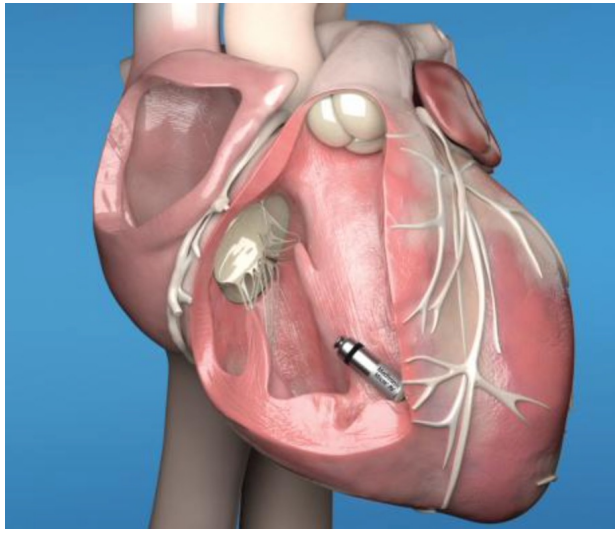
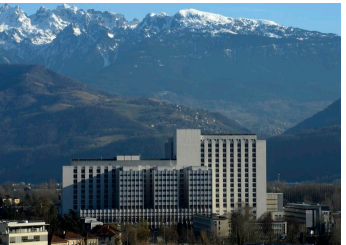


La fin des sondes endo cavitaires en stimulation cardiaque et défibrillation ?



Pascal Defaye
CHU Grenoble-Alpes

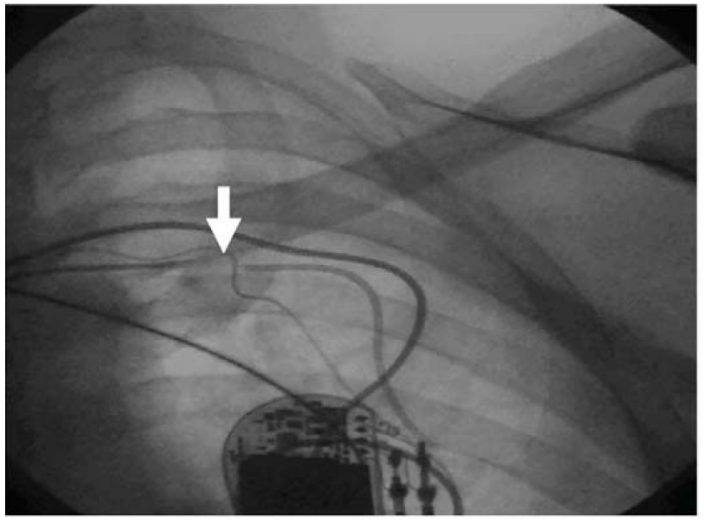
UGA Université Grenoble Alpes

CHU GRENOBLE ALPES

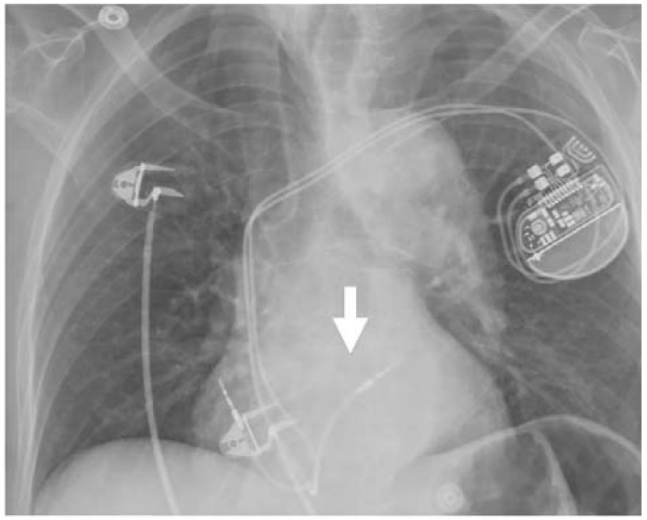
Why leadless? Unmet needs in cardiac pacing

- **Acute complications/ access issues**
  - **Pneumothorax**
  - **Hematoma**
  - **Venous access issues (dialysis, congenital heart disease)**

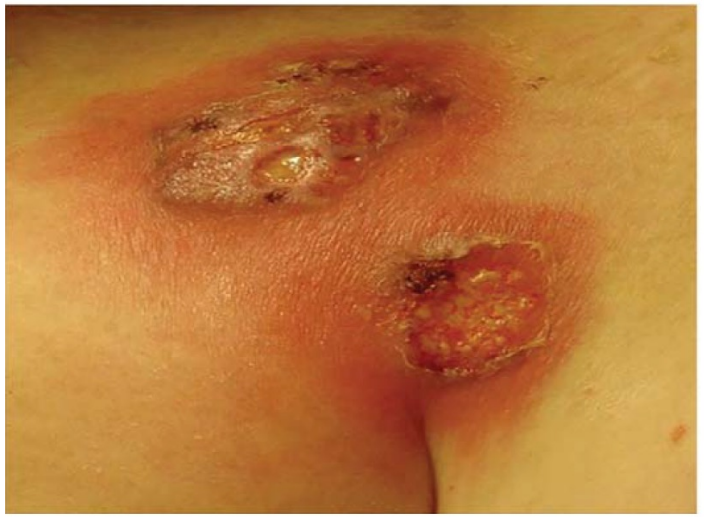
- **Long-term complications**
  - **Lead reliability (fracture, insulation)**
  - **Device pocket (erosion, discomfort)**
  - **Tricuspid regurgitation**
  - **Infection**



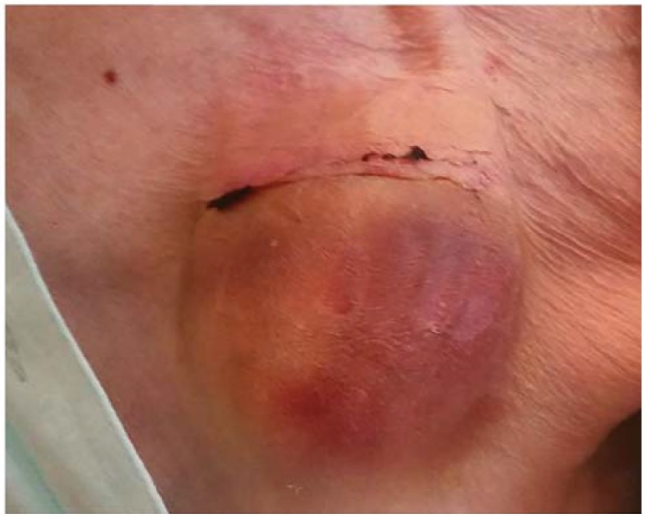
Lead fracture



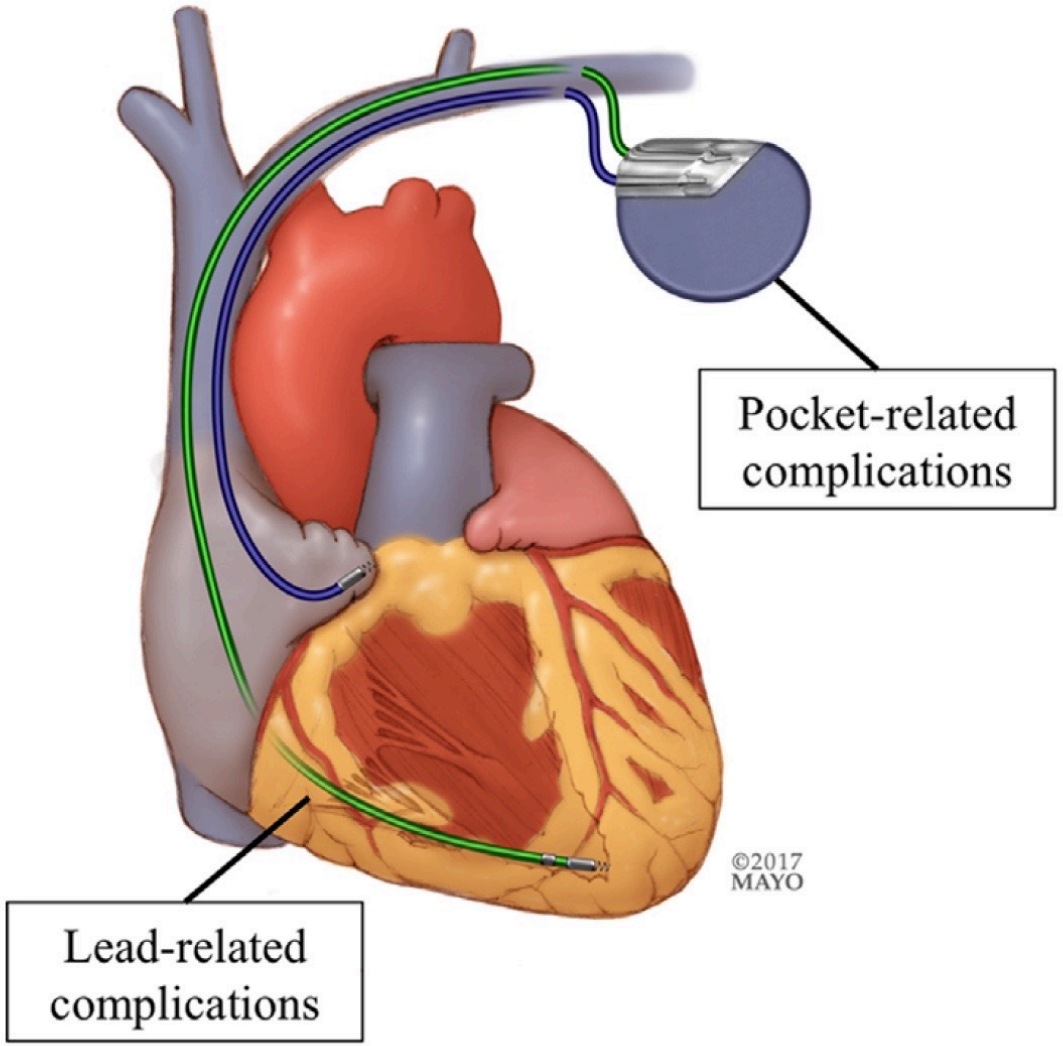
Lead dislodgment



Pocket infection



Hematoma



Transvenous pacemaker complications	Rate (%)
Immediate complications	
Pneumothorax	0.6-0.9 [3, 24]
Cardiac perforation	0.1 - 0.3 [3, 27]
Hematoma	0.2 – 0.7 [3, 26]
Intermediate complications	
Lead dislodgement	0.4 – 1.7 [3, 25]
Pocket revision because of pain	0.4 [3]
Late complications	
Lead-related re-intervention • Conductor fracture • Insulation break	1.7 - 2.4 [3, 25]
Pacemaker infections	1.8-1.9 per 1000 pacemaker years [4, 5]

Lee JZ et al.Trends in CV Medicine 2019

Pacing implantations
CHU Grenoble Alpes

- 1st Implantation : November 19th, 2013

- ***Total : 63 Nanostim/***
  165 Micra /
  10 EBR Wyse CRT
  7 AVEIR
  1/09/2021
  Total = 245 implantations

- Complications :

- ***1 tamponade with Nanostim : pericardiocentesis only***
- ***1 tamponade with Micra : sternotomy/ RV apical repair (2016)***

<0,4%

Procédures			dec.19 Quantité	dec.20 Quantité
PM	VVI	PRIMO-IMPL	65	67
		Changement Boit	9	6
		MICRA	25	45
		sous total	**99**	**118**
	DDD	PRIMO-IMPL	200	191
		Changement Boit	46	64
		sous total	**246**	**255**
	CRT	PRIMO-IMPL	60	69
		Changement Boit	6	12
		WISE	3	0
		sous total	**69**	**81**
	EPI	PRIMO-IMPL	0	0
		Changement Boit	0	0
		sous total	**0**	**0**
	TOTAL		**414**	**454**

=

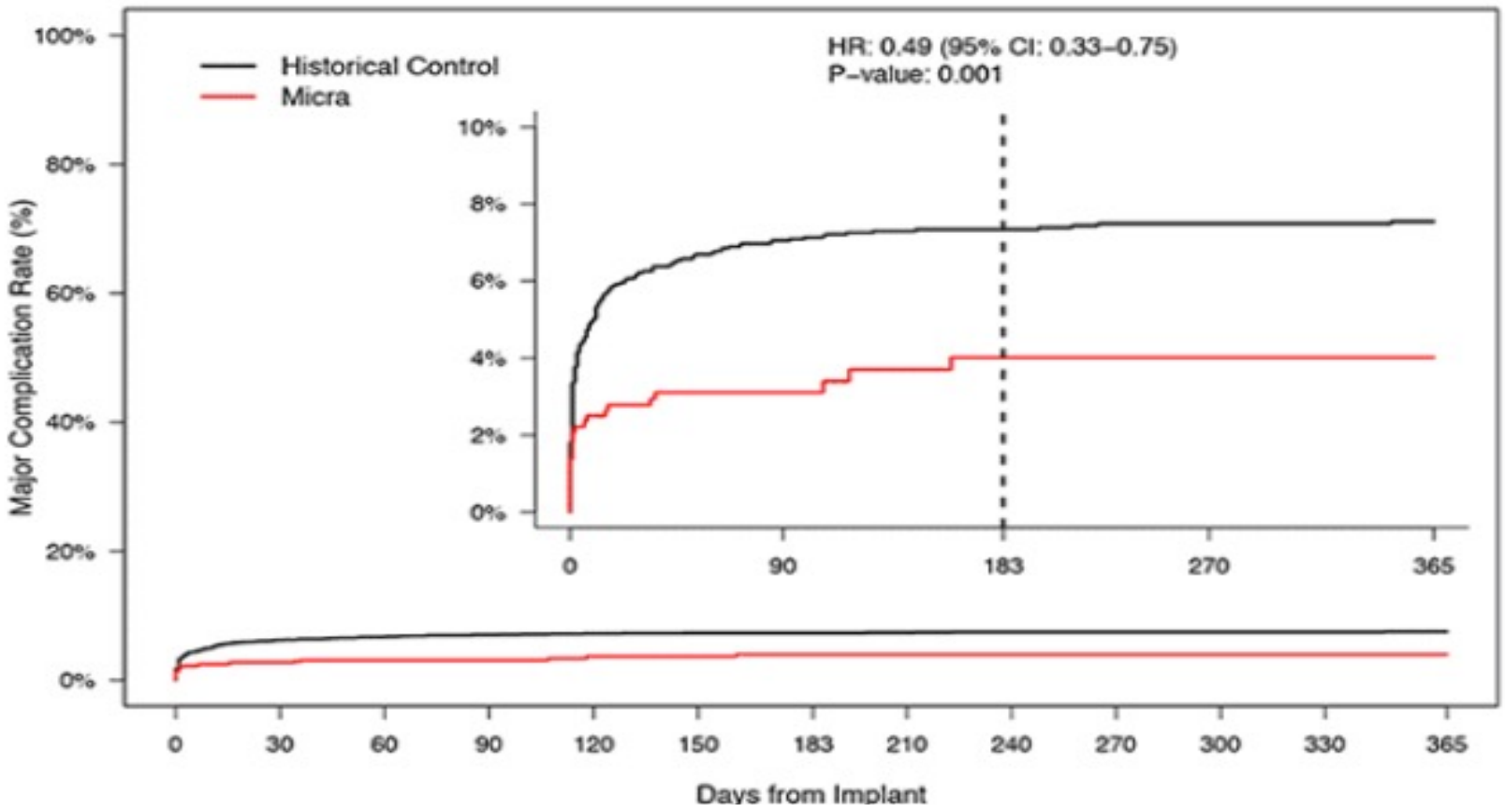
X 45%

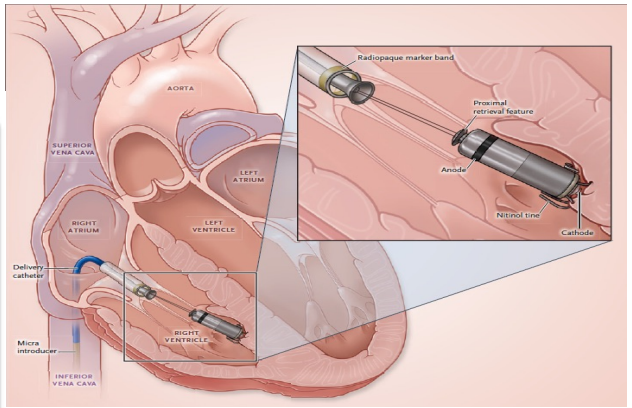
2021 août
26
5
58
7
96
132
49
181
53
1
0
54
0
0
331

A Leadless Intracardiac Transcatheter Pacing System

Dwight Reynolds, M.D., Gabor Z. Duray, M.D., Ph.D., Razali Omar, M.D., Kyoko Soejima, M.D., Petr Neuzil, M.D., Shu Zhang, M.D., Calambur Narasimhan, M.D., Clemens Steinwender, M.D., Josep Brugada, M.D., Ph.D., Michael Lloyd, M.D., Paul R. Roberts, M.D., Venkata Sagi, M.D., John Hummel, M.D., Maria Grazia Bongiorni, M.D., Reinoud E. Knops, M.D., Christopher R. Ellis, M.D., Charles C. Gornick, M.D., Matthew A. Bernabei, M.D., Verla Laager, M.A., Kurt Stromberg, M.S., Eric R. Williams, B.S., J. Harrison Hudnall, B.S., and Philippe Ritter, M.D., for the Micra Transcatheter Pacing Study Group*

Micra TPS study





51% fewer major complications than traditional pacemakers in the trial's historical control

