

Subkutan ICD: Hangi Hastalarda Kullanılmalı?

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İstanbul Girişimsel Kardiyoloji Kursu, 17-18 Şubat 2017

TRANSVENÖZ ICD

- İlk insan implantı 1980 yılında
- FDA onayı 1985 yılında
- İlk zamanlar yalnız şok özelliği
- Günümüzde pacing ve gelişmiş diskriminasyon özellikleri var.

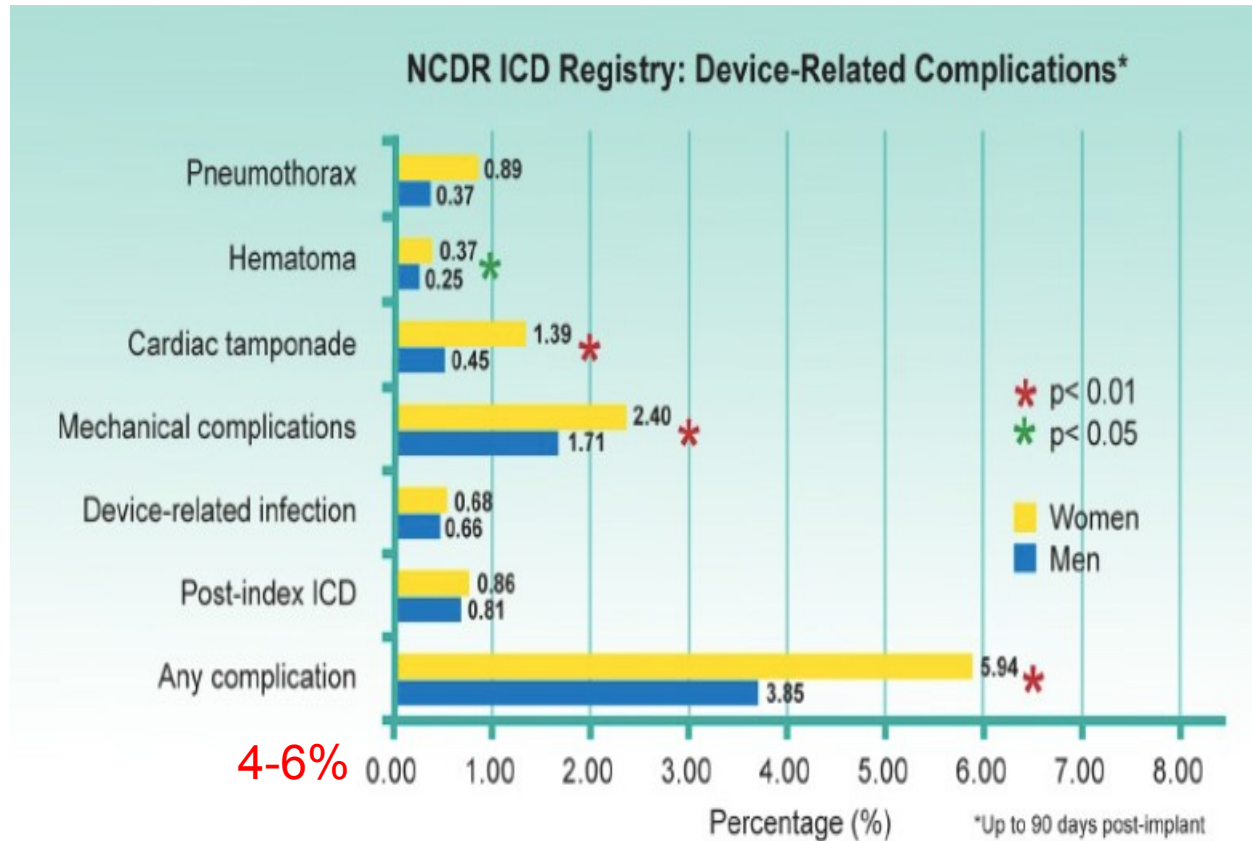


TRANSVENÖZ ICD'LER İLE İLGİLİ PROBLEMLER

- Venöz sistem içinde enfeksiyonlar
- İmplantasyon sırasında komplikasyonlar
- Uzun dönemde yüksek lead işlev kaybı oranı (10 yılda %20'ye kadar*)
- Anatomik ve yapısal anomalilerde (örn, konjenital kalp hastalığı, mekanik kapaklar) karşılaşılan implantasyon sorunları



TRANSVENÖZ ICD'LER: IMPLANTASYON İLE İLGİLİ KOMPLİKASYONLAR



2005-2012

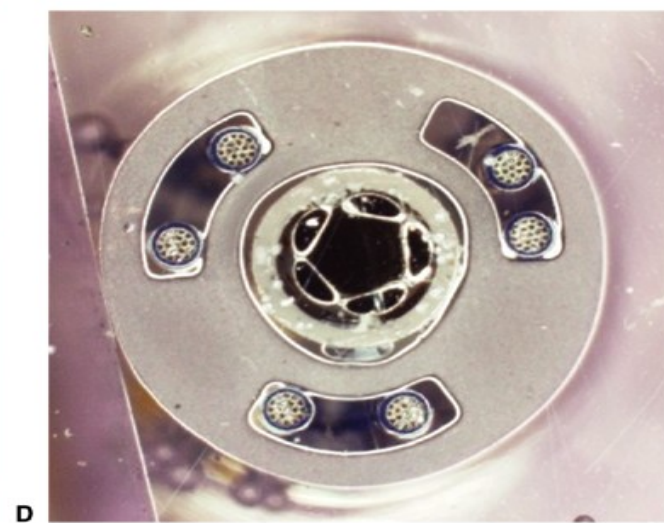
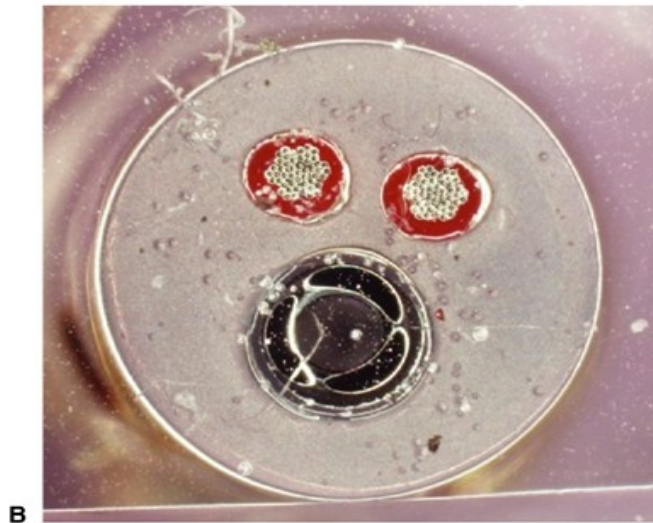
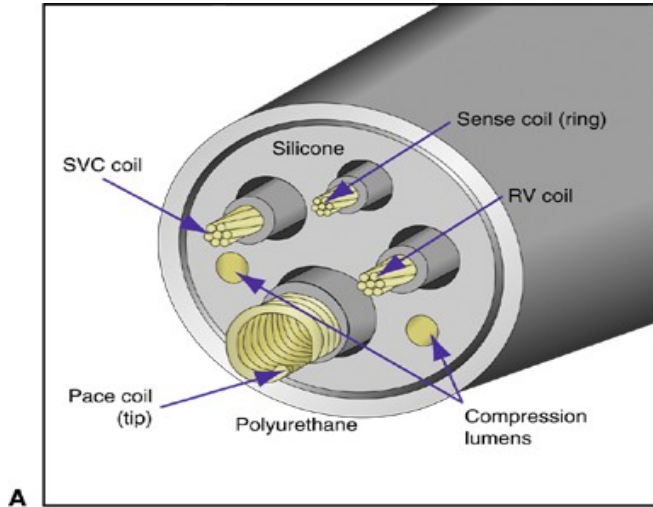
Russo et al. Am J of Cardiol 2015

TRANSVENÖZ ICD'LER: UZUN DÖNEM KOMPLİKASYONLAR

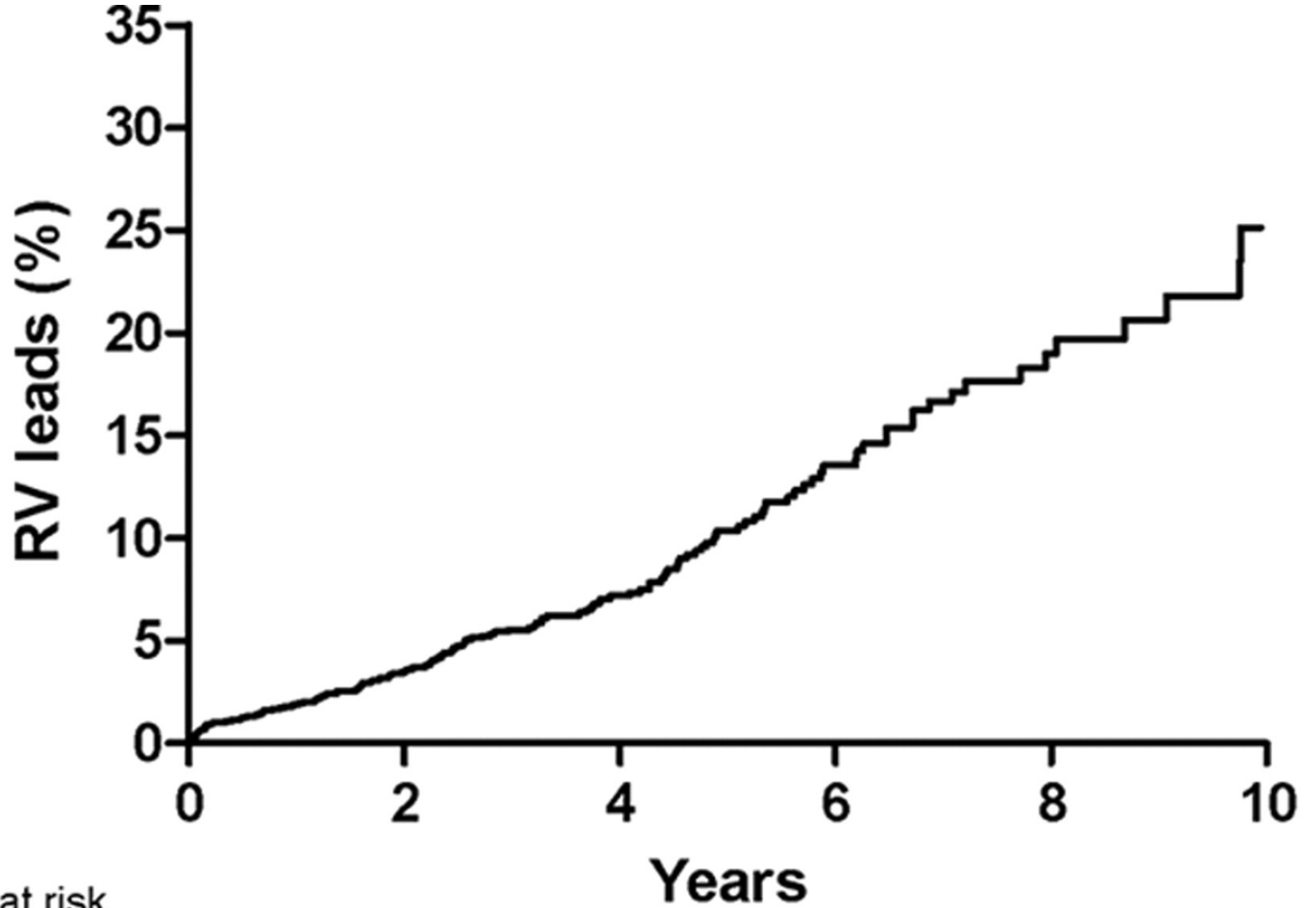
Table 3 Data on ICD-related complications

