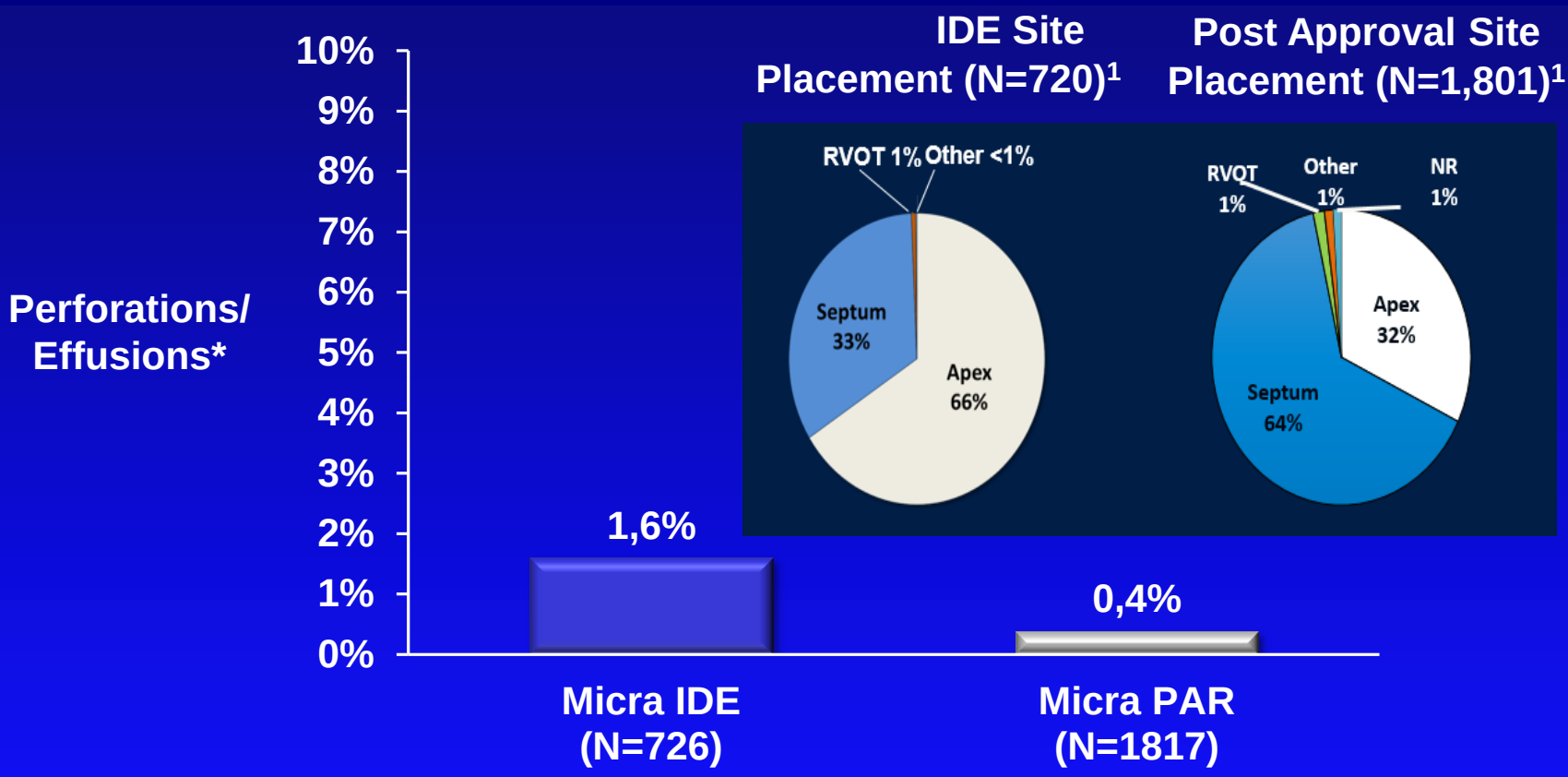
***After 12 implants, median implant time reduced to 25.9 mins***




*Results from IDE study


Duray et al. *Heart Rhythm*. 2017; 14:685-91
El-Chami MF et al. *Heart Rhythm*. 2017; In Press
El-Chami MF et al. *Pacing Clinical Electrophysiol.* 2017;1-9.
Nesse, H. Micra Clinical Evidence from IDE Trial and Post-Approval Registry. May 2018. Medtronic Data on File.

# Major Complications: Perforation / Effusion Rates Trending Lower

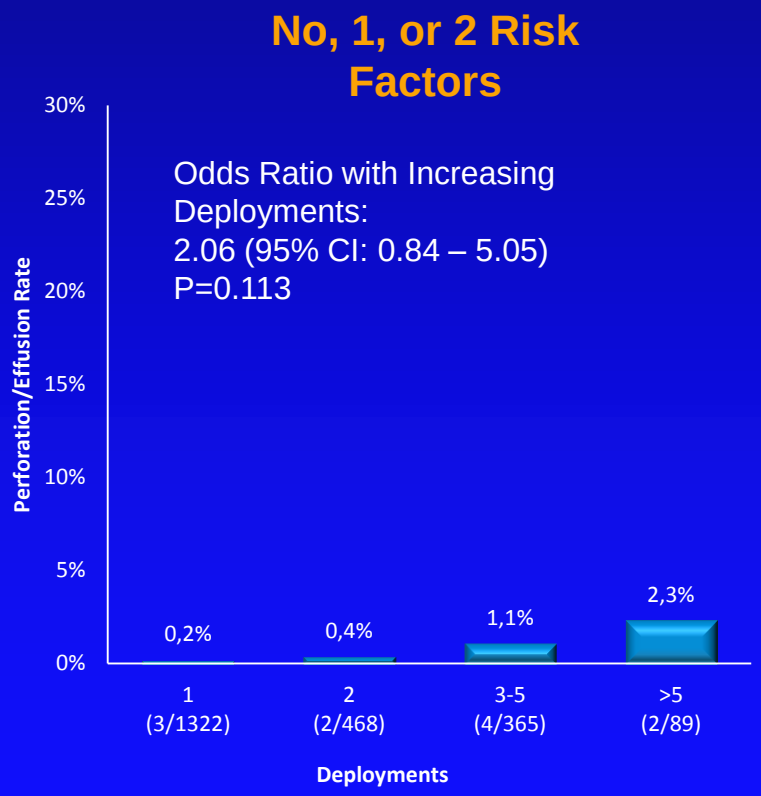


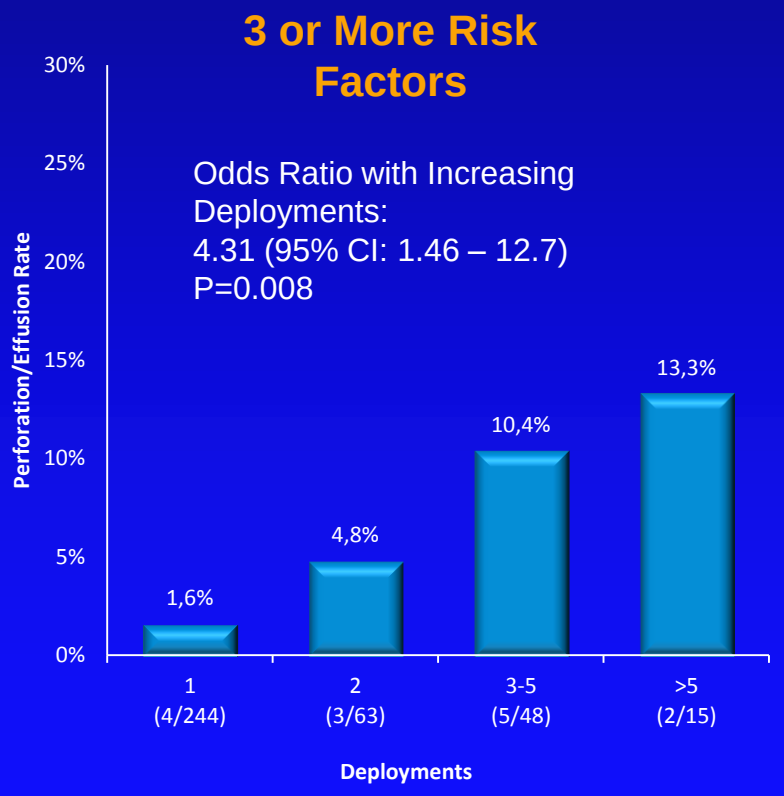

*For the IDE study, there were 13 total perforations/effusions (1.8%), 11 met the major complication criteria. For the Registry, there were 14 total perforations/effusions (0.77%), 8 met the major complication criteria.


