What is S-ICD?
Advantage vs Disadvantage

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Subcutaneous ICD (S-ICD)

- Extracardiac, extrathoracic, subcutaneous electrode
- The defibrillation coil (8 cm long) lies directly between two sensing electrodes and the S-ICD generator acts as the 3rd electrode, used for sensing and defibrillation.
Subcutaneous ICD (S-ICD)

Publication and Product Milestones

Key Studies

Over 6,000 Patients Enrolled in clinical trials
40,000 patients implanted

Enrollments as of Q4’16
Note: PRAETORIAN and ATLAS studies are randomized 1:1 S-ICD vs TV-ICD
MADIT-SICD is randomized 1:1 S-ICD vs conventional medical therapy
TV ICD vs S-ICD

Transvenous (TV) ICDs

- Provides effective defibrillation for ventricular tachyarrhythmias
- Intravascular/Intracardiac lead
- Provides Brady pacing
- Provides ATP for patients with incessant monomorphic VT
- Provides atrial diagnostics
- Familiar implant technique

Subcutaneous ICD (S-ICD)

- Provides effective defibrillation for ventricular tachyarrhythmias
- Extracardiac/subcutaneous lead
- No risk of vascular injury
- Low risk of systemic infection
- Avoids risks associated with endovascular lead extraction
- Fluoroscopy not required
EMBLEM™ MRI S-ICD Specifications

- **80 J** (Maximum) biphasic shock * 5 times

- **7.3 years** projected longevity: 3 full-energy capacitor charges per year

- **30 seconds** post-shock pacing (50bpm): pacing output is fixed at 200 mA and uses a 15 ms biphasic waveform.

- Single electrode connection

- Volume: **59.5cc**

- Weight: **130 grams**

- Size(W x H x D): **83.1 x 69.1 x 12.7 mm**
S-ICD vs TV ICD

Volume: 26.5cc
Weight: 60g

Volume: 59.5cc
Weight: 130g
Multiple studies demonstrate that young patients were particularly at risk of lead complications and that patients survived longer than their TV-ICD leads.

The risk of TV lead-related complications increased by ~2% per year\(^2\)

Age ≤ 65 is an independent predictor of TV lead failure\(^7\)

The ELECTRA registry reported 6.5% mortality at 1 year post TV lead extraction\(^{41}\)
TV-ICD complications

Endovascular infections were associated with higher risk of death when compared to a pocket infection. The ELECTRA Registry reported 15.1% mortality at 1 year following systemic infection resulting in TV lead extraction.
Combining these two studies provides a unique opportunity to evaluate safety and efficacy over a longer follow-up period and larger group of patients.

**EFFORTLESS**
N = 568*

**Both Studies**
N = 13

**IDE**
N = 308

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**Total Pooled**
N = 889

**Total Implanted**
N = 882

**Not Implanted**
N = 7

Mean follow-up 22 months

*Includes 314 enrolled prospectively and 254 enrolled retrospectively*

### S-ICD and TV-ICD Spontaneous Conversion Efficacy

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Spontaneous Shock Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-ICD* Pooled Data</td>
<td>98.2%</td>
</tr>
<tr>
<td>SIMPLE Testing Group</td>
<td>95.7%</td>
</tr>
<tr>
<td>SIMPLE No Testing Group</td>
<td>94.8%</td>
</tr>
<tr>
<td>ALTITUDE First Shock Study</td>
<td>99.8%</td>
</tr>
<tr>
<td>LESS Study</td>
<td>97.3%</td>
</tr>
</tbody>
</table>

*S-ICD Pooled Data excluded VT/VT Storm events

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**S-ICD Pooled Data**

100% Clinical conversion to normal sinus rhythm

- Of two “unconverted” episodes
  - One spontaneously terminated after the 5th shock
  - In the other episode, the device prematurely declared the episode ended. A new episode was immediately reinitiated and the VF was successfully terminated with one shock

