The S-ICD® System

Protection Without Touching The Heart

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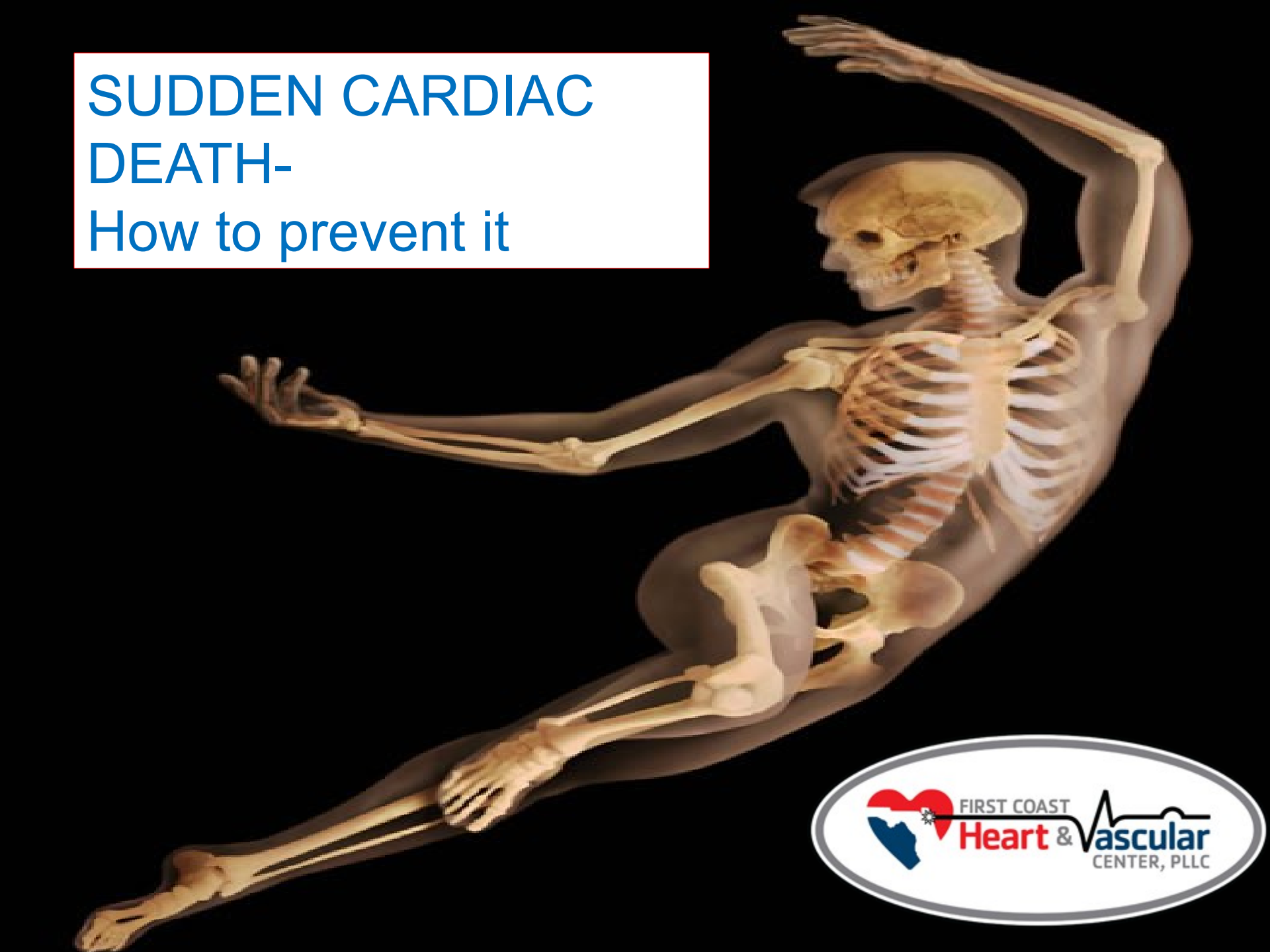
ELECTROPHYSIOLOGY

