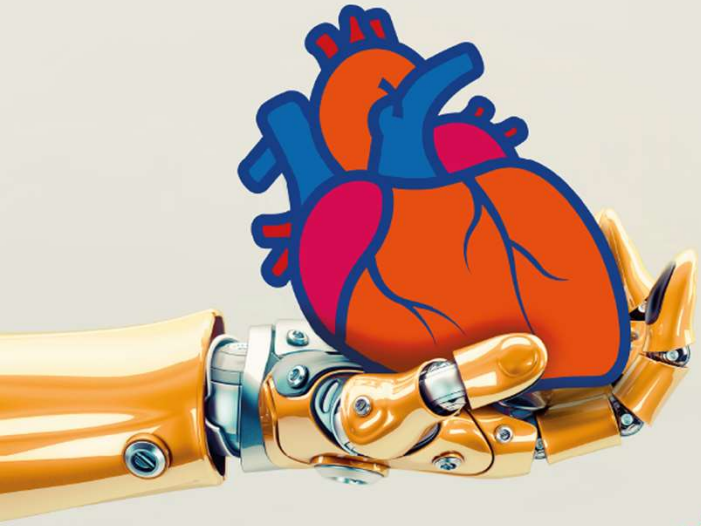

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DAVIDE GIORGI

I primi 10 anni del defibrillatore sottocutaneo: innovazioni tecnologiche e nuove sfide

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IL DEFIBRILLATORE SOTTOCUTANEO
CERTEZZE E PROSPETTIVE FUTURE

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Current TV-ICD technology limitations

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TV-ICD COMPLICATIONS

TV-ICD complications, both acute and chronic, are more prevalent than generally acknowledged

Infection Lead failure

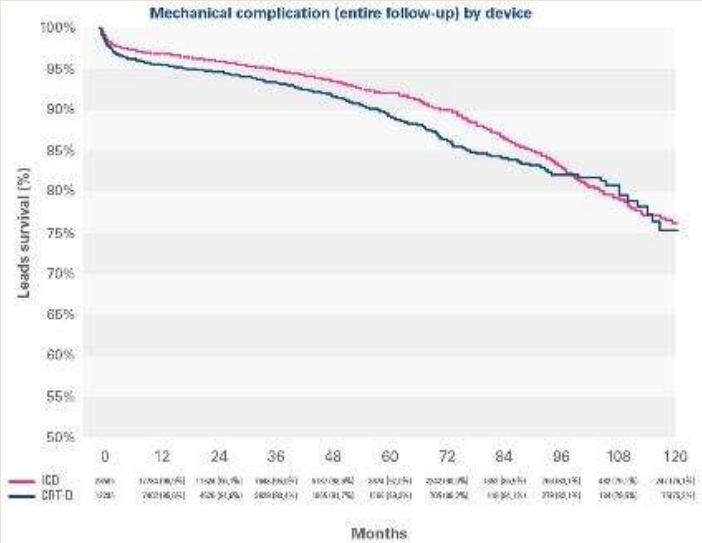
Risk of complication* at 6 years

15.5%

* Complication either: implant related, system/ lead related or infection (Infection, Device malfunction, Lead malfunction, Lead dislodgment, Pericardial effusion, Thrombotic event, Reintervention for pocket complication, Hematoma, Pneumothorax. Based on 4890 patients)

TV-ICD LEAD COMPLICATIONS

OPTUM database shows lead failure rate of ~25% at 10 years



PATIENT OUTCOMES FOLLOWING ICD INFECTION

Large vegetation on an extracted right ventricular ICD lead

In the ELECTRa registry,*

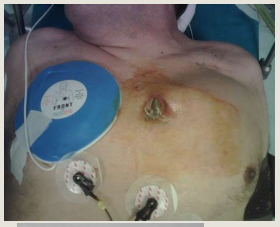
1 IN 6 patients died

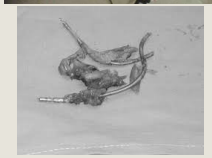
after systemic infection resulting in transvenous lead extraction

Low incidence of mortality linked to procedure, but significant post-procedural mortality, with a strong correlation between mortality and lead extraction for infection

* European Lead Extraction ConTrolled Registry (ELECTRa). This study only included TV ICD, mortality linked directly to procedure was 0.5%.[22]

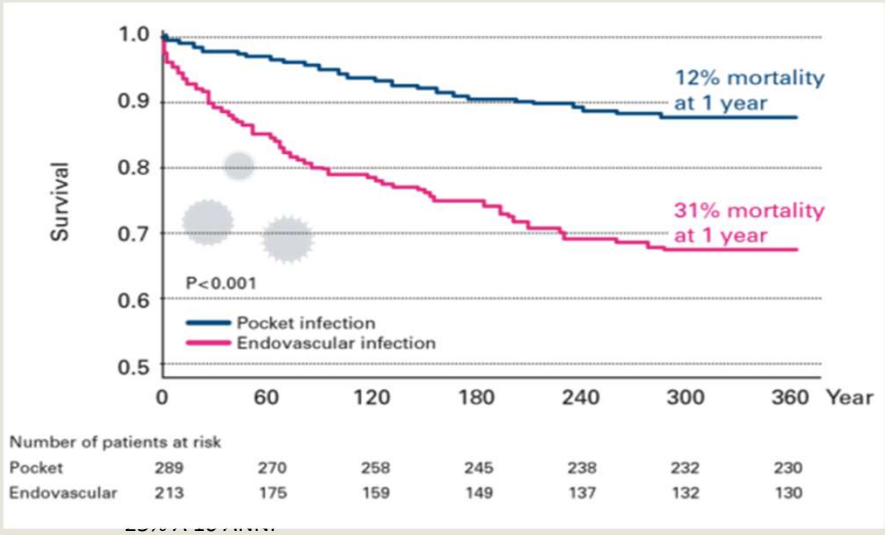
Limiti e Complicanze T-ICD





INFEZIONI:

- 0.5% al primo impianto
- 1-7% al secondo intervento [1]



- 40% popolazione pediatrica [3,4]

1. Poole Je et al. Circulation 2010; 122:1553-61
2 . Morrison et al. J CardiovascElectrophysiol 2010;21:671-7
3. Berul CI et al. J Am Coll Cardiol 2008;51:1685–1691
4. GradausR et al. Heart 2004;90:328–32910

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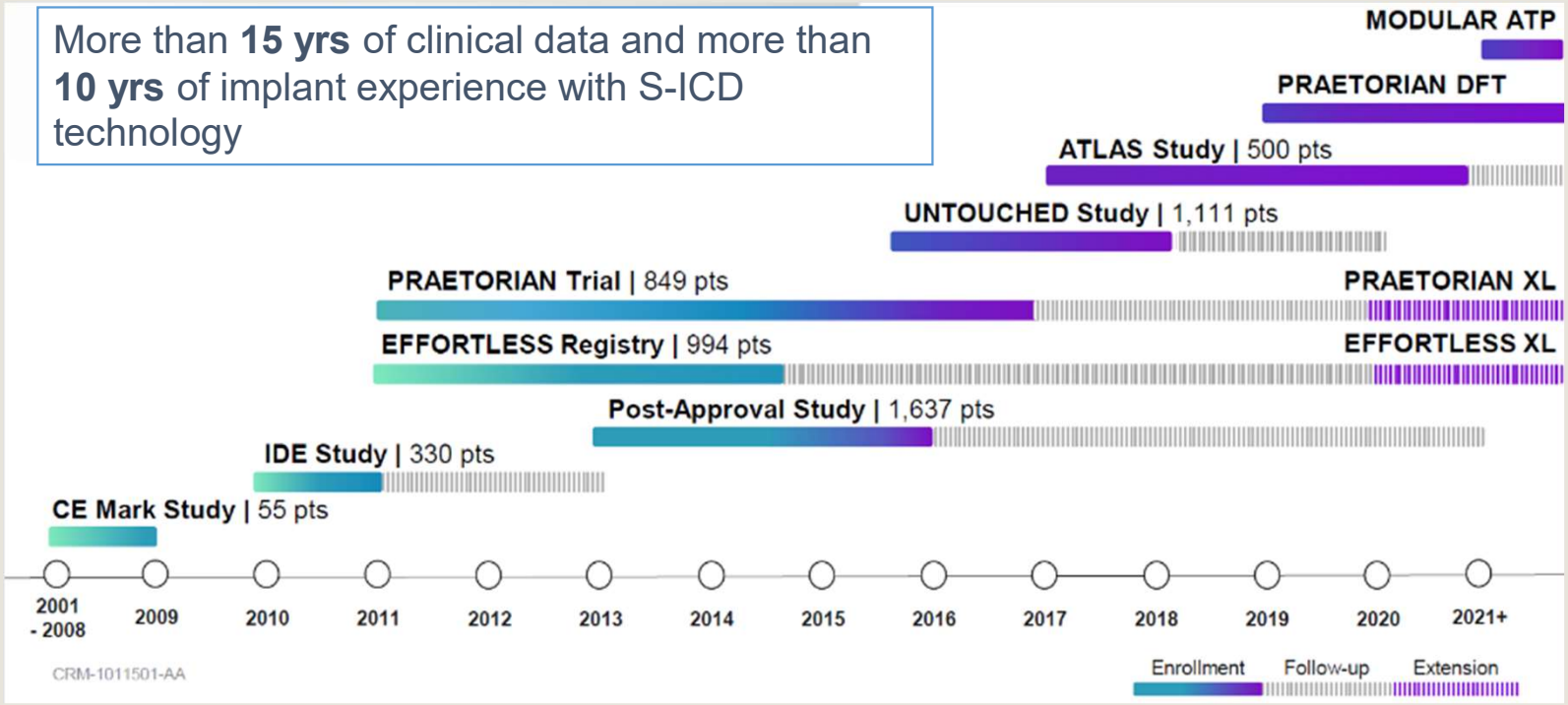
CLINICAL EVIDENCES

