S-ICD
SUB CUTANEOS IMPLANTABLE CARDIAQUE DEFIBRILLATOR.

INTRODUCTION

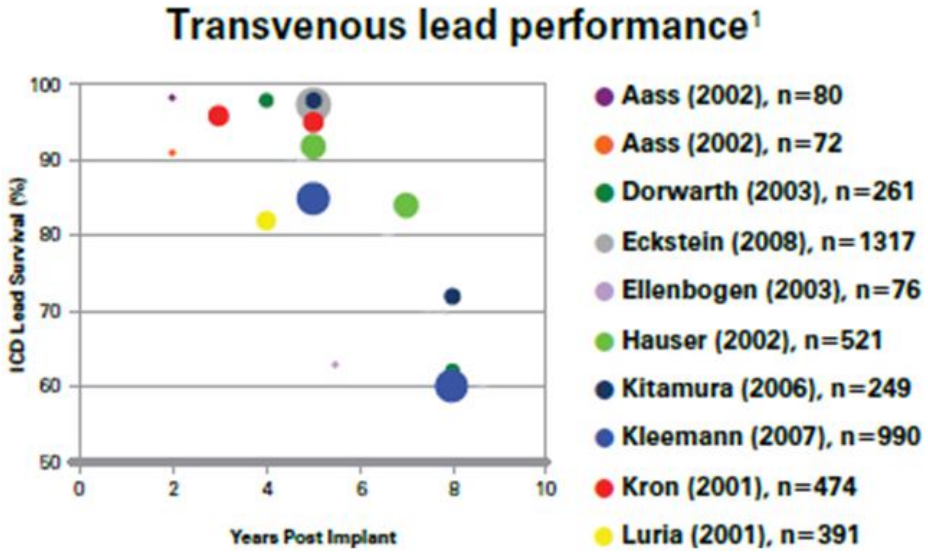
- Between nineteen and two thousand,many studies demonstrated the efficiency of ICD to reduce suden cardiaque death (reduction untill 50 % of sudden cardiaque death and up to 70 % of cardiaque rythmic mortality).
- The use of intra cardiaque leads increases the morbidity and relates to the efficiency of ICDs to reduce mortality

COMPLICATION RESULTING TO INTRA CARDIAQUE LEAD

- Acute :
  - Dislogdment lead.
  - Cardiaque perforation.
  - Tamponade.
  - Pneumothorax

- Chronical :
  - Systemic infection.
  - Lead alteration and inapproriate therapy.

TV-ICD COMPLICATION RISK



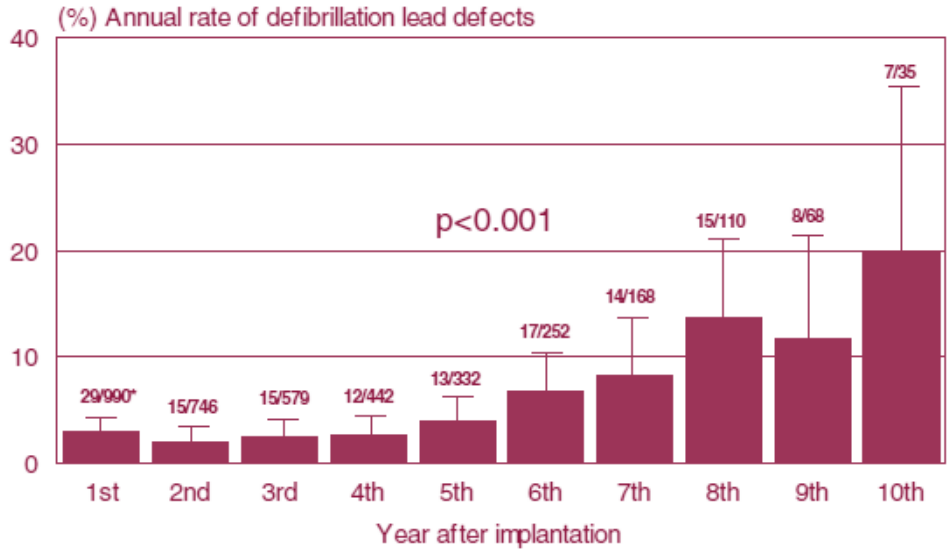
The S-ICD™ System eliminates the majority of the major complications associated with TV-ICDs including lead dislodgement, lead failure, endocarditis, and pneumothorax/hemothorax.

- The Danish Registry[2] demonstrated that up to **15%** of ICD patients are at risk of a complication within the first 6 months of implant.
- The majority of complications requiring invasive intervention included:
  - Lead related issues
  - Infection
  - Cardiac Perforation
  - Pneumothorax

1. Maisel WH, Kramer DB. Implantable cardioverterdefibrillator lead performance. Circulation 2008;117:2721-2723. doi: 10.1161/CIRCULATION AHA. 108.776807.
2. Kirkfeldt, R., et al. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark . European Heart Journal. Dec 2013

Preservation the heart and vessels of patients

- The rate of complication regarding defibrillation lead defects in order to require re intervention is about 20 % for 10 years.



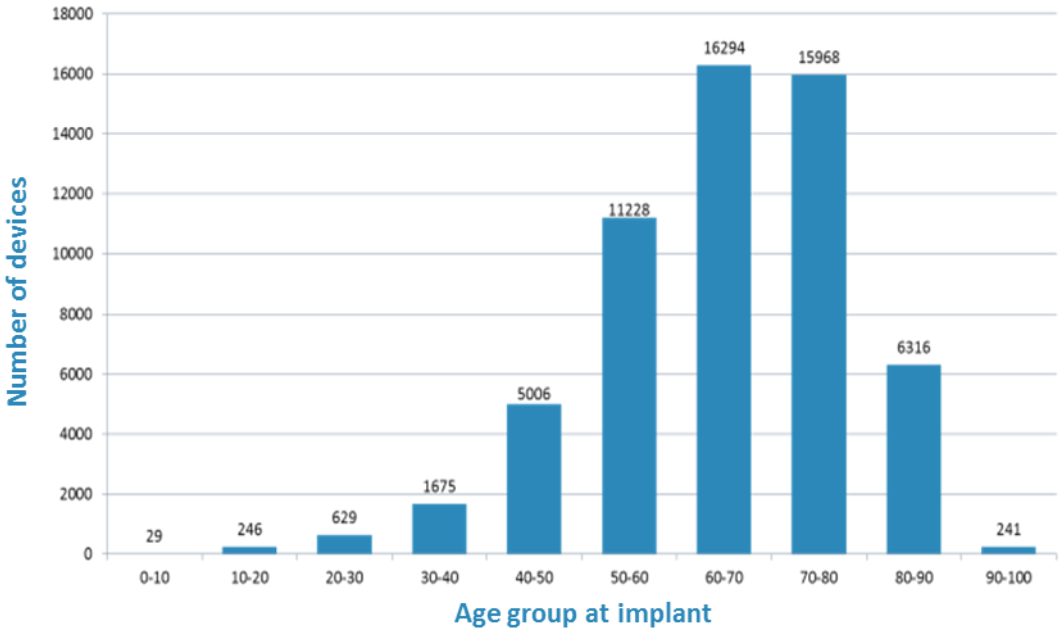
- The extraction lead procedure was difficult and the complication rate is high .[4].

3. Thomas Kleemann and al. Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years. Circulation.2007;115:2474-2480. The aim of the present study was to assess the annual rate of transvenous defibrillation lead defects related to follow-up time after lead implantation. A total of 990 consecutive patients who underwent first implantation of an implantable cardioverter-defibrillator between 1992 and May 2005 were analyzed. Median follow-up time was 934 days (interquartile range, 368 to 1870). The estimated lead survival rates at 5 and 8 years after implantation were 85% and 60%. The annual rate of ICD lead defects that require intervention increases with time and reaches 20% in 10 year-old leads.

4. Robert G. Hauser and al, Deaths and cardiovascular injuries due to device assisted implantable cardioverter-defibrillator and pacemaker lead extraction. Europace.2010;12:395-401. The aim of this study was to determine whether complications due to device-assisted lead extraction might be more hazardous than published data suggest, and whether procedural safety precautions are effective. We searched the US Food and Drug Administration's (FDA) Manufacturers and User Defined Experience (MAUDE) database from 1995 to 2008 using the search terms 'lead extraction and death' and 'lead extraction and injury'. The majority of deaths and injuries involved ICD leads, and most were caused by lacerations of the right atrium, superior vena cava, or innominate vein. Conclusion : These findings suggest that device-assisted lead extraction is a high-risk procedure and that serious complications including death may not be mitigated by emerg

