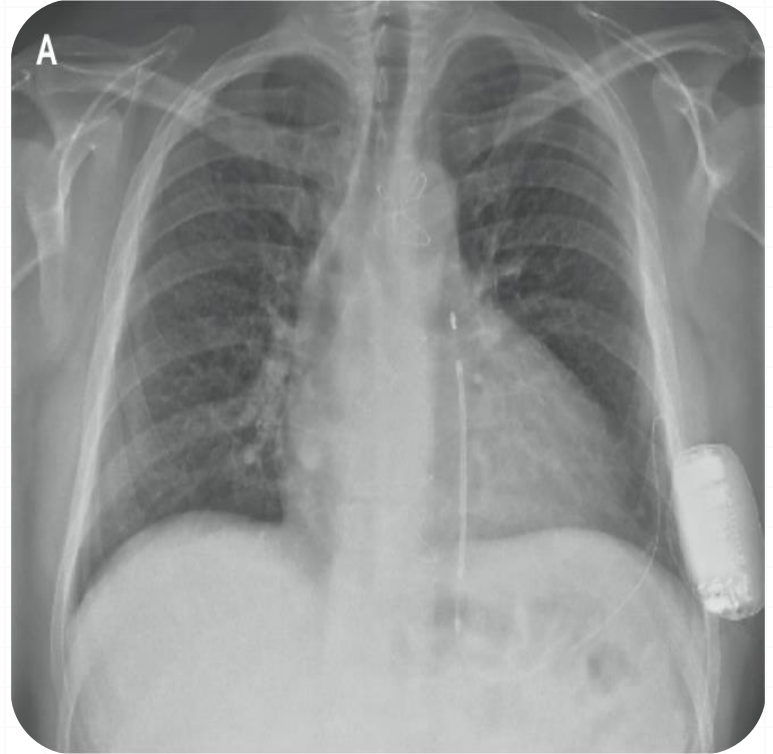
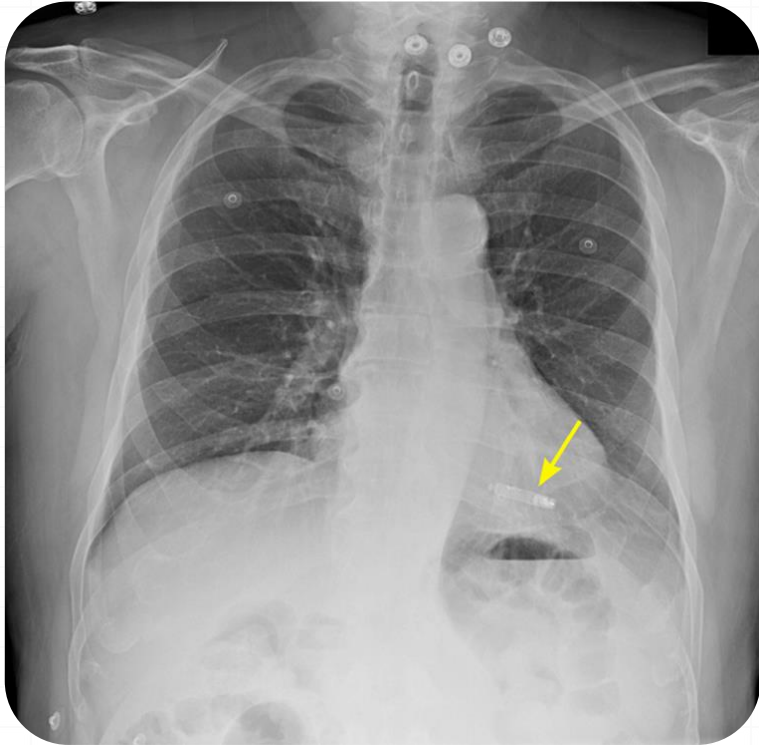


What's New in CIEDs

**Keimyung University Dongsan Medical Center
Hyung-Seob Park**



Transvenous CIEDs

- ✓ Technology:
 - Highly mature & reliable
 - Still includes generator, connectors and leads

- ✓ Procedure :
 - Surgical pocket + Transvenous leads

- ✓ Device issues – Pocket
 - Discomfort, Hematomas, Infections, Cosmetic concerns

- ✓ Leads
 - Mechanical failures
 - Infections; Extractions
 - Mobility restrictions
 - Incompatibility with MRI

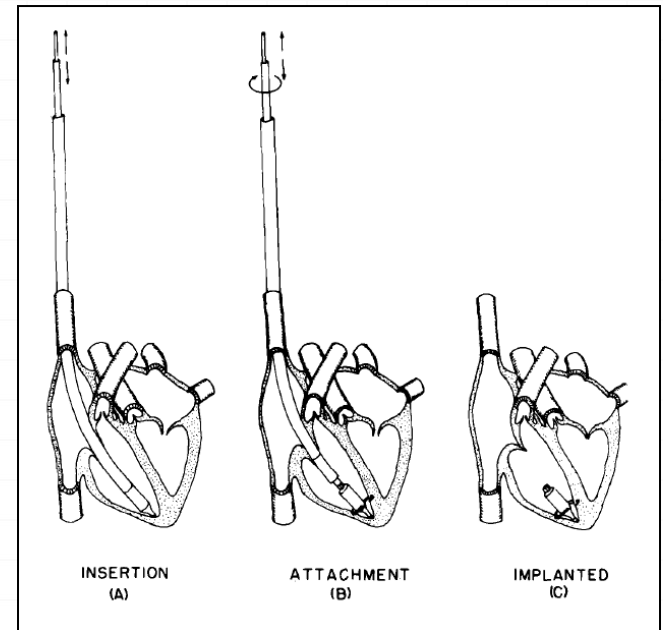
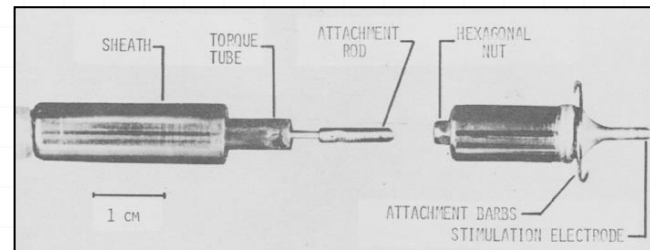
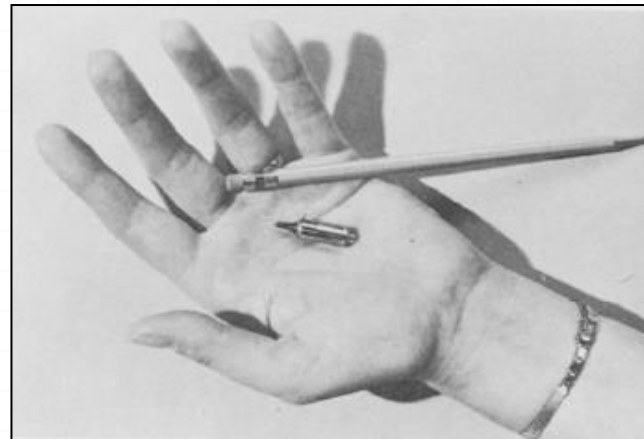
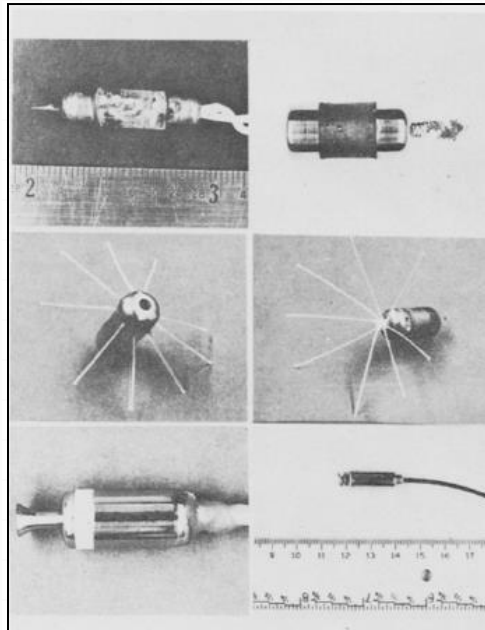
History of Leadless Pacing

J. ELECTROCARDIOLOGY, 3 (3-4) 325-331, 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.



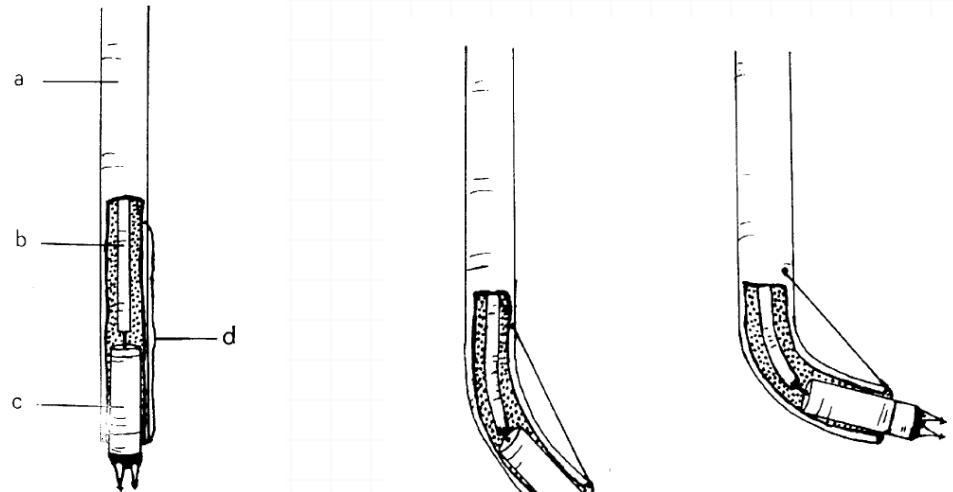
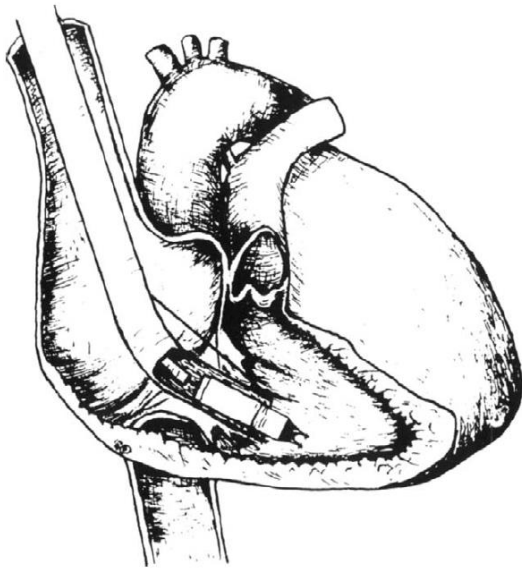
History of Leadless Pacing

© by EBM

EUR.J.CPE.1991.1:27-30

A Miniature Pacemaker Introduced Intravenously and Implanted Endocardially. Preliminary Findings from an Experimental Study

P.E. VARDAS, C. POLITOPOULOS, E. MANIOS, F. PARTHENAKIS, and C. TSAGARAKIS



- a: Guiding catheter
- b: Pusher catheter
- c: Miniature pacemaker
- d: Steering arm

What's Needed for a Leadless Pacemaker?

- ✓ Catheter-based delivery system
- ✓ High density energy source
- ✓ Low power electronics
- ✓ Novel communication scheme
- ✓ Biocompatible materials
- ✓ Dependable fixation design
- ✓ Retrievability capability

Leadless Pacemakers

LCP™ Nanostim/SJM



December 2012

Micra™ Medtronic



December 2013

WiCS™ EBR



May 2011

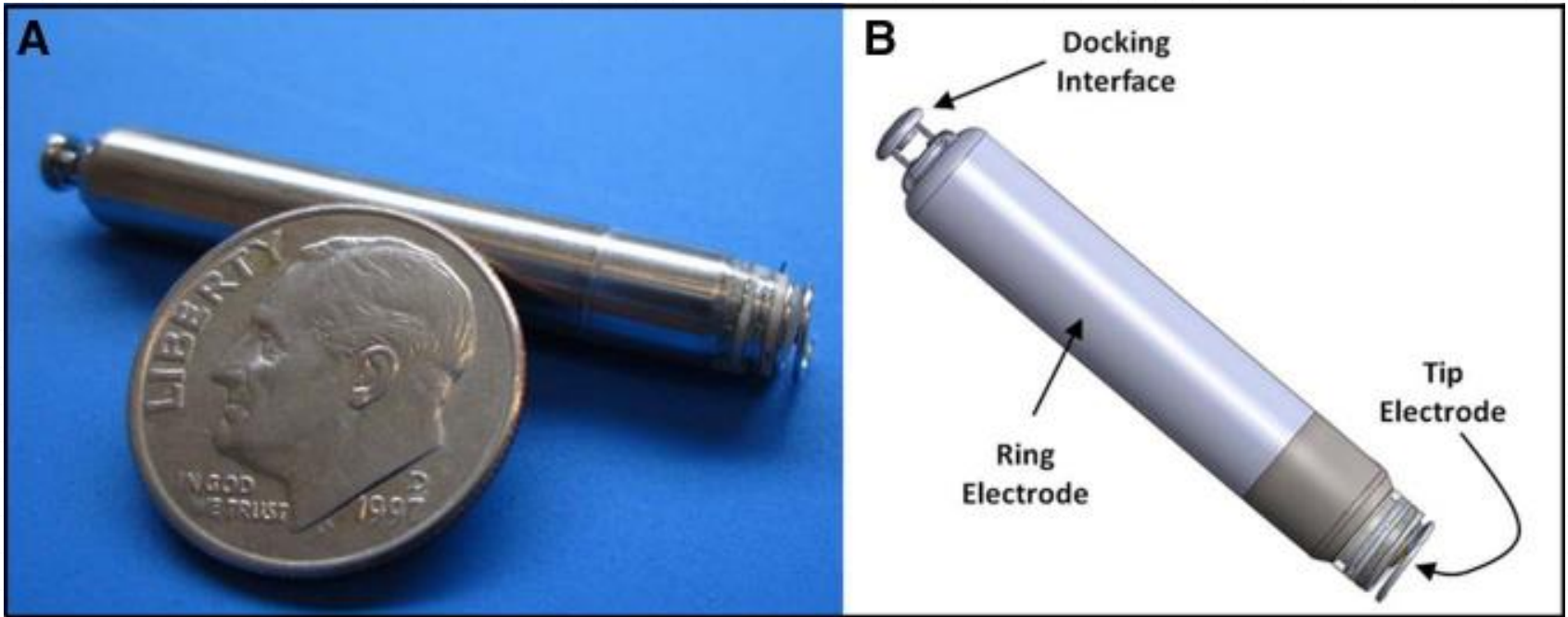
Nanostim™ Leadless Pacemaker

The Nanostim™ VVIR pacemaker is introduced through the femoral vein into the right ventricle.