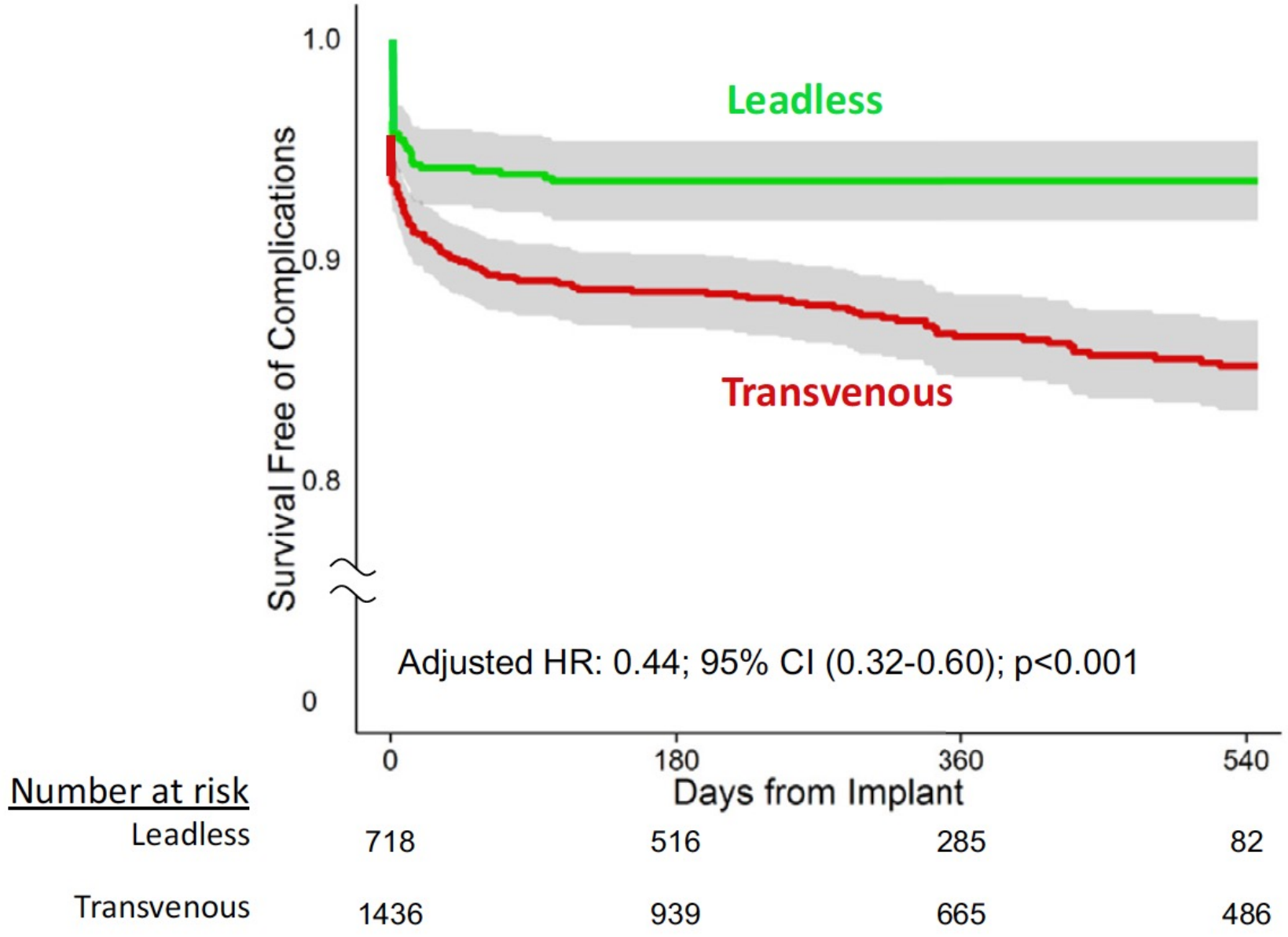
N Engl J Med 2016

Comparative study of acute and mid-term complications with leadless and transvenous cardiac pacemakers

Daniel J. Cantillon, MD, FHRS,* Srinivas R. Dukkipati, MD, FHRS,† John H. Ip, MD,‡ Derek V. Exner, MD, FHRS,§ Imran K. Niazi, MD,‖ Rajesh S. Banker, MD,¶ Mayer Rashtian, MD, FHRS,# Kenneth Plunkitt, MD, FHRS,** Gery F. Tomassoni, MD, FHRS,†† Yelena Nabutovsky, MS,‡‡ Kevin J. Davis, BS,‡‡ Vivek Y. Reddy, MD†

*From the *Cleveland Clinic, Cleveland, Ohio, †Icahn School of Medicine at Mount Sinai, New York, New York, ‡Sparrow Clinical Research Institute, Lansing, Michigan, §Libin Cardiovascular Institute of Alberta, Calgary, Alberta, Canada, ‖Aurora Medical Group, Milwaukee, Wisconsin, ¶Premier Cardiology, Newport Beach, California, #Huntington Memorial Hospital, Pasadena, California, **Naples Community Hospital, Naples, Florida, ††Central Baptist Hospital, Lexington, Kentucky, and ‡‡Abbott, Sylmar, California.*

Nanostim LCP : 714 pts
TVP : 1436 pts



Kaplan-Meier curve of the complications between LCP and TVP

Heart Rhythm 2018;15:1023–1030

Comparison of Two-Year Outcomes Among Patients Implanted with a Leadless versus Transvenous Single-Chamber Ventricular Pacemaker in the Micra Coverage with Evidence Development (CED) Study

Jonathan P. Piccini, MD, MHS, FHRS, Colleen Longacre, PhD, MPH, Lucas Higuera, PhD, Kurt Stromberg, MS, George Crossley, MD, FHRS, Robert C. Kowal, MD, PhD, Lindsay Bockstedt, PhD, Mikhael F. El-Chami, MD, FHRS

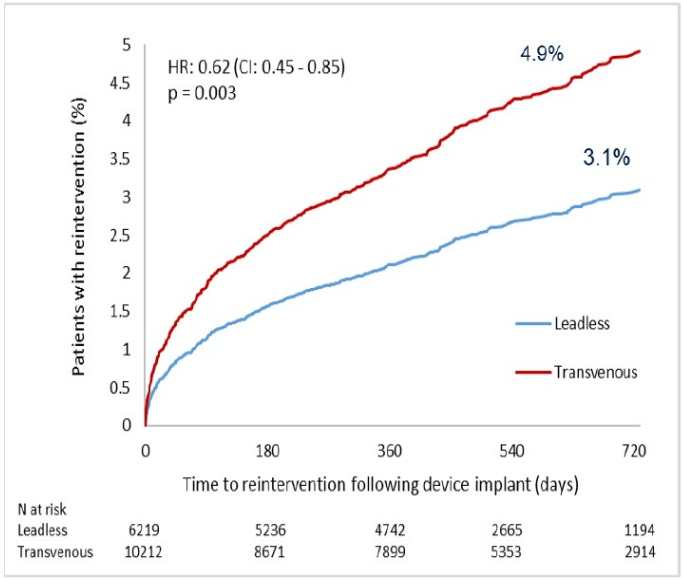
Reduced complications with Micra VVIR

38%lower rate of reinterventions
31% lower rate of chronic complications / transvenous VVI

2-Year Reintervention Results

- Significant 38% reduction in reinterventions in Micra vs. TV
- Fewer revisions, removals, and upgrades to dual-chamber and CRT, higher rate of replacements

	Leadless-VVI (N=6,219)	Transvenous-VVI (N=10,212)	Leadless-VVI vs. Transvenous-VVI	
Reintervention Type	2-Year Weighted CIF Estimates (95% CI)	2-Year Weighted CIF Estimates (95% CI)	Relative Risk Reduction (95% CI)	P-Value
Any reintervention	3.1% (2.8%-3.4%)	4.9% (4.5%-5.4%)	38% (15%-55%)	0.003
System reinterventions				
Revisions	*	0.6% (0.4%-0.8%)	80% (50%-92%)	0.001
Lead-related reinterventions	N/A	0.7% (0.5%-0.9%)	NE	
Replacement	1.1% (0.9%-1.3%)	0.4% (0.3%-0.6%)	-150% (-346%--40%)	0.002
System switch (replacement with opposite type of device)	0.4% (0.2%-0.5%)	0.3% (0.2%-0.4%)	-28% (-150%--34%)	0.463
Removal	*	0.8% (0.7%-1.1%)	95% (80%-99%)	<.0001
Upgrades				
Dual-chamber	0.4% (0.3%-0.6%)	0.8% (0.6%-1.0%)	42% (-2%-67%)	0.06
CRT	1.2% (1.0%-1.4%)	1.7% (1.4%-1.9%)	30% (4%-49%)	0.025



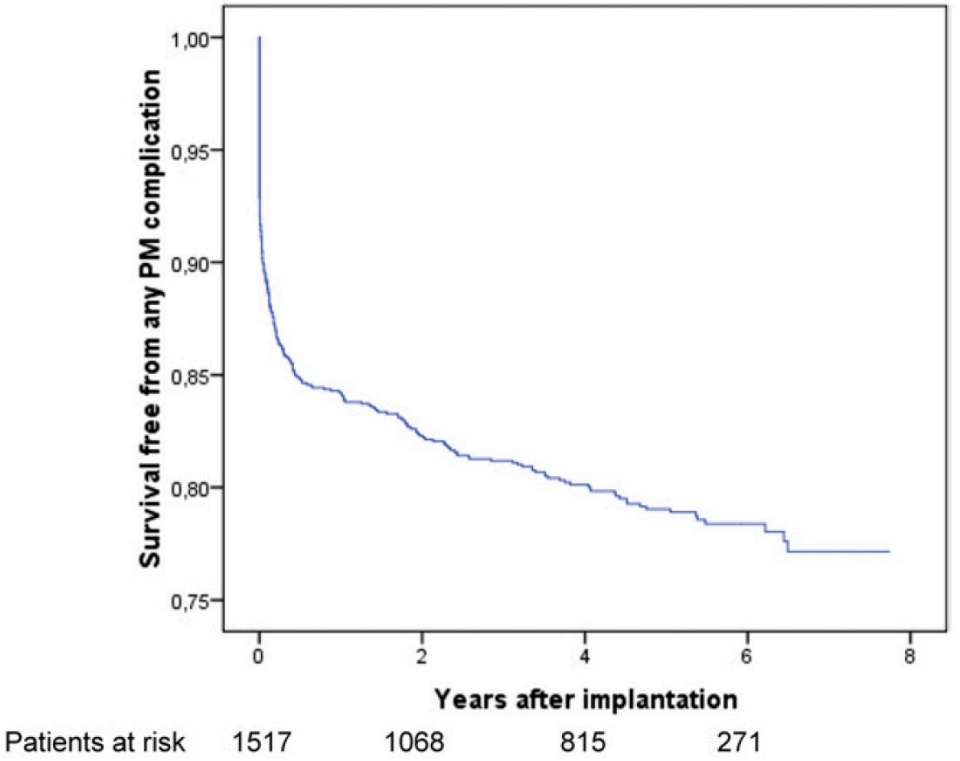
Piccini JP/ESC 2021

Incidence and predictors of short- and long-term complications in pacemaker therapy: The FOLLOWPACE study

Erik O. Udo, MD,*† Nicolaas P.A. Zuithoff,† Norbert M. van Hemel, MD, PhD,*
Carel C. de Cock, MD, PhD,‡ Thijs Hendriks,‡ Pieter A. Doevendans, MD, PhD,* Karel G.M. Moons, PhD†

Achilleion, Corfu, Greece

- Pocket-hematoma,
- infections
- Lead-fracture,
- TV-insufficiency:



Survival free from any PM complications
During a mean FU of 5,8 y

Heart Rythm 2012

Short-term implantation-related complications of cardiac rhythm management device therapy: a retrospective single-centre 1-year survey

Sami Pakarinen*, Lasse Oikarinen, and Lauri Toivonen

Complications rate of conventional pacemakers

Complications of cardiac rhythm device implantations during 3-month follow-up

Complication	*n*	% of all patients	% of all complications
Lead dislodgement	21	3.7	26.9
Pocket haematoma or bleeding	18	3.2	23.1
Pneumothorax	11	1.9	14.1
Device-related infection	11	1.9	14.1
Heart perforation	4	0.7	5.1
Cardiac tamponade	3	0.5	3.8
Symptomatic deep vein thrombosis	4	0.7	5.1
Non-pre-defined[a]	6	1.1	7.7

- 567 implantations
- 78 complications in 69 patients (12,2%)

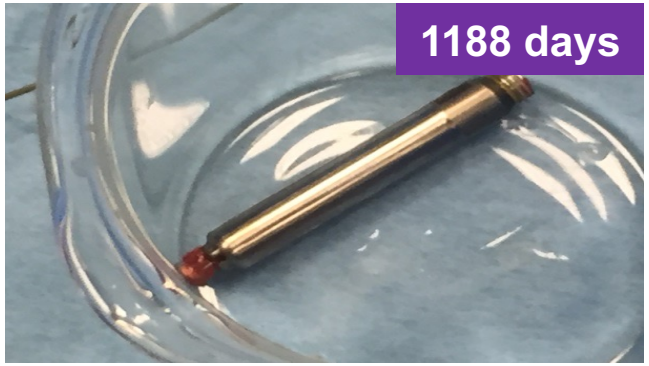
Europace 2010; 12:103–108

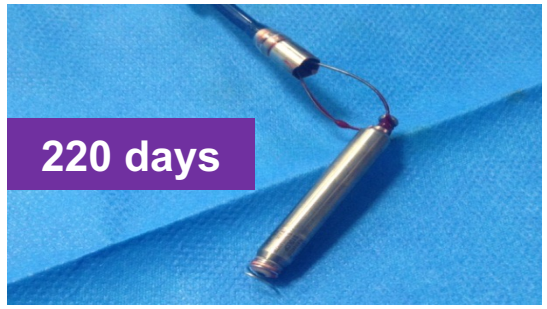
A worldwide experience of the management of battery failures and chronic device retrieval of the Nanostim leadless pacemaker

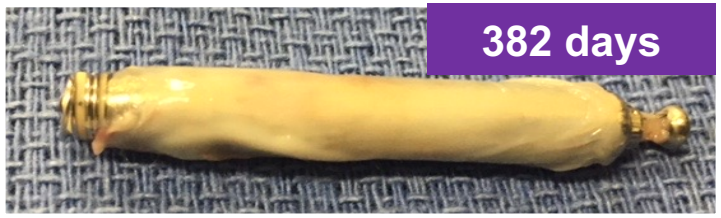
Dhanunjaya Lakkireddy, MD, FACC, FHRS,* Reinoud Knops, MD,† Brett Atwater, MD,‡ Petr Neuzil, MD,§ John Ip, MD,|| Elkin Gonzalez, MD,¶ Paul Friedman, MD, FHRS,** Pascal Defaye, MD,†† Derek Exner, MD,‡‡ Kazutaka Aonuma, MD,§§ Rahul Doshi, MD, FHRS,|||| Johannes Sperzel, MD,¶¶ Vivek Reddy, MD***

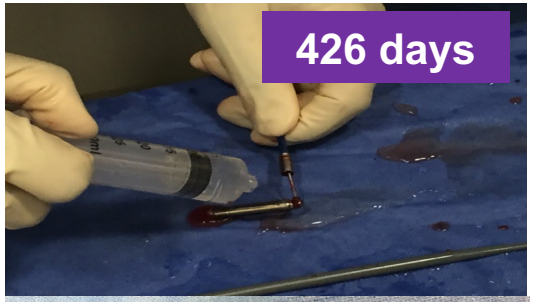
Nanostim Retrieval

Gross Pathology









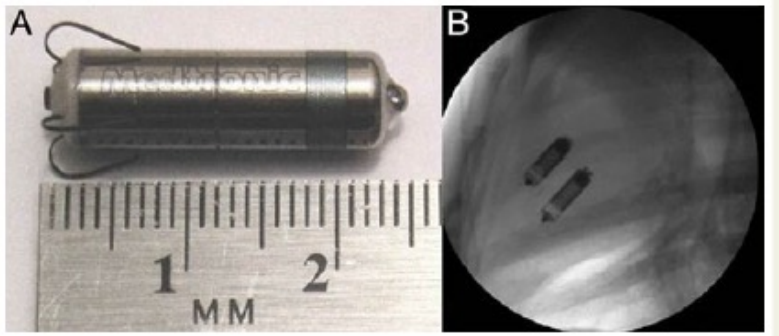
90.4% success retrieval/implant duration range: 0.2–4.0 years

Heart Rhythm 2017;14:1756–1763

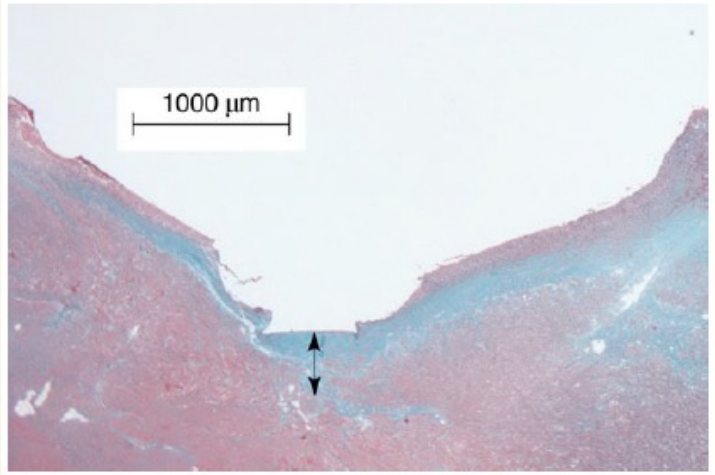
Multiple leadless pacemakers implanted in the right ventricle of swine

Keping Chen[1†], Xiaolin Zheng[1†], Yan Dai[1], Hao Wang[2], Yue Tang[3], Tingyu Lan[2], Jinping Zhang[2], Yi Tian[3], Baojie Zhang[3], Xiaohong Zhou[4], Matthew Bonner[4], and Shu Zhang[1*]

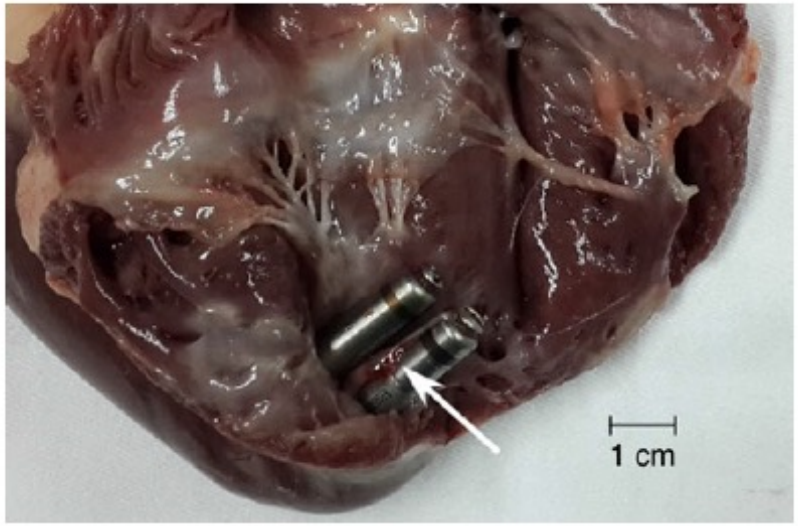
14 mini pigs received 2 leadless
1month interval between



Micra device and fluoroscopic imaging with Micra devices: (*A*) an example of the Micra device and (*B*) fluoroscopic imaging of two Micra devices implanted in the RV.



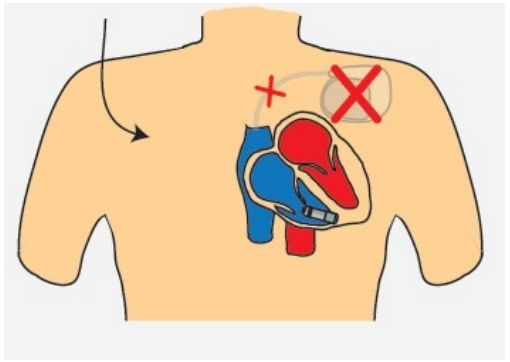
Tissue fibrosis beneath the Micra pacing electrode. Arrow indicates the thickness of the fibrosis measured from the endocardium where the device was placed.



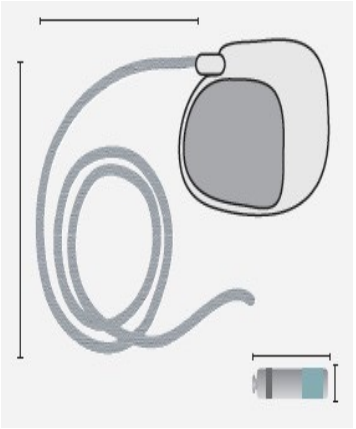
Fibrous tissue attaching around Micra devices observed at necropsy. Arrow indicates the fibrous tissue attachment.