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S-ICD complications

Kaplan-Meier Estimate of Freedom from Complications Following S-ICD Implantation

<table>
<thead>
<tr>
<th>No At Risk</th>
<th>878</th>
<th>791</th>
<th>731</th>
<th>707</th>
<th>650</th>
<th>591</th>
<th>525</th>
<th>414</th>
<th>303</th>
<th>217</th>
<th>162</th>
<th>123</th>
<th>105</th>
</tr>
</thead>
<tbody>
<tr>
<td>K-M Estimate (%)</td>
<td>99.0</td>
<td>93.4</td>
<td>92.3</td>
<td>92.0</td>
<td>91.4</td>
<td>90.9</td>
<td>90.6</td>
<td>90.2</td>
<td>90.0</td>
<td>89.7</td>
<td>89.7</td>
<td>89.7</td>
<td>88.9</td>
</tr>
</tbody>
</table>

**Acute Major Complications (% of patients)**

<table>
<thead>
<tr>
<th>S-ICD</th>
<th>Pooled Data</th>
<th>TV-ICD</th>
<th>NCDR Analysis (Peterson et al, JAMA 2013)</th>
<th>Meta-analysis (van Rees et. al. JACC 2011)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 %</td>
<td></td>
<td>3 - 5 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Hematoma, Lead or Device Mal-position or Displacement, Pneumothorax)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

S-ICD complications

### Complications

There were 59 patients with 72 complications at 180 days follow-up. Of these complications, infections and suboptimal implantation were most common (Table 2). The median time from implant to complication was 18 days (mean 45 ± 71). The complication rate decreased almost by half from 9.8 to 5.4% \( (P = 0.019) \) over the experience quartiles (Figure 1). The absolute risk reduction, therefore, was 4.4% between Quartiles 1 and 4, and the relative risk reduction was 44.8%. The largest decrease was seen between Q1 and Q2. The complication rate stabilized in Quartile 3, which represents >13 procedures per implanters and indicates the end of the learning curve. In a Cox proportional hazard model for complications, increasing experience reduced the occurrence of complications per quartile (HR 0.78, \( P = 0.045 \), Table 3).

In the univariable model, there was a non-significant trend towards fewer complication over the years 2009–2013 \( (P = 0.07) \). However, implant year was not retained in the multivariable model (Table 3). Implant year also did not interact with physician experience (Supplementary material online, Figure S1). No individual complication type was observed to drive the decrease in complications (Supplementary material online, Table S1).

The complication rate in implanters’ first four S-ICD patients for those who ended as relatively high-volume implanters (>5 implants, 50% of implanters) was compared with lower-volume implanters in the study (1–5 implants, 50% of implanters). Higher-volume implanters had a similar complication rate (9.4%, 95% CI 5.6–15.7%) in the first four implants to lower-volume implanters (10.2%, 95% CI 5.8–17.6%, \( P = 0.429 \)).

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**Table 2 Complications in the first 6 months**

<table>
<thead>
<tr>
<th>Description</th>
<th>Number of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>System infection</td>
<td>16</td>
</tr>
<tr>
<td>Electrode movement</td>
<td>7</td>
</tr>
<tr>
<td>Suboptimal electrode position</td>
<td>7</td>
</tr>
<tr>
<td>Erosion</td>
<td>5</td>
</tr>
<tr>
<td>Discomfort</td>
<td>4</td>
</tr>
<tr>
<td>Haematoma</td>
<td>4</td>
</tr>
<tr>
<td>Suboptimal pulse generator and electrode position</td>
<td>4</td>
</tr>
<tr>
<td>Adverse reaction to medication</td>
<td>3</td>
</tr>
<tr>
<td>Inadequate/prolonged healing of incision site</td>
<td>3</td>
</tr>
<tr>
<td>Incision/superficial infection</td>
<td>3</td>
</tr>
<tr>
<td>Pulse generator movement/revision</td>
<td>3</td>
</tr>
<tr>
<td>Suboptimal pulse generator position</td>
<td>2</td>
</tr>
<tr>
<td>Failed defibrillation threshold test</td>
<td>2</td>
</tr>
<tr>
<td>Acute hypoxic respiratory failure</td>
<td>1</td>
</tr>
<tr>
<td>Incomplete electrode connection to the device</td>
<td>1</td>
</tr>
<tr>
<td>Near syncope/dizziness/shortness of breath/confusion</td>
<td>1</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>1</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>1</td>
</tr>
<tr>
<td>Seroma</td>
<td>1</td>
</tr>
<tr>
<td>Suspected worsening of ischaemia</td>
<td>1</td>
</tr>
<tr>
<td>Suture discomfort</td>
<td>1</td>
</tr>
<tr>
<td>Undersensing</td>
<td>1</td>
</tr>
<tr>
<td>Grand total</td>
<td>72</td>
</tr>
</tbody>
</table>
Need for Pacing
Pacemaker Implant in MADIT II Control

