

**Advances in Cardiac Arrhythmias and Great Innovations in Cardiology**  
**XXVII Giornate Cardiologiche Torinesi**

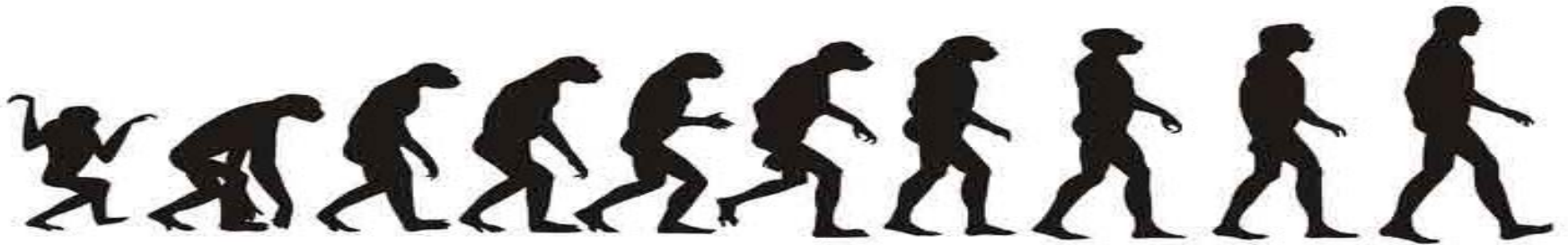
**New generations pacemakers  
and ICDs: an update**



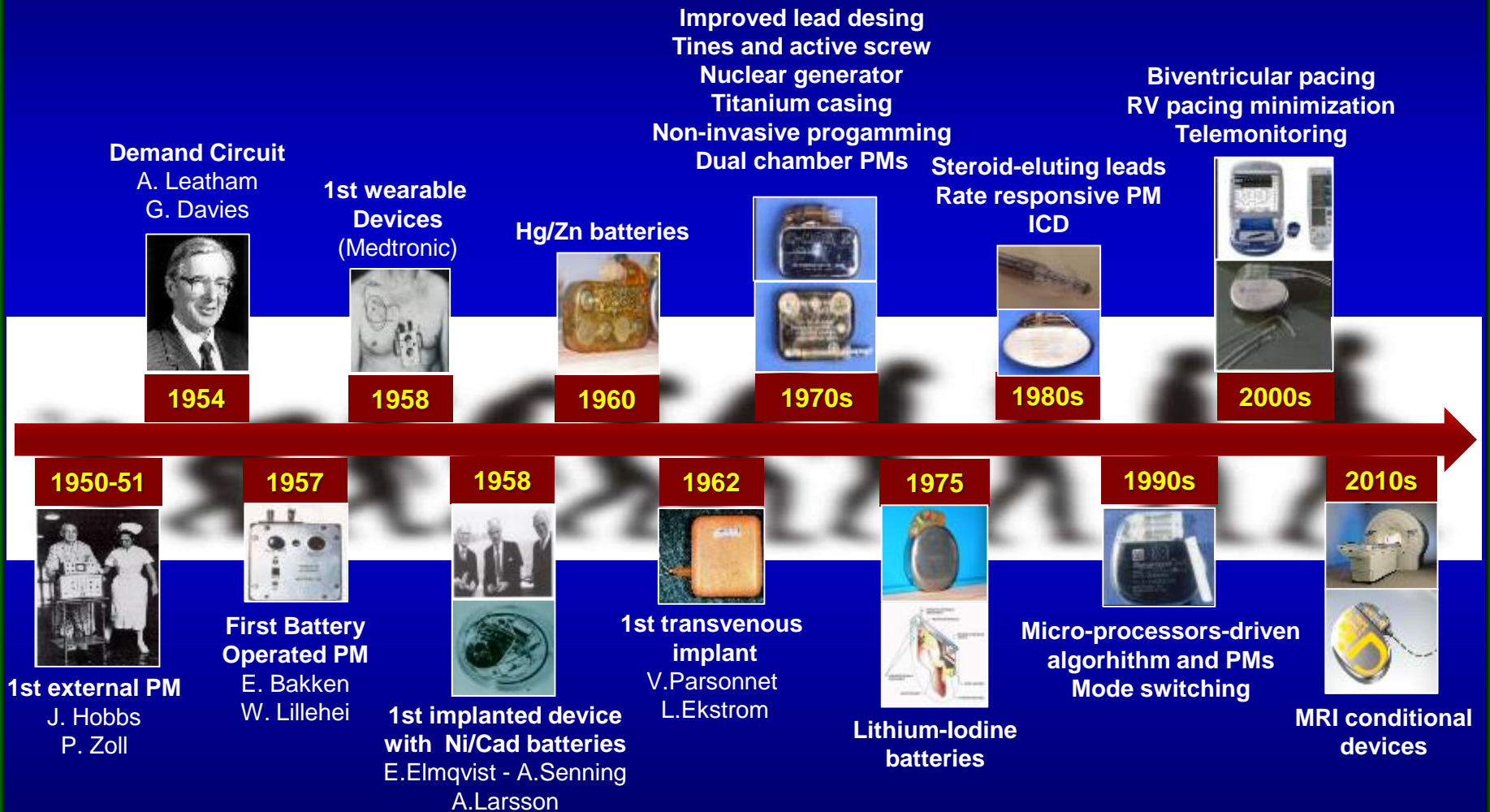
**Prof. Fiorenzo Gaita, MD**  
**Division of Cardiology**  
**Department of Medical Sciences**  
**University of Turin**



# Pacemaker's Evolution



# Pacemaker's Evolution



# Pacemaker Implants Worldwide

750.000 New cardiac PMs implanted / year

≈ **10%** of complications

TRAUMATIC



**1%**

POCKET-RELATED



**4.8%**

LEAD-RELATED



**5.5%**



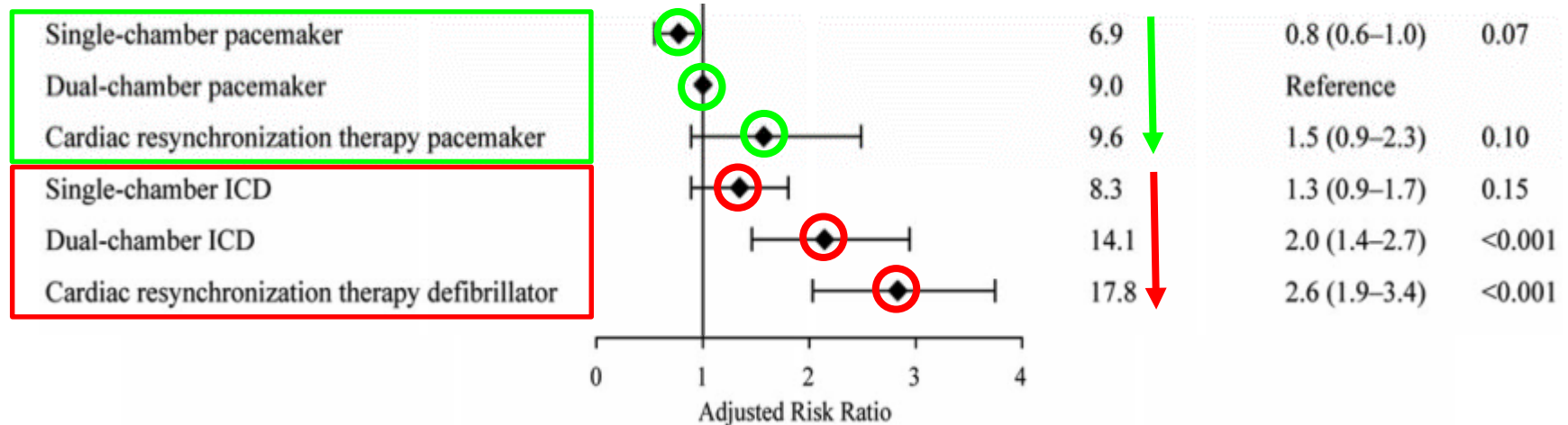
# N° of Leads and Complications

## Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark



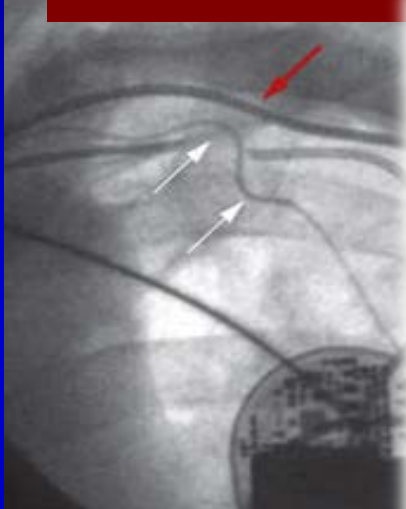
Rikke Esberg Kirkfeldt<sup>1,2\*</sup>, Jens Brock Johansen<sup>2,3</sup>, Ellen Aagaard Nohr<sup>4</sup>,  
Ole Dan Jørgensen<sup>2,5</sup>, and Jens Cosedis Nielsen<sup>1</sup>