Patients	Total number	Rate (95% CI) (% per year)	Complication type								
			Infection	Device malfunction	Lead malfunction	Lead dislodgment	Pericardial effusion	Thrombotic event	Reintervention for pocket complication	Hematoma	Pneumothorax
All patients	660/3006 (22)	4.4 (3.6–5.2)	122/4127 (3.0)	52/3183 (1.6)	349/3400 (10)	79/2229 (3.5)	35/3159 (1.1)	30/2513 (1.2)	35/2243 (1.6)	27/2060 (1.3)	15/2194 (0.7)
ARVC	125/535 (24)	4.2 (2.3–6.1)	14/579 (2.4)	9/535 (1.7)	76/614 (12)	20/461 (4.3)	5/535 (0.9)	7/535 (1.3)	4/535 (0.7)	14/535 (2.6)	4/535 (0.7)
Brugada syndrome	161/753 (21)	3.4 (2.5–4.3)	24/829 (2.9)	6/694 (0.9)	94/770 (12)	6/239 (2.5)	10/692 (1.4)	9/645 (1.4)	1/375 (0.3)	2/314 (0.6)	2/314 (0.6)
CPVT	11/13 (85)	21.2 (8.7–33.7)	2/13 (15)	1/13 (7.7)	7/13 (54)	1/13 (7.7)	0/13 (0)	0/13 (0)	3/13 (23)	0/13 (0)	0/13 (0)
Hypertrophic cardiomyopathy	248/1258 (20)	5.1 (3.8–6.4)	63/2214 (2.8)	22/1582 (1.4)	124/1582 (7.8)	38/1157 (3.3)	12/1509 (0.7)	9/961 (0.9)	13/961 (1.4)	9/827 (1.1)	4/961 (0.4)
LMNA cardiomyopathy	6/24 (25)	10.3 (2.1–18.6)	2/24 (8.3)	0/24 (0)	1/24 (4.2)	2/24 (8.3)	1/24 (4.2)	1/24 (4.2)	1/24 (4.2)	0/24 (0)	1/24 (4.2)
Long QT syndrome	104/399 (26)	7.0 (4.4–9.7)	14/430 (3.3)	13/311 (4.2)	41/362 (11)	12/311 (3.9)	7/362 (1.9)	4/311 (1.3)	13/311 (4.2)	2/323 (0.6)	4/323 (1.2)
Short QT syndrome	5/24 (21)	NR	3/40 (7.5)	1/24 (4.2)	7/35 (20)	0/24 (0)	0/24 (0)	0/24 (0)	0/24 (0)	0/24 (0)	0/24 (0)

TRANSVENÖZ ICD LEAD'LERİ



Yıllara göre tüm nedenlere bağlı lead işlev kaybının Kaplan-Meier eğrisi



Leads at risk

2161

1228

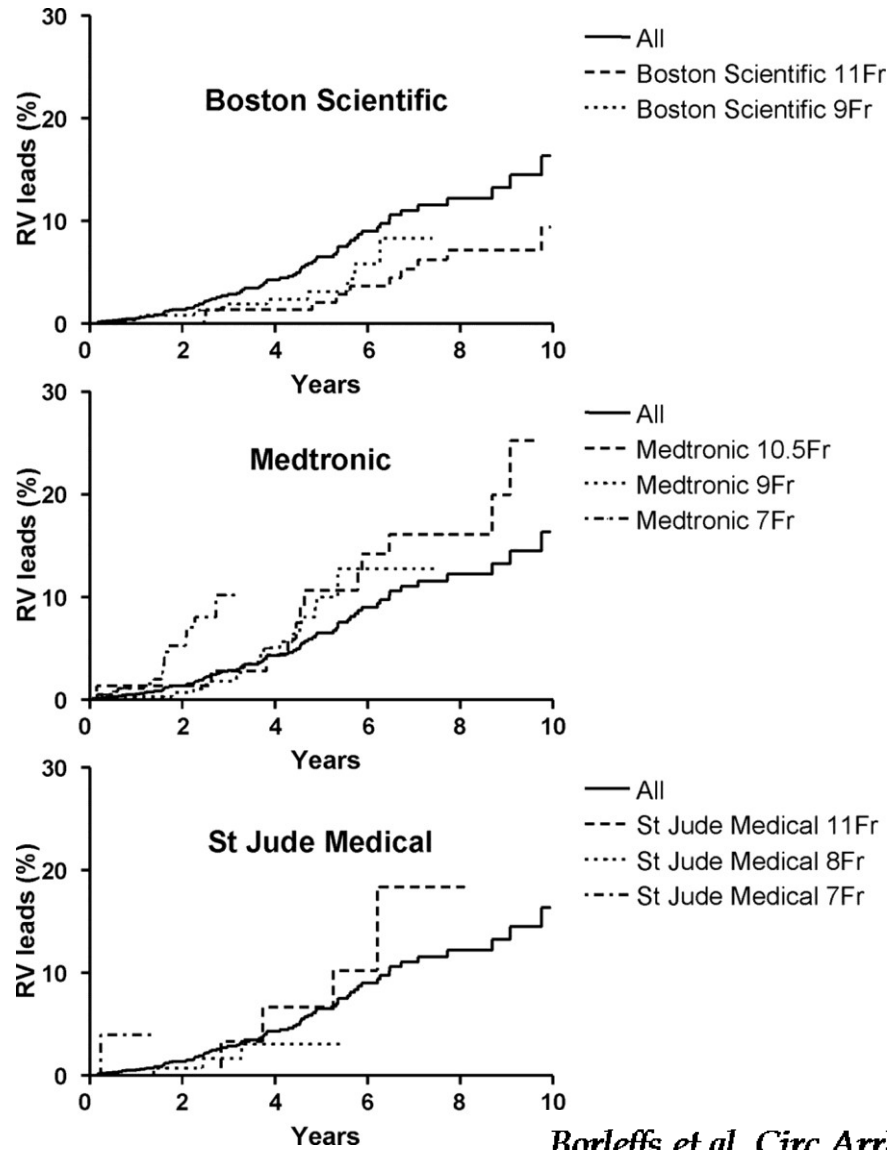
627

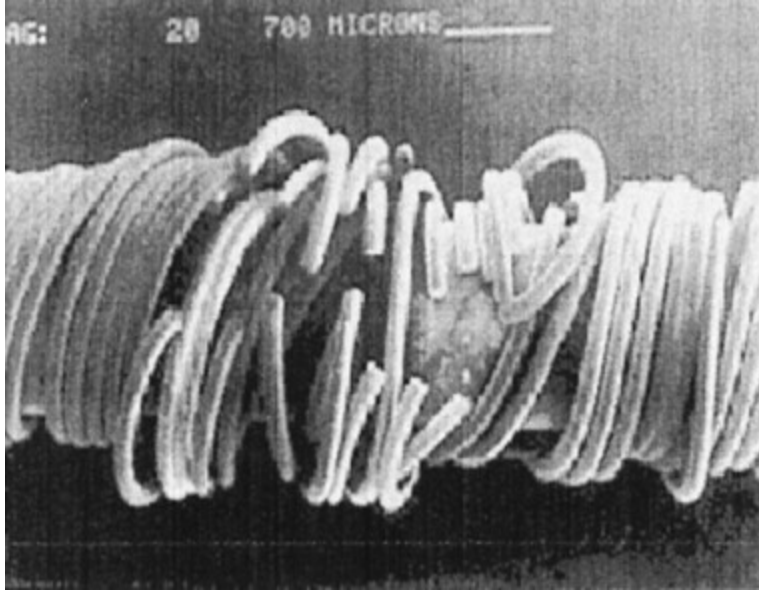
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116

