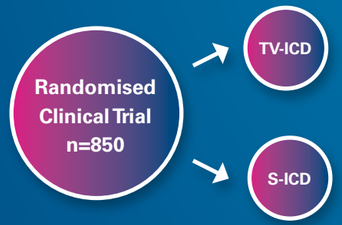
The future

S-ICD with Leadless Pacing System

In development is the EMPOWER™ Modular Pacing System, which includes a leadless pacemaker and the EMBLEM MRI™ S-ICD System, and is designed to be backwards-compatible with the EMBLEM™ S-ICD family. Whether patients with life-threatening arrhythmias subsequently develop a need for pacing or vice versa, this modular solution is designed to enable doctors to treat patients with the therapies they need, when they need them.

Concept device/technology. Not available for sale.



S-ICD Randomised Clinical Trial

PRAETORIAN[7] (n = 850) is an ongoing prospective multicentre trial, in which patients are randomised in a 1:1 ratio, either to S-ICD or Transvenous ICD. The aim is to compare ICD-related adverse events between TV-ICD and S-ICD. Results are expected in 2019.

S-ICD programming recommendations

Ventricular cut-off rate recommendations are being trialled in the UNTOUCHED[11] study (n = 1,100). The rate of S-ICD inappropriate shocks will be compared to the historical TV-ICD rates in the MADIT-RIT[13] study arms B and C. Results are expected 2020.

References

1. McLeod CJ, Boersma L, Okamura H, Friedman PA. The subcutaneous implantable cardioverter defibrillator: state-of-the-art review. Eur Heart J. 2015.
2. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death – European Heart Journal doi: 10.1093/eurheart/ehv316.
3. Bardy, G. H., W. M. Smith, et al. (2010). "An entirely subcutaneous implantable cardioverter-defibrillator." N Engl J Med 363(1): 36-44.
4. Weiss, et al. The Safety and Efficacy of a Totally Subcutaneous Implantable-Defibrillator. CIRCULATION. Vol. 128, no. 9. (August 2013.): 944-953.
5. Heart Rhythm - May 2012; Vol 9:5(S1-33) AB07-2.
6. Lambiase, et al. A worldwide experience with a totally subcutaneous ICD; Preliminary results of the EFFORTLESS S-ICD Registry. European Heart Journal Mar2014.
7. Olde Nordkamp, L.R. et al. Rationale and design of the PRAETORIAN trial: a Prospective, randomized comparison of subcutaneous and transvenous implantable cardioverter-defibrillator therapy. Am. Heart.J. 2012 May;163(5):753-760. e2. doi: 10.1016/j.ahj.2012.02.012.
8. M.C. 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. JACC 2015.
9. Priori, SG. et al. Eur Heart J. 2015 Aug 29. doi:10.1093/eurheartj/ehv316. Epub ahead of print.
10. S-ICD® System Post Approval Study: https://clinicaltrials.gov/ct2/show/NCT01736618.
11. Understanding Outcomes With the EMBLEM™ S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED): https://clinicaltrials.gov/ct2/show/NCT02433379.
12. Boersma L, et al. EFFORTLESS LBCT HRS 2016.
13. Moss AJ, Schuger C, Beck CA, et al. Reduction in Inappropriate Therapy and Mortality through ICD Programming. N Engl J Med 2012; 367: 2275 – 2283.

CRM_403703_AA_JUN2016. Printed in the The Netherlands by De Budelse/Gosling.

Boston Scientific
Advancing science for life™

www.bostonscientific.eu

S-ICD™ System Evolution

Boston Scientific
Advancing science for life™

The journey of the
Subcutaneous ICD

Device evolution

1ST GENERATION S-ICD

SQ-RX® S-ICD

In 2002 the proof of concept study began, and the 1st generation SQ-RX® S-ICD system was born. The S-ICD system swiftly gained market approvals in the EU (2009) and the USA (2012).

2ND GENERATION S-ICD

EMBLEM™ S-ICD

Launched in 2015, the **EMBLEM™ S-ICD** system was 20% thinner with 40% greater longevity compared to the 1st generation, and was enabled for LATITUDE™ NXT remote monitoring.

