

Empower & Modular ATP S-ICD

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MODULAR ATP



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ORIGINAL ARTICLE



A Modular Communicative Leadless Pacing– Defibrillator System

Authors: Reinoud E. Knops, M.D., Ph.D., Michael S. Lloyd, M.D., Paul R. Roberts, M.D., David J. Wright, M.D., Lucas V.A. Boersma, M.D., Ph.D., Rahul Doshi, M.D., Paul A. Friedman, M.D., [-34](#), for the MODULAR ATP Investigators* [Author Info & Affiliations](#)

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EMBLEM™ S-ICD + **EMPOWER™**
A209 and A219 Systems Leadless Pacemaker



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EMBLEM™ S-ICD Is Designed to be Compatible with the EMPOWER™ Leadless Pacemaker

TODAY'S S-ICD



S-ICD implant today is intended to be compatible with the EMPOWER™ leadless pacemaker (began trials in 2019)

FUTURE S-ICD Implantable Device Prototypes



**EMPOWER™ Modular Pacing & ATP System
EMBLEM™ Family of S-ICDs**



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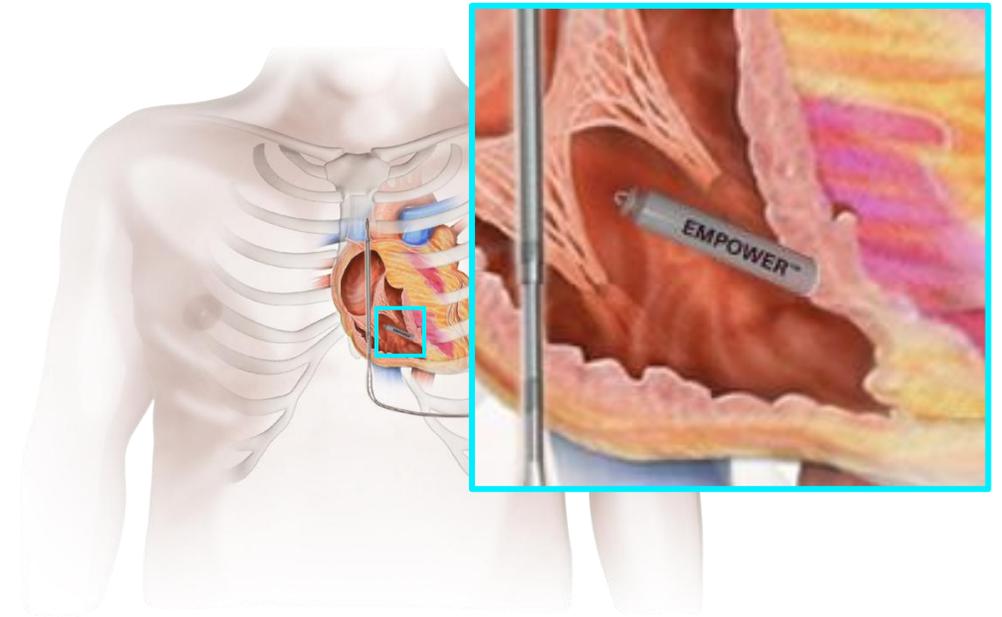


The EMPOWER LP Delivers Painless Intracardiac ATP Therapies

- The EMPOWER LP is designed to deliver intracardiac ATP and brady pacing therapy that should not lead to pain or discomfort, in contrast to extracardiac pacing

No patient in the 6-month endpoint cohort:

- Reported pain or discomfort during communication or ATP therapy from the LP.
- Requested LP therapy be turned off for any reason.

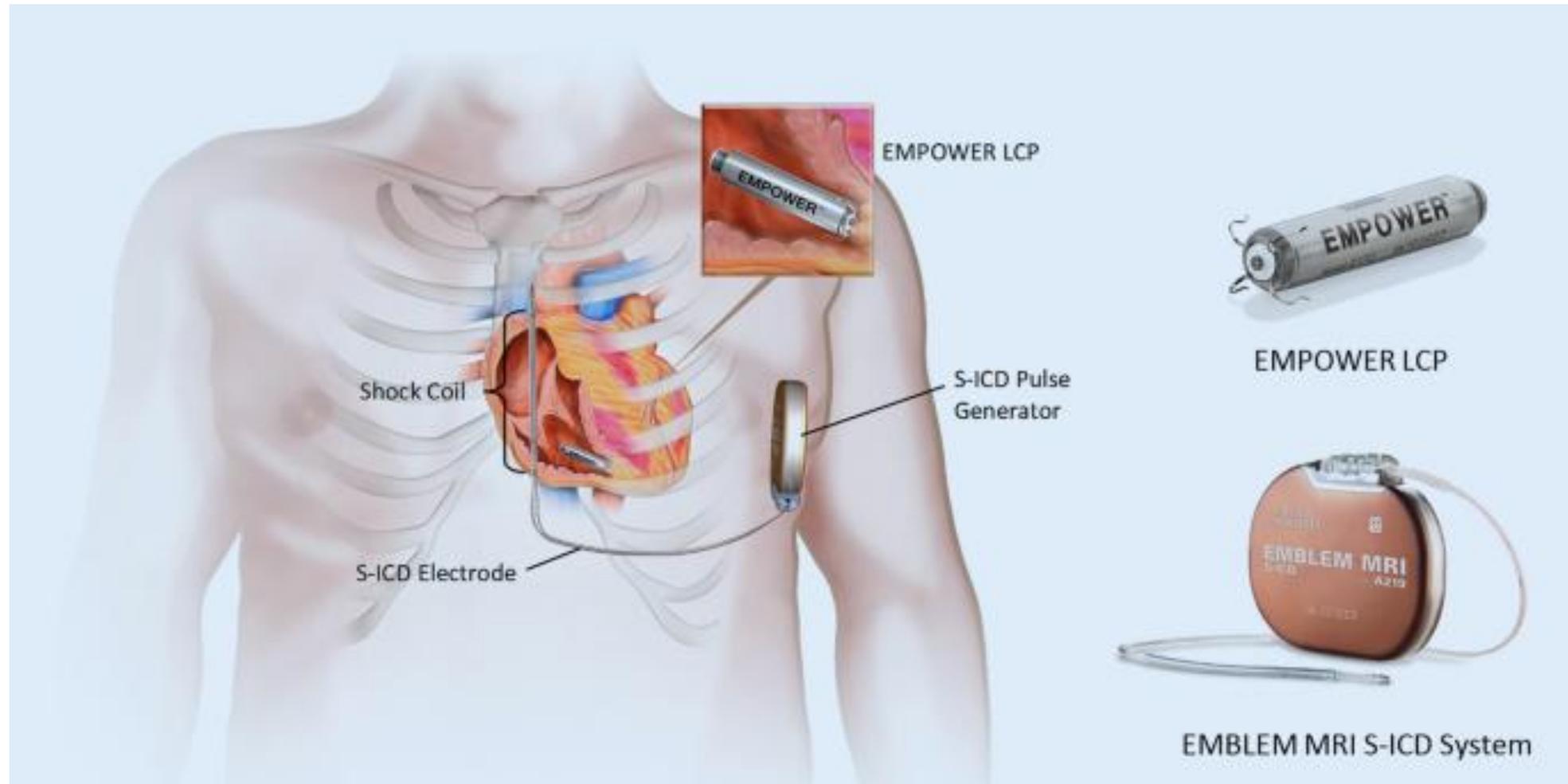


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Pivotal MODULAR ATP Trial



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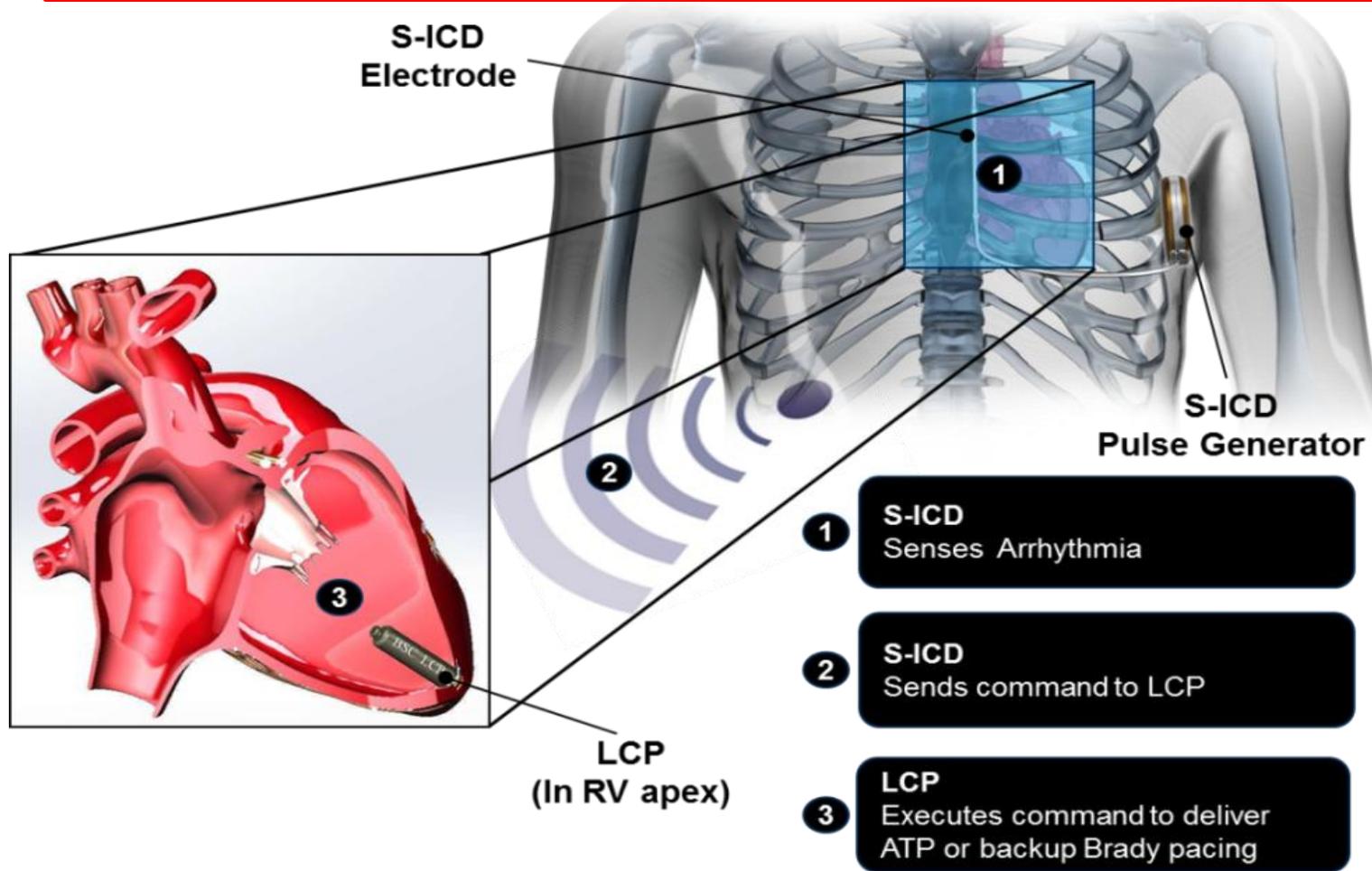
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Leadless & S-ICD