Preservation the heart and vassels of patients

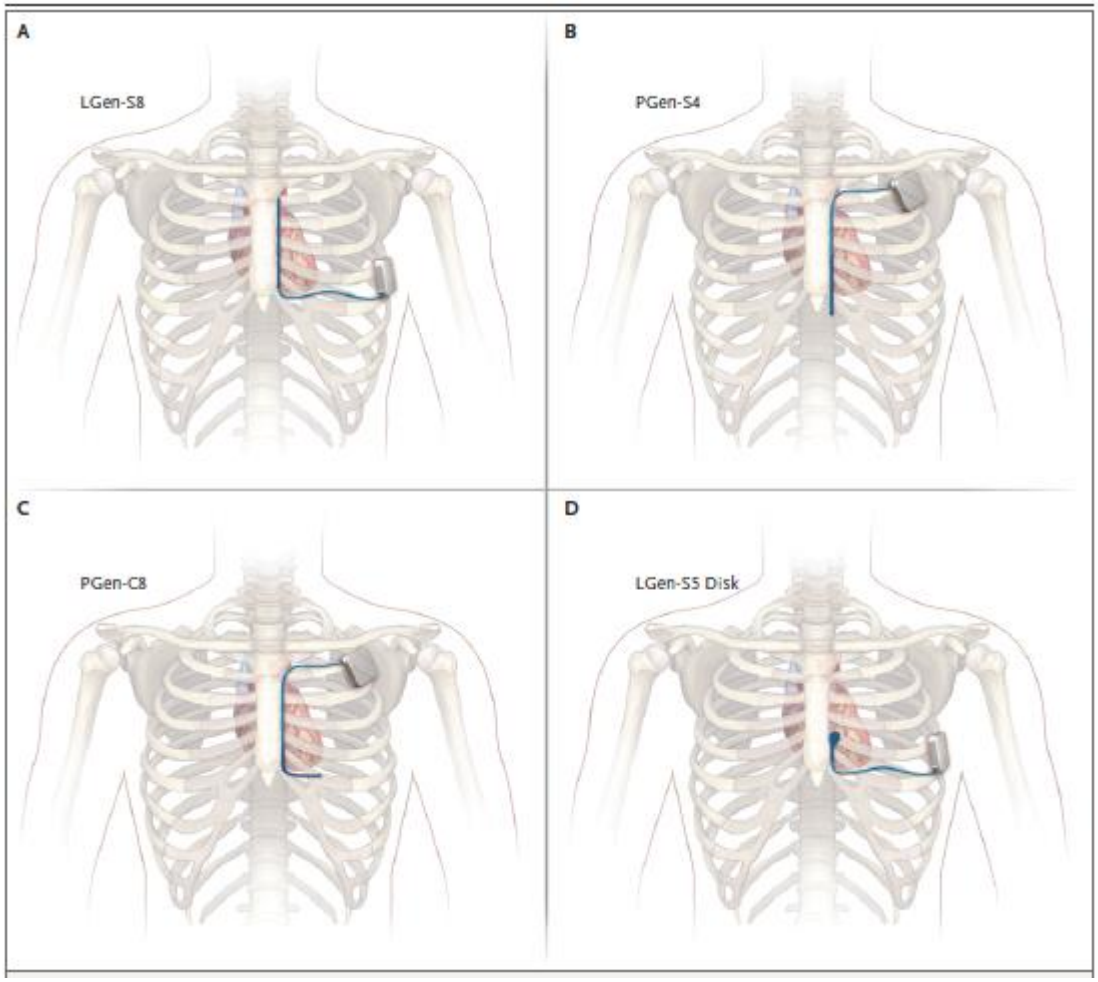
- Third of implanted patients was aged under 60 .
- 40% of implanted patients have life expectancy for about 10 years .



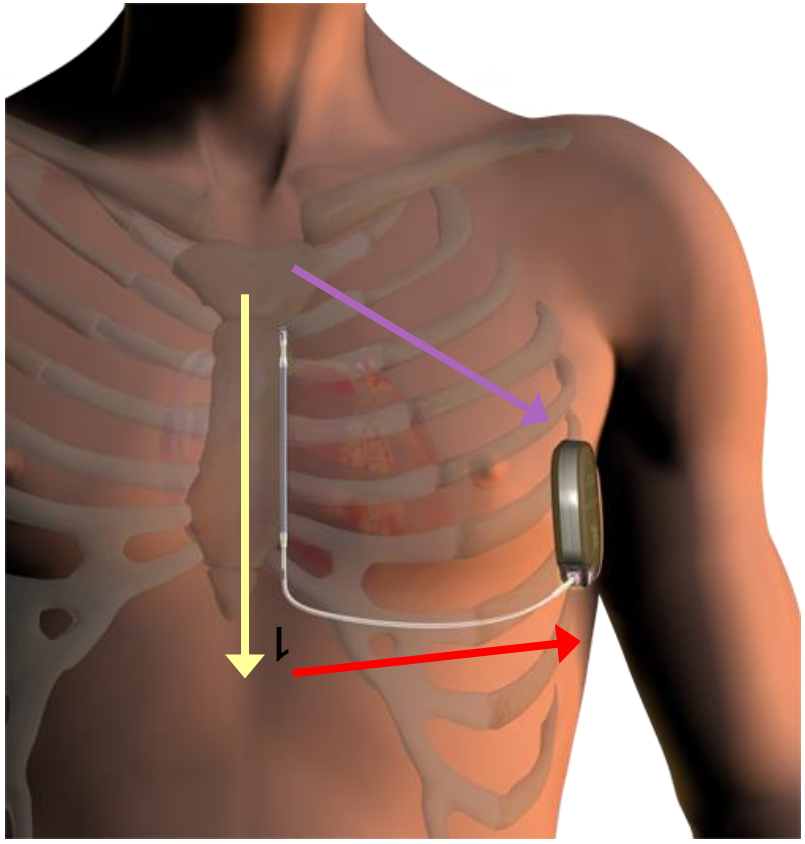
1. Leslie A. Saxon et al., The ALTITUDE Study Group Survival after ICD implant and incidence of device therapy in patient less than thirty years old, ESC 2011, BSC analyzed 57,632 patients implanted with ICDs from 1/1/2004 to 1/1/2010 followed on the LATITUDE® system. Of this population, 18,813 patients (33%) were younger than 60 years old.

2. Robert G. Hauser et al., The Growing Mismatch Between Patient Longevity and the Service Life of Implantable Cardioverter-Defibrillators. J Am Coll Cardiol 2005;45:2012-5. Over 100,000 patients received implantable cardioverter defibrillators (ICDs) in 2004. Over 40% of patients were still living at 10 years.

78 PATIENTS WAS IMPLANTED TO DETERMINING THE POSITION OF ICD



S-ICD® - DÉTECTION



- Three vectors from detection:

-Primary.

-Secondary.

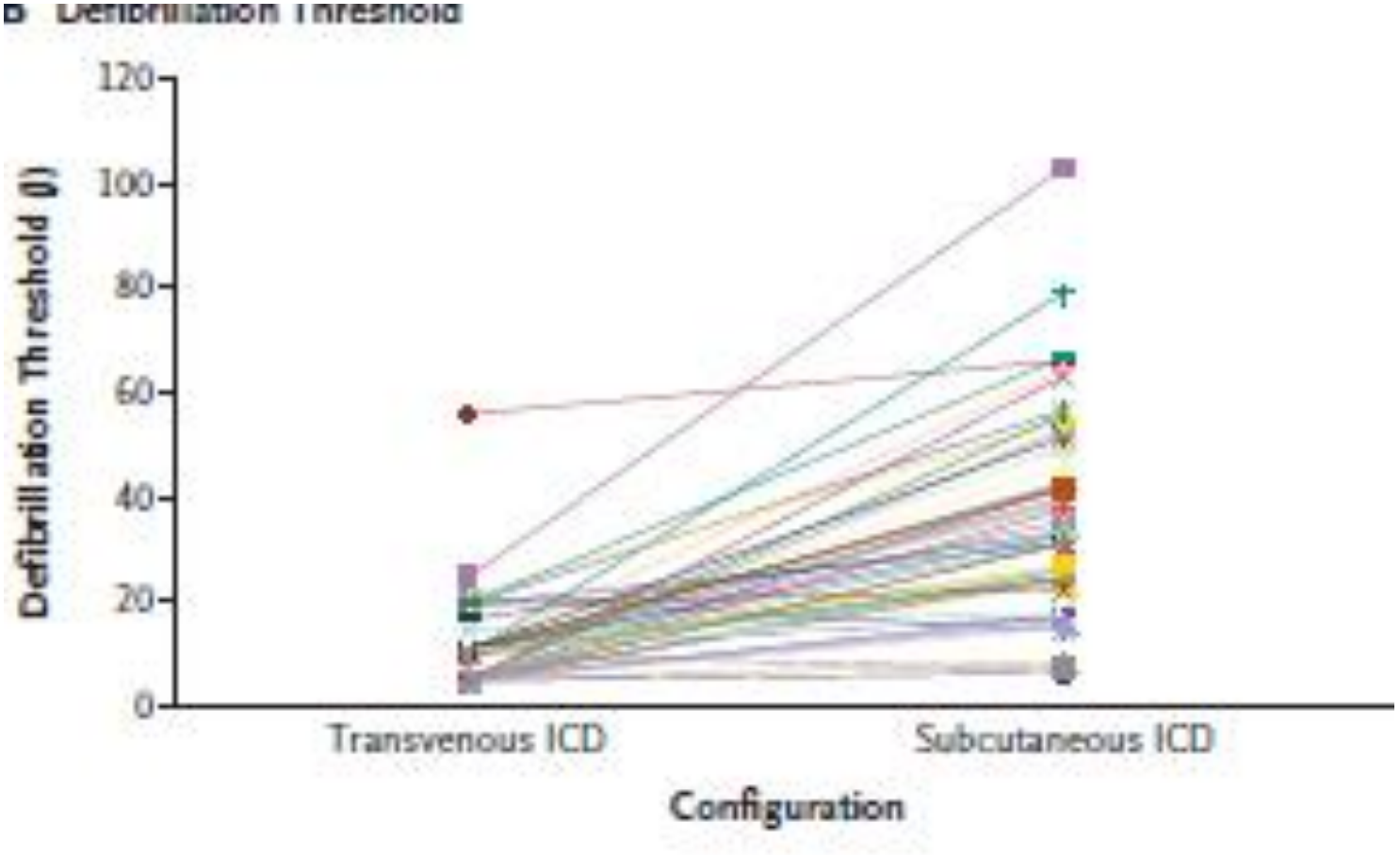
-alternate.

- Time to therapy delivrance:

-Induction 15 sec

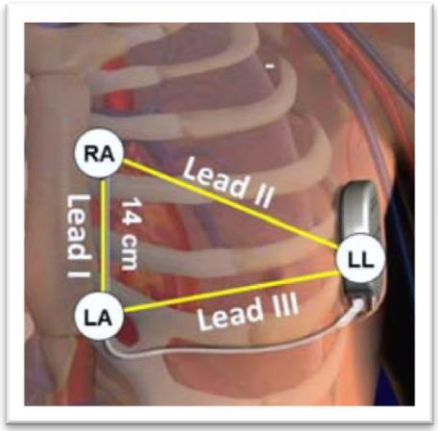
-Spontaneous 20 sec

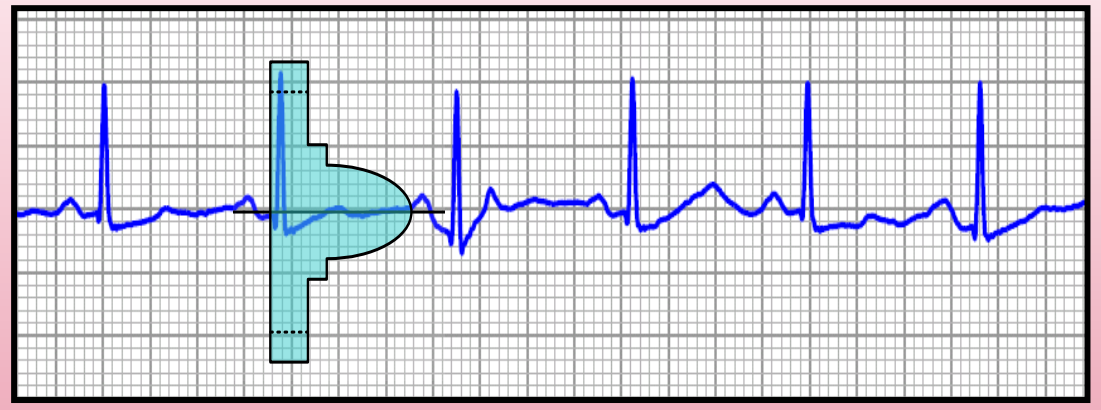
DEFIBRILLATION THRESHOLD IS MORE HIGH THAN ENDO CAVITARY.

