

PLACE

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA

Centro Congressi
di Confindustria

**Auditorium
della Tecnica**

9^a Edizione

**30 Settembre
1 Ottobre
2022**



S-ICD vs ICD: dall'equivalenza alla superiorità

**L'approccio modulare per una terapia personalizzata:
integrazione della tecnologia del leadless pacemaker con quella sottocutanea**

Viani S.
Pisa, Italy



Azienda Ospedaliero Universitaria Pisana





Elettrostimolazione tradizionale: l'Elettrocattetere Transvenoso è «l'anello debole» della catena



Road Map

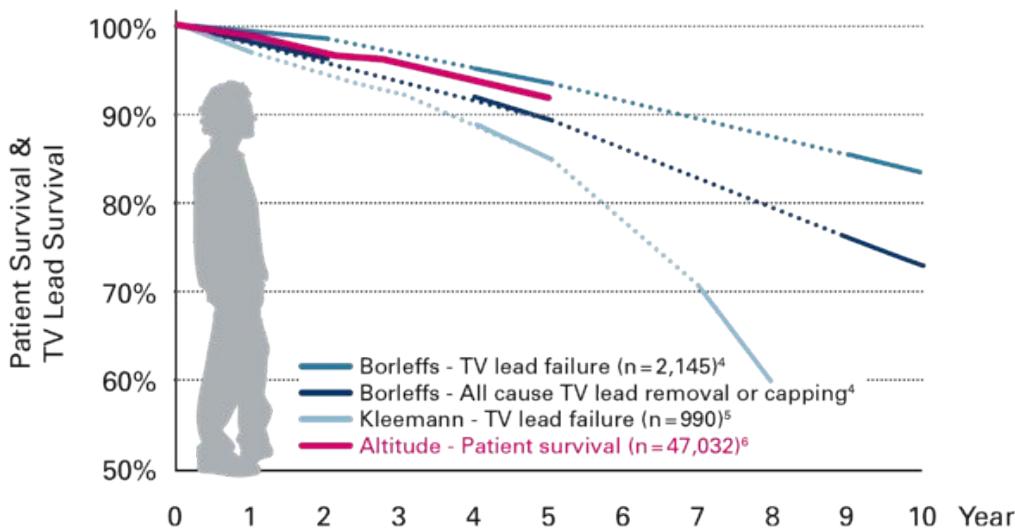


1. Perché immaginare una tecnologia «extravascolare»?
2. SICD e LPM sono compatibili ?
3. Soluzioni & Prospettive



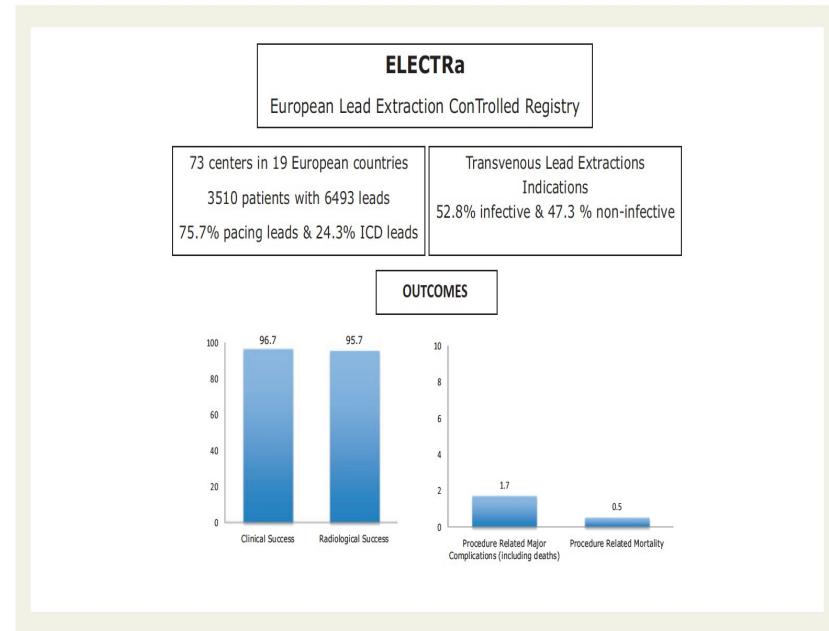
Overcome TV lead failure over time & complications associated with the need for lead extraction

"A lead is not forever" ICD patients, especially if young, are likely to outlive their TV lead



Borleffs CJW et al. Circ Arrhythmia Electrophysiol. 2009; 2:411-416
 Kleemann T et al. Circulation 2007 May 15;115(19):2474-80
 Saxon LA et al. Circulation 2010 Dec 7;122(23):2359-67

TV lead extraction, even in experienced hands, is not without complications



Bongiorni MG et al. European Heart Journal (2017) 38, 2995–3005

Perchè immaginare una tecnologia Extravascolare ?



Overcome inadequate vascular/ventricular access
Reduce events in high CIED infection risk patients



Canadian Journal of Cardiology 2012; 28(10):1210-1212 www.ncbi.nlm.nih.gov

Case Report

Implantable Cardioverter-Defibrillator Insertion in Congenital Heart Disease Without Transvenous Access to the Heart

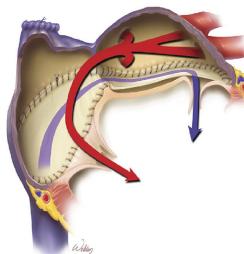
Pablo B. Ney, MD,¹ Martin S. Green, MD,¹ Farid Khairy, MD, PhD,¹ Yahya Alshehbaz, MD,² Paul Hendry, MD,³ and David H. Birnie, MD¹

¹ University of Manitoba, Winnipeg, Manitoba, Canada

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A



B

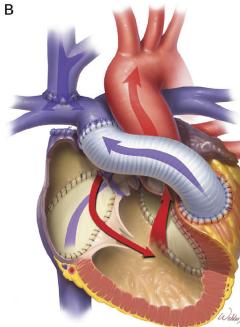
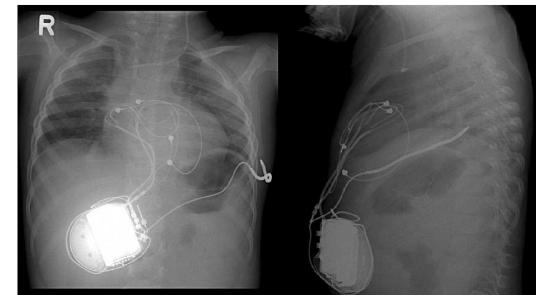


Figure 1. Corrective surgery. (A) Hemi-Mustard atrial redirection procedure together with a bidirectional Glenn shunt; (B) result after placement of homograft from the outflow tract of the right ventricle to the pulmonic artery. Reproduced from D. Barcino et al.² with permission from Cambridge University Press.

