The Subcutaneous ICD S-ICD



Scientific

Advancing science for life™

Implantable Device History



October 8, 1958 – The first fully implantable pacemaker

<u>Device Construction</u>: Commercially available Discrete Electronic Components encapsulated in an epoxy resin housing.

Device Longevity: 3 hours.

<u>Patient Profile</u>: 43 year old Swedish man Brady symptomatic at 28 BPM due to viral infection.

Patient endured a total of 28 Pacemaker implants over the course of his life and lived to the age of 86.

The implant regime allowed him to live an active life that included cycling, sailing and dancing over the course of his life.

Reference: Siemens AG, 2002-2015





Evolving ICD technology

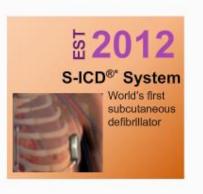










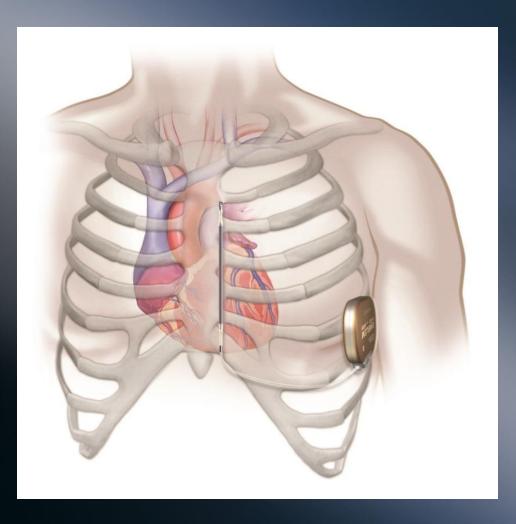




Transvenous and epicardial systems are however associated with complications related to the difficulty of maintaining long-term lead integrity and vascular access.



S-ICD System Overview



Entirely subcutaneous system

Does not require leads in the heart, leaving the vasculature untouched

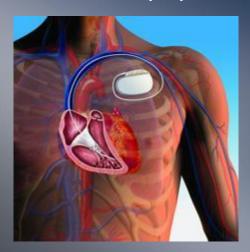
The device is implanted on the left side of the chest next to the rib cage.

There is one lead that is implanted just under the skin above the breastbone.

In contrast to the TV-ICD this system sends a shock without the use of wires implanted in the heart.

TV-ICD vs. S-ICD

Transvenous (TV) ICDs

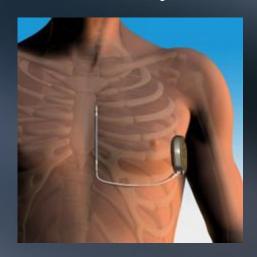


The device is implanted near the collarbone.

One or two leads are fed through a vein into your heart and across your heart valve.

The leads are attached to your heart wall for sensing of arrhythmias and therapy delivery.

The S-ICD System



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In contrast to the TV-ICD this system sends a shock without the use of wires implanted in the heart.

EMBLEM™ S-ICD System Components



EMBLEM™ S-ICD Pulse Generator

Volume: 59.5 cc
Weight: 130 grams
Thickness: 12.7 mm
Energy: 80J (delivered)

Waveform: Biphasic





EMBLEM™ S-ICD Subcutaneous Electrode



- 45 cm length
- 8 cm, 9 Fr shocking coil
- Two sensing electrodes

EMBLEM™ S-ICD Programmer



- AC Powered/Battery backup
- Wanded RF telemetry
- Wireless printing
- Micro SD Card

S-ICD™ Electrode: Designed for Durability



Less Biomechanical Stress

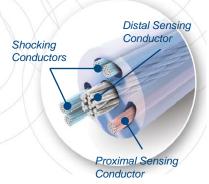
Located outside of the heart and ribcage, the EMBLEM S-ICD subcutaneous electrode is exposed to significantly less biomechanical stress than traditional transvenous leads:

- Not exposed to the dynamics and force of cardiac motion (~100,000 flexes/day)
- Not exposed to clavicular crush forces

Unique Construction

The subcutaneous electrode is uniquely designed to minimize the risk of insulation abrasion/breach and conductor fractures:

- Multistrand cable-core design provides exceptional strength
- · Durable polyurethane insulator
- · No hollow core, no inner coils
- Designed to withstand cardiopulmonary resuscitation (CPR) forces







Specifications

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Length	45cm
Distal tip size (Diameter)	12 Fr/4mm
Coil size (Diameter)	9 Fr/3 mm
Sensing location Distal Proximal	Distal electrode tip 120 mm from tip
Defibrillation location	20 - 100 mm from tip

Materials
Insulation
Electrodes
Conductors
Connector pin

Suture Sleeve

Polyurethane MP35N MP35N MP35N Silicone