SUDDEN CARDIAC DEATH-
How to prevent it



FIRST COAST Heart & Vascular CENTER, PLLC

Actress Brittany Murphy collapses and dies of suspected cardiac arrest

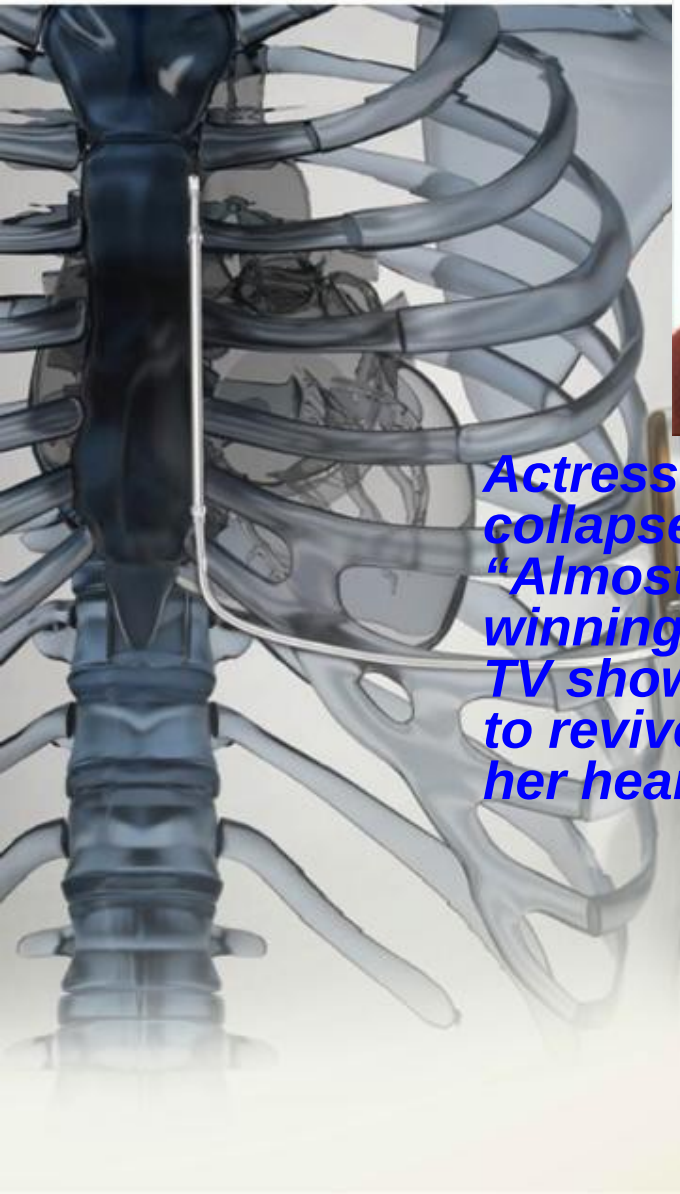
Mon, Dec 21, 2009

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



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

Arrhythmic Cause of SCD

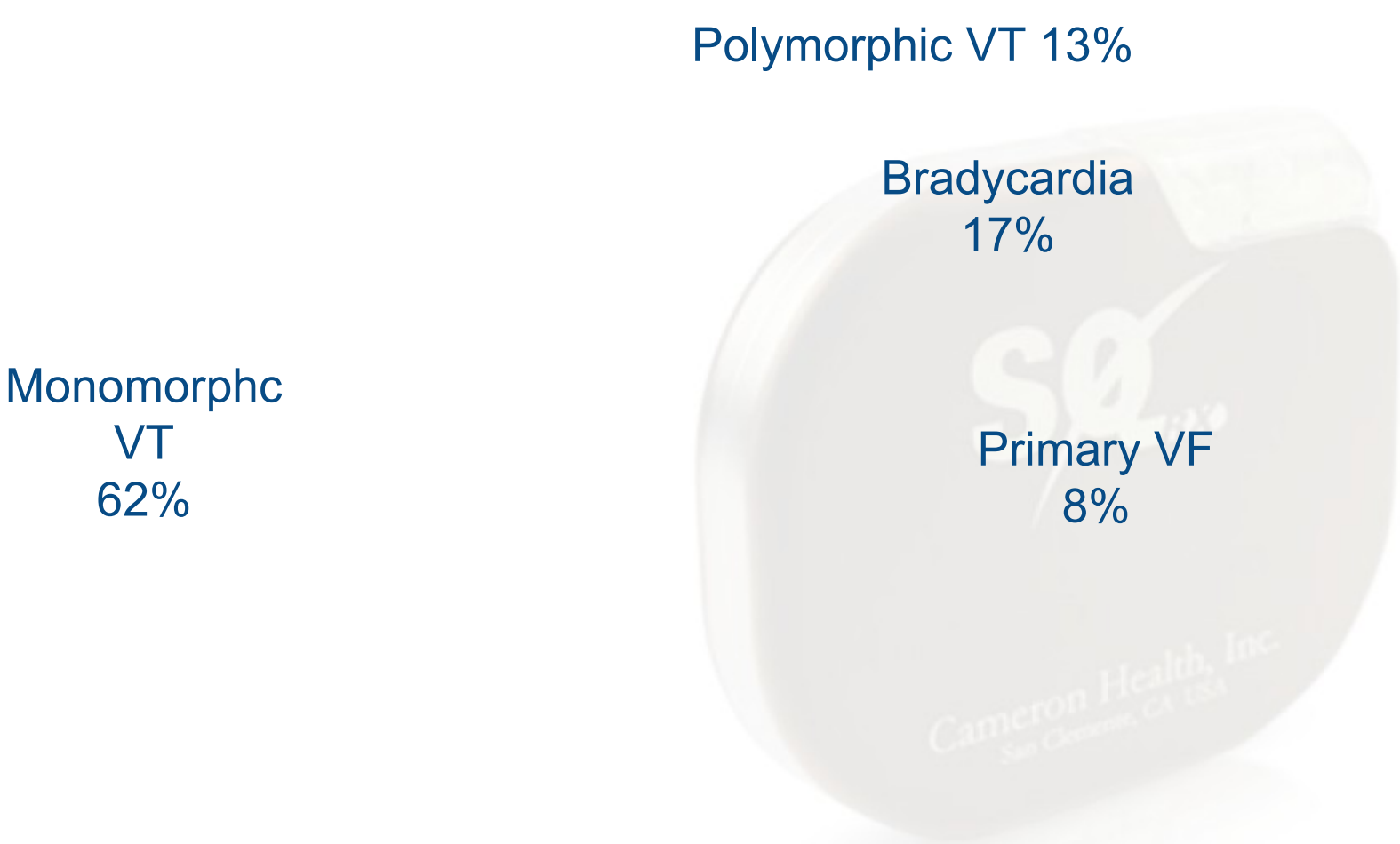
US vital statistics mortality data for 1989-1998 estimated 719,456 cardiac deaths for 2000; with 63% (456,078) being defined as SCD.1

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

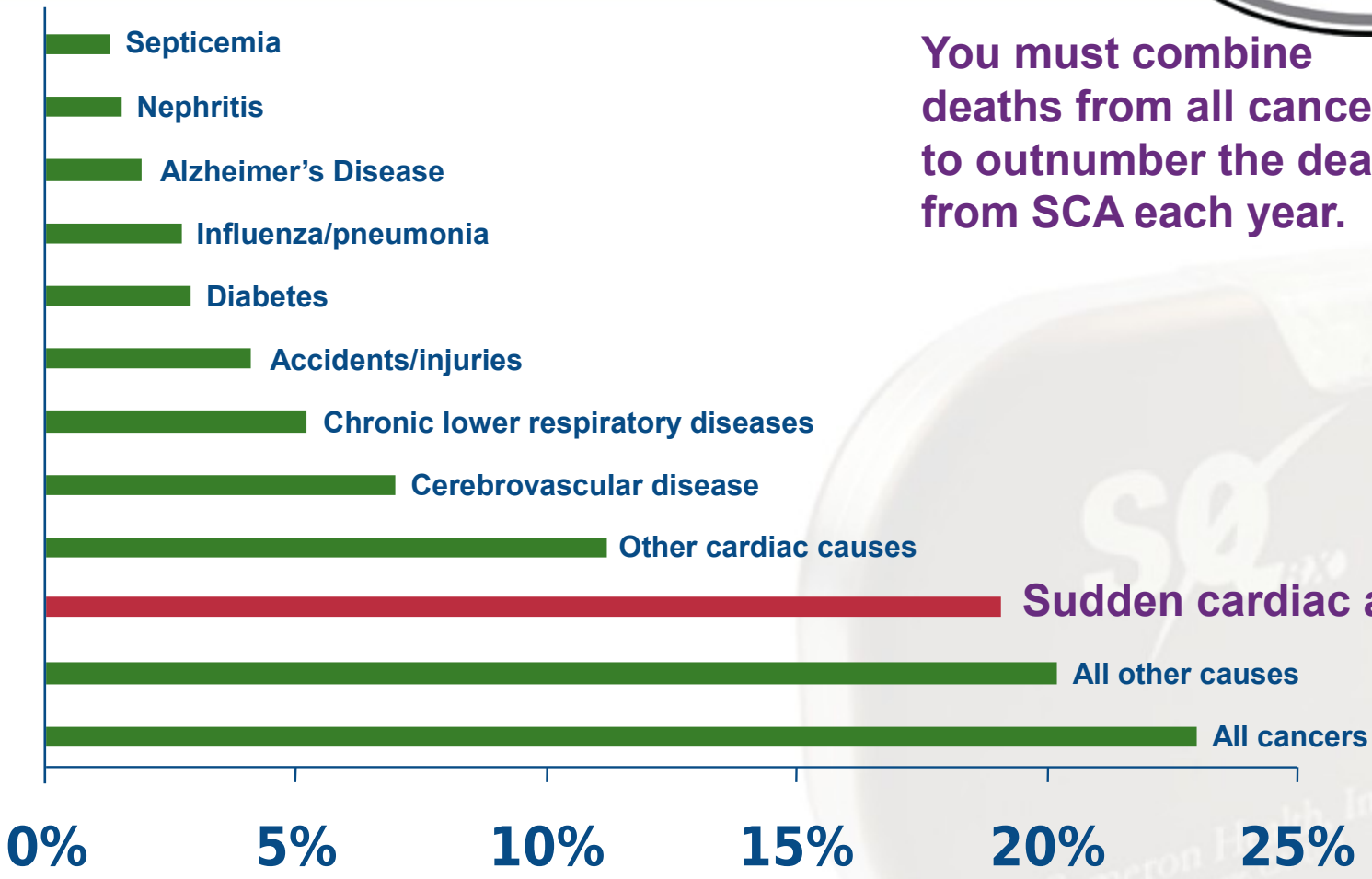
Cardiac and non-cardiac events that cause SCD can be indistinguishable from ventricular arrhythmias.