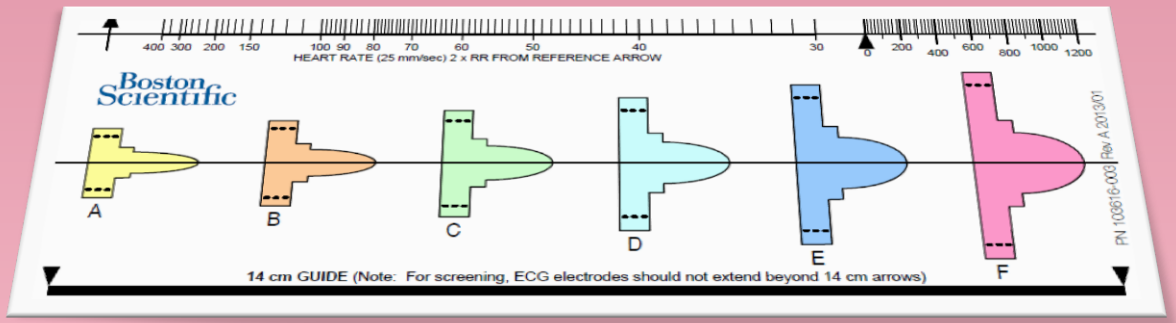


SCREENING PATIENTS

Before implantation an ECG with 3 derivations are used to screen patients







LEADING THE WAY IN SUBCUTANEOUS DESIGN

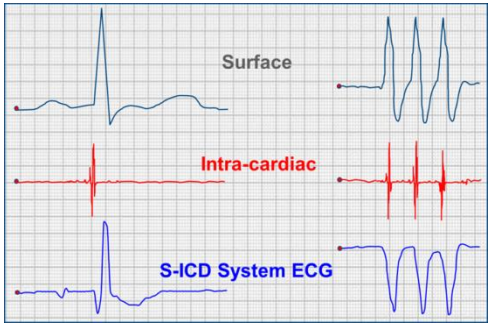
INSIGHT™ ALGORITHM

The EMBLEM™ S-ICD uses highly sophisticated technology to identify and classify a heart rhythm – rather than individual beats – to effectively sense, discriminate, and convert VT/VF.

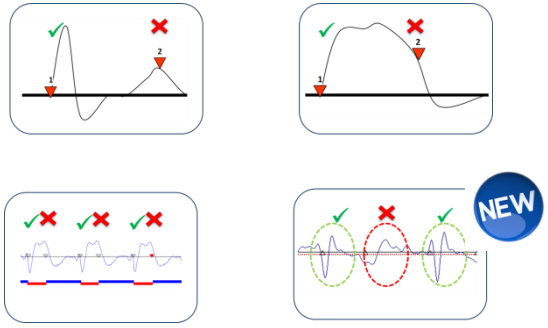
PHASE I: Detection — Subcutaneous signal detection

PHASE II: Certification — Heart rate determined

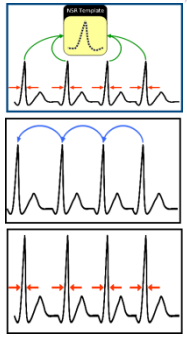
PHASE III: Therapy Decision — Heart rhythm assessed and confirmation for therapy



S-ECG is a high-definition morphologically rich signal similar to a surface ECG



Four double-detection algorithms designed to reduce oversensing



Three rhythm discriminators used to determine therapy delivery

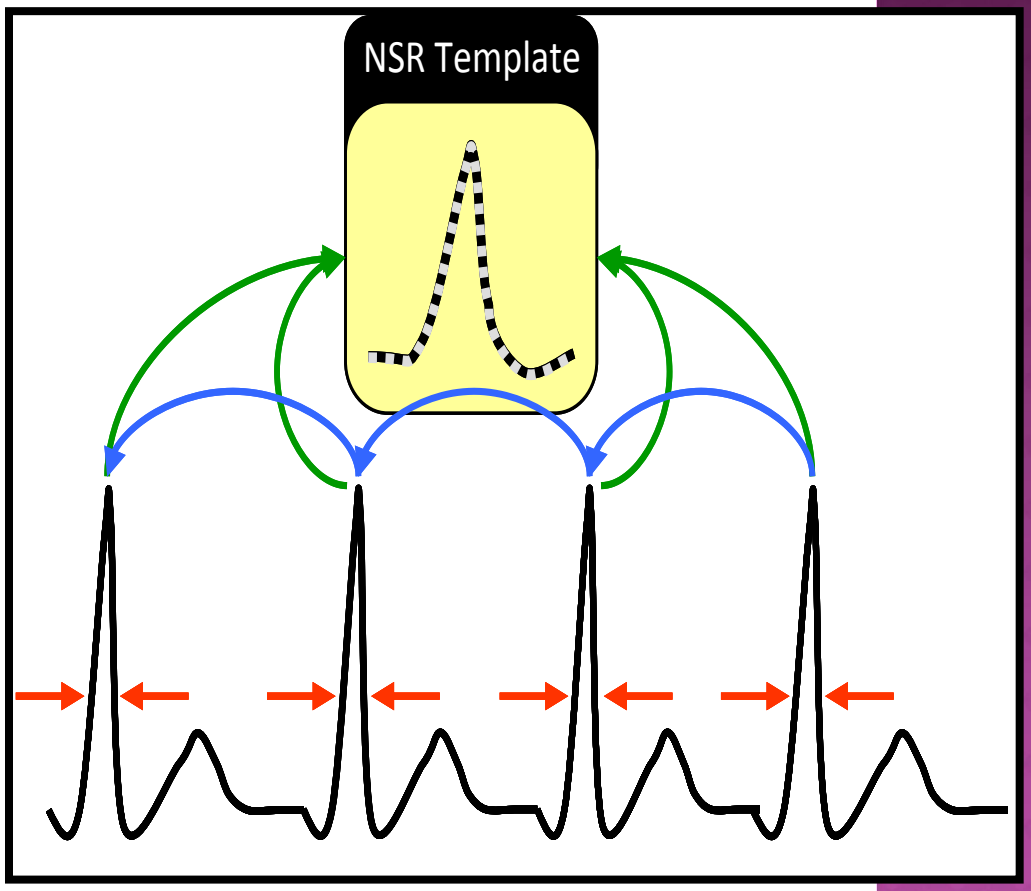
DISCRIMINANT INSIGHT™

Use simultaneous three methodes:

1/Static morphology analysis.

2/Dynamic morphology analysis.

3/ Width QRS analysis.

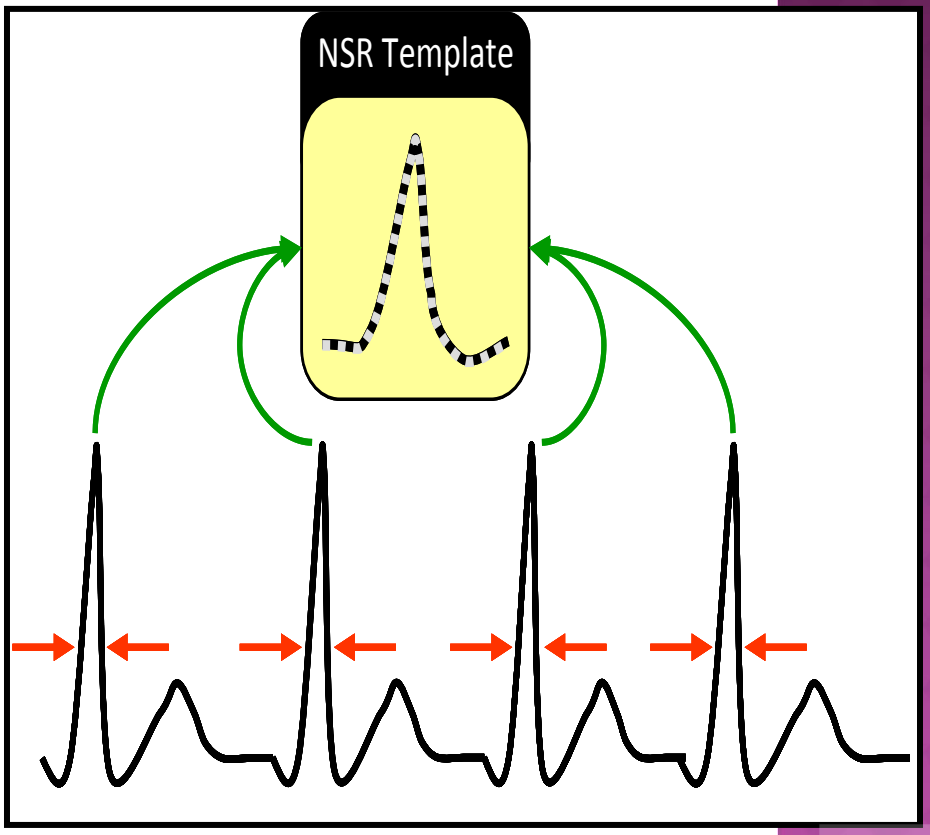


DISCRIMINANT INSIGHT™

Static morphology analysis:

To identify no treatment rate ;

The QRS are compare to template.

