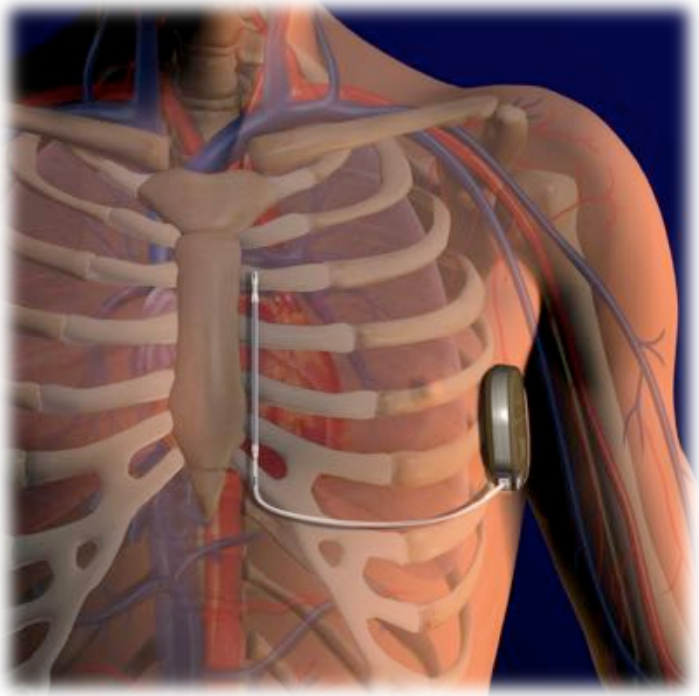
Venice, Italy October 16-18 2015

14th Edition

VENICE 2015 ARRHYTHMIAS



The Subcutaneous Defibrillator S-ICD: Advantages & Disadvantages

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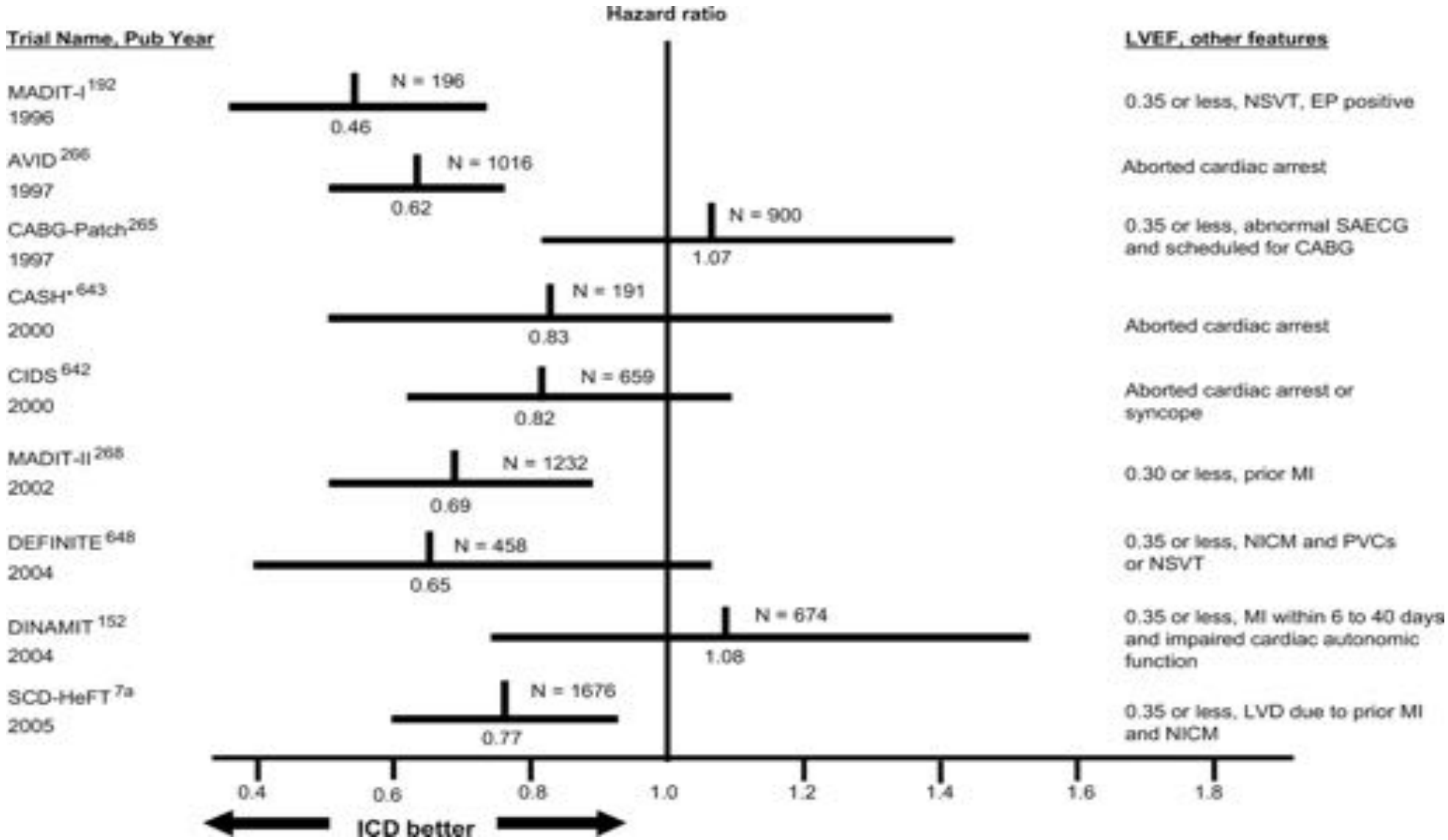
ICDs: hystorical background

• The inventor of ICDs was Mieczyslaw (Michel) Mirowski, a Polish cardiologist formed between Israel and United States.

Randomized Clinical Trials and ICDs



- ICDs have proven their efficacy and superiority to AADs for prevention of SCD in survivors of cardiac arrest and in selected pts at high risk.

- However, clinical benefits of conventional ICD therapy have been partially offset by the morbidity mostly related to the transvenous leads, the *weakest link* or *Achilles Tendon* of the transvenous ICD system.

Problematic aspects with transvenous leads:

- *Adequate experience*/skills are required to perform venous access and to position the intracardiac leads.

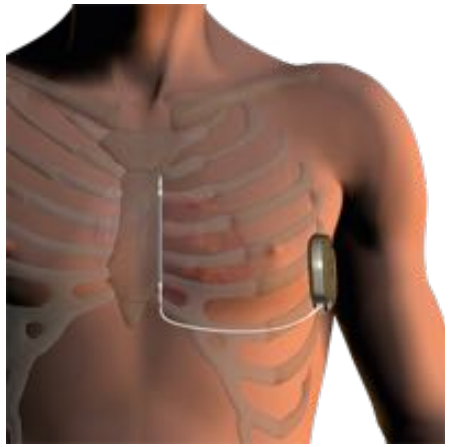
-Related complications: pneumothorax, hemothorax, cardiac perforation, pericarditis, venous occlusion/thrombosis, systemic infection/endocarditis, valvular dysfunction, lead dislocation/failure.

-*Fluoroscopy* is required.

- *Children*: - small venous capacity
- more prone to lead failure in the long term.
- growth!

- *Selected pts* **Venous anomaly/occlusion, no venous access to the heart**
Intracardiac shunts (thromboembolic risk)
High infection risk: HIV, dialisis Pts, etc.

-*Transvenous leads extraction*, when needed, is associated with considerable morbidity & mortality, and requires considerable skills/costs.



S-ICD Therapy

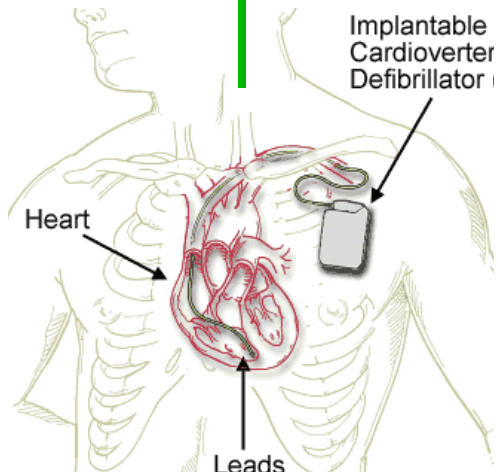
Aim of technology

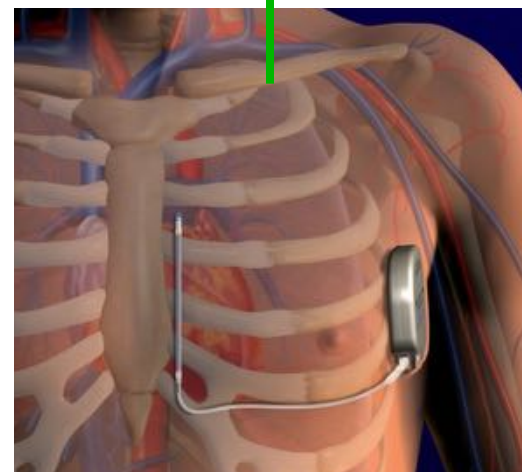
- The entirely Subcutaneous (S) -ICD is designed to provide the life-saving benefit of conventional ICDs whilst avoiding the shortcomings of transvenous leads.

- By simplifying implant techniques, S-ICD is also meant to expand the use of ICDs in clinical practice.

