20180608 KHRS Luncheon Symposium

Korea Real Experience with the S-ICD System

Hee Tae Yu, MD, PhD

Assistant Professor
Division of Cardiology, Severance Cardiovascular Hospital
Yonsei University College of Medicine

Transvenous ICD Limitations

Anatomical limitations

- Venous access issues

Implant risks

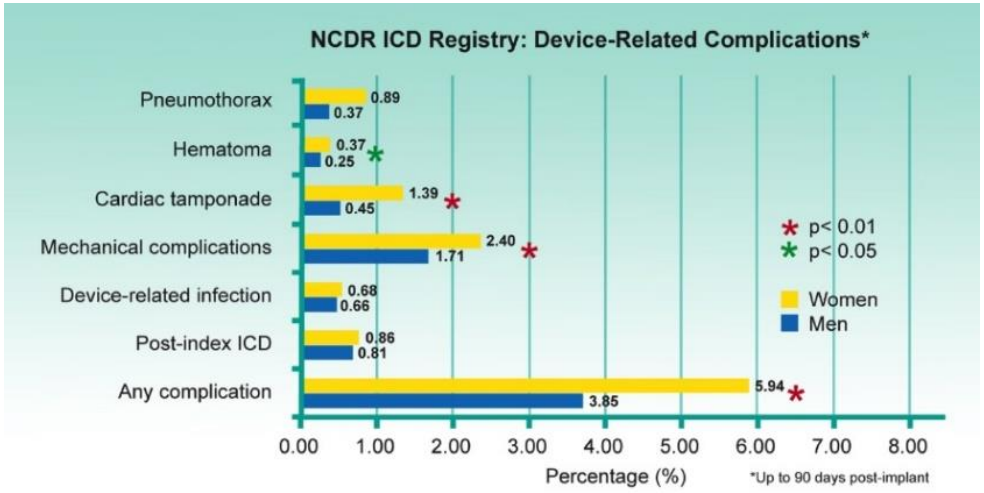
- Pericardial effusion/cardiac tamponade, perforation, pneumothorax, lead dislodgement, endocarditis, systemic infection, death

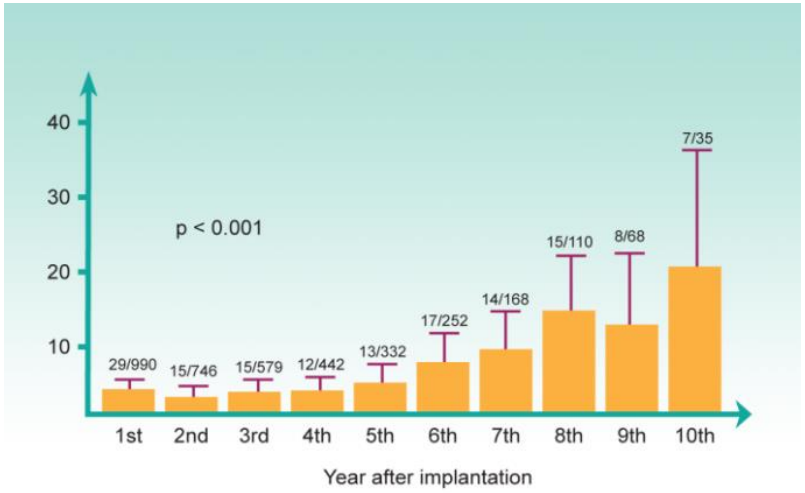
Lead failure risks

- Inappropriate shock/loss of therapy

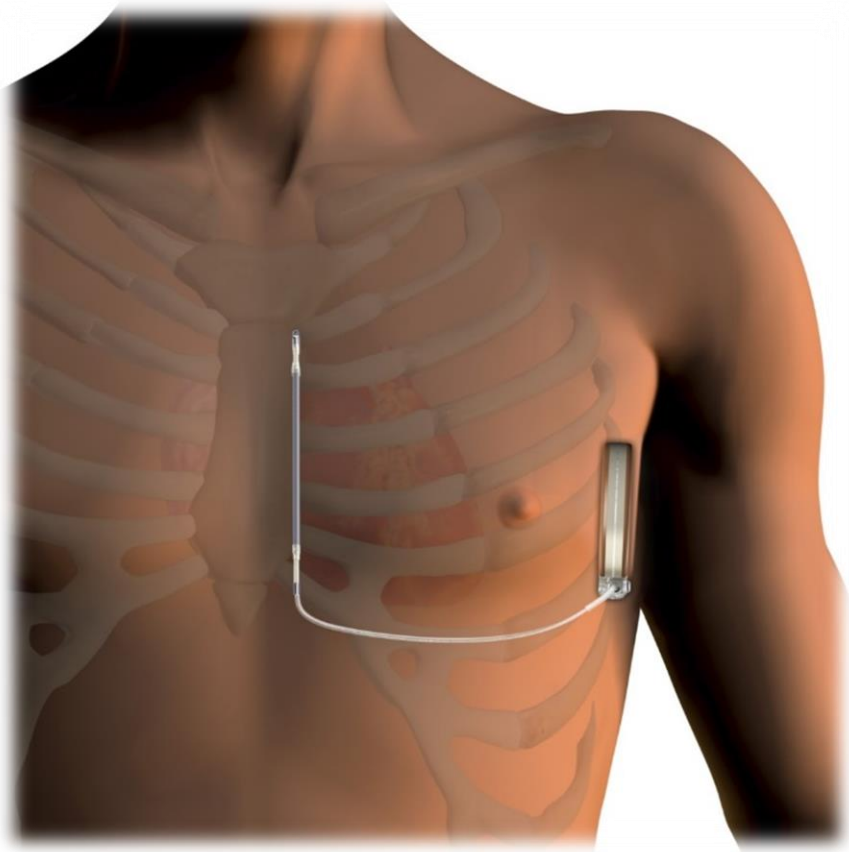
Explant risks

- Vessel dissection, perforation or occlusion, valve damage, bleeding, tamponade, systemic infection, death





Subcutaneous ICD Therapy



EMBLEM™ MRI S-ICD System

- **Entirely subcutaneous**
- **Does not require leads in the heart, leaving the vasculature untouched**
- **Placed using anatomical landmarks, reducing the need for fluoroscopy at implant**
- **Sophisticated algorithms provide effective detection and treatment of VT/VF[1,2]**

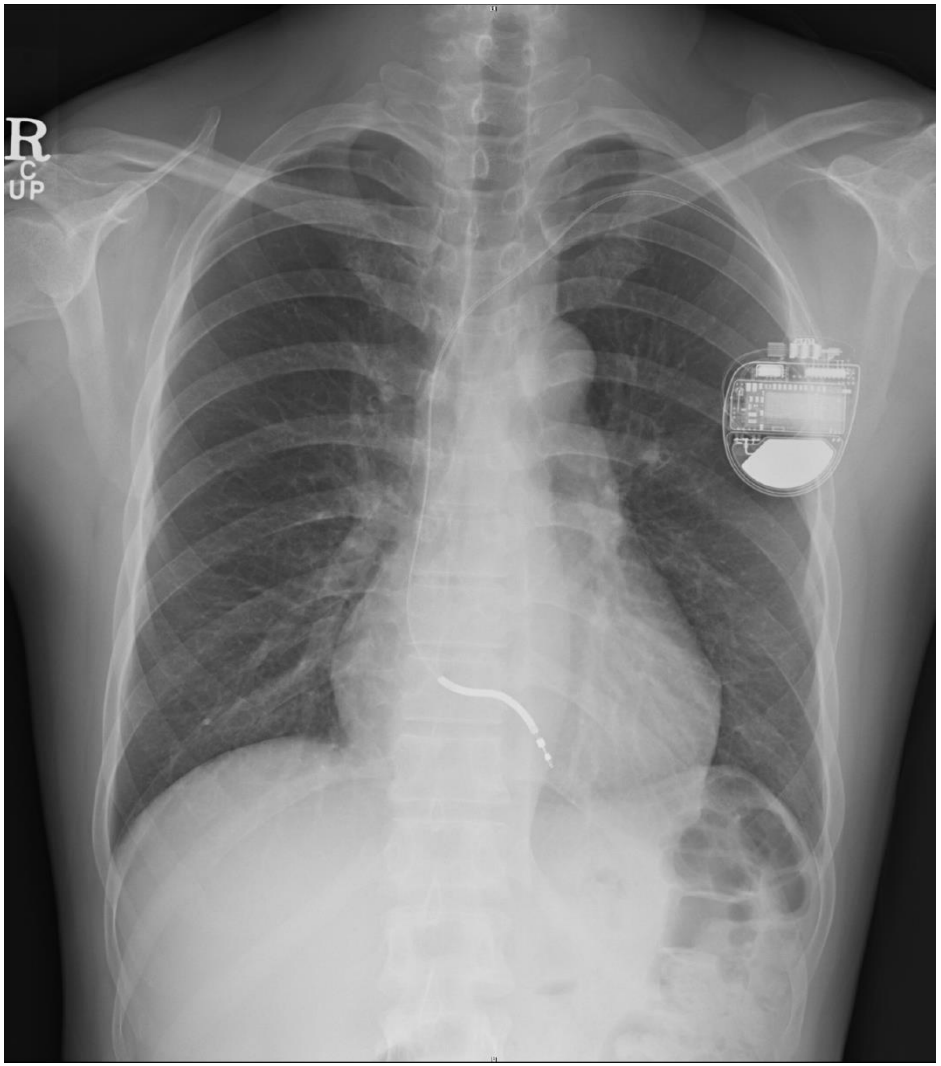
1: Gold *J Cardiovasc. Electrophysiol*. 2012, 23:359-366 2: Weiss *Circulation* 2013;128:944-953