- ✓ Energy efficient
 - ✓ High-capacity CFx battery
 - ✓ Lower resistance due to lack of lead
 - ✓ Low-power conductive communication
- ✓ Compatible with Merlin™ Patient Care System
- ✓ Electrode design is identical to a St. Jude Medical electrode with same steroid elution
- ✓ Designed to prevent dislodgement
 - ✓ Double fixation: single turn helix (x 2 pull-strength) plus angled nylon sutures
 - ✓ Radiographic indicator to ensure proper number of turns
- ✓ Tethered test mode for perioperative evaluation
- ✓ Designed for retrievability
 - ✓ Catheter-based retrieval system



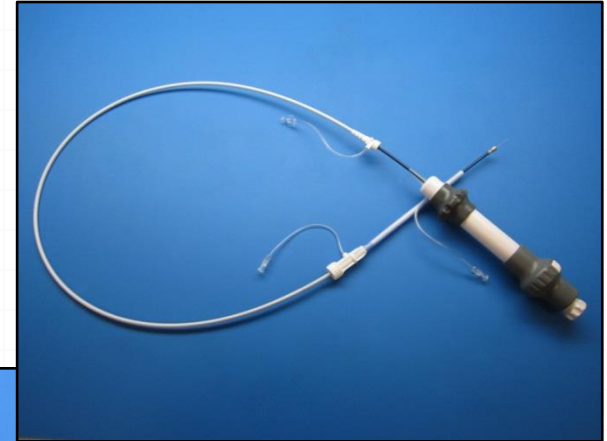
Nanostim™ Leadless Pacemaker



The Nanostim™ Leadless Pacemaker Delivery System

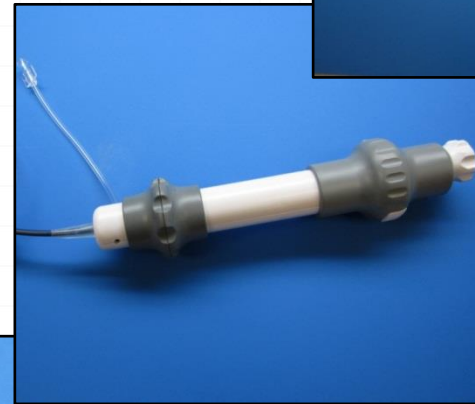
✓ Delivery catheter

- ✓ Soft, flexible, deflectable catheter tip designed to minimize complications
- ✓ Tethered feature
- ✓ Integrated protective sleeve
- ✓ 18 F

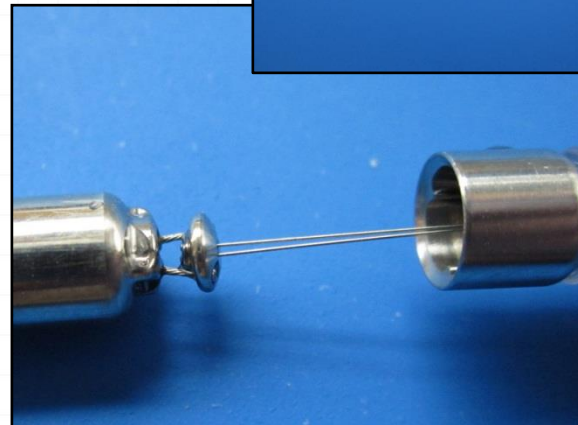


✓ Handle with four functions:

- ✓ Steering the deflectable tip
- ✓ Docking/undocking
- ✓ Rotating the device
- ✓ Releasing tether

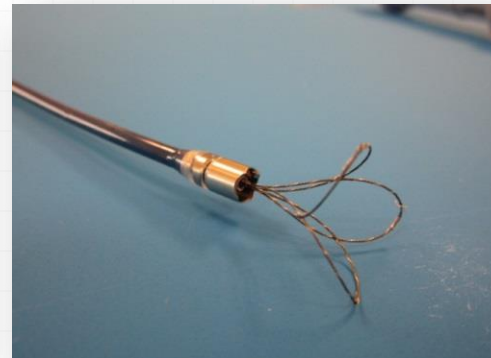
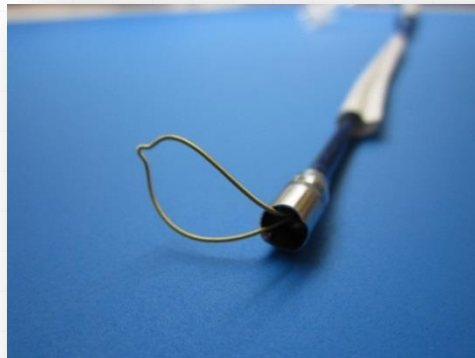


✓ 18 F introducer

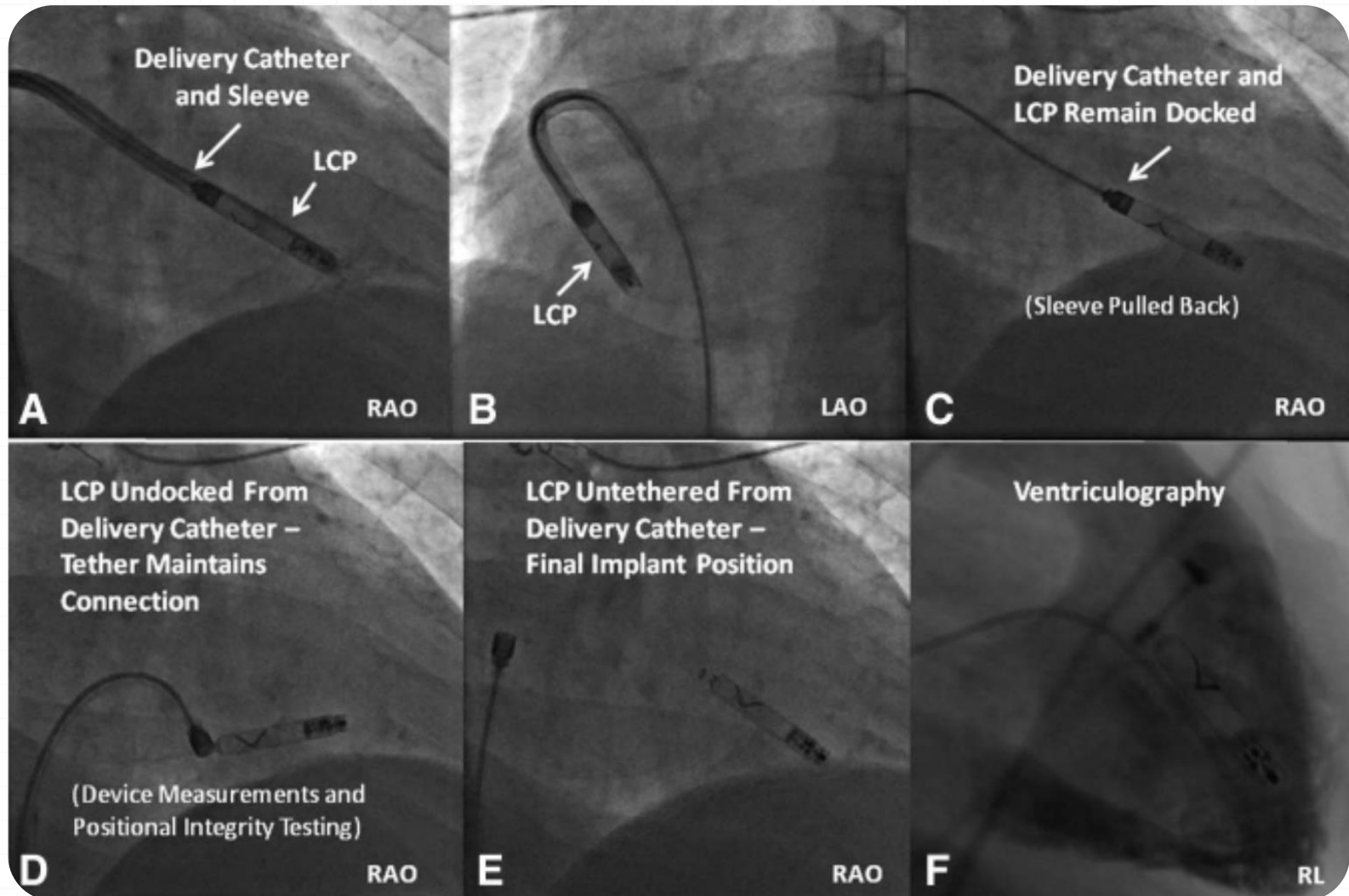


The Nanostim™ Leadless Pacemaker Retrieval System

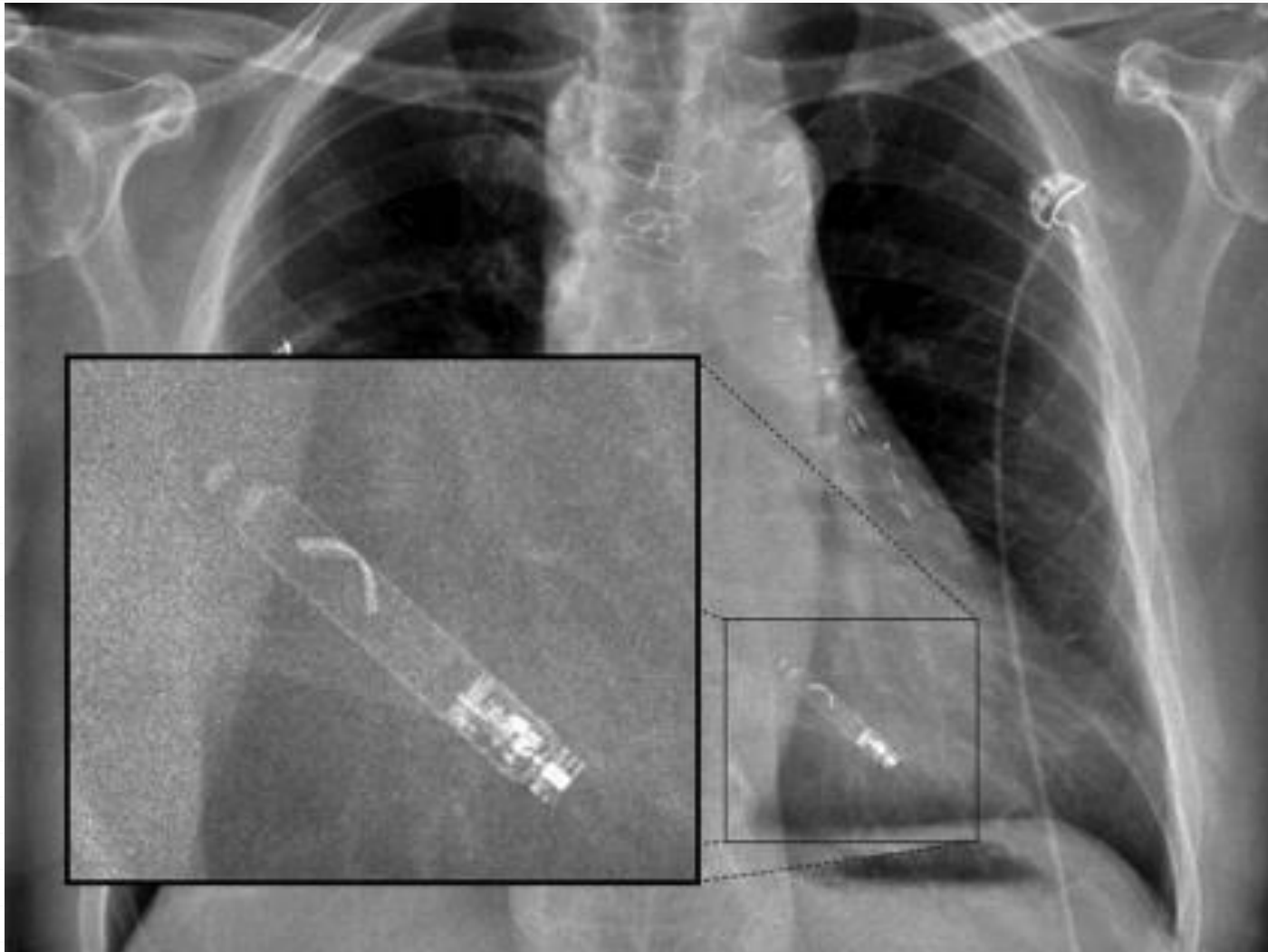
- ✓ Similar to delivery system
 - ✓ Flexible with deflectable tip
 - ✓ Integrated protective sleeve
 - ✓ 18 F
- ✓ Either single loop or triple loop snare
- ✓ Handle with three functions:
 - ✓ Steering the deflectable tip for accurate passage
 - ✓ Grabbing and docking the LP
 - ✓ Rotating the LP