1 Zheng Z. Circulation. 2001;104:2158-2163.
2 Albert CM. *Circulation*. 2003;107:2096-2101.

Underlying Arrhythmias of Sudden Cardiac Arrest



Leading Causes of Death in the U.S



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

National Vital Statistics Report. Oct. 12, 2001;49(11).

MMWR. State-specific mortality from sudden cardiac death – US 1999. Feb 15, 2002;51:123-126.

Magnitude of SCA in the U.S.

1 U.S. Census Bureau, *Statistical Abstract of the United States*: *2001*.
2 American Cancer Society, Inc., *Surveillance Research, Cancer Facts and Figures 2001*.
3 *2002 Heart and Stroke Statistical Update*, American Heart Association.
4 Zheng Z. *Circulation*. 2001;104:2158-2163.

Magnitude of SCA in the U.S.

450,000 per year[1]

1,200 per day

- 1 every 80 seconds

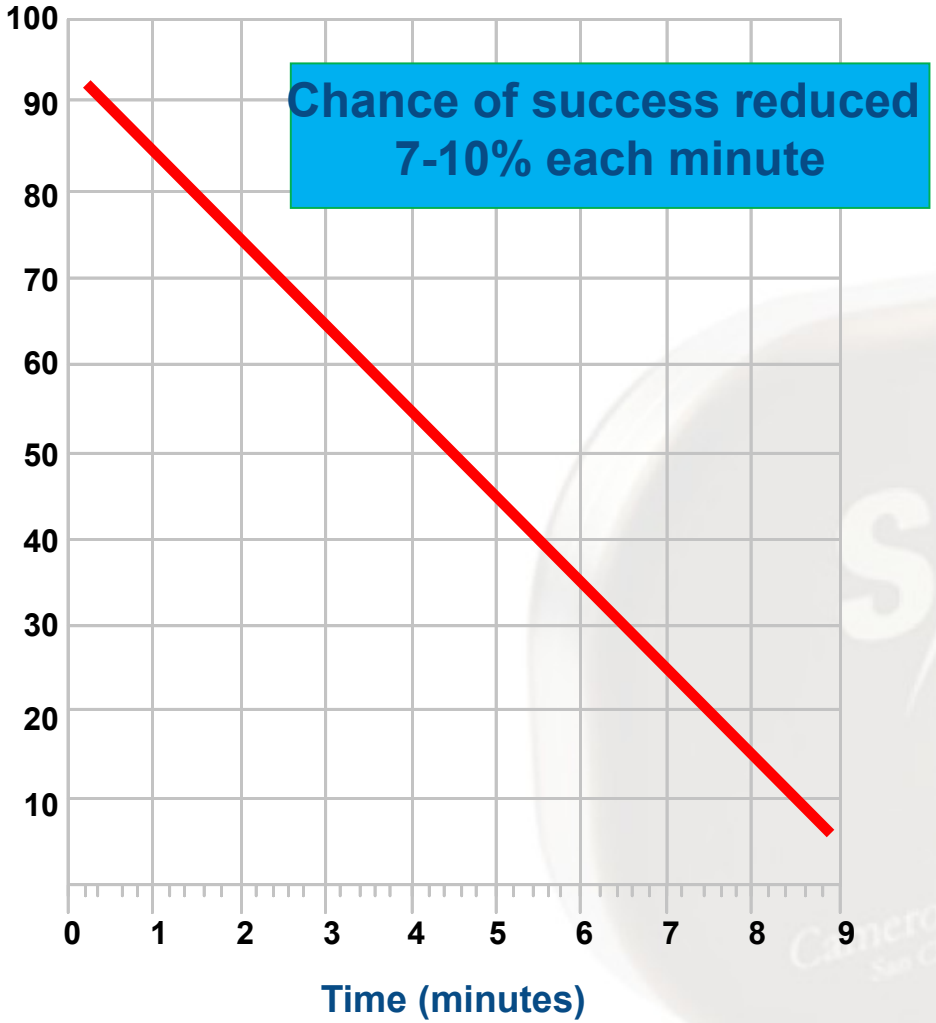
Coronary artery disease is present in 80-85% of patients who experience SCA.[2,3]

1 Zheng Z. *Circulation*. 2001;104:2158-2163.

2 Myerburg RJ, Heart Disease, *A Textbook of Cardiovascular Medicine*. 6th ed. W.B. Saunders, Co. 2001.

3 Cobb LA. *Circulation.* 1975;51(III):223.

SCA Resuscitation Success vs. Time*



mins RO. *Annals Emerg Med.* 1989;18:1269-1275.

SCA Chain of Survival Statistics

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.
2 Ginsburg W. *Am J Emer Med*. 1998;16:315-319.
3 Cobb LA. *Circulation.* 1992;85:I98-102.

SCA Chain of Survival

+ Evaluate Need for ICD

Early Access	Early CPR	Early Defibrillation	Early Advance Care	
1	2	3	4	5

www.americanheart.org The Links in the Chain of Survival
Adapted by Medtronic, Inc. to include refer to EP.

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.

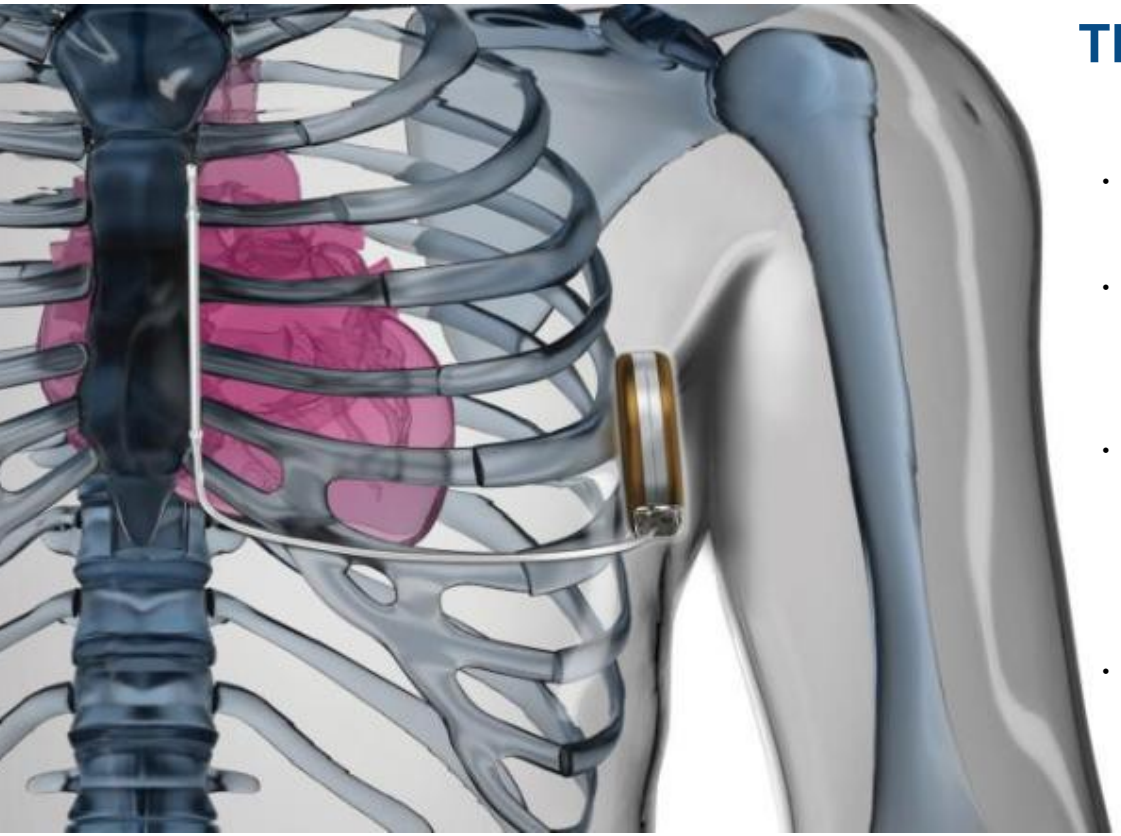
The S-ICD System is the world's first and only ICD that provides defibrillation therapy without touching the heart. The approval of the S-ICD System introduces a new category of defibrillators that enable you to offer more options to your patients and better balance risk with therapeutic benefit.