Nonthoracotomy Cardioverter Defibrillator Implantation in a 2-Year-Old Infant With Long QT Syndrome

Christian Schreiber, MD, PhD, Martin Kostolny, MD, Andreas Eicken, MD, and Rüdiger Lange, MD, PhD



Nephrol Dial Transplant (2016) 31: 2115–2122
doi:10.1093/ndt/gfw302
Advance Access publication 18 August 2016



Original Articles

Permanent cardiac pacing in patients with end-stage renal disease undergoing dialysis

I-Kuan Wang^{1,2,3}, Kuo-Hung Lin⁴, Shih-Yi Lin^{1,2,3}, Cheng-Li Lin^{3,6}, Chiz-Tzung Chang⁵, Tsung-Hai Yen^{7,8} and Fung-Chang Sung^{1,9}

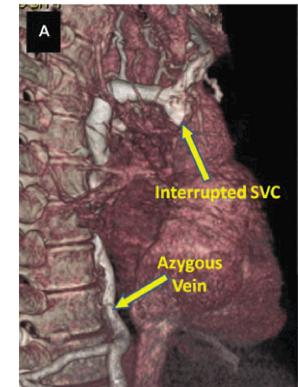
¹ Graduate Institute of Clinical Medical Science, China Medical University, Taichung, Taiwan, ² Department of Internal Medicine, College of Medicine, China Medical University, Taichung, Taiwan, ³ Department of Nephrology, Taichung Veterans General Hospital, Taichung, Taiwan, ⁴ Department of Cardiology, China Medical University Hospital, Taichung, Taiwan, ⁵ Management Office of the Hospital, China Medical University Hospital, Taichung, Taiwan, ⁶ College of Medicine, China Medical University, Taichung, Taiwan, ⁷ Division of Nephrology, Chang Gung Memorial Hospital, Taipei, Taiwan, ⁸ Chang Gung University College of Medicine, Taoyuan, Taiwan and ⁹ Department of Health Services Administration, China Medical University, Taichung, Taiwan

- Complex congenital heart disease
- Paediatric patients
- Congenital/acquired venous obstruction
- **High CIED infection risk patients**

Subcutaneous ICD Implantation in the Setting of an Occluded Superior Vena Cava

PETR NEUZIL, M.D., Ph.D.,^{*} JAN PETRU, M.D.,^{*} and VIVEK Y. REDDY, M.D.,^{*,†}

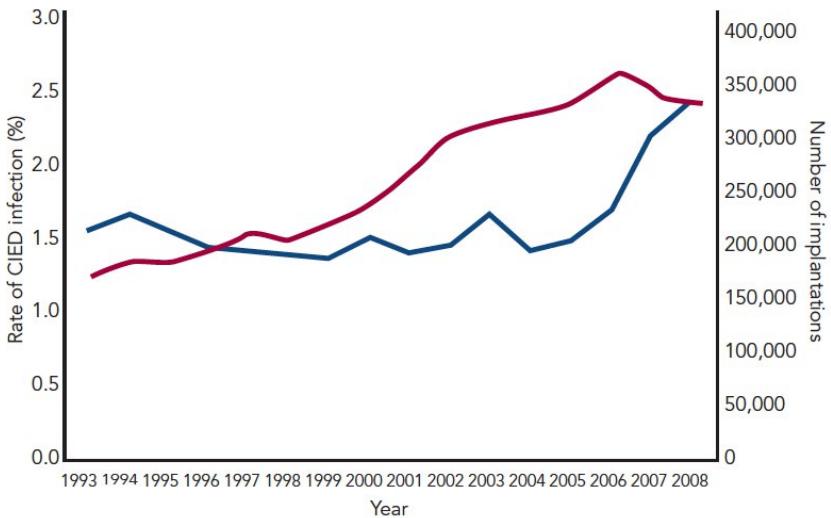
^{*}Department of Cardiology, Homolka Hospital, Prague, Czech Republic; and [†]Cardiac Arrhythmia Service, Mount Sinai Hospital, New York City, New York, USA





CIED infection: the size of the problem

Figure 1: Increasing Burden of CIED Infections with Time



Blue line = rate of CIED infection (%); Red line = number of implantations. Adapted from Greenspon et al., 2011.⁴

High Infective risk patients

- Young patients (more replacements expected)
- Recurrent infective disease
- Prosthetic valves
- Renal insufficiency (chronic dialysis)
- Diabetes
- Chronic anticoagulation (risk of pocket haematoma)
- *After TV lead extraction due to infection*





The NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

An Entirely Subcutaneous Implantable Cardioverter-Defibrillator

Gust H. Bardy, M.D., Warren M. Smith, M.B., Margaret A. Hood, M.B., Ian G. Crozier, M.B., Iain C. Melton, M.B., Luc Jordaens, M.D., Ph.D., Dominic Theuns, Ph.D., Robert E. Park, M.B., David J. Wright, M.D., Derek T. Connolly, M.D., Simon P. Flynn, M.D., Francis D. Murgatroyd, M.D., Johannes Sperzel, M.D., Jörg Neuzner, M.D., Stefan G. Spitzer, M.D., Andrey V. Ardashev, M.D., Ph.D., Amro Oduro, M.B., B.S., Lucas Boersma, M.D., Ph.D., Alexander H. Maass, M.D., Isabelle C. Van Gelder, M.D., Ph.D., Arthur A. Wilde, M.D., Ph.D., Pascal F. van Dessel, M.D., Reinoud E. Knops, M.D., Craig S. Barr, M.B., Pierpaolo Lupo, M.D., Riccardo Cappato, M.D., and Andrew A. Grace, M.B., Ph.D.