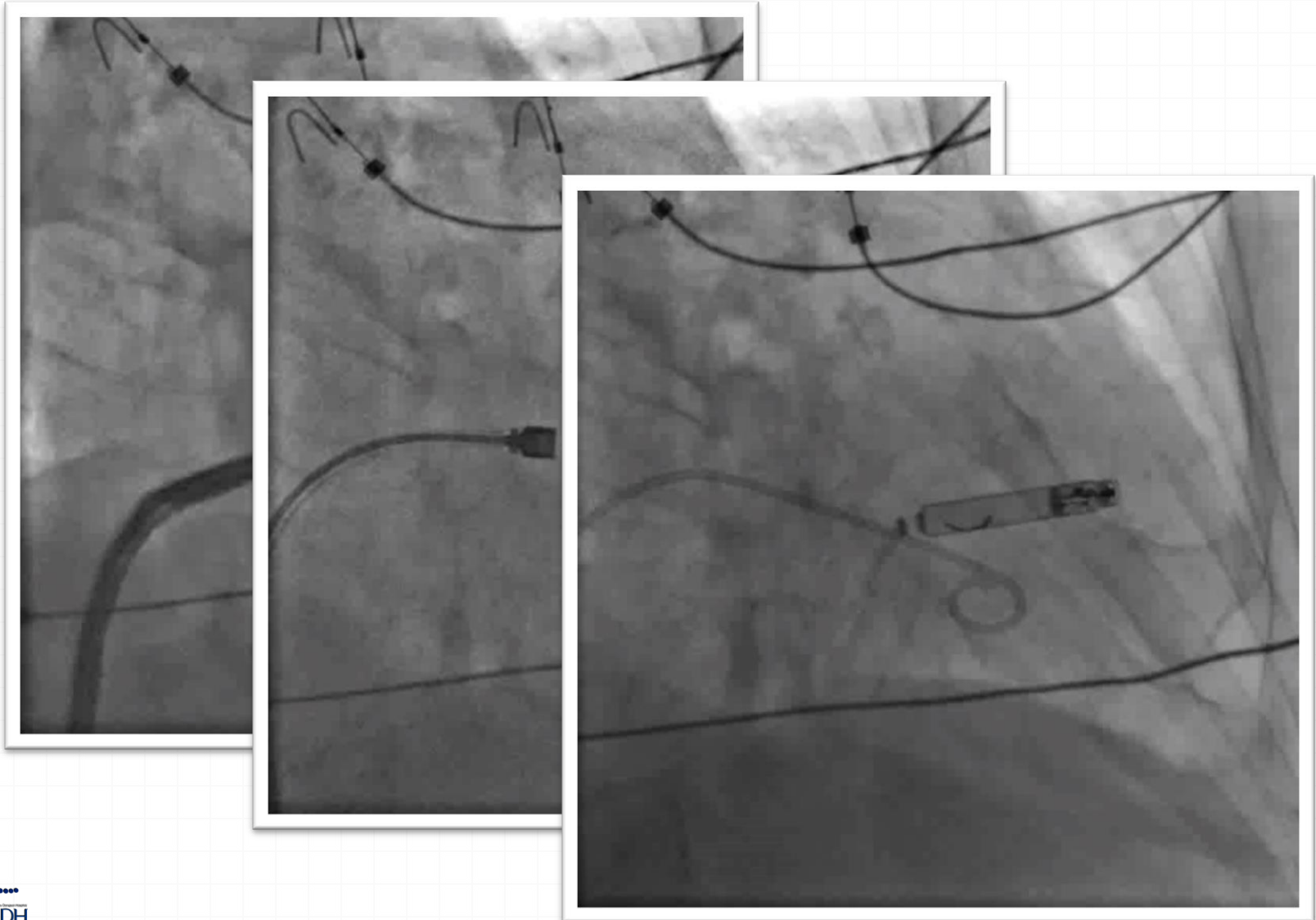
Leadless Pacemaker Implantation



Leadless Pacemaker Implantation



Leadless PMK at RV Base



Comparison with Conventional System

Attribute	Lead-based Pacemaker	Leadless Pacemaker
Implant procedure	Surgical pocket + lead (7 F)	Percutaneous femoral based delivery (18 F)
Implant time	30 – 40 minutes	15-20 minutes ¹⁵ (shorter patient recovery)
X-ray exposure	For implanter: Next to the X-ray tube	For implanter: Further away from the source
Connections	Lead-can connectors	None
Apparatus in vascular system (chronic)	Yes (lead)	No (leadless)
Apparatus through tricuspid valve (chronic)	Yes (lead)	No (leadless)
System removal	Specialization required	Removal tools available
Longevity (2.5V, 0.4ms, 60 bpm) Accent™ SR Inductive for lead-based (500 Ω for Accent, 600 Ω for leadless)	100% pacing – 11.2 years 75% pacing – 11.8 years 50% pacing – 12.5 years 25% pacing – 13.3 years	100% pacing – 9.8 years 75% pacing – 11.7 years 50% pacing – 14.5 years 25% pacing – 18.9 years
Battery Replacement	Pocket access	Femoral access: removal+ new implant Option for another adjacent implant
MRI compatibility	Conditional – image impact	MRI conditional status not yet determined

Key Benefits for Nanostim™ LP



Leadless Trial

Arrhythmia/Electrophysiology

Permanent Leadless Cardiac Pacing Results of the LEADLESS Trial

Vivek Y. Reddy, MD; Reinoud E. Knops, MD; Johannes Sperzel, MD; Marc A. Miller, MD;
Jan Petru, MD; Jaroslav Simon, MD; Lucie Sediva, MD; Joris R. de Groot, MD, PhD;
Fleur V.Y. Tjong, MD; Peter Jacobson, BS; Alan Ostrosff, MS; Srinivas R. Dukkipati, MD;
Jacob S. Koruth, MD; Arthur A.M. Wilde, MD, PhD; Josef Kautzner, MD, PhD;
Petr Neuzil, MD, PhD

Background—Conventional cardiac pacemakers are associated with several potential short- and long-term complications related to either the transvenous lead or subcutaneous pulse generator. We tested the safety and clinical performance of a novel, completely self-contained leadless cardiac pacemaker.

Methods and Results—The primary safety end point was freedom from complications at 90 days. Secondary performance end points included implant success rate, implant time, and measures of device performance (pacing/sensing thresholds and rate-responsive performance). The mean age of the patient cohort (n=33) was 77±8 years, and 67% of the patients were male (n=22/33). The most common indication for cardiac pacing was permanent atrial fibrillation with atrioventricular block (n=22, 67%). The implant success rate was 97% (n=32). Five patients (15%) required the use of >1 leadless cardiac pacemaker during the procedure. One patient developed right ventricular perforation and cardiac tamponade during the implant procedure, and eventually died as the result of a stroke. The overall complication-free rate was 94% (31/33). After 3 months of follow-up, the measures of pacing performance (sensing, impedance, and pacing threshold) either improved or were stable within the accepted range.

Conclusions—In a prospective nonrandomized study, a completely self-contained, single-chamber leadless cardiac pacemaker has shown to be safe and feasible. The absence of a transvenous lead and subcutaneous pulse generator could represent a paradigm shift in cardiac pacing.

Clinical Trial Registration—URL: <http://clinicaltrials.gov>. Unique identifier: NCT01700244.
(*Circulation*. 2014;129:1466-1471.)

Key Words: pacemaker, cardiac



Reddy VY et al. *Circulation*. 2014;129:1466-71.

Demographics and Procedural Details

Parameter	(n=33)
Age, y	76.5±8.4
Male, n (%)	22 (67)
Pacing indication, n (%)	
Permanent AF with AV block (including AF with a slow ventricular response)	22 (67)
Sinus rhythm with 2nd/ 3rd degree AV block and significant comorbidities	6 (18)
Sinus bradycardia with infrequent pauses or unexplained syncope	5 (15)
Implant success rate, n (%)	32 (97)
Procedure duration, min	28±17
Time to hospital discharge, h	31±20
Repositioning attempts (to achieve final implant position), n (%)	
0	23 (70)
1	4 (12)
2	4 (12)
3	2 (6)
Rehospitalized within 90 days, n (%)	3 (9)
Complication-free rate, %	94

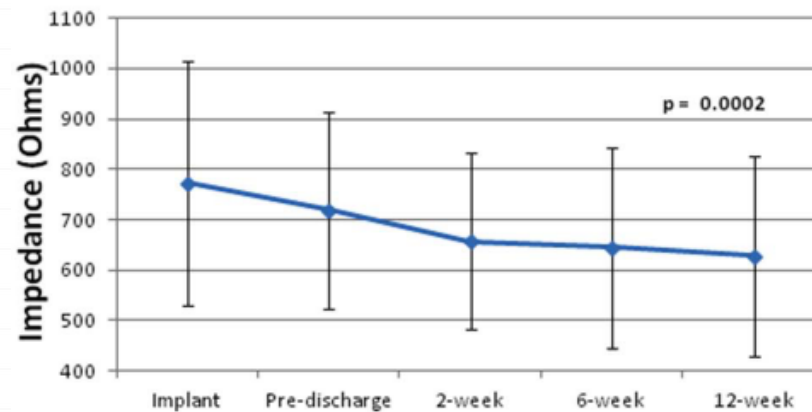
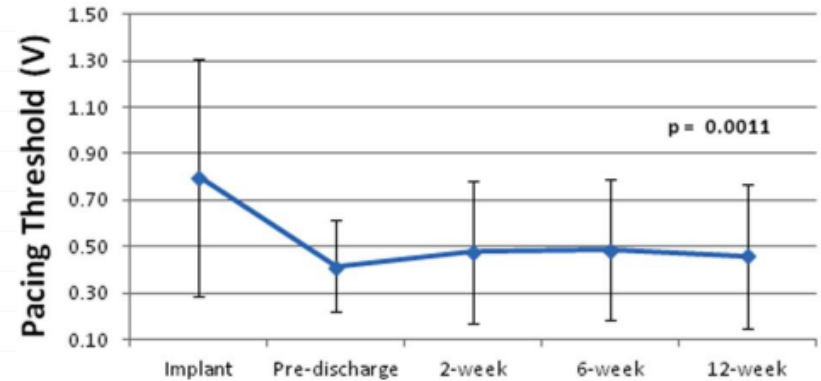
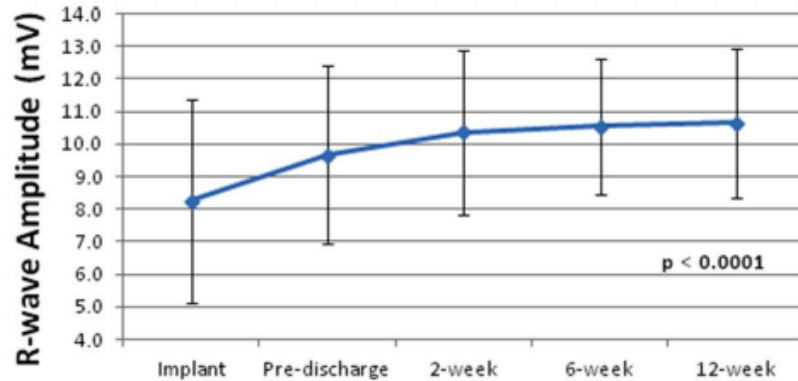
AF indicates atrial fibrillation; and AV, atrioventricular block.

Reddy VY et al. Circulation. 2014;129:1466-71.

Safety Endpoint

- ✓ 1 Minor Groin Hematoma, no treatment
- ✓ Cardiac Perforation & Tamponade
 - 70 year-old male with chronic AF, INR 2.1 at implant
 - Uncomplicated Surgical Repair
 - But during convalescence (5 days post-op)
 - Large right-sided stroke (INR = 1.5)
 - Expired

Device Performance Measurements



Chronic Performance of a Leadless Cardiac Pacemaker

1-Year Follow-Up of the LEADLESS Trial



Reinoud E. Knops, MD,* Fleur V.Y. Tjong, MD,* Petr Neuzil, MD, PhD,† Johannes Sperzel, MD,‡ Marc A. Miller, MD,§ Jan Petru, MD,† Jaroslav Simon, MD,† Lucie Sediva, MD,† Joris R. de Groot, MD, PhD,* Srinivas R. Dukkipati, MD,§ Jacob S. Koruth, MD,§ Arthur A.M. Wilde, MD, PhD,* Josef Kautzner, MD, PhD,|| Vivek Y. Reddy, MD§

ABSTRACT

BACKGROUND A leadless cardiac pacemaker (LCP) system was recently introduced to overcome lead-related complications of conventional pacing systems. To date, long-term results of an LCP system are unknown.