3RD GENERATION S-ICD

EMBLEM™ MRI S-ICD

The newest generation is the **EMBLEM MRI™ S-ICD** system. It is labelled for 1.5 Tesla full-body MRI scans and includes two new features, SMART Pass technology and AF Monitor™. SMART Pass will help ensure patients receive appropriate device therapy when needed, by enhancing the INSIGHT™ Algorithm, AF Monitor is a new detection tool designed to alert doctors of silent or new onset AF.

Why the S-ICD?

The Subcutaneous ICD system offers effective defibrillation against sudden cardiac death without transvenous (TV) leads. The S-ICD avoids risks for those patients who don't require pacing, and supports the greater recognition of the increasing long-term risks of endocardial leads, such as systemic infection, acute and chronic displacement, pneumothorax and lead fracture.

Patient population evolution

Patient prioritisation (as per McLeod et al, 2015)

Optimal S-ICD candidate[1]

Strong Indication

Young age*
Primary prevention
Poor vascular access
Previous infection
Infection risk (mechanical valves, diabetes, renal dysfunction)

Difficult venous access

Young patients facing a lifetime device therapy

Patients with particular risk of infection

Relative Contraindication

Need for ATP (difficult to define clinically)

Contraindicated

Pacing indication (bradycardia or CRT)
Failed screening (high inappropriate shock risk)

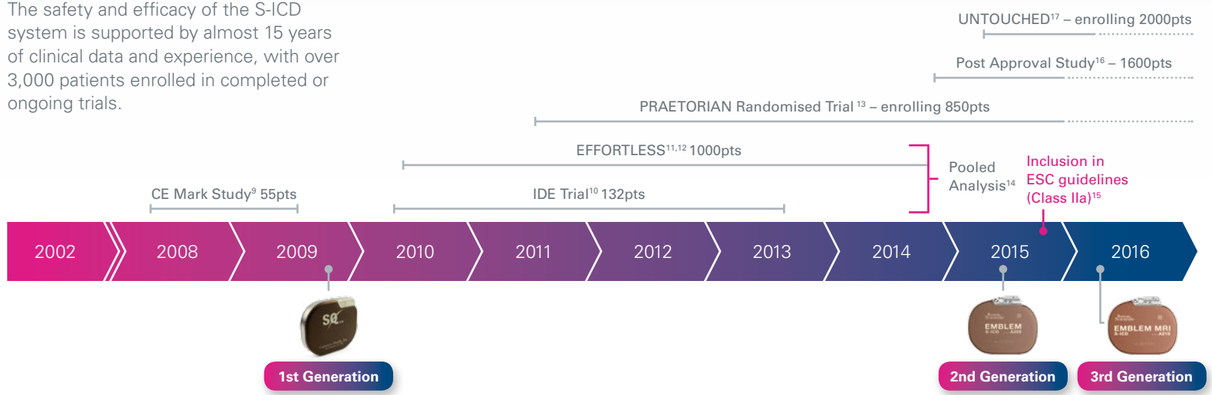
* <65 (10 – 15 years life expectancy) as defined by ESC guidelines for management of atrial fibrillation, 2011

Inclusion in the ESC Guidelines

Subcutaneous ICDs are now recommended in the 2015 ESC Guidelines as a Class IIa recommendation, and should be considered as an option for ICD patients who don't require pacing (brady, ATP, CRT).[2]

Clinical data evolution

The safety and efficacy of the S-ICD system is supported by almost 15 years of clinical data and experience, with over 3,000 patients enrolled in completed or ongoing trials.



Long-term data shows S-ICDs are safe and effective

The **EFFORTLESS[12]** multi-national registry includes over 985 patients, with up to five years of follow-up. The data further validates the efficacy with a 97.4% arrhythmia conversion rate, and revealed that few S-ICDs were removed due to a change of patient indication (0.5% removed for an ATP need, and 0.1% removed for bradycardia need). There have been no reports of systemic blood infections, cardiac injuries or endocarditis to date.

ZERO CARDIAC INJURIES, SYSTEMIC BLOOD INFECTIONS OR ENDOCARDITIS