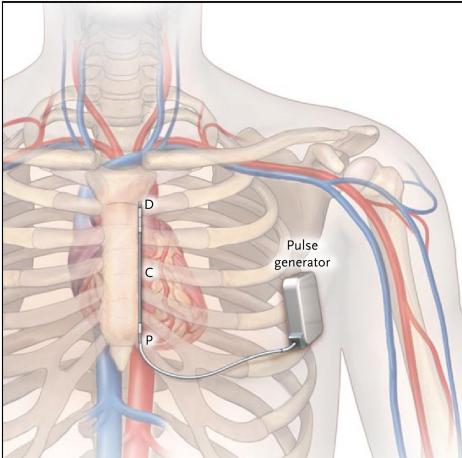


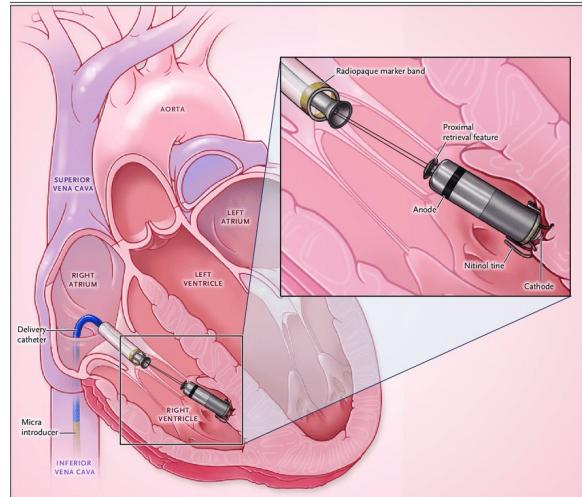
Figure 2. Locations of the Components of a Subcutaneous Implantable Cardioverter-Defibrillator in Situ.

The distal and proximal sensing electrodes (D and P, respectively) of the LGen-S8 device are shown, with the left lateral pulse generator and an 8-cm parsternal coil electrode (C).

ORIGINAL ARTICLE

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., Calamuber 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. Bernabe, 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*



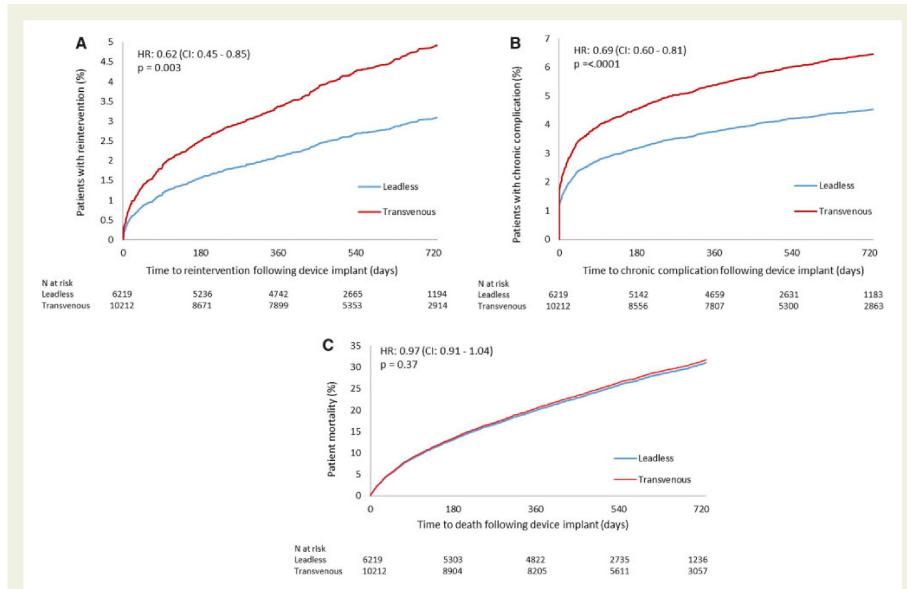
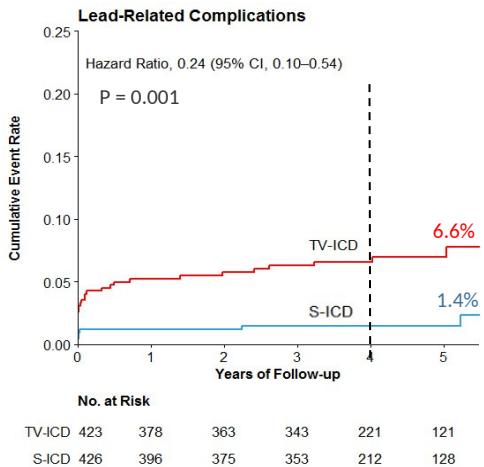
The NEW ENGLAND JOURNAL of MEDICINE

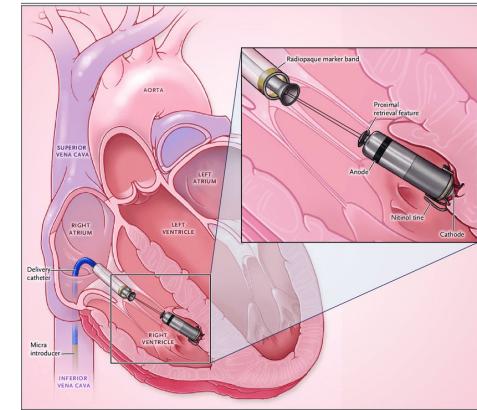
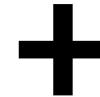
ORIGINAL ARTICLE