Durayet al. *Heart Rhythm*. 2017; 14:685-91
El-Chami MF et al. *Heart Rhythm*. 2017; In Press
Nesse, H. Micra Clinical Evidence from IDE Trial and Post-Approval Registry. May 2018. Medtronic Data on File

# Perforation/Effusion Risk factors

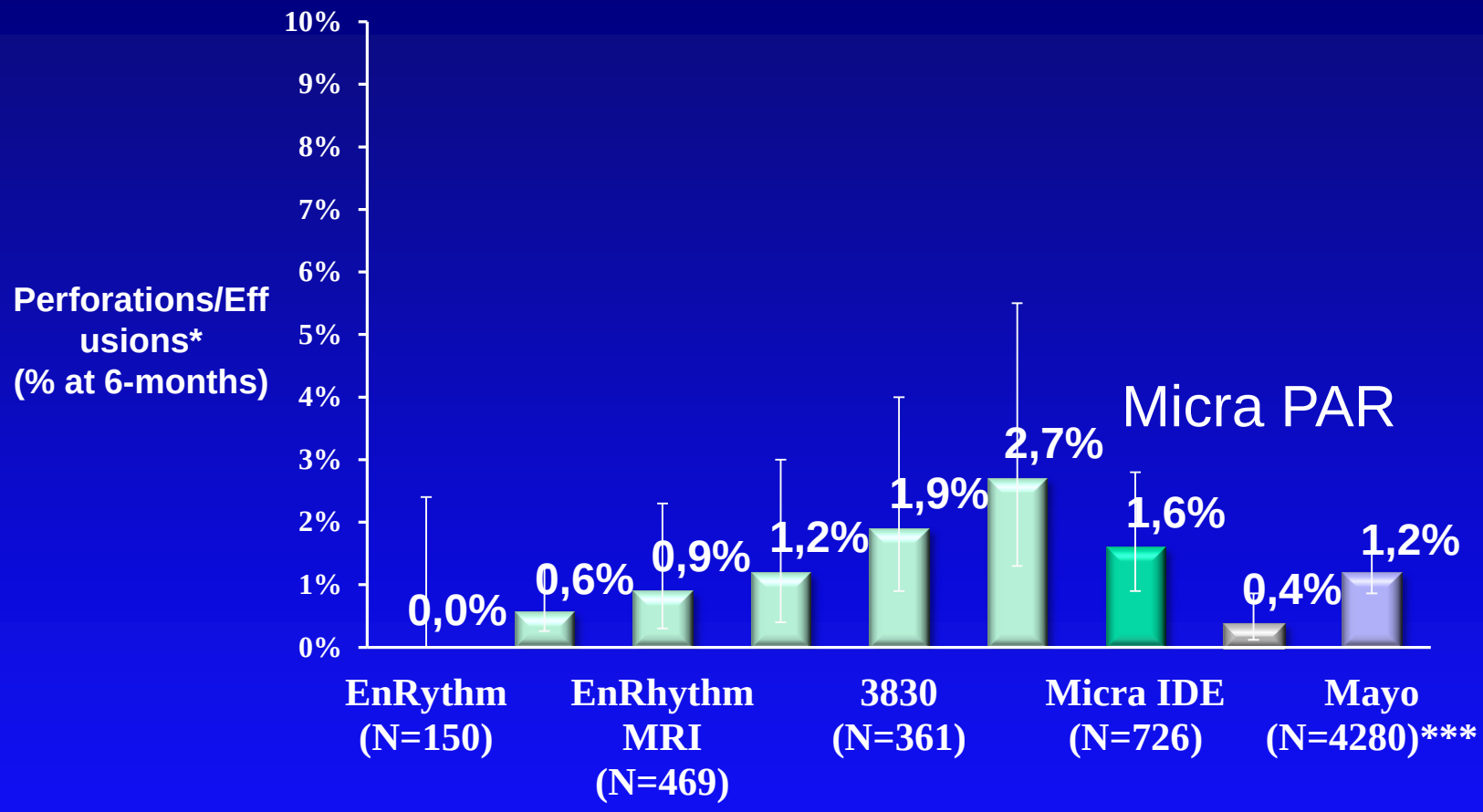
- Analysis of 2,500 pts. undergoing Micra implant by 335 physicians
- Risk factors for perforation/effusion: Age >85, low BMI, female sex, and COPD




1. Mont L. Risk Factors For Cardiac Perforation/Effusion in Leadless Pacemaker Patients: Experience With The Micra Transcatheter Pacemaker. HRS 2018; May 9, 2018; Boston, MA.

# Perforation / Effusion Rates



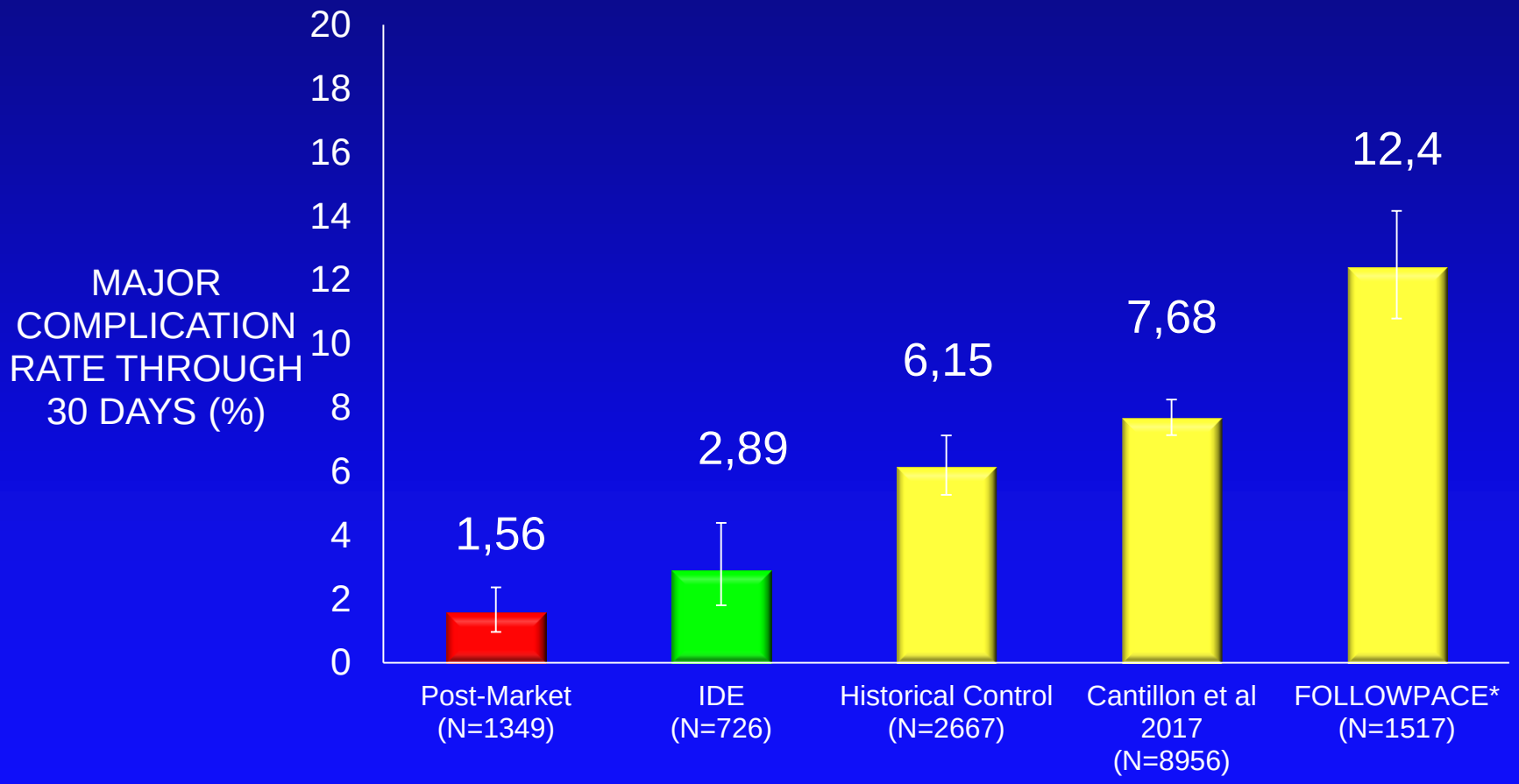

- **Meeting major complication endpoint criterion**

**** PAR major complications assessed through 30-days**

***** Clinical signs and symptoms of perforation from Mahapatra et al., 2005**


1. Reynolds DW. A Leadless Intracardiac Transcatheter Pacing System. *N Engl J Med*. Supplementary Index. February 11, 2016;374(6):533-541.
2. El-Chami MF. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results from the Micra Post-Approval Registry. Presented at: HRS 2018; May 10, 2018; Boston, MA.

