Subcutaneous ICD

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Contents

Introduction to the S-ICD System

Function of the S-ICD System

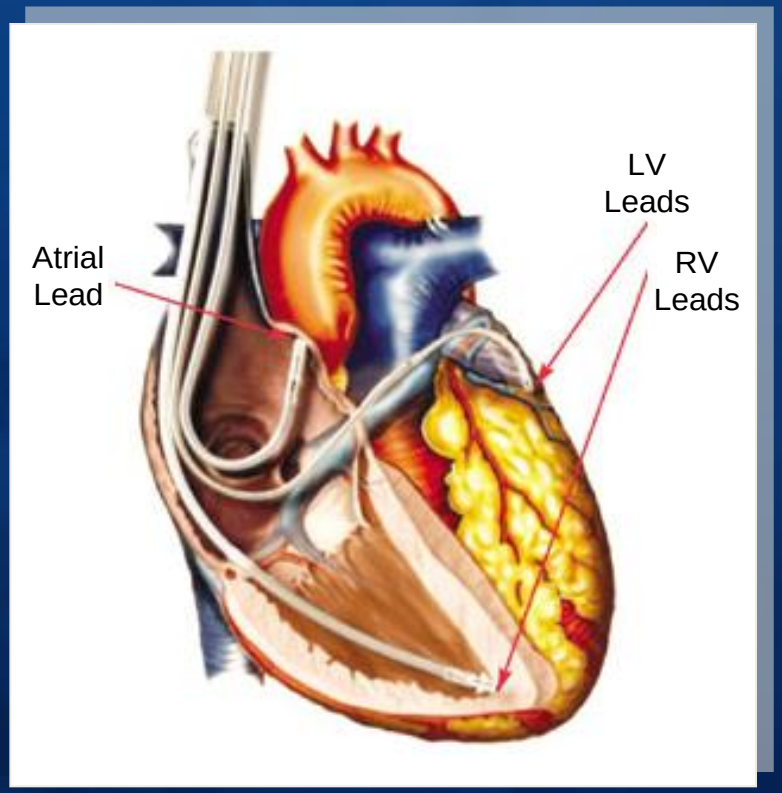
S-ICD System clinical evidence

Patient populations

Transvenous ICD Systems

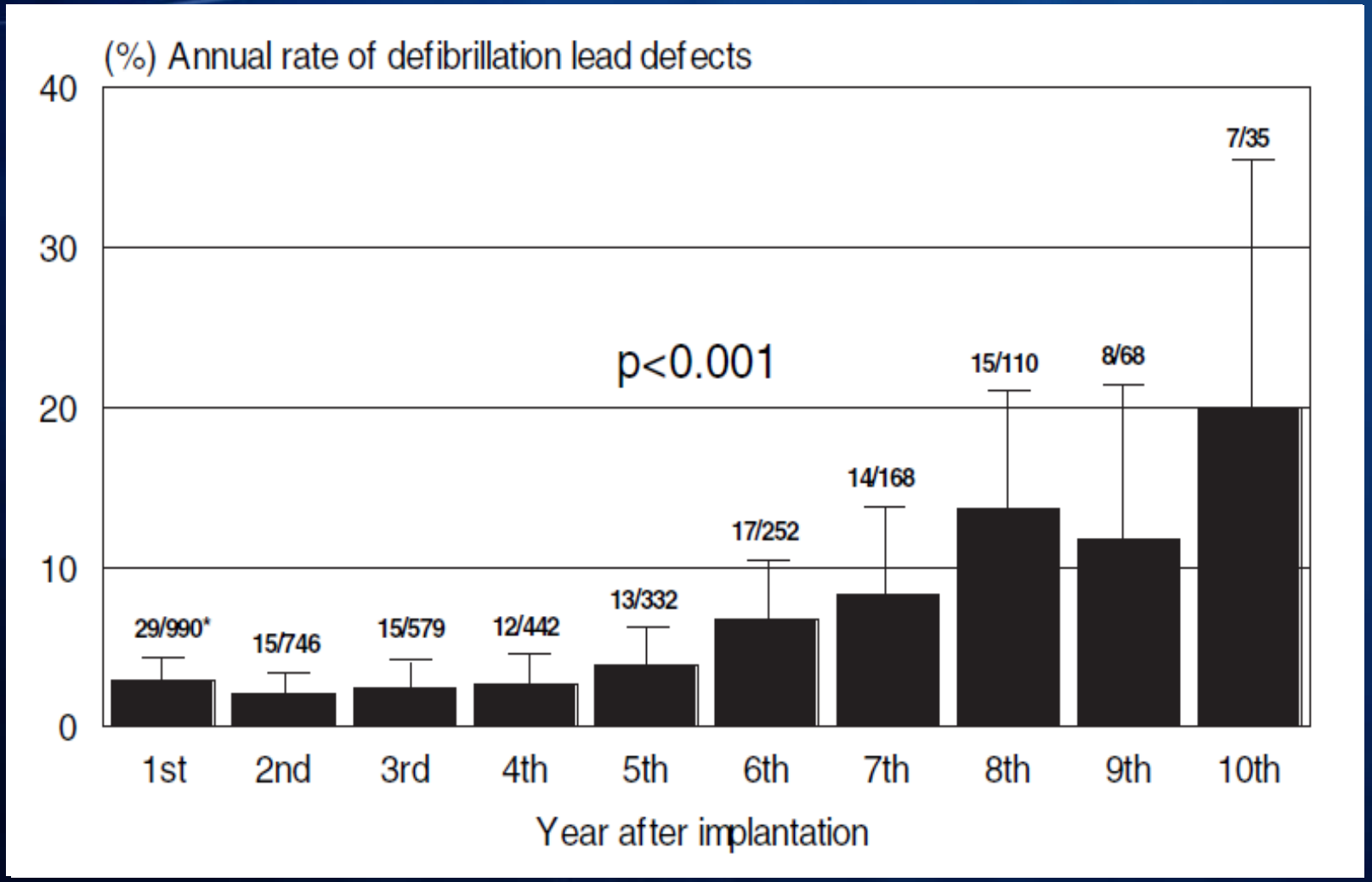
The current ICD approach while effective, is not without significant risks

- 11% ICD patients suffer complications during or shortly after implant
- Acute complications add significant costs to the healthcare system (>$7000/pt.)
- Infection rates are rising (one of the most serious complications)



Reynolds et al The Frequency and Incremental Cost of Major Complications Among Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators *JACC Aug 2006*
Saba et al Rising Rates of Cardiac Rhythm Management Device Infections in the United States: 1996 through 2003 JACC Aug 2006

Incidence of Lead Failures in Defibrillation Systems



Kleemann *et al.* Circulation May 2007

To overcome Limitations of Transvenous Leads

- **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

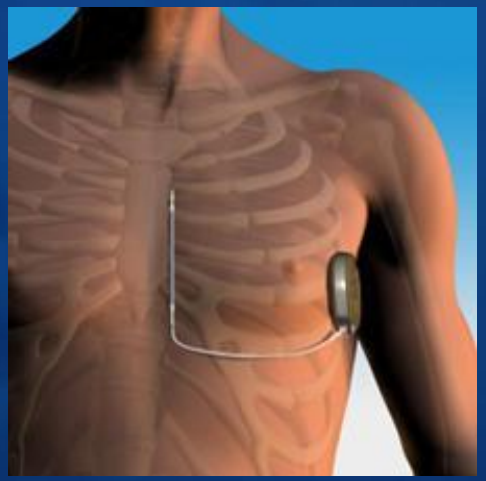
- **Explant risks**
  - Vessel dissection, perforation or occlusion, valve damage, bleeding, tamponade, systemic infection, death