**5918** consecutive patients  $\approx$  **10%** complications



# The Lead Is the Weakest Link

**CHRONIC STRESS BY  
BEATING HEART**



L of MEDICINE

pective

MARCH 8, 2012

**CELLS RER**

Here We Go Again — Another Failure of  
Surveillance

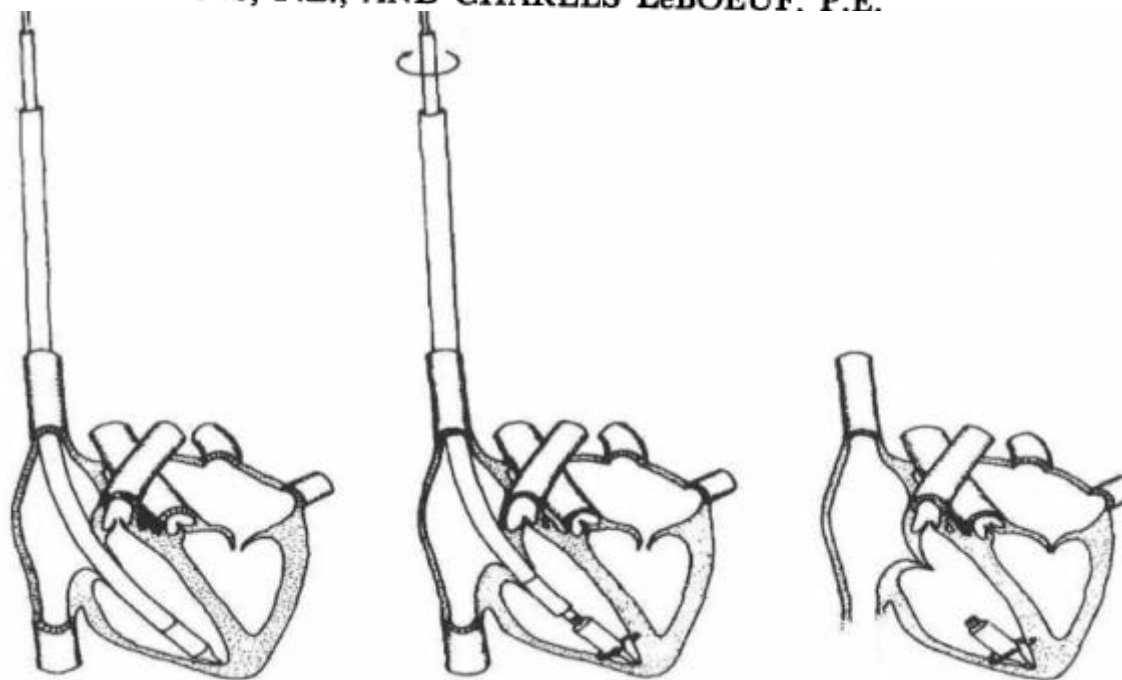
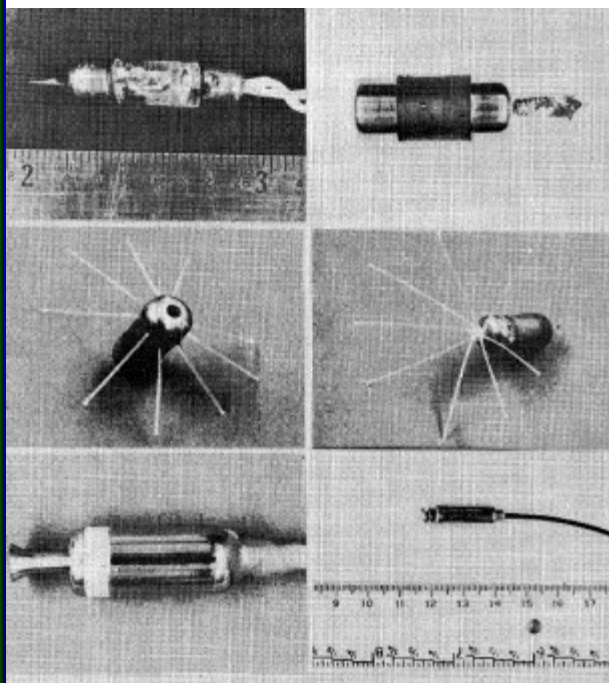
Robert G. Hauser, M.D.

# System Proposed by Spickler in 1970

## Special Article

### Totally Self-Contained Intracardiac Pacemaker\*

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D.†, PAUL KEZDI, M.D.  
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, P.E.



...very often the realization of an idea may take some time....



***Idea***



***Technology***

***(right tools)***



# Leadless Pacemakers

**NANOSTIM™ – SJM**



**MICRA™ – MEDTRONIC**

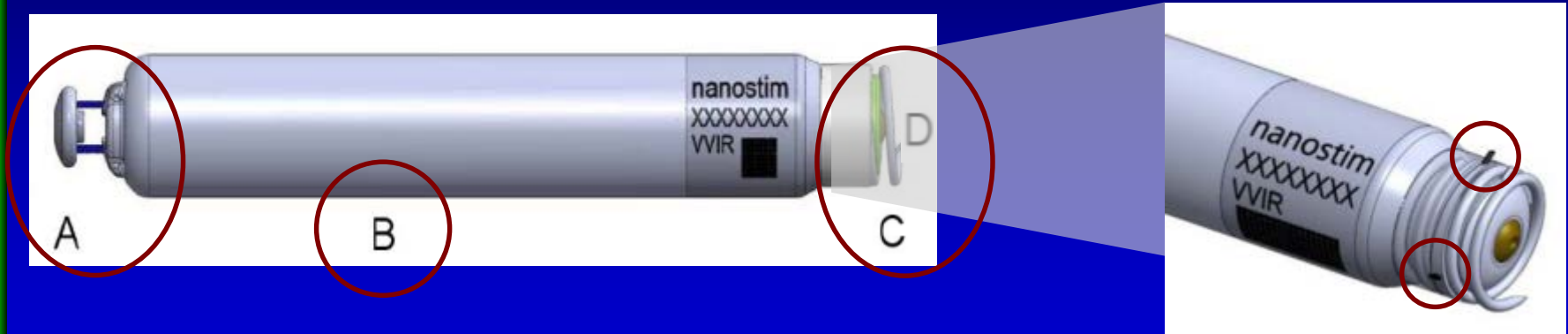


# Nanostim™ Leadless Pacemaker



- Self-contained intracardiac device
- Length: 42 mm, maximum  $\varnothing$ : 6 mm
- Weight: 2 g, volume: 1 cm<sup>3</sup>
- VVI / VVIR Pacemaker
- Temperature based rate-sensor

# Nanostim™ Leadless Pacemaker



A. Docking feature for delivery, repositioning, retrieval

B. Chemical lithium battery cell

**Longevity** → 2.5 V, 500  $\Omega$ , 60 bpm, pacing

↗ 100%: 9.8 y

↘ 50%: 14.5 y

C. Helix provides 1<sup>ary</sup> fixation, tines add 2<sup>ary</sup> fixation

D. Steroid-eluting electrode tip (dexamethasone)

# Nanostim™ Delivery Catheter

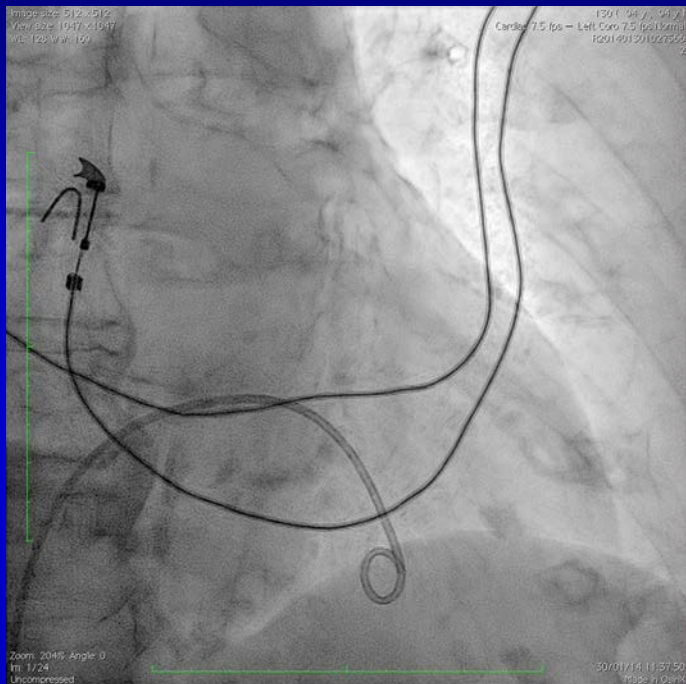
- Single-operator design
- 18 French introducer
- Steerable delivery catheter