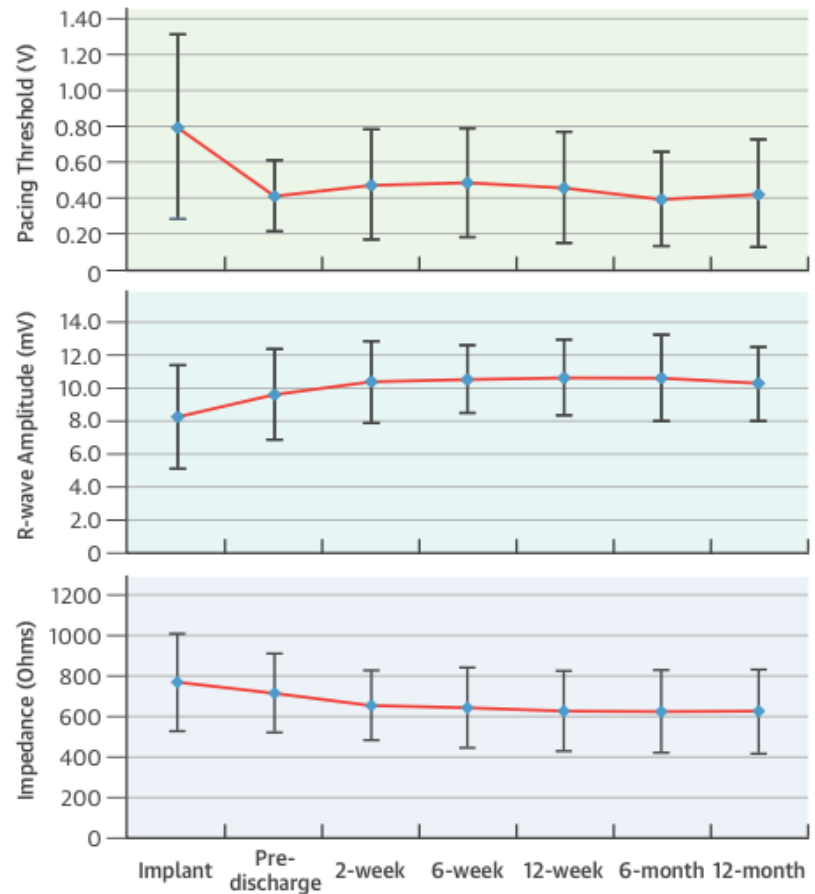
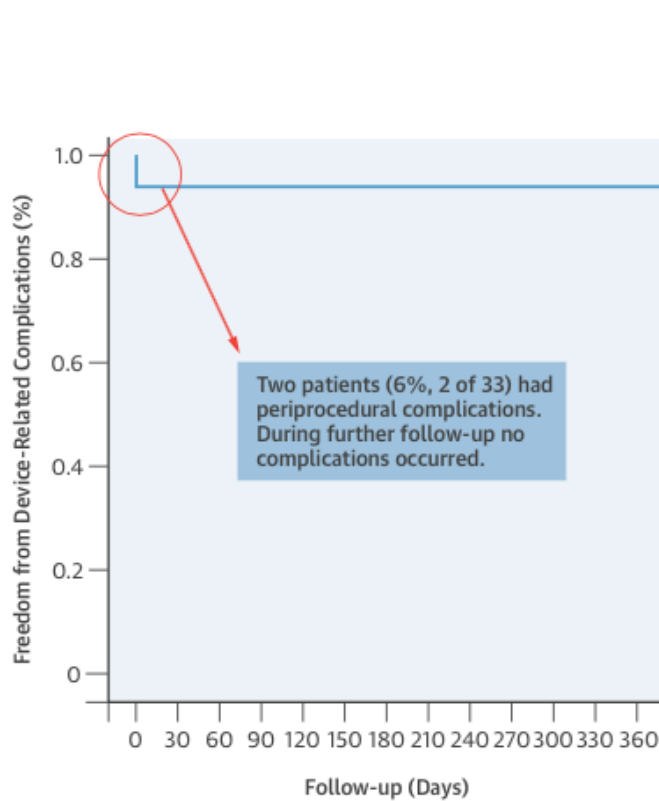
OBJECTIVES The aim of this study was to assess the complication incidence, electrical performance, and rate response characteristics within the first year of follow-up of patients implanted with an LCP.

METHODS We retrospectively assessed intermediate-term follow-up data for 31 of 33 patients from the LEADLESS trial cohort who had an indication for single-chamber pacing and received an LCP between December 2012 and April 2013.

RESULTS The mean age of the cohort was 76 ± 8 years, and 65% were male. Between 3 and 12 months of follow-up, there were no pacemaker-related adverse events reported. The pacing performance results at 6- and 12-month follow-up were, respectively, as follows: mean pacing threshold (at a 0.4-ms pulse width), 0.40 ± 0.26 V and 0.43 ± 0.30 V; R-wave amplitude 10.6 ± 2.6 mV and 10.3 ± 2.2 mV; and impedance $625 \pm 205 \Omega$ and $627 \pm 209 \Omega$. At the 12-month follow-up in 61% of the patients ($n = 19$ of 31), the rate response sensor was activated, and an adequate rate response was observed in all patients.

CONCLUSIONS The LCP demonstrates very stable performance and reassuring safety results during intermediate-term follow-up. These results support the use of the LCP as a promising alternative to conventional pacemaker systems. Continued evaluation is warranted to further characterize this system. (Evaluation of a New Cardiac Pacemaker; [NCT01700244](https://clinicaltrials.gov/ct2/show/study/NCT01700244)) (J Am Coll Cardiol 2015;65:1497-504) © 2015 by the American College of Cardiology Foundation.

CENTRAL ILLUSTRATION 1-Year Follow-Up of Patients Implanted With a Leadless Cardiac Pacemaker: Safety and Device Performance



Knops, R.E. et al. J Am Coll Cardiol. 2015; 65(15):1497-504.

(Left) Kaplan-Meier survival curve represents freedom from device-related complications: 2 patients had device-related complications (6%, 31 of 33), both periprocedurally. During further follow-up, no complications occurred in the remaining patients (n = 31). **(Right)** Device performance measurements of the leadless cardiac pacemaker. The mean value \pm SD of pacing threshold (at 0.4 ms [V]) **(right top)**; the R-wave amplitude (mV) **(right middle)**; and the pacing impedance (Ω) **(right bottom)** at each follow-up assessment.

The LEADLESS Pacemaker IDE Study (Leadless II)

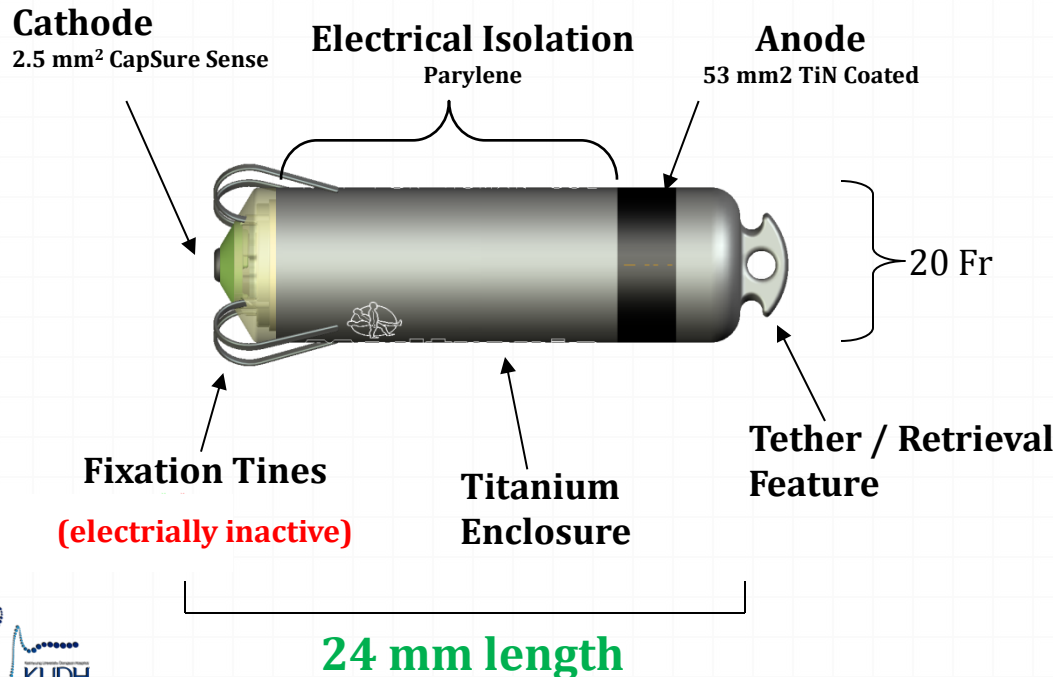
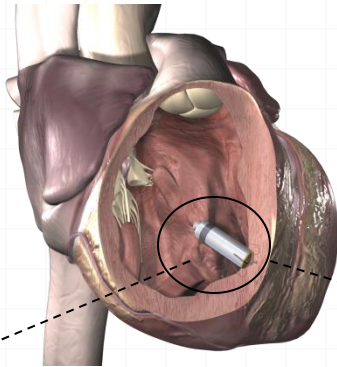
- ✓ Evaluate safety and effectiveness of the Nanostim™ leadless pacemaker in patients indicated for VVIR pacemaker
- ✓ Prospective, single-arm study
- ✓ Estimated Enrollment : 667 patients
- ✓ Primary Safety Endpoint
Complication Free Rate (Up to 6 months post implant)
- ✓ Primary Effectiveness Endpoint
Pacing Thresholds and R-wave amplitudes at 6 months

Micra™ Transcatheter Pacing System (TPS)

- ✓ 25.9 mm, < 1cc miniaturized VVIR pacemaker (Adapta pacemaker ~10cc)
- ✓ World's smallest, minimally invasive pacing system
- ✓ 10 year longevity
- ✓ Percutaneous access to RV apex via femoral vein
- ✓ Active fixation via 4 self-expanding “tines”



Technical Overview: Pacing Capsule



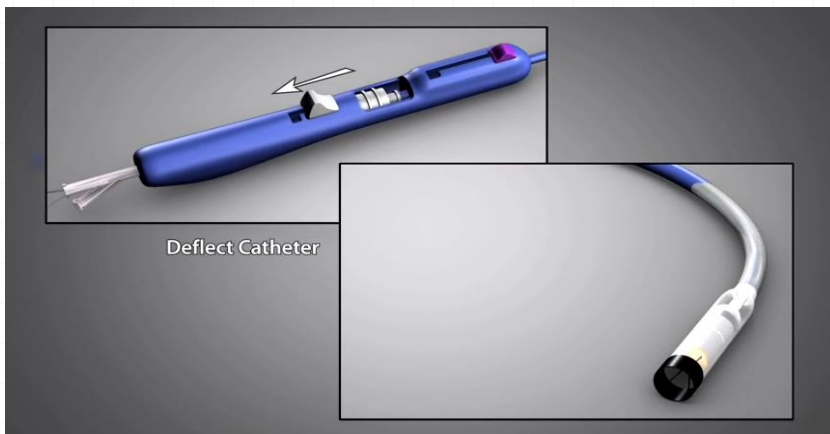
- *VVIR*
- *Volume: 0.75cc / Mass: 2g*
- *Programmable*
- *Bipolar sensing; 17mm spacing*
- *Capture Management*
- *Essential diagnostics (i.e., battery status, pacing threshold, pacing impedance, % paced)*
- *7 yr longevity (100% paced 60 bpm @ 2.0V pacing)*
- *Device can be inactivated at the end of battery life*
- *MR-conditional-MRI Scans*
- *RF communication with programmer and CareLink*



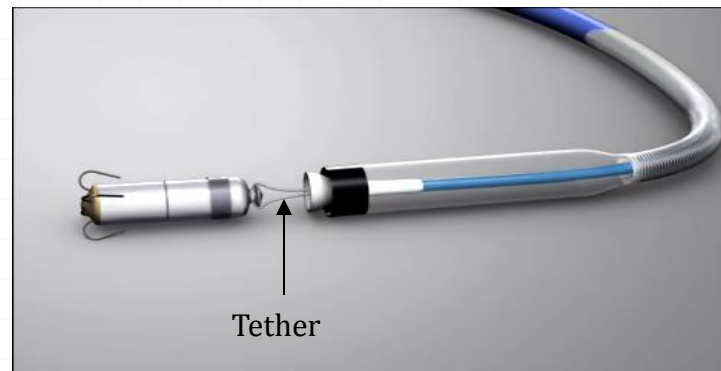
Technical Overview: Delivery System



- ✓ Non-OTW; 24F introducer sheath to RA
- ✓ Distal delivery cup to hold device; 22F
- ✓ 16F proximal shaft
- ✓ Fixed shape proximal curve
- ✓ Off-plane distal articulation
- ✓ 105cm working length (femoral)



Distal delivery cup to hold device; 22F



Implant Tether

- ✓ Facilitates fixation verification (Tug Test)
- ✓ Mechanism for re-capture of PLP Device
- ✓ Removable
- ✓ Medical Grade Suture material: PET with PTFE coating (braided)

Micra Transcatheter Pacing Study

- ✓ ClinicalTrials.gov Identifier : NCT02004873
- ✓ Single arm, multi-center global clinical trial
- ✓ Estimated Enrollment : 780 patients
- ✓ Study Start Date : November 2013
- ✓ Estimated Study Completion Date : June 2018
- ✓ At ~50 centers
- ✓ Primary Outcomes at 6 months :
 - Safety : Major complication-free rate
 - Efficacy : Low and stable pacing capture thresholds

