The S-ICD® System

Protection Without Touching The Heart

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ELECTROPHYSIOLOGY
SUDDEN CARDIAC DEATH - How to prevent it
Brittany Murphy, 32-year-old star of “8 Mile” and other films, died Sunday morning after collapsing at her Hollywood Hills home. She was transported by ambulance to Cedars-Sinai Hospital, where she was pronounced dead. Her cardiac arrest death is being attributed to natural causes.
Host of MEET THE PRESS at NBC

Tim Russert, host of NBC’s “Meet the Press” died of sudden cardiac arrest. Resuscitation on the 58-year-old journalist began immediately, and
Joe Strummer’s cardiac arrest came in 2002 after the 50-year-old musician had just returned from walking the family dog. The vocalist and guitarist for the punk rock band The Clash and for late-1990s band The Mescaleros, collapsed and died of sudden cardiac arrest at his home in Somerset, England. His wife found him and called police, who pronounced him dead. It was later determined that Strummer had an undiagnosed congenital heart condition.
Actress Tracey Conway was 38 when she collapsed onstage during a taping of KING-TV’s “Almost Live” in Seattle. The Emmy-Award-winning actress had just finished spoofing the TV show “ER.” Fortunately paramedics were able to revive Conway, making six attempts to restart her heartbeat with an AED.
US vital statistics mortality data for 1989-1998 estimated 719,456 cardiac deaths for 2000; with 63% (456,078) being defined as SCD.\(^1\)

A large study recently completed with 121,701 women (Nurse’s Health Study) over a 20 year period estimated 88% of sudden cardiac deaths were due to arrhythmic causes.\(^2\)

Cardiac and non-cardiac events that cause SCD can be indistinguishable from ventricular arrhythmias.

Underlying Arrhythmias of Sudden Cardiac Arrest

- Bradycardia: 17%
- Monomorphic VT: 62%
- Polymorphic VT: 13%
- Primary VF: 8%
Leading Causes of Death in the U.S.

You must combine deaths from all cancers to outnumber the deaths from SCA each year.

- Septicemia
- Nephritis
- Alzheimer's Disease
- Influenza/pneumonia
- Diabetes
- Accidents/injuries
- Chronic lower respiratory diseases
- Cerebrovascular disease
- Other cardiac causes
- Sudden cardiac arrest (SCA)
- All other causes
- All cancers

0% 5% 10% 15% 20% 25%


Magnitude of SCA in the U.S.

SCA claims more lives each year than these other diseases combined:

- Stroke: 167,366
- Lung Cancer: 157,400
- Breast Cancer: 40,600
- AIDS: 42,156
- SCA: 450,000

Magnitude of SCA in the U.S.

450,000 per year
1,200 per day
  - 1 every 80 seconds

Coronary artery disease is present in 80-85% of patients who experience SCA.

3 Cobb LA. Circulation. 1975;51(III):223.
SCA Resuscitation Success vs. Time*

*Non-linear

Chance of success reduced 7-10% each minute

Even in the best EMS/early defibrillation programs it is difficult to achieve high survival times due to many SCA events not being witnessed and the difficulty of reaching victims within 6-8 minutes.

- 40% SCAs not witnessed or occur in sleep\(^1\)
- 80% SCAs occur at home\(^1\)
- 5% estimated SCA out-of-hospital survival\(^2,3\)

\(^1\) Swagemakers V. *J Am Cardiol*. 1997;30:1500-1505.
Brief Summary

The S-ICD® System from Boston Scientific CRM

**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 ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

**Contraindications:** Unipolar pacemakers are contraindicated for use with the S-ICD System.

**Warnings and Cautions:** The S-ICD System contains sterile products for single use only. Do not resterilize. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. All Cameron Health implantable components are designed for use with the Cameron Health S-ICD System only. Connection of any S-ICD System components to any other ICD system will result in failure to deliver lifesaving defibrillation therapy.

**General:**
- External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.
- Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response.
- Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.
- The S-ICD System has not been evaluated for pediatric use.
- The S-ICD System does not provide long-term bradycardia pacing, Cardiac Resynchronization Therapy (CRT) or Anti-Tachycardia Pacing (ATP).

**Potential Adverse Events related to implantation of the S-ICD System may include, but are not limited to, the following:** Acceleration/induction of atrial or ventricular arrhythmia; Adverse reaction to induction testing; Allergic/adverse reaction to system or medication; Bleeding; Conductor fracture; Cyst formation; Death; Delayed therapy delivery; Discomfort or prolonged healing of incision; Electrode deformation and/or breakage; Electrode insulation failure; Erosion/extrusion; Failure to deliver therapy; Fever; Hematoma; Hemothorax; Improper electrode connection to the device; Inability to communicate with the device; Inability to defibrillate or pace; Inappropriate post-shock pacing; Inappropriate shock delivery; Infection; Keloid formation; Migration or dislodgement; Muscle stimulation; Nerve damage; Pneumothorax; Post-shock/post-pace discomfort; Premature battery depletion; Random component failures; Stroke; Subcutaneous emphysema; Surgical revision or replacement of the system; Syncope; Tissue redness, irritation, numbness or necrosis.
The S-ICD System is the world’s first and only ICD that provides defibrillation therapy without touching the heart. The approval of the S-ICD System introduces a new category of defibrillators that enable you to offer more options to your patients and better balance risk with therapeutic benefit.
Contents
Introduction to the S-ICD System