Cases:
The First Experiences In Severance Hospital

Case 1. M/49

- HCMP
  - maximal thickness: 18mm
- Sustained VT
- Syncope

- ICD implantation for secondary prevention on Jan 2015

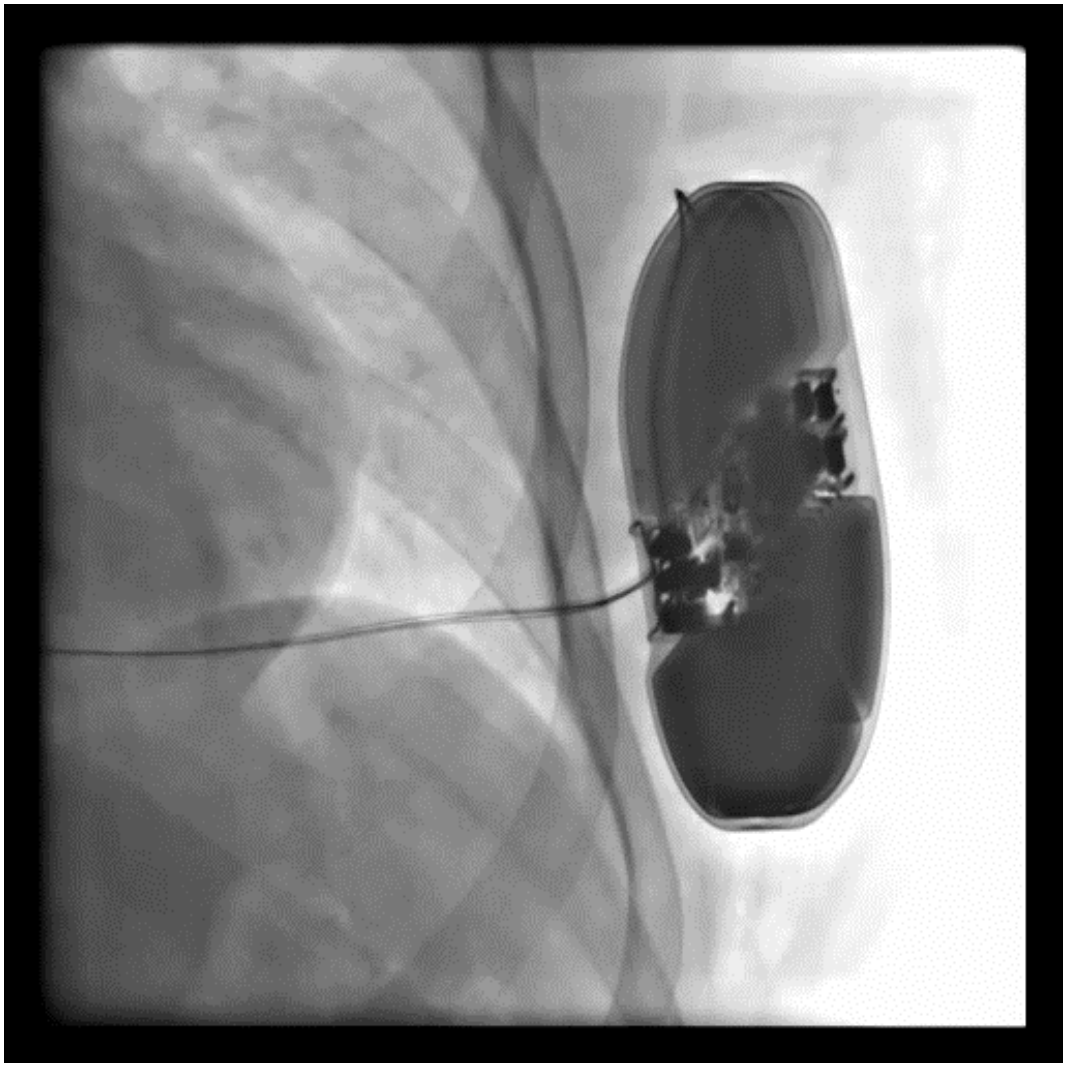


4 months later…

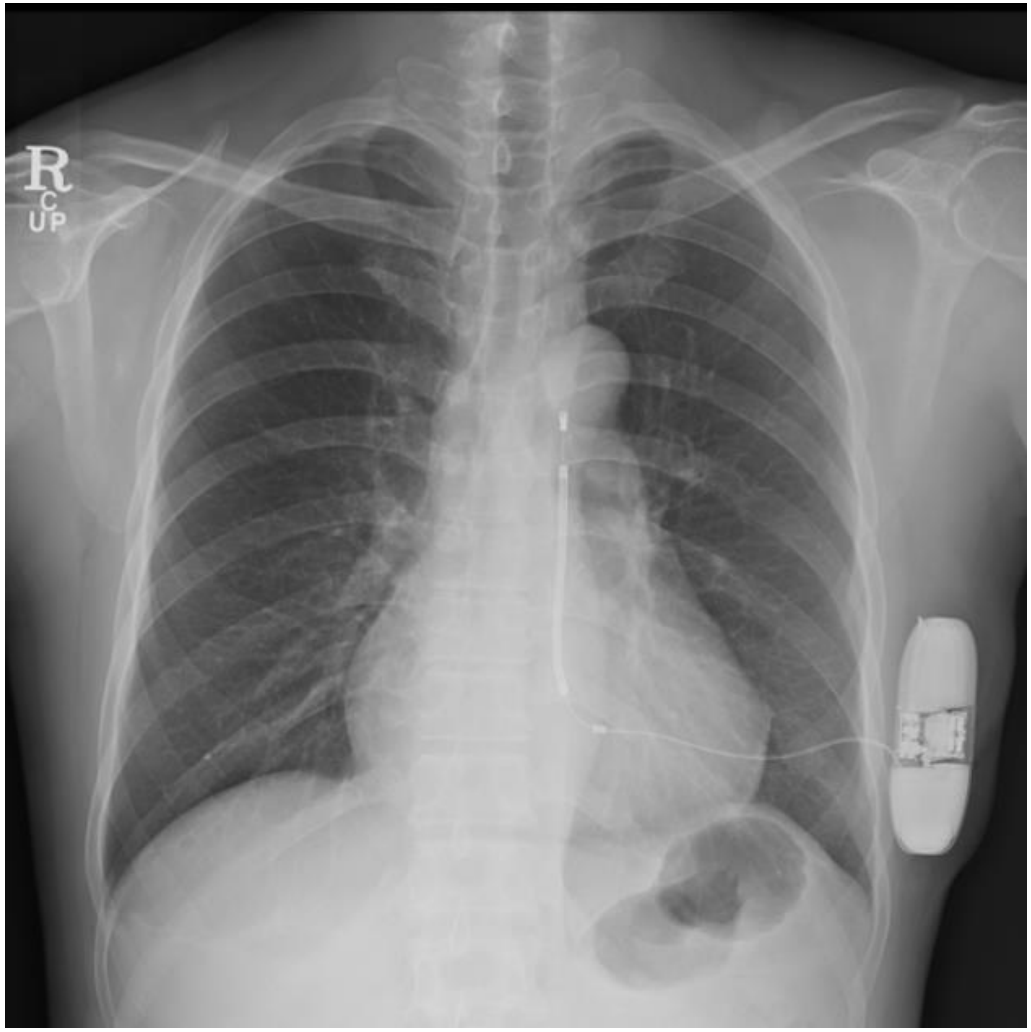
- Fever & pus drainage from pocket wound
- Erythema (+) / Tenderness (+)