Functional Integration



FUTURE S-ICD Implantable Device Prototypes



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Leadless brady & ATP & S-ICD

Implantable Devices



EMPOWER™ Modular Pacing System
EMBLEM™ Family of S-ICDs

EMPOWER™ Details

32.1 mm x 6 mm
0.8 cc

Active fixation talons
Tether / Snare port



EMPOWER™ Delivery and Retrieval



Preloaded delivery
catheter with
extendable inner
catheter



Dedicated
retrieval system with single
& tri-loop snares



Dedicated delivery and retrieval catheters

Programmiers

Model 3200 S-ICD Programmer



Next Generation
BSC 3300 LATITUDE
Programming System



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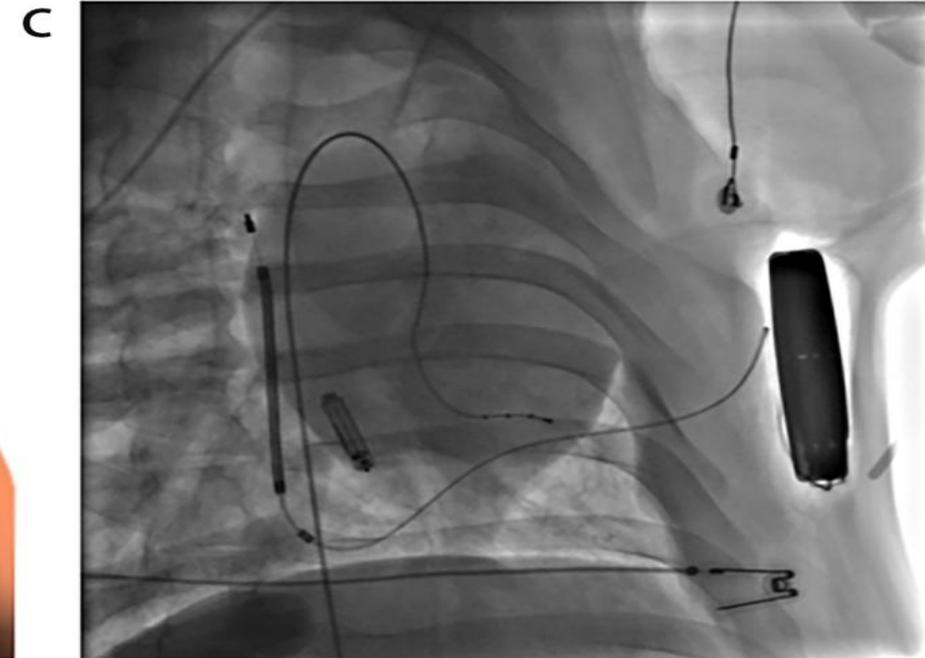
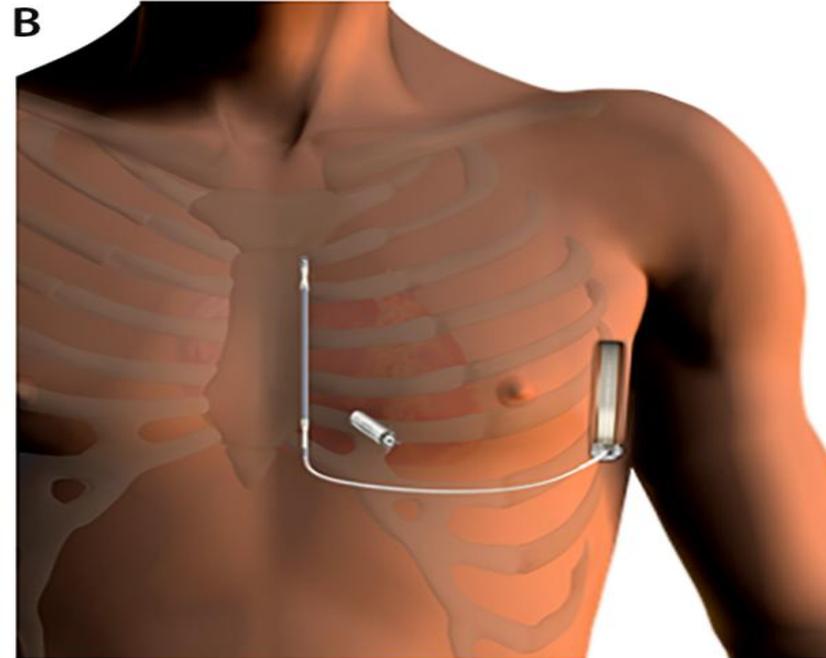
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Leadless ATP & S-ICD Communication:

Preclinical Study

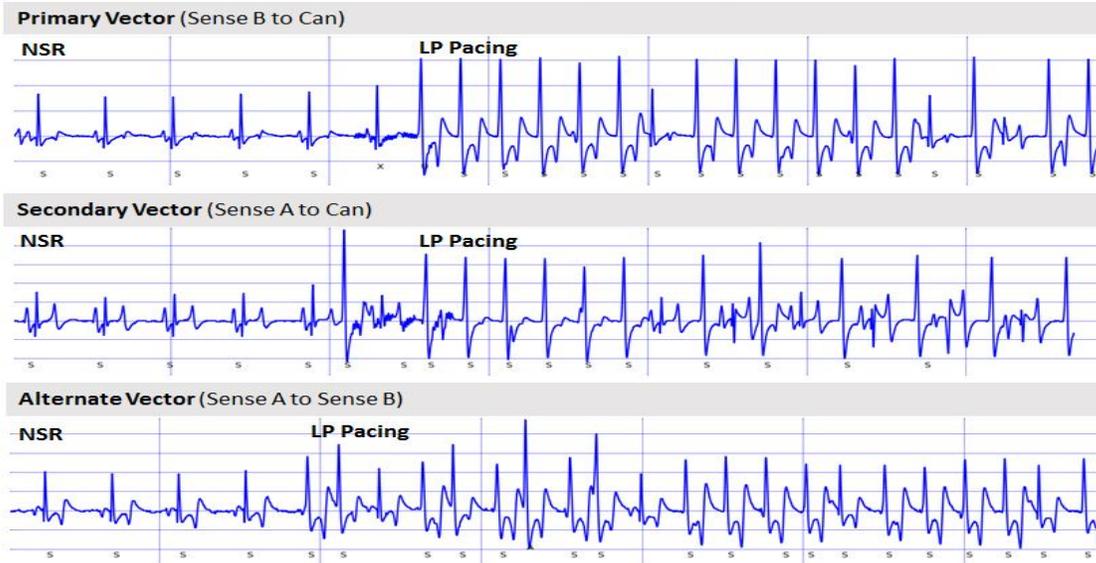
Koncept: Leadless Systém umožňuje brady pacing, ATP a defibrilaci



Leadless ATP & S-ICD Communication:

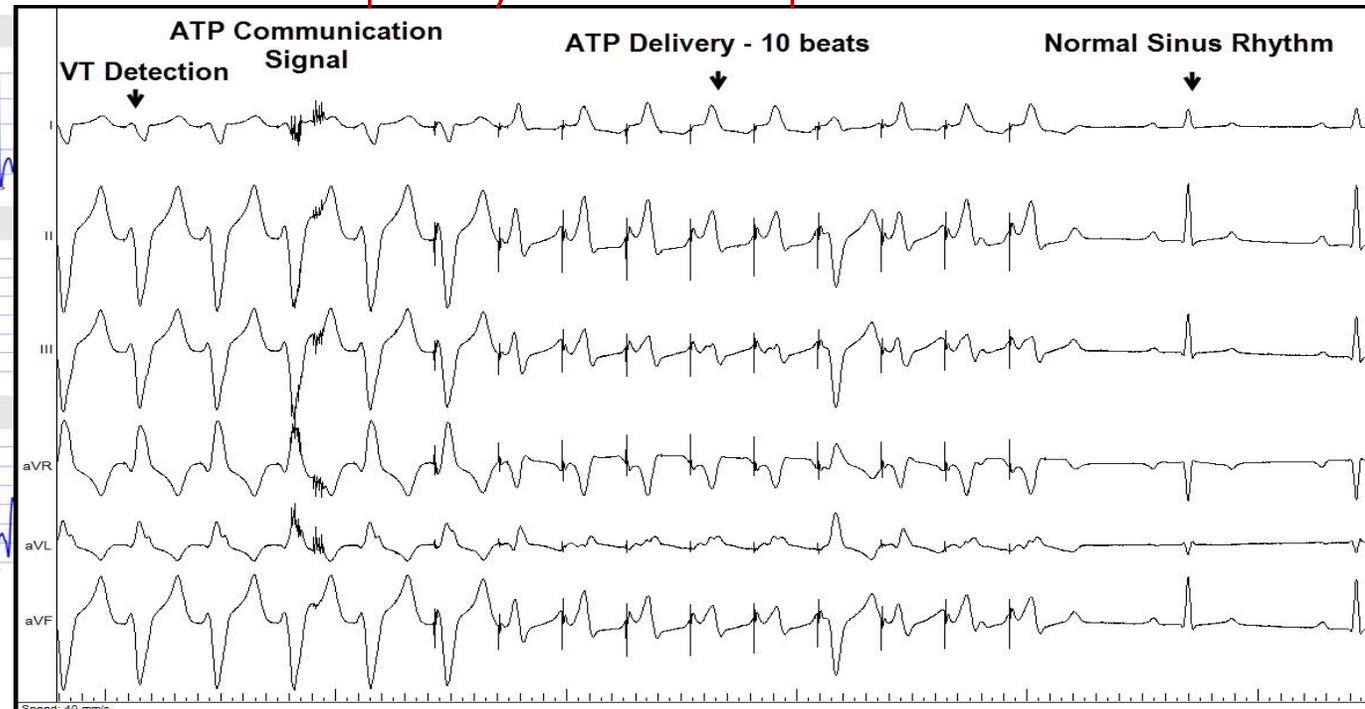
Preclinical Study

S-ICD diskriminace rytmu při stimulaci



Tjong F.V.Y. et. al., JACC:CE

ATP terapie vydaná LCP při detekci S-ICD

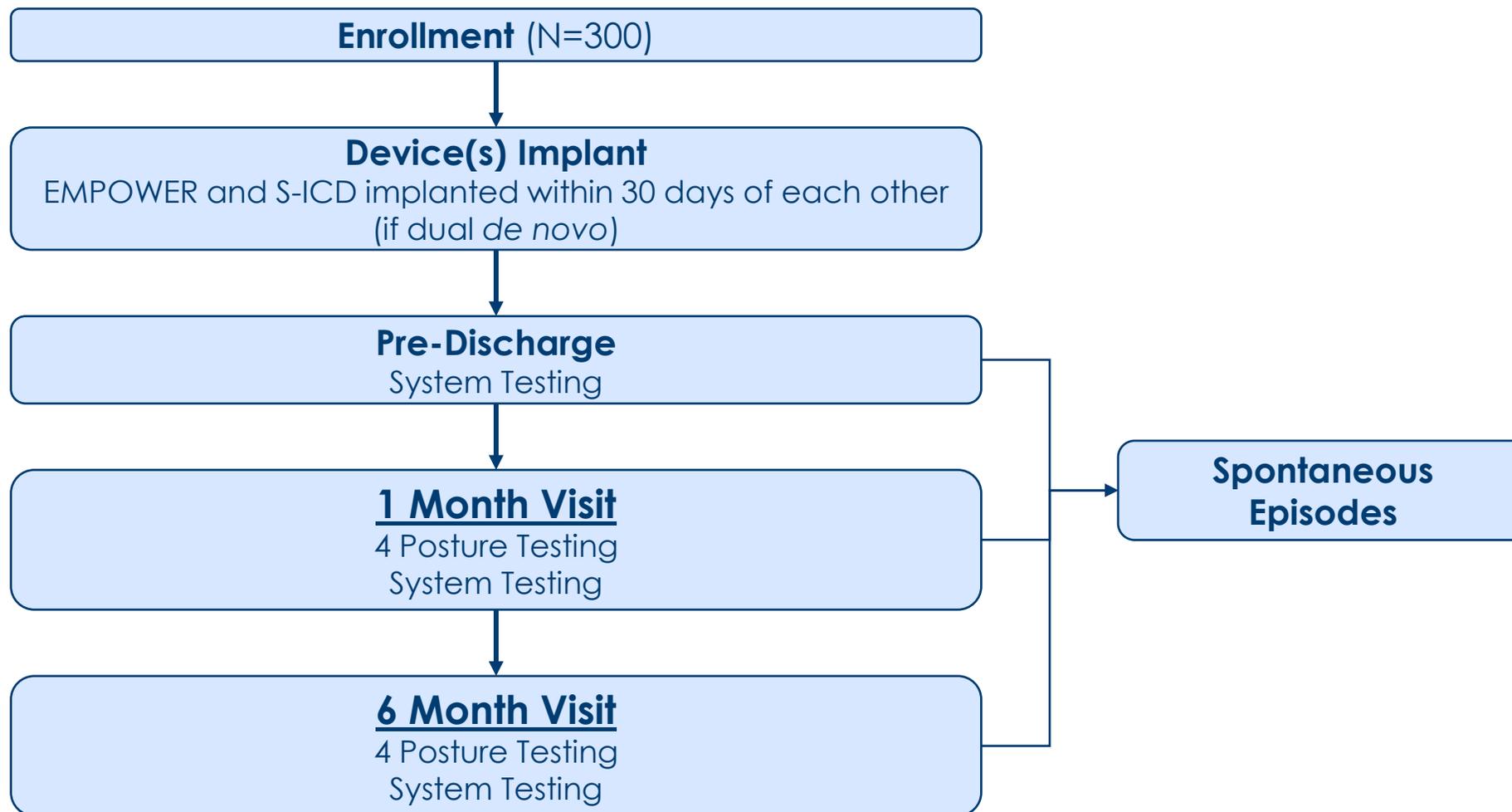


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MODULAR ATP Trial: *design and overview*



MODULAR ATP Trial: *Inclusion & Exclusion*

Inclusion

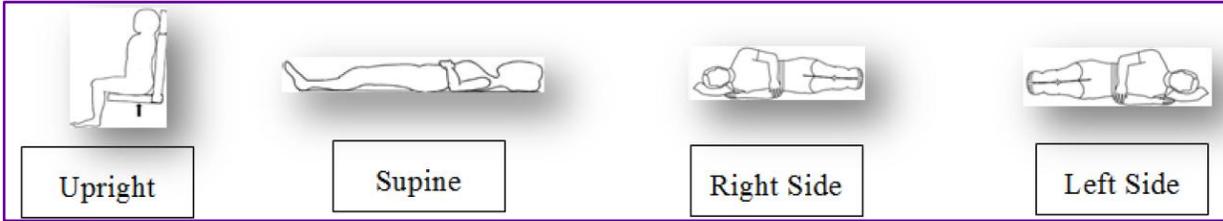
- Class I, IIa, or IIb guideline ICD indications, or an existing TV-ICD* or S-ICD
- History of at least one of the following:
 - Non-sustained MVT with LVEF \leq 50%
 - Sustained VA (secondary prevention) with LVEF \leq 50% or scar
 - Syncope of arrhythmic origin
 - Ischemic cardiomyopathy LVEF $<$ 35%
 - Nonischemic cardiomyopathy LVEF $<$ 35% + scar

Exclusion

- Need for chronic pacing or CRT
- Pacing not required for pacemaker-dependency, chronotropic incompetence, or ventricular dyssynchrony



MODULAR ATP Trial: 6-month's endpoints

Endpoint	Performance Goal
Major EMPOWER™ System and procedure-related complication-free rate	>86% ^a
Communication success rate between the S-ICD and EMPOWER LP Communication testing required in 4 body posters 	>88% ^b
% of patients with adequate pacing capture threshold (PCT) ≤ 2 V @ 0.4 ms	>80% ^c

^a The performance goal of >86% is similar to other LP performance goal endpoints – Nanostim³: > 86% and Micra⁴: > 83%.

^b The mCRM wireless communication is inductive, one-way communication from the S-ICD to the LP to request ATP delivery. The communication testing endpoint, which assessed pass/fail of communication at the programmed S-ICD Telemetry Setting, was required at the 6-month visit in 4 body postures..