Subcutaneous or Transvenous Defibrillator Therapy

Years of Follow-up	TV-ICD Cumulative Event Rate (%)	S-ICD Cumulative Event Rate (%)
0	0.00	0.00
1	~0.10	~0.08
2	~0.13	~0.11
3	~0.15	~0.13
4	~0.18	~0.15
5	15.7%	15.1%

Primary Composite Endpoint
 Inappropriate shocks and complications
 Hazard Ratio, 0.99 (95% CI, 0.71–1.39)
 P = 0.01 for noninferiority







S-ICD Pisa Experience (from April 2011 to December 2021)



Population and characteristics

N = 213

Age, y (range)	46 ± 13 (14 -81)
Male, n (%)	163 (77)
Mean EF	46.4 ± 13
EF \leq 35%	37%
Primary prevention	66%
Secondary prevention, n (%)	34%
De novo implant	57%
Previous lead extraction, n (%)	43%
Inter-muscular position, n (%)	89% (100% from 2015)
2 incisions technique	78% (98% from 2015)
Hybrid implant (S-ICD + LPM MDT MICRA) n (%)	8 (3.7)



Pt	Sex	Age	EF	Heart disease	PM indication	ICD indication	Previous CIED Extr.	Reasons for SICD/LPM	SICD first*	LPM first	Simul (<48 h)	FU months	SICD shock A/I	LPM Perf.
AS	M	58	55	HCMO	III AVB	I PREV	Y	VO (SVCS) + HIR (CIED infection) VO + HIR (CIED infection)	Y	-	-	59	N	OK
GM	M	71	35	CAD	III AVB	II PREV	Y	VO (SVCS)	-	-	Y	53	N	OK
DG	M	74	50	DCM	RBBB + LFB	II PREV	Y	VO	Y	-	Y	60	N	OK+
DBG	M	65	50	VALV + CAD	AF BRADY	II PREV	Y	VO + HIR (CIED infection)	-	-	-	43	N	OK
VS	M	82	30	DCM	III AVB	I PREV	Y	HIR (CIED infection)	Y	-	Y	38	N	OK
DGG	M	83	35	CAD	AF BRADY	II PREV	Y	HIR (ESRD)	Y	-	-	38	N	OK
LFA	M	74	30	CAD	SND	II PREV	N	Pt preference	Y	-	-	21	N	OK
GF	M	80	52	HCM	AF BRADY	I PREV	N	SICD>LPM* 2-5 years	62.5	-	-	9		
%	100						75				37.5	40+18		



This 3 year follow up data demonstrates that the need for pacing after implant of the S-ICD continues to be low

EFFORTLESS¹

S-ICD Pooled Data² Number/(% of Patients)

Extraction of S-ICD for new Pacing Indication	1/ (0.1%)	1/(0.1%)
Extraction of S-ICD for new ATP Indication	5 (0.5%)	1/(0.1%)
Extraction of S-ICD for new CRT Indication	4 (0.4%)	1/(0.1%)

1. Boersma et al Performance and outcomes in patients with the Subcutaneous Implantable Cardiac Defibrillator Mid-term follow-up. May 6th 2016 HRS LBCT1
2. Burke MC et al. Pooled Analysis of the EFFORTLESS and IDE Registry.



Mean follow-up was 40 ± 18 months

1 death ESHF

No device related complications

No device cross talks

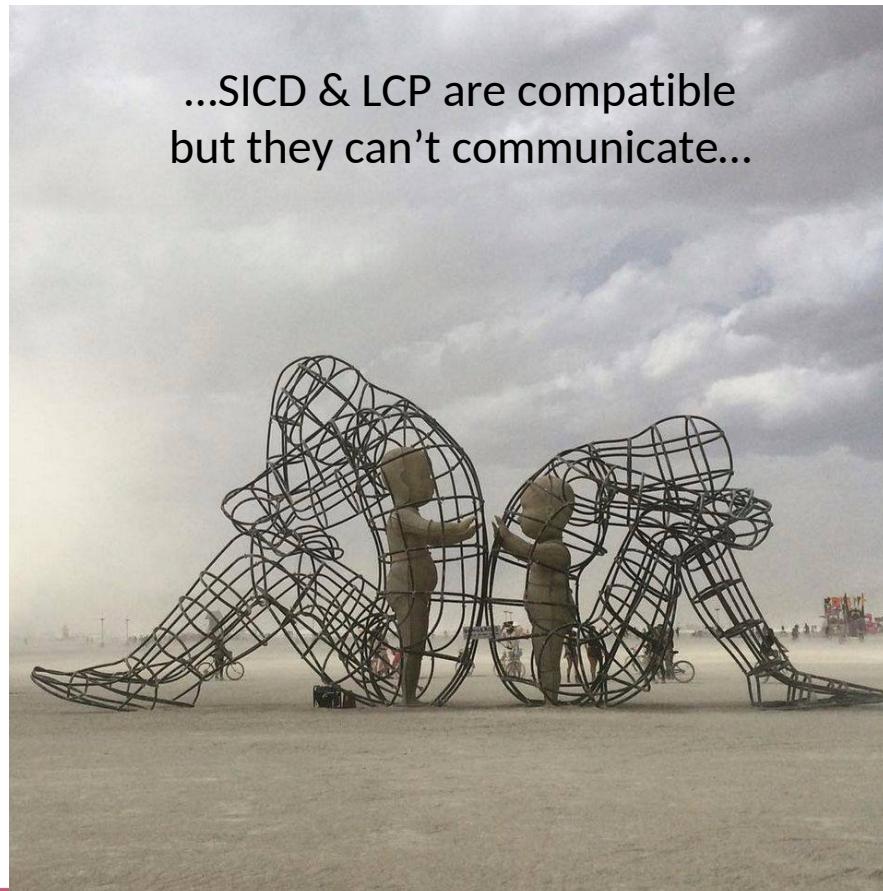


SICD limitations

- No pacing
- No ATP

LIMITATIONS

...SICD & LCP are compatible
but they can't communicate...