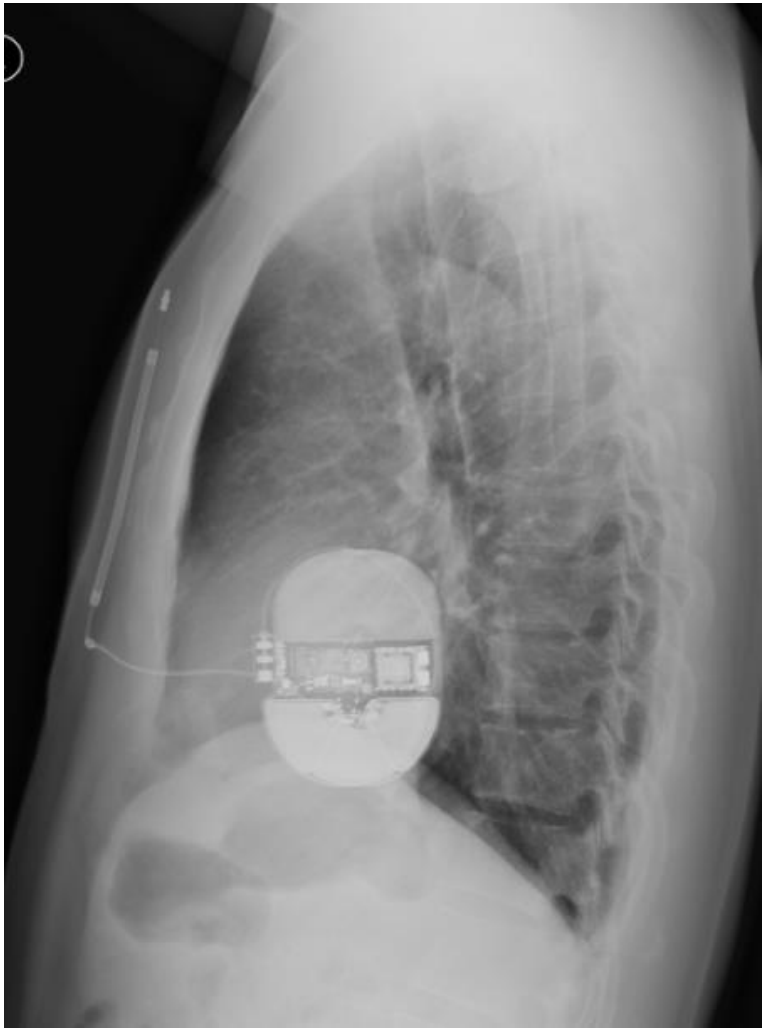
  → ICD & lead extraction

S-ICD implantation on Oct 2016



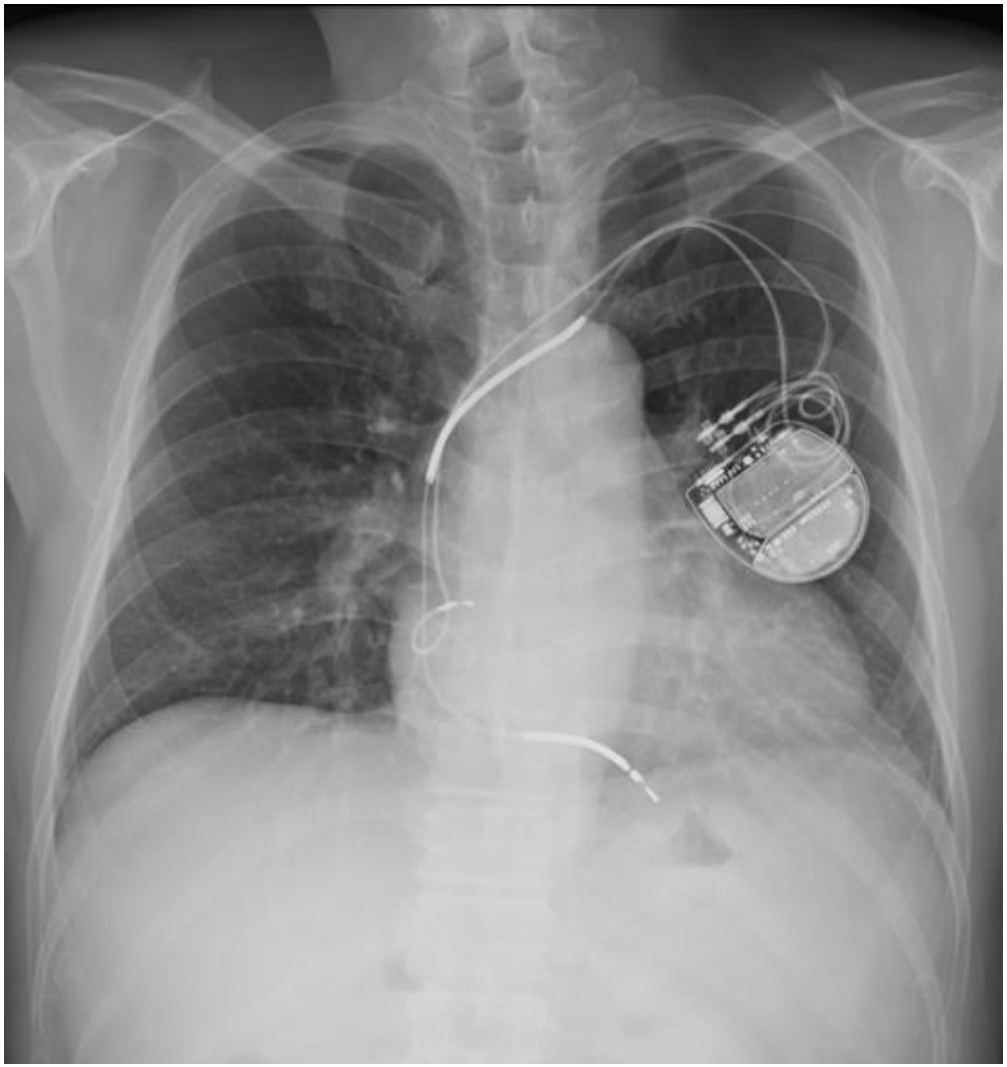
S-ICD implantation on Oct 2016





Case 2. M/56

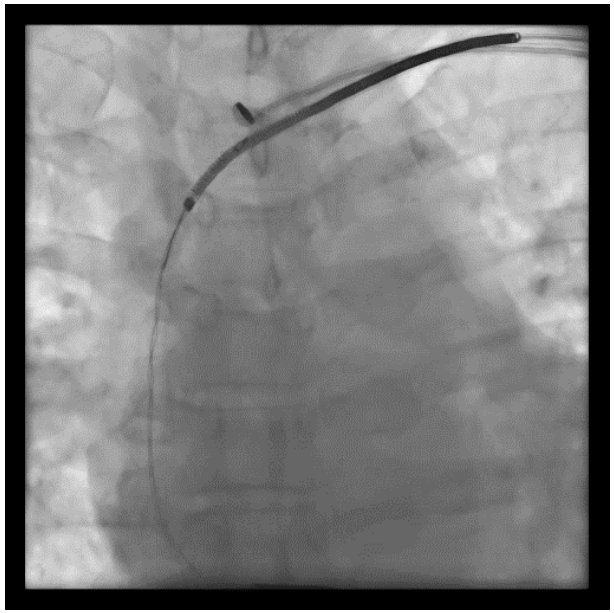
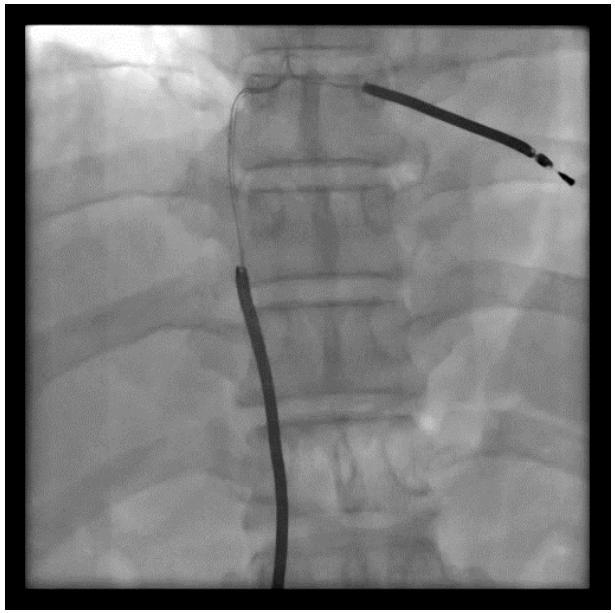
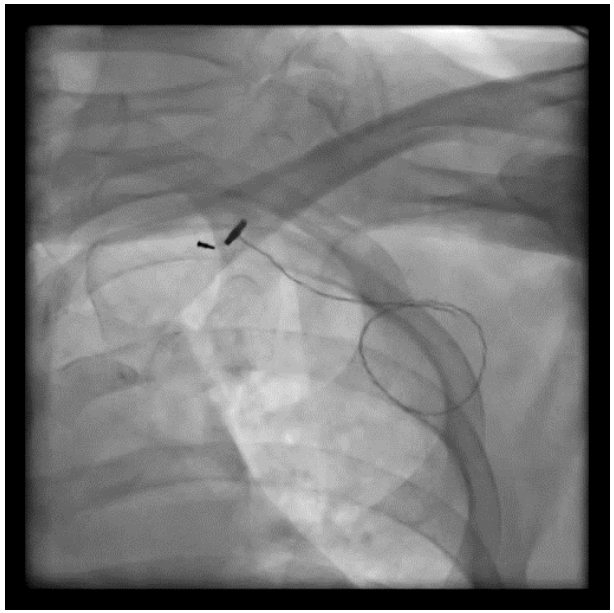
- **HCMP**
  - **maximal thickness: 37mm**
- **Nonsustained VT**
- **ICD implantation on Oct 2009**
- **G/C on Jul 2016**



1 week after G/C…

- Fever & Chill
- G(+) cocci from blood culture
- Echogenic mobile material in RA on TEE