Europace 2016 ; 18, 1748–1752

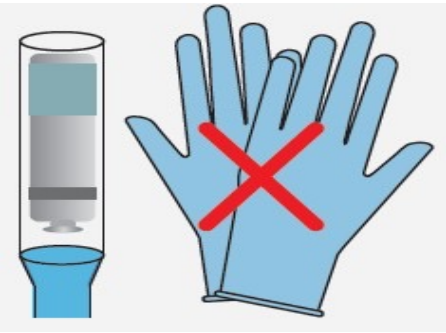
Low infection rate with leadless PM : why?



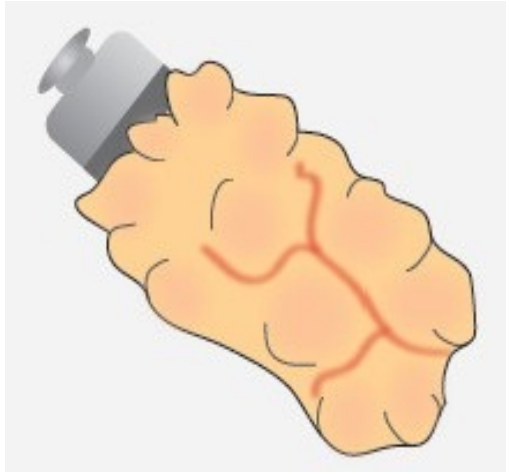
No lead, no pocket



Small size

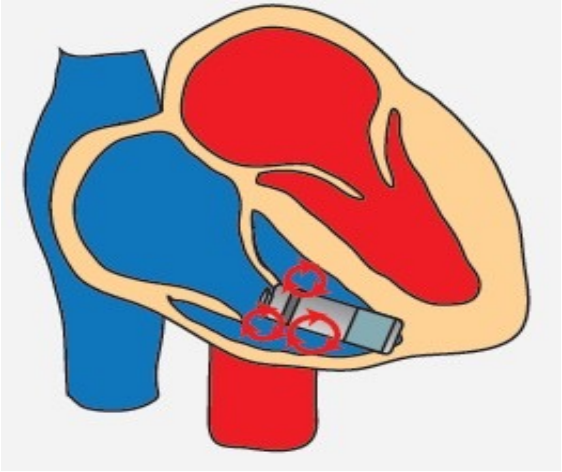


Reduced handling



Encapsulation

Protective covering



Turbulent flow

Arrêté du 21 février 2019 portant inscription du stimulateur cardiaque implantable simple chambre implanté par voie transcatheter MICRA de la société MEDTRONIC France SAS au titre III de la liste des produits et prestations remboursables prévue à l'article L. 165-1 du code de la sécurité sociale *(rectificatif)*

Société MEDTRONIC France SAS (MEDTRONIC)

Stimulateur cardiaque simple chambre, transcatheter, MEDTRONIC, MICRA.
Stimulateur cardiaque simple chambre implanté par voie transcatheter de la société Medtronic France SAS

INDICATIONS DE PRISES EN CHARGE

L'arrêté du 25 octobre 2018 limitant la pratique de l'acte d'implantation intraventriculaire droit d'un stimulateur cardiaque définitif simple chambre (de type VVIR), par voie veineuse transcathéter, sans pose de sonde » à certains établissements de santé en application des dispositions de l'article L. 1151-1 du code de santé publique prévoit les indications suivantes :

– Dysfonction sinusale lorsqu'une synchronisation auriculo-ventriculaire n'est pas nécessaire ;
– BAV sans rythme sinusal ;
– BAV en rythme sinusal avec un pourcentage de stimulation ventriculaire estimé faible (certains BAV paroxystiques) ;
– BAV en rythme sinusal lorsqu'une synchronisation auriculo-ventriculaire n'est pas nécessaire,

chez des patients à haut risque de complications liées à la sonde et pour lesquels le réseau veineux doit être préservé, ou pour lesquels une sonde endocavitaire est contre-indiquée.

Expanded indications for patients with risk factors

Environnement technique

Le plateau technique de rythmologie interventionnelle pour l'implantation du MICRA est identique à celui nécessaire pour une implantation de stimulateur cardiaque conventionnel en salle de cardiologie interventionnelle ou en bloc opératoire.

L'implantation du MICRA doit être réalisée dans un centre avec une activité de chirurgie cardiaque, en raison du risque lié à certaines complications rares mais potentiellement létales. Les plateaux techniques de rythmologie interventionnelle et de chirurgie cardiaque doivent être regroupés sur le même site, au cas où une conversion en urgence serait nécessaire.

Composition des équipes

La composition des équipes en salle est identique à celle nécessaire pour l'implantation d'un stimulateur cardiaque conventionnelle.

Une formation spécifique dédiée au dispositif MICRA est indispensable pour tous les opérateurs, incluant une formation théorique et pratique sur simulateur et sur animal proposée par le fabricant du dispositif, une formation théorique initiale dans un centre habilité et une formation pratique par compagnonnage (avec au moins 5 patients).

Volume d'activité

Un seuil de 2 implantations de MICRA par mois et par centre doit être atteint.

Prix :6300 € TTC depuis le 13 Mars 2019

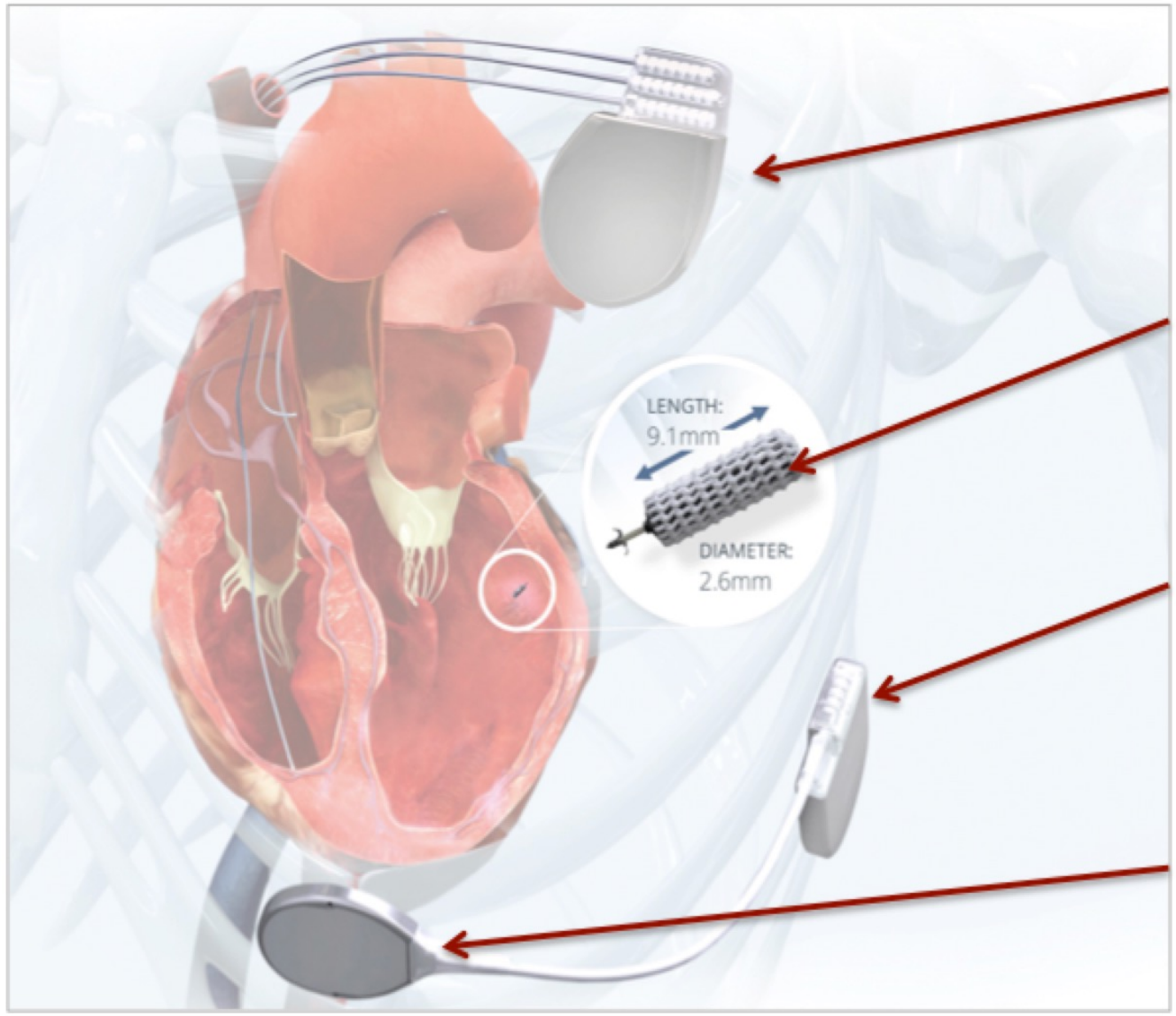
Leadless pacemakers – Extended Indications ??

- **Standard** : - Afib + bradycardia + preserved LV-function
  - SR + low expected pacing rate (e.g. intermittent AV-block)
- **Suitable** : - SR+Afib + cardioinhibitory vasovagal syncope
- **Advance** : - Congenital heart disease (paediatric and adult)
- **Promising** : - After previous device infections

Limitations and new challenges of LCP

- Implants at limited number of centers
- Still risk of trauma to heart or vascular system
  - Vascular injury due to large introducer sheaths
  - Tamponade
  - Device embolization
- No possibility of remote monitoring
- How to handle generator at end of system life
  - Long-term retrieval/extractability unknown
  - Need for multiple leadless for young patients

Système WiSE CRT



APPAREIL CO-IMPLANTE

Le pacemaker, DAI ou CRT co-implanté stimule le VD.

ELECTRODE RECEVEUSE

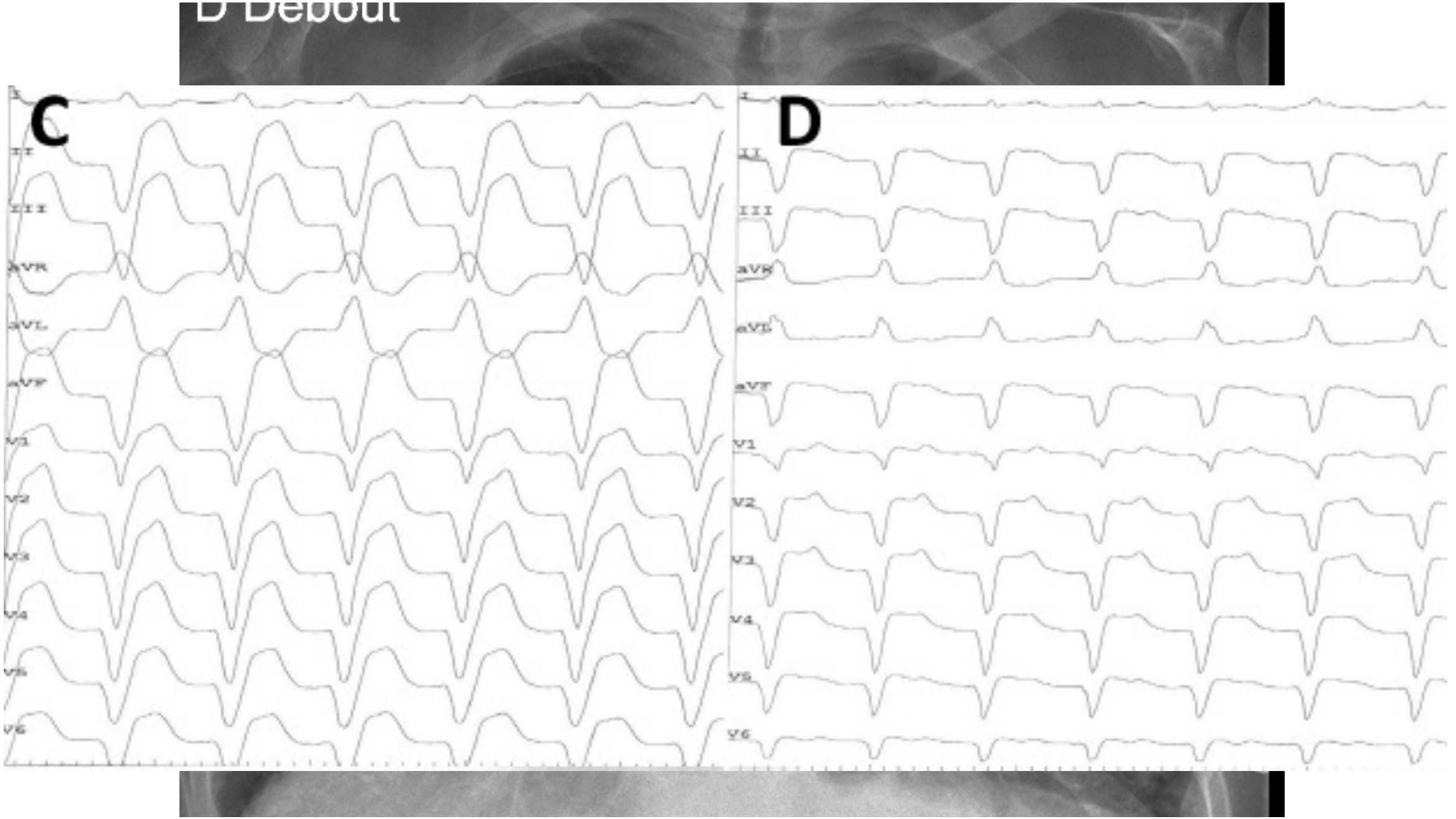
Implantée sur l'endocarde VG, elle convertit l'énergie des ultrasons en énergie électrique pour stimuler le VG.

BATTERIE

Implantée en sous-cutané sur la ligne axillaire moyenne, elle est connectée au transmetteur.

TRANSMETTEUR

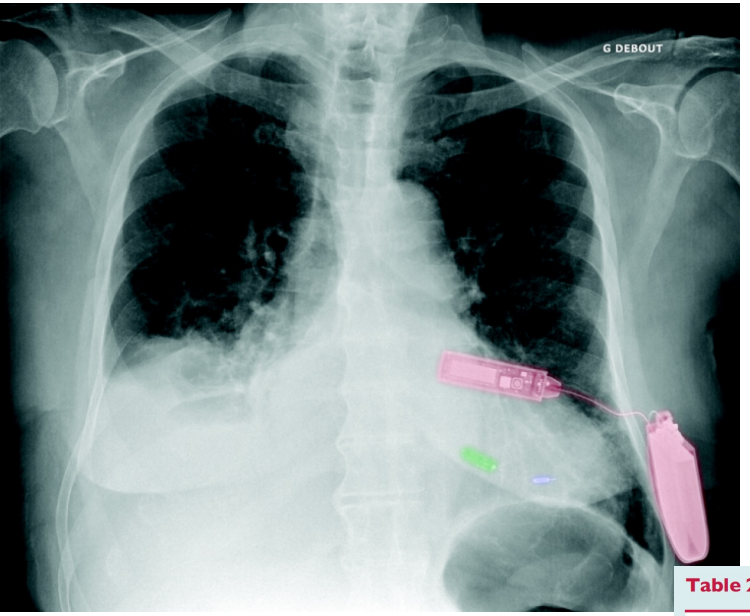
Le transmetteur ultrasonique est implanté en sous-musculaire au niveau d'une fenêtre échocardiographique. Synchronisé avec la stimulation VD, il permet de transmettre l'énergie ultrasonique à l'électrode receveuse pour permettre une stimulation biventriculaire.



“Stimulateur bi-ventriculaire sans sondes”

European experience with a first totally leadless cardiac resynchronization therapy pacemaker system

Adrien Carabelli [1], Mariem Jabeur[1], Peggy Jacon[1], Christopher Aldo Rinaldi[2], Christophe Leclercq[3], Giovanni Rovaris [4], Martin Arnold[5], Sandrine Venier[1], Petr Neuzil[6], and Pascal Defaye[1]*



8 patients

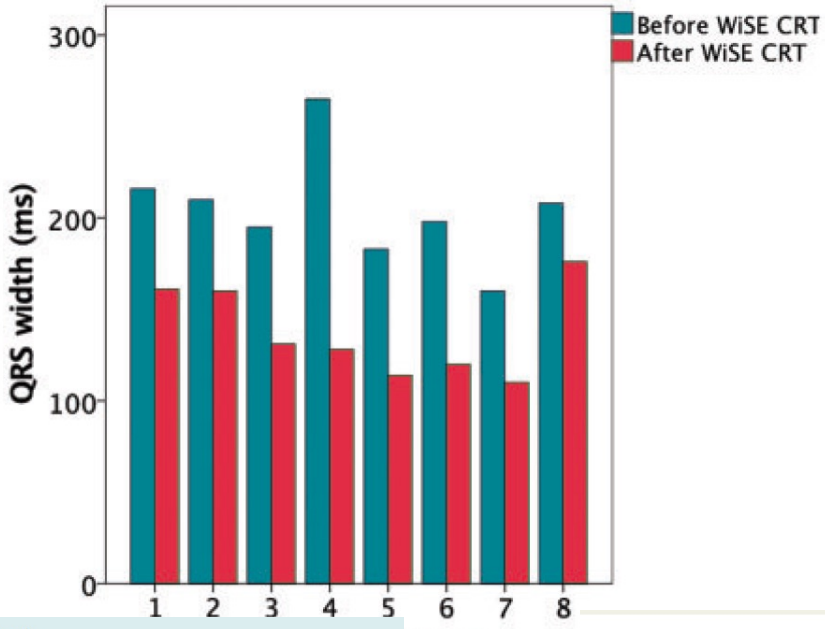
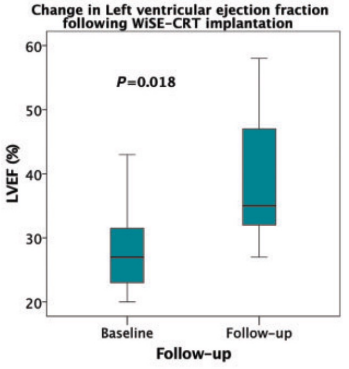
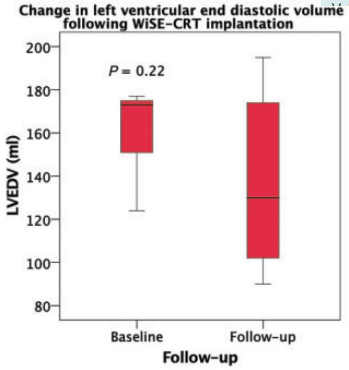
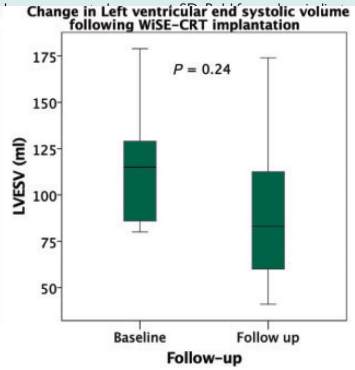