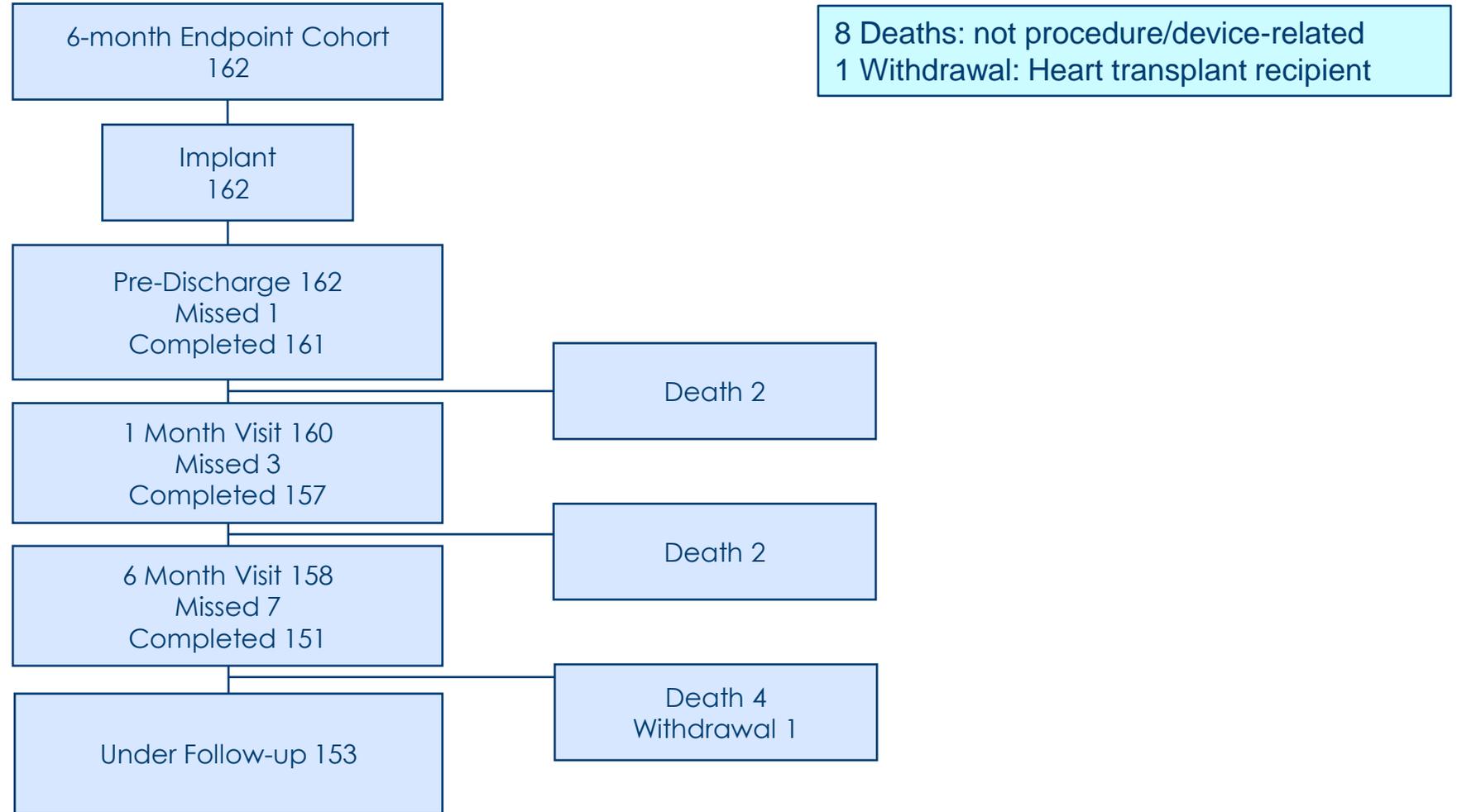


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MODULAR ATP Trial: *6-month endpoint follow-up*



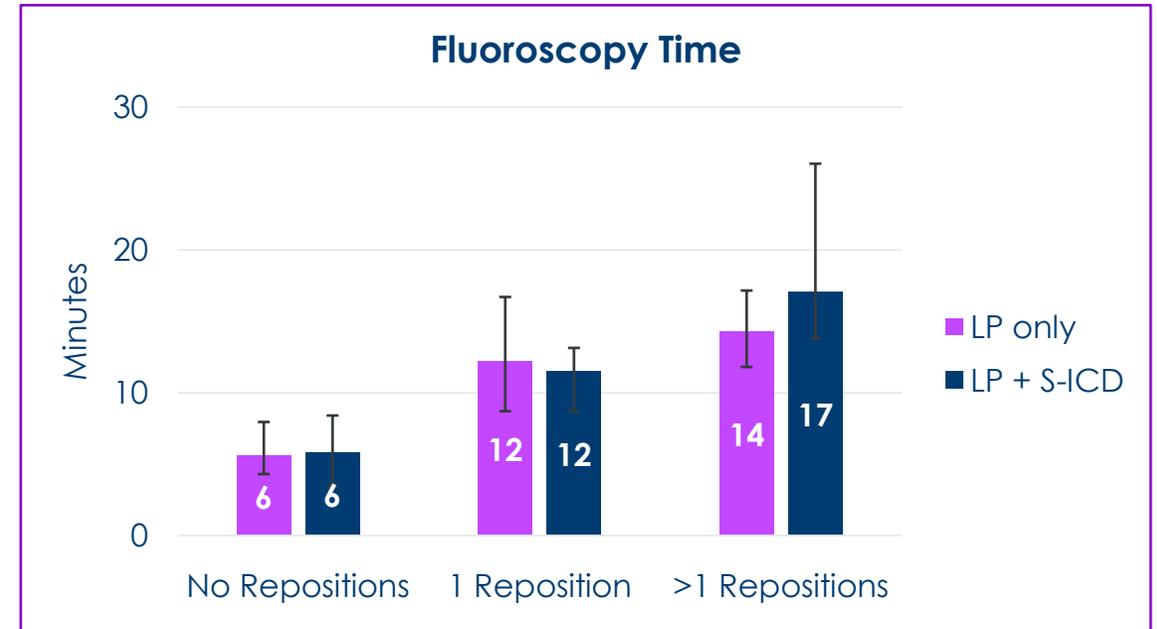
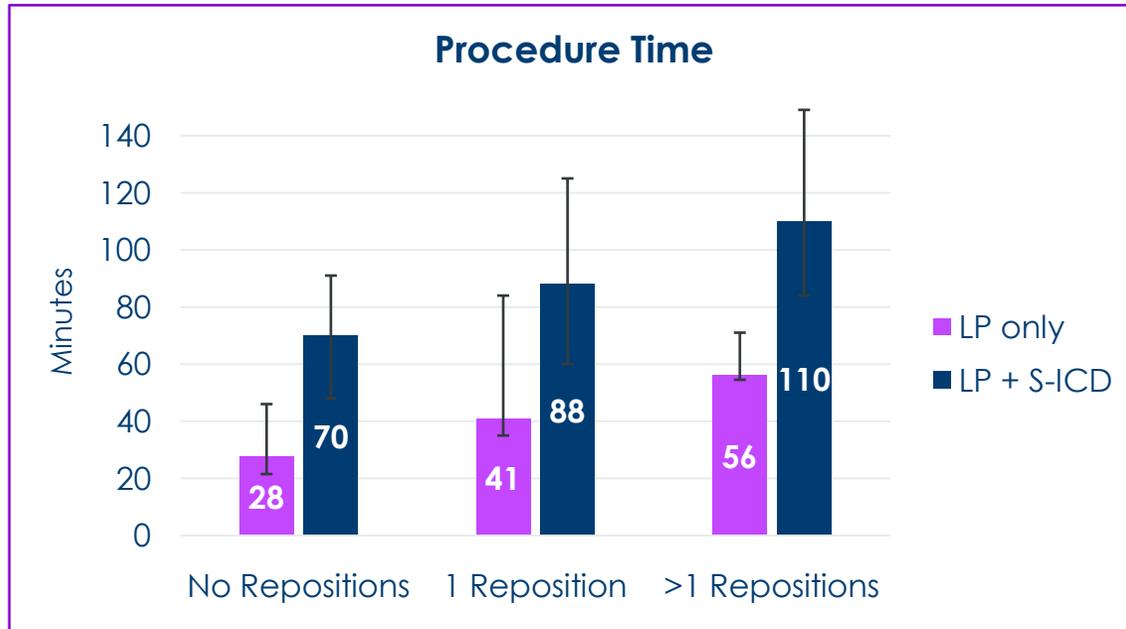
MODULAR ATP Trial: *Patient characteristics*

Characteristic	N=162
Age-yr	60±12
Female	27 (16.7)
Body-mass index†	29.8±5.9
Race/ethnicity, White	110 (67.9)
Race/ethnicity, Black or African heritage	12 (7.4)
Race/ethnicity, Other	10 (6.2)
Race/ethnicity, Not Disclosed	31 (19.1)
Primary prevention—no. (%)	87 (53.7)
Secondary prevention – no. (%)	75 (46.3)
NYHA Class I	40 (24.7)
NYHA Class II	82 (50.6)
NYHA Class III	38 (23.5)
NYHA Class IV	2 (1.2)
Diabetes—no. (%)	57 (35.2)
Hyperlipidemia—no. (%)	103 (63.6)
Renal dysfunction—no. (%)	32 (19.8)
LVEF – %	33.1±13

Characteristic	N=162
Ischemic cardiomyopathy	99 (61.1)
Non-ischemic cardiomyopathy	59 (36.4)
Other cardiac diseases	52 (32.1)
No Cardiac Disease History	9 (5.6)
Ventricular Arrhythmias	95 (58.6)
Sustained VT and non-sustained VT	19 (11.7)
Monomorphic VT – non-sustained	35 (21.6)
Monomorphic VT – sustained	31 (19.1)
Stable VT	24 (14.8)
Sustained VF and non-sustained VF	2 (1.2)
Sustained VF	3 (1.9)
Non-sustained VF	23 (14.2)
Transvenous pacemaker	0 (0.0)
Prior defibrillator	77 (47.5)
Transvenous defibrillator	16 (9.9)
Subcutaneous defibrillator	69 (42.6)



MODULAR ATP Trial: Procedure and fluoroscopy times



Median procedure times⁸

- LP implant only = 35 min
- Dual de novo (S-ICD and LP) = 77 min

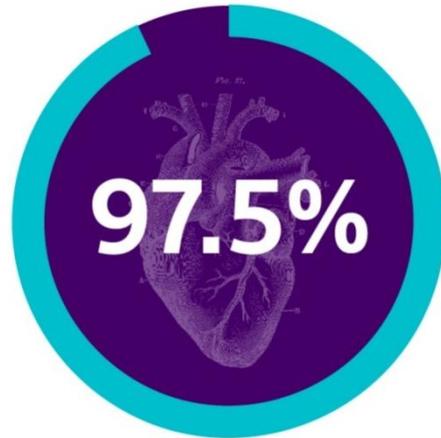
Median fluoroscopy times⁸

- LP implant only = 6.7 min
- Dual de novo (S-ICD and LP) = 6.8 min



MODULAR ATP Trial: Major LP Complication-Free Rate

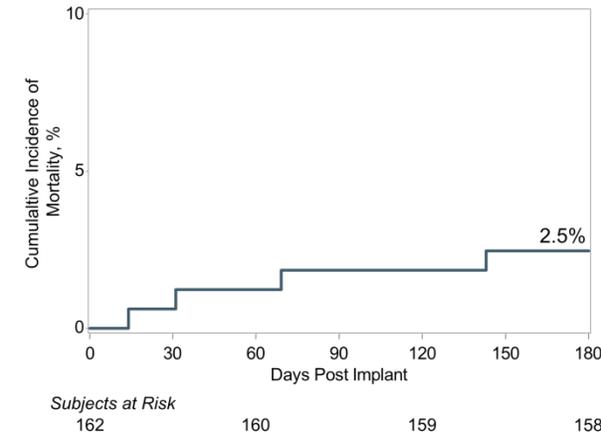
The EMPOWER System demonstrated a major complication-free rate (CFR) of 97.5%⁷ (n=162)