Lead extraction & OP on Jul 2016

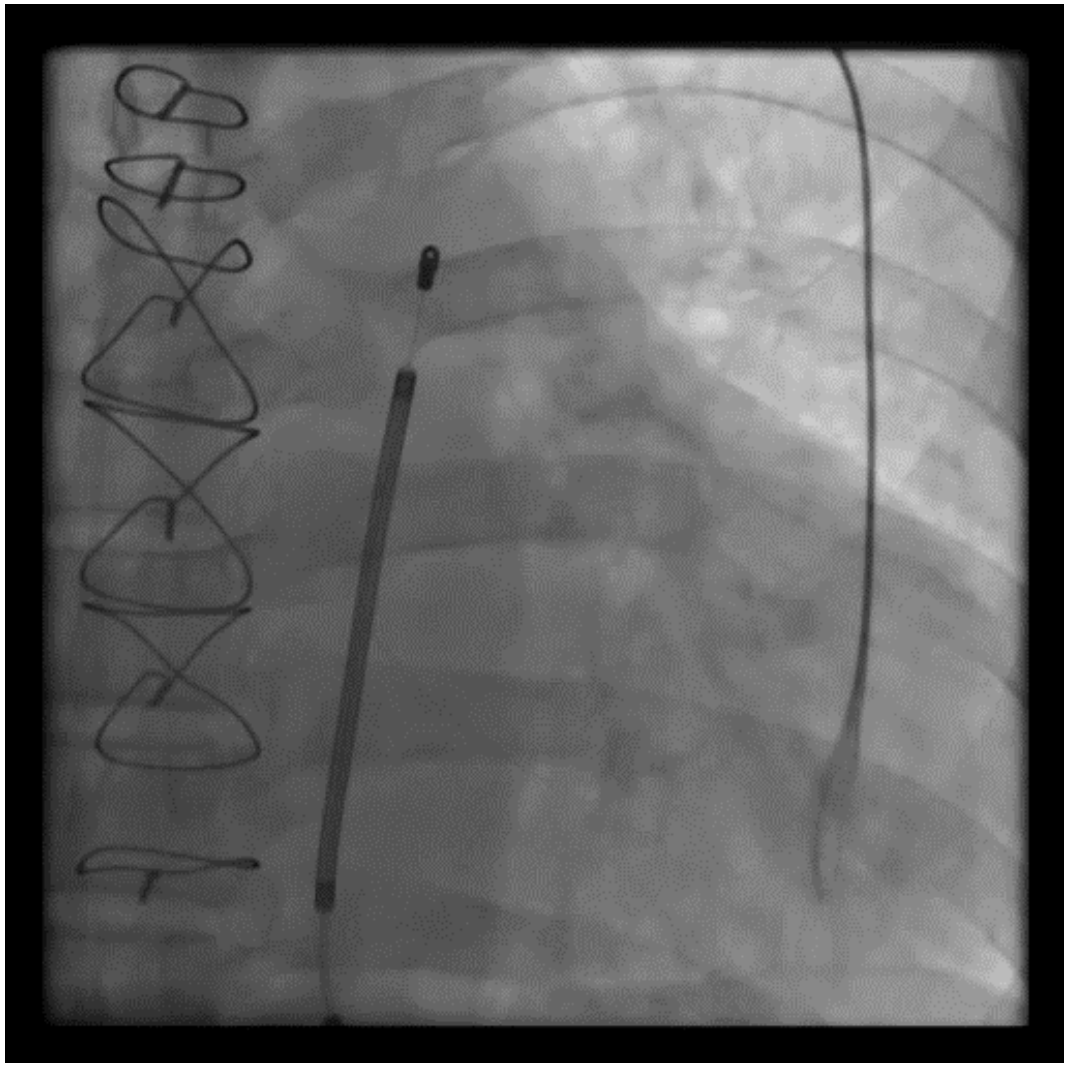




< Operative findings >

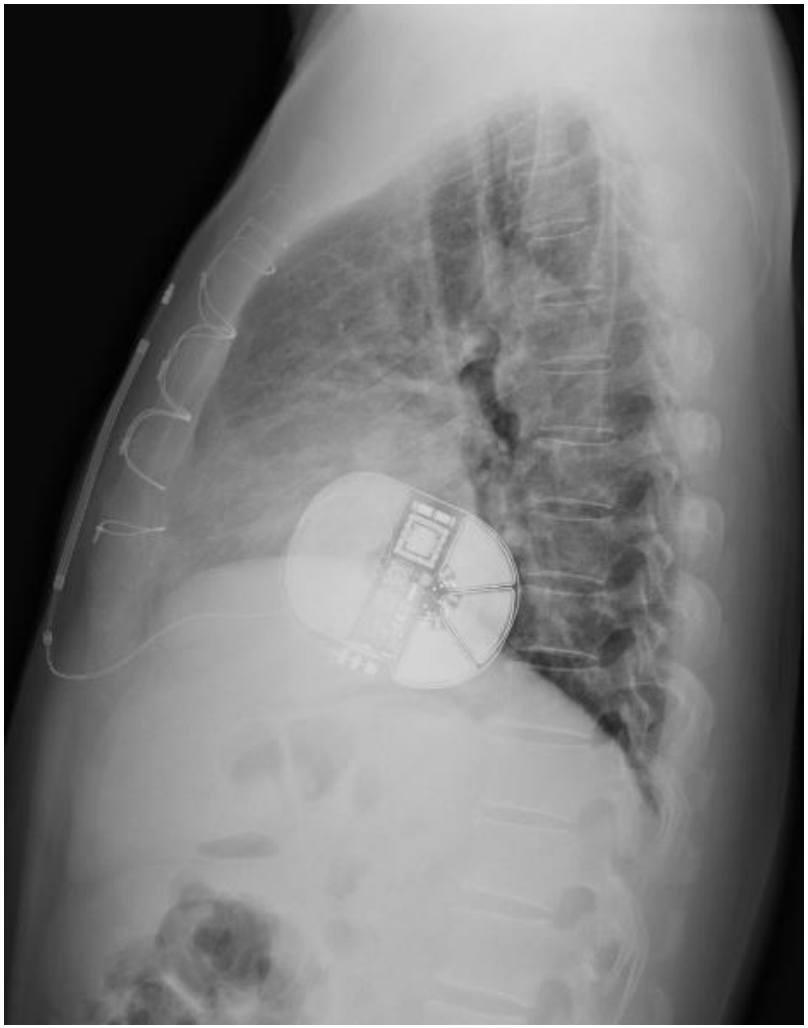
- ICD lead infection으로 제거되지 않아 open heart로 제거함
- V-lead 에 1x1cm sized vegetation (+)