Evolving ICD Technologies

1980 **1989** **2008**



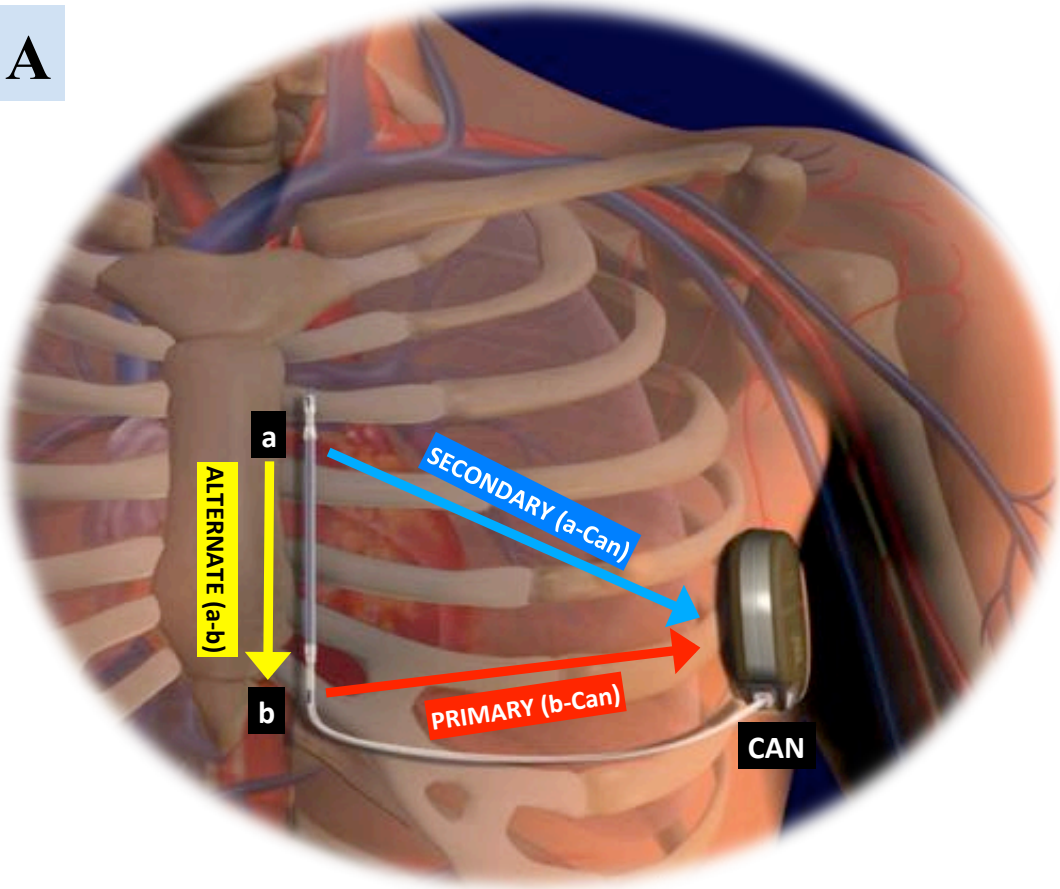


Epicardial ICD **Transvenous ICD** **Subcutaneous ICD**

Invasiveness

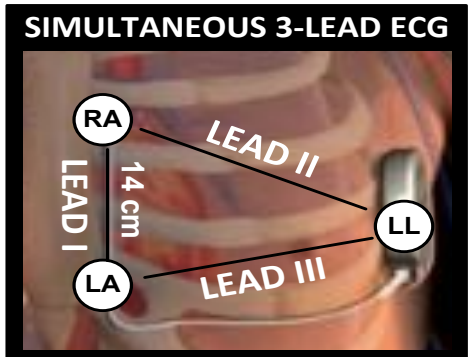
Most **Least**

A

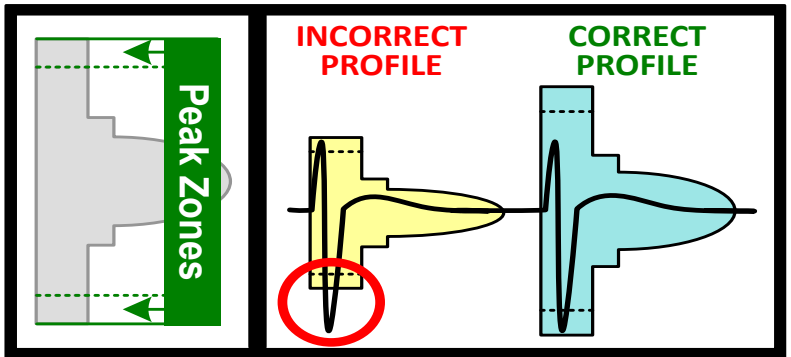


B

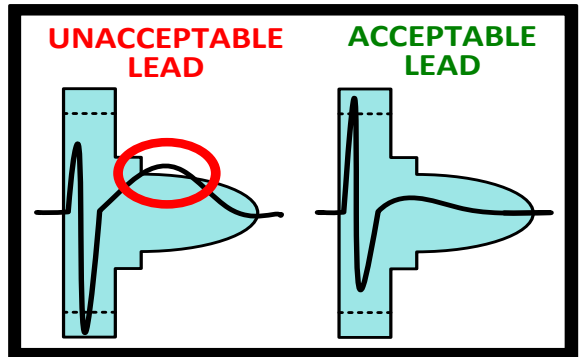
C



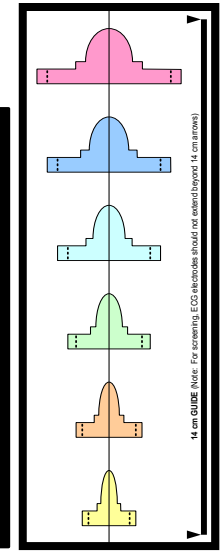
1. **RECORD**: Supine+Standing 25 mm/s, 5-20 mm/mV



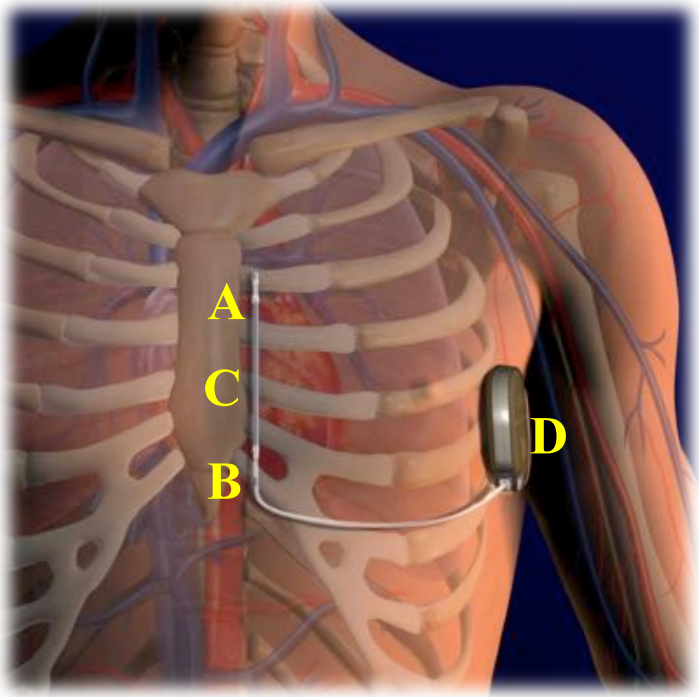
2. **SELECT** the colored profile. The largest QRS peak must be within a Peak Zone.



3. **VERIFY** at least one lead is acceptable in all postures.



The S-ICD System:



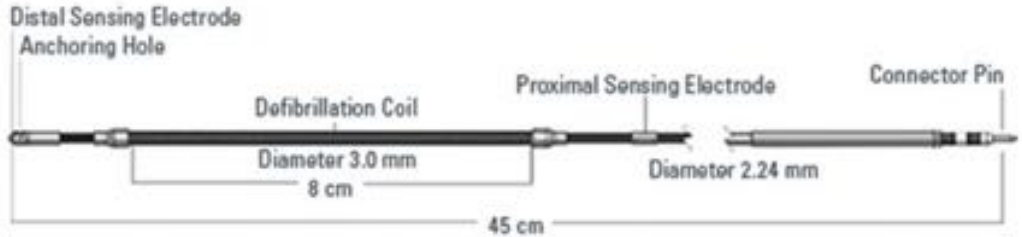
- Entirely subcutaneous technology
- Fluoroscopy is not required
- Canister C (left lateral thorax) connected to a single lead tunneled subcutaneously to the left parasternal line
- 3 sensing electrodes (A, B and D), Coil C
- A pre-operative screening tool to ensure adequate subcutaneous signals of pts

1st generation S-ICD
SQ-RX 1010
(Cameron Health)

2nd generation S-ICD
EMBLEM
(Boston Scientific)

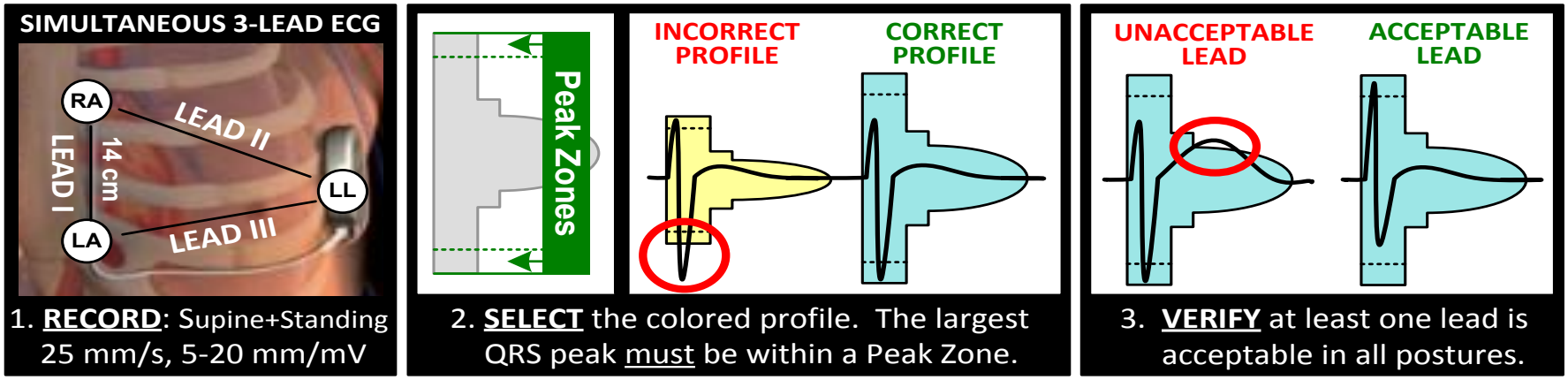
15.7 mm	Thickness ↓ 20%	12.7 mm
69.9 cc	Volume	59.5 cc
145 gram	Weight	130 gram
5.1 years	Longevity ↑ 40%	7.3 years
Not avaliable	Remote-Monitoring	LATTITUDE

