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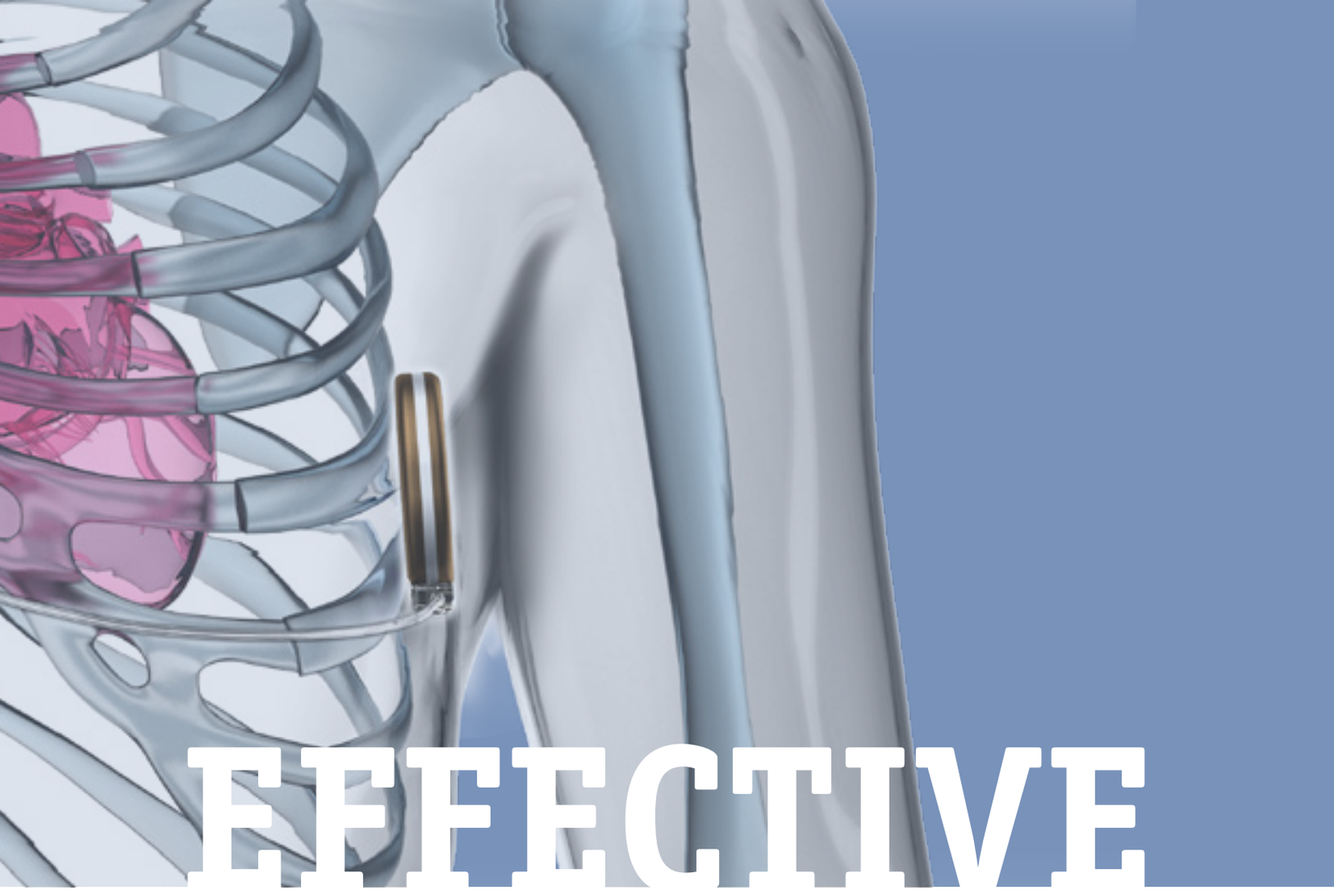
EMBLEM™ MRI S-ICD SYSTEM

UNTOUCHED

IMAGEREADY™
MR-Conditional Systems



EFFECTIVE

Defibrillation Without Transvenous Leads

EMBLEM MRI S-ICD System is the first and only subcutaneous implantable defibrillator that provides protection for patients at risk for sudden cardiac death while avoiding risks and complications associated with transvenous leads.