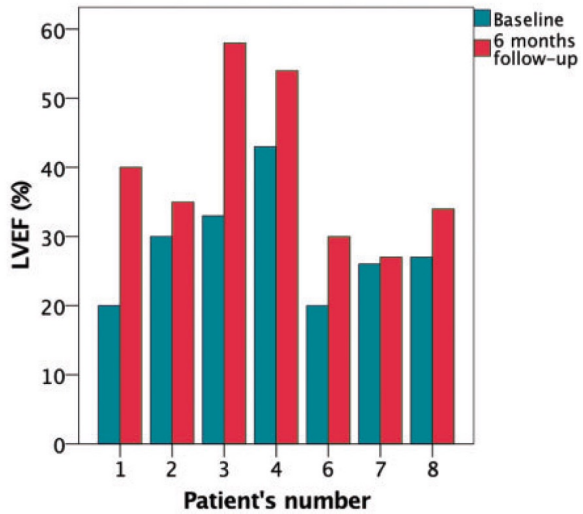
Table 2 Left ventricle function and volumes following WiSE-CRT implantation

Variables	Before WiSE-CRT implantation	After WiSE-CRT implantation	Change	*P*-value
QRS duration (ms)	204.37 ± 30.26	137.50 ± 24.75	−66.88 ±31.58	**0.012**
LVESV (mL)	117.33 ± 35.61	91.86 ± 48.43	−23 ± 27.77	0.24
LVEDV (mL)	160 ± 22.69	129.4 ± 40.70	−30.60 ± 29.30	0.22
LVEF (%)	28.43 ± 8.01	39.71 ± 11.89	+11.29 ± 8.46	**0.018**
NYHA	2.63 ± 0.51	2.29 ± 0.95		0.18







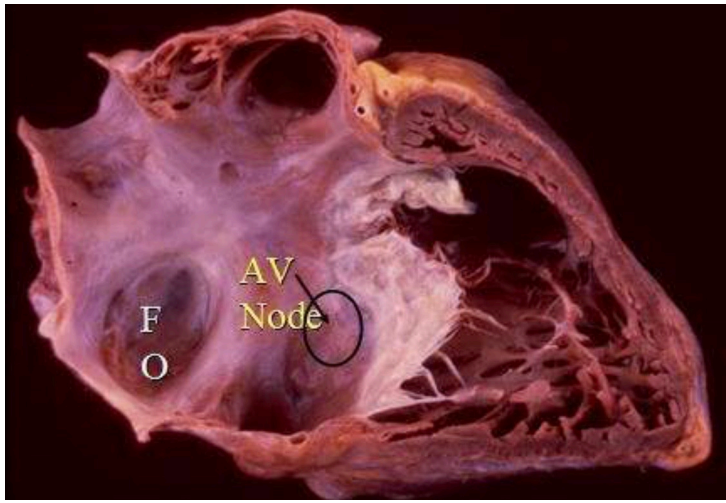


Europace December 14, 2020,

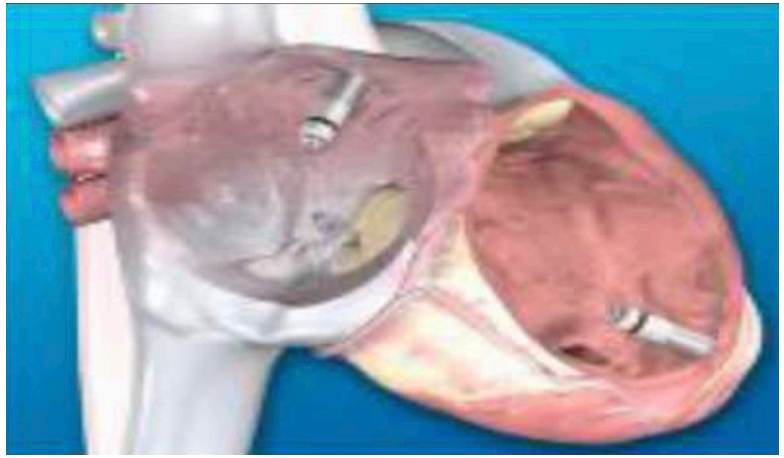
Dual chamber leadless pacemaker

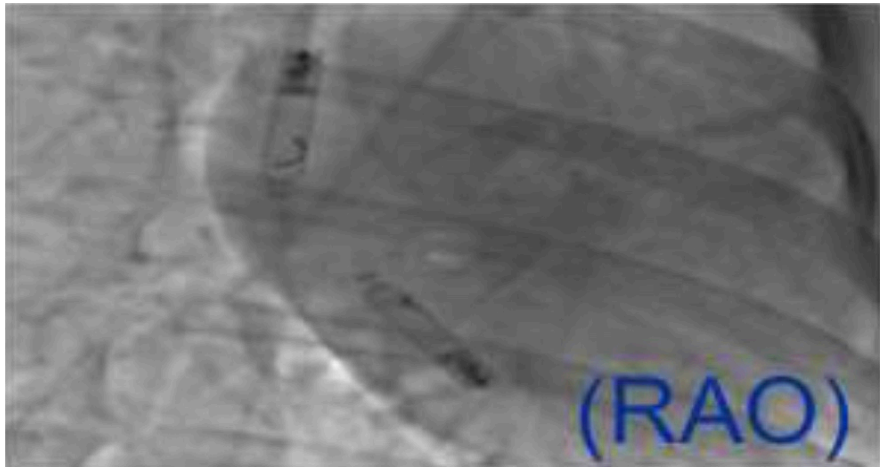
Requirements :

- **Safe atrial implant**
  - **Wall thickness vs fixation mechanism**
  - **Angle of implant/retrieval**
  - **>18 F catheter femoral**
- **Sufficient longevity**
- **Intrabody communication**
  - **Beat to beat communication**
  - **Programmable AV delay**
  - **Minimize V pacing**



IMM Montsouris/2015





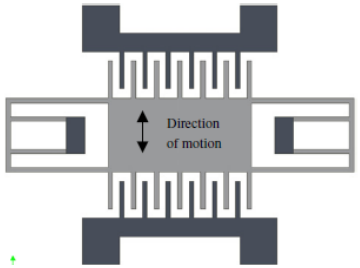
- **Common energy harvester energy source:**

  - Vibrations/inertia

Permanent near the heart
Easy transfer through packaging

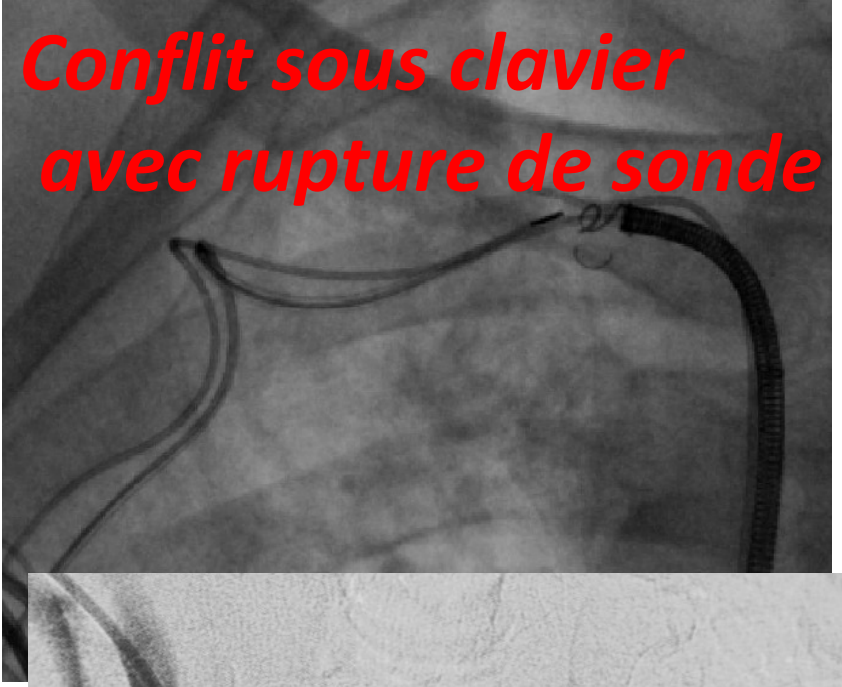
- **Vibrations / inertia energy transducers**

  - Electrostatic



  - Suited for miniaturization
  - Precharge needed or electret implementation

TIMC Grenoble

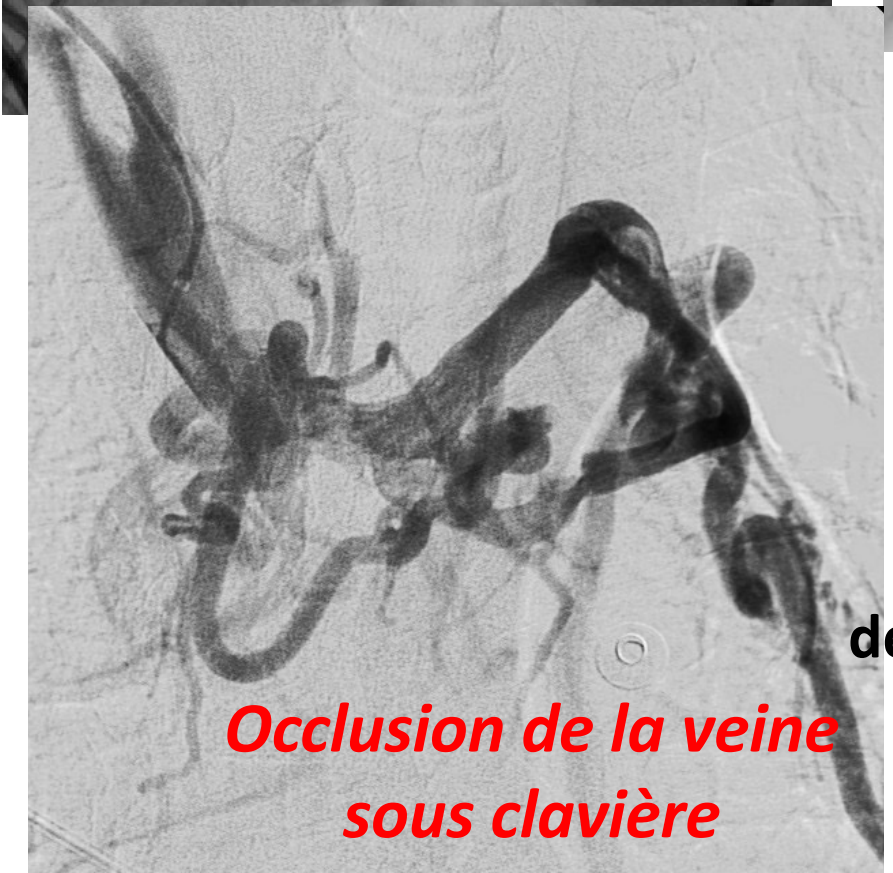


Conflit sous clavier avec rupture de sonde

Pneumothorax

DAI sous-cutané?? Pourquoi??

Performances des sondes

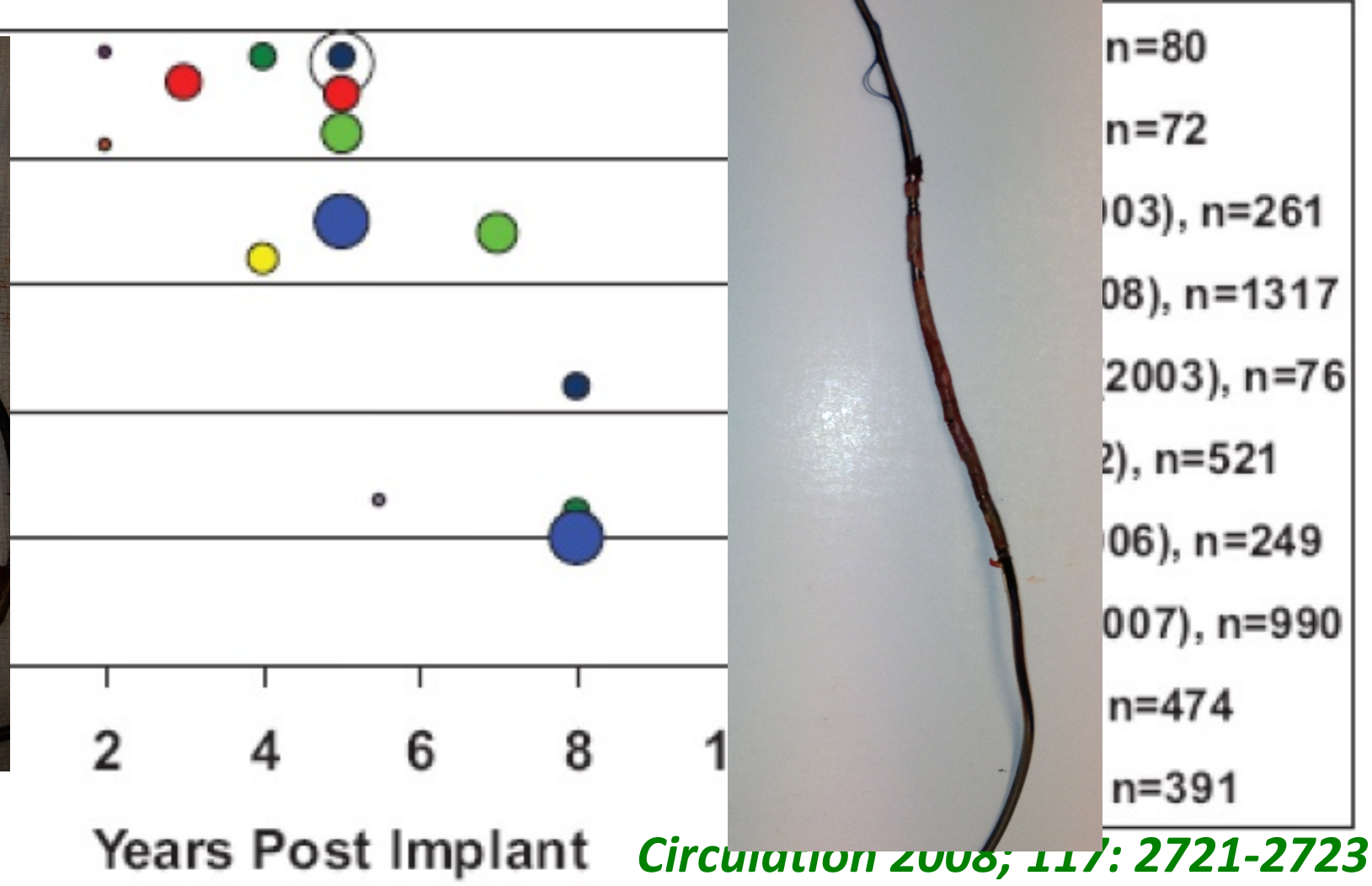


Occlusion de la veine sous clavière

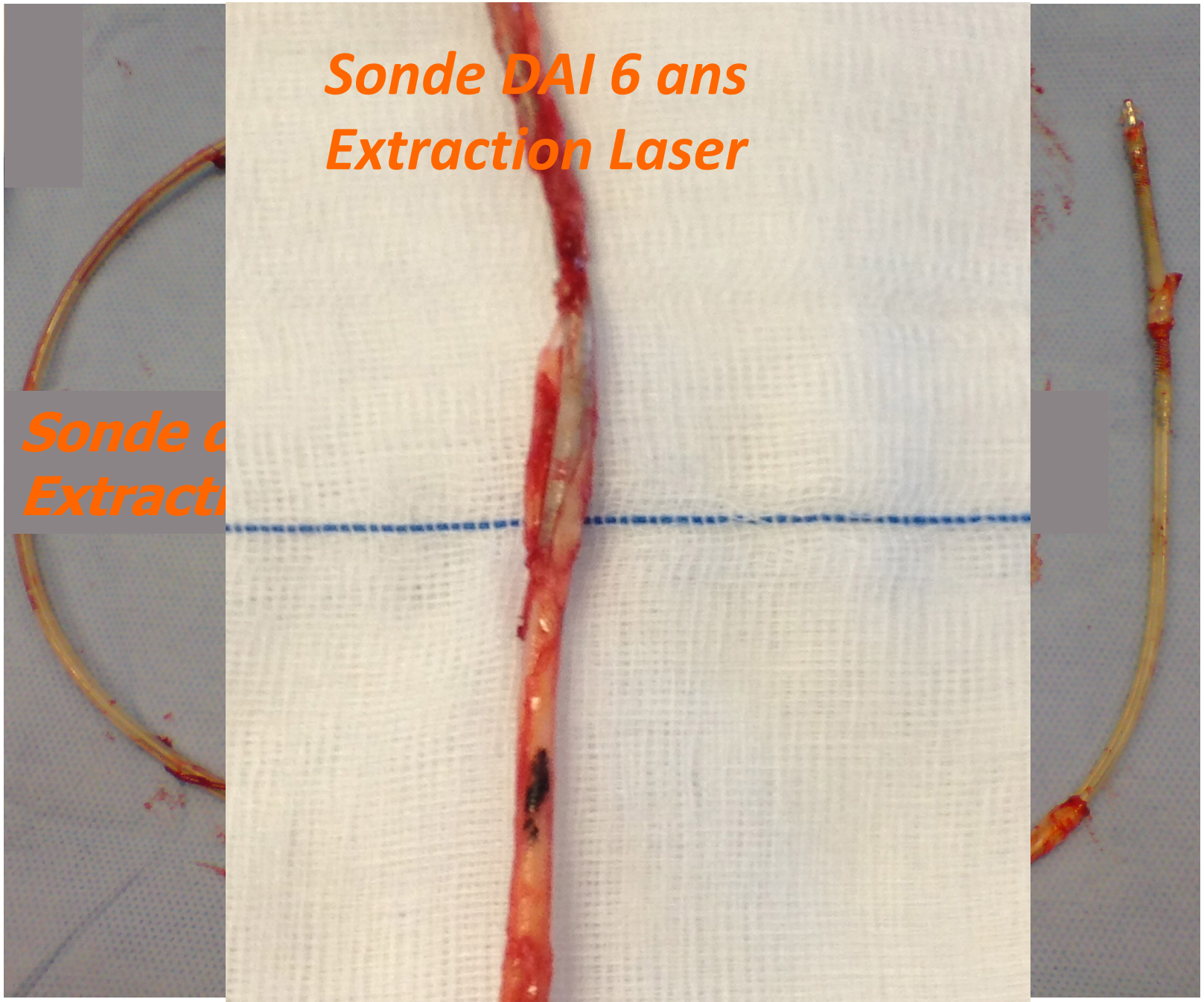
des

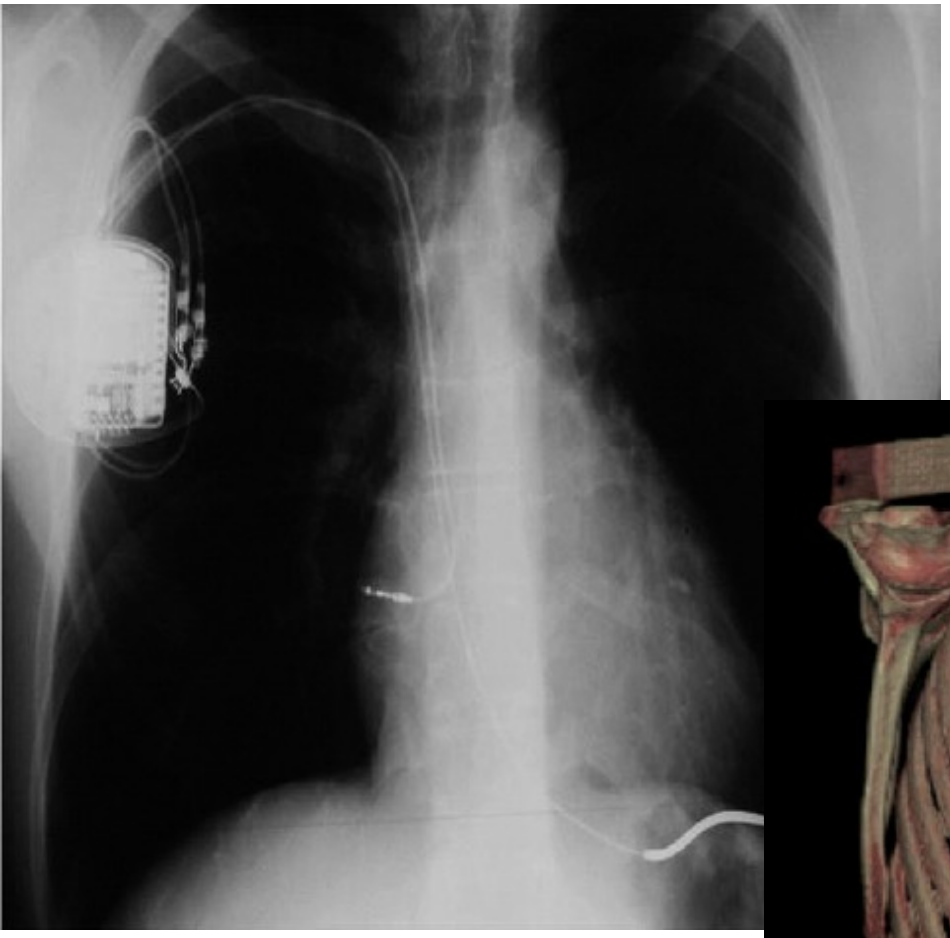
- **Performances des sondes endocavitaires à long terme imparfaites**
- **Complications liées aux sondes sont fréquentes**
  - **Thrombose**
  - **Fracture**
  - **Morbi/mortalité liée à l'extraction/manipulation sondes**
  - **Risque plus élevé chez les patients jeunes**