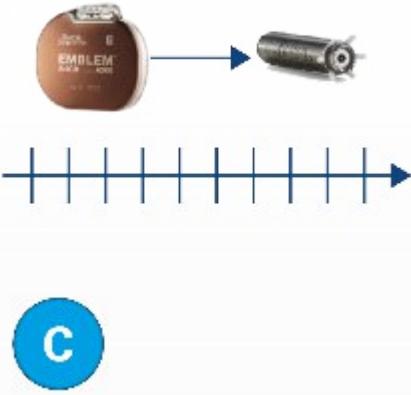
LPM limitations

- No Atrial pacing
- No AV synchr. (?)
- No LV pacing



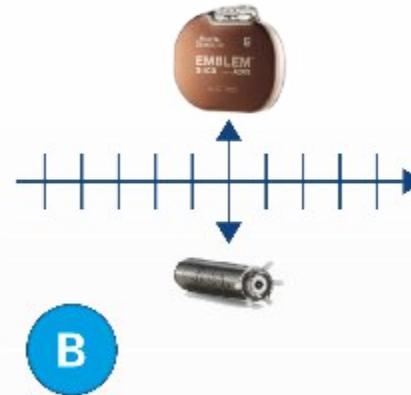
Modular CRM System* (mCRM): Leadless pacemaker (LCP) and S-ICD designed to deliver co-ordinated pacing and ATP

Overview of intended functionality and compatibility



- S-ICD implanted first
- LP implanted later

Potential application for patient with ICD indication at implant, who later develops a need for pacing.



- LP and S-ICD implanted together

Potential application for patient with pacing and ICD indication at implant.

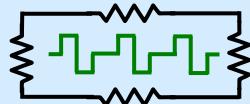


- LP implanted first
- S-ICD implanted later

Potential application for patient with pacing need, but no ICD indication at implant.

Modular CRM System Components

Communication Link



Pulse Generator



Delivery



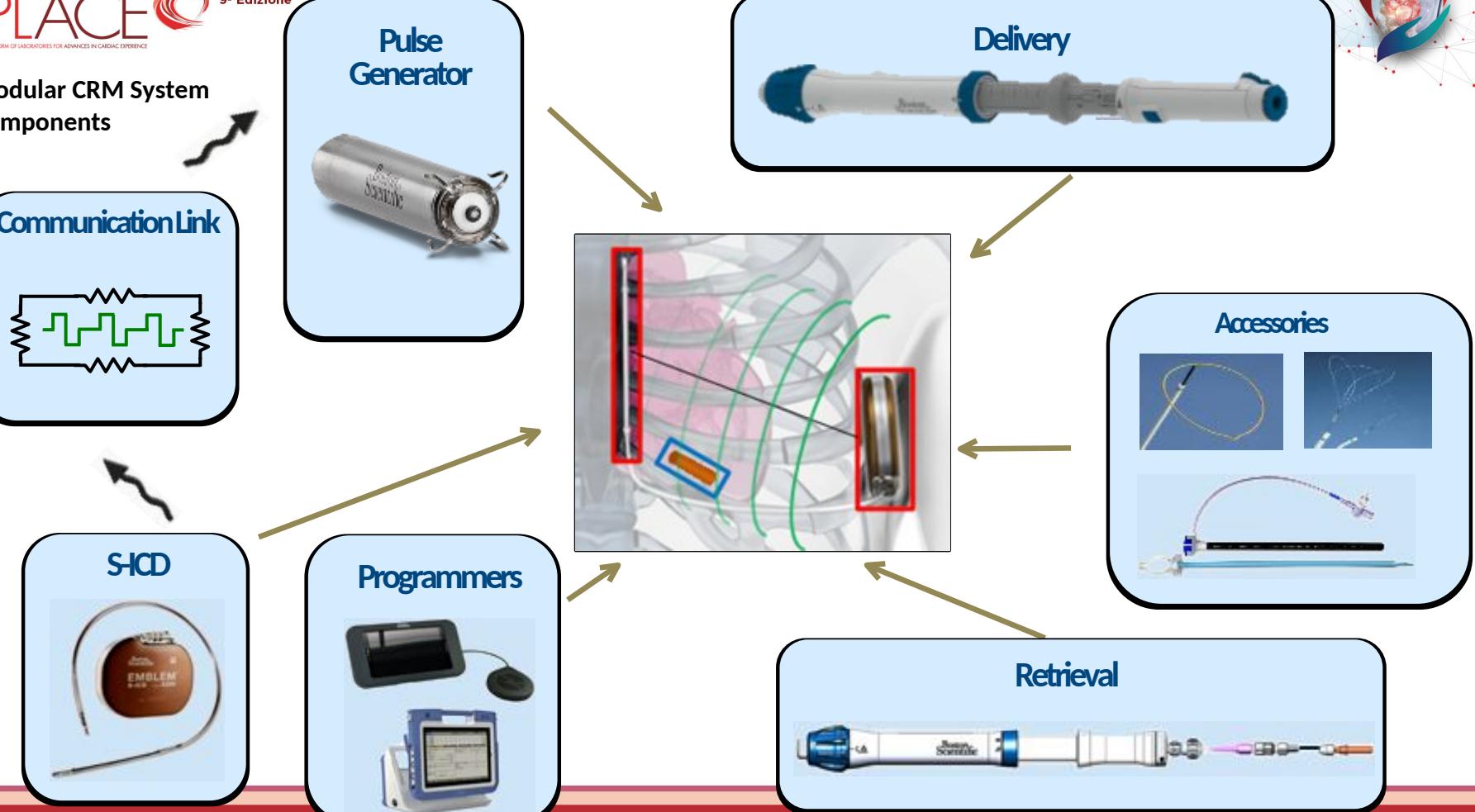
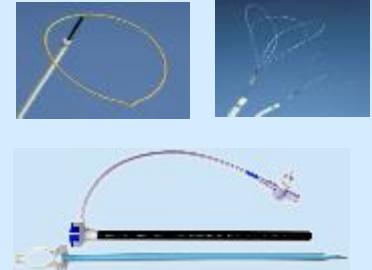
S-ICD



