

EMBLEM™ S-ICD System:

Reliable defibrillation without touching the heart – Factsheet

What is it?

EMBLEM™ S-ICD System is a **subcutaneous implantable defibrillator** (ICD) that senses, detects, and treats life-threatening ventricular tachyarrhythmias, **preventing sudden cardiac death (SCD)**.

Unlike a transvenous ICDs, where leads are fed into the heart through a vein and attached to the heart wall, the electrodes of the EMBLEM S-ICD System are placed just under the skin, **leaving the heart and veins untouched** and intact, thus avoiding potential complications associated with transvenous leads, such as infection and lead fractures.

SCD is the result of a sudden cardiac arrest (SCA), a very serious heart condition that can lead to death if not treated within minutes. **About 95% of people who have an SCA die before they reach 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.

Who is indicated to receive an EMBLEM S-ICD System?^{2,3}

Subcutaneous ICDs are an effective option for the majority of ICD patients with primary and secondary prevention^a indications who do not need pacing or cardiac resynchronization therapy.

Given the differences highlighted above, they are the preferred option in place of transvenous ICDs for patient who have no venous access (e.g., occluded vasculature) or those at high risk of complications from transvenous access (e.g., immunocompromised) – i.e., for those patients who are not eligible for a transvenous ICD. Since younger patients are more exposed to cumulative risks of transvenous lead failure, a subcutaneous ICD should also be strongly considered in patients with a life expectancy of over ten years.

How is it implanted?

The EMBLEM S-ICD System is **completely subcutaneous** and does not require leads in the heart. It consists of a pulse generator and a single lead (or electrode). Both are implanted subcutaneously and using anatomical landmarks just under the skin on the left side of the body, next to the rib cage. The implant procedure typically takes about one hour.

^a Primary prevention means that the patient is at increased risk of sudden cardiac arrest, but has not had an episode. Secondary prevention means the patient already had an episode of ventricular fibrillation.

How does it work?

The EMBLEM 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.

EMBLEM S-ICD 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.

Like anything that operates on a battery, the life of the S-ICD System will depend on how much of the battery is used, i.e. how many life-saving shocks it delivers. The EMBLEM S-ICD System is **projected to last more than seven years, 40 per cent more than its previous generation, decreasing the need for change-out procedures.**^{4,5}

The new design is **20 per cent thinner, improving the implant experience and patient comfort**, and it is also **enabled for use with the LATITUDE™ remote patient management system,**⁶ streamlining the follow-up of patients.

What does science say?

Two important clinical studies have been instrumental in demonstrating the S-ICD™ System as a compelling solution for the treatment of sudden cardiac arrest in a broad range of patients. Both studies showed that the S-ICD System is a safe and effective solution for sudden cardiac arrest.

The **US Investigational Device Exemption (IDE) study** was completed in 2011 and was the cornerstone for the FDA approval of the first generation of the device. The objective of this study was to evaluate the safety and effectiveness in the treatment of life-threatening ventricular arrhythmias. The data was published in 2013 in *Circulation*.⁷

The **EFFORTLESS Registry** is an ongoing^b registry in Europe and New Zealand aimed at demonstrating the early, mid-term, and long-term clinical outcome and cost effectiveness of the S-ICD™ System.

The latest data, published in the *Journal of the American College of Cardiology (JACC)* in April 2015, is based on a **pooled analysis** that combines the IDE study and the EFFORTLESS

^b Enrollment of 1000 patients has been closed. The study is now following up the patients as per protocol.

Registry data. The analysis demonstrates worldwide experience for the safety and efficacy of the S-ICD System over a longer follow-up period and in a larger diverse population by merging (“pooling”) the databases.⁸

Key results from the S-ICD Pooled Data Analysis⁸

- When compared to other studies on transvenous ICDs (TV-ICD), S-ICD was as effective as TV-ICD in treating spontaneous arrhythmias with a two year mortality rate that compared favorably with TV-ICDs.
- The acute major complication rate was lower when compared to studies with TV-ICD, likely because S-ICD doesn't require vascular access.
- There were zero endovascular infections or electrode failures which could be a factor in the observed low mortality rate.
- Patient selection, exclusion criteria and episode analysis suggests a limited benefit to antitachycardia pacing (ATP) therapy in these patients.
- Improvements in S-ICD screening and increased utilization of dual-zone programming were associated with a lower rate of inappropriate shocks.
- These data provide further support for the safety and efficacy of the S-ICD in a broad range of patients including primary prevention patients with an ejection fraction (EF) ≤ 35 .

Additional details on the clinical evidence are available [here](#).

Where is EMBLEM S-ICD available?

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. EMBLEM S-ICD System received CE mark and FDA approval in March 2015.

Who is 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.eu and connect on [Twitter](#) and [Facebook](#).

For additional information on EMBLEM, please visit the website for patients <http://www.s-icd.eu/> and our [newsroom](#).

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References

- ¹ American Heart Association. Heart Disease and Stroke Statistics – 2014 Update. *Circulation*. 2014;129:e28-e292.
- ² Poole-Gold, Who Should Receive the Subcutaneous Implanted Defibrillator?: The Subcutaneous Implantable Cardioverter Defibrillator (ICD) Should Be Considered in all ICD Patients Who Do Not Require Pacing. *Circulation* 2013
- ³ Indications for Use: The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias. Contraindications: The S-ICD System is contraindicated for patients with symptomatic bradycardia, incessant ventricular tachycardia and patients with documented spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing. SQ-RX® PULSE GENERATOR, A COMPONENT OF THE S-ICD® SYSTEM USER'S MANUAL MODEL 1010 – PN 1021980-10 Rev A 2011/12
- ⁴ PULSE GENERATOR USER'S MANUAL EMBLEM™ S-ICD Mod. A209 - 359279-001 EN EU 2014-06
- ⁵ SQ-RX® PULSE GENERATOR, A COMPONENT OF THE S-ICD® SYSTEM USER'S MANUAL MODEL 1010 – PN 1021980-10 Rev A 2011/12
- ⁶ EMBLEM S-ICD Labeling
- ⁷ Weiss, et al. The Safety and Efficacy of a Totally Subcutaneous Implantable-Defibrillator. *Circulation* 2013.
- ⁸ M 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, *J Am Coll Cardiol* 2015;65:1605–15

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations and with respect of local laws.

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