	6-month complication free rate
Nanostim	93.3% ⁹
Micra	96.0% ¹⁰

- EMPOWER's 6-month CFR are comparable to 6-month CFR of other LP systems

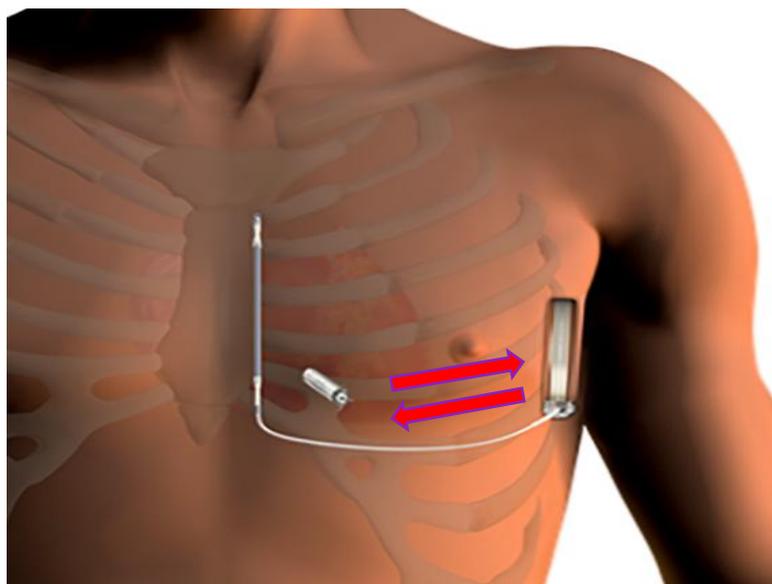
- Major LP-related complications⁷
 - 2: Myocardial perforation with tamponade
 - 1: Adverse reaction - vasovagal syncope – procedure
 - 1: LP inadvertently implanted in the left ventricle via interatrial septum
- 2 retrievals post implant⁷
 - Patient developed heart block
 - LP inadvertently implanted in LV
- Mortality risk: 2.5% (Kaplan-Meier)
 - 4 deaths** in first 6 months
- No deaths were device or procedure-related⁷



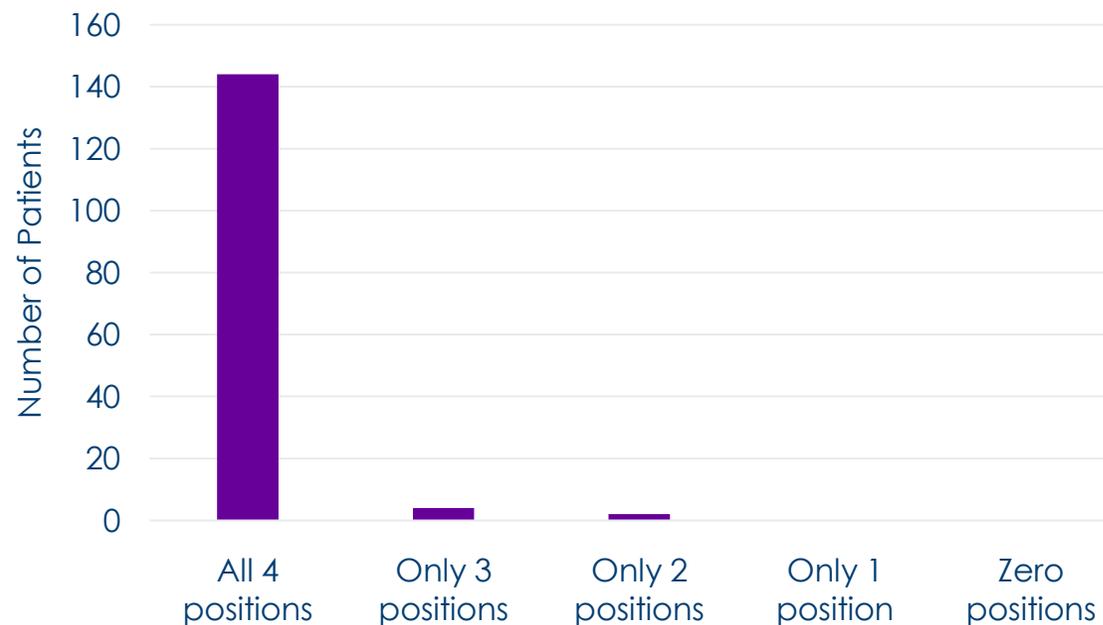
MODULAR ATP Trial: Communication success

S-ICD and EMPOWER LP

Communication success rate
98.8% between the EMBLEM S-ICD and
EMPOWER LP



Communication Success Across Patients (n=150**) ⁷



No patient experienced a failure of therapy delivery due to device communication failure.



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MODULAR ATP Trial: *Pacing Capture Threshold*

97.4% of patients experienced PCTs ≤ 2.0 volts (0.4 ms pulse width)⁷ (n=151)



- EMPOWER LP PCTs across patients in the 6-month endpoint cohort were 0.56 ± 0.49 V
- EMPOWER LP's 6-month PCT was similar to 6-month PCTs from other LP systems

	6-month PCT
Nanostim*	88% ⁹
Micra**	98.3% ¹⁰

* Nanostim PCT endpoint⁹: < 2.0 V at 0.5 ms and R-wave > 5 mV

** Micra PCT endpoint¹⁰: ≤ 2.0 V at a pulse width of 0.24 msec and an increase of ≤ 1.5 V from the time of implantation



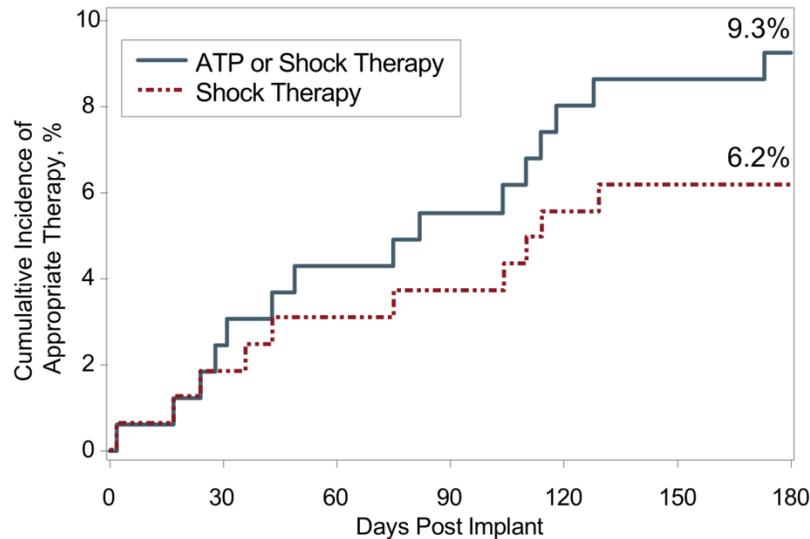
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Successful ATP therapy: 61.3%

- ATP delivered in 31 episodes in 13 patients⁷
- Appropriate therapy rate⁷ = 9.3%
- Appropriate shock rate⁷ = 6.2%



Subjects at Risk

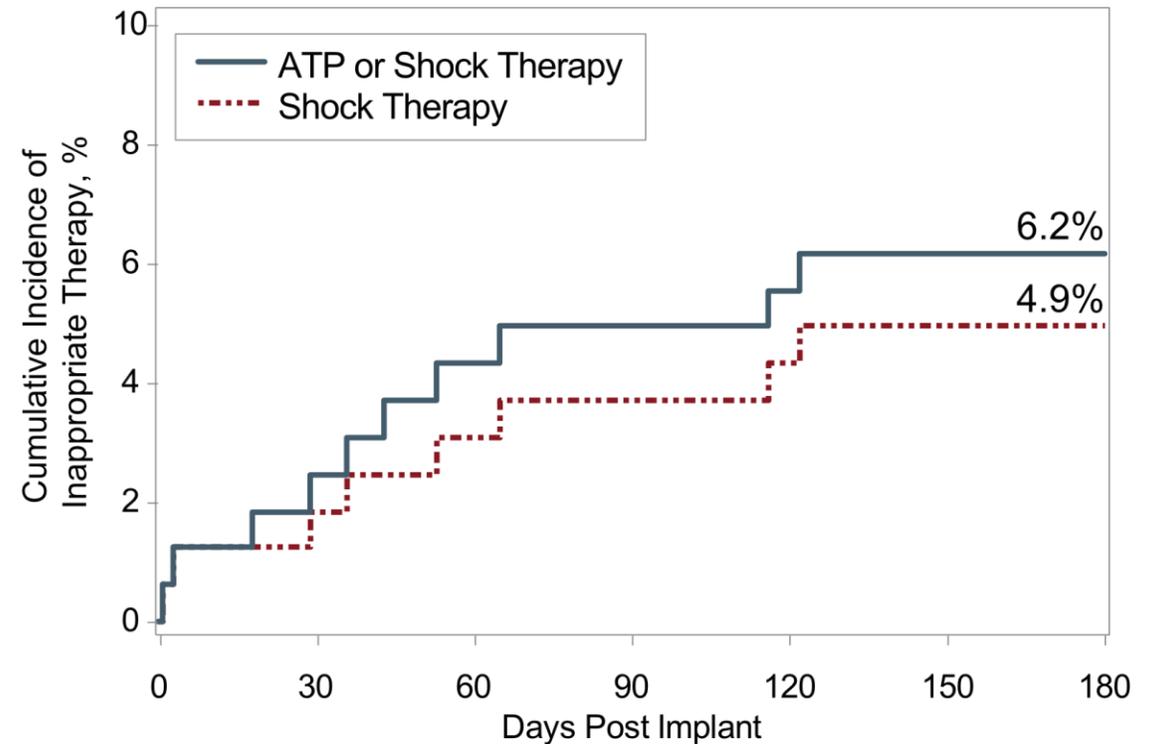
ATP or Shock Therapy	162	155	148	145
Shock Therapy	162	157	152	150