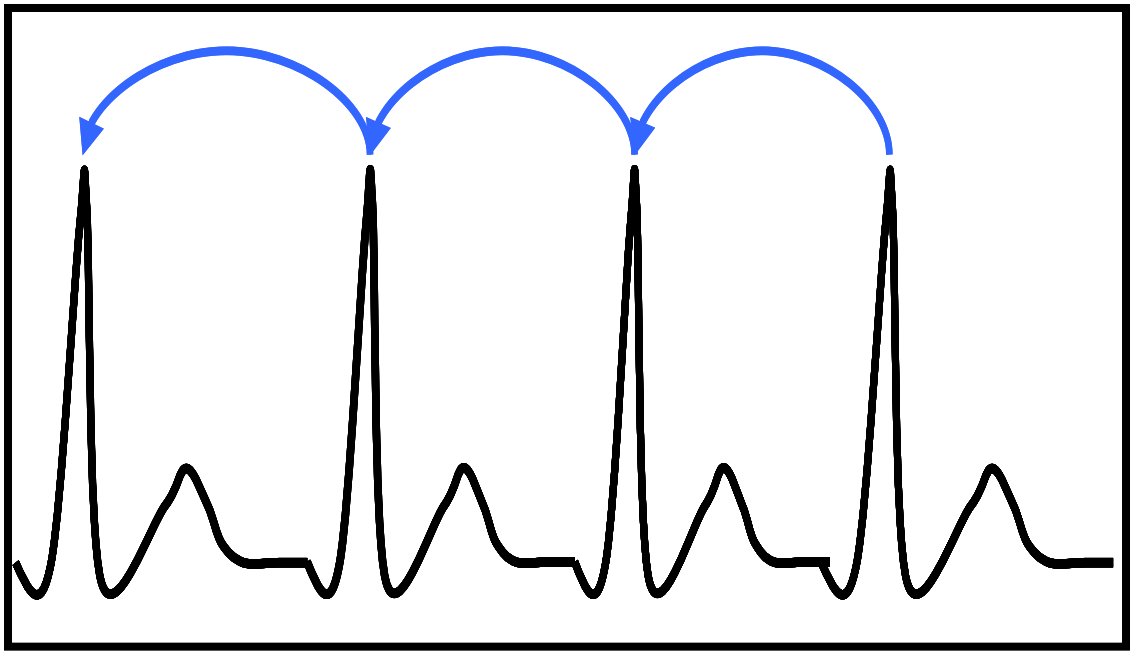


DISCRIMINANT INSIGHT™

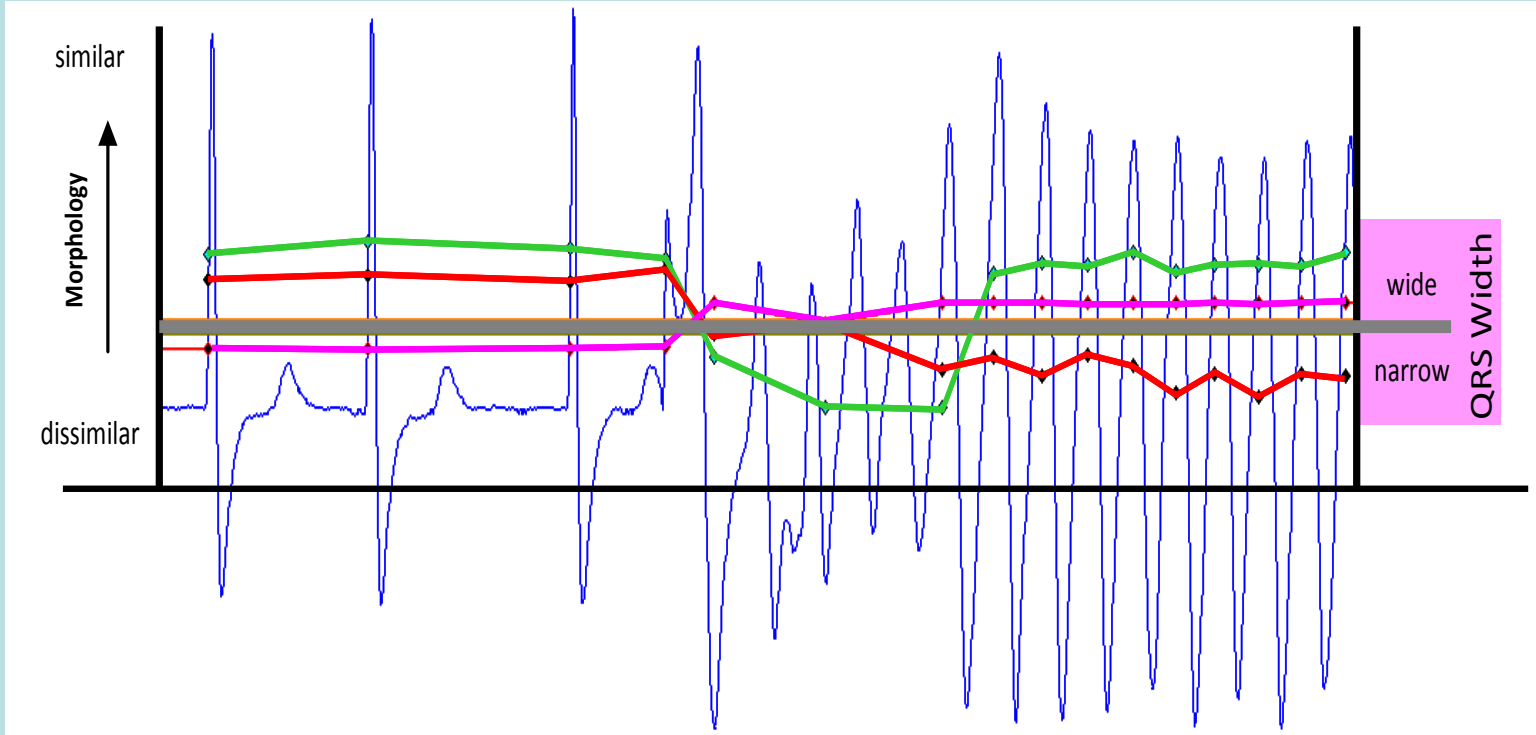
Dynamic analysis:

To identify treatment rate (the QRS are compared one to another) .

(Polymorphic QRS analysis).

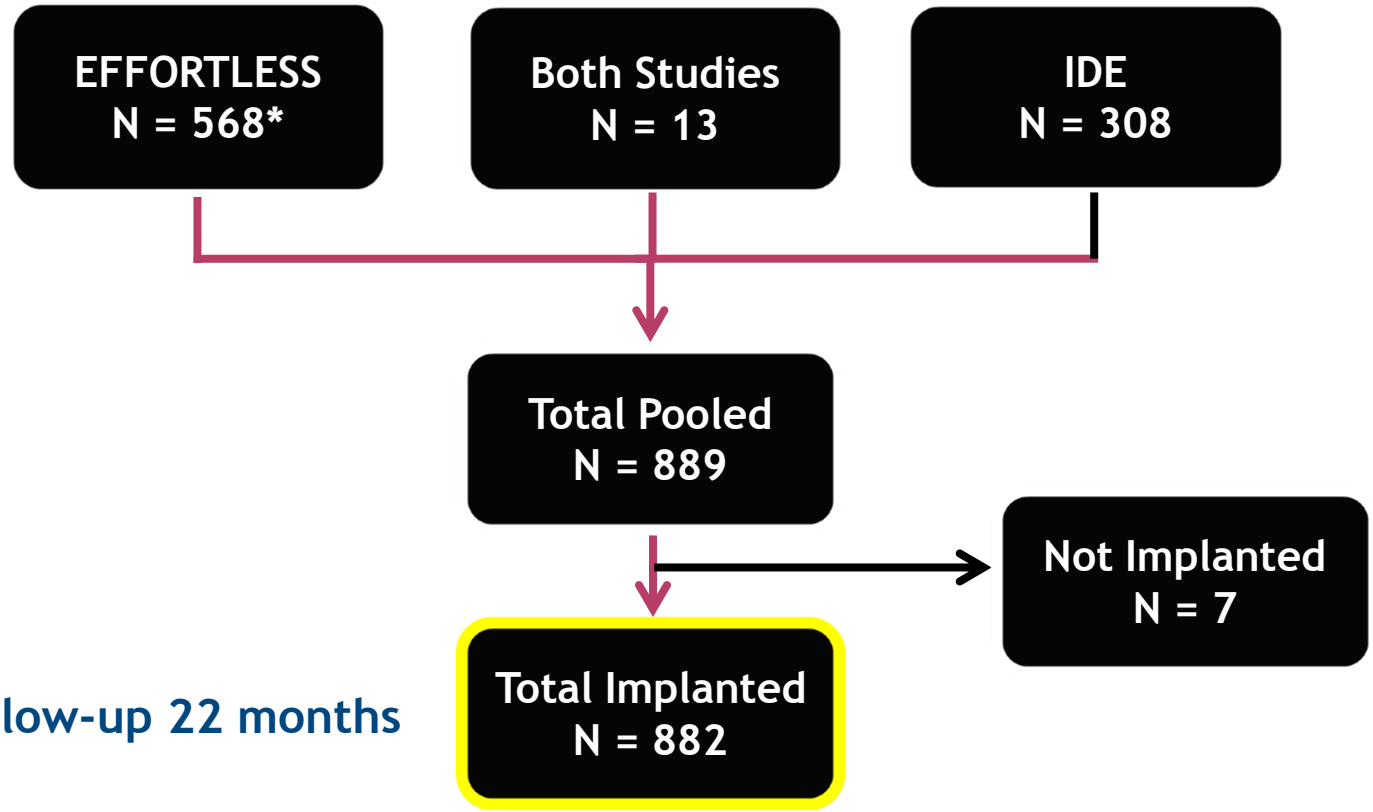


DISCRIMINANT INSIGHT™



Static analysis (red line decrease when VT) . In the same time the green line (dynamic analysis) stays normal when monomorphic VT and decreases when polymorphic VT . Pink line stays narrow in sinus rythme and widens in VT.

