

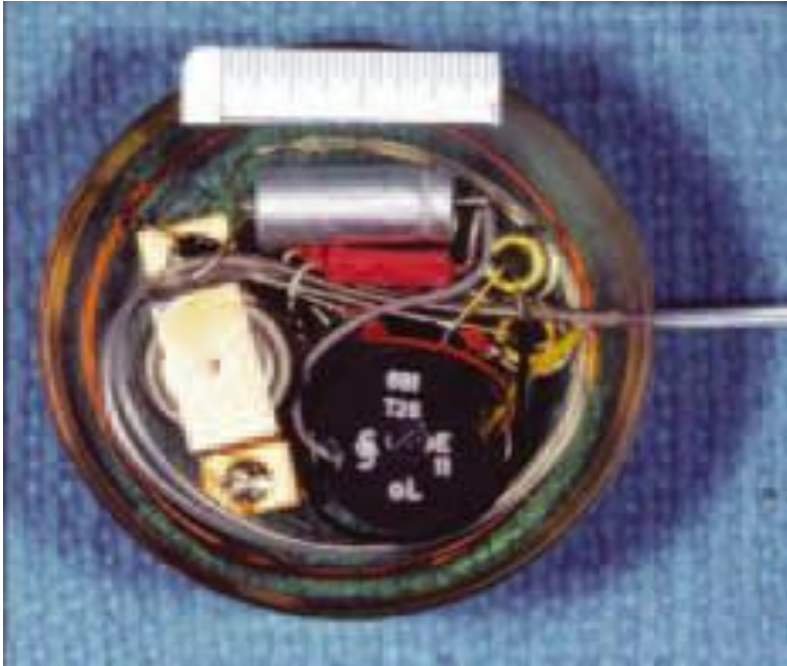
Leadless, Leadless, Leadless

Milan Chovanec

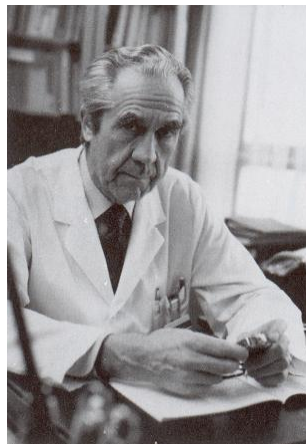
Kardiocentrum, Nemocnice na Homolce,
Praha, Česká Republika



První implantace trvalé kardiostimulace



- 8. října **1958**
- Karolinska Univerzita, Stockholm, Švédsko
- Implantace elektrody epikardiálně kardiologickým přístupem



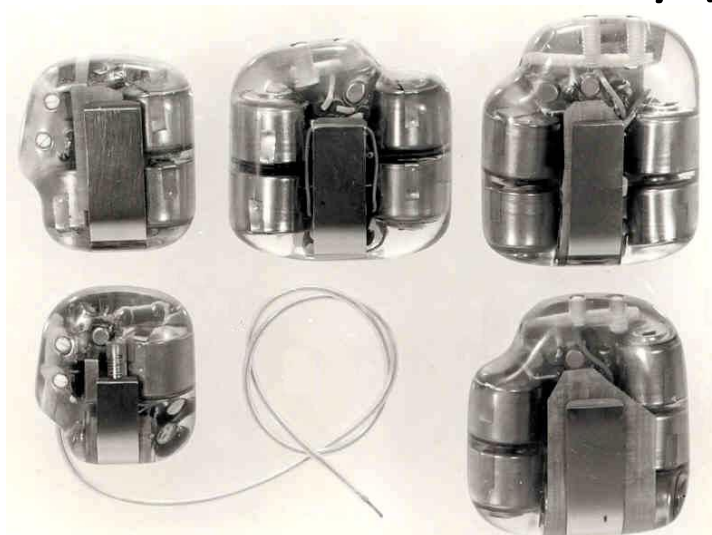
Ake Senning,
kardiolog



Rune Elmquist, lékař,
inženýr a vynálezce

Vývoj konvenční kardiostimulace

RIMEM V00 Pacemakery (1965)



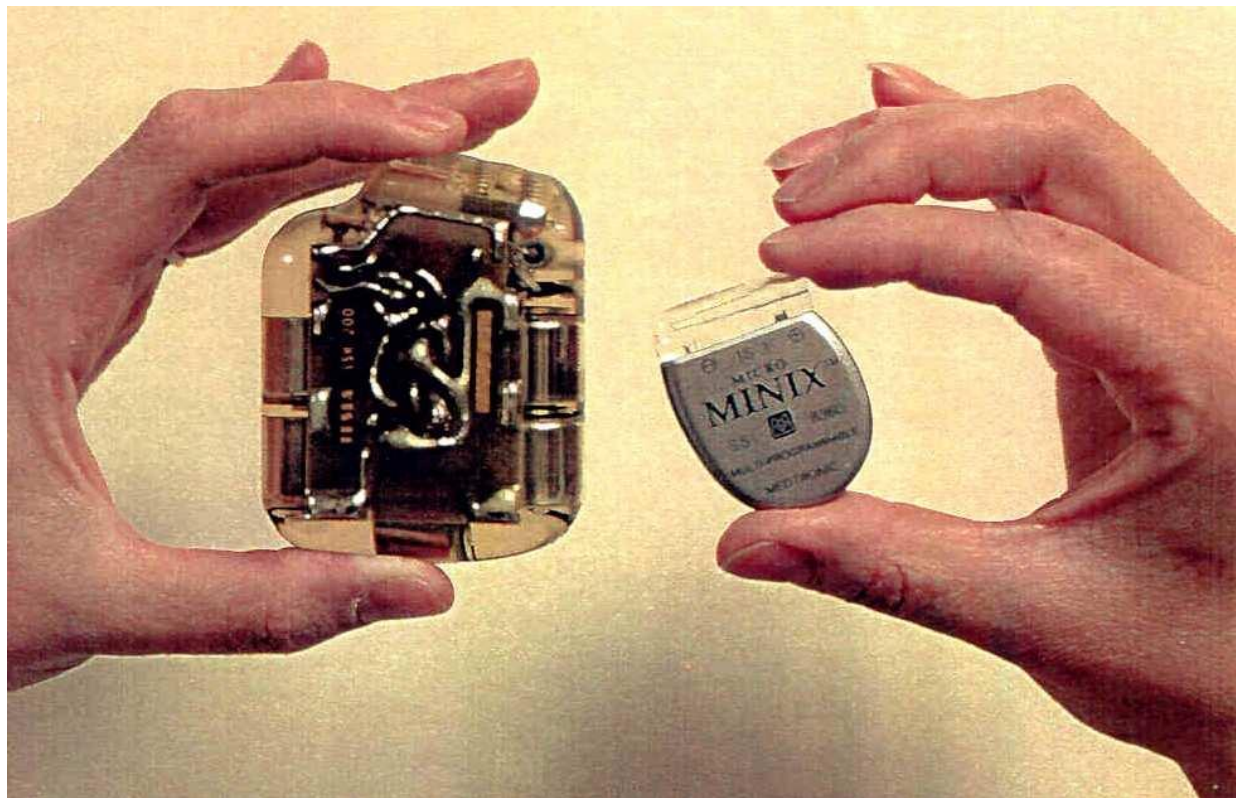
PATENTOVÁ LISTINA

ČÍSLO 1 2 4 9 0 1

ÚŘAD PRO PATENTY A VYNÁLEZY V PRAZE UDEJIL PODLE § 19 ZÁKONA Č. 34/1957 Sb. PATENT NA VYNÁLEZ
UVEDENÝ V PŘIPOJENÉM PATENTOVÉM SPISU

PŮVODCE VYNÁLEZU: Doc. MUDr. Bohumil Peleška, Praha
ing. Vladimír Bičík, Nové Strašecí

1970 vs. 2000



První koncept bezdrátové (leadless) kardiostimulace

Special Article

Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D., PAUL KEZDI, M.D.,
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, P.E.

SUMMARY

Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits make feasible a new generation of pacemakers, the intracardiac pacemaker (IC), i.e., a completely self-contained pacemaker implanted inside the right ventricle. Since the IC pacemaker has several problems associated with it, the development of the endocatheter electrode has broadened the scope of operative procedures to include a portion of the patient population. Two problems that still exist with conventional pacemakers are perforation or dislocation of the transvenous electrode and the short

circuits have been improved substantially. In addition, the development of the endocatheter electrode has broadened the scope of operative procedures to include a portion of the patient population. Two problems that still exist with conventional pacemakers are perforation or dislocation of the transvenous electrode and the short

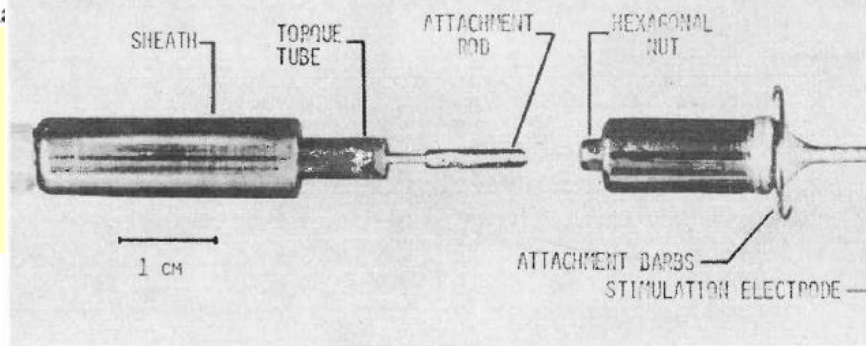


Fig. 4. Intracardiac pacemaker with catheter for transvenous insertion.

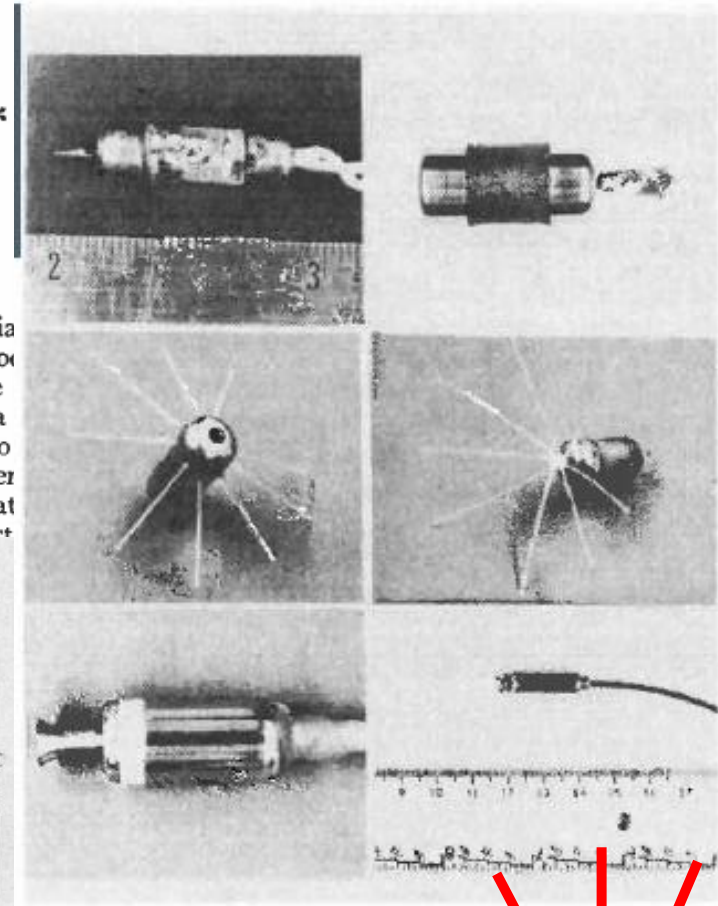
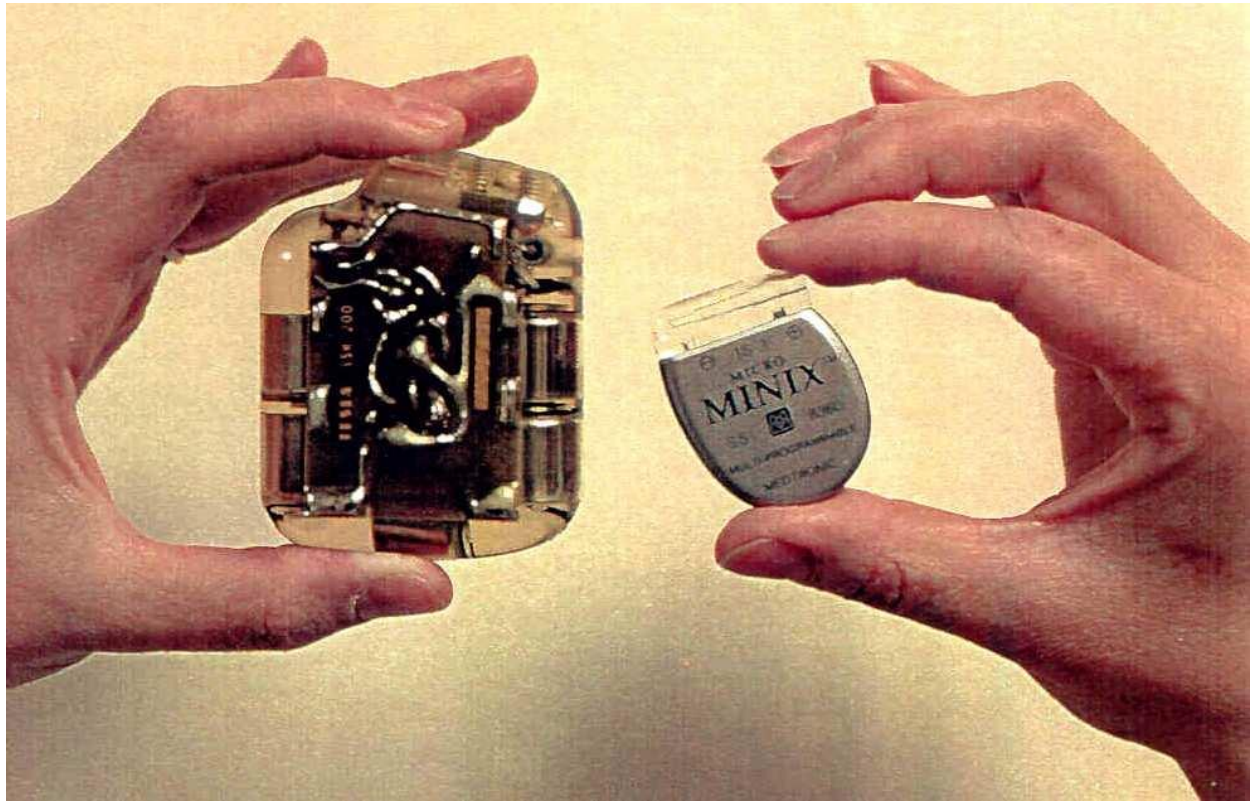