THE S-ICD JOURNEY TO FIRST LINE THERAPY

More than **15 yrs** of clinical data and more than **10 yrs** of implant experience with S-ICD technology

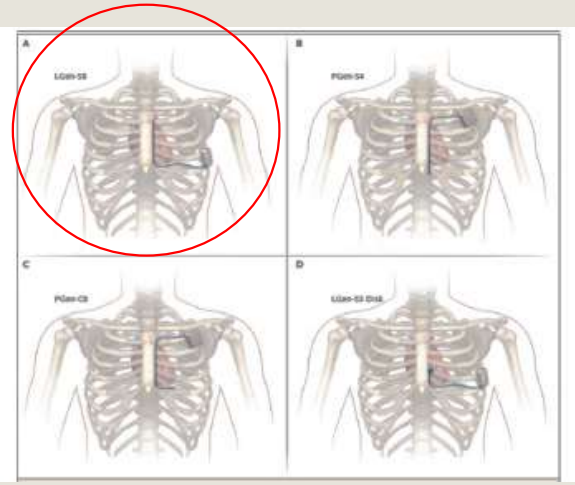


Click to edit Master title style

Proof of Concept Studies
(utilizing temporarily-inserted S-ICD™ Systems)

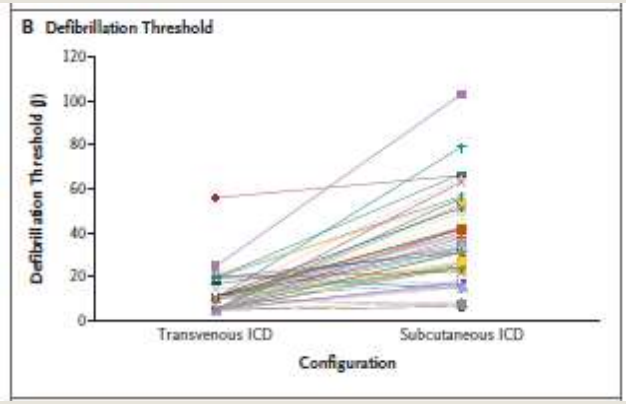
1. Electrode Configuration[1]
(Sept 2001-Feb 2004)

- N = 78 patients
- four configurations tested
- Configuration A had the lowest mean DFT



2. Defibrillation Threshold[1]
(April 2004-June 2005)

- N = 49, configuration A
- S-ICD as effective as TV-ICD for terminating induced VF
- S-ICD requires higher energy (avg of 36J vs. 11J)



1. Bardy, G. H., W. M. Smith, et al. (2010). "An entirely subcutaneous implantable cardioverter-defibrillator." N Engl J Med 363(1): 36-44

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S-ICD Prime indicazioni

S-ICD è il dispositivo preferenziale

- Senza accesso vascolare (occlusioni o anomalie congenite)
- Alto rischio di complicanze da impianto di ICD transvenoso (dialisi, pediatrici, immunocompromessi)
- Canalopatie (Brugada, sindrome QT lungo, cardiomiopatia ipertrofica)
- Precedente infezione di ICD o malfunzionamento elettrocateteri
- Storia di endocardite

S-ICD dovrebbe essere fortemente considerato

- Pazienti giovani
- Aspettativa di vita > 10 anni
- Prevenzione primaria in cardiopatia ischemica e non ischemica
- Protesi valvolare
- Donne (preferenza di posizionamento del generatore in sede ascellare)
- Pazienti selezionati in prevenzione secondaria (sopravvissuti a FV, senza evidenza di TV monomorfe)

Circulation
Arrhythmia and Electrophysiology

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
Jeanne E. Poole and Michael R. Gold

Table 2. Characterization of Patient Groups for S-ICD Implantation

S-ICD is preferred device
No venous access (occluded veins or congenital anomalies)
High risk of complications for transvenous systems have (dialysis, pediatric, and immunocompromised)
Channelopathies (long-QT syndrome, Brugada, hypertrophic cardiomyopathy)
Previous device infections or lead failures
History of endocarditis
S-ICD should be strongly considered
Young patients
Life expectancy >10 y
Primary prevention indicated patients with ischemic/nonischemic heart failure
Prosthetic valves
Women (preferred generator placement lateral wall)
Selected secondary prevention indicated patients (survivors of out-of-hospital VF, no evidence of monomorphic VT
S-ICD should be avoided
Systolic heart failure and LBBB who are indicated for CRT
Symptomatic bradycardia requiring pacemaker
Recurrent sustained monomorphic VT for whom ATP is deemed appropriate

ATP indicates antitachycardia pacing; CRT, cardiac resynchronization therapy; LBBB, left bundle branch block; S-ICD, subcutaneous implantable cardioverter defibrillator; and VT, ventricular tachycardia.

Linee guida ESC - 2015

Subcutaneous implantable cardioverter defibrillator

Recommendations	Class[a]	Level[b]	Ref.[c]
Subcutaneous defibrillators should be considered as an alternative to transvenous defibrillators in patients with an indication for an ICD when pacing therapy for bradycardia support, cardiac resynchronization or antitachycardia pacing is not needed.	IIa	C	157, 158
The subcutaneous ICD may be considered as a useful alternative to the transvenous ICD system when venous access is difficult, after the removal of a transvenous ICD for infections or in young patients with a long-term need for ICD therapy.	IIb	C	This panel of experts

ICD = implantable cardioverter defibrillator.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting recommendations.

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2017 AHA/ACC/HRS GUIDELINES

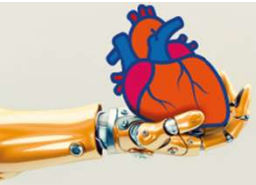
11.1. Subcutaneous Implantable Cardioverter-Defibrillator

Recommendations for Subcutaneous Implantable Cardioverter-Defibrillator
References that support the recommendations are summarized in Online Data Supplement 55.

COR	LOE	Recommendations
I	B-NR	1. n patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended (1-5).
IIa	B-NR	2. In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated (1-4).
III: Harm	B-NR	3. In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted (1-4, 6-8).

Recommendation-Specific Supportive Text:

An S-ICD may be preferred in patients who are at high risk of infection, such as those with a prior device infection, ESRD, diabetes mellitus, or who are chronically immunosuppressed.



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S-ICD LEAVES THE HEART UNTOUCHED

In the EFFORTLESS registry of almost

1000 PATIENTS OVER **3** YEARS,

there were:

Zero ENDOVASCULAR INFECTIONS[25]

Zero SYSTEMIC INFECTIONS[25]

Zero ELECTRODE FAILURES[25]

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WHO SHOULD RECEIVE AN S-ICD?