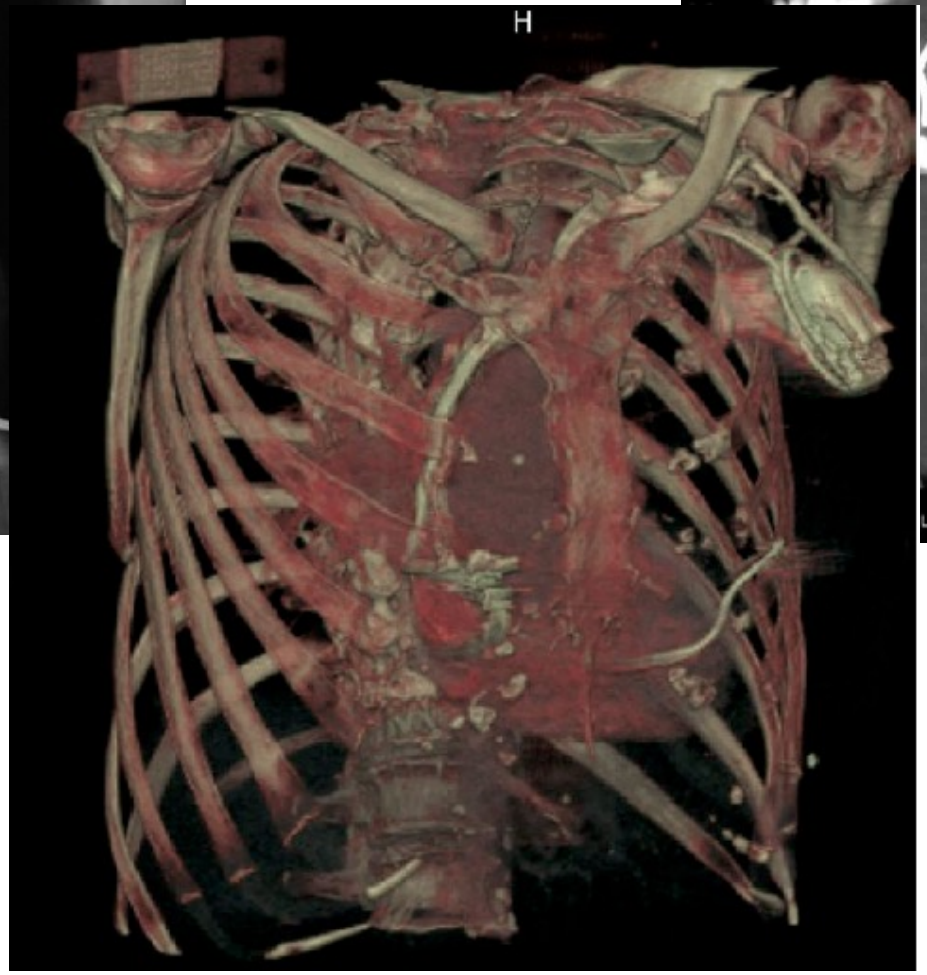
Performance des sondes de DAI

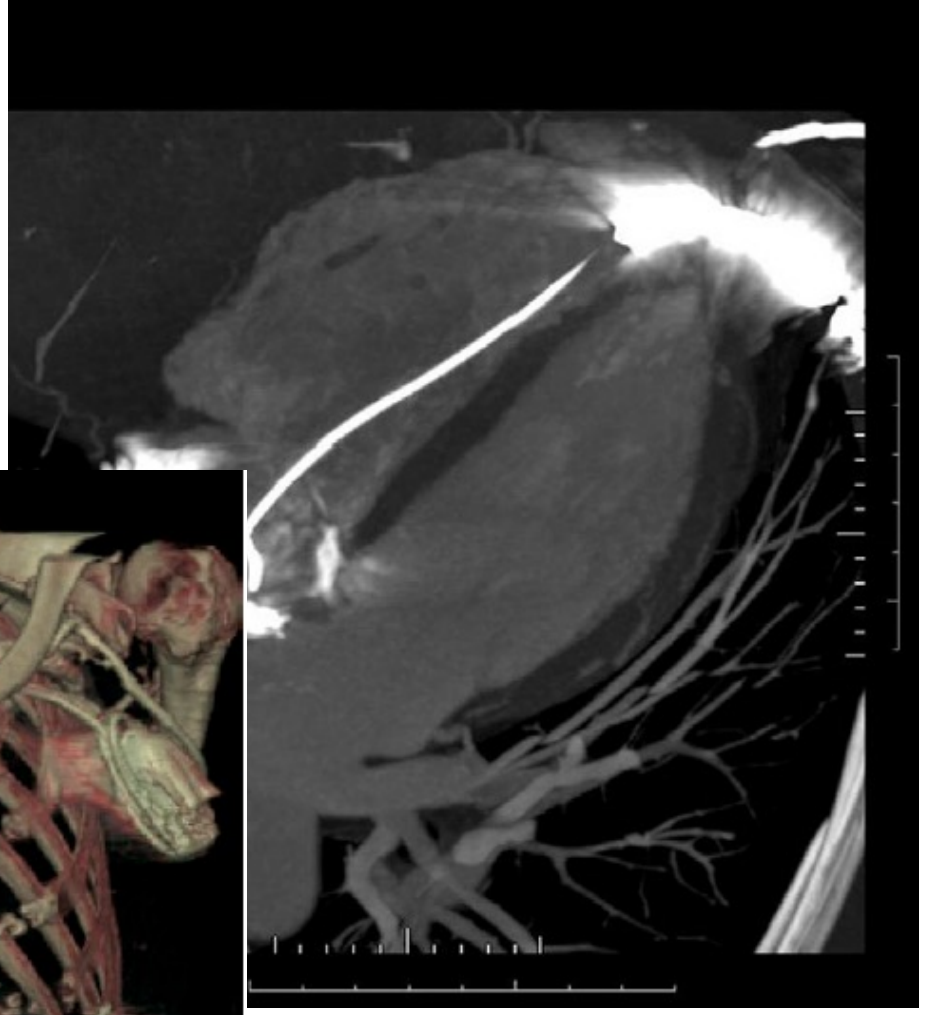


Circulation 2008; 117: 2721-2723


Sonde DAI 6 ans
Extraction Laser

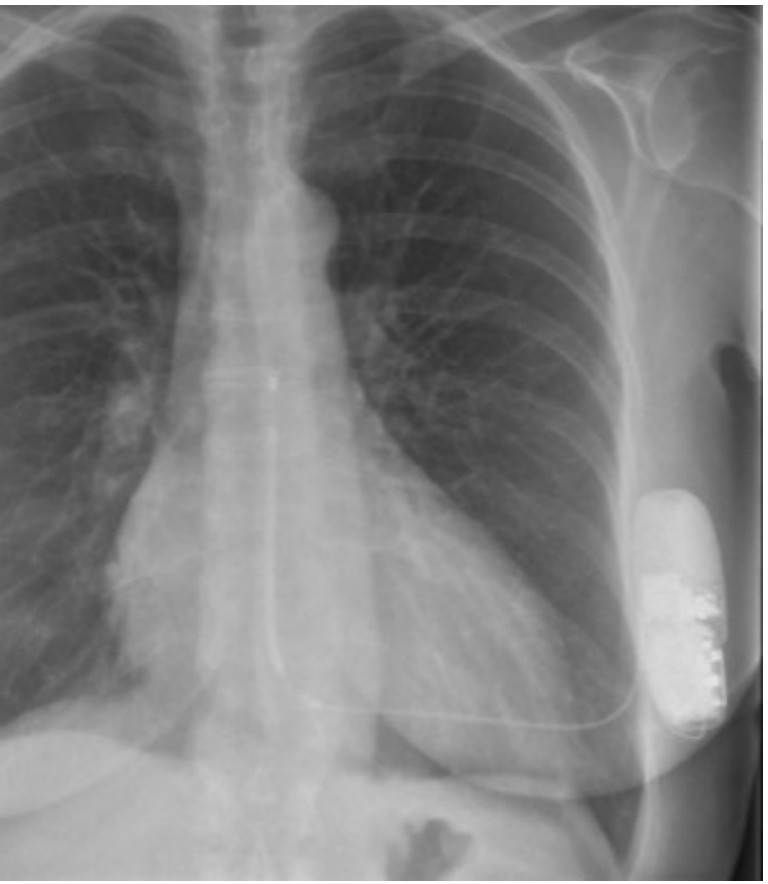






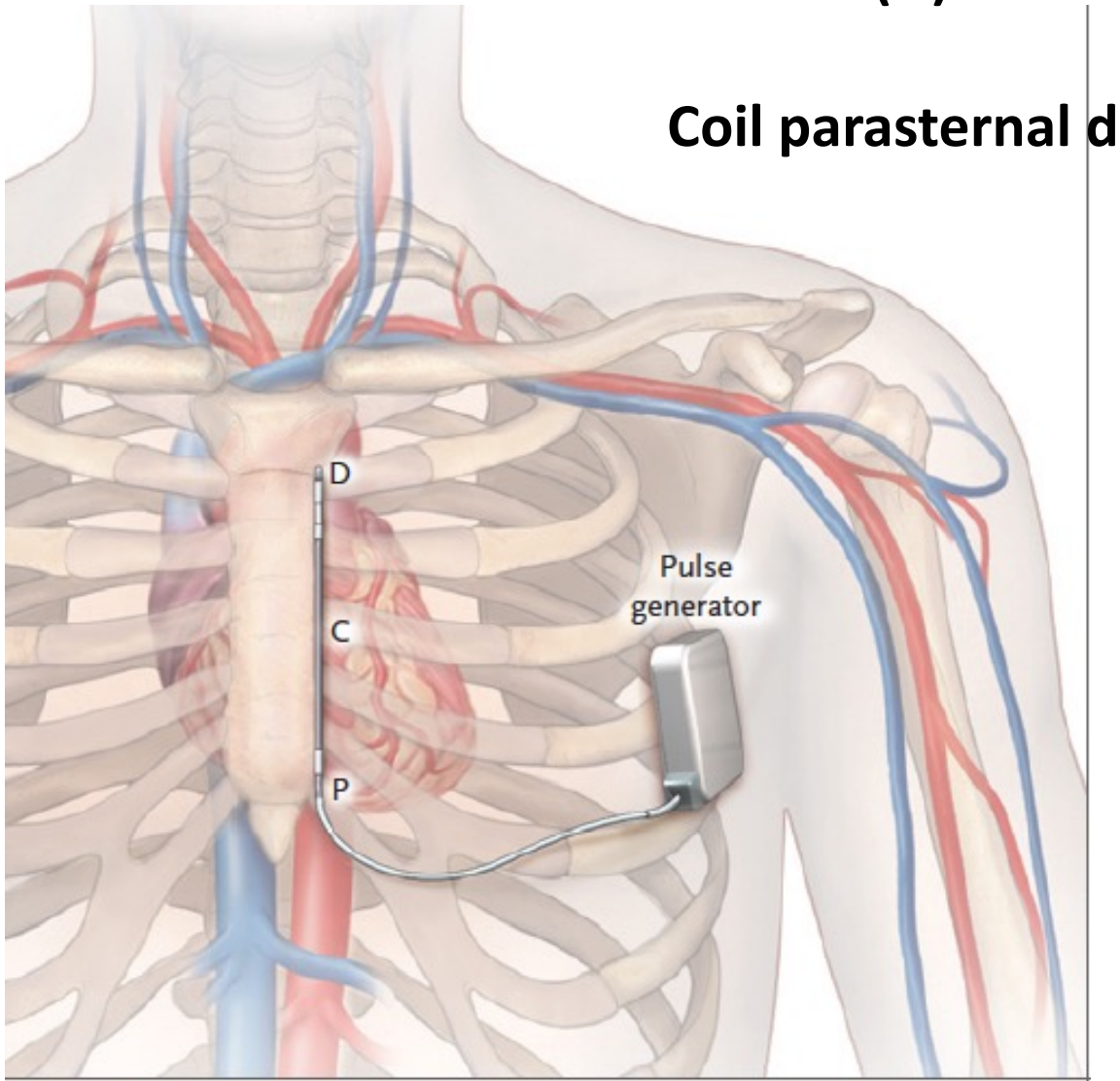
Perforation

DAI sous cutané



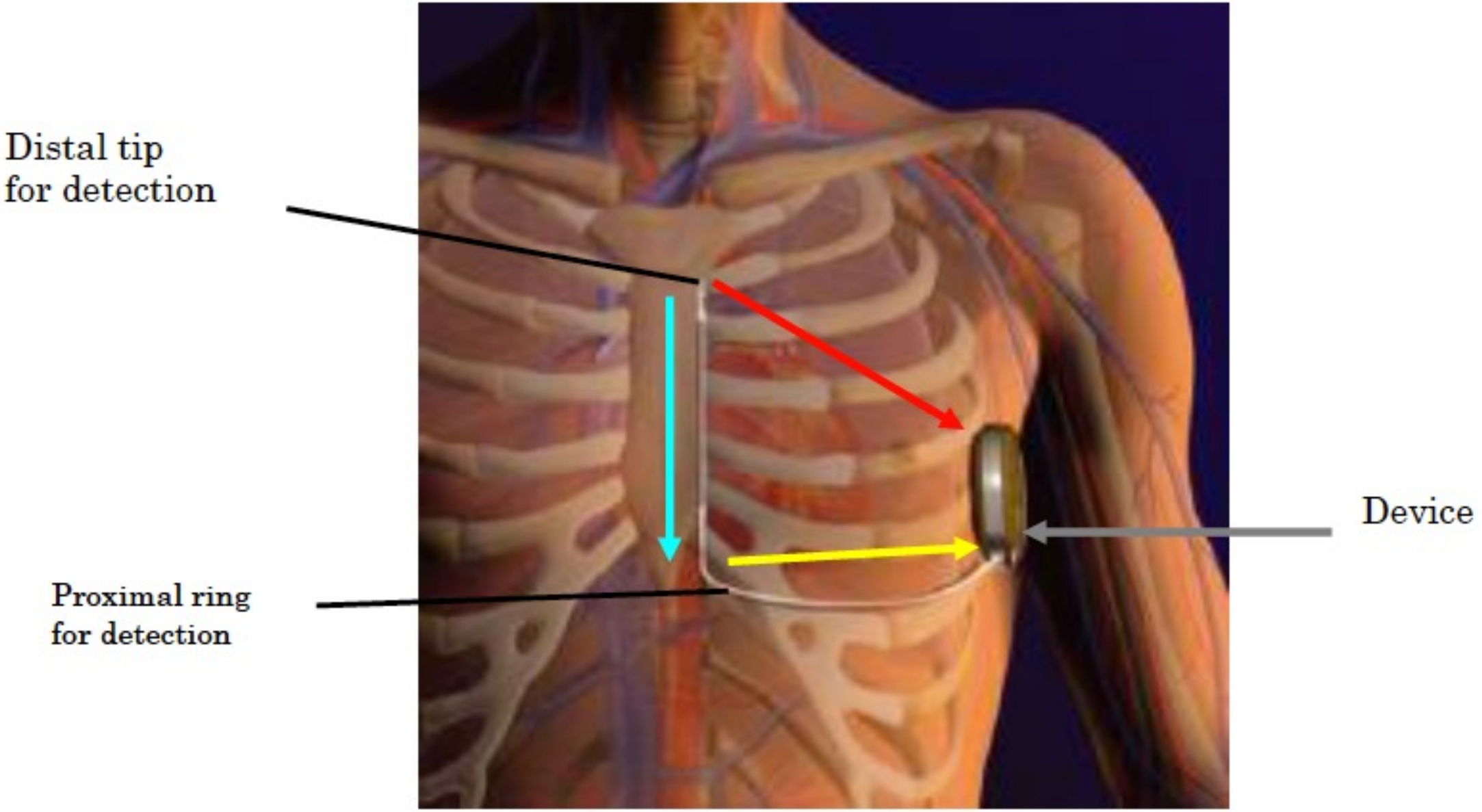
Electrodes de détection
Distale (D) et Proximale (P)

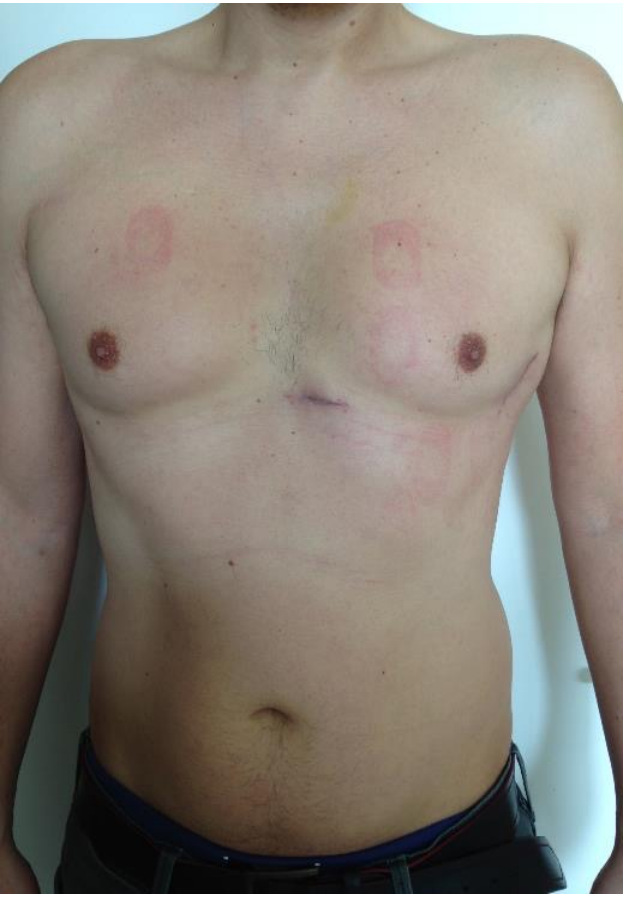
Coil parasternal de 8 cm (C)