Programmers



Accessories

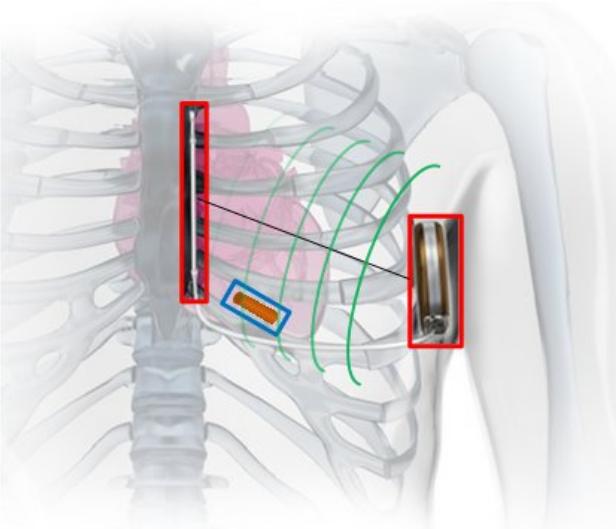


Retrieval



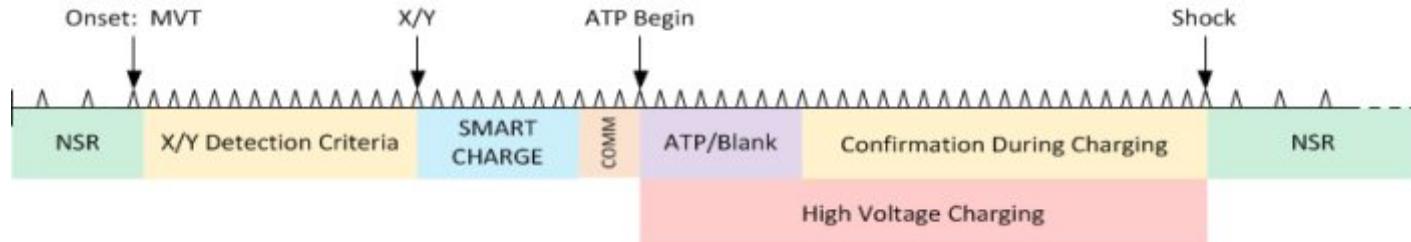


Operation of the Modular CRM System



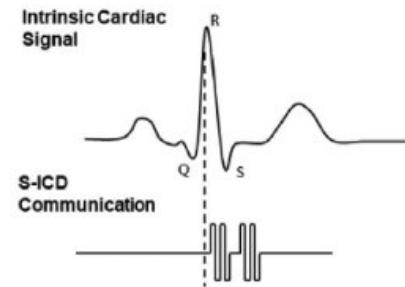
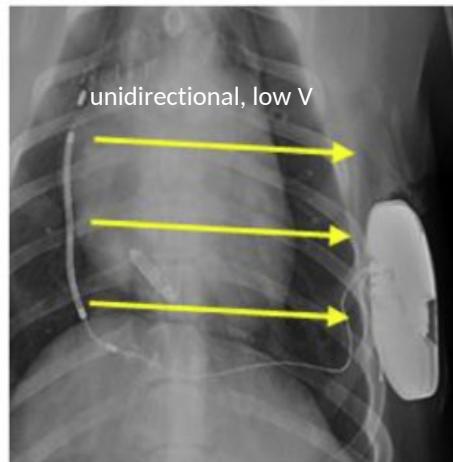
1. Leadless pacemaker designed to sense and treat **bradycardia** independently from the S-ICD
2. ATP schemes will be built into the leadless pacemaker, but can be activated only by the S-ICD or the programmer
3. S-ICD will continue to sense tachycardia, following which it is designed to command ATP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

Example of ATP during charge in the Shock Zone



Long-term performance of a novel communicating antitachycardia pacing-enabled leadless pacemaker and subcutaneous implantable cardioverter-defibrillator system: A comprehensive preclinical study

Karel T.N. Breeman, MD,* Bryan Swackhamer, BSCE,† Amy J. Brisben, PhD,† Anne-Floor B.E. Quast, MD, PhD,* Nathan Carter, MS,† Allan Shuros, MS,† Brian Soltis, MS,‡ Brendan E. Koop, PhD,‡ Martin C. Burke, DO,‡ Arthur A.M. Wilde, MD, PhD,* Fleur V.Y. Tjong, MD, PhD,*¹
Reinoud E. Knops, MD, PhD*¹



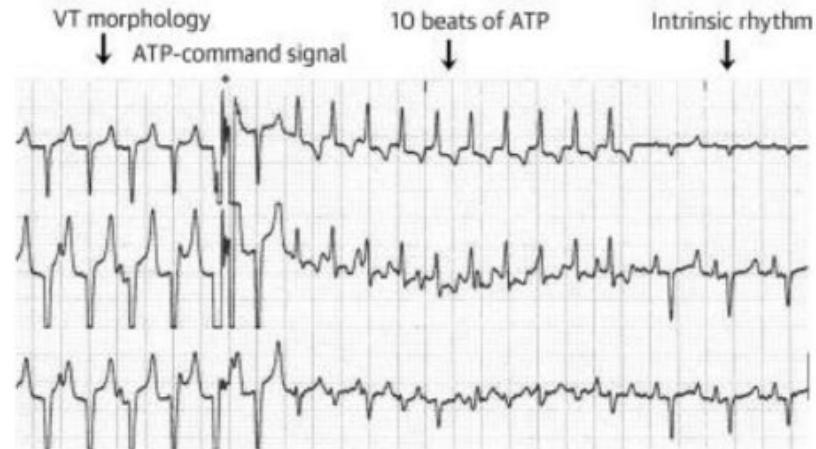
- Communication coupled to sensed R-wave
- Emitted signals are approximately 0.5-4V amplitude and 25kHz frequency
- Built-in redundancy of 2 messages sent

