The S-ICD® System: factsheet

Boston Scientific’s S-ICD® System is a defibrillator that senses, detects, and treats life-threatening ventricular tachyarrhythmias. Like standard transvenous implantable cardioverter defibrillators (ICDs), the S-ICD System is used to treat life-threatening ventricular tachyarrhythmias.

The S-ICD System is the world’s first and only subcutaneous implantable defibrillator that provides protection from sudden cardiac arrest (SCA) while leaving the heart and vasculature untouched. It uses highly sophisticated technology to identify and classify the heart rhythm—rather than individual beats—to effectively sense and discriminate ventricular tachycardia (VT)/ventricular fibrillation (VF) from other rhythms that do not require shock therapy.

SCA is a very serious heart condition that can lead to death, if not treated within minutes. More than 95% of sufferers die before they ever reach the hospital.1 An electrical shock administered to the heart can reset the heart’s rhythm and restore normal blood flow throughout the body. Implantable defibrillator systems are capable of automatically delivering these lifesaving shocks when needed. This is called defibrillation therapy.

Patient eligibility

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.

The System

The S-ICD System is completely subcutaneous and does not require leads in the heart, leaving the vasculature untouched.

The system consists of a subcutaneous pulse generator and a single subcutaneous lead. The pulse generator is implanted in a subcutaneous pocket on the left side of the chest, next to the rib cage. The lead is implanted using a subcutaneous approach instead of the standard transvenous approach required to implant traditional ICD leads. Since the S-ICD System utilises a single lead, there are no dual or multiple lead S-ICD Systems.

The design of the S-ICD System represents a major breakthrough in defibrillation therapy and provides an important new option for patients that are at risk of SCA.

Just as wires are used on patients’ chest to monitor their heart during an electrocardiogram or “ECG”, the S-ICD System similarly monitors the heart with a wire just under the skin. Only the
S-ICD System uses this ECG-like signal to monitor the heart for abnormal rhythms that indicate SCA.

When sudden cardiac arrest is detected, the electrode delivers a shock to the heart similar to external defibrillator paddles used by paramedics. Even without directly touching the heart, the shock can reset the heart’s normal rhythm.

The device can be placed strictly by anatomical landmarks, thus removing the need for fluoroscopy at implant. 95% of patients in the S-ICD System pre-approval (IDE) clinical study received the device using only anatomical landmarks (no medical imaging).

**The procedure**

Implantation of the S-ICD System typically takes about one hour.

- Depending on the hospital’s practice, the procedure is performed under general or local anesthesia. The implantation can be done without the need for fluoroscopy or other medical imaging during the surgical implant procedure. This is intended to reduce exposure to radiation and contrast dye during S-ICD implantation and may present a new opportunity in how to manage the cath lab schedule.
- A small incision is made on the left side of the chest, next to the rib cage.
- A pocket or pouch is formed under the skin, where the S-ICD System pulse generator will be placed.
- Two small incisions are made slightly to the left of the breastbone to allow the electrode to be placed under the skin.
- The electrode is then attached to the S-ICD System pulse generator.
- Using a separate programmer that looks much like a laptop, the S-ICD System is tested and the settings adjusted to suit the patient.
- The incisions are closed to complete the procedure.

Like anything that operates on a battery, the life of the S-ICD System will depend on how much of the battery is used. The battery is used every time the device delivers therapy. So the amount of therapy delivered affects the life of the battery. The S-ICD System is projected to last about 5 years.

**Existing clinical evidence**

The S-ICD System has clinical evidence from a large patient registry in Europe and a large US premarket (IDE) clinical study demonstrating:

- Effective detection and conversion of induced and spontaneous VT/VF episodes
- Low rates of significant clinical complications
- Effective discrimination of atrial fibrillation (AF) and supraventricular tachycardia (SVT) from ventricular tachycardia (VT)/ventricular fibrillation (VF)
- Rates of inappropriate therapy consistent with TV-ICDs
Feasibility and proof-of-concept studies on 127 patients were completed in 2005\(^3\), followed by a 55-patient European trial.

- **The multi-center, single arm, European study** that resulted in obtaining CE Mark for the S-ICD System showed:\(^3\)
  - 98% conversion success of induced VF
  - During long-term follow up (10±1 months), 12 spontaneous episodes of VT detected & successfully treated in 3 patients
  - Complications occurred during early cases and resulted in system improvements
- **The START study**, evaluating the S-ICD System algorithm demonstrated:\(^4\)
  - The S-ICD system appropriately withheld therapy in 98% of cases
  - Significant improvement over inappropriate shock rates with conventional ICDs
- **The 330 patient IDE Clinical Study** evaluated safety and effectiveness of the S-ICD System in the treatment of life-threatening ventricular arrhythmias. This prospective, multicentre, single-arm clinical study conducted in the U.S., Europe, and New Zealand met both primary endpoints – efficacy (acute VF conversion rate) and safety (freedom from device-related complications; freedom from all device-, labeling-, and procedure-related complications).\(^2\)
- **The EFFORTLESS registry**, a European registry designed to capture early, mid-term, and long-term clinical outcome and cost effectiveness data of the S-ICD System is currently on going. Preliminary results showed:\(^5\)
  - 210 active patients
  - 98.5% effective conversion of induced VT/VF within 1 procedure.
  - No inappropriate shocks have been recorded for AF/SVT within a programmed conditional shock zone.
  - Annual inappropriate shock rate of 7 percent with some of these patients receiving shocks due to the rate of the arrhythmia being so high that shock therapy is applied without discrimination.
  - Additional data coming from the EFFORTLESS registry will be presented at the EHRA EUROPACE 2013 congress.

**Market availability**
The S-ICD System has been available in the UK and other European Countries since July 2009 and was approved in the United States by the Food and Drug Administration (FDA) in September 2012.

**About Boston Scientific**
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address
unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

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