

Performance of a Miniaturized Transcatheter Pacing System: First-in-human experience

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Background

- **Permanent cardiac pacing is the only effective treatment for symptomatic bradycardia.**
- **Serious adverse events associated with conventional transvenous pacing system procedures range from 7.3%* – 12.4%†, and 4.2%† require reoperation.**
- **Miniaturized leadless pacing systems are a promising new solution that may reduce risks associated with traditional technology and improve patient satisfaction.**

*Medtronic reference dataset

†Udo et al. FOLLOWPACE. *Heart Rhythm* 2012;9:729.

Conventional



Micra TPS



Total volume

10.6 cc*

0.8 cc

Mass

21.5 grams

2.0 grams

Rate Response

Subcutaneous Accelerometer

Intracardiac Accelerometer

Communication

Model 2090 Programmer

Model 2090 Programmer

Fixation

Helical coil or tines

Flexible tines

MR conditional

1.5 T

1.5 T + 3 T

Battery Service Life

10.3 years†

9.6 years†

*Medtronic model ADSR01 with 30 cm by 6 Fr lead

†Projected based on ADSR01 and Micra use conditions of 100% pacing at 60 bpm, 1.5 V at 0.24 ms, and 500 Ω

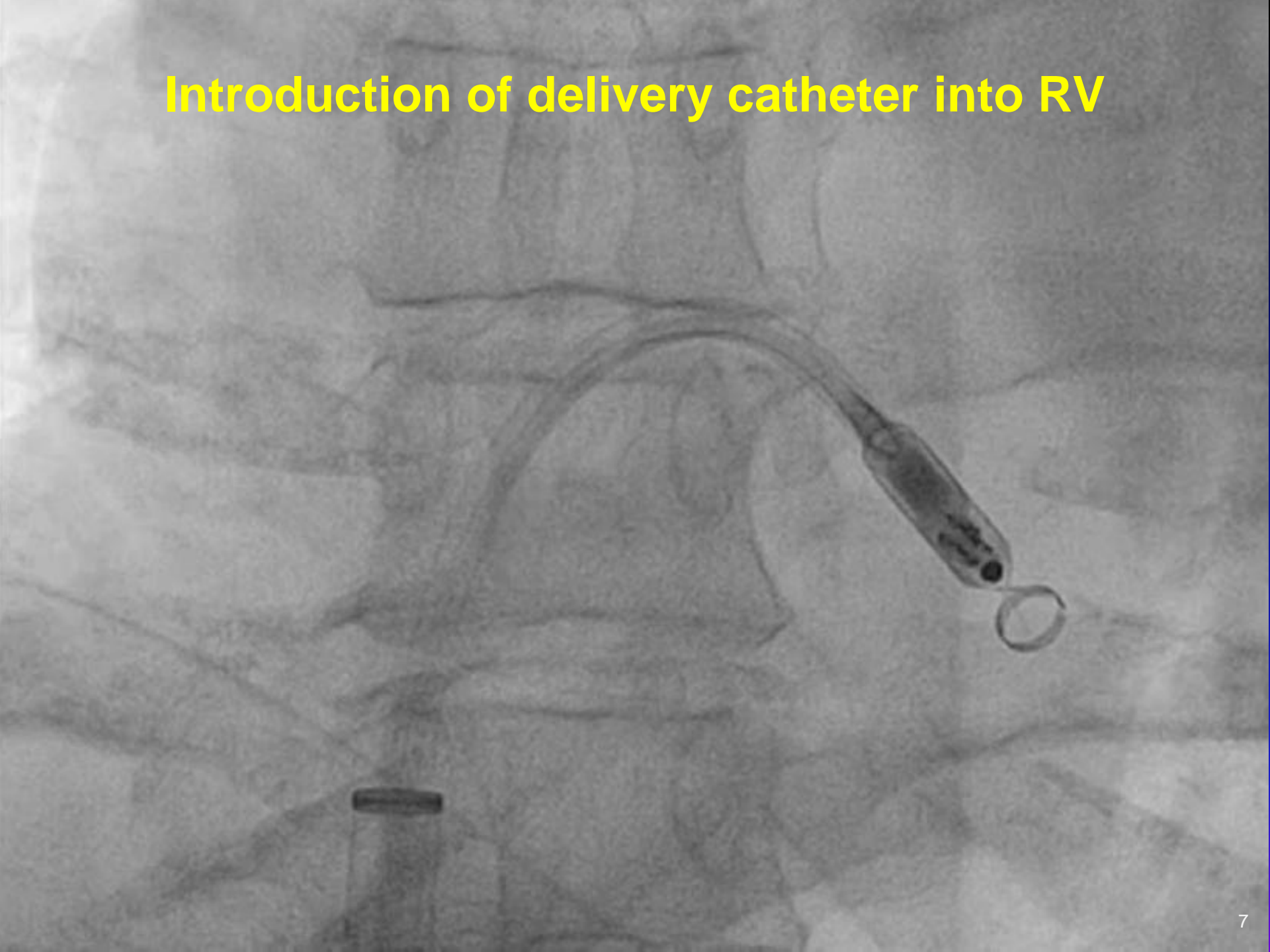
23Fr introducer + dilator over the wire



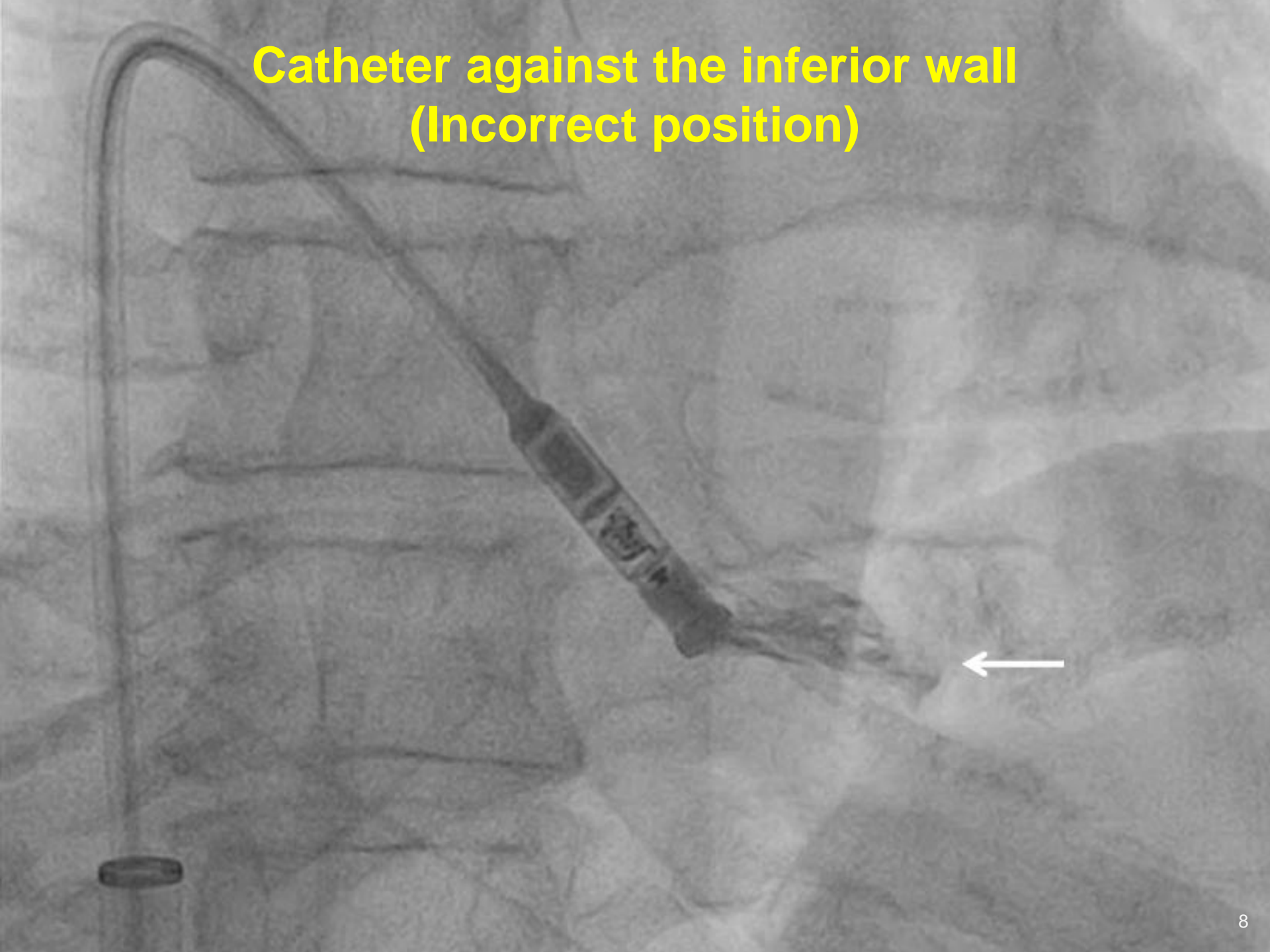
Introduction of delivery catheter into RA



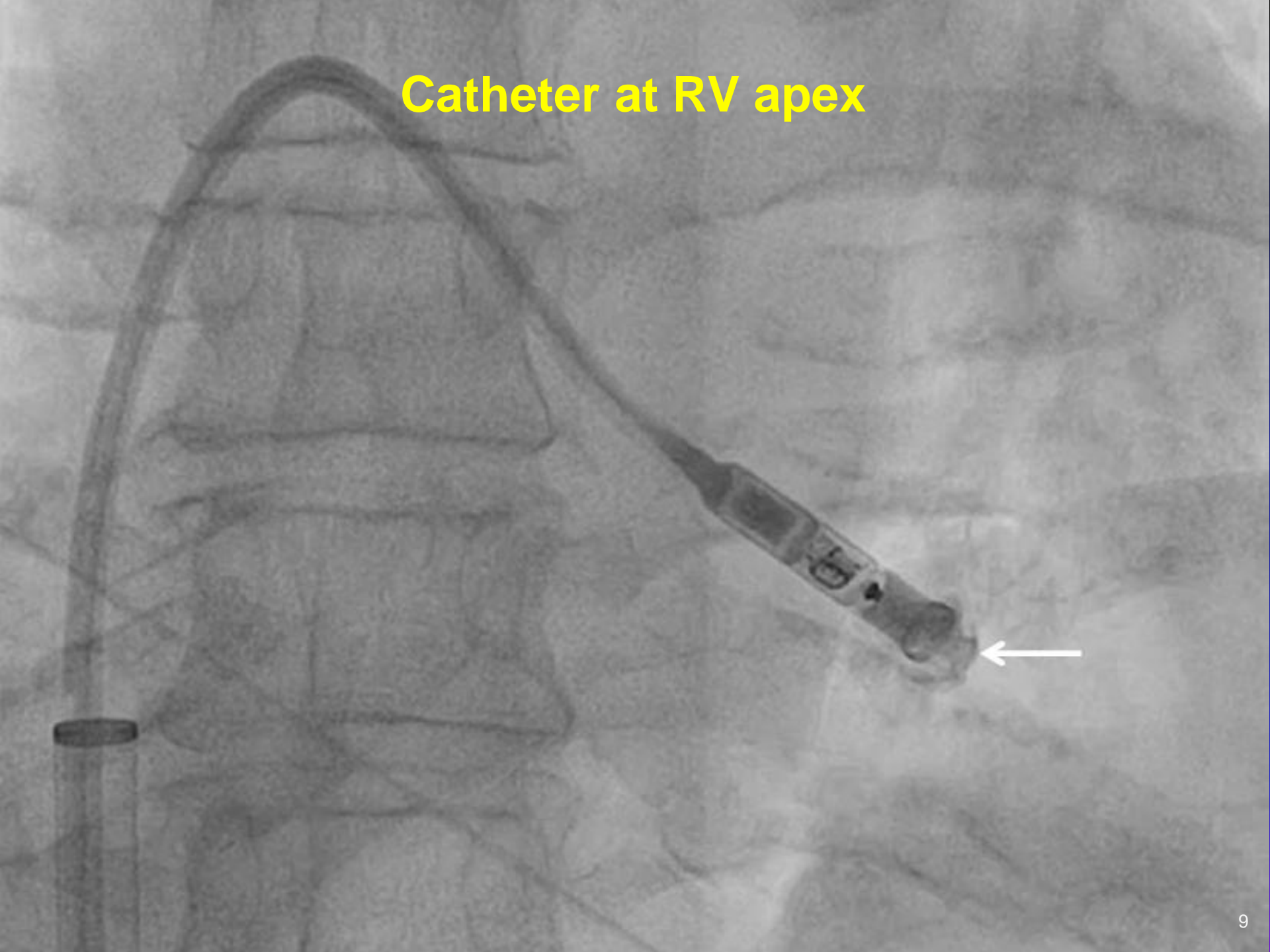
Introduction of delivery catheter into RV