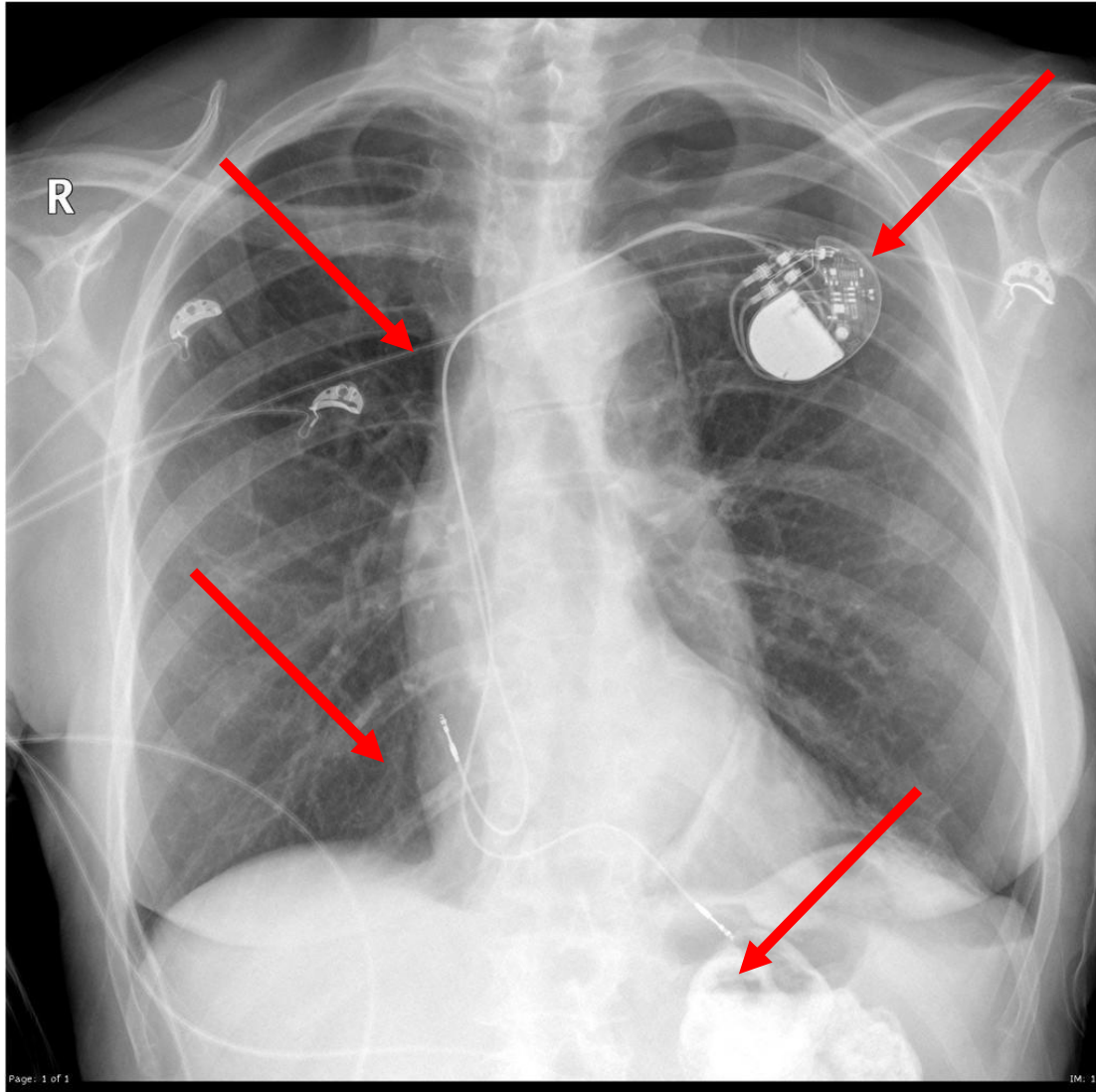
Fig. 2. Some early unsatisfactory dummy capsules used to explore attachment technique.

Betacel ®

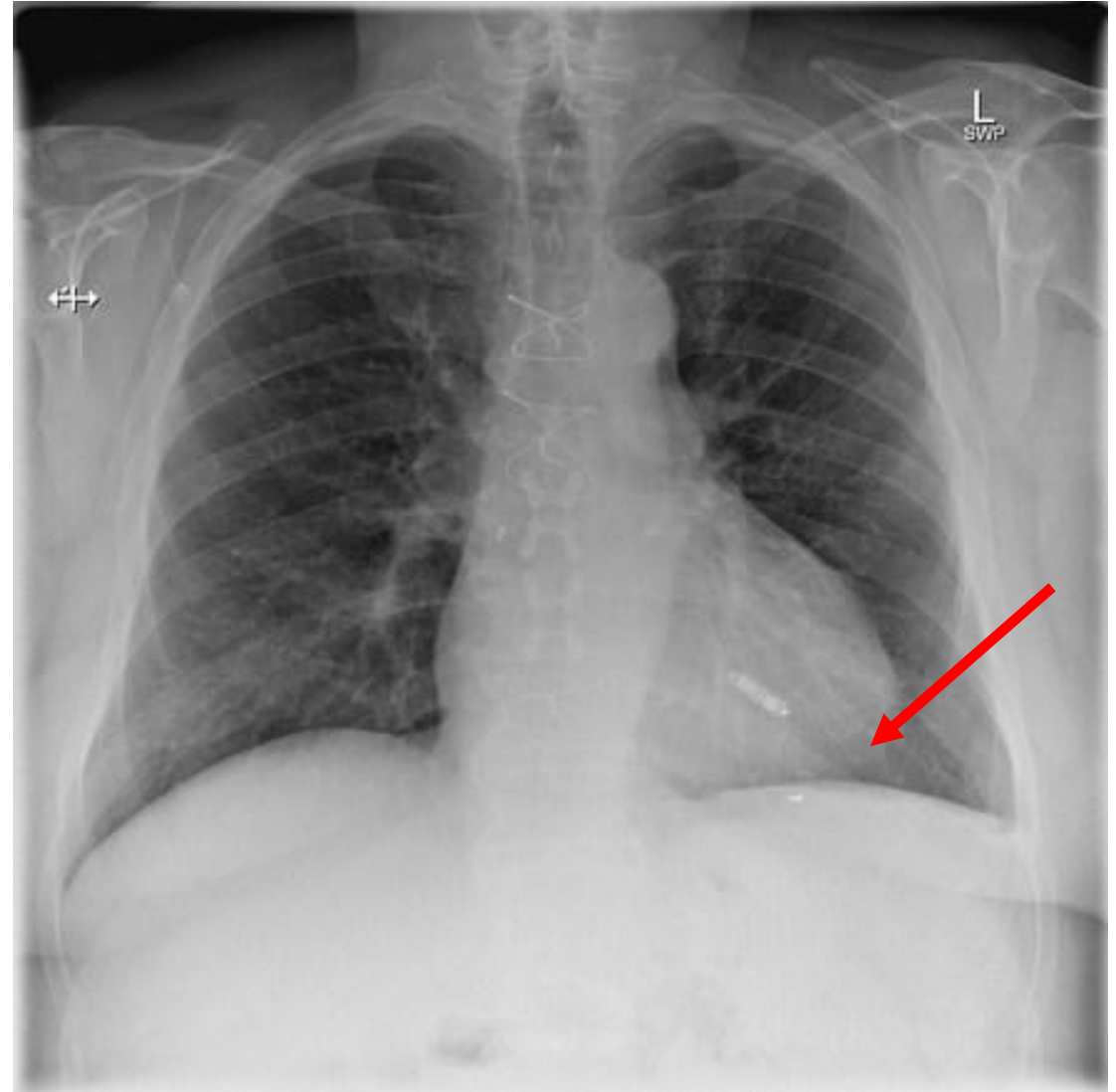
- betavoltaická baterie
- radioizotop Promethium -147
- Larry C.Olsen, McDonnell Douglas Corp.
- kardiostimulátor Betacel-Biotronik

Bezdrátová kardiostimulace





Konvenční DDD kardiostimulace



Leadless VVI kardiostimulace

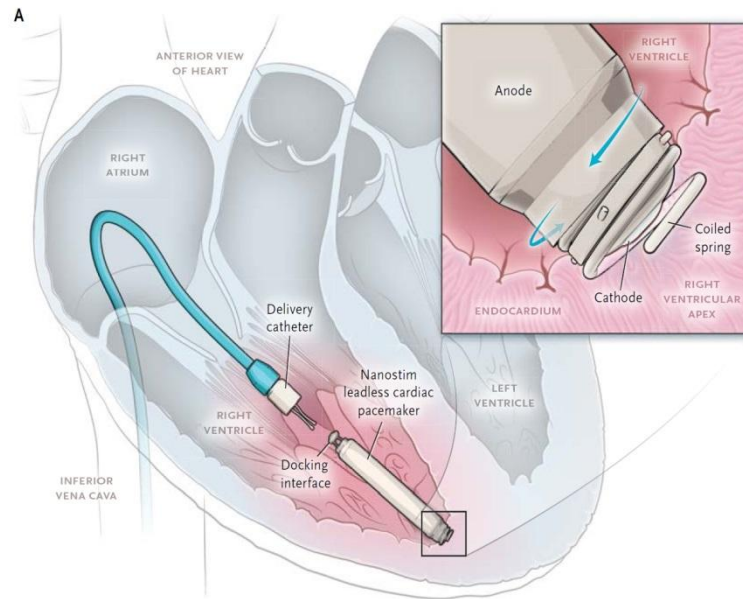
Bezdrátová kardiostimulace - možnosti

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker

Vivek Y. Reddy, M.D., Derek V. Exner, M.D., M.P.H., Daniel J. Cantillon, M.D., Rahul Doshi, M.D., T. Jared Bunch, M.D., Gery F. Tomassoni, M.D., Paul A. Friedman, M.D., N.A. Mark Estes, III, M.D., John Ip, M.D., Imran Niazi, M.D., Kenneth Plunkitt, M.D., Rajesh Banker, M.D., James Porterfield, M.D., James E. Ip, M.D., and Srinivas R. Dukkipati, M.D., for the LEADLESS II Study Investigators*



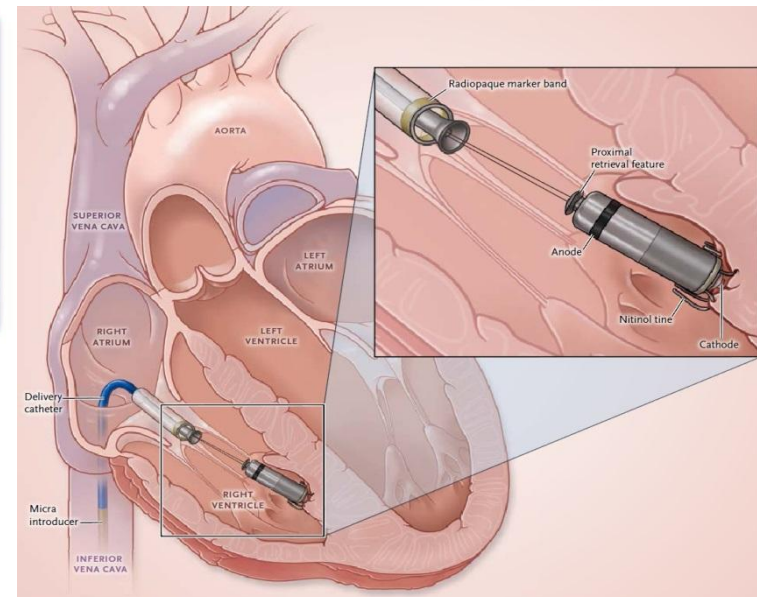
Reddy VY et al: NEJM 2015, Sept 17, 373: 1127.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

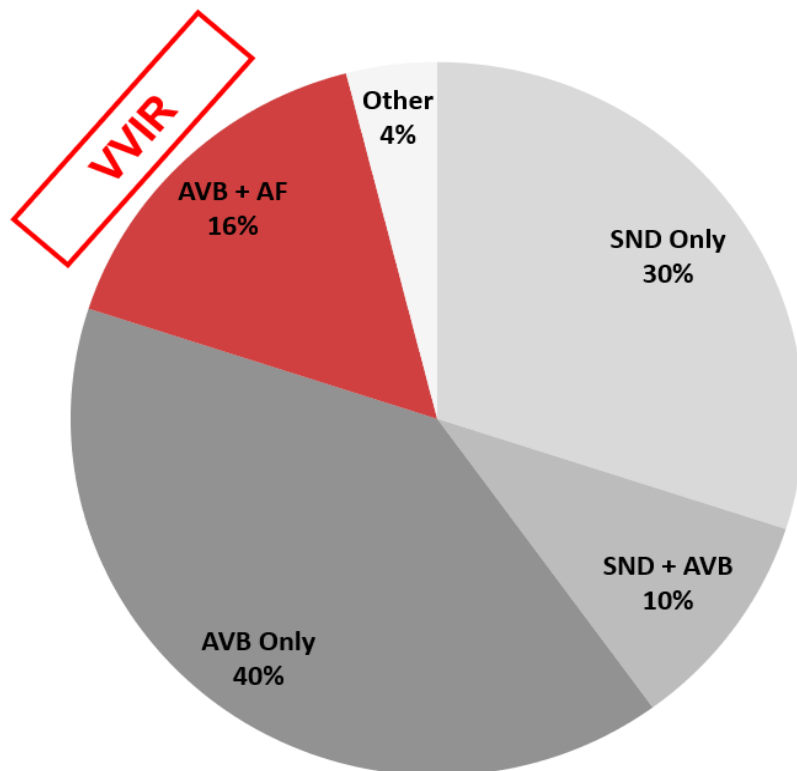
A Leadless Intracardiac Transcatheter Pacing System

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., 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 Bongiorno, 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*



Reynolds D et al: NEJM 2016, Feb 11 : 535.