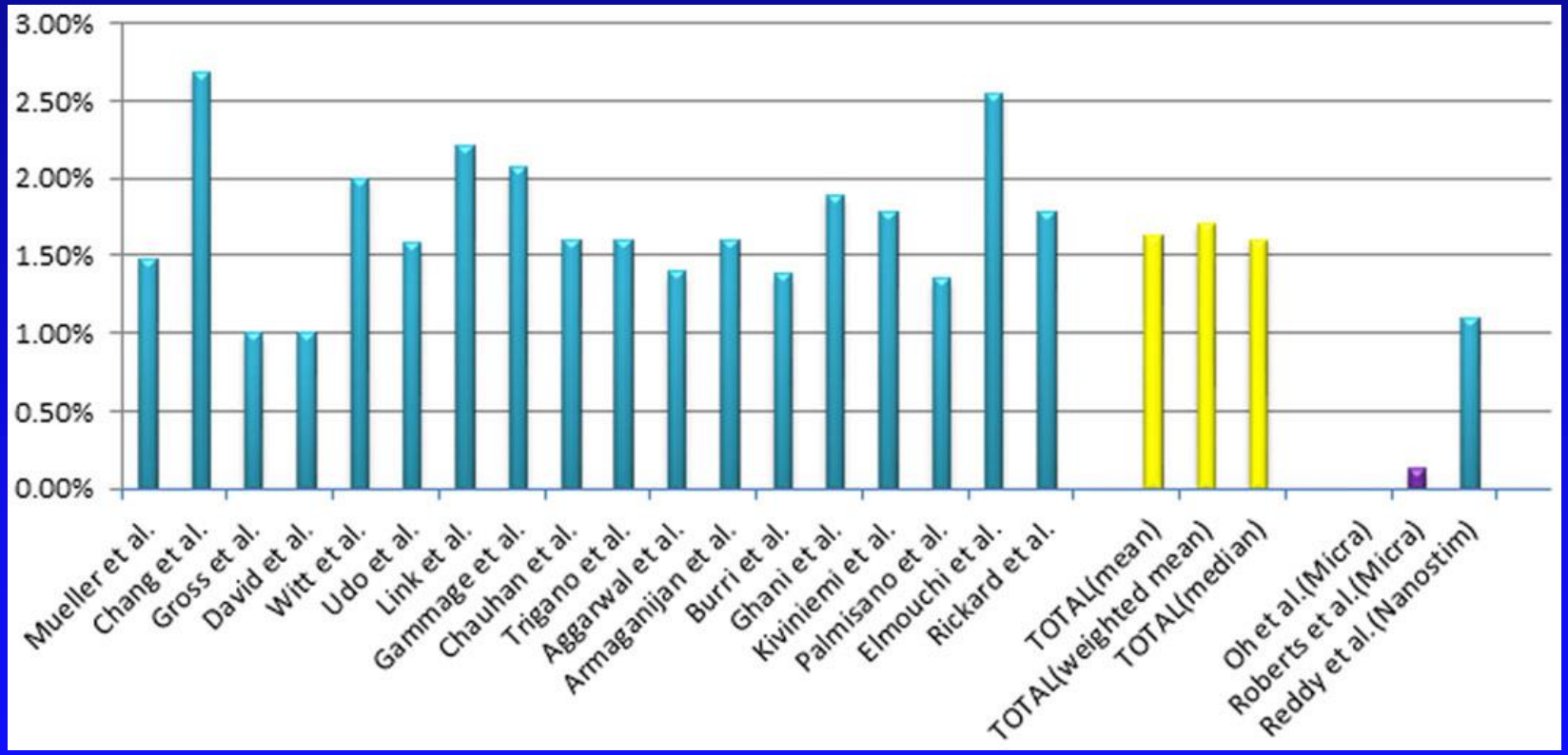
# Fewer Major Complications with Micra versus Transvenous VVI




*FOLLOWPACE complication rate is reported through 2 months

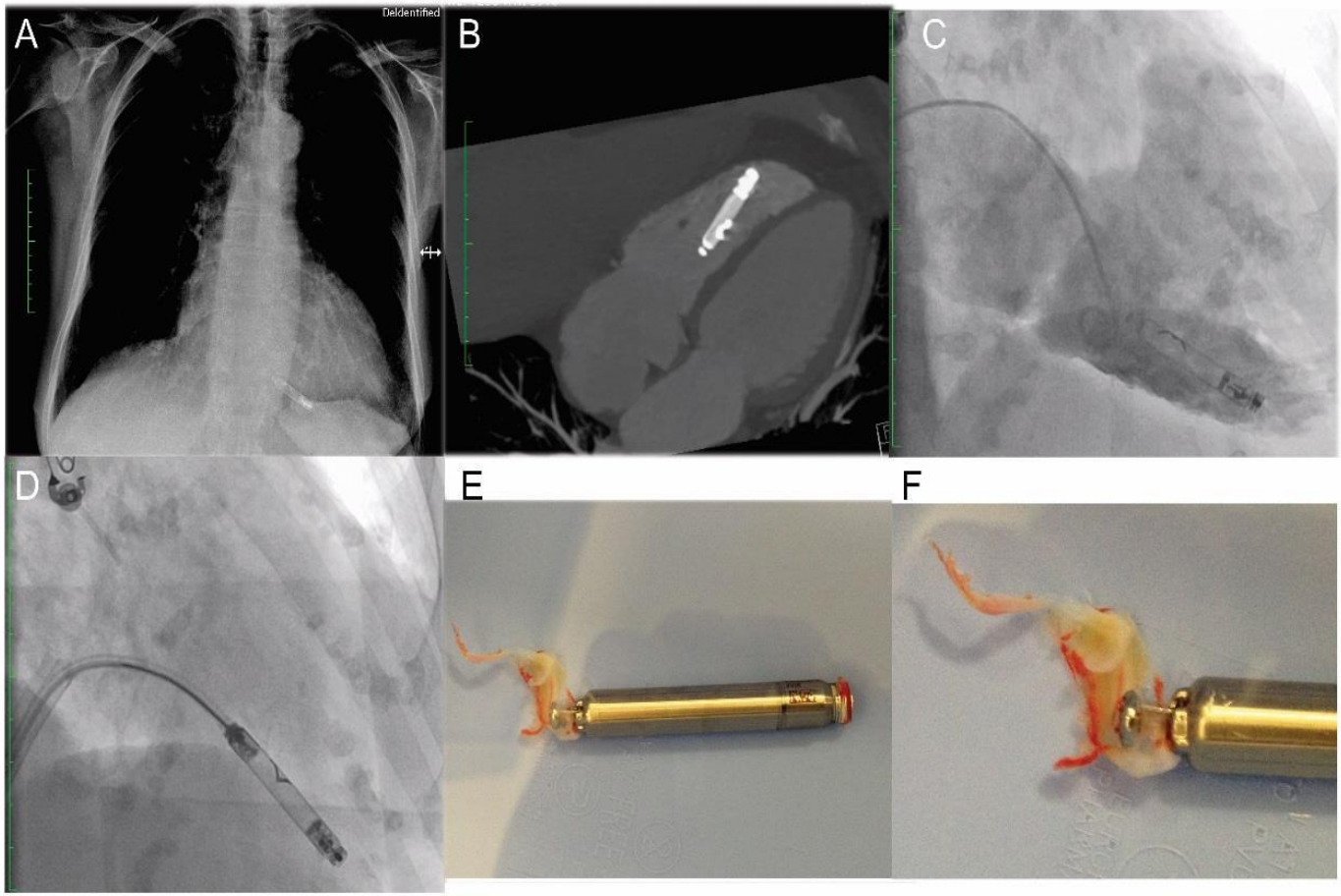
Duray GZ, et al *Heart Rhythm* 2017; Cantillon, et al *JACC EP* 2017; Udo, et al. *Heart Rhythm* 2012

# Incidence of pacemaker lead dislodgement in different studies




Wang et al. Pacing Clin Electrophysiol. 2018;41:1365–1371

A: X-ray and B: computer tomography image showing device in place before procedure;
C: Right ventricular angiography prior to snaring the device;
D: snare docked with the device; E: extracted device; F: fibrosis around docking knob

