**S-ICD Randomised Clinical Trial**

PRAETORIAN (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 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.

**S-ICD Randomised Clinical Trial**

S-ICD Randomised Clinical Trial n=850

S-ICD programming recommendations

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

**References**


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.


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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

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, ATR, CRT).^1

Patient prioritisation (as per McLeod et al, 2015)

• Strong Indication
  - Young age
  - Primary prevention
  - Poor vascular access
  - Previous infection
  - Infection risk (mechanical valves, diabetes, renal dysfunction)

• Relative Contraindication
  - Need for ATP (difficult to define clinically)
  - Contraindicated
  - Pacing indication (bradycardia or CRT)
  - Failed screening (high inappropriate shock risk)

Clinical data evolution

Clinical data evolution 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™ 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.

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