Substantial clinical evidence shows that the S-ICD is an appropriate choice of therapy for a majority of patients at risk of Sudden Cardiac Death

According to the Italian subcutaneous implantable cardioverter-defibrillator survey:

" S-ICD, **WHY NOT?** "

89%

of all ICD indicated patients were eligible to receive an **S-ICD**[35]

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Subcutaneous implantable cardioverter defibrillator implantation: An analysis of Italian clinical practice and its evolution☆

Antonio D'Onofrio [a,*,1], Paolo Pieragnoli [b], Mauro Biffi [c], Gerardo Nigro [d], Federico Migliore [e], Pietro Francia [f], Paolo De Filippo [g], Alessandro Capucci [h], Giovanni Luca Botto [i], Massimo Giammaria [j], Pietro Palmisano [k], Ennio Pisanò [l], Giovanni Bisignani [m], Carmelo La Greca [n], Berardo Sarubbi [o], Simone Sala [p], Miguel Viscusi [q], Maurizio Landolina [r], Mariolina Lovecchio [s], Sergio Valsecchi [s], Maria Grazia Bongiorni [t], on behalf of "S-ICD Rhythm Detect" Investigators

Multicenter Italian registry
607 patients enrolled

The proportion of patients with ischemic dilated cardiomyopathy and of those with left ventricular EF ≤ 35% increased over the years

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International Journal of Cardiology

Subcutaneous implantable cardioverter defibrillator implantation: An analysis of Italian clinical practice and its evolution☆

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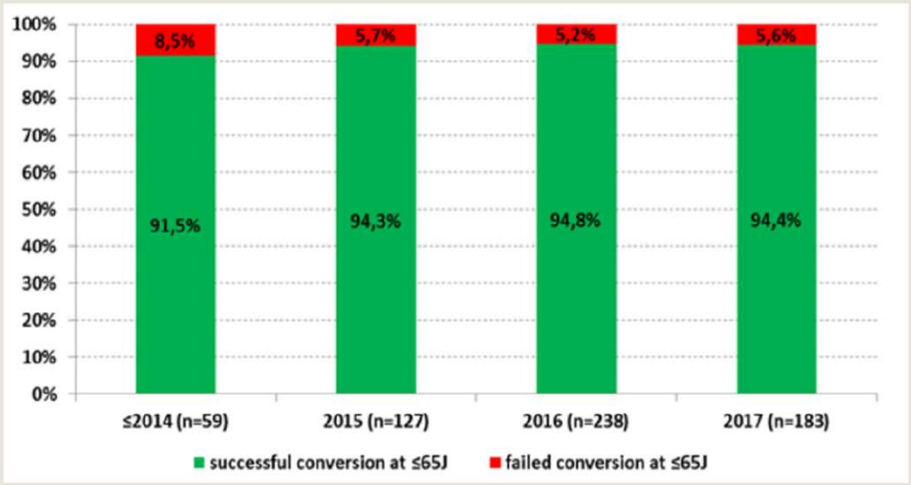

Summary of successful conversion (<80J):

99,8 %

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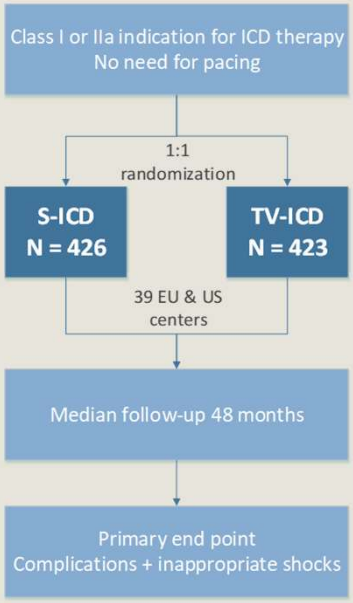
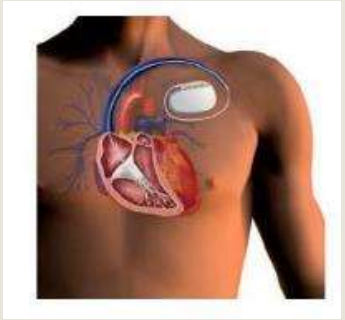
PRAETORIAN STUDY

Study design



vs



Inclusion criteria

- ≥18 yrs with a class I or IIa indication for ICD therapy for 1° or 2° prevention according to EU & US guidelines

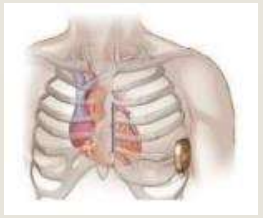
Exclusion criteria

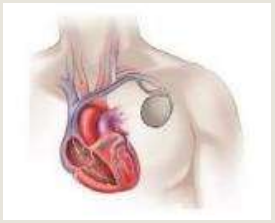
- Indication for pacing therapy: brady, CRT and ATP
- Failed S-ICD vector screening

Enrolment

- 849 patients from March 2011 to January 2017
- 39 centers in EU and US
- Standardized programming

PRAETORIAN STUDY





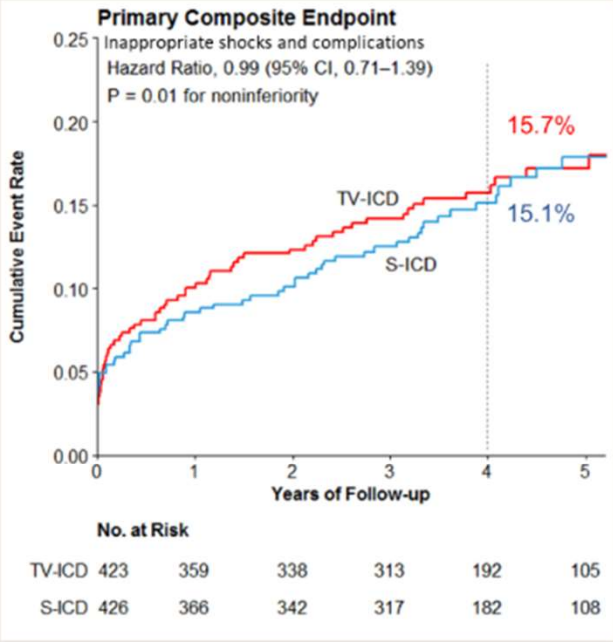
Baseline

	S-ICD (n = 426)	TV-ICD (n = 423)
Median age (IQR) – yr	**63 (54 – 69)**	**64 (56 – 70)**
Female sex – no. (%)	89 (20.9)	78 (18.4)
Diagnosis – no. (%)		
– **Ischemic cardiomyopathy**	**289 (67.8)**	**298 (70.4)**
– **Nonischemic cardiomyopathy**	**99 (23.2)**	**98 (23.1)**
– Other	38 (9.0)	27 (6.5)
Secondary prevention – no. (%)	**80 (18.8)**	**84 (19.9)**
Median ejection fraction (IQR) – %	**30 (25 – 35)**	**30 (25 – 30)**
Median BMI (IQR) – kg/m^2	27.0 (24.5 – 30.5)	27.9 (25.2 – 31.7)
NYHA class – no. (%)		
- Class I	144/423 (34.0)	136/421 (31.8)
- Class II	205/423 (48.5)	223/421 (53.0)
- Class III/IV	74/423 (17.5)	64/421 (15.2)

- ✓ "Typical" ICD population
- ✓ Composite endpoint (Complications + IAS)
- ✓ Standardized programming

PRAETORIAN STUDY

Primary endpoint



Primary Outcome: Non-inferiority Demonstrated

S-ICD had comparable performance to TV-ICD yet avoided serious complications

Confirms S-ICD can be the preferred choice for most ICD indicated patients w/o need for pacing

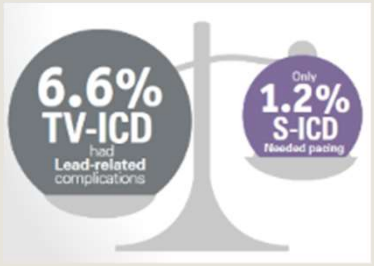
PRAETORIAN STUDY

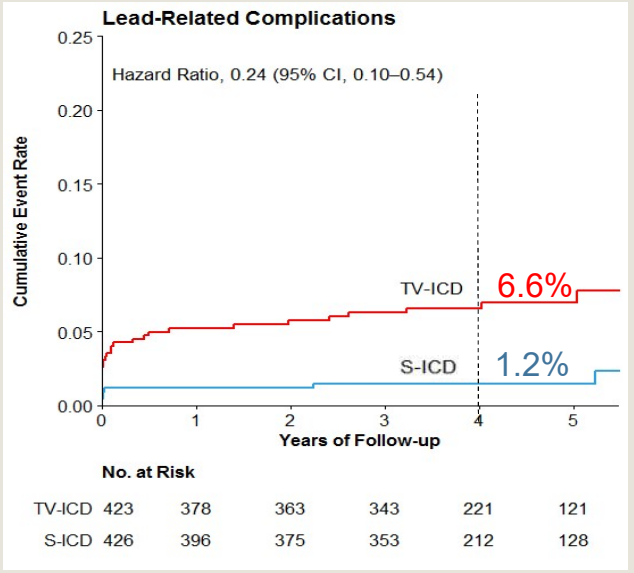
Lead-related complications

Significantly fewer lead-related complications

	S-ICD (N = 426)	TV-ICD (N = 423)
Primary composite endpoint	68 (15.1%)	68 (15.7%)
Device-related complications (P = 0.11)	31 (5.9%)	44 (9.8%)
– Infection	4	8
– Bleeding	8	2
– Thrombotic event	1	2
– **Pneumothorax**	**0**	**4**
– **Lead perforation**	**0**	**4**
– **Lead repositioning**	**2**	**7**
– Other	19	20
• **Lead replacement**	**3**	**9**
• Device or sensing malfunction	8	6
• Pacing indication	5	1
• Implantation or DFT failure	3	3
• Pain or discomfort	2	3