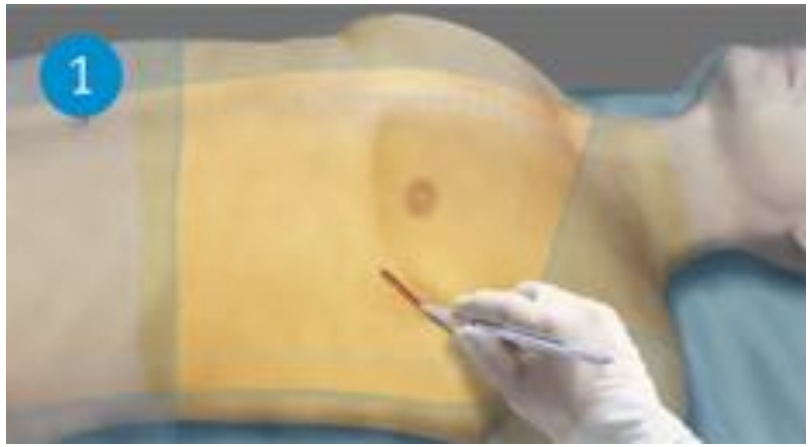
*From: Ali H, Lupo P, Cappato R. The Entirely Subcutaneous Defibrillator: A New Generation and Future Expectations. *Journal of Arrhythmia & Electrophysiology Review, August 2015;4(2):116-121.*

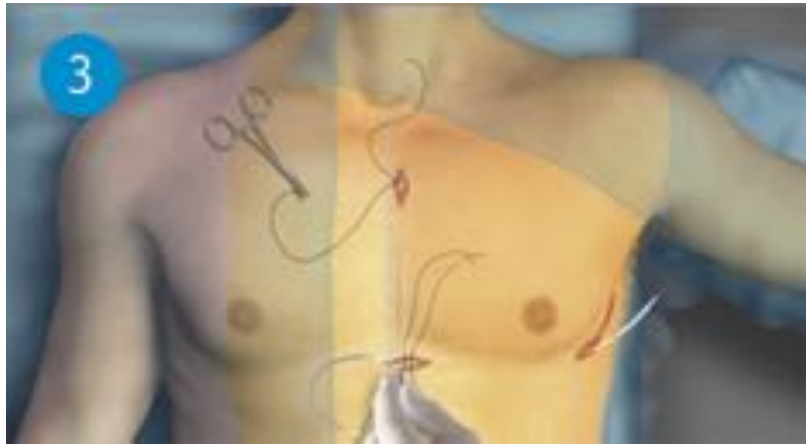


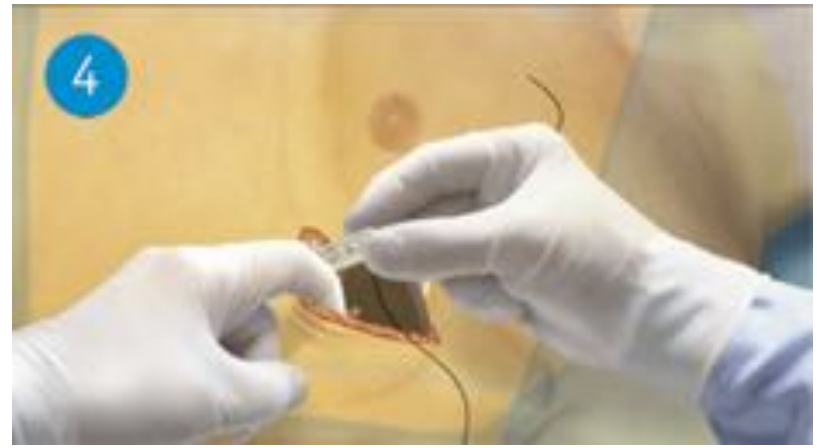
***The subcutaneous lead** A tripolar parasternal electrode (polycarbonate-urethane 55D, 3 mm diameter, 45 cm length)*

A *Pre-Operative Screening Tool* was developed to ensure that pts have suitable subcutaneous sensing signals