A new category of ICD

Transvenous (TV) ICDs

- Provides effective defibrillation for ventricular tachyarrhythmias
- Provides Brady pacing
- Provides ATP for patients with i ncessant monomorphic VT
- Provides atrial diagnostics
- Familiar implant technique

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 w/ endov ascular lead extraction
- Fluoroscopy not required

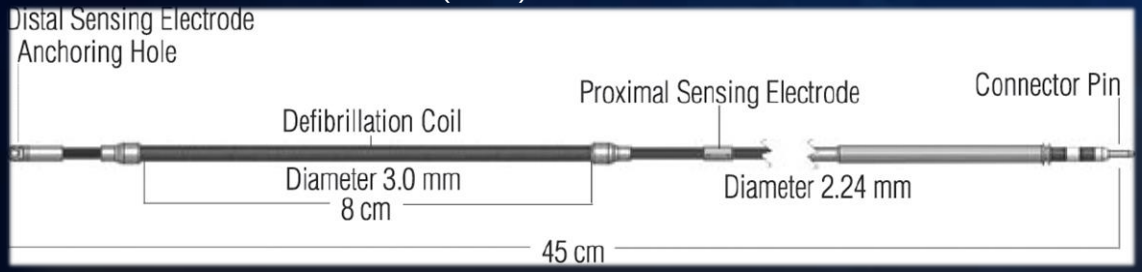
S-ICD™ System Components

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

Size & Weight Comparison –ICD

Autogen EL VR • D174	
Boston Scientific	
Device Type	ICD Single Chamber
Distrib. Market	Intl
NBG VVEV	X-Ray ID BSC 140
PHYSICAL CHARACTERISTICS	
Dimensions	Weight/volume
53.7x73.6x9.9mm	68.9g/29.5cc

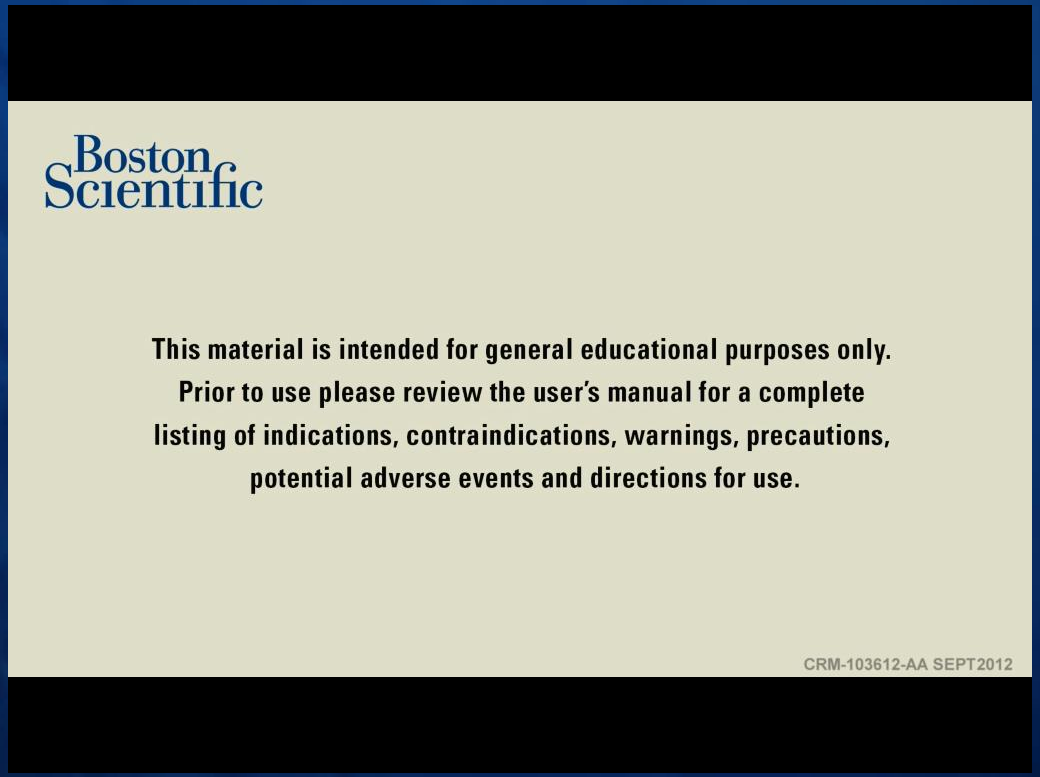
Evera XT VR • DVBB2D4	
Medtronic	
Device Type	ICD Single Chamber
Distrib. Market	Intl
NBG VVEV	X-Ray ID
PHYSICAL CHARACTERISTICS	
Dimensions	Weight/volume
64x51x13mm	77.0g/33.0cc

Ellipse VR • CD1277-36Q	
St Jude Medical	
Device Type	ICD Single Chamber
Distrib. Market	Intl
NBG VVEV	X-Ray ID KF
PHYSICAL CHARACTERISTICS	
Dimensions	Weight/volume
66x51x12mm	67.0g/30.0cc

Iforia 7 VR-T ProMRI • 390089	
Biotronik	
Device Type	ICD Single Chamber
Distrib. Market	Intl
NBG VVEV	X-Ray ID
PHYSICAL CHARACTERISTICS	
Dimensions	Weight/volume
65x52x11mm	80.0g/31.0cc

S-ICD System Implant Procedure

- Does not require venous access
- Designed to reduce cxs
- Designed to be predictable
- Does not require fluoroscopy
- 95% implanted using only anatomical landmarks (no medical imaging)



Burke M, et al. Safety and Efficacy of a Subcutaneous Implantable-Defibrillator (S-ICD System US IDE Study). Late-Breaking Abstract Session. HRS 2012.