Over 20 month median follow-up, in the control arm (OPT)
• 4.1% implanted with pacemaker
• 1.1% implanted with CRT

Baseline PR interval >200 ms significantly predicted subsequent PM/CRT implantation

Total Annualized Pacemaker Rate ~2% / year

HR=3.07
95% CI: 1.24-7.57, p=0.02
The need for ATP

- What is the percentage of patients that are at risk for recurrent monomorphic VT?

On a yearly basis, 1.8% incidence of Recurrent Monomorphic Ventricular Tachycardia, for which ATP might be beneficial

TV-ICD vs S-ICD complications

TV-ICD vs S-ICD complications

14 times the number of TV ICD lead complications requiring surgical intervention (11.5% vs 0.8% p=0.03)

Lead survival at 5 years was significantly better for S-ICD vs TV-ICD (99% vs 86% p=0.02)*

“Although ATP has been demonstrated to successfully terminate ~70 % of VT episodes, it did not result in fewer appropriate shocks in this cohort.”

No difference in rate of IAS for S-ICD vs TV-ICD

## Current Guidelines

<table>
<thead>
<tr>
<th>Guidance</th>
<th>2017 AHA/ACC/HRS Guidelines&lt;sup&gt;19&lt;/sup&gt;</th>
<th>2015 ESC Guidelines&lt;sup&gt;34&lt;/sup&gt;</th>
<th>For ICD patients…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>✓</td>
<td></td>
<td>With high risk of infection, including Diabetic patients (up to 35% of the ICD population)&lt;sup&gt;19&lt;/sup&gt;</td>
</tr>
<tr>
<td>Class Ila</td>
<td>✓</td>
<td>✓</td>
<td>Without need for pacing (CRT, bradycardia, ATP)</td>
</tr>
</tbody>
</table>
Current Guidelines

Class I Recommendation

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter defibrillator is recommended.</td>
</tr>
</tbody>
</table>

“The risk of infection appears to be lower with subcutaneous implantable cardioverter-defibrillators than with transvenous ICDs. Therefore, a subcutaneous implantable cardioverter defibrillator may be preferred in patients who are at high risk of infection, such as those with a prior device infection, ESRD, diabetes mellitus, or who are chronically immunosuppressed.”
# Current Guidelines

## Class IIa Recommendation

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class IIa</strong></td>
<td>In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated.</td>
</tr>
</tbody>
</table>

“Nonrandomized studies show that the subcutaneous implantable cardioverter-defibrillator reliably detects and converts VF during defibrillation threshold testing and successfully terminates spontaneous sustained VT that occurs during follow-up”. In the IDE study…“All spontaneous episodes of VT/VF recorded in 21 patients (6.7%) were successfully converted, and there were no lead failures, endocarditis or bacteremia, tamponade, cardiac perforation, pneumothorax, or hemothorax associated with the subcutaneous implantable cardioverter-defibrillator.”

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class IIa</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
Patient selection

Patient prioritization (as per McLeod et al, 2015)

**STRONG INDICATION**
- Young age*
- Primary prevention
- Poor vascular access
- Previous infection
- Infection risk (mechanical valves, diabetes, renal dysfunction)

**RELATIVE CONTRAINDICATION**
- Need for ATP (difficult to define clinically)

**CONTRAINDICATED**
- Pacing indication (bradycardia or CRT)
- Failed screening (high inappropriate shock risk)

* <65 (10 – 15 years life expectancy) as defined by ESC guidelines for management of atrial fibrillation, 2011
Patient Screening
Why is ECG Screening Necessary?