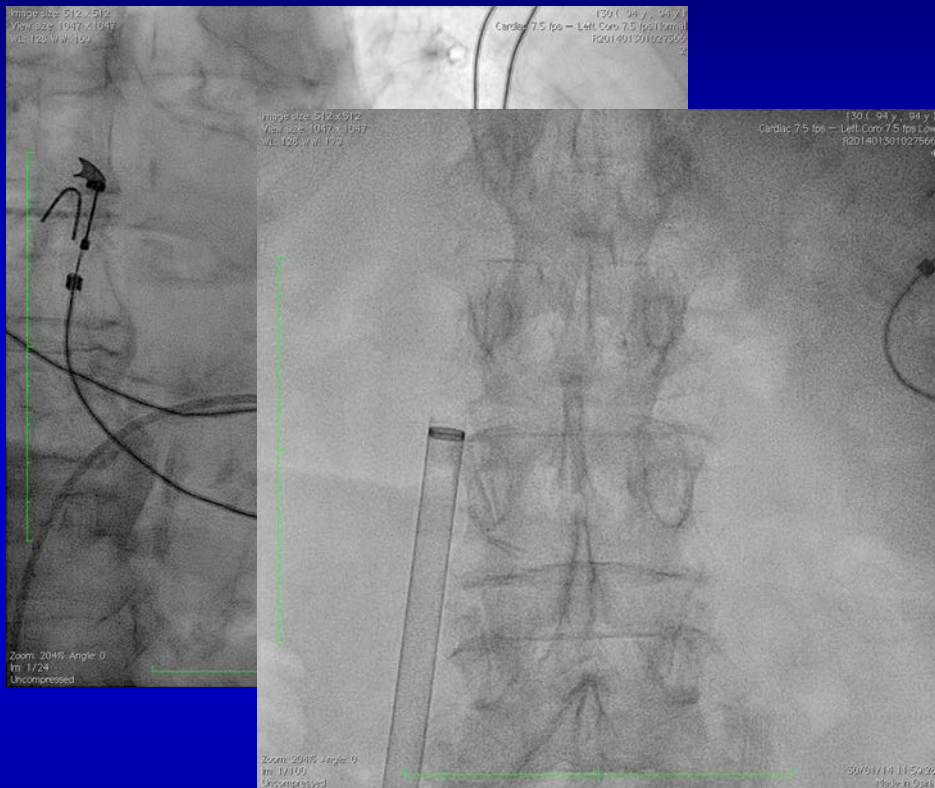
- Tethered connection to maintain device during measurements