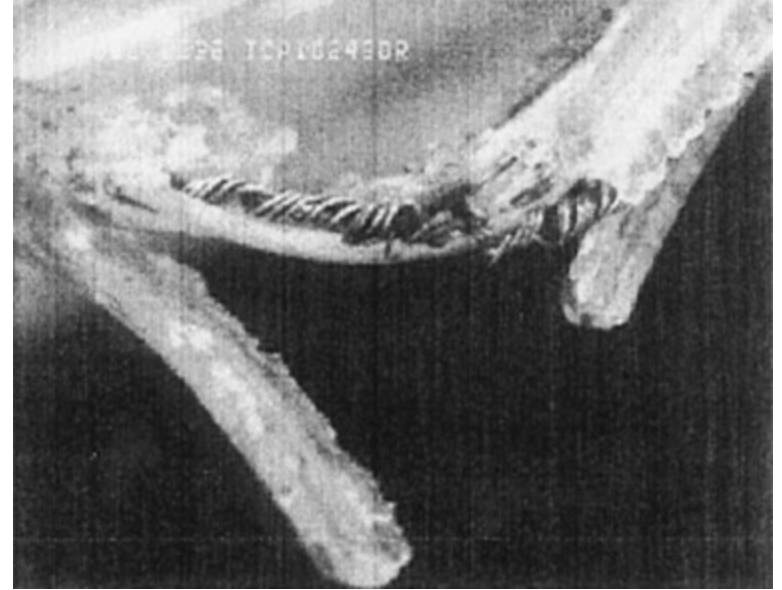
43

Boston Scientific, Medtronic ve St Jude Medical leadlerinin karşılaştırılması

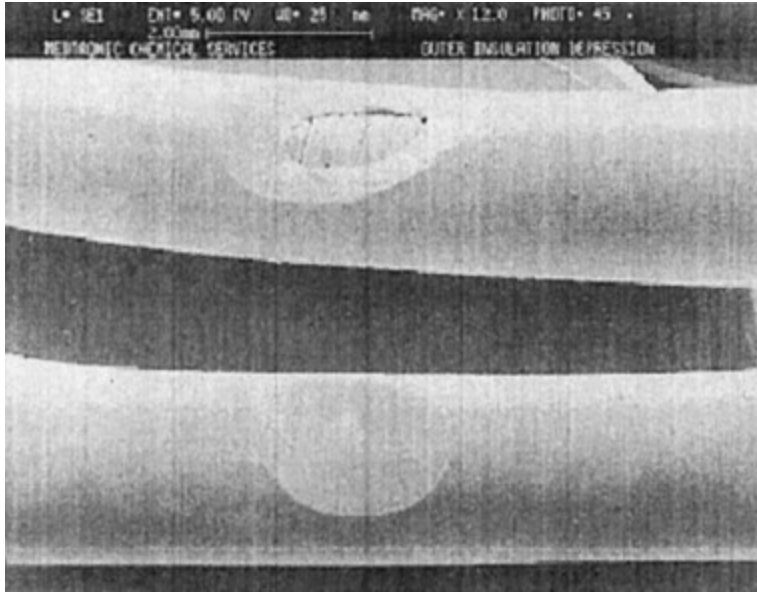




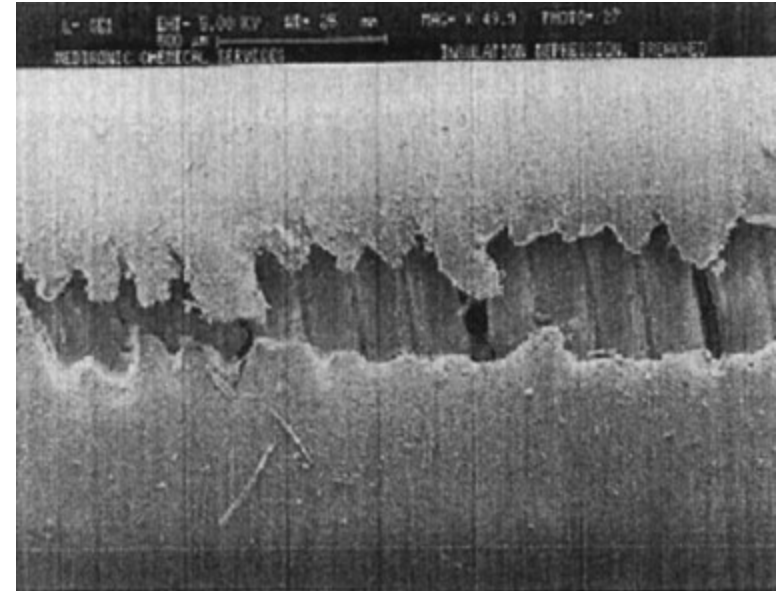
Kompresyona baėlı kondüktör kırığı



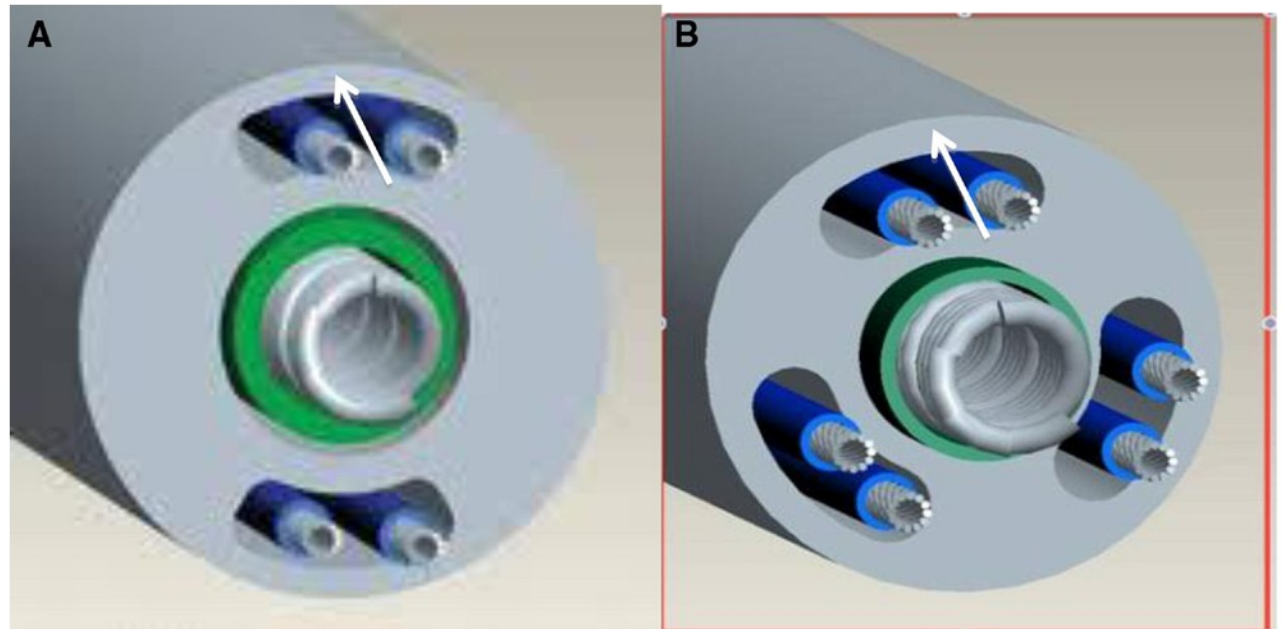
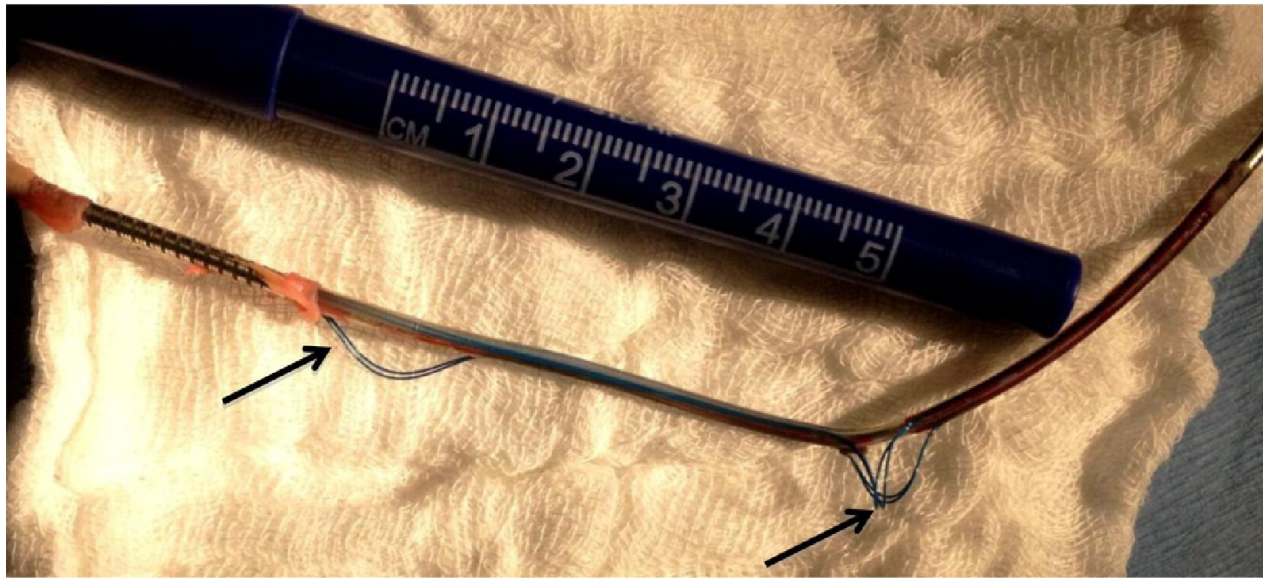
Sıkışmaya baėlı insüstasyon defekti ve kondüktör kırığı