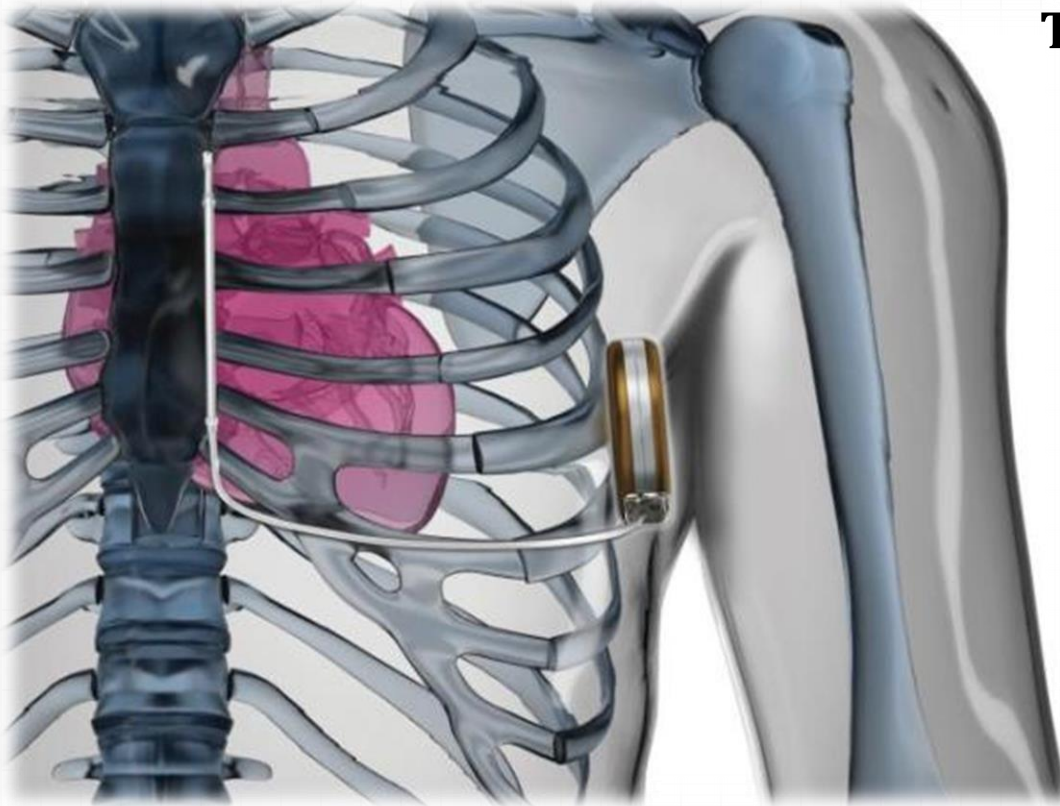


The S-ICD™ System

Design Goals of Subcutaneous ICD Therapy

- ✓ To avoid both the short- and long-term complications associated with transvenous leads
- ✓ To defibrillate with more uniform voltage gradients, reducing myocardial damage
- ✓ To sense activation across the whole heart, improving accuracy for arrhythmia detection.
- ✓ To provide an option for patient sub-populations for which TV-ICD is not ideal
- ✓ To reduce risk of lead failure in young and active patients

Effective defibrillation without transvenous leads



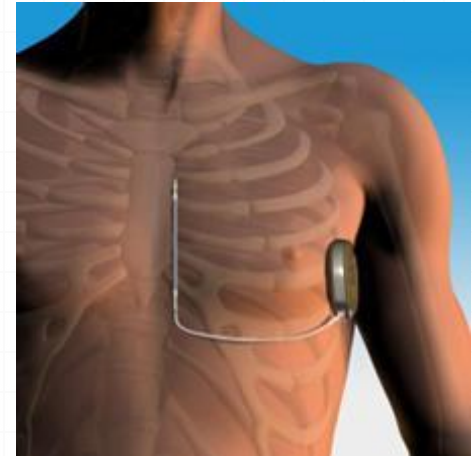
The S-ICD™ System:

- ✓ Entirely subcutaneous
- ✓ Does not require leads in the heart, leaving the vasculature untouched
- ✓ Placed strictly by anatomical landmarks, removing the need for fluoroscopy at implant
- ✓ Sophisticated algorithms provide performance equal to transvenous ICDs¹

1) Burke M, et al. Safety and Efficacy of a Subcutaneous Implantable-Defibrillator (S-ICD System US IDE Study). Late-Breaking Abstract Session. HRS 2012.
Gold M, et al. Head-to-Head Comparison of Arrhythmia Discrimination Performance of Subcutaneous and Transvenous ICD Arrhythmia Detection Algorithms: The START Study. Journal of Cardiovascular Electrophysiology; Vol 23:4(359-366)

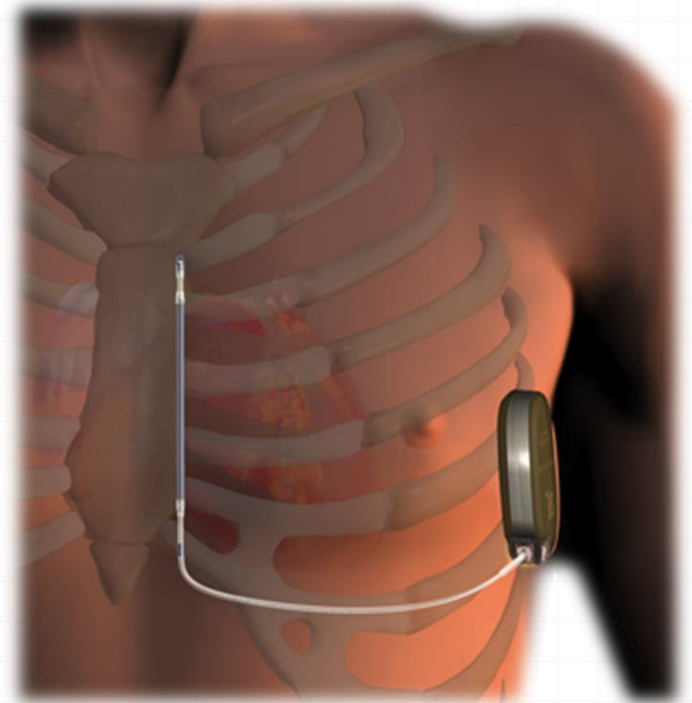
The S-ICD™ System

- ✓ Provides effective defibrillation for ventricular tachyarrhythmias
- ✓ No risk of vascular injury
- ✓ Low risk of systemic infection
- ✓ Preserves Venous access
- ✓ Avoids risks associated with endovascular lead extraction
- ✓ Fluoroscopy not required



The S-ICD™ System

- ✓ 80 joule (delivered) biphasic shock
- ✓ ≤ 10 seconds charge time to 80J
- ✓ 5.1 year projected longevity
- ✓ 30 seconds post-shock pacing
- ✓ Single electrode connection
- ✓ Full featured episode storage



ORIGINAL ARTICLE

An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

Gust H. Bardy, M.D., Warren M. Smith, M.B., Margaret A. Hood, M.B., Ian G. Crozier, M.B., Iain C. Melton, M.B., Luc Jordaens, M.D., Ph.D., Dominic Theuns, Ph.D., Robert E. Park, M.B., David J. Wright, M.D., Derek T. Connelly, M.D., Simon P. Fynn, M.D., Francis D. Murgatroyd, M.D., Johannes Sperzel, M.D., Jörg Neuzner, M.D., Stefan G. Spitzer, M.D., Andrey V. Ardashev, M.D., Ph.D., Amo Odoro, M.B., B.S., Lucas Boersma, M.D., Ph.D., Alexander H. Maass, M.D., Isabelle C. Van Gelder, M.D., Ph.D., Arthur A. Wilde, M.D., Ph.D., Pascal F. van Dessel, M.D., Reinoud E. Knops, M.D., Craig S. Barr, M.B., Pierpaolo Lupo, M.D., Riccardo Cappato, M.D., and Andrew A. Grace, M.B., Ph.D.

ABSTRACT

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Bardy at the Seattle Institute for Cardiac Research, 10115 NE 24th St., Bellevue, WA 98004, or at gbardy@sicr.org.

This article (10.1056/NEJMoa0909545) was published on May 12, 2010, at NEJM.org.

N Engl J Med 2010;363:36–44.
Copyright © 2010 Massachusetts Medical Society.

BACKGROUND

Implantable cardioverter–defibrillators (ICDs) prevent sudden death from cardiac causes in selected patients but require the use of transvenous lead systems. To eliminate the need for venous access, we designed and tested an entirely subcutaneous ICD system.

METHODS

First, we conducted two short-term clinical trials to identify a suitable device configuration and assess energy requirements. We evaluated four subcutaneous ICD configurations in 78 patients who were candidates for ICD implantation and subsequently tested the best configuration in 49 additional patients to determine the subcutaneous defibrillation threshold in comparison with that of the standard transvenous ICD. Then we evaluated the long-term use of subcutaneous ICDs in a pilot study, involving 6 patients, which was followed by a trial involving 55 patients.

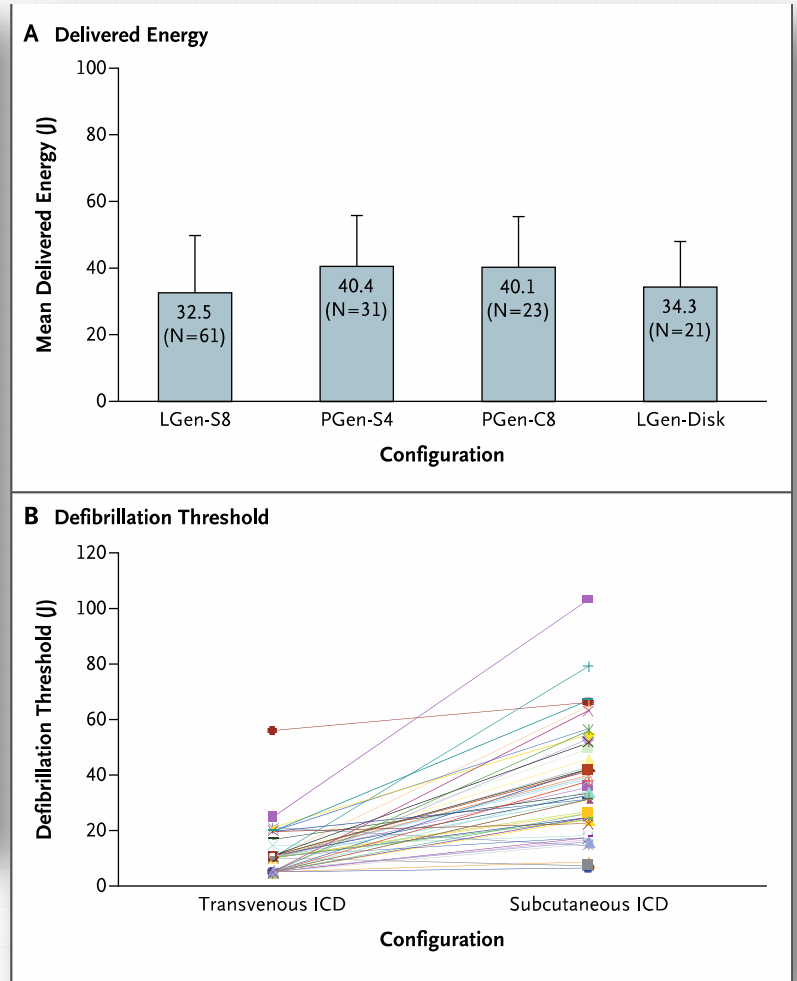
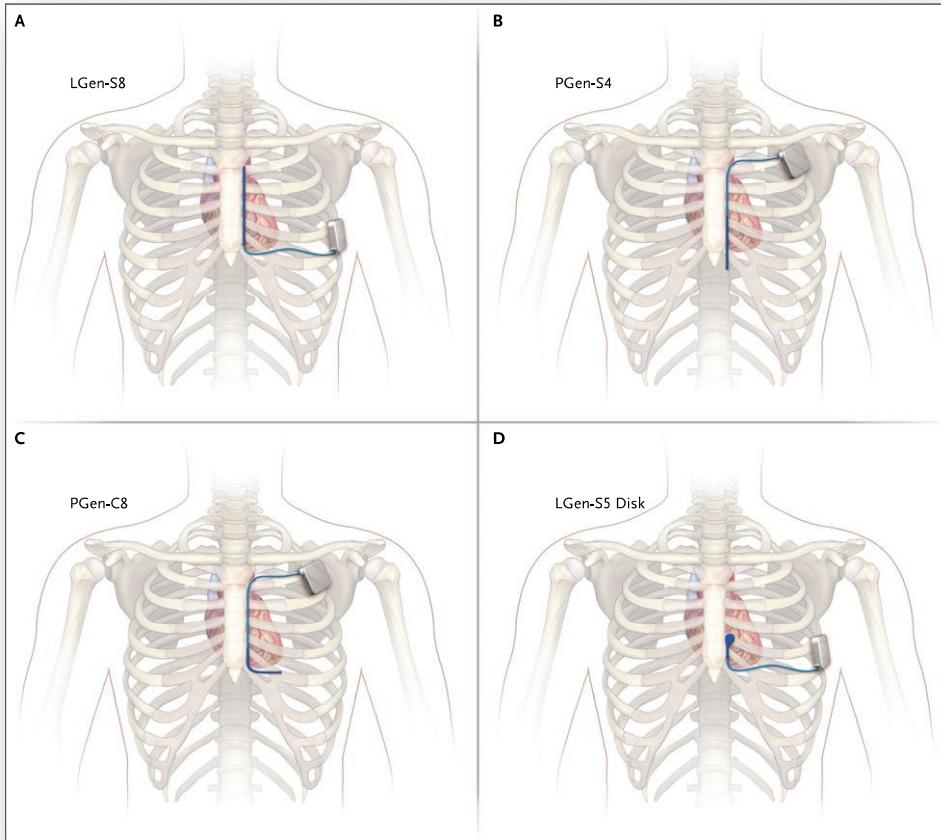
RESULTS

The best device configuration consisted of a parasternal electrode and a left lateral thoracic pulse generator. This configuration was as effective as a transvenous ICD for terminating induced ventricular fibrillation, albeit with a significantly higher mean (\pm SD) energy requirement (36.6 \pm 19.8 J vs. 11.1 \pm 8.5 J). Among patients who received a permanent subcutaneous ICD, ventricular fibrillation was successfully detected in 100% of 137 induced episodes. Induced ventricular fibrillation was converted twice in 58 of 59 patients (98%) with the delivery of 65-J shocks in two consecutive tests. Clinically significant adverse events included two pocket infections and four lead revisions. After a mean of 10 \pm 1 months, the device had successfully detected and treated all 12 episodes of spontaneous, sustained ventricular tachyarrhythmia.