→ Removal

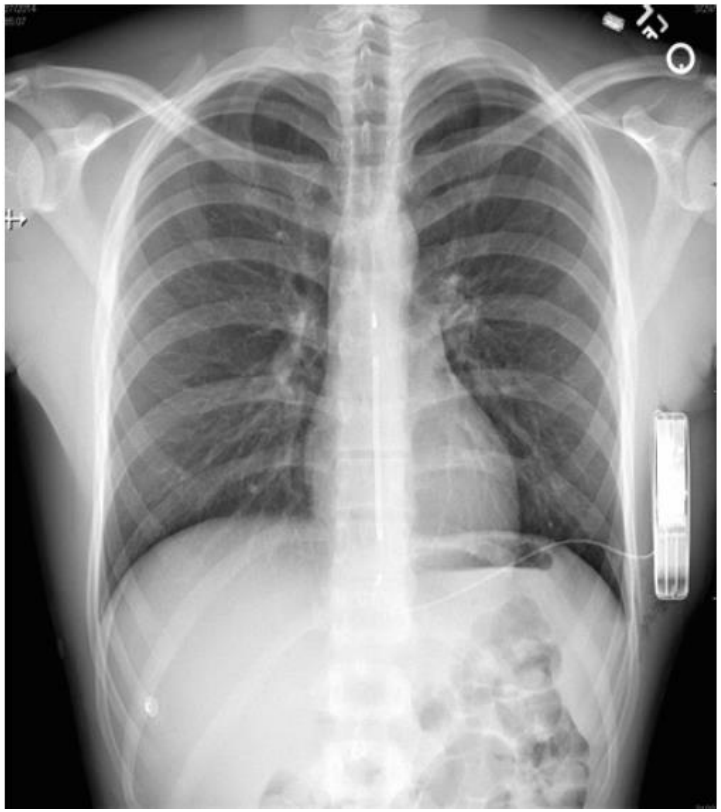
S-ICD implantation on Oct 2016

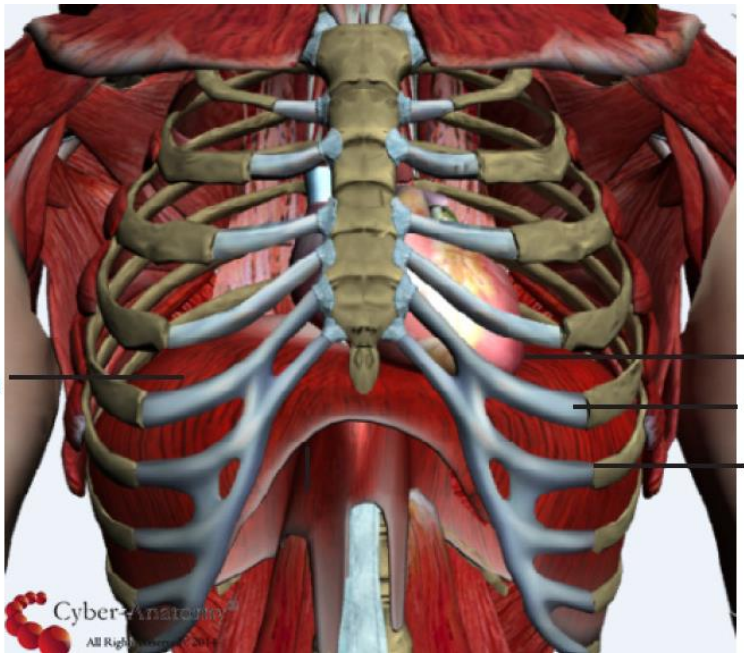


S-ICD implantation on Oct 2016



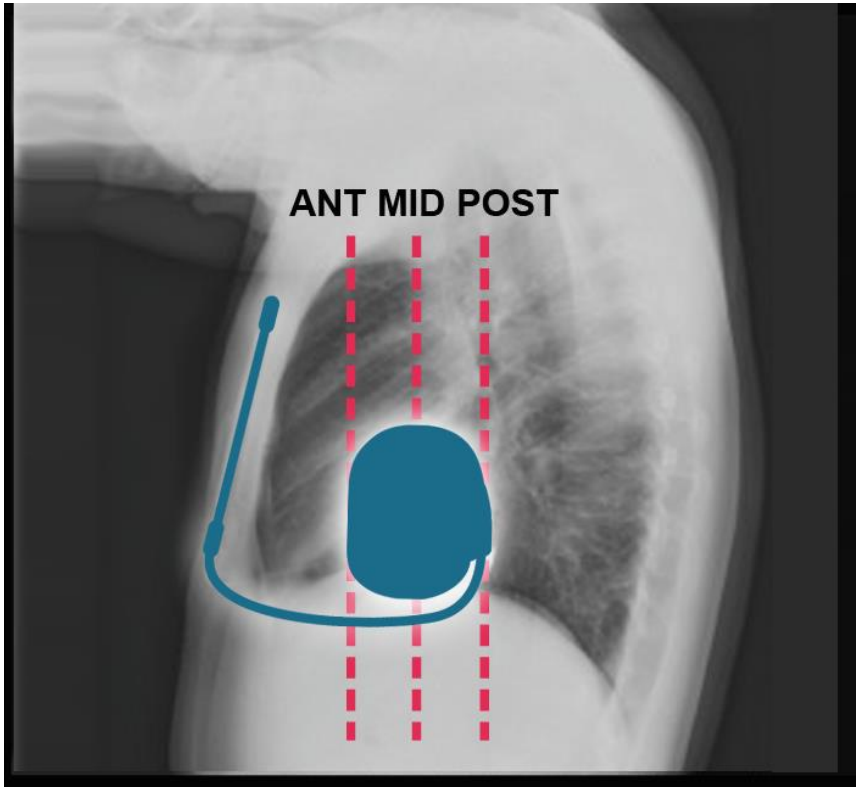
X-ray landmarks

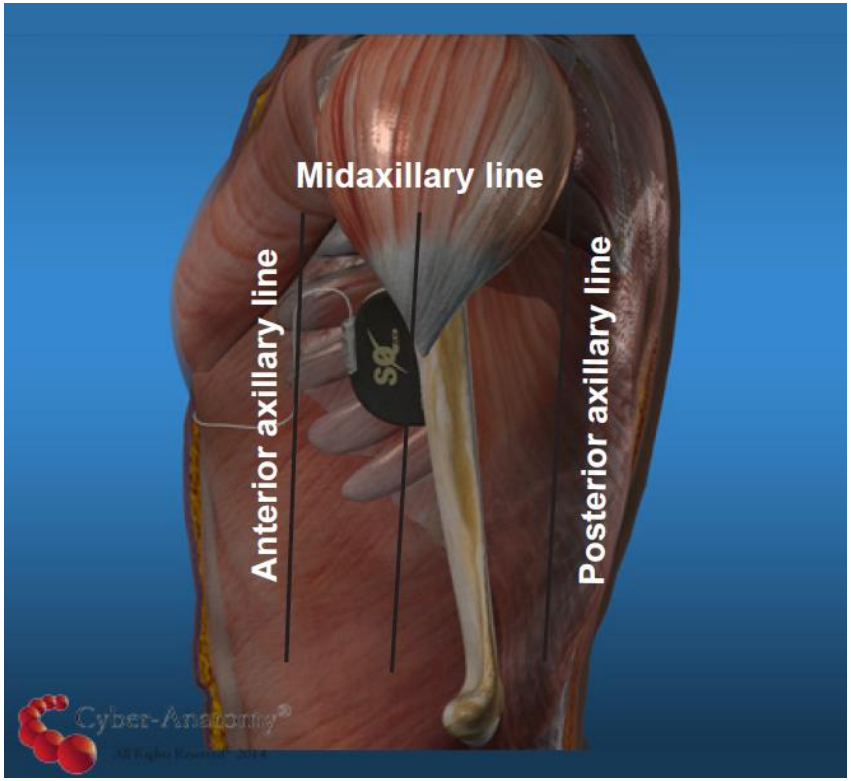




In the AP view, the sensing rings are parallel to one another and about 1 cm from the sternal midline. The pulse generator is at the mid-axillary line.

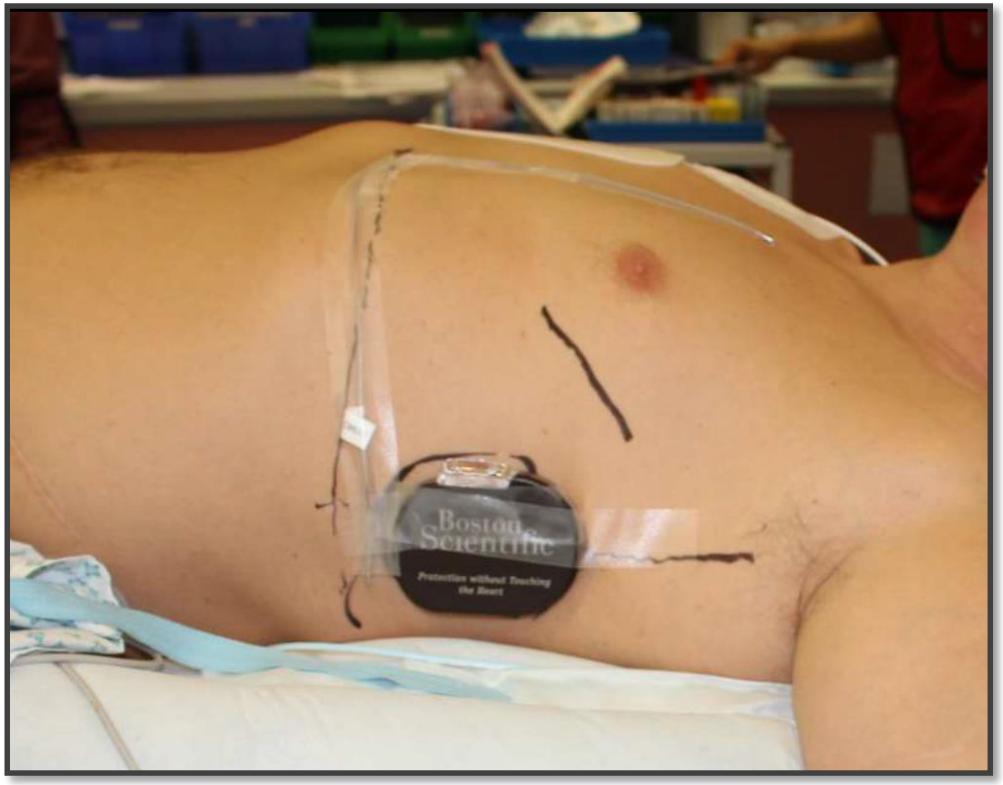
X-ray landmarks





- **In the left lateral view, the sensing rings appear to lie on the sternal surface.**
- **The ideal position of the pulse generator is between the 5th and 6th intercostal space at the mid-axillary line.**
- **The inferior edge of the device should not be below the xyphoid.**

Mark landmarks



Suggested Marking

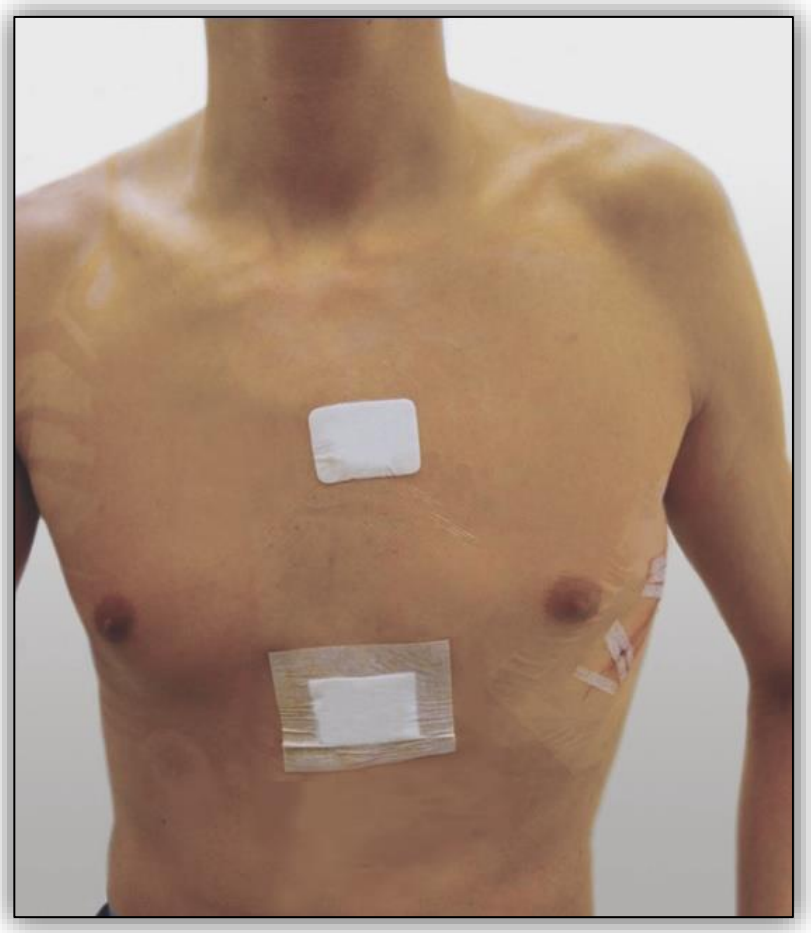
- Device placement / location and pocket incision
- Xyphiod incision
- Suprasternal notch
- Sternal midline
- Mid-axillary line

- **The system placement should reflect the original screening configuration.**
- **Confirm the ideal placement with Fluoroscopy while the Demo Device and Electrode are taped to patients skin surface.**