**Catheter against the inferior wall
(Incorrect position)**



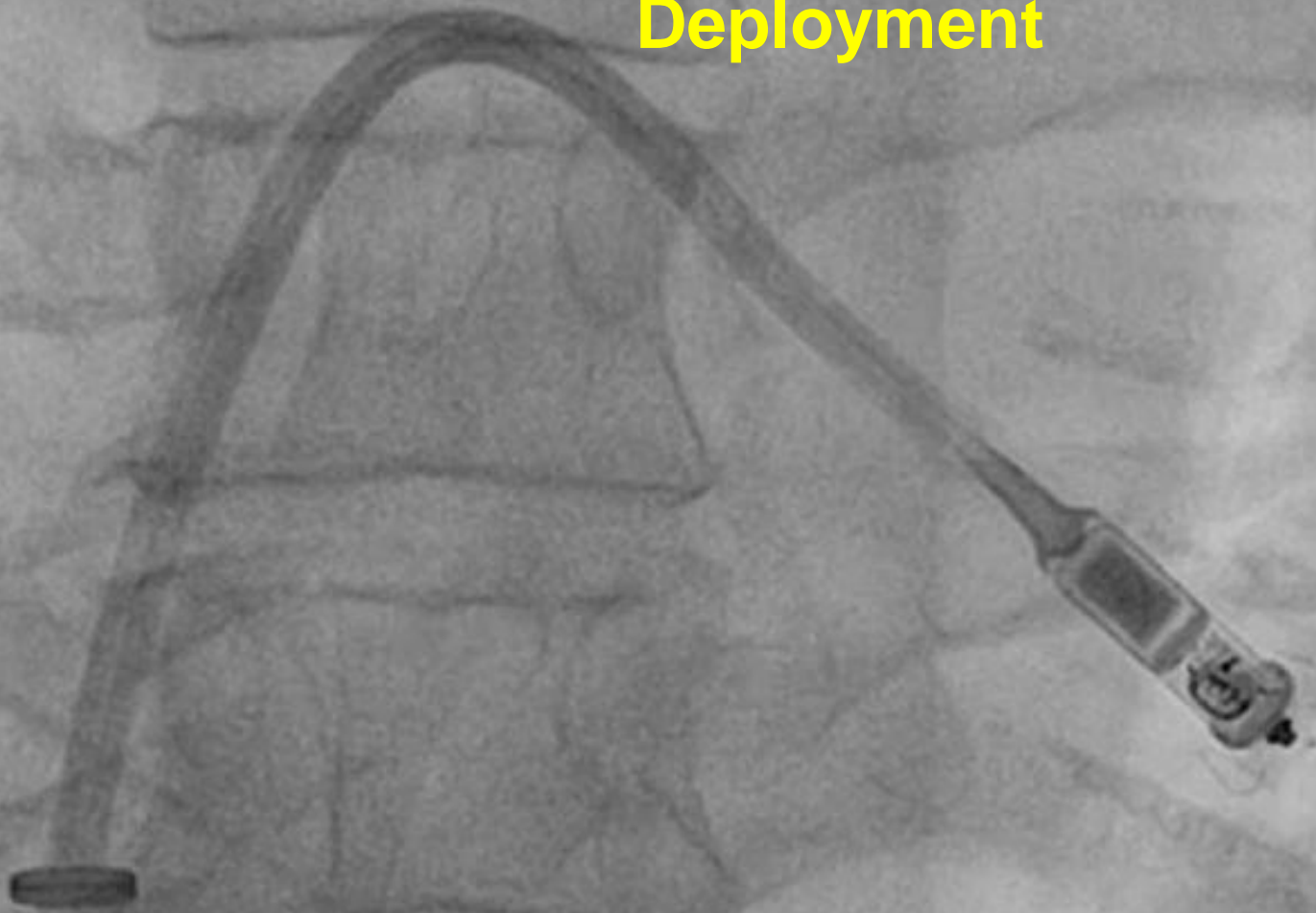
Catheter at RV apex



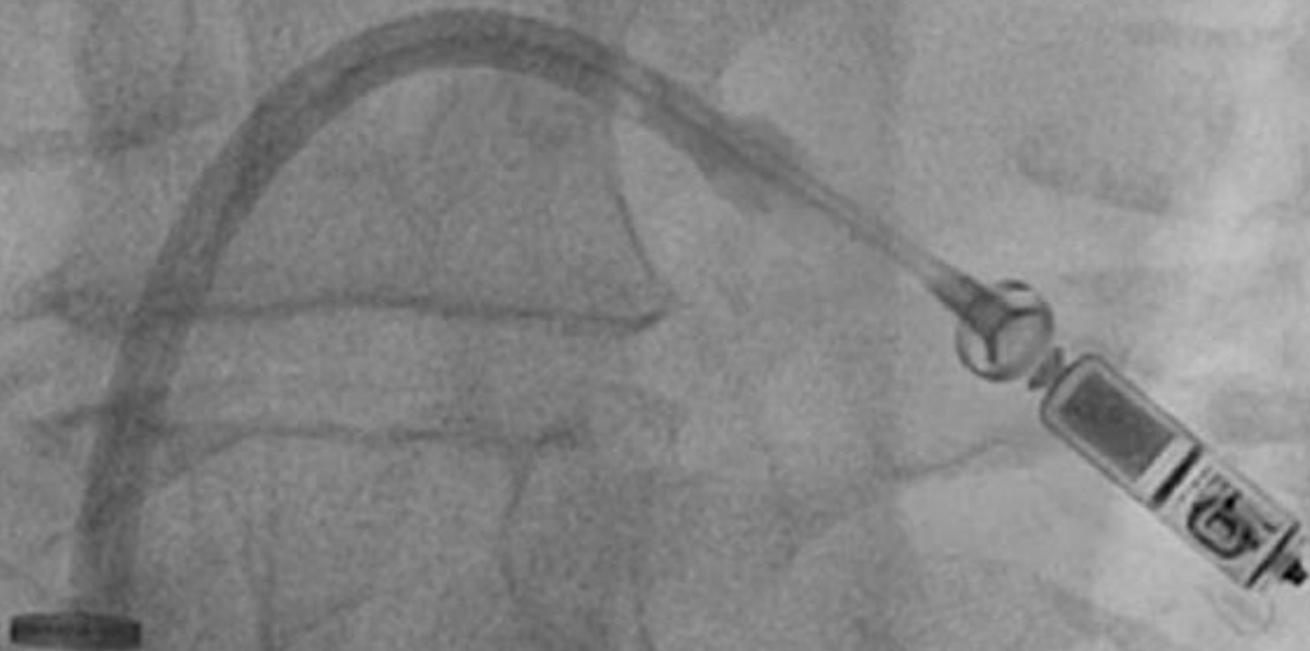
Catheter at RV apex