P = 0.001



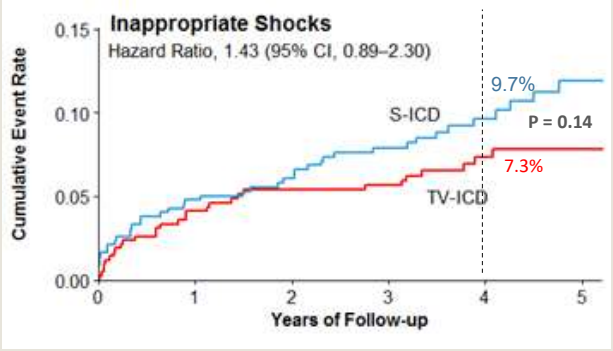


Inappropriate shocks

Non-significantly higher rate of IAS

	S-ICD (n = 426)	TV-ICD (n = 423)
Primary composite endpoint	68 (15.1%)	68 (15.7%)
Inappropriate shock	41 (9.7%)	29 (7.3%)
– AF/SVT	15	27
– Cardiac oversensing	20	2
– Noncardiac oversensing	8	0

P = 0.140



Comparable performance in the first 2 years due to new generation systems

Study limitations:

- ✓ Old device generations (less than 15% of patient with last gen and Smart Pass filter)
- ✓ Initial expertise with implant technique
- ✓ Old screening manual tool

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UNTOUCHED STUDY

Understanding Outcomes with the S-ICD In Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED)

Gold, et al

UNTOUCHED Study Design

Global, multicenter, prospective, nonrandomized study
De-novo implanted patients enrolled at 110 sites
Follow-up for 18 months
Pre-specified, device programming with a conditional zone of 200 bpm and an aggressive shock zone of 250 bpm
1111 patients enrolled

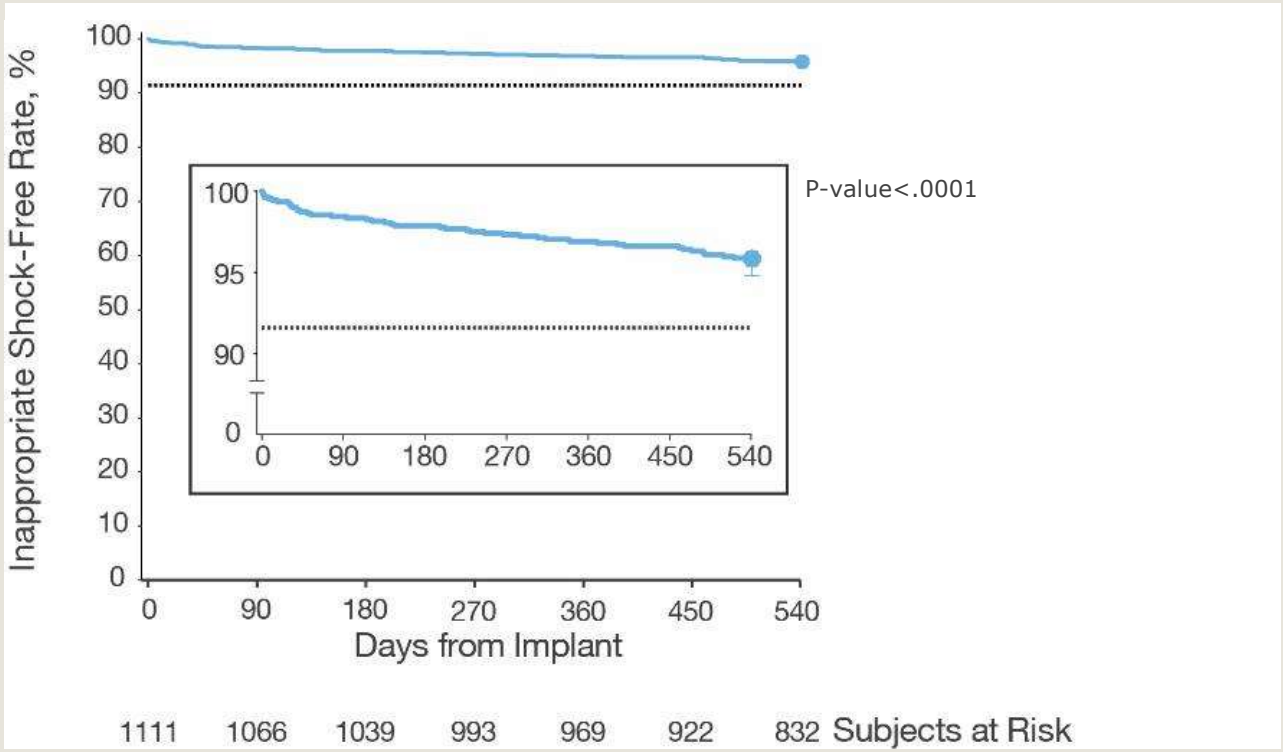
Inclusion Criteria
Primary prevention indication for SCD and LVEF ≤ 35% without a pacing indication who passed S-ICD screening vector test

Primary Endpoint
Inappropriate Shock-free rate at 18 months: performance goal of **91.6%**
Derived from MADIT-RIT IAS-free rate in Arms B and C: **94.6**%

Secondary Endpoints
All Cause Shock-free rate at 18 months: performance goal of **85.8%**
System and Procedure Related Complications at 30 days.

Understanding Outcomes with the S-ICD In Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED)