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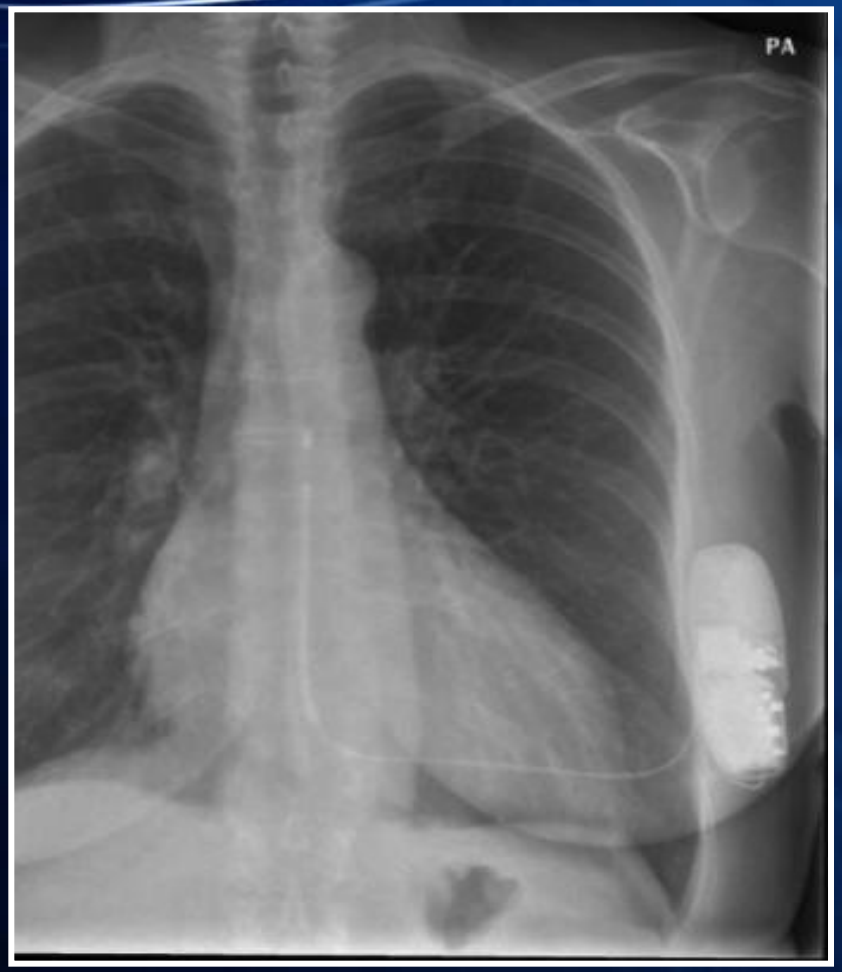
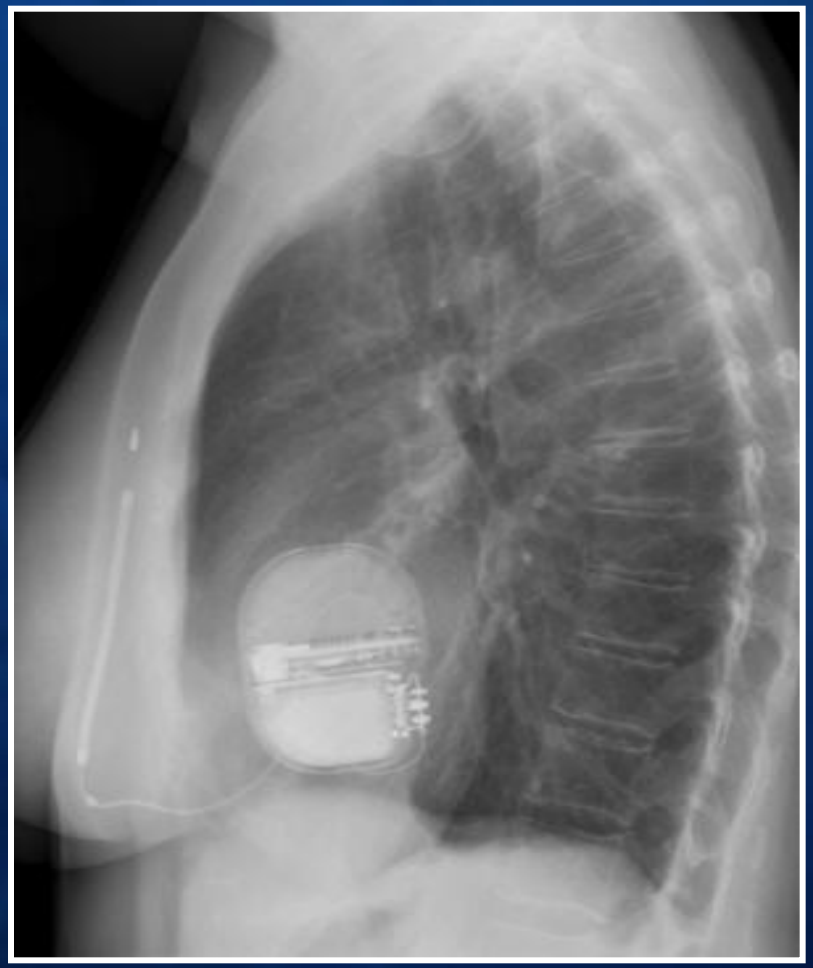
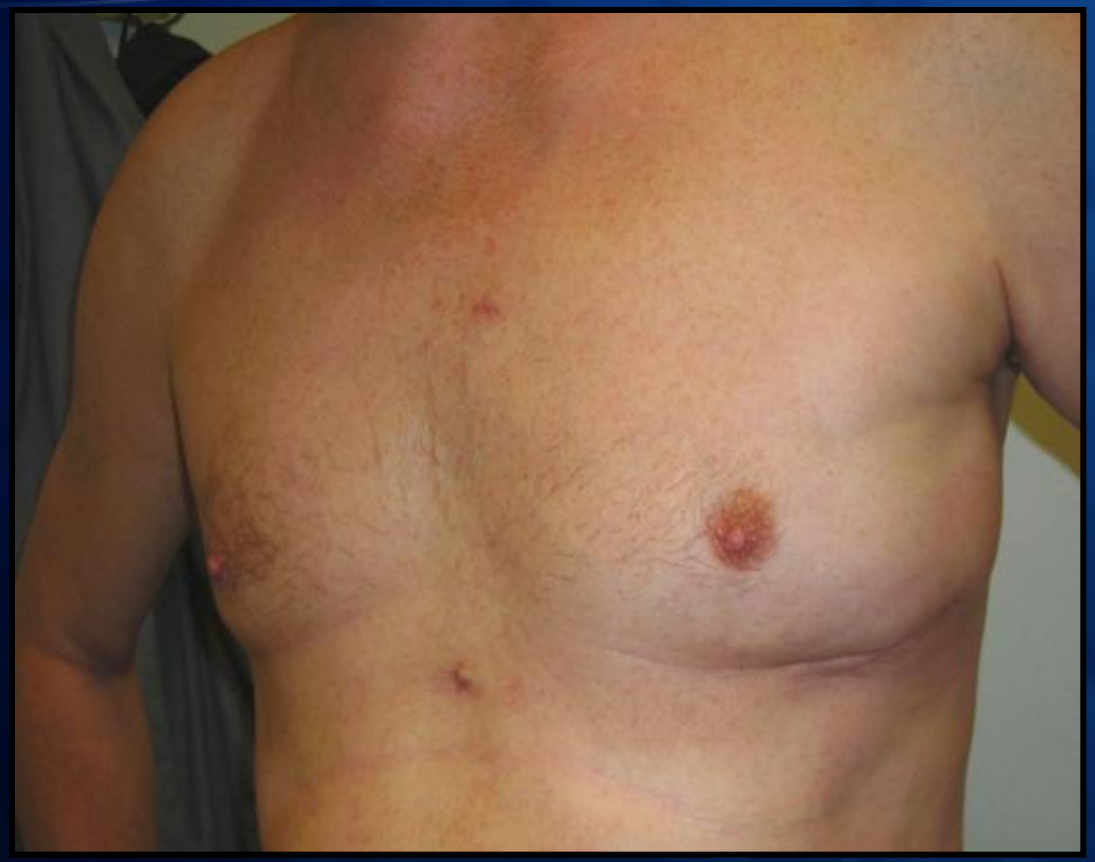
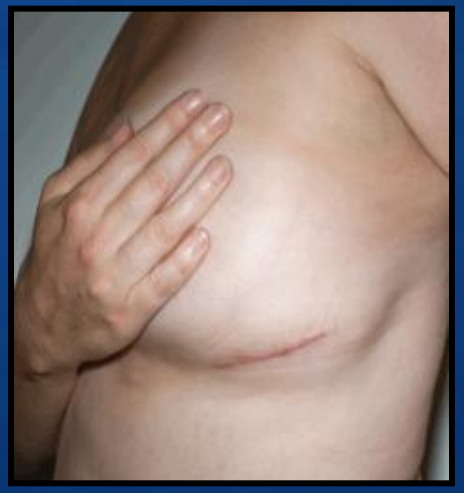
Ideal Device Placement