- ATP accelerated arrhythmia in 3 episodes⁷
- Episodes post ATP failure⁷:
 - Terminated by shock (9 episodes from 4 patients)
 - Self-terminated (after 2 ATP bursts (1 episode))
 - Arrhythmia stabilized to a rate below the conditional zone (2 episodes from 2 patients)
- ATP therapy provided by EMPOWER was similar to ATP success rates in other large ICD trials (46 – 72%) and similar to the EV ICD (70%)
 - However, the ATP or pause prevention pacing in the EVI ICD caused pain or discomfort in some patients, leading to the therapy being turned off or the device explanted.



Inappropriate shock and therapy

- Inappropriate therapy occurred in 14 patients with 36 episodes.
 - 67% of the episodes were cardiac oversensing of slow VT
- Risk of inappropriate therapy = 6.2%
- Risk of inappropriate shock = 4.9%
- Most inappropriate shocks were delivered to slower ventricular arrhythmias, this finding may be attributable to patient selection and device programming.
- No inappropriate episodes due to oversensing of pacing.
- At 6 months, the substernal ICD experienced an inappropriate shock rate of 8.5%.



Subjects at Risk

	0	30	60	180
ATP or Shock Therapy	162	154	151	149
Shock Therapy	162	156	153	151



Komunikace Leadless ATP & S-ICD:

Kazuistika

- Muž, 61 let
- ICHS (st.p. NSTEMI spodní stěny s dPCI ACD a RMS + 2x BSM 11/2006)
- Chronické srdeční selhání HFrEF (EF LK 20 %)

- V roce 2007 implantován transvenózní ICD v rámci sekundární prevence NSS
- Opakované infekční komplikace
- Leden 2022 extrakce původního ICD včetně elektrod

- **Únor 2022 - Implantace S-ICD - Boston Scientific EMBLEM MRI**



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Komunikace Leadless ATP & S-ICD:

Kazuistika

- Od první implantace ICD v roce 2007 zaznamenáno 90 incesantních epizod setrvalé KT
- Leden 2017 - Katetrizační RF ablace arytmogenního substrátu LK
- Pouze jediná epizoda setrvalé KT v únoru 2022 : Ukončena 1. výbojem S-ICD
- Středně významná mitrální regurgitace (konzervativní postup)
- Arteriální hypertenze
- Hyperlipoproteinemie
- Diabetes mellitus 2. typu na PAD
- Amauróza levého oka, revmatoidní artritida
- Prosinec 2023 implantace LCP EMPOWER (BSCI) v režimu VVICD : studie MODULAR ATP



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Komunikace Leadless ATP & S-ICD:

Kazuistika



SUMMARY REPORT

Report Printed: 01/02/2024 3:53 pm
Programmer Software Version: 1.04
Device Software Version: 3.2.662

Patient Name: 0492MA555
Last Follow-up Date: 12/19/2023
Follow-up Date: 01/02/2024
Implant Date: 01/25/2022

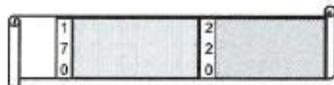
Device Model#: A219 EMBLEM™ MRI S-ICD
Device Serial#: 143993
Electrode Model#: 3501
Electrode Serial#: 200119
Pacemaker Model/Serial#: B170/151351

Programmable Parameters

Current Device Settings

Therapy: ON
Shock Zone: 220 bpm (ATP On)
Conditional Shock Zone: 170 bpm (ATP x2)
Post Shock Pacing: OFF
SMART Pass: OFF

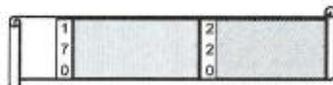
Gain Setting: 1X
Sensing Configuration: Secondary
Shock Polarity: REV



Initial Device Settings

Therapy: ON
Shock Zone: 220 bpm (ATP On)
Conditional Shock Zone: 170 bpm (ATP x2)
Post Shock Pacing: OFF
SMART Pass: OFF

Gain Setting: 1X
Sensing Configuration: Secondary
Shock Polarity: REV



Parameter changes this session: NO

Episode Summary

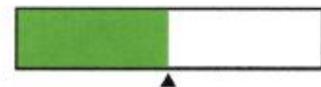
Since Last Follow-Up

Untreated Episodes: 0
Treated Episodes: 14
of Shocks Delivered: 24
of ATPs Requested: 9

Since Implant

Untreated Episodes: 0
Treated Episodes: 15
of Shocks Delivered: 30
of ATPs Requested: 23

