ICD-10 PCS Code Request: Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) Lead

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Agenda

1. S-ICD Overview
    a. Milestones, Payer Coverage, Volume
    b. S-ICD Indications
    c. TV-ICD/S-ICD
    d. Automated Screening Tool
    e. S-ICD Procedure: Implanting the S-ICD
2. S-ICD System Clinical Evidence
3. Summary

S-ICD is a Well-Established Therapy with Extensive Coverage by U.S. Payers

S-ICD Milestones

- FDA approved in the US Sept 2012.
- CE marked and available in Europe since Sept 2009.
- 2nd Generation device (EMBLEM) CE marked and FDA approved in 2015.
- S-ICD is actively marketed in >25 countries around the world.

Broad Coverage

- CMS coverage established in 2013.
- S-ICD is covered under the NCD for ICDs (updated February 2018).
  - No further restrictions on coverage beyond criteria specified in FDA indications
- All major U.S. Commercial Plans offer positive S-ICD coverage affecting over 92% (>187M) Commercial covered lives.[1]

S-ICD Procedure Volume

- Over 26,000 U.S. S-ICD implants since 2012 product launch.[2]
- 2017 MedPar Inpatient Volume:
  - 887 full-system implants (generator and lead).
- 2016 Site of Service, CY2016 Medicare Physician/Supplier Procedure Summary (PSPSF):
  - 36% Inpatient Hospital.
  - 63% Outpatient Hospital.

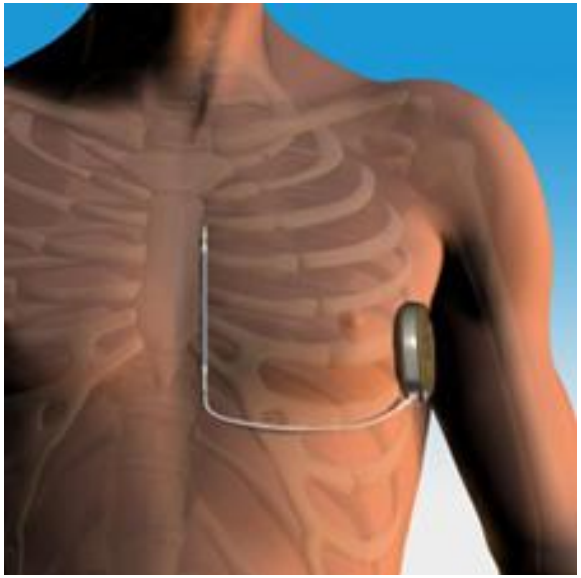
Transvenous vs. Subcutaneous ICD

Transvenous ICD

Documented Need for Bradycardia Pacing

Subcutaneous ICD (S-ICD)