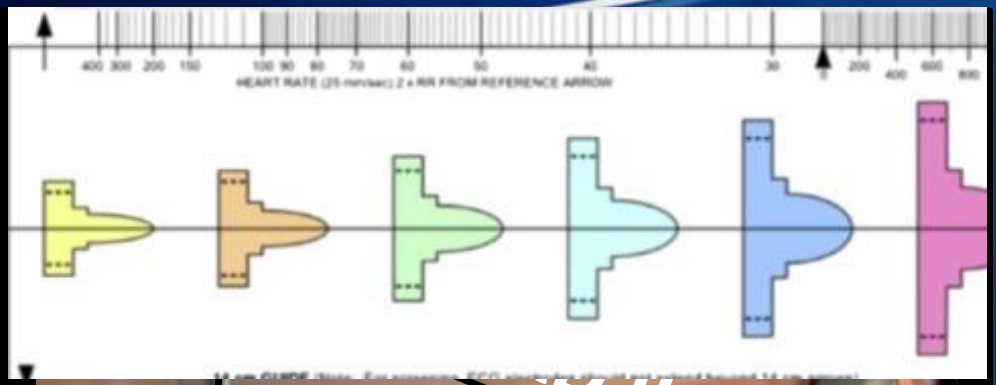


One Month Post-Operative Pictures

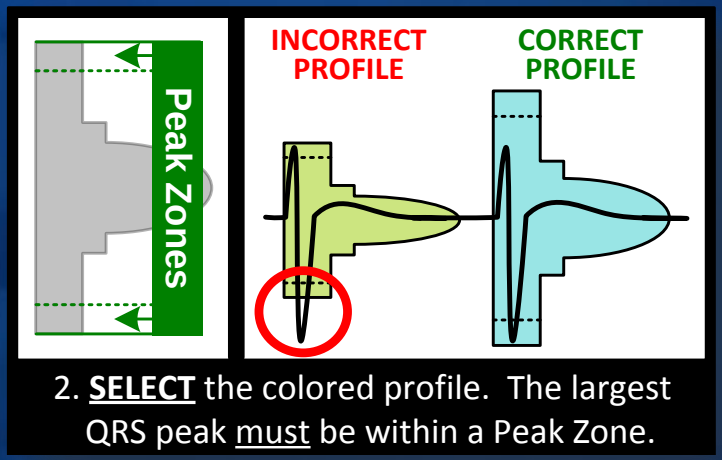




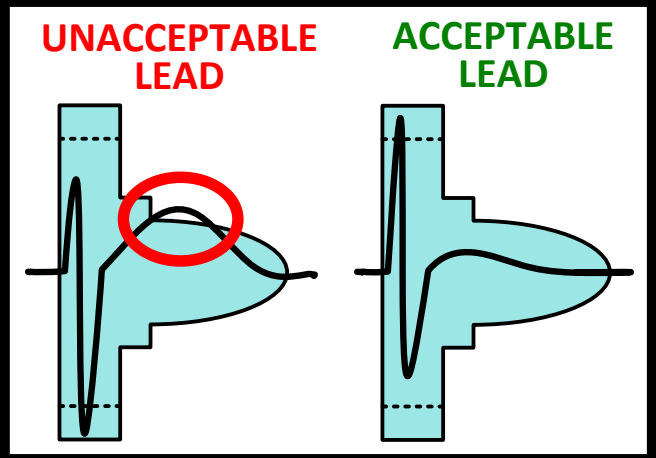
Patient Screening



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



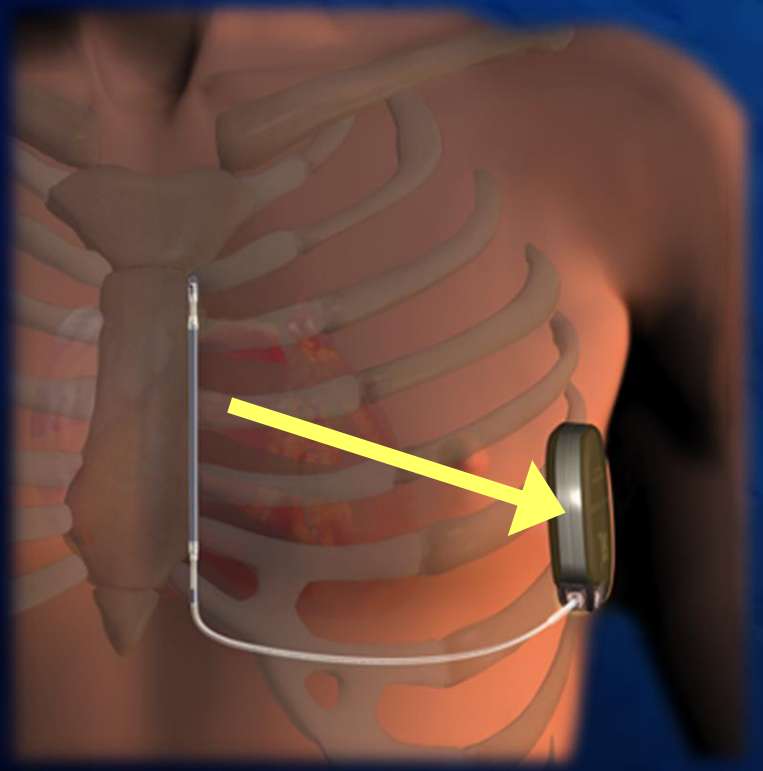
2. **SELECT** the colored profile. The largest QRS peak must be within a Peak Zone.



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

Burke M, et al. Safety and Efficacy of a Subcutaneous Implantable-Defibrillator (S-ICD System US IDE Study).. Late-Breaking Abstract Session. HRS 2012.

S-ICD System Highlights



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

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Pre-Clinical Studies
Chronic Evaluation Study

Study to Evaluate the Sub-Chronic Implantation of a Semi-functional Subcutaneous ICD (S-ICD®) in Humans