Battery Status



Remaining Battery Life to ERI: 43%

Electrode Impedance Status

⚠ System Impedance = 210 Ohms

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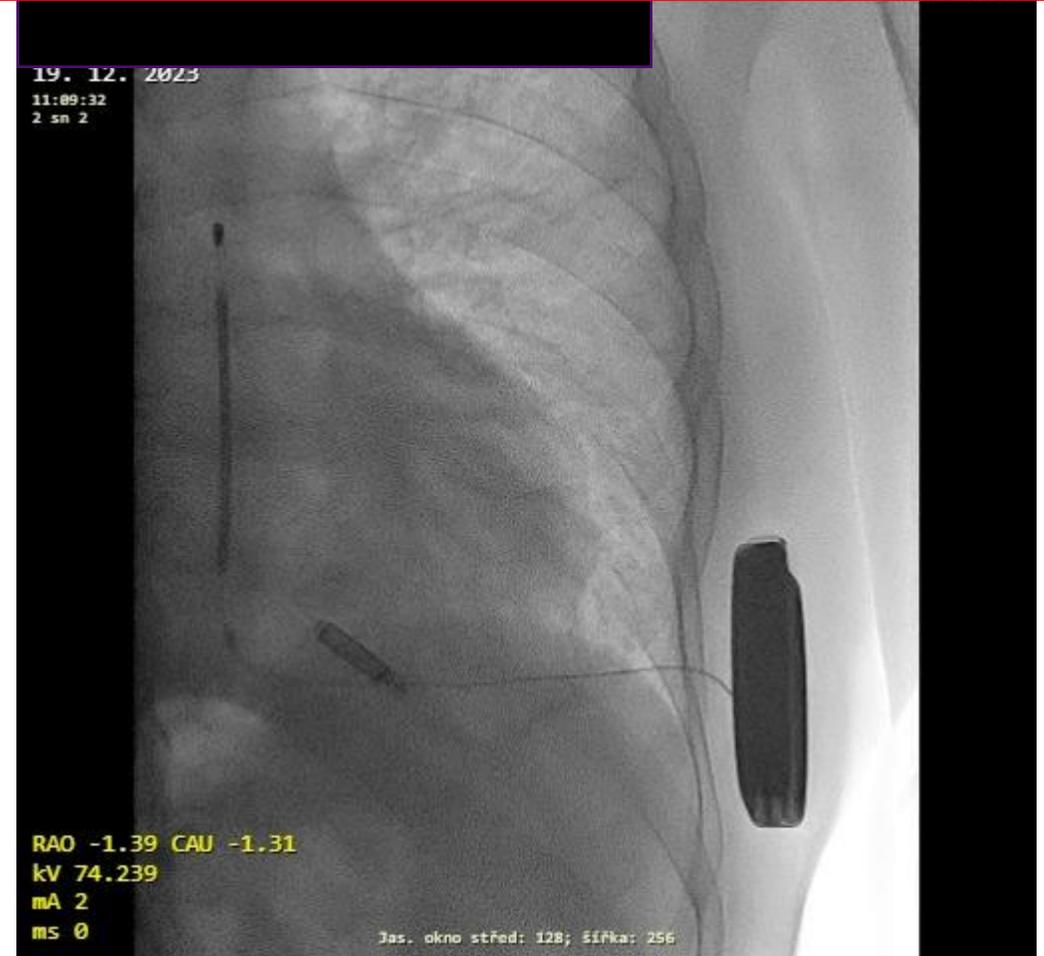
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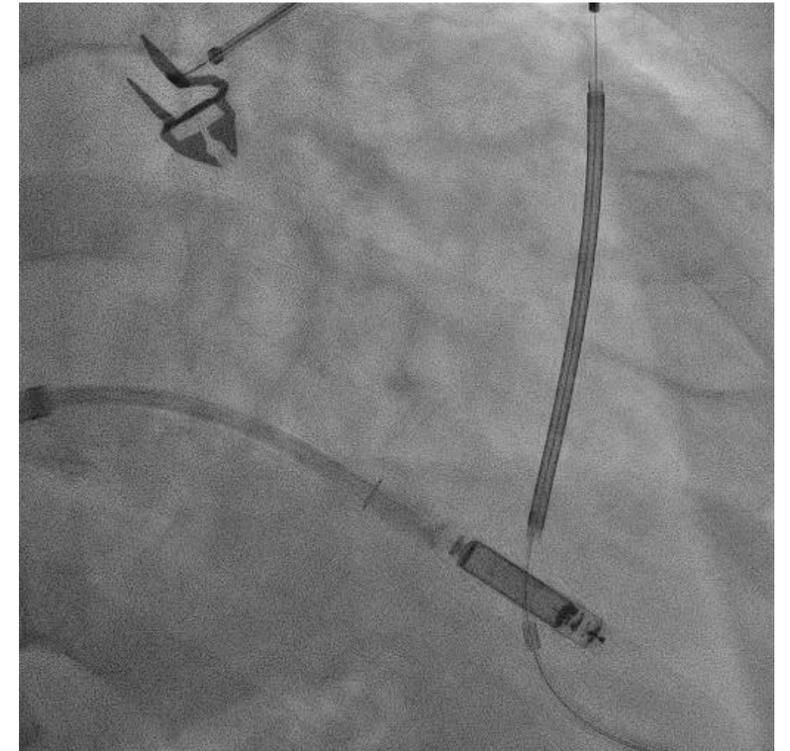
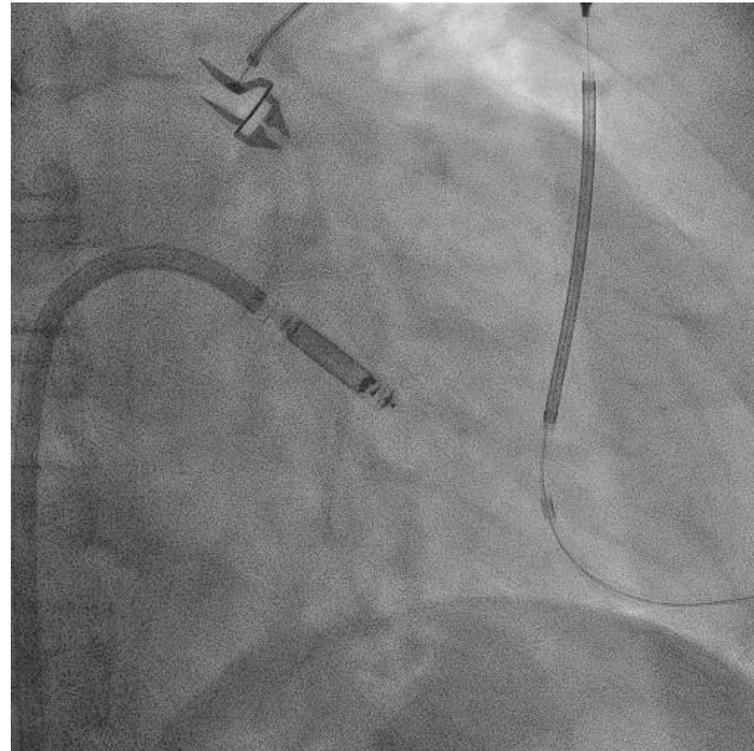
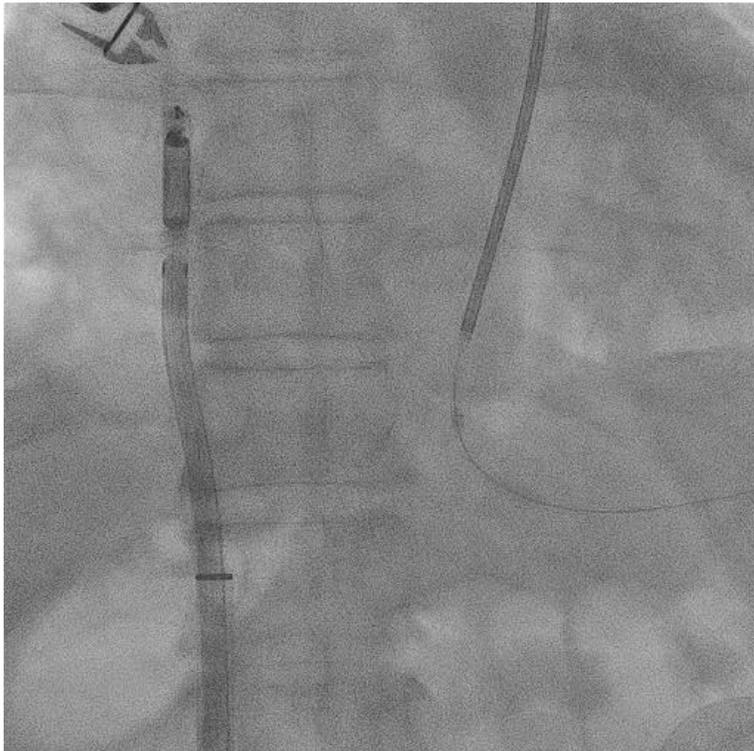
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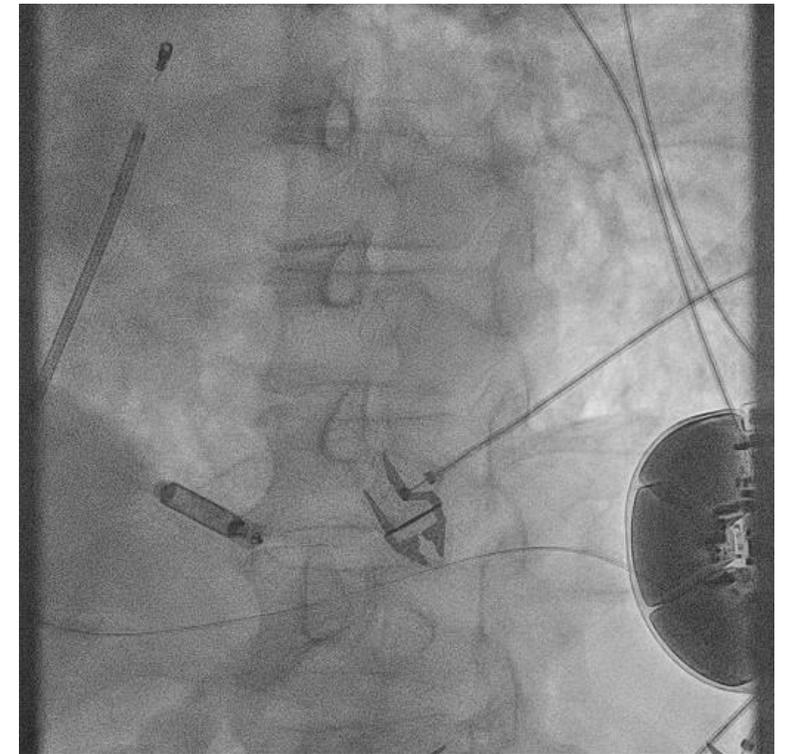
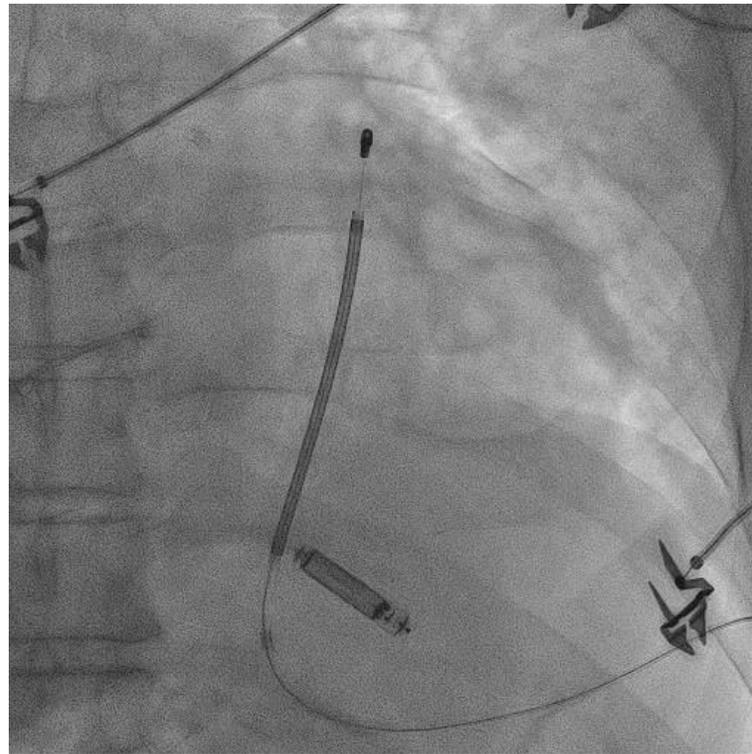
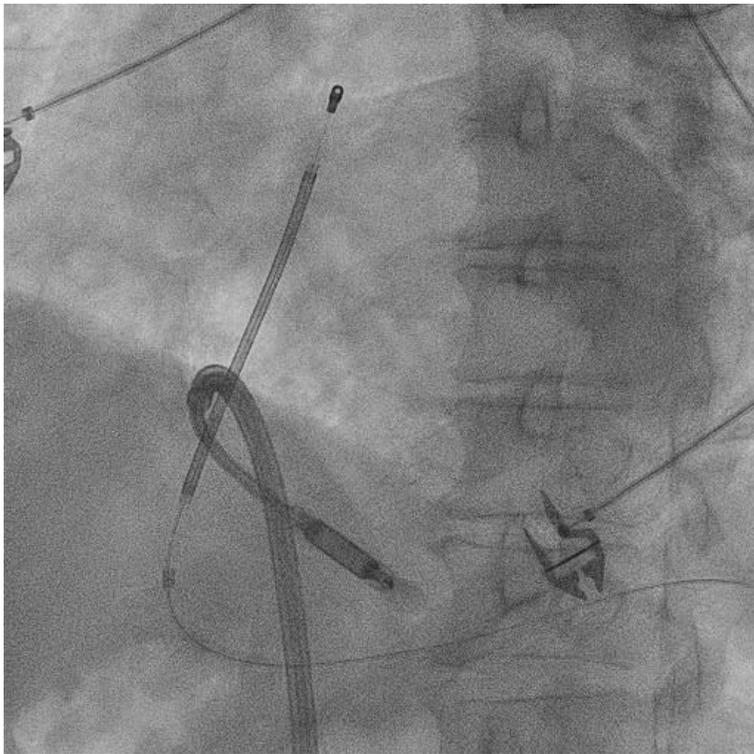
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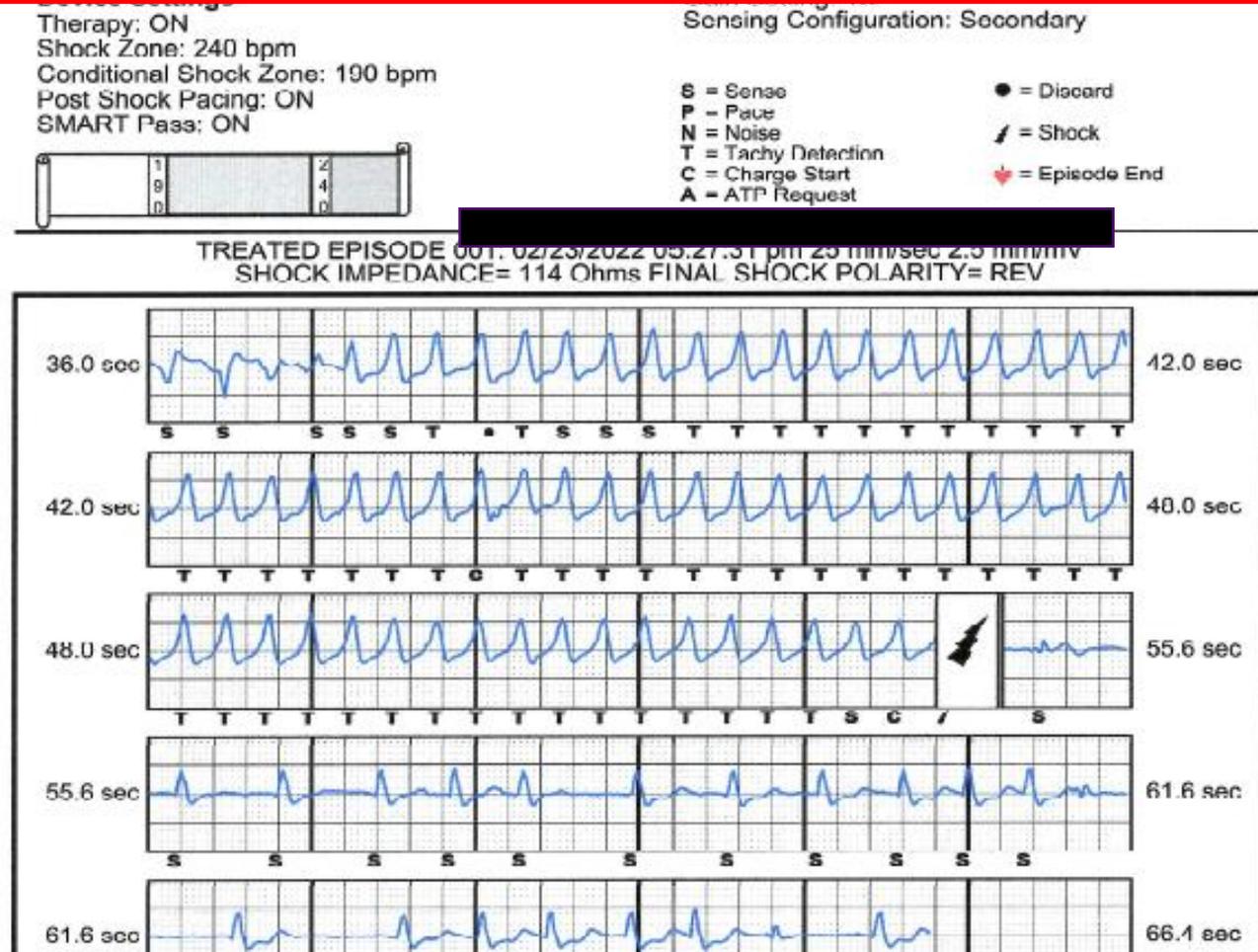
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MODULAR ATP Trial: Conclusion

