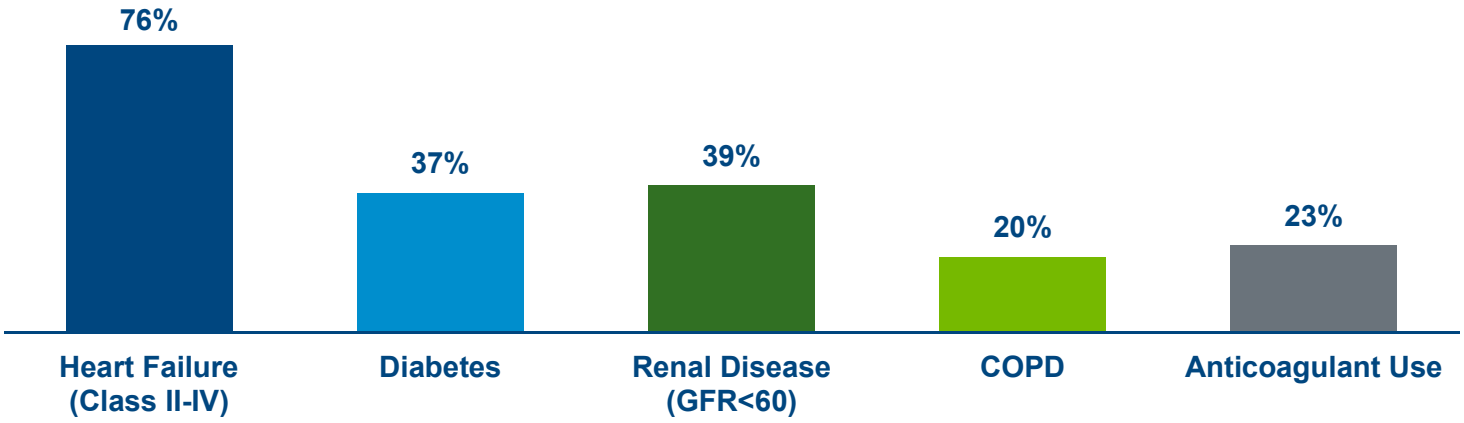
WHAT IS THE ROLE OF S-ICD FOR ICD PATIENTS AT HIGH RISK FOR INFECTION?

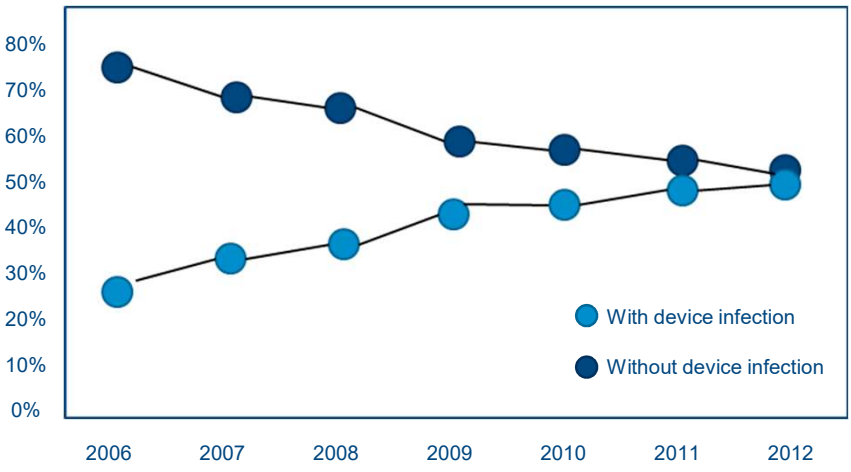
PATIENT COMORBIDITIES AND THE RISK OF INFECTION

~76% of ICD patients in the U.S. have ≥1 comorbidity associated with high risk for infection[1-2]



TRANSVENOUS LEAD EXTRACTIONS DUE TO INFECTION[5]

Trends in Transvenous Lead Removal by Indication

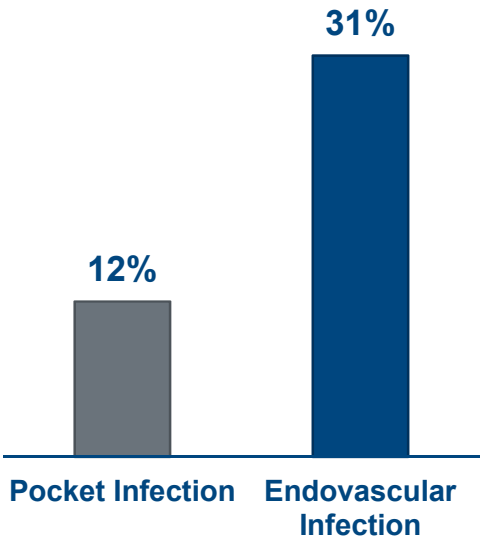


In 2012, approximately 12,000 transvenous leads were extracted. Approximately 6,000 or 50% of the extractions were for infection.

Data shows that extraction for device infection is increasing over time while extraction for mechanical lead failure is decreasing.

1 YEAR MORTALITY RATE OF 12-31% FOLLOWING LEAD EXTRACTION[6]

A study from the Cleveland Clinic found that patients with transvenous device infections had a 12% mortality rate for a pocket infection at 1 year and a 31% mortality rate for an endovascular infection at 1 year.



WHY S-ICD FOR PATIENTS AT HIGH RISK FOR INFECTION?[3-4]

No Serious Bloodstream Infections

There were **ZERO** cases of serious bloodstream infections with S-ICD in the EFFORTLESS 3 year follow-up study.[4]

AHA/ACC/HRS Guideline Recommended

S-ICD is Class I recommended for patients who are at high risk of infection or have inadequate vascular access and Class IIa recommended for any ICD patient if pacing is not required for bradycardia or VT termination or as part of CRT.

1. Polyzos, et al., Risk factors for cardiac implantable electronic device infection: a systematic review and meta-analysis. Europace, 2015.
2. Friedman, et al., Trends and In-Hospital Outcomes Associated With Adoption of the Subcutaneous Implantable Cardioverter Defibrillator in the United States. JAMA Cardiol, 2016.
3. Al-Khatib, et al., 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, Heart Rhythm 2017.
4. Boersma, et al., Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. J Am Coll Cardiol, 2017.
5. Deshmukh, et al. Trends in Use and Adverse Outcomes Associated with Transvenous Lead Removal in the United States. Circulation. 2015.
6. Tarakji KG, et al. Risk factors for 1-year mortality among patients with cardiac implantable electronic device infection undergoing transvenous lead extraction: the impact of the infection type and the presence of vegetation on survival. Europace. Apr 2014.

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 stimulation and impedance-based features are contraindicated for use with the S-ICD System.
WARNINGS
Concomitant use of the S-ICD System and implanted electromechanical devices (for example implantable neuromodulation/neurostimulation systems, 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. The S-ICD is intended as lifesaving therapy and should be seen as priority in the decision and evaluation of concomitant system implants over non-lifesaving applications. 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/or compromise its functionality. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. 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. Induction testing is recommended to ensure appropriate detection and time to therapy for the S-ICD and appropriate post-shock operation of the co-implanted device. Failure to ensure appropriate detection and time to therapy delivery of the S-ICD system could result in patient injury or death. Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions changes which may affect S-ICD sensing and therapy performance, re-evaluation of the co-implanted devices may be required. 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.
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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, supplemental precautionary information.
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, injury to or pain in upper extremity, including clavicle, shoulder and arm, 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. E) 046774 AI

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