<table>
<thead>
<tr>
<th>TV - ICD</th>
<th>VS</th>
<th>S - ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bipolar. (Near field sensing)</strong>&lt;br&gt;R wave potential in the RV&lt;br&gt;“More localized sensing”</td>
<td>sensing electrode config.&lt;br&gt;→ sensing field</td>
<td><strong>Extended bipolar. (Far-field sensing)</strong>&lt;br&gt;P-QRS-T wave in the heart&lt;br&gt;“broader sensing area”</td>
</tr>
<tr>
<td><strong>Fixation in the endocardium</strong>&lt;br&gt;- unaffected by cardiac axis associated with motion change</td>
<td>Endocardium contact by sensing elect.&lt;br&gt;→ signal morphology</td>
<td><strong>Outside the heart</strong>&lt;br&gt;- Small R-wave&lt;br&gt;- There is a possible to be affected by cardiac axis associated with position change or by physiological change such as an autonomic nerve system stimulation, electrolyte imbalance.</td>
</tr>
</tbody>
</table>
At least one common ECG lead (LEAD 1, 2, 3) must be deemed acceptable for all tested postures.

One of the LEAD 1, 2, 3 will be used as sensing vector of S-ICD.
Patients screening

Obtain a clean ECG:

- **Stable baseline.**
- **Record 10 – 20 seconds** of ECG in at least **2 postures** – Supine and Standing or Sitting

**ECG recording**

- Leads: I, II and III
- Sweep speed: 25 mm/sec
- ECG gain: 5 – 20 mm/mV
- Use the largest ECG gain that **does not clip** the peak of the QRS complex
- To yield an acceptable signal for testing, the **gain may be adjusted** for each ECG lead independently
1. **Select** the coloured profile from the Patient Screening Tool that best matches the amplitude of the QRS complex:
   - The peak of the QRS complex must fit within one of the Peak Zones as shown
   - For biphasic signals, the larger peak should be used to select the profile
   - ECG gains > 20 mm/mV are not permitted (5-20 mm/mV)

2. **Align** the left edge of the selected coloured profile with the onset of the QRS complex:
   - The horizontal line on the colored profile should be used as a guide for the ECG baseline
Automated Screening Tool performance

Automated Screening Tool is 24% more likely to predict the performance of Vector Select than the Manual Screening Tool.

Due to incorporation of Vector Select and digital filtering, Automated Screening Tool is expected to:

• Better reflect S-ICD function and to be more tolerant of large T-waves than Manual Screening Tool

• Provide more consistent outcomes by removing operator subjectivity

EMBLEM Automated Screening Tool is available through the Zoom Programmer (3120)
S-ICD Implantation procedure
Landmarking confirm with X-Ray
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.
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 5\textsuperscript{th} and 6\textsuperscript{th} intercostal space at the mid-axillary line.

The inferior edge of the device should not be below the xiphoid.
Defibrillation Protection

Shift the defibrillation pads to accommodate the larger implant area.
Pocket Formation

Ensure the PG pocket is below adipose tissue and deep enough to fully accommodate the PG.
Generator pocket options

- Subcutaneous
  - dissection to muscle fascia
  - least close to heart
- Intermuscular
  - between serratus and latissimus
  - close contact with chest wall and good cosmesis
- Submuscular
  - under serratus, against ribs
  - option for low BMI patients
Consider forming an intermuscular pocket to reduce the DFT In high BMI patients and improve comfort in low BMI patients.
Intermuscular pocket

**Figure 2.** Intermuscular pocket is created by blunt dissection between anterior surface of the serratus anterior muscle and the posterior surface of the latissimus dorsi muscle, over the left sixth rib between the midline and anterior axillary line (A and B). The pulse generator is placed into the virtual anatomical space between the two muscles and anchored to the fascia to prevent possible migration. Subsequently, the two muscles are sutured using conventional absorbable suture (C and D). [Color figure can be viewed at wileyonlinelibrary.com]
Xiphoid Incision

Make a 2 to 3 cm horizontal incision 1 cm above and 1 cm left of the inferior xiphoid process. Dissect to the fascial plane.
Proximal Electrode Positioning

Use the EDS to tunnel to the pocket; then remove the tunneling tool from the sheath.
Secure the suture sleeve to the deep fascia using at least two suture grooves.
Distal Electrode Placement – 2 incision technique