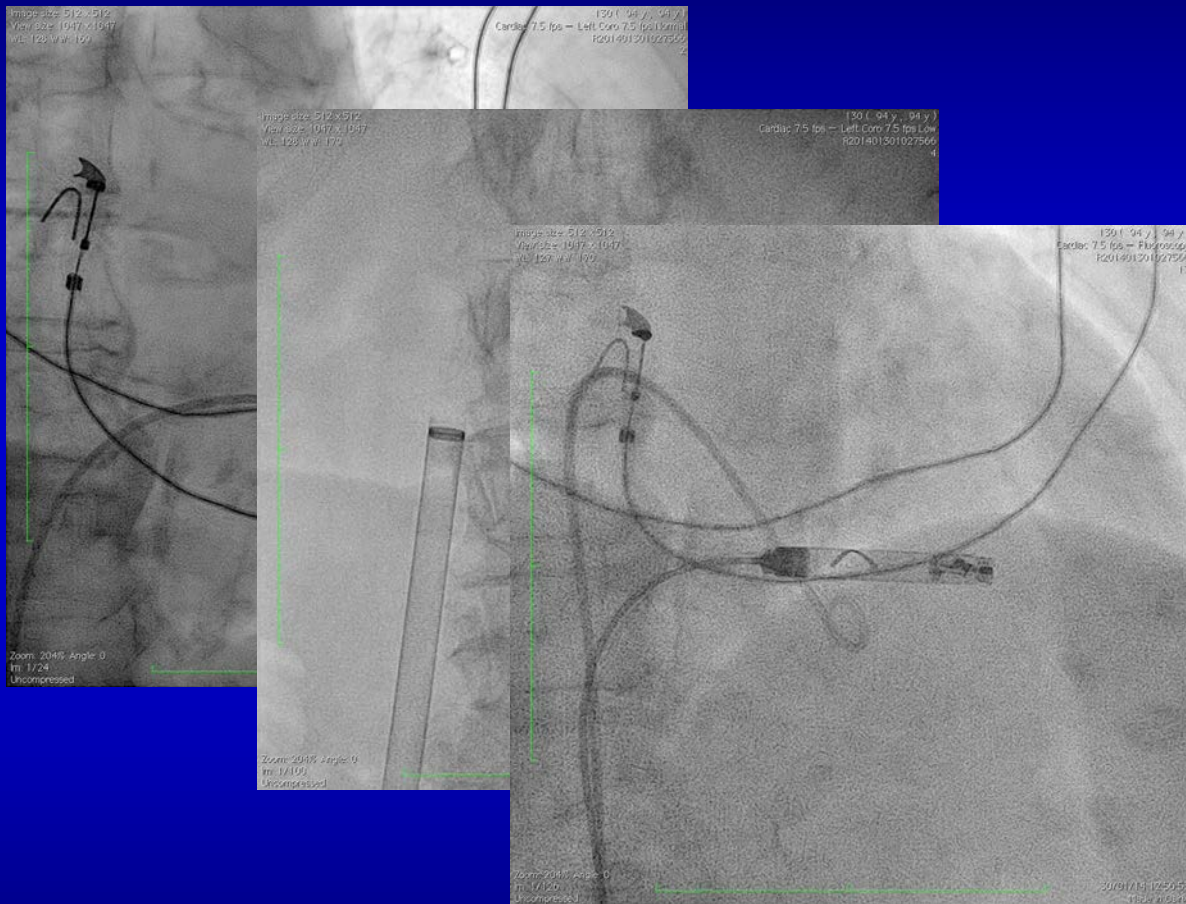
# Nanostim™ Implantation Case



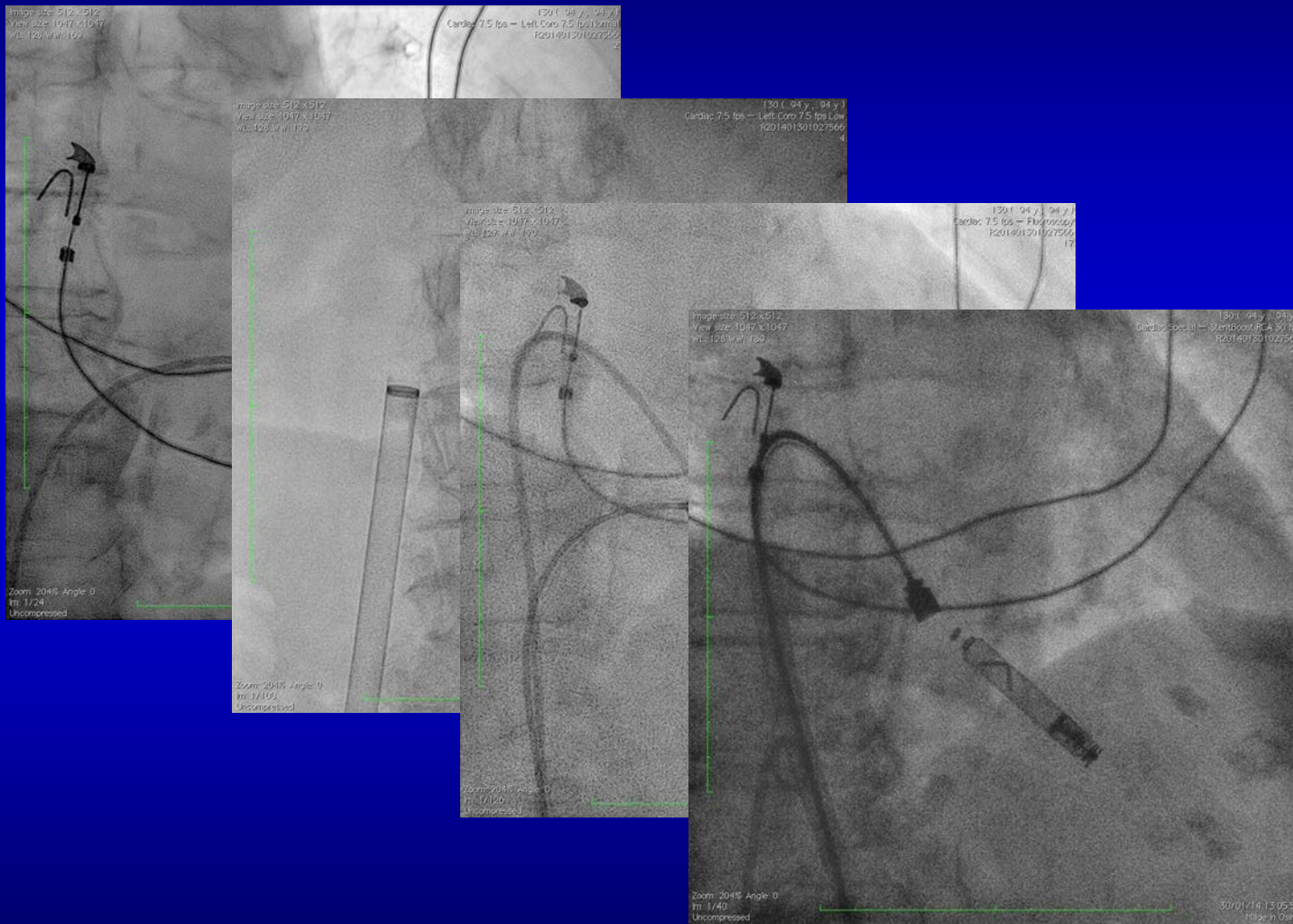
# Nanostim™ Implantation Case



# Nanostim™ Implantation Case

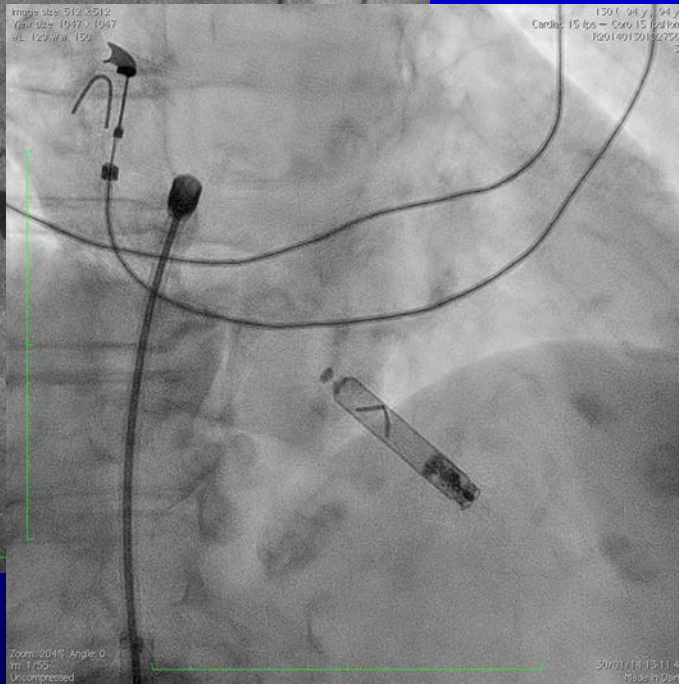
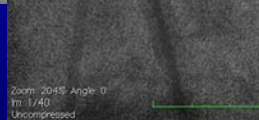
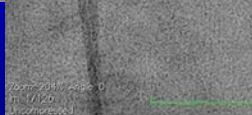
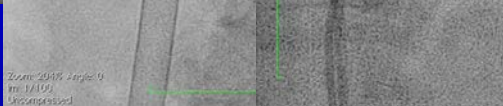
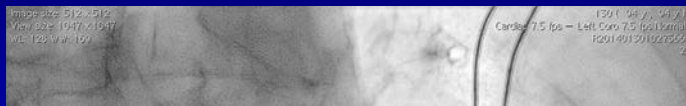


# Nanostim™ Implantation Case





# Nanostim™ Implantation Case



## Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker

Vivek Y. Reddy, M.D., Derek V. Exner, M.D., M.P.H., Daniel J. Cantillon, M.D., Rahul Doshi, M.D., T. Jared Bunch, M.D., Gery F. Tomassoni, M.D., Paul A. Friedman, M.D., N.A. Mark Estes, III, M.D., John Ip, M.D., Imran Niazi, M.D., Kenneth Plunkitt, M.D., Rajesh Banker, M.D., James Porterfield, M.D., James E. Ip, M.D., and Srinivas R. Dukkipati, M.D., for the LEADLESS II Study Investigators\*

- **Prospective, multicenter, non-randomized, FDA IDE study**
- **Total Cohort: All patients enrolled by June 2015 (n=526)**
- **Primary Endpoints:**
  - **Safety: freedom from Serious Adverse Device Effects**
  - **Efficacy: Acceptable pacing capture threshold (< 2.0 V @ 0.4 msec) and sensing amplitude (R wave  $\geq$ 5.0 mV)**

# Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker

Multicenter Study, 526 patients (mean age 75 yrs)

- Main indication to implantation:
  - Permanent AF with AV block 294 (56%)
  - Sinus bradycardia with pauses/syncope 186 (35%)
  - SR with 2<sup>nd</sup>/3<sup>rd</sup> degree AV block 46 (9%)
- Device successfully implanted in **504/526 (96%)** pts
- Duration of implantation **47±25'** / fluoroscopy **14±9'**

# Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker

**Follow-up (6.9 months)**

- **Adverse events 40/526 (7.6%)**

<b>Cardiac perforation</b>	<b>8 (1.5%)</b>
<b>Vascular complications</b>	<b>6 (1.1%)</b>
<b>Device dislodgement</b>	<b>6 (1.1%)</b>
<b>Device retrieval due to ↑threshold</b>	<b>4 (0.8%)</b>
<b>Procedure related death</b>	<b>2 (0.4%)</b>



# Clinical Case

R.B. 94 years old lady (59 kg, 160 cm, BMI 23)

12/2012 left-subclavear DDD-PM implant for 2:1 AV block

05/2013 transvenous lead extraction (left) for **infection**

05/2013 right-subclavear PM re-implant for persistent 2:1 and III grade AV block

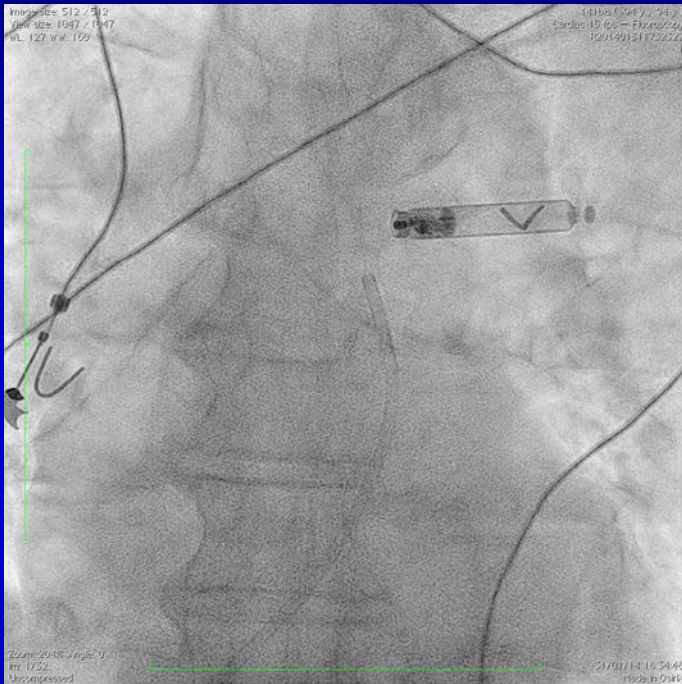
01/2014 transvenous lead extraction (right) for **infection**