No need for Bradycardia Pacing or Antitachycardia Pacing

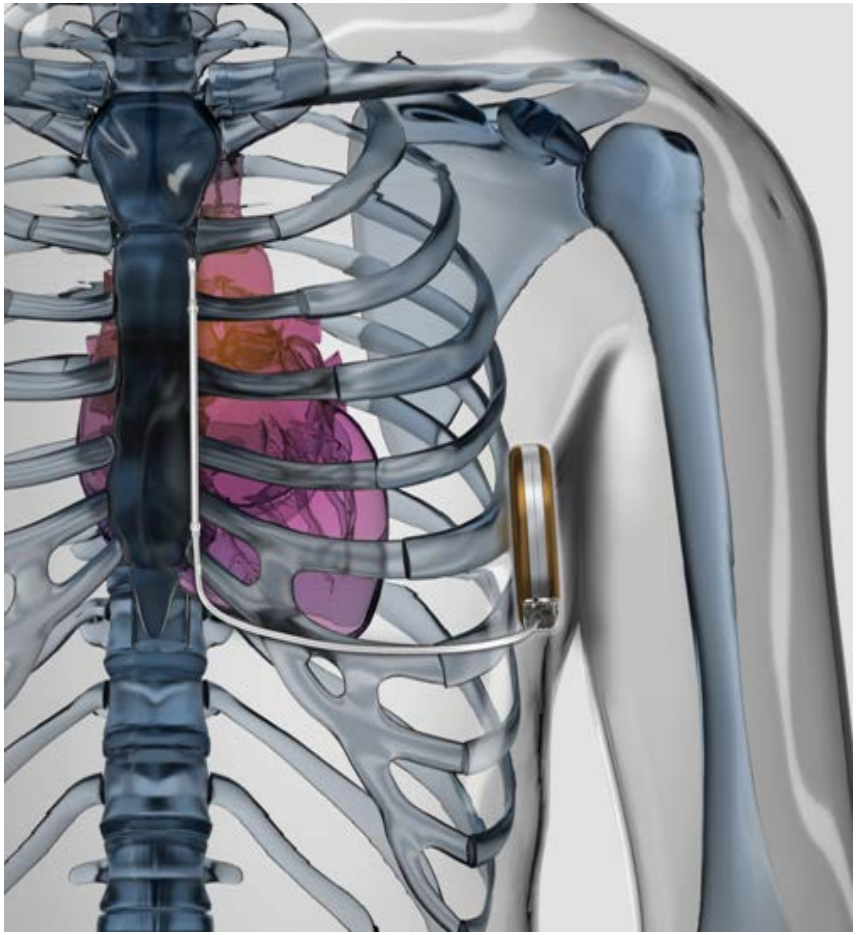


S-ICD Indications for Use

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

Effective Defibrillation without Transvenous Leads

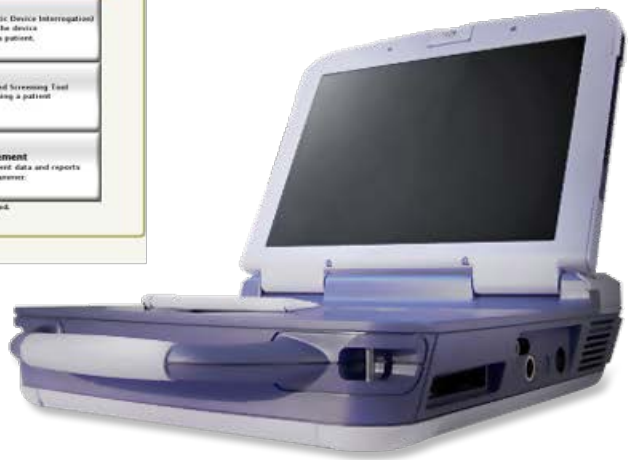


The S-ICD System:

- Completely subcutaneous. Does not require leads in the heart, leaving the vasculature untouched.
- Requires a different approach and technique compared with TV-ICD.
- Placed according to anatomical landmarks, removing the need for fluoroscopy at implant.