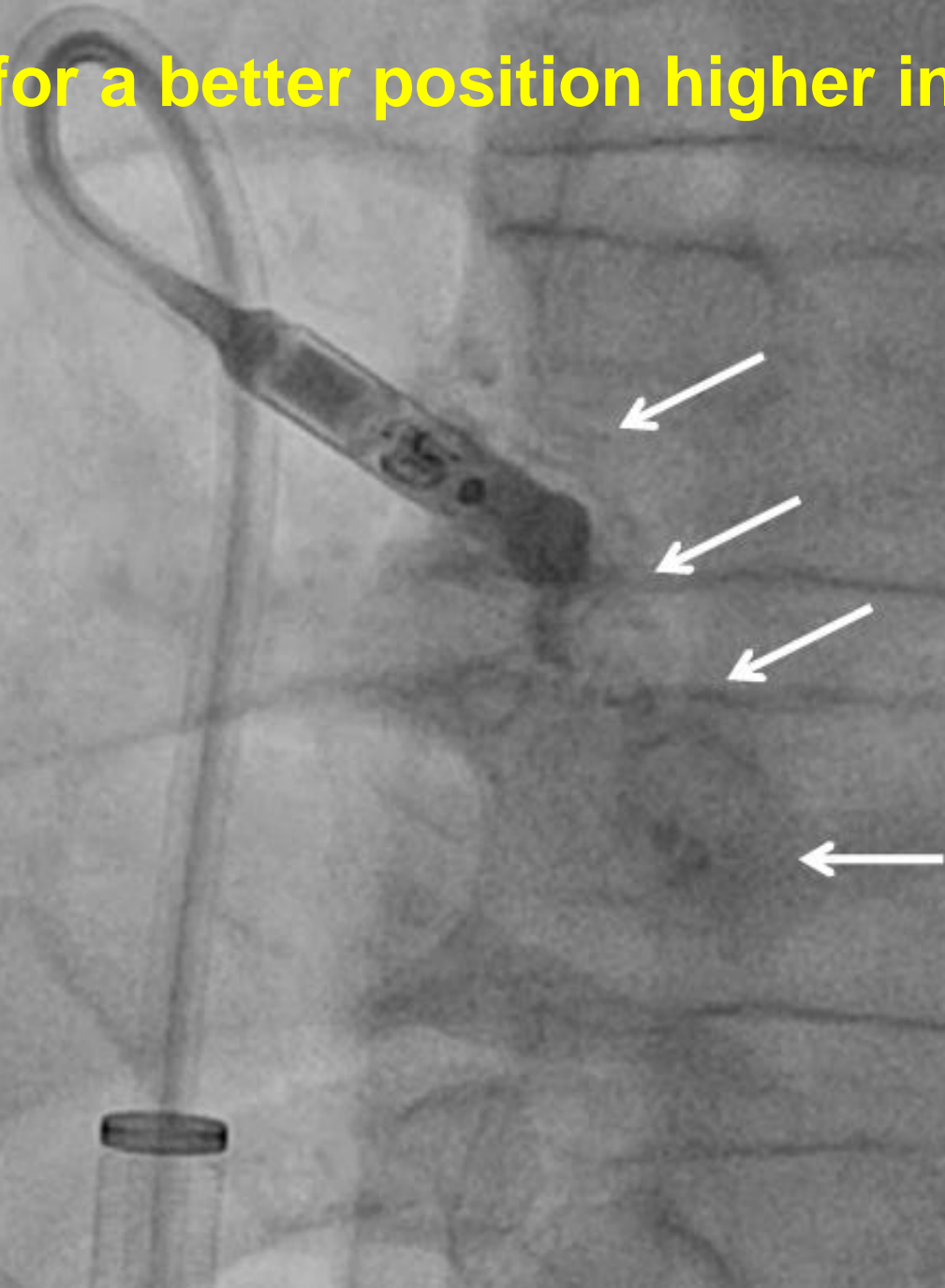
Deployment



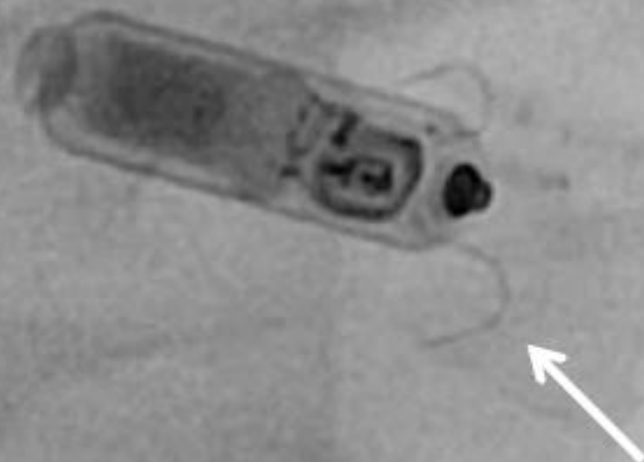
Pacemaker still attached



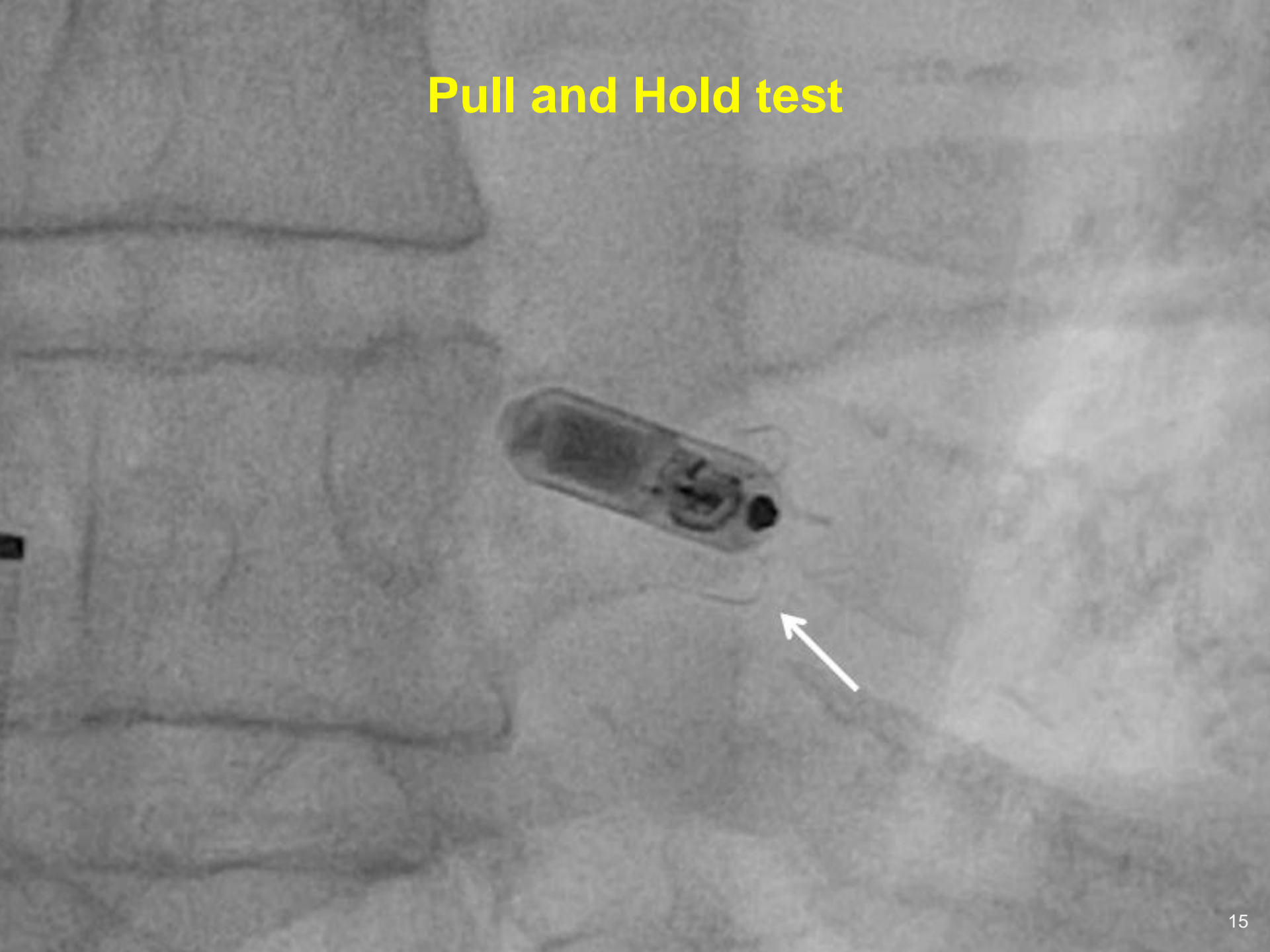
Search for a better position higher in RV