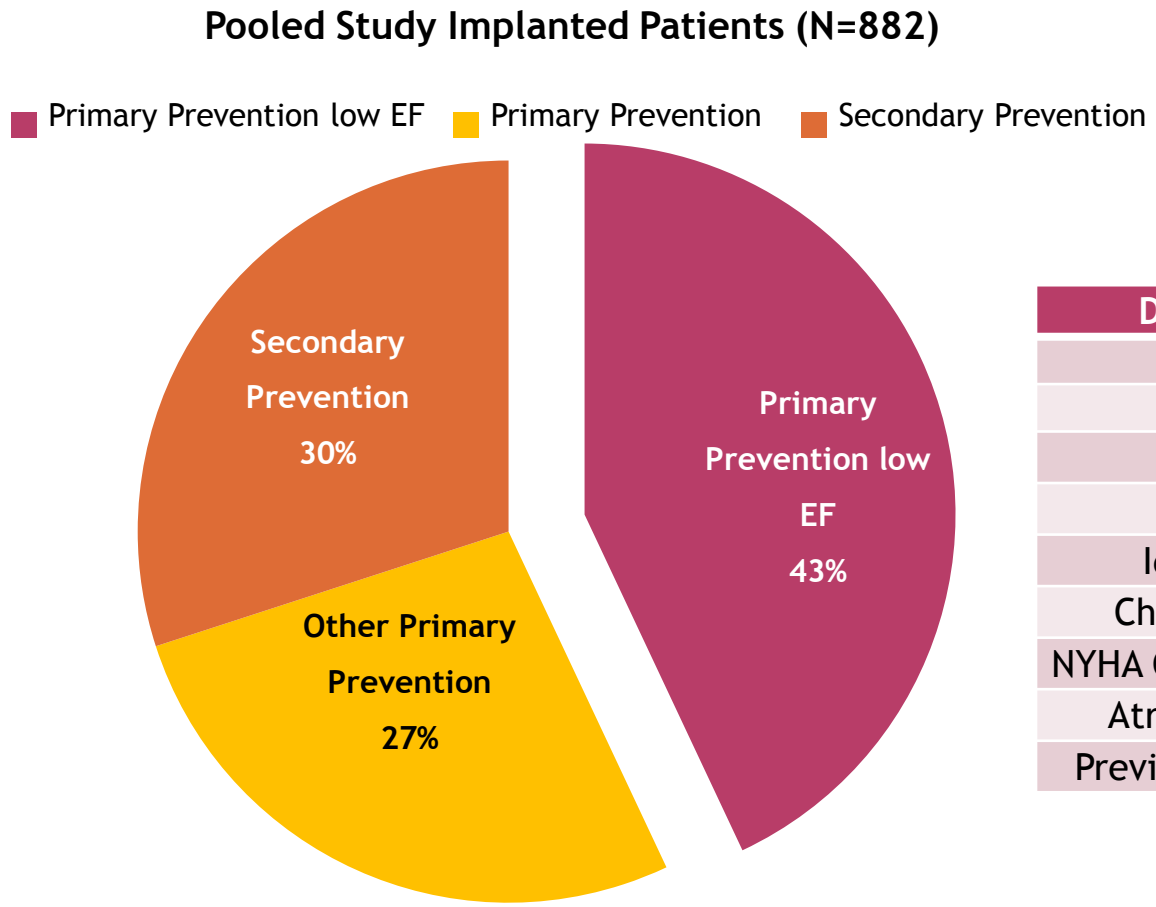
S-ICD POOLED ANALYSIS COHORT



Mean follow-up 22 months

S-ICD POOLED RESULTS DEMOGRAPHICS

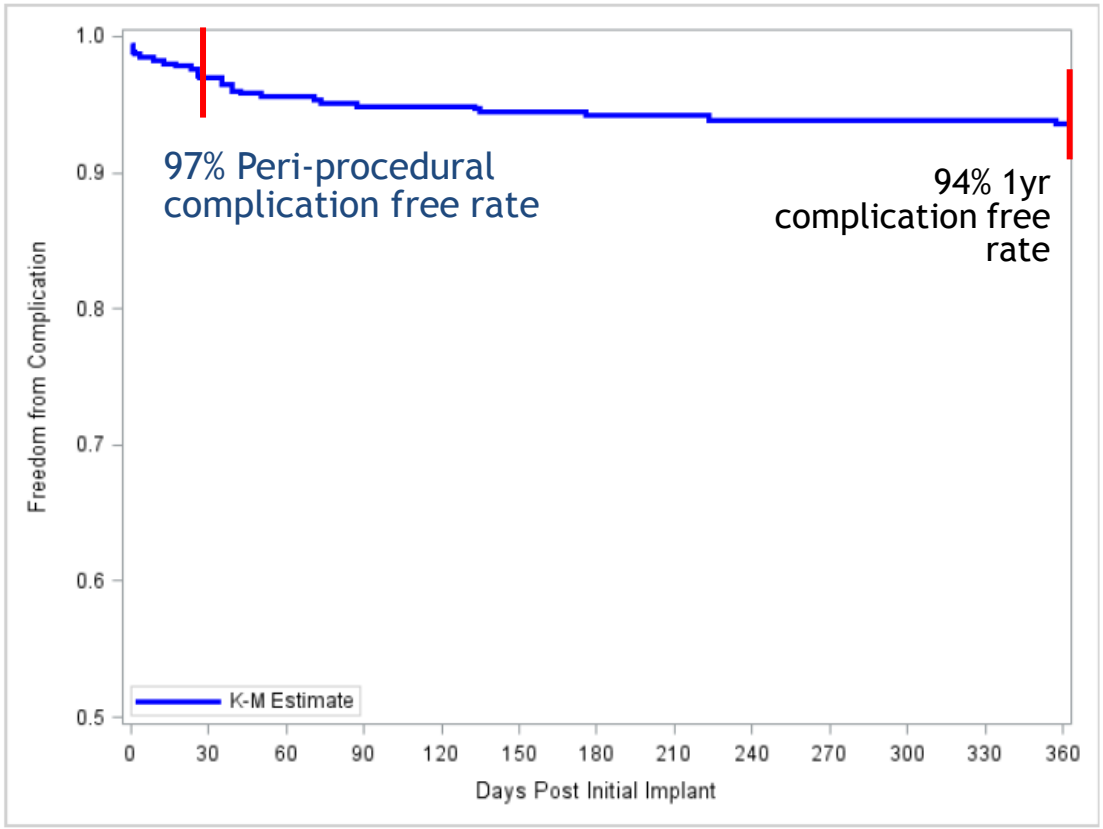
43% of the study population were Primary Prevention Patients with an EF ≤35%



Demographic	N (%)
Age (years)	50.3 ± 16.9
Male (n, %)	636 (72.5)
Ischemic	330 (37.8%)
Genetic	58 (6.7%)
Idiopathic VF	40 (4.6%)
Channelopathies	90 (10.3%)
NYHA Classification II-IV	327 (37.5%)
Atrial Fibrillation	143 (16.4%)
Previous Defibrillator	120 (13.7%)

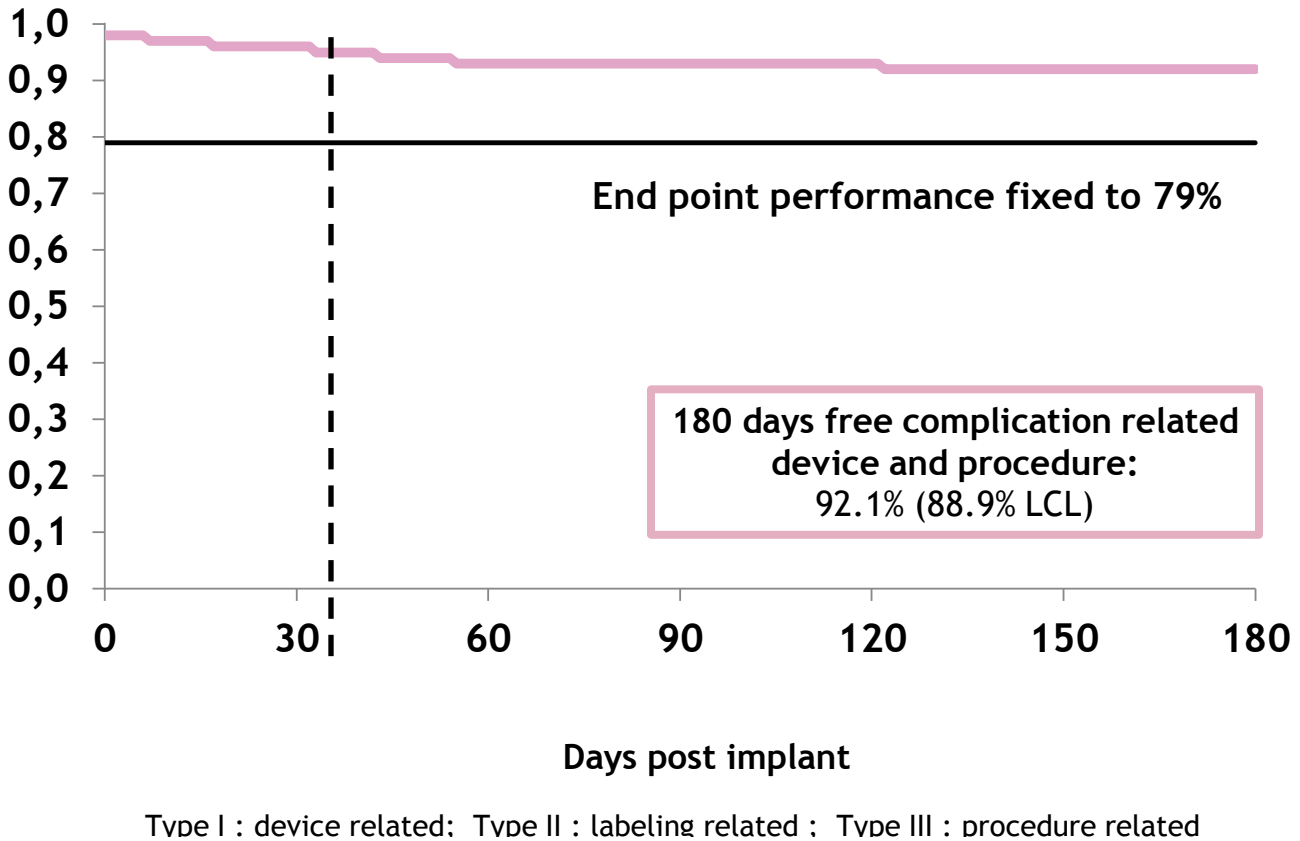
EFFORTLESS S-ICD™ SYSTEM REGISTRY COMPLICATION-FREE RATE

94% Complication Free at 360 days



Complication	Patients N (%)
Erosion or extrusion of implanted electrode or pulse generator	4 (0.9%)
Hematoma	1 (0.2%)
Failure to convert spontaneous VF episode	1 (0.2%)
Inability to communicate with device	1 (0.2%)
Inappropriate shock: oversensing	2 (0.4%)
Incision / superficial infection	2 (0.4%)
Near syncope/dizziness/shortness of breath/confusion	1 (0.2%)
Pleural effusion	1 (0.2%)
Pneumothorax	1 (0.2%)
Premature battery depletion	1 (0.2%)
Shock delivered for Non VT/VF	1 (0.2%)
System infection	11 (2.4%)
Suboptimal electrode position / electrode movemen	5 (1.1%)
Suboptimal pulse generator position	1 (0.2%)
Suture discomfort	1 (0.2%)
Total Complications (% of 456)	**29 (6.4%)**