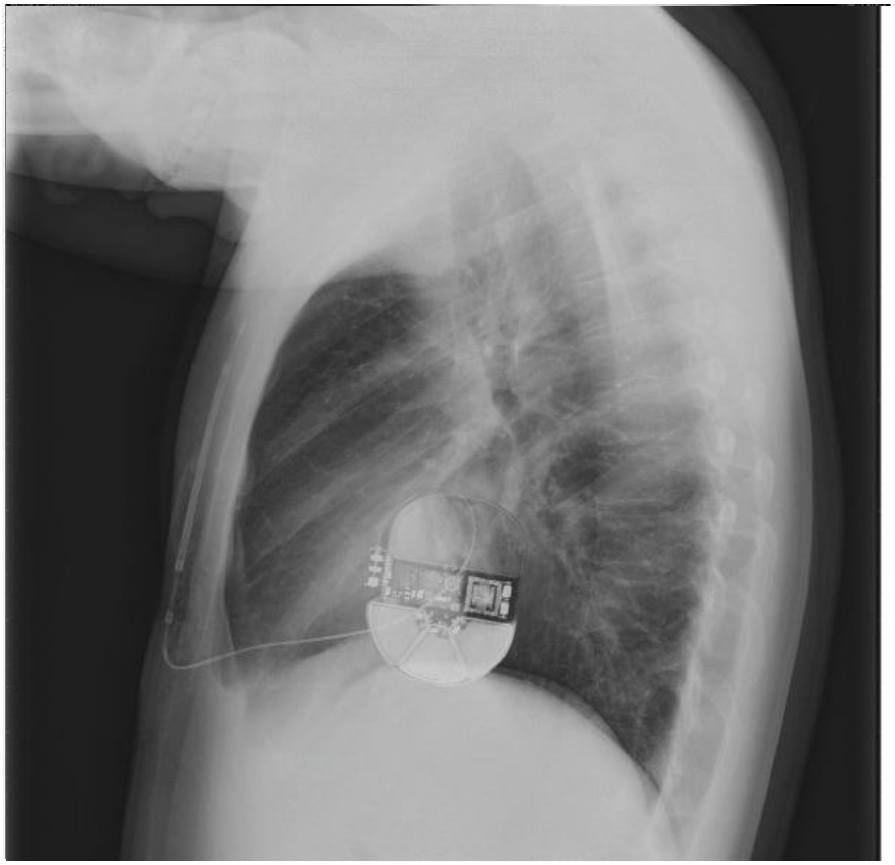
Implanting the system

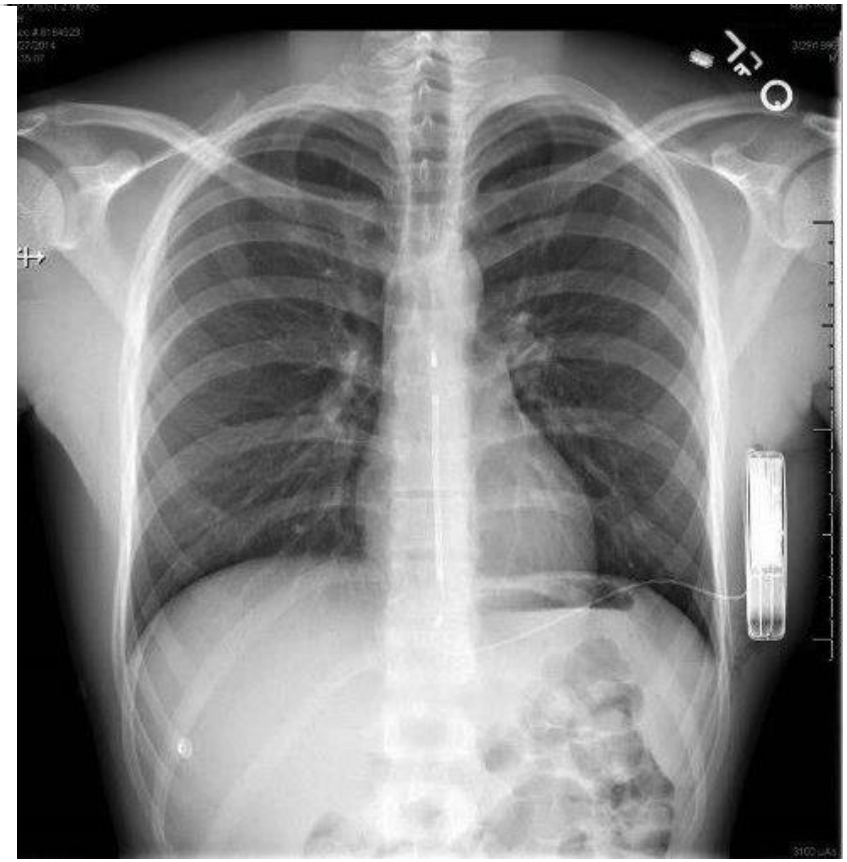
Completing the implantation

- Pocket antibiotics flush or antiseptic is recommended.
- Close pocket tissue layers & sternal incisions in standard fashion.
  - At least two layers of closure
- Apply standard wound dressings.
  - Pressure dressing
  - Include antimicrobial per preference or policy

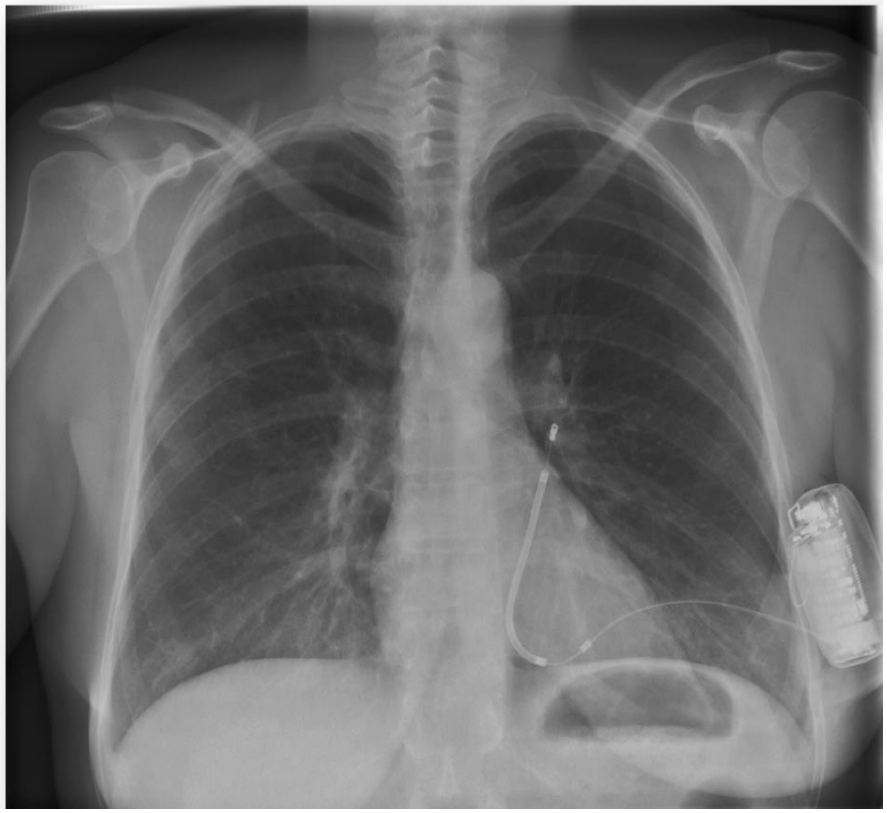


Optimal device placement

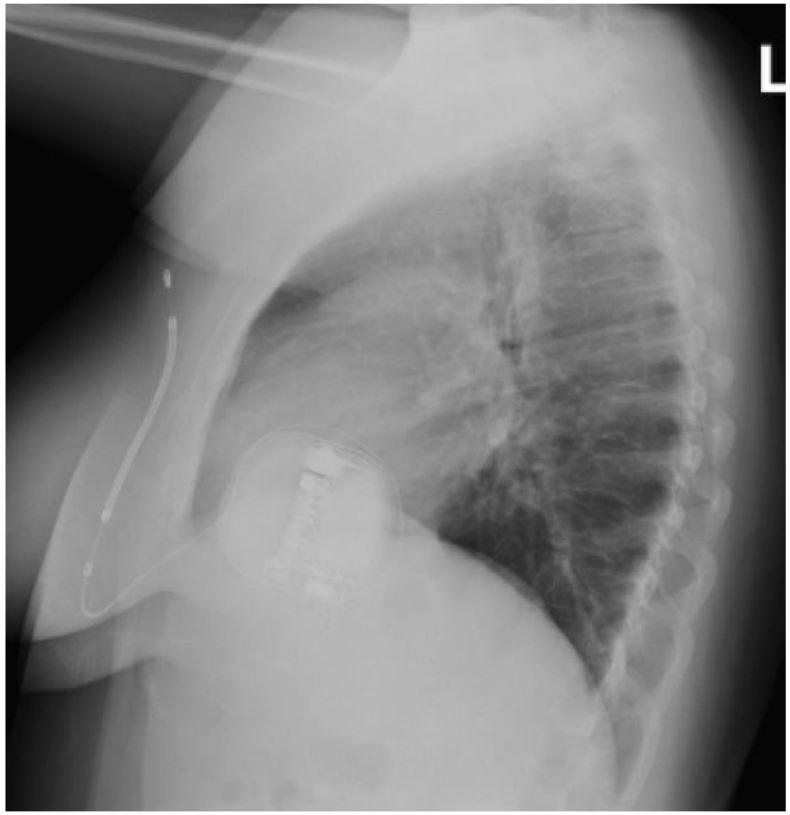




X-ray assessment



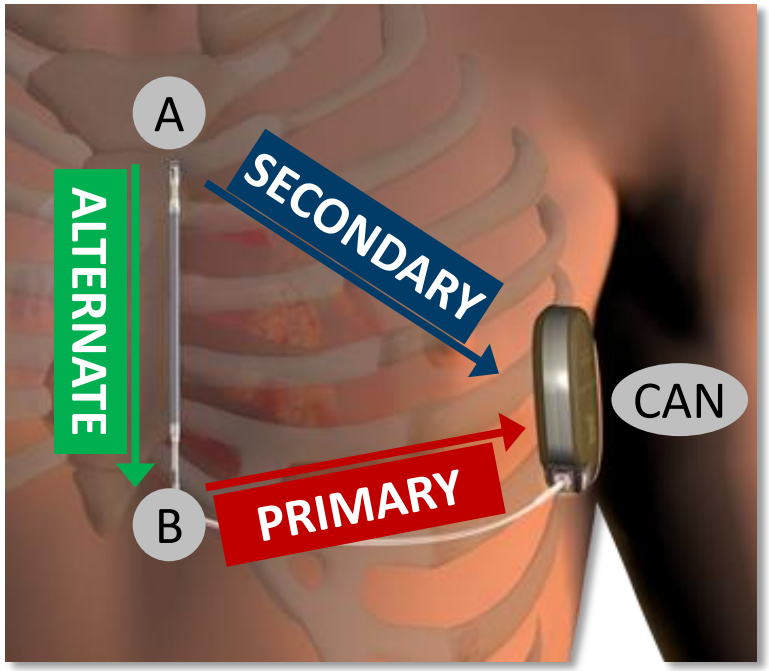
Electrode too lateral



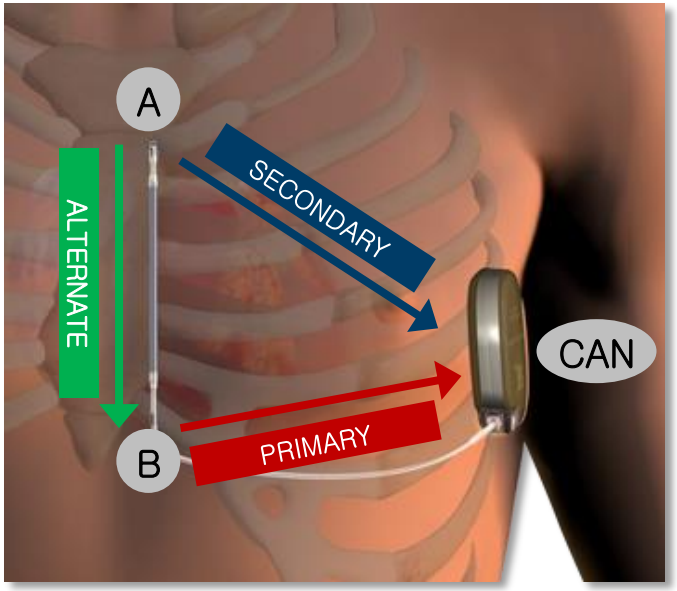
Electrode tip too superficial

Sensing the subcutaneous signal

- ✓ **3 Far-Field Sensing Vectors:**
  - ✓ **Detect the cardiac rhythm (3 different perspectives of electrical activity)**
  - ✓ **Capture high-resolution signals similar to a surface ECG**
  - ✓ **Utilizes both timing and morphology template**



