

S-ICD Post-Market Approval Study

Subcutaneous Implantable Cardioverter-Defibrillator (S-ICD) Late Breaking Clinical Trial Presentation from Heart Rhythm 2017^{1,2}

TRIAL DESIGN

The S-ICD Post-Market Approval Study is the largest cohort of S-ICD study patients to date in a non-randomized, standard of care registry that prospectively enrolled and followed recipients in the US, to document long-term safety and effectiveness outcomes. The current analysis was performed on perioperative variables, including patient demographics, implantation results and 30-day perioperative events.

STUDY POPULATION

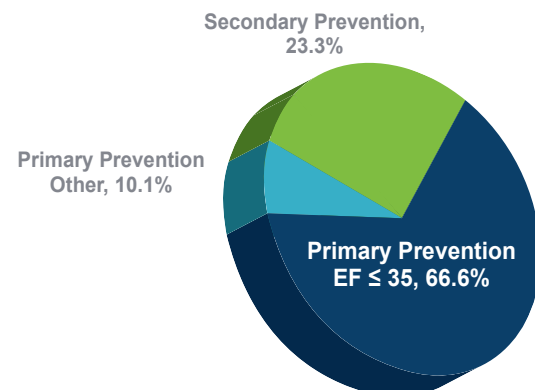
- 1637 patients implanted with the S-ICD at 86 centers in the US
- Key Inclusion Criteria
 - Eligible for implantation with an S-ICD system
 - Willing and able to provide written informed consent or have informed consent provided by a legal representative
- Key Exclusion Criteria
 - Life expectancy of less than 1 year
 - Ineligible for the S-ICD due to bradycardia or a history of pace-terminable ventricular tachycardia

PATIENT CHARACTERISTICS

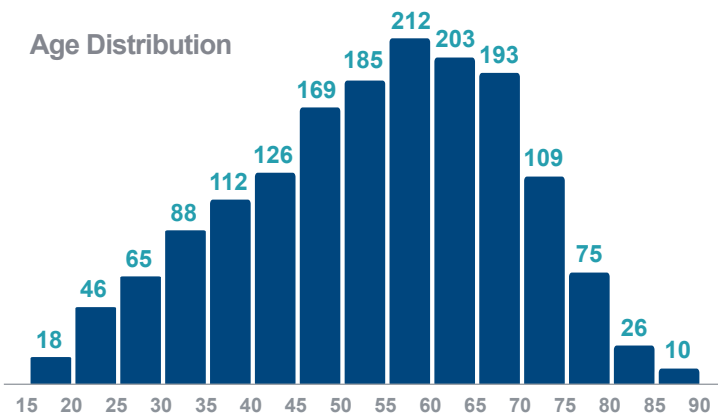
Characteristic	Mean ± Standard Deviation or % (N = 1637)
Age	53.2 ± 15.0
Gender (Male)	68.6%
Caucasian	60.2%
African American	28.2%
BMI (kg/m ²)	29.8 ± 7.6
EF	32.0 ± 14.6%
EF ≤ 35%	75.4%
Indication	
Primary Prevention	76.7%
Secondary Prevention	23.3%

Clinical use of the S-ICD was in a more traditional ICD indicated patient population

- 2/3 of S-ICD recipients were Primary Prevention Low EF (≤ 35%) patients

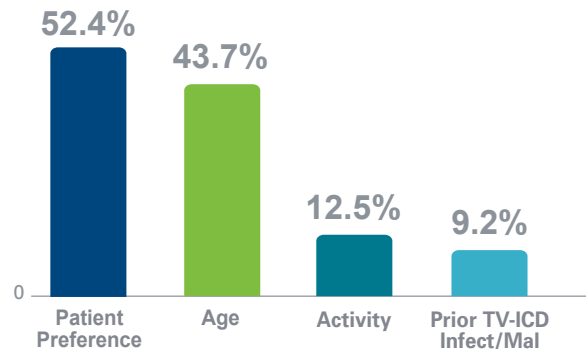


While the mean age of patients was 53.2, nearly half the study participants were between the ages of 50-70



Patient preference was the most common reason for selecting S-ICD

- 52.4% of study participants deemed suitable for a transvenous ICD noted patient preference as a reason for selecting the S-ICD



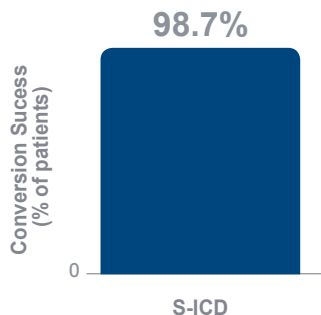
PROCEDURAL CHARACTERISTICS

Characteristic	%
Two Incision Technique	52.2%
Anesthesia	
General Anesthesia	64.1%
Conscious Sedation	35.8%
Use of Imaging	65.1%
Dual Zone Programming	97.2%

RESULTS

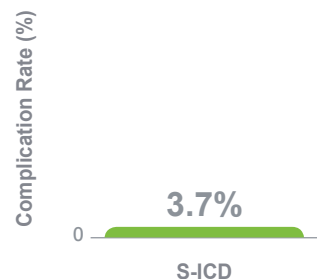
S-ICD demonstrated high conversion rates

- 98.7% of patients had successful conversion of induced VT/VF



S-ICD demonstrated low complication rates

- 3.7% complication rate at 30 days



CONCLUSIONS

In the largest prospective S-ICD study to date, with over 1600 patients, analysis of the implantation results and 30 day perioperative events demonstrated 98.7% of patients had a successful conversion of induced VT/VF and a 3.7% complication rate at 30 days.

EMBLEM™ MRI S-ICD System

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 pacing and impedance-based features are contraindicated for use with the S-ICD System.

Warnings Read the manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or sterilize. All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific S-ICD System only. Connection of any S-ICD System components to a non-compatible component will result in failure to deliver life-saving defibrillation therapy. Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Concomitant use of the S-ICD System and implanted electromechanical devices (for example a ventricular assist device, VAD, or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. Electromagnetic (EMI) or therapy delivery from the co-implanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the co-implanted device and compromise its functionality. To help prevent undesirable interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Do not implant in MRI site Zone III. Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. In patients with a deep implant placement (greater distance between the magnet and the pulse generator) magnet application may fail to elicit the magnet response. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reached may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

Precautions For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal and supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events 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/seroma, 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/nerve 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. Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.

Caution The law restricts this device to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

Information not intended for use or distribution in France.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.

(Rev. C)

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References:

1. Gold MR, et al. S-ICD Post Market Approval Study. Late Breaking Clinical Trial Presentation at Heart Rhythm 2017, Chicago, IL.
2. Gold MR, Aasbo JD, El-Chami MF, et al. The Subcutaneous ICD Post-Market Approval Study: Clinical Characteristics and Perioperative Results. Heart Rhythm Journal 2017.

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