IDE STUDY : THE PRIMARY SAFETY END POINT WAS 180 DAYS TYPE I COMPLICATION FREE RATE REACHED 99%



Type I : device related; Type II : labeling related ; Type III : procedure related

2. Weiss R et al. Safety and Efficacy of a Totally Subcutaneous Implantable-Defibrillator. Circulation 2013;128:944-953..330 patients were included in a prospective, non-randomized, multicenter trial with a standard indication for an ICD, who neither required pacing nor had documented pace-terminable VT. Nine patients were withdrawn prior to implant and out of 321 implant attempts (52+/-16 year-old, 74% male, LVEF=36+/-16%, Primary prevention indication = 79,4%). There were a total of 8 deaths (2.5%) during the study. 314 patients were discharged with S-ICD. The primary safety end point was the 180-day type I complication-free rate which reached 99.0% with a 95% lower confidence limit (2-sided) of 97.9%, above the performance goal of 79%. A total of 276 patients (87.9%) had a follow-up duration of ≥180 days. The primary effectiveness end point was the induced ventricular fibrillation conversion rate which demonstrated 100% acute conversion (304/304) with a 95% lower confidence limit of 98.8%, exceeding the prespecified performance goal of≥ 88%, with success defined as 2 consecutive ventricular fibrillation conversions (65J) of 4 attempts.

"A sensitivity analysis was performed in the safety cohort and included all device related (type I), labeling-related (type II), and procedure related (type III) complications. The 180-day type I through III complication-free rate was 92.1% with a lower confidence limit of 88.9%, once again above the performance goal (Figure 2). There were no cases of lead failures, endocarditis or bacteremia, tamponade, cardiac perforation, pneumothorax, hemothorax, or subclavian vein occlusion associated with the S-ICD System."

S-ICD POOLED RESULTS
SUMMARY OF INITIAL PROGRAMING

Statistic / Category	Pooled IDE and EFFORTLESS Patients
Lowest Rate Zone	Mean ± SD: 197.5 ± 19.2 bpm Median: 200.0 bpm
Zones (n, %)	
Dual Zone	689 (80%)
Single Zone	170 (20%)
Vector (n, %)	
Primary	452 (53%)
Secondary	313 (37%)
Alternate	94 (11%)

EFFORTLESS S-ICD™ System Registry
Implant Conversion Testing

- Successful conversion efficacy at implant defined as at least one successful conversion of an induced ventricular arrhythmia at ≤ 80J

Patient data	N	%
Complete data for evaluation	393	
Successful Conversion	392	**99.7**
• Repositioning required for initial failure	7	**1.8**
• Successful at ≤ 65J	373	95

Implant Conversion Efficacy was 99.7%

S-ICD POOLED RESULTS

S-ICD AND TV-ICD SPONTANEOUS CONVERSION EFFICACY

When evaluating TV-ICD studies[1-4], S-ICD was as effective as TV-ICD in treating spontaneous arrhythmias

	Spontaneous Shock Efficacy	
	First Shock	Final Shock in episode
S-ICD Pooled Data*	90.1%	98.2%
ALTITUDE First Shock Study[1]	90.3%	99.8%
SCD-HeFT[2]	83%	
PainFree Rx II[2]	87%	
MADIT-CRT[3]	89.8%	
LESS Study[4]		97.3%

* Excluded VT/VF Storm events

S-ICD Pooled Data	Of two "unconverted" episodes
100% Clinical conversion to normal sinus rhythm	• One spontaneously terminated after the 5th shock • In the other episode, the device prematurely declared the episode ended. A new episode was immediately reinitiated and the VF was successfully terminated with one shock

1 Cha YM et al. *Heart Rhythm* 2013;10:702-708. 2 Swerdlow CD et al. *PACE* 2007; 30:675-700. 3 Kutyifa V, et al. *J Cardiovasc Electrophysiol* 2013;24:1246-52. 4 Gold MR et al. *Circulation* 2002;105:2043-2048.

COMPLICATIONS

-IDE study:

- Infection 18 patients (5.8%). 4 requiring explant (1.3 %).
- Death : 8 patients (2.5%)
  5 non cardiac death.
  2 hemodynamic.
  1 Unknown.

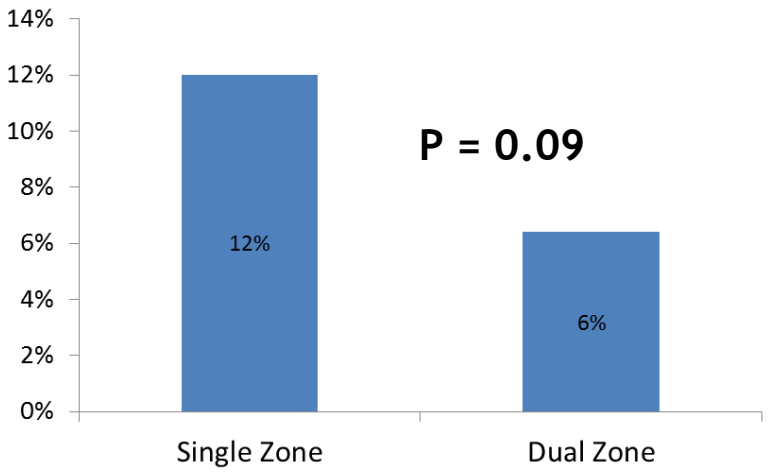
-EFFORTLESS study :

- infection 18 patients (2.2%).
  10 Explants (2 re-implant).
- Death : 9 patients.
  7 pump renal /fealure.
  1 arrhythmic.
  1 Unknown.

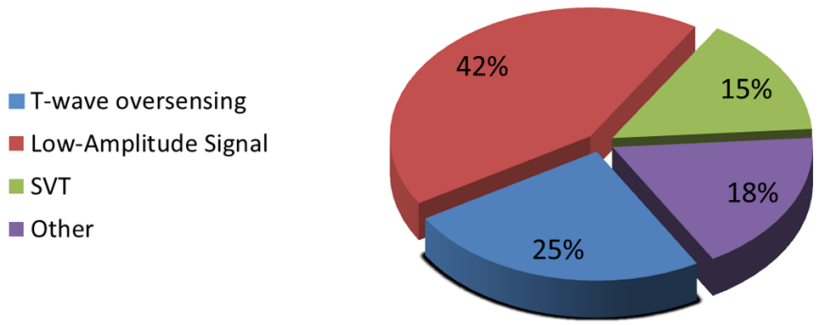
EFFORTLESS S-ICD™ System Registry
Inappropriate Therapy: Incidence

32 patients received 73 inappropriate shocks on average FU of 18 months, resulting in an inappropriate therapy rate of **7%** at 360 days.

IAS & Programming



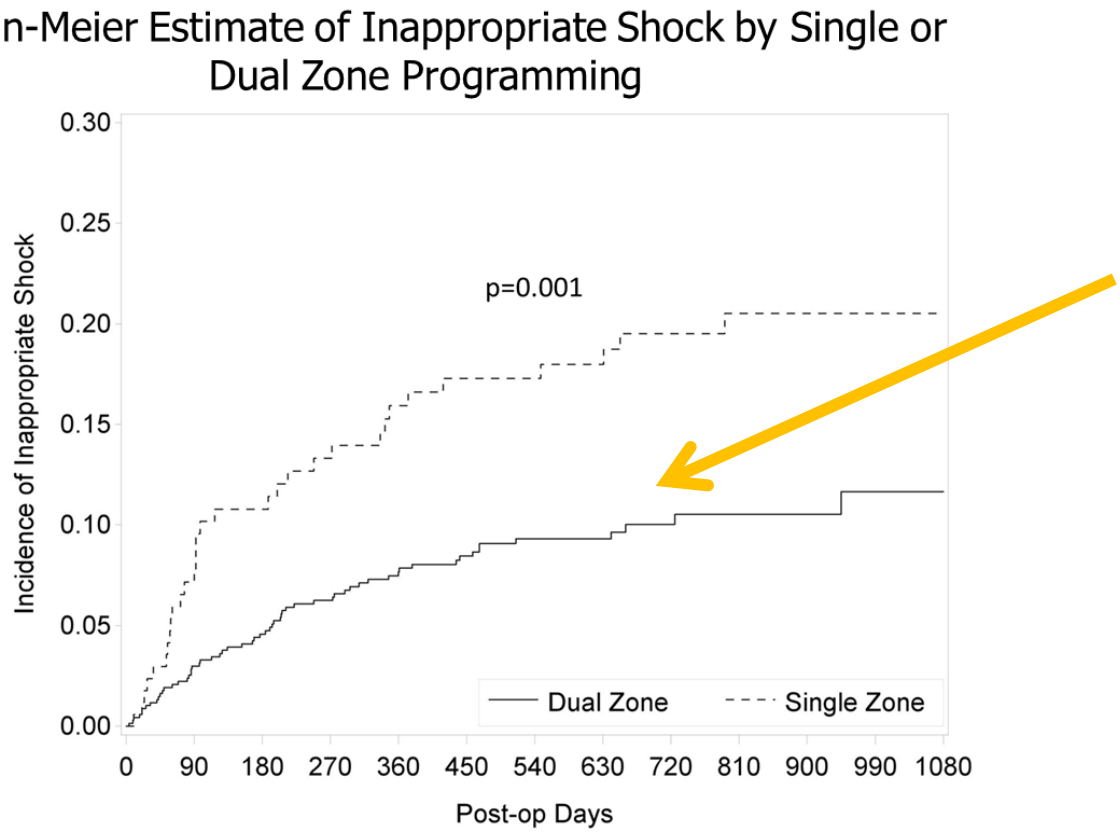
Reasons for IAS



- 82% of patients were programmed to dual-zone which reduced the inappropriate therapy rate to **6.4%**
- **Only one** inappropriate therapy has been recorded for AF/SVT within the programmed conditional zone in all S-ICD System clinical evaluations
- 72% of patients were **inappropriate therapy-free** after initial interventions (re-programming, exercise tests, medication changes)

