



# Continuing Nursing Education



Rijnstate. Voorop in zorg voor jou.



Rijnstate

# Transveneuze ICD en S-ICD

30-05-2023

Frank Brouwers

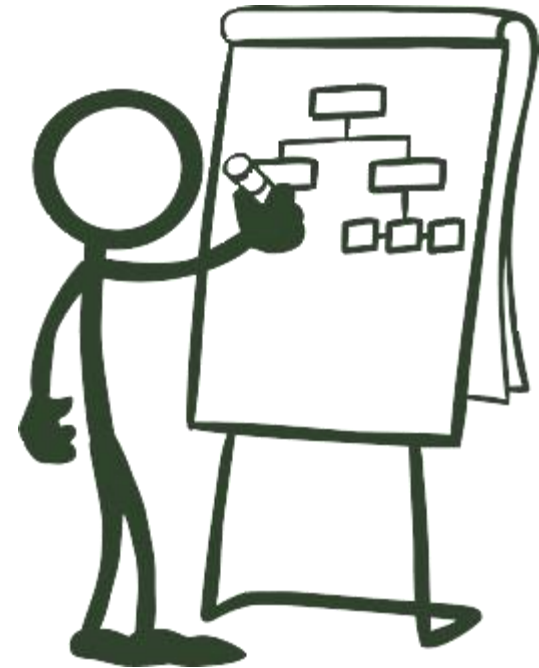


Rijnstate. Voorop in zorg voor jou.

<b>Disclosure belangen spreker</b>	
<b>Geen (potentiële) belangenverstremgeling</b>	GEEN
<b>Voor bijeenkomst mogelijk relevante relaties<sup>1</sup></b>	<b>Bedrijfsnamen</b>
<ul style="list-style-type: none"> <li>• Sponsoring of onderzoeksgeld<sup>2</sup></li> <li>• Honorarium of andere (financiële) vergoeding<sup>3</sup></li> <li>• Aandeelhouder<sup>4</sup></li> <li>• Andere relatie, namelijk ...<sup>5</sup></li> </ul>	<ul style="list-style-type: none"> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul>

# Waar gaat het over?

- Wat is een ICD
- Historie
- Indicaties
- Functie
- Implantatie
- Follow-up
  
- S-ICD



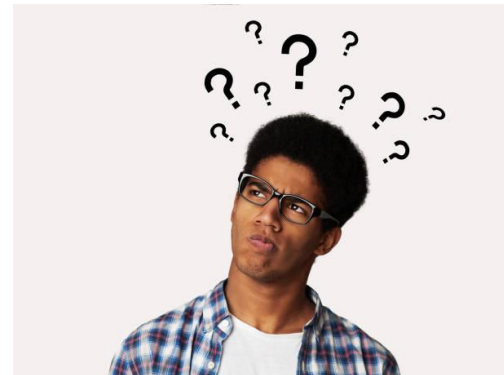
# “ICD”

A) International classification of disease



B) Implanterbare cardioverter defibrillator

C) Inwendig cardiaal device



# ICD

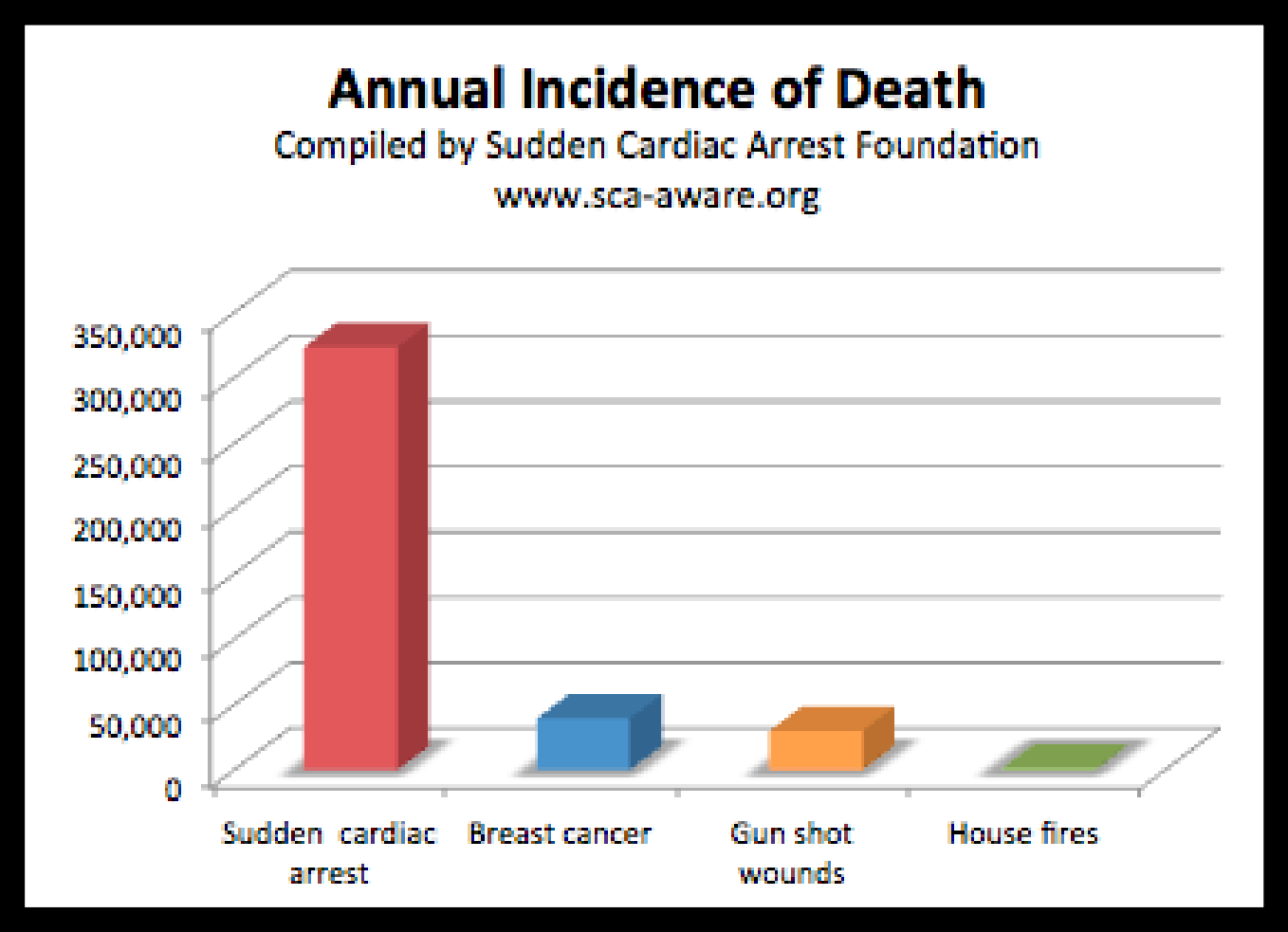
- Implanterbaar: subcutane plaatsing
- Cardioverter: omzetten / converteren van afwijkend hartritme naar normaal
- Defibrillator: toedienen van schok

Apparaat dat ingrijpt bij gevaarlijke hartritmestoornissen en hiermee voorkomen van hartstilstand

- Device
- Elektrode(n)

# Incidence of SCD

## SCD across Europe



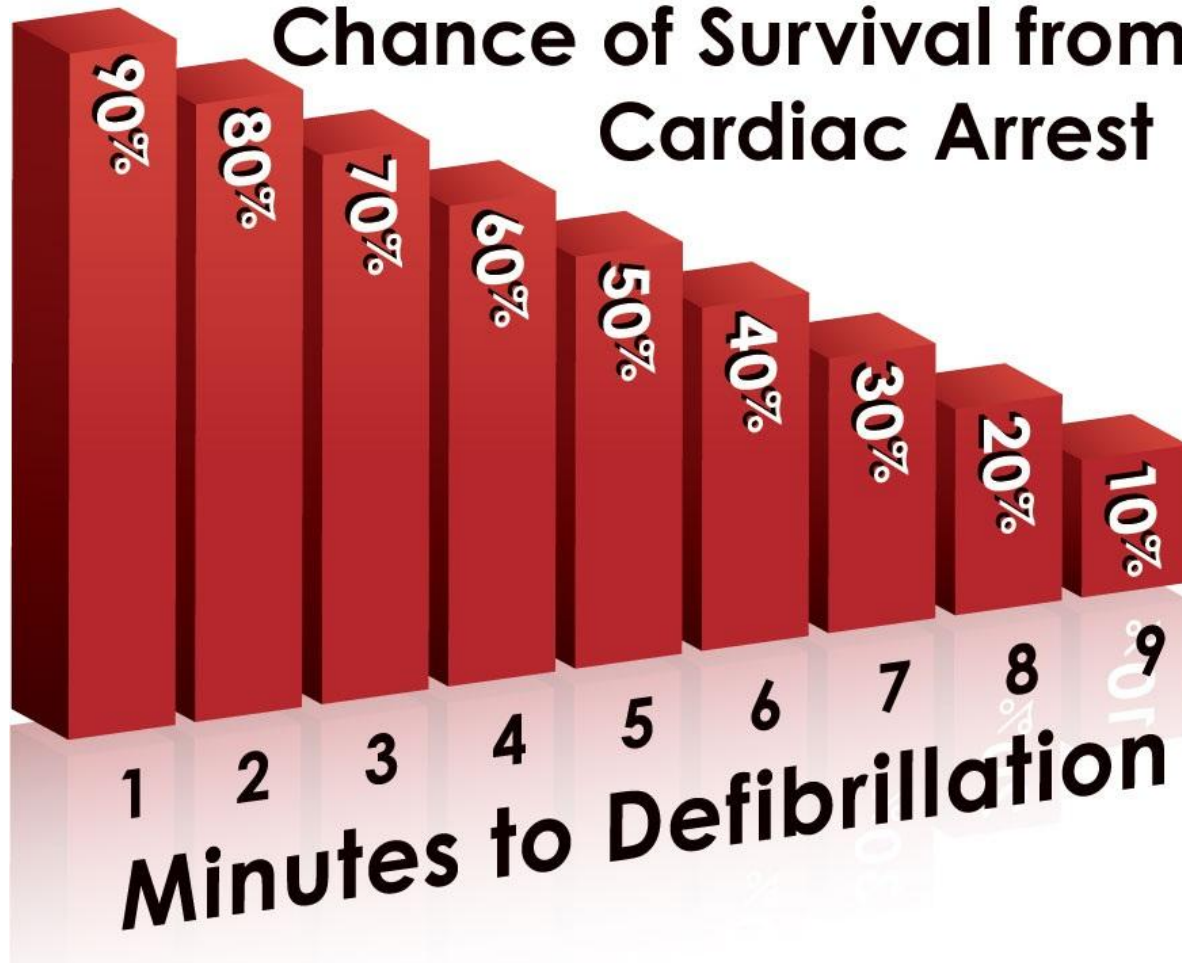
**SCD**

- US
- Eu

**1st d**



## Chance of Survival from Cardiac Arrest





# ICD vs pacemakers

A) Elke pacemaker is ook een ICD

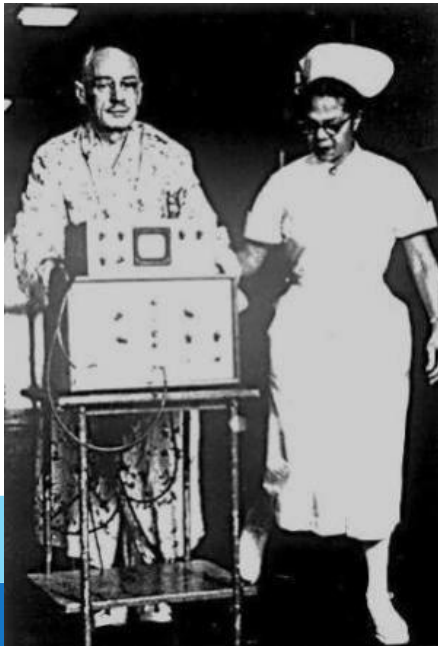
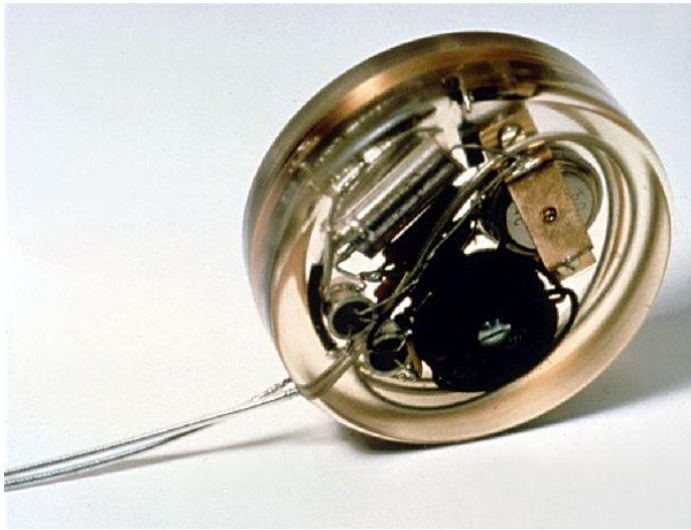


B) Elke ICD is ook een pacemaker

(bijna elke ICD...)



# Soorten devices



# Soorten devices



## EVOLUTION OF PACEMAKERS



Weight: 73.4g  
Size: 35cc

1958



Weight: 55g  
Size: 25cc

1981



Weight: 14g  
Size: 6cc

1995



Weight: 23g  
Size: 12.8cc

2009



Weight: 2g  
Size: 1cc

2015



# En de ICD dan?

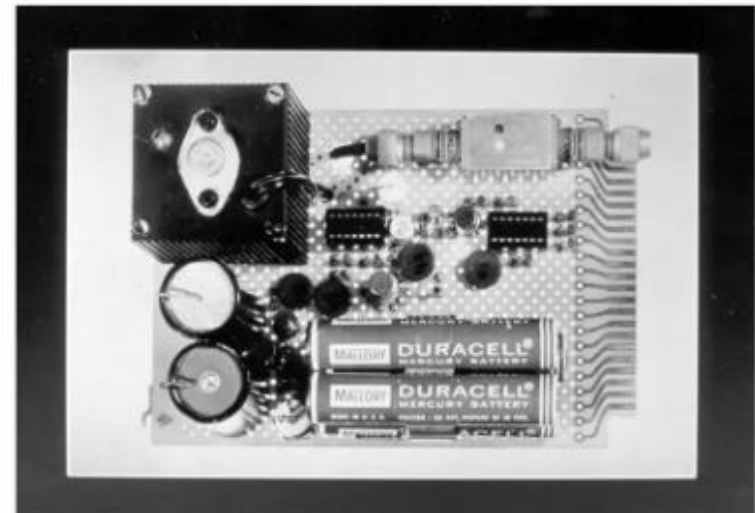
- 1947 – open thorax defibrillatie
- $\pm$  1955 – externe defibrillatie gesloten thorax



- 1962 – DC defibrillator, capacitor om energie op te slaan, transformator om af te geven

# En de ICD dan?

- 1969 - Dr. Mirowski and Dr. Morton Mower begin collaborating and develop the first experimental model



- 1975 – 1<sup>e</sup> implantatie in hond
- 1980 – 1<sup>e</sup> implantatie in mens



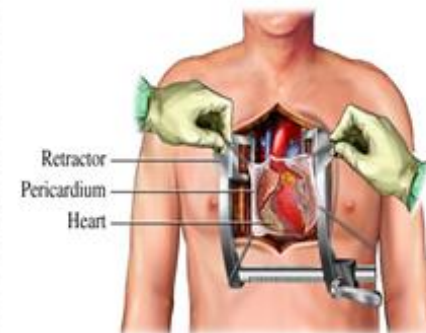
# Eerste generatie (begin jaren 80)

- Alleen 'VF' behandeling (shock only – 15s; 30J)
- Geen pacemakerfunctie
- 250g, 160cc
- Thoracotomie

The world's first  
ICD<sup>6</sup>

## AID B/BR

- 160 cc
- 30J max output
- Projected longevity of 1.5 years
- Minimal features



# Tweede generatie (eind jaren 80)

- Ontwikkeling van VA detectie (tov SR)
  - Mogelijkheid tot brady-therapie
- 1988 – 1<sup>e</sup> transveneuze lead
- Plaatsing: buikholte
- Lithium-zilver vanadium mangaan