43,000+
patients implanted
worldwide[1]

- **ELIMINATES** potential for **VASCULAR INJURY**
- **PRESERVES** venous **ACCESS**
- **REDUCES** potential for **SYSTEMIC INFECTION**
- **LEAVES** the heart & **VASCULATURE** untouched

With virtually 15 YEARS OF CLINICAL DATA AND EXPERIENCE supporting Boston Scientific's technology, the latest generation of the system now offers:

1. **MRI-conditionality** using ImageReady™ technology to provide full-body MRI-conditional scanning capabilities for a 1.5 T environment*[2,3]

2. **Superior AF/SVT discrimination** using INSIGHT technology along with SMART Pass to provide reduction in inappropriate shocks due to cardiac over-sensing[3,4]

3. **AF detection** using AF Monitor™ to assist in the detection of silent, new onset or the progression of atrial fibrillation[3]

*when the conditions of use are met

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EMBLEM™ MRI S-ICD SYSTEM

Subcutaneous Implantable Defibrillator

Why S-ICD?

The EMBLEM MRI S-ICD System is the only established and sophisticated category of subcutaneous defibrillators that enable healthcare providers to offer more options to patients who are at risk for sudden cardiac death while at the same time better balance the risks associated with transvenous leads.

Effective defibrillation[1]

S-ICD 98.2%

TV-ICD 97.3%

...but without the risk[1]

"S-ICD is designed to avoid transvenous lead issues

Complications associated with transvenous leads[1]:

Endocarditis • Perforation • Vascular complications • Lead fractures • Lead extractions • Lead dislodgement

Transvenous lead complications—both acute and chronic—can be avoided by choosing the S-ICD system

In addition to risks, consider the clinical advantages of the S-ICD System that can drive improved patient outcomes:

Effective defibrillation without transvenous leads	The subcutaneous placement of the electrode avoids many potential complications associated with transvenous leads	New alternative for prior transvenous ICD (TV-ICD) recipients who do not want or cannot have, another TV-ICD	A solution that leaves the heart and vasculature untouched

EMBLEM™ MRI S-ICD SYSTEM

Subcutaneous Implantable Defibrillator

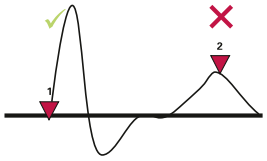
INSIGHT™ Algorithm

PHASE I
Detection

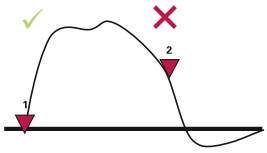
The DETECTION phase filters the Subcutaneous (S-ECG) signal and generates detections for further analysis. A variety of profiles are used for detection of signals.

PHASE II
Certification[1]

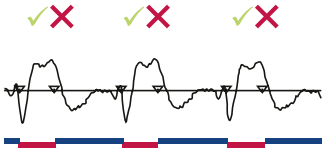
The CERTIFICATION phase analyzes the detected events and classifies them as cardiac or noise. Four algorithms are used to identify oversensing and ensure an accurate heart rate.