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 ICDs1

1) 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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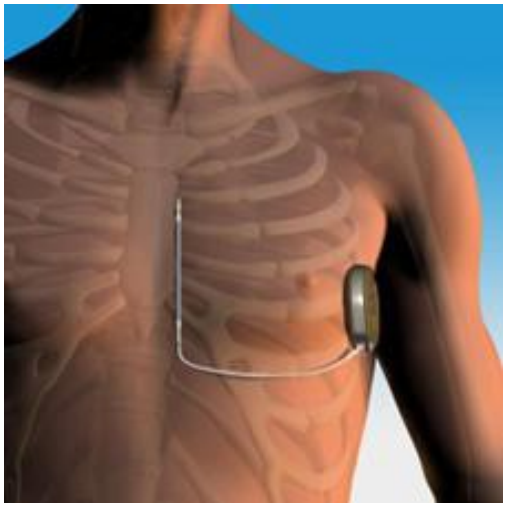
A new category of implantable defibrillators

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

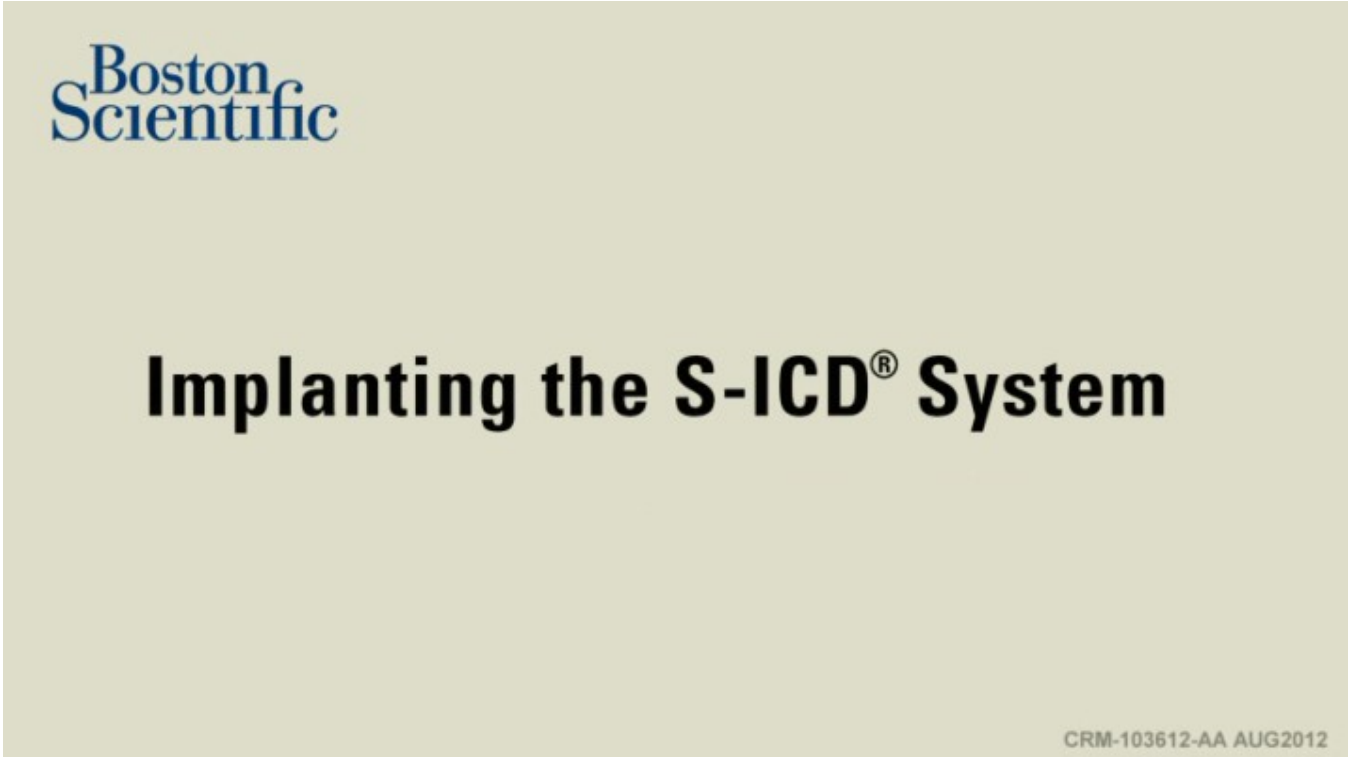
The S-ICD System



- Provides effective defibrillation for ventricular tachyarrhythmias
- No risk of vascular injury
- Low risk of systemic infection
- Preserves venous access
- Avoids risks associated w/ endovascular lead extraction
- Fluoroscopy not required