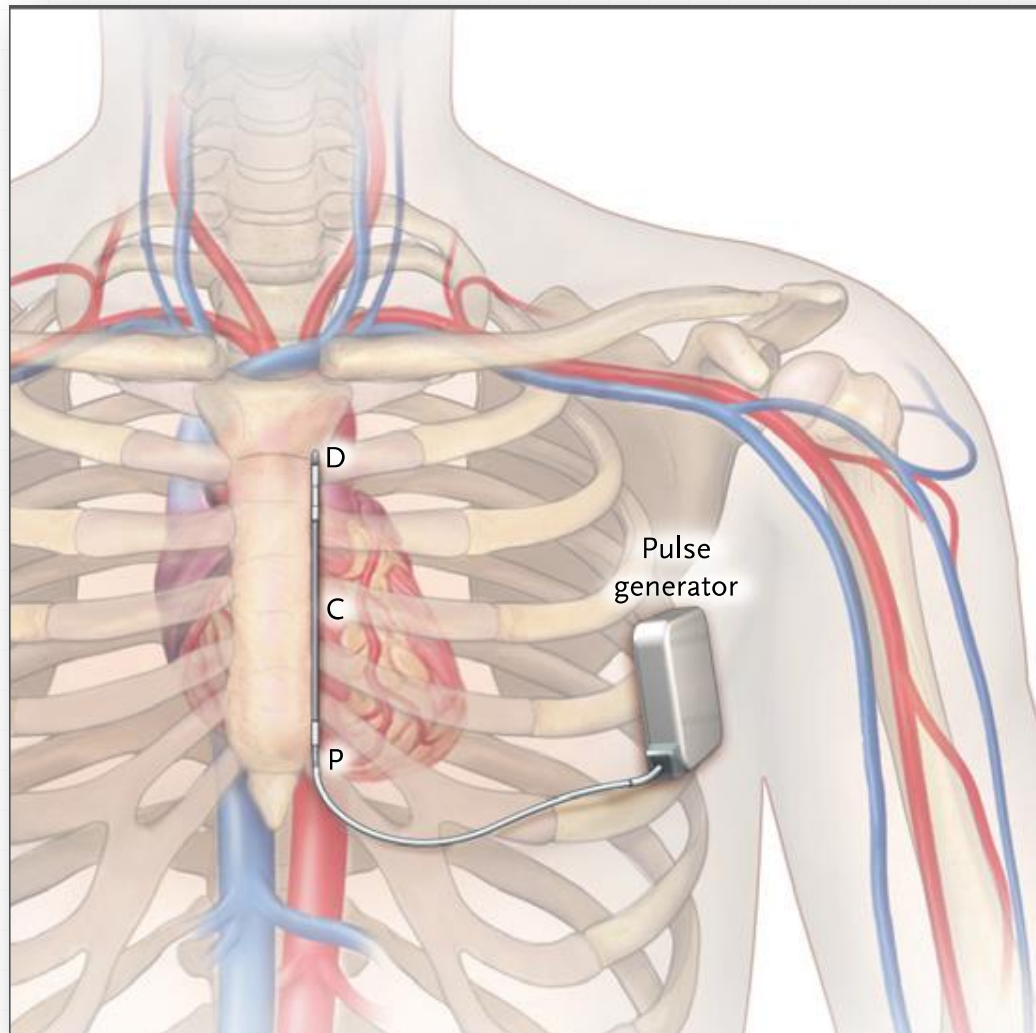
CONCLUSIONS

In small, nonrandomized studies, an entirely subcutaneous ICD consistently detected and converted ventricular fibrillation induced during electrophysiological testing. The device also successfully detected and treated all 12 episodes of spontaneous, sustained ventricular tachyarrhythmia. (ClinicalTrials.gov numbers, NCT00399217 and NCT00853645.)

Four Configurations of a S-ICD



Location of the Components of a S-ICD



Bardy GH et al. N Engl J Med. 2010;363:36-44.

S-ICD™ System Components

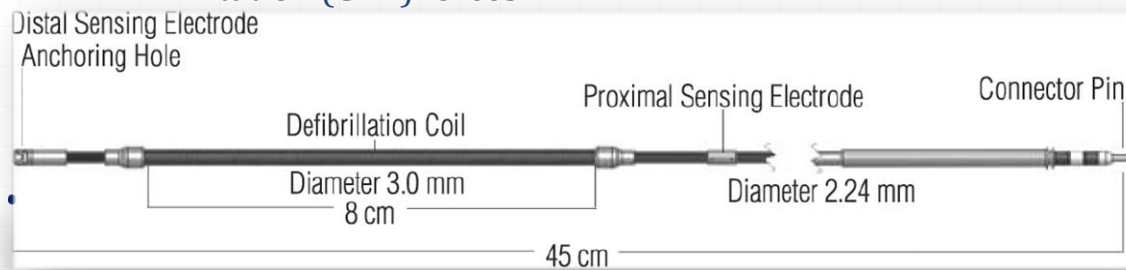
SQ-RX™ Pulse Generator



- Volume: 69 cc
- Weight: 145 grams
- Thickness: 15.7 mm
- Energy: 80J (delivered)
- Waveform: Biphasic

Q-TRAK™ Electrode

- Multistrand cable-core design
- No hollow core, no inner coils
- Durable polyurethane insulator
- Designed to withstand cardiopulmonary resuscitation (CPR) forces



Q-GUIDE™ Electrode Insertion Tool

- Single use tool
- 36cm total length
- 3mm shaft diameter



Q-TECH™ Tablet Programmer

- AC powered/battery backup
- Wanded RF telemetry
- Wireless printing
- Micro SD card



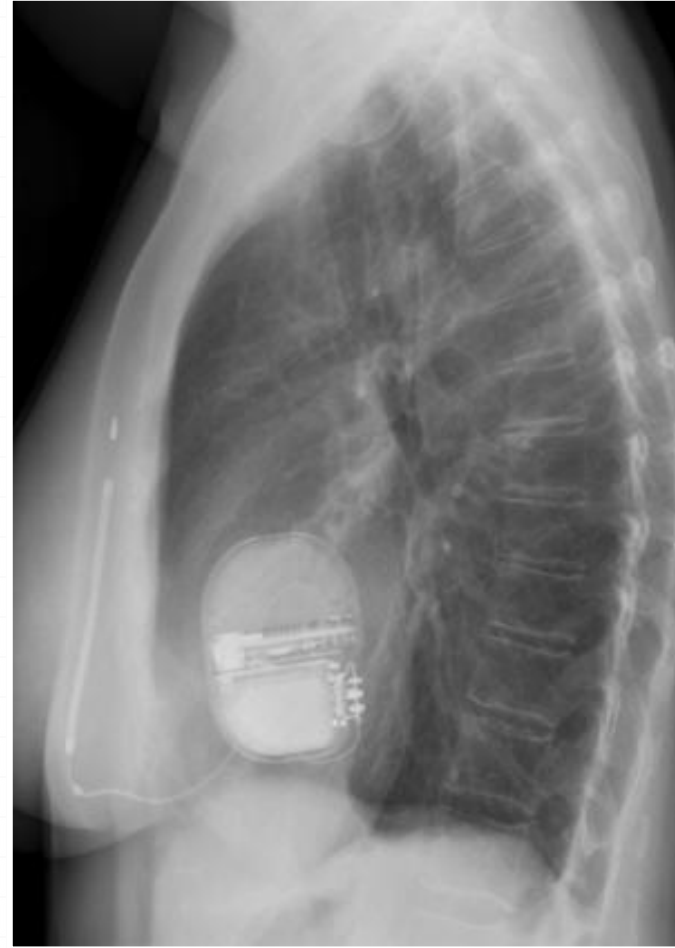
Implant Procedure

**Boston
Scientific**

**This material is intended for general educational purposes only.
Prior to use please review the user's manual for a complete
listing of indications, contraindications, warnings, precautions,
potential adverse events and directions for use.**

CRM-103612-AA SEPT2012

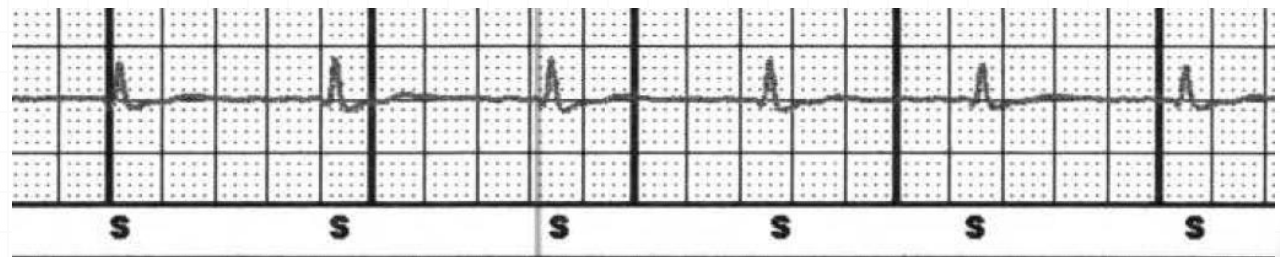
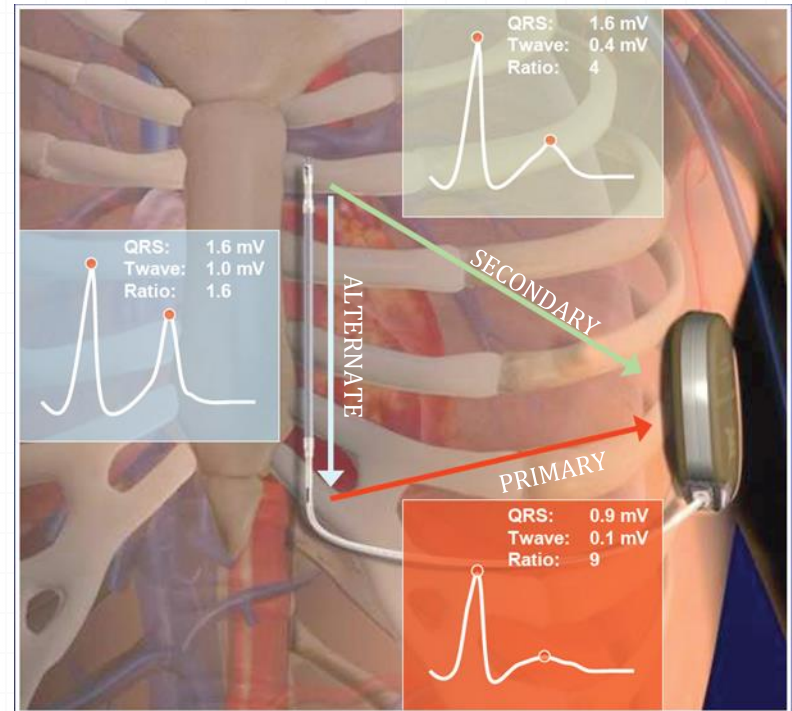
Ideal Device Placement