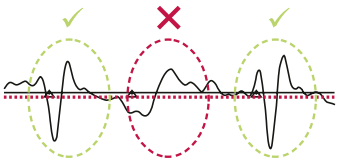


Static Template Analysis



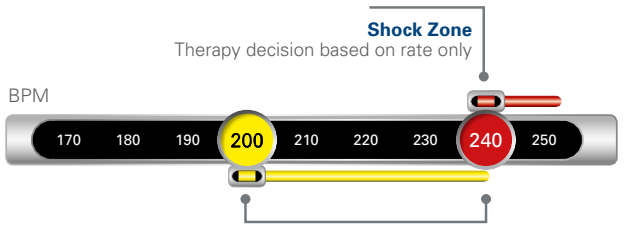
Wide Complex Analysis


Interval Analysis

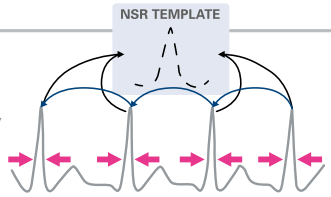

Alternating Morphology Analysis

PHASE III
Therapy Decision

During the Therapy Decision phase, the INSIGHT algorithm discriminates between treatable and other high-rate events such as AF, sinus tachycardia, and other SVTs, helping to avoid inappropriate therapy. The Conditional and Shock Zone settings are programmable.



The INSIGHT algorithm utilizes three simultaneous rhythm analyses to identify and classify the heart rhythm.



- **Static morphology analysis** identifies non-shockable rhythms, utilizing the Normal Sinus Rhythm (NSR) template
- **Dynamic morphology** analysis identifies shockable polymorphic rhythms by comparing each complex to the previous ones
- **QRS width analysis** compares the QRS width to the NSR QRS width

1. M.C. Burke et al. Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator: 2-year Results from a Pooled Analysis of the IDE Study and EFFORTLESS Registry. JACC 2015

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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 resterilize. 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 (and higher). During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter 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.

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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. For a list of all potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. Rx only.

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CRM-394206-AA AUG2016

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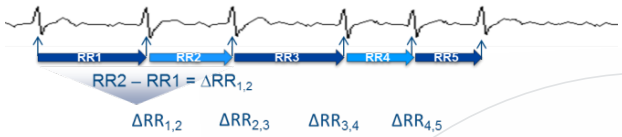
Subcutaneous Implantable Defibrillator

Third Generation Technology

1 AF Monitor™

Designed to assist in the detection of silent, new onset, or the progression of atrial fibrillation.[1]

- Uses Ventricular Scatter (R-R variability) and Heart Rate Density algorithms to determine atrial fibrillation
- Optimized for Positive Predictive Value (PPV) to reduce false positives

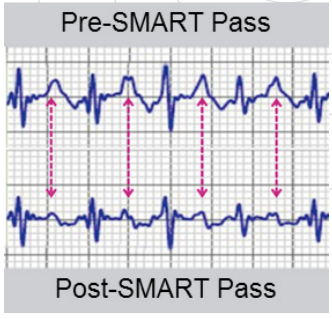


Metric	Definition	Result: EMBLEM MRI Manual[1]	Result: Boersma, et al[3]
Sensitivity	Patient has AF and monitor detects AF / Total Patients w/ AF	≥ 87%	94.9%
PPV	Patient has AF and monitor detects AF / Patients detected with AF by monitor	≥ 90%	100%

2 SMART Pass

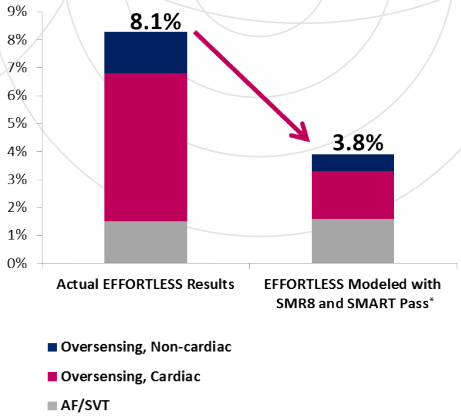
SMART Pass is a high pass filter designed to reduce cardiac over-sensing

- When EFFORTLESS IAS episodes were modeled with SMART Pass, cardiac over-sensing was reduced by 71% from EMBLEM devices[4]
- Advanced INSIGHT algorithm shown to have superior performance versus TV-ICDs on AF/SVT discrimination[1]
- Backwards compatible with EMBLEM S-ICD Systems



Example: Amplitude reduction by signal frequency which primarily reduces T-waves

Percent of Patients with Inappropriate Shock in the 1st year[4]