# Derde generatie (jaren 90)

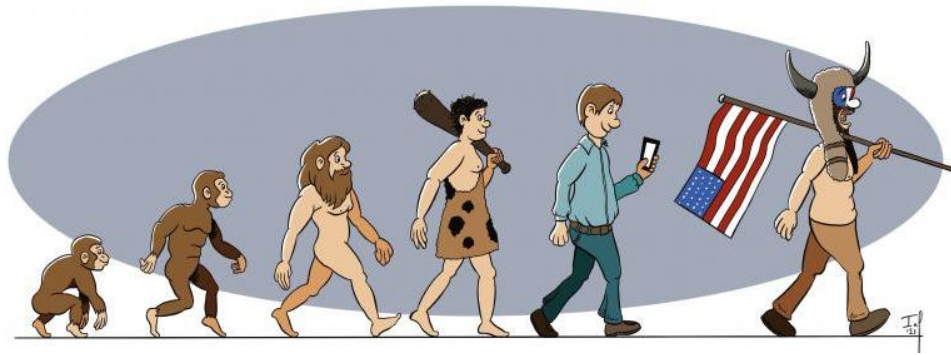
- 2k-systeem (1997)
- Introductie van ATP
- Meer programmeerbare functies
- Verbeterde discriminatie VT/SVT
  - Instelbare 'zones'
- Lead ontwikkeling
  
- Implantatie schouder regio



# Vierde generatie (hedendaags)

- ICD kleiner en verfijnd
- 80-90g (250), 30ml (145). <1 cm dik
- Batterijduur 9+ jaar
- Verdere ontwikkeling 3<sup>e</sup> generatie





Subcutaneous Defibrillator

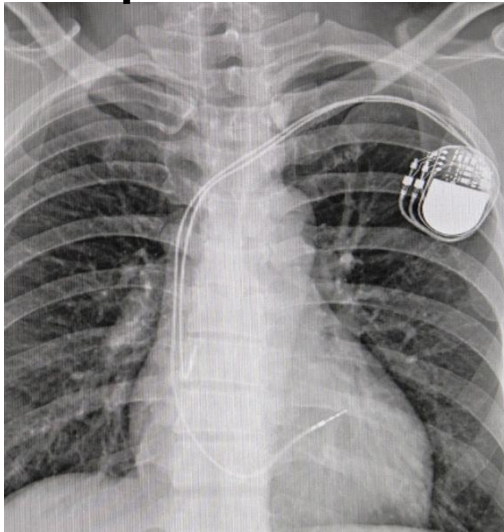
Transvenous Defibrillator

Permanent Pacemaker

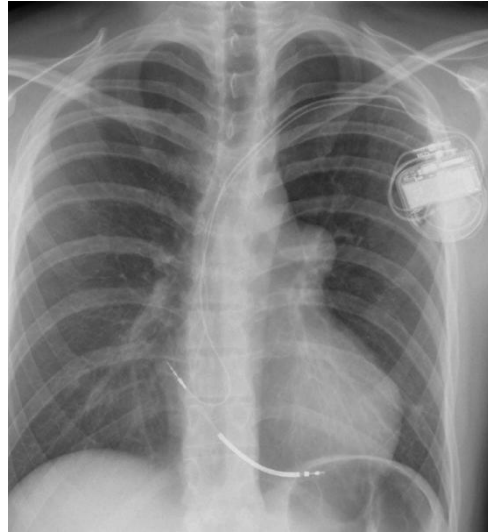
2020 – >200.000 implantaties per jaar



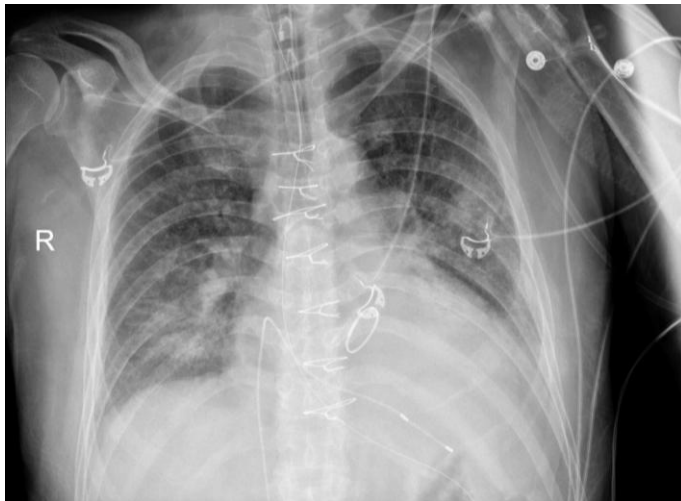
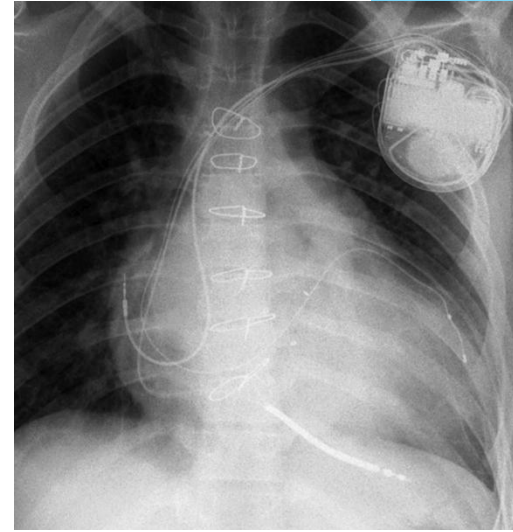
**DDD pacemaker**



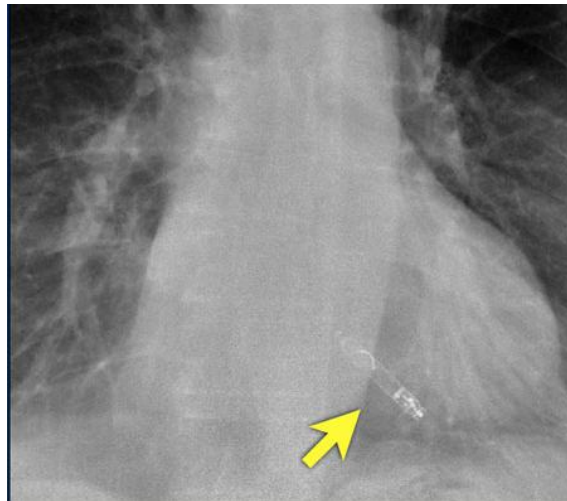
**ICD**



**CRT**



**Tijdelijke pacemaker**



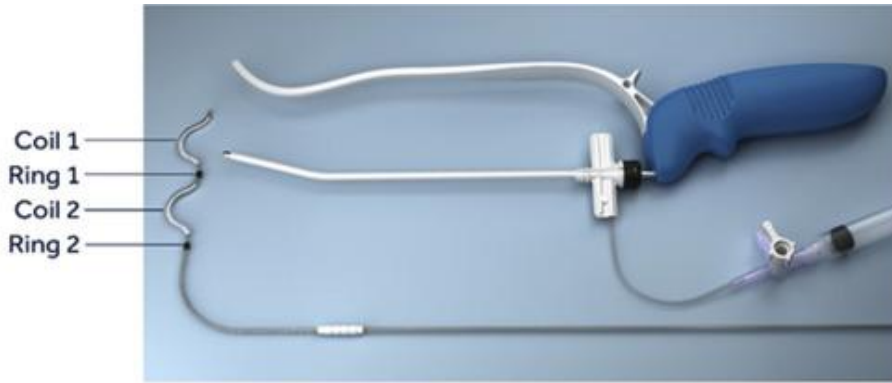
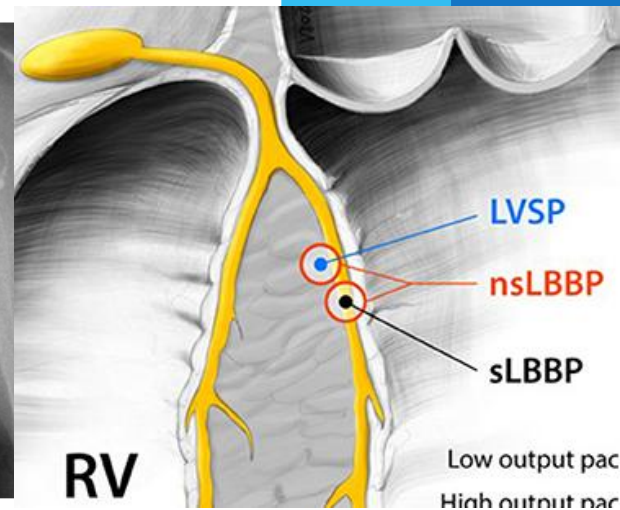
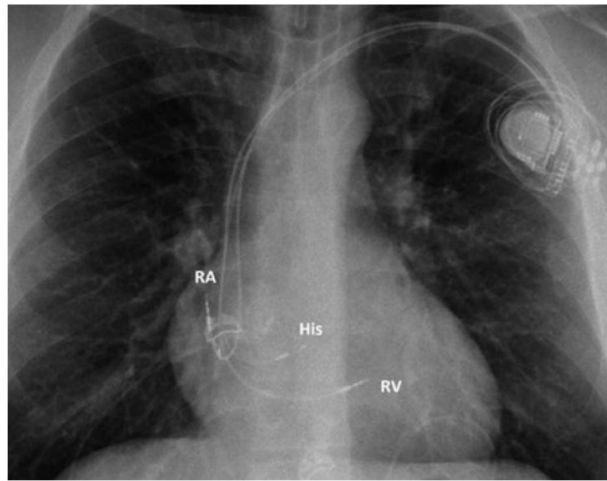
**Wireless pacemaker (MICRA)**



**Subcutane ICD**



# Conduction system pacing



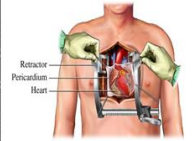
???

Extravascular ICD



Rijnstate

# Alternatieven



## AED



## Life Vest



# Alternatief...?



© EPA



Rijnstate

Schroeven

Leads

Setscrews—Each lead is held in place by a small screw to ensure electrical contact between the lead and the ICD.

Header

Header—The top part of the ICD is made of see-through plastic. It has several ports where one or more leads are inserted. The lead is gently but firmly inserted into the port.

Circuits

Circuitry—Every ICD contains complex micro-electronics that process incoming signals from the heart and produces outgoing responses. It also stores information for the doctor. An ICD is actually a mini computer.

Batterij

Battery—The ICD contains an internal power source. Most ICDs use a lithium battery. Battery power is used by the doctor, and when indicated, the battery is replaced (not just the battery).

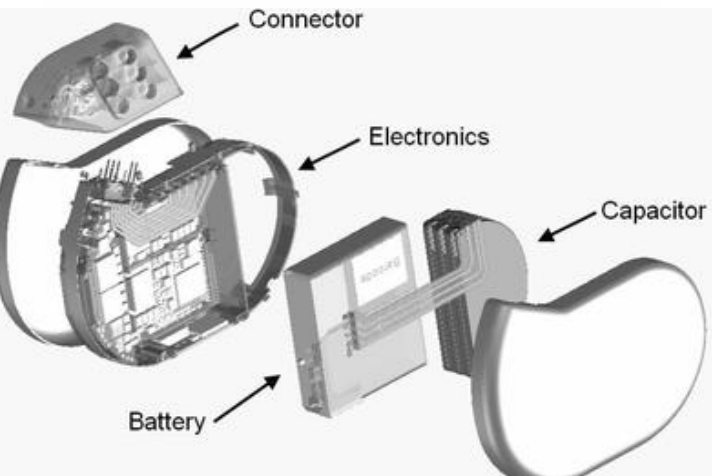
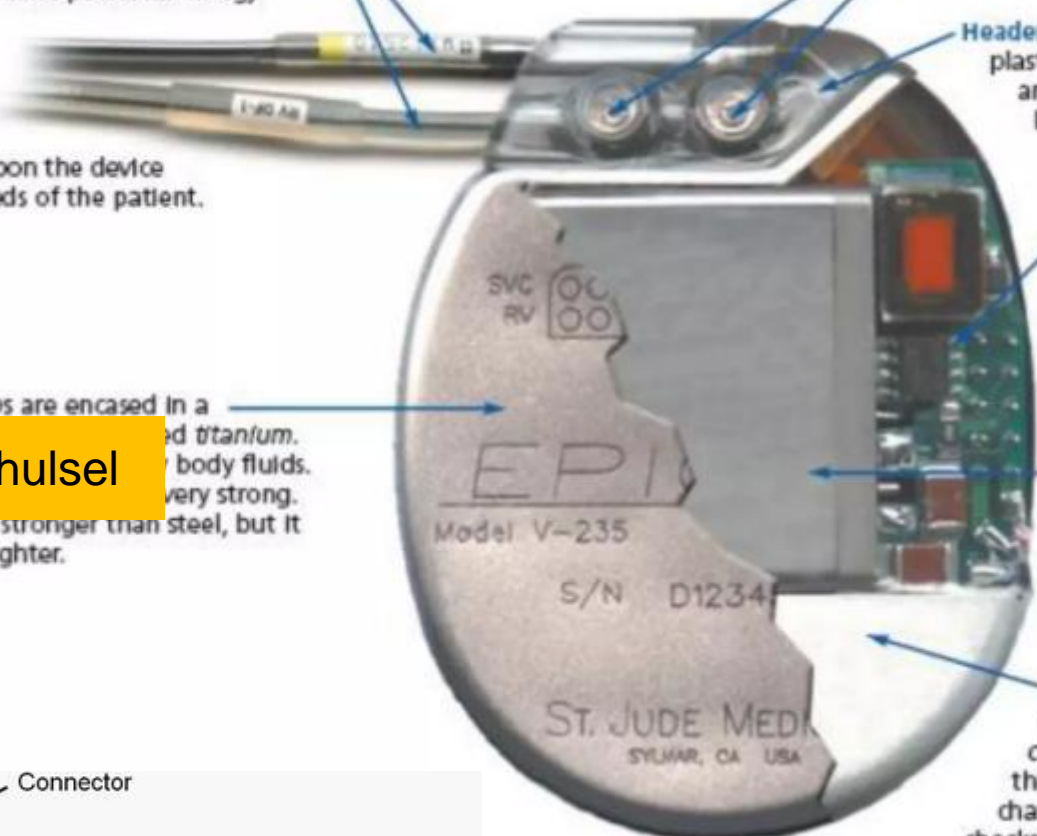
Capacitor

Capacitors—Ever wonder how a little device can generate so much electrical energy? The answer is capacitors. In an ICD, capacitors store the electrical energy that can be discharged as high-energy shocks when needed.

Leads—Cables that connect the implanted device to the patient's heart. They are used to sense the heart's activity and to help the ICD send powerful energy to the heart to stop abnormal fast heart rhythms. An ICD system can have one or more leads, depending upon the device and the specific needs of the patient.

Casing—Today's ICDs are encased in a lightweight, corrosion-resistant titanium. Titanium is resistant to body fluids. It is lightweight and very strong. Titanium is actually stronger than steel, but it can be up to 45% lighter.

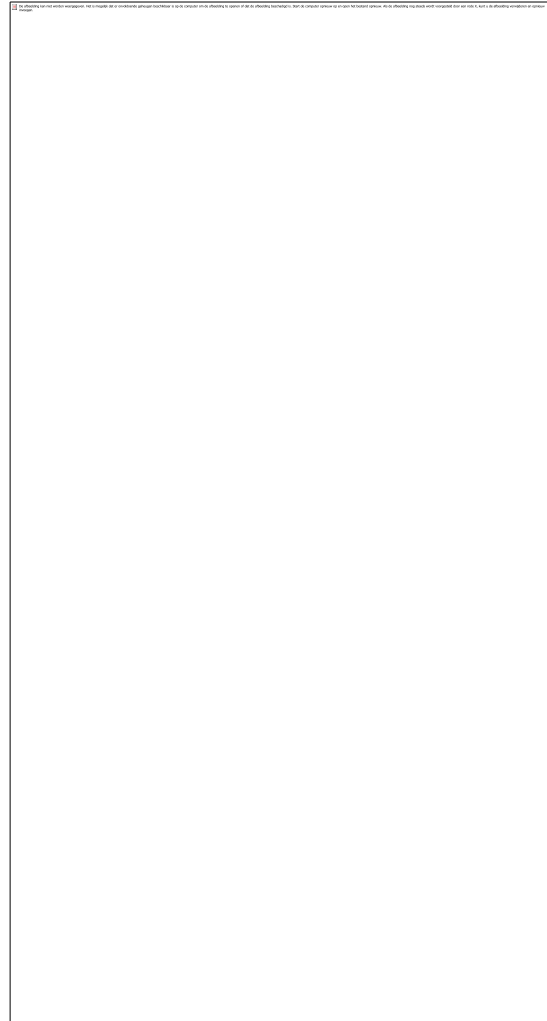
Omhulsel





# Waar zijn we gebleven

- ~~Wat is een ICD~~
- ~~Historie~~
- **Indicaties**
- Functie
- Implantatie
- Follow-up
  
- S-ICD



# Indicaties

## ICD voor tachy-aritmie:

- Secundaire preventie VT / VF
  - Primaire preventie VT / VF
- +/- pacemakerfunctie

Structurele afwijking/litteken  
Congenitaal  
Idiopathisch  
Catecholaminerg

Reversibel dus geen ICD  
Acute ischemie  
Intoxicatie/medicatie  
Elektrolyetstoornissen

## CRT

Cardiac resynchronization therapy  
bij hartfalen en dyssynchrone  
ventrikels

(+/- ICD)

# Secondary Prevention Trials

MADIT MUSTT MADIT II SCD-HEFT AVID CIDS CASH

## Antiarrhythmics Versus Implantable Defibrillators (AVID)

An overview of the AVID<sup>1</sup> trial is included below.