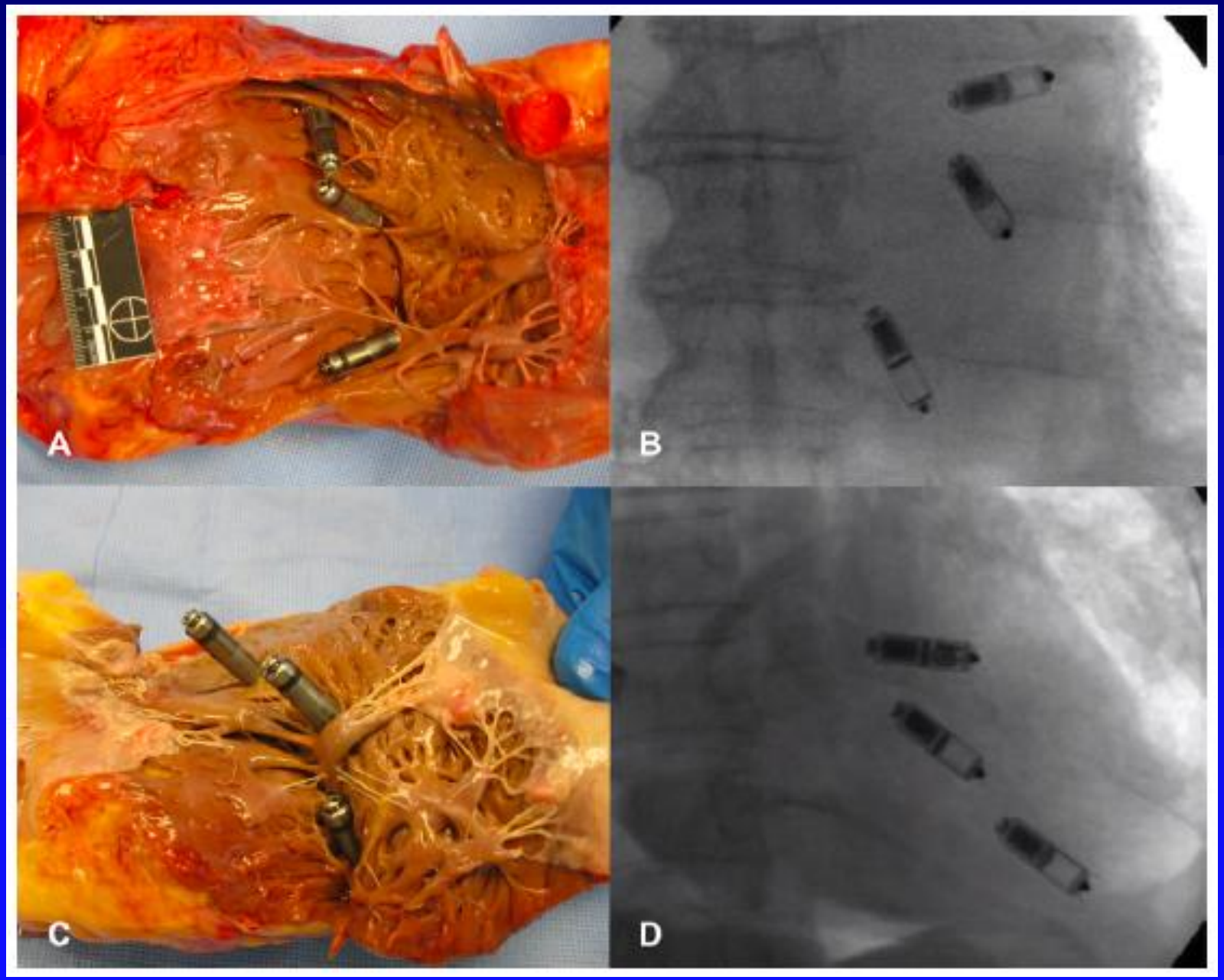



Jung et al. published online Europace first of July, 2016

Jung et al. published online Europace first of July, 2016

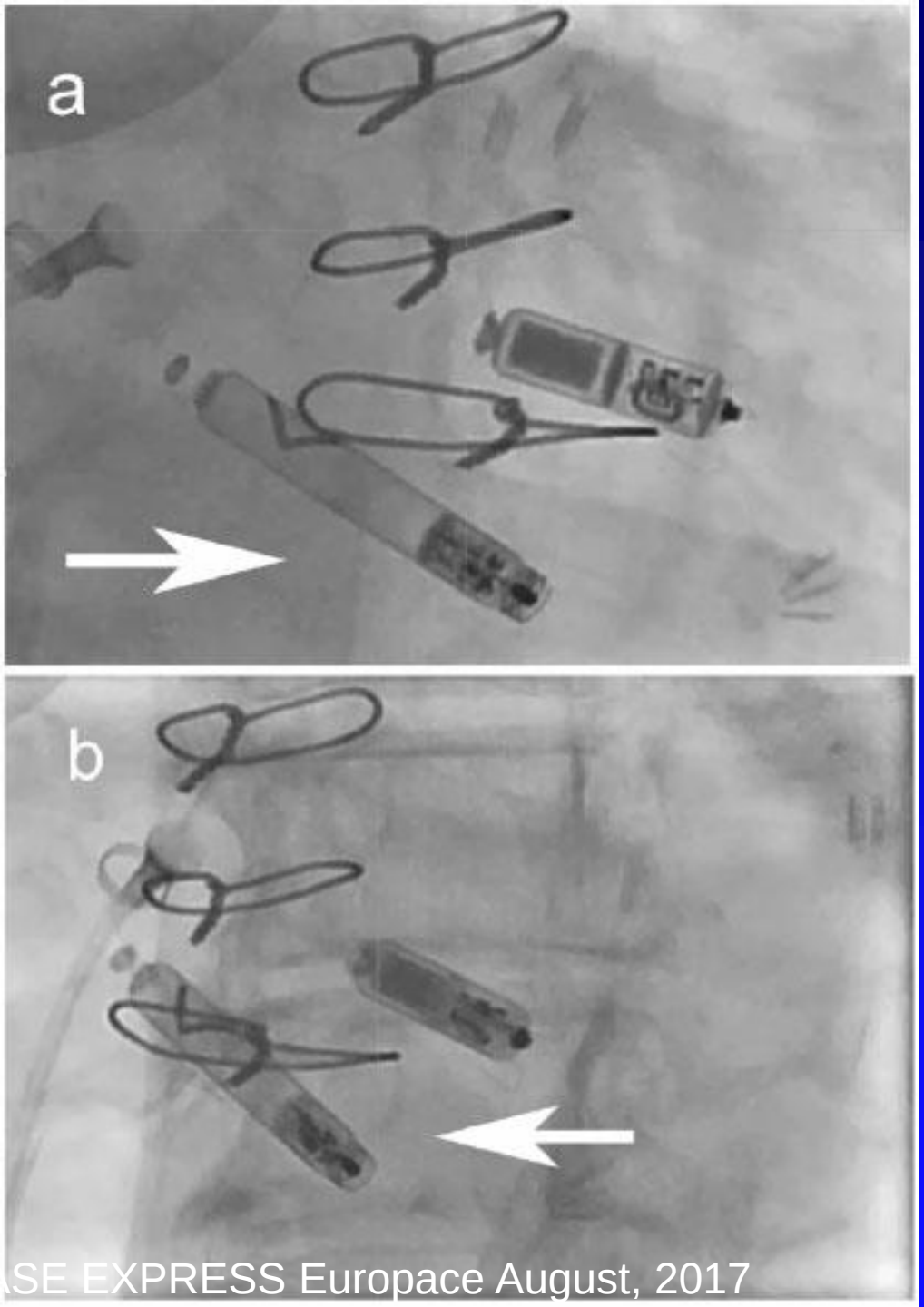
# Extraction of the Leadless Cardiac Pacemaker: A Multi-Center Experience