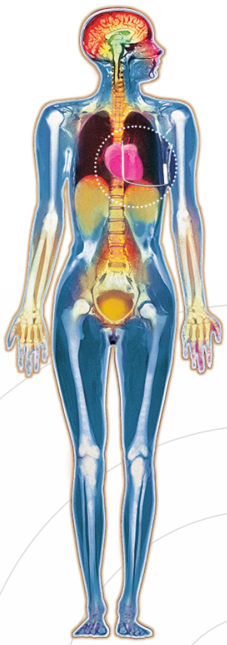
*Actual EFFORTLESS episodes were modeled with the next generation of software to determine an estimated 1-year rate of IAS.[4]

EMBLEM™ MRI S-ICD SYSTEM

3 ImageReady™ MR-Conditional System*[1,2]

Designed to allow full body, 1.5 tesla scans with no time limitations.
For more information and resources visit: www.bostonscientific.com/imageready

- 1.5T MR-conditional
- Automatic MRI Timeout Mode
- No exclusion zones
- No time limitations during MRI scan
- No patient restrictions
- Simple programmer interface
- Dedicated MRI report for clinic documentation
- MRI mode viewable on LATITUDE™
- Updated MR-conditional label for EMBLEM S-ICD System and S-ICD electrode



1. EMBLEM S-ICD, EMBLEM MRI S-ICD User's Manual, 359480-001 EN US 2015-11
2. EMBLEM MRI S-ICD A219: MRI Technical manual 359474-001 EN US 2015-11
3. Boersma, L. et al. Performance of a Novel Atrial Fibrillation Detection Algorithm for Use in Patients with a Subcutaneous Implantable Cardioverter Defibrillator. HRS 2016; AB05-02.
4. Theuns, D, et al. Evaluation of a Novel Algorithm Designed to Reduce Oversensing in the S-ICD. HRS 2016; AB05-01.
5. Gold, M.R., et al. (2011). "Head-to-Head Comparison of Arrhythmia Discrimination Performance of Subcutaneous and Transvenous ICD Detection Algorithms: The START Study." J Cardiovasc Electrophysiol. In press Epub doi: 10.1111/j. 1540-8167.2011.02199

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EMBLEM™ MRI S-ICD SYSTEM

Subcutaneous Implantable Defibrillator

Innovation Backed by Evidence

The US IDE Study, EFFORTLESS Registry, and Pooled Analysis 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]

- Largest patient cohort, longest follow-up period and most comprehensive data further demonstrates the worldwide safety and efficacy of the S-ICD System in a large diverse population

Largest Patient Cohort

Longest Follow-up Period

MOST *Comprehensive* DATA

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 %

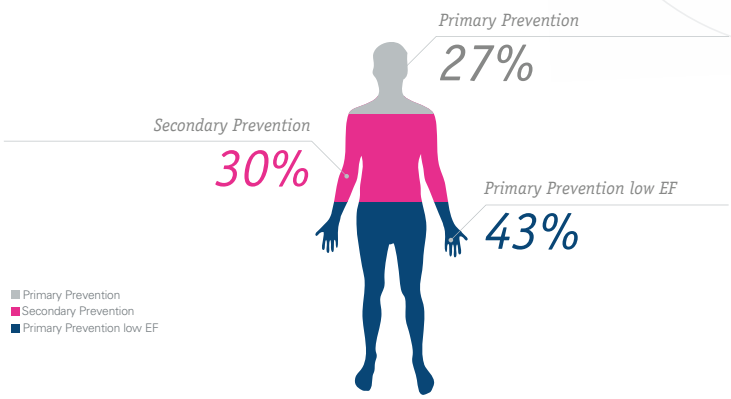
EFFORTLESS Registry Interim Results (Published in European Heart Journal in early 2014)[3]

- 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 Analysis Implanted Patients (n = 882)

43% OF THE S-ICD ANALYSIS POPULATION WERE PRIMARY PREVENTION PATIENTS WITH AN EF ≤35%



Demographic	N (%)
Age (years)	50.3 ± 16.9
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 %)
Atrial Fibrillation	143 (16.4 %)
Previous Defibrillator	120 (13.7 %)