S-ICD POOLED RESULTS
INAPPROPRIATE SHOCK BY PROGRAMMING

Significantly Lower Rate of Inappropriate Shocks with Dual Zone Programming

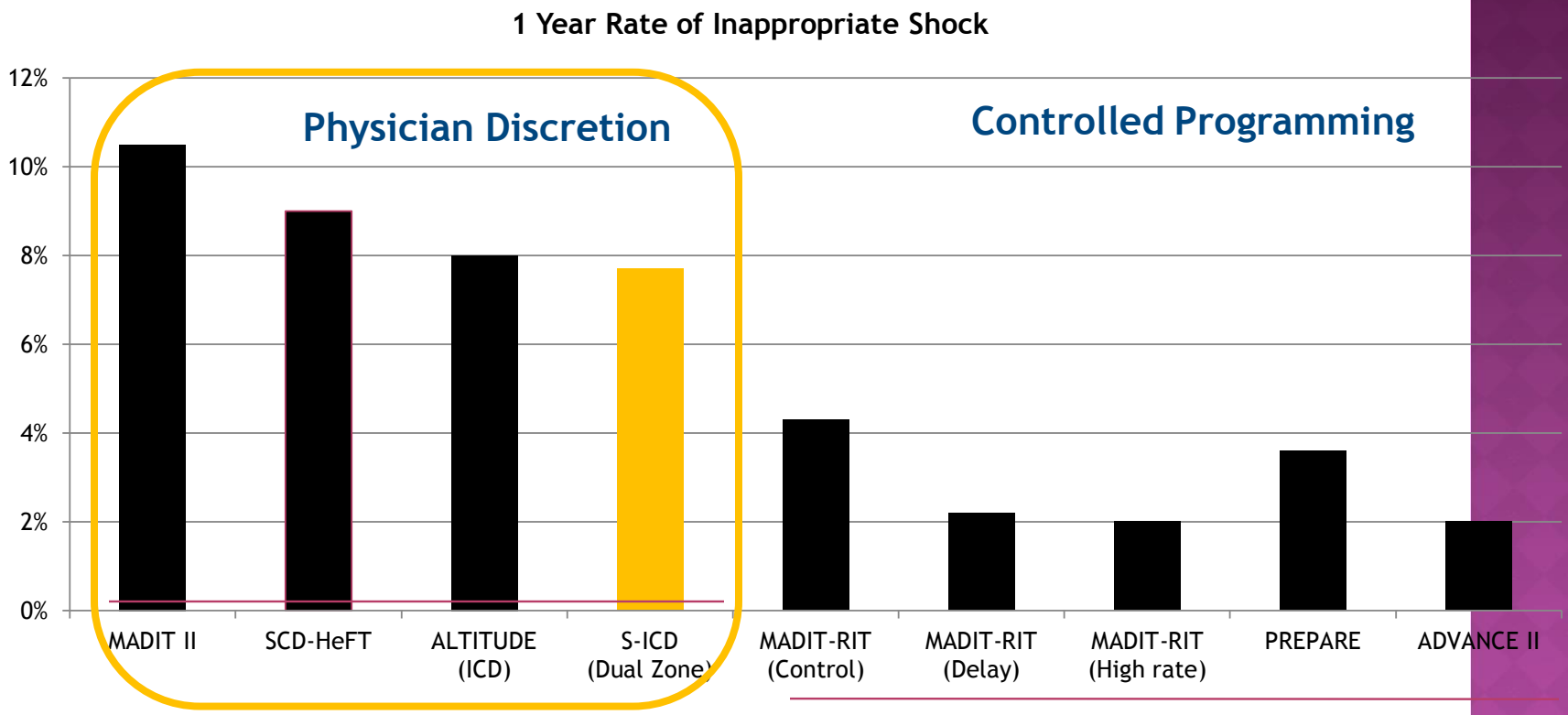


Dual Zone	No at Risk	688	634	576	546	494	441	378	279	180	120	89	66	56
	K-M Est. (%)	0.0	3.0	4.6	6.2	7.7	8.5	9.3	9.3	10.0	10.5	10.5	11.7	11.7
Single Zone	No at Risk	170	153	141	134	126	122	117	108	96	75	53	43	36
	K-M Est. (%)	0.0	7.8	10.8	13.3	15.9	17.3	17.3	18.0	19.5	20.5	20.5	20.5	20.5

INAPPROPRIATE SHOCK RATE

HOW DOES S-ICD COMPARE TO REAL WORLD PROGRAMMING WITH TV-ICD?

Rate of inappropriate shocks with S-ICD is similar to or lower than observed in real-world TV-ICD studies



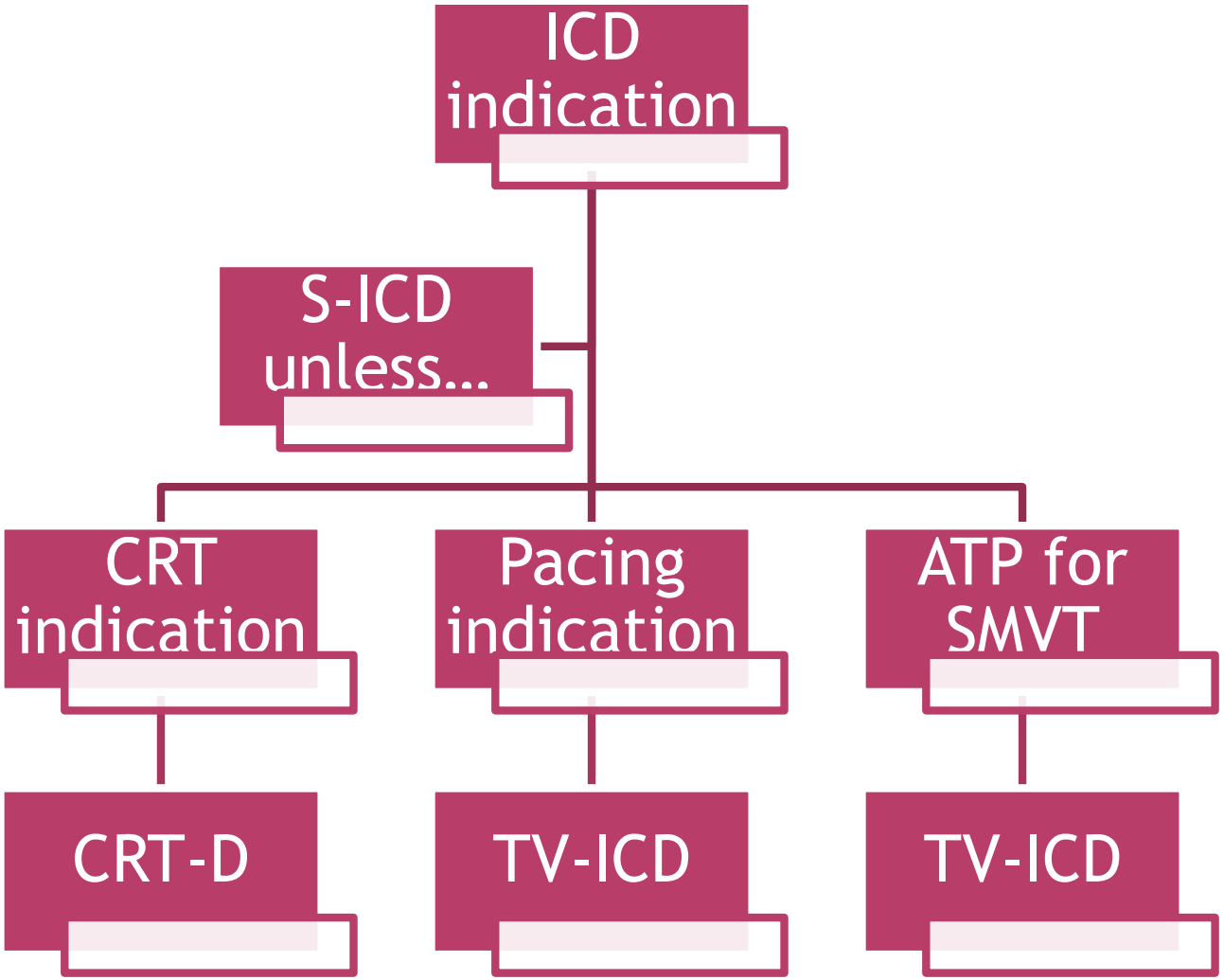
1 year Kaplan Meier incidence shown.
1 year rate for MADIT-RIT annualized at an average follow-up of 1.4 years

Daubert JP, et al. MADIT II , JACC 2008; 51:1357-1365.
Bardy GH,et al. SCD-HeFT. NEJM 2005; 352;3:225-237.
Saxon, LA et al. ALTITUDE, Circulation 2006; 114; 2766-2772.
Saxon LA et al. ALTITUDE, Circulation 2010; 122:2359-2367.

Wilkoff B, et al. PREPARE, JACC 2008; 52:541-550
Gasparini,M, et al. ADVANCE III, JAMA 2013; 309: 1903-1911.
Moss, A, et al. MADIT RIT, NEJM 2012; 367:2275-2283
Gold, et al. Pooled S-ICD data HRS 2014

WHO COULD RECEIVE THE S-ICD?

AN ONGOING PARADIGM SHIFT[1]



1. L Boersma. ICD from real life to the future: ICD innovations. ESC 2014

ICD PATIENT. EMBLEM™ S-ICD SOLUTION.

The majority of ICD-indicated patients are eligible for S-ICD implantation, as many do not require the need for bradycardia pacing or anti-tachycardia pacing.

Need for Bradycardia Pacing?

- In the MADIT II control arms the annualized need for a pacemaker was only **2**%[2]
- **Pro-arrhythmic effect of back-up pacing** occurs in 3% of ICD recipients and is responsible for up to 54% of all appropriate shocks[3]

Need for ATP?