Rhythm Detection Technology

Three far-field sensing vectors

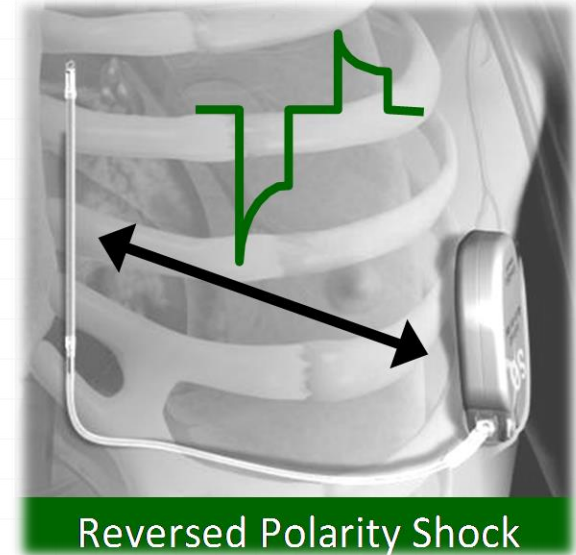
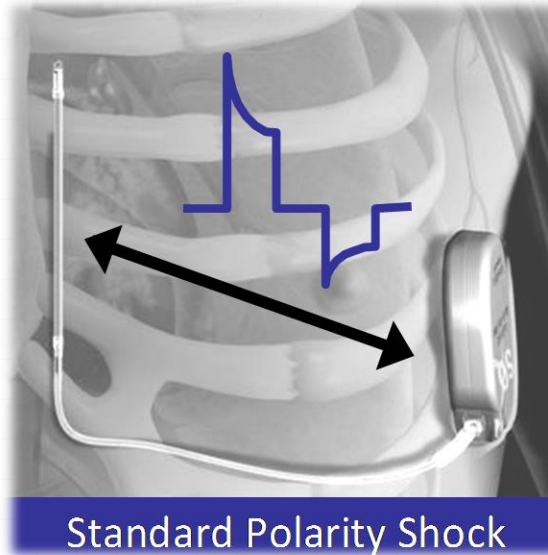
- Primary, Secondary, Alternate
- Automatic or manual vector selection
- Morphologically rich signal similar to a surface ECG
- Sense electrodes positioned away from large muscle groups
- Maximum flexibility to solve sensing issues non invasively
- Sense vector reprogramming



Therapy Delivery

Episodes

- Up to 5 shocks per episode @ 80J
- Up to 128 seconds of S-ECG storage per episode
- Storage of up to 44 episode



Adaptive Shock Polarity

- System remembers the polarity of the last successful shock and automatically selects this shock polarity for the first shock of an episode

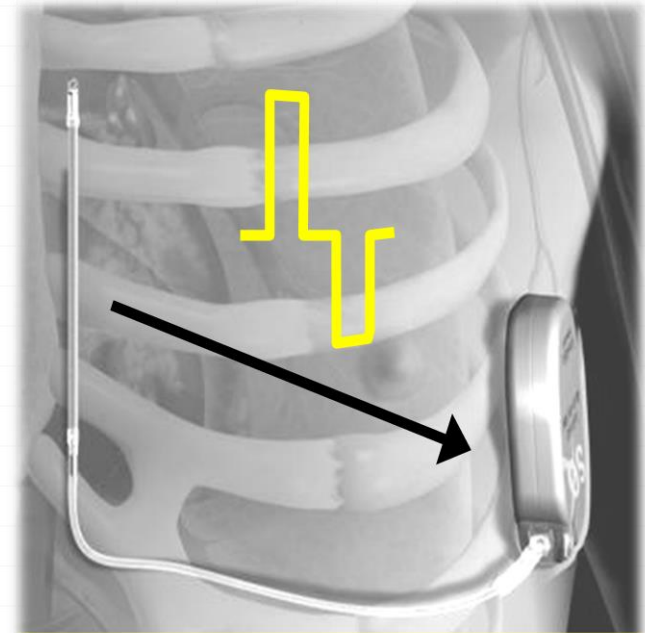
Shock Vector

- Encompasses the entire left chest
- Tolerant of a wide variety of cardiac sizes/ orientation/hypertrophy

Therapy Delivery

Post-Shock Pacing

- Transthoracic pacing
- Delivered for up to 30 seconds post-shock
- Demand based pacing @ 50 ppm using 200 mA



Standard Polarity Pace

Arrhythmia/Electrophysiology

Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator

Raul Weiss, MD; Bradley P. Knight, MD; Michael R. Gold, MD, PhD; Angel R. Leon, MD; John M. Herre, MD; Margaret Hood, MBChB; Mayer Rashtian, MD; Mark Kremers, MD; Ian Crozier, MBChB; Kerry L. Lee, PhD; Warren Smith, MD; Martin C. Burke, DO

Background—The most frequent complications associated with implantable cardioverter-defibrillators (ICDs) involve the transvenous leads. A subcutaneous implantable cardioverter-defibrillator (S-ICD) has been developed as an alternative system. This study evaluated the safety and effectiveness of the S-ICD System (Cameron Health/Boston Scientific) for the treatment of life-threatening ventricular arrhythmias (ventricular tachycardia/ventricular fibrillation).

Methods and Results—This prospective, nonrandomized, multicenter trial included adult patients with a standard indication for an ICD, who neither required pacing nor had documented pace-terminable ventricular tachycardia. The primary safety end point was the 180-day S-ICD System complication-free rate compared with a prespecified performance goal of 79%. The primary effectiveness end point was the induced ventricular fibrillation conversion rate compared with a prespecified performance goal of 88%, with success defined as 2 consecutive ventricular fibrillation conversions of 4 attempts. Detection and conversion of spontaneous episodes were also evaluated. Device implantation was attempted in 321 of 330 enrolled patients, and 314 patients underwent successful implantation. The cohort was followed for a mean duration of 11 months. The study population was 74% male with a mean age of 52 ± 16 years and mean left ventricular ejection fraction of $36 \pm 16\%$. A previous transvenous ICD had been implanted in 13%. Both primary end points were met: The 180-day system complication-free rate was 99%, and sensitivity analysis of the acute ventricular fibrillation conversion rate was $>90\%$ in the entire cohort. There were 38 discrete spontaneous episodes of ventricular tachycardia/ventricular fibrillation recorded in 21 patients (6.7%), all of which successfully converted. Forty-one patients (13.1%) received an inappropriate shock.

Conclusions—The findings support the efficacy and safety of the S-ICD System for the treatment of life-threatening ventricular arrhythmias.

Clinical Trial Registration—URL: <http://www.clinicaltrials.gov>. Unique identifier: NCT01064076.
(*Circulation*. 2013;128:944-953.)

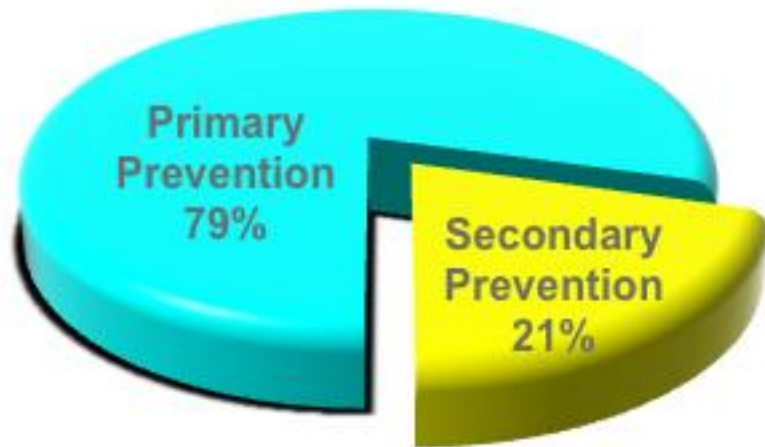
Key Words: defibrillators, implantable ■ heart arrest ■ tachycardia



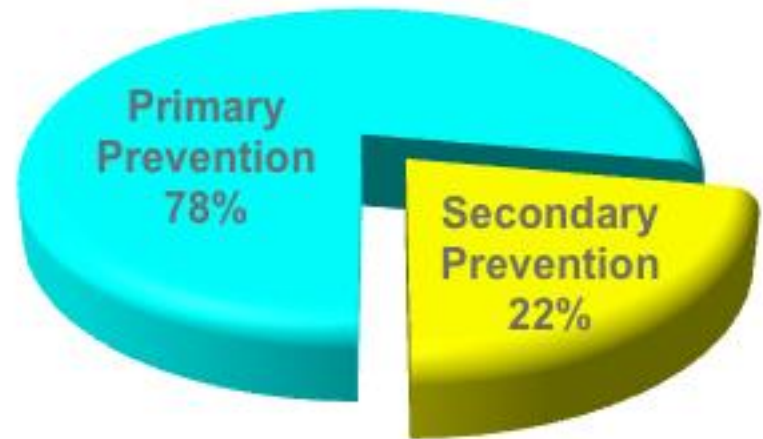
Patient Distribution

Patient Distribution Similar to NCDR Registry

S-ICD™ System IDE Study^a
n = 321 patients



NCDR ICD Registry^b
n = 486,025 patients



Effectiveness and Safety Endpoints

Effectiveness Endpoints Met

100% conversion of induced arrhythmias in evaluable patients

Safety Endpoints Met

99% Free from S-ICD™ System complications

Both endpoints met even under worst case sensitivity analysis

Spontaneous VF/VT Episodes

119 events in 21 patients

100% converted with 80J or spontaneously converted

92% first shock conversion efficacy

Complications

4.4% perioperative complication rate

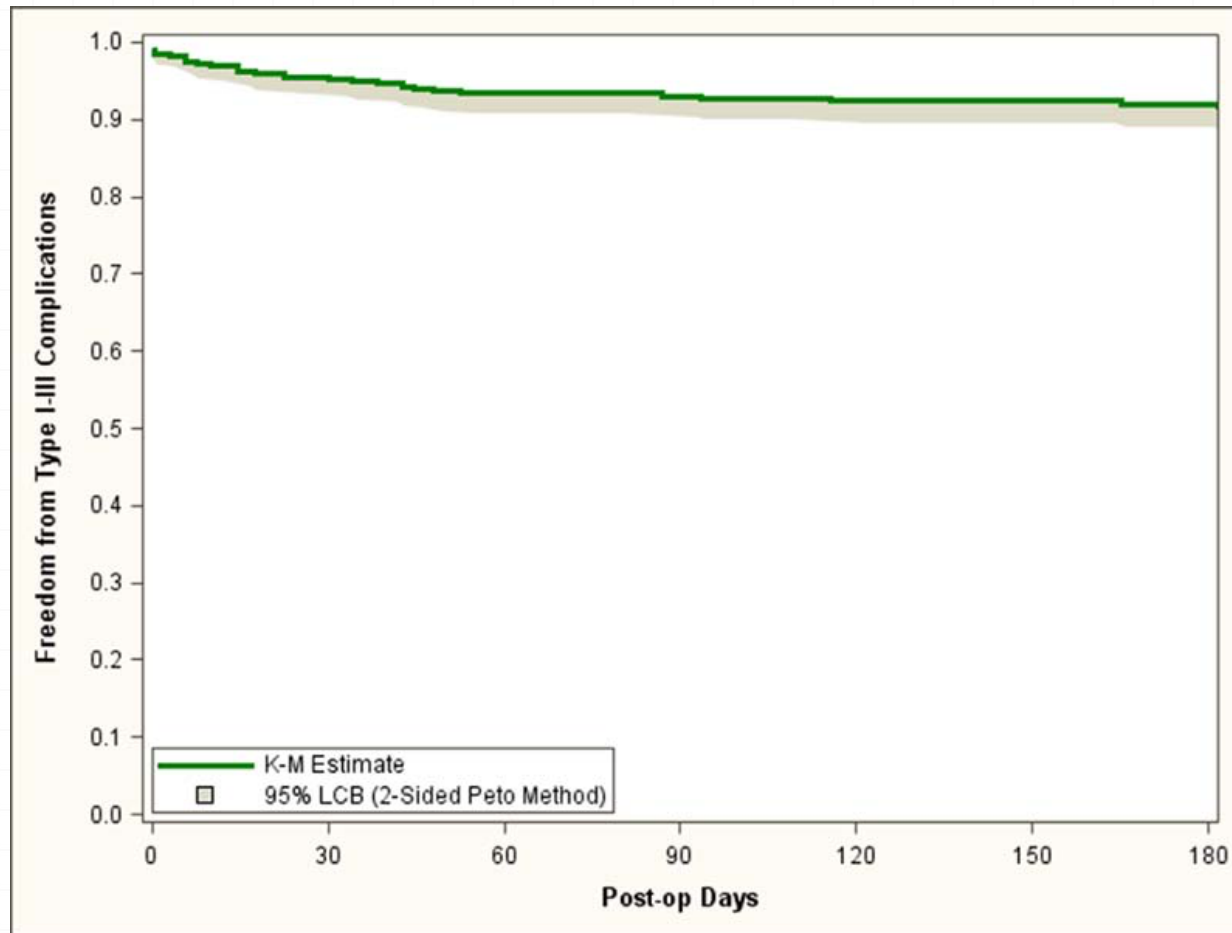
4 explant for infection (first 1/3 of pts)

No systemic infection or endocarditis

No arrhythmic deaths



Complication Free Rate



At Risk	321	302	294	294	291	288	260
KM Rate	100%	95.6%	93.4%	93.4%	92.7%	92.4%	92.1%
95% LCB	98.0%	93.3%	90.6%	90.6%	89.9%	89.5%	88.9%

Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry

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Aims

The totally subcutaneous implantable-defibrillator (S-ICD) is a new alternative to the conventional transvenous ICD system to minimize intravascular lead complications. There are limited data describing the long-term performance of the S-ICD. This paper presents the first large international patient population collected as part of the EFFORTLESS S-ICD Registry.