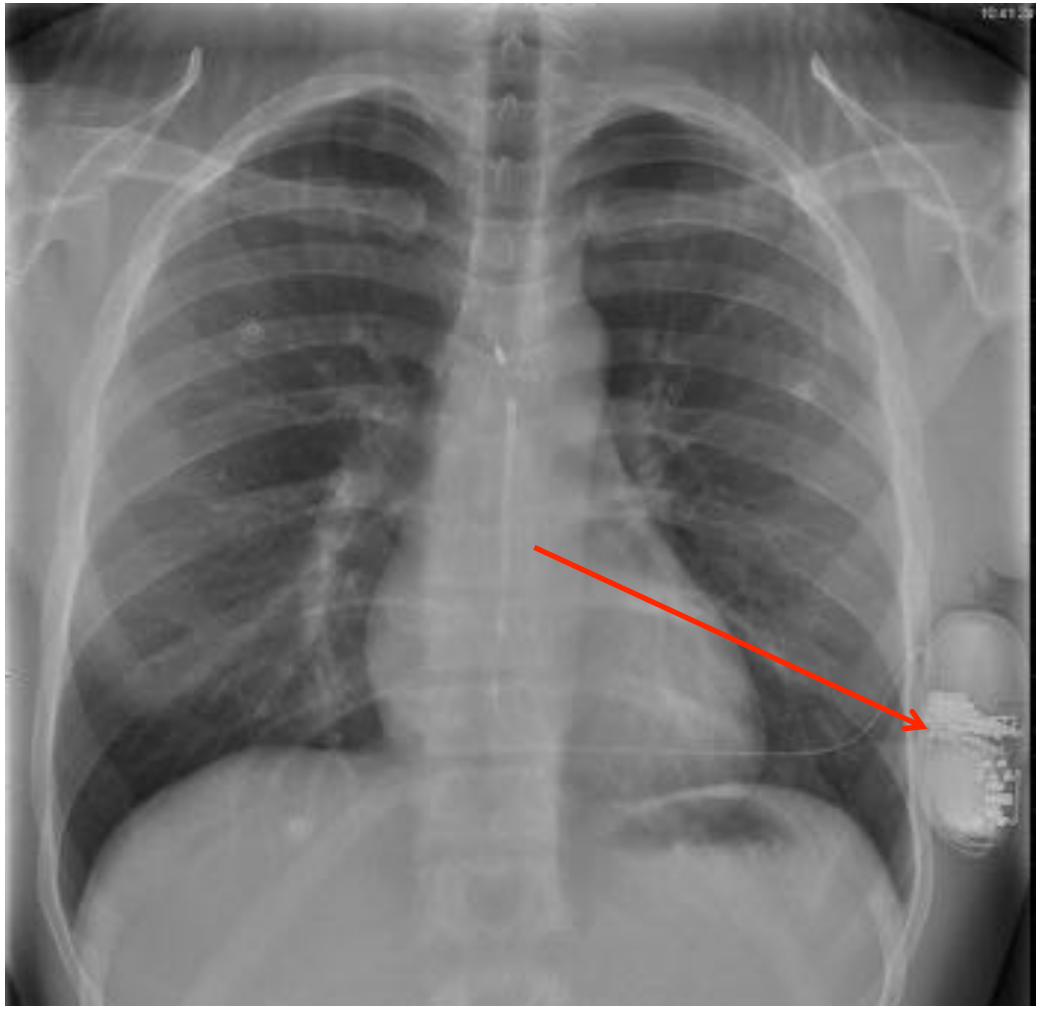


Implantation Technique

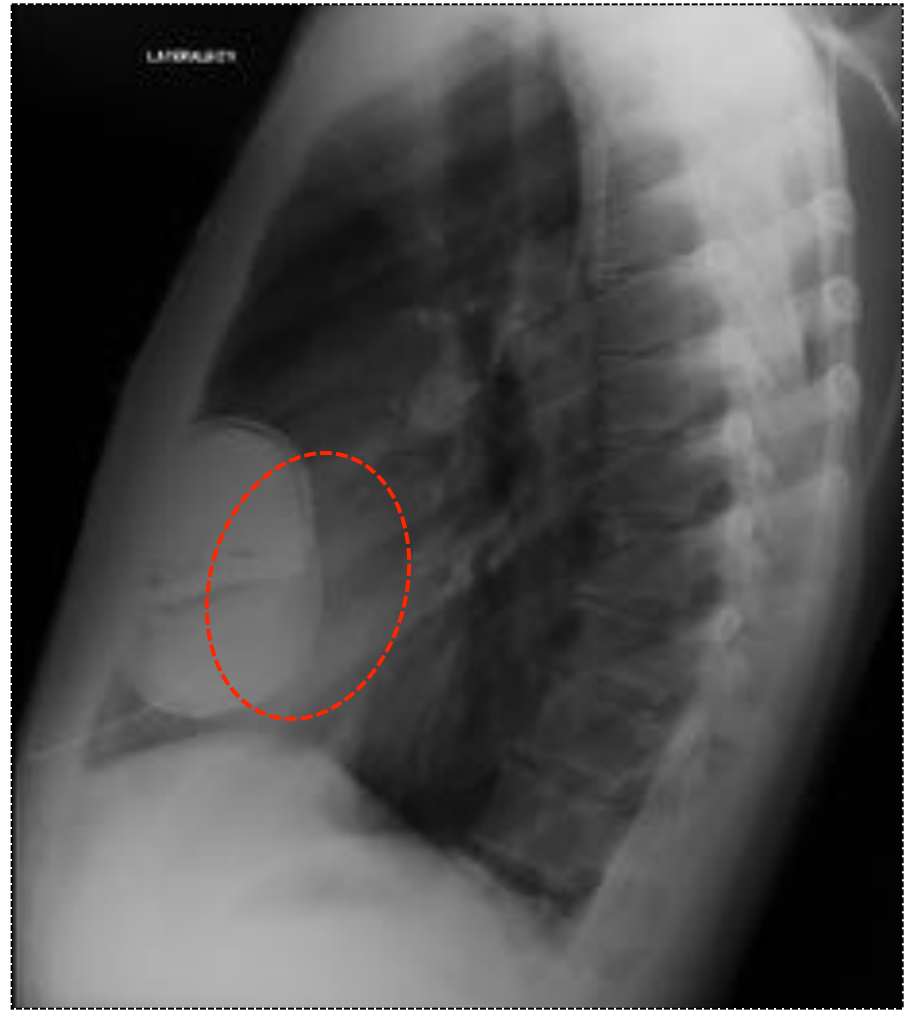
Cartoon by

Boston Scientific

PA and laterla CXR after S-ICD implantation:



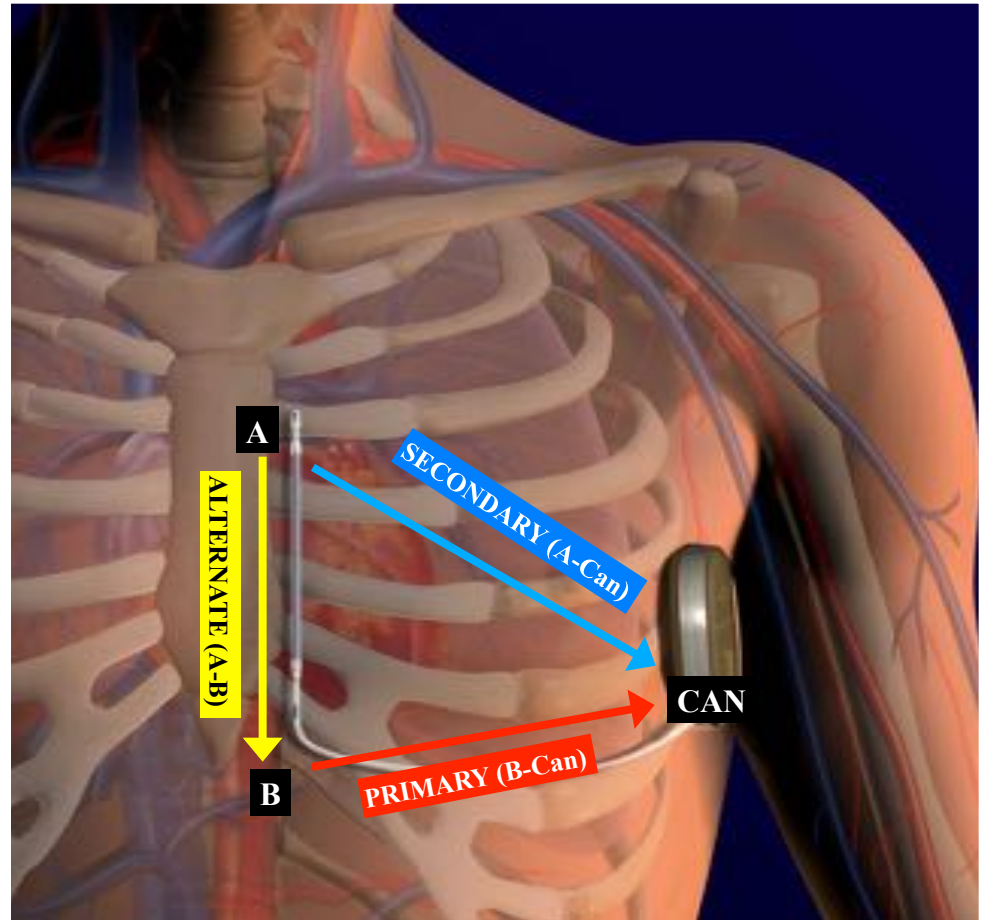
Optimal position: AP view



Sub-optimal position: lateral view

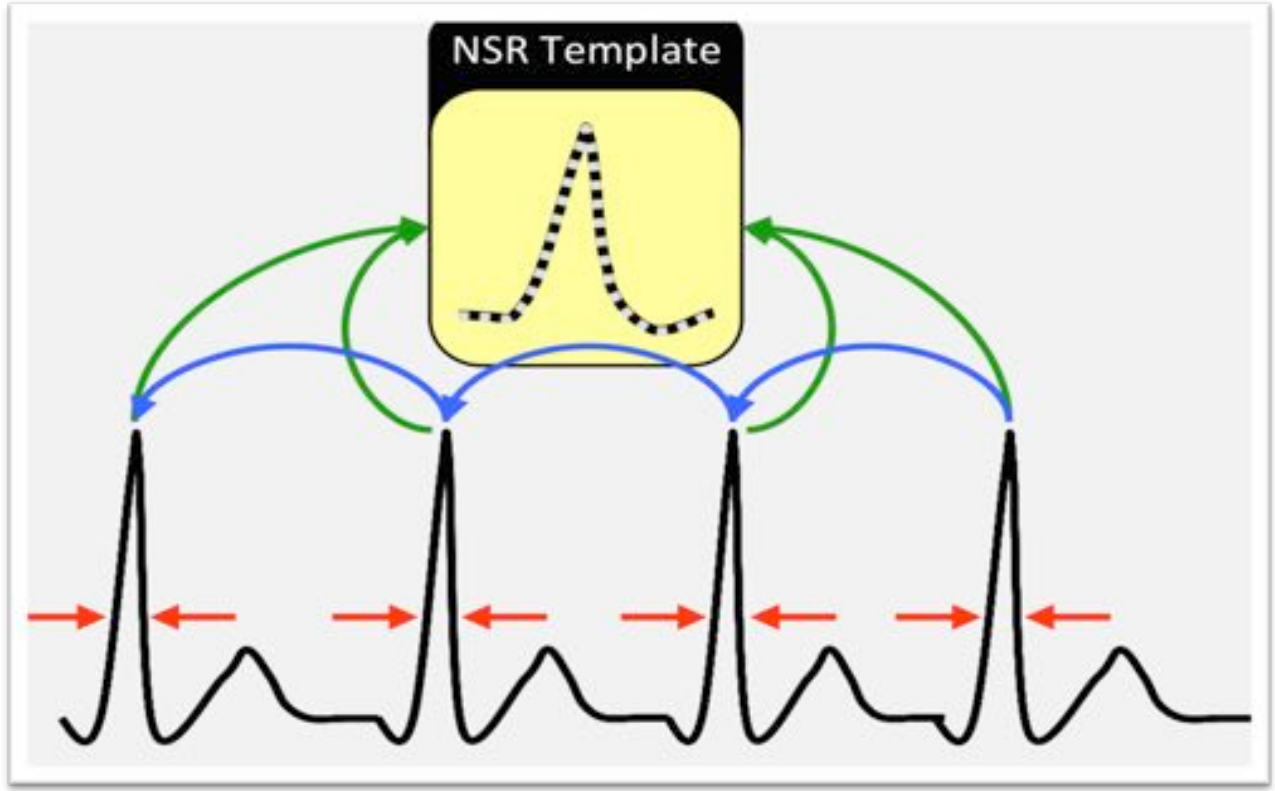
Sensing the subcutaneous signal….

- Three bipolar sensing vectors provide maximum sensing flexibility.
- The ICD automatically selects the signals from the best vector for arrhythmia detection and to avoid double counting and T-wave oversensing