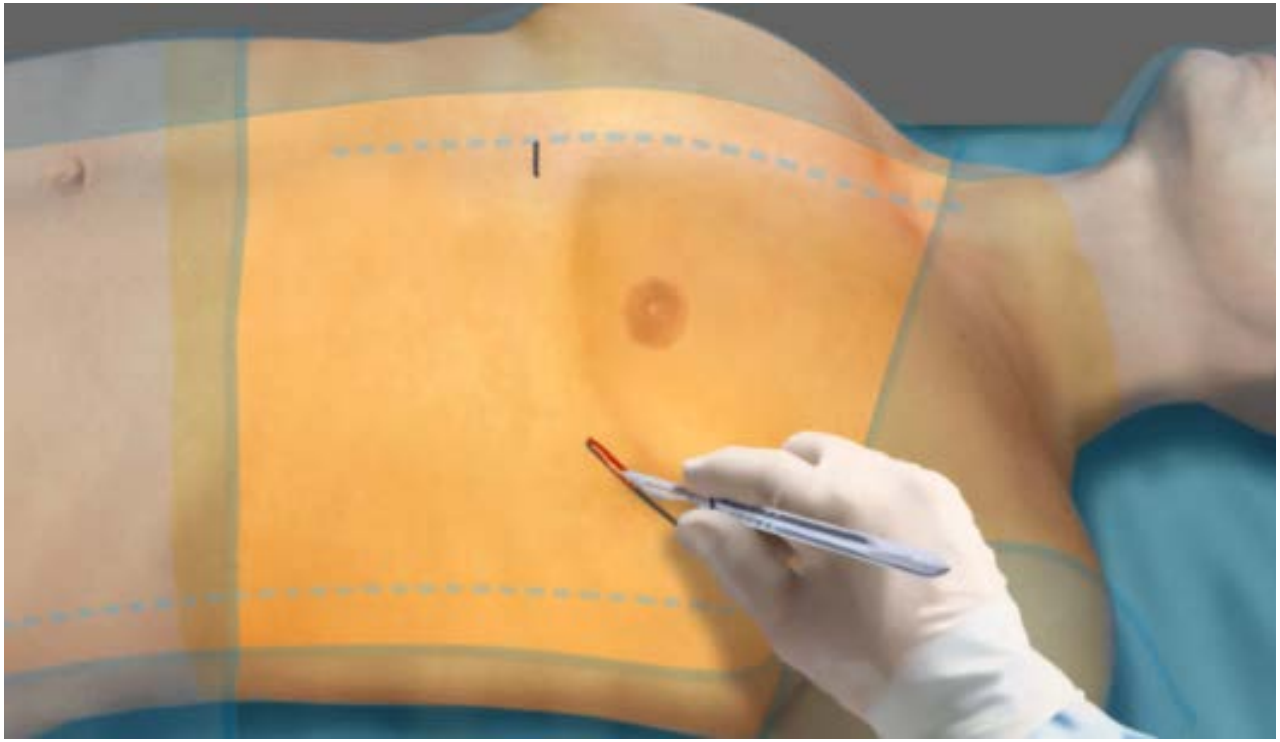
Automated Screening Tool

- Increases efficiency, decreases subjectivity in S-ICD patient screening and improves the screening workflow.
- The Automated Screening Tool applies the Vector Select algorithm that is used by the S-ICD to sense the cardiac signal, and is designed to more closely represent S-ICD device performance.[3]



Implanting the S-ICD

Creation of the Device Pocket



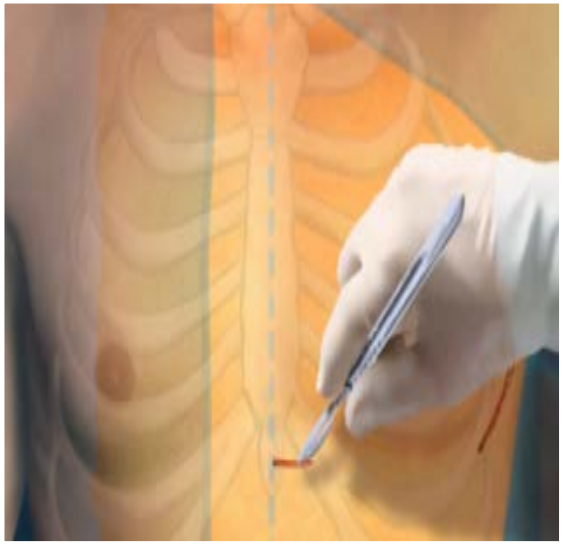
Implanting the S-ICD

Lateral Tunnel

Creation of the Lateral Tunnel

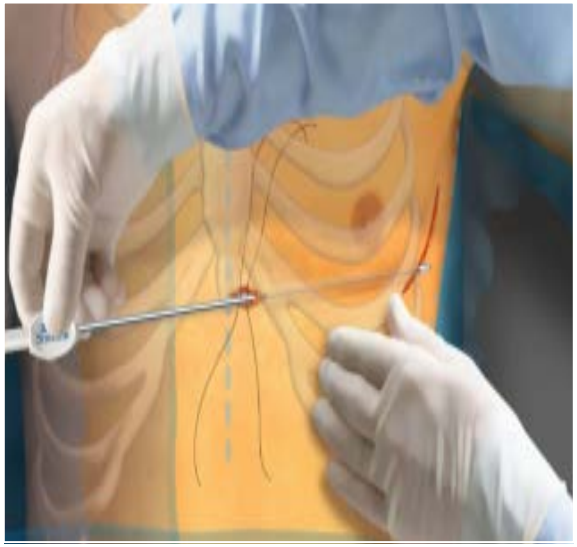
A small (~2cm) horizontal incision is made at the xiphoid process.

NOTE: The size and orientation of this incision may vary at the physician's discretion based on the patient's body habitus.