- In the MADIT-RIT, the increased use of ATP (Arm A) did **not** decrease the incidence of appropriate shocks[4]
- **Only 4-8%** of patients in Arms B and C received appropriate ATP[4]

1. V Kutyifa. et al. The Need for Pacing in patients who qualify for an ICD: Clinical Implications. ESC Abstract 2014
2. Theis, C, et al. Reduction of ICD shock burden by eliminating back-up pacing induced ventricular tachyarrhythmias. J Cardiovasc Electrophysiol. 2014 Aug;25(8):889-95
3. Moss, et al. Reduction in Inappropriate Therapy and Mortality through ICD programming. NEJM 376:24 2275-2283

ICD PATIENT. EMBLEM™ S-ICD SOLUTION.

The majority of ICD-indicated patients are eligible for S-ICD implantation, as many do not require the need for bradycardia pacing or anti-tachycardia pacing.

S-ICD System is the preferred device[1]

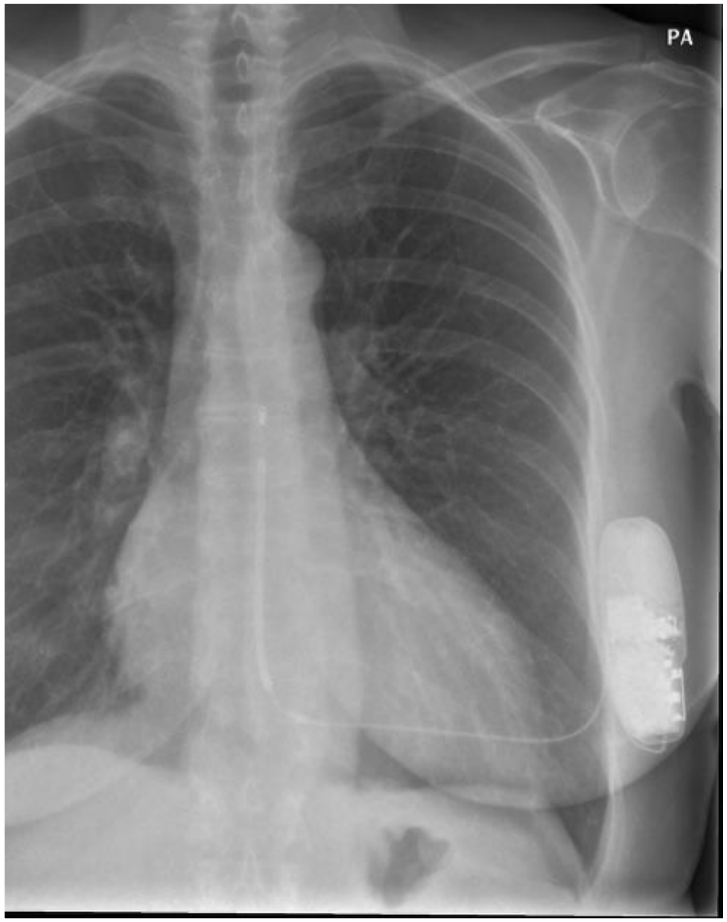
- No venous access (occluded or congenital)
- High risk of complications for TV-ICD (dialysis, pediatric, immunocomprised)
- Channelopathies (LQT, Brugada, .)
- Previous device infections or lead failures
- H/O endocarditis

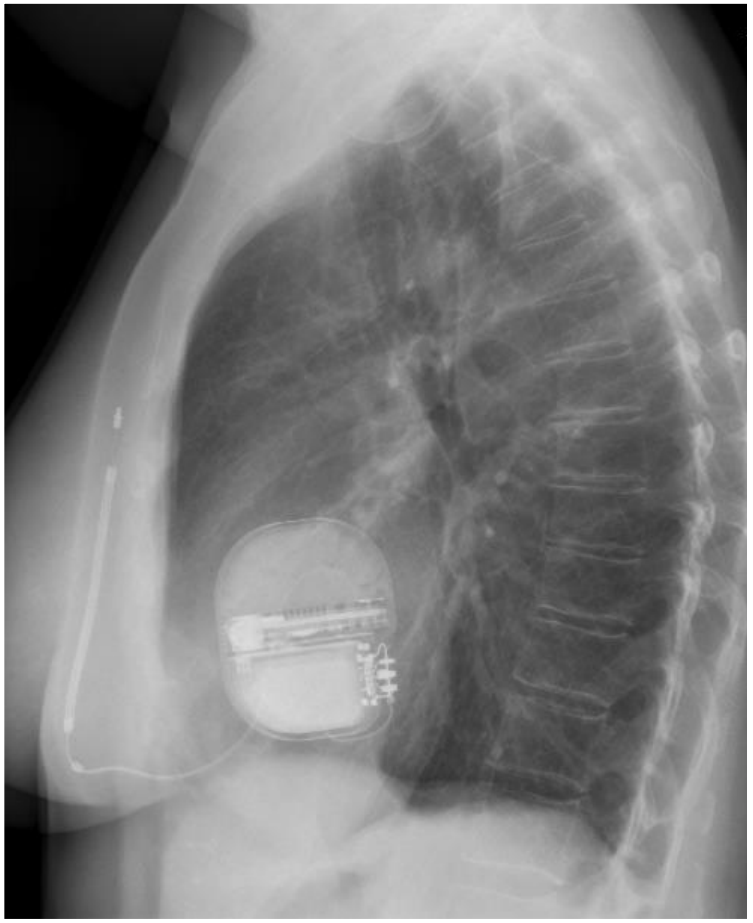
S-ICD System should be strongly considered[1]

- **Young patients**
- **Life expectancy >10 yr**
- Primary prevention with ischemic/non-ischemic heart failure
- Prosthetic valves
- Women (preferred generator placement)
- Selected secondary prevention (survivors of out of hospital VF, no evidence of MVT)

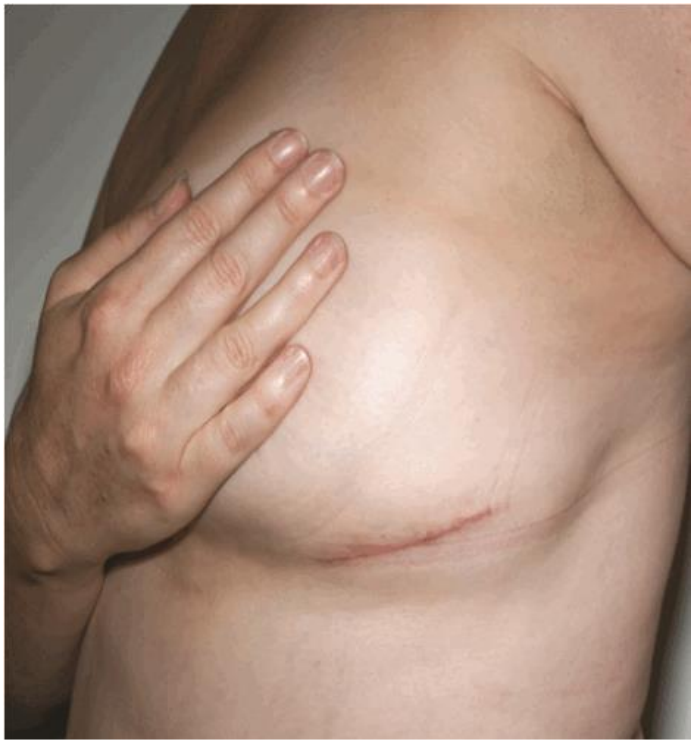
1. Poole, et al. Who Should Receive the Subcutaneous Implanted Defibrillator? The Subcutaneous Implantable Cardioverter Defibrillator (ICD) Should Be Considered in all ICD Patients Who Do Not Require Pacing. Circulation: Arrhythmia and Electrophysciology 2013; 6: 1236-1245

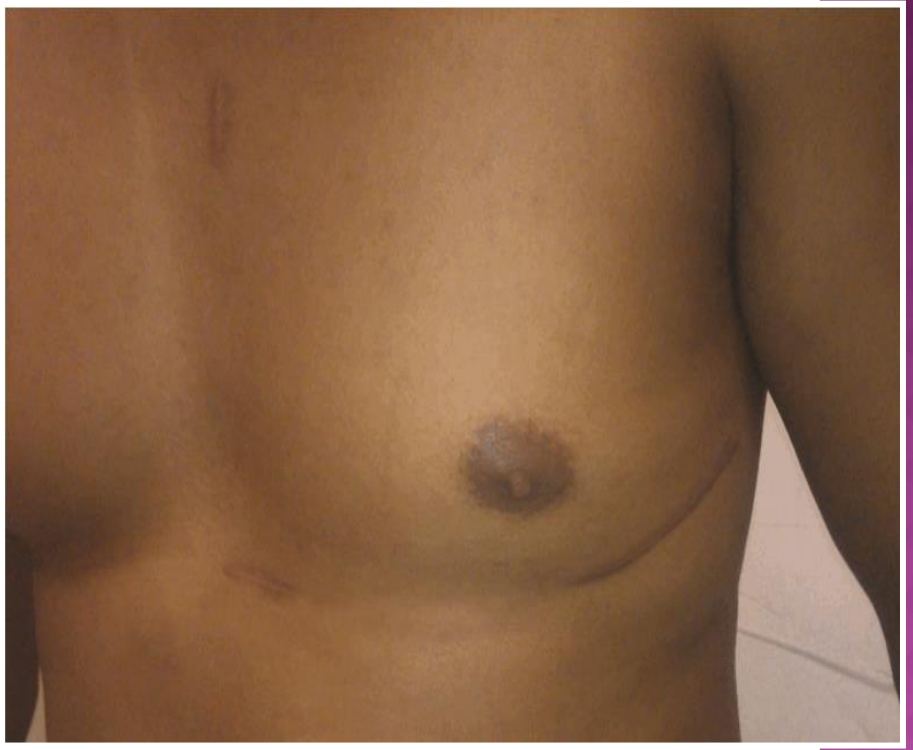
OPTIMAL IMPLANT





ONE MONTH AFTER IMPLANT





CONCLUSION

- The S-ICD is a new technology for sudden cardiac death treatment .
- The S-ICD has proven its safety and efficiency .
- The S-ICD has the same indications as TV-ICD excepting - CRT- pacing-efficient ATP therapy demonstraeted.
- In the future we will have – Telecardiology.
  - Pacing .