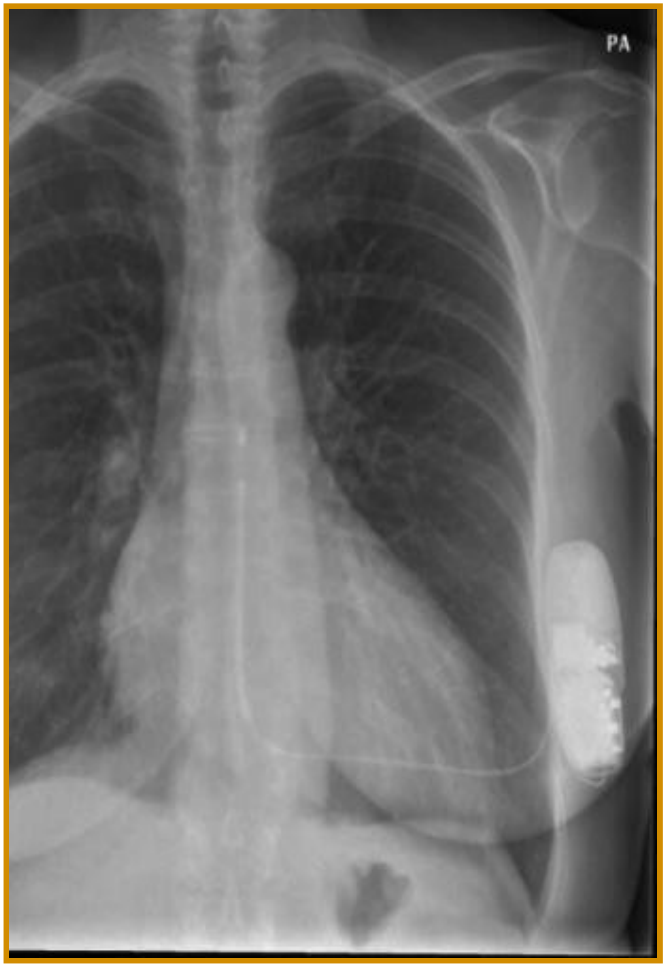
S-ICD System Implant Procedure

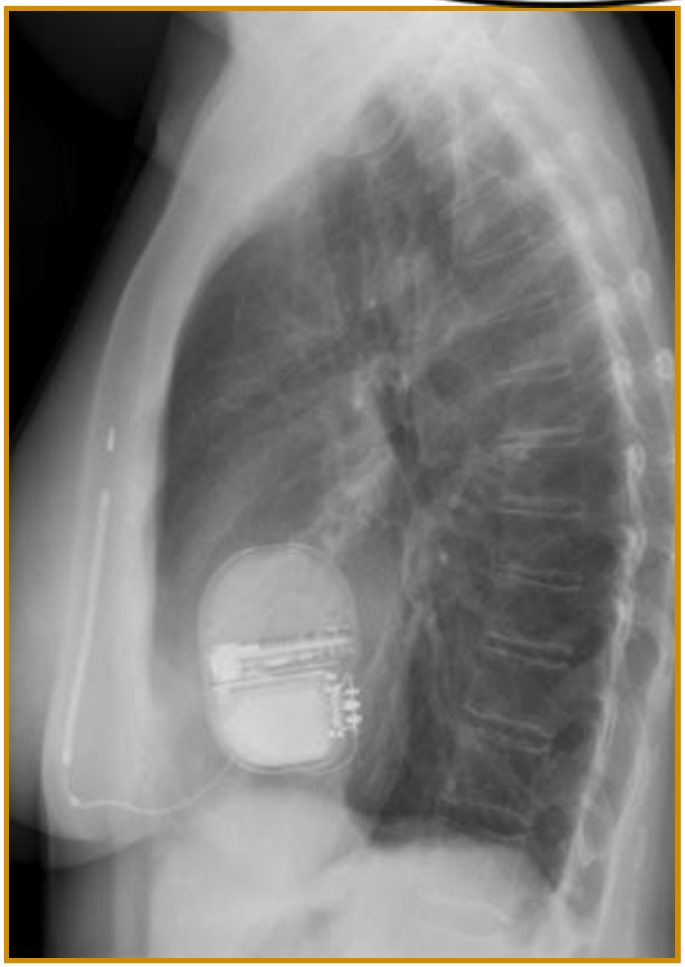
- Does not require venous access
- Designed to reduce complications
- Designed to be predictable
- Does not require fluoroscopy
- 95% implanted using only anatomical landmarks (no medical imaging)1



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

Ideal Device Placement





One Month Post-Operative Pictures

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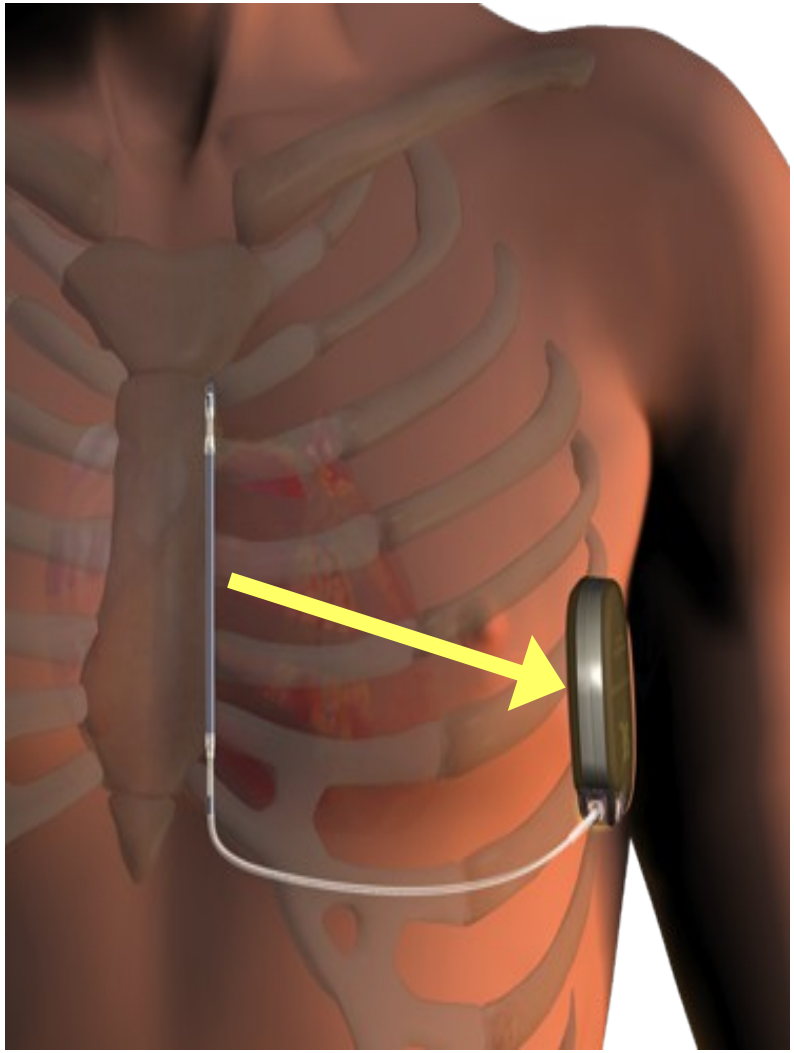
S-ICD System Highlights