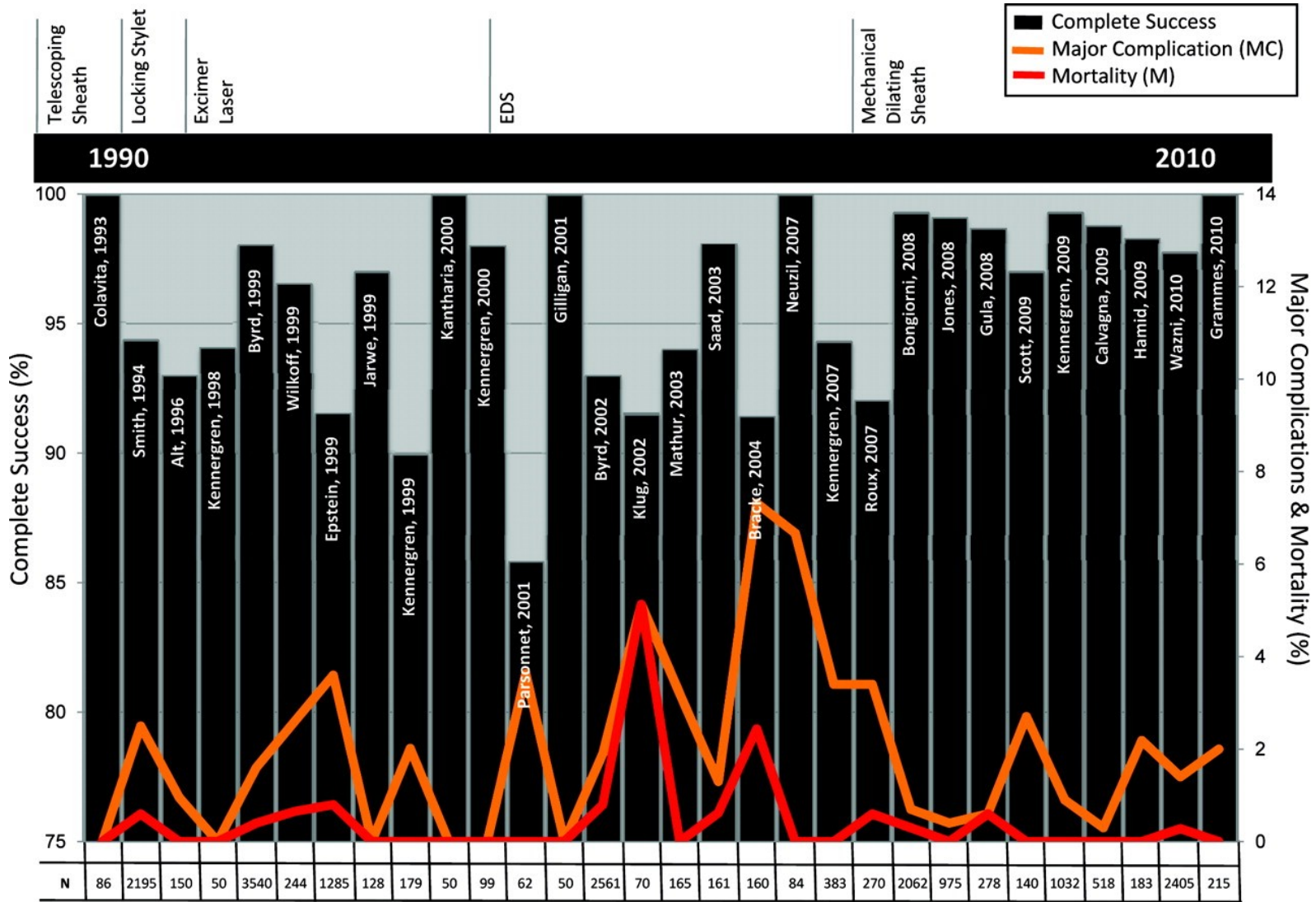


Sıyrılmaya bağlı insüstasyon defekti



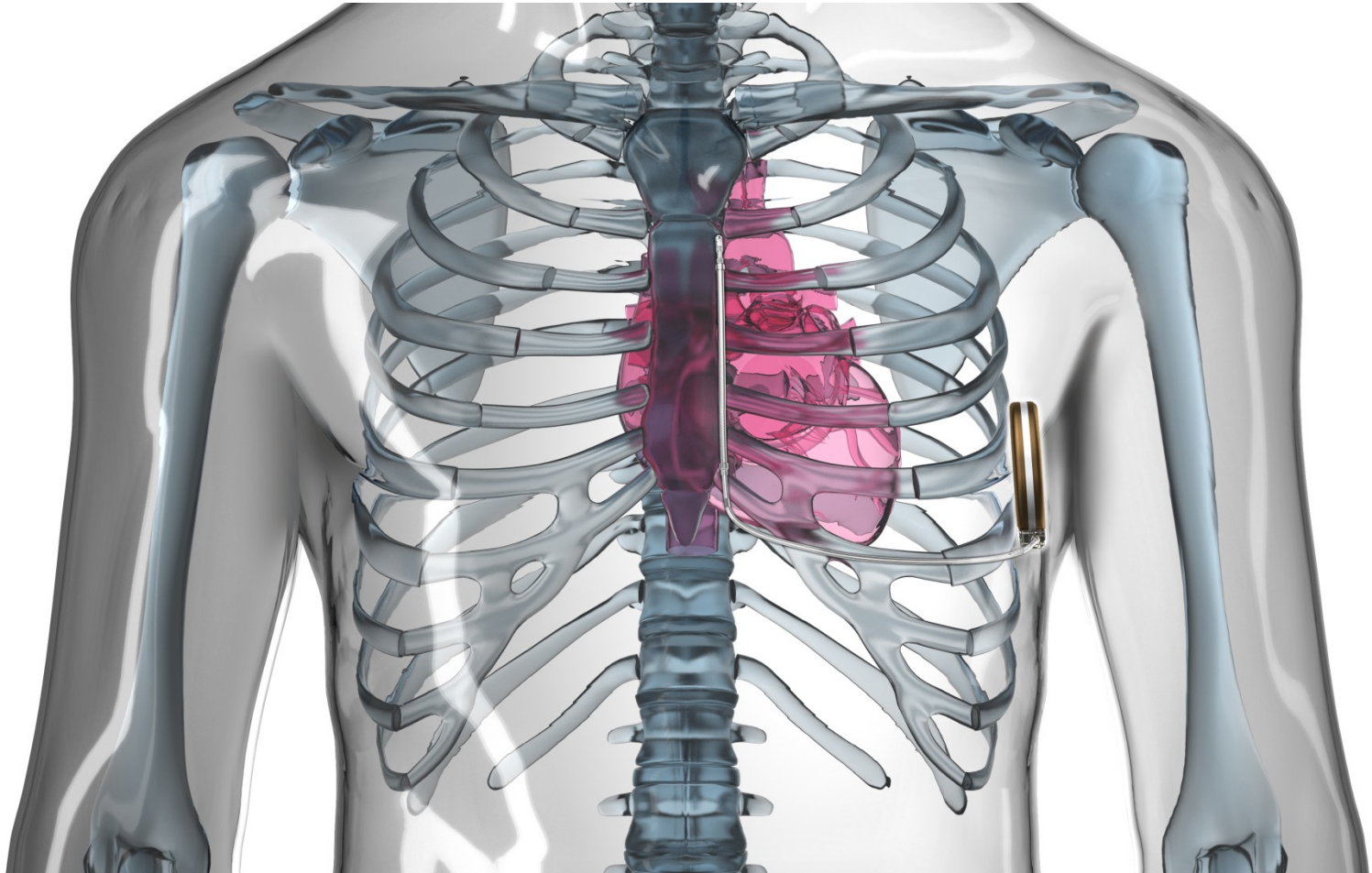
Traksiyona bağlı insüstasyon defekti





Composite MC 1.8%
Composite M 0.4%

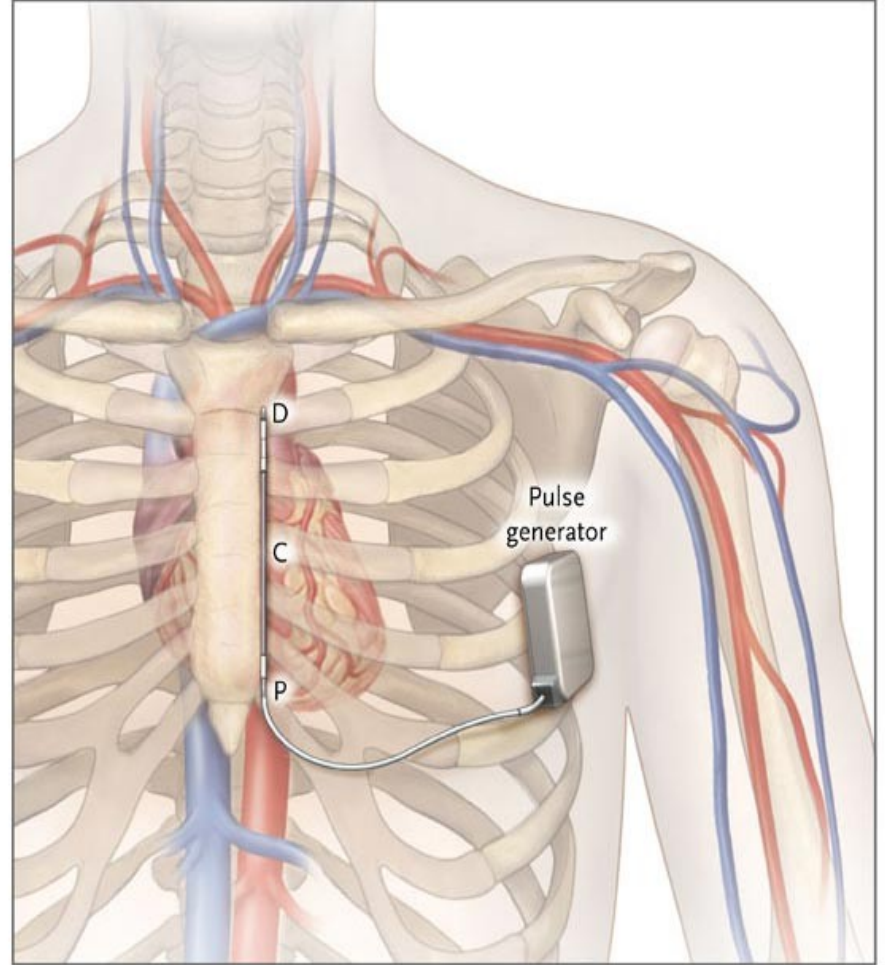
Çözüm: Subkutan ICD (S-ICD)?



S-ICD

- 45cm uzunluğunda daha güçlü ve dayanıklı lead
- 8-cm şok coil'i, 2 sensing elektrodu
- Elektrod sternum sol tarafına paralel olarak 1-2cm uzaklığa implante edilir
- Jeneratör 5-6. kosta hizasında mid-ve anterior- aksiller çizgi arasında yerleştirilir
- 80-J şok, ters şok polaritesi

Bardy GH, et al. An entirely subcutaneous ICD.
NEJM 2010;363(1);36-44



S-ICD Jeneratör



S-ICD™ System



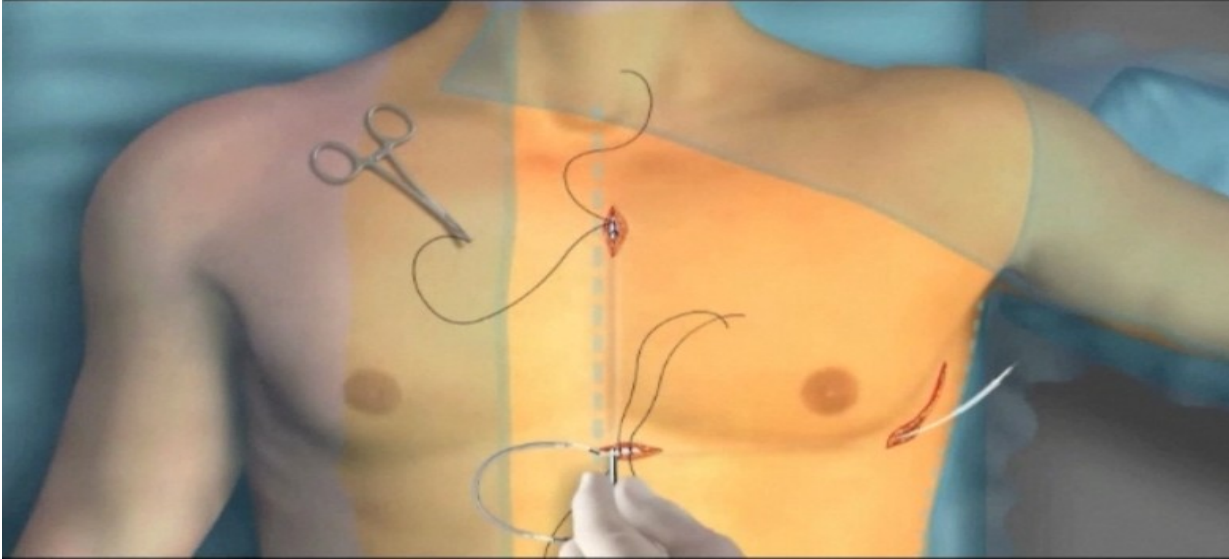
EMBLEM™ S-ICD System

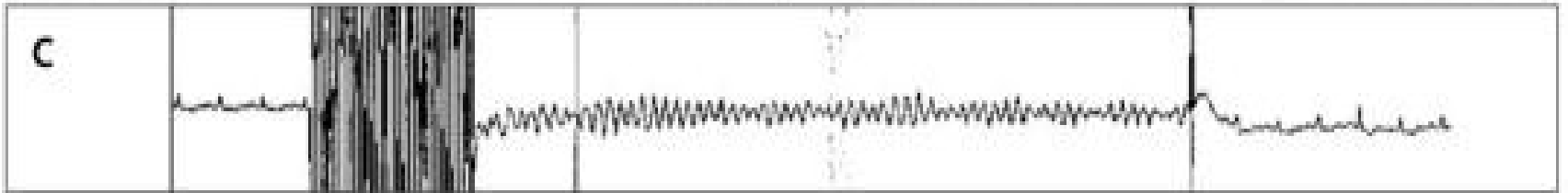
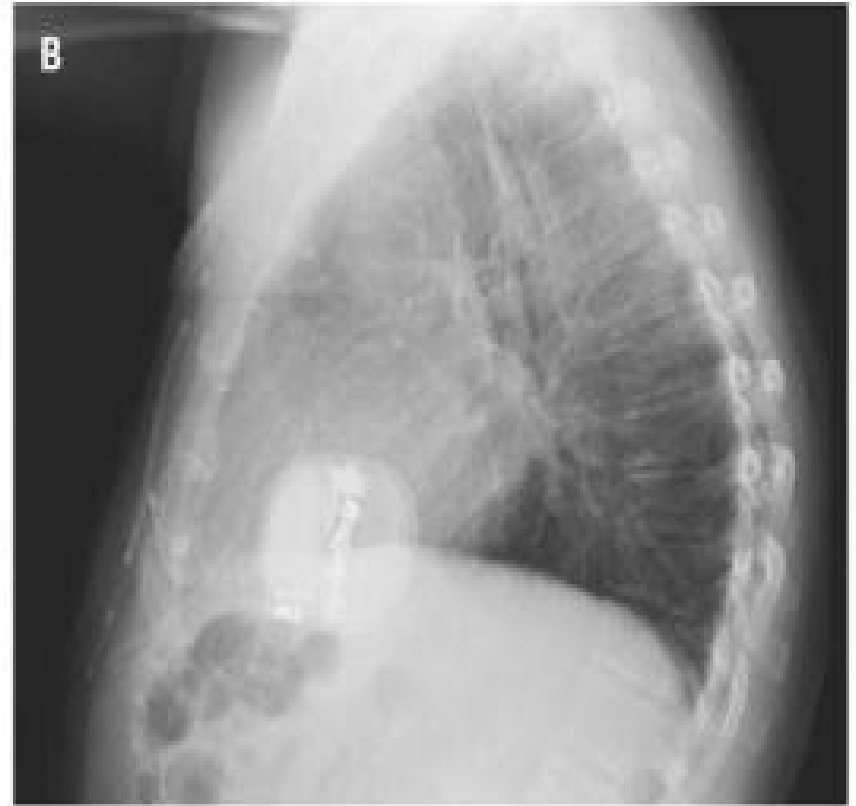


Single Chamber ICD

S-ICD İmplantasyonu

- Tüm komponentler deri altına implante edilir.
- 3 küçük insizyon (bazı merkezlerde 2 insizyon kullanılıyor).
- Hastaneye yatış gerekemeyebilir.