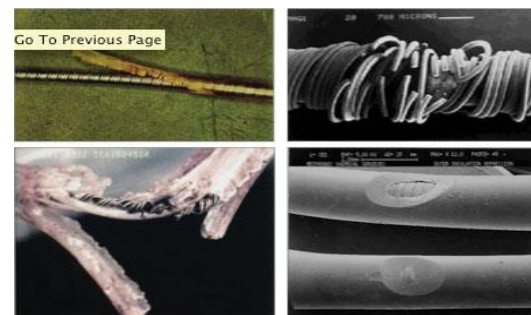
VVI leadless stimulace - indikace



- **VVI stimulace**
- Málo četné důvody stimulace (minimální potřeba stimulace, chronická FiS)
- Po nebo v průběhu infekčních komplikacích endovazálních systémů
- Stenózy/trombózy žilního systému
- Vrozené srdeční vady....nemožnost endovazálního přístupu

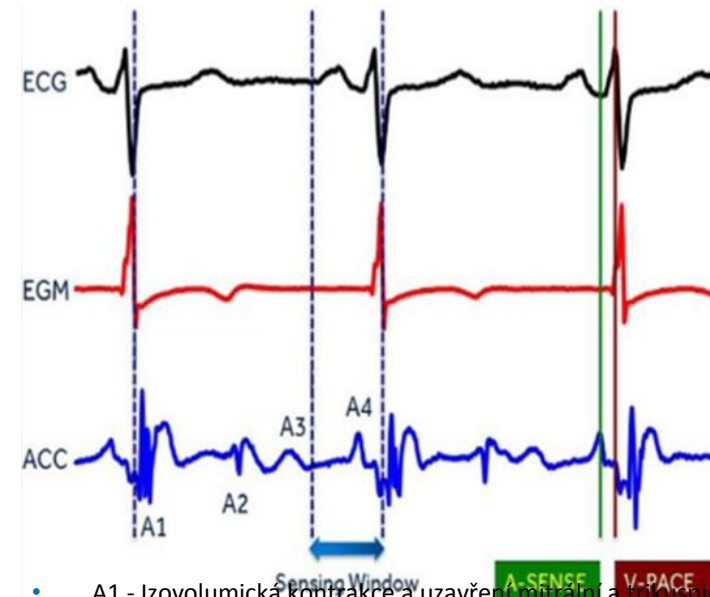
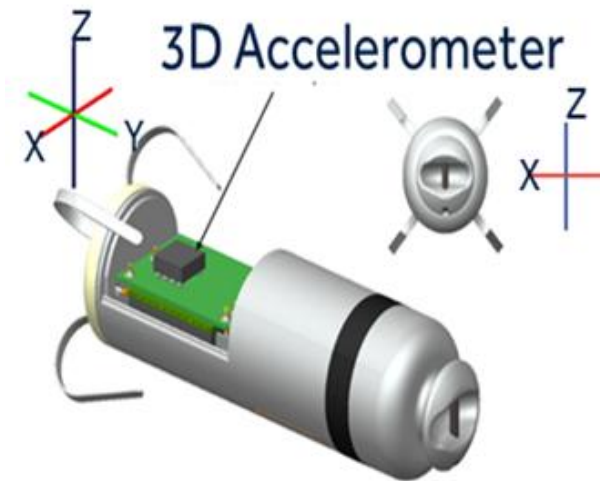
Bezdrátová kardiostimulace - výhody

- Infekce kapsy
- Hematom, dekubitus
- Dislokace elektrod
- Fraktury elektrod
- PNO
- Kosmetické důvody
- Dyskomfort
- Výborná fixační síla
- Nízké nároky na energii
- Dlouhá životnost baterie
- Tkáň-Přístoj, stabilní interface, sensing, práh, odpor...
- **MR kompatibilita** (certifikace pro 1,5 T MR systémy)



VDD leadless stimulance – Medtronic Micra™ AV

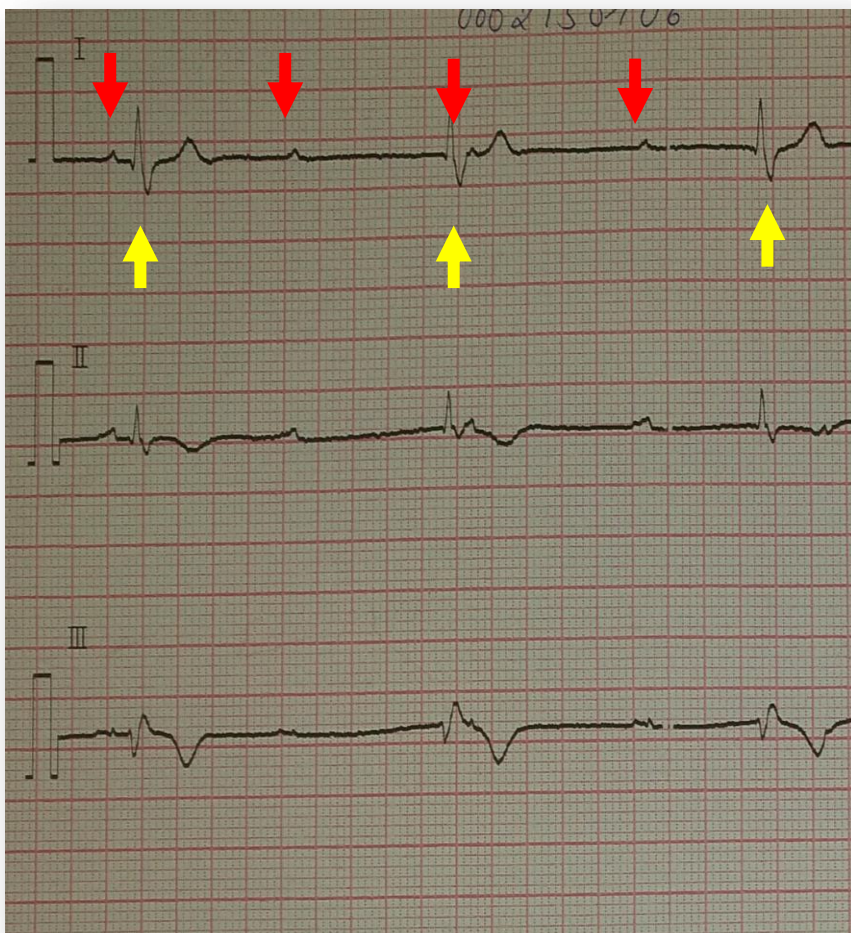
- Snímání vlastní síňové aktivity, sinusový rytmus
- kardiostimulátor Micra AV obsahuje 3 na sebe kolmé akcelerometry, které umožňují snímat pohyb přístroje ve všech 3 směrech volnosti.
- pomocí těchto akcelerometrů je přístroj schopen snímat mechanický pohyb chlopní a tak i aktivitu síní
- je tak schopný pracovat v režimu VDD



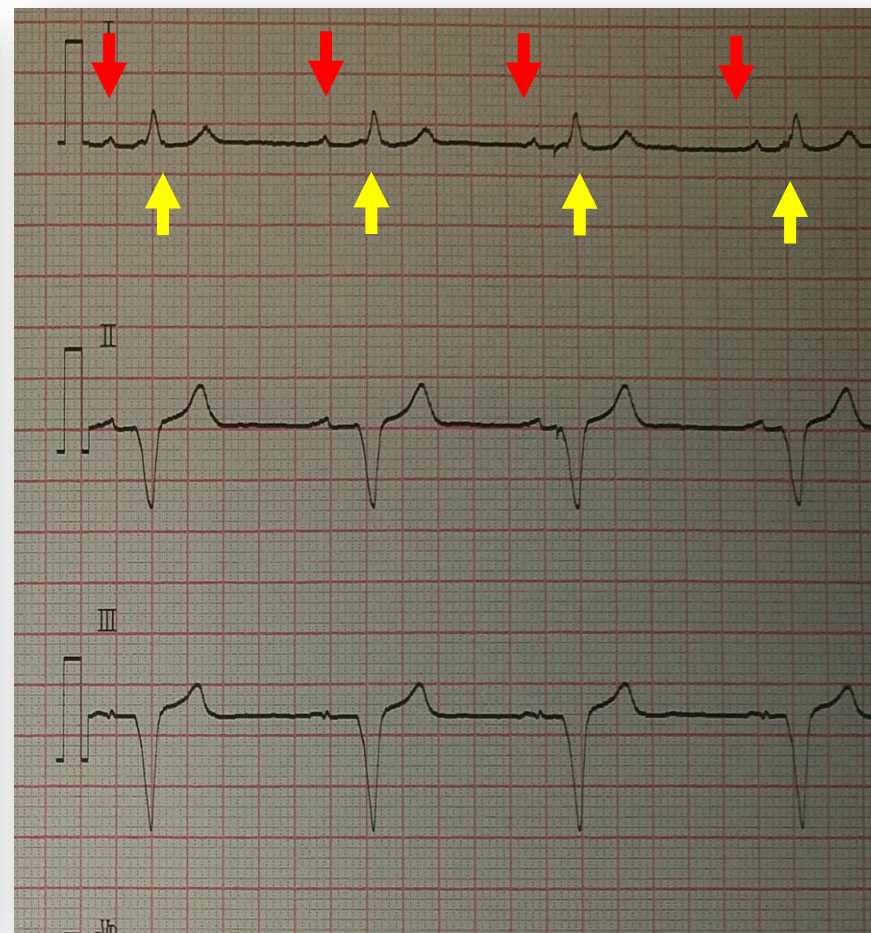
- A1 - Isovolumická kontrakce a uzavření mitrální a aortální chlopně
- A2 - Uzavření aortální a pulmonální chlopně
- A3 - Časně pasivní plnění komor
- A4 – Systola síní s aktivním plněním komor

VDD leadless stimulance – Micra™ AV

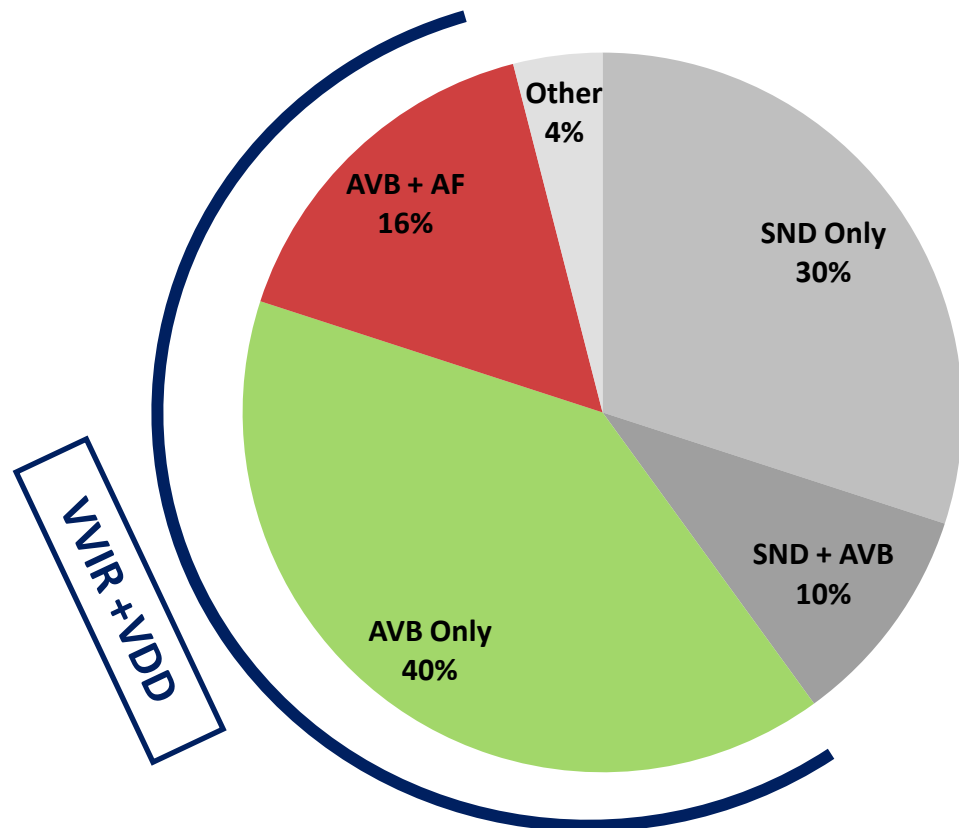
VVI stimulance



VDD stimulance



VDD leadless stimulance



- VDD stimulance
- Zachovalý sinusový rytmus
- Není 100% spolehlivá

Dvoudutinová leadless stimulace - Abbott AVEIR™ DR

Model	LSP201A (Pravá síň)	LSP202V (Pravá komora)
délka	32.2 mm (1.27 in)	38.0 mm (1.50 in)
šířka	6.5 mm (0.26 in)	6.5 mm (0.26 in)
objem	0.96 cm ³	1.1 cm ³
hmotnost	2.1 g	2.4 g
tip elektrody	Helical	Semispherical