### Secondary Prevention Trial

Protocol

**Results:**  
The ICD group experienced a 39% reduction in deaths in the first year, with a 27% and 31% reduction in years two and three.

Protocol – AVID Trial

**Hypothesis**  
To determine whether initial treatment strategy of ICD defibrillator or antiarrhythmic drug therapy results in longer life

39%

MADIT MUSTT MADIT II SCD-HEFT AVID CIDS CASH

## Canadian Implantable Defibrillator Study (CIDS)

An overview of the CIDS<sup>1</sup> trial is included below.

### Secondary Prevention Trial

Protocol

**Results:**  
The ICD defibrillator group experienced a 20% relative reduction in mortality in 3 years (P=0.14).

Protocol – CIDS Trial

**Hypothesis**  
Initial ICD defibrillator therapy will reduce the risk of arrhythmic death compared to amiodarone for patients at high risk for arrhythmic death due to ventricular tachycardia or ventricular fibrillation (VT or VF).

**Primary Endpoint**

- Total mortality

**Results**

- The ICD defibrillator group experienced a 20% relative reduction in mortality in 3 years (P=0.14).

20%

MADIT MUSTT MADIT II SCD-HEFT AVID CIDS CASH

## Cardiac Arrest Study Hamburg (CASH)

An overview of the CASH<sup>1</sup> trial is included below.

### Secondary Prevention Trial

Protocol

**Results:**  
The ICD group experienced a 21% reduction in mortality in 3 years (P=0.002).

Protocol – CASH Trial

**Hypothesis**  
To compare the incidence of recurrence of cardiac arrest, sudden cardiac death, cardiac mortality, and total mortality in patients treated with antiarrhythmic drugs versus ICD defibrillators.

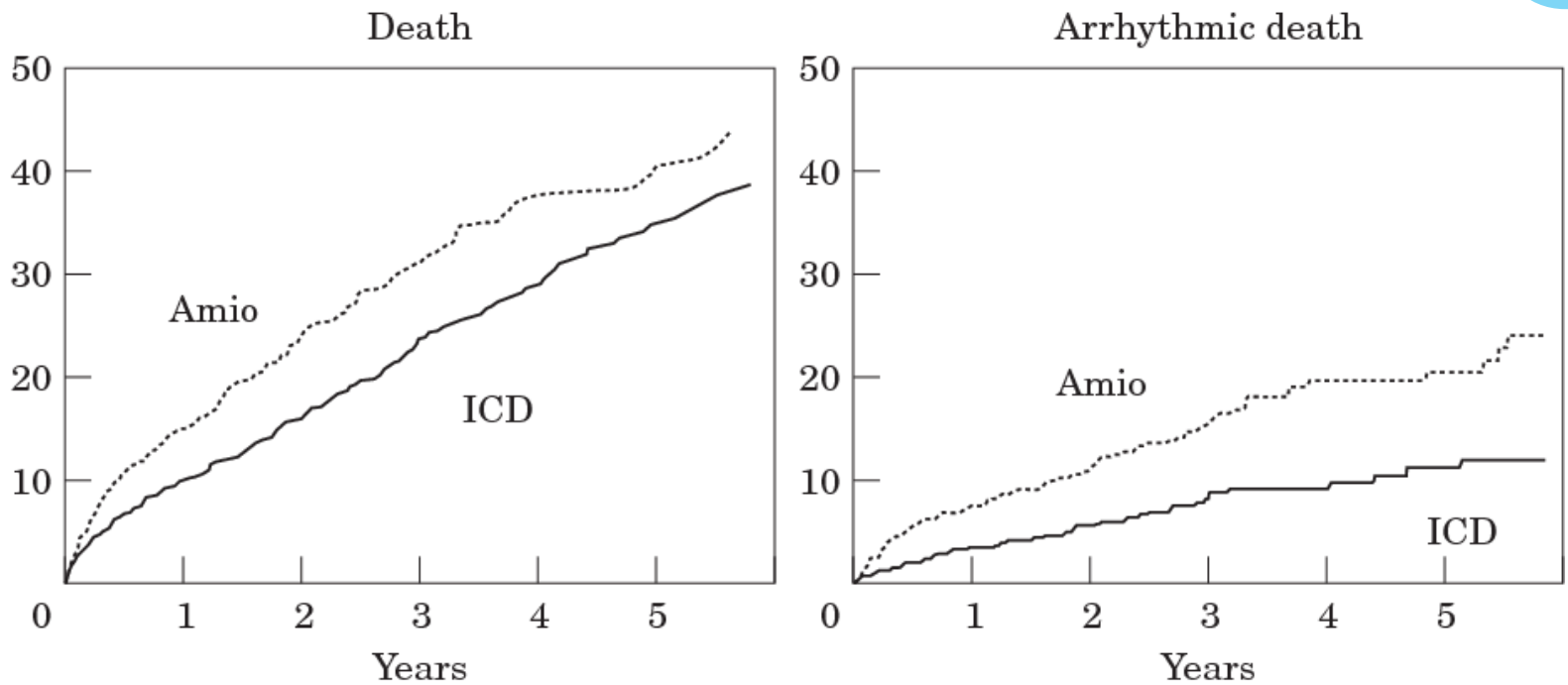
**Primary Endpoint**

- Total mortality

**Secondary Endpoints**

- Recurrences of cardiac arrest requiring cardiopulmonary resuscitation
- Recurrences of hemodynamically unstable ventricular tachycardia
- Incidence of drug withdrawal because of adverse effects

21%



Number at risk

ICD:	934	715	467	273	159	104	934	715	467	273	159	104
Amio:	932	664	427	248	128	82	932	664	427	248	128	82

**Figure 1** Cumulative risk of fatal events or the amiodarone (...) and ICD (—) treatment arms.



# Primary Prevention Trials

MADIT MUSTT MADIT II SCD-HEFT AVID CIDS CASH

## Multicenter Automatic Defibrillator Implantation Trial (MADIT)

An overview of the MADIT<sup>1-3</sup> trial is included below.

### Primary Prevention Trial – ICD Defibrillator vs. Antiarrhythmic Drug Treatment in Post-MI Patients

Protocol

**Randomization of patients who have a(n):**

- ▶ Q-Wave MI ≥ 3 weeks
- ▶ Asymptomatic, unsustained VT
- ▶ LVEF ≤ 35%
- ▶ Inducible, non-suppressible VT on EP testing w/procainamide
- ▶ NYHA Class I-III

**ICD (n = 95)**      **Conventional Therapy (n = 101)**

**Results:**  
The ICD group experienced a 54% reduction in overall mortality and a 75% reduction in arrhythmic mortality after a mean follow-up of 27 months.

Protocol – MADIT Trial

54%

MADIT MUSTT MADIT II SCD-HEFT AVID CIDS CASH

## Multicenter Automatic Defibrillator Implantation Trial II (MADIT II)

An overview of the MADIT II<sup>1-3</sup> trial is included below.

### Primary Prevention Trial – ICD Defibrillator vs. Antiarrhythmic Drug Treatment in Post-MI Patients

Protocol

**Randomization of patients who have a(n):**

- ▶ Q-Wave MI ≥ 4 weeks
- ▶ Asymptomatic, unsustained VT
- ▶ LVEF ≤ 30%
- ▶ ≥ 21 yrs, no upper age limitation
- ▶ No requirement for NSVT or EPS

Randomized 1,232 patients using a 3:2 ratio (ICD: non-ICD):

**ICD + Conventional Rx (n = 742)**      **Conventional Therapy (n = 490)**

(EPS after implant)      (Conventional post-MI drug Rx)

**20 months mean follow-up**

Avoid AAD  
Optimize: βB, ACE-I, Diuretics

Protocol – MADIT II Trial

31%

MADIT MUSTT MADIT II SCD-HEFT AVID CIDS CASH

## Multicenter Unsustained Tachycardia Trial (MUSTT)

An overview of the MUSTT<sup>1-3</sup> trial is included below.

### Primary Prevention Trial ICD – Defibrillator vs. Antiarrhythmic Drug Treatment in Post-MI Patients

Protocol

**Randomization of patients who have a(n):**

- ▶ Coronary artery disease (CAD)
- ▶ Asymptomatic, unsustained VT
- ▶ LVEF ≤ 40%
- ▶ Inducible VT on EP testing
- ▶ History of MI in 95%

**EPs**

**No Sustained VT Induced**      **Inducible Sustained VT**

**Registry (n=1435)**      **Randomized (n=704)**

**No EP-Guided Rx ACE I & βB (n=353)**      **EP-Guided Rx ACE I & βB (n=351)**

**Treatment at discharge:**  
AA Drugs = 45%  
ICD = 45%

51%

Year	Study	Patients	Indication	Study population	
1996	MADIT	196	Primary	Ischemic; LVEF: $\leq 35\%$ ; NYHA: I-III; asymptomatic NSVT or inducible VT on EPS	54%
1997	AVID	1013	Secondary	Symptomatic VT; survivors of SCD; LVEF: $\leq 40\%$	31%
1999	MUSTT	704	Primary	Ischemic; LVEF: $< 40\%$ ; asymptomatic NSVT	51%
2000	CASH	288	Secondary	SCD survivors, unstable VT	23%
2002	MADIT-II	1232	Primary	Ischemic; LVEF: $< 30\%$ ; more than 30 days from the onset of myocardial infarction	31%
2004	DEFINITE	458	Primary	Nonischemic (DCM); LVEF $\leq 35\%$ NSVT or premature ventricular complexes ( $\geq 10$ beats/hour) on Holter	14%
2004	DINAMIT	674	Primary	Ischemic, recent MI within 4-40 days; LVEF: $\leq 35\%$ ; impaired HR variability	
2004	COMPANION	1520	Primary	Ischemic and nonischemic; NYHA: III-IV; LVEF QRS: $> 120$ msec	-
2005	SCD-HeFT	2521	Primary	Ischemic and nonischemic; LVEF $< 35\%$ ; NYHA: II-III	20%
2016	DANISH	1116	Primary	Nonischemic; LVEF: $\leq 35\%$ ; NYHA: II-III (IV if for CRT); optimal medical therapy, including CRT	23%



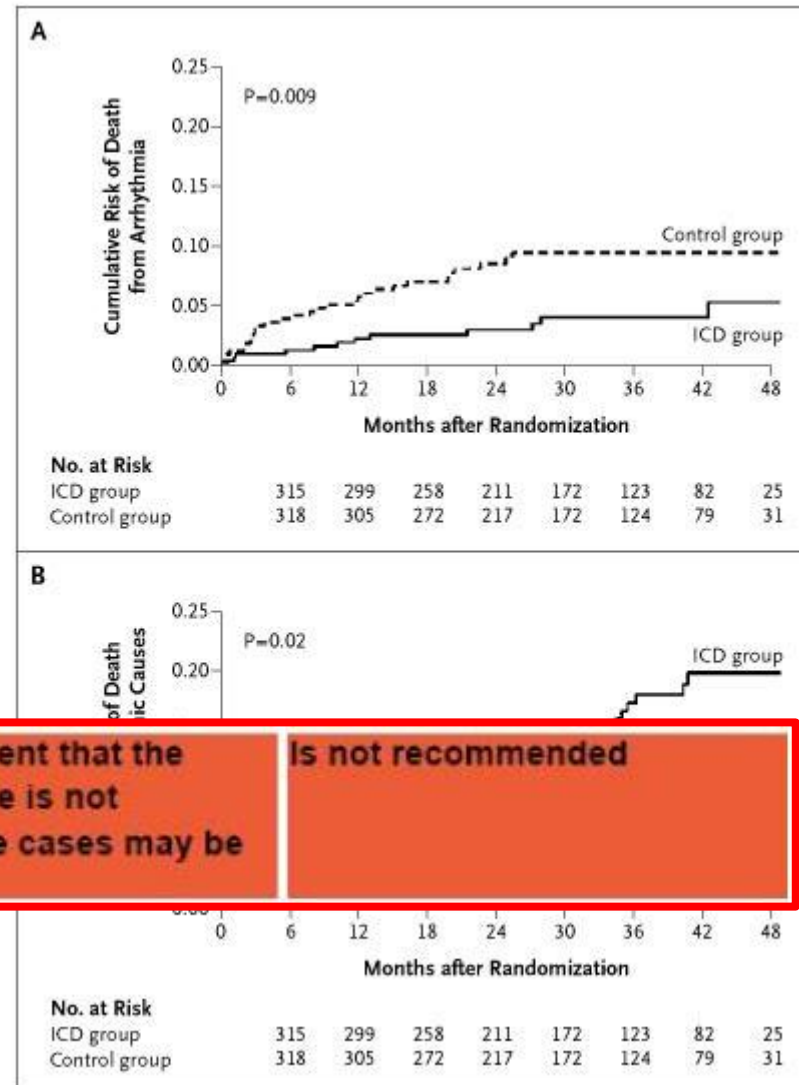
# DINAMIT

ORIGINAL ARTICLE

## Prophylactic Use of an Implantable Cardioverter–Defibrillator after Acute Myocardial Infarction

Stefan H. Hohnloser, M.D., Karl Heinz Kuck, M.D., Paul Dorian, M.D., Robin S. Roberts, M.Tech., John R. Hampton, M.D., Robert Hatala, M.D., Eric Fain, M.D., Michael Gent, D.Sc., and Stuart J. Connolly, M.D. for the DINAMIT Investigators\*

- ICD na infarct vs medx
- 6-40 dagen
- 674 patiënten
- LVEF <35%



**Class III**

Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.