30/01/2014 leadless pacemaker (Nanostim™) implant

# Final Leadless PM Position

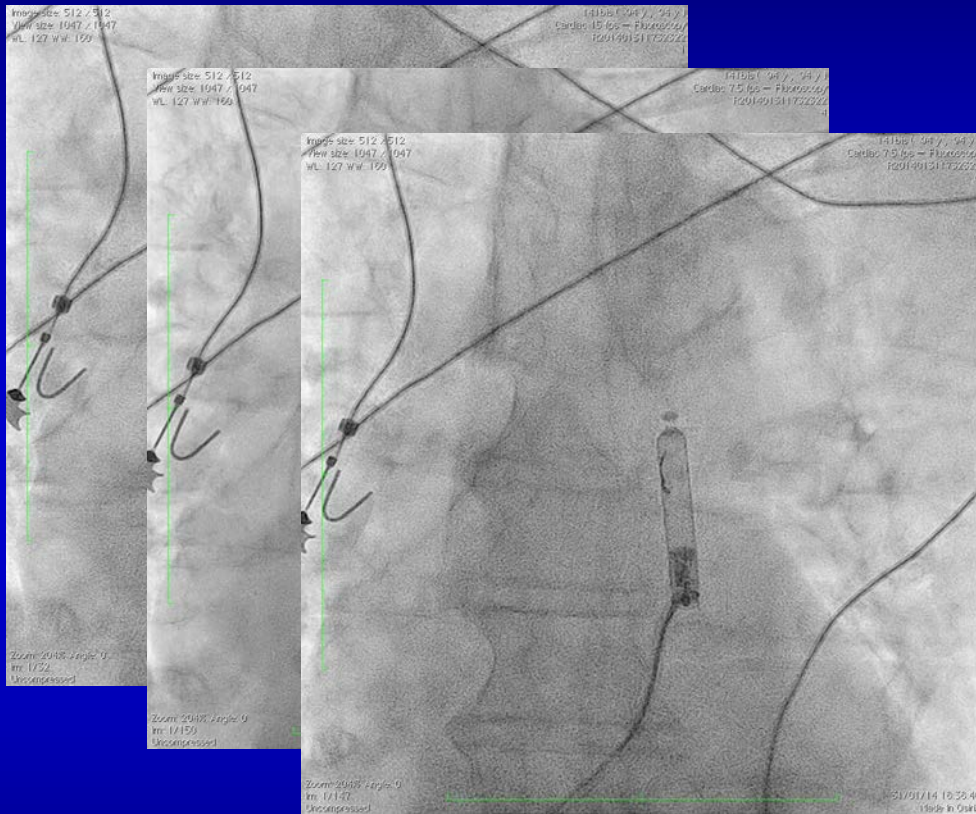


# Leadless PM Retrieval



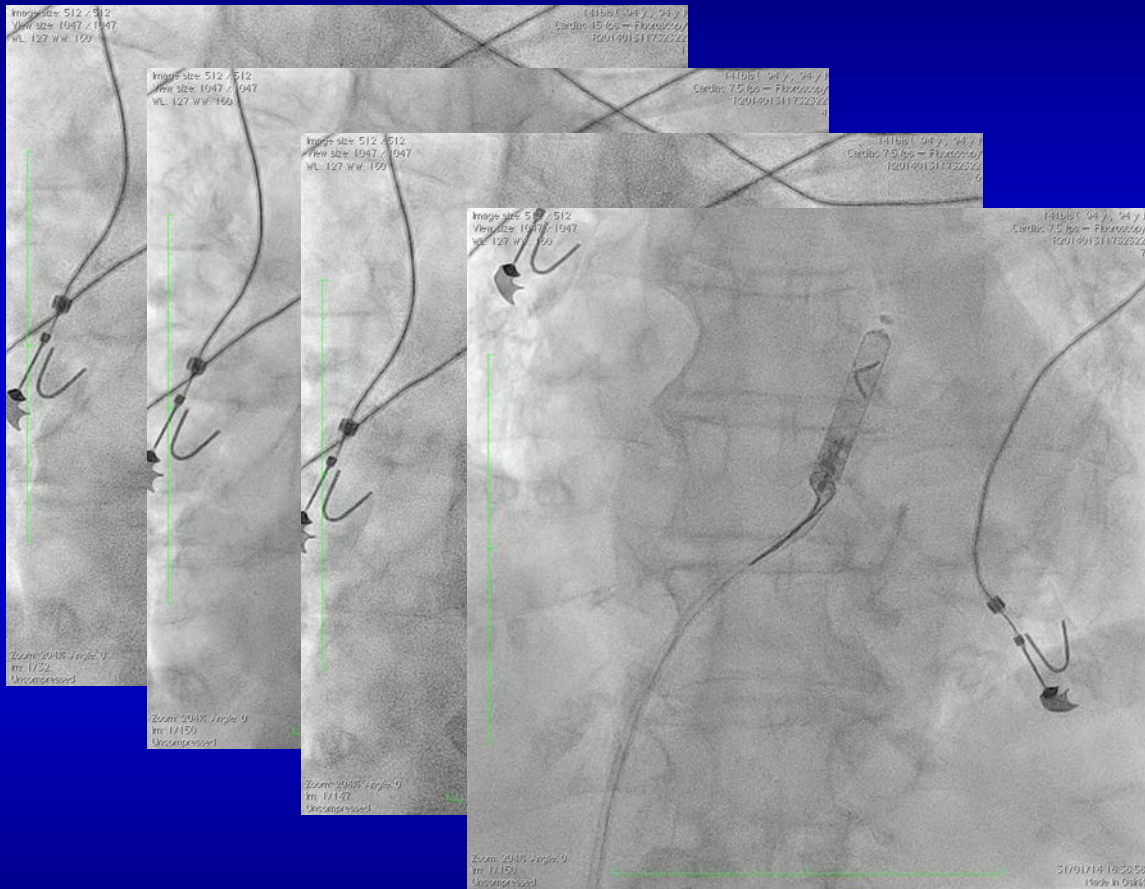


# Leadless PM Retrieval





# Leadless PM Retrieval





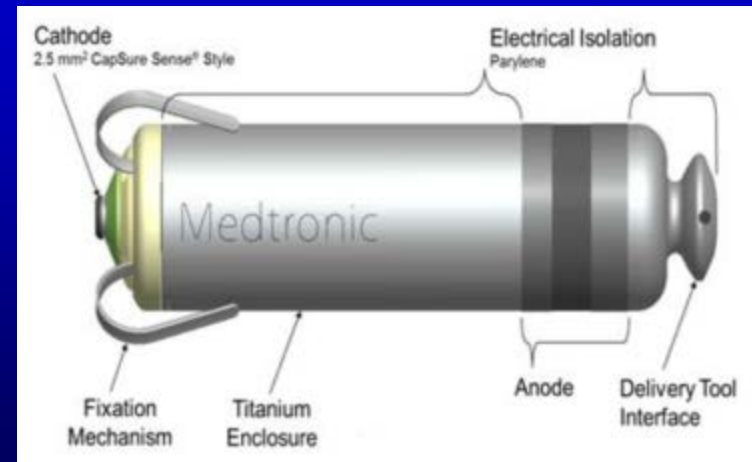


# Micra™ Transcatheter Pacing System



- Self-contained intracardiac PM
- Length: 25.9 mm, max  $\varnothing$ : 6.7 mm
- Weight: 1.75 g, volume: 0.8 cm<sup>3</sup>
- VVIR Pacemaker
- 3-axes accelerometer sensor

- Active fixation via 4 self-expanding nitinol tines
- Interelectrode spacing 17 mm