Pull and Hold test



Pull and Hold test



Aim

We analyze the first-in-human safety and efficacy performance of a novel self-contained miniaturized leadless pacemaker from the **Micra[®] Transcatheter Pacing Study**, a single-arm multicenter worldwide clinical trial.

The Micra Transcatheter Pacing Study: Primary Objectives

Safety: Freedom from major complications related to the Micra TPS and/or procedures at 6-month post-implant

- Assumed performance >90%
- Lower confidence interval >83%

Performance: Demonstrate low and stable thresholds at the 6-month visit

- Assumed performance of 89% with threshold $\leq 2V$ and no increase of $>1.5V$ (relative to implant)
- Lower confidence interval >80%

The Micra Transcatheter Pacing Study

Patients: *De novo* pacemaker with Class I or II guideline indication* for ventricular pacing

Enrollment:

- The current presentation gives the results of the early performance analysis that served for CE Mark
- 23 centers (Asia Pacific, Europe, United States)
- 37 implanters

*Epstein AE, et al. ACC/AHA/HRS 2008 Guidelines. Zipes DP, et al. ACC/AHA/ESC 2006 Guidelines.

Study Prespecified Analyses

Early Performance

N = 140

(60 pts to 3 months)

Primary Objectives

N = 700+

(300 pts to 6 months)

Long-term Performance

N = 700+

(700+ pts to 12 months)

Study enrollments completed

Early Performance Methods

- All patients with a Micra TPS implant attempt at time of data cut-off were included in this report.

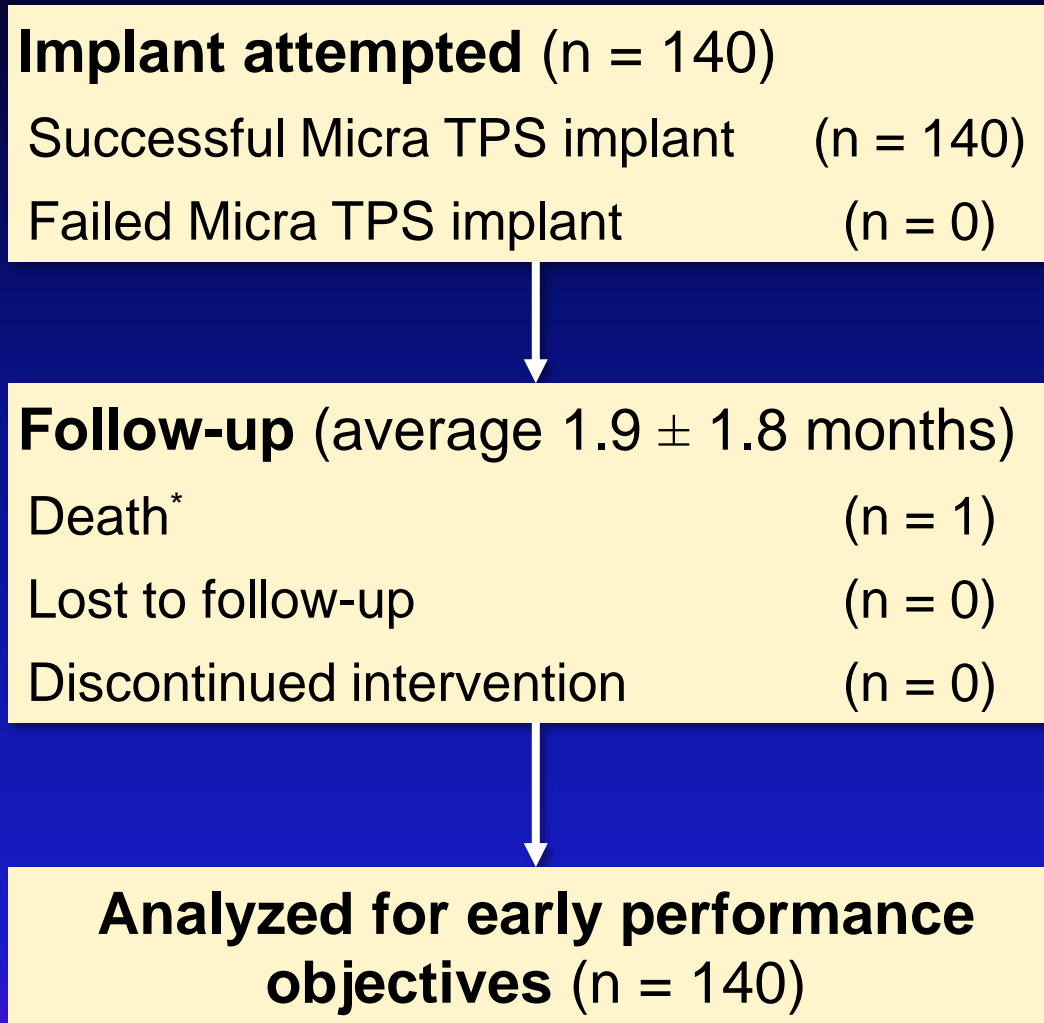
Safety

- All serious adverse events related to Micra TPS were collected.
- Relatedness was adjudicated by an independent clinical events committee.

Efficacy

- Micra TPS electrical measurements at implant, pre-hospital discharge, 1 month, and 3 month follow-up were summarized.

Patient Flow Diagram



*One patient death occurred 139 days post-implant, was not cardiovascular related, and was determined to be unrelated to the procedure or system.