Use of the tunneling tool

Use the dedicated tunneling tool, a tract is tunneled from the xiphoid incision laterally to reach the pocket incision.

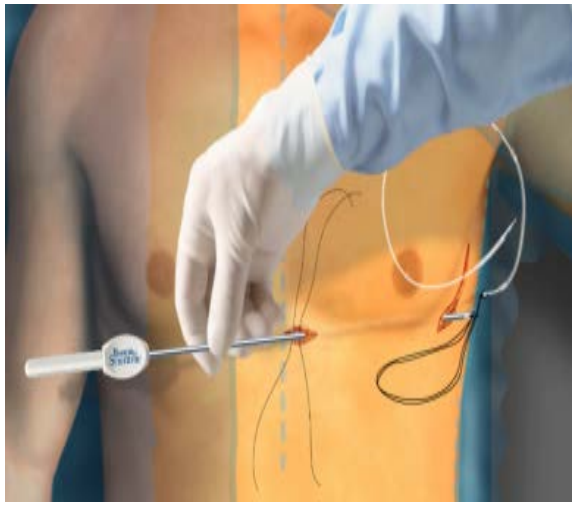


Implanting the S-ICD

Lateral Lead Placement

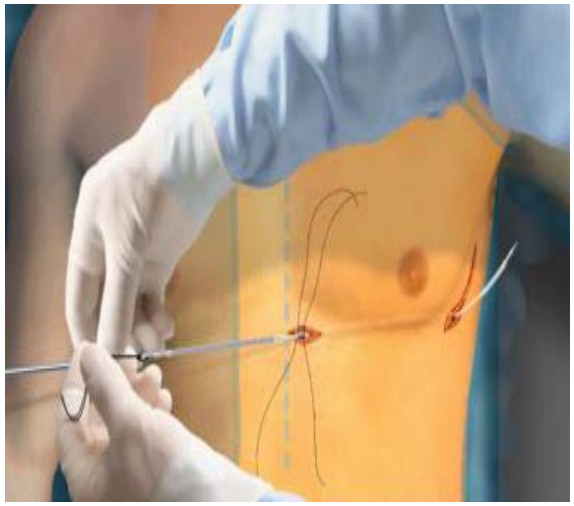
Lateral tunnel

Using conventional suture material, the anchoring hole at the distal end of the subcutaneous electrode is tied to the suture hole at the distal end of the tunneling tool.



Lateral tunnel (cont.)

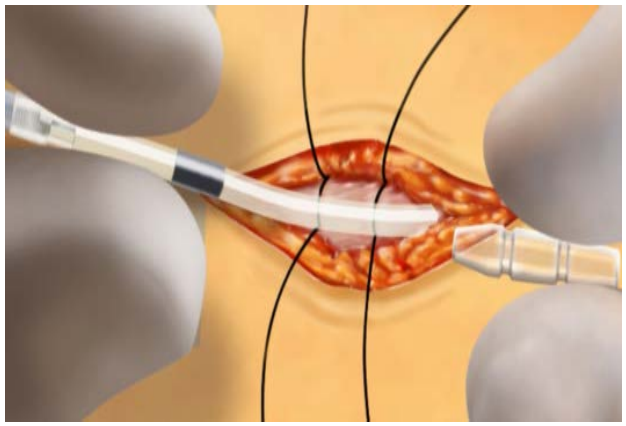
The tunneling tool, with the electrode attached, is then pulled back through the tunnel to the xiphoid incision until the proximal sensing electrode emerges.



Implanting the S-ICD
Superior Tunnel

Anchoring the Electrode at Xiphoid Incision

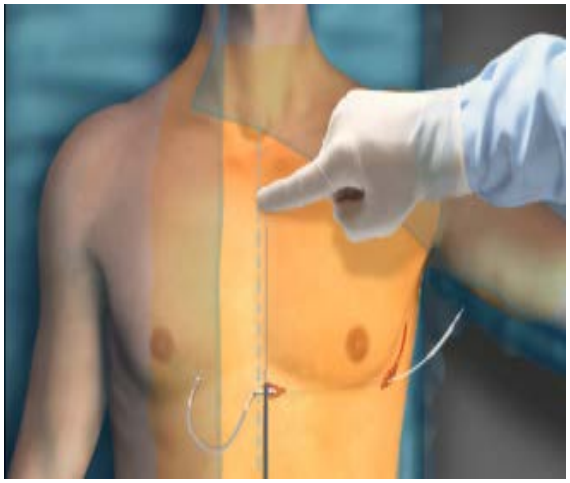
The integrated suture sleeve is anchored to the deep fascia using the suture grooves and pre-placed suture ties.. This ensures that it is secure on the electrode body, and that the electrode is anchored securely in place.