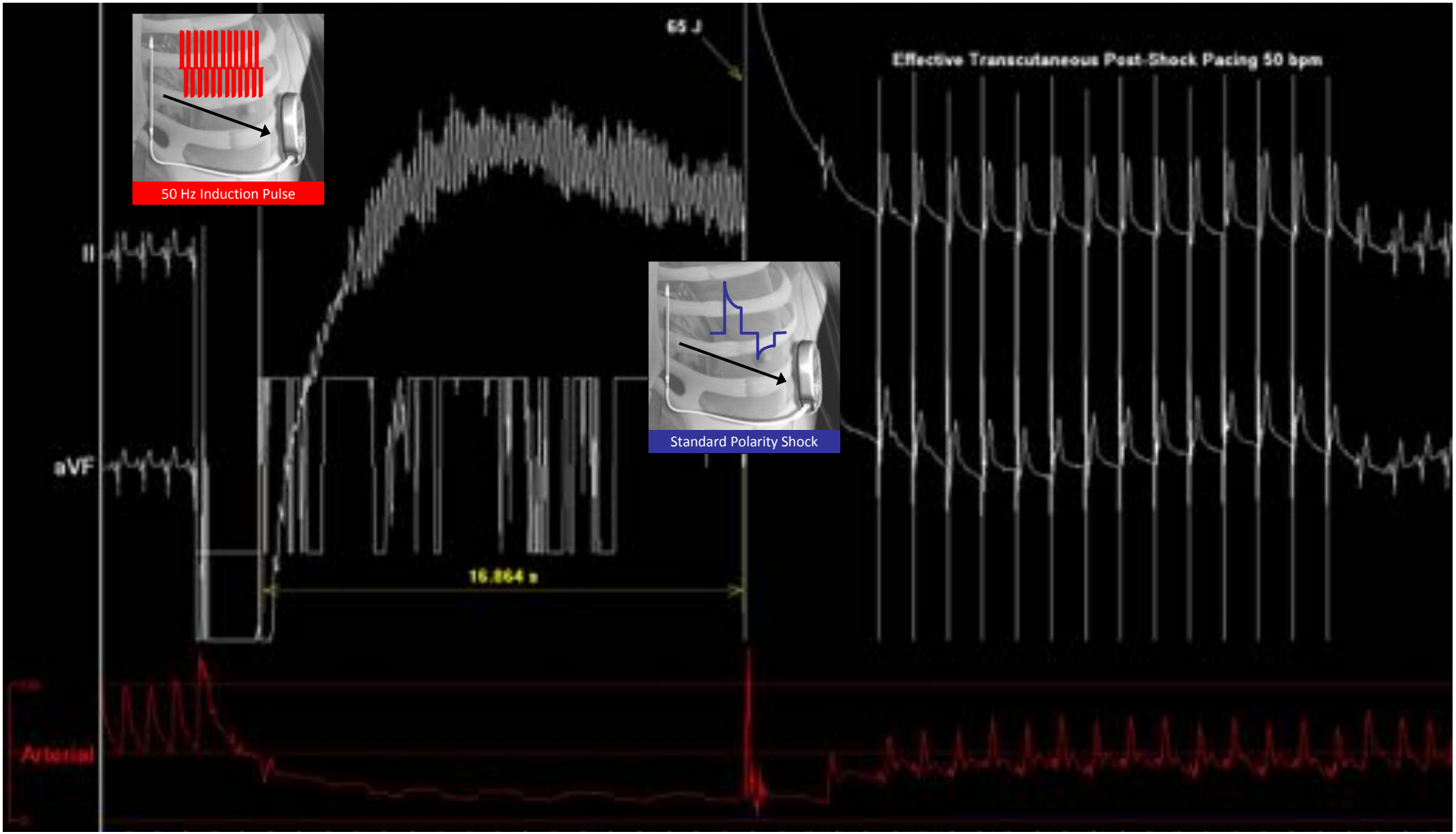
S-ICD
Rhythm Detection

- **All detection algorithms work together to identify S-ECG rhythm: heart rate, QRS width and dynamic template matching with learning from previous beats**

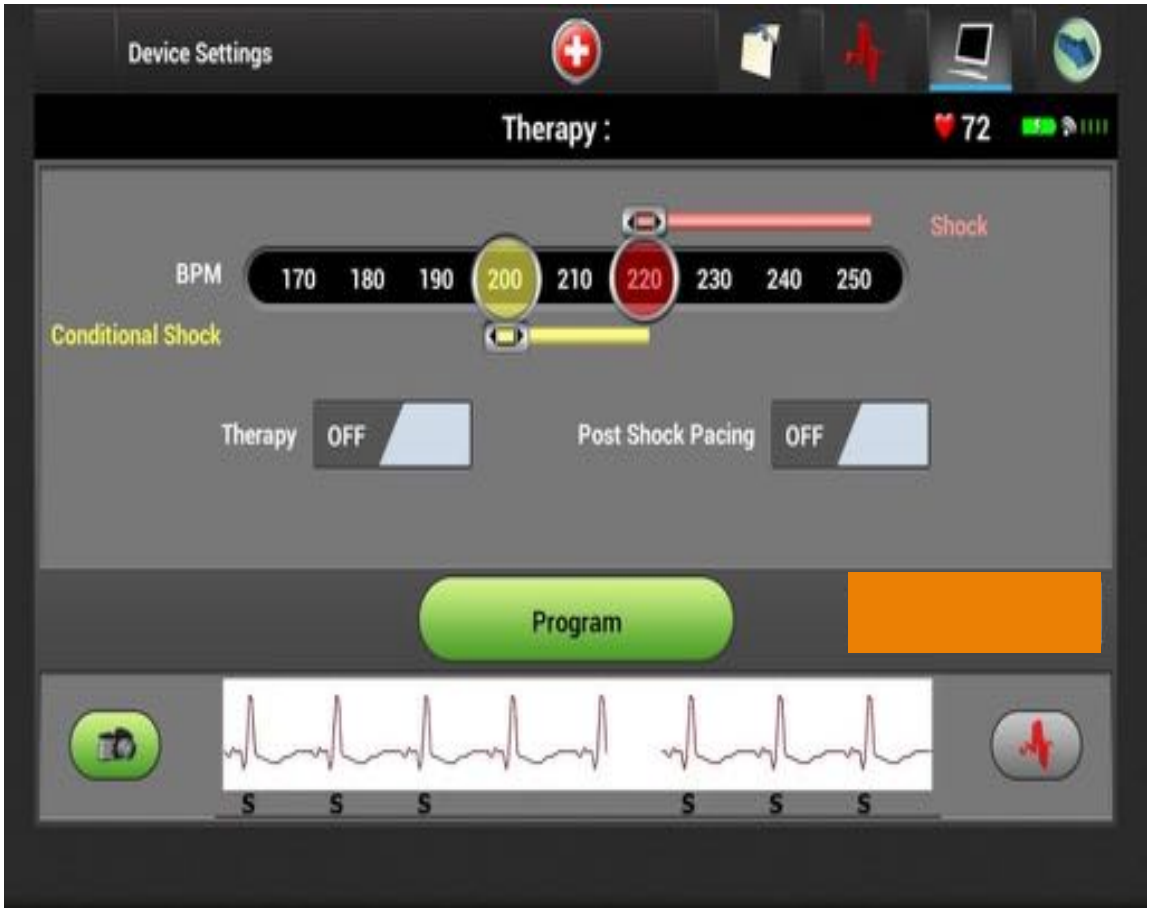


S-ICD Technical Manual

S-ICD Test in The EP-Lab, induced VF

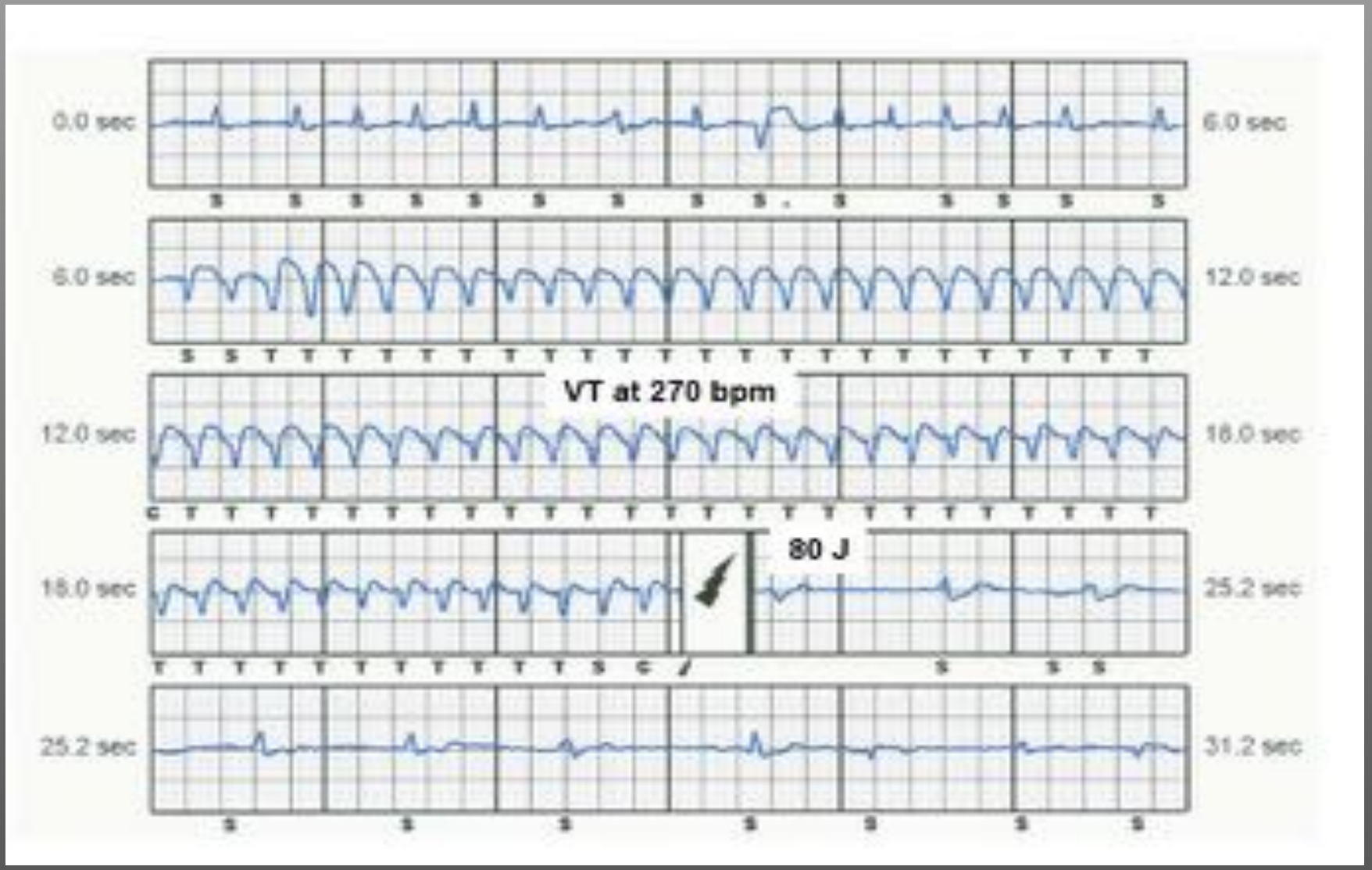


Programming Simplicity



Only few programmable parameters!
A programmable conditional shock zone (170-240 bpm)

Spontaneous Events



CE Trial; 55 Patients

Europe/New Zealand

- Enrolment: 55 pts 12 Dec 2008 → 13 Feb 2009. Follow-up 10 mo

Detection of VF

- 137/137 episodes: Sensitivity 100%
- Time-to-therapy: 14 ± 2 sec

Conversion of VF @ 65J

- 52/53 (>98%) pts met the primary conversion endpoint

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

An Entirely Subcutaneous Implantable Cardioverter–Defibrillator

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.)