October 2002 – April 2004

M Hood & WA Smith; Auckland City Hospital, New Zealand

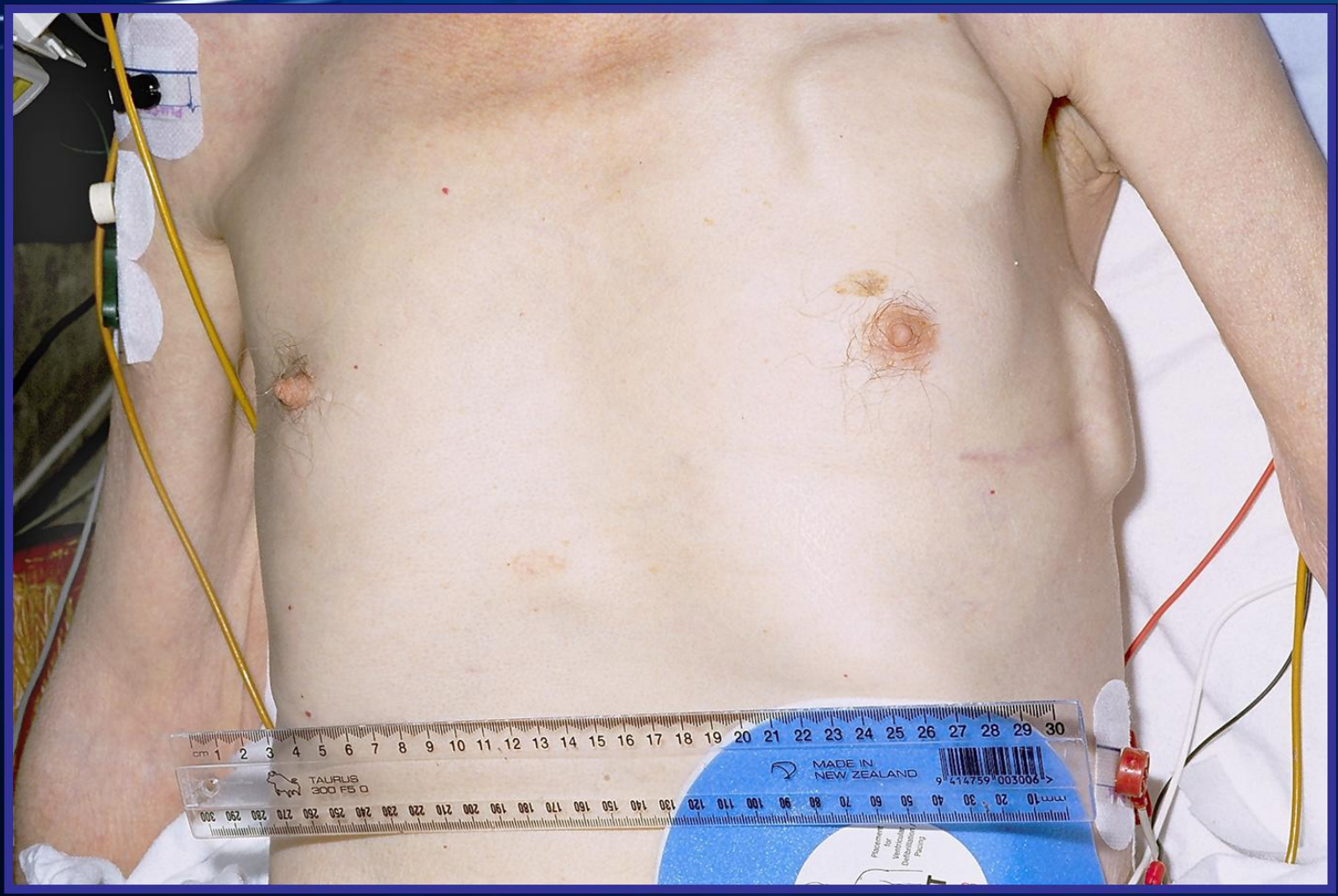
Chronic Evaluation Study
- Study Summary

- 7 patients participated in chronic study to evaluate form, fit, and migration of S-ICD system
- Active can emulator implanted in lateral pocket
- Prototype subcutaneous electrode implanted parasternally
- Standard TV-ICD also implanted

Chronic Evaluation Study Patient Questionnaire Results (n = 7)

	YES	NO	NO DIFF
Is there any discomfort from the S-ICD?	1	6	
Can you feel the ICD?	5	2	
Can you feel the S-ICD?	4	3	
Can you see the ICD?	5	2	
Can you see the S-ICD?	5	2	
Is the ICD comfortable?	7	0	
Is the S-ICD comfortable?	6	1	
Do you have any discomfort on/near the sternum?	1 (TV-ICD)	6	
Do you like the location of the S-ICD compared to the TV-ICD?	3	3	1
From a comfort perspective, if you could choose one over the other, which ICD system would you choose?	3 (S-ICD) 3 (TV-ICD)		1
If you knew the S-ICD would have fewer complications over 5 years compared to the TV-ICD, which ICD system would you prefer, presuming the TV-ICD is more comfortable?	7 (S-ICD)	0	

S-ICD implant site…



S-ICD System Clinical Evidence

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association

Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator

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

Circulation. 2013;128:944-953
doi: 10.1161/CIRCULATIONAHA.113.003042
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 0009-7322. Online ISSN: 1524-4539

IDE Clinical Study

Objective

- Evaluate the safety and effectiveness of the S-ICD™ System in the treatment of life-threatening ventricular arrhythmias

Design

- Prospective, non-randomized, multicenter, single-arm clinical study conducted in the United States, Europe and New Zealand

Enrollment

- Began January 2010, concluded May 2011

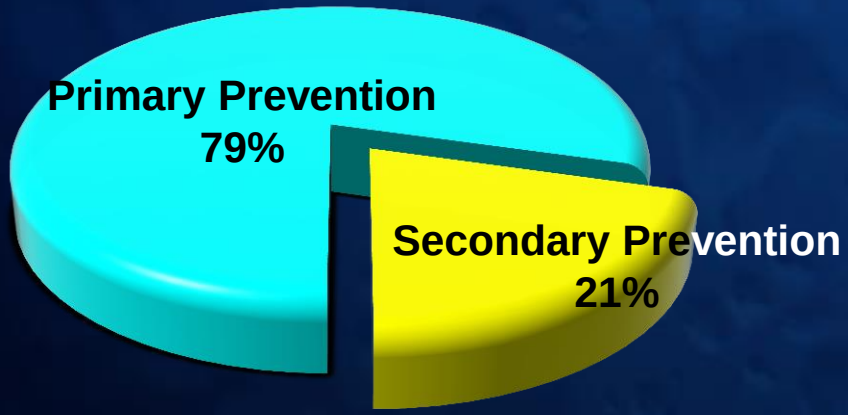
Weiss *Circulation* 2013;128:944–953

IDE Clinical Trial
: Primary & Secondary Prevention

Patient Distribution Similar to NCDR Registry

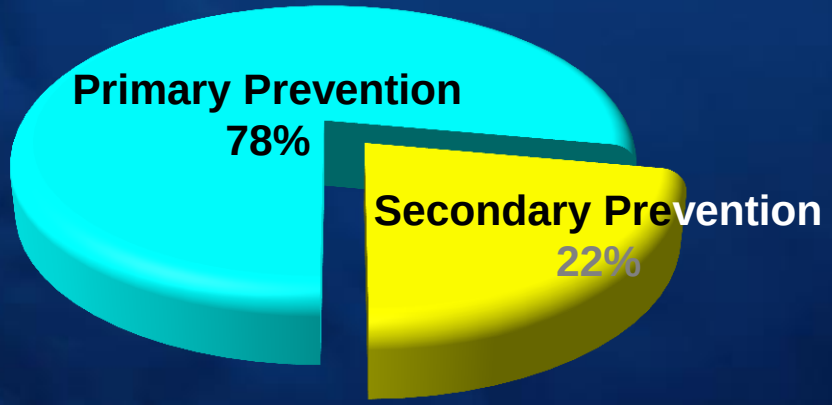
S-ICD™ System IDE Study[a]

n = 321 patients



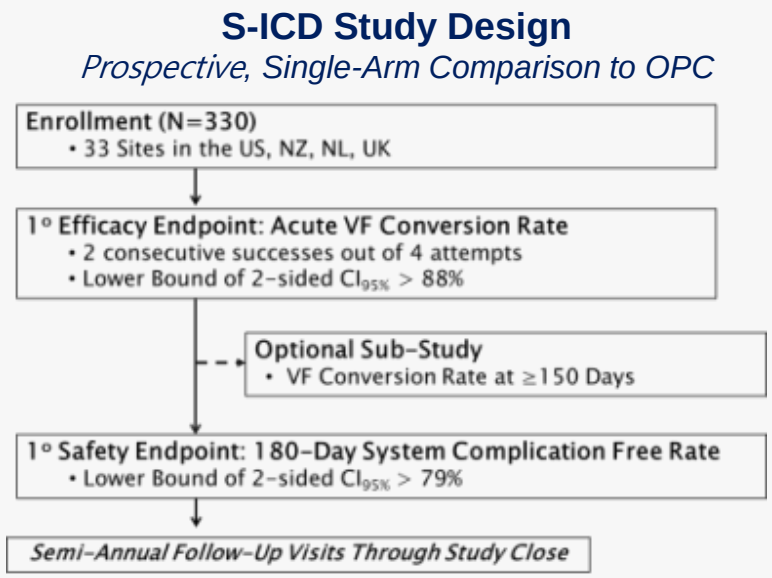
NCDR ICD Registry[b]

n = 486,025 patients



a: Weiss *Circulation* 2013;128:944–953 b: ACC's NCDR Registry
b: National Cardiovascular Data Registry: Implantable Cardioverter Defibrillator Registry