Creation of the Superior Tunnel

The distal tip of the tunneling tool into the xiphoid incision between the adipose and fascial plane and is used to tunnel subcutaneously towards the superior position, in parallel to the sternal midline.

- The tunnel must be made as close to the deep fascia as possible.
- The distal end should reach the desired location for the distal tip of the electrode.

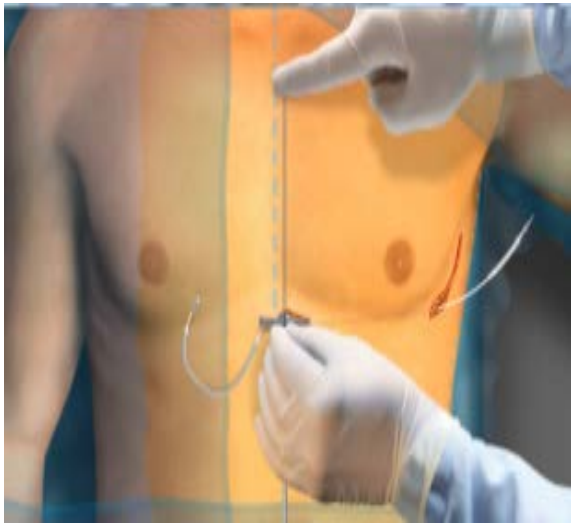


Implanting the S-ICD

Superior Lead Insertion

Completion of lead placement

The sheath is advanced over the tunneling tool, which is then removed, leaving the sheath accessible. The lead is inserted superiorly via the sheath.



Securing Pulse generator

A non-absorbable suture is tied to the suture hole on the device header.

Implanting the S-ICD

Securing the Device, Final Testing

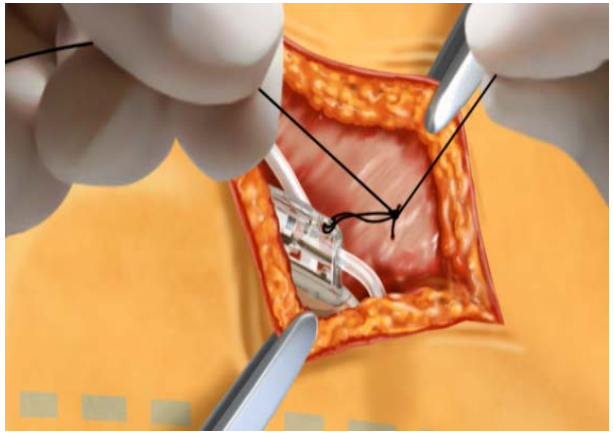
Insertion of device

The device is inserted into the subcutaneous pocket, with any excess subcutaneous electrode placed underneath the device.

Securing device

The device is then secured to the fascial place covering the serratus anterior muscle using non-absorbable suture material.

All air is expelled, the incisions are closed, and device setup and final device testing are performed.



S-ICD System Clinical Evidence

Growing Clinical evidence supports the S-ICD System

Recent Clinical Evidence

IDE Study (Weiss 2013)[4]

Study Design: Prospective, multi-center, single-arm IDE study in the US, UK, NZ, and Netherlands. N=314 patients with successful implantation (321 attempted).
Safety Results: Primary endpoint (Freedom from Type 1 complications) met with a 99% success rate. No lead failures, endocarditis, bacteremia, cardiac perforation, tamponade, pneumothorax, hemothorax, or subclavian vein occlusion. No known arrhythmic deaths.
Efficacy Results:100% success rate in primary endpoint treating induced ventricular fibrillation in the 304 patients who completed testing. Of the 899 episodes of induced VT or VF (acute or chronic), 897 (99.8%) resulted in accurate detection and defibrillation.