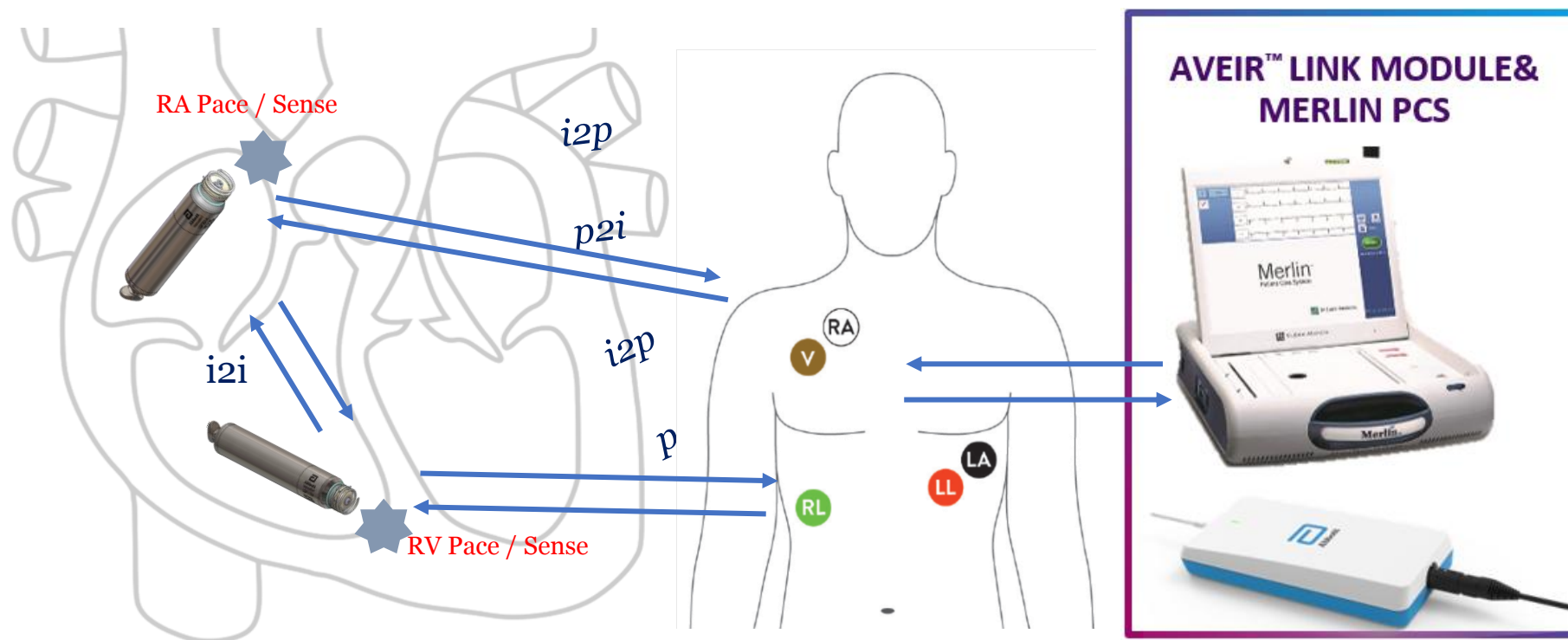


Primární místo fixace síňového stimulátoru: ouško pravé síně

Dvoudutinová leadless stimulace - Abbott AVEIR™ DR

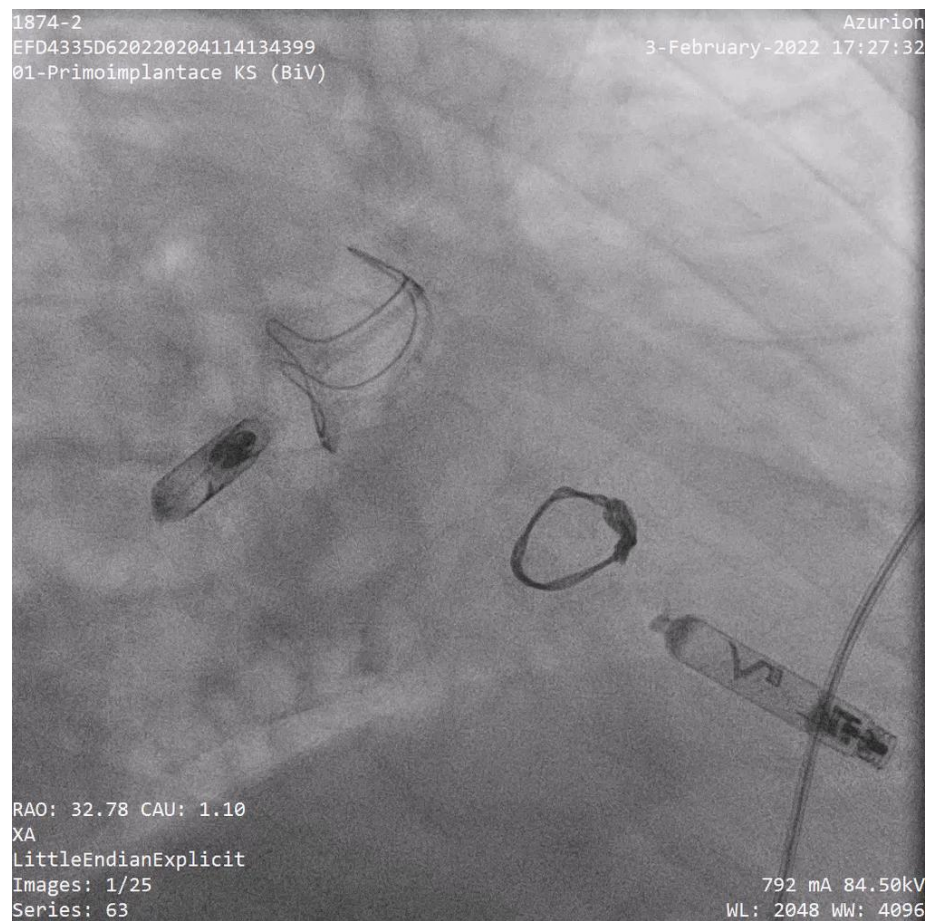
vzájemná komunikace „i2i“ (implant to implant)

- **Konduktivní komunikace** – využívá vodivé vlastnosti tkání a krve; vysílání/přijímání vysokofrekv. el. signálů (uA, pA), výkon v rámci uW ... minimální spotřeba energie



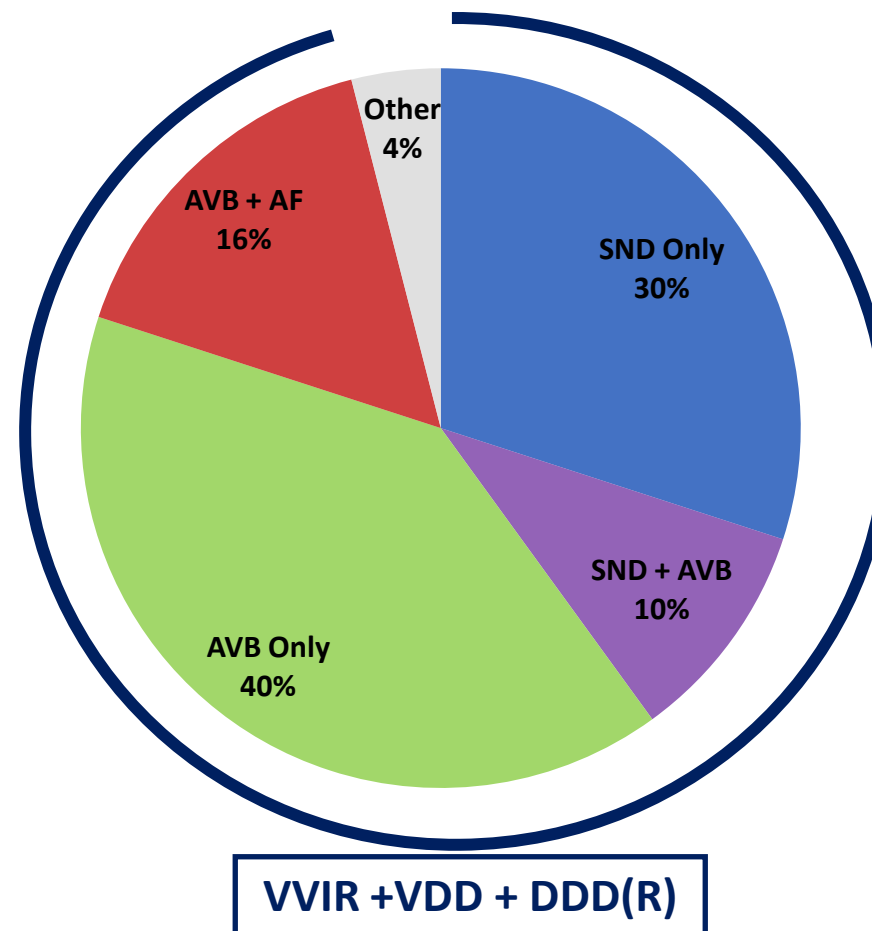
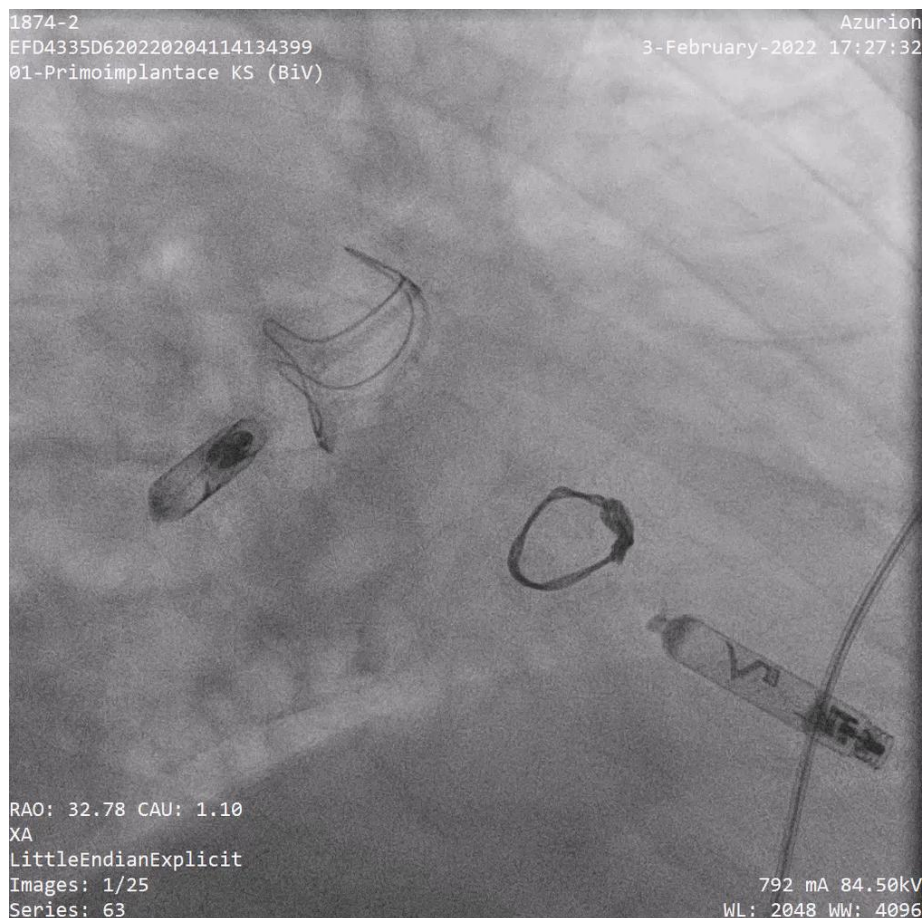
Dvoudutinová leadless stimulace - Abbott AVEIR™ DR

Snímek obou komponent stimulačního systému Aveir DR



Dvoudutinová leadless stimulace - Abbott AVEIR™ DR

Poloha obou komponent stimulačního systému Aveir DR

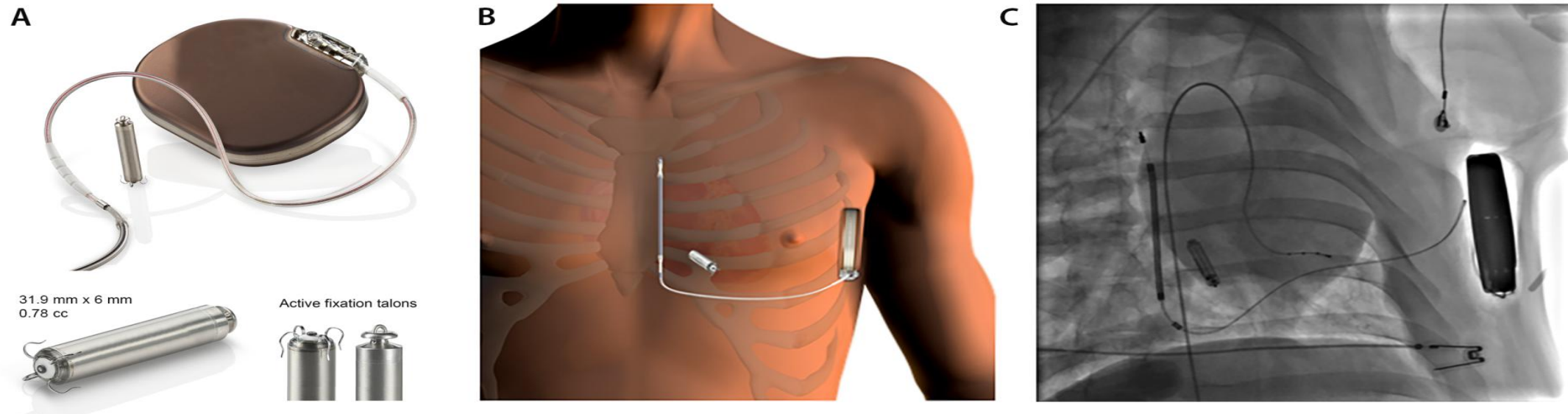


Based on PANORAMA, SavePace, MOST, OPTI-MIND, ESC Country & US Registries

Bezdrátová stimulace a nutnost defibrilace ...?

Leadless stimulace & S-ICD

Concept: Leadless System Delivers Pacing, ATP, and Defibrillation



Leadless pacemaker delivers stand alone bradycardia pacing as well as ATP therapy, as commanded by unidirectional communication from the S-ICD.

Leadless stimulance & S-ICD

EMPOWER™ Modular Pacing System

- VVIR leadless pacemaker with 8+ years longevity @100% pacing
- ATP activated by mCRM™ enabled S-ICD

mCRM Enabled EMBLEM™ S-ICDs

- Insight Algorithms with SMART Pass technology
- Up to 3 attempts of ATP in Conditional Zone
- QuickConvert in the Shock Zone

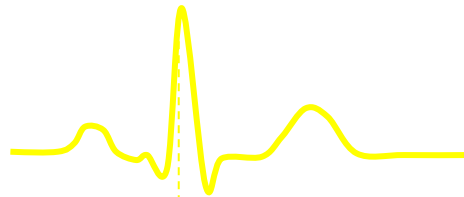
mCRM Compatibility

- EMPOWER™ MPS is designed so that all EMBLEM™ S-ICDs are capable of mCRM™ upgrade to benefit from modular therapy and TruATP™

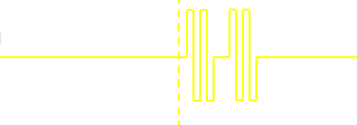
mCRM™ Communication

- Conducted telemetry signals sent from S-ICD
- Negligible battery impact on EMBLEM™ or EMPOWER™