**Is not recommended**

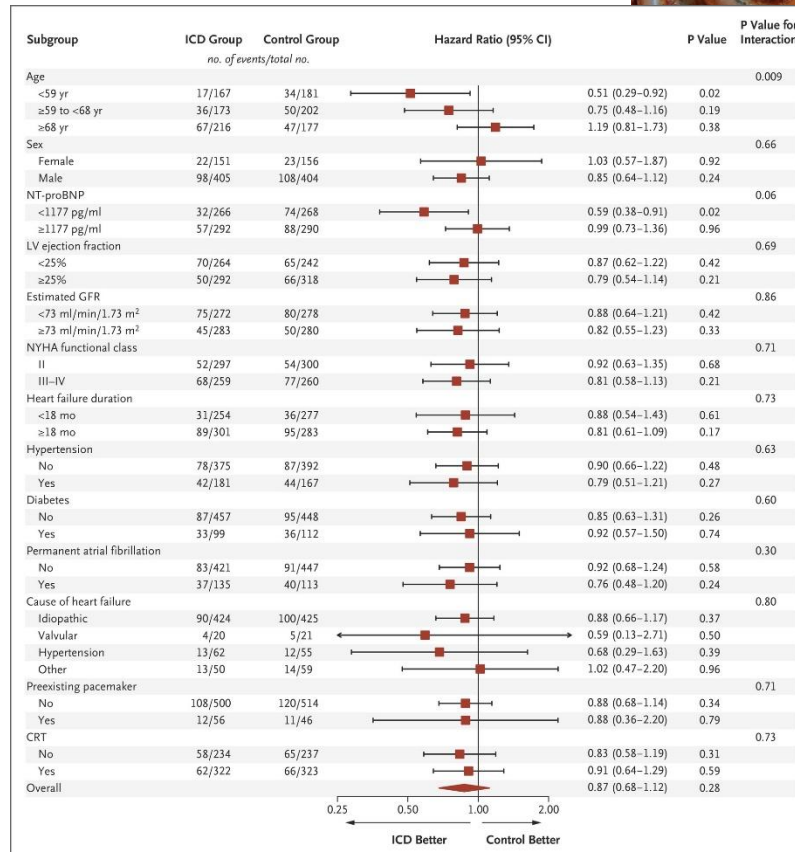
# Danish

## Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure

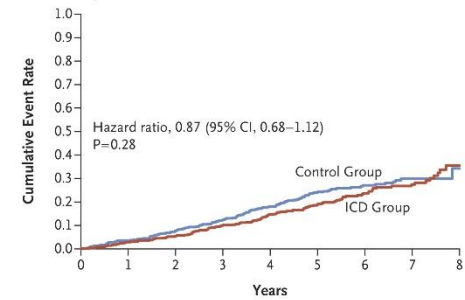
ORIGINAL ARTICLE

Lars Køber, M.D., D.M.Sc., Jens J. Thune, M.D., Ph.D., Jens C. Nielsen, M.D., D.M.Sc., Jens Haarlo, M.D., D.M.Sc., Lars Videbæk, M.D., Ph.D., Eva Korup, M.D., Ph.D., Gunnar Jensen, M.D., Ph.D., Per Hildebrandt, M.D., D.M.Sc., Flemming H. Steffensen, M.D., Niels E. Bruun, M.D., D.M.Sc., Hans Eiskjær, M.D., D.M.Sc., Axel Brandes, M.D., *et al.*, for the DANISH Investigators<sup>§</sup>

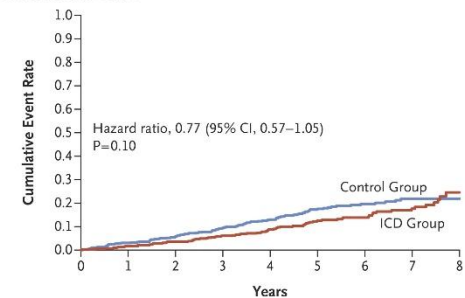
- 1116 pt, NICM
- ICD vs medx



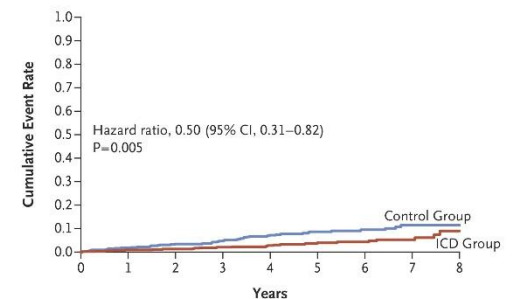
A Death from Any Cause



B Cardiovascular Death



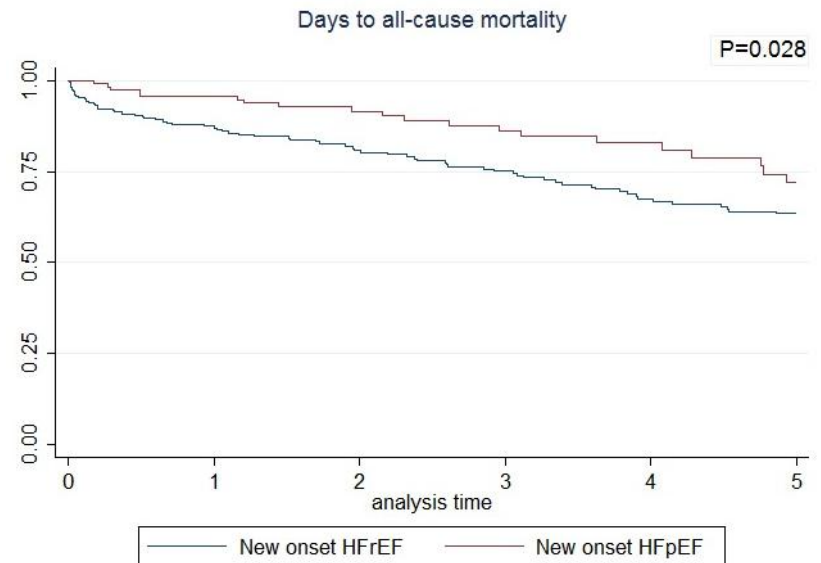
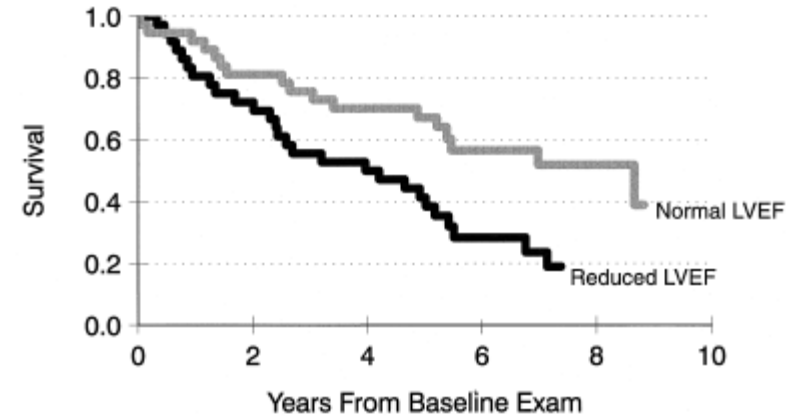
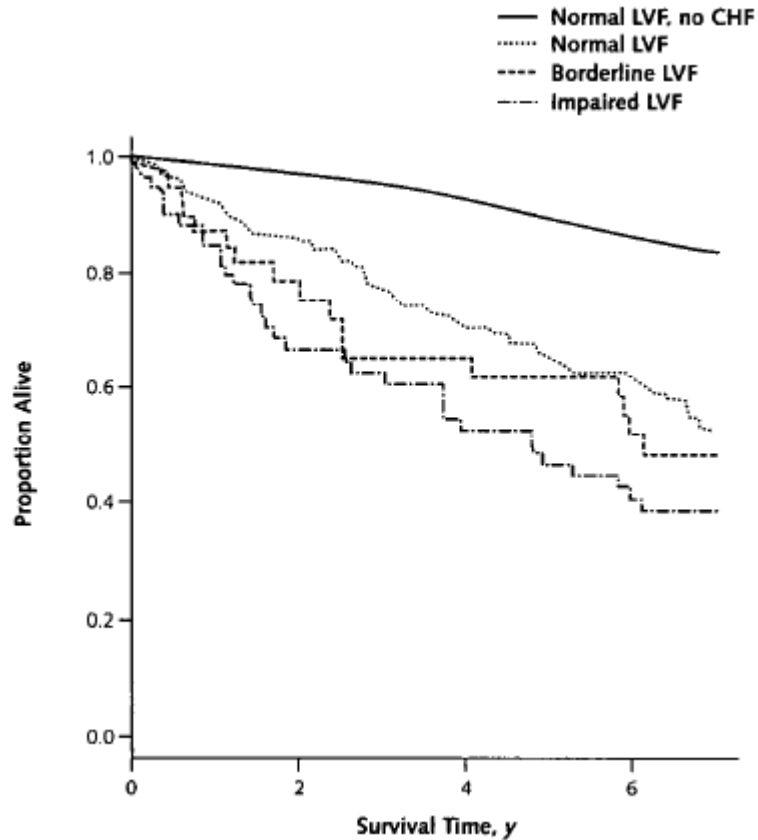
C Sudden Cardiac Death



No. at Risk	560	540	517	438	344	248	169	88	12
Control Group	560	540	517	438	344	248	169	88	12
ICD Group	556	540	526	451	358	272	186	107	17



# Prognosis

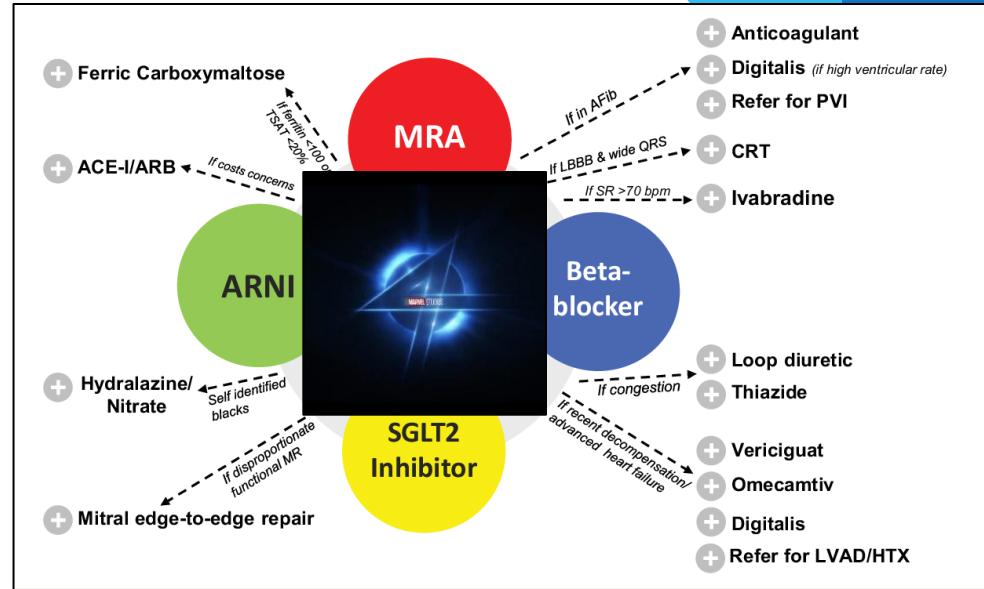


Framingham  
 Cardiovascular healthy study  
 PREVENT

# 1996

- ACE-i / ARB
- digoxine
- Betablokker?

# 2023



## NIEUWS

# Hartpatiënten krijgen veel te vaak een inwendige defibrillator, stelt het Zorginstituut

Cardiologen in Nederland plaatsen bij veel te veel patiënten inwendige defibrillatoren, apparaatjes die het hart een schok geven bij een ritmestoornis. In liefst een op de vijf gevallen draagt een zogeheten icd niets bij aan de overlevingskans van een patiënt, terwijl er wel een risico is op complicaties.



Zorginstituut Nederland



Luister naar  
22:15

## Cardioloog? 'Het voelde alsof het een keukenverkoper was'

**Hartimplantaten** Van Jakarta tot IJsselmuiden: verdachte cardiologen van het Zwolse Isala Ziekenhuis hebben op sommige plekken diepe sporen achtergelaten. Vier patiënten vertellen hoe ze - onterecht, in hun ogen - een hartapparaat kregen opgedrongen. „Potdomme. De snelheid waarmee is besloten, het gebrek aan uitleg, het feit dat ik daarvoor nooit klachten had: het klopt gewoon niet.”

# Richtlijnen: ESC

## Primary prevention

An ICD is recommended to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA class II–III) of an ischaemic aetiology (unless they have had a MI in the prior 40 days—see below), and an LVEF  $\leq 35\%$  despite  $\geq 3$  months of OMT, provided they are expected to survive substantially longer than 1 year with good functional status.<sup>161,165</sup>

I

A

An ICD should be considered to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA class II–III) of a non-ischaemic aetiology, and an LVEF  $\leq 35\%$  despite  $\geq 3$  months of OMT, provided they are expected to survive substantially longer than 1 year with good functional status.<sup>161,166,167</sup>

IIa

A

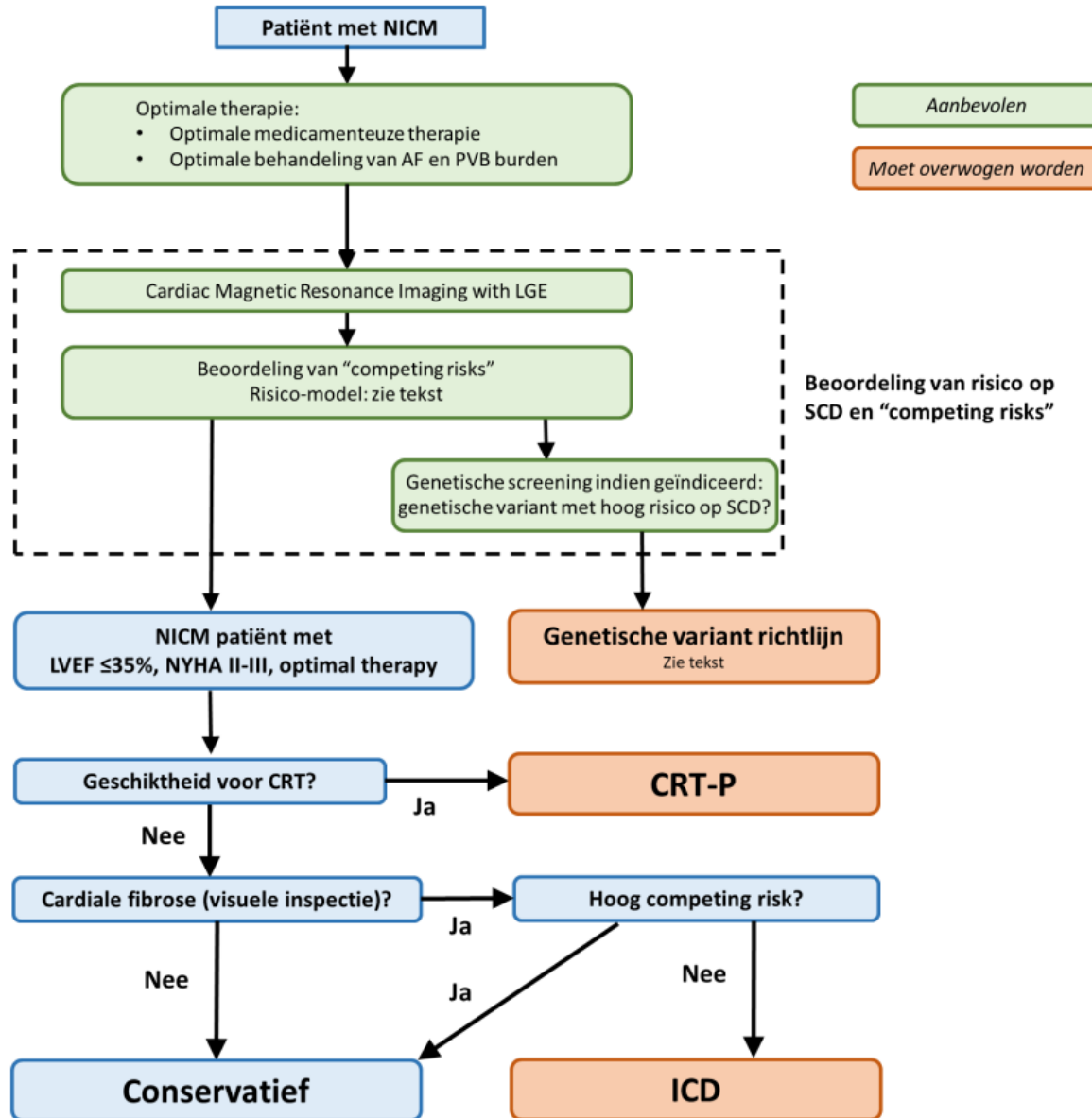
## Secondary prevention

An ICD is recommended to reduce the risk of sudden death and all-cause mortality in patients who have recovered from a ventricular arrhythmia causing haemodynamic instability, and who are expected to survive for  $>1$  year with good functional status, in the absence of reversible causes or unless the ventricular arrhythmia has occurred  $<48$  h after a MI.<sup>162–164</sup>

I

A

# Richtlijnen: NL



# Nieuw onderzoek...

Study short name	No. and year of registration	Indication	Patients' enrolment	Study title	Question addressed
PROTECT-ICD	NCT03588286, 2018	Primary	1058	Programmed Ventricular Stimulation to Risk Stratify for Early Cardioverter-Defibrillator (ICD) Implantation to Prevent Tachyarrhythmias Following Acute Myocardial Infarction	Can an EPS help decide to implant or not ICD in patients after MI with LVEF <40%?
EV ICD CA	NCT05049720, 2021	Class I or IIa according to guidelines	200	ExtraVascular Implantable Cardiac Defibrillator Continued Access Study	Describe a population with extravascular ICD.
CMR GUIDE DCM	NCT03993730, 2019	Primary	1880	Cardiovascular Magnetic Resonance GUIDEd Insertion of Implantable Cardiac Defibrillator in Dilated CardioMyopathy	Is an ICD superior to loop recorder in patients with DCM and LVEF <45%?
	NCT04505007, 2020	Primary	200	Guideline-Directed Medical Therapy in Patients After Implantation of Implantable Cardioverter Defibrillators to Improve Long-Term Outcomes	Do patients with heart failure and ICD need a structured team to implement guideline-directed medical therapy?
DanICD	NCT04576130, 2020	Secondary	1200	A Danish ICD study in Patients With Coronary Artery Disease Resuscitated From Ventricular Fibrillation	Is ICD indicated in secondary prevention after complete revascularization and with LVEF >35%?
ASE	NCT03802110, 2019	Primary and secondary	42	Acute Feasibility Investigation of a New S-ICD Electrode	Describe characteristic of a new s-ICD electrode configuration
PRAETORIAN-DFT	NCT03495297, 2018	Indication according to guidelines	965	A Randomized Trial of S-ICD Implantation With and Without Defibrillation Testing	Can the defibrillation test be omitted after S-ICD implant when the position is confirmed with PRAETORIAN score?
CHAGASICS	NCT01722942, 2012	Primary	1100	Amiodarone Against ICD Therapy in Chagas Cardiomyopathy for Primary Prevention of Death	Is ICD better than amiodarone in Chagas cardiomyopathy patients with documented nonsustained ventricular tachycardia in preventing SCD?
ReCONSIDER	NCT04246450, 2020	Primary	675	Arrhythmic Risk Stratification in Nonischemic Dilated Cardiomyopathy	Can we find a new way to stratify arrhythmic risk in patients with nonischemic dilated cardiomyopathy combining noninvasive risk factors and electrophysiologic studies?
CMR_GUIDE	NCT01918215, 2013	Primary	1055	Cardiac Magnetic Resonance GUIDEd Management of Mild-moderate Left Ventricular Systolic Dysfunction	Is an ICD superior to loop recorder in patients with HF and LVEF >35 and <50% measured by CMR?
LEADR	NCT04863664, 2021	According to guidelines	500	Lead EvaluAtion for Defibrillation and Reliability	To describe new-generation ICD lead in a wide population
	NCT03530904, 2018	According to guidelines	400	Comparison Between Early and Late Mobilization After Cardiac Device Implantation	Are 4 hours enough or is better a bed restriction till the morning after the procedure of CIED implant?