# Micra™ Additional Features

## INTRODUCER



## DELIVERY SYSTEM

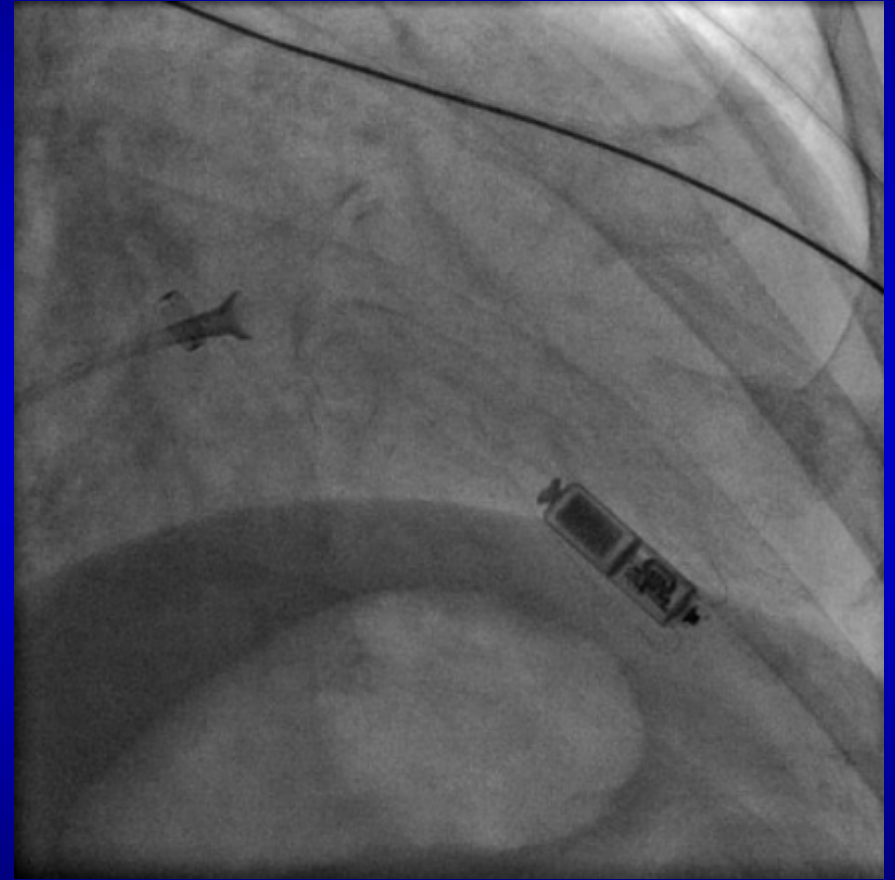
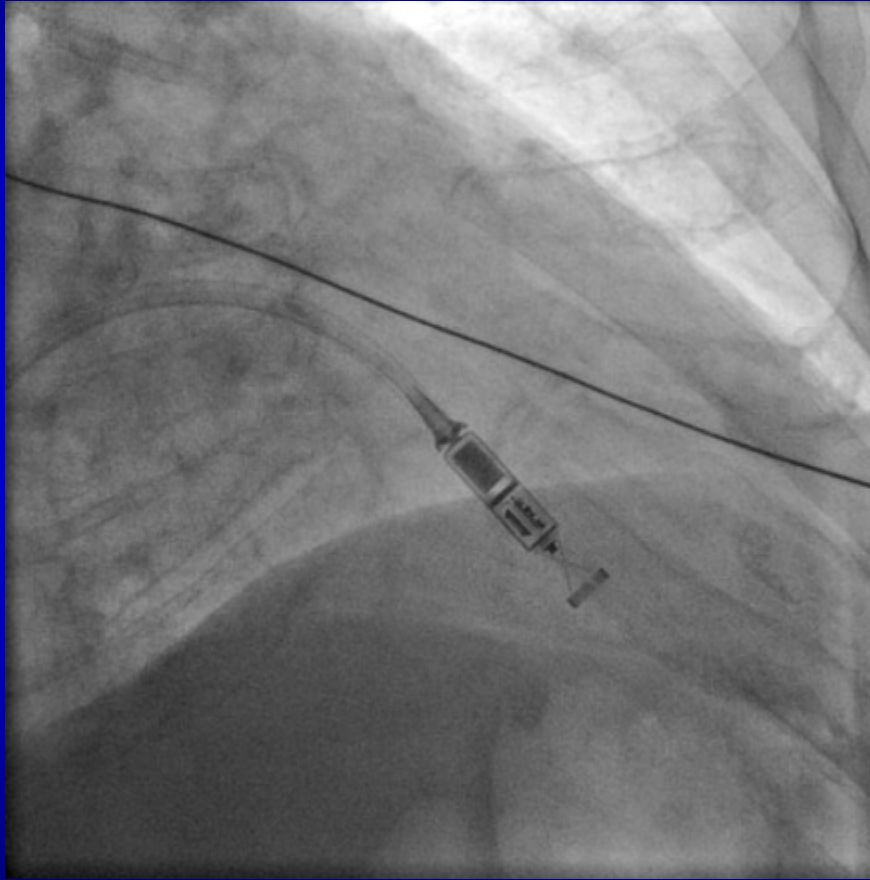


- Communication with 2090 programmer
- Battery longevity estimates:
  - **10.1 years** @ 1.5 V, 0.24 ms, 500  $\Omega$ , 100% VP





# Micra™ Implantation Case



# Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study

Philippe Ritter<sup>1\*</sup>, Gabor Z. F. ... Steinwender<sup>3</sup>, Kyoko Soejima<sup>4</sup>, Razali Omar<sup>5</sup>, Lluís M... ersma<sup>7</sup>, Reinoud E. Knops<sup>8</sup>, Larry Chinitz<sup>9</sup>, Shu Zhang<sup>10</sup>, Calambur... John Hummel<sup>12</sup>, Michael Lloyd<sup>13</sup>, Timothy Alexander Sim... Andrew Voigt<sup>15</sup>, Verla Laager<sup>16</sup>, Kurt Stromberg<sup>16</sup>, Matthew D. Bonner<sup>16</sup>, Todd J. Sheldon<sup>16</sup>, and Dwight Reynolds<sup>17</sup>, Micra Transcatheter Pacing Study Group

**ONGOING**

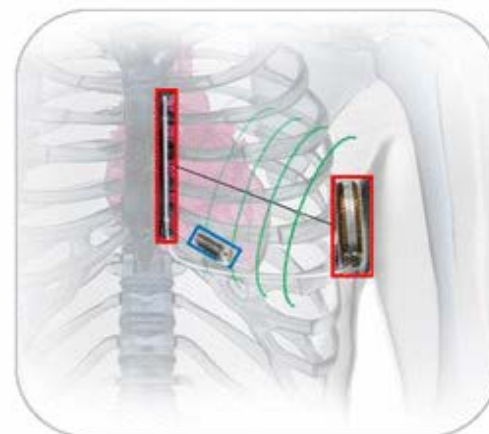
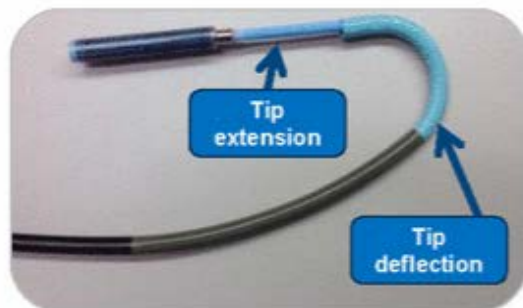
- **140** patients enrolled so far (Target N = 720)
- **100%** successful implants
- Average implant time **37** minutes
- Electrical measurements in expected ranges
- **1 (0.7%)** pericardial effusion without tamponade
- **11 (8%)** vascular complicationsa at puncture site

# Other Manufacturers



**SORIN GROUP**  
AT THE HEART OF MEDICAL TECHNOLOGY

**Boston  
Scientific**



pointe stimulatrice

## Program Goals

- Paired with S-ICD™ (ATP)
- Single chamber
- Dual chamber & CRT applications pending

## Key Features

- Fixation / rate response
- Delivery system with atraumatic tip
- Communication (S-ICD)

## Status

- Development phase
- Clinical planning

S-ICD™ System & VVIR development complete 2016E

S-ICD™ system & VVIR development complete 2016E

# Leadless PM - Conclusions

Leadless right ventricular pacing has been proved feasible, with advantages for **selected patients** in terms of lead failure and infective complications

Most common procedure related adverse events include risk of cardiac perforation and vascular access complications

# **Leadless PM**

## **Limitations and Open Questions**

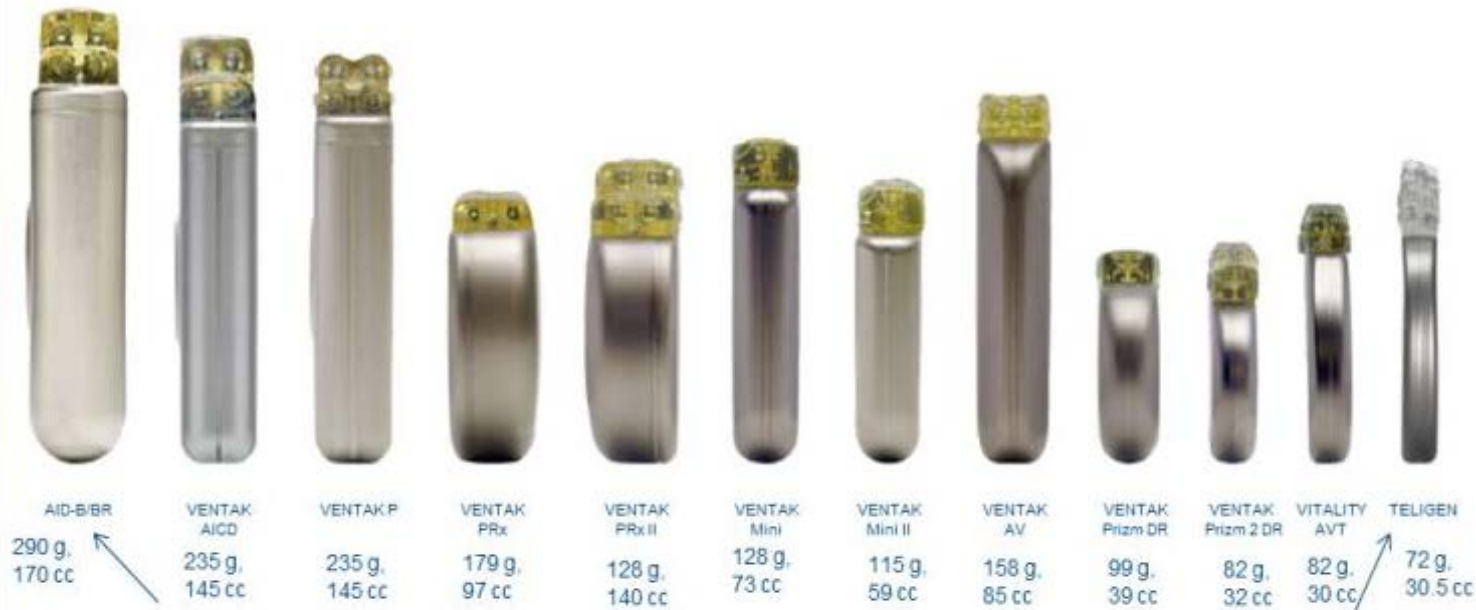
**Leadless pacing is currently limited to single right ventricular pacing**