Boston Scientific does not promote the pediatric use of S-ICD

EMBLEM™ MRI S-ICD SYSTEM

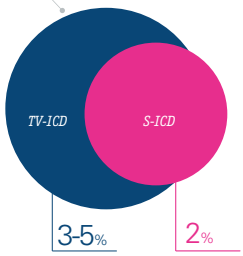
2. Data from the Pooled Analysis has demonstrated a SAFE solution for sudden cardiac death

Complications

= ZERO
Systemic Blood Infections or Endocarditis
Electrode Failures
Cardiac Injuries

There were zero endovascular infections or electrode failures.[1]

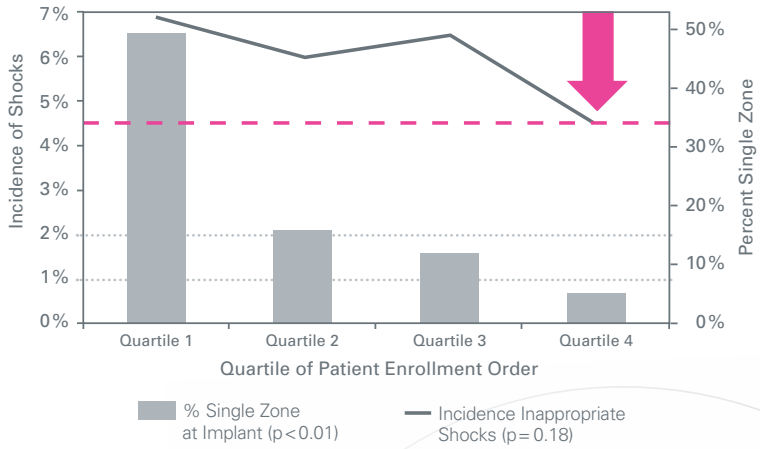
S-ICD HAD LOWER ACUTE MAJOR COMPLICATIONS THAN SEEN IN TV-ICD STUDIES[8,9]



Lower acute major complication rate (Hematoma, lead or device mal-position or displacement, pneumothorax) likely because S-ICD doesn't require venous access.[1]

Inappropriate Shock (IAS)

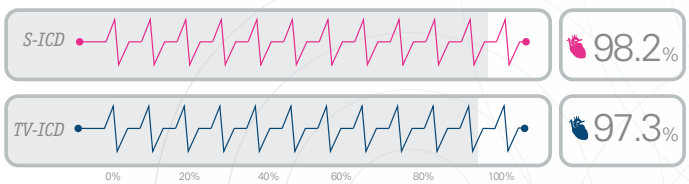
AT 6 MONTHS, IAS RATE REDUCED BY 34% WITH A 4.5% INCIDENCE OF IAS[1]



Improvements in S-ICD screening associated with patient selection and adoption of dual zone programming were associated with a lower rate of inappropriate shock.[1]

3. Data from the Pooled Analysis has demonstrated an EFFECTIVE solution for sudden cardiac arrest

S-ICD EFFECTIVENESS DATA SHOWED SIMILAR RESULTS TO TV-ICD DATA IN TREATING SPONTANEOUS ARRHYTHMIAS[4-7]



1 Burke MC et al. Pooled Analysis of the EFFORTLESS and IDE Registry. JACC 2015; online April 20th.
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 Cha YM et al. Heart Rhythm 2013;10:702–708.
5 Swerdlow CD et al. PACE 2007; 30:675–700.
6 Kutyifa V, et al. J Cardiovasc Electrophysiol 2013;24:1246-52.
7 Gold MR et al. Circulation 2002;105:2043-2048.
8 NCDR Analysis (Peterson et al, JAMA 2013)
9 Meta-analysis (van Rees et. al. JACC 2011)

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EMBLEM™ MRI S-ICD SYSTEM

Subcutaneous Implantable Defibrillator

Patient Selection

Who Should be Considered for the EMBLEM S-ICD System*

Characterization of Patient Groups for S-ICD Implantation based on the Poole and Gold publication