- The M-CRM system achieved all pre-specified safety and effectiveness 6-month endpoints and the results demonstrated the safety profile of the EMPOWER LP system.
- The EMPOWER LP's complication free rate of **97.5%** is comparable to complication free rates of other LP systems.
- The communication success rate was **98.8%** between the S-ICD and EMPOWER LP.
- Almost all patients (**97.4%**) had a low and stable PCT (≤ 2.0 volts) and is similar to other LP systems. No late repositions or retrievals for PCT were necessary.



CAUTION:

The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

mRCM™ System – designed for the future of personalized patient care

- Upon the EMPOWER™ Leadless Pacemaker* and mCRM system* receiving FDA approval, EMPOWER will be the first and only LP designed to be a standalone VVIR pacemaker** that is compatible with all existing EMBLEM™ S-ICD devices as part of the mCRM system.¹
- Will provide an upgrade pathway to patients with an EMBLEM S-ICD who develop a need for ATP or VVIR pacing.¹
- Designed to deliver painless intracardiac ATP and/or brady pacing.^{1,7}
- Designed to provide upgrade pathways regardless if the EMBLEM S-ICD or EMPOWER LP is implanted first.¹



* Caution: Investigational Device. Limited by US law to investigational use only. Not available for sale.

** Rate-response results will be reported in a future publication.

Practical implications of MODULAR & APPRAISE ATP Trials¹⁵

“Together, data from the MODULAR ATP and APPRAISE ATP trials reinforce the promise of the groundbreaking mCRM System, illustrating a clear path forward for physicians to offer therapies that prevent sudden cardiac death and deliver ATP for the small number of patients who benefit from it.”

“Instead of subjecting all patients to the risks of more invasive approaches, such as placing leads in the heart or tunneling them under the sternum to provide therapies they might not require, these data indicate physicians may have the opportunity to tailor therapy to the patient’s individual needs and health.”

- Ken Stein MD, Global Chief Medical Officer BSC

References

1. Lloyd MS, Brisben AJ, Reddy VY, et al. Design and rationale of the MODULAR ATP global clinical trial: A novel intercommunicative leadless pacing system and the subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm O2*. 2023;4(7):448-456. Published 2023 Jun 2. doi:10.1016/j.hroo.2023.05.004.
2. Knops RE, Pepplinkhuizen S, Delnoy P, et al. Device-related complications in the subcutaneous and transvenous ICD: a secondary analysis of the PRAETORIAN trial. *Eur Heart J*. Aug 28 2022;43(47):4872-4883. doi:10.1093/eurheartj/ehac496
3. Healey JS, Krahn AD, Bashir J, et al. Perioperative Safety and Early Patient and Device Outcomes Among Subcutaneous Versus Transvenous Implantable Cardioverter Defibrillator Implantations : A Randomized, Multicenter Trial. *Ann Intern Med*. Nov 8 2022;175(12):1658-1665. doi:10.7326/M22-1566
4. Leong D, Dokainish H, Mondesert BA, et al. LB-456090-2 Effects of Implantable Cardioverter-Defibrillator Leads on the Tricuspid Valve and Right Ventricle: A Randomized Comparison of Transvenous versus Subcutaneous Leads. *Heart Rhythm*. May 16 2023.
5. Payne JE, Gold MR. A Substernal Defibrillator Lead With Pacing Capability: Another Tool in the Toolbox? *JACC Clin Electrophysiol*. Feb 2019;5(2):197-198. doi:10.1016/j.jacep.2018.12.006.
6. Romers H, van Dijk V, Boersma L. Evolution of extravascular implantable cardioverter-defibrillator therapy for ventricular arrhythmias. *Heart Rhythm O2*. Jan 2023;4(1):59-64.
7. Knops R, et al. Tachycardia Therapy and Trial Endpoint Results of the First Modular, Intra-body, Communicating Subcutaneous Defibrillator-Leadless Pacemaker System: MODULAR ATP Interim Cohort. *Heart Rhythm Society Late Breaking Clinical Trials and Science LB-469805-03*. 2024.
8. Knops RE, Lloyd MS, Roberts PR, et al. A Modular Communicative Leadless Pacing-Defibrillator System. *N Engl J Med*. 2024. DOI: 10.1056/NEJMoa2401807.
9. Reddy VY, Exner DV, Cantillon DJ, et al. Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker. *N Engl J Med* 2015;373(12):1125-35. DOI: 10.1056/NEJMoa1507192.
10. Reynolds D, Duray GZ, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. *N Engl J Med* 2016;374(6):533-41. DOI: 10.1056/NEJMoa1511643.
11. Knops RE, van der Stuijt W, Delnoy P, et al. Efficacy and Safety of Appropriate Shocks and Antitachycardia Pacing in Transvenous and Subcutaneous Implantable Defibrillators: Analysis of All Appropriate Therapy in the PRAETORIAN Trial. *Circulation* 2022;145(5):321-329.
12. Wathen MS, DeGroot PJ, Sweeney MO, et al. Prospective randomized multicenter trial of empirical antitachycardia pacing versus shocks for spontaneous rapid ventricular tachycardia in patients with implantable cardioverter-defibrillators: Pacing Fast Ventricular Tachycardia Reduces Shock Therapies (PainFREE Rx II) trial results. *Circulation* 2004;110(17):2591-6. DOI: 10.1161/01.CIR.0000145610.64014.E4.
13. Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. *N Engl J Med*. 2022;387(14):1292-1302.
14. Crozier I, Haqqani H, Kotschet E, et al. Three-year chronic follow-up from the pilot study of a substernal extravascular implantable cardioverter-defibrillator. *Europace* 2023;25(10). DOI:10.1093/europace/euad301.
15. [May 18, 2024. Boston Scientific Press Release: Results of the MODULAR ATP Trial.](#)