**Long-term reliability data are lacking**

**How patients should be managed at the time of elective battery replacement?**



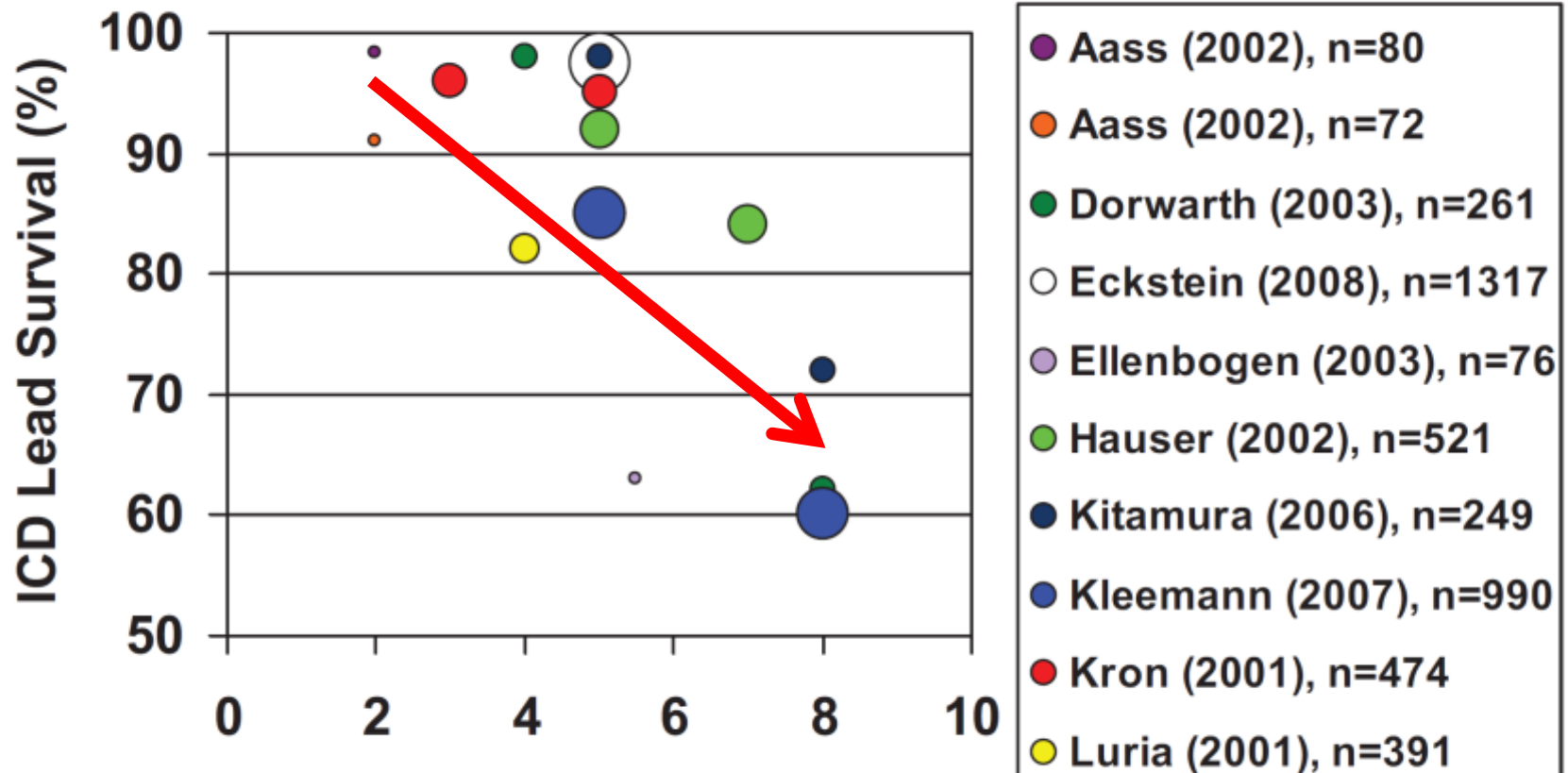
# ICD's Evolution



1980 primo defibrillatore automatico impiantato

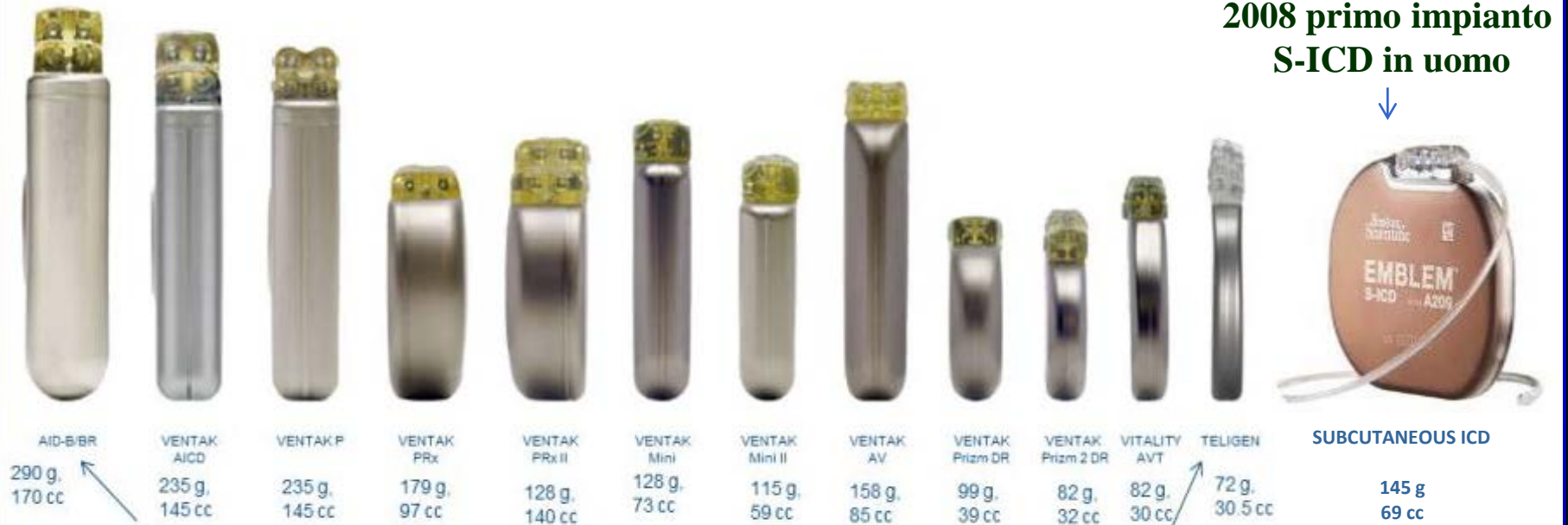
2008 primo defibrillatore biventricolare con spessore < 1 cm