S-ICD (IDE) Study met both effectiveness and safety endpoints



Primary effectiveness endpoint met*

– 100% conversion rate of induced arrhythmias in evaluable patients

Primary safety endpoint met*

– 99% 180-day Type I Complication-Free Rate

** Both endpoints met even under worst case sensitivity analysis*

Additional Study Results:

- 100% spontaneous VT/VF episodes (n=109) converted with 80J shock or spontaneously
- 13.1% incidence of inappropriate shock over the 11 month mean f/u
- 95% implanted using only anatomical landmarks (no medical imaging)
- 99% of implanted patients had no electrode or pulse generator movement throughout follow-up period

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Burke M, et al. Safety and Efficacy of a Subcutaneous Implantable-Defibrillator (S-ICD System US IDE Study). Late-Breaking Abstract Session. HRS 2012.

EFFORTLESS Registry Interim results manuscript

European Heart Journal Advance Access published March 26, 2014

European Heart Journal
doi:10.1093/eurheartj/ehu112

CLINICAL RESEARCH
Arrhythmia/electrophysiology

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

Pier D. Lambiase[1]*, Craig Barr[2], Dominic A.M.J. Theuns[3], Reinoud Knops[4], Petr Neuzil[5], Jens Brock Johansen[6], Margaret Hood[7], Susanne Pedersen[8,9], Stefan Kääb[10], Francis Murgatroyd[11], Helen L. Reeve[12], Nathan Carter[12], and Lucas Boersma[13], on behalf of the EFFORTLESS Investigators

EFFORTLESS Registry

Observational standard of care evaluation

Objective

- Document clinical, system, and patient-related outcome s data from S-ICD patients implanted since the comme rcial release of the S-ICD System.

Design

- Observational, non-randomized, multicenter, single-arm registry conducted in Europe and New Zealand.
  - 1000 patients; 50 centers
  - 12 months; 60 months clinical follow-up

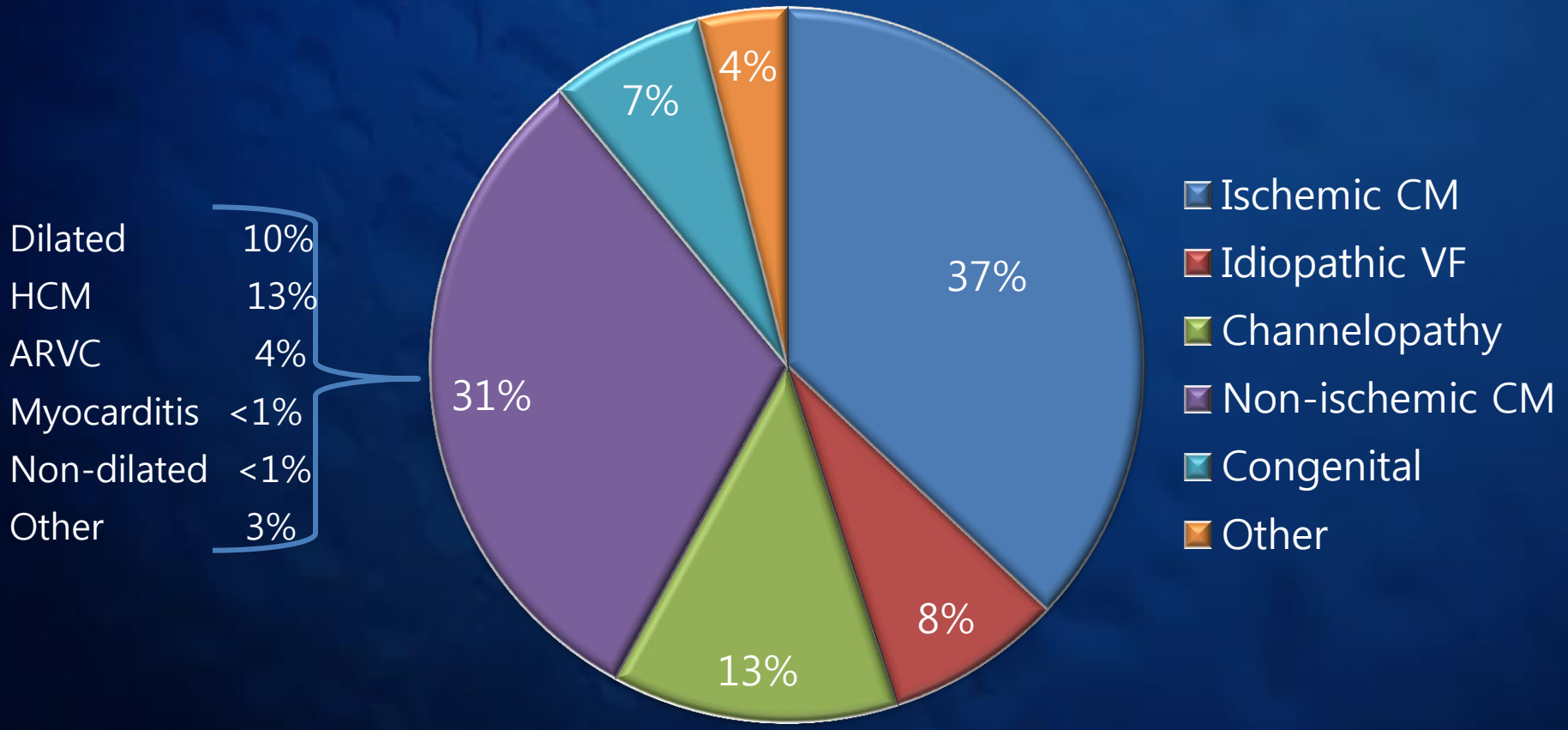
Enrollment

- Prospective and retrospective.

Pedersen *PACE* 2012;35:574–579

EFFORTLESS Registry
Broad Range of Clinical Indications

Patients with a broad range of cardiac conditions have received the S-ICD™ System (N=472)



Significant proportions of historically more difficult to treat indications (non-ischemic, congenital and channelopathies) representing >50% of total population