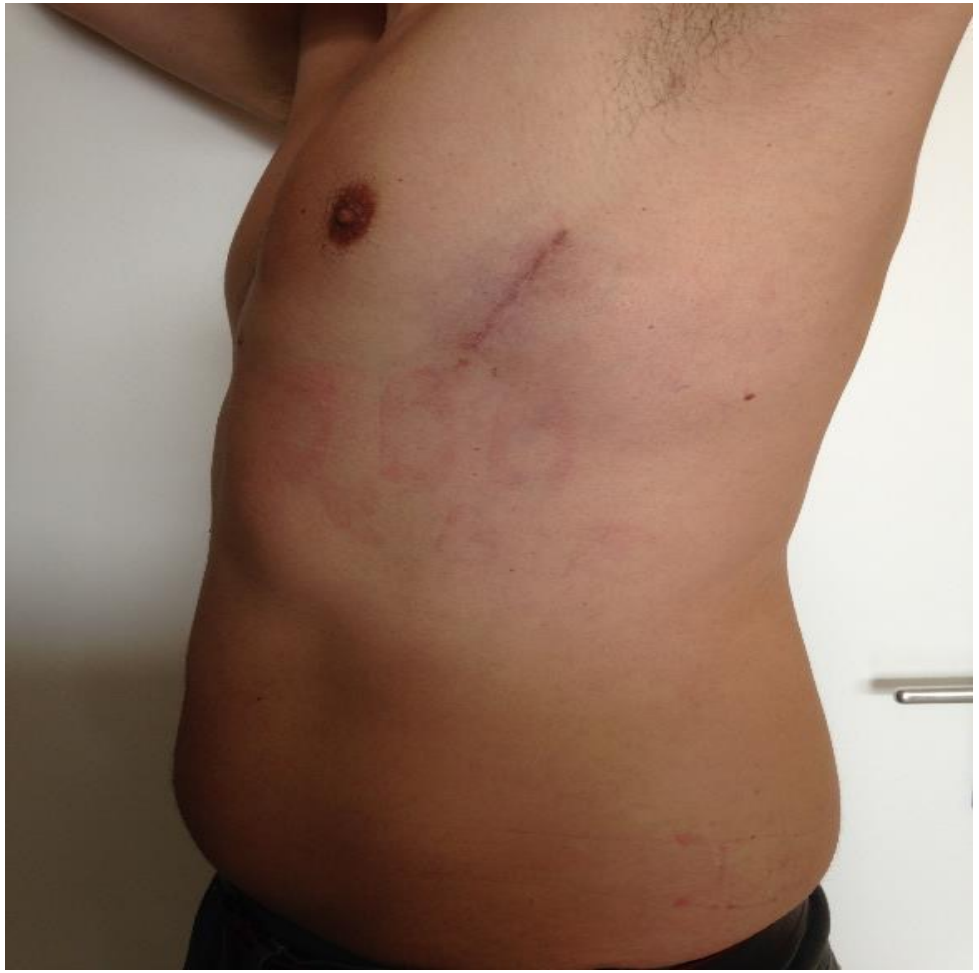


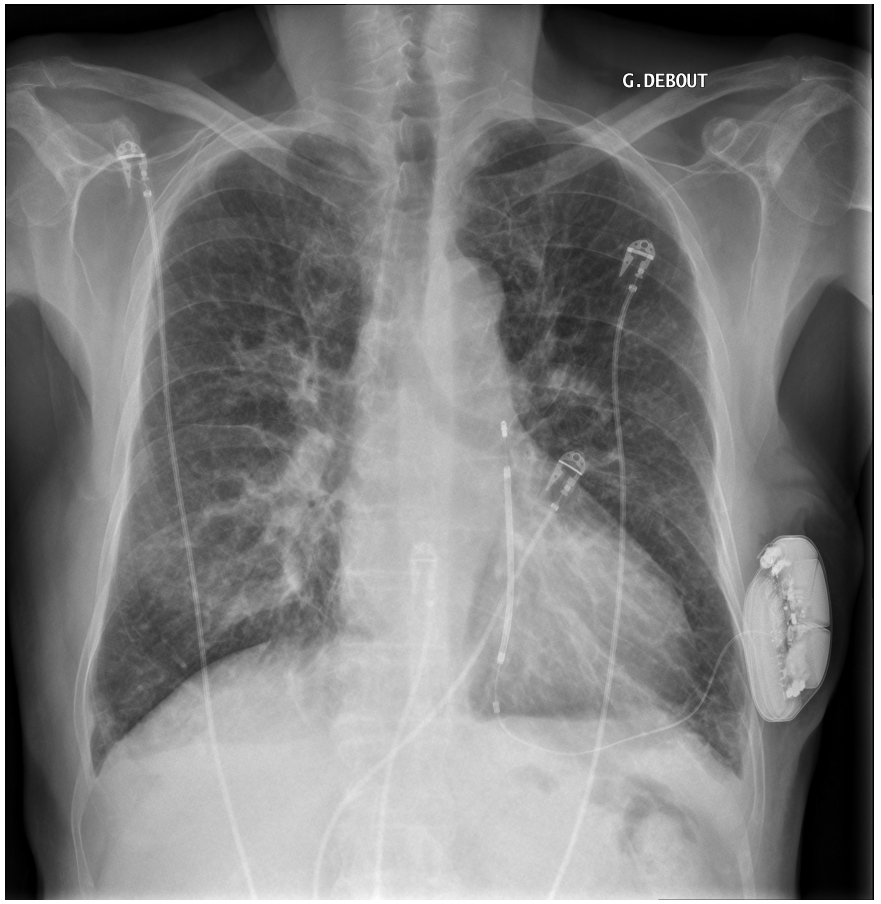
- **Totalement sous cutané :**
- **Ne nécessite aucune électrode « dans ou sur » le cœur**
- **Pas besoin de fluoroscopie**

3 differents vectors for sensing : primary (yellow), secondary (red) and alternative vector (blue)



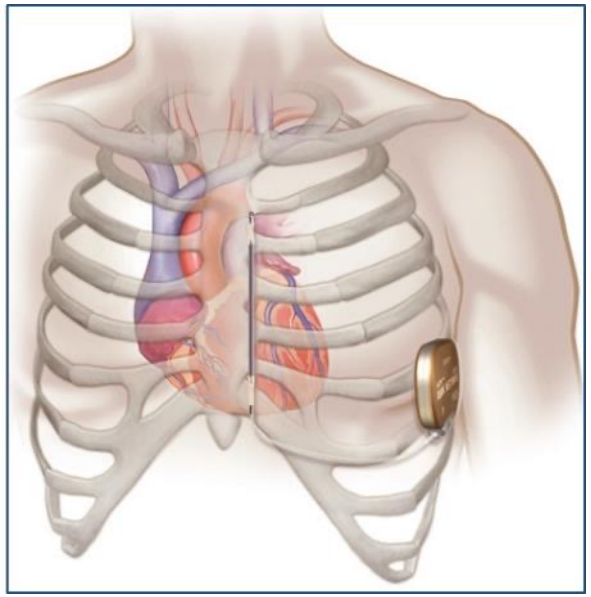






Technique 2 incisions

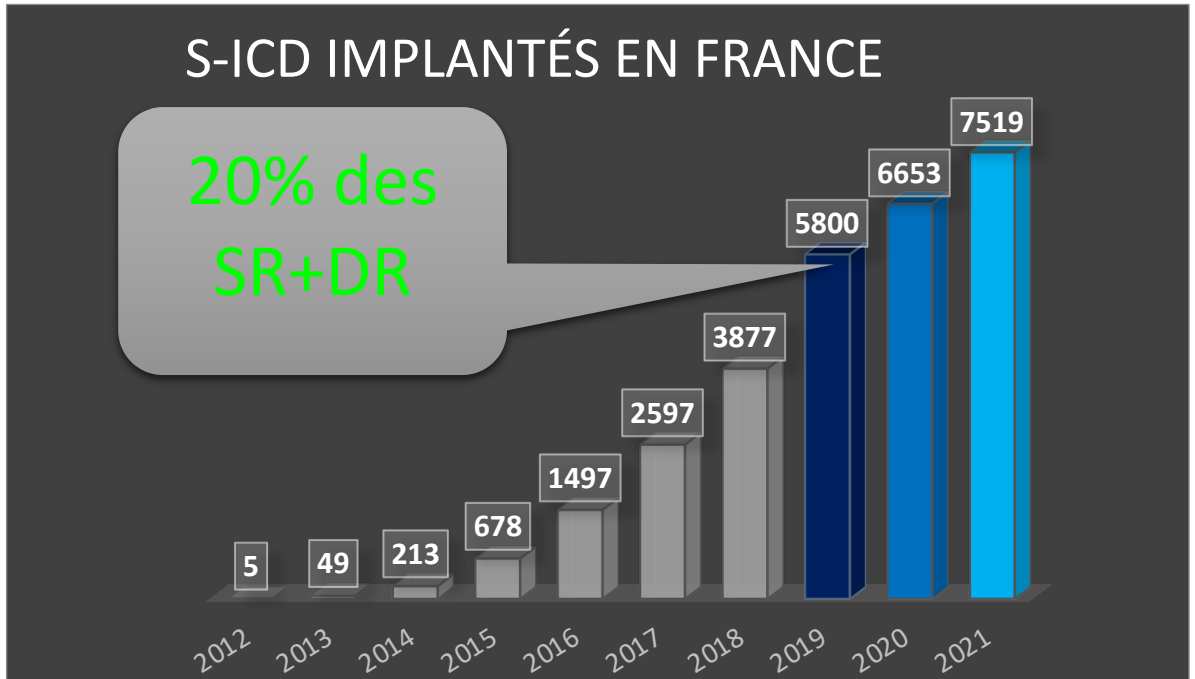
S-ICD en France



7500 S-ICD implantés en France depuis 2012

130 centres actifs

Tendance **+150 S-ICD / mois** en 2018



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)

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

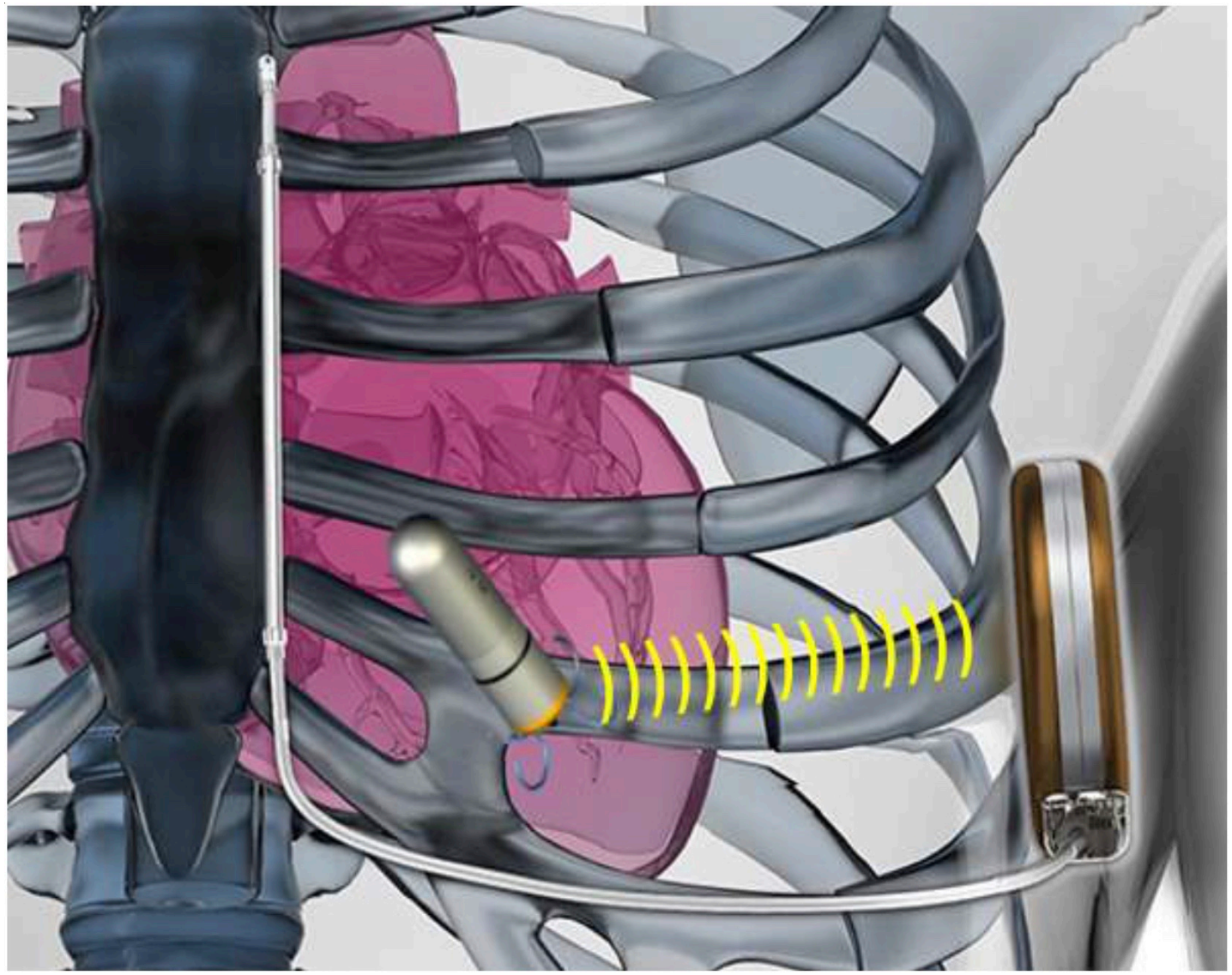
EHJ 2015; 36: 2793–2867

Future Directions

Limitations of the S-ICD :

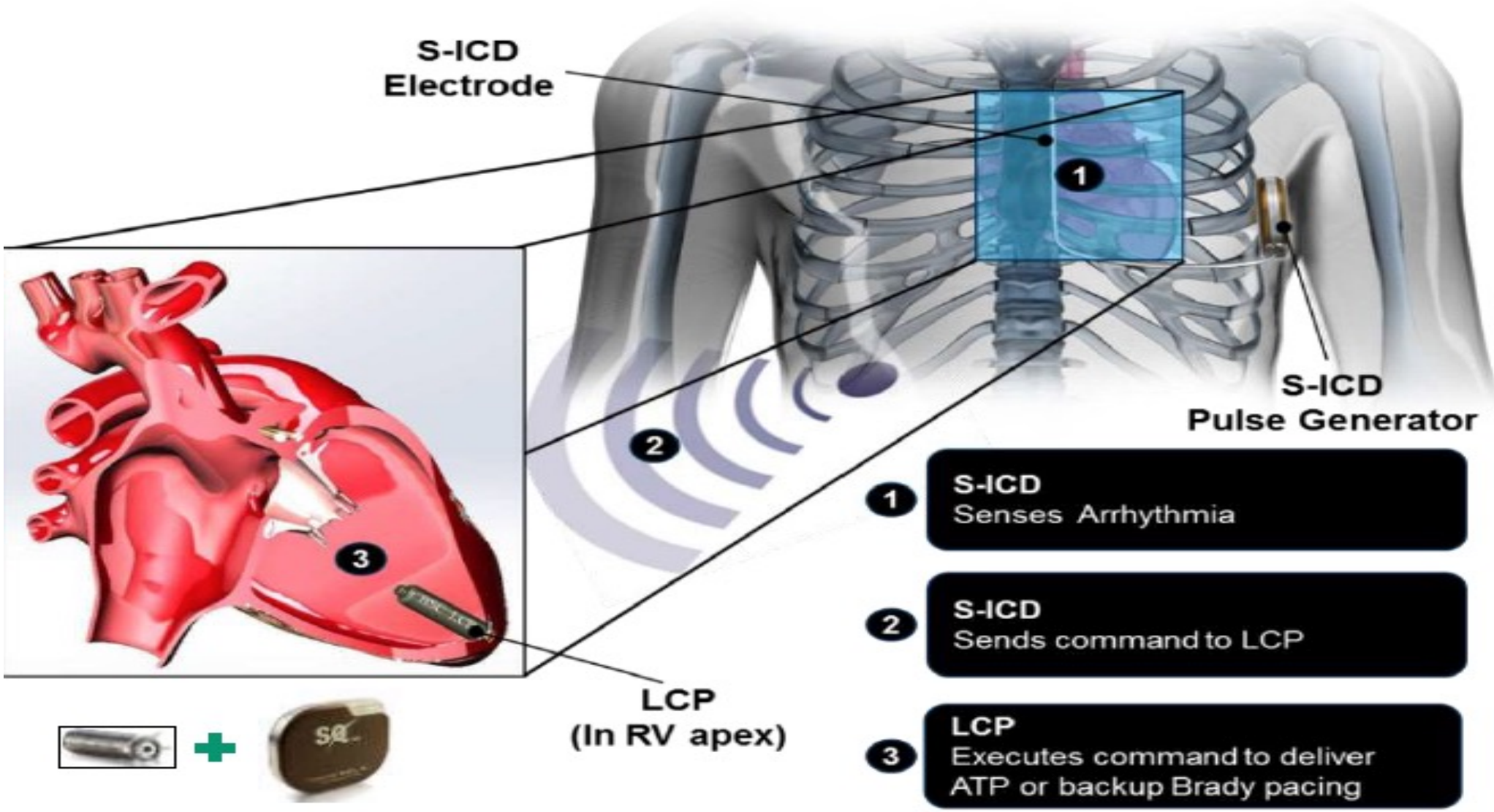
S-ICD patients may develop a need for:

- **Pacing support** (0.06%-2.4%/year)
- **ATP** for recurrent monomorphic VT (0.4%-1.8% /year)



Burke MC .
J Am Coll Cardiol. 2015; 65(16):1605–1615
Poole JE.
Circ Arrhythm Electrophysiol. 2013;6:1236-1245.

Leadless pacing :
Complementary to S-ICD (2020??)



Boston Scientific

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Subcutaneous or Transvenous Defibrillator Therapy

R.E. Knops, L.R.A. Olde Nordkamp, P.-P.H.M. Delnoy, L.V.A. Boersma, J. Kuschyk, M.F. El-Chami, H. Bonnemeier, E.R. Behr, T.F. Brouwer, S. Kääb, S. Mittal, A.-F.B.E. Quast, L. Smeding, W. van der Stuijt, A. de Weger, K.C. de Wilde, N.R. Bijsterveld, S. Richter, M.A. Brouwer, J.R. de Groot, K.M. Kooiman, P.D. Lambiase, P. Neuzil, K. Vernooy, M. Alings, T.R. Betts, F.A.L.E. Bracke, M.C. Burke, J.S.S.G. de Jong, D.J. Wright, J.G.P. Tijssen, and A.A.M. Wilde, for the PRAETORIAN Investigators*

EDITORIALS

Transvenous or Subcutaneous ICD — Similar but Different

Mark S. Link, M.D., and Jose A. Joglar, M.D.