Reddy,... Jung et al. Circulation AE, 2016


A
B
C
D

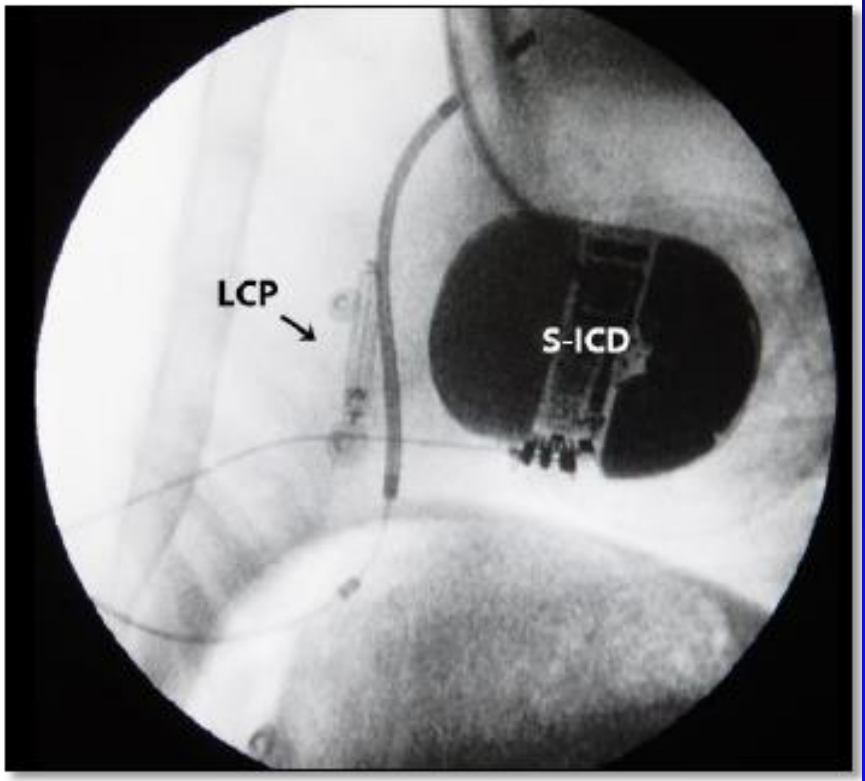
# RAO View: Pull and Hold Test


Jung et al. EP CASE EXPRESS Europace August, 2017




Jung et al. EP CASE EXPRESS Europace August, 2017

# Leadless Pacemaker and Subcutaneous Defibrillator

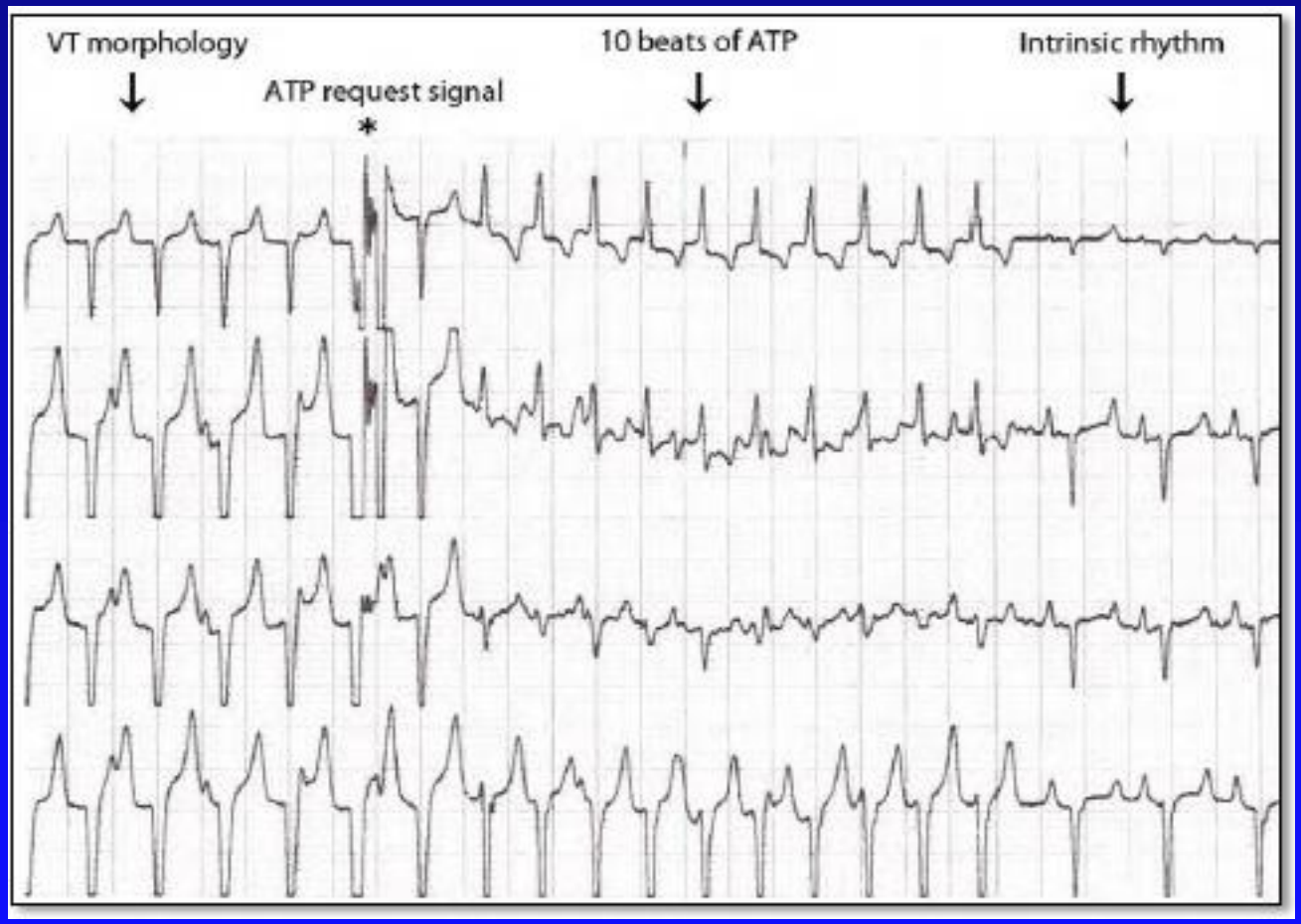




Images of the Prototype LCP, along with prototype firmware of S-ICD

Tjong et al, JACC Letters, http://dx.doi.org/10.1016/j.jacc.2016.02.039

Images Courtesy of Dr.Tjong

# The First Report on Communicating Leadless Anti-Tachycardia Pacemaker and Subcutaneous Implantable Defibrillator



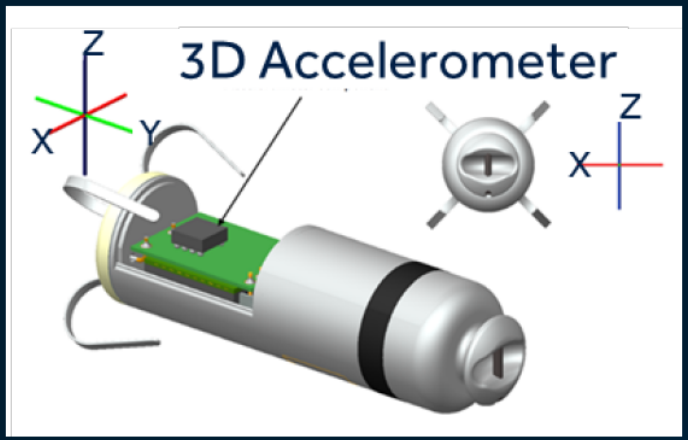

Tjong et al, ACC2016,Moderated Poster Session, First Report on Communicating Antitachycardia Pacing-Enabled Leadless Pacemaker and Subcutaneous Implantable Defibrillator

**Accelerometer-based atrioventricular synchronous pacing with a ventricular leadless pacemaker: Results from the Micra atrioventricular feasibility studies**

Larry Chinitz, MD, FHRS,* Philippe Ritter, MD,† Surinder Kaur Khelae, MBBS, FHRS,‡ Saverio Iacopino, MD,§ Christophe Garweg, MD,¶ Maria Grazia-Bongiorni, MD,‖ Petr Neuzil, MD,** Jens Brock Johansen, MD, PhD,†† Lluis Mont, MD, PhD,‡‡ Efrain Gonzalez, MD,§§ Venkata Sagi, MD, FHRS,¶¶ Gabor Z. Duray, MD, PhD,‖‖ Nicolas Clementy, MD,*** Todd Sheldon, MS,††† Vincent Splett, MS,††† Kurt Stromberg, MS,††† Nicole Wood, BS,††† Clemens Steinwender, MD‡‡‡§§§

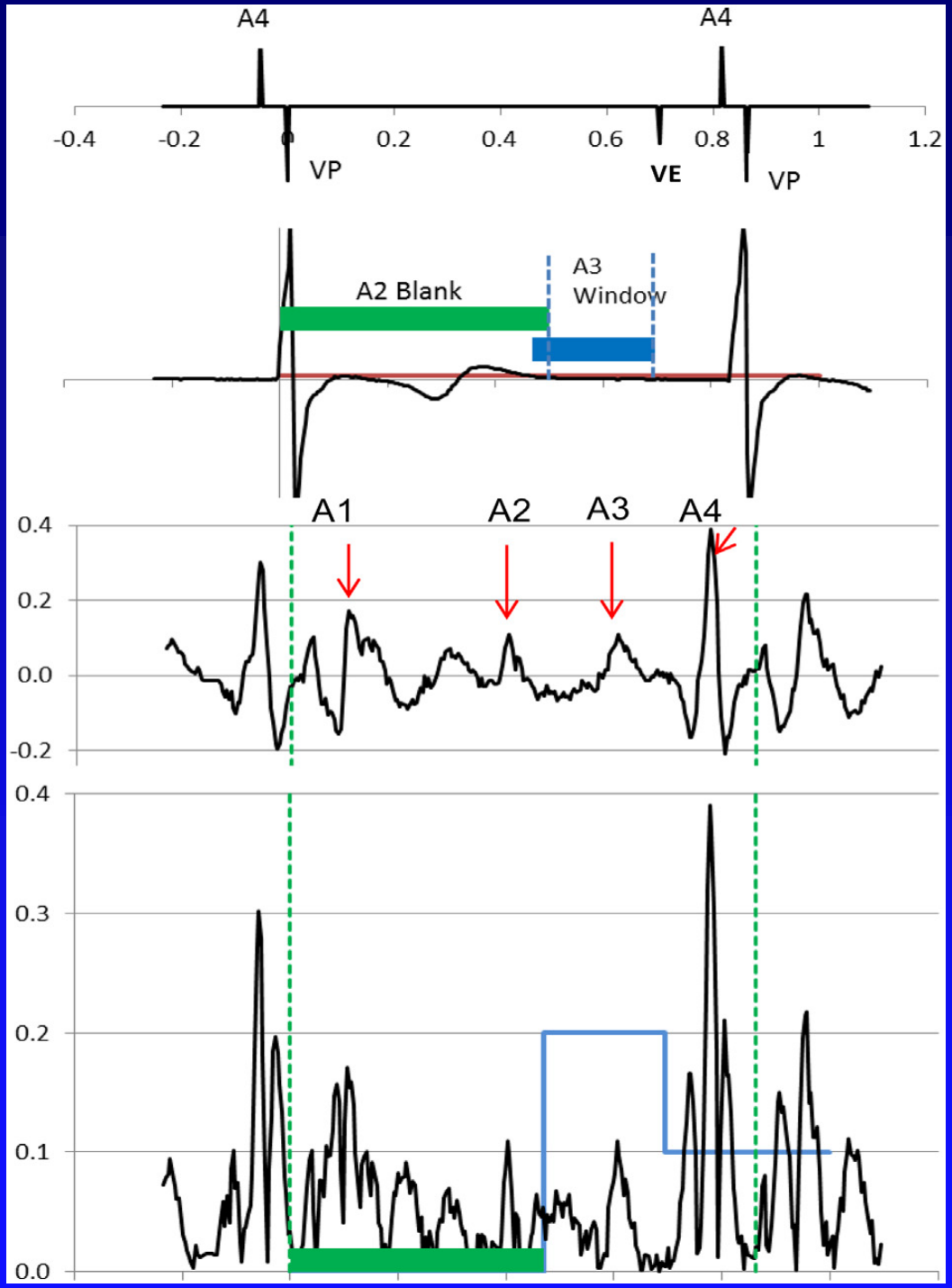
# Micra Accelerometer Technology

- Sensing the atrial activity is necessary to provide AV synchrony
- Micra contains a 3 axis accelerometer
- Sensing the atrial contraction using the accelerometer may provide a signal for AV synchrony