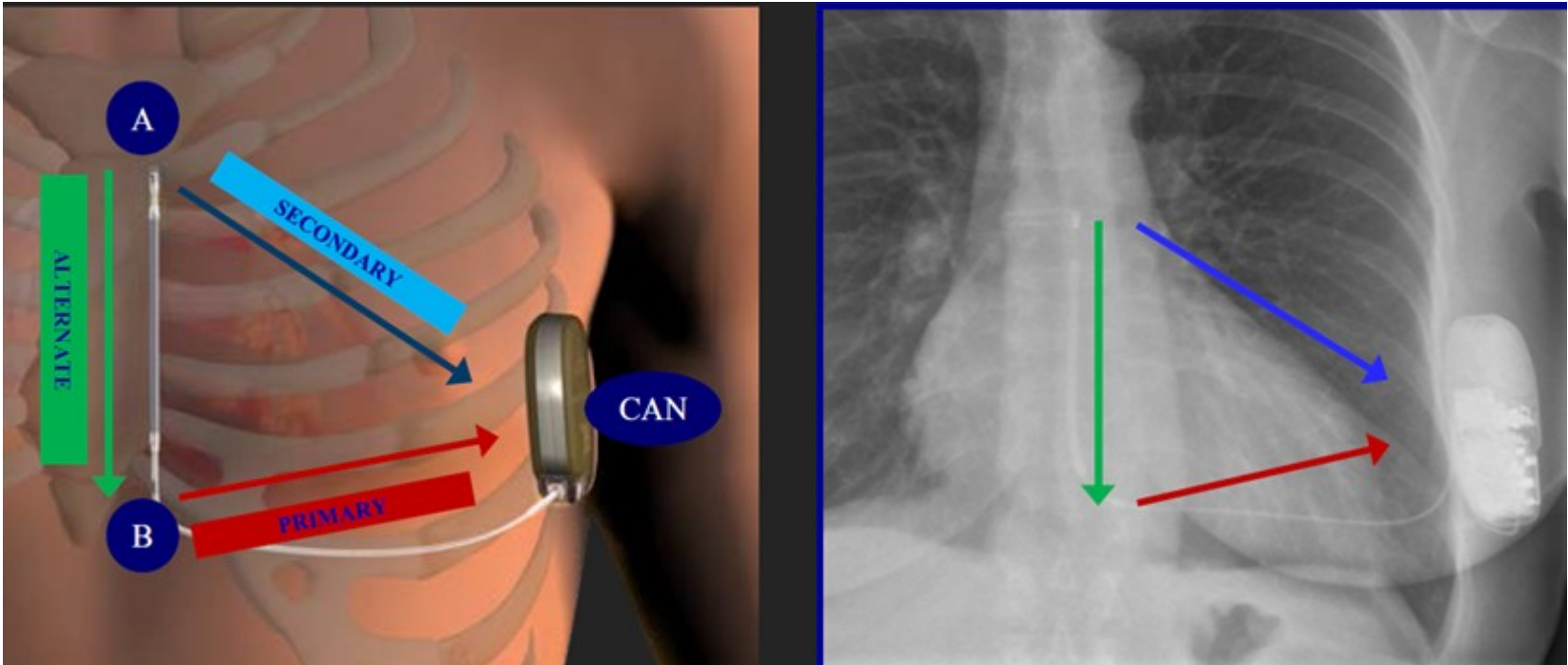




Subkütan Sinyalin Sense Edilmesi

‘Far-field sensing’ vektörleri

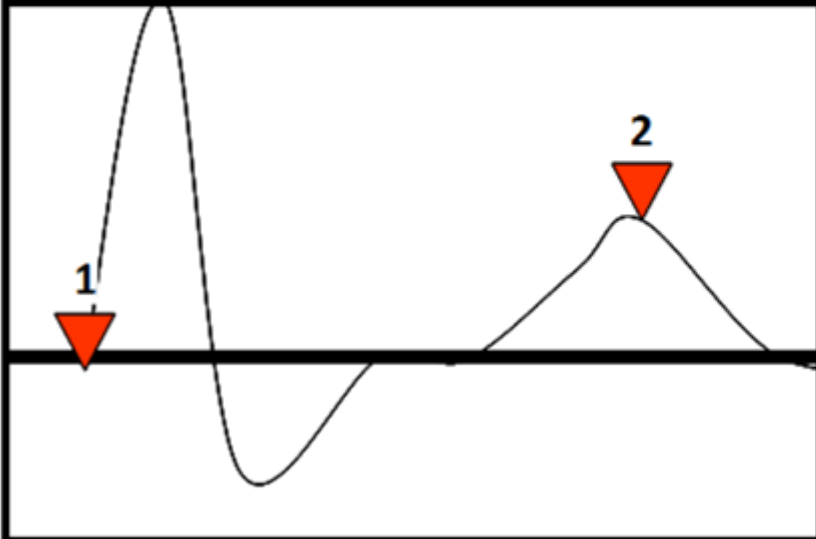
- Kardiyak ritmin görülmesi (3 farklı perspektiften elektriksel aktivitenin görülmesi)
- Morfolojik olarak yüzey EKG’sine benzer yüksek çözünürlüklü sinyaller



Prominent T-waves and wide QRS complexes can pose challenges

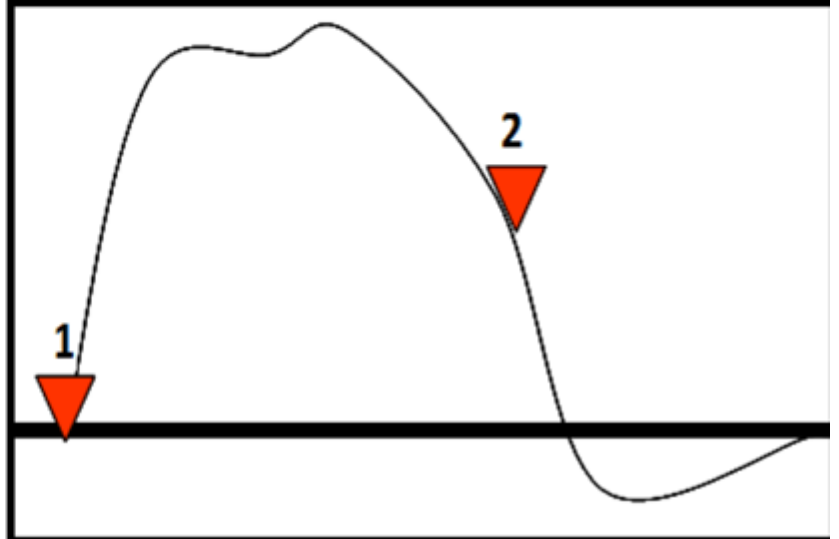
Example:

T-wave double detection



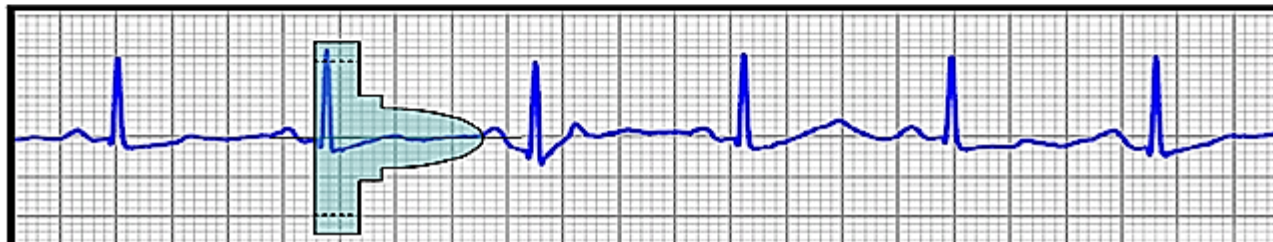
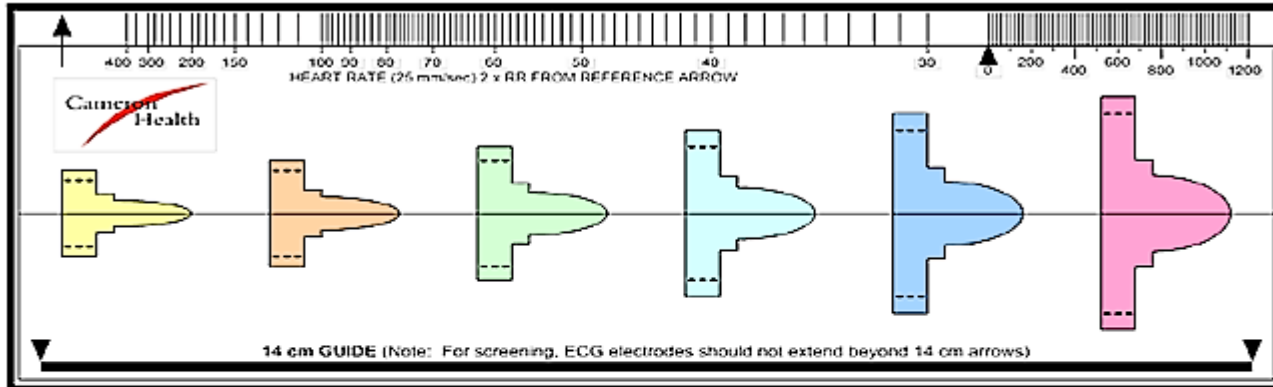
Example:

Wide complex double detection

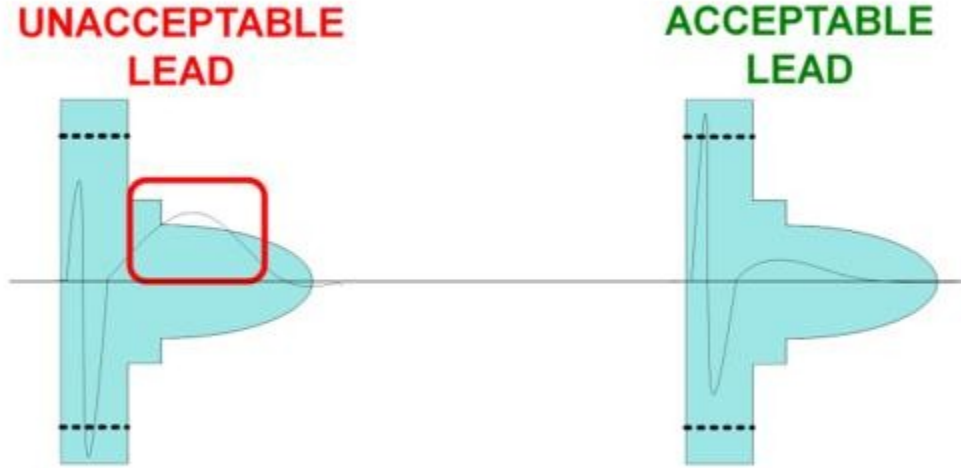


S-ICD için Uygunluk Testi (“Screening Tool”)

Yüzeysel EKG kullanılarak S-ICD için uygun subkütan sensing sinyali olan hastaların tespitinde kullanılır.



Lead Uygunluđu



Hastanın S-ICD sistemine uygunluđu için en az bir EKG lead'inin teste uygun bulunması gereklidir.