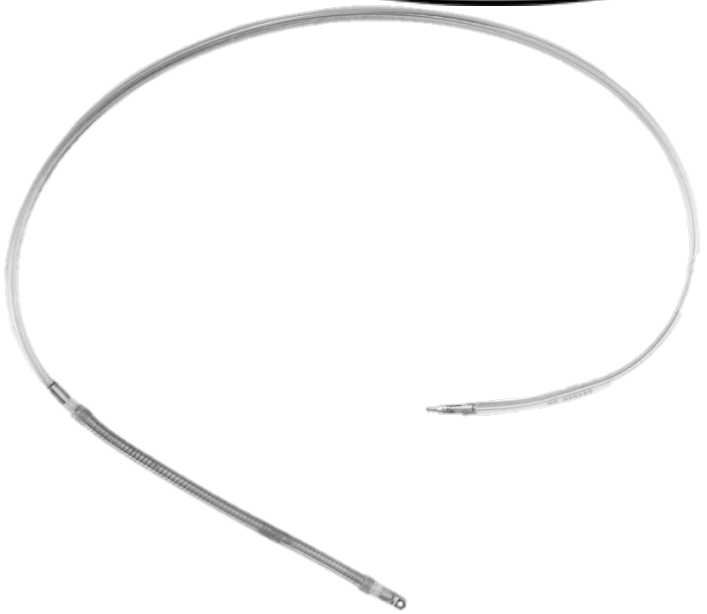


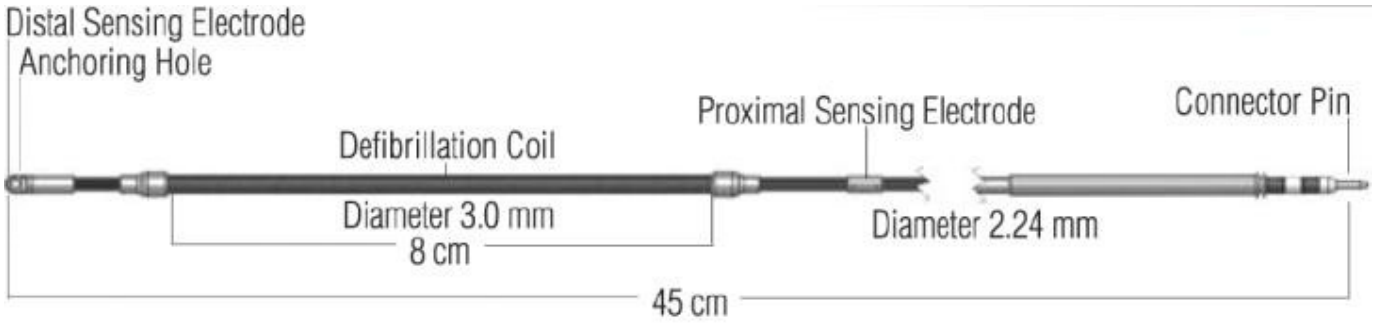
- 80 joule (delivered) biphasic shock
- Charge time to 80J ≤ 10 seconds
- 5.1 year longevity
- 30 seconds post-shock pacing
- Single electrode connection
- Full featured episode storage

Subcutaneous Electrode

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





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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

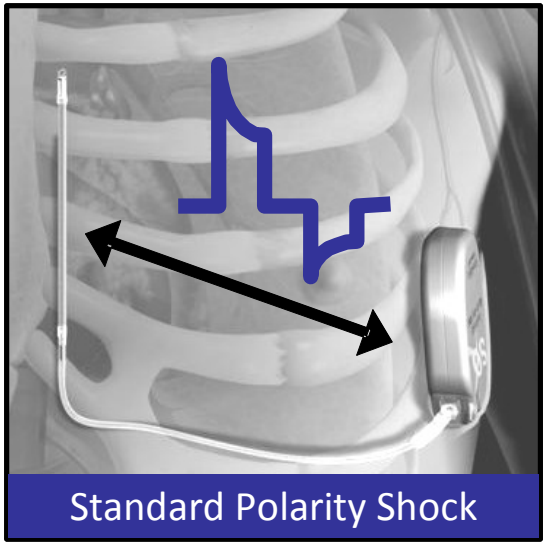
Therapy Delivery

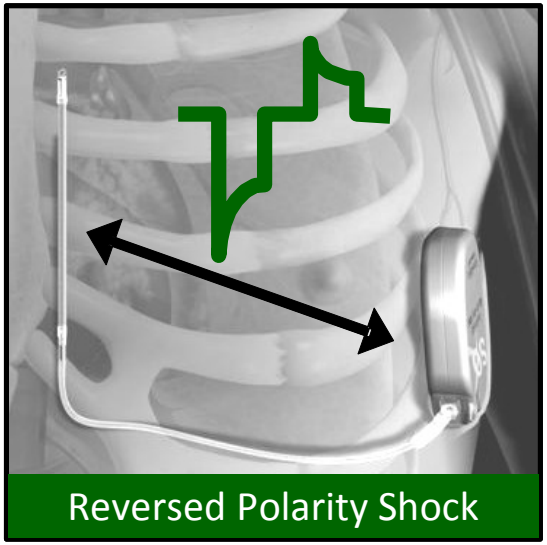
Episodes

- 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





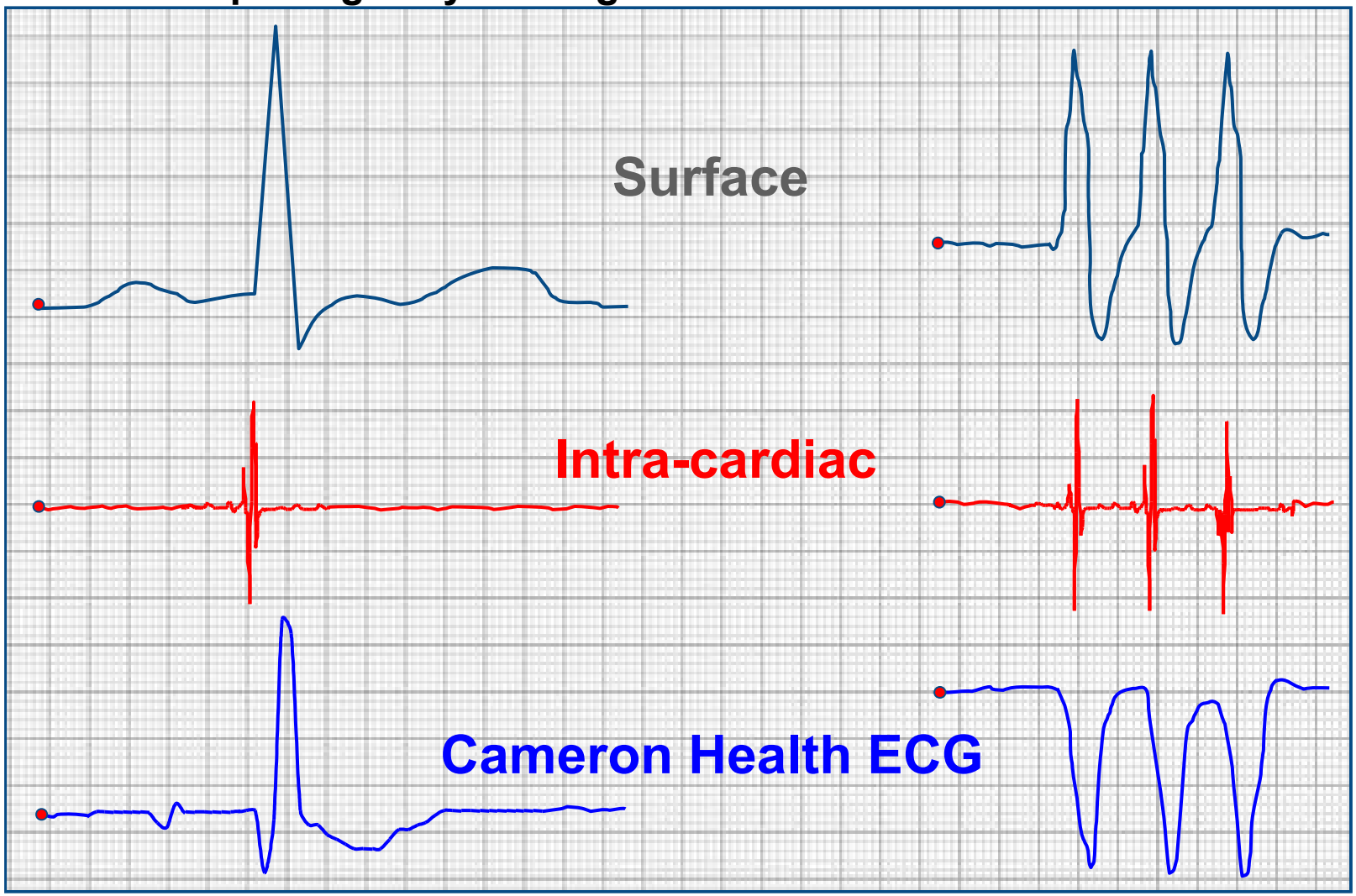
Function of the S-ICD System

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

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

The Subcutaneous Signal

The S-ICD System captures high-resolution, morphologically rich signals similar to a surface ECG