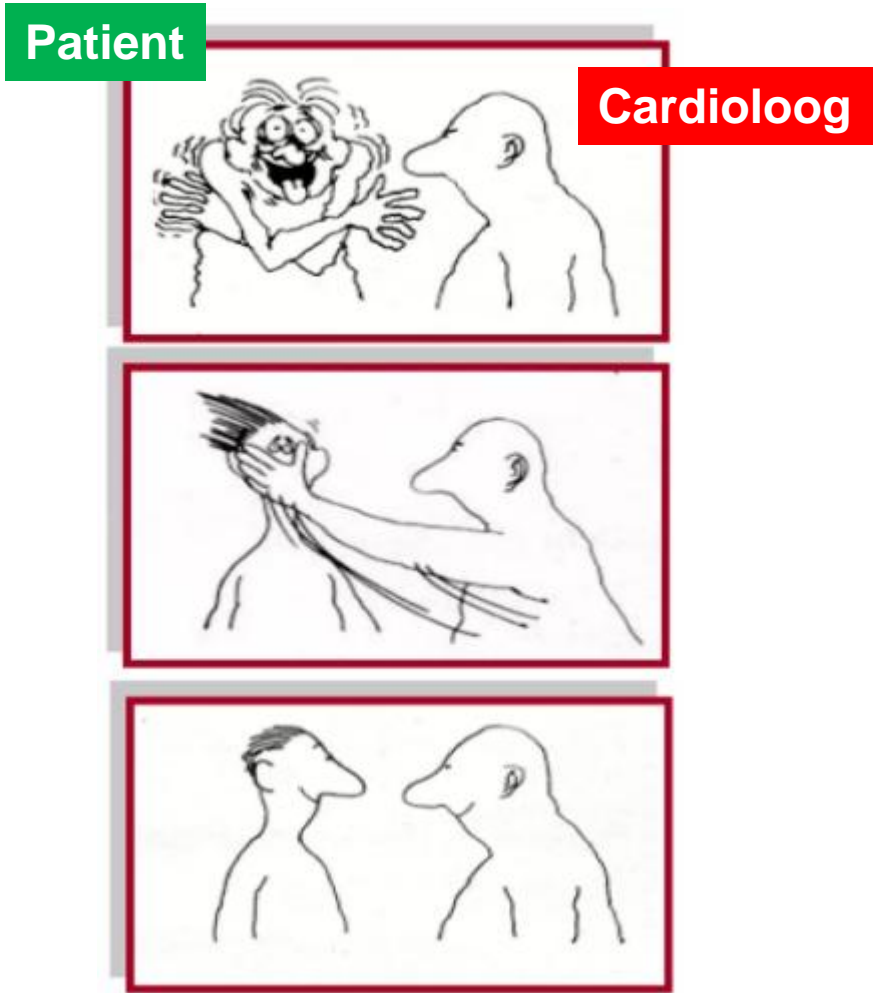


# Toekomst...?



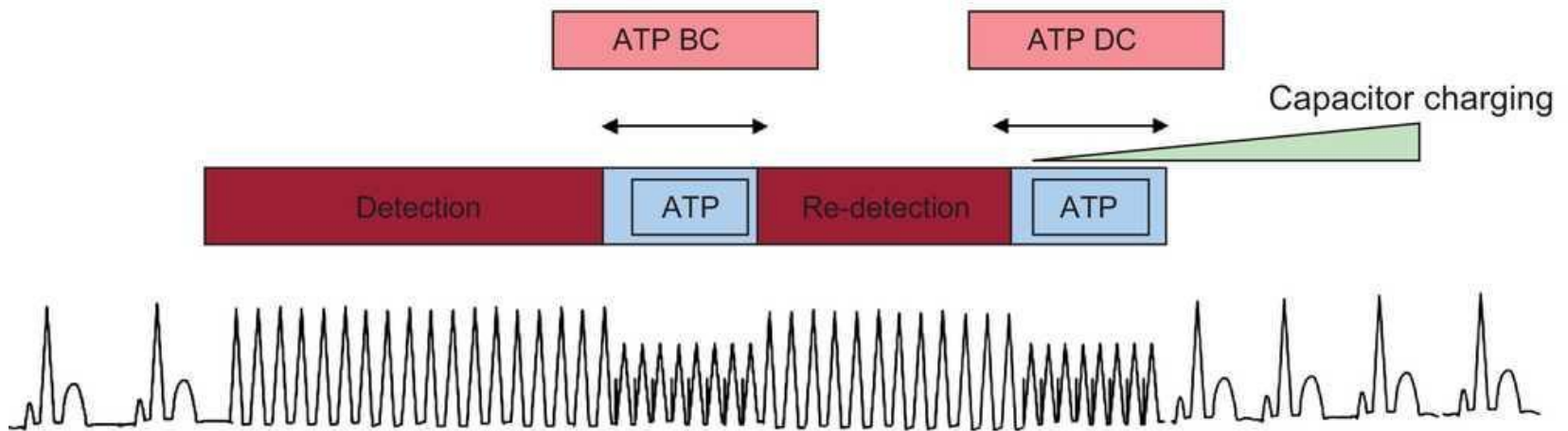
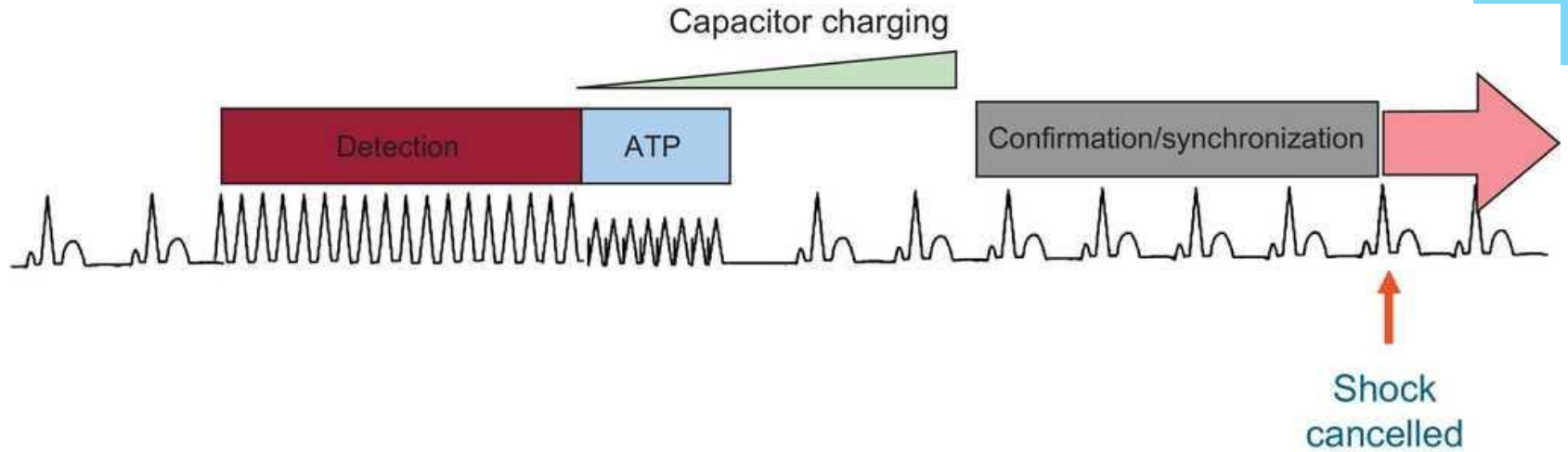
# Functie van een ICD

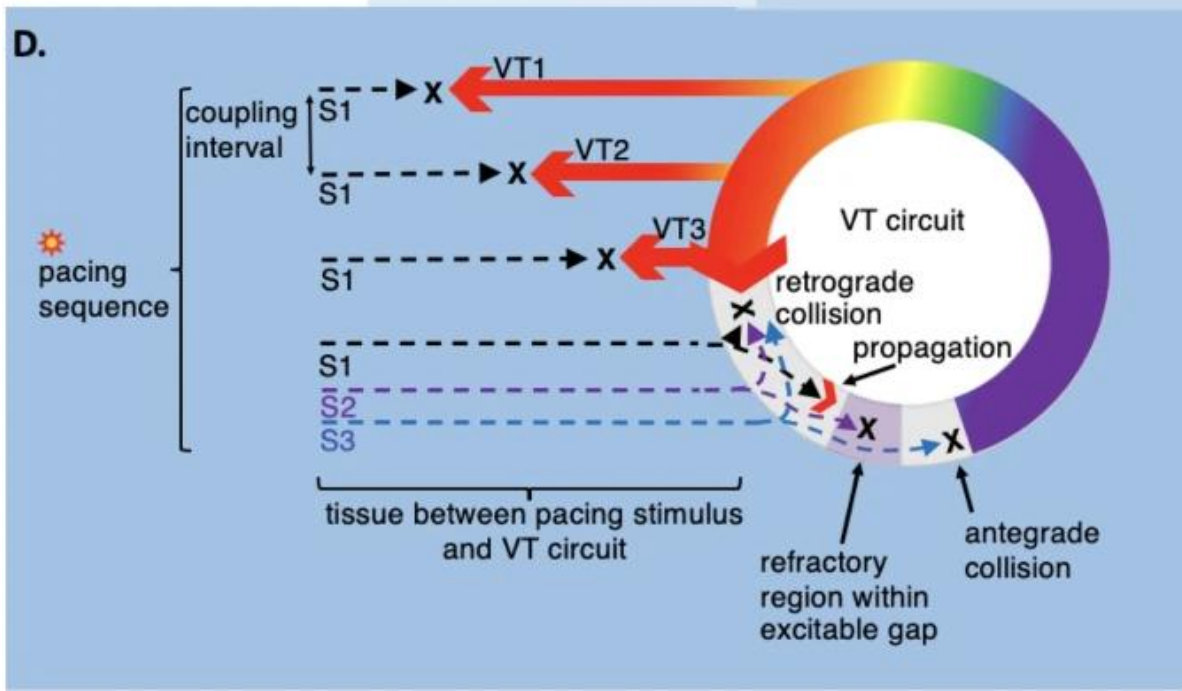
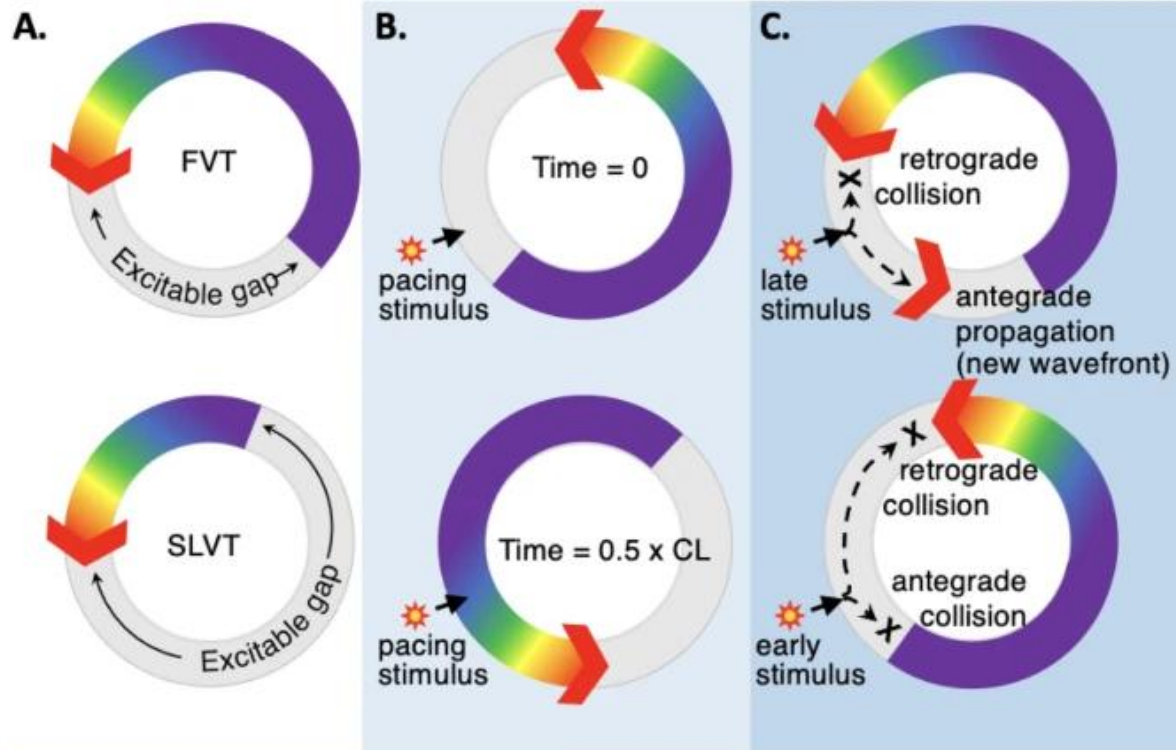
- Pacemaker
- ICD
  - Shock
  - ATP





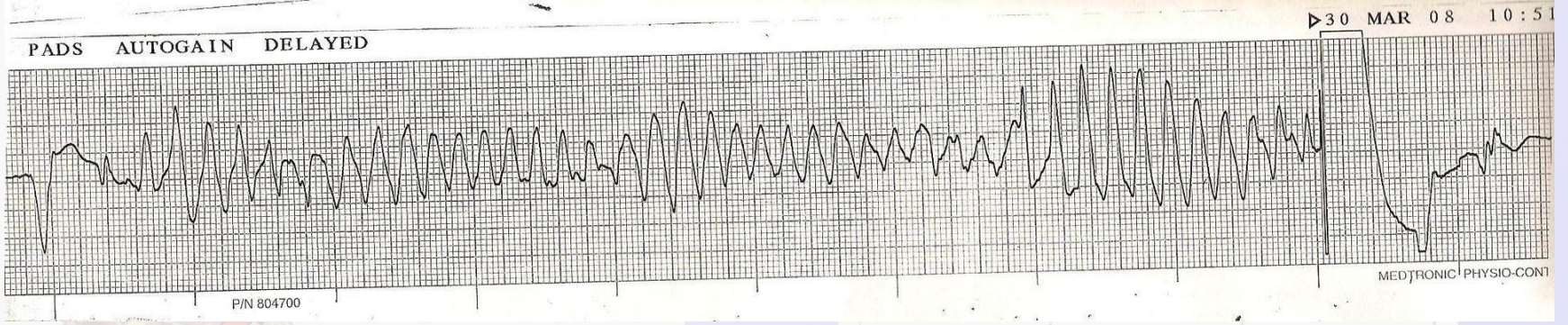
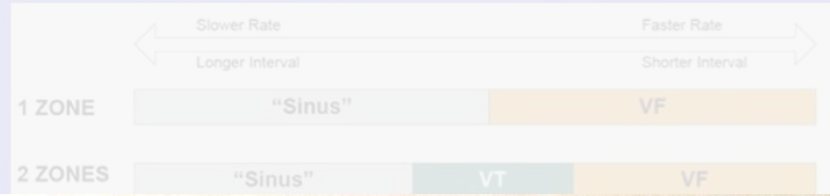
# ATP tachycardia pacing