# ICD Lead Performance



**≈ 20-30% ICD transvenous lead fail by 10 yrs**

# ICD's Evolution



2008 primo impianto S-ICD in uomo

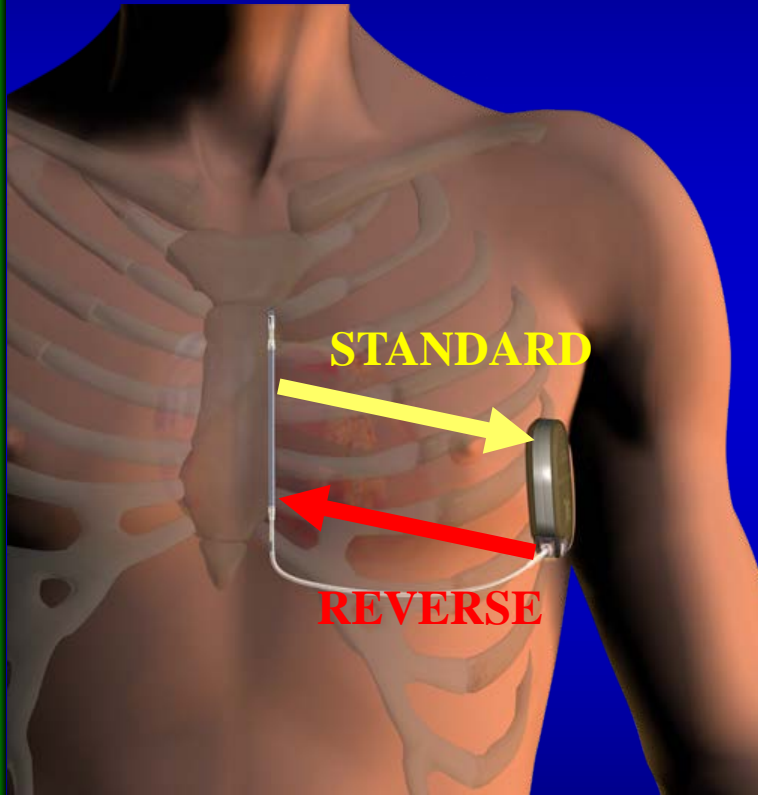


SUBCUTANEOUS ICD

1980 primo defibrillatore automatico impiantato

2008 primo defibrillatore biventricolare con spessore < 1 cm

# S-ICD™ – General features



- Biphasic shock, 50% tilt
- 80J (delivered)
  - Up to 5 shocks per episode
  - Charge time for 80J  $\leq$  10 sec
- Adaptive shock polarity
- Post-shock transcutaneous pacing (VVI@50bpm, 30 s)
- No ATP
- Battery longevity: 7.4 years\*

\* Normal use, defined as 3 full-energy capacitor charges per year

# S-ICD™ – Implant Procedure

Create  
Device Pocket

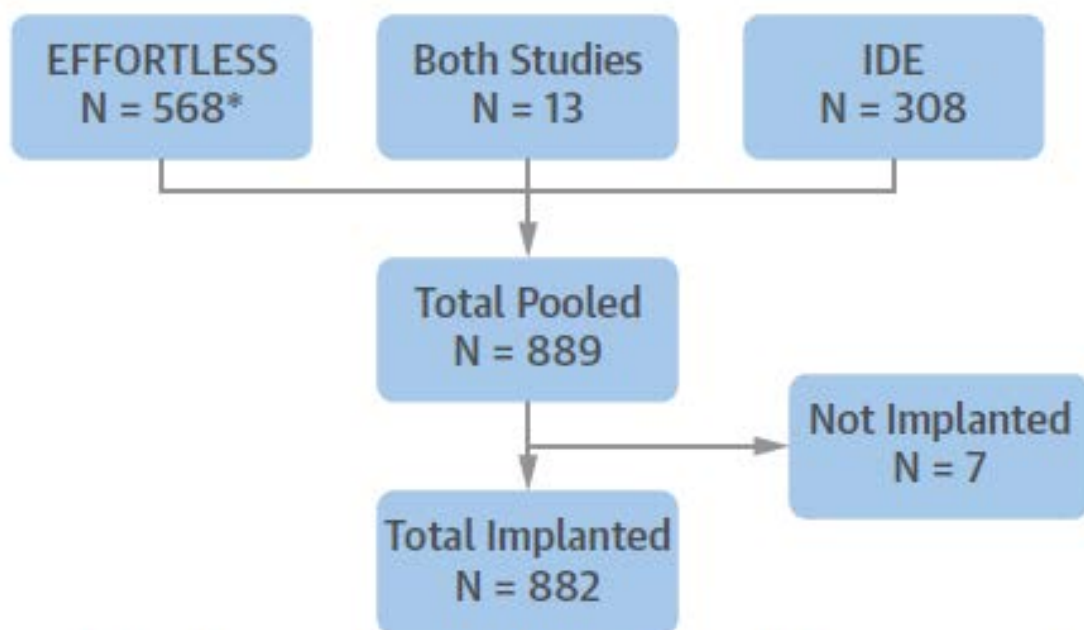




# 568 EFFORTLESS + 321 IDE patients

## Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator

2-Year Results From a Pooled Analysis of the IDE Study and EFFORTLESS Registry

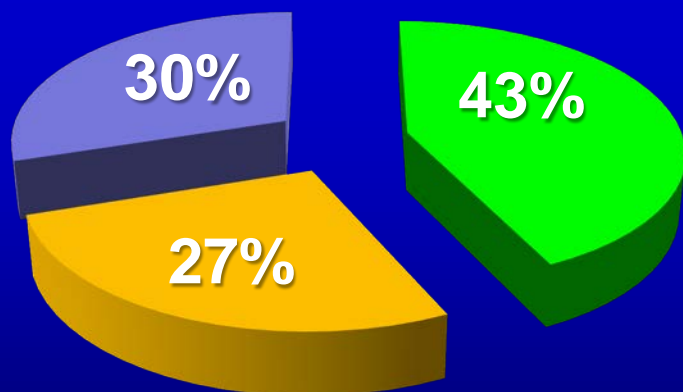


\* Includes 314 enrolled prospectively and 254 enrolled retrospectively

# 568 EFFORTLESS + 321 IDE patients

43% implanted for SCD 1ary prevention + EF <35%

- 1ary prevention low EF
- 1ary prevention other
- 2ary prevention

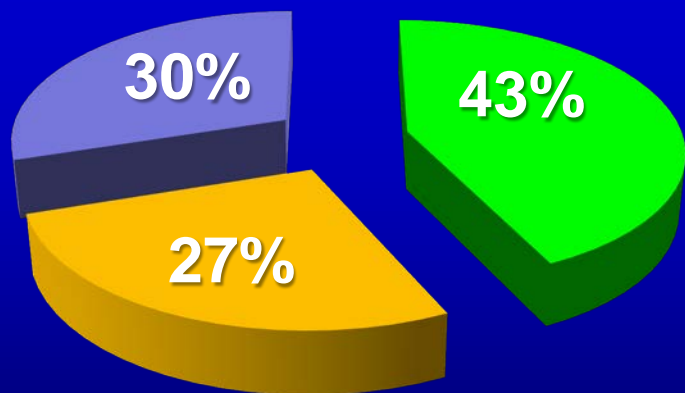


Demographic	
Age (years)	50.3 ± 16.9
Male (n, %)	636 (72.5)
Ischemic	330 (37.8%)
Genetic	58 (6.7%)
Idiopathic VF	40 (4.6%)
Channelopathies	90 (10.3%)
NYHA Classification II-IV	327 (37.5%)
Atrial Fibrillation	143 (16.4%)
Previous Defibrillator	120 (13.7%)

# 568 EFFORTLESS + 321 IDE patients

43% implanted for SCD 1ary prevention + EF <35%

- 1ary prevention low EF
- 1ary prevention other
- 2ary prevention



Demographic	
Age (years)	50.3 ±16.9
Male (n, %)	636 (72.5)
Ischemic	330 (37.8%)
<u>Genetic</u>	<u>58 (6.7%)</u>
<u>Idiopathic VF</u>	<u>40 (4.6%)</u>
<u>Channelopathies</u>	<u>90 (10.3%)</u>
NYHA Classification II-IV	327 (37.5%)
Atrial Fibrillation	143 (16.4%)
Previous Defibrillator	120 (13.7%)

# 568 EFFORTLESS + 321 IDE patients

- **Mortality 3.2% at 2 years**
- **First shock efficacy: 90.1%**
- **All 5 shocks set efficacy: 98.2%**

# Subcutaneous-ICD – Concerns

- **No antibradycardia / biventricular pacing**
- **Shock only / No antitachycardia pacing available**
- **Weight, dimensions and costs are higher than standard ICDs**



# New ESC VT and SCD Guidelines

## Subcutaneous implantable cardioverter defibrillator

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref. <sup>c</sup>
Subcutaneous defibrillators should be considered as an alternative to transvenous defibrillators in patients with an indication for an ICD <u>when pacing therapy for bradycardia support, cardiac resynchronization or antitachycardia pacing is not needed.</u>	IIa	C	157, 158

# Potential S-ICD candidates

**Young patients (e.g channelopathies)  
without anticipated need for  
antibradycardia / antitachycardia or  
biventricular pacing are the best  
candidates for S-ICD**

*Thank you for your attention!*