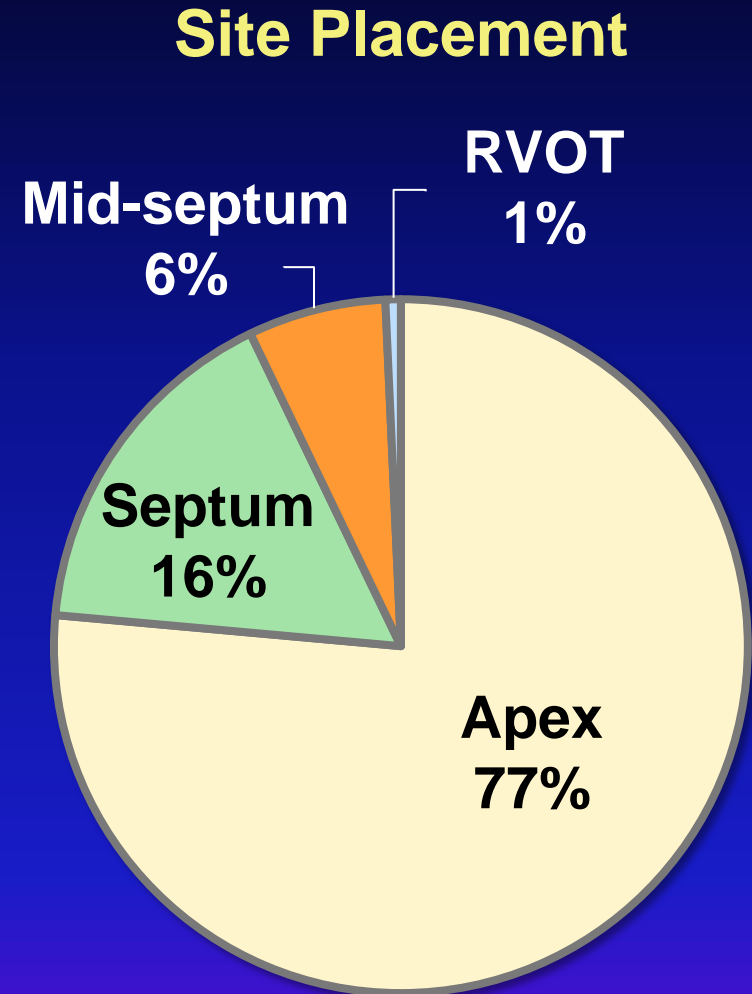
Baseline Characteristics

	Patients (n=140)
Male gender	85, 61%
Age (years)	78 (21 – 94)
Height (cm)	170 (144 – 190)
Weight (kg)	76 (41 – 148)
Body Mass Index	26 (20 – 45)
One or more comorbidity	136, 97%
Primary Indication	
Bradycardia with permanent or persistent AT/AF	91, 65.0%
Sinus node dysfunction	22, 15.7%
Atrioventricular block	19, 13.6%
Other reasons	8, 5.7%

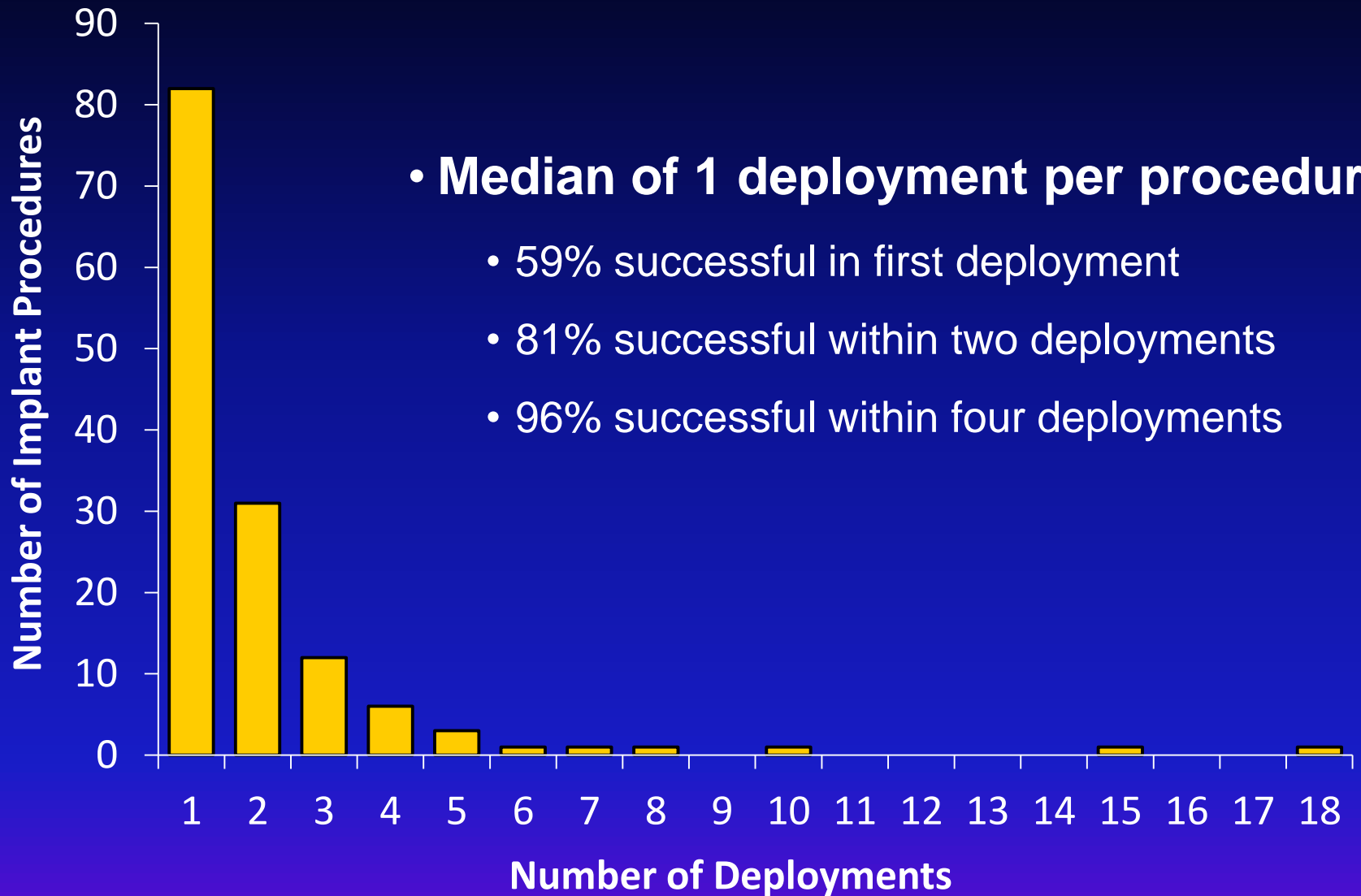
Median and ranges reported

Results: Micra TPS Implant

- **100% implant success**
(140 of 140 attempts)
- **Mean implant time was 37 ± 21 min** (introducer in / introducer out)
- **Anticoagulation approach**
 - All catheters heparinized
 - Baseline Status: 44% patients on anticoagulant, 29% on anti-platelet
 - Intra-procedure: 40% received Heparin IV bolus



Micra TPS Deployments During Implant



Results: Safety

(n=140)

- **Serious Adverse Event rate 5.7%**
 - 7.3% SAE at 1 month in Medtronic reference dataset
 - 12.4% complication at 2 months in FOLLOWPACE
- **2 patients with prolonged hospitalization (1.4%)**
- **No unforeseen events (0%)**
- **No device telemetry issues (0%)**
- **No dislodgements (0%)**
- **No infections (0%)**
- **No reoperations (0%)**
- **No related deaths (0%)**