PRIMARY ENDPOINT: Inappropriate Shock-Free Rate at 18 Months



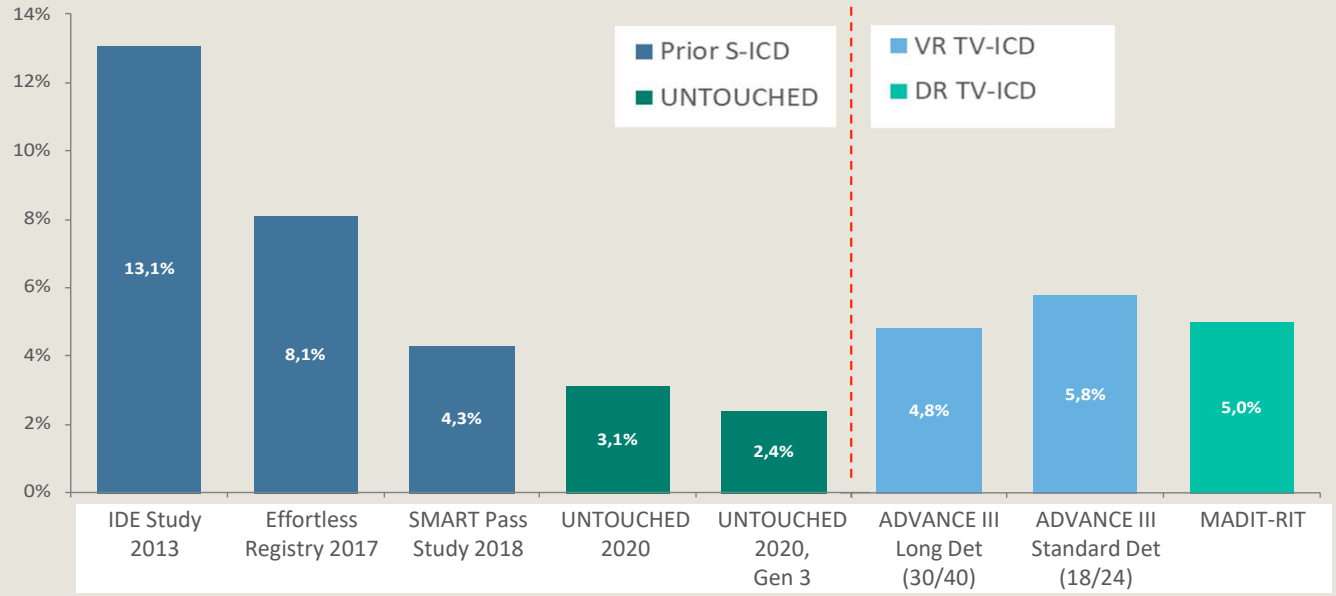
IAS-Free Rate 95.9%

Performance Goal 91.6%

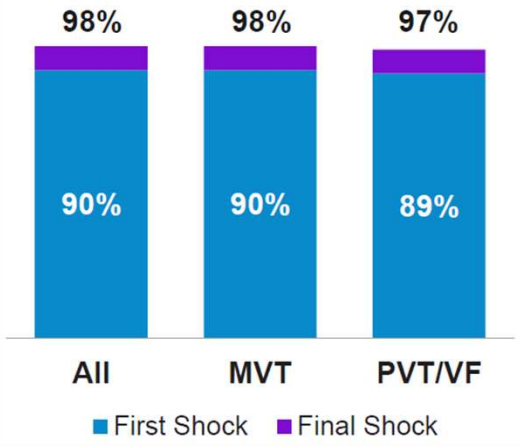
UNTOUCHED STUDY

Understanding Outcomes with the S-ICD In Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED)

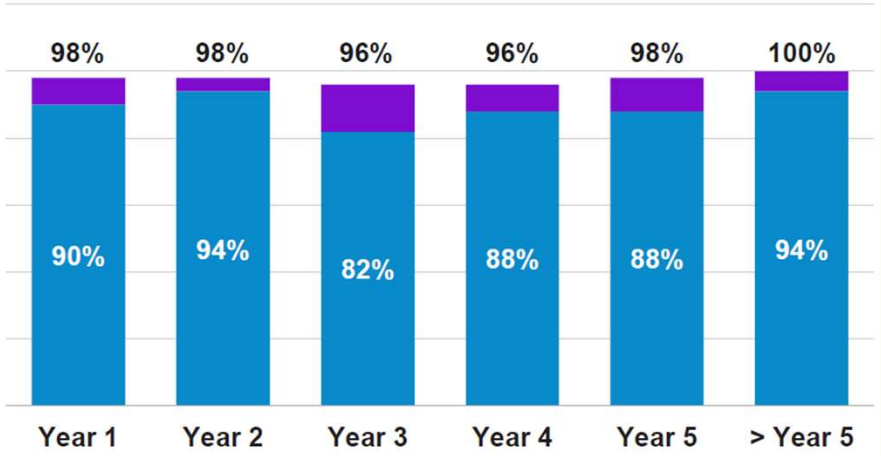
One Year Inappropriate Shock Rates for S-ICD & TV-ICD



EFFORTLESS demonstrated **high overall final shock efficacy of 98% over long-term follow-up of 5 years.**[5]

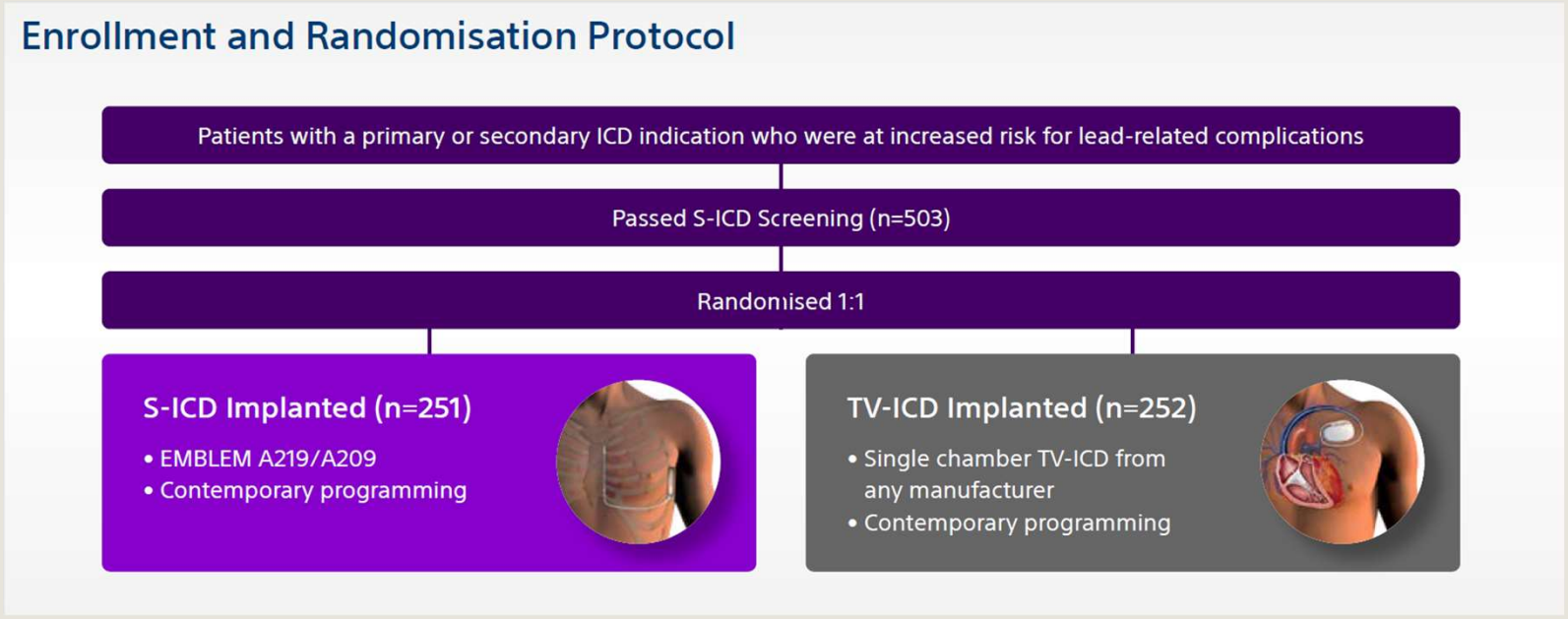


Final shock efficacy for discrete spontaneous episodes **was consistently 96% - 100% over the 5 year follow-up.**[5]



ATLAS Trial

The ATLAS Trial is an investigator-sponsored research study (ISR) initiated, prospective randomised controlled trial where the primary objective was to evaluate lead-related complication rates between the S-ICD and single chamber TV-ICD devices at 6 months after implant. The trial randomised 503 patients, between February 2017 and July 2021



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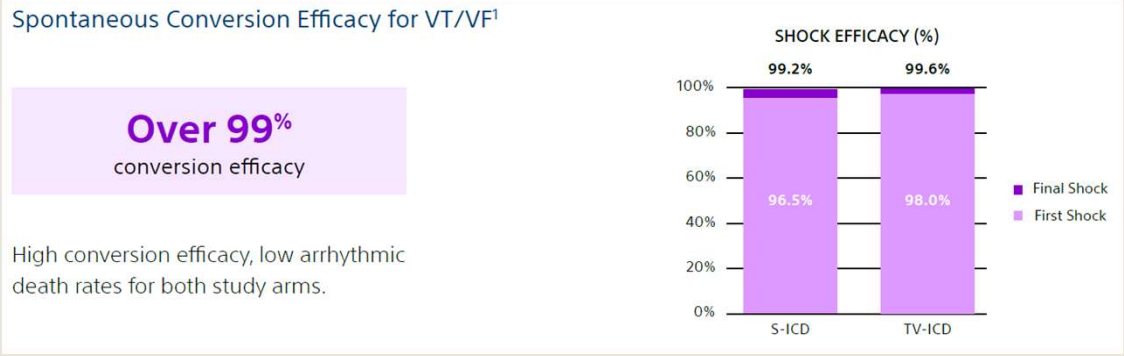
ATLAS Trial

Primary Outcome

S-ICD is Superior to TV-ICD

Lead-related complications

The ATLAS trial met its primary superiority endpoint demonstrating a highly significant 92% fewer serious lead-related complications for EMBLEM™ S-ICD patients (1 patient, 0.4%) compared to any manufacturer's single chamber TV-ICD devices (12 patients, 4.8%). p=0.003



Optimal S-ICD candidate

STRONG INDICATION

Young age*

Primary prevention

Poor vascular access

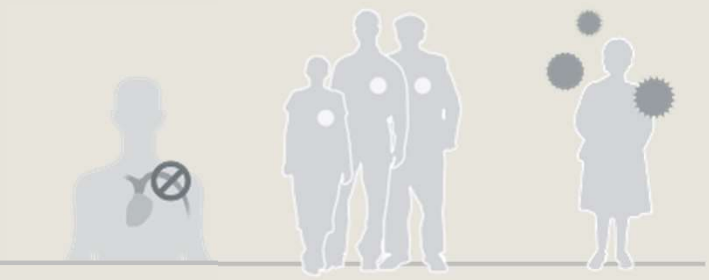
Previous infection

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

McLeod CJ, Boersma L, Okamura H, Friedman PA. The subcutaneous implantable cardioverter defibrillator: state-of-the-art review. Eur Heart J. 2015 Oct 29.