- No incision at the sternal notch end
- Superior tunnel with EIT through peel a way sheath
- Remove tool
- Pass lead up the sheath
- Push forward on the lead as the sheath removed, to avoid dislodgement
- Avoid air in tunnel - leads to noise or high DFT
Superior tunnel

- Angle tunnel tool downwards, to keep the tool on the fascia
- Feel the tool over the bone tissue
- Aim parallel to mid sternal line - 1 to 2 cm from the sternal midline when creating the superior tunnel.
- Avoid too much dissection, which can allow air
- Keep some distance from sternal wires
PG Positioning

Insert torque wrench into seal plug prior to placing electrode into header. Connect electrode and ensure the connection is secure. Anchor PG in pocket.
PG Positioning

- SERRATUS ANTERIOR
- LATISSIMUS DORSI
Pocket closure

- Suture generator to muscle fascia, to avoid migration, and inappropriate shocks
- Flush saline or hydrogen peroxide into pocket, and incisions to remove air
- Massage out air
- Close wounds prior to testing DFT
For the IDE study, the Shock zone was set to 170 bpm and the initial shock to 65 joules at Standard polarity.

During induction testing, a 50 Hz, 200 mA pulse is delivered. Observe and call out induction progress: Sensing, Detection, Charging.
Case
Case

• 19 yrs, male

• 2019년 2월 2차례 syncope
• Syncope로 타병원 내원하여 VF으로 defibrillation 시행.
• Long QT syndrome 의심되어 gene study 시행
• S-ICD implantation 위해서 전원.
Other study

• TTE
  No significant abnormal findings in this study

• CAG with spasm provocation test
  Insignificant stenosis, negative spasm test
Screening

**Screened Position (Relative to Sternum)**

<table>
<thead>
<tr>
<th>Posture</th>
<th>Heart Rate</th>
<th>Lead I</th>
<th>Lead II</th>
<th>Lead III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supine</td>
<td>READING</td>
<td>PASS</td>
<td>PASS</td>
<td>PASS</td>
</tr>
<tr>
<td>Standing</td>
<td>EXERCISE</td>
<td>FAIL</td>
<td>FAIL</td>
<td>FAIL</td>
</tr>
<tr>
<td>Other postures or heart rate tested</td>
<td>DESCRIPTIVE</td>
<td>PASS</td>
<td>PASS</td>
<td>PASS</td>
</tr>
<tr>
<td>WA</td>
<td></td>
<td>FAIL</td>
<td>FAIL</td>
<td>FAIL</td>
</tr>
<tr>
<td>Right Sternum</td>
<td></td>
<td>PASS</td>
<td>PASS</td>
<td>PASS</td>
</tr>
<tr>
<td>Mid-Sternum</td>
<td></td>
<td>FAIL</td>
<td>FAIL</td>
<td>FAIL</td>
</tr>
</tbody>
</table>

Mark all acceptable ECG leads:
A surface ECG record is acceptable if all evaluated postures and heart rates are marked as PASS for that lead.

For an individual surface ECG lead (e.g., Lead I, II, or III) to pass, all QRS complexes and morphologies must pass the evaluation.

S-ECG screening Lead positions:

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

- **Simultaneous 3-Lead ECG**
  - **Incorrect Profile**
  - **Correct Profile**
  - **Unacceptable Lead**
  - **Acceptable Lead**

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.
Chest X-ray
Appropriate shock?
T wave oversensing -> inappropriate shock
Appropriate shock
Modular CRM System Program

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

Design Goals:
- Fixation / rate response
- Telescoping delivery system with atraumatic tip
- Communication (S-ICD)
S-ICD Conclusions

• S-ICD: option for less invasive device therapy
  • Class IIa Indication in the ESC guidelines (2015)
  • Class I, IIa Indication in the AHA guidelines (2017)

• Real World data supports S-ICD as safe and effective use in a broad range of patient populations

• Patients ECG screening need.

• Young age, high risk of infection, poor vascular access preferred S-ICD

• AV block, need pacing, ATP, CRT preferred TV-ICD

• Randomized evidence is on its way
  PRAETORIAN (S-ICD vs TV-ICD), PRAETORIAN DFT (DFT vs No DFT)
Thank You For Your Attention!

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If you have any question, don’t hesitate to e-mail me.

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