Bardy et al, NEJM 2010;363:36

S-ICD Therapy

EFFORTLESS

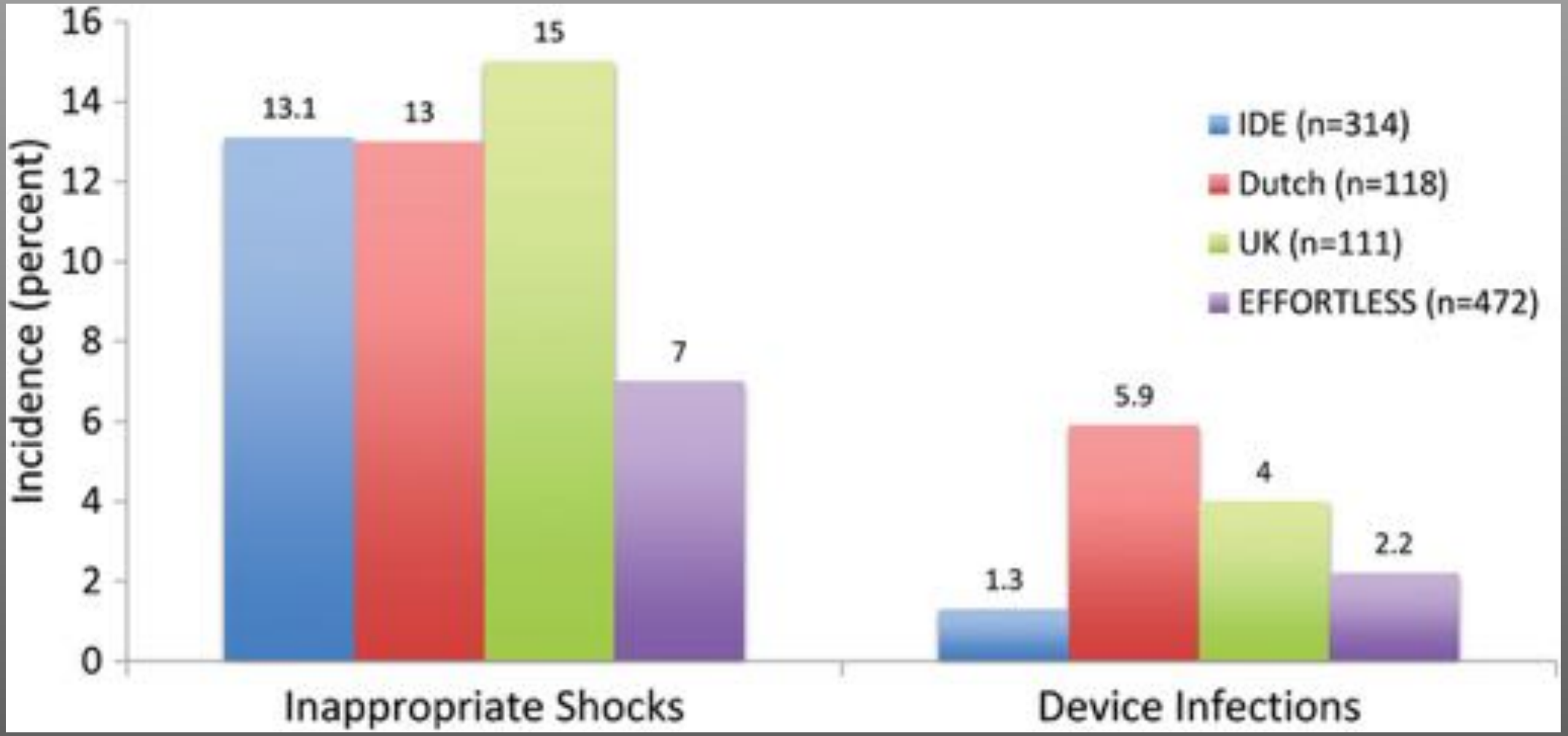
Evaluation oF FactORs AffecTing the CLinical Outcome and Cost EffectiveneSS of the S-ICD

The EFFORTLESS S-ICD Registry Design

- International, multicentre, standard of care Registry to collect short, mid and long-term operational and clinical outcome data on the S-ICD system
- Retrospective and prospective patients implanted since CE mark
- Aiming to recruit up to 1000 patients
- 5 year data post implant
- Centers to be included from all current commercial countries

S-ICD Cohorts/ Clinical Trials	No.Patients	Mean Age .yrs	♂%	I ° Prevention %	EF%	Ischemic%	Follow-up (mo)	Sucessful termination of *induced VF*	Sucessful termination of *spontaneous VT/VF*	Inappropriate shocks	Infection rate
CE Trial Bardy et al/NEJM 2010	55	56	80%	78%	34%	67%	10 ±1	98%	100%	9%	3.6 %
IDE Study (US FDA) Weis et al/Circulation 2013	314	52	74%	79%	36%	41%	11	100%	95.2%	13%	5.6 %
UK Cohort Jarman et al/Europace 2013	111	33	-	50%	-	14%	12	100%	100%	15%	9.9 %
Dutch Cohort Nordkamp et al/JACC 2012	118	50	75%	60%	41%	38%	18	100%	100%	13%	5.9 %
German I Cohort Aydin et al/CircArrhy 2012	40	42	70%	42.5 %	47%	22.5 %	7.6	97.5%	100%	5%	-
German II Cohort Case-Control Study Kobe et al /H.Rhythm 2013	69	45	72%	59.4 %	46%	15.9 %	7.2	95.5%	100%	7.2%	1.4 %
EFFORTLESS Registry Lambiase et al/EHJ 2014	472	49	72%	63%	42%	37%	18. 6	99.7%	100%	13%	2.8%
Pooled data (EFFORTLESS+ IDE) Burke et al/JACC 2015	882	50		70%	40%	37.8	21.	98.6%	98.2%	13.1 at 3 years	11.1 at 3 years

S-ICD Therapy



The START Study: Subcutaneous vs Transvenous Arrhythmia Recognition Testing

Head-To-Head Comparison of Arrhythmia Discrimination Performance of Subcutaneous and Transvenous ICD Arrhythmia Detection Algorithms: The START Study

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KENNETH A. ELLENBOGEN, M.D.,¶ MARK A. WOOD, M.D.,¶ and MARTIN C. BURKE, D.O.**

From the *Medical University of South Carolina, Charleston, South Carolina, USA; †Erasmus MC, Rotterdam, the Netherlands; ‡Northwestern University, Chicago, Illinois, USA; §Cameron Health Inc., San Clemente, California, USA; ¶Virginia Commonwealth University, Richmond, Virginia, USA; and **University of Chicago, Chicago, Illinois, USA

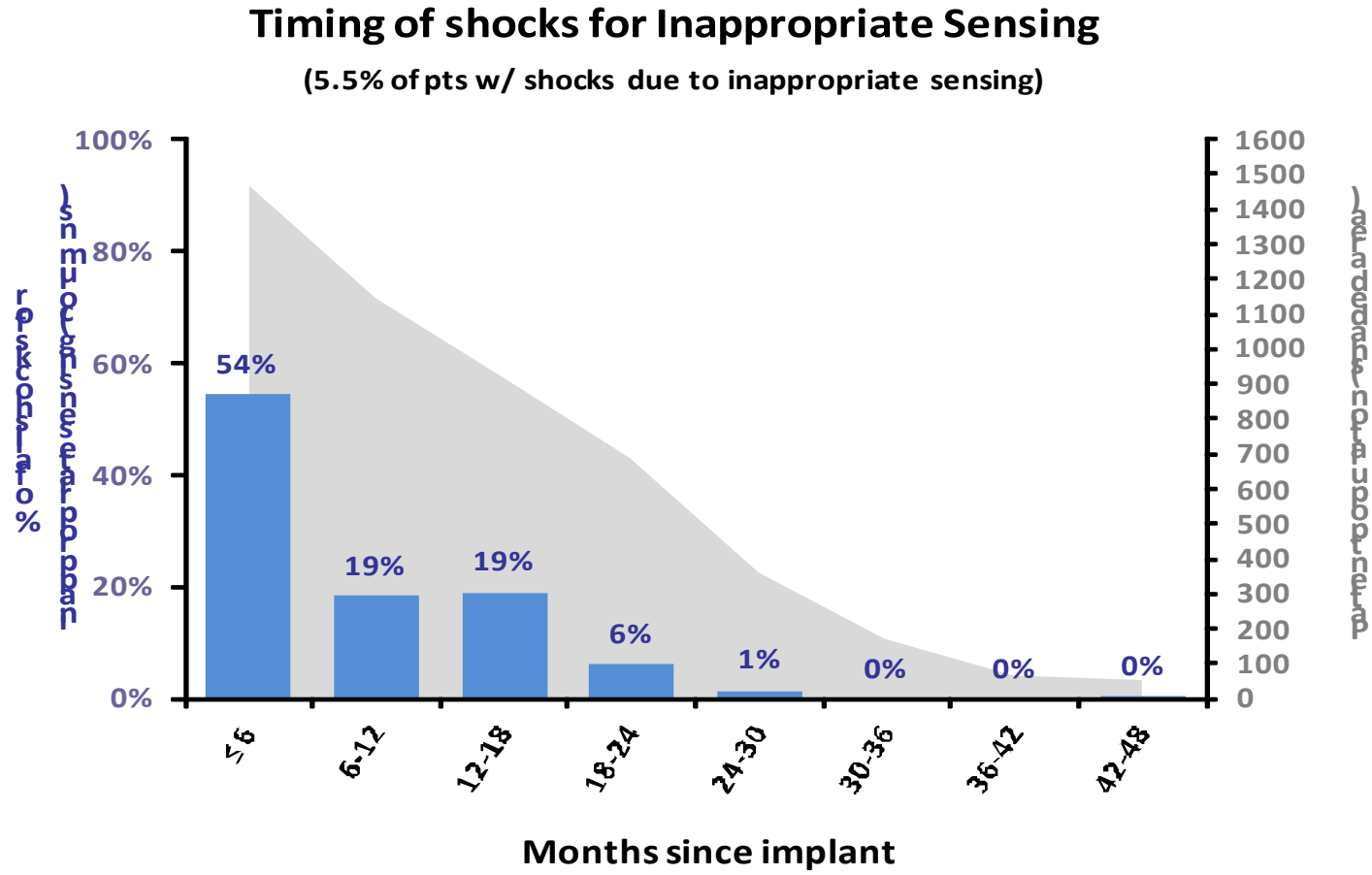
Results: **Appropriate detection of ventricular tachyarrhythmias for subcutaneous and TV devices in single- and dual-zone configurations was 100% and >99%, respectively. Specificity for supraventricular arrhythmias was significantly better for the S-ICD system compared to 2 of 3 TV systems, as well as the composite of TV devices (98.0% [S-ICD] vs 76.7% [SC-TV range: 64.0–92.0%] vs 68.0% [DC-TV range: 32.7–89.8%; P < 0.001]).**