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S-ICD implant workflow evolution

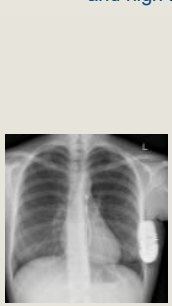
Intermuscular approach

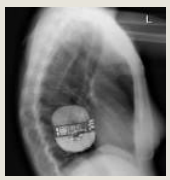
- Make an incision along the inframammary crease.The pocket is created by blunt dissection between the **Serratus anterior and Latissimus dorsi muscles** (muscle fibres are not cut).2

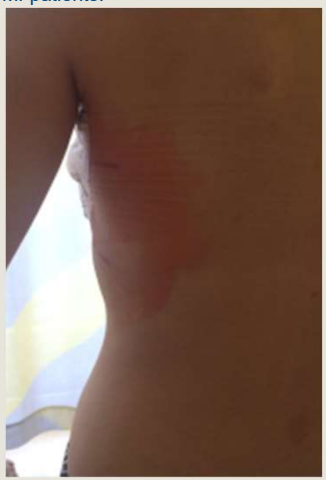
Benefits of Intermuscular device positioning highlighted in literature:

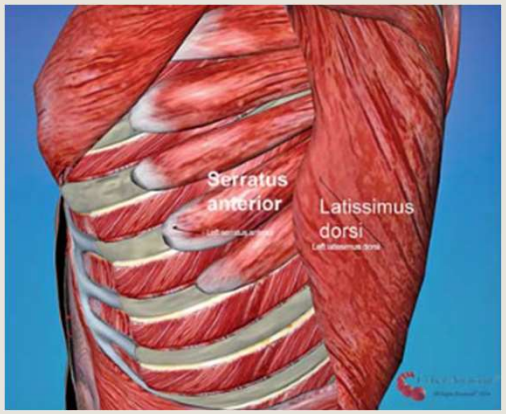
- ✓ Optimal position for DFT and impedance measurements (dorsal/posterior, under adipose tissue)
- ✓ Reduced risk of pocket complications (erosion and infection)
- ✓ Reduced device migration
- ✓ Consistency in implant technique
- ✓ Patient comfort: device is protected by muscle layer
- ✓ Cosmetic outcomes: can is less visible

Intermuscular device placement is particularly beneficial in low and high BMI patients.







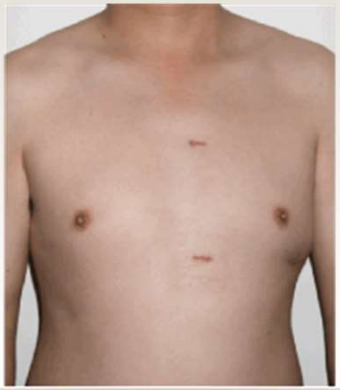


TWO INCISION TECHNIQUE

Optimising the S-ICD Experience

May reduce procedure time due to elimination of the superior parasternal incision

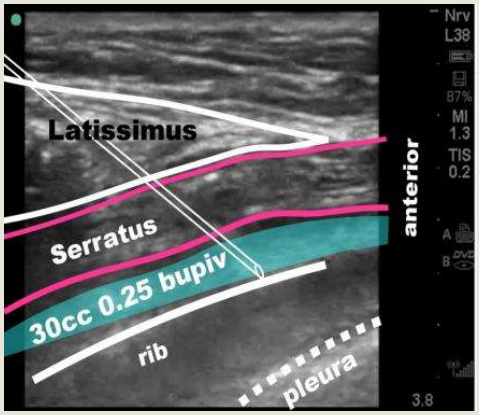
"Pairwise comparison of implantation techniques demonstrated that the 2-incision technique with the pulse generator in the subcutaneous position was significantly shorter in procedure duration than the other 3 implant techniques"[94]



Improves Cosmetic Outcome for Patients

- ✓ Elimination of scar improving cosmetic outcome
- ✓ Removing superior incision as a site of potential discomfort[98]

Anaesthesia options



Anaesthesia Methods

General anaesthesia

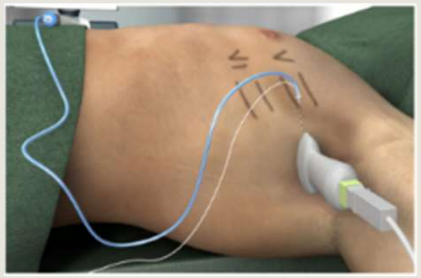
Induced coma, unconsciousness, amnesia, analgesia. Fully supported by an anaesthesiologist, patient is intubated.

Conscious sedation

Type of sedation in which the patient can respond to verbal directions, but feels little to no pain

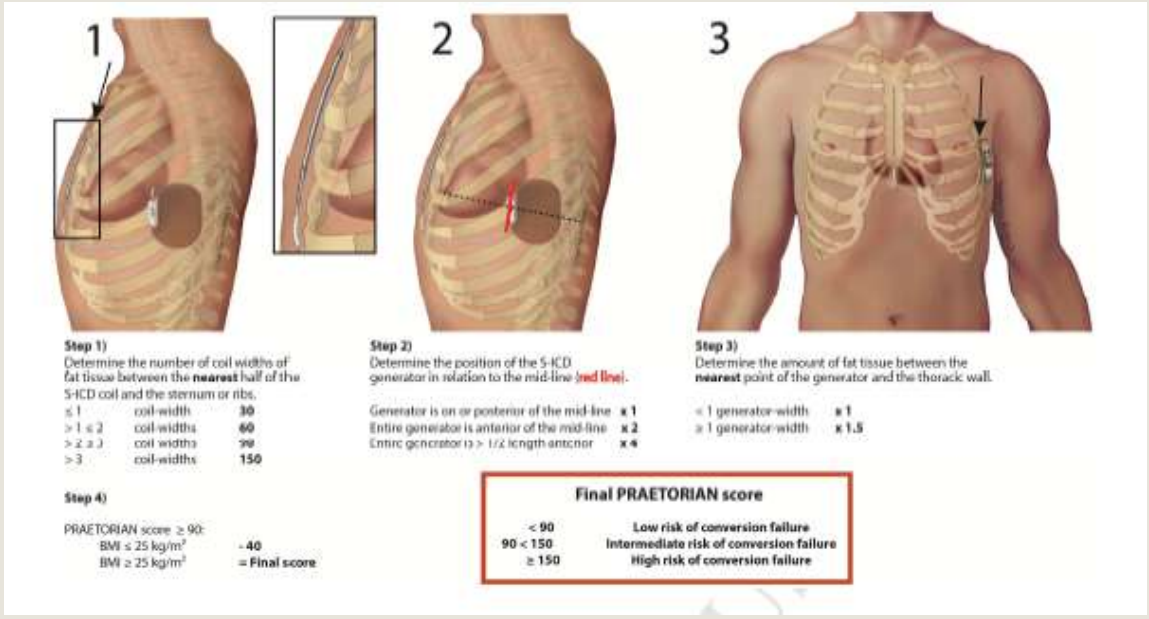
Regional Anaesthesia

Absence of sensation in regions of the body.
Ex: Serratus Plane Block - an ultrasound guided thoracic block



Droghetti, Andrea, et al. "Ultrasound-guided serratus anterior plane block combined with the two-incision technique for subcutaneous ICD implantation." Pacing and Clinical Electrophysiology 41.5 (2018): 517-523.