# ICD programming

## Typical ICD settings: 1-3 zones



	166 min <sup>-1</sup>	181 min <sup>-1</sup>	250 min <sup>-1</sup>
Monitor		ATPx2, 36,0J, 36,0J, 36,0Jx2	36,0J, 36,0J, 36,0Jx4

**SVT / VT  
discrimination**

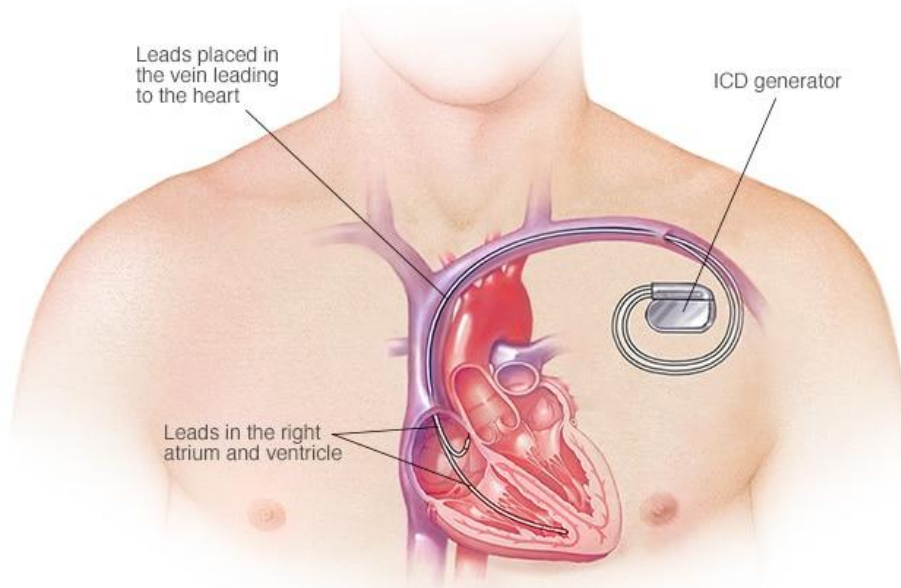
pacing

# Hoelang moeten we nog?

- ~~Wat is een ICD~~
- ~~Historie~~
- ~~Indicaties~~
- ~~Functie~~
- **Implantatie**
- Follow-up
  
- S-ICD



# Implantatie



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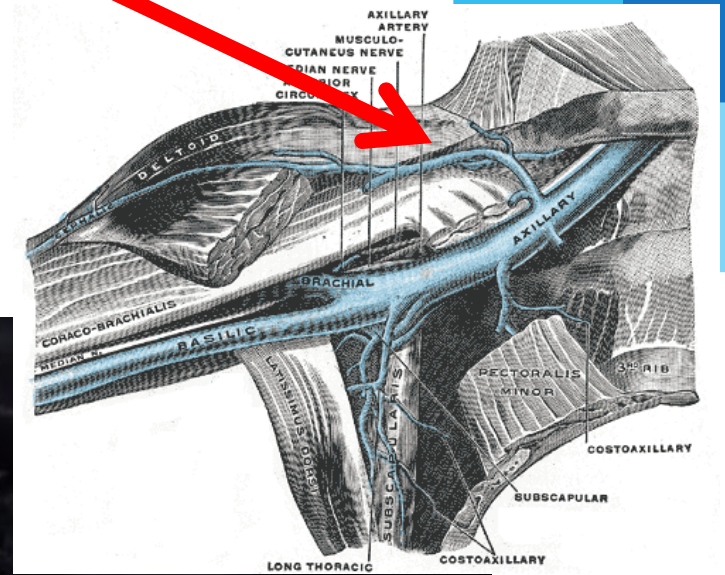


Make devices great again!



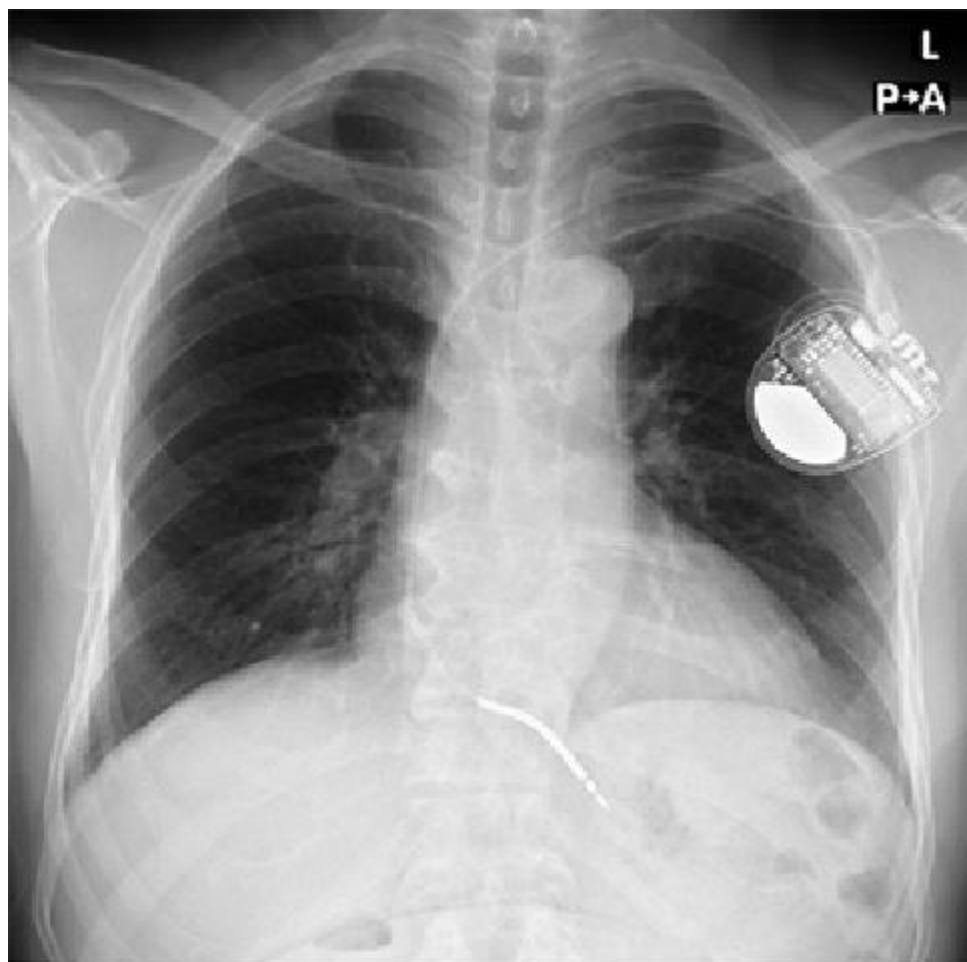
Rijnstate











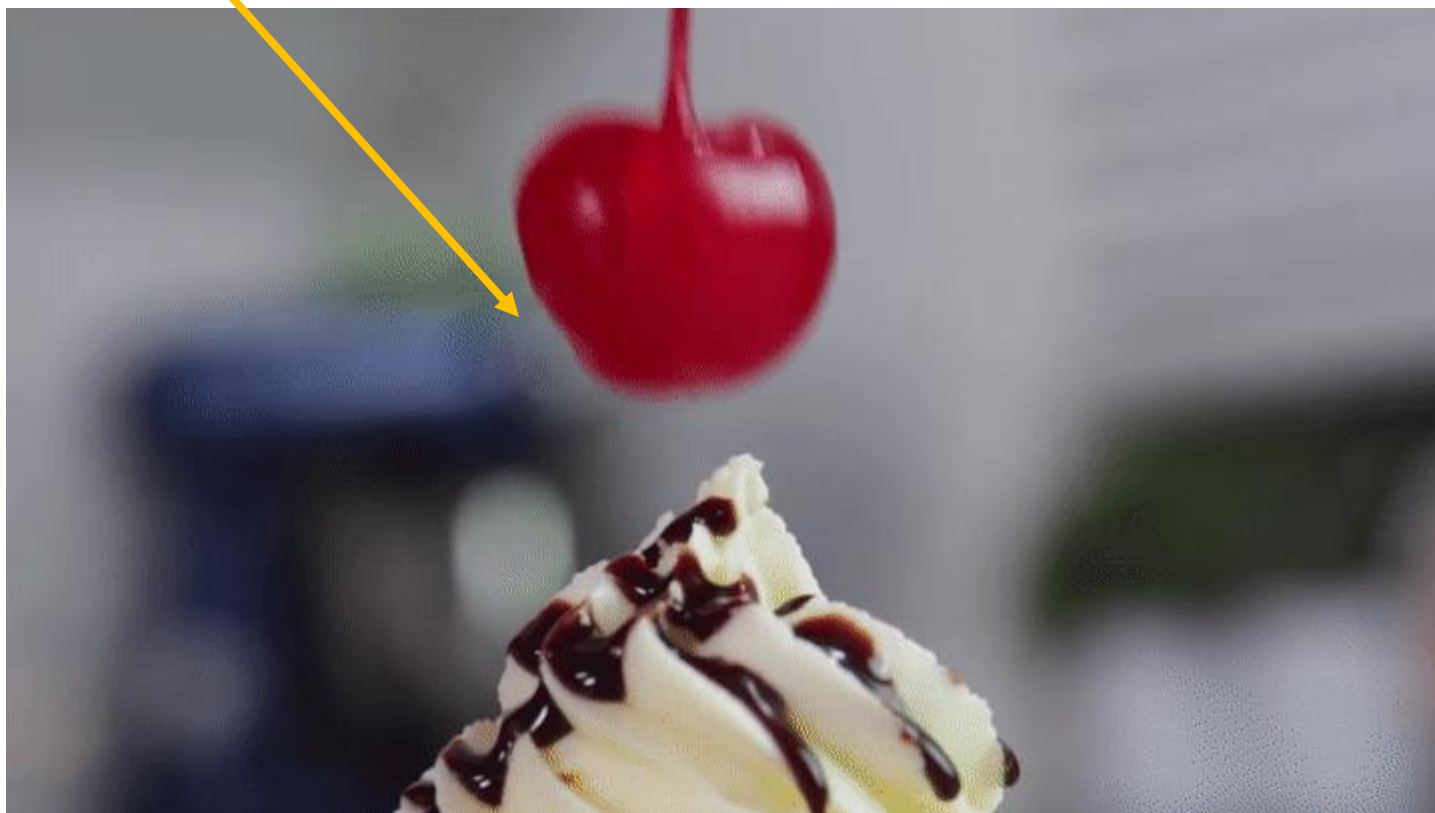
- Procedure time: 30-45min

# Direct na implantatie

- Wondgenezing 1 à 2 weken
- 4 weken beperking arm/schouder
  - Nadien: geen beperking
  - Cave: frozen shoulder
- Rijbewijs regels (code 100)
  - Primaire preventie: 2 weken na impl
  - Secundaire preventie: 2 maanden na impl



# De S-ICD



# Never change a winning team?



2015

2023

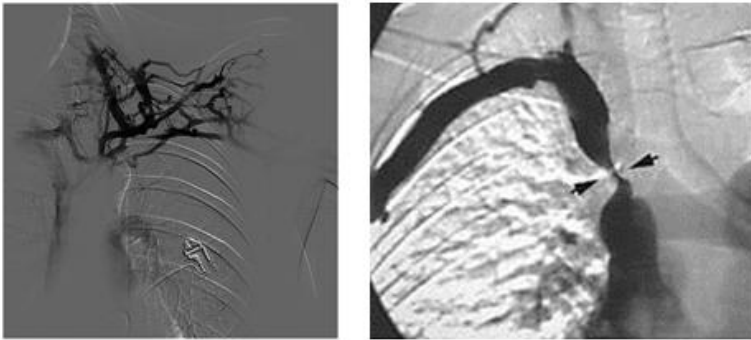


# Never change a winning team?

## Alternative for

Boston Scientific

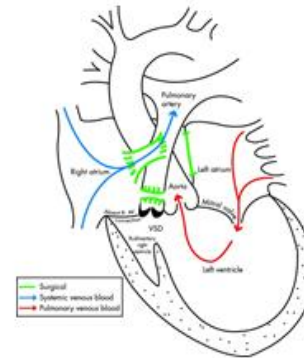
Obstructed Venous systems



## Alternative for

Boston Scientific

▪ Congenital heart disease



## Alternative for

Boston Scientific

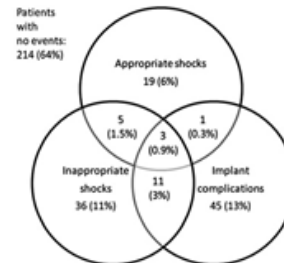
▪ High risk infections & endocarditis



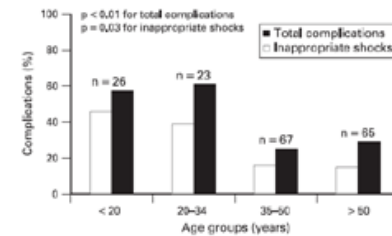
## TV-ICD performance in HCM

Boston Scientific

High rates of TV lead complications and Inappropriate shocks



Heart 2012;88:115e125, page 121



Heart 2009;95:709-714, page 713

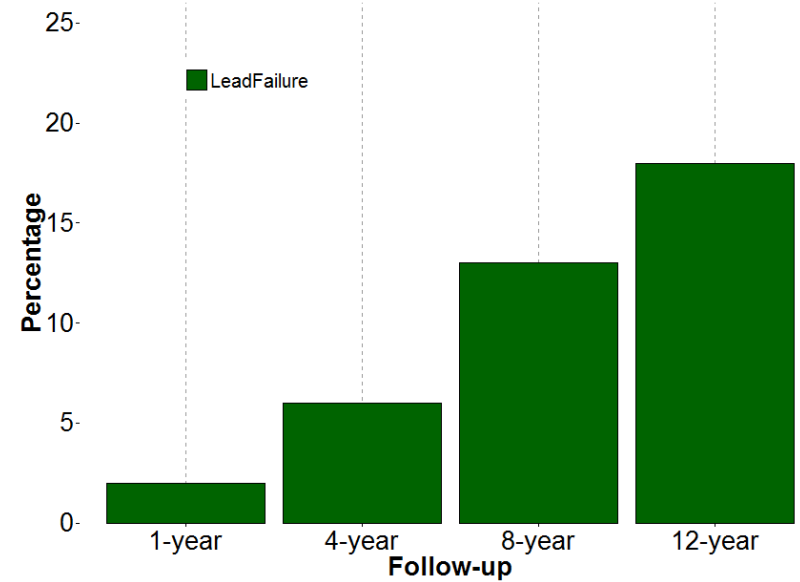
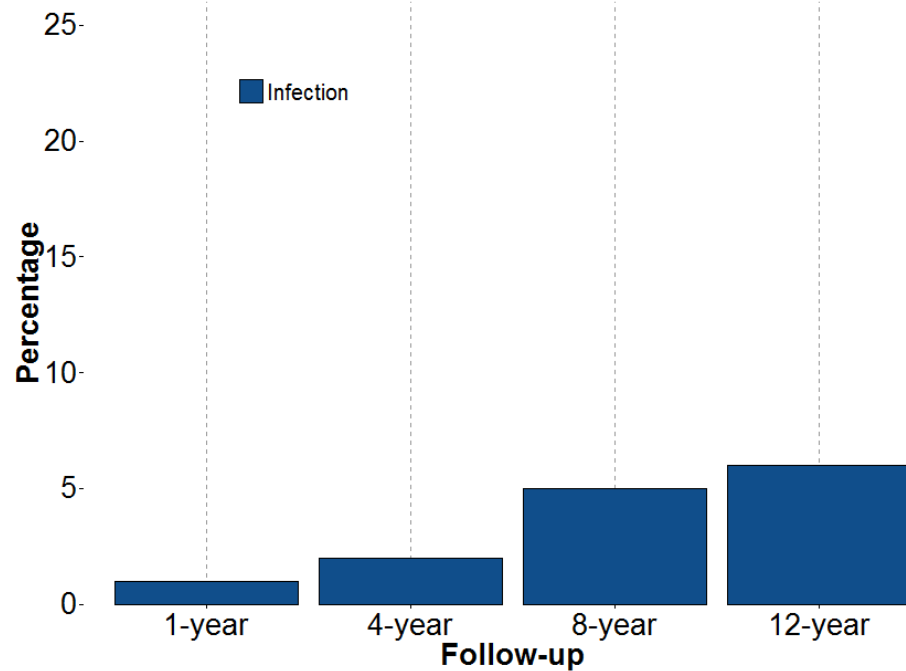
ICD adverse events are high in HCM (up to > 40% @ 5 years) due to:

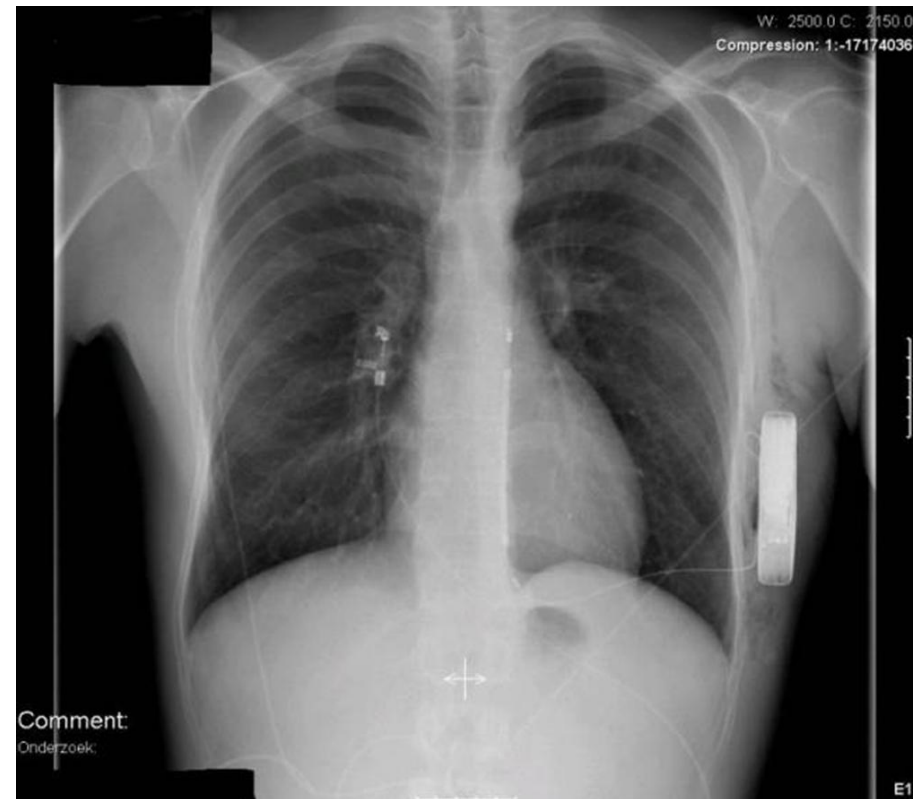
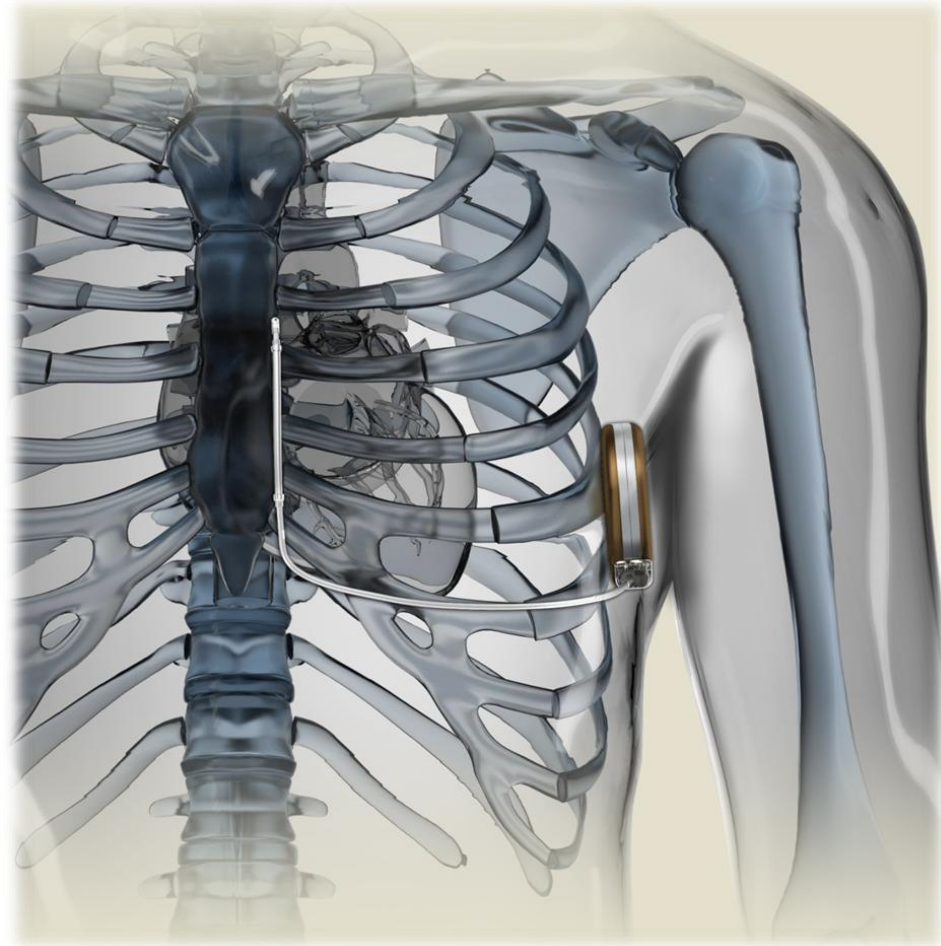
- high incidence of IAT (21%)
- high incidence of other device related complications (21%) ⇒ cumulative risk for lead failure in young ICD recipients (up to 25%\*)



Rijnstate

# Adverse events Transvenous ICD therapy





# Indicatie voor S-ICD

- S-ICD is bedoeld voor primaire of secundaire preventie van SCD in patiënten, zonder
  - indicatie voor pacing
  - frequent voorkomen van VT's (ATP)





# Clinical Evaluations and Studies

STUDY	STUDY TYPE	PATIENTS	SITES	COMMENTS
<b>Configuration Determination</b>	Proof Of Concept	78	1	Sep 2001 – Feb 2004
<b>Defibrillation Threshold</b>	Proof Of Concept	49	-	April 2004 – June 2005
Initial Chronic Human Validation Study: S-ICD™ System	Safety and Performance	6	2	Study completed: 2008
S-ICD System- CE Clinical Integration	Safety and Performance	55	8	Study completed: 2009
<b>START Study (Sensing)</b>	Performance	64 (96 episodes)	-	Study complete Published in J Cardiovascular EP 2011
IDE Clinical Study	Safety and Efficacy	330	33	Study Completed: 2012 Published in Circulation 2013
EFFORTLESS Registry	Real World	1000	50	Registry Completed 2014 First results published in Eur. Heart J 2014
<b>Praetorian</b>	Randomised Clinical Trial (S-ICD v TV ICD)	840	~25	Ongoing and expanded to US in 2015
US Post Approval Study	Real World	1600 expected	150	Ongoing

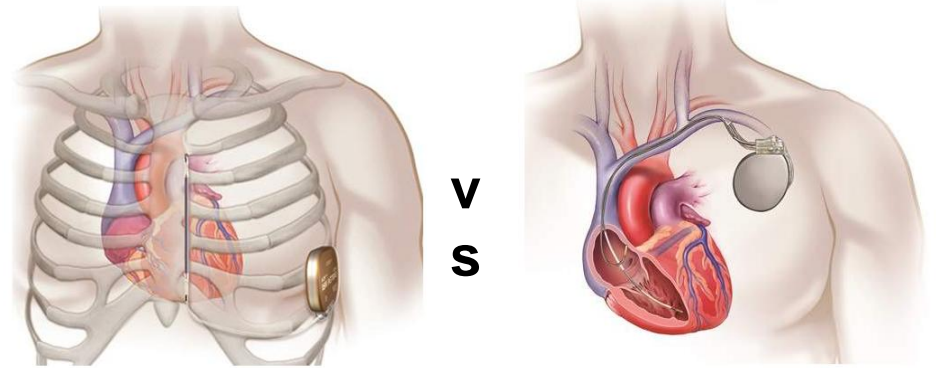
Published in NEJM 2010

**Class I & IIa indication no need for pacing**

**n=849**

**S-ICD**

**TV-ICD**



**Median follow up 48 months**

**Primary Endpoint: Non-Inferiority  
Complications + Inappropriate shocks**

**Results HRS 2020**

**Prospective Randomized  
Head-Head**

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

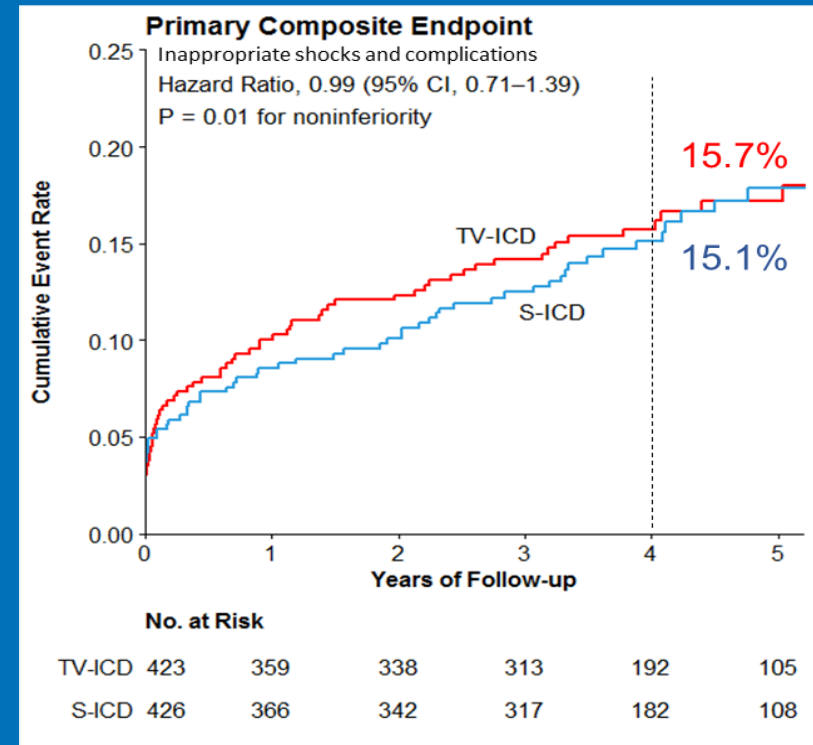
# Primary Outcome: Non-inferiority Demonstrated

The PRAETORIAN Trial<sup>1</sup>

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

- ✓ Infections that required lead extraction
- ✓ Lead complications

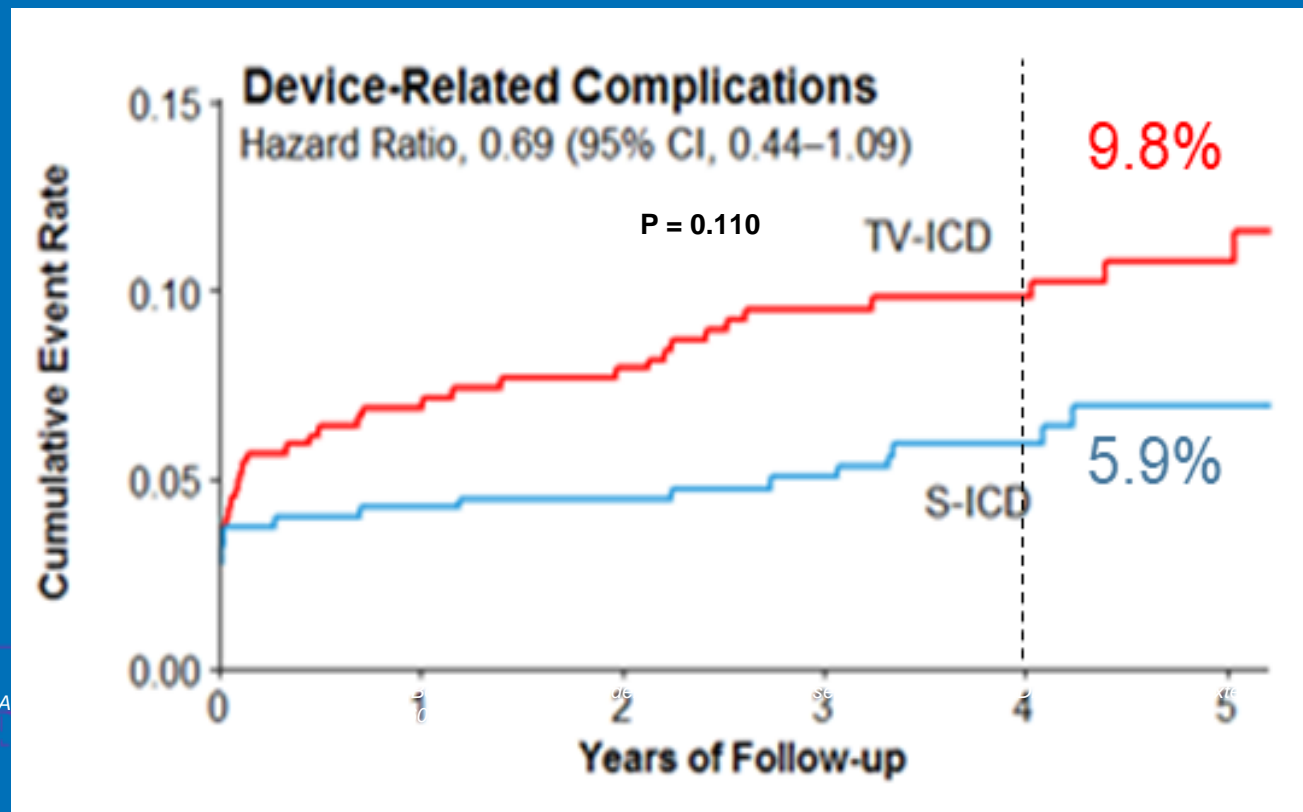
**Confirms S-ICD can be the preferred choice for most ICD indicated patients w/o need for pacing**