PRAETORIAN

- Noninferiority trial
- ICD indication (primary or secondary prevention) with no pacing or CRT indication,
- Randomized (1:1) to receive :
  - Subcutaneous ICD
  - Conventional Transvenous
- Superiority analysis prespecified if non-inferiority was established
- TV-ICD : single chamber

Transvenous ICD (all manufacturers)

- **Monitor VT zone > 167 bpm**
- **VT cutoff rate : as close as 182 bpm,**
- **VF cutoff rate > 250 bpm**
- **Long detection**

Subcutaneous ICD (Boston ☺)

- **Of course, no monitor zone (☺, ☺, ☺, ☺, ☺)**
- **VT (conditional) zone > 180 bpm**
- **VF (Unconditional) zone > 250 bpm**
- **Pass algorithm "on" once it became available in April 2016**

NEJM 2020;383:526-36

Praetorian ICD Results

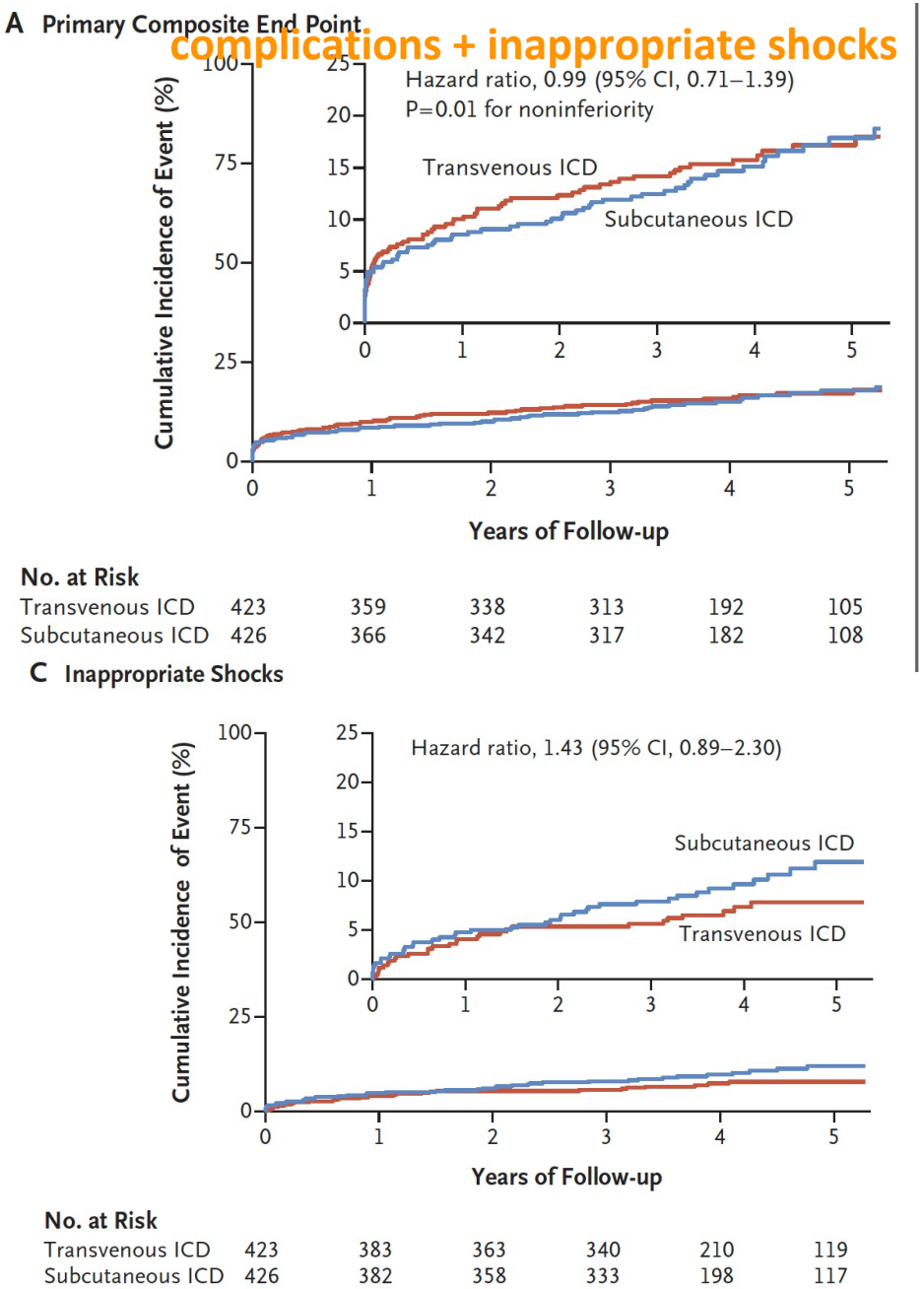
- 03/2011 ➔ 01/2017 : 876 patients enrolled in Europe and in the US (39 centers)

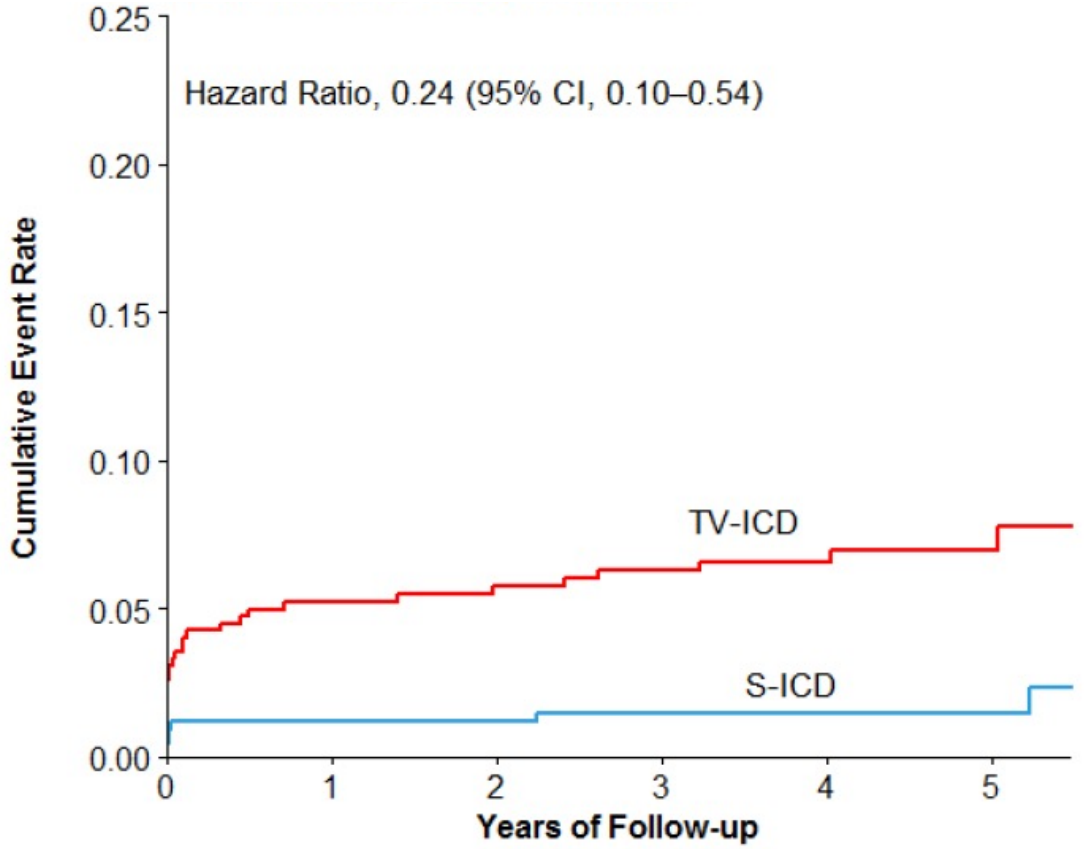
Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Subcutaneous ICD (N=426)	Transvenous 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 (23.2)
Genetic arrhythmia syndrome	20 (4.7)	18 (4.3)
Hypertrophic cardiomyopathy	15 (3.5)	7 (1.7)
Idiopathic ventricular fibrillation	11 (2.6)	5 (1.2)
Congenital heart disease	3 (0.7)	3 (0.7)
Other†	4 (0.9)	1 (0.2)
Secondary prevention — no. (%)	80 (18.8)	84 (19.9)
Median ejection fraction (IQR) — %	30 (25–35)	30 (25–35)
Mean QRS duration — msec	105±19	105±20

NEJM 2020;383:526-36

I[ary] endpoint : Composite of device-related complications + inappropriate shocks





Lead complications

NEJM 2020;383:526-36

ORIGINAL RESEARCH ARTICLE

Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial

Michael R. Gold, MD, PhD
Pier D. Lambiase, PhD
Mikhael F. El-Chami, MD
Reinoud E. Knops, MD,

- **Primary prevention patients with LVEF≤35% and no pacing indications were included**
- **Programmation : rate-based therapy delivery for rates ≥250 bpm and morphology discrimination for rates ≥200 and <250 bpm**

Variable	(N=) mean± standard deviation, or n/N (percent)
Patient characteristics	
Age, y	(N=1116) 55.8±12.4
Women, N (%)	286/1116 (25.6)
Black, N (%)	239/1020 (23.4)
Height, in	(N=1095) 67.9±4.3
BMI, kg/m^2	(N=1093) 30.2±7.3
Previous MI, N (%)	453/1099 (41.2)
Previous valve surgery	36/1114 (3.2)
History of AF, N (%)	142/1116 (12.7)
Ischemic cause, N (%)	570/1065 (53.5)
LVEF, %	(N=1116) 26.4±5.8
NYHA class II/III, N (%)	888/1013 (87.7)
High blood pressure, N (%)	787/1116 (70.5)
Diabetes, N (%)	364/1116 (32.6)
Kidney disease, N (%)	160/1116 (14.3)

Variable	(N=) mean± standard deviation, or n/N (percent)
Procedural characteristics	
S-ICD screening performed	1111/1111 (100.0)
S-ICD screening performed using AST	305/1110 (27.5)
>1 passing vector at screening	705/814 (86.6)
Initial device at implant	1104/1110 (99.5)
2-Incision technique	769/1111 (69.2)
Procedure duration, min	(N=1094) 57.9±27.0
Gen 3 device with SMART Pass filter	671/1111 (60.4)
DFT performed within first 30 days	911/1111 (82.0)

Circulation. 2021;143:7–17

ORIGINAL RESEARCH ARTICLE

Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial

Michael R. Gold, MD, PhD
Pier D. Lambiase, PhD
Mikhael F. El-Chami, MD
Reinoud E. Knops, MD,

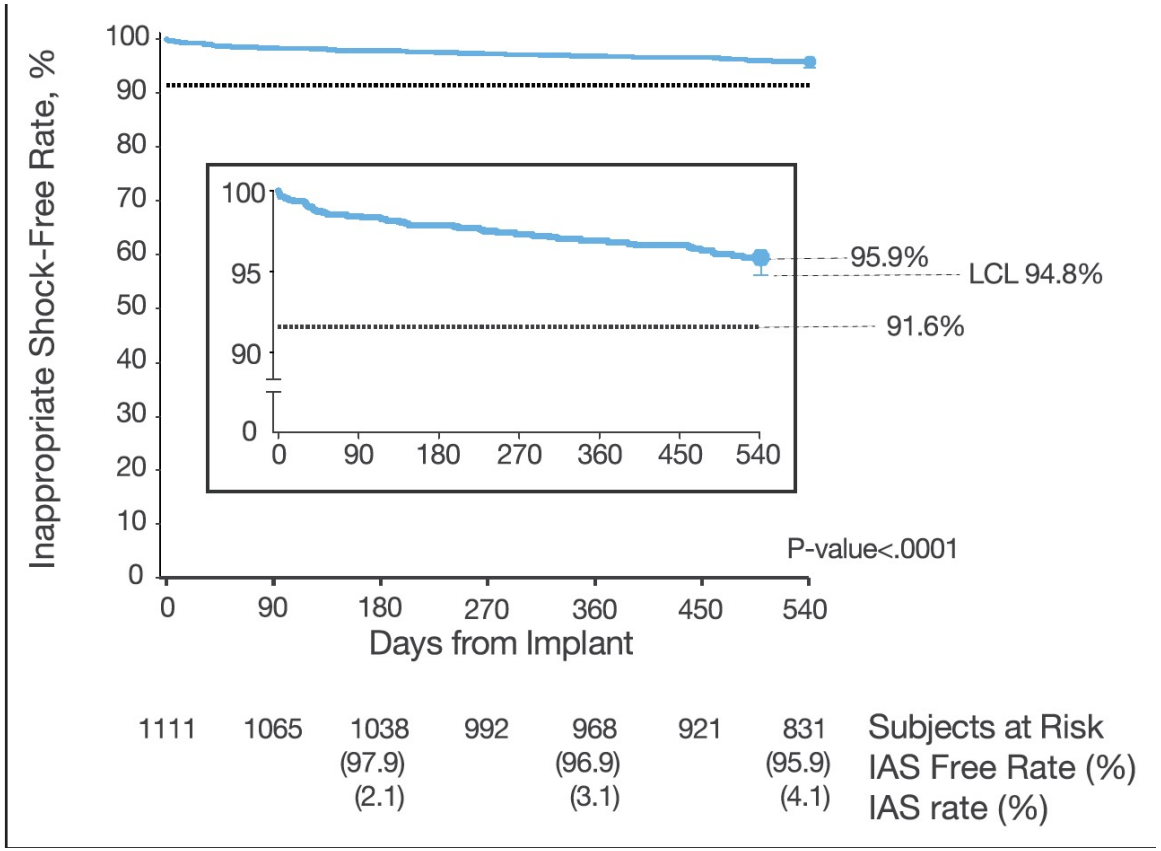


Table 3. Cause of Inappropriate Shock

IAS category	Total Episodes	Total Subjects n (% of 1111)
Cardiac	70	30 (2.7)
T-wave oversensing	35	18 (1.6)
Other cardiac oversensing	14	10 (0.9)
Oversensing of VT/VF below rate zone	21	4 (0.4)
Noncardiac	17	16 (1.4)
Myopotential	3	2 (0.2)
Other noncardiac oversensing	14	14 (1.3)
SVT	0	0 (0)
Discrimination error	0	0 (0)
SVT above discrimination zone	0	0 (0)
Other	1	1 (0.1)
Total	88	45 (4.1)