The PRAETORIAN SCORE is a non-invasive method to evaluate the S-ICD implant position



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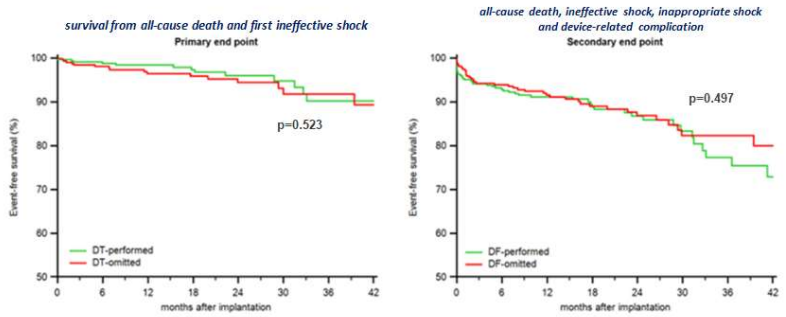
DFT

Circulation: Arrhythmia and Electrophysiology
December 02, 2021
RESEARCH LETTER

Safety of Omitting Defibrillation Efficacy Testing With Subcutaneous Defibrillators: a Propensity-Matched Case-Control Study

Valter Bianchi, MD; Giovanni Bisignani, MD; Federico Migliore, MD; Mauro Biffi, MD; Gerardo Nigro, MD; Stefano Viani, MD; Fabrizio Caravati, MD; Luca Checchi, MD; Pietro Francia, MD; Paolo De Filippo, MD; Domenico Pecora, MD; Carlo Lavalle, MD; Antonio Scalone, MD; Pietro Rossi, MD; Pietro Palmisano, MD; Giovanni Licciardello, MD; Roberto Ospizio, MS; Mariolina Lovecchio, MS; Sergio Valsecchi, PhD; Antonio D'Onofrio; on behalf of "S-ICD Rhythm Detect" Investigators

Results



Kaplan–Meier estimates of time to the primary endpoint and secondary endpoint

There was no significant difference in the in the primary or in the secondary outcome between the two groups in analysis

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S-ICD features and future evolution

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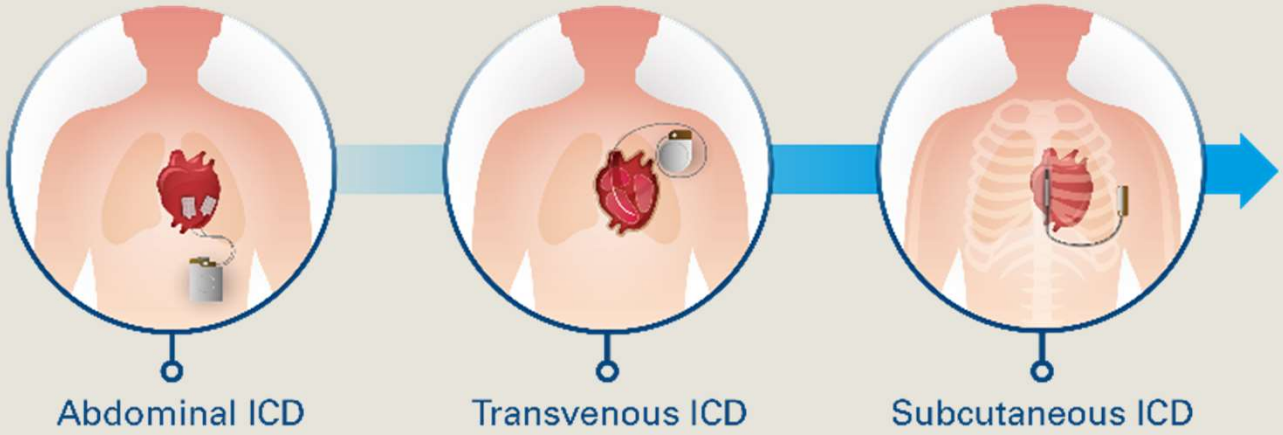
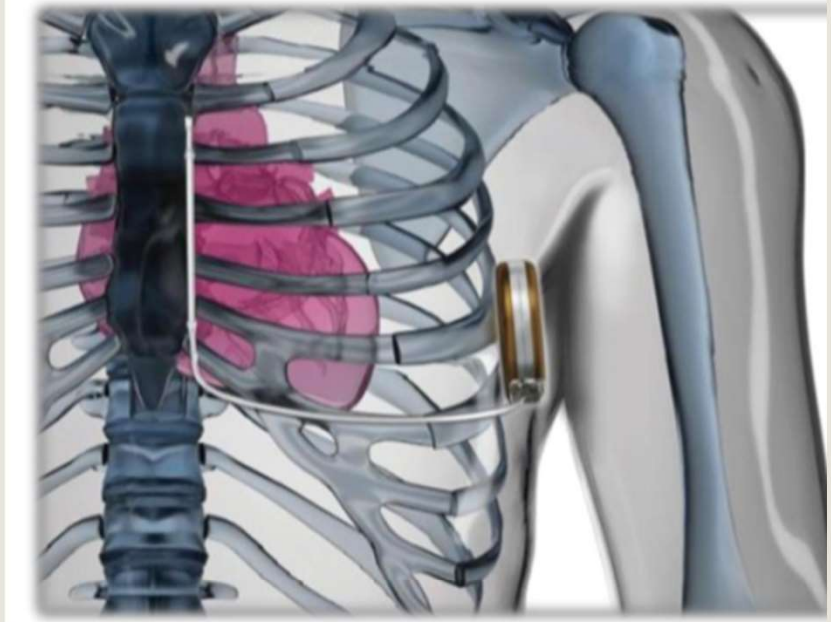
WHY THE S-ICD SYSTEM?

A less invasive solution for patients at risk of sudden cardiac death



S-ICD: Subcutaneous-Implantable Cardioverter Defibrillator

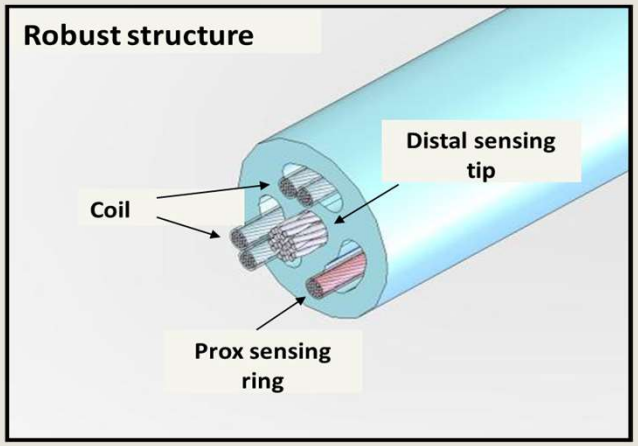


The S-ICD System:

- Entirely subcutaneous
- Does not require leads in the heart, leaving the vasculature untouched
- Sophisticated algorithms provide performance equal to transvenous ICDs[1,2]
- 80J max output
- Adaptive shock polarity
- 9s charge time for 80 J

1. Burke M., et al. "Safety and Efficacy of a Subcutaneous Implantable-Defibrillator " Late- Breaking Abstract Session. HRS 2012
2. Gold M, et al. Head-to-Head Comparison of Arrhythmia Discrimination Performance of Subcutaneous and Transvenous ICD Arrhythmia Detection Algorithms: The START Study. Journal of Cardiovascular Electrophysiology; Vol 23:4(359-366)

The S-ICD System
Electrode characteristics




Wouldn't take no for an answer

Ikpah had experimental defibrillator implanted to return to court

Amy Farnum, NCAA.com

- High axial strength
  - Central multi-strand cable, end to end
  - No stylet lumen
- Low stress environment cf. intracardiac
- Optimal tensile strength and abrasion resistance
- No physical limitations for patients

What to expect from the future?

2002 — **1ª Generazione**

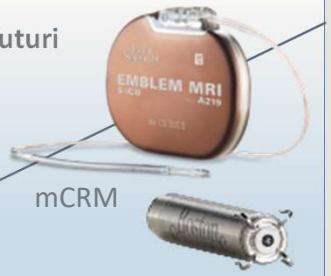
2009

2012 — Boston Scientific

2015 — **2ª Generazione**
- Dispositivo più piccolo e sottile e di lunga durata
- Compatibile con LATITUDE™1

2016 — **3ª Generazione**
- SMART Pass
- Compatibilità RM
- Monitor AF™

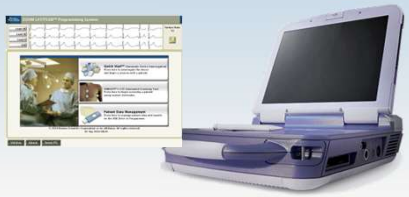
2017 — **Sviluppi futuri**



mCRM

- Nuovo elettrodo,
- Sistema di posizionamento degli elettrodi (EDS)
- Labeling tecnica 2 incisioni