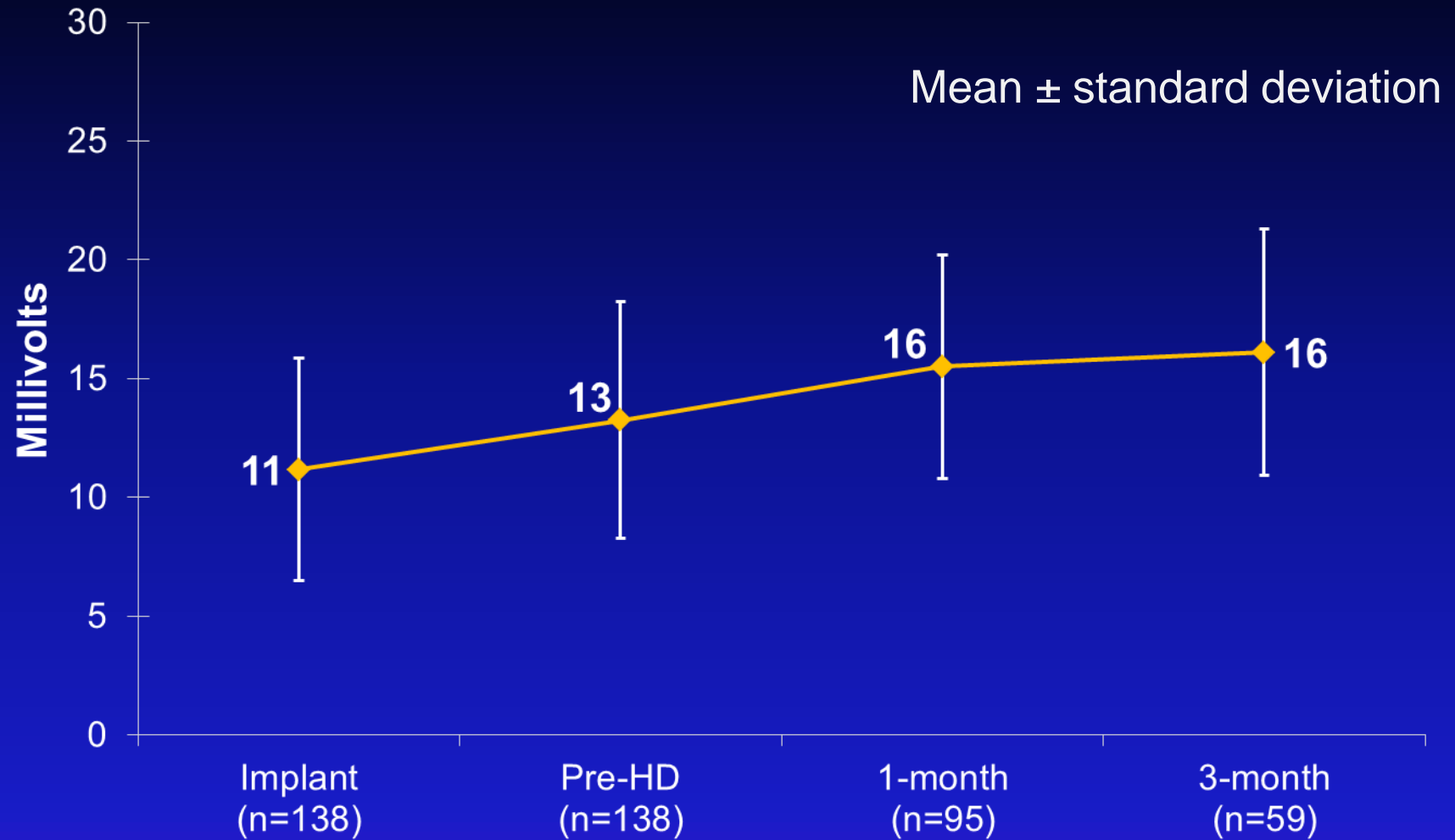
Serious Adverse Events

	Resulting in death, re-operation, or hospitalization	N (pts, %)
DYSRHYTHMIAS		
Transient AV block	No	2 (2, 1.4%)
RBBB	No	1 (1, 0.7%)
VT	No	1 (1, 0.7%)
VF	No	1 (1, 0.7%)
CARDIAC		
Pericardial effusion, no tamponade	1 hospitalization prolonged >48 hrs	1 (1, 0.7%)
Acute MI	for both events in same patient*	1 (1, 0.7%)
Pericarditis	No	1 (1, 0.7%)
OTHER		
Arterial pseudoaneurysm	1 hospitalization prolonged >48 hrs†	1 (1, 0.7%)
TOTAL	3 (2, 1.4%)	9 (8, 5.7%)