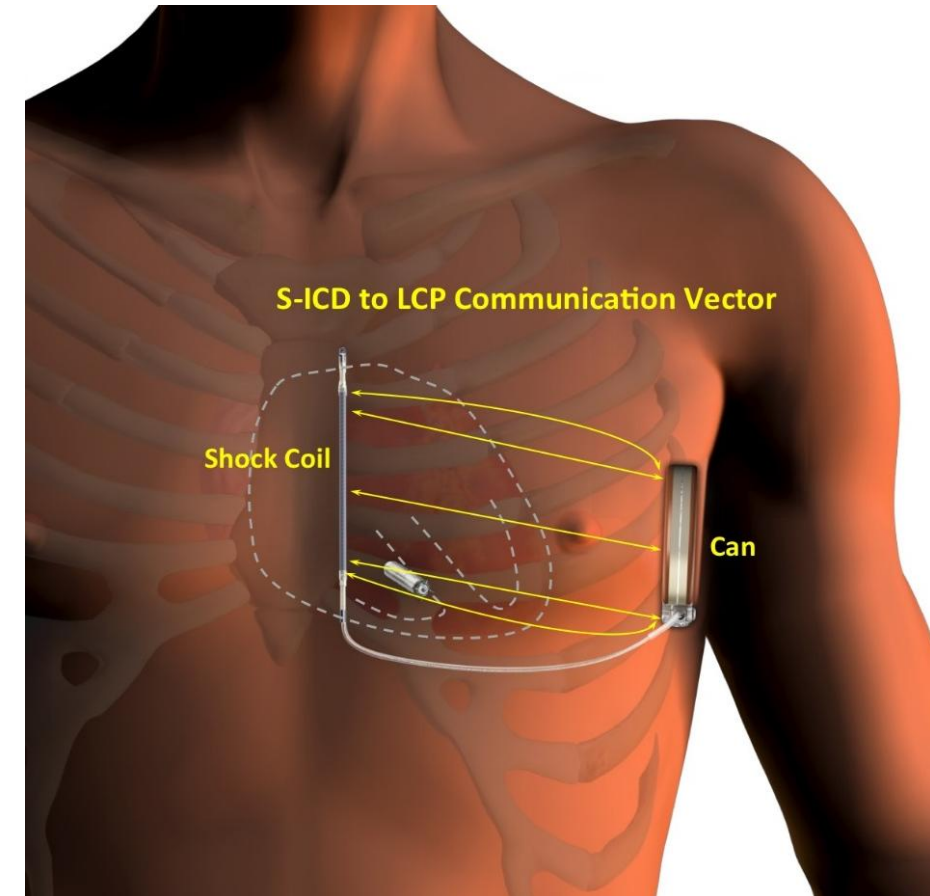
Intrinsic Signal



S-ICD Communication

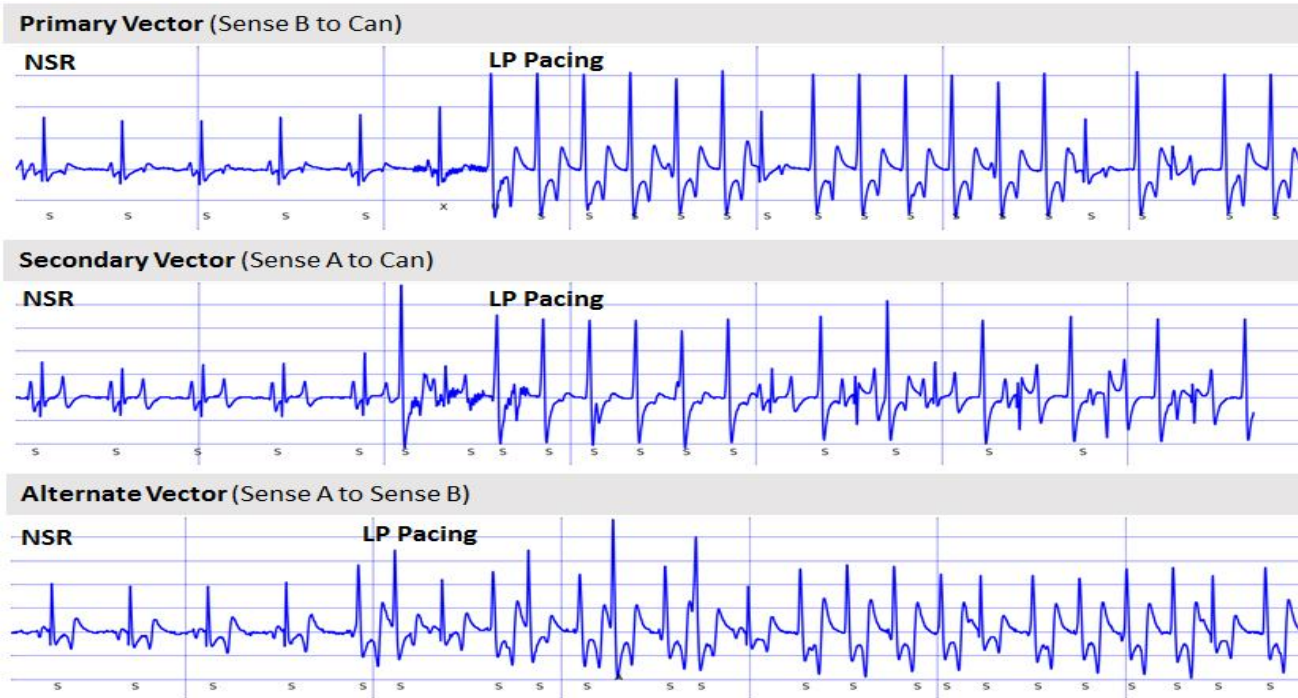


- Coupled to R-wave
- Voltage and pulse width similar to existing lead impedance measurement
- Built-in redundancy



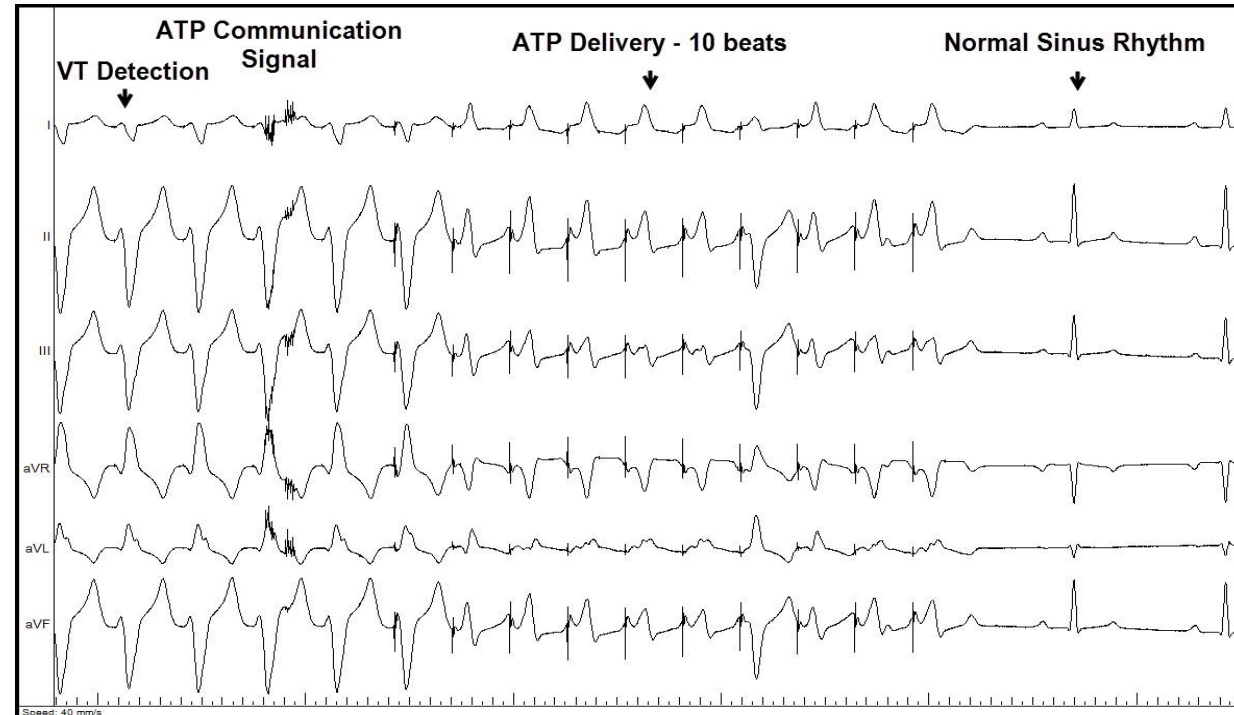
Leadless stimulance & S-ICD

S-ICD Discrimination during High Rate LP Pacing



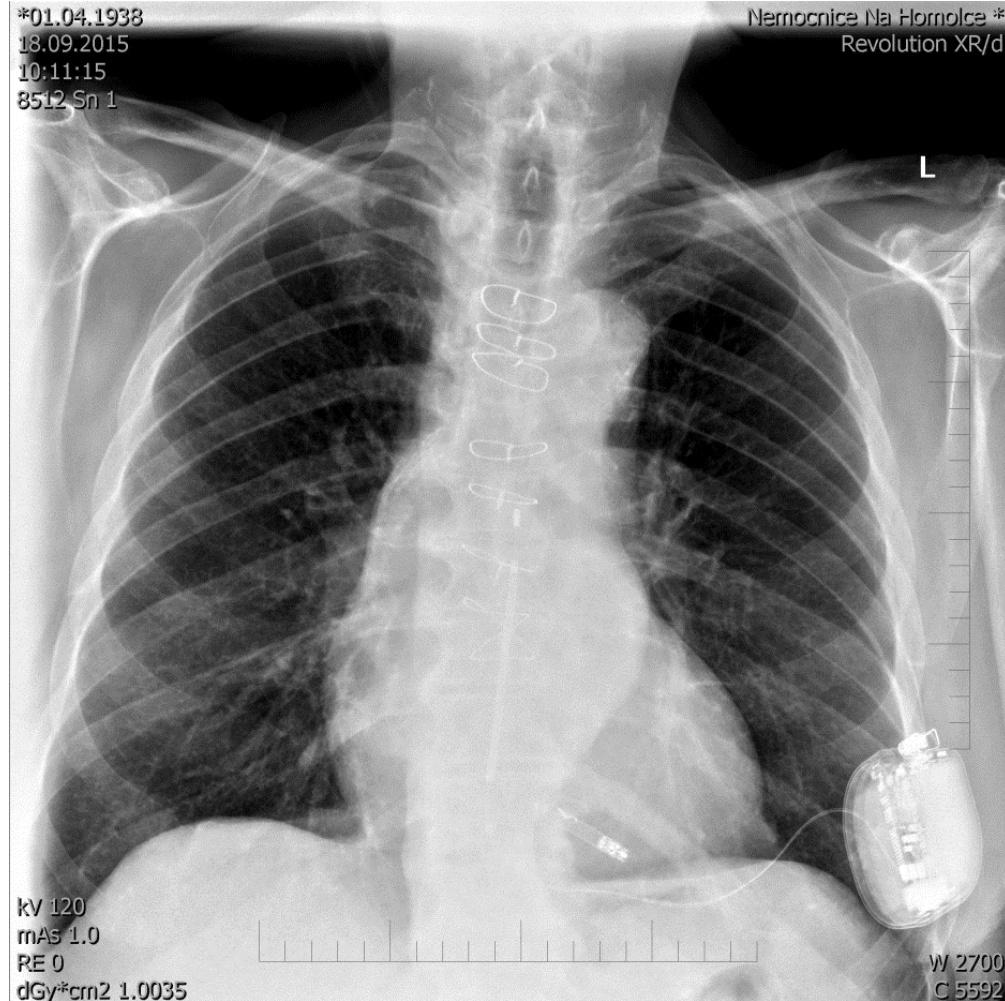
S-ICD rhythm discrimination is adequate during normal sinus rhythm (NSR) and during high-rate leadless pacemaker (LP)

ATP Delivery by the LP Commanded by the S-ICD

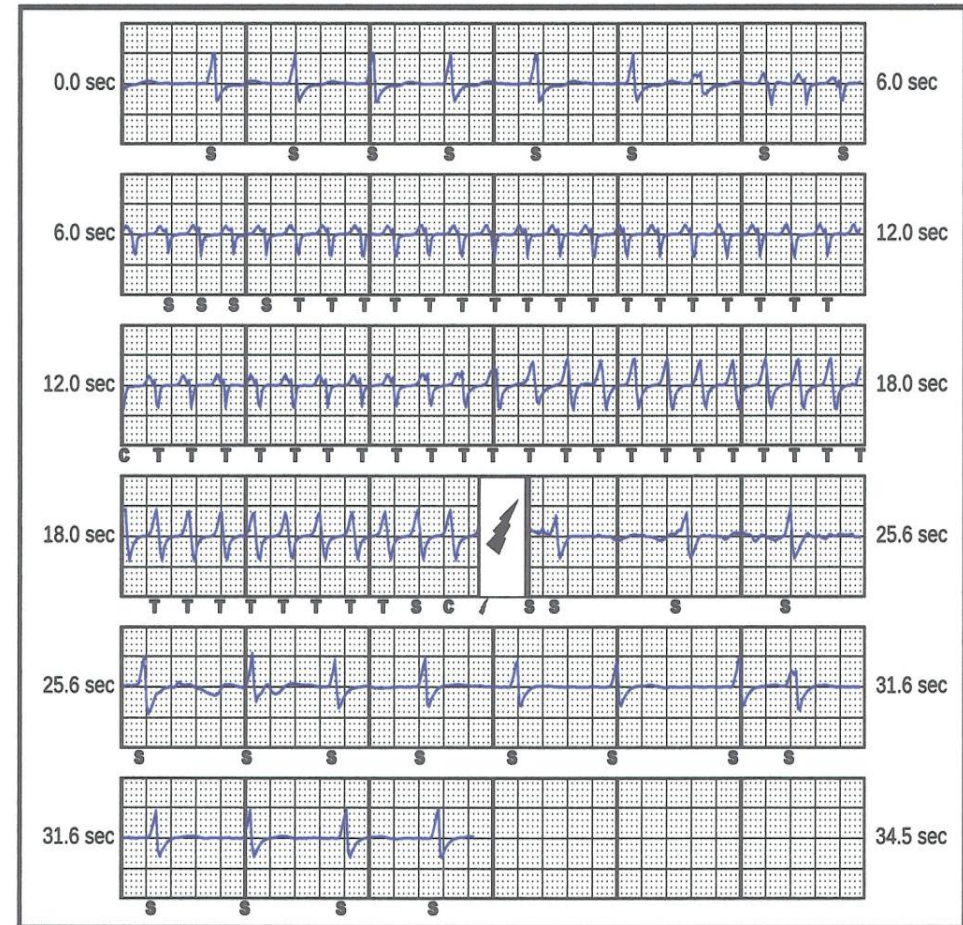


A simulated MVT triggers an ATP request from the S-ICD, which results in 10 beats of ATP delivered by the LP.