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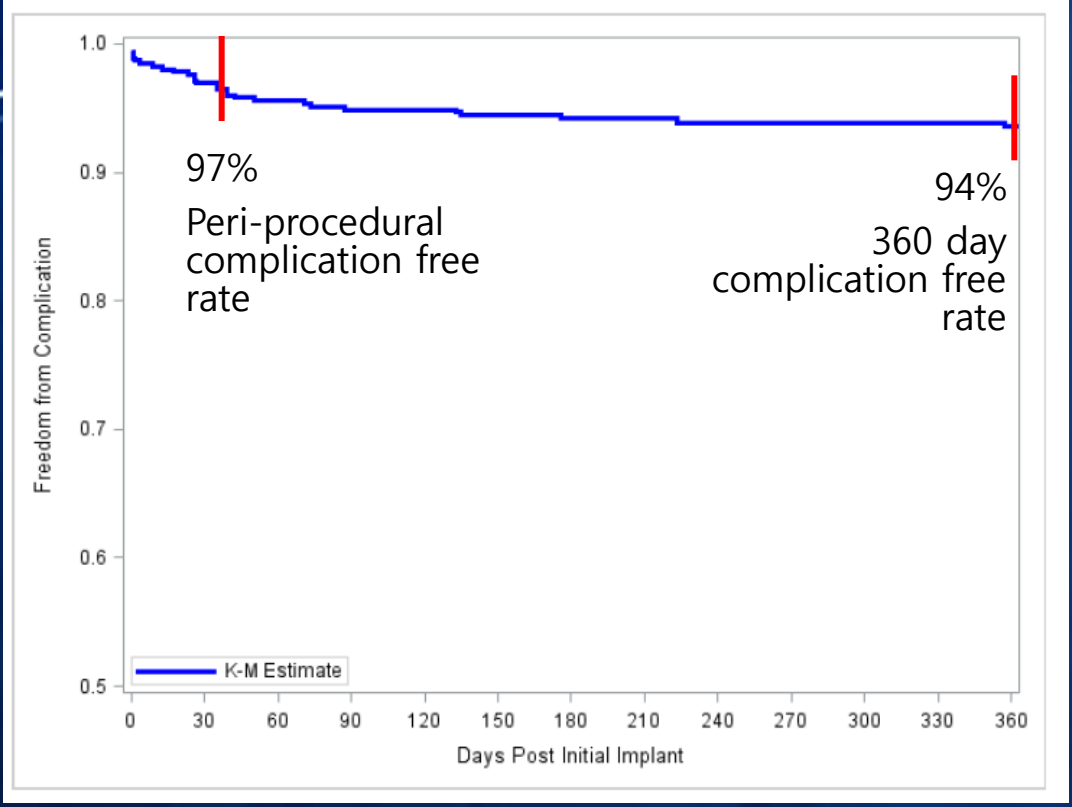
Lambiase *European Heart Journal* published online March 26, 2014

Interim Results



Spontaneous VF/VT Episodes

- 93 events in 33 patients
  -> 100% clinical conversion
- 88% first shock conversion efficacy

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

Lambiase *European Heart Journal* published online March 26, 2014

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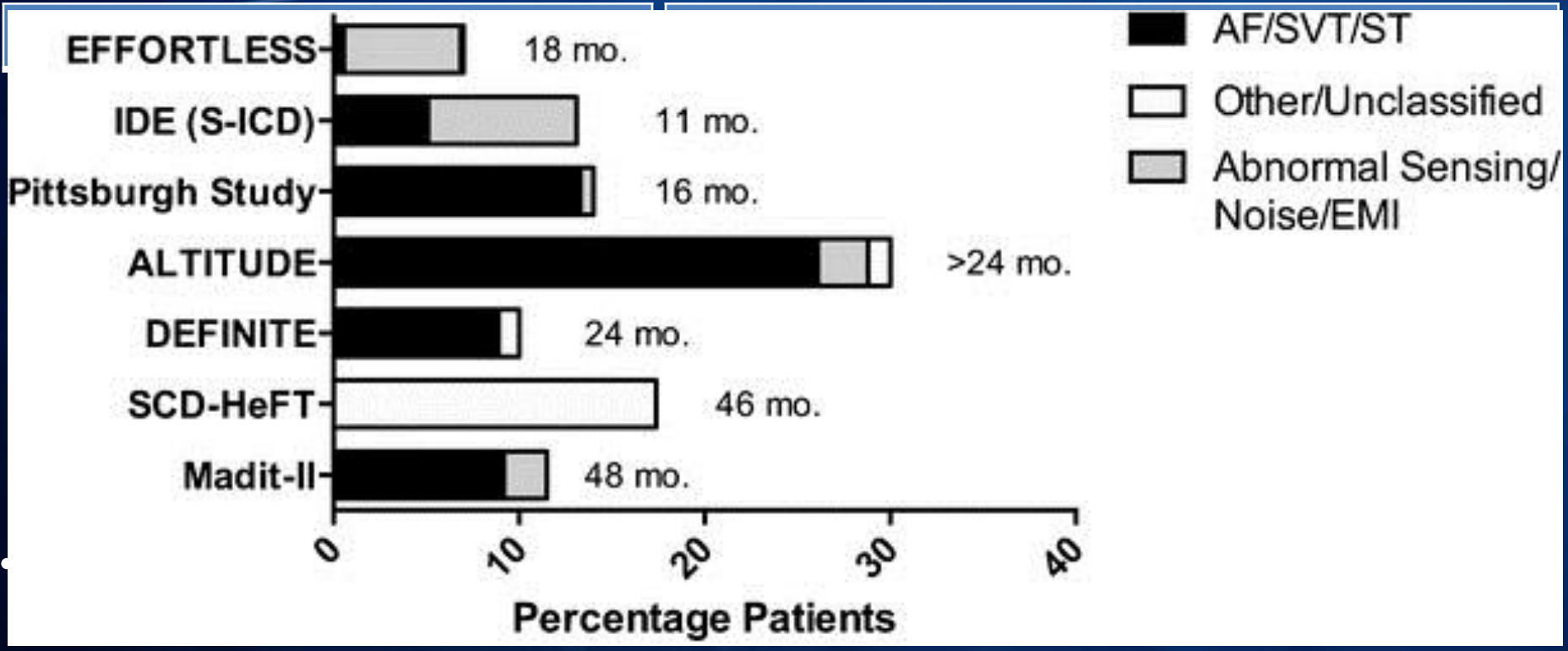
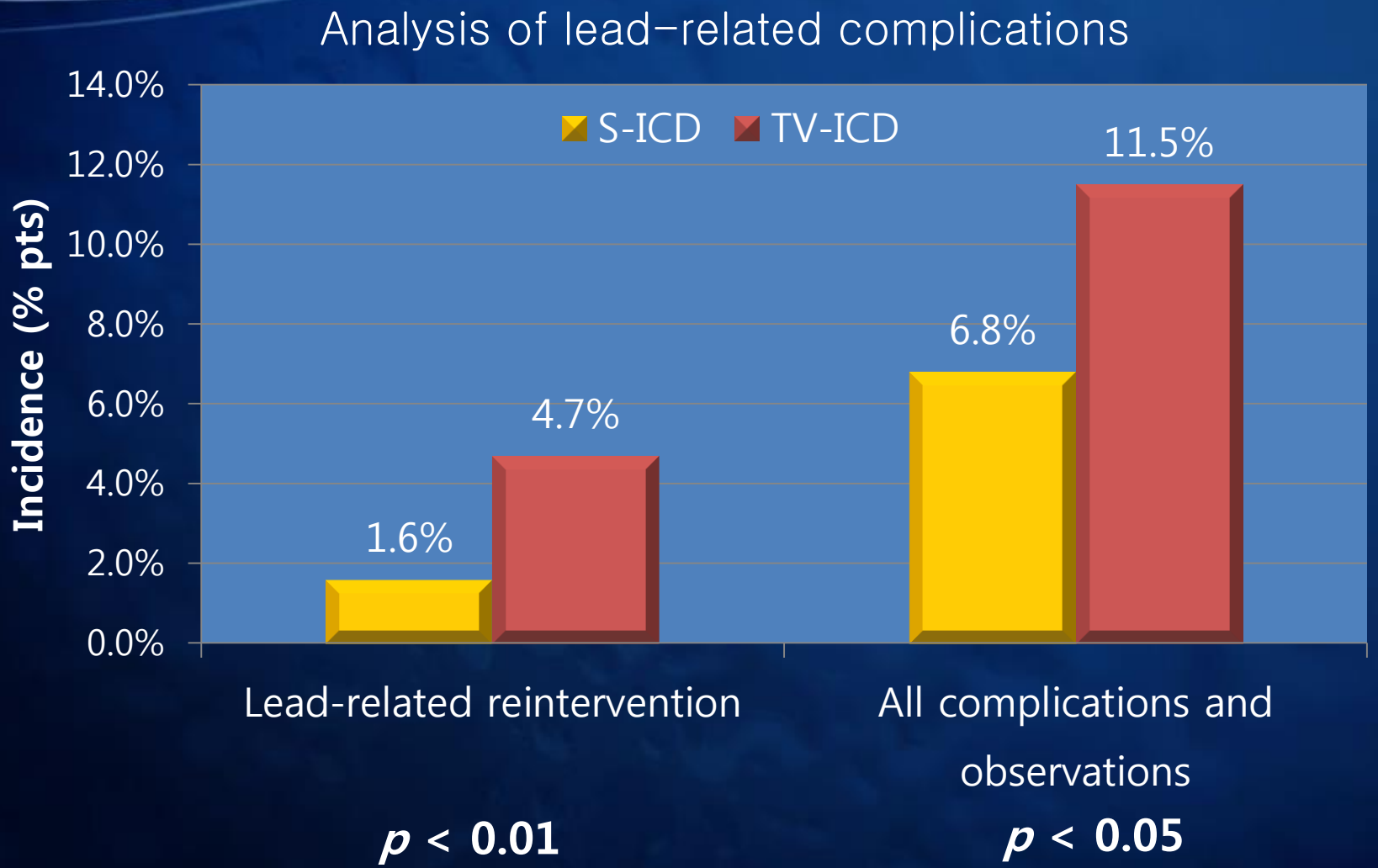
EFFORTLESS Registry
Inappropriate Therapy: Incidence