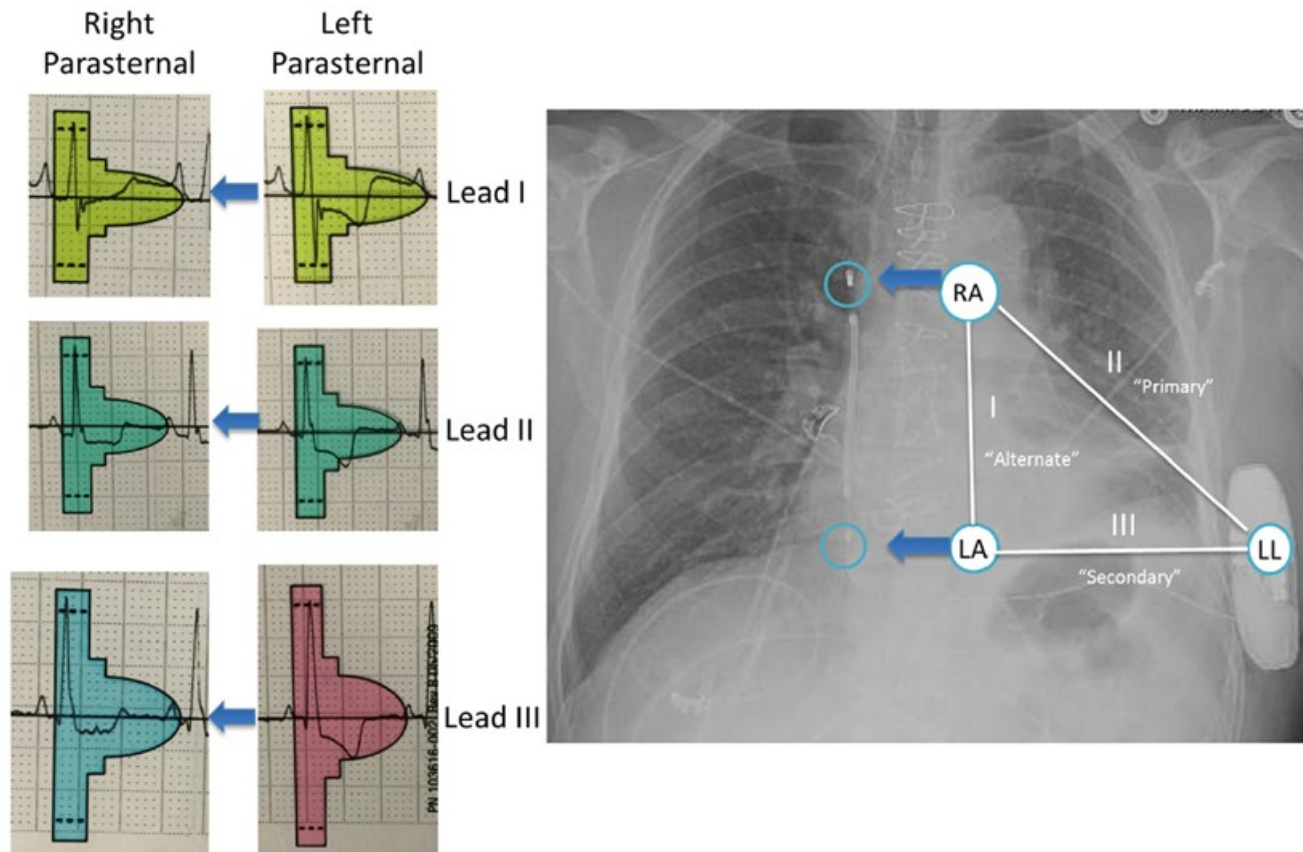
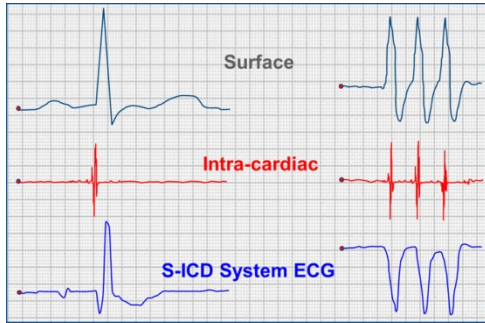
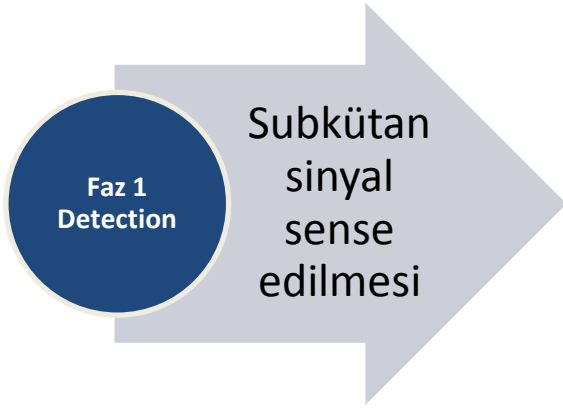
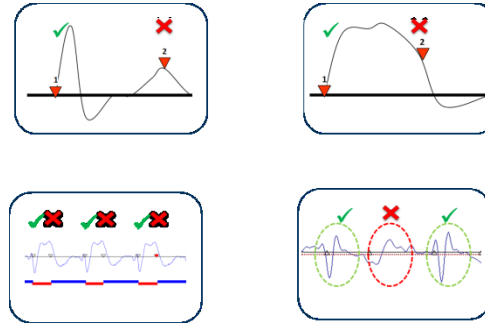


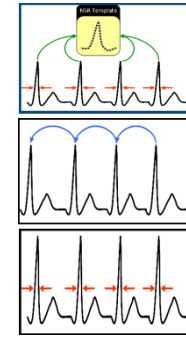
Fig. 2 – Right and left parasternal screening for the S-ICD. With left sided screening, the T wave inversions fall outside of the template. With right-sided screening, however, the QRS and T waves are within the template. Chest X-ray shows right-sided lead placement.



S-ECG morfolojik olarak yüzey EKG'sine benzeyen yüksek çözünürlüklü sinyal



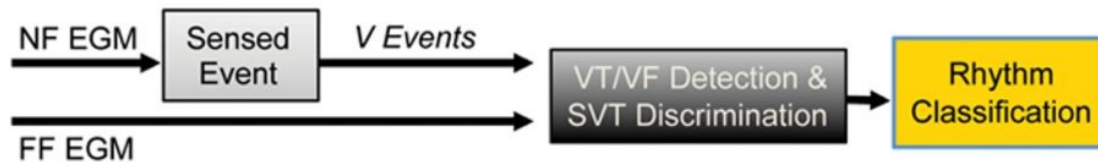
Oversensing'i önlemek için 4 çift-detection algoritması



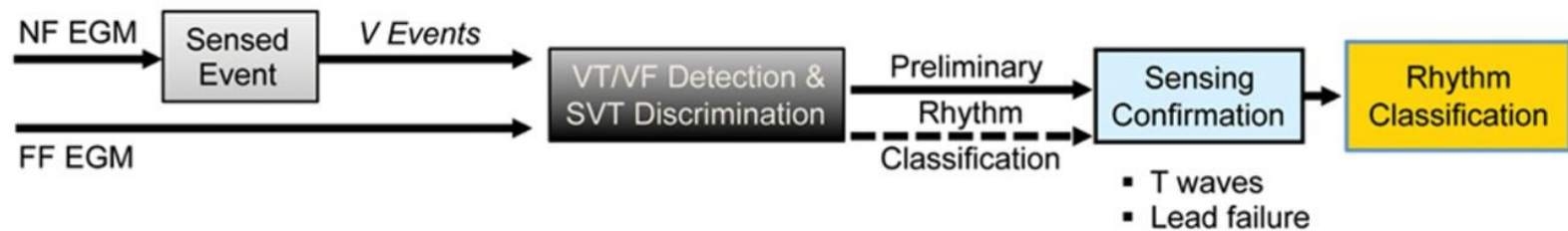
Tedavi uygulamasına kara vermek için 3 ritm diskriminasyonu

Signal processing architecture for sensing and detection.