Leadless stimulance & S-ICD

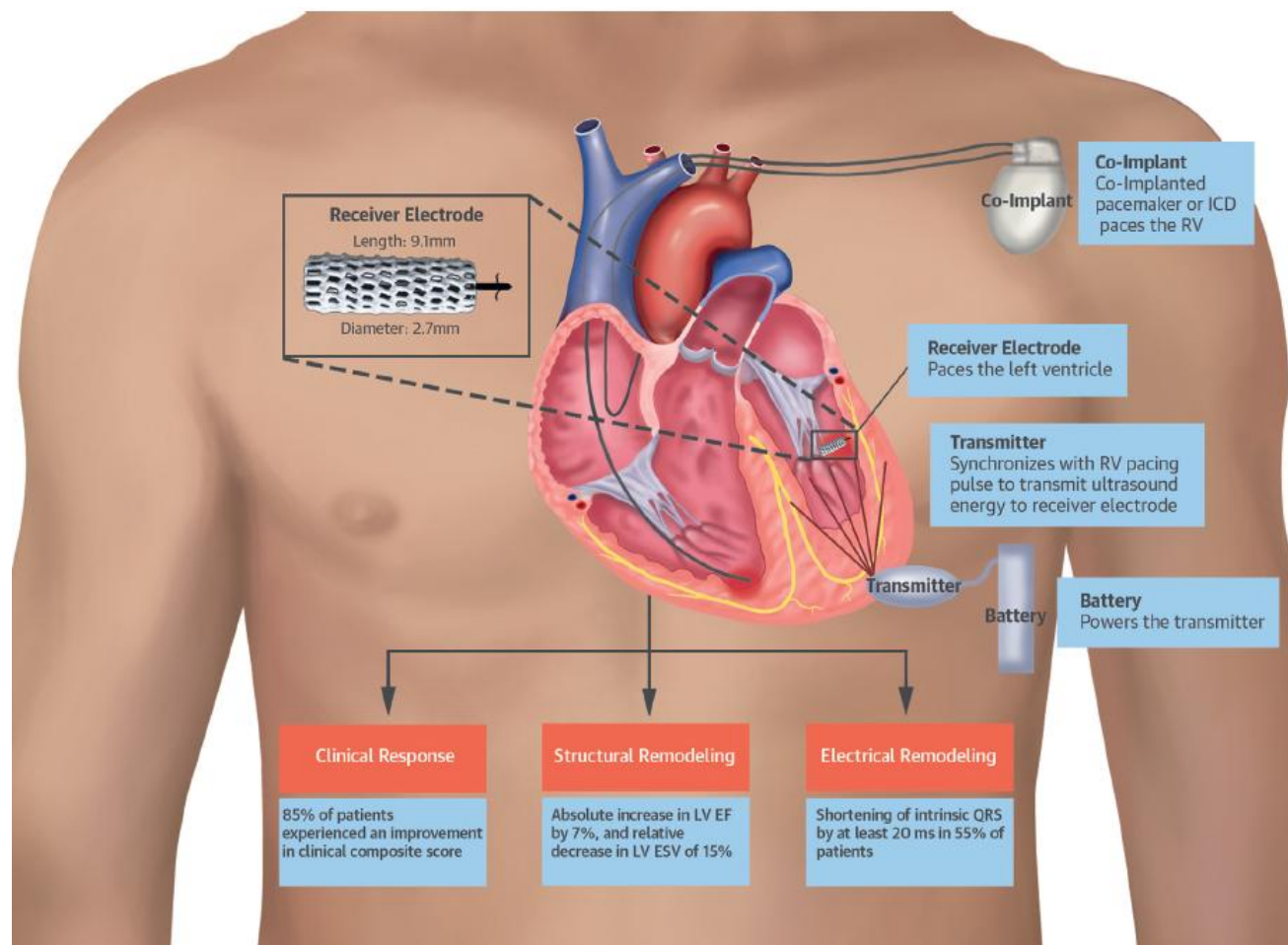


Post-shock pacing



Bezdrátová stimulace u pacientů se srdečním selháním s nutností CRT

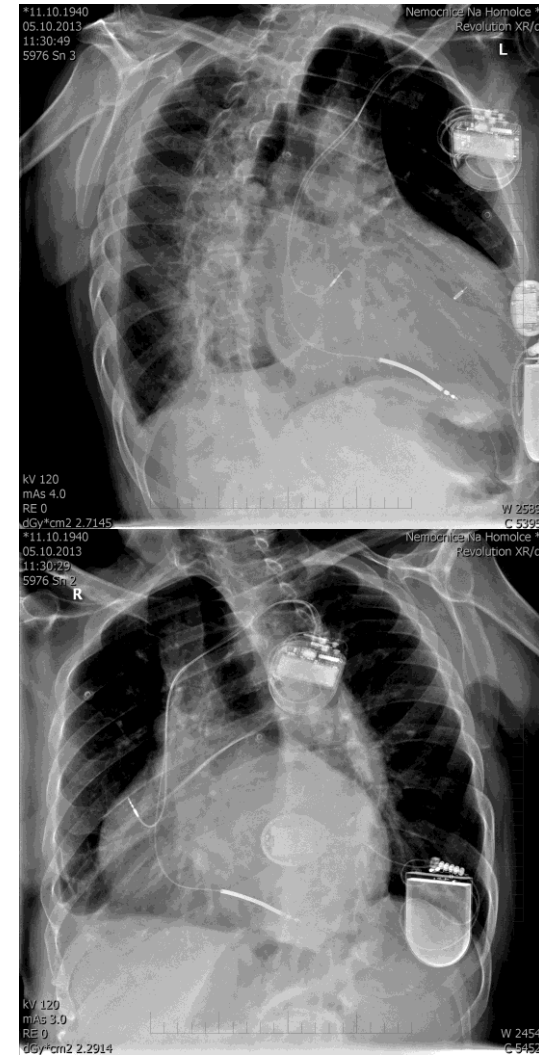
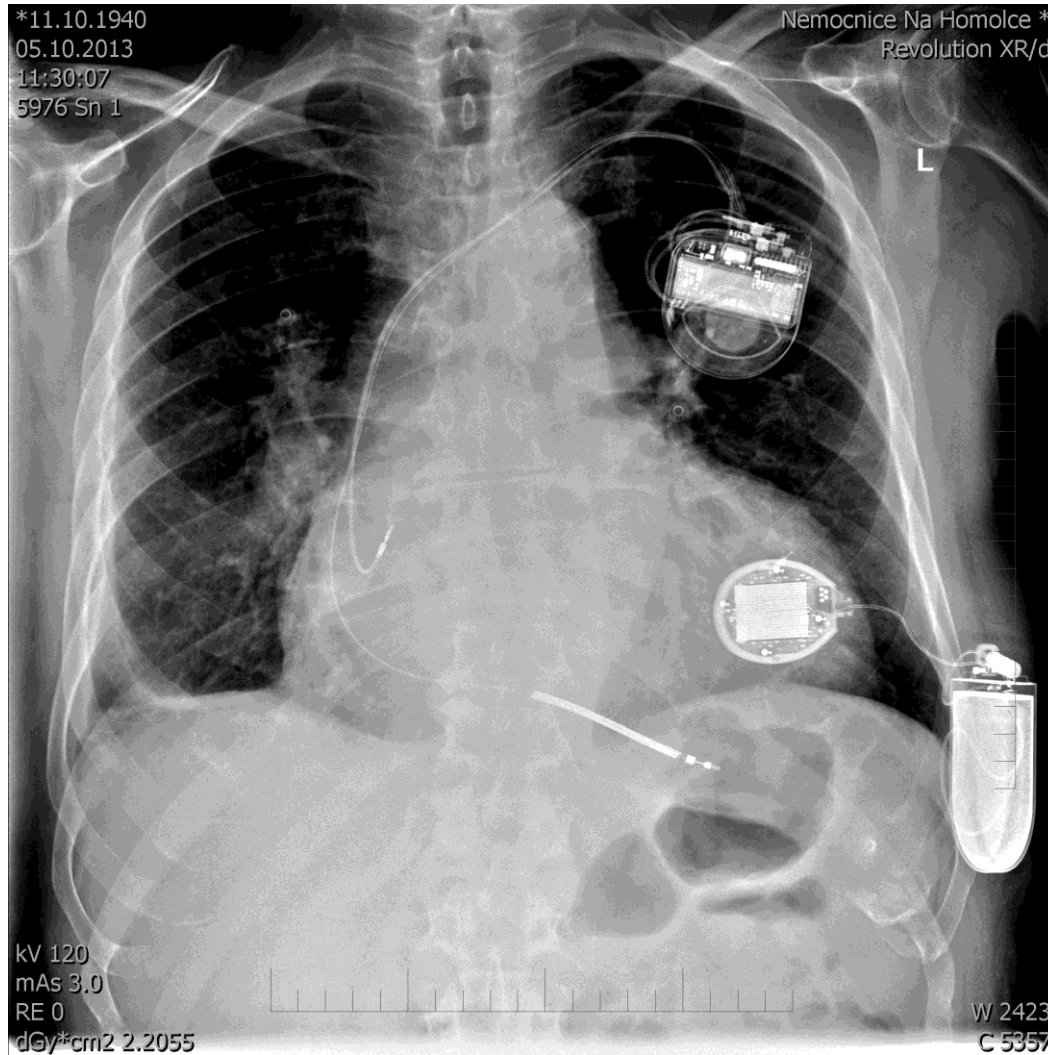
WiCS – ultrazvuková stimulace levé komory schéma implantovaného systému



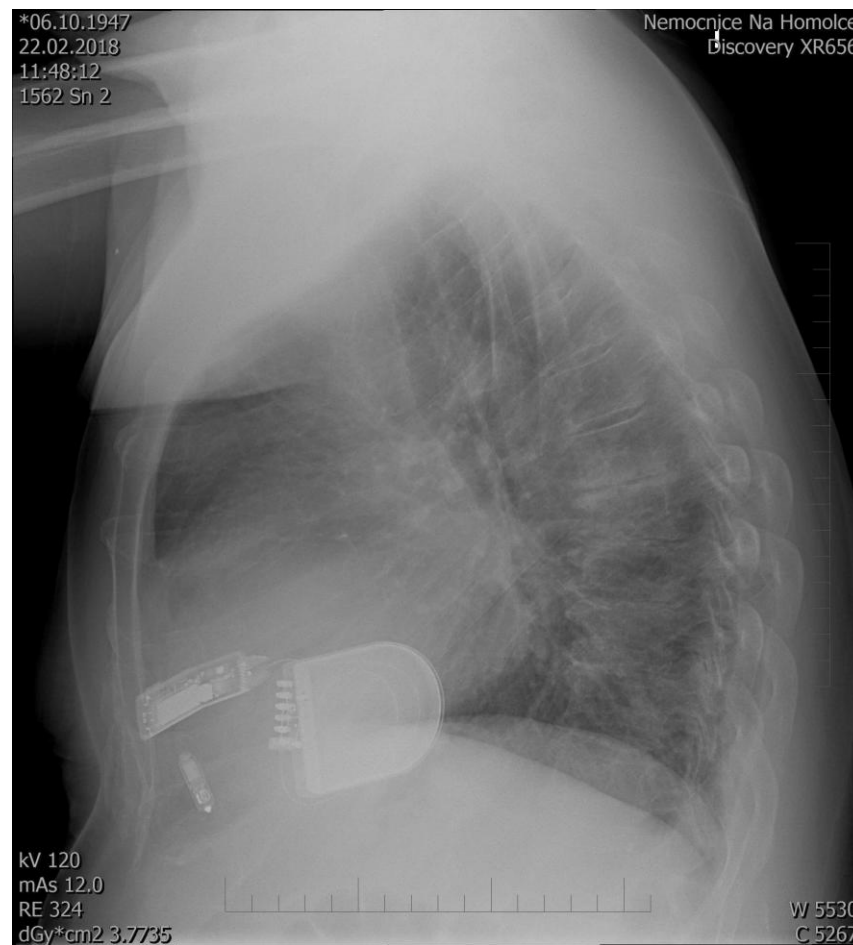
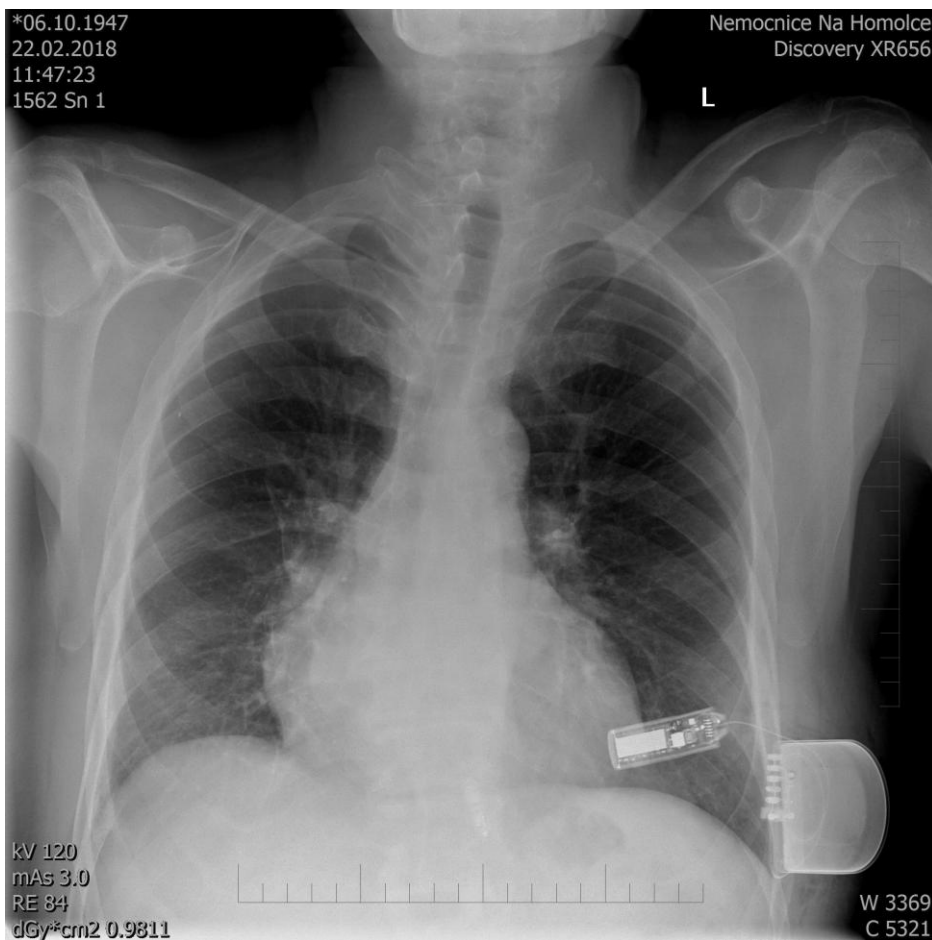
Reddy, V.Y. et al. J Am Coll Cardiol. 2017;69(17):2119-29.