- 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.

Lambiase *European Heart Journal* published online March 26, 2014

Analysis of EFFORTLESS S-ICD™ Registry (n=369) and Danish TV-ICD Registry (n=784)



Johansen presentation AB05-04 *HRS* 2013, Denver CO

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S-ICD System Implant Post TV-ICD explant

Prior TV-ICD

EFFORTLESS & IDE (N = 98/683)

	EFF (n=369)	IDE (n=314)
S-ICD implant post TV-ICD explant	55 (15%)	43 (14%)
TV-ICD explant for infection	34 (62%)	33 (77%)
Re-infection post S-ICD implant	2	0
1 yr mortality post S-ICD implant	1 (2.9%)	0

The S-ICD System appears to be a safe and feasible alternative for high risk patients following a TV-ICD extraction

Suitable for a diverse patient population

The S-ICD System is an effective solution for a majority of primary and secondary ICD candidates.

- Ideal option for patients with primary electrical or structural heart disease.
- Appropriate for patients with bipolar pacemaker therapy, as well as those with prior transvenous systems.

Indications for Use

- The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients **who do not have**:
  - **Symptomatic bradycardia**
  - **Incessant VT, or spontaneous, frequently recurring VT that is reliably terminated with ATP**

Appropriate Use of the S-ICD™ System

Poole JE, Gold MR. *Circ Arrhythm Electrophysiol* 2013;6:1236-1245

Strong Candidates

- No vascular access
- History of recurrent TV lead infections/fractures
- Renal failure, diabetes, immuno-compromised

Reasonable Candidates

- Young patients with primary electrical problems
- Patients with a primary prevention indication
- Prior VF arrest
- Prosthetic valves

Inappropriate Candidates

- Patients with bradycardia pacing indications
- Need for CRT
- Recurrent monomorphic VT

In Conclusion

The S-ICD™ System

- Is entirely subcutaneous
- Does not require leads in the heart, leaving the vasculature untouched
- Is placed using anatomical landmarks, removing the requirement for fluoroscopy at implant

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a: Weiss *Circulation* 2013;128:944-953; b: Lambiase *European Heart Journal* published online March 26, 2014

In Conclusion

The S-ICD™ System has over 1300 patients in clinical studies

- 6.8% have received appropriate, life-saving shocks
- 99.8% sensitivity: 897/899 induced episodes appropriately sensed (IDE)
- Treatment times comparable to TV-ICDs (~20 sec)
- No lead failures
- No systemic infection or endocarditis
- Inappropriate Shock Rate comparable to TV-ICD

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a: Weiss *Circulation* 2013;128:944-953 b: Lambiase *European Heart Journal* published online March 26, 2014

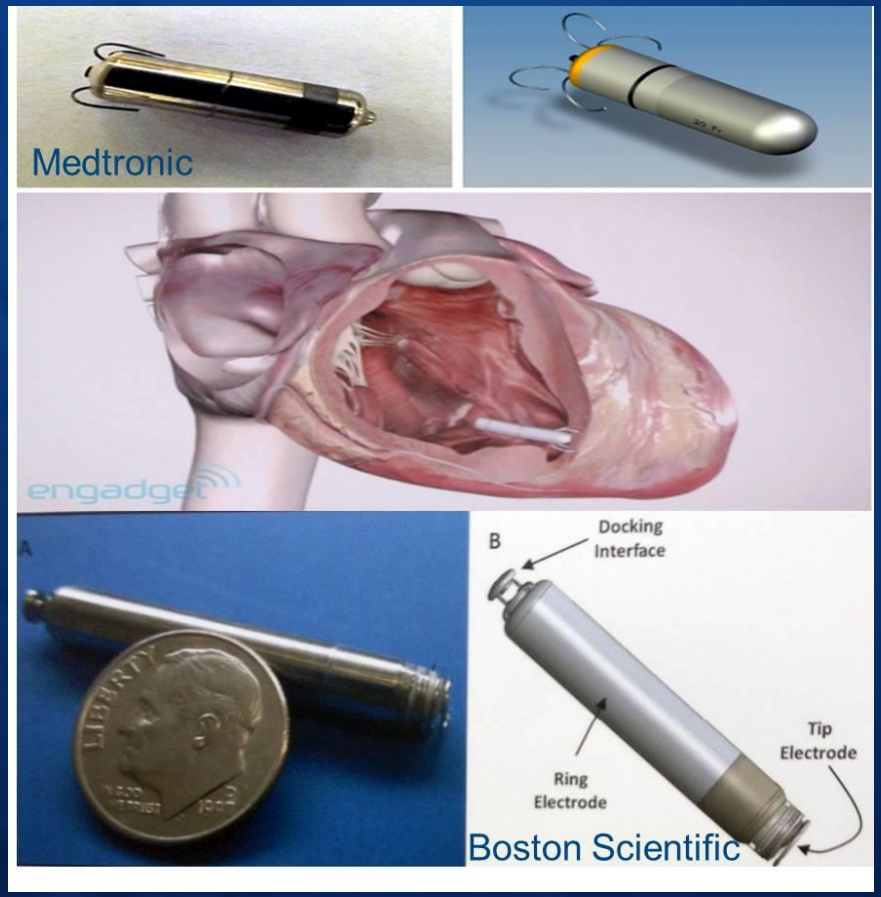
To be improved…

- Volume
- Inappropriate shock
  - T-wave oversensing
- Lack of anti-tachycardia pacing
- Battery life

a: Weiss *Circulation* 2013;128:944-953 b: Lambiase *European Heart Journal* published online March 26, 2014

표 5: 기계 규격

모델	치수 W x H x D(mm)	질량(g)	부피(cm^3)	커넥터 유형[a]
A209	83.1 x 69.1 x 12.7	130	59.5	SQ-1 S-ICD 커넥터(비표준)



Battery life; 7.5 years

감사합니다