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

Chinitz, et al. Heart Rhythm 2018;15:1363–1371




# Overview of the atrioventricular synchronous algorithm developed from MASS/MASS2 accelerometer signals

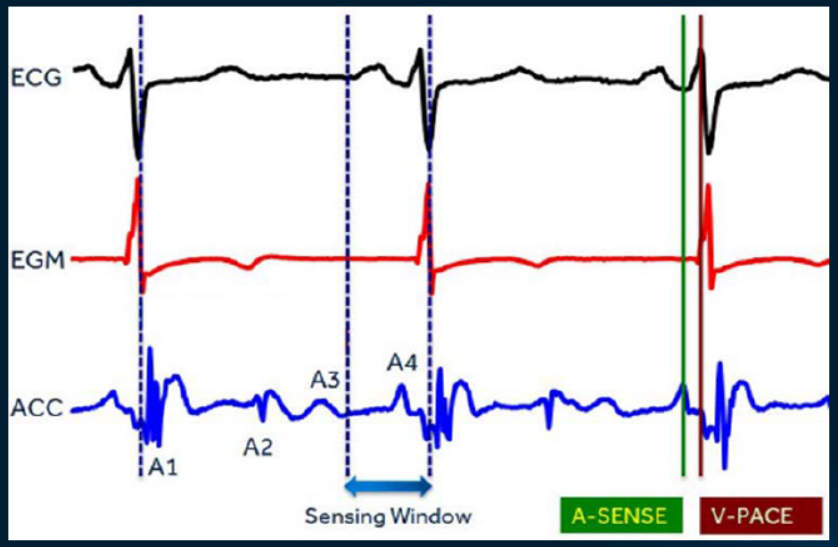
Chinitz, et al. Heart Rhythm 2018;15:1363–1371

# Atrial Contraction Detection Via Accelerometer

- MASS/MASS2 studies collected open-loop data
  - N=75 patients
  - Showed intracardiac accelerations related to atrial contraction can be measured via the accelerometer in Micra
- MARVEL tested the closed loop performance

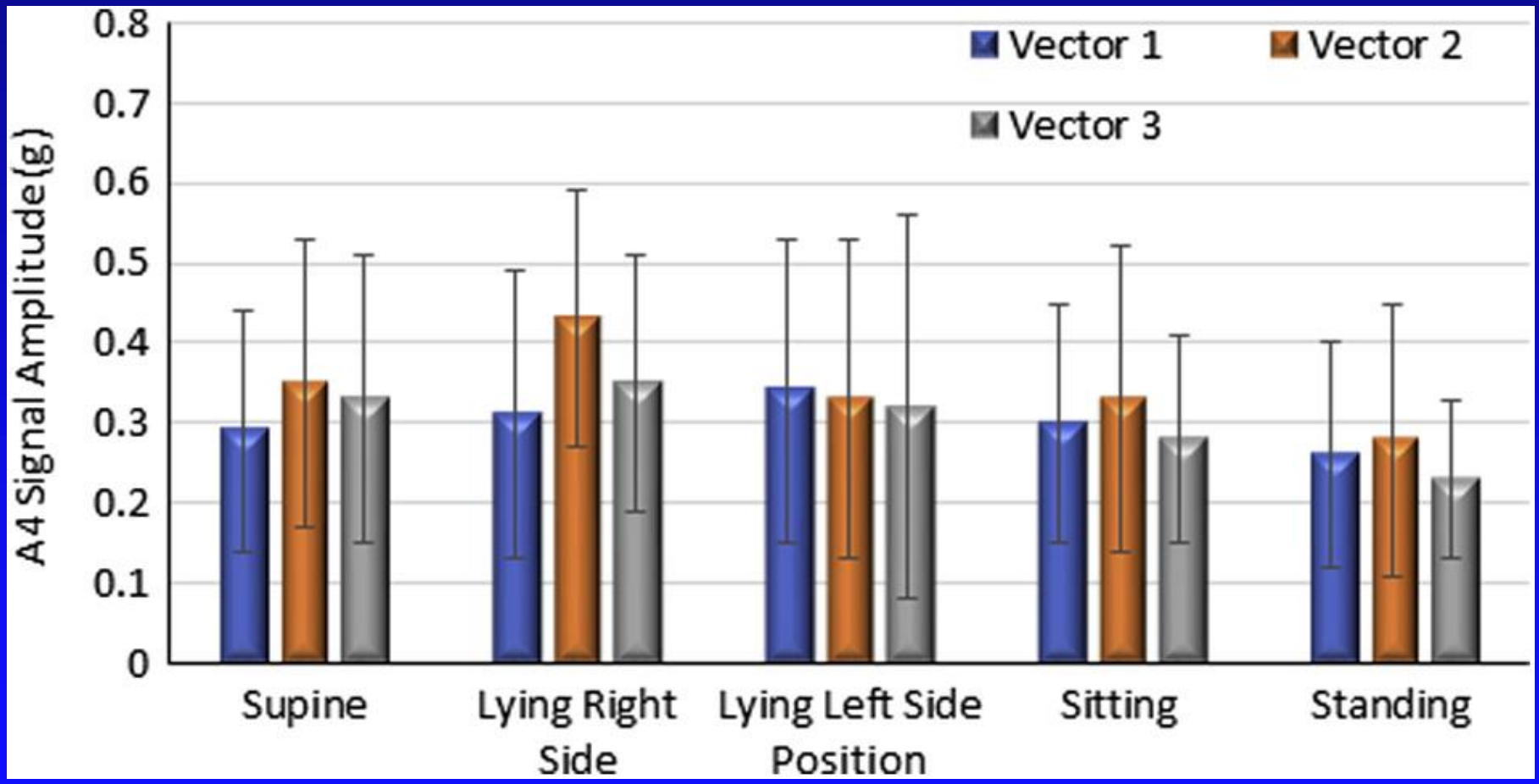
Algorithm is for investigational use only

NCT numbers: NCT02930980, NCT03157297




- **A1** – Isovolumic contraction and mitral/tricuspid valve closings
- **A2** – Aortic/pulmonic valve closing
- **A3** – Early passive ventricular filling
- **A4** – Atrial contraction generating active filling

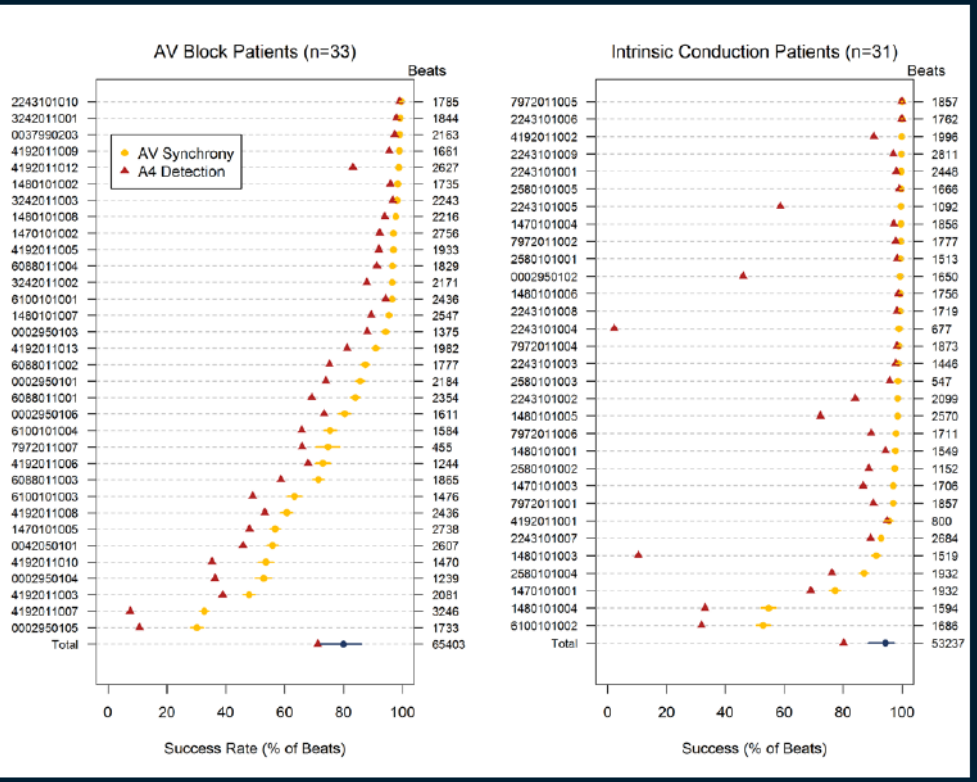
# A4 signal amplitude from patients with normal sinus function and intrinsic conduction requiring infrequent pacing