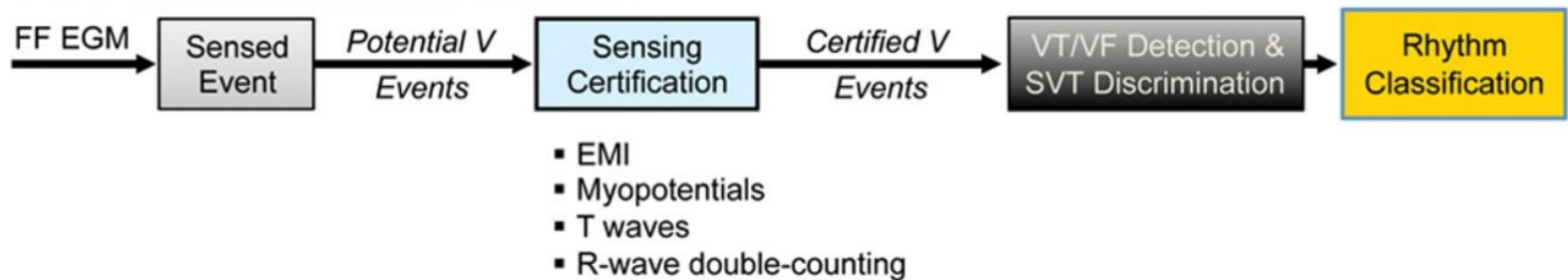
A “Conventional” ICD Architecture



B “Enhanced” ICD Architecture



C S-ICD™ Architecture



Charles D. Swerdlow et al. *Circ Arrhythm Electrophysiol.*
2015;8:212-220

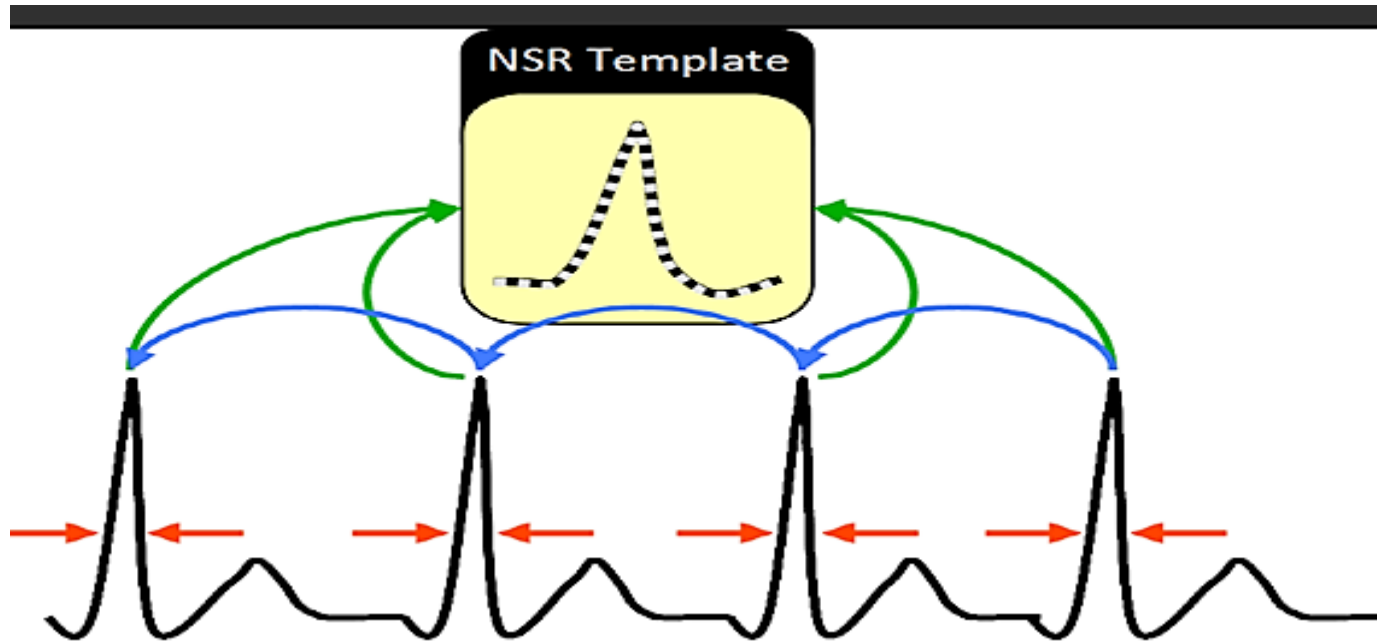
S-ICD Ritm Diskriminasyonu

S-EKG'nin doğru tanınması ve sınıflandırılması için 3 tanımlanmış method

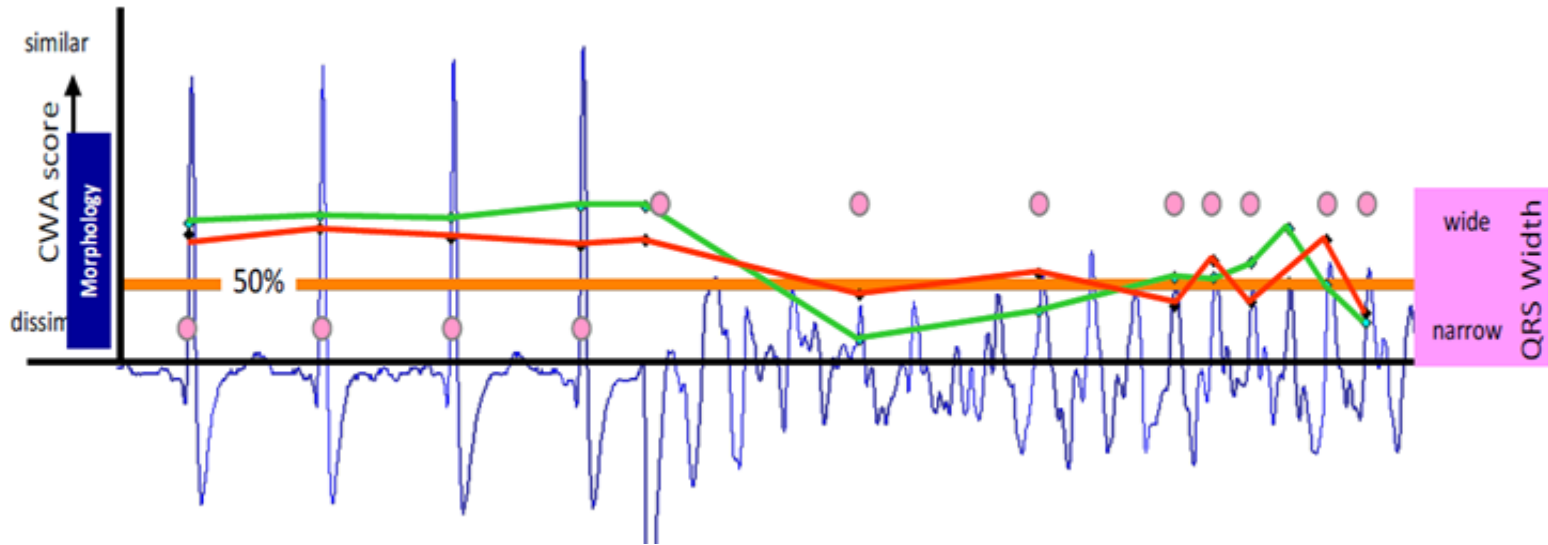
1- Statik morfoloji analizi

2- Dinamik morfoloji analizi

3- QRS genişliği analizi



S-ICD Ritm Diskriminasyonu: VT/VF



Statik morfoloji (kırmızı çizgi) ve dinamik morfoloji (yeşil çizgi) VT/VF sırasında düşerken QRS genişliği (pembe) ventriküler taşiaritmi sırasında artmaktadır.

Key Milestones

Jul 2008 *start Chronic II study*¹
Dec 2008 *start CE study*¹

Jan 2010 *start US IDE study*²
May 2010 *CE study published in NEJM*¹
Nov 2010 *start EFFORTLESS registry*³

March 2012 *Acquisition Cameron Health by BSC*
Oct 2012 *US Commercial launch*

Mar 2014 *EFFORTLESS Registry – Preliminary results of largest cohort of patients*⁵

2002

2008

2009

2010

2011

2012

2013

2014

2015

Proof of concept studies

Sep 2009 *Commercial launch Europe*

Feb 2011 *start PRAETORIAN randomized trial*
Oct 2011 *START study published*⁴

AUG 2013 *IDE Study published in Circulation*²

2015: EMBLEM™ S-ICD System Launch

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

ie Safety and Efficacy of a Totally Subcutaneous Implantable-Defibrillator . Circulation 2013.

- May 2012; Vol 9:5(S1-33) AB07-2.

al. (2011). "Head-to-Head Comparison of Arrhythmia Discrimination Performance of Subcutaneous and Transvenous ICD Arrhythmia Detection Algorithms: The START Study." J Cardiovasc Electrophysiol. In p 0-8167.2011.02199

. A worldwide experience with a totally subcutaneous ICD; Preliminary results of the EFFORTLESS S-ICD Registry. European Heart Journal Mar2014.

S-ICD çalışmaları

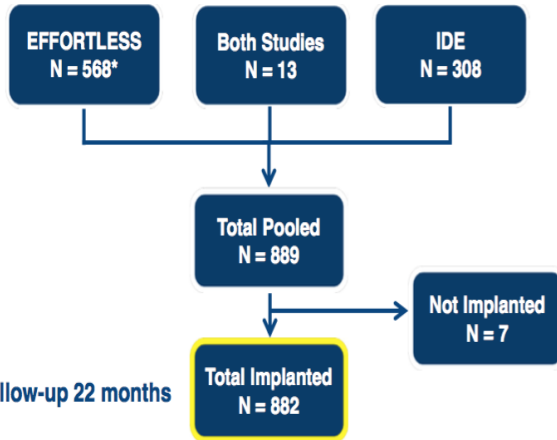
TABLE 1 Summary of S-ICD Trials

	Bardy et al. (15) (n = 55)	Dabiri Abkenari et al. (16) (n = 31)	Aydin et al. (18) (n = 40)	Jarman et al. (22) (n = 111)	Olde Nordkamp et al. (17) (n = 118)	Köbe et al. (20) (n = 69)	Weiss et al. (21) (n = 330)	Lambiase et al. (24) (n = 472)	Burke et al. (23) (n = 883)
Age, yrs	56 ± 13	53 ± 4	42 ± 15	33	NA	46 ± 16	52 ± 16	49 ± 18	50 ± 17
Male	80	77	70	NA	75	72	74	72	72.5
Follow-up	10 ± 1 months	286 days	229 days	12.7 ± 7.1 months	18 ± 7 months	217 ± 138 days	330 days	558 days	651 ± 345 days
Ischemic cardiomyopathy	37 (67.0)	18 (58.0)	9 (22.5)	15 (14.0)	45 (38.0)	11 (15.9)	137 (41.4)	166 (37.0)	330 (37.8)
LVEF	35 ± 14	38 ± 15	47 ± 15	NA	41 ± 15	46 ± 16	36 ± 16	42 ± 19	39 ± 18
Primary prevention	43 (78.0)	21 (67.0)	17 (42.5)	55 (50.0)	71 (60.0)	41 (59.4)	262 (79.0)	282 (63.0)	610 (69.9)
Inappropriate shocks	5 (9.0)	5 (16.0)	2 (5.0)	17 (15.0)	15 (13.0)	3 (4.0)	41 (13.0)	32 (7.0)	14 (2.5)
Appropriate therapy (% successful)	3 (100.0)	4 (100.0)	4 (96.4)	13 (100.0)	8 (100.0)	3 (100.0)	21 (95.2)	33 (100.0)	111 (98.2)
Complications									
Infection	2 (3.6)	1 (3.2)	0	11 (9.9)	7 (5.9)	1 (1.4)	18 (5.6)	11 (2.3)	14 (1.5)
Lead migration	6 (10.9)	2 (6.4)	0	0	3 (2.5)	0	0	4 (0.8)	7 (0.8)
Device erosion	0	0	0	2 (1.8)	2 (1.7)	0	0	4 (0.8)	12 (1.4)
Hematoma	0	0	0	0	0	1 (1.4)	0	1 (0.2)	4 (0.4)
Patient characteristics									
Ischemic cardiomyopathy	37 (67.0)	18 (58.0)	9 (22.5)	15 (14.0)	45 (38.0)	11 (15.9)	137 (41.4)	166 (37.0)	330 (37.8)
Dilated cardiomyopathy	10 (18.0)	4 (13.0)	9 (22.5)	5 (5.0)	30 (25.4)	25 (36.2)	NA	43 (9.1)	277 (31.8)
HOCM	NA	NA	5 (12.5)	22 (20.0)	NA	10 (14.5)	NA	58 (12.2)	
Congenital heart disease	2 (4.0)	NA	NA	13 (12.0)	1 (0.8)	3 (4.4)	NA	33 (7.0)	
Brugada syndrome	NA	2 (6.5)	NA	14 (13.0)	NA	NA	NA		
Idiopathic VT/VF	NA	5 (16.1)	12 (30.0)	17 (15.0)	15 (13.0)	NA	NA	34 (8.0)	40 (4.6)
Ventricular noncompaction	NA	1 (3.0)	NA	NA	NA	NA	NA		
Valvular heart disease	NA	1 (3.0)	1 (2.5)	NA	NA	NA	NA		
Long QT	NA	NA	NA	10 (9.0)	NA	NA	NA		
CPVT	NA	NA	NA	7 (6.0)	NA	NA	NA		
Inherited channelopathy		5 (16.1)		31 (27.9)	27 (23.0)	14 (20.3)		60 (13.0)	90 (10.3)
Other	6 (11.0)	NA	13 (32.5)	13 (12.0)	57 (48.0)	NA	NA	14 (2.9)	

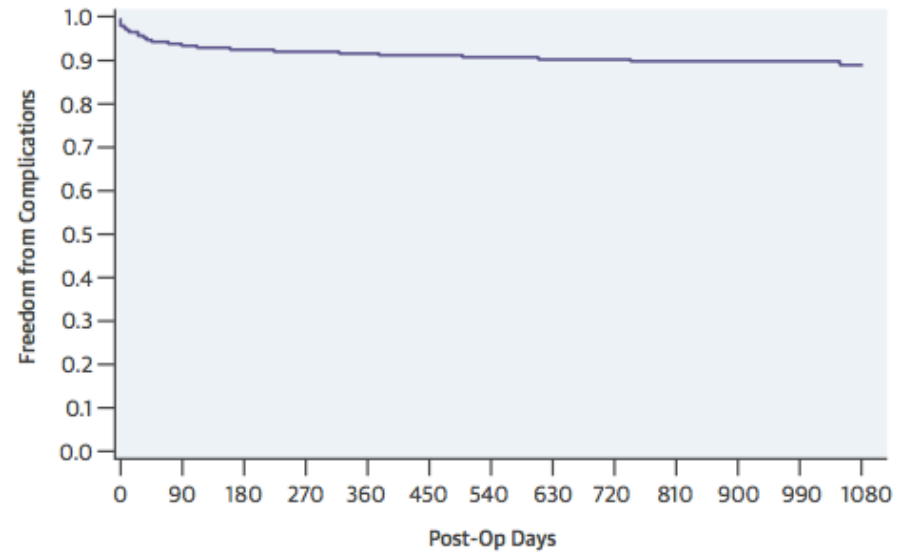
Values are mean ± SD, %, or n (%).

CPVT = catecholaminergic polymorphic ventricular tachycardia; HOCM = hypertrophic obstructive cardiomyopathy; LVEF = left ventricular ejection fraction; NA = not available; S-ICD = subcutaneous implantable cardioverter-defibrillator. VF = ventricular fibrillation; VT = ventricular tachycardia.