Conclusion: **Appropriate ventricular arrhythmia detection is excellent for all ICD systems evaluated; however, specificity of supraventricular arrhythmia discrimination by the S-ICD system is better than discrimination by 2 of 3 TV systems.** *(J Cardiovasc Electrophysiol, Vol. 23, pp. 359-366, April 2012)*

S-ICD System Performance:

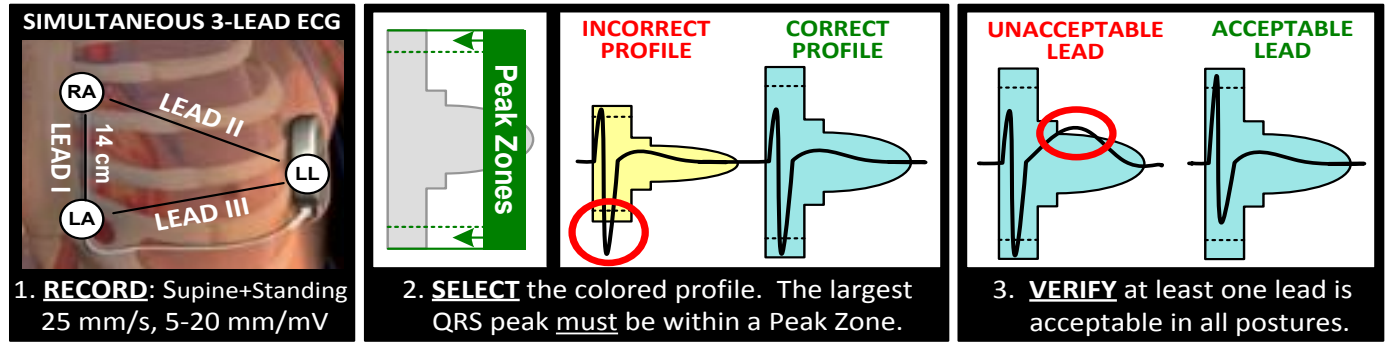
Therapy Delivery (inappropriate therapy)…

- **Inappropriate Therapy:**
  - Low annual inappropriate shock rate
  - Reprogramming has been very successful at mitigating further events
  - Of the inappropriate therapy delivered, the majority occurred within the first six months from implant and was subsequently managed with reprogramming



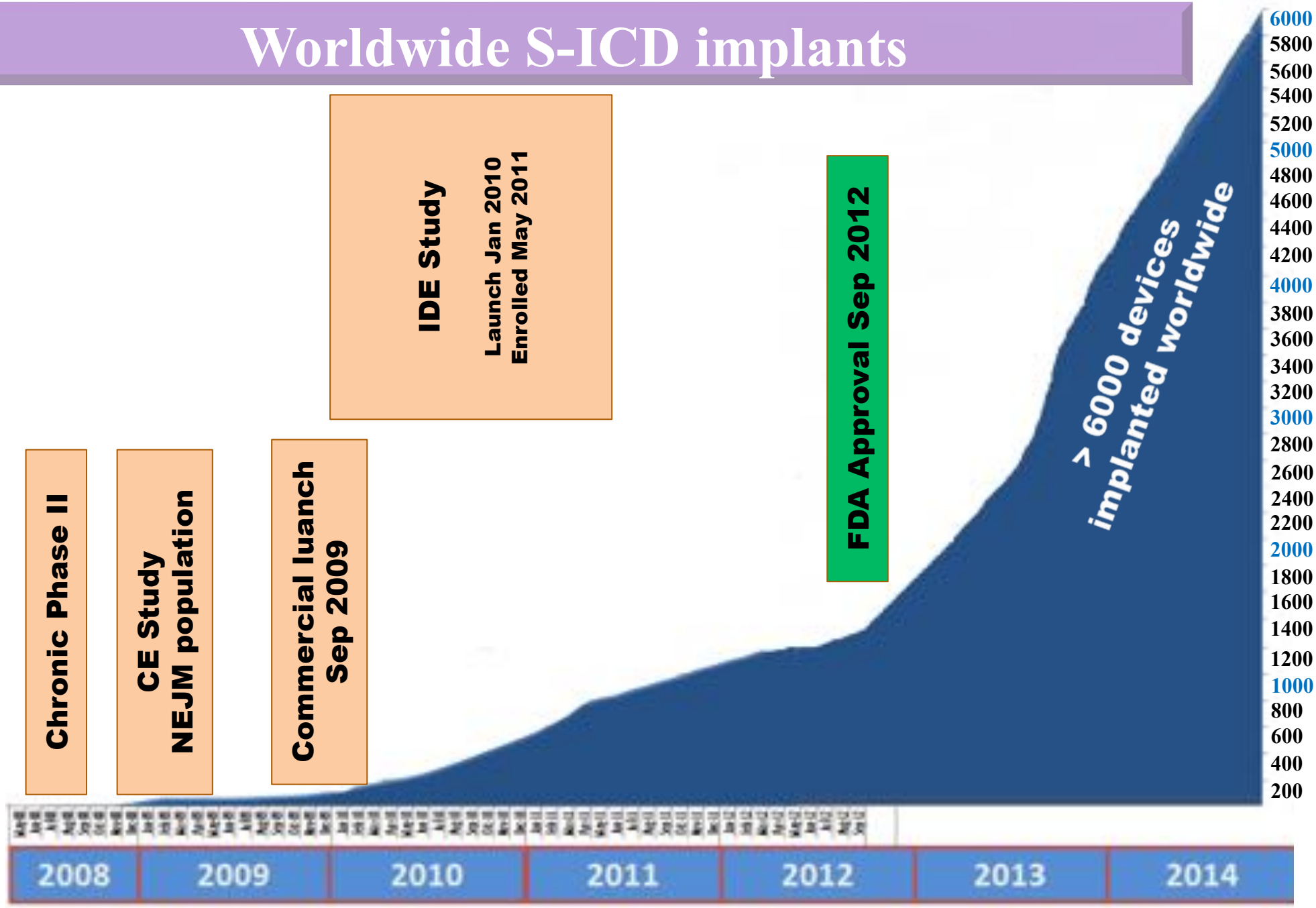
How to minimize inappropriate shocks in S-ICD Pts?!

- ***Patient screening*** **prior to the implant to insure adequate transcutaneous signals (pre-operating screening tool)**