Chinitz, et al. Heart Rhythm 2018;15:1363–1371

# Marvel Study (n= 64 pts)

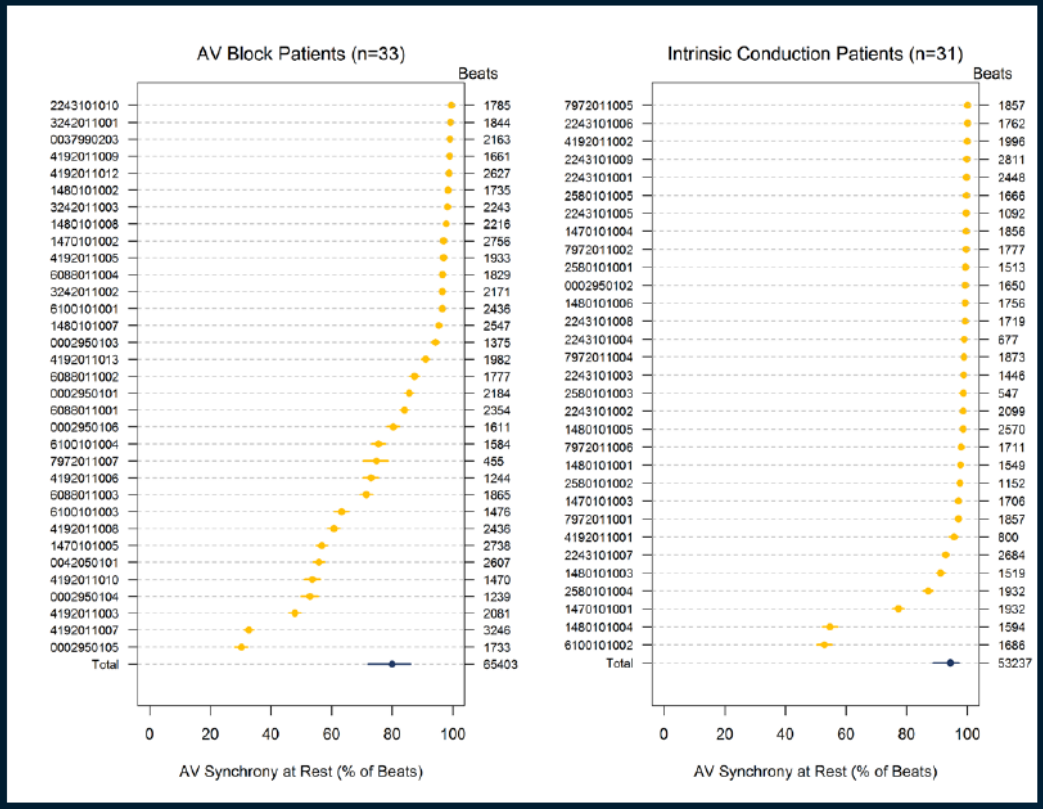
# A4 Detection and Rate Smoothing




- Average A4 detection 71.3% in AVB patients
- Rate-smoothing algorithm
  - If A4 not detected, ventricular pace delivered at rate smoothed interval rather than lower rate.
- Use of algorithm improved the AVS rate to 80.0%

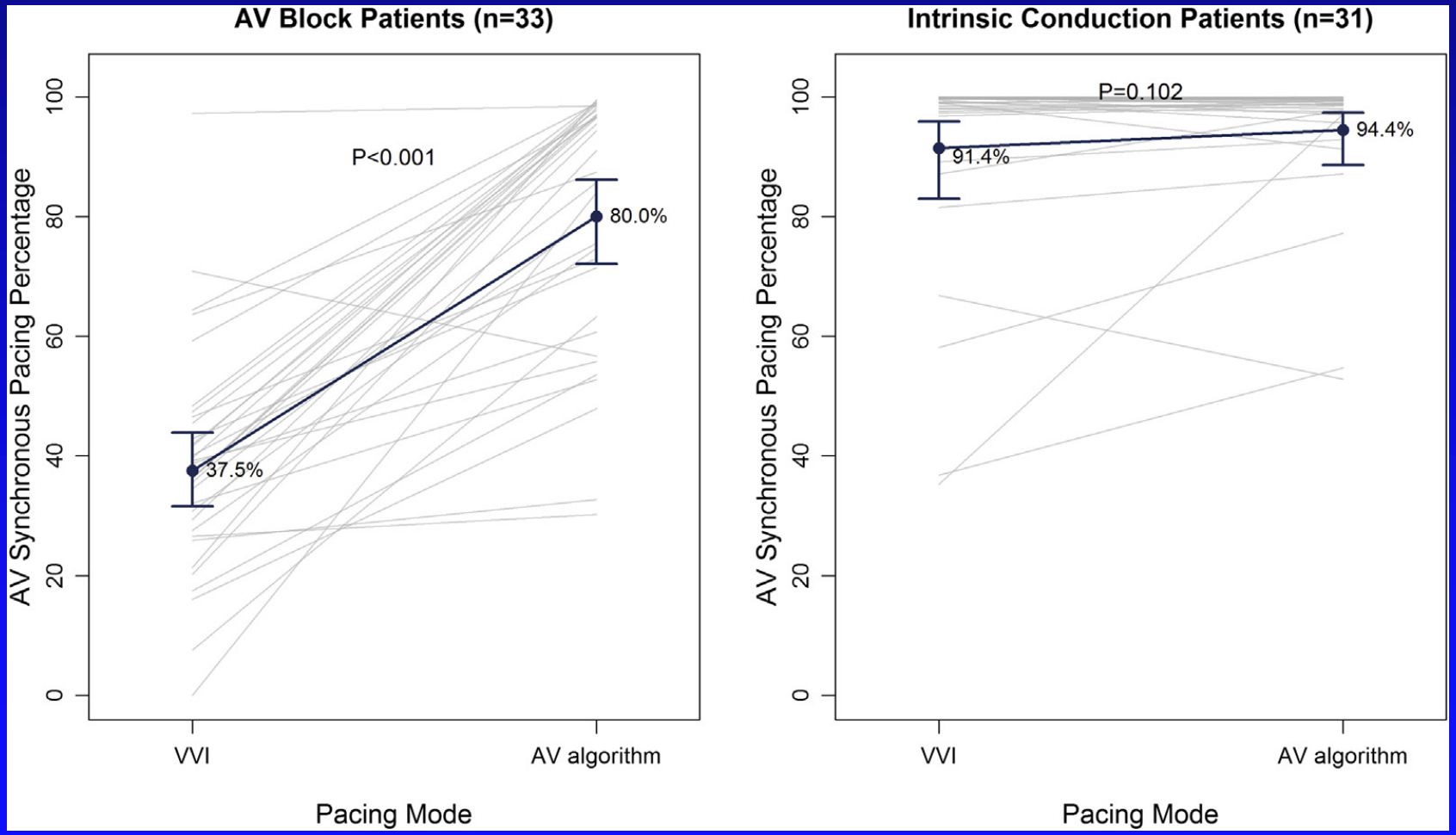
# Marvel Study (n= 64 pts)