*Occurred in patient with 18 deployments who had 3 vessel disease

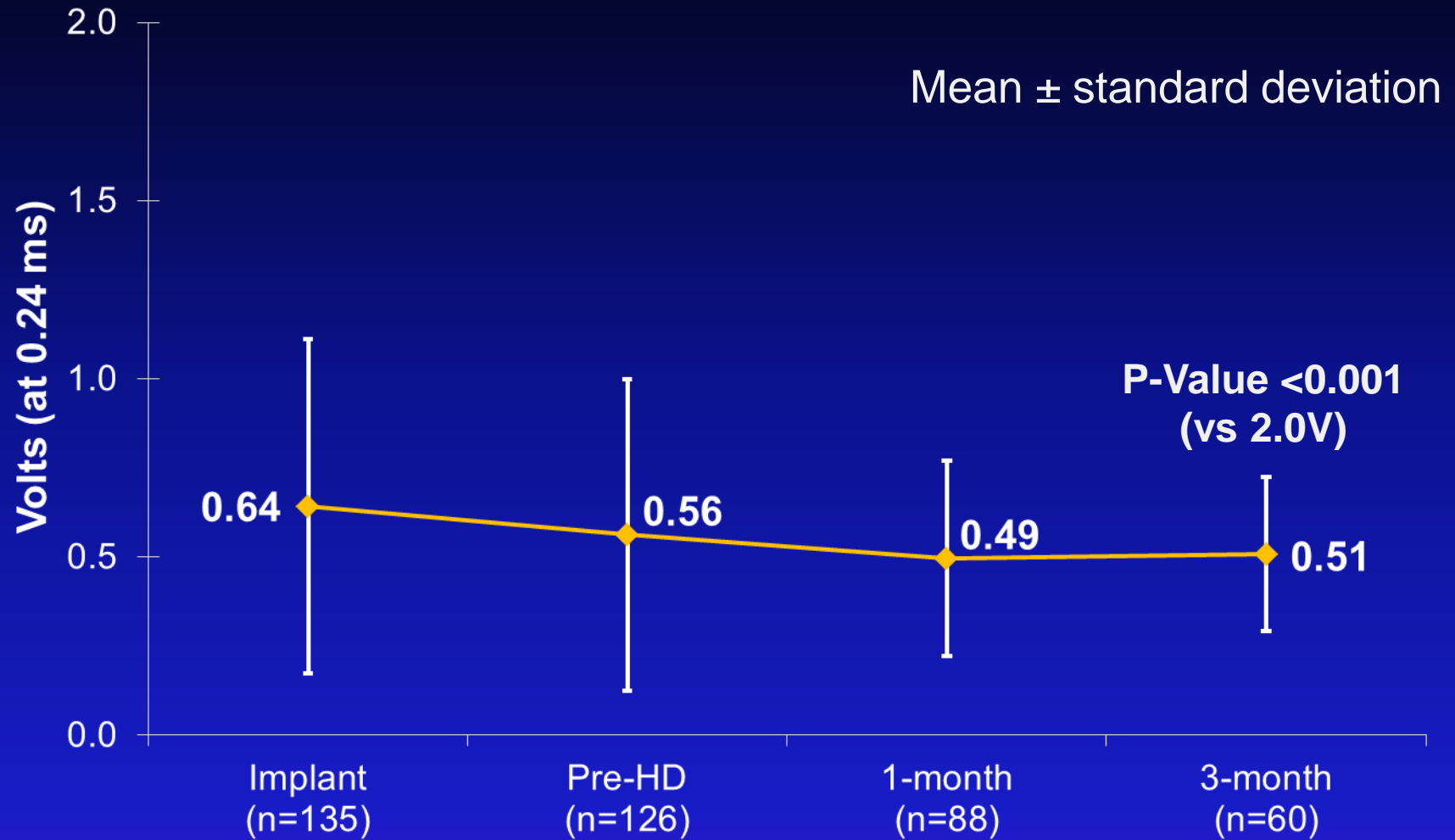
†Resolved after thrombin injection

R-Wave Sensing Amplitude



Min	3	3	2	2
Max	20	20	21	21

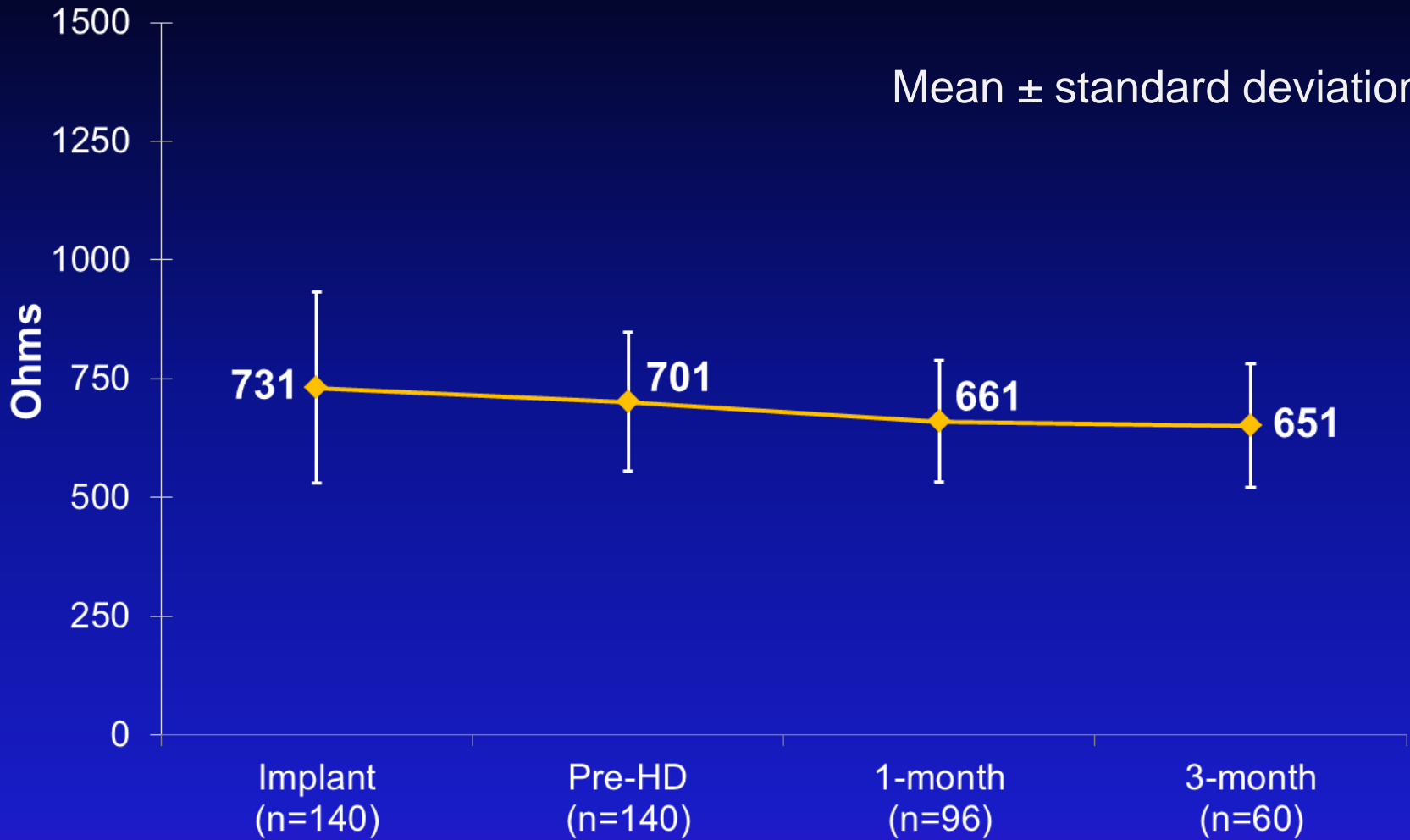
Pacing Capture Threshold



Min	0.25	0.25	0.25	0.25
Max	3.50	3.00	2.13	1.25

Pacing Impedance

Mean \pm standard deviation



Min	450	440	420	450
Max	1540	1130	1080	1000

Expected Micra TPS Longevity

Based on use conditions of 60 patients followed to 3 months

- Median pacing = 49% (IQR 10%, 75%)
- Median pacing capture threshold at 0.24 ms = 0.38 V (IQR 0.38 V, 0.57 V)
- Median pacing impedance = 640 Ω (IQR 540 Ω , 725 Ω)

Battery longevity estimated at an average of 12.6 years (range 8.6 – 14.4 years)*

*Estimate does not include pacemaker dependent patients and assumes thresholds remain stable for device lifetime.

Conclusions

Early performance of first 140 patients provides initial evidence that Micra TPS can safely and effectively be applied.

- 100% implant success in wide range of patients
- No procedural-related deaths
- Serious adverse event rate with Micra TPS appears to be in line with traditional systems
- Electrical performance is excellent and remains stable at 3 months, with expected average longevity of ≥ 10 years

Long-term safety and benefit will be further evaluated in the ongoing trial.