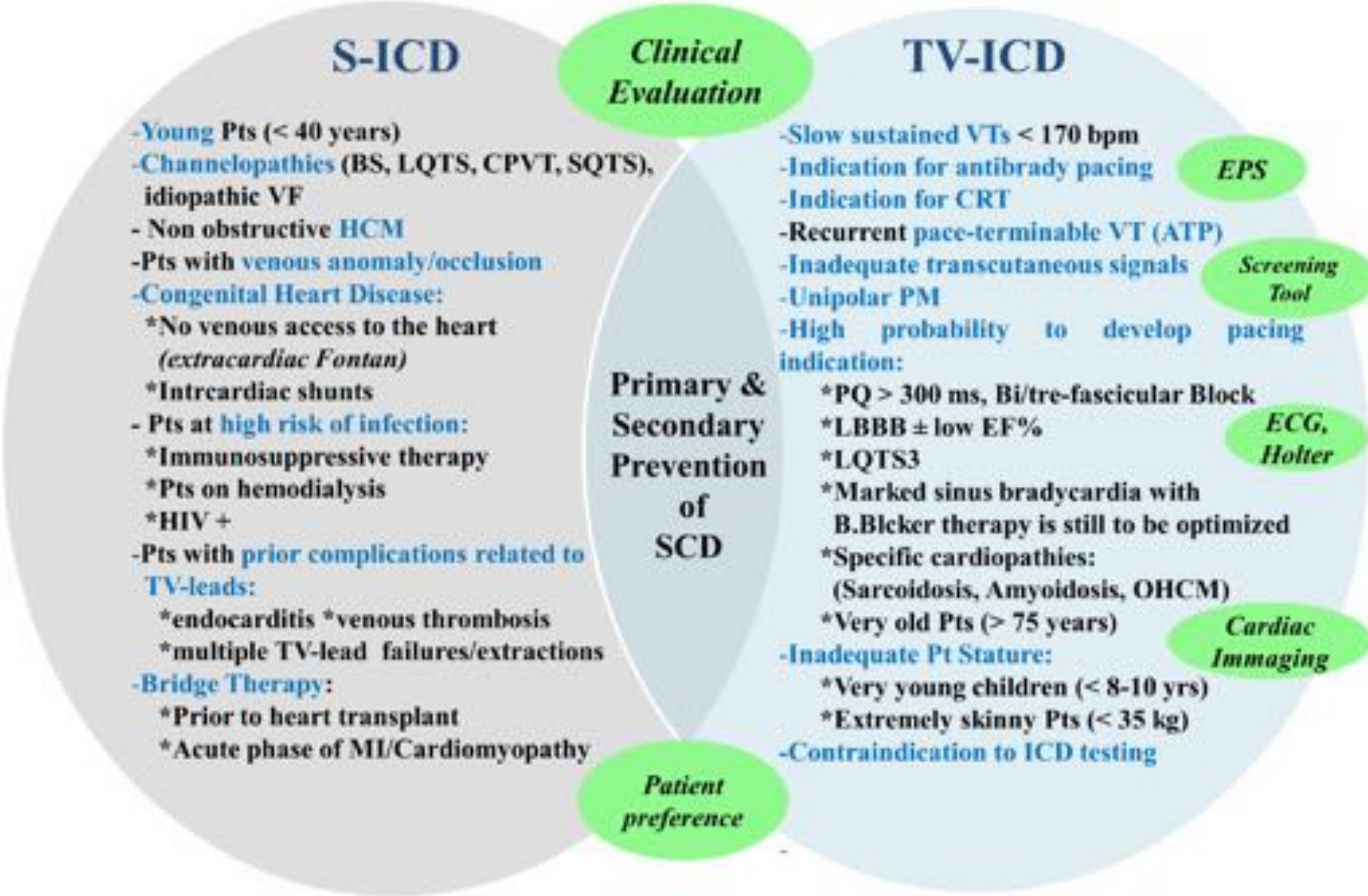


- ***Device optimizing*** **to select the best sensing vector (supine/orthostatic positions)**
- ***Dual zone programming*** **is preferred (ex: conditional shock zone 180-220 bpm, shock zone >220 bpm)**
- ***Exercise test*** **maybe helpful to evaluate the occurrence of myopotential oversensing/functional BBB during excercise**

Worldwide S-ICD implants



Advantages/Disadvantages	TV-ICD	S-ICD
Data on long-term performance	++	-/+
Chronic Pacing: antibrady- CRT- ATP	++	- (only 30 sec post-shock)
Device size/volume	++	+/-
Device longevity	> 10 years	> 7 years
Remote monitoring	++	Lattitude
MRI Conditional	already availiable	(2016?)
Cosmetic aspect	+	+/- (in women +?), submascular!
Device cost $	-/+	--
Lead performance	+/- (recalls, lead failures, crush syndrom)	++
Fluroscopy during implantation	-	+
Need for deep sedation/general anesthesia	+	-
DFT is mandatory	+/- not routinely performed	- recommended
Programming	Complex, numerous parameters programmable	simple, flexible sensing (3 vectors)
Serious acute complications/infections	- -	+
Extraction complexity	- -	+
Detection & Defibrillation efficacy	++	++
Inappropriate therapies	+/- (AF + SVT)	+/- (TWOS)



*From: Ali H, Lupo P, Cappato R. The Entirely Subcutaneous Defibrillator: A New Generation and Future Expectations. *Journal of Arrhythmia & Electrophysiology Review, August 2015;4(2):116-121.*

The PRAETORIAN Trial

A Prospective, RAndomizEd comparision of subcuTaneOus & tRansvenous ImplANTable cardiovertor-defibrillator therapy

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Lucas V. A. Boersma, MD, PhD,[d,n] Johannes S. Bos, MD, PhD,[e,n] Peter Paul H. M. Delnoy, MD, PhD,[f,n]
Pascal F. H. M. van Dessel, MD, PhD,[a,n] Antoine H. G. Driessen, MD,[g,n] Joris R. de Groot, MD, PhD,[a,n]
Jean Paul R. Herrman, MD, PhD,[h,n] Luc J. L. M. Jordaens, MD, PhD,[i,n] Kirsten M. Kooiman, CCDS,[a,n]
Alexander H. Maass, MD, PhD,[j,n] Mathias Meine, MD, PhD,[k,n] Yuka Mizusawa, MD,[a,n]
Sander G. Molhoek, MD, PhD,[l,n] Jurjen van Opstal, MD, PhD,[m,n] Jan G. P. Tijssen, PhD,[a,n]
and Arthur A. M. Wilde, MD, PhD[a,n] *Amsterdam, Maastricht, Nieuwegein, Nijmegen, Zwolle, Rotterdam, Groningen, Utrecht, Breda, and Enschede, The Netherlands; and Seattle, WA*

Study Design The PRAETORIAN trial is an investigator-initiated, randomized, controlled, multicenter, prospective 2-arm trial that outlines the advantages and disadvantages of the subcutaneous ICD. Patients with a class I or IIa indication for ICD therapy without an indication for bradypacing or tachypacing are included. A total of 700 patients are randomized to either the subcutaneous or transvenous ICD (1:1). The study is powered to claim noninferiority of the subcutaneous ICD with respect to the composite primary endpoint of inappropriate shocks and ICD-related complications. After noninferiority is established, statistical analysis is done for potential superiority. Secondary endpoint comparisons of shock efficacy and patient mortality are also made.

ESC Guidelines 2015

4.3.2 Subcutaneous implantable cardioverter defibrillator

Subcutaneous implantable cardioverter defibrillator

Recommendations	Class[a]	Level[b]	Ref.[c]
Subcutaneous defibrillators should be considered as an alternative to transvenous defibrillators in patients with an indication for an ICD when pacing therapy for bradycardia support, cardiac resynchronization or antitachycardia pacing is not needed.	IIa	C	157, 158
The subcutaneous ICD may be considered as a useful alternative to the transvenous ICD system when venous access is difficult, after the removal of a transvenous ICD for infections or in young patients with a long-term need for ICD therapy.	IIb	C	This panel of experts

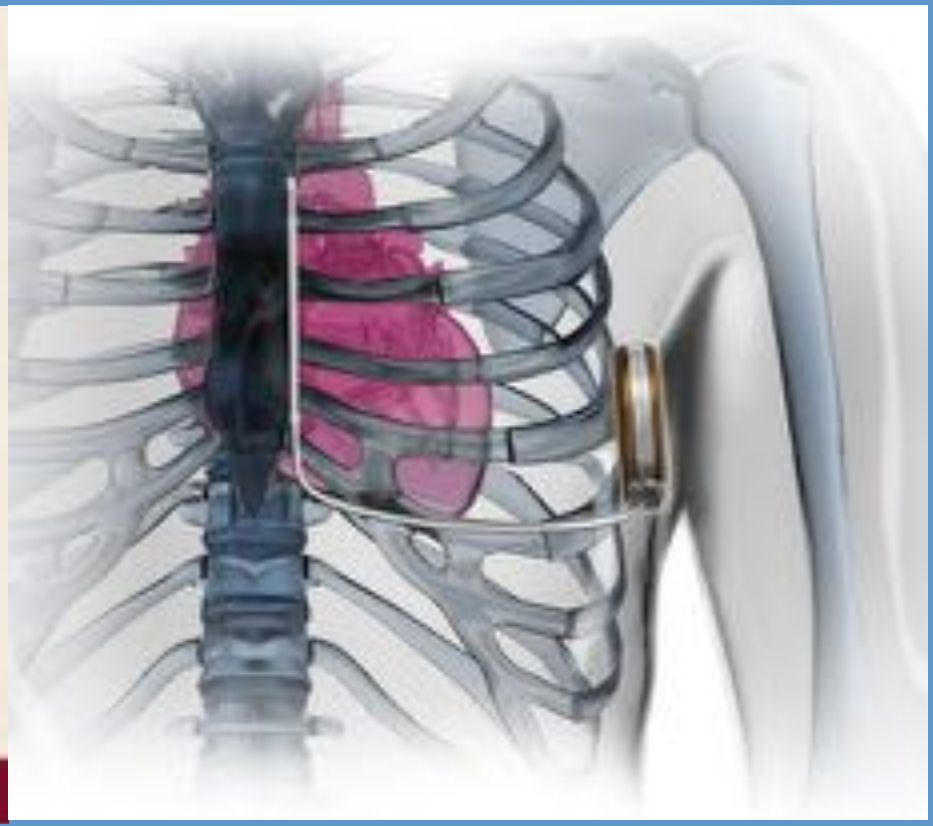
ICD = implantable cardioverter defibrillator.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting recommendations.

Classes of recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended/is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
Class IIa	*Weight of evidence/opinion is in favour of usefulness/efficacy.*	Should be considered
Class IIb	*Usefulness/efficacy is less well established by evidence/opinion.*	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

CONCLUSIONS

- **After more than a decade of continuous research/studies, the S-ICD has become a *real life* clinical practice for primary/secondary prevention of SCD unless pacing is required.**
- **S-ICD avoids procedural difficulties/complications associated with TV- leads, and does not require routine fluoroscopy use.**
- **The S-ICD is particulary beneficial in young patients, those with electrical syndromes, patients who had already experienced complications related to the TV-leads (serious infections, venous occlusion..)**
- **Further technology innovations as *Leadless Pacing*, if integrated with the S-ICD might offer an attractive therapeutic approach in the future**
- **Considering the simplicity of its implantation/removal, the S-ICD may fill the gap between the current indications for ICD therapy and the clinical practice. *It might expand indications for ICD therapy in the future?!***



Thank you for your attention