Sensing the subcutaneous signal



SELECT SENSE CONFIGURATION

↓

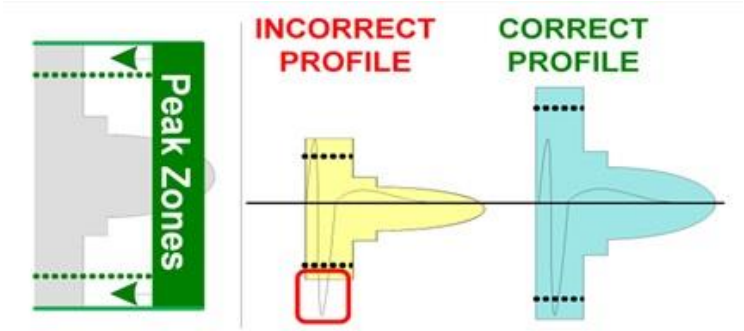
ANALYZE IMPACT OF POSTURE

↓

FORM QRS TEMPLATE

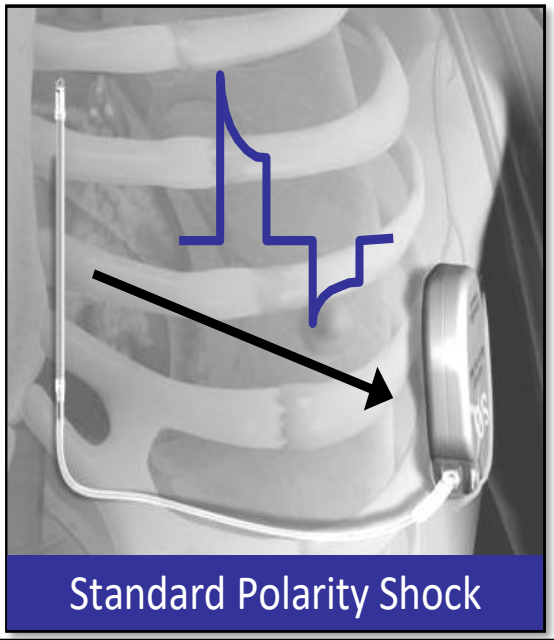
Automatic Setup Analyzes:

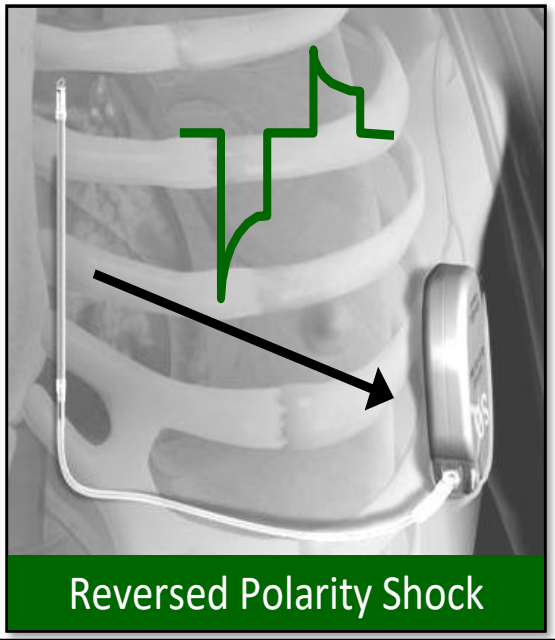
- QRS and T-wave amplitudes
- QRS:T-wave ratios (amplitude and timing)
- Patient posture
- QRS morphology and width



Therapy delivery

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

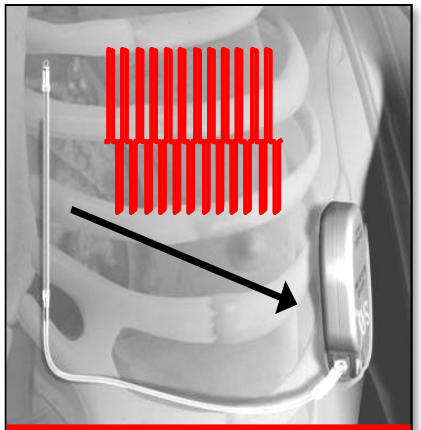




Therapy delivery

Induction

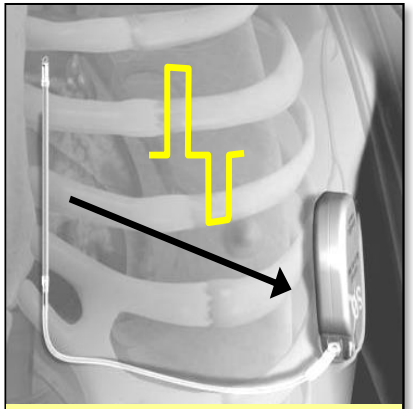
- Induction capability directly from the S-ICD® System programmer
- 200 mA @ 50 Hz
- Programmable first shock energy



50 Hz Induction Pulse

Post-Shock Pacing

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



Standard Polarity Pace

S-ICD Study

S-ICD™ System Study	Study Type	Patients	Sites	Comments
Feasibility and Proof of Concept Studies[1]	Acute	78 + 49	Not reported	Study completed: 2005 Published in NEJM
Initial Human Validation Study[1]	Chronic Safety and Performance	6	2 (NZ)	Study completed: 2008 Published in NEJM
CE Clinical Study[1]	Chronic Safety and Performance	55	8 (OUS)	Study completed: 2011 Published in NEJM
IDE Clinical Study[2]	Chronic IDE	330	33 (US, EU, NZ)	Study completed: 2011 Published in Circulation
EFFORTLESS Registry[3,4]	Chronic Post-Market OUS Registry	1.000	50 (EU)	1000 patient enrollment completed end 2014
Post Approval Study[6]	Chronic Post-Market Trial	Goal; 1616	Multi-center (US)	Enrolling
PRAETORIAN Trial (Investigator Sponsored Research funded by a grant from Boston Scientific)[5]	Chronic Post-Market Randomized Trial	Goal: 850	Multi-center (EU, US)	Enrolling Investigator-initiated, randomized, controlled, multi-center, prospective 2-arm trial (S-ICD System vs. TV-ICD Systems)
UNTOUCHED[7]	Chronic Post-Market Trial	Goal = 1100	Multi-center (EU, US)	MADIT II/SCD-HeFT indications

1. Bardy, G. H., W. M. Smith, et al. (2010). "An entirely subcutaneous implantable cardioverter-defibrillator." N Engl J Med 363(1): 36-44.
2. Weiss, et al. The Safety and Efficacy of a Totally Subcutaneous Implantable-Defibrillator . CIRCULATION. Vol. 128, no. 9. (August 2013.): 944-953.
3. Heart Rhythm - May 2012; Vol 9:5(S1-33) AB07-2.
4. Lambiase, et al. A worldwide experience with a totally subcutaneous ICD; Preliminary results of the EFFORTLESS S-ICD Registry. European Heart Journal Mar2014.
5. Olde Nordkamp, L.R. et al. Rationale and design of the PRAETORIAN trial: a Prospective, Randomized comparison of subcutaneous and transvenous Implantable cardioverter-defibrillator therapy. Am. Heart.J. 2012 May;163(5):753-760.e2. doi: 10.1016/j.ahj.2012.02.012
6. S-ICD® System Post Approval Study: https://clinicaltrials.gov/ct2/show/NCT01736618
7. Understanding Outcomes With the EMBLEM™ S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED): https://clinicaltrials.gov/ct2/show/NCT02433379

Implant and Midterm Outcomes of the S-ICD Registry : The EFFORTLESS Study

N = 985

FU: 3.1 ± 1.5 years

CENTRAL ILLUSTRATION Outcomes After S-ICD Implantation: 1-Year EFFORTLESS Registry