# AV Synchrony by Patient



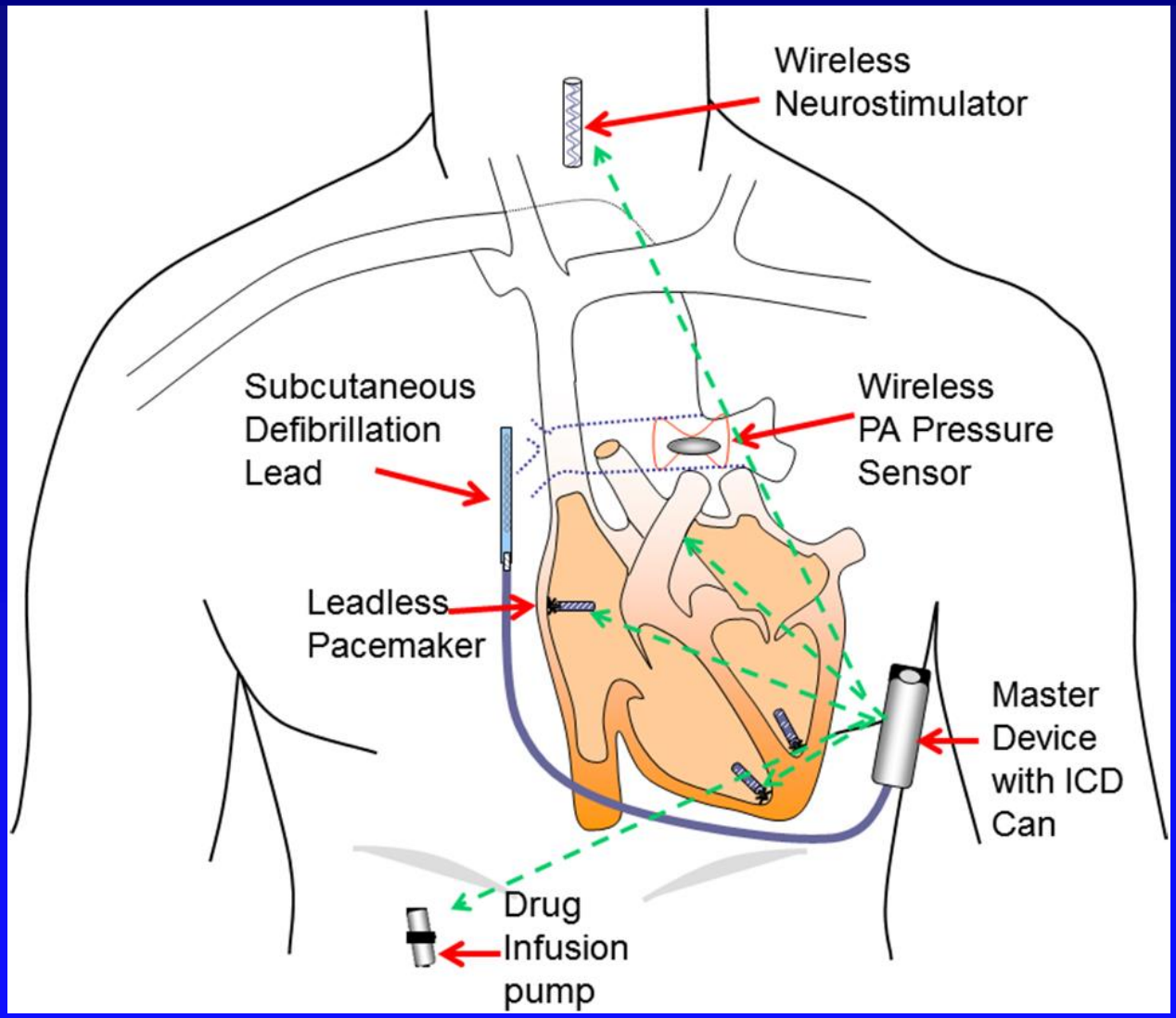

- Average AVS rate 87.0% (95% CI: 81.8%-90.9%)
- Range of AVS 30.2% to 100%
- 83% patients AVS rate >70%
- Reasons for AVS rate <70%
  - Sinus arrhythmia
  - PVCs
  - Low A4 amplitude

# AV synchronous pacing percentage during AV algorithm pacing vs VVI mode by predominant rhythm during rest




Chinitz, et al. Heart Rhythm 2018;15:1363–1371

# The future of electro therapy

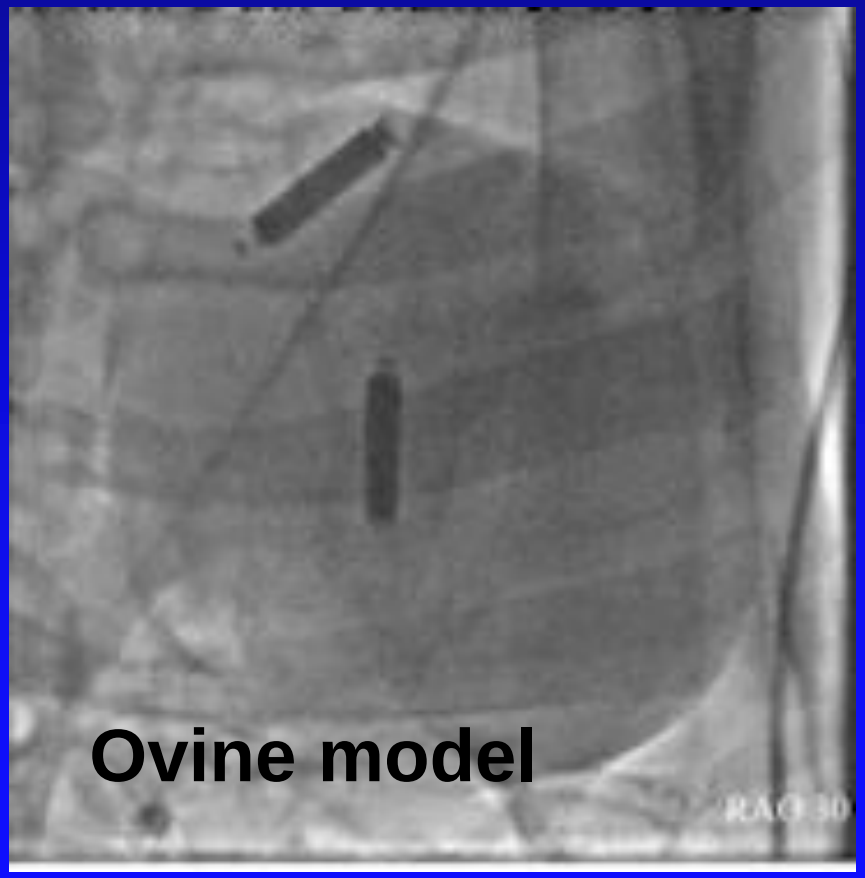


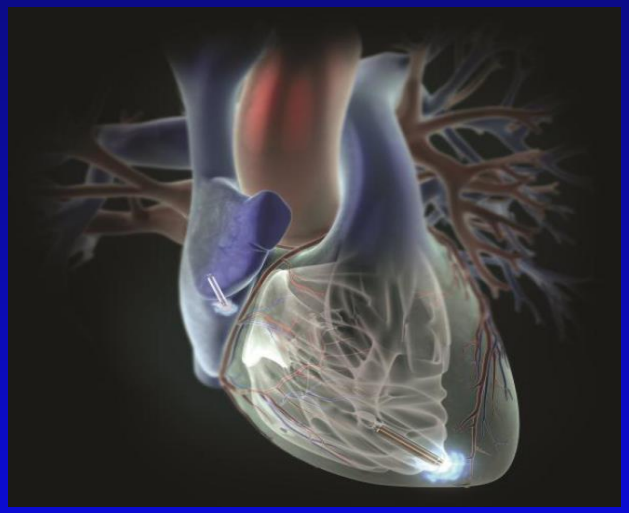
# Conclusions

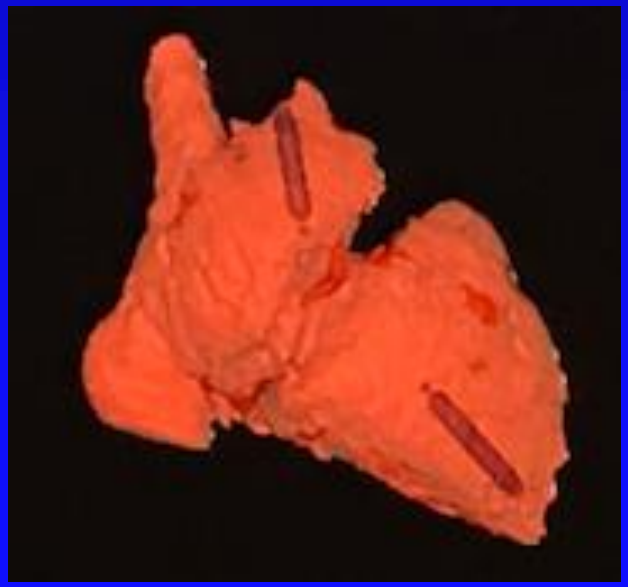
- Leadless cardiac pacing represents the future of cardiac pacing systems
- Pocket- and lead related complications are not evident with leadless pacing
- In a real-world setting and in the hands of new operators the leadless pacemaker can be implanted successfully with low complication rates
- Ready for Prime Time: The future will be the leadless dual-chamber system for the majority of the patients

# Thank you for your Attention

Leadless dual chamber device





# Key Results Summary

- AV synchrony during a period of rest in 64 patients was 87.0%
- AV block patients (n=33):
  - AV synchrony improved from 37.5% to 80.0%
  - Stroke volume improved with AV synchrony
- Sinus arrhythmia, low A4 amplitude, and PVCs contributed to lack of AV synchrony
- No association between time of implant and AV synchrony (unpaired tests)
- No pauses, no instances of pacemaker-mediated tachycardia
- No adverse events related to the device or algorithm were reported

# Conclusions

- Accelerometer based atrial sensing is both feasible and significantly improves AV synchrony in patients with AV block and a single-chamber leadless pacemaker implanted in the RV
  - Improvements in AV synchrony led to improvements in stroke volume in AV block patients
  - AV synchrony was similar during postural maneuvers
- AV synchrony was not compromised in patients with intrinsic AV conduction
- Future clinical studies and circuitry enhancements are planned to further assess this novel technology for providing AV synchrony in a leadless pacemaker