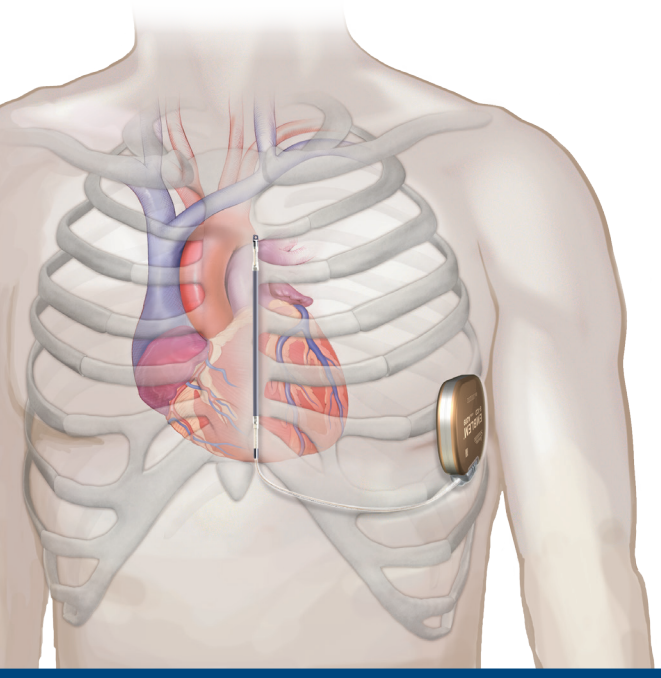
Boston Scientific
Advancing science for life™

Referring patients at risk of Sudden Cardiac Arrest?

THINK S-ICD *first.*

When you're referring a patient who is indicated for an ICD, consider an S-ICD: the first and only FDA-approved subcutaneous implantable defibrillator that leaves the vasculature untouched and avoids the risks associated with transvenous leads.

IMPORTANT FACTS TO KNOW ABOUT EMBLEM™ S-ICD SYSTEM



S-ICD PLACEMENT

What is an S-ICD?

A new generation of ICD therapy, S-ICD protects against sudden cardiac arrest and:

- Is implanted just underneath the skin on the left side of the chest next to the rib cage
- Analyzes heart rhythm using a subcutaneous electrode to effectively sense, discriminate and convert VT/VF
- Leaves the heart and blood vessels untouched and intact

Who may benefit from an S-ICD?

S-ICDs are appropriate for a wide range of indicated patients and are preferred for those who have:[1]

- No venous access
- High risk of complications for TV-ICD
- High risk of infections
- Channelopathies (LQT, Brugada, HCM)
- History of endocarditis

S-ICDs are also a good option for patients who are 70 and younger and/or lead an active lifestyle.

How does an S-ICD compare to an ICD?

- S-ICDs are designed to allow self-termination of non-sustained tachyarrhythmias
- They offer the same protection against sudden cardiac arrest as ICDs[2,3,4]

What are the benefits of an S-ICD?

An S-ICD:

- Eliminates the potential for vascular injury
- Reduces the potential for systemic infection
- Preserves venous access and avoids potential complications associated with endovascular lead implantation or extraction
- Requires few or no upper-body restrictions and is compatible with an active lifestyle

Learn more about how an S-ICD can protect your patients against sudden cardiac arrest at **bostonscientific.com/thinksicd.**

1 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: Arrhythmia and Electrophysiology. 2013; 6: 1236-1245.

2 Weiss R, et al. Safety and Efficacy of a Totally Subcutaneous Implantable-Cardioverter Defibrillator. Circulation 2013. 2013; 128:944-953.

3 Lambiase, et al. Worldwide Experience with a Totally Subcutaneous Implantable Defibrillator: Early Results from the EFFORTLESS S-ICD Registry. European Heart Journal Mar2014.

4 Head-to-Head Comparison of Arrhythmia Discrimination Performance of Subcutaneous and Transvenous ICD Arrhythmia Detection Algorithms: The START Study. Journal of Cardiovascular Electrophysiology. 2012 Apr; 23(4):359-66.

Emblem™ S-ICD System from Boston Scientific CRM

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. 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. Do not expose a patient to MRI scanning. 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. B)

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