Methods and results

The EFFORTLESS S-ICD Registry is a non-randomized, standard of care, multicentre Registry designed to collect long-term, system-related, clinical, and patient reported outcome data from S-ICD implanted patients since June 2009. Follow-up data are systematically collected over 60-month post-implant including Quality of Life. The study population of 472 patients of which 241 (51%) were enrolled prospectively has a mean follow-up duration of 558 days (range 13–1342 days, median 498 days), 72% male, mean age of 49 ± 18 years (range 9–88 years), 42% mean left ventricular ejection fraction. Complication-free rates were 97 and 94%, at 30 and 360 days, respectively. Three hundred and seventeen spontaneous episodes were recorded in 85 patients during the follow-up period. Of these episodes, 169 (53%) received therapy, 93 being for Ventricular Tachycardia/Fibrillation (VT/VF). One patient died of recurrent VF and severe bradycardia. Regarding discrete VT/VF episodes, first shock conversion efficacy was 88% with 100% overall successful clinical conversion after a maximum of five shocks. The 360-day inappropriate shock rate was 7% with the vast majority occurring for oversensing (62/73 episodes), primarily of cardiac signals (94% of oversensed episodes).

Conclusion

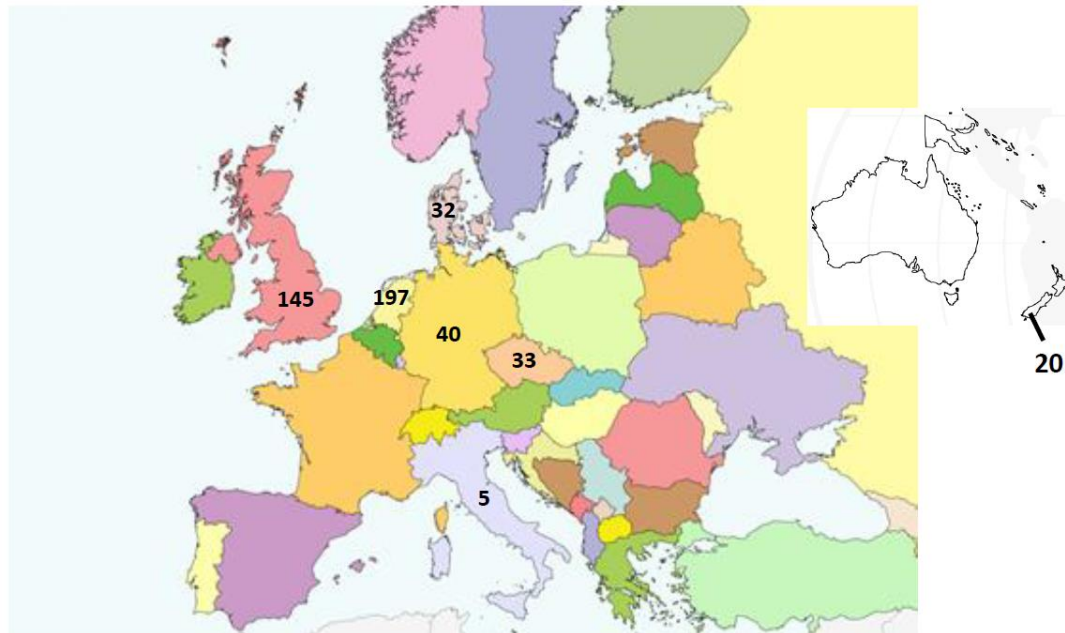
The first large cohort of real-world data from an international patient S-ICD population demonstrates appropriate system performance with clinical event rates and inappropriate shock rates comparable with those reported for conventional ICDs. Clinical trial registration URL: <http://www.clinicaltrials.gov>. Unique identifier NCT01085435.

Keywords

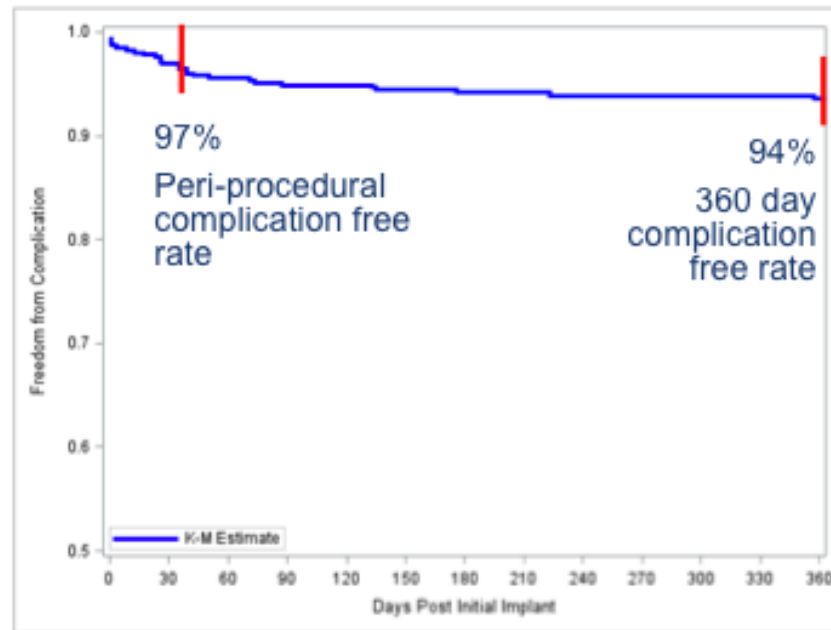
Subcutaneous ICD † Ventricular arrhythmias † Cardiac arrest † Primary prevention † Secondary prevention

EFFORTLESS Registry

- ✓ 472 patients enrolled between Feb 2011 and April 2013
 - 63% primary prevention – typical for EU
 - 49 ± 18 years (range 9 – 88) – younger demographic
 - 558 day mean follow-up (range 13 – 1342 days)
- ✓ 232 patients enrolled in QOL sub-study (not yet published)



EFFORTLESS Registry



Spontaneous VF/VT Episodes

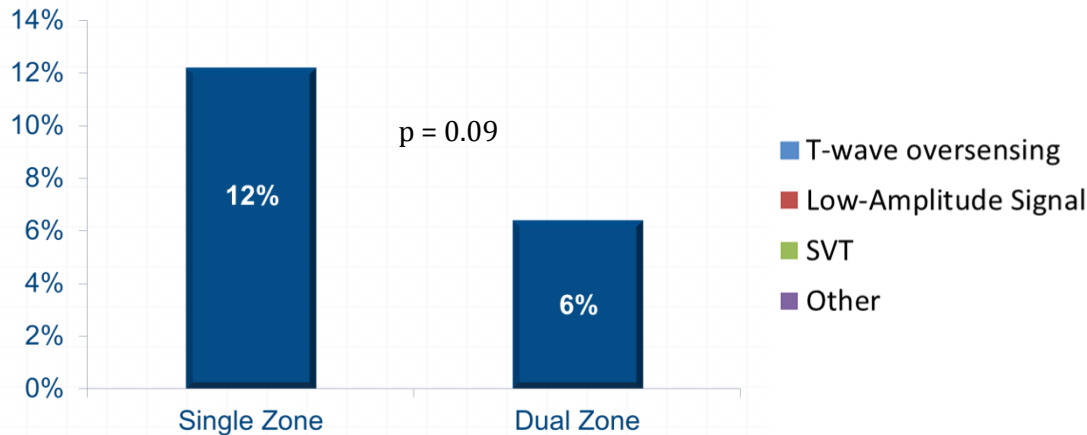
- 93 events in 33 patients
- 100% clinical conversion
- 88% first shock conversion efficacy
- No arrhythmia related syncope
- One arrhythmic death
 - Recurrent VF & severe bradycardia
 - Proper device function

Complications

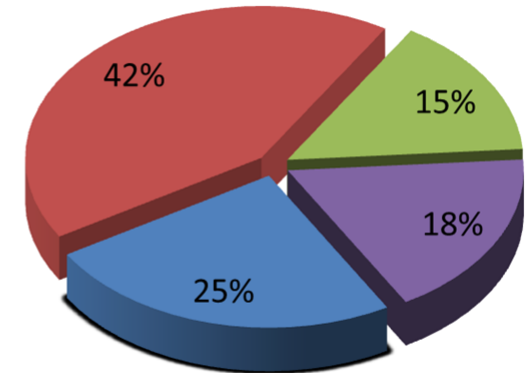
- 97% complication free at 30 days
- 94% complication free at 360 days
- 1.8% permanent explant for infection
- No systemic infection or endocarditis
- No lead fractures

Inappropriate Therapy

IAS & Programming

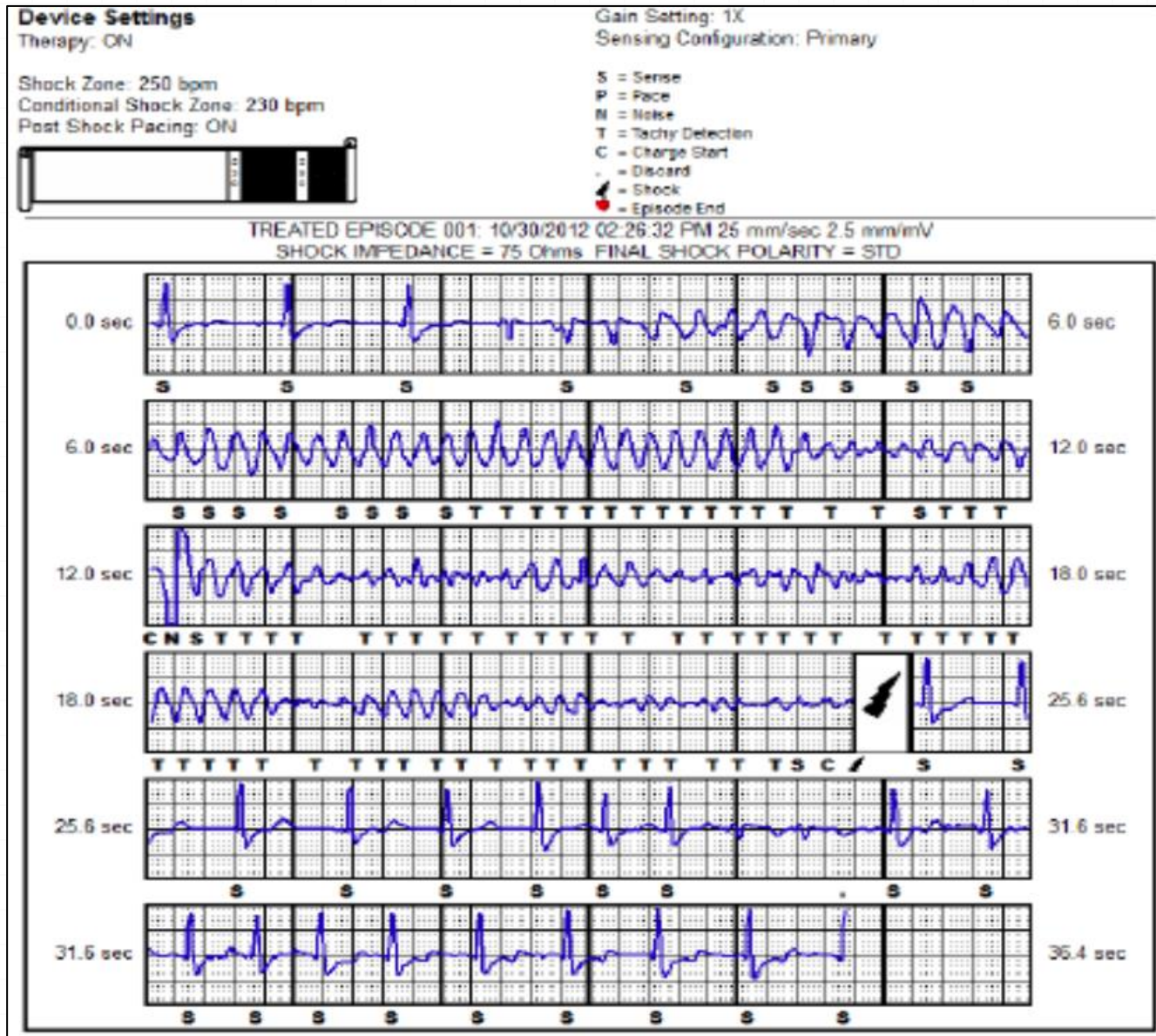


Reasons for IAS



- ✓ 82% of patients received dual-zone programming; with an inappropriate shock rate of 6.4%.
- ✓ Only 9 study patients (2%) experienced inappropriate shocks after initial interventions (re-programming, exercise tests, medication changes).
- ✓ Only one VF/SVT discrimination error in the conditional shock zone.

Appropriate Shock for Clinical Event of VF



CONTROVERSIES IN ARRHYTHMIA AND ELECTROPHYSIOLOGY

Who Should Receive the Implanted Defibrillator

The Subcutaneous Implantable (ICD) Should Be Considered in Who Do Not Require Pacing

Jeanne E. Poole, MD; Michael R. Gold, MD, PhD



Table 2. Characterization of Patient Groups for S-ICD Implantation

S-ICD is preferred device

No venous access (occluded veins or congenital anomalies)

High risk of complications for transvenous systems have (dialysis, pediatric, and immunocompromised)

Channelopathies (long-QT syndrome, Brugada, hypertrophic cardiomyopathy)

Previous device infections or lead failures

History of endocarditis

S-ICD should be strongly considered

Young patients

Life expectancy >10 y

Primary prevention indicated patients with ischemic/nonischemic heart failure

Prosthetic valves

Women (preferred generator placement lateral wall)

Selected secondary prevention indicated patients (survivors of out-of-hospital VF, no evidence of monomorphic VT)

S-ICD should be avoided

Systolic heart failure and LBBB who are indicated for CRT

Symptomatic bradycardia requiring pacemaker

Recurrent sustained monomorphic VT for whom ATP is deemed appropriate



Thanks for your attention !!