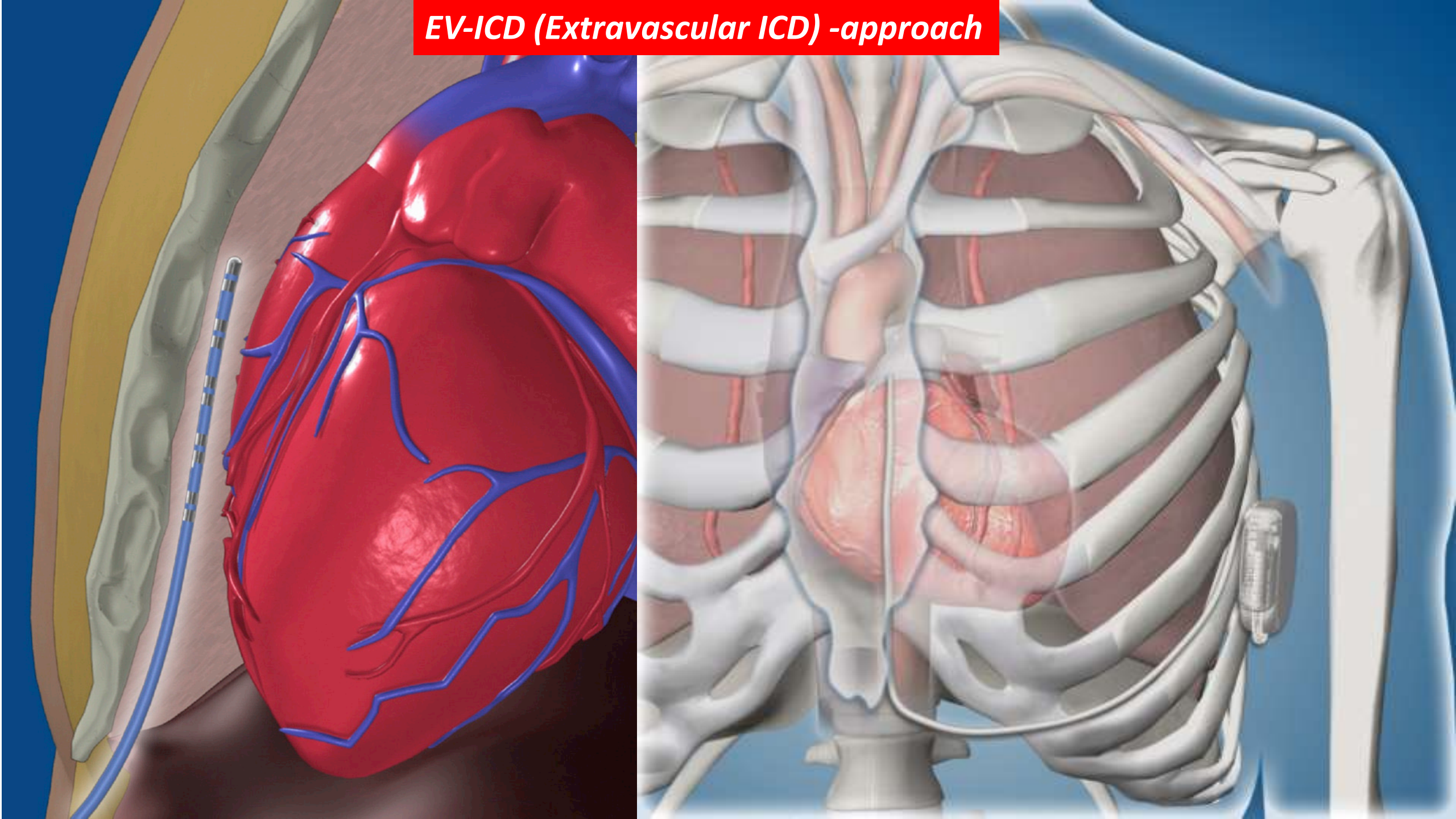
Inappropriate shock free rate

3.1% at 1 year

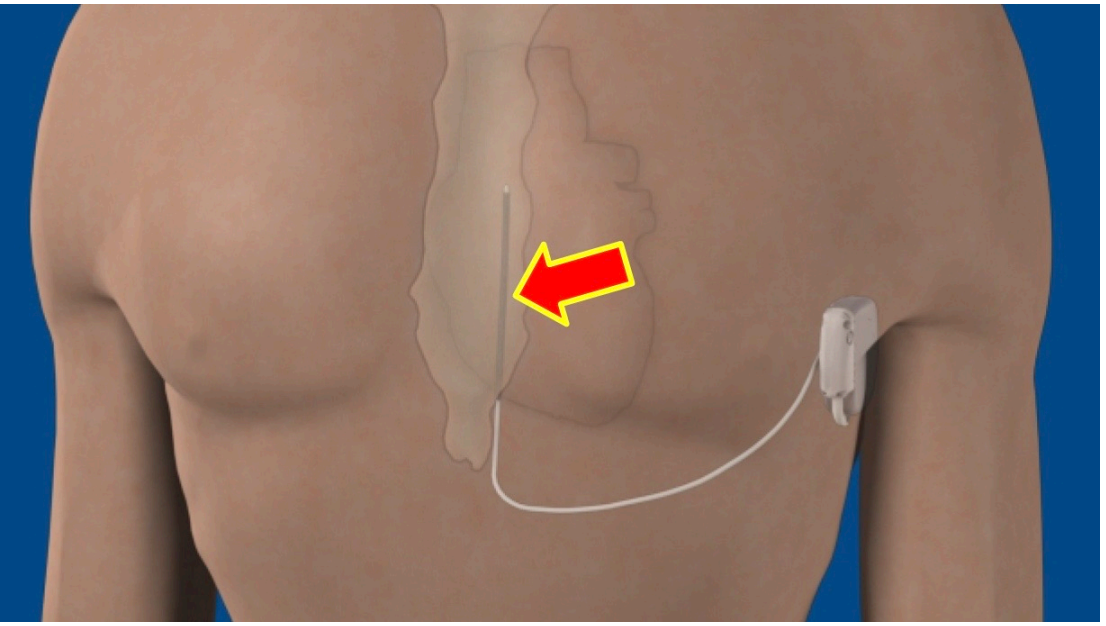
Cause of inappropriate shock

Circulation. 2021;143:7–17

EV-ICD (Extravascular ICD) -approach



Proposed Solution: Position the Lead Under the Rib Cage

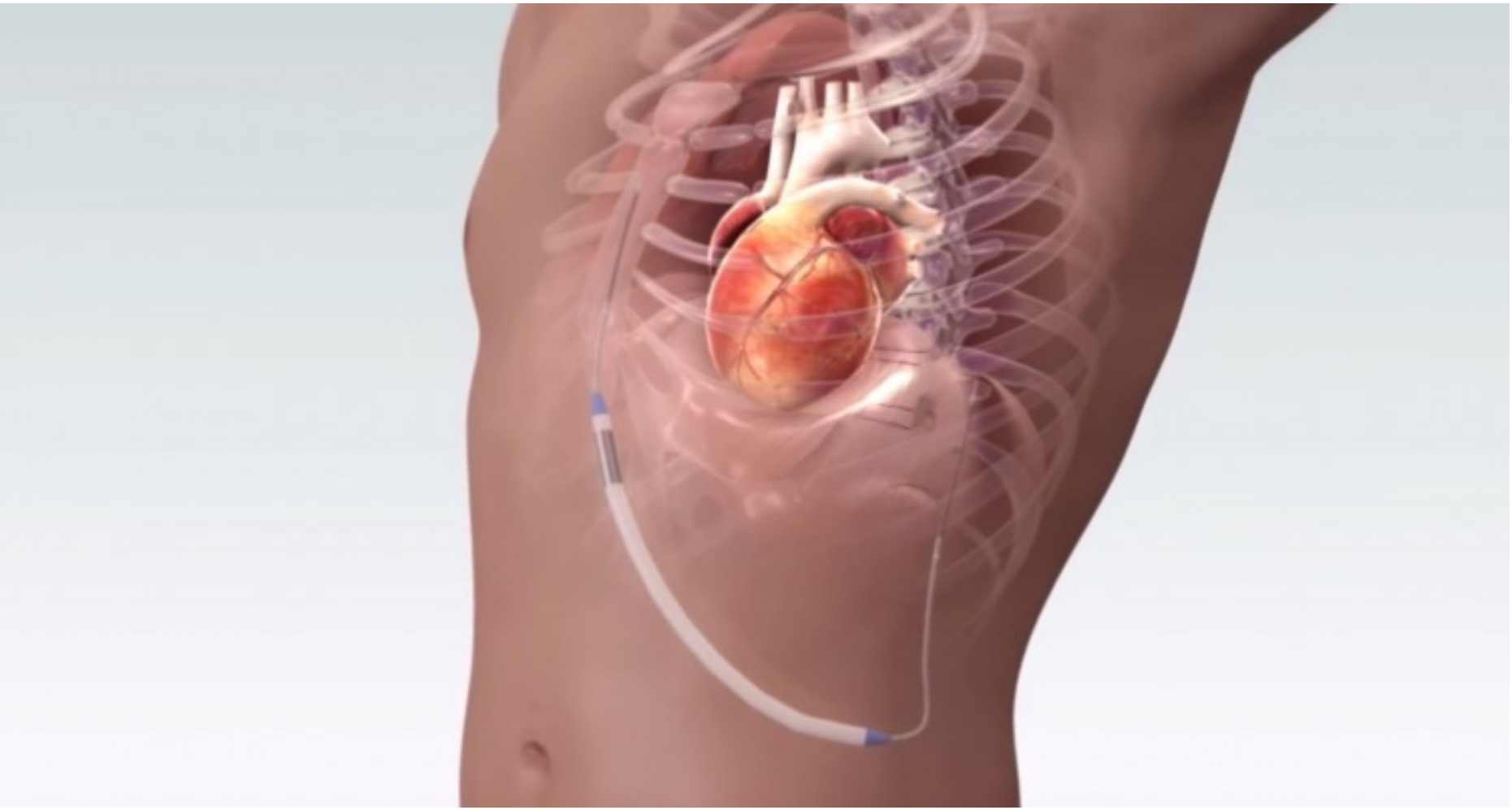


Hypothesis: A substernal defibrillation lead implant is feasible and provides opportunity for …

- **Lower defibrillation thresholds (DFTs)**
- **Smaller device size like TV-ICD**
- **Greater device longevity**
- **Delivery of pacing therapy, including ATP**

Medtronic

The “String” ICD

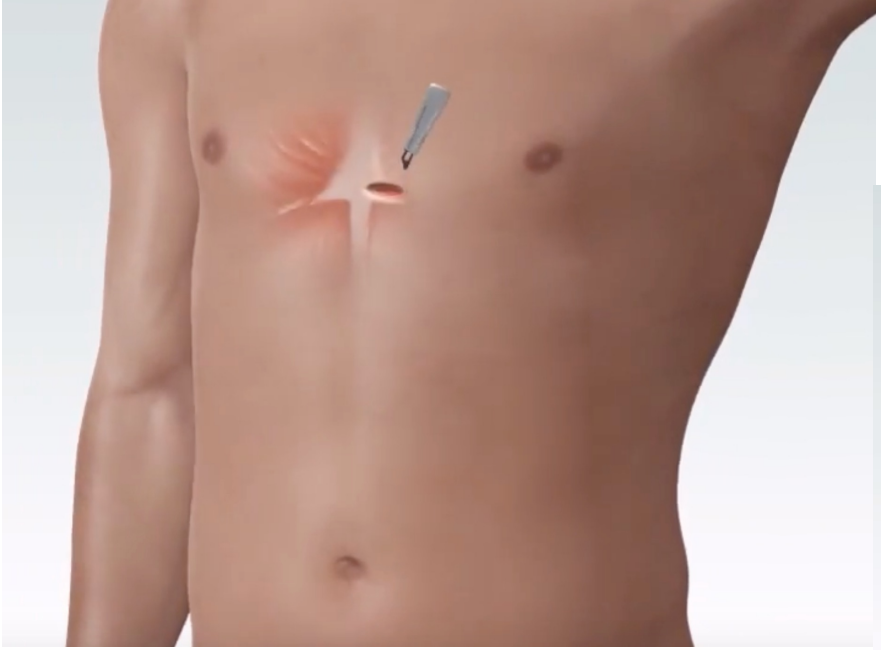


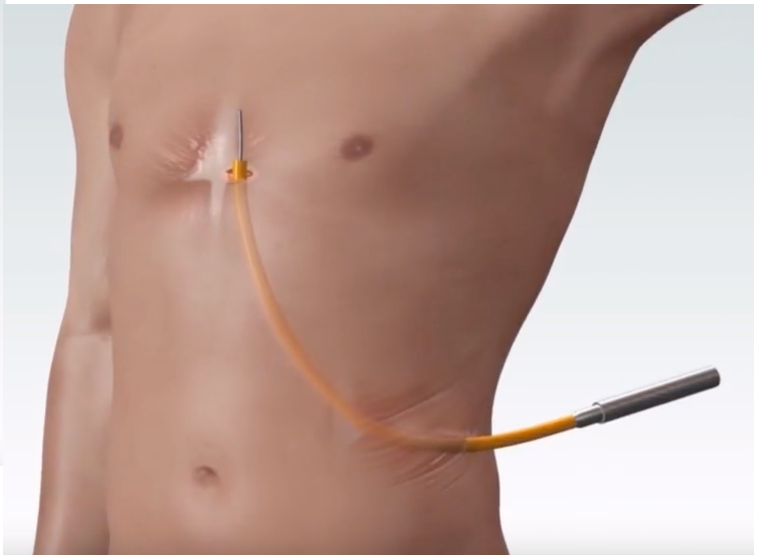
ISSD

Implantable
Sucutaneous
String
Defibrillator

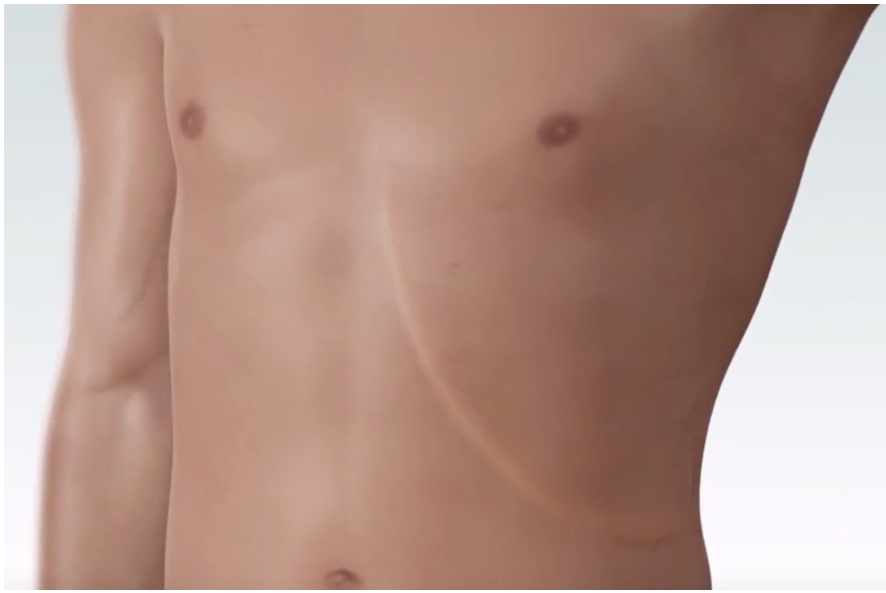
NewPace®

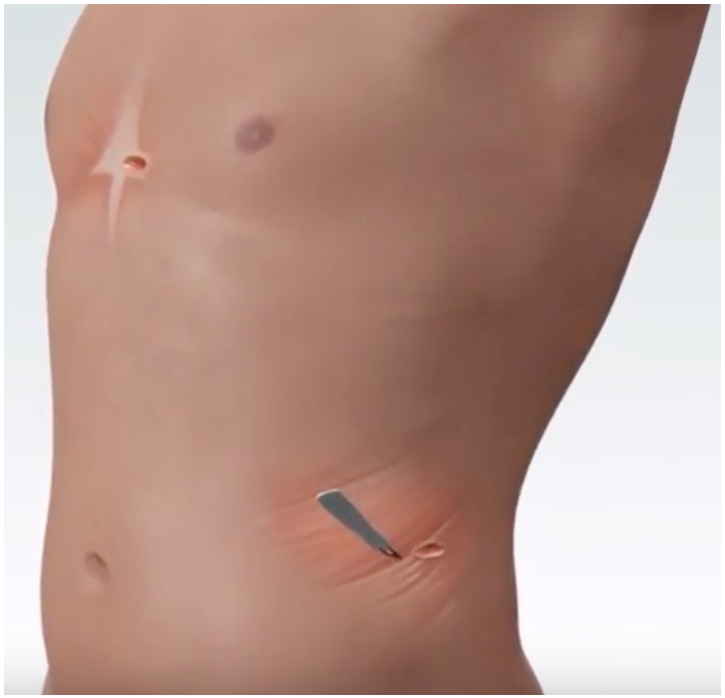
The "String" ICD



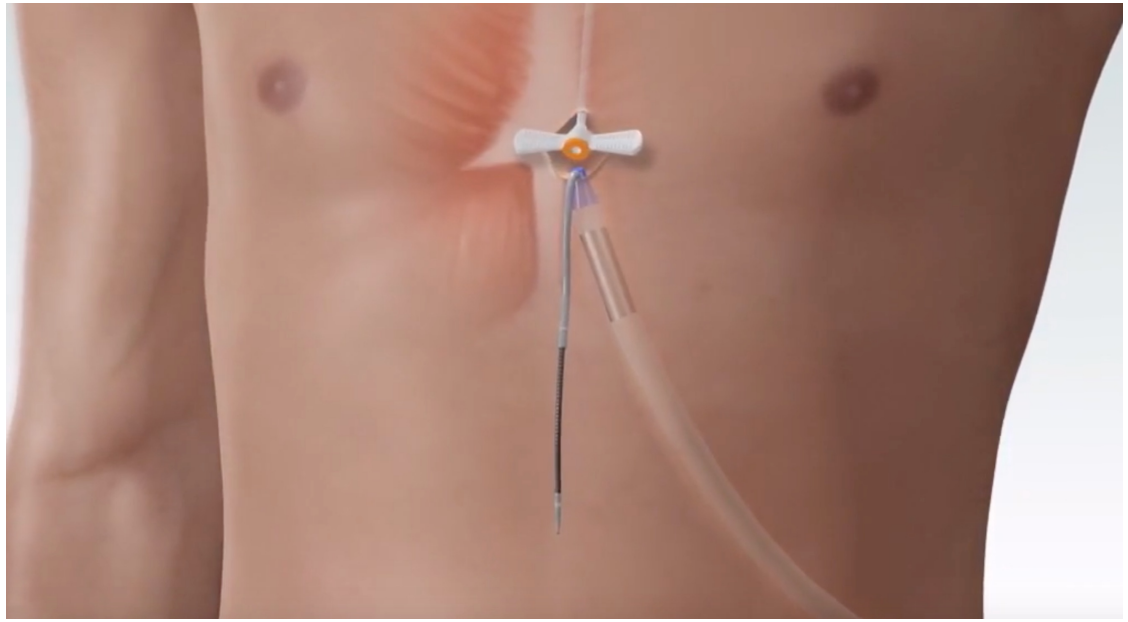


Easy implantation : no pocket





Minimal protrusion
Maximum confort



La fin des sondes endo cavitaires en stimulation cardiaque et défibrillation ?

- **Oui +++ à moyen terme : fin des sondes endocavitaires**

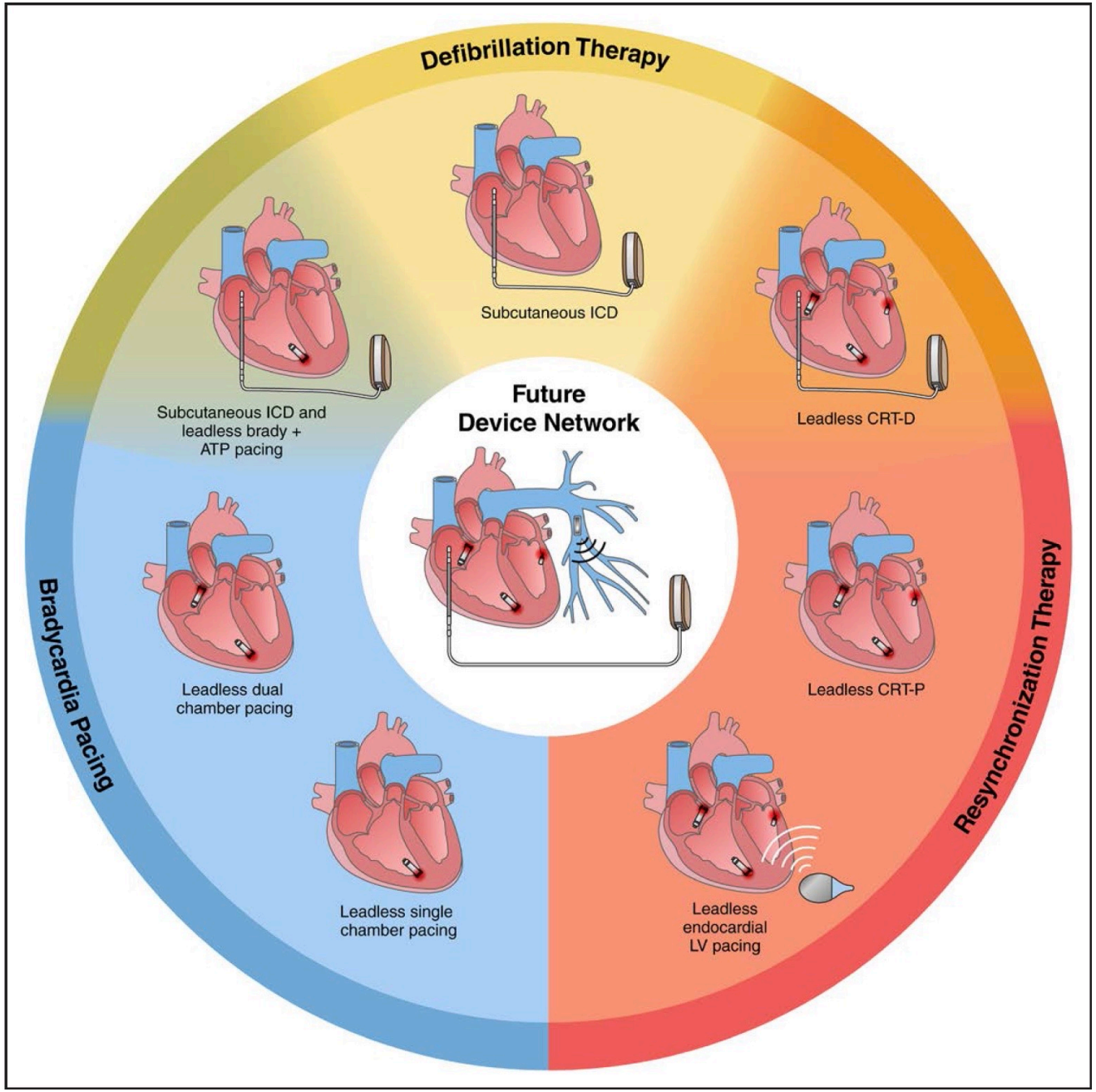
  Maillon faible en PM et DAI

- **Etat de l'art actuel stimulation sans sonde:**
  - **efficacité , sécurité en stimulation VVI**
  - **50% réductions risque / VVI conventionnel**
  - **Extensions des indications : syncope, post infection, congénital malgré indications France HAS/SS restreintes**

- **Développement +++ du DAI sous-cutané : 40% des DAI VVI**

Validation de son efficacité et sécurité : PRAETORIAN, UNTOUCHED

- **Future : association leadless PM + S-ICD → extension des indications**


Defibrillation Therapy
Subcutaneous ICD
Subcutaneous ICD and leadless brady + ATP pacing
Future Device Network
Leadless CRT-D
Leadless dual chamber pacing
Leadless CRT-P
Bradycardia Pacing
Resynchronization Therapy
Leadless single chamber pacing
Leadless endocardial LV pacing