Latest EFFORTLESS Results (Boersma 2017)[5]

Study Design: Single arm, multi-center study with 985 implanted subjects; 928 with 1-year follow-up. Average follow-up of 3.1 years.
Safety Results: S-ICD complication rates were 0.3% and 2.0% at 30- and 360-days. 98% freedom from S-ICD complication at 1-year. No reports of endocarditis. System and procedure complication rate 4.1% at 30-days; 8.4% at 360 days: 48 patient deaths reported (4.8%). No deaths were associated with the S-ICD system procedure.
Efficacy Results: 99.5% of subjects at implant had a successful conversion of induced ventricular tachycardia or fibrillation.10.6% (annual incidence 3.4%) had appropriately treated VT or VF episodes.

Recent Clinical Evidence (cont.)

Early Post-Approval Study Results (Gold, 2017)[6]

Study Design: Prospective, 86 U.S. center registry, N=1,637 patients with 30-day follow-up.
Safety Results: 96.2% 30-day complication-free rate. 99% freedom from complications directly caused by the S-ICD device at 30 days.
Efficacy Results: Induced ventricular tachycardia/ventricular tachycardia successfully converted in 98.7% of patients. First shock conversion achieved in 95.6%.

Meta-Analysis of Case Controlled Studies (Basu-Ray, 2017)[7]

Study Design: Five studies met inclusion criteria; 257 abstracts screened.
Safety Results: Fewer lead complications occurred in S-ICD groups (OR=0.13).
Similar infection rate between groups (OR=0.75). No differences in system or device failure (OR=1.13)
Efficacy Results: Overall inappropriate therapy similar between groups (OR=0.87) but nature of the inappropriate therapy was different; TV-ICD group primarily due to SVT; S-ICD primarily due to oversensing

Propensity Matched Analysis of NCDR ICD Registry (Friedman, 2016)[8]

Study Design: Matched 1,920 S-ICDs to the same number of single and dual chamber TV-ICDs
Safety Results: In the entire S-ICD population (N=3,703) there was a rate of 1.2% overall complications, including cardiac arrest (0.4%), death (0.3%), and lead dislodgement (0.1%). No reports of stroke, TIA, pericardial tamponade, pneumothorax, or cardiac perforation. Only 5 (0.1%) required a system revision during the index hospitalization. In matched analysis, no significant differences in overall complication rates or in-hospital mortality rates.
Efficacy Results: Of the 2,791 who underwent DFT testing, 99.7% were successfully defibrillated at 80J or less. Mean length of stay for S-ICD was similar to Single Chamber ICDs but significantly shorter compared to Dual Chamber ICDs (1.2 vs. 1.5 days)

2017 AHA/ACC/HRS Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death[9]

Class I Recommendation:

In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed or anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended. (LOE: B-NR)

Class IIa Recommendation:

In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed not anticipated. (LOE: B-NR)

Class III (Harm) Recommendation:

In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted. (LOE: B-NR)

LOEB: NR = Moderate quality evidence from 1 or more well-designed, well-executed non-randomized studies, observational studies or registry studies. Meta analysis of such studies.

Summary

- Recent clinical publications continue to demonstrate the safety and efficacy of the S-ICD system.
- S-ICD is covered by Medicare and vast majority of U.S. Commercial Payers.
- The lack of a dedicated ICD-10-PCS code does not facilitate accurate reporting and tracking of the subcutaneous lead implant procedure for patient outcomes, cost and any device-related complications necessary for data analysis.

References

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8. Friedman DJ, Parzynski CS, Varosy PD, Prutkin JM, Patton KK, Mithani A, et al. Trends and In-Hospital Outcomes Associated With Adoption of the Subcutaneous Implantable Cardioverter Defibrillator in the United States. JAMA Cardiol 2016. 1(8): p. 900-911.
9. Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB, Deal BJ, Dickfeld T, Field ME, Fonarow GC, Gillis AM, Hlatky MA, Granger CB, Hammill SC, Joglar JA, Kay GN, Matlock DD, Myerburg RJ, Page RL, 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. *Heart Rhythm. 2017. Epub before print.* doi: 10.1016/j.hrthm.2017.10.036.

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 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 it's 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 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.

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.

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

(Rev. C)