This KM Curve is for the primary COMPOSITE Endpoint IAS and complications

# All Device-related Complications

The PRAETORIAN Trial<sup>1</sup>





Rijnstate

# Subcutane-ICD Implantatie





Keynote

# Positie incisie



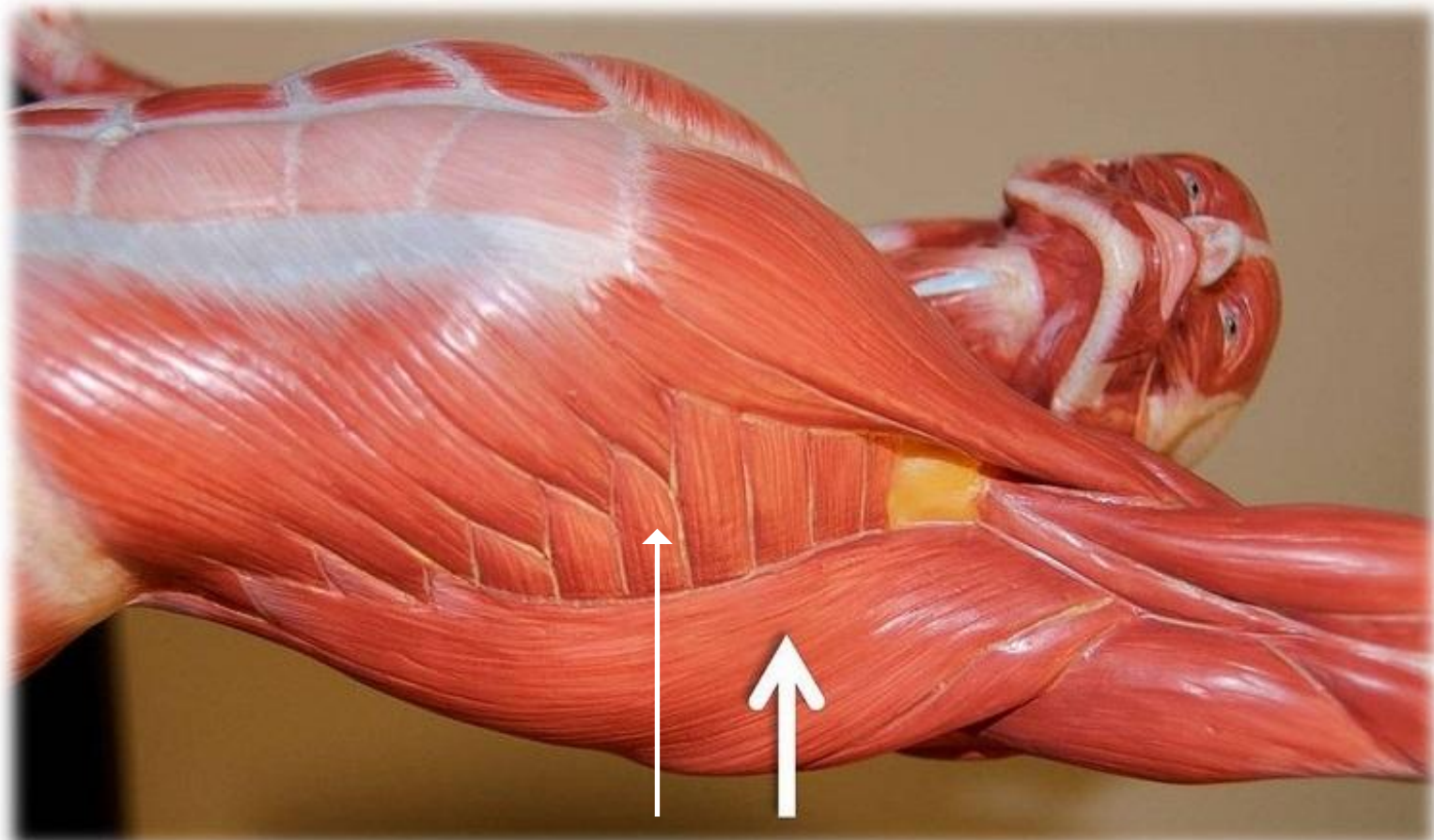
# Positie lead



# Desinfecteren en verdoven





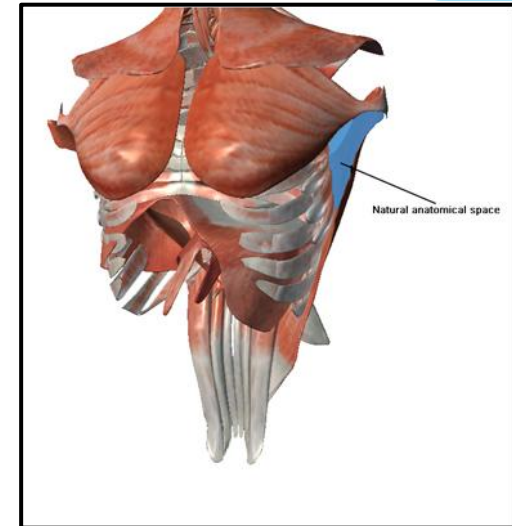


Musculus Serratus Anterior

Musculus Latissimus Dorsi

## Musculaire pockets



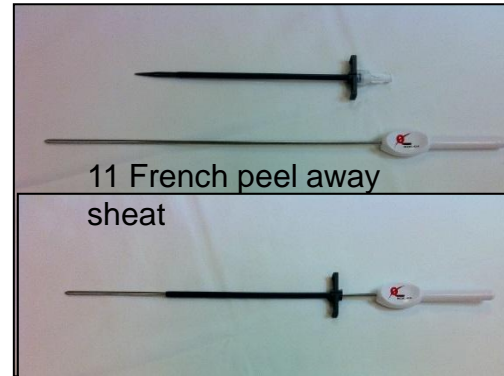
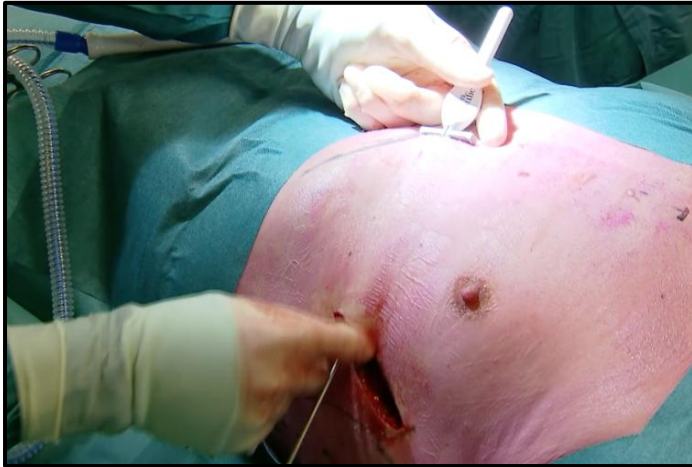


Er bestaat echter enige anatomische variatie

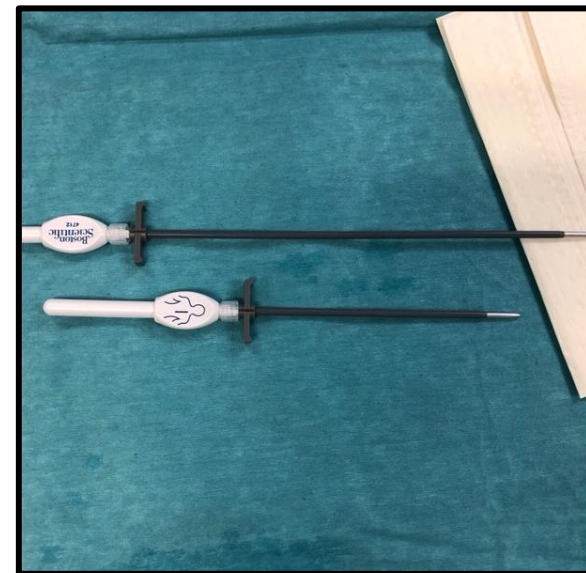


# M. Latissimus dorsi



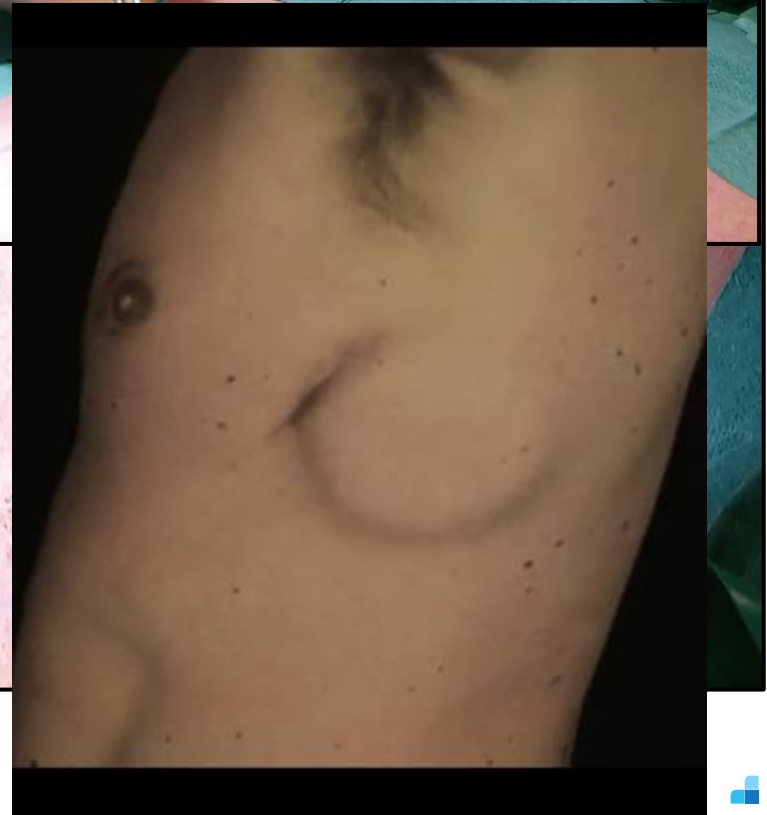
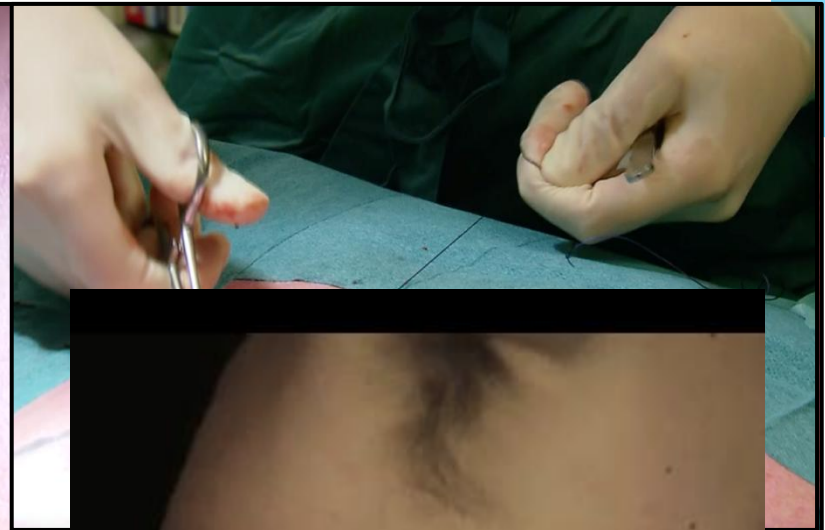
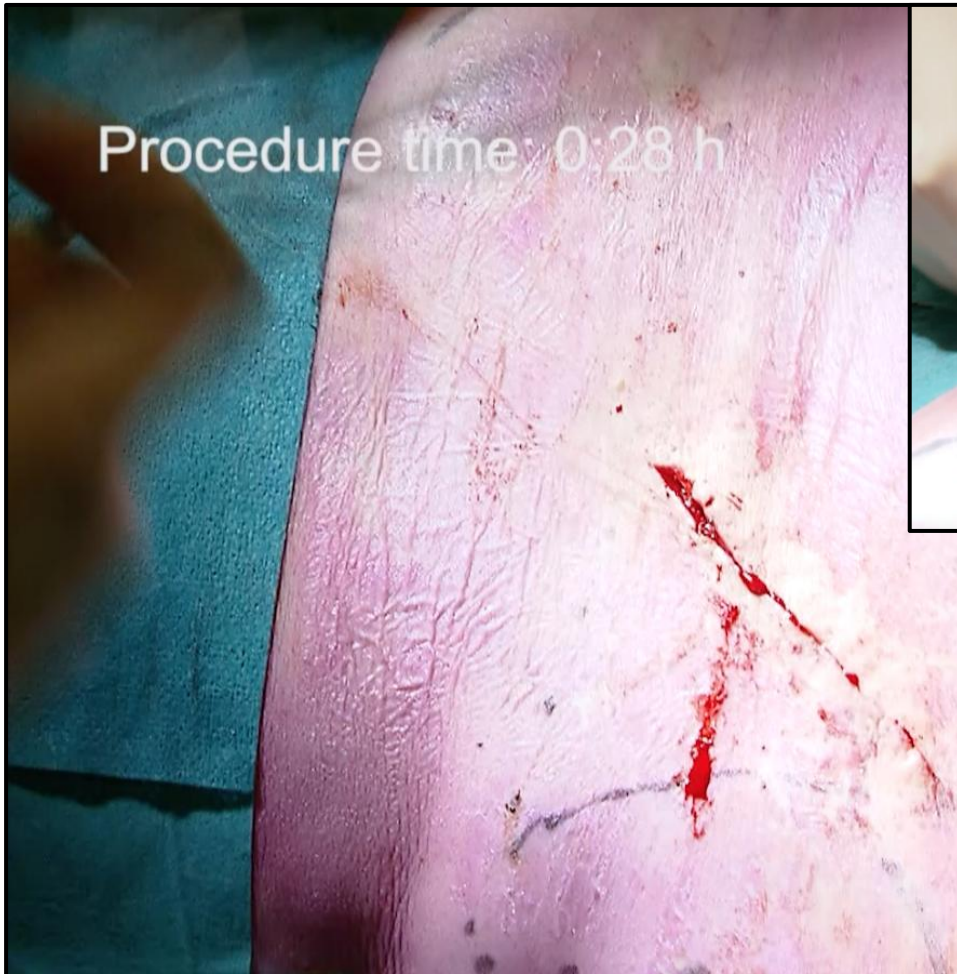


Vanaf april 2018



**Xiphoid naar pocket**





## Sluiten incisie

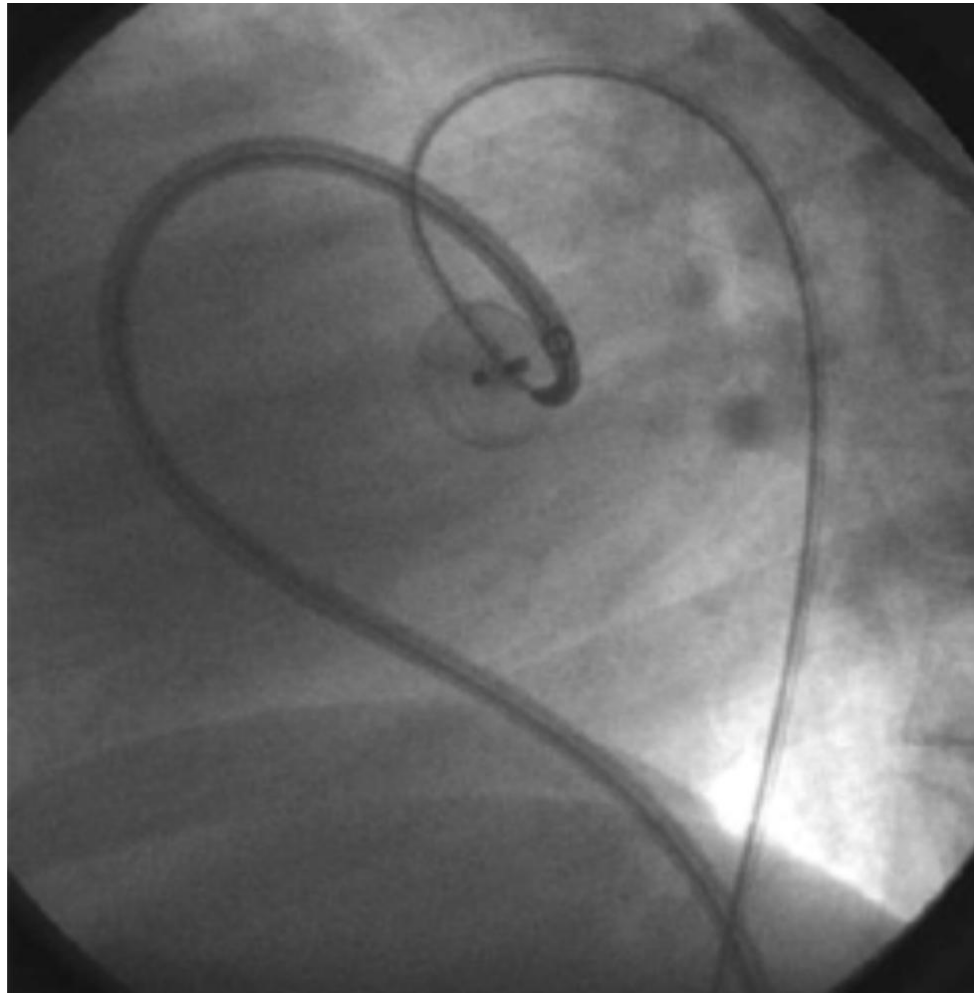
# Na implantatie

- Geen bewegingsbeperking
- Thoraxfoto nadien i.p. niet nodig
  - Wel geadviseerd -> leercurve!
- Grotere wond: kan langer pijnlijk zijn
  
- Wel optimalisatie van S-ECG signaal (technicus)
- Rijbewijs regels: idem als bij TV-ICD
- Magneetapplicatie: idem als bij TV-ICD





# Dank voor uw aandacht!



[fbrouwers@rijnstate.nl](mailto:fbrouwers@rijnstate.nl)



Rijnstate





# Magneet behaviour

- Pacemaker: Asynchrone fixed rate pacing
- ICD: VT detectie en shockfunctie uit, geen asynchrone pacing
- Reset van dysfunctie