38 SICD + LPM canine subjects
Evaluated up to 18 months

Results

- mCRM communication success 99.8% (1022/1024)
- Mean CT at 18 m: 1.8 ± 0.7 V (> parallel < CT)
- P/R/I 18 m: 0.7 ± 0.4 V, 619.1 ± 90.6 U, and 20.1 ± 8.4 mV

Modified from Heart Rhythm 2022;19:837-846



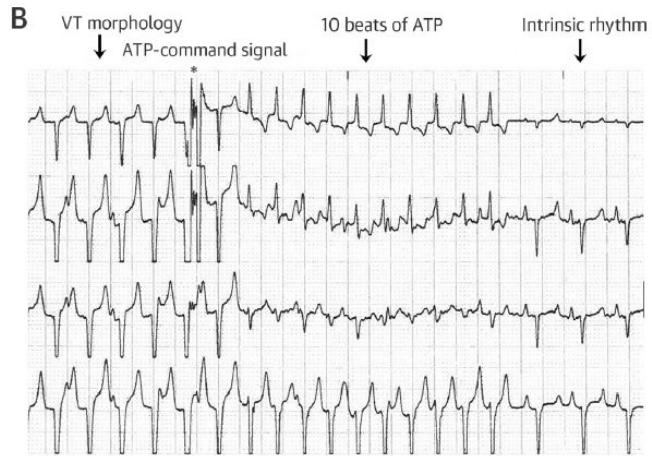
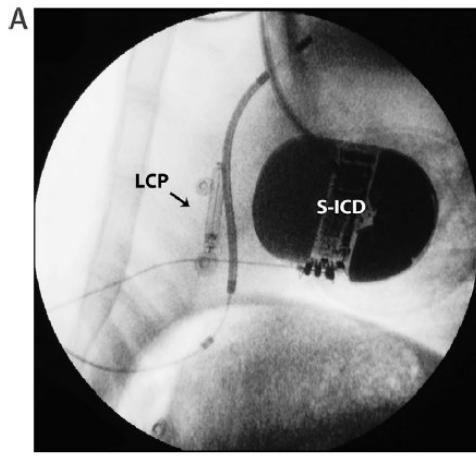
Communicating Antitachycardia Pacing-Enabled Leadless Pacemaker and Subcutaneous Implantable Defibrillator

CrossMark

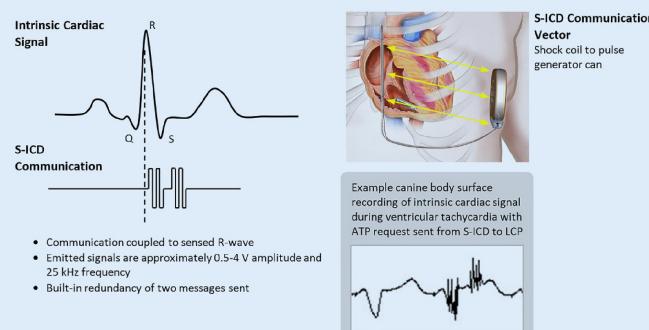
Table 1 Acute and 3-month EMPOWER LCP performance showing favorable pacing and sensing performance over the course of the study. Values are n (%) or mean \pm standard deviation

	Acute Performance (n = 40)			3-Month Performance (n = 23)			<i>p</i> Value
	Baseline	Ovine (n = 8)	Swine (n = 5)	Canine (n = 27)	7 Days	28 Days	
Implant Success	8 (100)	5 (100)	26 (96)	—	—	—	—
LCP Position							
RV Apex	8 (100)	4 (80)	12 (46)	—	—	—	—
RV Apical Septum	0	0	14 (54)	—	—	—	—
RV Outflow Tract	0	1 (20)	0	—	—	—	—
LCP Electrical Performance (n = 8)	(n = 5)	(n = 26)	(n = 23)	(n = 23)	(n = 23)	(n = 23)	
Pacing Threshold, V at 0.5 ms	1.10 \pm 0.81	0.53 \pm 0.49	0.37 \pm 0.19	0.56 \pm 0.37 ^b	0.54 \pm 0.30 ^b	0.72 \pm 0.45 ^{b,c}	<0.001
R-Wave Amplitude, mV	6.6 \pm 1.4	28.3 \pm 5.8	25.8 \pm 5.1 ^d	26.3 \pm 6.8 ^d	25.0 \pm 9.4 ^d	23.3 \pm 9.4	<0.001
Impedance, Ω	665 \pm 225	753 \pm 118	826 \pm 171 ^d	785 \pm 129 ^d	827 \pm 105 ^d	728 \pm 141 ^c	0.04
LCP Post Shock Performance (n = 8)	(n = 2)	(n = 1)	(n = 1)			(n = 7)	
Pre- to Post Shock Change in Pacing Threshold, V at 0.5 ms	0.0 \pm 0.5	0.1 \pm 0.1	0	—	—	0.0 \pm 0.1	—
Pre- to Post-Shock Change in Impedance, W	18 \pm 49	26 \pm 40	5	—	—	-48 \pm 58	—

FIGURE 1 Combined Implant of ATP-Enabled Leadless Cardiac Pacemaker and S-ICD



(A) Combined implantation of the leadless cardiac pacemaker (LCP) prototype in right ventricular apex and subcutaneous implantable cardioverter-defibrillator (S-ICD) in sheep. **(B)** Episode of simulated ventricular tachycardia (VT) (left ventricular pacing) followed by manually triggered S-ICD anti-tachycardia pacing (ATP)-command resulting in successful ATP-delivery by the LCP (10 beats, at 81% of coupling interval).



Implanted A209/A219 S-ICD are upgradable via firmware



Try the modernized [ClinicalTrials.gov beta](#) website. Learn more about the [modernization effort](#).