The S-ICD™ System is preferred for:

- No venous access (occluded or congenital)
- High risk of complications for TV-ICD(dialysis, immunocompromised)
- Channelopathies (LQT, Brugada, HCM)
- Previous device infections or lead failures
- H/O endocarditis

The S-ICD System should be strongly considered for:

- Younger patients
- Life expectancy > 10yr
- Primary prevention with ischemic/ non-ischemic heart failure
- Prosthetic valves
- Women (preferred generator placement)
- Selected secondary prevention (survivors out of hospital VF, no evidence of MVT)

The S-ICD System should be avoided

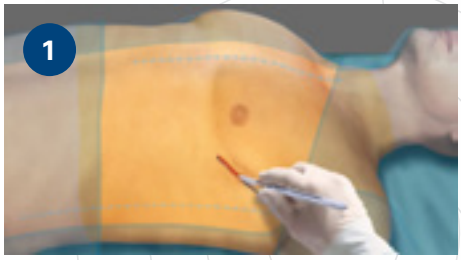
- Systolic HF and LBBB → CRT
- Symptomatic bradycardia requiring pacing
- Incessant or spontaneous, frequently recurring MVT that is reliably terminated with ATP

*Based on the article by Dr. Jeanne Poole and Dr. Michael Gold: Poole, J and Gold, M. Who Should Receive the Subcutaneous Implanted Defibrillator? The Subcutaneous Implantable Cardioverter Defibrillator Should be Considered in all ICD patients Who Do not Require Pacing. Circulation 2013; 6: 1236-1245.

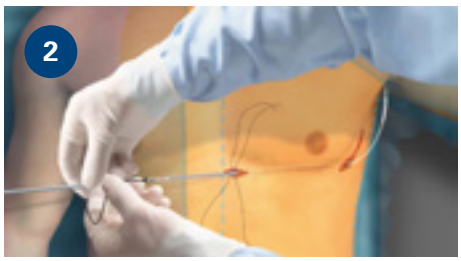
Implant Technique

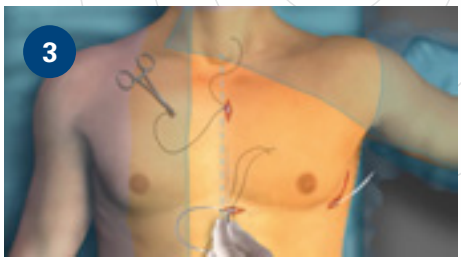
Before implant, record a 3-lead surface ECG to assess the appropriateness of surface signals that correlate with device detection.

*Please see labeling for full implant instructions

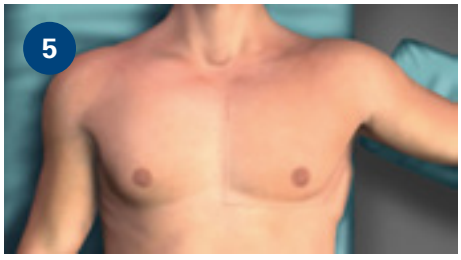


Once the patient has been properly prepped and draped, an incision is made to place the pulse generator at the mid-axillary line between the 5th and 6th intercostal spaces.





The electrode is positioned through two subcutaneous tunnels from the pocket to the xiphoid incision and from the xiphoid to the superior incision.