Effective Defibrillation without transvenous leads
Defibrillation without transvenous leads

The S-ICD System:

- Completely 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, if not better than, transvenous ICDs

A new category of implantable defibrillators

Transvenous (TV) ICDs

- Provides effective defibrillation for ventricular tachyarrhythmias
- Provides Brady pacing
- Provides ATP for patients with incessant 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 with endovascular lead extraction
- Fluoroscopy not required
S-ICD System Implant Procedure

- Does not require venous access
- Designed to reduce complications
- Designed to be predictable
- Does not require fluoroscopy
- 95% implanted using only anatomical landmarks (no medical imaging)\(^1\)

Ideal Device Placement
One Month Post-Operative Pictures
S-ICD System Highlights

- 80 joule (delivered) biphasic shock
- Charge time to 80J ≤ 10 seconds
- 5.1 year longevity
- 30 seconds post-shock pacing
- Single electrode connection
- Full featured episode storage
**Q-TRAK® Subcutaneous Electrode**

- Multistrand cable-core design
- No hollow core, no inner coils
- Durable polyurethane insulator
- Designed to withstand cardiopulmonary resuscitation (CPR) forces
- Subcutaneous placement avoids intra-cardiac biomechanical stresses
  - Does not need to be as flexible as transvenous lead
S-ICD System Components

Q-GUIDE™ Electrode Insertion Tool (EIT)

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

Q-TECH™ Programming System

- Battery operated (rechargeable)
- Wanded RF telemetry
- Wireless printing
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 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
Function of the S-ICD System

Accurate Detection of VT/VF
Effective Discrimination of AF & SVT1

The S-ICD System captures high-resolution, morphologically rich signals similar to a surface ECG.
Sophisticated Rhythm Detection Technology

Three far-field sensing vectors
- Primary, Secondary, Alternate
- Automatic or manual 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
INSIGHT™ Rhythm Discrimination

Three Simultaneous Rhythm Analyses:

1. **Static morphology analysis** identifies non-shockable rhythms, utilizing the NSR (normal sinus rhythm) template.

2. **Dynamic morphology analysis** identifies shockable polymorphic rhythms by comparing each complex to the previous ones.

3. **QRS width analysis** compares the QRS width to the NSR QRS width.
• Studies have shown that the S-ICD System’s dual zone programming using the INSIGHT algorithm reduces the likelihood of inappropriate shocks

• The INSIGHT algorithm identifies and evaluates a heart rhythm rather than individual heart beats to effectively discriminate VT/VF.

• Similar to PREPARE Study programming, the INSIGHT algorithm only initiates therapy for longer duration tachyarrhythmias.


2) Wilkoff, et. al. Results From the PREPARE. JACC. Vol. 52, No. 7, 2008
The algorithm utilizes three distinct analyses to correctly identify and classify the S-ECG signal.

### Sophisticated Therapy Options

<table>
<thead>
<tr>
<th>Conditional Shock Zone</th>
<th>The activated INSIGHT algorithm discriminates between treatable and other high-rate events such as AF, sinus tachycardia, and other SVTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smart Charge</td>
<td>Smart Charge automatically extends initial detection time to allow self termination of non-sustained tachyarrhythmia's</td>
</tr>
<tr>
<td>Shock Confirm</td>
<td>If spontaneous termination is detected after charging is initiated, the algorithm withholds therapy.</td>
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Growing body of clinical evidence supports both safety and efficacy of S-ICD System
**S-ICD (IDE) Study met both effectiveness and safety endpoints**

**S-ICD Study Design**
*Prospective, Single-Arm Comparison to OPC*

- **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

**Additional Study Results:**

- 100% spontaneous VT/VF episodes (n=109) converted with 80J shock or spontaneously converted
- 0 patients experienced a shock due to discrimination error in Conditional Shock (dual) zone
- 79% of patients were primary prevention indication
- 63% of patients with VT/VF rhythms meeting criteria to charge avoided therapy delivery without any reports of syncope
  - Algorithm prevents therapy for VT/VF rhythms that are likely to spontaneously terminate
- 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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*Both endpoints met even under worst case sensitivity analysis*
Additional S-ICD System Clinical Results

Preliminary Results of the EFFORTLESS S-ICD Registry1

- 210 Active Patients
- 98.5% effective conversion of induced VT/VF within 1 procedure
- No inappropriate shocks have been recorded for AF/SVT within a programmed conditional shock zone
- Annual inappropriate shock rate of 7% with some of these patients receiving shocks due to Rate > Shock Zone
- Mean time to therapy: induction ~16 seconds; spontaneous ~20 seconds
  - Comparable to transvenous systems:

1) Heart Rhythm - May 2012; Vol 9.3(S1-SS) AB07-2
* At nominal settings for each respective company. Based on a VT at 200 bpm with device nominal settings where ATP is unsuccessful, and there is a 9 second maximum energy charge (this 9 second charge time may vary over the life of the device). The time outcomes used in the graph above are based on calculations derived from labeling information and may not necessarily be indicative of clinical performance.
Patient Populations

Patients from a broad range of indications have received the S-ICD System

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 ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing
EFFORTLESS Registry demonstrates a broad range of clinical indications

Patients from a broad range of clinical indications have received the S-ICD System
Primary Prevention Patients are the most likely candidates for the S-ICD System

S-ICD System Indication in US IDE Study1 (n=321)

European S-ICD System Implants2 (n=471)


2. As of Q2 2012. Data on file
Questions?

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