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EMBLEM™ S-ICD SYSTEM

Subcutaneous Implantable Defibrillator

Innovation Backed by Evidence

Three important clinical studies have been instrumental in demonstrating the S-ICD System as a compelling solution for the prevention of sudden cardiac death in a broad range of patients.

2-year Results from a POOLED Analysis of the IDE Study and EFFORTLESS Registry (Published in JACC in early 2015)[1]

- 882 patients, Average Follow-Up: 651 days
- Largest patient cohort, most comprehensive data and longest follow-up period further demonstrates the worldwide safety and efficacy of the S-ICD System in a large diverse population
- Combining the studies provides a unique opportunity to evaluate:
  - Complications
  - Spontaneous events

US IDE Study (Published in Circulalon 2013)[2]

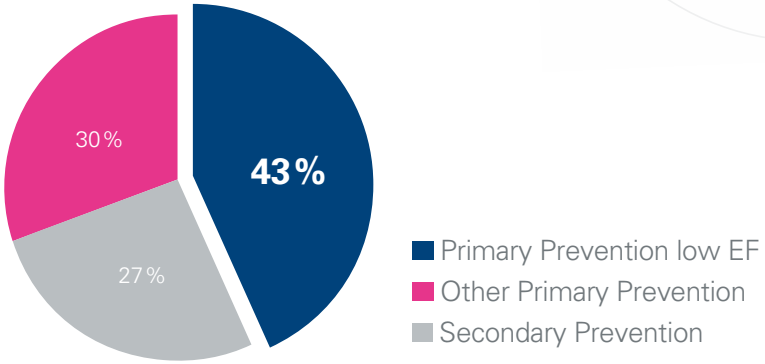
- 321 patients, Average Follow-Up: 11 months
- Completed in 2011 and was the cornerstone for US FDA approval
- Primary Safety Endpoint: 180-Day S-ICD System Complication Free Rate compared to prespecified goal of 79 %
- Primary Efficacy Endpoint: Induced VF conversions of 4 attempts compared with prespecified goal of 88 %

EFFORTLESS Registry Interim Results (Published in European Heart Journal in early 2014)[3]

- 456 patients, Average Follow-Up: 558 days
- Ongoing Registry In Europe and New Zealand
- Primary Outcome Measures:
  - Perioperative S-ICD System Complication Free Rate
  - 360 Day S-ICD System Complication Free Rate
  - Inappropriate shocks for AF/SVT

1. The S-ICD System has been implanted in a BROAD RANGE OF PATIENTS

POOLED Study Implanted Patients (n = 882)



Demographic	N (%)
Age (years)	50.3 ± 16.9[4]
Male	636 (72.5 %)
Ischemic	330 (37.8 %)
Genetic	58 (6.7 %)
Idiopathic VF	40 (4.6 %)
Channelopathies	90 (10.3 %)
NYHA Classification II-IV	327 (37.5 %)
Arial Fibrillation	143 (16.4 %)
Previous Defibrillator	120 (13.7 %)

43% of the study population were primary prevention patients with an EF ≤ 35%[1]

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2. Data has demonstrated a SAFE solution for sudden cardiac death

Complications

ZERO[1]

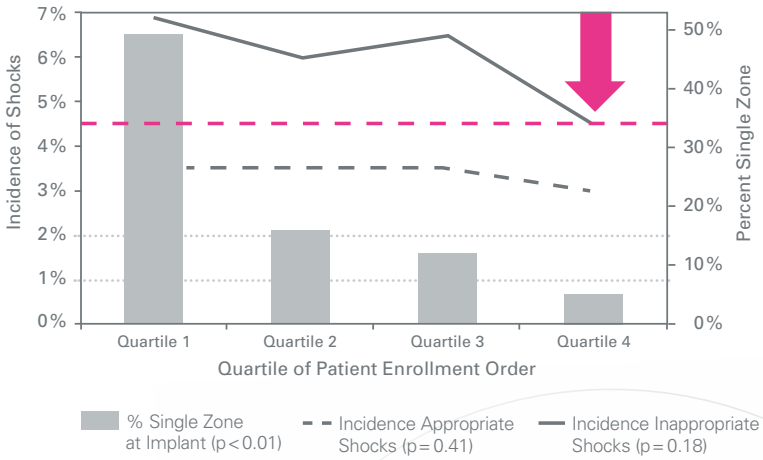
Electrode Failures, Systemic Blood Infections, Endocarditis or Cardiac Injuries

The lack of problematic consequences of endovascular complications including systemic infections could be a factor in the observed low mortality rate (Tarakji KG et al Europace 2014).

In the IDE Study, there were no explants due to infection in the last 2/3 implantations.

Inappropriate Therapy

34 % reduction with a **4.5 % incidence** of IAS at 6 months[1]



Improvements in S-ICD Screening and adoption of dual zone programming were associated with a lower rate of Inappropriate Therapy.

3. Data has demonstrated an EFFECTIVE solution for sudden cardiac arrest

Conversion Efficacy of Induced Arrhythmias

98.6 %[1]

The S-ICD System consistently demonstrates effective conversions of induced arrhythmias.

Conversion Efficacy of Discrete Spontaneous Arrhythmias

98.2 %[1]

Clinical conversion of spontaneous arrhythmias was achieved in all patients.

First Shock Efficacy

91.1 %[1]

The S-ICD System first shock conversion efficacy is in line with rates published for TV-ICDs.[3]

1 Burke MC et al. 2-years Results from Pooled Analysis of the EFFORTLESS and IDE Registry. JACC 2015.
2 Weiss, et al. The Safety and Efficacy of a Totally Subcutaneous Implantable-Defibrillator. Circulation 2013.
3 Lambiase, et al. A worldwide experience with a totally subcutaneous ICD; Preliminary results of the EFFORTLESS S-ICD Registry. European Heart Journal 2014.
4 BSC does not promote the pediatric use of S-ICD

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