Automated Screening Tool



» **100.000 pazienti impiantati in tutto il mondo**

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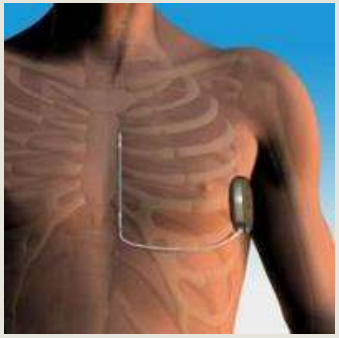
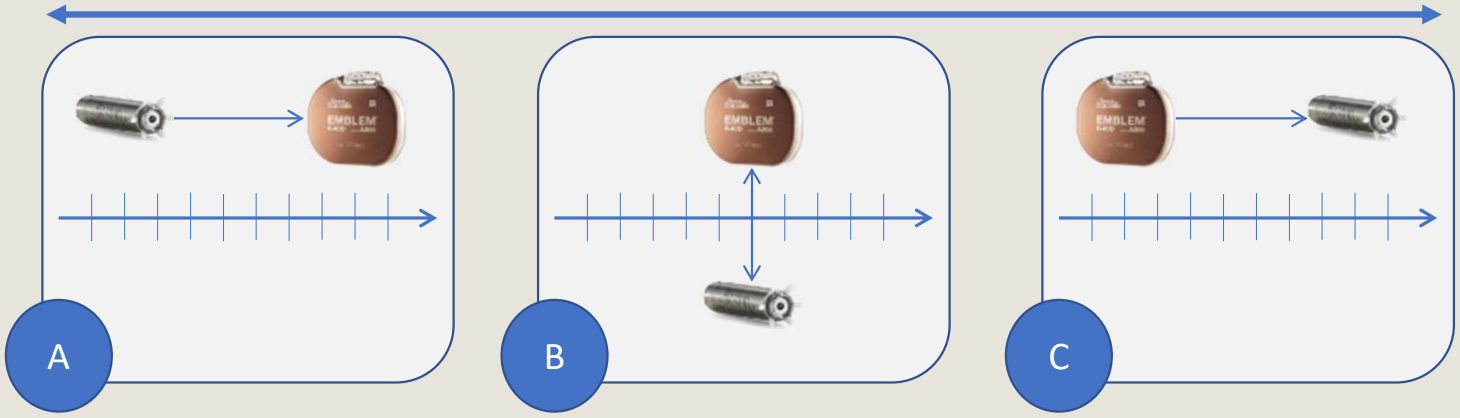
Value of a Modular CRM System



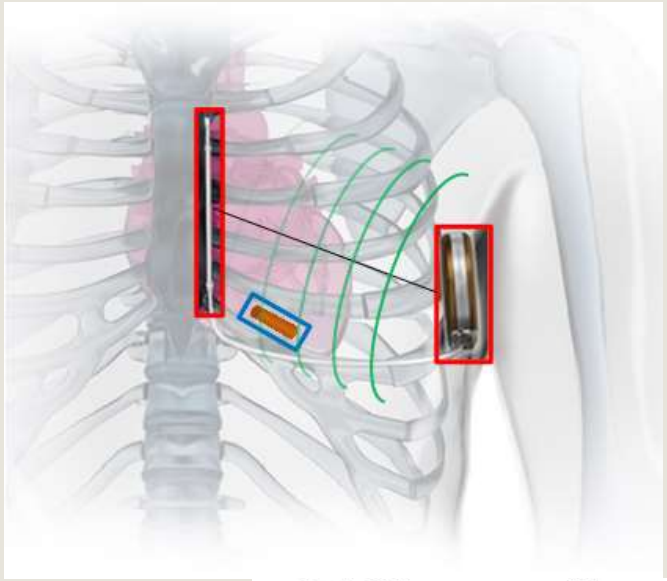


- Leadless Pacemaker Implanted First
- S-ICD Implanted Later

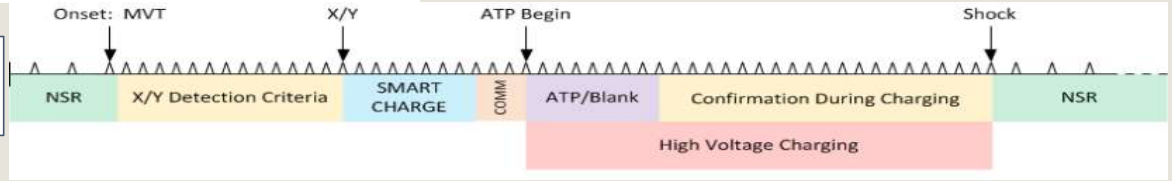
- Leadless Pacemaker and S-ICD Implanted Together

- S-ICD Implanted First
- Leadless Pacemaker Implanted Later

Operation of the Modular CRM System



1.Leadless pacemaker designed to sense and treat bradycardia independently from the S-ICD
2.ATP schemes will be built into the leadless pacemaker, but can be activated only by the S-ICD or the programmer
3.S-ICD will continue to sense tachycardia, following which it is designed to command ATP in the leadless pacemaker prior to a shock



Example of ATP during charge in the Shock Zone

Published Pre-Clinical Data for BSC's mCRMTM System

Summary of pre-clinical data published online in paper titled:
"The modular cardiac rhythm management system: the EMPOWER leadless pacemaker and the EMBLEM subcutaneous ICD"

Schwerpunkt

Herzschr Elektrophys 2018 · 29:355–361
https://doi.org/10.1007/s00399-018-0602-y
Received: 25 September 2018
Accepted: 9 October 2018
Published online: 31 October 2018

F. V. Y. Tjong[1] · B. E. Koop[2]

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[2] Boston Scientific Corporation, St. Paul, USA

The modular cardiac rhythm management system: the EMPOWER leadless pacemaker and the EMBLEM subcutaneous ICD

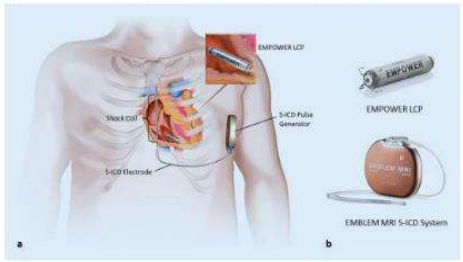

Fig. 1 ◂ The modular cardiac rhythm management (mCRM) system. **a** Depiction of implanted mCRM system. **b** Close-up images of EMPOWER and EMBLEM MRI devices (not to scale). *S-ICD* subcutaneous implantable cardioverter–defibrillator, *LCP* leadless cardiac pacemaker. © 2017 Boston Scientific Corporation or its affiliates. All rights reserved. Used with permission of Boston Scientific Corporation

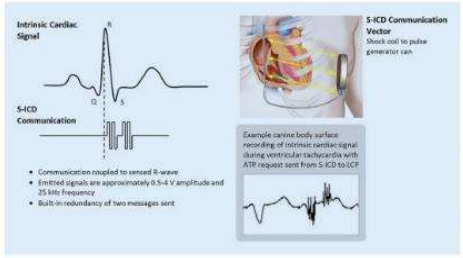

Fig. 2 ◂ Device–device communication of the mCRM system. Depiction of how communication messages are sent from S-ICD to EMPOWER LCP via conducted signals. The EMPOWER LCP senses the conducted signals via its cathode and anode, which are also used for sensing intrinsic cardiac signals. *mCRM* modular cardiac rhythm management, *S-ICD* subcutaneous implantable cardioverter–defibrillator, *LCP* leadless cardiac pacemaker, *ATP* antitachycardia pacing

1. Tjong, F.V.Y. & Koop, B.E. Herzschr Elektrophys (2018) 29: 355. https://doi.org/10.1007/s00399-018-0602-y

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THINK S-ICD FIRST

The EMBLEM MRI S-ICD System

- **Is the first and only subcutaneous implantable defibrillator that leaves the heart and vasculature untouched.**
  Provides effective defibrillation with performance comparable to studies with TV-ICD[25]
  Demonstrated in a meta-analysis to be superior to TV-ICD in avoiding lead complications[26]
- **S-ICD is recommended in AHA/ACC/HRS guidelines with a Class I and a Class IIa recommendation, and a Class IIa in ESC guidelines**[19,34]
  As per the guidelines, S-ICD is the preferred solution for patients at increased risk of infection e.g. diabetic patients (~35% of the ICD population)[19]
- **S-ICD is a suitable solution for the majority of the patients at risk for sudden cardiac arrest**[19,34]
- **Is not a niche choice, with 15 years of clinical experience, > 100,000 patients implanted with S-ICD and > 10,000 patients enrolled in clinical studies worldwide.**
  Provides a reliable and sophisticated technology as the result of 10 years of implant experience