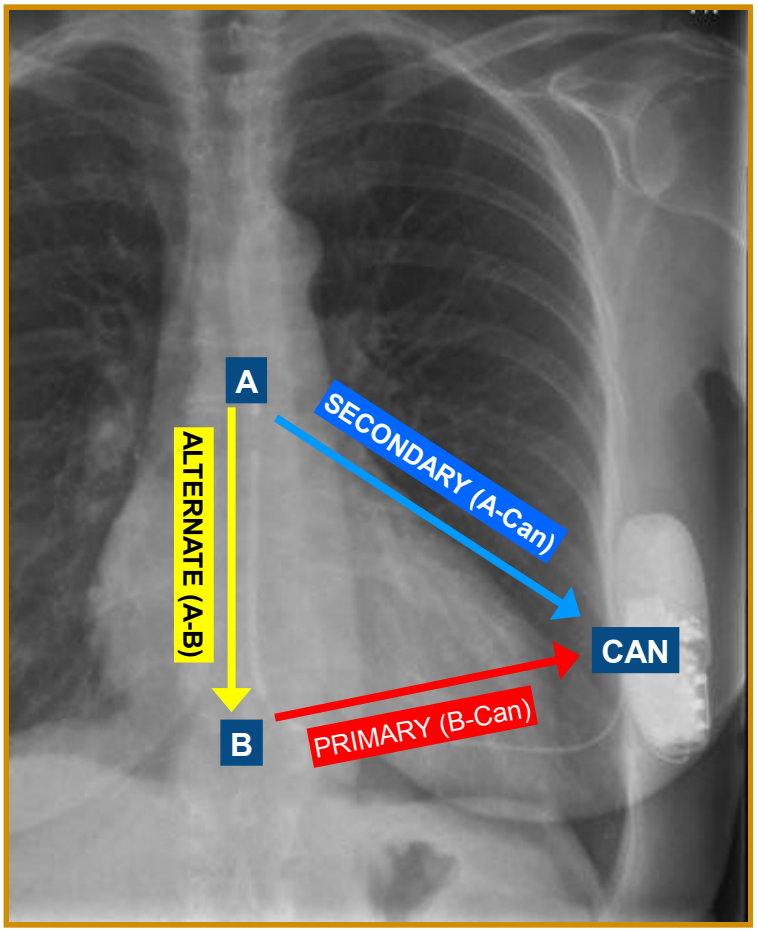
Sophisticated Rhythm Detection Technology

Three far-field sensing vectors

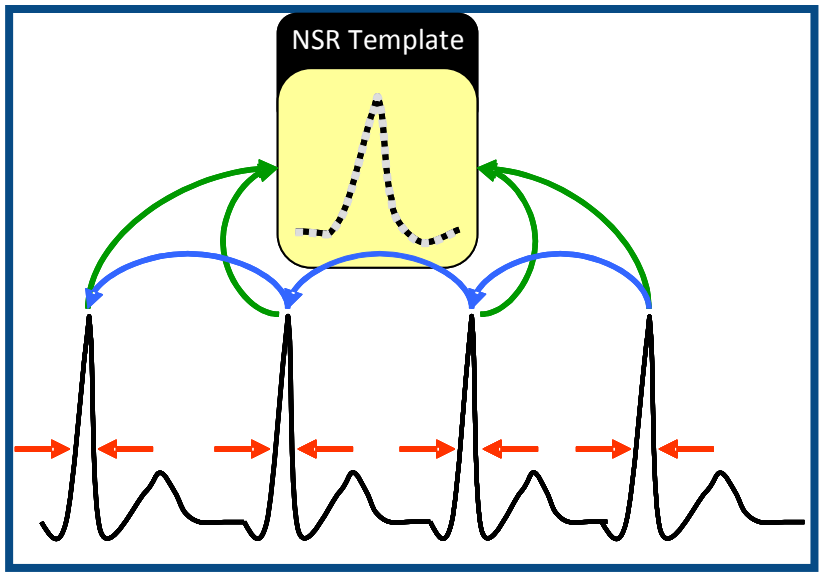
- Primary, Secondary, Alternate
- Automatic or manual selection
- Morphologically rich signal similar to a surface ECG
- Sense electrodes positioned away from large muscle groups

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

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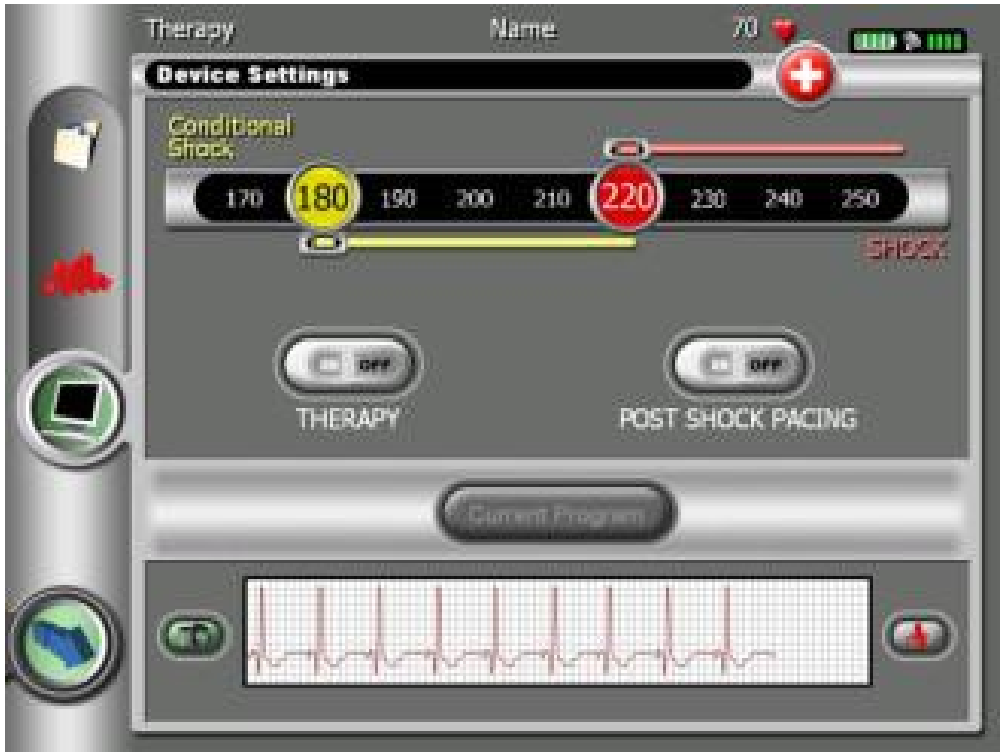
INSIGHT™ Rhythm Discrimination

- Studies have shown that the S-ICD System's dual zone programming using the INSIGHT algorithm reduces the likelihood of inappropriate shocks1
- 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



1) Burke M, et al. Safety and Efficacy of a Subcutaneous Implantable-Defibrillator (S-ICD System US IDE Study). Late-Breaking Abstract Session. HRS 2012.
2) Wilkoff, et. al. Results From the PREPARE. JACC. Vol. 52, No. 7, 2008

INSIGHT™ Rhythm Discrimination

The algorithm utilizes three distinct analyses to correctly identify and classify the S-ECG signal.