ÇALIŞMALAR: ETKİNLİK VE GÜVENLİK



	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%	



No. at Risk	878	791	731	707	650	591	525	414	303	217	162	123	105
K-M Estimate (%)	99.0	93.4	92.3	92.0	91.4	90.9	90.6	90.2	90.0	89.7	89.7	89.7	88.9

Burke MC et al. *JACC* 2015; 16:1605-15
 Cha YM et al. *Heart Rhythm* 2013;10:702–708
 Swerdlow CD et al. *PACE* 2007; 30:675–700
 Kutiyfa V, et al. *J Cardiovasc Electrophysiol* 2013;24:1246-52
 Effortless registry, Lambiase P, *Eur Heart J.* 2014 Jul 1;35(25):1657-65
 IDE study, Weiss R, *Circulation.* 2013;128:944-953

ETKİNLİK

Elektrod kırıkları
Sistemik efeksiyon/Endokardit
Vasküler/Kardiyak Hasarlanma

YOK

IDE çalışması ve EFFORTLESS Registry'den elde edilen data; düşük komplikasyon oranı ve yüksek konversiyon etkinliği

**Yüksek konversiyon
etkinliği²**

96%

EFFORTLESS Registry;
558 günlük takip döneminde her bir
epizod için spontan konversiyon
etkinliği

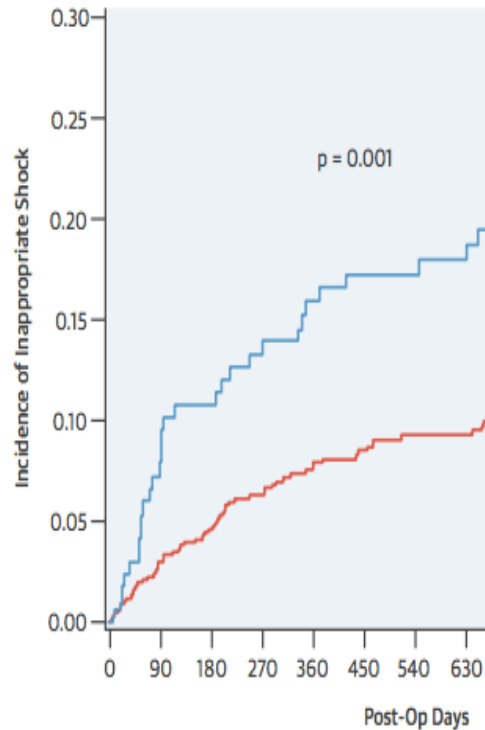
**Uygunsuz tedavi
yaşamama oranı²**

93.6%

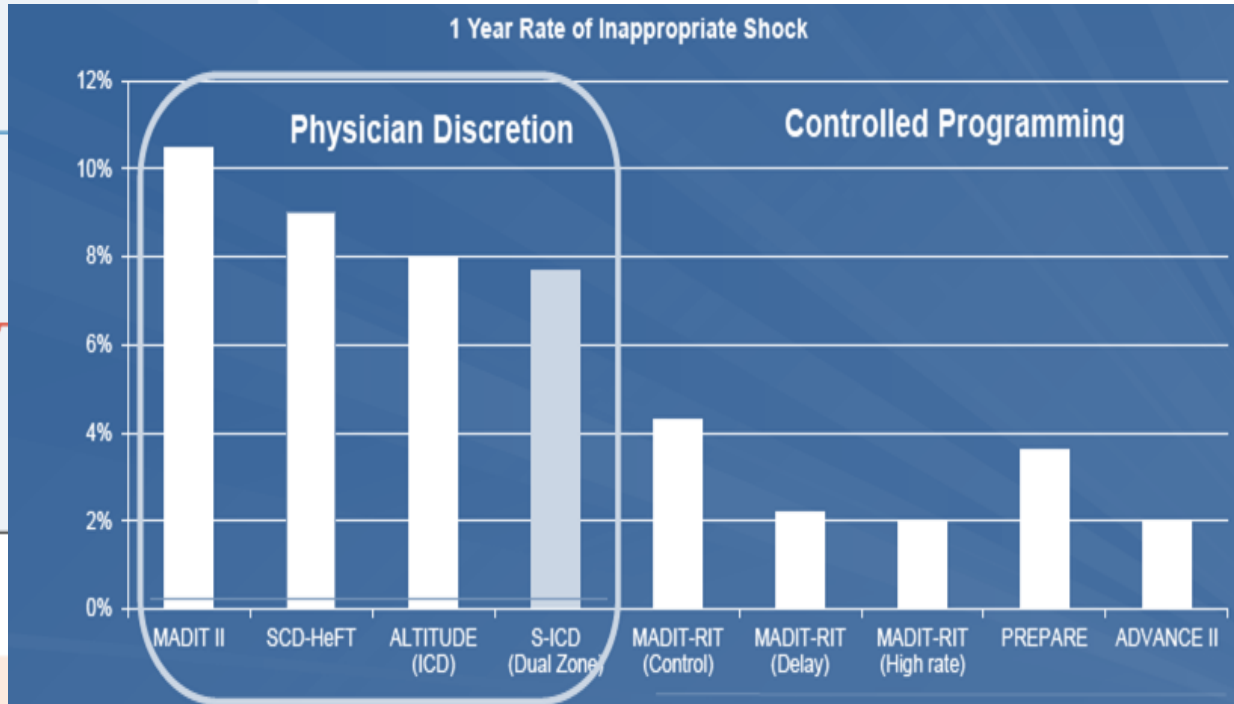
EFFORTLESS Registry; Çift zon
programlama ile uygunsuz tedavi
yaşamama oranı

1. Leon, A, et al. Outcomes in Patients Receiving a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD): IDE Results at 22 Months. Abstract, HRS 2014.
2. Lambiase, P, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS Registry. EHJ, Mar 2014

Çalışmalar: Uygunsuz şok oranları



	No. at Risk	688	634	576	546	494	441	378	279
Dual Zone	K-M Estimate (%)	0.0	3.0	4.6	6.2	7.7	8.5	9.3	9.3
Single Zone	No. at Risk	170	153	141	134	126	122	117	108
	K-M Estimate (%)	0.0	7.8	10.8	13.3	15.9	17.3	17.3	18.0



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.

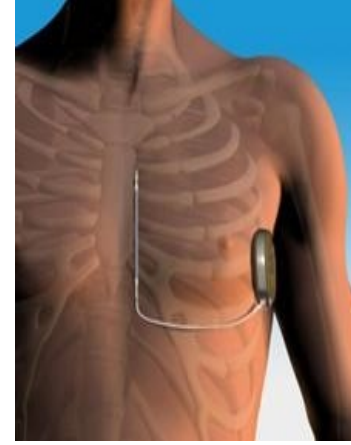
Moss, A, et al. MADIT RIT, NEJM 2012; 367:2275-2283

Gold, et al. Pooled S-ICD data HRS 2014

* Burke MC et al. JACC 2015; 16:16

TV-ICD vs S-ICD

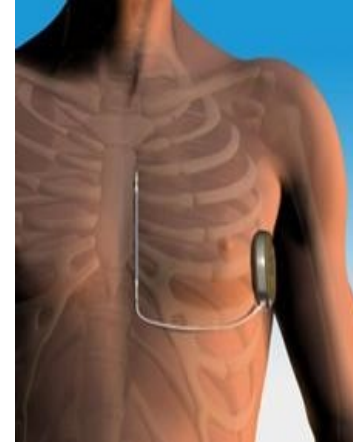
AVANTAJLAR



- VT/VF için etkin defibrilasyon
- Anti-bradikardi pacing
- ATP
- Atrial ve ventriküler diyagnostikler
- Implantasyona aşinalık yüksek
- Ekstravasküler
- Sistemik enfeksiyon için düşük risk
- Venöz yol korunuyor
- Endovasküler lead ekstraksiyonu ile ilgili riskler yok
- Daha az floroskopi

TV-ICD vs S-ICD

DEZAVANTAJLAR



- Cep enfeksiyonları
 - Jeneratör komplikasyonları
 - Uygunsuz şoklar
- Sistemik enfeksiyon riski
 - Ven trombozu/stenozu
 - Lead fraktürü
 - Endovasküler ekstraksiyon ile ilişkili riskler
- Pacing yok, ATP yok
 - Gelişmiş diyagnostik yöntemler yok
 - 80J
 - Büyük jeneratör
 - Uzun dönem güvenlik ve etkinlik datası henüz yok

S-ICD ilk seenek olarak düşünülebilir

- Venöz ulaşımın mümkün olmadığı konjenital kalp hastaları
- Santral venlerin stenozu veya obstruksiyonu
- Endokardit veya cihaz ilişkili enfeksiyon varlığı
- Endovasküler lead enfeksiyonu açısından yüksek risk altında olan hastalar; diyaliz, immünsupresyon, kanser, kronik kateter ihtiyacı
- Kardiyak transplantasyon adayları

S-ICD alternatif olarak düşünülebilir

- Aktif yaşam tarzı ve uzun ömür beklentisi olan genç hastalar
- Kalıtsal genetik aritmojenik sendromlar (Brugada, Uzun ve Kısa QT sendromları..)
- Hipertrofik kardiyomiyopati
- Protez kalp kapağı bulunması (enfeksiyon riski)
- İskemik/noniskemik dilate kardiyomiyopatide primer koruma amaçlı
- Hastane dışı VF yaşayanlarında sekonder koruma amaçlı

S-ICD Önerilmeyen Durumlar

- İmplant öncesi taramada ('screening') uygun bulunmayan hastalar (%7 civarı)
- Sürekli pacing ihtiyacı olan semptomatik bradikardi varlığı
- Önceden implante edilen unipolar pacemaker (sensing ve detection sorunlarına neden oluyor)
- CRT ihtiyacı olan hastalar
- ATP ile tedavi edilebilen tekrarlayan sürekli monomorfik VT varlığı
- Anatomik özellikler; subkutan dokusu zayıf olan ince hastalar, 'pectus excavatum'

KILAVUZLAR

2014 ESC Guidelines on diagnosis and management of hypertrophic cardiomyopathy

The Task Force for the Diagnosis and Management of Hypertrophic Cardiomyopathy of the European Society of Cardiology (ESC)

Authors/Task Force members: Perry M. Elliott* (Chairperson) (UK) Aris Anastasakis (Greece), Michael A. Borger (Germany), Martin Borggrefe (Germany), Franco Cecchi (Italy), Philippe Charron (France), Albert Alain Hagege (France), Antoine Lafont (France), Giuseppe Limongelli (Italy), Heiko Mahrholdt (Germany), William J. McKenna (UK), Jens Mogensen (Denmark), Petros Nihoyannopoulos (UK), Stefano Nistri (Italy), Petronella G. Pieper (Netherlands), Burkert Pieske (Austria), Claudio Rapezzi (Italy), Frans H. Rutten (Netherlands), Christoph Tillmanns (Germany), Hugh Watkins (UK).

Practical aspects of implantable cardioverter defibrillator therapy

Recommendations	Class	Level
Prior to ICD implantation, patients should be counselled on the risk of inappropriate shocks, implant complications and the social, occupational, and driving implications of the device.	I	C
β -Blockers and/or amiodarone are recommended in patients with an ICD, who have symptomatic ventricular arrhythmias or recurrent shocks despite optimal treatment and device re-programming.	I	C
Electrophysiological study is recommended in patients with ICD, and inappropriate shocks due to regular supraventricular tachycardias, to identify and treat any ablatable arrhythmia substrate.	I	C
A subcutaneous ICD lead system (S-ICD™) may be considered in HCM patients who do not have an indication for pacing.	IIb	C

www.escardio.org/guidelines European Heart Journal (2014);35:2733-2779 - doi:10.1093/eurheartj/ehu284



- 2014 ESC hipertrofik kardiyomiyopati kılavuzunda S-ICD'ye de yer ayrılmış. ¹
- S-ICD'lerin yer aldığı ilk kılavuz

2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC)

European Heart Journal 2015
doi/10.1093/eurheartj/ehv316



• Device therapy - Subcutaneous cardioverter defibrillator

Subcutaneous cardioverter defibrillator		
Recommendations	Class ^a	Level ^b
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
The subcutaneous ICD may be considered as a useful alternative to a 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

- SC defibrillators are effective in preventing SD.
- Data on long-term tolerability and safety are currently lacking.
- The device is not suitable for patients who require bradycardia pacing, CRT or those who suffer from tachyarrhythmias that can be easily terminated by ATP.

CCS/CHRS 2016 Implantable Cardioverter-Defibrillator (ICD) Kılavuzu

17. We recommend a subcutaneous ICD be considered in patients with limited vascular access or pocket sites in whom an ICD is recommended (Strong recommendation; Low quality evidence)

- **Ventriküllere ulaşımın zor olduğu konjenital kalp hastaları**
- **TV-ICD ile tromboembolik komplikasyonlara meyil yaratan şantları bulunan konjenital kalp hastaları**
- **Cihaz ile ilişkili enfeksiyon öyküsü olan hastalar**
- **Kronik kateter bulunması gibi venöz yolun başka nedenle kullanıldığı hastalar**

TEŐEKKÜR EDERİM