WiCS – ultrazvuková stimulace levé komory

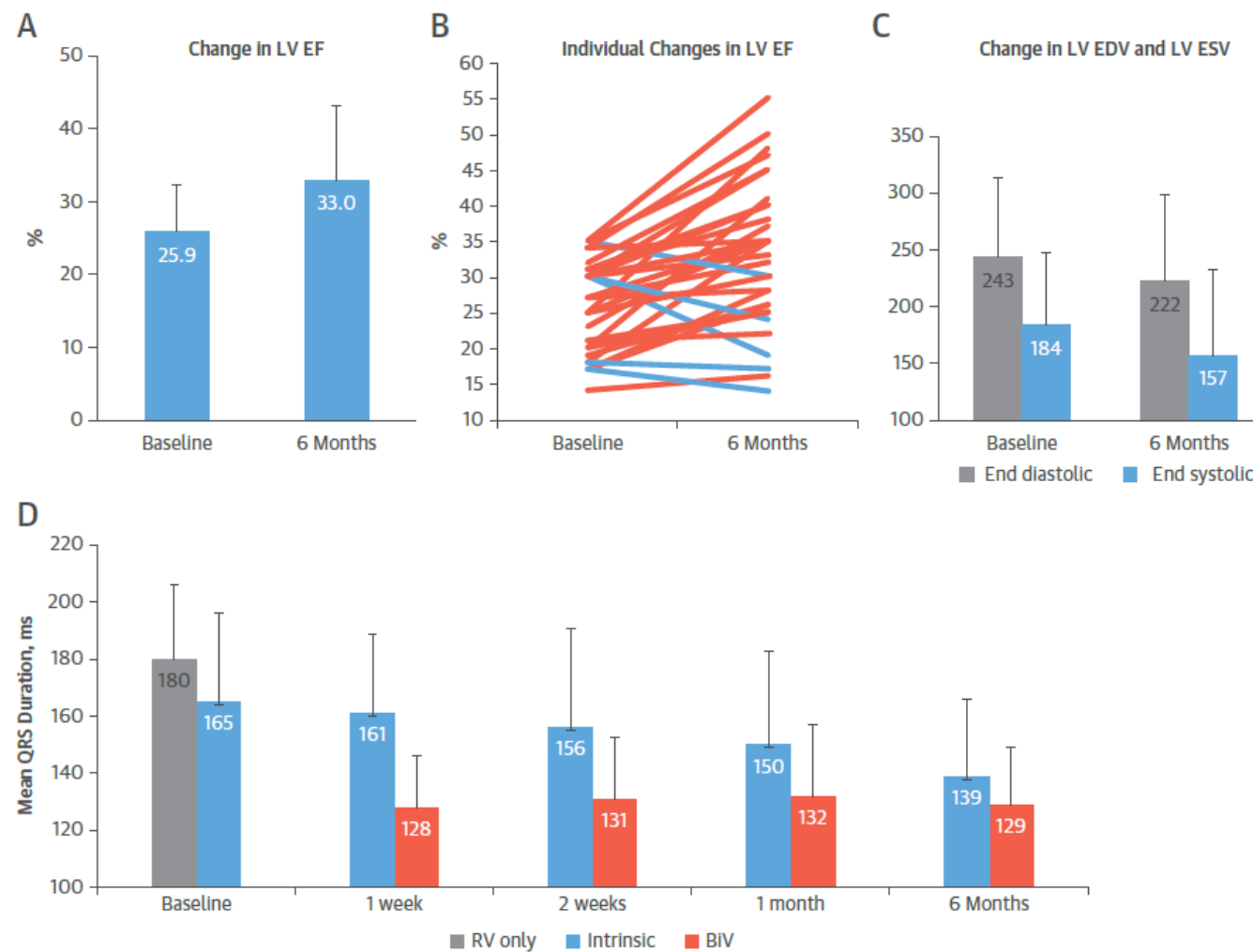
Rtg snímky integrovaného systému



Bezdrátová stimulace & WiCS systém

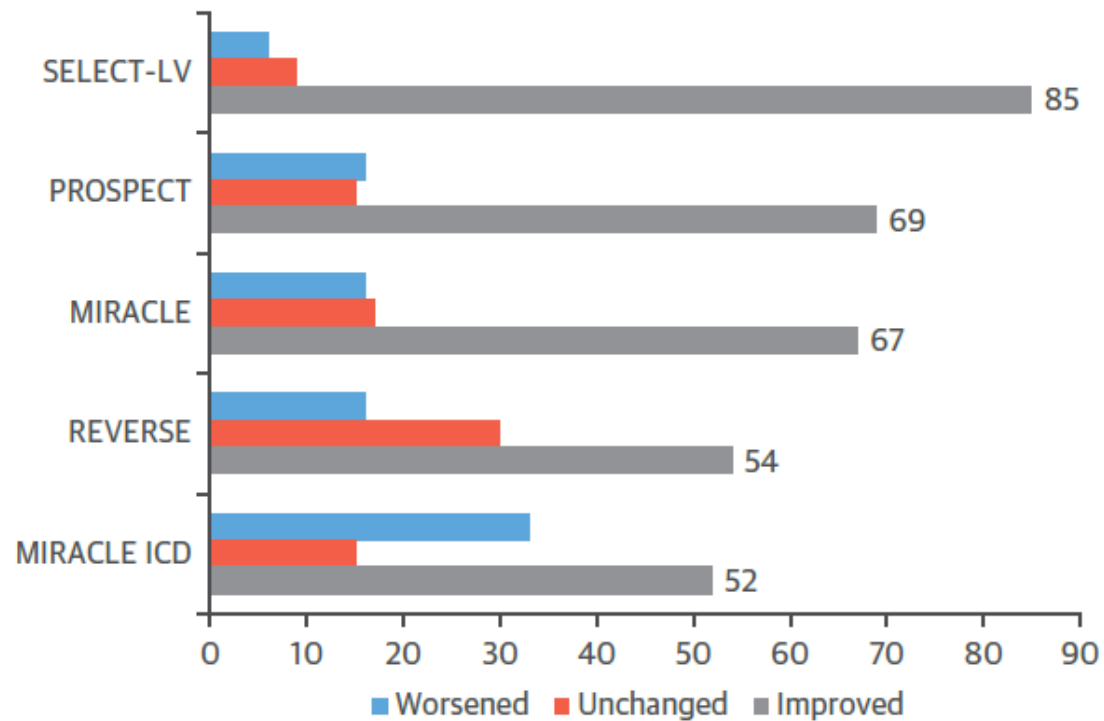
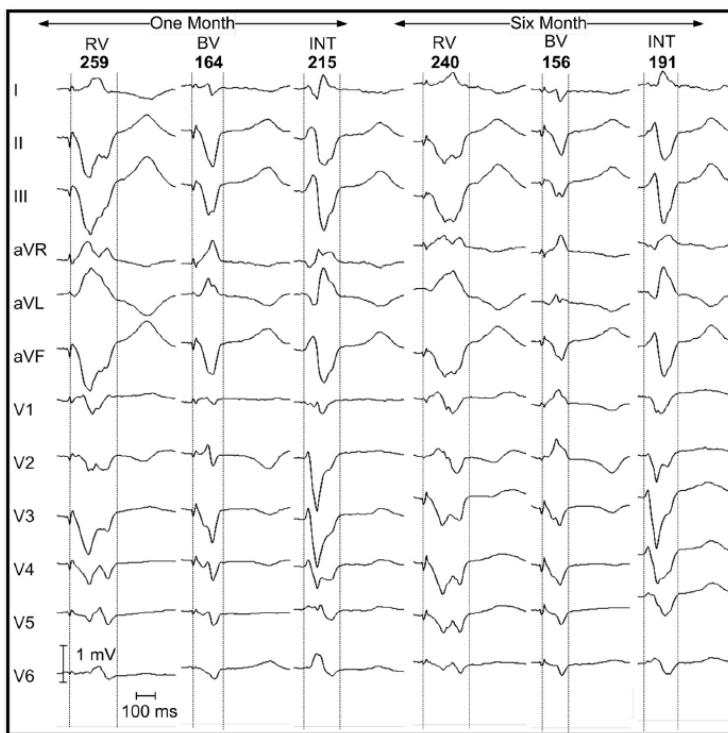


Bezdrátová stimulace – WiCS systém (EBR) Select-LV studie



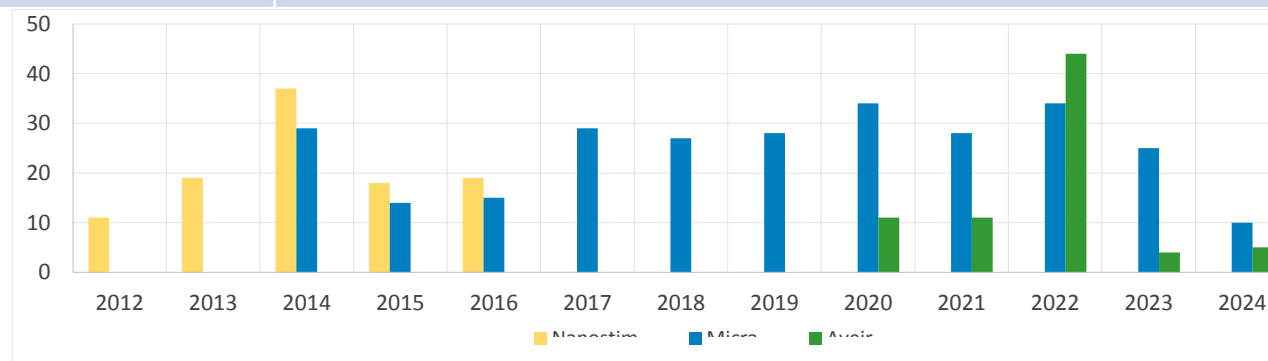
Bezdrátová stimulace – WiCS system (EBR) Select-LV studie

Parameter	Baseline	6 Months	Change	p Value	Response Definition	Response Rate at 6 Months (%)
LVESV, ml (n = 25)	183.8 ± 62.9	157.0 ± 75.7	-26.8 ± 45.1	0.007	≥15% relative reduction	52
LVEDV, ml (n = 25)	243.1 ± 70.7	222.4 ± 77.0	-20.6 ± 41.5	0.02	≥10% relative reduction	40
LVEF, % (n = 32)	25.9 ± 6.4	33.0 ± 10.3	+7.1 ± 8.0	<0.0001	≥5% absolute increase	66
NYHA functional class I/II/III/IV	3/24/73/0	24/67/3/6	+0.8 ± 0.8		≥1 class improvement	67



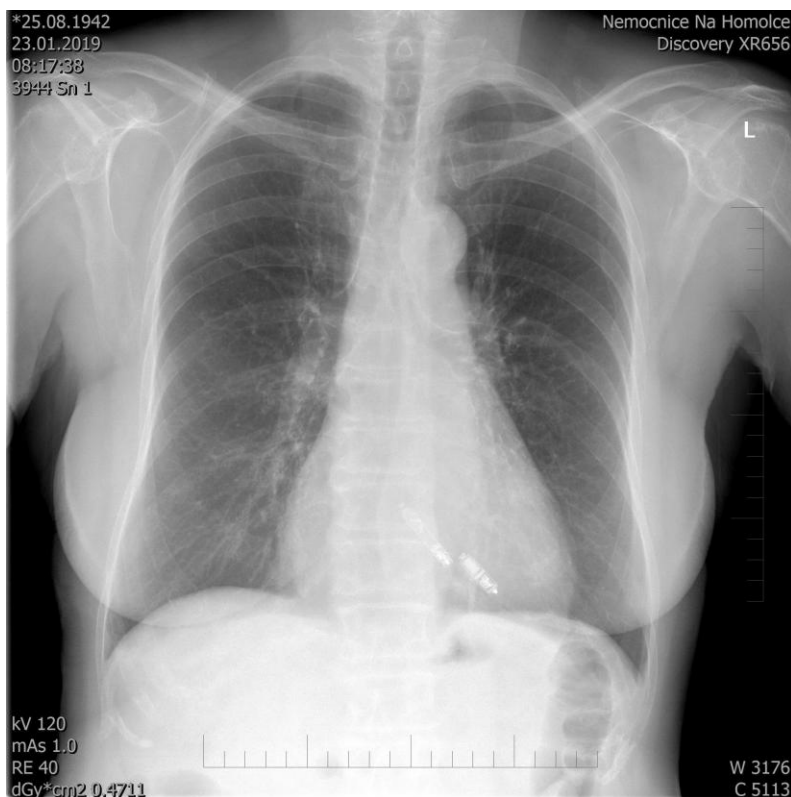
Leadless stimulace v NNH

Leadless pacing v NNH: 2012 - 2024	
Σ	491 Nanostim 104, Micra TPS 273(VR 249, AV 24), Aveir 75 (VR 35, AR 2, DR 38), Modular ATP(Empower) 1
Věk	70,5 (20 – 92) let
Muži	311 (64%)
Úspěšnost	99%
Stimulační parametry	Stim.práh: < 1 V / 0,25- 0,4 ms Velikost vlny R: 4,6 – 20 mV
Jiná než VVI stim.	8x (2 x <u>leadless + WiCS</u> , 6 x <u>leadless + S-ICD</u>)
Komplikace	0,8 % (4x dislokace) 0,2 % revize třísla, infekce, 1x perforace



Leadless stimulance – vybití zdroje, reimplantace

- Původní doporučení výrobců:
... implantovat „nový“ přístroj + ponechat „starý“ přístroj na místě ...!?!



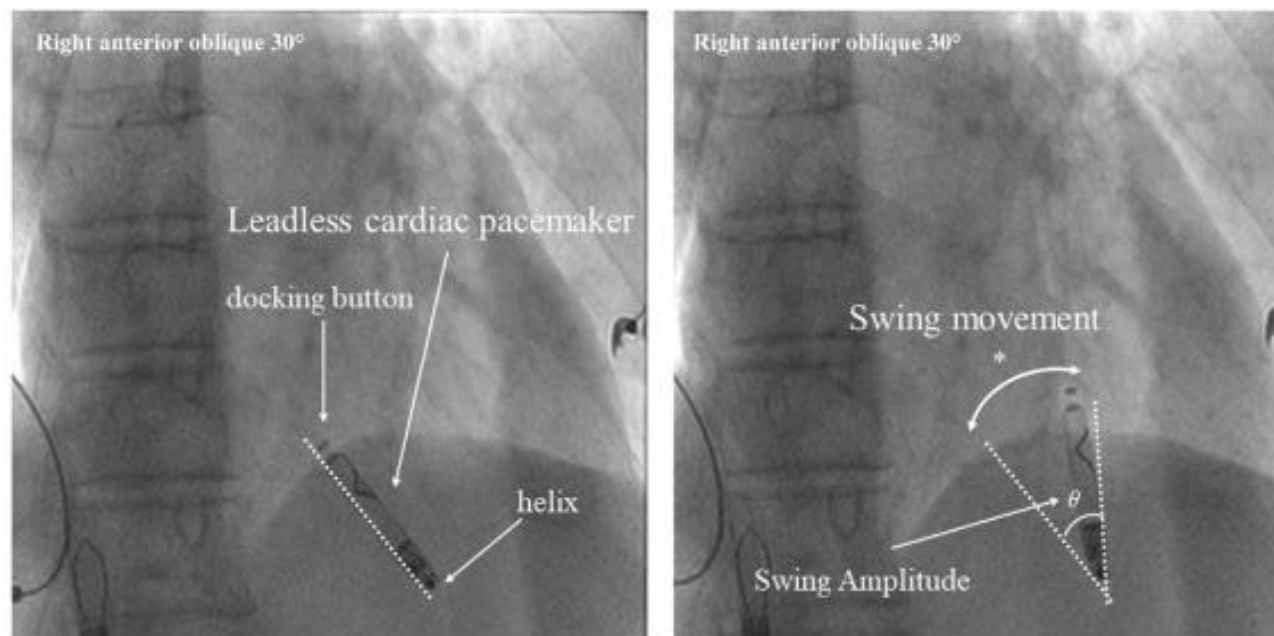
Bezdrátová stimulace – extrakce

fy. Abbott – systémová chyba batérových zdrojů napříč portfoliem výrobků ...“štěstí v neštěstí....?”