Sophisticated Therapy Options

Conditional Shock Zone	The activated INSIGHT algorithm discriminates between treatable and other high-rate events such as AF, sinus tachycardia, and other SVTs
Smart Charge	Smart Charge automatically extends initial detection time to allow self termination of non-sustained tachyarrhythmia's
Shock Confirm	If spontaneous termination is detected after charging is initiated, the algorithm withholds therapy.

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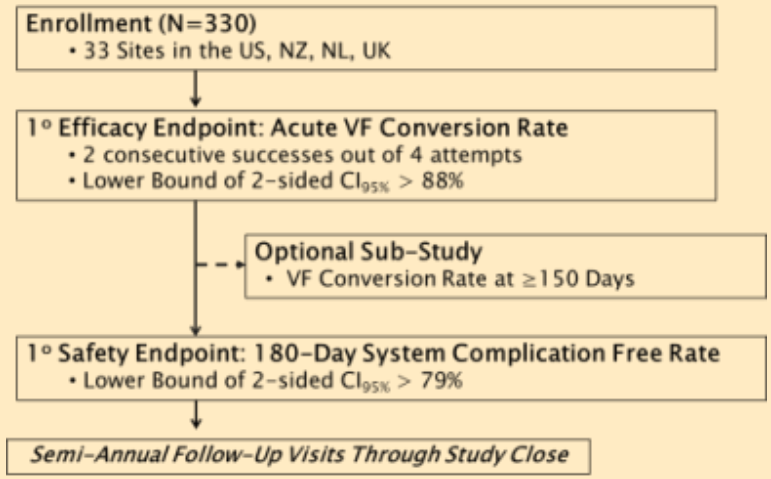
S-ICD System Clinical Evidence

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:

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

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)

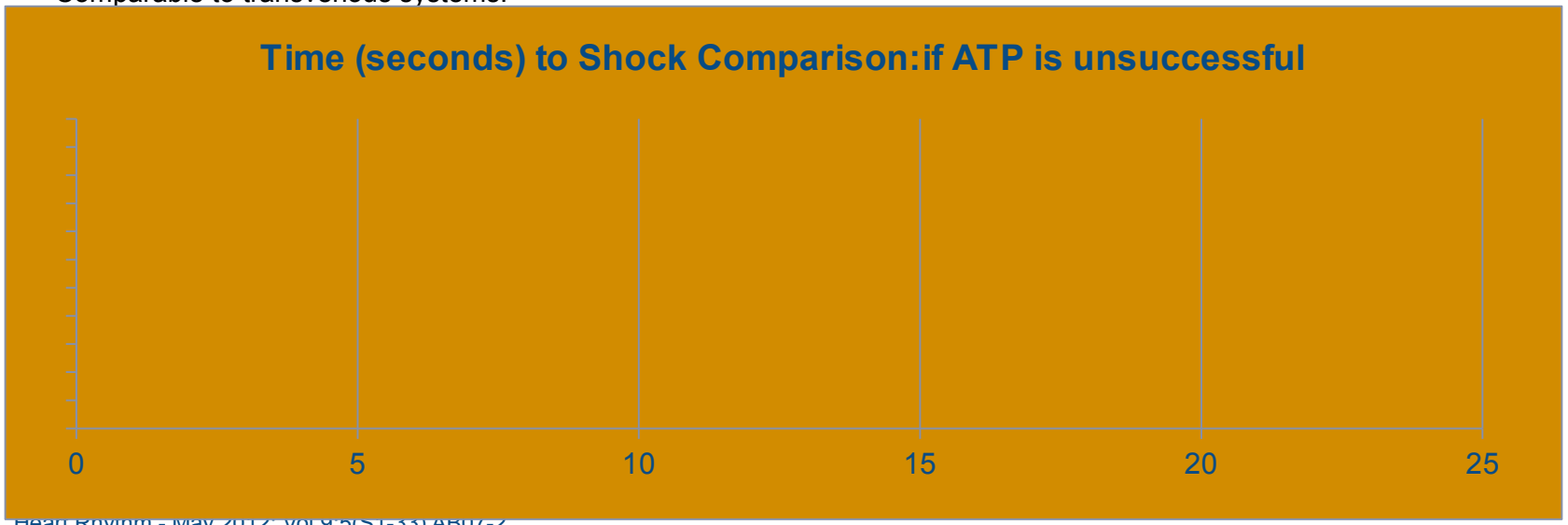
99% of implanted patients had no electrode or pulse generator movement throughout follow-up period

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

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 9:5(S1-33) 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

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

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 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

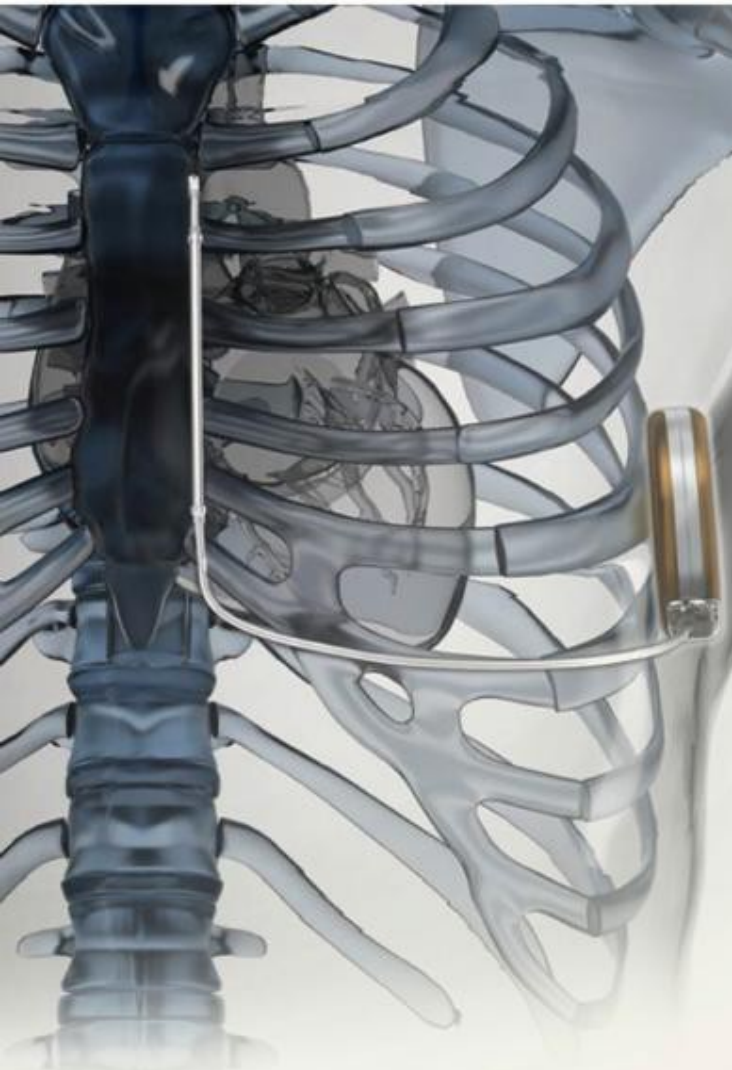
Lambiase, EFFORTLESS S-ICD Registry, HRS 2012, Boston, MA

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)

1) Burke M, et al. Safety and Efficacy of a Subcutaneous Implantable-Defibrillator (S-ICD System US IDE Study). Late-Breaking Abstract Session. HRS 2012.
2) As of Q2 2012. Data on file



Questions?


THANK YOU