U.S. National Library of Medicine
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Effectiveness of the EMPOWER™ Modular Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing (MODULAR ATP)

A The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [Disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT04798768

Recruitment Status Active, not recruiting
First Posted March 15, 2021
Last Update Posted June 3, 2022

2 Protocol Synopsis

MODULAR ATP Clinical Study

Effectiveness of the EMPOWER™ Modular Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing

Sponsor:
Boston Scientific Corporation

Information provided by (Responsible Party):
Boston Scientific Corporation

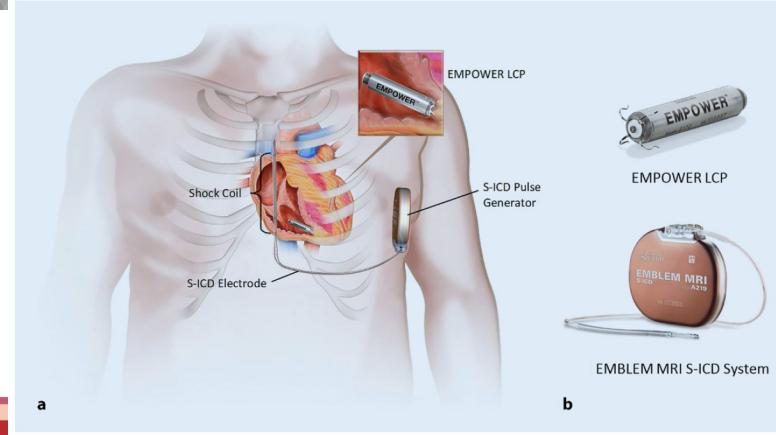
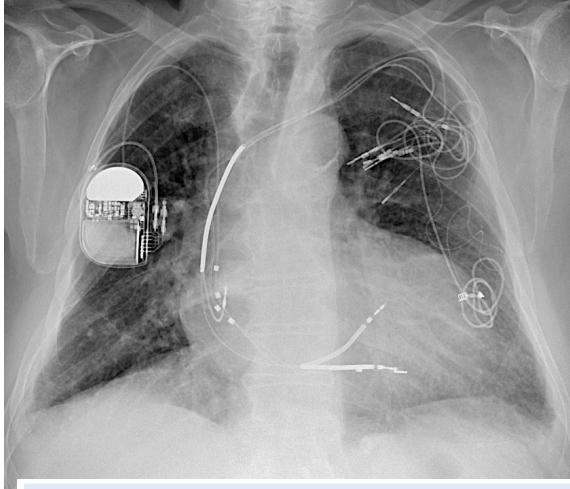
[Study Details](#) [Tabular View](#) [No Results Posted](#) [Disclaimer](#)

MODULAR ATP Clinical Study

Effectiveness of the EMPOWER™ Modular Pacing System and EMBLEM™ Subcutaneous ICD to Communicate Antitachycardia Pacing

C1907
CLINICAL INVESTIGATION PLAN

Study Objectives	To demonstrate the safety, performance and effectiveness of the EMPOWER™ Modular Pacing System (MPS), as well as the EMPOWER and EMBLEM™ Subcutaneous ICD Coordinated System. Additionally, data from this study may be used to support pre-market and post-market approval requirements for the EMPOWER MPS.
Planned Indication(s) for Use	The mCRM Modular Therapy System is intended to provide: <ul style="list-style-type: none"> Defibrillation (tachyarrhythmia) therapy from the S-ICD, which is used to treat rhythms associated with sudden cardiac death (SCD), such as VT and VF Anti-tachycardia pacing (ATP) therapy, commanded from the S-ICD and provided from the EMPOWER System for the treatment of MVT Anti-bradycardia pacing from the EMPOWER System to detect and treat bradyarrhythmias and to provide pacing support after defibrillation therapy

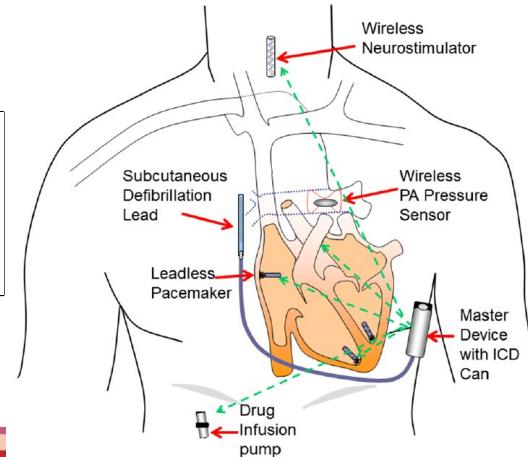
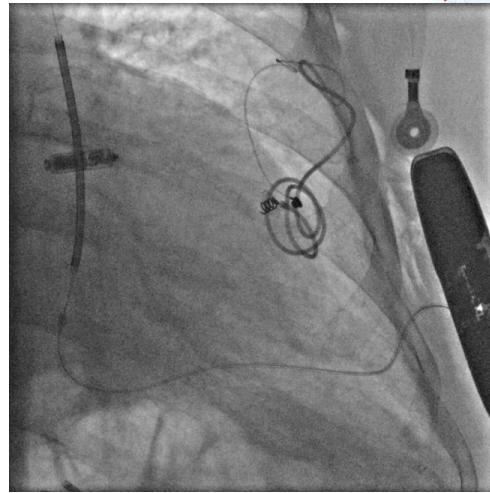


The Future

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*Maastricht Heart Center, Department of Clinical and Experimental Cardiology, Amsterdam University Medical Center, Location Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands
†Boston Scientific Corporation, St. Paul, USA

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

The Present





PRECISION MEDICINE *(when one size doesn't fit all: the Modular approach)*

Most medical treatments are designed for the "average patient" as a one-size-fits-all-approach, which may be successful for some patients but not for others.

Precision medicine is an innovative approach to tailoring disease prevention and treatment that takes into account differences in people's genes, environments, and lifestyles.

The goal of *precision medicine* is to target the

- *right treatments*
- *to the right patients*
- *at the right time.*

FDA Definition