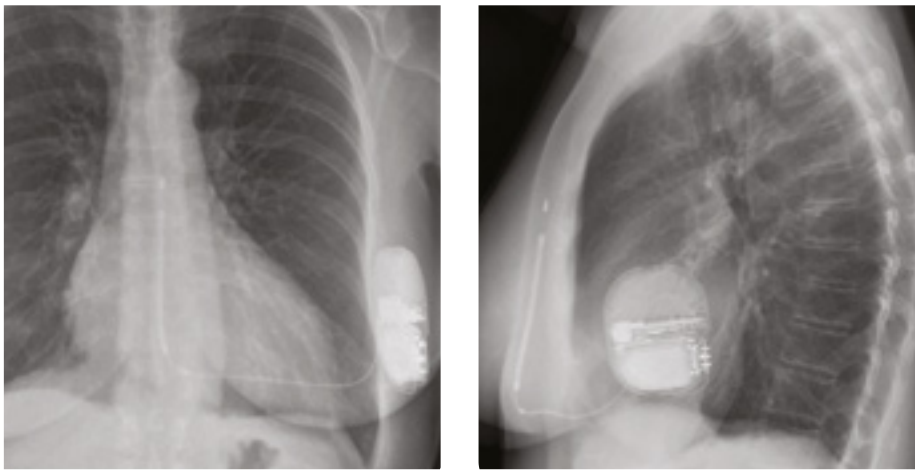
The pulse generator is then connected to the subcutaneous electrode and secured in the pocket.

EMBLEM™ MRI S-ICD SYSTEM

Optimal
S-ICD Placement

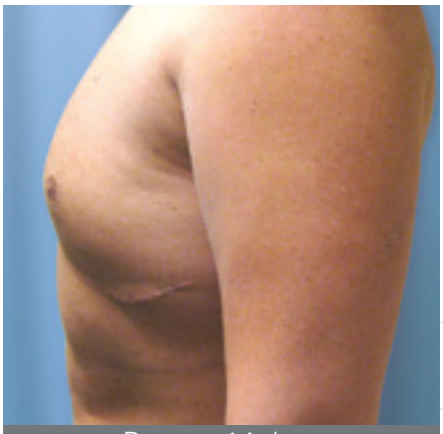
Post-implant X-rays show optimal placement of the pulse generator and subcutaneous electrode.

Note: This image shows the placement of the S-ICD™ System in a patient. Device location recommendations do not change from the S-ICD System to the EMBLEM S-ICD.

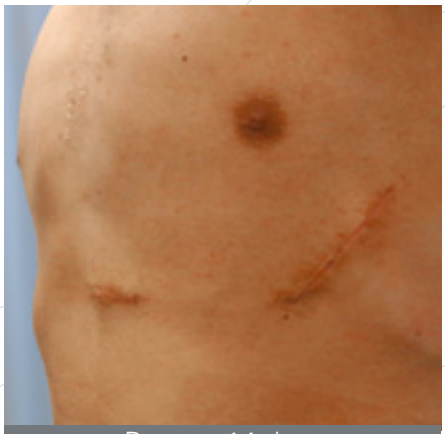


Excellent Cosmetic Outcome

The pulse generator's discrete pocket placement offers excellent aesthetic results, even in slender patients. Once implanted, the EMBLEM S-ICD System is designed to not limit range of motion and most patients are able to resume normal daily activity shortly after the procedure.



Post-op 14 days



Post-op 14 days

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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EMBLEM™ MRI S-ICD SYSTEM

Subcutaneous Implantable Defibrillator

EMBLEM MRI S-ICD System Individual Components

Model Number	Description
A219	EMBLEM MRI S-ICD Pulse Generator
3401	EMBLEM S-ICD Subcutaneous Electrode
4711	EMBLEM S-ICD Subcutaneous Electrode Insertion Tool
3200	EMBLEM S-ICD Programmer

*The EMBLEM MRI S-ICD pulse generator is also compatible with the 3400/3010 Subcutaneous Electrode and the 4710/3400 Subcutaneous Electrode Insertion Tool

1. Boston Scientific CRM Product Performance report. June 2016.
2. EMBLEM S-ICD, EMBLEM MRI S-ICD User's Manual, 359481-001 EN US 2015-11
3. EMBLEM MRI S-ICD A219: MRI Technical manual 359475-001 EN US 2015-11
4. Gold, M. R., et al. (2011). "Head-to-Head Comparison of Arrhythmia Discrimination Performance of Subcutaneous and Transvenous ICD Arrhythmia Detection Algorithms: The START Study." J Cardiovasc Electrophysiol. In press Epub, doi: 10.1111/j.1540-8167.2011.02199

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