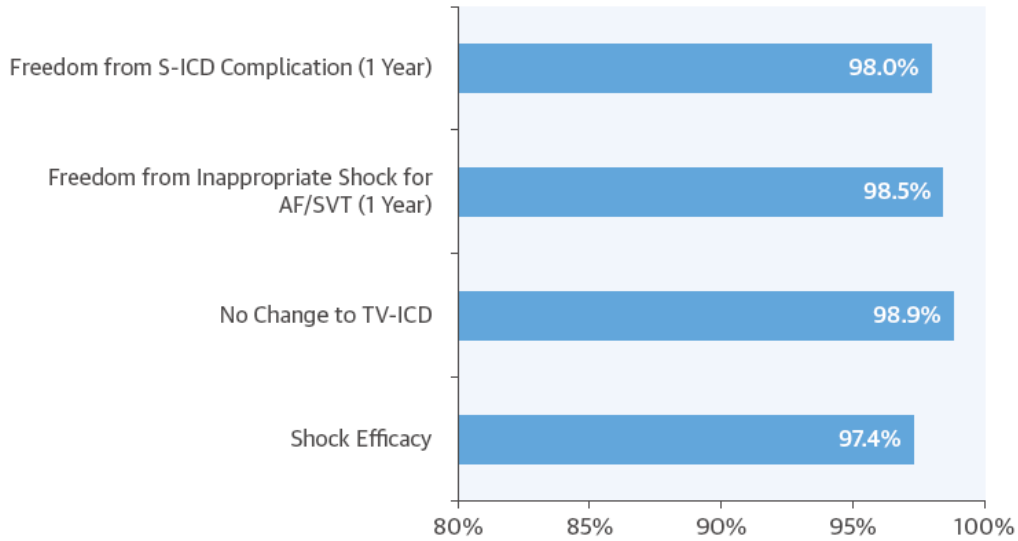


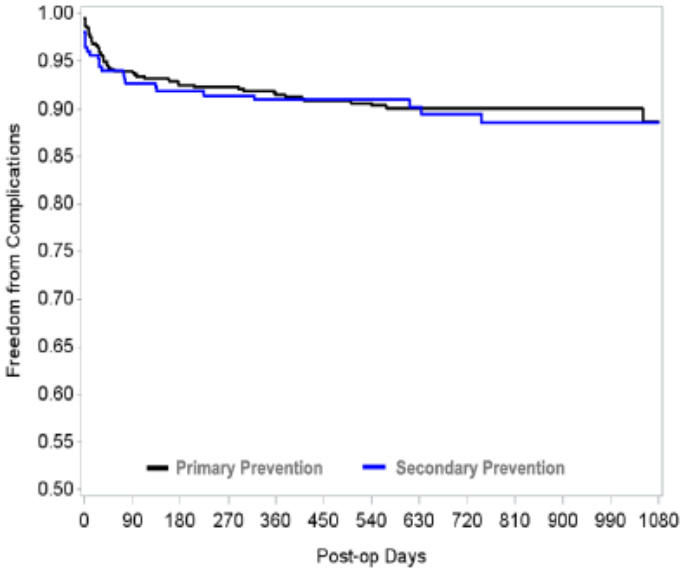
TABLE 2 Complications

Description	Events	Patients	% of Patients
Infection requiring device removal	27	24	2.4
Erosion	17	17	1.7
Inappropriate shock: oversensing	12	11	1.1
Other procedural complications	13	10	1.0
Hematoma	9	9	0.9
Discomfort	8	8	0.8
Suboptimal electrode position	7	7	0.7
Electrode movement	7	7	0.7
Premature battery depletion	5	5	0.5
PG movement	6	5	0.5
Unable to convert during procedure	6	5	0.5
Incision/superficial infection	5	5	0.5
Other technical complications	4	4	0.4
Suboptimal PG and electrode position	3	3	0.3
Inability to communicate with the device	3	3	0.3
Inappropriate shock: SVT above discrimination zone (normal device function)	2	2	0.2
Suboptimal pulse generator position	1	1	0.1
Total	135	115	11.7

Boersma L *et al*. J Am Coll Cardiol 2017;70:830–41

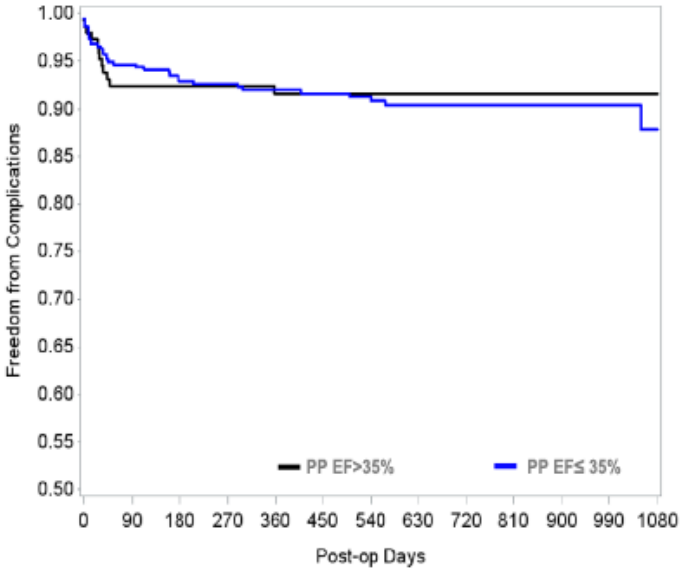
KM curves: freedom from device- and procedure-related complications

A **Primary vs. Secondary Prevention**



Primary	# at Risk	599	540	492	478	442	406	360	270	189	132	92	66	60
	(%)	99.5	93.8	92.5	92.3	91.5	90.9	90.4	90.1	90.1	90.1	90.1	90.1	88.7
Secondary	# at Risk	247	221	210	200	179	162	142	122	93	65	54	41	36
	(%)	98.0	92.8	91.9	91.5	91.0	91.0	91.0	90.3	89.5	88.5	88.5	88.5	88.5

B **Primary Prev: EF ≤35%, vs. >35%**



PP EF≤35	# at Risk	377	341	308	300	279	260	231	169	111	72	49	35	32
	(%)	99.5	94.7	92.9	92.6	92.0	91.7	90.9	90.5	90.5	90.5	90.5	90.5	87.8
PP EF>35	# at Risk	147	130	123	120	111	97	83	66	52	40	28	21	18
	(%)	99.3	92.5	92.5	92.5	91.6	91.6	91.6	91.6	91.6	91.6	91.6	91.6	91.6

Boersma L *et al*. Heart rhythm 2017;14:367–75

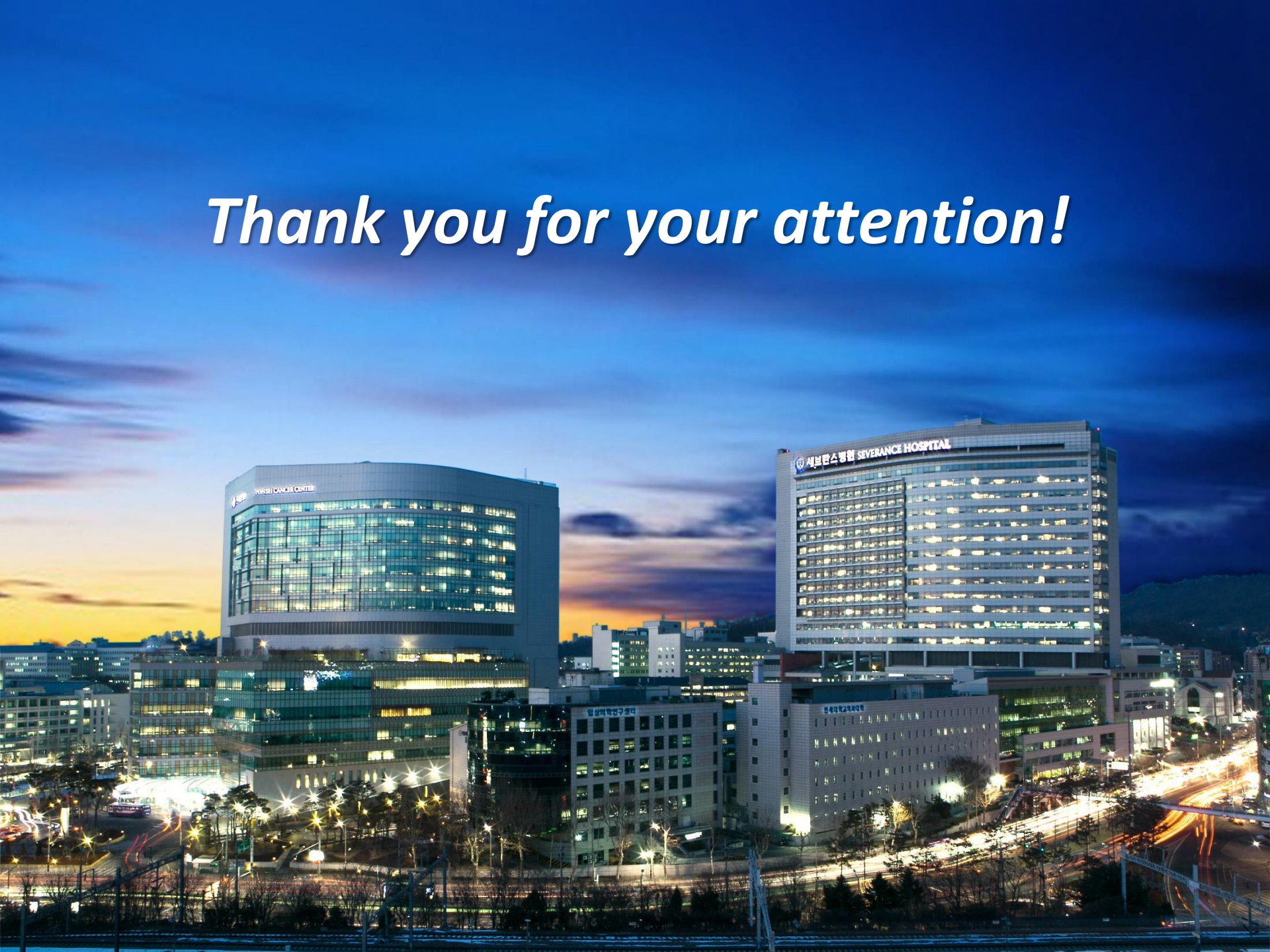
Summary (1)

- **Patient Screening**
  - Use the ECG screening tool to verify the acceptability of the surface ECG for rhythm detection and discrimination.
  - A patient is considered suitable for an S-ICD System if at least one ECG lead is acceptable in two patient postures.

- **Patient Preparation**
  - Use X-ray landmarks to plan pulse generator and electrode placement.
  - Mark incision sites and the sternal midline before patient draping.

Summary (2)

- **Implant Considerations**
  - **Close the deep tissue layer before induction testing to ensure good tissue-electrode contact.**
  - **To prevent tissue dryness/trapped air, keep incisions moist before and during incision closure.**
  - **To expel any trapped air, apply firm pressure during inner layer closure.**

- **Patient Care**
  - **To prevent infection, consider prophylactic antibiotics.**
  - **Adjust pulse generator placement as needed to ensure patient comfort.**

Thank you for your attention!