	Leadless pacing – EXTRAKCE v NNH
Σ	<u>34</u>
Věk [r]	78,0 ± 8,1
Muži	21 (63%)
Doba od implantace [r]	4,3 ± 1,3 (2,0; 6,1)
Lokalizace	Apex – 21 (62%), Midseptum – 7 (21%), spodní stěna – 6 (18%)
Důvod extrakce	<u>Porucha zdroje</u> – 29 (85%), upgrade na CRT – 5 (15%)
Úspěšnost	29 (85%) Swinging movement vs. Non-swinging movement
Fluoro [min]	15,0 ± 13,9
Komplikace	0

Prediktory úspěšné extrakce – „swinging movement“

CENTRAL ILLUSTRATION: "Swing Movement" of the Leadless Cardiac Pacemaker



Minami, K. et al. J Am Coll Cardiol EP. 2020;6(14):1744-51.

Inovated Retrieval System

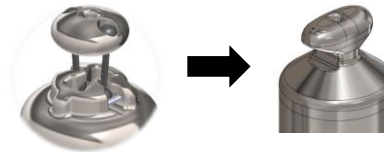
- LP Retrievability Features

- Single-turn helix to allow LP to easily unscrew from tissue
- Docking Button to facilitate mating with Retrieval Catheter
- Titanium housing to maximize torque transfer and minimize tissue ingrowth

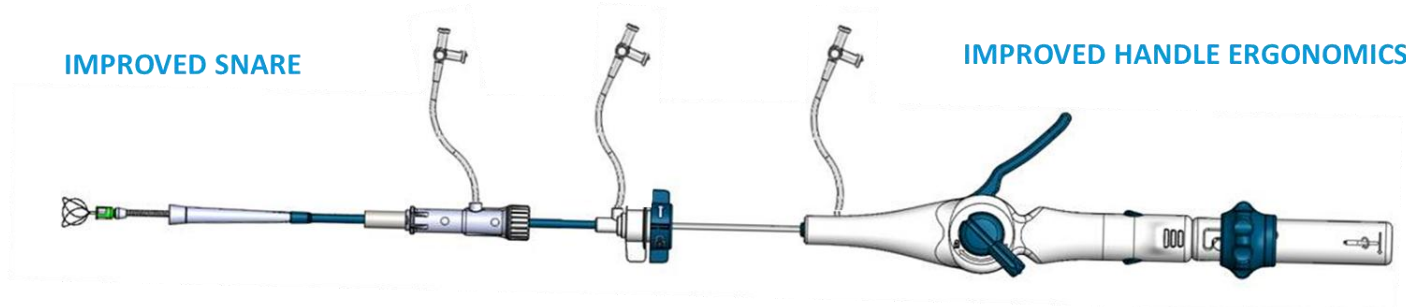


- Design Improvements

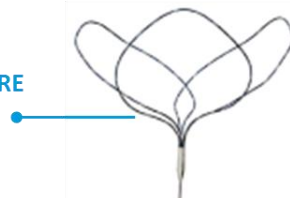
- Fixed-post docking button
- Retrieval catheter



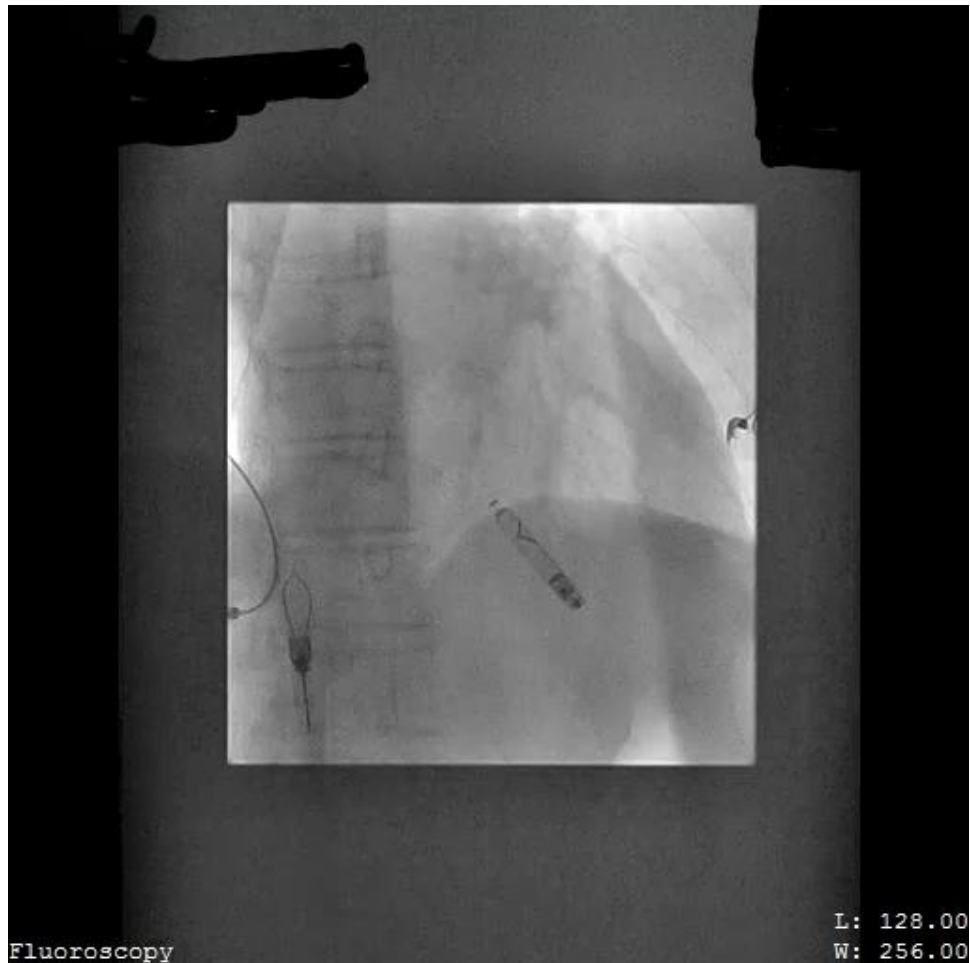
LEVERAGED AVEIR™ SHAFT IMPROVEMENTS



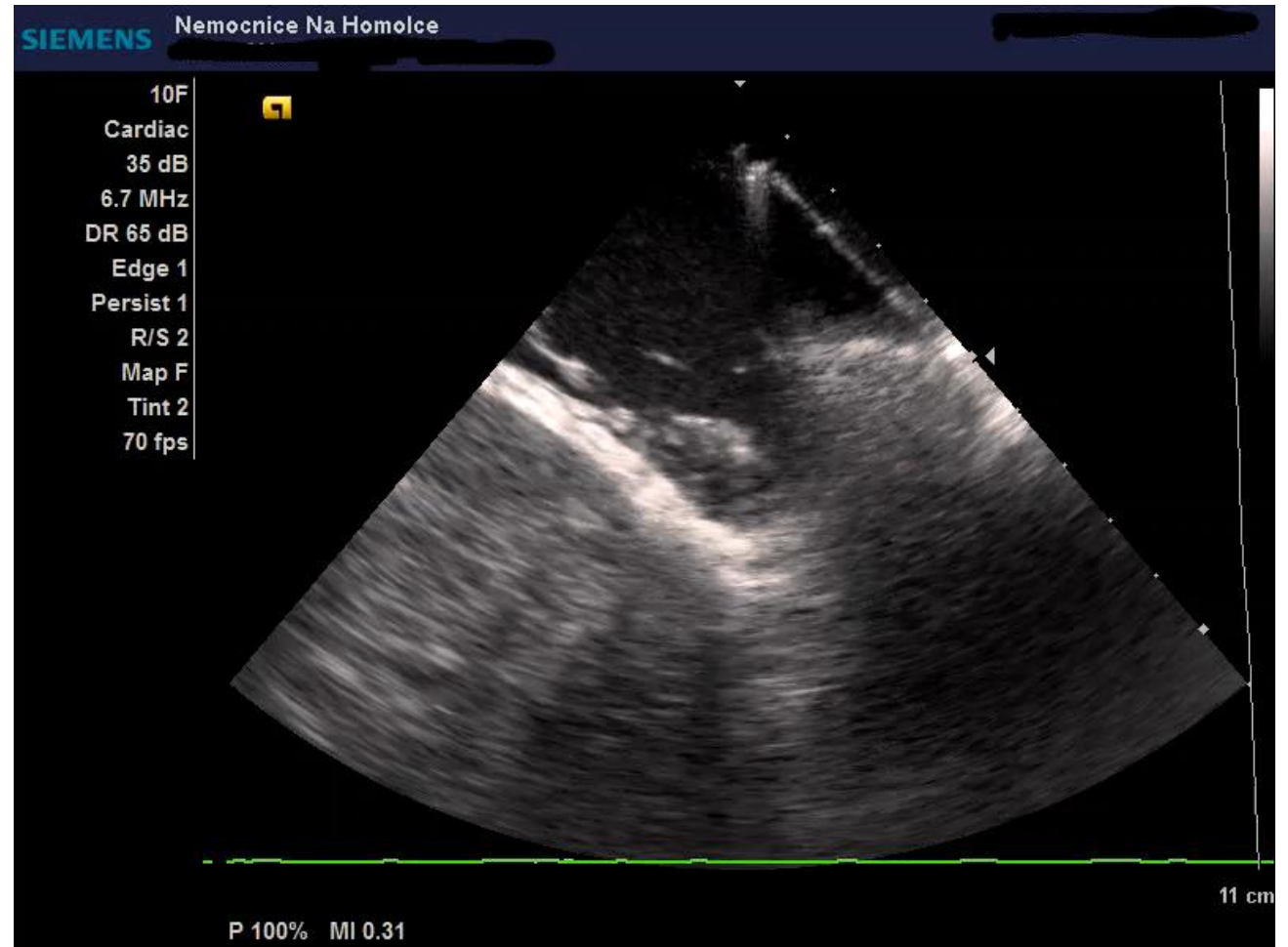
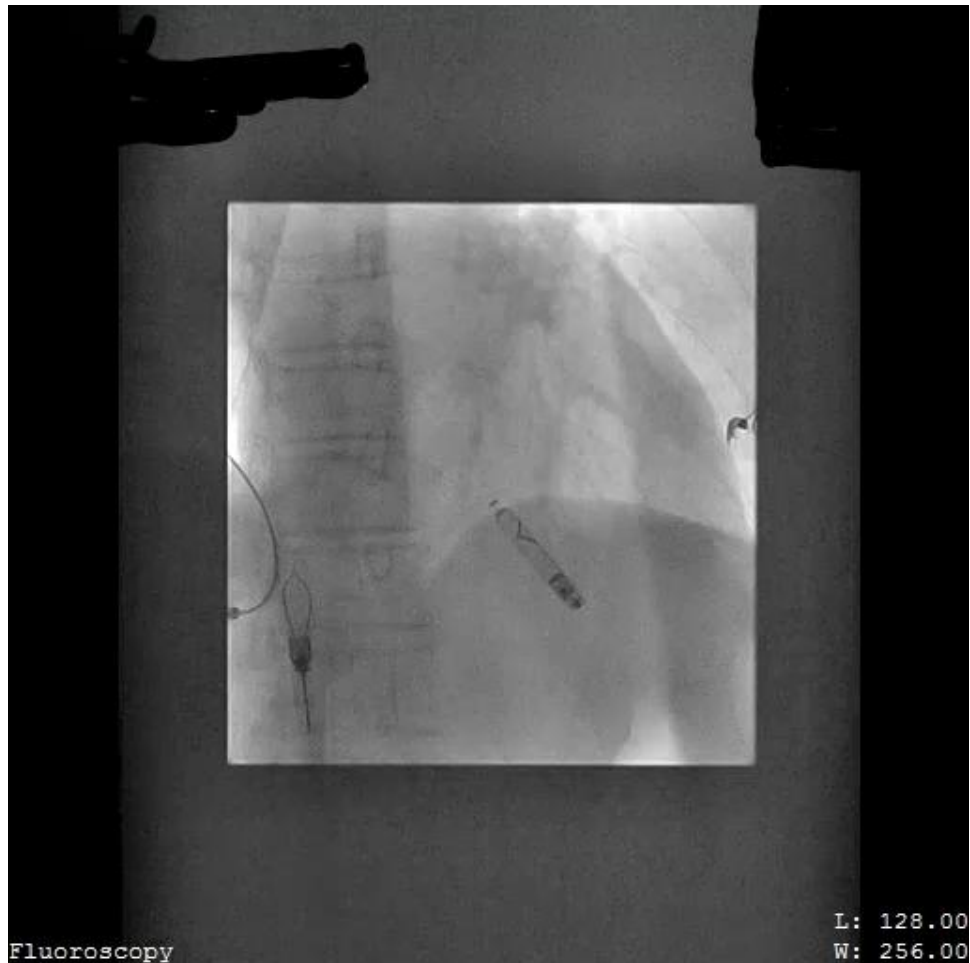
TRI-LOOP SNARE
Improved ease-of- use



Prediktory úspěšné extrakce – „swinging movement“



Prediktory úspěšné extrakce – „swinging movement“



Prediktory úspěšné extrakce – „swinging movement“



Prediktory úspěšné extrakce – „swinging movement“

Retrieval procedure	
Success	29/34 (85%)
Fluoro time (min)	15.0 ± 13.9
Adverse events	0 (0%)
Reimplantation	
Micra™	26
Nanostim	1
Transvenous biventricular pacing system	5
Transvenous dual-chamber pacing system	2

	Swing Movement	No Swing Movement	<i>P</i> .value
Number of patients	25	9	
Success rate	100% (25/25)	56% (5/9)	<0.001
Fluoro time (min)	12.7 ± 8.6	45.6 ± 19	<0.001
Swing amplitude (degree)	40.4 ± 10.2	5.0 ± 3.5	<0.001
Duration of implant (days)	1583 ± 507	1617 ± 458	0.67
Implant location			
Right ventricular septal apex	20 (80%)	1 (11%)	0.0016
Right ventricular mid-septum	2 (8%)	5 (56%)	0.009
Right ventricular inferior wall	3 (12%)	3 (33%)	0.11

Bezdrátová kardiostimulace - shrnutí



- Plnohodnotná klinicky efektivní metoda srdeční stimulace
- Pokrývají celé spektrum indikací trvalé stimulaci (VVI, VDD, DDD, BiV, +ICD...)
- Stabilní stimulační parametry
- Žádné infekční komplikace
- Možnost extrakce
- MR kompatibilní